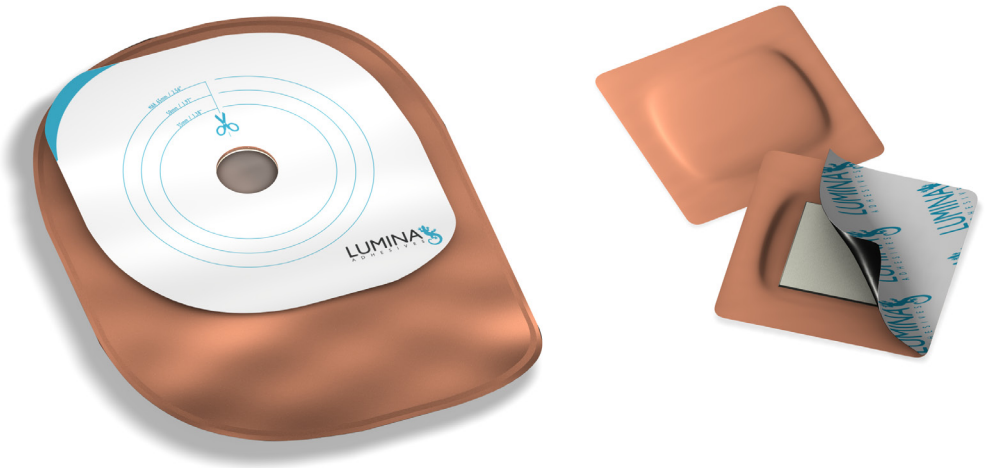
CHALMERS



Design development of Multi-layered Wound dressings and Ostomy products

Master of Science Thesis in the Industrial Design Engineering programme

CHRISTER OLOFSSON & CHRISTOFER WIK

Department of Product and production development
Division of Design and Human Factors
CHALMERS UNIVERSITY OF TECHNOLOGY
Gothenburg, Sweden, 2011

Design development of Multi-layered Wound dressings and Ostomy products

CHRISTER OLOFSSON & CHRISTOFER WIK

Department of Product and Production Development
CHALMERS UNIVERSITY OF TECHNOLOGY
Göteborg, Sweden 2011

Design development of Multi-layered Wound dressings and Ostomy products
Christer Olofsson & Christofer Wik

Department of Product and Production Development
Division of Design & Human Factors
CHALMERS UNIVERSITY OF TECHNOLOGY
SE- 412 96 Göteborg
Telephone + 46 (0)31-772 1000

Cover figure:
A common type of wound dressing and ostomy bag. Figure created by Christer Olofsson

Göteborg, Sverige 2011

PREFACE

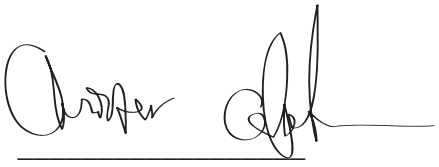
This master's thesis was carried out in cooperation with Lumina Adhesives in Gothenburg, Sweden, during the spring of 2011. The thesis is the final part of the Masters of Science program in Industrial Design Engineering at Chalmers University of Technology and comprises of 30 credits.

We would like to thank our supervisor and examiner Jessica Dagman at the Department of Product and Production Development, Division of Design and Human Factors Engineering, Chalmers University of Technology for great support and feedback.
We would also like to thank Lumina Adhesives for the opportunity to carry out the project and especially our contact Daniel Jacobsson who has put down a lot of time and work to help us make the project successfull.

Additionally we would like to thank the following people for their valuble contributions:
Isabelle Andersson and Marie Ingemansson who acted as the opponents of the thesis.
Bo, Hanna, Magnus, Mats, Stefan, Ylva and Zhi at Lumina Adhesives.
Patric Apelgren at Brady Converting
Ralf Rosenberg, programme coordinator at Industrial Design Engineering, Chalmers

Göteborg, May 2011

Christofer Wik



Christer Olofsson

ABSTRACT

A central problem for medical skin products such as wound dressings and ostomy bags are the contradictory demands on strong and safe adhesion and the possibility to remove the products easily and without pain. Lumina Adhesives solve this by providing an adhesive whose adhesion decreases drastically when exposed to light. Developing wound dressings and ostomy bags that can fully take advantage of this technology is a complicated design challenge.

Through a user-centered design development process, product solutions have been designed. By mapping all technical, medical and user demands, a holistic view has been taken on the problem which has been broken down into partial problems to address one at the time. Solutions and designs have been evaluated, tested in prototypes and redesigned in an iterative process. The final results are designs that allow the user to utilize the full functionality of Lumina's technology in an easy-to-use and comprehensible way.

SAMMANFATTNING

Sjukvårdsprodukter som med ett adhesiv fästs på hud har en inneboende motsättning mellan behovet av kraftig och säker fastsättning och möjligheten att enkelt och smärtfritt avlägsna produkten. Lumina Adhesives lösning på detta grundproblem är ett adhesiv vars vidhäftningsförmåga kraftigt reduceras då det utsätts för solljus. Att utveckla produkter såsom sårförband och stomipåsar som fullt utnyttjar fördelarna med denna teknik är ett utmanande designproblem.

Genom en användarcentrerad produktutvecklingsprocess har designlösningar för de nämnda produkterna tagits fram. Genom att kartlägga alla tekniska, medicinska och användarkrav har en holistisk bild av problem erhållits, vilket sedan har brytits ned i delproblem som angripits var för sig. Framtagna lösningar och designförslag har utvärderats, testats med prototyper och omdesignats i en itterativ process. Slutresultatet består av designlösningar som möjliggör för användaren att utnyttja funktionaliteten i Luminas adhesionsteknik på ett lättanvänt och lättförståligt sätt.

TABLE OF CONTENTS

1. INTRODUCTION

1.1 Background

Medical conditions such as chronic wounds and stomas requires medical products to be attached to the skin as part of the user's daily life. The products used for these conditions aim to provide functionality the body is unable to. A wound dressing can protect the inside of the body from foreign microbes like healthy skin does and at the same time support the body in the healing process. An ostomy product collect the stoma to allow the patient to dispose of it in a controlled manner - a stoma patient has no control over when the excrements are exiting the body . To function as intended the products need to be securely attached to the skin, but at the same time they need to be replaced frequently which means they should also detach easily when wanted to.

Lumina adhesives develops and commercialize products based on a unique technical adhesive platform, where its attachment is intensely reduced by exposure to ordinary light from the blue part of the visible spectrum. The benefit with this technology is a strong and secure fixation which can easily be removed when desired without leaving sticky residues.

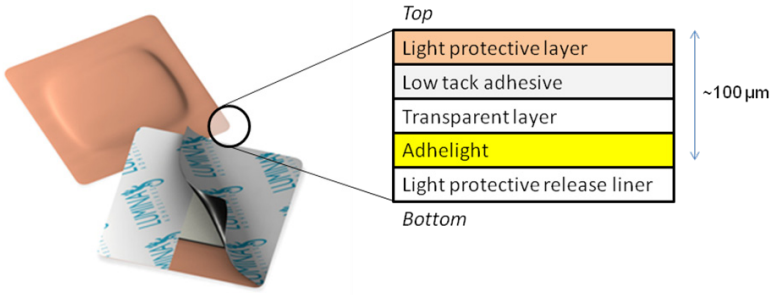


Fig. 1.1: Conceptual design of stick-on bandage for skin.

To be able to fully utilize the benefits from this technology when used in stick-on products, Lumina works with a layer design (see fig1.1). The adhesive, called Adhelight, is covered by a light protecting layer as long as the adhesion is intended to be kept intact. When the product is to be removed the light protecting layer is removed, exposing the adhesive to light through a transparent layer. This reduces the adhesion and the transparent layer can easily be removed together with the adhesive.

When applying the technology to wound dressings and ostomy products the solutions deviates from conventional interaction. Since the products are new in terms of functionality, interaction and handling they need to be designed in a way that communicates this. Through a user centred development process the final products can allow the users to take

advantage of the full benefits of the technology. The project therefore serve to investigate and develop user centred solutions for wound dressings and ostomy products.

The aim of the thesis project is to improve the usability and overall user experience of the products. The end users are in need of the products due to their state of health. Products that are adapted to their needs and experiences would improve their life during the healing process; or in chronic cases - improve the quality of life. This would in extent give an edge for the company towards the competitors. Without a solution that is quick and easy to use the product will be more tedious and slower to use which would make it less attractive compared to its competitors.

1.2 Purpose

The purpose of the project is to develop one or several design solution(s) for wound dressings and ostomy bags (hereafter collectively referred to as products), utilizing Adhelight as a technical platform. To meet the needs of the users consideration should be taken to usability, technical demands (e.g. materials selection), existing product design and aesthetics. The presence of different material layers requires the design to guide the user in the handling of the product to secure the relation between intention and action. The following question is therefore asked:

How can layer structured wound dressings and ostomy bags using Adhelight be designed to secure functionality and communicate interaction?

1.3 Aim

Considering the background and purpose stated above, the product communication should be as clear as possible without interfering with functionality. The aim of the project is therefore to create wound dressing designs and ostomy designs that:

- Allow easy handling of the products.
- Allow the users to understand the handling of the products.
- Make sure that the interaction surfaces do not interfere with the functionality and safety of the products.
- Are suited for mass production.
- Are in line with medical demands.

1.4 Research questions

To be able to fulfil the purpose and to reach the aim, information has to be gathered that can answer the following questions:

- What criteria determine the success of the products?
- What properties makes the products easy to understand?

- Who are the users of the products?
- What materials are suitable for the products?
- What are the manufacturing demands?
- What medical demands needs to be considered?

1.5 Scope

An important focus of the project is to utilize the solution(s) in large scale production, something that should be taken into consideration at an early stage.

The project will consist of user studies, creative design solutions, materials selection, prototyping and verification and validation through practical tests to optimise the solution for optimal performance. The user product experience will be examined, mainly with respect to the visual and tactile experience.

In the development process priority will be given to develop the wound dressing first, as it has potential to reach the market earliest, and ostomy bags second. In discussions with Lumina it was decided that the wound dressings should be developed into one working product concept with functioning prototypes to verify it. The development of the ostomy bags should stay at a more conceptual level.

1.6 Limitations

The cost perspective of the products is important, but more in terms of production procedure rather than material cost. No detailed costing will be made for the designs.

The Adhelight technology is the basis for Lumina Adhesives products and all designs will use it. Design concepts not using this technology will not be considered. The project also will not put any work into developing Adhelight itself in terms of properties or composition.

1.7 Transfer of solutions

The project aims to provide solutions that are general to the degree that they can be applied on other current and future products. Due to this it is important to communicate the reasoning and background to why and how results were reached, as well as why a solution may work in theory but not in practice. The theories and results in this report are also intended to provide guidance for Lumina Adhesives when working with future products.

To be able to provide transferral of solutions it is important to provide the tools we used creating them. That way the tools can be reapplied in future projects.

2. THEORETICAL FRAMEWORK

This chapter will account for the theoretical basis of the project. Design theory, product semiotics, usability are presented together with theory on wound care, ostomy and light degradable adhesive.

2.1 Design theory

There are many meanings to the word *design* depending on language, context and the individual interpreting the word. For this thesis, design will be seen as the merger of several factors defining the product. The model in figure 2.1 describes fairly well how the design process works. A common misconception is that design is either pure aesthetics or the technical blueprint, but the design process is more than this. To be able to create a successful and attractive product the technical factors have to be merged with aesthetics, market needs, technology, financial factors, the history of products and human factors.

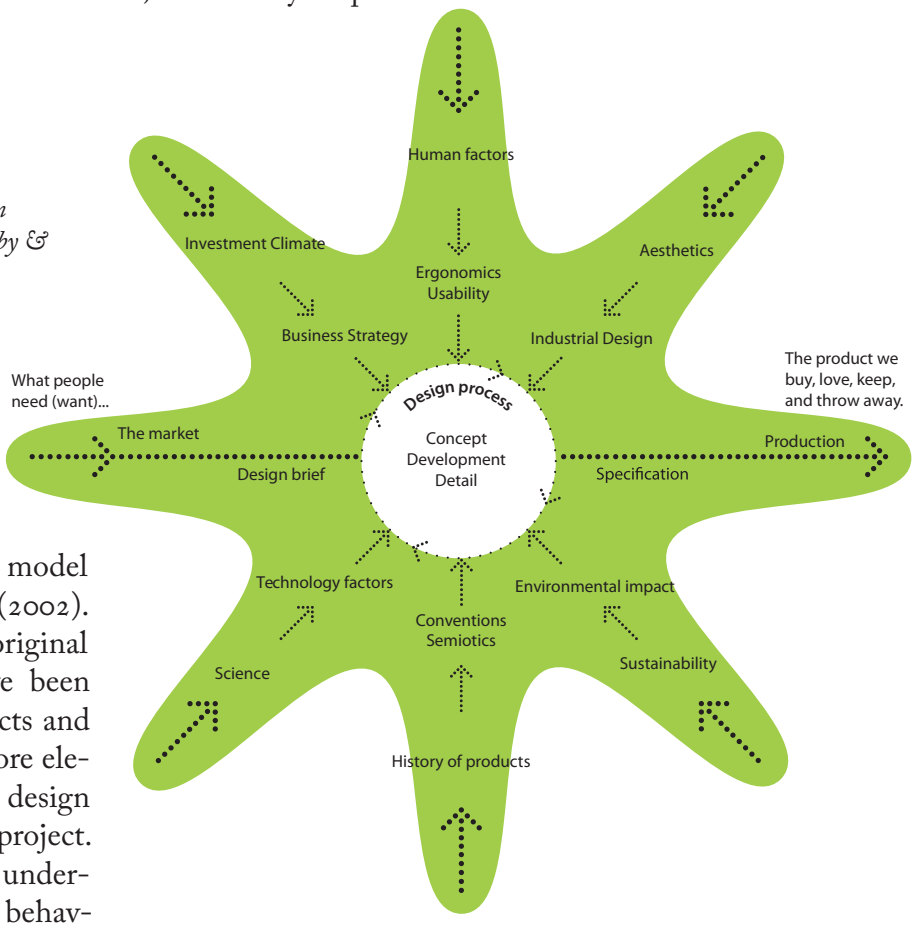


Fig. 2.1 Based on model from Materials and design by Ashby & Johnson (2002),

The model is based on a model by Ashby & Johnson (2002). Compared to the original model two factors have been added; history of products and Human factors. These core elements are central in the design process used in this project. Human factors are the understanding of the human behaviour, physical and mental functionality and limitations, values and needs. Taking the perspective of the user is essential to be able to create a product that can become a reality rather than just an artefact that works in theory but not in practise. History of products is a factor affecting the perception of products, the accumulated knowledge and experience people have from products. An example could be a car, which most modern people would recognize for what it is, while a caveman would most certainty not due to missing a frame of reference. The reference frame enables the product to com-

municate what it is and how it operates.
The role of the product designer vary depending on where in the process he/she enters and how far the product is to be taken. In modern industry there are high demands on the designer, the ability to comprehend and utilise complex technical factors can make the product design process rather extensive. One of the best ways of accumulating the knowledge needed to create the whole picture is to ask questions and utilise the resources at hand. Colleges, experts and written sources can provide the information needed, but the right questions has to be asked. The tool is simple curiosity, something provided by human nature.

2.3 Semiotics

Semiotics is defined by Monö (2004) in Design for product understanding (p.58) as: *"The study of signs and sign systems and their structure, properties and role in socio-cultural behaviour"*. What this means is that products act as signs and communicate with the users in different ways. The users get input through various senses, interpret the input and then perform an action depending on the interpretation. How they act (or react) depends on the product, the context and the user. The reaction can be a feeling such as happiness or disgust as well as an action, e.g. pushing a door instead of pulling.

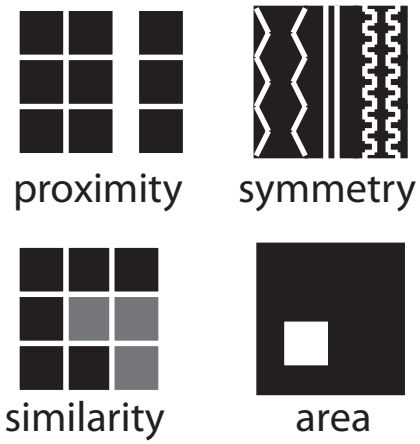


Fig. 2.2 examples of the gestalt laws.

Semiotics is the study of how items communicate and what they communicate. Based in different ways on how humans process information different results can be created. The gestalt laws are relevant examples; proximity, similarity, area and symmetry are ways for humans to group and structure visual information. (fig. 2.2)

When using the gestalt laws the opposite also need to be considered. As people group symmetry into one common group, they will also group the deviations (dissymmetry) in a separate group. If five buttons are green and one button is red one can assume the green buttons have some connection while the red does something completely different.

But semiotics is not limited to visual communication. The connection between visual expression and interaction affects the trust people have for a product. When the different sensory input match, the product can be considered to be honest in its expression, while a product that express premium quality but when interacted with communicate cheapness does not. The reaction, wanted or not, will be different.

When communicating with the user through a product it is difficult to know what the user knows from before and how she/he will react. But conventions, associations and use of common solutions can help the user when deciding how to act or interact. The designer should lead the user through the interaction, by deciding what feedback the product will give.

2.4 Wound Care

There are different classifications of medical products depending whether if they come into direct contact with the patient or not and what significance it has for the patient's health. There is a difference between functional materials and non-functional materials in this context. A material not in direct contact with the skin does not necessarily have to conform to the classification standards, while the product as a whole still has to be classified. (Jacobsson, 2011-b)

2.4.1 Human skin

The human skin consists of *epidermis* and *dermis*, where epidermis is the outermost layer (fig.2.3). When adhesive products are placed on the skin some consideration needs to be taken. An adhesive with high shear strength or inflexible material may cause the two skin layers to move in relation to each other, which can cause blisters. A high tear strength adhesive may cause skin damage or wounds when it is removed from the skin. (Coloplast, 2007)

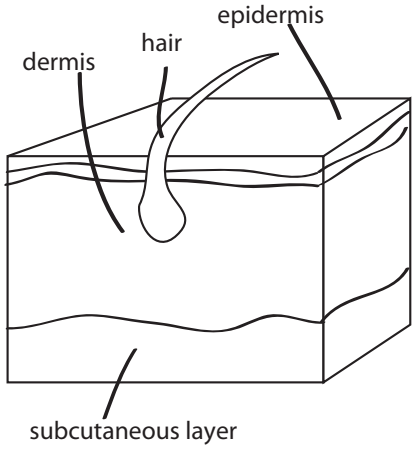


Fig. 2.3 The layers of the human skin.

The skin regulates the body temperature through perspiration. When part of the skin is covered by a product the perspiration should be able to leave the skin surface in some way. If the sweat is not allowed to leave the surface it will increase the water level in the affected skin area and change the properties of the skin. It may cause damage, pain, discomfort and even hamper the healing process. The materials covering the wound and skin must provide a sufficient degree of moisture vapour transmission rate (MVTR) to avoid problems. (Baranoski & Ayello, 2007)

2.4.2 Treatment of wounds

There are many different types of wounds and depending on the properties of the wound treatment, different padding materials are relevant. But in essence it is common to provide drainage of wounds, while still providing a moist environment, (Jacobsson, 2011). According to Baranoski & Ayello, (2007), a wound dressing should:

- *Maintain a moist environment.*
- *Be absorbent.*
- *Provide thermal insulation.*
- *Act as a bacterial barrier.*
- *Eliminate pain at the wound site and not cause pain on dressing removal.*

The wound dressing should provide a moist environment, but not to a degree where it becomes wet. The adhesive and materials should not absorb liquid to a degree where they loose integrity or functionality. The materials covering the wound should provide a high MVTR (Moisture vapour transmission rate, details in chapter 2.6.2) to prevent the wound from becoming too wet. The wound pad has to be covered with a material that allows moisture to pass through, but also acts as a liquid seal and a bacterial barrier. (Jacobsson, 2011-a)

In essence this means covering the wound pad with as few layers as possible, thus maximising the MVTR.

2.5 Ostomy

There are two main types of ostomy, *ileostomy* and *colostomy*, the difference is what part of the intestines that is extracted. This will result in different placements of the stoma on the abdomen, the texture of the excrement and whether it is extracted or retracted. The ileostomy is made of the small intestine, while the colostomy is, as the name suggests, made of the colon. Both types of ostomy can be either temporary or permanent. (Coloplast, 2007)

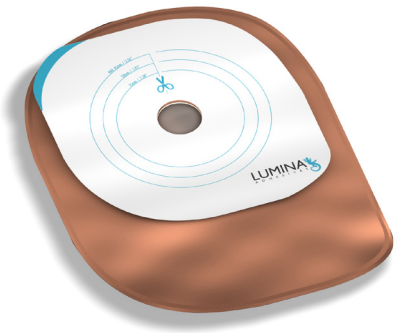


Fig. 2.4. An ostomy bag.

2.5.1 Physical and psychological factors

As mentioned, each individual has got different types of stoma in terms of size, shape and placement. But the surrounding area can also vary due to scar tissue, type of skin and craftsmanship of the surgeon. Over time the texture of the skin may also change due to the frequent removal of *stratum corneum* - dead cells. (Coloplast, 2007)

There are some users that need to visually inspect their discharge to assess their physical conditions. There may be blood in the stool or colouring that needs to be kept track of. (Jacobsson, 2011); (Colostomy - my journey, 2008)

The patch attaching the product to the skin need to allow the perspiration from the skin to be removed, either by passing through the material or to be absorbed. An example of an ostomy bag is shown in figure 2.4.

Ostomy is a life changing procedure since the users need to adapt to new daily routines and accept the bodily changes - both in terms of function and visual appearance. But what has to be taken into consideration is that a patient often can have suffered of constant pain, social difficulties and sudden discharge of faecal matter. Although getting an ostomy may seem like a very negative experience to the average person, the people who get relieved of their previous conditions can have a different experience. The ostomy becomes a relief, something that can be seen on different forums and blogs

on the Internet. The ostomy in it self should not limit people from living a normal life with physical activities and social interaction. As J. Grossman expresses it on her blog "*I've had my ostomy for six years and every day I am thankful for how healthy I feel because of it. World Ostomy Day is the perfect time to show this to Canadians.*" There is still a stigma surrounding the life with an ostomy, but there are support groups and campaigns working to create acceptance as a normal medical condition. (Grossman, 2009), (*Number twos - Life with Ulcerative Colitis*, 2007)

2.6 Functionality of skin products

A wound dressing, ostomy bag or similar product is attached to the skin to cover a certain area. The attachment is done by a medical grade adhesive and the properties of the adhesives are adjusted by chemists according to what the specific needs are, (Jacobsson, 2011). The material that is attached to the skin can consist of different materials, which can deliver different properties and functionality, (Baranoski & Ayello, 2007). There are several central technical factors which needs to be considered when attaching products to the skin, especially when done repeatedly over an unlimited time span.

2.6.1 Adhesive strength

A very strong adhesive will secure the product to the skin but may also cause pain when removed, a not so strong adhesive will of course have the opposite effect. All adhesives have a relationship between shear force (τ) and tear force (σ), which is roughly described in figure 2.5. This is relevant when considering the functionality of the adhesive. It is not possible to have both properties high without having a really strong adhesive force as a whole. The balance between these two forces affects the functionality of the product. An ostomy bag has higher need for shear strength than a wound dressing due to its placement and the forces it is affected by. (Jacobsson, 2011-b)

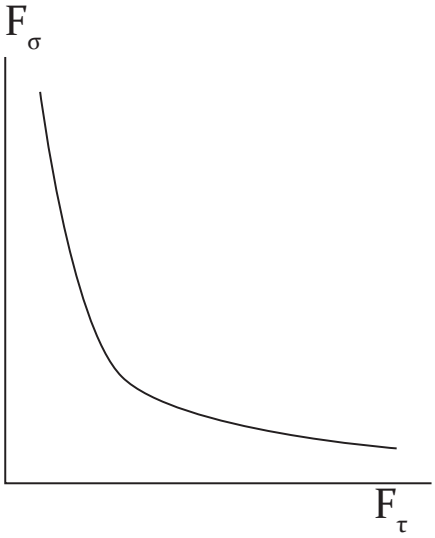


Fig. 2.5. The relation between how much shear and tear force that an adhesive can resist.

2.6.2 MVTR

Moisture vapour transmission rate (MVTR) is a measure of the passage of water vapour through a substance, usually in the unit $g/m^2/day$, (Jacobsson, 2011). This property differs a lot between materials and having a high enough MVTR in products attached to the skin is vital to avoid maceration of the skin. Depending on what kind of adhesive is used the covering layers may have to allow for vapour to pass through, otherwise the adhesive may loose its integrity and release from the skin, (Coloplast, 2007). It is relevant to consider that each single of the covering materials in the product may have a high MVTR, while the complete product have a much lower MVTR, (Jacobsson, 2011).

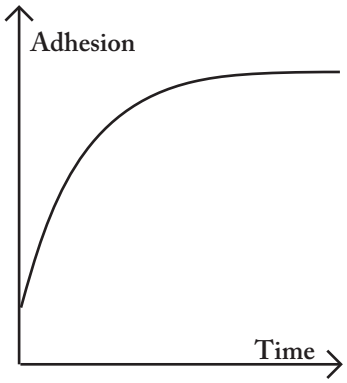


fig 2.6. Adhesion over time

2.6.3 Adhesion over time

The adhesives commonly used for these products have different properties in terms of adhesion over time, this means that when the product is attached to the skin the adhesion increases over time before it is at full effect (fig. 2.6). This property is relevant since it may allow the user to remove and reattach the product in case it was at a bad position the first time. (Jacobsson, 2011)

2.6.4 Residuals

Some adhesives leave residuals when removed, this may prevent the next product from attaching properly and may create air pockets in the affected areas. For the ostomy products this may allow for the corrosive content to leak out between the skin and the adhesive. (Coloplast, 2007)

2.6.5 Flexibility

When the products are attached to the skin, the products have to be flexible enough to allow for the forces to be absorbed by the product rather than transferred into the skin. If the product is too stiff and hard it will hold the epidermis fixed, while the dermis will move. This situation will cause friction between the two, causing blisters, pain and discomfort. (Coloplast, 2007)

2.7 Usability

Usability is defined by the International Standards Office (1998) as the effectiveness, efficiency and satisfaction with which specified users can achieve specified goals in particular environments, (Jordan, 1998). Jordan divides usability into five components that reflect that possibility for the usability to change for a specific user by time and experience. The components are Guessability, Learnability, Experienced user performance, System potential and Re-usability.

Guessability is defined by Jordan as a "cost", measured in for example time and numbers of errors, for the user to sucessfully use a product for the first time. The lower this cost is, the higher the products guessability is. Guessability becomes an important issue for users who have to use a product for the first time without demonstration or instruction.

Learnability denotes the users cost for learning to use a product with a high level of competence after the initial use. The learnability becomes important for products that the user is going to use many times and where it is important to become proficient with the use in a relatively short time.

Experienced user performance refers to the level of performance an experienced user of a specific product can achieve. For some tasks such as the exercise of professional work, it is

important for the user of the product to perform with a high level of performance.

For some products it is relevant to consider the *system potential*, which can be defined as the theoretical maximum level of performance a product allows.

The *Re-usability* of a product is relevant when it is likely that a user will not repeat her/his interaction with the product for a long time so that his/her performance with it decrease.
To make the product more comprehensible it would be desirable to make the usage consistent. The products are built up by layers that are to be removed in different steps, due to this the interaction should follow the same procedure. (Jordan, 1998)

2.8 Designing pleasure

Jordan (2000) extends usability beyond viewing products as tools supporting users to complete a certain task. Products can evoke feelings and people can create personal bonds to their items. Instead of limiting the design process to only consider satisfaction, efficiency and effectiveness, emotional responses should also be considered. Jordan argues that "*...when people get used to having something, they then start looking for something more.*".

Similar to Marslow's hierarchy of needs, consumers eventually want more from a product than just functionality and usability - pleasure (fig. 2.7). (Jordan, 2000) But it is important to remember that usability and pleasure are subordinated to functionality. A product with good usability and pleasurable appeal is seldom considered useful if it does not deliver its functionality.

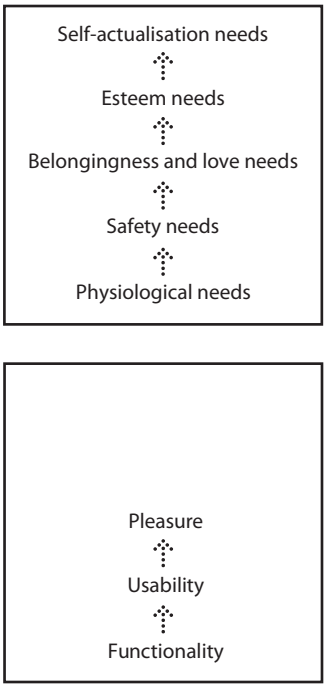


fig 2.7. Based on model from Designing pleasure P. W. Jordan (2000).
Upper: Marslow's hierarchy of needs. Lower: A hierarchy of consumer needs.

2.9 Users

In "Work and Technology on Human Terms", Bohgard et al. (2007) divide users of a product into different categories. The categorization is beneficial to identify the different needs of different kinds of users.

Primary users are the ones who use a product for its main purpose, for instance a person using a suitcase to carry his belongings, (fig. 2.8).

A secondary user may also use the product, but not for its main purpose, this could be someone using the suitcase as a seat to rest his legs, (fig. 2.9).

A side user is affected by the product without using it, in the example it could be someone who is forced to walk around the suitcase if it is placed in her/his way, (fig. 2.10).

Fig 2.8. Two primary users pulling their belongings in suitcases.

Fig 2.9. Two secondary users, utilizing a suitcase as a sitting surface rather than carrying their belongings.

Fig 2.10. Side users affected by a suitcase in the middle of the walking path.

Fig 2.11. A friendly co-user helping a critical user (not in picture) with the heavy bag.

Co-users work with or collaborate with the primary or secondary user, without interacting directly with the product. In the example of the suitcase it could be a fellow traveller, (fig.2.11).

Critical users are users with special needs or limitations. A product adapted to the critical users can often function well for non-critical users. In the context of a suitcase it could be a user with reduced muscle strength. By making sure he/she could use the product, non-critical users could benefit from it as an extra feature.

2. 10 Layer structure and function

2.10.1 Release liner

The release liner is a material covering the sticky surface. To be able to remove the release liner without removing the adhesive from the other layer the release liner must have less attraction force to the adhesive than the other layer. This can be done by choosing specific materials with right surface properties or by coating it with silicone. The release liner also have to protect the adhesive from light. (Jacobsson, 2011-a)

2.10.2 Adhelight

Lumina adhesive's technical solution is a light switching adhesive. It remains sticky until it is exposed to light, at that point it switches to a less sticky state. If it is exposed to ordinary indoor lightning it make take a few minutes for it to switch. To reduce this time a flashlight with blue diodes is normally used to illuminate the adhesive, which reduces the time to switch to a few seconds. When switched the product can be removed without pain and residuals. Since the adhesive has to be exposed to light to switch and release the Adhelight has to be attached to a transparent film. (Jacobsson, 2011-a)

2.10.3 Light protection

To prevent the adhesive from switching, the adhesive has to be protected from light until the removal. In production and laboratory this can be done by filtrating out the unwanted light frequencies. In products it can be beneficial to protect the adhesive from the whole visible light spectrum. (Jacobsson, 2011-a)

This can be done by having particles of other materials blocking the visible light - coal, titanium or silver oxides can be used. Both from an economical and environmental perspective, coal is preferable in favour of the more scarce materials. However, the coal will make the material black which may not be suitable for some products. (Jacobsson, 2011-a)

2.10.4 Visible layer

The visible layer is the surface exposed to the surrounding. This layer should communicate the function and interaction with the user. It is also central for what the product communicates in terms of expression, values and what emotions it evokes in the user. Due to the light protection being integrated or placed under the visible layer, there may be some black bleed effect where the black layer is visible through the top layer, making the visible layer appear darker than intended. (Jacobsson, 2011-a)

2.10.5 The whole product

When the layers are combined into one sandwich structure the whole product will have some additional demands as a whole. The MVTR of the whole product has to be maximised for the wound treatment. It is also sought after to prevent the perspiration from the skin to accumulate since it can macerate the skin and/or reduce the attachment properties of the adhesive. (Jacobsson, 2011-a)

2.10.6 Adhesives and layers

By choosing layer properties correctly an adhesive between layers can be designed to have stronger attachment to one layer than the other. As an example, this technique is used for release liners to allow them to release from the adhesive without tearing it from the other layer. (Jacobsson, 2011-a)

2.10.7 Layer fluid resistance

The side of the product that is exposed to the surrounding need to have resistance against fluids. This to prevent the adhesive from absorbing water and losing its properties as well as prevent maceration of the skin. (Jacobsson, 2011-a)

2.10.8 Bacterial barrier

For both products it is important to provide a bacterial barrier. The wound dressing need to keep bacteria and foreign microbes out of the wounds, while the ostomy should keep the bacteria locked in. (Jacobsson, 2011-a)

2.10.9 Padding, welds and other optional layers

Depending on the product, additional factors have to be taken into consideration. The wound padding has a certain height since it is porous to absorb and transport liquid. The Ostomy bag may have to be welded onto the attachment plate, this will change the material properties in the weld area. There can also be layers added to provide additional functionality, how this may affect the product as a whole has to be taken into consideration. (Jacobsson, 2011-a)

3. METHODOLOGY

This chapter explores the various methods used in the thesis. The methods are divided according to what phase they were used in. Methods were chosen to make sure all the relevant factors were taken into consideration and carried through the whole project cycle.

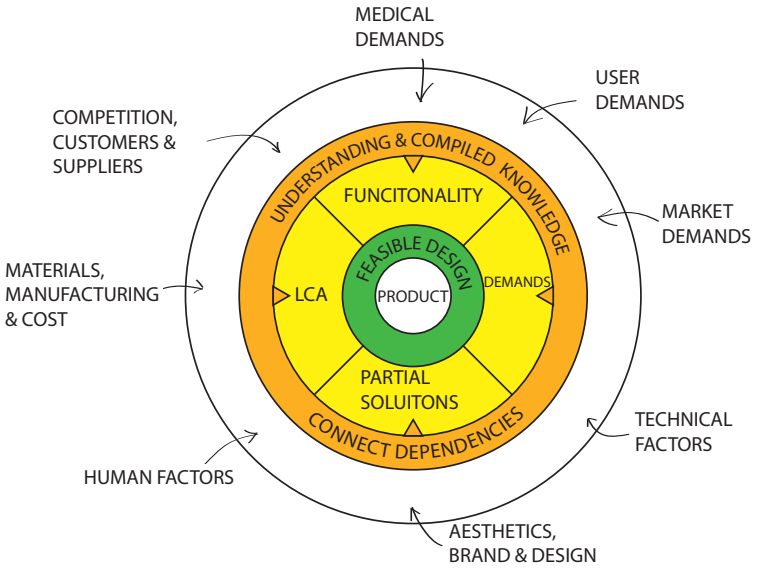


Fig. 3.1 The wheel of information transformation.

3.1 The overall approach

The products have many factors involved and to be able to get a decent overview different areas were identified and listed. Once the different areas had been investigated the dependencies between them were mapped out. The following step was to compile the information into different areas to provide functional support for the product development. The final step was to create feasible designs where the gathered information functioned as verification of the solutions created. The final product is the last step of the information transition where it met the different initial demands as a physical artefact.

As described by Muller (2001, p.148):
"Product designing implies that a product idea needs to be worked out into a detailed design for a product. In design methodology, this development is also presented in phase-like stages, starting with the product idea. This process is structured in such a way that categories of activities belonging together result in a certain design stage."

This results in different types of information being processed by different activities in each design stage. Before the next stage is started the previous one is evaluated, the next stage

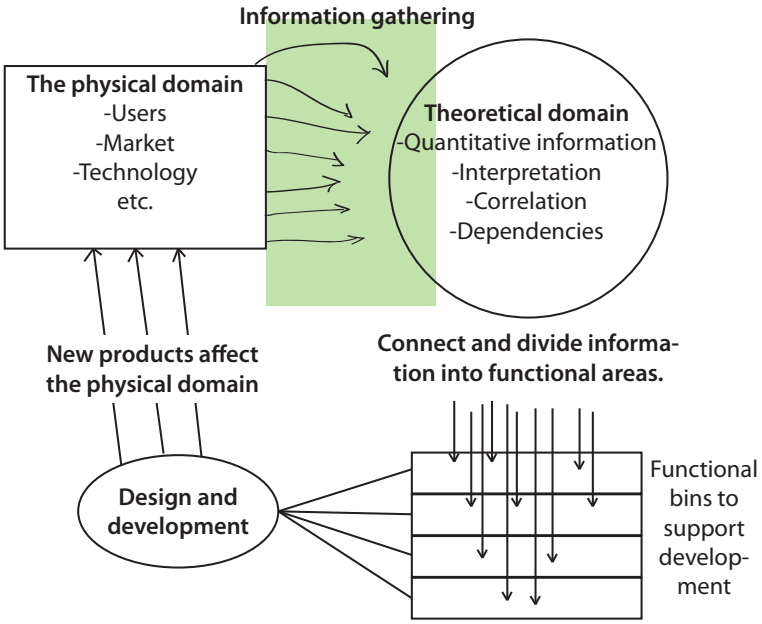


Fig. 3.2 Cyclic information transformation events, an example can be found in appendix II.

has to begin with a formal decision to go ahead with. If a decision can not be reached the previous stage has not reached the qualitative point required and needs to be iterated. Our design process can be seen in fig.3.3.

From a wider perspective the information flow can be described as a cyclic event. Every time a new product is introduced to the physical domain new values, impressions and factors are created. When the next product development cycle is started new factors affects the information gathering. A simple example of this can be seen in figure 3.2 and is further explained in Appendix II.

The models describe how complex product development can be handled. The main problem is to be able to create a complete and useful overview of the project at hand. To achieve this the information gathered from the physical domain (or reality) should be picked apart; redundant information will emerge and when the information is divided into the functional bins redundant factors will also be created.

The reason for creating the functional bins with redundant factors is to have relevant verification surfaces. This makes it easier to create partial solutions that do not conflict with other areas. E.g. a manufacturing process solution not conflicting with medical demands. This information cycle runs in parallel with the design process, but through user studies the effects on the physical domain can be iterated into the information gathering process. New information that emerge during the project can then be added into the relevant functional bins.

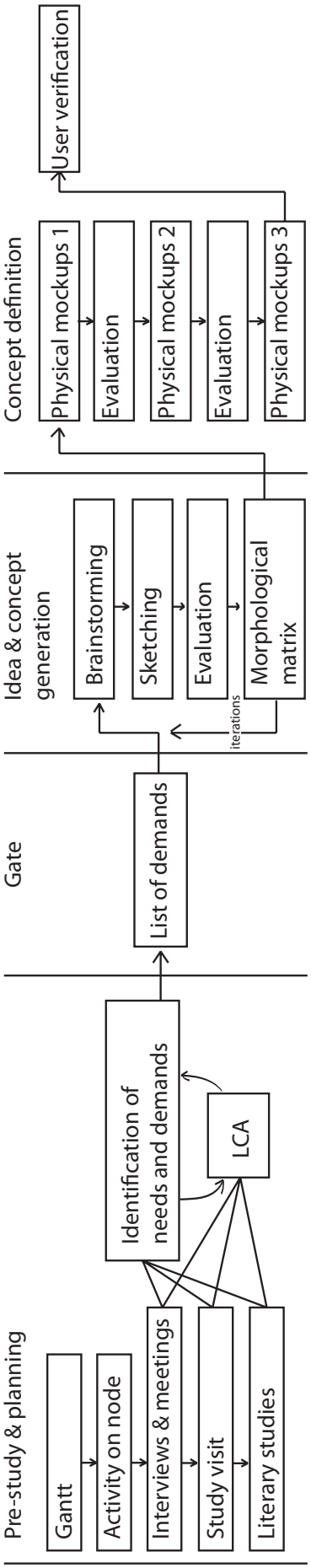


Fig. 3.3. Flowchart of the methods used in each phase.

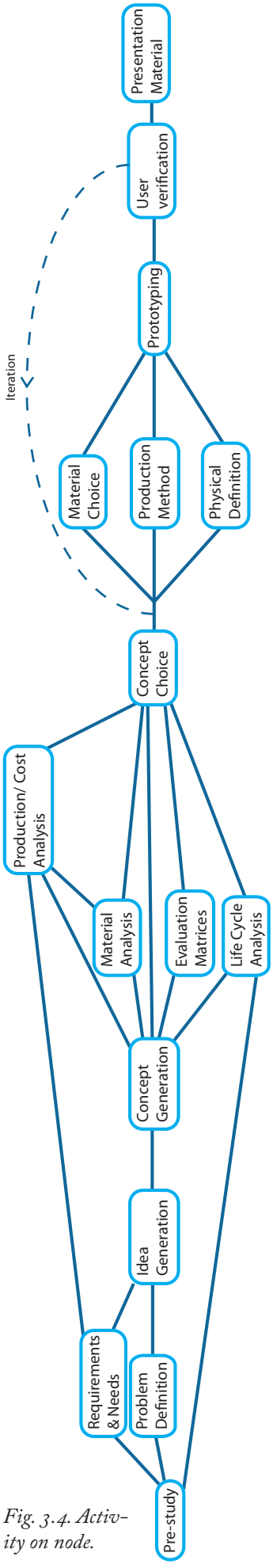


Fig. 3.4. Activity on node.

3.2 Pre-study and planning

Through the pre-study necessary information to execute the project was gathered. Numerous subjects and sources of information were explored including:

- Legislation and standards
- Market and competitors
- The existing products of Lumina Adhesives
- The Adhelight adhesive
- The Packaging and distribution of Lumina products
- The core values of the Lumina brand and product branding
- The Stakeholders in the project
- The requirements and needs.

3.2.1 Gantt

A Gantt chart is a way to illustrate relationships between activities and time, (Maylor, 1996). On the y-axis of the chart all mayor activities of the project are listed, the x-axis represents time. Each activity is assigned a limited time frame to be executed. The Gantt chart is one of the simplest and quickest ways to create a time plan and gives a good overview of the project. The Gantt chart can be found in Appendix I. As most planning it has to be seen for what it is - a suggestion from yourself at a point in time when you did not know much about the project, to yourself in a time when you know more. Therefore it is wise to reevaluate the schedule on a continuous basis.

3.2.2 Activity on node

The activity on node chart is a method to create an overview of the activities in a project. It visualizes what activities will be performed in a project, how long time each activity should be allowed to take, which activities that are performed in sequence and which are independent from each other. In the diagram activities are represented as boxes (nodes) and their links by arrows. In this project the Activity on node were modified to leave out the time factor, bacouse its main purpose was to map the dependencies of activities and the time requirements for most activities was unknown. The Activity on node chart can be seen in fig. 3.4. (Maylor, 1996)

3.2.3 Interviews

By performing interviews and meeting with representatives from Lumina a fast and effective introduction into the products was achieved. All interviews were either open, which means that interview questions were created during the inteview rather than in advance, or semi-structured, which implies that some interview questions and topics are formulated in advance of the interview but follow-up and deepening questions are formulated during the course of the interview, (Johannesson et al. 2004). By accumulating a base knowledge of the terminology, materials involved, the competition and

other relevant factors, the literary studies could be executed with focus on new areas and in depth studies.

3.2.4 Study visit

To get a better insight into how the products are made, a converter company was visited. Converters process film materials into multilayered products - as the name suggests, they convert film materials into products or semi-products. The information received from a professional while having the opportunity to ask relevant questions shortens the gap between theory and practise.

3.2.5 Literature studies

A literature study is relevant to get information from previous studies and to allow for fact based decisions to be made. But aside from scientific articles, printed material and technical documentation there are social media allowing for non-intrusive user data to be collected. Social media such as blogs can allow insight into the everyday life of an end user.

The benefit of a public online diary is that the writer does not know or may not consider the blog being read by product developers. In effect it is an opportunity to receive neutral information. Even if there is a risk of the blog being a sham, the content can be evaluated in context of how deep the knowledge of the products are. Finally a blog can be anonymous, which means embarrassing details and situations may be described in detail - something that may not surface in a face to face interview.

3.2.6 Modified LCA

During the project a modified version of the traditional life cycle assessment was created. The traditional LCA is used to evaluate the environmental impact of the product on its environment through out its life, (Johannesson et al. 2004). By reversing the LCA to see how the environment affects the product throughout its life a stage dependent overview could be mapped out. The analysis was used to provide an overview of the products transformation during their life. The reason for this is mainly that the products themselves will transform due to layers being removed, they will be exposed to different external environments and the users will have different demands on the products in different phases.

Osborn's checklist

Put to other uses? As it is?... If modified?..

Adapt? Is there anything else like this?

What does this tell you? Is the past comparable?

Modify? Give it a new angle? Alter the colour, sound, odour, meaning, motion, and shape?

Magnify? Can anything be added, time, frequency, height, length, strength? Can it be duplicated, multiplied or exaggerated?

Minify? Can anything be taken away? Made smaller? Lowered? Shortened? Lightened?

Omitted? Broken up?

Substitute? Different ingredients used?

Other material? Other processes? Other place? Other approach? Other tone of voice? Someone else?

Rearrange? Swap components? Alter the pattern, sequence or layout? Change the pace or schedule? Transpose cause and effect?

Reverse? Opposites? Backwards? Reverse roles? Change shoes? Turn tables? Turn other cheek? Transpose '+/-'?

Combine? Combine units, purposes, appeals or ideas? A blend, alloy, or an ensemble?

(*Österlin*, 2003)

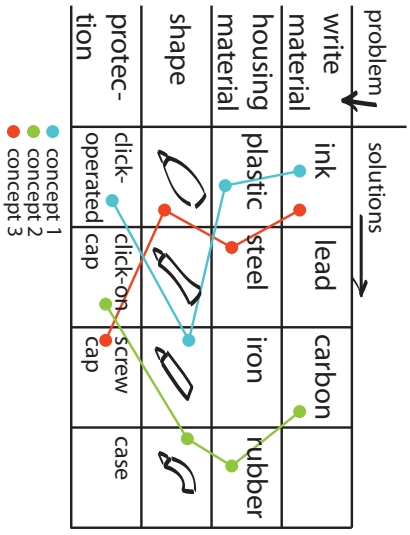


Figure 3.5. Example of a morphological chart.

3.3 Idea generation

The idea generation aims to spawn a large quantity of solutions. Several different methods and tools were used.

3.3.1 Brainstorm

There are numerous procedures for a brainstorming session. Most include some important marks of a good brainstorming session:

- No criticism against ideas. This limits the creativity and may shoot down good or brilliant ideas to early because they at the time seem to unconventional or irrational.
- Working on each other's ideas. Cooperation inspires creativity, and letting a new person work on an idea allow it to be developed in new ways.

(Johannesson et al. 2004)

3.3.2 Sketch models

These models are fast to make and inaccurate, little work are put into details. They are used as a tool for developing ideas rather than to illustrate ideas. Working in three dimensions reveals alot more information than two dimensional pictures and spawns more ideas. The sketch model work process is iterative, it allows continuos changes to even the most important properties of a concept. (Österlin, 2003)

3.3.3 Osborn's Checklist and SCAMPER

Osborn's checklist (Österlin, 2003) or its derivative SCAMPER (Michalo, 1991) are ways of helping creativity on the way. Even if there is a definition of Osborn's checklist and SCAMPER, they are not tools that necessarily needs to be used as a separate step in the process. Both methods aim to twist and turn a problem and can be used passively during e.g. thinking, sketching and brainstorming. SCAMPER is an acronym of Substitute, Combine, Adapt, Modify, Put to other use, Eliminate, Reverse.

3.4 Concept generation

In the concept generation the ideas were developed and combined in order to make more extensive, although still non-detailed product concepts.

3.4.1 Morfologic chart

The morphological matrix is a tool to generate concepts from ideas in a structured and ordered way . You divide the function of the product in to several partial functions and list them on an axis. On the other axis you list possible solutions for the partial functions. This gives an overview over the quantity of ideas you have generated and if there may be certain areas in need of more creative focus. In the next step you combine one solution from each partial function into overall

concepts. In this way you obtain concepts that in different way solve the main function of the problem and also gain insight into which partial solutions that are compatible with each other (figure 3.5). (Johansson et al. 2004)

3.4.2 Transformation

The different individual parts of the product is systematically arranged in all thinkable ways. The result is one or several sheets of possible variations of the product. It is a good tool to create a high volume of variations, some of them may be new and exciting while others may be utterly useless and unrealistic (figure 3.6). (Österlin, 2003)

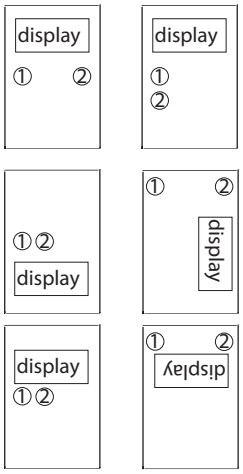


Figure 3.6. Example of a transformation.

3.4.2 Design sketches

Design sketches are simple drawings on paper that are rough and imprecise). They intend to show the lines, general expression or shape of a product (figure 3.7).
(Österlin, 2003)

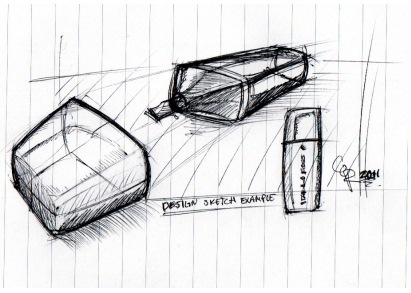


Figure 3.7. Example of a design sketch.

3.4.3 Cut-pictures

A cut-picture is a sketch where the product is split somewhere, it can be used to describe measurement, function and/or shape (figure 3.8). (Österlin, 2003)

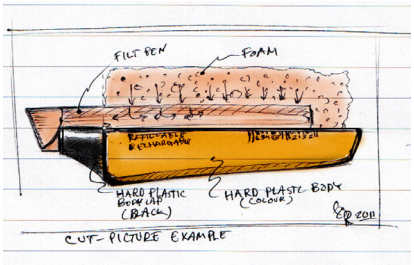


Figure 3.8. Example of a cut-picture.

3.4.4 Renderings

The renderings intend to present the product in a more realistic way, it can be used to give a better apprehension of how the product may look in its finished state. It is often made in perspective with realistic colours, shadows and reflections (figure 3.9). (Österlin, 2003)

3.4.5 Problem hierarchies (abstraction)

By asking why a problem should be solved the reason to the problem may be found one level up. It can also be called problem abstraction. When the source of the problem is found it can be reformulated and addressed at a lower level again. (Österlin, 2003)

An example could be a ketchup bottle with the problem to solve expressed as: "Make it easier to squeeze out the ketchup." by asking "why should the problem be solved?" the source could be formulated as "People can not get the ketchup out of the bottle because it is at the bottom and the opening is in the top."

Now the problem can be expressed as "Make it easy to get the ketchup out of the container.", going down one level again the problem may be solved by having the opening in the bottom where the ketchup is.

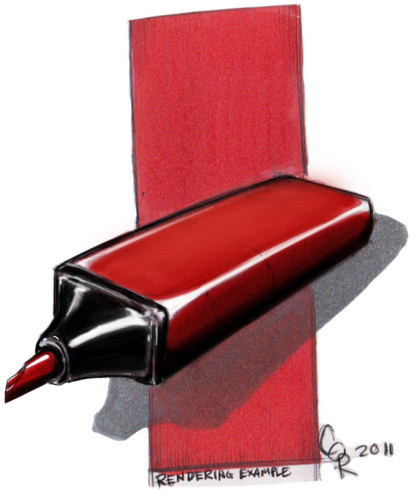


Figure 3.9. Example of a basic rendering.

3.5 Evaluation Phase

In the evaluation phase the concepts are evaluated in order to determine which are viable as solutions and to provide a basis for the decision of which concept will be developed further.

There are several types of matrix methods to measure the concepts ability to meet the set requirements. These are used to give a quick idea of the strengths and weaknesses of a concept and also to filter out concepts that are not viable.

3.5.1 Evaluation matrix

The evaluation matrix used was developed from a critera evaluation method which can be found in Johansson, Persson & Pettersson (2004). It was done to give an absolute evaluation how well each concept would meet the requirements and perform on its own. This was done to avoid the potential problems with only using a relative evaluation - If all concepts are bad there is still one winning (figure 3.10).

criteria to evaluate	weight 1-3	points for item 1	points for item 2	points for item 3
critera a	Wa	P1a	P2a	P3a
critera b	Wb	P1b	P2b	P3b
critera c	Wc	P1c	P2c	P3c
sum		$\sum_{na}^{c}(w_i \cdot p_{1n})$	$\sum_{na}^{c}(w_i \cdot p_{2n})$	$\sum_{na}^{c}(w_i \cdot p_{3n})$

Figure 3.10. A principle example of an evaluation matrix.

3.5.2 Pugh Concept Selection

This matrix is a way to compare different concepts relatively to one mediating concept. This gives a relative result that indicates if the solutions are better or worse than the object of reference. The purpose of using the matrix was to evaluate which concept to go ahead with. The categories to evaluate towards can be how well they meet the demand list, if all concepts meet the demands equally other factors can be created to serve as comparison points (figure 3.11).
(Johannesson, Persson & Pettersson 2004)

criteria to evaluate	reference item.	item 1	item 2
critera a	0	+	0
critera b	0	+	-
critera c	0	0	+

0 = same as reference
+ = better than reference
- = worse than reference

Figure 3.11. Example of a pugh concept selection.

3.5.3 Mock-ups

Mock-ups can be made for different purposes, to get an idea of proportions, how an item is handled or how it is perceived in reality. A mock-up is a preliminary model for display, demonstration or testing, (Österlin, 2003). In this project mock-ups were made in three different phases. First as proof of function, second as technical evaluation and finally for user testing and verification. (Chapter 5.3)

3.6 Concept definition phase

The last phase consists of the further development of the chosen concept into a final product/products. The main work in the phase is to develop and define all the details of the concept with respect to:

- Production method and process
- Material specifications
- Physical definition – measurements, dimensions and tolerances.

The phase also include further prototyping and testing of the concept to evaluate it before the last details are defined.

3.6.1 Functional prototypes

Functional models are made to test the functionality, expression and interaction of a concept (figure 3.12). To make the results valid, you attempt to use material, form and accuracy that are as similar to the intended mass produced products as possible, (Österlin, 2003). The prototypes in this phase were made using the correct intended materials and form. Because of the intended production method of the product, different methods had to be used to make the prototypes, which where made in a laboratory.

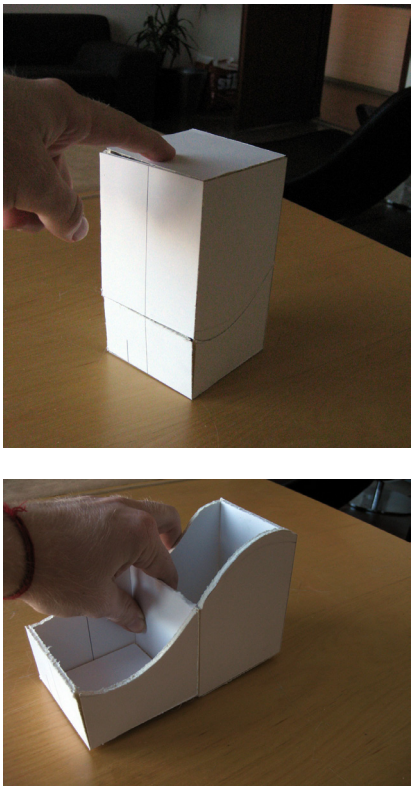


Figure 3.12. Example of functional prototypes.
(Photos by David Gillblom, 2009)

3.6.2 User tests

User tests are intended to provide information on how the users interact with and respond to the product. In some tests any random person may act as a user, while other requires the actual end users to test the products. In this project it may be relevant to get feedback from the health care professionals since their opinion of the products will affect the use, purchase and recommendations of the products. But it depends on how far the development reach, to test functionality of different solutions any user with basic experience of similar product may suffice.

The main purpose of the testing is to evaluate if the interaction surfaces functions as intended, do they communicate well enough to the users and does the product behave as intended?

Considering that the wound dressing will be attached to one person (patient) and interacted with by another (health care professional), the natural study format would be co-discovery. Two participants work together to try out a product, the observer can record or document their dialogue without being intrusive, (Jordan, 1998). The method is relevant because a dialogue is forced since one person is likely to invoke pain in some degree when removing the wound dressing.

To make sure concerns and the spontaneous reactions can be captured it is beneficial to instruct the participants to think out loud while they test the products. It also stimulates the participants dialogue with each other. Most important of all it is an opportunity for the investigators to take part of issues or reactions that were not anticipated to be important. (Jordan, 1998)

4. PRE-STUDY

The pre-study aims to gather and explore all factors and information needed for the product development through answering the research questions posed in chapter 1.4.

4.1 Legislation and standards

There are some legislation and standards that are relevant for this kind of products:
- ISO 10993: Bio compability
- ISO 9001 or ISO 13485: Quality systems
- FDA (Federal Drug Administration) approved
(Jacobsson, 2011-b)

For the project the most important implication of these documents is that materials have to be tested and approved to be used in medical products. However, if certain materials have been used for other products with the same or a similar application and have been approved and are still in use today, they do not have to be approved again if used in new products. But this also means that the solutions in this project can not be dependent on new and untested materials due to the years required of medical testing and verification.

4.2 Market and competitors

Wound dressings and ostomy products are in the higher end of the scale when it comes to skin close products. They are intended for chronic situations and are required to be sterile. The wound dressings are not to be confused with sticking plaster found in the grocery store. The market has got quite a few competitors and when looking on the adhesive competition there are three main competing solutions:
- Polyacrylate adhesives
- Hydrocolloid
- Silicone gel adhesives

The main problem is to balance strong adhesion with the ability to remove the products without pain, not leaving any residues and being able to let vapour from the skin pass through. To make an impact on the market the solution has to allow the adhesive to solve these issues.

The market for medical products is fairly conservative in terms of design and visual expression. Some colours are not recommended to use, such as:
Black - Associated with death or dead tissue
Yellow - The colour of ichor
Red - The colour of blood
(Jacobsson, 2011-a)

Traditionally the colours used are white, light blue, beige (skin colour) and hospital green, (Jacobsson, 2011-b). As

Wim Muller writes (2001, p. 139): *"[...]blue-greens (short waves) [...] are considered as cool, distancing and relaxing"*. They are also commonly associated with hygiene and are the ones normally used as the main colours in medical products. Most colours may however be used for graphical details or text, where they do not attract to much attention.

4.3 The Adhelight adhesive

Adhelight is a pressure sensitive adhesive that lose most of its adhesion when exposed to light. The transition is called a switch and the technology works through a cross-linking process, changing the adhesive from a sticky to a non-sticky state. This means the adhesive has to be protected from light exposure until the switch is wanted. (Lumina Adhesives, 2011)

4.4 Packaging and distribution

Wound dressings need individual packaging which allows sterilization of both the package and its contents using ethylene oxide. The packages are then packed in larger units for transportation and distribution. The reason for the individual packages are to be able to keep the wound dressing sterile until it is to be attached to the skin. Ostomy bags are in general packed in a package containing several bags and sterilization is not required. (Jacobsson, 2011-a)

4.5 The core values of the Lumina brand

The goal of Lumina's products is to provide "Secure fixation in combination with easy/pain free/trauma free removal without leaving adhesive residuals". General values that Lumina want their products to express are: high technology, medical technology, life science, innovation, patient care, light & easy to use. (Jacobsson, 2011-a)

4.6 Materials

The medical use of the products in question puts several requirements on the product. The materials have to be suitable for use on human skin. In the case of the wound dressing, the materials also have to be able to be sterilized using ethylene oxide gas. Due to regulations all new materials used in medical products have to be tested and approved, which is a lengthy process and should be avoided if possible. The easiest way to handle the medical requirements is arguably to use materials that are already used, and thus approved, in other medical products. This includes hundreds of different materials for numerous applications. The common material types that are used in these kind of skin close products are polyurethane (PU), polypropylene (PP), different polymer foams, polyethylene terephthalate (PET), polyethylene (PE), paper derivatives, woven and non-woven fabrics, siliconized films and peelable adhesives. (Jacobsson, 2011-a)

4.6.1 Material properties

The thickness of a material layer used in these products vary depending on material and its purpose. As a generalisation they can be divided in sheets and pads and are in general between 15µm-35µm and 10-30mm respectively. (Jacobsson, 2011-a)

The foams and textiles are porous and provide a better MVTR than the sheets - but they also absorb liquid which is both a pro and a con. They function well for draining the wounds, but since they should not absorb liquid from the outside they have to be covered by other materials.

4.7 Manufacturing

The most used way of producing wound dressings is by first producing or buying film on a roll and then process these (converting) at a combiner company.

The product is then built up layer by layer. Depending on the exact structure of the product, different material inputs can affect the efficiency, effectiveness, cost and complexity of the manufacturing.

Each layer used in the product manufacturing is produced separately. In the case of thin plastic films common methods is by blowing material up a tube, cut the cylinder in half and roll it up. Adhesives are usually coated on a film and covered with protection film on the other side. It is usually beneficial to coat the adhesive on the film that will be placed on the finished product rather than on two release liners in order to save steps in the product assembly process. (Apelgren, 2011)

At the combiner company the separate materials are converted and laminated into a product. Films are cut with a rotary die before laminated onto the other films when modification of the shape is needed. A basic illustration of the converting process is found in figure 4.2. Under certain circumstances it is possible to use "kiss-cut" , which is a technique in which a cut is made into a multi-layer sheet, but only cutting through a few of the layers. However, there are limitations to the kiss-cut process since these films are very thin, due to this it is more beneficial to cut before the lamination. (Jacobsson, 2011-a)

The orientation of the cuts and placement of materials can drastically change the manufacturing process. (Apelgren, 2011)

There are two ways of placing things in the production process. Either by lamination from roll to roll, or through "pick and place", placing a component on the film using a robot.

Pick and place can under the right circumstances be very precise and allows to place components in places where it is not possible through ordinary lamination. The process is however very expensive in comparison to lamination and it is therefore avoided when possible. (Jacobsson, 2011-b)

In short terms the converting process can be summarized as the removal of material from films and lamination of the remaining material together.

"*Generally speaking, a key technological requirement is to provide all the desired functions of the coating (optical, barrier, adhesive, electrical, catalytic, etc.) while controlling the interfaces and micro-structures (film, charge dispersion, orientation, crystallinity, porosity, etc.).* " (Fillon, 2010, p. 241.)

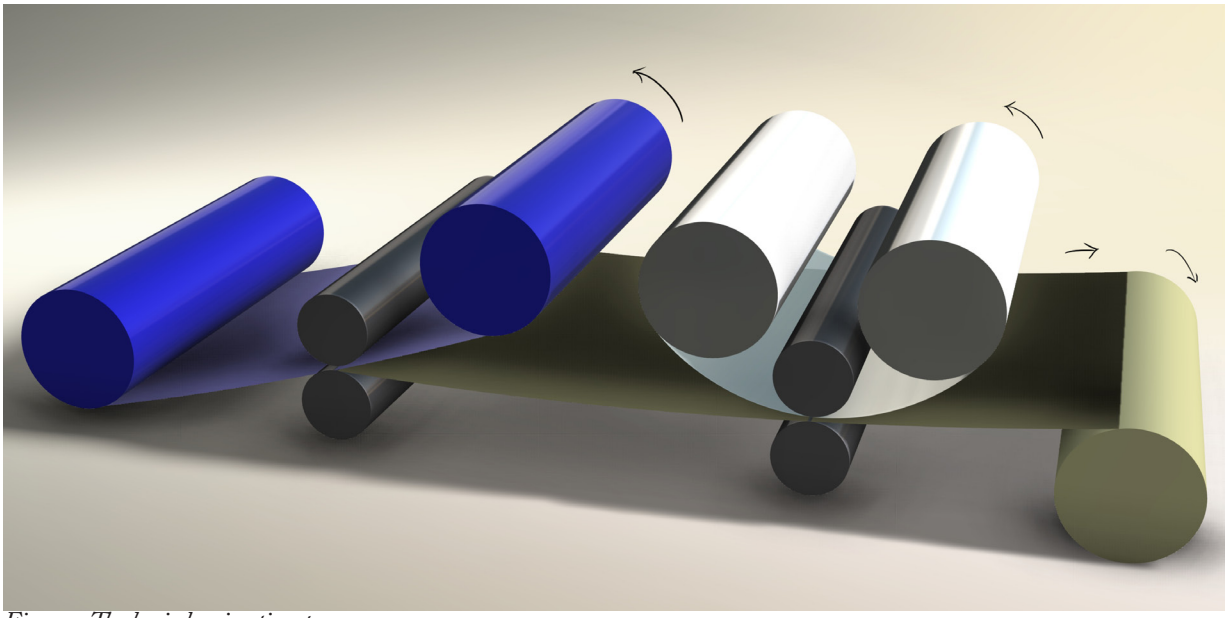


Fig. 4.2 The basic lamination process.

4.8 Users of the wound dressing

The users of the different products have been identified as to who's needs should be taken as first priority. It is important to be able to visualise and adapt the products to the primary users in case of conflicting demands. A second aspect is to be able to take the perspective of different users to be able to include them in the development.

4.8.1 Primary users

One can argue that the patients wearing the wound dressings should be considered as the primary users since the main function of it is to protect the wound. However in most cases it is professionals such as doctors, surgeons and nurses that applies the dressing, inspects it during the use and removes it. There are some situations where other people like caregivers, helpers and family members might apply and/or remove the product from the patient. Because of the listed people being the ones that mainly interacts with the product it might be more correct to define them as primary users.

For the primary users it is critical with interaction, use, understanding and trust.

4.8.2 Secondary users

The secondary user are in most cases the patient due to their passivity in relation to the product. The patient is wearing the wound dressing, but is not interacting with it. As long as the product is attached and is not disturbing the patient, the relationship is passive.

For the secondary users it is critical with functionality, reliability and comfort.

4.8.3 Critical users

Patients with wounds placed in non-visible areas might have to rely on touch which creates certain demands to consider.

4.8.4 Non-users

Family members and other people that are exposed to the visual expression of the product are categorized as non-users. They are not directly in contact with the product, but can react to it when they see it.

4.8.5 Handling

When applying the wound dressing, there has to be some control over the material without it sticking to the fingers of the user. Even if the users receive training on the products, it needs to be very clear that the light protecting frame is not to be removed until the dressing is to be removed from the skin.

4.9 Users of the ostomy bag

The user groups of the colostomy bags are different than for the wound dressings.

4.9.1 Primary users

The primary users of the colostomy bag are the end-users, the ones with the stoma. The age span consists mainly of adults, because the illnesses that can result in a stoma often are discovered amongst adults. Common reasons can be perforation of the abdomen (accidents, stabbings), Cancer, Crohn's disease and Ulcerus colite. The ostomy bag is most often changed once a day or more, this is in most cases done by the primary user themselves. The primary users are also to the highest degree affected by the ostomy in social contexts, often in terms of worry of leakage, smell, noises and/or visibility of the bag. (American Cancer Society, 2011a and 2011b)

4.9.2 Secondary users

Secondary users are specialist nurses who educate the ostomy patients in the usage and help them choose a suitable product. According to a market study made by Lumina most users tend to stick to the first product they try, given that the product function well enough.

4.9.3 Critical users

Patients who are disabled, physically or mentally, can have more difficulties using the products. Reasons could be having difficulties to understand how to, or having limited precision or motor skills.

4.9.4 Non-users

Family members and people in the surrounding can be affected by smell, visible leakage or mental effects the primary user may experience and express. They are not directly in contact with the product, but can react to it when they see, hear or smell the product.

4.9.5 Handling

Each stoma is individual in size, shape and placement, due to this the hole in the bag must be re-sized to fit the individual user. In most cases this is done with a special scissor that does not have sharp points to avoid perforating the bag. When applying the ostomy bag the hole should fit over the stoma as perfectly as possible to avoid the excrements getting in contact with the skin or adhesive since it contains corrosive fluids. The light protecting layer has to be secure to a degree where the ostomy can not release prematurely.

4.9.6 Hygiene

Human excrement is not hygienic or considered as something one should be in contact with. It can also discolour clothes, which can be a social issue, as well as the smell. The users should be able to wear and replace their product without any major risks of leakage and smear. The leakage can occur at the contact surface between the skin and the adhesion plate, faulty containment bag and at the contact border between bag and plate.

A potential risk for smear, leakage and splashes can occur if the removal procedure can not be done in a controlled fashion. E.g. if a strong pull outwards is required there is less control over the situation due to the strong muscle force continuing in a fast movement right after the point of release. The users can not be expected to react fast enough to discontinue the movement or activate an opposite muscle response in time.

4.10 Pleasure in medical products

Wound care and ostomy may not be associated with pleasures due to the medical nature of when they are needed. But if comfort is considered as removal of discomfort the products can deliver functionality that, relative to other products, provide pleasure.

Based on this model the adhesive solution can deliver a functionality that in effect can meet the desires of the users. The ostomy can allow the user to meet their self-actualisation needs by allowing them to participate in social activities, sports or other situations where concern for leakage and smell may be an issue. In this dimension the actual risk of leakage or smell is not the main concern, even if the product is safe as fort knox, the perception of the product not being safe will hamper their safety needs which spreads down the chain.

If the product provide good usability, e.g. making sure the user feel and know that they are in control, their mind will not be occupied with the possibilities of unforeseen events.

In the case of these products, it is not really feasible to expect the users to expect a personal bond to the products, where they invest their passion and love. In contrast to other products like accessories, sports equipment or other products that are selected by choice and taste. But, the professionals using and/or recommending the products can find them to be their "weapon of choice" if they prove to provide a better life for the end users. The reason for this can be that the products makes their professional life easier, they do not have to worry or consider that they invoke pain when applying and remov-

ing the products from the skin. They do not have to worry that they recommend an inferior product and they can rely on the products to provide a not so steep learning curve.

If the products manage to meet the desires and needs of both the end users (patients) and the professionals, a lot will be gained in terms of wound treatment and quality of life.

4.11 Modified LCAs

In the analysis every step in the products life cycle, from the manufacture of the components to the disposal of the used product, has been analysed from the perspective of the different stakeholders. In each step the analysis has revealed the products functions, the relation to surrounding users and the various requirements. The method revealed not only a large quantity of requirements, but also gave a deeper insight into in which stages of the product life cycle certain requirements were most important. The realization that several requirements could be removed from the product in certain stages elicited new ideas on how to implement functions. This also made it possible to move functionality between system borders, e.g. integrating packaging and release liner. The LCAs for wound dressings and ostomy bags can be found in figures 4.3 and 4.4 respectively.

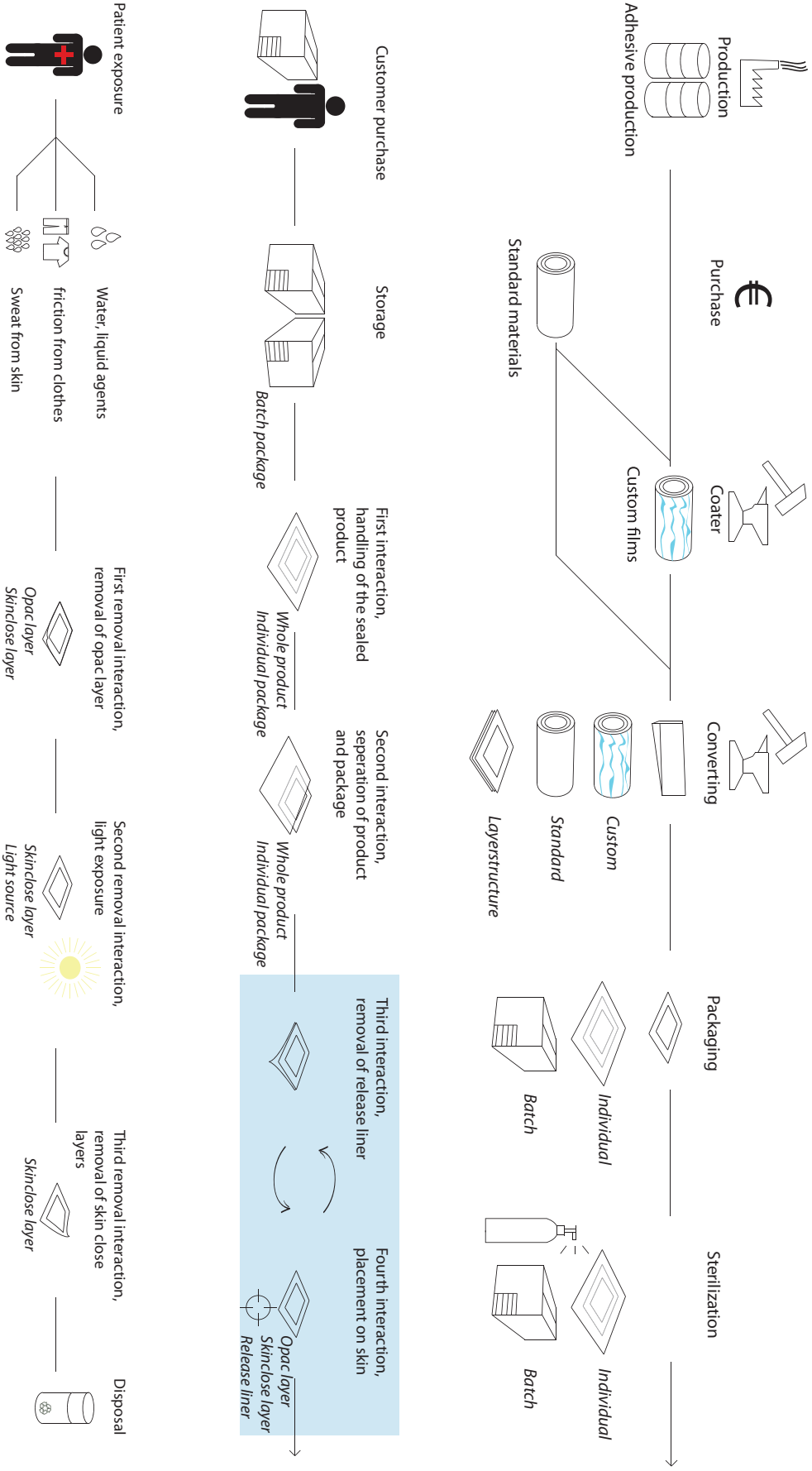


Fig. 4.3 Theoretical lifecycle of a wound dressing. The layout with demands can be found in appendix III.

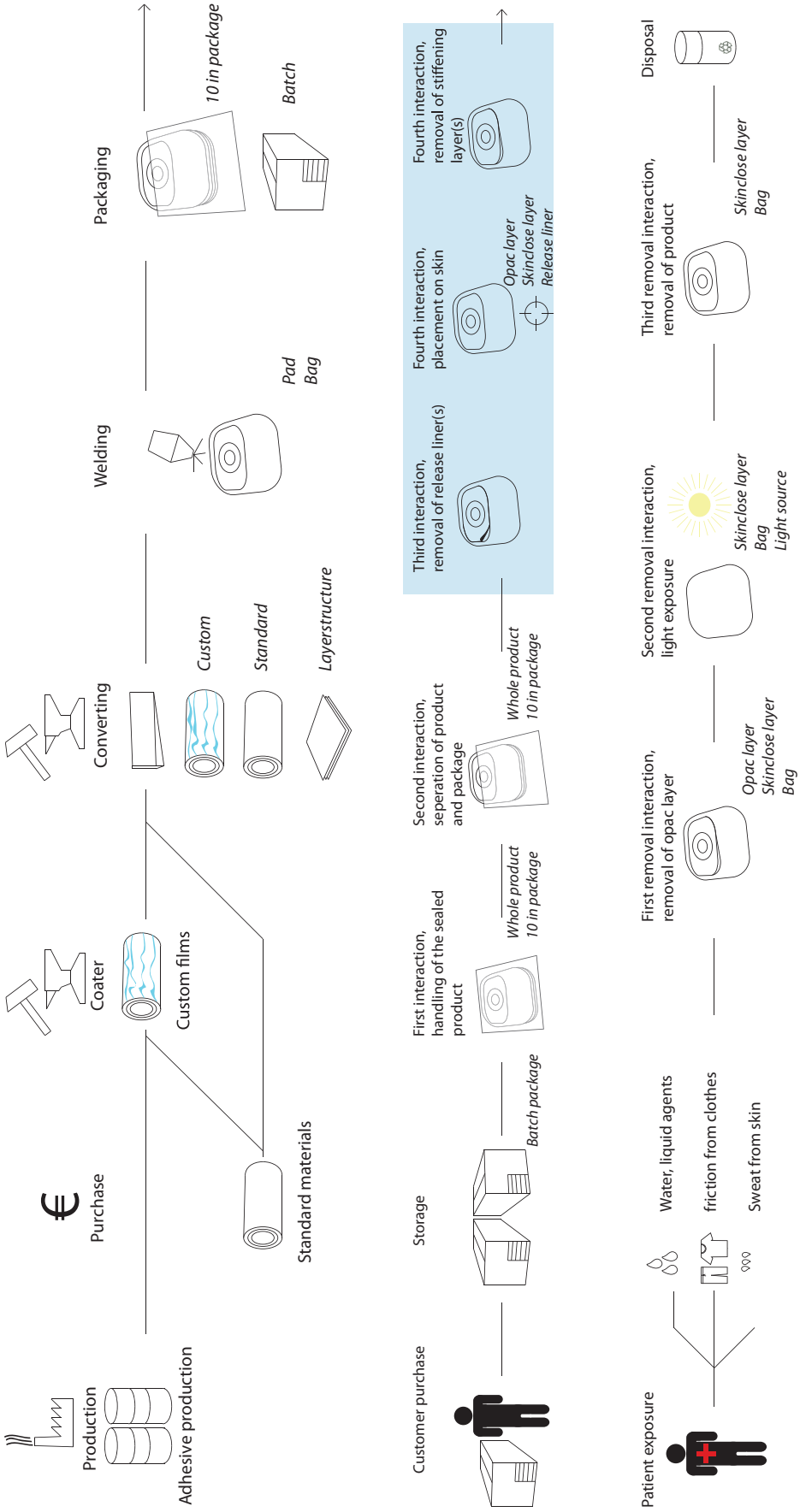


Fig. 4.4 Theoretical lifecycle of an ostomy bag. The layout with demands can be found in appendix III.

4. 12 Design factors

Since the products transform in each phase in the life cycle, the user need to transform as well. This requires the product to communicate different things in different situations. Visually the product transforms as well, which means there are opportunities to use different means of communication in different steps.

4.12.1 Communication of shape and form

As described in chapter 4.2 the medical business is said to be a bit conservative and products are limited to a certain mellow aesthetic. Consumer products have a larger degree of freedom when it comes to colours, print and shape - while high end products should communicate trust, reliability, functionality and safety. This limits the choice of colour to white, beige and similar light colours without strong associations. There is an exception for small graphical details if needed, but it should be kept toned down.

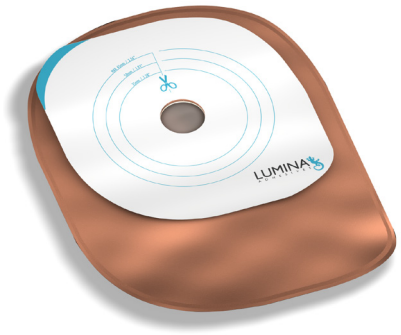


Fig. 4.5 Ostomy bag before the release liner is removed.

The shape of the products are more free than the choice of colours, but they are close to two dimensional and the main variability is in that dimension. There is however a possibility to work in the third dimension by working with the different layers. This becomes more of a visual expression since the layers are laminated together.

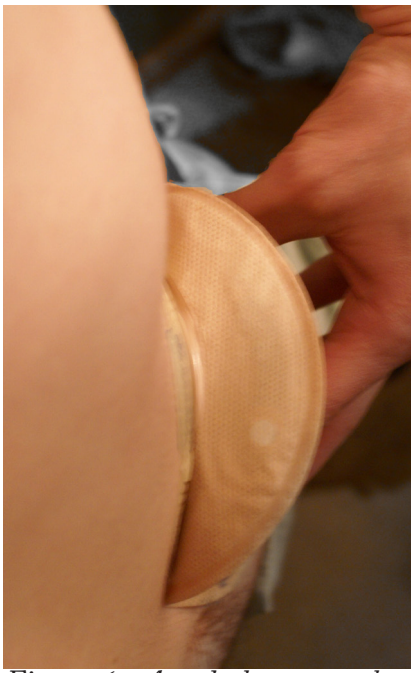


Fig. 4.6. Attached ostomy bag from the perspective of the user.

The ostomy products have got a more two sided expression than the wound dressings. The attachment plate is visible for the user when they attach and remove the product (fig. 4.5). While its attached to the body the bag visually covers the back of the attachment plate. For the user the view angle will be from above, seeing the top part of the bag (fig 4.6).

The shape of the release liners and packaging can steer how the users will interact with them. It can be beneficial to create a behaviour that avoid exposing the wound pad for other surfaces than the wound.

4.12.2 System borders

When evaluating the functionality of the product the layers can be divided into a system of functional groups. With a system approach different functions can be moved between the functional groups to create new solutions to the same functionality. One example could be using the packaging as release liner.

4.12.3 Technical shape factors

The total adhesion force is determined by the adhesive area in contact with the skin. Looking from the bottom side of a wound dressing the contact surface consist of a frame holding the wound pad to the skin. (Fig. 4.7)

Fig. 4.7 Bottom side of a wound dressing.

Surrounding the pad with adhesive also provide protection from dirt, foreign microbes and bacteria by sealing in the wound area.

Edges and corners are exposed to mechanical stress from the outside, e.g. outside corners can be ripped up by a shirt or bedsheet. To circumvent this, the products can benefit from curved edges that spread the force. This is basic mechanics to spread the force over an area, mechanical stress is described as:

$$\sigma = F/A; \text{ If } F>0, \text{ then } \lim_{x \to 0} F/x \to \infty, \text{ where } A=x.$$

By providing a larger area for the force to spread over, the likelihood of the stress to exceed the adhesion strength can be decreased.

The inside cutout on the wound dressing light protective frame may tear if the corners are sharp instead of rounded. In this case it is mainly about controlling what direction the applied forces propagate when removing it.

The ostomy bag is welded to the attachment plate, which may affect the material properties like vapour handling, attachment properties and flexible behaviour. The shape of the weld is often round to avoid weak points in the product, but also follows the correlation of the stoma being roundish as well as the opening.

The wound pad area needs to have high MVTR, why this should not be covered with the light protecting film if possible. In theory a strip of light protection could cross over the pad area without reducing the MVTR too much.

When working with ostomy it is easy to forget how they are made, e.g. a bag is made by two or several sheets that are laminated/welded together. So the technical structure is always layers stacked up on each other.

4.13 Requirement list

Throughout this chapter various demands, needs and requirements are identified. Together they form the basis for a requirement list for the wound dressings and one for the ostomy bags. The requirement lists can be found in Appendix IV.

5. CONCEPT DEVELOPMENT

In this chapter the concept development process will be presented. Each concept will be presented from its origin as an idea to a full concept.

5.1 Idea generation

From the list of demands and the modified LCA different critical functions of the two product applications were identified. These functions were formulated as partial problems and used as starting points for the creative phase of the project. The problems are also formulated in order to be product neutral; the formulated problem and its possible solutions are relevant for both of the product types that are the subject of this study.

The problems formulated were:

- How can you place the product on the skin?
- How can you remove the light protection?
- How can you communicate the interaction?
- How can you package and protect the product before use?

With these problems as a starting point the idea generation began. To generate ideas, brainstorming in pairs were mixed with individual work supported by the SCAMPER method. The tools used were sketching by hand, sketch models and computer design software to produce design sketches, cut-pictures and renderings. The initial aim was to increase the amount of ideas without screening out ideas due to feasibility.

5.2 Functions

The initial concept phase addressed the formulated problems as mentioned in 5.1. To expand the amount of conceptual solutions, technical feasibility was somewhat disregarded. The first concept phase resulted in different solutions on how to place the product and how to remove the product.

5.2.1 Application of the product on the skin

The application of the product is to a great extent dependent on how the release liners work; the design of the release liner can steer or even force the users to interact with it in a certain way. A common problem is that the adhesive side can stick to hands or protective gloves, making the product lose some of its adhesion and making the interaction difficult.

A second problem when placing the product is that the thin and flexible material can result in the adhesive side attach to itself in a fold. There is a third problem with product application which is specific for wound dressings. Some products on the market got adhesives which allow them to be detached

and reattached if it is placed in a faulty way, without loss in its adhesive capability. This is not suitable with Adhelight since it immediately get a strong attachment when applied, it would be very beneficial to be able to place it correctly the first time.

To address these issues the release liners could be designed to allow the user to attach the product to the skin without getting the protective gloves stuck to the adhesive side and at the same time support the aim of the user.

Solution ideas for applying the product developed into three different concepts. The concept ideas are all exemplified by the wound dressing product, although some of them may be applicable on other products.

5.2.2 Removal of the product

Removing the product requires the light protective layer to be separated from the transparent film. This requires the user to be able to remove the protection in some way and also understand how to do it.

The main challenge here is to create a product which is easy for the user to remove the light protection when is needed, but where the light protection is still well protected from detaching when it is not wanted. Another critical challenge is to create solutions that are possible to manufacture at a reasonable cost. It is also highly desirable that the manufacture do not result in unnecessary waste of material, both from ecological and economical reasons.

The design process in this problem area resulted in four different wound dressing concepts.

5.2.3 Packaging

The packaging serves the purpose of keeping the wound dressing sterile and to maintain the sterile state of the wound dressing it is removed just before the wound dressing is to be attached. This led to the idea that the release liner and the packaging could be integrated into one function. It could result in lesser material usage and fewer steps required to attach the dressing.

5.2.4 Visual communication and interaction

The intended interaction has to be communicated to the users, some of the solutions presented this in their geometrical shapes, while others might have to be complemented with colour and/or graphical details by printing on the top layer. Printing would however add another step in the manufacturing process with additional demands on precision.

5.2.5 Additional ideas

The users of a wound dressing are for obvious reasons in pain or discomfort. By making cutouts or patterns in the protective layer or the pad the dressing could provide some mental relief and positive relation to its usage.

5.2.6 Evaluation

The batch of initial ideas were created with some disregard to feasibility since it serves a purpose to create a high volume of ideas. The idea generation phase allows the process of data in a free environment and make connections between different conditions and limitations. Due to the high volume of external factors involved it was a suitable approach to address different formulated problems in isolation from each other.

When evaluating the concepts the new questions arose which had not surfaced earlier in the project and the problems could be abstracted to a higher level once the initial problems had been processed.

To achieve functionality for removing the light protection layer the problem was abstracted to:
- *How can the transparent layer be exposed to light?*

From the idea with the pattern cutouts the problem with the light protection layer was exposed, the thickness is decreasing the MVTR, which in turn led to another series of questions:
- *How can the adhesive be protected from light?*
- *Can the top layer be modified to provide a higher MVTR?*

These questions were taken into the concept development phase as additional topics to develop.

5.3 Mock-ups

After evaluating how the solutions would be feasible, mock-ups were created to get a better understanding of how the materials behave. A variety of shapes with different adhesives were cut out and attached to the chest, the person wearing the cutouts went to the gym to see if they would stay on after heavy exercise. The purpose was to test if different shapes would have more beneficial properties. The experiment relieved some limitations in some of the concepts.

To evaluate the concepts further, more complex mock-ups were needed, which had to be made in a laboratory.

5.3.1 Physical mock-ups and technical testing

To test the different solutions, mock-ups were made of release liners, Adhelight, PU-film, peelable adhesive, light protecting film, PU-foam and woven material. The purpose was to evaluate how the different solutions would behave when interacted with.

The materials provided were the same as the ones intended for the final product. The adhesives were however of the configuration available, their ability to withstand shear and normal stress might differ from the intended. This was however good enough for the purpose of the tests. The making of the mock-ups were a bit complicated since the materials are very thin and got an adhesive component.

5.4 Concept generation

From the conceptual solutions, new definitions of problems were listed into a morphological matrix (Appendix VII). By combining different solutions in different areas the creative phase had to result in problem solving where different non-dependent solutions had to be adapted and tweaked into working combination. This resulted in a deeper understanding of the technical dependencies, e.g. how the light protecting layer could be attached, which in turn could be used to clearly define holistic concepts that could be evaluated as finished products.

5.5 Concept evaluation

The different concepts for product removal were evaluated with an evaluation matrix and with Pughs method for concept selection, both Matrixes can be found in Appendix V.

Four different concepts where chosen for the evaluation: (A), (B), (C) and (D). When choosing criteria to evaluate the concepts by, emphasis was put on the products semantic function and communication to the primary user, avoiding the risk of causing pain or discomfort for the secondary user and to make the production as simple and cheap as possible.

A few examples of the semantic function criteria were:
- The interaction should have a low occurrence of errors and errors shall not lead to dire consequences.
- The product should be usable by users of various dispositions.
- The product should communicate its use.

By evaluating the criteria based on how the solution could be interpreted and what the consequences could be the benefits and limitations of each technical solution could be reviewed. Also, the process showed to what degree each technical solution would limit the semantic communication.

Fig. 5.1 Examples of common food packages in Sweden.

5.5.1 Evaluation matrix

The matrix gave some very clear results. According to the criteria, weights and evaluation chosen, two concepts stood out as superior and two as inferior. (C) and (D) concepts both got high scores, they are both better than the others at communicating their use. (C) has an interaction area whose shape deviates from the overall shape, while (D) is removed by pulling the edge of the wound dressing, a type of interaction that makes it similar to existing products (Figure 5.1). They have advantages when it comes to manufacturing and especially the (C) will have a very simple and cheap manufacturing process.

(A) and (B) concepts received few points. The interaction in both concepts requires a pinching grip to get it off, a way of interacting which has no parallels in similar products. To get a grip with the pinch requires much more force to be applied towards the patients skin and it is also possible to involuntarily pinch the skin underneath the wound dressing. This is a great disadvantage when treating patients with potentially very sensitive skin. The only criteria according to which concept (A) and (B) give a significant advantage is when considering the risk of the light protection layer to detach prematurely. In these two concepts the interaction areas are well protected from outside force.

5.5.2 Pugh's matrix

In this matrix the four removal concepts are compared with the original Lumina wound dressing prototype. The results are similar to those of the evaluation matrix. It shows that concept (C) and (D) are better than the original prototype when it comes to interaction and minimizing the discomfort for the user, while concepts (A) and (B) are at the same level or worse. It is however clear that all four of the concepts are better than the original prototype when it comes to protection from premature detachment and manufacturing factors.

5.6 Concept choice

Based on the results of the concept evaluation matrixes and the mock-up testing two of the four removal concepts were chosen for further development. (C) and (D) were assessed to allow a quick and easy removal of the layer, enable good understanding of its interaction and be relatively economical and uncomplicated to manufacture. The two other concepts, while showing some potential and benefits, was judged as less suitable for the specific products. They may however be useful when applying the technology to other future products.

6. CONCEPT REFINEMENT

The choice of two wound dressing concepts resulted in development focusing on refining these two concepts and developing further. Mock-ups were made of the two concepts to try out variations of the concepts before deciding on a design. When the mock-up tests were done blueprints were made for each concept in order to make functional prototypes. These prototypes were used in a final user test.

6.1 Wound dressing mock-ups

To evaluate and analyse the applicability and properties of the two concepts a new number of mock-ups were made. The two concepts, (C) and (D), were made in a number of variations and configurations. To save material and time, several solution variations were included in the same mock-up.

6.2 Prototypes

Based on the results from the test of the mock-ups it was decided to go ahead with two design concepts based on (C) and (D). The exact design was specified as blueprints and prototypes were made in a laboratory with premium materials by experienced lab staff. The making of the prototypes were a bit difficult since the design is adapted to work for industrial mass production rather than prototyping.

6.3 User tests

Final user tests were made to evaluate the functionality of the products. They were constructed mainly to find out how the design solutions would behave during use for three days and when being removed.

6.3.1 Test setup

Due to the tests being technically oriented and for confidentiality reasons, staff from Lumina was chosen as the most suitable participants in the test. Since they are involved in the product development they are more prone to follow the instructions given than a random person on the street - e.g. wearing wound dressings for three days, covering them with a plastic wrap while showering etc. A full description of the test procedure can be found in Appendix VIII.

To compensate for certain limitations of the material used for the prototypes it was decided that the dressings should not be exposed to water and no sporting activities should be performed while wearing the wound dressings.

Three subjects wore four bandages each and a fourth subject wore three, for a total of fifteen tested prototypes. Of these, five were of the (C) design, five of the (D) design and as a

reference, five were of an old prototype design. All the wound dressings were applied by the same person to make sure there were no discrepancy due to variables in the application. Five subjects were used to remove the prototypes, each taking away three.

When the wound dressings were to be removed a rotational schedule of five different people removing one of each type of wound dressings. This was done to get different hand sizes, different states of mind and personalities to be able to spread reactions. The tests were made as co-discovery, documented with film camera and the participants were asked to think out loud.

6.3.2 Test results

From the user tests it was concluded that prototype (C) worked as good as the original design while (D) was difficult to remove. The reason is that the interaction surface is at the outer edge of the product and it is difficult do separate the protection layer from the rest. The problem boils down to not having enough negative force provided by the Adhelight in the area. After a few days the outer edges of the wound dressing is not as fixated to the skin anymore. This is a result of the human skin releasing dead skin cells, external mechanical stress and other uncontrollable factors.

After the removal the participants were asked to fill in a short questionnaire mainly to allow them to express additional opinions they might have reflected on afterwards.

7. RESULTS

In this chapter the results will be presented at a principle level without exposing the technical solutions. Some of the descriptions may be vague due to the design solutions being integration of technology, manufacturing and user aspects.

7.1 Wound dressing

The development of the wound dressings resulted in two final concepts that were made into functional prototypes. They were tested and evaluated to see how the solutions would function in a real user environment. At this stage the design solutions had to be tested on a technical evaluation basis.

7.1.1 Concept 1: (C)

The first wound dressing conveptis simple in its construction, appearance and does not change much in the manufacturing process. The main concern was if the interaction surface of the light protection layer would be easy enough to remove, the second concern was if the interaction would be too close to the wound. The technical testing did however prove the solution to function well and did not require pressure on the wound area to release.

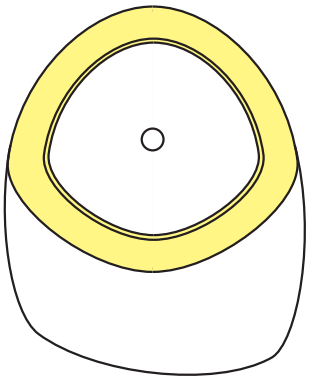
The benefits with the solution are that the interaction surface is clearly visible due to the geometrical shape breaking the homogeneity of the rest of the shape and that it is protected from mechanical stress from the outside. The removal of the product has to be decisive, but the separation of the layers proved to be functioning well.

7.1.2 Concept 2: (D)

The second wound dressing conccept has the interaction surface on the outside edge of the shape. This creates an area which is easier to get hold of with a finger and more closely resemble the conventional means of removing a wound dressing. One of the concerns for this concept was that the interaction surface do not attach to the skin and is more exposed to external mechanical stress. But since the light protection material has very low friction it is unlikely it will stick to textiles. In order for it to be removed by accident an object has to be pushed under the interaction surface to force it to release.

An additional concern is if the edges of the wound dressing releases from the skin it may prove to be difficult to separate the layers. This could be mitigated by adjusting the properties of the adhesion.

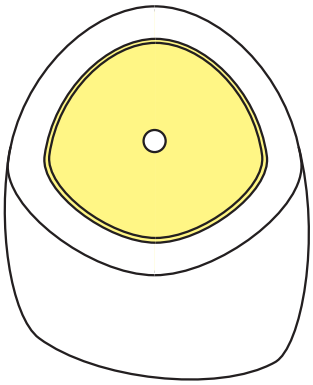
The concept also requires print to indicate the interaction area since it is hidden inside the shape of the product. The principle of the solution could be modified to extend outside the shape to provide a geometrical que. But due to the complexity of the technology it is difficult to evaluate the performance without an industrially produced prototype.



7.2 Ostomy bags

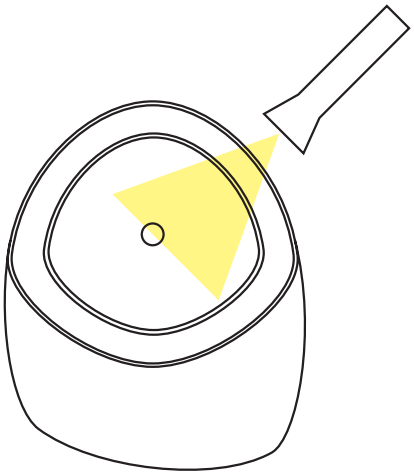
The concept development of the ostomy bags stopped at an earlier stage than the wound dressing. The result consists of four solutions solving the major problem with exposing the inside area of the adhesion plate with light - that is inside the weld between inner bag and adhesion plate.

By changing the shape, structure and form of the existing layers interactions surfaces could be created. The four concepts allow different manufacturers to adapt the technical platform to their current design without changing their current principle functionality.



7.2.1 Concept 1: The grip

Through a technical solution the product design allow the patient to use a two step method to release the product from the skin. During the second step the patient naturally get a solid grip of the ostomy bag with the same hand holding the flashlight. The benefit for the patient is that it will allow them to have one free hand when removing the bag from the skin, allowing them to hold a napkin under the stoma to prevent leakage from running down on to their pants.



7.2.2 Concept 2: The circle

The second solution allows the patient to expose the internal and the external area at the same time. The solution is based on a one step solution where the patient use the special flashlight described in 2.10.2, to illuminate the whole attachment plate in a circular motion.

The benefit for the patient is having one clear way of removing the product and being able to decide where they want the adhesive to release first.

7.2.3 Concept 3: Concentration

By removing the light protection and the bag, the patient can expose the adhesive to light and remove the adhesive part from the body.

The benefit for the patient is being able to dispose of the bag with its content and then being able to focus on removing the adhesive. In practise it reduces the mental load on the users since they do not have to focus on handling the faeces at the same time as releasing the adhesive from the skin.

It may also solve the potential problem with very loose and dark stoma covering the transparent film. This could in some cases prevent the light from reaching the adhesive.

7.2.4 Concept 4: Remove and recycle

By separating different parts of the ostomy bag one part of it can be placed in a recycle bin while the parts still attached is exposed to light. If made of suitable materials, the second part could be flushed down the toilet.

The benefit for the patient is allowing them to choose a more environmental friendly solution as well as getting a very distinctive removal. Since the outer bag is relatively large compared to the other parts of the product this may allow for users with limited grip strength or motorical precision to handle the product in an easier way.

8. RECOMMENDATIONS

8.1 Transferring solutions

An important intention for this project has been to find design solutions where the interaction and technical solutions can be applied to other Lumina products. Some of the concepts have solutions that work for most products, others only work for a few. The concepts and designs in this report should be kept in mind when future products are developed. Motivation for using the same solution for several products could range from fundamental goals of brand recognition, through the wish to utilize user understanding of old products when learning new, to practical concerns such as benefits in production. One should however be cautious not to choose the solution for a specific product based only on the mentioned reasons or by routine. Even if a solution was the best choice for an old product and is transferable to a new product, it is not necessarily a good solution for the new one. A new product means a new user situation and new circumstances, that has to be analysed.

8.2 Wound dressings

The two resulting wound dressing concepts both have their respective advantages and disadvantages. Both may be further refined into very well working products. After the user tests it however seems like the D-concept in its current form still has problems with the adhelight sometimes detaching from the skin during removal. It seems to be an inherent issue with the design, caused by the removal interaction taking place along the side where the edge of the adhelight is exposed. It is reasonable that this problem can be minimized and even turned into a rare occurrence, by working with optimization of the shape of the different layers and the adhesion of the two different adhesives. However, considering the success of concept C the logical step seem to be concentrating on that design for the further development. More user tests of concept C would be the natural next step.

8.3 Ostomy bags

The four concepts each has their advantages and disadvantages. Continued development would be to refine the concepts regarding material, production method and technical solutions. Making mock-ups or prototypes would give opportunity to see and try out the concepts in their physical form.

9. DISCUSSION

9 .1 The process

The development of multilayered products for medical use can be a complex endeavour due to the large amount of conflicting demands and factors.

The question "*How can layer structured wound dressings and ostomy bags using Adhelight be designed to secure functionality and communicate interaction?*" frames the project rather well and there is not one simple answer to it. The question includes the major challenge of the product, the difficulty to merge all technical and medical factors (function) and to transform them into functional surfaces that communicates with the user (interaction).

Due to the products being transformed throughout their life cycle, the approach to analyse the demands in each life phase allowed the development to become more structured. The classic expression "divide and conquer" applies in many development projects, but the difficulty can be to identify where to divide. The decision to draw the line between the different life phases was natural since we noticed some of the demands only applied in certain passages.

Much of the information gathered were provided by Lumina and can of course be questioned as non-documented sources. But it would be next to impossible to accumulate the information volume solely through literary studies in this short time span. By utilizing the professional sources at the company the information gathering process was reduced to a less time consuming process than one could expect.

To process the information and validate it we screened out the factors we identified as relevant, then interpreted, formulated and created different kinds of presentation formats of it; Modified LCA, dependency charts, demand lists etc. By iterating these presentations with Lumina our understanding of the somewhat complex system of factors allowed for a solid foundation to start the creative process on.

Many of the solutions, concepts and ideas are based on our experience of interaction, visual communication, usability and ergonomics. The reason we have not performed the much valuable user tests with subjects from outside the company is much due to the time restrictions and the confidentiality surrounding the technology. The concept were more subjected to technical testing, even if a certain solution would work communication wise it might not prove to be a robust enough solution in terms of functionality and reliability. The

importance of visual communication and aesthetically pleasing design solutions, has to be weighted against the fact that the users of the products will receive some form of training before using them. In the end the reliability and functionality is more important for patient security than clarity.

Since we decided to deal with the wound dressing as our first priority and the ostomy products as second we were able to reduce the workload. While processing the wound dressing new perceptions and ideas emerged which later on could be modified and transformed to the ostomy products. It is difficult to describe the mental process that takes place, but suffering under heavy constrains, solutions and alternatives merge naturally.

Working with design in a creative process with heavy technical constraints can resemble being a detective. You do not create the answers, they are already there - it is just a question of finding them.

9.2 Sustainability and environment

The complex grid of demands made it difficult to focus on sustainability, when it comes to medical products the safety of the patient is the most important factor of all. The high demands on the materials and the procedure required to get a new material approved by FDA makes it difficult to take new materials into consideration.

During the development we have tried to work with designs that do not create a lot of waste. This can be done by only using the material layers required for technical functionality and changing the design to provide interaction surfaces. By taking into consideration that the manufacturing materials are delivered on rolls, the square shape design produce less waste than a round shape would. In addition to the waste factor one of the release liner solution reduces the transportation volume, which is a larger benefit than reducing weight since the products are so thin and light.

9.3 Lesson learned

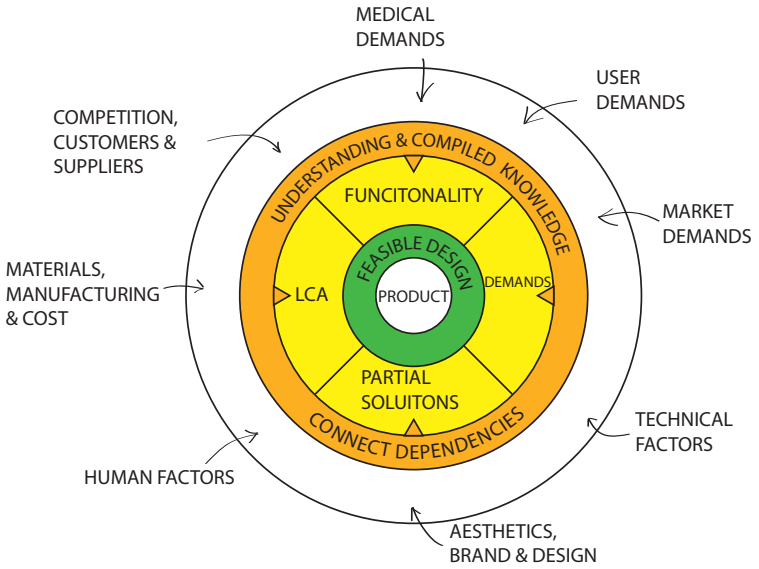
The use of industrial design methodology has proven to deliver a very structured way of reaching results. Creativity and creation is a natural part of the process and allow alternate perspectives to be taken.

The process is well adapted to factoring in a wide range of dependencies, but without the support of professionals from the industry this project would have been next to impossible to realise.

10. CONCLUSIONS

The initial question in 1.2: "*How can layer structured wound dressings and ostomy bags using Adhelight be designed to secure functionality and communicate interaction?*" has been answered through the work process. The prototype results are just derivatives of the work process and as mentioned in the discussion, the answers and solutions are there - it is just a matter of finding them.

By approaching the problem in accordance with the model from chapter 3 we were able to merge the wide range of factors into a manageable format. The challenge with multilayered products are to be able to comprehend the dependencies between layers, functionality and how they interplay with their surroundings.



The wheel of information transformation.

The wound dressing has not undergone huge changes from the initial Lumina prototype since much of the design had solved several of the technical problems. But without going through the whole process this would not have been known. Even if the wound dressing was close to final design from the start, the knowledge accumulated in process was transferred to the development of the ostomy bag.

To develop the communicative interaction of the thin multilayered products the problem should be approached in 3 dimensions. When the product is attached it communicates as a two dimensional surface (e.g. screen interface or graphic) and the visual communication is static. When the products interacted with it acts in three dimensions, the material deforms and the user get constant feedback from the product.

The last aspect is to design for is how the product changes over time, when crossing the different life phases. The user is unaware of what will happen in the next life phase and may forget what happened in the previous. Each stage has its own communication needs witch should be addressed in the design.

During the project the group discovered some technical solutions that had been discarded a long time ago - but new perspectives and materials made them relevant again.

The final concepts did not change much of the materials, layer structures or manufacturing process. But embedded in the existing products were a large volume of development potential by just modifying the technical structure and by moving around some functionality.

Small changes can make a world of difference under the right circumstances.

II. LIST OF REFERENCES

American Cancer Society (2011a) Ileostomy: A guide [Online] March 2011, Available from <http://www.cancer.org/acs/groups/cid/documents/webcontent/002870-pdf.pdf> [Accessed: 28nd May 2011]

American Cancer Society (2011b) Colostomy: A Guide [Online] March 2011, Available from <http://www.cancer.org/acs/groups/cid/documents/webcontent/002823-pdf.pdf> [Accessed: 28nd May 2011]

Apelgren, P. (2011) *Study visit at converter company,* [interview], Kungälv, 8th February 2011

Ashby, M. & Johnson, K, (2002), *Materials and design - the art and science of material selection in product design.* Second edition, Burlington, Elsevier Ltd.

Baranoski, S. & Ayello, E. A. (2007) *Wound Care Essentials: Practice Principles,* 2nd edition, Philadephia, Lippincott Williams And Wilkins

Bohgard, M, Karlsson, S, Lovén, E, Mikaelsson, L, Mårtensson, L Osvalder, A, Rose, L, & Ulfvengren, P (2008) *Work and Technology on Human Terms,* Stockholm, Prevent

Coloplast, (2007) *Your guide to ostomy adhesives,* [online] Available from: <http://www.coloplast.com/SiteCollectionDocuments/pdf/Guide_to_Ostomy_Adhesives.pdf> [Accessed 28th may 2011]

Colostomy - my journey (2008) [Online] Available from <http://www.colostomy-myjourney.blogspot.com> [Accessed: 28nd May 2011]

Fillon. B. (2010) Polymer Thin Films –Processes, Parameters and Property Control, Micro-Manufacturing Engineering and Technology 2010, *Pages 241-263*

Grossman, J. (2009) *Uncover Ostomy* [Online] Available from: <http://uncoverostomy.com/blog/> [Accessed: 28nd May 2011]

International Standards Organisation (1998) ISO DIS 9241-11, *Ergonomics of Human System Interaction*, Geneva, ISO

Jacobsson, D. (2011-a) *Discussion on medical regulations,* [interview] Lumina Adhesives Göteborg, 1st February 2011

Jacobsson, D. (2011-b) *Discussion on medical regulations,* [interview] Lumina Adhesives Göteborg, 11th February 2011

Johannesson, H., Persson J. & Pettersson, D. (2004) *Produktutveckling - effektiva metoder för konstruktion och design,* Stockholm, Liber AB

Jordan P. W. (1998) *An Introduction to Usability,* London, Taylor & Francis Ltd

Jordan, P.W. (2000) *Designing Pleasurable Products,* London, Taylor & Francis

Lumina Adhesives (2011) *Lumina Adhesives: Technology* [Online] Available at <http://www.luminaadhesives.se/technology-2> Accessed on 29th may 2011

Maylor, H. (1996) *Project Management,* 4th edition, Harlow, Pearson Education

Michalo, M. (1991) *Tinkertoys: A Handbook of Business Creativity,* California, Ten Speed Press

Monö, R. (2004), *Design for product understanding,* First edition, Stockholm, Liber AB

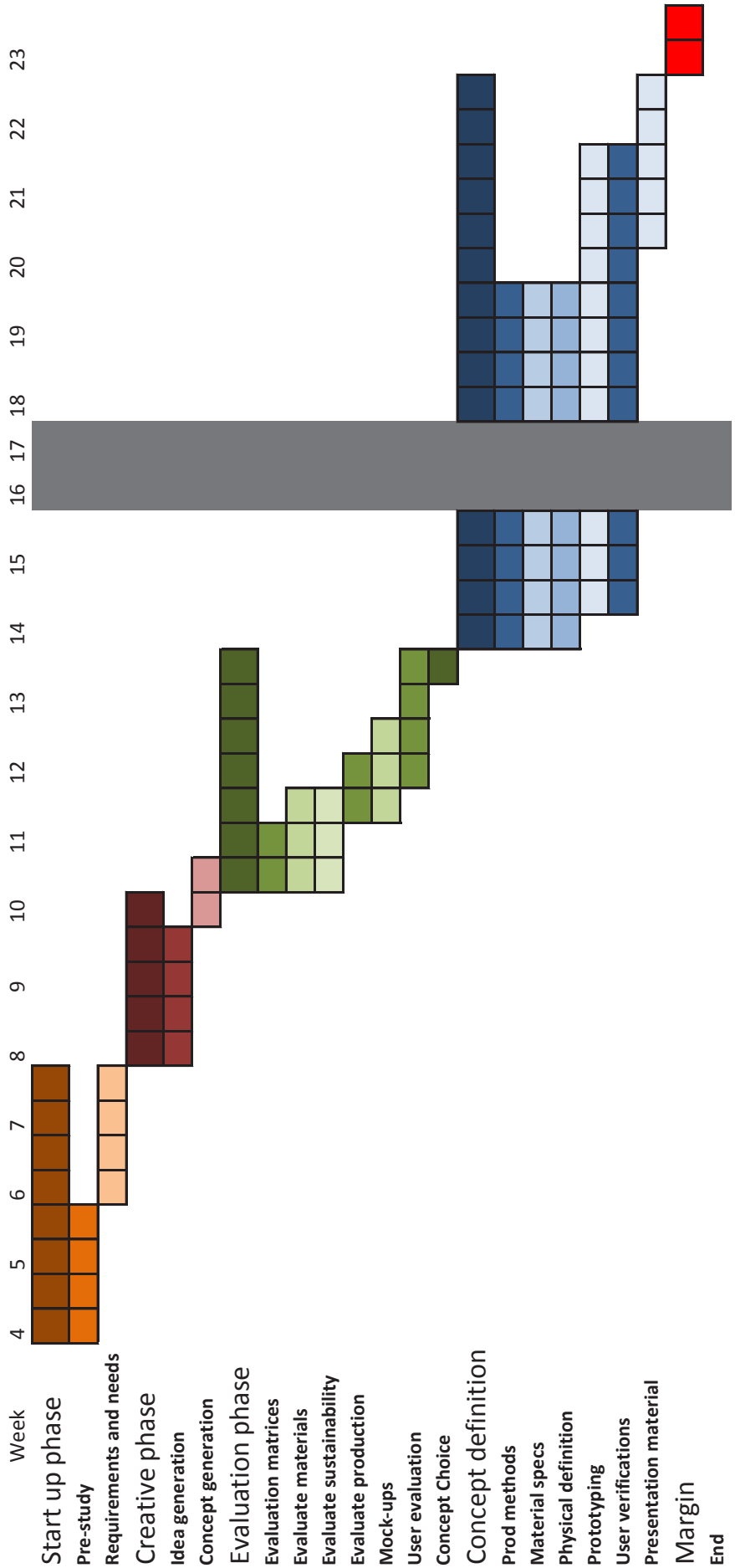
Muller, W. (2001) *Order and Meaning in Design,* Utrecht, Lemma Publishers

Mycoted (2006) [Online] Avalible from <http://www.mycoted.com/Osborn's_Checklist> [Accessed 3rd June 2011]

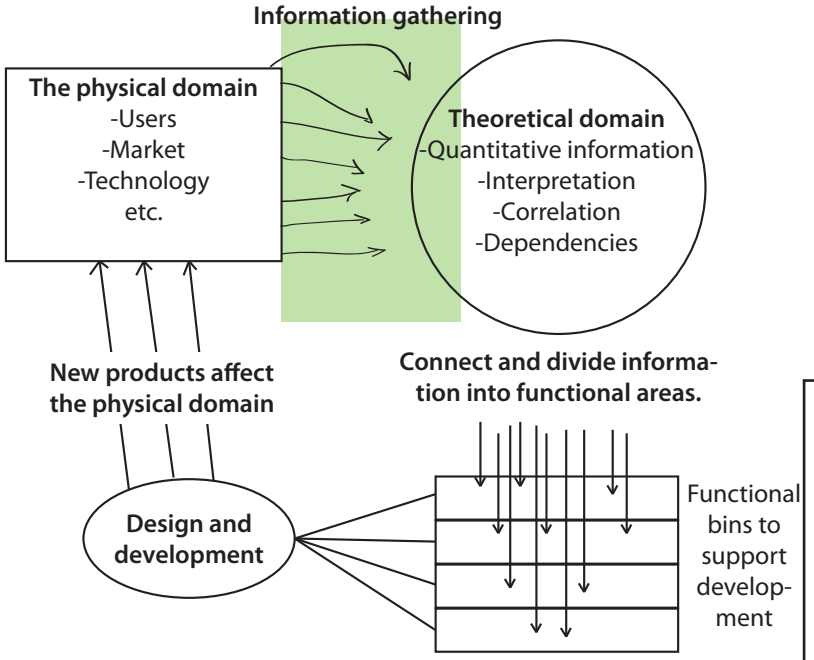
Number twos - Life with Ulcerative Colitis (2007) [Online] Available from <http://numbertwos.blogspot.com/> [Accessed: 28nd May 2011]

Österlin, K. (2003) *Design i fokus för produktutveckling,* Malmö, Liber

APPENDIX I: GANTT CHART

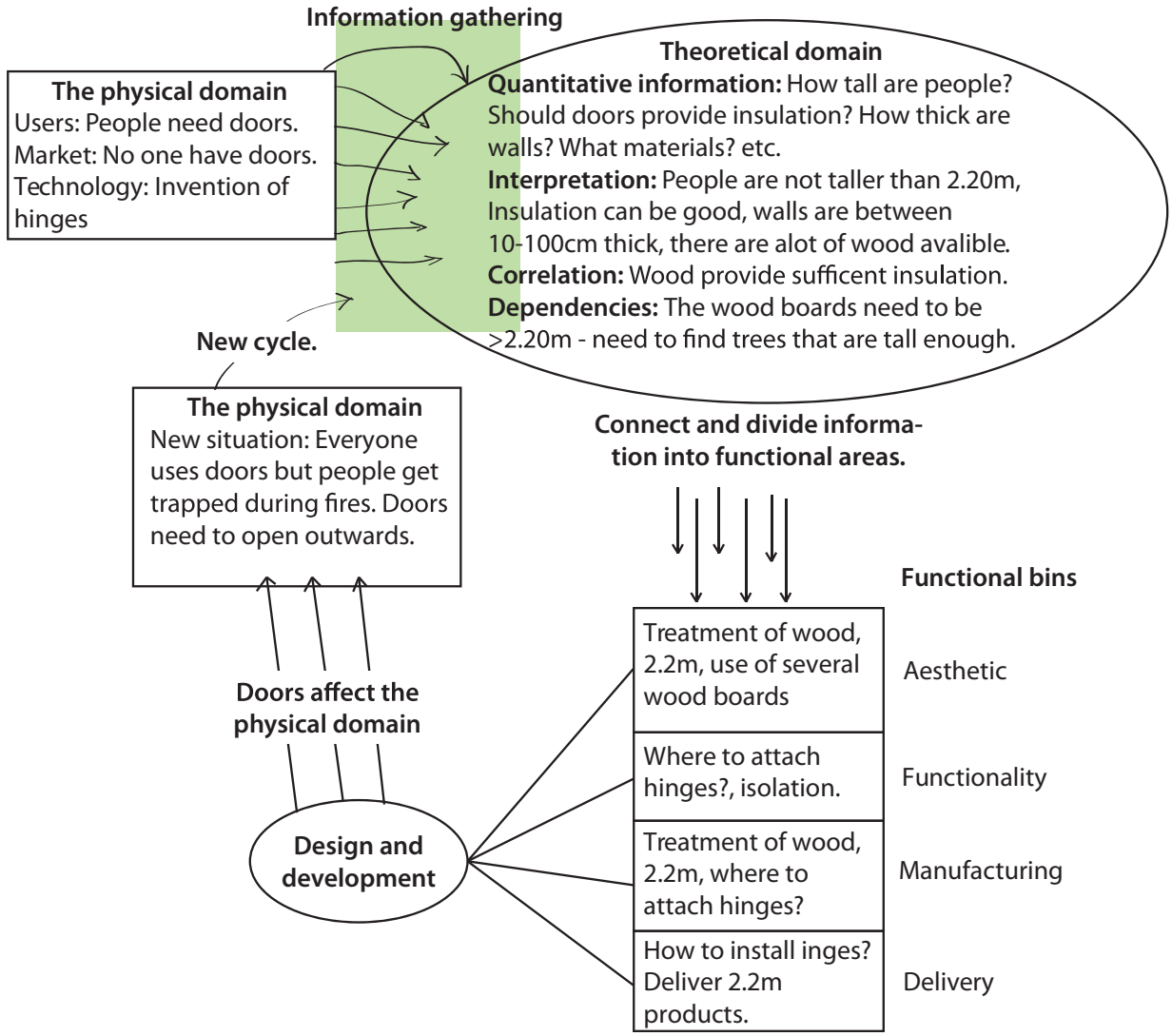


APPENDIX II: CYCLIC INFORMATION

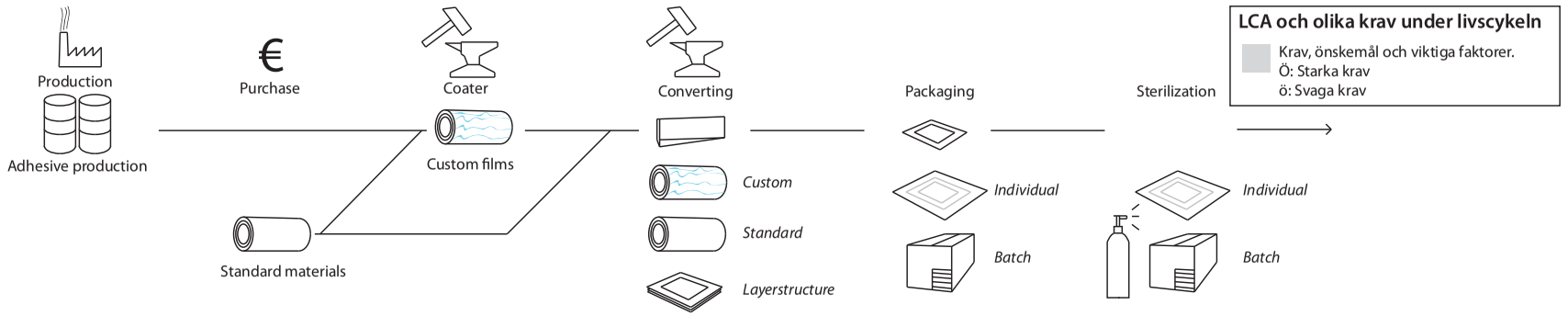


The made up example below describes an example on how products affect the physical domain and in turn bring new information and demands into the theoretical domain.

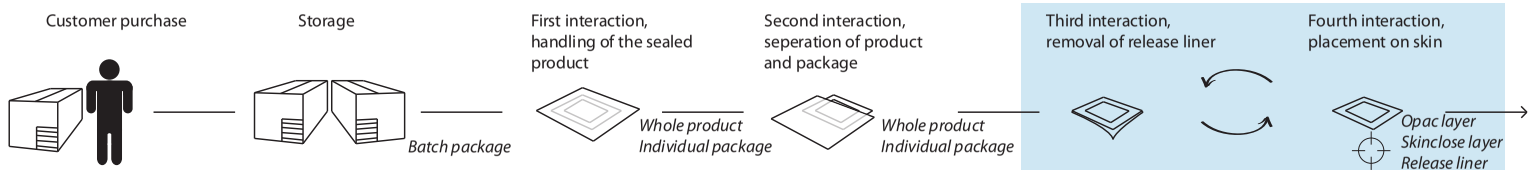
Notice the redundant information in the functional bins.



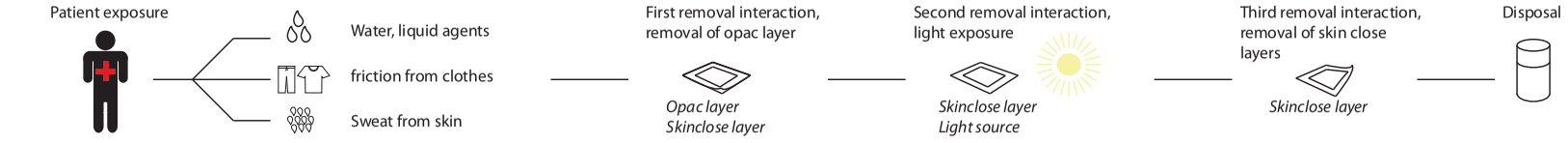
M-LCA with demands for a wound dressing.



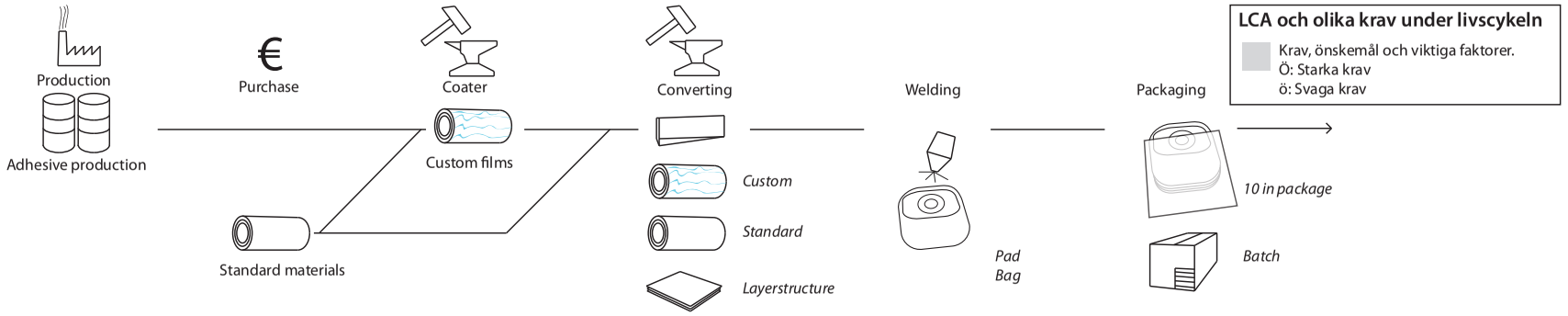
| Outside scope |	Ö: så många standardmaterial som möjligt. Ö: fördelar om de redan är klassade	ö: Så mycket som möjligt göras i denna fasen om transport inte äter upp convertingbesp.	Ö: Orientering av produkten på rulle Ö: Keep it simple Ö: Undvika pick and place Ö: Bygga runt toleranser Ö: Minimera antalet verktyg/stationer	- Begränsa utrymmeskrav i förpackning	- Släppa igenom gas (Funkar för alla material = ok)



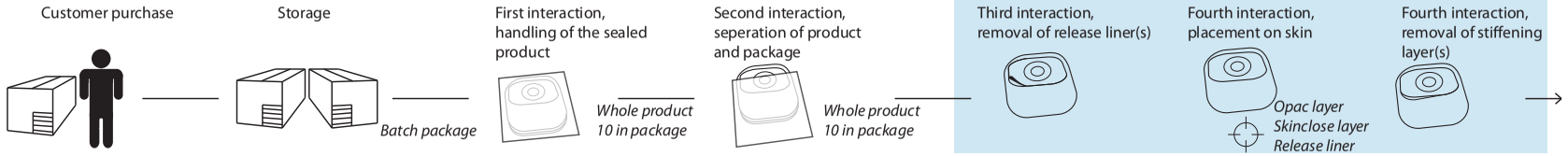
- Trovärdig - Ekonomiskt bärbar - Förstagångsanvändare ... (- En lång lista med mjuka värden)	ö: Ej ta mer plats förpackad än individuellt	- Ej bli kontaminerad - Releaseliner och opac lager ska inte lossna när produkten är ipackad. - Förstå var den ska öppnas.	- Ej skada produkten vid öppnande.	- Visuell cue till handhavande - Gripability - Hålla i utan att den fastnar i egna händer - Förstå vilken release line som ska bort (konventioner)	- Helst placera rätt från början - Visuellt stöd på något sätt. - Stiffness (inte fladdra)



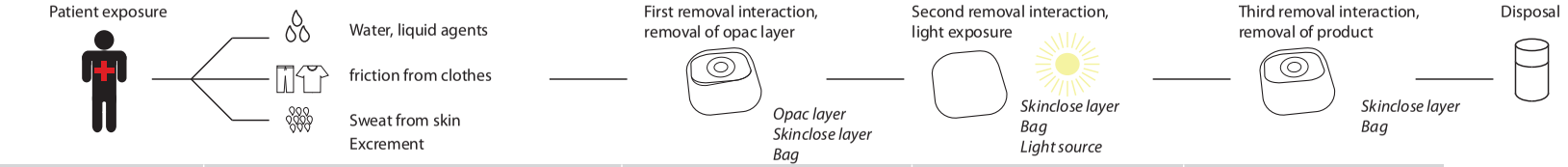
- Olika miljöer - Olika hudtyper - Olika sjukdomar - Felanvändning - Olika mentala tillstånd	- MVTR - Vattenresistens - Inte lossna ofrivilligt - Adhesion (Adhelight + Silicon) - Styvhet (hudskav, maxkrav) - Glatt yta v.s. "ruggig" - Krav enligt kravlista	- Visuell cue på handhavande - Få tag i lagret (Gripability) - Strength (Shear, tensile) Får ej gå av halvvägs -Stiffness (beror på handhavande) - Elasticitet (a<x<b)	ö: Visuell cue av switch	- Low pain and trauma - No residuals - Skin close layer cannot fall apart on removal. - Strengh (minimum demand) - Gripability	- Hushållsavfall - Energiåtervinning



| Outside scope |	Ö: så många standardmaterial som möjligt. Ö: fördelar om de redan är klassade	ö: Så mycket som möjligt göras i denna fasen om transport inte äter upp convertingbesp.	Ö: Orienteringar Ö: KISS Ö: Undvika pick and place Ö: Bygga runt toleranser Ö: Minimera antalet verktyg/stationer - Stapelbar	Sammanfogning av platta och påse.	ca. 10 enheter i en påse. ca. 3 påsar i en låda.



- Trovärdig/pålitlig - Ekonomiskt bärbar - Förstagångsanvändare viktigt. - Låg error rate - Sjukvårdspersonal har stor påverkan.	ö: Ej ta mer plats förpackad än individuellt - Körs ofta hem till anv. ~6mån användning i en lev.	- Releaseliner och opac lager ska inte lossna när produkten är ipackad. - Kunna öppna och återförsluta förpackning.	- Ej skada produkten vid öppnande.	- Visuell cue till handhavande - Gripability - Hålla i utan att den fastnar i egna händer - Förstå vilken release line som ska bort (konventioner) - Få steg och styv vid påsättning	- Helst placera rätt från början - Stiffness (inte fladdra)



- Olika miljöer - Olika hudtyper - Olika stomi - Felanvändning - Olika mentala tillstånd - Kunna placeras på både höger och vänster sida av kroppen. - 3h-3dagar	- MVTR - Fogproblematiken - Vattenresistens (Tåla bad) - Inte lossna ofrivilligt - Adhesion (Adhelight + Akrylat) - Styvhet (hudskav, maxkrav) - Glatt yta v.s. "ruggig" - Inget läckage (lukt, vätska)	- Visuell cue på handhavande - Få tag i lagret (Gripability) - Strength (Shear, tensile) - Får ej gå av halvvägs (bredd på remsa.) -Stiffness (beror på handhavande) - Elasticitet (a<x<b)	ö: Visuell cue av switch Ö: Lättillgängligt att belysa.	- No residuals - Skin close layer cannot fall apart on removal. - Strengh (minimum demand) - Gripability - Kunna interagera med en hand.	- Vanligen hushållsavfall, kan skilja sig från land till land. - Energiåtervinning

Krav/	Krav p hela produkten	Frklaring/vrigt
Krav	Bibehålla optimalt fuktig sårläkningsmiljö	Även förhindra att adhesivet blir fuktskadat då för mycket fukt kan störa funktionaliteten.
Krav	Skydda adhesivlagret från ljus	Annars switchar det
Krav	Exponera adhesivlagret för ljus när och endast när önskat	För att kunna ta bort produkten från huden
Ö	Kombinera så många lager som möjligt hos coater	Minimerar kostnad vid converting
Krav	Optimera flexibilitet	Förhindra friktion mellan dermis och epidermis, smutsränder etc.
Krav	Om svart lager existerar, göra det ej synligt.	Svart associeras med död
Krav	Tydliga interaktionsytor	Lättförståeligt för kund
Ö	Optimera material till lager	Olika lager fyller olika funktioner, de samverkar, motverkar och kostar olika.
Ö	Använda standardmaterial där det är möjligt	Minimerar kostnad
Ö	Använda redan klassade material	Minimerar kostnad
Ö	Optimera placering och orientering av eventuell tab	Minimerar kostnad
Ö	Undvika pick and place	Minimerar kostnad
ö	Minimera krav på noggrannhet	Minimerar kostnad, möjligt att designa runt toleranskrav
Ö	Minmera antal stationer vid converting	Minimerar kostnad
ö	Visuellt och haptiskt stöd för placering av förbandet på hud	Minimera risken att förbandet placeras fel
Ö	Ha en styvhet som är lämplig för användningen	
Krav	Ska tåla olika användningsmiljöer	
Krav	Ska fungera för olika hudtyper	
Krav	Ska fungera för olika åkommor	
Ö	Interaktionen ska ha en låg grad av felanvändning	
Krav	Felanvändning ska ej kunna leda till förödande konsekvenser	
Ö	Felanvändning bör kunna återhämtas	Möjlighet att rätta till fel
ö	Produkten bör kunna användas av användare i olika sinnelag	Även om användaren är trött, stressad etc, bör produkten kunna användas
Krav	Produkten ska kunna avlägsnas utan att switchas utan större skador på hud	
Krav	- Sitta på i upp till 7 dagar (utan att falla isäker/lossna)	
Krav	Vara möjlig att tillverka med liknande design i olika storlekar och former.	
Ö	Minimera smärta/irritation vid borttagning av förbandet	Adhelight samt att skummet ej fastnar i såret

	Förpackning	
Krav	Medge sterilisering med ethyleneoxid	Enda steriliseringsmetoden som adhelight klarar

Krav	Inte riskera att bli kontaminerad i förpackat tillstånd	Vid normal användning
Krav	Releaseliuner och Opac-lager ska ej kunna lossna i förpackning	Vid normal användning
Krav	Förpackningens öppnande ska inte kunna skada innehållet	
ö	Medge Flexibilitet vid val av paketeringslösning	gör det möjligt för kund att paketera själv eller inte
ö	Minimera utrymmesåtgång vid förpackning	Helst inte ta mer plats i storpack än samma antal utan förpackning.
Ö	Förmedla hur den ska öppnas i förpackat tillstånd	
	Krav p specifika lager	
	Release liner	
Krav	Skydda adhesivlagret från ljus	Skydd för adhelightlagret före appliceringen av förbandet
Krav	Tydlig interaktionsyta	Ska inte kunna förväxlas med det ljusskyddande lagret, följa konventioner
Krav	Lätt att ta bort när så önskas	
Krav	Medge bra grepp	
Krav	Ej fastna i händer vid borttagande	
Ö	Ha optimal flexibilitet/styvhet.	ska vara flexibelt nog att kunna "peela" bort.
	De 3 lagren nedan fyller primärfunktionen för dess medicinska syfte, också det lager som lever längst i livscykeln.	
	Adhelight	
Krav	Fästa mot hud	Hålla förbandet på plats
Krav	Släppa igenom fukt från huden	Teknisk lösning/reglerar miljön
Ö	Fästa kudd-lagret	Håller på plats
Ö	Fästa release linern?	Undviker att releasen lossnar oönskat
Krav	Klass1	Klass 1 på de aktuella applikationerna.
Krav	Ej lämna residuals	Kan vara utanför vårat scope
Krav	Ska sitta hårt under lång tid och sedan lossna lätt utan att ge smärta/hudirritation.	
	Bandage/padding	Tjockleken beror på materialval
Krav	Släppa igenom fukt	Undviker att förbandet dränks
Variabelt	Låta adhesivlagret fästa mekaniskt om switch i processen	Om övertäckt = switchar ej, fäster ändå. Om glatt förband = sämre mekaniskt fäste
Krav	Ska inte fastna i såret	ge smärtfri borttagning utan att riva upp såret
Krav	Absorbera fukt.	

Krav	Bibehålla fuktig miljö	Optimerar läkeprocessen

	Hudnära lager	Transparent lager
Krav	Släppa igenom ljus	Möjliggör Switch
Krav	Släppa igenom fukt från huden	Möjliggör dränering
	Skall agera bakteriebarriär	
Krav	Balanserad flexibilitet	Förhindra hudfriktion
ö	Medge visuell bekräftelse när Switch ägt rum	Underlättar användningen för användaren
Krav	Ha lämplig Tensile och Shear Strength	Ska inte kunna gå sönder vid avlägsnande
Ö	Ska vara greppvänligt	Underlättar avlägsnandet
Krav	Vara vattenavstötande om vatten kommer i kontakt med detta lager vid duschning	
	Lagren nedan har i syfte att skydda adhelight och kommunicera med användaren, lever näst längst i livscykeln.	
	Adhesivlager för ljusskyddande lager	
Krav	Fästa i hudnära lager och ljusskyddande lager (hårdare mot det ljusskyddande)	håller det ljusskyddande lagret på plats så länge det är önskvärt
Krav	Släppa igenom fukt från huden	Undviker att den friska huden skadas
	Ljusskyddande lager	Ett funktionellt lager och två lager för färgoptimering
Krav	Förhindra att adhelight switchar	Bibehåller förbandets fästförmåga så länge det är önskvärt
Krav	Sitta säkert kvar så länge det önskas	Får ej lossna i andra situationer än då det är önskat
Krav	Ha lämplig Tensile och Shear Strength	Ska inte kunna gå sönder vid avlägsnande
Krav	Ska ha lämplig E-modul	För att möjliggöra avlägsning
Krav	Släppa igenom fukt från huden (hög MVTR).	
	Visuell/haptisk yta	Den yttersta ytan på förbandet som användaren interagerar med
Krav	Inneha accepterad färg	Vit, beige/hudfärgad, sjukhusgrön. Nödvändigt för att möjliggöra acceptans av användarna
Krav	Medge avtagande av ljusskyddande lager	Den viktigaste interaktionen för användaren då förbandet sitter på plats
Krav	Kommunicera interaktionen	För att förhindra felanvändning och för att göra användningen lättförstådd,
Krav	Medge bra grepp	

Krav/ ☐nske	Krav p☐ hela produkten	F☐rklaring/☐vrigt
Krav	Medge fastsättning av uppsamlingspåse mot hud utan läckage	
Krav	Transportera bort fukt från huden	Förhindrar obehag
Krav	Skydda adhesivlagret från ljus	Annars switchar det
Krav	Exponera adhesivlagret för ljus när och endast när önskat	För att kunna ta bort produkten från huden
Ö	Kombinera så många lager som möjligt hos coater	Minimerar kostnad vid converting
Krav	Ej förorsaka hudskador	Förhindra friktion mellan dermis och epidermis, smutsränder etc.
Krav	Om svart lager existerar ska det vara dolt	Svart associeras med död
Krav	Tydliga interaktionsytor	Lättförståeligt för kund
Ö	Optimera material till lager	Olika lager fyller olika funktioner, de samverkar, motverkar och kostar olika.
Ö	Använda standardmaterial där det är möjligt	Minimerar kostnad
Ö	Använda redan klassade material	Minimerar kostnad
Ö	Optimera placering och orientering av eventuell tab	Minimerar kostnad
Ö	Undvika pick and place	Minimerar kostnad
ö	Minimera krav på noggrannhet	Minimerar kostnad, möjligt att designa runt toleranskrav
Ö	Minmera antal stationer vid converting	Minimerar kostnad
ö	Visuellt och haptiskt stöd för placering av påsen	Minimera risken att förbandet placeras fel
Ö	Ha en styvhet som är lämplig för användningen	Olika krav i olika användningsfaser
Krav	Ska tåla olika användningsmiljöer	
Krav	Ska fungera för olika hudtyper	
Krav	Ska fungera för olika kroppformer	Kunna fästas på olika typer av lekamen
Krav	Ska kunna placeras på höger såväl som vänstersida av buken	Vertikal symmeri är önskvärt
Krav	Minimera risk för läckage	
Ö	Svetsfogen bör ej orsaka kraftigt reducerad MVTR	
Ö	Produkten bör kunna hanteras med endast en hand	
Ö	Interaktionen ska ha en låg grad av felanvändning	Fel kan få konsekvenser som förmår användaren att byta märke
Krav	Felanvändning ska ej kunna leda till förödande konsekvenser	
Ö	Felanvändning bör kunna återhämtas	Möjlighet att rätta till fel
ö	Produkten bör kunna användas av användare vid olika sinnelag	Även om användaren är trött, stressad, ofokuserad etc, bör hon/han fortfarande kunna använda produkten
Krav	Produkten ska kunna avlägsnas oswitchad utan större skador på hud	
Krav	Användaren ska kunna bada med produkten utan att funktionen fallerar	
Krav	Klass 1	

Krav	Inneha accepterad färg	Nödvändigt för att möjliggöra acceptans av användarna
Ö	Plattan bör vara stapelbar för produktion	
Ö	Materialet bör medge svetsning tillsammans med påsmaterialet	
	Förpackning	
Krav	Releaseliner och Opac-lager ska ej kunna lossna i förpackning	Vid normal användning
Krav	Förpackningens öppnande ska inte kunna skada innehållet	
ö	Medge Flexibilitet vid val av paketeringslösning	gör det möjligt för kund att paketera själv eller inte
ö	Minimera utrymmesåtgång vid förpackning	Helst inte ta mer plats i storpack än samma antal utan förpackning.
Ö	Förmedla hur den ska öppnas i förpackat tillstånd	
	Krav p specifika lager	
	Release liner	
Krav	Skydda adhesivlagret från ljus	Skydd för adhelightlagret före appliceringen av förbandet
Krav	Tydlig interaktionsyta	Ska inte kunna förväxlas med det ljusskyddande lagret, följa konventioner
Krav	Lätt att ta bort när så önskas	
Krav	Medge bra grepp	
Krav	Ej fastna i händer vid borttagande	
Ö	Skillnaden mellan release liner och ljusskyddande lagret bör vara tydligt	
	De 3 lagren nedan fyller primärfunktionen för dess medicinska syfte, också det lager som lever längst i livscykeln.	
	Adhelight	
Krav	Fästa mot hud	Hålla förbandet på plats
Krav	Transportera bort fukt från huden	Teknisk lösning/reglerar miljön
Krav	Sitta hårt (men inte för hårt)	lossna lätt utan att ge smärta och hudirritation vid borttagning
Ö	Fästa release linern?	Undviker att releasen lossnar oönskat
Krav	Ej lämna residuals	Kan vara utanför vårat scope
	Hudnära lager	Transparent lager
Krav	Släppa igenom ljus	Möjliggör Switch
Krav	Släppa igenom fukt från huden	Möjliggör dränering
Krav	Balanserad flexibilitet	Förhindra hudfriktion
ö	Medge visuell bekräftelse när Switch ägt rum	Underlättar användningen för användaren

Krav	Ha lämplig Tensile och Shear Strength	Ska inte kunna gå sönder vid avlägsnande
Ö	Ska vara greppvänligt	Underlättar avlägsnandet
	Lagren nedan har i syfte att skydda adhelight och kommunicera med användaren, lever näst längst i livscykeln.	
	Adhesivlager för ljusskyddande lager	
Krav	Fästa i hudnära lager	håller det ljusskyddande lagret på plats så länge det är önskvärt
Krav	Släppa igenom fukt från huden	Undviker att den friska huden skadas
	Ljusskyddande lager	Ett funktionellt lager och två lager för färgoptimering
Krav	Förhindra att adhelight switchar	Bibehåller förbandets fästförmåga så länge det är önskvärt
Krav	Sitta säkert kvar så länge det önskas	Får ej lossna i andra situationer än då det är önskat
Krav	Ha lämplig Tensile och Shear Strength	Ska inte kunna gå sönder vid avlägsnande
Krav	Ska ha lämplig E-modul	För att underlätta avlägsning. Bör ej vara för sladdrig eller för styv
Krav	Medge avtagande av ljusskyddande lager	Den viktigaste interaktionen för användaren då förbandet sitter på plats
Krav	Kommunicera interaktionen	För att förhindra felanvändning och för att göra användningen lättförstådd,
Krav	Medge bra grepp	

APPENDIX V: EVALUATION MATRIX

	Weight	(A)
Use/user factors		
The interaction should have a low occurance of errors and errors shall not lead to dire consequences	2	0
The product should be usable by users of various dispositions	1	0
Minimize pain/irritation for the patient caused by the removal	3	0
The product should communicate its use	3	0
Use should be possible for users with different hand sizes.	1	0
The risk of premature detachment of the light protection should be low	2	2
Production/technical factors		
Minimize the demands on precision in production	1	1
Minimize the number of steps in the production	3	0

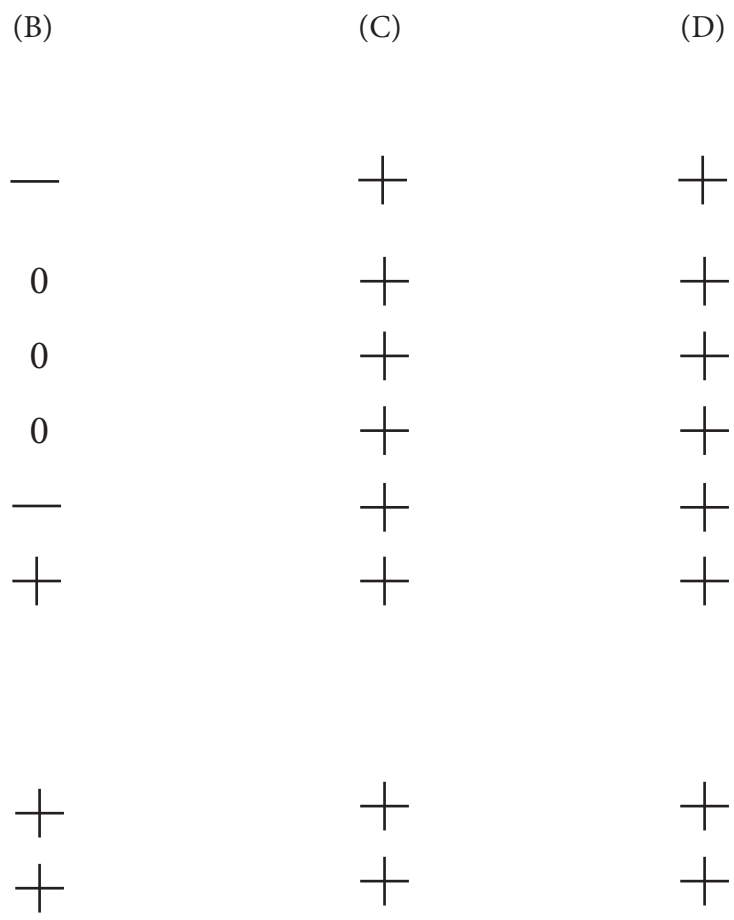
Use/user factors	4
Production/technical factors	1
Total	5

(B)	(C)	(D)
0	1	2
1	2	2
1	2	2
1	2	2
0	1	1
2	1	0
1	2	1
0	2	1
11	19	19
1	8	4
12	27	23

APPENDIX VI: PUGH MATRIX

	(A)
Use/user factors	
The interaction should have a low occurance of errors and errors shall not lead to dire consequences	—
The product should be usable by users of various dispositions	—
Minimize pain/irritation for the patient caused by the removal	0
The product should communicate its use	0
Use should be possible for users with different hand sizes.	—
The risk of premature detachment of the light protection should be low	+
Production/technical factors	
Minimize the demands on precision in production	+
Minimize the number of steps in the production	+

Jämförelse med orginalprototyp


(B)
(C)
(D)
0
0
0

APPENDIX VII: MORPHOLOGIC MATRIX

Function ↓ / Means →					
Light protect	black x	black y			
occular inspection	peep-hole	signal	lid	frame	gridpad
remove release liner	alternate shapes	no-liner	candy package	chewing gum	pull-around
Place product	dragan	tent	window	rubbery	
Visual expression	stripes	cutouts	stable	soft	melt pattern
Remove product	A	B	C1	C2	D

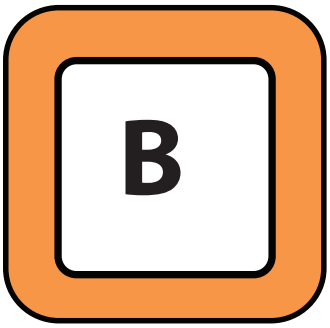
APPENDIX VIII: USER TEST PROCEDURE

1. Application

All wound dressing prototypes will be applied by the same person. This is someone who has good experience with the task and has extensive knowledge of the product and working with Adhelight products.

- The skin should be cleaned before the prototypes are applied.
- Effort should be put in making sure the prototypes are applied in a correct fashion with minimal wrinkling.
- Placement of the prototypes will be different for each user (according to placement of products on the next page).

Wound dressings will remain applied to the arms for 72 hours. During this time the dressings should be covered during showers and shall not be exposed to unusual wear in general.



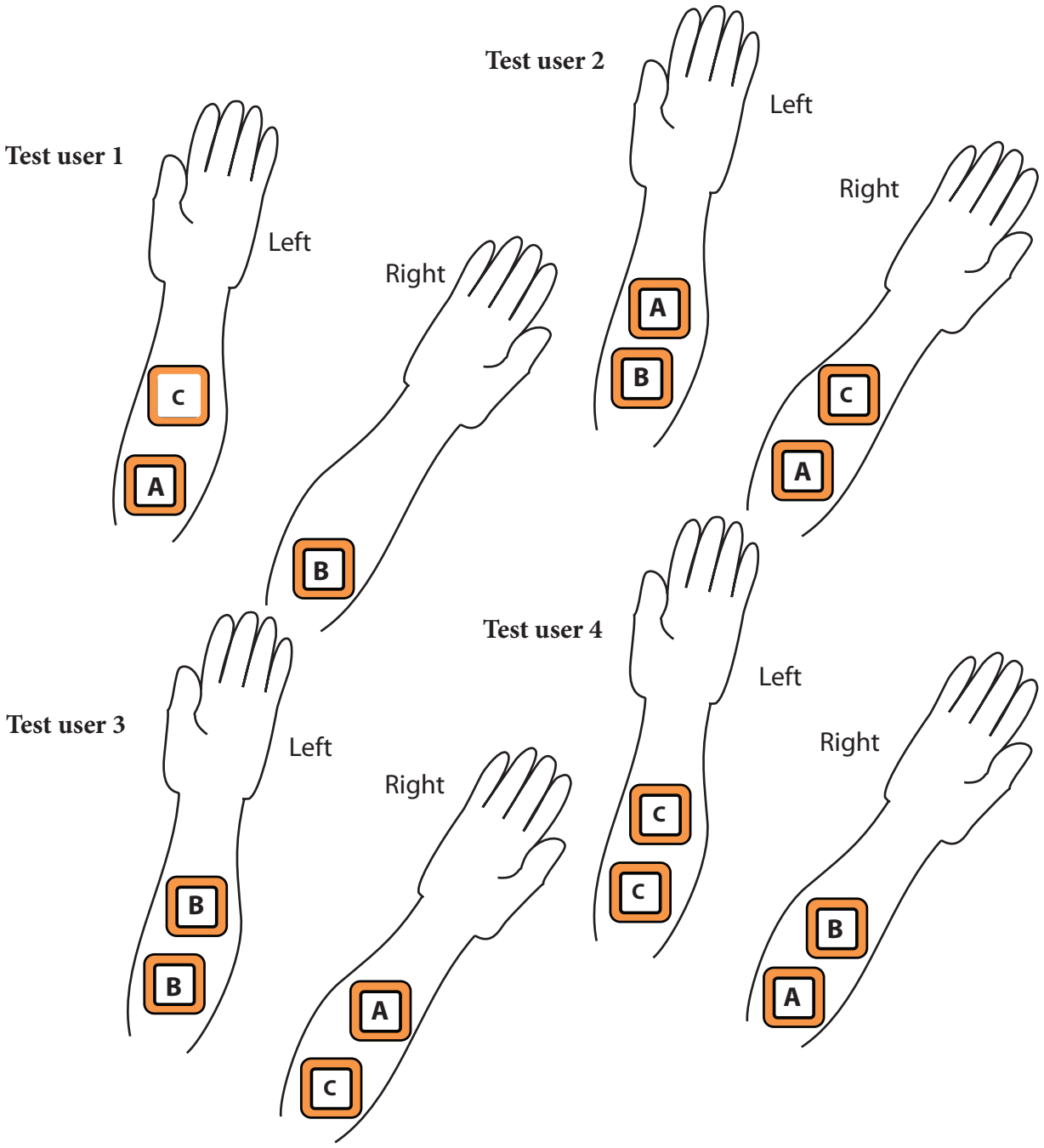
2. Removal

Each of the test subjects will remove the prototypes from one other subject, no one will remove their own prototypes.

Before the removal the person that has carried the prototypes will be asked a few interview questions (see interview guide) The removal process will be filmed and observed by the test leaders.

The test subjects are encouraged by the test leaders to comment their own experience throughout the removal. The person carrying the prototypes are asked to comment how each removal feels to the skin. The one removing is asked to "think out loud" when removing each prototype.

After all prototypes has been removed, the person that carried the prototypes will be asked a few interview questions (see interview guide). The person that removed the prototypes is given a questionnaire where they can grade certain aspects of the test experience.


Test user 1
Left
Right
C
A
B
Test user 2
Left
Right
A
B
C
A
Test user 3
Left
Right
B
B
A
C
Test user 4
Left
Right
C
C
B
A

Interview questions for the prototype carrier:

1. Before the removal:
Did any of the bandages detach prematurely?
If so which one? Placement:
Type:
What did you do when it happened?
Why do you think it detached?

Did you experience any concern for any of the wound dressings while wearing them? E.g. that one of them would detach.

Did you experience any other problems while using the wound dressings?

2. After the removal
During the removal, did you experience pain or discomfort at the removal of anyone of wound dressings? (Even the slightest pain or discomfort is relevant)

Any other comments?