B. PROJECT BRIEF

Personal Project Brief - IDE Master Graduation

TU Delft

New leakless sheath design for endovascular aortic surgery — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 04 - 01 - 2021 — 02 - 07 - 2021 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Aortic aneurysms can be treated by open surgery or endovascularly, by placing stent grafts in the vessel. Initially it was only possible to use these stent grafts in aneurysms that did not incorporate significant side branches to the kidneys, intestinal organs, stomach and liver. Due to technological improvements, it is possible to place stent grafts, that are fitted with holes (fenestrations) or side branches. These fenestrations and branches enable stent graft placement for complex aneurysms by incorporating visceral arteries into the treatment zone.

These stent grafts are implanted by minimally invasive, percutaneous surgery using access sites such as the brachial (arm) artery and the femoral (thigh) arteries (image 1b). After puncture, a sheath is placed in the vessel, functioning as a re-usable access point to the arterial system (image 1a). The sheath prevents blood from flowing out of the artery and enables entrance of tools into the arteries. Watch this video for an example https://www.youtube.com/watch?v=uP4RpilGMbE.
Oftentimes, current sheaths start leaking. Therefore, this project focuses on the design of a new, leak-proof sheath and the process of this medical device development (MDD).

The main stakeholders (image 1c) involved are:
• Two performing surgeons: aiming for perfectionism to execute the procedure as medically effective and neat as possible.
• Scrub nurse: assisting surgeons, aiming to be ‘one-step-ahead’ of what the surgeon needs.
• Patient: getting an improved medical condition, without negative side-effects by treatment.
• Sales representative of medical equipment (stent graft brand): ensuring smooth and intended use of company’s product to sell as many as possible medical products (sheaths) and holding large market share.
• Other relevant stakeholders: anesthetists, radiologists, sterilization department, hospital procurement.

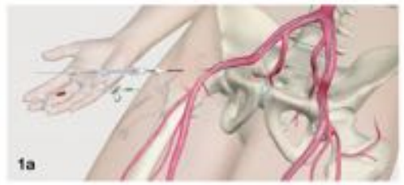
The current context is being influenced by two main limitations, that inherently form an interesting gap for this design project:

Firstly, only a small number of companies produce medical supply for endovascular surgery. Therefore, the development depends on these companies, which have a strong market position and financial interest.
The strong market position is a consequence of the high threshold to enter the market, formed by:
• the strict medical requirements for CE- and FDA-marking (regarding development, production, materials, sterilization) leading to long time-to-market and high development costs.
• brand-loyalty by surgeons and hospitals, based on experience and quality trust.

Both reasons also lead to the main opportunity for an industrial design project: to look at the problem, context and design opportunities from a fresh perspective, without being restrained by risks influencing market position, a high market-entrance threshold or acquired working habits.

Secondly, resources necessary for surgery should be kept to a minimum. Therefore new devices should not significantly increase surgery duration and material costs.

introduction (continued): space for images



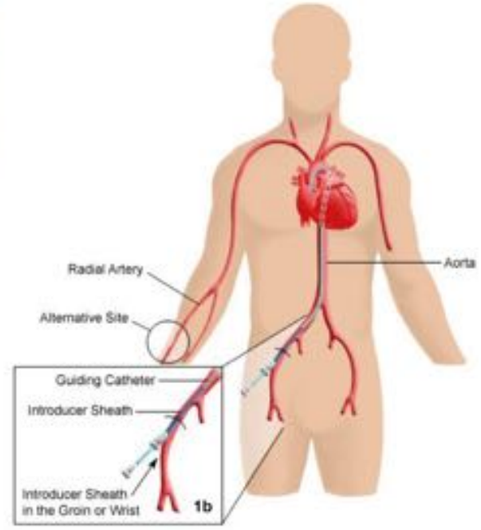
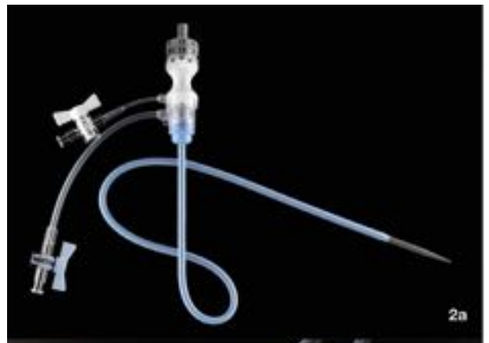


image / figure 1: 1a & b: sheath access sites for percutaneous surgery, 1c: main stakeholder map



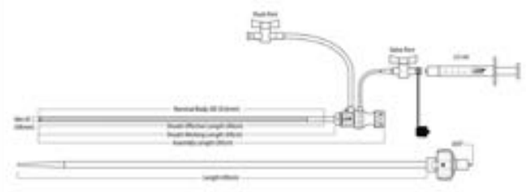


image / figure 2: 2a, b & c: GORE DrySeal Sheath with balloon-valve, 2d: sheath with x-cut flexible silicone valve

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

Advancing technology requires multiple tools (catheters, guide wires, sheaths) to be inserted through the sheath valve into the patient's arterial system to enable the implantation of complex stent grafts. Currently, sheaths with two different types of valve exist on the market. One has a flexible silicone layer (membrane) with an X-shaped cut, through which the tools can be inserted (image 2d). In practice, during use with more than two tools, additional punctures into the flexible layer in the four quarters around the X-shaped cut allow for insertion of multiple (up to four) catheters or sheaths.
The second type of valve has a balloon like wall, which can be inflated around the inserted tools to decrease the size of the opening of the valve and close it off (image 2a, b & c).

However, development of sheaths is slacking compared to the stent technologies. Current sheaths allow a maximum of two tools to be introduced through its valve, before blood starts leaking from the artery. With every additional tool being introduced, the valve's capability of adequate closure is reduced. This leakage can lead to significant blood loss for the patient. During lengthy complex endovascular procedures the patient can lose up to 2 liters of blood, making expensive recycling of homogeneous blood (cell saving) or even blood transfusion necessary.

This issue of blood leakage from the sheath should be addressed in this project, to ensure reduced leakage during the full surgery procedure when introducing more than two wires. In parallel, the complexity of the MDD process (Appendix A) should be analysed with support of collected information from various MDD experts, such as a medical design agency, material suppliers or production facilities.

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

Developing a new sheath design to enable leak-less implantation of fenestrated stent grafts with use of 4 tools for endovascular treatment of aortic aneurysms. Parallel to designing the device, this medical device development process will be analysed and evaluated.

Develop a sheath that enables the use of 4 tools and 1 wire in parallel at least, while limiting leakage or even remaining leakproof. This can be in the form of a new sheath design or an add-on to existing sheaths.
The most important sub-challenges are:
1. Closing the valve cavity created by introducing multiple tools, even during peak blood pressures of 160-180 mmHg.
2. Allowing the tools to be moved in/out through the sheath valve repeatedly. This can occur around 30-40 times during one surgery and currently leads to tearing of the membrane valve. No unintended (torn off) material should enter the blood system.
3. Size limitations: the outer diameter of the sheath should remain as small as possible (max. 24 french = +- 1 cm), while it should allow insertion of 4 tools of 7 french in parallel (in special cases a fifth is used, but only after removing the previous four).
Besides, the product development process of the medical device will be analysed and evaluated, regarding its steps, regulations to be met, stakeholders, and experiences with collaboration between the main stakeholders: medical specialists and designers. This results in a future roadmap for further MDD.

Finally, deliverables will be a physical prototype (functional & aesthetic), CAD model, project report, presentation, and possibly a paper (exemplary case of collaboration between various disciplines).

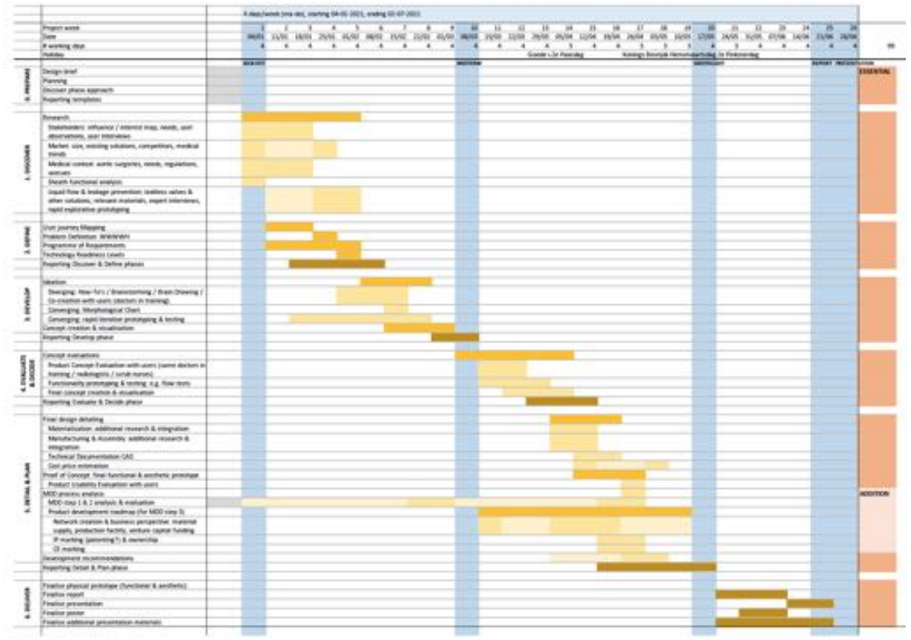
Personal Project Brief - IDE Master Graduation

TU Delft

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any, for instance because of holidays or parallel activities.

start date 4 - 1 - 2021 2 - 7 - 2021 end date



The approach of the project is divided into six phases based on the stages defined by the Delft Design Guide: preparation, discover, define, develop, evaluate & decide, detail & plan, and deliver. In between these stages, reporting deadlines are planned to ensure ongoing documentation of the project. These six phases represent a breakdown of the first two steps in the complete Medical Device Development process (consisting of 6 steps in total) as defined by Marešová et al. (2020), which can be found in Appendix A. Throughout the project an ongoing analysis and evaluation of the MDD process will be performed.

1. DISCOVER & 2. DEFINE: researching the problem, its context, stakeholders, and market to create a targeted problem definition and programme of requirements (5 weeks).
3. DEVELOP: idea generation by diverging and converging, resulting in multiple visualised concepts (5 weeks).
4. EVALUATE & DECIDE: functional and usability evaluation of concepts, leading to an iterated final concept (4 weeks).
5. DETAIL & PLAN: final concept detailing for materialisation, production, and CAD modeling and achieving proof of concept by testing a functional and aesthetic prototype. In parallel, a recommended roadmap for future MDD steps will be defined, based on the proof of concept evaluation and MDD process analysis (6 weeks).
6. DELIVER: the final 6 weeks are meant for implementing feedback of the Greenlight meeting and finalising the deliverables.

The kick-off of the project will be held in the week of the 4th of January 2021. Finally, the project will be concluded with a presentation in the week of July 28th 2021. During the course of the project, I will be working on it from Monday through Thursday. On Fridays I will be working on extracurricular activities, thus these are not included in the planning.

Personal Project Brief - IDE Master Graduation

TU Delft

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

As an IPD student you mostly just encounter a small part of the design process, something I realised during projects at previous internships. Especially in medical device development (MDD) the process is more elaborate, due to strict regulations, necessary documentation, production and sterilisation requirements, and lastly fixed working procedures and personal habits of medical staff.

During my recent internship at the MDD-team of the Amsterdam UMC I learned more about the process in practice and I would like to apply these new learnings, as well as get more experienced with the specialties of MDD by involving stakeholders in two ways:

1. by creating a network of relevant stakeholders. As I enjoy creating involvement and collaborations with multiple parties, something I realised during design projects as well as a board year experience, this is an interesting method to gather expert knowledge and experience from practice. Especially in the medical context, multiple backgrounds are relevant due to the required expert know-how. In this project, knowledge is required about topics such as vascular surgeries, flow and materials engineering, sterilisation, regulation, and market opportunities. This could also add to formulating a market based business proposition, by quantifying the market need and size, as well as the product's viability.

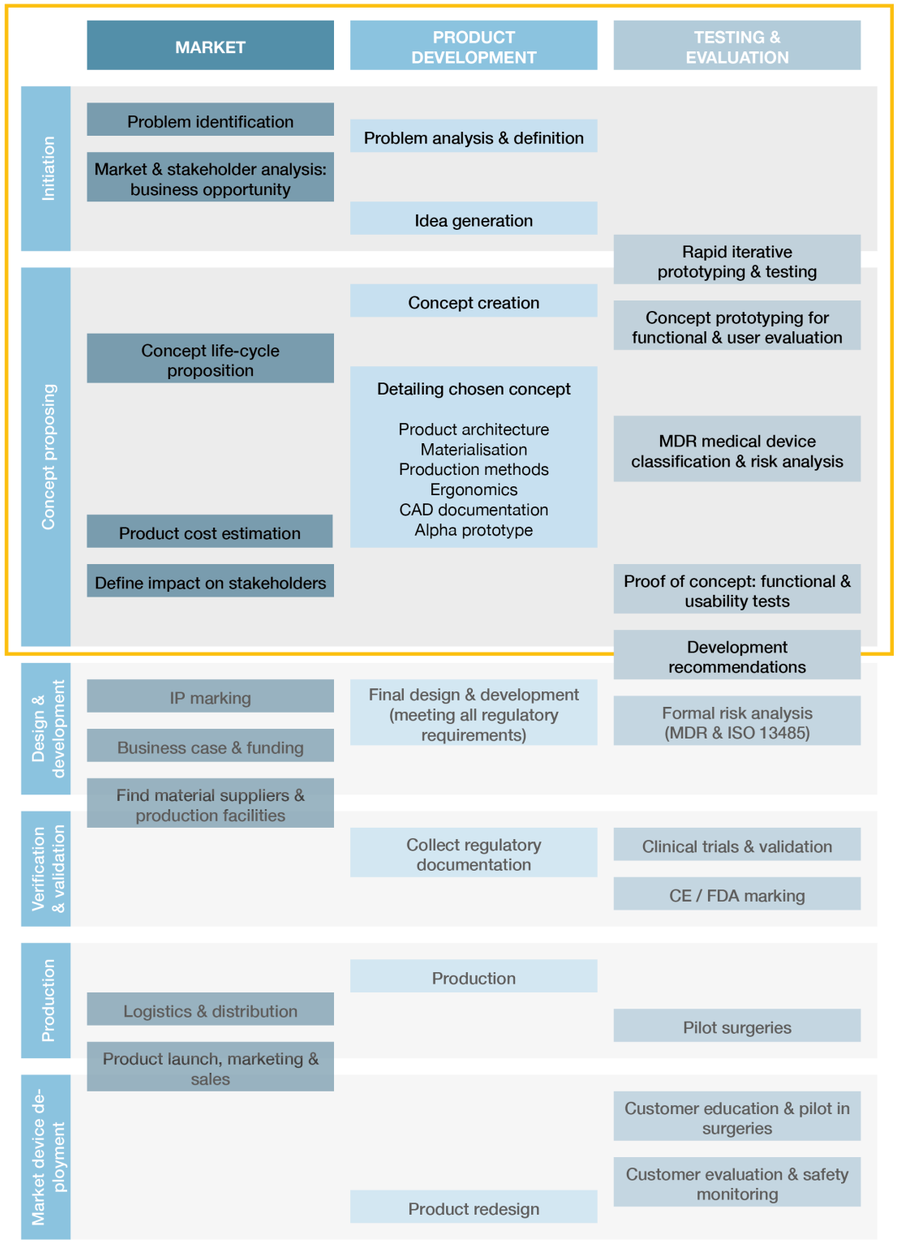
2. by involving stakeholders in the design process to make use of their knowledge and experience, and design a product that really fits their need and working style. Therefore, I would like to dive into the working process of the surgeons on a typical surgery day during which sheaths are used. The surgeons can be involved through co-creation sessions during for example problem definition, idea generation or concept creation.
However, it is important to keep in mind the current situation regarding Covid-19, as this might influence the planning and execution of these sessions. In that case, (online) alternative ways of executing this method should be thought of, possibly in combination with user interviews and journey mapping. Prototypes are valuable for (early) co-evaluation with users: being able to hold, try and see a possible solution from different angles in 3D allows fast understanding by the users, leading to realistic feedback.

Lastly, I would like to prove my product design articulation competences that I have gained during my studies. This means strong showcasing of skills concerning aesthetic form-giving and CMF (Colour, Material, Finish), ergonomics and typical use-cues for surgeons. I want to do this by focusing on achieving high quality visualisation through design drawing, CAD renderings and an aesthetic prototype.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

C. MEDICAL DEVICE DEVELOPMENT



Medical Device Development process based on the six steps defined by Marešová et al. (2020): Initiation, Concept proposing, Design & development, Verification & validation, Production, Market device deployment. The tasks divided over the three columns Market, Product Development and Testing & Evaluation are formulated according to the sub-steps identified by Marešová and complemented with own experience of the design process.

Marešová, P., Peter, L., Honegr, J., Režný, L., Penhaker, M., Augustýnek, M., ... & Kuča, K. (2020). Complexity Stage Model of the Medical Device Development based on Economic Evaluation—MedDee. Sustainability, 12(5), 1755.