Portable GynoCare

Product report

01/02 - 31/05 - 2023

Aalborg University **MSc04 ID1**
Josefine Kildeberg Paulsen
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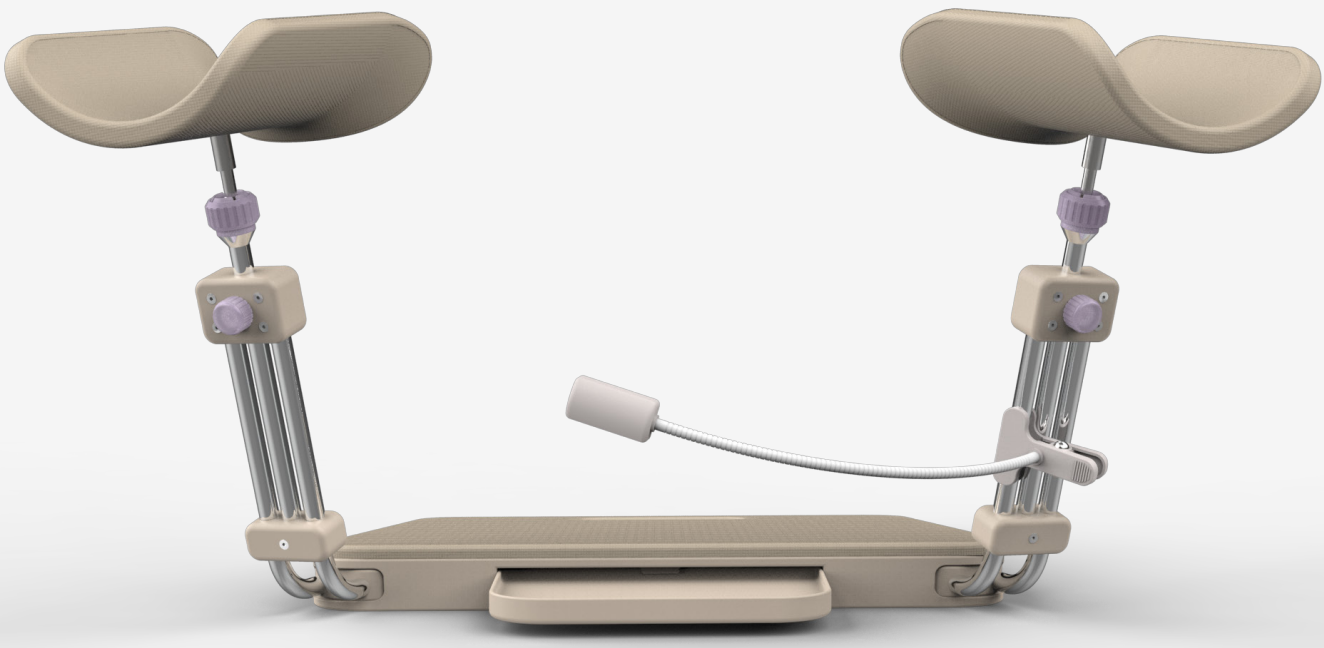

The Design Team

Victoria Holm Pedersen

Josefine Kildeberg Paulsen

Abstract

The number of home births in Denmark has increased more than 150% within the last 10 years. Home births have several advantages for mothers, who are more in control and benefit from the enhanced production of birth hormones during birth due to the well known and secure setting at the home. However, the working conditions for midwives are more difficult at home births, since they do not have the same setup as the hospital. This is especially a problem when suturing postnatal tears. In order to assist the midwife when suturing postnatal tears for home births in different settings, a product can be designed to assist with holding the mother's legs in the correct position for suturing, similar to the stirrups used at the hospital for suturing today. This will also improve the working position of the midwife while suturing. By doing research and conducting interviews with multiple midwives and mothers, the needs and requirements of these user groups are understood. This is used to make sketches of concepts, CAD models and mock-ups, which are tested with midwives and shown to mothers to evaluate the function, use, interaction and perception of the concepts. The resulting product is a rigid bottom plate designed with adjustable stirrups to accommodate the optimal position of the legs for different mothers in a home birth setting. The product can be easily cleaned in the home after use and includes an optimal light source for suturing in both light and dark settings and an instrument tray for the suturing kit. The stirrups can be detached from the bottom plate for easy transportation. The product can potentially standardise the quality and procedure of suturing postnatal tears at home births and help the midwife obtain a more ergonomic position while suturing.

Titlepage

Title: Portable CynoCare

February 1st 2023 - May 31st 2023

MSc04 ID1

Main supervisor: Christian Tollestrup

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Pages: 24

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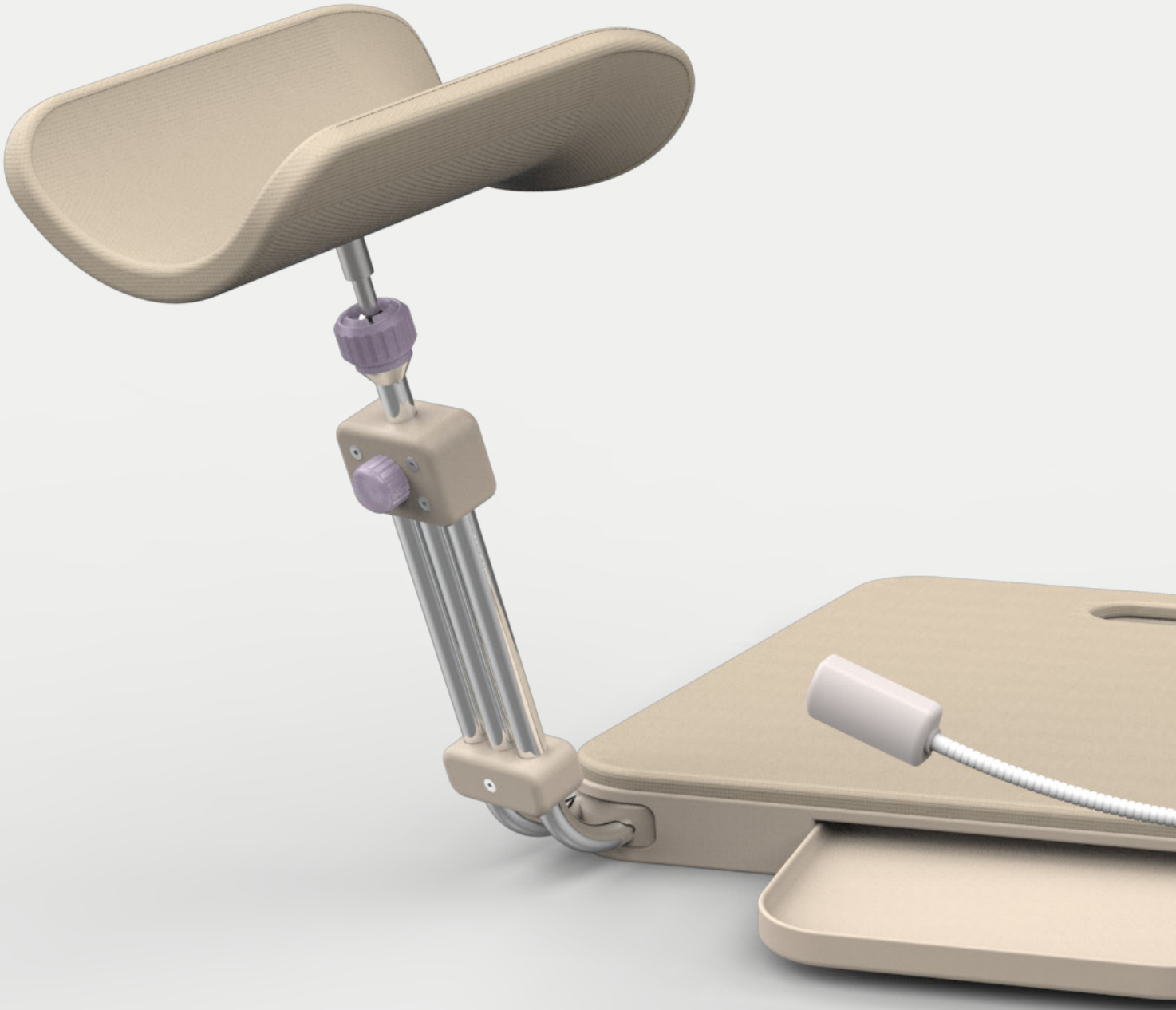
TAL·COAT

Suturing tears at home births

Today, when suturing postnatal tears at home births, the midwife is not able to position the mother correctly. It is important that the muscles in the perineum are aligned in order to suture the tear correctly together.

The difficulties with the positioning of the mother, causes the midwife to end up in bad ergonomic positions because the situation is exhausting for the mother. Therefore, the midwife compromises her own position to make it as comfortable as possible for the mother given the situation.

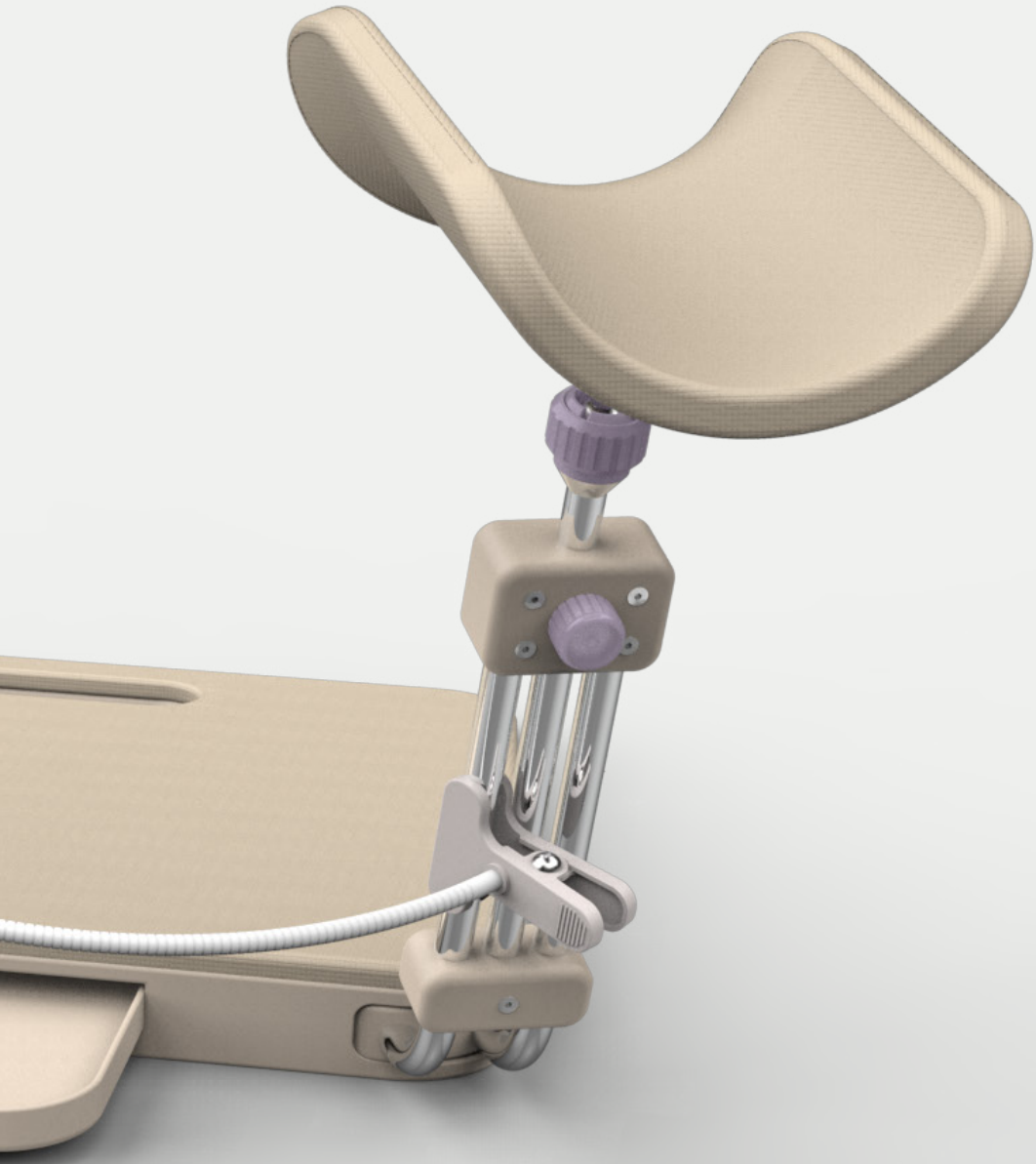

Universal



Portable GynoCare

Portable GynoCare is a pair of transportable gynaecological stirrups that can be used when assessing and suturing postnatal tears at home births. Using this medical equipment allows the midwife to do quality suturing and standardises the way of suturing at a home birth. A conveniently located instrument tray enables the midwife to have her instruments right in front of her. Furthermore, a light can be clicked on, providing optimal illumination of the tears, which is especially useful when suturing at night.

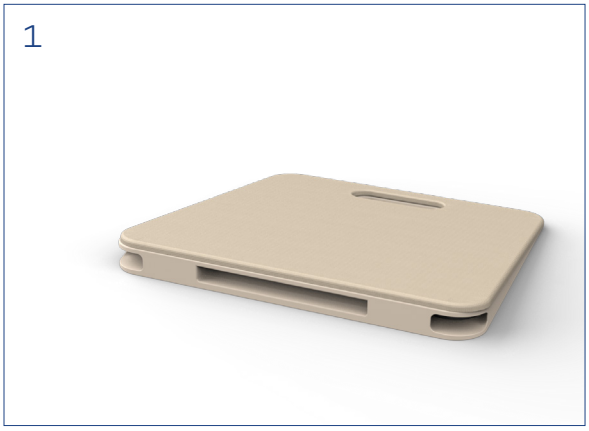
Functions such as height adjustment, a spherical joint and PUR covers for the contact areas enable Portable GynoCare to be adjusted to fit the individual mother as well as providing some comfort in an uncomfortable situation.



Set it up

Portable GynoCare is easy to set up and requires only 4 simple steps;

1

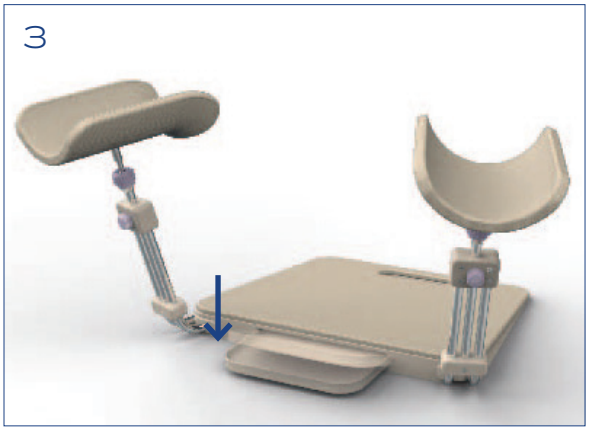


The bottom plate is placed where the suturing is to take place.

2

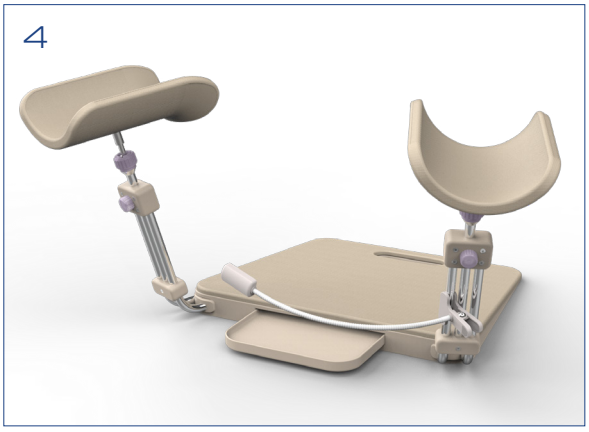
The stirrups are attached.

3



The instrument tray is attached.

4



The light is clicked on.

... and Portable GynoCare is ready for use.

Places of use

Due to the bottom plate, the assessment and suturing can be performed in multiple places in the home, e.g. the dining table, the couch and the bed, while still maintaining the correct position of the mother.

Suturing on the dining table is recommended since this allows the midwife to sit in a good ergonomic position.

Dining table

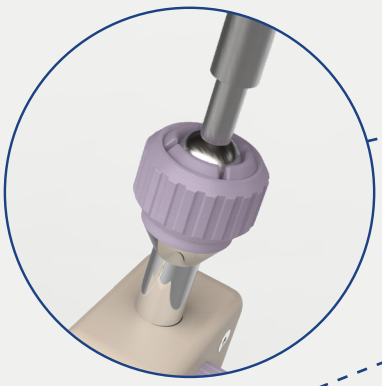
Couch

Bed

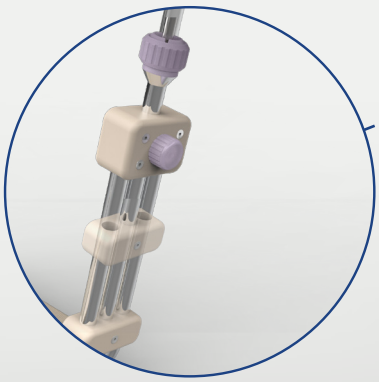
A comfortable position

The overall situation of being sutured is not comfortable for the mother since she is sore and exhausted after giving birth. Therefore, to provide a comfortable position for the mother, while still enabling the midwife to place her in the lithotomy position, Portable GynoCare is designed to provide adjustability and comfort for the individual mother.

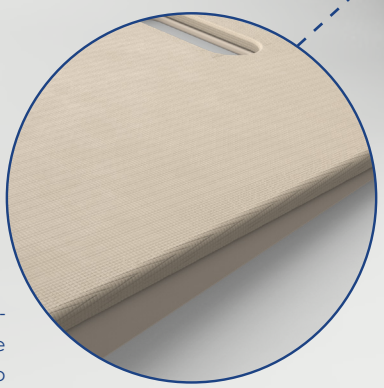
The calf-holders are covered in PUR foam for a comfortable interaction.



A spherical joint makes it possible to adjust the calf-holders in the optimal angle for the individual mother.



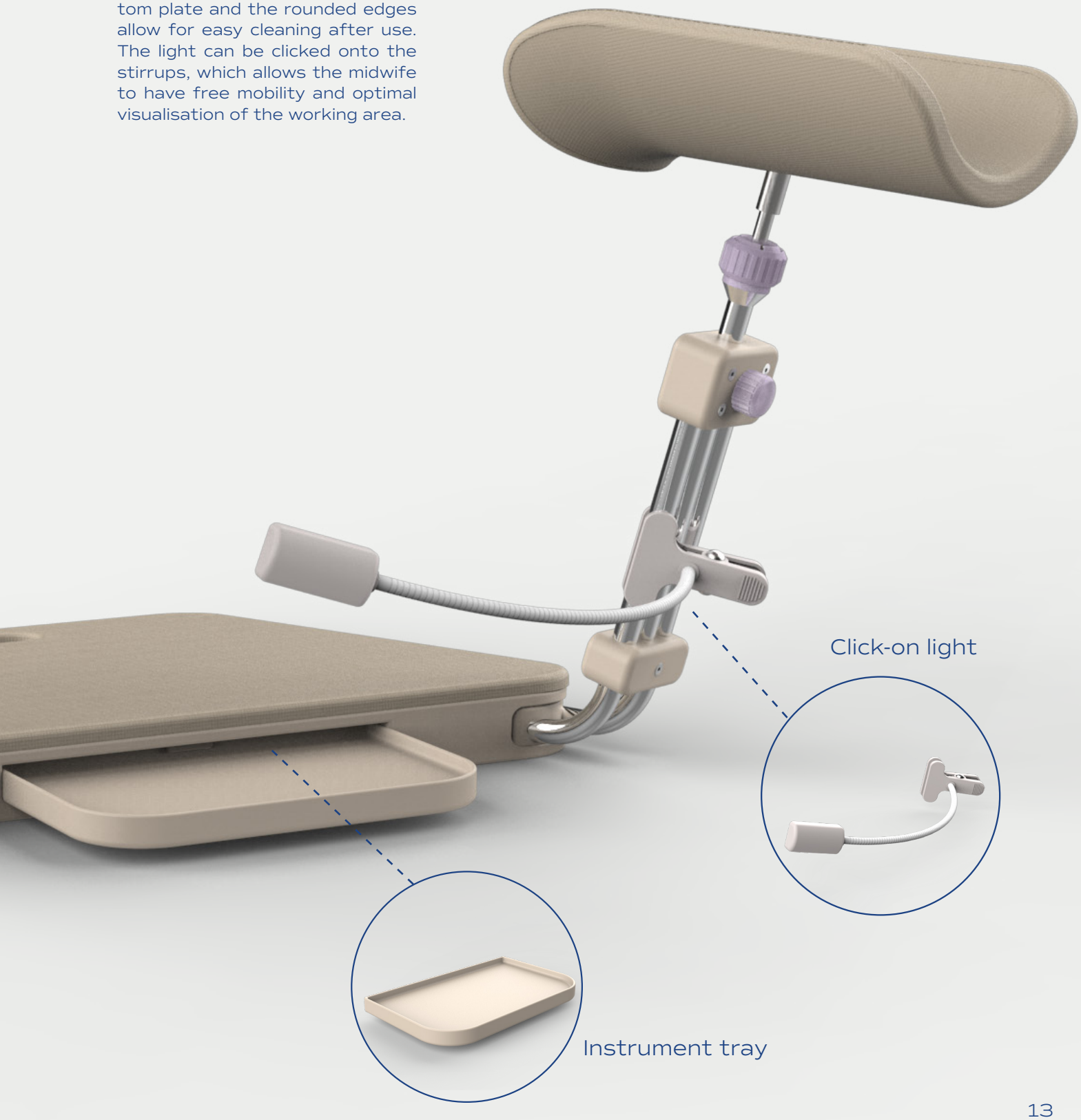
Height adjustment enables the stirrups to be adjusted to fit the individual mother.



A bottom plate cover in PUR provides a soft surface to lie on while being sutured, which can take up to 1.5 hours.

Add-ons

To accommodate the suturing procedure, an instrument tray and light can be attached onto Portable GynoCare. The instrument tray is easily slided into the bottom plate and the rounded edges allow for easy cleaning after use. The light can be clicked onto the stirrups, which allows the midwife to have free mobility and optimal visualisation of the working area.



Use scenario

Portable GynoCare is set up where the assessing and suturing is to take place.

The mother is placed on the bottom plate.

The stirrups and calf-holders are adjusted to the mother.

The instrument tray is attached.

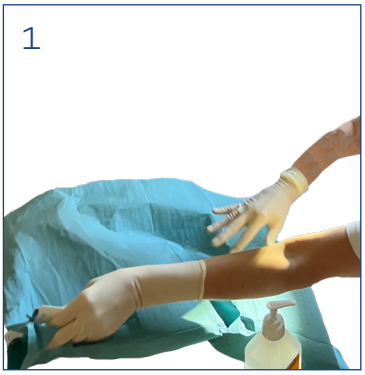
The mother quickly lifts up the buttocks and a sterile sheet is tucked underneath.

The light is clicked on and the instruments are placed on the instrument tray.

Light is turned on and the midwife can start suturing.

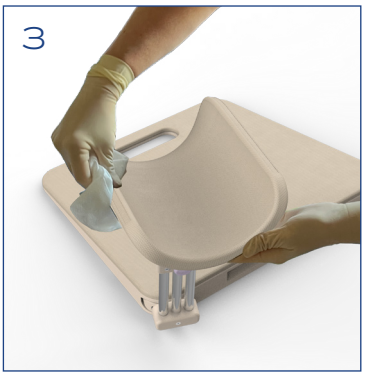
Cleaning scenario

Portable GynoCare can fit into the midwife's existing cleaning routine at a home birth and be cleaned and disinfected using alcohol wipes.



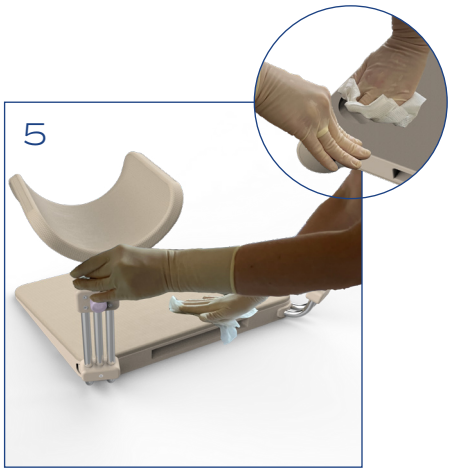
The instruments and sterile sheet are put in separate bags. The instruments are reusable and the sterile sheet is thrown out.

The instrument tray and light is detached and wiped off.



The calf-holders are wiped off.

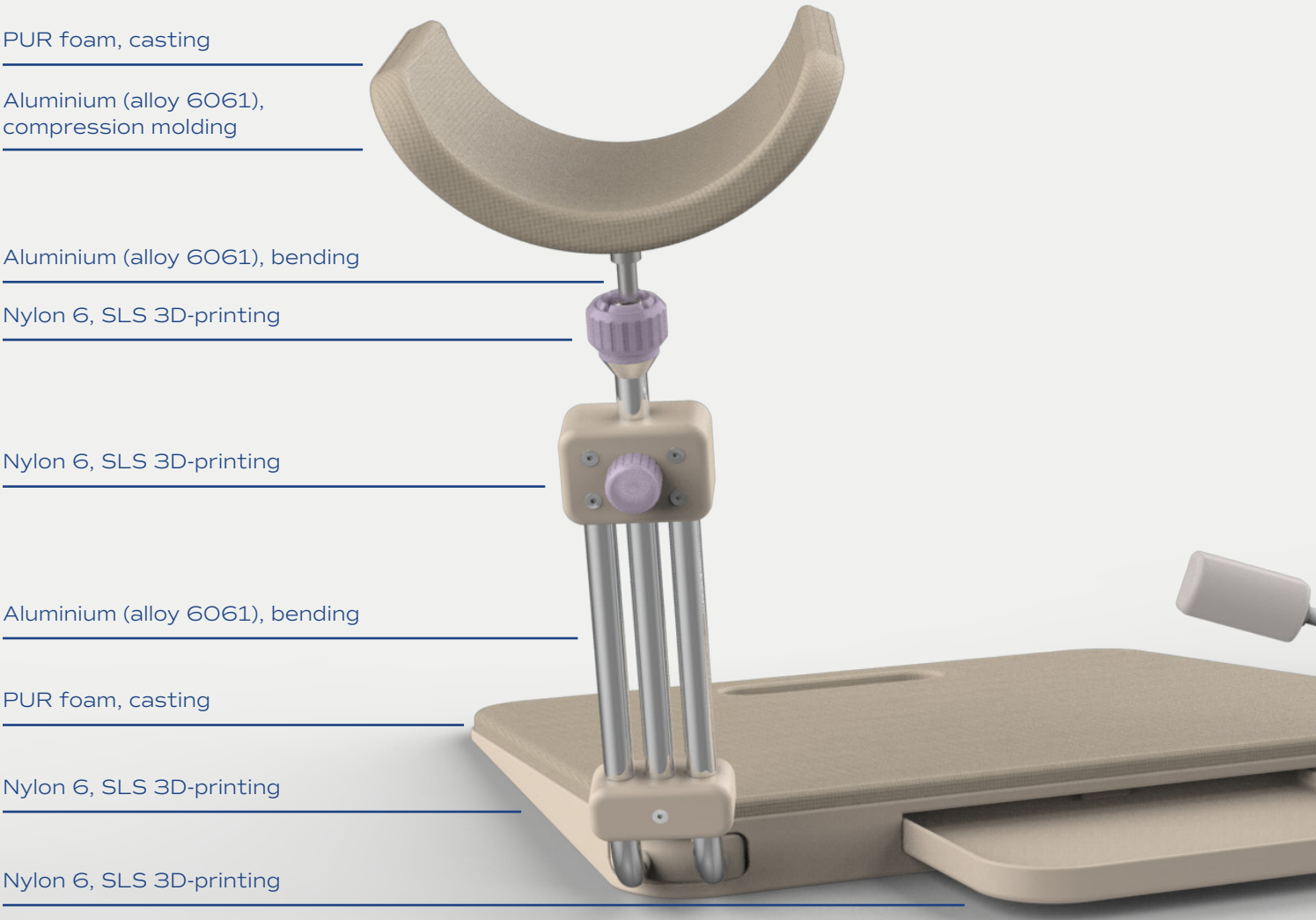
The stirrups are wiped off.



The bottom plate is wiped off including the holes in the bottom.

The stirrups are detached.

Portable GynoCare is packed away and ready for the next home birth.


PUR foam, casting
Aluminium (alloy 6061), compression molding
Aluminium (alloy 6061), bending
Nylon 6, SLS 3D-printing
Nylon 6, SLS 3D-printing
Aluminium (alloy 6061), bending
PUR foam, casting
Nylon 6, SLS 3D-printing
Nylon 6, SLS 3D-printing

Materials

Specifications

Total product weight: 5 kg

Cleaning: >80° and chemically resistant

Height adjustment: 34-50 cm.

Dimensions:
Bottom plate:
H: 40 mm x W: 550 mm x L: 450 mm

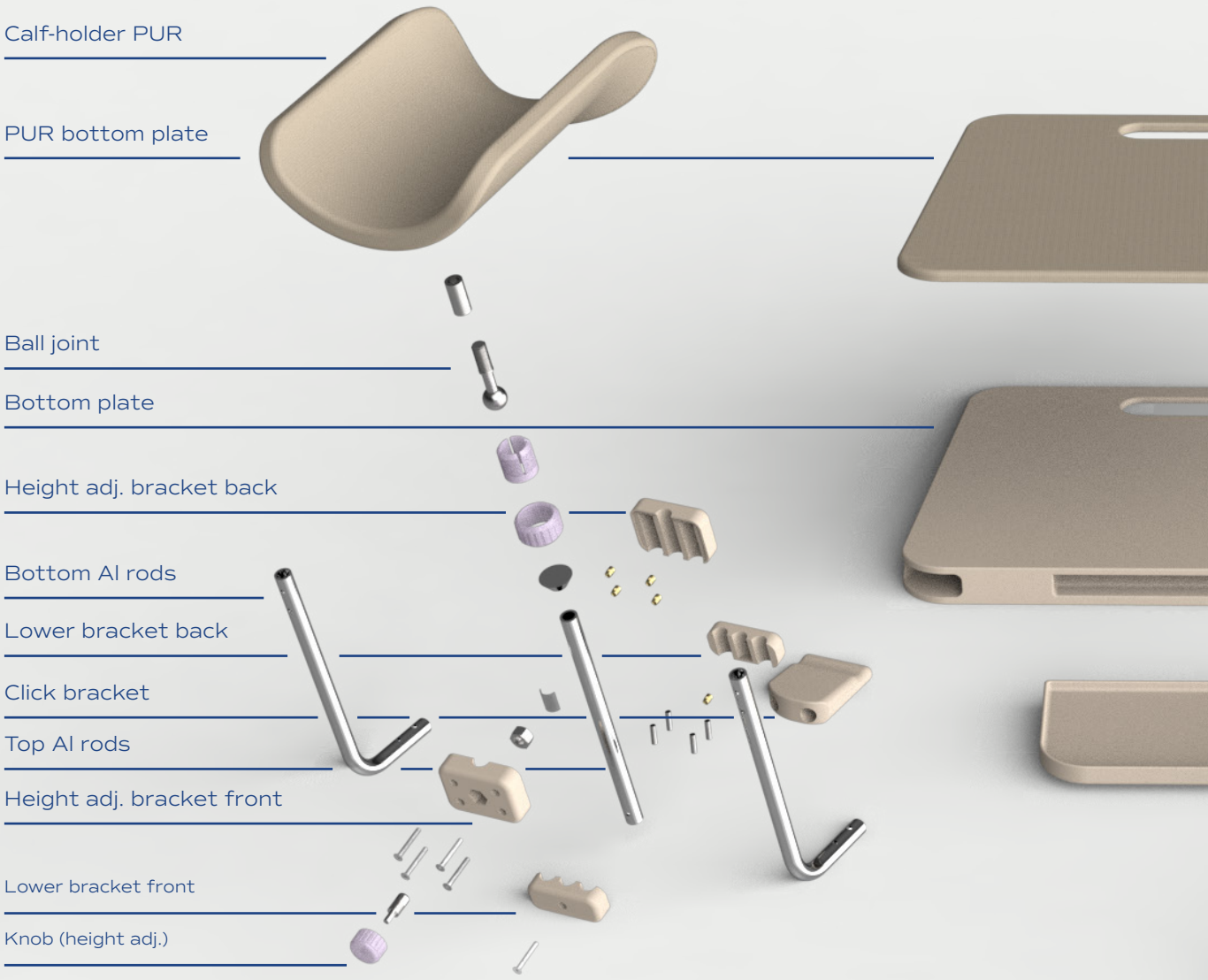
Stirrups total height:
600 mm

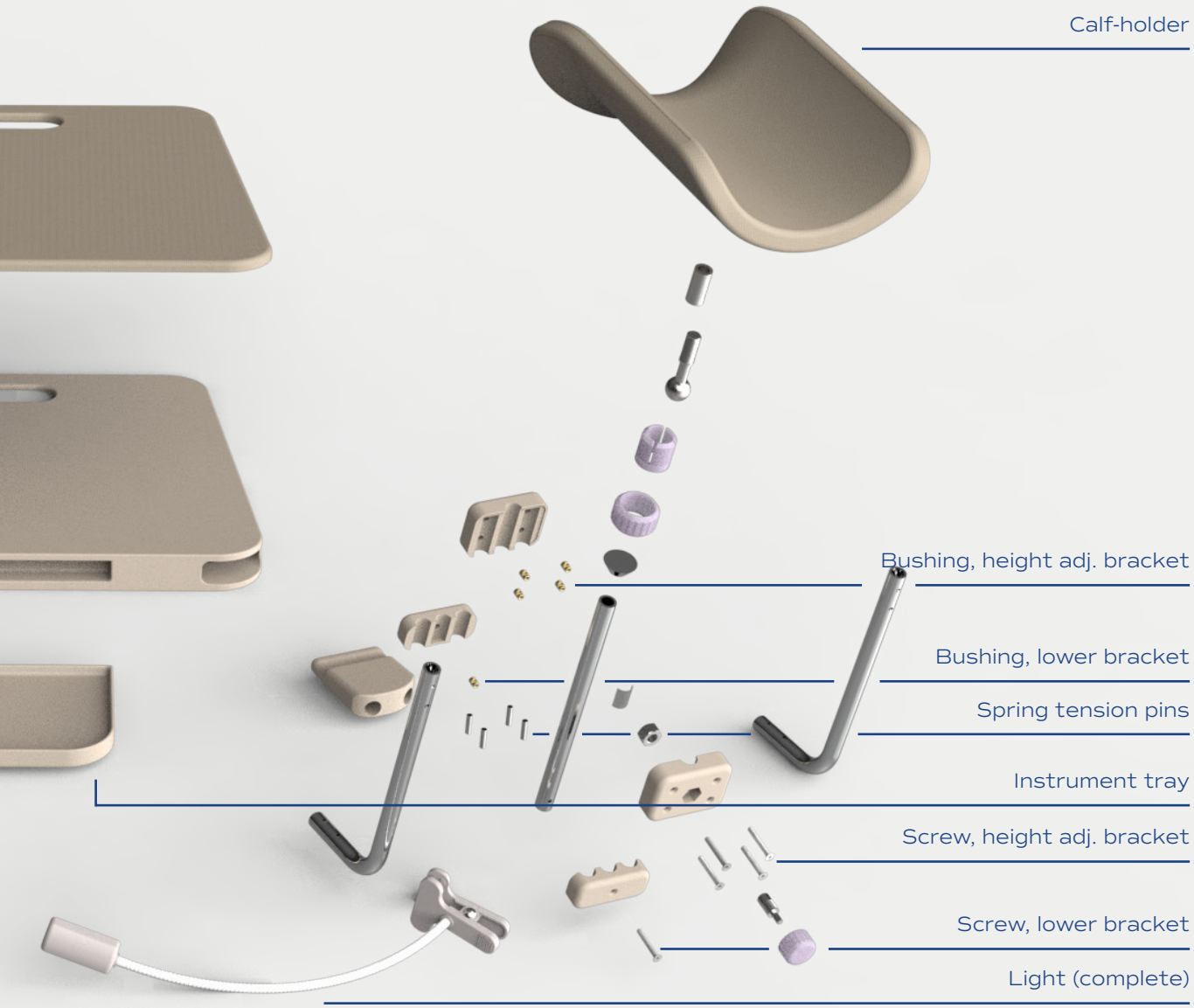
Product with stirrups detached:
H: 220 mm x W: 550 mm x L: 450 mm

Calf-holder:
L: 250 mm x Ø180 mm

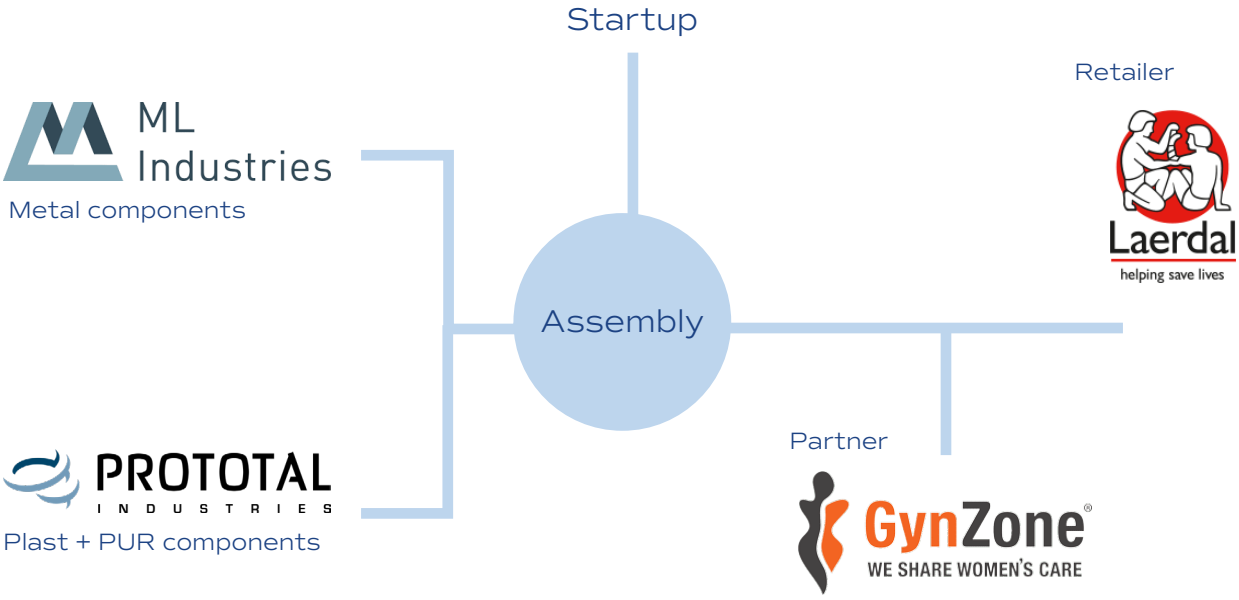
Instrument tray:
H: 19 mm x W: 250 mm x L: 150 mm

Exploded view

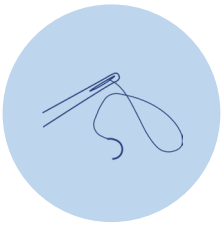



Calf-holder
Bushing, height adj. bracket
Bushing, lower bracket
Spring tension pins
Instrument tray
Screw, height adj. bracket
Screw, lower bracket
Light (complete)

Value chain



Value proposition



With a Portable GynoCare it is possible to do **quality suturing.**

What is provided with a Portable GynoCare is **better ergonomics for the midwife.**

Having a Portable GynoCare the goal is to **standardise suturing at home births.**

Price

Investment **1,200,000 DKK**

Sales for breakeven **41 units**

Breakeven **3 years**

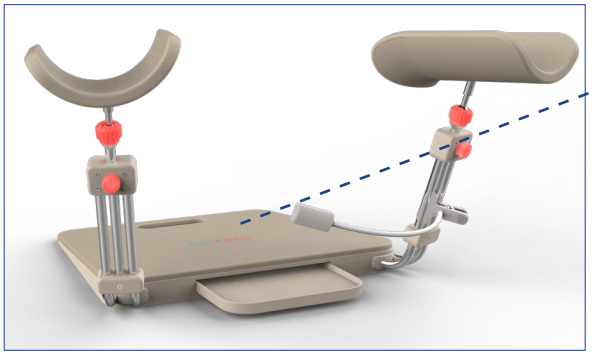
Cost price: **6,062 DKK**

Retail price:
29,000 DKK

Scale potential

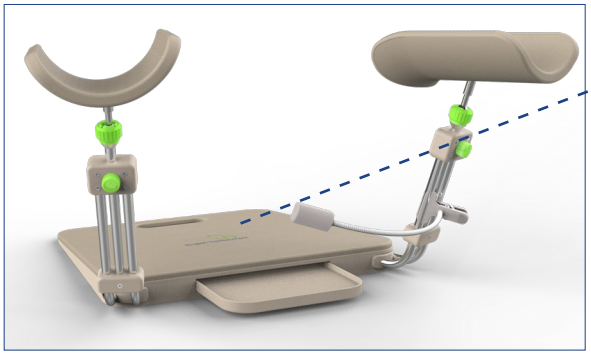
Portable GynoCare has the potential to be scaled to other markets including AmiAmi, moveable ER's and Doctors Without Borders. Here, the product is the same and can be used for various gynaecological purposes, while customisations can be made through logos on the bottom plate cover as well as a colour on the interactions matching the colours of the logos.

Ami Ami



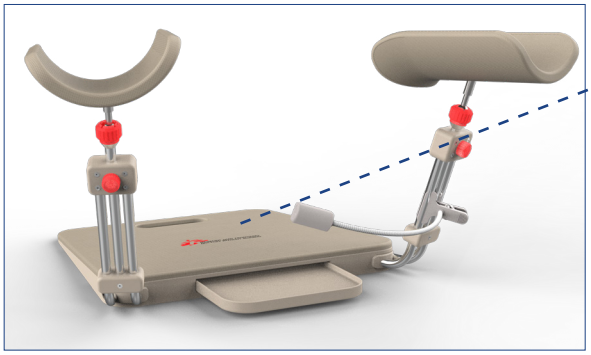
AmiAmi is an organisation focusing on social work and healthcare outreach for migrants who have experienced prostitution and been victims of human trafficking (AmiAmi, n.d.).

South Denmark Region



Moveable ER's is a new emergency vehicle aiming to create a better partnership between paramedics and the ER's (TVS, 2022).

Doctors Without Borders



Doctors Without Borders is a humanitarian relief agency who provides emergency medical aid to the people in need in more than 70 countries around the world (Doctors Without Borders, 2023).

Other scale potentials are LDCs and war-stricken countries.

References

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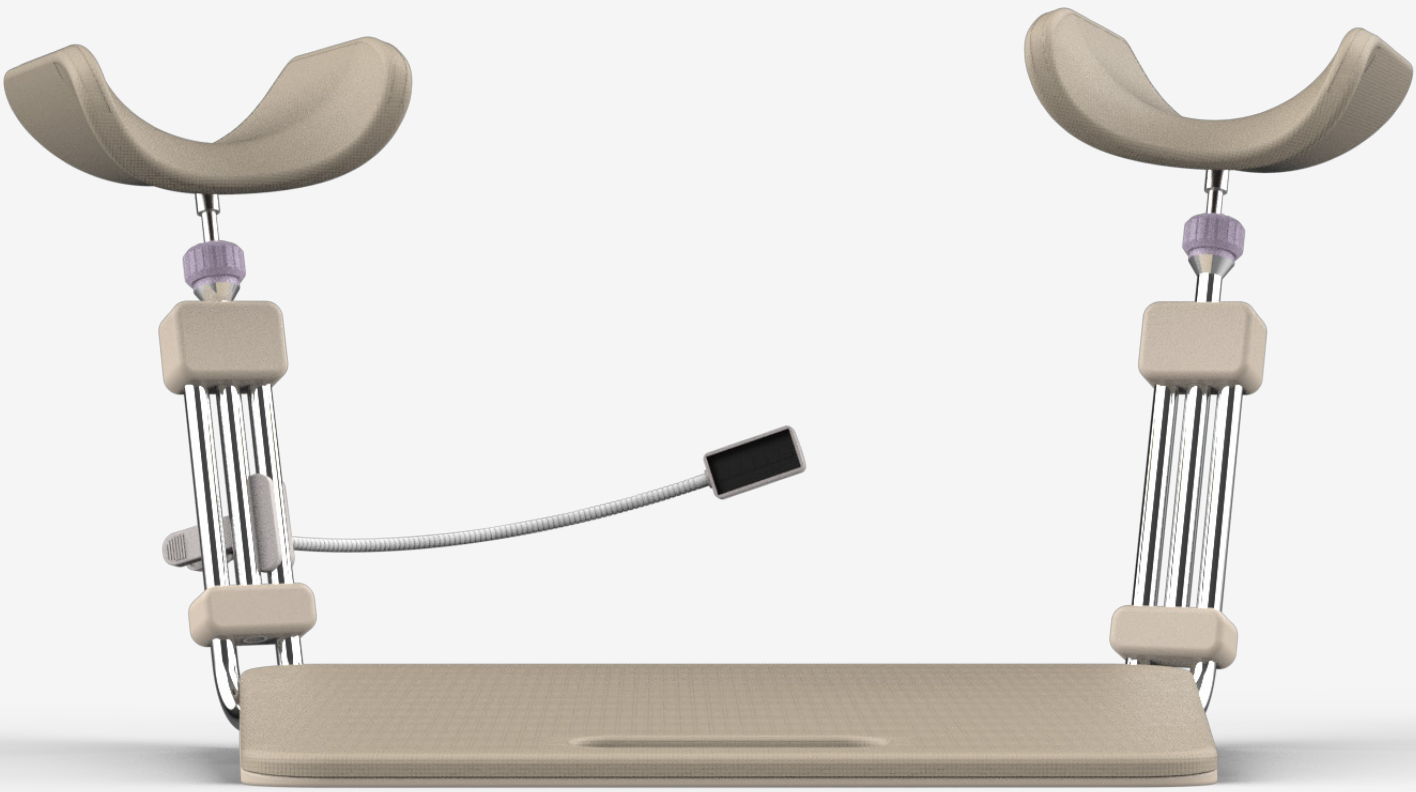
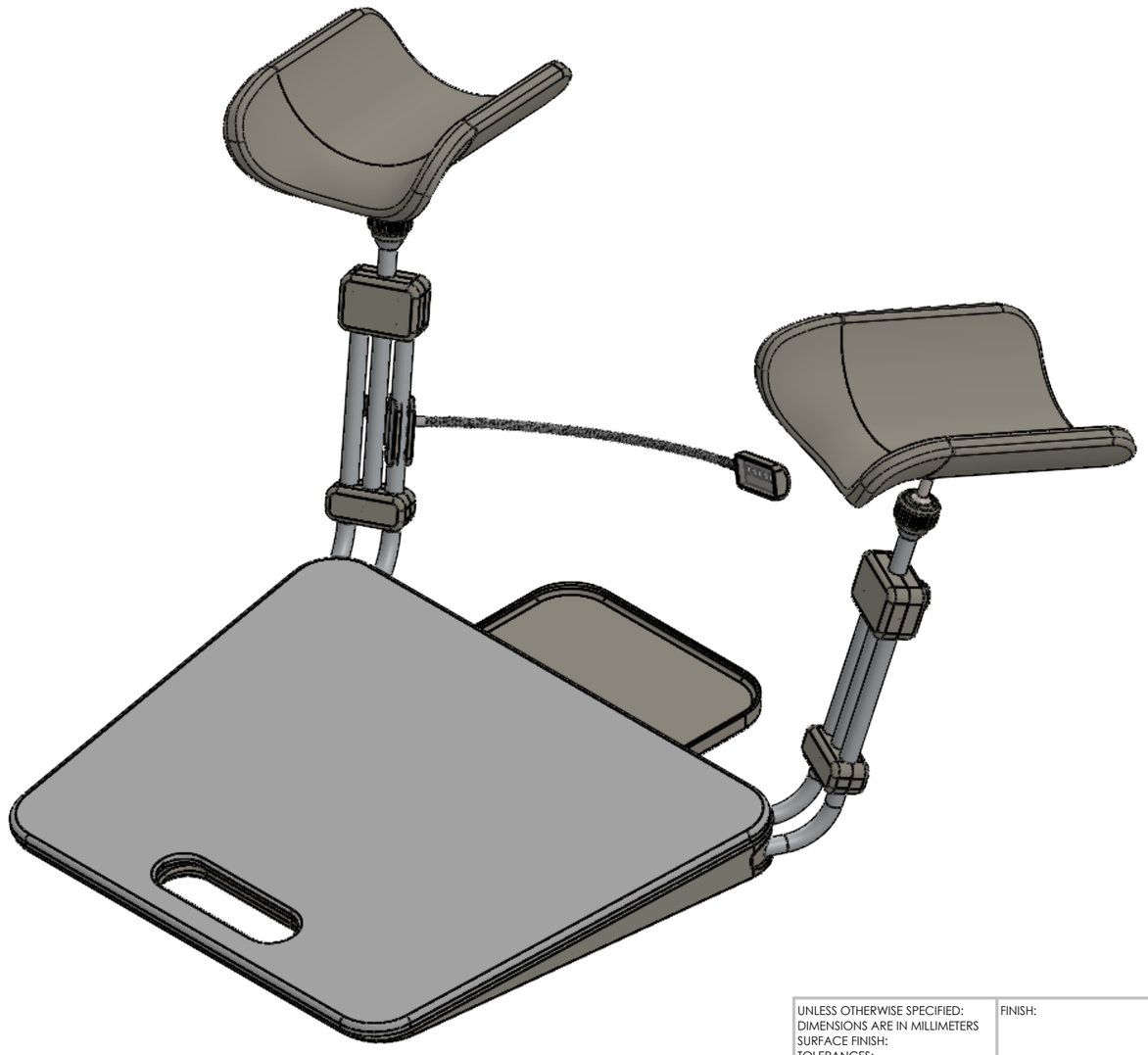


AALBORG UNIVERSITET



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CHK'D							
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Q.A				MATERIAL:		DWG NO.	A3
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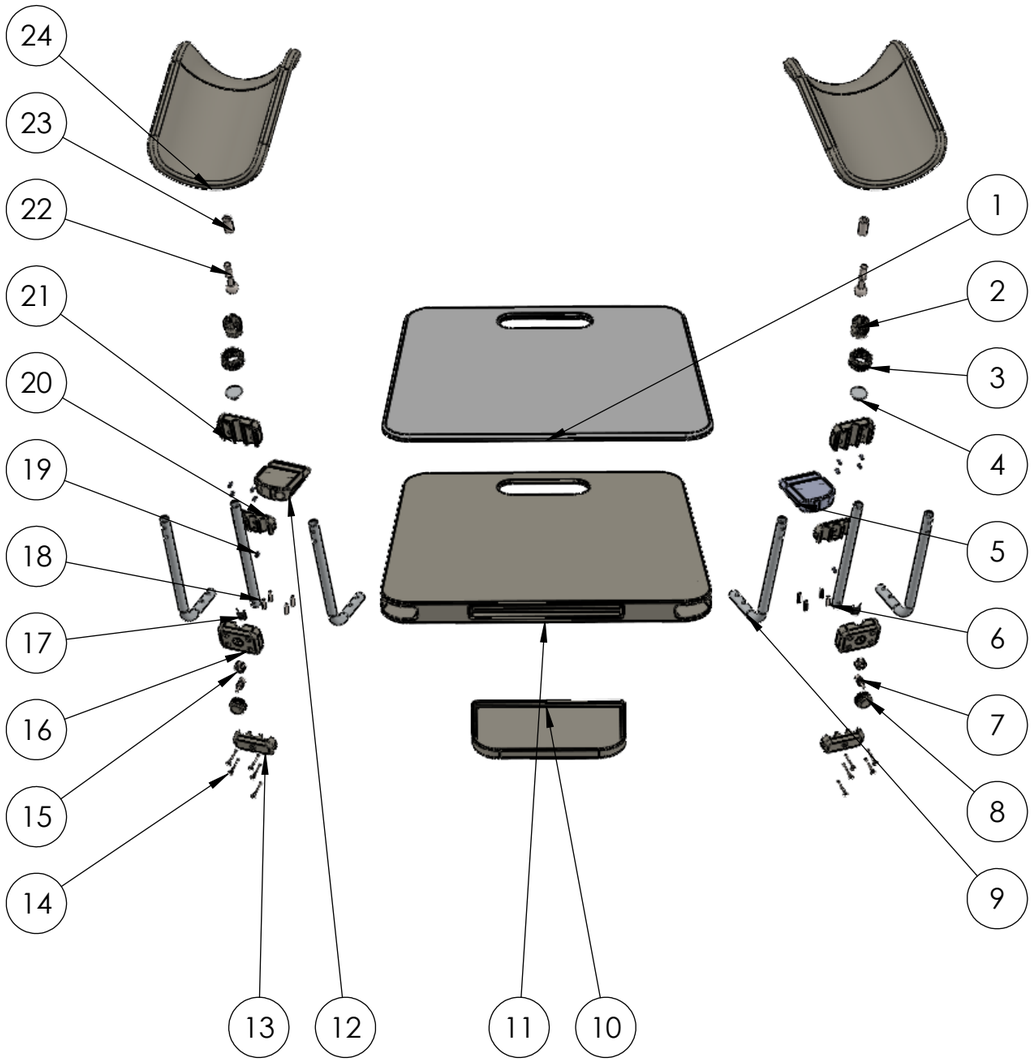

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2	Middle part ball joint	Nylon 6	SLS 3D-printing	2
3	Adjustable ball joint	Nylon 6	SLS 3D-printing	2
4	Top bracket	Aluminium (alloy 6061)	Bending	2
5	Click bracket, right	Nylon 6	SLS 3D-printing	1
6	Upper Al rod	Aluminium (alloy 6061)		2
7	Connecting bar	Aluminium (alloy 6061)	Bending	2
8	Knob	Nylon 6	SLS 3D-printing	2
9	Lower Al rod	Aluminium (alloy 6061)	Bending	4
10	Instrument tray	Nylon 6	SLS 3D-printing	1
11	Bottom plate	Nylon 6	SLS 3D-printing	1
12	Click bracket, left	Nylon 6	SLS 3D-printing	1
13	Lower bracket front	Nylon 6	SLS 3D-printing	2
14	M4x30,counter sunk Screws	Galvanized steel		10
15	Hexagon Nut ISO 4033 - M10 - W - N	Steel		2
16	Height adj, bracket front	Nylon 6	SLS 3D-printing	2
17	Silicone part	Silicone		2
18	DIN EN ISO 8750-5x10-St (tension springs)	Aluminium (alloy 6061)		10
19	M4 Sonic Brass Insert (bushing)	Brass		10
20	Lower bracket back	Nylon 6	SLS 3D-printing	2
21	Height adj. bracket back	Nylon 6	SLS 3D-printing	2
22	Ball joint	Aluminium (alloy 6061)	Bending	2
23	Calf holder tap	Aluminium (alloy 6061)	Bending	2
24	Calf-holder PUR	PUR foam	Casting	2

UNLESS OTHERWISE SPECIFIED:
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SURFACE FINISH:
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LINEAR:
ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING

REVISION

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TITLE:

Exploded view + BOM

DWG NO. A3

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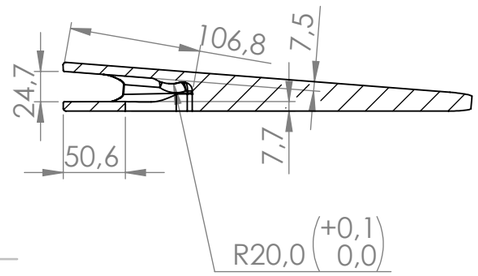
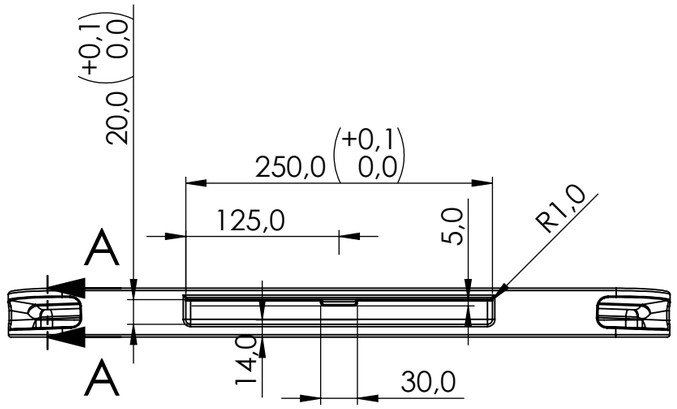
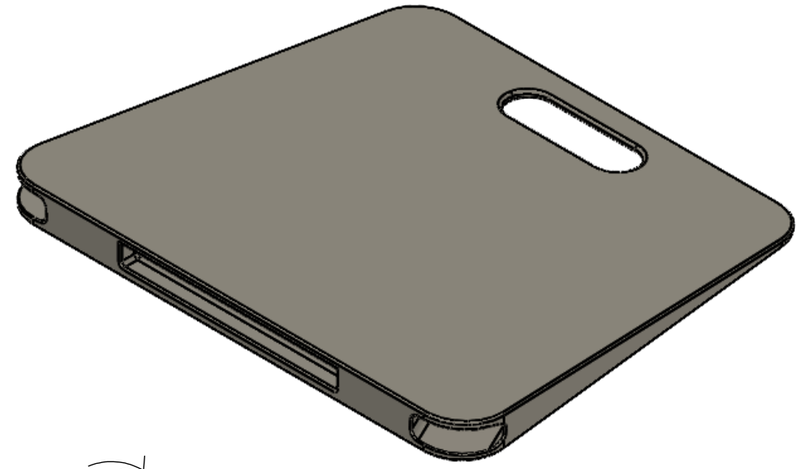
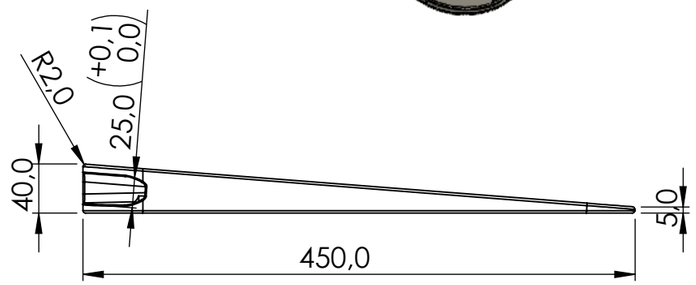
SHEET 2 OF 8

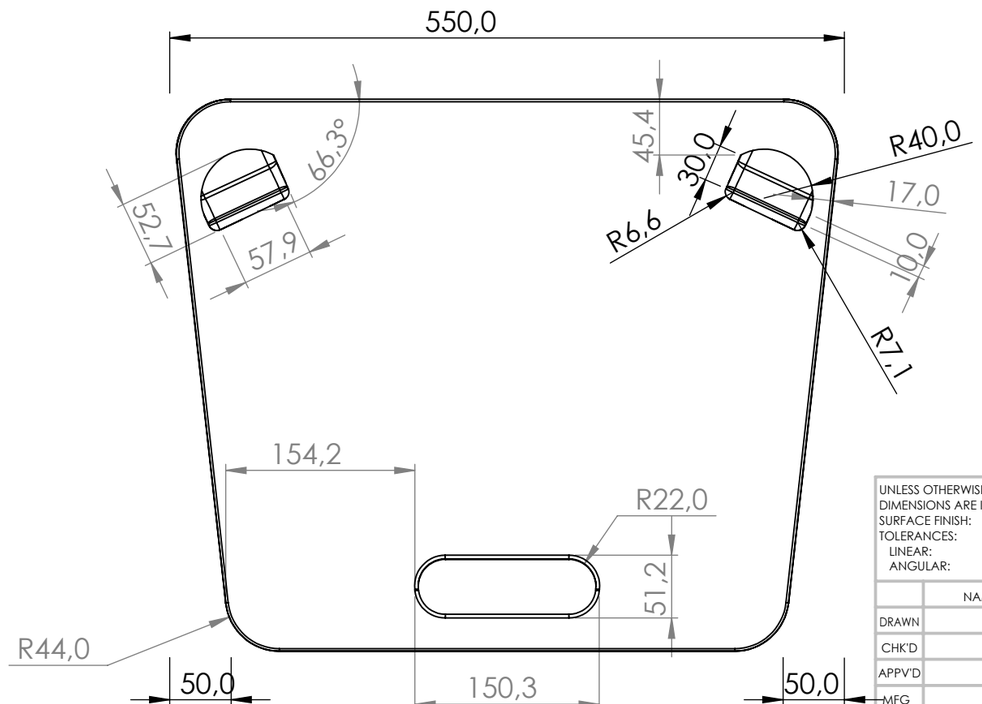
SECTION A-A











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CHK'D							
APPV'D							
MFG							
Q.A				MATERIAL:		DWG NO.	A3
				Nylon 6, SLS 3D-printing			
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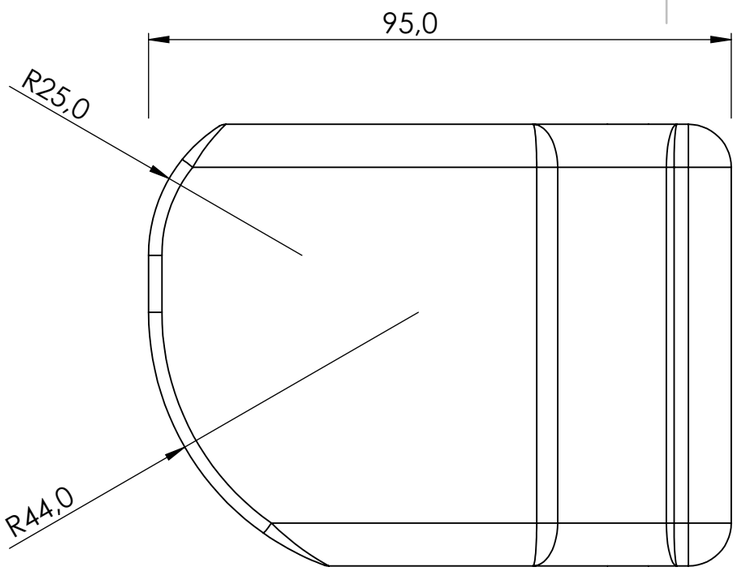

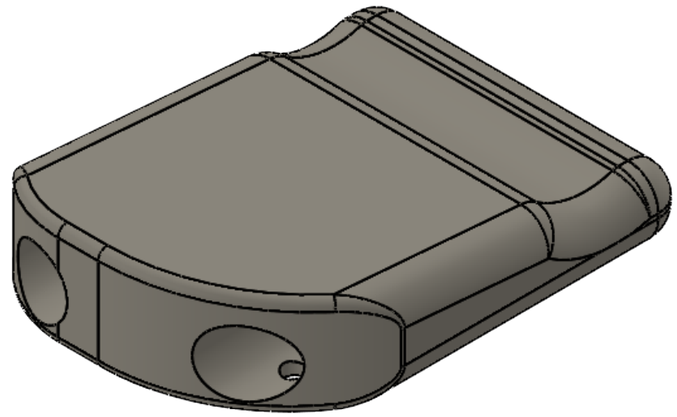

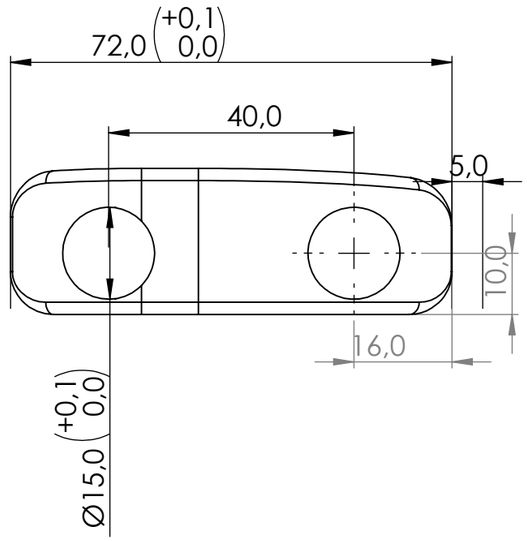

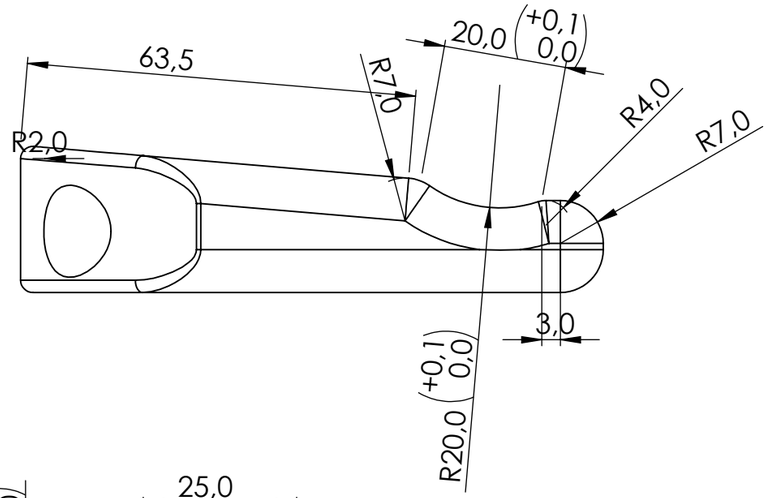

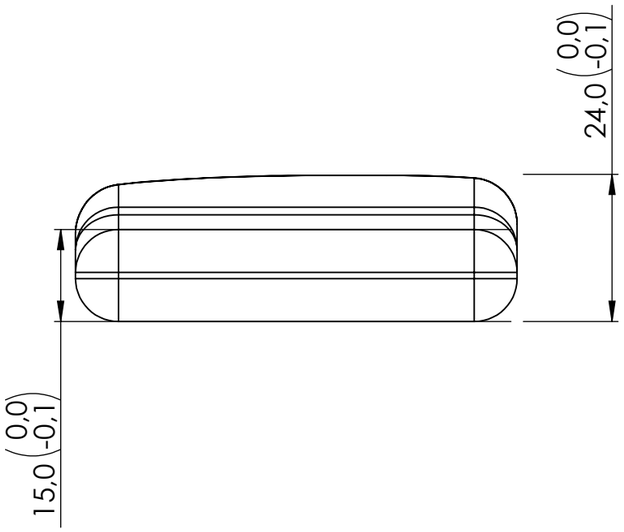

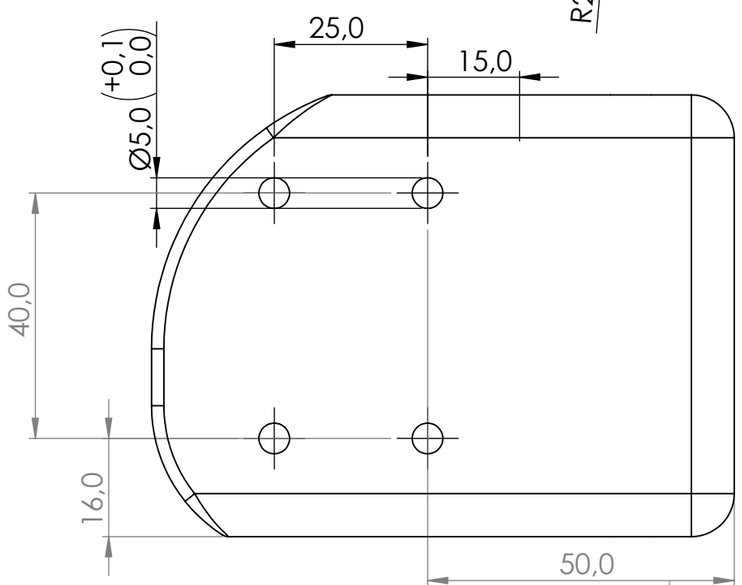

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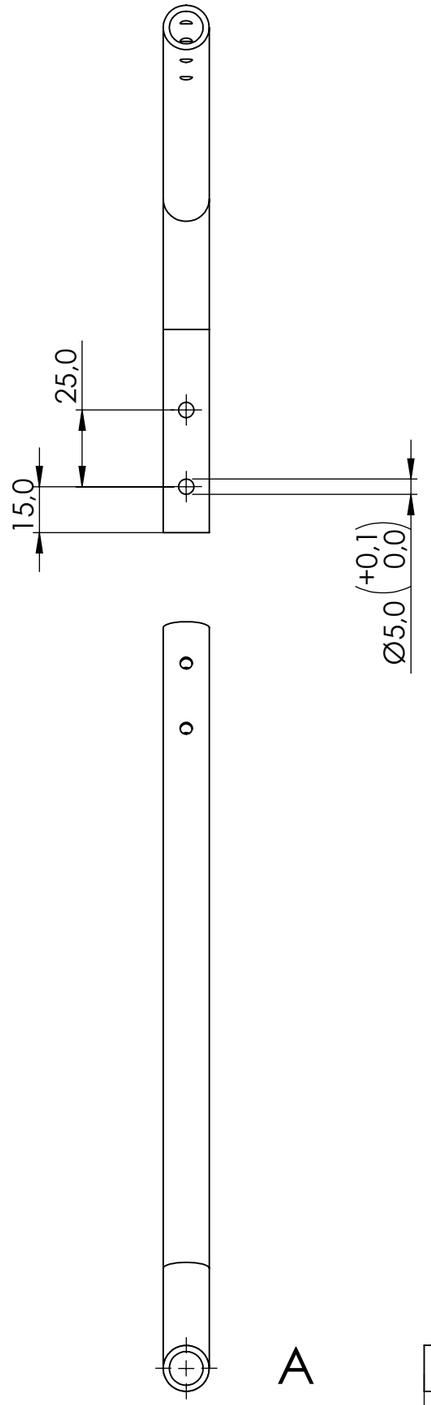

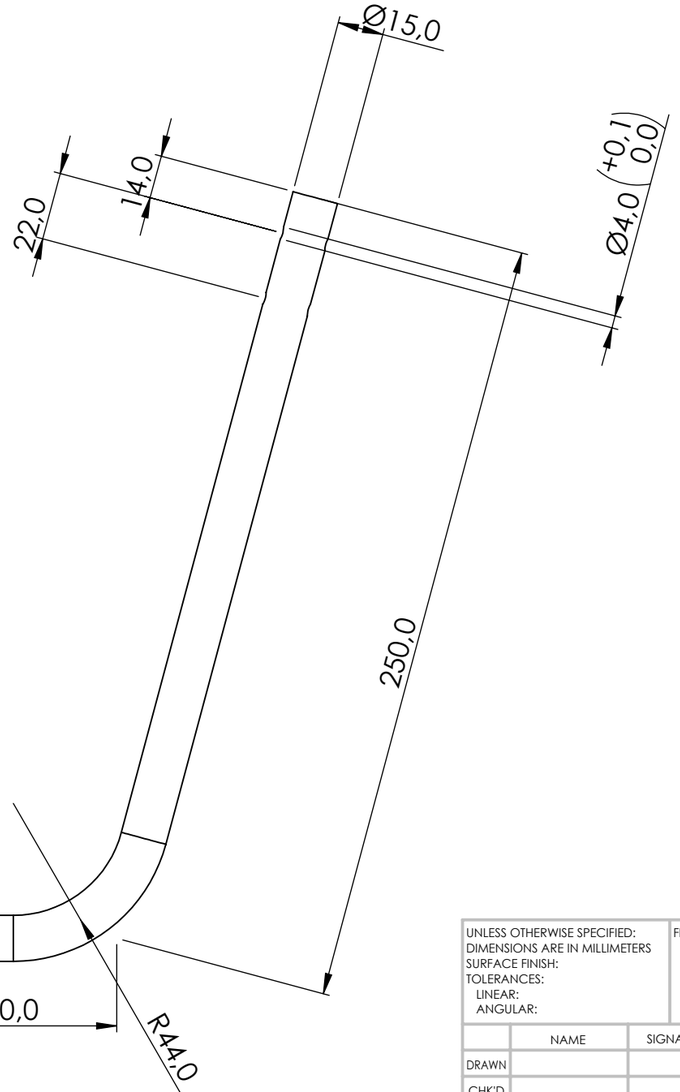

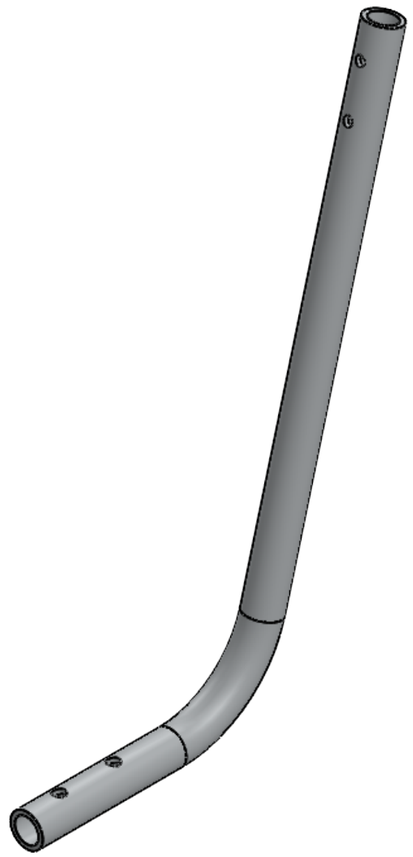

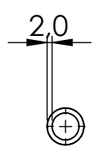

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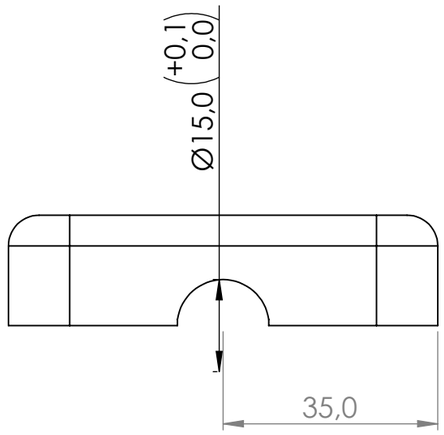

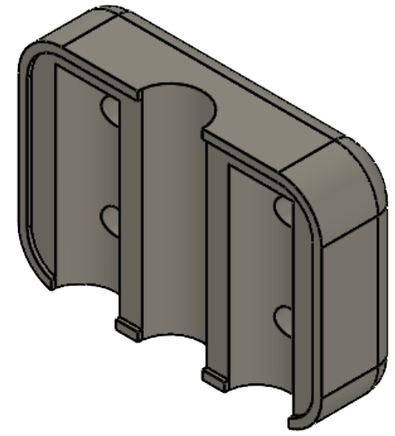

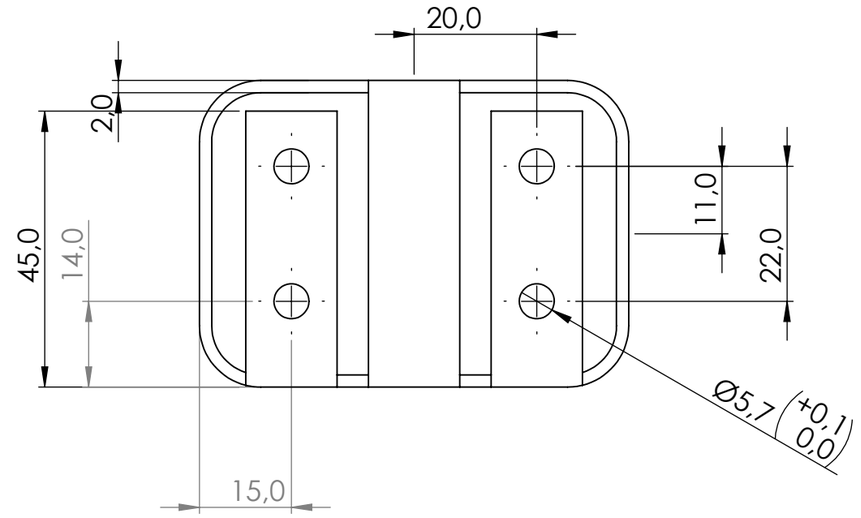

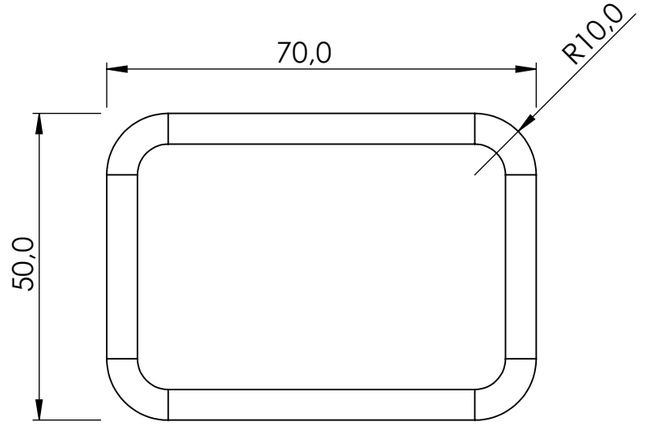

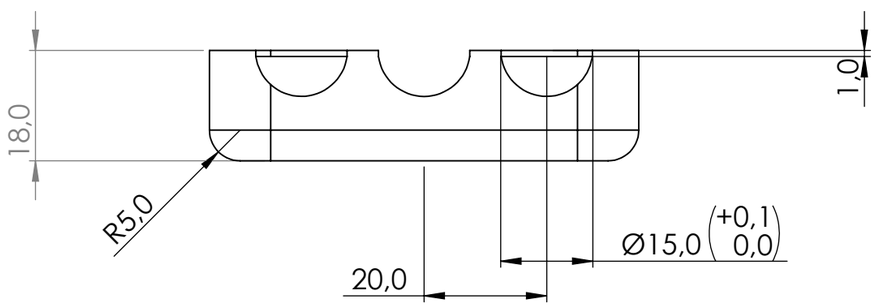

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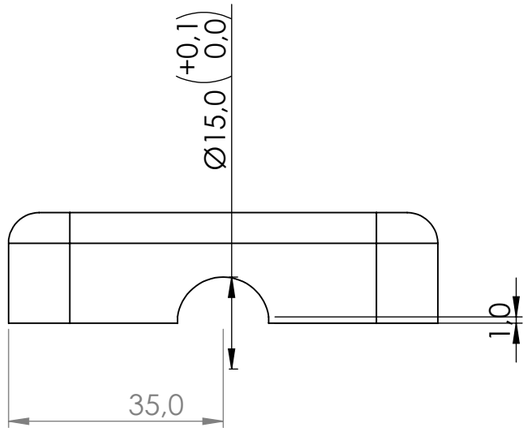

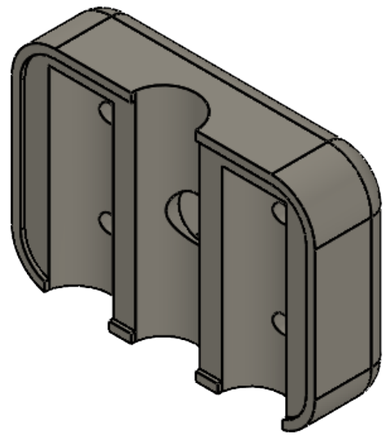

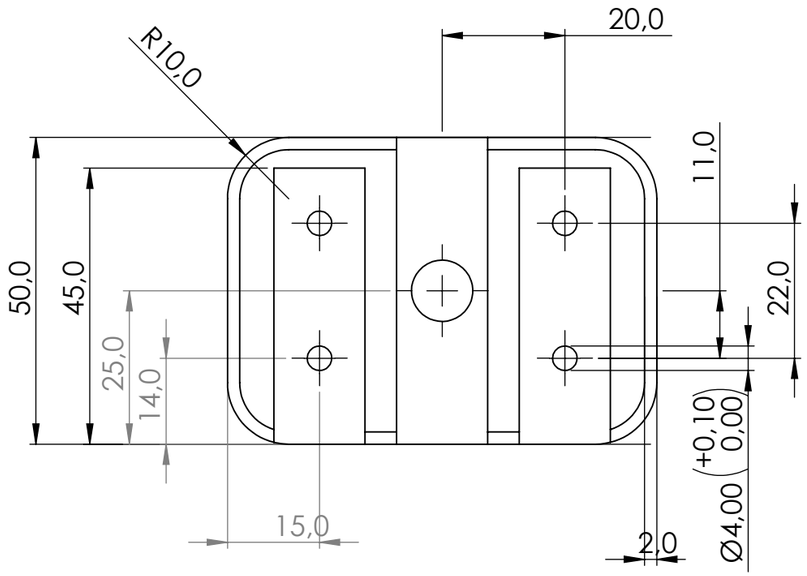

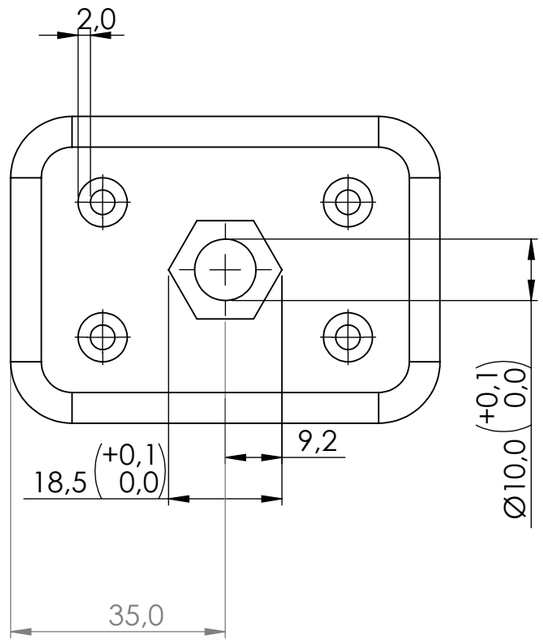

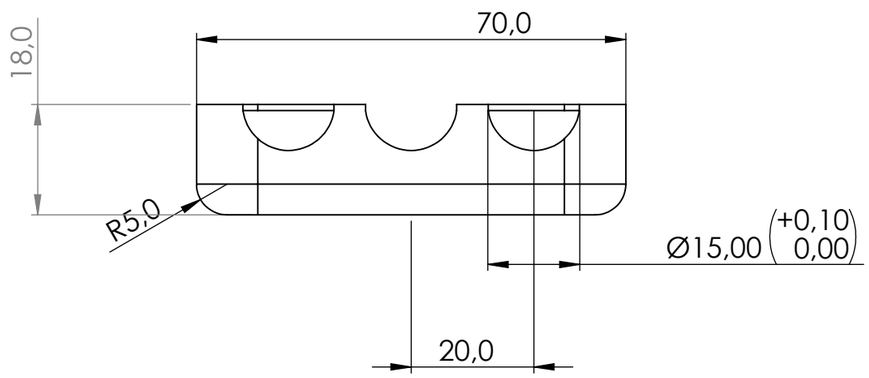

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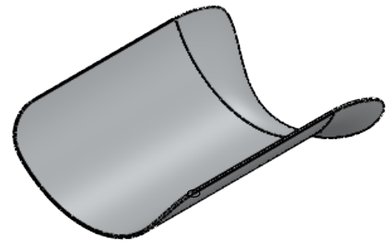

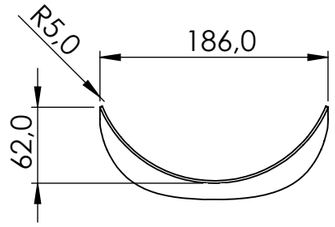

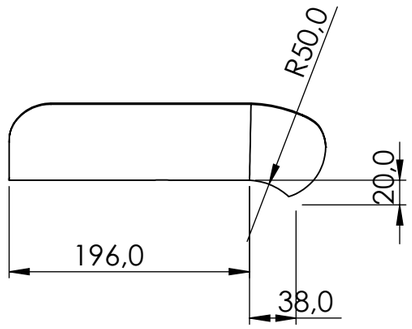

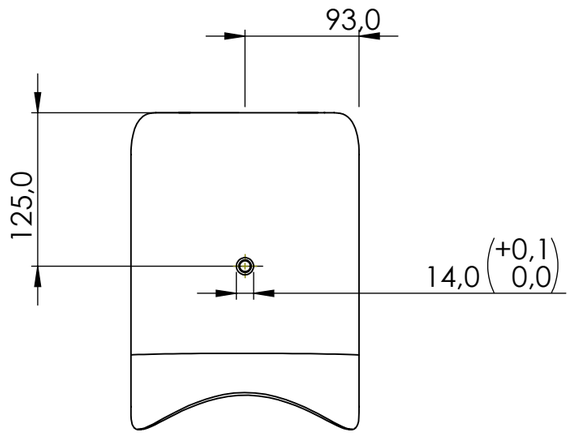

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MFG							
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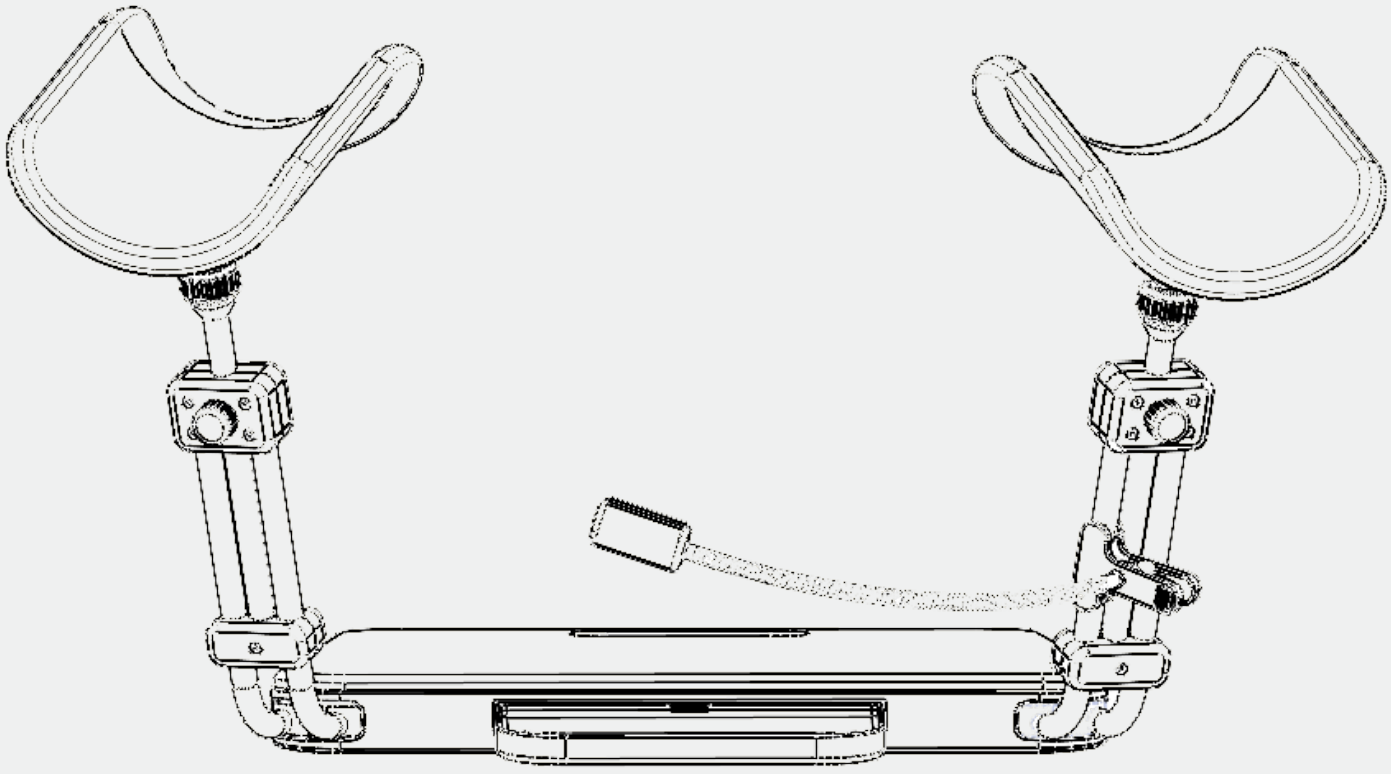
Portable GynoCare

Process report

01/02 - 31/05 - 2023

Aalborg University **MSc04 ID1**
Josefine Kildeberg Paulsen
Victoria Holm Pedersen



Titlepage

Title: Portable GynoCare

February 1st 2023 - May 31st 2023

MSc04 ID1

Main supervisor: Christian Tollestrup

Co- supervisor: Lars Rosgaard Jensen

Pages: 100

Pages of appendix:

ill. 1

Preface

This process report is part of a Master's thesis written in the spring of 2023 by two 10th semester students at the Industrial Design education at Aalborg University. The process report is one of four parts of the Master's thesis together with the product report, Appendix and technical drawings. The process report is an understanding and reflection of the design-process towards designing a product for aiding midwives when suturing postnatal tears at home births.

A huge thank you is addressed towards midwife Dorte Sloth Svendsen from Aalborg University Hospital for assistance with identification of the initial problem for the thesis and numerous interviews, feedback and user tests. Another thank you is addressed towards the mothers and other midwives, who were interviewed for the thesis and helped with testing of concepts. This provided a valuable insight into home births from different perspectives and the problems that are faced for both mothers and midwives.

Lastly, a big thanks is addressed to the supervisors for the thesis Christian Tollestrup and Lars Rosgaard Jensen for assistance, guidance and supervision throughout the project.

Abstract

The number of home births in Denmark has increased more than 150% within the last 10 years. Home births have several advantages for mothers, who are more in control and benefit from the enhanced production of birth hormones during birth due to the well known and secure setting at the home. However, the working conditions for midwives are more difficult at home births, since they do not have the same setup as the hospital. This is especially a problem when suturing postnatal tears. In order to assist the midwife when suturing postnatal tears for home births in different settings, a product can be designed to assist with holding the mother's legs in the correct position for suturing, similar to the stirrups used at the hospital for suturing today. This will also improve the working position of the midwife while suturing. By doing research and conducting interviews with multiple midwives and mothers, the needs and requirements of these user groups are understood. This is used to make sketches of concepts, CAD models and mock-ups, which are tested with midwives and shown to mothers to evaluate the function, use, interaction and perception of the concepts. The resulting product is a rigid bottom plate designed with adjustable stirrups to accommodate the optimal position of the legs for different mothers in a home birth setting. The product can be easily cleaned in the home after use and includes an optimal light source for suturing in both light and dark settings and an instrument tray for the suturing kit. The stirrups can be detached from the bottom plate for easy transportation. The product can potentially standardise the quality and procedure of suturing postnatal tears at home births and help the midwife obtain a more ergonomic position while suturing.

Reading guide

The process report is divided into five chapters regarding background knowledge, research, concept development, specifications of the final product proposal, and epilogue, even though the design process is iterative. Throughout the report, elaboration of tests, research, calculations or notes from interviews are presented in the Appendix.

The content of some of the sections lead to identification of requirements for the product design. The requirements are presented in the bottom of the sections in a box as seen below. Development of the requirements can be tracked by a system with numbers and letters, where the number refers to the section and letter refers to the sequence of the requirements. The old requirement is either changed or specified by turning into the new requirement marked by an arrow as presented below.

[1.3e] → [1.12a] Example of changed requirement

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Introduction

In 2021, there were 58,430 births in Denmark where 1,870 of them took place at home. This is equivalent to 3.2% which is an increase of more than 150% within the last 10 years. (Sundhed.dk, 2022) (Danmarks Statistik, 2022) (Sundheds-datastyrelsen, 2017) Home births have multiple advantages for the mothers giving birth at home and is also advantageous for society. It has been estimated that a home birth is approximately 7,800 DKK cheaper than a hospital birth. (Thomsen and Brix, 2017)

Even though home births can be advantageous for mothers, the working conditions for the midwife assisting the home birth are more difficult compared to a hospital birth. Since the midwives are usually working alone at home births and do not have the same setup as at the hospital, the midwives have to be more well-prepared and able to identify upcoming problems before they occur. Especially assessment after birth and possibly suturing of postnatal tears at home births can be challenging for the midwife due to the different settings of the individual home. 86% of all first time mothers tear after birth and therefore need suturing (Drechsler, n.d.a). In general, this is a delicate subject and something that is not spoken much about outside the midwife profession.

During suturing of postnatal tears at home births, the ergonomic position of the midwife normally gets compromised, since the mother is positioned in a non-optimal way. The correct positioning of the mother is crucial in order to suture the tissue and muscles correctly together to avoid transferring the mother to the hospital for suturing.

The scope of this master's thesis is to design a product which aids the midwife while suturing postnatal tears at home births by enabling the correct position of the mother in different settings. This is done to obtain quality suturing outside the hospital setting and standardise the procedure for suturing postnatal tears at home births.

The user panel

The user panel for this project consists of three user groups in order to understand different aspects of the problem and obtain feedback on concept development.

Primary user:
Home birth midwife

The product will be a work tool for the midwife.

ill. 2

Dorte
Sloth Svendsen

ill. 3

Sanne
Lykke Wilhelmsen

ill. 4

Camilla
Rosborg Larsen

ill. 5

Lillian
Bondo

ill. 6

Maria
Nielsen

ill. 7

Maryam
Gjerde

ill. 8

Angela
Wakeford

ill. 9

Sam
Simpson

Tertiary user:
Vice Head of midwives

Responsible for purchasing new equipment for the midwives.

ill. 10

Line
Hundebøl Nielsen

Secondary user:
Home birth mothers

The product is used on them at home birth.

ill. 11

Cecilie
Alletorp

ill. 12

Siv
Fuglsang

ill. 13

Malene
Schøler

ill. 14

Anne
Kock Nielsen

ill. 15

Anne-Katrine
Perez Rüsz

ill. 16

Rikke
Højgaard

ill. 17

Karina
Søborg Madsen

ill. 18

Christiane
Pedersen

ill. 19

Line
Birk Bos

ill. 20

Henriette
Munch Chistensen

ill. 21

Ane
Thomsen

ill. 22

Mette
Smeenge

00 - Background

ill. 23

This chapter presents the preliminary thoughts and information gathered before beginning the work on the Master's thesis. It includes an initial interview with a midwife, which was the foundation for the initial problem identification and resulting project direction.

0.1 Motivation and initial interview

The motivation for this Master's thesis originates from an assumption that mothers giving birth at home need something to improve their overall situation, hereby making the home birth experience better.

An initial interview with Dorte Sloth Svendsen (see Appendix 1), home birth midwife from Aalborg University Hospital, is conducted prior to starting the project. Here, she demonstrated some of the problems regarding home births which both she and her coworkers are experiencing. She explains that when midwives are assisting at delivering a baby at a home birth, they do not have the same setup or equipment as at the hospital. This is valid through the whole process including before (prenatal), during (delivery), and after birth (postnatal).

A midwife is typically alone during a home birth. Therefore, she needs to be ten steps ahead at all times to avoid critical situations from happening. During the interview, three postnatal problems are shown and discussed;

Suturing at home

Space for equipment

ill. 24

Need for a specific space well suited to place equipment.

No leg support

ill. 25

Need for something to hold the mother's legs in the correct position to avoid bad ergonomic positions.

Lack of lighting

ill. 26

Lack of proper lighting while suturing is often a problem, especially during the evening and night.

These problems all relate to when the midwife is assessing the mothers' external and internal genitalia and suturing postnatal tears at home births. Currently, when mothers are being sutured at home, they need to hold their own legs, or support them on the midwives thighs, which in both cases require a certain strength for both the midwife and mother. Furthermore, there is usually no optimal space for equipment, which forces the midwife into unergonomic positions, and since most births take place at night, illumination of the working area when assessing and suturing potential tears is often poor.

Needs and prioritisation

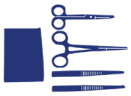
From the initial interview, three potential solution areas are seen, based on the three individual problems which Dorte presents. It is expected that the solution to these problems can take the form of a single product instead of three separate products. However, it is difficult to solve everything at once and it is therefore chosen to prioritise the needs;

ill. 27

1. Support for the legs

ill. 28

2. Illuminated work area



ill. 29

3. Space for the suturing kit

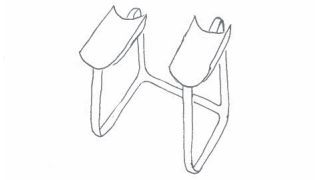
Light and space for the suturing kit are the second and third priorities, because it makes more sense to solve the problem of placing the mother's legs correctly first, since this has the largest impact on the midwife's ability to suture tears properly.

Evaluation

At home births, the midwife does not have access to the same equipment as at the hospital. Since the midwife is typically alone at a home birth, she could benefit from something to assist her for suturing of postnatal tears. From the initial interview with Dorte Sloth Svendsen, three problems that she and her colleagues usually face are identified, which is the need to hold the mother's legs correctly, have proper working light and a place to conveniently place the instruments for suturing. These problems are prioritised and since this was an initial introduction to the problems, further examination of these problems has to be made. Therefore, home births in general, knowledge from more midwives into the problems and scenarios and whether there is already a related product on the market should be investigated.

0.2 Preliminary directions

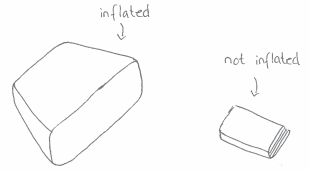
Based on the initial interview and the presented solution areas being something to hold the mother's legs, three preliminary directions have been set up;



ill. 30

Rigid, floor-based support

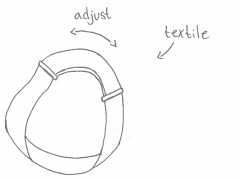
Similar structure to the ones at the hospital beds, but in a portable way.



ill. 31

Inflatable support

A support that does not take up much space during transportation, but can be inflated at arrival.



ill. 32

Textile-based support

Using a piece of textile wrapped around the legs and mother's neck. A low-weight and soft solution that can be washed.

Advantages and disadvantages can be seen for all the preliminary directions. The textile-based support could be easy to adjust and soft to wear for the mother, but might be harder to clean in the home. The inflatable support is good for taking up less space for transportation, but might not provide the desired support. The rigid support would be very good for placing the mother's legs in the correct position and easy to clean, but it might be more uncomfortable for the mother. Therefore, research into the different directions of a product solution has to be made.

01 - Research

ill. 33

This chapter presents research into different aspects of home births. It examines the problem scenario, the suturing process, the equipment used by the midwives as well as the home birth experience for the mothers, market analysis and thorough research into the correct position of the mother for suturing, light and ergonomics for the midwife. The section is based on qualitative, semi-structured interviews with mothers and midwives as well as desk research.

1.1 Initial research

The purpose of this section is to understand the circumstances around the identified problems further. Therefore, it is decided to perform initial research into the concept of home births in general. It is necessary to examine who gives birth at home, what the differences are between a home birth and a hospital birth and why mothers choose to give birth at home.

When can you give birth at home?

In Denmark, the majority of mothers give birth at a hospital, since hospital births are the default if e.g. a home birth or clinic birth has not been requested. However, in order to have a home birth, the mother needs to be approved by a midwife. The mother needs to live up to the following main criteria in order to be approved (Regionshospital Nordjylland, 2019);

- Give birth within the timeframe (37+0 and 42+0).
- The baby lies correctly with the head facing down.
- BMI below 35.
- A good health without any chronic illnesses or medical prescriptions.
- The birth has to begin spontaneously, without labour-inducing drugs.
- An uncomplicated pregnancy.
- No uterine inertia, green amniotic fluid or fever during birth.
- Any previous births have been uncomplicated.

If a mother does not meet these criteria, the midwife advises her to have the birth at the hospital instead. This can also be the case close to or during labour, resulting in moving the birth from the home to a hospital. However, according to the health legislation in Denmark, a pregnant woman has the legal right to give birth at home with a midwife present, even if it is not recommended by a midwife (Jordemoderforeningen, 2020).

Why have a home birth?

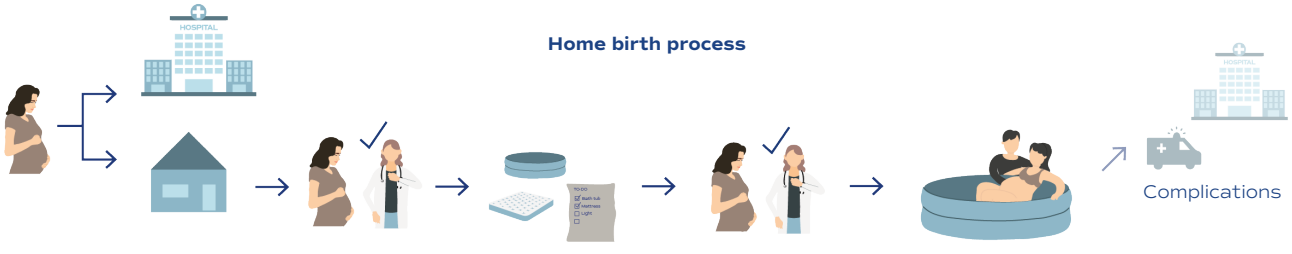
There are many advantages to home births, the biggest being that there are fewer severe tears (Olsen, n.d.) because the mothers are less affected by the medical procedures performed to speed up the birth (Forældre og Fødsel, n.d.). Other advantages are that the drive to the hospital is avoided, there are fewer procedures and the mothers feel safer in their own home. This is important for the production of oxytocin, also called the birth hormone, which increases contractions. The production of endorphins is also increased at home, which is important since they work as pain relievers. Some disadvantages are that no medical pain relief is available and that there is about a 12% risk of being transferred to the hospital due to complications. (Hjemmefødselsordning Sjælland, 2023) (Privatjordemoder.dk, 2023) Even though it is commonly believed, there is no evidence that there is a larger risk associated with giving birth at home compared to a hospital in general. However, some studies show a small increase in the risk for first time mothers giving birth at home. (Schultz and Glerup, 2017)

Preparation for home birth

More preparation goes into a home birth for the mother and partner compared to a hospital birth. When a home birth has been arranged, the midwife provides a list of things that need to be prepared at home before the birth. This includes proper lighting, food and drinks for the midwife and mother and equipment to aid during birth such as towels, a bucket, cloths, birthing pool, proper seating for the midwife etc. (Regionshospital Nordjylland, 2019). The preparation for the birth at home is one of the factors which results in the reduced price of a home birth compared to a hospital birth. (Thomsen and Brix, 2017). The price of a home birth is 19,848 DKK, compared to the price of a hospital birth for a first time mother which is 27,262 DKK (Thomsen and Brix, 2017).

Evaluation

There are specific requirements that need to be fulfilled in order to be approved by a midwife for a home birth, even though everyone in Denmark has the right to give birth at home. Home births have several advantages including fewer medical procedures and less severe tearing, and there is only a small risk of being transferred to the hospital due to complications. The mother has to prepare more for a home birth, and only one midwife attends which results in the price of a home birth being lower than a hospital birth.



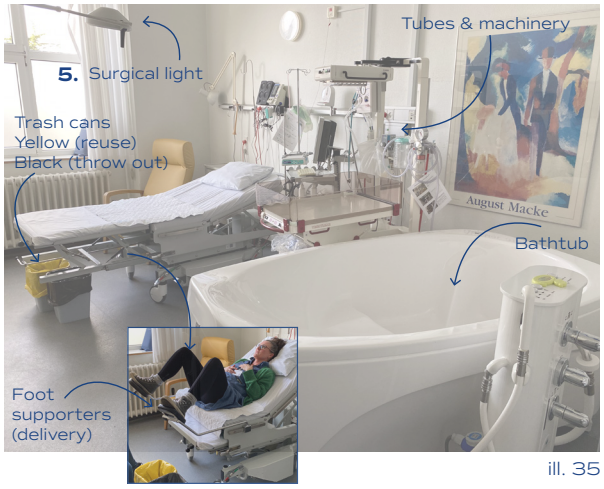
ill. 34

1.2 Midwife equipment

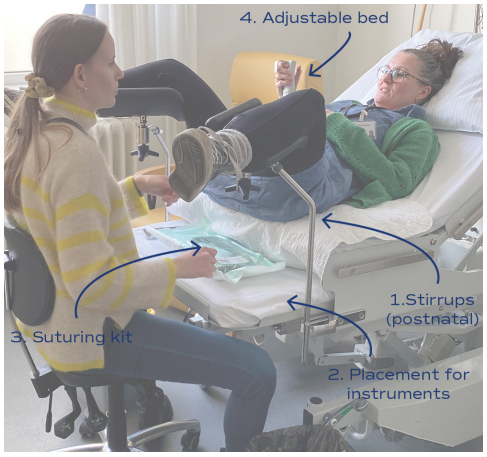
The purpose of this section is to understand the difference in equipment available for suturing postnatal tears at hospital births compared to home births as this is identified as the main difference during the initial interview (Section O.1 Motivation and initial interview). The differences are evaluated by visiting midwife Dorte Sloth Svendsen at Aalborg University Hospital with (see Appendix 2), where she goes through the equipment and setup for birth, assessment and suturing of postnatal tears at the hospital and for a home birth.

Hospital

Even though delivery rooms can be very different from hospital to hospital, the equipment for a typical delivery room at Aalborg University Hospital is shown in illustration 35. The delivery room is also where mothers are sutured if necessary. Therefore, the equipment for suturing is also ready in the same room, and the bed can be adjusted for this purpose. When the mother is sutured, the setup is usually similar to the one presented in illustration 36.



ill. 35



ill. 36

1. Stirrups

The stirrups are mounted on the bed after birth and are used to hold the mothers legs in the correct position during suturing. The stirrups can be adjusted in height, width and angle of the actual calf-holder, which is made from soft leather to make them comfortable and easy to clean.

2. Placement for instruments

The bottom part of the bed can be moved underneath the bed frame to create a place ideal for placing the instruments necessary for suturing.

3. Suturing kit

A sterile sheet is placed underneath the mother for suturing. The suturing kit consists of a kidney tray for the instruments, gauze pads for cleaning up blood, and the instruments used for suturing, see illustration 37. A threaded needle is used for the actual suturing and is not part of the kit.

4. Adjustable bed

The bed can be adjusted in the height to provide the optimal ergonomic position for the midwife while suturing.

5. Surgical light

The light source can be adjusted in position and intensity for proper illumination of the work area.

ill. 37

Home

At home births, the midwives do not have the same equipment and setup as at the hospital, even though the suturing kit is the same as at the hospital. All the equipment the midwives from Aalborg University Hospital bring for a home birth is in the bag shown in illustration 38. They bring only the necessary equipment needed and some things for emergencies, like for resuscitation, even though they hardly ever use it. The bag is large (L: 56 cm, H: 38 cm, W: 30 cm) and weighs 11.5 kg, so in cases where the midwife has a birth in an apartment building without an elevator, it is a lot to carry. Therefore, Dorte notes that a potential solution should be as lightweight as possible.

ill. 38

During the visit, Dorte says that there are many foreign types of bacteria at the homes compared to the hospital, and therefore she needs to clean the bag properly after each home birth to make sure not to transfer any bacteria to the hospital or other homes.

Additionally, Dorte says that there are different degrees of tearing during birth and that midwives are only allowed to suture first and second degree tears. If the tear is of the third or fourth degree, a doctor needs to suture it instead. Even though these rules also apply at the hospital, they have more consequences for home births, since the midwife is alone and will have to transfer the mother to the hospital for suturing if the tear is too severe or the midwife is in doubt about the severity of it. Since the setup at home is often not ideal compared to the hospital, it is easier for the midwife to get in doubt about the severity of the tear and therefore the risk of transferring the mother to the hospital increases.

Evaluation

It is found that the equipment for hospital births and home births are not identical. For home births, the midwives only bring the bag with the suturing equipment and some other things for emergencies. Therefore, they lack proper lighting and somewhere to place the mother's legs in the correct position for suturing. It is found that the solution to such a problem should weigh as little as possible and be easy to clean. It should be examined further what the specific requirements are for cleaning a medical product at home. Additionally, it is found that not all tears can be sutured at home, since it is the severity of the tear that dictates if the midwife is allowed to suture it or not. Generally, a further elaboration of the problems regarding suturing postnatal tears at home births is needed to understand the impact of having less equipment for home births. Therefore, more knowledge about the situation for suturing tears of the first and second degree at home is needed, to examine what equipment could be ideal to aid the suturing process after a home birth.

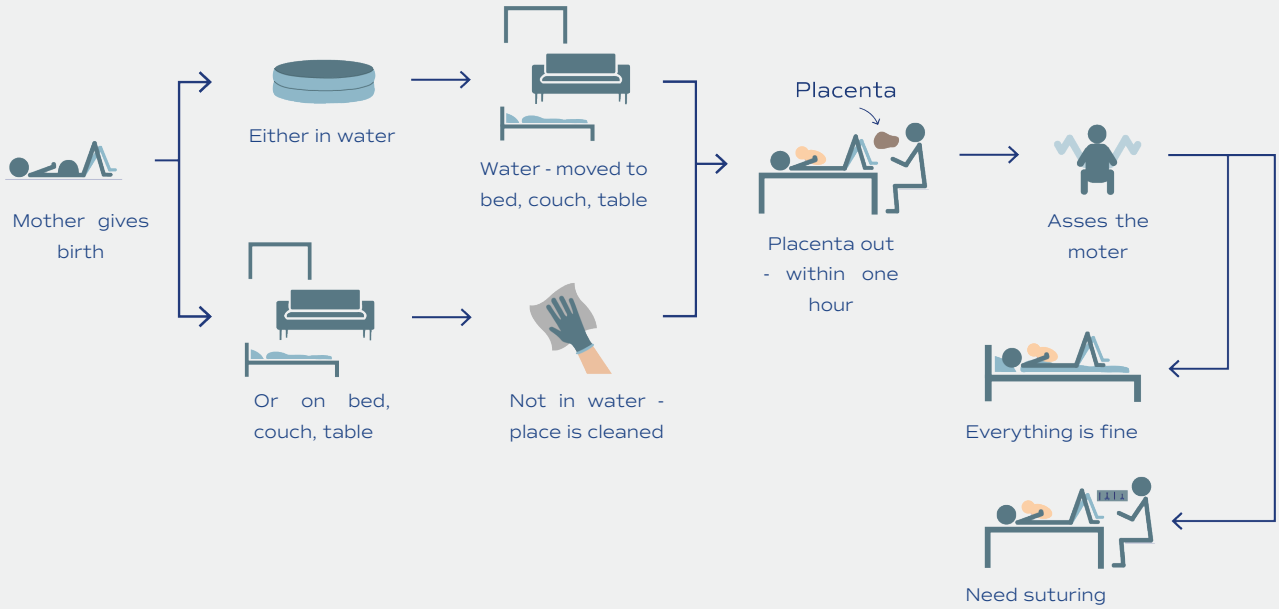
[1.2a] Be lightweight (< 11.5 kg)
[1.2b] Fit into the cleaning process
[1.2c] Fit the individual mother

1.3 Understanding the problem

The purpose of this section is to understand the problems related to suturing postnatal tears at home. The knowledge is based on qualitative, semi-structured interviews with four home birth midwives, Dorte (Appendix 2) and Sanne (Appendix 3) from Aalborg University Hospital and Maria and Lillian from Copenhagen University Hospital (Appendix 4). The problems regarding correct positioning of the mother, the ergonomics of the midwife, the lack of light and the equipment position are presented.

When the midwife has attended a home birth and the mother has just given birth to the baby, the steps presented in illustration 39 are usually followed prior to suturing.

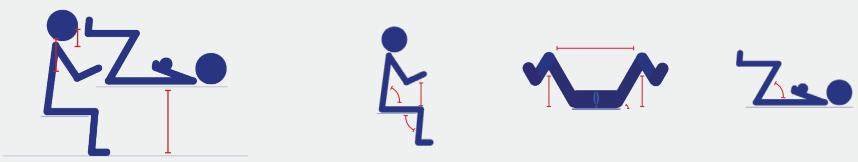
Steps prior to suturing



ill. 39

The optimal position

An optimal position of the mother's legs is essential when the midwife needs to suture, since the muscles need to be aligned properly and relaxed to suture the genitals correctly. The optimal position for the mother and midwife when suturing is based on the optimal conditions at the hospital where stirrups and all relevant equipment is available, see illustration 40.



ill. 40

The midwives explain that ideally, there is a certain angle between the mother's body and legs to obtain a good view of the genitals and having the genitals pointing upwards to provide better access. The mother's legs are spread as far apart as possible and laying symmetrically in height so the midwife has adequate space to suture. The mother's buttocks have to be levelled, meaning that the mother should preferably lay on a hard surface. Lastly, the mother should be at a height for the midwife to easily see the genitals, and the mother's buttocks should be close to the edge so the midwife can sit in a good ergonomic position as at the hospital. In this position, the mother lays correctly and is able to relax the muscles, if she has something to support her legs in that position, which makes it easier to suture the correct muscles together.

Positioning the mother and midwife

Since the mother can be sutured at various locations for a home birth, e.g. the bed or on the dining table, all the correct circumstances, as previously mentioned, for suturing the mother are rarely met. After speaking with the midwives, it is found that there are two main ways to position the mother at home births, see illustration 41 and 42. In each position, there are different ways the midwife can position herself for suturing.
If the mother is placed near the edge, there are typically four main ways of placing the legs, which have their own advantages and disadvantages (see illustration 41). When the mother is placed near the edge, it is often easier for the midwife to obtain a good ergonomic position, making it easier to suture. However, since there is no support for the legs sideways and forward, this is often a more exhausting position for the mother and the mother's feet often slide down from the edge, which is not ideal.
If the mother is placed far from the edge, she can typically lay in three different positions (see illustration 42). These are often more comfortable for the mother and it is easier for her to spread her legs more. However, in these positions, the midwife's ergonomic position is more compromised to obtain a better view of the genitalia. These positions are exhausting to work in after a short time and the midwife will have to take small breaks during suturing. However, these positions are often chosen because the alternative position near the edge is exhausting for the mother. The midwife typically chooses the position of the mother based on the well-being of the mother and the possibilities at the specific home.

Placed near the edge

ill. 41

Father holding the legs.

Feet on midwife's lap/legs.

Feet on chair.

Feet on the edge.

Placed far from the edge

ill. 42

Frog possition.

Asymmetrical half-frog position.

Legs bended.

Ergonomics for the midwife

Laying on the stomach, reaching forward.

Sitting close to the edge, bending forward.

Sitting at table

ill. 43

Asymmetrical position with the legs.

On the knees, bending forward.

Sitting sideways.

To avoid some of these problems, the midwives sometimes make use of coping mechanisms where they create home-build solutions to place the legs in positions where they can suture properly. Some of these are presented in illustration 44 and 45.

ill. 44

Underpants around the knees to support the legs outwards when the mother is placed near the edge. The mother's feet are placed on the midwife's thighs. The underpants take up some of the view.

ill. 45

Use a rebozo sheet that is wrapped around the shoulders and under each knee to support the legs outwards and pointing the genitalia upwards. This does not fit all sizes of women, it can not be adjusted and some women do not like the confinement.

ill. 46

The midwives sometimes use a cutting board, see illustration 46, to place under the mother's buttocks to have a more solid surface when suturing in places with soft underlayment.

None of these coping strategies are ideal, since they either restrict the view of the genitalia for the midwife or can be uncomfortable and restrictive for the mother.

From the interviews with the midwives, it is known that they want their own ergonomic position to be prioritised. As Sanne said during an interview:

"This is only one day for the mother, but everyday for the midwife"

However, it is found that when the midwives are out assisting a home birth, they often do not prioritise their own ergonomic position, since they would rather be gentle towards the mother, who is tired after giving birth as well as having no other alternative.

What they **SAY:**

Take care of themselves

What they **DO:**

Take care of the mother

Light for suturing

Since most births take place at night, proper lighting is important to visualise potential tears, see the different layers and muscles and suture them properly. At home births, it is the mother who is responsible for providing the light, which means that there is no consistency in the type of light, the intensity, the colour, and the direction of it. It can be everything from a small flashlight to a large industrial projector lamp. Therefore, some midwives choose to bring their own headlamp, so they know that they have adequate lighting for the suturing process. It is individual for the midwives what type of light they prefer, some see advantages in using a headlamp because the light is centred towards the genitalia. The downside is that some midwives experience blinding the mother when looking at her and some midwives do not like the expression when using a headlamp. Here, the projector lamp is advantageous, but the room is too illuminated compared to what is necessary. In general, the midwives say that too much light is not good for the mother's and baby's hormones, because it decreases the production of oxytocin.

Placement for the suturing kit

Normally, the midwife does not lay out the suturing kit until she knows where the mother is being sutured, since there is a risk of having to change position for the suturing process. This is because the equipment is sterile, and therefore, when it is placed, it should be avoided to move it in order to keep it sterile for the suturing procedure. However, in a few cases the tear might be worse than expected or the working position is not optimal, meaning that the midwife needs to move the equipment and mother to a new location for suturing. Three potential ways the midwives place their suturing equipment are presented in illustration 46-48.

ill. 47

On a table besides

The midwife needs to twist her body every time she needs to grab an instrument. This results in a bad ergonomic position for the midwife.

ill. 48

On the lap

Having the instruments on the lap is unstable and requires the midwife to sit still during suturing. This position is only possible if the mother's buttocks is placed near the edge.

ill. 49

Behind her buttocks

The ideal place for the instruments is right behind the mother's buttocks. But if the mother is placed optimally, which is near the edge, there is no space for it. If the midwife places the mother further from the edge to have space for the instruments, it causes the midwife to further distance herself from the genitals.

Non-optimal conditions

The setup for suturing at a home birth is important for the quality of suturing. If the optimal conditions are not met, this can result in:

Bad ergonomics

Bad ergonomic position for the midwife. This is something that makes some midwives choose not to attend home births, since the working conditions are worse.

Risk of transfer

Due to bad positioning of the mother as well as inadequate light to see the muscles that should be sutured, the mother sometimes has to be transferred to the hospital to be sutured under better conditions.

Prolonged suturing

It can take longer to suture the tears. This is not ideal, since the midwife risks having a bad ergonomic position for a longer time, the genitals swell after a short time making it harder to suture, and the suturing process is generally unpleasant for the mothers.

Exhausting position

The position can be exhausting for the mother. This results in cramps and shaking, making it more difficult to suture properly.

Evaluation

It is important that the mother is positioned optimally in order to suture postnatal tears properly. However, it is not easy to obtain an ideal position for both the mother and a good ergonomic position for the midwife at the same time for home births. Furthermore, bad lighting is often a problem during suturing, which can make it hard to assess the size of the problem. Lastly, the positioning of the equipment for suturing can also result in a bad ergonomic position for the midwife. Moreover, it should be examined what the optimal light for the midwife is for suturing at home births and how the most optimal ergonomic position is obtained for the midwife as well as the mother.

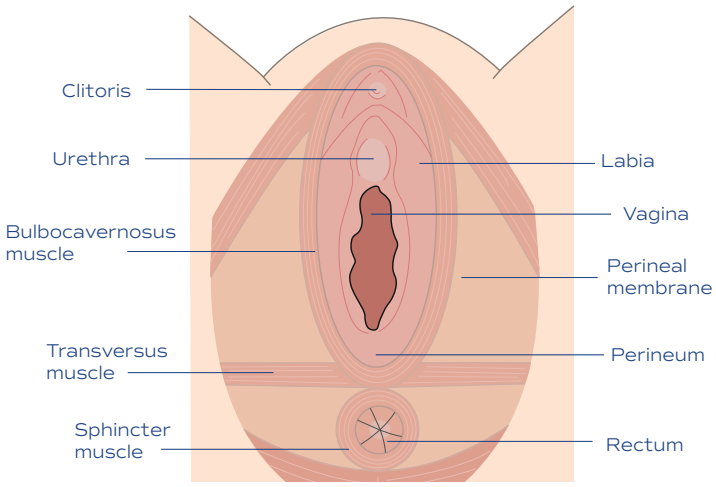
[1.3a] Mother's legs should be supported to relax and be separated
[1.3b] Mother's buttocks should be placed on a rigid surface
[1.3c] Mother's legs should be symmetrical
[1.3d] Mother's knees should be pointing outwards
[1.3e] Optimal ergonomic position for the midwife
[1.3f] Mother placed in proper height for suturing
[1.3g] Mother's tailbone should be placed at the edge of the surface
[1.3h] Proper light for suturing (intensity, colour, and direction)
[1.3i] Space for suturing kit behind the buttocks

1.4 When is suturing needed

After learning about the different degrees of tearing, it is necessary to find more information about when suturing is needed, why tears occur and the significance of the different degrees of postnatal tearing. This is done through desk research.

Why do tears occur?

A tear occurs because the baby's head is relatively large compared to the opening in the vagina, which means that the perineum, see illustration 50, needs to be dilated and stretched a lot for the baby to be pushed out (Drechsler, n.d.a). The more elastic the tissue is, the lower the risk of tearing (Roswall, n.d.). Tears are frequent when giving birth and can involve the perineum, labia, vagina, and rectum, see illustration 50 (Ramar and Grimes, 2022). Statistics from 2011 show that 86% of all first-time mothers get one or several tears, because the perineum needs to dilate for the first time and 43% tear the second, third, or fourth time they give birth. (Drechsler, n.d.a)



ill. 50

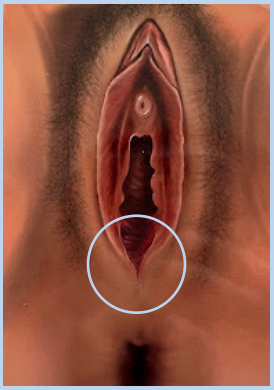
Degree of tearing

The four degrees of tearing are presented in illustration 51-54. A **first degree tear** is only a shallow tear of the perineum. Most of the time, this degree of tear does not involve the muscles but only the skin and mucous membrane. (Drechsler, n.d.b) A **second degree tear** is a tear of the perineum that involves the pelvic floor which is around the opening of the vagina. (Drechsler, n.d.b) A **third degree tear** is a partial tear of the sphincter muscle, see illustration 50. Here, there is still some of the membrane left around the rectum. This tear can be sutured in the delivery room by the doctor, but depending on the tear the doctor can move to the operating room. (Drechsler, n.d.c) Lastly, a **fourth degree tear** is a tear of both the sphincter muscle and the rectum. This degree of tear is always sutured in the operating room. (Drechsler, n.d.c) Aside from these four degrees of tears, there are two other tear types which can occur.

A **labia tear** is a little cut in the bottom of the labia by the bulbocavernosus muscle, see illustration 55. (Drechsler, n.d.d)

An **episiotomy tear** is from a cut done by midwives on purpose, see illustration 56. (Drechsler, n.d.e) In the past, women were always cut when giving birth but nowadays, they only do it if the baby has a heart murmur and if the cut results in the baby coming out faster. Another case is if the baby needs to come out with a suction cup, if the perineum is not stretched enough and the labour has been going on for many hours.

First degree tear



ill. 51

Second degree tear

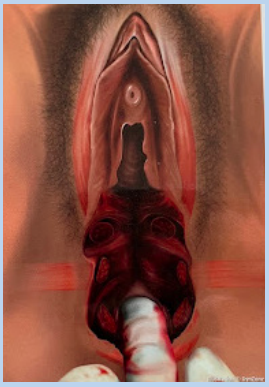
ill. 52

Can be sutured at home by the midwife.

Third degree tear

ill. 53

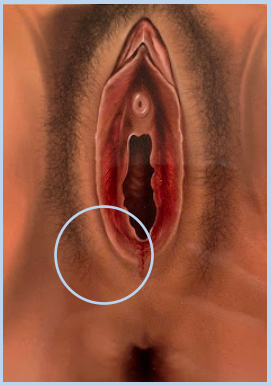
Fourth degree tear



ill. 54

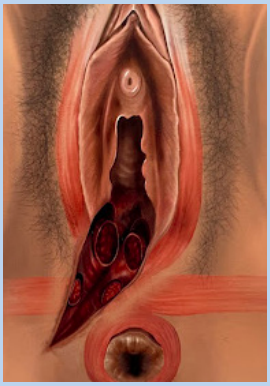
Need to be sutured at the hospital by a doctor.

Labia tear (first degree tear)



ill. 55

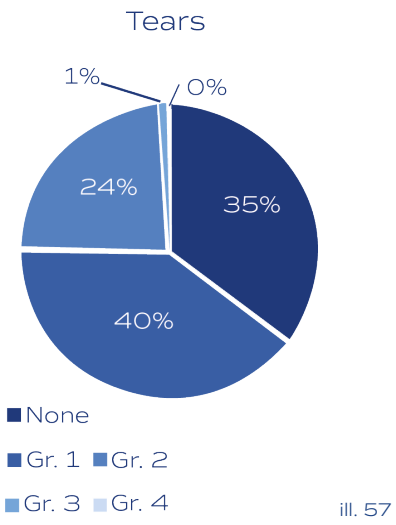
A episiotomy tear (second degree tear)



ill. 56

Distribution of tearing at home births

Statistics regarding the degrees of tearing are only available for births in general, which means that the data mostly covers hospital births. However, it was possible to obtain data about postnatal tears from 2022 from the 411 home births in Region H., Copenhagen University Hospital in Denmark. Here, the distribution of tears is shown in illustration 57. It is seen that 64% of the mothers had a first- or second degree tear, which was sutured at home. 35% of the mothers had no tears while only 1% had a third degree tear. It should be noted that the data does not provide information about whether any of the mothers had to be transferred to the hospital during their home birth. The data from Copenhagen University Hospital shows that the approximately 99% of tearing at the home births in 2022 was either non-existing or a first or second degree which can be sutured by the midwife. However, the data does not show if the mothers were first time mothers or not, which could influence tearing.



ill. 57

Evaluation

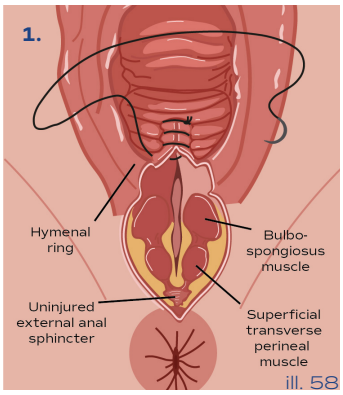
A better understanding of the different degrees of tearing is obtained as well as the percentage of mothers who tear during birth. It is also found based on the data from Copenhagen University Hospital, that most of the tearing at home births is either non-existing, first degree or second degree, and can be handled by the midwife, even though the number of individuals in the study is limited. It should be examined what the detailed procedure of suturing postnatal tears is at home births and how the severity of the tear influences the procedure.

1.5 The suturing procedure

In this section, the procedure of suturing postnatal tears, and the problems faced in this regard, is presented in detail for home births. Knowledge about the procedure is based on semi-structured qualitative interviews with home birth midwives Sanne Lykke Wilhelmsen and Maria Nielsen as well as desk research. The full interviews are presented in Appendix 3 and 4, respectively.

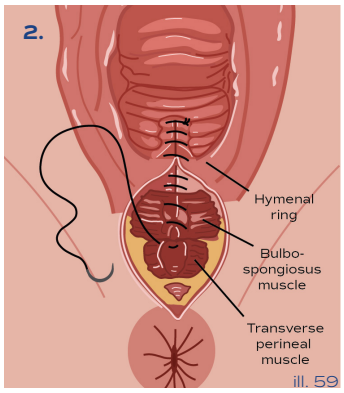
How to suture tears

As previously presented, the worst tear a midwife can suture by herself at a home birth is of the second degree. The suturing process of a second degree tear is presented in illustration 58-60 (Arnold, Sadler and Leli, 2021).



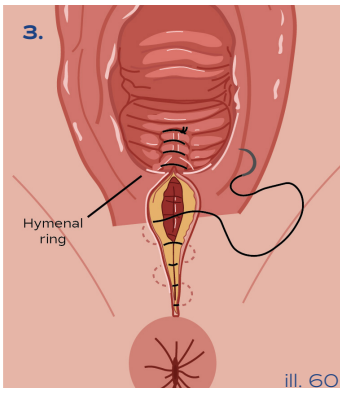
ill. 58

An initial stitch is made inside the vagina and the midwife starts suturing downwards towards the hymenal ring.



ill. 59

The muscles in the perineum are sutured together through continuous stitches.

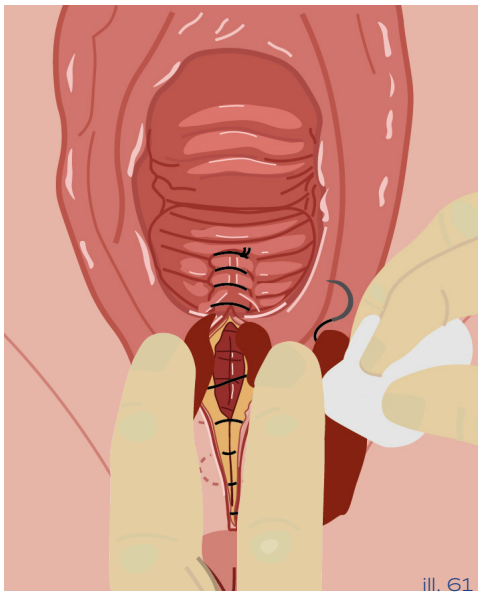


ill. 60

The vulva is sutured from the bottom up and the suture is tied with a knot at the hymenal ring.

Difficulties in the suturing procedure

Home birth midwife Sanne Lykke Wilhelmsen is interviewed to know more about the procedure and difficulties faced when suturing a second degree tear. She describes that the midwife uses the thumb and forefinger of their non-dominant hand to open the vagina and suture with their dominant hand. They do this almost blindly, since while trying to see the tear, it bleeds from the wound from the placenta, so they need to dab on the bleeding at the same time, see illustration 61). The midwife places a stitch through the skin, then has to let go with their non-dominant hand to pick up a forceps and use it to grab the needle and pull it through whilst dabbing bleedings. As the procedure takes some time, the mother often gets tired and spreads her legs less in order to relax. Therefore, the midwife has to ask the mother to spread her legs more or reposition her, which also takes time. Additionally, if the mother is overweight, it becomes increasingly difficult to suture due to excess skin and thicker layers of tissue to spread and suture.



ill. 61

Time of the procedure

Depending on the degree of the tear and the position the mother lies in, the suturing at home births can take from 15 minutes to 1.5 hours. Typically, suturing takes 30-45 minutes, which includes positioning of the mother and finding equipment. Sanne comments on the time it takes to suture even smaller tears at home births compared to the hospital;

15 min = fast
30-45 min = typical
60-90 min = long time

”When a small tear happens at the hospital, it is nice for the mother and when it happens at home it is hallelujah for the midwife because then it doesn’t take long to fix”

This is because the setup for suturing is not ideal for home births compared to the hospital, as presented in Section *1.3 Understanding the problem*, and therefore smaller tears are good for the midwife, since it does not take as long to fix. This means that the mother might be less exhausted and more relaxed due to a shorter procedure, which is important for suturing the muscles correctly together. If the muscles are not sutured together correctly, the mothers can experience pain and urinary and/or anal incontinence for the rest of their life. Another consequence can be pain during intercourse because they might have been sutured together too tightly. (Ramar and Grimes, 2022)

Another important aspect of suturing is how well the anaesthesia works. Home birth midwife Maria explains that **a big part of getting the muscles relaxed is the anaesthesia**, but if the mother is positioned badly, good anaesthesia is not enough.

Evaluation

A deeper understanding of the suturing procedure is obtained. The process can be quite tedious and involves the midwife to change hands to hold different instruments and reposition the mother if she gets exhausted. Suturing can take up to 1.5 hours for complicated tears which results in an unpleasant position for the mother for a long time. A product used to hold the mother's legs in the correct position could be used to shorten the suturing time, since the mother is in the correct position and able to relax.

[1.5a] Mother's legs should be fixed in the supported position to keep them spread

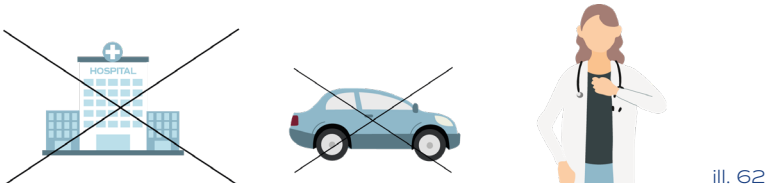
1.6 Mother's experience

The purpose of this section is to understand how the secondary users, the mothers, experience home births compared to hospital births. Often when designing products for health care, the secondary user is forgotten. (Tenhue, 2016) Semi-structured interviews with twelve mothers have been conducted to gain insight into the thoughts behind a home birth, the experience specifically for the suturing process and to obtain the perspective from the mothers regarding what they would prefer, in terms of a product solution, to aid the suturing process. Notes from the interviews are presented in Appendix 5.

Why do mothers choose home births?

From the interviews it is found that there are various reasons for choosing to have a home birth. However, many of the same reasons recur when interviewing the different mothers.

1. Many of them mention that previous births have been quite fast and therefore, they fear transportation to the hospital, since they are worried about not getting there in time.
2. One of the other frequent reasons for choosing a home birth is that the mothers find it more relaxing and calm to give birth at home. At the hospital, it is generally more stressful for most of the mothers. There are machines, beeping sounds, a lot of personnel and everything needs to be rushed. At home, you have the midwife to yourself and you can do everything at your own pace, which often results in less severe tearing as presented in Section *1.1 Initial research*.
3. Also, you do not feel like you have to ask permission to e.g. go to the bathroom or change position, since you feel more secure at your own home. Additionally, the partner is more involved in the home birth, since they often need to assist at certain tasks as the midwife is alone.



Less stressfull | Avoid drive | Midwife to yourself

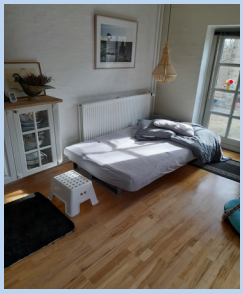
ill. 62

Preparation for home births

Most of the mothers prepare themselves more for home births compared to hospital births. As presented in Section *1.1 Initial research*, at home births, the mothers are in charge of more of the practical preparation, in terms of getting the items ready to assist the birth. However, the mothers also prepare themselves more mentally for giving birth at home, e.g. through reading articles, listening to podcasts and attending home birth cafes and pain tolerance courses. This is partially because there is less pain relief medication available at home births. However, many of the mothers mentioned that prior to giving birth at home, they have read about the advantages of giving birth at home in terms of the natural production of hormones such as oxytocin and adrenaline, which e.g. work as pain relievers.

Suturing at home

When interviewing the mothers, it is found that suturing at home births can take place on many different locations in the house, whether it is on a small couch, a chaise long, the countertop, the dinner table, or in the bed. The pictures below show some of the places the interviewed mothers have been sutured.



Daybed ill. 63

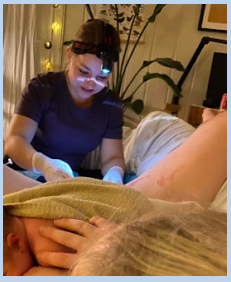
Mattress ill. 64

Coffee table ill. 65

Dining table ill. 66

Chaise long ill. 67

Bed ill. 68



Couch ill. 69

The suturing process is normally not a pleasant experience for the mothers, since they are in an exposed position and the tissue is very sore after giving birth. Furthermore, the mothers explain that it is exhausting to be sutured, because they just gave birth and either have to hold their legs themselves, or get their partner to hold them, while the midwife is suturing. Sometimes their legs start cramping and they move around which prolongs the suturing. Many of them share that their legs feel like cooked spaghetti and are shaking when they have to hold them for a longer period of time while being sutured, which is very uncomfortable. Usually, the mothers do not have any energy left for being sutured after giving birth, and they just want it to be over. On the other hand, they also want to be sutured properly, since they know that it can lead to severe problems, if you are not sutured properly.

Additionally, the moveable light that the mother is asked to prepare by the midwife for the home birth is usually a light source which is readily available at her home. The following different types of light sources that have been used for home births are identified through the interviews:

ill. 70 Floor lamp

ill. 71 Projector lamp

ill. 72 Headlamp

ill. 73 Small lamp

ill. 74 Flashlight

Several of the mothers do not like the feeling when the midwife is using a headlamp as the light source, since the mother feels like the midwife is “exploring” her genitals.

A new product for home births

The mothers are asked about their opinions regarding a potential product for aiding the midwives while suturing postnatal tears. Some of the mothers are already very aware that the midwife often has bad ergonomic working positions during birth and suturing and they try to make the situation better for the midwife when possible. Most of the mothers are happy about the calmness about a home birth and do not want to introduce too many products into the process, since they want the process to be far from the hospital experience. However, the mothers also note that they are willing to accept that the midwife is using such a product, if it means that it will improve the quality of the suturing. However, a product should not feel like a hospital product, meaning that it should **not look or feel cold and sterile**. This would resemble the hospital, which some of the mothers are trying to avoid.

Evaluation

The interviews with the mothers have shown that mothers choose to have a home birth for several reasons, some being fear of transportation to the hospital and wanting to have a calm and less stressful birth. The mothers generally prepare themselves more for a home birth compared to a hospital birth, but they are not able to provide uniform conditions for the midwife when it comes to position and light for suturing. Additionally, most of the mothers agree that a product to assist the midwife for suturing tears would be welcome if it increases the quality of suturing, but the product should not resemble the hospital. However, the resemblance to hospital equipment can not be completely removed, since the midwife also brings equipment for suturing to the home birth.

[1.6a] Should not resemble hospital equipment
[1.6b] The procedure should be able to take place in different places in the home (bed, couch, dining table etc.)

1.7 Market analysis

This section explores the market for a product solution for aiding the midwife at home births. Potential competing products are examined through desk research.

Products on the market with similar functionality or use as the product to aid the midwives for home births are examined, since it needs to be identified if these products could be direct competitors to a product solution. Four similar products are identified and compared to the function of the potential product solution in terms of advantages and disadvantages.

ill. 75

Stand Alone Prep Stand

This is used in the operating room for leg surgeries where it is placed next to the surgical table, but it can stand alone. (Medicus Health, 2022)

This product is portable but not collapsible. Furthermore, a midwife would need two of these for a home birth. Therefore, this would not be a directly competing product, because it does not take the positioning of the mother when suturing into account.

Cost: 7,113 DKK

ill. 76

Leg Holder Rest Support

These stirrups look very similar to the stirrups at the hospital, except that these can be mounted onto other surfaces. (Ebay, 2023)

The problem with these is that they require to be mounted onto a stiff and flat surface. This limits the use case in the home, since some mothers are being sutured on a soft surface such as the couch.

Cost: 1,704 DKK

ill. 77

Hegenberger Speculum

The Hegenberger Speculum is placed inside the mother's vagina to open it up and help give the midwife a better and more clear view when suturing. (Teknologisk Institut, n.d.a)

Furthermore, it works as a third hand so the midwife can use both hands for suturing. This helps to suture more correctly. (Hegenberger Medical, 2023) It is not a directly competing product, but it is the newest on the market within equipment for midwives.

It is a single use product, so it is expensive in the long run. It helps the midwife to suture the mother after giving birth, but it does not position the mothers legs correctly, so it does not solve the main problem for suturing at home births.

Cost: 200 DKK

ill. 78

Portable Gynecological Bed

The portable gynaecological bed has a setup which is quite similar to the setup at the hospital, with stirrups to hold the legs in the correct position.
(Amazon.com, 2023)

This product would not be optimal for home births since it is too large and impractical to bring and set up for the midwife.

Cost: 5,833 DKK

Evaluation

It is found that a completely competing product, in terms of positioning the mother correctly for suturing, does not exist. All products examined, which could be potential competitors, are priced at 7,200 DKK at the highest. The Hegenberger Speculum is cheap and helps to do better sutures, but it is not directed for home births. Therefore, there could be a market potential for a product solution specifically for home births since none of the products examined are targeting this field.

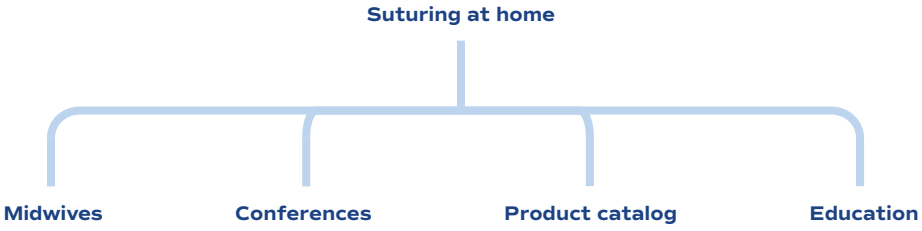
1.8 Market potential

The objective of this section is to examine the market potential for a product solution for aiding the midwife at home births. The quantity of products which can potentially be sold are examined through a semi-structured interview with the Vice Head of midwives from Aalborg University Hospital, Line Hundebøl Nielsen (see Appendix 6), and the potential market for the product is examined through desk research.

It is now known that a product that solves the problems described does not exist, wherefore it is relevant to look into the market potential of the product. Therefore, an interview with the Vice Head of midwives, who is in charge of buying new equipment for the midwives at Aalborg University Hospital, is arranged.

Here, the importance of correct positioning is confirmed as well as the potential for such a product. There are only **23 birthplaces** in Denmark, meaning that the market would quickly be saturated. Line estimates that **approximately 100 products** in total could be sold in Denmark to these birthplaces. However, Line suggests looking at the market outside Denmark, e.g. The Netherlands or Africa, since there are a larger proportion of home births in these countries. As for the requirements, the product needs to be CE-approved, otherwise the midwives will not buy it. She thinks that the product could be priced around 10,000 DKK. Line says that there is a large market potential for such a product since it would provide quality suturing and a more ergonomic position for the midwife.

When the midwives need to purchase new equipment, the Head of midwives tells the purchasing department what equipment they would like and then the department buys it for them. Vendors can also bring a catalogue to show off new products that could be of interest to the midwives. Otherwise, the midwives can go to a conference to be presented with new, unique products by different vendors. Lastly, educational sessions can also be arranged for the midwives to teach them how to use a new product for their work.



How many give birth at home?

The number of home births in Denmark was 1,870 in 2021 (Sundhed.dk, 2022). However, Denmark is a smaller country and therefore, it is relevant to examine the number of home births in neighbouring countries as well. From researching literature, the percentage of home births in the EU (Galková et al., 2022) as well as the total number of live births in the EU is found (Eurostat, 2020). The data is presented in table 1. Data for the table is based on statistics and publications from 2019. However, it is found that these numbers might be higher today. For example, the total percentage of home births in Denmark was 1.4% in 2019, but this percentage has increased to 3.2% in 2021 (Sundhed.dk, 2022).

Country	Home birth %	Live births pr. year	Number of home births
Belgium	1.1	116,100	1,277
Bulgaria	-	61,500	-
Czechia	0.25	112,200	281
Denmark	1.4	61,200	857
Estonia	0.45	14,100	63
Finland	0.2	45,600	91
France	1	753,600	7,536
Croatia	-	36,100	-
Ireland	0.2	59,800	120
Italy	0.1	420,200	420
Cyprus	-	9,600	-
Lithuania	0.8	27,400	219
Spain	0.32	357,900	1,145

Based on the data from the table, it is seen that the total number of home births in the EU is 54,618 in 2019. Of these, the largest contributors to the total number of home births in the EU are The Netherlands (50.5%), Germany (18.5%) and France (13.8%).

Generally, the lowest prevalence of home births exists in European countries and Central Asia, while the highest is found in some African countries with home birth percentages up to 78% (Hernández-Vásquez et al., 2021). Therefore, there is a large difference in the proportions of births worldwide that take place at home. However, it should be noted that not all home births are assisted by a midwife, meaning that a high number of home births in a country does not necessarily mean a large market potential.

Sweden	1	114,500	1,145
Hungary	0.9	93,100	838
Malta	0.3	4,400	13
Germany	1.3	778,100	10,115
The Netherlands	16.3	169,100	27,563
Poland	0.03	375,000	113
Portugal	1	86,600	866
Austria	1	85,000	850
Romania	0.25	185,700	464
Greece	0.3	83,700	251
Slovakia	0.25	56,100	143
Slivenia	0.15	19,300	29
Latvia	1	18,800	188
Luxembourg	0.5	5,200	31
In total			54,618

Table 1

Evaluation

A market potential is identified for aiding the midwife in terms of a more ergonomic position and quality suturing of the mother. However, the market in Denmark is small with the potential to sell about 100 products. Therefore, it is relevant to look at the potential outside Denmark as well. When looking at the number of home births, the biggest market in the EU is seen in The Netherlands, Germany and France. However, fewer home births are carried out in the EU compared to other countries such as some African countries. These countries could face other problems and require different solutions compared to western countries when it comes to home births. However, they could still be a large potential market for a product solution.

[1.8a] Should have a CE-certification
[1.8b] Should have a retail price of approximately 10,000 DKK

1.9 Midwives outside Denmark

The purpose of the section is to present a perspective from midwives outside of Denmark. This is done to determine if there are other trends or problems that should be taken into consideration when designing a product solution for a market outside Denmark. Information from midwives who work or have worked outside Denmark is gathered through semi-structured interviews with home birth midwives Angela Wakeford (South Africa and United Kingdom), Sam Simpson (United Kingdom) and Maryam Gjerde (Canada and Australia). Notes from the interviews are presented in Appendix 7.

In general, the problems faced when aiding with home births in other countries are the same as in Denmark, based on the interviews with the three midwives. However, there are some differences that are pointed out. For example, there are two midwives assisting every home birth in both South Africa and the United Kingdom, one for the mother and one for the baby. Additionally, there can be large differences in the prevalence of home births due to the health insurance in the particular country. Some choose to have a home birth, since they have to pay themselves and the home birth is the cheaper alternative. Others choose to have a home birth because they want a natural birth, since some of the countries, like South Africa, only offer births through C-section due to fear of legal actions if something goes wrong.
From the interviews, it is found that the rules for suturing are the same, since the midwives are only allowed to suture first and second degree tears at the home like in Denmark. Likewise, the midwives confirm that it can take everything from 5 minutes to 1.5 hours to suture a tear at home. However, a difference is that all the home birth midwives that were interviewed are from the private sector. This is because the countries that these midwives represent generally do not use midwives for hospital births. Instead, doctors and nurses are used. Therefore, home birth midwives are largely present in the private sector instead. Additionally, it is found that all the midwives use their own cars to drive to home births, and the equipment is stored in their cars as well. Compared to Sam and Maryam, Angela brings a lot of equipment in the car for a home birth.

ill. 82

ill. 79

ill. 80

ill. 81

All the midwives express that a product to help position the mother, thereby making it easier to suture post-natal tears, is very interesting and shares their positive thoughts as well as concerns.

Angela:
Angela has 40-50 home births per year. She sutures approximately two out of five mothers at birth, while the others typically do not need suturing. She also says that she already brings a suction unit for home births, which weighs around 15-20 kg. Therefore, she would like a product to be as lightweight as possible. Additionally, she notes that a product should not look or feel like hospital equipment.

Sam:
Sam says that the mindset of the midwives needs to be changed, since they are used to finding creative solutions to circumvent the problems at home births. They need to know that there is a product that can assist them. Furthermore, she notes that a product should be tested thoroughly so it can be trusted to work as intended, and that it should be easy to use, without adding too much complexity to the work of the midwife.

"This product need to change people's mindset - it might be difficult since this has been done the same way for many years"

Maryam:
Maryam, who has been a midwife in both Australia and Canada, notes that there is a difference between being a private home birth midwife and one who works for the government. As a private home birth midwife, they need to buy their own equipment, and therefore, a product should not be too expensive. Maryam compares the possible price range of the product to a heart rate monitor, which is priced around 3,500-5,500 DKK, if they should be interested in buying it. Furthermore, she says that the process of using the product should be thought through, since the product should e.g. be easy to clean if it comes in contact with bodily fluids. Lastly, she notes that attention should be given to laws and legislations in the different countries, since some countries have strict rules for e.g. certification in terms of allergies.

Evaluation
It is found that the problems faced during home births are largely the same in Denmark and other countries based on the interviews with other midwives. However, some important differences are found in regards to home births in regards to the market being largely dominated by the private sector outside Denmark. It is important to take into account the concerns and thoughts expressed in terms of weight and price of a product solution, if the intention is to sell the product to markets outside Denmark as well.

[1.9a] Have a maximum retail price of 5,500 DKK for private sector

1.10 The home birth scenario

The objective of this section is to collect the knowledge from the interviews with the home birth midwives Dorte Sloth Svendsen (Appendix 2), Sanne Lykke Wilhelmsen (Appendix 3), Maria Nielsen and Lillian Bondo (Appendix 4), the midwives from outside Denmark (Appendix 7) and the mothers (Appendix 5). This information is used to map out a complete home birth scenario in order to identify what workflow a product solution should be used in and thereby what additional requirements can be identified for the product.

From the Section *1.1 Initial research*, the procedure of getting approved for a home birth and the requirements are known. Additionally, the suturing process itself is described in more detail in the Section *1.5 The suturing procedure*.

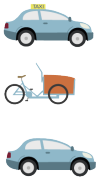
In general, the home birth scenario can be divided into; **before the baby is born** and **after the baby is born**. The scenario is a simplified version taking into account only the major points of the midwife's work for a home birth.

Before the baby is born

Midwife receives a call from department or directly from the mother

Brings the equipment and a personal bag with computer

mother's home
max 60 min away



Drives to the mother using her own car, a taxi or a Christiania bike

Apartment

House

Grabs the equipment and walks to the home. The mother's partner might help carry

Assists birth
right away

Examines baby andmother
→ waits and prepares for birth
→ assists birth

General orientation

ill. 83

Baby is born in water or on bed/sofa

A home birth typically takes 6-8 hours - can take up to 12 hours

After the baby is born

Birth in water → move to bed/sofa/dining table

Birth in bed etc. → clean area

Waits for birth of placenta

(30-60 min after birth)

Establishes breastfeeding

Placenta

Placenta is out

(within an hour)

Gets the mother to pee

Non-optimal position
for suturing → the
mother might be moved

Assesses the mother for tears and if the whole placenta is out

Places the mother in the most optimal way for suturing in the given home

Partner finds
a lamp

Finds suturing kit and sterile sheet

Sutures the mother's tears

Cleans the area and divides waste into regular- and biological waste

ill. 84

Important for a product solution:

1. The product should be easy to transport along with the remaining equipment
2. Can the mother keep laying down while being installed in the product for assessment and suturing?
3. The product should be easy to clean on the spot
4. The product should quickly be made ready for a new birth

Since the whole process of a home birth typically takes 6-8 hours, and can take up to 12 hours, the midwives want a product to be very easy to set up and handle. This is because the midwives can be exhausted after the delivery process, where they also have bad working positions for longer periods of time while assisting in the delivery.

Evaluation

From the scenario, some important points for the product are identified. It is found that the product should be easy to transport along with the other equipment, and that it should be easy to clean the product. Furthermore, the product should be easy to handle for the midwives, who might be exhausted from a prolonged delivery process and it should be convenient and quick to get ready for the next home birth.

[1.10a] Easy to assemble
[1.2b] → [1.10b] Can be cleaned in the home or at the hospital
[1.10c] Can be easily transported from a car to the home

1.11 Correct position of mother

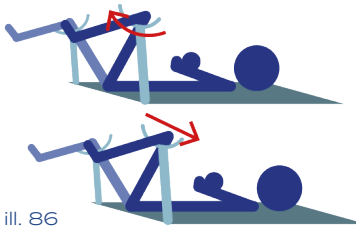
This section presents research into the optimal position of the mother for suturing postnatal tears. This information is gathered through desk research.

In order to obtain the optimal view of the perineum, the mother's legs need to be positioned correctly. From an earlier interview (Appendix 4), Maria Nielsen refers to a video lesson from Malene Hegenberger, who is the midwife and inventor behind the Hegenberger Speculum, where she explains about the correct positioning of the legs before suturing.

In the video, Malene Hegenberger explains the three steps for a correct positioning before suturing. Here, the steps are based on the mother laying on a hospital bed with the legs in the stirrups and not a home birth, but the principles can still be used for home births (Hegenberger Institute, 2023).

ill. 85

Get the woman's buttocks all the way up to the edge of the bed, see illustration 85.



ill. 86

The stirrups are turned so the lower leg and knees are pointing outwards. This opens up the perineal area for inspection. It moves most of the weight away from the thighs and the buttocks. The knees pointing outwards is the most important step for optimal positioning for suturing, see illustration 86.

ill. 87

If possible, have a slight trendelenburg - it is really beneficial for the midwife's own ergonomics but also for when you are suturing and screening, see illustration 87.

It is found that trendelenburg is a position where the whole body is angled, with the head pointing downwards (Steris Healthcare, 2020). Instead, what could be beneficial is to have a slight pelvic tilt for the mother (Suits, 2021). This means that you are tilting the pelvis a little bit upwards, which gives a good and clear view of the urethra, vagina and anus (Hegenberger Institute, 2023). The recommended pelvic tilt is 13 +/- 6º (Suits, 2021). In addition, it is found that the optimal position for the mother is called the standard lithotomy position, where:

- The knees are bent at 70-90°
- The hip flexes until the thighs are angled 80-100°
- The legs should be separated 30-45° from the midline

ill. 88

The position is often used during childbirth or surgeries involving the pelvic area, because it provides the optimal view and access to the perineum. (Wilson, 2018) (Tollefson et al., 2010) Generally, the optimal position of the mother for suturing according to the requirements mentioned is not obtained during home births today, since the midwives do not have the setup for providing the optimal position.

Evaluation

It is found that the optimal position for the mother for suturing postnatal tears is with the buttocks at the edge of the underlayment, the knees pointing outwards and the pelvis tilted slightly upwards. Additionally, it is found that the lithotomy position is often used for childbirth and surgeries and can provide valuable pointers towards the way the mother should be positioned in relation to the product. However, the mother is rarely positioned in the optimal way for suturing at home births today.

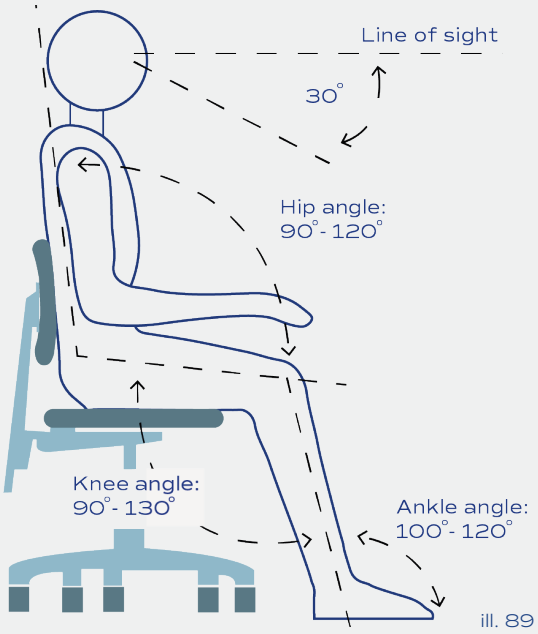
[1.3a] + [1.3c] → [1.11a] Mother's legs should be supported in the lithotomy position (the knees are bent 70-90°, the thighs are angled 80-100° and the legs are separated 30-45° from the midline)
[1.11b] The buttocks should be tilted (13 +/- 6°)

1.12 Ergonomic position for the midwife

This section introduces what the requirements are for a good ergonomic position for the midwife when suturing postnatal tears. The information is gathered through desk research.

When the midwife is suturing postnatal tears, in most cases, it is not possible for her to do this standing up due to the height the mother is lying in. Therefore, in order to have a good ergonomic position, the midwife will have to be sitting down, and the ergonomics of working in a sitting position is examined.

According to the Canadian Centre for Occupational Health and Safety, there are 23 general recommendations for working in a sitting position with good ergonomics, even though the exact position depends on the individual (CCOHS, 2022). Among these, the most important recommendations for the midwife when suturing are identified and presented in illustration 88 (CCOHS, 2022):



ill. 89

Feet:
Feet flat on the floor or footrest.
The ankle joints should be in front of the knees.

Knees:
The knee joints should be at or below the hip.

Elbows:
The elbows should be tucked in, close to the body, at an angle around 90°.

Back:
Avoid slouching, bending to the side or bending forward.
The back should be straight (avoid twisting) and in an upright position.
Use the back support of the chair in the correct region (curve in the lower back).

Shoulders:
Shoulders should be low and relaxed.
Keep the upper arms between vertical and 20° forward.

Neck:
The head should be aligned with the spine.
Chin should be tucked in and avoid bending forward when looking forward or down

General:
Keep all joints such as the ankles, knees and hips at an angle of 90° or slightly higher.
The working position should be changed frequently, but within recommendations.
Avoid sitting for more than 50 minutes at a time.
The viewing angle of the object should be 10° to 30° below the line of sight.

Furthermore, according to the International Health Facility Guidelines, the optimal working height for a seated user using a keyboard is obtained by using a table with a height of 61-76 cm (International Health Facility Guidelines, 2015). This is the closest approximation to the optimal height for the midwife to work in, even though she is suturing instead of using a keyboard.

From Section *1.3 Understanding the problem*, it is known that the midwife can suture the mother in many different locations, including the bed, the couch or the dining table. The height of a standard bed is 63.5 cm on average (Casper Editorial Team, 2021). This means that some beds might be fine, but others might be too low for suturing in the proper height for the midwife. Furthermore, the bed is typically not ideal since it is not possible to sit upright and avoid bending forward, since the midwife's legs can not be positioned underneath the bed, which would be the case if seated at a table. The standard seat height of a couch is typically in the range 38-51 cm, making it too low for suturing in an ergonomic position (Medley, 2023). However, a standard dining table has a height range of 71-76 cm, making it ideal for suturing in the correct height and most ergonomic position (Caballero, 2021). Therefore, the dining table is the best location when using the product solution for suturing the mother.

ill. 90

Generally, not all the requirements for an ergonomic position of the midwife are fulfilled by the midwife while suturing, since she will typically have to bend forward, reach out further with the arms than recommended and look with a viewing angle higher than 30° below the line of sight. These problems might not be possible to circumvent, since it might not always be possible to have the correct setup at e.g. the dining table. However, it is noted that the position at the dining table, with the mother near the edge of the underlayment, is generally much better than having the mother far from the edge, since this deviates more from a good ergonomic position.

Evaluation

Information about an ergonomic position when working in a sitting position is obtained. It is important to sit upright, keep the correct position of the joints and generally be relaxed and not twist the body. These conditions are rarely met by the midwives while suturing tears at home births today. Furthermore, based on the optimal working height for seated work, it is found that the optimal place for suturing the mother is at the dining table, even though all requirements to obtain a good ergonomic position might not be fulfilled after all due to the nature of the workflow of suturing postnatal tears.

[1.3e] → [1.12a] The midwife's ergonomic position fulfils the recommendations
[1.3f] → [1.12b] Mother placed in proper height for suturing (61-76 cm from the ground when midwife is sitting down)

1.13 Light for suturing at home births

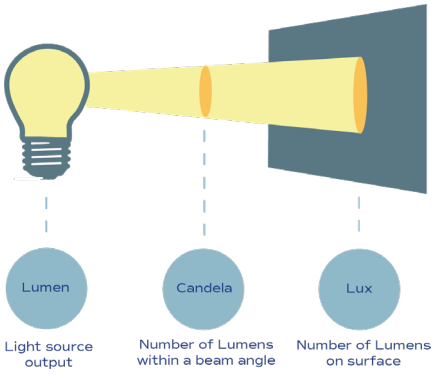
The objective of this section is to examine what the ideal light is for suturing postnatal tears at home births. This is done by evaluating what is used for a hospital birth compared with the light used today at home births. The information is gathered through desk research and the second interview with Dorte Sloth Svendsen (Appendix 2).

As presented in Section *1.3 Understanding the problem*, too much light is not good for the mother or baby in general right after birth. However, it is very important to have the optimal light for the midwife while suturing postnatal tears, to avoid problems with assessing the tears and the resulting risk of the mother being transferred to the hospital.

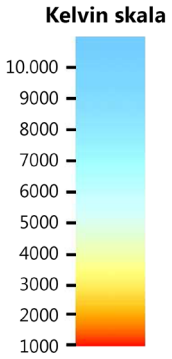
What is light?

To understand what light is optimal for the midwife for suturing, it is important to understand the different expressions used to describe light (Pande-lampe.dk, 2017):

Lumen: The total amount of light emitted by a light source (360°around it).
Luminance: The total amount of light (measured in lx) that hits a certain area (1 lx = 1 lumen per square metre).
Kelvin: The colour temperature of the light (a high number means a colder, more blue expression of the light).
Candela: The amount of light that a light source emits in a given direction.
CRI (Color Rendering Index): How good the colour of the light reproduces the actual colours - the quality of the light source (a value closer to 100 gives a better reproduction of the colours).



ill. 91



ill. 92

It is found that the most important thing to consider is the amount of light that hits a given area, when the midwife needs to suture. Therefore, the lux and CRI could be good indicators of the light source.

Surgical light at the hospital

In a hospital setting, the ideal light for surgical procedures is often a combination of overhead lights and headlights, to increase the light intensity and avoid shadows in the working area. Headlights are good for targeting a specific area with the desired lighting, but are generally not good to use by themselves without additional light, since this can cause eye strain. Generally, the light for surgeries should be of high quality and be able to produce a high level of illumination of 40,000-160,000 lx, since blood absorbs light. Additionally, the best surgical light settings are similar to bright daylight, with a colour temperature of 3,000°-6,700° K and a CRI of 85-100 Ra. (BFW, 2021)

An overhead light source, see illustration 93, and a headlamp, see illustration 94, for surgical procedures at the hospital are examined to find their specifications. Both have a high luminance and a colour temperature of 4,500° K, similar to daylight. Additionally, both of the light sources have a high CRI value, which reproduces the natural colours well.


ill. 93

Berchtold Chromophare D300 Exam Light System (Maxim Medical Services, n.d.)
Luminance: 50,000 lx at 1 metre
Colour temperature: 4,500° K
CRI: 88 Ra
Light field diameter: 140 mm
Price: 11,158 DKK


ill. 94

Heine LED forehead lamp
(Medshop.dk, 2022)
Luminance: 50,000 lx at 250 mm
Colour temperature: 4,500° K
CRI: 90 Ra
Spot adjustment: 30-80 mm at 420 mm
Light intensity control: 0-100%
Price: 10,190 DKK

Light for home births today

Typically, the midwives use either a headlamp for home births that they bring themselves or a light source that the mother has provided. The specifications of some of the typical light sources used are examined. Generally, these are much cheaper than the surgical lights and have a lower colour temperature. Additionally, the light intensity is typically expressed in lumen for light sources for private use, while it is more often expressed in terms of luminance for professional light sources. Of the three products, the headlamp is the one that reduces unwanted shadows of the working area the most. Additionally, for the three products, the light intensity is either really low or quite high in the case of the projector lamp. However, it is not easy to compare the light sources directly with the surgical ones. Therefore, it would be beneficial to test the lighting needed more specifically for suturing at home births, to find the optimal specifications of the light that should be used and an optimal placement of the light source.

ill. 95

Click on lamp
(IKEA, 2023)

Light type: LED
Colour temperature: 2,700° K
Lumen: 220 Lm
Price: 149 DKK

ill. 96

Projector lamp
(Lomax, n.d.)

Light type: LED
Colour temperature: 3,000° K
Lumen: 4,000 Lm
Price: 175 DKK

ill. 97

Headlamp
(Eventyrsport.dk, 2023)

Light type: LED
Colour temperature: Unknown
Lumen: 350 Lm
Price: 226 DKK

Optimal light source

When knowing the specifications of the light used surgically, it should be examined what kind of light source can provide this type of light. One of the most optimal types of light for this task are LED's since they are very efficient, do not emit much excess heat and have a long lifespan compared to e.g. halogen light bulbs (SCREWFIX, 2023). Furthermore, the CRI value of LED's are generally 80 to 90+ Ra, meaning that the colours of the light are satisfactorily reproduced, giving a more natural look compared to e.g. fluorescent lighting (LUMENS, 2023). Also, the colour temperature of LED's can typically range from 2,700° K to 5,000 ° K, which means that the desired colour temperature can be matched (Lighting Design Studio, n.d.).

Evaluation

It is found that the characteristics of light can be expressed in terms of both lumen, luminance, kelvin, candela and CRI. Furthermore, the optimal light specifications for surgical lighting is presented as well as the lighting that is most often provided for the midwives at a home birth. It is clear that the light for home births can sometimes be problematic, and tests of the optimal light for suturing at home births should be conducted to identify the ideal light intensity as well as the placement of the light. However, the light should be of high quality, with a high CRI value and a colour temperature similar to daylight.

[1.3h] → [1.13a] Proper light for suturing (CRI value > 90 Ra and colour temperature of 4,500° K +/- 300° K)

1.14 Instruments for suturing

The purpose of this section is to examine the instruments used for suturing postnatal tears at home births and compare with the setup at the hospital in order to identify the requirements. This is primarily done through desk research, supported by conversations with the midwives Dorthe Sloth Svendsen and Maria Nielsen to understand the differences between the equipment used in Aalborg and Copenhagen (see Appendix 8).

From Section *1.2 Midwife equipment*, it is known that the midwives use an instrument kit for suturing. These instruments are researched in more detail to understand what each individual instrument is used for, their sizes and if there are any differences in the kits that different midwives use. Three different suturing kits are presented in illustration 98-100.

ill. 98

1 x Toothed forceps, 12 cm (disposable instrument)
1 x Surgical scissors, 14.5 cm (disposable instrument)
1 x Needle holder, 12 cm (disposable instrument)
5 x Gauze swabs
5 x Gauze pads, 7.5 x 7.5 cm
1 x Sterile sheet, 60 x 50 cm
(Praxisdienst, n.d.)

ill. 99

1 x Toothed forceps, 12.7 cm
1 x Dissecting forceps, 12.5 cm
1 x Surgical scissors, 11.5 cm
1 x Needle holder, 13.5 cm
1 x Towel Dressing 45 cm x 45 cm
1 x Tray, 18 cm x 9 cm x 9 cm
1 x Sterile sheet
(Podiatry world, 2023)

ill. 100

1 x Toothed forceps
2 x Needle holder,
1 x Surgical scissors
1 x Scalpel

Dimensions:
15 x 15 x 1 cm

Instruments are for educational purposes only. Not for surgical use.
(Simulab, 2023)

It is seen that the suturing kits are quite similar, all containing a forceps, needle holder, scissors and gauze swabs or similar. The forceps is used to grab the needle after bringing the needle through the skin, or hold the tissue, while the needle holder is used to hold the needle itself and bring it through the tissue while suturing. The scissors are used to cut the thread. Lastly, the gauze or towel is used to clean the blood away to enhance the view. In general, the needle and thread are not contained in a normal suturing kit. The largest part of the suturing kit is the tray which can be used to hold the instruments during suturing. Therefore, for easy accessibility, a space at least the same size as the tray should be available to place the suturing kit.

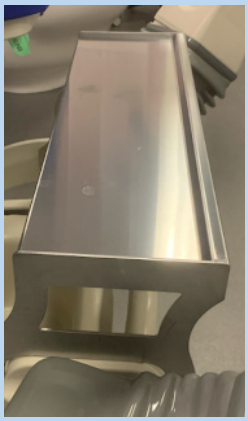
Dorthe Sloth Svendsen (Aalborg) and Maria Nielsen (Copenhagen) were contacted to find out what their standard suturing kits contain and their sizes. In Aalborg University Hospital, they use a kidney tray with a size of 20 x 15 cm to fit everything from the suturing kit. The suturing kit is quite standard with instruments similar to the ones presented above. The kit is placed on the bottom of the bed at hospital births as presented in Section *1.2 Midwife equipment*. In Copenhagen University Hospital, they have a metal tray to place the suturing kit on for hospital births. Similarly, the suturing kit, which is placed in a plastic container with a size of approximately 18 x 9 cm, does not deviate much from the standard ones. The main difference between the two suturing kits is that in Aalborg, the instruments in the suturing kit are reused by cleaning, disinfection and sterilisation while the instruments are thrown out in Copenhagen after use. For both suturing kits, the threaded needle is not a part of the suturing kit itself. In Aalborg, the kidney tray is being faced out to save material.

Aalborg

ill. 101

20x15 cm

Copenhagen



ill. 102

ill. 103

18 x 9 cm

Evaluation

It is found that suturing kits can vary a bit from each other, but mainly include the same instruments for suturing, like a forceps, needle holder, scissors and gauze swabs or similar. Additionally, it is found that the suturing kits used at Aalborg University Hospital and Copenhagen University Hospital are quite similar as well, even though the instruments in Copenhagen are not reused. The largest identified suturing kit is in Aalborg, which needs a space of at least 20 x 15 cm to fit.

[1.3i] → [1.14a] Space for suturing kit behind the mother's buttocks (min. 20 x 15 cm)

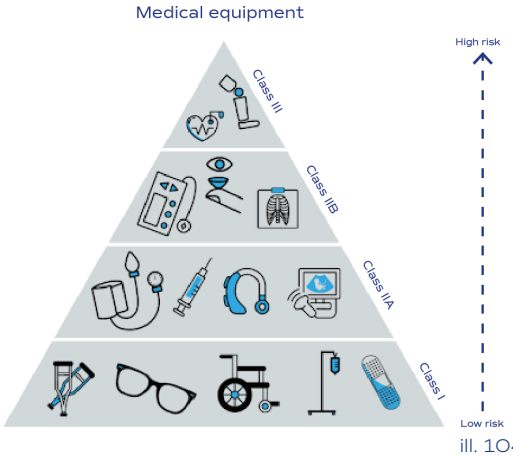
1.15 Medical devices

The purpose of the section is to understand what medical products are and what specific requirements there are for medical products. Additionally, the objective is to examine the rules and regulations for cleaning medical products. The information is collected through desk research.

Since a product designed to assist the midwife when suturing postnatal tears at home births is going to be used in a medical environment, it is important to know what the exact rules and regulations are in this field for certification, use and cleaning of such a product.

Medical classification

Medical devices are products that are used to prevent, relieve, diagnose or treat a disability, disease or injury. This can be anything from a wheelchair or a pacemaker to a medical mobile phone app and surgical equipment. Medical devices can be grouped into four categories, which are I, IIa, IIb and III, see illustration 104. Class I is the lowest



ill. 104

risk class while Class III are the highest risk products. An example of a Class I product could be a walker, while a pacemaker is a Class III medical device. The classes are used to dictate what requirements that should be fulfilled by the manufacturer before marketing the product. (Danish Medicines Agency, 2023) The product for aiding the midwife for suturing postnatal tears at home births is in Class I, since it is a product for holding the mother's legs in the correct position. This is because it is a low risk device, which is non-invasive, since it is not installed within the body for short or long term (Obelis Group, 2019).

Certification

Like other medical devices, the product would need to be CE marked in order to be used as a medical device. It is required by the EU that medical devices need to be CE marked before going on the market. The CE marking shows that the product lives up to EU legislation. (Danish Medicines Agency, 2023) When the product is in Class I, no permission is needed to place a CE marking on a product, but the manufacturer is responsible for ensuring that the product lives up to all requirements (European Union, 2023). In some cases, and always valid for medical products of higher classes, a notified body will be hired as an external party to ensure that the requirements for the CE marking are met. (Danish Medicines Agency, 2023)

Cleaning of medical devices

Cleaning of medical devices is essential if they have to be used multiple times for different patients. This is because the microorganisms of the patient have to be removed before the next patient can use the device. Depending on what the device is used for, the device will have to be cleaned, cleaned and disinfected or cleaned, disinfected and then sterilised. It is important to perform these procedures in the correct order, since e.g. clean is a prerequisite for something to be disinfected. The way the device needs to be cleaned depends on what the device is used for according to the following classification:

- **Non-critical device:** generally only comes into contact with intact skin, or does not come in contact with the patient.
- **Semi-critical device:** comes into contact with intact mucous membranes without penetration of tissue.
- **Critical device:** for surgical and other invasive procedures. Comes into contact with sterile tissue.

The product for aiding the midwife while suturing falls in the category of a non-critical medical device, since it is supposed to hold the mother's legs in the correct position. Therefore, it will normally be enough to clean the product without disinfection or sterilisation. However, in situations where there is contamination of biological matter or fluids like blood, the product will need to be cleaned followed by disinfection. (Statens Serum Institut, 2022) In case of disinfection, this can be done either mechanically by an instrument-dishwasher, which cleans and disinfects using heat, or by manual cleaning followed by chemical disinfection of the instruments. For a uniform disinfection and prevention of contaminating the surroundings, mechanical disinfection is generally recommended. If the product is to be mechanically cleaned and disinfected it should be able to withstand 90°C for 1 minute, 85°C for 3 minutes or 80°C for 10 minutes. (Statens Serum Institut, 2022) If the product is to be chemically disinfected, this can be done using e.g. alcohol or chlorine as disinfection agents. (EpiGuard, 2023)

Evaluation

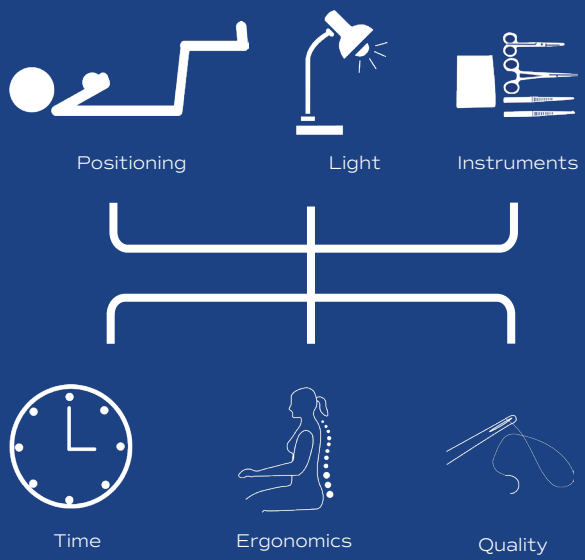
Medical devices are classified into certain categories depending on the intended use. The product for aiding the midwife with suturing of postnatal tears at home births most likely falls in the lowest-risk category (Class I) of medical devices, since it is used to hold the mother's legs in the correct position and not used for invasive procedures. Furthermore, the product will have to be CE marked in order to be used as a medical product. Lastly, the product will need to be cleaned after each use. It is also likely that it will have to be disinfected due to the risk of biological matter or fluids contaminating the product.

[1.2b] → [1.10b] → [1.15a] Can be cleaned and disinfected in the home (chemically, using alcohol wipes)
[1.2b] → [1.10b] → [1.15b] Can be cleaned and disinfected at the hospital (mechanically, 80°C for 10 min)

1.16 Design brief

Problem summary

There are numerous problems for the midwife at a home birth, especially when suturing postnatal tears. These are primarily related to the position that the mother lays in for suturing, the lack of proper lighting and the placement of the instruments for suturing. These have a large influence on the ergonomic position of the midwife, which is often compromised, the time it takes for suturing and the quality of the suturing in general. If the conditions are too poor, the mother risks being transferred to the hospital for suturing. The suturing process at a home birth can take a long time (up to 1.5 hours) and be quite exhausting for the midwife. It can be exhausting for the mother to hold her own legs as well, but it is only one day for the mother, while it is every day for the midwife. Therefore, the midwife needs a solution that can ease the suturing process. Today, there are no products on the market, which target midwives at home births or solve all of these problems simultaneously.



ill. 105

Thesis statement

How can a product enable quality suturing of postnatal tears at home births and improve ergonomics of the midwife by ensuring the correct position of the mother, adequate lighting of the perineal area and optimal placement of the instruments for suturing?

Valuemission

Our vision is to obtain quality suturing at home births by standardising and providing the optimal working conditions for the midwife.

Business case

Currently, a product potential is seen for aiding midwives with suturing postnatal tears at home births, since no such products solving the same problems are on the market. Even though the number of products that could be sold in Denmark is only estimated to be about 100, there is a market for selling the product in Denmark in a price range of 3,500-10,000 DKK, as well as selling to countries in the EU or other countries in the longer term. The product could be sold either to private birth clinics or to the public sector, where the largest potential is seen in the public sector due to the number of home births assisted by them and the possibility to sell at a higher price due to larger budgets.

User needs and requirements

Positioning of mother and midwife

Section	Requirements	Specifications
[1.2c]	Fit the individual mother	
[1.3a] + [1.3c] → [1.11a]	Mother's legs should be supported in the lithotomy position	The knees are bent 70-90°
		The thighs are angled 80-100°
		The legs are separated 30-45° from the midline
[1.3b]	Mother's buttocks should be placed on a rigid surface	
[1.3d]	Mother's knees should be pointing outwards	
[1.3e] → [1.12a]	The midwife's ergonomic position fulfils the recommendations	
[1.3f] → [1.12b]	Mother placed in proper height for suturing	61-76 cm from the ground when midwife is sitting down
[1.3g]	Mother's legs should be fixed in the supported position to keep them spread	
[1.5a]	Mother's tailbone should be placed at the edge of the surface	
[1.6a]	Should not resemble hospital equipment	
[1.6b]	The procedure should be able to take place in different places in the home	Bed, couch, dining table etc.
[1.11b]	The buttocks should be tilted	13 +/- 6°

Cleaning

Section	Requirements	Specifications
[1.2b] → [1.10b] → [1.15a]	Can be cleaned and disinfected in the home	Chemically, using alcohol wipes
[1.2b] → [1.10b] → [1.15b]	Can be cleaned and disinfected at the hospital	Mechanically, 80°C for 10 min

Transportation

Section	Requirements	Specifications
[1.2a]	Be lightweight	< 11.5 kg
[1.10a]	Easy to assemble	
[1.10c]	Can be easily transported from a car to the home	

Place for instruments

Section	Requirements	Specifications
[1.3i] → [1.14a]	Space for suturing kit behind the mother's buttocks	Min. 20 x 15 cm

Light for suturing

Section	Requirements	Specifications
[1.3h] → [1.13a]	Proper light for suturing	CRI value > 90 Ra and colour temperature of 4,500° K +/- 300° K

Price and certifications

Section	Requirements	Specifications
[1.8a]	Should have a CE-certification	
[1.8b]	Should have a retail price of approximately 10,000 DKK	
[1.9a]	Have a maximum retail price of 5,500 DKK for private sector	

Conflicting requirements

[1.12a] midwife's ergonomics ⟷ [1.6b] suturing at different locations

The product is hospital equipment ⟷ [1.6a] should not resemble hospital equipment

[1.8b] retail price of approximately 10,000 DKK (public sector) ⟷ [1.9a] maximum retail price of 5,500 DKK (private sector)

[1.3g] tailbone at the edge ⟷ [1.14a] instruments right behind mother's buttocks

02 - Concept development

106

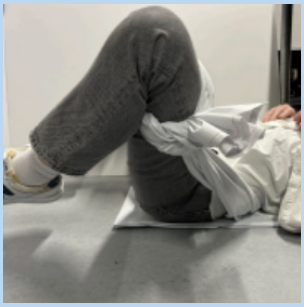
In this chapter, concepts are developed and knowledge from Chapter 01 Research will be used as a guideline and foundation towards developing a product proposal. The chapter includes tests with the users to verify the concepts. All concepts developed throughout this chapter do not necessarily take all the information gathered in Chapter 01 Research into account, since the research has been conducted in parallel with concept development.

2.1 Initial concept development 1.0 - leg position

The objective of this section is to develop initial concepts to be presented at milestone 1 based on knowledge from the midwives and mothers.

Three initial concepts are developed based on the preliminary ideas about a product solution from Section *0.2 Preliminary directions*. These are presented in illustration 107-109. The focus of these concepts was primarily on ease of transportation and the mother's wellbeing while the concept is used. None of the concepts utilise the preliminary idea of a rigid structure placed on the floor, since suturing can take place at many different places in the home based on the interviews with midwives and mothers. If a rigid structure placed on the floor should be used both for the bed, the couch and on the dining table, it should be height adjustable to many different heights and would probably take up a lot of space in order to be stable. Therefore, this idea is not made into a concept.

Concept 1 - textile



ill. 107

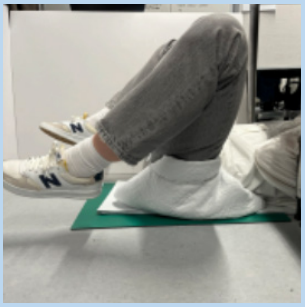
Textile is wrapped around the lower back and attached to the legs, thereby holding the legs. Should provide the same effect as the rebozo sheet, but without the feeling of confinement.

Concept 2 - inflatable

ill. 108

Each leg is supported by an inflatable object that the legs can rest on. Should save space for transportation.

Concept 3 - rigid structure



ill. 109

A rigid structure that supports the top part of the thighs, including a solid surface to make sure the buttocks lie flat.

Evaluation

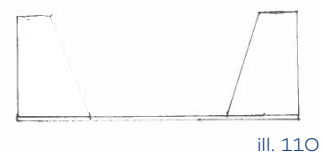
The three concepts are only initial and difficult to evaluate, because there is a lack of knowledge on e.g. what a good position is for the mother at this point. Furthermore, when evaluating the ideas, it becomes clear that the concepts focus mostly on the mothers, since they have been designed with the main focus to be comfortable for the mother. However, as the midwives are the main users of the product, they should be considered more in future concepts. Therefore, it might be necessary to consider solutions that are more rigid and adjustable, which were initially discarded.

2.2 Concept development 2.0 - holding the mother's legs

The objective of the section is ideation and concept development of concepts for holding the mother's legs while suturing. The focus is to create concepts that can be used at various locations (soft and hard surfaces) and are easy to bring along by the midwife (lightweight and easy to set up).

Ideation

Initially, eight different ideas are sketched out, which are seen in illustration 110-119.

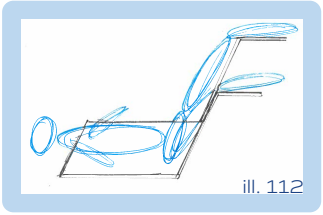


ill. 110

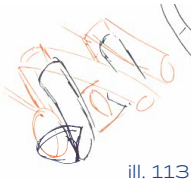
Two inflatable pillows which are connected. Saves space.

ill. 111

Rigid bottom plate with textile stirrups.

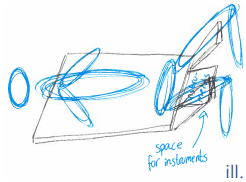


ill. 112



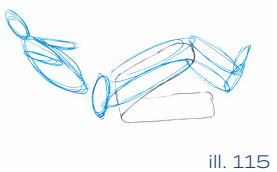
ill. 113

Rigid plate with attached stirrups. Legs are held by the mother's own body weight.



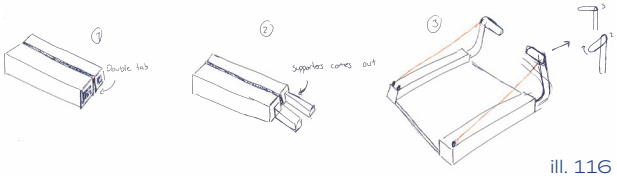
ill. 114

Rigid plate with something to support the legs and a place for the equipment.



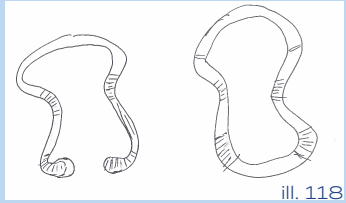
ill. 115

Spring-like rigid support for the legs.

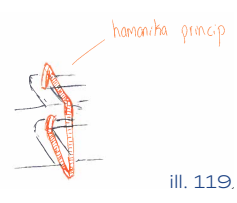


ill. 116

Foldable bottom plate with knee supports to the sides.

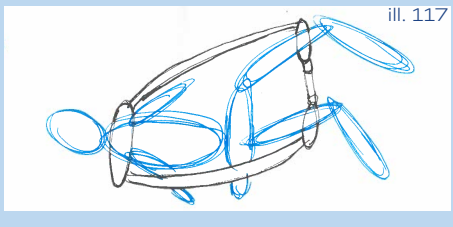


ill. 118



ill. 119

Rigid structure with foam supporting the legs at the knees using the lower back.



ill. 117

Adjustable rebozo-inspired textile supporting the legs using the lower back.

The ideas for possible concepts are evaluated in order to identify strengths and weaknesses. Having a bottom plate which the mother is laying on seems like a good idea, since it is important to have a solid underlayment to ensure levelling of the buttocks. The idea with an inflatable support might be good for transportation, since it can be made very compact, but it is not easy to visualise a solution, where it can easily be adjusted for different mothers. Additionally, the rebozo-inspired solutions should be examined further, since the rebozo sheet works fine for supporting the legs, but could be refined to provide additional support and adjustability while being a relatively simple concept. Generally, the idea about a rigid structure is more adjusted towards the needs of the midwife, since it could provide her with a similar setup for correct suturing as at the hospital. On the other hand, the ideas with textile focus more on the mother's needs in terms of providing comfort using soft materials.

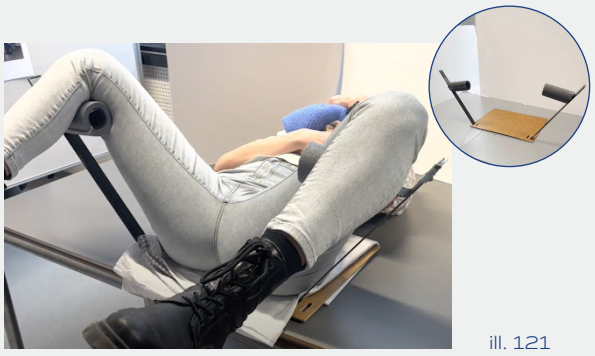
From this, three concepts are chosen to be developed further; one that uses textile similar to the rebozo sheet, one with a more rigid structure similar to what is used at the hospital, but with a bottom plate, and a combination of using textile and a rigid structure.

Three concepts

Models of the three concepts are built in order to take them to the hospital for testing with the midwives, since it is necessary to test if they can in fact hold a person's legs.

Both concept 1 and 2 are based on a bottom plate to level the mothers buttocks, just like the midwives use a cutting board today. Here, the intention is that the plate can be placed under the mother without her having to move.

ill. 120



ill. 121

ill. 122

Concept 1: Textile

The textile is mounted onto the bottom plate. The textile straps are put around the knees and adjusted to fit the mother. Thereby, the mother's knees are supported by her own weight. The knees are given additional support to the sides by joining the textile straps in the middle.

The focus of this concept is to reduce the feeling of confinement for the mother compared to the rebozo sheet.

Concept 2: The stirrup

Stirrups are mounted on a bottom plate. The stirrups are equipped with foam to make them comfortable for the mother. The height can be adjusted to the individual mother by adjusting where on the stirrup the foam pads are attached. There is support at the back of the knee for a simple construction.

The stirrups can be mounted into different placements on the plate to accommodate both wide and narrow hips.

Concept 3: The ring

The ring-shaped structure is placed at the lower back and is brought around the knees to support the legs.

It was decided to eliminate the third concept, because it was not possible to relax in the back, it was not easy to adjust and the knee supports slipped down easily.

Own test

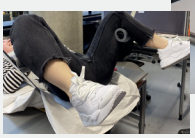
The two remaining concepts were casually tested on other students, mainly to examine if they could fit different people.

ill. 123

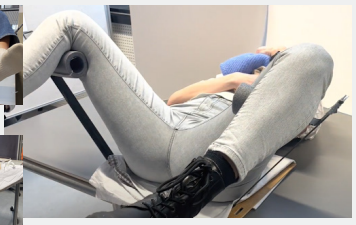
Concept 1: Textile

+ Compared to rebozo, it was easier to adjust
+ No feeling of interference with the upper body
- A bit difficult to put on the test person
- The buttocks should be placed as close the the edge of the plate as possible in order to support the legs

ill. 124



ill. 125



ill. 126

Concept 2: The stirrup

+ Good width between stirrups allows for easy placement of the person
+ Good support for the knees
+ Supports the legs without effort
- The legs are very wide for small people
- Not easy to adjust up and down

Evaluation

Eight different ideas were illustrated and three were chosen for concept development and functional model creation. These were based on textile, inspired by the rebozo sheet, a rigid structure with a bottom plate and a combination of a rigid structure and textile. The combination concept was ruled out since the model did not work as intended and the two remaining concepts were casually tested. However, the concept with textile and the one with stirrups should be tested further with midwives, to evaluate if they work as intended in different scenarios, e.g. on a soft surface like a bed or a couch.

2.3 Test and feedback 1.0 - midwife

The objective is to test the functional models with midwife Dorthe Sloth Svendsen from Aalborg University Hospital to get feedback on the pros and cons of the models in different scenarios (see Appendix 9).

The two concepts are shown to and tested with Dorte on a bed to test the most difficult scenario when the solution is placed on a soft surface. In general, Dorte sees potential in both concepts.

Concept 1: Textile

ill. 127

ill. 128

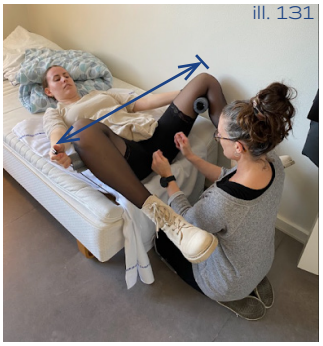
ill. 129

+ She was really fond of having something with textile because it does not take up much space and is easy to bring along.

- Unsure how to adjust it.
- The heels are too close to each other for proper suturing, see illustration 127.
- The textile slides down a little bit towards the feet when wearing it, thereby offering less support and making it uncomfortable to wear, see illustration 128.
- Is there proper blood circulation to the lower legs if the mother should lay there for a long time? see illustration 129.
- Maybe there is too much difference between small and large legs - is there enough textile to reach all the way around for bigger women?

Concept 2: The stirrup


ill. 130


ill. 131


ill. 132

+ Very fitting for the suturing in relation to the placement of the legs - heels are far away from the work area and the legs are relaxed.
+ The blood circulation might be a little better for this concept, see illustration 130 But it is questioned if it will be comfortable for the knees over a longer time.
- The distance between the stirrups is too large, see illustration 131.
- When using it on a soft surface like the bed, the bottom plate was too soft resulting in the legs falling forward - would like for the knees to be closer to the mother thereby having the weight of the mother's legs over herself, see illustration 132.

In general

Dorte sees a potential in both of the concepts, if the disadvantages mentioned during testing could be improved. Therefore, neither of the concepts are ruled out. Dorte saw an advantage in having a bottom plate, which is used for levelling the mother's buttocks. However, she saw a potential in making the plate longer in order to have a place for the suturing kit, see illustration 133. Furthermore, both concepts were designed to be placed under the mother without moving her from where she is laying. This did not work as intended, since the plates were too large for both concepts to slide under the mother. However, Dorte noted that this would not be a problem, since she expects that the mother is able to get up and lay on top of the plate for suturing.
Generally, if the product is made of textile, the midwife would need more of the products, since it has to be washed after each use. However, if a textile product could be enrolled in the laundry system already used at the hospital, which could be advantageous.


ill. 133
Place for instruments


ill. 134
Slide plate under buttocks

Evaluation

The two concepts were tested with midwife Dorte Sloth Svendsen. She saw potential in both of the models tested. However, there were some disadvantages with both concepts in terms of the bottom plate, which was too soft to be used on a soft surface. However, if the drawbacks are improved, both concepts have potential to be useful to assist the midwife for suturing at a home birth. Additionally, Dorte could see an advantage in having space on the bottom plate for the suturing kit.

!

It is found that the requirement [1.3e] → [1.12a] of fulfilling the recommendations for an ergonomic position of the midwife can not be fulfilled. This is because the mother can be sutured in various locations and it can therefore not be ensured that the midwife is sitting on a chair in a good position. However, if the requirements [1.11a] mother's legs are held in the lithotomy position and [1.3g] the mother's tailbone is close to the edge of the surface, the midwife's ergonomic position will still be improved compared to now. If the requirement [1.12b] where the mother is placed in the proper height for suturing is fulfilled, the midwife will most likely have a good ergonomic position.

~~[1.3e] → [1.12a] → [2.3a] The midwife's ergonomic position fulfils the recommendations~~

2.4 Concept development 3.0 - three directions

In this section, work with the two concepts continues to obtain new concepts based on the feedback for further validation and test.

The two concepts tested in Section *2.3 Test and feedback 1.0 - midwife* need to be improved by implementation of the feedback from the tests. Additionally, the correct positioning of the mother was researched at this point (Section *1.11 Correct position of mother*) to obtain knowledge about the optimal way to place the mother's legs for suturing. This information led to the identification of two directions;

ill. 135

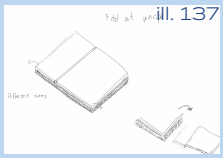
Textiles + plate

ill. 136

Stirrups + plate

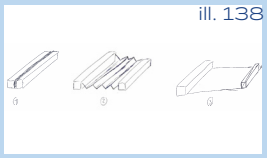
Both directions include a bottom plate like the current concepts. However, it is found from the research that the bottom plate should be rigid to obtain levelling of the mother's buttocks, like they do with the cutting board currently, and that it would be beneficial for the bottom plate to be angled to obtain pelvic tilt for the mother. Since the two concepts are both based on a bottom plate, ideation and sketching is performed on how this plate might become easier to transport for the midwife and be adjustable for women of different sizes.

Size adjustable plate



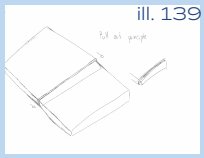
ill. 137

Foldable to different sizes - an additional section can be folded out.



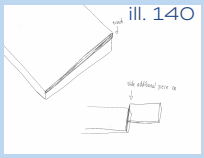
ill. 138

Accordion-principle. Only draw the length of plate out that is needed.



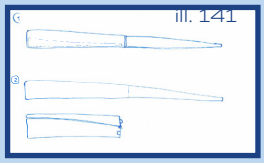
ill. 139

Sleeve principle - one part can be drawn out from the other.



ill. 140

One part of the plate (needed size) can be slided onto the main plate.



ill. 141

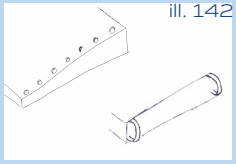
Click-system or hinge to fold the plate in half.

Due to problems with e.g. lack of rigidity for the accordion based principle and an edge that is uncomfortable to lay on for the sleeve principle, the click or hinge system in illustration 141 is chosen. Fewest drawbacks are seen for this idea.

Plate with instruments and light

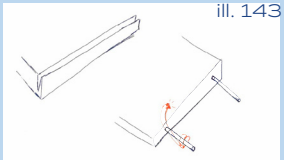
For the two directions with a rigid bottom plate, it could be beneficial to incorporate instruments and light for suturing as a part of the bottom plate. Different ideas are sketched out.

ill. 142



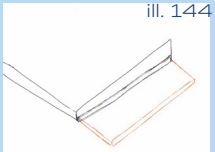
Pre-drilled holes at different positions in the light for easy attachment of light source and instruments at variable positions.

ill. 143



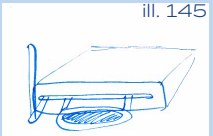
Rods in the plate can be drawn out for attachment of light source and instruments.

ill. 144



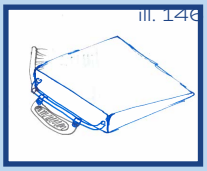
A tray for the suturing instruments can be slided onto the plate.

ill. 145



Pre-made wide slot that instruments and light can be attached in and adjusted horizontally.

ill. 146



A handle for lifting the plate.
Kidney tray and light can be clicked directly onto the handle.

Since it would be favourable for the midwife to have something to lift the plate in, the solution with the handle is chosen as seen in illustration 146. This also allows the midwife to use the handle as an interface for the kidney tray, which some midwives use today for their instruments. In this way, no additional tray for instruments is needed and this saves some space. Additionally, this reduces holes and crevices in the plate, which could be unfavourable for cleaning.

The textile concept

The main problems in the test for the concept with textile were that the textile slided down when supported by the lower back and it was not straightforward to adjust. Additionally, support at the knees is necessary to obtain better circulation to the lower legs. Based on this, a textile concept is developed based on a rigid plate and improvement to the above mentioned problems.

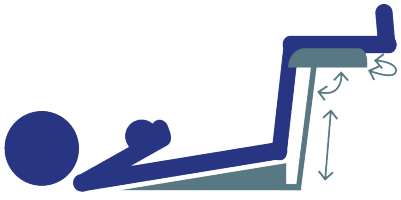
ill. 147

ill. 148

The concept is based on support at the neck to avoid sliding of the textile. The textile can be adjusted to obtain different lengths around the neck and between the legs using the same principle as a backpack strap. Furthermore, additional support is added at the back of the knees.

The stirrups concept

The main problems in the test for the concept with stirrups were that the stirrups were placed too far apart and that the setup was hard to adjust for different mothers. Based on this, a concept with stirrups is developed based on a rigid plate and improvement to the above mentioned problems, which is similar to the stirrups used at the hospital.

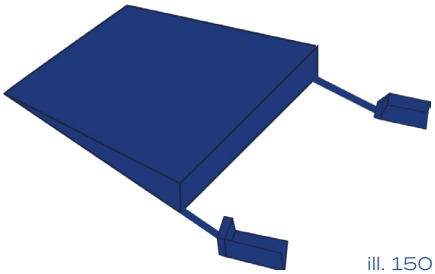


ill. 149

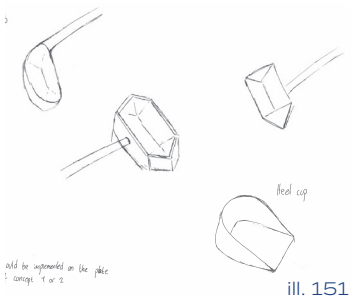
The concept is based on the stirrups being clicked onto the bottom plate. The stirrups are height adjustable and the supports for the calves can be angled up or down while the support can also be rotated.

A new direction - foot support

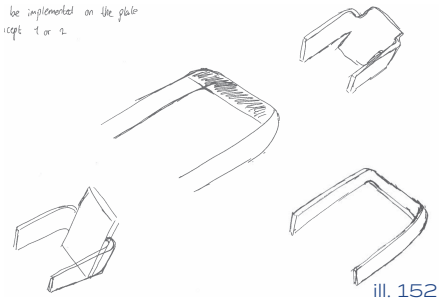
While developing the stirrups concept, it was noted that this concept takes up a lot of space. Therefore, an idea was to add a more compact and simple direction of the rigid concept, inspired by the foot supports that are used at the hospital during birth, see illustration 150. Ideation of this concept is presented in illustration 151-152, where different sketches are made to examine how the feet should be placed in a footholder to still obtain an optimal position.



ill. 150



ill. 151



ill. 152

Construction of the three concepts

Common for the three concepts is that they are all based on an angled, rigid plate with a handle that can be used as the interface for both lighting and placement of instruments, see illustration 153.

On the handle, two smaller clamps are made so the single-use kidney tray can be easily mounted.

ill. 153

Concept 1 - textile

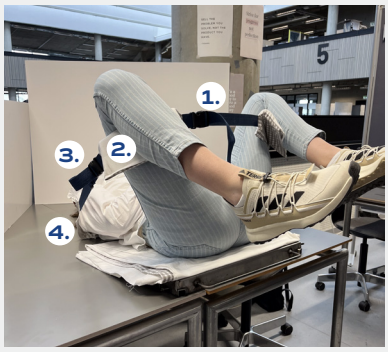
ill. 154

Concept 2 - stirrups

ill. 155

Concept 3 - foot support

ill. 156



ill. 157

1. Adjustment between knees
2. Knee support (cushioned metal piece)
3. Adjustment of length around the neck
4. Thick textile for support around neck and shoulders

ill. 158

1. Adjustment for height
2. Rotational adjustment of calf-holder
3. Angular adjustment of calf-holder
4. Stirrups easily slided into the plate

ill. 159

1. Simple foot supports easily slided into the plate

Evaluation

Based on the research and tests, it is found that it is beneficial to have a rigid and angled bottom plate for the concepts. Therefore, this is the basis for the further concept development. It is examined how this plate can be adjusted in size to fit different mothers and ease the transportation. Additionally, implementation of instruments and light for suturing is examined as an integrated part of the bottom plate. It is found that it would be most beneficial to have a handle which functions as an interface for light and instrument placement. The two concepts with textile and stirrups are developed further based on the feedback from the test with midwife Dorte Sloth Svendsen. Furthermore, an additional concept inspired by the foot supports at the hospital is developed. The three concepts should be tried in a realistic setting, which can be used to validate if they perform as expected.

Even though the research suggests the optimal position for the mother, it is still chosen to develop and test out two concepts which do not live up to all recommendations about the optimal position (concept 1 and 3). This is to challenge the premise and see if a simpler solution can be made to obtain adequate support for the legs while having other advantages in terms of ease of application, simplified construction and materials etc.

2.5 Test and feedback 2.0 - midwives and mothers

The objective is to get feedback on the functional models with midwives from both Aalborg University Hospital, Copenhagen University Hospital and outside Denmark (Appendix 10) on the positioning of the mother that the models provide and the placement of light and instruments. Additionally, it is to obtain feedback from mothers (Appendix 11), to get their perspective in terms of how they feel about the expression and use of the models.

The three concepts are tested by two home birth midwives from Aalborg University Hospital, Dorte and Camilla, to get feedback on the concepts. Additionally, the concepts are presented at online meetings with two additional midwives, Maria from Copenhagen and Maryam who has experience as a midwife from Canada, Ghana and Australia. Written feedback on videos of the use of the concepts is obtained from three of the mothers previously interviewed. The main feedback for the concepts is presented below;

Concept 1 - textile

ill. 160

Midwives:

+ Looks like the mother is very comfortable in this position.
+ Is quite similar to the rebozo sheet that they are sometimes using now.
+ Does not take up a lot of space.
+ It is nice that the mother can help with adjusting the position herself.
- **The position is not correct for suturing. The mother's knees are too close to the head resulting in stretching of the skin.**
- The mother's feet are not spread enough apart, so they are in the way of the midwife's working area.
- It is not easy to adjust to a comfortable position for all mothers.

Mothers:

+ **Maintains the feeling of a safe home birth without association to the hospital.**
+ Interesting because it looks soft and comfortable.
- Is it a hygienic solution?
- Maybe it will not be comfortable to lay in for a long time.
- Is it possible to relax enough?

Concept 2 - stirrups

ill. 161

Midwives:

+ **Laying in the completely correct position.**
+ **Works well for both hard and soft surfaces.**
+ Can be used for all degrees of tears.
+ Advantage that the mother can not put the knees together.
+ More comfortable and relaxing for the mother.
- Would be nice if the angle of the legs could be adjusted so it is not too narrow or wide depending on the mother.
- The biggest downside is that it takes up a lot of space.
- It would be nice if the angle of the calf-holders could be adjusted.
- Something soft for the places which the mother lays directly on (plate and calf-holders).

Mothers:

+ Looks very nice to lay in and possible to fully relax the legs.
+ Looks like there is nice space to work for the midwife.
- **For some it breaks the illusion and associates too much with the hospital.**
- Takes up a lot of space.

Concept 3 - foot support

ill. 162

Midwives:

+ Good with space for the midwife
+ Nice, unhindered view of the work area.
- Worried that the mother might put the knees together or not relax enough.
- No support for the knees to the sides.
- **Not good for laying on a soft surface since it results in arching of the mothers back and resulting in tension of the muscles.**

Mothers:

- The legs are supported in one direction, but the knees lack some kind of support to the sides.
- Maybe it will not be comfortable to lay in for a long time.

The midwives see advantages and disadvantages with all of the concepts. They consider both the comfort for the mother but especially the correct position for proper suturing. Concept 1 is the least invasive. However, the position is not correct for suturing properly and it is hard to adjust to different sizes of mothers which is why the concept is discarded. For concept 2, the midwives see a lot of potential for the solution, since it is similar to the stirrups already used at the hospital. However, this solution might break the illusion about the home birth a little bit for some mothers. On the other hand, some of the mothers still think it is more important to lay in the optimal position for suturing. For concept 3, there are mostly drawbacks since both the midwives and mothers note that support for the knees to the sides is missing, and this does not enable the mother to relax properly. Therefore, to obtain a comfortable position for the mother and also a correct position for suturing, the best concept to develop further is concept 2.

General feedback

Generally, the feedback from the midwives is centred around that the angled plate is a nice idea, since it results in the desired pelvic tilt and levelled buttocks. This is especially the case when the concepts are used on hard surfaces. However, the **plate can be a bit hard to lay on**, so either a **softer solution has to be implemented**, or the midwife has to cushion the plate with something. Additionally, it is **nice to have light close by**, but the midwives note that it is too close to the genitals to be sterile. They are also very positive about having a place for their instruments. However, the solution with the kidney tray is not ideal, since not all midwives use such a tray for the instruments. They think that it should rather be a plate or similar that can be attached to the handle, which can be covered by sterile fabric and the equipment is laid out on top of that. The midwives note that an **optimal place for their instruments is more important for them compared to a proper light** source on the product. Lastly, the midwives think that the product should be easy to assemble within 5 min.

ill. 163

Softer plate (here sheets are used as soft surface)

ill. 164

Standard solution for instrument

Optimal placement for light

Own feedback for concept 2

After choosing concept 2, we identified some other problems that could be improved for the concept.

ill. 165

Due to the 90° angle of the stirrups, the buttocks can not be moved all the way out to the edge of the plate. The stirrups could be angled to solve this problem.

ill. 166

Turning the calf-holder is not optimal, since it turns too close to the knee, creating an unnatural position. To solve this problem, the stirrup beams should be connected to the middle of the calf-holder.

Feedback from milestone 3

ill. 167

Prior to the milestone, concept 2 was quickly 3D modelled, in order to get a sense of the overall product. Also, considering the transportation and reduction in weight of the concept, the materials for the model were carbon beams and plastic for the rest of the model. This also provided the concept with a less industrial look compared to the model in all metal.

The feedback revolves around the perception of the product both in terms of the product language and the product experience, which is something that is not yet integrated but something that is considered already. For example, it was advised to look at other products specifically made for women.

Evaluation

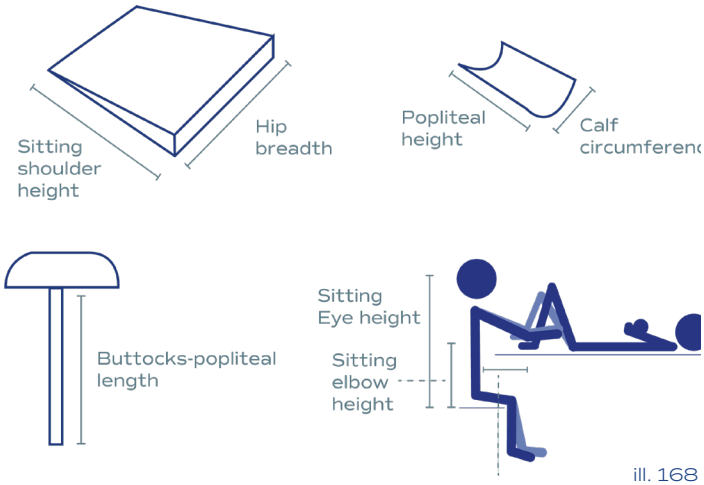
The three concepts are tested with midwives and receive feedback from some of the mothers. Based on the tests and feedback, it is chosen to continue with development of concept 2 with stirrups, since the optimal position of the mother's legs is prioritised by both the midwives and mothers. However, concept 2 needs to be improved in terms of being more adjustable in order to fit more women of different sizes. Therefore, more knowledge is needed on how to adjust this concept to different women in terms of the plate, calf-holder, height adjustment and optimal placement of the light for the midwife. Additionally, the material choice and corresponding strength of the concept should be considered, since the concept should be able to actually hold the mother's legs.

[2.5a] The surfaces that interact with the mother's skin should be soft
[1.10a] → [2.5b] Easy to assemble (within 5 min)

2.6 Anthropometric analysis

The objective of this section is to find information about the measurements of the body of different women in different parts of the world in order to know within what ranges the product solution should be able to be adjusted and the minimum size requirements for the different parts of a product solution. This is done through desk research. All calculations and values for the full analysis are presented in Appendix 12.

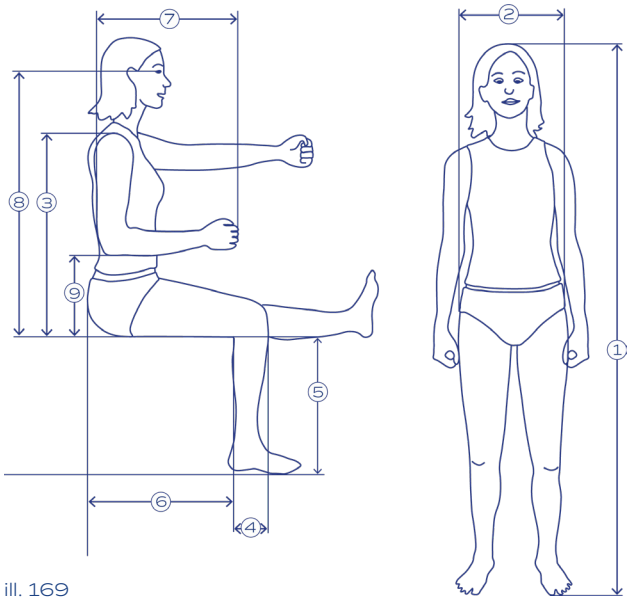
Since the concept should be adjustable in terms of the height of stirrups, angle of stirrups etc. to suit different mother's, it is necessary to find out the measurements of different women for which the product solution could be used. This to find the minimum requirements for the size of the plate, size of the calf-holder, stirrups height adjustability as well as the possible position of the light for suturing. For this task, anthropometric data is considered. Anthropometric data is: "[...] *the science that defines physical measures of a person's size, form, and functional capacities.*" (CDC, 2022) Hereby, it is possible to obtain the measurements for e.g. the length of legs, hip width and calf circumference. The measurements needed are the ones presented in illustration 168.



ill. 168

Anthropometric data

It is difficult to obtain up-to-date anthropometric data for different countries. Generally, there are no collected works comparing this type of data for different countries, for all of the values that are needed for this project. Therefore, the data which is used in this project is based on five different countries (**Turkey** (Iseri and Arslan, 2009), **Malaysia** (Karuppiah et al., 2011), **Indonesia** (Wibowo, Soni, and Salokhe, 2012), **Belgium** (University of Alberta Library, 2005) and **Norway** (SINTEF UNIMED, 1992)) and the data is of varying age. These countries are chosen since data for women was available and since it includes countries from both Europe, Asia and the Middle East. One of the sources is dated all the way back in 1992 and the data examines different age groups. However, it is assumed that the values from these countries will provide a good pinpointer for the approximation of the size adjustability of the product solution, since the minimum and maximum values across all the countries are considered as the range.
For each measurement of interest, the 5th and 95th percentile of the measurement is considered for the five countries. Here, the lowest 5th percentile and highest 95th percentile across all countries are chosen to get the requirements for the minimum and maximum values of adjustment in order to consider even the extreme cases. The minimum and maximum values obtained from the data are collected in table 2. The country which the data comes from is shown by abbreviation with the first letter of the country.



ill. 169

	No. - measurement	P5 (cm)	P95 (cm)
	1 - Stature	143.9 (I)	186.1 (B)
Bottom plate	2 - Hip breadth	24.5 (T)	44.5 (B)
	3 - Sitting shoulder height	41.4 (I)	67.6 (N)
Calf-holder	4 - Calf circumference	31.5*	47.2*
	5 - Popliteal height (lower leg)	34.4 (T)	48.9 (B)
Height adjustment	6 - Buttocks-popliteal length	39.4 (I)	53.9 (B)
Position of light	7 - Elbow fingertip length	38.8 (T)	46.7 (N)
	8 - Sitting eye height	59.4 (M)	84.8 (B)
	9 - Sitting elbow height	14.3 (M)	28.7 (T)

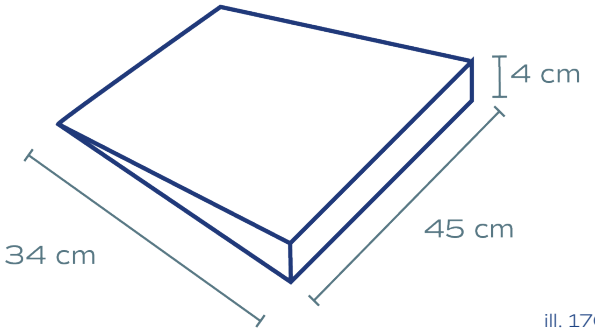
Table 2

*Values are based on another source from the United States (McDowell et al., 2008).

Plate size

In order to accommodate the largest hip breadth of 44.5 cm found in table 2, the plate should have a width of at least 45 cm. Additionally, the sitting shoulder height is used to determine how far the bottom plate should reach from the buttocks and to the back for support. It is assumed that it should be at least halfway up the back for good support, so the largest value (67.6 cm) is divided by two to obtain a minimum plate depth of 34 cm.

From Section *1.11 Correct position of mother*, it is known that the plate angle should be 13 +/- 6° to get the optimal pelvic tilt. Here, the lowest value possible is chosen since the bottom plate is solid and will weigh more for a larger angle, resulting in more material. Therefore, the value is chosen as 7°. This can be used to calculate the minimum height of the plate by using this angle and the minimum plate depth. This results in a minimum height of 4 cm.

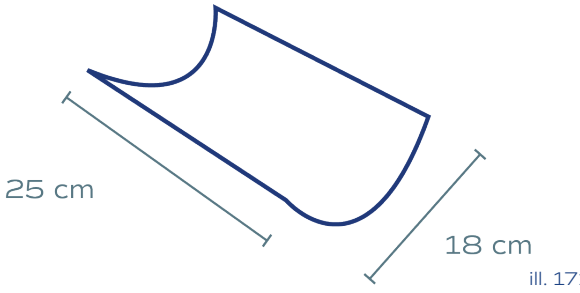


ill. 170

Calf-holder size

The popliteal height is used to determine the length of the calf-holder by assuming that the calf-holder should cover at least half of the calf. The longest calf (48.9 cm) is divided by two to get an estimation of the midpoint. Therefore, the calf-holder should be at least 25 cm in length.

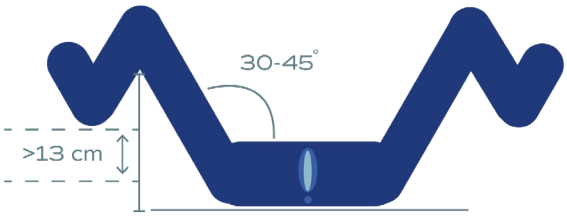
The diameter of the calf-holder is estimated by using the calf circumference for the biggest calf (47.2 cm). The circumference is divided by pi to approximate the diameter of the calf. This is found to be 15 cm. 20% extra (3 cm) is added to the diameter as a safety factor for when the calf is pushed down and flattens out and since the calves of pregnant women can be swollen. This gives a total diameter of the calf-holder of at least 18 cm.



ill. 171

Height adjustment

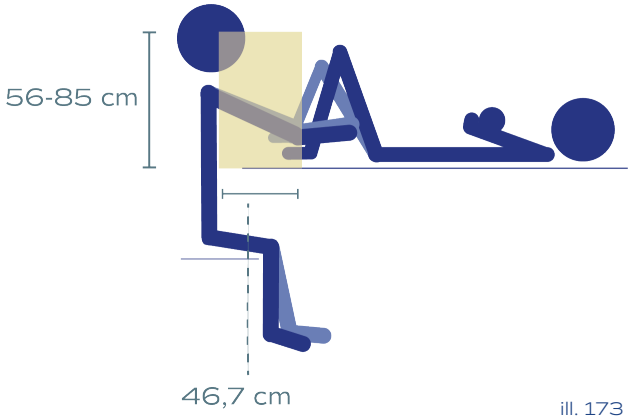
The buttocks popliteal length is used to determine the range of height adjustment for the stirrups. Here, the lowest and highest values from the table are used to determine the height the stirrup should be in to accommodate the calf. This is done for both the highest and lowest angle the legs should be angled, namely 30º and 45º, which was found in Section *1.11 Correct position of mother*. For 30º angling of the legs from the edge of the plate, the shortest leg requires the stirrup to be in a height of 27.9 cm, while the longest requires 38.1 cm. This is a 10.3 cm difference, which is the range the stirrup should be adjusted within. For 45º angling of the legs, the difference is calculated the same way to obtain 12.6 cm. Therefore, the stirrups should be adjustable within these limits depending on the angle chosen, which is not a wide span of adjustment needed.



ill. 172

Light placement

It is known that the light has to be placed somewhere between the midwife and the perineum. In order for the midwife to keep a good ergonomic position, it is assumed that the light source is at the elbow of the midwife at the furthest. Therefore, the highest elbow fingertip length can be used to obtain the furthest horizontal distance the light can be from the perineum. The highest value for elbow fingertip length is 46.7 cm. For the position of the light in the vertical position, the sitting eye height is used if the midwife is e.g. sitting on the bed at the same height as the mother. The highest value for this is 84.8 cm. If the midwife is sitting on a chair, the sitting elbow height can be used if it is subtracted from the sitting eye height, to find the maximum height the light could be placed in. The highest value for this is calculated as 56.1 cm. Therefore, the highest the light should be placed vertically is between 56 cm and 85 cm above the plate.



ill. 173

Evaluation

Based on anthropometric data for women from Turkey, Malaysia, Indonesia, Belgium and Norway, the minimum range of adjustment and size of the concept is determined. This includes the size of the plate, height adjustment of the stirrups, the size of the calf-holder and the area in which the light is to be placed. This can be used for more detailed measurements for the product solution.

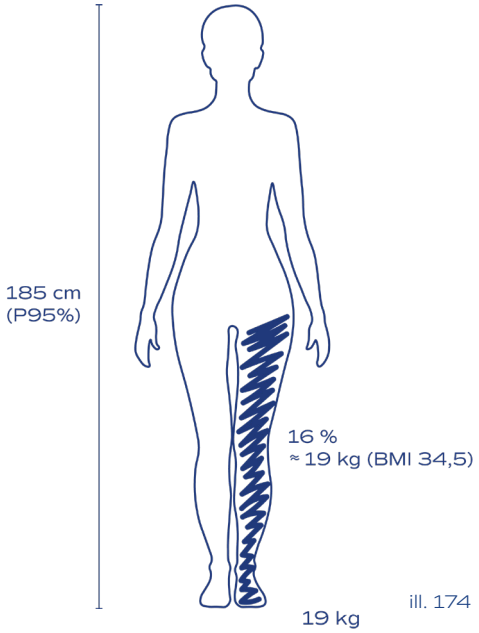
[1.2c] → [2.6a] The plate should fit 95% of all mothers (> H4 x L34 x W45 cm)
[1.2c] → [2.6b] The stirrups should be adjustable in height to fit 95% of all mothers (> 13 cm)
[1.2c] → [2.6c] The calf-holder should fit 95% of all mothers (L25 x D18 cm)
[2.6d] The light should be placed between the midwife and the mother (maximum L47 x H85 cm from the mother's buttocks)

2.7 Weight considerations

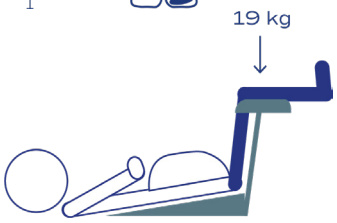
The purpose of this section is to examine the weight that the product solution needs to withstand when the mother's legs are placed in the stirrups, since the stirrups are the most critical point in terms of load. Furthermore, it is to obtain a general understanding of the weight distribution of women. This is performed through desk research.

Based on a study from 2014, 95% of 20 year old women in Denmark are 185 cm in height or below (Tinggaard, Jeanette et al., 2013). The data from this study also shows that the height does not increase notably after age 18. Therefore, 185 cm is used as an estimate for the calculation of the weight the concept needs to withstand. From Section *1.1 Initial research*, it is known that the highest BMI allowed for a home birth is 35. Therefore, for the chosen height, the weight of a woman in the category medical overweight with a BMI just below the limit allowed for home birth (34.5) is calculated to be 118 kg to get the assumed worst possible scenario of the load. Assuming that a leg constitutes 16% of the total weight (Albertslund Kommune, 2019), this would result in a weight of the leg for this woman of 19 kg. This is the static weight that the stirrups should be able to withstand in extreme cases. However, this is the weight of the whole leg, while it is primarily the weight of the lower leg that the stirrup should be able to support, but the exact weight distribution is not easy to estimate, see illustration 175.

Generally, the weight distribution of pregnant women can be different than other women, since fluid can accumulate in the tissue and some of the weight will be centred on the stomach as the baby grows (Mikkelsen, 2022). Therefore, the weight of the leg might be less for the same BMI for a pregnant woman.



ill. 174



ill. 175

Evaluation

The weight that the concept needs to withstand is calculated based on the height of 95% of 20 year old Danish women and an assumption of the highest BMI acceptable of 34,5. This results in a weight of the whole leg for this extreme case, that the stirrups should be able to withstand, of 19 kg. However, the weight distribution is unknown for pregnant women compared to non-pregnant women and it is hard to estimate the proportion of the total leg's weight that the stirrup should actually hold.

[1.2c] → [2.7a] The product can hold the weight of 95% of all mothers (≤ 118 kg)

2.8 Test of proper light

The objective of this section is to test the settings for proper lighting for suturing, in order to determine the specifications and placement of the light source for the product solution. This is done through tests with midwife Dorte Sloth Svendsen, simulating both day and night settings at a home birth (Appendix 13).

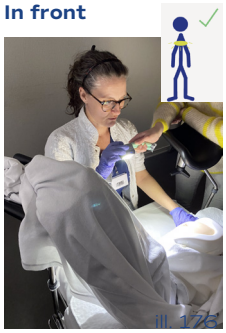
For the tests, the light sources used are three headlamps with lumen of 100/450 Lm, 300 Lm and 600 Lm, where a LuxMeter is used to measure the luminance. The distance from the light source to the perineum is found through anthro-

pometric data (Section *2.6 Anthropometric analysis*), and the diameter of the light is measured during the test to calculate the desired lumen of the light source. To simulate a perineum, a phantom of a tear from Aalborg University Hospital is used.

Placement of light source

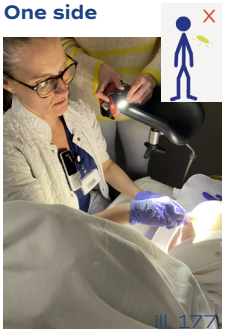
It is important that the placement of the light source does not interfere with the midwife's work and preferably casts no shadows over the working area. Therefore, different placements of the light are examined.

In front



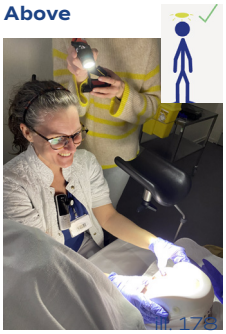
ill. 176

One side



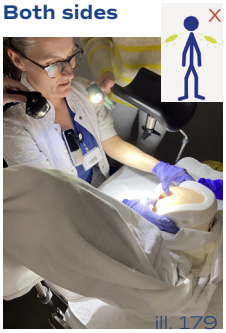
ill. 177

Above



ill. 178

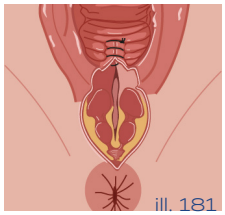
Both sides



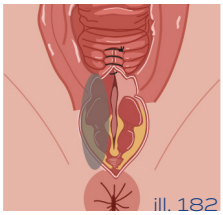
ill. 179

Above + below

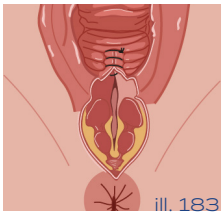
ill. 180



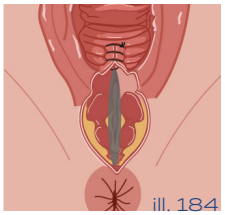
ill. 181



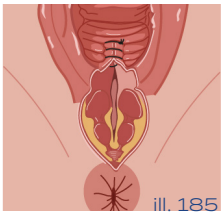
ill. 182



ill. 183



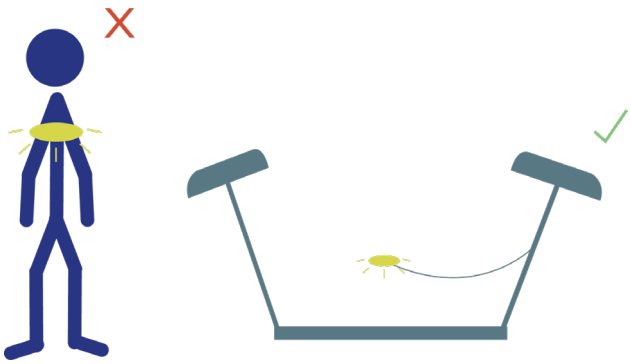
ill. 184



ill. 185

The light in front or above is clearly preferred, since this provides good lighting of the perineum without casting shadows in the working area. The solution with a light source both above and below does not provide a better result than these two. Therefore, it would be an unnecessary complication of the light source to add two in this case. Furthermore, having the light from either one side or both sides casts shadows around the tear at different locations. It is not severe, but it is still less ideal than the light placed in front or above.

When knowing that the light source should be placed in the middle, either in front of or above the midwife's head, it was discussed if the light should be placed on the product or the midwife's chest. It is found that the light source should not be attached to the midwife, since it is more optimal for the light to follow the line of sight. For example, if the working position is not optimal for suturing, the midwife's position might cause bad lighting of the perineum if attached to her body. Additionally, it is preferred if the light source is adjustable in terms of position. During the tests, the different headlamps are tested out, and Dorte prefers the one with 600 Lm, since it provides a lot of light and is more focused compared to the other headlamps.

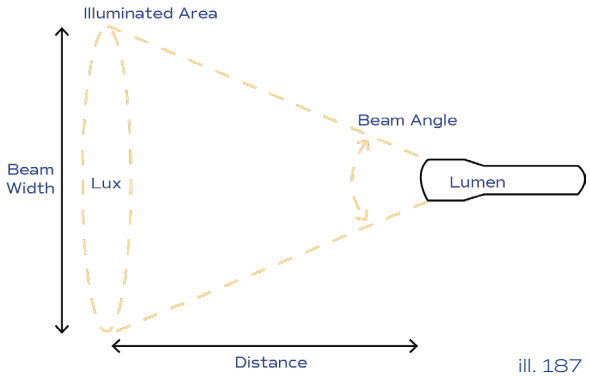


Light on midwife Light on product ill. 186

Light intensity

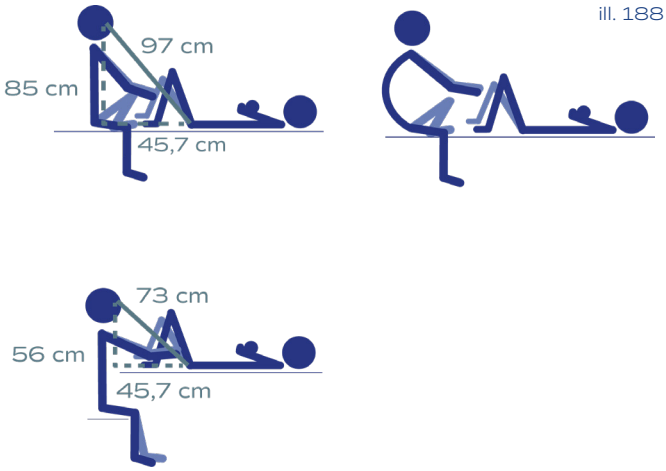
The best positions of the light (in front of the midwife and above the midwife's head) are tested with the preferred headlamp at 600 Lm to determine how much light in terms of luminance is needed for the suturing in different settings. Based on this, a light source with the needed lumen can be identified for the product solution.

To determine the lumen, the measurements shown in illustration 187 need to be known. During the test, the beam width can be determined as the area of the perineum that needs to be illuminated, the luminance can be measured with the Lux-Meter and the distance from the light source can be determined. Based on the distance, the beam angle can be calculated.



ill. 187

Based on the data from Section *2.6 Anthropometric analysis*, the light path can be determined if it is assumed that the light is at eye height (e.g. like a headlamp) either if the midwife is sitting correctly (56 cm) or at the same height as the mother (85 cm), see illustration 188. This gives a light path between 73 cm and 97 cm depending on if the position. However, it is not realistic that the midwife is placed at this height. This is because the midwife, like Dorte shows in the test, will never sit completely upright, since she needs to learn forward and bend down to get a better view of the perineum. This brings the eyes and the corresponding placement of the light closer than the first estimation. Therefore, the luminance is tested based on the distance that the midwife (Dorte) is sitting in while having a good position to suture from the phantom. These distances are 37 cm from light source to perineum if the light source is placed at the midwife's chest and 63 cm if placed above the head. The luminance is measured at these distances. Based on the tests, the highest luminance needed is 15,000 lx, which is found at the dark room setting. This will require the light source to be able to adjust the intensity to a lower level.



ill. 188

ill. 189

ill. 190

To calculate the lumen of the light source needed based on the luminance, the beam width at the illuminated area is measured to be 18 cm. From this, and the assumed longest distance to the light source to simulate the most extreme scenario (63 cm), the light angle that the light needs to have can be calculated as 16º. Therefore, the light needs to be quite focused. Based on the light angle, the longest distance and the maximum luminance, the lumen needed for the light source is calculated as 364 Lm. This assumes that only the area of 18 cm in diameter is lit up, which is why this lumen is lower than the light source tested.

Therefore, a light source with a lumen of about 400 Lm can be chosen with the possibility to reduce the intensity. This would give adequate light in all the settings imaginable. Otherwise a light source with a higher lumen can be chosen, if the light angle is not low enough.

Evaluation

Based on tests of placement of the light source, it is found that it should be placed in the middle, either above the head of the midwife or in front. Furthermore, it is found that the distance to the light source should not be based on the anthropometric data, but instead on the user test with the position the midwife will usually work in. Based on the test of the luminance, the distance to the light source and the area that nights to be illuminated, the specification of the light source is found to be about 400 Lm with a focused beam of light at a light angle of 16°.

[2.6d] → [2.8a] Light should be placed in front of or above the midwife
[1.3h] → [1.13a] → [2.8b] Proper light for suturing (CRI value > 90 Ra, colour temperature of 4,500° K +/- 300° K, at least 15,000 lx and illuminated area of ≥18 cm)

2.9 Product language

The objective of this section is to analyse the elements at the hospital and at home to obtain an understanding of the expression that the two settings give. This is to identify and determine a product language of the product solution that does not resemble a hospital environment. Desk research is used to examine the settings and analyse the meaning of colours in general and specifically for female products.

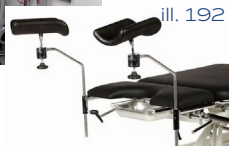
The product design language of the product needs to be examined to translate the core-values of the product into physical elements including how the product should look and be perceived by the users (Dalton, 2021). It is important for the look of the product to minimise the association with the hospital, since that is part of the reasons why mothers choose home births. The product itself will most likely look like medical equipment, but the analysis is necessary to determine how the product language can be changed for the better.

Hospital and home environment

The hospital and home environments are analysed in terms of colour, materials as well as the perception.

Hospital environment

ill. 191



ill. 192

Materials and colours:
- Cold materials
- White colours (and light blue)
- Metal look
- Shiny surfaces

Perception:
- Sterile
- Nothing is hidden
- Industrial expression
- Practical and functionable
- Unpersonal
- Function over form
- Clean smell

Home environment

ill. 193

ill. 194

Materials and colours:
- Wood
- Fabric
- Mixed colours
- Soft colours

Perception:
- Personalised
- Comfortable
- Warm
- Known environment

From this analysis, it is found that the materials and colours for the product need to be examined more closely, since they can result in certain expressions of the product. For example, the metal and white colours at the hospital give a cold, sterile and impersonal feeling, while the home association results from the warmer colours or soft materials. Therefore, it needs to be examined how the product language can be more personalised and targeted towards women and home births.

Expression of product categories

Since the product solution is a medical product, it would also be relevant to resemble a similar product language. However, it should also be clear that it is a product targeted for women and home births. Therefore, different products for medical use and different female products are analysed in terms of colour, form and perception.

Medical products

ill. 195

ill. 196

ill. 197

The goal is a place in between medical products and female products.

Female products

ill. 199

ill. 201

ill. 198

ill. 200

It is seen that the products for medical use are generally either white, black, grey or different nuances of blue. The materials used are often made of plastic or metal and the products can be characterised by their function, sometimes indicated by contrast colours. On the other hand, the female products are often almost a caricature, since very strong colours such as neon pink or purple are used. Otherwise, pastel colours are used. The shape of these products are often organic with rounded edges and the expression of the products is rather simple. The product language of the product for suturing at home birth should neither strongly signal association with the hospital, nor a strong expression of a female product with strong purple colours. Instead, the product should feel warm and neutral in the expression. This could be done by using colours that give a warm feeling. Also, focus on the functionality of the product could be indicated by contrast colours.

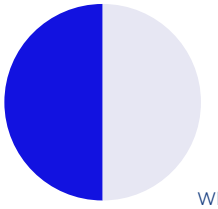
Colour meaning

The meaning and associated feelings of different colours are examined to understand what nuances of colours might be well-suited for the product solution.

"*The color, materials and finishing (CMF) [...] can be loosely defined as the use of color to improve a product's usability or to elicit an emotional response from the consumer*" (Xavier Creative House, 2018).

It is examined why the colours used at the hospital are in fact used. It is found that white or a blue colour palette often is the choice when it comes to medical equipment and establishments, see illustration 195-201 (Sparrow, 2017). Furthermore, it is found that the use of darker or lighter colours creates a different expression and feeling.

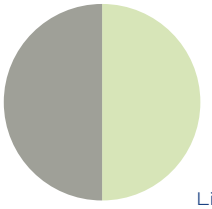
Medical products



ill. 202

Blue colours (Sparrow, 2017):
Reflects least amount of light
Least harsh on the surgeons' eyes

White colours (Sparrow, 2017):
Expression of cleanliness and sterility for medical equipment



ill. 203

Darker colours (Park, 2015):
Seem heavier
Feeling of being strong and secure

Lighter colours (Park, 2015):
More lightweight look
Signify cleanliness and purity

Generally, it is found that "*warm colors [...] elicit empathy. They are appropriate for home-care products*" (Sparrow, 2017). Furthermore, warm colours promote a feeling of warmth, comfort and home. (Hinz, 2018)

Line's perspective

In an interview with midwife Line Hundebøl Nielsen (see Appendix 14), the product presented at milestone 3 (see illustration 167) is presented and discussed. Line expresses that it is a very good idea to use colours, which are not normally used for normal hospital equipment to give a feeling more appropriate for a home birth. Furthermore, she suggests that a pattern could be used for the product solution, since this is something which would never be seen for hospital equipment and therefore, the product might not be associated with the hospital. Also, a pattern might make it easier to hide potential blood stains from the mothers, but on the other hand might make it more difficult to clean, since the stains are harder to identify.

Evaluation

The environment of the hospital and home are different in terms of the perception and the materials and colours used. The hospital resembles a more clean, sterile and cold environment while the softer materials at home signal warmth and comfort. Additionally, different products are examined to understand the product language. It is found that the product should neither completely resemble hospital equipment, nor should it look like stereotypical female products with strong colours. Lastly, the meaning and association of different colours are examined. Warm colours are generally desired for the product solution to create the right association of warmth and comfort for the home birth.

[1.6a] → [2.9a] The product should not resemble the hospital (dominant colour should be light and warm and shapes should be rounded)

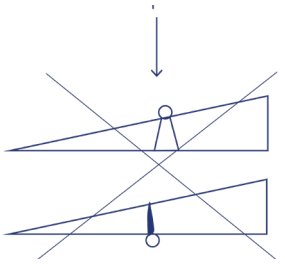
2.10 Construction development

The objective of this section is to continue the development of the concept solution chosen in Section 2.5 Test and feedback 2.0 - midwives and mothers, by including the knowledge from research, tests and interviews to obtain the correct angles and adjustability for different women. All iterations and thoughts for the construction development are presented in Appendix 15.

The main focus during further development of the construction of the product solution has been to obtain the correct position of the mother's legs, ease the transportation of the product for the midwife and proper cleaning of the product to live up to medical standards. However, these three focus points turned out to be difficult to combine and many iterations were performed for the construction development. Especially the details about the stirrups in terms of attachment to the bottom plate, angles and adjustability, combined with the need for easy cleaning and transport, was hard to fulfil. During the construction development, the knowledge from Section *1.15 Medical devices* was obtained and therefore, several requirements for cleaning of medical products had to be acknowledged as well. An overview of the development and different solutions is presented in illustration 204-213, followed by an elaboration of each step.

Concept development timeline

1: Non-foldable plate



ill. 204

ill. 205

A) Fixed angles and movable width

ill. 206

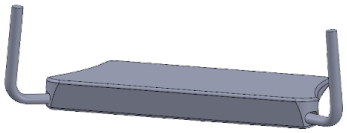
B) Fixed angles at the corner.

ill. 207

C) Straight-up stirrups with angular rotation like the hospital.

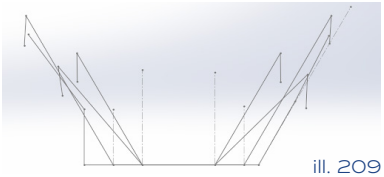
2: Stirrup construction with correct positioning

3: Straight-up stirrups with angular rotation like the hospital. Combined stirrup and handle.



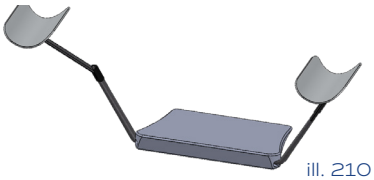
ill. 208

4: Evaluation of angles and adjustability



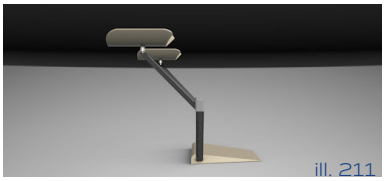
ill. 209

5: Legs in the same plane as the stirrups



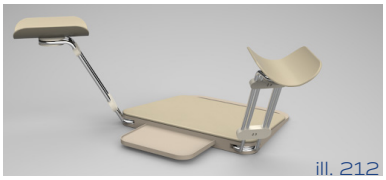
ill. 210

6: Transportation, cleaning and price



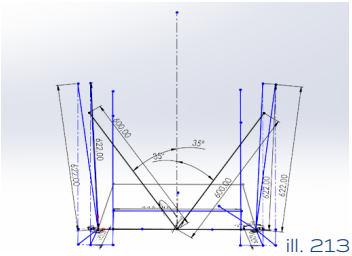
ill. 211

7: Easy cleaning and rotational joint in bottom plate



ill. 212

8: Correct angle definition

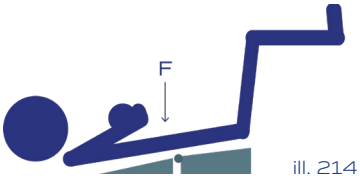


ill. 213

1 Non-foldable plate

From Section *2.4 Concept development 3.0 - three directions*, it was found that the plate should be foldable or able to be either clicked or slide together in different sections to ease transportation. It is discussed that the easiest of these solutions would be folding of the plate since this is more simple and intuitive when setting up the product. Two different solutions for folding the plate using a hinge are presented in illustration 214-217.

Hinge in the top



ill. 214

ill. 215

+ Folding the plate with a hinge in the top is intuitive and creates a shape that is easy to fold for transportation, see illustration 215.
- The hinge position can cause the plate to bend or deform due to the applied weight. To avoid bending, the hinge should be lockable, which complicates the solution, see illustration 214.

Hinge in the bottom

ill. 216

ill. 217

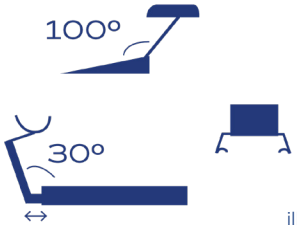
+ The hinge position creates a more stable solution compared to the hinge in the top, see illustration 216.
- Folding the plate with a hinge in the bottom is not as intuitive since the plate needs to be lifted or flipped before folding, see illustration 217.

Furthermore, having a hinge in the plate is a potential risk of collection of dirt which could make the product harder to clean. Dividing the plate in two with a hinge in between also makes the plate less rigid and more fragile. Therefore, to make the construction more simple, it is chosen to make the plate non-foldable, in a single piece.

2 Stirrup construction with correct positioning

The concept with stirrups from Section *2.5 Test and feedback 2.0 - midwives and mothers* is developed further in terms of construction. This is done to be able to accommodate different sizes of mothers based on the anthropometric analysis in terms of width and height adjustability of the stirrups. Additionally, the mother should be able to be placed in the lithotomy position, wherefore the solution should be adjusted to these angles for mothers of different sizes.
Based on the stirrups concept, three variations were sketched and evaluated.

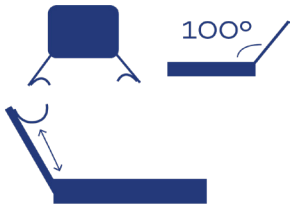
A) Fixed angles and movable width



ill. 218

Stirrups with fixed angles to the side and forward. The calf-holder can be height adjusted along the stirrup and the width can be adjusted horizontally by moving a rod in and out of the bottom plate.

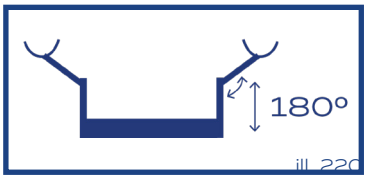
B) Fixed angles at the corner



ill. 219

Stirrups are placed at the corner and the angles to the side and forward are fixed. The calf-holder can be height adjusted along the stirrup, making the distance shorter between the legs.

C) Straight-up stirrups with angular rotation like the hospital



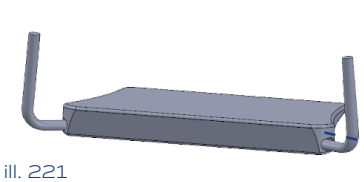
ill. 220

Similar to the stirrup setup at the hospital. The stirrups are attached vertically to the bottom plate and can be height adjusted. The angle of the stirrups can be adjusted 180° horizontally.

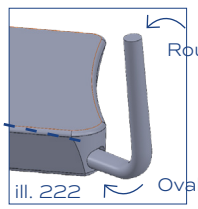
Generally, all of these variations enable the mother to be placed in the lithotomy if the stirrups are placed in the indicated positions. However, there are some critical points for some of the concept variations. For variation A, it could be a problem having a rod to move in and out of the bottom plate in terms of problems with cleaning and fixation of the rod in the correct position. For variation B, the problem is that the fixed angles cause the legs to move too close to the body when the height of the stirrup is lowered. Therefore, variation C is chosen for further development, since it seems to have fewer disadvantages.

3 Straight-up stirrups with angular rotation like the hospital.

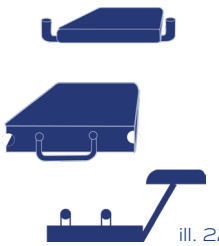
Different ideas about the design of variation C are evaluated. For this concept, the stirrups are attached in holes in the bottom plate. The weight of the mother when she lies on the plate acts as a counterweight to keep the stirrups in place. The holes in the plate for the stirrups are oval (see illustration 221), since the stirrups should not be able to rotate when they have been attached. But a round profile is used further up to the rod (see illustration 222), where rotation of the joint connected to the calf-holder is found. Furthermore, it is sketched how the components can serve multiple purposes, minimising the space the product uses. A combined stirrup and handle solution is presented in illustration 223. Here, the instrument tray can be attached in holes in the front of the plate when the stirrups are used, and these holes are used to turn the stirrups into a handle for transportation.



ill. 221



ill. 222

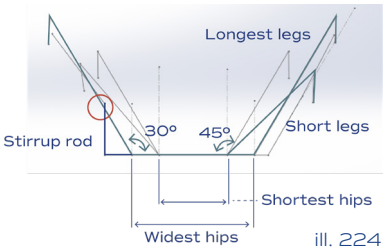


ill. 223

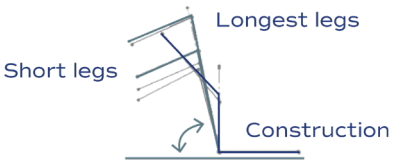
However, the double functionality idea had different problems. Firstly, the stirrups would need to be locked in place when used for the mother and need to be unlocked again for use as a handle. This would require a specific locking and unlocking mechanism and this double function complicated the construction. Secondly, it is not ideal to use the stirrups as the handle as well, since connection of the oval ends would require each stirrup to be different, which in turn makes it more difficult to make a locking mechanism when they are used as stirrups. Additionally, the construction with the horizontal part of the stirrup seems odd, since the vertical stirrup rod is placed far from the bottom plate.

4 Evaluation of angles and adjustability

Based on the concept so far, it is unclear if the concept complies with the correct position of the mother. Therefore, the different angles to the side between 30° and 45° and forward between 80° to 100° are sketched for women with the widest and most narrow hips in combination with both the shortest and longest legs, based on the anthropometric analysis.



ill. 224

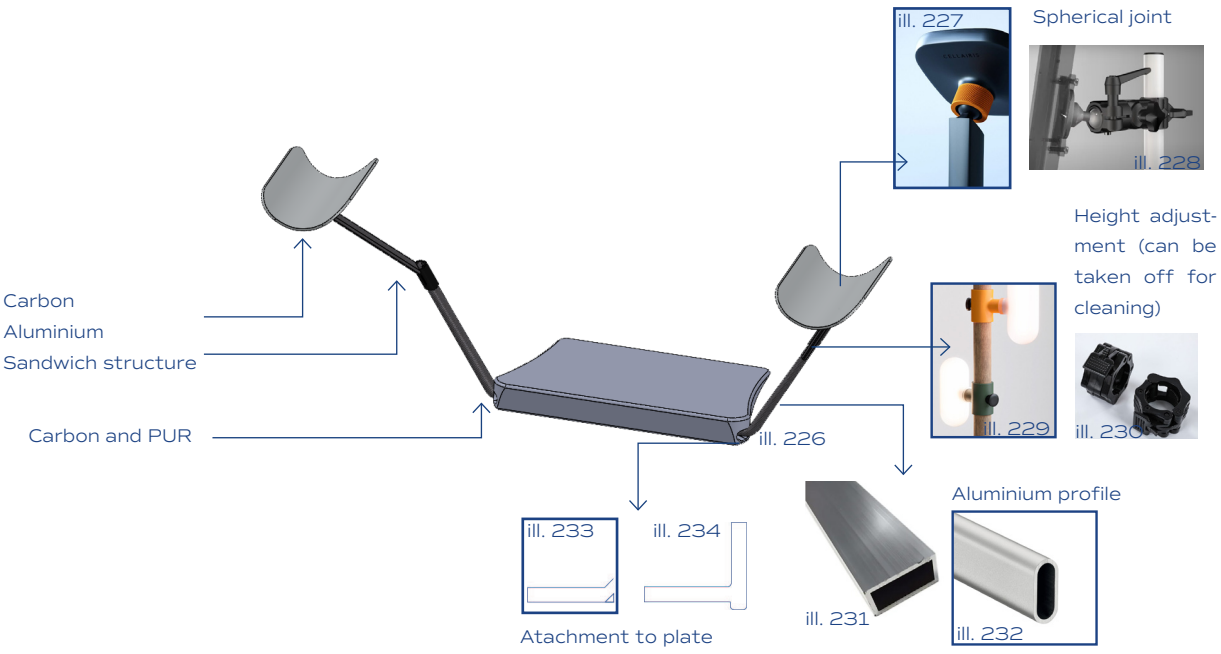


ill. 225

Here, it is found that for a woman with the widest hips, the leg will conflict with the stirrup rod even at an angle of 30° to the side, see illustration 224. Naturally, this will also be a problem at higher angles. This causes the concept to not fit all women. Therefore, it is necessary to discard this variation of the solution and take a step back to evaluate earlier concepts.
When seeing the concept from the side (see illustration 225), it is seen that the forward angle does not change when the angle to the side changes. Therefore, it is assumed that a solution where the leg is placed in the same plane as the stirrups at the sideways angle of 30°, and can be adjusted in height along the stirrup, might solve the problem with conflict between the legs and stirrups. This will result in the mother's legs to be angled sideways somewhere between 30° and 45° as desired. This is somewhat similar to variation A from earlier in this section, but with the stirrup fixed in the width at the bottom plate. Therefore, this concept is refined and used for further development.

5: Legs in the same plane as the stirrups

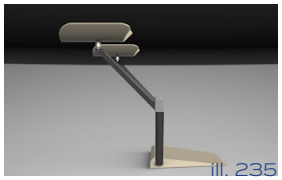
The construction of a concept with the mother's legs in the same plan as the stirrups is developed. The considerations about the details for the individual parts, materials and functions of the concept are presented in illustration 226-234.



The focus has been on making interactions that take up as little space as possible and are easy to understand. Generally, the product language is aimed towards being simple and with rounded shapes. For the calf-holder joint, the solution with a simple joint is chosen to save space and for easy interaction. PUR is added to the bottom plate and calf-holders to ensure the comfort for the mother. This material is chosen in combination with carbon for the rest for the construction to make it as lightweight as possible. Different stirrups are considered and an oval profile is chosen since the oval shape is recognisable in terms of the product language for female products and to give a softer expression of the stirrups. Lastly, regarding assembly of the product, different ways of clicking the stirrups in place in the bottom plate are considered, since we want to avoid having to attach or detach the stirrups using a button or similar on the side or bottom of the plate. The solution is to click the stirrup in place by sliding it over a small edge, which locks it in place.

6 Transportation, cleaning and price

The product is evaluated in terms of transportation, cleaning and price. In order to ease transportation of the product, it was decided to make the bottom plate shorter, since the bottom plate is no longer foldable. Additionally, the plate is made narrower towards the head to save material (see illustration 237). The concept is built in metal to evaluate the concept.

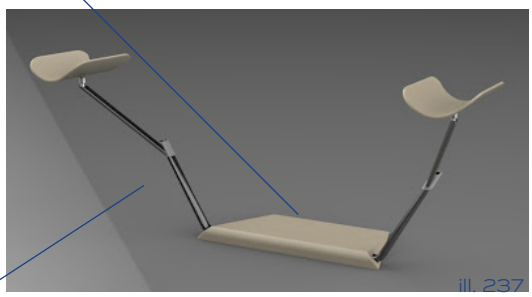

ill. 235

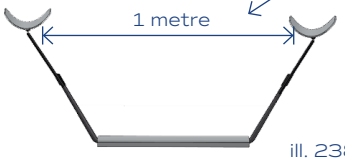
1) Shorter plate → product is tilting
When the plate is shortened, the mass midpoint of the concept changes due to the reduced mass of the plate. This causes the product to tilt towards the stirrups under its own weight.

2) Prototyping → rod sticking out
The expression of the product was not desirable for this concept, since the rest of the stirrup is sticking out if the stirrups are adjusted to a lower height (see illustration 236).


ill. 236

3) Feedback from clinical nurse
A clinical nurse from Aalborg University Hospital noted that one should be aware about holes in the concept for the intended use due to cleaning issues. She is worried about inaccessible holes that can not be cleaned properly. Also, there should be no sharp corners or edges.


ill. 237



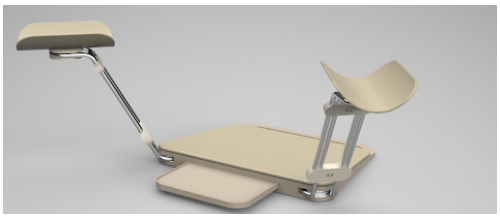
ill. 238

4) Large distance between legs
When 3D modelling the concept, it is found that for the outer position of the stirrups, there is a large distance of 1 metre between the mother's legs. It seems unrealistic to spread the legs that much.

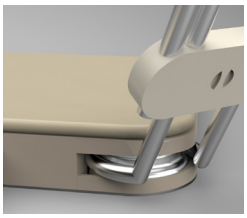
5) Production
For the production of the concept, there is doubt about how the stirrups are attached to the bottom plate and how the bottom plate is constructed in terms of the addition of PUR on the top. Also, it is found that the use of carbon for the bottom plate and stirrup rods is an expensive solution, even though the strength-to-weight ratio is high. An alternative material might be necessary to reduce the production cost.

7 Easy cleaning and rotational joint in bottom plate

A new concept is ideated and created to solve the problems of the previous concept solutions. This is done with inspiration from the construction principle of the lamp seen in illustration 240. The concept is presented in illustration 239.


ill. 239


ill. 240


ill. 241

The use of stirrups with two rods made in aluminium might solve some of the problems. Here, the rods can move in parallel past each other when height adjusting, avoiding rods sticking out from the stirrup. The calf-holder is added to the two rods on the top and rods for the stirrups are bended in the bottom for attachment in the holes of the bottom plate. This allows the stirrups to be adjusted horizontally as well. The bottom plate consists of a milled-out top part and a bottom part that can be detached, giving access to the corner-holes for better cleaning.

Feedback from milestone

- How is the interaction?
- How is the corner fastened?
- Different ways of interacting → unify them.
- In general, how are the details?
- Does it work in reality?

Feedback from clinical nurse at Aalborg University Hospital

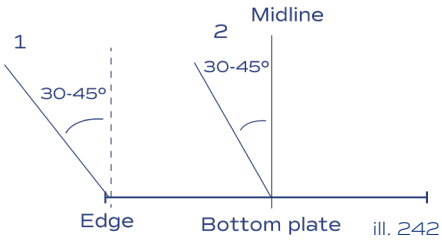
- How can the corner be cleaned properly?
- If the stirrups can be put in the dishwasher at the hospital, there is no problem cleaning them.

!

It is important to ensure proper cleaning of the product solution. Since it can not be controlled if the midwives return to the hospital after a home birth to put the product in the dishwasher, it is decided to design the product so it can be cleaned in the home by the midwife.

8 Correct angle definition

The main problem when designing the stirrups has been to obtain the correct position of the mother based on the required angles and the differences in size to accommodate different mothers. Based on the concept evaluated in terms of transportation, cleaning and price, it is found that the distance between the mother's legs is quite large, which seems unrealistic. Therefore, the definition of separation of the legs at 30°-45° from the midline from Section *1.11 Correct position of mother* is reviewed again. Here, it is found that the definition of the angles was misunderstood (see illustration 241), since the separation of the legs should be from the midline (2), where we have measured the angle from the edge of the plate (1).



ill. 242

Therefore, it is not possible to conclude whether previous concepts could have worked well due to the misunderstanding about the angles. However, the current concept is kept and simplified in construction based on the correct understanding of the angles. The stirrups are changed so they are locked in position and angled 30° angle to the side from the midline. This will cause the mothers with the widest hips to have a separation of the legs of 30° from the midline, while mothers with more narrow hips will separate their legs more, but not less than 45°.

Evaluation

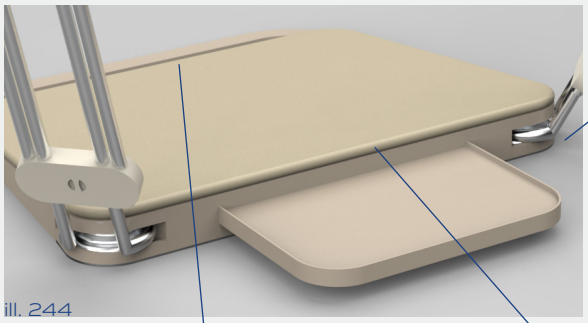
For the construction development, the main issues have been to have the mother positioned in the lithotomy position, cleaning of the product, transportation and price of the materials for construction. One of the things that has been hard to consider is that two different price ranges have been considered, a higher for the public sector, and a lower for the private sector. Here, it is chosen to move forward with designing the product focusing on the public sector, since it seems like another product solution at a lower price range would be preferable for private clinics. Furthermore, the focus has been on the stirrups design, since it is desired to make the product easy to disassemble into multiple parts to ease transportation. In this regard lightweight materials such as carbon were considered, but discarded due to a high production price. It is found that holes and crevices should be avoided if the product should be thoroughly cleaned. Lastly, it is found that the definition of the angles for separation of the mother's legs was misunderstood, which influences the construction of the stirrups.

~~[1.9a] → [2.10a] Have a maximum retail price of 5,500 DKK for private sector~~

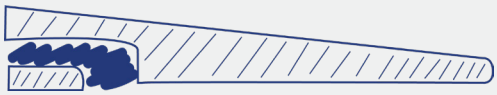
2.11 Detailing

The objective is to detail the final product proposal. This is done for the different parts of the product, including the bottom plate, stirrups and attachment of these, the instrument tray, the light source and solution for transportation.

Bottom plate and handle

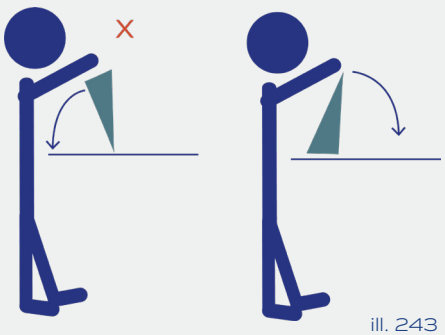


ill. 244



ill. 247

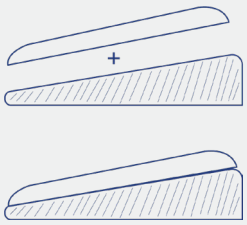
A hole in the bottom of the higher end of the bottom plate is made where the stirrups are attached to make space for proper cleaning of the holes for the stirrups. Thereby, the holes can be cleaned thoroughly without disassembling the bottom plate.



ill. 243

The handle is attached to the lower end of the bottom plate since this makes it easier to place the product on a surface and flip it down to make it ready. Also, the handle should not be in the way during suturing, since it is not used for this process.

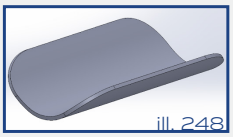
ill. 245

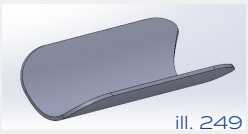


ill. 246

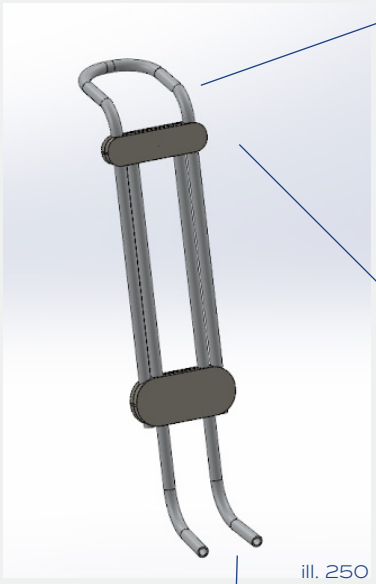
The top part of the bottom plate should be made from a soft material that is either part of the plate or could be placed on top to make the plate softer. To obtain a soft surface for the mother which lives up to all requirements for cleaning, the top part of the bottom plate is made from PUR foam (inspired by Leander Matty, see illustration 245. The foam is casted directly onto the bottom plate, since it should not be removable for simplicity. The soft surface should always be available as opposed to being an active choice for the midwife to attach.

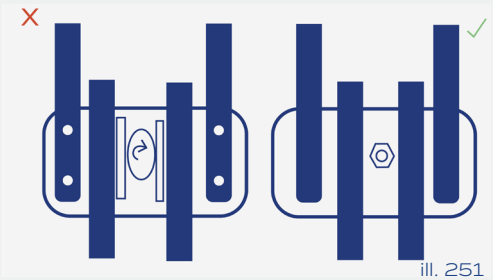
Stirrups


ill. 248


ill. 249

The general shape of the calf-holder should be similar to the one for the stirrups at the hospital to ensure proper support. Different shapes are considered, with a trade-off between proper support of the calf to the side when the leg is angled sideways and a calf-holder taking up the least amount of space to ease transportation. The smallest calf-holder is chosen (see illustration 248), since it still provides adequate support while being smaller. The calf-holder is made from metal covered in PUR foam on all surfaces for a uniform expression and a soft and comfortable feeling for the mother's legs.


ill. 250



ill. 251

A hole in the bottom of the higher end of the bottom plate is made where the stirrups are attached to make space for proper cleaning of the holes for the stirrups. Thereby, the hole For height adjustment of the stirrups, two different solutions are considered involving a plastic bracket. Either tightening of a component within the bracket locks the stirrups in place by pushing out on the metal rods or the bracket itself can be loosened and tightened around the metal rods to enable height adjustment of the stirrups. The second solution is chosen, due to its simplicity and fewer components. s can be cleaned thoroughly without disassembling the bottom plate.

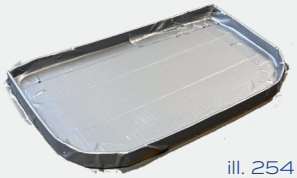

ill. 252

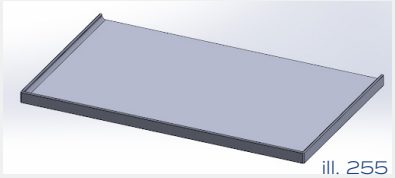

ill. 253

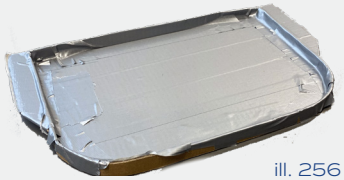
For attaching the stirrups to the bottom plate, the initial idea is based on the component in illustration 252. The component would be at the bottom part of the stirrups and a fixed metal rod inside the hole of the bottom plate is where the stirrups are clicked onto the plate. However, due to the hole in the bottom plate for cleaning, a fixed metal rod inside the hole would make it difficult to clean. Therefore, instead of clicking the stirrups in place, a solution is made where the component is cut in half and turned sideways on the stirrups. The stirrups should just be slided into the holes over the bump. This is adequate since the weight from the legs is primarily pushing down on the stirrups.

Instrument tray

Shape

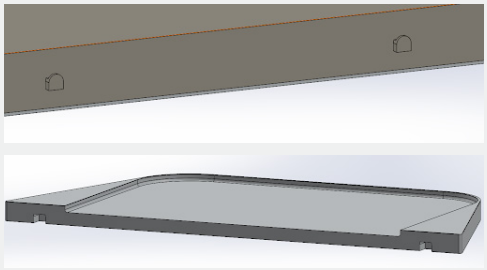

ill. 254

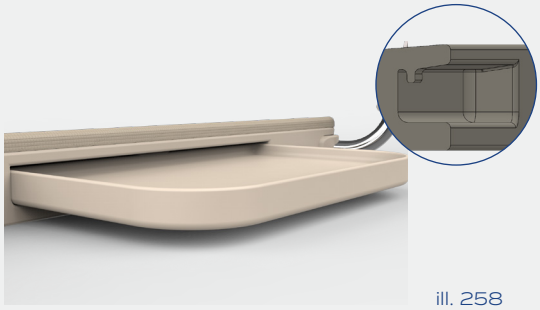

ill. 255


ill. 256

Different shapes for the instrument tray are tried out, including one with handles on the site for attachment. It is found that handles are not necessary to attach the tray, since it is easier to just hold the tray itself in the sides. The rounded tray is chosen to avoid sharp corners that are hard to clean.

Attachment


ill. 257

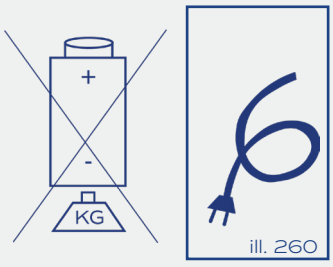

ill. 258

Two solutions for attachment of the instrument tray to the bottom plate are considered. One where the bottom plate has some knobs sticking out that the instrument tray is attached to, see illustration 257, and one where there is a hole in the bottom plate for attachment. The first solution is more simple but it is not clear if there is enough support for the instrument tray. Therefore, a hole in the bottom plate the size of the instrument tray is made and the instrument tray is attached by sliding it in at an angle and locking it in place via the edge (see illustration 258).

Light

For the light source, possible solutions are only ideated and not tested out. Since the light source should not be placed on the midwife (see Section *2.8 Test of proper light*), it is chosen to have a light source which could preferably be attached to the stirrups or secondarily some of the surrounding parts of the product solution, e.g. the instrument tray. The light source should be positioned in front of or above the head of the midwife. The light source is inspired by the simple lamp in illustration 259. The solution is a light with a cord and a flexible arm that can be clicked onto the stirrups. It is decided to place the light source in front of the midwife to avoid a long flexible arm for the light above the midwife's head, which is impractical.


ill. 259

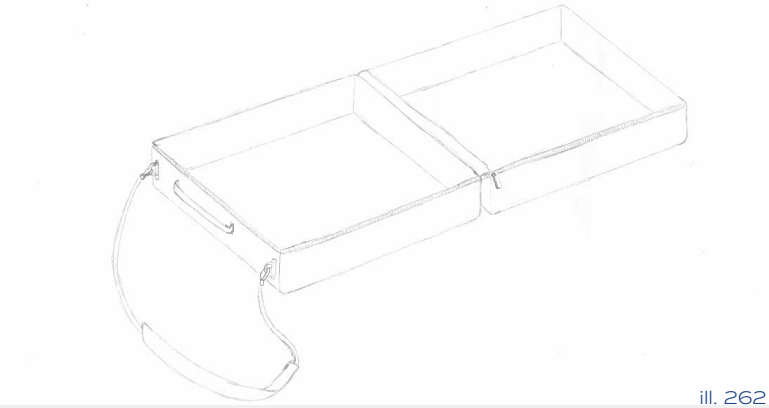


ill. 260


ill. 261

Bag for transportation

For the transportation to and from the home birth, the product solution should be disassembled and carried in a bag. This is also to ensure that the product is kept clean until it should be used for the next home birth. Design of the bag for transportation is limited only to ideation and possible solutions are not tested out. The idea is that the bag has small compartments for all parts to have their own space to be able to easily locate them. This is based on inspiration from the hospital bag which the midwives bring to home births, where all the equipment has a permanent space, so the midwife always knows where the specific instrument is. The bag should look like the sketch in illustration 262.



ill. 262

Evaluation

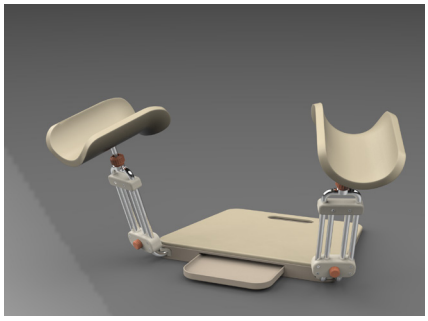
In general, various choices were made regarding details on the product solution specifications. Many of these were focused on cleaning and ease of transportation for the product, in terms of making the different spaces available for cleaning and reducing the size and weight of the solutions. The solutions need to be tested to validate, if the correct solutions are chosen or if other solutions are preferable.

2.12 Test and feedback 3.0 - midwives and mothers

The objective of this section is to obtain feedback on the expression and use of the product solution from various midwives and mothers (see Appendix 16) and test the product solution in terms of functionality and details with midwife Dorte Sloth Svendsen from Aalborg University Hospital (see Appendix 17).

Online feedback

A model of the detailed concept solution is made (see illustration 263) and presented through online interviews to some of the mothers and midwives who were previously interviewed. Feedback on the model is therefore based on them seeing the product online, and on the explanation of the model functions, without the mothers or midwives actually testing out the functions.
Some of the main points of feedback from the mothers were:



ill. 263

ill. 264

If the product was presented beforehand (e.g. at a home birth café), it would not be a problem that the midwife used it at a home birth. It would be part of the package for a home birth.

ill. 265

An advantage is seen in the fact that the risk of being transferred to the hospital due to non-optimal conditions for suturing can be reduced by using the product.

ill. 266

The product solution does not appear sterile or clinical, which is something that can break the illusion of a home birth.

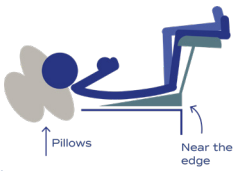
"I am impressed. You have converted a critic."

One of the mothers, who was initially sceptical about having a large instrument for home birth, expressed that she could easily see the product being used at a home birth.

Generally, the mothers think that the product solution looks welcoming and warm, and that it looks familiar in terms of equipment that is recognisable for gynaecological examinations.

The main points of feedback from midwives from both Denmark, the United Kingdom, South Africa and Canada were:

Optimal position



ill. 267

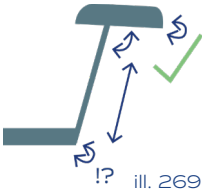
The product solution seems perfect for suturing as long as pillows or similar are placed to support the mother's bag. It looks like the mother is lying comfortably and in the correct position, but it is important that the product is placed close to the edge of the surface it is placed on to make space for suturing.

Instrument tray

ill. 268

Is there a risk that the midwife might lean on the instrument tray, which would compromise the sterility of the sterile sheet? Maybe just place the instruments on the thighs instead.

Adjustability



ill. 269

Great that the stirrups can be adjusted both in height and at the joint for the calf-holder. But one of the midwives expresses concern about the fixed angle of the stirrups in terms of adjustability.

Cleaning

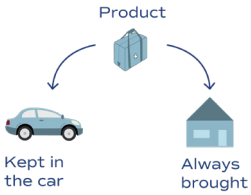
ill. 270

ill. 271

If you just have some alcohol-wipes it would be easy to clean it at the home. None of the midwives express any issues with cleaning, and they would only wipe off the surfaces of the bottom plate and the calf-holders unless visible blood got on the product, where a more thorough cleaning is needed.

ill. 272

Light is nice to have, but is not the highest priority. Placement of the light source in front of the midwife is good, but the midwife needs to adjust her routine to this placement.



ill. 273

Some of the midwives would just keep the product in the car and bring it in if it should be used. Others would bring it inside the home right away.

ill. 274

The midwives think that a weight of 5 kg, which is the current weight of the solution, is fine and could realistically be brought along with the rest of the equipment.

ill. 275

Generally, it is a new way of working for the midwives when using the product. They will have to adjust their routine for suturing.

One of the midwives expresses that it looks really professional and well suited for the job. The large potential for the solution to be used in LDC countries is mentioned again. Generally, the midwives are positive about the product solution and could see themself using the product for suturing after a bit of adjustment to the new workflow.

Test with midwife

A model of the product solution is tested with midwife Dorte in a bed, on a couch and on a table. Generally, the model worked as intended and Dorte was very pleased with the interaction. Of course, there were also things that could be improved. The main feedback on the test is summarised here:

ill. 276

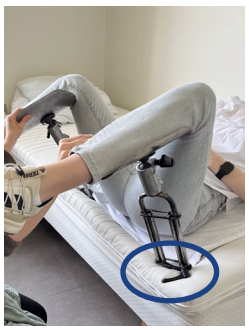
The midwife sits in the best position at a table.

ill. 277

The backside of the calf-holder pushes against the back of the knee.

ill. 278

Works way better than expected on the couch (tested on a couch with a depth of only 50 cm).



ill. 279

The interaction for the height adjustment for the stirrups should be on the upper bracket, since the lower bracket is hard to access on a soft surface.


ill. 280

It works well to have the instrument tray for the suturing instruments. If the midwife should be placed ideally, she has to be so close to the mother that the midwife's legs are separated. Therefore, the instruments can not be placed on the thighs.

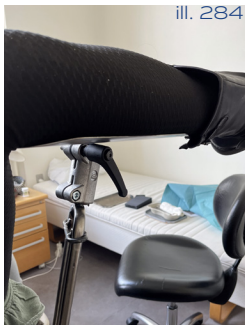

ill. 281

More support is needed for the calf-holder to the sides.


ill. 282

ill. 283

Instrument trays of 28x18 cm and 25x15 cm were tested. The smallest is ideal, since there is little risk of the arms touching the sterile sheet for this size.


ill. 284

The lowest height of the stirrups was tested for a person of 178 cm and one of 168 cm and fitted both. However, the lowest setting of the stirrups would be too high for shorter people. When the calf-holder can be tilted forward, less height is needed. So the lowest height of the stirrups has to be lower.

Feedback from Vice head of midwives

Vice head of midwives Line also joined the test and expressed that it would be a big plus for the hospital or private midwives to brand themselves as a place that can deliver quality suturing at home births if they have the product. Thereby, mothers wanting a home birth might choose a midwife who has this product over others. She says that the current product solution could be sold for up to 50,000 DKK, but if it was about 30,000 DKK it would be easier to get funding. Furthermore, she says that it would be possible to expand the use of the product for other tasks than suturing at home births. For example, it could be sold as a portable gynaecological bed for maternity clinics, "rolling" medical clinics or relief organisations like AmiAmi, who help victims of human trafficking.

Evaluation

The feedback from midwives and mothers is generally positive and a large potential is seen for the product solution. The mothers seem fine with the idea of using the product for home births, since it is also in their best interest to be sutured properly and the product solution does not associate with general hospital equipment. Additionally, the midwives are positive about the design and professional expression of the solution and express that it looks comfortable for the mother to be placed in the correct position. Further, the midwives think that the product solution could easily be cleaned in the home. However, they express some concerns as well in terms of possible leaning on the instrument tray and the fixed angle of the stirrups in terms of adjustability. But if the product was implemented as part of their routine for suturing, it could be a valuable tool. From the test with midwife Dorte Sloth Svendsen, identified some issues that could be improved in terms of height adjustability and the calf-holder. However, the feedback was generally very good and Dorte sees a large potential in the product.

[1.2a] → [2.12a] Be lightweight (≤ 5 kg)
[1.8b] → [2.12b] Can have a retail price of up to 50,000 DKK

2.13 Updated requirements

Positioning of mother and midwife

Section	Requirements	Specifications
[1.2c] → [2.6a]	The plate should fit 95% of all mothers	> H4 x L34 x W45 cm
[1.2c] → [2.6b]	The stirrups should be adjustable in height to fit 95% of all mothers	> 13 cm
[1.2c] → [2.6c]	The calf-holder should fit 95% of all mothers	L25 x D18 cm
[1.2c] → [2.7a]	The product can hold the weight of 95% of all mothers	≤ 118 kg
[1.3a] + [1.3c] → [1.11a]	Mother's legs should be supported in the lithotomy position	The knees are bent 70-90°
		The thighs are angled 80-100°
		The legs are separated 30-45° from the midline
[1.3b]	Mother's buttocks should be placed on a rigid surface	
[1.3d]	Mother's knees should be pointing outwards	
~~[1.3e] → [1.12a]~~	~~The midwife's ergonomic position fulfils the recommendations~~	
[1.3f] → [1.12b]	Mother placed in proper height for suturing	61-76 cm from the ground when midwife is sitting down
[1.3g]	Mother's tailbone should be placed at the edge of the surface	
[1.5a]	Mother's legs should be fixed in the supported position to keep them spread	
[1.6a] → [2.9a]	The product should not resemble the hospital	Dominant colour should be light and warm and shapes should be rounded
[1.6b]	The procedure should be able to take place in different places in the home	Bed, couch, dining table etc
[1.11b]	The buttocks should be tilted	13 +/- 6°
[2.5a]	The surfaces that interact with the mother's skin should be soft	

Cleaning

Section	Requirements	Specifications
[1.2b] → [1.10b] → [1.15a]	Can be cleaned and disinfected in the home	Chemically, using alcohol wipes
[1.2b] → [1.10b] → [1.15b]	Can be cleaned and disinfected at the hospital	Mechanically, 80°C for 10 min

Transportation

Section	Requirements	Specifications
[1.2a] → [2.12a]	Be lightweight	≤ 5 kg
[1.10a] → [2.5b]	Easy to assemble	Within 5 min
[1.10c]	Can be easily transported from a car to the home	

Place for instruments

Section	Requirements	Specifications
[1.3i] → [1.14a]	Space for suturing kit behind the mother's buttocks	Min. 20 x 15 cm

Light for suturing

Section	Requirements	Specifications
[1.3h] → [1.13a] → [2.8b]	Proper light for suturing	CRI value > 90 Ra, colour temperature of 4,500° K +/- 300° K, at least 15,000 lx and illuminated area of ≥18 cm
[2.6d] → [2.8a]	Light should be placed in front of or above the midwife	

Price and certifications

Section	Requirements	Specifications
[1.8a]	Should have a CE-certification	
[1.8b] → [2.12b]	Can have a retail price of up to 50,000 DKK	
~~[1.9a] → [2.10a]~~	~~Have a maximum retail price of 5,500 DKK for private sector~~	

03 - Product

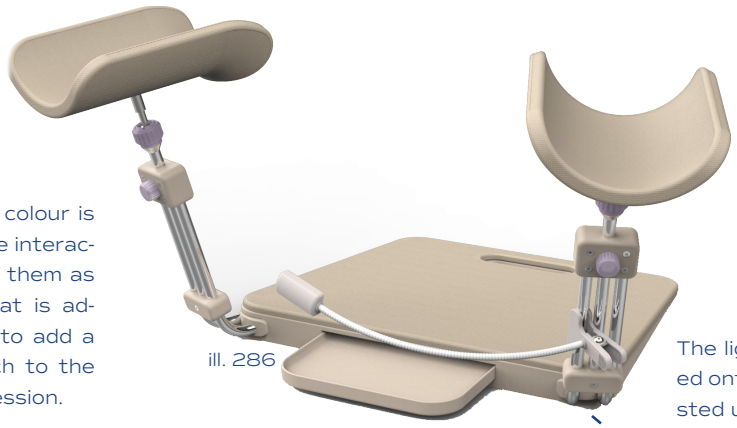
In this chapter, the final product proposal is described. This includes details regarding the materials for the different parts of the product based on strength calculation, estimated production cost and methods and strategies for getting the product on the market, including estimated budget and business plan.

3.1 Portable gynaecological stirrups

After the final test of the product solution, the construction was developed further in terms of the stirrup solution. The final product proposal is presented in illustration 286.

The dominant colour for the product is in a beige nuance to obtain a warm and welcoming expression but with a neutral colour that fits in the home environment and is neither strictly feminine nor similar to hospital equipment.

The stirrups are designed with an open structure with one rod in the middle and two rods in the bottom. This is to give more strength at the base of the stirrup and to allow for easy cleaning. The height adjustment of the stirrups is moved to the top bracket for easy interaction.



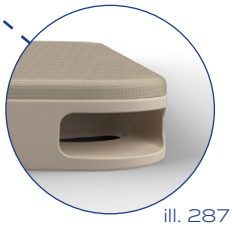
ill. 286

A pale purple colour is chosen for the interactions to mark them as something that is adjustable, and to add a feminine touch to the product expression.

The light source can be clicked onto the stirrups and adjusted using a flexible arm.

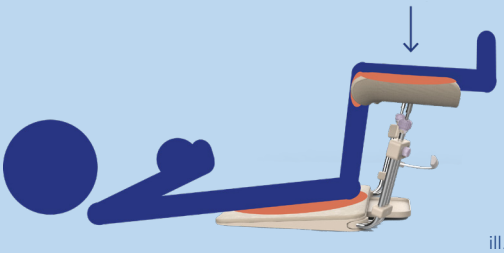
The mother's tailbone can be placed at the edge of the bottom plate while the instrument tray is readily available in front of the genitals.

The stirrups are attached by clicking them into the holes in the bottom plate.



ill. 287

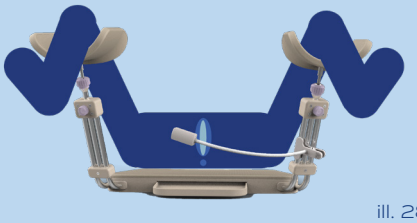
Sideview



ill. 288

The mother's thighs are angled approximately 90°, depending on the height adjustment. The calf-holder can be adjusted using the ball joint for finer adjustment and to bend the knees into 70-90°. The calf-holder and top of the bottom plate are covered by PUR foam for a soft interaction.

Front view



ill. 289

The stirrups can be height adjusted from the lowest position of 34 cm vertically from the bottom plate to 50 cm to accommodate different mothers. This ensures that the mothers leg's are separated 30-45° from the midline, depending on the height adjustment.

3.2 Use at home

Assembly

It was found that it should be easy to assemble the product solution in only a few steps. Therefore, the product can be quickly assembled in three steps, see illustration 290.

1.

First, the bottom plate is placed on a surface.

2.

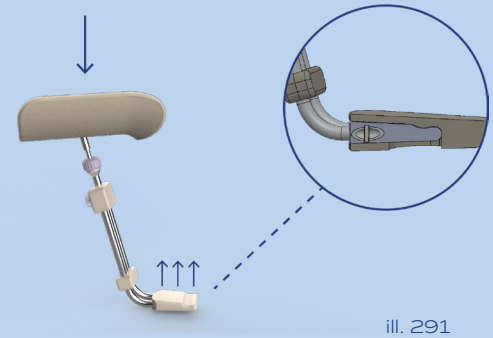
The stirrups are clicked in place.

3.

If suturing is needed after assessment, the instrument tray and light is attached.

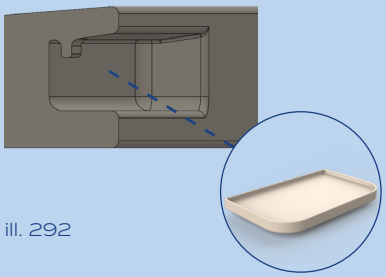
ill. 290

The stirrups are clicked in place in the holes in the bottom plate using an assembly bracket which has a dent. The stirrups are kept in place when weight is applied on them, making the dent on the bracket lock it in place in the hole in the bottom plate.



ill. 291

The instrument tray is attached in the hole in the bottom plate by sliding it in at an angle and locking it in place via an edge in the top of the hole and support for the lower part of the tray inside the hole.



ill. 292

Preferably, the product should be assembled by the midwife in the waiting time during delivery of the baby or by the mother's partner. It is recommended to assemble the product before delivery so the product is ready for both assessment and suturing when needed. This also increases the quality of assessment of possible tears.

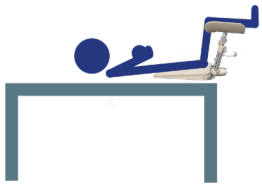
Placement

The product is designed for use on both hard and soft surfaces. It is recommended to place the product so the midwife can sit on a chair or stool to obtain a working height of 61-76 cm to ensure the most optimal ergonomic position in the home.

The product is expected to typically be used in one of three places; the bed, the couch or the dining table. For each of these, there are certain things to be aware of when using the product.

The depth of the couch should be at least 50 cm so the product can be adequately supported.

If the bed is very soft, the product should be placed 1-2 hand-widths from the edge of the bed to avoid tilting.

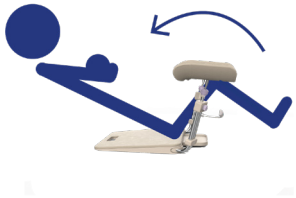


If the dining table is used for the product, it should be examined if the dining table can hold the weight of the product and mother.

ill. 293

For installing the mother correctly in the product, it is recommended that the mother sits on the edge of the bottom plate. Then she leans backwards to lay down on the back, so the tailbone is at the very edge of the bottom plate, and the legs are installed in the stirrups, see illustration 294. The mother's back should be supported by pillows, blankets or similar like they normally do at a home birth, so she is lying comfortably when breastfeeding the baby while being sutured.

The mother sits in the edge of the bottom plate.



She leans backwards

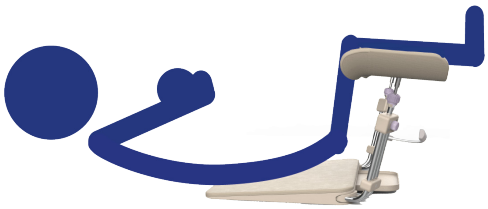
She lays down with the tailbone is at the very egde of the bottom plate

ill. 294

3.3 Strength of stirrups

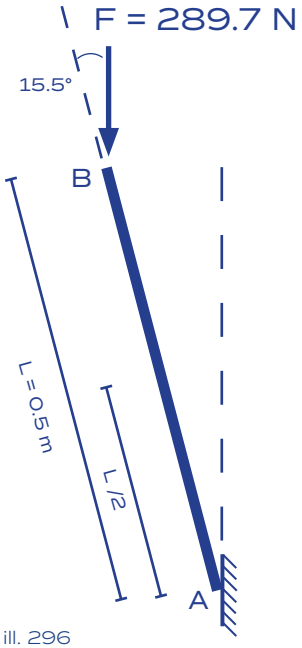
A static analysis of the construction is made to calculate the stresses that the stirrups are subjected to and the maximum deformation of the stirrups under the maximum loads expected. This is used to decide the dimensions and materials for the stirrups.

The maximum load found for the mother laying still in the stirrups is 19 kg for each stirrup (*see Section 2.7 Weight considerations*), for a woman in the 95th percentile of the tallest women with the highest BMI allowed for home birth (118 kg) identified by the anthropometric analysis (see Section *2.6 Anthropometric analysis*). However, in the final test of the product proposal, it was found that more weight might be applied to the stirrups, when the mother is lifting up her buttocks by supporting the legs on the stirrups, so the midwife can place the sterile sheet below her (see illustration 295).



ill. 295

Here, it is estimated that half of her body weight (the lower body) is supported by the stirrups, which is halved since the force is divided on the two stirrups. Therefore, for the heaviest woman, this results in 59 kg for the lower body and 29.5 kg for each stirrup. This results in a force of F = 289.7 N. This is a rather extreme case with a large load due to the mothers high body weight over a short time, but is used to calculate the stresses and deformations to take into account the worst case scenario. All calculations for the normal case and the case of the mother lifting her buttocks are presented in Appendix 18.



ill. 296

The force applied acts on the stirrup as presented in illustration 296. The full length of the stirrups at the highest position is L = 0.5 m. The stirrup is simplified as a beam which is not bent into the hole of the bottom plate. Instead, it is calculated as a cantilever beam fastened at the bottom plate. It is assumed that the single beam in the middle is connected to the two outer beams using a bracket that can sustain the load and that the middle and outer beams are in sequence. The length of the middle beam alone is 0.25 m which is the same for the two outer beams (see illustration 297).

ill. 297

Based on the forces acting on the stirrup, a free body diagram for the stirrup is set up and the coordinate system is arranged based on the stirrup. From the free body diagram, the reaction forces for the stirrup can be determined using the equilibrium equations (see illustration 298).

ill. 298

The sum of the forces in the x-direction:

$$\Sigma F_x \overset{\rightarrow +}{} = 0 : -R_{ax} + F \cdot \cos(\theta) = 0 \leftrightarrow R_{ax} = F \cdot \cos(\theta)$$

$$R_{ax} = 279.2\ N$$

The sum of the forces in the y-direction:

$$\Sigma F_y \overset{\uparrow +}{} = 0 : R_{ay} - F \cdot \sin(\theta) = 0 \leftrightarrow R_{ay} = F \cdot \sin(\theta)$$

$$R_{ay} = 77.4\ N$$

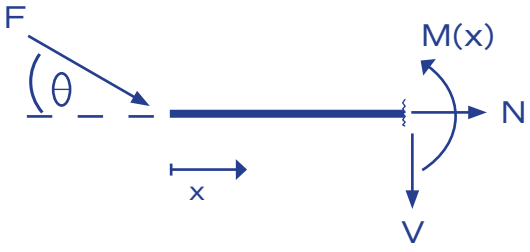
The sum of the moments around point A:

$$\Sigma M_A \overset{\curvearrowright +}{} = 0 : M_a - F \cdot \sin(\theta) \cdot L = 0 \leftrightarrow M_a = F \cdot \sin(\theta) \cdot L$$

$$M_A \overset{\curvearrowright +}{} = 38.7\ Nm$$

Internal forces and moment

The internal forces are determined based on the free body diagram presented in illustration 299 and equilibrium equations.



ill. 299

The sum of the internal forces in the x-direction:

$$\Sigma F_x \overset{\rightarrow +}{} = 0 : F \cdot \cos(\theta) + N = 0 \leftrightarrow N = -F \cdot \cos(\theta)$$

$$N = -279.2\ N$$

The sum of the internal forces in the y-direction:

$$\sum F_y \overset{\uparrow +}{} = 0 : -F \cdot \sin(\theta) - V = 0 \Leftrightarrow V = -F \cdot \sin(\theta)$$

$$V = -77.4 \text{ N}$$

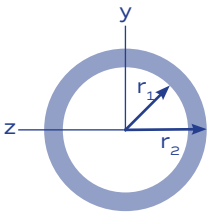
The sum of the moments at the cut:

$$\sum M_x \overset{\curvearrowright +}{} = 0 : -M(x) - F \cdot \sin(\theta) \cdot x = 0 \Leftrightarrow M(x) = -F \cdot \sin(\theta) \cdot x$$

$$M_x \overset{\curvearrowright +}{} = -38.7 \text{ Nm} \cdot x$$

Stresses in the stirrups

The stresses in the middle beam and the outer beams are calculated separately. For the middle beam, the stresses are calculated for its length (x = 0.25 m) and the total force acting on the end of the beam. For the two outer beams, the stresses are calculated for the full length of the stirrup (x = 0.5 m), but the force applied is divided by two, since it is assumed to be symmetrically distributed for the two beams. All beams have the same hollow circular cross section and corresponding radii (see illustration 300) (Gere and Goodno, 2013).



$r_1 = 5.5$ mm

$r_2 = 7.5$ mm

ill. 300

The standard equations for this cross section are used to calculate the shear stress, normal stress and bending moments (see table 3). These are used to calculate the von Mises stress that the stirrups are subjected to.

Parameter	Value
Moment of inertia (I)	1.77×10^{-9} m^4
Statical moment of area (Q)	1.70×10^{-7} m^3
Width (b)	4 mm
Shear force (V)	-77.4 N
Maximum shear stress $\left(\tau_{max} = \frac{V \cdot Q}{I \cdot b}\right)$	-1.87 MPa
Normal force (N)	-279.2 N
Cross section (A)	$8.2 \cdot 10^{-5}$ m^2
Normal stress $\left(\sigma_N = \frac{N}{A}\right)$	-3.4 MPa
Distance to neutral axis (y)	7.5 mm
Moment (M)	x = 0.25 m: -19.4 Nm x = 0.5 m: -38.7 Nm
Bending moment $\left(\sigma_M = \frac{M \cdot y}{I}\right)$	x = 0.25 m: -82.2 MPa x = 0.5 m: -82.2 MPa
$\sigma_x = \sigma_N + \sigma_M$	x = 0.25 m: -85.6 MPa x = 0.5 m: -85.6 MPa
von Mises stress $(\sigma^1 = \sqrt{\sigma_x^2 + 3 \cdot \tau_{xy}^2})$	x = 0.25 m: -85.7 MPa x = 0.5 m: -85.7 MPa

Table 3

It is seen that the von Mises stress is equal for the middle beam and outer beams due to the halved force but doubled distance from the applied force for the outer beams. Furthermore, it is seen that the normal stress and shear stress are quite small compared to the bending moment, which is the dominant force contributing to the total von Mises stress. In this scenario, the material chosen for the stirrups should have a yield stress higher than 85.7 MPa to avoid plastic deformation when in use. Therefore, aluminium (series 6000) is considered for the stirrup rods to have a material of a lower price and adequate strength as well as a lower weight compared to steel.

Deflection

The deflection of the stirrups is calculated using the superposition principle (Gere and Goodno, 2013). This is done by calculating the deflection and angle of rotation of the outer beams and adding this to the deflection of the middle beam to obtain the total deflection (see illustration 301).

Here, the calculation is based on the same case again with a weight on each stirrup of 29.5 kg and a resulting force of 289.7 N. The material used for the stirrups is aluminium with an elastic modulus of E = 69 GPa.

First, the deflection due to bending of the part BC of the beam is calculated using the standard case of a cantilever beam:

$$\delta_1 = \frac{F \cdot L^3}{3 \cdot E \cdot I}$$

Here, the length of the beam is L = 0.25 m and F is the shear force (V).

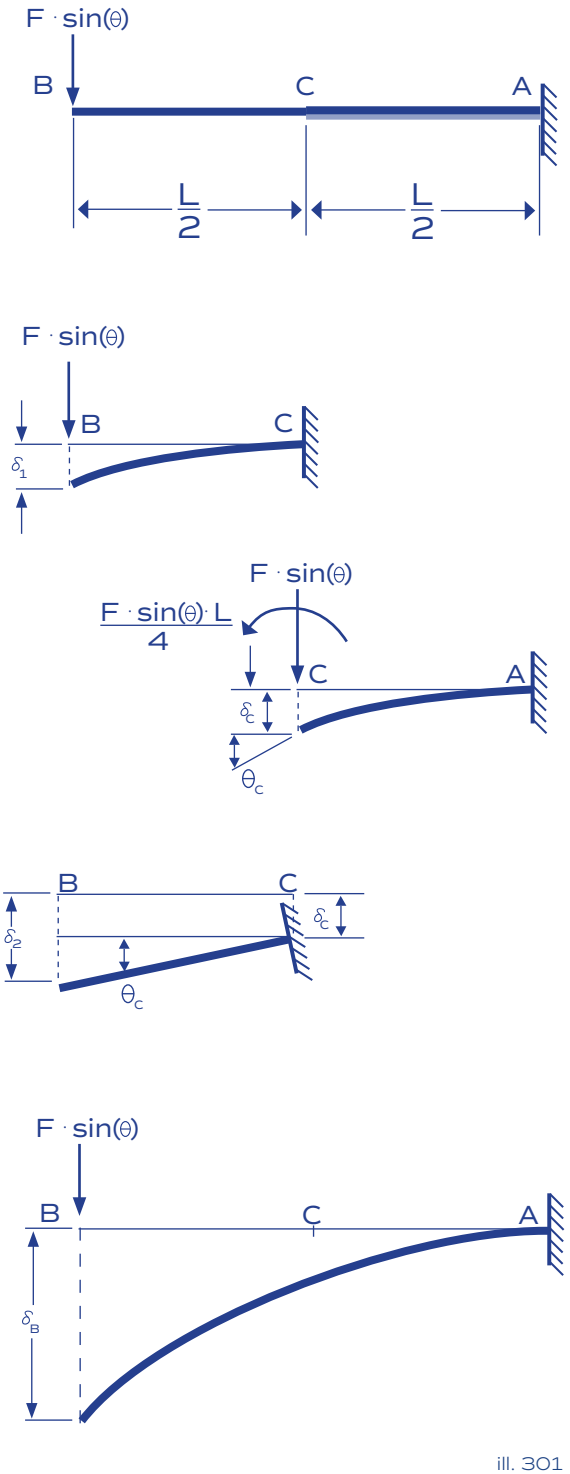
The deflection in point C due to bending of the part CA and angle of rotation in point C, which also contributes to the deflection at point B, are calculated using the standard cases for these for a cantilever beam in terms of a point load and bending moment added together:

$$\delta_C = \frac{F \cdot L^3}{3 \cdot E \cdot I} + \frac{M_o \cdot L^2}{2 \cdot E \cdot I}$$

$$\delta_C = \frac{F \cdot L^2}{2 \cdot E \cdot I} + \frac{M_o \cdot L}{E \cdot I}$$

Here, the length of the beams are L = 0.25 m, since this is the length of the section CA for which the deflection and angle of rotation in point C is calculated. The forces are halved compared to section BC since there are two beams. The results in a moment of:

$$M_o = \frac{F \cdot L}{4}$$



ill. 301

The resulting displacements produce an overall downward displacement of the end B which is equal to:

$$\delta_2 = \delta_c + \theta_c \cdot L$$

where L is again 0.25 m.

The total deflection in point B is calculated as the sum of the deflections δ_1 and δ_2:

$$\delta_B = \delta_1 + \delta_2$$

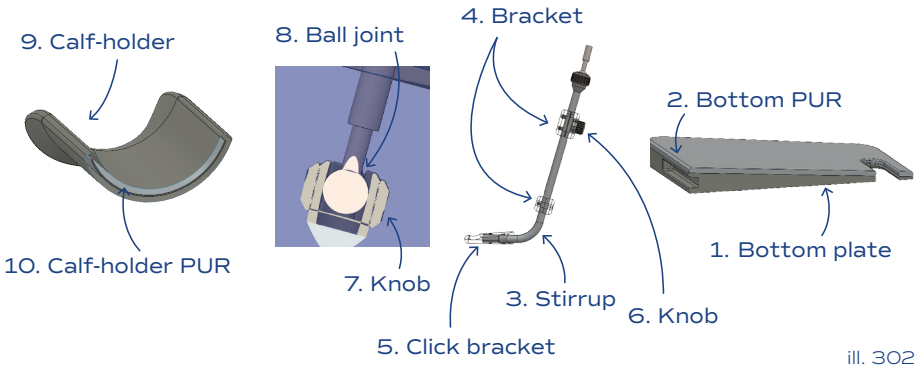
It is seen that for a mother of 118 kg, the deflection is only 1.49 cm, which is acceptable for the intended use. For the material chosen for the stirrups, a safety factor of 1.2 should be divided by the yield stress to take into account variations in the materials. However, the safety factor is not large, since failure of the product is non-critical and a very high weight of the mother, which is higher than expected in nearly all cases, has been considered.

Parameter	Value
δ_1	-0.33 cm
δ_c	-0.41 cm
θ_c	-0.030°
δ_2	-1.16 cm
δ_B	-1.49 cm

Table 4

3.4 Manufacturing

The product consists of five main types of components, which are presented in illustration 302. The choice of materials for the different components is based on considerations in terms of weight, strength, production cost and cleaning of the components.



ill. 302

Construction with high strength and low weight

For the stirrups (3), the primary materials that have been considered are aluminium and carbon (see Section *2.10 Construction development*). Carbon provides the highest strength and lowest weight which is desirable. However, due to the shapes of the stirrups, a special mold for production would need to be bought. After talking to a manufacturer, it was estimated that such a mold could cost up to 400,000 DKK. Therefore, carbon is an expensive solution due to the low number of units to be produced.

Instead, an aluminium alloy is chosen for the stirrup construction (3), the calf-holder (9) and the ball joints (8) due to the strength and low weight compared to other metals. Additionally, no mold is needed for constructing the stirrups in aluminium, since it can be bent into the shape needed for the stirrups using a suitable tube bending die. The type of aluminium alloy for the stirrups is chosen based on the yield strength, which should be higher than 86 MPa when applying a safety factor of 1.2. The aluminium alloy 6061 is chosen, since it has a yield strength of 240 MPa (Anderson, Weritz and Kaufman, 2019) (200 MPa taking the safety factor into account). The 6000-series of aluminium alloys is very versatile and often used in the medical wor-

ld (Clinton Aluminum, 2020). Further, the chosen alloy has good weldability (Anderson, Weritz and Kaufman, 2019), which is needed since the ball joint needs to be welded onto the top of the stirrup for attachment of the calf-holder. The ball joints are constructed by die casting, while the calf-holder is made by compression molding.

Bottom plate, brackets and knobs

For the bottom plate (1), brackets (4,5) and knobs (6,7) for adjustment, the focus has been that the interaction with the product should not be cold like metal. Therefore, different kinds of construction plastics are considered. Here, the important parameters have been the strength and for the plastic to live up the requirements for cleaning, including chemical resistance. Additionally, since the bottom plate is the largest part of the construction, it is important to use a plastic that can be coloured to obtain the desired expression.

Nylon 6 is chosen due to its low density and other desirable properties for the intended use. Some of the relevant properties for nylon are presented in table 5 (Induflex, n.d.):

Compared to other plastics considered, nylon can withstand temperatures high enough for cleaning in a dishwasher at the hospital at 80-90°C if necessary (see Section *1.15 Medical devices*). Furthermore, the chemical resistance allows for cleaning with alcohol wipes and the wear resistance and high stiffness is desirable for repeated use. For critical load-carrying structures like the brackets, fiber-reinforced nylon could be used to obtain higher ultimate strength of these parts.

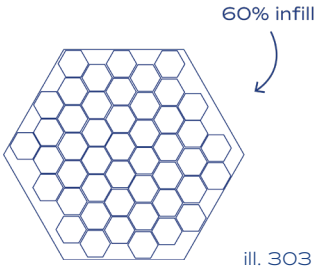
Maximum temperature	100°C
Moisture absorption	High
Friction	Very low
Chemical resistance	Good
Stiffness	Stiff
Colourable	Yes
Wear resistance	Fine

Table 5

Production and surface finish

Due to the low number of units needed to be produced initially, the bottom plate and the brackets are produced by SLS 3D-printing to obtain the desired shapes. This type of additive manufacturing also allows for reduced weight and material cost, since an estimated infill of 60% with a honeycomb infill pattern, see illustration 303, is adequate to obtain the strength needed (3DPROS, 2021) (Clevercreations, 2023). If a higher number of units were to be produced, injection molding could be a faster and cheaper production method, but this method requires expensive molds not justified by a low number of units.

Since nylon has a high, but reversible, moisture absorption capability, it would be advantageous to provide a surface coating on the bottom plate. Here, a vaporisation process called 3S specifically developed for nylon could be used to treat the surface. This produces a chemical alteration of the surface to obtain a water resistance and an extra smooth surface which is easy to clean. (Teknologisk Institut, n.d.b)



ill. 303

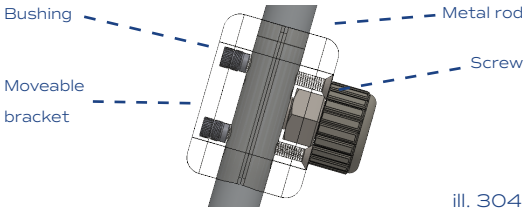
A soft surface for the mother

For the top of the bottom plate (2) and outside the calf-holder (10), where the mother's skin interacts with the product, a soft and comfortable surface is desired. Therefore, cushioning in terms of flexible integral PUR foam is chosen. This is because integral PUR allows for a porous foam in the middle with a pore-free surface which is strong and physically, chemically as well as water resistant (Plastindustrien, n.d.).

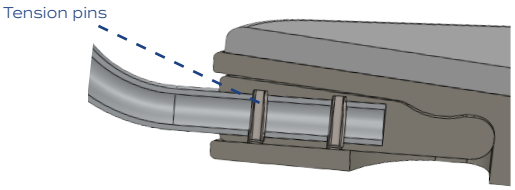
For production of the PUR foam, an aluminium mold is made for casting the foam for both the bottom plate and the calf-holder. Therefore, both calf-holders are identical so a single mold can be used. (Tinby, 2017)

Assembly of stirrup

The stirrup construction is the only one that consists of multiple components. The stirrups are assembled by using the brackets (4,5). Here, the movable brackets (4) are fastened to the metal rods of the stirrup using brass bushings which are heated into the plastic, see illustration 304. A screw is used to tighten the bracket. In the bottom bracket (5), the metal rods for the stirrups are fastened using spring tension pins and closed off using silicone, see illustration 305.



ill. 304



ill. 305

Cost price

Based on the chosen materials and production methods, a rough estimate of the cost price of 1, 25 and 100 units of the product is made. The estimated cost price does not include investments such as molds (see Section *3.7 Budget*) and an estimate for the price of the instrument plate and light is also included even though these are not described in detail in terms of manufacturing. The estimated cost price is presented in table 6:

Items	**No.**	**Cost price (DKK)**			**% of total**
		1 unit	25 units	100 units	1 unit
Bottom plate	1	750	450	360	12
PUR bottom plate	1	225	135	108	4
Bottom Al rods	4	1,740	560	528	29
Spring tension pins	8	6.4	4.8	3.8	0
Top Al rods	2	300	180	144	5
Calf-holder	2	150	120	96	2
Calf-holder PUR	2	450	270	216	7
Click bracket	2	290	174	139	5
Lower bracket front	2	250	150	120	4
Lower bracket back	2	250	150	120	4
Screw, lower bracket	2	1.6	1.0	0.8	0
Bushing, lower bracket	2	3.0	2.5	2.0	0
Height adj. bracket front	2	250	150	120	4
Height adj. bracket back	2	250	150	120	4
Screw, height adj. bracket	8	6.4	3.8	3.0	0
Bushing, height adj. bracket	8	96	56	45	2
Knob (height adj.)	2	90	54	32	1
Ball joint	2	350	210	168	6
Instrument tray	1	145	87	70	2
Light (complete)	1	149	100	80	2
Labour	0.5 (h)	225	225	180	4
Packaging	1	35	27	22	1
Miscellaneous	1	50	50	40	1
Total cost price		6,062.4	3,310.1	2,728.1	

Table 6

It is seen that the aluminium rods constitute a total of 34% of the production cost. Furthermore, the brackets add up to 21% of the cost price. Therefore, it could be beneficial to examine solutions which could reduce the material costs for these components of the design. Further, half an hour of manual labour is used to assemble the product. It could also be beneficial to reduce the number of components to be assembled in order to reduce the assembling time of the product.

3.5 A new medical product

The portable gynaecological stirrups is a Class I medical product based on the information from Section *1.15 Medical devices*. Therefore, the product needs to go through a procedure of risk assessment and clinical evaluation intended for medical products before it can go on the market. A brief overview of this procedure is presented in illustration 306 (Danish Medicines Agency, 2023).

From idea to deployment

ill. 306

1) If an idea for a new medical product has been raised and can be realised, a prototype of the product is made, typically in collaboration with a medical company. For this project, the current state is the ideation phase, where different mock-ups have been initially tested. The next step would be making a prototype of the product for the testing phase. (Danish Medicines Agency, 2022)

2) In the test phase, the product needs to go through clinical user tests of its functions and safety (risk assessment). Since there are no directly comparable products on the market with associated data and documentation, the clinical evaluation of the product has to rely on the results of clinical tests. The tests need to include the strength of the product and tests in different use scenarios to identify potential risks when using the product, e.g. crushing hazards when changing the height of the stirrups or tilting if the product is placed on a soft surface. Data from these tests needs to be evaluated to ensure that the safety and performance of the product is as prescribed and to document that the advantages of using the product outweighs the potential risks. (Danish Medicines Agency, 2022)

When the clinical evaluation has been performed on the product and a declaration of conformity has been signed, the product can be CE approved and is allowed for marketing. The product needs to undergo post market clinical follow up (PMCF) where errors and incidents reported from users or distributors need to be evaluated. Here, it should be examined if the use manual of the product should be updated, if changes to the product should be made or if the product should be withdrawn in the worst case. (Danish Medicines Agency, 2022)

3.6 Business plan

A business plan is made if one were to make a start-up selling the product. The business plan is made for the current state, where the product has to go through clinical evaluation and certification and subsequently needs to be launched. Until now, the design of the product has focused mainly on suturing at home birth. However, as presented in Section *2.12 Test and feedback 3.0 - midwives and mothers*, transportable gynaecological stirrups could be used for other customer segments and is not limited to suturing at home births. Still, during the first years of implementation, the business plan focuses on selling the product to midwives with the intended use for home births on the Danish market, since this is the largest easily accessible market in Denmark for the product. Afterwards, sales are intended to expand to the EU and possibly other countries in the longer term. Therefore, two different strategies are made for sales in and outside Denmark, since potential barriers when selling the product outside Denmark should be considered (regulations, customs, language and cultural differences).

Customer segments
- Midwives - government and private sector
- Outreach work and healthcare organisations (e.g. AmiAmi)
- Relief organisations (e.g. Red Cross and MSF)

Value proposition
- Standardising out-of-hospital gynaecological examination and treatment
- Enhanced quality and optimal conditions for gynaecological operations
- Better experience for the examinee

Channels
- Danish market - direct sales (product catalogue, fairs, website)
- Outside Denmark - retailers (avoid language or cultural barriers)

Customer relationship
- Educational - courses in use (attracting customers early and keeping them)
- Free service - yearly service check

Revenue streams
- Direct sale (pay up front or instalment)
- Fixed pricing - volume and variants dependent (customisation)
- License - cleaning articles

Key resources and activities
- Certifications and sales terms
- Sales and education
- Product development (variants, additional out-of-hospital products
- Sparring and testing with users

Key partners
- Prototal Damvig (plastic components)
- ML Industries (metal parts)
- GynZone (education and collaboration)
- Laerdal (retailer)

Cost structure
- Creating customer relationship through courses, training and education
- Certification and development

3.7 Budget

A rough estimate of a budget is made for the implementation of the product. During the start-up year (Year 0), testing, certification and clinical evaluation of the product is performed and investments are made in order to start up the production. In the following years, ramp-up of production focuses on the Danish market, where Year 3 is launch of the product on markets outside Denmark.

The cost price of the product was estimated in Section *3.4 Manufacturing*. Other than the cost price, investments are needed in Year 0 for getting the product approved and production started. The investments required for this process are presented for Year 0 in table 7:

Consultancy; Clinical evaluation (prototypes and tests) and certifications	150,000 DKK
Molds	150,000 DKK
Tools	50,000 DKK
Starting inventory (5 units)	29,187 DKK
Total one-time investment	**379,187 DKK**

Table 7

For the budget (table 8), the turnover and production costs per year are estimated to calculate the contribution margin. The fixed costs are subtracted to obtain the pretax return. These are used along with the investment costs to estimate the return of investment and the size of the bank loan or investment needed for making the business viable in terms of cash flow. The detailed budget estimations are presented in Appendix 19. The budget is made excluding VAT. This is because companies buying the product in Denmark will have to pay VAT, but the VAT will be returned later due to danish rules in this regard for companies. If the product sold is in the EU (business to business), the sales price is excl. VAT. Therefore, the budget presented in table 8 is excl. VAT.

For this budget, the maximum sum of loans and investments needed to start up the business during the first few years is approximately 1.2 million DKK, which is needed after Year 1. It is seen that the total balance will be positive after Year 2 with a profit of about 200,000 DKK. Few products are sold initially since starting up the production requires testing, prototypes and certification. 41 products have to be sold to break even and pay back the loans and possible investments. After Year 2, the profit could be used for possible changes in production methods or development, which might be necessary for entering markets outside Denmark.

DKK	Year 0	Year 1	Year 2	Year 3
Units sold	5	25	100	
Sales price (excl. works)	29,000	29,000	29,000	29,000
Turnover	145,000	725,000 DKK	2,900,000 DKK	5,800,000
Production costs per unit	-6,062	-3,310 DKK	-2,728 DKK	-1,800
Total production cost	-30,312	-82,753 DKK	-272,808 DKK	-360,000
Contribution margin	**114,688**	**642,248**	**2,627,192 DKK**	**5,440,000**
Total fixed costs	-669,000	-891,450	-1,237,478	-1,724,601
Pretax return	**-554,312**	**-249,203**	**1,389,715**	**3,715,399**
Investment	-379,187			
Return of investment				
Balance, previous year	0	-933,499	-1,182,702	207,013
Pretax return (including investment)	-933,499	-249,203	1,389,715	3,715,399
Total balance	**-933,499**	**-1,182,702**	**207,013**	**3,922,412**

Table 8

04 - Epilogue

4.1 Conclusion

This Thesis focused on designing a product which could aid midwives when suturing postnatal tears at home births in order to provide a better experience for the mother and midwife. Therefore, Portable GynoCare is designed to provide similar working conditions for the midwife as at the hospital, but as a transportable solution adjusted for the home birth environment.

A new setup for home births

To obtain a similar setup for suturing as at the hospital, the focus was on placing the mother in the optimal position for suturing, easy access to the instruments and having a proper light source. The optimal position for the mother is created using the adjustable stirrups designed to fit mothers of different sizes by keeping the mother's legs in the lithotomy position. Even though Portable GynoCare can not ensure that all requirements for a good ergonomic position for the midwife is fulfilled, it improves the working positions for the midwife by placing the mother in an optimal, relaxed position for suturing close to the midwife, which gives optimal visualisation of the area and speeds up the suturing process. Moreover, the instruments for suturing can conveniently be placed in front of the midwife in the instrument tray, which also eases the suturing process. The main thing missing for the ideal home birth setup is the light source, for which the requirements have been identified, but a solution has not been fully designed. It would have to be examined if a specific light source would have to be designed for Portable GynoCare or an existing solution could be modified for the intended use instead.

A medical product for home

To make a product that would fit into the home birth context, a trade-off between the ease of use, cleaning, transportation and the expression of the product has been considered. To fit into the midwife's home birth routine, Portable GynoCare is designed for easy cleaning and transportation through the choice of materials and possibility of detaching the stirrups. Still, some of the areas of the product can be harder to clean than first intended, even though the design allows for thorough cleaning of the whole product at home. The product consists of only three main parts, which makes it easy to assemble and disassemble. However, it could be favourable to examine if the size of the different components could be optimised for reduced size and weight for easier transportation. Also, it was important to obtain a balance between the medical function of the product and the expression, which should not give the feeling of medical equipment. Portable GynoCare uses colours and shapes to associate less with a hospital environment, but a complete distinction from medical products is not obtained, since the functionality has been prioritised over the expression of the product.

A product with potential

Even though Portable GynoCare is designed for suturing at home birth, additional market potential is seen for the same product in other countries as well as for other uses than home births. Since a similar product does not exist, Portable GynoCare could be used for standardising gynaecological examinations and treatment in out-of-hospital settings. Thereby, the product has market potential around the world, including LDC countries, where a cheaper variant of the product with less adjustability could be designed for non-suturing purposes.

4.2 Reflection

Stirrups

The most challenging part of the product turned out to be the stirrup construction due to the different requirements for the stirrups being the correct position of the legs, low weight, heigh strength and ease of cleaning. One of the key challenges was to understand the requirements for the different angles for the optimal position, and how these could be visualised and implemented for women of different sizes to allow adjustability. An example is the challenge that when placing the stirrup at a specific angle, the wrong angles were obtained when adjusting the height of the stirrups. This caused several iterations with the same outcome, until it was found that this was caused by misunderstanding one of the definitions for the correct position. Another challenge was that the requirements for cleaning were unknowingly highly prioritised. Some of the initial designs were discarded due to rods sliding inside each other, creating spaces that were not possible to keep properly clean. Therefore, the final product design is based on these choices and the design is highly influenced by the requirement for easy cleaning, even though the current solution just creates some areas between the metal rods that take longer to clean. Since the stirrup construction has adequate strength for the intended purpose, a simpler stirrup construction might be more ideal e.g. with rods sliding inside each other, in order to reduce the number of components and complexity of the product design.

User involvement

Throughout this project, an essential part of the design process has been user involvement of both midwives and mothers. Expert knowledge from these users has been important to drive the design process, because the designers did not have any prior knowledge about the area regarding suturing at home births. For example, if the knowledge and perspectives from the mothers had not been examined, the product design would most likely have deviated towards a completely functional product optimal for the midwives, without considering the comfort or expression of the product towards the mothers. This user-driven innovation method has been highly advantageous in terms of the choices for the design, but has also provided some challenges in terms of conflicting wishes from the primary and secondary users.

Prototyping

The primary design approach has been prototyping through building mock-up models. This approach has been valuable, since the most promising concepts were quickly identified by being mocked-up and tested with midwives which provided an overall direction for the project. However, as the prototypes became more detailed and harder to produce later in the project, the prototyping was very time consuming and fewer were made. This is because we wanted to make the actual interactions and functions, but these were hard to replicate through prototyping. This resulted in stalling of the product development. Instead of prototyping a whole product solution, smaller components with the right interactions could have been made and tested to understand the functions and provide valuable insights for detailing of the final product proposal without necessarily testing it on users. Further, since the prototyping approach has only mimicked the actual use scenario, the next step in the product development would be testing a prototype in an actual use scenario, to validate if the functions and interactions work as expected.

Design research

The design research in this project has primarily utilised a participatory mindset, since the users are identified as the experts. In this participatory design process, a combination of a research-led and a design-led approach has been used. A preference towards the research-led approach has been identified, since data has been systematically analysed based on user tests with mock-up models, and a broad range of topics regarding home birth have been researched. For example, the dimensions and adjustability of the product was determined based on anthropometric analysis. A downside to this approach has been that it limited the creative ideation process and restricted the possibilities of what could be designed. However, the design-led approach has still been used initially in product development to stimulate creativity and ideation of various solution types, while the research-led method has been more dominant in the later stages of product development.

4.3 References

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11. Own Illustration

12. https://www.facebook.com/siv.kristiansen.1

13: https://www.facebook.com/malenescholer

14: https://www.facebook.com/anne.kochnielsen

15: https://www.facebook.com/annekathrine.rusz

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17: Own illustration

18: https://www.linkedin.com/in/christiane-lindrup-b32703bb/?originalSubdomain=dk

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21: Own illustration

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23-49: Own illustration

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244: https://www.babysam.dk/matty-puslepude-inkl-topper-cappuccino?gclid=CjwKCAjw36GjBhAkEiwAKwIWycseDTMrqkpDh35Q7qp4B3AcciYLXHnMxSqN1tHw9qKCv1rids3b_xoCsCIQAvD_BwE&gclsrc=aw.ds

245-250: Own illustration

251: https://swfile.azureedge.net/sw6media/thumbnail/2c/8e/f7/1651610098/35f6aa321622afb64b6019ccec129186-7018343M_1920x1920-optimized.jpg

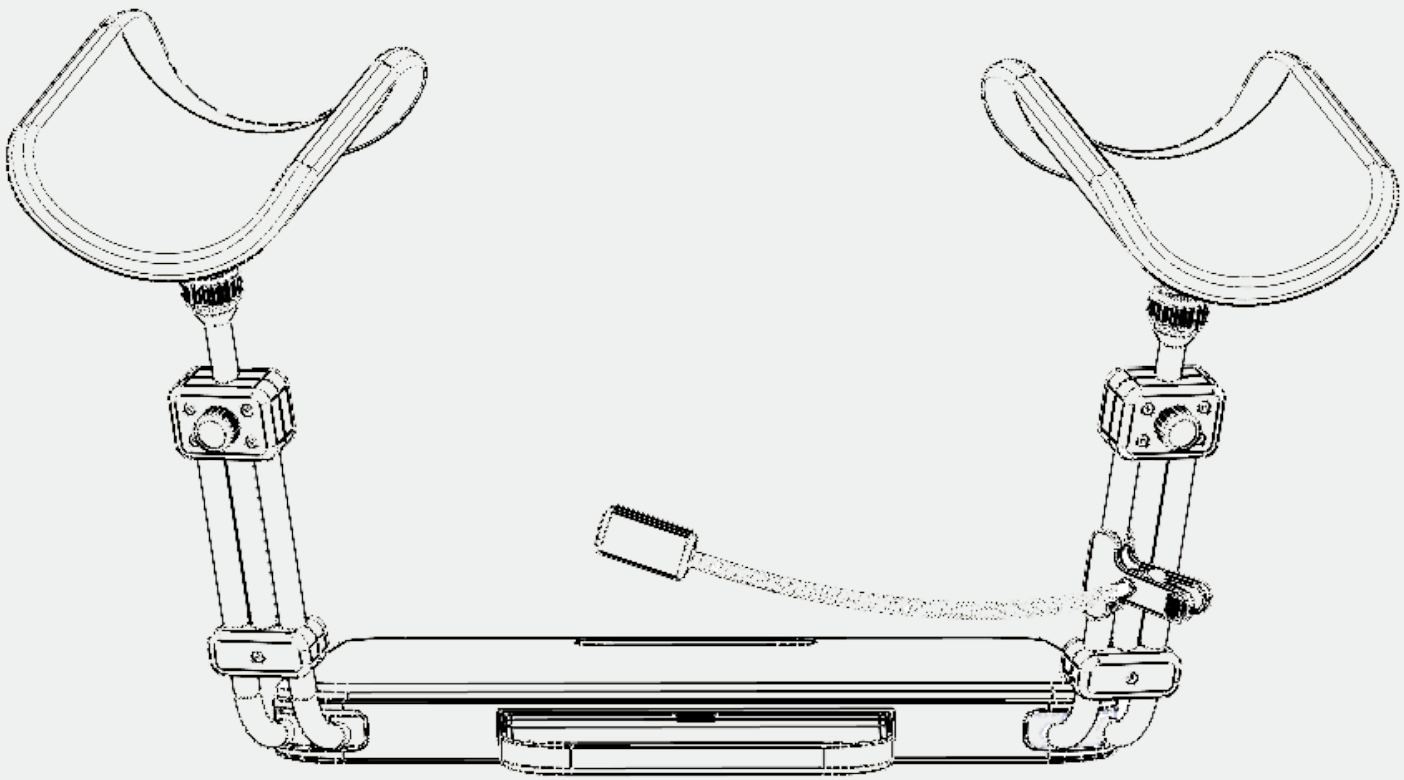
252-258: Own illustration

259: https://www.lampegiganten.dk/prios-harumi-led-klemmelampe-hvid.html

260-306: Own illustration

Tables:

1-8: Own tables



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