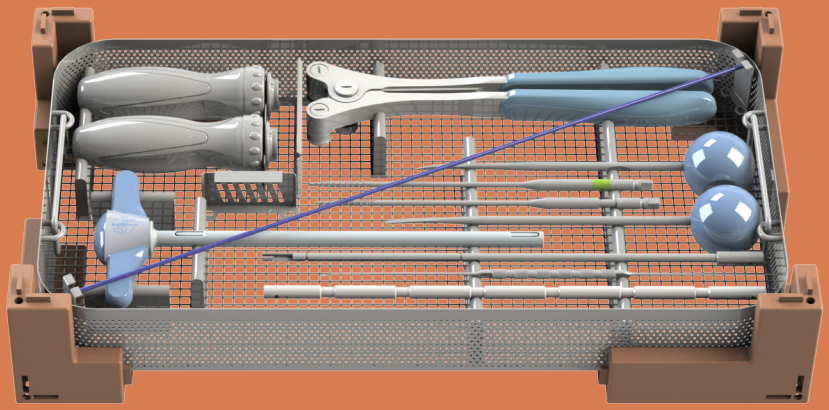
MASTER THESIS

A MODULAR CASING FOR TRANSPORTING STERILE SURGICAL INSTRUMENTS



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VAN STRATEN MEDICAL
'Providing Value to Life'

Preface

This thesis is the result of my graduation project at Van Straten Medical, and the final deliverable for obtaining my Msc degree in Industrial Design Engineering at the University of Twente.

During the last 8 months, I have learned to apply knowledge of my bachelor's and master's degree into a problem that was completely new to me. Finding each and every problem of current methods, analysing these problems, and translating these problems into solutions was an interesting learning experience.

This project was done in collaboration with Van Straten Medical, a company with almost fifty years of experience in the medical sector. For the past couple of years they have become a leading example of how to make the medical sector more sustainable. They provided me with the opportunity to see this change from a front row seat.

And that is why I want to thank Niels van Straten for this opportunity and helping me with all kinds of questions. I also want to thank all other colleagues and fellow-inters for their help: from troubleshooting 3D printing errors to participating in brainstorm sessions, from being subjected to usability testing to showing me the tricks of the trade in the medical sector.

I also want to thank Edsko Hekman, for always giving clear and straight-to-the-point advice on making progress in the project while keeping an eye on the scope. I would also like to thank Gabriëlle Tuijthof and Eric Lutters for a fresh perspective on the project, from a more external point of view.

Sanne Schoneveld
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Abstract

There is not yet a good way of transporting sterile surgical instruments in DIN baskets between instrument manufacturers, central sterilization departments, and care facilities. Maintaining the sterile barrier with current transportation methods is not reliable. Current methods are also wasteful or difficult to use. As many instrument manufacturers are going to use DIN baskets as transportation method in the future, a solution for shipping sterile surgical instruments in DIN baskets safely, reliably, and a way of keeping instruments that belong to one surgical set together is a must. Using different design methods like analysing, brainstorming, and decision making, a product is developed that solves current transportation and logistical issues.

The product that is realised is a modular divider system. This divider is the building block for the system. Depending on the orientation of the divider, it fits on different heights of DIN baskets. With a clicking mechanism, the dividers with DIN baskets can be stacked together to form a set of baskets. With some accessories, the divider system fits in current transportation containers of different dimensions. The divider system integrates into the current system and replaces the use of bubble plastic. The divider system can be used for transportation between instrument manufacturers, central sterilization departments and care facilities. A Failure Modes & Effects Analysis, usability test, and functionality test show some improvement points for the current product. Although a final concept is presented, the product is still in its infancy. Some additional design engineering is needed to implement this product into the current system.

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List of abbreviations

Corresponding Dutch abbreviations are written in italic

ADR	Accord relatif au transport international de marchandises Dangereuses par Route
CSD *CSA*	Central Sterilization Department *Centrale Sterilisatie Afdeling*
DIN	Deutsche Institut Für Normung
FMEA	Failure Modes & Effects Analysis
IFU	Instructions for use
ISO	Institution for Standardization Organization
MDR	Medical Device Regulation
NEN	Nederlandse Norm
OR	Operating Room
RSCs	Rigid Sterilization Containers
SPS *DSMH*	Sterile Processing Specialist *Deskundige Steriele Medische Hulpmiddelen*
SPT *MSMH*	Sterile Processing Technician *Medewerker Steriele Medische Hulpmiddelen*

01

Context

Sterilization of surgical equipment is a key element in modern medicine. Without sterile equipment, patients may contract serious illnesses as a result of contamination. A reliable product that can help maintain this sterility during transportation of surgical equipment is essential. Before this product is discussed, the context of the design assignment is briefly explained. Also, a preliminary problem definition is given and the methods that are used to execute the assignment are explained.

1.1. Van Straten Medical

The company for which this assignment is carried out supplies surgical instruments and surgical disposables to hospitals and private clinics in the Netherlands and abroad. They have a department that repairs instruments that have been rejected to be used, which prevents these instruments from ending up in a landfill.

Lately, Van Straten focusses on circular innovations in the medical field. One of the company managers, Bart van Straten, investigated if surgical polypropylene sterile wrap can be recycled into new products [1]. He is currently researching the opportunities for products that can be made from recycled polypropylene.

1.2. Care facilities

Different types of surgical equipment are needed for specific medical procedures. For a single hip replacement surgery for example, different types of scalpels, hammers, files, probes, and chisels are needed. After use, these instruments need to be cleaned, disinfected, and sterilized in order to be used for the next patient.

All instruments that are needed for a specific surgery form a surgical instrument set. These instruments are stored in so-called DIN baskets, see Figure 1. One surgical set can be split along multiple DIN baskets. All storage cabinets, washer-disinfector machines, and other equipment in these care facilities are dimensioned according to the dimensions of these baskets.

1.3. DIN baskets

The DIN baskets follow German standards for dimensions made by the Deutsches Institut für Normung (DIN). These baskets are made from medically approved stainless steel. They provide a way to transport instruments between facilities safely, while allowing the instruments to be disinfected and sterilized in the same baskets.

The bottom of the basket is made from cross-wired stainless steel material. This construction allows the basket to be light-weighted and the basket including the instruments can be washed from every direction. Van Straten Medical uses a special method for keeping the instruments fixed in their designated places using silicone holders. These holders are cut in such a way that the instruments in the basket are kept in place during transport and cleaning.

1.4. Central Sterilization Department

Sterilization of the equipment happens at a Central Sterilization Department (CSD). Van Straten Medical works closely together with CSA Services Bv., a CSD that is in the same building. Instruments that were used in surgery, are transported to a CSD in their DIN baskets. The contaminated instruments are handled with care, since personnel could be infected while touching the instruments in an unsafe manner.

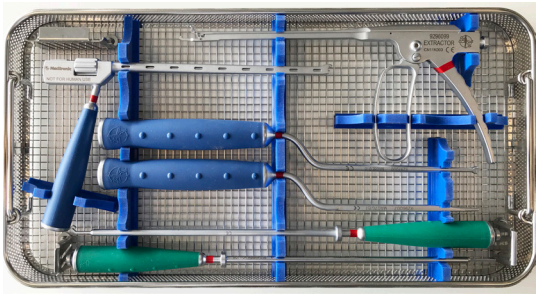

Figure 1: A DIN basket with surgical instruments and blue silicone holders

The sterilization process at a CSD happens in a certain order: cleaning, disinfection, and sterilization. Instruments that were used during a medical procedure are taken out of their baskets and manually cleaned. All visible protein, fat, blood, and human tissue is removed. The instruments are placed back into their baskets and go into a washer-disinfector, which disinfects the instruments with hot water and detergent. After drying, the instruments are checked for functioning and placed back into their DIN baskets. The baskets are wrapped in sterilization wrap, see Figure 2.

With the help of hot steam, the sets are then sterilized in an autoclave. High temperatures and high pressures inside the autoclave open the fibres of the sterilization wrap. When the steam reaches the instruments, the instruments are sterilized. When the temperature in the autoclave is lowered and the pressure drops, the fibres close and the sterilization wrap forms a sterile barrier. While the sets can be stored for up to 3 months in the sterile chamber, in practice sets are quickly picked up by a courier to be transported to care facilities, where they are used for new procedures.

1.5. Instrument firms

Instrument firms like Medtronic, Stryker, and NuVasive manufacture surgical instruments. There are different methods to transport these instruments to a CSD. Often these firms have their own transportation trays, see Figure 3. These trays are similar to DIN baskets but differ in size and are often made from aluminium. While these trays are great for shipping instruments from A to B, instruments cannot be disinfected and sterilized in these trays. For that reason, instrument firms are switching from shipping instruments in these trays to shipping in DIN baskets.

1.6. Transportation of sterile instruments

Currently there is not yet a good way of transporting instruments in DIN-baskets. By lack of a better solution, conventional euro sized containers are used in combination with a foam, bubble plastic, or Velcro layer. Another problem is keeping wrapped baskets safe after sterilization. These conventional containers are not specifically designed for sterile transport. These conventional containers in combination with bubble plastic are used by lack of a better solution.

Figure 2: Wrapped instrument sets in wire baskets

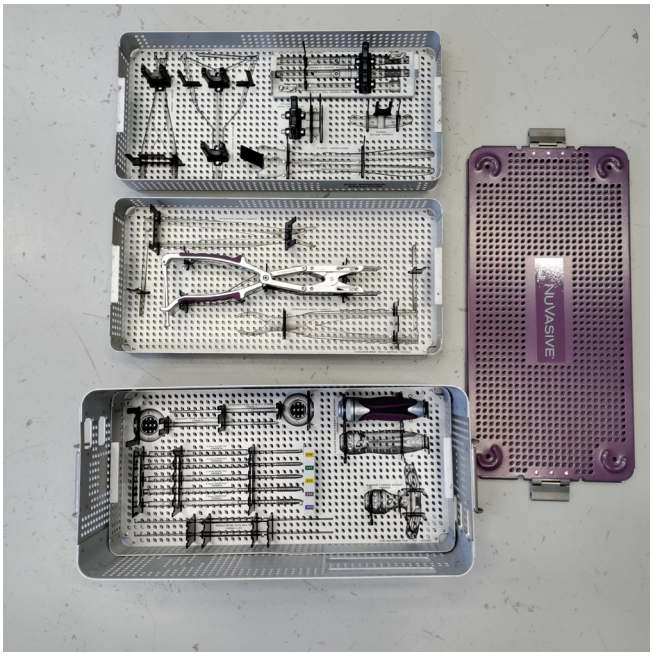

Figure 3: Surgical instruments in robust aluminium tray

A layer of bubble plastic is placed on the bottom of a conventional transportation container, the sets are placed on top of the bubble plastic, and between each set a layer of plastic wrap is placed, see Figure 4. The bubble plastic prevents slipping of the sets inside the box and puncturing the sterile barrier. The plastic does not protect the sets from weather conditions, falls, and impacts. If a tear is found in the sterilization wrap, the surgical set needs to be considered unsterile. This means that a set is sent back to the CSD, needs a new sterilization cycle, and a medical procedure might be cancelled last minute.

1.7. Preliminary problem definition

The purpose of this thesis is to show the development process of a product that aims to help transport sterile and contaminated surgical equipment in DIN baskets safely and reliably. While instrument firms are switching from shipping instruments in aluminium robust trays to shipping instruments in DIN baskets, they need a way to keep instruments for one specific medical procedure together. Furthermore, the transportation system should replace the bubble plastic and provide a robust solution to transport sterile instruments from the CSD to a care facility.

Figure 4: Euro containers with sets wrapped in bubble plastic

1.8. Methods

To carry out the assignment, the Double Diamond model is used [2]. For this framework, the design process is divided into four phases, see Figure 5. During the Discover phase, the design problem and its context are analysed more in-depth. The goal is to understand and have experience with the design problem and to gather information in a diverging matter. Desk research, field research, and interviews with stakeholders are used to gather information about transportation methods of sterile and contaminated instrument sets. This will be discussed in Chapter 2: Situation Outlining and Chapter 3: Design Analysis.

During the Define phase, the information and experience gathered in the previous phase are used to define the design challenge. The information is narrowed down in a converging way to come to a problem definition. For this, desk research and close contact with stakeholders is used to narrow down to the problem. This will be described in Chapter 4: Translation Into Design.

During the Develop phase, solutions are generated to solve the design problem defined in the previous phase. This is again done in a diverging way, to think of as many solutions as possible. Different ideation and iteration techniques can be used to generate ideas. Also brainstorming sessions and focus group meetings can be used to come up with solutions. This will be described in Chapter 5: Concept Generation.

During the last phase, the Deliver phase, the possible solutions are tested for reliability and achievability, and one of the solutions is chosen to solve the design problem. Focus group meetings and different types of selection methods can be used to evaluate the best possible solution. This will be discussed in the latter part of Chapter 5: Concept Generation and Chapter 6: Realization.

After a solution is developed, it will be tested in Chapter 7: Testing. Some recommendations for the design and the implementation of it will be given in Chapter 8: Discussion & Recommendations. Finally, this thesis will be concluded in Chapter 9: Conclusion.

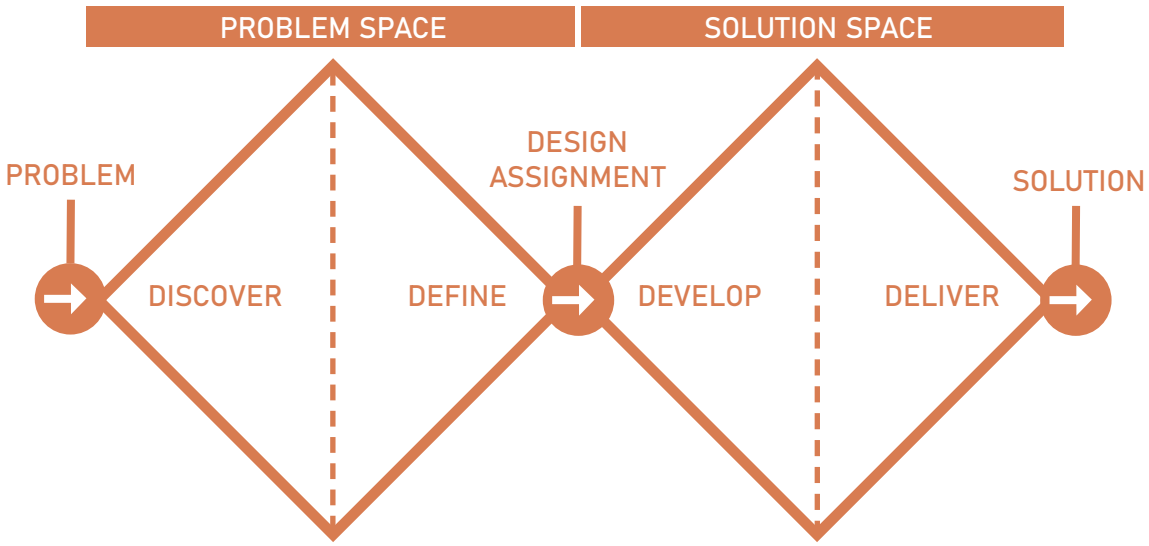

Figure 5: The Double Diamond Model [2]

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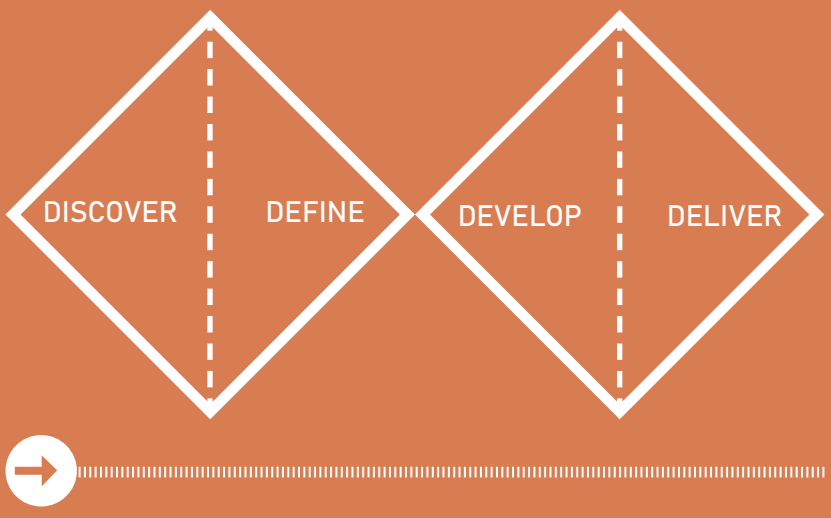
Situation Outlining



For one single medical procedure, many surgical instruments are needed. The transportation cycle of these instruments, and therefore a possible product that aids this transport, is analysed in more depth. This research is executed by interviewing operation assistants [3] [4], sterile processing experts [5] [6], a sterile processing technician [7], and a loaner set expert [8].

A distinction can be made between a basic surgical set and a loaner surgical set. Often, care facilities have their own basic instruments like scissors, scalpels, and other regularly used tools. All instruments needed to perform a basic procedure form a basic surgical set. For more advanced surgeries, a care facility might need to use additional medical equipment. In these cases, a care facility can loan a surgical set specifically designed for a certain medical procedure. Both use cycles of a basic and a loaner set will be analysed in more depth. After that, other types of sterile barriers and different transportation methods will be discussed.

2.1. Basic surgical sets

Care facilities are often the owner of their own basic instruments. They are responsible for the functioning of the instruments. Most care facilities have their own CSD, where the instruments are processed as described in 1.4. Some smaller care facilities might outsource the cleaning process to an external CSD like CSA Services Bv. To get an insight in all transportation steps, the use cycle of a surgical set is mapped for both care facilities with and without internal CSD.

2.1.1. Use cycle of sets at internal Central Sterilization Departments

A simplification of the use cycle of sets for care facilities with internal CSDs can be seen in Figure 6. After surgery, an operation assistant takes all instruments from the operation table and places them back into their DIN baskets. The baskets containing the instruments are carried from the Operating Room (OR) to an outer hall just outside the OR. These instruments form a biohazard, since they can be contaminated with blood, bone residue or other forms of human tissue. The baskets are often placed in a closed trolley, see Figure 7.

A sterile processing technician (SPT), who is a staff member of the CSD, picks up the trolleys and transports them to the CSD. They clean, disinfect, and sterilize the instruments as described in 1.4. Sterile instrument sets are stored in a storage room. Each set has a label containing information about the contents of the set. When a set is needed again, the SPT places all sets needed for a procedure on a trolley. The trolley is transported from the CSD to the outer hall of the

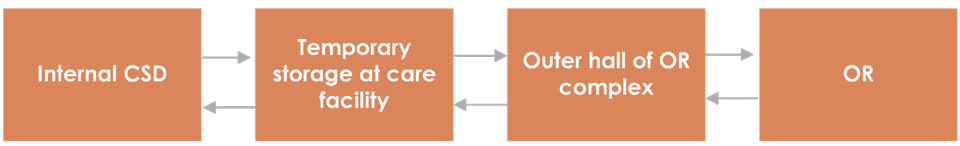


Figure 6: Use cycle of sets at internal CSDs

Figure 7: Trolley for storing and transporting surgical sets

OR. An operation assistant takes the DIN baskets out of their layer of sterile wrap. They lay out the instruments for the surgeon and the instruments are used for surgery. After surgery, the cycle repeats itself.

2.1.2. Use cycle of sets at external Central Sterilization Departments

The use cycle of sets at care facilities that do not have their own CSD, can be seen in Figure 8. These care facilities rely on an external CSD. The process is similar to the cycle described in 2.1.1., but the instruments are transported to the CSD by road. After surgery, all sets are placed in containers or carts. These get picked up by a courier who transports them from the care facility to the external CSD in a van. Staff at the external CSD takes the DIN baskets containing the instruments out of the transportation containers.

After sterilization, the staff of the CSD places the wrapped sets back in transportation containers. A courier picks up the containers with sterile instruments and transports them back to the care facility.

A logistician of the care facility often receives the containers. In some smaller care facilities, the operation assistant fulfils this task. The containers are temporarily stored at the care facility, and picked up by an operation assistant to bring them to the OR complex. There the instruments are used in surgery and the cycle repeats itself.

2.2. Loaner surgical sets

When care facilities need instruments that they do not own themselves, they can rent a surgical set from an instrument firm. These sets are called loaner sets.

2.2.1. Use cycle of loaner sets

The use cycle of loaner sets is simplified in Figure 9. An order is placed at the firm asking for a surgical set. The firm then sends a surgical set to the care facility. These instruments are currently often transported in robust aluminium trays as described in 1.5. The trays with instruments are disinfected but not sterile.

At the CSD, the instruments are taken out of their aluminium trays and placed in DIN baskets. These baskets including the instruments undergo the disinfection and sterilization cycle described in 1.4. The sterile sets are shipped to the OR, where the instruments are used. After use, the instruments are sent back to the internal or external CSD. Here, the instruments undergo only a cycle of disinfection. After disinfection, the instruments are placed back into their aluminium trays and are transported back to the instrument firm.

Since the instrument firm cannot validate if the instruments have been properly disinfected, the instrument firm disinfects the instruments again. Also, the aluminium trays undergo a cycle of disinfection. Note that a loaner surgical set undergoes three cycles of disinfection for one procedure, compared to only one cycle of disinfection for basic sets.

2.2.2. Loaner sets in DIN baskets

Most instrument firms that lend their instruments to care facilities are multinational corporations. Large instrument firms like Stryker, Medtronic, NuVasive and many others have their headquarters in the

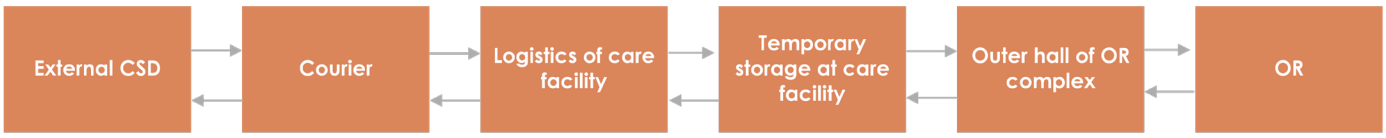


Figure 8: Use cycle of sets for care facilities without internal CSDs

United States where DIN baskets are not widely used. While aluminium trays are widely used and validated for disinfection in the United States, European care facilities all work with DIN baskets. European washer-disinfectors are often validated only for DIN baskets since they use alkaline detergents instead of enzymatic detergents, the sterilization wrap size fits the DIN size, and all hospital trolleys and storage systems are conform DIN sizes.

Instruments and aluminium trays are going through a separate washer-disinfector process for multiple reasons. The washer-disinfector is not validated for being able to clean the instruments properly while they are in their aluminium trays. These trays often have small holes, and the water cannot reach the instruments. Also, corrosion of the aluminium can leave a layer of white powder on the instruments and the trays. Therefore, trays undergo a less invasive setting of the washer-disinfector machine.

Because of the drawbacks of aluminium trays and adapting to the European market, more instrument firms are looking for possibilities to switch from the aluminium trays to DIN baskets. This means that transportation systems need to be adapted to these baskets as well.

Switching to DIN baskets has many benefits, but some challenges arise. One of the biggest problems is that the instruments that belong to one set have to be distributed among multiple DIN baskets. The aluminium tray is quite big and has up to three inlays. All instruments that belong to one specific set can fit in the aluminium tray and are kept together by the tray itself. When the instruments are transferred to DIN baskets, up to three baskets might be used to hold one surgical set. These baskets must be kept together to avoid logistical problems.

2.2.3. Set configurations

DIN baskets come in a variety of dimensions, but are often similar in width and length. The dimensions of the most commonly used baskets can be found in Table 1. Baskets, including their heavy surgical equipment, can weigh up to 8 kg per basket.

These baskets can come with an additional lid. This enables the baskets to be stacked on top of each other and protect the instruments. In practice however, lids are not commonly used in the Netherlands during transportation from CSD to OR. In other countries it is more common to use a lid during transportation.

A lid adds 5 mm on top of the basket. If the set is wrapped in sterile wrap, around 10 mm is added on the short sides and top of the basket. Around 5 mm is added on the long sides and bottom. The maximum dimensions of the most commonly used baskets, with lids and sterile wrap, can be found in Table 1.

As described earlier, the instruments of one surgical set might be distributed among multiple DIN baskets. For this reason, different configurations can be made. In practice, the DIN-6 is commonly used with additional DIN baskets on top. The most commonly used configurations can be found in Figure 10.

2.3. Types of sterile barriers

The sterilization wrap that has been described is

Figure 9: Use cycle of loaner sets

Table 1: Dimensions of most commonly used DIN baskets

Name:	Basket dimensions (width, length, height) (mm)	Maximum dimensions: Basket with wrap and lid (width, length, height) (mm)
DIN-10	250 x 480 x 100	260 x 500 x 120
DIN-6	250 x 480 x 60	260 x 500 x 80
DIN-4	250 x 480 x 40	260 x 500 x 60
Half-DIN	250 x 240 x 60	260 x 260 x 80

not the only type of a sterile barrier system for DIN baskets. A sterile barrier is a layer of packaging that minimizes the risk of ingress of microorganisms and allows an aseptic presentation of the sterile contents at the point of use [9].

2.3.1. Sterilization wrap

Sterilization wrap is the most commonly used type of sterile barrier in the Netherlands. It is often made from multiple layers of polypropylene. Van Straten Medical and CSA Services Bv. use the Halyard sterilization wrap [10]. These wraps are specifically designed to fit around a DIN basket and are validated for European autoclaves.

Sterilization wrap has a few major disadvantages. If a small tear is found after unwrapping a set, the set is defined as unsterile. This is evaluated by holding the sterile wrap against a light source. If there is a tear, light will come through. A surgical set then has to go back to the CSD for a new round of disinfection and sterilization, and a surgery might be cancelled. Also, the wrap is wasteful since it cannot be reused.

The biggest benefit of sterilization wrap is that it is easy to validate if the set remains sterile. Also, it is easy to use and does not add much weight to a set. Furthermore, one of the company managers researched opportunities for recycling the wrap [1]. The results showed that it is feasible to recycle the sterile wrap into high-quality raw material for injection moulding new parts.

2.3.2. Rigid sterilization containers

Rigid Sterilization Containers (RSCs) are a well-known alternative for keeping surgical instruments sterile during transport. An example of an RSC can be seen in Figure 11. DIN baskets can be put into the RSC. The DIN baskets and RSCs need to be disinfected separately, since the RSC needs a different setting in the washer-disinfector.

After the DIN basket and instruments have been disinfected, they are placed back into the RSC again. The lid is closed, and the RSC containing the set is placed in the autoclave. A filter system allows the steam to enter the container and sterilize the DIN-basket and set. This filter closes after sterilization, creating a sterile barrier. An indicator shows if the RCS contains a sterile set which has not been opened. After sterilization, the RSC can be picked up by the courier and transported to care facilities, without

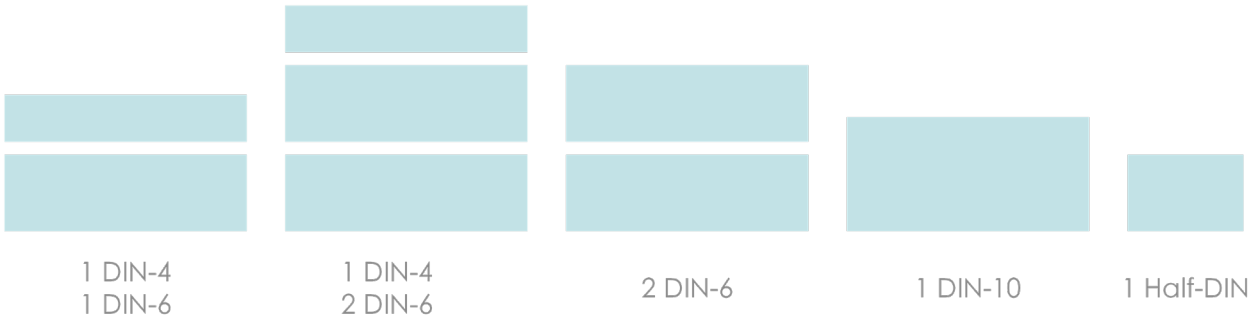


Figure 10: Most commonly used configurations of surgical sets

using another transportation container. This means that the RCS replaces the sterile wrap, bubble plastic, and conventional transport box.

The RSC has many advantages over the sterile wrap. The instruments are better protected during transport, since the sterile wrap can tear more easily. This means there is a smaller risk that a set will need to be sent back to the CSD, if the set is unsterile due to damaged packaging. Also, the RCS system is more sustainable in the long run.

A study by the TU Delft researched the environmental impact of sterilization packaging for surgical instruments, by comparing the life cycle of the RCS system versus the sterilization wrap system [12]. Three sustainability indicator systems (carbon footprint, ReCiPe, and eco-costs) all showed that the RSC system is superior to the sterilization wrap system in terms of sustainability. The analysed RSC has 85% less environmental impact in carbon footprint, 52% in ReCiPe, and 84.5% in eco-costs; and an ecological advantage already occurs after 98, 228, and 67 out of 5000 use cycles, respectively. This seems phenomenally sustainable.

The RCS seems to be superior to the sterile wrap system, however the system also has many disadvantages. The RSC system is a huge investment. A care facility needs to replace the sterile wrap and buy containers. Often, the care facility also needs to switch to DIN baskets that fit into the RCS of a certain company, like BBraun. Also, CSDs need to invest in an extra disinfection machine, since the RCS itself needs a cycle of disinfection as well. Furthermore, an extra investment is needed for storage space for all RCSs.

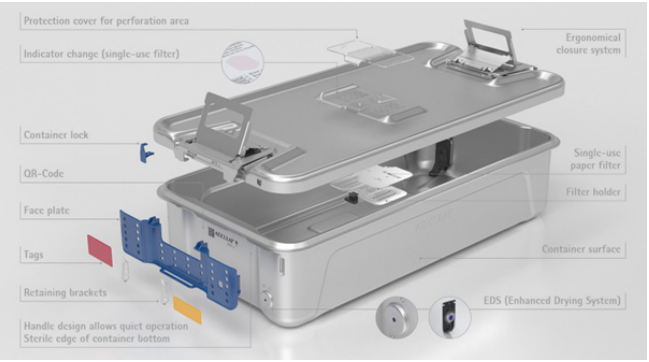


Figure 11: AESCULAP Aicon® sterile container system from B Braun [11]

Since an extra cleaning and disinfection cycle is needed, cleaning a single set requires more working hours from SPTs. The system is also heavier, which makes it less ergonomic for SPTs, transport couriers, logisticians, and operation assistants.

The biggest disadvantage of the RSC is that it is not easy to validate sterility. While an indicator indicates if the container has been opened after sterilization, it is not easy to assess leaks in the sterile barrier. A recent article even showed a scandal of recalling RCSs after tests showed potential breaches [13]. For these reasons, sterilization wrap is the most used and preferred method in the Netherlands.

2.3.3. ULTRA sterilization bag

Another sterile barrier system is the Amcor Ultra laminar bag [14], see Figure 12. DIN baskets can be inserted into the bag. The bags consist of two layers: an inner bag for sterility, and an outer bag for toughness. A tough and puncture-resistant porous web allows steam into the packaging while in the autoclave, and provides a safe barrier during transport. The transparent packaging allows CSD and care facility staff to visually inspect the instruments. The bags are rather user friendly, since the bags are easy to fill and peel open. This type of packaging is mostly aimed at in-hospital transport. The bags are not suitable to transport DIN baskets from an external CSD to a care facility without any other layer of protection. Also, the bag is not reusable and therefore wasteful. For these reasons, sterilization wrap is preferred for sterile transportation of DIN baskets between external locations.

2.4. Types of transportation

To transport a surgical set from one place to another, different methods and products can be used. To analyse these methods, different care facilities and central sterilization departments across the Netherlands were visited. For this thesis, methods at CSA Services Bv. are analysed in more depth as a case study.

2.4.1. Containers vs carts

After sets are sterilized, CSA Services Bv. works with two different types of transportation depending on the wishes of the care facility for which the sets are sterilized. They use containers or carts to transport the sterile sets to the care facility.

Containers

Smaller care facilities often work with shipping in containers. The sterile baskets are placed in these containers and transported in a van. These containers are standardised containers, that are not specifically designed for transportation of sterile or medical equipment. Most containers are based on European regulations, which require a container to be 400 by 600 mm in width and length. This dimension is based on optimal stacking on so-called euro-pallets, which are widely used in transportation across Europe [15].

Different types of containers are used for transporting DIN baskets, each with different dimensions. The

Figure 12: Amcor ULTRA sterilization bags [14]

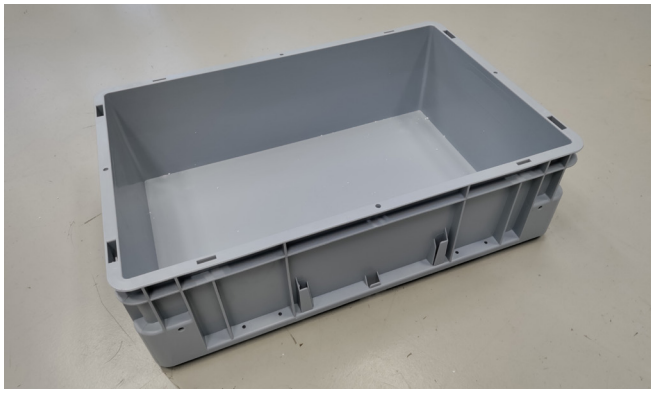


Figure 13: The RAKO euro container

Figure 14: Crocolid container of Medtronic, with inner extrusions

Figure 15: The Crocolid container of NuVasive, with inner extrusions

most commonly used container is the RAKO euro container (Figure 13). Instrument firms have their own containers for transportation to a CSD (Figure 14 and 15). A big client of Van Straten is Retina Eye Center, who also have their own containers.

Since the DIN baskets must fit inside the containers, an overview of the inner dimensions of each container can be found in Table 2 . These containers all have different heights and widths. Some containers have draft angles and inner extrusions, while others have smooth insides and orthogonal corners. Other care facilities use even more types of containers, but all follow European regulations and are around 400 by 600 mm in length and width.

Carts

Instead of using containers, CSA Services Bv. also works with modules that are placed in carts. The sterilized sets are put into a module. The modules are then inserted like a drawer into a cart, which can be seen in Figure 16. The carts are loaded into a bigger van and are dropped off at the care facility as a whole. This type of transportation already works quite well, since the drawers already act as a bumper.

2.4.2. Integrated vs. segregated

Another distinction is integrated versus segregated transport. Segregated transport is in this case defined as using two types of containers: one for sterile transportation and one for contaminated transportation. These containers are often exactly the same, but have a different colour or big label indicating if they are used for sterile or contaminated transport. In this way, containers used for sterile transport remain clean.

Integrated transport in this case is defined as using one container to transport both sterile and contaminated instruments. This means that the container needs to be disinfected before use. Disinfection of these containers can be done in two ways: by thermic or chemical disinfection.

For thermic disinfection, the containers are put into the washer-disinfector of the CSD, on a different setting than DIN baskets. Water and detergent wash the container, and hot temperatures make sure the container is disinfected.

For chemical disinfection, the container is first cleaned manually with a cloth of soap and water. After

Table 2: Container inner dimensioning

Container type:	Inner dimensions (mm)	Inside characteristics	Used for:
Firm-specific euro container: Medtronic	375 x 595 on bottom 415 x 635 on top 315 in height	Draft angle, extrusions of 5 mm on bottom	Transportation between instrument firm & CSD
Firm-specific euro container: NuVasive	350 x 600 on bottom 395 x 635 on top 300 in height	Draft angle, extrusions on sides	Transportation between instrument firm & CSD
RAKO euro container	365 x 565 175 or 125 in height	No draft angle, smooth insides	Transportation between care facility & CSD
Retina Eye Center container	325 x 500 on bottom 365 x 540 on top 300 in height	Draft angle, extrusions of 5 mm on short sides	Transportation between care facility & CSD (segregated)

that, an alcohol cloth is used to wipe the container from the inside and out. After that, the entire container is sprayed with alcohol and dried until it is ready to be used again.

2.4.3. Dedicated vs non-dedicated

Another duality in transportation is dedicated versus non-dedicated transport. Dedicated transport is a type of transportation where a vehicle is used exclusively for a specific assignment or a specific client. The way of transportation is adapted to the type of package that needs to be delivered. Transportation between CSA Services Bv. and care facilities is a form of dedicated transport: the courier drives specifically for bringing medical equipment from one place to another.

On the contrary, non-dedicated transport is a type of transportation where a package is sent via regular distribution channels. The content or destination of the package is not taken into account. The packaging needs to fit standards for shipping and needs to be quite robust since all packages are handled in the same way, regardless of the fragility of the contents. For non-dedicated transport, the packaging needs to be validated for the type of transport by using European regulations.

2.4.4. Bumper systems

The containers and carts might also have a bumper system inside. For segregated systems for example, containers often have an inner layer of foam to protect the sterilization wrap from tearing during transport, see Figure 17. This foam is not disinfectable (being able to be disinfected by thermic or chemical disinfection).

Also the instrument firms use bumpers to transport their sets to a CSD. This differs per firm. For Medtronic, a combination of carton, polystyrene, and Velcro is used to keep the robust aluminium trays in place during transport, see Figure 18. NuVasive uses layers of foam to fill up the empty space in a Crocolid container. These types of bumper systems are not easy to use, since it is a hassle to fill up the container. Also, these systems are not disinfectable.

Another type of bumper is plastic bubble wrap. This wrap is used for integrated transportation between CSD and care facility. The bubble wrap surrounds the DIN baskets wrapped in sterile wrap and prevents the baskets from slipping around in their euro containers. However, it does not fixate the baskets and the wrap is quite wasteful.

2.5. Conclusion

A few interesting features of the current situation come from this investigation. A big difference can be made between basic surgical sets and loaner surgical sets. Where basic surgical sets are mostly transported from an internal or external CSD to the OR, loaner surgical sets require an extra step of transportation between the CSD and instrument firm. The cycle of a loaner set is especially interesting for this project, since a product can aid in both transportation between CSD and OR, as well as CSD and instrument

Figure 16: A transportation cart for modules

firm. The product could also potentially help in the logistics of an instrument firm to keep configurations of sets together.

Another interesting part is the fact that instrument firms are switching from robust aluminium trays to DIN baskets to transport their instruments in Europe. This opens up a huge market potential, since there is not yet a good way of transporting their instruments safely to a client. Also, their logistics have not yet been adapted to these DIN baskets, and a new product can help with that.

It also becomes clear that there are different types of sterile barrier systems, but sterilization wrap is still the most commonly used method in the Netherlands. The wrap needs to be protected from tearing, and a product should help with that.

A problem however is the dimensioning. DIN baskets come in different heights and widths, and sterilization wrap and a possible lid add a few millimetres in height and width as well. Also, the containers in which the DIN baskets are currently transported in come in different heights and widths, and come with or without draft angles. Most containers follow euro regulations and are around 400 by 600 mm in length and width.

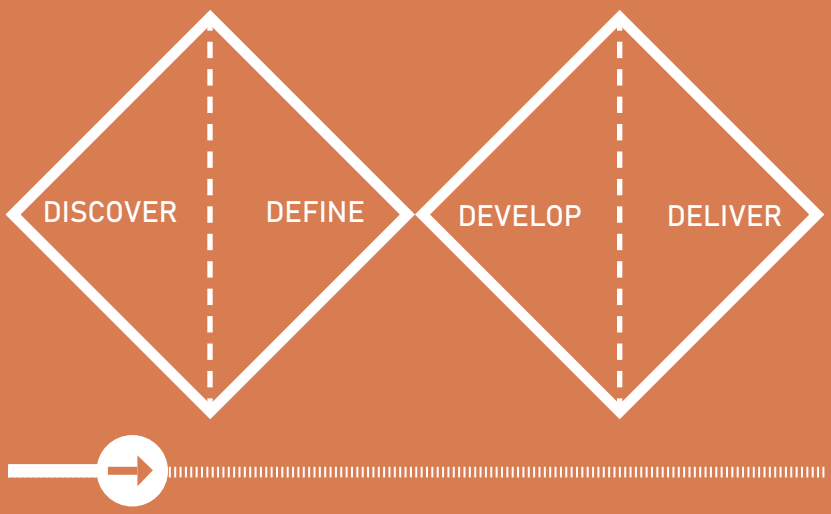
There also is not a good bumper system for transporting DIN baskets. Current methods all have their drawbacks, and are not disinfectable by thermic or chemical disinfection. In order for the novel product to be used in integrated transport, it needs to be disinfectable. This adds some additional design requirements. These requirements will be taken into account in Chapter 4: Translation Into Design.

Figure 17: Retina Eye Center container with foam layer

Figure 18: Medtronic container with bumper system

03

Design Analysis



After exploring the current situation around the transportation of surgical instruments, a few problems with the current transportation methods arise. A novel product could help with these problems. In the analysis, the design problem and context of a possible novel product will be analysed.

3.1. Product function analysis

A product function analysis is a method to explore the design problem in more depth [15]. More details are collected about the stakeholders and how they are involved in the project. The interaction between stakeholders and their goals is mapped. Furthermore, an insight into functions the product must fulfil and unique selling points can be a helpful starting point for the generation of product concepts.

3.1.1. Stakeholders

The stakeholders can be split into two main groups. Primary stakeholders are those individuals who will primarily use the product, in this case the sterile processing technician, courier, logistician, and operation assistant. Secondary stakeholders are all the others. In this case: Van Straten Medical, Greencycl, CSDs, Instrument firms, care facilities, and sterile processing experts.

Van Straten Medical

The company for which the assignment is carried out, is Van Straten Medical. They are able to use the findings of this research, and able to proceed with the development of a novel product. The company is currently looking for opportunities to use recycled polypropylene granulate which they collected, to injection mould new products. If a novel product can be made from recycled polypropylene, this will back up their research that polypropylene can indeed be used to manufacture new medical devices. It would also be profitable if they can sell the innovative product to their customers.

Greencycl

As a closely linked company, Greencycl works together with Van Straten Medical to develop sustainable medical devices. They can help in the further development of an innovative product. Since Greencycl was founded as recently as in 2019, helping to bring a sustainable product for the medical sector on the market can help them gain more credibility.

Central sterilization departments

Hospitals might have their own CSD, or use an external CSD. The department is mostly concerned with cleaning, disinfecting, and sterilizing medical equipment efficiently while complying with regulations for sterility. The CSD in the same building as Van Straten, CSA Services Bv. might be the first CSD to implement a novel product. They can help gain more information about the implementation and limiting factors for a novel product. If a surgical set is unsterile upon arrival, they are responsible for re-sterilizing that set. The CSD is therefore interested in a good transportation method that protects wrapped sets during transport.

Instrument firm

An instrument firm supplies the surgical instruments that need to be sterilized. They are responsible for safe shipping instruments from their firm to a hospital or CSD. Many firms are currently looking at switching their logistic system from aluminium trays to DIN baskets and might benefit from a packaging type that supports that. These firms are the owner of their loaner instrument sets, and if a novel product does not protect these instruments, they are responsible for the costs.

Care facilities

CSA Services mostly sterilizes surgical tools for smaller care facilities, from which most are orthopaedic. These smaller care facilities don't have a CSD of their own. If an innovative product is created, they might want to switch their current system to a

new one.

CSA Services also sterilizes loaner sets for bigger hospitals. These hospitals have their own CSD, but need to take a certain surgical set on loan if they need it. Bigger hospitals have their own transport boxes, and switching to a new system might be more difficult. In either case, the hospital staff needs to be willing to handle the new transportation boxes.

Sterile processing expert

The sterile processing expert (SPE) is responsible for making sure that the instruments that end up at an OR are sterile. The SPE often works for multiple CSDs at once, and often has direct contact with the directive of a hospital. The SPE has access to regulations about the sterilization cycle and must translate these documents into pragmatic implementations specifically for a certain CSD. If an innovative container is approved by the SPE while later it appears to be misfunctioning, they will be responsible.

Sterile processing technician

The sterile processing technician (SPT) is the main employee of the CSD. They clean the surgical instruments, place them in their DIN baskets, and make sure that they are sterilized. To become an SPT, a person must follow a 2-year post-secondary vocational education. Tasks of the SPT include taking DIN baskets out of the containers, precleaning the instruments, working with the disinfection machine, checking the functioning of each instrument, wrapping the set in sterilization wrap, making sure that the autoclave did a proper sterilization cycle, and making sure that containers with sterilized sets are properly sealed and ready for shipping.

Courier

The courier transports the surgical sets in their containers to a hospital that needs the surgical tools. When picking up sterile sets, the sets are already in their designated containers which are closed and sealed. The courier moves the containers from the export place at the CSD to a van. The courier drives to hospitals, where he drops off the containers and picks up containers with used instruments.

Logistician

Depending on the care facility, a logistician receives everything that is shipped there. For smaller care facilities, the operation assistant takes care of this task. The logistician receives the containers with sterile instruments. The logistician has direct contact with the containers and must make sure these arrive at their designated destination inside the hospital. At instrument firms, a logistician is also in place to receive and ship instrument sets.

Operation assistant

The operation assistant lays out the instruments for the surgeon and is responsible for making sure all instruments that are needed for a procedure are present. They are also responsible for checking if the set is sterile after transport. Depending on the hospital, the operation assistant also deals with the container in which instruments are transported.

3.1.2. Interests and values

For each stakeholder, the most important interests are summed up in Table 3. Most stakeholders have some sort of financial interest in the outcome of the research. Also, some stakeholders have credibility to gain or to lose. Instrument firms, CSDs and care facilities all have an interest in safer transportation which has multiple benefits as described earlier. For all users that actually use the product on a day-to-day basis, the product must fulfil its function and be easy to handle.

3.1.3. Functions

The next step in a product function analysis is describing the functions that the product must fulfil.

Product functions

- To contain the DIN basket with and without sterilization wrap
- To protect the sterilization wrap from tearing
- To protect the surgical instruments from mechanical disturbances
- To keep configurations of DIN baskets together
- To support maintaining the sterile barrier

On top of these functions, the product should bring added values for each stakeholder, as seen in Table 3.

User requirements for value

- To make the transportation more efficient regarding time
- To be a better financial option
- To bring credibility
- Being easy to handle

3.1.4. Unique selling points

In order for the product to be innovative, it should have one or multiple unique selling points [15]. This differentiates a product from its competitors. As described earlier, there is not yet a proper way of transporting DIN baskets to CSDs or hospitals. By lack of a better alternative, bubble plastic, foam layers, and regular containers are used. Since many instrument firms are switching to transporting their instruments in DIN baskets as well, this opens up a market potential for a new product that can solve multiple issues at the same time.

Another unique selling point would be if the product would fit around different types of DIN baskets, and fit inside different transportation containers, all with different dimensions. This means that the product should be modular in some sort of way. Lastly, a

Table 3: Stakeholders and their interests

Stakeholder	Interest	Value
Van Straten Medical	Product should protect sterile barrier Product should protect instruments Product should be reliable	Financial interest Credibility
Greencycl	Product should be sustainable Product should be reliable	Financial interest Credibility
Central sterilization department	Product should protect sterile barrier Product should protect instruments Product should be reliable	Financial interest Credibility
Instrument firm	Product should protect instruments Product should be reliable	Financial interest Credibility
Care facility	Product should protect sterile barrier Product should protect instruments Product should be reliable	Financial interest Credibility
Sterile processing expert	Product should be easy to use Product should protect sterile barrier Product should protect instruments Product should be reliable	Credibility
Sterile processing technician	Product should be easy to use	Credibility Handleability
Logistician	Product should be easy to use	Handleability
Operation assistant	Product should be easy to use	Handleability

unique selling point would be if the product could be made from recycled polypropylene, since Van Straten is currently researching this sustainable option.

3.2. Regulations

In the medical sector, many guidelines apply to the design of a novel product. There are some guidelines that Van Straten, CSDs, couriers, and care facilities must follow. From each guideline, requirements and statements applicable to the design of a novel product are summarized in bullet points. In these requirements and statements, the term "product" is used to describe the product that is to be designed for this thesis, and "packaging system" is used to describe all layers of packaging in which a DIN basket will be transported in. The most important regulations that have an impact on the design of a novel product can be found below. These are further elaborated on in Appendix A.

3.2.1. CSA Services Protocol

The CSD of Van Straten, CSA Services, has its own protocol for transporting medical equipment in a safe manner [16]. The protocol mainly describes the tasks of the SPT and the courier. The requirements for the packaging system are summarized:

- The packaging system must be able to resist cleaning by alcohol.
- The packaging system must be able to be sealed so it cannot be opened during transportation.
- The packaging system must be able to communicate if it contains unsterile, sterile, or contaminated sets.

3.2.2. NEN-EN-ISO

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The ISO develops and publishes standards for the development and promotion of international standards for technology, scientific testing, working conditions, and more. The Nederlandse Norm (NEN), publishes Dutch regulations. With an ISO or NEN-EN-ISO certification, companies can demonstrate that their products meet the agreed specifications. Applicable regulations for this project can be found in Table 4. The sterilization process and transport of sterile goods must comply with these standards.

- External transport must have at least three layers of packaging.
- The packaging system must have a label for traceability.
- Outer containers of the packaging system must be able to be sealed.

Table 4: Applicable NEN-EN-ISO regulations

Document number	Document name	Contents
NEN R5401	Ontvangst, Transport en opslag van steriele medische hulpmiddelen binnen zorginstellingen [17]	Responsibilities of involved staff members, packaging requirements, external transportation requirements, and storage requirements
NEN B5000	Verpakkingsmiddelen ten behoeve van sterilisatie [18]	Packaging methods for sterilized goods
R5301	Houdbaarheid van gesteriliseerde medische hulpmiddelen in instellingen [19]	Shelf life calculations of sterilized medical devices.
R3210-1	Verpakken van te steriliseren medische hulpmiddelen in instellingen en sterilisatiebedrijven [20]	Responsibilities of staff members handling transportation boxes, attention points of containers, requirements for containers
ISO 11607-1	Packaging for terminally sterilized medical devices [9]	Transportation requirements, packaging requirements
ISO 15883	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests	Requirements and use of washer-disinfectors

- Sterile and contaminated sets cannot be transported in a container simultaneously.
- If a container is used for both sterile and contaminated sets, the container must be disinfected before sterile transport.
- The packaging of the sterile set must be checked and undamaged when it enters the care facility.
- The transportation of sterile medical equipment and therefore the packaging system is under the responsibility and supervision of the SPE.
- Dimensions of the instrument basket and packaging layers should be conform each other.
- The packaging system must minimize safety risks, provide physical protection, and being compatible with the contents.
- The packaging system should protect the sterility, efficacy, and functionality of the instrument.
- Seals around the packaging should show by design in which direction the packaging has to be opened
- Thermic disinfection of the packaging must follow national standards based on time and temperature to reach an A_0 value for disinfection. In practice, this means 80°C for 10 minutes, 90°C for 1 minute or 93°C for 30 seconds. This, however, depends on the settings of a specific washer-disinfector.

3.2.3. HalYard Sterilization Wrap Instructions

Van Straten Medical uses HalYard Sterilization Wrap to form a sterile barrier around the instruments. The instructions for use (IFU) [10] describe some additional precautions as well. It also describes that the wrap should be in accordance with NEN-EN-ISO standards.

- Sterilization wrap needs to be inspected for damage, wetness, or any sign of potential contamination prior to using the contents
- If sterilization is performed by an outside contract facility, it is recommended that wrapped devices should be protected from contamination by additional covering.

3.2.4. Instrument firm Instructions For Use

Instrument firms have their own IFUs that they supply to clients. Organizations that work with these instruments, like CSDs, care facilities, and Van Straten, must follow these instructions. For this thesis, three IFU's are reviewed from three large instrument firms: Medtronic [21], Nuvasive [22], and Johnson&Johnson [23].

- If the material of the product is a metal, only devices with similar metallic composition can be placed together in an ultrasonic washer. This means that the product should be from stainless steel, or be washed separately.
- The product must be processed separately from soiled devices.
- If devices cannot be quickly reprocessed, they must be kept moist during transport. Therefore, a product must allow this process and withstand this moisture during transport.
- Soiled instruments should be transported separately from non-contaminated instruments.
- Alkaline cleaning agents have a pH value between 8.0 and 11.0, therefore a product must withstand these pH values.
- Before disinfection, possible lids or accessories of the product should be removed or opened if removal is not applicable.
- End of life of the product is determined by excessive wear and damage from normal use.

3.2.5. ADR

The Accord relatif au transport international de marchandises Dangereuses par Route (ADR) is a European agreement concerning the international carriage of dangerous goods by road [24]. Since the used instruments that are transported from the

hospital to the CSD are contaminated, transportation methods could fall under this agreement as well since they form a biohazard.

- For medical devices or equipment potentially contaminated with or containing infectious substances which are being carried for disinfection, cleaning, sterilization, repair, or equipment evaluation, the packaging must be designed and constructed in such a way that, under normal conditions of carriage, they cannot break, be punctured, or leak their contents.
- Packaging should meet general packaging requirements, which are based on normal conditions of carriage. These include oscillations, shocks, forces, humidity, and pressure differences during carriage.
- The packaging system should be capable of retaining the medical devices and equipment when dropped from a height of 1.2m.
- Packaging shall be marked "Used medical device" or "Used Medical Equipment".
- When using overpacks, these shall be marked in the same way, except when the inscription remains visible.
- When recycled plastic is used as a material for the product, specific properties must be guaranteed and regularly documented as part of a quality assurance program. Additives are allowed only if the physical or chemical properties are not negatively influenced.

3.2.6. MDR

The Medical Device Regulation (MDR) is a legal framework for medical devices. It also describes legal responsibilities for the assessment of certain categories of medical products [25]. Also accessories to devices might fall under the MDR. Since a transportation box for medical devices does not specifically enable the instruments to be used or specifically assist its medical functionality, it is not an accessory for a medical device. Therefore, the MDR is not applicable for the design of a novel transportation container.

3.3. Packaging requirements

The novel product eventually adds a layer of packaging during transportation and storage. There are a few themes that should be considered and will form a basis for requirements.

3.3.1. General packaging guidelines

An extensive guide on packaging [26] is evaluated to dive deeper into packaging guidelines. Three themes that are most applicable to this research are: types of packaging functions, protection, and European regulations.

Packaging functions

According to the guide, there are five types of packaging functions:

- **Containing the contents**. The box should keep the contents together, like the different configurations or single DIN baskets.
- **Facilitate transport and storage**. The box should aid in transporting and handling the contents and should also ensure that the contents can be stored adequately.
- **Protect the contents from the environment or the environment from the contents**. If the box is transporting sterile items, it should protect the sterilization wrap from tearing or water. If the box is transporting used items that form a biohazard, it must protect the environment and people working with the box from leaking blood and human tissue.
- **Inform**. The box should contain information about the contents.
- **Facilitate end of use and end of life**. At the end of life, the box must be able to be disposed of.

Protection types

According to the guide, the packaging must protect the contents against:

- **Mechanical influences like shocks, sliding, vibrations, pressure, surface damaging, and electrostatic discharge**. These could pose problems and the packaging should therefore withstand packaging tests
- **Weather conditions like rain, moisture, temperature, light, dust.** These all have an effect on the sterile barrier and material properties of a product.
- **Theft.** The instruments are extremely expensive and should not be stolen from a van.

European regulations

Packaging regulations vary per country. Regulations that most come into play here are handling requirements for users and dimensioning. Handling requirements vary per country but overall, the amount to be lifted by hand is 25 kg depending on repetitiveness of movement, distance to be covered and the torsion during the lift. This means that the total weight of the packaging, DIN basket, and its contents cannot weigh more than 25 kg.

Dimensioning plays a big role in this project as well. There are standard dimensions widely used in Europe, so-called euro dimensions. The basis volume is mostly based on Euro pallets and the most used width and length is 600 by 400 mm. In this way, Euro pallets can be filled to their full extend. These dimensions have formed the basis for the euro containers described in 2.4.1.

3.3.2. Packaging for fragile goods

Fragile items are those that are highly susceptible to damage, and require special packaging when moved or shipped. Several blogs help people find the correct packaging for their fragile items [27] [28]. Some findings can be implemented into the design of an innovative transportation container, since it must be able to transport the surgical instruments safely.

- The outer layer of packaging should be firm and not easy to break.
- For shipping, the outer layers of packaging should be stackable.
- The size of the box should be the right fit around fragile goods. If the outer box is too large, goods can move around and break inside the box. If the outer layer is too small, items can be squished, or it is not easy to take them out.
- Partitions or dividers can provide an additional layer of protection if multiple fragile items are stored in one box.
- Outer boxes can only handle a maximum amount of weight. Therefore, divide the weight among multiple boxes if needed.
- Proper labelling prevents the boxes from being opened unnecessarily

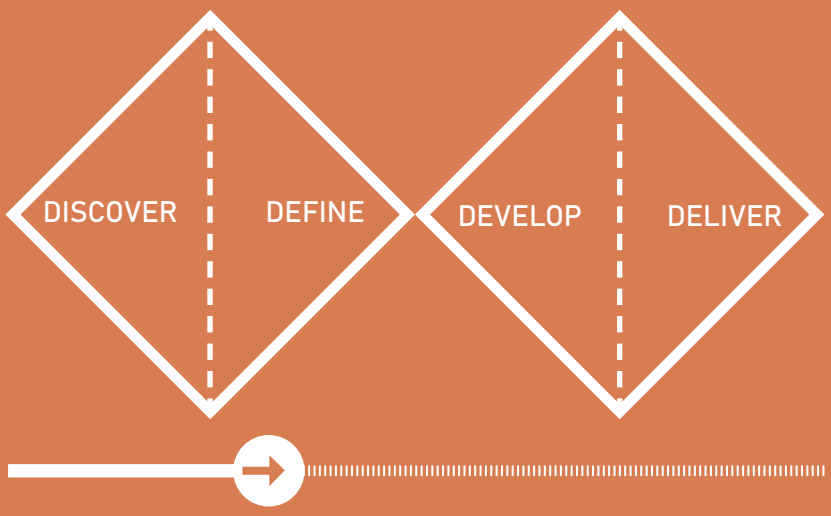
3.4. Conclusion

In the product function analysis, the context of the product and the impact that it might have becomes more clear. Regulations play a huge role in the development of a novel product. Although there are strict regulations for the sterilization process itself, the regulations for transporting sterile goods are quite vague and interpretable. The NEN-EN-ISO regulations form a basis, but the SPE must eventually decide how to interpret the regulation and what pragmatic actions must be taken during transport.

Everything that must be considered for the design of a novel container while analysing the CSA Services Protocol, NEN-EN-ISO, HalYard wrap guide, and ADR is translated into requirements in the next chapter. Furthermore, ideas from different sectors provide some possibilities for the design. These are also translated into requirements. Also, some ideas can be taken into account during the concept development.

04

Translation into design



The results from Chapter 2 and 3 show that there are many possibilities for a product that can help with the transportation of sterile instruments. During this chapter, the focus of the area is narrowed down. This is part of the next phase of the Double Diamond model: Define. First, the project is demarcated. After that, the requirements for a new product help define the limits of a possible solution. All functional and legal requirements coming from the previous chapters need to be taken into account during the design phase.

4.1. Design Assignment

As seen in previous chapters, the current method of transporting surgical instruments has many problems. A possible product could solve these issues for both transportation between CSD and OR, and CSD and instrument firm.

For transportation between CSD and OR, the most common protection method for integrated transport is bubble wrap. This method is wasteful, does not properly protect the sterile barrier, and does not fixate DIN baskets in their bigger euro size containers.

For transportation between instrument firm and OR, there is no integrated method yet at all since instrument firms are currently switching from their robust aluminium trays to DIN baskets. These are now fixated with bumper systems, but these are not easy to use and are not disinfectable. Also, there is not yet a good way of keeping different configurations of DIN baskets that contain one surgical set together.

There are many aspects that need to be considered for the design. The transportation containers all have different dimensioning. DIN baskets also have different dimensioning, depending on if they are wrapped, have a lid, or what height of basket is used. The product needs to be disinfectable in order to be used for integrated transportation. The product should also comply with different regulations.

These considerations limit the design and allow for some design space as well. Firstly, the assignment is to design a physical product that helps solve the issues that are part of the current situation, and it should comply with current transportation methods. The assignment is not to design a new infrastructure: this is too much of an investment and cannot be achieved easily.

The product should have two main functions:

1. Protecting the sterile wrap and surgical instruments in DIN baskets of different dimensions during transportation
2. Keeping configurations of different DIN baskets together

These main functions will be translated into requirements, which can be found in 4.3. First, a demarcation is made for what will be part of the project and design, and what not.

4.2. Demarcation

- The product that is to be designed must be integrated into the current infrastructure, designing a new infrastructure is not part of this project.
- The product is specifically designed to fit around standard size DIN-baskets of 250 x 480 mm, with or without sterilization wrap or lid.
- The product is specifically designed for fitting inside a euro size container. Since the infrastructure of Retina Eye Center is based on segregated transport, this type of container will be out of scope. Also cart transportation is out of scope, since this type of transportation is already running smoothly.
- The product is mostly applicable for transportation of surgical instruments between external locations, via road. Non-dedicated transport will be out of scope.
- The product is mostly applicable for integrated

transport and could be used for both sterile, unsterile, and contaminated instruments.

- Labelling is out of scope, since the euro container should have all information.
- The product does not necessarily have to be a watertight layer, since the method that it replaces is not an official packaging layer according to NEN-EN-ISO regulations.
- The product does not form a sterile barrier, since the sterilization wrap is the sterile barrier.
- The product does not have to be sterilizable, only disinfectable.

4.3. Requirements

The requirements for the product are divided into different categories.

Functional Requirements

- The product should provide a way to keep the 4 most common configurations of surgical sets together
  - A: 1 DIN-6
  - B: 1 DIN-6 + 1 DIN-4
  - C: 2 DIN-6 + 1 DIN-4
  - D: 1 DIN-10
- The product should provide a way to protect sterilization wrap around DIN-baskets during transportation
  - The inside of the product should not have any sharp edges
  - The product should fit tightly around the DIN-baskets
  - The product should protect the DIN-baskets from oscillations and other forms of mechanical disturbances during transportation
- The product should help protect the sterility, efficacy, and functionality of surgical instruments
  - The product should fit around both DIN-baskets in sterile wrap and DIN-baskets without sterile wrap
  - The inner width and depth of the product should be bigger than 253 x 483 mm
- The product should fit inside a euro-sized container
  - The outer width and depth of the product should be smaller than 552 x 352 mm
  - The product should take the draft angle of euro containers into account

Performance Requirements

- The product should be reusable
- The product including its contents should have a maximum weight of 8

Safety Requirements

- The product should be safe to use
  - There should not be a chemical reaction between product's materials and detergents, water, or alcohol
  - The product should not have any sharp edges

Patient & User Requirements

- Taking the product out of a euro container should be as easy as possible
- Taking the DIN-basket out of the product should be as easy as possible
- The product should be intuitive to use

Physical Characteristics

- The product should be disinfectable by a washer-disinfector machine
  - The product should withstand water of 93 °C for 30 seconds, 90 °C for 1 minute, or 80 °C for 10 minutes
  - The product should be waterproof
  - The product should withstand alkaline detergents
  - The product should withstand a pH value of

11.0

- The product should not have notches on opposed sides in which a layer of water can form
- No type of ink, stickers, or added colouring can be used

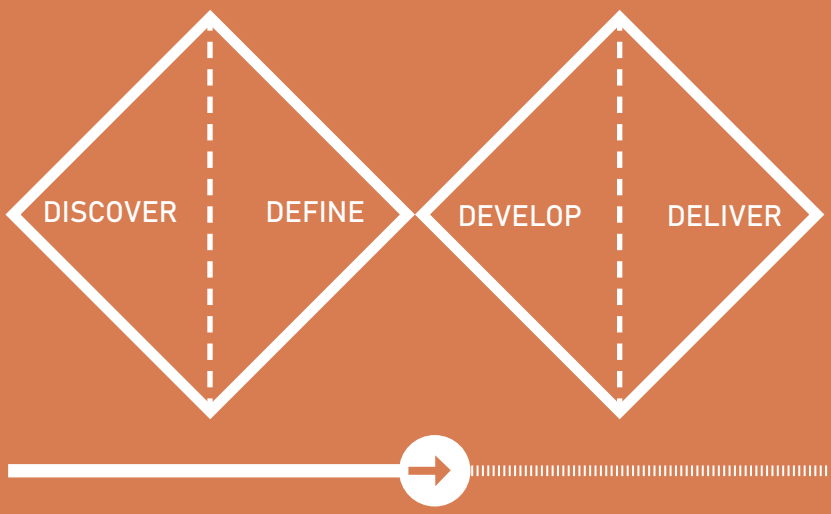
- The product should be disinfectable by hand
  - The product must withstand mechanical cleaning by hand
  - The product must withstand chemical disinfection with alcohol
- The product should contain information for traceability, except when the inscription of a packaging layer underneath the product remains visible.

Wishes

- The product can provide a way to keep a half DIN-basket part of the configuration as well
- The product can provide a way to keep other configurations of sets together as well
- The weight of the product can be minimized
- The product can be made from a combination of recycled polypropylene material and thermoplastic elastomers
- The manufacturing costs of the product can be minimized
- The number of materials used in the product can be minimized
- The product can be stackable or foldable
- The product life can be maximised

05

Concept Generation



After demarcating the project and defining all requirements that must be taken into account for the development for a novel product, the definition of the problem that a novel product must solve is clear. The solution, however is not determined at all yet. Now all possible ideas for a product can be sought, which corresponds with the next phase of the Double Diamond model: Develop.

In order to come up with ideas for the design problem, two separate focus group meetings were held. The intention of the first meeting was to generate many ideas for different parts of the problem. The focus of the second meeting was to converge and look at which concepts could be reliable, which corresponds to the final phase of the Double Diamond model: Deliver.

5.1. Focus group meeting 1

The first focus group was planned according to 12 steps found in literature [29]. The problem definition and the topic of the brainstorm session were clearly defined, and participants were asked to read through the problem definition in advance. This document can be found in Appendix B. The session was held with the help of two fellow graduation interns at Van Straten Medical Bv. and one staff member of the research & design department. These participants come from diverse backgrounds to facilitate exploring ideas from different perspectives, while being similar in age-group and hierarchical status within the company, to avoid status anxiety.

The session took place in a closed room with no interruptions. The participants were able to speak freely and write or draw all ideas on post-its. After clarifying the problem statement and planning of the session, the participants were asked to follow four ground rules of brainstorming [30], first published by Alex Osborn, the widely acknowledged father of brainstorming:

1. Judicial judgement is ruled out
2. "Free-wheeling" is welcomed
3. Quantity is wanted
4. Combination and improvement are sought

First, reversed and directed brainstorming techniques were used to produce ideas about the two main functionalities of the product. After that, brainwriting was used to generate ideas for four spatial problems.

5.1.1. Phase 1: Reversed and Directed Brainstorming

The product must fulfil two main functions:

1. Protect the surgical instruments and sterile wrap during transportation
2. Keep configurations of different DIN baskets together

For each function, the participants were first asked to produce ideas that would fulfil the opposite function, cause, or worsen the problem, also known as reverse brainstorming. Then, participants were asked to produce ideas that would facilitate the function and solve the problem, also known as directed brainstorming.

Participants were asked to first brainstorm individually and write as many ideas as possible down on post-its. After sharing ideas within the group, an affinity diagram of ideas was made to categorize ideas. After that, participants added new ideas inspired by the ideas of participants. These affinity diagrams can be found in Appendix C. For each session, the main findings are found below.

Protecting

Reverse brainstorming: How to cause tears in the sterilization wrap? What are the worst ways to protect the baskets? Which materials would not work?

- Using sharp objects

- A non-sustainable layer
- Not supporting the baskets
- Not fixating the baskets, too much room for movement

Directed brainstorming: How to prevent tears in the wrap? What are good ways of protecting the baskets? Which materials would work?

- Using dividers to prevent friction between mesh-baskets
- Fixate baskets by rigid layers, clamping mechanisms, or belts
- Mechanical expansions like springs, bumper systems, or air expansion
- Bumper systems
- Materials: rigid plastics, silicone, non-slip materials, soft material for protection

Keeping configurations together

Reverse brainstorming: what are the worst ways of keeping configurations together? Wat would not be user friendly at all? What would be a logistical nightmare for an instrument firm?

- If the product is too permanent, it is not easy to take it apart
- Logistic challenges like unstandardised dimensioning, storage problems, loose parts
- Not being user friendly like being too heavy, too much cognitive load, having sharp edges, or having no handles

Directed brainstorming: How can these configurations be kept together? Wat makes the product user friendly? How can the product fit on different heights of DIN baskets?

- Systems that can click together
- User friendly features like not having sharp edges, ergonomic handling, easy to process information
- Fixate configurations together
- Modularity by adjustable features, dividers, multi-purpose parts
- Solutions where the DIN-baskets can be taken out from the side

5.1.2. Phase 2: Brainwriting

Brainwriting is a technique where participants write down their ideas about a particular question for a few minutes individually. Then, each person passes their ideas to the next person who uses them as a trigger for adding or refining their own idea [29]. For this session, brainwriting was used to generate idea for four different themes: adjustability of height , adjustability of width ability to take DIN-baskets out of the product, and ability to click layers together, see Figure 19.

After two rounds, the participants were presented with an inspiration sheet with images of different systems that could serve as inspiration for the brainwriting exercise, which can be found in Appendix D. Since all 4 participants generated 3 ideas for each theme, a total of 48 ideas were generated. The ideas generated during the brainstorming sessions were later reviewed and processed into an affinity diagram for each problem, see Figure 20.

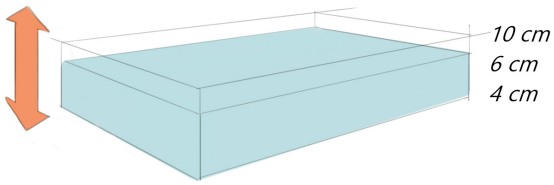
5.1.3 Phase 3: Processing of Focus Group 1

The processing of the brainstorm session took place after the brainstorm session itself. Here, the findings of the brainstorm session are translated into possibilities for a design.

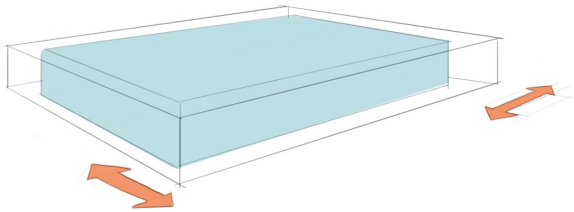
- Either handles or ergonomic spaces are needed in which hands can fit
- Ribs or handles could make the product more ergonomic
- Divider systems on the side of DIN baskets can fixate them
- A system that surrounds the entire basket
- An adjustable exoskeleton

- Tensile materials could help adjustability and as bumper system
- The product should not be too heavy
- The product should not have sharp edges both for ergonomics and protecting the sterilization wrap
- Clickable systems should not be too permanent

Furthermore, together with the results discussed in previous chapters, different concepts are thought of, which will be discussed in the next section.



Adjustability of height



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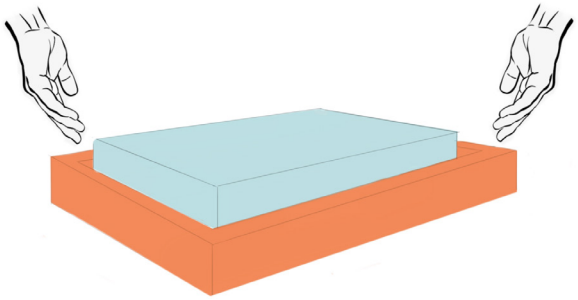
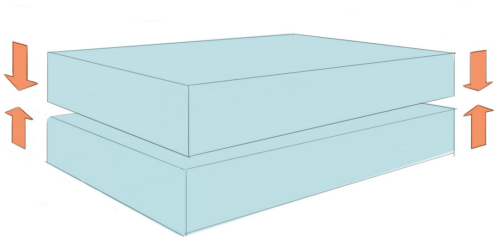
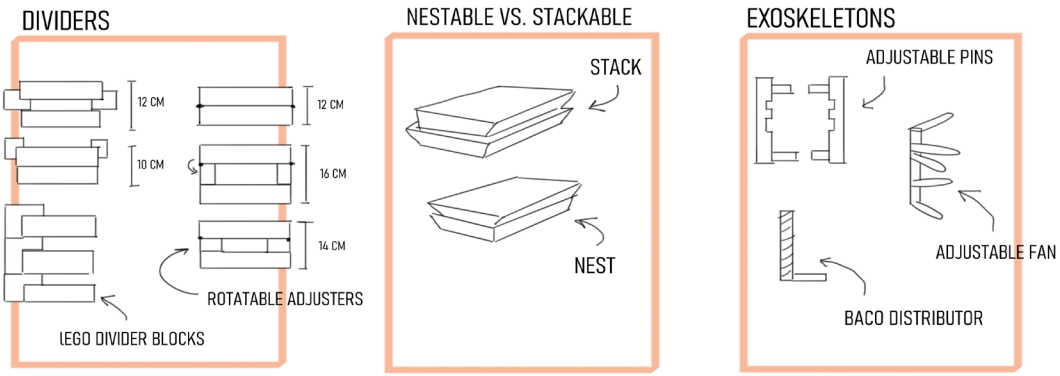


Ability to take DIN baskets out of the product

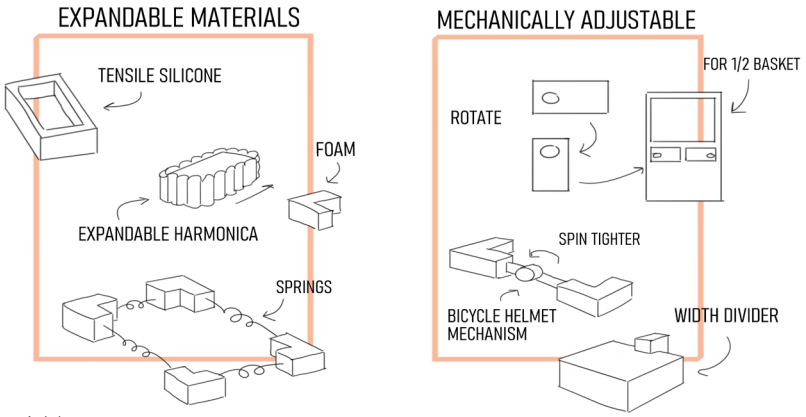


Ability to click layers together

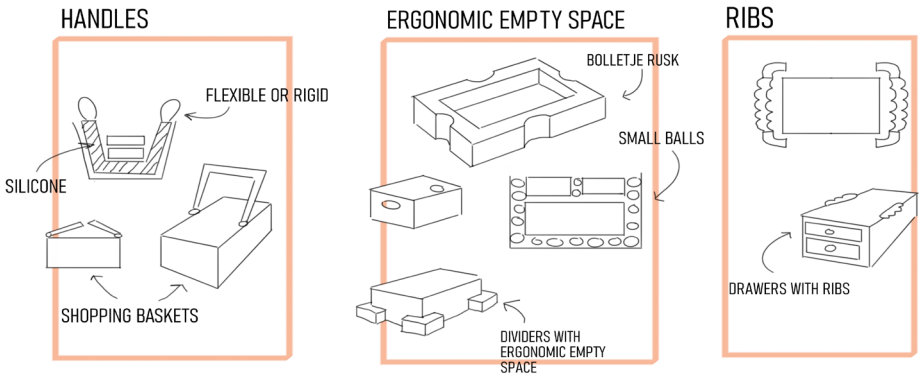
Figure 19: Brainwriting themes



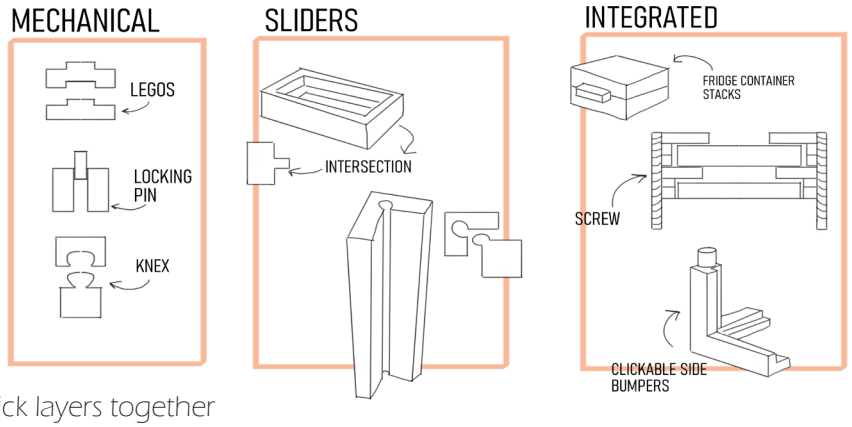
Adjustability of height



Adjustability of width



Ability to take DIN baskets out of the product



Ability to click layers together

Figure 20: Affinity diagrams from brainwriting exercise

5.2. Focus Group 2

For the second focus group meeting, the most important stakeholders were gathered. This group consisted of four people: the head of the CSD, the manager of the CSD, the sterile processing expert of Van Straten, and the external supervisor. These people all come from different backgrounds and had different perspectives on the product.

The purpose of this meeting was to update these stakeholders on the design process and evaluate three concepts that were created in the processing of the previous focus group meeting. Feedback from different perspectives was given for each concept, and at the end the concepts were compared. This process will be described below.

5.2.1. Concept A

The first concept is a stackable tray in which 1 DIN basket can fit, see Figure 21. With a clicking mechanism, these trays can be stacked together to form a set configuration. These trays come in the dimensions for a basket of 60 and 40 mm in height, with a universal lid. For a basket of 100 mm in height, the upper basket can be flipped 180 degrees to form a tray in which a basket of 100 mm can fit.

Advantages

- This system serves a good way of keeping configurations of surgical sets together
- It is an innovative solution to a simple problem
- The system is quite robust and has a high chance of withstanding the drop test

Disadvantages

- If the middle basket is needed, the entire configuration must be disassembled first
- The clamping mechanisms are prone to building up dirt in the washer-disinfector

Feedback

- The clamping system should be as simple as possible
- The lid should cover the tray on each side, such that the wrapped sets remain dry if the lid is wet due to for example rain
- The clamping insertions should not have any “dead end” notches, in which water during disinfection cannot flow

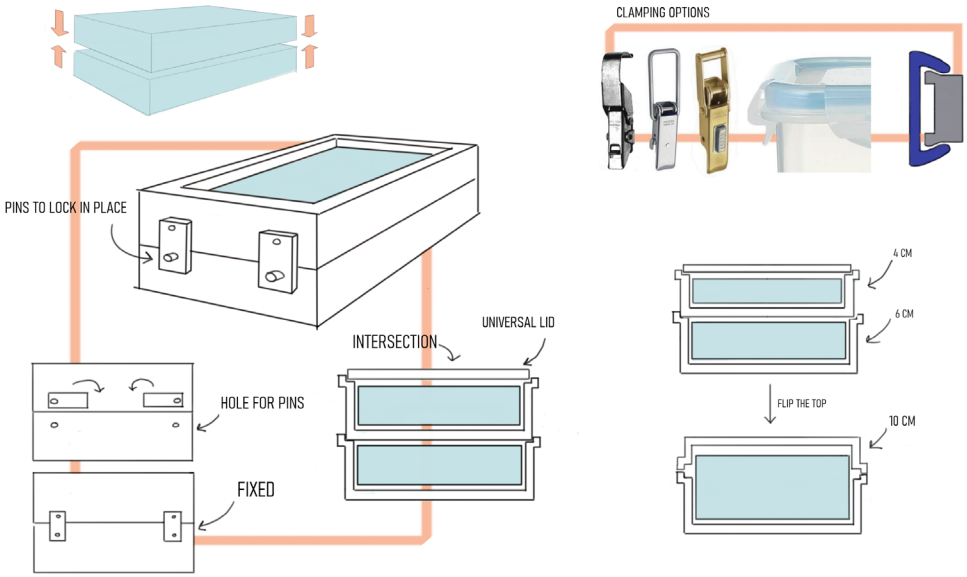


Figure 21: Concept A

5.2.2. Concept B

The next concept is built up from modular divider blocks, see Figure 22. These dividers have a different length in x, y, and z direction corresponding to the three most common heights of DIN baskets. In this way, the divider can be placed in such a way that it fits on all heights of DIN baskets. These dividers can be placed in a euro container or can be stacked like blocks to form a frame around a set configuration.

Advantages

- It is a modular system that fits on all configurations of sets
- It is an inventive way of both protecting the sets from mechanical influences while keeping configurations of sets together
- It is a simple system that is easy to handle by the CSD
- The divider blocks are easily disinfectable by the washer-disinfector
- The divider blocks are also able to fit around ISO size baskets or DIN baskets with another width and length
- This system allows some additional cooling after the sterilization process

Disadvantages

- The system is less robust and might not survive the drop test

Feedback

- The best way to implement this system is to use two types of transportation:
  - For sterile & contaminated transport between CSD and hospital, the divider blocks can be placed in the euro container without forming a frame
  - For transport between instrument firm and CSD and storage at the instrument firm the blocks can form a frame in which sets remain together
- A wedge can be used to help with the draft angle on the euro container
- The middle plate does not offer an advantage and might be left out

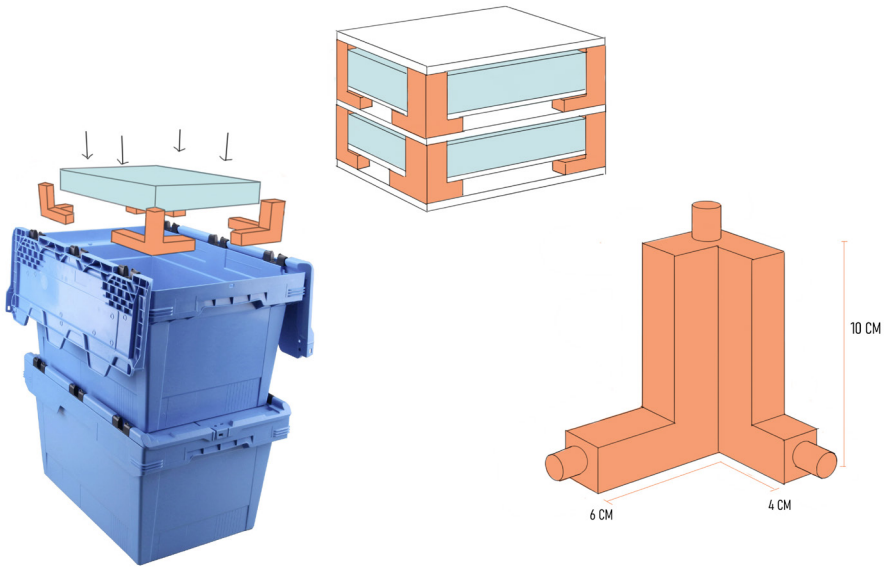


Figure 22: Concept B

5.2.3. Concept C

The next concept is a container with a height adjustable lid, see Figure 23. Baskets can be stacked in the container, and a lid fixates the baskets such that they cannot move.

Advantages

- Storage at an instrument firm is simple, since the baskets remain together in 1 configuration
- It is a robust system that protects the baskets

Disadvantages

- The mechanism on the lid is less robust and is prone to breaking
- All clamping mechanisms are difficult to clean in the washer-disinfector due to hinges or dead-end spaces
- Taking out the lower basket requires taking all baskets out of the container first
- It is less of an inventive system

Feedback

- Add ergonomic space in which hands can fit, such that it is easier to take the baskets out of the container
- Make the lid mechanism as simple as possible such that it is easy to clean

5.2.4. Concept comparison

Unanimously, all stakeholders thought that Concept B was the most inventive and had the most potential of being a workable solution to the problem definition. The modularity of the product is unlike any other product on the market for transporting sterile goods. Some additional feedback about the details of the product in terms of disinfection and transportation was given, which will be iterated on in the next chapter.

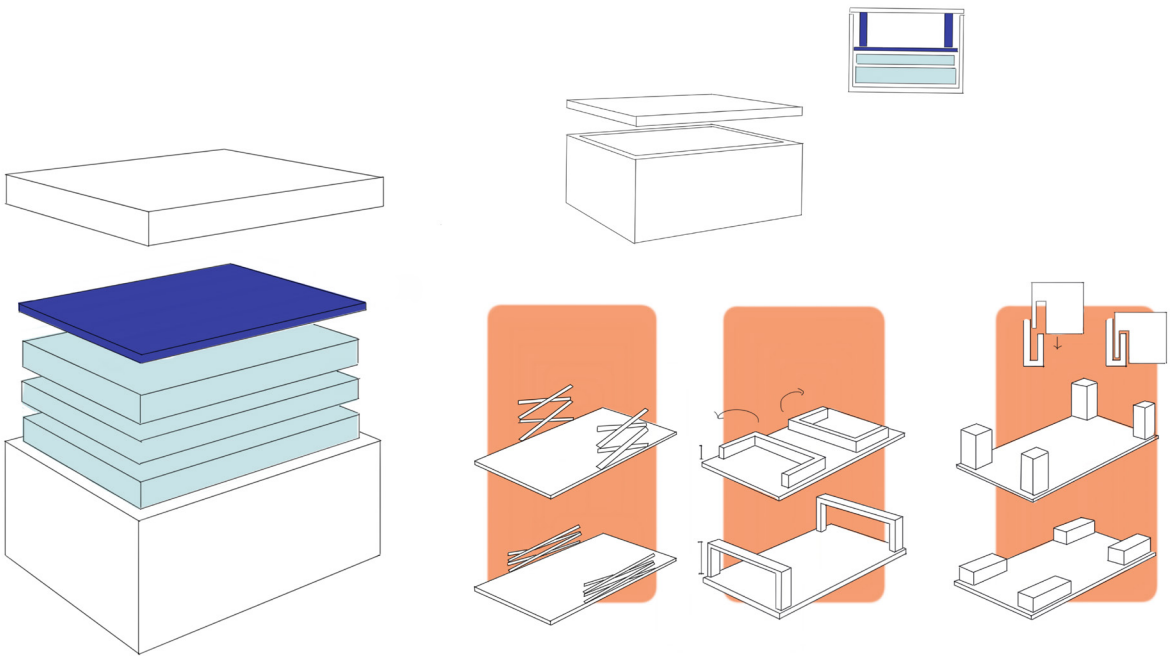
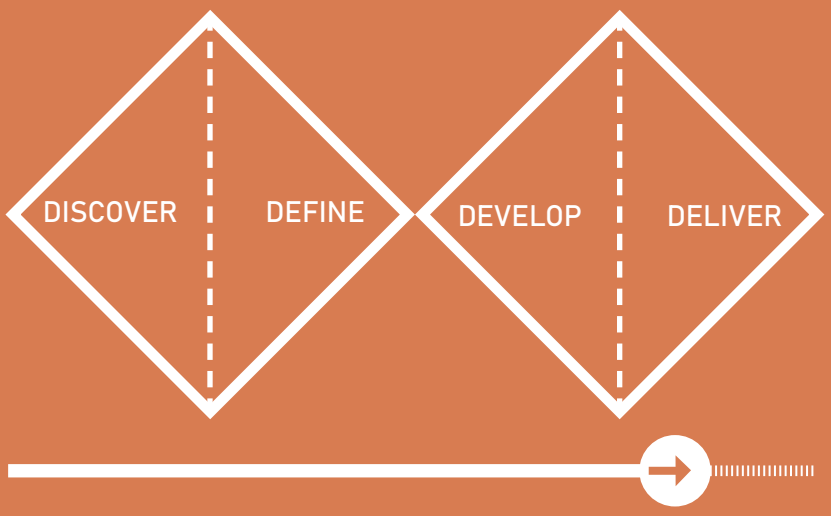


Figure 23: Concept C

06

Realization



The concept that is chosen by the focus group is a modular divider system. In this chapter, some iterations, details, implementations, and accessories are discussed.

6.1. Divider iterations

The product is a modular divider system that can be used to transport DIN baskets of different heights from the instrument firm to the CSD, and from CSD to the hospital. The main part of the product are modular divider blocks. These dividers can form an exoskeleton around a set of multiple DIN baskets. As can be seen in Figure 24, the product fits around each type of DIN basket.

To realize the product, a few problems still need to be solved and some parts need to be worked out further. However, this is a non-chronological process. For each issue, a succession of exploring different solutions in a diverging way is followed by making decisions for a solution in a converging way. These problems were not solved in succession, but rather solved during the same period of time. See Figure 25 for chronological iterations of the divider.

As one of the requirements, the divider must be able to be disinfected by a washer-disinfector. This means that hot water and alkaline products clean the divider. For disinfectability, the product should be quite robust and not easy to break or tear. The product should not have any notches or cavities on opposite sides in which water can form. Also, the product should be as simple as possible: each type of complexity, degrees of freedom, or additional features make the product more difficult to disinfect. Keeping the divider as simple as possible is considered in all iterations.

6.1.1. Basic shape

The DIN baskets need to be able to rest on the divider. As can be seen in Figure 26, possibilities for this are explored. A first iteration is making slots in the inner side of the divider, on which the baskets can rest. These slots were widened by 10 mm to leave more space for the DIN baskets to rest on.

Small fillets are added on all other sides of the product, such that it does not have any sharp edges that can tear the sterile wrap. Also, these edges are easier to clean. The height and width of each side are dimensioned such that the both minimum and maximum dimensions of the baskets (depending on adding sterile wrap and a lid, as described in 2.2.3.) fit on the divider.

6.1.2. Clicking system

One of the features of the product is being able to click multiple dividers into each other to form layers of DIN baskets. One of the main requirements for

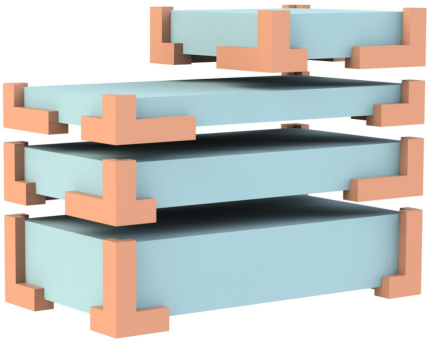


Figure 24: Dividers that fit on each type of DIN basket

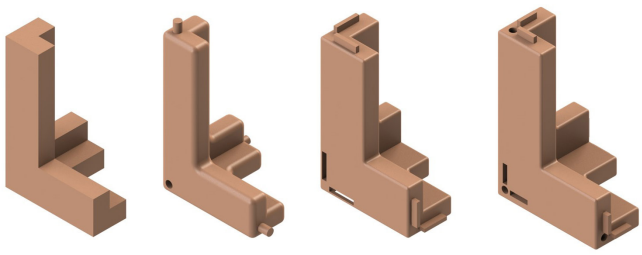


Figure 25: Chronological iterations of the divider

being able to disinfect the product is that it must not have any small notches or complex shapes in which dirt can form. An idea similar to LEGOS for example would be great for stability and fastening, but the notches are too difficult to clean.

Mechanical fasteners often have a male extruded part, and a female embedded part. A few ideas are possible for fastening the dividers with a male and female part, see Figure 27. The dividers need to be easy to assemble and disassemble, there should be no opposite cavities in which water can form, and the clicking system needs to prevent the divider from sliding. Therefore, the latter option of small slots is chosen.

6.1.3. Fitting inside the euro box

The euro containers in which the dividers are placed, all have different dimensions. Most containers however are much bigger on either side as can be seen in Figure 28.

Increasing the thickness of the divider walls would overcome this dimensioning. Since the system is modular in 3 axes, this feature will also increase the height as can be seen in Figure 29. The feature disables three baskets to fit in one container, and is therefore not an option.

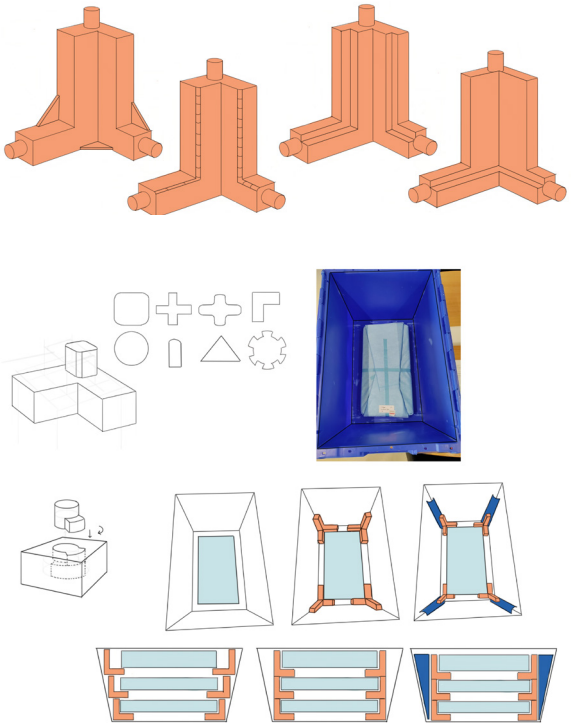


Figure 26: First iterations on divider system

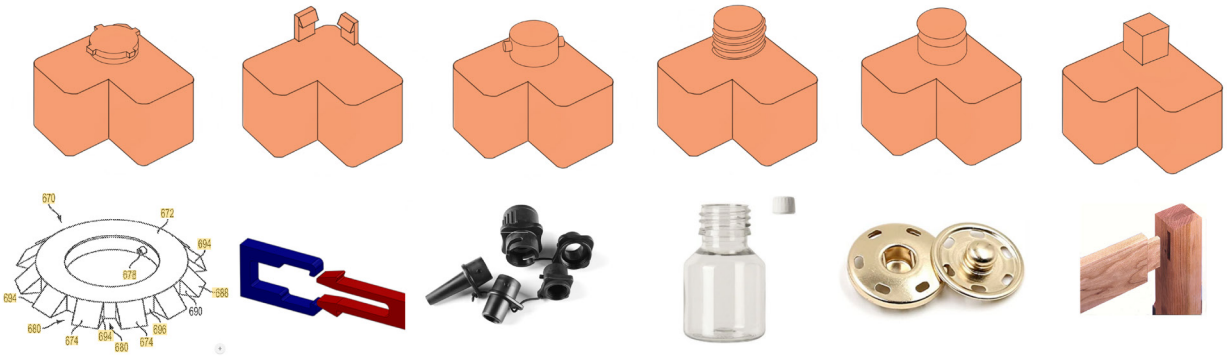


Figure 27: Iterations for clicking system

Another problem is that some euro boxes in which the dividers and DIN baskets are placed, have draft angles. The firm-specific container becomes wider in two directions. A possibility that can solve both issues at the same time is using spacers, see Figure 29. These spacers can be manufactured specifically for specific containers in which the baskets are transported in. These can be from a much cheaper material and a simple manufacturing process. Therefore, these spacers must be as simple as possible.

6.1.4. Permanent system for logistics at instrument firm

One requirement for the product is being able to keep the configurations of sets together. The dividers can be the building blocks for keeping them together. Pins can be used to fixate the dividers onto the basket and to keep multiple baskets together. However, these pins can be only used in one direction since these will collide, as can be seen in Figure 31.

When using pins vertically, a scaffold-like exoskeleton can be made from the dividers. Clamps and knobs on the tops and bottoms of each pin could prevent vertical movement of the dividers.

6.1.5. Usability

When loading the baskets into a euro box, the baskets cannot be loaded in with the dividers already on: they would simply fall off because of gravity. Placing the first four dividers at the bottom in the exact correct position before loading the basket probably will be a hassle as well. Therefore, the spacers should be placed in the container before loading the dividers and basket.

Another possibility for solving this issue is using trays on which the four dividers plus a DIN basket are placed, see Figure 32. These trays however should not add too much weight, since the basket is already quite heavy. The trays should also be modular and able to be used for three heights of DIN baskets and their corresponding orientation of dividers. The trays should have the same clicking system as the divider, such that the tray can be clicked on the dividers of the layer underneath.

This tray could improve the usability of the dividers and could also provide a solution to fit a half-DIN basket on top since it could rest on the tray. However, this tray adds more weight, height, and more loose parts in a container. Users can easily fit their hands within each divider, so the tray might be unnecessary.

6.2. Final Concept

The final concept is a modular divider, which is the building block for transporting DIN baskets of different heights. Some accessories are available to aid the divider.

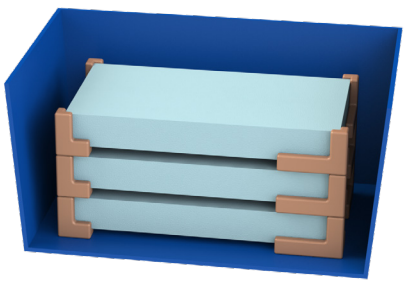


Figure 28: DIN baskets inside Medtronic container

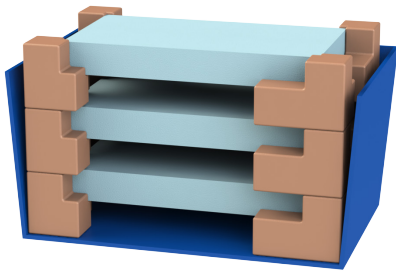


Figure 29: Dividers with increased thickness, inside Medtronic container

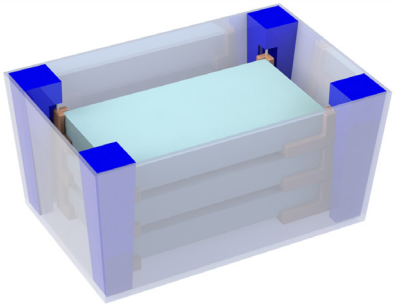


Figure 30: Divider system and spacer system, in Medtronic container

6.2.1. Divider

Since the divider has a different length in three different axes, the divider fits around a DIN basket of 40, 60, or 100 mm depending on the orientation. Four dividers are needed to support one DIN basket, see Figure 33. The dividers fit around both baskets with and without sterile wrap or lids.

These dividers can be stacked on top of each other with the help of slots. In this way, the dividers cannot slide in two directions, they can only move vertically. The dimensioning of the divider allows a DIN basket to rest on the divider and provide enough strength to support a DIN basket of 8 kg.

Also, there is enough room between each DIN basket for some additional cooling down of sterilized sets. A cylindrical hole in the divider allows the divider to be used in combination with a pin system, see Figure 34. This hole also allows disinfection of the notches for the clicking system since water can flow through the notches.

The dividers can be made from a mix of recycled and virgin polypropylene granulate, or any other type of plastic.

The divider system aids the current transportation boxes. Instrument firms, hospitals, clinics, and CSDs can still use their current transportation boxes that contain all labelling, provides a shockproof way of transport, and protects the baskets from weather conditions.

6.2.2. Accessories

Multiple accessories are available that aid the modular divider.

Spacers

Spacers can be used to fixate the DIN basket and dividers in a container. These are placed in the corners of the container as can be seen in Figure 35. They can be made specifically for a certain container, and for transportation with or without sterile wrap. They should be from a softer material that acts like an additional bumper, like silicone. These should be disinfectable as well.

Pin system

A pin system can be used to keep different configurations of sets together. Four cylindrical pins of stainless steel can be cut into a length such that a certain configuration of dividers fit together. Small silicone knobs and clamps at the bottom and top prevent horizontal movement of the dividers, see Figures 36 and 37. These knobs and clamps could be bought in bulk, as long as they are disinfectable. Also, these knobs prevent surface scratching on the bottom of a euro container. This also adds some friction to fixate the system even more.

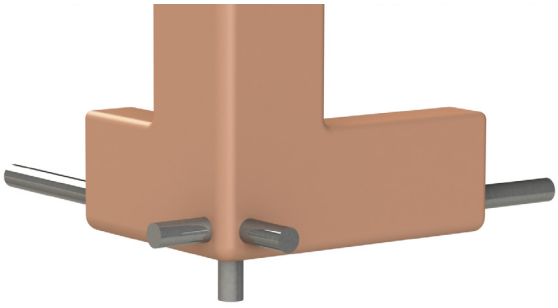


Figure 31: Collision of pins due to modularity of divider

Figure 32: Possibility for tray accessory

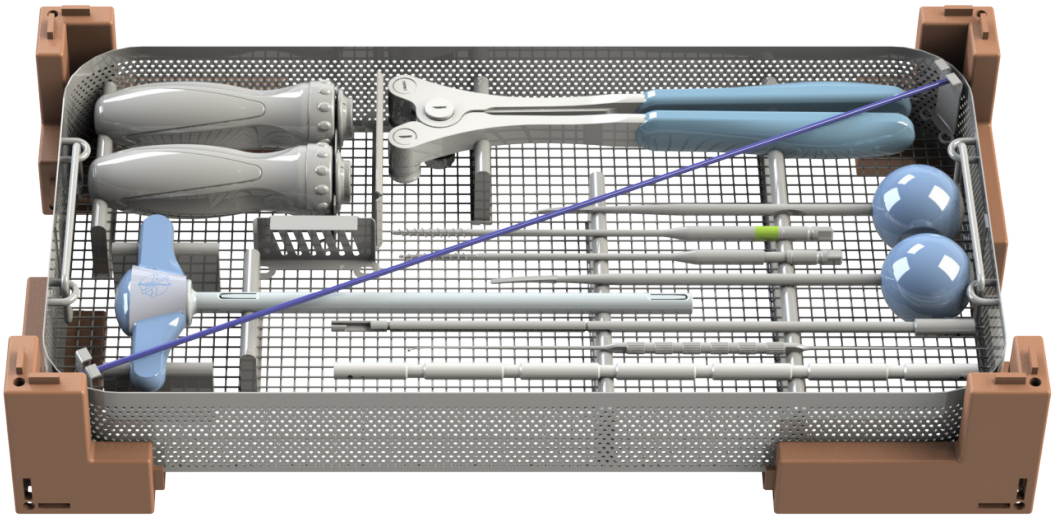


Figure 33: A DIN basket with four dividers

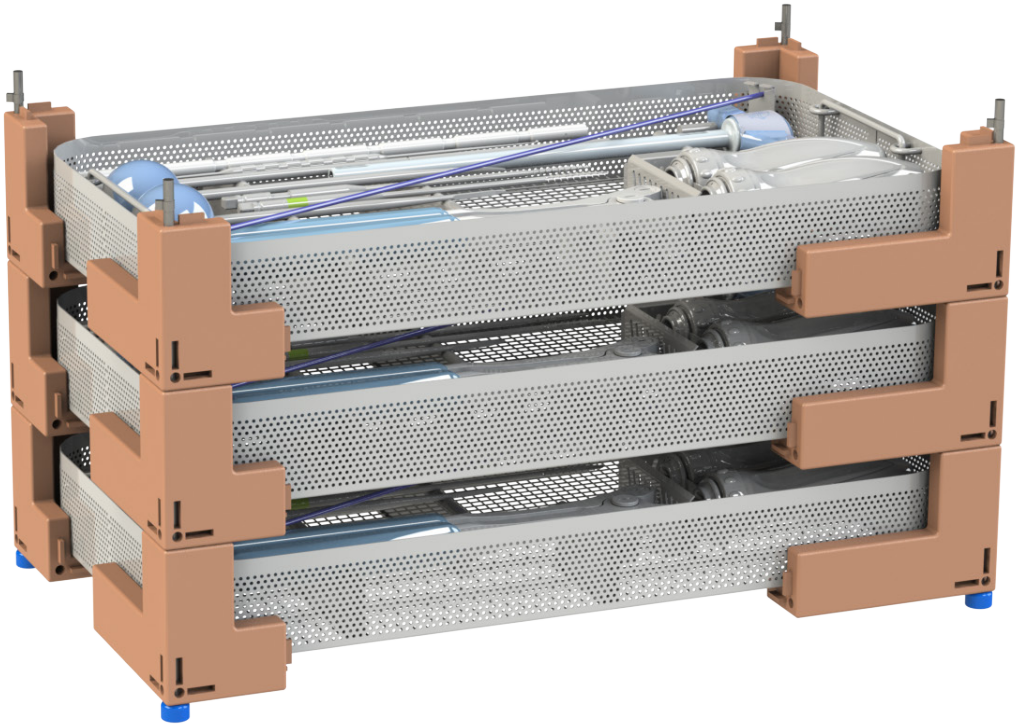


Figure 34: Divider system of 3 DIN-6 baskets with pin system

6.2.3. Use

This system is most applicable for transporting loaner surgical sets from an instrument firm to a CSD, and from a CSD to a care facility. An elaborate use cycle of the entire system can be found in Appendix F. Instrument firms and CSDs are the main target group for selling the system to. The dividers are universal and can be bought in bulk. The accessories need some client-specific manufacturing.

The dividers can be used in combination with spacers and a pin system. For transportation between CSD and care facility, it is recommended to only use the spacers and dividers. For transportation between CSD and instrument firm, it is recommended to use the spacers and pin system. In this way, configurations of sets can remain together.

Each component must be disinfected after transporting a contaminated basket. Therefore, each component must be disassembled. A full description of the assembly and disassembly of the structure can be found in Appendix F.

6.3. Prototyping

To come to the final concepts, different prototypes were used. A first prototype was made on a 1:2 scale with a 3D printer, as seen in Figure 38. A carton prototype of the DIN basket was also made on a 1:2 scale. With this prototype, the dividers were made bigger and higher. It also helped with defining directions of slots and in which ways the divider

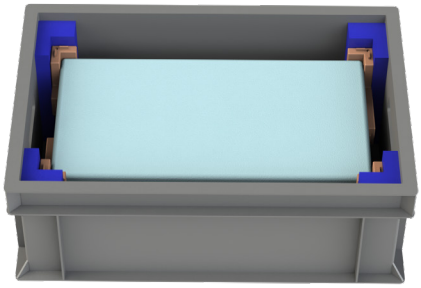


Figure 35: RAKO euro box with DIN baskets, dividers, and spacers

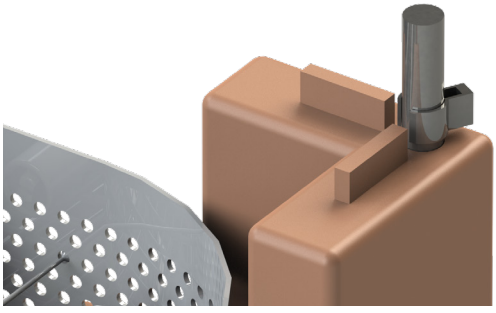


Figure 36: Clamp attached to pin system

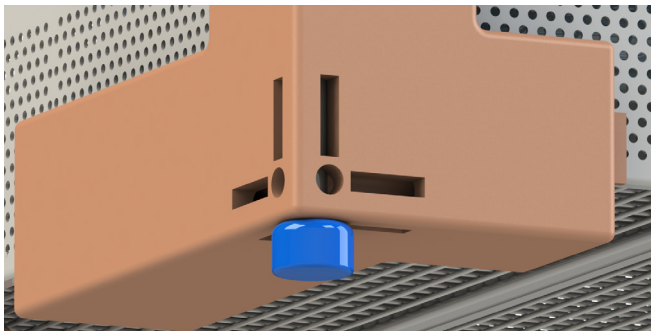


Figure 37: Knob attached to pin system

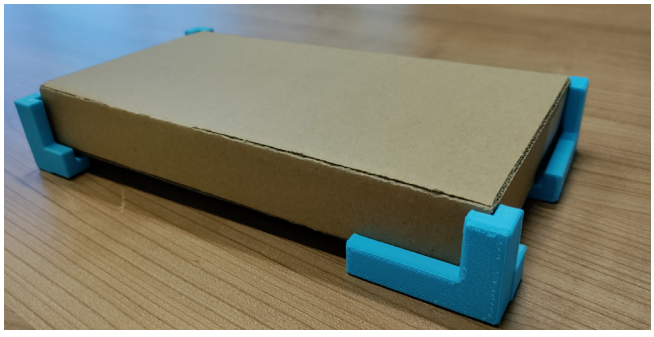


Figure 38: Prototyping on 1:2 scale

could be stacked in each configuration.

Before the second prototype was made, only the clicking system was 3D printed to determine the correct fitting, taking the tolerances of the 3D printer into account.

A second prototype was made with a 3D printer on a 1:1 scale, see Figure 39. A technical drawing of the prototype can be found in Appendix G. Together with existing euro boxes, wooden cylinders to simulate the pins, and foam spacers to simulate the spacer, functionality tests and usability tests can be performed which will be discussed in the next chapter.

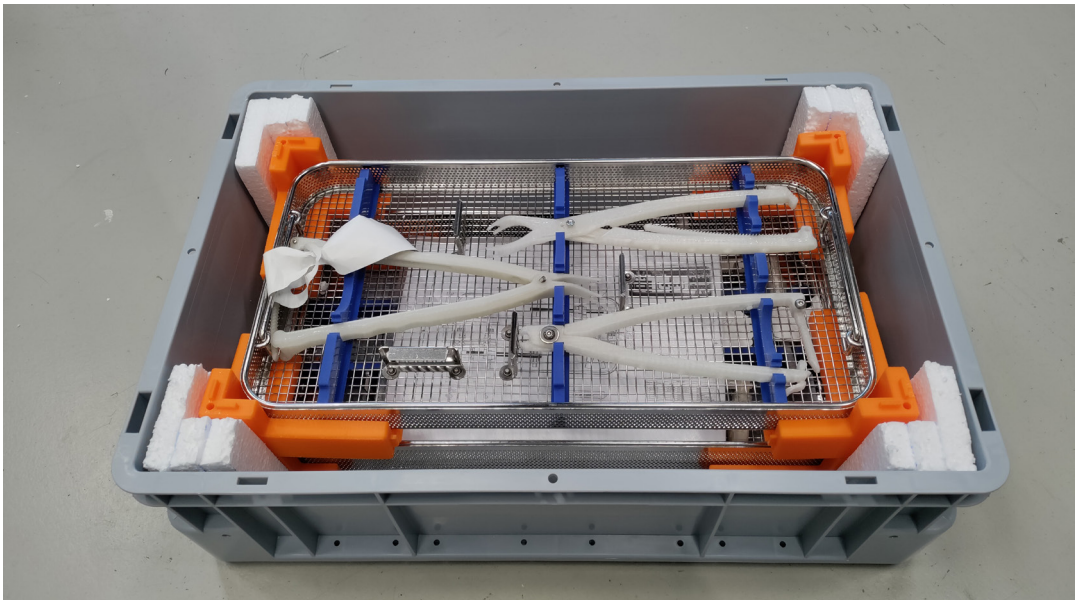
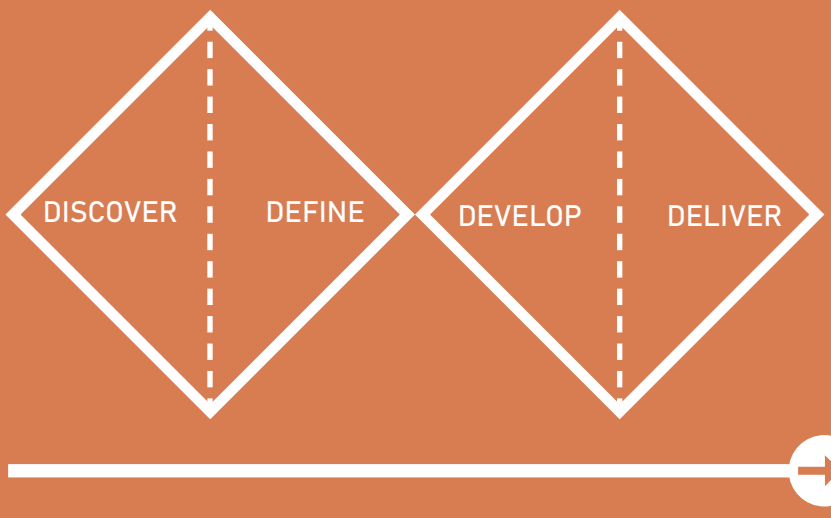


Figure 39: Prototype on 1:1 scale, with euro box, foam spacers, and DIN baskets

07

Testing



To test if the product fulfils it functions, it must be tested. To test the product, a Failure Modes & Effects Analysis (FMEA), usability test, and functionality test were performed. The FMEA formed the basis for determining the protocols of the usability and functionality test. The results of the usability and functionality test were then used in the FMEA, see Figure 40. Therefore, first the test protocols and then the results of each test will be discussed.

7.1 Test protocols

For determining the types of tests, the design problem from 4.1., the requirements from 4.3., and the FMEA were used to determine the types of tests. For each test protocol, feedback from the SPE [5] was asked since they must approve of the safety and functionality of the product if it will be used.

7.1.1. FMEA protocol

An FMEA is a systematic method for identifying and preventing product and process problems before they occur [31]. For an extensive FMEA, it is advised that the team for executing the analysis should consist of people with various backgrounds and interests in the product. Since this FMEA serves as a low-key analysis to explore in what ways the current product can be improved, the analysis is based on methods that require less time and resources.

The objective of the FMEA is to look for all possibilities a product can fail. Failure occurs when the product cannot execute the tasks that the product must be able to perform. The severity, occurrence probabilities, and detection probabilities of each failure are estimated which will result in a risk priority number. This number is used to rank the failures and see what failure modes need to be attended to first.

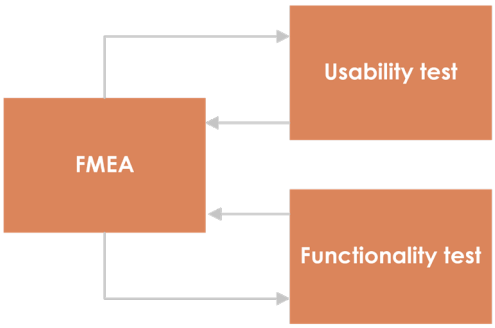


Figure 40: Test protocol interaction

For this FMEA, the system with dividers, spacers, pins, and knobs as described in 6.2. is taken into account as the product to be tested. The use cycle (Appendix E) and assembly and disassembly procedure (Appendix F) were used to come up with potential failures of using the product. Also failures that occurred during the usability and functionality test were used as potential failure modes. The execution of the FMEA can be found in Appendix H.

7.1.2. Usability test protocol

With a usability test, the user-friendliness, wishes and expectations of the user, and how the product is handled, are tested [15]. In the requirements it is stated that the product should be intuitive to use, it should be easy to take the product out of the euro container, and it should be easy to take the DIN basket out of the product. These requirements, along with other interactions between the product and its user, will be tested with a usability test.

The product is unlike any other product that is currently used for transporting surgical instruments in DIN baskets. Therefore, it might not be intuitive to use and the function of the product might be unclear. Also, the FMEA shows that many failure modes occur due to misuse of the product.

As seen in the product function analysis, the primary users are sterile processing technicians, logisticians, and in some cases operation assistants. The courier handles a closed, sealed container with the product in it, but does not touch the product itself. Some logisticians and SPTs might know a bit about the novel product, since they work at the same company during the execution of the assignment. Therefore,

3 novices (people who are new to the company and therefore know nothing about the product) are asked to do the test as well.

The main objective of this test is to find qualitative and quantitative information about the interaction between a user and the product. A main part of this, is the intuitiveness of the product. Also, problems with assembly and disassembly, and how much time certain tasks take are key factors in the usability of the product. Furthermore, some qualitative feedback about disinfectability can be asked to SPTs.

The test protocol can be found in Appendix I. For this test, a DIN-6 and DIN-4 basket, 8 dividers, spacers, and a euro container are used, since this is the most common configuration for transporting loaner sets. The pin and knob system was not tested, since this would not be the most common configuration and the emphasis lies on the dividers themselves. Testing the pin and knob system would also take too much time from participants.

The usability test consisted of 3 stages:

- Testing intuitiveness: does the shape of the product imply a certain way of using it? Is it clear that the 3 dimensions in 3 axes conform three heights of DIN baskets?
- Testing time: How long does it take to assemble and disassemble DIN baskets with dividers in euro boxes? Is there a learning curve?
- Asking for qualitative feedback about the product. What can it be improved?

7.1.3. Functionality test protocol

With a functionality test, the functions of the product must be tested [15]. This product fulfils multiple functions. The main two functions are casing DIN baskets of different heights and widths and protecting the sterile barrier system.

This can be tested by simulating a ride from CSA Services Bv. to a care facility and back. After the ride, it can be tested if the dividers still case the DIN baskets and if the sterile barrier is broken. For this test, wrapped DIN baskets were sterilized, packed in the euro box with the dividers, and driven around by the courier of CSA Services Bv. After that, the euro container was reviewed if all elements stayed in place and the sterilization wrap was tested for tears and holes.

For this type of testing, the worst-case scenario provides the most efficient results [15]. If the dividers survive the worst-case scenario, they have the biggest chance of surviving more common scenarios as well. For this reason, the baskets were filled with the maximum available weight, and were driven around for the maximum amount of time possible. The courier was asked to not be careful with the euro container.

The test procedure can be found in Appendix J.

7.2. Results

After discussing the protocols of the tests, the results will be discussed. The interpretation of the results will be discussed in Chapter 8.

7.2.1. FMEA results

From the FMEA, 32 potential failure modes were thought of. From the worst-case potential effects of these failures, 20 of these failures result in the sterile barrier being punctured. This results in the risk of the patient getting infected during surgery. Of the remaining 12 failures, 7 of them result in personnel being at risk of infection. Both of these effects have a high severity rating. From the remaining failure modes, not using the pin and knob system result in low RPNs.

Out of 42 detection methods, 23 methods rely on checking if the sterile wrap remains intact, before the failure can reach the patient.

The failure modes with a Risk Priority Number higher than 200 were assessed for taking action. Actions that can improve the design of the current product are

making sure that users know how the product works. This can be done by providing clear instructions for use or improving the design by showing information about the orientation on the divider, for example with an engravement.

Another point of attention is the clicking mechanism of the divider: the tolerances need to be optimised such that the dividers click together easily and stay clicked during transport. The last point of attention is keeping a close eye on manufacturing: the surface roughness of the product should be low, and it should not have any sharp edges.

7.2.2. Usability test results

For this usability test, 3 logisticians, 3 sterile processing technicians, and 3 novices performed the test individually. Operation assistants were not available. As a non-intended coincidence, none of the participants had prior knowledge of the product. Therefore, no distinction between groups is made for data about intuitiveness of the product.

Quantitative results

All quantitative results can be found in Appendix K. Quantitative results about the intuitiveness of the product can be found in Figure 41. The time it took for participants to assemble the structure according to the assembly procedure can be seen in Figure 42, where a clear curve can be seen between the first and second trial. The average assembly time for trial 1, 2 and 3 were 263, 81, and 73 seconds respectively.

The time to disassemble the structure can be seen in Figure 43, where the curve is less prominent. The average disassembly time for trial 1, 2 and 3 were 25, 21, and 20 seconds respectively.

Qualitative results

During the usability test, all participants were asked for feedback about the product. Many participants were held back by the clicking mechanism: the tolerances of the prototype differed per divider. Therefore, it was difficult to stack the dividers on top of each other. Most participants had difficulties recognizing which orientation of the divider fits on which DIN basket. Some participants had ideas for showing which divider orientation matches a certain DIN basket height, by using colour codes or engravings.

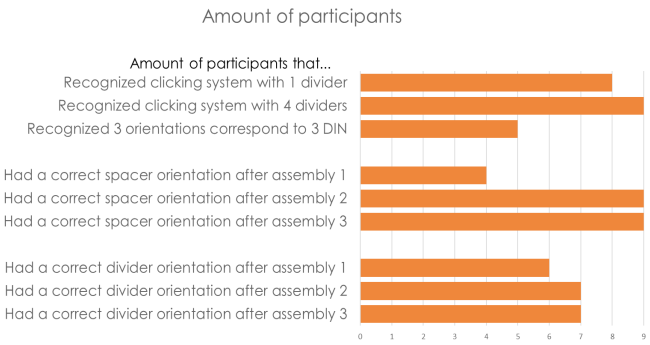


Figure 41: Qualitative resuls from intuitive testing during usability test

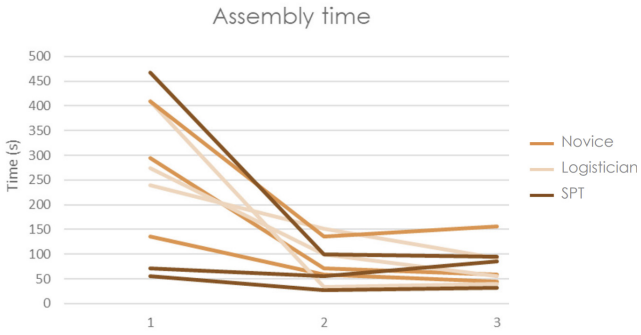


Figure 42: Time for assembly during usability test

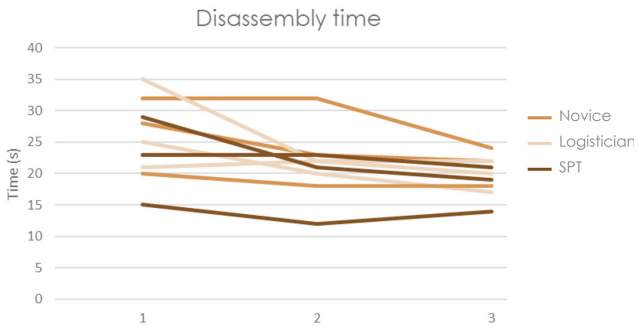


Figure 43: Time for disassembly during usability test

Also, the spacers were confusing. These can be put in the box in various ways and since they are not symmetrical, only one way of placement is correct. They thought that colour coding or engraving could help with that.

The SPTs were asked for additional feedback about the disinfectability of the product. All SPTs thought the divider system was disinfectable. The lumen and clicking system are the most difficult parts to disinfect. These can be easily cleaned by pre-cleaning them by using a brush on the extrusions and spraying the lumen with water.

7.2.3. Functionality test results

For this functionality test, three DIN baskets were filled with stainless steel validation material by an SPT. The maximum weight a DIN basket can carry is 8 kg. The baskets were filled with a smaller amount of weight, since this was the only material available that is validated to go through the autoclave.

The baskets weighed 2.65, 2.75, and 4.65 kg. They were assembled according to the assembly procedure in Appendix F. The heaviest basket was placed on top, since this weight creates the most momentum for all dividers. The container was driven around for 215 km in a span of 3.5 hours.

Evaluating the contents of the container after the ride, it can be seen that all dividers have stayed in place and are still clicked on top of each other. None of the dividers or accessories broke. However, three dividers stacked on top of each other have turned around 15 degrees along their own axis, see Figure 44. This creates the problem that the outer corner of the short side of the divider almost seems to pierce the sterilization wrap.

After unwrapping each set, two of three wraps did not have any holes or tears. The wrap from the upper basket had a tear of around 5 mm, see Figure 45. This tear originates from the place where the short side of the angled divider seemed to puncture the wrap. The tear was only found in the outer layer of the wrap.

The inner layer of the wrap was still intact. However, this basket would be rejected for sterility. All wraps were assessed for a second opinion by an SPT, who had experience in recognizing tears in sterile wrap.

7.3. Conclusion

The results of the tests show that there are some potential errors of the divider system. The results of each test will be interpreted in the next chapter.

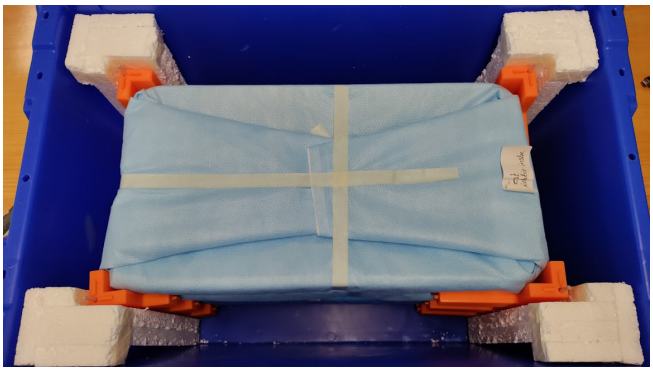


Figure 44: Divider system with sterile DIN baskets after functionality test

Figure 45: Tear found in sterile wrap after functionality test, caliper for size reference

08

Discussion & Recommendations

In this chapter, the results of the previous chapter will be interpreted and some recommendations for a future design will be given. Also, the concept will be evaluated according to the design brief and requirements. Some recommendations for implementation and future testing will be given.

8.1. Test results discussion & recommendations

The aim of the tests that were performed was to find potential improvement points, test the usability, and test the functionality of the novel product. The first tests showed some problems with the presented design.

The FMEA showed that a large amount of failure modes result in the sterile barrier being punctured. To detect these effects, it is important to check the sterile wrap before a procedure especially when the divider is just on the market. The risk of sterile barrier puncturing can be minimized by paying close attention to potential causes in future development of the divider, like minimizing surface roughness, minimizing sharp corners, and writing clear use instructions.

Both the FMEA and usability test showed that it is not completely clear how to use the product without instructions. Not knowing how to use the product can result in many errors. A clear learning curve can be seen in Figure 42 comparing the first and second trial. A less clear learning curve can be seen between the second and third trial. This implies that participants knew how to use the product after explanation.

Still, an average of 73 seconds to pack the baskets into the container at the last trial is quite long. This mostly related to the clicking system not working correctly. In future work, the tolerances of this clicking mechanism need to be thoroughly researched.

Disassembly took a lot less time than assembly, with an average of 20 seconds during the last trial. A less prominent learning curve can be seen. This implies that the disassembly took less mental load and is much faster than assembly.

There is not much difference between groups. However, since only three people of each group were tested, this data is not sufficient to estimate the difference between groups.

To reduce the risk of misuse of the product, clear instructions for use need to be written and all potential users must be updated about the novel system before implementation. Also a small indicator for which orientation of the divider fits which height of DIN basket can solve some errors. Since any type of ink will be washed off in the washer-disinfector, and injection moulding with multiple colours of plastic will be more expensive, a small engravement on the divider can show how the divider must be placed in the container for a certain height of DIN basket.

Another big problem with usability are the spacers. Many participants had difficulties with placing them in the box. These spacers could also have certain engravements as well to show where they belong.

During the usability test, SPTs were asked about the disinfectability of the product. All SPTs said that the product is disinfectable. They gave recommendations to first preclean the lumen of the divider. This can be taken into account in the instructions for use.

The functionality test showed that the divider punctures the sterile wrap when it turns around its own axis during transportation. The knob system could have contributed to this problem, since the small knob has less friction with the bottom of the euro container.

The divider can be improved to lower the risk of puncturing the sterile wrap. The corners of the divider that sits against the basket can be rounded off even more. Also the surface roughness needs to be minimised, especially on these places.

The prototype was 3D printed with PLA, which resulted in a relative high surface roughness. The actual product would have a more silicone-like material. If the material has more friction with the bottom of the container, it is less likely to slide into an angle during transportation. These material properties and the divider shape all need to be taken into account in the future development of the product.

8.2. Design brief discussion & recommendation

Looking back on the design brief, the aim of the project was to develop a product that fulfils two main functions:

1. Protect the sterile wrap and surgical instruments in DIN baskets of different dimensions during transportation
2. Keep configurations of different DIN baskets together

The first functionality test already shows that the current product does not fulfil the function of protecting the sterile wrap during transportation. However, the product does fit around DIN baskets of different heights and widths, depending on if the height of the basket and addition of sterile wrap and lids.

With the pin, clamp, and knob system, different configurations of baskets can be kept together. Up to three baskets fit into a container, but the divider system can also be used for a configuration that only consists of one basket. Since the system first needs to be disassembled before taking the configuration out of the box, the configurations are not kept together.

Also for logistics at instrument firms, there is not yet a good solution to keep these baskets together. The divider now works for transporting equipment between facilities, but an additional design with the basis of dividers can form a solution for storing the dividers in their configurations as well. A scaffold-like structure, similar to the pin, knob, clamp and divider system, can be thought of to keep up to 3 DIN baskets together.

This structure as a whole can be placed in storage of an instrument firm. In this way the configurations of sets can remain together, to avoid logistical problems. The wishes of the instrument firm need to be thoroughly implemented.

8.3 Implementation recommendations

While a final product has been presented, some additional design steps are needed for actually implementing the divider into the current system. Many stakeholders are involved in the process of shipping instruments, especially for loaner sets.

Elaborate communication with these stakeholders is needed to further improve the product, since they will be responsible for possible contamination or malfunction of surgical equipment that is transported with the novel divider. They will also be the target group for selling the product to. Furthermore, the SPE must be involved during implementation, since he must accept integration of a novel product into the current infrastructure.

The stakeholders that were interviewed for this thesis mostly are from Van Straten, CSA Services Bv. and Medtronic. Other CSDs and instrument firms might have a different opinion about the product and might have new ideas. Also for dimensioning, the input from stakeholders is needed. Each care facility, instrument firm, or CSD might have their own container. The spacer can be designed to fit a specific container.

A wilder idea for this product is implementing it in a whole different sector than the medical sector. The main function of the divider is protecting contents of different heights and widths, in a modular way. This might solve issues in other sectors where problems with transportation, logistics, or storage occur.

8.4. Design Engineering recommendations

All recommendations that have been given in 8.1., 8.2., and 8.3. can be taken into account for a new version of the current product. It is recommended to enter a new phase of diverging to think of ideas for solving problems of the current product, and then converging to choose which ideas would work best.

During this additional design engineering, manufacturing of the product must be kept in mind. For a redesign, limitations and opportunities for injection moulding should be taken into account from the start. The current design of the divider is not able to be injection moulded in one piece because of undercuts of the extrusions and a lack of draft angles. These features can be adapted to fit the manufacturing process.

Also the materials for the design are not fully defined. A recommendation for using recycled polypropylene for the divider, stainless steel for the pins, and silicone for the other accessories is given, but this is not thoroughly worked out. Other materials can be considered as well. The material depends on the current costs, manufacturing process, and the status of the research of Bart van Straten about material properties of recycled polypropylene with additives. Here, ISO standards must be thoroughly checked.

During additional design engineering, it can be explored if some wishes of the requirement list can be fulfilled as well. The current system can for example case a half-DIN basket, but this cannot be stacked on top of a full-length DIN basket.

8.5. Testing recommendations

During and after the design of a new version of this divider, some additional tests must be done to validate the functionality of the product.

Repetition of tests

After a redesign, the three tests that were already performed can be repeated. The FMEA can be executed with an interdisciplinary team to think of more failure modes. Also input about occurrence rates and detection methods can be used to achieve a realistic RPN.

The usability test can be performed with more people and also extreme users. Different circumstances like time pressure, social pressure, cold or hot temperatures, or wearing gloves can be tested. The performed usability test focussed on qualitative and quantitative research. A second usability test can focus on quantitative research even further.

The functionality test was only performed once, which does not create reliable data. Producing and loaning the material needed to perform this functionality test was already a favour from CSA Services Bv, and could therefore not be repeated. For future development, this test must be repeated to create more quantitative data. Different weights of DIN baskets, different euro containers, and different configurations of baskets should all be tested.

Drop test

One quite important test that must be done to validate the functioning of the product, is a drop test. For transportation between CSD and care facility, the euro box with spacers, dividers, and DIN baskets will be dropped from a height of 1.2 meter. This requirement originates from analysing ISO regulations. For transportation between instrument firm and CSD, a drop test must be performed for each instrument firm-specific euro box. These firms have their own version of a drop test, where the box is dropped from a certain height, from different angles.

Disinfectability test

One requirement for the divider and accessories is that they must all be disinfectable. This is determined both by the geometry of the product as well as its materials.

Water must be able to reach all parts of the product, and the product should dry properly. All SPTs that were participants in the usability test thought that the product was disinfectable.

A better way to test this requirement is with a Browne Test Soil kit. After the dividers and accessories are drenched in testing soil, they can be tested in a washer-disinfector. If the divider is properly disinfectable, water will reach all parts of the product and no trace of the soil will be left.

Also the disinfectability of materials should be considered. When recycled polypropylene is used, the impact of the washer-disinfector cycle on the material properties shall be tested. Also the divider shall be tested for this, since it might break after a few cycles of disinfection. This will also give more information about the life span of the product.

These tests can all be performed to get results about the product. The biggest question however, is if the new system is better compared to current systems like bubble wrap and foam layers. The results of these tests should be compared, to see if the novel divider system adds value and is superior to the current system.

09

Conclusion

The purpose of this thesis is to show the development process of a product that aims to help transport sterile and contaminated surgical equipment in DIN baskets safely and reliably. Problems with the current transportation methods are analysed and have been translated into a design assignment. Different solutions for this design assignment are explored, and a product aiding current transportation methods of sterile surgical instruments is presented.

The novel product is a modular divider system that fits around different DIN baskets and fits inside different euro containers. The product is especially designed for integrated, dedicated transportation of DIN baskets in containers. This type of transportation currently does not have a proper product that protects the sterile barrier and keeps configurations of DIN baskets together. The number of DIN baskets that will be shipped will increase, since more and more instrument firms are switching to transportation in DIN baskets. Therefore, this product can fill a huge gap in the market.

While a product has been presented, it is still in its infancy. Additional design engineering, testing, and validation is needed to further develop the product and implement it into the current transportation infrastructure.

The product is designed in such a way that it fits the requirements described after the design assignment. Some requirements, however, need further testing for proper validation. These tests can take place in a later stage of future development.

This thesis forms the basis for future research and design engineering of the divider system. However, the biggest question that remains to be answered, is if the novel divider system adds value and is superior to the current transportation system.

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