Appendix

A. Medical Definitions

All relevant medical terms that are used in the project will be briefly explained in this section.

For more (short) definitions please go to:
Medical Dictionary of Health Terms: A-C - Harvard Health
URL: https://www.health.harvard.edu/a-through-c

or
Medical Dictionary (thefreedictionary.com)
URL: https://medical-dictionary.thefreedictionary.com/

Overweight and obesity

The measure of underweight or overweight is the Body Mass Index (BMI). BMI is the quotient of body weight in kilograms and the square of height in metres [kg/m2]. For adults aged 20 years or older, the criteria are:

- Underweight: BMI < 18.5

- Normal weight: BMI >= 18.5 and < 25.0

- Overweight: BMI >= 25.0

Moderately overweight: BMI >= 25.0 and < 30.0

Severely overweight/obese: BMI >= 30.0 and <35.0

Extremely overweight/morbidly obese: BMI >= 40 or >= 35 with additional medical complaints, such as diabetes (diabetes), cardiovascular disease or joint problems (Centraal Bureau voor de Statistiek, 2023).

Laparoscopy

A type of surgical procedure that allows a surgeon to access the inside of the abdomen and pelvis without having to make large incisions in the skin. A.k.a. keyhole surgery or minimally invasive surgery (NHS, 2021).

Laparoscope

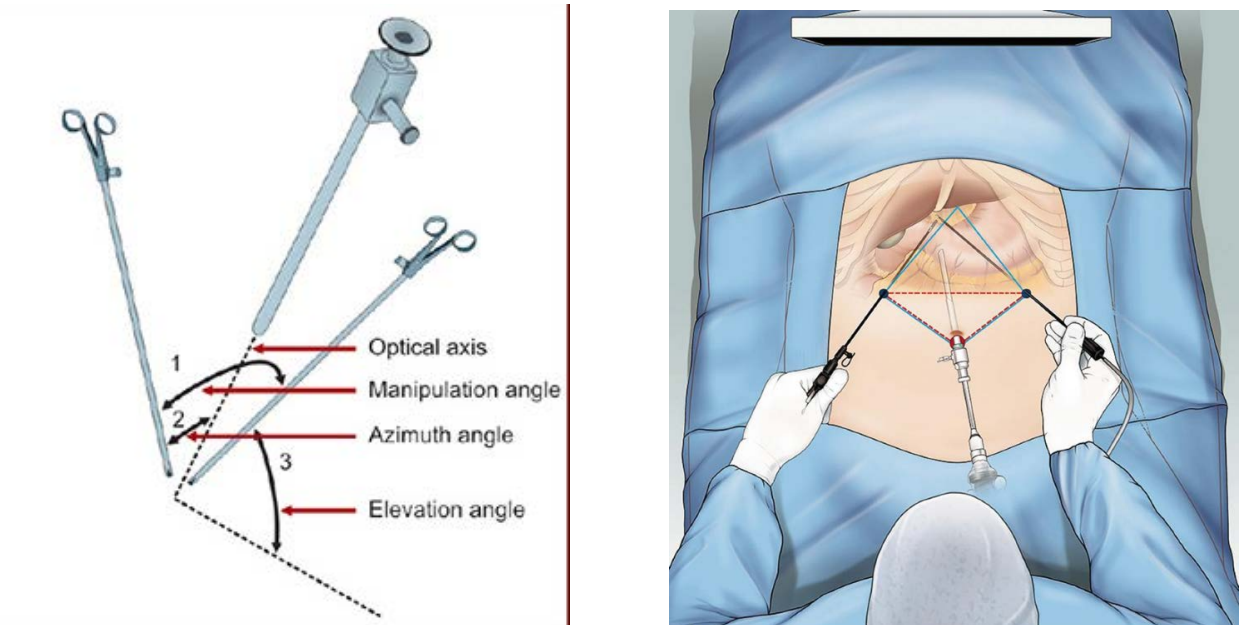


Figure A-1 Fulcrum effect (Wochner, 2022)

A small tube that has a light source and a camera, which relays images of the inside of the abdomen or pelvis to a television monitor (NHS, 2021).

Trocar

A sharp-pointed instrument equipped with a cannula; used to puncture the wall of a body cavity and withdraw fluid or to introduce an endoscope.

(The free dictionary, n.d.)

Fulcrum effect

Motion inversion due to a tipping point in the abdominal wall (or in the trocar). When moving the handle in a certain direction, the end will move in the opposing direction. See Figure A-1.

Bariatric surgery

Surgery for people with a body mass index (BMI) of 40 or more, or a BMI between 35 and 40 and an obesity-related condition that might improve if you lost weight (such as type 2 diabetes or high blood pressure), in order to provide significant long-term weight loss. Only applicable when all other

weight-loss methods were unsuccessful.
A.k.a. metabolic surgery (NHS, 2023)

See Figure A-2 for an illustration.

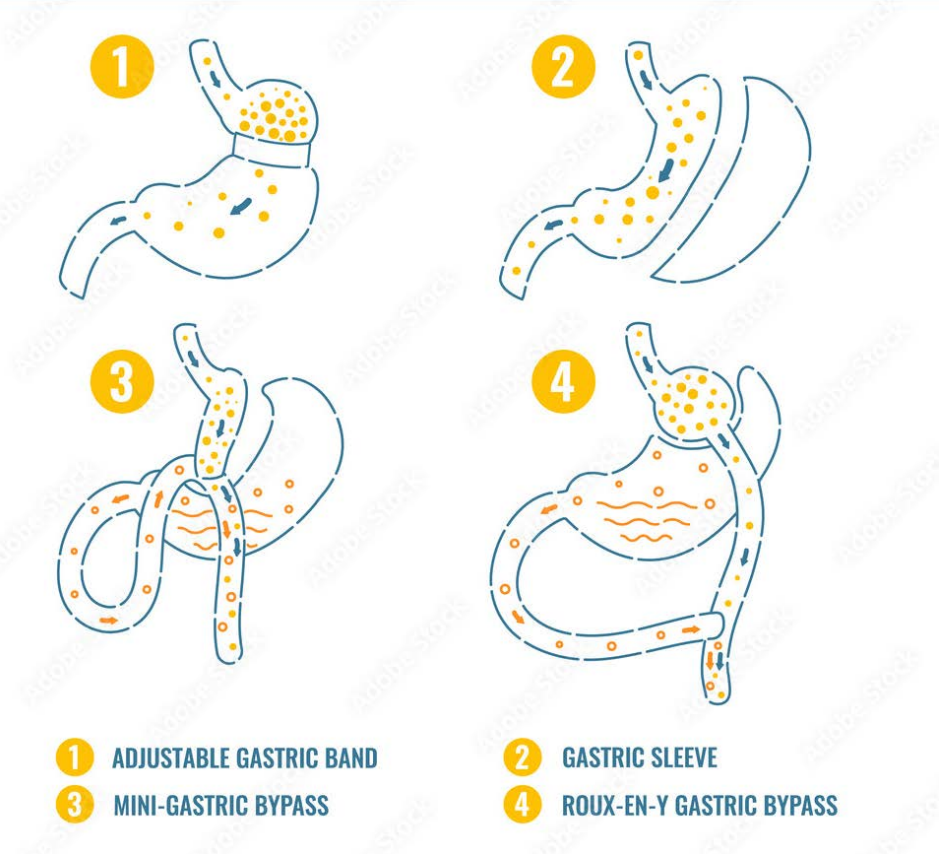


Figure A-2 Baraitric surgery procedures (Adobe stock, n.d.)

The most common types are:

gastric band – a band is placed around your stomach, so you do not need to eat as much to feel full

gastric bypass – the top part of your stomach is joined to the small intestine, so you feel fuller sooner and do not absorb as many calories from food.

A.k.a. Roux-en-Y gastric bypass

sleeve gastrectomy – some of your stomach is removed, so you cannot eat as much as you could before and you'll feel full sooner

Gastro-intestinal (GI) anastomosis

Intestinal anastomosis is a surgical procedure performed to establish communication between two formerly distant portions of the intestine. This procedure restores intestinal continuity after the removal of a pathologic condition affecting the bowel.

This includes hemicolectomy, jejunojejunostomy, gastrojejunostomy, ileocolic anastomosis,

colorectal anastomosis, esophagogastric anastomosis and more.

(Kate & Kalayarasan, 2022)

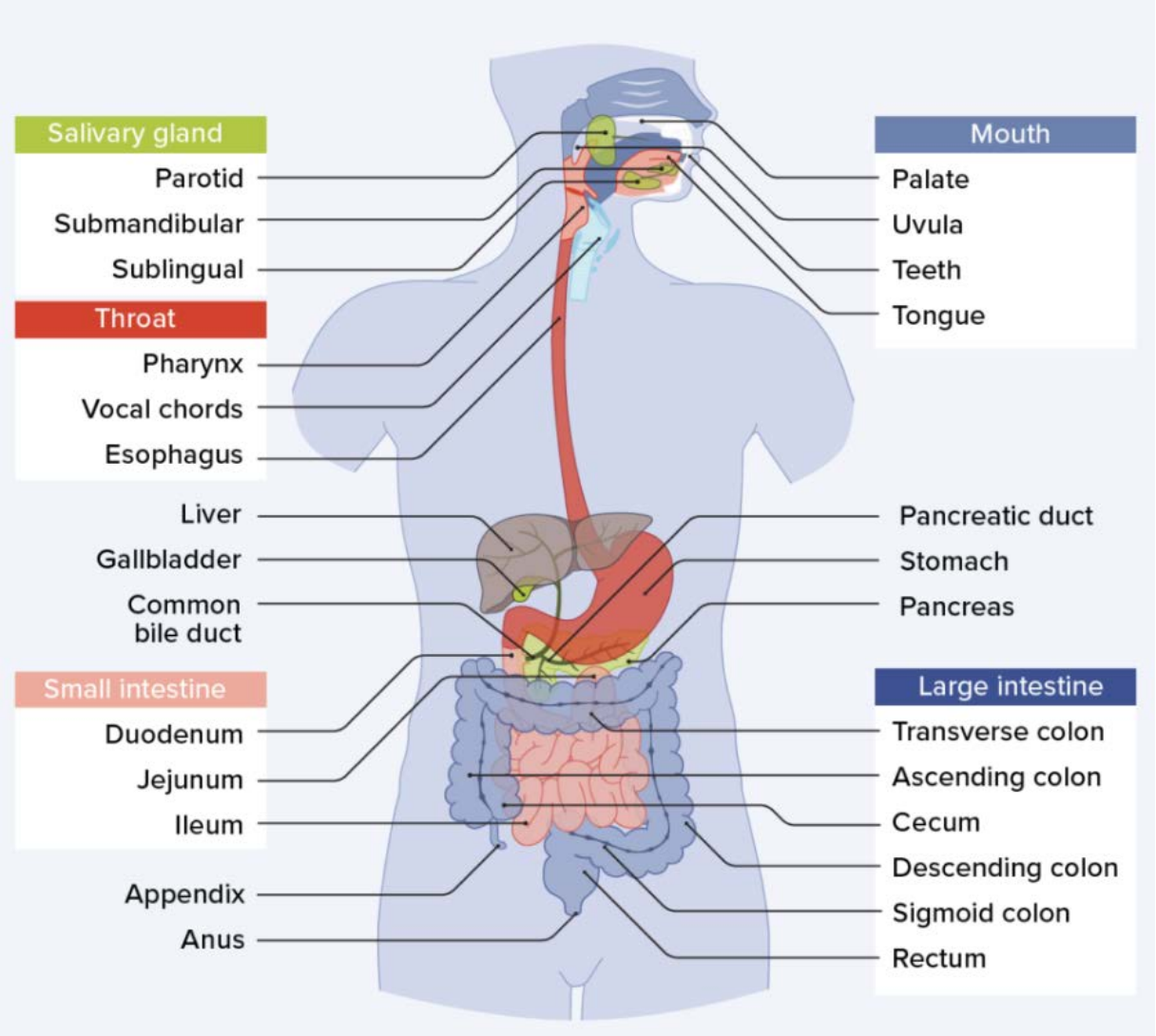


Figure A-3 The digestive system (Newman, 2023b)

Duodenum

The upper part of the small intestine (Newman, 2023)

Jejunum

The middle part of the small intestine (Newman, 2023)

Ileum

The lower part of the small intestine (Newman, 2023)
(See Figure A-3)

Ostomy

A surgically created opening connecting an internal organ to the surface of the body. Different kinds of ostomies are named for the organ involved. The most common types of ostomies in intestinal surgery are an “ileostomy” (connecting the ileal part of the small intestine to the abdominal wall) and a “colostomy” (connecting the colon, or, large intestine to the abdominal wall).

(United Ostomy Associations of America, Inc, 2023)

Jejunojejunostomy

Jejunojejunostomy is a surgical technique used in an anastomosis between two portions of the jejunum.

Methylene blue

A dye used for controlling the water tightness of the anastomosis. It is introduced through the

mouth and the surgeon checks if there are any leaks around the performed anastomosis (Wochner, 2022).

Mesentery

A fold of membrane that attaches the intestine to the abdominal wall and holds it in place (Figure A-4). It Is part of the peritoneal lining that extends from the posterior peritoneum and suspends bowel loops. The mesentery is composed of two thin layers of fibrofatty tissue, which surrounds and contains the vascular and lymphatic structures (Figure A-5) supplying

either the small bowel or colon. The purpose of the peritoneum and mesentery is to provide a smooth and frictionless surface between the solid organs. See Figure A-6

(Gore & Levine, 2014)

Mesenteric defect

Mesenteric defects are intentionally created in the Roux-en-Y gastric bypass procedure, being classically known as a Petersen's hernia. The mesenteric defect in such cases, called Petersen's defect, is located between the transverse colon and the mesentery of the alimentary limb (the segment of the jejunum from the jejunojejunostomy until the connection with

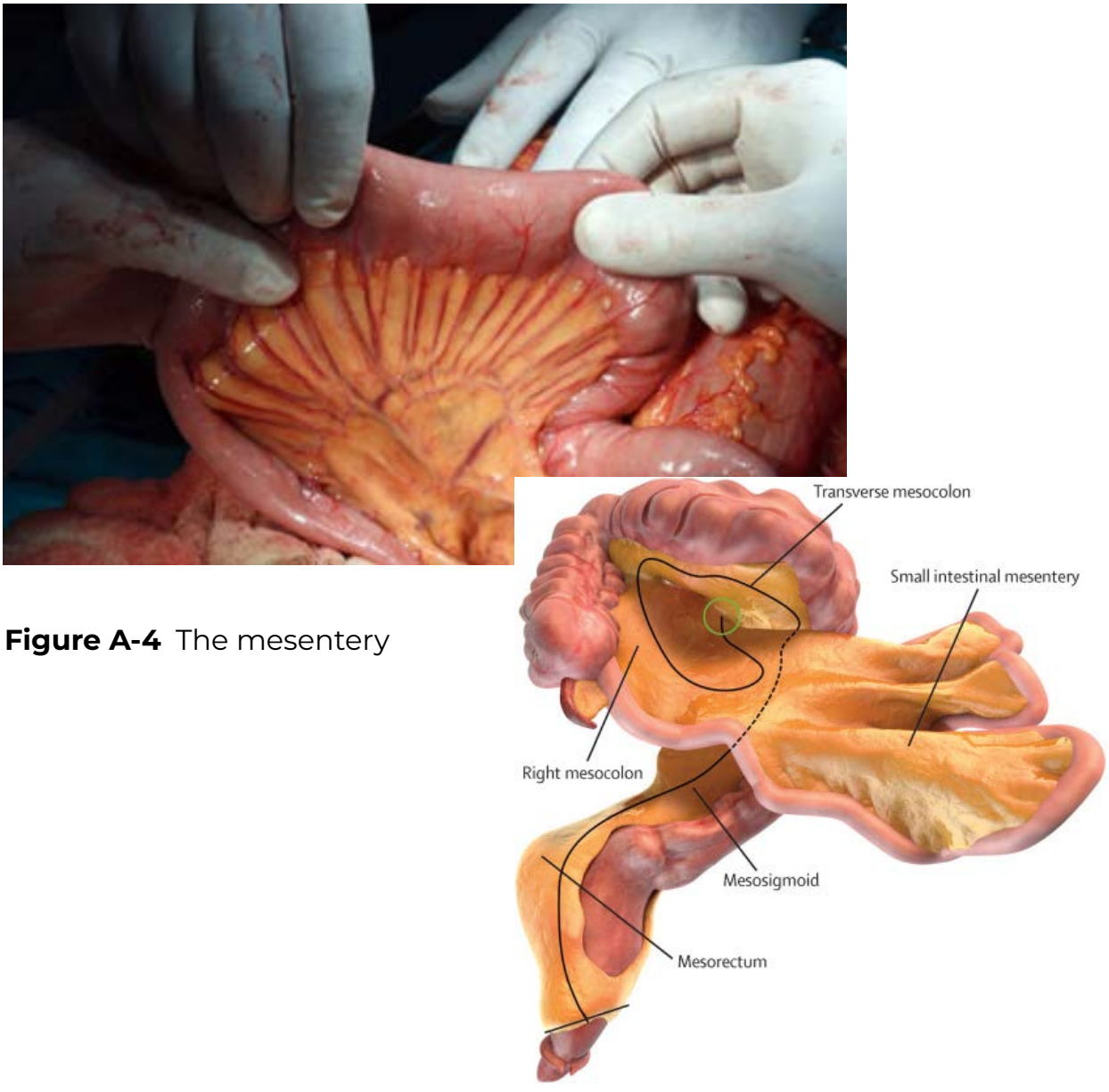


Figure A-4 The mesentery

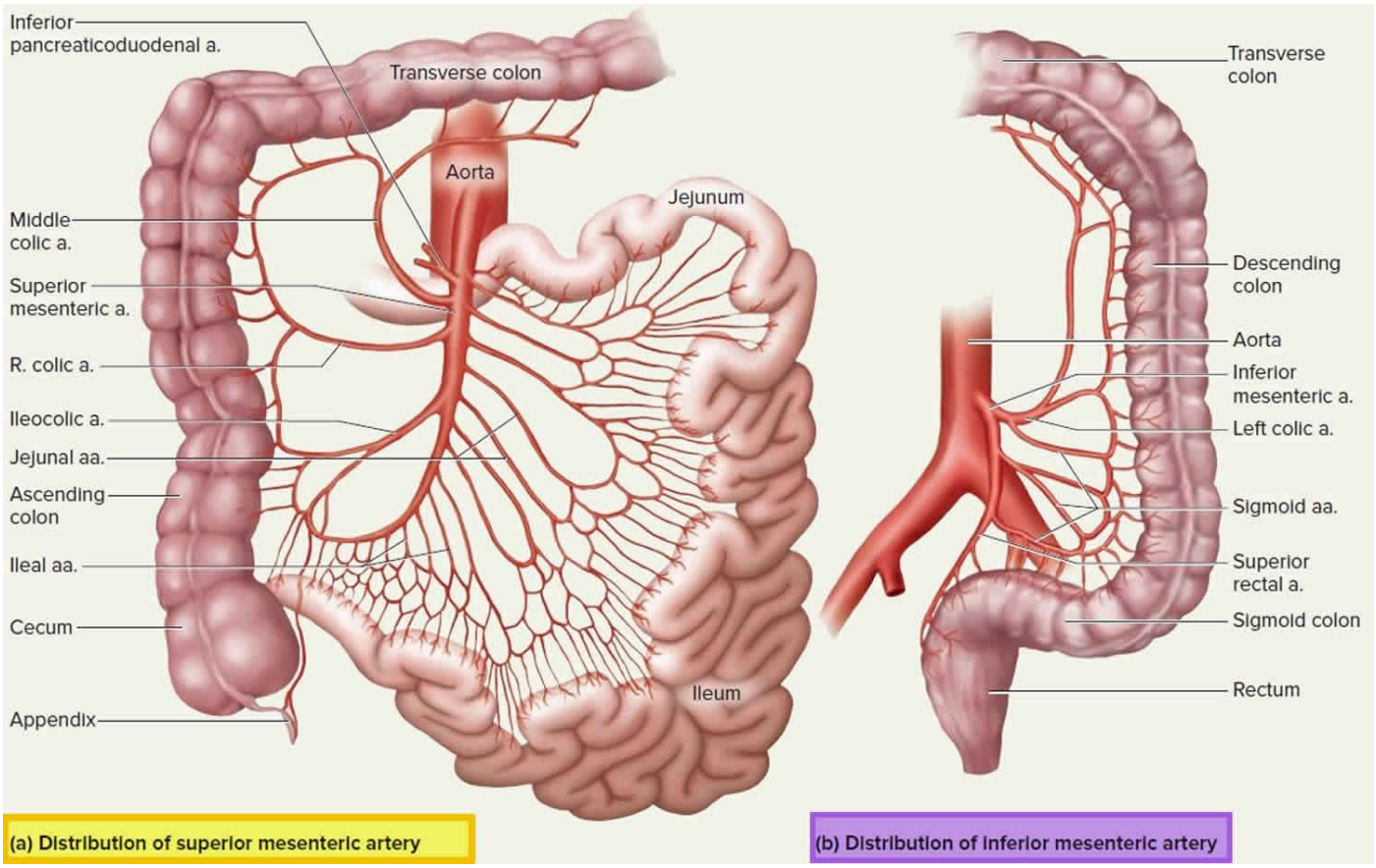
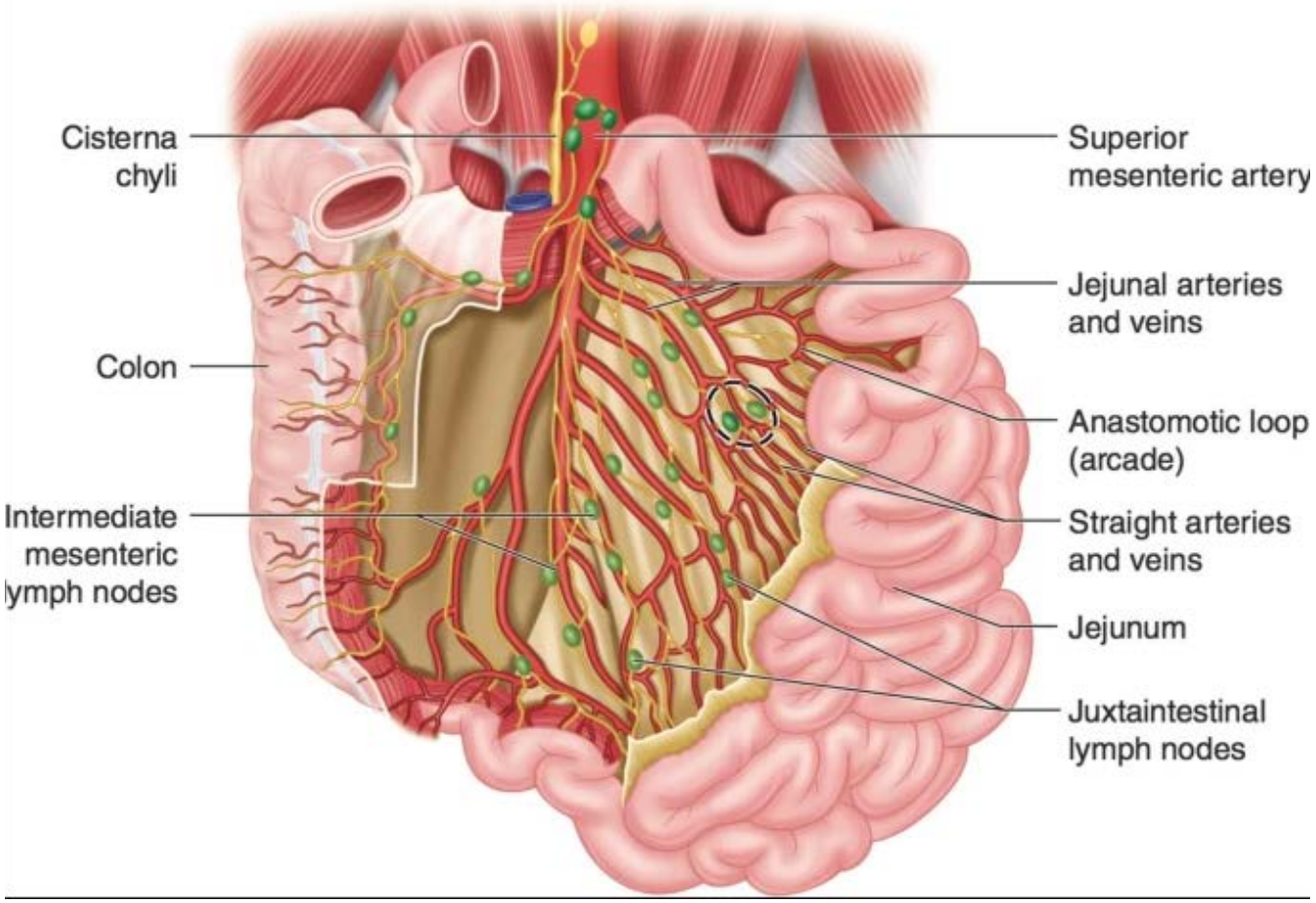


Figure A-5 The mesenteric artery (top) and lymph nodes (bottom) (Health Jade Team, 2018)



the proximal segment of the stomach) at the level of the jejunojejunostomy Wochner, N., 2022).

Internal herniation

Refers to the protrusion of internal organs through a weak abdominal tissue wall. This causes small bowel strangulation, which then causes intestinal obstruction.

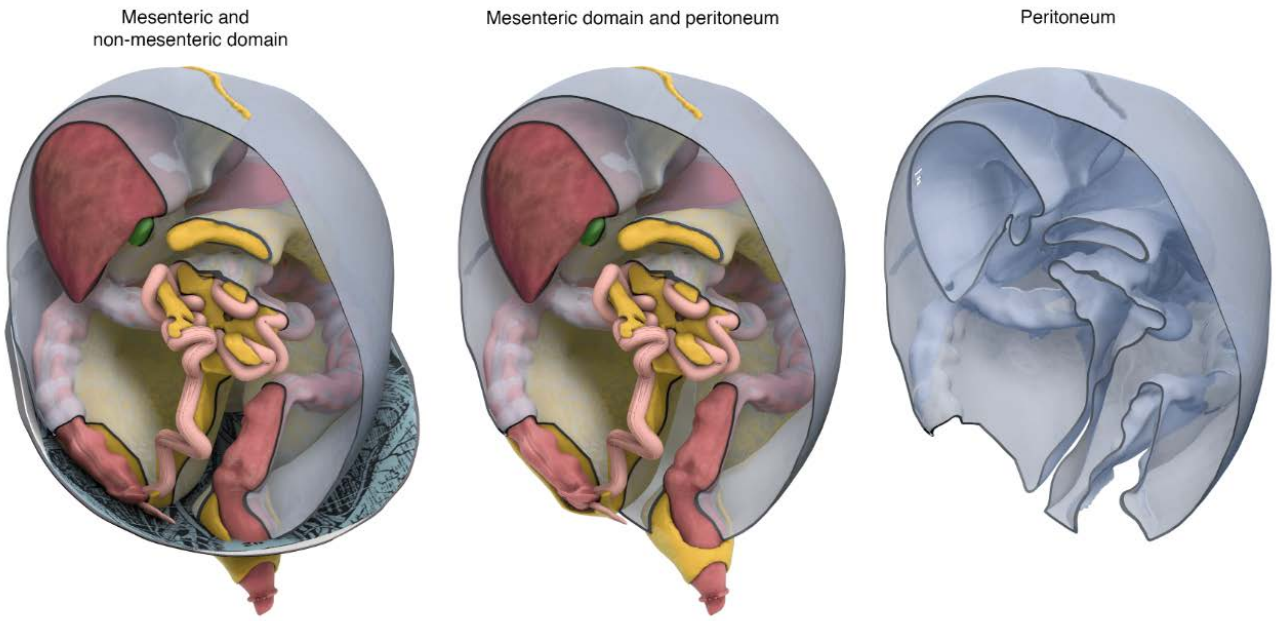


Figure A-6 The peritoneum (Springer Nature & Coffey, 2 B.C.E.)

Peritoneum

The serous membrane lining the cavity of the abdomen and covering internal organs (NCI Dictionary of Cancer Terms, n.d.-a). See figure A-6

Omentum

Fold of peritoneum connecting the stomach with other abdominal organs (NCI Dictionary of Cancer Terms, n.d.-b).

Pneumoperitoneum

Pneumoperitoneum is the presence of air or gas in the abdominal (peritoneal) cavity. To create the artificial space to perform surgery, CO2 is insufflated with an insufflation device (pump) into the intraabdominal vacuum (Schneider & Feussner, 2017a).

B. List of requirements

The following list of requirements has been compiled based on the gathered information throughout the project (Zijlstra et al., 2020, p.103). This comprehensive list serves several purposes: managing complexity, ensuring alignment between designers and medical experts, and facilitating the selection of the most promising ideas based on essential characteristics. The requirements are derived from a variety of sources, including medical academic literature, observations in the operating room, personal communication with experts, and compliance with legislative rules such as ISO and CE marking requirements set by the European Union.

Type	Category	Nr	Requirement	Source	Status
01. Performance					
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 so nothing gets caught behind it	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 rules and regulations	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 product cost	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 facilities	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 weight	36	Must be suitable for laparoscopic setting, therefore fit inside a 12 mm trocar	Wochner, N. (2022)	Included
Requirement	10. Size and weight	37	Must not weight over 200 grams	From findings: 02 - 21 | s	Difficult to as...
Investigate	10. Size and weight	38	Product should have maximum dimensions of 4 x 55 x 20 cm (incl handle)	Own deduction	Included
Requirement	10. Size and weight	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, appearance and finish	41	Surface finishes of different components must match each other	Own deduction	Not yet inclu...
Nice to have	11. Aesthetics, appearance and finish	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, appearance and finish	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 span	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 rules and regulations	48	Usability engineering must be applied, safety by design	ISO 62366-1	Not yet inclu...
Investigate	14. Standard rules and regulations	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 rules and regulations	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 liability	69	The staples must not get jammed when the product is in use	Risk Analysis	Difficult to as...
Requirement	22. Product liability	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 and initiation of use	71	Must be sterile when coming out of the packaging	ISO 62366-1	Included
Investigate	23. Installation and initiation of use	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 and initiation of use	73	The product must be easily understandable for a bariatric surgeon	Own deduction	Difficult to as...
24. Resue, recycle, refurbish					
Nice to have	24. Resue, recycle, refurbish	74	The handle must have a minimum of hinges and bolts, to facilitate recycling	(Schneider & Feussner, 2	Included

Consent form for observations (Dutch)

Toestemmingsverklaring observatie

U wordt verzocht om deel te nemen aan een onderzoek genaamd ‘observatie ter verkenning van de operatieve omgeving’ op 3 maart 2023. De observatie zal worden uitgevoerd door Louise van den Wildenberg van de TU Delft. Het doel van dit onderzoek is om omgevingsfactoren te achterhalen die van invloed zijn op de cognitieve en fysieke ergonomie van de chirurg. De data zal gebruikt worden voor het ontwikkelen van nieuw chirurgisch gereedschap en een master thesis inclusief publicatie. U wordt gevraagd om toestemming voor het maken van beeldmateriaal, waarbij u niet herkenbaar in beeld zal worden gebracht. Verder worden er notities gemaakt, waarbij alle data anoniem zal worden verzameld. Uw deelname aan dit onderzoek is volledig vrijwillig en u kunt zich elk gewenst moment terugtrekken zonder hier een reden voor te geven.

Uw toestemming:

❏ Ik bevestig dat ik het bovengenoemde informatie over het onderzoek gedateerd 03-03-2023 heb gelezen en begrepen. Ik heb de mogelijkheid gehad (1) om de informatie te overwegen en (2) om vragen te stellen en naar tevredenheid antwoorden te krijgen.

❏ Ik bevestig dat ik deelneem aan dit onderzoek en geef mijn toestemming. Ik begrijp dat het onderzoek wordt uitgevoerd in overeenstemming met de informatie op het informatieformulier waarvan ik een kopie heb bewaard.

❏ Ik begrijp dat ik mij op elk moment kan terugtrekken uit het onderzoek, zonder gevolgen, en dat ik geen reden hoef op te geven voor mijn terugtrekking.

❏ Ik ben op de hoogte van het feit dat ik kan worden opgenomen via video of audio en dat er foto's kunnen worden genomen voor analysedoeleinden.

❏ Ik begrijp dat alle opgenomen informatie alleen zal worden gebruikt voor de in de beschrijving beschreven doeleinden.

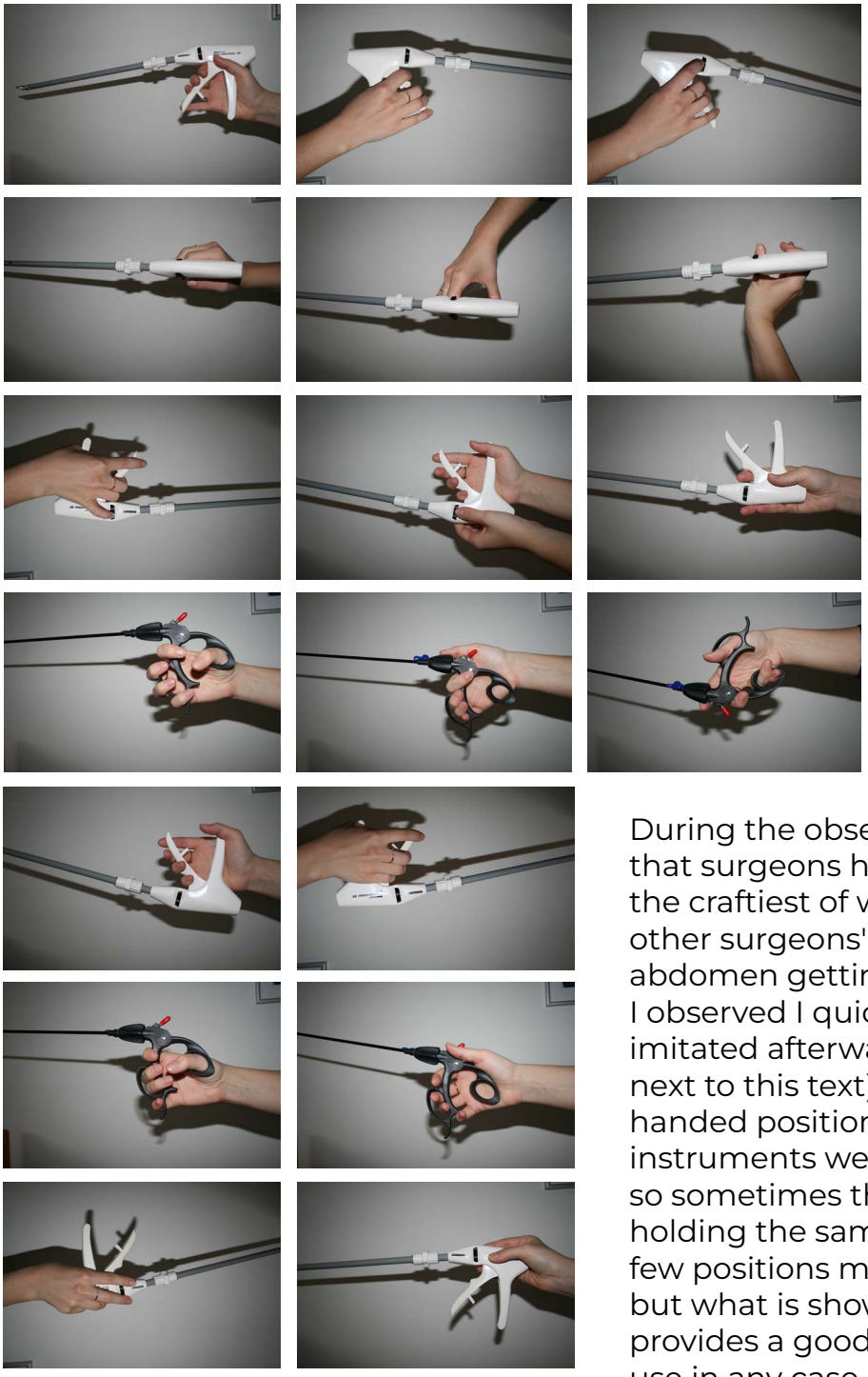
❏ Ik begrijp dat alle gegevens worden geanonimiseerd en dat gezichten op foto's worden uitgesloten of vervaagd.

_____	_____	_____
Naam deelnemer	Handtekening	Datum

_____	_____	_____
Naam onderzoeker	Handtekening	Datum

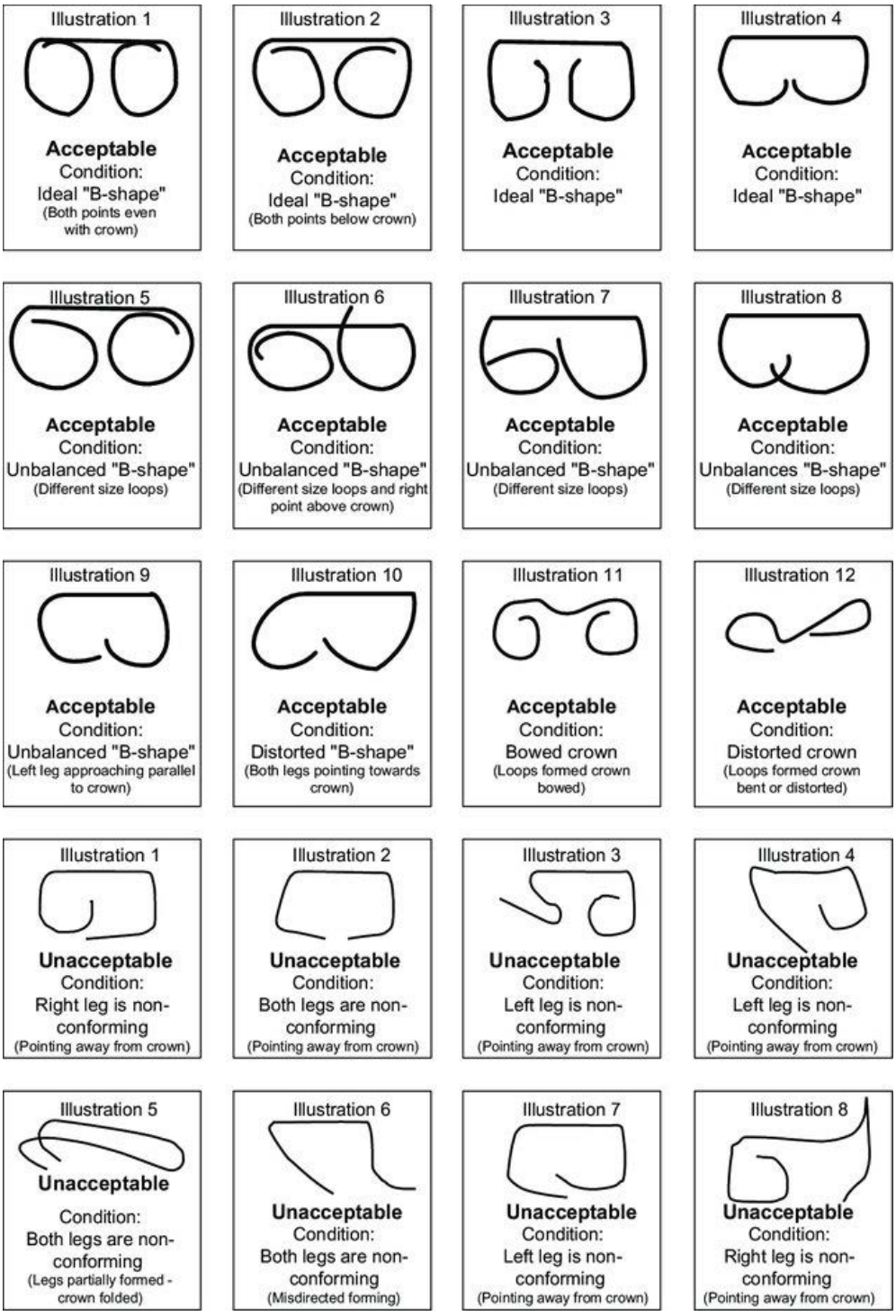
Contactgegevens van de onderzoeker:
Naam: Louise van den Wildenberg
E-mail: [redacted]
Nummer: [redacted]

D. Positions of handle usage during surgery



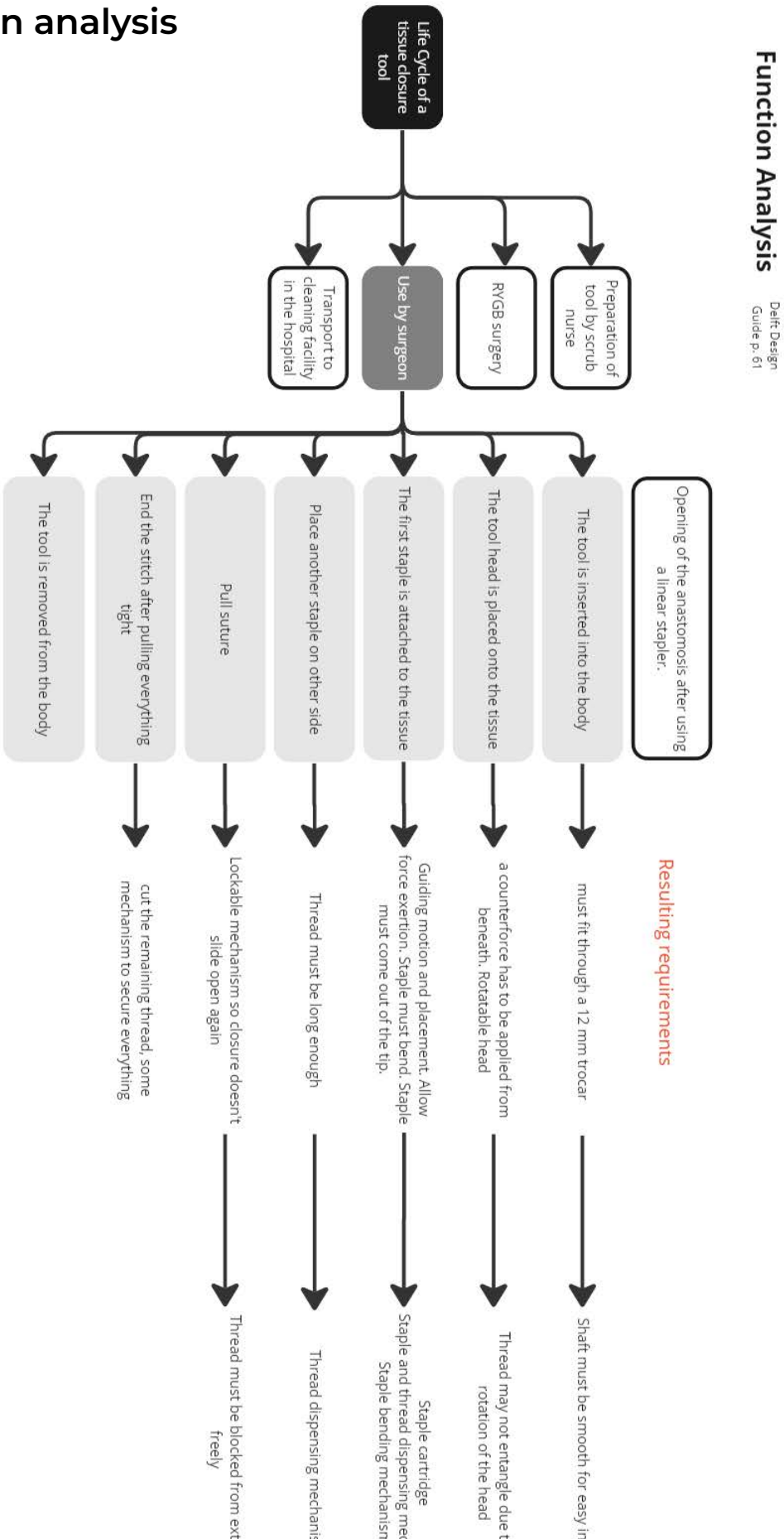
During the observations, it was observed that surgeons held their equipment in the craftiest of ways. It is due to either other surgeons' arms or the patient's abdomen getting in the way. The positions I observed I quickly sketched on paper and imitated afterwards (see the photographs next to this text). These are only the one-handed positions. At some points, the instruments were being held by two people so sometimes there were two right hands holding the same handle. It is possible that a few positions might have slipped my mind, but what is shown here in the photographs provides a good impression of their actual use in any case. It can be deduced that the final handle design should be able to be used from various different angles. Of course, the size of the handle in comparison to the varying hand sizes of surgeons has to be taken into account.

E. Acceptable and unacceptable staple shapes



These are illustrated examples of acceptable and unacceptable staple shapes after bending (Chekan & Whelan, 2014). Here the example was taken of the standard shape of staples for making an anastomosis, however, the shape of the bent legs also applies to the mesentery to ensure proper hold.

F. Function analysis



G. Market analysis, Laparoscopic fixation methods and state-of-the-art equipment

The primary fixation method used in laparoscopic surgery is suturing by hand, which is still widely used and has been refined over the years. However, several other devices and methods have been developed, attempting to improve tissue closure processes. This chapter will provide an overview of these alternative methods, in addition to the foregoing market analysis done by Wochner (2022), to identify unmet needs and market gaps.

Suturing by Hand:

The traditional method of laparoscopic fixation involves suturing by hand. This technique involves the use of various suture types, such as polyglactin, polyglycolic acid, or polydioxanone, and optimised needle holders, such as curved, straight, or self-anchoring needle holders, to close tissue. This technique is versatile, reliable and is generally the preferred method for closing mesenteric defects. However, suturing by hand is time-consuming, requires skilled operators, and can be uncomfortable for the surgeon. Moreover, the needle drivers are reusable so little waste is involved in using this method, as only the packaging of the sutures is thrown away.

Nowadays, there are suture variants with barbs on them, which prevent the suture from slipping back and thus eliminating the need for tying knots. More about barbed sutures can be found in Appendix I. However, the rest of the procedure is still the same, thus still demanding great efforts from the surgeon. The barbed sutures are more expensive but are more cost-effective given the time it saves in tying knots (M. de Brauw, personal communication, 2023).

Suturing devices:

Several devices have been developed to offer closure options for challenging tissues. A few examples are the RD180® DEVICE from LSI Solutions (n.d.) (Joshi et al., n.d.), Endo Stitch and SILS Stitch from Medtronic (n.d.), the Overstitch by Apollo endosurgery (n.d.), the Cor-Knot automated fastener (LSI Solutions, 2023), the Capio™ SLIM by Boston Scientific (2023) and the AcuStitch LLC (AcuStitch LLC, 2021).

These devices have several benefits, including a reduction of closure time,

consistency, reduced trauma compared to suturing by hand and ease of use in areas with limited access and visibility. However, these devices are expensive (which is a big factor in their availability), and are not suitable for all types of tissue and/or surgical applications.

Only the devices from Medtronic have been used by surgeons in the Netherlands to close or fixate tissue. However, they were used for other applications than for closing mesenteric defects (Y. Acherman, personal communication, April 2023).

All of these are single-use devices, leading to increased waste compared to suturing by hand.

The ProxiSure made by Ethicon (part of johnson&johnson) is the only suturing device I found that is reusable (Ethicon, 2017b). Nonetheless, it is unobtainable and has vanished from the Ethicon and Johnson & Johnson Medtech sites.

Staplers:

Several types of staplers have been developed to simplify the closure process: linear

cutting staplers, linear non-cutting staplers, and circular staplers. However, these three are not suitable for mesenteric tissue closure. There was a special variant of linear non-cutting staplers called Temporarily Flexible Linear Staplers (Sodergren et al., 2011) but it is not on the market anymore for unknown reasons (Schneider & Feussner, 2017).

In the past, staples were made of stainless steel, whereas at present most of them are made of a biocompatible titanium alloy (Toure, 2021). The only stapler used for closing mesenteric windows is the endo universal hernia stapler (Medtronic, 2023). However, it turns out that with these about 50% of the staples fall out over time (Wochner 2022; personal communication, 2023).

Alternative Closure Methods:

Other closure methods, such as clips, tacks, and rivets, have been developed to provide alternative closure options. Examples of clips include LAPRA-TY® Suture Clips (Ethicon, 2019), Aesculap challenger Ti-P (B. Braun SE, n.d.), the OTSC clip (Ovesco Endoscopy AG, n.d.) and Padlock clip (STERIS, 2023) are examples of clips that are easy to use and provide secure closure. However, clips are not meant to seal larger windows but are used to quickly seal narrow openings in case of leakage, for example (personal communication, 2023).

Tacks, such as the ProTack (Medtronic, 2023b) and Fastouch by ViaSurgical (Ofek Levin, 2015) are used for laparoscopic mesh fixation. Using mesh to close mesenteric defects, like the BIO-A® (W. L. Gore & Associates, Inc., n.d.), was proven safe and effective and has led to a complete reduction of Petersen's internal herniations (Skidmore & Aarts, 2021). However, surgeons are reluctant to use mesh as it introduces quite some foreign material into the body (Y. Acherman, personal communication, April 2023), plus it is relatively expensive ($580,-).

Adhesion formation with the use of YAG laser welding (1 W and 10.6-sec pulses) may also be an interesting closure method. The laser repair method significantly reduces the time needed to fix an enterotomy, and it is a straightforward procedure with a noticeable decrease in the formation of adhesions after repair (Cespanyi et al., 1987). Were this to be used to grow two pieces of mesenteric tissue to one another, it would still require additional reinforcement of sutures or staples before the two sections can grow together.

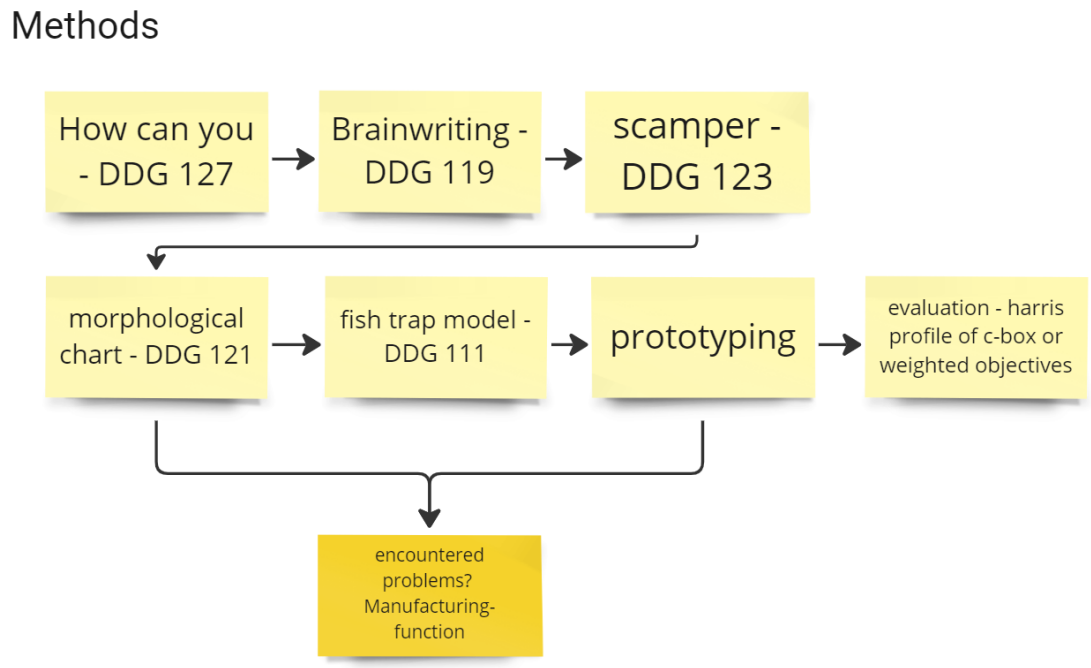
Another alternative could be special tape, made from polyacrylic acid and reinforced with polyvinyl alcohol and biodegradable polyurethane (Massachusetts Institute of Technology, 2022). However, this is not yet on the market, they still seek FDA approval to test the tape in medical settings. Glubran Glue (N-butyl-2-cyanoacrylate (NBCA) has been used to close mesenteric defects (Skidmore & Aarts, 2021). Unfortunately, glueing MDs with this glue was proven not beneficial (Skidmore & Aarts, 2021)

As the use of tape and/or glue is a fundamental mechanics problem, namely adhesion, in an extremely challenging environment (inside the body) I have not looked into this much further for this project.

Segmented instruments, Robot-assisted and autonomous devices:

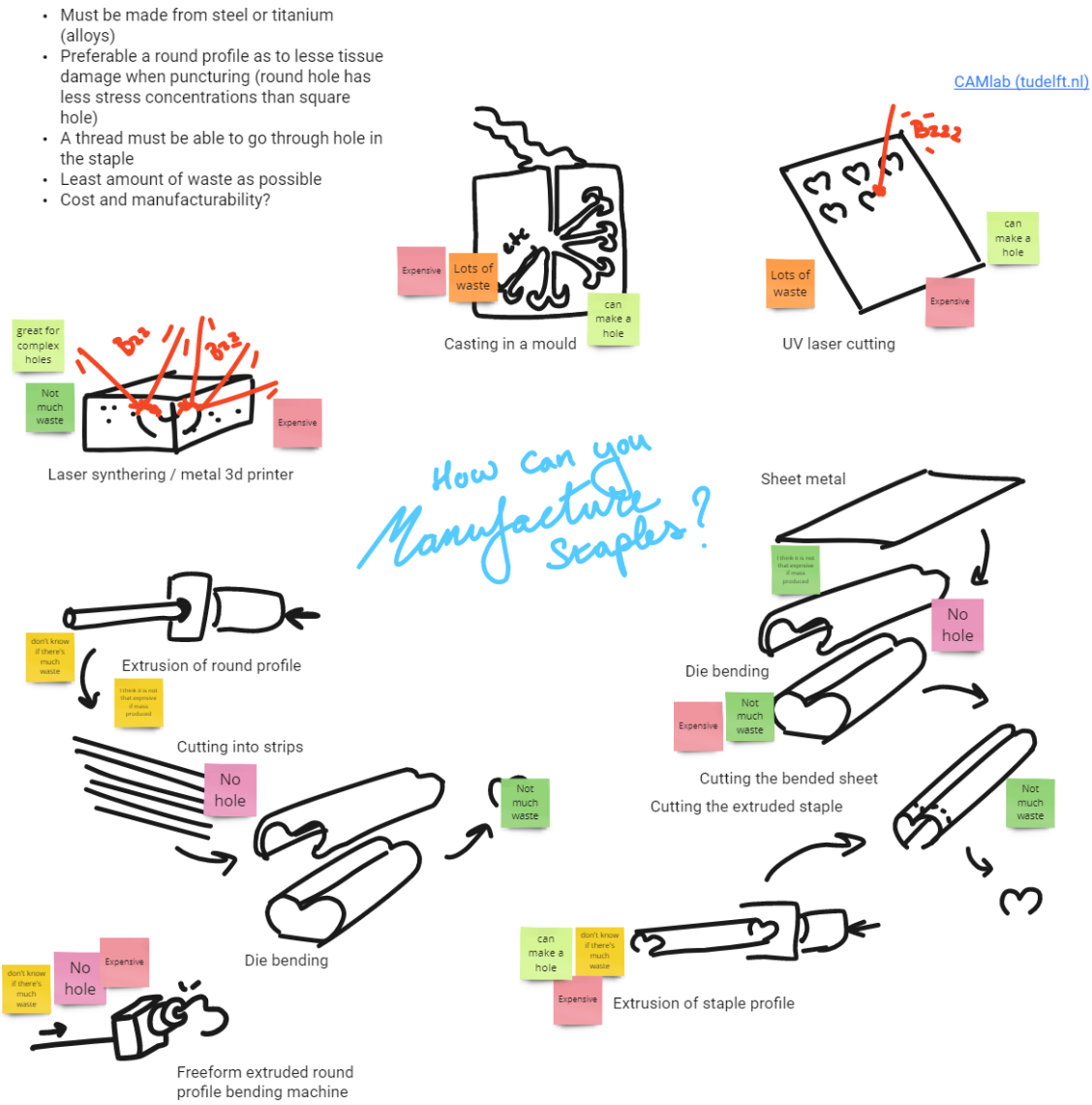
Multiple segmented instruments, such as the Gerdx system, provide an option for suturing in small spaces. Robot-assisted instruments, such as the Da Vinci robot and Endo Samurai, provide a precise and minimally invasive option for laparoscopic closure. These options are incredibly expensive, delicate, and complex, and practically never deployed for 'simply' closing MDs, as it is not cost-effective. This type of equipment is therefore not within the scope of this project.

H. Design process of the staple



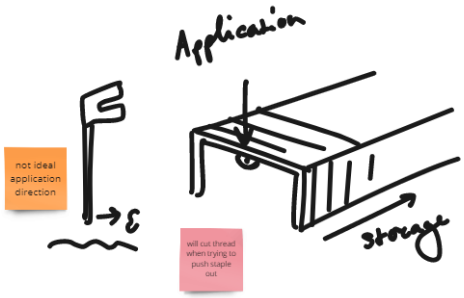
Using these steps as a guide for ideation, I began making simple sketches to illustrate some ideas. These ideas were based on the staples designed by Natalie Wochner (2022) in the figure below.

Figure FIX: Staple designed by Natalie Wochner (2022).

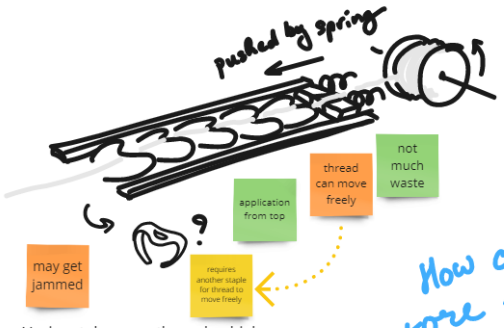


These ideas were made to provide an answer to the question “How can you manufacture staples?” based on the How-tos method from the delft design guide (p. 127)

- Must be feasible
- Thread must be able to go through hole in the staple freely, until surgeon decides to fix it
- Application direction must be perpendicular to tissue surface
- May not get jammed
- least amount of waste as possible
- least amount of necessary mechanical parts needed

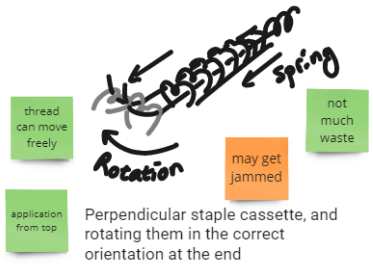


Perpendicular staple cassette.
mechanism like regular office staplers

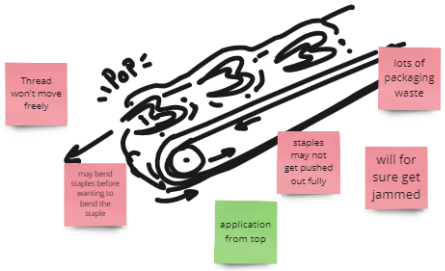


Horizontal groove through which the staples get pushed out in the right orientation by a spring.

How can you store pre-threaded staples?

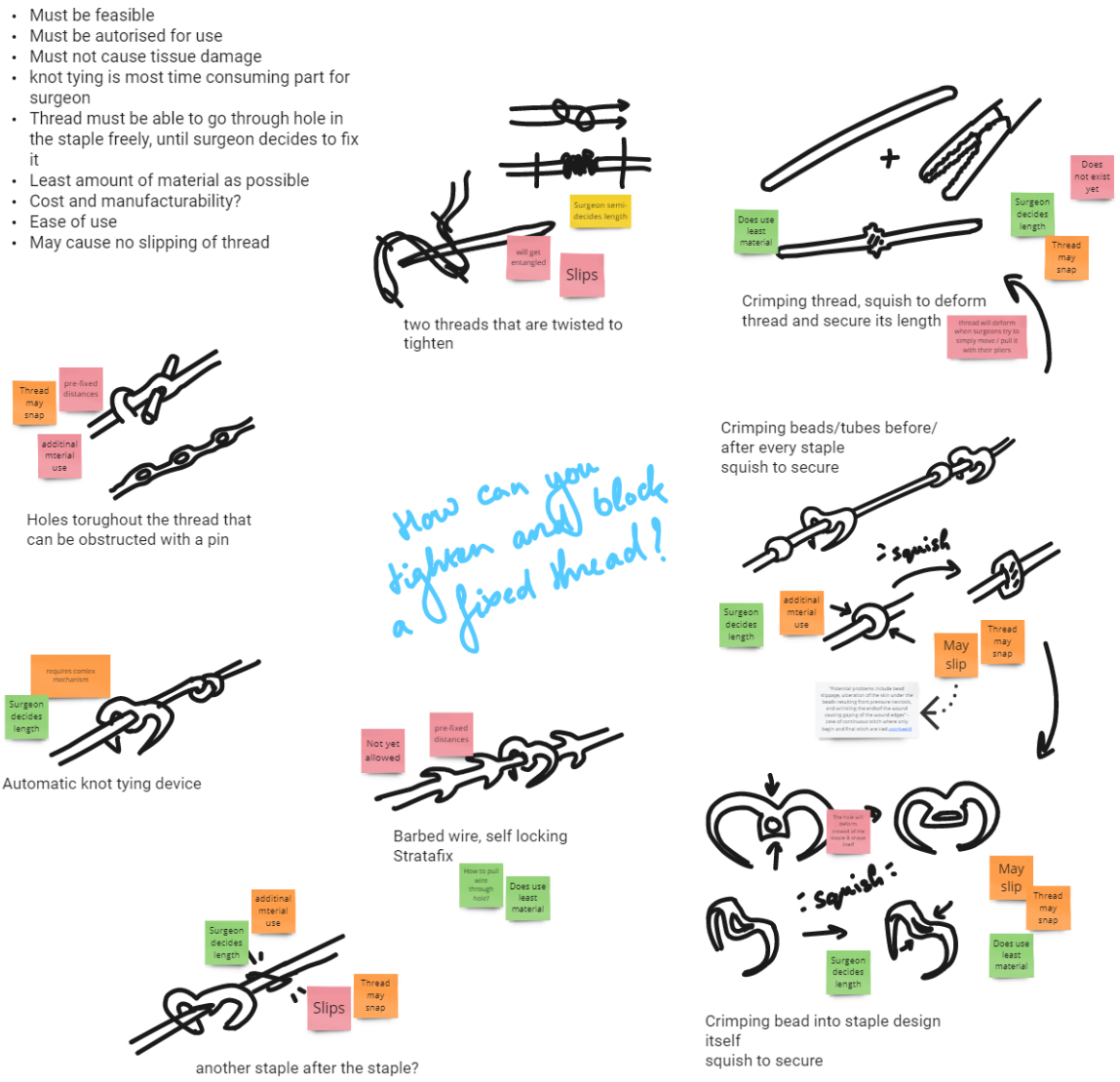


Perpendicular staple cassette, and rotating them in the correct orientation at the end



Blister packaging dispensing
pushing the staples out

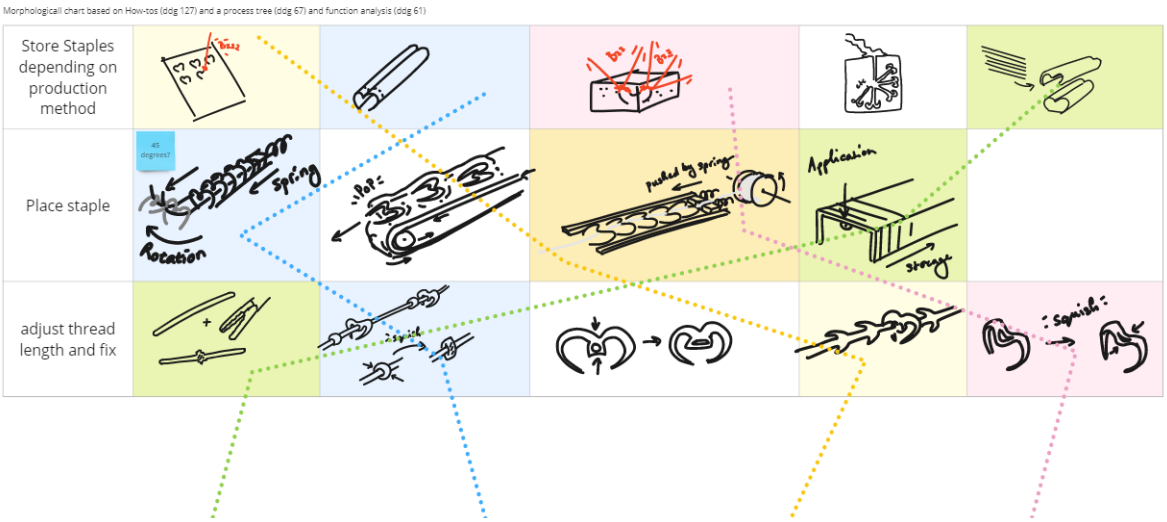
These ideas were made to provide an answer to the question “How can you store pre-threaded staples?” based on the How-tos method from the delft design guide (p. 127)



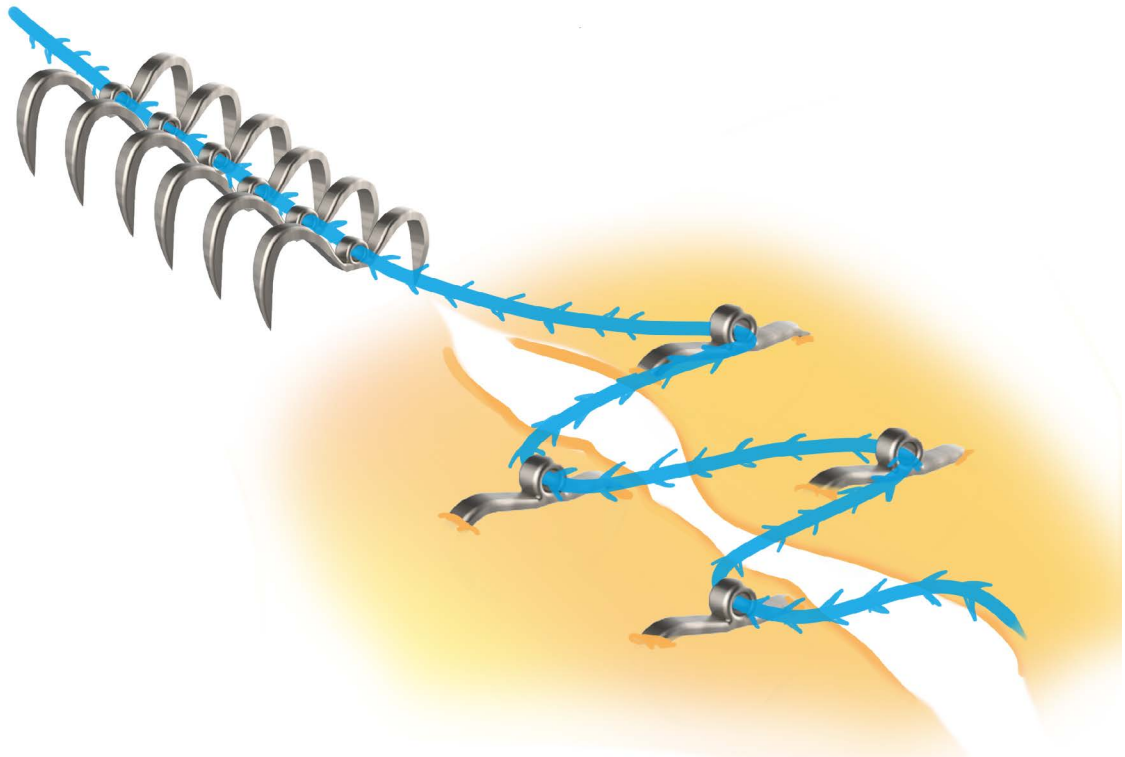
These ideas were made to provide an answer to the question “How can you tighten and block a fixed thread?” based on the How-tos method from the delft design guide (p. 127)

Then a concise list of requirements, from the List of Requirements, that were relevant for the question was written down. Then the concepts that did not meet the requirements were eliminated or revised until they did meet them using the scamper method from the delft design guide, p. 123). Finally the ideas were compared to one another using a harris profile (delft design guide, p 193) by means of the criteria with a sliding scale (e.g. provide a minimal amount of residual waste).

Then, the remaining most fruitful ideas were put together in a Morphological chart (delft design guide, p. 121) as can be seen below.



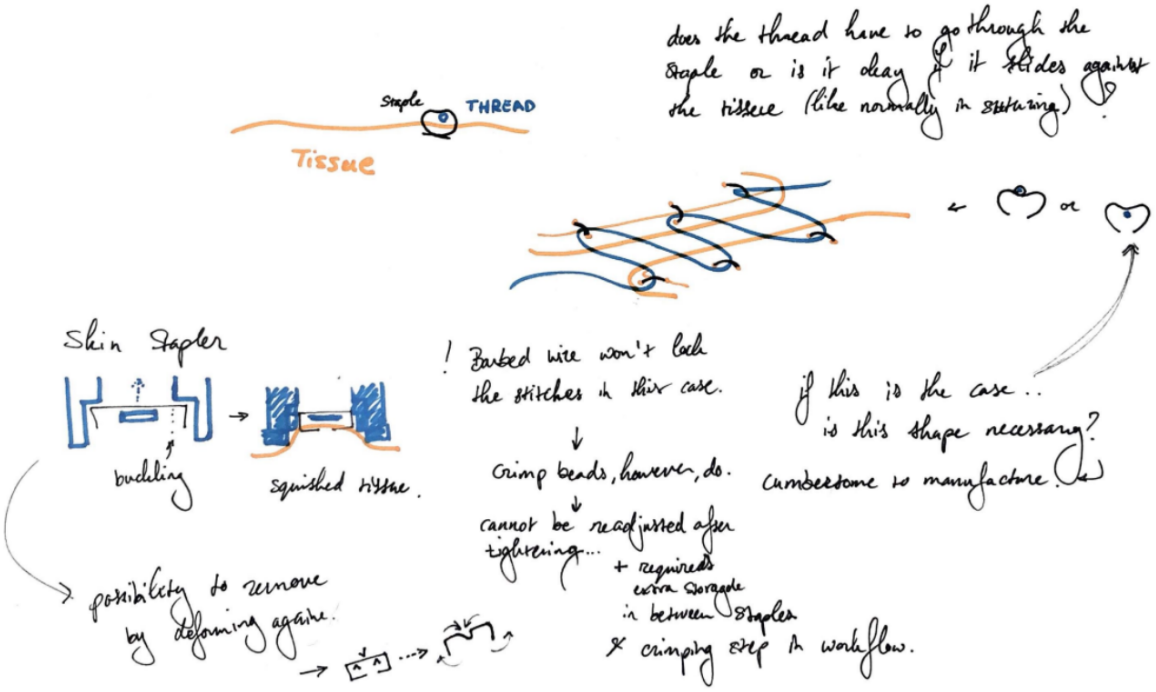
The next step is to make some simple models to test and evaluate each. I realised later, however, that none of these options was possible due to the pre-threaded nature of these staples.



As can be seen in this illustration I made, the barbed sutures will make the cartridge jam completely when trying to provide more sutures. An option to get around this by using a fixed amount of wiring per staple has been considered. However, this would result in there being more and more thread between the applicator and open tissue window after each tightening

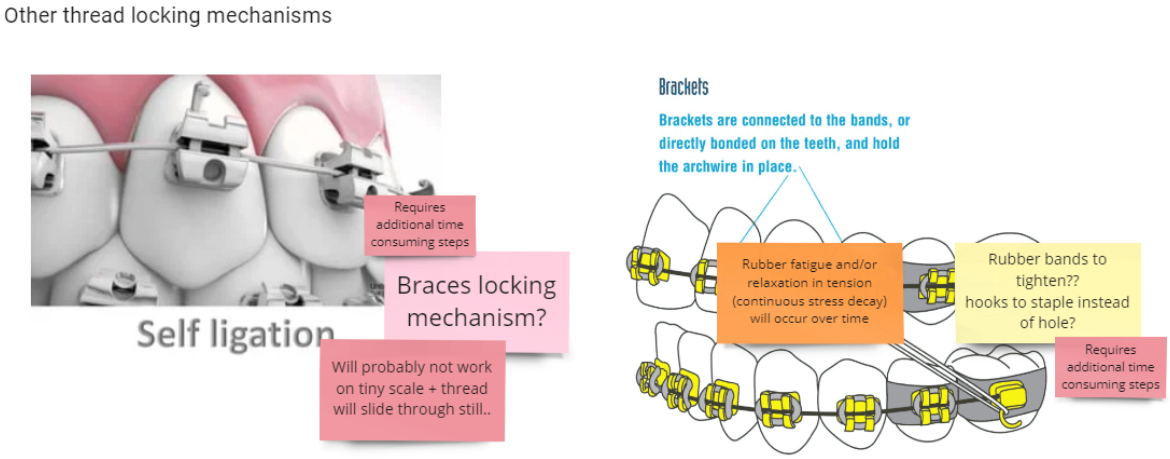
of the suture. Pre-wired staples would cause a lot of additional difficulties, hence I decided to avoid this altogether and look for an alternative.

Using the brainwriting and -drawing method (delft design guide p. 119), I wrote down the questions that came to mind and different possible solutions.



In doing so, I wondered whether it was necessary to run thread through a hole, but instead simply clamp it between a staple and the tissue. In addition, I was curious to know if it was possible to secure the thread in another way after tightening.

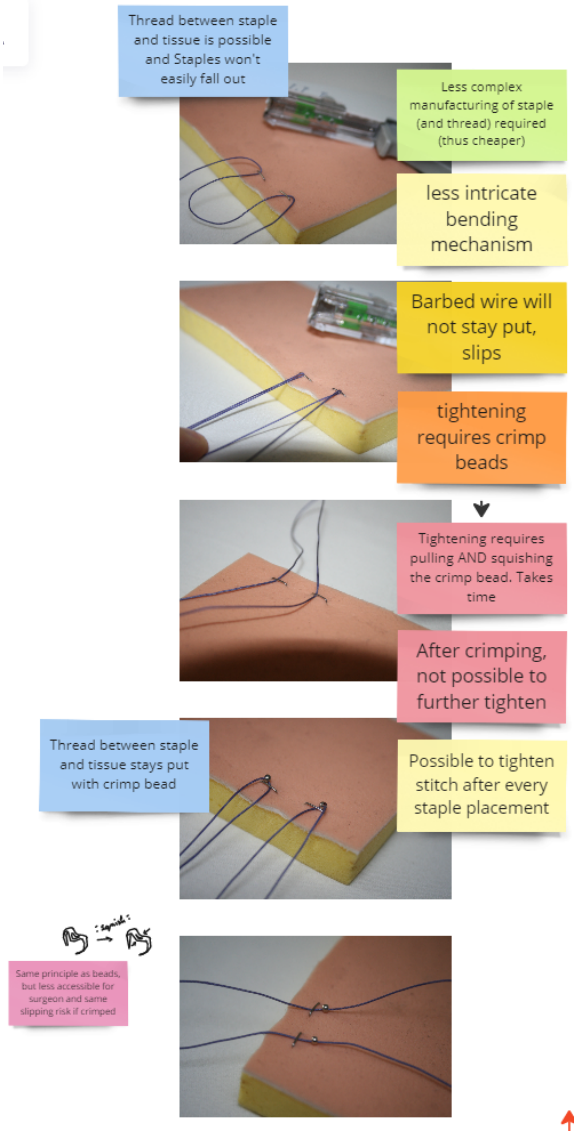
Based on the preceding ideation on "how to tighten a fixed thread?", I started looking further into thread-locking mechanisms. An example of this can be seen in the picture below.

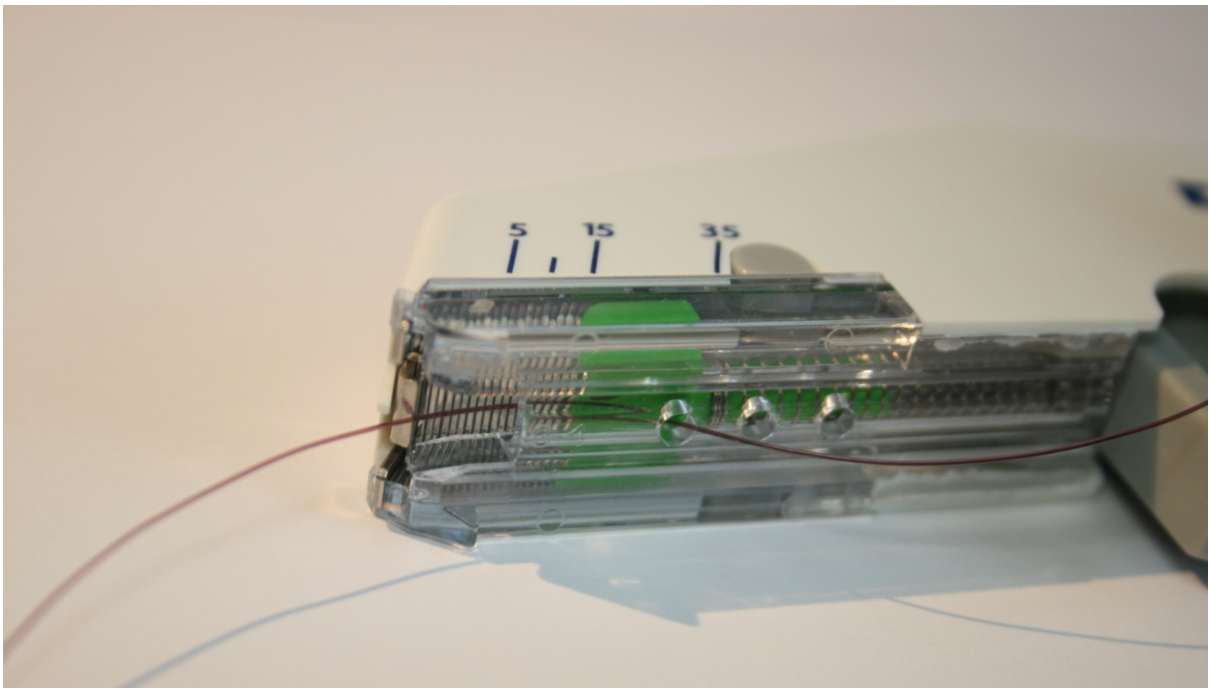


In addition, I took an extra step back by leaving the staple out of the equation altogether and looking only at a suture fixing Examples include the SLIS stitch, Isi's RD180® line or the proxisure. These several devices offer a similar automated suture procedure. I then checked

with surgeon Yair Acherman (personal communication, March 9, 2023) whether these devices offer a better alternative to conventional stapling and suturing. He did use the endo stitch in the past for transanal application. "It can be used in any scopic procedure. Works perfectly but we can do it faster when doing it the conventional way"
Besides, he has “definitely seen and heard” of the Isi from Proxisure but never had to use it as he has had no need for it. “The conventional way works just as 'fast' and well.” Besides, it costs much less money, for the same result.
Given that none of these devices thus are currently utilised within the application of closing mesenteric defects, as they offer no better alternative than the traditional ways, I will leave this method of closure out of further consideration.

Then, using a skin stapler, a string and crimp beads, I did a simple test to see if securing sutures was possible by simply clamping it in place. In the picture below it can be seen what that looked like. The staples and wire stayed in place just fine, which thus gave the impression that this could be a good option for further development. However, there is much more friction in this test than in the abdominal cavity. The peritoneal tissue consists of special cells (serous lining cells) that produce an aqueous secretion (peritoneal fluid) (Medicinfo, 2021). The smooth surface of the tissue and peritoneal fluid acting as a lubricant will maybe allow for this closure method to still slide open again.





Picture of the skin stapler with a simple nylon fishing thread.

Thereby, the question arose as to what the best application direction was (as shown in the image below). However, the report of the previous project (Wochner, 2022) showed afterwards that surgeons preferred an application directly from the top, for better manoeuvrability.
In addition, it occurred to me that, based on the requirement that the surgeon's workflow should be as simple as possible (see list of requirements). This means that retaining tissue using a hook is not advantageous compared to the number of steps the surgeon has to take. Given that for every staple he places, he then has to turn the head of the application 180 degrees each time. So an additional hook will not be implemented, as it would require too many additional steps for the surgeon.

Then I had two main idea directions I could explore:
1) Staples without holes, normal suture thread and the use of crimp beads
(or maybe a staple that could be crimped itself)
2) Staples with holes and barbed suture, where a pre-defined length of suture would be provided

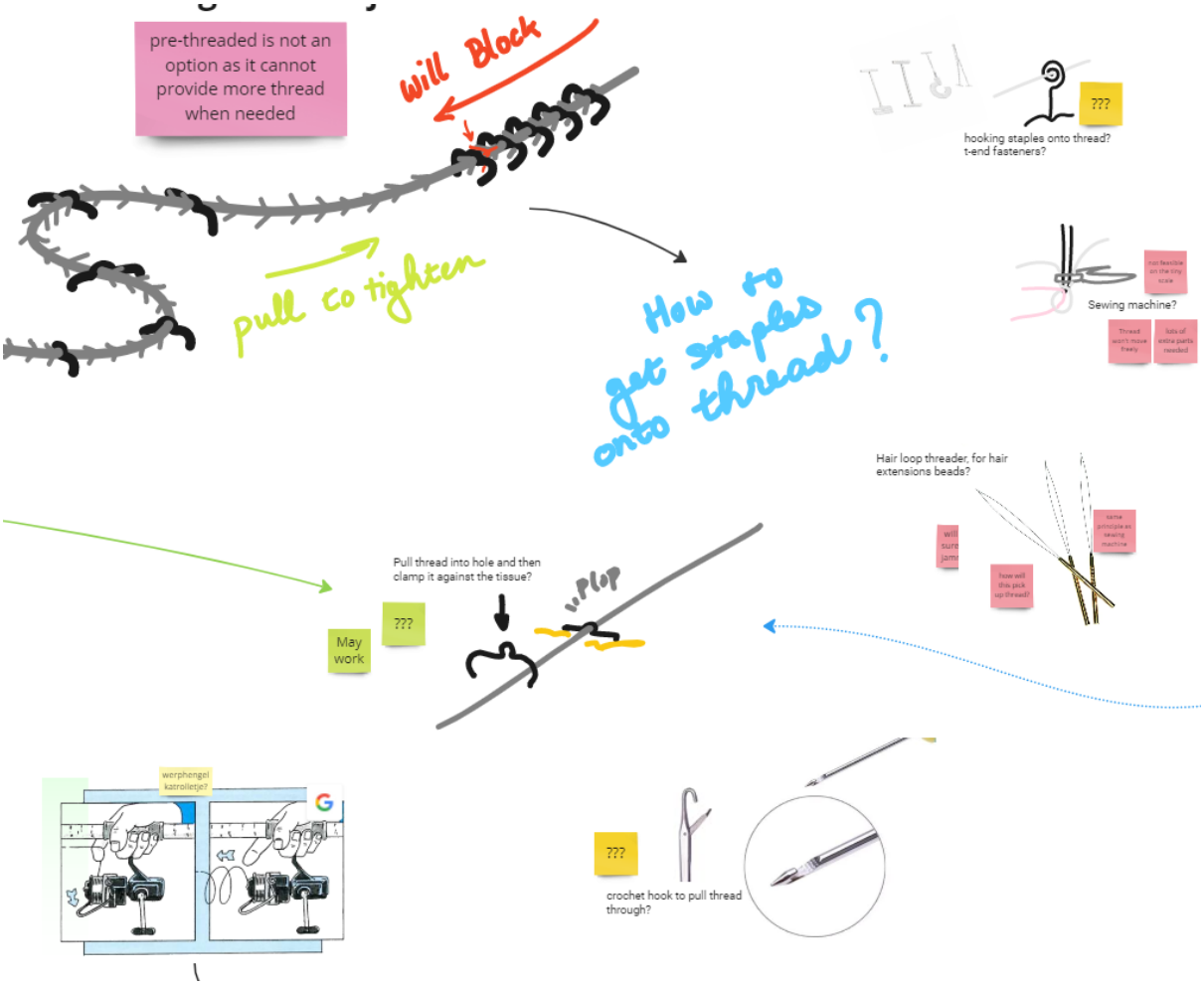
Harris profile | Staples without holes, normal thread & crimp beads

	--	-	+	++
Wire stays put after tightening, no slipping			thread will relax over time in both cases	
Time efficient (# steps needed)				
Possibility to tighten even more				
Manufacturability				
Possibility to provide more thread (in between staples)				

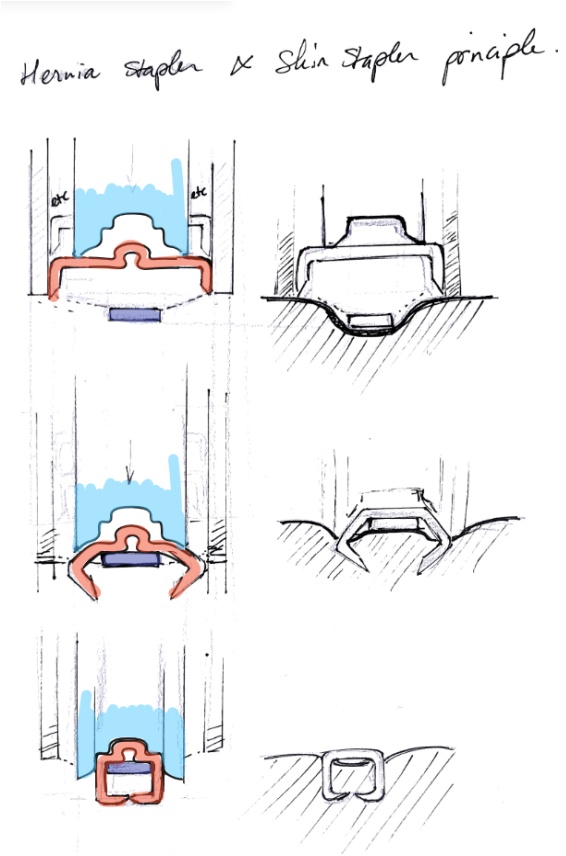
Harris profile | Staples with holes & barbed wire

	--	-	+	++
Wire stays put after tightening, no slipping			thread will relax over time in both cases; does this work?	
Time efficient (# steps needed)				
Possibility to tighten even more				
Manufacturability				
Possibility to provide more thread (in between staples)				

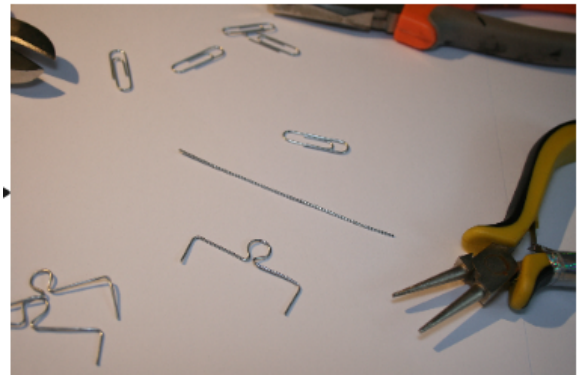
Using a Harris profile, it was possible to get a good idea of the pros and cons of these two global ideas ((Zijlstra et al., 2020, p. 139). However, I was still of the opinion that the final idea had to meet all the requirements. For this reason, I continued to ponder how I could creatively combine the two idea directions so that the final idea would meet all these requirements.

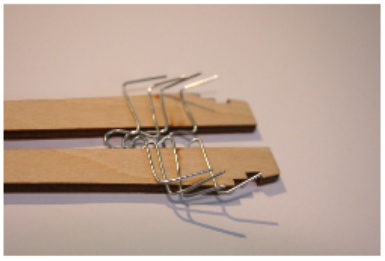


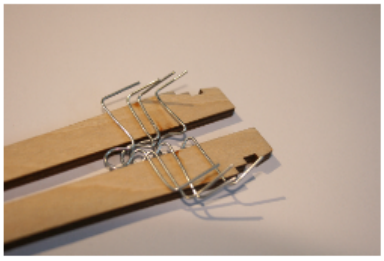
In doing so, I answered the question "How to get staples onto thread?" with several braindrawings (Zijlstra et al., 2020, p.119). These different ideas were then simply evaluated against relevant criteria from the list of requirements. Actually, all the ideas turned out not to be too thriving except one: Combining clamping and a hole in a staple, which offered a good mix between the two preceding ideas from the harris profile.

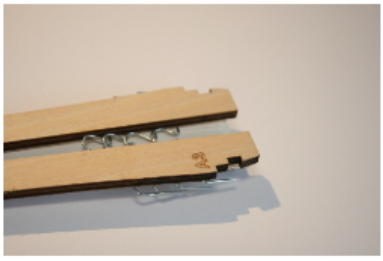


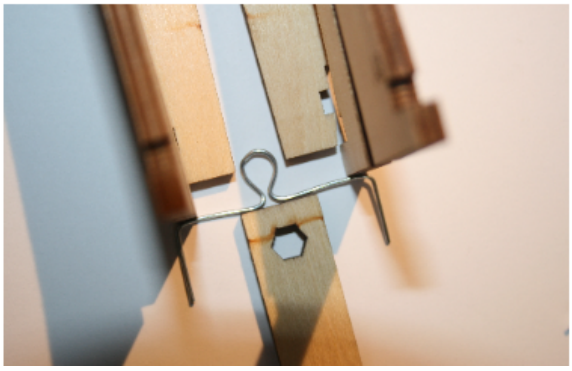
In doing so, I sketched an initial idea based on the deflection mechanism of a Covidien skin stapler and endo hernia stapler (picture above) and then proceeded to test it with a low-fidelity model as soon as possible (picture below).

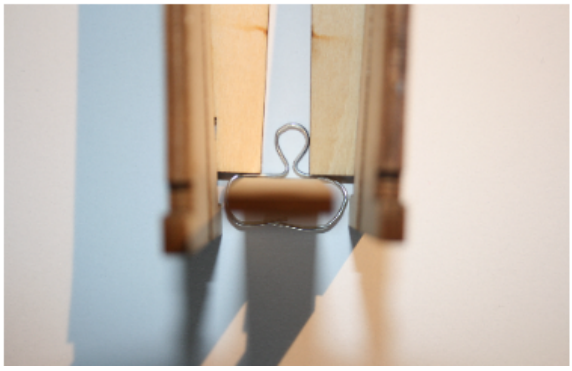






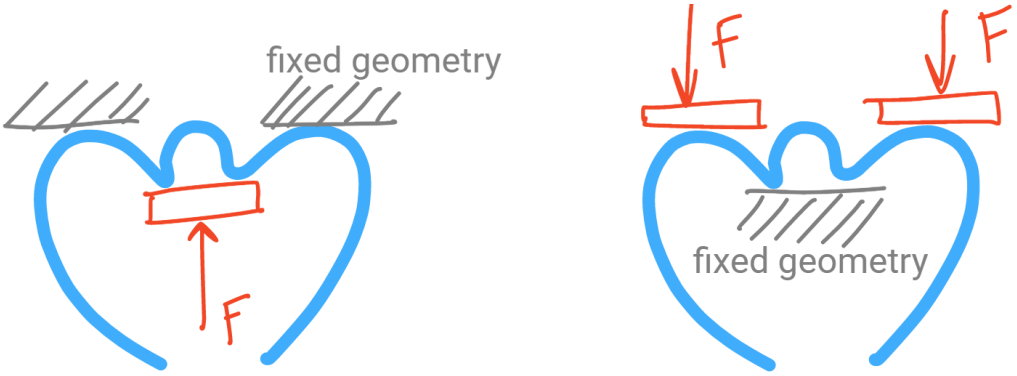






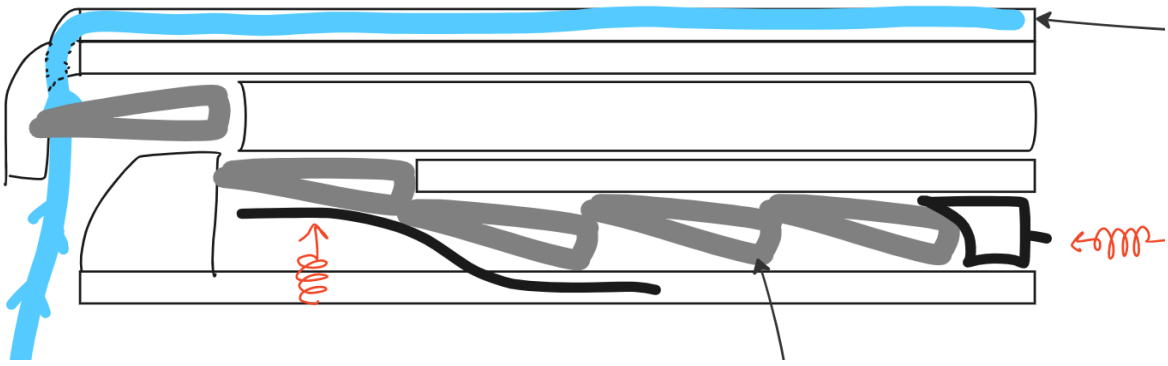
These low fidelity models were made with some wooden pieces I had lying around and bent paper clips. This simple mechanism provided promising results, so this is where I continued the design process.

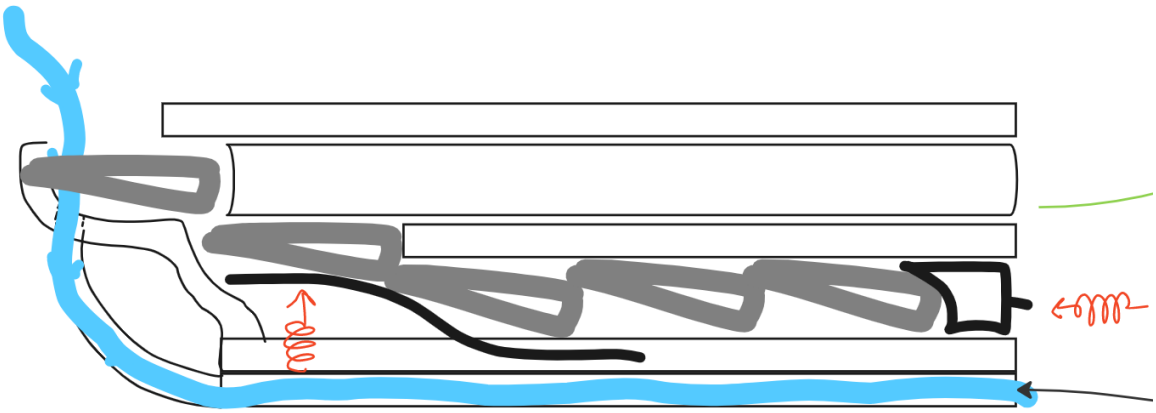
I wondered whether the deformation of the staple would be initiated by a force from below of from above, like in the picture below:



However, the staple needs to be fixed onto a barbed wire in the staple part with the circular profile (I shall call this the head for convenience), which will therefore need wire running in the third dimension. This makes it impractical to have the bending mechanism deliver a force from the underside of the head because then the wire will also have to move up and down.

Then I considered the location of the staples' suture's storage with regard to the place where bending will take place.





In doing so, it was pretty soon clear that it is more practical to keep the thread and staples on the same side of the bending mechanism, as you get a better view of the staple placement from above. You also have a less sharp bend that the thread has to go through, which is advantageous for smooth dispensing (otherwise you experience more friction). and finally, this allows for a single cartridge that can be placed on the applicator in which thread

and staples are delivered. (here I assumed that the handle and a part of the applicator shaft shall be reusable, in order to reduce the amount of medical waste. Thus creating the need to only discard a cartridge at the end of the surgery).

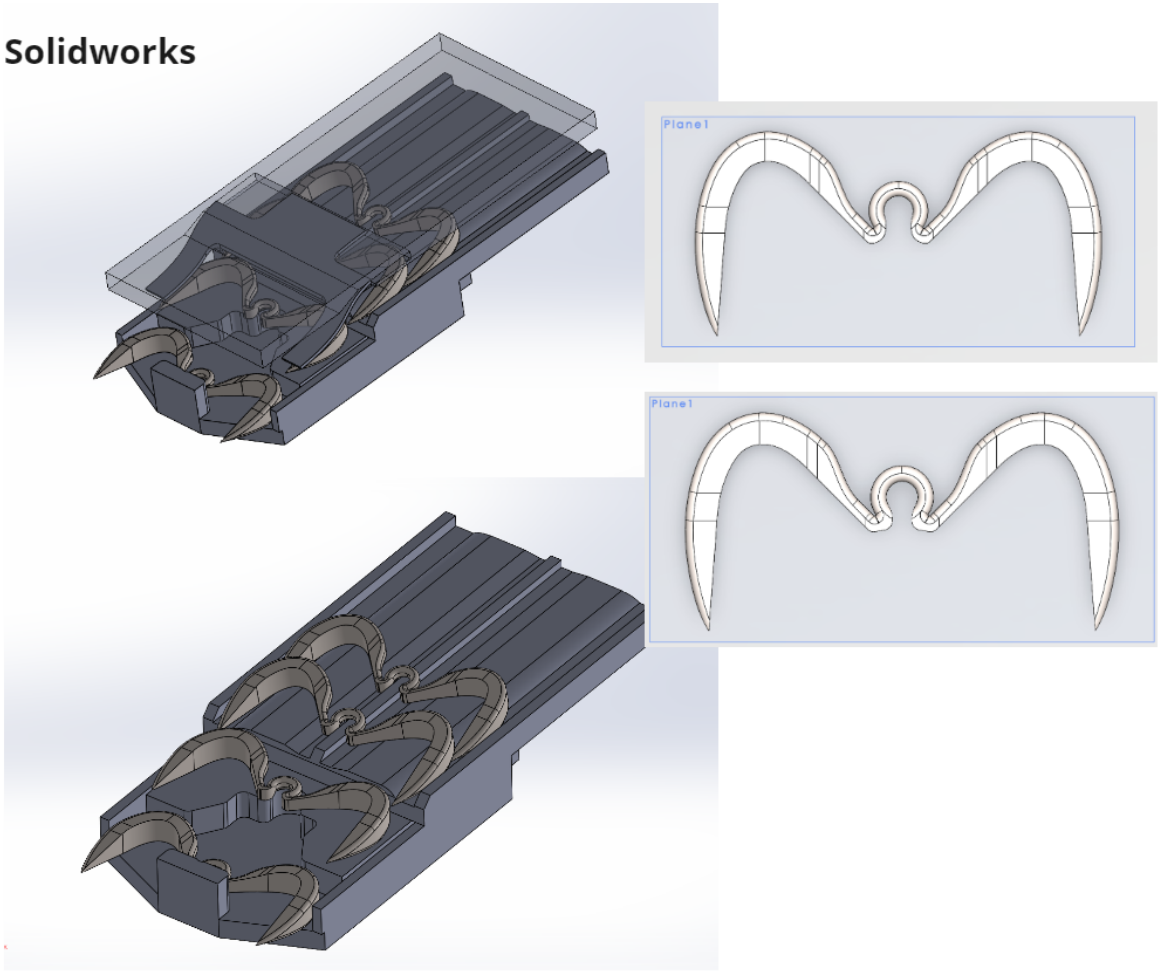
This mechanism did raise a lot of new questions such as: How many staples can be put in a row?, how do I get them to the bending part?, how do I get them through the storage? what is the best angle to insert the staples? to store?, how do I keep staples in place while bending? and so on.

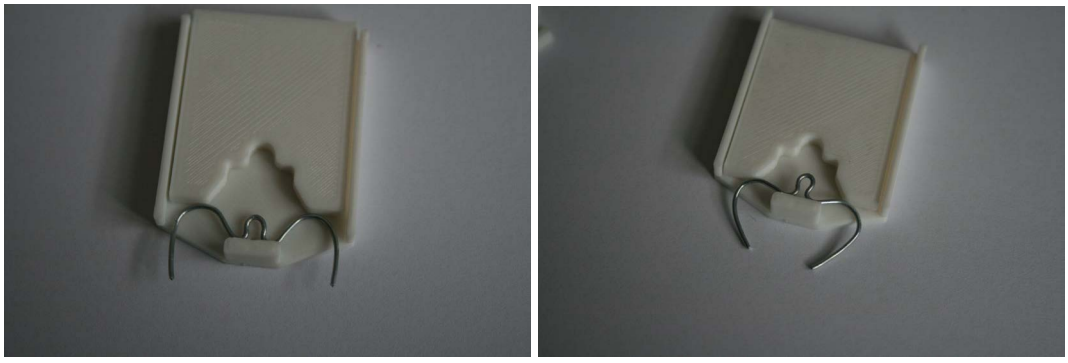
I decided to make a few 3D CAD models for every mechanism separately to answer each of these questions (as can be seen in the picture below). Also, a .dxf drawing was made to produce staples using a laser cutter. All following mechanism designs were worked out separately hereafter.

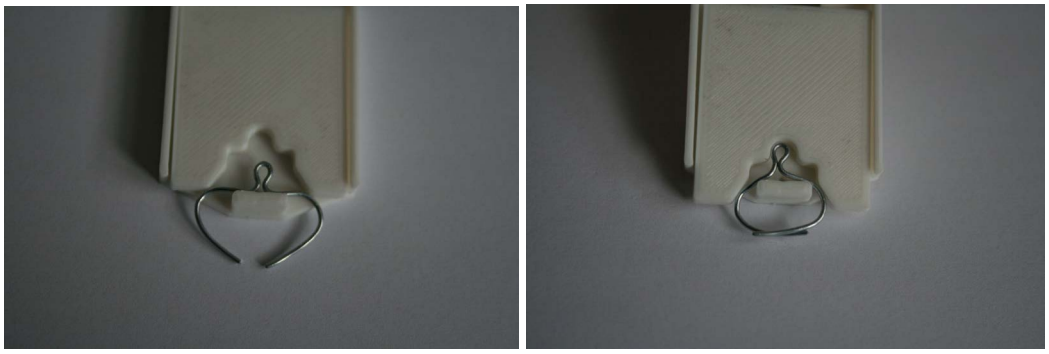
a few staples were 3d printed on a 5:1 scale, to get a grasp on the real-life proportions. Then the staples were prepared for laser cutting by means of a 2d drawing (.dxf file) that would later be cut out in a 1 mm thick steel sheet.
In the meanwhile, when waiting for the staples to be cut, I bent a few paperclips in the same way as the overall staple shape and used those to test the shape of the bending rod with.

(When bending the normal staples afterwards, I found out that those required less force to bend and had less spring back than the paper clips. This is probably due to the difference in thickness and the profile of the parts.)

When bending with the bending rod with the chamfered edge between the edge and the notch, the insides of the shoulders are bent inwards. This is desirable as it would make sure the staple would stay put on the barbed suture, while still remaining possible to slide through the circular profile of the staples' head.


Solidworks
Plane1
Plane1





I. Barbed suture design

Barbed sutures are used as an alternative to traditional smooth sutures for MD closure due to their unique design that prevents tissue slippage. This design will also use sutures with barbs so that the MD can only be closed and will not slip open again after tightening.
The strength of this multi-factorial component is dependent on the following elements: Barbing pattern, barb geometry (depending on its manufacturing method), the number of barbs and the material.

Barbing pattern
The barbs are small, hook-like structures that protrude from the suture and hook onto the head of the staple, providing greater holding strength than just friction.
There are multiple barbed suture designs to choose from, as seen in Figure I-1 (Ingle et al., 2013).

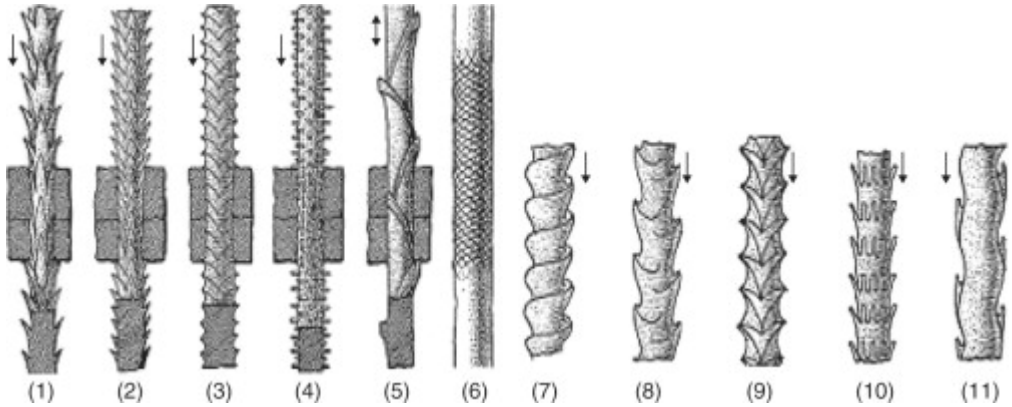


Figure I-1: Different types of barbed suture designs (Ingle et al., 2013).

In all these different designs, spirality and distance between barbs are important. Spirality is defined as how tight the spiral pattern is around the device, like thread on a screw.
Pitch is the distance between the barbs, expressed in barbs per unit length (Figure I-2). A balance must be achieved here for optimal strength, depending on the application. In the case of our application, it is desired that a staple can reside in between two barbs, so the distance will have to be slightly more than the thickness of one staple head.

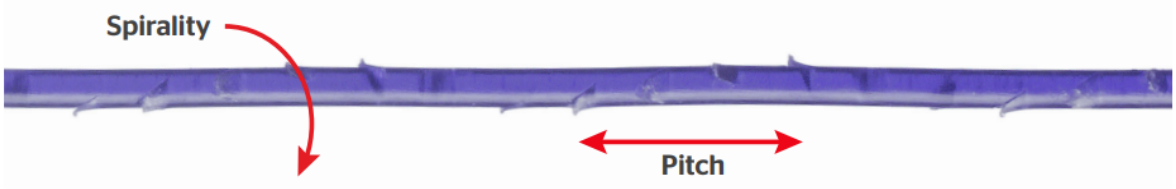


Figure I-2: spirality and pitch that influence the overall suture strength (Ethicon, 2017).

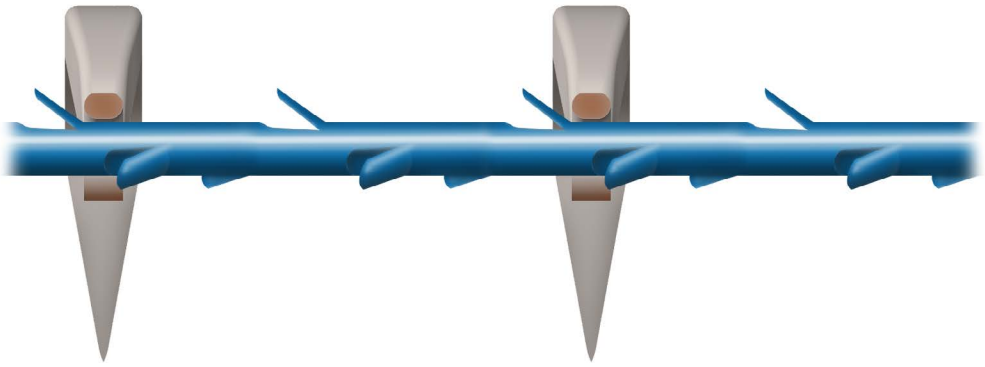


Figure I-3: The desired relation between the pitch of barbs on the suture thread and the thickness of the staple head.

In addition, it is possible to opt for an internal braided structure. The problem with woven monofilament sutures, however, is that they can attract bacteria that multiply in the interstices between the filaments, where they are shielded from the host's inflammatory response, resulting in infection (Nambi Gowri & King, 2023). Due to the requirement to minimise the risk of infection, this option will not be explored further.

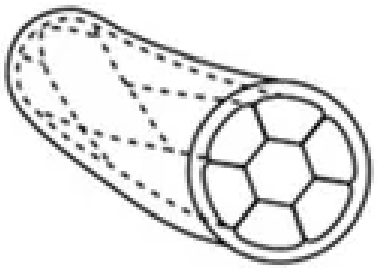


Figure I-4: Braided monofilament suture (Nambi Gowri & King, 2023)

Barb geometry and manufacturing

There are three design principles that influence the geometry of the barbs, and thus also its strength: Cut depth, cut angle and barb length. These can be seen in the figure below. A balance has to be made between those three elements. When increasing cut depth, for example, the barbs will be larger but will decrease the size of the core and thus decrease overall tensile strength.

Most of these barbed sutures are manufactured using a sharp razor to cut the filament to generate the required design as can be seen in Figure I-5.

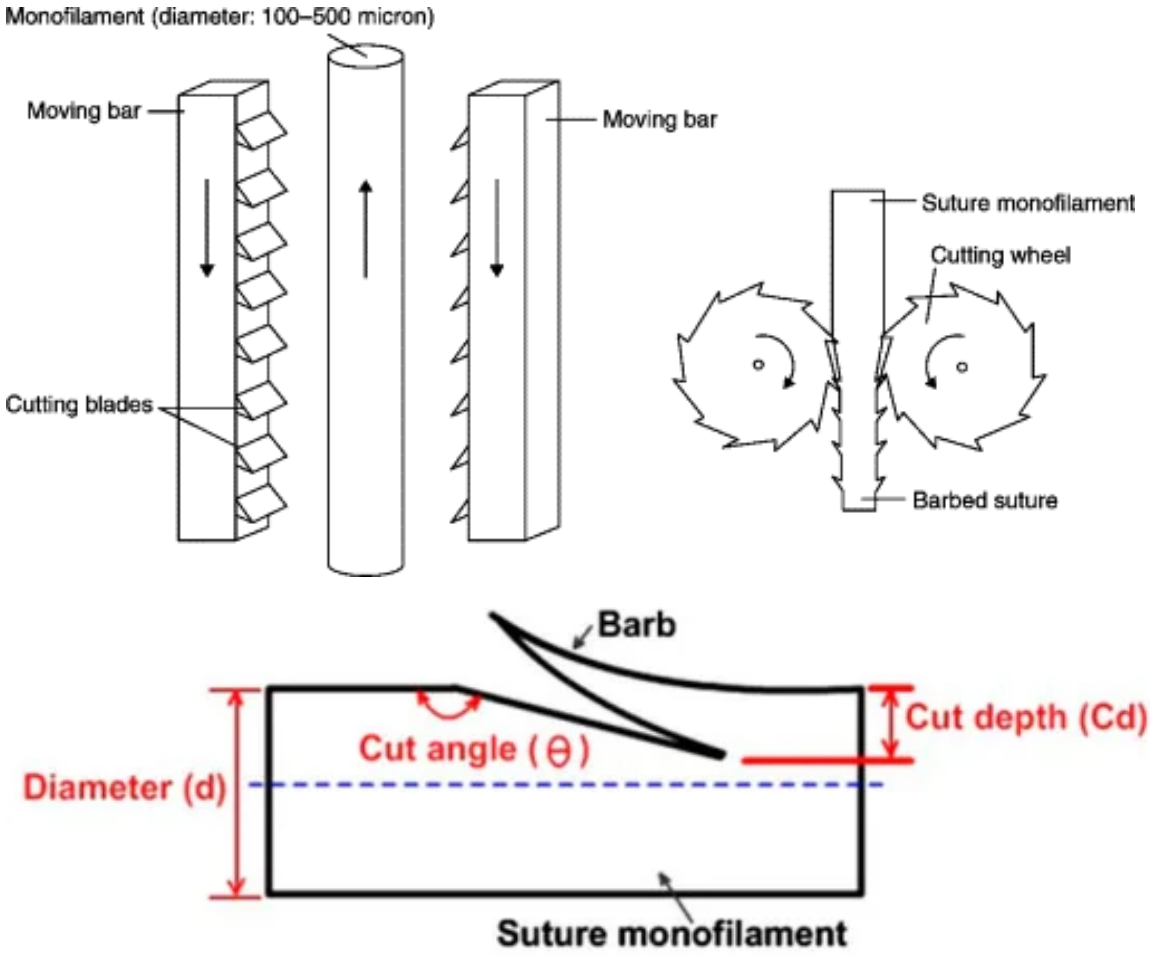


Figure I-5: a barbed suture manufacturing method using sharp blades to cut barbs (top) and the resulting barb (bottom) (Ingle et al., 2013).

The design of the barbed suture is required that it should fit easily through the staple head towards one side, and towards the other side, the barbs should keep the wire from slipping back. It would be ideal to have multiple barbs positioned at an equal circumference to evenly distribute the pressure on the staple. However, this approach would entail cutting the barbs at the same height, which reduces the inner radius of the thread and increases the risk of breakage.

To overcome this problem, the suture will be made by means of a dual cut, so that the barbs can still collapse to slide through the head of the staple, without making the inner radius too small (Figure I-6).

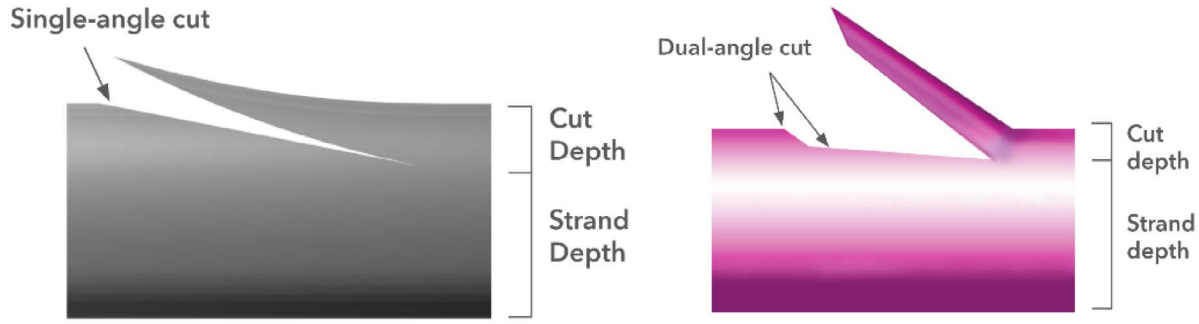


Figure I-6: Single angle cut barb (left) and dual angle cut barb (right) (Nambi Gowri & King, 2023)

However, with this method, there is considerable local bending present. The amount of force one barb can withstand without toppling over or breaking off is still unknown.

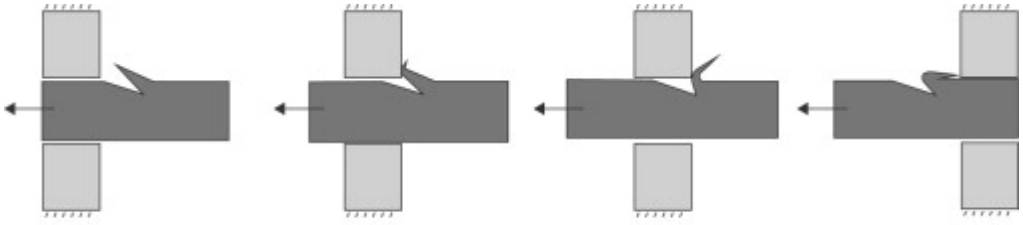


Figure I-7: Risk of undesired bending of the barbs (Ingle et al., 2013)

Material

The choice of material is perhaps the most important factor in the strength of the whole suture. Generally, polymers are used for this application. Polymers have different tensile strengths and duration of tensile strength retention rates (also called breaking strength retention (BSR)) (Kreszinger et al., 2018).

A literature review by Laarhoven (2016) shows that the non-absorbable "V-loc" sutures, made of polybutester (PBT), offer by far the strongest tensile holding strength compared to other suture threads on the market. Here it was indicated that three articles report a suture strength per mm ranging from 1.1N ± 0.15N to 1.4N ± 0.28N for the 2-0 size.
However, it is essential to consider environmental factors such as the effect of various enzymes, pH, temperature and bodily fluids, which may affect tensile strength (Kreszinger et al., 2018).

As cited in the study by Nambi Gowri & King (2023):

“The major limiting factor is the production rate of barbed sutures. From a current commercial perspective, the manufacturing of barbed sutures is expensive, since it requires skilled technicians and specialized equipment and assemblies to produce consistent barbed sutures”
In addition, the raw materials required for PBT are also very hard to come by. According to Jeroen Reijers, Senior Remote Sales Representative for Surgical Innovations at Medtronic, their company is struggling with "huge backorders" due to raw material scarcity.

To establish the effect of environmental factors, as well as the strength of individual barbs, further research is needed. As I do not have the ability to produce several design options myself, I will only be able to test with the V-loc PBT in format 3-0 and 4-0. In this regard, I cannot do any long-term in vivo tests either, therefore I will have to assume that the design and strength of these V-loc sutures are sufficient to suit my envisioned application as the literature review by Laarhoven (2016) suggests.
Some sutures have an additional antibacterial/antimicrobial coating (e.g. triclosan) to reduce the incidence of surgical site infections (SSIs). This coating must be part of additional research as well.

J. Bending test

In consideration of the choice of material for the staples, surgical stainless steel emerges as a viable option due to its extensive use in staple production (Schneider & Feussner, 2017b). Grade 316L stainless steel, in particular, possesses a metallurgical composition that makes it a low-allergy material. Additionally, its non-magnetic properties ensure that it does not interfere with sensitive equipment. However, in the event that stainless steel does not exhibit sufficient strength for this specific application, an alternative worth considering is a titanium alloy. Titanium alloys offer a better strength-to-weight ratio, are not as stiff and are commonly employed in staple manufacturing (Ulbrich, 2023; Schneider & Feussner, 2017b).

Regarding the staple design, the intention is to create a round profile to facilitate tissue penetration. Nevertheless, manufacturing such a profile is difficult, particularly on such a small scale where cost becomes a significant factor. Consequently, a rectangular profile was chosen as it offers greater ease of manufacturing, for the purpose of this test. Expert advice from G.E.J. Emmaneel, a precision and microsystems engineering specialist at the Mechanical Engineering Department of Delft University of Technology, suggests that laser cutting would be the most suitable method for producing these staples for testing purposes (personal communication, March 30, 2023).

Expected deformation

Staples are freely supported (not clamped), with the staple supported at one point, and loaded at two points. This test is destructive. That is, the load will be increased until the material fails.

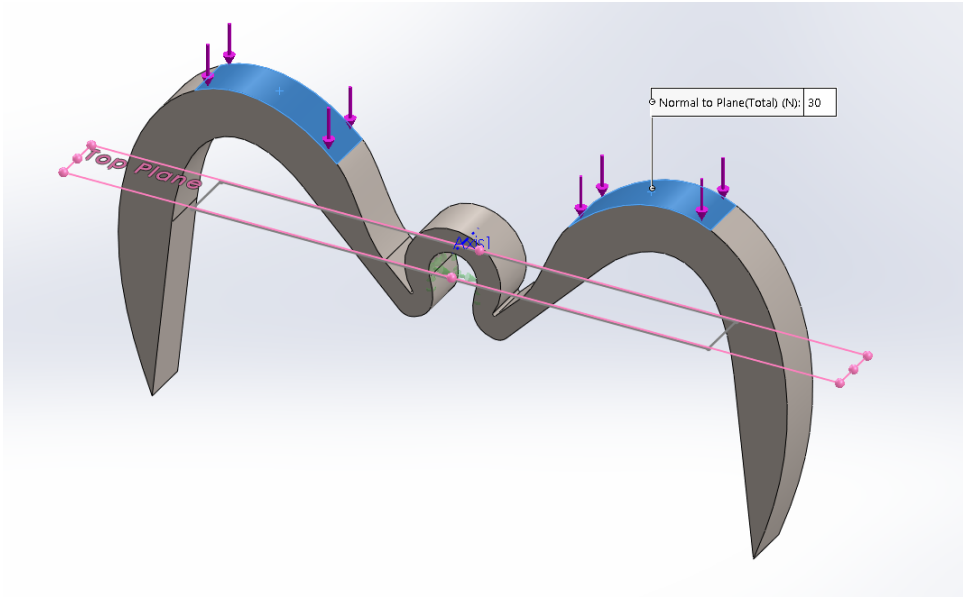


Figure J-1: A SolidWorks model of a laser-cut staple. The arrows indicate the direction of the force applied during bending

A force of 25 Newtons was used in order to get to the intended shape after bending. The force was Normal to the top plane as can be seen in the screenshot above. A fixture on a cylindrical face (0rad) was chosen to be at the top half part of the inner diameter of the head of the staple, as this is part of the staple that will have the least displacement and will sit on top of the barbed wire (providing some degree of counterpressure as well).

The mesh was put on the finest quality, with 29 nodes. The display of the resultant displacement was chosen to be on a true scale. The material was chosen to be alloy steel (SS) with the Linear Elastic Isotropic model type, as this was the type of steel with properties that most closely resemble the surgical stainless steel I intend to use. The Large displacement option was included to run the analysis.

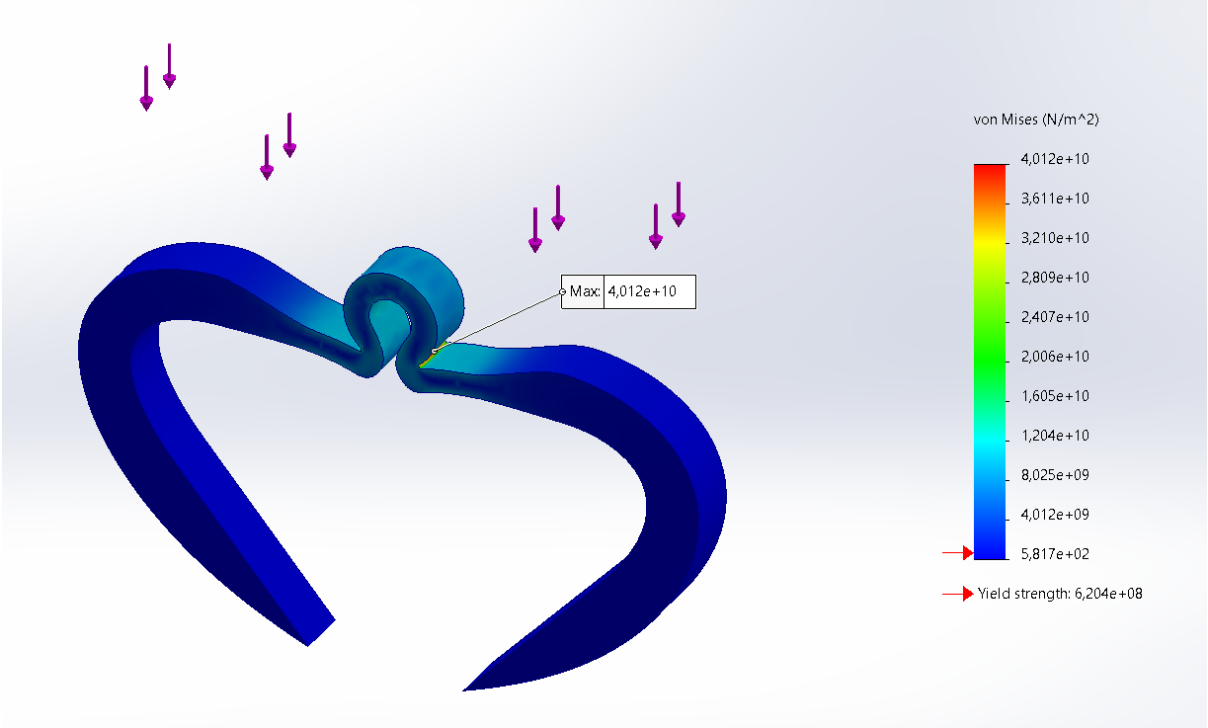


Figure J-2: A SolidWorks model of a laser-cut staple after the linear simulation had run. This simulation indicates a desired deformation, where the shoulders are closed (encapsulating the barbed suture) and the legs are (almost) closed

After the simulation had run, the von Mises stresses (true scale) remained quite low throughout the whole staple body. Except for the shoulders, where a maximum von Mises stress of 4.012e+10 was indicated in the corners. This is not only higher than the yield strength of 6.204e+8 (as desired), but also than the ultimate tensile strength of 7.238e+8 (according to SolidWorks). Thus indicating that it will fail there.
The displacement happened on the desired places, which were targeted on the shoulders (as they were designed to be the thinnest part). Upon closer inspection, it can be seen that the shoulders close around the contours of the inner diameter (where the barbed wire will sit), which is exactly what is needed.

Ideally, the staple has to deform above yield strength and below tensile strength (ultimate strength). No necking (insnoering in Dutch) nor tearing should occur, as the staple will then not be strong enough.

To simplify this situation in a non-linear problem, we can simulate the situation incrementally using ‘pseudo-time’. Here the Plasticity - von Mises model type is used.
When doing the non-linear simulation, I had to decrease the external load drastically, from 25N to 5N. At that load, the staple does not close all the way.

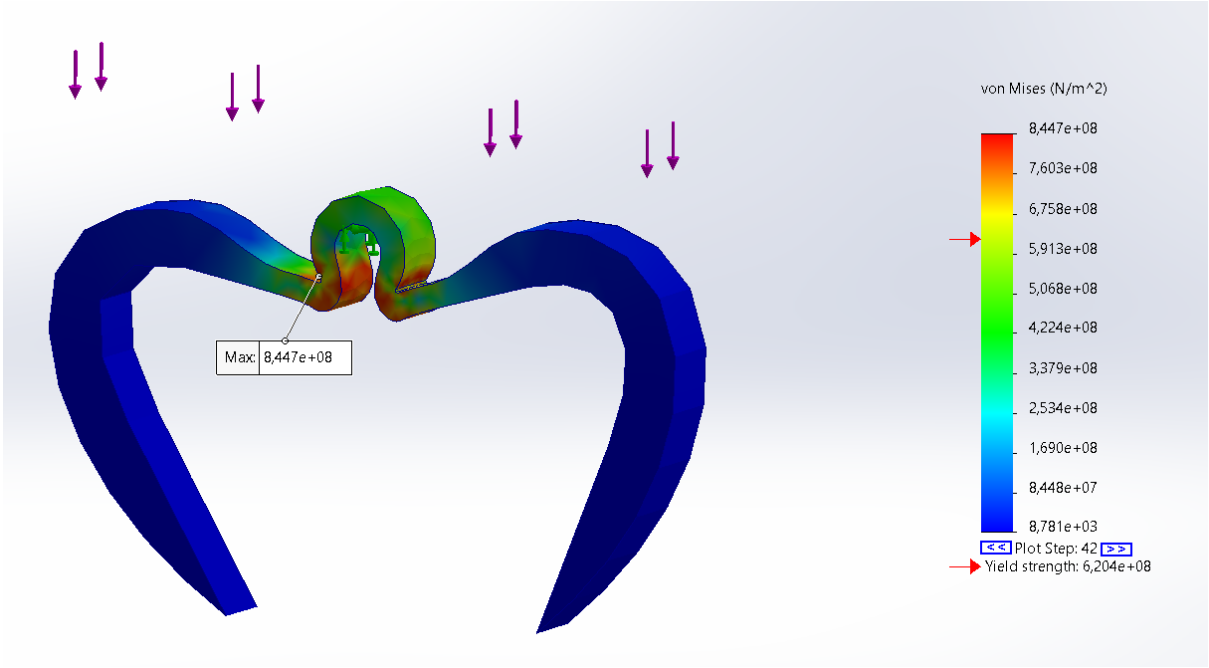


Figure J-3: A SolidWorks model of a laser-cut staple after the non-linear simulation. The red-coloured parts indicate material failure.

Again, the maximum deformation (of 8.447e+08) is not only higher than the yield strength of 6.204e+8, but also higher than the ultimate tensile strength of 7.238e+8 (according to SolidWorks). Thus indicating that the material will fail at those red-indicated parts.

In the intended design, however, we have a different boundary scenario than the one modelled here, due to the special shape of the bending rod. This implies that the nature of contact between the bending rod and staple changes during the bending motion and some support will come from the barbed suture as well).
Also, the inhomogeneity of the material will probably cause complications, which for example could imply that one side bends more than the other.
Such effects can only be identified through testing in real life; by measuring the force during deformation and analysing the results. This has to be measured on a microscale, probably under a microscope.
If problems do occur, just as SolidWorks suggests, that would imply that another material or design is needed.

Real deformation

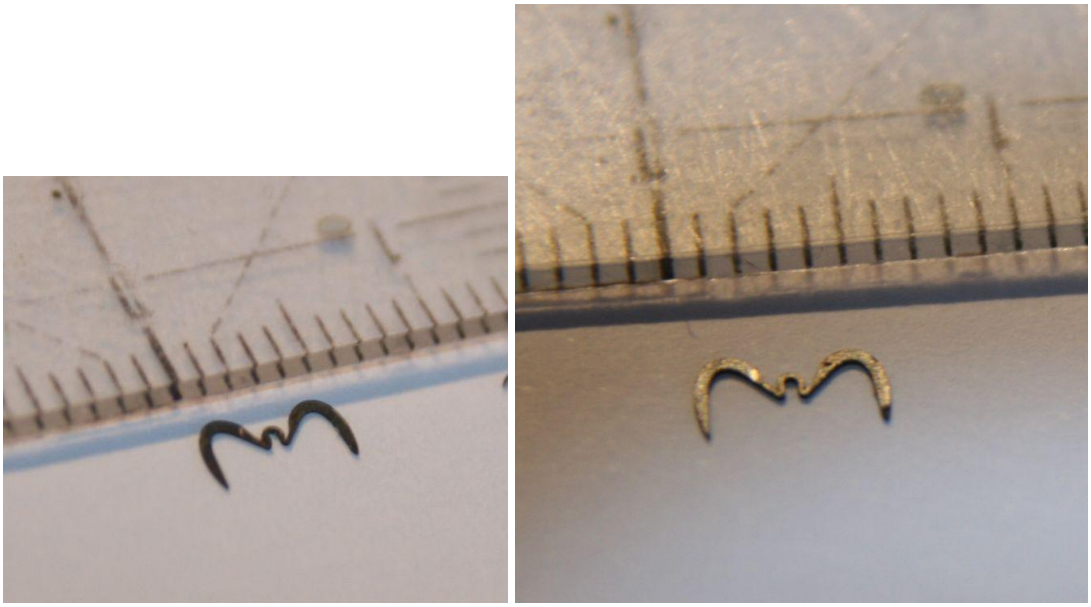


Figure J-4: These are pictures of the 1:1 scale staples, which are 5,5 mm wide, 2,5 mm high and 0,4 mm thick. Manufactured with the aid of a UV laser cutter.

Test setup

Materials

- Microscope
    - incl. white paper
- Tweezers (to handle the staples)
- Tape (to not lose the staples)
- Universal testing machine (UTM)
    - I used the Zwick/Roell ProLine UTM
    - Software to run the device was included (TestExpert II)
- A clamping setup for the UTM
    - I made one myself using a 3D printer

Clamping setup

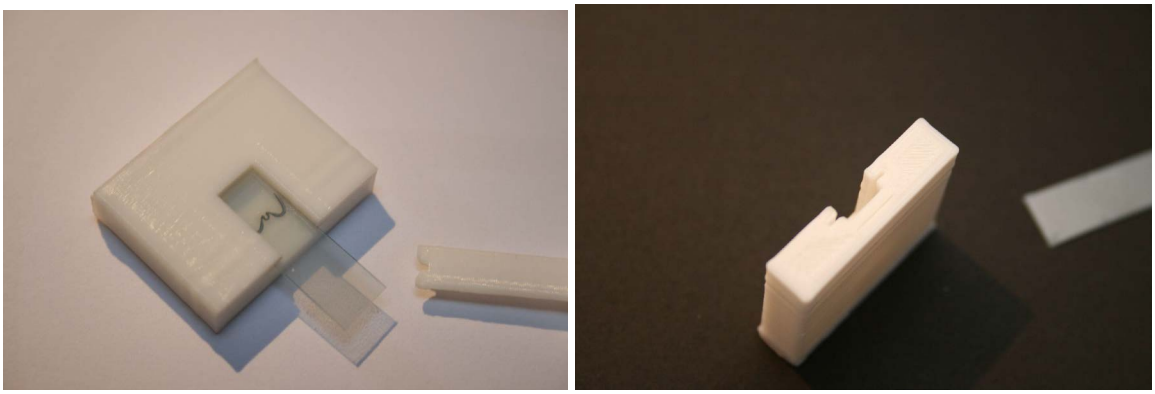


Figure J-5: The 3D printed clamping setup to put in the UTM with a removable window

I modelled and 3D printed a simple holder piece to place the staple onto during bending and made a simple pusher for the staple. In the holder, there is a little perch for the staple to be placed upon, just like in the intended applicator design. A slot was made for a piece of plastic to slide through as I needed to be able to change the staples for each test and needed to be able to still see what happened during bending (which is why I didn't use a spring as in the intended applicator design).

Microscope

Before and after bending, I placed the staples under a digital microscope to see where the material would deform/necking would occur/fail. As I cannot see it with the naked eye.

Figure J-6: staple as seen by the naked eye

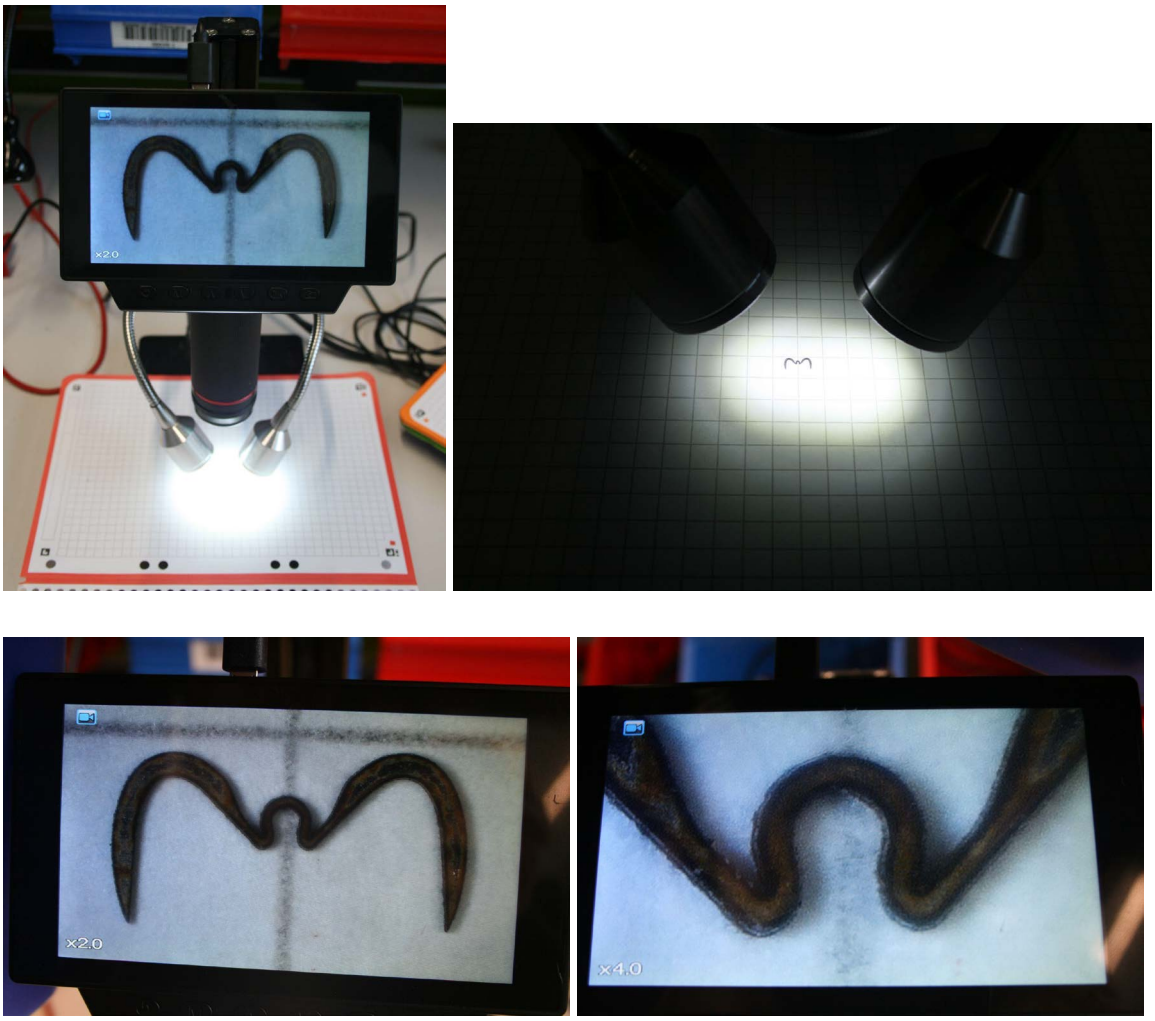


Figure J-7: staple under the microscope

Compression test

I was not allowed to change the load cell myself. This may be done only by specialised people. So I had to make a special appointment and reservation to conduct the bending tests.

First I had to choose which load cell I wanted to use for the compression setup of the machine. It is important to know what maximum force can be applied to my setup. Here I had the option of 1kN and 500 N load, so I opted for the 500N load. I configured the machine to stop the test when it would measure a strength drop of ≥ 80% and/or when having a maximum displacement of 1,5 millimetres after touching the staples.

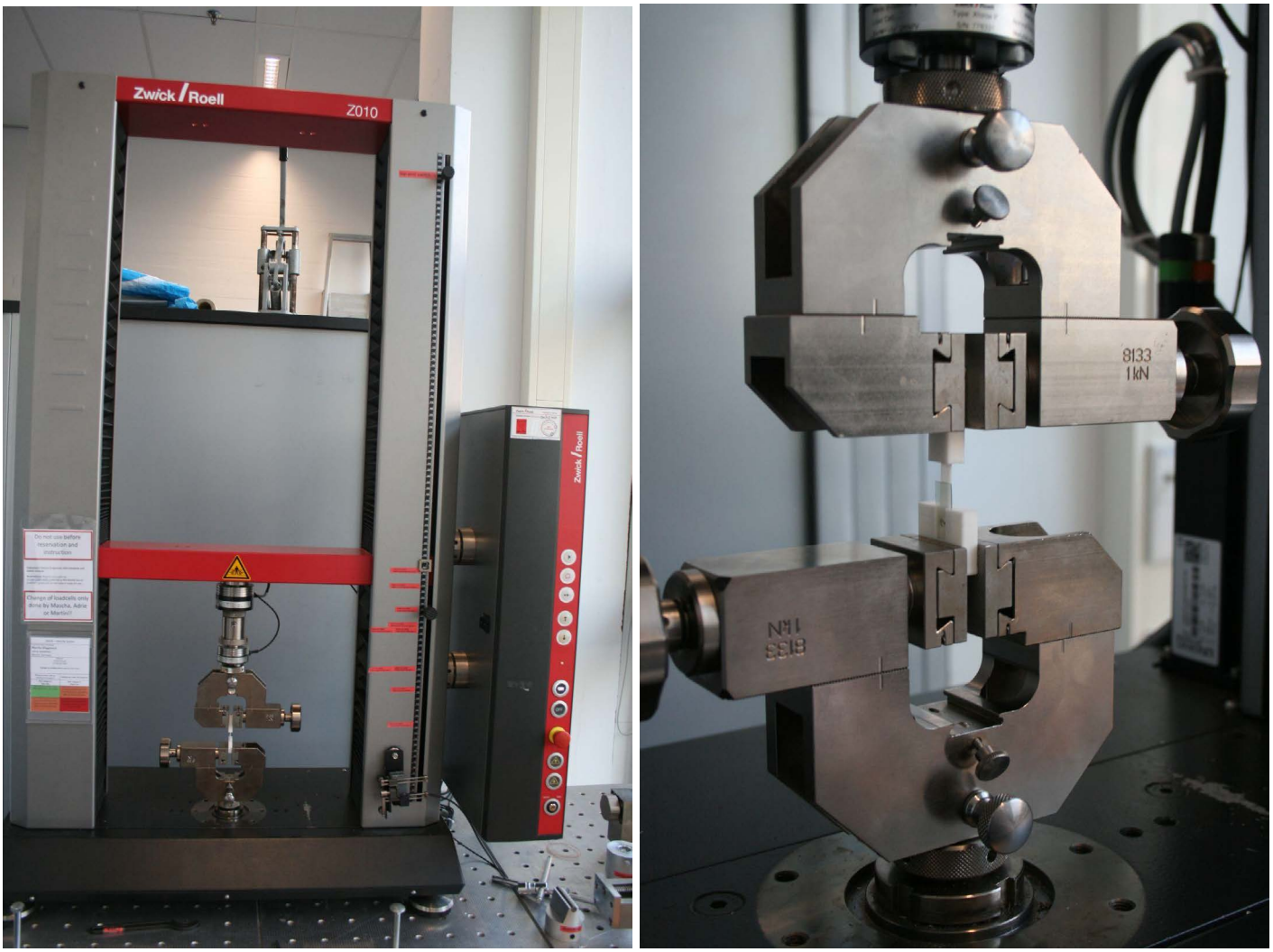


Figure J-8: The UTM with the 3D-printed clamping setup in its grips

First I had to measure the thickness and width of my 3D-printed setup with a calliper. Only then I could position the setup in the middle of the grips and in the centerline of the load cell. Next, I could move the upper grip downwards to make sure both ends of my specimen aligned correctly for bending the staples.

Then I placed the staple into the setup using two tweezers and placed the plastic window into the dedicated slit as can be seen in the picture below.

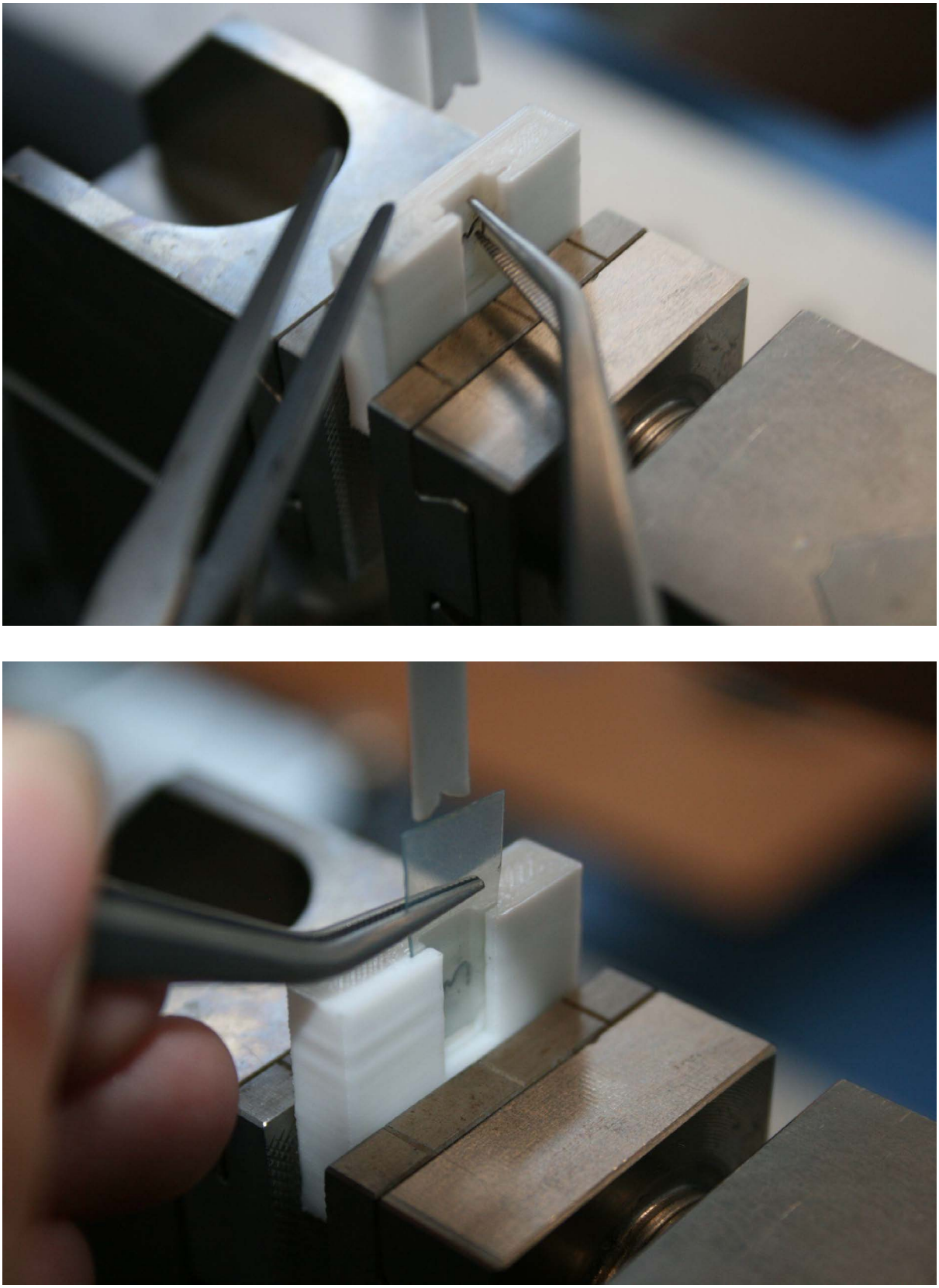


Figure J-9: placing a staple into the setup

The programme that is used to control the UTM is called TestExpert II. In this programme, the test parameters were defined and a pre-test was run two times before committing to the actual test, to make sure everything went well.

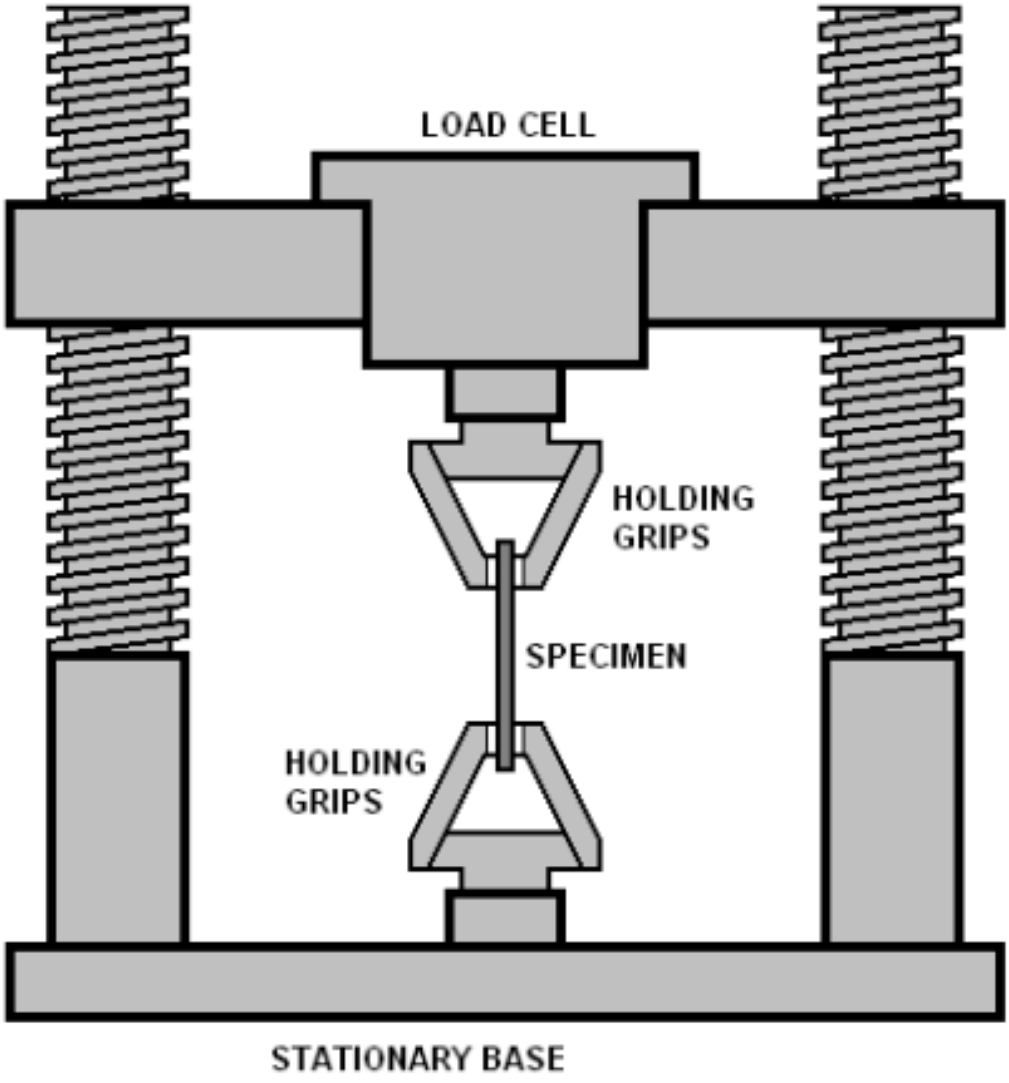


Figure J-10: Approximate position of the grips in relation to the specimen.

Placement and clearance are of utmost importance and the staples require meticulous application into the setup.

Results

	$F_{max\ (N)}$
Test 1	8,40154
Test 2	18,69559
Test 3	40,41072
Test 4	3,534857
Test 5	6,491344
Test 6	7,301009
Test 7	15,27171
Test 8	4,604272
Test 9	3,791528
Test 10	3,492548

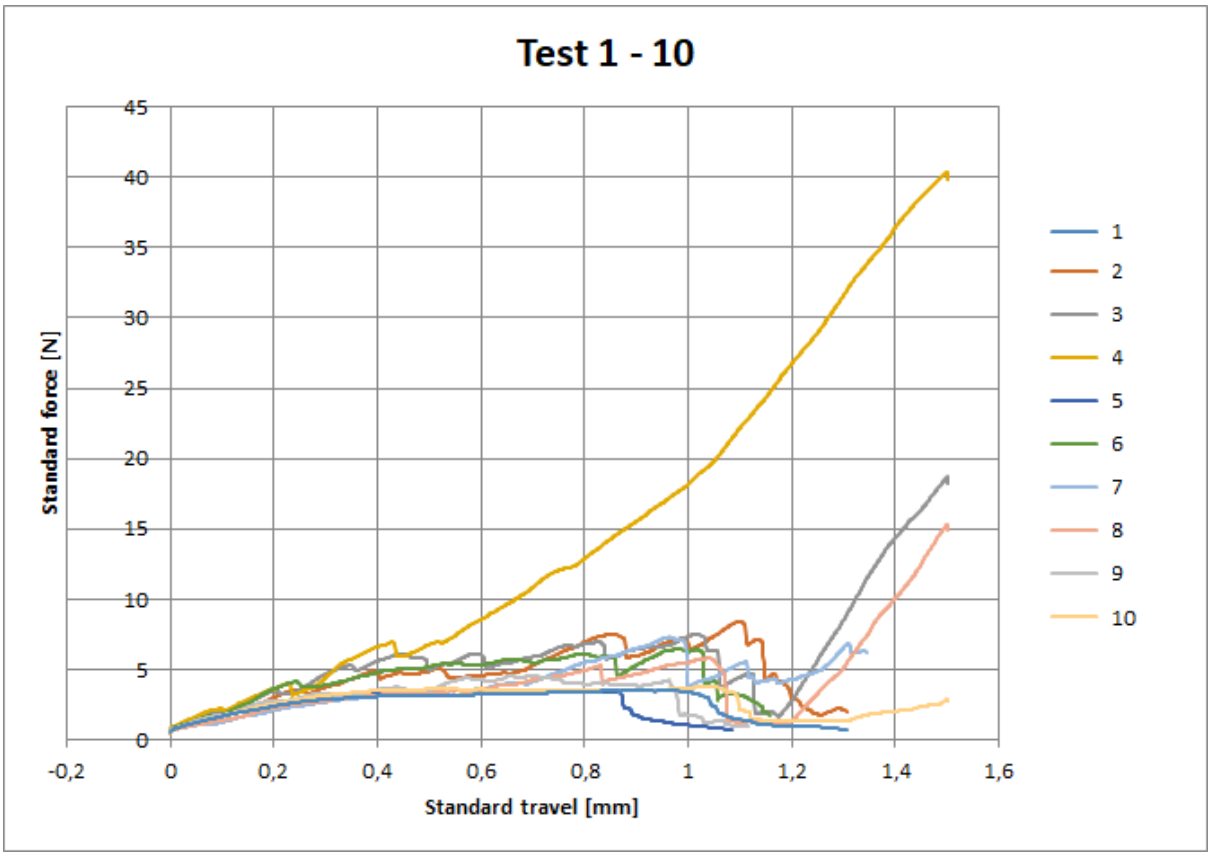


Figure J-11: The test results of staples 1 to 10, showing the force needed for deformation.

As can be seen in the table and graph, the required force to bend the staples ranges from 3N to 20N, with an outlier of 40,4 N.

Here it can be seen that in 3 out of 10 staples (numbers 3, 7 and 8), there is a considerable increase in force after a strength drop of about 3 N has taken place. This can be explained by the pusher pushing the staple against the die and thus only compressing the sandwiched material of the staples.

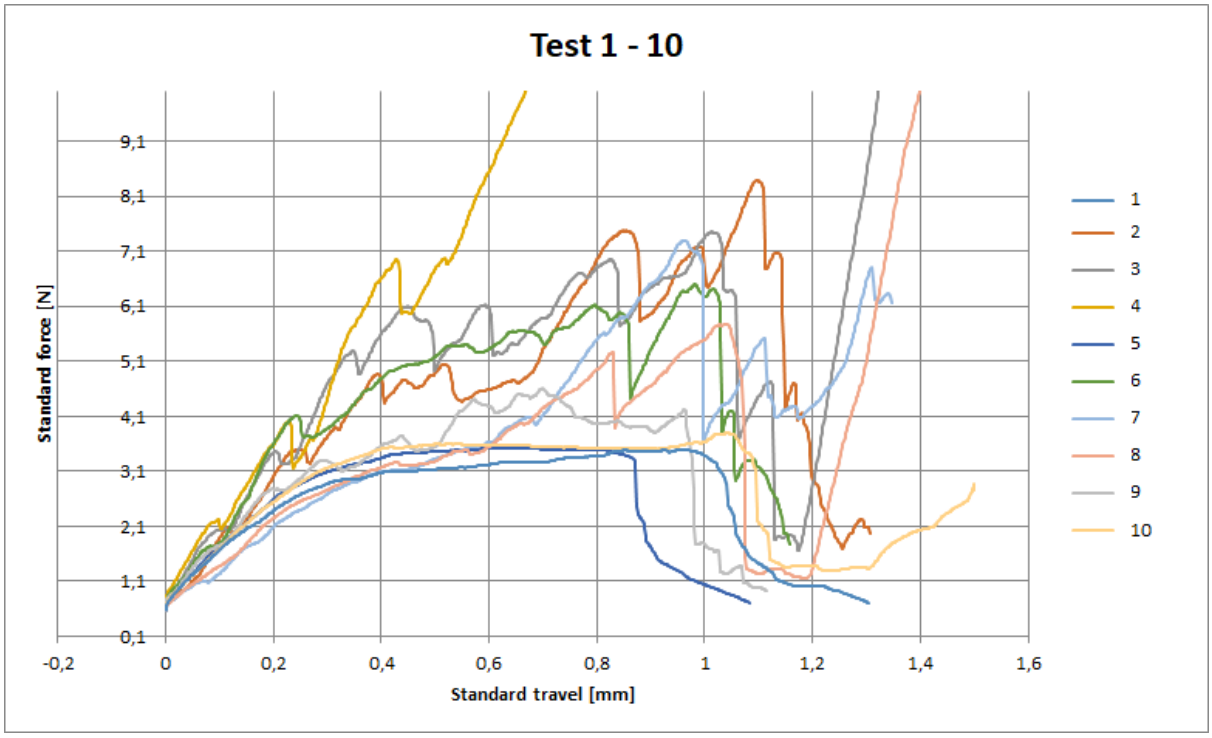


Figure J-12: A graph displaying the force in Newton against the displacement in millimetres for each staple during bending.

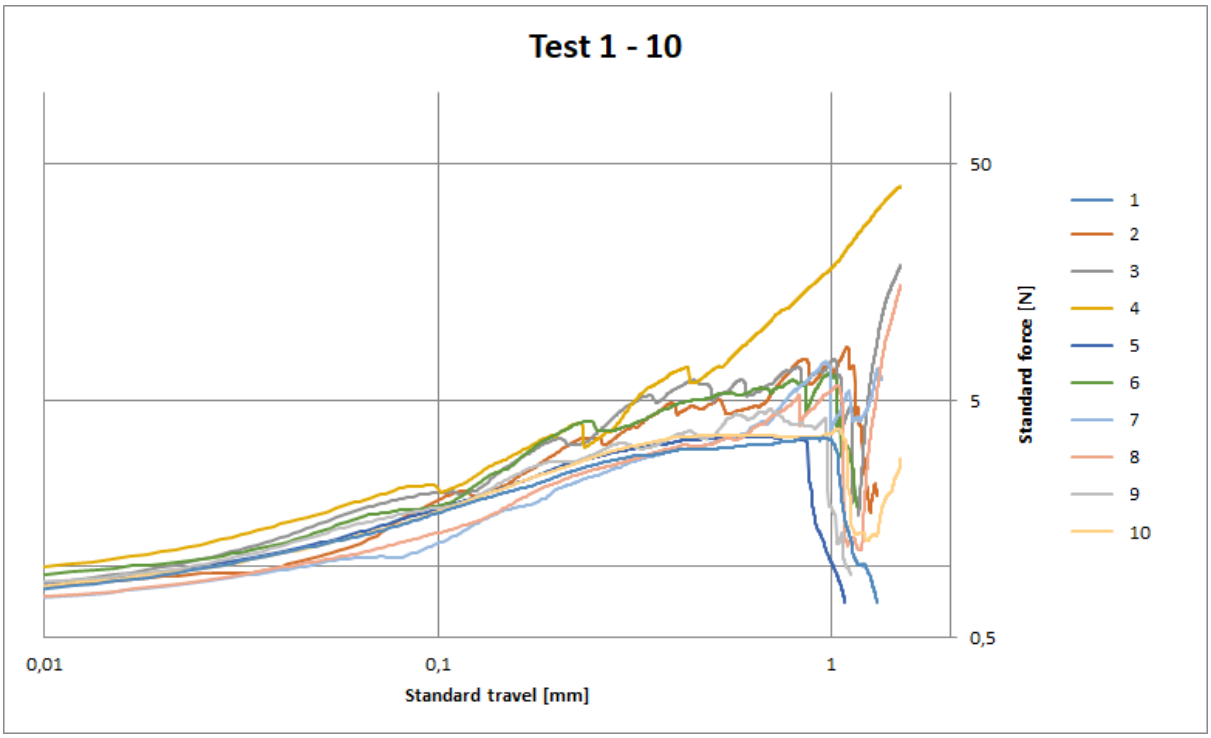


Figure J-13: A graph displaying the force in Newton against the displacement in millimetres for each staple during bending, on a logarithmic scale.

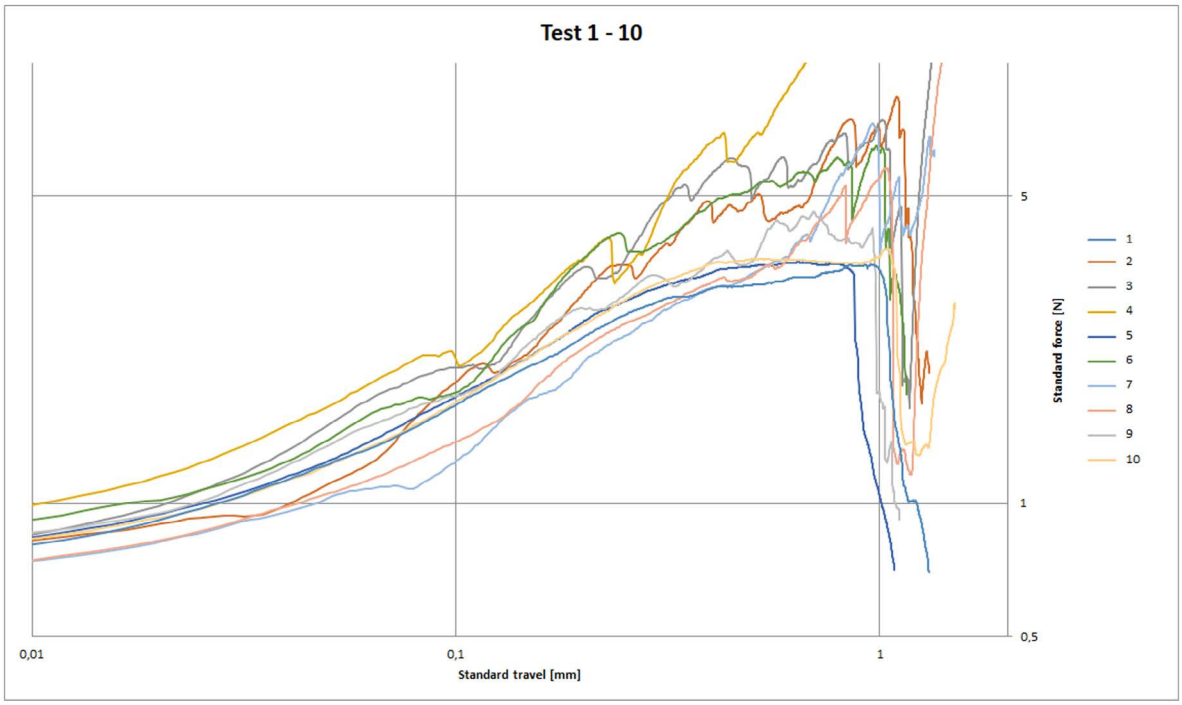


Figure J-14: A graph displaying the force in Newton against the displacement in millimetres for each staple during bending, on a logarithmic scale.

Looking at the forces involved before this strength drop, it can be seen that no more than 10 Newtons are required to bend all staples.

The elastic limit to where the yield starts is around 3 Newton for all staples. After that, a short softening followed by a fairly stable plastic flow happens for staples 1, 7 and 10. And for the other staples, softening and hardening are alternated per about every 0.2 mm displacement.

The software indicated that 6 out of 10 staples measured a break around 1 mm displacement. strangely enough, none of the staples was broken afterwards. However, when viewed under the microscope, most of them exhibited substantial tearing at the location where I expected the necking would happen.

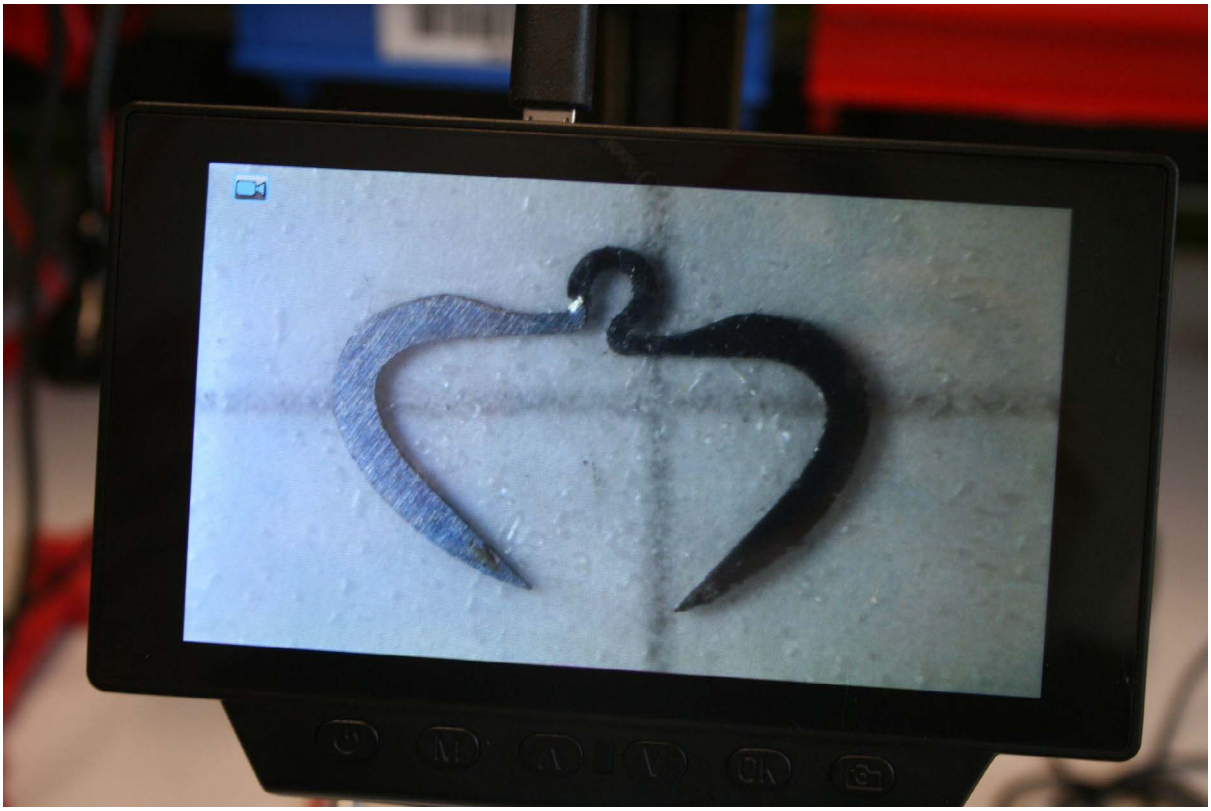


Figure J-15: A staple with a big tear just above the shoulders. No zoom

Figure J-16: The same staple from the previous picture, but zoomed in x3.8 times on the tear

Figure J-17: Another staple with a huge tear at the same location. Zoomed in x2.4.

Figure J-18: The same staple, but zoomed in at x4.0

Closer inspection shows that both cracks run exactly along the grooves of the steel plate from which the staples were laser-cut. In addition, it can be seen that only one side is considerably bent, while the other side is barely bent. It probably won't take long before a ductile fracture occurs in these examples.

Discussion

Large-scale 5:1 staples deform into the desired shape without tearing or breaking, when appropriate force is applied. However, at the actual 1:1 scale, as shown in the images above, the staples do tear when force is applied. This can be explained by several small-scale effects.

In materials science, a dislocation is a crystallographic defect or irregularity within a crystal structure. The presence of dislocations strongly influences many properties of materials. This phenomenon is key to understanding why some metals have a strength that is far below their ideal strength (Ashby et al., 2019). When enough stress is applied, the material undergoes plastic deformation, through the motion of these dislocations. These dislocations have to overcome a friction-like resistance per unit length. In larger structures, as this length is bigger, this would require much force (Ashby et al., 2019; Hibbeler, 2014).
When the grain size becomes comparable with the feature size of the product in micro-scaled deformation, the individual grain property, grain morphology, and crystalline orientation could significantly affect the overall deformation response and brings up the so-called size effect, which impedes the direct application of the well-established macro-scaled knowledge to micro-scale (Tang et al., 2020).

Edge cracks and surface roughness can also influence the strength of steel. A crack acts as a stress concentrator, leading to a local increase in stress and a reduction in the strength of the material. Surface roughness can similarly act as a stress concentrator, leading to an increase in the local stress and a reduction in the strength of the material. Additionally, surface roughness can lead to variations in the local crystal orientation and impurity distribution, which can further contribute to inhomogeneous deformation and weakening of the material (Ashby et al., 2019, Chapter 10).

To avoid the staples from failing, a more homogeneous material is required (e.g. a monocrystalline), with a higher ultimate tensile strength relative to the yield strength, higher fracture toughness and a better surface finish when manufactured.

When looking at the maximum imposed strain we get 5.363e-01, according to SolidWorks (2023).

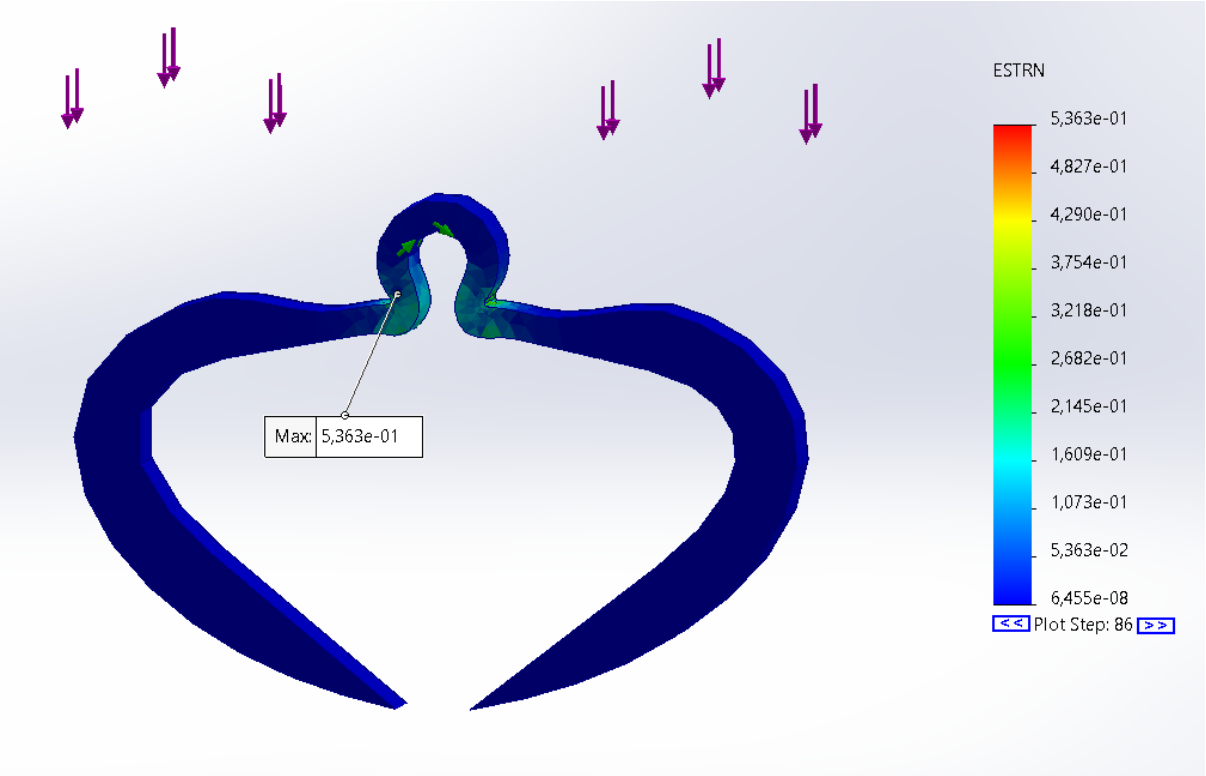


Figure J-19: The imposed strain of 5.363e-01 (SolidWorks 2023).

To select a new material, I need to maximise the range between the tensile and yield strength. Here I will choose a strain percentage of 0,6 that the material must be able to endure without breaking. In addition, it is important to include all other requirements in the material selection, including that it must belong to the USP Class VI, ISO 10993 (medical grades), be biocompatible and be non-ferromagnetic in case the patient ever needs an MRI or NMRI scan.

When inputting this information in the software programme GRANTA EduPack (2020), it provides martensitic nickel-titanium alloy and austenitic nickel-titanium alloy as resulting options to choose from.

As austenitic materials are more ductile than martensitic materials, I will opt for the austenitic nickel-titanium alloy as the most suitable material for the staples.

Nickel-titanium alloys are already commonly used for bone fixation, ankle, and foot surgery. Saleeb et al. found that body temperature-activated NiTinol staples show an increase in compression force, a phenomenon known as "inverse relaxation," which may be an interesting phenomenon to further look into (Ghosh et al., 2022).

Melt casting (or melt extrusion) is widely used to create metal and alloy staples (Schneider & Feussner, 2017b). 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 (see References list). These go much more in-depth about these topics than is possible in this report.

K. Design process of the cartridge

Staple storage

The staples needed to be stored lengthwise, to optimize the needed space in the diameter of the applicator shaft. However, when laying the staples completely flat after one another, the staples deformed when pushed from either side. Thus they were put at a slight angle of 15 degrees, to prevent them from deforming when pushed.

Next, to prevent the staples from skewing, the cartridge had to support the staples to keep them at a correct angle.

Figure K-1: cut out the silhouette of a staple at a 15-degree angle as an extruded 3d print, to support the staples while preventing them from skewing.

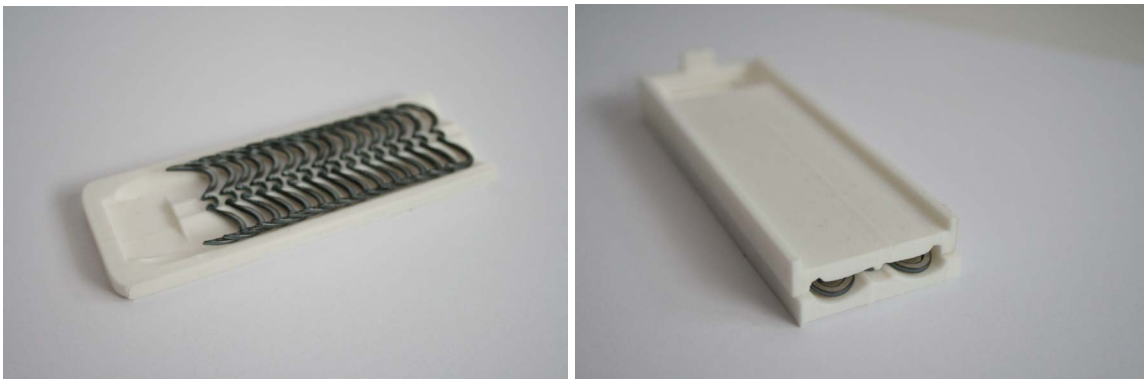
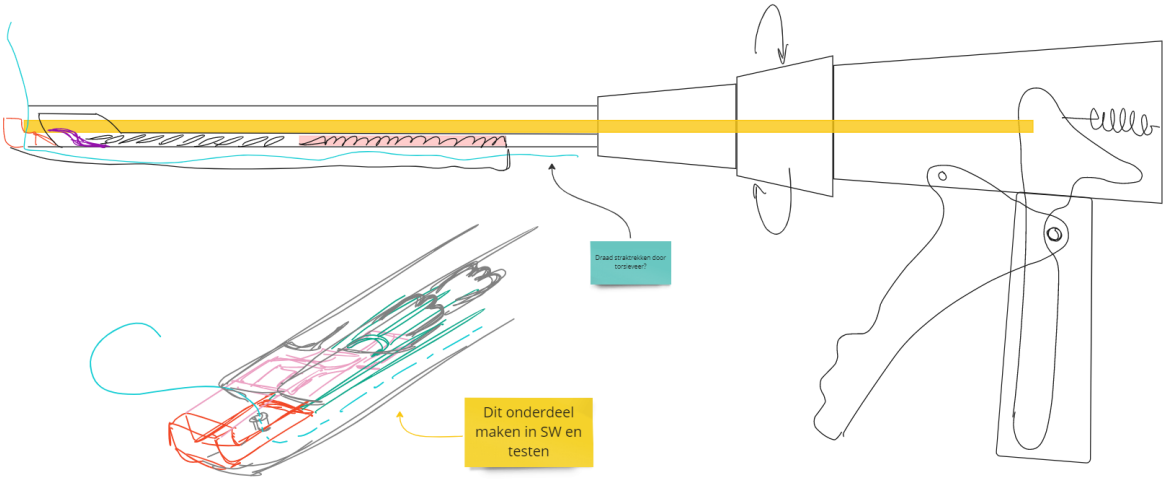


Figure K-2: a 3D printed model of a staple supporting cartridge, with laser-cut staples placed into it.

Staple displacement

To get from the cartridge to the bending location, the staples must be moved, as seen in the pictures below.



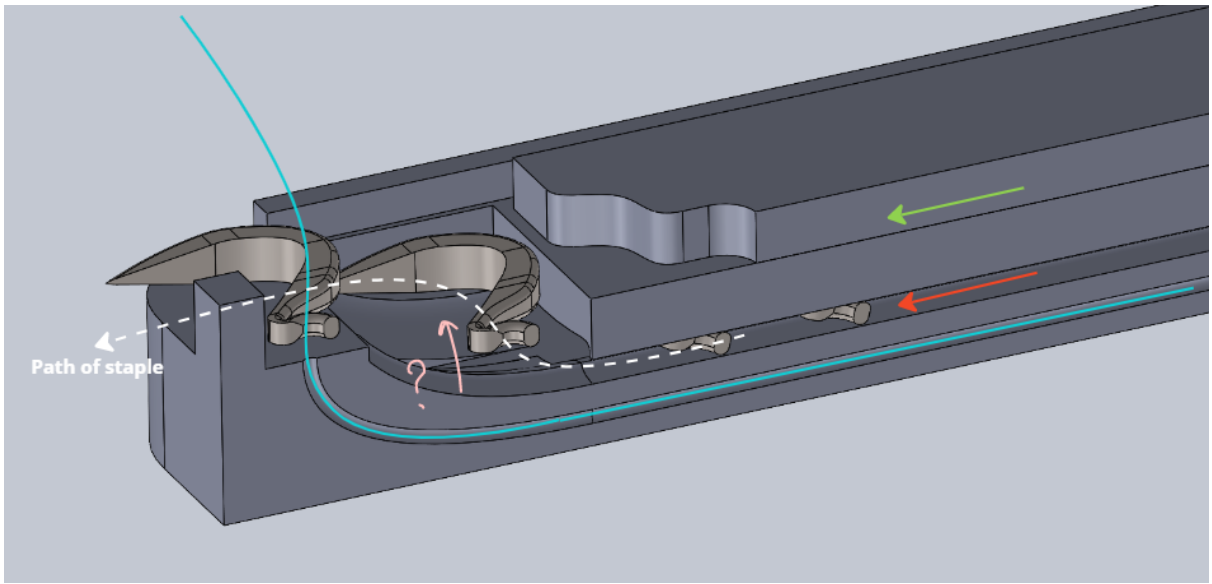


Figure K-3: The displacement path that the staple needs to follow.

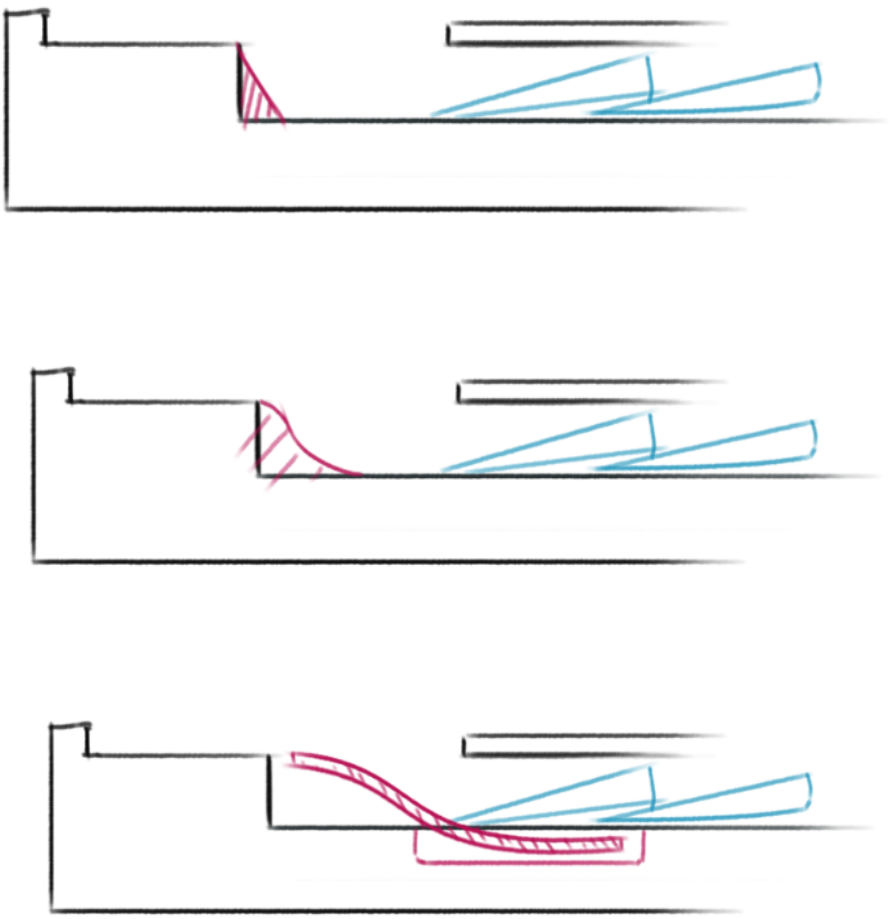


Figure K-4: Sketches of the cross-section of a chamfer (top), chute (middle) and spring (bottom) as displacement mechanisms

A few designs were drawn and then modelled using SolidWorks. One with a chute, another one with a spring, and a last one with a chamfer.

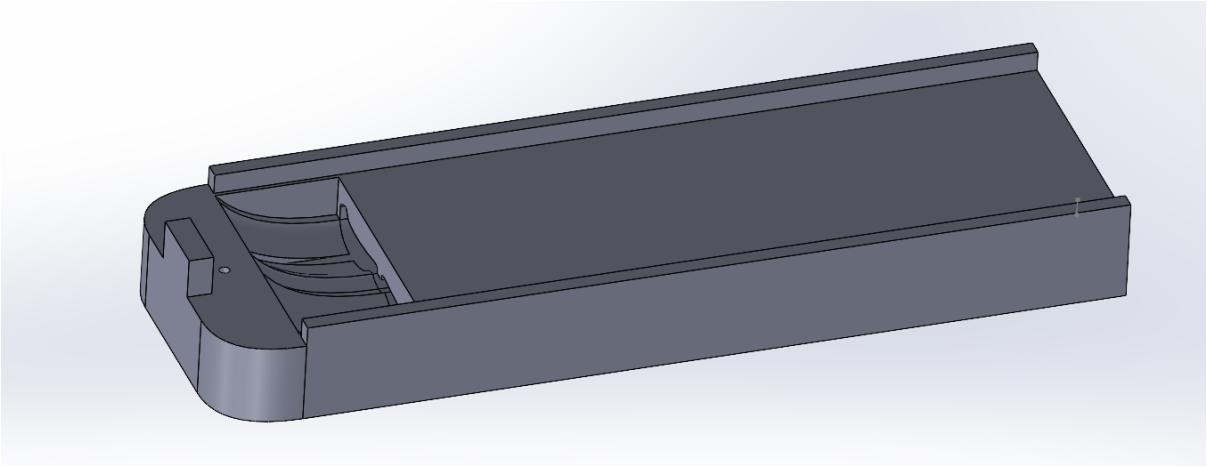


Figure K-5: A 3D model of the slide for displacement

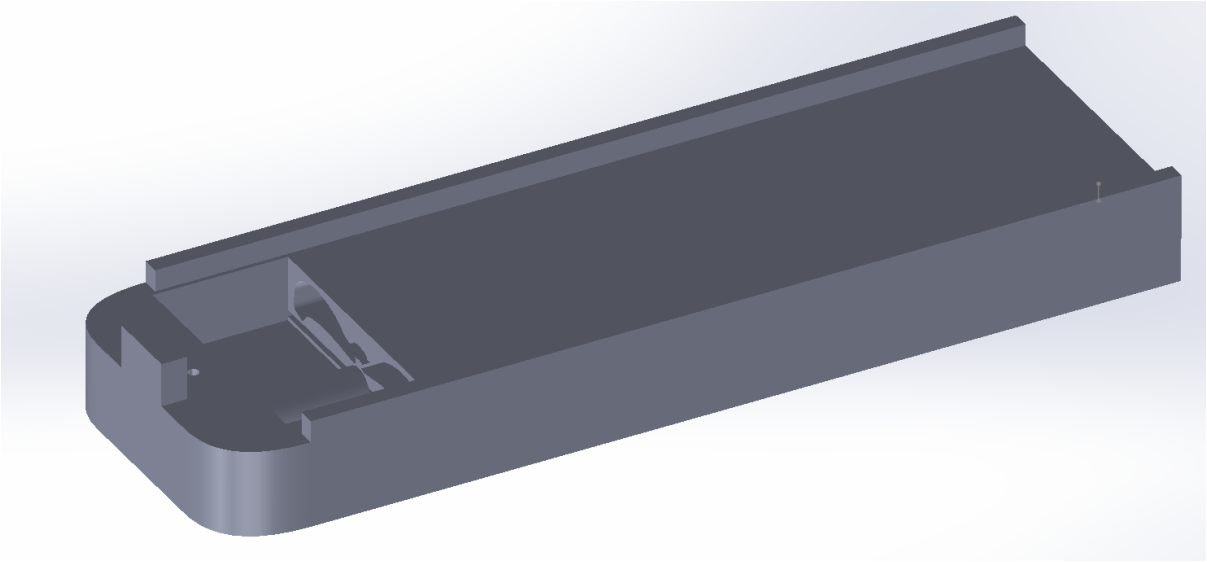


Figure K-6: A 3D model of the spring for displacement (spring is not visualised here, as in the model only the space for the spring is made)

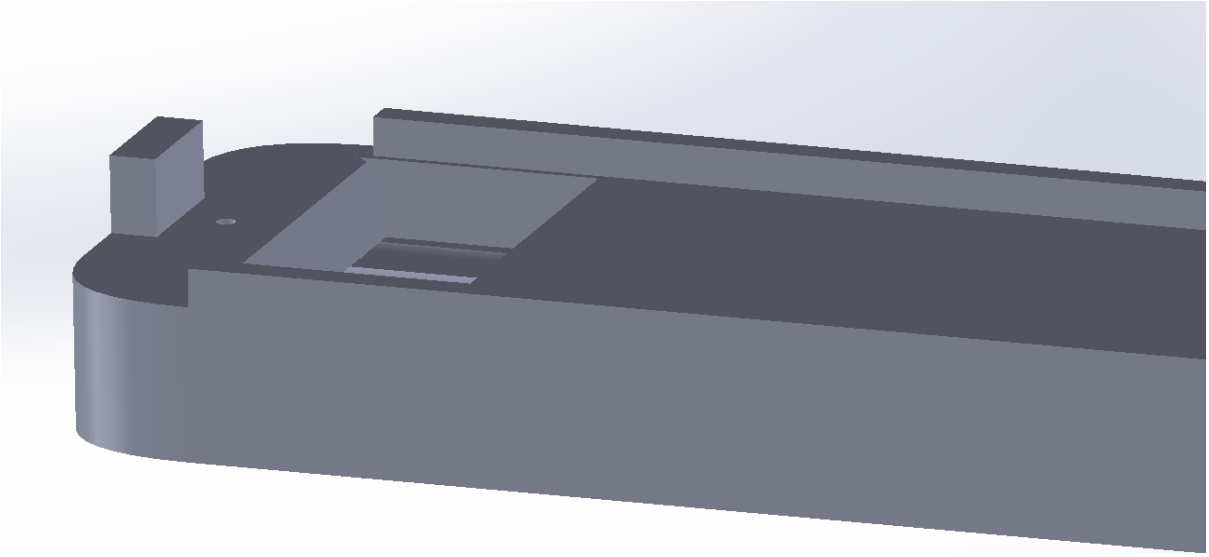


Figure K-7: A 3D model of the chamfer for displacement

When testing with the 3D-printed models, the slide mechanism was eliminated directly. It caused the staples to rotate 90 degrees instead of sliding in the same orientation (as sketched in Figures K-8 and K-9).

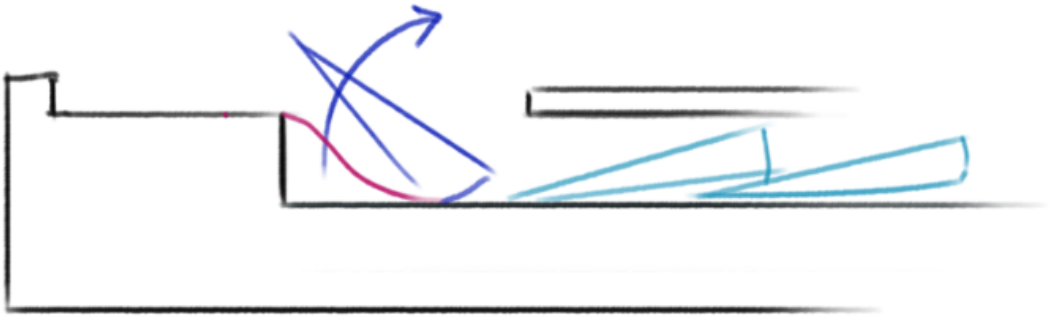


Figure K-8: A schematic drawing of staples tilting 90 degrees, as a result of the slide design.

Figure K-9: 90-degree rotation caused by the slide

And a simple corner with no mechanism caused a 90-degree rotation in the opposite direction. So that was not a good option either.

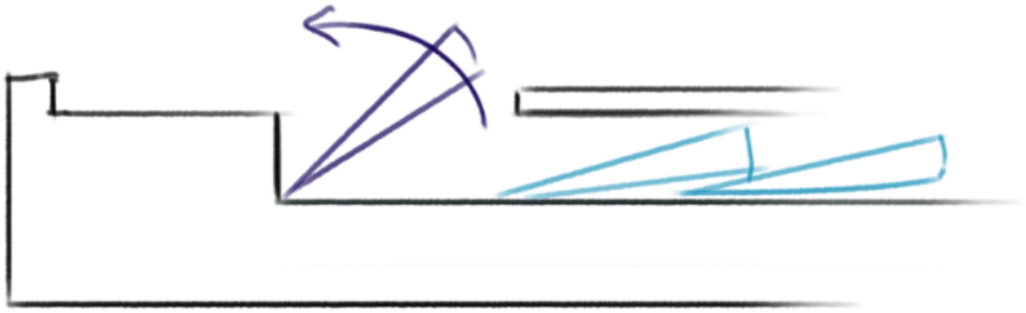


Figure K-10: A schematic drawing of staples getting stuck and rotating 90 degrees, due to the abrupt corner in the design

Figure K-11: 90-degree rotation due to staples getting stuck in the bottom corner when using no mechanism at all

The spring caused the same problem of rotation as the slide when too stiff and a rotation the other way around when not strong enough. I wasn't able to get it just right. It might work in theory but I'm unsure about this one.

The chamfer was able to provide the desired result when using not too big, nor too small of an angle. This still needs to be tested more thoroughly with a longer cartridge and in various orientations, but it was the most promising one of all.

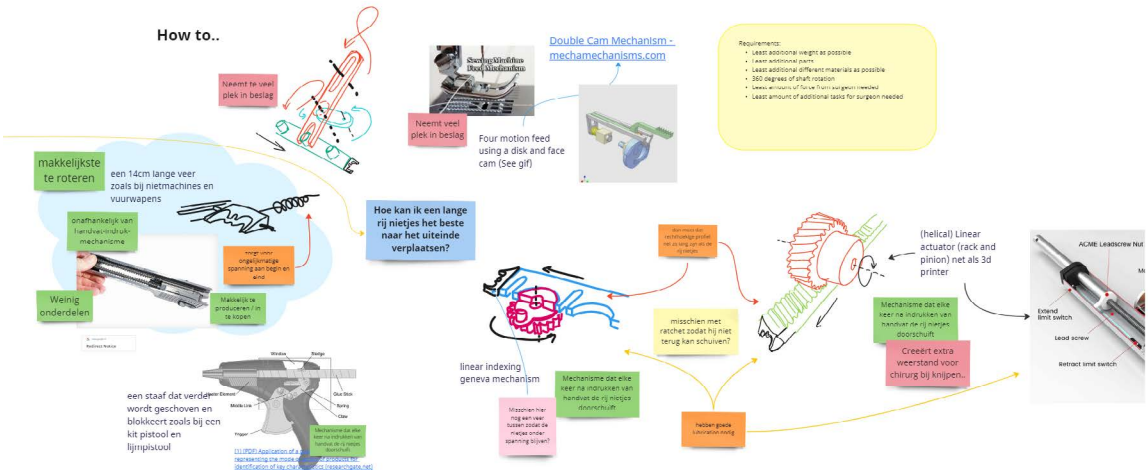


Figure K-12: Ideation through brain drawing and how-tos. Then ranked using a deconstructed Harris profile, colour coded with the aid of Post-Its. In the light yellow square, the necessities for this part were written down.

I made another ideation with the aid of brain drawing and how-to's Zijlstra et al., 2020, and chose a simple spring-loaded mechanism as the most promising outcome.

Using the question "How to displace a long row of small units?" I sketched some ideas and possible solutions for this problem (brain drawing and how-to's from the Delft design guide (Zijlstra et al., 2020). Here I used some existing mechanisms found in 3d printers, glue guns, sewing machines, etc. as inspiration (as they are known to work reliably).

Then I rated all of the sketched mechanisms using these requirements:

- At least additional weight as possible
- Least amount of parts needed
- At least additional different materials as possible
- 360 degrees of shaft rotation must be possible
- The least amount of force from the surgeon needed
- The least amount of additional tasks for the surgeon needed

Almost all mechanisms were a bit complex, requiring lots of intricate parts and/or were just too big to fit into a diameter of a max of 12mm (which is the inside diameter of a standard trocar). Only the mechanism of using a spring attached to a shape that touches the staples resulted in a promising outcome.
It would not require much additional space, is lightweight, easy to manufacture, does not require additional external force to operate and requires only two parts to function.

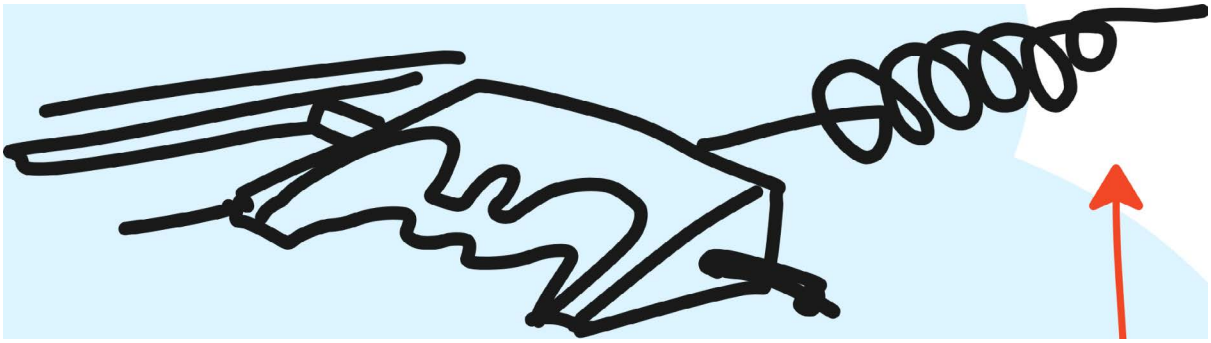


Figure K-13: A sketch of the spring-loaded pushing mechanism.

This part was again, modelled and 3D printed. With the use of springs from two deconstructed pens, simple tests were conducted.

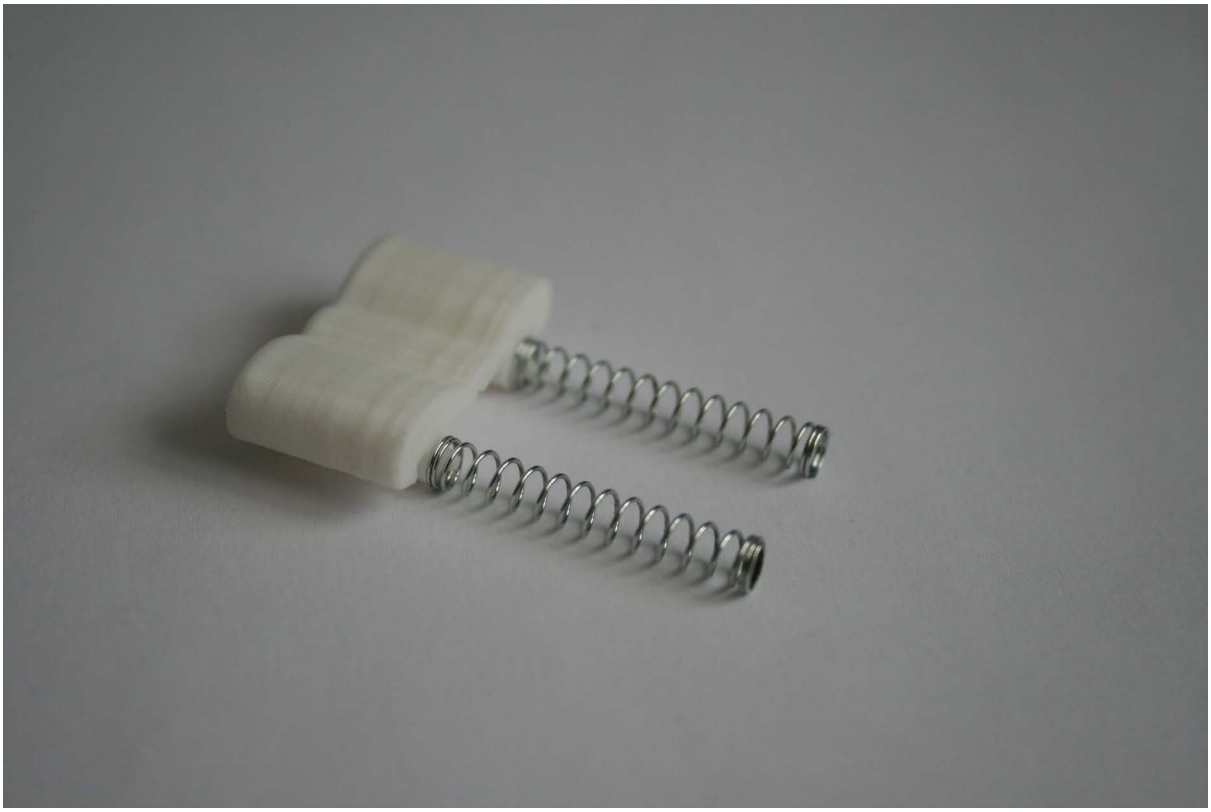
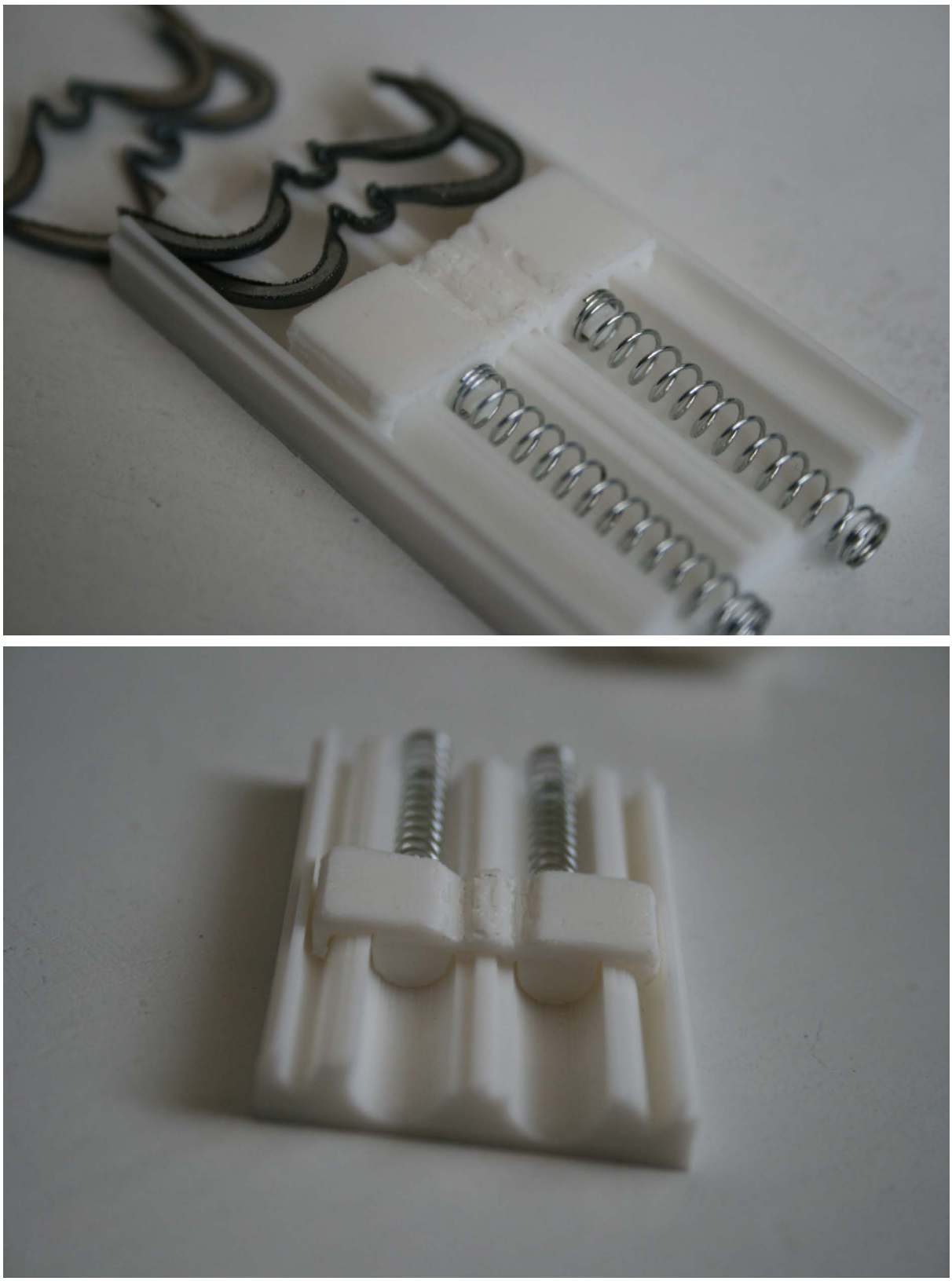


Figure K-14: A 3D printed model of the spring-loaded pushing mechanism.



K-15: Two photographs of a low-fidelity model of the springloaded mechanism. The cover here has been dismounted, as otherwise the inside cannot be shown.

Figure K-16: A bigger 3D printed model of the cartridge, used to test if the mechanism would still work with a bigger amount of staples. Here the springs from pens were used, as I was awaiting new springs to arrive in the mail. These pen springs were not strong enough...

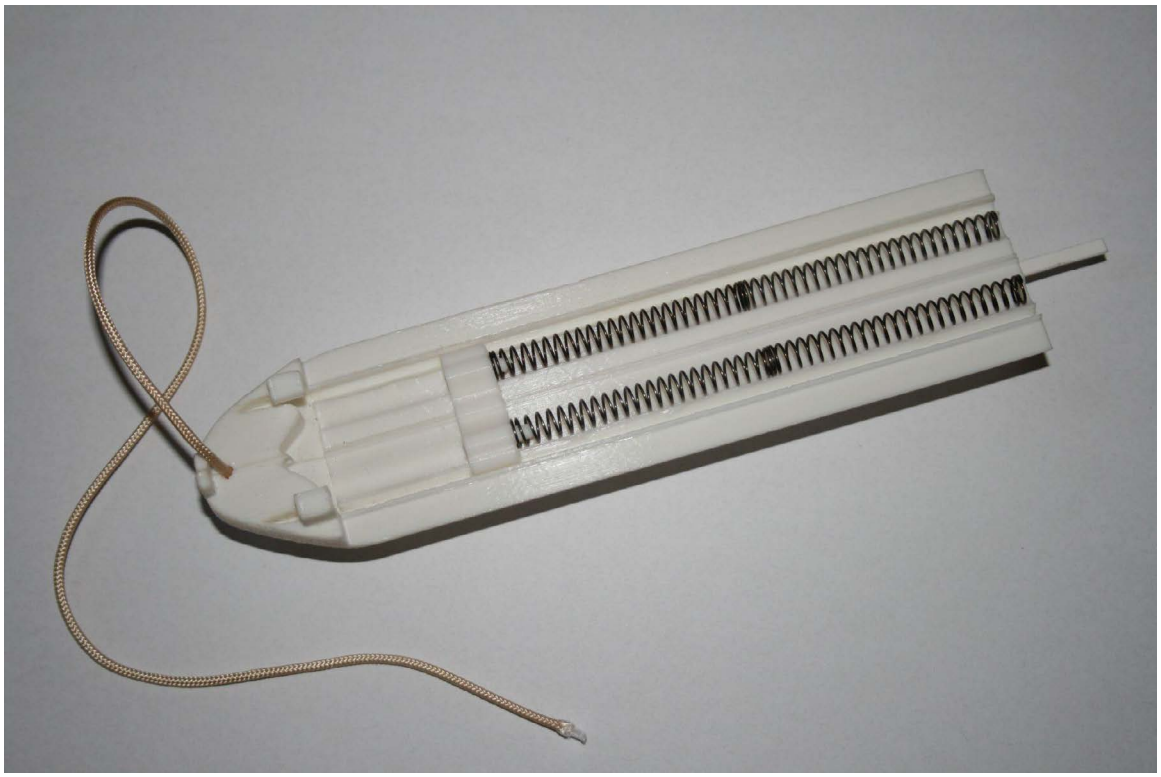


Figure K-17: A scale model of the final design, with the right springs. Using the same staples as in the previous model, this mechanism was tested to work well, until the springs were not long enough to reach the end.

Still, it remains unknown what the ideal spring rate (or stiffness) of the compression spring needs to be. This depends on its length (in compressed and normal state) and on how much friction will it need to overcome.

Barbed suture dispenser

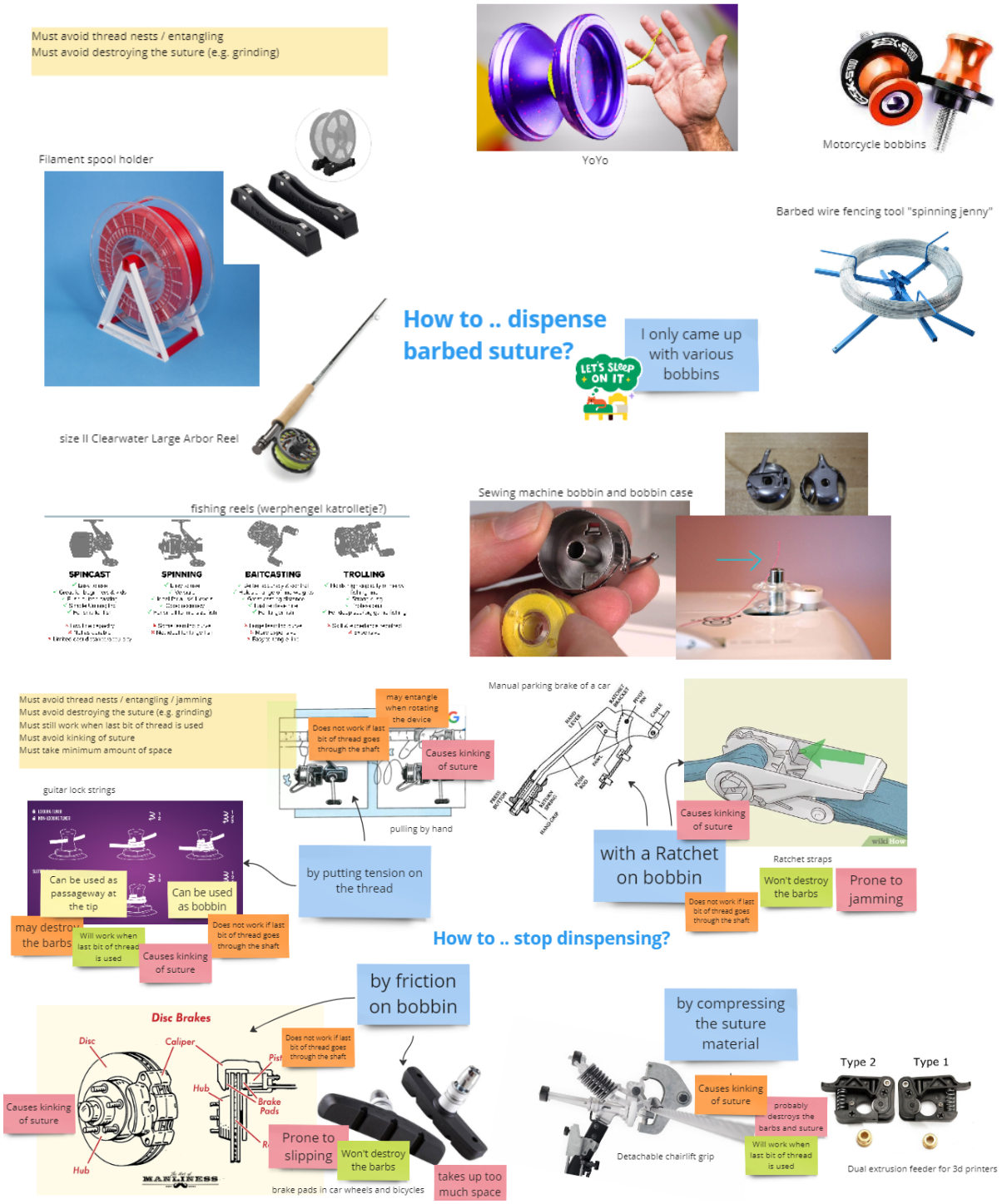


Figure K-18: The result of an extensive brainwriting and -drawing session.

To generate ideas for dispensing the barbed suture, I employed the brainwriting and drawing method once again (Figure K-18). This involved addressing two key questions: "How to dispense" and "How to stop dispensing." Utilizing a light yellow square on the board, I listed the requirements and ranked the ideas using a deconstructed Harris profile, represented by colour-coded Post-it notes. Interestingly, all the dispensing mechanisms that emerged involved some form of bobbin.

Regarding the challenge of preventing suture dispensing, I faced uncertainty regarding the most suitable mechanism among the options generated. To address this, I temporarily set aside this aspect and proceeded to tackle the next problem at hand.

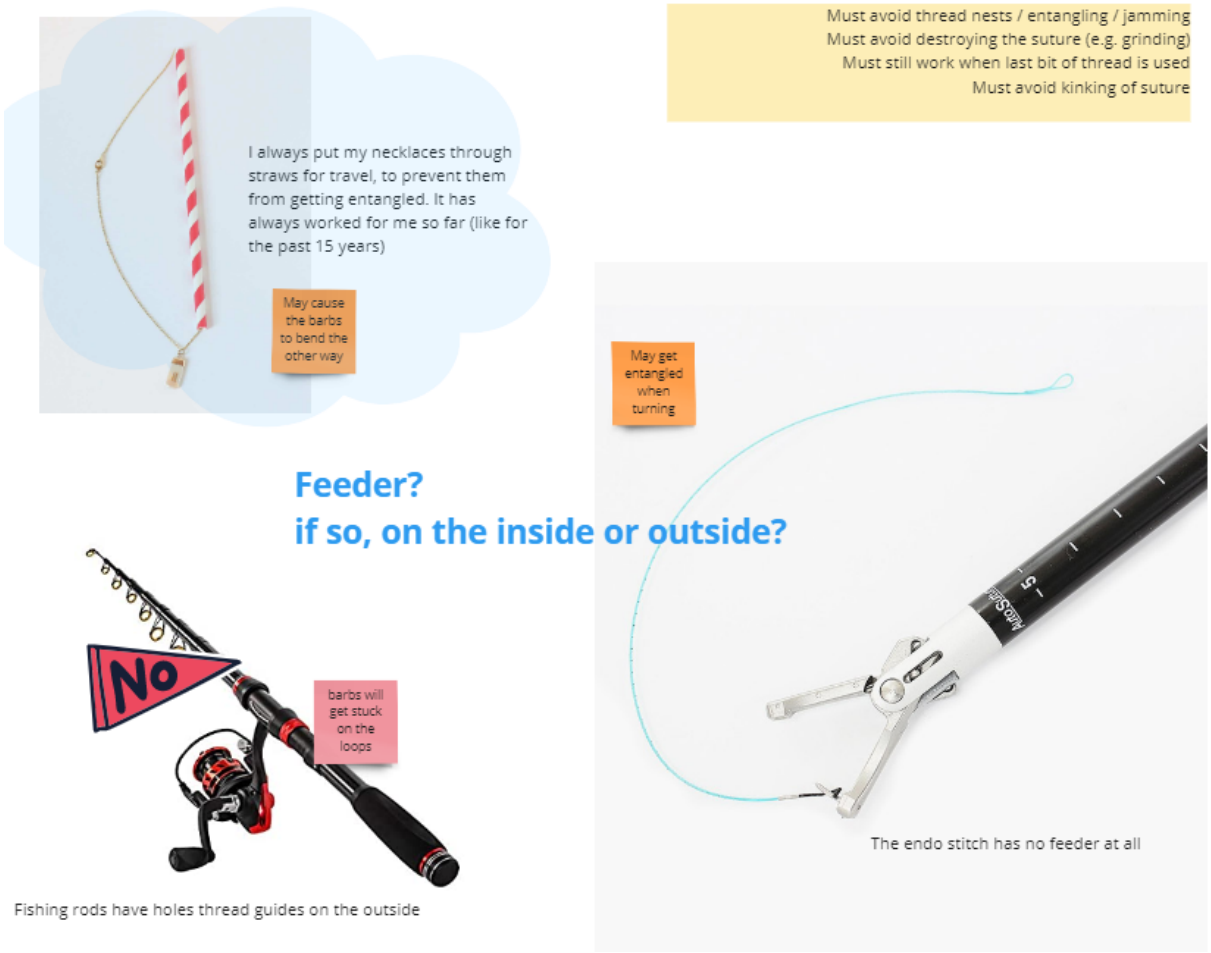


Figure K-19: Three options generated during brainstorming, on how to get the suture to the right place.

Then, during additional brainstorming, I discovered three potential options for guiding the barbed suture from the cartridge to the tip of the device: passing it completely through a cylindrical shaft, routing it through a series of cylinders, or keeping it entirely outside of the shaft. Considering the requirement to minimize entanglements, suture kinking, and thread nests, I decided to pursue the approach of using a cylindrical shaft that would provide full protection for the entire length of the suture.

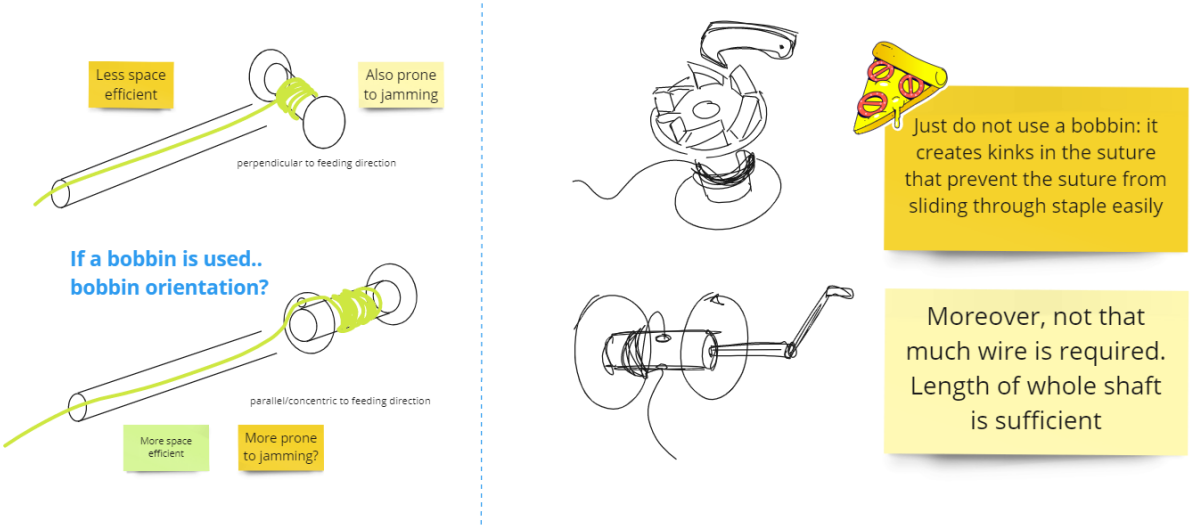


Figure K-20: Sketched bobbin orientations.

This decision then posed the challenge of routing the suture from the bobbin through the cylindrical shaft to the tip of the device while ensuring it would not get jammed, stuck, or encounter similar issues. I sketched out potential orientations for the bobbin, but both options carried the risk of getting stuck due to the barbs hooking onto various nooks and crannies. Additionally, given the small size of the bobbin, the suture would likely kink excessively. As a result, I decided to eliminate the use of a bobbin. With the shaft's length estimated to be approximately 30 centimetres, I determined it would be sufficient for closing an entire defect, rendering the bobbin unnecessary.

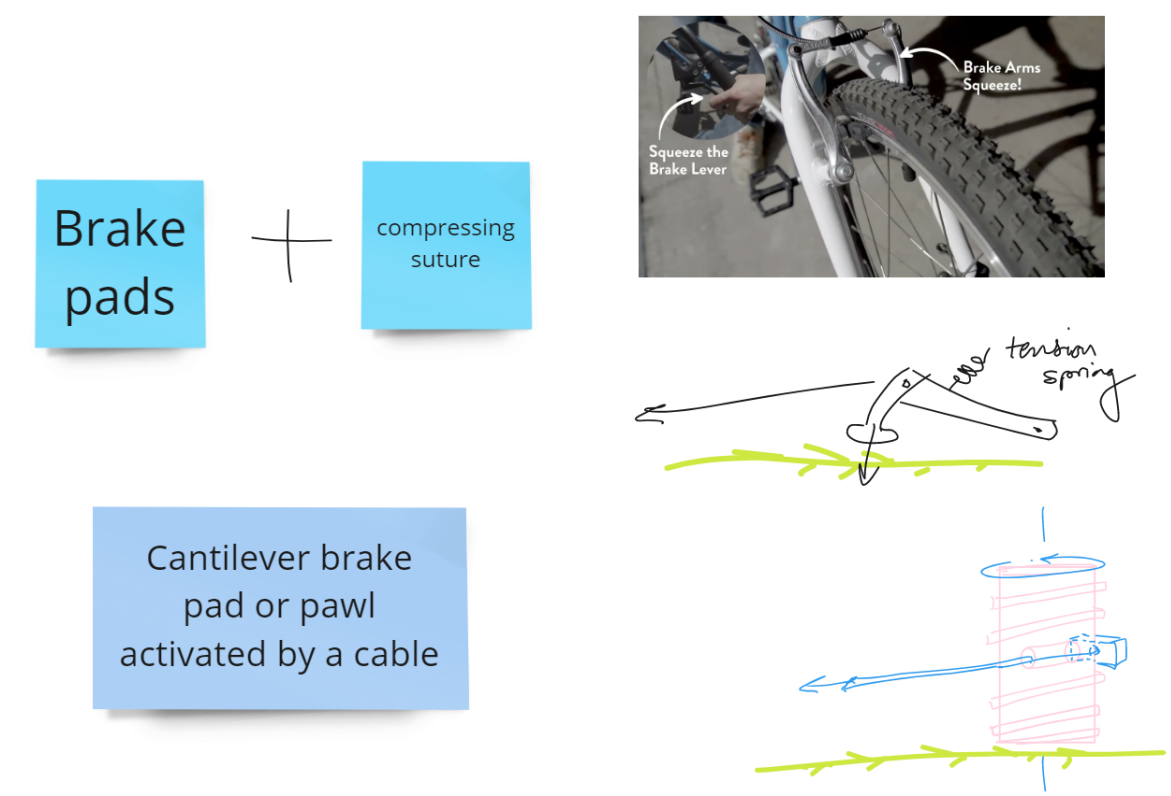


Figure K-21: The decision to combine friction and compression to block the suture.

After eliminating the bobbin, I explored alternative methods to physically restrain the suture from moving. Combining the principles of friction and compression, I drew inspiration from a piano hammer and bike brake pads. I created a 3D model of a small cantilevered hammer and designed an enclosure for it. Passing the suture through the enclosure, I pulled on the string, causing the hammer to compress the suture. The friction generated by this compression prevented the suture from moving as I pulled on it. Seen in Figure K-22.

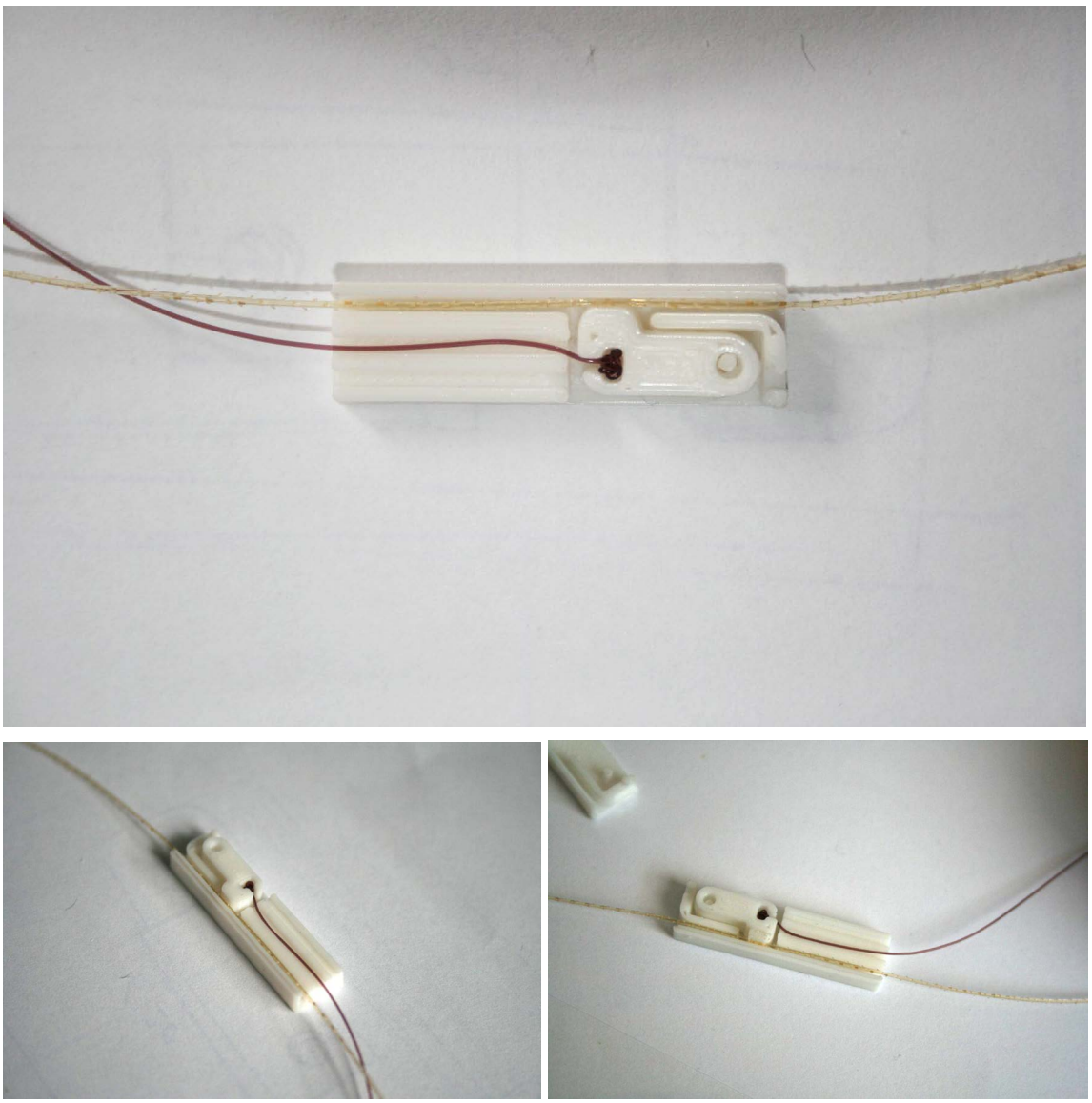
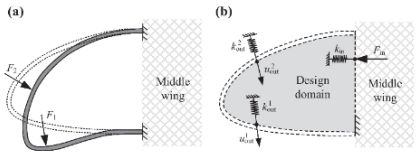


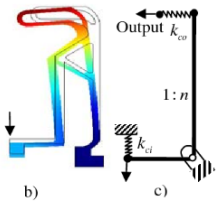
Figure K-22: A 3D printed model (2:1 scale) of a tiny hammer. When the red string is pulled, the hammer compresses the suture, restraining it from movement, even when pulled upon.

However, upon further consideration, I realized that this design involved numerous components and could be challenging to manufacture on a small scale. To address this concern, I sought to simplify the design by utilizing a compliant mechanism (Figure K-23). Through a process of trial and error, I iterated towards the design depicted in Figure K-24, which provided a more streamlined and efficient solution.

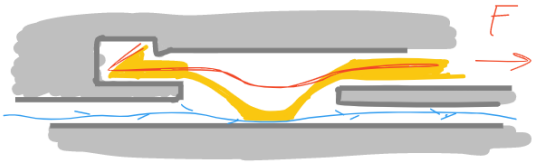


Design of compliant mechanism-based variable camber morphing wing with nonlinear large deformation - Yaqing Zhang, Wenjie Ge, Ziang Zhang, Xiaojuan Mo, Yonghong Zhang, 2019 (sagepub.com)

[PDF] Design of Compliant Mechanisms for Practical Applications using Selection Maps | Semantic Scholar



This still takes up a bit too much space for my liking. I think that a compliant mechanism is a better alternative. This will take up less space, needs less components and can be made out of a single material. (maybe even an bistable switch?) (can I do this with topology optimization in SW?)



Something like this maybe

Figure K-23: Inspiration to make a compliant mechanism, from an academic paper of an aeroplane wing (top) and a schematic drawing of my idea (bottom)

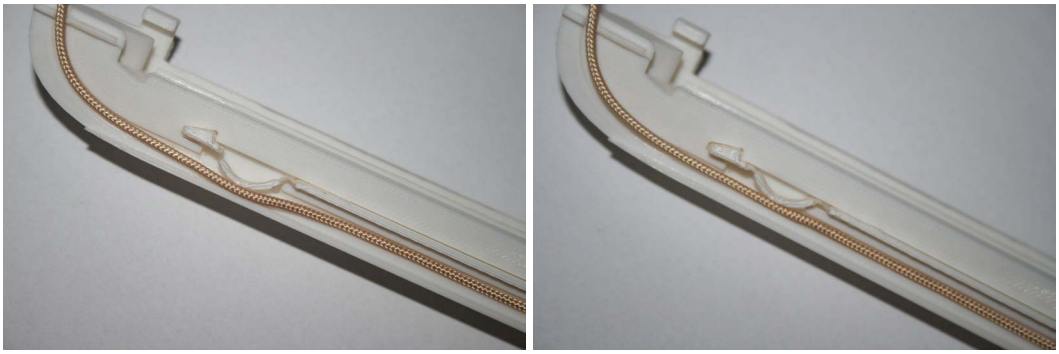


Figure K-24: The final compliant mechanism used to lock the suture

Subsequently, to activate the compliant mechanism, it was necessary to incorporate a button into the handle design that would allow the surgeon to engage the locking principle. To achieve this, I decided to divide the rotation knob on the end of the shaft and introduce a pushing function. However, I soon realized that it would be impractical for the surgeon to continuously press this button while tightening the suture. Therefore, I needed to devise a way to lock the mechanism with a single press and unlock it with a simple movement.

To address this challenge, I conducted another brainstorming and drawing session, evaluating each idea based on its adherence to the requirements (Figure K-25). Using a deconstructed Harris profile and colour-coded Post-it notes, I assessed the various possibilities. Ultimately, I selected a ratchet and linear teeth mechanism for its simplicity, minimal number of parts, and space efficiency. This solution allowed for the desired single-press activation and straightforward unlocking, fulfilling the surgeon's needs effectively.

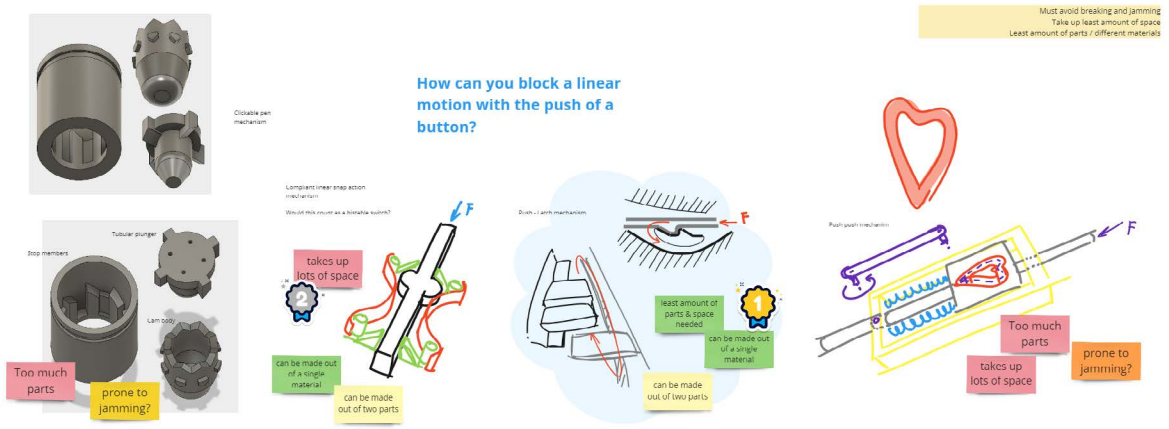


Figure K-25: Brainwriting and drawing, followed by a ranking with post-its, to choose the best idea, based on the requirements in the top right corner.

Subsequently, I proceeded to create additional 3D printed models at a 5:1 scale to test the functionality of the ratchet mechanism. With a simple push, the ratchet would engage between the two teeth, producing an audible "click" sound. This ratchet was connected to a long rod, which, in turn, exerted pressure on the rod of the compliant mechanism in the cartridge, causing it to compress the suture. Upon a second push, the ratchet would move behind the second tooth, and the compliant mechanism, exerting force against the rod, would push the ratchet back to its original position. Figure K-26 displays external images of these components in their final form for reference.

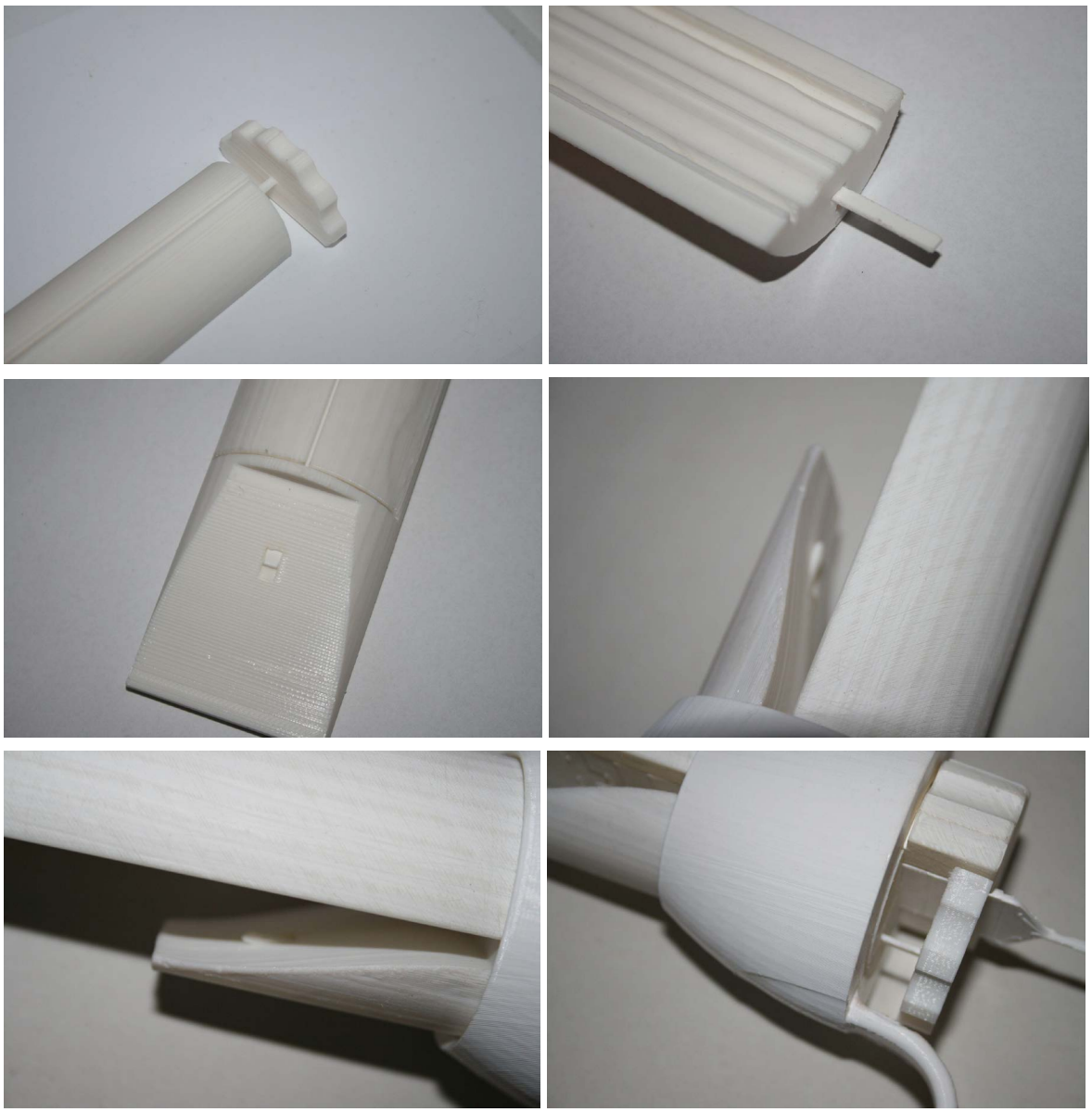


Figure K-26: Photographs of the double-push mechanism, as seen from the outside.

L. Design of the handle

Although designing a handle with considerations for ergonomics, tactile feedback, manoeuvrability, comfort, and intuitive use is essential for creating a successful medical device, it was not possible to implement all these aspects in this project due to time constraints. The focus of this project was to establish a solid foundation for further iterations in the future. Therefore, the risk analysis, bending behaviour of staples, assembly of all parts of the device, and so on, took priority over ergonomics and handle design. The more technical aspects were crucial for creating a basis that can be further developed and improved upon in future iterations. The handle design is an important aspect and should be looked into in a follow-up project, but for now, it is implemented in this project.

Handle design plays a crucial role in the usability and overall user experience of surgical devices. However, some existing handles, such as the ENDO GIA stapler, have been found to be cheap, wobbly, and made of squeaky plastic, which surgeons have expressed dissatisfaction with during the observations (Appendix C). Given that the handle is the component with which surgeons interact the most, providing them with haptic proprioception, poorly manufactured handles must be avoided.

There are numerous design options available for handles, as highlighted in the screenshot from a Miro board on the next page spread, but identifying the most suitable design remains a huge challenge. Thorough research in this area is still necessary, but the next page already offers an overview of various options from academic literature. These can roughly be categorised in three groups: pistol, hybrid and in-line handles, depending on the orientation of the handle.

In this project, a novel approach was adopted by using a single component, single material, and compliant mechanism as a handle. This mainly serves as an inspiration for future researchers, as compliant mechanisms are rarely utilized in medical devices but offer great opportunities for material and component reduction. Additionally, the handle used in this project was aimed at reusability, where only the shaft and cartridge would need to be discarded, while the handle itself could be reused. This consideration aligns with the objective of reducing unnecessary medical waste in the long term. By exploring innovative handle design concepts and focusing on sustainability, advancements can be made in reducing the waste created by single-use medical devices.

Further development of the design necessitates anthropometric research to ensure an ergonomic handle. Considering the diverse hand sizes of surgeons, there are several options to explore: customizing handles for individual surgeons, implementing a sizing system, or utilizing a single-size approach. It is crucial to ensure

that the design remains ergonomic and user-friendly regardless of the orientation in which it is used, including upside down, left-handed, right-handed, etc. Additionally, the possibility of incorporating an articulating, multi-degree-of-freedom (DOF) handle should be considered.

To enhance grip comfort, the addition of a voluminous rubber-like material on the handle, fitting within the palm of the hand, could be explored. This would provide a more secure and comfortable grip during surgical procedures.

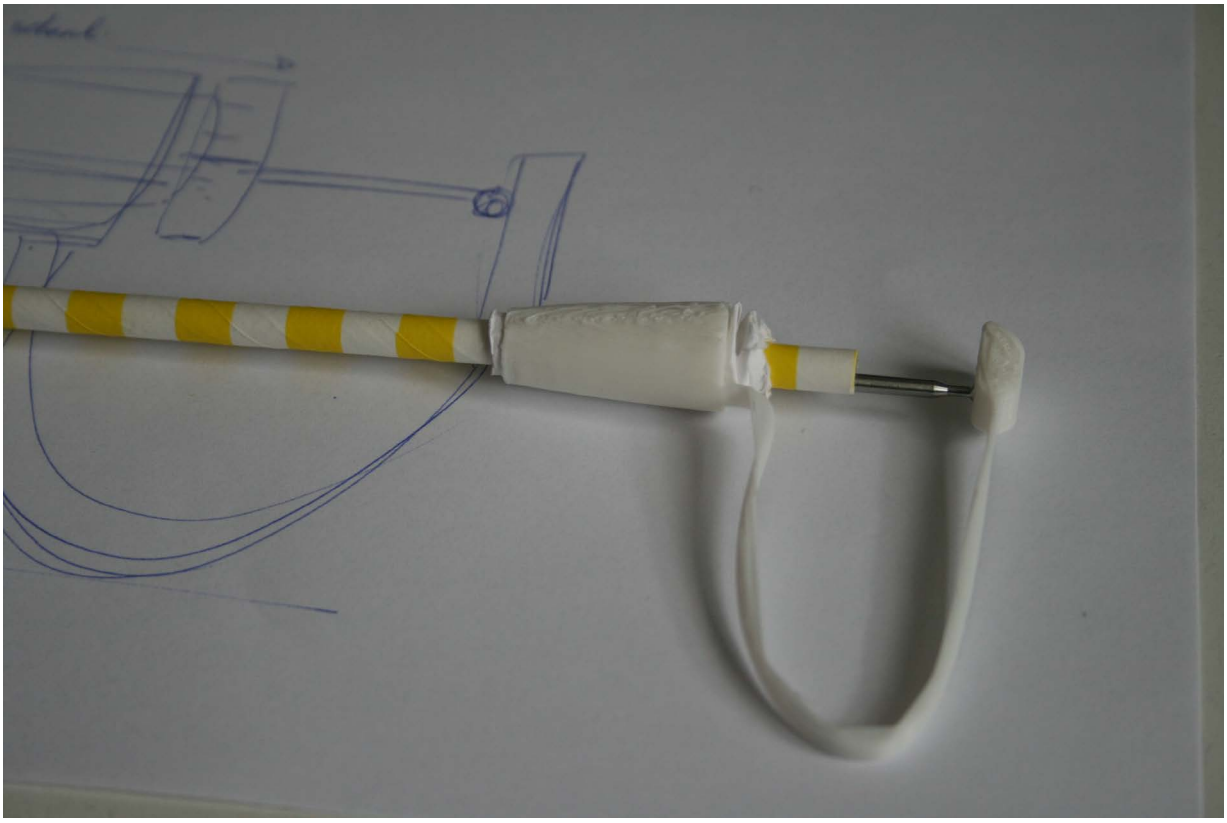
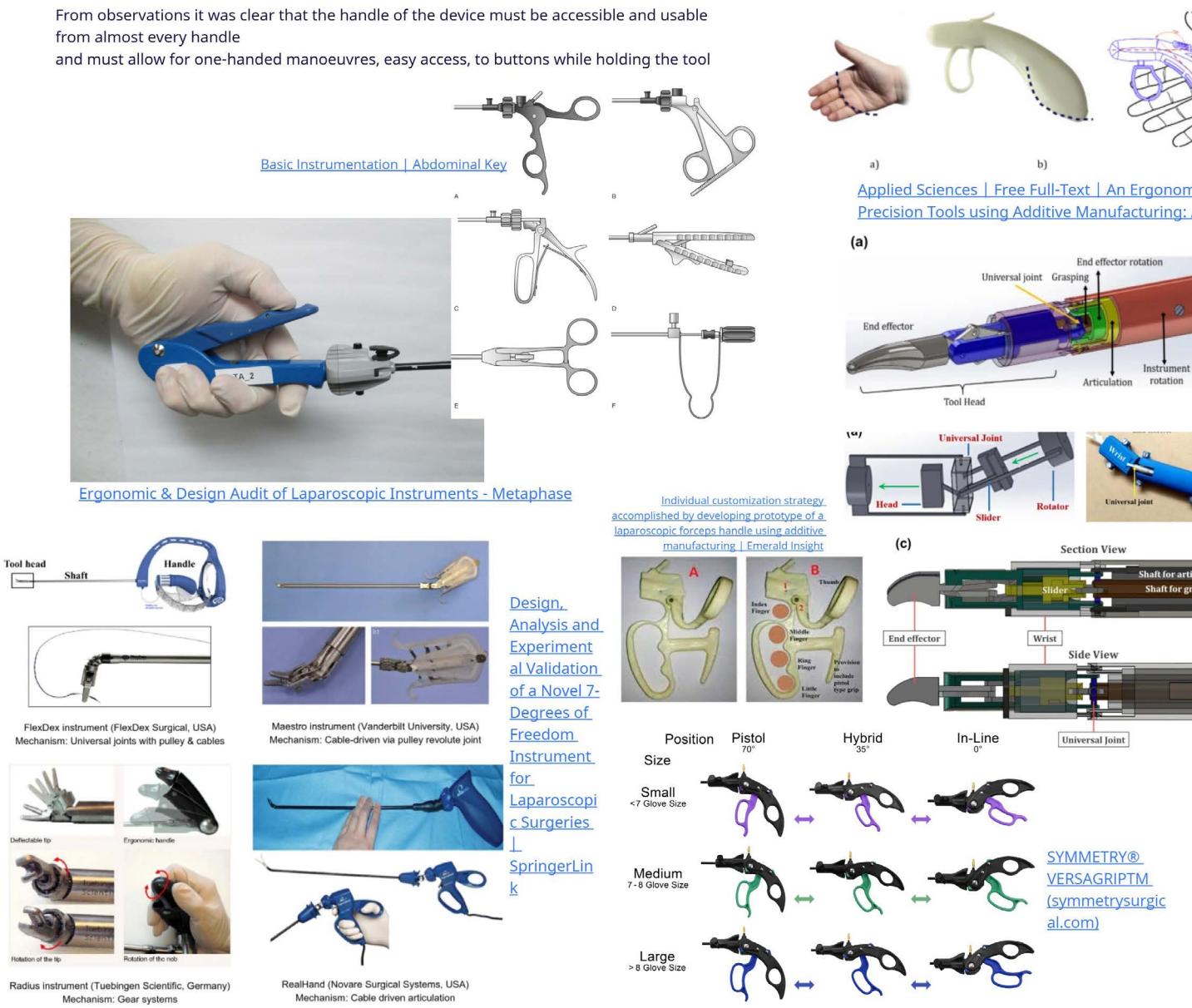


Figure L-1 A tiny low-fidelity version of the handle, made with 3D printed PLA. On the inside, a component from a conventional needle driver is used to act as the back end of the punch as it has roughly the same dimensions. The outside is a paper straw, slid into the cylindrical part of the mini handle. This was used to test whether the compliant mechanism would work. It did.

Figure L-2 An overview of various handles found in academic literature. The handles are all fully mechanically operated, so no robotic needle drivers are shown here. The focus here is on the various handle grip designs and hand

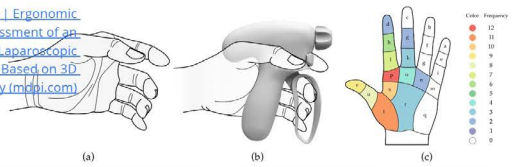


c)

[ic Customized-Tool Handle Design for A Case Study (mdpi.com)](#)

[(34) Feature of the Month: Needle Holders | Advanced Endoscopy Devices - YouTube](#)

[IJERPH | Free Full-Text | Ergonomic Design and Assessment of an Improved Handle for a Laparoscopic Dissector Based on 3D Anthropometry (mdpi.com)](#)



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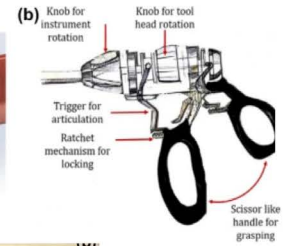
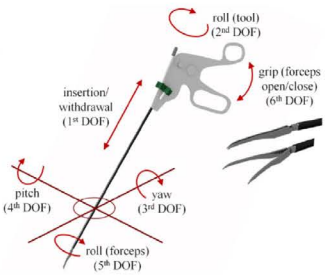


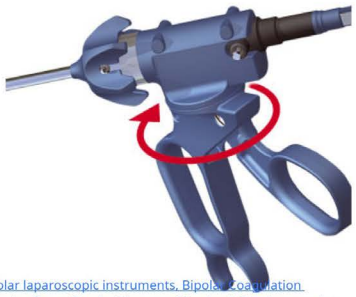
e Handles Tested in Section A

[(1) (PDF) Multi-DOF (Degree of Freedom) Articulating Laparoscopic Instrument is an Effective Device in Performing Challenging Sutures (researchgate.net)](#)

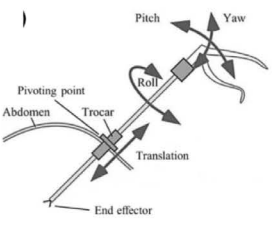
[Design, Analysis and Experimental Validation of a Novel 7-Degrees of Freedom Instrument for Laparoscopic Surgeries | SpringerLink](#)

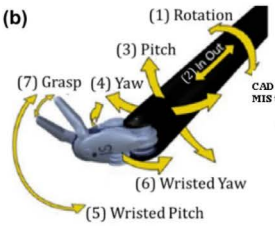


[PDF] FlexDexTM: A Minimally Invasive Surgical Tool With Enhanced Dexterity and Intuitive Actuation | Semantic Scholar

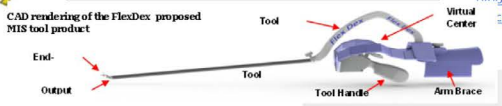


Bipolar laparoscopic instruments, Bipolar coagulation grasping force, Bipolar Dissector Maryland, Bipolar grasping forceps, bent, Bipolar Delta grasping forceps, Bipolar forceps, Bipolar forceps for bipolar coagulation forceps :romed.com)



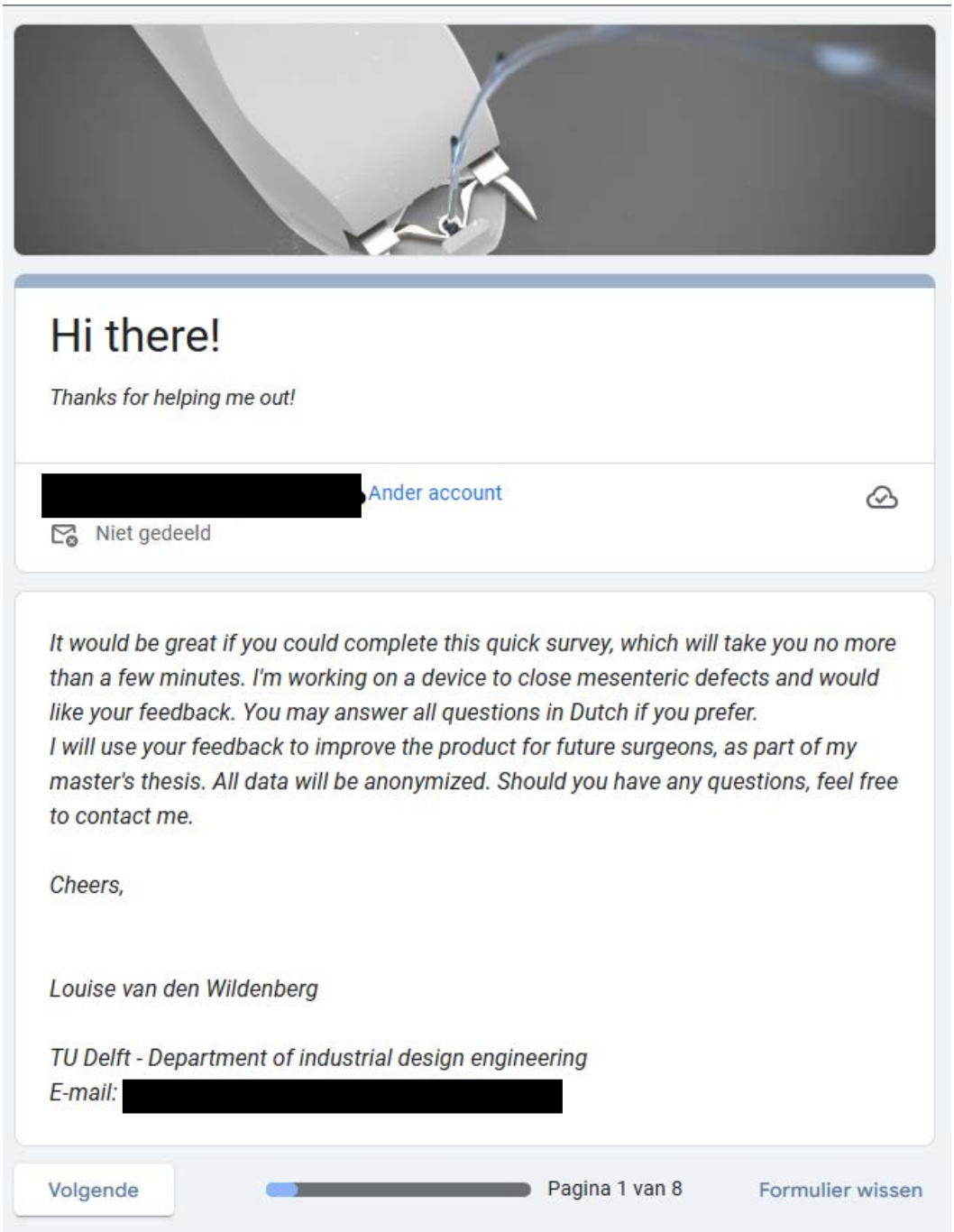


[Design, Analysis and Experimental Validation of a Novel 7-Degrees of Freedom Instrument for Laparoscopic Surgeries | SpringerLink](#)



[ERAGONmodular - Richard Wolf (richard-wolf.com)](#)

M. Product evaluation questionnaire and results



Hi there!

Thanks for helping me out!

[redacted] Ander account

Niet gedeeld

It would be great if you could complete this quick survey, which will take you no more than a few minutes. I'm working on a device to close mesenteric defects and would like your feedback. You may answer all questions in Dutch if you prefer.
I will use your feedback to improve the product for future surgeons, as part of my master's thesis. All data will be anonymized. Should you have any questions, feel free to contact me.

Cheers,

Louise van den Wildenberg

TU Delft - Department of industrial design engineering
E-mail: [redacted]

Volgende Pagina 1 van 8 Formulier wissen

Let's start by getting your name

Your full name *

Jouw antwoord

Personal information

Your age *

Jouw antwoord

Your gender *

Jouw antwoord

Your primary contact email address

Jouw antwoord

Hospital affiliation

The hospital or medical institution you work for *

Jouw antwoord

The hospital's or medical institution's address

Jouw antwoord

Experience

How many years of experience do you have in performing bariatric surgeries? *

Jouw antwoord

Approximately how many laparoscopic Roux-en-Y gastric bypass (LRYGB) procedures have you performed per year? *

Jouw antwoord

Do you consider the closure of mesenteric defects as a standard part of LRYGB? *

Jouw antwoord

Challenges

These questions are aimed at the challenges and limitations you face during mesenteric defect closure surgeries (as the last part of gastric bypass surgeries).
By focusing on your personal experiences, valuable insights can be gained for the improvement and refinement of the device.

In your opinion, what are the critical factors that contribute to successful mesenteric defect closure, and have you encountered any difficulties in achieving those factors?

The factors you describe here will aid you in answering upcoming questions.

Jouw antwoord

Have you encountered any complications or limitations associated with the closure techniques or devices currently available on the market?

Think maneuvrability, haptic feedback, visibility, safety, stability, noise, leakage, slippage, etc.

Jouw antwoord

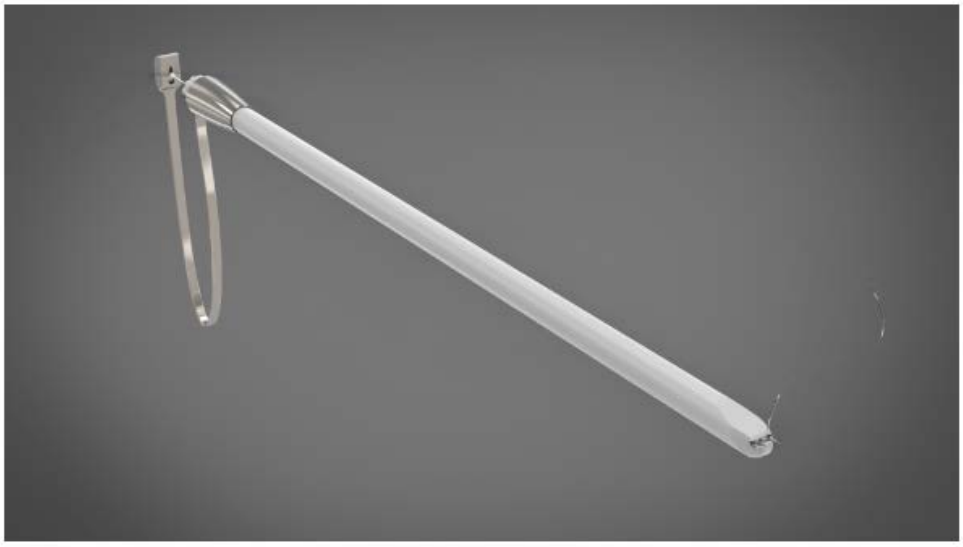
Vorige Volgende Pagina 3 van 8 Formulier wissen

The device

The following bit serves to provide an explanation of the device. Hereafter, questions about this device will follow.

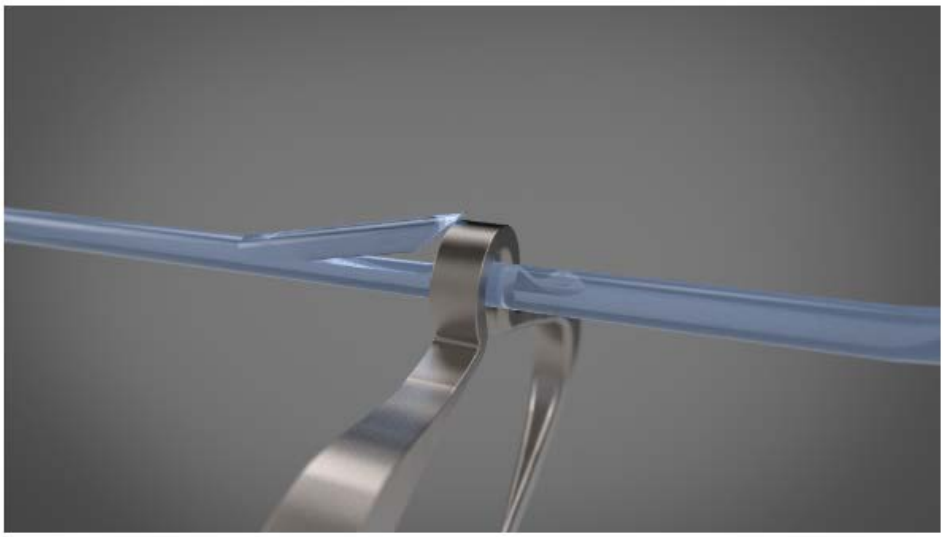
During laparoscopic Roux-en-Y gastric bypass surgery, closure of mesenteric defects (MDs) is an essential step to prevent potential internal herniation, high-grade bowel obstruction, bowel necrosis and other serious complications. While various techniques for closing these MDs exist, in practice, only suturing by hand provides a safe way to fully close them.

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. This device should help maintain low complication rates while minimizing time and cognitive strain spent on defect closures. This device involves no suturing and does not require tissue alignment beforehand.

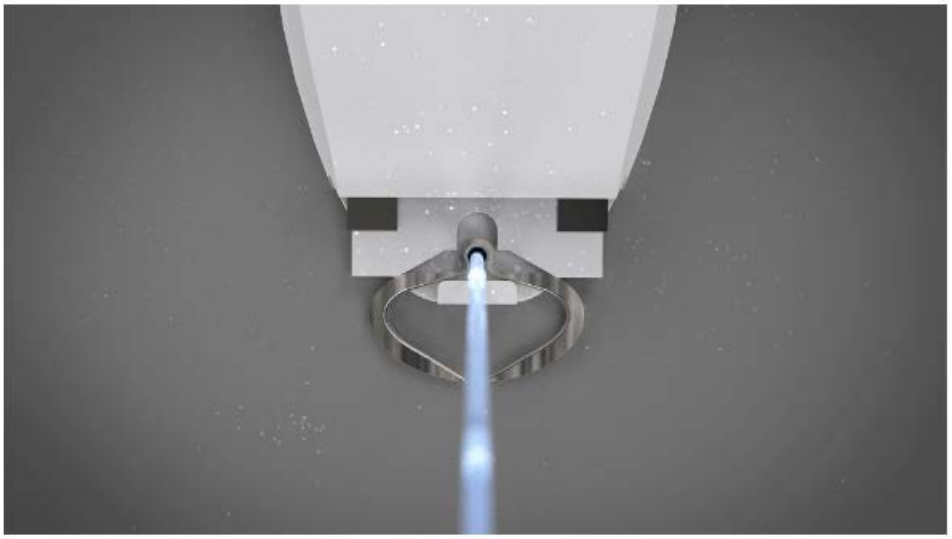


This device incorporates an optimised staple shape and barbed sutures to allow for a continuous shoelace-like technique.

This makes it possible to tighten the suture whenever you wish, without it sliding open again. After the last staple is placed, the whole suture can be tightened at once. Then, the remaining barbed suture can simply be cut off with laparoscopic scissors and the suture remains firmly locked.

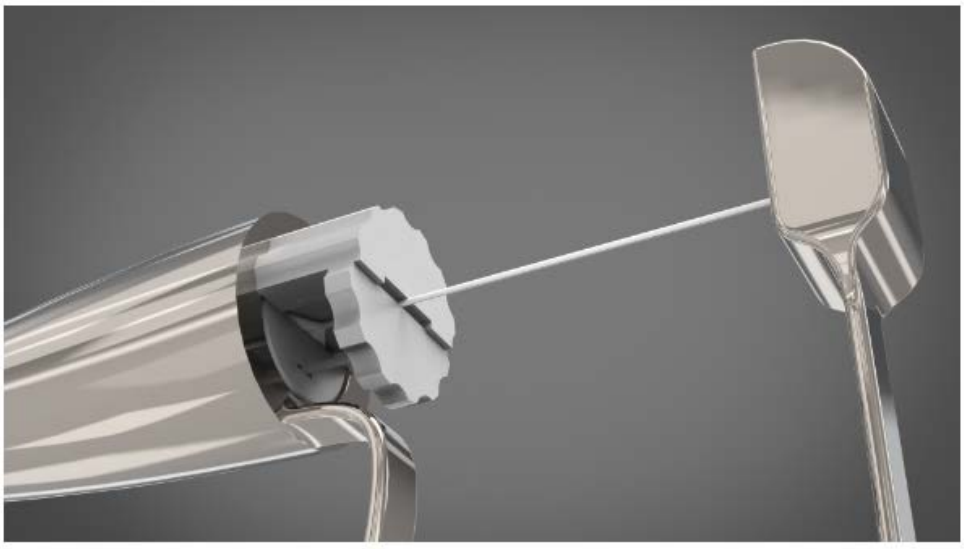


Once the device is inserted through a trocar and pressed with the tip against mesenteric tissue, the staples can be placed by squeezing the handle. Staples are placed onto a barbed suture and simultaneously inserted into the mesenteric tissue with a single squeeze.

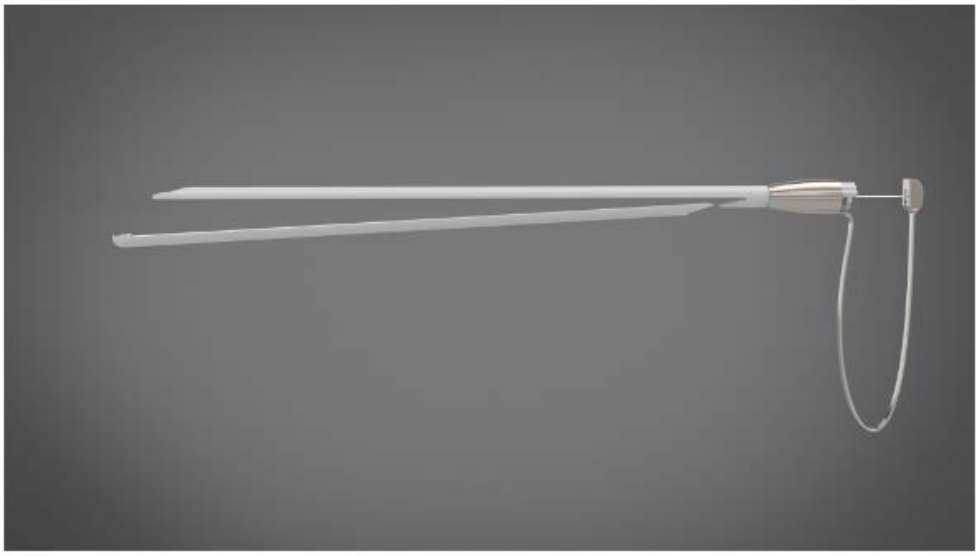


The handle is made of a single piece of surgical stainless steel, featuring a compliant U-like shape, allowing the handle to spring back to its original position after placing a staple. Since the positioning and bending of staples derives directly from the surgeon's actions, the haptic feedback surgeons receive is immediate.

The rotation knob on the side of the handle allows for 360 degrees of rotation. Half of this rotation knob, also functions as a button. When pressed, the barbed suture is restrained from dispension, in order to tighten the suture. Pressing this button again allows the suture to be dispensed freely again.
Here, both features are in an accessible location for the surgeon's thumb and index finger for convenient single-handed use.



A single cartridge contains sufficient staples to completely close a mesenteric defect without having to reload halfway through.

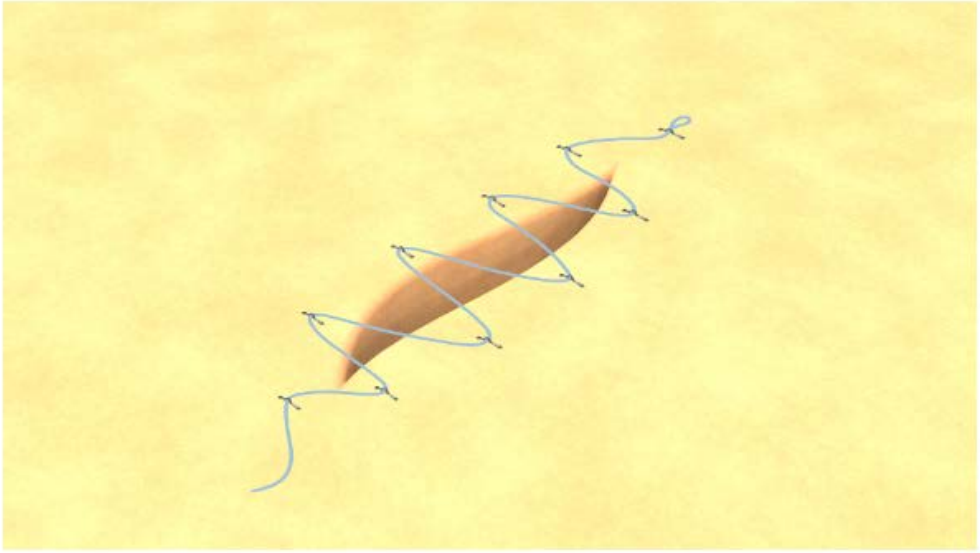


Vorige | Volgende | Pagina 4 van 8 | Formulier wissen

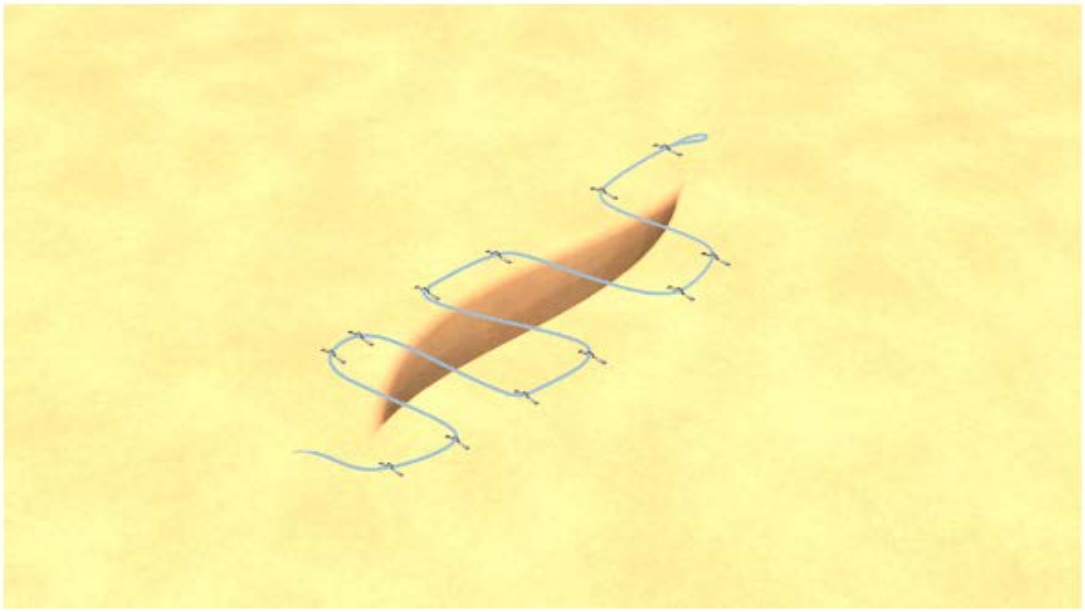
Technique

Staples can be placed continuously on alternating sides of the mesenteric defect. However, the suture pattern is for you to decide..

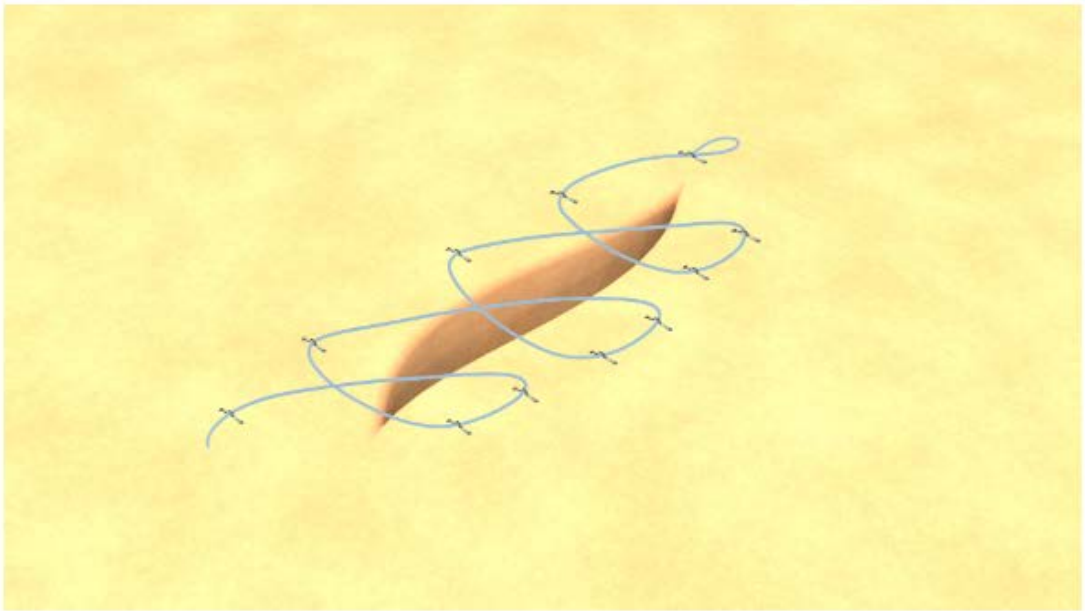
Option 1: Zigzag



Option 2: Horizontal mattress



Option 3: Running cross (one-sided)



Which technique would you apply with the device?

More options are possible, e.g. a double sided running cross or a lembert suture.

- [ ] Option 1: Zigzag
- [ ] Option 2: Horizontal mattress
- [ ] Option 3: Running cross (one-sided)
- [ ] Anders: _____

Please substantiate your choice.

Jouw antwoord

Vorige | Volgende | Pagina 5 van 8 | Formulier wissen

The following questions regard the aforementioned product.

How well does the device cater to the requirements of successful mesenteric defect closure procedures?

Consider the critical factors you formulated previously.

	1	2	3	4	5	
Does not fulfill my requirements at all	○	○	○	○	○	Aligns perfectly with my requirements

Do you consider the device to be innovative compared to existing solutions in the market?

Please substantiate.

Jouw antwoord

Based on the available information, how would you rate the perceived quality of the device?

	1	2	3	4	5	
Poor	○	○	○	○	○	Excellent

What factors contribute to your assessment of the device's quality?

Jouw antwoord

Based on the available information, how would you rate the perceived effectiveness of the device?

Consider comparing it to manual suturing or regular staplers.

	1	2	3	4	5	
Very ineffective	○	○	○	○	○	Very effective

Based on the available information, how would you rate the comfort of using the device?

Consider comparing it to manual suturing or regular staplers.

	1	2	3	4	5	
Very uncomfortable	○	○	○	○	○	Very comfortable

What aspect of the device should be altered to improve your comfort?

Jouw antwoord

Do you foresee any complications or limitations with this device?

Please substantiate.

Jouw antwoord

Are there any functions or features you would like to add to the device?

Jouw antwoord

For what other applications would this device be useful?

Jouw antwoord

Vorige Volgende Pagina 6 van 8 Formulier wissen

Closing remarks

Do you have any remarks?

Jouw antwoord

Vorige Volgende Pagina 7 van 8 Formulier wissen

Thank you!

Thank you for completing my questionnaire. I truly appreciate your contribution and the time that you have committed to evaluate my device proposal.

Vorige | Verzenden | Pagina 8 van 8 | Formulier wissen

Occurrence scale

Subjective estimate of occurrence

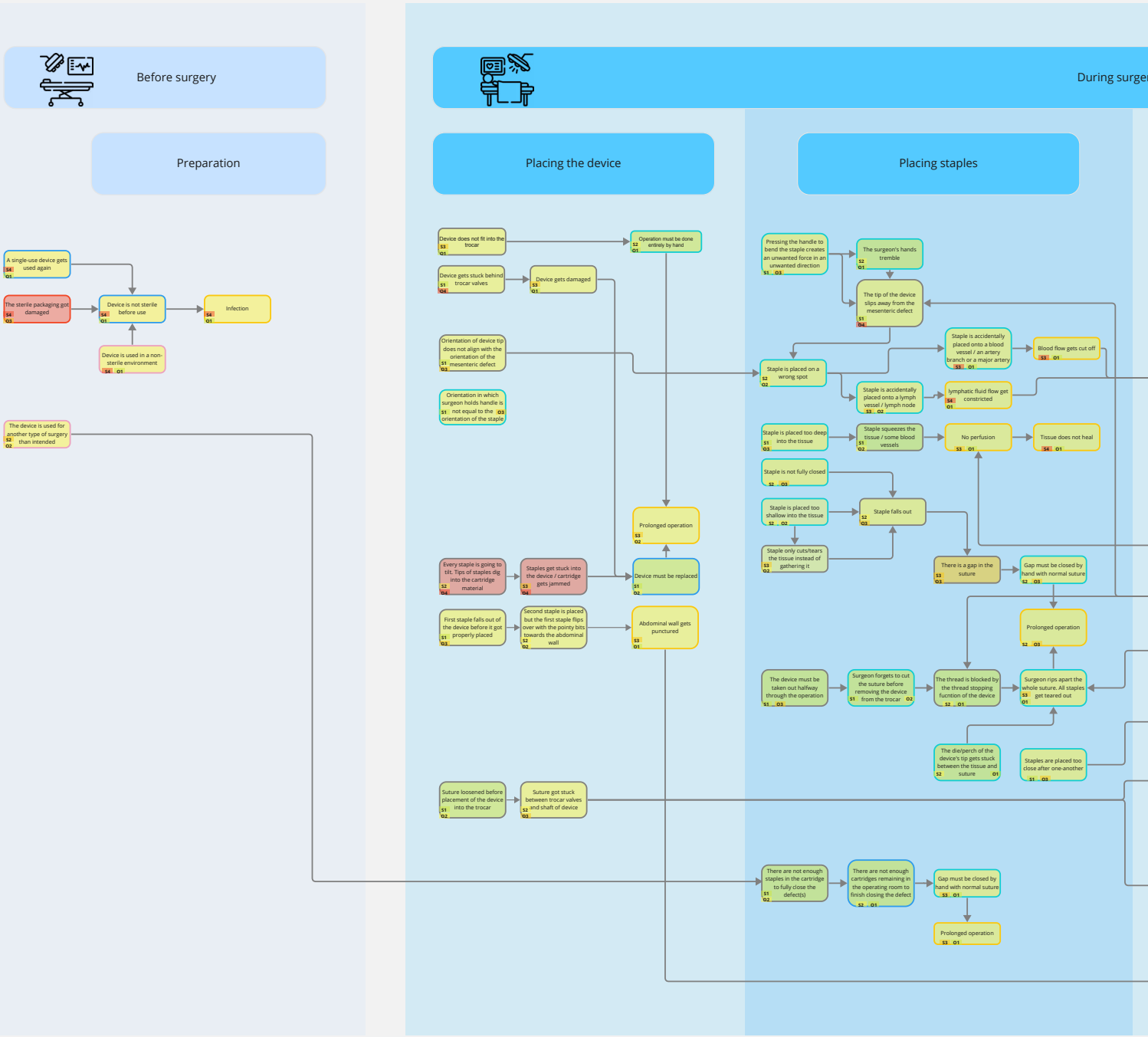
Rank		Definition	Occurrence probability Logarithmic scale
1	**Very unlikely**	Extremely rare event. The occurrence of the event is not reproductible. Never occurs during the product lifetime.	P < 0,01%
2	**Improbable**	Event rarely occurs. There is indirect evidence of the event. Could occur due to unusual 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%

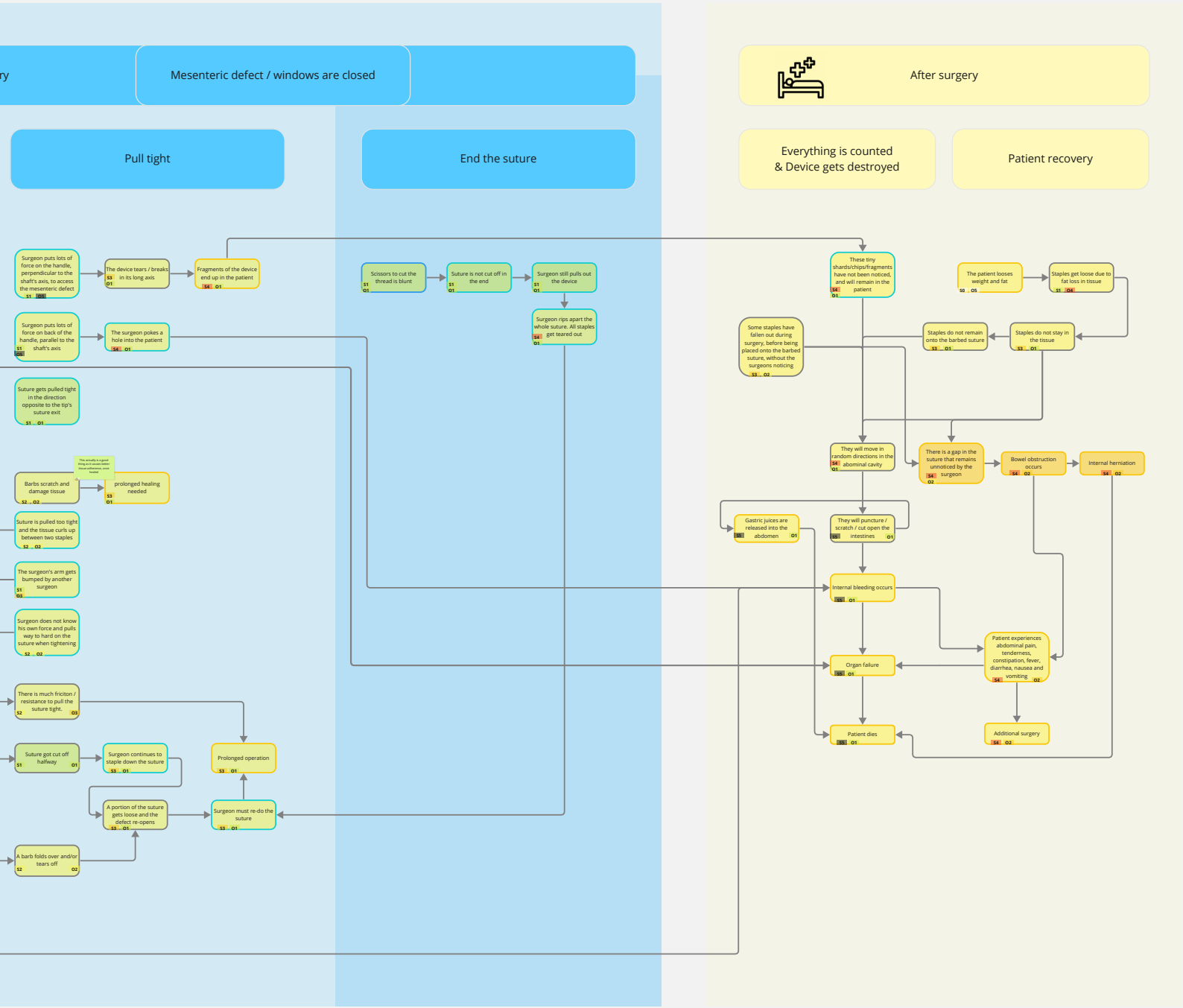
These are indicated with a letter O + rank

Severity scale

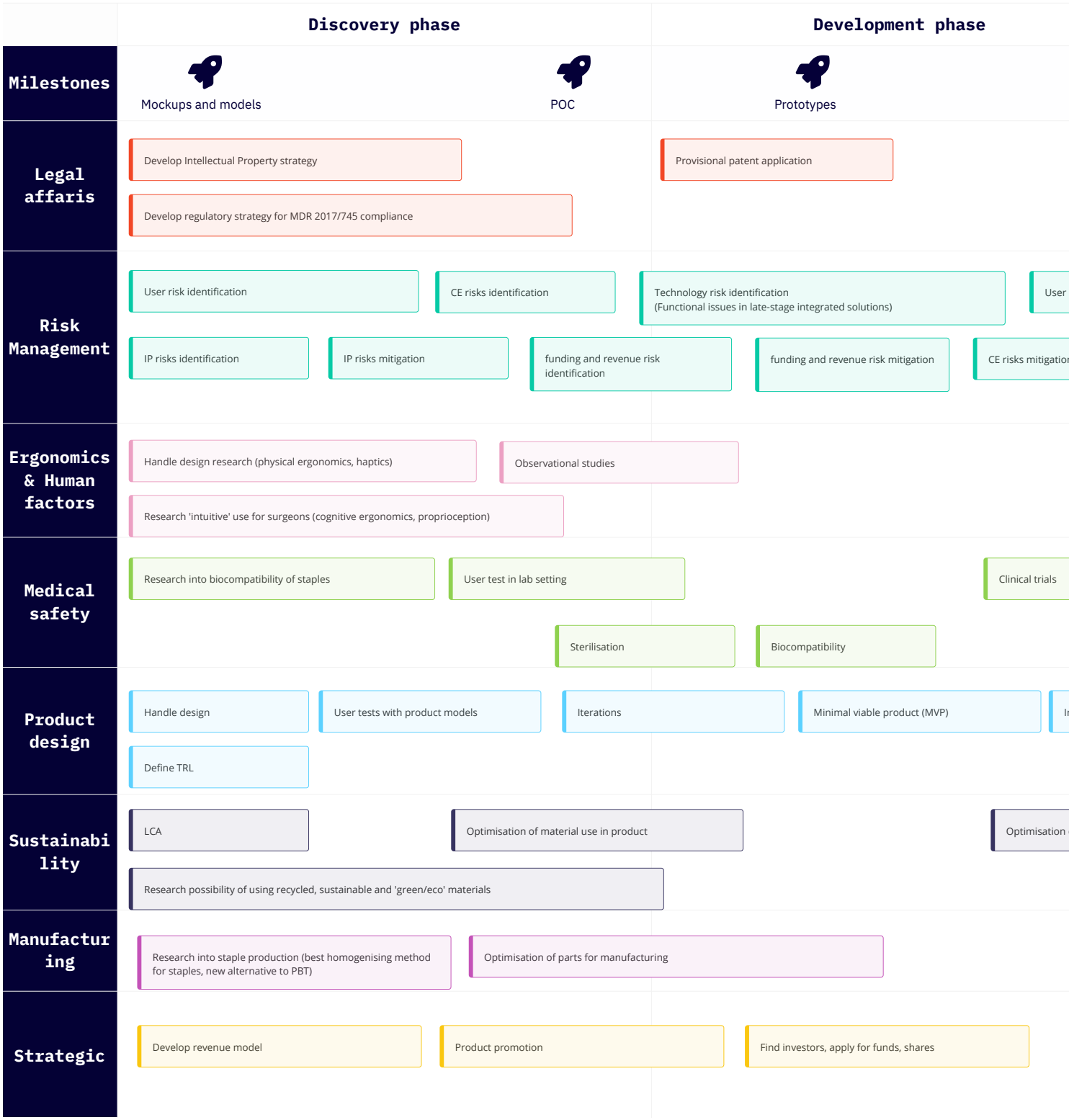
Rank		Definition	Example
1	**Insignificant**	No impact on patient safety. No impact on the surgeon. Minor nuisance of <10 minutes for the surgeon. of <10 minutes for the surgeon.	The surgeon briefly maintains an uncomfortable position, has to briefly exert force to place a staple, tissue slips out of 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.

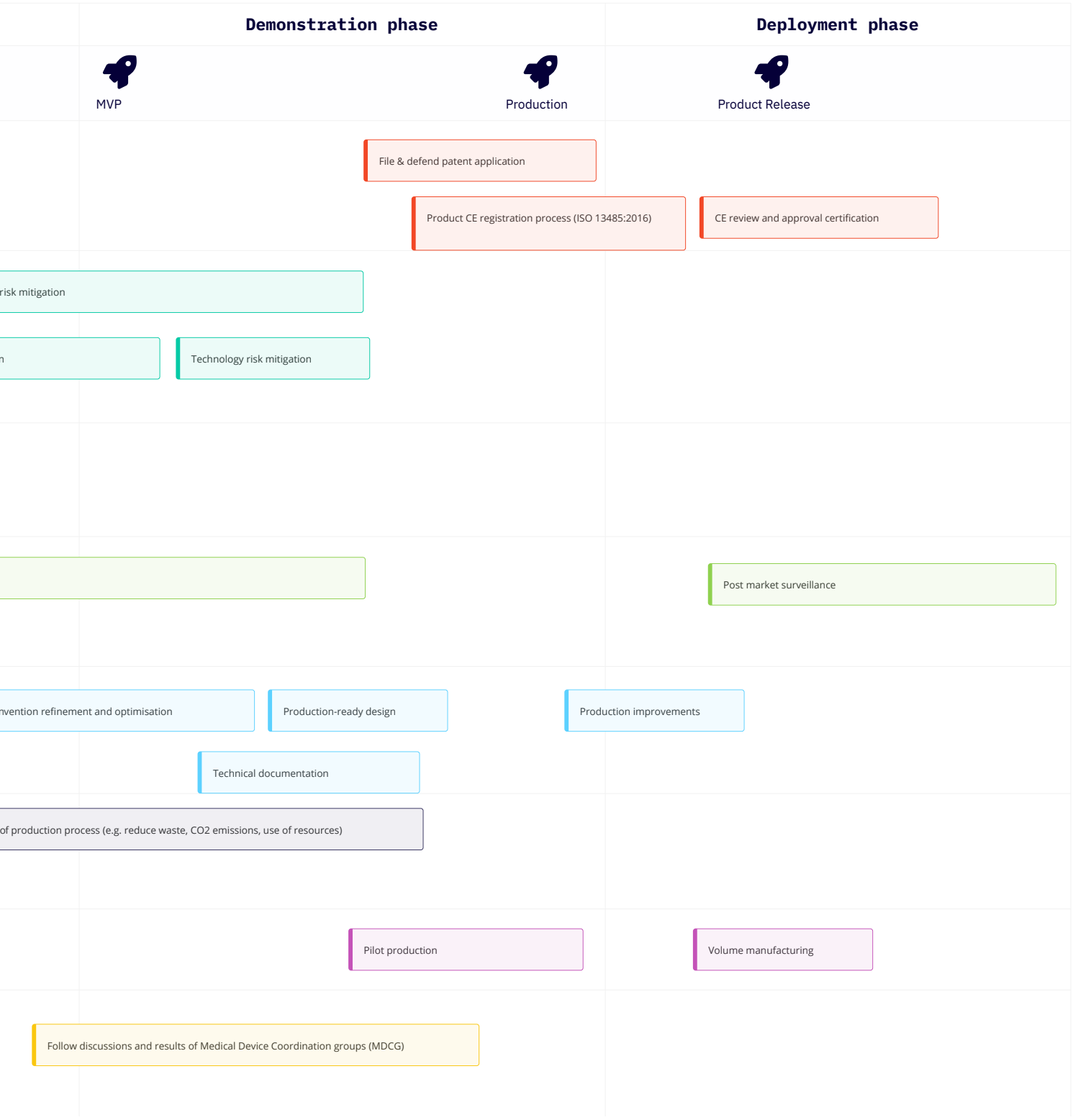
These are indicated with a letter S + rank


Before surgery
During surge
Preparation
Placing the device
Placing staples
A single-use device gets used again
The sterile packaging got damaged
Device is not sterile before use
Infection
Device is used in a non-sterile environment
The device is used for another type of surgery than intended
Device does not fit into the trocar
Operation must be done entirely by hand
Device gets stuck behind trocar valves
Device gets damaged
Orientation of device tip does not align with the orientation of the mesenteric defect
Orientation in which surgeon holds handle is not equal to the orientation of the staple
Prolonged operation
Every staple is going to tilt. Tips of staples dig into the cartridge material
Staples get stuck into the device / cartridge gets jammed
Device must be replaced
First staple falls out of the device before it got properly placed
Second staple is placed but the first staple flips over with the pointy bits towards the abdominal wall
Abdominal wall gets punctured
Suture loosened before placement of the device into the trocar
Suture got stuck between trocar valves and shaft of device
Pressing the handle to bend the staple creates an unwanted force in an unwanted direction
The surgeon's hands tremble
The tip of the device slips away from the mesenteric defect
Staple is placed on a wrong spot
Staple is accidentally placed onto a blood vessel / an artery branch or a major artery
Blood flow gets cut off
Staple is accidentally placed onto a lymph vessel / lymph node
lymphatic fluid flow get constricted
Staple is placed too deep into the tissue
Staple squeezes the tissue / some blood vessels
No perfusion
Tissue does not heal
Staple is not fully closed
Staple is placed too shallow into the tissue
Staple falls out
Staple only cuts/tears the tissue instead of gathering it
There is a gap in the suture
Gap must be closed by hand with normal suture
Prolonged operation
The device must be taken out halfway through the operation
Surgeon forgets to cut the suture before removing the device from the trocar
The thread is blocked by the thread stopping fucntion of the device
Surgeon rips apart the whole suture. All staples get teared out
The die/perch of the device's tip gets stuck between the tissue and suture
Staples are placed too close after one-another
There are not enough staples in the cartridge to fully close the defect(s)
There are not enough cartridges remaining in the operating room to finish closing the defect
Gap must be closed by hand with normal suture
Prolonged operation


Mesenteric defect / windows are closed
After surgery
Pull tight
End the suture
Everything is counted & Device gets destroyed
Patient recovery
Surgeon puts lots of force on the handle, perpendicular to the shaft's axis, to access the mesenteric defect
The device tears / breaks in its long axis
Fragments of the device end up in the patient
Surgeon puts lots of force on back of the handle, parallel to the shaft's axis
The surgeon pokes a hole into the patient
Suture gets pulled tight in the direction opposite to the tip's suture exit
Barbs scratch and damage tissue
prolonged healing needed
Suture is pulled too tight and the tissue curls up between two staples
The surgeon's arm gets bumped by another surgeon
Surgeon does not know his own force and pulls way to hard on the suture when tightening
There is much friciton / resistance to pull the suture tight.
Suture got cut off halfway
Surgeon continues to staple down the suture
Prolonged operation
A portion of the suture gets loose and the defect re-opens
Surgeon must re-do the suture
A barb folds over and/or tears off
Scissors to cut the thread is blunt
Suture is not cut off in the end
Surgeon still pulls out the device
Surgeon rips apart the whole suture. All staples get teared out
These tiny shards/chips/fragments have not been noticed, and will remain in the patient
The patient looses weight and fat
Staples get loose due to fat loss in tissue
Some staples have fallen out during surgery, before being placed onto the barbed suture, without the surgeons noticing
Staples do not remain onto the barbed suture
Staples do not stay in the tissue
They will move in random directions in the abominal cavity
There is a gap in the suture that remains unnoticed by the surgeon
Bowel obstruction occurs
Internal herniation
Gastric juices are released into the abdomen
They will puncture / scratch / cut open the intestines
Internal bleeding occurs
Patient experiences abdominal pain, tenderness, constipation, fever, diarrhea, nausea and vomiting
Organ failure
Patient dies
Additional surgery

O. Roadmap


Discovery phase
Development phase
Milestones
Mockups and models
POC
Prototypes
Legal affaris
Develop Intellectual Property strategy
Provisional patent application
Develop regulatory strategy for MDR 2017/745 compliance
Risk Management
User risk identification
CE risks identification
Technology risk identification
(Functional issues in late-stage integrated solutions)
User
IP risks identification
IP risks mitigation
funding and revenue risk identification
funding and revenue risk mitigation
CE risks mitigation
Ergonomics & Human factors
Handle design research (physical ergonomics, haptics)
Observational studies
Research 'intuitive' use for surgeons (cognitive ergonomics, proprioception)
Medical safety
Research into biocompatibility of staples
User test in lab setting
Clinical trials
Sterilisation
Biocompatibility
Product design
Handle design
User tests with product models
Iterations
Minimal viable product (MVP)
Define TRL
Sustainability
LCA
Optimisation of material use in product
Optimisation
Research possibility of using recycled, sustainable and 'green/eco' materials
Manufacturing
Research into staple production (best homogenising method for staples, new alternative to PBT)
Optimisation of parts for manufacturing
Strategic
Develop revenue model
Product promotion
Find investors, apply for funds, shares


Demonstration phase
Deployment phase
MVP
Production
Product Release
File & defend patent application
Product CE registration process (ISO 13485:2016)
CE review and approval certification
risk mitigation
Technology risk mitigation
Post market surveillance
nvention refinement and optimisation
Production-ready design
Production improvements
Technical documentation
of production process (e.g. reduce waste, CO2 emissions, use of resources)
Pilot production
Volume manufacturing
Follow discussions and results of Medical Device Coordination groups (MDCG)

DESIGN FOR our future

TU Delft

IDE Master Graduation

Project team, Procedural checks and personal Project brief

This document contains the agreements made between student and supervisory team about the student's IDE Master Graduation Project. This document can also include the involvement of an external organisation, however, it does not cover any legal employment relationship that the student and the client (might) agree upon. Next to that, this document facilitates the required procedural checks. In this document:

- The student defines the team, what he/she is going to do/deliver and how that will come about.
- SSC E&SA (Shared Service Center, Education & Student Affairs) reports on the student's registration and study progress.
- IDE's Board of Examiners confirms if the student is allowed to start the Graduation Project.

USE ADOBE ACROBAT READER TO OPEN, EDIT AND SAVE THIS DOCUMENT

Download again and reopen in case you tried other software, such as Preview (Mac) or a webbrowser.

STUDENT DATA & MASTER PROGRAMME

Save this form according the format "IDE Master Graduation Project Brief_familyname_firstname_studentnumber_dd-mm-yyyy". Complete all blue parts of the form and include the approved Project Brief in your Graduation Report as Appendix 1 !

family name: van den Wildenberg
initials: L given name: Louise
student number: 4829174
street & no.: [redacted]
zipcode & city: [redacted]
country: [redacted]
phone: [redacted]
email: [redacted]

Your master programme (only select the options that apply to you):

IDE master(s): ★ IPD ○ DfI ○ SPD
2nd non-IDE master:
individual programme: - - (give date of approval)
honours programme: ○ Honours Programme Master
specialisation / annotation: ★ Medisign
○ Tech. in Sustainable Design
○ Entrepeneurship

SUPERVISORY TEAM **

Fill in the required data for the supervisory team members. Please check the instructions on the right !

** chair: Richard H. M. Goossens dept. / section: HCD
** mentor: Ernest J. J. van Breemen dept. / section: SDE
2nd mentor: Yair Acherman
organisation: Spaarne Gasthuis Hoofddorp
city: Hoofddorp country: The Netherlands

comments (optional)

Chair should request the IDE Board of Examiners for approval of a non-IDE mentor, including a motivation letter and c.v..

Second mentor only applies in case the assignment is hosted by an external organisation.

Ensure a heterogeneous team. In case you wish to include two team members from the same section, please explain why.

APPROVAL PROJECT BRIEF

To be filled in by the chair of the supervisory team.

chair Richard H. M. Goossens date 20 - 02 - 2023 signature JamfProtect Client 8C16DCF8-7FFB-5AAE-9F8A-5998A1D115AB Digitally signed by JamfProtect Client 8C16DCF8-7FFB-5AAE-9F8A-5998A1D115AB Date: 2023.02.21 15:46:47 +01'00'

CHECK STUDY PROGRESS

To be filled in by the SSC E&SA (Shared Service Center, Education & Student Affairs), after approval of the project brief by the Chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total: 24 EC

Of which, taking the conditional requirements into account, can be part of the exam programme 24 EC

List of electives obtained before the third semester without approval of the BoE

★ YES all 1st year master courses passed

NO missing 1st year master courses are:

name Robin den Braber date 28 - 02 - 2023 signature Robin den Braber Digitaal ondertekend door Robin den Braber Datum: 2023.02.28 10:17:10 +01'00'

FORMAL APPROVAL GRADUATION PROJECT

To be filled in by the Board of Examiners of IDE TU Delft. Please check the supervisory team and study the parts of the brief marked **. Next, please assess, (dis)approve and sign this Project Brief, by using the criteria below.

- Does the project fit within the (MSc)-programme of the student (taking into account, if described, the activities done next to the obligatory MSc specific courses)?
- Is the level of the project challenging enough for a MSc IDE graduating student?
- Is the project expected to be doable within 100 working days/20 weeks ?
- Does the composition of the supervisory team comply with the regulations and fit the assignment ?

Content: ★ APPROVED NOT APPROVED

Procedure: ★ APPROVED NOT APPROVED

- also approved for Medisign

comments

name Monique von Morgen date 06 - 03 - 2023 signature

Development of a surgical tool to facilitate mesenteric tissue closure

project title

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

start date 13 - 02 - 2023 07 - 07 - 2023 end date

INTRODUCTION **

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

Suturing by hand is one of the most challenging tasks in minimally invasive surgery. It requires fine motor skills and visuospatial abilities from the surgeon which requires a lot of cognitive resources. The aim of this project is to find an alternative method for tissue closure which is suitable for laparoscopic surgery.

In a previous master's thesis, a new method for tissue closure has been explored on the example of gastric bypass procedure. The result is a method which is a combination of stapling and suturing. It shows promising outcomes for the closure of the mesenteric windows (this is one of the last steps of gastric bypass surgery where the mesenteric tissue needs to be closed to prevent internal herniation and high grade bowel obstruction (Medical College of Wisconsin, z.d.)).
The method is in the first stage of development and has been evaluated by interviewing surgeons. It can be found in the Repository of TU Delft (Wochner, 2022).

The key research question for this project is whether it is possible for a combination of stapling and suturing to be a (leakproof) option for internal tissue closure, following the example of mesentery defect (and eventually GI anstomosis).

The embodiment of the product in form of further development of the mechanics is needed. Therefore a functioning prototype, to reach the "proof of concept", will be developed as to answer the research question.

References:

Medical College of Wisconsin. (z.d.). The Impact of Closing the Mesenteric Window When Harvesting Ileumin Genitourinary Reconstructive Surgery. ics.org. Geraadpleegd op 31 januari 2023, van https://www.ics.org/Abstracts/Publish/326/000527_poster_20160701_055835.pdf

Wochner, N. (2022). Alternative closure method for laparoscopic gastrointestinal anastomosis | TU Delft Repositories. https://repository.tudelft.nl/islandora/object/uuid:1a5db094-4e54-4061-9b70-75b2111de28a?collection=education

References of images used on the next page:

Centre for Strategic Healthcare Development. (2019). Laparoscopic Appendectomy. Laparoscopic Appendectomy. https://www.surgery.ae/laparoscopic-appendectomy/

Wang, E., Shope, T. Alternative Method of Mesenteric Defect Closure after Roux-en-Y Gastric Bypass. OBES SURG 29, 751 753 (2019). https://doi.org/10.1007/s11695-018-03652-z

space available for images / figures on next page

introduction (continued): space for images

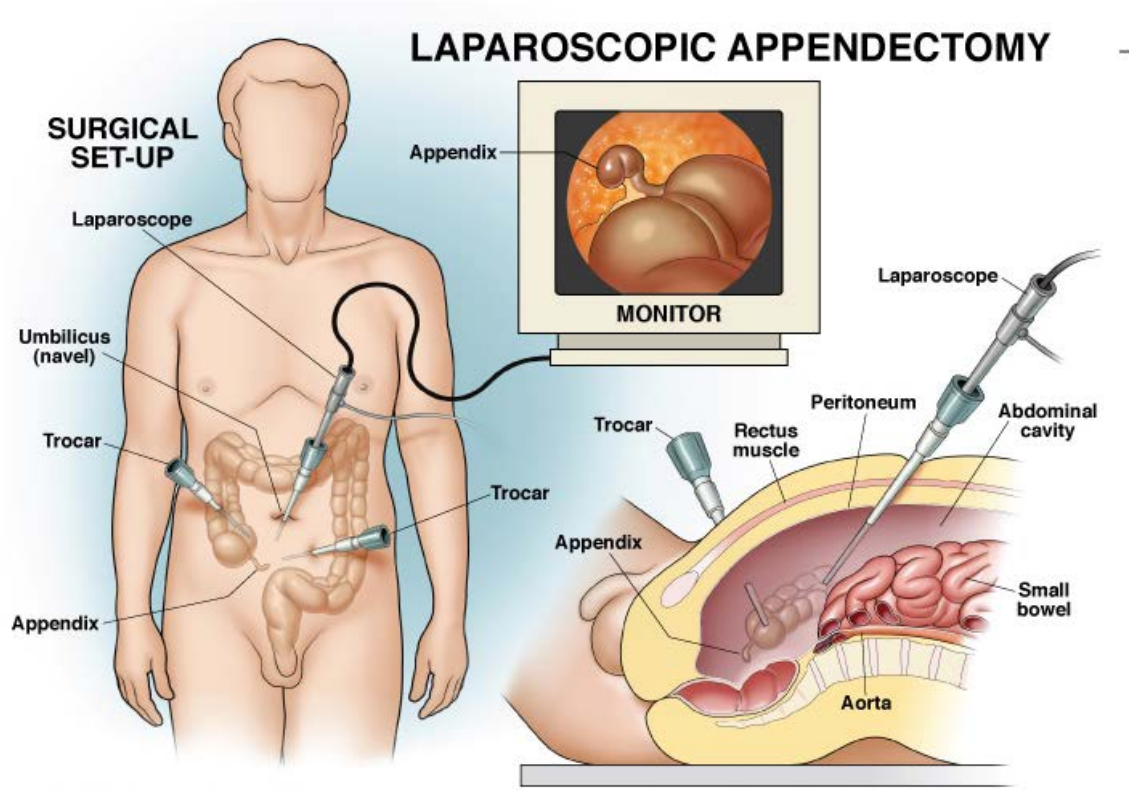


image / figure 1: A schematic representation of (an example of) laparoscopic surgery (Centre for Strategic Healthcare D

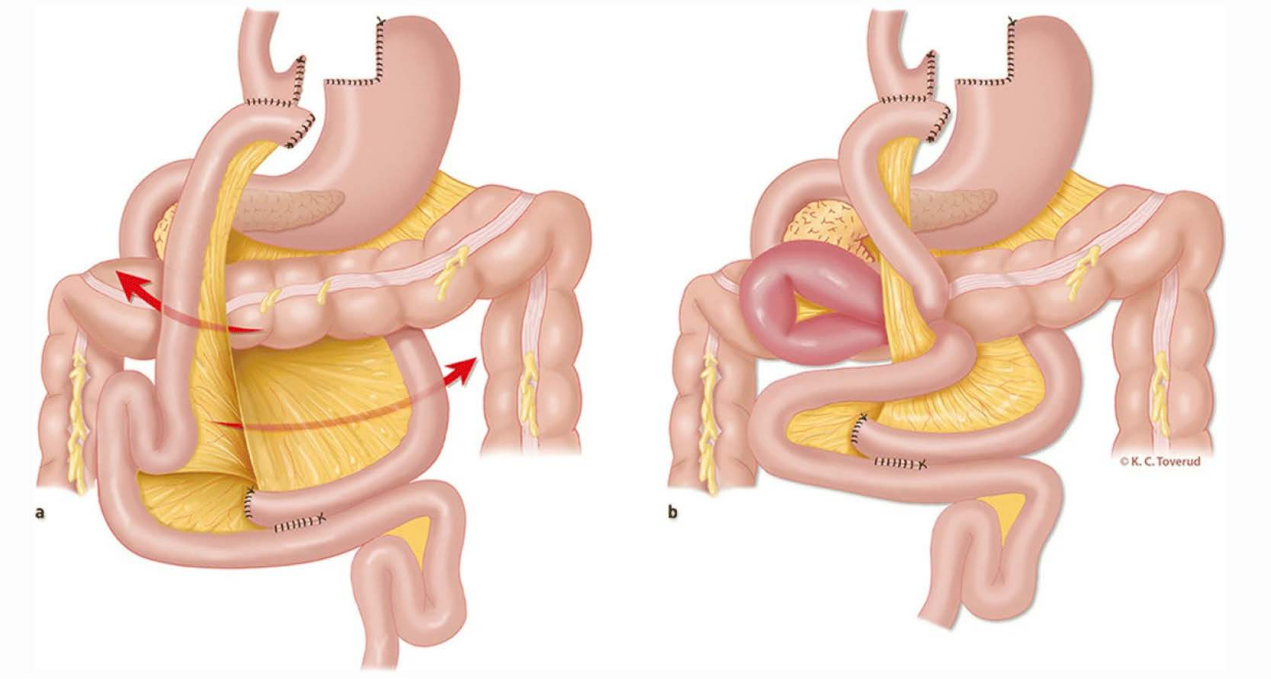


image / figure 2: A schematic of Roux-en-Y gastric bypass with two potential mesenteric defects: (a) between the alime

PROBLEM DEFINITION **

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

Currently the closing of mesenteric tissue is mainly done with staplers and suturing the remaining opening (see figure 2). Although the stapler is a useful tool to quickly suture two sections, it lacks precision and often leaves openings that still need to be closed by hand. This requires fine motor skills and visuospatial abilities from the surgeon, requiring a high level of cognititve resources. When surgeons try to compensate for the lack of precision with the stapler, they end up placing more staples, leading to excessive material in the abdomen.

The aim is to enable a faster, safer and more precise procedure while avoiding subsequent complications by designing a less complex solution for the surgeon than current closure practice. Thereby, the surgeon must be given the necessary flexibility to adapt the closure to environmental conditions. By reducing the surgeon's cognitive load, ergonomic comfort and performance should be improved.

ASSIGNMENT **

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

Design an alternative surgical tool for laparoscopic internal tissue closure following the example of mesentery repair (and possibly a leakproof option for gastrointestinal anastomosis) that provides a less complex procedure for the surgeon than the current closure practice.

I aim to reach a 'proof of concept' by testing a prototype on mesenteric tissue of a pig and/or swine as it closely resembles that of a human (Treffalls et al., 2022).

My tasks will entail:
* research of requirements for mesenteric repair (including interviews and observations in the operating room)
* develop and improve upon the cartridge and stapling mechanism
* build a test setup and a working prototype, detailling staples and suture (staple strength and tissue behaviour)
* build a test setup and prototype suitable for mesentery closure, with mesenteric tissue
* work in close contact to end users (surgeons) during the whole project (research - development - evaluation)
* build a test setup and prototype suitable for anastomosis closure, with leakage tests

References:

Treffalls, R. N., Stonko, D. P., Edwards, J., Abdou, H., Savidge, S. G., Walker, P., Scalea, T. M., & Morrison, J. J. (2022). Characterization of the mesenteric circulatory physiology during hemorrhagic shock in a swine model. Surgery in Practice and Science, 10, 100119. https://doi.org/10.1016/j.sipas.2022.100119

PLANNING AND APPROACH **

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

start date 13 - 2 - 2023 7 - 7 - 2023 end date

Month	February		March					April				May				June					July
Calendar week	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
Project week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	x	19	20
Analysis																					
Literature analysis /Context analysis/ State of art																					
Legislation / EU regulations																					
Observations																					
Workflow/ Stakeholder analysis																					
Formulate list of requirements																					
Reformulate problem definition/ goal&vision																					
Ideation/ Conceptualisation																					
Ideation sketching/ exploration																					
Rapid prototyping/ Experiments																					
First concepts																					
Prototyping/ Evaluation																					
Protoype/ Iterations/ Experiment setup																					
Evaluation/ (User) testing																					
Improvements/ Iterations																					
Detailing/ Construction																					
Construction/ Implementation/ Materials /Cost																					
Final testing																					
Reporting																					
Write findings/ report																	80% of final				
Make Showcase																				Hand in all	
Prepare presentation																					Present
Milestones	Kick off meeting (day 1)				Present / discuss Interim results			Midterm evaluation (day 40)					Present / discuss Interim results				Green light (day 80)				**Graduation (day 100)**

My project planning consists of an additional week, as I will be abroad in week 25.

The milestones are based on the graduation manual, indicated in orange. Here the milestones can be planned more precisely and are tentatively indicated per week.

In addition, two extra milestones are indicated in green, to serve as interim presentation moments to update the client on the progress.

I do not wish to dwell as long on doing preliminary research, considering that a great deal of research has already been done in the previous project. In the first few weeks, I will do additional research on the topics that were not comprehensively addressed in the previous project.

subsequently, it can be seen that the reporting stands throughout practically the entire project. I intend to record my process throughout the project and keep a synopsis of each development to serve as a basis for the final thesis.

Initials & Name L van den Wildenberg 6269 Student number 4829174

Title of Project Development of a surgical tool to facilitate mesenteric tissue closure

MOTIVATION AND PERSONAL AMBITIONS

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

I find medical product development incredibly interesting and meaningful, hence I am following the Medisign track. Within the MSc programme, I was lucky enough to have two big medisign projects in my first year (for ACD & AED), for which I took every opportunity to learn and expand my skills. I would love to continue learning and growing within the field of medical product design.

I particularly enjoyed the course AED, while mainly focusing on ergonomics. During electives in my second year, I learned a lot about (cognitive) ergonomics and complex systems within healthcare environments as well. While this remains a very interesting direction for me, I would like to gain more technical knowledge within my final master project, as I feel I currently know relatively little about this.

I will have to further develop my technical skills so that they match what is demanded from the labour market within positions that seem interesting to me. These require, among other things, producing high-quality products using (complex) CAD software (e.g. SolidWorks), making and understanding technical drawings, building models and up-to-date knowledge of production techniques and materials. In addition, I have very little experience in constructing accurate models meeting the medical industry regulations.

Thus within this project, I aim to learn about constructing physical prototypes, taking into account materials and production methods for medical applications. I will work out whether the product would function and be cost effective; design turning research ideas into technical plans using CAD/CAE software; testing collecting and analysing data from tests on prototypes; modifying designs and re-testing; reporting progress and evaluating the product.

FINAL COMMENTS

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