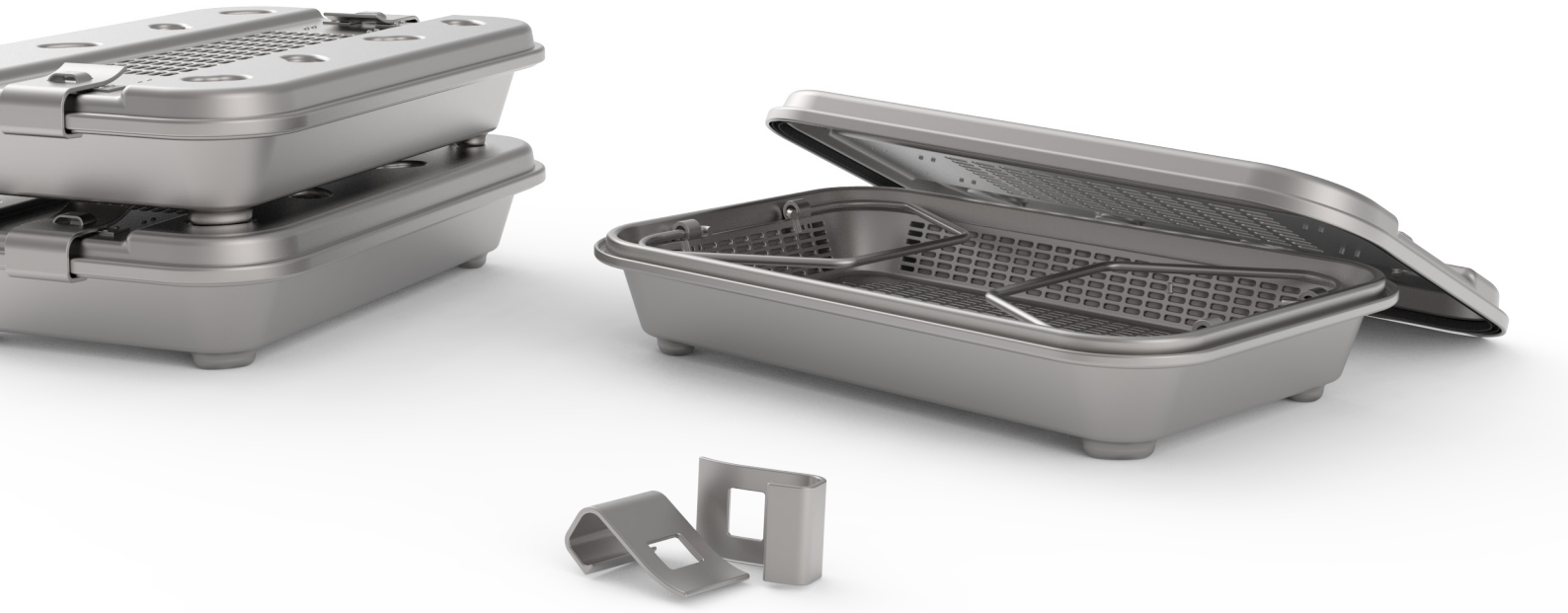
CLEANETIC PRO

the future of sterilisation containers



Product report June 2023
Master thesis - MA4-ID7
Jonas Schaldemose Andersen
Marie Louise Bay Christensen

TITLE PAGE

Title:	CLEANETIC PRO
Theme:	STERILE PACKAGING FOR SURGICAL INSTRUMENTS
University:	AALBORG UNIVERSITY
Project team:	MA4-ID7
Project period:	01.02.23 - 23.06.23
Main supervisor:	CHRISTIAN TOLLESTRUP
Co-supervisor:	MIKAEL LARSEN
Section:	PRODUCT REPORT
Pages:	20

ABSTRACT

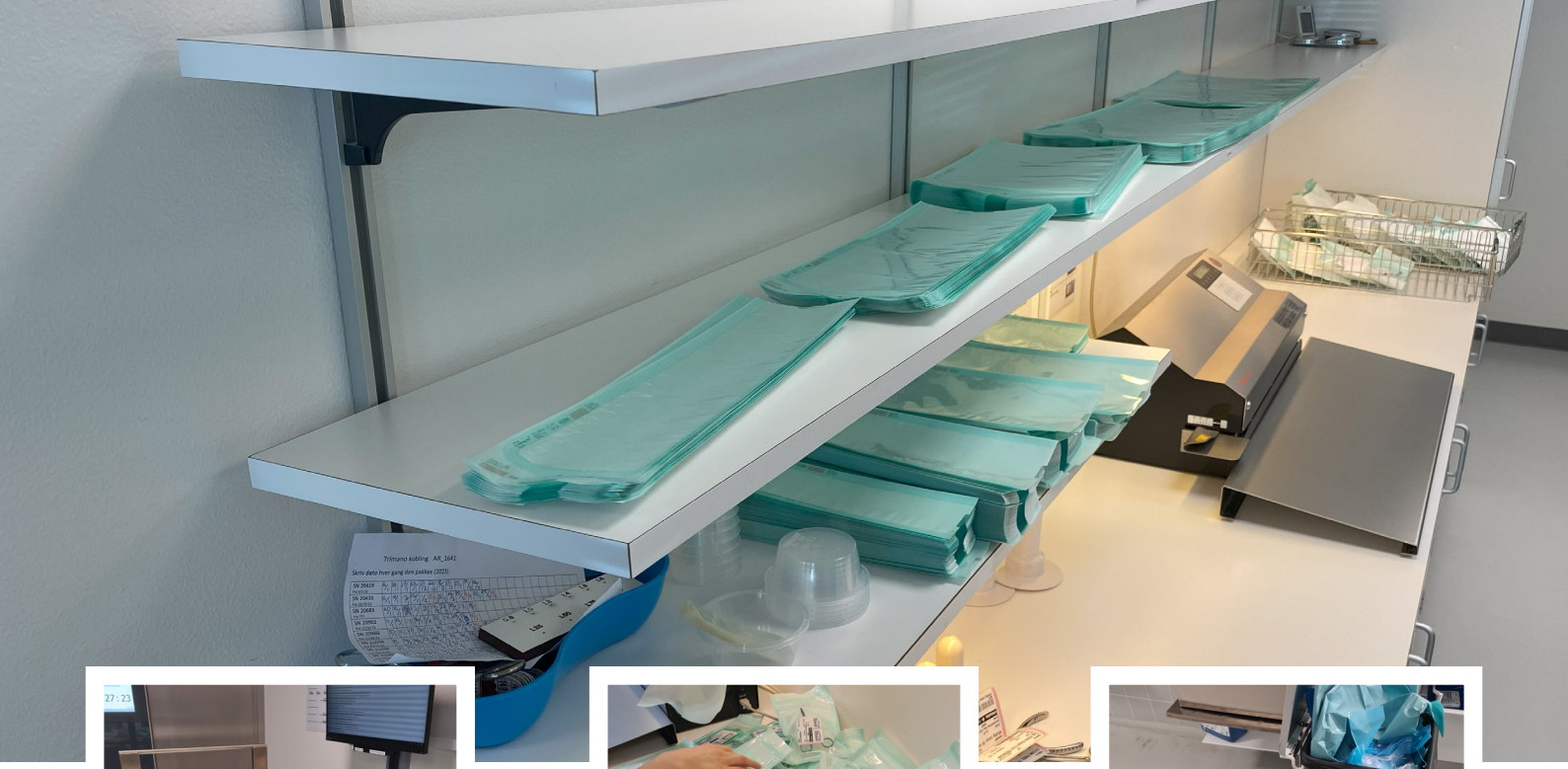
Denne rapport indeholder en gennemgang af processen bag designet af en steril container til genbehandling af små kirurgiske instrumenter og sæt. Den danske regering har med klimaloven fra 2019 sat et mål for at reducere CO2 udledningen med 70% inden 2030, hvilket på regionalt niveau har ført til et øget fokus på nedbringelsen af de store mængder affald fra hospitalssektoren. Dette betyder et større fokus på udskiftning af emballager og engangsartikler til genanvendelige produkter som kirurgiske metal instrumenter. En stigning i brug af genanvendelige instrumenter vil medføre et øget pres på sterilcentralerne, og dermed forbruget af engangsemballage, herunder autoklaveposer, der på nuværende tidspunkt bortskaffes efter brug. I projektet arbejdes ud fra en kvalitativ metode med brugerinddragelse, da analyser har vist at implementering af nye produkter på markedet drives af udbud i tråd med overordnede mål, mens den endelige implementering sker på baggrund af behov på det operationelle niveau. Analysens genstand er Farsø Hospital og sterilcentral, hvor det gennem interviews og acting out med personalet blev klart, at særligt operationssygeplejersker oplever udfordringer med ergonomi og kontrol, når de håndterer autoklaveposer. Ved at arbejde iterativt med designprincipper, der vil tilgodese sygeplejerskerne og bevare strukturen i sterilcentralen, er der, med udgangspunkt i sutursæt, skabt et steril containersystem til små instrumenter, der kan minimere brugen af engangs-autoklaveposer. Cleanetic PRO er således et bud på, hvordan sygehusvæsenet kan deltage i den grønne omstilling, samtidig med at personalets behov tilgodeses.

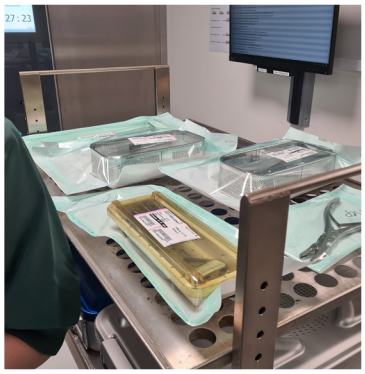
TABLE OF CONTENT


LÆSESTOF
REKVISITIONER

01 RETREATMENT

The Central Denmark Region alone use more than 40.000 suture kits anually and that switching to reusable devices could reduce CO2 emissions by 90%. This entails the regions to look at the implementation of more reusable instruments, which would lead to an increased need for sustainable packaging. Reusable instruments are utilised in a loop as seen in the illustration below, the retreatment takes place in three overall steps of *cleaning, disinfecting and sterilising* happening in the sterile processing department (SPD) connected to the hospital. In the loop of retreatment two main stakeholders should be addressed: The **SPD-nurses** and the **OP-nurses** from the surgical department.





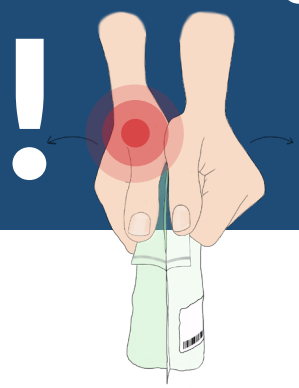
02 AUTOCLAVE POUCHES

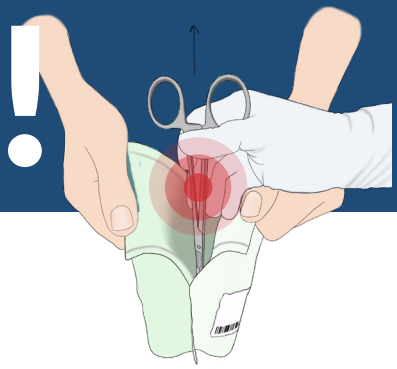
Autoclave pouches are typically used for repacking small surgical instrument kits and solo instruments. They consist of one side in Tyvek fabric filtering out any unwanted micro organisms and the other in non-recyclable plastic. The pouches are inexpensive and flexible when utilising capacity in the SPD, but comes with a line of disadvantages as well. The pouches are quick and flexible to use in the sterile processing department, but the surgical nurses are having difficulties handling the instruments from pouches aseptically without strains and uncertainty.

AN INFINITE LOOP OF SINGLE USE PLASTIC PACKAGING

SENSITIVE TO TOUCH BY WET HANDS

FRAGILE IN CONTACT WITH SHARP INSTRUMENTS






Mai-Britt Rasmussen

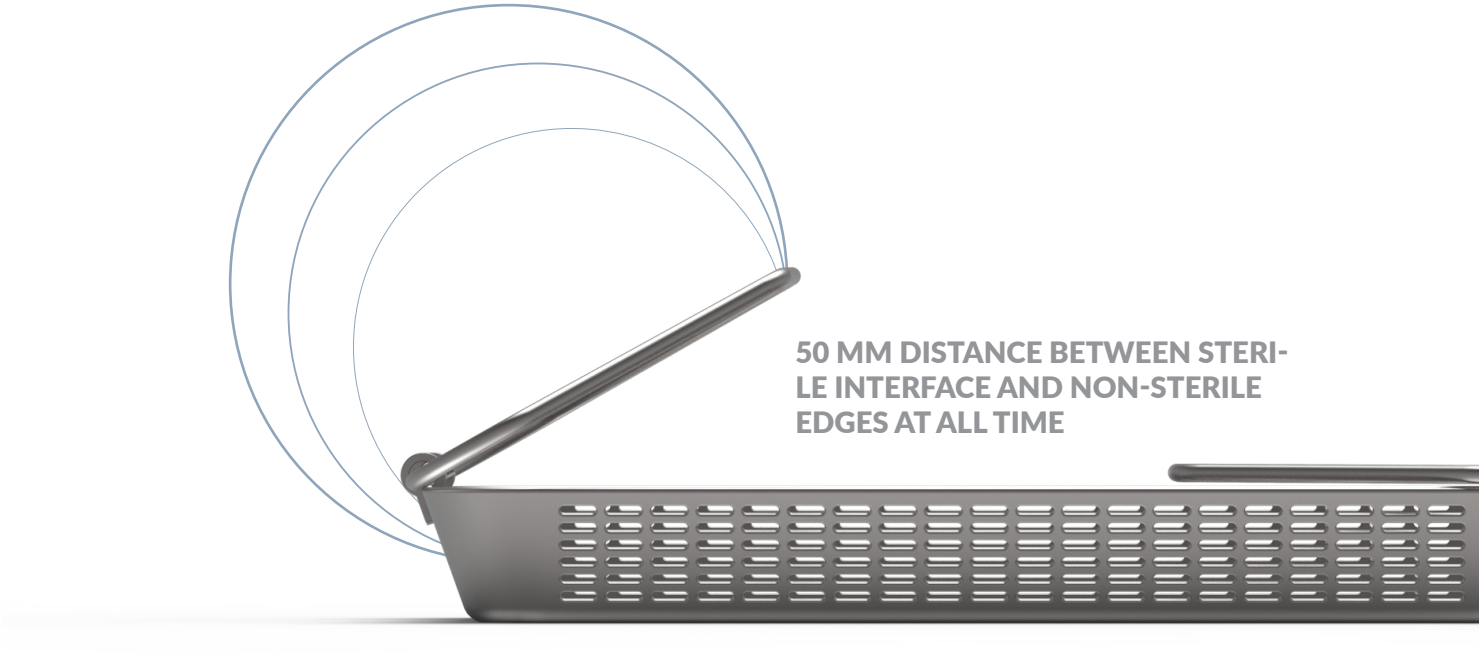
CLEANETIC PRO

the future of sterilisation containers

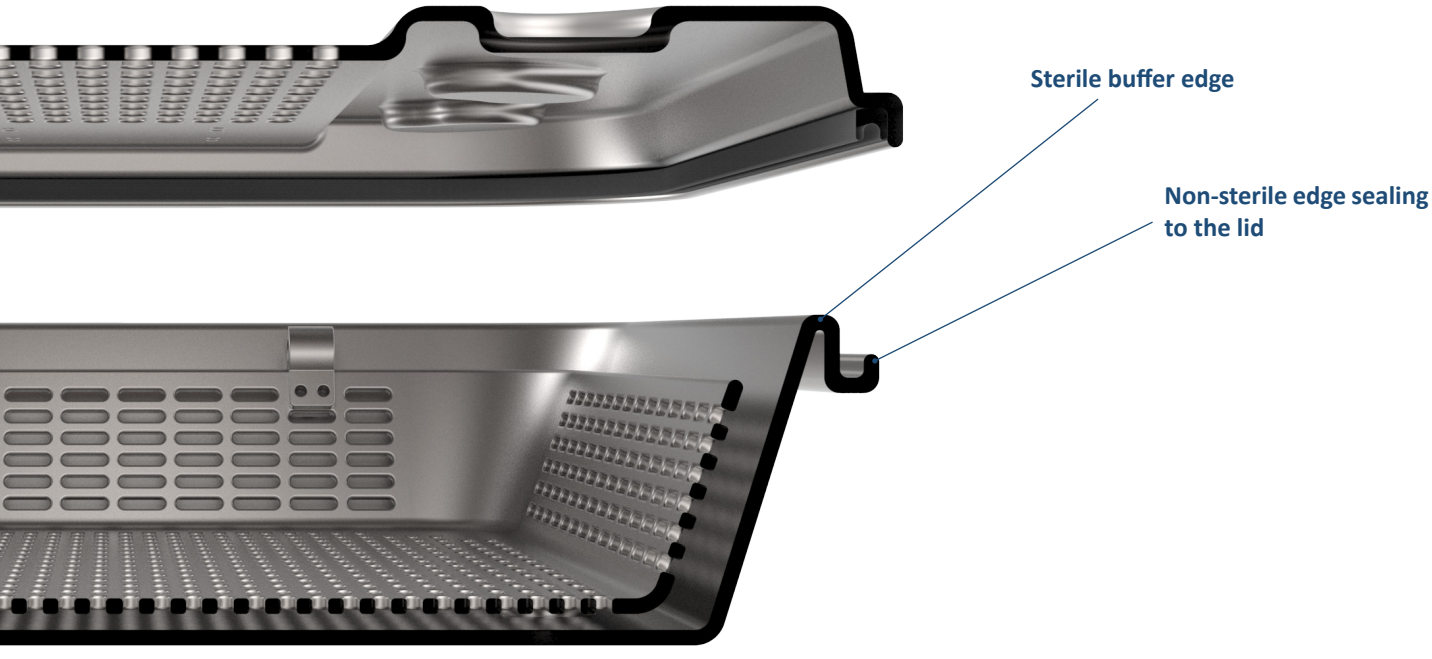
Cleanetic PRO is a reusable packaging solution for repacking suture kits and other smaller surgical instruments, while increasing comfort for the OP-nurses and thereby patient security. With a risk reducing interface the nurse feel safe and can securely retrieve the instruments without extra precaution. Cleanetic PRO can function on its own or as a supplementing container for larger instrument kits.

04 RISK REDUCING DESIGN

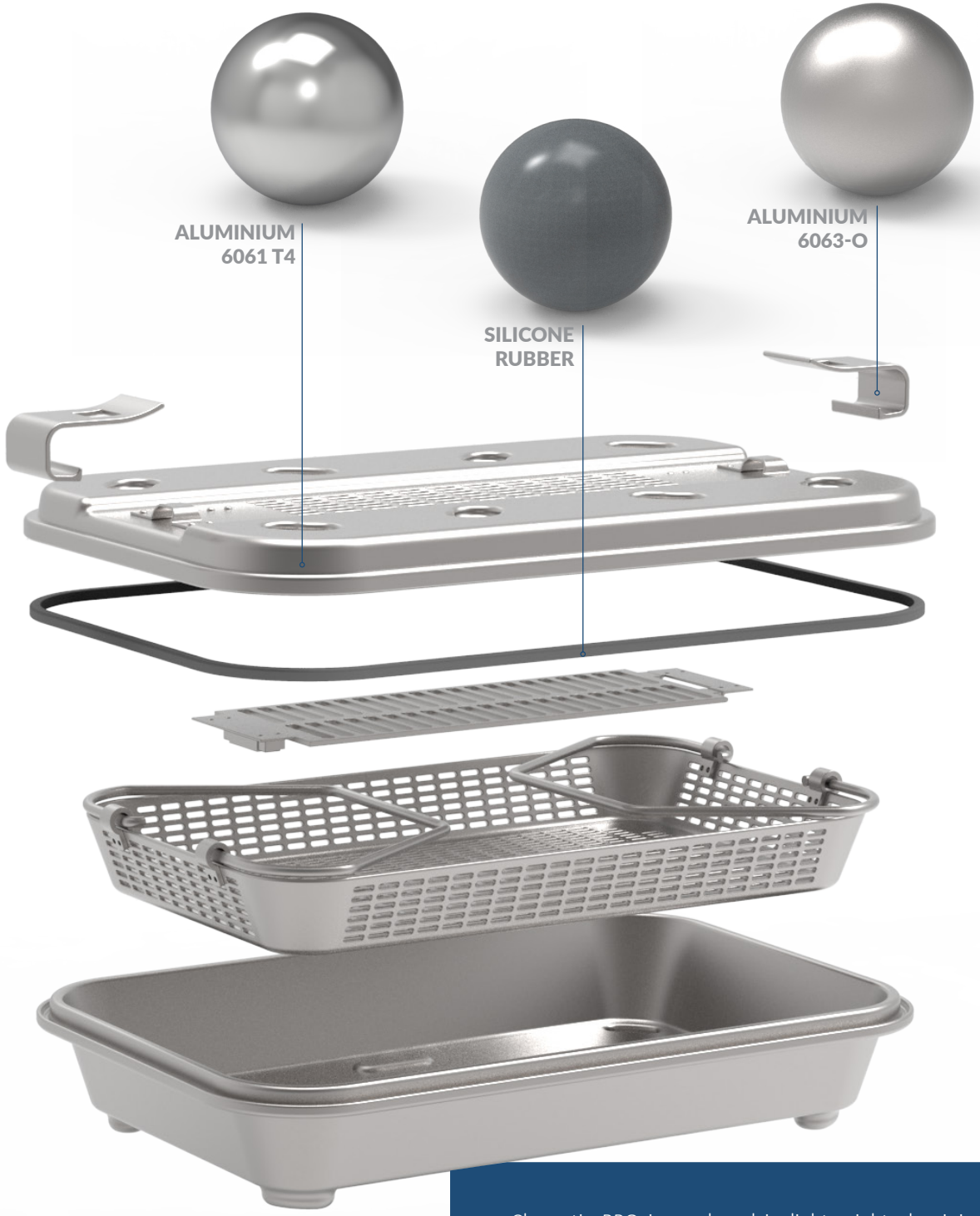
In Cleanetic PRO details have been perfected to aid a safe and natural workflow around the instruments. OP-nurses should always feel confident that they are not compromising patient security or straining themselves in akward positions.



50 MM DISTANCE BETWEEN STERILE INTERFACE AND NON-STERILE EDGES AT ALL TIME



05 PARTS & MATERIALS



Cleanetic PRO is produced in lightweight aluminium that withstand autoclavation up to 134°C, integrated in the lid is a silicone rubber gasket to make the container seal airtight anywhere else than by the filter.

06 IN SURGERY

Taking the instruments out from storage

Placing Cleanetic PRO on the clean table

Breaking the seal and opening the lid

The sterile nurse easily grabs the inner tray with the instruments

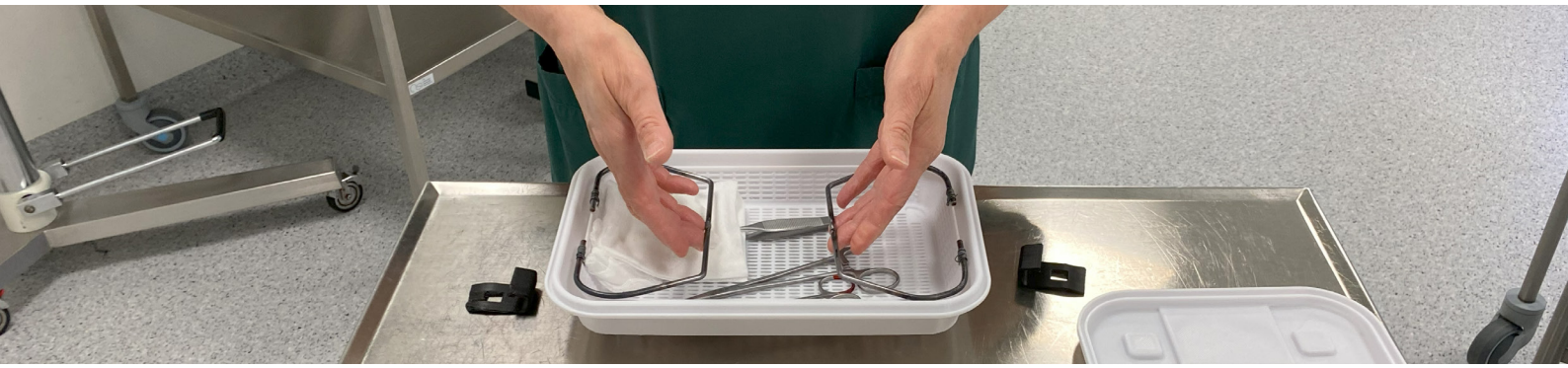
Another (sterile) nurse puts down a sterile covering sheet

Lifting the lid towards one self to avoid contaminating the instruments

Lifting the tray with palms of the hands facing each other, no need for awkward workarounds

Lifting the inner tray in the handles that due to their rigidity lets the nurse control the tray

Placing the inner tray and the instruments on the table with a sterile sheet



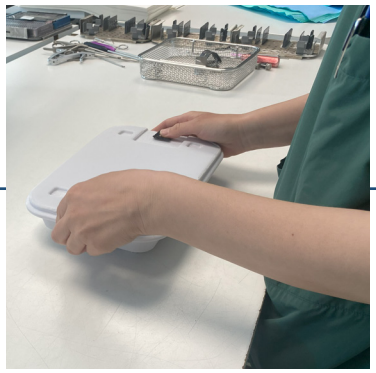
Handling packaging along with instruments can be tricky as the sterile interfaces are often placed very close to surface only being clean. If a sterile nurse touches a clean surface while handling the instruments, the whole kit will be sent back to retreatment and exchanged for a new, while the nurse will have to change clothes. With Cleanetic PRO the nurse is ensured a natural workflow in ergonomically easing positions minimising the risk of mistakes.

07 IN THE SPD

Mechanical wash on racks

Assembly with instruments

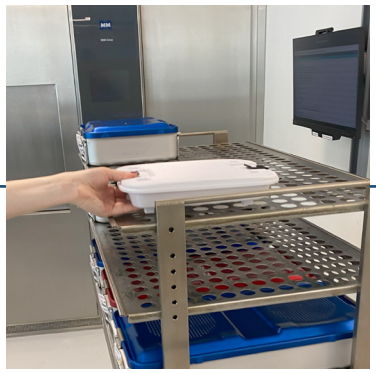
Placing inner tray in bottom part



Sealing the lid

Placing the closing clips

Closing the lid



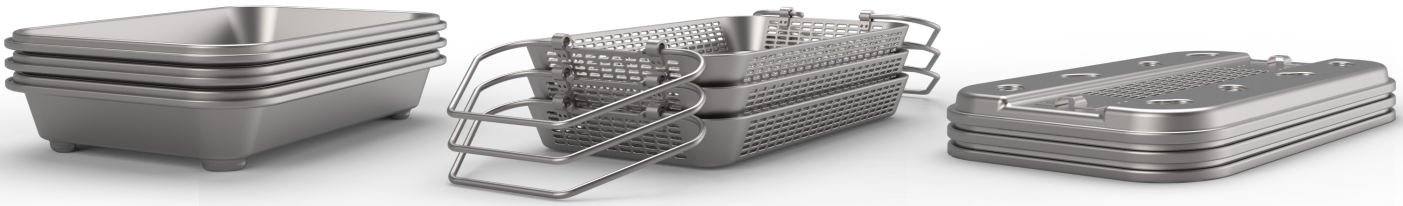
Placing on the trolley for steam autoclavation

Steam autoclavation and cooling

Packing for storage until next use-cycle

08 SPACE OPTIMISATION

Empty stacking
To accomodate the capacity of the SPDs current system each part of Cleanetic PRO is stackable to ensure a collection of emoty buffer containers are always riht there when you need them.



Stacking in the autoclave
To ensure optimal utilisation of resources Cleanetic PRO is designed fill out every space in the steam autoclave, minimising the run-time and CO2-e spent on retreatment.

09 CO2-E REDUCTION

No more disposable pouches and need for large incineration! Cleanetic PRO is the sustainable alternative to autoclave pouches, with an estimated reduction of 74% CO2-e.

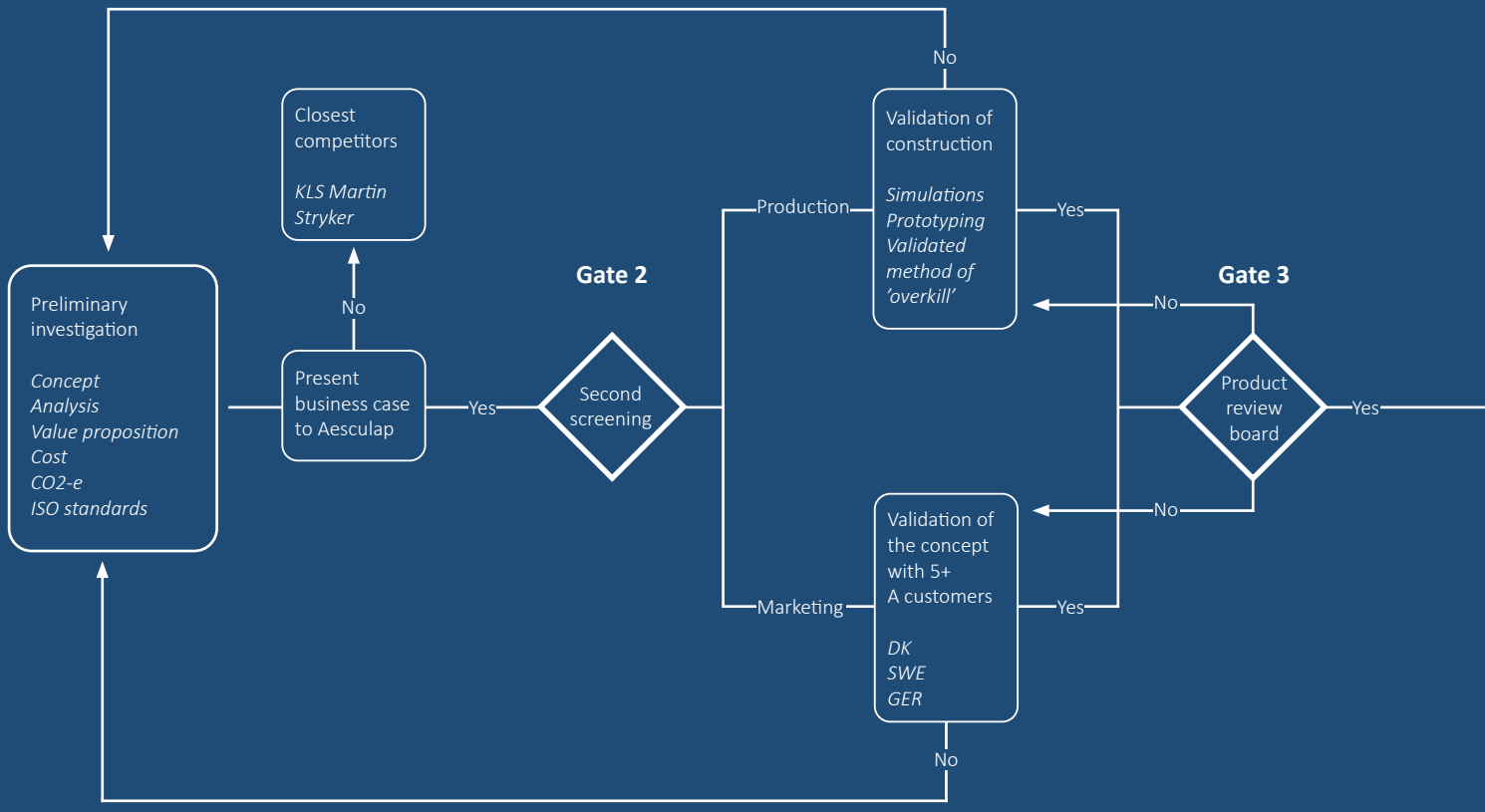
Which is equivalent driving 737 km. in the avarage car

74%

INDICATIVE CO2-e REDUCTION IN MATERIALS

10 IMPLEMENTATION

Contract with Aesculap for finalising Cleanetic on a consultancy basis plus an exclusive licensing agreement (e.g. with a 5% royalty), exclusivity based on an annual minimum royalty (based on agreed min. turnover). No need to assess the other partnership modes such as contract manufacturing, franchising or joint venture from a risk point of view; the team assesses the advantages in teaming up with a strong, global partner like Aesculap to outbalance all disadvantages. In case Aesculap decides not to enter in a partnership, other options remain open.

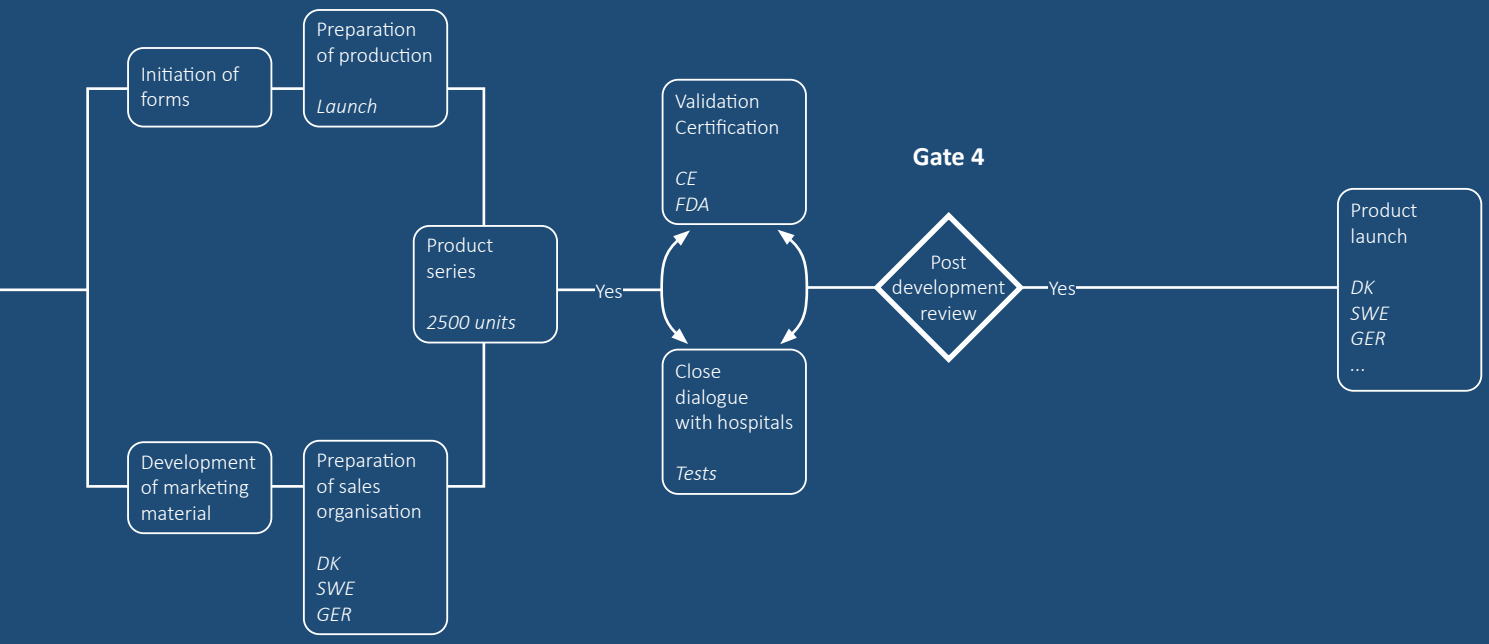


Detailed investigation

Essential design parameters, such as the lid, the angled sides, inner tray and bottom edges needs further development. With a more in-depth research of the total cost, appropriate material utilisation, CO2-e and assurance that Cleanetic PRO compiles with the necessary ISO-standards- It is possible to present a concept with a valueproposition that provides a headstart in the transitioning towards reusable instruments.

Development

Once through the second gate, validation of construction and marketing and high end prototyping is required in addition to simulations and the validated method of overkill.



Testing & Validation

Once Cleanetic PRO goes through the product review board, no further larger developments will be made, as initiation of forms and a series 0 would be prepared for launch, where validation and certifications are assured in close dialog with hospitals before the actual product launch in Denmark, Sweden, Germany.

TECHNICAL DRAWINGS

Cleanetic PRO, June 2023
Master thesis - MA4-ID7
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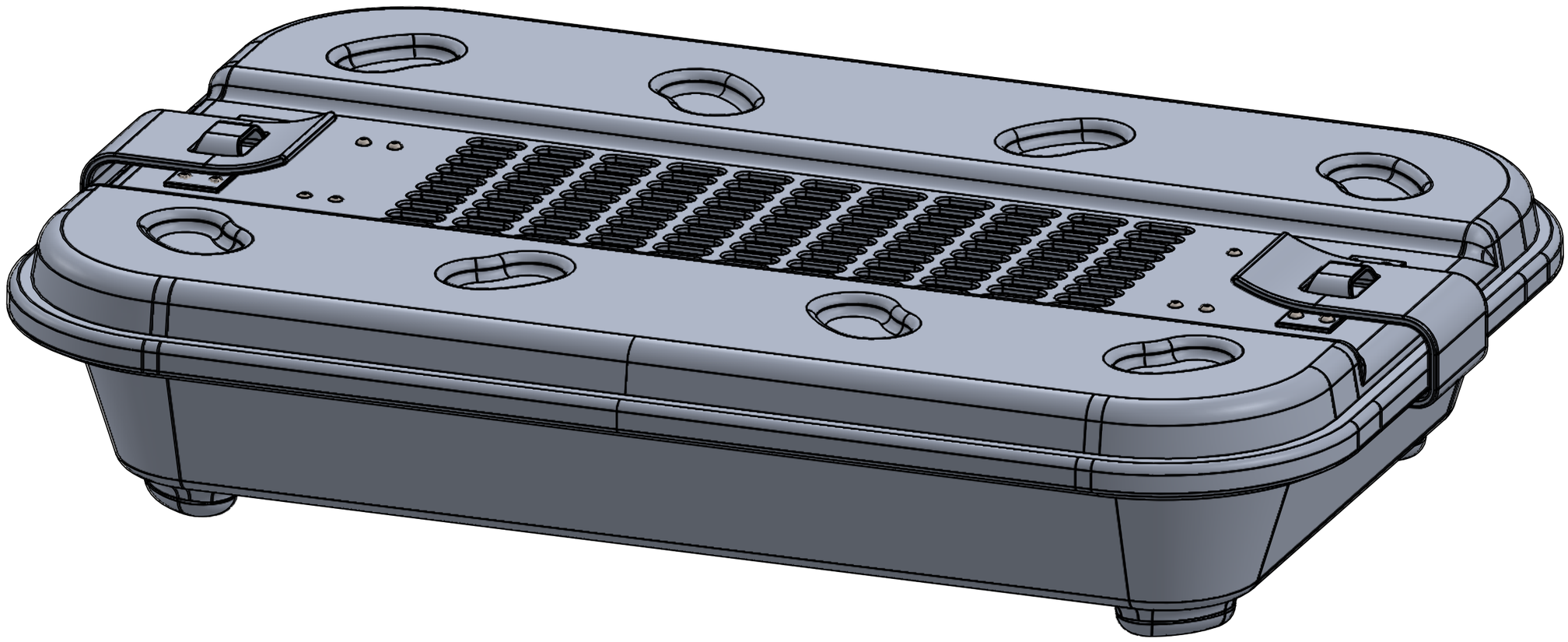
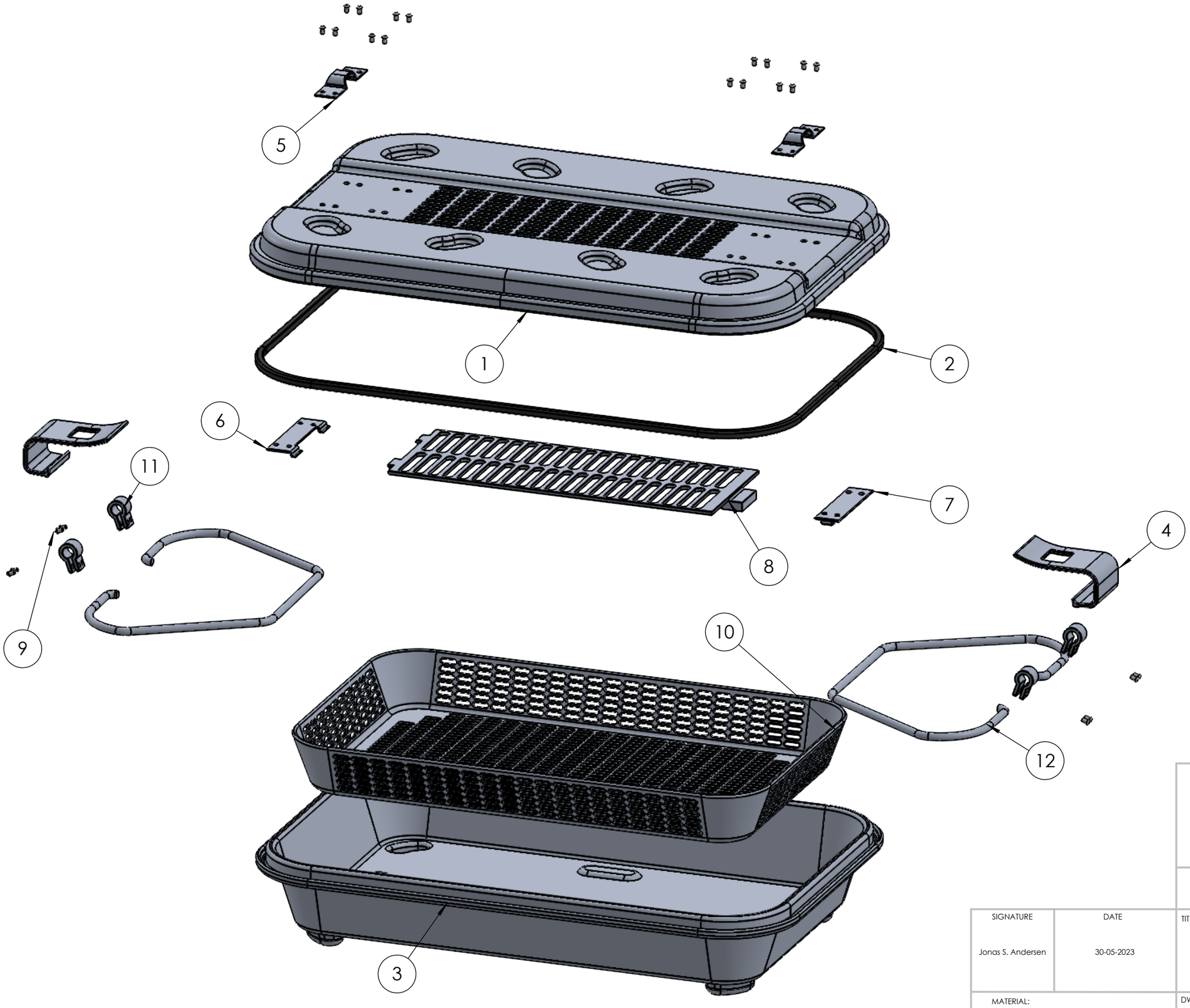


Cleanetic PRO
Industrial Design MSc04
Master thesis

DO NOT SCALE DRAWING

NAME	DATE	TITLE:
Jonas S. Andersen	30-05-2023	DIMETRIC VIEW, CLEANETIC PRO
MATERIAL:		DWG NO. 1 — A3
WEIGHT: 700g	SCALE: 1:1	SHEET 1 OF 5



CLEANETIC PRO
Industrial Design MSc04
Master Thesis

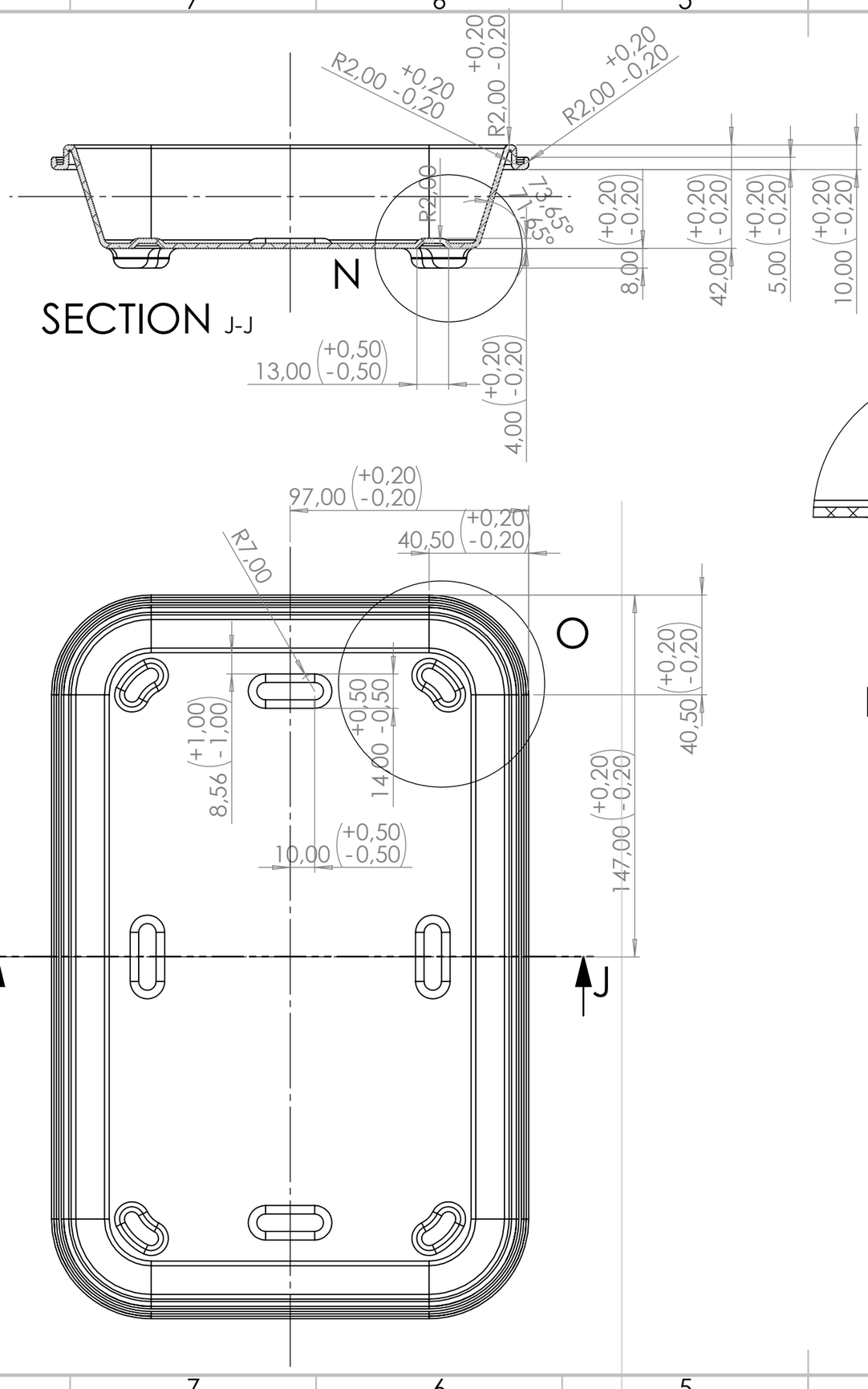
DO NOT SCALE DRAWING

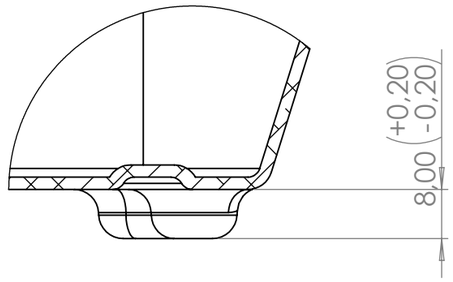
SIGNATURE	DATE	TITLE:
Jonas S. Andersen	30-05-2023	EXPLODED VIEW, CLEANETIC PRO
MATERIAL:		DWG NO. 2 — A3
WEIGHT: 700g	SCALE:1:2	SHEET 2 OF 5

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	Lid	Aluminium 6061-T4	1
2	Silicone gasket	Silicone (standard)	1
3	Bottom	Aluminium 6061-T4	1
4	Lock	Aluminium 6063-O	2
5	Upper hinge	Aluminium 6061-T4	2
6	Filter holder hinge	Aluminium 6061-T4	1
7	Filter holder lock	Aluminium 6061-T4	1
8	Filter holder	Aluminium 6061-T4	1
9	Revit	Aluminium (standard)	20
10	Inner tray	Aluminium 6061-T4	1
11	Inner tray hinge	Aluminium 6061-T4	4
12	Handles	Aluminium 6061-T4	2

Cleanetic PRO
Industrial Design MSc04
Master thesis

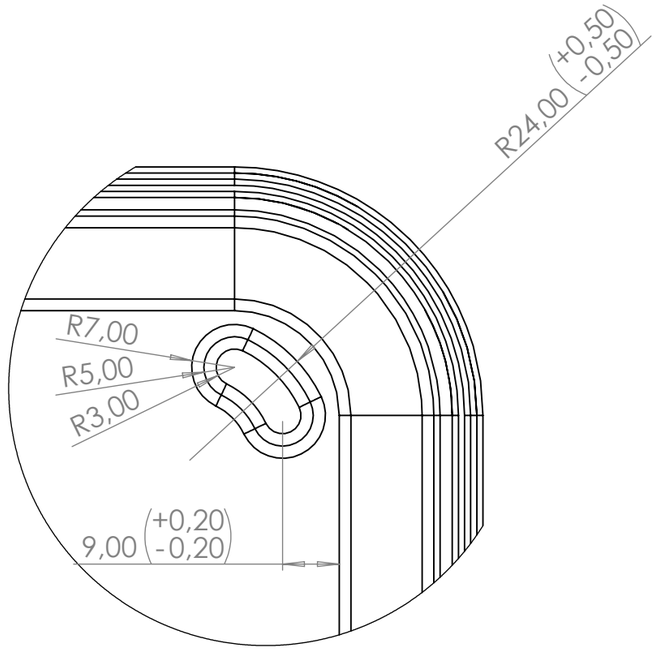
NAME	DATE	TITLE:
Jonas S. Andersen	30-05-2023	CLEANETIC PRO, BILL OF MATERIALS (BOM)
MATERIAL:		DWG NO. 3 A3
WEIGHT: 700g		SHEET 3 OF 5





DETAIL N

SCALE 1 : 1



DETAIL O

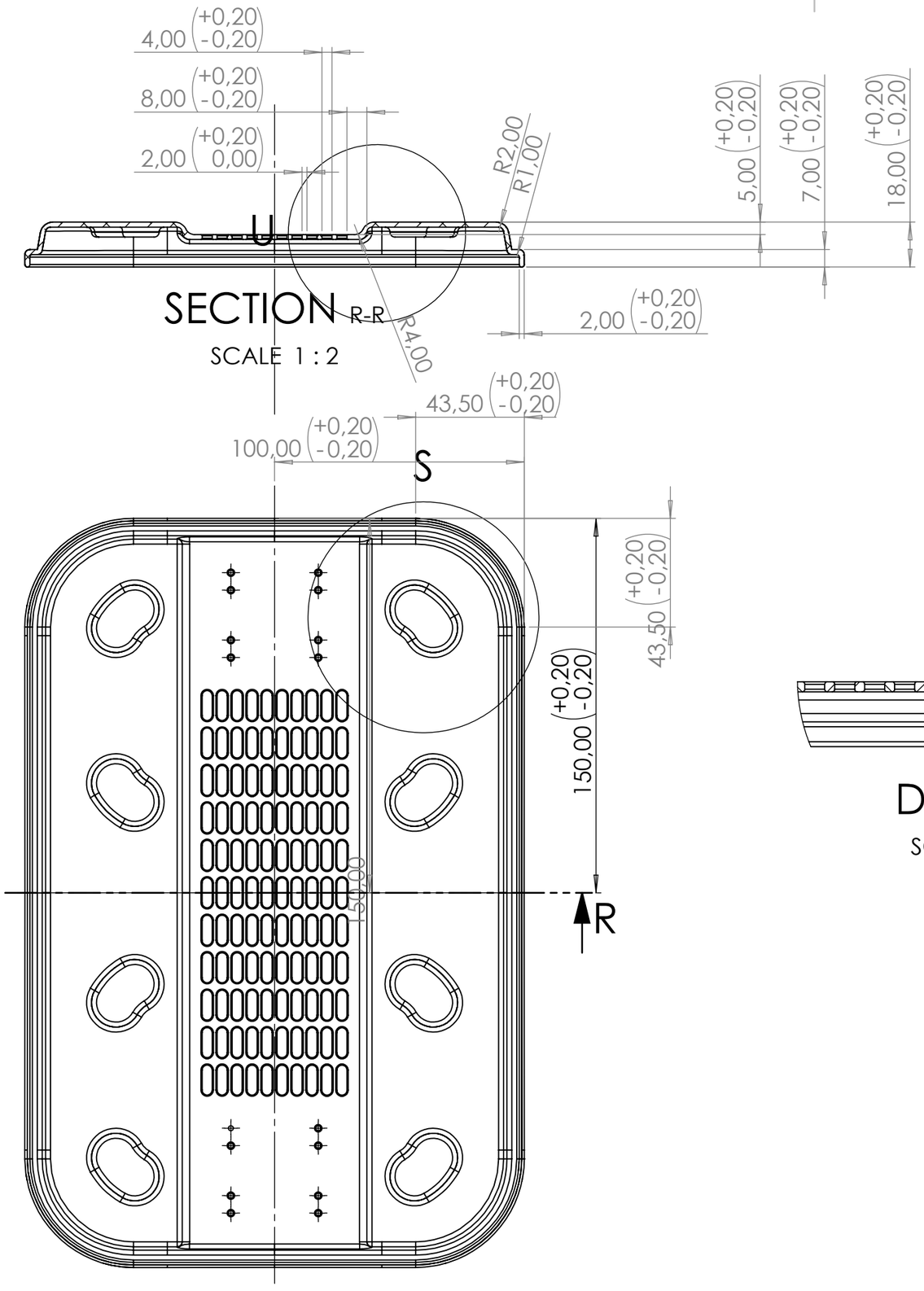
SCALE 1 : 1

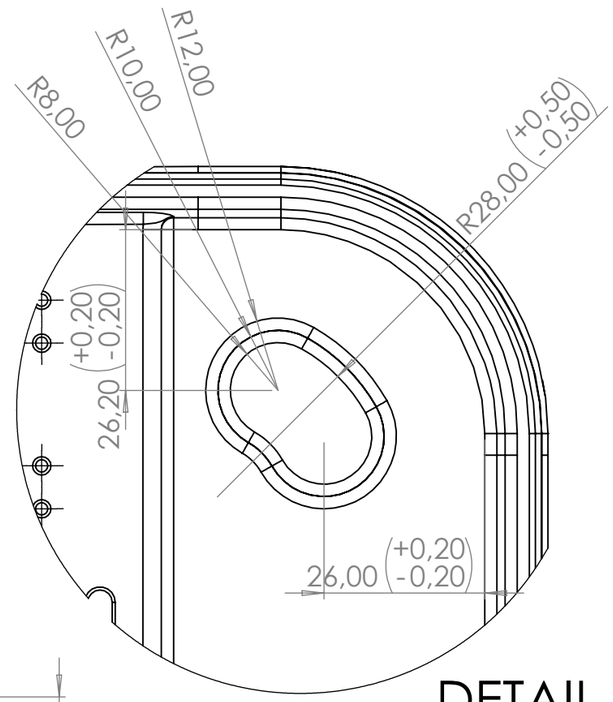
DIMENSIONS ARE IN MM

NAME:	DATE	AUTHOR
Jonas S. Andersen	30-05-2023	Cleanetic PRO IINDUSTRIAL DESIGN MSc04 ID7 MASTER THESIS

MATERIAL:	PART NAME	
Aluminium 6061-T4	Bottom	A3

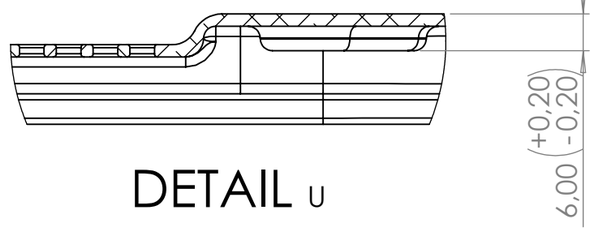
WEIGHT: 292 g	SCALE: 1:2	SHEET 4 OF 5





DETAIL S

SCALE 1 : 1



DETAIL U

SCALE 1 : 1

DIMENSIONS ARE IN MM

NAME	TITLE:	AUTHUR	
Jonas S. Andersen	30-05-2023	CLEANETIC PRO INDUSTRIAL DESIGN MSc04 ID7 MASTER THESIS	
MATERIAL: Aluminium 6061-T4		PART NAME: Lid	A3
WEIGHT: 217g		SCALE: 1:2	SHEET 5 OF 5

CLEANETIC PRO

Process report, June 2023
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Jonas Schaldemose Andersen
Marie Louise Bay Christensen

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INTRODUCTION

Each year the Danish hospital industry produces almost 39.000 tonnes of waste which meets the case of approximately 4.4 tonnes of waste produced every hour from the hospitals alone (Vange, 2023). This makes the five regions of Denmark look to single use articles in the healthcare sector, where both reduction in consumption and waste sorting are on the agenda. Meanwhile, a lot of hospitals in Denmark are not only descarding single use plastic, but also single use surgical instruments in metal. Additionally, analysis from the Central region of Denmark shows that a transition from single use til reusable suture kits could save mindblowing 90% CO2-e. The paradox is that as soon as a hospital changes into reusable instruments, each instrument kit is re-packed in an infinite loop of single use plastic packaging.

This project explores the possibility of creating a reusable packaging option for sterile processing departments that makes for an alternative to single use plastic and considers both the needs of the operational and the strategic level in the healthcare sector.

READING GUIDE

This project consists of four individual parts:

Product report: Presenting Cleanetic PRO
Technical drawings: Technical specifications
Process report: Explaining the process
Appendix: Worksheets, methods, pictures/illustrations and calculations

This project is documented in 6 phases describing the divergent and convergent process of framing problem and solution space, iteratively concept development in close connection to the users, material and production specifications, along with a business case and cost estimation. Throughout the report part conclusions and specifications will occur as illustrated below.

SIDE NOTE

The side note can contain information that was found in parallel with the ongoing chapter or information needed to make sense of the next chapter.

Quotes from users will be presented like this if relevant to the information in the chapter

Part conclusion summing up the most important points from the chapter

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You will find the need listed under this number in the design brief

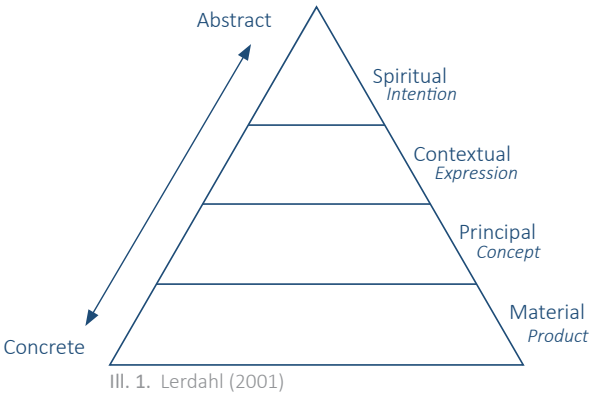
Insight obtained through the chapter

! *Need identified during the chapter (X)*

→ *Specification or metric obtained during the chapter*

As a consequence another parameter has changed

Needs and specifications obtained during the project will continuously be summed up in design briefs categorised by the method of Ulrich and Eppinger (2000). Here needs are identified and specified during the design process, and the importance of each need is listed as a way of navigating and prioritising.



Ill. 1. Lerdahl (2001)

Through the project phase introductions will describe the process in relation to Lerdahl's pyramid (Lerdahl, 2001), that visualises how a project navigates between abstract and concrete levels. The four levels in lerdahl's pyramid relates to the spiritual level of intention, contextual level of expression, principal level of concept and the material level of the product. To achieve a product proposal every level must have been utilised and connected. (Lerdahl 2001, 100-106)

USERS & EXPERTS

Throughout the project the team has had several contextual interviews in Farsø Hospital, in both the sterile processing department and the surgical department. Here two nurse from each department have been very helpful in providing valuable insights and feedback to the concepts.

Maria Jørgensen
Farsø Hospital
Sterile Processing Department

Annette Rohde Brander
Farsø Hospital
Sterile Processing Department
& Procurement Manager

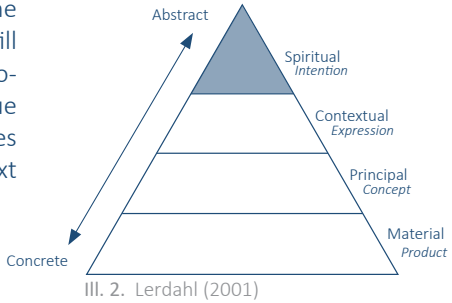
Janni Linnemann
Farsø Hospital
Surgical Department

Mette Nielsen
Farsø Hospital
Surgical Department

A big thank you to Maria and Annette from Farsø sterile processing department, and Janni and Mette from Farsø surgical department, we could not have done this project without you!

PHASE | 0

Throughout this first initial phase it is explained how the team started in the abstract level in Lerdahl's pyramid where the intention of the project was still unclear and the team investigated opportunities to find a purpose of the project. The mission of reducing waste from hospitals was quick to take form due to utilising contacts and areas of interest. Through this phase the team moves down towards the more concrete, but still fuzzy level of describing context and the users in it.



Ill. 2. Lerdahl (2001)

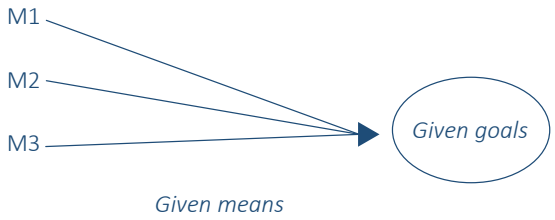
0.1 FLY IN

Goals & Objectives

The individual goals of each team member for the master's thesis project were externalised and ranked to provide a sense of common direction. Three areas of common interest were identified: the healthcare sector, packaging design including foods and beverages, and the outdoor gear industry. Three main goals were set from the beginning of the project: to lay a foundation for launching a start-up by gaining as much knowledge as possible within one of the three areas of interest with the aspiration to create a positive environmental impact by reducing CO2-e or waste produced by products within Denmark and potentially developing countries; and to pursue a project that could lead to conducting fieldwork abroad with the mentality "saving the world with one product at a time.". Therefore, the team looked to The United Nations' 17 sustainable development goals, where especially the goals 3: Good health and well-being, 10: Reducing inequalities and 12: Responsible consumption and production were intended as a guide and used as means for achieving a goal of working abroad and to create a positive environmental impact.

Contacts

The team's network was reviewed to determine the available resources and means required to act on the established objectives and potentially achieve the set goals (Sarasvathy, 2006). Here it became clear that a dominant group of people in the team's network were nurses, doctors, and general people with a connection to the hospital industry. Both team members were aware that a significant amount of waste is generated in the healthcare industry, which corresponded well with one of the areas of shared interest. This prompted the team to conduct further research.



Ill. 4. Sarasvathy

Ill. 3. UN's sustainable development goals

WASTE FROM DANISH HOSPITAL

According to research, Danish Hospitals generate 4.4 metric tonnes of waste per hour, which is equivalent to over 38.911 metric tonnes per year (Vange, 2023). On average barely 25% of waste is recycled, and the five Danish regions aim to increase the amount of waste recycled by 20-70% by 2030 (Vange, 2023), which necessitates a significant logistical change at the operational level – but whose responsibility is it? And what is currently being done to effect that change?

0.2 RESPONSIBILITY

With sustainability and waste management as the main drivers of the project, the team wanted to know the actors responsible for implementing changes towards a more sustainable healthcare system. The procurement agents were unable to specify the quantities and models purchased, necessitating additional desktop research and phone calls to investigate who decides what is purchased and in what quantities. Within the scope of this study, the research team was referred to various Danish hospital actors and encountered a complex system with multiple layers of responsibility. Following, the team attempted to map the various levels of decision-makers and their responsibilities

State

At the top is the state, which sets the financial framework and national goals regarding the climate in accordance with EU directives (Sundhedsreformen, 2022) that the Danish regions then specify.

Danish Regions Interest and Employer Organisation

Danish Regions is an interest and employer organiDanish Regions is an interest and employer organisation that governs the individual region's interests at a national level and is an entity that makes overall analysis and a more specific framework that leads to a set of requirements for a more sustainable future (Om Danske regioner). The Danish regions interest and employer organisation has developed a strategic plan for a greener hospital transition by 2030, with a goal of reducing regional CO2-e emissions by 75% between 2018 and 2030, with 50% of that reduction being by direct regional efforts (Grønne Hospitaler).

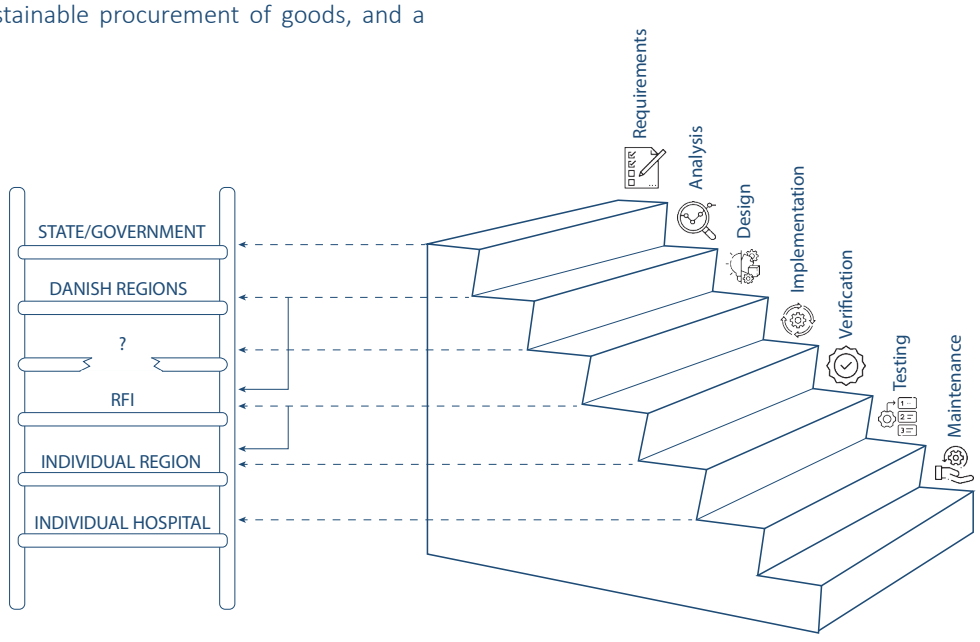
The strategy encompasses four key areas: climate-friendly buildings, greener fuels and optimised infrastructure, sustainable procurement of goods, and a circular economy with minimal waste. Danish hospitals will focus on the two parameters over which they have direct control: climate-friendly buildings and greener fuels and infrastructure. In terms of sustainable procurement of goods and a circular economy with minimal waste, the regions will prioritise clearer demands for a more sustainable procurement process that is in line with the UN's goals, such as a longer product lifetime and an emphasis on repair and leasing deals.

The Regions Joint Procurement Organisation

Furthermore, it was discovered that each region is a Furthermore, it was discovered that each region is a member of the Regions Joint Procurement (RFI) organisation, which seeks to manage and coordinate as many procurements as possible across the five regions in compliance with EU directives to reduce the number of individual tender processes (RFI.DK - in English).

Individual regional procurement departments

The procurement agents from the North Denmark Region noted, however, that specific instruments, such as oximeters and other operational equipment, were purchased by each hospital within its own region, as each hospital has its own jurisdiction and regionally specific purchasing restrictions due to tenders. If a tender is to be issued for new oximeters, a hospital department with an open procurement procedure will form a user group that consists of regional strategic procurement agents, operational staff, legal staff, and economists. Typically, the operational staff, composed of doctors and nurses, will have the final say about which products meet the requirements and practical application of the specific department.



Ill. 5. Ladder of responsibility

As it was determined that the two key areas of sustainable procurement of goods and a circular economy with minimal waste are not under the direct control of the individual region, it is the responsibility of external entities to design procurement goods that meet the specifications and analysis made by the Danish regions and the individual regions. Multiple interviews with nurses indicate that the regional goals are not necessarily reflected in the implementation, verification, and testing of new products at the operational level, and a key takeaway is that the operational level has the authority to reject a product, even if it has undergone all the preceding steps. This means that communication between the strategic and operational levels is essential for developing products that meet both workflow and strategic objectives, and that a lack of specific data from regional analysis, from which specific requirements can be derived, may reduce the incentive for external entities to implement concrete changes for a more sustainable development.

0.3 SINGLE USE PRODUCTS IN DANISH HEALTHCARE

Over the last ten years the use of sterile single use medical products have been increasing significantly, and it can be debated whether it is feasible to out phase the products completely from the Danish hospitals (Johnsen, 2020). Nonetheless, in 2019 the Danish government put forward an ambitious climate law targeting a 70% reduction in CO2 before 2030 compared to numbers from 1990 (Grønne Hospitaler). This has prompted the regions into contributing with additional goals for reducing CO2, amongst which the goal of reducing emission from hospital operations by 50% has been presented. This includes four areas of interest: Climate-friendly buildings, green fuel and optimised transport, sustainable purchasing, and circular economy without waste (Grønne Hospitaler), meaning that the hospitals are now facing a change, where the use of single use products are to be evaluated and optimised.

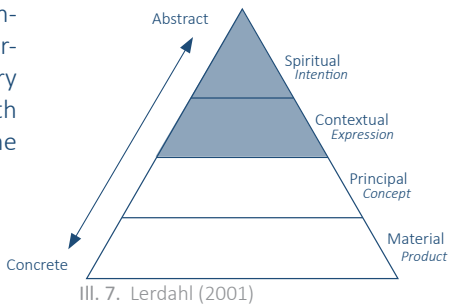
An article from Center for Sustainable Hospitals, states that the use of 40.426 single use suture kits (sewing kits for hospitals) in the Central Denmark Region causes an amount of 3,2 tonnes metal waste each year from this region alone, and analysis show that changing from single use metal suture kits to reusable metal suture kits will save 90% CO2 (Ny analyse: Flergangs-metalinstrumenter 2022). This indicates that a switch to reusable metal instruments is one area, where a significant reduction can be obtained, why the team predicts that this will be implemented over the next period of years.

During research on the subject the team discovered that the reusable surgical instruments that are currently in the system are handled in sterile processing departments that are most commonly an integrated department in the hospital. Here instruments are cleaned and sterilised, then re-packed, and stored to be reused (Sterilcentralen). The team notices the paradox of reusable instruments being packed in single use packaging over and over again, creating an infinite packaging waste, and to gain more information they manage to get in contact with the sterile processing department in Farsø Hospital, which is part of the Aalborg University Hospital.

Ill. 6. Instruments and packaging

PHASE | 1

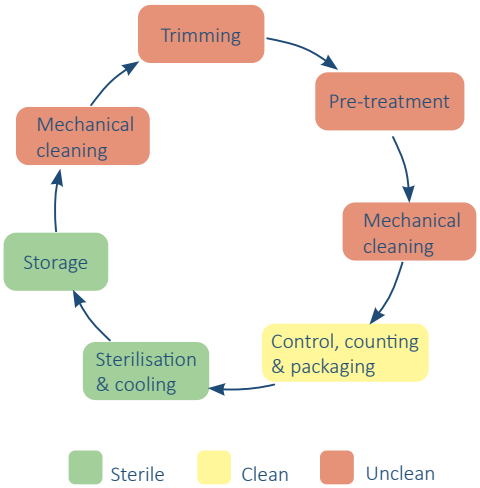
This second phase describes how the team approached initial research involving users. Here the team moved more towards a concrete level in Lerdahl's pyramid, describing the context and the users and obtaining boundary conditions that provided a solid foundation for the wanted interaction with the product, which led to the team setting up an interaction vision for the product.



Ill. 7. Lerdahl (2001)

1.1 STERILISING SURGICAL INSTRUMENTS

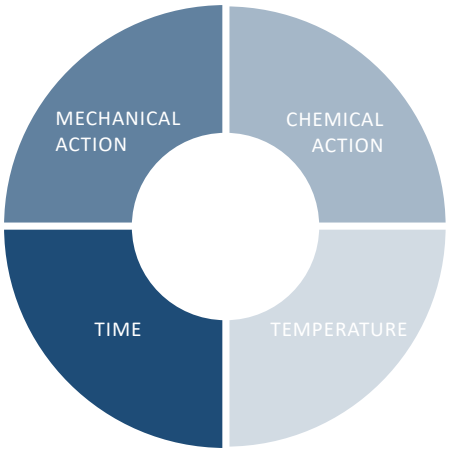
In the preparation for the initial observations at the central sterile processing department (SPD) at Farsø Hospital, the team was referred to the National Infection Hygienic Guidelines (In Danish: Nationale infektionshygiejniske retningslinjer (NIR)) provided by Statens Serum Institut (SSI), which focus on the topic of cleaning reusable surgical instruments and the associated requirements (App. 2). Through NIR it was discovered that the cleaning and sterilisation of instruments is defined as 'retreatment' that encompasses seven main parameters in three separate departments (see ill 8).



Ill. 8. Adapted from Central Enhed for Infektionshygiejne (2019)

SINNER'S CIRCLE

Sinner's Circle (see illu 9) is a model and principle that is utilised in the cleaning of equipment in sterile processing departments. It describes the four variables affecting the outcome of a cleaning cycle; water temperature, mechanical treatment, chemicals and time. These elements are interdependent and it is stated that extending one element will negate the need of another, for instance, it would be possible to reduce the time if the temperature is increased. According to NIR, the preferred method for disinfecting instruments in Denmark is to use high temperatures when possible. Additionally, machine wash is preferred over manual wash as it increases control and validation, while minimising the personnel's contact with sharp instruments and thereby the risk of cuts and injuries. (Central Enhed for Infektionshygiejne, 1. udgave 2019)



Ill. 9. Sinner's circle adapted from Central Enhed for Infektionshygiejne (2019)

SPAULDING'S CLASSIFICATION & SAL

Medical instruments are divided into three categories called the E.H. Spaulding's Classification (Central Enhed for Infektionshygiejne, 1. udgave 2019):

- **Non-critical equipment** *never touches the patient or only touches the patient's intact skin*
- **Semi-critical equipment** *is in contact with intact mucous membranes but does not permeate it.*
- **Critical equipment** *is used in invasive surgical procedures that come into contact with sterile tissue.*

The required level of cleanliness varies depending on the classification shown above. The vast majority of instruments passing through a sterile processing department are classified as 'critical' and must be sterilised as a result. This means that there must be no more than one living microorganism on one unit (instruments etc.) taken from a million sterile units, which is equivalent to a 'sterility assurance level' (SAL) of 10-6 (IBID s.). Even though sterility is essential, it should be noted that it is impossible to prove whether or not a product is sterile. Therefore sterilisation units adhere to a validated systematic method of 'overkill' in which instruments are cleaned, disinfected, and sterilised in three separate steps. (IBID s.)

RISK ASSESSMENT

The staff in the SPD is highly trained in the correct procedures for handling instruments, which is crucial as retreating the instruments requires an individual risk assessment for each instrument. This indicates that even though the system and method seems very rigid, personnel are frequently tasked with determining whether smaller deviations or irregularities in the method comprises sterility. Listed below are instances in which an individual risk assessment should be conducted

- *Before a new procedure is implemented*
- *Before new instruments are purchased*
- *Before new instruments are taken to use*
- *When instruments are omitted, and an alternative product is to be found*
- *When guidelines are to be re-evaluated - national or local*

Additionally NIR is listing examples of what human factors might constitute a risk:

- *The personnel neglects to act according to the guidelines*
- *The personnel acts according to the guidelines, but does it incorrectly*
- *The personnel is acting in way that is not described in the guidelines*
- *The personnel is not sufficiently educated/lacks knowledge*

(IBID s.)

TECHNICAL STANDARDS

Throughout the NIR-report is referred to multiple ISO-certifications that all packaging and products should obtain. Additionally is mentioned the requirement for the material to not affect the instruments in any way, neither their visual appearance or their material properties. This sets some advanced requirements for the material of the product, which can not yet be defined.

TIME & TEMPERATURES

NIR states that the instruments can be mechanically cleaned on three settings and sterilised in a steam autoclave on two settings. This exemplifies how Sinner's Circle is utilised in the SPDs. (IBID s.)

Machine wash programs:	**Steam autoclave programs:**
80°C for 10 minutes *85°C for 3 minutes* *or* *90°C for 1 minute*	*134°C for 3 minutes* *or* *121°C for 15 minutes*

In the report, it is stated that the retreatment process consists of three steps: cleaning, disinfecting, and sterilising. This means that the respective items must be able to withstand temperatures between 80°C and 90°C for an extended period of time, as well as the use of a steam autoclave. This is required to adhere to the validated method of overkill used for critical medical equipment for which a 'sterility assurance level' (SAL) of 10-6 is required.

The detailed flowcharts illustrated the complexity of the sterile processing department, but it is not necessarily a reflection of the actual use-case of a sterile processing department, as personal risk assessment plays a significant role in ensuring the correct validated method of sterilisation. This made it even more important to conduct field research to observe and collect qualitative data on how Farsø Hospital determines whether a retreatment process is approved.

! *To withstand mechanical disinfection (1)*

→ *80-90°C for 1-10 minutes*

! *To withstand sterilisation in steam autoclave (2)*

→ *121-134°C for 3-15 minutes*
→ *A pressure of 3 bar*

! *Must comply with ISO-standards described in NIR (3)*

1.2 STEAM AUTOCLAVATION

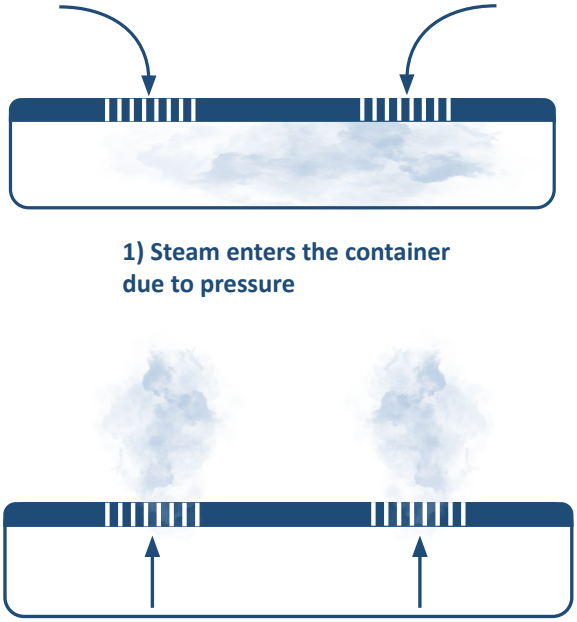
A steam autoclave sterilised instruments by infusing hot steam into the packaging under a pressure of 3 bar. The steam causes bacteria and micro organisms to die and leaves the instruments ready for next surgery. It can compromise the sterility if the instruments are not drying and cooling properly after sterilisation, due the the filters being highly sensitive to moisture.

SIZE OF STEAM AUTOCLAVE

The team measured the room in the steam autoclave in Farsø to being H60 x W60 x L100 cm.

Ill. 10. Steam autoclave in Farsø

Ill. 11. Dustbags



Ill. 12. Steam autoclaving

PACKAGING

The functional principle of packaging for steam autoclavation is an air tight sealing that leaves air to flow in and out the filter when under pressure. The filter absorbs unwanted microorganisms and leaves the instruments sterile and protected after sterilisation. In Farsø they use single use filters, while the container is guaranteed a use of 5,000 use-cycles. The sterility of instruments within each type of packaging has a different shelf lifespan, which can be prolonged to up to 5 years by using 'dust bags'- an extra layer of plastic to go around the packaging after autoclavation. (See illu)

DUST BAGS?

In the SPD in Farsø the team learned that the packaging is packed in yet another layer of plastic to prolong the sterility. Maria explained that this is not commonly done in other SPDs, where the procedure is to retreat the un-used instruments when shelf life expires. In Farsø the estimated shelf life is 2-6 months for sheets and pouches and 12 months for containers.

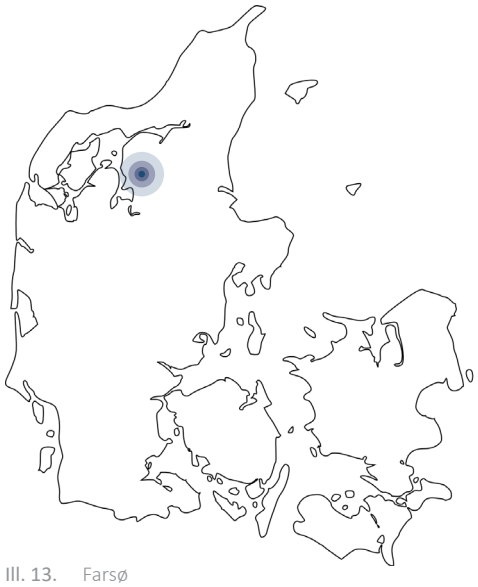
1.3 FIELDWORK IN FARSØ

The team had gained a basic knowledge of what a sterile processing department does and how retreatment functions as a result of the investigation of NIR and the applicable regulations. Nonetheless, there were still a great deal of unknowns regarding what occurs between the primary elements of the process, such as how the instruments are transported? What is the capacity of the SPD at Farsø Hospital? How strictly does the sterile processing department separate the clean and unclean instruments? The team was met by the SPD-nurse Maria Jørgensen in order to answer these 'unknowns'.

FARSØ HOSPITAL

Farsø Hospital is a smaller hospital in the North Denmark Region and a part of Aalborg University Hospital, with approximately 4000 surgeries a year (Informationsfolder om: Farsø Sygehus - en vigtig del af Nordjyllands sundhedstilbud 2018). At Farsø Hospital, the staff in the SPD consists of two nurses and four social and healthcare assistants (SOSA), where the nurses also function as the local procurement agents for the SPD and decide what new equipment is acquired by the hospital. This results in an exceptionally close relationship between the operational level and the administrative/strategic level within the hospital, which is just one example of how Farsø Hospital sets itself apart from other, larger hospitals.

In addition, Farsø Hospital has taken a number of steps to become more sustainable and reduce waste, such as sorting the majority of its plastic waste for a local plastic company, Genplast, to collect and recycle, and transitioning to almost exclusively reusable surgical instruments. This may be due to the fact that Farsø Hospital primarily performs scheduled surgeries, resulting in less pressure on the emergency room (ER) than AAUH, Aalborg. According to the ladder of responsibility (c.f Ladder of responsibility), the initiatives of Farsø Hospital appear feasible due to the direct communication and mix of responsibility between the various departments, which is not the case for larger hospitals such as AAUH, Aalborg.



Ill. 13. Farsø

PACKAGING & INSTRUMENTS

Depending on the type of instrument kit being packaged, the sterile processing department at Farsø Hospital has three options for packaging. Surgical instrument kits vary significantly in both complexity and size, as each kit serves a unique purpose. Large, medium, and small kits and solo instruments are packaged in metal trays wrapped in plastic sheets, aluminium containers, or autoclave pouches.

Ill. 14.

Ill. 15.

Ill. 16.

Large complex instrument kits (40< cm)
The large and complex instrument kits often contain a variety of smaller items in various sizes , allowing the surgeon to determine which size is the best fit for the patient. Each item in these kits is fixed to a specific location.
When purchasing these types of instrument kits, a reusable perforated metal tray that is specially fitted to that exact kit will be included. New items, e.g., screws and braces, are added to it as they are used in surgery. These kits are wrapped in two layers of single-use SMS-plastic sheets made of polypropylene (Sterile Barrier Systems 2023), with the outer layer classified as 'clean' and the inner layer as 'sterile'. These sheets function as a filtering membrane that allows steam and air to pass through while preventing contamination by microorganisms.


Ill. 17. Sheets

Medium large instrument kits (25-40 cm)
Reusable aluminium containers are used for medium or large instrument kits with lower complexity and larger solo instruments. These containers include a lid with a disposable filtering membrane that must be replaced after each use cycle, a bottom component, and an inner perforated tray. Some of the most important functions of the container is to seal it airtight, with the filter serving as the only entrance and exit for air and steam.
For medium sized or large instrument kits with lower complexity and larger solo instruments, reusable aluminium containers are used. These containers consist of a lid with a single-use filtering membrane that is to be changed once every use-cycle, a bottom part, and a perforated inner tray. The most important job for the container is to seal airtight, making the filter the only entrance and exit for steam and air.


Ill. 18. Containers

Small instrument kits & solo instruments (25> cm)
The small instrument-kits and solo instruments with low complexity are packed in single-use sterilisation pouches in composite plastic and Tyvek fabric, which functions as the filtering membrane (Factory price tyvek pouch material). After the pouch is packed with one or more instruments, it is sealed, much like a sous vide machine, and lined up in an additional tray with either plastic against plastic or fabric against fabric, allowing the optimal autoclaving and cool time.


Ill. 19. Pouches

THE INSTRUMENT-LOOP

As indicated by NIR, Farsø Hospital was divided into unclean, clean, and sterile zones for cleaning, disinfecting, and sterilising surgical instruments (c.f. 1.1 Sterilising Surgical Instruments). In the unclean zone, instruments are cleaned manually with rinsing water and brushing, and occasionally with an ultrasound basin if necessary, before being loaded onto machine racks (similar to dishwashers) and cleaned by a machine programme at 80-90°C for 1-10 minutes (Central Enhed for Infektionshygiejne 2019). With the use of a pass-through lock door, the instruments are transferred directly from the washer to the clean department, where they are dried and then thoroughly inspected for defects and imperfections.

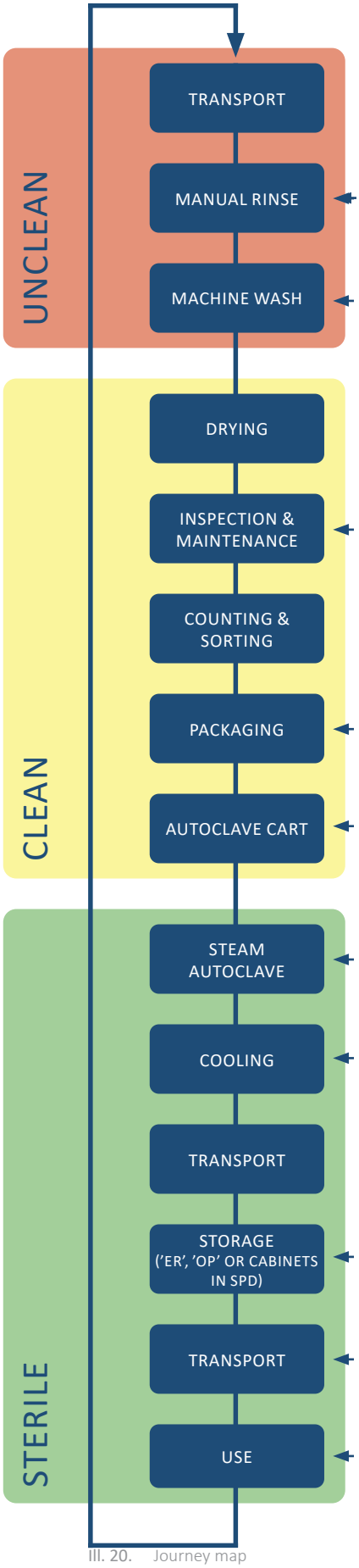
Once the instruments have dried and been through a control check, they are gathered and packed in accordance with specific packing lists. The packaging is sealed and labelled, allowing the content to be scanned and thereby tracked throughout the system. All packaging contains visible chemical indicators that reveal whether or not the package has been autoclaved. The instruments are then loaded onto a cart for the steam autoclave. The various packaged instruments are packed as closely as possible to maximise the space in the autoclave.

The trolley is then pushed into the steam autoclave, and the instruments are sterilised for 3 minutes at a pressure of 3 bars and a temperature of 134° C. Other sterile processing departments use a programme of 121° C for 15 minutes; temperature and time are interdependent, as described by Sinner's Circle (c.f. 1.1 Sterilising Surgical Instruments).

After autoclaving, the instruments are transferred directly into the sterile department to cool down. During this time the autoclave pouches and wrapped trays are sensitive to touch that harbours undesirable microorganisms.

After cooling, the packages are transferred to clean storage, where the aluminium containers and wrapped trays are primarily stored in closed movable cabinets and the pouches are either stored in the sterile department, in movable cabinets, the emergency room (ER), or the operating room (OP). The instruments' sterility has a limited shelf life during storage. If the shelf life has expired, the instruments are transported to the sterile processing department, where they are repackaged.

When it is time to use the instrument kits, the complete cabinet for the surgery in question is retrieved from storage and moved to the preparation room. Here, the surgery nurses, also known as OP-nurses, remove the instruments they require and return the packaging to the SPD's unclean department to be scanned and then discarded.

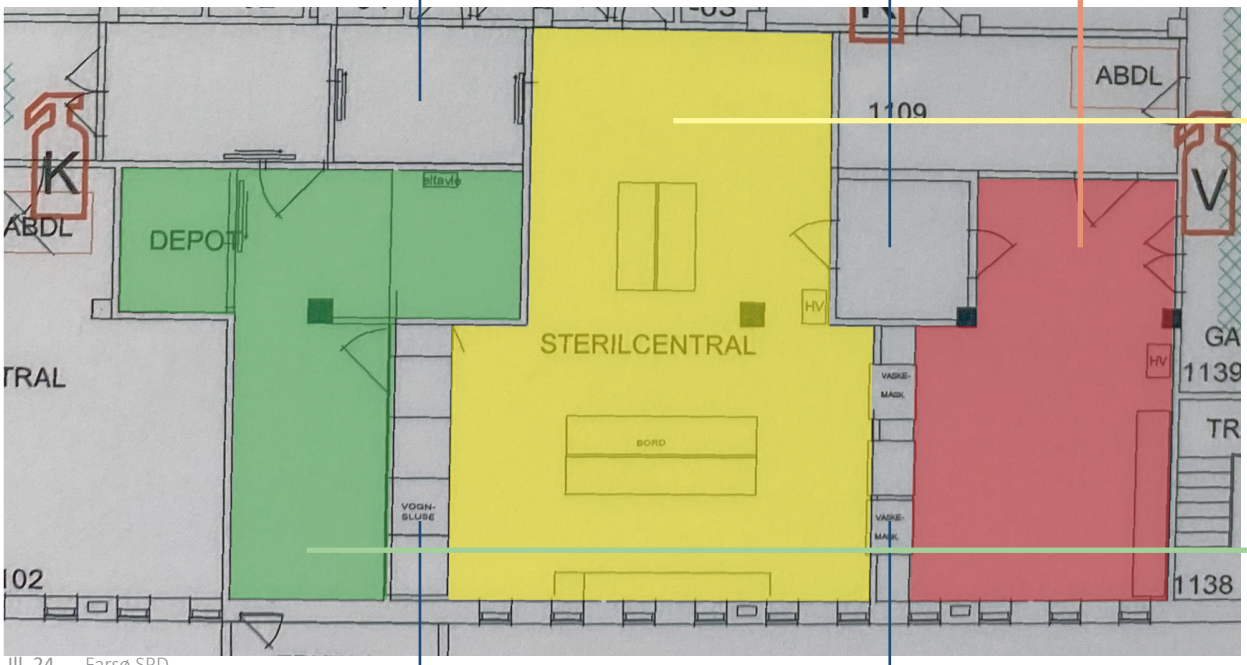


Ill. 20. Journey map

THE SYSTEM

The system in the sterile processing department of Farsø is very carefully planned out, and it is a context where details matter. To the left (see ill X) is an overview of the department that consists of a sterile, clean and an unclean under-departments. Every room is connected by a lock in a machine; either the machine washer or the steam autoclave. Personnel are to pass through the departments in separate locks, that regulates air pressure in a way that controls microorganisms in the air and ensures that the sterile and clean departments stay uncontaminated.

Ill. 21. Passage between zones

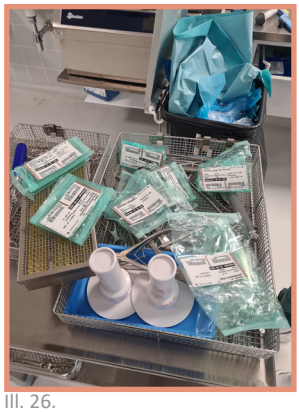


Ill. 24. Farsø SPD

Ill. 22. Lock to the sterile zone through the steam autoclave

Ill. 23. Lock to the clean zone through the mechanical wash

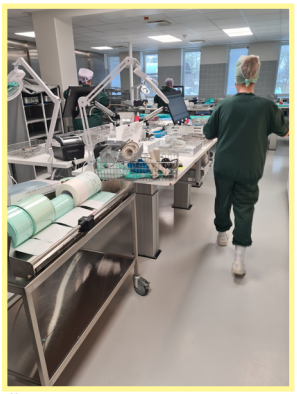

Ill. 25.


Ill. 26.


Ill. 27.


Ill. 28.


Ill. 29.


Ill. 30.


Ill. 31.


Ill. 32.


Ill. 33.


Ill. 34.


Ill. 35.


Ill. 36.

After observing the rigid system in the SPD, the team was aware that some parameters of the context were not to be changed and that a product proposal would have to adapt in order to become a valid solution. These parameters would for instance be dimensions of the machine washer racks and the steam autoclave.

! *To accomodate the current (physical) system (11)*

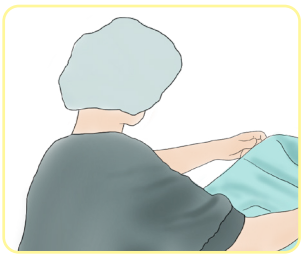
→ *Must fit the racks of the mechanical washer*

→ *Must fit into the steam autoclave*

→ *Must fit into cabinets for transport and storage*

WHAT HAPPENS DURING SURGERY?

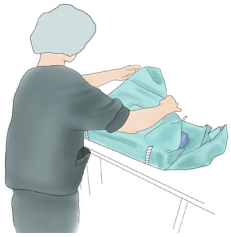
Naturally, the team had many questions regarding how each packaging type was handled outside of the SPD. A brief meeting with Anne Marie Brix, one of the senior OP-nurses at Farsø Hospital was arranged. It was described how the OP-nurses in the operating room handle each type of packaging and the respectable challenges they face. It is essential to note that OP-nurses work in pairs, with one nurse being 'clean' and the other 'sterile' (App. 3).

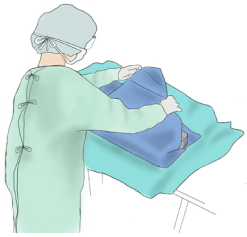


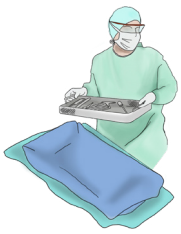
Clean OP-nurse (No gloves)

Sterile OP-nurse (Gloves)

Ill. 37. Scenario with sheets



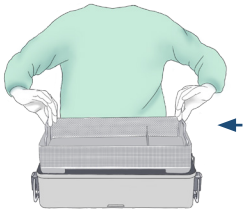




Sheets

The clean nurse will open the green outer sheet and step away. Then the sterile nurse will open the inner blue sheet and transfer the tray with instruments to a trolley covered by a sterile cover-sheet. The sterile nurse will then open the trays and make sure all instruments are easily accessible during surgery and move the table into the surgery room.

Ill. 38. Scenario with container

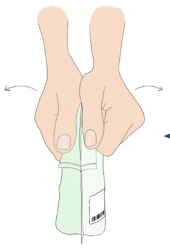


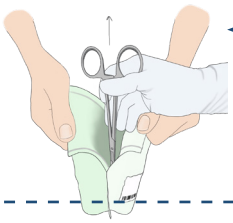
Awkward lifting causes strain

Container

A clean nurse opens the clamps and lifts the lid towards his or her own body when opening the container in order not to reach over the sterile instruments. If the clean nurse reaches over the sterile instruments, the whole set would be considered unclean and would be transferred to the SPD. Then a sterile nurse wearing gloves will take out the inner tray with instruments and take it to the surgery room.

Ill. 39. Scenario with pouches





Wobbly, non-rigid structure causes instability

Slippery, small interface causes strain

Pouch

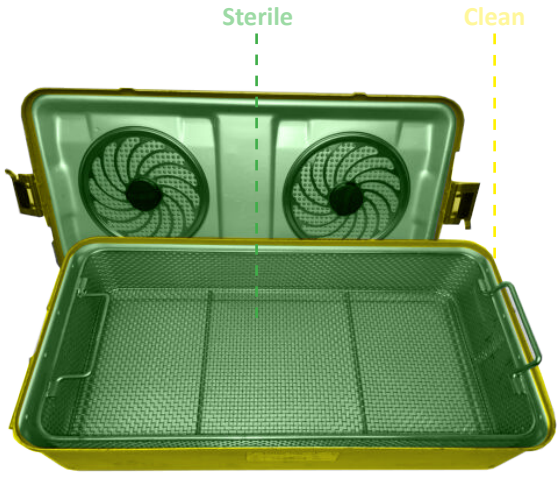
As is the case with the sheets and containers, two nurses, one clean and one sterile, are required to open the autoclave pouches. The clean nurse will place his or her thumbs and index fingers on each side of the opening and pull it open while supporting the instruments in an upright position. Then, a sterile nurse will remove the instruments from the packaging without touching the pouch and take them to the operating room.

Complications

Anne Marie explained how both the containers and the pouches can be a challenge to handle for the OP-nurses. The edge on the container, where the lid seals to the bottom, is dividing the clean from sterile areas of the container (See illu. 40). The inner-tray and the inner surface of the container is categorised as sterile, while the outer surface is categorised as clean. This implies that the sterile nurse handling the sterile inner tray must avoid touching the outer surface or the edge where the transition from clean to sterile occurs, as she must remain sterile. If she does touch the clean area, she will need to change gloves, clothes, and the instruments will be exchanged for a new packaging. To avoid touching anything other than the sterile interface of the handles, nurses lift the inner-tray and instruments in an awkward position with the back of their hands facing each other (See illu 38), which causes strains as the tray is often heavily loaded with numerous surgical steel instruments.

Anne Marie explained that the material is extremely slick, necessitating a great deal of effort and force to maintain a grip and pull the plastic open. Many nurses suffer from hand pain and injuries as a result of performing this task numerous times per day. Therefore, they are emphasising teaching new nurses to use their entire hand when grasping the pouches and not just using their thumbs and index fingers.

The procedure is extra straining as the nurses have to be very careful not to compromise the sterility when opening the packaging. Here it is important that the instruments are not tilting over the edge of the packaging whilst being pushed up from the packaging, just enough for the sterile nurse to grab them and lift them out without touching the edge of the pouch.



Ill. 40. Zones of cleanliness on the container

! *To minimise risk of contamination by enabling the OP-nurses to handle securely (12)*

→ *Must allow for OP-nurses to lift with palms of their hands facing each other*

→ *Must have interfacing with a suitable size and texture/grip*

Based on observations and interviews with Maria from SPD and Anne Marie from OP, the team was able to identify the main areas where the current packaging types are inadequate:

• The types of single-use packaging, being the sheets and pouches, contribute to the hospital's waste production, whereas the pouches are not recyclable.

• The container and pouches create an awkward and straining workflow for the OP-nurses, which ultimately compromises sterility and safety.

• Containers can't be used for every instrument kit as they take up a lot of storage space when empty.

The information gained from the situated interview and acting out (Sperschneider & Bagger, 2003), allowed the team to list the initial set of user-needs from different stakeholders (App. 4).

WHY ARE POUCHES NOT RECYCLED?

The local collector of plastic waste from Farsø Hospital is the company, Genplast. The team contacted Genplast to ask why the recycling-firm does not want to collect plastic from the autoclave pouches. Here it is explained that the pouche's transparent side is made from multiple layers of varying plastic types, making it impossible to recycle. The reason for this most likely is that the material should be welded to the Tyvek fabric while withstanding pulsating pressure in the autoclave along with punctures and cuts from the instruments.

1.4 COLLECTING DATA

After the visit to Farsø the team had observed two problem areas with the packaging for reusable instruments that are retreated, but the project still required a more specific framing. In order to define an initial framework, the team conducted research to describe the hypotheses and relationship between instrument kit quantities and the use of each packaging type. No concrete data demonstrated the distribution of use across the various instruments and packaging types, leading to alternative methods.

By contacting the Centre of Sustainable Hospitals (CFSH) in the Central Denmark Region, the team was met by the project manager Lærke Dahl to determine whether they could point the team in the right direction or provide additional insights. Lærke was kind enough to provide the team with a recent, unpublished report on packaging within the sterile processing department that she had created. This report compared the use of sheets and containers for large instrument kits, focusing primarily on the parameters of cost and CO2-e emission and taking into account the entire most of the use cycle, which includes manual and machine washing of the containers, but excludes autoclaving.

Lærke also referred to Mathias Sehested, an additional manager at CFSH who is currently working on a project involving metal instruments and sterilisation units and therefore has contacts with a number of other sterile processing departments in the Central Denmark Region. Mathias reported that they had decided to focus their project on suture kits, which are typically small instrument kits packed in autoclave pouches. In addition, he presented some of the findings from their analysis, which revealed that the switch from single-use to reusable suture kits saves 27.600 kg of CO2, which is equivalent to a 90% reduction, and that the packaging for reusable suture kits is responsible for 30% of the total CO2-e emission.

Even though their project focuses exclusively on the instruments, there is an indicative figure, that packaging is a large part of the overall CO2-e emissions within Danish hospitals, as every smaller reusable instrument or set is packed in autoclave pouches. When asked what he considers to be the greatest challenge in the transition from single-use to reusable instruments, Mathias responded, "*Capacity is by far the greatest obstacle. The established sterile processing departments have already reached their maximum capacity, and it will be costly to add new buildings, machines, personnel, etc.*" Unfortunately, he was unable to pass on the unpublished report, and he had limited access to other sterilisation units.

920 kg CO2-e/year*

From single use packaging for reusable suture kits in Central Denmark Region

*Calculations in WS. 5

"Capacity is by far the greatest obstacle. The established sterile processing departments have already reached their maximum capacity, and it will be costly to add new buildings, machines, personnel, etc."

- Mathias Sehested, Project manager at CFSH

After immensely trying to find data describing the use-distribution of instruments and packaging types, the team ended up relying on establishing new contacts, which was both time consuming and uncertain. To find an argument for which type of instrument kit to take as starting point, the team discussed the possibility of gathering information from other Danish hospitals as a part of a triangulation process (Carter et al., 2014) in order to obtain a more complete picture of the nurses' potential pains and unmet needs and to design a product proposal with a long lasting user-fit (Haase & Laursen, 2019). As no other hospital could be reached and the project timeline was evaluated, it was decided to stop the diverging and top-down approach (Maxey, 2012) and spend time understanding the complexities of the case at Farsø Hospital first.

Ill. 41.

1.5 FRAMING

The scope of the project had been narrowed down to Farsø Hospital, but the complexity of the problem and the stakeholders' correlation had the team struggling to find a suiting approach to address a concrete problem. Creating customer profiles (Osterwalder et al., 2014) for each stakeholder was attempted as a way of navigating potential value propositions within each type of packaging. In this chapter the team sought to understand what should be done in order to "do the right thing" and become able to "do the things right".

CUSTOMER PROFILING

By limiting the scope of the project to Farsø Hospital, the team aimed to develop a value proposition that met their specific requirements. Using a participatory mindset (Sanders & Stappers, 2008), a customer profile was created with the assumed and identified jobs, pains and gains (App. 6) in order to establish a baseline for conversation and co-creation process with the two primary stakeholders at Farsø Hospital. (Sanders & Stappers, 2008)

It was anticipated that it would be possible to frame the project with all three packaging types in order to determine which had the most potential for initial concept development. Initially, it was believed that there would be five separate stakeholders at Farsø Hospital. The primary stakeholders, being the SPD- and OP- nurses, and secondary stakeholders including porters, cleaning personnel, and procurement agents,

1. Nurses in the SPD (SPD-nurses)
2. Nurses in the surgical department (OP-nurses)
3. Purchasers
4. Cleaning staff
5. Porters

with the SPD-nurses and procurement agents at Farsø Hospital being the same individuals. (App. 4)

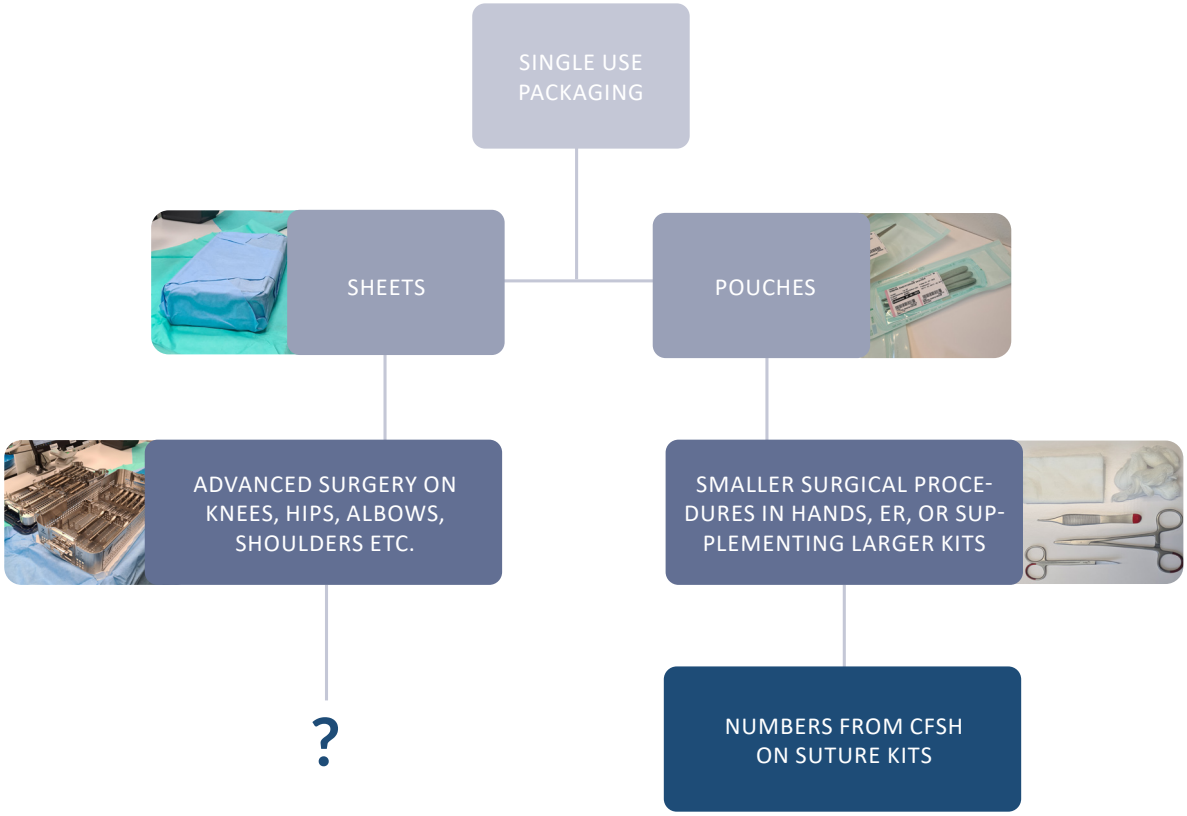
The primary stakeholders, being the SPD- and OP-nurses, and secondary stakeholders including porters, cleaning personnel, and procurement agents, with the SPD-nurses and procurement agents at Farsø Hospital being the same individuals. (App. 4)

The stakeholder's observed and assumed jobs; functional, social, and emotional jobs, gains and pains were enumerated and ranked for each type of packaging (sheets, containers and autoclave pouches) to produce five distinct customer profiles (App. 7). The relatively large number of stakeholders along with the three types of packaging resulted in the system's complexity increasing proportionately, and indicated a system permeated with interdependencies and clearly defined boundary conditions. It was noted that several of the pains and gains were related but prioritised/ranked differently for each stakeholder, but the activity did not supply more overview or basis to choose one packaging type as focus.

CHOICE OF DIRECTION

To define a customer profile and thus, a value proposition, the team needed to structure the problem and identify the core-problems within a specific packaging type. The initial objective of the project was to reduce waste generated by single-use healthcare products. Therefore, the feasibility of designing a reusable alternative to fit both single-use autoclave pouches and sheets was investigated, despite the fact that autoclave pouches are primarily used for small instrument-kits and solo instruments and sheets are used for large instrument-kits that include metal trays that are purchased alongside the instruments (refer to 1.2 Fieldwork at Fars Hospital).

Even though the team had specific data on the autoclave pouches and suture sets from CFSH, a comprehensive session of desk research was initiated to determine the extent of the CO2-e impact that small to large instrument sets and sheets had. A process that proved to be extremely difficult, as no specific statistics on other instrument kits or sheets were to be found at the time. This was partially due to the instruments abbreviated names and partly due to their extreme specificity and complexity of the topic. As a consequence the team returned to the information already provided by Mathias from the Centre for Sustainable Hospitals regarding the analysis of a transition to reusable suture kits, which are known to be packed in autoclave pouches (c.f. 1.3 Collecting Data).



Ill. 42. Choosing suture kits

While including all three packaging types and discovering the coherence and interdependencies across stakeholders, the team encountered an overwhelming level of complexity, and the need to define a problem frame (Haase & Laursen, 2019) became evident. To reduce complexity, the team chose to focus on a concept proposal aiming to replace the use of autoclave pouches, with a starting point in suture kits, as this was an instrument kit that was both manageable in size and complexity while possible to obtain data on thanks to the project in CFSH. Furthermore, the team was able to source a single use suture kit from Farsø Hospital that could be used for testing and further development. Discussing the pains and gains extracted from the needs of both groups of nurses at Farsø Hospital created clarity of additional requirements, and with the scope narrowed down the team could now revise the pains and gains specifically to fit in relation to the pouches.

Focus on autoclave pouches and suture kits.

Ill. 45. Single use suture kit

WHAT IS A SUTURE KIT?

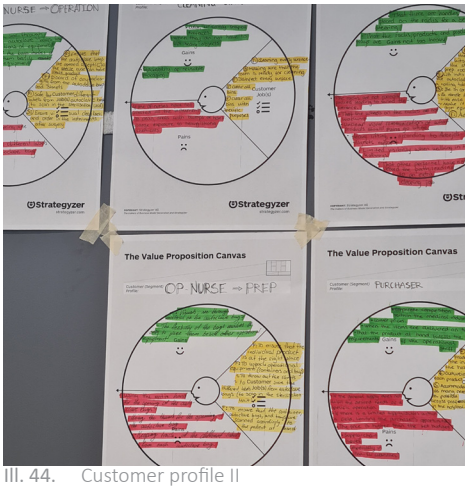
A suture kit is a sewing kit for hospitals used in all surgeries no matter their size. The kit consist of a pair of scissors, a pair of pliers to hold the needle and a tweezer, along with sterile cloth. The suture kit is falling under the category 'small instrument kits' in the three instrument sizes defined by the team:

Small instruments: 25> cm **Medium instruments: 25-40 cm** **Large instruments: 40< cm**

KEY DILEMMAS

After choosing to focus on autoclave pouches, the team resumed the creation of customer profiles with a focus on the pouches before beginning concept development of a new reusable solution (App. 7). The jobs, pains and gains were relisted and ranked for each stakeholder/user. The exercise was still based on assumptions derived from the first field excursion to Farsø Hospital, but narrowing down the packaging types aided in the prioritisation and specification based on assumptions. Only two primary stakeholders (SPD- and OP-nurses) had been contacted, and the team had only spoken to one of three secondary stakeholders (Procurement agents). Using the journey map (CF. journey map) in conjunction with the construction of customer profiles, the exercise revealed that the relationships between the various stakeholders and the autoclave containers were not necessarily the same. This prompted the team to identify the most significant dilemmas and potential conflicts of interest among the various stakeholders.

Ill. 43. Customer profile I



Ill. 44. Customer profile II

Based on the customer profiles key-dilemmas in the project were formulated:

1. The bag's lack of rigidity is an advantage for the sterile processing department, but an inconvenience for the OP-nurse.

2. A reusable packaging solution would reduce hospital waste in accordance with regional goals, but increase the sterile processing department's physical workload and need for storage space, necessitating system adjustments that could lead to the operational level potentially discarding a new solution.

DESIGN BRIEF 1

	Need	Origin	Imp.	Spec.	Origin	Metric
1	To withstand disinfection	Sterilising surgical instruments	1	Must withstand mechanical wash.	SSI	Must withstand: 80°C for 10 minutes 85°C for 3 minutes 90°C for 1 minute
2	To withstand sterilisation	Sterilising surgical instruments	1	Must withstand a steam autoclave.	SSI	Must withstand: 134°C for 3 minutes 121°C for 15 minutes
						Must withstand a pressure of 3 bar
3	To meet current standards and regulations	Sterilising surgical instruments	1	Must comply with ISO-standards described in NIR	SSI	DS/EN ISO 11607-1, 14937:2009, 10993-1:2009, 11138, 14161, 15882, 11140, 17664, 868-2
4	To not have hollow holes or spaces that cannot be rinsed through	The instrument loop	1			
5	To be able to open and disassemble for cleaning	The instrument loop	2			
6	To be space-efficient when stored empty	The instrument loop	2			
7	To include visual indicators that the package has been sterilised	The instrument loop	1			
8	To include spot for labels to track instruments	The instrument loop	1			
9	To utilise room in the autoclave	The instrument loop	2			
10	To allow for instruments to be sterilised by steam	The instrument loop	1			
				Must be sealed air tight	Steam autoclavation	
11	To accomodate the current (physical) system	The system	3	Must fit the racks of the mechanical washer		
				Must fit into the steam autoclave		
				Must fit into cabinets for transport and storage		
12	To minimise risk of contamination by enabling the OP-nurses to handle securely	What happens during surgery?	3	Must allow for OP-nurses to lift with palms of their hands facing each other		
				Must have interfacing with a suitable size and texture/grip		

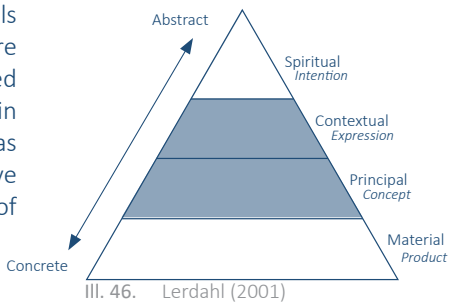
After the initial research of the context in the SPD and OP, the team was able to set up an interaction vision describing the to be scenario that the team aimed to create. (WS 7)

Interaction vision for the OP-nurses:
Natural, like filling a glass of water
Confident, like knowing the lyrics to your favourite song
Reassuring, like having an airbag in the car

Interaction vision for the SPD-nurses:
Systematic, like checking chores off a list
Secure, like a quality bike lock
Convenient, as a cutlery tray in your kitchen drawer

PHASE | 2

Through sketching the team moved towards the principal level of Lerdahls pyramid. Here specific principles for function and form took shape and were evaluated in cooperation with the users. This shows how the team moved between the contextual and principal level by understanding the concepts in their context with the nurses. The team found that the level of innovation was adjusted in the products as the concepts were developed, and the innovative elements became incremental but had a significant influence on the use of the product.



Ill. 46. Lerdahl (2001)

2.1 SKETCHING

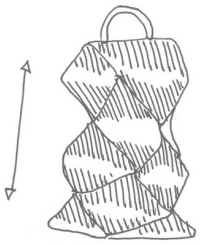
The process of sketching took place concurrently with collecting data. This chapter shows how the team moved from a mindset of creating radical innovation to the SPD to discovering that boundary conditions called for a more conservative approach.

BRAIN POOL WRITING

In parallel with research and collecting data, an initial collective brainstorm-sketching was used to explore and visualise potential new and innovative principles. With a brain pool writing approach (Tollestrup, 2004), the team openly sketched random ideas for a limited set of time and shared the ideas to gain inspiration from each other. This exercise functioned as a way of emptying the mind and sharing how the individual members' perceived a potential solution space. At this point in time, the team had not chosen a specific instrument set, which resulted in a variety of shapes as illustrated (illu. 47-51)

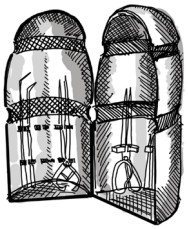
The main takeaway was that the group would have to decide to work with either small or large sets. Smaller instrument sets, such as suture kits were chosen based on the existing acquired data and the fact that Farsø Hospital provided the team with a smaller suture kit, making it a tangible starting point.

Based on this decision it was possible to sketch and generate ideas in a more structured manner that suited the preliminary boundary conditions, where each functionality was considered in respect to the journey map.



Ill. 47.

Ill. 48.



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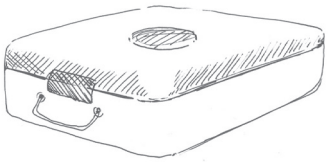

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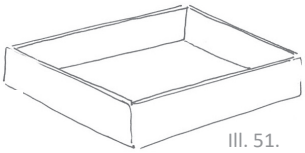
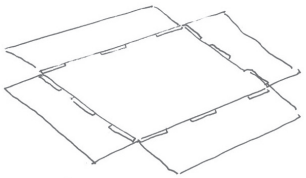
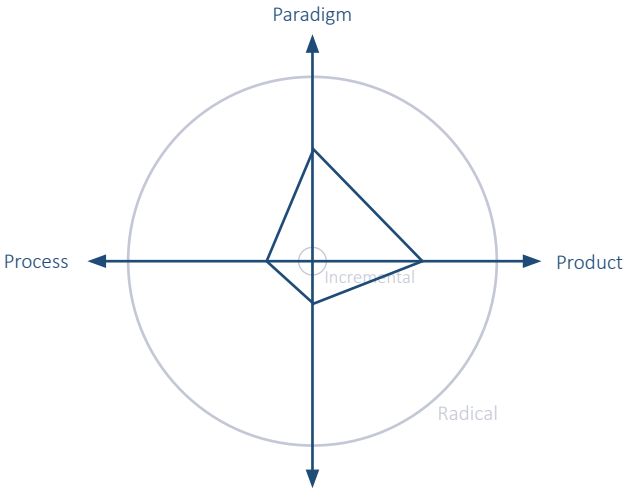


Ill. 51.



4P-MODEL

To visualise the development in the team's comprehension of the targeted concept proposal the 4 ps of innovation is utilised (Gonzales et al., 2023). Initially the team explored a variation of shapes and principles to make a compressible product proposal that could fit the limited room capacity in the SPD. Here the concept sketching was without limitation from boundary conditions, mostly driven by the need to be space efficient, which was prioritised as an important need. The team the incentive to consider a paradigm innovation where the change from single use packaging would bring small changes in the workflow.

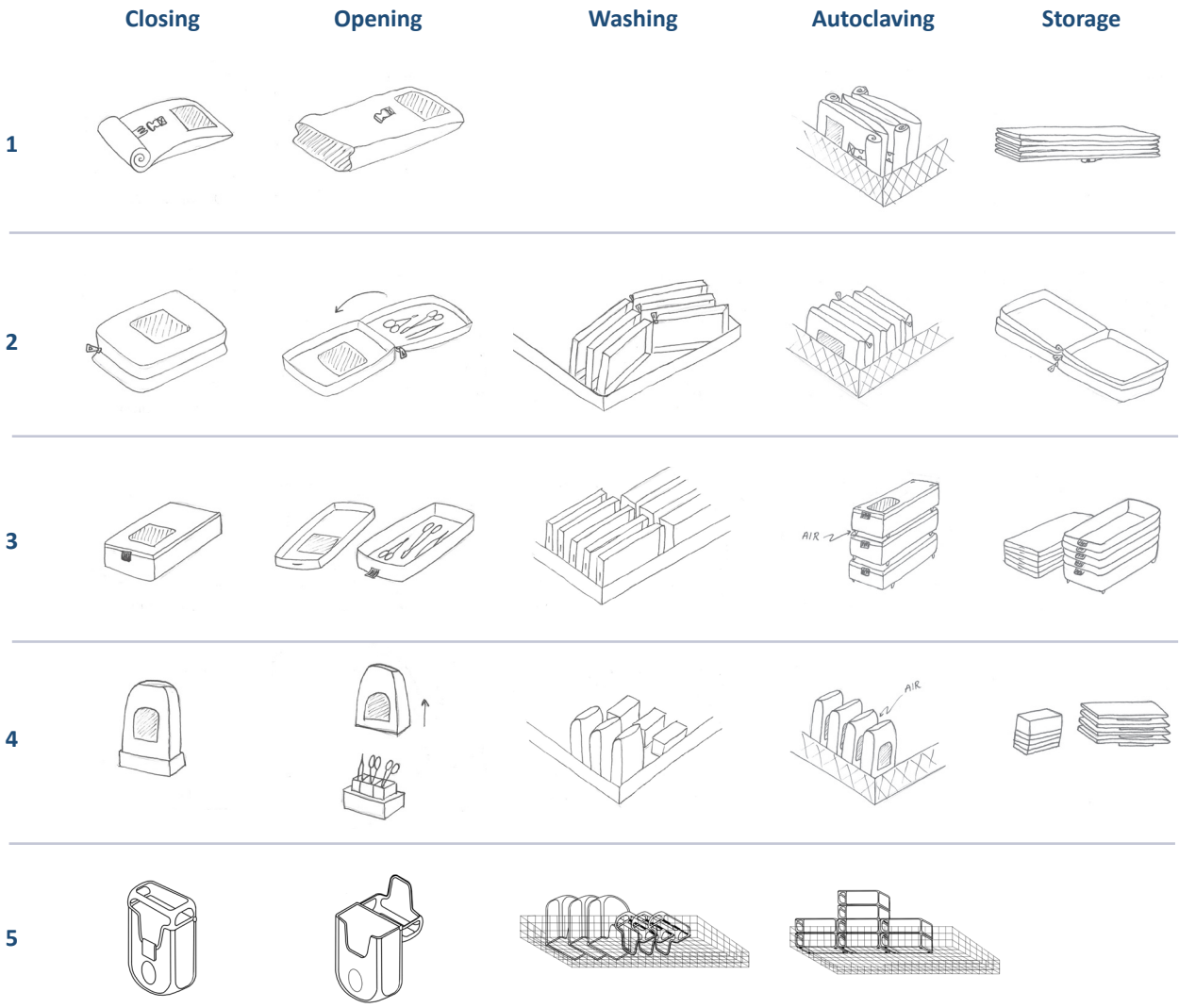


Ill. 52. 4P model I

FOCUSED SKETCHING

Based on the decision to work with small instrument kits with a starting point in suture kits, it was possible to focus the ideation process and generate ideas in a more structured manner that suited the preliminary boundary conditions, where each functionality was considered in respect to the journey map. Here the scenarios were: Closing mechanism, opening an aseptically removal of tools, machine cleaning, loading in autoclave(How does steam enter the packaging?) and the general storage when not in use. (App. 9)

Several of the concepts focused on accomodating a balance in key-dilemma no. 1 (C.f. Framing), by combining rigidity with flexible elements.

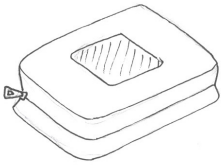


Ill. 53. Structured sketching

Each concept was evaluated based on its strengths and weaknesses of the functional principles:

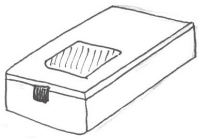
1. A soft silicone bag with a roll-top closure

The packaging may not have an airtight seal and may be difficult to clean in a washing machine. In addition, the instruments would be less accessible to the OP-nurses, as the sterile nurse would have to either stick his or her hands into the bag or have the clean nurse push them out from the bottom. On the other hand, the soft material would make it compressible and stackable, requiring minimal storage space.



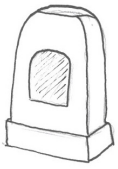
2. A soft silicone bag with a full opening and a zipper closure

The team acknowledged that it may be difficult to have an airtight seal with a zipper and discussed alternative methods of sealing a bag. Moreover, the nurses would have easy access to the instruments, but the team discussed if the movement of opening the lid would result in moving a non-sterile surface across the sterile instruments and cause the entire packaging to become contaminated.



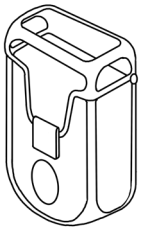
3. A small container

The container had already demonstrated its viability in larger sizes, and the team was aware that the reason they were being used for other purposes was because of the SPD's space constraints. This concept optimises storage by stacking, but the team was uncertain as to whether the instruments could be removed from the small container without a tray.



4. Foldable top and rigid bottom

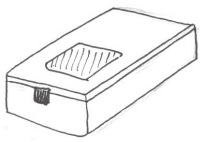
The team saw an opportunity to save space in the SPD by combining folding and stacking in storage and attempting to combine a softer material with a rigid shape in an attempt to solve one of the key-dilemmas of rigidity (refer to customer profiling). In addition, the sterile nurse would have easy access to the instruments, ensuring an aseptic opening.

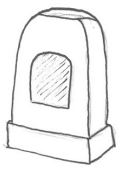


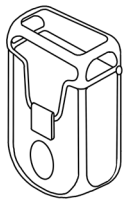
5. Standing container with hinged lid and see-through window

Attached to the bottom lid, the standing container would transform into a rigid autoclave pouch that serves as storage for the individual instruments, making the instruments more accessible and enhancing control during the aseptic opening. Ideally, it would conserve space in the autoclave and the SPD due to its ability to be stacked flatly on the shelf.

The team selected concepts three, four, and five for further development after evaluating each concept in relation to the journey map and predetermined requirements. This was determined based on the concepts' ability to meet the requirements in each of the five scenarios, with concepts one and two being discarded due to their lack of an airtight seal and the assumed difficulties in retrieving the instruments aseptically.







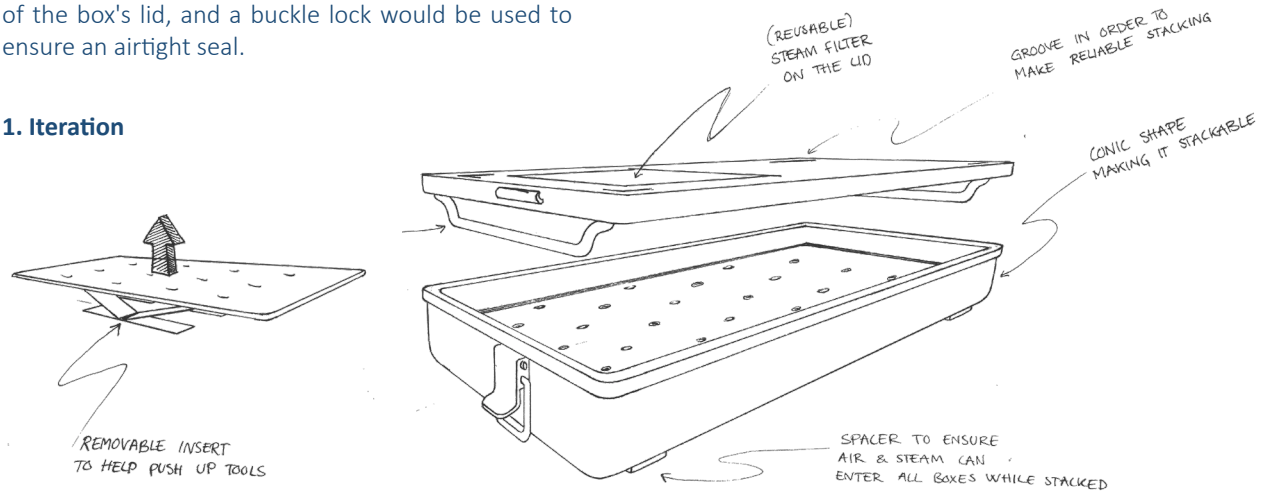
2.2 DETAILS & MOCK-UPS

More detailed sketches were created before building mock-ups. Each concept was illustrated with zooms of the most important functional principles

THE CONTAINER

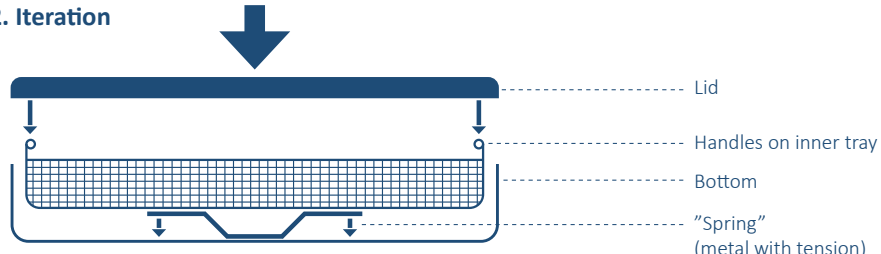
The distinctive characteristic of the container is its bottom, which featured a metal "spring" that would lower the instruments when closing the lid. When opening the container, the spring would elevate the inner tray containing the instruments, making aseptic opening simpler. A rubber strip would seal the edge of the box's lid, and a buckle lock would be used to ensure an airtight seal.

1. Iteration



Ill. 54. Container concept, 1. iteration

2. Iteration



Ill. 55. Container concept, 2. iteration

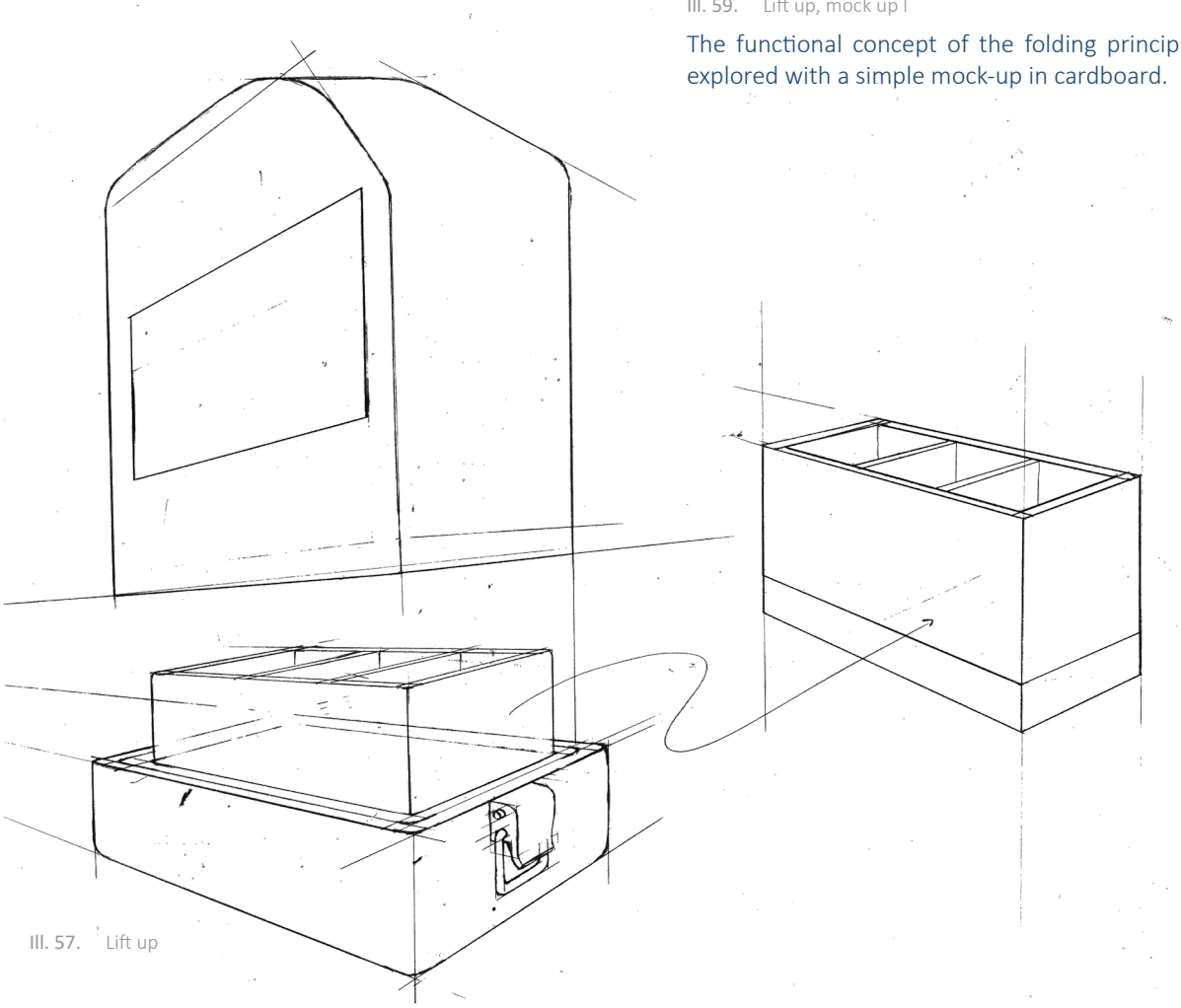
Ill. 56. Container concept, mock-up

LIFT UP

The concept of lift-up packaging combined folding principles in the lid with a rigid, stackable base. The instruments would be held in a stable position for the nurse to grab and retrieve aseptically, with a transparent middle section providing nurses with visual indicators of the instruments contained within.

Ill. 59. Lift up, mock up I

The functional concept of the folding principle was explored with a simple mock-up in cardboard.

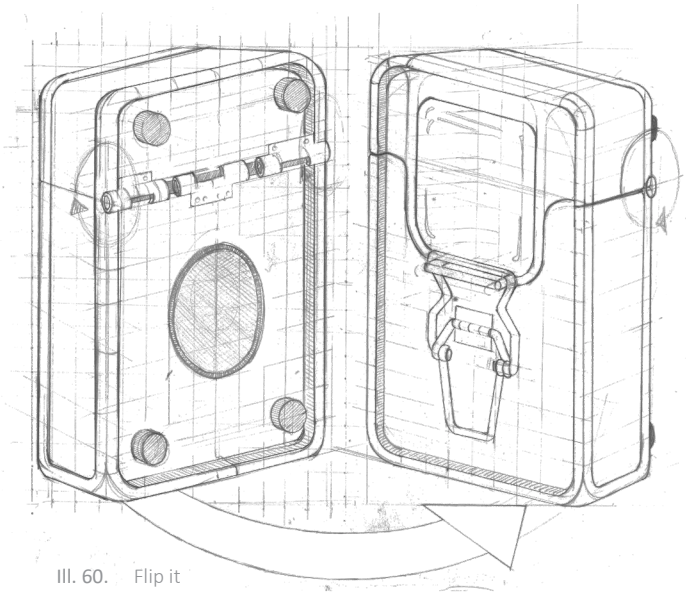


Ill. 57. Lift up

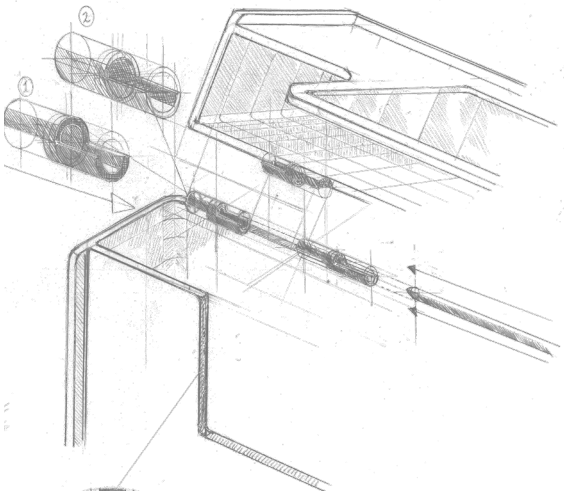
Ill. 58. Lift up, mock up II

FLIP IT

A cleaning-friendly concept in which the lid is attached with a hinge to the base and can be separated during cleaning. Additionally, it featured a filter on its back and a transparent window on the front for visual cues about the instruments inside. The concept would be handled in an upright position, but should be stacked in the autoclave on its back, which is why legs were added to the back.



Ill. 60. Flip it



The concept of flip it did not have an inner compartment to remove with the instruments, but top-part shaped to make them easy accessible. Furthermore, the hinges should be easy to disassemble.

Ill. 61. Flip it, mock up

2.3 SECOND FIELDTRIP

A second visit to Farsø Hospital was planned in order to obtain feedback on the three concepts from the two key stakeholders, the SPD and OP nurses, reevaluate the assumed jobs, pains, and gains with both stakeholders, and observe the work in the sterile processing department in order to obtain additional requirements for future concept development.

PAINS & GAINS

By discussing the assumed jobs, pains, and gains, it was envisioned to eliminate any incorrect pains and gains associated with the current autoclave pouches and to assess the relative importance of each (App. 7).

SPD nurse
Maria found could not at that moment assign specific numerical values to the jobs, pains and gains, but she agreed that it could be difficult to place the autoclave pouches correct in the autoclave and the ability to design her own system was the most satisfying aspect of the autoclave pouches. She would take a large tray of suture sets, and because of the pouches placement and stackability, fill several autoclave pouches before sealing them individually, and then fill a separate tray with autoclave pouches. Maria explained that while this sequential procedure worked well for the pouches, filling an instrument container for larger operations demanded more care.

OP nurses
Mette Nielsen and Jannie Linnemann stated that opening the bags aseptically was of the utmost importance and that the current method could cause pain in the thumbs and be difficult to maintain stability. Additionally, they agreed that visual communication is essential but would not assign them specific numerical values either.

Ill. 62. Evaluating concepts with OP-nurses

Based on Maria, the SPD nurse, and Mette Nielsen and Jannie Linnemann, the OP nurses, the team was unable to obtain their specific ranking of the pains and gains, but through conversation, the team was able to extrapolate some of the most prominent ones, allowing them to rank them. In the initial conversations, the assumed jobs of the customer profiles were overlooked, which may have caused some initial misunderstandings and misconceptions in the following concept development.

! *To accomodate a systematic method of packaging multiple sets simultaneously (13)*

2.4 USER TEST I

The strategy was to present the concept and observe how each stakeholder approached the product and involve the stakeholders in a co-creation (Sanders & Stappers, 2008) of the design process, hear their feedback, and discover any latent needs through their actions.

When the concept prototypes were presented to the SPD and SU nurses, their purpose and initial value proposition were explained: to eliminate the need for autoclave pouches for suture kits and potentially other instrument sets. The participants were then given one model at a time along with a suture kit and asked to handle it as they believed they would in their department.

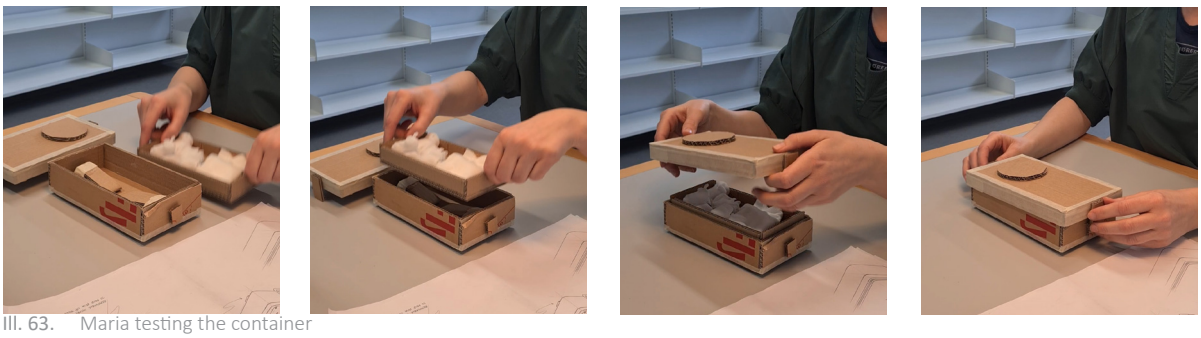
THE SPD

Maria began by arranging the three models and suture kit components in front of her, just as she would have done in the sterilisation unit. She then took turn packing each model while commenting on the procedure.

THE CONTAINER

"This is pretty simple as I recognise it from the other containers - I call this a container, I don't know if that is correct to assume?"

"If I had more than one I would stack them onto each other and carry a few onto the table for the autoclave."



Ill. 63. Maria testing the container

Maria believed that the spring principle could be adequately cleaned in the sterilisation unit, but she stressed that the design must be simple enough to be thoroughly rinsed. Then she questions its durability, arguing that the benefit must be significant for the extra cleaning effort to be worthwhile, and that the larger containers have an extra seal that is put on the locking mechanism of the container to assure that it has not been opened.

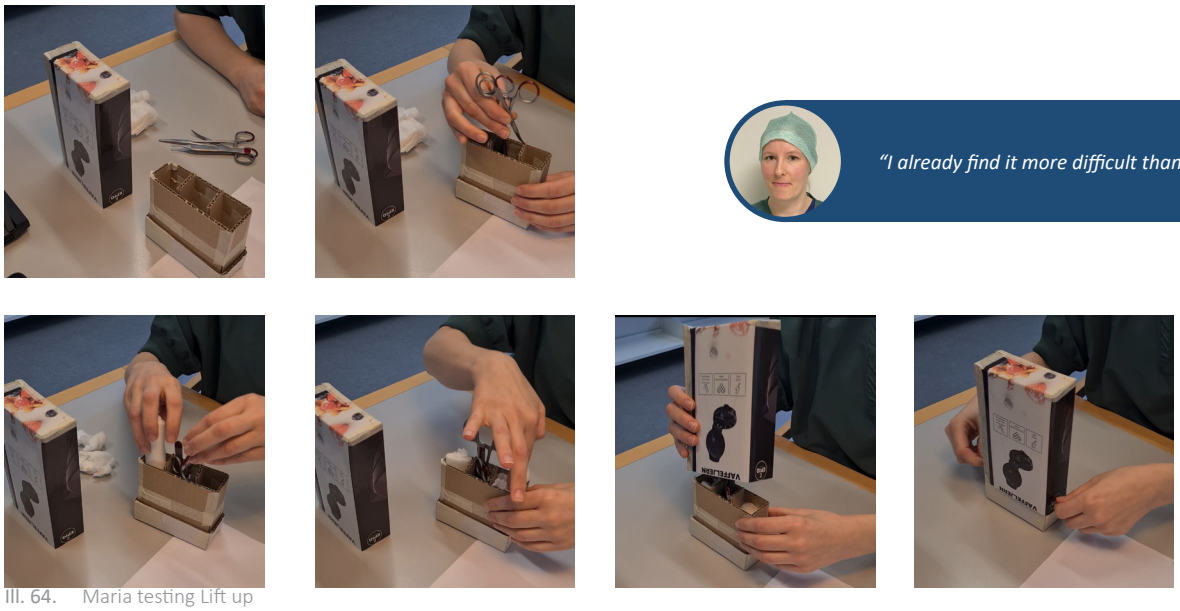
! *The complexity needs to be as simple as possible to be easy to rinse (14)*

! *The packaging must consider a breakable seal in the closing mechanism (15)*

! *To stack multiple different sizes of packaging in the autoclave (16)*

! *To handle multiple packed containers at once (17)*

LIFT UP



Ill. 64. Maria testing Lift up

"I already find it more difficult than the pouches."

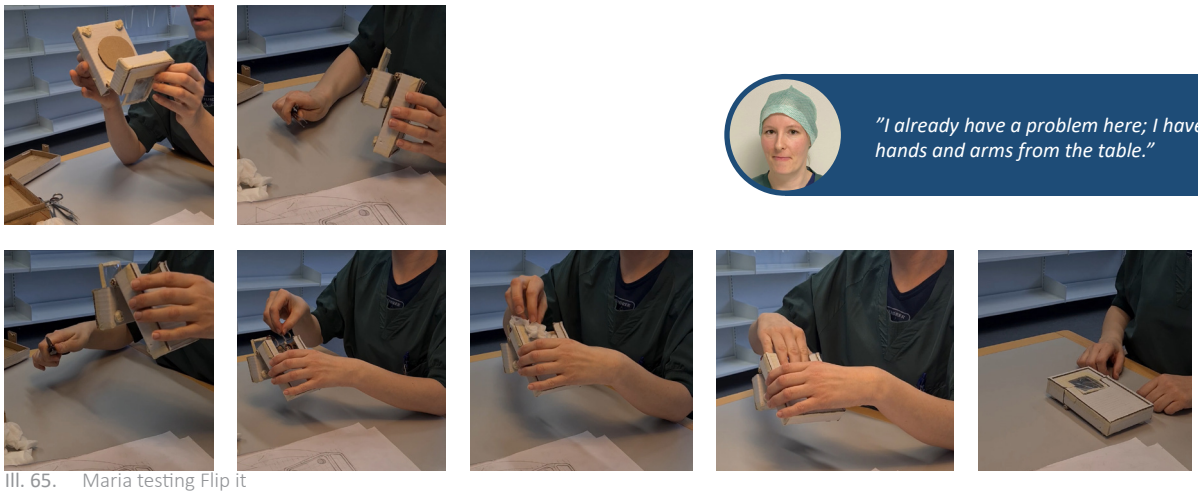
Maria mentioned that she could not position the instruments and fabric in a single motion, but instead had to handle each component separately, which would take more time. As a result, she questioned the packaging's three compartments and stated that she would prefer a single compartment for cleaning. She also stated that she would not mind if the instruments were not fixed and could move around.

Time efficiency is key in the sterile processing department, and too many steps in assembling is a pain.

! *To be time efficient (18)*

! *To be assembled in as few steps as possible (19)*

FLIP IT



Ill. 65. Maria testing Flip it

"I already have a problem here; I have to lift my hands and arms from the table."

Maria was unsure how she would wash the model, so she held it up and described it as "something like this" (Illu. 65). She was also concerned about the cleanliness and durability of the hinges, stating that air must be able to flow between components that cannot be separated. To place the instruments in the packaging, Maria had to lift both her hands and the packaging off the table, which caused instability and uncertainty. When asked if the fact that the filter was at the bottom of the packaging was a problem, Maria explained that she did not believe it to be a problem that bottom of the design.

The filter can also be placed in the packaging's bottom

! *For stability, the packing process should take place on the table (20)*

Ranking the concepts
When asked to prioritise the concepts after personal preference and the ten assumed most important aspects (see illu spiderweb), Maria listed the following:

1. Container
"It is recognisable and easier to assemble than the others and can fit with the other containers in the autoclave, but it also takes up a lot of space outside the autoclave. "

2. Lift up
"It takes a long time to place instruments and cloth individually, because of the three compartments and I am not sure it fits that well in the current system of the autoclave"

3. Flip it
"I have to lift my hands and pack it in the air and that takes a lot of time"

Indicating that habitual and recognizable parameters may be of importance in terms of overall implementation

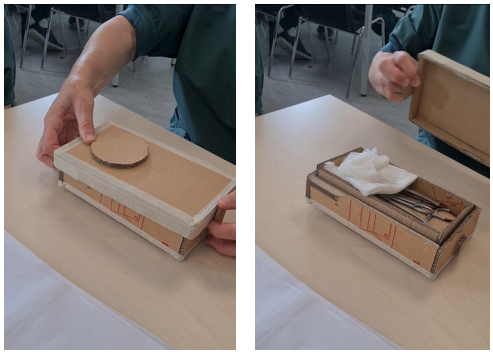
(6) To be space-efficient when stored empty

→ The bottom, lid and inner tray must be stackable when disassembled

THE SURGICAL DEP.

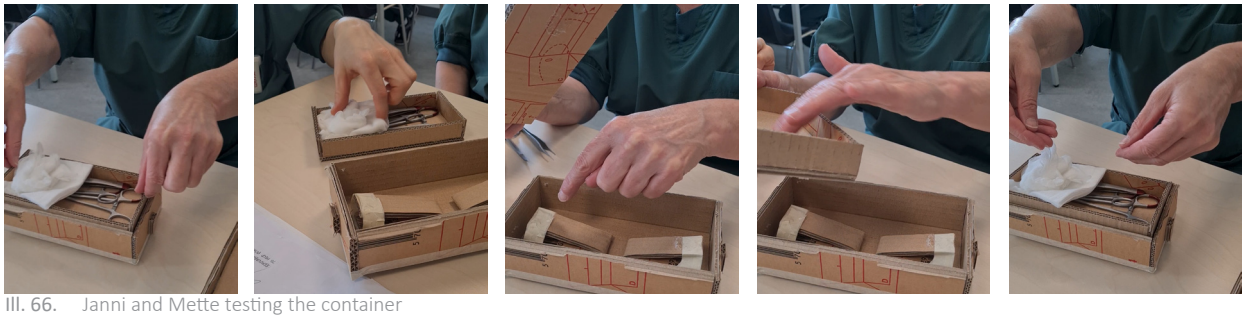
Mette Nielsen and Jannie Linnemann, two OP nurses, were prepared to assist the team in evaluating the three concepts. Each concept was packed as it would have been packed in the SPD, with a suture kit, and placed in front of the nurses to act out (Sperschneider & Bagger, 2003) the scenario of unpacking it in the preparation room.

THE CONTAINER



"It would be fairly easy to touch the edge with either your hands or the cuffs of the lab coat - could the handles be closer to the centre?"

"We check for contaminants such as bone fragments or moist areas that could compromise the sterility of the instruments."



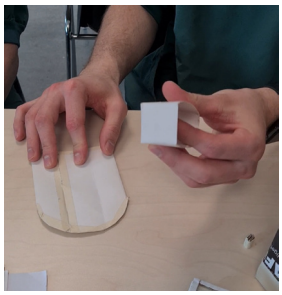
Ill. 66. Janni and Mette testing the container

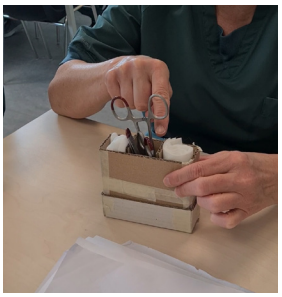
Most importantly, it was discovered that the OP nurses collect and return the packaging, whether it be containers, trays, or pouches, rendering the secondary stakeholders of porters and cleaners redundant, as they have no direct contact with the packaging. Both Mette and Jannie recognised the shape and function of the container, making it feel natural to use. The edge would need to be sterile, or the tray and handles would need to be further away from the non-sterile edge, in order to minimise contamination and the need to discard both the instrument and its packaging. In addition, the design must provide a clear view of the interior of the packaging to detect or feel any contaminants.'

The number of stakeholders is reduced; only OP-nurses are in direct contact with the packaging from surgery to SPD.

! To permit OP-nurses to inspect the cleanliness of the packaging (21)

LIFT-UP





Ill. 67. Janni and Mette testing Lift up

"Opening it this way would be a risk because the edge will be unsterile and I risk touching the instruments with it. "

"We have to inspect the bottom as with the container. This may be difficult due to the tall sides. "

"I do not know if it is even possible to sterilise the instruments in this, as there are no holes in the inner compartment"

"We use the transparent part of the autoclave pouches and the 'mouth' of the instruments to communicate what instrument is needed"

The most essential takeaway from this concept was that a nurse selects a piece of instrument based on the visual indicators of the instrument's mouth that is seen throught the autoclave pouch. The nurses have to put their fingers into the packaging to retrieve the instruments, which is not a problem aseptically, but as the non-sterile edge is dragged over this sterile part, it might contaminate the rest and constitute a risk.

The edge is to be considered unsterile. It is important for the communication in OP to be able to identify the tip of the instruments through the packaging.

***!** To be able to see the mouth/tip of the instruments (22)*

***!** To not risk edges touching sterile parts (23)*

”It would do this as a clean nurse, using both hands, but it might be difficult in the emergency room.”

“Again, I would risk touching the edges when taking the instruments and then both instruments and packaging must go to the sterile processing department.”

“The edges have to be sterile somehow”

FLIP IT

Ill. 68. Janni and Mette testing Flip it

Due to the fact that the clean nurse had to lift the design into the air and use both hands to open it, the concept resembled an autoclave pouch the most. As with the concept Lift up, the opening of the bag would have a high risk of compromise the aseptic conditions. In addition, Mette used the tweezers of the suture set to remove the remaining cloth from the packaging, indicating a lack of space and as a result difficulty controlling whether or not it is moist or has any bone fragments remaining in the packaging.

(12) To minimise risk of contamination by enabling the OP-nurses to handle securely

→ Must not risk touching an unsterile edge.

Ranking the concepts

When asked to prioritise the concepts after personal preference and the ten assumed most important aspects (see illu spiderweb), Mette and Jannie listed the following:

1.Container

“We are used to using our containers, so I prefer this one also over the autoclave pouches, you get a better overview.”- Mette

2. Flip it

"It would need a sterile edge to be used”- Jannie

3. Lift up

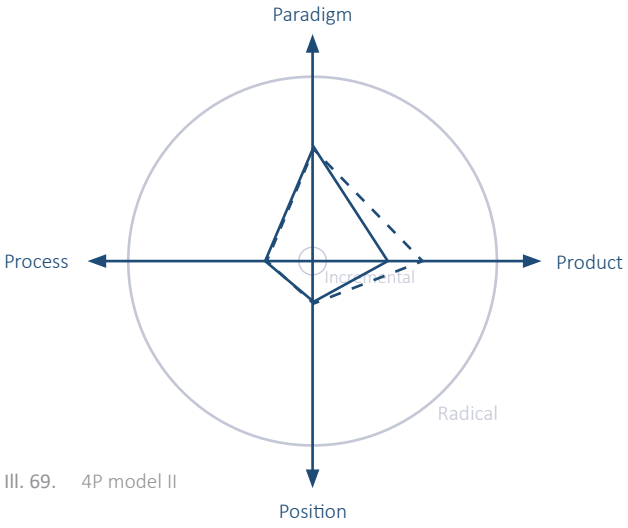
"From an ergonomic standpoint, lifting is difficult because you must simultaneously hold the top and bottom, especially if the object is larger."- Mette

Indicating again that habitual and recognizable parameters may be of importance in terms of overall implementation

The stakeholders' reluctance to assign precise numerical values to the respective drawbacks and benefits was a key learning from the user test. In retrospect, an alternative approach could have been to initiate the conversation with follow-up questions regarding the observed pains and gains of the initial visit to determine whether the individual stakeholder agreed or disagreed. Moreover, because the models lacked the functional requirements of sterile packaging, such as a functioning locking mechanism, the team drew additional sketches to illustrate the particulars of each concept. This proved difficult to comprehend and may have contributed to confusion during the actual use case discussion, resulting in the rating of individual concepts based on what each stakeholder already knows to be effective, indicating the rigidity of the system and the difficulty of implementing radical new concepts unless they are thoroughly tested and approved.

4P- MODEL

After user testing in Farsø Hospital, the team found that the users were highly affected by what they found recognisable. One of the reasons behind might be that the validated process of sterilising the instruments is unpredictable and other concepts might function, but no one can tell until the product has been validated. Therefore, the users stick to the functional principles they know, which makes it hard to gain positive feedback on more innovative suggestions, which proposed a dilemma for the team who still had to utilise the users as the experts. The team found that the system in both the SPD and the surgical department is rigid and with little room to break regulations, therefore it was not set out to design a radically innovative product, as the team learned that fairly small changes and adjustments would cause a ripple effect in a complex system. This led to the realisation that the level of innovation in the product proposal would most likely be incremental with a view on the full concept, being a container. The product innovation in the design would instead be in the detail, where the team sought out functional principles that would make this container set apart from others. The evolution is described through the 4Ps of innovation in ill. 69. (Gonzales et al., 2023)



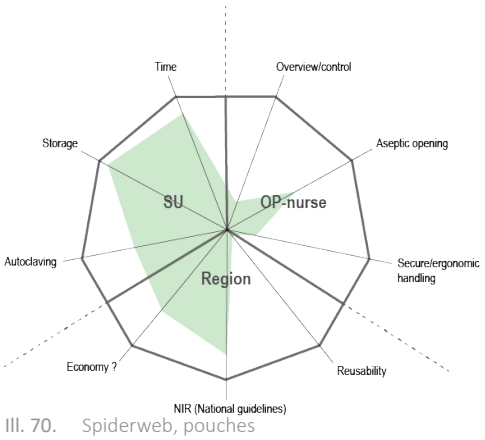
Ill. 69. 4P model II

SPIDERWEB

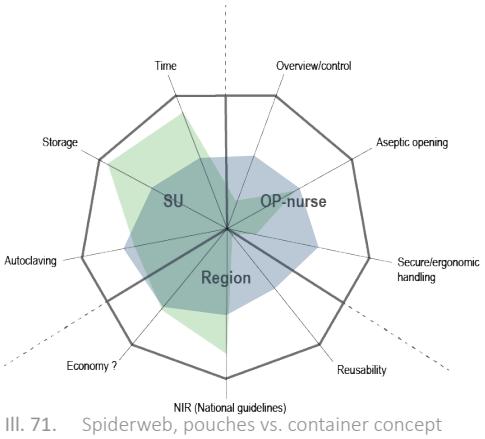
Based on the conversations with both of the main stakeholders, the team created an assumption-based spiderweb of the nine most prominent aspects so far observed. To visualise the strengths and weaknesses of the concept in relation to each stakeholder, each concept was mapped in a spiderweb comparing the concepts to the benchmark of the autoclave pouch. (App. 10)

Based on the user test, it would be extremely challenging to compete with the functionality and time efficiency of the autoclave pouches in the SPD, when trying to provide better options for aseptic opening and overview for the OP-nurses. Nonetheless, the concept proposals evaluated during the second visit to Farsø Hospital revealed that only the container surpassed the pouches on multiple parameters for the OP nurses.

The secondary stakeholder, regional procurement agents, was also considered, as they would likely have an impact on future concept development with parameters such as cost, NIR compliance, and CO2-e emission. At this point in the concept development process, the team is unable to make financial projections; therefore, all three concepts are set to be identical to the pouches. CO2-e emission is not calculated either, which is why 'reusability' is currently described in the spiderweb. The team chose to further develop the container concept based on how well each concept met the diverse needs of each primary stakeholder, including the SPD and OP-nurses.



Ill. 70. Spiderweb, pouches



Ill. 71. Spiderweb, pouches vs. container concept

Choosing to investigate the container-concept further.

2.5 BENCHMARKING

A lack of official standards in the design of reusable packaging options for SPDs led the team to use the current containers and metal trays in Farsø as benchmarks. Technical details are measured directly on the containers and trays, while pros and cons are listed to identify what problems might be solved in a better product.

In general with new products for sterilising instruments, everything goes through a validated process, meaning that a new product, e.g. packaging can comply with all standards and regulations, but still not pass the validation. This means that not a lot of standard measurements are to be found on for example level of airflow in and between the containers. As the aluminium container is currently the only reusable packaging solution at Farsø sterile processing department that comply with the ISO standards evident from NIR, and has been validated, the team used them for benchmarking. Therefore the containers were analysed together with SPD-nurse Maria and OP-nurse Anne Marie from Farsø, to provide benchmark requirements and boundary conditions for a product proposal for reusable packaging.

Visible indicators on the seal and filter show whether the container has been autoclaved.

Ill. 72. Benchmarking I

Gap for creating airflow to the filter was measured to 1 cm.

Air gap allowing a surface to be sterilised was measured to 2 mm

Ill. 73. Benchmarking II

By taking a set in the existing container from Aesculap the team could determine some assumed standards of air flow for steam autoclaving. During the investigation the team found that the Aesculap containers have a guaranteed number of 5,000 use cycles (AESCULAP® STERILE CONTAINER SYSTEM). Furthermore the team investigated the materials used and concluded that a special type of aluminium made the containers lightweight and resistant to chemical reactions with salt and protein from blood remains. Unfortunately it was not possible to obtain the precise type or treatment in the aluminium, but the team set out to use the same material.

(4) To not have hollow holes or spaces that cannot be rinsed through

→ *All tubes and holes must have an airgap of 2 mm*

(10) To allow for instruments to be sterilised by steam

→ *Filters must have 1 cm of airflow until a solid surface*

! *To be produced in aluminium (24)*

2.6 FUNCTIONAL PRINCIPLES

To validate the container concept, the team had to come up with a solution that would benefit the workflow of the OP-nurses and the overall safety so much that it would outweigh the additional time and space spent packing the instruments in the sterilisation unit (cf. Customer profiling).

The team was aware that it would be difficult to compete with the autoclave pouches in the SPD in terms of space optimization and time, but saw potential opportunities for the optimization of containers in two scenarios: stackability of the individual empty stored part of the containers and a more space efficient loading into the steam autoclave. Combined with the acquired requirements, the team focused primarily on the following three design parameters:

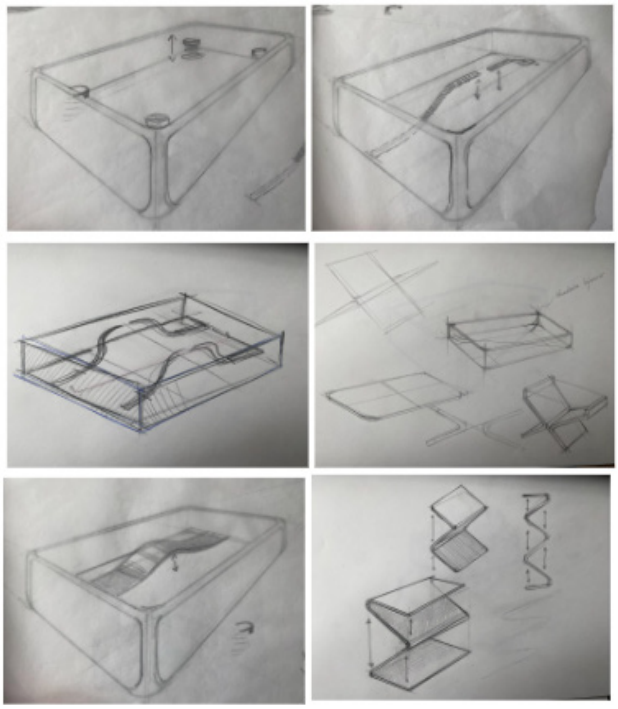
A) Greater separation between the sterile and clean areas
B) Stackability during storage
C) Product scalability

GREATER SEPARATION

For the container to be opened aseptically, it is crucial that the sterile nurse remain sterile. This means that the sterile nurse cannot risk touching a non-sterile surface under any circumstances, necessitating awkward working positions (see illustration 38)

Interface on inner-tray
Several spring-principles were investigated to determine the feasibility of designing a better aseptic opening that could reduce retreatment of unused equipment but without luck, as it did not accommodate the needs of either stakeholder and seemed more gimmicky than functional (App. 11). The primary issue with implementing a spring was that it reduced the OP-nurses' view of the bottom making it more difficult to see and feel for contaminants and added manual labour to the SPD.

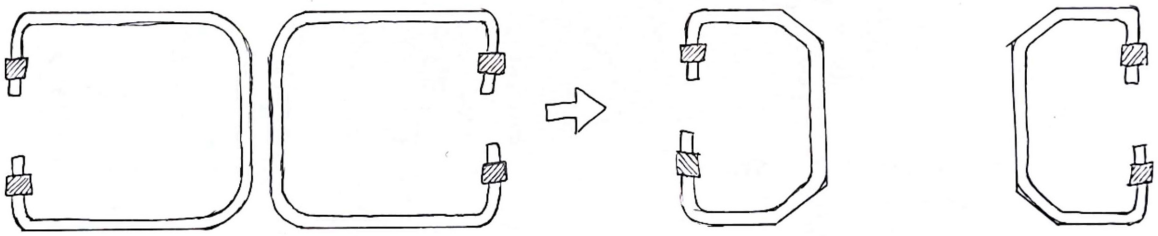
The spring was eliminated due to the need of making the concept as simple as possible to be easy to clean and due to the OP-nurses' need to control the packaging both visually and by touch. Instead the team focused on how to design the handles with best possible feedforward (Wensveen et al., 2004) to encourage the nurses to handle ergonomically correct and thereby minimise the risk of insecurity leading to contamination.



Ill. 74. Sketches on spring principle

During an initial sketch in 3D, a concept with enlarged handles and interfaces on the inner tray were presented. With this concept the handles and the edge of the bottom part, which are potential risk areas for accidentally touching or brushing the container with a medical gown sleeve, were moved further away from each other (See illu. 75). This would provide the OP-nurses with an interface as far from the tray's edges as possible, with the intention of reducing the precision required to remove the tray aseptically. The fact that the handles were almost touching did not accommodate this, resulting in the length of the handles to be reduced by half, with the intention of further testing.

Ill. 75. First 3D-sketch



Ill. 76. Iteration on the handles

Sterile edge

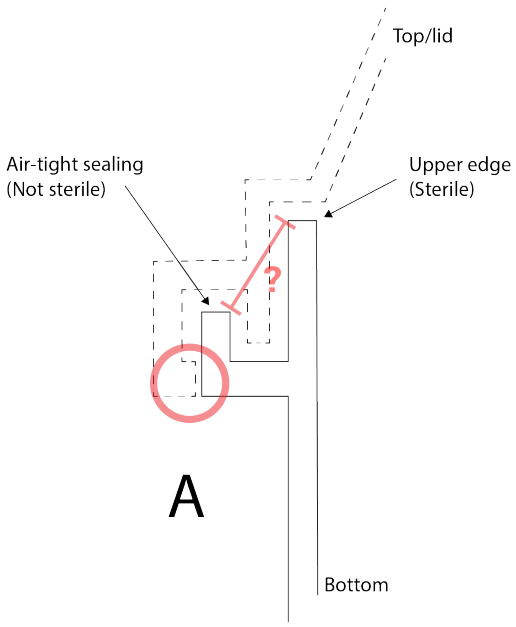
To reduce the risk of touching the non-sterile edge of the bottom portion of the container, a greater separation was made between the non-sterile edge of the bottom part and the edge of the inner tray (illustration).

Bottom

In addition to the separation between the edge of the inner tray and the bottom portion, an effort was made to create a sterile "buffer edge" by lowering the edge where the lid should seal the container.

The initial concept (illu 77) depicts a section cut, as well as a few crucial points in terms of production methods. It was discussed how much space would be required between the two edges for it to function as intended, keeping in mind that the nurses should also feel confident, relying on the principle. As an assurance would require testing with the OP-nurses, a distance of 1 centimetre was assumed.

During the process, the respective production methods of the lid and bottom part were considered. All of the containers used in the sterilisation unit are made of aluminium, a lightweight material that is known to perform well for both OP and SPD nurses. All of the containers in the sterilisation unit are made of aluminium, a lightweight material that is known to function well for both the OP and SPD nurses. It was determined that deep drawing aluminium sheets would be the preferred production method based on

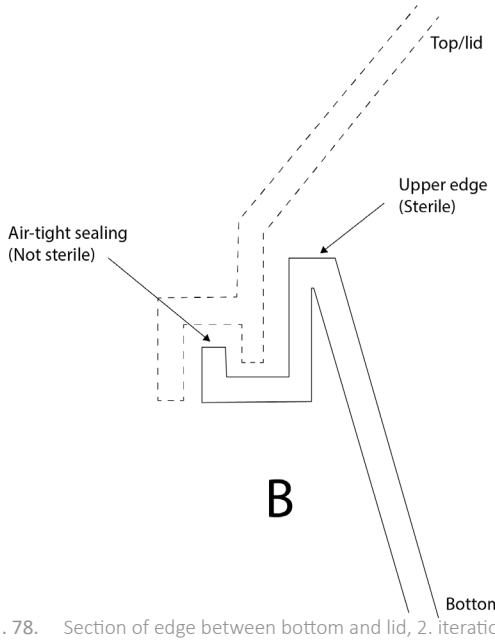


Ill. 77. Section of edge between bottom and lid, 1. iteration

the assumption that there would be a large number of units with an estimated thickness of 2mm (Deep drawing – from simulation to 3D lasering: Meconet Oy 2022). As a result, the team reconsidered the design of the edge to render it more likely to be deep drawn. (B, illu X).

Lid

Parallel to the design of the bottom part, the lid's design would make deep drawing nearly impossible. Another iteration (illustration 78) was created in an effort to incorporate the need for transparency that the OP-nurses highly valued in the other mock-up concepts. Seeing the 3D sketch (without exact measurements) with materials, however, prompted the team to consider whether it would be cheaper, simpler, and more practical to manufacture the entire lid from the transparent material. To accomplish this, it was necessary to locate a material, most likely plastic, that could be transparent and withstand the autoclave's harsh conditions. The production method of injection moulding was considered, which is why the design of the lid was modified from proposal A to proposal B by removing a small undercut. Additionally, the shape was simplified so that more air and steam could flow to the sterile edge of the container (Illu x. B). Because the components are interconnected, making the lid transparent necessitated moving the filter to the bottom of the container.



Ill. 78. Section of edge between bottom and lid, 2. iteration

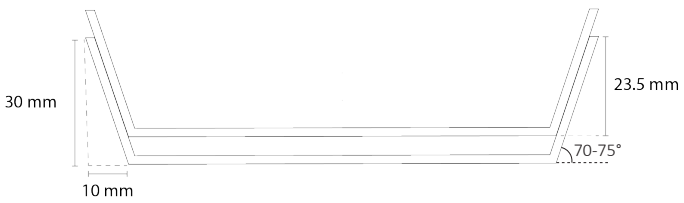
(22) To be able to see the mouth/tip of the instruments

→ The lid should be produced in transparent plastic by injection moulding

As a consequence of the lid's transparency, the filter should be placed in the bottom

EFFICIENCY IN EMPTY STORAGE

Making a product that was efficient during empty storage' was one of the primary focuses, which mainly involved the stackability of the individual parts, such as the bottom, lid, and inner tray. As the bottom was the component with the most volume and the one that would define the boundaries of the inner tray, it was prioritised first. In Solidworks, simplified versions of the base were drawn with 1:1 dimensions. Each model was tested in Solidworks to determine its stacking depth, and the results were measured. Afterwards, a section was extracted from each version and exported to Illustrator, where the dimensions were plotted on the illustration. This exercise revealed that a 10-millimetre offset of the lower edge of the bottom resulted in a 23.5-millimeter stack, which was deemed acceptable after considering that the configuration of the separate edges would fill the space left in the top, preventing a tight fit that could cause vacuum and make it difficult for personnel to separate two bottoms. Thus, the angle A for adequate stacking was determined to be between 70° and 75° (illu 79)



Ill. 79. Initial testing of the stackable principle (bottom)

(12) Must not risk touching an unsterile edge.

→ The lateral distance between the sterile and clean edges should be 1 centimetre

(6) The bottom, lid and inner tray must be stackable when disassembled

→ The angle of the bottom must be angled from 70° to 75°

→ The angle of the inner tray must be angled from 70° to 75°

SCALABILITY

As the objective was to design an alternative to the nine autoclave pouches used in the SPD, with a starting point in autoclave bags fitting suture kits, the feasibility of covering a broader range of instruments and pouch sizes was investigated. With the assistance of the procurement manager at Farsø Hospital, Annette Rohde Brander, an attempt was made to retrieve specific data regarding all the respectable instrument sizes, the assigned autoclave pouch size, and the usage rate at Farsø Hospital. This proved to be a tedious process, as the data had to be extracted from another hospital, necessitating the team to make an assumed estimate.

Deciding on sizes

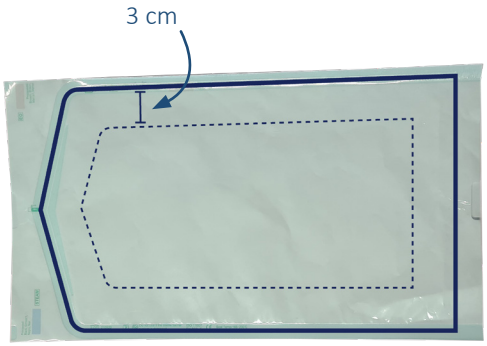
To establish a valid estimate, the team measured all nine pouches provided during the initial visit to Fars, which represented 9/42 pouches available from Mpack (Pat, Sterilization pouches, flat, heat seal). The inner dimensions of each pouch were listed in a table (See Illu 80).

According to NIR, instruments packed in autoclave pouches must be at least three centimetres away from the welding that forms the pouch's edge (See Illustration 81). This indicates that the actual length and width of instruments packed in autoclave pouches are 6 cm smaller in length and width than the pouch's inner dimensions (NIR). To create a margin of freedom when estimating the needed sizes of containers, a limit of subtracting 3 cm in each direction was made (See illu. 80, assumed instrument sizes). To exemplify: a 17 x 13 cm pouch would be substituted for a container with an inner tray in the size 14 x 10 cm. Leaving additionally 3 cm for a margin when the instruments are placed in the tray.

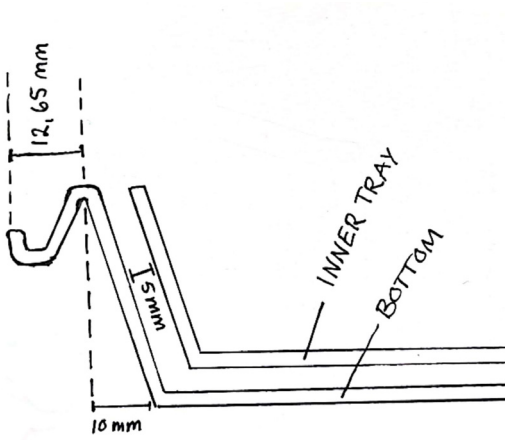
To determine the outer dimensions of the containers, the team had to determine how much space the sterile edge-system, the space between the top edge of the bottom container and inner-tray, and the offset of the lower bottom added to the outer measurements. This was accomplished based on the dimensions of 3D sketching, calculations and sketches on paper. (App. 12)

No.	The pouch's outer measurements (LxW)(cm)	The pouch's inner measurements (LxW)(cm)	Assumed instrument size
1	20 x 15	17 x 13	14 x 10
2	27 x 7.5	23.5 x 5.5	21.5 x 2.5
3	30 x 10	27 x 8	24 x 5
4	32 x 18	28.5 x 16	25.5 x 12
5	40 x 15	37 x 13	34 x 10
6	40 x 10	37 x 8	34 x 5
7	40 x 20.5	36 x 18	33 x 15
8	50 x 25	46 x 22.5	43 x 19.5
9	50 x 30	46 x 27	43 x 24

Ill. 80. Table I



Ill. 81. Room for instruments in a pouch



Ill. 82. Section cut of bottom and inner tray

SIZE OF AUTOCLAVE

During the second visit in Farsø the team measured the steam autoclave to H60 x W60 x L100 cm.

For each respectable autoclave pouch, the outer dimensions of the substituting nine containers were defined (Table X, column 'non-structured sizes'). Calculations were made to find a fitting denominator that would make the sizes of containers fit together in a common stacking system. (App. 12). In order to design a system, where the container sizes would waste least possible space in the steam autoclave, a common denominator of five was chosen due to it fitting the optimal container sizes within 3 cm for each measurement, meaning that the team could afford to wiggle the sizes due to the margin left earlier when deciding on how much space the instruments take up. Furthermore, the denominator of five would fit the measurements of the steam autoclave which is H60 x W60 x L100 cm. Therefore the sizes were reevaluated to fit a system (See table x, column 'container sizes w/ denominator 5').

No.	Assumed instrument sizes	Container: Non-structured	Container sizes w/ denominator 5
1	14 x 10	20 x 18	20 x 15
2	21.5 x 2.5	26 x 8	25 x 10
3	24 x 5	30 x 11	30 x 10
4	25.5 x 12	31 x 18	30 x 20
5	34 x 10	40 x 16	40 x 15
6	34 x 5	40 x 11	40 x 10
7	33 x 15	39 x 21	40 x 20
8	43 x 19.5	49 x 25	50 x 25
9	43 x 24	49 x 29	50 x 30

Ill. 83. Table II

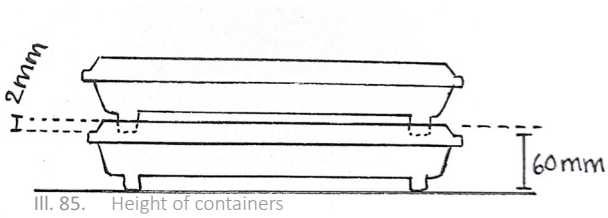
Ill. 84. Testing sizes

Since no data was found on which are the most commonly used pouches and instruments, and it was known that the size of suture kits could vary (Source), the team decided to make an educated guess as to which container would hold the greatest number of smaller instrument kits, which were defined as instruments and instrument kits under 25 cm in length. (cf. Source) On the basis of these hypotheses, it was determined to concentrate on three of the smallest container sizes because the medium and larger sizes were too similar to existing solutions for larger and more complex instrument sets:

20 x 15 x 6 cm
30 x 10 x 6 cm
30 x 20 x 6 cm

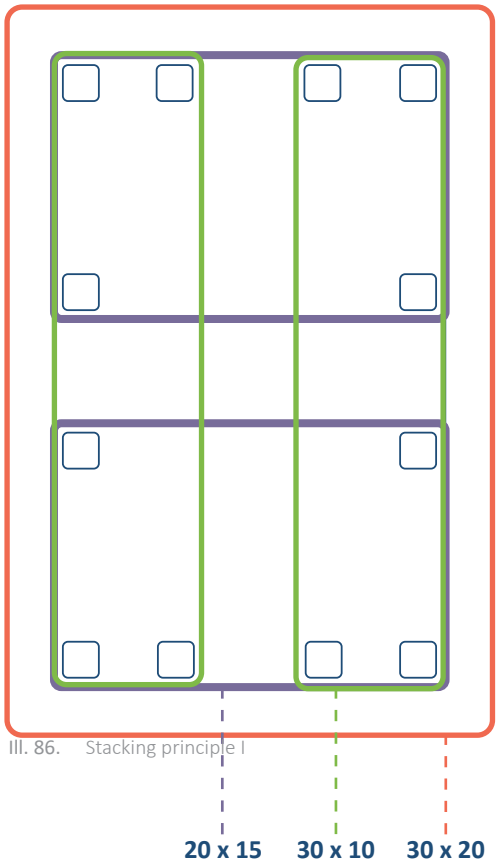
By selecting these precise dimensions, it seemed possible to create a stacking system that would allow for proper stacking and potentially maximise space used in the autoclave, However, this would necessitate more work on a systematic staking design where the feet and suitable holes in the lid allowed for stacking between all three containers.

As most of the small instruments observed being packaged in autoclave pouches at Farsø Hospital were relatively flat, the team assumed a height based on the autoclave's height of 60 cm, which would accommodate ten containers of 6 cm in height (See illu. 85). The assumption was that this height would accommodate most small instrument kits, but this would have to be tested further and with better data to obtain a satisfactory estimation.

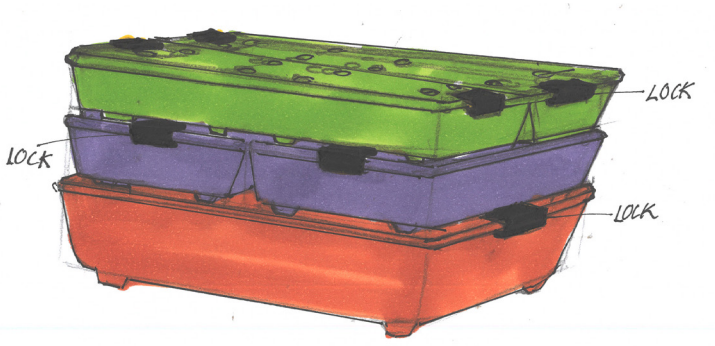


Ill. 85. Height of containers

To facilitate stacking, the feet and lids needed to be compatible across a variety of sizes and angles. Sketches of a square system for the grooves in the lid based on the placement of the containers' feet were made, with the difference in length and width for the holes in the lid and feet at the bottom taken into consideration (illustration 86 + 87).



Ill. 86. Stacking principle I



Ill. 87. Stacking principle II

Working iteratively between these three sizes resulted in a basic concept with a form and measurements based on the set and assumed requirements for its functionality.

A lot of measurements and compromises were made during this chapter. The team did not succeed in making a 'one size fits all' container, but reached a selection of sizes to 'fit most' of the smaller instruments used at Farsø Hospital, that also correlated in terms of stacking of the individual parts and potentially in the autoclave- This would have to be tested.

During the process the placement of the air filter in the container was concluded to fit in the bottom, as the lid should allow for transparency and grooves for stacking, while the intended production of the lid was injection moulding. The team knew that this was a compromise, as the OP-nurses were contradicting in needing both transparency for visual cues of the instruments and an overview of the bottom of the container.

(9) To utilise room in the autoclave

→ The containers must fit in a stackable system despite variations in size

→ Sizes in the system are
20 x 15 x 6 cm
30 x 10 x 6 cm
30 x 20 x 6 cm

→ Grooves in lid must accommodate for several sizes of containers for stacking

DESIGN BRIEF 2

	Need	Origin	Imp.	Spec.	Origin	Metric
1	To withstand disinfection	Sterilising surgical instruments	1	Must withstand mechanical wash.	SSI	Must withstand: 80°C for 10 minutes 85°C for 3 minutes 90°C for 1 minute
2	To withstand sterilisation	Sterilising surgical instruments	1	Must withstand a steam autoclave.	SSI	Must withstand: 134°C for 3 minutes 121°C for 15 minutes
						Must withstand a pressure of 3 bar
3	To meet current standards and regulations	Sterilising surgical instruments	1	Must comply with ISO-standards described in NIR	SSI	DS/EN ISO 11607-1, 14937:2009, 10993-1:2009, 11138, 14161, 15882, 11140, 17664, 868-2
4	To not have hollow holes or spaces that cannot be rinsed through	The instrument loop	1	All tubes and holes must have an airgap of 2 mm	Benchmarking	
5	To be able to open and disassemble for cleaning	The instrument loop	2			
6	To be space-efficient when stored empty	The instrument loop	2	The bottom, lid and inner tray must be stackable when disassembled	User test, SPD	The angle of the bottom must be angled from 70° to 75°
						The angle of the inner tray must be angled from 70° to 75°
7	To include visual indicators that the package has been sterilised	The instrument loop	1			
8	To include spot for labels to track instruments	The instrument loop	1			
9	To utilise room in the autoclave	The instrument loop	2	The containers must fit in a stackable system despite variations in size		Sizes in the system are 20 x 15 x 6 cm 30 x 10 x 6 cm 30 x 20 x 6 cm
				Grooves in lid must accommodate for several sizes of containers for stacking		
10	To allow for instruments to be sterilised by steam	The instrument loop	1	Filters must have 1 cm of airflow until a solid surface	Benchmarking	
				Must be sealed air tight		
11	To accomodate the current physical system	The system	3	Must fit the racks of the mechanical washer		
				Must fit into the steam autoclave		
				Must fit into cabinets for transport and storage		
12	To minimise risk of contamination by enabling the OP-nurses to handle securely	What happens during surgery?	3	Must allow for OP-nurses to lift with palms of their hands facing each other		
				Must have interfaces with a suitable size and texture/grip		
				Must not risk touching an unsterile edge	User tests, OP	The lateral distance between the sterile and clean edges should be 1 centimetre
13	To accomodate a systematic method of packaging multiple sets simultaneously	Second fieldtrip	4			
14	The complexity needs to be as simple as possible to be easy to rinse	User tests, the SPD	3			

15	The packaging must consider a breakable seal in the closing mechanism	User tests, the SPD	2			
16	To stack multiple different sizes of packaging in the autoclave	User tests, the SPD	3			
17	To handle multiple packed containers at once	User tests, the SPD	4			
18	To be time efficient	User tests, the SPD	2			
19	To be assembled in as few steps as possible	User tests, the SPD	3			
20	For stability, the packing process should take place on the table	User tests, the SPD	2			
21	To permit OP-nurses to inspect the cleanliness of the packaging	User tests, the OP	1			
22	To be able to see the mouth/tip of the instruments	User tests, the OP	2	The lid should be produced in transparent plastic by injection moulding	Functional principles	
23	To not risk edges touching sterile parts	User tests, the OP	1			
24	To be produced in aluminium	Benchmarking	2			

Time efficiency is key in the sterile processing department, and too many steps in assembling is a pain.

The filter can also be placed in the packaging's bottom

Indicating that habitual and recognizable parameters may be of importance in terms of overall implementation

The number of stakeholders is reduced; only OP-nurses are in direct contact with the packaging from surgery to SPD.

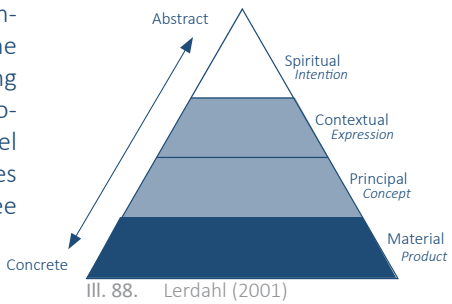
The number of stakeholders is reduced; only OP-nurses are in direct contact with the packaging from surgery to SPD.

The edge is to be considered unsterile. It is important for the communication in OP to be able to identify the tip of the instruments through the packaging.

As a consequence of the lid's transparency, the filter should be placed in the bottom

PHASE | 3

In this phase the team initiated detailed 3D-sketching to handle interdependencies in the product. Here the principles in the product are detailed and the team moves to the most concrete level in Lerdahl's pyramid when describing the product, considering materials and production. In this phase the first whole concept proposal is obtained and by taking it back on the contextual level and evaluating with the users, the team obtains information that necessitates changes that create a ripple effect. The team therefore moved between three of the levels from abstraction to concrete product elements.



Ill. 88. Lerdahl (2001)

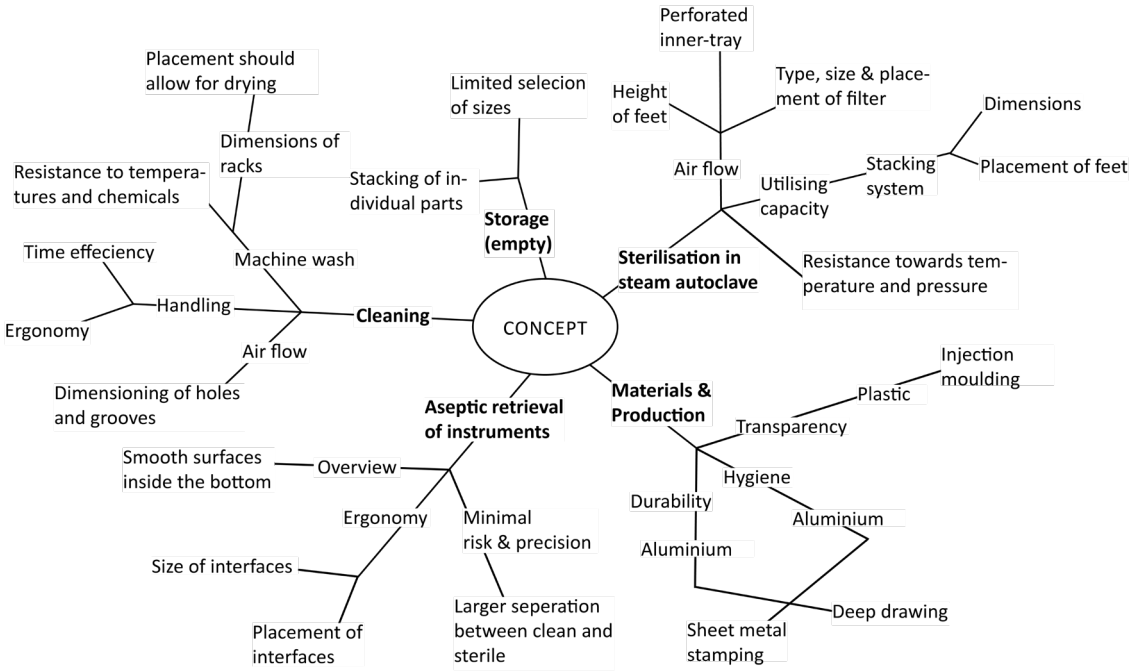
3.1 3D-SKETCHING

With the second draft of specifications, a 3D model could be constructed, and some of the fuzzier parameters could be specified using 3D printing. During the process of 3D modelling, it became apparent that a number of measurements were inaccurate and that each component of the concept and its functional characteristics were intricately interconnected. By designing sequentially instead of in parallel it became possible to reduce complexities, as the team was unable to make specific design decisions when examining all elements and parameters simultaneously. In the section that follows, the challenges of sequentially working with a single parameter in an interdependent system are illustrated.

The sequential approach resulted in five main zooms of working principles. Several of these elements had previously been under development (c.f. Functional Principles): *The edge, lid, bottom, inner-tray, and the closing mechanism*.

COMPLEXITY & INTERDEPENDENCIES

With each iteration of the individual design features, the complexity increased, and parameters such as storage when empty, sterilisation in a steam autoclave, materials and production, an aseptic retrieval of instruments, and 'cleaning' (See illu X) revealed several interdependencies (App. 13) and contradictory design principles. As demonstrated, the complexity of each parameter increased in tandem with the team's learning process, necessitating a classification of the importance of each specification. Working sequentially on one component (lid, tray, bottom, etc.) while continuously checking for misalignments, 3D modelling was initiated with the objective of attaining a viable 3D printed prototype for additional user testing.



Ill. 89. Interdependencies

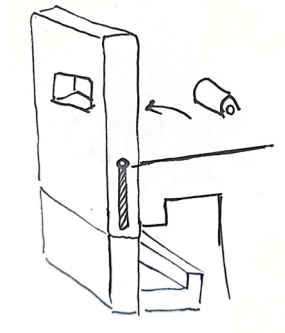
3.2 CLOSING MECHANISM

Even though the team worked iteratively between the five areas of interest, the closing mechanism was severely neglected due to a lack of overview and the inability to comprehend the extent to which the locking mechanism would impact and be impacted by other design principles as well as the model's functional characteristics.

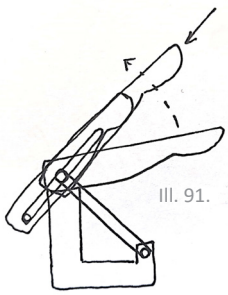
Due to this, the team began iterating on the closing mechanism very late in the process. Using a nearly complete 3D model as a starting point, the team began drafting by hand. With prior knowledge of how the current autoclave container locks functioned, the current lock required the edge to be remodelled to maintain the fixed dimensions, resulting in a cascade of changes to the interdependencies and a small change margin (App. 13).

The difficulty of the closing mechanism came down to:

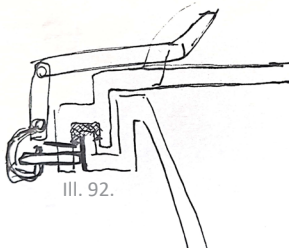
- That the placement of the closing mechanism would disturb the stackability of the individual bottom and lid
- That the closing mechanism would add to the total length of the container.
- That placing the closing mechanism on the lid, would potentially break the visibility to the instruments.
- That placing the closing mechanism on the lid, would potentially hinder the need of the additional plastic seal, making it problematic to stack the containers.



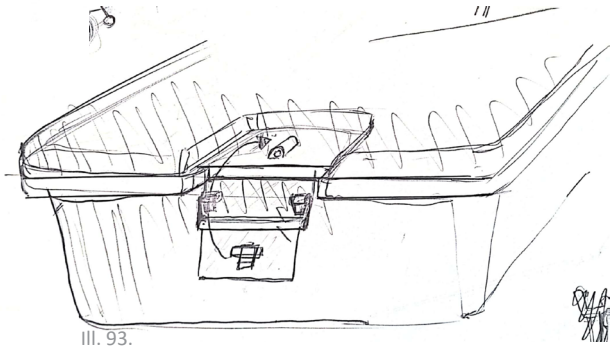
Ill. 90.



Ill. 91.

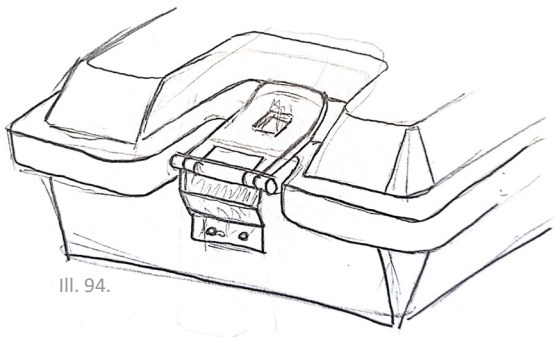


Ill. 92.



Ill. 93.

Due to a scheduled third visit at Farsø Hospital and a deadline of having a tangible 1:1 concept ready, a compromise was made by creating a recess on the top of the lid and a flexible non-attached clip-lock that did not compromise the total height by using the edge as a groove to lock in place, but added 4mm to the overall length. It was believed that by inserting a core pin during injection moulding, a small loop functioning as a lock and placement of the seal could be produced.



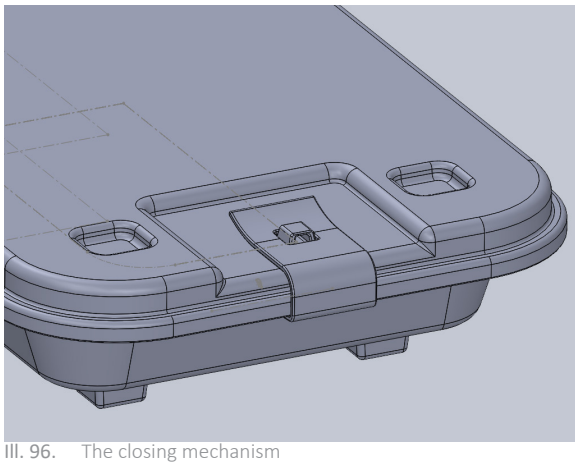
Ill. 94.

GO-JACK

"FlexClean in-tray accessories for flushing tubes
The GO Jack® is an instrument spacer made of used & recycled sterile wrap. Designed as a "jack" to open hinged instruments. Easy & useful, both sides can be used to open a hinge."
- Supplier's description of GoJack (Go jack)

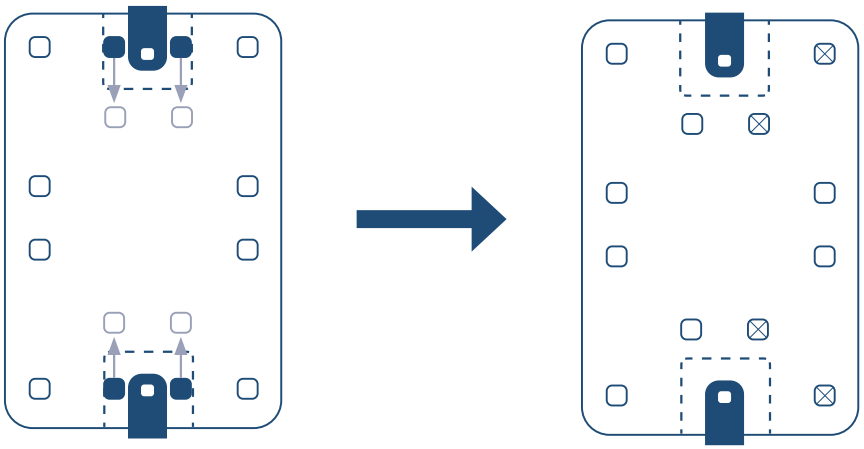
Ill. 95. Go Jack

The team discussed which material would have a fitting flexibility, and remembered that during the first visit at Farsø Hospital a small device was presented. Its purpose was to keep instruments open during machine wash and it was produced in recycled sheet packaging from sterilisation units (c.f. GoJack). If the clips could be produced in the same material, they would be more sustainable and add a circular economy element to the container. The team knows that the sheets are made primarily from polypropylene (PP) which on its own can withstand sterilisation by 121°C, but not 134°C as is used at Farsø Hospital (Sterilisable and Autoclavable Medical Grade Plastics). This meant that the recycled plastic material would most likely become very fragile and break after every use cycle, constituting a risk of implementing a single-use product within the container. The team knew that savings in the final CO2-e cost would be a crucial part of the product's success, and therefore opted for a more durable solution, which was producing the clip in aluminium sheet metal.



Ill. 96. The closing mechanism

By selecting the clip as the closing mechanism, a recess was created in the top portion of the lid, removing two of the assigned grooves for the legs of the 30 x 10 cm container, thereby compromising the stacking system for the 30 x 10 cm container atop a 30 x 20 cm container(See illu 97).



The legs and grooves for the 30 x 10 container must be moved to fit the solution for the closing mechanism

The legs from the 30 x 10 container will now fit in the marked grooves

Ill. 97. Moving grooves in the lid

3.3 CONCEPT 1.0

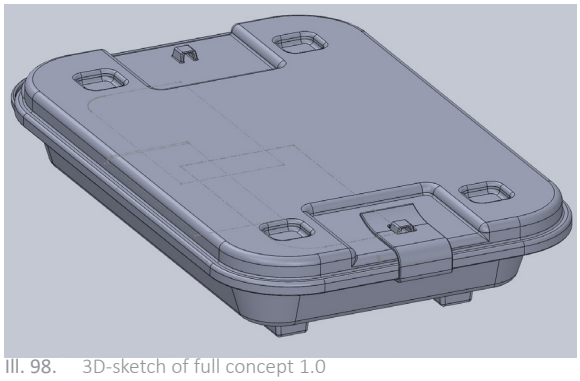
After iterations and testing in 3D-sketching, the team reached the first complete product proposal. This chapter sums up the concept in materials, production, and unique selling points.

CONCEPT

Based on the dimensions of the largest of the three containers, 30 x 20 x 6 cm (L x W x H), this primary concept proposal represented a minimally viable product for reusable suture sets and similar-sized instrument sets. The last implemented feature was the clips for closing, which caused a compromise to move some of the grooves in the lid for stacking different sizes (c.f. Closing mechanism, compromise).

OBS!

This is not depicted in the 3D model, where the only grooves depicted are those that would allow for the stacking of containers of the same size, 30x20x6 cm as the model had to be 3D printed for additional user testing. Additionally, the thickness of the lid, inner tray, and bottom would be 2 mm, as a thickness less than this would prevent the printing of a functional prototype. In addition, the specific alloys have not yet been selected, but since the current standard for larger containers is aluminium, it was assumed to be functional in aluminium (App. 14).



Ill. 98. 3D-sketch of full concept 1.0

MATERIALS & PRODUCTION

The concept consisted of six individual components, which are described in the following chapter. The materials for each component was selected based on the following requirements:

Withstand steam sterilisation and machine wash
Must be capable of being utilised at least 5000 times
Used in injection moulding
Must be transparent

Ill. 99. Exploded concept 1.0

Ill. 100. Lid

Lid

PPSU was chosen at the time, used in other medical grade equipment (Medical Grade PPSU rods and plates), as it is both transparent and can withstand steam autoclave sterilisation at 134° C, though only up to 1500 cycles (Sterilisable and Autoclavable Medical Grade Plastics). As mentioned earlier, injection moulding would be the preferred method of manufacturing, with an extraction core for the loop of the closing mechanism. To make the sealing between the bottom and the lid airtight, a standard silicone/rubber edge would be implemented separately.

It was known that the extraction core could cause potential problems in the manufacturing process due to its complexity that may also have caused a significant rise in the overall price. Other materials were considered such as PSU, PEEK, PP, but they did not live up to the requirements (App. 14).

Ill. 101. Inner tray

Inner-tray

The inner-tray was thought to be cut, perforated and then deep drawn from an aluminium sheet with a thickness less than 2mm. Alternatively, a few design modifications could have been made, making it a sheet metal design that could be cut, perforated, and bent.

Ill. 102. Bottom

Bottom

An aluminium sheet would be cut and deep drawn using the same production method as the inner tray. At this time, the complexity of manufacturing the edge had not been further investigated.

Ill. 103. Closing mechanism (clips)

Closing mechanism/clips

The clips for keeping the container securely closed and sealed were considered as a separate, loose part with the same fit for multiple container sizes, making them more cost-effective and simple to replace if lost. Extrusion followed by hole stamping was regarded as the manufacturing method. At the time, stainless steel was believed to be an alternative to aluminium, which would require a thinner profile; however, the exact alloy was not investigated and further testing was required as material flexibility was needed for it to be flexible enough to work.

Ill. 104. Clamps and handles

Clamps & handles

The small clamps with the function of holding the handles in place while simultaneously allowing steam to permeate were also assumed to be manufactured from aluminium by extruding the profile and then cutting the holes. Moreover it was considered that the handles were made from a standard 4 mm round aluminium bar that was bent and cut.

! *The material for the closing mechanism needs to be flexible (25)*

PRODUCTION CONCERNS

There were some preliminary concerns regarding the design and the designated production method. It came to the group's attention that deep drawing an angled edge in one setting could cause the aluminium to buckle, especially at the sides of the inner tray and bottom. Moreover, the sharp edges and depth could cause the design to crack due to the thinning of the material. Initially, the thickness of the sheets was set to 2 mm due to 3D printing, which may have been excessive for the actual structural integrity of the containers. This would have to be tested.

Ill. 105. The package of 5,000 use cycles

Using the current Aesculap containers as the benchmark for the use of aluminium, it was assumed to be able to work for at least 5,000 cycles. PPSU is only validated for 1500 use cycles in steam autoclaving (Sterilisable and Autoclavable Medical Grade Plastics), which necessitated a total use of more than three lids to one bottom and inner-tray, adding to the overall waste produced compared to the current reusable containers, with a lid of aluminium. No CO2-e calculations were initiated at the time to prove or disprove if the principle would increase the CO2-e cost too much, requiring further investigation.

Ill. 106. Concept 1.0, heroshot

UNIQUE SELLING POINTS

- **Space optimising stacking-system**
- **Risk reducing interfaces with improved ergonomics**
- **Transparent lid for quick and simple inspection**

3.4 USER TEST II

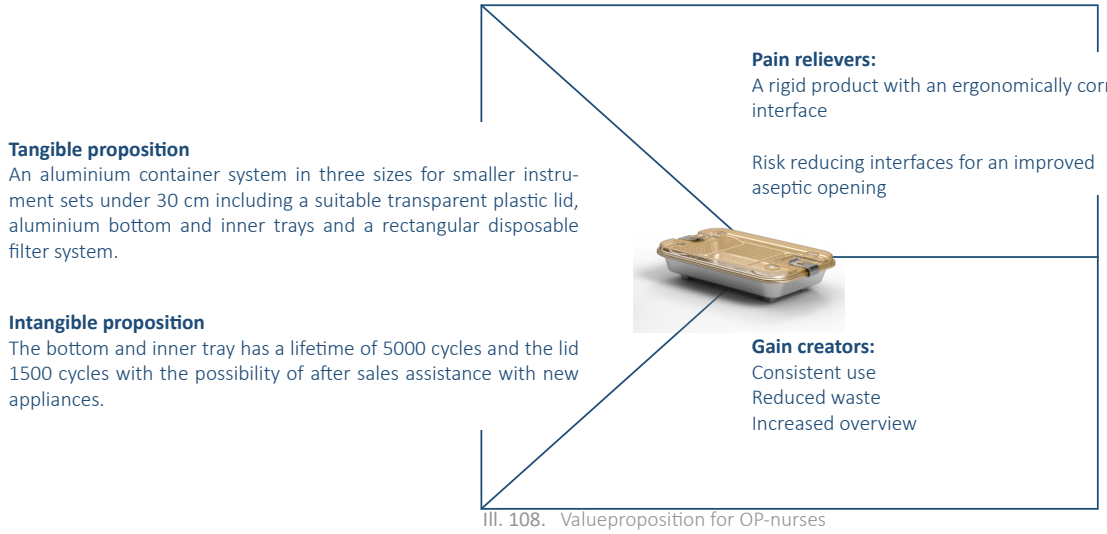
The purpose of the third visit to Farsø Hospital was to present the concept proposal and receive feedback on the given value proposition. With a 1:1 3D-printed model, it was possible to demonstrate every feature except the lid's transparency. Again, the SU-nurses Maria Jørgensen and Annette Rohde Brander and Mette Nielsen were willing to assist.

VALUE PROPOSITION & FEEDBACK

The strategy of the user test was to present the value proposition on a slideshow while simultaneously utilising the concept proposal to clarify the assumed pains and gains and how the concept proposal accommodated these and to see if the stakeholders disagreed (c.f. Customer profiling) (App. 15). The value proposition would serve as a means of structuring the feedback and ensuring that the choices made during the design remained relevant to a potential substitute for the autoclave pouches. The product's overall tangible and intangible qualities were described.

Ill. 107. Maria with concept 1.0

The value proposition for the OP-nurses



Ill. 108. Valueproposition for OP-nurses

Mette's feedback was overwhelmingly positive (App. 15), and she confirmed that the rigidity of this container would be preferable to the floppy pouches, which she explained were difficult to use, particularly for less experienced nurses. She also mentioned that the container's durability was a significant benefit, as it is difficult to inspect pouches for small holes caused by sharp instruments, which would compromise the pouch. It was also mentioned that the concept provided a better overview; however, the placement of

"It is a lot easier and doesn't take a lot of practice, very quick to figure out."

"It just needs a label so I can scan it into the system."

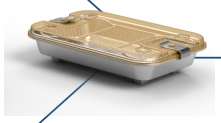
the filter and recess at the bottom could cause some complications during the control of potential contamination, where Mette previously used her hands. Mette believed that the container would be the best alternative for use in an ideal world, but she was sceptical about the sustainable win in the end, particularly due to the relatively poor durability of the lid that needed to be exchanged. She was also unsure about the idea of a plastic lid and stated on multiple occasions that the lid's transparency may not be worth a significant compromise in terms of general durability and environmental impact, stating that transparency was a "nice to have" but not a "need to have" because existing labels on individual containers could be scanned and the appropriate instrument set would appear on the screen.

Ill. 109. Mette lifting the inner tray

The value proposition for the SPD-nurses

Tangible proposition
An aluminium container system in three sizes for smaller instrument sets under 30 cm including a suitable transparent plastic lid, aluminium bottom and inner trays and a rectangular disposable filter system.

Intangible proposition
The bottom and inner tray has a lifetime of 5000 cycles and the lid 1500 cycles with the possibility of after sales assistance with new appliances.



Pain relievers:
The rigid aluminium casing and plastic lid minimises fluids permeating the container and allows for a more secure handling of the product

A rigid space optimising system for the autoclave

Gain creators:
Consistent use
Reduced waste
Increased overview

Ill. 110. Value proposition for SPD-nurses

Maria was initially not convinced that the containers would take up less space in the autoclave than the current packaging of autoclave pouches. She stated that the pouches were tightly packed, but as she realised that the pouches were not being stacked vertically She reconsidered. Further testing and comparative analyses with filled autoclaved pouches would have to be made in order to answer this truthfully. While Maria confirmed that the container would provide the advantage of reducing the risk of human error and being a more durable concept that would provide a more consistent use and reduce the use of disposable waste (App. 15), it was also mentioned that the plastic lid would be a significant disadvantage in the sterilisation unit, as plastic has a much longer drying time in the washing machine due to a much faster cooling rate than metal. As a result, the sterile processing department had gradually stopped purchasing plastic products that require machine washing and would much prefer the use of metal instruments/packaging.

"I'm actually thinking that it might take up more room in the autoclave than the pouches, unless we are packing different instruments - then it might be useful for utilising the space."

"This [the container] will exclude the risk of 'human-mistakes', when the nurses touch the filter with wet or moist hands without noticing."

"We are trying to avoid buying any new plastic products; metal is much more preferred."

Surprisingly, Maria liked the closing mechanism, and the idea of keeping the clips in a separate place, as long as all three containers would be using the same size. However, she required proof that it would actually seal tight enough.

The most important takeaway from the second round of user tests was that the proposed concept's functionality provided much-needed improvements over autoclave pouches, particularly for OP-nurses. However, a misunderstanding regarding the significance and precise meaning of visual indicators and the need to see the mouth of the instruments resulted in the production of a transparent plastic lid with the filter placed in the bottom, limiting the OP-nurse's ability to conduct a thorough inspection and control for potential contaminants. In addition, it was recently discovered that the sterilisation unit no longer wished to use plastic products; this was another crucial factor that had not been identified during the initial visits. Overall, the presentation of the value proposition was successful, as the majority of assumed pain relievers and gain generators were approved and constructive feedback was provided for future development.

~~! To be able to see the mouth/tip of the instruments (22)~~

PART REFLECTION

The creation of a transparent lid had been a driving force and one of the unique selling points of the container concept, but it was revealed that it was based on a misinterpretation of user needs, as the main stakeholders meant that a scannable solution could be sufficient. On the other hand it could be argued that by having a transparent top, it would require fewer steps for the identification of the instruments within, potential mislabeling and therefore the need to transport an unused instrument back to the SPD. In retrospect, this may have been due to the abrupt shift from a research-led participatory approach to a more design-driven, user-centred design approach, after each visit, where explicit and observable needs were used as guidelines for the design and the implicit meaning of terms such as "transparency" was not adequately explored (Sanders & Stappers, 2008).

DESIGN BRIEF 3

	Need	Origin	Imp.	Spec.	Origin	Metric
1	To withstand disinfection	Sterilising surgical instruments	1	Must withstand mechanical wash.	SSI	Must withstand: 80°C for 10 minutes 85°C for 3 minutes 90°C for 1 minute
2	To withstand sterilisation	Sterilising surgical instruments	1	Must withstand a steam autoclave.	SSI	Must withstand: 134°C for 3 minutes 121°C for 15 minutes
						Must withstand a pressure of 3 bar
3	To meet current standards and regulations	Sterilising surgical instruments	1	Must comply with ISO-standards described in NIR	SSI	DS/EN ISO 11607-1, 14937:2009, 10993-1:2009, 11138, 14161, 15882, 11140, 17664, 868-2
4	To not have hollow holes or spaces that cannot be rinsed through	The instrument loop	1	All tubes and holes must have an airgap of 2 mm	Benchmarking	
5	To be able to open and disassemble for cleaning	The instrument loop	2			
6	To be space-efficient when stored empty	The instrument loop	2	The bottom, lid and inner tray must be stackable when disassembled	User test, SPD	The angle of the bottom must be angled from 70° to 75°
						The angle of the inner tray must be angled from 70° to 75°
7	To include visual indicators that the package has been sterilised	The instrument loop	1			
8	To include spot for labels to track instruments	The instrument loop	1			
9	To utilise room in the autoclave	The instrument loop	2	The containers must fit in a stackable system despite variations in size		Sizes in the system are 20 x 15 x 6 cm 30 x 10 x 6 cm 30 x 20 x 6 cm
				Grooves in lid must accommodate for several sizes of containers for stacking		
10	To allow for instruments to be sterilised by steam	The instrument loop	1	Filters must have 1 cm of airflow until a solid surface	Benchmarking	
				Must be sealed air tight		
11	To accomodate the current physical system	The system	3	Must fit the racks of the mechanical washer		
				Must fit into the steam autoclave		
				Must fit into cabinets for transport and storage		
12	To minimise risk of contamination by enabling the OP-nurses to handle securely	What happens during surgery?	3	Must allow for OP-nurses to lift with palms of their hands facing each other		
				Must have interfaces with a suitable size and texture/grip		
				Must not risk touching an unsterile edge	User tests, OP	The lateral distance between the sterile and clean edges should be 1 centimetre
13	To accomodate a systematic method of packaging multiple sets simultaneously	Second fieldtrip	4			
14	The complexity needs to be as simple as possible to be easy to rinse	User tests, the SPD	3			

15	The packaging must consider a breakable seal in the closing mechanism	User tests, the SPD	2			
16	To stack multiple different sizes of packaging in the autoclave	User tests, the SPD	3			
17	To handle multiple packed containers at once	User tests, the SPD	4			
18	To be time efficient	User tests, the SPD	2			
19	To be assembled in as few steps as possible	User tests, the SPD	3			
20	For stability, the packing process should take place on the table	User tests, the SPD	2			
21	To permit OP-nurses to inspect the cleanliness of the packaging	User tests, the OP	1			
~~22~~	~~To be able to see the mouth/tip of the instruments~~	~~User tests, the OP~~	~~2~~	~~The lid should be produced in transparent plastic by injection moulding~~	~~Functional principles~~	
23	To not risk edges touching sterile parts	User tests, the OP	1			
24	To be produced in aluminium	Benchmarking	2			
25	The material for the closing mechanism needs to be flexible	Material & production	2			

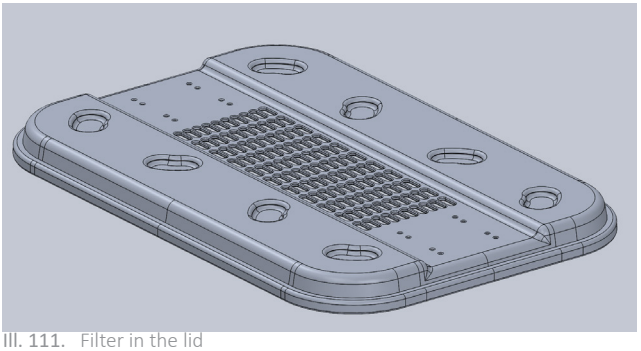
By selecting the clip as the closing mechanism, a recess was created in the top portion of the lid, removing two of the assigned grooves for the legs of the 30 x 10 cm container, thereby compromising the stacking system for the 30 x 10 cm container atop a 30 x 20 cm container(See illu X).

3.5 REDESIGNING THE LID

During the third field trip at Farsø Hospital, the team discovered a misalignment between the importance of the requirement of transparency, that resulted in major changes of other design parameters and their functionality (c.f. Design brief 2). As transparency was no longer a requirement, it became possible to utilise aluminium as the main material of the concept, giving it an estimated 5000 cycles of washing and autoclaving.

FILTER

As a consequence, the filter could be moved to the lid, making it possible to have a flatter bottom, excluding the recess of the legs, for the OP-nurses to control and inspect for any potential contaminants.



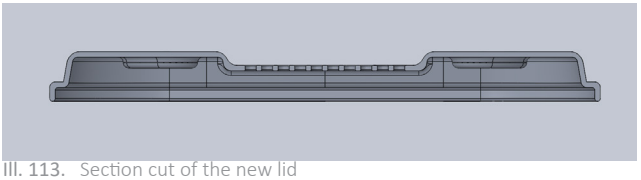
Ill. 111. Filter in the lid

LEGS

It was necessary to reevaluate the stacking of the three smaller containers because the location of the filter affected the placement of the feet. The 30x10 cm container was eliminated due to the filter's likely instability and the lack of space for additional recesses in the lid's middle, leaving the system with the 30 x 20 cm and 20 x 15 cm containers. Additionally, the design was rounded to facilitate thorough drawing.

The shape of the feet were redesigned to be easier in production. Beforehand, they were square and required a deep shape to gain the wanted height. This was changed into a more rounded shape that would allow for easier deep drawing along with reducing the height, making it more likely that the material would not yield.

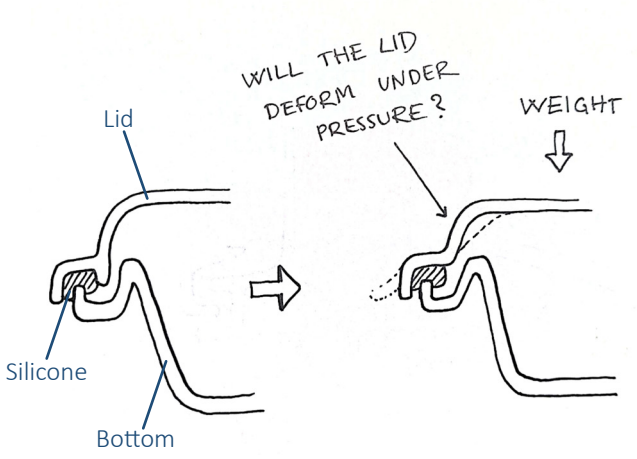
Ill. 112. Iteration on the legs



Ill. 113. Section cut of the new lid

THE EDGE

To accommodate deep drawing in aluminium, the design of the edge had to undergo a second iteration. One of the most important characteristics of the previous edge was the designated recess, which was intended for a silicone sealing that would be pressed against the edge's sides, thereby making it airtight. Due to the angled sides and lid, there may be a risk of deformity, due to the pressure occuring while stacked in the steam autoclave (see illu 114). - this needs further testing (solidworks simulations).



Ill. 114. Section cut on the lid, 3. Iteration

3.6 CLEANETIC PRO 2.0

Ill. 115. Exploded view on Cleanetic PRO 2.0

UNIQUE SELLING POINTS

- **Risk reducing design**
- **Larger interfaces provides better ergonomic use**
- **A space optimising stacking-system**

Ill. 116. Cleanetic PRO 2.0, heroshot

3.7 MATERIALS

Ill. 117. Aluminium 6061 T4

ALUMINIUM 6061 T4

As it is currently unknown which specific types of aluminium alloys are used in autoclave containers on the market, aluminium 6061 in T4 (The Online Materials Information Resource I) and T6 (The Online Materials Information Resource II) in harder tempers were investigated , with deep drawing being considered as the production method for the lid, inner tray, and bottom part as they both offer great corrosion resistance in terms of machine washing, which is done separately with only aluminium containers and autoclaving with a mix of aluminium containers and surgical steel. It was determined that smaller components, such as hinges, machineable filtration locks, and standard 4mm rods for the handles, were made of 6061 t4.
6061 T4 was selected because it has the same Young's modulus as T6 (Team, 2021) and is less expensive than T6.- additional analysis is required due to concerns regarding the material's hardness and the complexity of the lid and bottom's edge, which could cause complications.

Ill. 118. Aluminium 6063-O

ALUMINIUM 6063-O

As the separate locks needs flexibility to function as intended aluminium 60 63-O was chosen, as it also has great corrosion resistance. Aluminium 6063-O (Aluminum 6063) was chosen for the distinct locks due to its excellent corrosion resistance and formability (Eagle Aluminum, 2023), as well as its flexibility (Aluminium 6061 vs 6063- what's The difference 2023).

Ill. 119. Silicone rubber

SILICONE RUBBER

In order to make the container airtight around the edges and only allow steam to permeate through the designated filter, as seen in the benchmark containers, a similar silicone rubber material was chosen for the edge seal; however, additional analysis is required to determine the optimal material that can withstand 5000 cycles without compromising its functionality.

As the container must be washed in a machine in order to be reprocessed, it is crucial that all metal sections are made of aluminium and not a combination of aluminium and stainless steel, as this could lead to galvanic corrosion (Marsh Fasteners, 2023). Moreover, the lock must be flexible due to its function as a clamp, which requires it to be forced over the edge. The complexity of the model must be analysed further if the toughness of the material chosen for deep drawing causes any complications.

Material price is 19.4 DKK per unit, at 10.000 units.

App. 18

MATERIAL COST

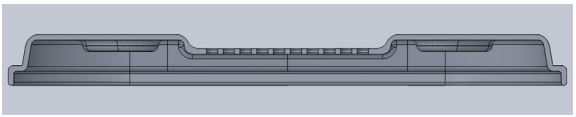
With the intention of producing the three largest parts in aluminium 6061-t4 sheets via deep drawing, a high-volume manufacturing procedure (Webteam, 2020), 10,000 units were selected as a starting point for the estimated material cost (s scale?ee Does it). With the use of solidworks, the given materials were selected and an estimated weight of the given components were made (App. 18).

3.8 PRODUCTION

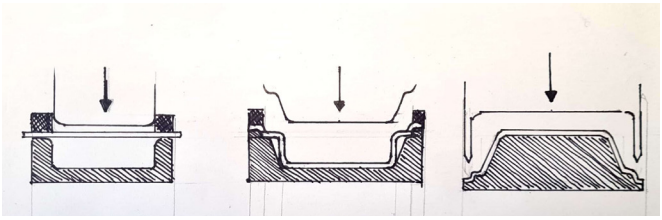
THE LID

The lid is believed to be deep-drawn from a 2-millimetre-thick sheet of aluminium 6061-T4 using three moulds. One for the initial deepening of the lid, another for creating the angled sides and edges, and a third for cutting the side flanges. As a result of its sharp bends and the need for a perpendicular cut when cutting the edges, it is known that there may be some difficulty in producing the edges.

In addition, holes are punched or drilled for the filter opening, the upper hinge, filter holder hinge, and filter holder lock, prior to deep drawing, for which standard aluminium rivets are intended.



Ill. 120. Section cut of the lid

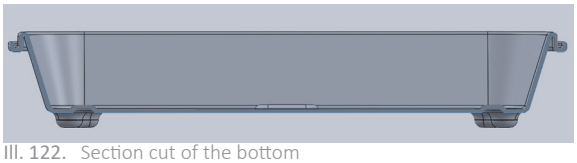


Ill. 121. Deep drawing the lid

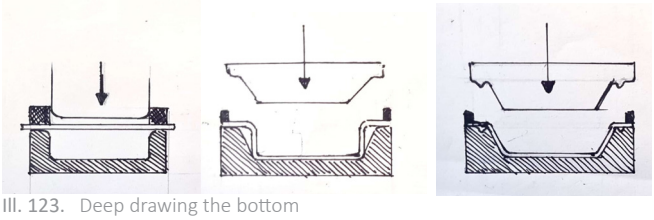
THE INNER TRAY

Using four moulds, the bottom is likely deep-drawn from a 2-millimetre-thick sheet of aluminium 6061-T4 with the use of 4 deep drawing tools. One for the initial deepening of the lid, one for creating the angled sides and edges, one for creating the edge, and one for cutting the flanges. As with the lid, the sharp bends and the need for a perpendicular cut when cutting the edges may pose some production challenges; this requires further investigation.

OBS: Notably, the legs and inner grooves of both the bottom and the lid are not depicted in the illustrations for the deep drawing process; these grooves are intended to be created in the same step as where the sides are deep drawn at an angle.



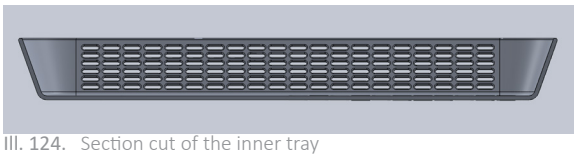
Ill. 122. Section cut of the bottom



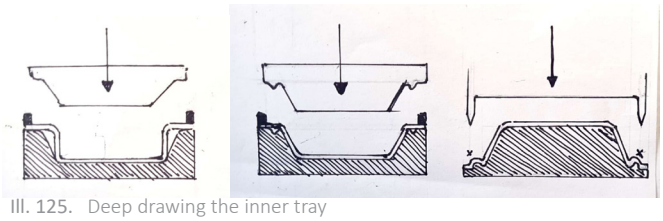
Ill. 123. Deep drawing the bottom

THE INNER TRAY

The inner tray may also be deep-drawn from a 2-millimetre-thick sheet of 6061-T4 aluminium with the use of 2 deep drawing tools. The sides and bottom are first punched or drilled with holes. After that, the sheet metal is initially deepened, and then the sides are angled. It is acceptable for the holes to be deformed as long as they maintain a 2mm diameter.



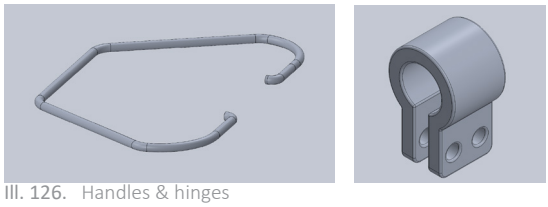
Ill. 124. Section cut of the inner tray



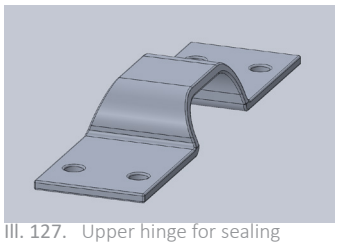
Ill. 125. Deep drawing the inner tray

ADDITIONAL PARTS

The handles are thought to be formed from a standard 4mm aluminium 6061-T4 rod that is bent into the desired shape. Aluminium 6061-T4 sheet with a thickness of 1 mm is used to create the following: The upper hinge has been stamped and cut to accommodate an angle that makes it possible for the lock to click onto the lid and for the lid to be easily removed. The desired form is achieved by cutting, stamping, drilling, and bending the lock and hinge of the filter holder. In the filter holder, the desired shape and holes are cut and stamped. The precise locking mechanism of the filter holder must be investigated further. The inner tray hinges are cut, drilled with holes, and shaped as desired. The desired shape for the lock is cut from an aluminium 6063-O sheet with a thickness of 2mm; a hole is drilled for the protrusion of the upper hinge, and it is bent to the desired shape. For additional information (App. 17)



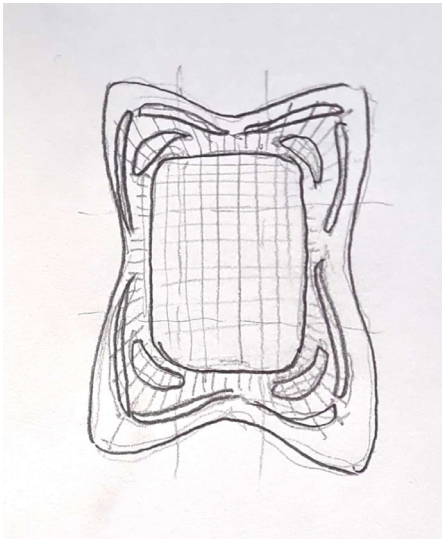
Ill. 126. Handles & hinges



Ill. 127. Upper hinge for sealing

OBS! DEFORMATION & WRINKLES

Additional research, analysis and simulations in Solidworks must be made to get an understanding of the risk of the lid, inner tray and bottom to wrinkle during deep drawing (ill. 128)



Ill. 128. Wrinkles and deformation caused by deep drawing

A conservative guess was made that the production of the three major parts would require eight moulds, maybe more, depending on the smaller steps required for the production of the edges on the bottom and the lid. With a rough estimate of each mould costing 250.000 DKK, it would require an initial investment of 2.000.000 DKK. An alternative to this could be the use of hydroforming, which is good for smaller quantities and can produce complex shapes. Doing this would likely reduce the initial investment in moulds, but would not accommodate the need for larger quantities (Vasile, 2016).

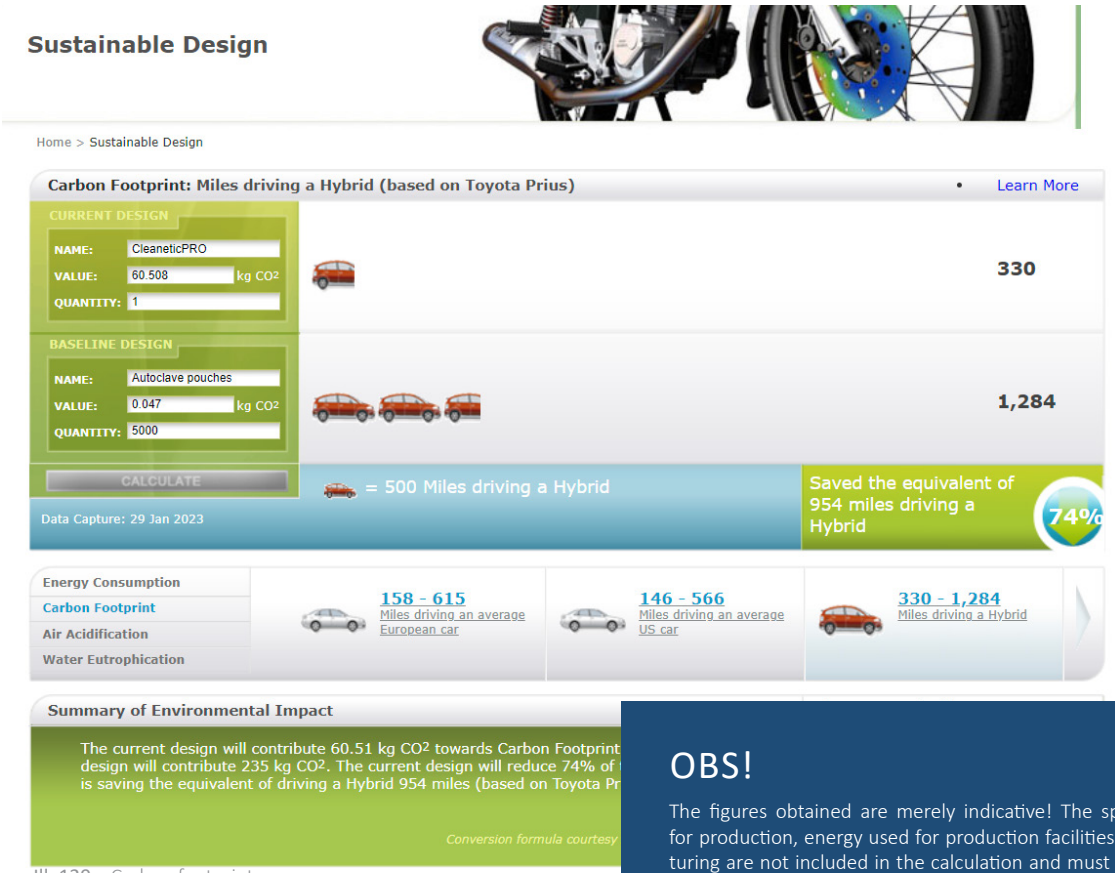
3.9 CO2-e ESTIMATION

With the initial calculation of the autoclave pouches CO2-e being 23g (See ws 25) and an additional publication in Oxford Academic stating the total footprint of autoclave pouches to be 44g of CO2-e per use. Moreover, stating that high-temperature incineration may increase the CO2-e with additionally 33-55 percent (Rizan et al., 2021). A rough conservative estimate of 32g + 44% = 47 g CO2-e per use cycle is made for a comparative analysis utilising Solidworks Life Cycle Design Based Assessment (LCDA) (What is Life Cycle Assessment (LCA) 2021).

The specified material and method of production were plotted into Solidworks' sustainable add-in program (App. 44). The parameters included the site of use and production, which was defined to be Europe, the material, the production method with a standard scrap rate of 5%, the coating, the end of life, and transportation. As the European objective for recycled aluminium packaging is 60% by 2030 (Packaging waste), is was determined, that the end of life estimation would be based on; 60% recyclable aluminium, 30% landfill, and 10% incineration with the primary mode of transport to be by truck with a standard maximum distance of 1931 km.

It is assumed that regional procurement will replace the containers after approximately 10 to 15 years, despite the fact that containers and inner compartments from companies such as Aesculap come with a lifetime warranty (Terms and conditions of sale). As a result, all product components were designed to have a 15-year lifespan. This is an approximation that requires further investigation.

60.5 kg CO2-e (reuseable 5000 cycles)
47g CO2-e * 5000 cycles = 235 kg CO2-e



Ill. 129. Carbon footprint

OBS!

The figures obtained are merely indicative! The specific country for production, energy used for production facilities and manufacturing are not included in the calculation and must be researched further, along with unknown parameters, for a Life Cycle Assessment (LCA) to be complete. In spite of its indicative nature, an LCDA can be used for further development in order to adjust individual parameters and reduce CO2-e of the product. Illustration of a 60kg x 1 CO2-e compared to 0,047 kg x 5000- equals to a 74% reduction in CO2-e equivalent to driving 157 miles compared to driving 419 miles in the average European car.

The LCDA's output indicates a 74% reduction in CO2-e of production based on the estimated 47g CO2-e of disposable pouch. It is most likely that the actual values are slightly higher or lower since not all inputs were found to satisfy all of the LCDA's parameters; this would necessitate additional analysis. Furthermore the analysis demonstrates that the weight of the inner tray, bottom, and lid are the primary factors that determine the weight of the overall carbon impact (App. 5). With the knowledge that aluminium can be deep drawn to as little as 0.5mm (Deep drawing - from simulation to 3D lasering: Meconet Oy 2022), it was assumed that the thickness of the lid, inner tray, and bottom could be reduced by between 40 and 50 percent, reducing the total material price per unit to **11.64 DKK** and CO2-e with 85% to **36.3 Kg CO2-e** (See WS 45).

COMPARATIVE DATA

By using the initial findings through the use of Solidworks LCDA and the CO2-e estimate of the autoclave pouches an initial comparative CO2-e estimation was found. The comparison is based on the findings of a medical journal that compared the CO2-e emissions of large containers, trays wrapped in sheets, and autoclave pouches in relation to the number of instruments contained within. It was determined that the implementation of a reusable container would eliminate the need for disposable autoclave pouches, thereby eliminating end-of-life transportation and incineration that contributes to the emission of additional CO2-e. However, a reusable container would require machine washing, which would increase the container's overall CO2-e emissions.

According to research, each use of a washing machine emits 3,74 kg of CO2-e, while each autoclaving emits 12,13 kg CO2-e (Rizan et al., 2021). At Farsø Hospital, a similar washing and autoclave programme was observed and utilised, but the duration of use between the journal article (Ibid.) and the duration at Fars Hospital does not correlate, making the numbers questionable. Due to it being the only indicative numbers an estimate was made:

Considering that the washing machines at Fars are estimated to have a capacity of 24 containers per cycle and that the space optimisation of the current container versus the autoclave bags has not been tested, it is assumed that approximately 36 pouches and containers are sterilised simultaneously, which corresponds to the findings of the British journal article (Ibid.).

Wash: 3.74 kg CO2-e / 24 containers = 0.115 kg CO2-e per cycle per unit
0.115 kg CO2-e * 5000 cycles = **779 kg CO2-e**

Sterilisation: 12.13 kg CO2-e / 36 units = 0.336 kg CO2-e per cycle per unit
0.336 kg CO2-e * 5000 cycles = **1680 kg CO2-e**

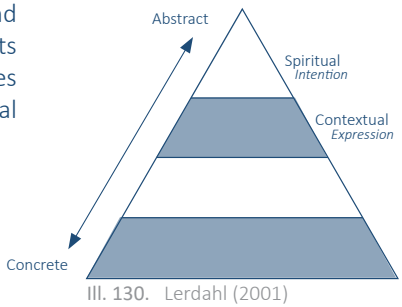
The use of a container for 5000 cycles:
36.3 kg CO2-e + 779 kg CO2 + 1680 kg CO2-e = **2495.3 kg CO2-e**

The use of 5000 autoclave pouches:
235 kg CO2-e + 1680 kg CO2-e = **1915 kg CO2-e**

Even though the CO2-e of the container reduced the impact by 85% compared to the autoclave bags in terms of material, production, and end of life, the additional washing will be a significant factor in the overall CO2-e calculations, according to the estimated calculations. Using the container over 5000 with the current data will not be more environmentally friendly, as the increase in kg CO2-e will be 23.2%. This must be taken with a grain of salt due to the numerous uncertainties, particularly in regards to washing time and space utilisation and optimisation within the machine washer - This would need to be investigated further using data from one of the five Danish regions.

PHASE | 4

In the following phase it is described how the team expands the context and relates the product proposal to the bigger picture. Here the team reflects upon the industry in which the product will be adapted and the opportunities within. In Lerdahl's pyramid the team is now jumping between the contextual level and the material level.



Ill. 130. Lerdahl (2001)

4.1 DOES IT SCALE?

The project's unit of analysis has been the sterile processing department at Farsø Hospital in Region Nord; The department's estimated total demand in the product category of 30x20x6cm containers is **200 units**. Evidently, this volume is insufficient to support a business case; therefore, a thorough segmentation of the Danish public and private health care sector is required to estimate the total potential demand in Denmark, and in subsequent steps, in the Nordic countries and EU. On the basis of data from Farsø Hospital and desktop research, it is possible to calculate the Danish demand and estimate the country's scaling potential.

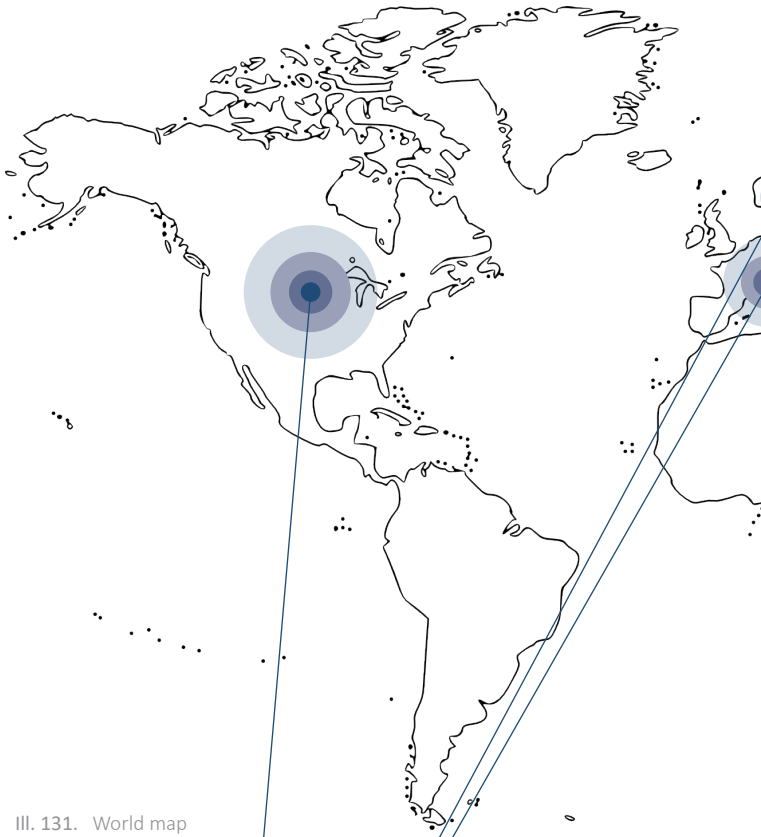
It is found that Farsø Hospital performs approximately **4.000 surgical operations** (orthopaedic and emergency combined) annually (Informationsfolder om: Farsø Sygehus- en vigtig del af Nordjyllands sundhedstilbud 2018), which gives a ratio of **1 unit to 20 surgeries**. The ratio of 1/20 is based on planned and emergency operation and is thus subject for further analysis.

According to the medical newsletter Dagens Medicin, Danish public hospitals performed **245.000 planned surgical operations** in the first three months of 2023, an increased value of 10% compared with 2022, It is expected to rise even further, as is the volume of surgical procedures performed in private clinics (Thieden, 2023). Assuming an even quarterly distribution, this equates to approximately **1.000.000 planned surgical operations at Danish public hospitals each year.**

With the estimated demand at Farsø Hospital, a conservative and preliminary estimate of the total Danish demand would therefore be in the range of **50.000 units.**

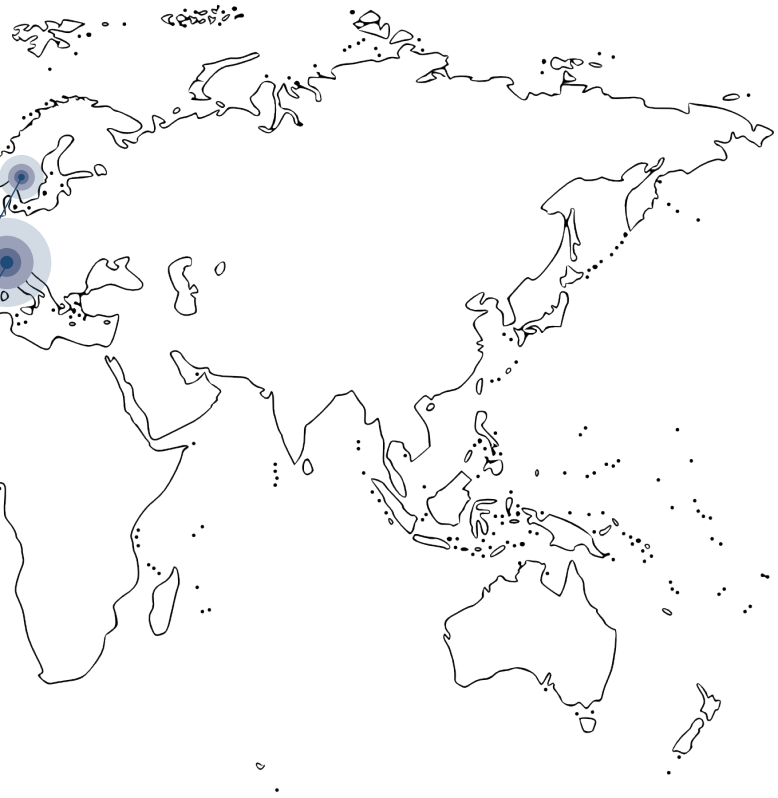
4000 planned operations/200 units = factor of 20
1.000.000 planned operations/factor of 20 = 50.000 units

Research indicates that Danish public hospitals are under pressure, partly due to a shortage of qualified staff and partly due to the treatment guarantees that were reinstated following the pandemic in early 2022 (Patientrettigheder Genindføres I dag 2022). Private hospitals are expected (Thieden, 2023) to benefit from this and perform more surgical operations and, not only 'trivial' but also of a more complex nature. As the private sector is gaining weight (Moestrup &



Ill. 131. World map

Ill. 132. Scaling Cleanetic PRO



Overgaard, 2023) This necessitates an examination of the demand for the need in this industry, where certain requirements may vary.

Using the same metrics for this product category, the total Scandinavian demand for **Cleanetic PRO** could exceed **150.000 units**, with the Norwegian population being slightly smaller than the Danish population and the Swedish population being approximately 60% larger, for a total of approximately 22 million people (Scandinavian countries 2023).

EU-level statistics are challenging to interpret. Most likely, the previously mentioned indications are scalable to the EU, but this necessitates a more thorough, in-depth market analysis than what EU statistics report (Statistics explained). Initial desktop research reveals that "… globally, a staggering 310 million major surgeries are performed each year; around 40 to 50 million in USA and 20 million in Europe" (Dobson, 2020).

According to Marketsandmarkets, a US based B2B market research firm, the global market for sterilisation container systems is expected to exceed **USD 375 million by 2026**, up from USD **324 million in 2021** with an **annual growth rate of 3%** (Sterilisation container systems market size, share: 2022 - 2026); a similar study by GlobeNewswire estimates a total value of USD 389.5 million by 2029 (Fortune Business Insights, 2023).

Among the major drivers that will increase the volume of surgical operations and procedures are advances in surgery – more advanced procedures, less hospitalisation, more out-patients – and the demographic development – increasing life expectancy, active lifestyles – which e.g. contribute to the growth in artificial joint surgery, hips and knees in particular (Hip replacement market size & share: Forecast report: 2031)

According to studies, the global sterilisation container market represents a significant volume and revenue, is steadily growing, and based on key information from Farsø Hospital, the team finds the initial assessments of the potential in Denmark and Scandinavia of 50.000 and 150.000 units respectively adequate for an initial screening - but also highlights the need to gather further market intelligence for a proper segmentation. While it is difficult for a startup to compile structured, fact-based market intelligence, it is probably readily available in the marketing departments of major established competitors. In addition to geographic and macroeconomic parameters, additional segmentation should incorporate a more in-depth analysis of the national health care sector's structure, specific regional versus local procurement procedures, and loyalty & frequency indicators (Region Midtjyllands Strategi for bæredygtighed 2023).

4.2 INDUSTRY STRUCTURE

The med tech industry can be analysed using Porter's Five Forces model; an effective tool for assessing the industry's current state that can be used as a basis for positioning and evaluating strategic options (source) - in this case for sterile processing containers.

Ill. 133. Adapted from Porter's five forces (Hollensen, 2011)

The supplier power is assessed to be relatively high; as in other segments of the med tech industry, this market is dominated by relatively few global companies (Fortune Business Insights, 2023), which are represented by subsidiaries in the most significant export markets and distributors in the less significant markets - an example could be B Braun: (see illu) with a high brand equity, manufacturing capacity and global supply chains & logistics to ensure deliveries.

The threat of new entrants is assessed to be minimal; Even if capital requirements are "modest," (see Production) a new entrant encounters an established, consolidated industry with companies that have achieved economies of scale, with strong brand equity and customer relationships, and in addition to the obvious competitive parameters in manufacturing and distribution: quality assurance expertise, testing and established relationships with notified bodies for CE and FDA approvals, which is a crucial part of market entry.

The threat of substitutes is assessed to be low; Hospital procedures and processes in the sterile processing department, whether semi-automated or fully automated, must adhere to the highest hygiene and durability standards, as hospitals have either invested in or re-invested in capital equipment (autoclaves + washing machines). At Farsø Hospital, particularly within the SPD, there was a clear emphasis on quality over price, with new procurement typically based on the importance of 40% quality and 60% price, which the SPD has been able to change to 60% quality and 40% price.

"At Farsø, we've been able to switch the priorities so that the procurement is now based 60% on quality and 40% on cost."

The **buyer power** is perhaps the most intriguing 'force'; this relates to the EU in general, most likely also to the United States, but initially, when looking at Denmark is it assumed to be **high**; following the national goals for 2030, all regions in Denmark are focusing on sustainability materialised in 2025 and 2030 (min. emission) goals and achieving CO2 neutrality in 2050; an example is the January 2021 the Central Denmark Region Strategy for Sustainability (Region Midtjyllands Strategi for bæredygtighed, 2023), where one of the ambitions is to achieve a 67% reduction in CO2 from 2018 to 2030 incl. goods and services, i.e. including this product category.

The Danish industry association Medicoindustrien is in close dialogue with Danish regions to debate and address the needs and challenges arising from - in a global perspective - the most ambitious climate policies in Denmark. Moving on to capital equipment, the initial procedure has centred on packaging, as packaging is an integral element of numerous products' CE certification and FDA approval (Bæredygtighed). As environmental, social and corporate governance (ESG) reporting will be mandatory in EU for the larger companies in the industry from 2024, and later for the small and medium-sized enterprises (SME's). This could easily become a central criterion for procurement divisions, a "licence to operate," and thus a formidable barrier for underperforming companies.

Even though individual hospitals may have some say regarding preferences (c.f. responsibility), the trend is towards strengthened regional tender processes and purchases for all hospitals in the region; while

the winner does not necessarily take it all, it restricts competition and excludes suppliers for the duration of the frame agreement.

The fifth and resulting power is the **intensity of rivalry** among industry competitors, which is deemed to be **high** as a result of buyer power; in accordance with Porter's generic strategies, this indicates the need for strong differentiation strategies, i.e. a focus on differentiation criteria that directly address the primary stakeholder needs (c.f. Ladder of responsibility).

Competitors – Key players in the sterile container industry include a dozen companies including KLS Martin, B. Braun (Aesculup), Johnson & Johnson, Stryker – all of which the team has seen represented with containers at Farsø Hospital and NAU - and a handful of other companies (source).

Contrary to the initial goal of developing Cleanetic PRO as a platform for a genuine Danish start-up venture, it can be concluded, based on the analysis above, that a partnership or cooperation with an industry incumbent partner, providing the opportunity to enhance and differentiate an existing portfolio through existing distribution channels, is a more direct path to volume and market shares given the market's configuration and conservative dynamics.

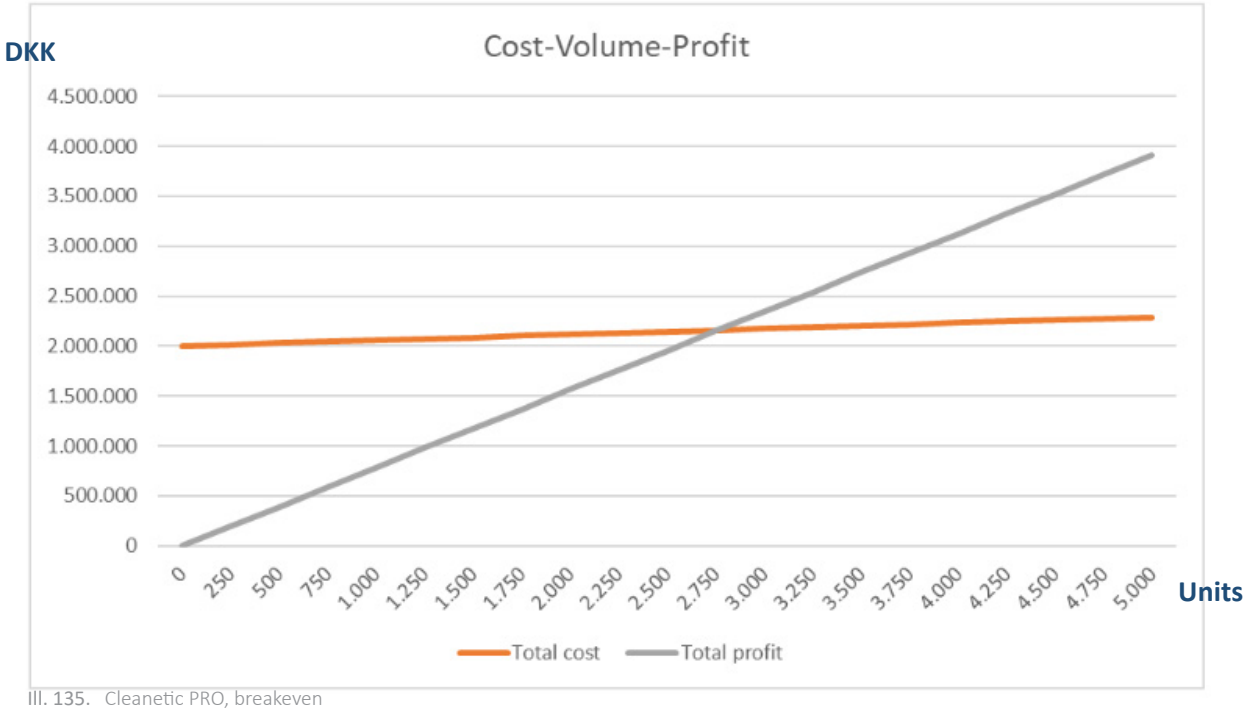
4.3 COST ESTIMATION

With an investment of eight tools totaling 2.000.000 DKK (c.f. Production), a total material cost of 11.61 DKK per unit (App. 16), a labour and assembly cost of 43.38 DKK per unit, cost of transportation of approximately 10 tonnes of cargo over a distance of 1,931 km (App. 19), and the exclusion of overhead, a preliminary cost estimate is formulated.

The Cost-Value-Profit ratio was calculated using the optimised unit cost price and an end-user target price that, at 1,400 DKK, is neutral compared to hospitals' current pouch expenses of 0.28DKK per pouch (App. 19). The profit is equal to the manufacturing entity's gross margin excluding overhead costs and expenses for quality control, marketing, sales, research and development, and administration. Excluded from this calculation is a deliberate 40% margin reserved for the national sales offices.

Cleanetic PRO - Manufacturing costs, price & profit calculations					
Variable costs @ 10000 units	**Qty.**	**Price (1)**	**Price (opt. #2)**	**Production Method**	**Prodcution location**
Material price per unit USD		2,80	1,68	@ 10.000 units	Germany
Material price per unit DKK		19,35	11,61	Deep drawing	
Labour DKK per unit		43,38	43,38		
Transport DKK per unit		1,44	1,44		
#1 Thickness 2mm due to 3D print					
#2 Assuming a 40% reduction of material when optimized for production					
LCDA calculation in separate doc (reference)					
Fixed costs (investment in tools, DKK)		2.000.000,00	2.000.000,00		
Target market price per unit (DKK)		**1.400,00**	**1.400,00**		
Net transfer price ab factory (DKK)		840,00	840,00	Sales Off. 40% margin	
Manufacturing costs Aesculap		64,17	56,43		
Aesculap net profit per unit (DKK)		775,83	783,57		

III. 134. Cleanetic PRO, manufacturing cost



III. 135. Cleanetic PRO, breakeven

The above calculations are entirely indicative, but the team is confident that properly disclaiming them is sufficient to initiate a conversation with an industry incumbent partner. The point of break-even is a relatively modest number of Cleanetic units, and the calculations provide the foundation for a comprehensive joint revision utilising partner company metrics and data on all of the previously mentioned shortcomings. The target price for the end user may be lower due to the additional CO2-e and cost of machine washing, or it may be higher due to the benefits of limited waste handling, process improvement, and streamlining in the SPD, as well as over gains for both of the primary stakeholders; this would require further analysis.

4.4 STRATEGIC FIT

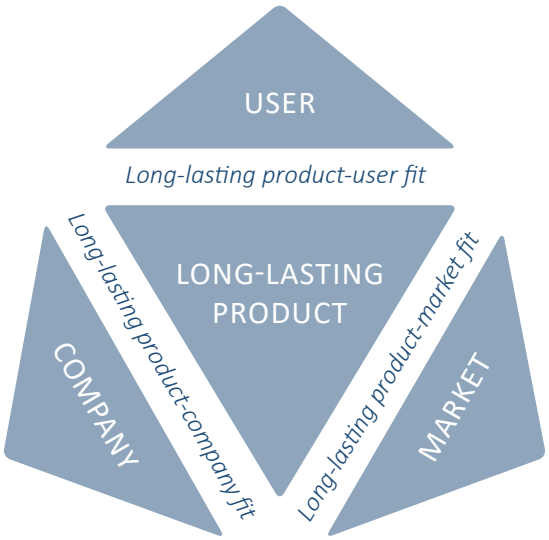
Initial analysis indicates that Cleanetic PRO per se has the properties and attributes to provide a long-lasting-product user fit (Møller & Laursen, 2022), but it will require organisational capabilities and resources of an incumbent to harvest the full potential as it is a solution that potentially can be targeted on a global scale.

Through dialogue with the SPD and SU nurses at Fars Hospital, a preference for B Braun's Aesculap sterile containers was identified, despite having both KLS Martin and Stryker. Aesculap is selected in the following section for the implementation of Cleanetic PRO, in part due to the positive bias at Fars Hospital, which has proven to influence the design process along the way, with Aesculap's large sterile container being set as the early benchmark for a sterile container (see Benchmarking) and partly based on desk research.

Aesculap, based in the United States, was acquired by the German company B. Braun in 1996; Aesculap is thus the surgical division in the highly diversified B. Braun portfolio of companies and markets & distributes its product portfolio through the global network of sales offices (in Africa, only South Africa) in the B. Braun Group (AESCULAP surgical instruments).

Cleanetic PRO has the potential to enhance Aesculap's sterile container portfolio by providing a value proposition in line with the environmental goals in the healthcare industry, and also serve as a catalyst for a portfolio revision, with the potential substitution of autoclave pouches. In addition, Cleanetic PROcan directly benefit from Aesculap's core competencies in research and development, quality assurance and certification, manufacturing experience, effectiveness, and logistics. Cleanetic PRO enhances and benefits from Aesculap's organisational strengths while providing a **long-lasting product-company fit** (Møller & Laursen, 2022)

Even though Cleanetic PRO is unique and indicates the potential for a stronger proposition for a long-term competitive fit, between the primary stakeholders' needs and Aesculap's potential future strategy towards the substitution of disposable packaging (Ibid. s. 44), it is not impossible to imitate; however, by being the first mover, Aesculap gains a competitive advantage and is able to pro-actively influence sterile processing departments and regional procurement departments and thereby create a long-lasting product market fit (Ibid. s. 59)

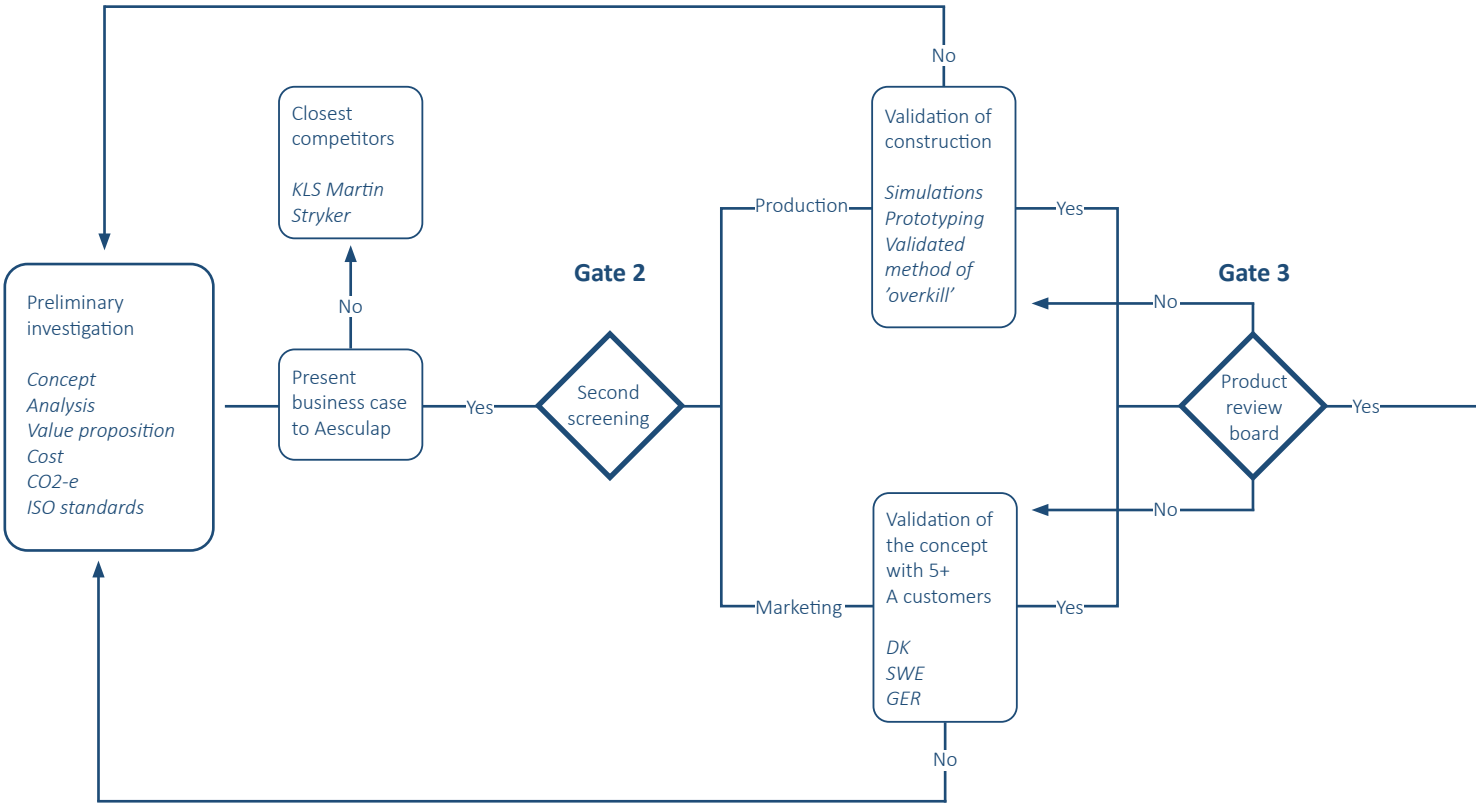


Ill. 136. Adapted from 'Design for Longevity' (Møller & Laursen, 2022)

It is promising that Cleanetic PRO could tap into the statement in Aesculap's 'Foundation of our Business'; "Company growth is financed through internal resources, an innovative strength, and the commitment to uphold this directive for future generations.", aligning it with the company's values, purpose, and culture (Møller & Laursen, 2022), which, along with the indications of the potential for a long-lasting product user, company, and market fit, could be part of the long-term credibility of Aesculap, that would strengthen their future competitive advantages as a frontrunner in the European Hospitals 'green' transitioning and goal of CO2-e neutrality in 2050 (Green transition).

4.5 BUSINESS CASE

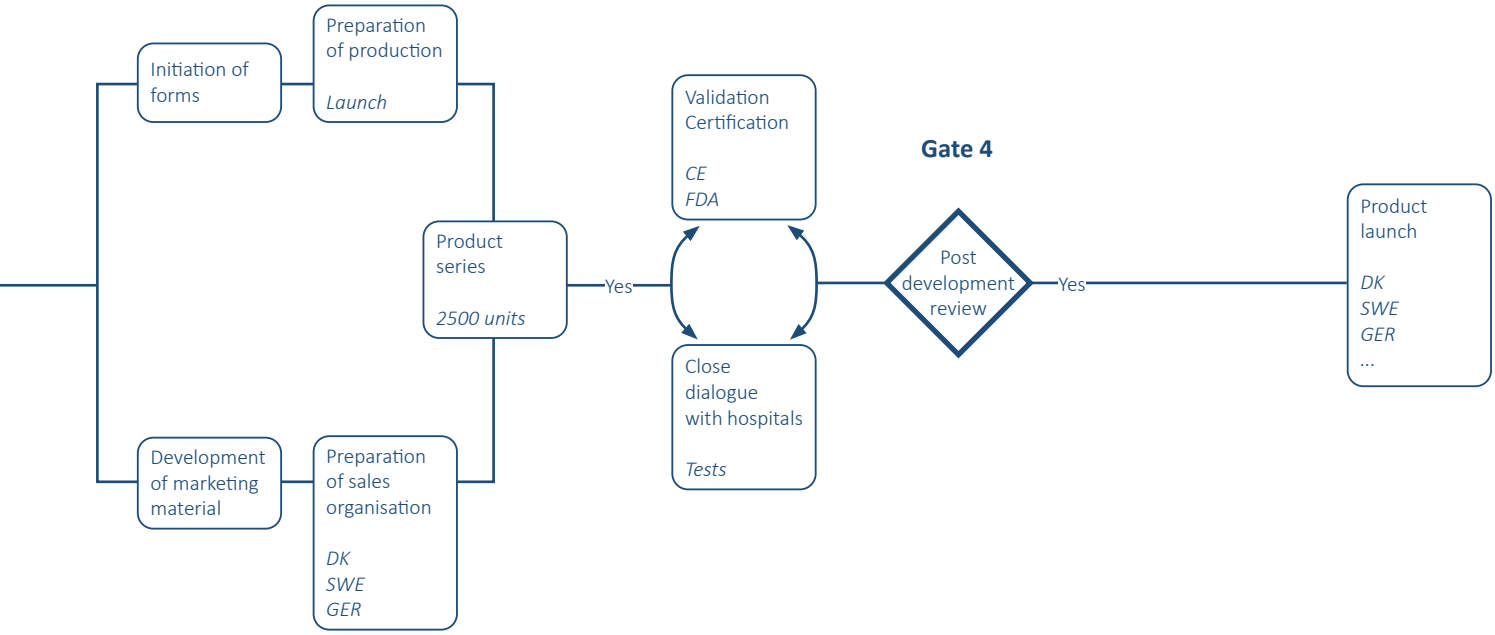
Contract with Aesculap for finalising Cleanetic on a consultancy basis plus an exclusive licensing agreement (e.g. with a 5% royalty), exclusivity based on an annual minimum royalty (based on agreed min. turnover). No need to assess the other partnership modes such as contract manufacturing, franchising or joint venture from a risk point of view; the team assesses the advantages in teaming up with a strong, global partner like Aesculap to outbalance all disadvantages. In case Aesculap decides not to enter in a partnership, other options remain open, ref. 'competition'.



Ill. 137. Product implementation plan

Detailed investigation
Additional development is required on the critical design parameters, such as the lid and the angled side of the lid, inner tray and bottom. Additionally further research regarding overall cost, proper use of materials and CO2-e is required. Lastly the insurance that the following concept lives up to the required ISO-standards. Once at a proof of concept as well as comprehensive CO2-e, cost analysis and value proposition it can be presented to Aesculap.

Development
Once through the second gate, a validation of construction and marketing is required with the use of 5A's customer journey (Sertis, 2022) and through Aesculap's high-end prototyping facilities in Germany, additional simulations and the validated method of overkill can be tested.



Testing & Validation

If the concept goes through the product review board, no further larger development will be made, as initiation of forms and a series 0 would be prepared for launch, where validation and certifications are assured in close dialog with hospitals before the actual product launch in Denmark, Sweden, Germany.

SPECIFICATIONS

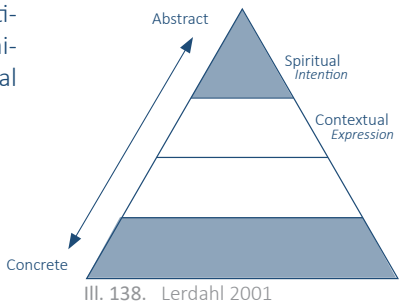
The table below sums up requirents that have been specified at this point in the project into specifacations that can be confirmed or measured. All needs with the importance of 1 have been adressed, except for two (need no. 7 and 8). Needs from previous design briefs would still be relevant in a potential further development of the concept, as well as current specifications and metrics are not defined sufficiently on all parameters.

Specification	Metric
Must withstand mechanical wash.	Must withstand: 80°C for 10 minutes 85°C for 3 minutes 90°C for 1 minute
	Must be produced in Aluminium 6061 T4
Must withstand a steam autoclave.	Must withstand: 134°C for 3 minutes 121°C for 15 minutes
	Must withstand a pressure of 3 bar
	Must be produced in Aluminium 6061 T4
Must comply with ISO-standards described in NIR	DS/EN ISO 11607-1, 14937:2009, 10993-1:2009, 11138, 14161, 15882, 11140, 17664, 868-2
All tubes and holes must have an airgap of 2 mm	
The concept must be able to dissassemble into five parts: *The lid, the filter-holder, the inner tray, the bottom and the closing clips*	
The bottom, lid and inner tray must be stackable when disassembled	The angle of the bottom must be angled from 70° to 75°
	The angle of the inner tray must be angled from 70° to 75°
The containers must fit in a stackable system despite variations in size	Outer dimensions of the assembled containers must be L20 x W15 x H6 cm L30 x W10 x H6 cm L30 x W20 x H6 cm
~~Grooves in the lid must accommodate for several sizes of containers for stacking~~ All three sizes of containers must include grooves in the lidt for the other two sizes as well	
Must include a single use filter	The legs must be 12 mm in height.
~~Must be sealed air tight~~ Air must only pass through the filter	Filters must have 1 cm of airflow until a solid surface
	The lid must include a rubber gasket.
Must fit the racks of the mechanical washer	
Must fit into the steam autoclave	Measurements must be divisable to 60 cm
Must fit into cabinets for transport and storage	
Must allow for OP-nurses to lift with palms of their hands facing each other	The size of the handles' interface on the inner tray must be min. 10 cm
Must have interfaces with a suitable size and texture/grip	
Must not risk touching an unsterile edge	The lateral distance between the sterile and clean edges should be 1 centimetre
Must be able to handle several assembled containers at once	The grooves in the lid should be 2 mm in depth
The filter must be placed in the lid	
The closing mechanism should be flexible	The closing mechanism should be produced in Aluminium 6063-O

7	To include visual indicators that the package has been sterilised	The instrument loop	1			
8	To include spot for labels to track instruments	The instrument loop	1			

EPILOGUE

In this last phase the relation between the final product proposal and the initial vision and goals is reflected upon, to conclude whether consensus is obtained between the material level of the product and the abstract and spiritual level in Lerdahl's pyramid. Has the product fulfilled its mission?



Ill. 138. Lerdahl 2001

5.1 CONCLUSION

The purpose of the project was to reduce the use of single-use packaging in the Danish hospital industry, which is one of the essential areas for clearer procurement demands if the five Danish regions are to reach their common goal of reducing total CO2 emissions by 70% by 2030 and to be in line with UN goals (Grønne Hospitaler). Cleanetic PRO was estimated to reduce CO2-e emissions when compared to the use of disposable autoclave pouches in terms of material and production over the product's lifetime. However, further analysis indicates that Cleanetic PRO does not reduce CO2 emissions after 5000 cycles due to the additional step of machine washing. The estimations were based on an unpublished report from the Centre for Sustainable Hospitals and an English-based analysis of the overall CO2-e impact of sterile containers, sheet wraps, and autoclave pouches with respect to the number of instruments within. Even though the washing machine and autoclave were of similar design to those at Fars Hospital, the numbers indicated the use of a different system, with different time and temperature requirements that are not necessarily directly applicable but are indicative. Further analysis and concept development are therefore required.

In terms of sustainable procurement of goods and a circular economy with minimal waste, it was learned that the region will prioritise clearer demands for a more sustainable procurement process that is in line with UN objectives, such as a longer product lifetime and an emphasis on repair and leasing deals.

During the three visits to Farsø Hospital, the team gained valuable insights into the overall Danish healthcare system, the sterilisation of surgical instruments, and the systems of a smaller sterile processing department that were not included in the acquired national guidelines (NIR). One of the acquired insights was the parameter of personal risk assessments, which vary for each individual in the sterile processing department at Farsø Hospital and each specialised department as a whole, indicating a rigid yet complex system that, despite streamlined national specification metrics, guidelines, and a regional joint procurement agency, can act and procure new goods based on their respective risk assessments. This suggests that despite the current expression of good intentions from a strategic standpoint, a shift towards a more sustainable procurement process emerges when the overall needs of the operational level have been met.

Cleanetic PRO is designed to accommodate stacking, both of each individual component and in the autoclave, in order to optimise the available space in the autoclave. The team identified that storage-related boundaries would be one of the major obstacles to the implementation of additional reusable sterile containers. As Cleanetic PRO has not yet been subjected to a comparative test, it cannot be asserted that it is in fact a space optimisation solution in the sterile processing department. This will require additional testing.

The project's primary objective included laying the groundwork for the potential launch of a startup. Through preliminary user tests, analysis of the industry structure, scalability, and key financial figures, it has been determined that Cleanetic PRO has potential through contracting with an industry incumbent partner on a consultancy basis plus an exclusive licence agreement (e.g., with a 5% royalty), exclusivity based on an annual minimum royalty, as opposed to a traditional start-up.

5.2 REFLECTION

Due to the rigidity of the system in both the sterile processing and surgical departments, a number of design challenges were addressed through reflection in action rather than reflection on action, evaluating the contextual significance of isolated parameters for each stakeholder (Laursen & Tollestrup, 2017). As a result, the design process evolved into the creation of a series of compromises that would permit adaptation to the structure of the SPD, while enhancing gain-creators for the OP-nurses and strategic levels, such as the region and government, in an effort to reduce CO2 emissions and overall waste in the healthcare industry.

During the process of sequentially fragmenting and addressing the individual design parameters of Cleanetic PRO, the distinction between the two categories of users became evident; the SPD served primarily as a source of boundary conditions, whereas the surgical department had more explicit, observable, and applicable needs that could be translated into tangible design parameters. During the initial design phase, the team tended to prioritise the needs of the OP-nurses, despite the fact that the SPD specifications should have been reevaluated and possibly prioritised earlier, as the concept would only function if it met the specified boundary requirements, which could have been tested.

With each visit to Farsø Hospital, the team alternated between a research-driven user-centred approach with contextual inquiry, treating users as subjects, and a participatory mindset that leaned towards Co-creation (Sanders & Stappers, 2008). During the team's visit to Farsø Hospital, the SPD- and OP-nurses were viewed as partners in order to articulate and address the unique needs of each stakeholder in order and to develop a valid, long-lasting value proposition with a strong user fit (Haase & Laursen, 2019). As the OP- nurses had the most specific needs, it is possible that they significantly influenced the group's sense of direction, resulting in the prioritisation of specific needs such as "transparency" that were not further defined, as the team viewed them as the subject matter experts.

After each visit, the gathered information was quickly revised and used to update the design briefs, but the team then turned to research to support the decisions made rather than testing the tangible parameters at hand, such as space optimisation in the autoclave. Even though the team was aware of the group's tendency to frame potential problems from a top-down perspective rather than a bottom-up approach, it is evident in the process report that details parameters such as CO2-e estimation, the potential of scaling and implementation plans, and concept implementation were prioritised.

Changes to the lid's rim on the most recent version of the Cleanetic PRO container are a cause for concern. By the third and final field trip to Fars, the team discovered a misunderstanding regarding the lid's transparency, which had repercussions for the remainder of the design. To rectify the error and comply with the findings, the team decided to redesign the lid so that it could be manufactured using aluminium deep drawing. With the new edge, the inner supporting edge has been eliminated, relying on the material's hardness to maintain its shape during a stacking scenario in which the weight of other instrument kits will press down on the lid. The concern is whether the edge of the lid and the silicone rubber are susceptible to deformation; this would require further investigation and testing.

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ILLUSTRATIONS

All illustrations without reference to source are owned by the team.