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Development of a surgical tool to facilitate mesenteric defect closure

Using an alternative method to close mesenteric windows during minimally invasive gastric bypass surgery

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Abstract

This project focuses on the development of a novel surgical tool designed to facilitate internal tissue closure in minimally invasive surgery, specifically targeting mesenteric defect closures during Gastric Bypass procedures.

The tool incorporates innovative staples and barbed sutures, distinct from conventional methods and existing market tools. The surgical tool features optimized staples made from biocompatible NiTinol, with dimensions of 1.5 x 5.5 x 0.5 millimetres, facilitating tissue penetration while minimizing tissue squishing. The barbed sutures, composed of PBT with dual-cut barbs in alternating tri-radial rows, provide a secure closure mechanism. The applicator, with a diameter of 9 mm and usable length of 35 cm, enables single-handed operation with right- and lefthanded use. The cartridge consists of 80 staples and 30 centimetres of barbed suture, enough to close an entire defect. The tool's design and functionality aim to enhance the efficiency of internal tissue closure procedures, reducing time, physical exertion, and cognitive load for surgeons.

The project follows a systematic and iterative design approach, best represented by the triple diamond method. A first phase involved extensive literature and market research, exploration and observations in the operation room. In a second phase, various methods such as brainwriting and CAD design are employed to generate ideas and models. Then in a final phase, through comprehensive testing and evaluation, a first version of the device called StapleStitcher, has been established, serving as a solid foundation for future iterations.

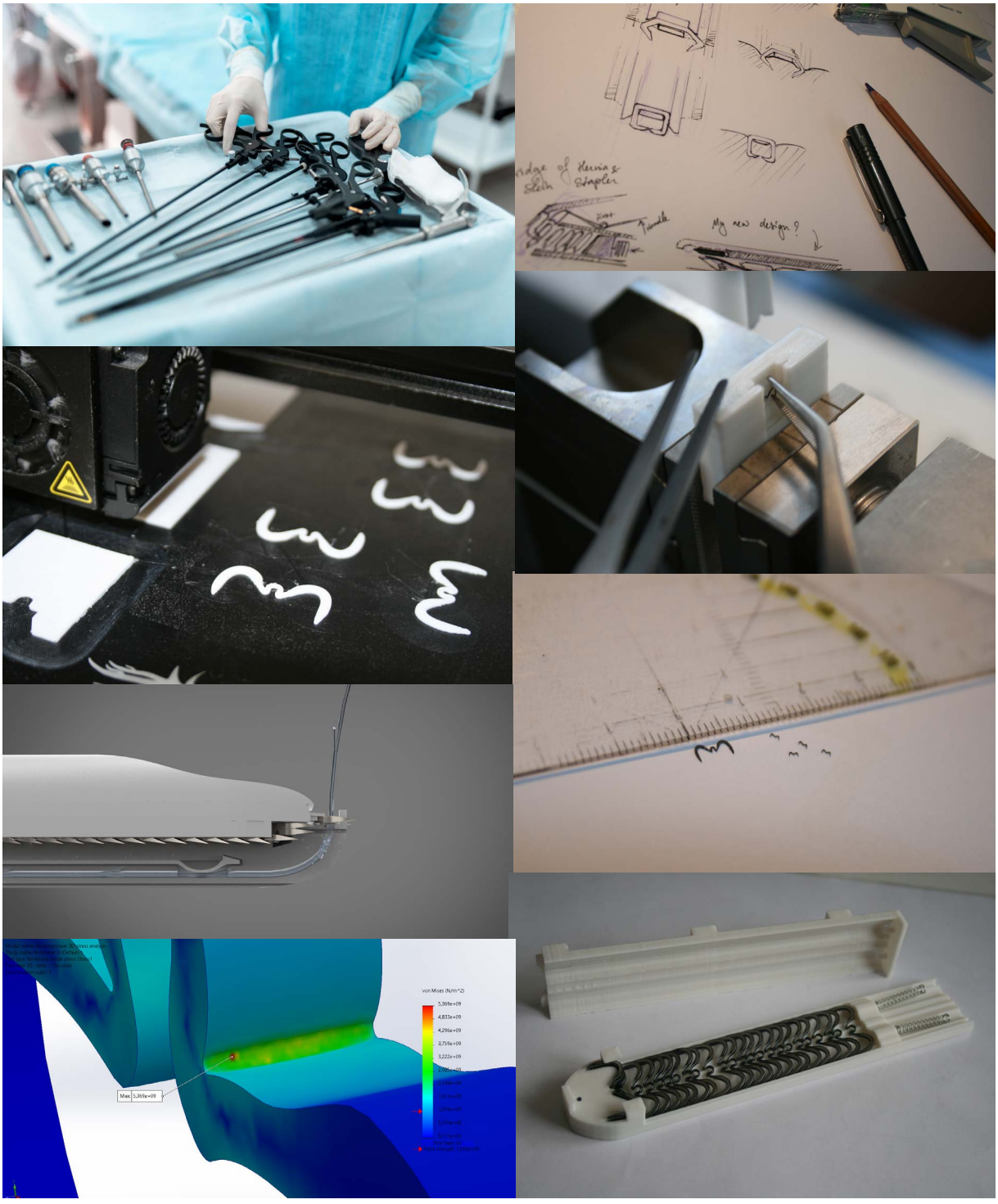
The evaluation of the proposed surgical tool has yielded overall positive feedback from bariatric surgeons. This was conducted through a questionnaire. They recognised its innovativeness and some explicitly expressed interest in further development.

Additionally, a risk analysis was conducted to identify potential hazards associated with the use of the surgical tool. The analysis addressed factors such as mechanical failure and user-related issues. Mitigation strategies derived from the analysis and feedback from surgeons informed recommendations for further research, collaboration, and development to optimize the surgical tool for clinical implementation.

In conclusion, the development of the novel surgical tool presents an opportunity to simplify and enhance internal tissue closure procedures in minimally invasive surgery. By incorporating innovative staples and barbed sutures, the tool offers potential improvements in surgeon comfort and efficiency. However, further research, collaboration, and refinement are necessary to fully harness the StapleStitcher's potential and ensure successful integration into clinical practice.

Keywords

Minimally Invasive Surgery, Laparoscopy, New Surgical Instrument, Gastric Bypass, Mesenteric defect closure



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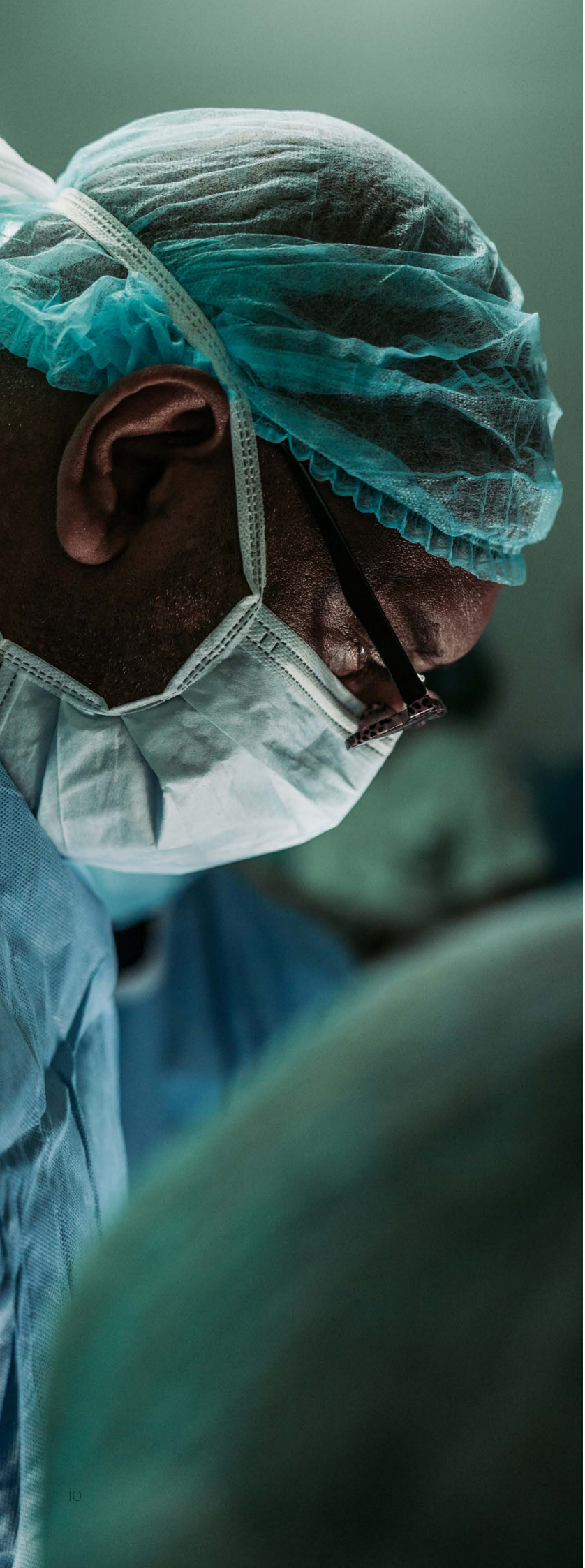
List of abbreviations

MIS	Minimally invasive surgery
LRYGB	Laparoscopic Roux-en-Y gastric bypass
MD	Mesenteric defect
BO	Bowel obstruction
IH	Internal herniation
EHS	Endo hernia stapler



Introduction

A previous master's thesis (Wochner, 2022) examined a novel approach to tissue closure, specifically focusing on gastrointestinal anastomosis in a gastric bypass procedure. The method involved a combination of stapling and suturing and was evaluated through interviews with surgeons. However, it was determined that this method was not suitable for gastrointestinal anastomosis. As a result, alternative applications were explored, and surgeons identified its potential for enhancing the closure of mesenteric windows.

The primary aim of this project is to investigate the feasibility of utilizing a combination of stapling and suturing as a viable method for internal tissue closure, specifically focusing on the mesenteric defect (MD) as a case study.

In order to ensure clarity and a common understanding of the medical terminology used within this project, a list with definitions is provided in Appendix A.

Background

Overweightedness and obesity are defined as abnormal or excessive fat accumulation that pose serious health risks e.g. cardiovascular diseases, musculoskeletal disorders, diabetes and cancer (Dutch government, ministry of health, z.d., WHO, 2021). In 2021, half of the Dutch people aged 18 or older were overweight: 36 per cent were moderately overweight and 14 per cent were severely overweight (obese) (CBS, 2022). According to *The Global Burden of Disease*, the amount of people that are overweight has reached epidemic proportions. Being overweight has been recorded as the cause of death for over 4 million people annually (WHO, 2020).

Nonoperative treatment for obesity - consisting of dietary changes, increasing physical activity and behavioural modifications - has little proven benefit for the majority of obese people, as only 4% of the cases resulted in maintaining long-term weight loss (Mitchell & Gupta, 2022).

Bariatric surgery refers to a series of surgical procedures that reduces food intake, therefore causing obese people to lose weight. A meta-analysis found that bariatric surgery resulted in greater long-term weight loss, a higher remission rate of type 2 diabetes, lower plasma triglyceride, greater improvement in the quality of life, and reductions in medicine use when compared to nonoperative treatments (Mitchell & Gupta, 2022).

Fun fact: The term 'bariatric' comes from the Greek "baros" (weight, burden) and the suffix "iatros" (physician, healer) (Harper, 2022).

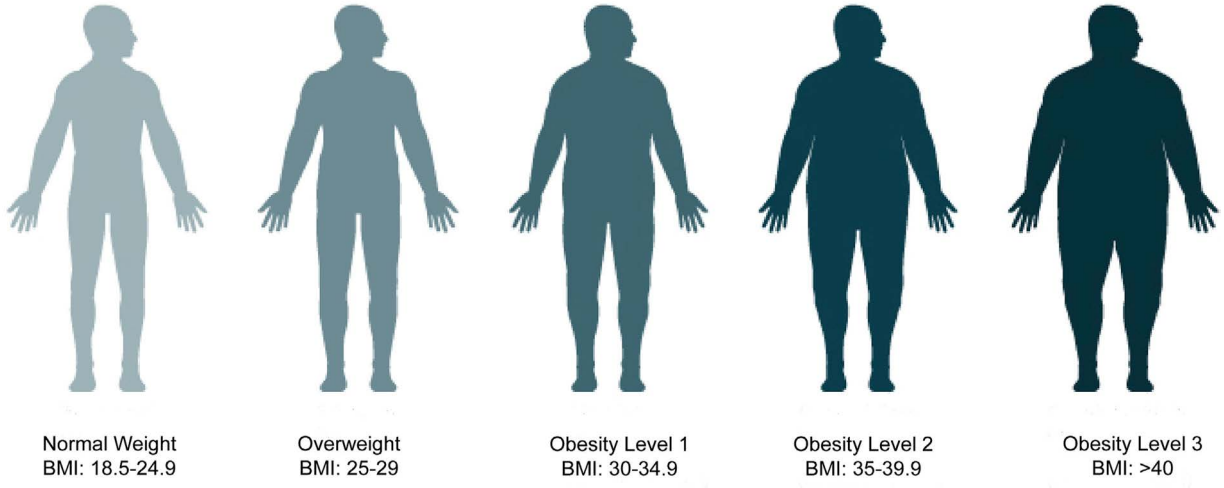


Figure 1. The different levels of obesity ranked by BMI range (Higuera-Hernández et al., 2018)

Gastric bypass

Three main bariatric surgery procedures are widely used: gastric bypass, gastric banding and sleeve gastrectomy. Gastric bypass is the most common procedure worldwide and involves creating a small stomach pouch and re-routing a portion of the digestive system resulting in reduced food intake and stimulating satiety (see Figure 4)(Kang & Le, 2017).

Gastric bypass surgery is usually performed laparoscopically (Wochner, 2022). Laparoscopy is a type of surgical procedure that allows a surgeon to access the inside of the abdomen and pelvis without making large incisions in the skin (0.5 to 1.5 cm) (Figure 2 and Figure 3). The surgeon is using a laparoscope, which provides a light and camera, and the image is projected on an external screen. This procedure is also known as keyhole surgery or minimally invasive surgery. A detailed explanation of the surgery can be read in Appendix C.

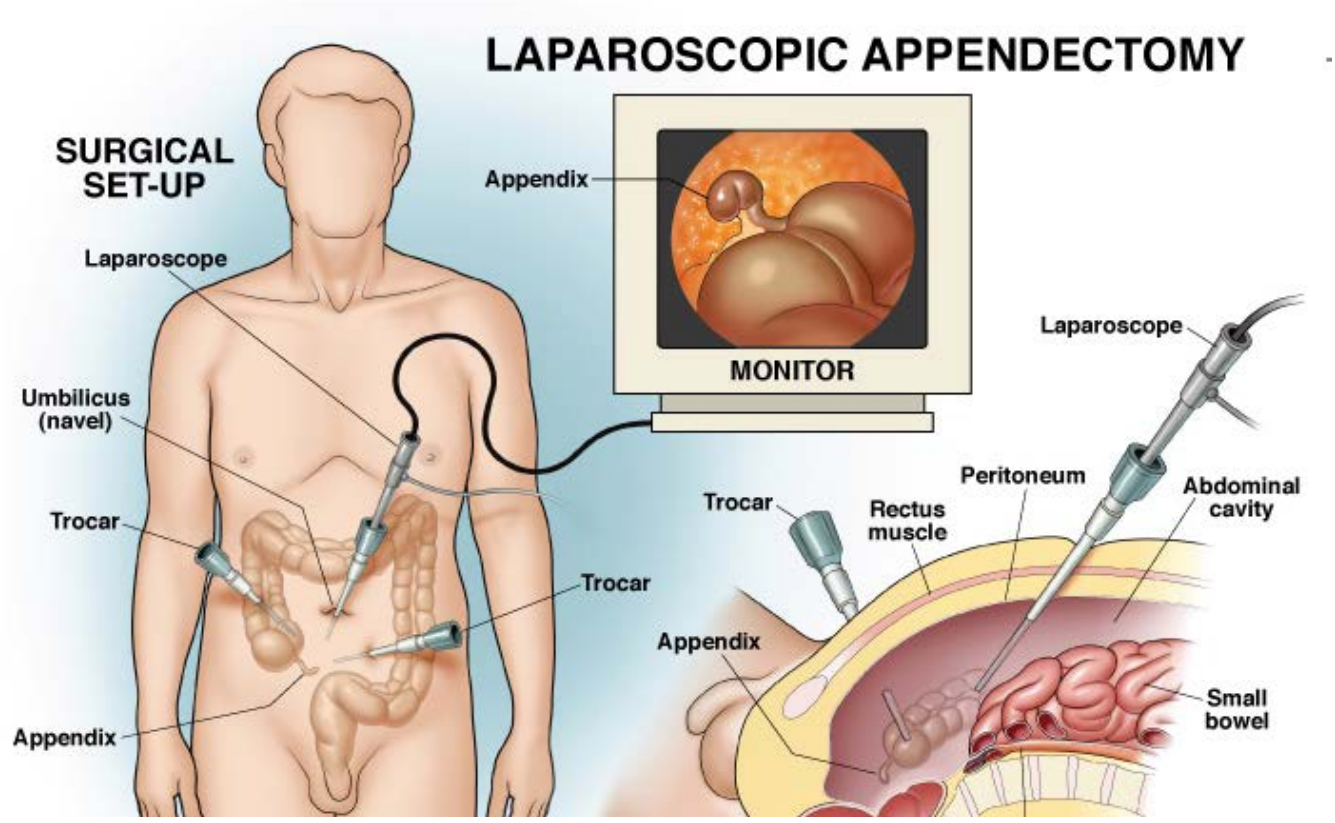


Figure 2. A schematic representation of (an example of) laparoscopic surgery (Centre for Strategic Healthcare Development, 2019)

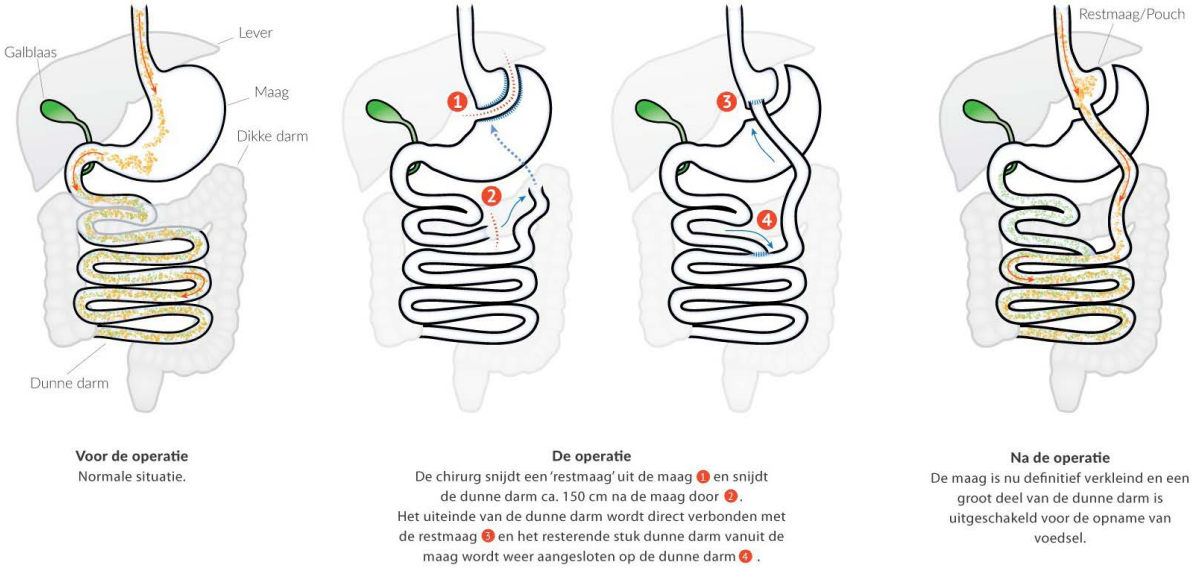


Figure 4. A schematic representation of the Roux-en-Y Gastric Bypass surgery (Nederlandse Obesitas Kliniek, 2020)

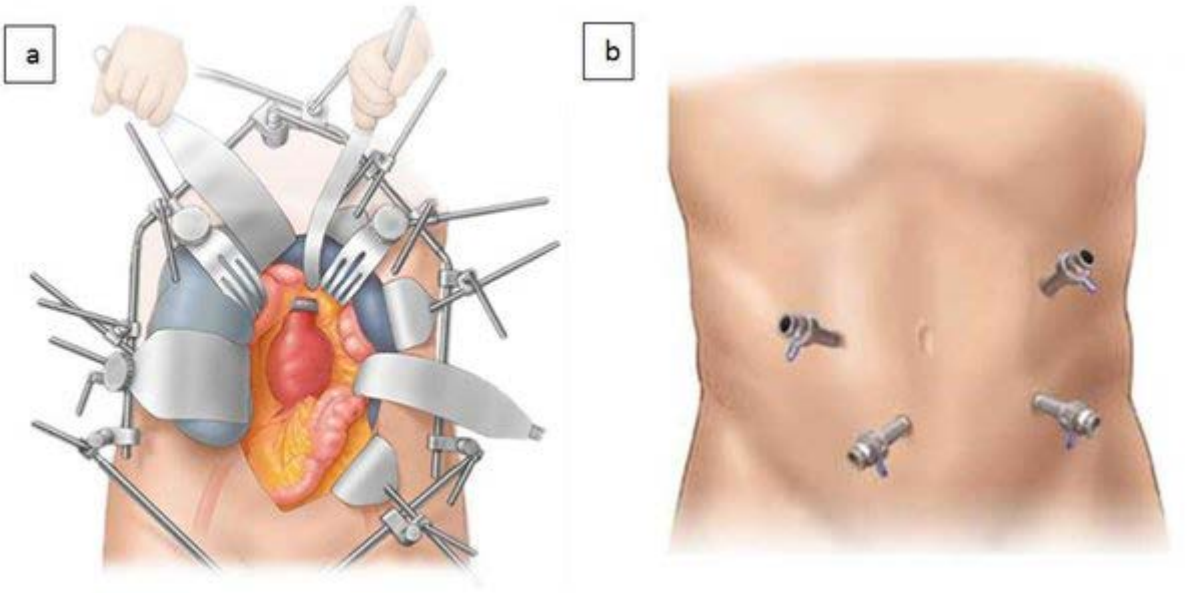


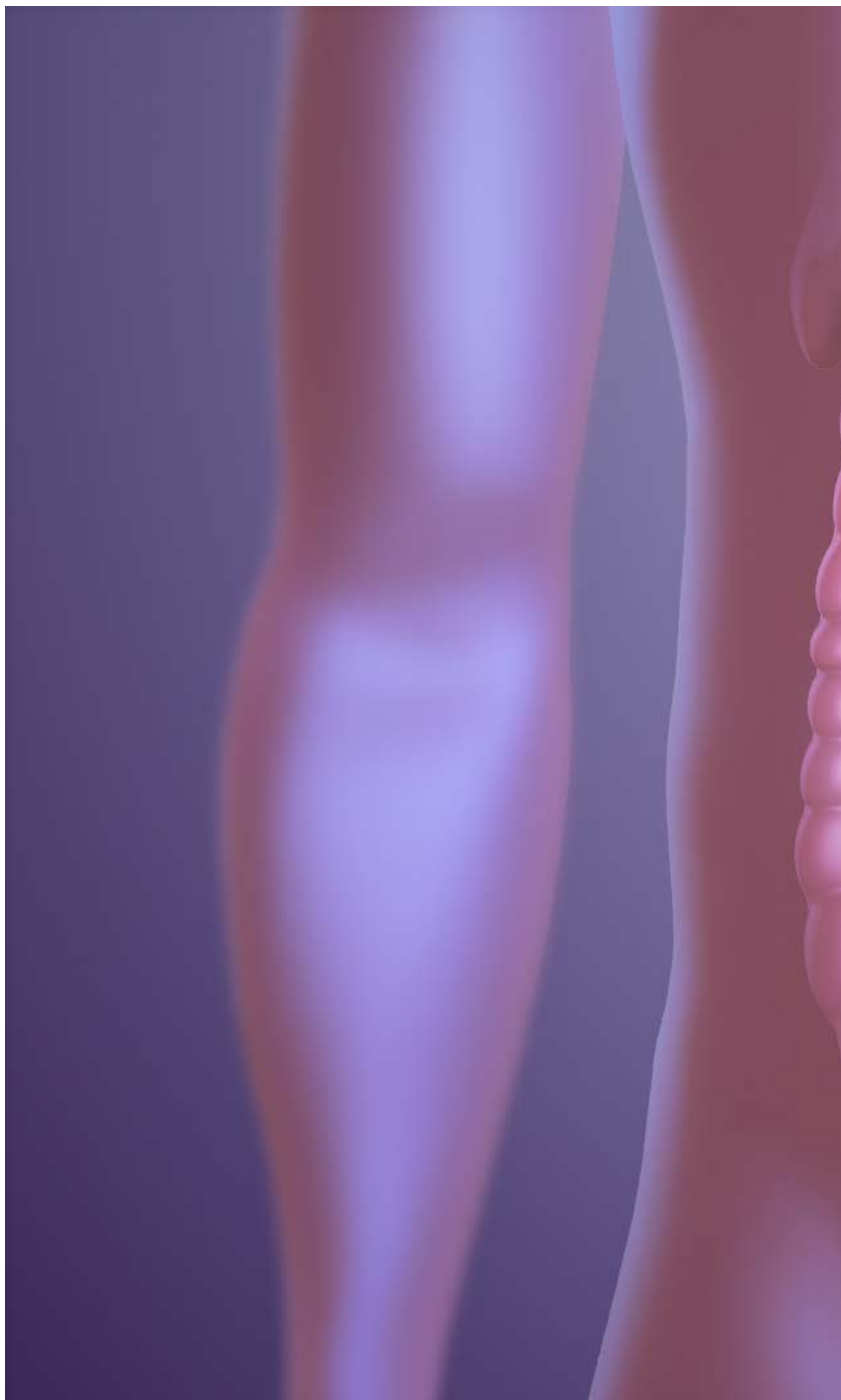
Figure 3. Difference between the incisions of open surgery (left) and laparoscopic surgery (right) ((Zhao, 2015)

Mesenteric defects

While the laparoscopic Roux-en-Y gastric bypass (LRYGB) procedure has been successful in achieving weight loss, it is not without potential complications. One such problem is the open space that is left in the abdominal fibrofatty tissue after dividing the small bowel and rerouting the intestines (which is called the construction of the gastro-jejunal and jejuno-jejunal anastomosis). This open space is known as a mesenteric defect (MD), which is about 2 - 5 cm long (Xu & Zhou, 2023)(See Figure 7). One or more intestinal loops can incarcerate and lead to high-grade bowel obstruction (BO), internal herniation (IH), and other serious complications at these sites (Alhamdani, 2020; Collard et al., 2020)(See Figure 6). Closure of the MD is the final step in the LRYGB procedure and is essential in preventing these complications (Medical College of Wisconsin, z.d.). The importance of MD closure has been emphasised in various studies. A study published in the medical journal *The Lancet* found that closure of these defects was associated with a lower risk of IH and BO, notwithstanding the increased risk of stricture caused by kinking of the jejunojejunostomy (Stenberg et al., 2016; Collard et al., 2020).

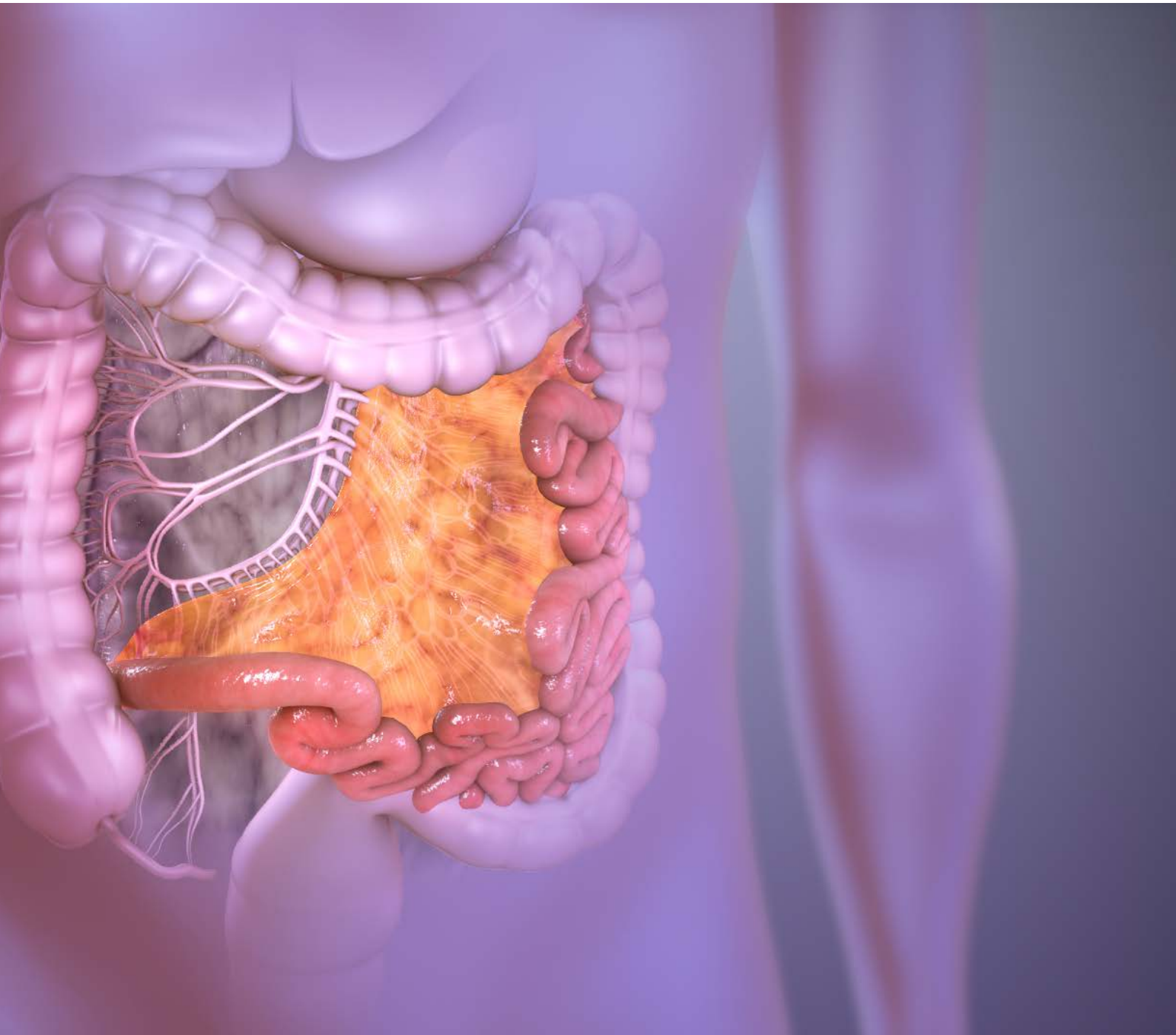
According to surgeon Y. Acherman (personal communication, February 16, 2023) and the research by Collard et al. (2020), the prevalence of IH after LRYGB is around 10% to 16%, and is more frequently found when these defects are not closed.

Petersen's IH is one of the most frequent IHs following Bariatric surgery, followed by



Mesojejunal's IH (Lopera et al., 2018). Within this project, the focus is on the Petersen's space and the mesojejunal space, as they contain mesenteric tissue on both sides of the window, as opposed to the trans-mesenteric defect, in which stitching through the alimentary limb itself is required. As this poses significantly more risks, closing that tiny defect will not be taken into consideration for this project.

Figure 5. The yellow-ish tissue that can be seen below is the mesentery. This fatty tissue attaches the intestines to the posterior abdominal wall. For more visuals, please refer to Appendix A.



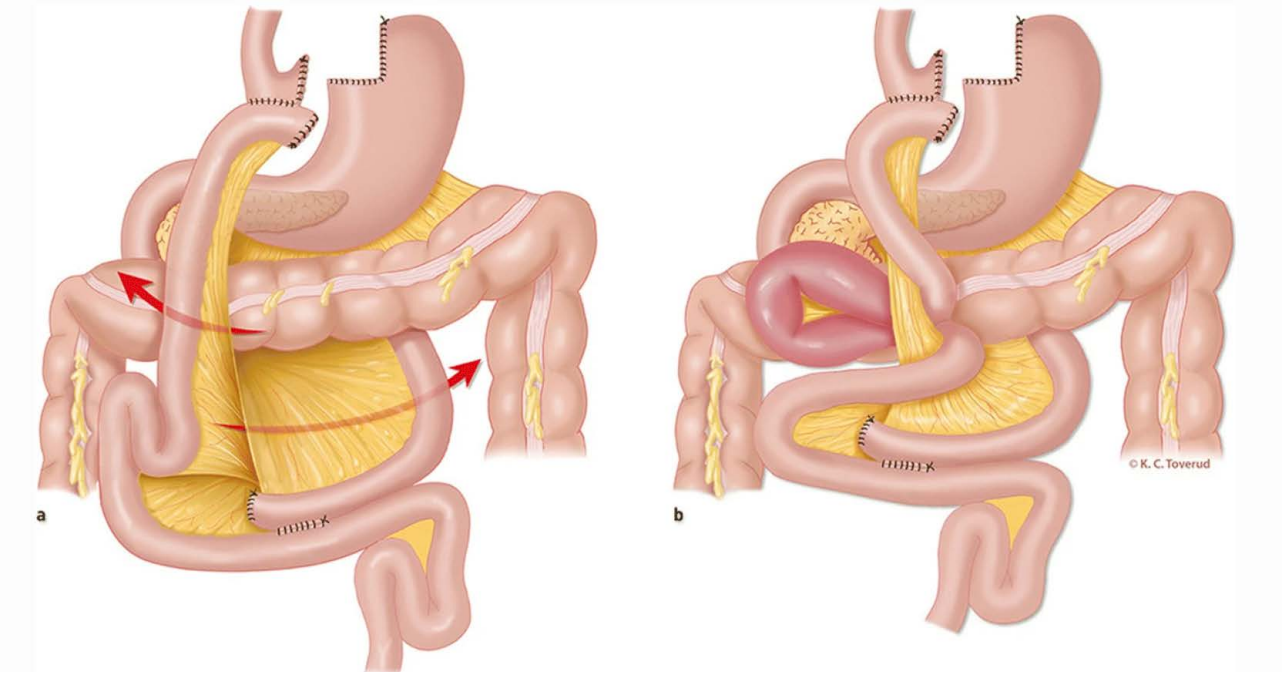


Figure 6. A schematic of two potential MDs: (a) between the alimentary limb mesentery and the transverse mesocolon, (b) between the jejuno-jejunostomy mesentery (Wang & Shope, 2019).

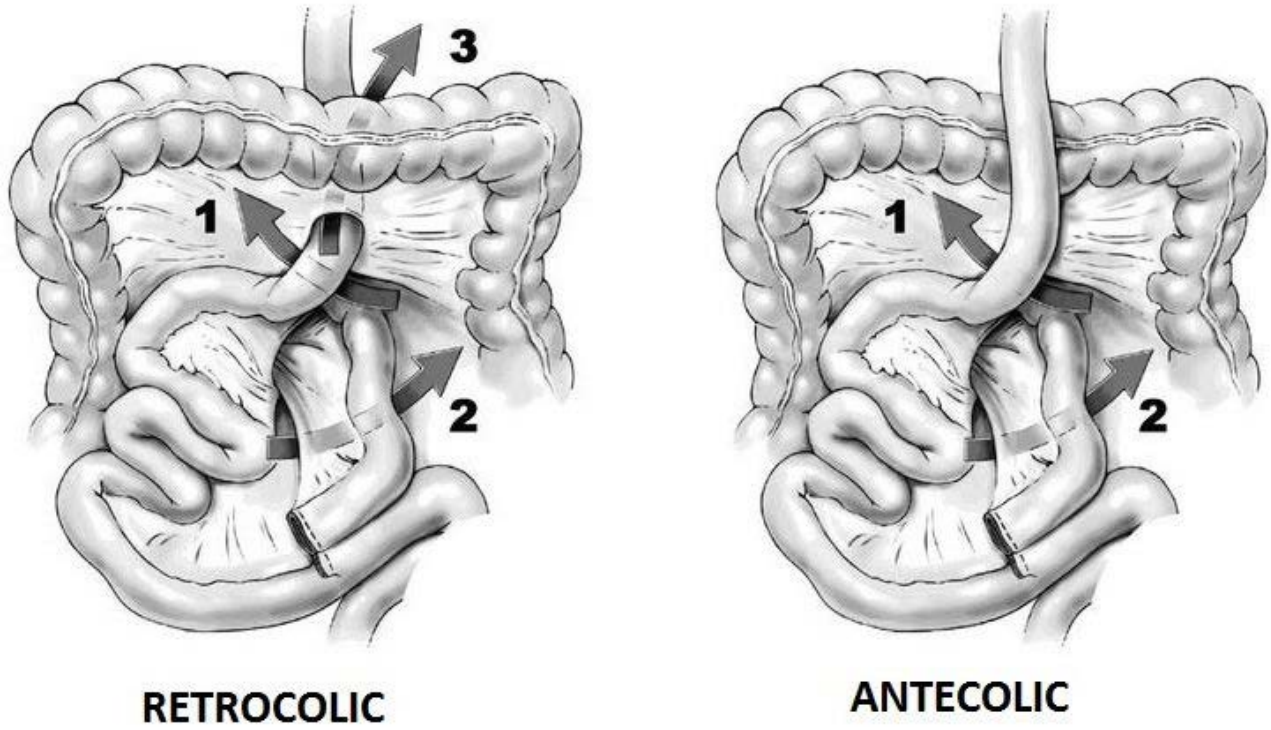


Figure 7. A schematic representation of the different spaces created between the mesenteric structures according to the type of RYGB performed (i.e. retro-colic (trans-mesocolic) and ante-colic). 1 Petersen's space, 2 Mesojejunal space (inter-mesenteric space), 3 Transverse mesocolic space (Pokala et al., 2022).

Procedures for closing mesenteric defects

During laparoscopic Roux-en-Y gastric bypass surgery, as explained in the previous chapter, closure of the MD is an essential step to prevent internal hernias. While various techniques for closing these defects exist, in practice, sutures and staples are typically used as they offer a safe and trusted way to fully close the defects. Alternative procedures can be found in Appendix G.

Suturing by hand

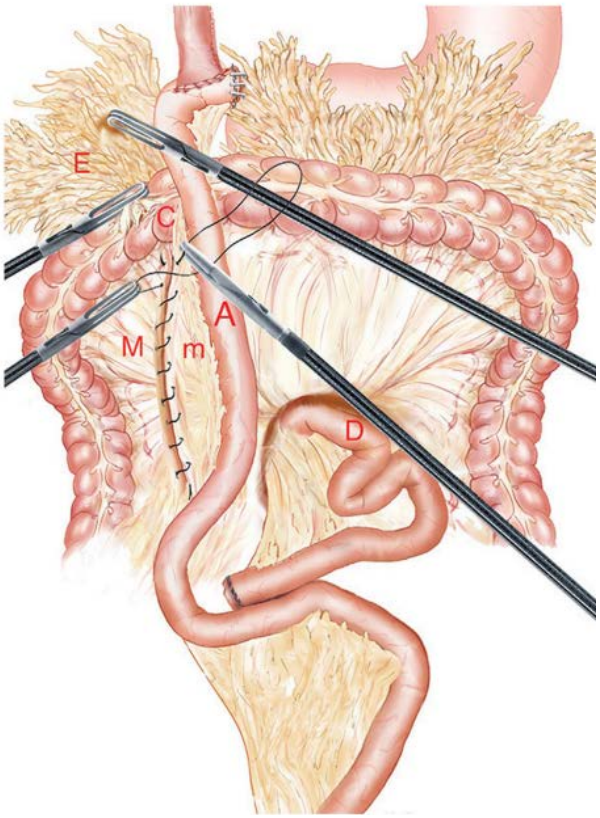
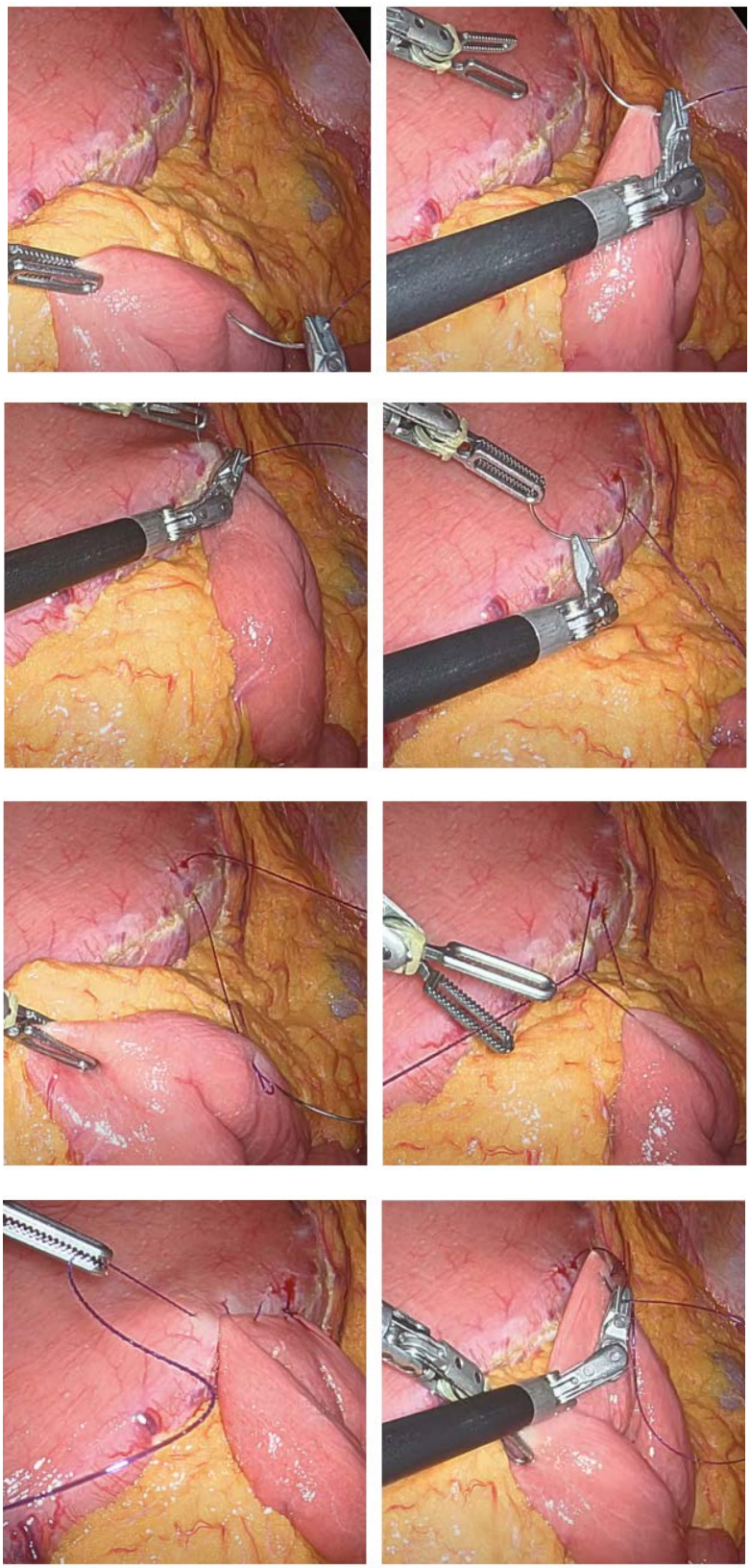


Figure 8. Representation of the procedure of sewing the Petersen's space by hand (Collard et al., 2020).

During the manual suturing of the MD, an assistant grasper is used to maintain the transverse colon (C) cephalad in position to expose the bottom of the Petersen's defect. The alimentary limb (A) is then pushed to the patient's left to enhance the exposure of the space, and the defect is closed using non-absorbable sutures (as the tissue will not grow together). The suture must close the defect between the mesentery (m) and mesocolon (M) completely. Care must be taken to ensure that omental fringes or the greater omentum (E) are not included in the suture (Collard et al., 2020). What this broadly looks like is shown in Figure 8.

This procedure requires a total of five hands. Here, an assistant operates the laparoscope, another assistant operates two graspers to expose the defect and ensure that other body parts do not interfere with the suture and, lastly, the lead surgeon utilises two more graspers for the suturing itself.



While holding the tissue with the left grasper, the surgeon pierces the needle through the tissue.

Depending on the space, the surgeon may grasp some tissue directly or pull the needle fully through the tissue first before piercing the other side of the defect.

The second option takes longer since the needle needs to be handed over twice between the instruments.

Once the needle is pierced through both tissues, the surgeon grabs the tip of the needle and pulls it through the tissue.

The surgeon hands over the needle to the needle holder and pushes it through the suture's loop. Again, the surgeon needs to hand over the needle between its graspers back and forth.

The surgeon tightens the suture by pulling it with the grasper. When all stitches are done and pulled tight, the end of the suture is cut with a dissector.

Figure 9. An example of what laparoscopic suturing actually looks like, as seen by surgeons on their screen. In this example an anastomosis is executed with the help of robotic graspers, but the workflow remains the same (Wochner, 2022).

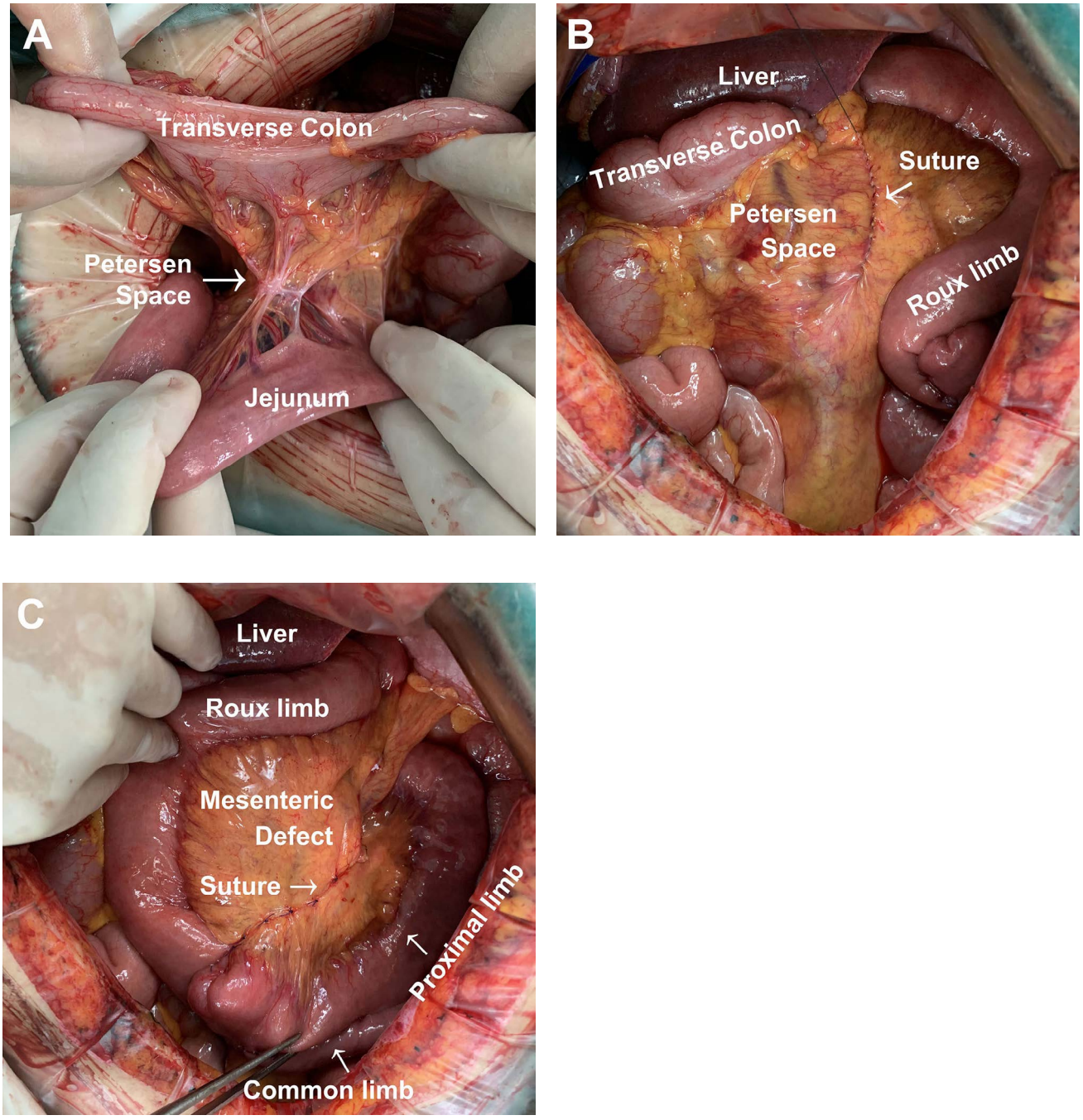


Figure 10. An example of the petersen's space as seen in an open surgery (A), what the petersen's space looks like when it is sutured close (B) and what the mesojejunal space looks like when sutured close (C) (Liu et al., 2021).

Stapling

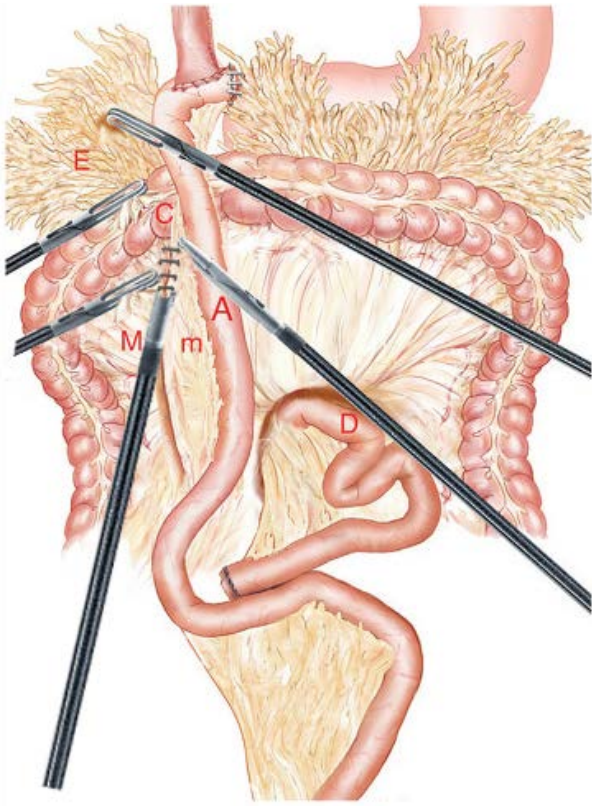


Figure 11. Representation of the procedure of closing the Petersen's space with the aid of a stapler (adapted from Collard et al., 2020).

During the closure of the MD by stapling, an assistant grasper is used to maintain the transverse colon (C) and expose the Petersen's defect, while the alimentary limb is pushed to the patient's left to optimize the exposure of the space. Two graspers are then used to hold each side of the tissue and align it for stapling, and for providing counterpressure to the stapler. The defect is closed using non-absorbable staples, and care is taken to avoid including omental fringes or the greater omentum (E) in the stapling process.

This procedure requires a total of six hands. Here, an assistant operates the laparoscope, another assistant operates two graspers to expose the defect and ensure that other body parts do not interfere with the stapling, two more graspers are needed for aligning the mesenteric tissue and, lastly, the lead surgeon utilizes the stapler to close the window.

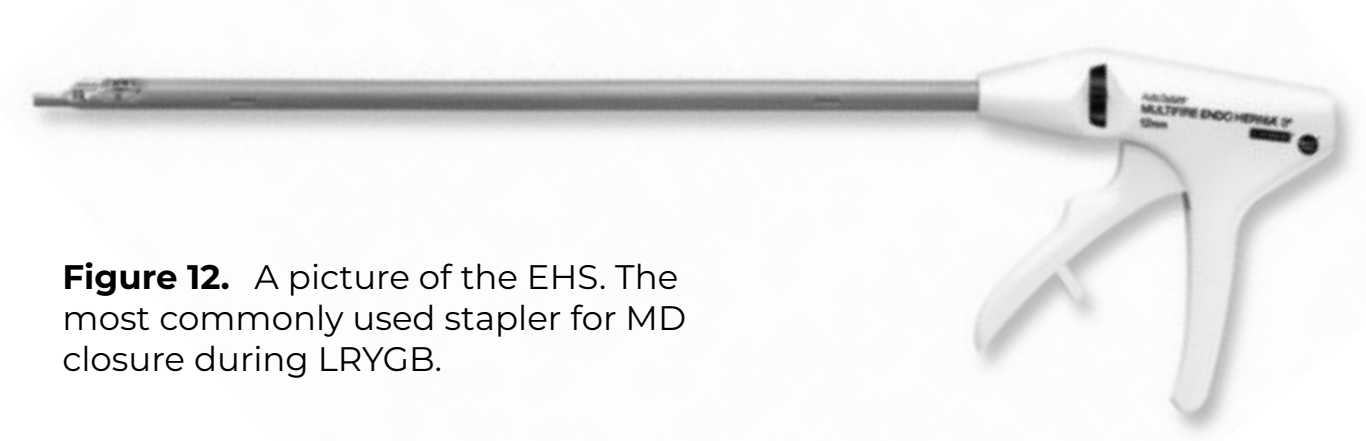
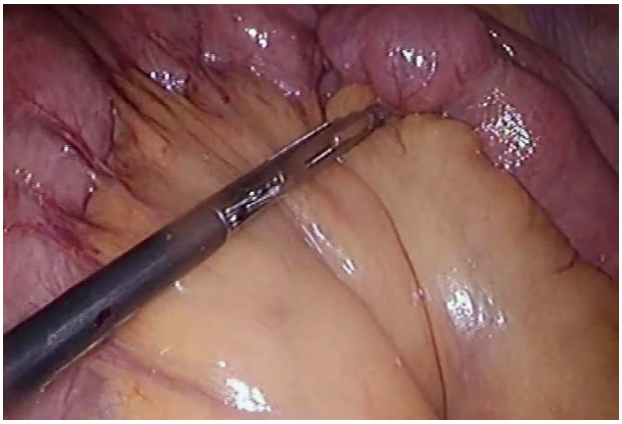
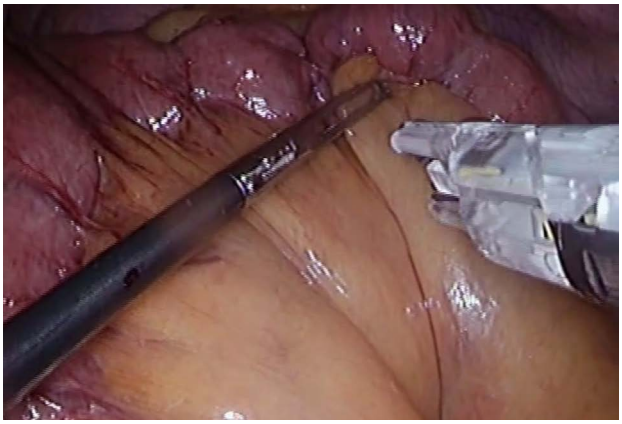


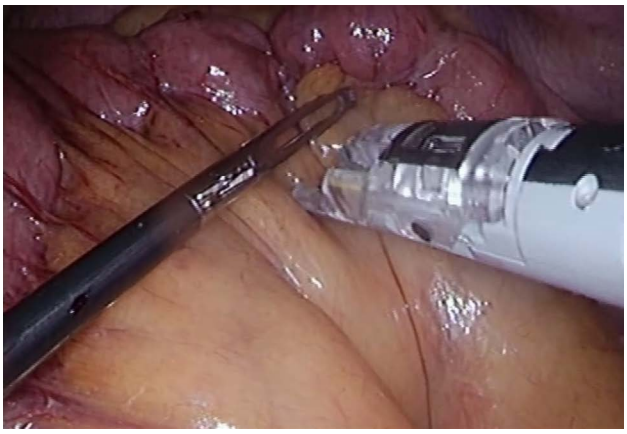
Figure 12. A picture of the EHS. The most commonly used stapler for MD closure during LRYGB.



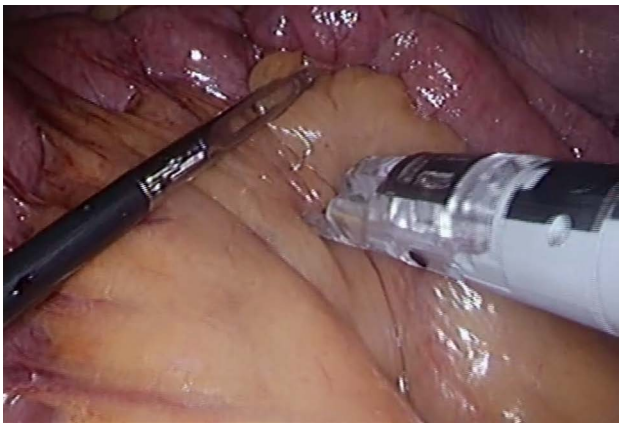
First, the mesentery is held with a grasper. Contrary to what the literature described, only one grasper is used here.



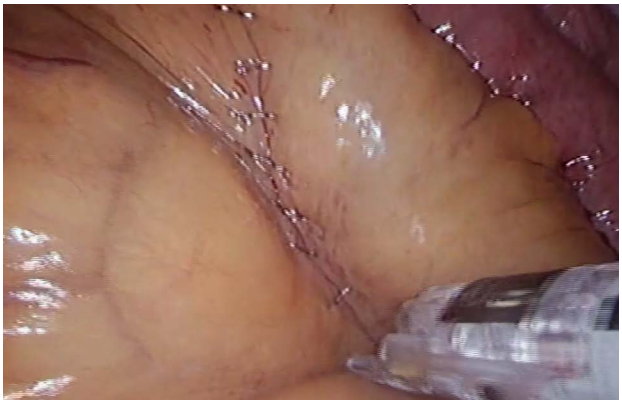
Then, the EHS is inserted and turned until the staples are aligned perpendicularly to the 'line' of the defect.



When correctly aligned, the EHS is pushed against the tissue and the first staple is placed. Surgeons often try to hook one side of the staple firmly into the tissue, then pull towards the other side and only then place the staple.



Note that the surgeon starts stapling the defect at the point furthest away from him and moves towards him when he does not staple the defect.



Here it can be seen that, especially in the middle, even an excellent surgeon sometimes does not manage to place all the staples perfectly.

Figure 13. An example of what laparoscopic stapling actually looks like, as seen by surgeons on their screen. These are screenshots from a video provided by surgeon Y. Acherman (2023).

Problem definition

Closing MD during laparoscopic surgery presents several challenges to the surgeon. As mentioned by Berguer et al. (2001), laparoscopic surgery requires greater concentration and puts more cognitive stress on the surgeon compared to open surgery. The technical and ergonomic difficulties faced by the surgeon also contribute to the complexity of the procedure (Leonard et al., 2014). The surgeons are watching the three-dimensional procedure on a two-dimensional screen, reducing depth perception and causing perceptual errors (Chung & Sackier, 1998; Sinha et al., 2017). Additionally, the magnification of objects closest to the laparoscope gives a degraded visual image of the anatomy (Gallagher et al., 2003).

The difficulties also include specific hand-eye coordination, which can cause misinterpretations of angular relationships due to the tools not being at the same angle as the camera axis (Gallagher et al., 2003) (See Appendix A and Figure 14). Furthermore, the surgeon does not have direct control over the position and orientation of the laparoscope, which can lead to disorientation and misinterpretation (personal communication, March 3, 2023). The Fulcrum effect (Appendix A) causes movements performed to be shown in opposite directions on the screen (Harrington, 2018)

The tactile feedback when manipulating organs is reduced, and the force

transmission ratio is worse with 4-6 times more force needed due to the long instruments used (Berguer, 1999). This causes ergonomic discomfort since the surgeon has to hold their arms higher than usual while pulling the shoulders and elbow up (personal communication, March 3, 2023). They are not allowed to leave their arms dangling to rest either, as they must remain within the sterile area. In addition,

Figure 14. Surgeons watching the screen during laparoscopic surgery. As can be seen this surgery requires great hand-eye coordination with indirect vision.

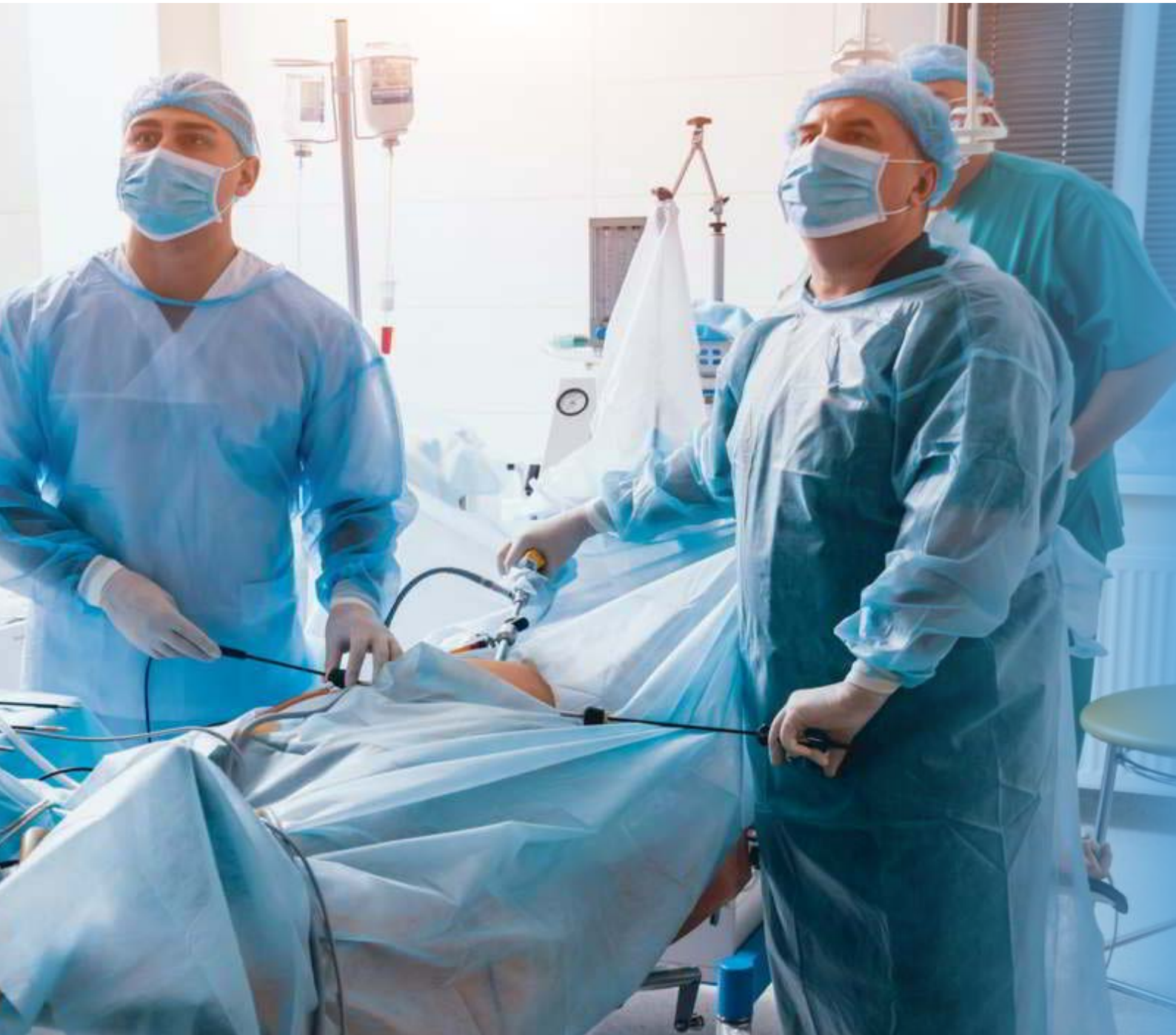


Figure 15. Surgeon using his tools upside down.

there is very little space for the surgeons to manoeuvre, they are intertwined with each other's arms during surgery, resulting in surgical equipment being used sideways and upside down for longer periods of time (Figure 15)(Appendix D).

The challenges involved in closing mesenteric defects by hand include the transfer of the needle from one grasper to another, tissue slipping due to its elasticity, and difficulty positioning the tissue correctly (See Figure 16)(Wochner, 2022). As pointed out by Leonard et al. (2014), the difficulties associated with laparoscopic surgery are most significant when the task requires precision, repetition, and flexibility, such as reconstructing or suturing (Harrington et al., 2018).

Moreover, the study by Lazaridis et al. (2022) showed that in almost half of the patients, at least one MD reopened despite routine closure of both MDs with non-absorbable sutures during primary LRYGB (for both interrupted and non-interrupted stitches). Consequently, almost half of the patients remained at risk of potential IH despite primary closure. One possible explanation is that mesenteric fat loss no longer provides adequate closure of MDs (Lazaridis et al., 2022; personal communication, March 3, 2023). Closing the Petersen's space and the mesojejunal space with a stapler requires perfect alignment of both sides of the mesenteric window. The stapler used must be refilled three to four times during surgery, requiring cumbersome

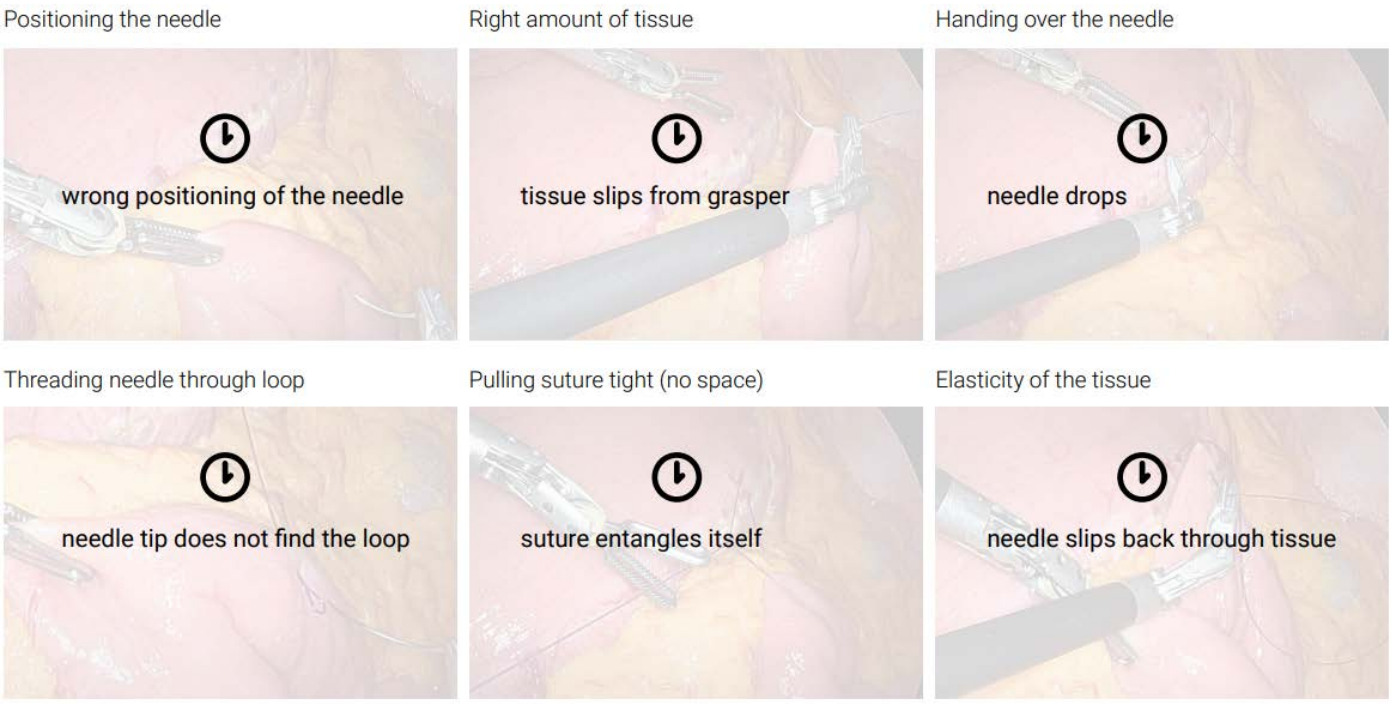


Figure 16. Challenges of suturing by hand (Wochner, 2022).

additional steps and precious time (personal communication, March 3, 2023). Moreover, 50% of all staples fall out over time, due to these not being positioned correctly, to begin with, or due to mesenteric fat loss afterwards (personal communication, March 3, 2023).

Both of these closure procedures have the potential to go very wrong. Therefore, they should only be done by experienced surgeons who have been trained to do it (Alhamdani, 2020; personal communication, March 3, 2023).

The primary aim of this project is to develop a new technique for closing mesenteric defects after Roux-en-Y gastric bypass surgery that is more efficient than traditional suture lines and staplers. The proposed solution should help maintain low complication rates while minimizing intra-operative costs and time spent on defect closures by providing an alternative approach that involves no suturing and does not require tissue alignment.

These requirements, along with others that must be met by the product in order to be successful, are compiled in a comprehensive list of requirements (Appendix B)(Zijlstra et al., 2020, p.103). Figure 17 illustrates the prioritisation of the formulated requirements.

The project's most relevant requirements focus on ensuring adequate long-term closure and healing of the tissue after surgery, which are critical for patient safety. The comfort of the surgeon is also important as it directly impacts the

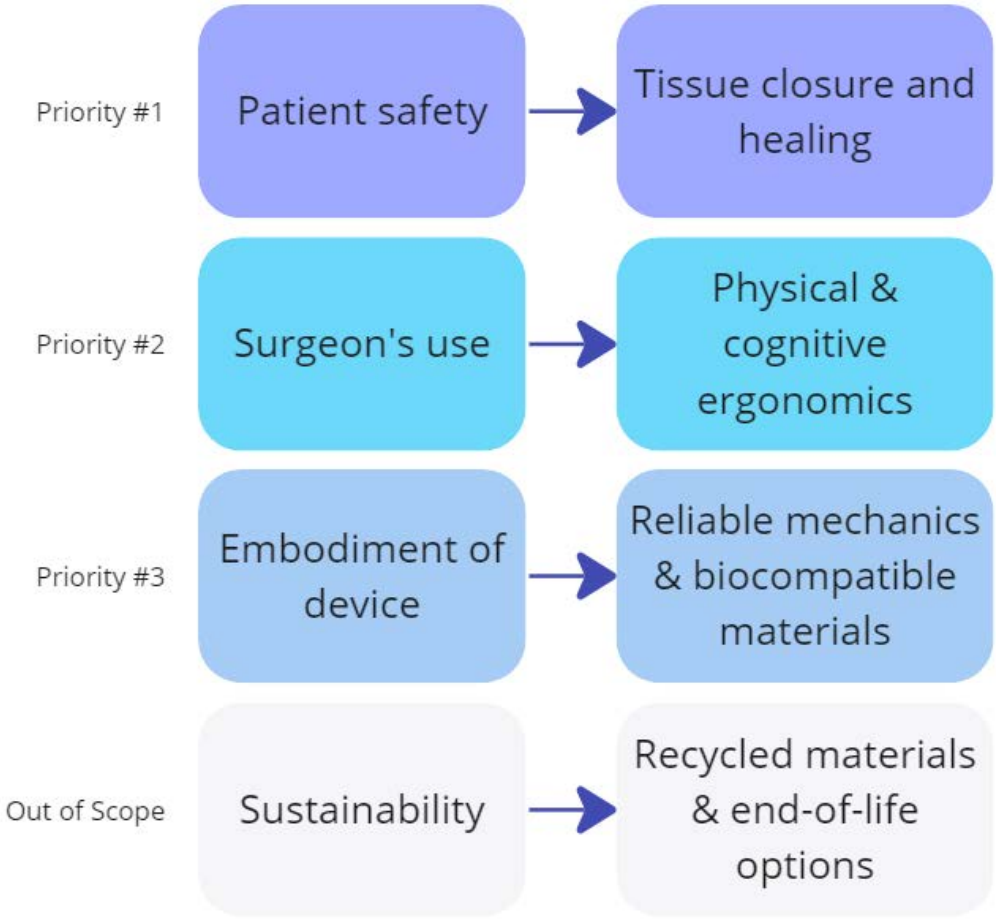


Figure 17. Overview of prioritised requirements.

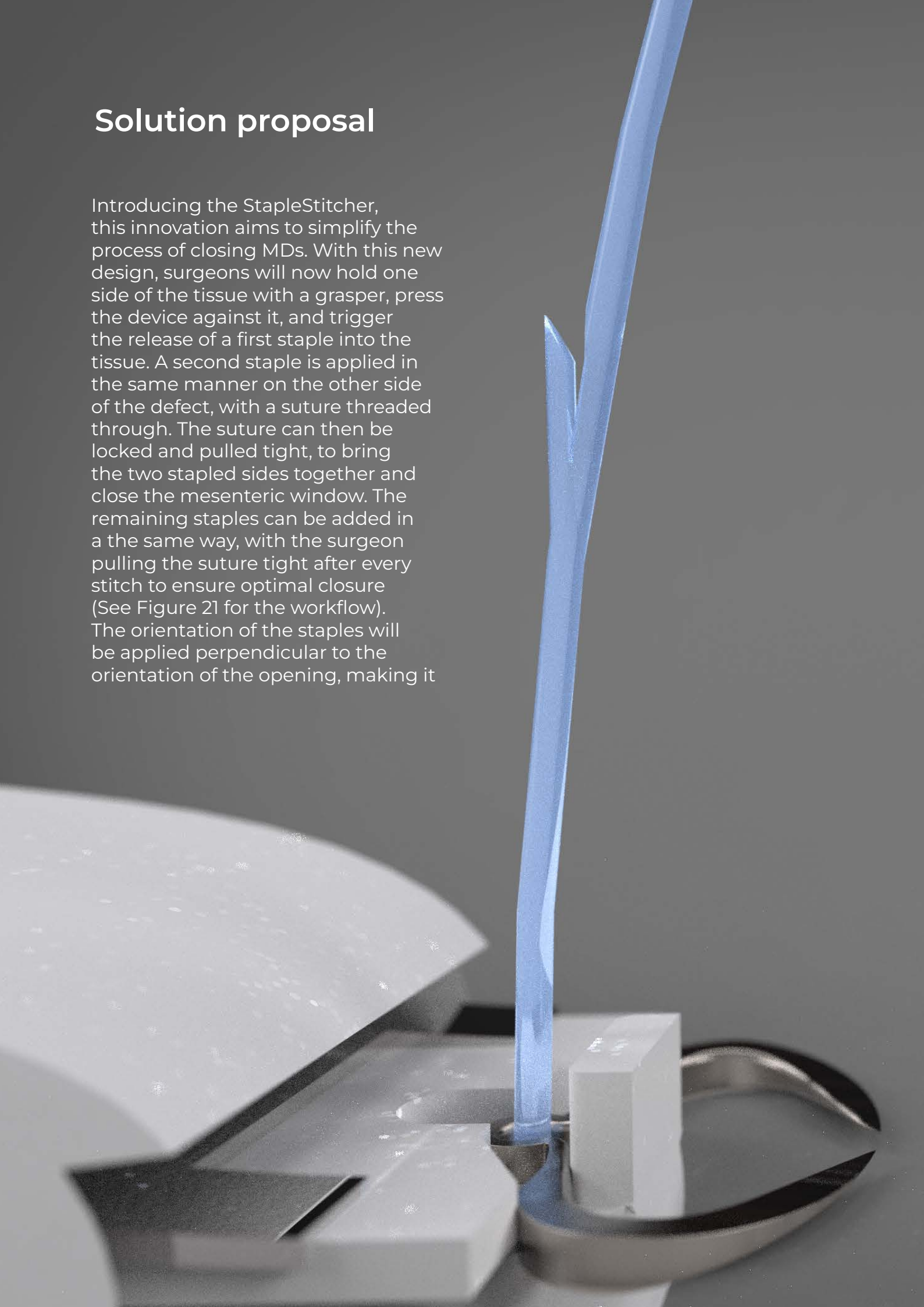
quality of the surgical outcome. Physical ergonomics play a role in providing the surgeon with appropriate haptic feedback and easy access to the defect. Cognitive ergonomics considers the difficulty of the operation and the time required for defect closure. The embodiment of the solution must enable the surgeon to perform all necessary actions without adverse health effects on the patient. Lastly, sustainability is a consideration that can only be addressed once the three prioritized requirements have been successfully met.

Initial research by Wochner (2022) has been done on alternative closure methods and devices. These were then examined for costs, closure times, comfort, ease of use, safety, fixation quality, and suitability for closing mesenteric defects. Additionally, a further search, complementary to that of Wochner's, can be found in Appendix G. Nonetheless, in practice, no devices or methods were found to be used to close MDs other than the previously mentioned staplers and manual closure using sutures.

A search for a comparable mechanism, in totally unrelated areas of application, was conducted but that too resulted in a dead end. The entire internet was scoured, featuring a quadrilingual search, but to no avail. It seems that a mechanism involving wiring and staples, tacks or other combination does not yet exist. Furthermore, the orientations of staples in staplers, tacks in tackers and nails in nail guns were always found to be perpendicular to the application direction and never parallel. This entails that a new type of cartridge has to be invented, in order to fit through a trocar. These identified gaps and unmet needs allow the creation of a product that differentiates itself from all other devices on the market.

Solution proposal

Introducing the StapleStitcher, this innovation aims to simplify the process of closing MDs. With this new design, surgeons will now hold one side of the tissue with a grasper, press the device against it, and trigger the release of a first staple into the tissue. A second staple is applied in the same manner on the other side of the defect, with a suture threaded through. The suture can then be locked and pulled tight, to bring the two stapled sides together and close the mesenteric window. The remaining staples can be added in a the same way, with the surgeon pulling the suture tight after every stitch to ensure optimal closure (See Figure 21 for the workflow). The orientation of the staples will be applied perpendicular to the orientation of the opening, making it



easy for the surgeon to place staples and pull the suture tight, instead of having to rotate every alternating staple. This new workflow allows for easier closure, fewer manoeuvres needed and thus less discomfort and cognitive strain. By incorporating an optimised shape of staples and barbed sutures, this device may offer a more secure closure that is less likely to slip open, providing better patient outcomes (Figure 18 and 19).

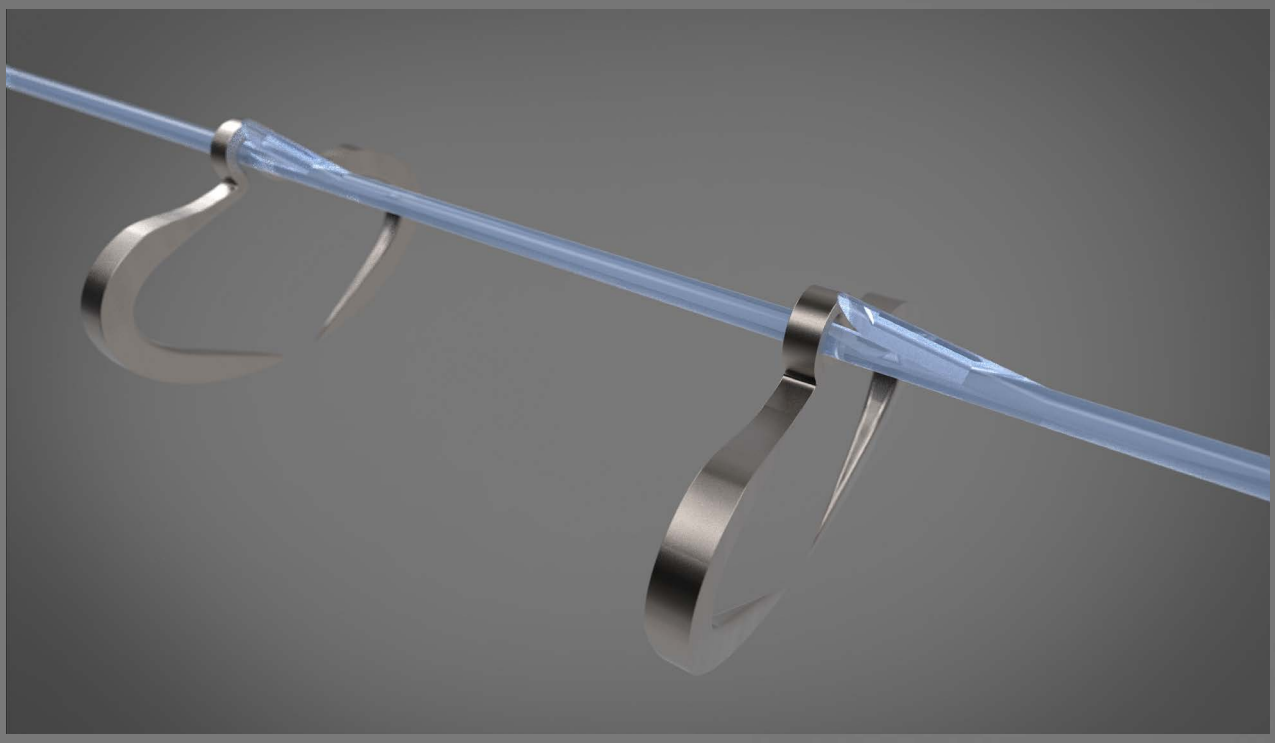


Figure 18. Staples clicked and bent onto the barbed suture.

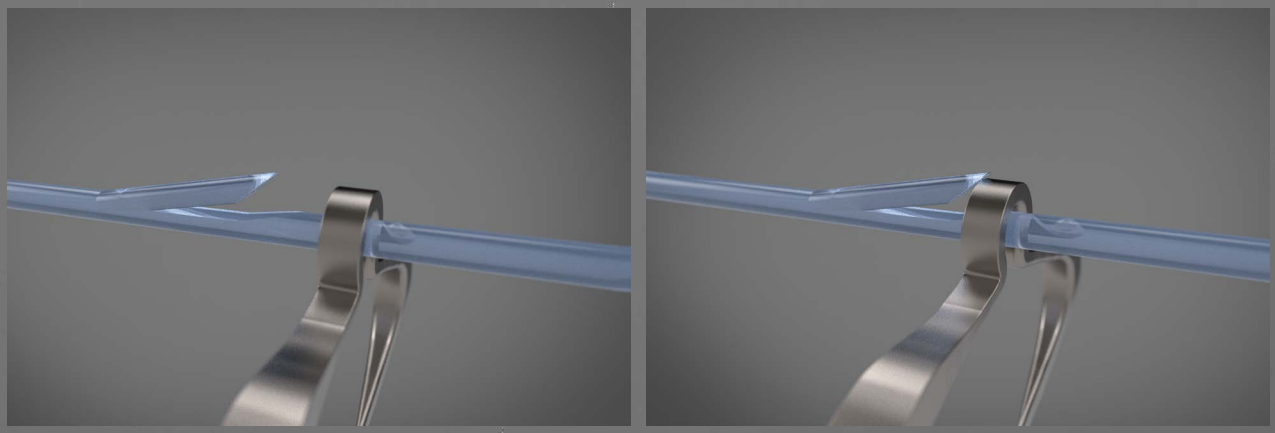
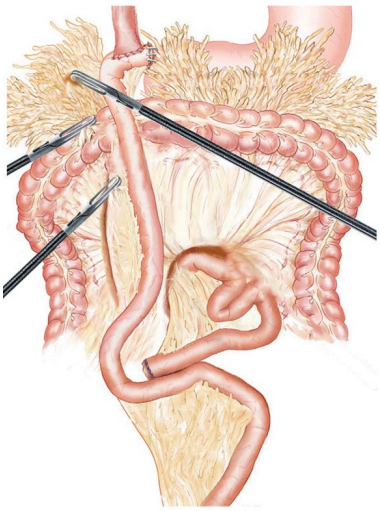
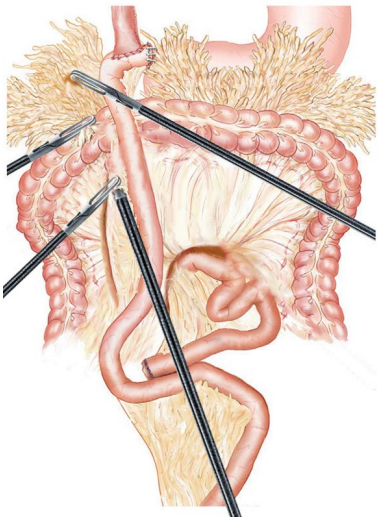


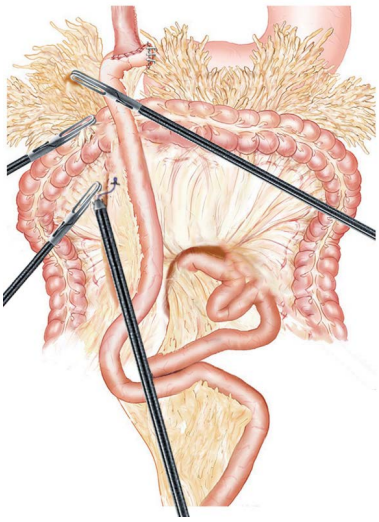
Figure 19. The barbs from the barbed suture refrain the suture from sliding back open.



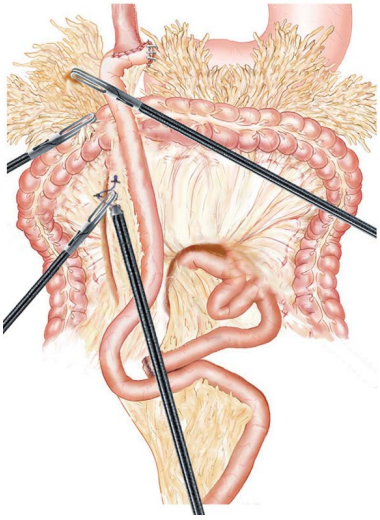
Hold tissue with grasper



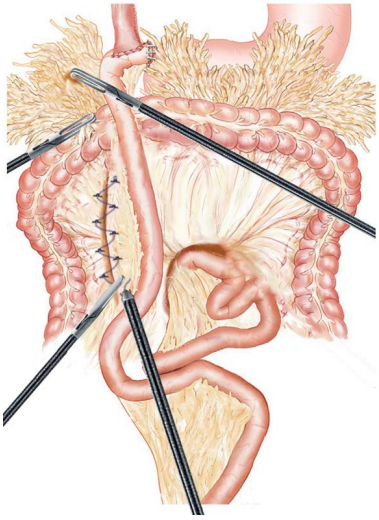
Place the first staple



Place the second staple



Continue until the end of the defect



Tighten everything at once and cut the remaining strand with scissors

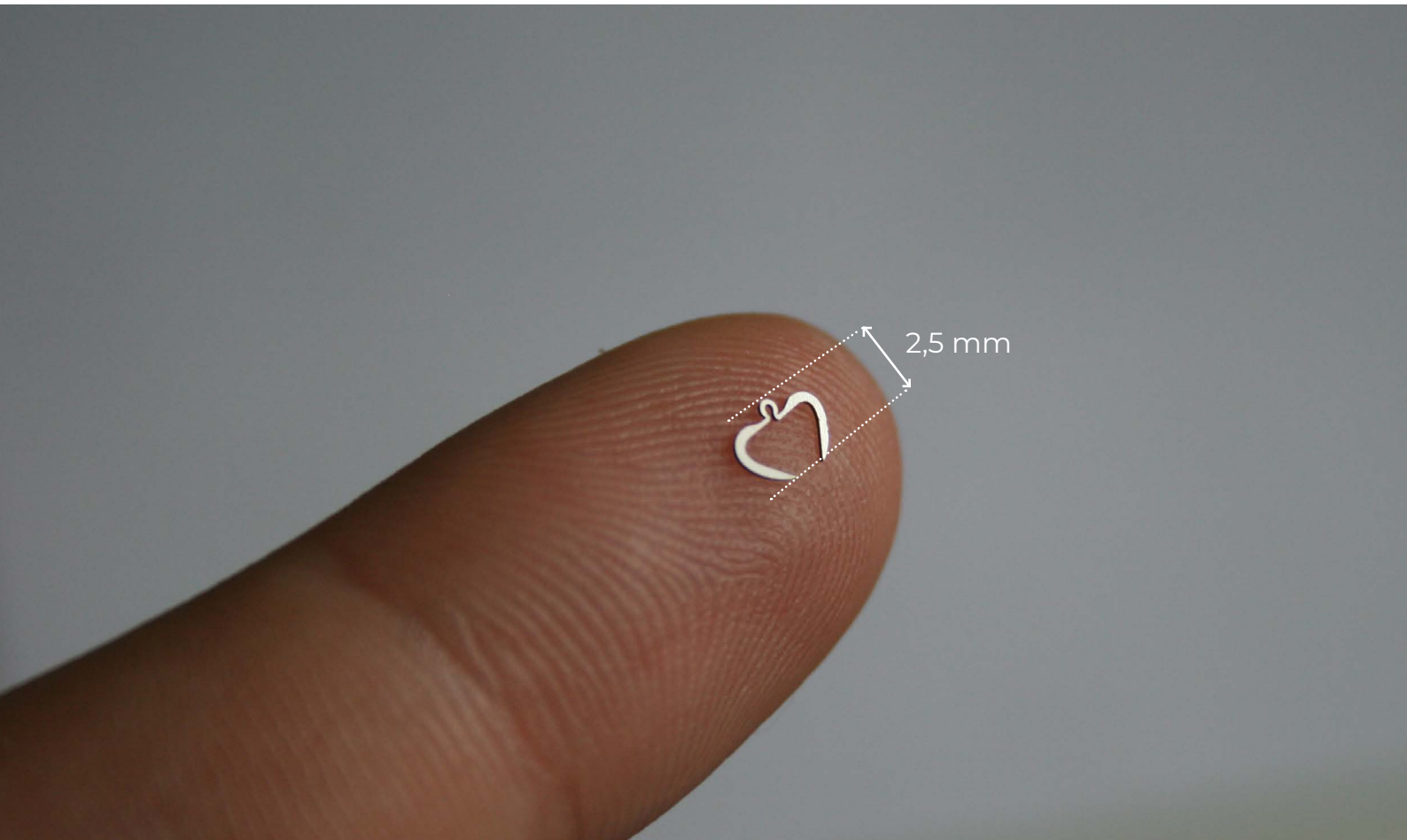
Figure 20. The new workflow using the StapleStitcher. Visualised in the same manner as the aforementioned suturing and stapling. The device here is visualised in black, unlike the renders where it is seen in white (adapted from Collard et al., 2020).

Staple and suture design

Staples

These staples are placed onto the barbed suture, just before bending them into the mesenteric tissue. When the staples are applied to the tissue, the shoulders of the staples close during bending, preventing the suture from getting out. The head of the staples is designed with a slanted side at the bottom to easily guide the suture into the opening, and a convex fillet on the outside edges for easy tightening of the suture. The shoulders of the staples are made thinner than the legs to ensure that the material bends in that location, and ends up forming a “B-shape” (Appendix E). This staple’s legs have a rounded-off profile, to achieve optimal tissue piercing while mitigating the risk of tissue tearing. Additionally, the staple legs are designed with atraumatic tapered tips, incorporated to minimize tissue squishing and reduce the potential for necrosis and additional tissue damage. The height of the unbent staple is 2,5 mm, its length is 5,5 mm and its width is 0,5 mm. Renders of the staple can be seen in Figure 22.

Figure 21. A photograph of a lasercut staple model, used in strength tests. This example has been bent halfway. Fingertip for scale.



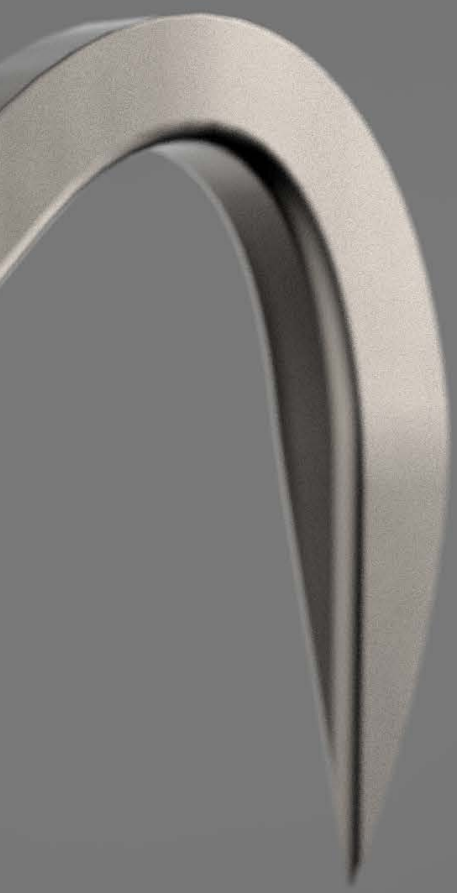
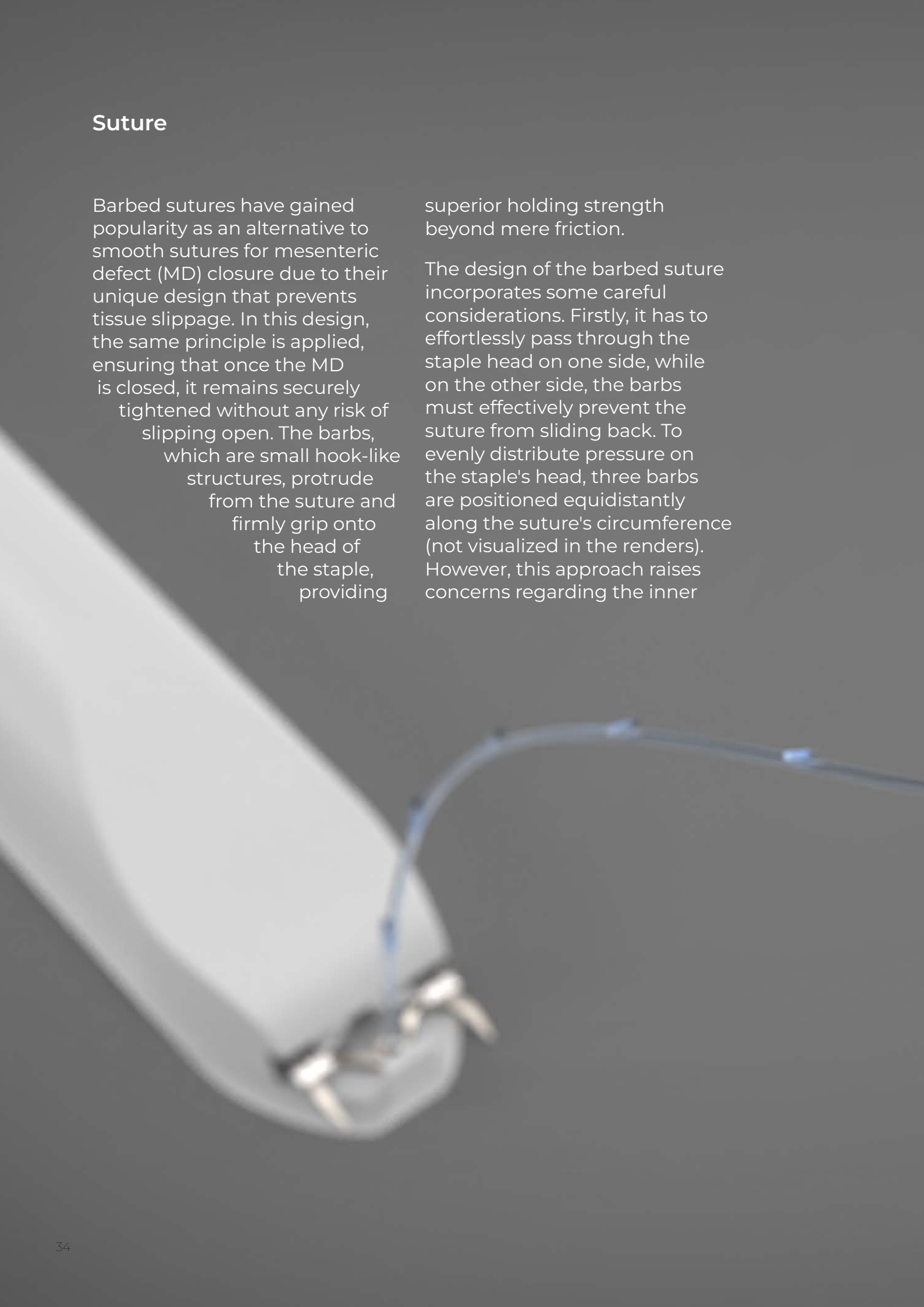


Figure 22. Renders showcasing the specially designed staple featuring slanted opening to guide barbed suture ito the head (bottom left), a fillet at the side of the head to reduce friction whe tightening the suture (bottom middle), a rounded-off profile on the legs for optimal tissue piercing and atraumatic tapered tips to minimize tissue squishing and reduce the risk of necrosis and additional tissue damage (bottom right).

Suture

Barbed sutures have gained popularity as an alternative to smooth sutures for mesenteric defect (MD) closure due to their unique design that prevents tissue slippage. In this design, the same principle is applied, ensuring that once the MD is closed, it remains securely tightened without any risk of slipping open. The barbs, which are small hook-like structures, protrude from the suture and firmly grip onto the head of the staple, providing superior holding strength beyond mere friction.

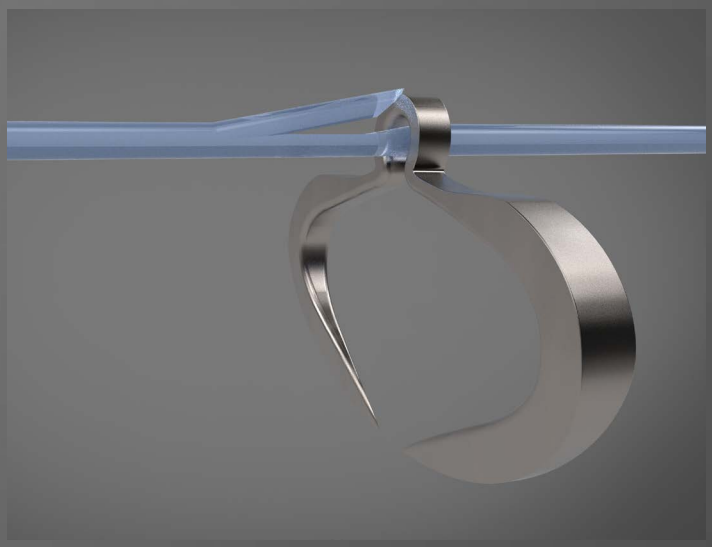
The design of the barbed suture incorporates some careful considerations. Firstly, it has to effortlessly pass through the staple head on one side, while on the other side, the barbs must effectively prevent the suture from sliding back. To evenly distribute pressure on the staple's head, three barbs are positioned equidistantly along the suture's circumference (not visualized in the renders). However, this approach raises concerns regarding the inner



radius of the suture, as cutting the barbs at the same height may increase the risk of breakage. To address this challenge, a dual-cut technique is employed in the suture manufacturing process (Appendix I). This allows the barbs to collapse and smoothly slide through the staple head, while maintaining an adequate inner radius.

Moreover, ensuring the stability of the entire suture is of utmost importance. To prevent the suture from slipping through all staples when tightened, a loop has been incorporated at the beginning of the suture (which can be seen next to this text). This loop acts as a stopper, restricting the suture's movement beyond the first staple. Consequently, the suture can be securely tightened without the need for additional knots.

Figure 23. Render showing the dual-cut design of a single barb. Only one barb has been visualised instead of three for simplicity.



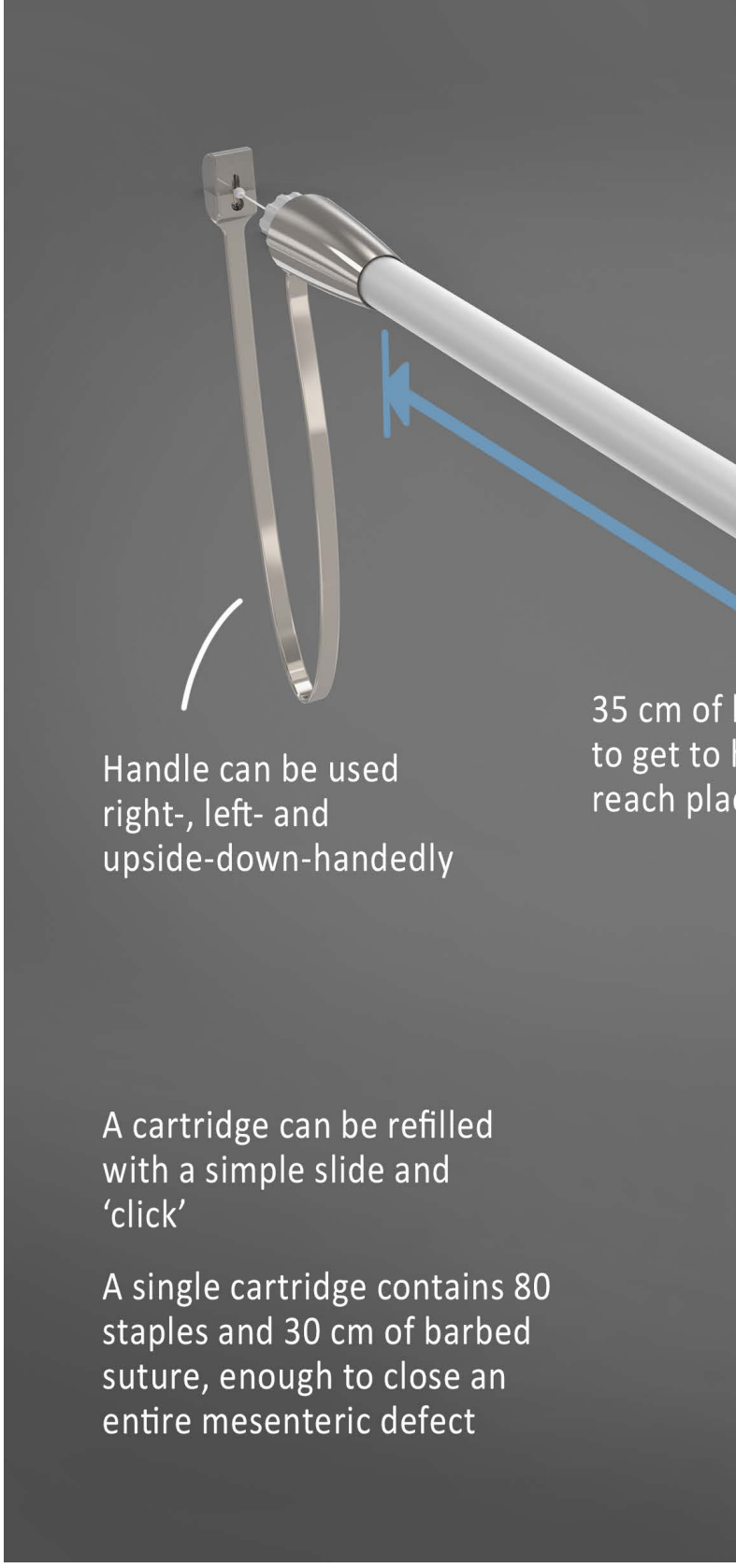
Applicator design

The successful implementation of the stapling and suturing technique for mesenteric defect closure relies heavily on the design of a specialized applicator. This chapter delves into the intricacies of the StapleStitcher's design, highlighting its key features, components, and mechanisms.

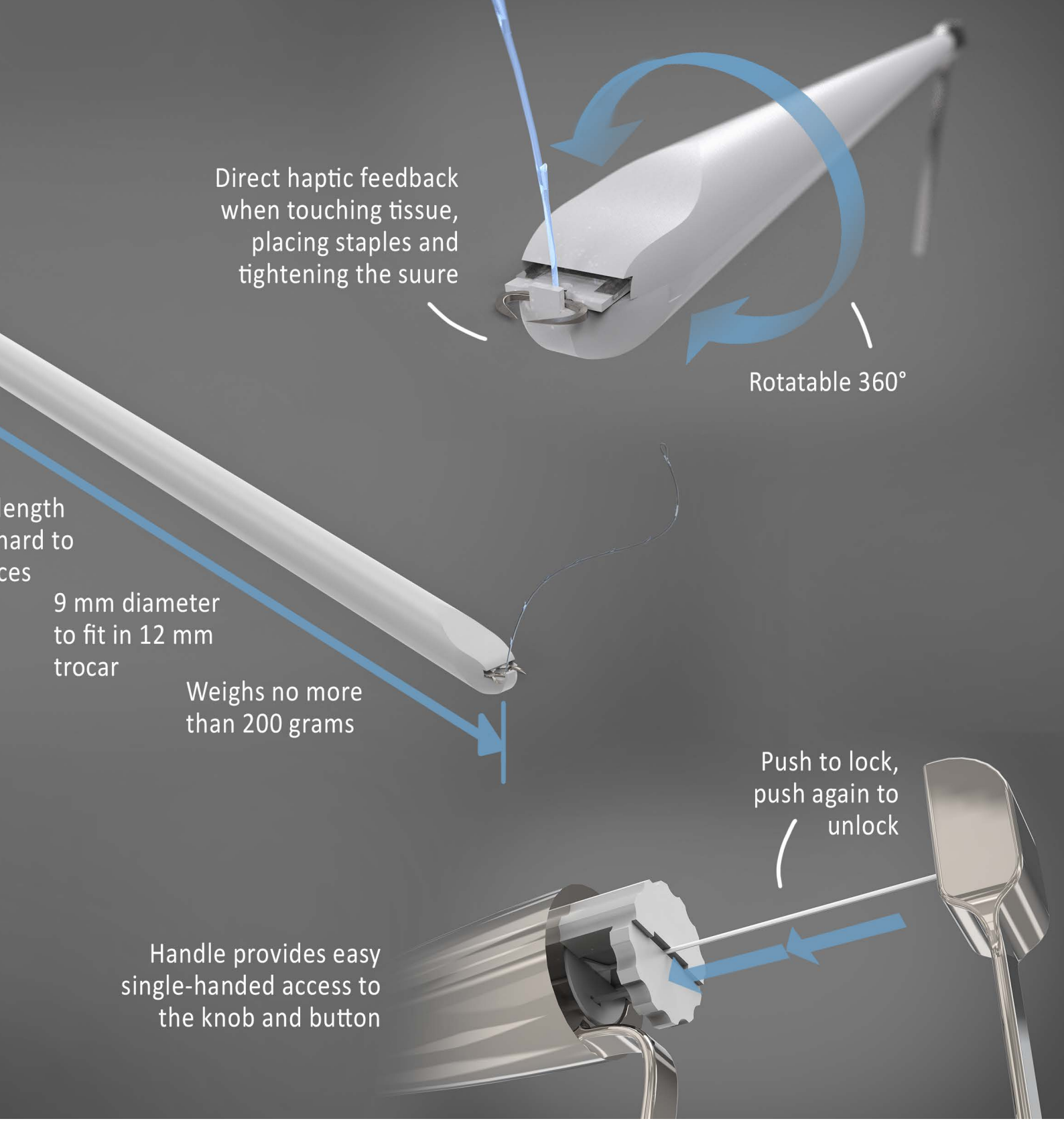
The StapleStitcher incorporates a range of noteworthy features, each contributing to its functionality and ease of use. The function overview in Figure 24 provides a comprehensive view of these features.

To begin with, the design includes a rounded off tip and a round shaft, facilitating effortless insertion into a trocar. With a diameter of only 9 mm, it seamlessly fits into a standard 12 mm trocar. The stiff shaft design ensures direct haptic feedback, enabling surgeons to operate the device intuitively.

The handle of the StapleStitcher offers convenient access to essential controls. It allows for 360-degree rotation, granting surgeons control over the device's positioning. The suture locking button, easily accessible on the handle with a double-push mechanism, enables tightening of the sutures.



Considering user comfort and maneuverability, the device has been engineered to maintain a total weight of under 200 grams. The handle, slightly heavier than other components, contributes to better balancing and handling, ensuring



optimal control and stability during use.

In terms of cartridge usage, a single cartridge is sufficient for closing a single defect. Therefore, during a Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) procedure, a total of only 2 cartridges need to be utilized, further streamlining the surgical workflow.

Figure 24. A function overview of the device.

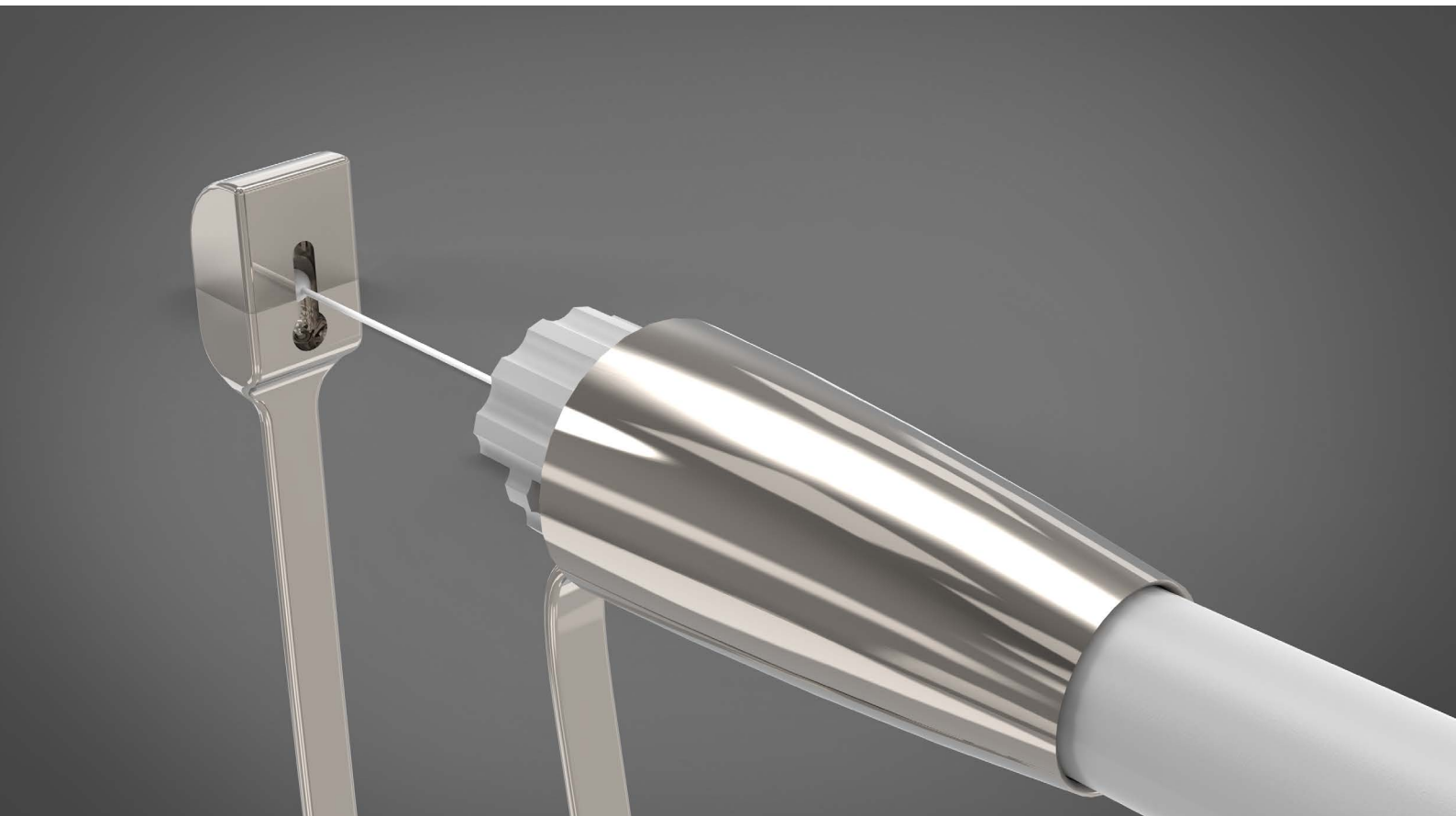
Handle

The handle of the StapleStitcher is made of surgical stainless steel, featuring a unique compliant U-like shape. This design serves a dual purpose: firstly, it enables the handle to be pressed inward to bend the staples as will be explained in the 'bending staples' subchapter, and secondly, it allows the handle to effortlessly spring back to its original position after staple placement.

This innovative handle design also serves as a source of inspiration for future medical device designs, as compliant mechanisms are infrequently employed in medical devices despite their potential for reducing material and component usage. Moreover, in this device, only the shaft and cartridge require disposal while the handle itself can be reused. This was implemented to reduce unnecessary medical waste generated by single-use devices. Additionally, the reusable and easily cleanable nature of the handle contributes to its eco-friendliness, an indispensable quality in today's context.

The handle's user-friendly functionality is enhanced by its easy assembly process. The back end

Figure 25. The handle's back end incorporates a slot with a concave sphere, designed to accommodate the insertion of the punch.



of the handle can be moved downward, and simultaneously, the loaded cartridge and shaft, can be seamlessly slid into the handle's cylinder. A circular ridge of the outside of the shaft will act as a snap fit, 'clicking' into the circular slot on the inside of the handle's cyclinder, restraining the assembly from sliding, while still allowing for 360 degrees rotation of the shaft. Then, the back end of the punch (with a sphere at the end) can be inserted into the corresponding groove in the handle. The slot in the handle enables the punch to slightly slide upward as the handle is pressed inward and vice versa.

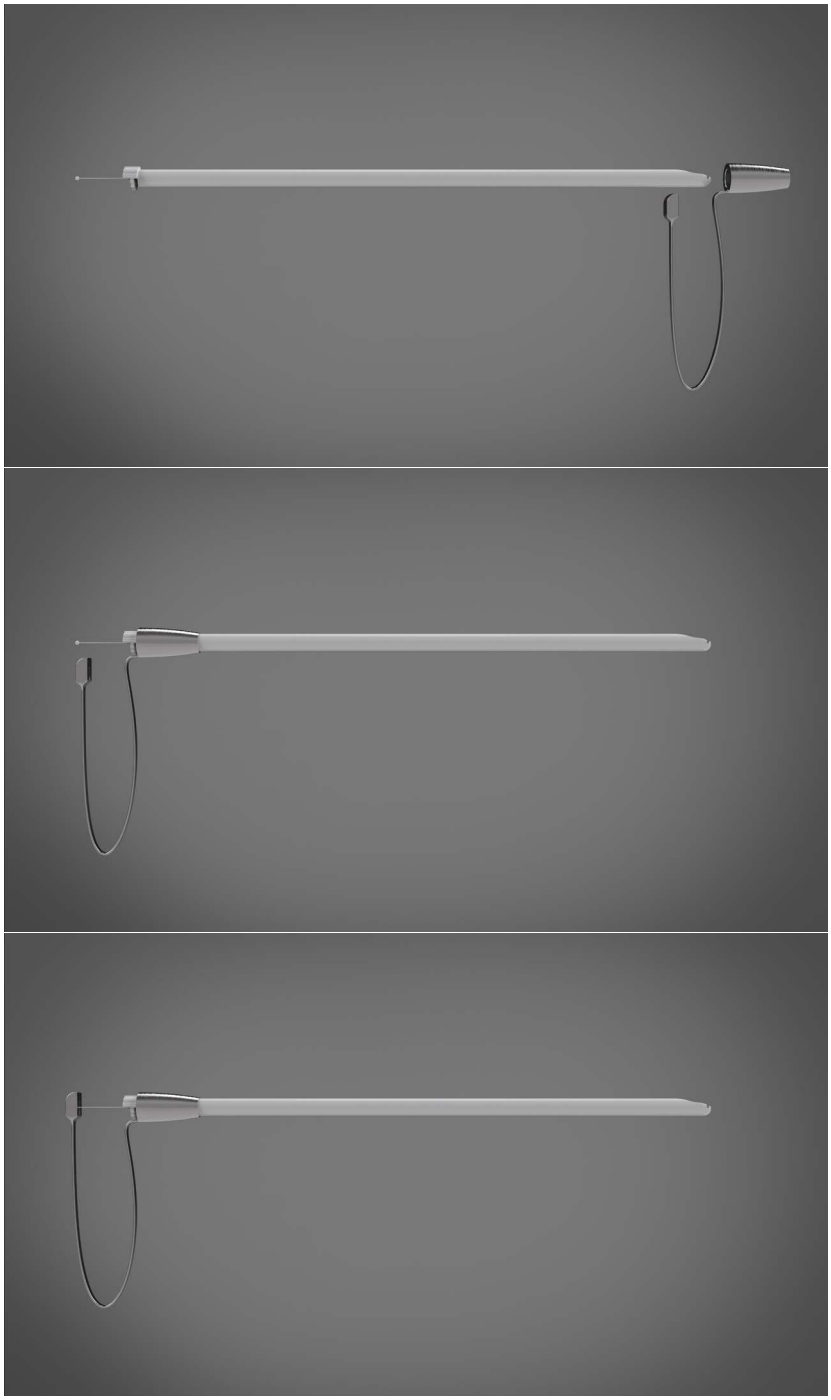


Figure 26. An overview of the assembly of the handle. In this example the cartridge is already loaded onto the shaft. It can be seen that the back-end of the handle is pushed downward, before the shaft can be slid into the cyllindrical part of the handle. Then the back-end can be pulled up and aroud the punch, so that the punch will move along with the movement of the handle's back-end.

Bending staples

Through a series of rapid iterations, a punch with an optimised shape for the bending of staples was created. This process took into account the areas where the staples needed the most support and where pressure should be applied to achieve the desired bent shape. Here, it was carefully considered when and where the staples should be “clicked” onto the barbed suture to ensure the staples will stay in place during deformation into tissue. The resulting shape of the punch was tested to be effective in providing the necessary support to ensure the correct bending of staples. The bending test can be found in Appendix J. In Figure 27 and 28 is visualised how the punch picks up a staple from the cartridge, moves it onto the suture and pushes it against the die (the die is the little extruded piece onto which the staple rests during bending).

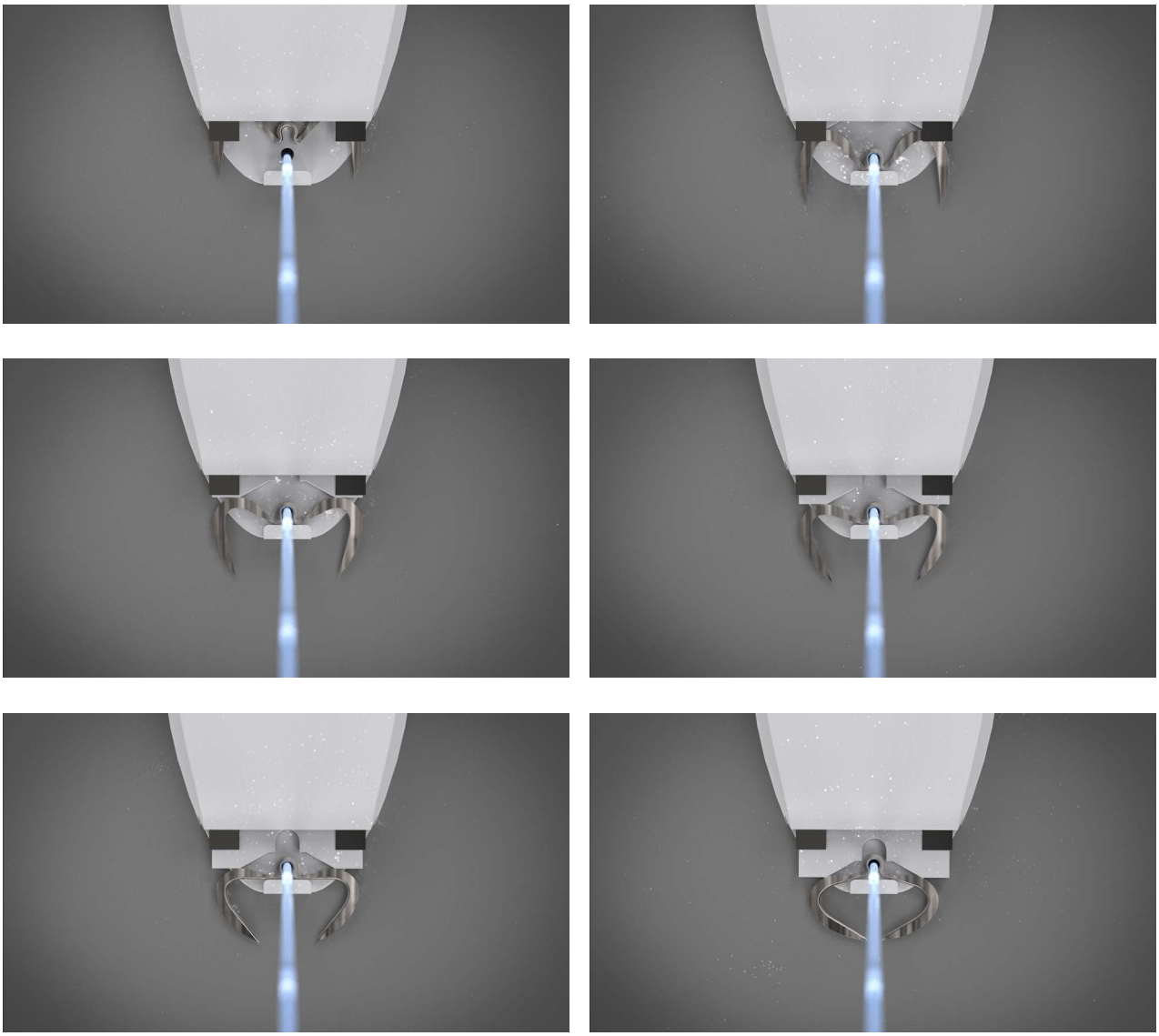
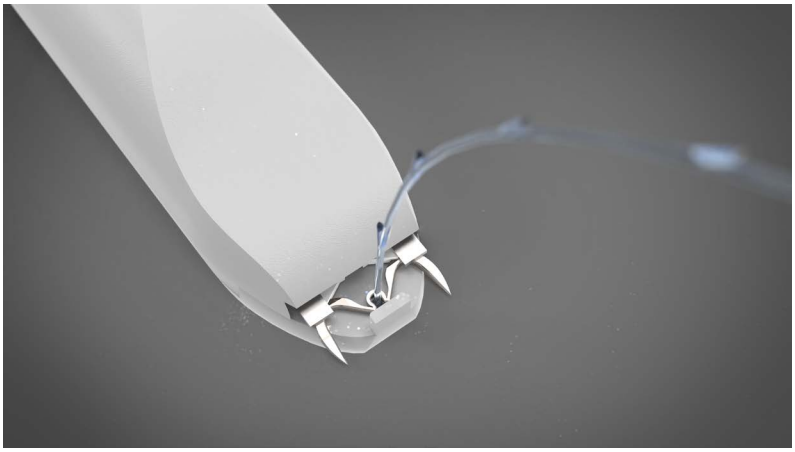


Figure 27.
When removing the cover and placeholder the punch is revealed, as can be seen in the top two renders. Here it can be seen, on the bottom two renders, how the punch slides underneath an overhang, picks up a single staple, slides it forward to the tip, onto the barbed suture and against the die.



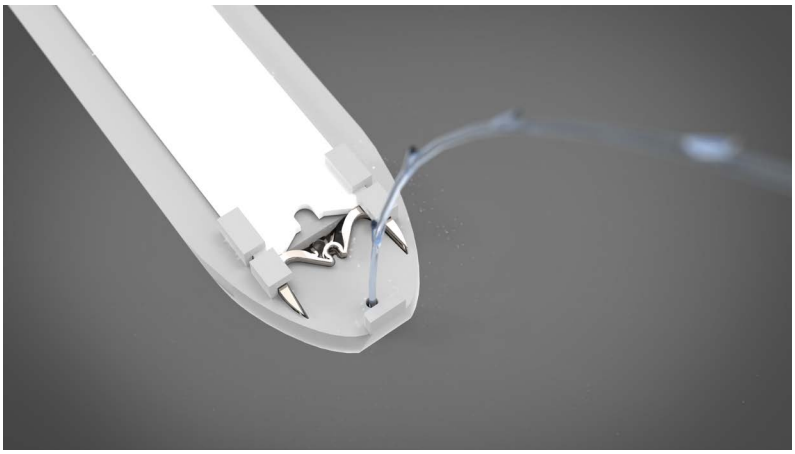
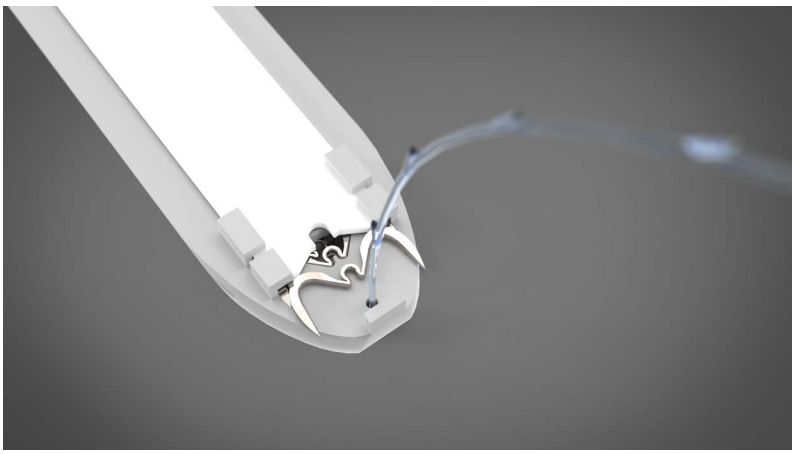
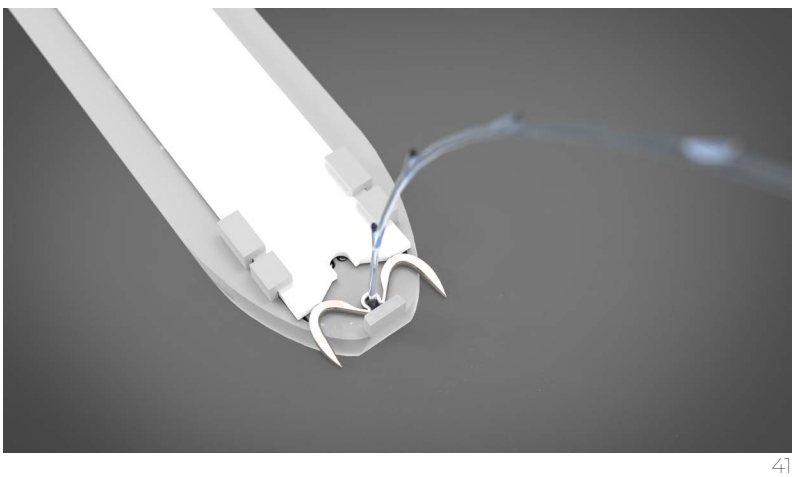


Figure 28.
When a staple pushed against the die, it will start to deform. The punch has been designed to ensure the staples deform to the desired position. This process is illustrated in the renders left, from top left to bottom right.





Placeholder

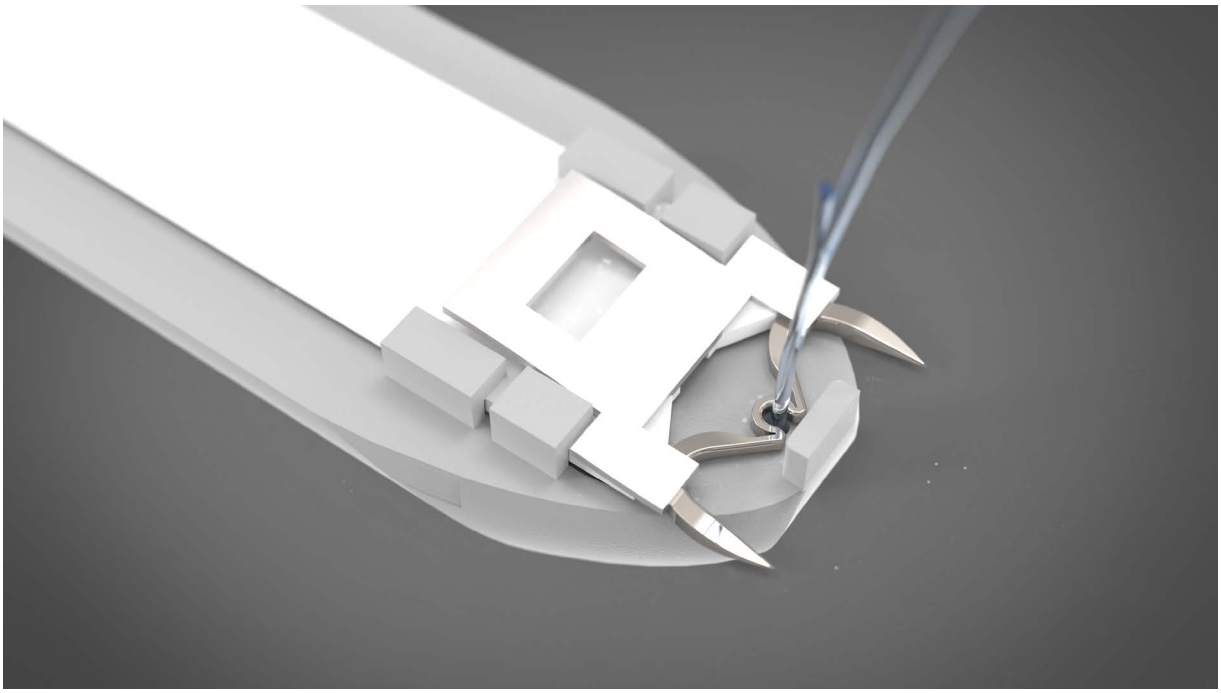


Figure 29. A render of the placeholder, a spring, that will hold the staples in place when bending.

A spring will ensure that the staples do not fall out of the tip when bending them. The spring must only hold the staple in place while bending as the staples must be released afterwards, which is the reason it only pushes the staple down against the top part the legs (Figure 28 and 29). When bent, the staples are not touched by the spring anymore and can thus slide off of the die.

Cartridge

The cartridge design plays a crucial role in ensuring the seamless functionality of the device. The cartridge design is crucial for the proper functioning of the surgical device as a whole. Reloading the cartridge is quick and easy, achieved by simply sliding it into the slot and clicking it into place. The audible click confirms that the cartridge has been placed correctly.

Inside the cartridge, each component serves a specific function to ensure optimal performance. Meticulous attention has been dedicated to designing the cartridge to dispense staples in a straight line, free from tilting or jamming issues. A key aspect of achieving this objective involved orienting the staples as flat as possible, leading to a compact and efficient design.

However, an entirely horizontal orientation of the staples caused them to bend and jam against the cartridge's side walls. To overcome this issue, an initial assumption of a 15-degree angle was made, which underwent validation through rapid testing using a 3D-printed model, as outlined in Appendix K.

This design achieves efficient staple deployment while maintaining a compact cartridge. This critical component ensures the reliable and effective functioning of the system as a whole.

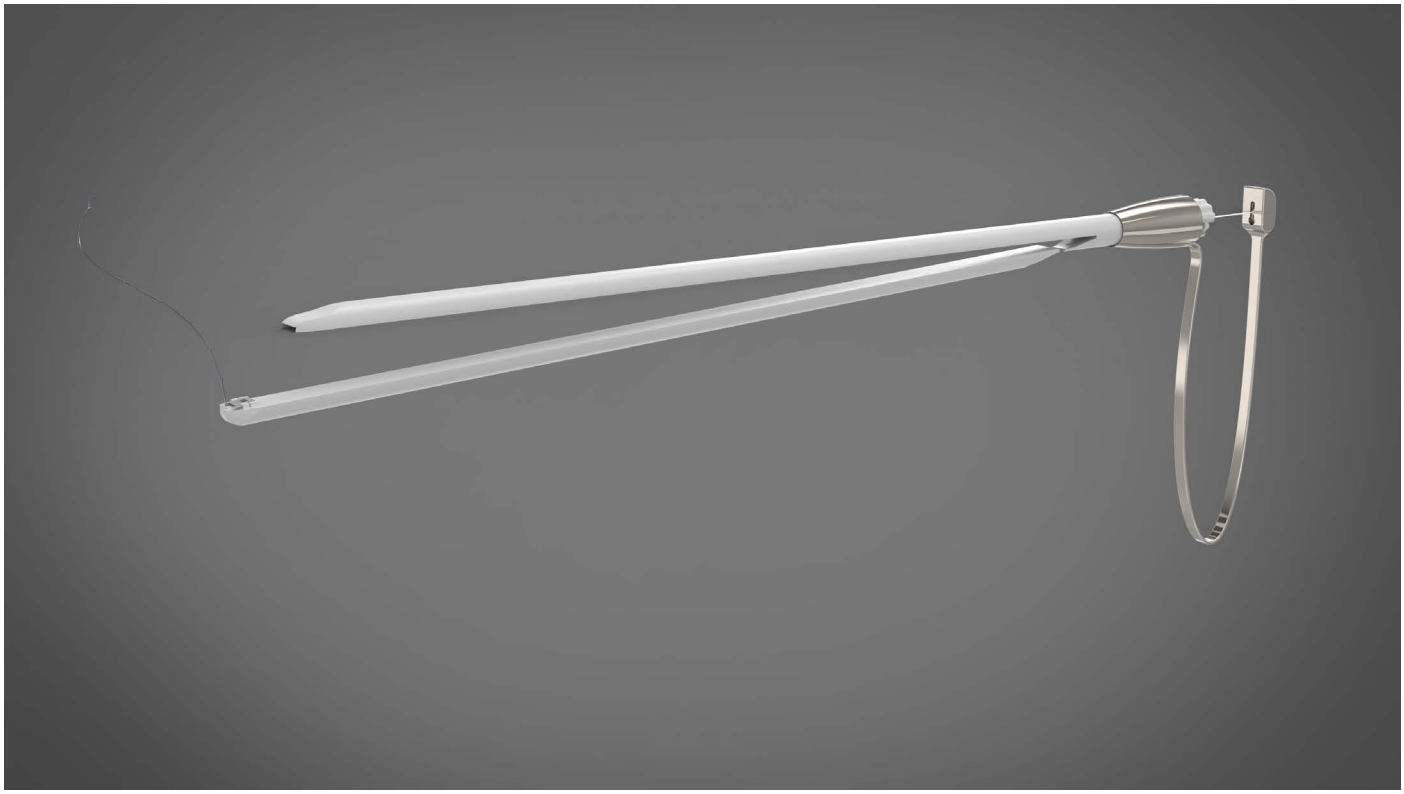
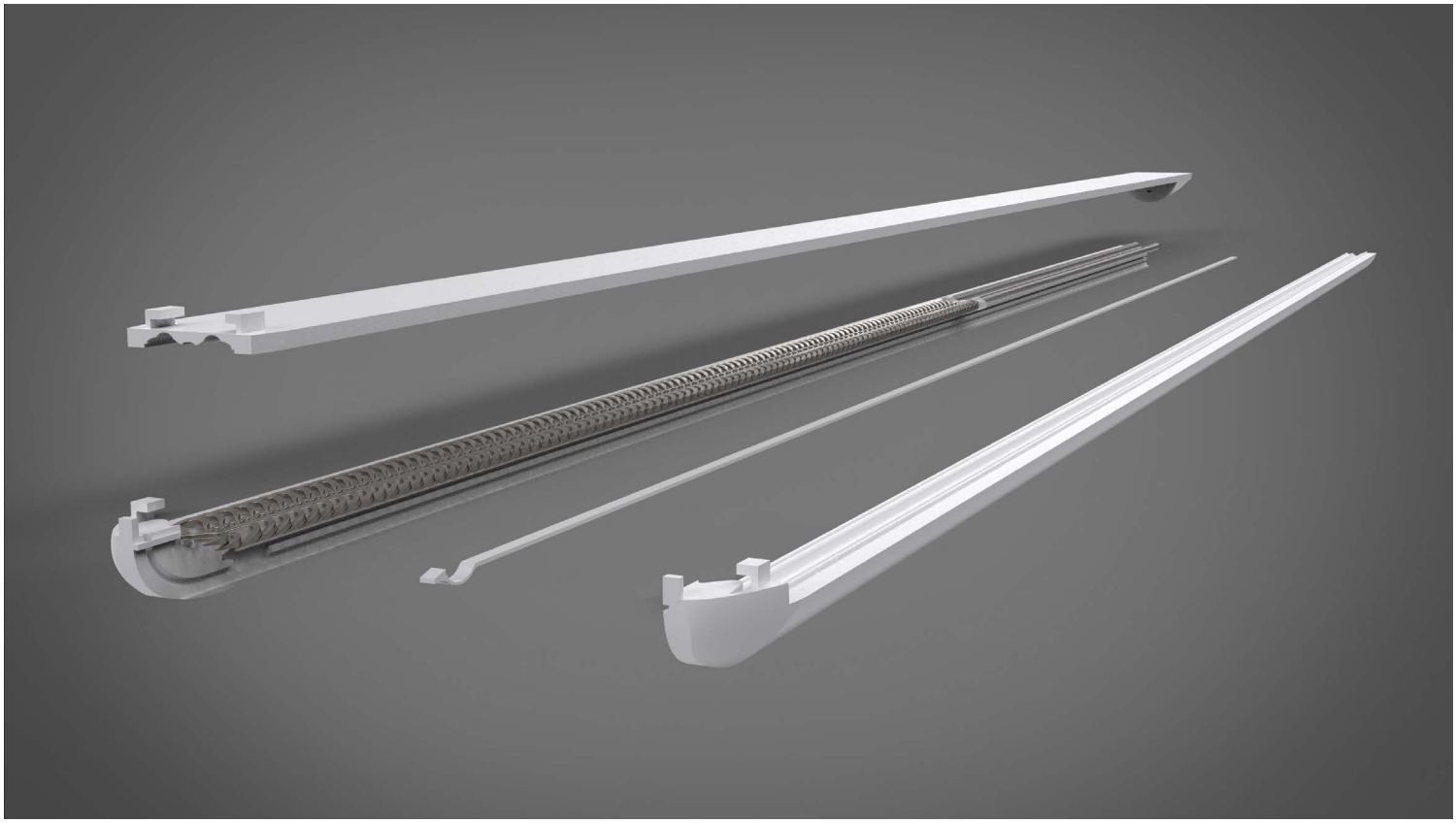
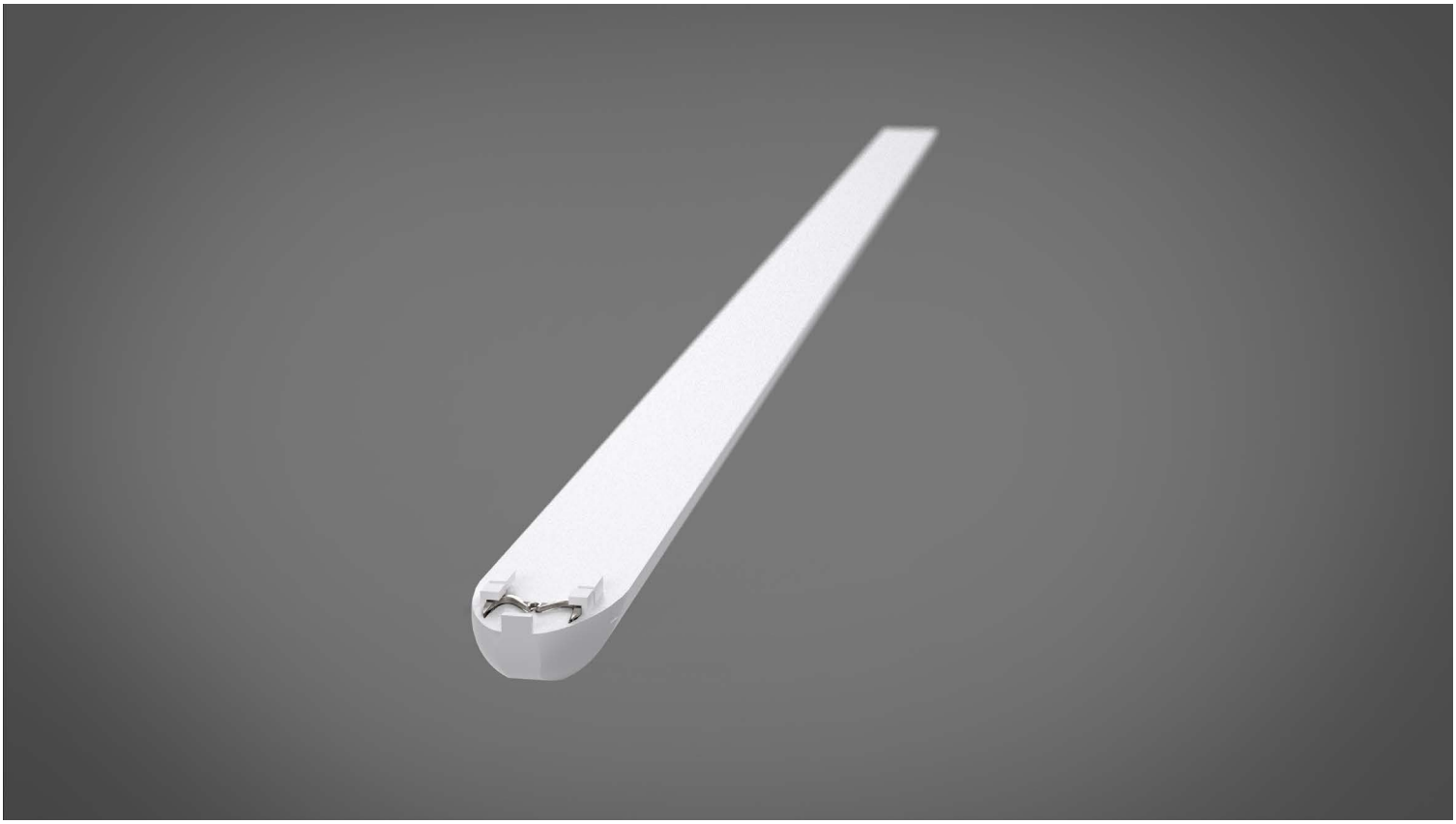


Figure 30. A render of the cartridge and how it is inserted into the applicator.

Figure 31. In the bottom two renders, the back (left) and front (right) of the cartridge can be seen. In the top left render, another viewpoint of inserting the cartridge into the main shaft can be seen. On the top right, an exploded view of the cartridge can be seen. All components of the cartridge will be explained hereafter.





Staple ‘elevator’

To transfer the staples from the cartridge to the bending compartment, various designs were tested using 3D printed models with a chute, a spring, and a chamfer (Appendix K). Through these tests, it was found that a simple angled chamfer at the end of the cartridge was the most effective design. This design allowed the staples to be pushed forward in the cartridge and slide under each other at the end, resulting in the front staple being pushed upwards. At the top end, a slight overhang has been made to prevent the top staple from going up any further, while allowing the pushing rod to slide through, picking up the top staple and sliding it forward. This overhang has a ridge on the outside edge, that acts as a snap-fit which hooks onto the cover when the cartridge gets reloaded (which is not visualised in the renders).

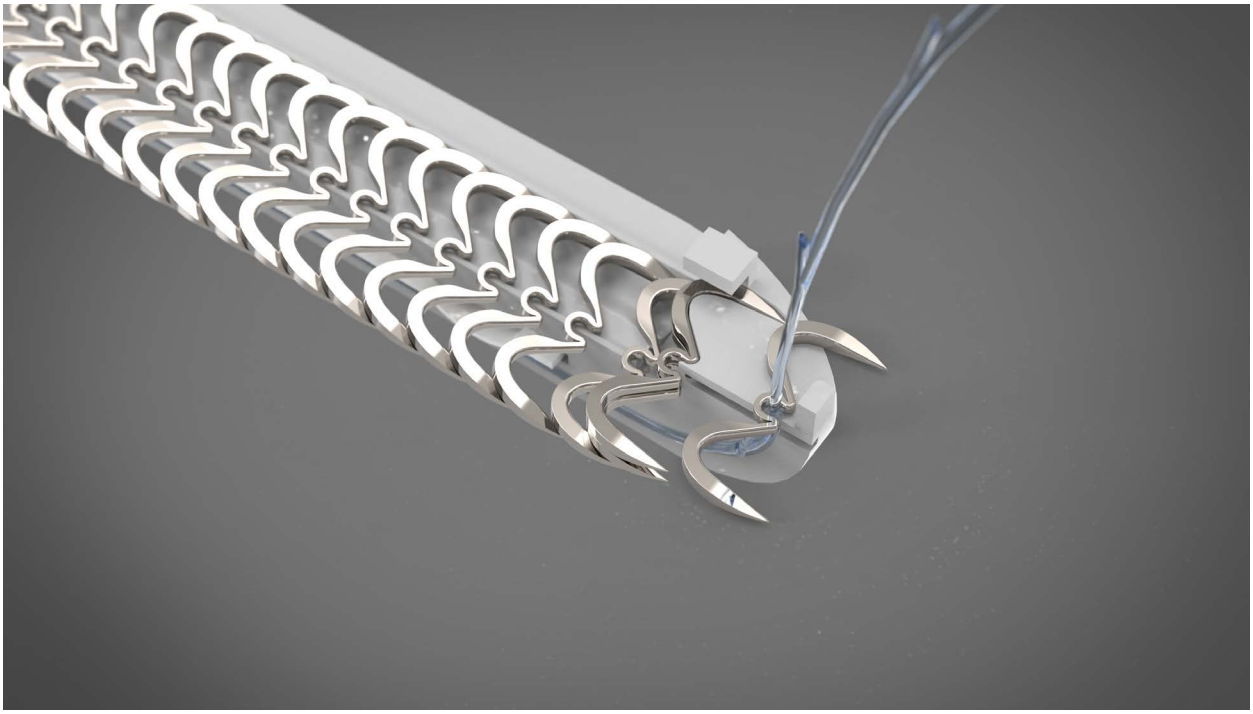


Figure 32. Here it can be seen how the staples slide under each other at the front end of the cartridge. The top staple, held back by the overhanging pieces, is not visualised to clearly show the shape of the ‘elevator’. This compartment constraints the staples from moving in any unwanted direction, before getting picked up by the punch.

Springloaded pusher

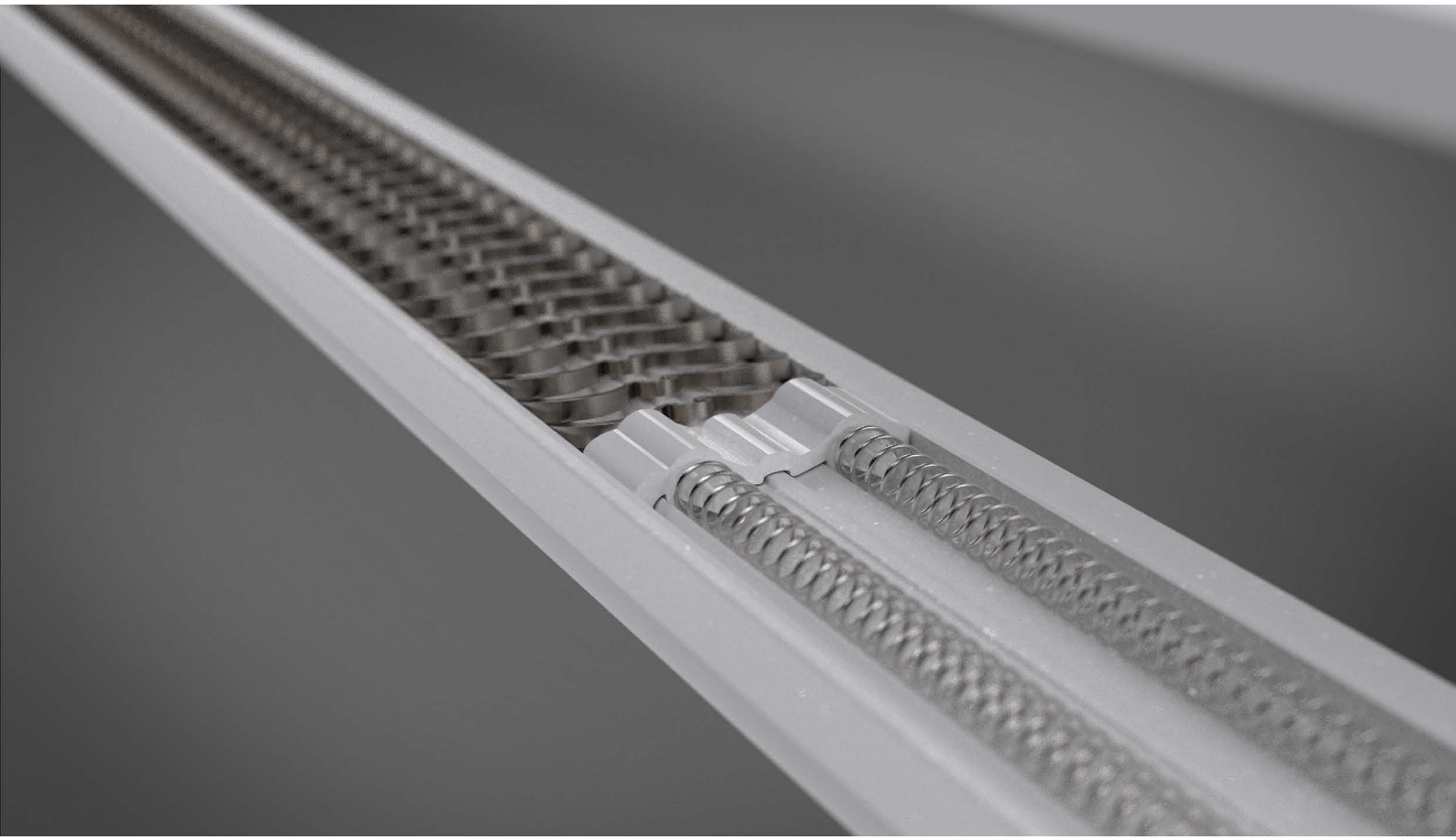


Figure 33. The springs are attatched to the pusher. The pusher is a plastic component that ensures forward movement of the staples, without causing damage.

The cartridge incorporates a spring mechanism to move the staples towards the front end. This design choice was based on its simplicity, minimal parts, and independence from the movement of the pushing rod (refer to Appendix K for the design process). A specially shaped 'pusher' (depicted in Figure 33) is strategically positioned between the staples and springs. The springs are attached to the pusher, enabling them to exert forward pressure on the staples. The naturally varying tension of the spring between its initial and final position effectively moves the staples without causing damage. The pusher is created by taking the silhouette of a 15-degree tilted staple, slightly reducing the contours for smooth sliding within the cartridge, and then extruding it.

Suture locking

On the inside of the cartridge, a tiny compliant mechanism is implemented. In its natural position, the compliant mechanism acts as a normal wall, against which the barbed suture can move freely. When a force acts upon the compliant mechanism however, the crescent part gets pushed toward the barbed suture, providing enough friction for it to restrain it from further dispensing. When the barbed suture is locked like this, it allows the surgeon to tighten the suture and thus close the MD. This single-piece design eliminates the need for additional fasteners or complex locking mechanisms.

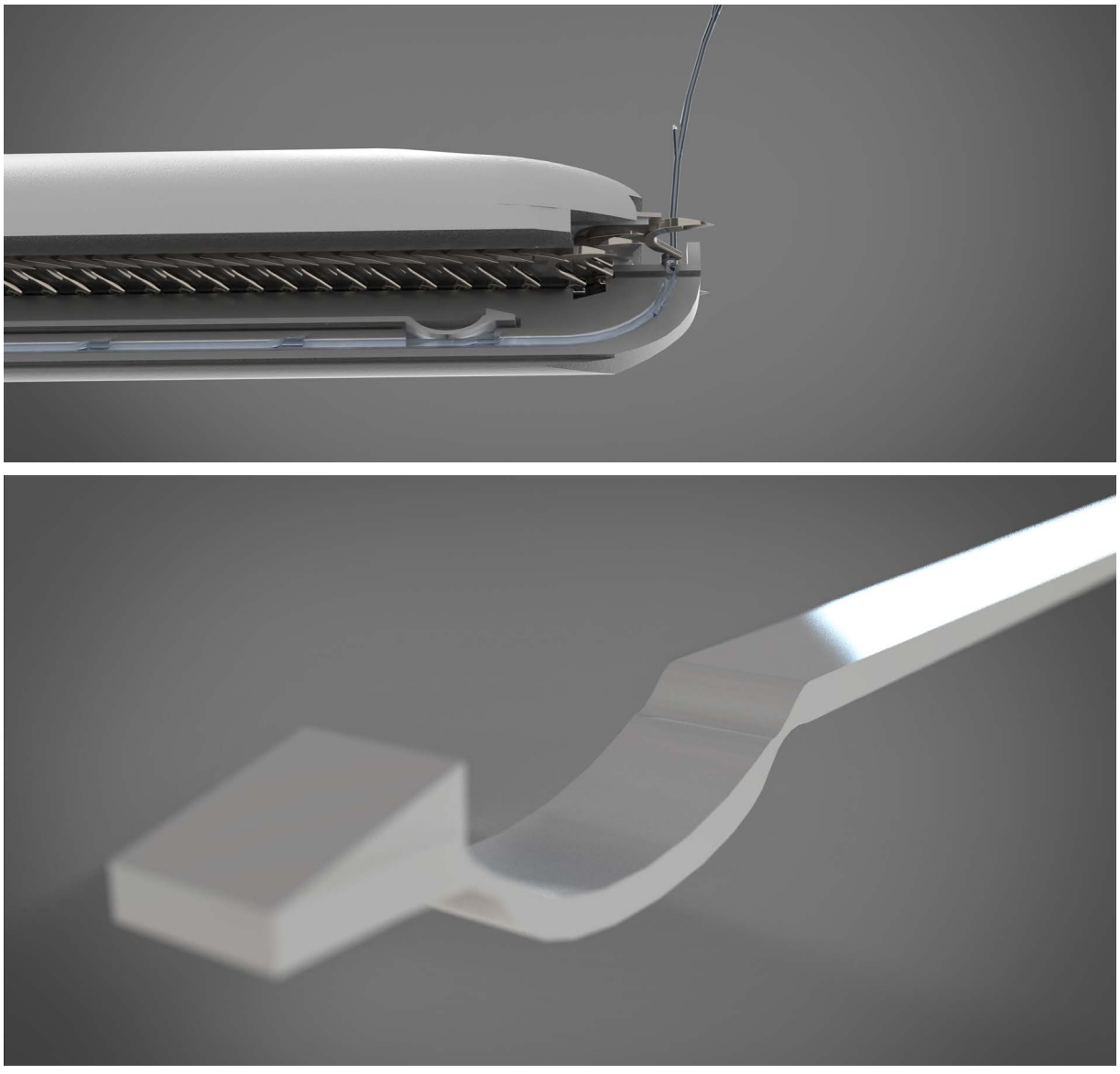
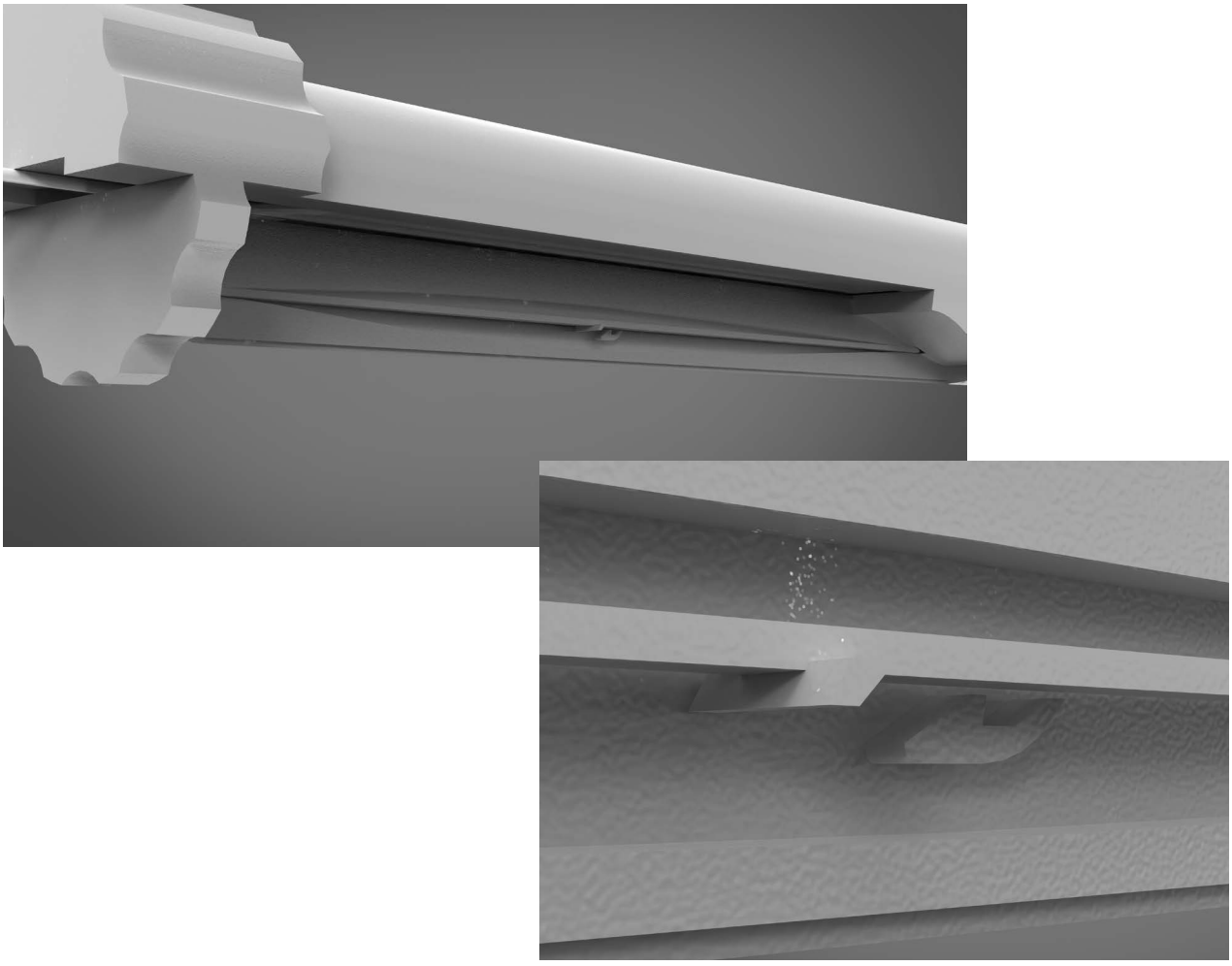


Figure 34. The compliant mechanism in the cartridge, with a crescent part that gets pushed against the barbed suture.

The force that acts upon that compliant mechanism, is provided through the double-push mechanism at the rear-end of the shaft, accessed at the handle. When pressed, the barbed suture is restrained from dispensation, in order to tighten the suture. Pressing this button again allows the suture to be dispensed freely again.

On the inside, another compliant mechanism is used. Due to this feature, the component itself can act as a pawl, moving along two linear ratchet teeth. When pushed in between the two teeth, it produces an audible ‘click’, that serves as a simple feedback mechanism for the surgeon that the barbed suture is now locked, and ready for tightening.

Figure 35. The double-push mechanim, with two linear teeth and a single ratchet, that pushes against the compliant mechanism inside the cartridge.



Packaging and instructions

The packaging design of a single-use laparoscopic stapler plays a crucial role in ensuring the device's integrity and usability. The primary purpose of the packaging is to maintain sterility throughout the shipping and storage process until it reaches the surgical environment. Additionally, the packaging serves as a protective carrier, safeguarding the stapler from any potential damage during transportation.

Efficiency is key when it comes to packaging design, and it should be fast and easy to open.

Clear use cues in the form of labelling and instructions on the packaging should be concise and easily understandable, providing clear guidance to the scrub nurse regarding the proper handling and usage of the stapler and its cartridge. This allows the scrub nurse to quickly access the device without delays or complications, streamlining the surgical workflow.

To achieve these objectives, the packaging is typically manufactured using thermoforming technology, with Eastar™ 6763 copolyester as the material of choice (as a PETG alternative). Eastar™ 6763 copolyester offers excellent clarity, impact resistance, and biocompatibility (ISO 10993), making it suitable for maintaining a sterile environment for the stapler (Medical Device and Diagnostic Industry, n.d.; Thibault, 2017). The packaging is then sealed using pharma-grade sealing machines, ensuring the integrity and sterility of the contents until the moment of use.

ISO 11607 (Parts 1 and 2) regulates package design, emphasizing the importance of treating sterile packaging as a comprehensive system. This system comprises both the sterile barrier and external protective packaging, ensuring the safe delivery of the device from manufacturing to the sterile field. Designing such packaging requires thorough design, verification, and validation processes, considering the various stresses the package will face during distribution. Compliance with ISO 11607 ensures that the package meets the necessary requirements for maintaining sterility and protecting the integrity of the medical device.

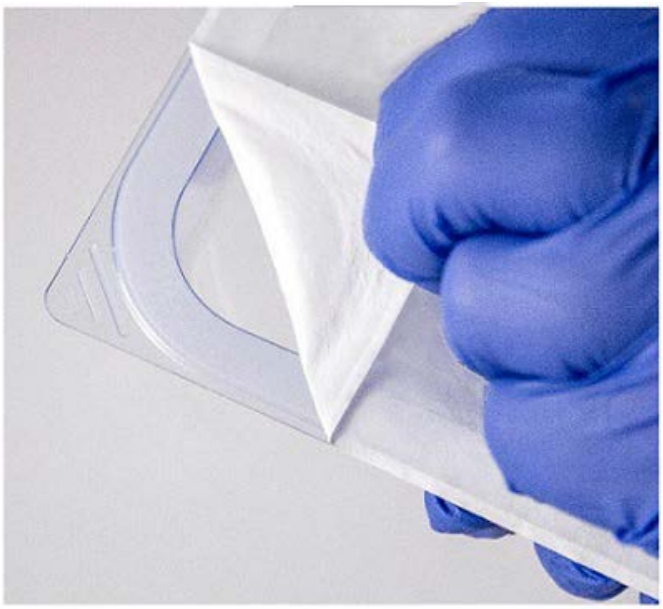


Figure 36. A photoshopped example of a lid that is easy to open. This example also has an elevated edge onto which the lid is glued for a sterile barrier.

Safety

In the development of medical devices, safety is of utmost importance. To be used within the European Union, the product must obtain a CE mark. This requires the qualification and classification of the medical device and the establishment of a risk management system.

This risk-based system of medical device legislation uses a set of criteria, in order to determine classification. These criteria have been incorporated into the list of requirements, which can be read in Appendix B and a risk analysis, which can be read in the evaluation chapter.

Since we are dealing with penetration of the human body, through surgery, this device can be classified as surgically invasive. However, the staples and barbed sutures remain in the human body, so this part falls under implantable devices (Medical Device Coordination Group, 2021).
The clear conclusion here is that the manufacturer would have a choice of applying a single class to the whole device or carrying out separate conformity assessment procedures for the applicator on one hand and the barbed suture and staples on the other hand (Medical Device Coordination Group, 2021).
The applicator falls under class IIa, which is intended for medical devices with low to medium potential risk. The staple and barbed suture fall under class III, which is the class associated with the highest risk (Medical Device Coordination Group, 2021).
To specifically address medical device risk management, ISO 13485 was applied, with further guidance from ISO 14971 and ISO 62366 (parts 1 and 2). While a comprehensive Failure Modes and Effects Analysis (FMEA) was not feasible at this early stage, a preliminary hazard analysis (PHA) was conducted to identify potential hazards. To further analyze the interdependencies of these hazards and facilitate early risk identification, the fault tree method (FTA) was employed. This can be found in Appendix N.

Most of the risks identified are dependent on the surgeon. An example of this is the improper bending of the staple, which in turn may compromise the strength and integrity of the staple line, creating the probability of a small gap, which in turn elevates the risk of an IH (Chekan & Whelan, 2014).
It is therefore essential that clear instructions are given to the surgeon before use, in addition, to use cues and instructions on the product packaging according to ISO 20417.

Materials and manufacturing

The staples will be made from an austenitic nickel-titanium alloy, also called NiTinol (See Appendix J for substantiation). This alloy is already commonly used for bone fixation, ankle, and foot surgery (Ghosh et al., 2022). The staples will be manufactured using melt casting (or melt extrusion), which also is widely used to create metal and alloy staples. The process involves melting the alloys at high temperatures (>1200-2000 °C), homogenizing, and extruding them into precise dimensions. The resulting staples undergo annealing treatment, and ultrasound cleaning, and are then ejected and cooled for proper compactness (Ghosh et al., 2022). NiTinol is suitable for this manufacturing process (CES Edupack, 2020).

For more about surface treatments for nickel-titanium-tissue reactions please refer to an article on biomaterials and -engineering by Hanawa (2019) and for the biocompatibility of the material please refer to a book by Brunette et al. (2001) in which it is thoroughly reviewed. These go much more in-depth about these topics than is possible in this report.

The barbed suture will be made of polybutester (PBT), as that material offers by far the strongest tensile holding strength compared to other polymers on the market (Laarhoven, 2016) An additional antibacterial/ antimicrobial coating (e.g. triclosan) will reduce the incidence of surgical site infections (SSIs). The suture will be manufactured using sharp razors to cut a monofilament to generate the required design (which can be seen in Appendix I).

The placeholding spring will be made out of biocompatible stainless steel (e.g. F139 316LVM) as it will also get in contact with internal tissue and bodily fluids.

All other components will be made of a medical grade polypropylene (ISO10993), as this is lightweight, cost-effective and stress, cracking, impact and fatigue resistant (GRANTA EduPack, 2020). For these components, high-precision injection moulding is the most suitable manufacturing method.

Regardless of the type of material used in the product, the amount of it and the total surface area need to be as small as possible to reduce the risk of infection.

Since most parts will be injection-moulded, understanding the process' shortcomings is essential. These include the presence of flash, parting lines, weld lines, knit lines, gate marks, and ejector pin marks on the final parts. Especially highly complex and tiny parts often lead to additional challenges. Further optimisation of all parts is needed to ensure reliable results.

Cost

While mechanical solutions generally incur higher material costs, a more expensive device can be financially advantageous if it significantly reduces procedural time compared to the current method (Elmallah et al., 2017).

At this stage, it is challenging to determine the precise costs of the new device due to the need for optimization of manufacturing and material usage. However, based on available data, an educated guess can be made regarding the cost comparison between the new device and existing methods.

The cost of a barbed suture is approximately €18,- (one is needed for each defect), and one minute in the operating room is estimated at €16,- (Wochner, 2022). When considering the time required for an expert surgeon (ca. 5 minutes) and a less experienced surgeon (ca. 8 minutes) (Y. Acherman, personal communication, 2023), the cost of the time spent on MDs is estimated at around €104,-. This results in a total estimated cost of €140,-.

The EHS costs approximately €160,-, with each cartridge priced at €100,- (Wang & Shope, 2019; Y. Acherman, personal communication, 2023). Around 4 cartridges are needed per surgery, resulting in an initial cost of €560,-. Considering the closure time of MDs with the EHS (ca. 3.5 minutes)(Y. Acherman, personal communication, 2023), the additional cost is estimated at €56,-, bringing the total cost of using the EHS to around €616,-.

When comparing the new device to the EHS, it is evident that the new device has simpler mechanics in its shaft but more complex elements in its cartridge. Assuming that the shaft costs about €100,- (less than the EHS) and the cartridges about €150,- (more than the EHS), the initial cost would be around a €400,-. Taking into account potential time savings of around one minute, due to simplified stapling procedures and reduced reloading, the estimated total cost of using the new device is €440,-.Note that additional cost for the reusable handle is still to be included, contingent on its expected lifespan.

However, based on the comparison, it is reasonable to assume that the final total cost of using the new device will fall somewhere between the cost of the barbed sutures and the EHS.

It is worth mentioning that obtaining medical design approval and conducting clinical tests are cost-intensive processes. However, these steps are essential to ensure the device's safety, efficacy, and to mitigate potential complications and readmissions. In the long run, such processes are necessary to reduce the cost of associated complications and readmissions.

Design method and process

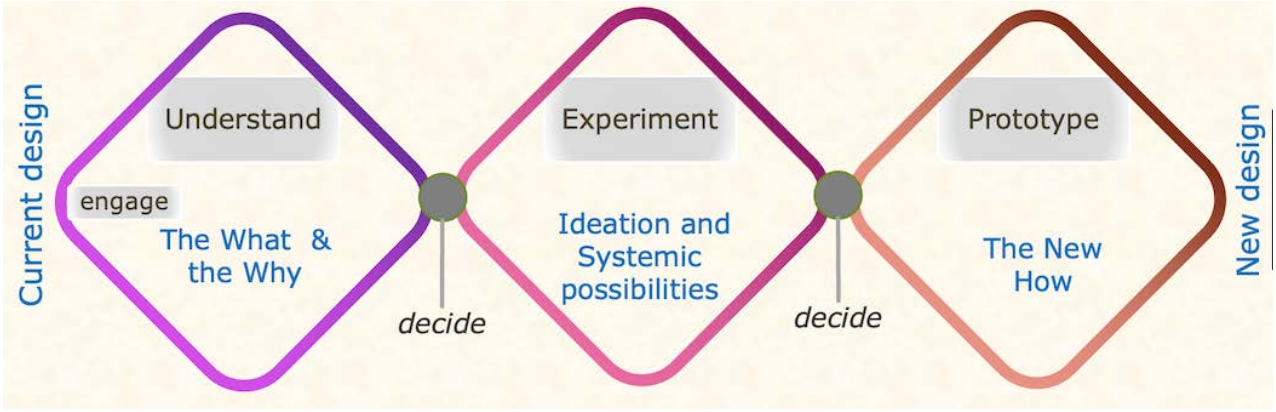


Figure 37. The triple diamond design process (Mortimer, 2022).

The development and design process employed in this project follows the Triple Diamond method, which encompasses three distinct phases: Understanding, Experimenting, and Testing. The understanding phase involved extensive research, including scientific literature analysis, observations and technical product analysis, to gain a comprehensive understanding of the problem domain and identify user needs and insights. This research provided the foundation for defining a clear set of requirements against which the final product could be benchmarked.

The experimenting phase involved various methods such as how-tos, brainstorming, brainwriting, morphological charts, Harris profiles, CAD design, and quick model-making (Zijlstra et al., 2020). These methods were employed to generate ideas and explore different design possibilities. The iterative nature of this phase allowed for continuous refinement and assessment of each component's functionality.

For the testing phase, the generated ideas and models were quickly tested and evaluated based on the obtained results. This iterative process facilitated the identification of effective design solutions on a component-by-component basis. The majority of these components were built and tested using 3D-printed models at a scaled-up 5:1 ratio. In some cases it was necessary to consider the material's flexibility in relation to its thickness, thus requiring different scaling. The evolution of each component can be found in Appendices H to L.

Throughout the design process, specific functions of the device

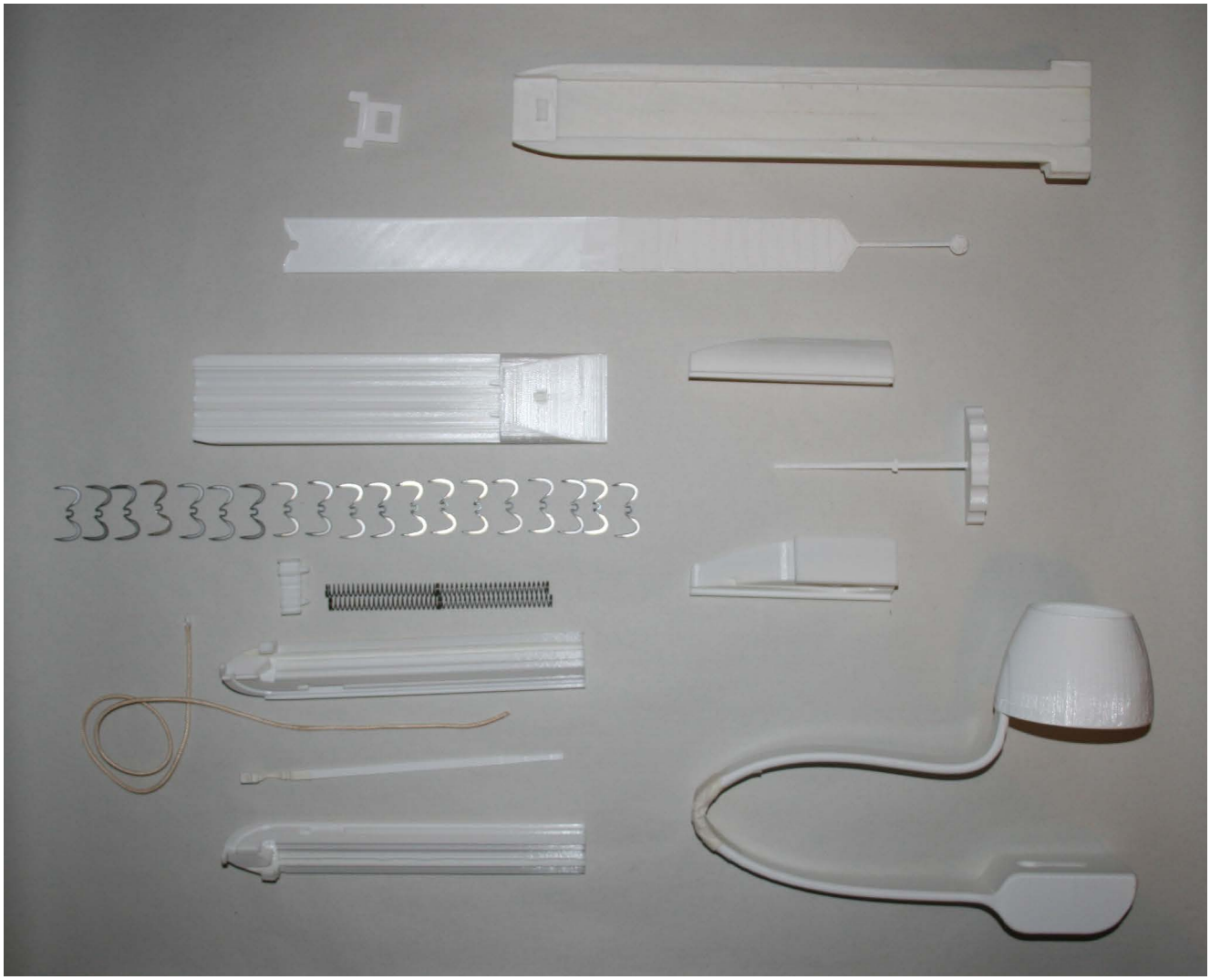


Figure 38. An exploded view of a 5:1 scale model of the device. Here the total length was shortened to fit within a standard 3D printer. It can also be seen that the compliant mechanisms are scaled differently, otherwise they would not be compliant anymore.

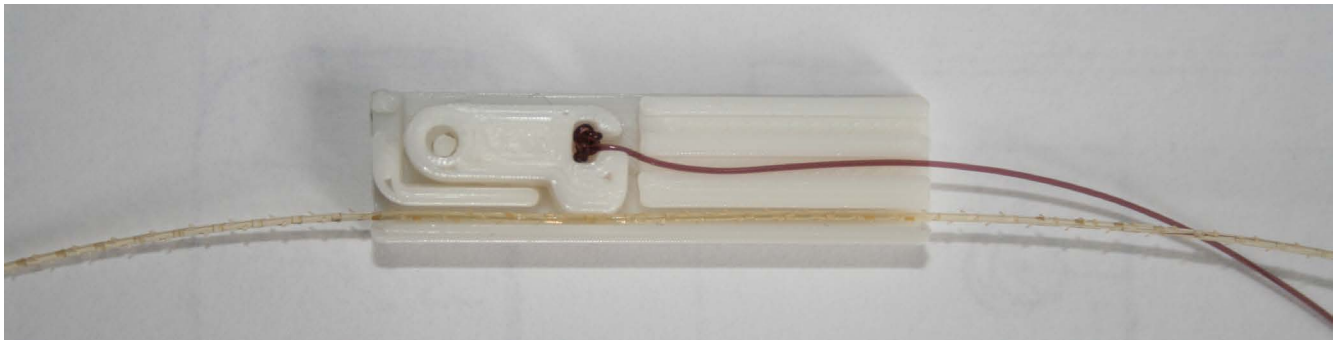


Figure 39. The first model of the suture locking mechanim. Here I used a tiny hammer, attatched to a string that could be pulled. This was a simple test to make sure friction would be enough to keep the barbed suture from moving freely.

were carefully considered, such as bending staples, delivering the required amount of suture, storing the necessary staples, and transferring them to the bending position. Separate mechanisms were developed for each task, with an iterative approach guiding their conception and refinement. Ultimately, these individual components were integrated to create a cohesive and unified device. A function analysis was made at first, to formulate the functions that the device must perform, shown in Appendix F.

Certain aspects, such as the barbed suture and staple, were deliberately prioritized in the development. This strategic decision allowed for the establishment of a solid foundation upon which the entire device could be built. By then focusing on the feasibility of the device first, this research can ensure a strong groundwork for refinement and improvement in future research.

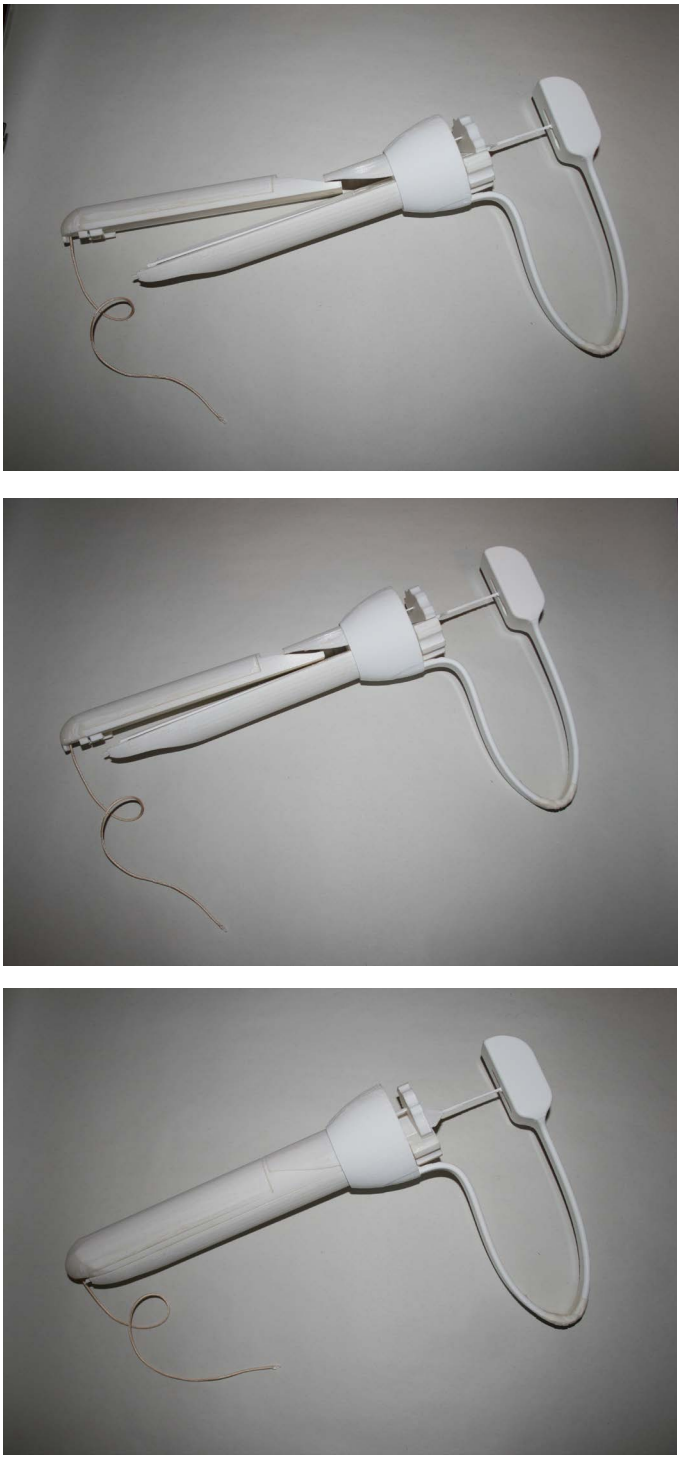


Figure 40. These photographs show the cartridge insertion process. It can be seen that the scaled cartridge fits well into the slot. It can also be seen that the back-end of the punch is very thin. This not scaled 5:1, but remained on its 1:1 thickness to check whether it would suffer from buckling.

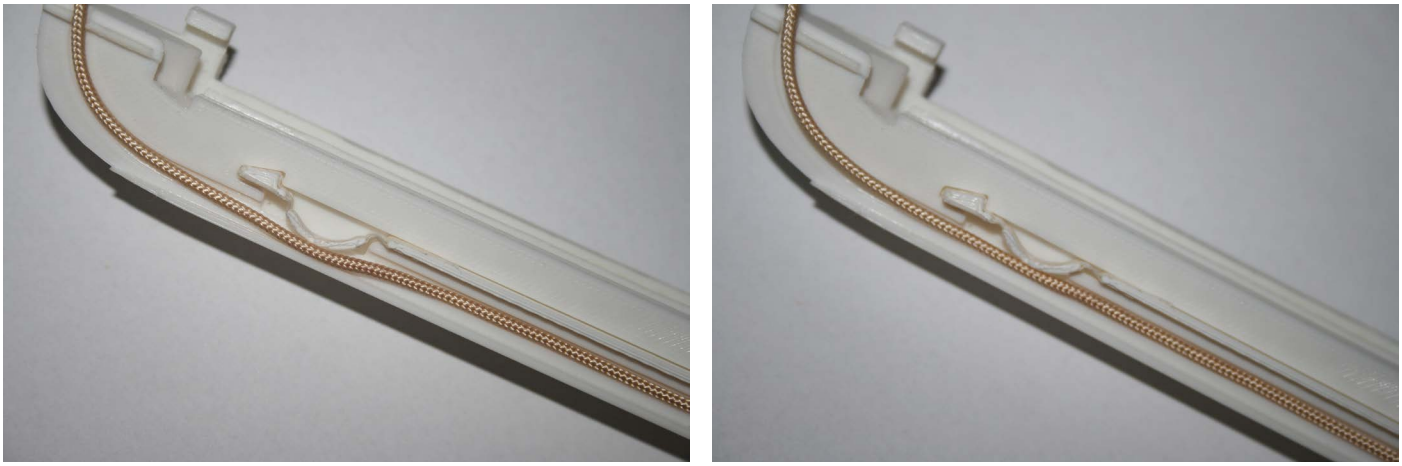


Figure 41. The final model of the compliant mechanism. Here it can be seen on the left, that the barbed suture gets compressed when the piece is pushed. On the right the 'natural' state can be seen, where the suture can move freely.

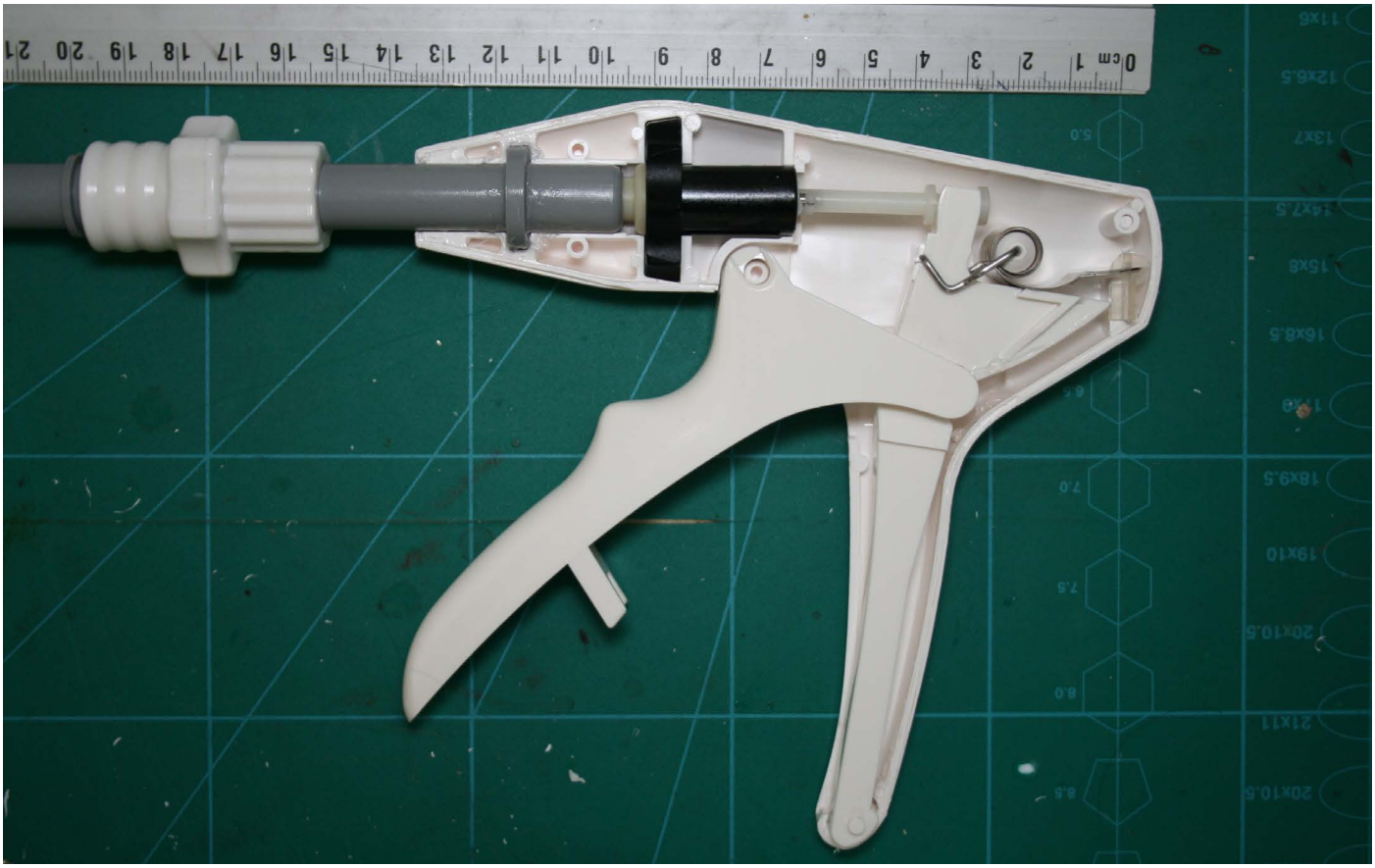


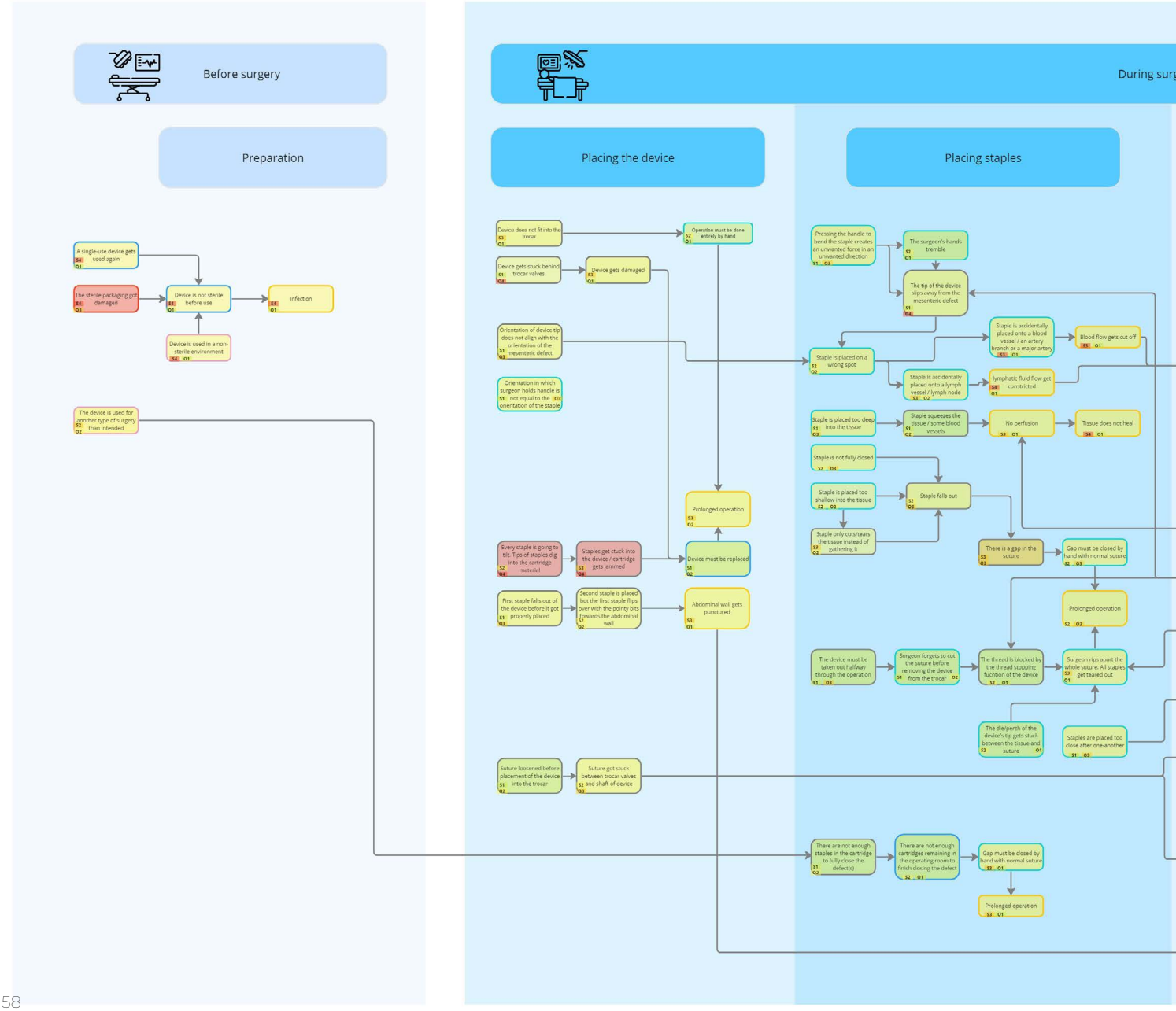
Figure 42. The inside of the handle of an EHS, that was taken apart. This gets incinerated after surgery, so it is made of cheap plastic.

Evaluation

The StapleStitcher will be evaluated by means of a risk assessment, the compliance to the list of criteria and finally surgeons' opinions.

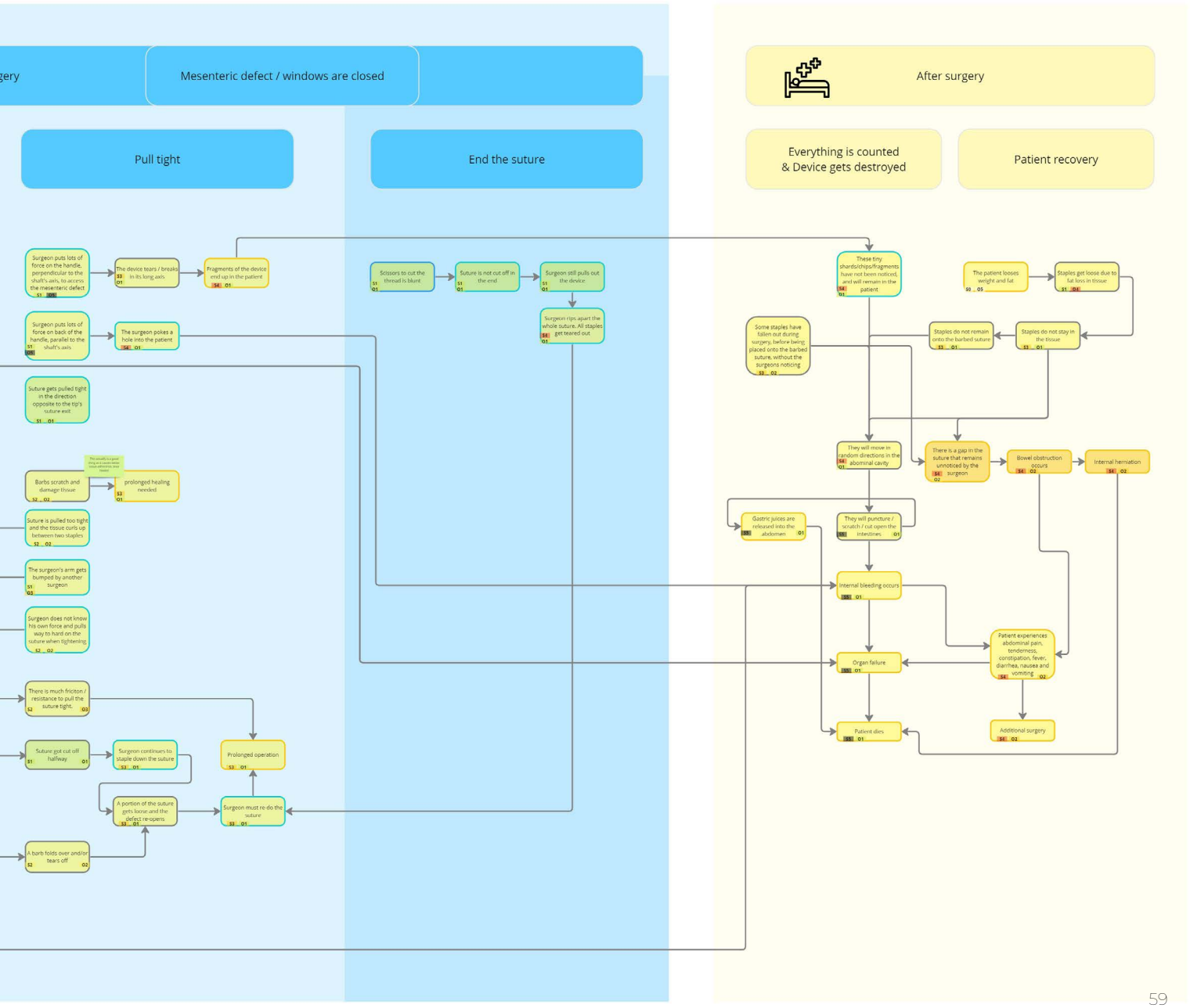
Risk analysis

In the realm of medical device development, effective risk management is vital to ensure the safety and reliability of devices. Given the early stage of the project, a Failure Modes and Effects Analysis



(FMEA) was not feasible. Instead, a preliminary hazard analysis (PHA) was conducted to identify potential hazards. The fault tree method (FTA) was employed to systematically analyze and understand the interdependencies of these hazards, aiding in the early identification of risks (Figure 43 and Appendix N). Various scenarios were discussed during a collaborative session with Remi Veenman, medical business director from Spark Design and Innovation, by utilizing the NEN-

Figure 43. An overview of the identified risks, using the fault tree method. The risks are linked to scenarios that caused them and scenarios that could happen as a result, using arrows, to visualise the interdependencies.



EN-ISO 14971:2019, IDT norm. This provided a comprehensive list of features to address in the risk analysis.

When assessing risks, it is crucial to consider the varying severity and probability of these risks. Risks can range from temporary discomfort to severe long-term damage or even fatal outcomes.

The risk overview illustration provides a visual representation of the severity and occurrence scales using a color-coded ranking system. Both ranking systems can be seen in Figure 45. Risks are categorized based on their severity, denoted by a letter “S” followed by a rank, and their likelihood of occurrence, represented by a letter “O” followed by a rank. The severity and occurence scales assign distinct colors to indicate the severity level and probability of occurence of each risk.

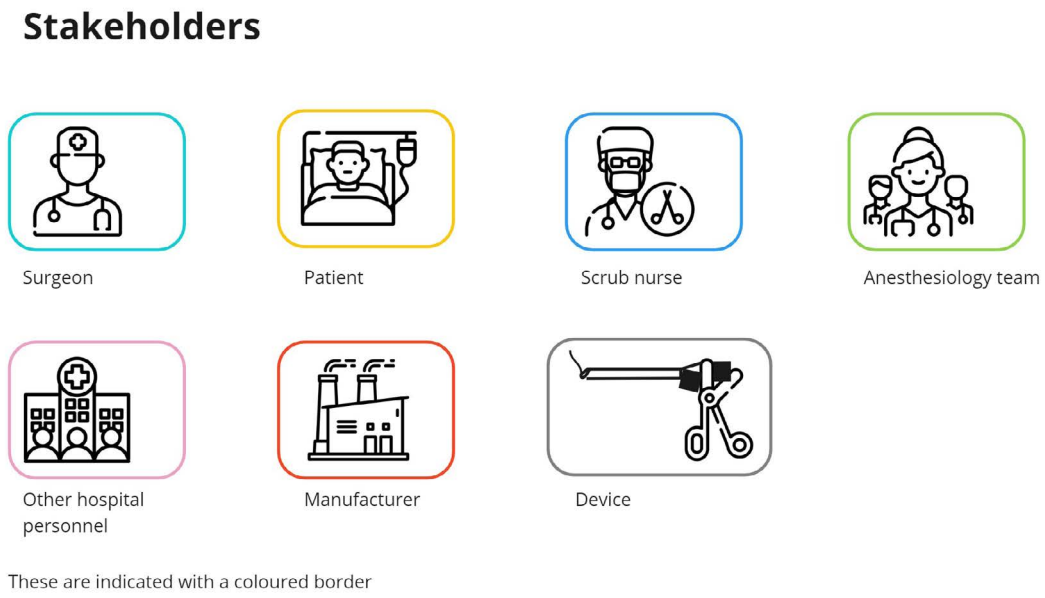


Figure 44. The risk overview incorporates a color-coded border system to indicate the stakeholder responsible for each identified risk. However, specific to the yellow borders, they are used to highlight risks that pertain to patient safety and potential health effects.

Figure 45. The risk overview illustration displaying the severity and occurrence scales with color-coded ranking system.

Severity scale

Rank		Definition	Example
1	**Insignificant**	No impact on patient safety. No impact on the surgeon. Minor nuisance of <10 minutes for the surgeon. of <10 minutes for the surgeon.	The surgeon briefly maintains an uncomfortable position, has to briefly exert force to place a staple, tissue slips out of the grasper. Temporarily reduced product performance.
2	**Minor**	No impact on patient safety. No injuries to the surgeon. Discomfort of and/or inconvenience up to 10 minutes for the surgeon.	Nausea, muscle stiffness after operating in an unusual position/posture. Degraded product performance.
3	**Moderate**	Slight impact on patient safety, no significant harm. Slight impact on the surgeon, no significant harm. Surgery delayed up to 30 minutes. Product failure.	Broken instrument outside the patient's body, instrument failure before use. Loss of product function.
4	**Major**	Temporary injury to patient, reversible. Broken fragment(s) in patient's body. Surgery delayed > 30 minutes and/or Additional surgical interventions needed.	Foreign material inside the patient's body, broken component, revision surgery needed. Safety related product failure.
5	**Catastrophic**	Significant impact on patient safety, hazard could lead to long-term damage, serious physical injury or even death. Significant impact on the surgeon, hazard could lead to long term damage, serious physical injury or even death.	Organ failure, coma, death. Catastrophic safety related product failure.

These are indicated with a letter S + rank

Occurrence scale

Subjective estimate of occurrence

Rank		Definition	Occurrence probability **Logarithmic scale**
1	**Very unlikely**	Extremely rare event. The occurrence of the event is not reproductible. Never occurs during the product lifetime.	P < 0,01%
2	**Improbable**	Event rarely occurs. There is indirect evidence of the event. Could occur due to unusual situations.	0,01% > P < 0,1%
3	**Moderate**	Occasional event. There is direct evidence of the event. Occasional occurrence during the product lifetime.	0,1% > P < 1%
4	**Probable**	Likely event. There is strong direct evidence of the event. Event could occur regularly during the product lifetime.	1% > P <10%
5	**Very probable**	Near certain occurrence. There is irrefutable direct evidence of the event. The event could repeatedly occur in a single product's lifetime.	P > 10%

These are indicated with a letter O + rank

Risk priority rating

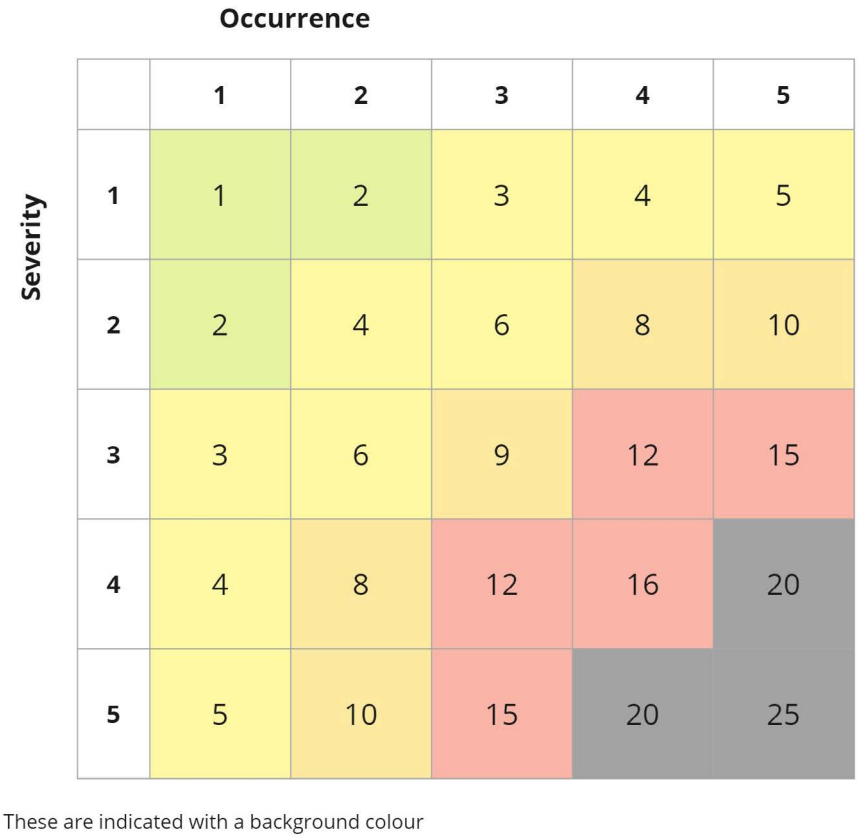


Figure 46. Risk Priority Matrix illustrating the combined scores of severity and occurrence. The matrix helps determine the priority hazards to address, with higher scores indicating a greater potential impact and likelihood.

To effectively prioritize and address the risks, a categorization system based on severity and occurence scales has been made (Figure 46). By combining these scales, a comprehensive understanding of the priority and urgency of risk mitigation efforts can be obtained, to address the most critical problems first.

It is important to consider the likelihood of detection as a factor influencing the severity of risks. However, in this analysis, the assessment of likelihood of detection was not included due to its complexity and the limitations of available data. Evaluating the likelihood of detection requires a comprehensive understanding of various factors, such as detection methods, monitoring systems, and human factors, which were beyond the scope of this particular analysis.

The following section outlines the identified priority risks, with a focus on those that received the highest rating. It is noteworthy that a significant number of higher risks are associated with incorrect usage of the device, primarily attributable to the surgeon. This underscores the critical importance of providing comprehensive instructions and training to surgeons prior to using the device. By addressing these risks through effective training and clear guidance, the potential for adverse events can be greatly minimized, ensuring the safe and successful utilization of the device in surgical procedures. Other important priority risks include the following.

Staples jamming or getting stuck in the device:
To mitigate this risk, it is essential to ensure that the device is designed to prevent staples from jamming or getting stuck. This can be achieved by optimizing the cartridge for smooth staple delivery and incorporating simple methods to detect and address any potential jams.
To address this risk, a smoother surface and lubricant could be used inside the cartridge. Next, a transparent piece of plastic can be added alongside the staples in the cartridge. This allows for easy identification of jams and provides surgeons with visibility on the remaining staples

Unnoticed gap in the suture:
The risk of unnoticed gaps in the suture may arise when staples fall out of the tissue, potentially due to inadequate placement. To mitigate this risk, it is imperative that surgeons receive thorough instructions and training prior to using the device. However, addressing the risk in the case of tremendous (mesenteric) fat loss, comprehensive clinical testing is crucial to assess the impact of mesenteric fat loss on staple retention. Post-surgery monitoring should be conducted to detect any if there is any occurrence of staples falling out and whether it results in gaps large enough for the small bowel to pass through. In such case, corrective measures should also be investigated, to see if simply tightening the barbed suture to close the gap would result in proper closure.

Sterile packaging damage without detection:
To address this risk, a robust quality control process should be implemented for the packaging of sterile items. Additional protection, such as special boxes, should be used during shipping to minimize the chances of damage. Furthermore, incorporating visual indicators, e.g. a colour changing chemical reaction, in the packaging may help visualize any potential contamination, enabling timely detection and appropriate action.
Overall, a proactive risk mitigation strategy should be implemented in future research to address these priority risks. This includes a combination of design improvements, quality control measures, rigorous testing, and ongoing monitoring. By effectively managing these hazards, the safety and performance of the device can be optimized, ensuring successful outcomes in minimally invasive surgical procedures.

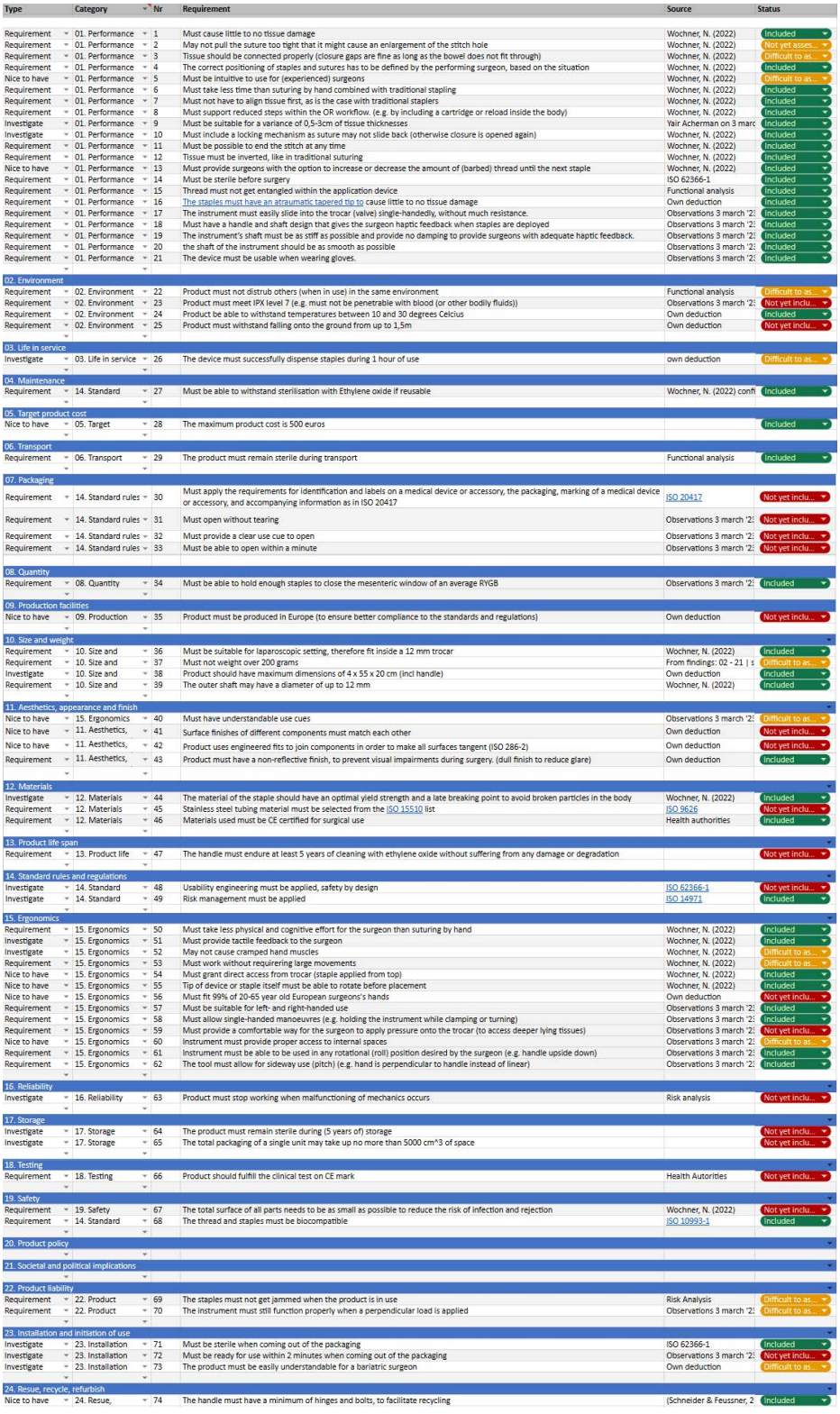
Compliance to Requirements

The previously prioritised criteria for patient safety, surgeon's comfort, and embodiment have been partially met (Figure 47). In terms of patient safety, the StapleStitcher seems to be able to fully close the two MDs, preventing BOs and IHs. Furthermore, the specially shaped legs of the staples, including atraumatic tapered tips, minimize tissue squishing and reduce the risk of necrosis and additional tissue damage, promoting faster healing.

Regarding the surgeon's comfort, the StapleStitcher allows for direct, top-down access to the defect. Its stiff shaft provides direct haptic feedback, before and during the placement of staples. The entire MD closure procedure is streamlined, by eliminating the need for tissue alignment before stapling, thus reducing the number of needed hands and precise manoeuvres.

Regarding embodiment, the cartridge is designed to provide enough staples to fully close a MD, enhancing efficiency and ease of use during surgery. Again, biocompatible materials are utilized to ensure patient safety, and the placement of staples and suture technique may be chosen according to the surgeon's preference. The handle design makes it possible to use the StapleStitcher sideways, left- and righthandedly, upside down or in any other desired orientation while providing direct access to the necessary buttons.

Overall, the StapleStitcher successfully meets the prioritised criteria for patient safety, surgeon's comfort, and embodiment. However, lots of formulated requirements still remain unfulfilled, as they can only be evaluated in a later stage of the design process (e.g. requirements about the product’s finishing, packaging, shipping, etc). In Figue 47 an overview can be seen of what requirements have been fulfilled an which have not. The list can also be seen in Appendix B.



Type	Category	Nr	Requirement	Source	Status
Requirement	01. Performance	1	Must cause little to no tissue damage	Wochner, N. (2022)	Included
Requirement	01. Performance	2	May not pull the suture too tight that it might cause an enlargement of the stitch hole	Wochner, N. (2022)	Not yet asses...
Requirement	01. Performance	3	Tissue should be connected properly (closure gaps are fine as long as the bowel does not fit through)	Wochner, N. (2022)	Difficult to as...
Requirement	01. Performance	4	The correct positioning of staples and sutures has to be defined by the performing surgeon, based on the situation	Wochner, N. (2022)	Included
Nice to have	01. Performance	5	Must be intuitive to use for (experienced) surgeons	Wochner, N. (2022)	Difficult to as...
Requirement	01. Performance	6	Must take less time than suturing by hand combined with traditional stapling	Wochner, N. (2022)	Included
Requirement	01. Performance	7	Must not have to align tissue first, as is the case with traditional staplers	Wochner, N. (2022)	Included
Requirement	01. Performance	8	Must support reduced steps within the OR workflow. (e.g. by including a cartridge or reload inside the body)	Wochner, N. (2022)	Included
Investigate	01. Performance	9	Must be suitable for a variance of 0,5-3cm of tissue thicknesses	Yair Acherman on 3 marc	Included
Investigate	01. Performance	10	Must include a locking mechanism as suture may not slide back (otherwise closure is opened again)	Wochner, N. (2022)	Included
Requirement	01. Performance	11	Must be possible to end the stitch at any time	Wochner, N. (2022)	Included
Requirement	01. Performance	12	Tissue must be inverted, like in traditional suturing	Wochner, N. (2022)	Included
Nice to have	01. Performance	13	Must provide surgeons with the option to increase or decrease the amount of (barbed) thread until the next staple	Wochner, N. (2022)	Included
Requirement	01. Performance	14	Must be sterile before surgery	ISO 62366-1	Included
Requirement	01. Performance	15	Thread must not get entangled within the application device	Functional analysis	Included
Requirement	01. Performance	16	The staples must have an atraumatic tapered tip to cause little to no tissue damage	Own deduction	Included
Requirement	01. Performance	17	The instrument must easily slide into the trocar (valve) single-handedly, without much resistance.	Observations 3 march '23	Included
Requirement	01. Performance	18	Must have a handle and shaft design that gives the surgeon haptic feedback when staples are deployed	Observations 3 march '23	Included
Requirement	01. Performance	19	The instrument's shaft must be as stiff as possible and provide no damping to provide surgeons with adequate haptic feedback.	Observations 3 march '23	Included
Requirement	01. Performance	20	the shaft of the instrument should be as smooth as possible	Observations 3 march '23	Included
Requirement	01. Performance	21	The device must be usable when wearing gloves.	Observations 3 march '23	Included
02. Environment					
Requirement	02. Environment	22	Product must not distrub others (when in use) in the same environment	Functional analysis	Difficult to as...
Requirement	02. Environment	23	Product must meet IPX level 7 (e.g. must not be penetrable with blood (or other bodily fluids))	Observations 3 march '23	Not yet inclu...
Requirement	02. Environment	24	Product be able to withstand temperatures between 10 and 30 degrees Celcius	Own deduction	Included
Requirement	02. Environment	25	Product must withstand falling onto the ground from up to 1,5m	Own deduction	Not yet inclu...
03. Life in service					
Investigate	03. Life in service	26	The device must successfully dispense staples during 1 hour of use	own deduction	Difficult to as...
04. Maintenance					
Requirement	14. Standard	27	Must be able to withstand sterilisation with Ethylene oxide if reusable	Wochner, N. (2022) confi	Included
05. Target product cost					
Nice to have	05. Target	28	The maximum product cost is 500 euros		Included
06. Transport					
Requirement	06. Transport	29	The product must remain sterile during transport	Functional analysis	Included
07. Packaging					
Requirement	14. Standard rules	30	Must apply the requirements for identification and labels on a medical device or accessory, the packaging, marking of a medical device or accessory, and accompanying information as in ISO 20417	ISO 20417	Not yet inclu...
Requirement	14. Standard rules	31	Must open without tearing	Observations 3 march '23	Not yet inclu...
Requirement	14. Standard rules	32	Must provide a clear use cue to open	Observations 3 march '23	Not yet inclu...
Requirement	14. Standard rules	33	Must be able to open within a minute	Observations 3 march '23	Not yet inclu...
08. Quantity					
Requirement	08. Quantity	34	Must be able to hold enough staples to close the mesenteric window of an average RYGB	Observations 3 march '23	Included
09. Production facilities					
Nice to have	09. Production	35	Product must be produced in Europe (to ensure better compliance to the standards and regulations)	Own deduction	Not yet inclu...
10. Size and weight					
Requirement	10. Size and	36	Must be suitable for laparoscopic setting, therefore fit inside a 12 mm trocar	Wochner, N. (2022)	Included
Requirement	10. Size and	37	Must not weight over 200 grams	From findings: 02 - 21 | s	Difficult to as...
Investigate	10. Size and	38	Product should have maximum dimensions of 4 x 55 x 20 cm (incl handle)	Own deduction	Included
Requirement	10. Size and	39	The outer shaft may have a diameter of up to 12 mm	Wochner, N. (2022)	Included
11. Aesthetics, appearance and finish					
Nice to have	15. Ergonomics	40	Must have understandable use cues	Observations 3 march '23	Difficult to as...
Nice to have	11. Aesthetics,	41	Surface finishes of different components must match each other	Own deduction	Not yet inclu...
Nice to have	11. Aesthetics,	42	Product uses engineered fits to join components in order to make all surfaces tangent (ISO 286-2)	Own deduction	Not yet inclu...
Requirement	11. Aesthetics,	43	Product must have a non-reflective finish, to prevent visual impairments during surgery. (dull finish to reduce glare)	Own deduction	Included
12. Materials					
Investigate	12. Materials	44	The material of the staple should have an optimal yield strength and a late breaking point to avoid broken particles in the body	Wochner, N. (2022)	Included
Requirement	12. Materials	45	Stainless steel tubing material must be selected from the ISO 15510 list	ISO 9626	Not yet inclu...
Requirement	12. Materials	46	Materials used must be CE certified for surgical use	Health authorities	Included
13. Product life span					
Requirement	13. Product life	47	The handle must endure at least 5 years of cleaning with ethylene oxide without suffering from any damage or degradation		Not yet inclu...
14. Standard rules and regulations					
Investigate	14. Standard	48	Usability engineering must be applied, safety by design	ISO 62366-1	Not yet inclu...
Investigate	14. Standard	49	Risk management must be applied	ISO 14971	Included
15. Ergonomics					
Requirement	15. Ergonomics	50	Must take less physical and cognitive effort for the surgeon than suturing by hand	Wochner, N. (2022)	Included
Investigate	15. Ergonomics	51	Must provide tactile feedback to the surgeon	Wochner, N. (2022)	Included
Investigate	15. Ergonomics	52	May not cause cramped hand muscles	Wochner, N. (2022)	Difficult to as...
Requirement	15. Ergonomics	53	Must work without requirering large movements	Wochner, N. (2022)	Difficult to as...
Nice to have	15. Ergonomics	54	Must grant direct access from trocar (staple applied from top)	Wochner, N. (2022)	Included
Nice to have	15. Ergonomics	55	Tip of device or staple itself must be able to rotate before placement	Wochner, N. (2022)	Included
Nice to have	15. Ergonomics	56	Must fit 99% of 20-65 year old European surgeons's hands	Own deduction	Not yet inclu...
Requirement	15. Ergonomics	57	Must be suitable for left- and right-handed use	Observations 3 march '23	Included
Requirement	15. Ergonomics	58	Must allow single-handed manoeuvres (e.g. holding the instrument while clamping or turning)	Observations 3 march '23	Included
Requirement	15. Ergonomics	59	Must provide a comfortable way for the surgeon to apply pressure onto the trocar (to access deeper lying tissues)	Observations 3 march '23	Not yet inclu...
Nice to have	15. Ergonomics	60	Instrument must provide proper access to internal spaces	Observations 3 march '23	Difficult to as...
Requirement	15. Ergonomics	61	Instrument must be able to be used in any rotational (roll) position desired by the surgeon (e.g. handle upside down)	Observations 3 march '23	Included
Requirement	15. Ergonomics	62	The tool must allow for sideway use (pitch) (e.g. hand is perpendicular to handle instead of linear)	Observations 3 march '23	Included
16. Reliability					
Investigate	16. Reliability	63	Product must stop working when malfunctioning of mechanics occurs	Risk analysis	Not yet inclu...
17. Storage					
Investigate	17. Storage	64	The product must remain sterile during (5 years of) storage		Not yet inclu...
Investigate	17. Storage	65	The total packaging of a single unit may take up no more than 5000 cm^3 of space		Not yet inclu...
18. Testing					
Requirement	18. Testing	66	Product should fulfill the clinical test on CE mark	Health Autorities	Not yet inclu...
19. Safety					
Requirement	19. Safety	67	The total surface of all parts needs to be as small as possible to reduce the risk of infection and rejection	Wochner, N. (2022)	Not yet inclu...
Requirement	14. Standard	68	The thread and staples must be biocompatible	ISO 10993-1	Included
20. Product policy					
21. Societal and political implications					
22. Product liability					
Requirement	22. Product	69	The staples must not get jammed when the product is in use	Risk Analysis	Difficult to as...
Requirement	22. Product	70	The instrument must still function properly when a perpendicular load is applied	Observations 3 march '23	Difficult to as...
23. Installation and initiation of use					
Investigate	23. Installation	71	Must be sterile when coming out of the packaging	ISO 62366-1	Included
Investigate	23. Installation	72	Must be ready for use within 2 minutes when coming out of the packaging	Observations 3 march '23	Not yet inclu...
Investigate	23. Installation	73	The product must be easily understandable for a bariatric surgeon	Own deduction	Difficult to as...
24. Reuse, recycle, refurbish					
Nice to have	24. Reuse,	74	The handle must have a minimum of hinges and bolts, to facilitate recycling	(Schneider & Feussner, 2	Included

Figure 47. The list of requirements. The requirements are categorized using a traffic light system, with green boxes indicating compliance, red boxes indicating non-inclusion, and orange boxes indicating partial inclusion or other difficulties with the assessment.

Surgeons' opinion

I conducted a questionnaire among surgeons to gather their feedback on the proposed mesenteric defect closure product, seen in Appendix M (Zijlstra et al., 2020, p. 49). I received a total of 10 responses from surgeons, of which most are affiliated with the Dutch Society of Metabolic and Bariatric Surgery. The participants are all Male, between the ages 45 and 65. All of them consider the closure of MDs as a standard part of LRYGB.

The survey began by asking the surgeons to define critical factors that contribute to successful mesenteric defect closure. Subsequently, the survey explored the surgeons' experiences regarding complications, limitations, and difficulties encountered during mesenteric defect closure.

"To invest enough time during the operation to visualise and close both defects."

"When using staples, catching the tissue before staple formation. When suturing, it takes more time."

"technique, technique, technique and patient factors."

"Quick, persistent, stable closure. At least 50% will open up."

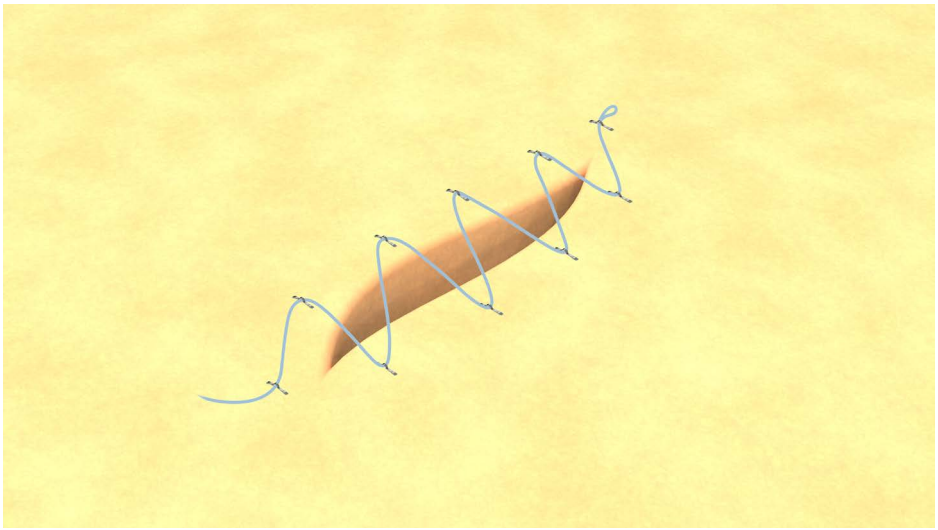
"Hernia staplers are insufficient in grasping enough tissue and give inadequate closure."

"You are short of a hand to get proper exposure, hence the EHS stapler is used which can work single-handedly, but it does not suffice either. So suturing is better, but that took a lot of time, cave bleeding."

Their formulated insights served as valuable criteria against which the product could later be benchmarked.

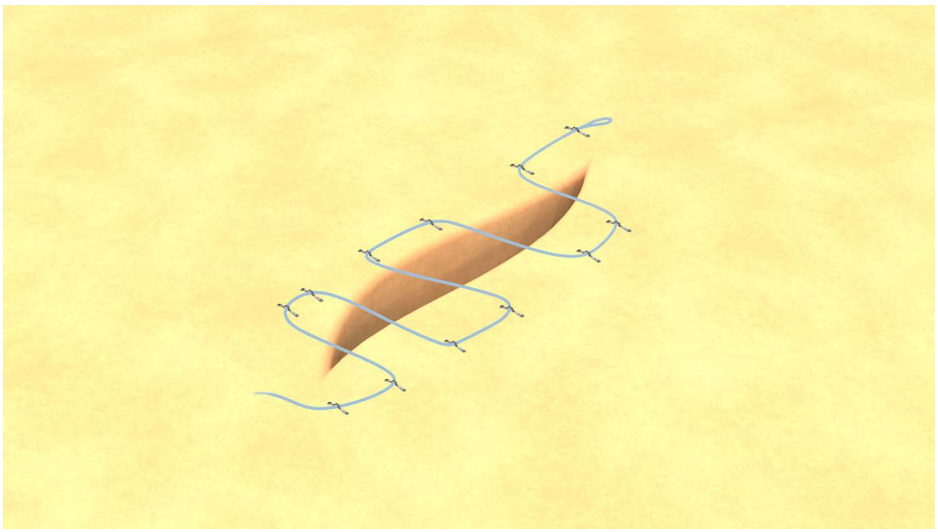
Next, the survey provided the product proposal, utilizing a combination of rendered 3D CAD models, textual concepts, and an animation (Zijlstra et al., 2020, p. 135). This multimedia approach aimed to provide a comprehensive understanding of the proposed StapleStitcher and its functionality.

The survey also briefly focused on the surgeons' preferred closure technique using the StapleStitcher and the reasons behind their choice. Here they were given three examples, as seen in Figure 48.



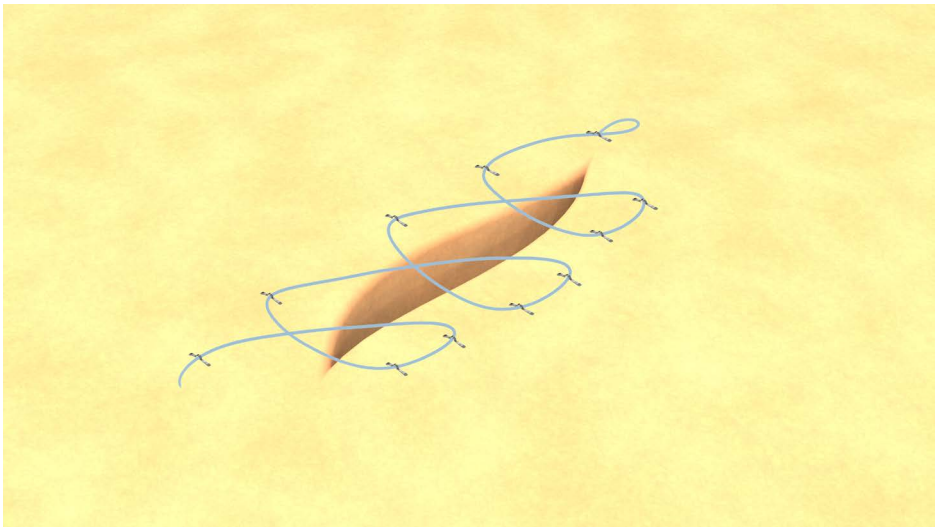
Option 1:

Zigzag



Option 2:

Horizontal mattress



Option 3:

Running cross (one-sided)

Figure 48. The three provided examples of suturing techniques. Surgeons were given the option to choose multiple and to provide another thechnique.

These options were based on already well-established suture techniques and hence provided options that surgeons are already familiar with. They were allowed to select multiple options and to provide another technique if they wanted.

There was something to be said for all the options, with the zigzag, in particular, being chosen for the simple reason that “it would tighten easier”. The horizontal mattress was chosen as “Some tissue needs more traction than others, for those patients a mattress type suture is more favourable” and “better strength”. The running cross was chosen because of “even less chance of slippage” and finally an additional option with a double layer of zigzags was chosen “for better closure”.

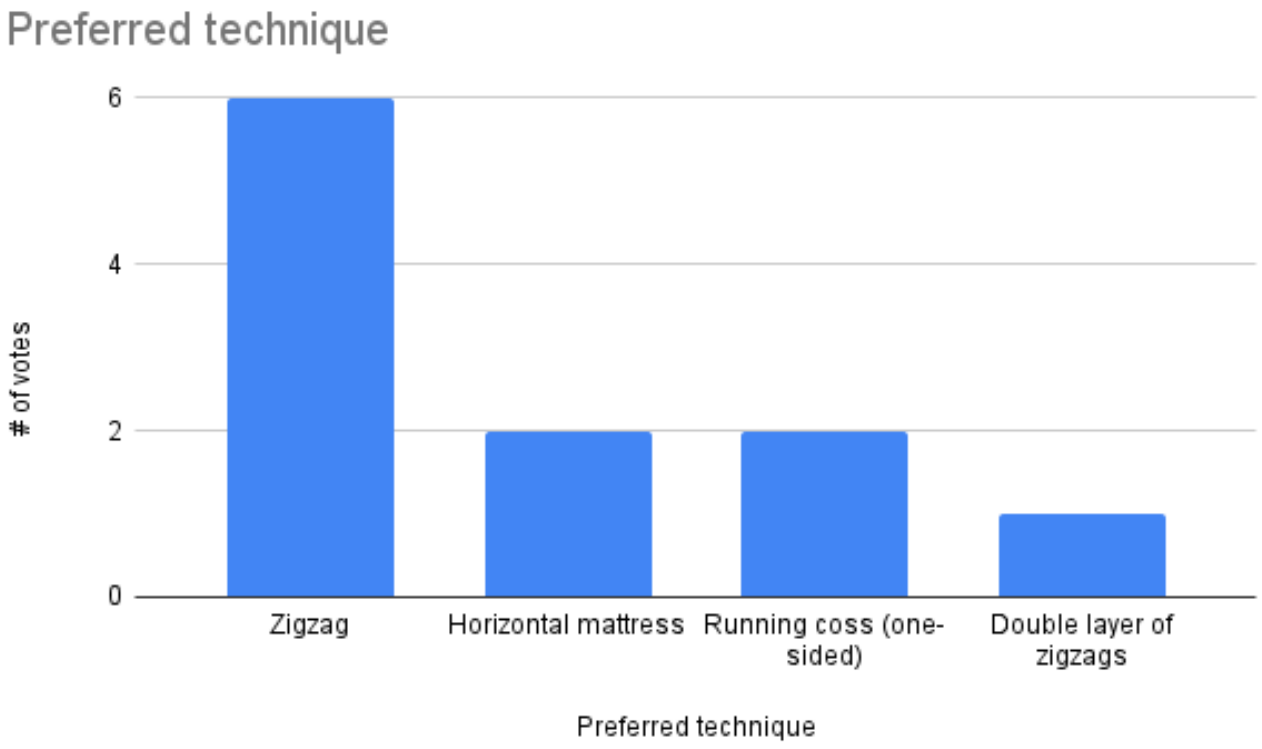


Figure 49. A graph showing that the ziagzag is the preferred suturing technique when using the StapleStitcher.

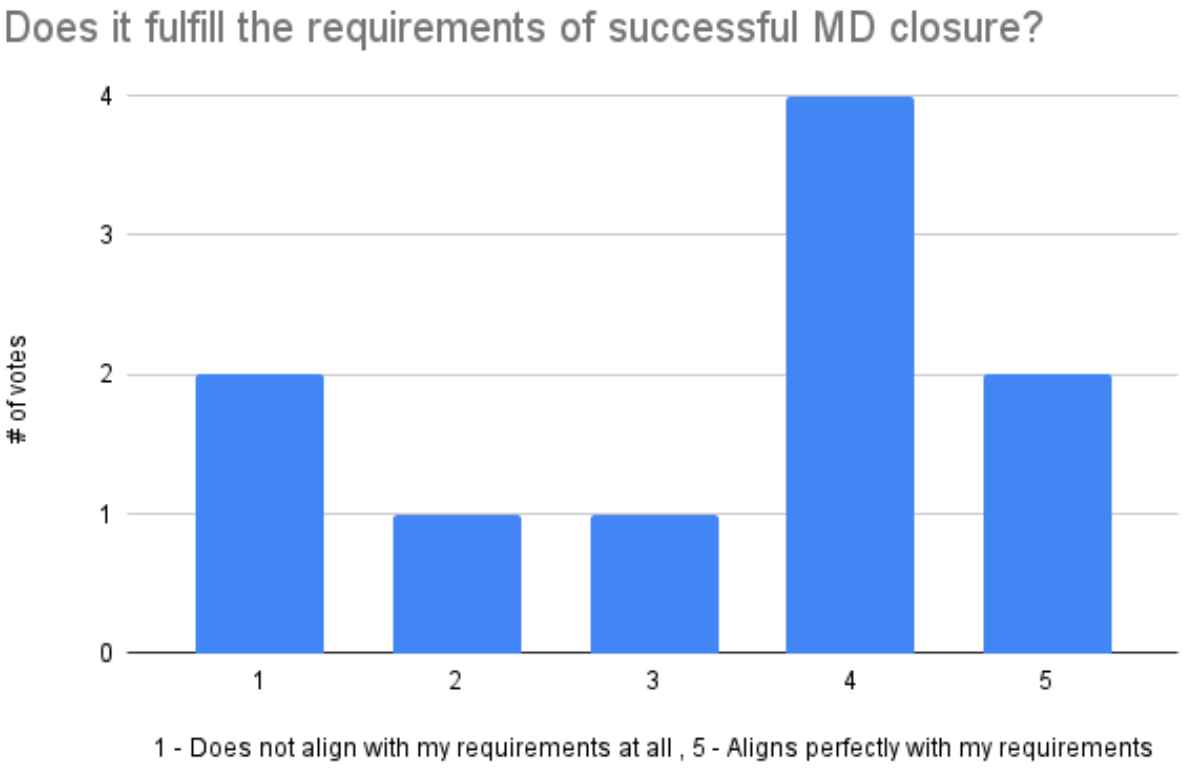


Figure 50. A graph showing whether the StapleStitcher aligned with the surgeons' requirements.

To assess the StapleStitcher's suitability for MDs closure, the survey inquired whether the proposed device fulfilled the requirements previously defined by the surgeons. Here, the opinions differed.

*The poorer ratings can be explained by the fact that "**Most limitations are tissue-related.**" and therefore the product in itself cannot improve upon that aspect much.* In addition, a surgeon pointed out that "***staples are too atraumatic***". He explained that "***The tissue of the sides of the MD have to grow together. With this system, the two sides remain intact and therefore the tissue will have less tendency to grow together***."

Another surgeon, who found that it aligned well with his requirements, wrote: "***It appears easier in use seeing that there's no need to align directly and that the suture can be tightened later***".

Additionally, questions were asked to gauge the surgeons' perceptions of the StapleStitcher's effectiveness, quality, innovativeness, and comfort.

When asked, "Do you consider the device to be innovative compared to existing solutions in the market?", the majority of respondents (9 out of 10) answered positively. Here are a few examples of their responses:

"YES"

"Yes, but the success depends mainly on the success of the staples holding the tissue."

"Yes, but I still have a lot of questions about its long-term effects, cost, etc."

"Absolutely, unprecedented"

"Amazing!"

These responses indicate that the surgeons perceive the StapleStitcher as innovative in comparison to current solutions. However, some respondents expressed concerns about factors such as long-term effects, highlighting the need for further research.

When asking the surgeons to rate the perceived quality and comfort of the StapleStitcher based on the available information, the surgeons mainly indicated that they could not really rate it without having seen and used it in real life:

"Can't evaluate it, as I would have to have it in my hands."

"It depends on handling the device."

"It remains to be seen how good the staples will grab the tissue."

"Depends on cost, effectiveness, time, and eco-friendliness."

"I have to see and feel it in real life first."

"Have to see it at work first"

"I don't know the device good enough to have an opinion about it"

"The handling is still unknown to me."

Subsequently, the questionnaire asked surgeons to suggest additional functions or features that could improve the performance of the StapleStitcher or address specific needs in closing mesenteric defects:

"Automatic stabilizing / tightening the thread per staple."

"Feedback system after placing a staple confirming that the staple is placed."

"An indication for how much suture length is remaining."

When asked if the StapleStitcher could be suitable for any other fields of applications, the surgeons provided the following responses:

"Inguinal surgery"

"Intestinal anastomosis"

"Lap rectopexy"

"TAPP"

(which stands for transabdominal preperitoneal repair)

"Closing of ventral hernia defects as a part of IPOM"
(which stands for intraperitoneal onlay mesh technique)

These responses suggest that the surgeons see potential applications for the StapleStitcher beyond mesenteric defect closure. They envision its use in various surgical procedures such as inguinal surgery, intestinal anastomosis, lap rectopexy, transabdominal preperitoneal repair and for the repair of incisional and parastomal hernias. This reveals the versatility and adaptability of the device in different clinical scenarios, expanding its potential utility beyond its primary intended purpose.

Some closing remarks of surgeons included:

“Keep me posted!”

“I am curious to see the end result”

“Nice approach to a common problem in bariatrics. I would like to hold the instrument sometime. I am always ready for consultation.”

“proof is the eating of the pudding”.

These final remarks indicate the interest of these surgeons in the StapleStitcher and its future developments.

The insights gathered from this evaluation process with surgeons provide valuable feedback on the proposed product, helping to refine its design and address concerns and suggestions identified by the surgical community.

Discussion and Limitations

In assessing the feasibility of each component within the proposed StapleStitcher, a series of tests were conducted. A notable innovation that showed promising results during testing was the concept of the staples clicking onto the suture. However, it should be noted that the true scale of the product posed challenges in terms of manufacturing. The precision engineering required for the components resulted in high production times and manufacturing costs. Financial limitations in the beginning of the project restricted the purchase of more ideal alloys like titanium or nitinol and advanced manufacturing techniques such as casting and wire EDM. So I only carried out tests with the available technologies and materials at the TU Delft.

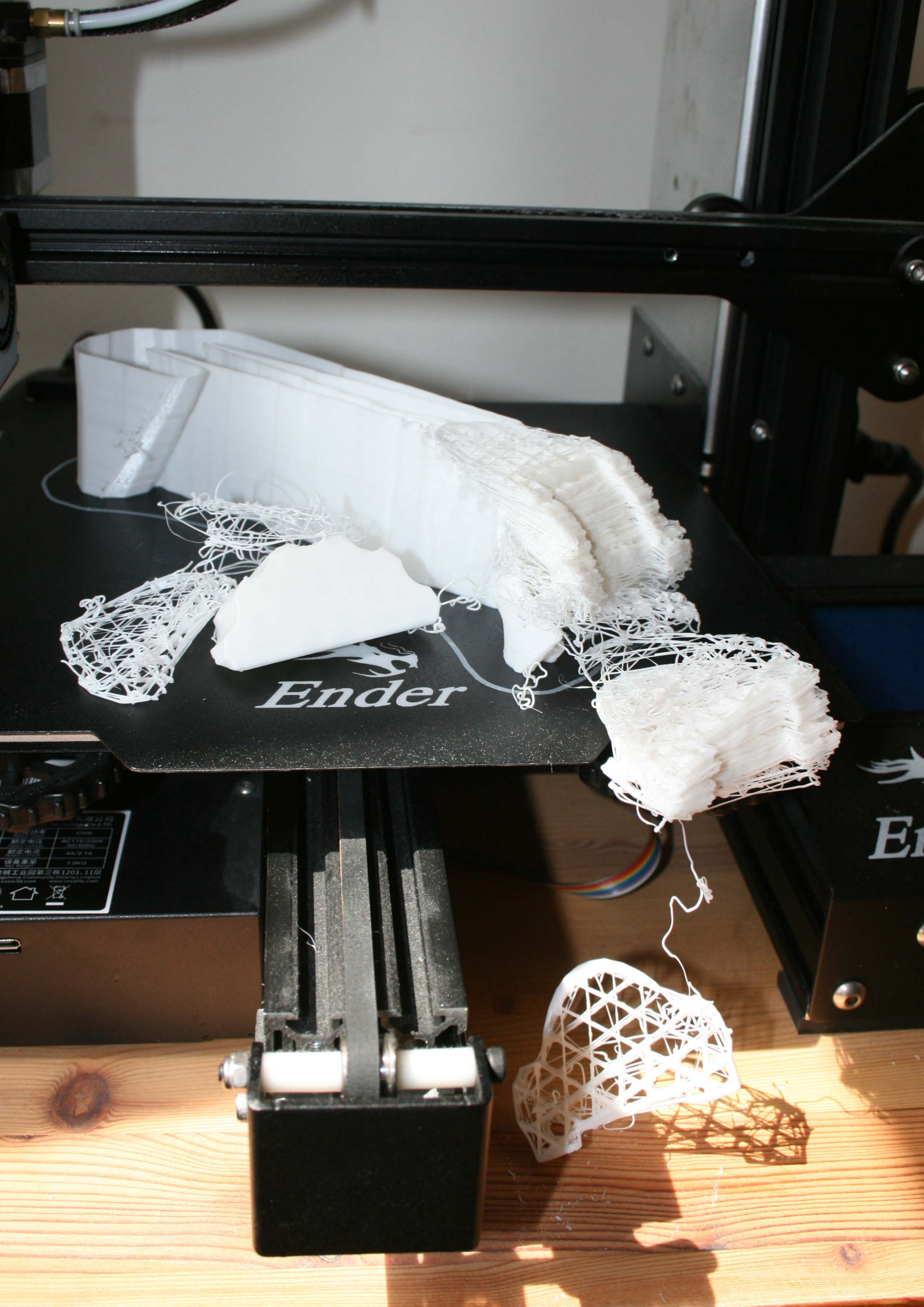
Financial limitations restricted the purchase of commonly used surgical devices for the analysis of mechanisms in this study. As a result, the examination was limited to dissecting a single hernia stapler and reviewing patents of existing mechanisms in medical devices to gather relevant information for ideations.

Next, the small scale necessitated the exploration of special mechanisms, like bio-inspired mechanisms from micro-organisms, origami, etc. which added complexity to the project.

Fortunately, it led to the interesting finding of compliant mechanisms. For example, for barbed suture blocking, a hammer that required 3 parts made of different materials. The latter was later substituted by a compliant mechanism made of just one material and requiring only one part. Compliant mechanisms however, are rarely used in medical devices, making this a potential source of inspiration for future developments in the medical field.

Alas, time constraints limited the ability to comprehensively test the completed mechanisms together, resulting in solely the testing of individual mechanisms instead. Some issues were encountered during modelmaking as well, resulting in even less time for tests. Still, the simple tests combined indicate that the StapleStitcher holds promise in terms of its technical feasibility and the potential for introducing a novel solution to the field of mesenteric defect closure.

Regarding desirability, specific demands surgeons may have were established through observations, conversations and literature. These were then formulated as concretely as possible in the list of requirements and used to evaluate ideas throughout the design process. Subsequently, by means of a questionnaire, the StapleStitcher was evaluated by surgeons. Obtaining a statistically significant sample of surgeons for evaluation of the tool was challenging. This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led to the use of a questionnaire rather than direct interaction with the surgeons. The assistance of the DSMBS was crucial in facilitating the evaluation.

The interpretation of their responses should take several factors into consideration. Surgeons, in general, tend to be highly critical and sceptical of new products, which is understandable given the potential risks and implications for patient outcomes (Birchley et al., 2020). Their cautious approach reflects their commitment to patient safety. Additionally, surgeons may downplay the cognitive difficulty, precision, and expertise required for laparoscopic surgery, and take great pride in mastering such complex procedures (Wochner, 2022; personal communication during observations). The statement "*if you can't suture, you shouldn't do LRYGB!*" - expressed by one of the surgeons - indicates a misconception that the proposed StapleStitcher would completely replace manual suturing. Another important aspect to mention is that the responses were obtained through a method of voluntary participation. This may have introduced a bias, as those who chose to respond may have different opinions and experiences compared to those who did not participate. This could influence the overall representation of surgeon perspectives in the study. Next, it is important to be aware of the neutral response bias, where respondents may choose neutral or ambiguous responses to avoid expressing strong opinions or taking a stance. This can be seen in the questions about quality, comfort and effectiveness. Fortunately, due to the substantiation of every surgeon the overall feedback could still be correctly interpreted.

Taking these biases into account, it is crucial to acknowledge the limitations of the study and the need for further research and validation to obtain a comprehensive understanding of surgeons' perspectives on the StapleStitcher.

Complementing the questionnaire data with qualitative insights would

provide a valuable addition to the study. Exploring aspects such as ergonomics in more detail by allowing surgeons to physically interact with the device through physical models can provide valuable insights. Which is also something that is expressed by most of them during the evaluation.

Thus the ultimate proof of desirability lies in the hands-on experience of the surgeons themselves, as they will need to test the StapleStitcher firsthand to provide a more comprehensive assessment.

Finally, the viability of the StapleStitcher is based on the identified need to improve mesenteric defect closure in laparoscopic Roux-en-Y gastric bypass surgeries. The StapleStitcher shows the potential in enabling substantial reductions in time, complexity, and effort required for the closure process. In addition, the StapleStitcher has been found to entirely differentiate itself from all other alternative devices on the market, which has been reaffirmed in the evaluation of surgeons. By addressing these key factors, the StapleStitcher holds promise for enhancing overall comfort for the surgeon and efficiency of the surgical procedure.

However, as the product progresses towards further development for manufacturing, a subsequent study should be conducted to perform a comprehensive cost analysis. By examining the various cost factors associated with production, including materials, labor, and operational expenses, a clear understanding of the economic viability of the project can be obtained. This analysis will determine whether the project has a solid financial justification to warrant its continuation.

Furthermore, in this design phase, in vitro/in vivo tests were way out of scope. The safety of the product could only indirectly be assessed with the aid of a risk analysis. Further development and embodiment of the StapleStitcher will make such research possible, and a re-assessment of safety should be done.

Recommendations

Given that the project is still in the early stages of the design process, as mentioned in the discussion and limitations section, there are still considerable aspects that will need further research and development.

To advance the development of the StapleStitcher and address the identified areas for improvement, a comprehensive set of recommendations and a roadmap are proposed. These recommendations aim to ensure the device's successful evolution and alignment with the needs of surgeons while enhancing patient safety in minimally invasive surgery.

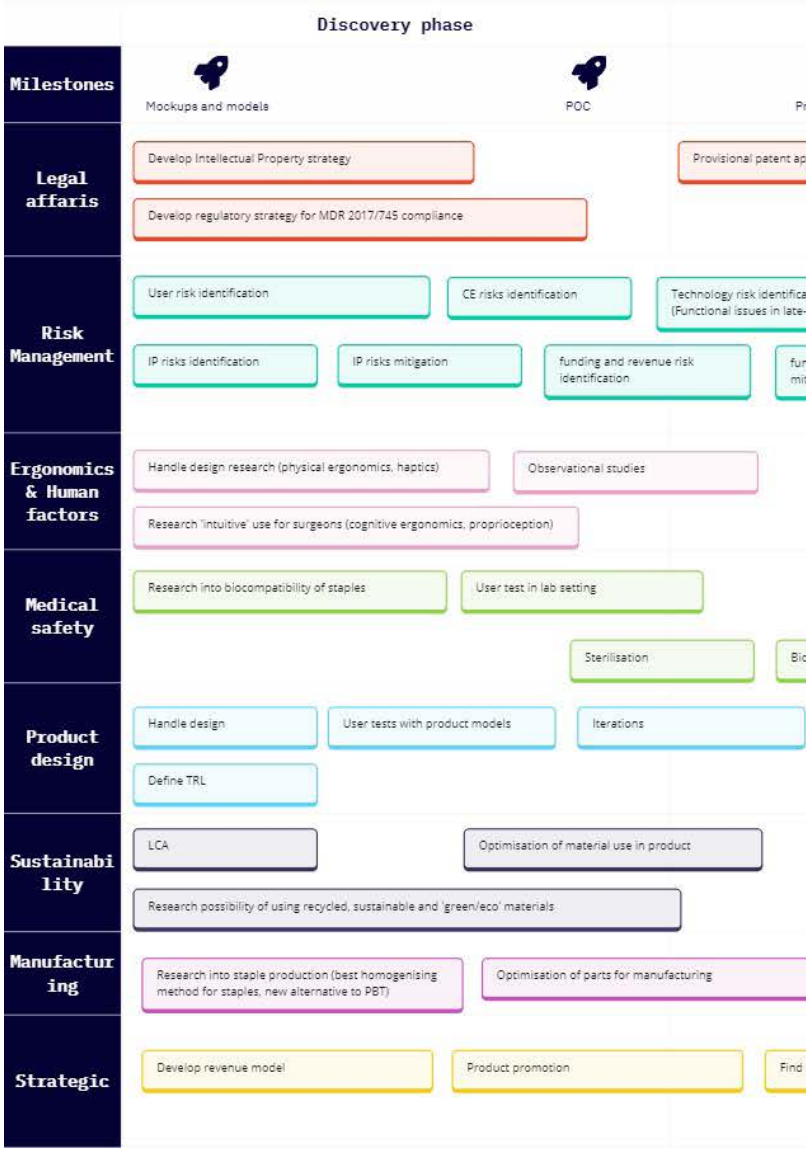
Enhancing Product Safety through Clinical Testing and Risk Analysis:

First of all, as became clear in the risk analysis, most identified risks are a consequence of how the surgeon uses the product. The product's safety mey be improved by incorporating clear visual indicators, ergonomic features, and intuitive controls. This will minimize the potential for errors or mishandling during surgical procedures.

Equally important is the provision of comprehensive instructions manuals and valuable training resources that will aid surgeons to effectively and safely utilize the StapleStitcher. By prioritizing intuitive design and comprehensive training, the StapleStitcher can mitigate risks and enhance patient safety throughout its utilization in surgical settings. A way of achieving this is to conduct verification experiments throughout the project using a co-evolutive methodology as proposed by Rasoulifar et al. (2007).

To further improve upon the safety

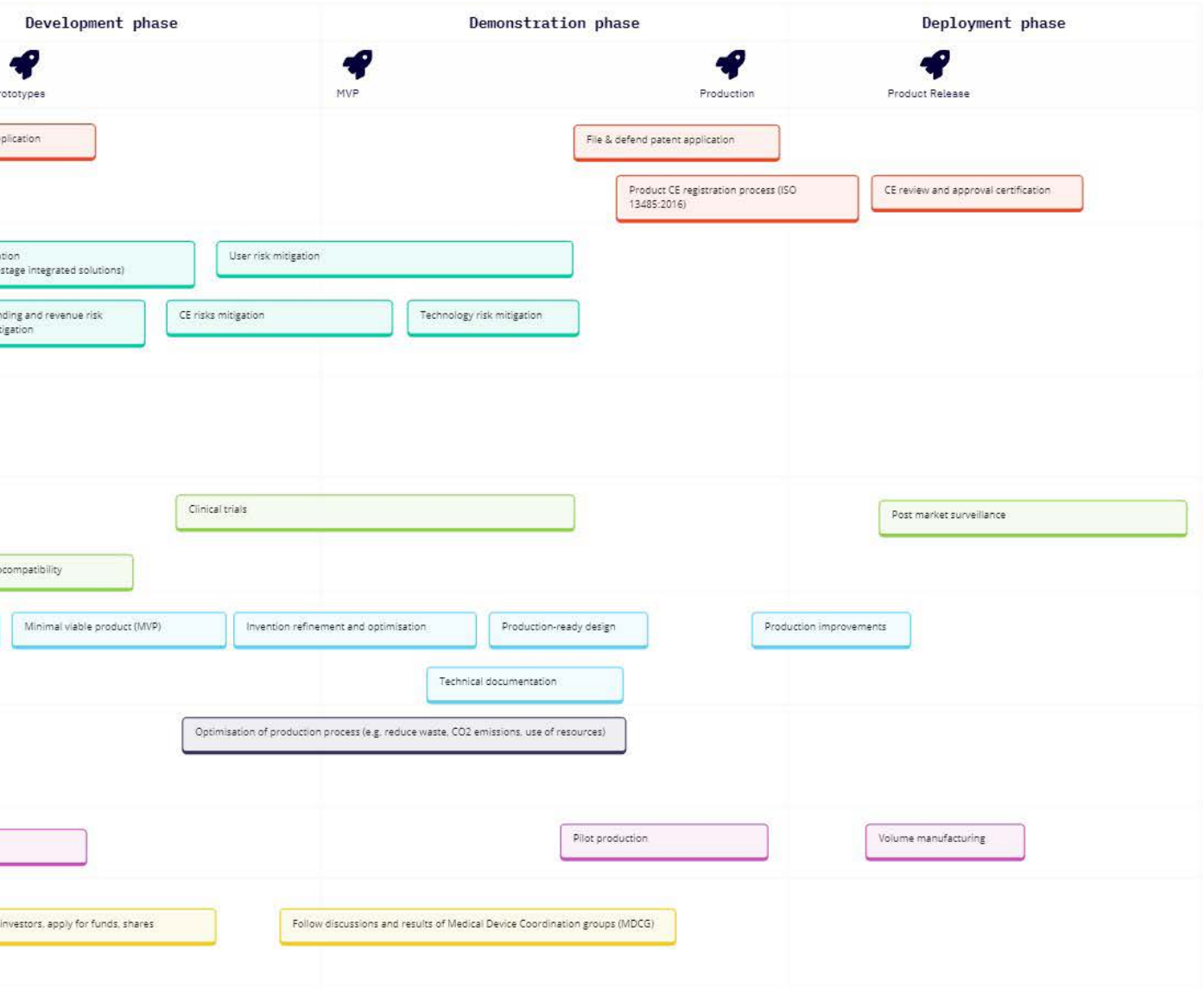
Figure 51. A roadmap showing the key areas for improvement.



of the StapleStitcher, conducting comprehensive clinical testing with a large and diverse group of surgeons is highly recommended. These clinical tests should be accompanied by rigorous risk analysis conducted in accordance with established CE guidelines to ensure that the StapleStitcher meets the highest safety standards.

Legal, Strategic Affairs, and Funding:

Addressing legal and strategic affairs is paramount to the StapleStitcher's success. Developing a regulatory strategy for CE compliance and



ensuring adherence to relevant regulations is crucial.

Another critical step in the project's progression is conducting a thorough cost analysis to determine the economic viability of the tool. This analysis should consider various cost factors, including materials, labour, and operational expenses. Understanding the financial implications will provide valuable insights for determining the project's continuation and resource allocation.

Additionally, creating a comprehensive revenue model and considering long-term investment requirements will provide a clear understanding of the financial landscape.

To secure the necessary resources, strategic design and effective product promotion should be utilized. Attracting investors and seeking funding opportunities early in the project's progression is essential. Exploring the potential for forming a start-up or collaborating with an established company can optimize the product's development and manufacturing processes.

Sustainability & manufacturing

To ensure the sustainability of the StapleStitcher and minimize its environmental impact, a comprehensive approach should be taken throughout the entire product life cycle. This involves optimizing manufacturing techniques and material usage to reduce waste, carbon emissions, and water usage. Collaborating with material science experts and manufacturers can provide valuable insights into alternative materials, production and assembly techniques to improve sustainability. To exemplify, exploring sustainable alternatives for the PBT barbed suture, which are not susceptible to material shortages, should be considered.

Incorporating robust quality control methods, including Failure Mode and Effects Analysis (FMEA), mitigates the risk of manufacturing errors or defects and helps prevent detrimental consequences associated with poor performance.

Component-Specific Recommendations:

Several components of the StapleStitcher warrant specific attention for further improvement. The staples and sutures, for instance, should yet undergo testing with casted NiTinol to assess their true performance.

The handle design is another critical aspect that requires refinement. Extensive research on the ideal shape, grip strength and proprioception is recommended to optimize the surgeon’s comfort during surgery. Anthropometric considerations, ensuring compatibility with surgeons' hands, and minimizing wobble and shakiness will contribute to stable staple placement and improved overall usability.

For the cartridge, more thorough testing is necessary to identify and address any potential jamming issues. Implementing a hard and

smooth surface on the inside, such as a thin layer of ceramics, can prevent the staples from jamming or other operational disruptions. Additionally, researching biocompatible lubricants may help improve the smoothness of dispensing staples.

Regarding the compliant mechanisms, exploring a more restricted path of movement may further enhance their functionality, as now there is still lots of space left for components to wobble. Additionally, integrating a pseudo-rigid spring to ensure proper retraction after use would improve usability and durability. Evaluating material fatigue and cycles to failure will provide valuable insights into the robustness and longevity of the compliant parts.

Additional features and fields of application:

To enhance the functionality of the StapleStitcher, several additional features can be considered. One recommendation, derived from the risk analysis, is the inclusion of a transparent window that allows for visualizing the remaining sutures and staples. Furthermore, the possibility of incorporating a mechanical counter that subtracts a digit each time a staple is placed could be explored. However, it is important to carefully consider the potential impact on size and weight if such features are added.

Another valuable addition could be the implementation of a ratchet mechanism or a similar mechanism between the punch and the cover. This would ensure that staples can only be released once they have undergone complete deformation. Such a mechanism would also reduce the risk of staple dislodgement due to incomplete deformation.

Currently, a grasper is required to provide counter pressure during staple placement. To further streamline the procedure and reduce the need for additional assistance, it may be worth investigating the possibility of incorporating an integrated grasper that can hold the tissue in place before staple deployment.

Based on feedback from surgeons, the inclusion of an automatic stabilization and tensioning mechanism for the barbed suture appears to be of interest. However, the trade-off between the potential benefits and the added bulk and weight needs to be carefully evaluated.

Finally, exploring the application of the StapleStitcher for closing other types of hernias, such as inguinal hernias, in addition to mesenteric defects following procedures like hemicolectomy, would be an intriguing field for further research.

By following this roadmap and implementing the recommended actions, the further development of the StapleStitcher will be guided effectively. These measures address key areas for improvement, enhance the StapleStitcher’s performance and usability, and pave the way for successful integration into the field of minimally invasive surgery, ultimately benefiting both surgeons and patients.

Conclusion

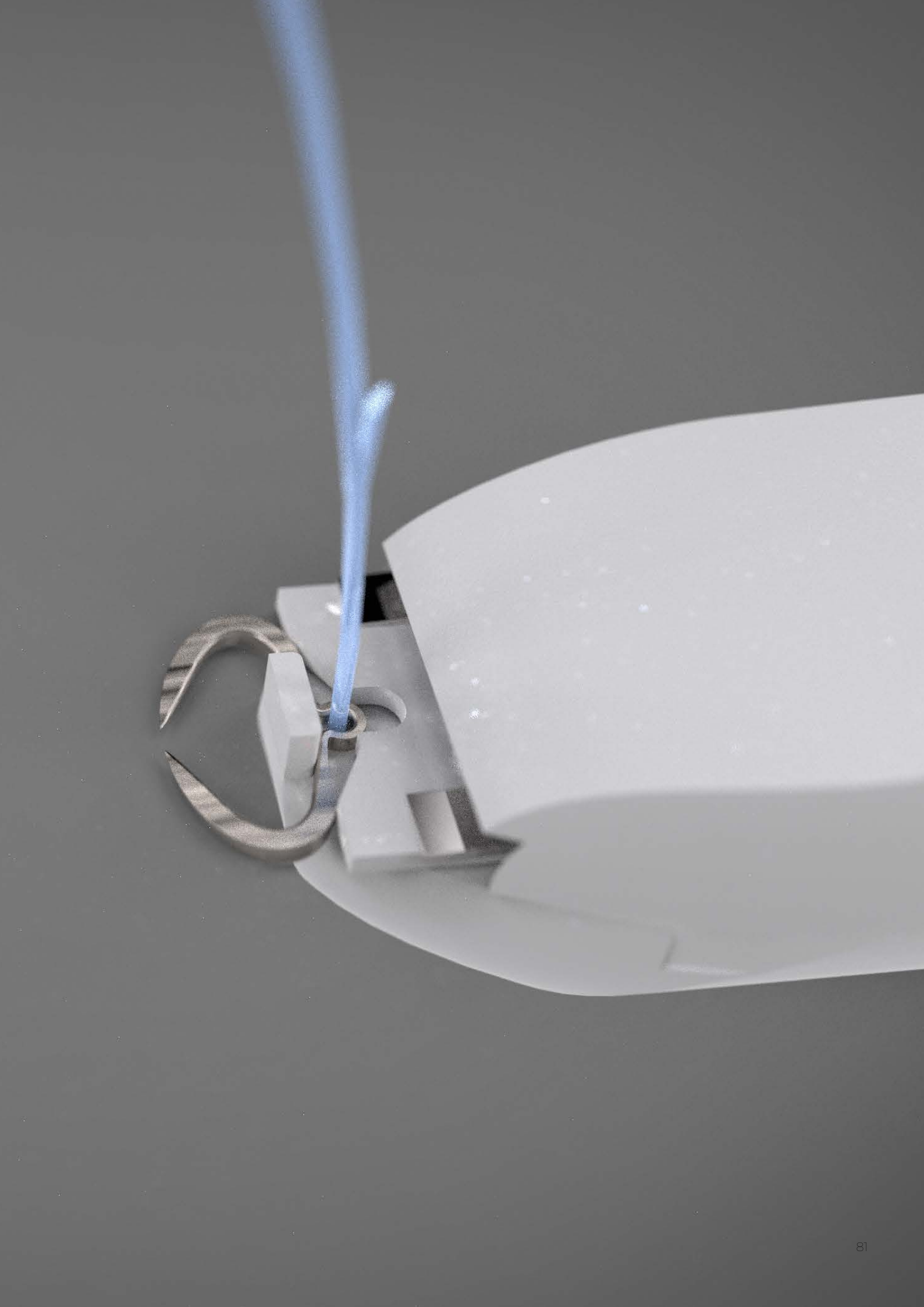
In conclusion, this report has presented the development of a novel surgical tool for minimally invasive surgery, specifically targeting mesenteric defect closure. The tool combines innovative staples and sutures, distinct from conventional methods and existing market tools. Comprehensive modelling, testing, and evaluation have resulted in the first iteration of the StapleStitcher. By simplifying the surgical workflow, the tool has the potential to reduce the surgeon's time, physical exertion, and cognitive load during the closure of the defects. The specific focus on the mesenteric defect closure during Gastric Bypass surgery highlights the project's practical application.

I employed a systematic and iterative design approach, specifically utilizing the triple diamond methodology supplemented with additional methods e.g. from the Delft Design Guide (Zijlstra et al., 2020). This approach enabled a deep understanding of the underlying problems, identification of essential components, and development and testing of each component individually before integrating them into a complete device. This iterative approach not only facilitated continuous improvements but also laid a solid foundation for future studies and advancements in the field.

The evaluation of the StapleStitcher through a questionnaire among bariatric surgeons has revealed overall positive feedback and its alignment with their requirements for successful mesenteric defect closure. Surgeons recognized the product's innovativeness and expressed interest in its further development. Consequently, the StapleStitcher can be considered a valuable addition to surgeons' armamentarium, potentially even lowering the threshold for defect closure.

The project is still in the early design stage, which is evident from the insufficiently fulfilled list of requirements and remaining risks from the risk analysis. Thus further research, collaboration and development are crucial to address remaining risks and ensuring a successful product outcome and clinical implementation.

However, this report still offers a promising outlook for future advancements in the field of bariatric surgery, with the newly developed tool revealing the potential for improved surgeon’s comfort and enhanced efficiency.



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