Creating an Improved Decoupling System for the Veress Plus

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Abstract

Laparoscopic surgery is the golden standard in minimal invasive surgery. But even though it only has a rare occasion of giving complications, about 70% of major complications happen during the first entry of the body. The two most commonly used entry methods are the Hasson open method, and the Veress Needle closed method. A recent development to the Veress Needle was found to be much safer in clinical studies by automatically decoupling the user when they pass through the parietal peritoneum, yet still has room for development. The main focus of this resides in enhancing the decoupling mechanism to be less vulnerable to its user. This will be achieved by shielding off the critical parts during operation and by guiding the user during the reloading to prevent damage to the device. These goals are divided into subproblems, and individual solutions are found. Based on the previous solutions several concepts are created and the most promising one chosen for prototyping and testing. After several iterations using rapid prototyping using 3D printing a final prototype was made from stainless steel. This final prototype was then used to execute a series of tests using ten participants which used the device for 99 times in total. During these tests the device was tested on reloadability and its transition between its three phases. Each participant also filled in a five-point Likert scale questionnaire and gave open feedback on their desired changes to the device. The testing of the prototype showed it was easily reloadable and had a phase transition success rate of 62.6% between phase one and two and 59.7% between phase two and three Based on these results it was found that the transition between the real design and the prototype was done unsuccessful, several areas of improvement where identified as a result of the testing but no guarantee was found that the new system could equal or surpass the reliability of the Veress Plus.

Keywords: Laparoscopy, Entry technique, Veress needle, Safety Mechanism, Veress Plus

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1. Introduction

1.1. Problem Definition

Minimal invasive surgery (Figure 1) improves on trauma, pain, and recovery time [1] One of these methods is laparoscopic surgery [2] [3]. The first entry in these procedures can however be dangerous as there is no visual feedback. To improve the haptic feedback the Veress needle (VN) gives a small shake when the needle punctures through the skin. To stop the needle the surgeon needs a lot of experience and still 70% of the major complications happen during this step [4]. To reduce these risks the Veress Plus (VP) was made. This introduces a mechanism that decouples the needle from the surgeon stopping the punctuating movement. This reported a 78% decrease of overshoot in the second preclinical study. This same preclinical study also brought to light two complications of the Veress Plus. Firstly, it was noticed that it was possible for the user to place the fingers on critical components when using the needle resulting in malfunctioning. And secondly it was noticed that it was possible to incorrectly reload the VP reducing its lifetime and reliability. This has been improved in later design by using a different material and by limiting its movement.

1.2. Research Goal

The goal of the research is to create a new decoupling mechanism, where all critical parts are inaccessible when the needle is prepared for operation, with a single action reload that will not decrease the lifetime and reliability of the needle. Other requirements are to still hold on to the minimalistic design principle used in the original decoupling mechanism. This leads to the following research goal.

The design, development and validation of an improved decoupling device for the Veress needle that is less vulnerable to finger positioning during use and easier to reload.

1.3. Thesis Layout

Section 2 “Background” will explain the history and advantages of laparoscopic surgery, the VP and a more in-depth explanation of entry complications will be given. Section 3 “State of the art” will discuss the state of the art of the VP at this moment, describing its components and the functionalities that it has. Section 4 “Design Requirements and criteria” will analyze the problem further putting in design criteria . Section 5 “Conceptual design” will explain the design obstacles and various approaches. The different solution concepts will be explained, and it will guide you through the design phases. Section 6 “Chosen Design” will explain the final design more in-depth and explain the first prototype. Section 7 “Concept evaluation” will explain the testing procedures and the criteria implemented. Section 8 “Results” will show the results of the tests and evaluate the design compared to the requirements. Section 9 “Discussion” will discuss the results, further research, and weaknesses. In section 10 “Conclusion” a recap will be made about the major findings.

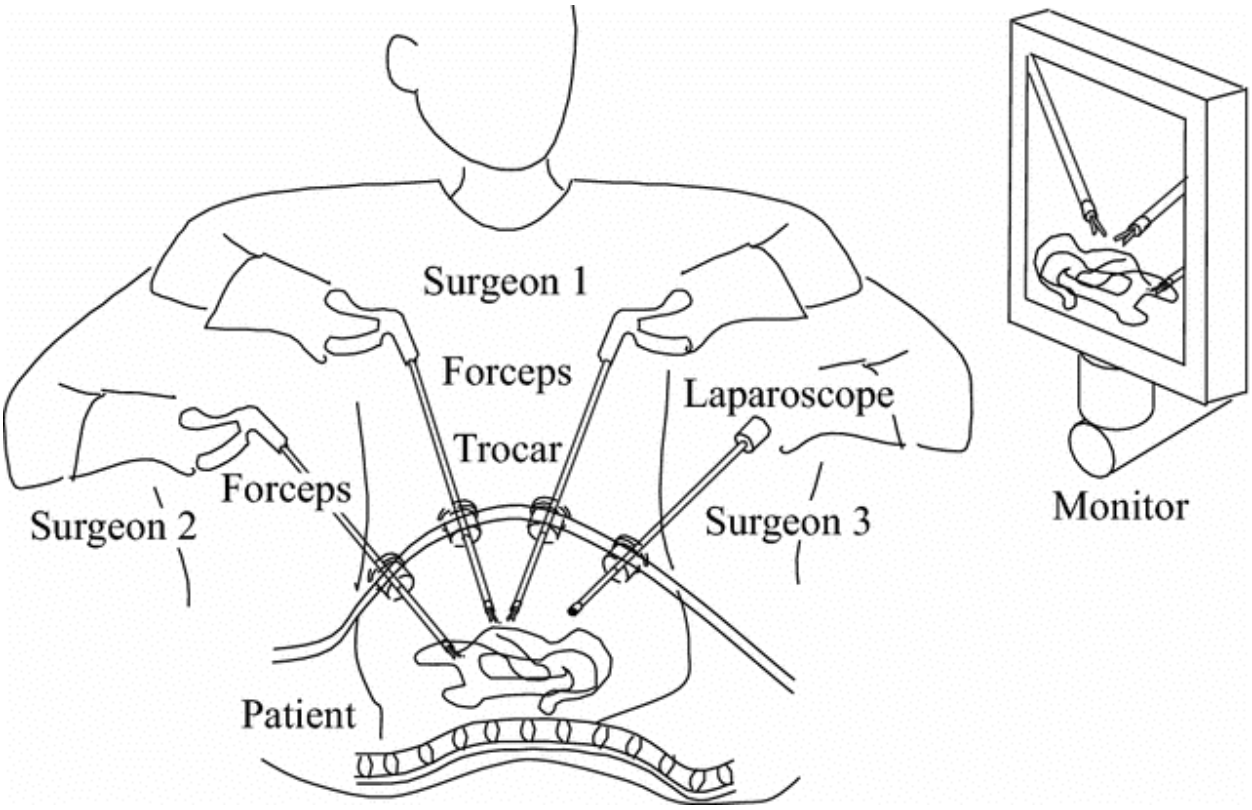


Figure 1:Laparoscopic surgery [5]

2. Background

2.1. Laparoscopic surgery

Laparoscopic surgery is the golden standard that has replaced open surgery in urology, surgery, and gynecology [2]. This way of surgery reports 40% less smaller complications and an equal number of major complications [4]. Other advantages of minimal invasive surgery include less trauma as there is less tissue damage which in turn also reduces pain and allow for faster recovery [1]. Still 70% of major complications happened during primary port entry [4].

During Laparoscopic surgery, an access point is made in the belly either under the floating rib or around the navel button. This is mostly done by the VN which punctures a hole (2.0-2.7 mm) or using the Hasson method [6] which makes a small cut (5-10 mm). This access point is used to insufflate the belly with gas (CO_2) to create space for the operation and ensure that subsequential tools can access safely. After the belly is expanded, slender operation devices like a light, a camera and clamps are inserted to perform the operation. [6]

2.2. Veress Needle

Figure 2: Veress Needle (Kangjimed, 2022)

This technique involves the VN (Figure 2). This so-called closed technique, makes a blind insertion directly into the peritoneal cavity [6] [2] [3] and has a mechanism that gives haptic feedback to the user when insertion is completed (Figure 3) after which it directly acts as the insufflation device. This technique makes a smaller hole and is quicker than the Hasson method. But even with this haptic feedback, incidents of injuries using the VN happen [7]. One study in 2010 even reported that 57.3% of the respondents had either experienced or witnessed a complication in a laparoscopic entry [8] resulting in 36.5 % of surgeons preferring the Hasson method for patients with low BMI [9].

2.3. Analysis of complications

The reason why this VN is so difficult to use can be accounted for by a lack of visual feedback caused by the minimized entry area. As there is no visual feedback, the surgeon needs to focus on the small source of haptic feedback that will be returned at the moment the Parietal Peritoneum is penetrated. When the needle moves past the necessary insertion depth (a few millimeters after penetration) this is called overshoot and holds the risk of hitting an intestine or vein that might be cut as well causing a complication. There are two grounds for this overshoot. First ground is the time it takes for the signal to arrive from the hand to the brain, the brain to formulate a response and for this response to return to the hand, also known as reaction time. Which is modified by several varied factors [10]. The second ground is the force the hand is already asserting to push through the Parietal Peritoneum (Clinical studies performed in 2021 and 2022). This can of course be trained to improve the reaction time and for the surgeon to put less pressure a little before full penetration allowing less force to be build up (Clinical studies performed in 2021 and 2022).

2.4. Veress Plus

A different solution that has recently been designed, is the VP which can decouple the surgeon from the needle at the moment of penetration. The clinical studies of the VP showed a 78% (Clinical study 2022) reduction of overshoot, and a strongly reduced learning curve [3]. It however also encountered a weakness of the decoupling mechanism. The two-step way of loading the VP can give complications in using the device as it won't function properly when loaded wrong, and as the decoupling device is on the outside of the needle it is possible to place the fingers on top of the decoupling mechanism and press into it. This will result in a malfunctioning of the device and can potentially be even more dangerous if a surgeon expects it to work. In the second clinical study (2022) it was observed that placing the grip further away from the

decoupling device had a positive result on the reliability of the device. This showed once more the relevance of protecting the mechanism from the user. The problem can however not be considered solved as different surgeons have diverse ways of holding the needle and patients with a high BMI might need to be treated with a shorter handhold. Because of these issues it is desired to find a different way of decoupling the needle that can solve these problems.

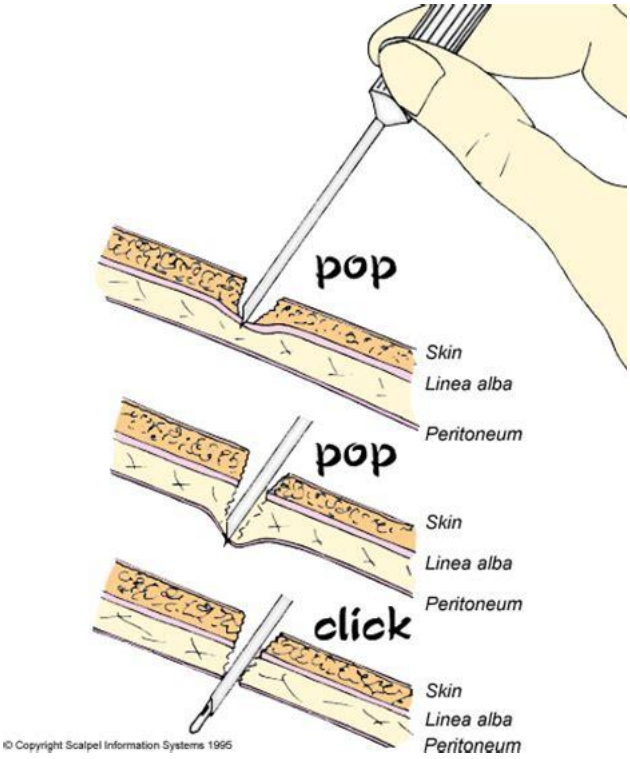


Figure 3: Working Veress needle (Scalpel information System, 1995)

3. State of the art

In this chapter the individual components of the VP will be discussed, their placement to one another, the way they function will be described and decoupling mechanisms in general will be discussed.

3.1. Veress Plus components

The VP, as can be seen in Figure 4, has an inner stylet (1) meant to allow gas flow that can be regulated by a small air lever (1a) just underneath the top (not depictured) and linked to a valve all the way on top (1b). The inner stylet is linked to the middle canula, with a ring (1c) screwed onto the middle canula, that is shape locked to the inner stylet but has room around it to move along the length of the inner stylet. It is pushed to one end by a spring (1d). The inner stylet also has a small, pointed lever (4) at one end attached through a bracket (1e) at attachment point 1f. This lever pushes down on to a flexure (5) with a hook at its end that couples to the middle canula (2). The middle canula has a sharp edge (2a) at its bottom and has small ridges (2b) a little bit higher to provide more friction and tactile feedback. It also has a small pin (2c) on its side to guide the handhold during its placement as well as to catch rotational forces during operation, ensuring these do not preemptively decouple the system. The outer handhold cylinder (3), starts a little bit thicker, with a flexure (5) connected at (3a), meant to couple it to the middle canula and becomes smaller towards the bottom, allowing for a more stable and precise grip. It also has a gap (3b), parallel to the flexure to guide it.

3.2. Veress Plus Workings explained

When the VP is loaded, the lever (4) must be pushed up and the handhold cylinder (3) slid up along the middle canula (2), ensuring the guiding pin (2c) and gap (3b) fit together. This ensures the hook at the end of the flexure (5) can hook behind the middle canula ring (2d). Once done the lever (4) can be released to press down on the flexure (5). Now a small incision can be made at either the Palmer point or the Umbilical point (preference differs based on surgeon and BMI of patient) to cut

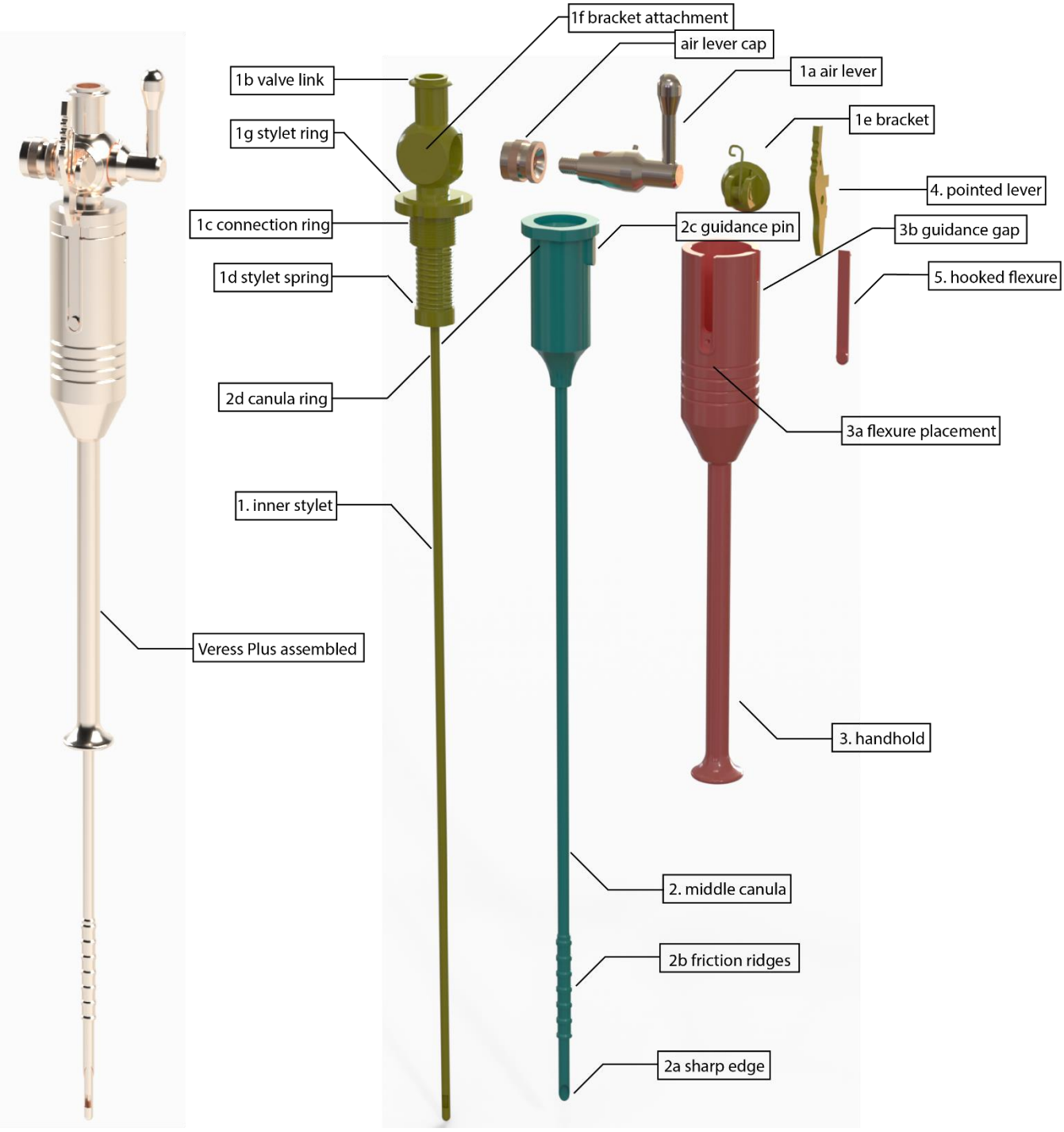


Figure 4: Veress Plus components Stylet: Yellow, middle canula: Blue, Handhold: red

through the tough outer skin. Then the VP can be placed on the desired entry spot and pressure can be applied through the handhold towards the subcutaneous tissue. This pressure will build up till, it overcomes the spring (1d) force between the inner stylet (1) and the middle canula (2) allowing the stylet to retract into the middle canula (2)

and subsequently the cutting edge (2a) of that middle canula (2) to cut through the different layers of tissue. Due to this retracting motion the lever (4) will slide off the flexure (5). When the middle canula (2) cuts through the parietal peritoneum, there is space allowing the force against the inner stylet (1) to drop. This allows the inner spring (1d) to push the stylet (1) out and at the same time the lever (4) on the top will use its pointed shape to push the hook at the end of the flexure (5) away from the middle canula (2), subsequently decoupling the middle canula (2) and the outer handhold cylinder (3). As all force is applied to this outer handhold cylinder (3), this will shoot downwards whilst the users reflexes kick in to stop the motion. During the continuing motion of the user, the middle canula (2) and stylet (1) will hold still in place, thus preventing any danger of punctuation of organs or arteries due to overshoot.

3.3. Decoupling mechanisms

A decoupling mechanism as described here exists of two objects, which have one or multiple degrees of freedom connected to one another, which have an intended method of releasing one or multiple degrees of freedom via one or multiple inputs.

Decoupling mechanisms can be categorized using two characteristics that will explain most of the systems working principle. Their mechanism, meaning the part that changes for decoupling to ensue, and their trigger, meaning the input signal that causes a change to happen, that will result in decoupling. One can distinguish between the initial trigger and the trigger that eventually connects to the mechanism, as it might be possible to change the trigger before arriving at the mechanism. Different existing inputs are force/position, speed, acceleration, pressure, deformation, and heat. Different mechanisms for decoupling exist out of a hook, spring force, stiffness/friction, magnetic force internal shifting components or components that break off entirely.

Most decoupling mechanisms work in two steps being the coupled phase, and the decoupled phase [11]. In the VP design force/position is the input for the mechanism with a hooked flexor and a pointed lever as the clasping and decoupling for the system. This creates a decoupling mechanism that works in three phases, where three distinct parts have different workings in three phases as can be seen in Figure 5. (Phase 4 is a decoupled phase that is the same for every device and will not be discussed further during this research). Phase one, the needle is at rest, coupled and ready for use. Here the inner stylet is pushed down compared to the middle canula as much as possible, and the handhold cylinder and middle canula are coupled. With the pointed lever resting on top of the hooked flexure. The second phase where it is punctuating the layers of skin. The inner stylet is being pushed up compared to the middle canula, the handhold cylinder is still coupled to the middle canula, and the hooked lever has been allowed to turn further towards the inner stylet. In the last punctuated phase, the stylet has no more push against it. It is pushed back to its original position in the middle canula, resulting in the pointed lever pushing the hooked flexure away from the middle canula, resulting in a decoupling of the handhold.

3.4. Detailed description problematic component interaction

As previously mentioned, there are two problematic interactions in the device that can either be negative on the acceptance of the device or have a critically negative effect on the functionality of the device (references to parts will still refer to Figure 4). The first one has to do with the reloading. This interaction has been improved during the making of this paper reducing it from a risk

to the device durability to a risk to its acceptance. The reloading of the device is done in two separate steps. The first of these steps is pressing in the pointed lever Part 4. This needs to be done as the connected spring presses it onto the gap of the stylet ring Part 1g and prevents the hooked flexure Part 5 from taking occupying this space to hook behind the canula ring Part 2d hence preventing the device from being coupled. In the older version pressing the pointed lever would bend the hooked flexure away from the device to a degree that could cause fatigue when done frequently. In the newer version the amount the lever can be rotated up has been limited to prevent this fatigue. This does request a higher understanding of the device by the surgeon and supporting personnel potentially reducing acceptance. The second problematic Interaction is more crucial as it can prevent the device from decoupling which could cause more damage then not having a decoupling mechanism in the system. This is due to possible reliance of a surgeon on the device which could lower their own reaction speed. This problem is caused as the hooked flexure Part 5 is accessible during use. Since this is the part preventing the handhold from sliding over the canula it is one of the most crucial parts. The accessibility allows for a surgeon to put their hand on the hooked flexure and press it into place during use. This will have no visible effect on the device, until the parietal peritoneum has been passed and the stylet presses back down. At this point, as previously explained the pointed lever Part 4 is pressed against top of the hooked flexure Part 5 and presses it away from the canula ring. When at this moment a finger is placed and pressed against the hooked flexure, this force can easily be greater than the force exerted by the pointed lever Part 4, thus preventing it from decoupling. As a result the needle will retain any force the surgeon is exerting on the needle and it will press down and through any subsequent tissue, until the surgeon stops the motion.

3.5. Research Goal

Design an alternative decoupling system for the Veress Plus, that gives no access to critical parts during use and guides the user in a single action during the reload. To validate the working of this design and decide if it can replace the existing system.

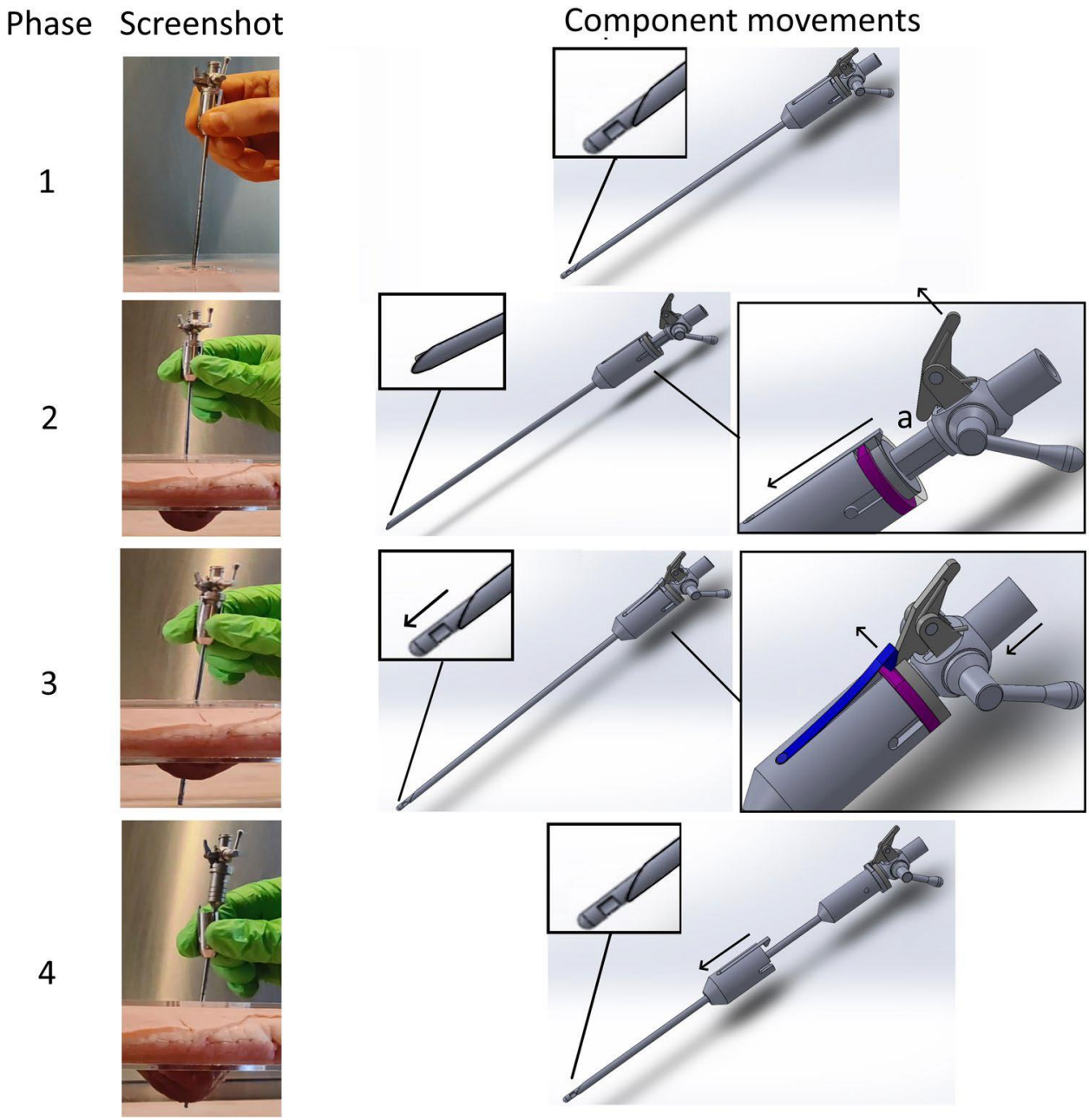


Figure 5: VP In phases from top to bottom. 1, Rest 2, Layer punctuating 3 and 4, Punctured and decoupled [3]

4. Design Requirements and criteria

This section will specify distinctive design requirements and criteria that an innovative design has to abide by. Several features of the existing design will be discussed and stated why they need to be different.

4.1. Final design specifications

Table 1: Design requirements and specifications

Design Requirements	Specifications
Dimensional	
Length	≤ 110 mm
Diameter	≤ 20 mm
Material	
General material	Sterilizable materials
Flexible material	Sterilizable materials
Quality and reliability	
Lifetime	≥ 200 cycles and ≥ 5 years
Malfunctions	≤ VP
Critical parts	No accessible critical parts during usage
Design	
Cleanability	Must be possible to disassemble
Actions to reload	1
Complexity	≤5 parts
Phases for decoupling	3

4.2. Dimensions

To improve acceptability of the needle it is desired to stay as close as possible to the original dimensions. Ideally there would of course be no expansion in dimension, but this would result into miniaturized systems that would increase costs and might also result in less reliability. Thus for allowable dimensions the needle was compared to allowable dimensions of a pen. Here it is desirable to have circular diameters of ≤ 20 mm. Here the width is related to its speed and precision where a smaller diameter improves precision, and a bigger diameter improves speed. Ideally precision is achieved here. It is also indicated that a pen should have the same width as the hand using it. [12] One of the larger hand sizes (width) found was 97.20 ± 11.37 allowing for a maximum length of ~110 mm [13] As the handhold can be elongated if needed, it is not required to reach this length.

4.3. Materials

We desire the VP to be sustainable and reusable. Hence the device needs to be reusable for a number of cycles and all parts need to be cleanable. The device must also be designed from materials that can be reused and constructed in such a way that different materials can easily be disassembled at the end of life. Lastly these materials need to be able to withstand high temperatures for automated sterilization.

4.4. Quality and Reliability

4.4.1. Lifetime

It is desired that the needle has a lifetime of at least two hundred uses and 5 years with its individual parts, when properly maintained. This is the lifetime guaranteed by the existing reusable Veress Plus.

4.4.2. Malfunctions

The device should have a reliability rate of equal to, or better than, the decoupling system of the VP before it can be implemented.

4.4.3. Non accessible critical parts during use

As explained in section 3.4, the reliability of the device is damaged by its exposure of critical parts during use. It might be possible to train users not to place their fingers on critical parts. However, looking at the situation in which the VP is used, it is expected to be a high stress environment with a lot of different inputs. Hence improving the device in a way that it is no longer possible to access the system during use, will increase the reliability of the VP as well as decrease the workload of the surgeon (if only in the slightest way). It is there for

desired to make any critical component inaccessible during use.

4.5. Design

4.5.1. Cleanability

It is desired to reuse the device for a number of cycles, as there is increased emphasis placed on proper cleaning for which the responsibility lies with the manufacturer [14]. Keeping this in mind it is desired to have smooth surfaces and no slits within a single component. Hence either parts need to be welded together or it must be easy to be disassembled and reassemble as this needs to be done every cycle ensuring anything on them can be washed off.

4.5.2. Single action reloading

The initial reason for this paper is to improve upon the reliability and to decrease the vulnerability of the device to the user. One of the vulnerabilities in the VP can be identified as a loading that requires several steps of the user as described in section 3.4. Thus, to improve upon this, it is desired to create a system that needs only a single action to load the device. If possible, this one action should be guided by the device itself.

4.5.3. Complexity

Studying decoupling mechanisms, it becomes clear that without breaking components, a three-phase decoupling system will also need at least 3 parts to function [11]. To facilitate an improvement on the old system, it is also desired to not excessively increase the number of components. The VP has five parts that can move individually related to the decoupling system (Stylet, middle canula, handhold, pointed lever and hooked flexor), Figure 4 has these components marked one to five. As it is desired to keep the complexity to a minimum, the new system should have no more than 5 moving parts.

4.5.4. Three phase mechanism

This three-phase system is quite different from most decoupling mechanisms that work in a classical two-phase system, where one part has the sole use of facilitating the decoupling mechanism. This is problematic as such a system would decouple at the first contact with the body, instead of decoupling after penetration. It is therefore essential to create a three-phase decoupling mechanism, which registered the pushing action and prepares itself for decoupling after penetration of the abdominal wall.

5. Conceptual design

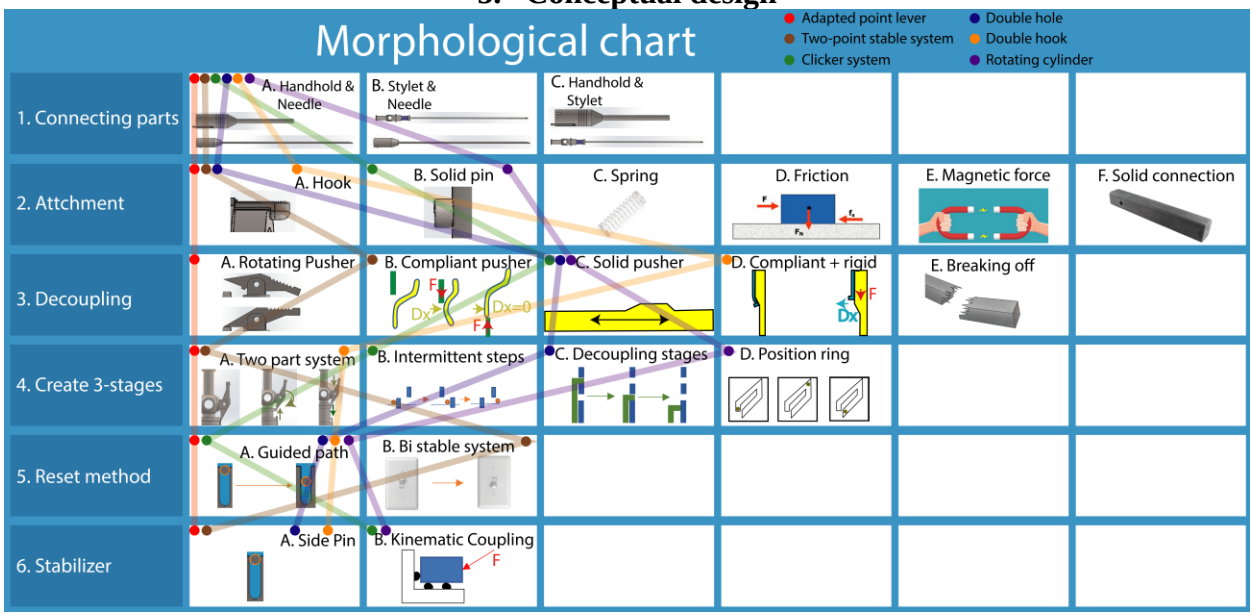


Figure 6: Morphological chart

In this section we will discuss the design obstacles and their solutions, put these into a morphological chart (Figure 6) and create different concepts from it. Then we will compare them to various demands and select the system that is the most viable solution. The creations themselves were all aimed to have a three-phase system as well as to reload in a single action and should in theory be able to achieve both these demands. The different aspects of row one, two and three in Figure 6 that aren't used in any concept, have not been used because no working combination were thought of to adapt them into a reusable three phases system.

5.1. Design obstacles

The design itself can be subdivided into various subproblems. Both problems and solutions are based on a previous literature study [11].

5.1.1. Connecting parts

The system exists out of three major parts (Stylet, middle canula and handhold cylinder) which will need to be connected. Two parts need to have a coupling/uncoupling connection and the third needs to provide a trigger to switch in between these states. This part is included to indicate that alternative possibilities have been considered. The original VN and VP takes their triggers from the inner stylet and changing this would mean a change to the entire system rather than its decoupling subcomponent. No viable systems for the alternative two options where found without altering the entire needle.

Different combinations of functionality

- **Handhold and needle coupled:** This system couples the handhold to the middle canula and puts the main decoupling action on the inner stylet.
- **Stylet and needle:** Here a coupling mechanism would exist between the inner stylet and the middle canula and would require the handhold to have the decoupling system.
- **Handhold and stylet:** Here the handhold would be coupled to the stylet, having the decoupling system connected to the middle canula.

5.1.2. Attachment

Before the system is decoupled, it needs a way to attach the handhold to the rest of the needle first

Different attachment methods

- **Hook:** A hook that holds onto the needle.
- **Solid pin:** An unmovable pin that follows a predictive path.
- **Spring:** The handhold is being kept in place by a spring.
- **Friction:** Enough friction is created between the two parts to keep them from moving separately.
- **Magnetic force:** A magnetic force is used to connect two parts together.
- **Solid connection:** The two parts are either created as one or fixed together.

5.1.3. Decoupling

In the first two phases the handhold is coupled to the system. To ensure there is a way to decouple the system going into phase three

Different decoupling mechanisms

- **Rotating pusher:** A rotating part that only acts like a pusher after or before rotation.
- **Compliant pusher:** A pusher that is deformable to forces from one side and pushes against forces the other direction.
- **Solid pusher:** A pusher that pushes whenever it comes into contact with anything.
- **Compliant/rigid pusher:** a combination of two pushers, where a flexible pusher that bends away from force initially will push after being backed up by the rigid pusher.
- **Breaking off:** breaking the parts to separate them.

5.1.4. Create 3-phases

As the system needs to be a three-phase system to be able to function the way it is desired to. A system must be created to allow for these three positions.

3-phases systems

- **Two-part system:** where one system releases in the second phase and the other one releases in the third phase.
- **Intermittent steps:** several obstructions that are encountered one at a time.
- **Decoupling phases:** here the system decouples from the first phase, to be locked into the second phase, where it needs to be decoupled again.
- **Phase tracking ring:** a separate ring that tracks the separate phases.

5.1.5. Reset method

As the device needs to be reusable, there needs to be a way to reattach the handhold to the rest of the needle

Reset methods

- **Linear guide:** A linear path combined with a solid pin to ensure a predetermined path.
- **Bi stable system:** A system that is stable in two stadia.

5.1.6. Stabilizer

To ensure the system does not rotate or move in an unexpected way.

Stabilizers

- **Linear guide:** A linear path combined with a solid pin to ensure a predetermined path.
- **Kinematic coupling:** a shape, that combined with a directional force, ensures no unexpected movement is possible.

5.2. Concepts and grading

In this section we will introduce the different concepts resulting from Figure 6, that can be reloaded in a single action and that have a three-phase system. They were scored based upon formerly mentioned criteria with an added criterion of system specific expected problems. The criteria and their weight are listed in Table 2**.** A higher number is considered positive. This table should give more insight to the scoring given to each design.

Table 2: Criteria (Vertical) and their weight (horizontal more points scored is better)

	1	2	3	4	5
Complexity	7 parts	6 parts	5 parts	4 parts	3 parts
Expected Diameter [mm]	20	18	16	14	12
Ease do disassemble (number of screws)	4	3	2	1	0
Expected unique problems	Expected not to work	Expected system failure	Big complication	Minor problem	No problems

5.2.1. Adapted pointed lever

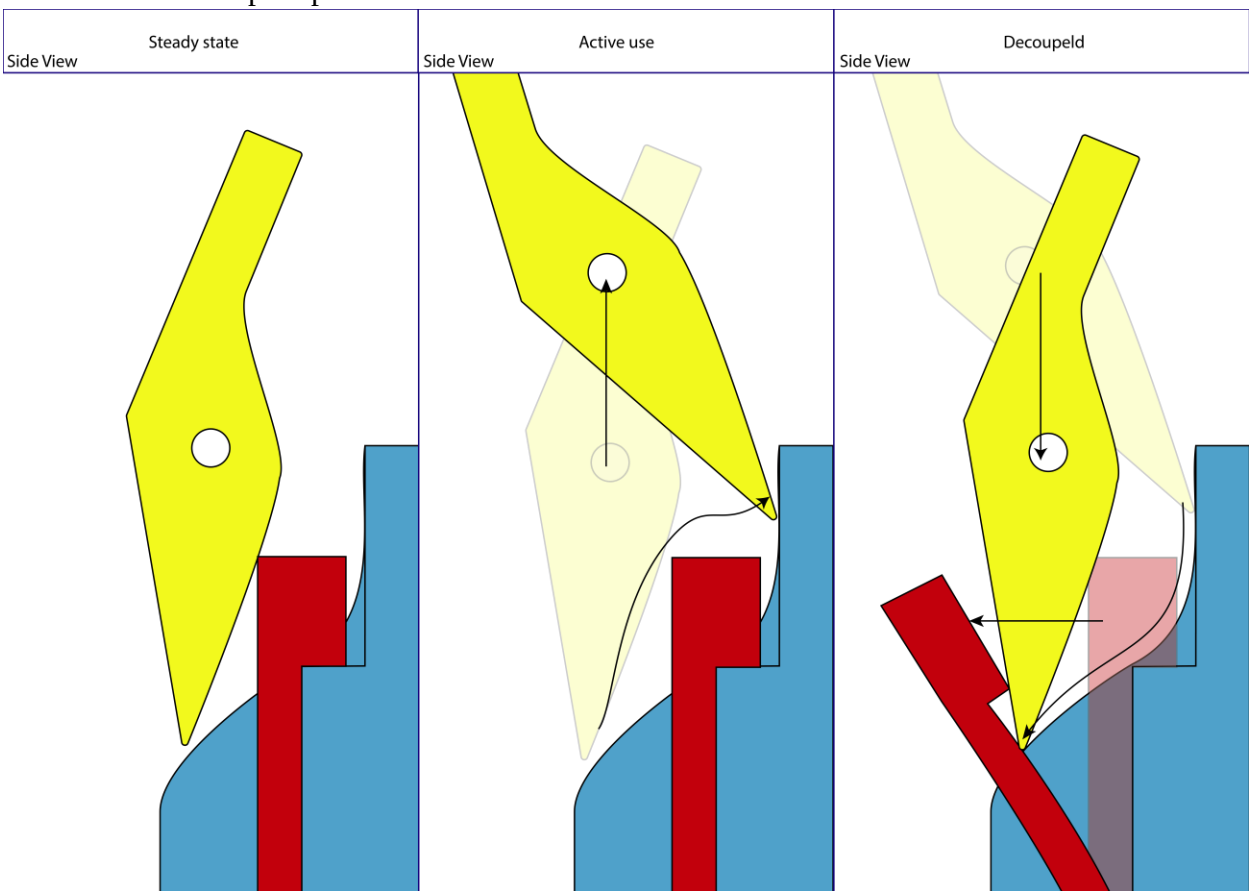


Figure 7: Adapted pointed lever, left sketch steady state middle, sketch active state, right decoupled state.

The adapted pointed lever can be seen in Figure 7**.** Any reference to parts will refer to this Figure. Within this Figure the color red is connected to the handhold, the color blue is connected to the middle canula and the color yellow to the inner stylet. Any arrows point out the movement that has happened since the last picture. It still has a hooked flexure attached to the handhold, that hooks behind the middle canula. The pointed lever is still attached to the inner stylet but wider than the hooked flexure, the middle canula has an extra ramp next to the sharp edge, where the hooked flexure hooks onto it.

Workflow. When the system is loaded as can be seen in the most left sketch. The hooked flexure is locked on top of the middle canula and has the pointed lever resting on top. When the needle is pressed into punctuating the abdomen layers, the pointed lever is pushed upwards and without resistance will turn towards the middle canula as, can be seen in the middle sketch. When the needle punctures through the abdomen the, inner stylet shoots down and the pointed lever follows the new attached ramp, scooping the flexure away from its hold and decoupling it, then the pointed lever will follow its route along the ramp, ending in a position, where its point is slightly higher than the thickness of the hooked flexure. The last step is the reloading phase, where the flexure can simply be pushed up again. As the pointed lever is already opened far enough by the ramp, the hooked flexure will push at the bottom of the hooked flexure opening it up, just a little bit before hooking onto the middle canula.

Complexity (3 Points)

This system has five parts (stylet, middle canula, handhold, pointed lever and flexor).

Expected Diameter (3 Points)

This system is close to the original one. To ensure that the critical parts are inaccessible, it will need to be enlarged by 3 mm on one side, to conceal the flexor resulting in 16 mm diameter

Ease do disassemble (3 Points)

This system needs 2 screws to disassemble. One to disconnect the flexure and one to disconnect the needle from the stylet

Expected unique problems (3 Points)

The key issues with this system, would be to get it inside of the needle and what kind of complications this will give.

5.2.2. Two-point stable switch

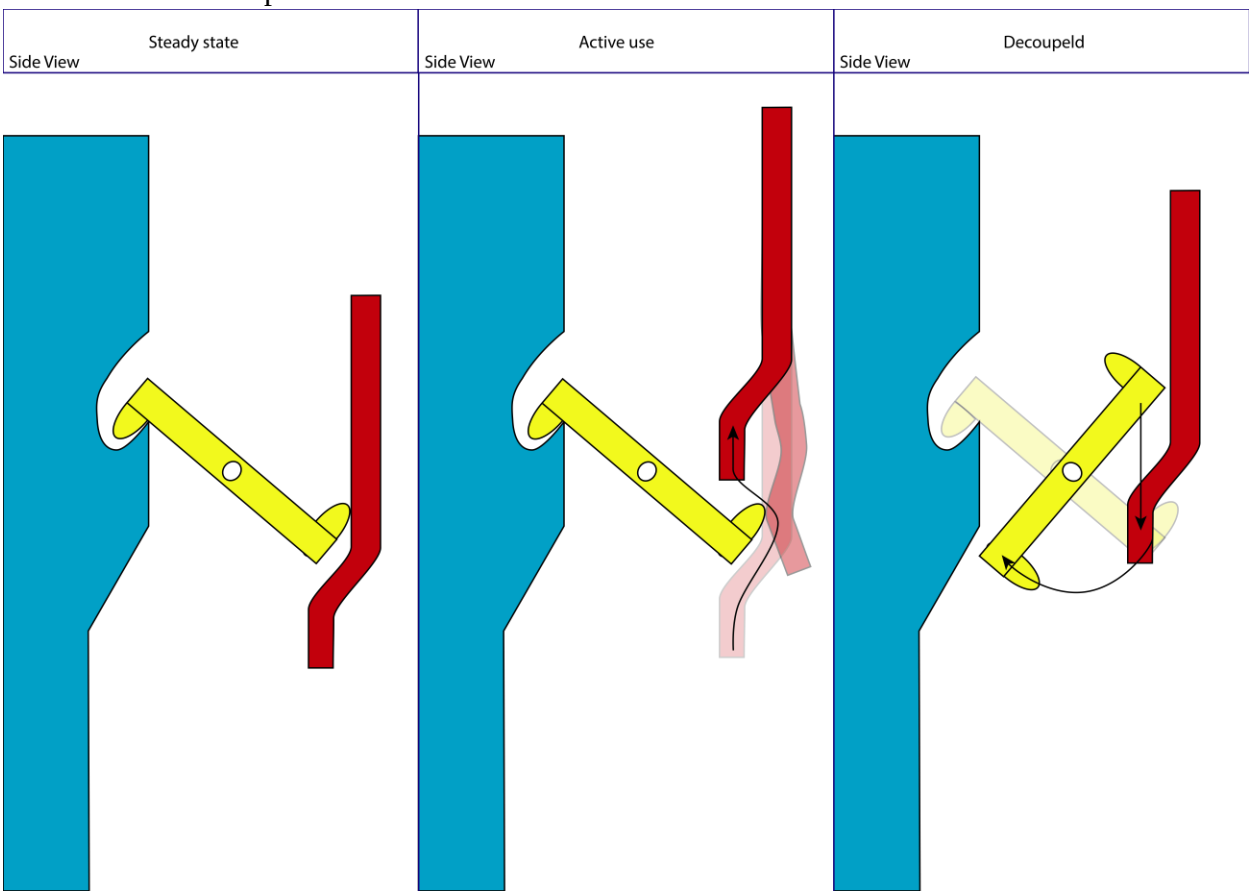


Figure 8: Two-point stable switch, left sketch steady state middle sketch active state, right decoupled state.

The two-point stable switch, which can be seen in Figure 8**.** Any reference to parts will refer to this Figure. Within this Figure, the color red is connected to the handhold, the color blue is connected to the middle canula and the color yellow to the inner stylet. Any arrows point out the movement that has happened since the last picture. There is a two-point stable switch attached to the handhold cylinder, that has its stable positions approximate ninety degrees apart. At the end of both sides of the switch, there is a small hook. The middle canula has a hole in its shape, that should allow the two-point stable switch to hook into. There is a flexure attached to the inner stylet, which is shaped in a way that force from up should push it to the inside(right), but should push against force from the bottom.

Workflow. In the first locked/hooked phase, the two-point stable switch is hooked into the little hole of the middle canula, as can be seen in the left sketch and the flexure rests underneath it. When the inner stylet is pushed up, the flexure connects with the two-point stable switch, which cannot turn further into the middle canula and thus pushes back. The flexure will give in and bends sideways (to the right), to pass by the two-point stable switch ending above it. When the needle punctuates through the abdominal wall, the inner stylet will push down hence pushing the flexure into the other hook of the two-point stable switch, which will push it to turn into its other uncoupled stable position. When the needle is reloaded, the existing objects will push the air lever, making it automatically lock again.

Complexity (3 Points)

This system has 5 parts. (Inner stylet, middle cannula, handhold cylinder, air lever and flexor).

Expected Diameter (4 Points)

This system is intended to be on the inside of the original needle, but has several miniaturized parts that make assembly of the device more difficult. It has an expected diameter of 14 mm.

Ease do disassemble (2 Points)

This system needs 3 screws as it will need to disconnect the needle from the stylet, a flexor from the handhold and the air lever from the stylet.

Expected unique problems (2 Points)

Major problems expected in this design, involve big movable parts in between the inner stylet and middle canula, where there is not a lot of space. And a short lifetime expectancy, that might be improved by smaller movement, but will still be an issue.

5.2.3. Clicker system

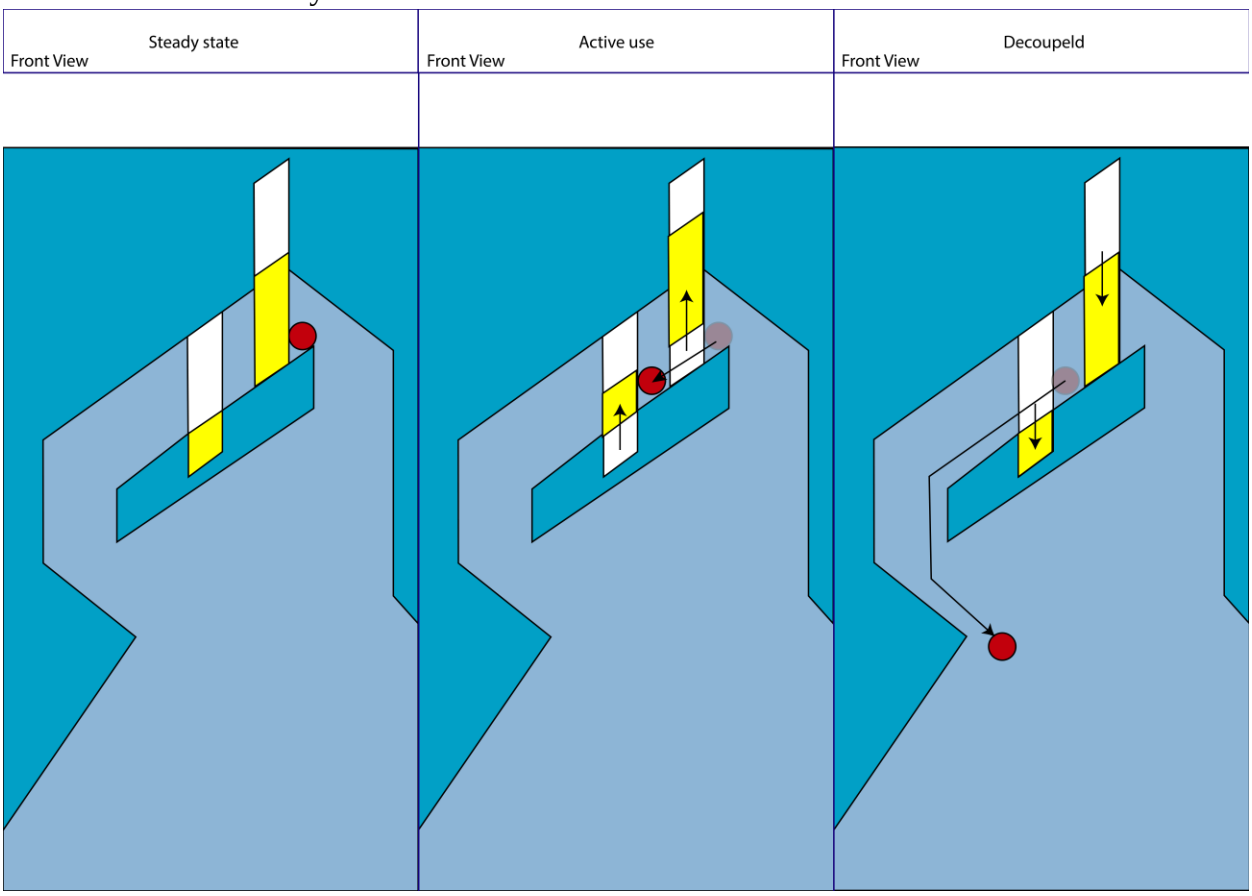


Figure 9: Clicker system, left sketch steady state, middle sketch active state, right decoupled state

The Clicker system can be seen in Figure 9. Any reference to parts will refer to this Figure. Within this Figure the color red is connected to the handhold, the color blue is connected to the middle canula and the color yellow to the inner stylet. Any arrows point out the movement, that has happened since the last picture. In this front view we can see a small red pin, that is connected to the handhold cylinder. The handhold cylinder is being pushed down by an extra spring added to the system. There are two rectangles that move in between the different sketches, which are attached to the inner stylet and the rest of the topography is etched into the middle canula. It is important to note that this would normally be round, but has been formed straight for the first concept phase.

Workflow, In the left sketch, we can see the locked/ready phase were the green pin, which is being pushed downwards, is shape locked in the topography. When the needle is being pushed into the abdomen, the two rectangles which are connected to the inner stylet move upwards. This allows the green pin, which is being pulled downwards to slide to the side past the first rectangle, being stopped again by the second, that moved up as well. When the needle punctures the abdominal wall, the inner stylet is released allowing the two rectangles to move down again and the green pin to continue its way out of the system entirely, thus decoupling it. To load the device, the entire topography is shaped in a way to guide the green pin towards its near ready state, where, when released, it will place

itself (due to the extra spring force) into its loaded phase again.

Reflect on the list of demands

Complexity (5 Points)

This system will exist of only 3 parts (Inner stylet, middle cannula, and handhold cylinder). this system has one extra spring. As the spring that actuates the pointed lever in the original system is not counted, this will not be counted to the total amount of parts either.

Expected Diameter (4 Points)

It is possible to create the system in the existing space of 13 mm.

Ease do disassemble (4 Points)

This system needs only one screw to disassemble.

Expected unique problems (4 Points)

The biggest issues involving this system, are the expected rotation that individual parts will need to make. For this we will look at the rotation friction of the needle itself, as well as the friction between the parts. The Double hole mechanism can be seen in Figure 10**.** Any reference to parts will refer to this Figure. Within this Figure the color green is connected to the handhold, the color blue is connected to the middle canula and the color yellow to the inner stylet. Any arrows point out the movement, that has happened since the last picture. In this side view we can see a flexure with a hook, that is connected to the handhold cylinder. There are two holes in the middle canula and the inner stylet has an extrusion with inclined sides, that sticks partly through the middle canula. When the thicker part of the inner stylet is in front of a hole, it blocks this hole.

5.2.4. Double hole

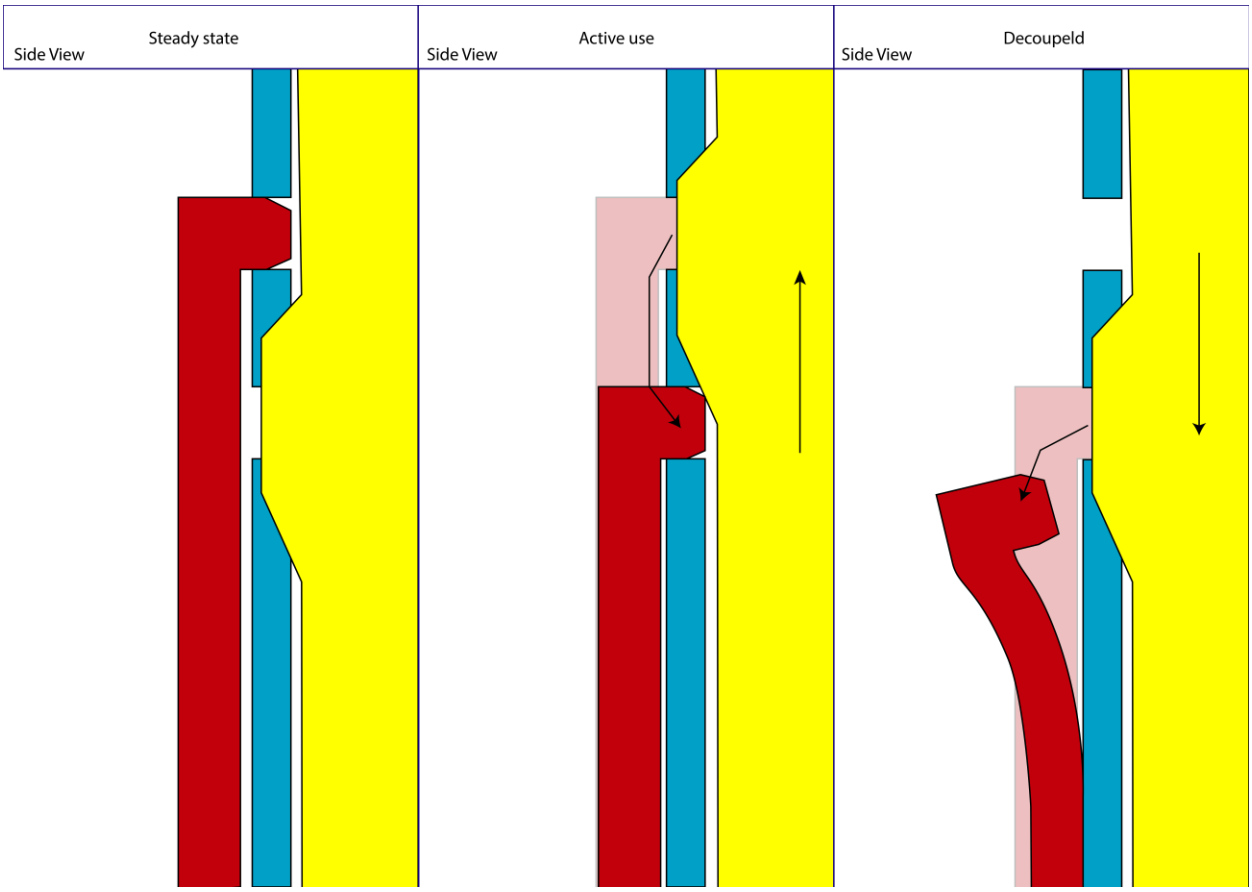


Figure 10:Double hole mechanism, left sketch steady state, middle sketch active state, right decoupled state

Workflow. In the most left sketch, we see the flexure locked in the top hole and the system at rest. When the needle is being pushed into the abdominal wall, the stylet will move upwards taking the extrusion up with it. This movement opens the lower hole in the middle canula and then pushes the flexure out of the upper hole. The flexure then moves down, till it finds the second opening where it locks again. When the needle punctures the abdominal wall, the stylet will be pushed down again, using its extrusion to push the hooked flexure out of the lower hole and effectively decoupling it. The needle can then be reloaded by pushing the handhold cylinder up, till it clicks in the upper hole. It will skip the lower one as the extrusion is blocking it.

Reflect on the list of demands

Complexity (4 Points)

This system consists of 4 parts (Inner stylet, middle canula, Handhold and flexor)

Expected Diameter (4 Points)

It is possible to create the system in the existing space of 13 mm.

Ease do disassemble (3 Points)

This system needs two screw to disassemble (Needle from stylet and flexor)

Expected unique problems (3 Points)

One expected issue with this system, is its ability to lock in the lower hole, after being forced out of the upper hole.

5.2.5. Double hook

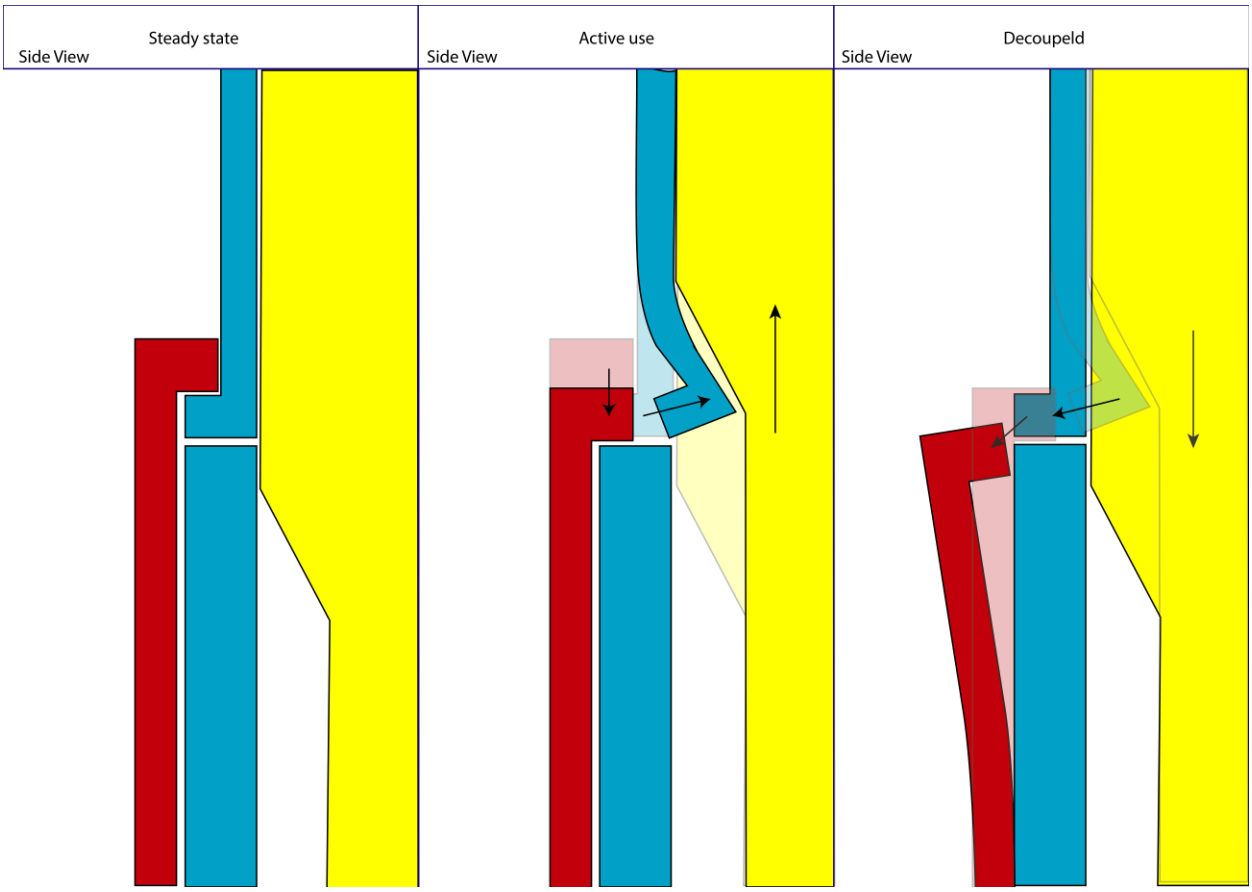


Figure 11: Double hook mechanism, left sketch steady state, middle sketch active state, right decoupled state.

The Double hook mechanism can be seen in Figure 11**.** Any reference to parts will refer to this Figure. Within this Figure the color red is connected to the handhold, the color blue is connected to the middle canula and the color yellow to the inner stylet. Any arrows point out the movement, that has happened since the last picture. In the left sketch we can see a red flexure, that is connected to the handhold cylinder and a blue flexure, that is connected to the middle canula. It is important to note, that the inwards position seen in the middle sketch, is the default position and its position in the side sketches, and is because the widening of the inner stylet is there pushing it.

Workflow. The locked starting position as seen in the left sketch, has the inner stylet pushing the blue flexure to the outside, where the green one can hook behind it. When the needle is pressed into the abdominal, wall the inner stylet moves up. When it becomes smaller, it gives space to the blue flexure to move inwards and give space to the green flexure, that then hooks behind the normal wall of the middle canula. As can be seen in the middle picture, when the needle punctures the abdominal wall, the inner stylet shoots downwards once more pushing the blue flexure outside, which in turn pushes the hook on the green flexure away and uncoupling it. When the device is reloaded, you must only slide the outer handhold cylinder upwards till the green flexure locks behind the blue flexure again.

Reflect on the list of demands

Complexity (3 Points)

This system consists of 5 parts (Inner stylet, middle canula, Handhold, inner flexor and outer flexor)

Expected Diameter (4 Points)

It is possible to create the system in the existing space of 13 mm.

Ease do disassemble (2 Points)

This system needs three screw to disassemble (Needle from stylet and flexor)

Expected unique problems (5 Points)

There are no specific problems expected with this system.

5.2.6. Rotating cylinder

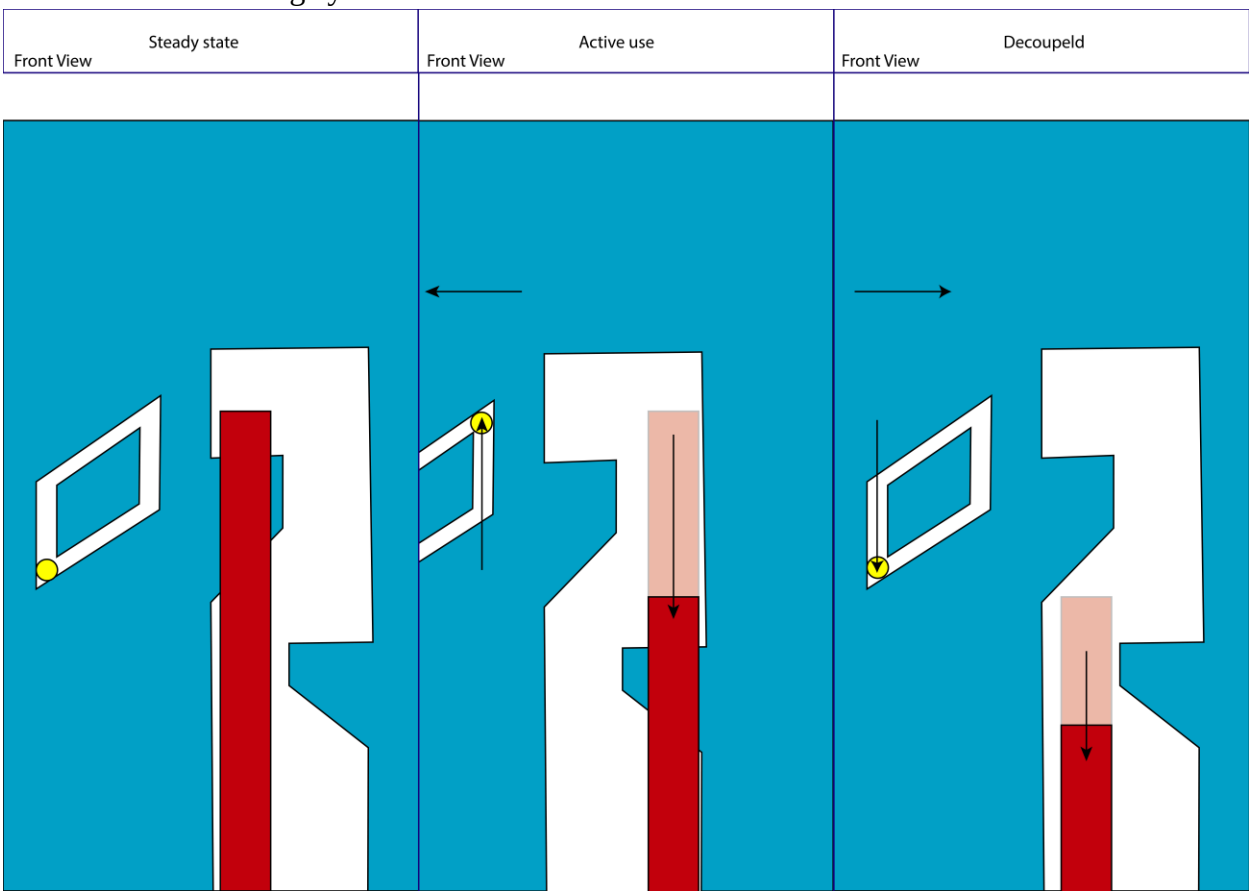


Figure 12: Rotating cylinder, left sketch steady state, middle sketch active state, right decoupled state.

The Rotating cylinder can be seen in Figure 12**.** Any reference to parts will refer to this Figure. Within this Figure the color red is connected to the handhold, the color blue is connected to the middle canula and the color yellow to the inner stylet. Any arrows point out the movement, that has happened since the last picture. In this system, a cylinder is added to the system attached to the middle canula. This cylinder can turn right and left, but not move up and down compared to the middle canula. It has two shapes taken out, one has a small extrusion from the inner stylet in it and can be described as a sideways diamond, this is the left extrusion in picture. The other one has an extrusion from the handhold in it (red rectangle) and can be described as a two shape. This is the right one in each sketch.

Workflow. When the system is locked and ready to go, the stylet extrusion is at rest on the left bottom. And the handhold extrusion is locked on top of the two, as can be seen in the left picture. When the needle is pressed into the abdominal wall, the stylet will move up, which will push the stylet extrusion against the diamond shape and thus force the cylinder to turn in clockwise direction (seen from top), which will move the two sideways and allow the handhold extrusion to move downwards till halfway the two. When the needle punctures the abdominal wall, the stylet will move downwards again, having its extrusion push the cylinder in counterclockwise direction and thus spinning the two sideways, releasing the handhold extrusion and decoupling the system. When reloading the system, the two shape has inclined planes at the bottom,

letting itself be forced to turn, when the handhold extrusion pushes upwards and thus giving space for the device to be loaded in a single motion.

Reflect on the list of demands

Complexity (4 Points)

This system consists of 4 parts (Inner stylet, middle canula, Handhold and rotating cylinder)

Expected Diameter (3 Points)

The extra ring will need extra space hence it is expected to fit in 16mm.

Ease do disassemble (3 Points)

This system needs two screw to disassemble (Needle from stylet and pin from rotating cylinder)

Expected unique problems (3 Points)

A complication expected with this system is the amount of internal friction that might be involved with the cylinder turning.

5.3. Selection

The scoring was already marked during their reflection phase. Scorings is once more listed in Table 3. here we can also find their total scoring. Please note that although it is attempted to make the scoring objective it is still based upon the insight of the engineer involved. The expected unique problems are considered especially important and thus the scoring of that category has been doubled. Based on this scoring we will continue to make the Clicker system.

Table 3: Criteria and their weight

	Complexity	Expected diameter	Ease to disassemble	Expected unique problems x2	Total scoring
Adapted pointed lever	3	3	3	3 (6)	15
Two-Point stable switch	3	4	2	2 (4)	13
Clicker system	5	4	4	4 (8)	21
Double hole mechanism	4	4	3	3 (6)	17
Double hook mechanism	3	4	2	5 (10)	19
Rotating cylinder	4	3	3	3 (6)	16

6. Chosen concept.

In this chapter we will discuss a 3D rendering of the chosen concept.

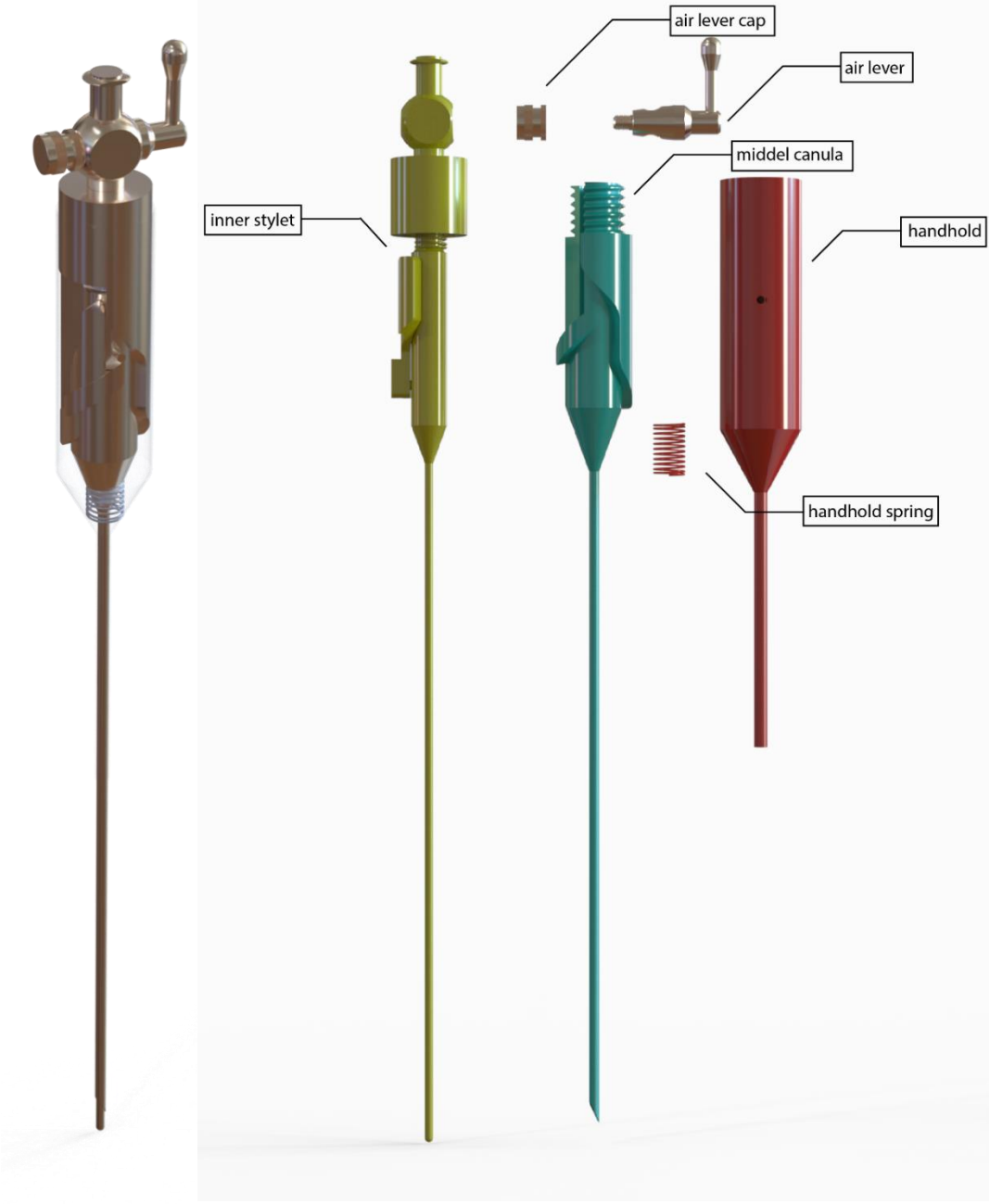


Figure 13: Veress needle based on the clicker concept with transparent handhold and colored components.

6.1. Concept design

Based on the clicker concept, a new design of the Veress Needle was made, as can be seen in Figure 13. In this section everything will refer to this figure. The main components of the needle (stylet, middle canula, handhold, air lever and air lever cap) are made of SAE 304 stainless steel. This steel is known to be used in needles and syringes and is known to be sterilizable [15]. There are two springs of which one is new, this one has been showed in red. The other one is slightly visible on the stylet, but as it is also part of the original VP, it is not individually shown. It uses the same material for the springs as the original VP, to ensure its durability.

In this new variation, the Veress needle is fully covered by the handhold, allowing for no interaction with its critical components. The inner stylet has been slightly adapted, allowing for the cap that connects the stylet to the middle canula above the already existing spring, to turn for the screw wire. This is because the extrusions on the stylet bellow this cap are used as blockers for the handhold and at the same time block the middle canula from turning, thus taking up an alignment function as well. The middle canula in blue, when seen from below, has almost only diagonal surfaces to guide the handhold on the desired starting position. When the handhold is moved up as far as it can be, it will be locked in between the highest diagonal part of the middle canula and the most right extrusion from the yellow stylet. When released, it will press itself down using the added spring into the desired starting position. Here the design will go through the phases as described in section 5.2.3. and they will be described in section 6.3 again. The air lever and cap have been showed here as they can be taken of the device. They are not colored, as they have no function in the decoupling nor are they changed from the VP.

6.2. Final Prototype

The final prototype was made with stainless steel, except for the cylinder of the handhold, that was made from a transparent plastic PMMA. In Figure 14 Figure 1, you can see the components of the prototype. Here the inner stylet, needle, moving bars and all the pins are made from 316 stainless steel, the spring is made of spring steel. The Inner stylet and pins where fabricated on a turn table, the needle and moving bars where fabricated on a five-axis milling machine, the spring was store bought and the handhold adapted from a tube. Except for the stylet spring, all parts were made by DEMO from the TU Delft. As we desire to test this prototype, when it pierces through a fabric, it has gotten a rounded tip and a needle point. It can be seen that some changes where made from the original design. This is to minimize the production cost and focus the test purely on the functionality of the decoupling system and the reloading. Everything extending above the spring on the stylet, which has to do with the air flow has been taken off. To simplify the Middle canula attachment to the inner stylet, it has been combined with the screw to normally placed on the stylet and allow the middle canula to slide onto the stylet. The stylet extrusions have been made as separate part, which can be screwed onto the inner stylet after the middle canula has been placed on. To keep the mechanism as visible as possible, the handhold has been kept small as well during the process of adaptation. The lower spring has been removed as well, trying to observe the system without the input of extra forces.

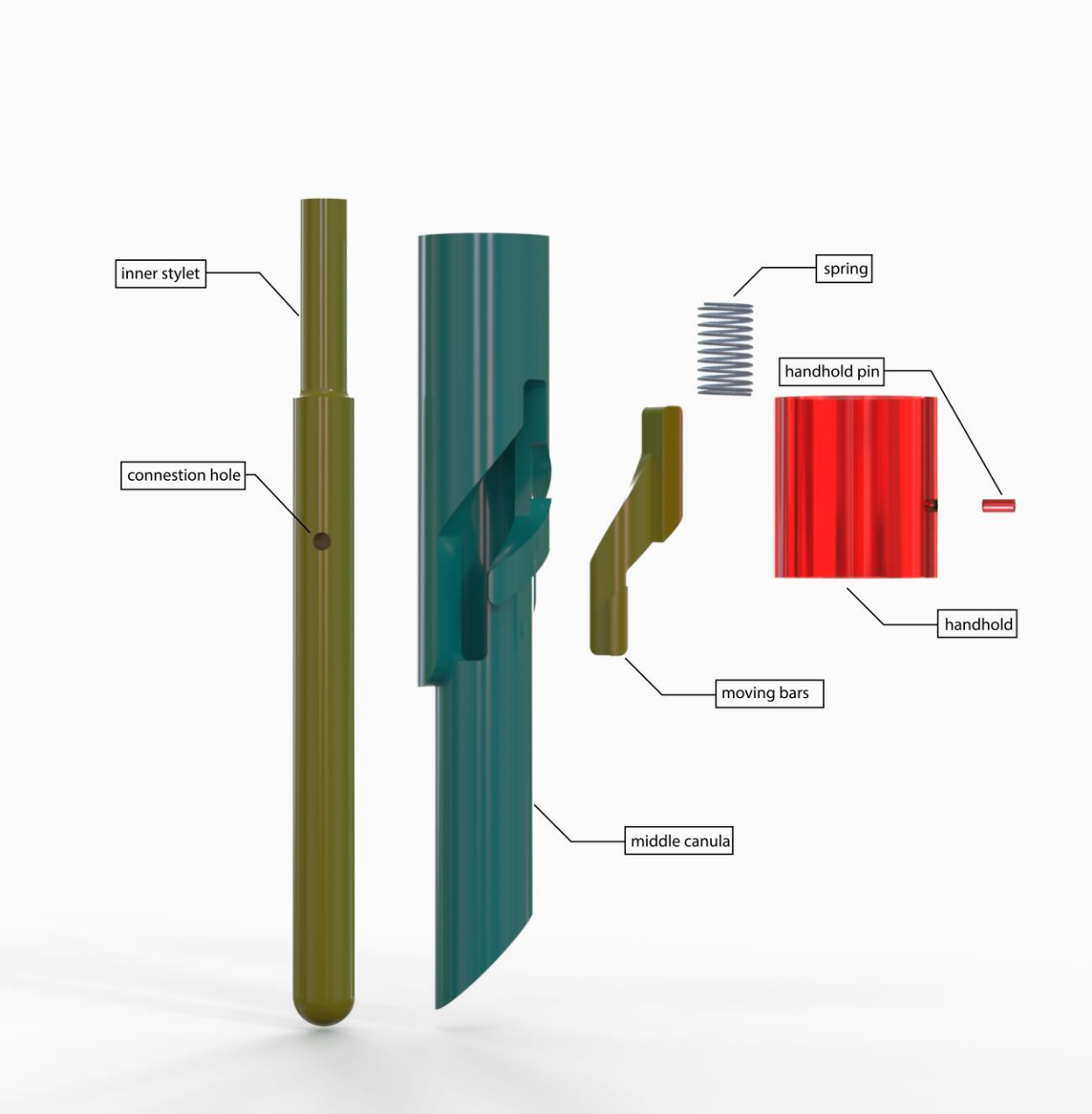


Figure 14: Prototype parts

6.3. Working principle

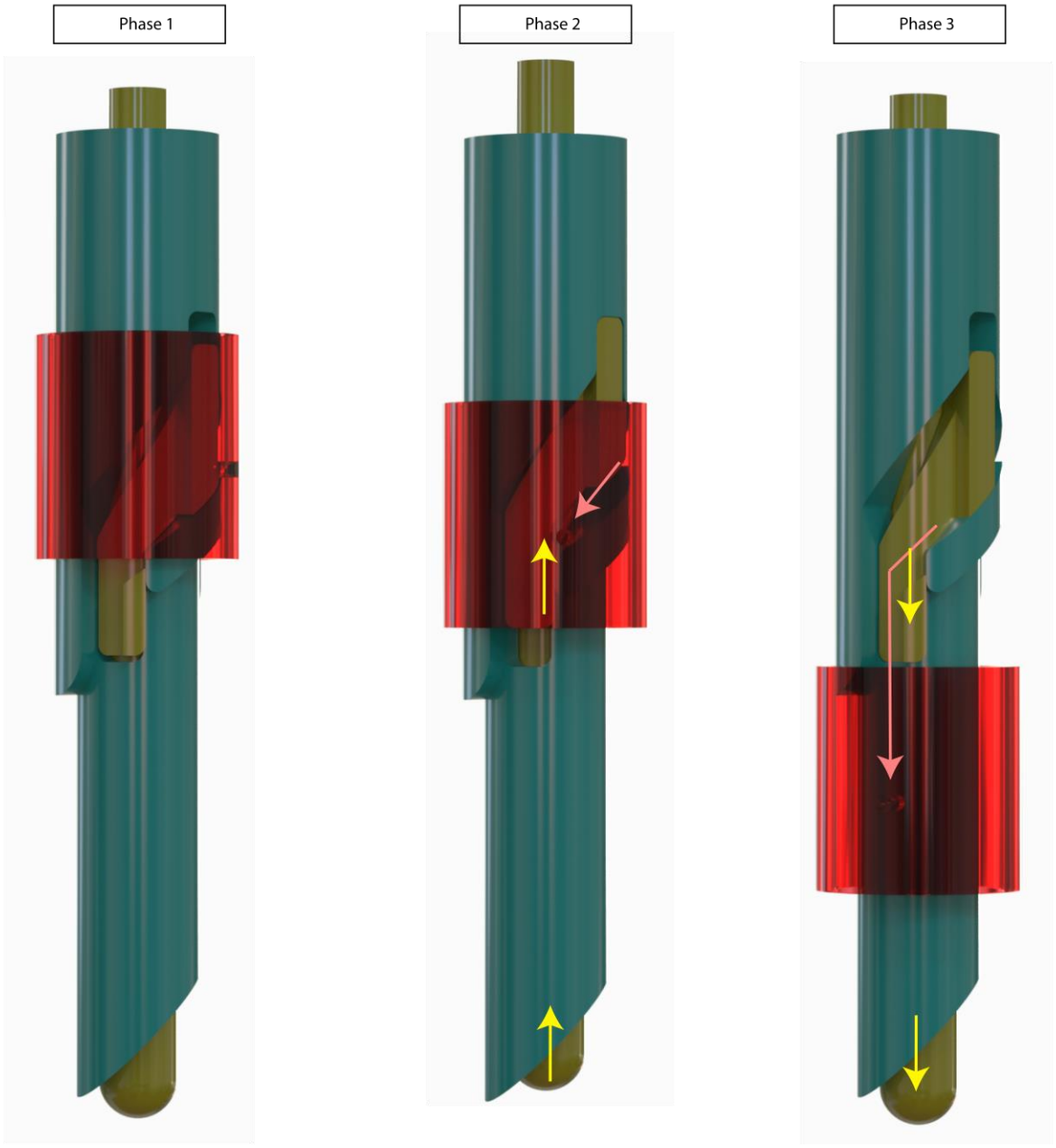


Figure 15: 3 stages of the prototype, stage one on the left till three on the right

To use the prototype, the handhold is pushed up with the red pin Figure 15. The geometry of the needle will guide it to the correct position in most cases (It is possible to move the handhold into the exit slit, but it will directly slide out again when doing this, making clear it was loaded incorrectly). The red pin has to be on the right side of the yellow bars. When the handhold is released, it will then sink into its loaded position as can be seen in phase one of Figure 15. When the prototype is pressed into the test stand, the yellow inner stylet is pressed up taking the vertical bars with it, as shown by the yellow arrows in phase two. This allows the red pin to move underneath the right yellow bar and be stopped by the left yellow bar (movement shown with the red arrow in phase two). This second phase allows for the needle to cut with its exposed sharp edge. When the sharp edge cuts through the layer and enters past the barrier, the yellow inner stylet is pushed back down due to the internal spring force, taking the left yellow stopper with it, as shown with the yellow arrows in phase three. This allows the red pin to move past the left stopper and move out of the system, decoupling the handhold as visible with the red arrow in phase three of Figure 15.

7. Concept evaluation

In this section, the prototype will be analyzed and we will discuss the testing goals, means of evaluation, criteria, setup, instruction and finally the testing results will be discussed.

7.1. Testing Goals

The testing goals are based upon the original research question.

The design, development and validation of an improved decoupling device for the Veress needle, that is less vulnerable to finger positioning during use and easier to reload.

The main goal is to evaluate the performance of the system, looking at the transition between phases all the way, till the device is decoupled from the handhold, when a testing barrier is punctuated. This will be done by asking participants to execute a task several times, which will be filmed.

The reloading and handling of the device, will be evaluated by filming the reloading and giving a questionnaire using a five-point Likert scale, to gain the opinion of the user.

7.2. Type of research

For the type of research, it was decided to use quantitative experimental research, where the tasks, the method of data collection and the method of data analysis are predefined, resulting in an experiment that can be replicated in the future. It will exist out of both an executable task and a questionnaire.

7.3. Population/sample

The ideal sample group would consist of medical personal, who are trained in the use of the original Veress Needle. This group is however very busy and at this phase it will most likely only give a small advantage, because the device only roughly resembles the Veress needle. Since the design is meant to be simple to use, it is deemed as acceptable when an easily available group of non-experienced users test the device. For this reason, ten university students have been asked at random to participate. This sample size is deemed to be enough based on the early phase of the design.

7.4. Data Collection Method

The tests will exist out of two parts. The first part is the loading of the device. Can this be done with a single movement and is it simple? The participants will be filmed, while reloading the device (Evaluation point one).

Secondly, the participants will be asked to place the prototype into the test stand and push it through the fabric material. This will be filmed and evaluated as well. (Evaluation point two and three).

After all the tests are done, the participants will be given a five point Likert scale questionnaire.

7.5. Data evaluation method

7.5.1. Scoring of evaluation points, the following scoring can be assigned, based on visual results and will be assigned by the observer.

1 Ease of reload

1: Requested researcher to help with reloading (after six seconds)

2: Took over six seconds to reload

3: Needed to push or pull somewhere

4: Needed two hands, but in a single motion

5: Can be done by single handed actioned

The second part to test are the three-phases of rest, active use, and decoupling.

2 Transitions from phase one to two.

Successful transition

Instant decoupling

Unforeseen event that needs explanation

3 Transitions from phase two to three

Successful decoupling

No decoupling

Overshoot, device decoupled, but is fully inserted into test stand

Unforeseen event that needs explanation

4 Questionnaire

The following questions are based upon a five-point Likert scale. The best to worst will be alternated between one to five and five to one, to exclude the possibility of a number bias. These questions will be filled in by the participant.

4.1 Did the device feel easy to reload?

4.2 Was it difficult to understand how to use the device?

4.3 Was it easy to understand how the device functions?

4.4 Were the instructions clear to you?

4.5 Do you feel this system works?

The last question is an open question

4.6 Is there anything you would like to see improve in this device?

7.5.2. Pass Criteria for evaluation points

Criterium 1 Ease of reload

Average scoring > 3.5

Criterium 2 Transition from phase one to two.

≥90% Successful

Criterium 3 transition from phase two to three

≥90% Successful

Criteria 4 Questionnaire

There is no hard pass/fail criterium in this, but it will be taken under consideration in the discussion afterwards.

7.6. Testing setup

As a test setting, a table is reserved. Placed on this table is a laptop, a box of fabric, the prototype and a small two-part 3D printed test cube, made from resin. This test cube (Figure 16) has a hole in the middle of it, when seen from the top. This hole is meant as access point for the prototype to be placed into. In between the top and bottom part, a piece of fabric (made of 75% viscose and 25% binder), can be spanned using four pointed extrusions from the top part, which are also used to hold the top part in place. The device can be placed in the hole in the top and pushed through the fabric.

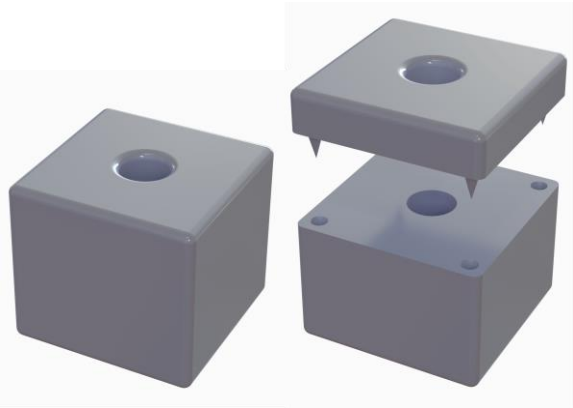


Figure 16: Test stand

7.7. Task execution

(See Flowchart 1) The participant is lead to the testing table. Here they will fill in some demographic data and sign an informed consent form acknowledgement that they agree to the test and the risk involved including their right to stop the test without any consequence. They will also be notified that they can contact the researcher at any time and request for their data to be deleted if so desired. Afterwards they will get the following explanation of the device:

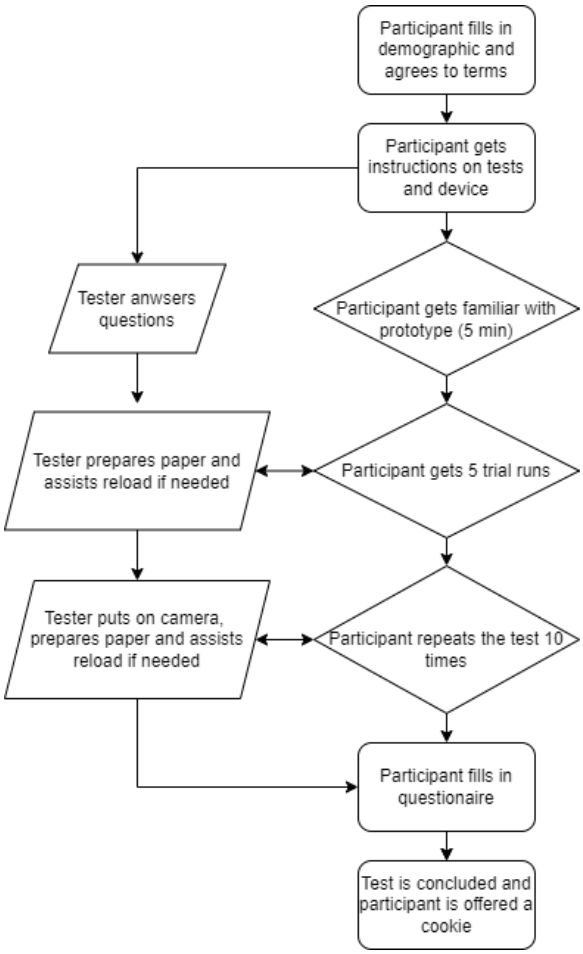
"This is a decoupling system, meant to be implemented in a Veress Needle. A Veress Needle is a first access device in minimal invasive surgery and is used to insufflate the body. At this phase, the prime functions of the decoupling system are being tested to see if it is easy to use, in both its reloading and decoupling capabilities. To test this, we will first show you how the device is used and then give you five minutes to play with it. Afterwards you will get five practice attempts to reload the device and then push it into the test stand. After these, you will have ten repetitions, which will be filmed and used to collect or final data. After the ten repetitions you will be asked to answer six questions, reflecting your experience with the prototype. Have you understood so far or would you like me to repeat something?"

"We will continue the explanation on how the prototype works. The metal part exists out of a inner tube and outer tube, where the rounded tip at the bottom extrudes past the sharp edge of the outer tube. When pressed against something, the inner tube will move up, which will bring these small bars halfway up as well. When the needle cuts through the barrier, the inner tube will be released again moving the small bars back down. The plastic transparent cylinder is the handhold that you will be using and slides over the metal cylinders. As you can see, here the handhold has a metal pin in it. To reload the device, you are meant to bring the metal pin all the way to the top here and then place it next to the first metal bar. The device is now loaded and ready to be used. When during use, the bars move up the metal cylinder will turn inside the handhold. And when the bars move downwards the handhold will be released. Try to hold the handhold in such a way, that the metal pin is visible and aimed at the camera during each step to ensure visibility of the process. Do you have any questions?"

During the second part of this explanation, the prototype will be used to clarify the explanation given.

"We will continue the explanation on how the prototype works. The metal part exists out of an inner tube and outer tube, where the rounded tip at the bottom extrudes past the sharp edge of the outer tube. When pressed against something, the inner tube will move up, which will bring these small bars halfway up as well. When the needle cuts through the barrier, the inner tube will be released again moving the small bars back down. The plastic transparent cylinder is the handhold that you will be using and slides over the metal cylinders. As you can see here, the handhold has a metal pin in it. To reload the device, you are meant to bring the metal pin all the way to the top here and then place it next to the first metal bar. The device is now loaded and ready to be used. When during use the bars move up, the metal cylinder will turn inside the handhold. When the bars move downwards, the handhold will be released. Try to hold the handhold in such a way, that the metal pin is visible and aimed at the camera during each step to ensure visibility of the process. Do you have any questions?"

The prototype is then given to the participant to explore, and any subsequent questions are being answered in the following five minutes . Then they will be told to place the needle in the hole in the test setup, where they will have to push the cylinder down, holding a constant force that slowly builds up. They will notice a first movement as the needle turns into phase two and will be decoupled after they penetrate the paper. Alternative outcomes are an instant decoupling in the transition from phase one to two. Or a lack of decoupling from phase two to three.



Flowchart 1: Activities of participant and tester.

After five practice rounds, the subject will puncture ten times while being filmed. After this execution, the participant will be given some time to fill in the final questionnaire. As a thank you for participating they will be offered a cookie

8. Results

8.1. test results

Results are based on ten participants (N=10). A total of 99 tests where filmed (one video was corrupted). Only 62 tests successfully transitioned from phase one to phase two, thus, there were only 62 tests of the transition of phase two to phase three.

Table 4: Demographics

Demographic	
Male/Female	9/1
Age(max/average/min)	33/24.5/20
PHD	1
University Master	5
University Bachelor	2
MBO (Secondary vocational education)	2

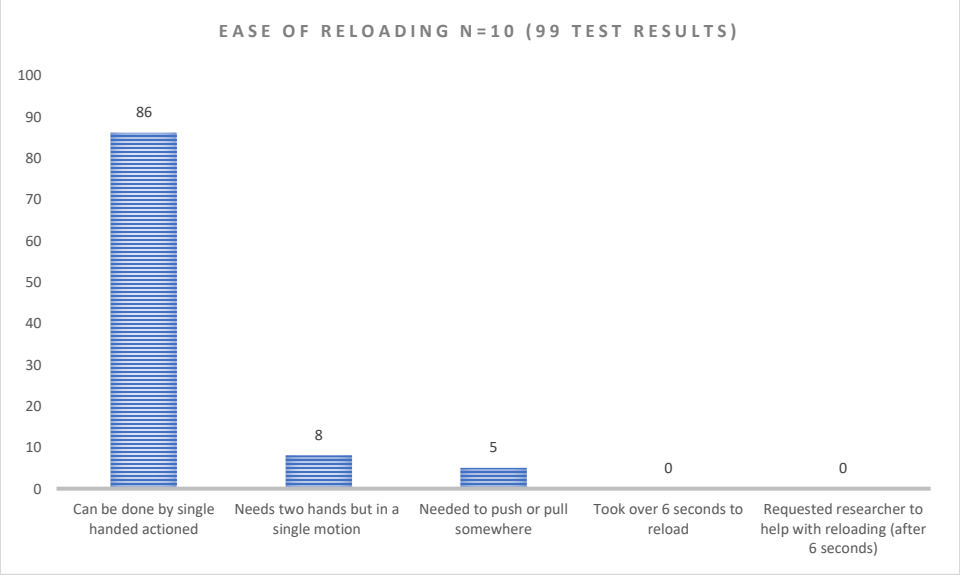


Figure 17: Ease of reloading results

Average ease of reloading = 4.82 (out of 5)

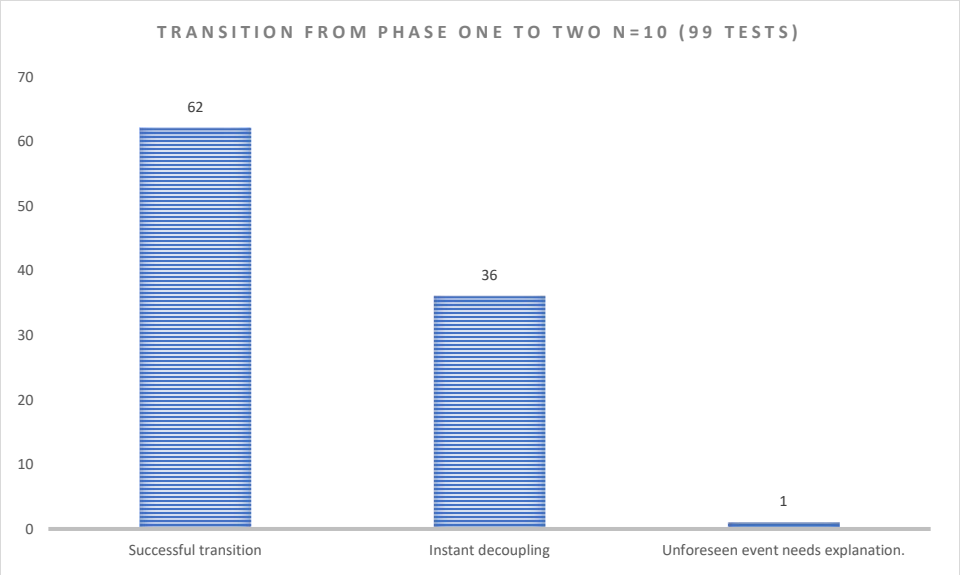


Figure 18: Transition phase one to two results

Percentage of success = 62.6

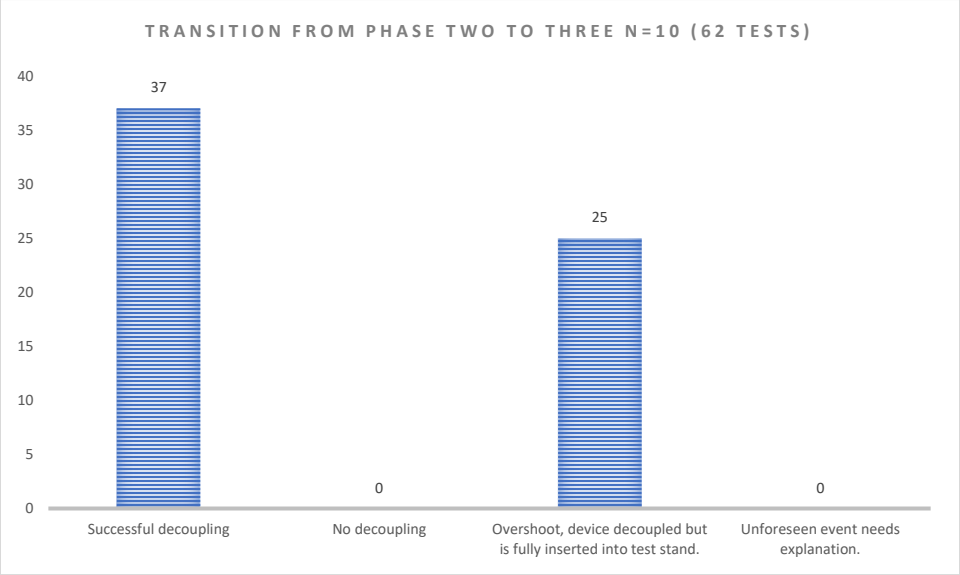


Figure 19: Transition phase two to three results

Percentage of success =59.7

Table 5: Five-point Likert scale answers and average

	1 (Not at all)	2	3	4	5 (very much)	Average
The device felt easy to reload	0	0	0	4	6	4.6
It was difficult to understand how to use the device	6	4	0	0	0	1.4
It was easy to understand how the device works	0	0	0	6	4	4.4
The instructions where clear to me	0	0	0	2	8	4.8
This system works well	0	0	3	4	3	4.0

8.2. Evaluation to criteria

Here the original evaluation criteria is measured to the standard, achieved by the tested design as can be seen in table 7. There are some sidenotes to give here. The general used material involves a plastic tube for the prototype, but this would be a metal tube for actual production. This will also bring the diameter back withing the desired range. The full device is also supposed to have a longer handhold, ensuring that there are no critical parts that can be held during operation.

Table 7: Design requirements, specifications and final result.

Design Requirements	Specifications	Achieved
Dimensional		
Length	≤ 110 mm	90 mm
Diameter	≤ 20 mm	16 mm
Material		
General material	Sterilizable materials	SAE 304 stainless steel
Flexible material	Sterilizable materials	Spring steel
Quality and reliability		
Uses (If properly maintained)	≥ 200 cycles ≥ 5 years	
Malfunctions	≤ VP	
Critical parts	No accessible critical parts during usage	
Design		
Cleanability	Must be possible to disassemble	
Actions to reload	1	1
complexity	≤ 5 parts	3 parts
Phases for decoupling	3	

8.3. Evaluation criteria elaborated

8.3.1. Dimensions.

The dimensions are well within the desired range.

8.3.2. Material

Using SAE 304 stainless steel and spring steel allows for the device to be both durable and sterilizable.

8.3.3. Quality and reliability

The device has either solid parts or springs, which will allow the system to be used past the desired specifications. The test show that the reliability of the system is not on parr with the Veress Plus. The critical parts are within the diameter of the handhold.

8.3.4. Design

It is possible to disassemble the prototype cleaning. There are no flexures used in the design. The tests conducted show it is easy to reload in a single movement. It only has three parts and the device decouples in three phases.

9. Discussion

In this chapter we will discuss the results of the experiments, the comparison to the original design criteria, feedback of test participants and advised changes to the future design, based on the testing experience.

9.1. Expected bias.

Looking at the Demography the participant group existed mostly out of males, around the age of 24.5 years and has a high education. All of these biases should mostly affect the reloading of the device, as this can be influenced by skill. The expected effect of these biases on the decoupling of the device is little.

9.2. Discussing test results

The device has shown a lot of its potential in the found results. The demographics show that the tests were done with a younger range of people then the intended user database. The results showed no difference in an education group, but was composed out of 90% males. These means that although both the practical results and the questionnaire show that the device is easy to use, it might be good to still test for this, if the device gets tested within its intended user group. User feedback shows that the device is simple in its working principle, but not all users considered the device to work well. Looking at the results of using the device where each phase had a ~60% of success (resulting in 36% perfect functionality). It can be seen that the questionnaire does not reflect the actual results. Within the first 4 questions, it can be explained as the questionnaire reflects the user experience more than the results achieved. Looking at the functionality of the system, the success cannot be seen as a coincidence. However looking at the overall success rate, the device is not reliable. Likely, the slope of the diagonal plane on the middle canula and the size of the second stopper on the stylet, will change the success rate. The transition between phase one and two is tightly linked to the length of the second stopper. The transition between phase two and three might be a more delicate matter as it is tightly linked to friction as well. This is related to the overall design as can be found in the appendix.

Open feedback

Personal feedback of the users mostly covered the handhold being user unfriendly at this time and not actually covering the inner system. They desired a bigger handhold with a more ergonomic grip.

9.3. Future work and recommendations

During testing, it was found out that the design path had left an error when it transitioned from the original design to the prototype. Rapid prototyping was used implementing 3D printing and this meant some changes were made, but were not turned back when transitioning back to machining. The second stop which was made smaller to facilitate functionality despite the increased friction, found in between plastic components compared to steel components, was left in place Figure 20. This might very well be an explanation for why the phase one to two transition scored lower than expected and it is advised to lengthen this again, to be in line with the general slope. The transition from phase two to phase three is however the final

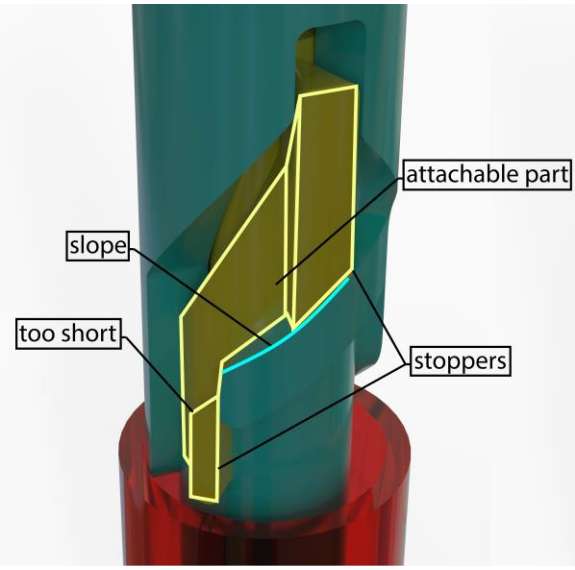


Figure 20: zoomed view of clicker system

most crucial aspect of the device, as it actually decouples the user preventing it from doing damage. When the device did not work, it could be seen on the video that the yellow stylet and blue needle did not turn inside the red handle. This can be improved in several aspects.

Ways to improve phase one to two transition

- **Slope:** Increasing the slope of the pathway ,created by the stylet and needle, giving more resulting turning force,
- **Spring:** placing a spring in, between the handhold and the needle, creating internal force that pushes the needle to turn easier in the handhold (a feature that existed in the original design but was excluded going into the test instrument).
- **Friction:** Reduce friction in the device, allowing the diagonal force from the handhold, to turn the rest of the device.

To reduce friction in the device, there are two aspects already found at this time. One design aspect that was encountered to have undesired results, was the inner stylet consisting out of two parts, being one cylinder and a small attachable part, which can be screwed on (Another design flaw added in the transition to the test instrument). During operation, the attachable part on the inner stylet was being pushed away by the middle canula and the screw that held the two together was not able to resist all the forces, allowing for undesirable movement in the system and causing additional friction. The second easier solution to reduce internal friction, is to make the device longer than the prototype. This second part should already happen in the original design. The last method to reduce internal friction, which might be considered, is to make the forces more symmetrical by putting a pin on the second side of the handhold and mirroring the pathway to the other side of the stylet and needle (In this case Figure 20 would look the same when looked at from the back). Most of these design flaws have entered the device, during the conversion from the original design to the Test instrument.

10. Conclusion

The overall goal of this research was: *The design, development and validation of an improved decoupling device for the Veress needle, that is less vulnerable to finger positioning during use and easier to reload.*

The pen inspired clicker system showed the most potential of the different designs. This design fulfills part of the original goal of the research, but its test prototype brought to light, that it needs further development to reach a higher reliability and several methods to improve this have been identified. The test however, gives no guarantee that it will equal or surpass the reliability of the Veress Plus.

Appendix 1 Forces and their locations

To fully understand the prototype, it is important to analyze the forces that work on the parts, during the different phases of the device. Since the decoupled phase holds no more forces, it will be left out. Each phase will be analyzed in a static state and then hypothesized what will happen when it becomes dynamic. These static phases are visualized in Figure 21. In that figure, the desired forces that are supportive to the design are colored red and the extra reactive forces are colored blue. Most of the blue forces shown, are forces that create extra amounts of friction. Every force F also has a distance to the origin L. For ease of calculation, F1 and F2 forces are considered pure negative Z forces (0,0,F1 and 0,0,F2 where x,y,z) and have a distance from the origin (L1x,0,0 and L2x,0,0). Forces F3 and F4 on the handhold Pin, are considered to have a distance to the origin (0,L3y,0 and 0,L4y,0). During use, the handhold should not turn, but instead the needle and stylet should turn in the handhold. This base assumption will be used in both phases. Corners will also be indicated as the same number as the force, hence the corner in which force F4 enters is Alpha4 (0,α4,0), which is in this case a corner around the Y axis. Forces that are related, have the same number in between parts. So a force present in both the handhold and the needle are called F4 and F4' subsequently.

A breakdown of the forces and location of forces displayed in Figure 21.

$$F_1 = 0,0,F_1 \quad L_1 = L_1,0,0$$

$$F_2 = 0,0,F_2 \quad L_2 = L_2,0,0$$

$$F_3 = -F''_3 = F_3,0,0 \quad L_3 = L'_3 = 0,L_{3y},0$$

$$F_4 = -F'_4 = cos(\alpha_{4x})F_4,0,cos(\alpha_{4z})F_4 \quad L_4 = L'_4 = 0,L_{4y},0$$

$$F_5 = -F'_5 = 0,F_5,0 \quad L_5 = L'_5 = 0,L_{5y},L_{5z}$$

$$F'_{5.1} = -F''_{5.1} = 0,F'_{5.1},0 \quad L'_{5.1} = -L''_{5.1} = 0,L'_{5.1y},L'_{5.1z}$$

$$F_6 = -F'_6 = 0,F_6,0 \quad L_6 = L'_5 = 0,L_{6y},L_{6z}$$

$$F'_{6.1} = -F''_{6.1} = 0,F'_{6.1},0 \quad L'_{6.1} = -L''_{6.1} = 0,L'_{6.1y},L'_{6.1z}$$

$$F'_7 = -F''_7 = 0,0,F'_7 \quad L'_7 = L''_7 = 0,0,L'_{7z}$$

$$F'_8 = -F''_8 = \cos(\alpha_{8x})F'_8,\cos(\alpha_{8y})F'_8,0 \quad L'_8 = L''_8 = L'_{8x},L'_{8y},L'_{8z}$$

$$F'_9 = -F''_9 = \cos(\alpha_{9x})F'_9,\cos(\alpha_{9y})F'_9,\cos(\alpha_{9z})F'_9 \quad L'_9 = L''_9 = L'_{9x},L'_{9y},L'_{9z}$$

$$F''_{10} = 0,0,F''_{10} \quad L_{10} = 0,0,L_{10z}$$

$$F_{11} = 0,0,F_{11} \quad L_{11} = L_{11x},0,0$$

$$F_{12} = 0,0,F_{12} \quad L_{12} = L_{12x},0,0$$

$$F_{13} = -F''_{13} = F_{13},0,0 \quad L_{13} = L'_{13} = 0,L_{13y},0$$

$$F_{14} = -F'_{14} = cos(\alpha_{14x})F_{14},0,cos(\alpha_{14z})F_{14} \quad L_{14} = L'_{14} = 0,L_{14y},0$$

$$F_{15} = -F'_{15} = 0,F_{15},0 \quad L_{15} = L'_{15} = 0,L_{15y},L_{15z}$$

$$F'_{15.1} = -F''_{15.1} = 0,F'_{15.1},0 \quad L'_{15.1} = -L''_{15.1} = 0,L'_{15.1y},L'_{15.1z}$$

$$F_{16} = -F'_{16} = 0,F_{16},0 \quad L_{16} = L'_{15} = 0,L_{16y},L_{16z}$$

$$F'_{16.1} = -F''_{16.1} = 0,F'_{16.1},0 \quad L'_{16.1} = -L''_{16.1} = 0,L'_{16.1y},L'_{16.1z}$$

$$F'_{17} = -F''_{17} = 0,0,F'_{17} \quad L'_{17} = L''_{17} = 0,0,L'_{17z}$$

$$F'_{18} = -F''_{18} = \cos(\alpha_{18x})F'_{18},\cos(\alpha_{18y})F'_{18},0 \quad L'_{18} = L''_{18} = L'_{18x},L'_{18y},L'_{18z}$$

$$F'_{19} = -F''_{19} = \cos(\alpha_{19x})F'_{19},\cos(\alpha_{19y})F'_{19},\cos(\alpha_{19z})F'_{19} \quad L'_{19} = L''_{19} = L'_{19x},L'_{19y},L'_{19z}$$

$$F''_{20} = 0,0,F''_{20} \quad L_{20} = 0,0,L_{20z}$$

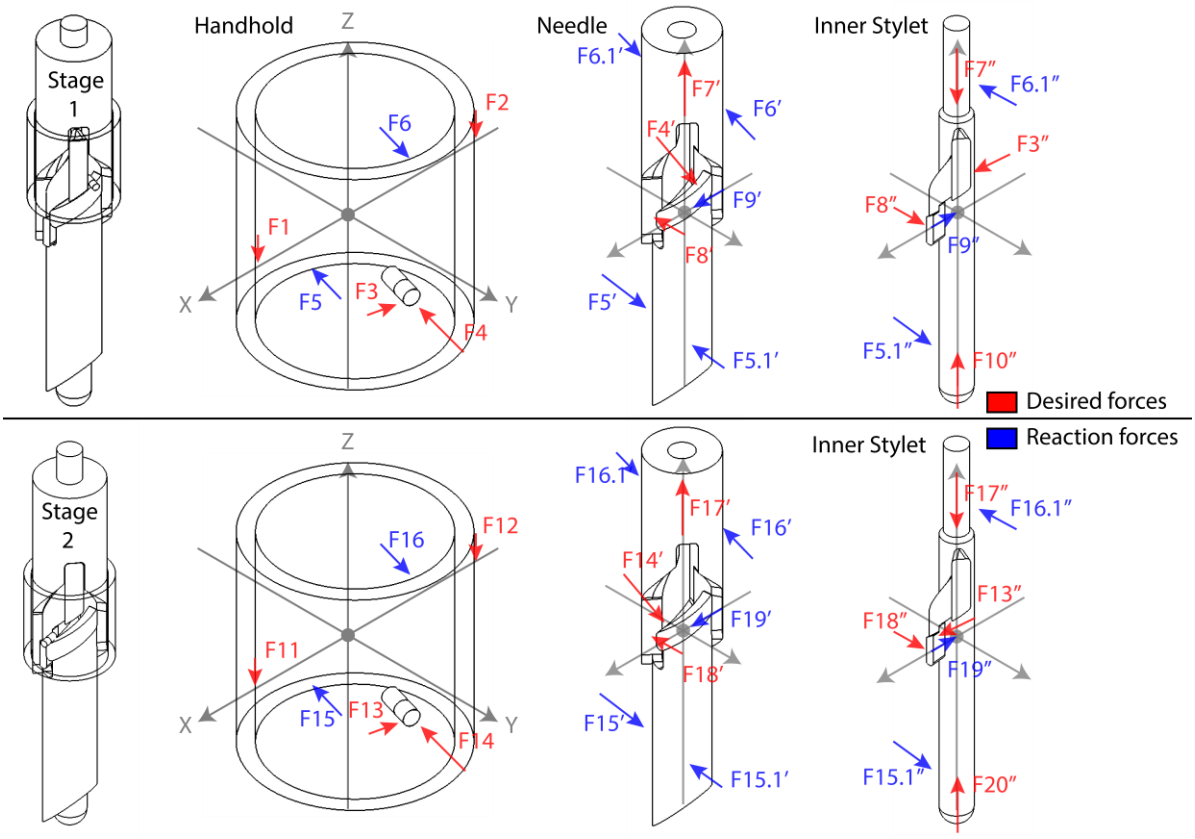


Figure 21: First and second phase with forces for each individual parts.

There is the following force and momentum balances.

Phase 1 Handhold

Equation 1 $F_x = F_3 + cos(\alpha_{4x})F_4$

Equation 2 $F_y = F_5 + F_6$

Equation 3 $F_z = F_1 + F_2 + cos(\alpha_{4z})F_4$

Equation 4 $M_i = L_{4y}cos(\alpha_{4y})F_4 - L_{5z}F_5 - L_{6z}F_6$

Equation 5 $M_j = -L_{1x}F_1 - L_{2x}F_2$

Equation 6 $M_k = -L_{3y}F_3 - L_{4y}cos(\alpha_{4x})F_4$

Phase 1 Needle

Equation 7 $F_x = cos(\alpha_{4x})F'_4 + cos(\alpha_{8x})F'_8 + cos(\alpha_{9x})F'_9$

Equation 8 $F_y = F'_5 + F'_{5.1} + F'_6 + F'_{6.1} + cos(\alpha_{8y})F'_8 + cos(\alpha_{9y})F'_9$

Equation 9 $F_z = cos(\alpha_{4z})F'_4 + F'_7$

Equation 10 $M_i = L_{4y}cos(\alpha_{4z})F'_4 - L'_{5z}F'_5 - L'_{5.1z}F'_{5.1} - L'_{6z}F'_6 - L'_{6.1z}F'_{6.1} - L'_{8z}cos(\alpha_{8y})F'_8 + + L'_{9z}cos(\alpha_{9y})F'_9$

Equation 11 $M_j = L'_{4x}cos(\alpha_{4z})F'_4 - L'_{4z}cos(\alpha_{4x})F'_4 + L'_{4z}cos(\alpha_{8x})F'_8 + L'_{4z}cos(\alpha_{9x})F'_9$

Equation 12 $M_k = L'_{8x}cos(\alpha_{8y})F'_8 + L'_{9x}cos(\alpha_{9y})F'_9 - L'_{4y}cos(\alpha_{4x})F'_4 - L'_{8y}cos(\alpha_{8x})F'_8 - L'_{9y}cos(\alpha_{9x})F'_9$

Phase 1 Stylet

Equation 13 $F_x = F''_3 + cos(\alpha_{8x})F''_8 + cos(\alpha_{9x})F''_9$

Equation 14 $F_y = F''_{5.1} + F''_{6.1} + \cos(\alpha_{8y})\, F''_8 + cos(\alpha_{9y})F''_9$

Equation 15 $F_z = F''_7 + F''_{10}$

Equation 16 $M_i = -L''_{5.1z}F''_{5.1} - L''_{6.1z}F''_{6.1} - L''_{8z}\cos(\alpha_{8y})\, F''_8 - L''_{9z}cos(\alpha_{9y})F''_9$

Equation 17 $M_j = L''_{3z}F''_3 + L''_{8z}cos(\alpha_{8x})F''_8 + L''_{9z}cos(\alpha_{9x})F''_9$

Equation 18 $M_k = F''_{8x}\cos(\alpha_{8y})F''_8 + F''_{9x}cos(\alpha_{9y})F''_9 - L''_3F''_{3y} - L''_{8y}cos(\alpha_{8x})F''_8 - L''_{9y}\ cos(\alpha_{9x})F''_9$

Phase 2 Handhold

Equation 19 $F_x = F_{13} + cos(\alpha_{14})F_{14}$

Equation 20 $F_y = F_{15} + F_{16}$

Equation 21 $F_z = F_{11} + F_{12} + cos(\alpha_{14z})F_{14}$

Equation 22 $M_i = L_{14y}cos(\alpha_{14z})F_{14} - L_{15z}F_{15} - L_{16z}F_{16}$

Equation 23 $M_j = -L_{11x}F_{11} - L_{12x}F_{12}$

Equation 24 $M_k = L_{15x}F_{15} + L_{16x}F_{16} - L_{13y}F_{13} - L_{14y}cos(\alpha_{14})F_{14}$

Phase 2 Needle

Equation 25 $F_x = cos(\alpha_{14x})F'_{14} + cos(\alpha_{18x})F'_{18} + cos(\alpha_{19x})F'_{19}$

Equation 26 $F_y = F'_{15} + F'_{15.1} + F'_{16} + F'_{16.1} + cos(\alpha_{18y})F'_{18} + cos(\alpha_{19y})F'_{19}$

Equation 27 $F_z = cos(\alpha_{14z})F'_{14} + F'_{17}$

Equation 28 $M_i = L'_{14y}cos(\alpha_{14z})F'_{14} - L'_{15z}F'_{15} - L'_{15.1z}F'_{15.1} - L'_{16z}F'_{16} - L'_{16.1z}F'_{16.1} - L'_{18z}cos(\alpha_{18y})F'_{18} - L'_{19z}cos(\alpha_{19y})F'_{19}$

Equation 27 $M_j = L'_{14z}cos(\alpha_{14x})F'_{14} + L'_{18z}cos(\alpha_{18x})F'_{18} + L'_{19z}cos(\alpha_{19x})F'_{19} - L'_{14x}cos(\alpha_{14z})F'_{14}$

Equation 28 $M_k = L'_{18x}cos(\alpha_{18y})F'_{18} + L'_{19x}cos(\alpha_{19y})F'_{19} - L'_{14y}cos(\alpha_{14x})F'_{14} - L'_{18y}cos(\alpha_{18x})F'_{18} - L'_{19y}\ cos(\alpha_{19x})F'_{19}$

Phase 2 Stylet

Equation 29 $F_x = F''_{13} + cos(\alpha_{18x})F''_{18} + cos(\alpha_{19x})F''_{19}$

Equation 30 $F_y = F''_{15.1} + F''_{16.1} + \cos(\alpha_{18y})F''_{18} + cos(\alpha_{19y})F''_{19}$

Equation 31 $F_z = F''_{17} + F''_{20}$

Equation 32 $M_i = -L''_{15.1z}F''_{15.1} - L''_{16.1z}F''_{16.1} - L''_{18z}\cos(\alpha_{18y})F''_{18} - L''_{19z}cos(\alpha_{19y})F''_{19}$

Equation 33 $M_j = L''_{13z}F''_{13} + L''_{18z}cos(\alpha_{18x})F''_{18} + L''_{19z}cos(\alpha_{19x})F''_{19}$

Equation 34 $M_k = L''_{15.1x}F''_{15.1} + L''_{16.1x}F''_{16.1} + L''_{18x}\cos(\alpha_{18y})F''_{18} + L''_{19x}cos(\alpha_{19y})F''_{19}$

It can be seen that the formula's for both phases don't change. For this reason we will only solve for the first phase.

To solve for all

$F_1 = F_2 = user\ force$

$F_3 = -F'_3 = -cos(\alpha_{4x})F_4$

$F_4 = -F'_4 = -\frac{F_1+F_2}{cos(\alpha_{4z})}$

$\alpha_{4z}\ \&\ \alpha_{4x} = Design\ choice$

$F_5 = -F'_5 = -F_6$

$F'_{5.1} = -F''_{5.1} = -F'_5 - F'_6 - F'_{6.1} - cos(\alpha_{8y})F'_8 - cos(\alpha_{9y})F'_9$

$F_6 = -F'_6 = -\frac{L_{4y}cos(\alpha_{4y})F_4}{(L_{5z}-L_{6z})}$

$F'_{6.1} = -F''_{6.1} = \frac{L_{4y}cos(\alpha_{4z})F'_4 - L'_{5z}F'_5 - L'_{5.1z} - L'_{5.1z}F'_5 - L'_{5.1z}F'_6 - L'_{5.1z}cos(\alpha_{8y})F'_8 - L'_{5.1z}cos(\alpha_{9y})F'_9 - L'_{6z}F'_6 - L'_{8z}cos(\alpha_{8y})F'_8 + + L'_{9z}cos(\alpha_{9y})F'_9}{(L'_{5.1z}+L'_{6.1z})}$

$F'_7 = -F'_7 = F'_{10} = -cos(\alpha_{4z})F'_4 = -2F_1$

$F'_8 = -F''_8 = \frac{-cos(\alpha_{4x})F'_4 - cos(\alpha_{9x})F'_9}{cos(\alpha_{8x})}$

$F'_9 = F''_9 = \frac{-\left(L'_{8y}cos(\alpha_{4x}) - L'_{8x}cos(\alpha_{8y})\frac{cos(\alpha_{4x})}{cos(\alpha_{8x})} - L'_{4y}cos(\alpha_{4x})\right)}{(-L'_{8x}cos(\alpha_{8y})\frac{cos(\alpha_{9x})}{cos(\alpha_{8x})} + L'_{9x}cos(\alpha_{9y}) + L'_{8y}cos(\alpha_{9x}) - L'_{9y}cos(\alpha_{9x}))F'_9}F'_4$

Forces desired to be minimized as they are causing additional friction

$$F'_5, F'_{5.1}, F_6, F_{6.1}$$

Appendix 2 questionnaire

Gender:

Age:

What is the highest form of study you have done (or are doing):

During this study your hands will be filmed during the experiments to collect data. Do you agree in participating in this study and with that to be filmed. You can request any data of yours to be deleted at a later date. please type" I [Name] herewith agree to the terms of this study, knowing both data and visual material will be used" :

5 point Likert scale questions

	1 (not at all)	2	3	4	5 (very much)
The device felt easy to reload					
It was difficult to understand how to use the device					
It was easy to understand how the device works					
The instructions where clear to me					
This system works well					

Is there anything you would like to see improve in this device?:

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