REPORT

DESIGN OF A DEPLOYER DEVICE FOR ENDORETRACTOR

INDUSTRIAL DESIGN PROJECT II
IDP 602

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INTRODUCTION

Fig. A.1: The gallbladder seperated from the body and the bile stones.
Source: *Self Photograph, Shashwat Hospital, Pune.*

A.1 | INTRODUCTION

During a laparoscopic Cholecystectomy, traditionally four incisions are made. One for the Laparoscope, two ports are the operating ports and one port is to hold the gallbladder to expose the Calot's Triangle that needs to the Cauterized to separate the gallbladder from the liver. Endoretractor was designed by Lata Chawla, with BETiC and under the guidance of Dr. Rasik Shah to hold the gallbladder in place. This device eliminated one port and human assistance required during the surgery.

As the Endo retractor in itself is an innovative design there were no specific devices used to deploy it. A crude set of devices and a lengthy procedure was used to test and validate the device. As the device is soon to be launched into the market, the need to have a sophisticated deployer device arose.

A.2 | LAPAROSCOPY: CURRENT SCENARIO

Laparoscopy is also known as Minimal invasive surgery or as keyhole surgery. In this small incisions are made and the internal organs are viewed using a light and camera (laparoscope) which is inserted through the incision. Different tools are also inserted through the incisions to operate on the internal organs.

There has been a major shift towards Laparoscopic surgery from Open surgery due to the multiple benefits that it comes with. Apart from being less painful for the patient, it also reduces the chance of infection and reduces the procedure time. It is also beneficial as it leaves very tiny visible scars, and the recovery time of the patient is also reduced.

Due to constant innovation this field is evolving very fast, and the goal is to have safe and effective procedures with minimal invasion.

Fig. 1: The image shows the incisions made during a laparoscopic cholecystectomy.

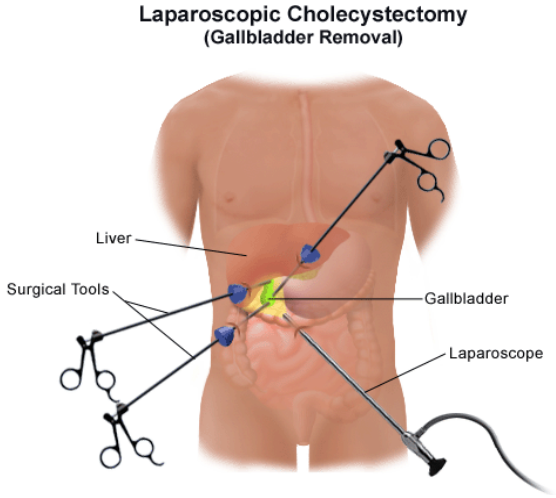


Fig. A.2: A regular set up for a Cholecystectomy.
Source: https://www.elcaminohospital.org/sites/ech/files/library_images/126078.gif, 21/11/2016 : 12:53PM

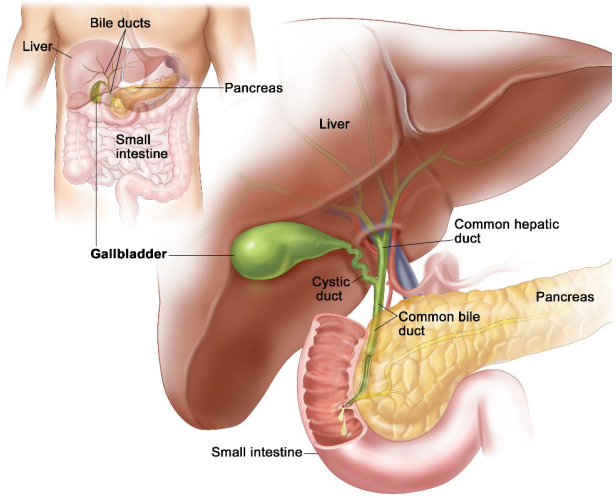


Fig. A.3: Anatomy of a gallbladder
Source: https://www.cancer.gov/images/cdr/live/CDR658899.jpg, 21/11/2016 : 12:53PM

A.3 | GALLBLADDER

Gallbladder is a small pear shaped organ which is attached to the liver. It is responsible for storing and releasing the bile secreted by the liver into the intestine periodically.
The overall dimensions of the gallbladder are approximately 80 mm length and 40 mm diameter. In case of bile stones or cancer of the gallbladder, there arises a need to remove the gallbladder. The human can survive without the gallbladder.

The procedure to surgically remove the gallbladder is called as
cholecystectomy.

A.4 | CHOLECYSTECTOMY

Surgical removal of the gallbladder is called as the cholecystectomy. These days the procedure is performed laparoscopically, and take about an hour and a half depending on the level of complication.

The basic steps involved in the procedure are as follows:

1. The incisions are made on the abdomen and ports are inserted. Port 1,is a 10 mm port for laparoscope, Port 2 and 3 are 10 mm and 5 mm ports respectively for the grasper and other operating tools. Port 4 is a 5 mm port to hold the gallbladder to expose the Calot's triangle.
2. The Gallbladder is lifted using a grasper inserted through Port 4 to expose the Calot's triangle.
3. The tissue is cauterized to expose the Cystic duct and the artery. The artery and cystic duct are clamped and then cut.
4. The gallbladder is then further separated from the bottom part of the liver using cauterization.
5. The separated organ is taken out from the body and the incisions are sutured.

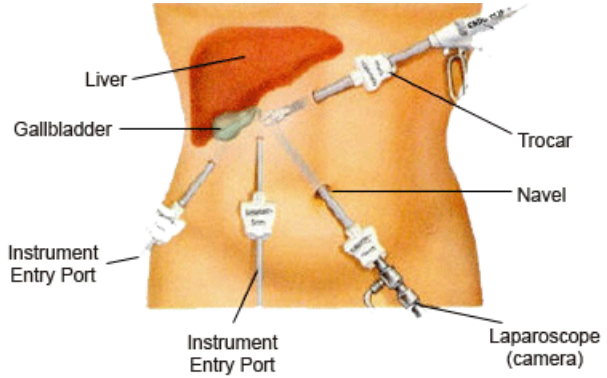


Fig. A.4: The positioning of the ports.
Source: http://www.thelaparoscopicsurgeon.in/wp-content/uploads/2015/01/Laparoscopic_Surgery_to_Remove_Gallbladder-Dr_Phillips_General_Surgery_Associates1.gif, 21/11/2016 : 01:03 PM

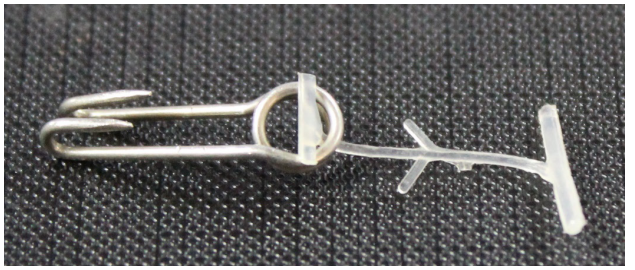


Fig. A.5: Endo retractor
Source: Photograph by Lata Chawla

A.5 | ENDORETRACTOR

Endoretractor is a device designed by Lata Chawla. It is a device that holds the gall bladder to expose the Calot's triangle. The device is inserted into the gallbladder and then hooked onto the peritoneum (inner abdominal wall) to lift the gallbladder. This was taken as a taken as a starting point for this project. The device has been tested and patented and thus no changes were made in this device.

This device eliminates the need for an additional incision and in turn human assistance. The device thus reduces the chance of infection, human error and cost and manpower required during the operative.

Also, as we are moving very swiftly towards single port surgery, this device is a huge advantage.

A.6 | CURRENT DEVICE

As the device is new, a very crude deployment device is used. A set of the following devices are used currently:

Trocar
Needle with a plunger
A grasper
Endoretractor

There is a very strict dimensional constraint as the largest trocar is 10 mm diameter. To fit in the multiple devices through it and to operate them simultaneously is a very difficult task.

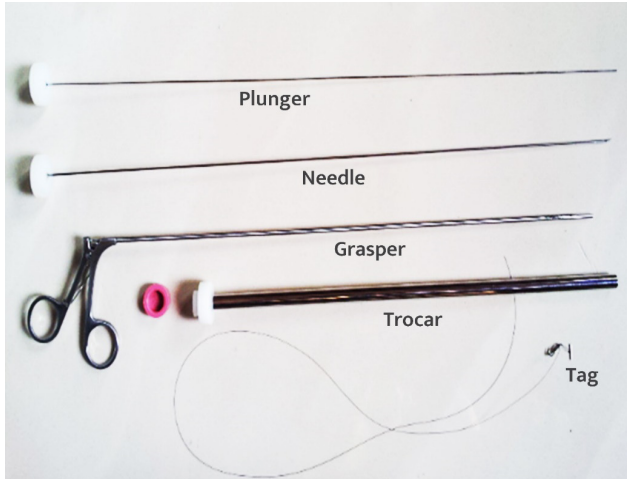


Fig. A.6: Devices used currently to deploy the tag and the hook.
Source: Photograph by Lata Chawla

A.7 | NEED FOR A NEW DEPLOYER

The current process used to deploy the Endoretractor is complicated and time consuming. Its was basically a crude process developed to test the Endoretractor. There is no specifically designed device to perform the task.
There are more than 5 steps involved in deploying the endoretractor and two devices need to be used to perform the task. Operating two devices simultaneously from the same port is chaotic.
The accuracy of the devices is very less and its problematic to locate, stabilize and pierce the gallbladder as there is no stable base.
To ensure the success of the retractor a simple and easy to use deployer is essential.

B.

DATA COLLECTION

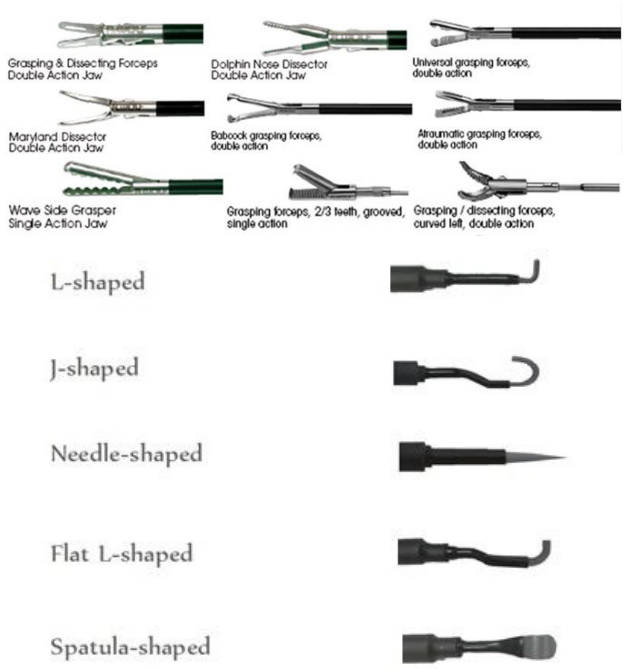


Fig. B.1: Different types of laparoscopic devices available in the market.
Source: http://www.laparoscopy.am/, 10/03/16

B.1 | MARKET STUDY

The most preliminary requirement for the project was understanding the endoretractor its use and understanding the basic anatomy of the human body. Also it was essential to study the laparoscopic procedure in detail in terms of the setting, the instruments, the interaction of the users with the devices, area mapping and the task allocation to the users.

Four incisions are made on the abdomen, carbon di oxide gas is inserted into the cavity to inflate it. Trocars and cannula are inserted through the incisions as guides for the operating instruments. The trocar has a membrane that acts as a barrier to not let the carbon di oxide gas leak out.

The first port is for the laparoscpe, the second and the third port are the operating ports, and the fourth port is used to hold the gallbladder to expose the Calot's triangle.

STUDY OF DEVICES AND HANDLES:

There are multiple types of devices used to perform different tasks. The devices are generally designed to be used through 5 mm to 10 mm diameter port. The length is according to the task they are designed for and usually range from 18 mm to 45 mm.

Different types of graspers, scissors, hooks for cauterization and retractors are currently available in the market. They come with various types of handles and mechanisms depending on the movement required and their use.

There are four major categories of handles used for these devices:

Shank Handle
Pistol Handle
Axial Handle
Rod Handle

Each handle has its own special use, but the pistol handle is the most commonly used.

The tasks to be performed require great precision as well as a stable grip on the device, thus it is crucial for the device to have a appropriate and good grip.

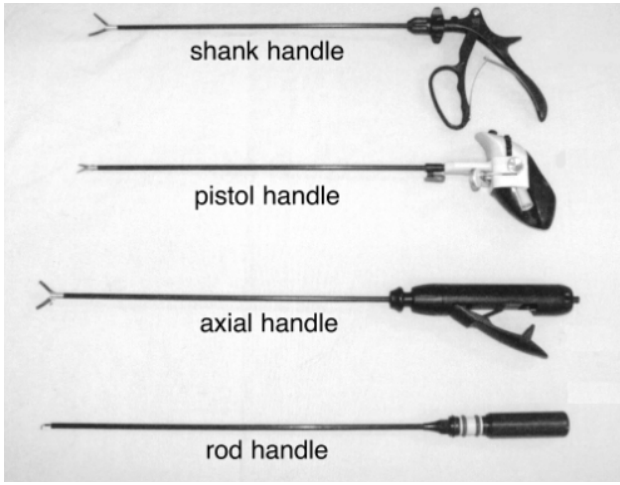


Fig. B.2: Different types of laparoscopic devices handles
Source: https://openi.nlm.nih.gov, 10/03/16

B.2 | USER STUDY

To get a better understanding of the process, it was necessary to observe a live surgery. Dr. Pushparaj Karmarkar, a senior surgeon and the chairman and managing director of Shashwat Hospital, in Pune with an experience of more than 27 years. I got to observe two cholecystectomy procedures performed by him. Even though it was a traditionally performed laparoscopic cholecystectomy, the insights about the procedure, the surgeons interaction with the tools and the assistants and the human involvement in the setup.

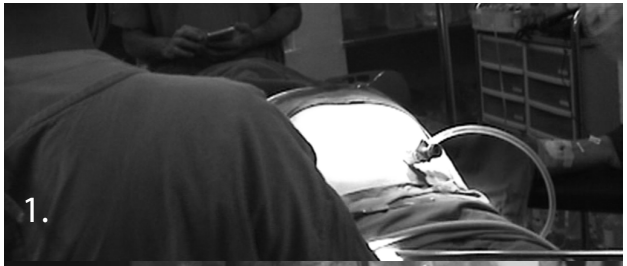


Fig. B.3: Images i.,2, 3. and 4. show the processes involved in attaching the ports
Source: Self photograph, Shashwat Hospital, Pune.

INSIGHTS

1. The surgery period is about 30 mins to 1 hour mostly.

2. A surgeon, and two assistants directly participate in the surgery, whereas an anesthetist, and two other assistants are also present in the operation theatre.

3. The surgeon, two assistants and the patient are all positioned in a 4 sq. feet area.

4. Operating in such a small space is very critical for the surgeon.

5. The instruments in the port 2 are changed frequently. Approximately 8- 10 times. This increases the time required for the surgery.

6. Port 4 is used only to hold the gallbladder in place. An assistant is engaged throughout the surgery to hold the grasper.

7. Operating while viewing the image on the screen is a difficult task and keeping the instrument simple to use is very essential.

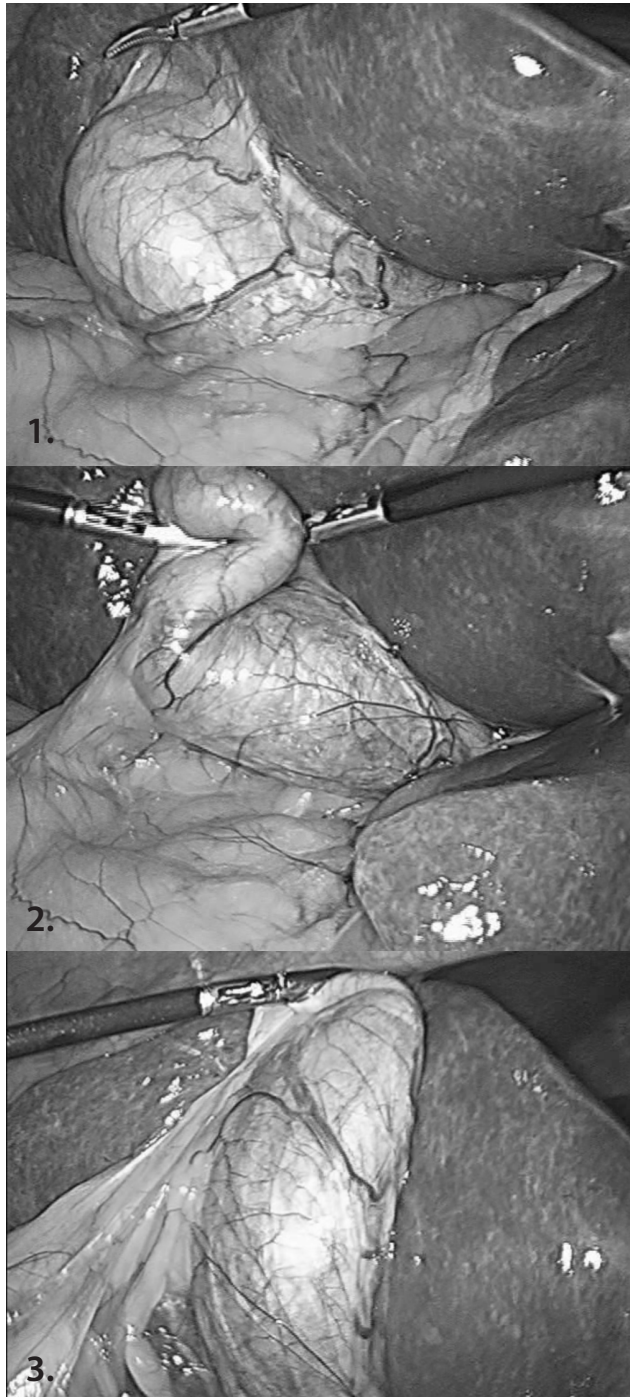


Fig. B.4: The images on the left are of the first operative surgery observed.
Source: Laparoscope Photography, Shashwat Hospital, Pune

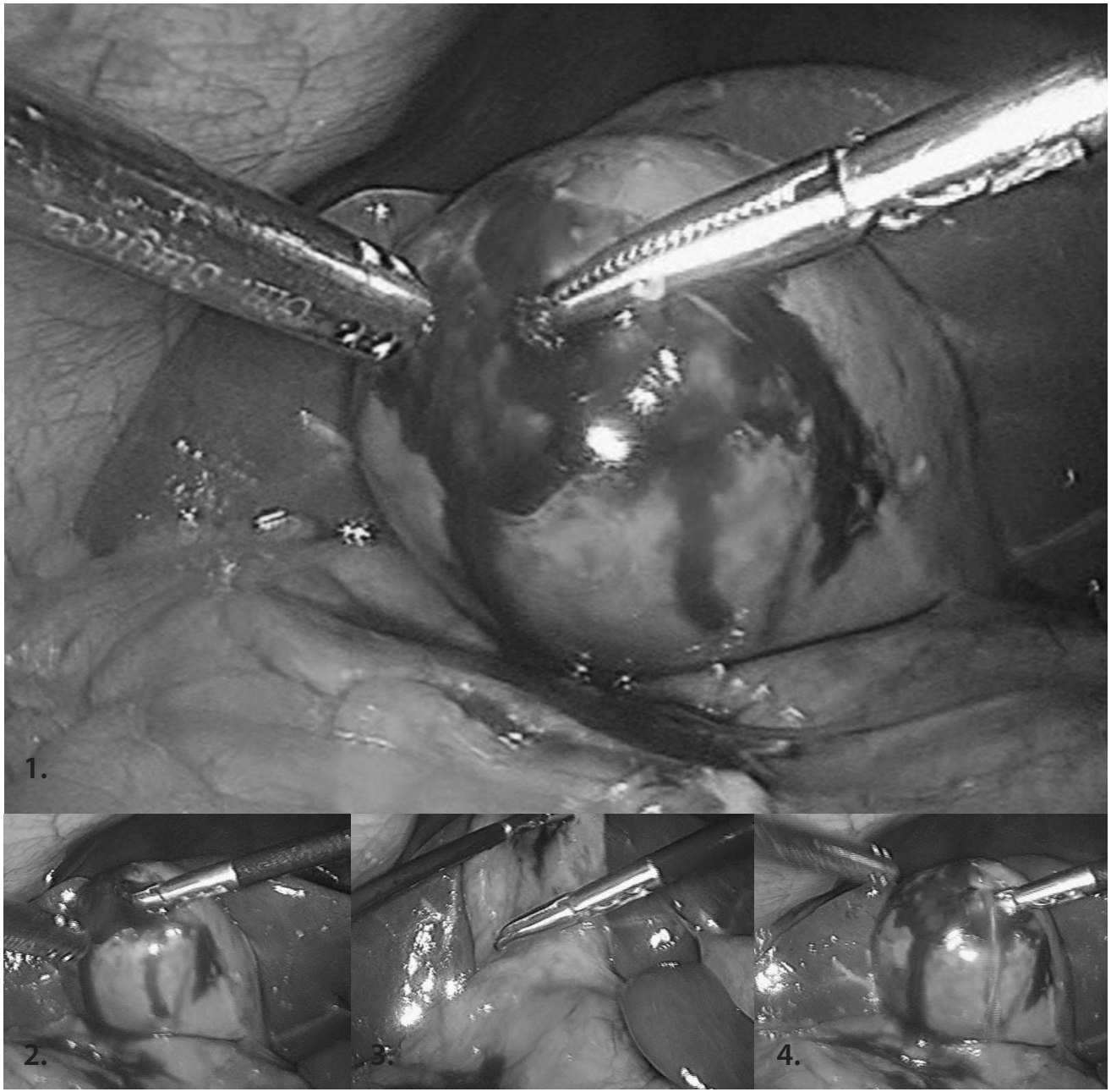


Fig. B.5: The images on the top are of the second operative surgery observed.
Source: Laparoscope Photography, Shashwat Hospital, Pune

B.3 | ERGONOMIC PRINCIPLES

Principles for designing multifunctional hand tools:

1. The operator should not have to observe the controls to operate it.

2. The hand should remain in contact with the primary controls throughout the critical operations of the system.

3. The operator should be able to activate the auxiliary controls without losing the physical contact with the primary controls.

4. The force required to operate the trigger should be less than 1/4th of the maximum force the fingers are able to generate.

B.4 | ANTHROPOMETRIC DATA

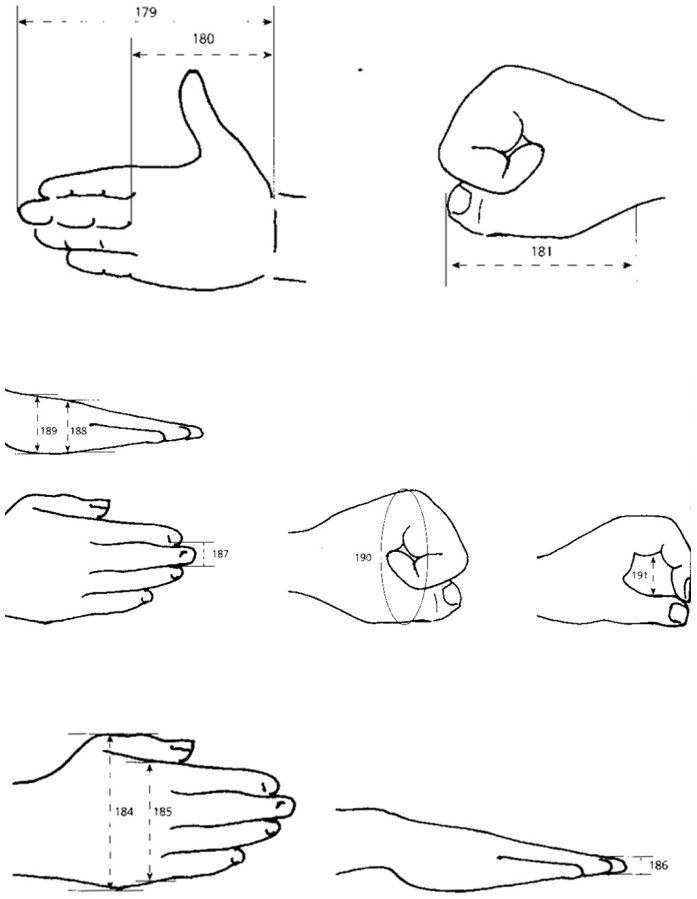


Fig. B.5: Anthropometric dimensions of a hand
Source: Indian Anthropometric Dimensions, Debkumar Chakrabarty, 1997

R.No.	Parameters		Min	Percentiles 5th	25th	50th	75th	95th	Max	Mean	±SD	Ratio
187	**Finger-tip breadth**	Male	13	13	14	15	16	17	20	16	1	0.01
		Female	10	11	12	12	13	15	16	13	1	0.01
		Combined	10	12	13	14	15	17	20	15	2	0.01
191	**Grip inside diameter, maximum**	Male	39	42	46	49	51	56	60	50	4	0.03
		Female	39	40	42	46	49	52	57	47	5	0.03
		Combined	39	41	46	49	51	56	60	49	4	0.03
185	**Hand breadth without thumb at metacarpal**	Male	60	72	77	81	85	90	100	82	6	0.05
		Female	60	66	69	71	75	79	92	73	5	0.05
		Combined	60	68	74	79	84	90	100	80	7	0.05
186	**Finger-tip depth**	Male	10	11	12	13	14	15	18	14	1	0.01
		Female	8	8	9	10	11	13	15	11	1	0.01
		Combined	8	10	12	13	14	15	18	14	2	0.01
180	**Palm length**	Male	86	92	99	103	107	114	176	104	8	0.06
		Female	84	86	91	94	97	103	113	95	5	0.06
		Combined	84	89	96	101	106	114	176	103	8	0.06
181	**Fist length**	Male	73	85	93	99	105	115	127	101	9	0.06
		Female	52	61	87	93	101	106	117	92	13	0.06
		Combined	52	81	92	98	104	115	127	99	11	0.06

180	**Palm length**	Distance from the base of the palm to the base of the middle finger (at the palmar surface).
181	**Fist length**	Length of the hand grip in the same line of the long axis of the hand from the base of the palm to the tip of the fist, wherever found.
185	**Hand breadth, without thumb, at metacarpal**	Maximum breadth across the palm at the distal ends of the metacarpal bones (where the fingers join the palm) of the index and the little finger.
186	**Finger-tip depth**	Maximum distance between the dorsal and the palmar surfaces of the tip of the middle finger.
187	**Finger-tip breadth**	Maximum distance across the lateral surfaces of the tip of the middle finger.
191	**Grip inside diameter, maximum**	Maximum inside grip diameter, measured by sliding the hand down a graduated cone until the tips of the thumb and the middle finger remain touched to each other.

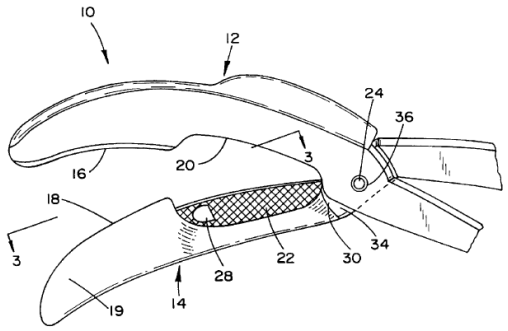


FIG.1A

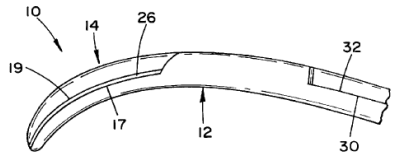


FIG.1B

Fig. B.6: The description of the mechanism.
Source: Patent ID: US 6024744

Sr. No.	Patent No.	Name	Relevance	Source
1.	US4347932	Tag pin	Tag packaging and alignment	United States Patents
2.	US5417701	Surgical device with magnetic needle holder	Grasping detailing	United States Patents
3.	US6024744	Combined bipolar scissor and grasper	Scissor and grasper integration	United States Patents
4.	US6042538	Device for Endoscopic Vessel harvesting	Holding the vessel in place	United States Patents
5.	US5312434	Medical Instrument	Mechanism understanding	United States Patents
6.	US5509922	Endoscopic surgical instrument	Mechanism understanding	United States Patents
7.	US5925064	Fingertip mounted minimally invasive surgical instrument and method of use	New technique	United States Patents

B.5 | PATENT STUDY

A patent study was done to understand mechanisms and development in laparoscopic tools like graspers and retractors. The device needed to be a combination of a few different instruments and for that studying patents devices in multiple areas was essential.

The following table lists the patents that were studied.

Patent regarding a combined bipolar scissor and grasper (US 6024744), integration of two different types of devices and the integration of the two into a single device.

B.6 | FEASIBILITY ASSESMENT

The Endoretractor is a breakthrough development in the laparoscopic devices. Currently there are multiple retractors available for cholecystectomy, but most of them are either need to be used by piercing through the abdominal wall. Thus this device has multiple advantages over these available retractors. Also with respect to a conventional laparoscopic surgery this reduces an incision, a human involvement resulting in lower costs. Also the device is hugely beneficial during single port surgery.
The device can also be used for other laparoscopic procedures, where retraction of organs is essential. The deployer and the retractor will be a couple as the use and success of the retractor is hugely dependent on the deployer.

B.7 | SWOT ANALYSIS

The SWOT Analysis is done for both the retractor and the deployer together as they will be sold together:

STRENGTH:

Removing a human assistance and an incision.
Huge advantage during a single port surgery.
Reduces surgery cost.
Is not specific to cholecystectomy, can be used for retraction in other surgeries.
The deployer makes it easy to use and is quick.

OPPORTUNITY:

There is a huge market for the device as the procedures are swiftly moving towards minimal invasions.
The device can be used in other laparoscopic procedures like hysterectomy, to retract the organs.
The device is not highly priced, thus enabling the hospitals to take quick purchasing decisions, and helps in reducing the surgery cost drastically.
The device has been designed by taking feedback from some of the eminent laparoscopic surgeons in India, and is Endorsed by them.

WEAKNESS:

The traction cannot be adjusted by the tag.
The gallbladder needs to be pierces, can be difficult in cases where the gallbladder is swollen, and can cause bile leak.
The device can be used only to deploy, removal of the tag is still not addressed.

THREAT:

The major threat to the device is other innovative retractors be currently designed.
As the device is new, it will take sometime to get acceptance from the surgeons.
There is a major threat that the device can be replicated if the design is not properly protected.

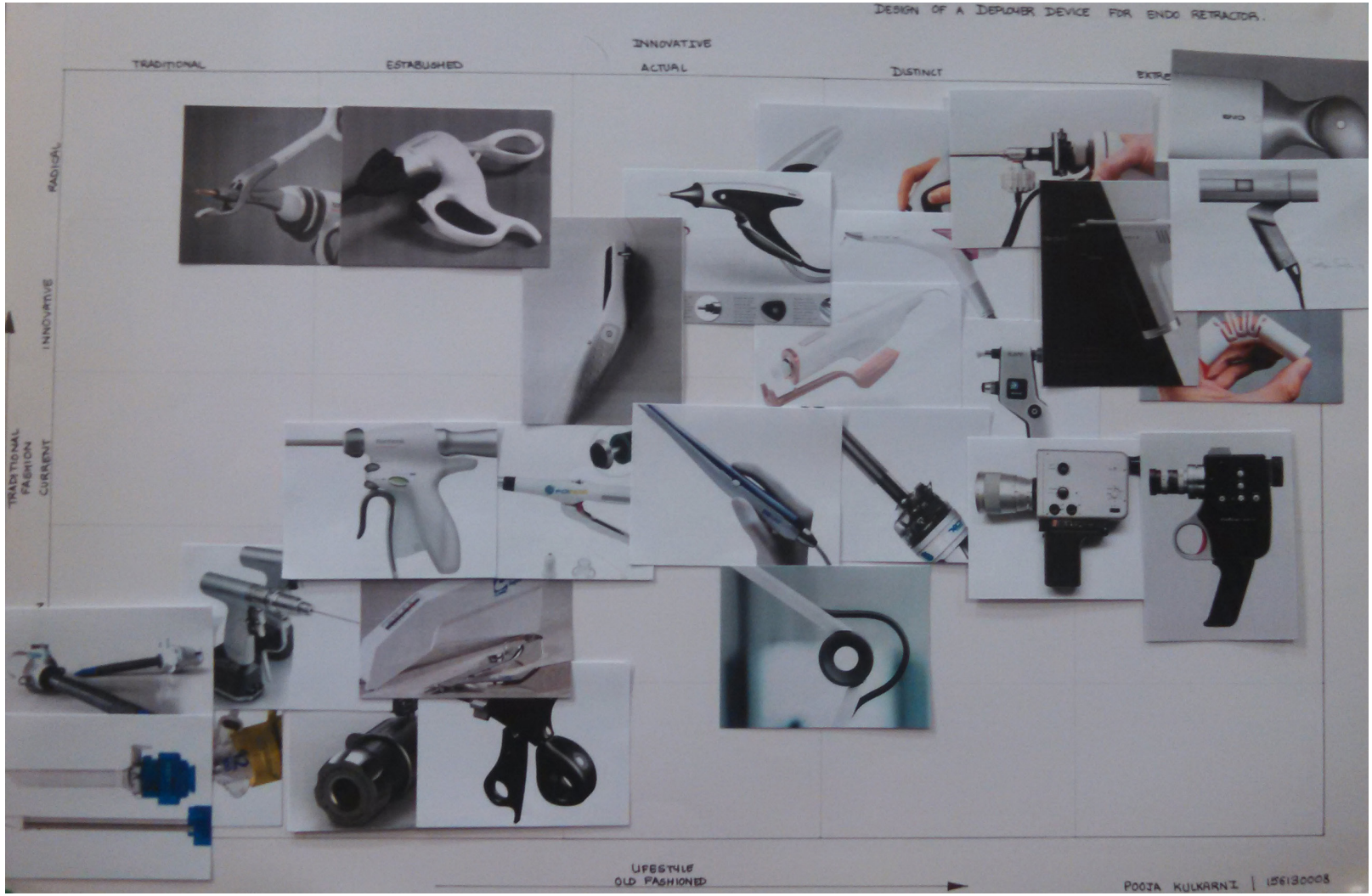
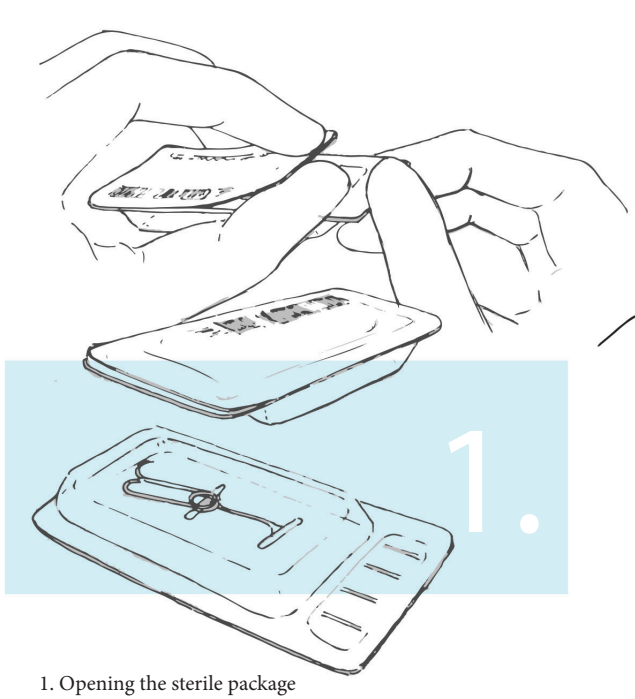


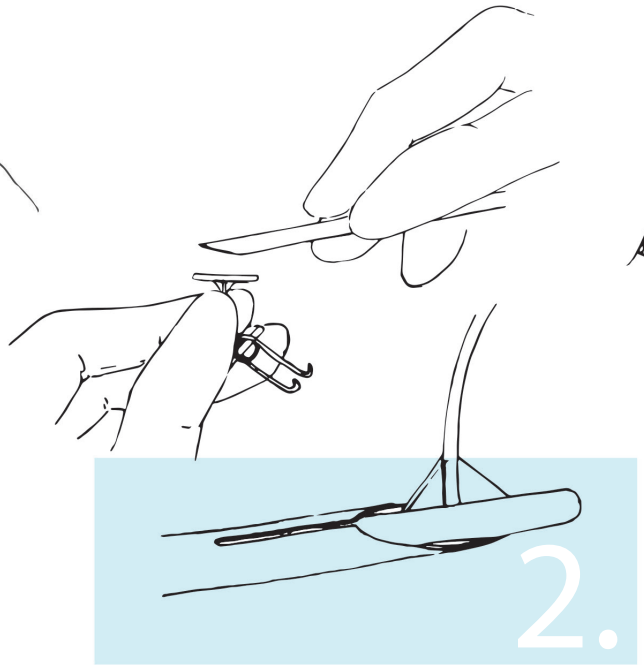
Fig. B.7: Visual Perception Matrix chart
Source: Self Photograph, IDC School of Design

B.8 | VISUAL PERCEPTION MATRIX

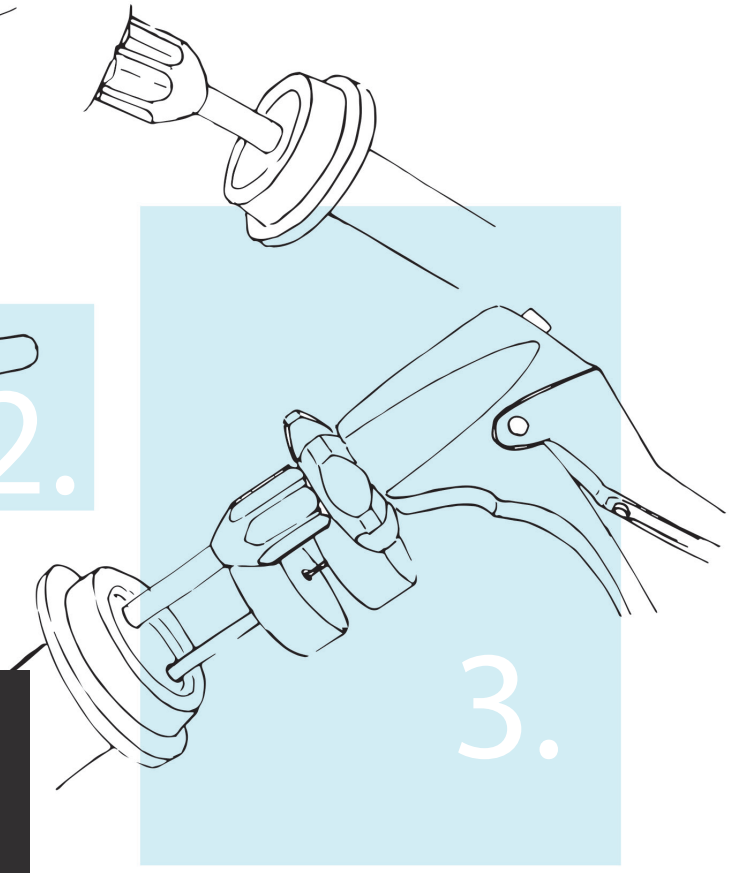
Visual Perception matrix for the parallel products. This task was done under a workshop conducted by Mr. Ashok Panwalkar to understand the placement of the product.



1. Opening the sterile package



2. Attaching the tag to the neede



3. Using the grasper and the needle through the same trocar is very difficult.

B.9 | TASK ANALYSIS

PREPARATION

It is very difficult to attach the Tag to the needle. The time taken for a novice user is 3 to 5 mins.

As the tag needs to be attached at the sharp tip of the needle there is a possibility of injury to the user, which can lead to contamination.

The inner diameter of the trocar is about 9 mm and the opening for the instrument is 5 mm. The hook is approximately 7 mm in length and 4-5 mm in width. Its very difficult to rightly orient the hook and to insert it through the trocar.

Due to this the hook dislodges from the Tag multiple times.
The needle is about 30 mm in length. While attaching the tag there is a possibility of the needle bending. This results in inefficient functioning of the needle.

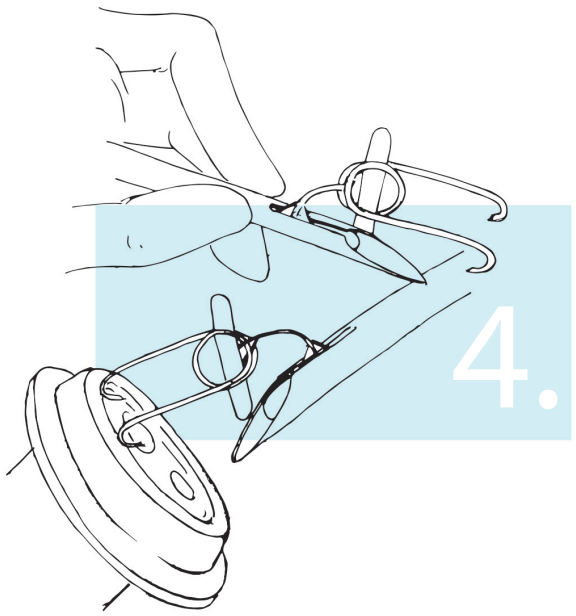
DEPLOYMENT OF TAG

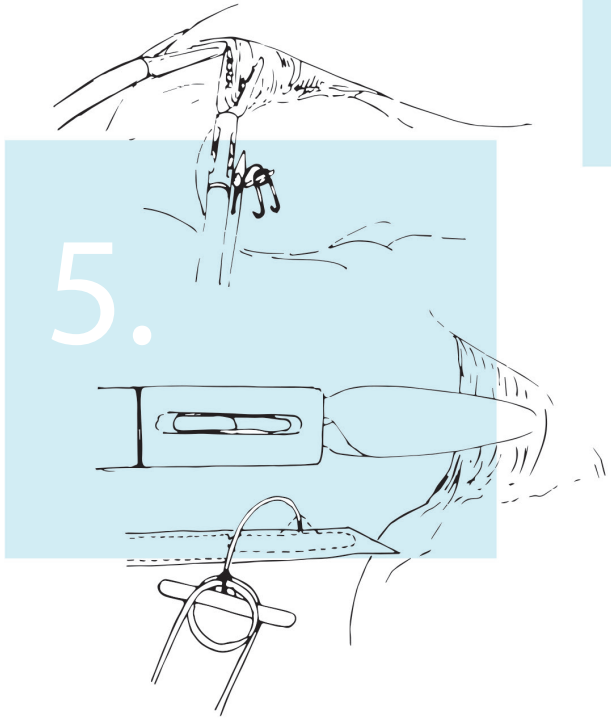
The tag springs back on bending the hook and does not remain coaxial to the needle, leading to difficulty while piercing and deployment.

Piercing the gallbladder is difficult as it shifts.

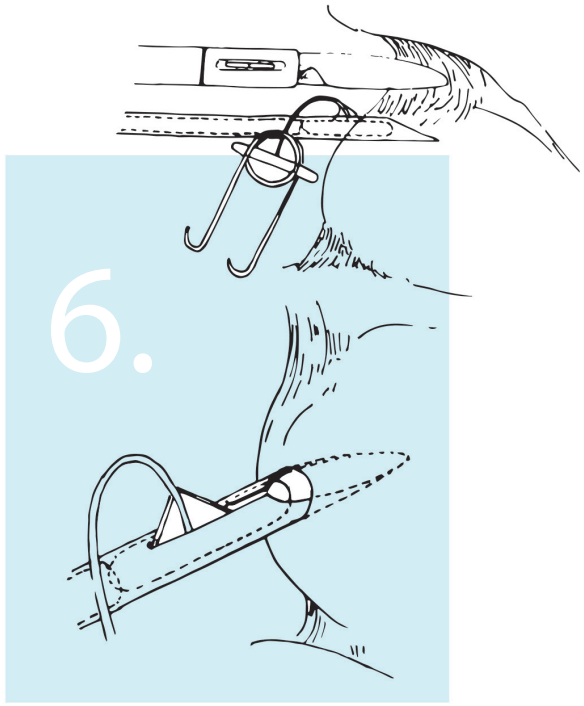
The hook is difficult to locate and orient while attaching to the peritoneum, as it dangles off the needle.

4. Inserting the tag attached to the needle through the trocar.

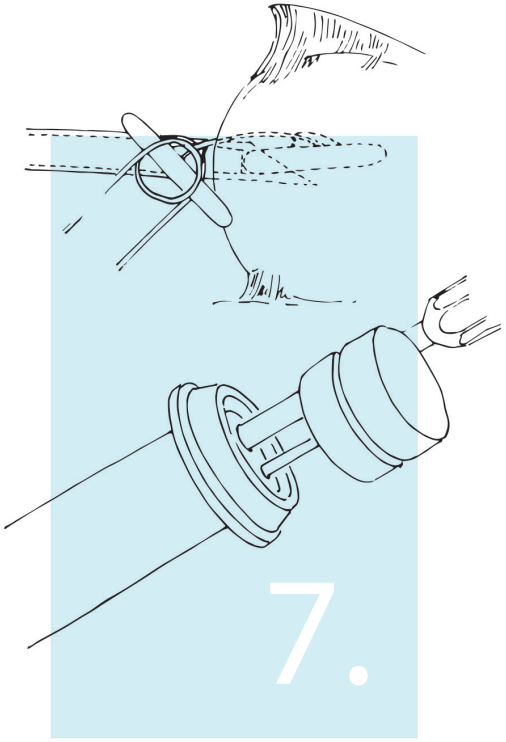




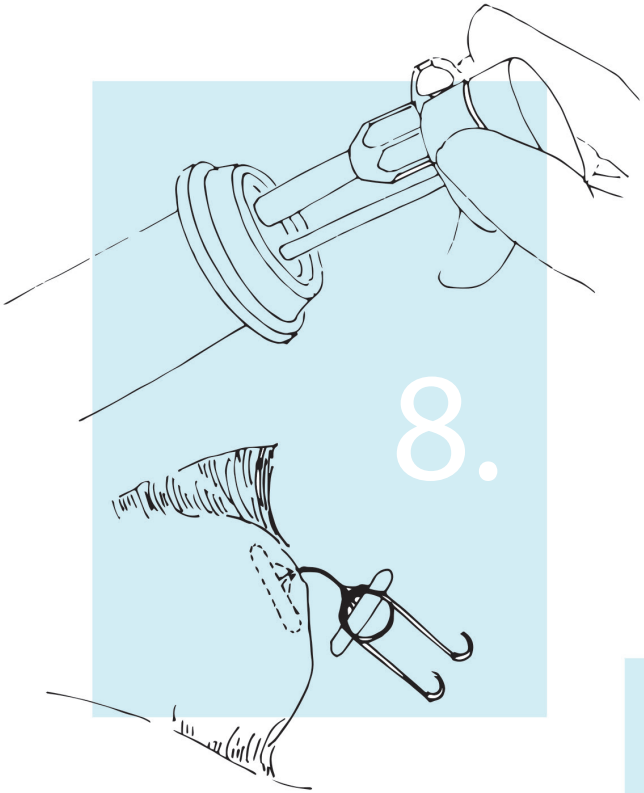
5. The grasper is used to stabilise the gallbladder.



6. Piercing the gallbladder.

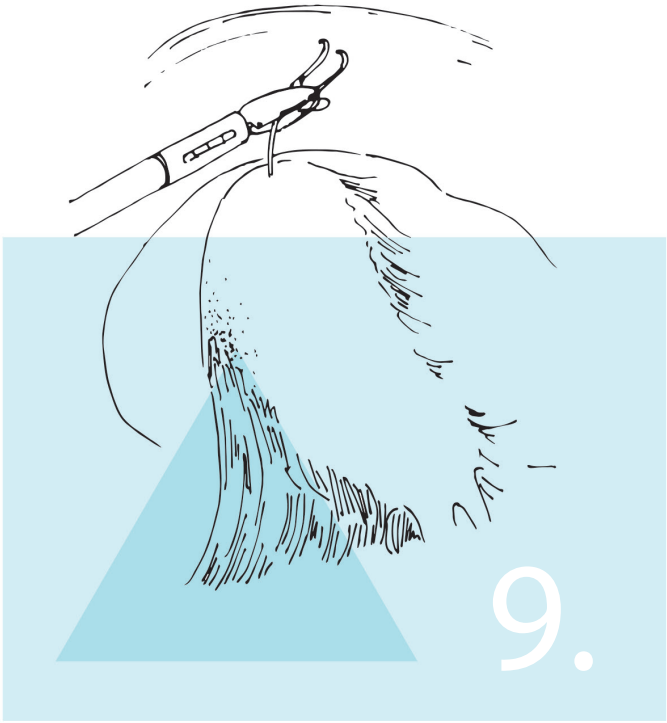


7. The plunger is pushed to deploy the tag.



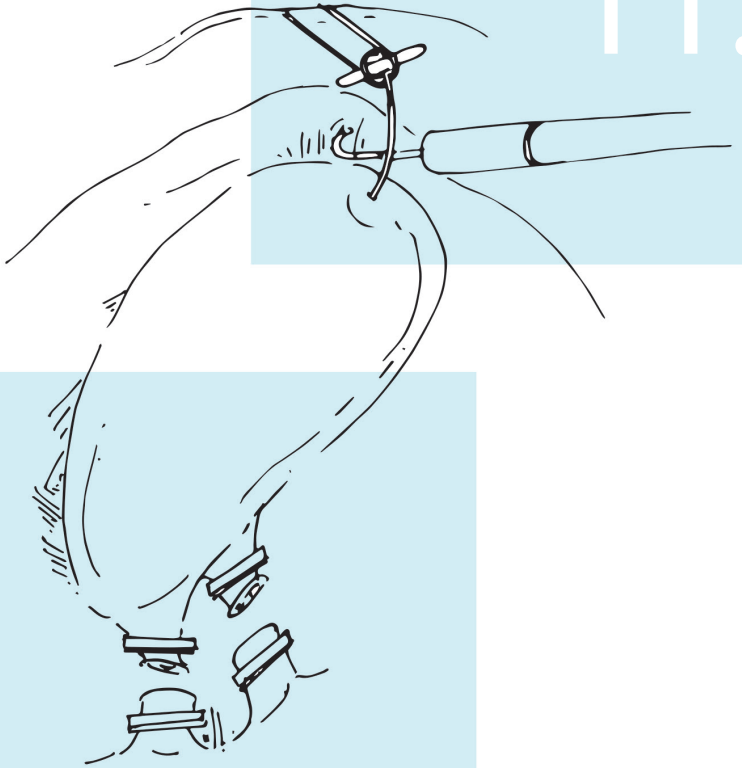
8. The needle is removed from the trocar.

9. The grasper is used to attach the hook to the peritoneum.

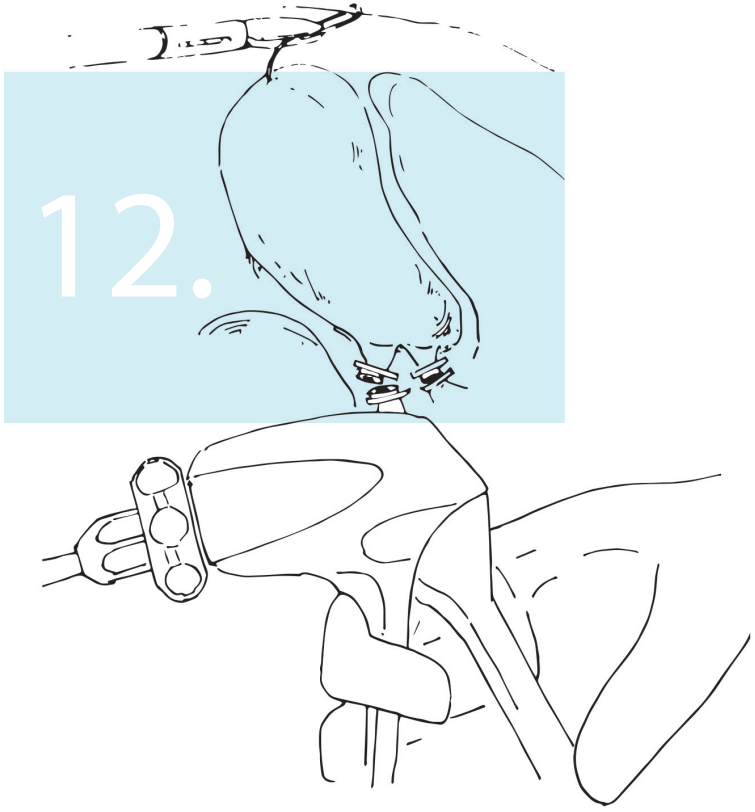


SEPERATION OF THE GALLBLADDER

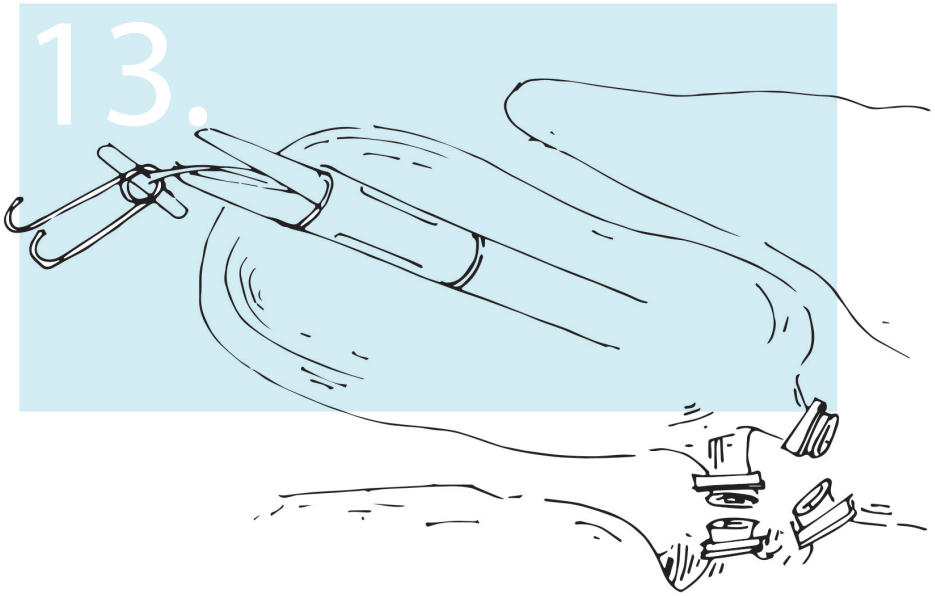
10. The tissue is cuterized, the cystic duct and artery are clamped and then cut.



11. The tissue attaching the gallbladder to the liver is cauterized and the gallbladder isseperated.



12. The grasper is used to unhook the gallbladder.

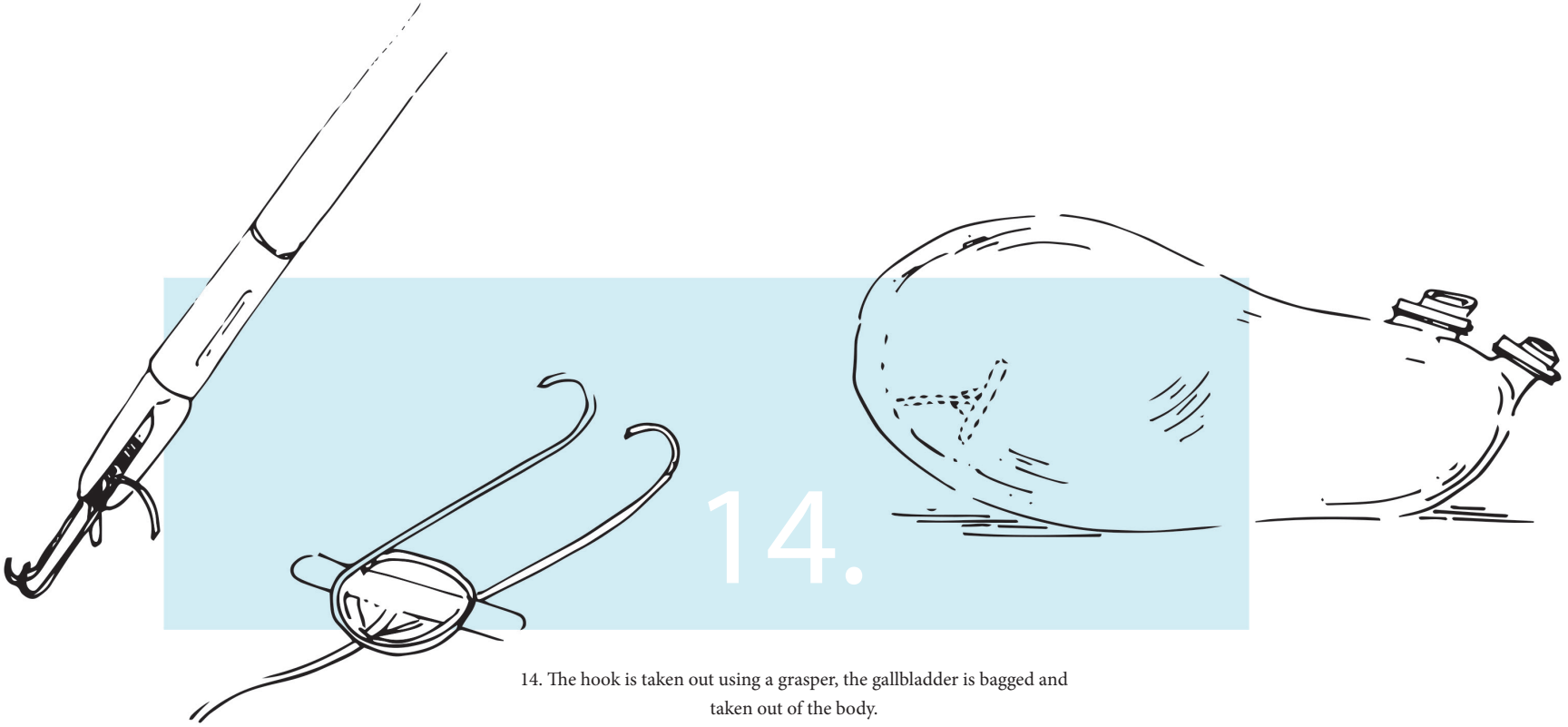


13. The tag is cut.

REMOVAL OF THE TAG

The scissors need to be inserted to cut the tag.

Removing the hook from the trocar is tricky as it has sharp ends.



14. The hook is taken out using a grasper, the gallbladder is bagged and taken out of the body.

C.

DESIGN BRIEF

To design an ergonomic laparoscopic device for the deployment of the endo retractor.

PRIMARY NEED:

The device should be ergonomic and easy to use.
The device should be made using biocompatible material and should be designed so as to not cause any damage to the surrounding organs.
The retractor should be easy to load and deploy.
As it is a class II device, it should be able to withstand autoclave temperatures.
The device should be usable through a 10 mm port.

SECONDARY NEED:

Minimal damage should be caused to the gallbladder and the surrounding organs while they are being handled.
It should be an all integrated design to reduce the steps involved and to facilitate easy deployment of the tag.

Issues:

CURRENT DEVICE:

The device requires 5 steps just to deploy the tag.
Difficult to use two instruments through a single trocar.
Accuracy of piercing the gallbladder to deploy the tag is less.

SERVICING REQUIREMENT:

The device should be able to stand class II sterilization procedures.
The device should be usable through a 10 mm port.

MANUFACTURING REQUIREMENT:

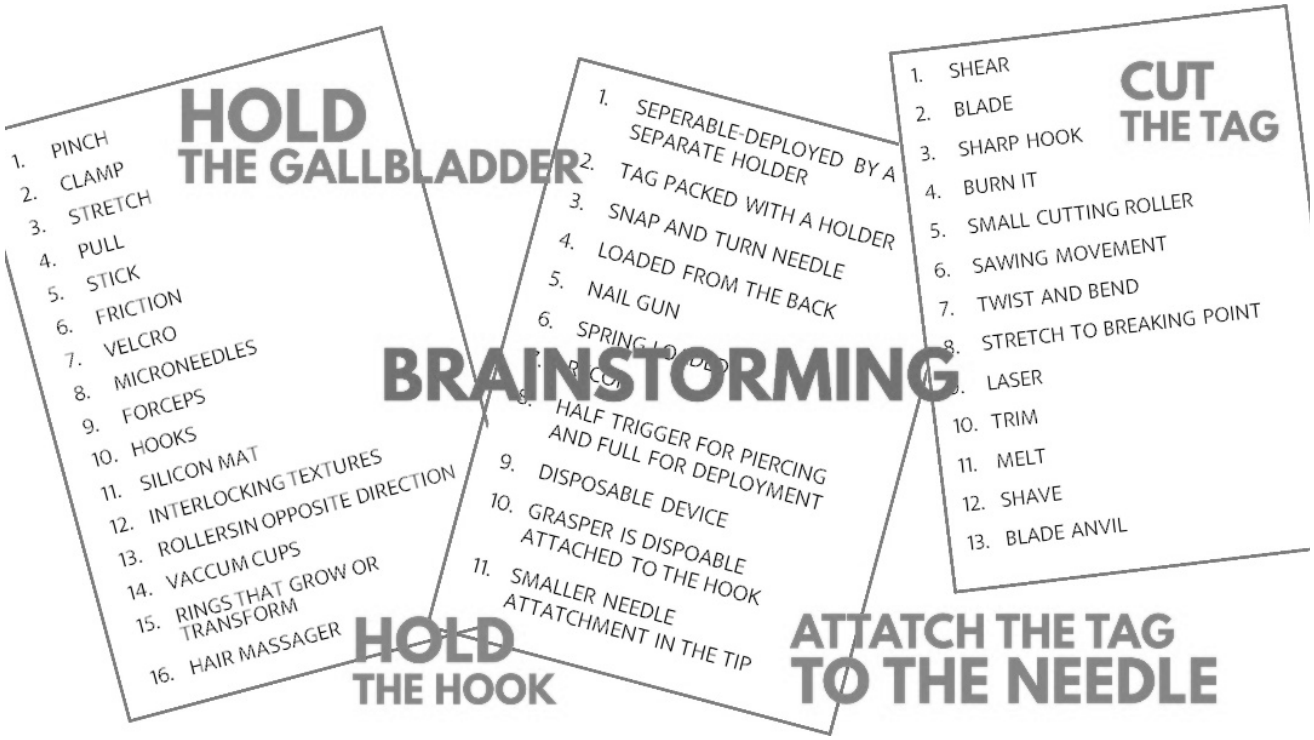
The materials used should be biocompatible.
The device should be easy to clean and maintain.
The device should have a comfortable ergonomic grip.

OPERATIONAL REQUIREMENT:

The device should be prepared in order to facilitate ease of use during the procedure.
The device will be used in a sterile environment after sterilization.

D.

IDEATION PHASE 1



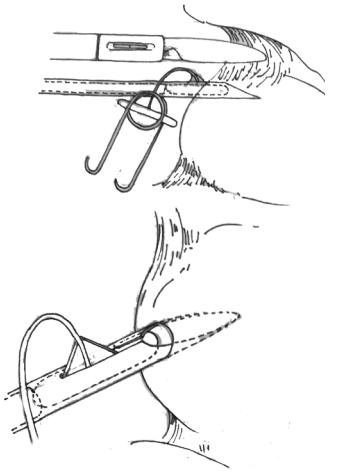
D.1 | BRAINSTORMING

From the data collection and Task Analysis brainstorming for the problems was done to find out multiple ways of solving the problem. Also after discussion with Dr.Rasik Shah it was decided to focus only on the problems associated with the deploying of the tag and design a deployer.
Brainstorming for the following was done:
Stabilizing the gallbladder
Hold the hook
Attach the tag to the needle
Cut the tag

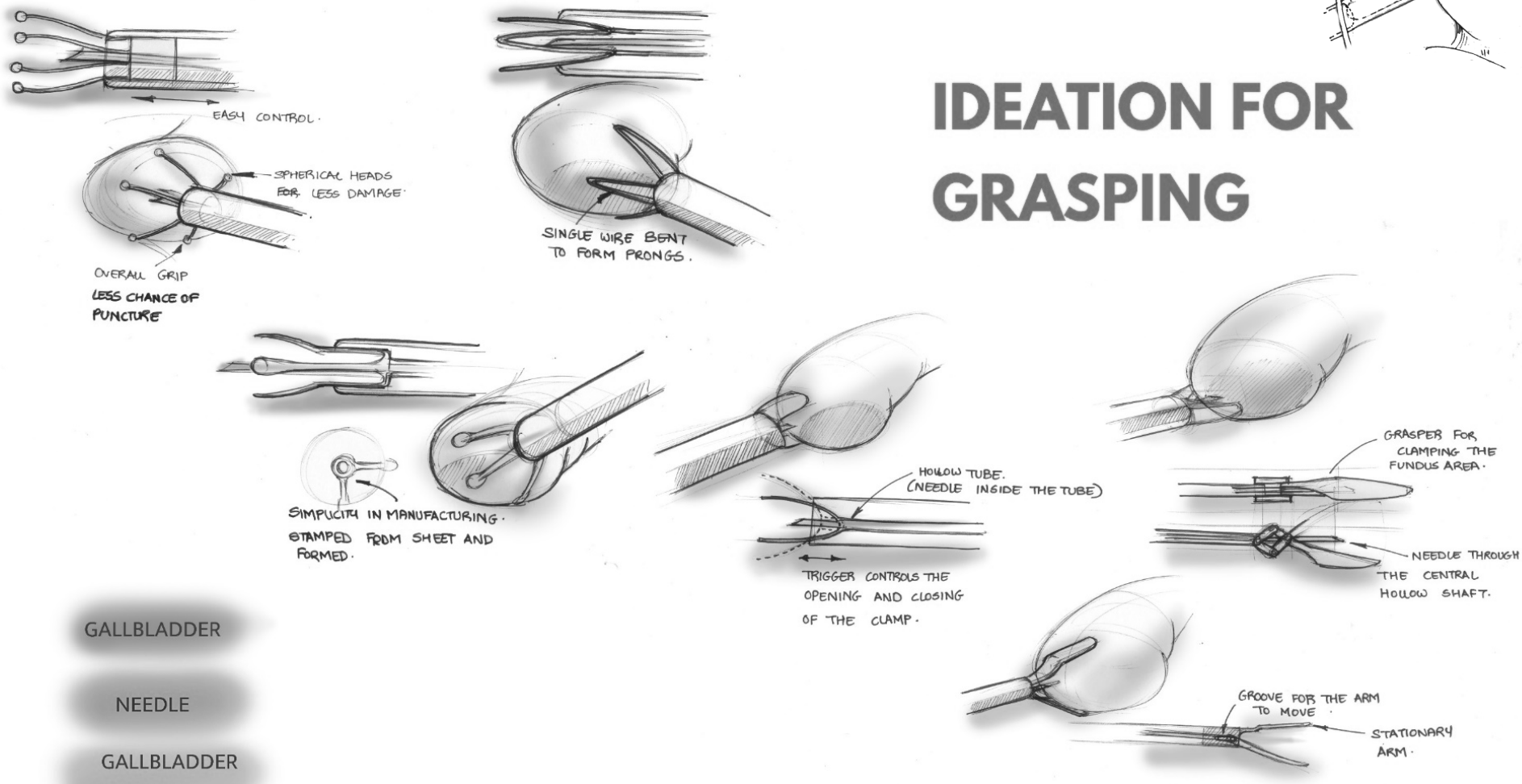
D.2 | STABIIZING THE GALLBLADDER

After the Task Analysis the major problem that was observed was the stabilization of the gall bladder. Unless it was stabilized piercing it wouuld have been very difficult. Fig. : show the multiple ways in which the gallbladder can be stabilized.

PROBLEM:
The gallbladder shifts due to force of the needle as it doesnot have any stiff back. The wallthickness of the human gallbladder can vary from 3 mm to 8mm. Using graspers is difficult in the case of very thinwalled or highly inflamed gallbladders, as it can lead to bile leak.



IDEATION FOR GRASPING

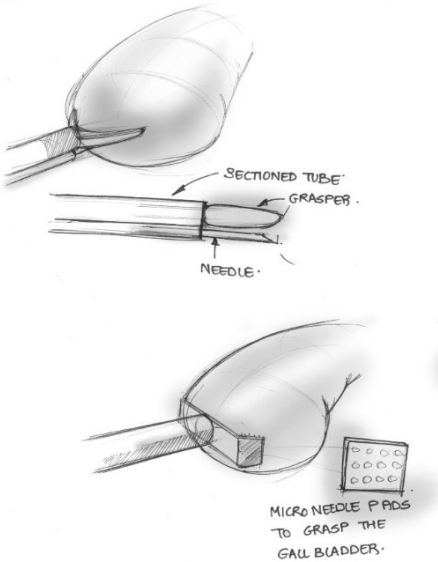


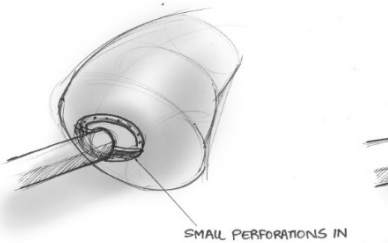
GALLBLADDER

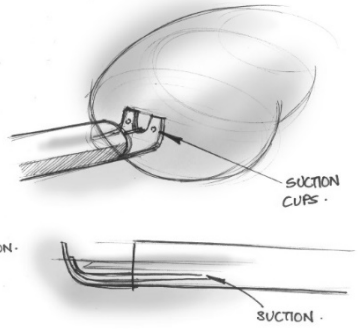
NEEDLE

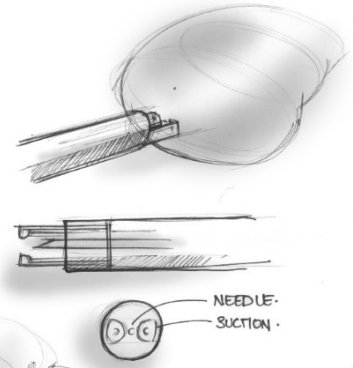
GALLBLADDER GRASPING

IDEATION FOR GRASPING 2





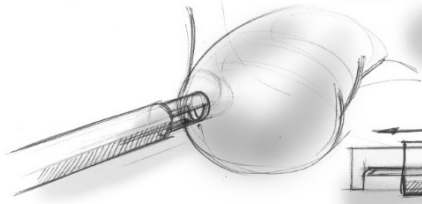




GALLBLADDER

NEEDLE

GALLBLADDER GRASPING



ROTATE: FOR ADJUSTING THE SUCTION ARM.

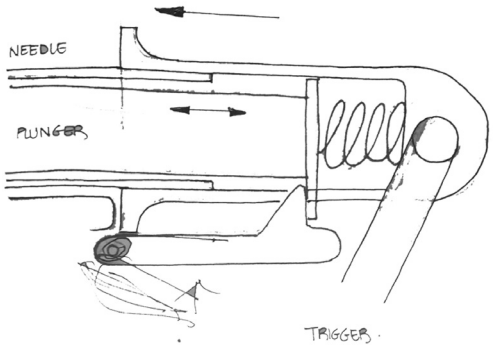
BUTTON: FOR GENERATING SUCTION.

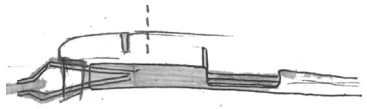
HALF TRIGGER: FIRE THE NEEDLE.

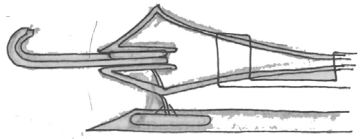
FULL TRIGGER: DEPLOY THE TAG.

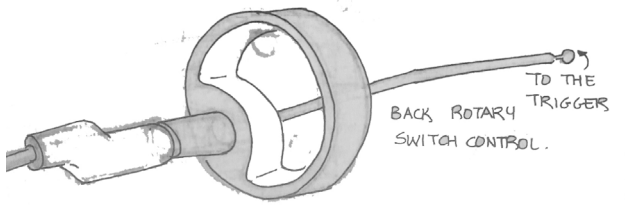
D.3 | DEPLOYING THE TAG

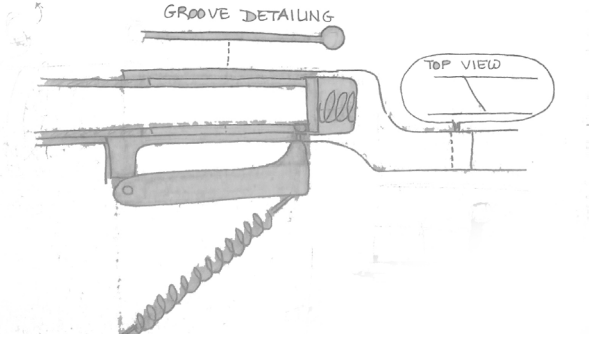
The tag is attached to the needle and is deployed in the gallbladder after piercing it. Fig. shows the multiple wasy in which a tag can be deloyed. The ideation is for a single control which pierces the gallbladder as well as deployes the tag.

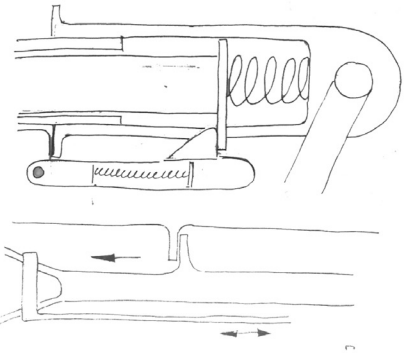


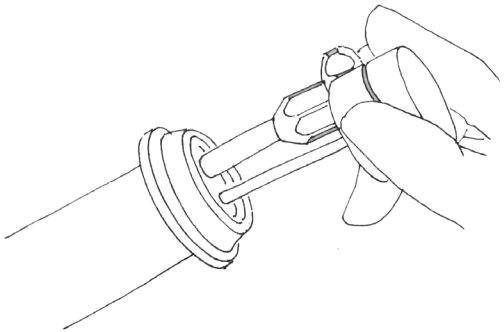


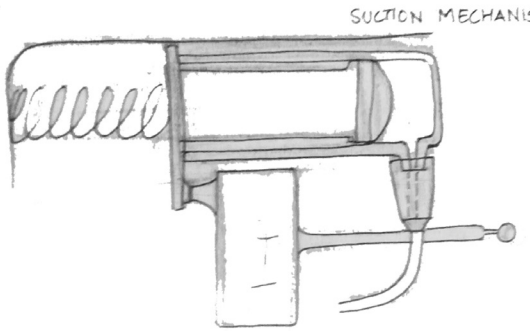


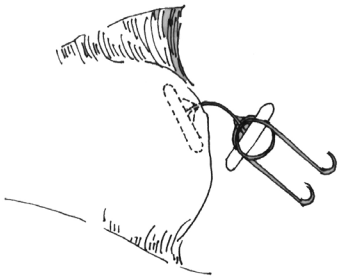






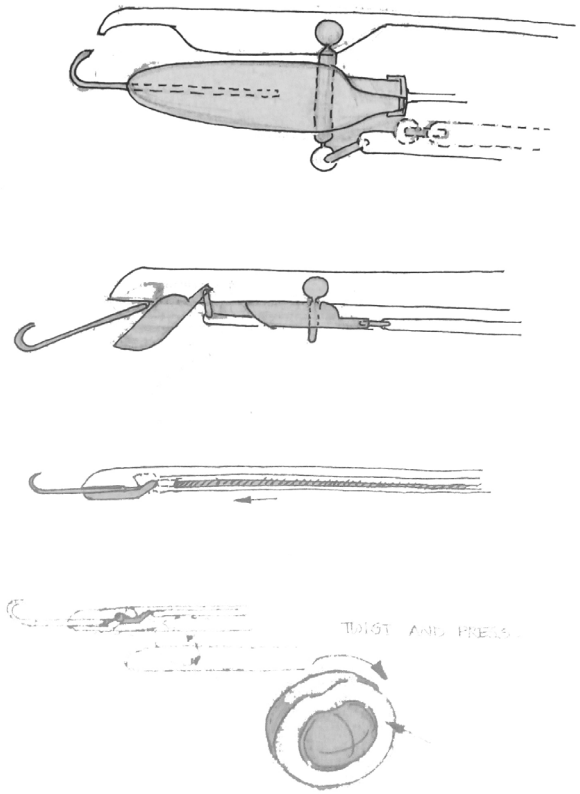


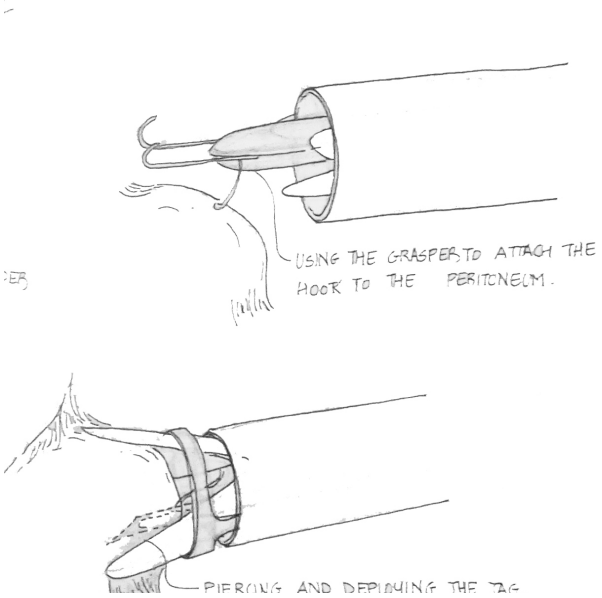


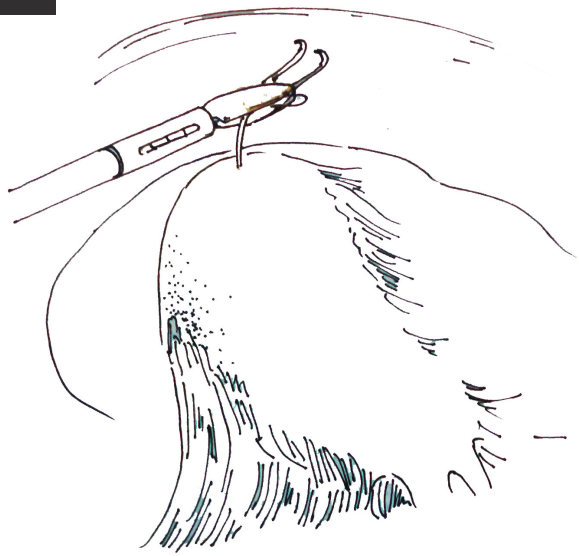


PROBLEM:
Currently the device has two different controls to operate it. The lower disc is to push the needle while the upper disc is to push the plunger to deploy the tag. Thsi can cause accidents as there is no measure to avoid the plunger being pushed before the needle is into the gallbladder. Also, the device is not easy to use.

PROBLEM:
Aligning the hook and grasping it once it is inside the body is difficult. The hook has been designed so that it can be attached to the peritoneum when it is parallel to the wall.
The hook dislodges while inserting it in the trocar currently, thus it was essential to have a dedicated position for it in the device.

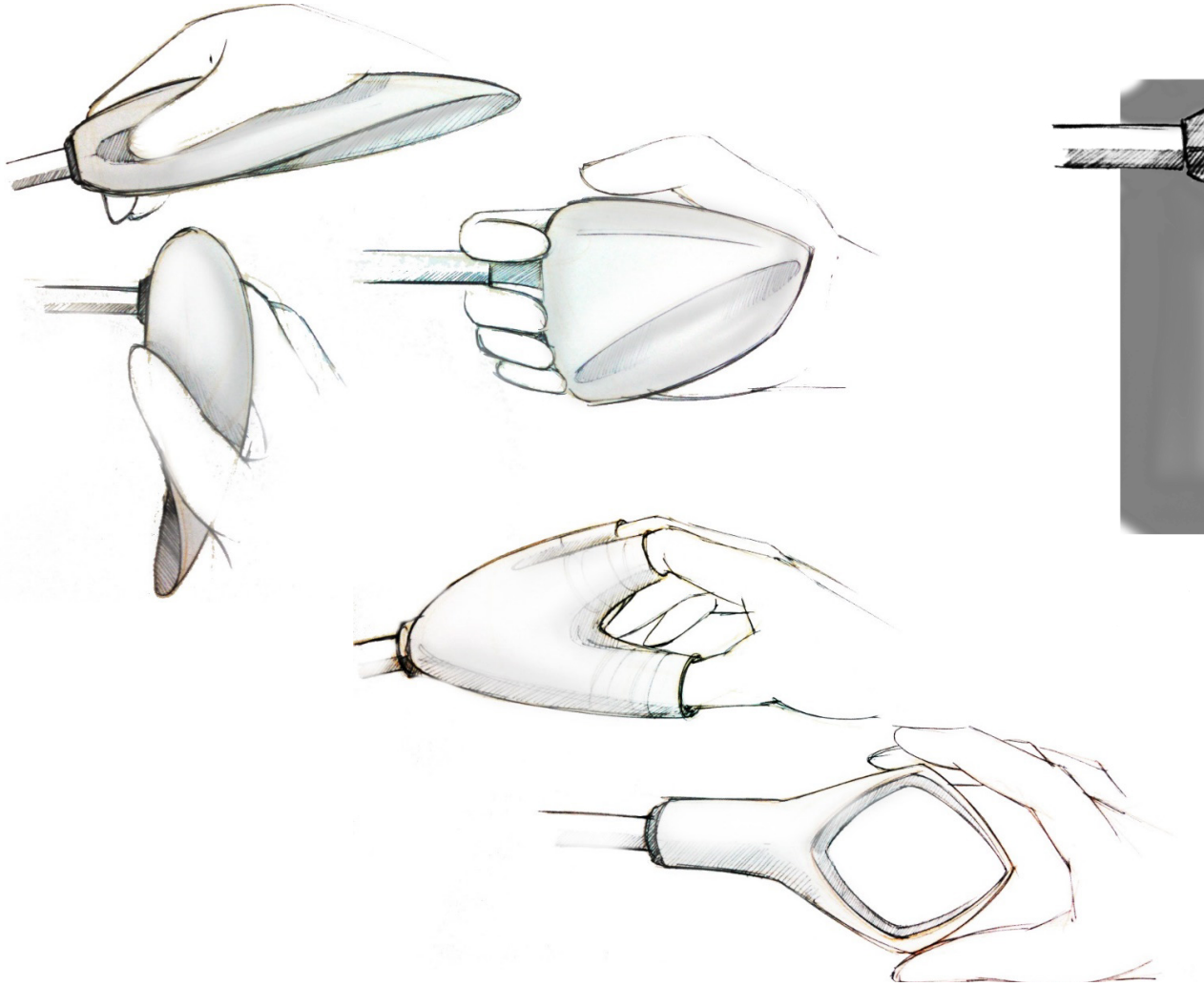


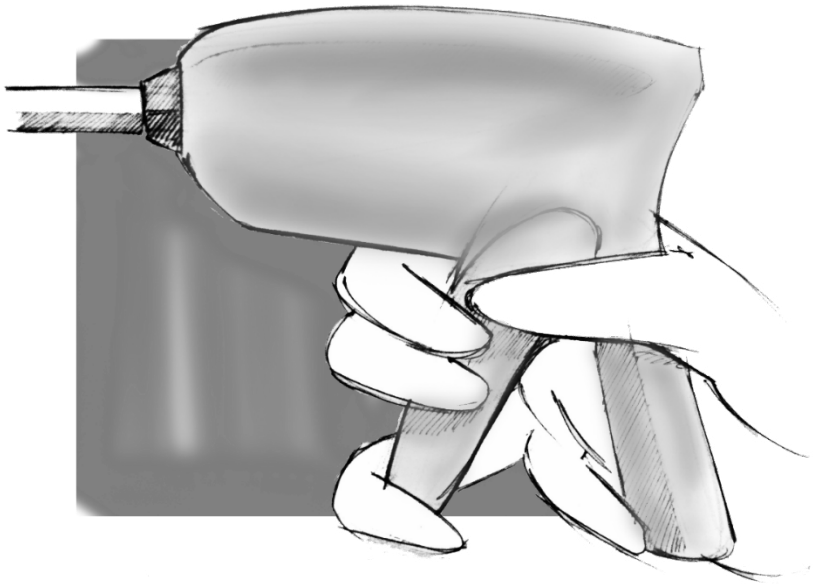




D.4 | POSITIONING OF THE HOOK

A dangling hook outside the device was a major problem with the current device, thus it was essential to have a dedicated positioning for the hook which keeps it from dislodging and also doesnot damage the organs while the device is in use, as the hook has pointed sharp ends. Fig. shows the explorations for the hook positioning.





PROBLEM:
The devicce has three major operations, stabilizing the gallbladder, piercing the gallbladder and deploying the tag and attaching the hook.
The device requires the user to have a precise movement and also a stable grip on the device.

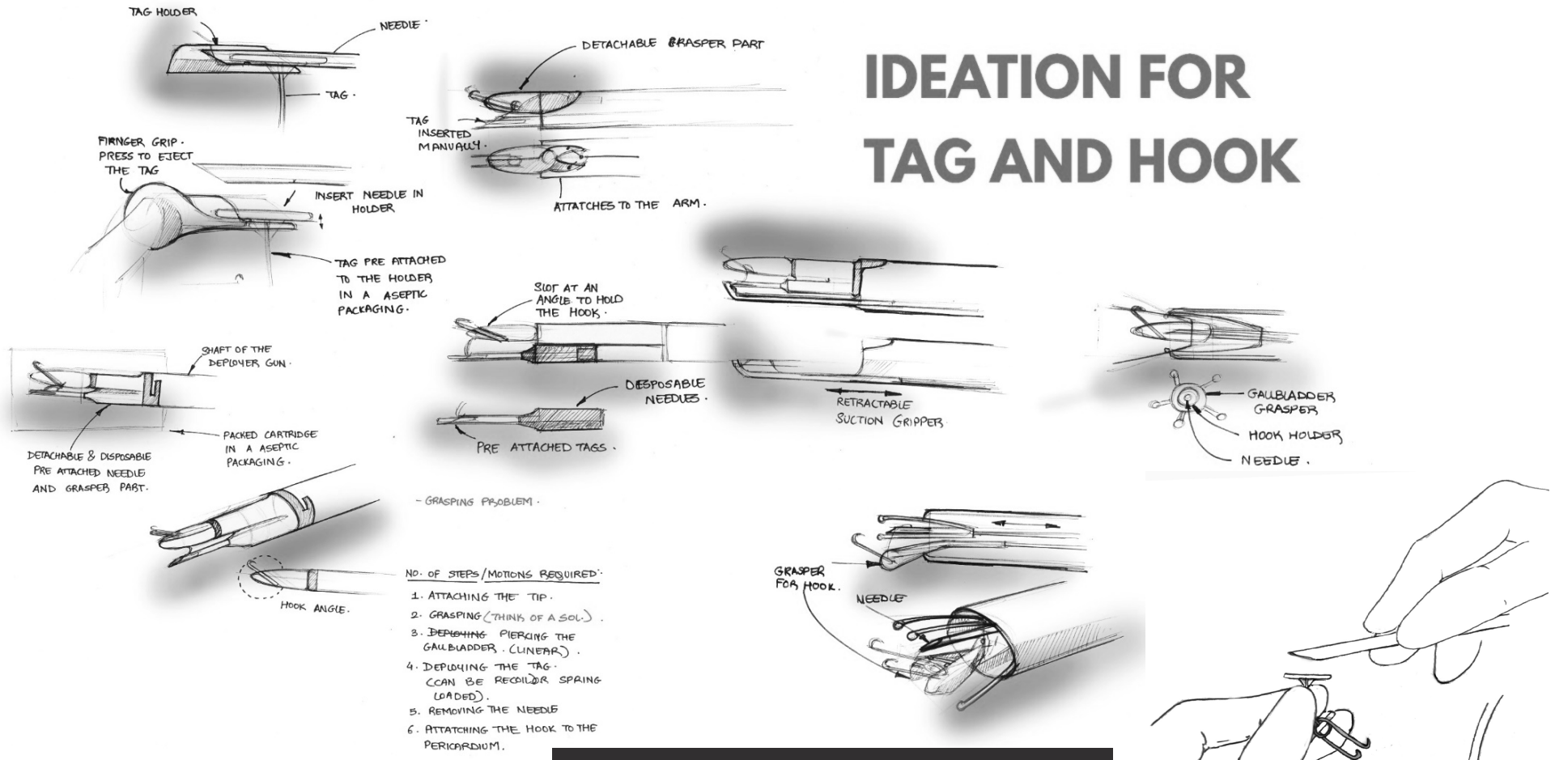
Thus, the pistol grip which is the most commonly used grip for the surgical tools was chosen, it provides the user both a precise movement and control over the device as well as a stable grip.

D.5 | FORM EXPLORATION FOR THE HANDLE

Orientation and use of the device is a crucial element of the process and designing a handle that would be ergonomis, while facilitating three different operations was a difficult task. Fig. shows the different types of handle as their use.

D.6 | TAG AND HOOK

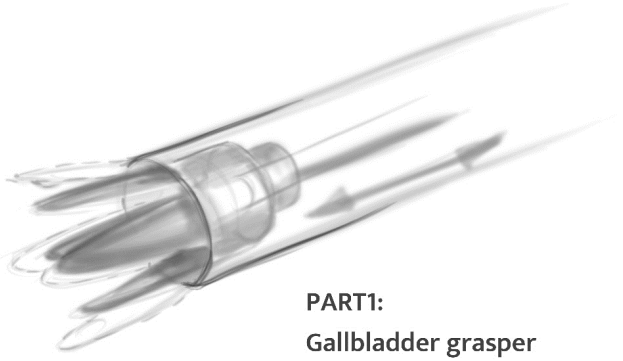
Attaching the tag and the hook to the device is a problem in the current device. The fig. shows ideations regarding the same.



PROBLEM:
Attaching the tag to the hook is difficult, it has to attached at the sharp end of the needle. This has a huge chance for accidentents and thus contamination.
This ideation has not currently been addressed in the current device, but it can be addressed in the future.

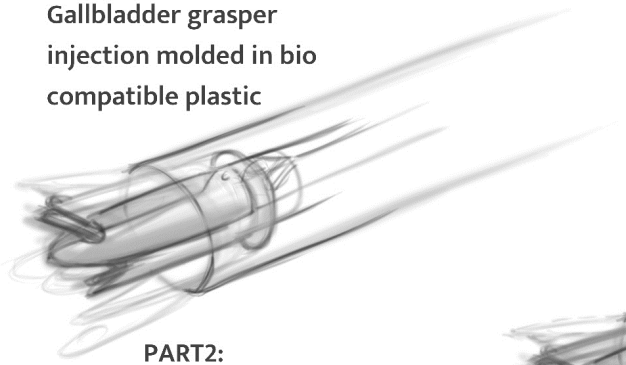
D.7 | MECHANISMS

Fig. and show the mechanisms that can be used for the deployer. Two different approaches to stabilise the gallbladder asre used, a mechanical grasping method and grassping using suction.

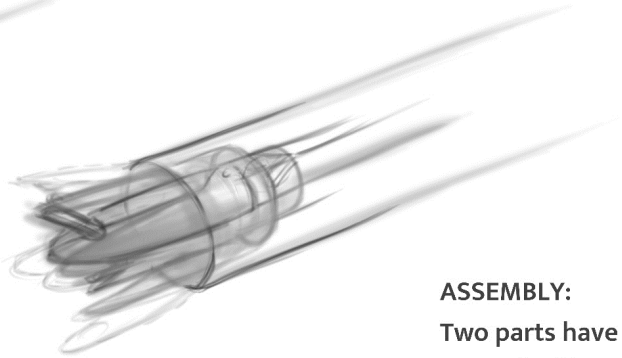


PART1:
Gallbladder grasper injection molded in bio compatible plastic

CONCEPT 1



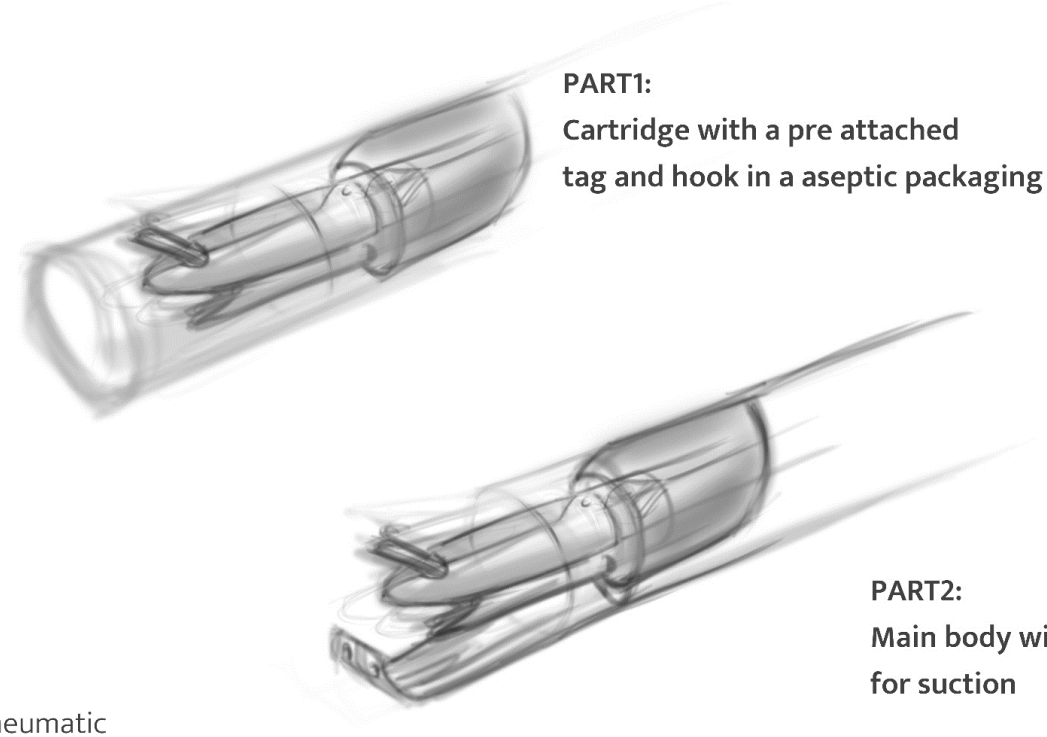
PART2:
Hook and tag preattached to a disposable tip



ASSEMBLY:
Two parts have to be attached.
Prepacked in a aseptics packaging

Linear movement for the gallbladder grasper.
Linear movement for the hook deployer
Half trigger press for the needle to pierce
Full trigger press for the deployment of the tag

Fig. shows the mechanical grasper, flower grasper.



PART1:
Cartridge with a pre attached tag and hook in a aseptic packaging

CONCEPT 2

PART2:
Main body with an attatchment for suction

Suction generation, pneumatic
Linear movement for the hook deployer
Half trigger press for the needle to pierce
Full trigger press for the deployment of the tag

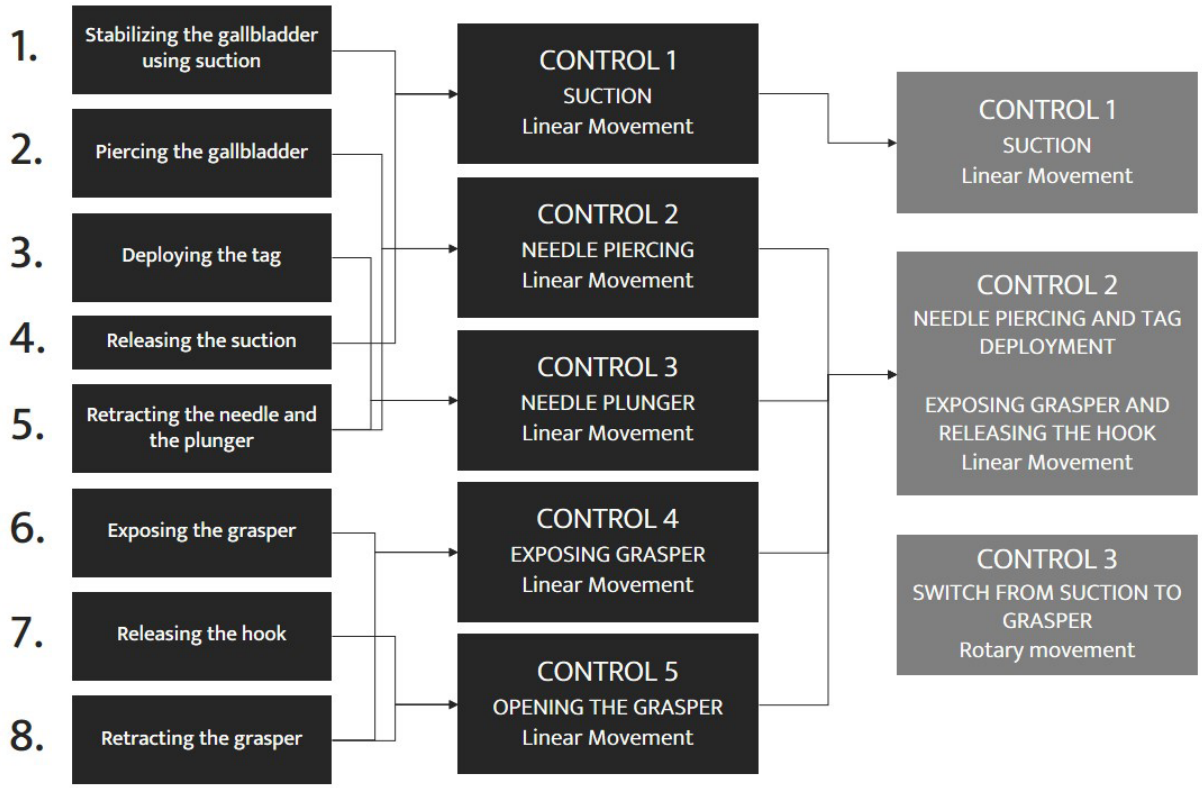
Fig. shows the suction being used to stabilize the gallbladder. The testing for this technique was essential as it has not been used in a laparoscopic device to hold an organ prior to this.

E.

IDEATION PHASE 2

E.1 | CONTROL ALLOCATION

The number of tasks that are performed are 8, alloting them a control 5 different controls would have been required to perform the tasks, which would have increased the cognitive load on the user and also made the controls difficult to map on the deivce.
Fig. shows the task and the controls that were earlier alloted to them, also the optimised solution is shown on the left



E.2 | FINGER ALLOCATION

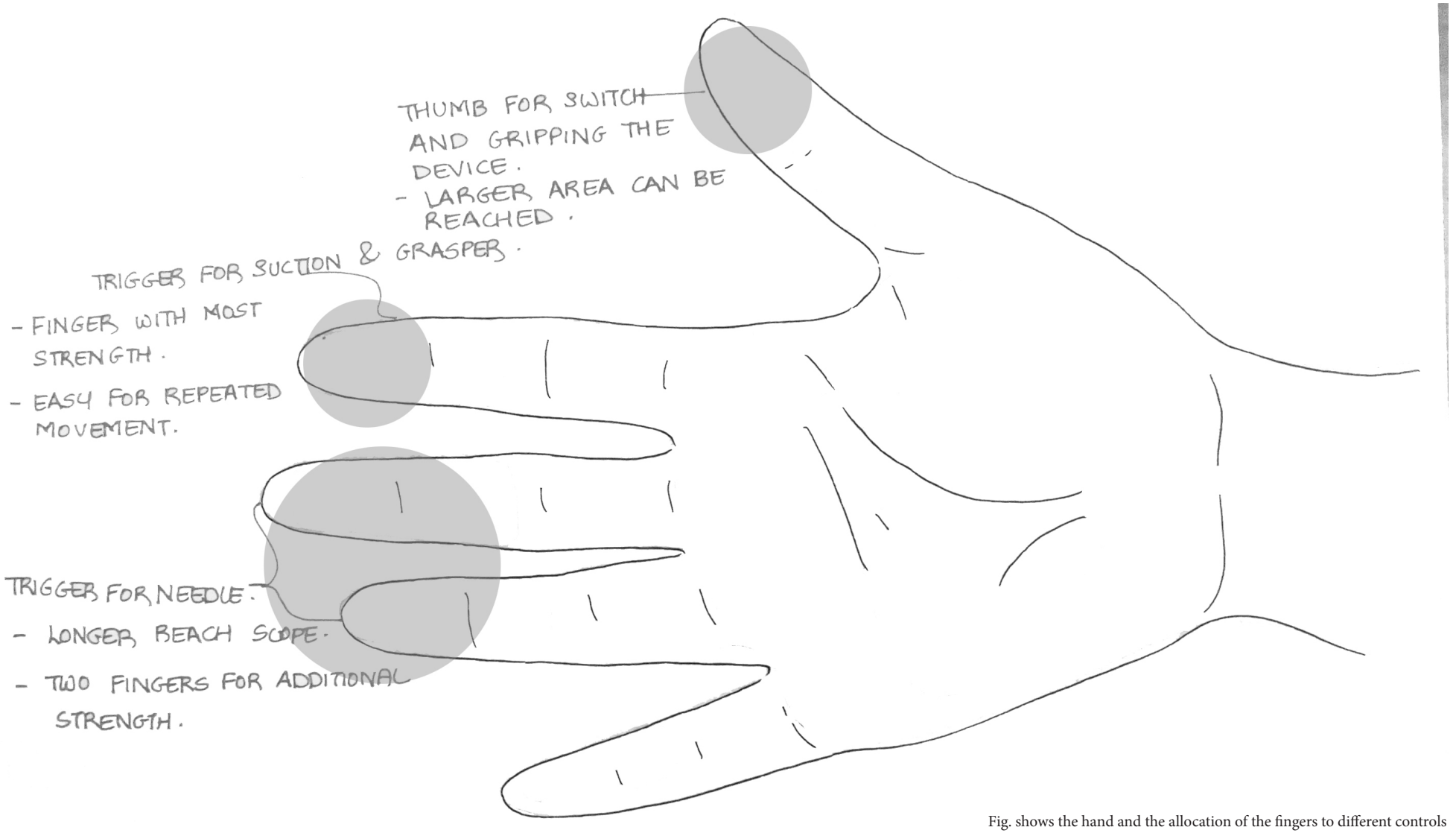


Fig. shows the hand and the allocation of the fingers to different controls in the device.

E.3 | INSPIRATION BOARD

A modern, futuristic style was chosen for the device, based on the aesthetic language followed by the contemporary designs. The trends show the devices going towards a more organic formal language. Play of colors and textures is very crucial. Fig. is the inspiration board for the device.

Fig. E.1: Inspiration Board
Source: https://in.pinterest.com/pin/317503842460372350/
https://in.pinterest.com/pin/187180928240451507/
https://in.pinterest.com/pin/329607266462625602/
https://in.pinterest.com/pin/329607266462610276/
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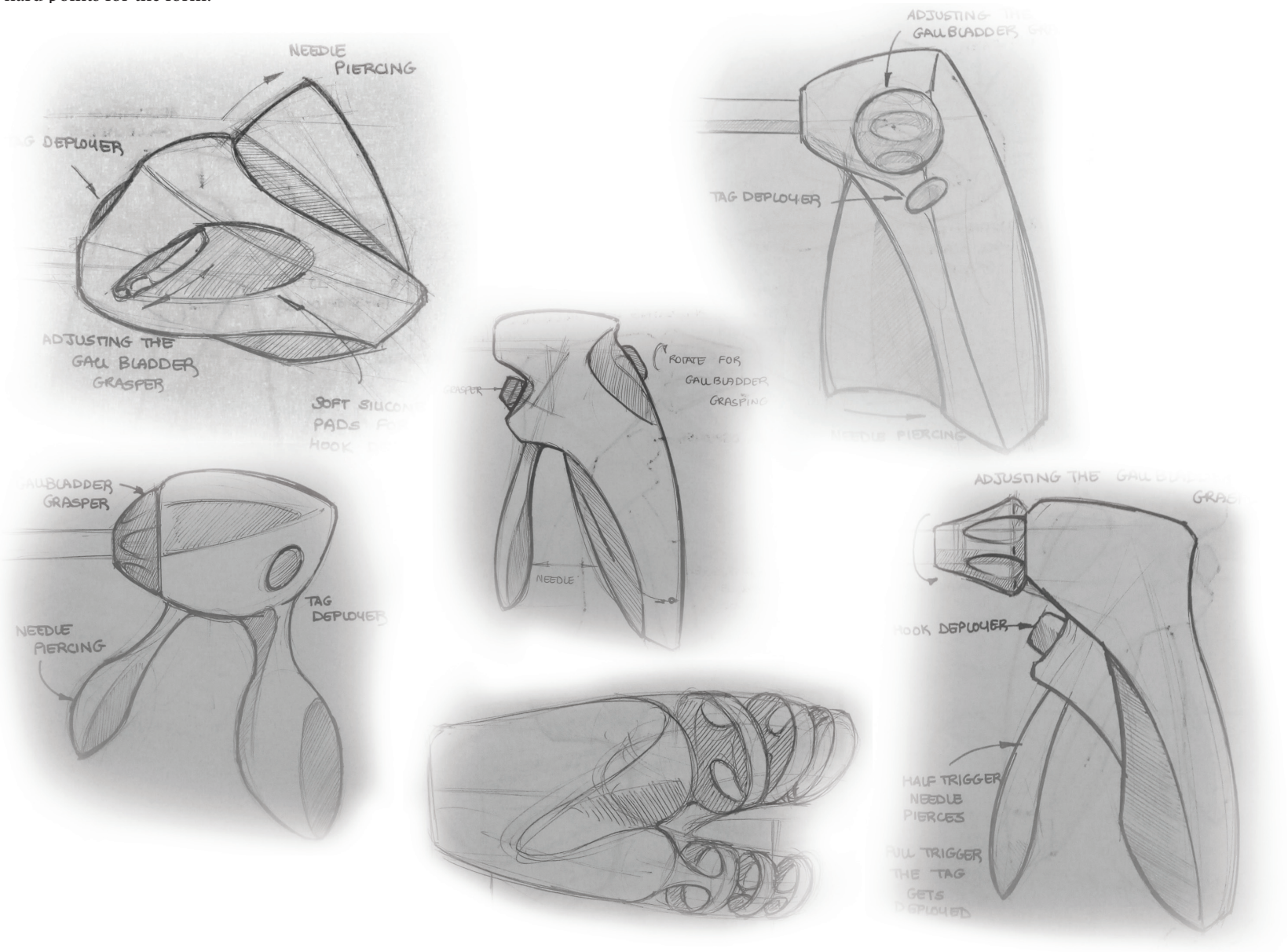
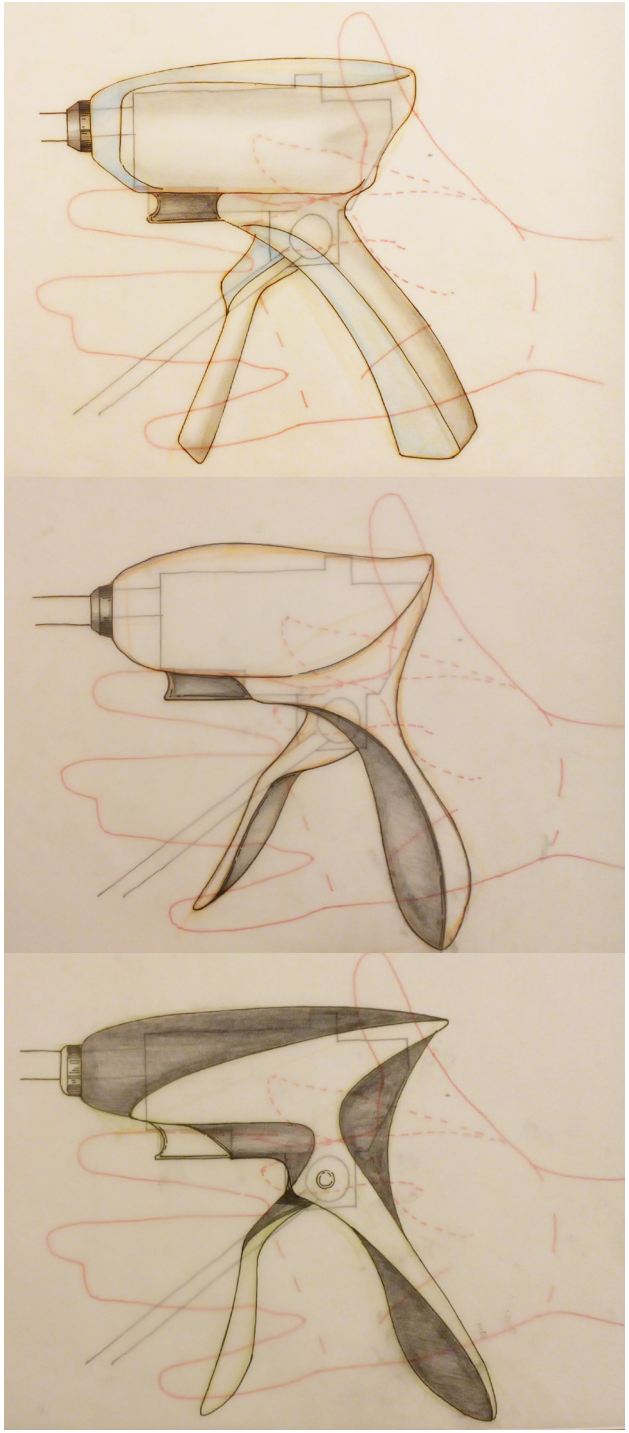
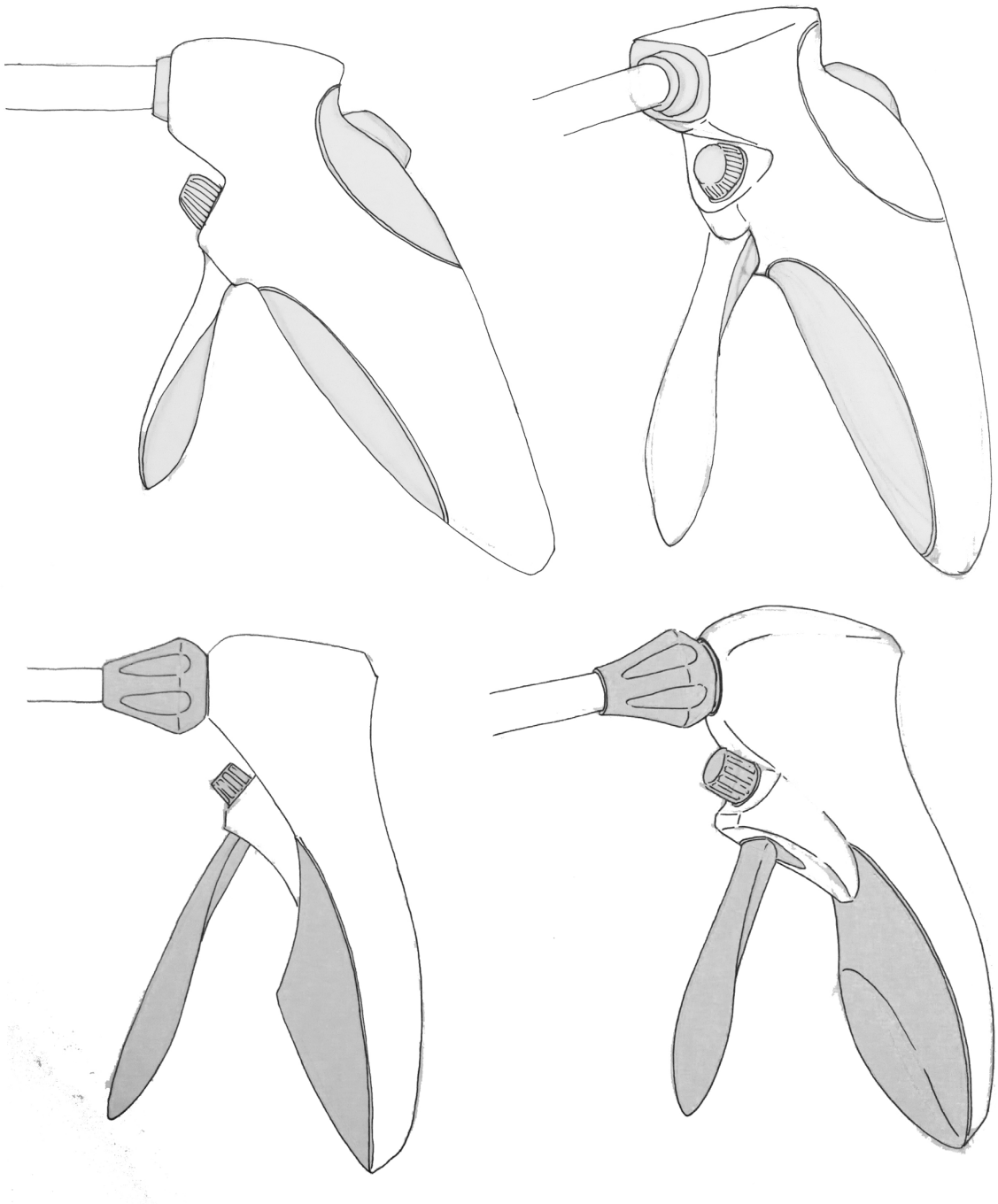
E.4 | FORM EXPLORATION

Form exploration to finalise the look.
Fig. shows the mechanism and the hand dimensions to generate the hard points for the form.







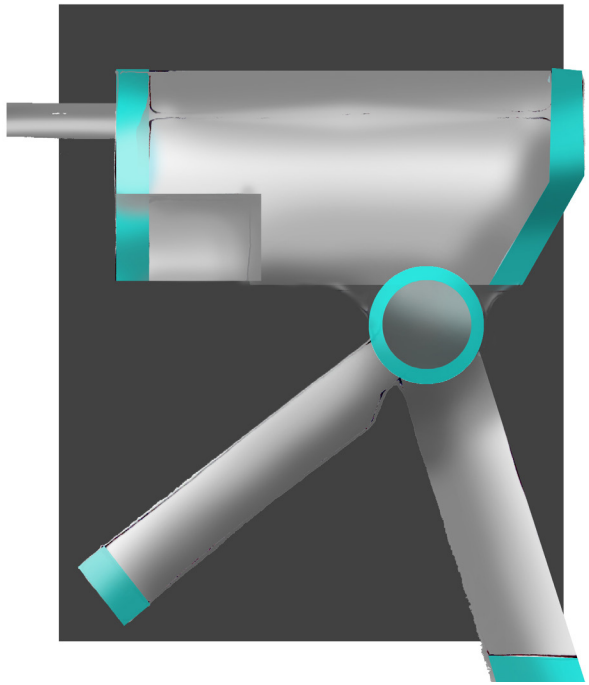
E.5 | CONCEPT EVALUATION

The suction concept required testing to validate it. It was carried out on a lamb's gallbladder. From the testing it was found out that suction is efficient in stabilizing the gallbladder and also does not damage the gallbladder.

Displacement of the Plunger: 10ml Syringe with dia. 16 mm is 1.5-2 mm for holding the goat's gallbladder with a wall thickness of 0.5-1 mm.

	Flower Grasper	Suction
Mechanism control	Linkages, other mechanical mediums can be used	Controlled by Suction machine or inbuilt chamber in the device
Movement required for operation	Linear	Linear
Components	Grasper, shaft, control	Suction head, tube, chamber, control
Precision	Focused precise movement	Focused movement required to locate the gallbladder
Advantages	1. Easier to clean and maintain 2. Less number of components 3. Requires light pressure	1. Less possibility of damage as the head is made from silicone 2. Very little pressure is required 3. Possibility to develop similar devices 4. Easier to operate individually
Disadvantages	1. Can puncture the gallbladder 2. The grip is not that good 3. Requires more space 4. Will require a grasper from port 3 to hold the liver	1. Has multiple components 2. Validation is essential for suction and to check the pressure required to hold it

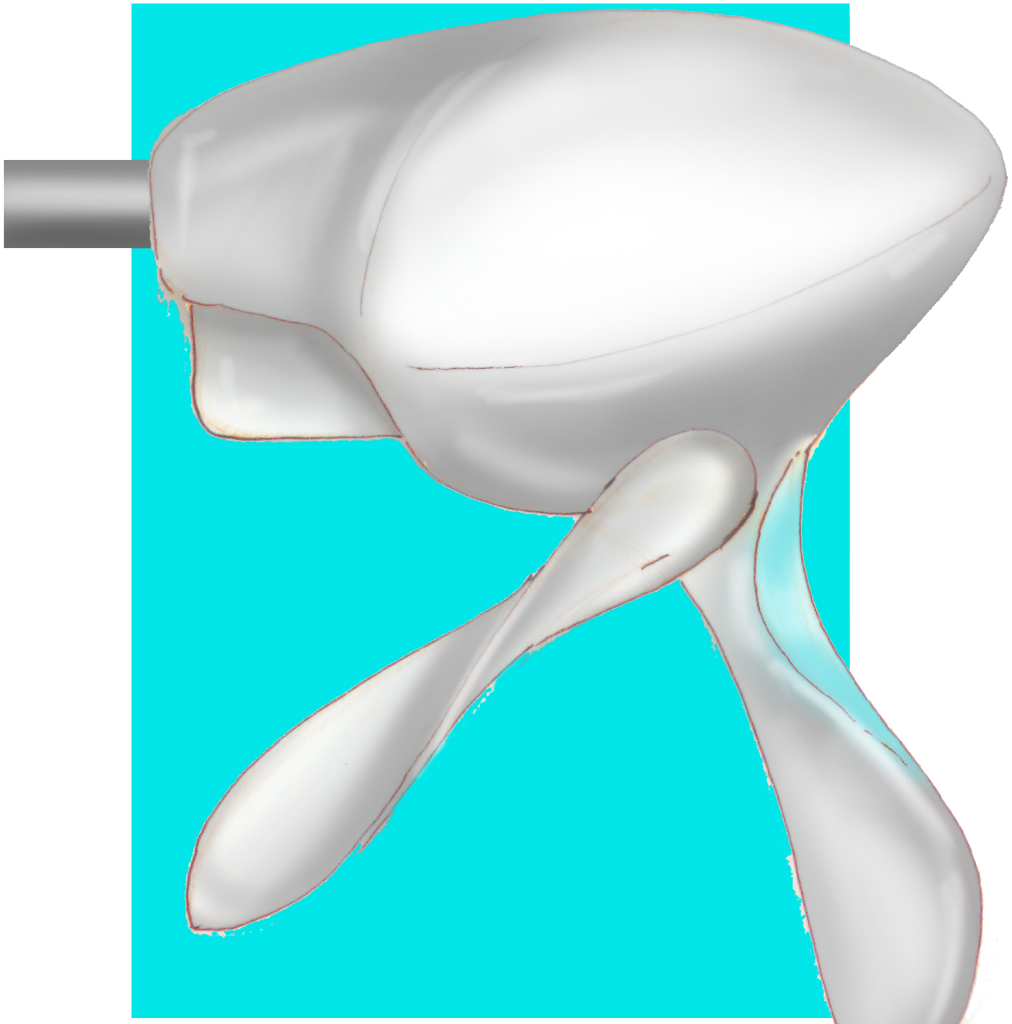
The table above shows the comparative study between the Flower grasper and the suction concept.

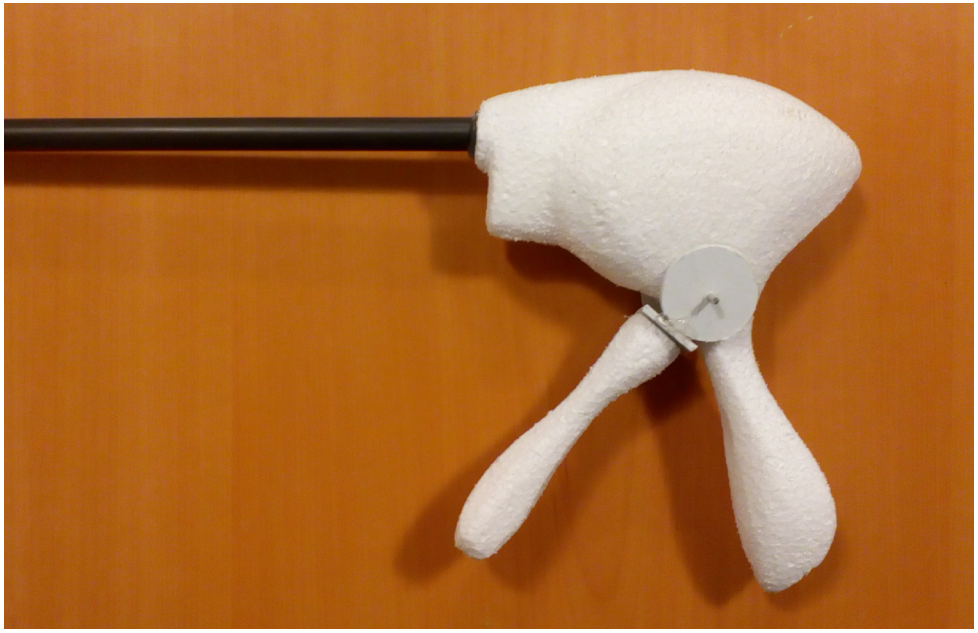


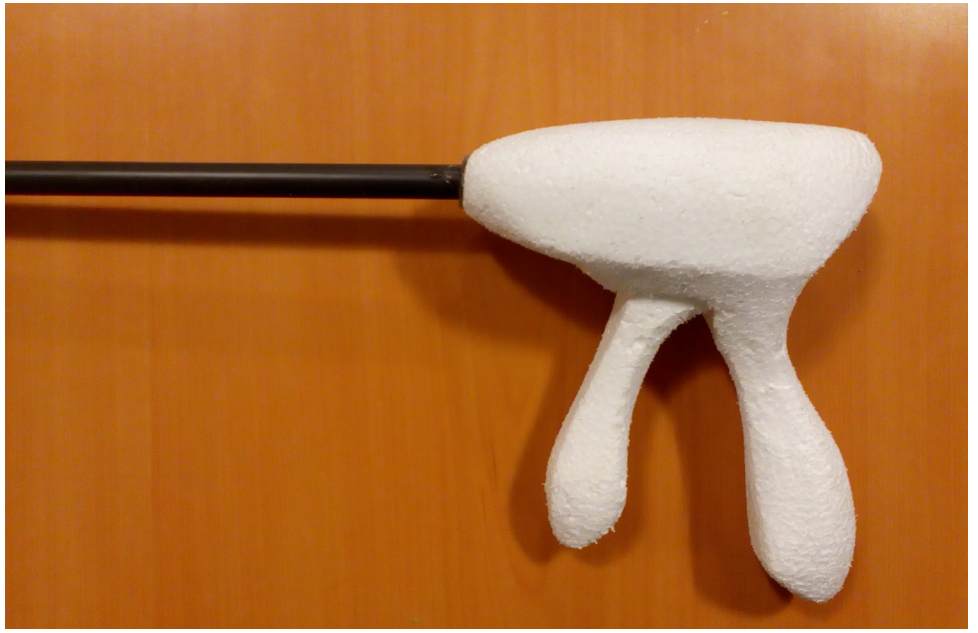
E.6 | FINAL CONCEPT FORM

The suction concept required testing to validate it. It was carried out on a lamb's gallbladder. From the testing it was found out that suction is efficient in stabilizing the gallbladder and also does not damage the gallbladder. Fig. shows the final form of the device

1. Trigger for suction and grasper.
2. Trigger for needle and plunger.
3. Switch button for switching the mode for suction to grasper.







E.7 | FINAL CONCEPT

The suction concept required testing to validate it. It was carried out on a lamb's gallbladder. From the testing it was found out that suction is efficient in stabilizing the gallbladder and also does not damage the gallbladder. Fig. shows the final form of the device

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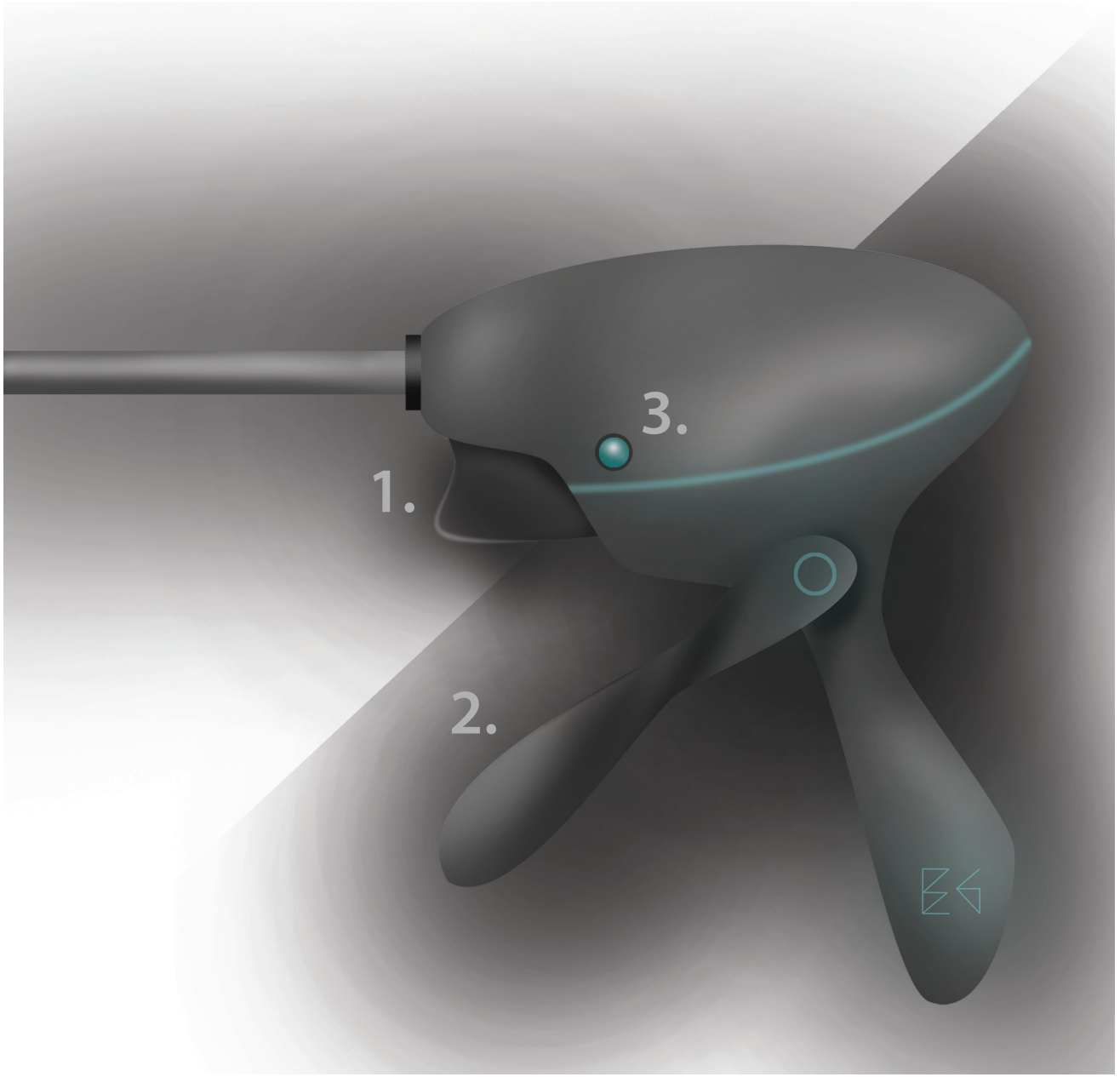
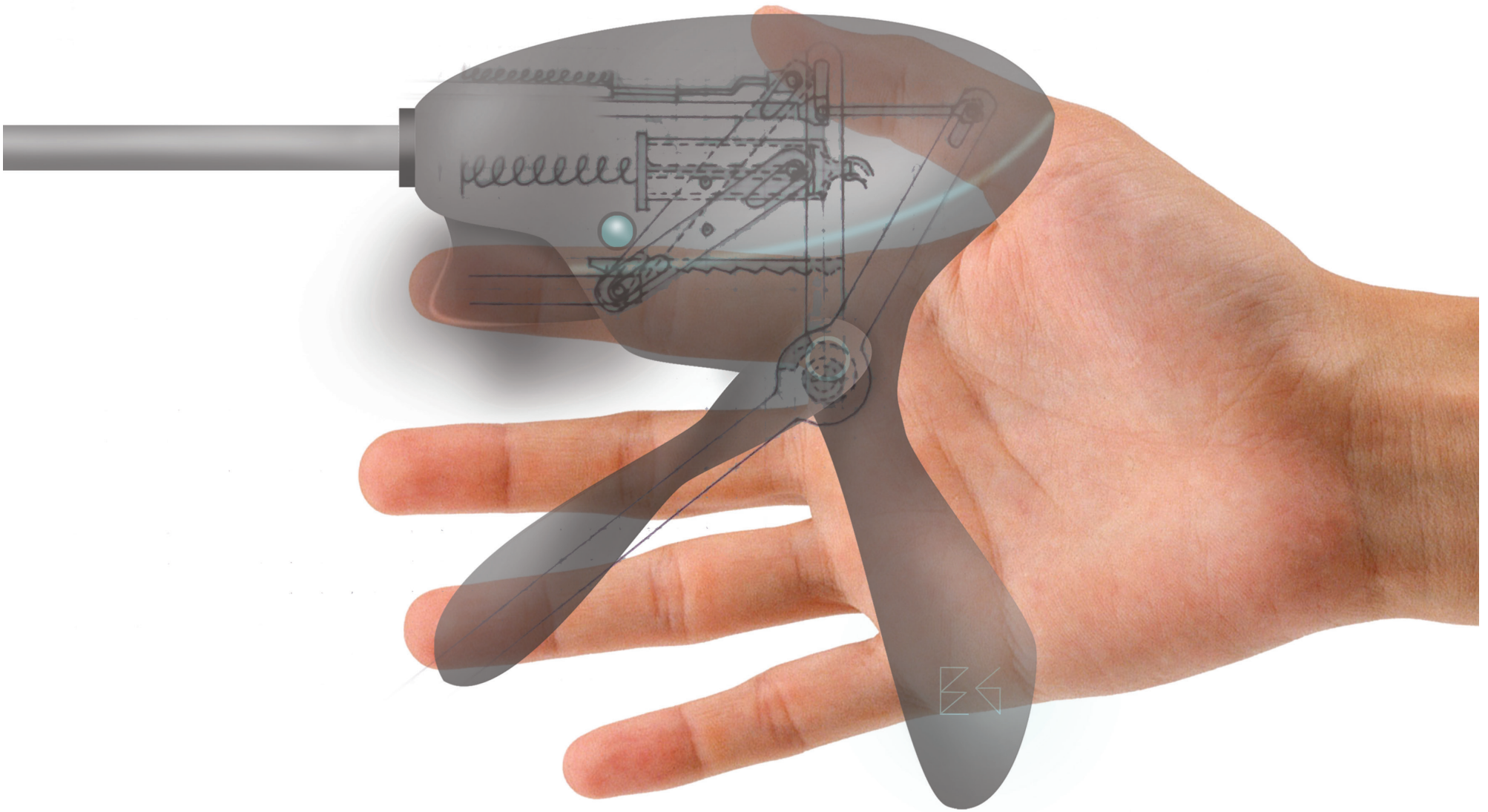
3. Switch button for switching the mode for suction to grasper.





F.

DESIGN AND DETAILING

F.1 | MECHANISM

The fig shows the mechanism concept for the device. This mechanism has been worked on by the team at BETiC. The design for manufacturing will be developed by them,

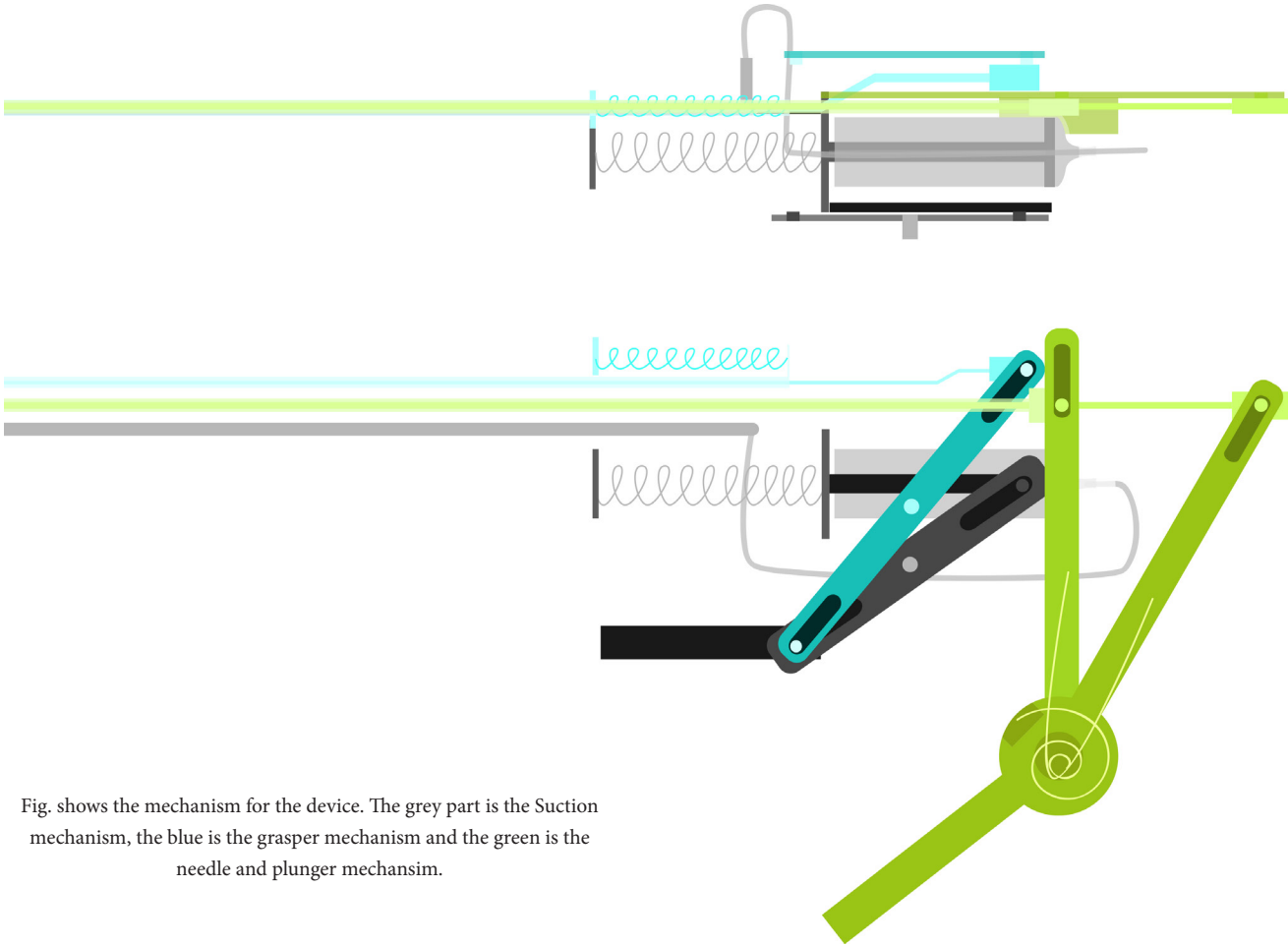


Fig. shows the mechanism for the device. The grey part is the Suction mechanism, the blue is the grasper mechanism and the green is the needle and plunger mechansim.

F.2 | MECHANISM AND MANUFACTURING PROCESSES

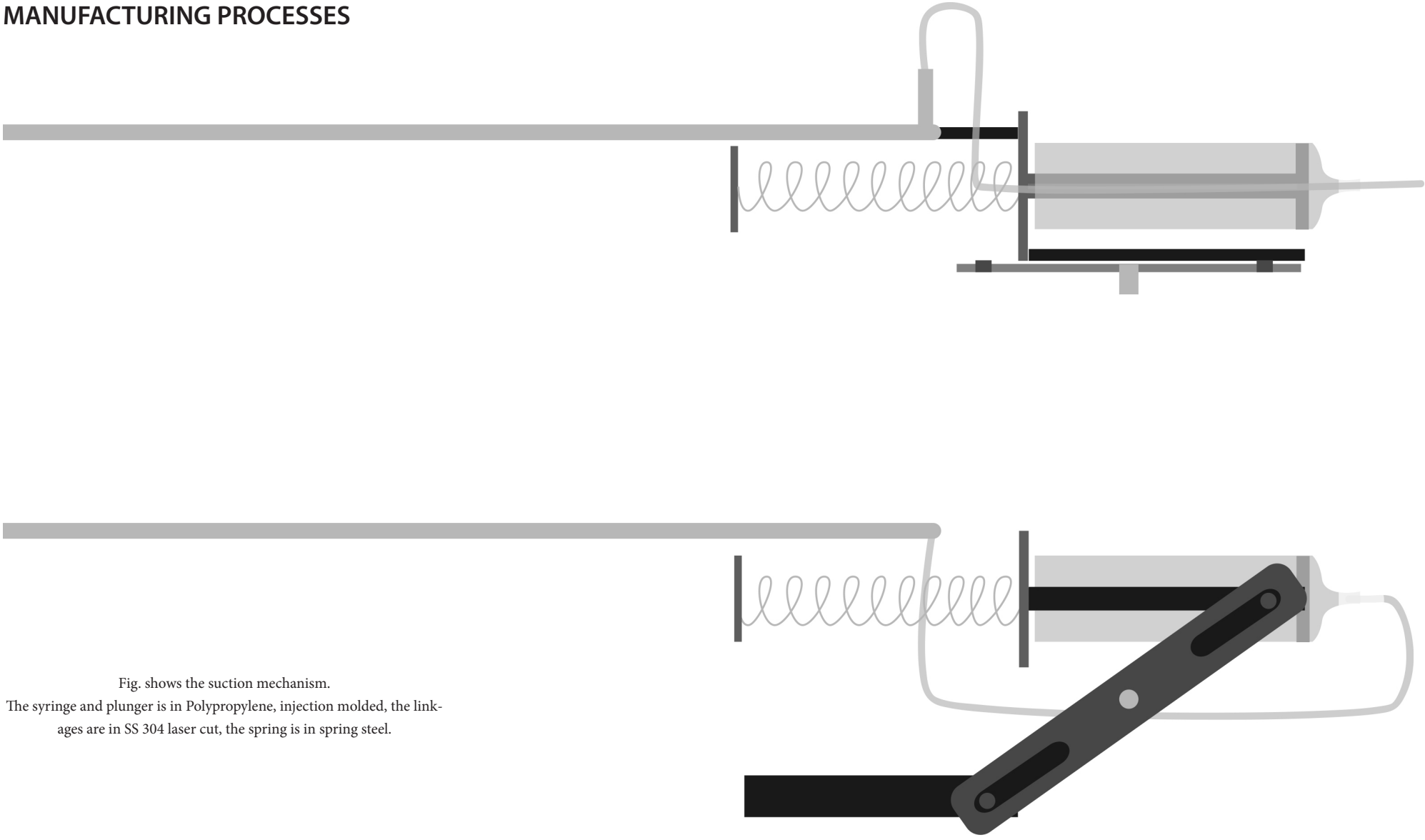


Fig. shows the suction mechanism.
The syringe and plunger is in Polypropylene, injection molded, the linkages are in SS 304 laser cut, the spring is in spring steel.

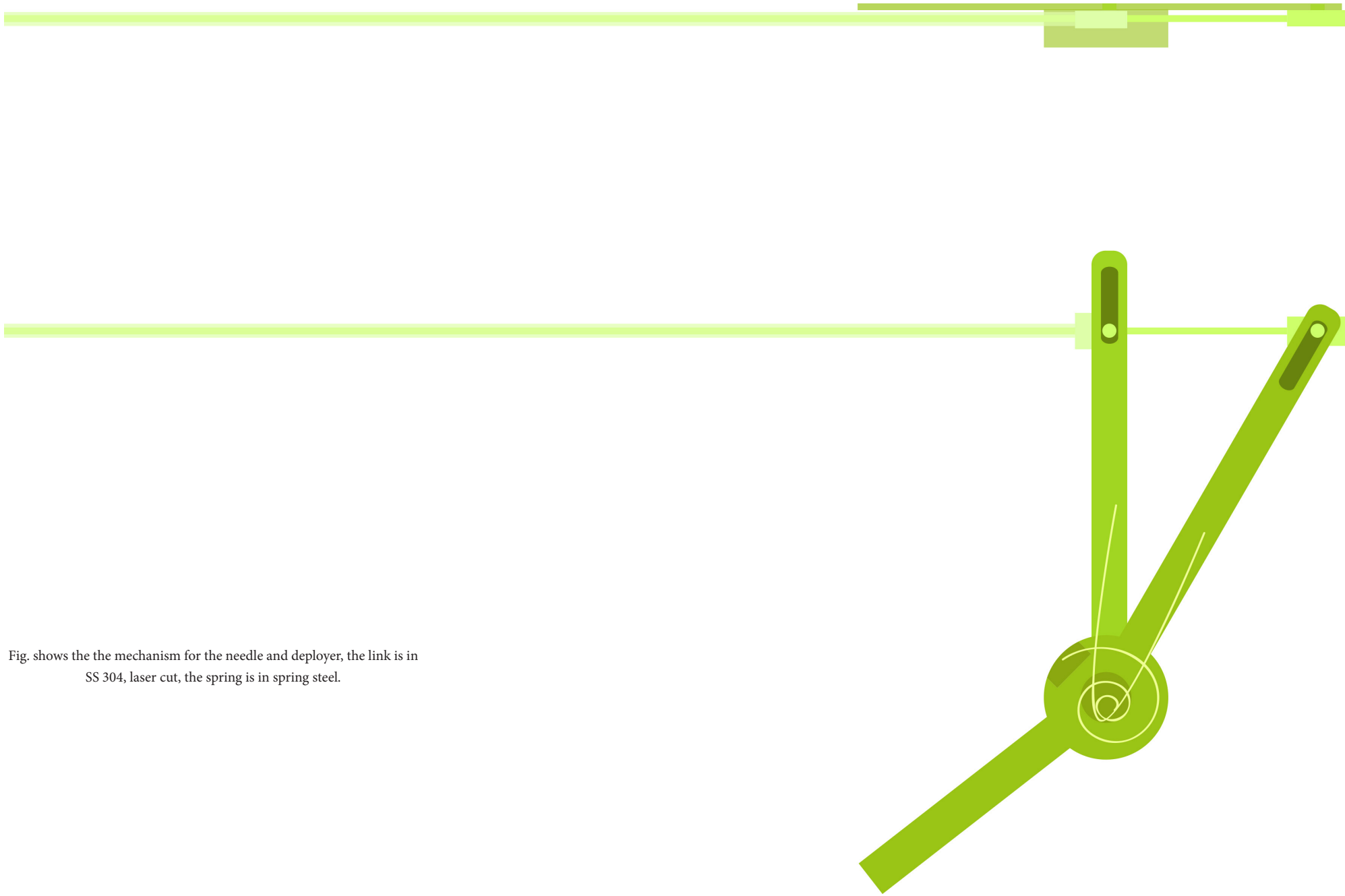


Fig. shows the the mechanism for the needle and deployer, the link is in SS 304, laser cut, the spring is in spring steel.

Fig. shows the mechanism for the grasper. The spring is in spring steel, link is in SS304. The grasper is in 0.3 mm SS 304 and spring steel.

G.

BRANDING
VALUE PROPOSITION
BUSINESS CANVAS

G.1 | BRANDING

ENDOGUN

G .2 | VALUE PROPOSITION

CUSTOMERS

The customers can be divided into the following categories:
Primary being the doctor, who is using the product directly.
Secondary being the hospital management, who takes the purchasing decision.
Tertiary being the hospital staff who is responsible for maintenance, and the patient who is being operated.

The purchasing decision is generally taken collectively by the doctors and the management board. A doctor is the primary influencer who will propose the purchase to be performed. Thus the product should primarily be focused towards the doctor.

VALUE ADDITION

Primary User

The device reduces an incision, thus reducing the chance of infection.
It is easy to install and thus saves time.
The device has been designed so as it is easy to use even for novice users, the learning time required for the device is less.
The handle design is Ergonomic.

Secondary User

The device eliminates a human assistance required during the procedure, thus reducing the cost.
It is reusable thus the recurring cost is just of the Endoretractor.
It reduces the surgery time thus increasing the productivity.
This device is a huge aid for single port surgeries, thus making it a must have tool for a hospitals that encourage research.

G.3 | BUSINESS CANVAS

Key Partners:

BETiC : Biomedical Engineering and Technology (Incubation) Centre, IIT Bombay

IDC School of Design, IIT Bombay

OM Surgicals

Dr. Rasik Shah

Key Activities:

Laparoscopic Product design
Biomedical Product Design
The deivce in Particular is a easy to use retraction device and deployer system.

Key Resources:

Product Designer, innovative product design, interacting design between the product and the User, Ergonoic considerations, Mechanism Conceptualisation

Value Provided:

The device helps in retraction of the gallbladder.
It reduces an incision
Reduces a human assistant
Results in lowered chance of infection
Is hugely advantageous for single port surgeries.

Customer Relationships:

One to one basis costumer interaction initially, to demonstrate the advantages of the device.
Later the interaction could be through Biomedical Product journals and Expos.

Channels:

OM Surgical is a well established brand for the Indian laparoscopic devices.
The interaction will be through them or through BETiC

Customers:

Laparoscopic Surgeons

Hospitals

Costs:

Deployer will be a one time investment while the Endoretractors will be a recurring cost.

Revenue and Benefits:

Revenue generation for projects and future product development.
Funding innovation projects.

G.4 | FUTURE SCOPE

The next step is to refine the form and mechanism, and fianlise the design for manufaturing for the same.

The over all branding and packaging of the device.

Packaging for the tag.

H.

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https://patents.google.com/

PRESENTATIONS:

Research on laparoscopy by Dr.Hemant Bhansali

Endoretractor by Lata Chawla

PEOPLE:

Dr. Rasik Shah
Dr. Pushparaj Karmarkar
Dr. Alka Ranade
Dr. Aparna Kulkarni
Dr. Trimbak Kawdikar
Sanket Pai
Shrishail Hamine