SURGEON FRIENDLY BIOPSY DEVICE AND TISSUE COLLECTION DEVICE FOR CANCER DIAGNOSIS

INDUSTRIAL DESIGN PROJECT III

MDP- 458

BY

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2016

Declaration

I declare that this written submission represents my idea in my own words and where other ideas or words have been included, I have adequately selected and referred the original source.

I also declare that I have adhered to all principles of academic honesty and integrity and have not misinterpreted or fabricated or falsified any ideas / data / facts / sources in my submission.

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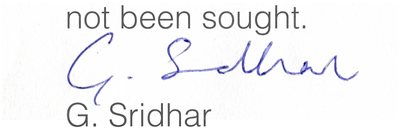


G. Sridhar

M. Des, Industrial Design, 2014-16

Approval

Industrial Design Project 3

Surgeon friendly biopsy device and Biopsy sample collection system for cancer diagnosis
By: Sridhar Geddala
M.Des Industrial Design 2014-2016

Is approved as a partial fulfilment of requirement of a post graduate degree in Industrial Design at IDC, IIT-Bombay.

External examiner

Internal examiner

Project Guide

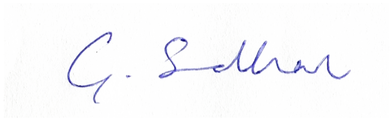
Chairperson

Co-Guide (for Prof. B. RAVI)

Acknowledgement

I would firstly thank my guide, Prof. V Bapat for all the support and valuable inputs that he gave me during the course of this project. A lot of this project would not been possible without his guidance. I would thank BETiC team for their constant support and guidance.

I would also like to thank my parents and batch mates who supported me morally to make this happen.



G. Sridhar
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Abstract

The growing risk and awareness of cancer led to increase in early cancer diagnosis. Biopsy is the most common procedure to diagnose cancer. Needle biopsy using a coaxial needle is the most commonly used biopsy for soft tissues tumours. The project focuses on redesigning soft tissue biopsy device handle, which is ergonomic, easy to use and has features like variable throw length and uses existing Bard co-axial needle. Another aspect of the project focuses on designing a Tissue collection device, in the place of existing steel bowl. The initial research includes field visits, patent study, and market analysis of existing products. After studying the sub-functions of a reusable biopsy device (Bard Magnum) and activity analysis it was observed that the design of the device can be improved further.

Keeping Product interactions, ergonomics, and aesthetics as focus areas; many ideations were done. Different forms are explored by changing the position of the actuation buttons and considering ergonomics. The Bolt and Nut mechanism developed by BETiC is modified to fit in to the different forms of the device. In the final form all the interactions are possible with single holding posture.
The tissue collection bowl uses a small vibrator to separate the tissue sample from the needle and has a small removable plate for transferring the tissue sample to the formalin bottle.

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1. Introduction

The growing risk and awareness of cancer led to increase in early cancer diagnosis. Biopsy is most common procedure to diagnose cancer. Needle biopsy using a coaxial needle is the most commonly used biopsy for soft tissues tumours. The project focus on redesigning soft tissue biopsy device handle, which is ergonomic, easy to use and having features like variable throw length and uses existing bard co-axial needle. In the second part it focuses on designing Tissue collection device, in the place of existing steel bowl.

Fig 1 Biopsy

2. Initial brief

To redesign a reusable soft tissue biopsy device handle using bolt and nut mechanism, the device should use existing bard coaxial needle, easy to use, ergonomic, easy to sterile and low cost manufacturing.

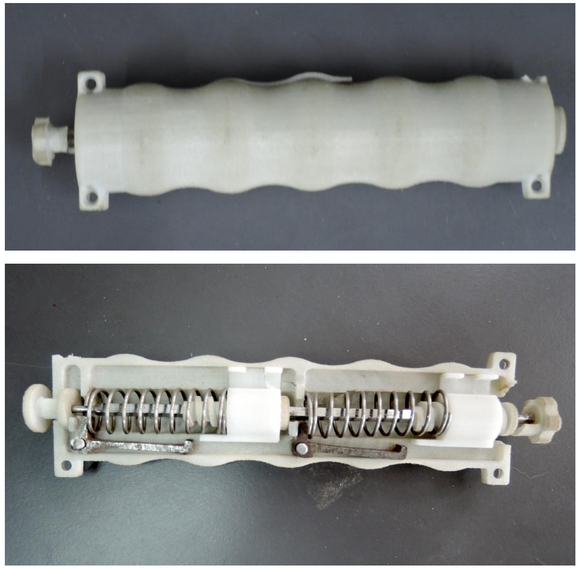


Fig2 prototype using bolt and nut mechanism

(The bolt and nut mechanism is designed by Mr Shivam Mittal, (Mech eng., IIT Bombay 13-15), the mechanism has some advantages over existing devices in the market like 1. Reusable handle at low cost 2. Incremental variable throw length3. Uses existing bard coaxial needle)

3. Research

The research include field visits, patent study and market analysis of existing products.

Research on Biopsy process

Initial Research is done to understand types of cancers and different types of biopsies. In the later stage research is restricted to tru cut or soft tissue biopsy devices, as the initial brief is to design a reusable soft tissue biopsy gun.

Research on Biopsy devices

A study on existing core needle biopsy devices, advantages and disadvantages, patents study. Other existing features were discussed in this part

Fig 3 Biopsy

Fig 4 Biopsy devices

3.1. Biopsy process

A needle biopsy is often used on tumours that your doctor can feel through your skin, such as suspicious breast lumps and enlarged lymph nodes. When combining an imaging procedure, such as X- ray, needle biopsy can be used to collect cells from a suspicious area that can't be felt through the skin.

Needle biopsy is also known as percutaneous biopsy. It removes tissue using a hollow tube or a needle. The needle is passed several times through the tissue to take multiple samples so as to decrease the sampling error. Needle biopsy is done with CT scan or Ultrasound. These imaging tools help guide the surgeon to the right area.

Fig 5 Biopsy

3.2. Cancer sites and biopsy types

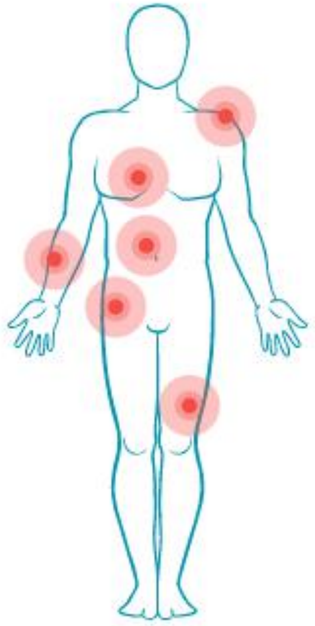


Fig 6 Cancer sites

Cancer sites

1. Bone marrow
2. Gastro intestinal tract
3. Lung
4. Liver
5. Prostate
6. Nervous system
7. Urogenital system
8. Breast
9. Lymph node
10. Muscles and skin

Biopsy types

1. Bone marrow biopsy(Blood cancer, leukaemia, lymphoma/multiple myeloma)
2. Endoscopy Biopsy(cystoscopy to collect tissue from bladder/Bronchoscopy to collect sample from lung)
3. Needle biopsy-
    1. Fine needle Biopsy
    2. Core needle Biopsy
    3. Vacuum assisted biopsy
    4. image Guided Biopsy

3.3 Deciding parameters

The deciding parameters for choosing biopsy type include

1. How suspicious the tumour looks
2. How big is the tumour
3. Where it is in the breast
4. How many tumours are there
5. Other medical problems
6. Personal preference

3.4 Types of needle biopsy devices

Fig 8. Fine-needle aspiration. During fine-needle aspiration, a long, thin needle is inserted into the suspicious area. A syringe is used to draw out fluid and cells for analysis.

Fig 9. Core needle biopsy. A larger needle with a cutting tip is used during core needle biopsy to draw a column of tissue out of a suspicious area.

Fig 10. Vacuum-assisted biopsy. During vacuum-assisted biopsy, a suction device increases the amount of fluid and cells that is extracted through the needle. This can reduce the number of times the needle must be inserted to collect an adequate sample.

3.5 Core needle biopsy

In core needle biopsy a large coaxial needle with a cutting tip at the end is inserted into the tumour to collect the sample. A mechanism called sequential firing is used to fire the needle into the tumour. First the inner needle with a notch at the tip will enter the tumour, followed by the outer hallow needle. The outer needle cuts the sample that slides in to the notch of the inner needle. Practical experiments shown that the throwing speed should be 8 mts/sec

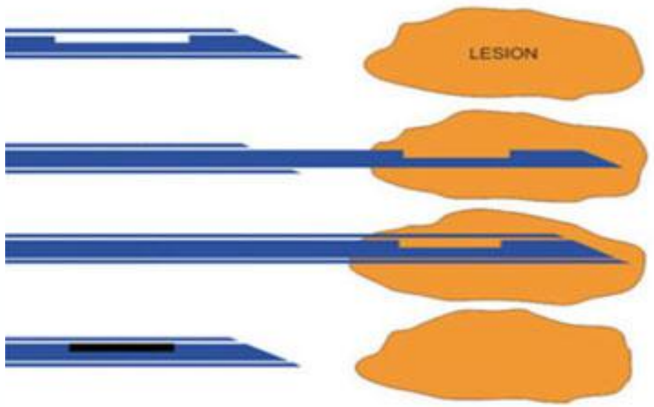


Fig 11 core needle

3.6 Core needle biopsy advantages and drawbacks

Advantages

- Accurate if done by an experienced surgeon
- It is quick and easy
- It does not require an open surgery and causes minimal damage to the patient
- The chances for infection are also less compared to open surgeries.
- Recovery time is less for patient in needle biopsy

Drawbacks

- Needle may miss a tumour
- Multiple samples are taken at different angles to minimise the sampling error
- It may not give full information about the tumour as the sample might get crushed
- In some cases surgical biopsy is needed to get the complete information on the tumour
- If the test comes positive then the whole tract of the needle entry will be cleared out in the final surgery to avoid contamination of the rest of the body.

3.7 Market study on biopsy devices

Fig 12 Bard Automatic use and throw

Fig 13 Bard Automatic use and throw

Fig 14 Achieve Automatic biopsy
Use and throw

Fig 14 Bard Magnum reusable device

Fig 15 Alfagun Reusable device

Fig 16 Cook Reusable device

3.8 studying the sub functions using bard magnum

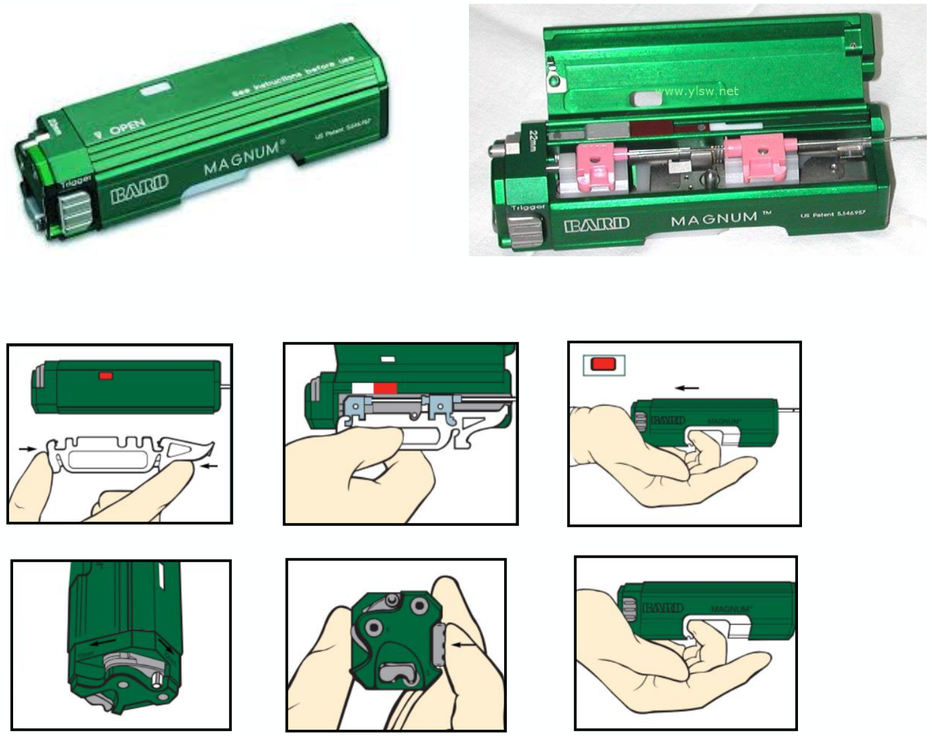


Fig 17 Bard magnum sub functions

As the initial brief is to design a reusable biopsy handle the sub functions of the device are studied on the existing device Bard magnum

Sub functions of the device

1. Loading needle
2. Actuating device
3. Lock mechanism
4. Adjusting throw length
5. Triggering
6. Collecting sample

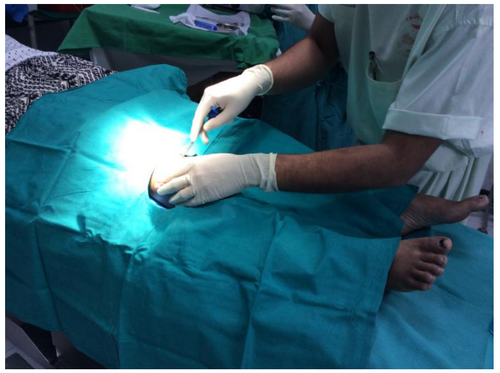
3.9 Patent study

Patents related to different reusable biopsy devices are studied to understand different alternative mechanisms

Sub Function	Observation
1.Loading needle Mechanism	EP1135065B1,
2.Driving Unit /Actuation mechanism US2012	US 4944308, US 20100228146 A1
3. Length adjustment mechanism	US2012/025230A1, US 4958625A
4. Locking Mechanism	
5. Trigger Mechanism	
6. Sample collection	US 20100228146 A1
7. Needle design	US 20120220894 A1, US 20040133124 A1

3.10 Field visit: Tata Cancer centre

Fig 18 Tata cancer memorial hospital



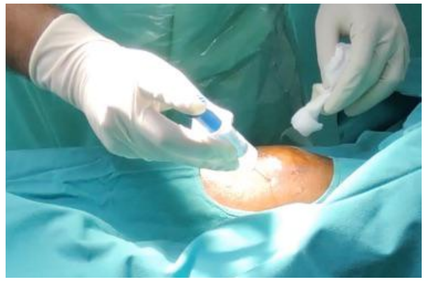
As part of field visit Tata cancer memorial hospital is visited to observe the biopsy processes and to take necessary inputs from the doctors

3.11 Activity analysis

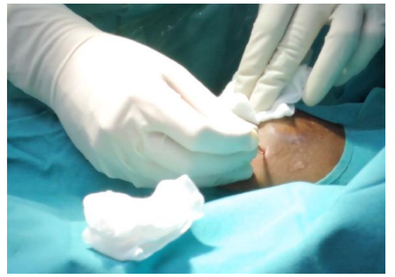
00:00 min — 05:00 min — 06:00 min — 07:00 min

Cleaning the device

Cleaning biopsy spot with Betadine



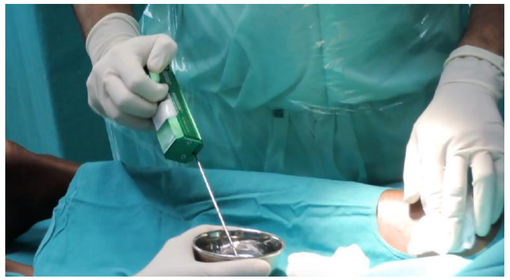
Giving Anaesthesia



Making a cut at Biopsy spot

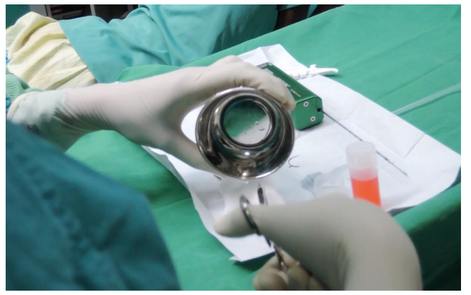
08:00 min — 18:00 min — 19:00 min — 25:00 min

Biopsy



Removing the samples

Stitching the Biopsy spot



collecting the samples

3.12 observations from the field visit

Activities of doctor

1. Mark the biopsy spot
2. Apply Betadine
3. Give anaesthesia
4. Make a small cut on the spot
5. Insert biopsy needle and collect sample
6. Insert in water bowl to separate sample
7. Actuate the device and repeat the process for 3 to 4 times
8. During the entire process doctor covers the biopsy spot with one hand and do all the actions with one hand.
9. Stitch the biopsy spot

Activities of Nurse

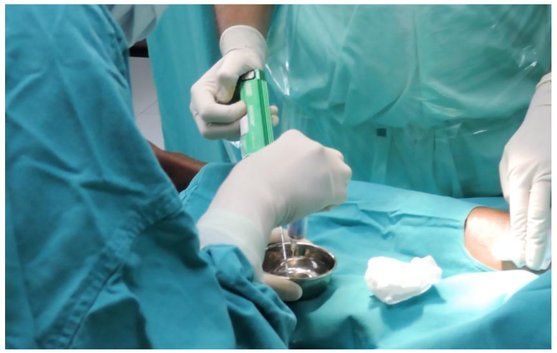
1. Pass the devices in order
2. Pass cotton and water to clean the needle and biopsy area
3. Separate sample using needle
4. Check the quality of the sample
5. Transfer samples to formalin solution
6. Stick label and name it
7. Clean the bowl and biopsy handle

Key points

1. Doctor uses only one hand during the entire biopsy to stop the bleeding and the other hand to do the biopsy.
2. All the other operations on the biopsy device like actuation, adjusting the throw length should be done with one hand
3. Separating the tissue, transferring the tissue to formalin solution, passing the devices to doctor, checking sample quality, cleaning and dressing are all done by nurse.

3.13 problem Identification

1. Different holding postures are needed for different sub-activities of the device
2. For device actuation the holding posture is not very ergonomic and less comfortable



1. Most of the times the sample taken out sticks to the needle and doesn't come easily, the nurse has to take it manually using another needle.
2. Transferring the sampling to the Formalin bottle is not designed properly and it takes multiple attempts to transfer the samples to the formalin bottle

4.Refined design brief

1. Redesign a Surgeon friendly reusable biopsy handle, with following requirements

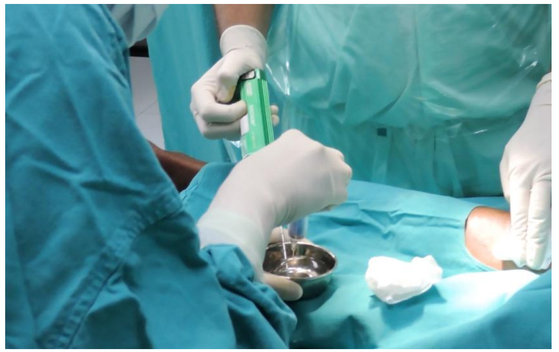
    Can be used with existing Bard co- axial needle

    Ergonomic and comfortable to do all the sub functions

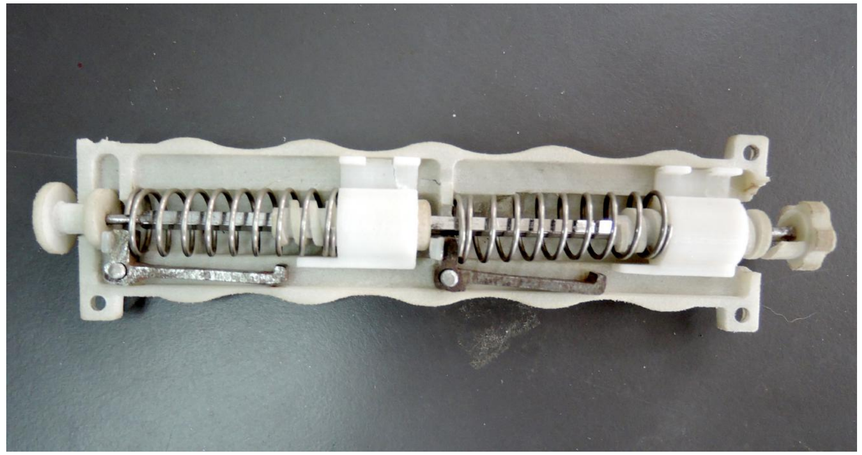
    Minimum holding postures

    Uses Bolt and nut mechanism

2. Design a tissue collection system, the system should simplify the process of transferring the samples to the formalin bottle.



5. Redesigning reusable biopsy handle



To redesign a reusable biopsy handle which uses screw and nut mechanism which allows variable throw length and uses existing bard coaxial needle and with following desired features

1. Ergonomics
2. product interface design
3. Aesthetics

5.1 studying bolt and nut mechanism

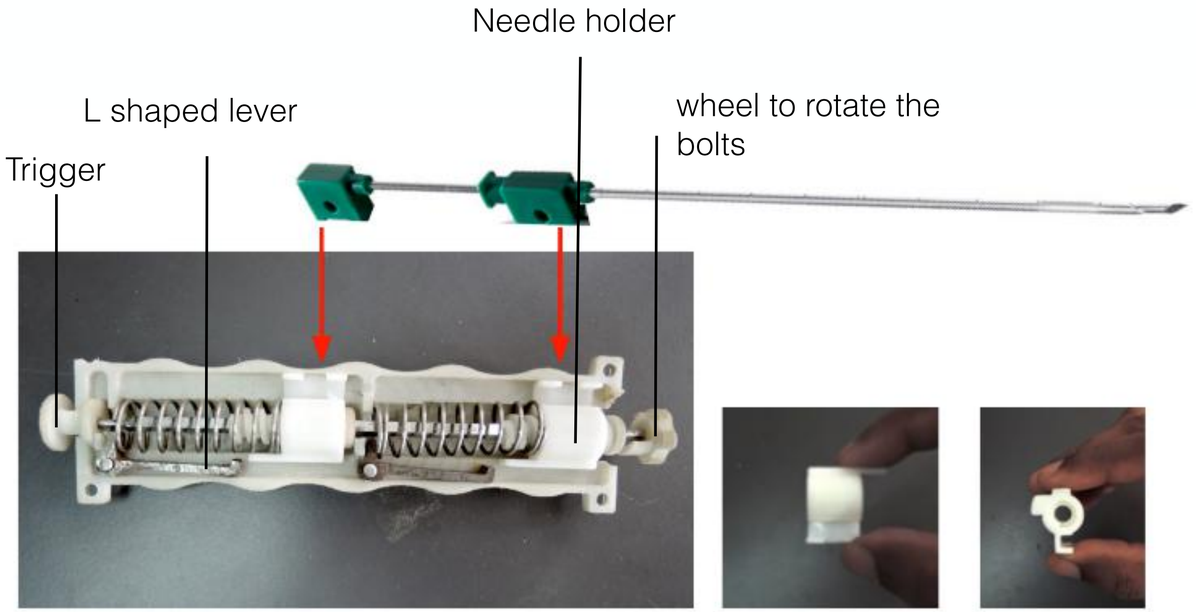


Fig 20 spring loaded mechanism uses sequential firing concept

Fig 19 needle holder profile

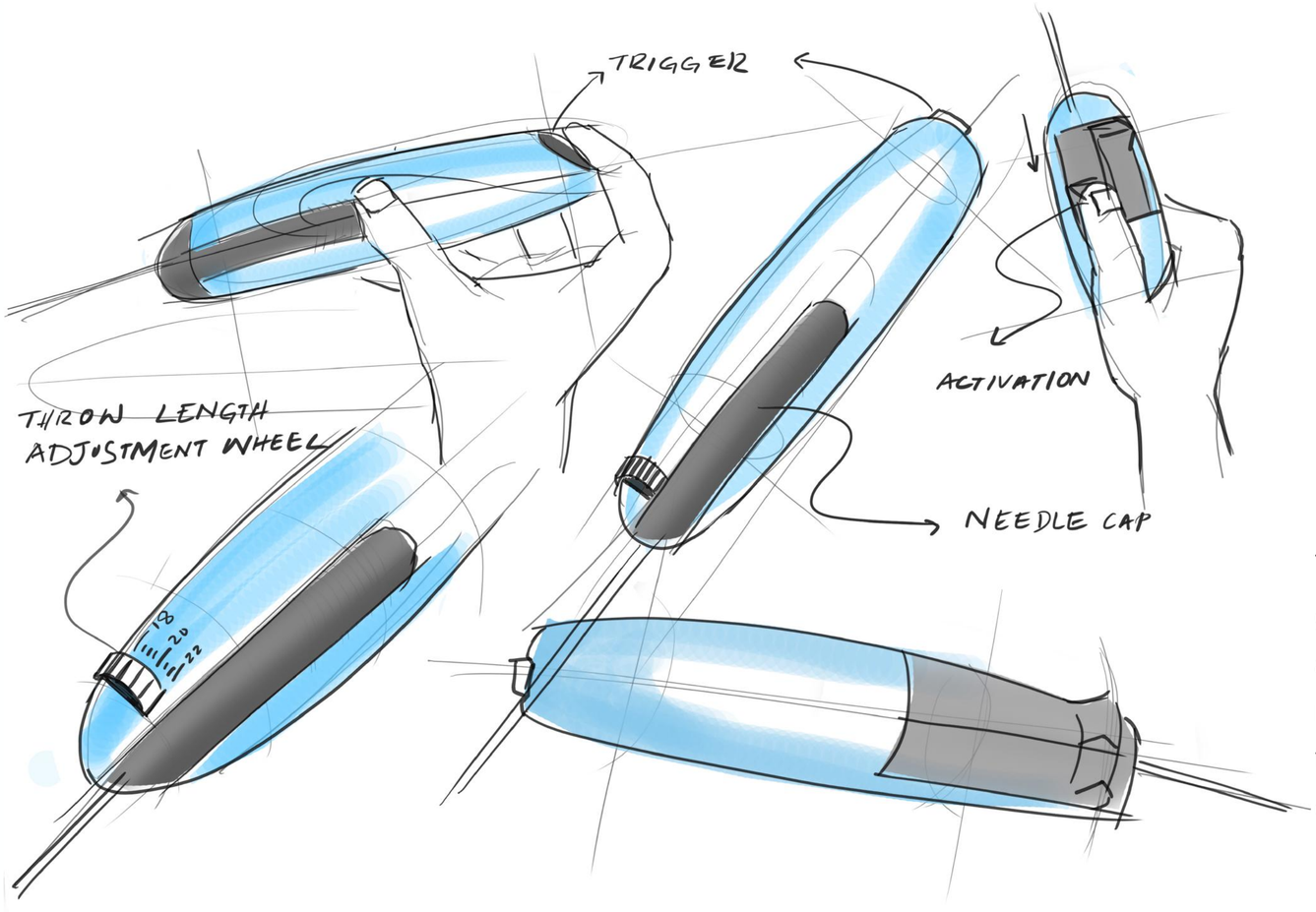
The bolt and nut mechanism uses springs to load energy to fire the needles. The needle holders acts as nuts and bolts are rotated on a central axis, such that the holders move to and fro to adjust the throw length.Two external buttons are used to push the both the needle holders to lock them with the L shaped levers.The levers get released and needle is fired by pressing the trigger.

5.2 Mood board

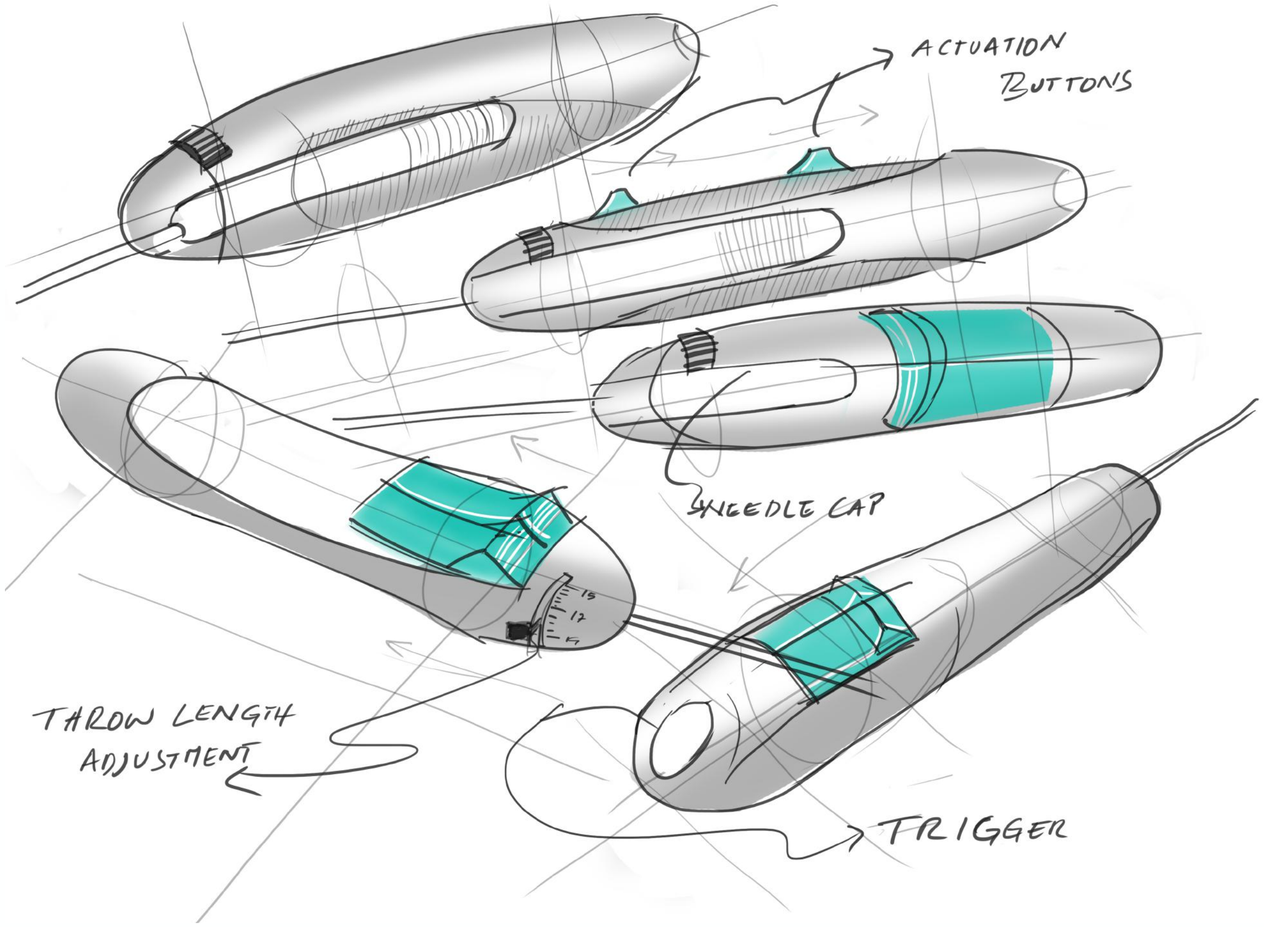
Keywords

- Soft
- Friendly
- value

5.3 Form ideation one

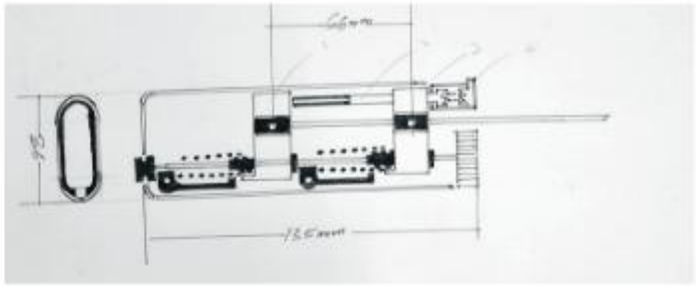


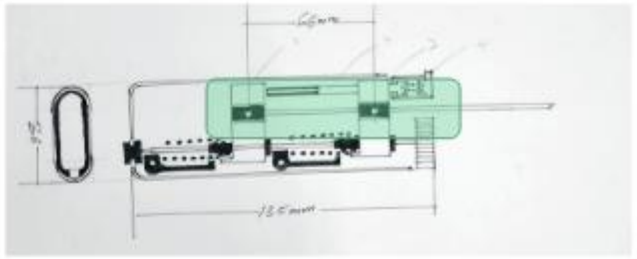
The initial ideations were done by giving a basic form to accommodate the Bolt and nut mechanism and to understand the possible interactions with the device

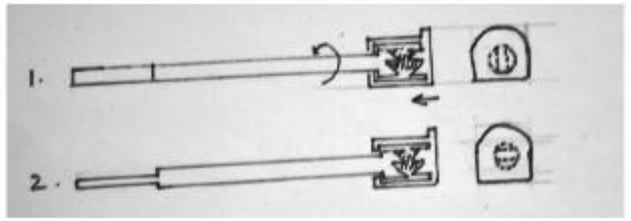


Further different forms were explored by changing the actuation buttons position. Actuation buttons push the needle holders and lock them to the L shaped levers.

5. 4 Bolt and nut mechanism two



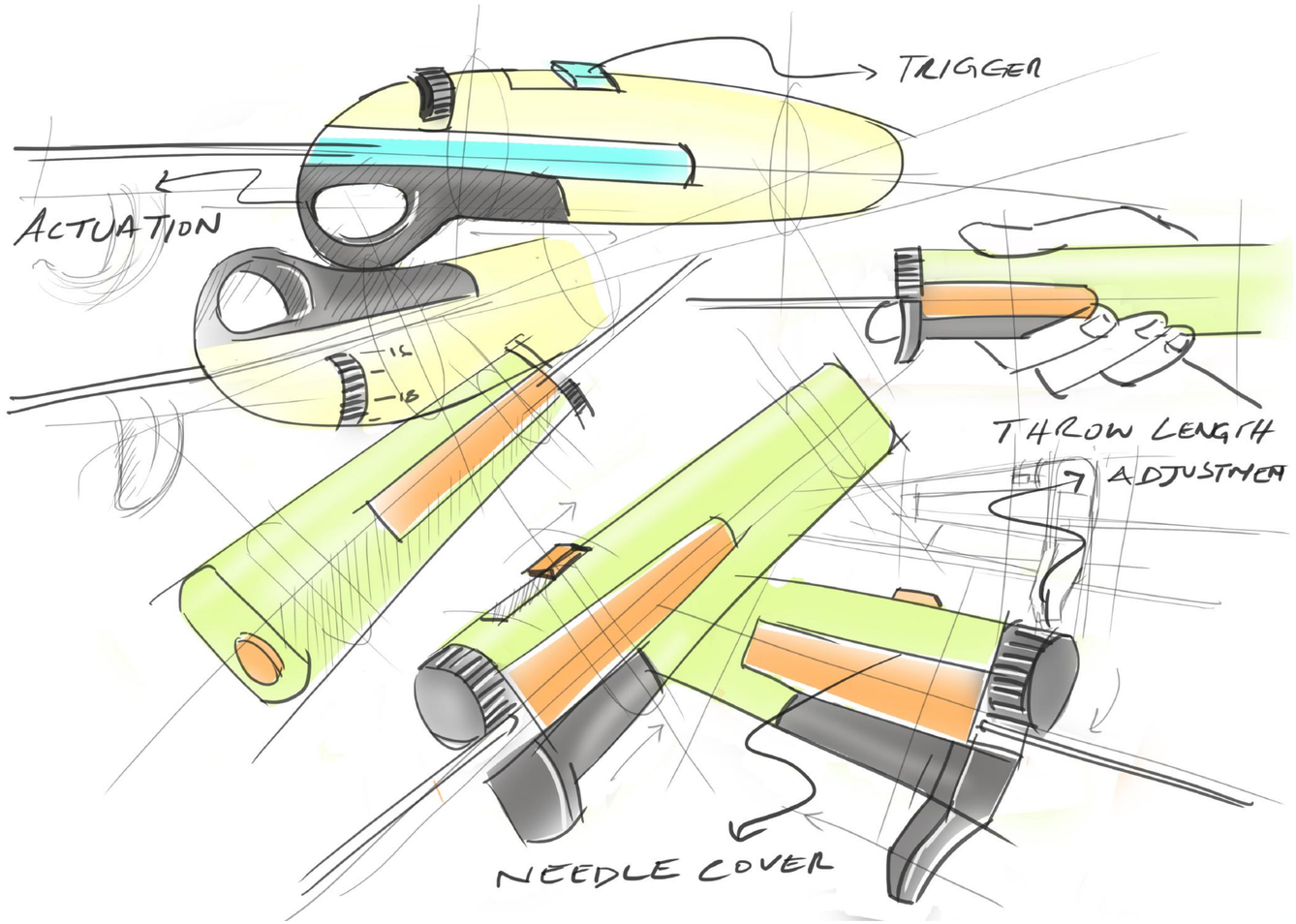




The bolt and nut mechanism is slightly modified such that the needle holders can be pushed with one single button. this is possible by changing the design of the needle holders and the actuation button.

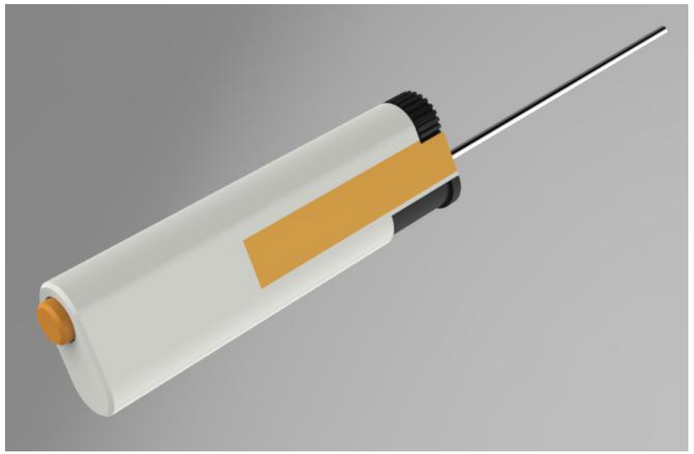
Fig 22 one actuation button mechanism

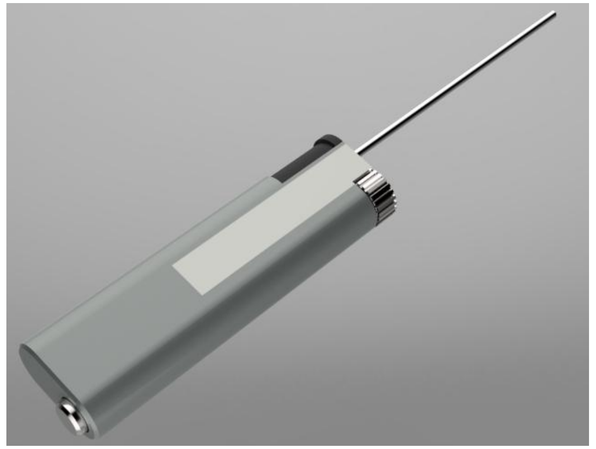
5.5 Form ideation two

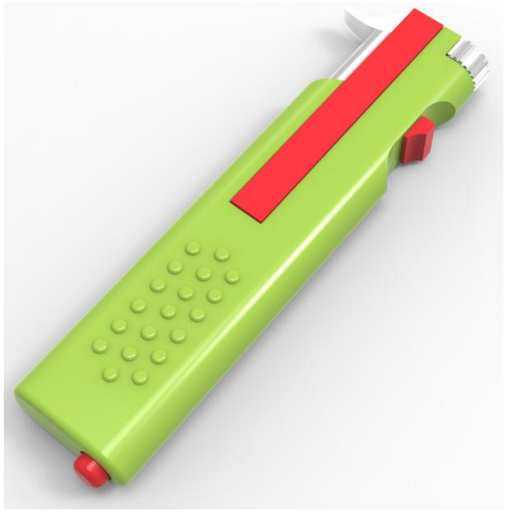


Using single button actuation, different forms were explored which will have better ergonomic grip as the form will be much sleeker such that doing the sub functions is much easier.

Renders







5.6 Prototype one

Prototype 1

The first prototype is made to understand all the interactions, like loading the needle, actuation, trigger, ergonomics and comfort. Further the device is taken to the doctor for the feedback and further changes.

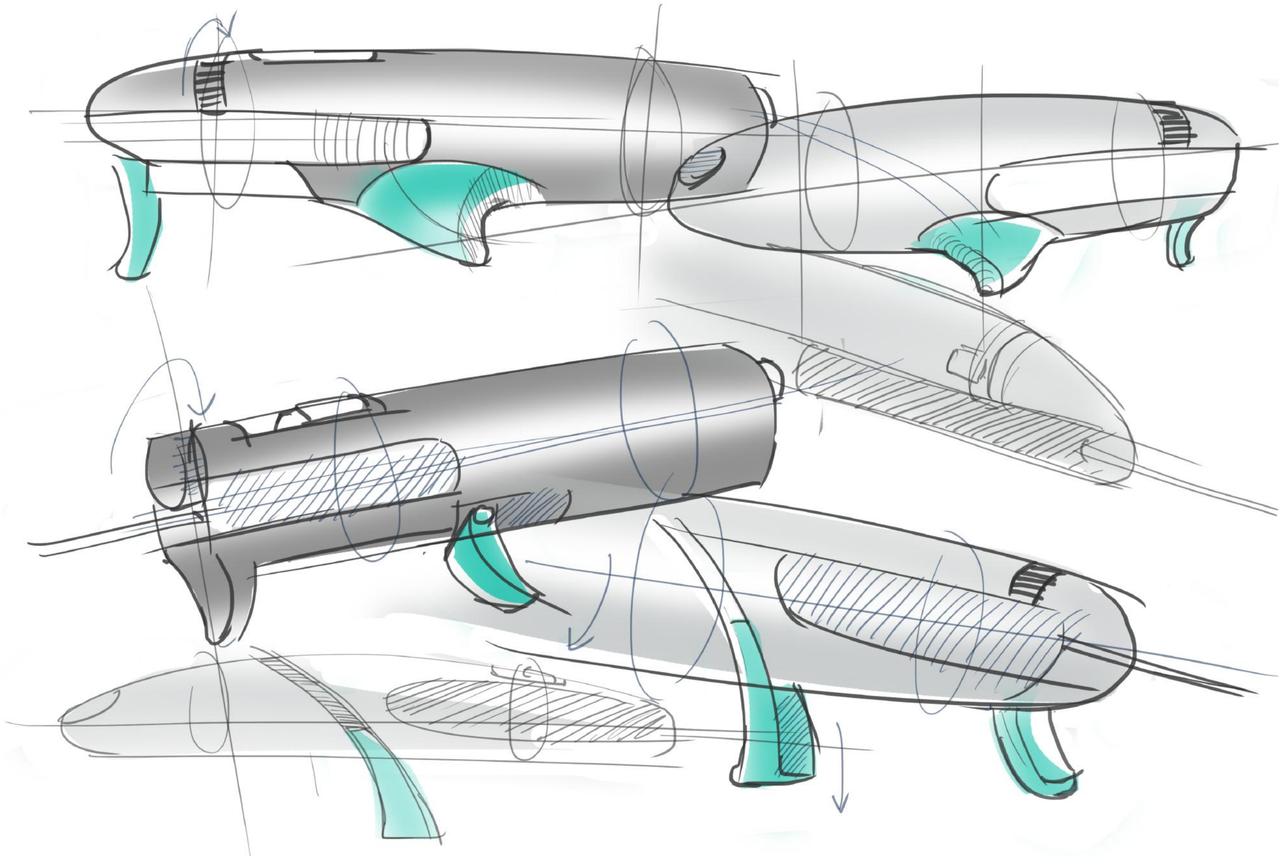
5.7 Feedback

Fig 23 Hinduja hospital

Fig 24 Dr Manish Agarwal

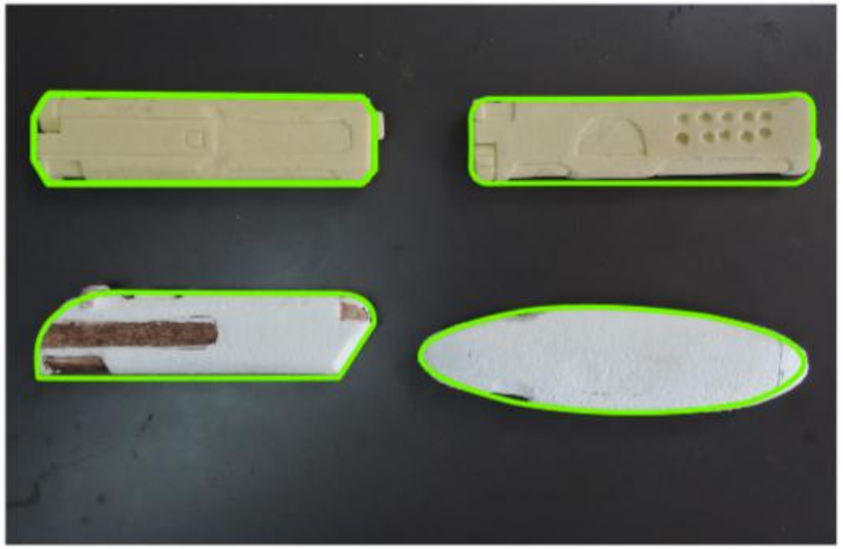
Feed back on the new design is taken from Dr Manish Agarwal on the new forms. The feed is positive on the sleeker design as it is better ergonomic than the existing products. Further ideation and form study is done to improve the form and design .

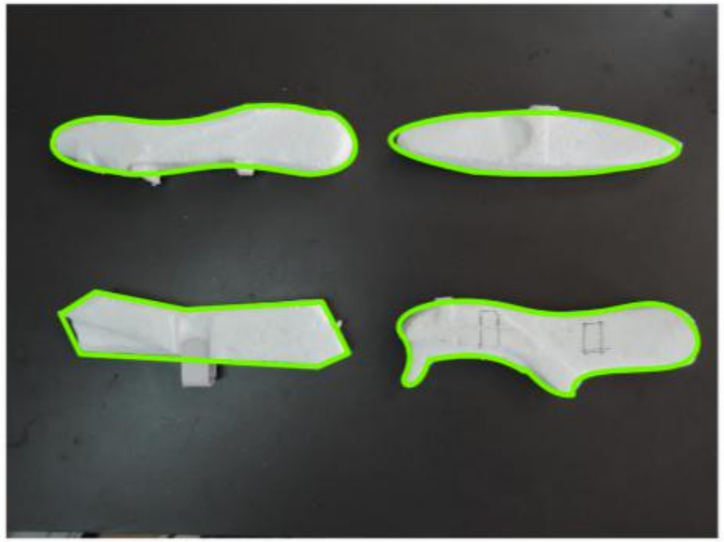
5.8 Form ideation 3



During the actuation the device is hold like pistol. A grip is needed for the thumb to make it comfortable to hold like pistol and still have the minimal grip. So different ideations give gip for the thumb are explored.

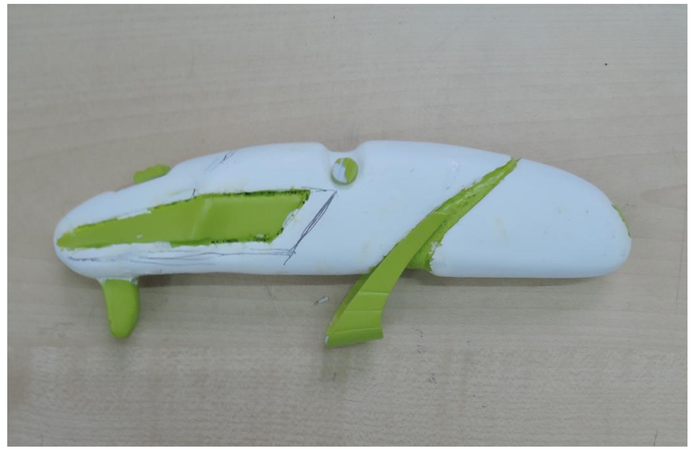
Form ideation





Different form ideation

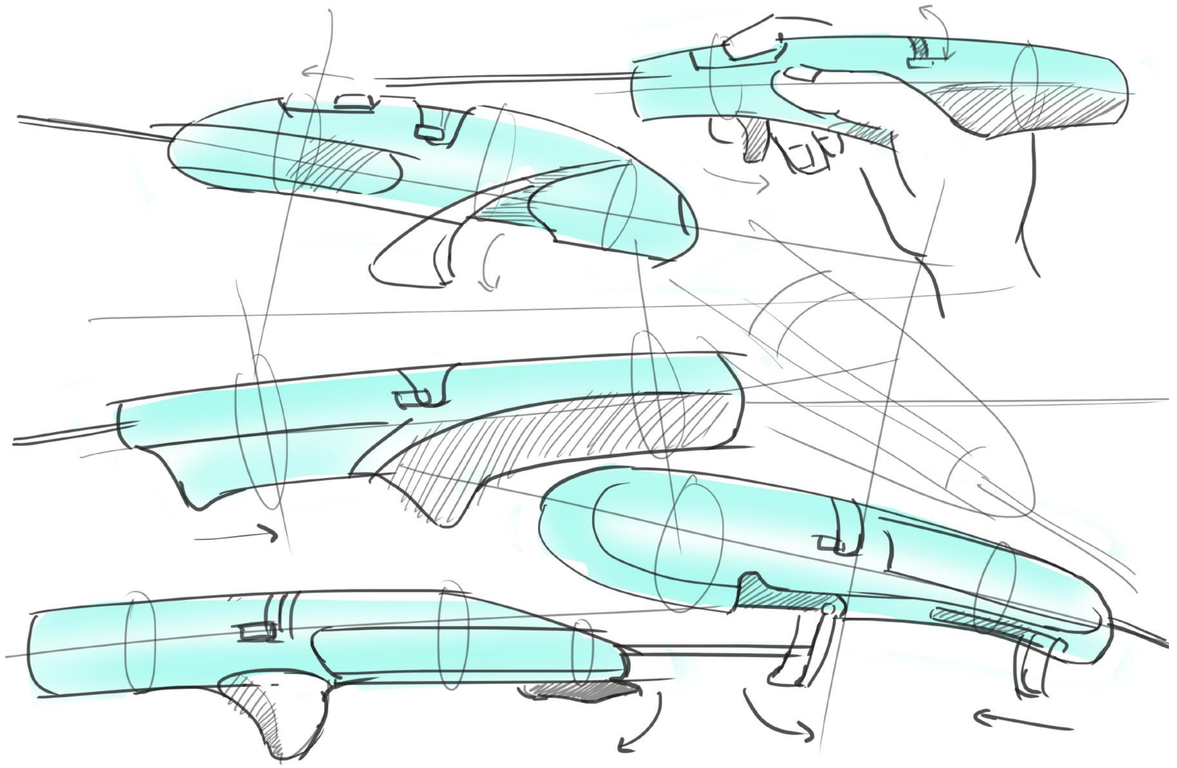
5.9 Prototype two



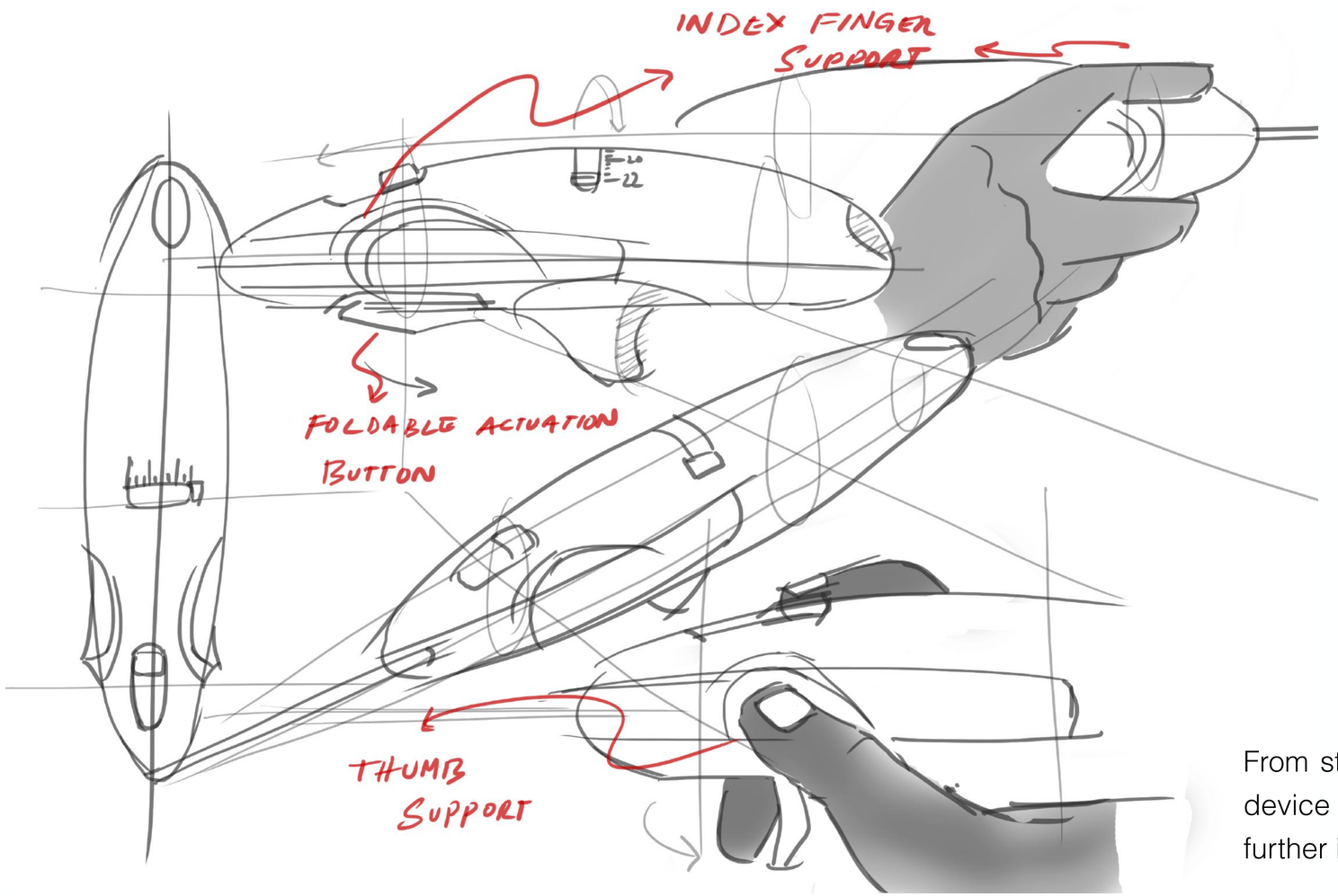
One of the form is selected and a prototype is made to understand the interactions and ergonomics of the device.

A prototype is made to the dimensions and to further decide on the form , aesthetics and ergonomics of the device.

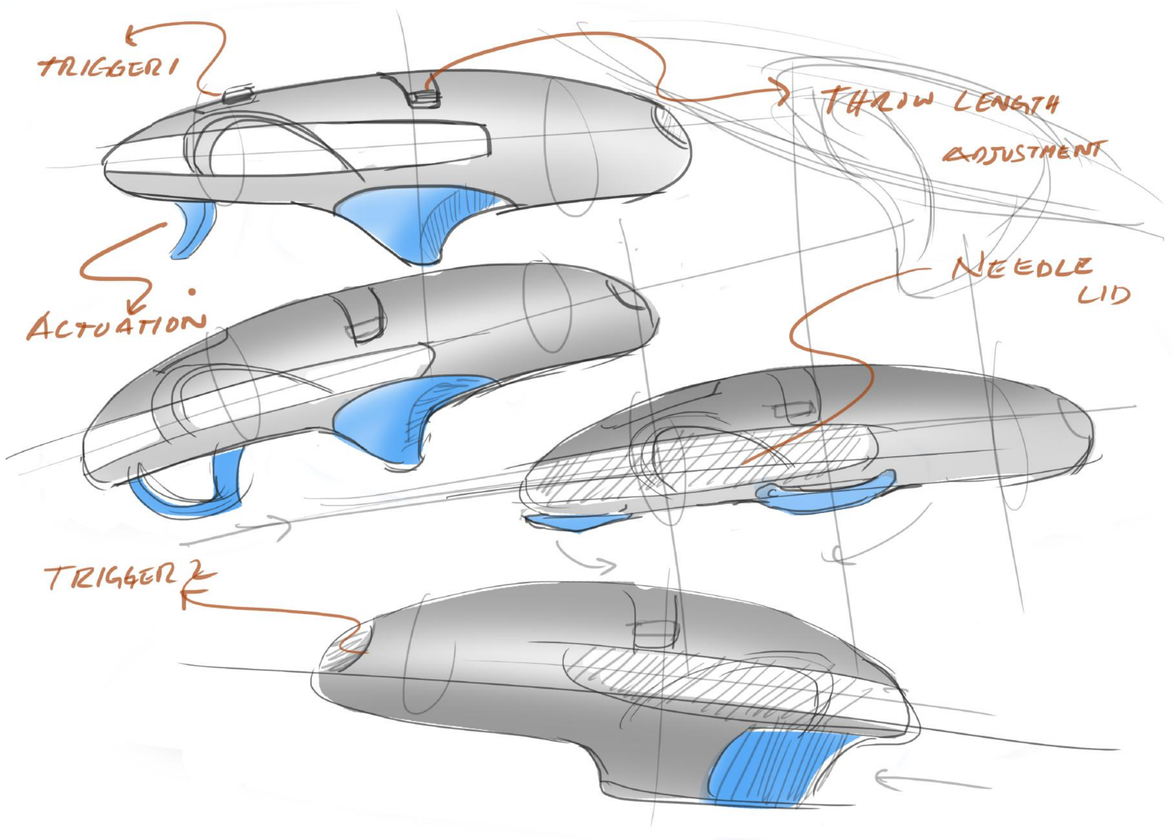
5.10 Form ideation four

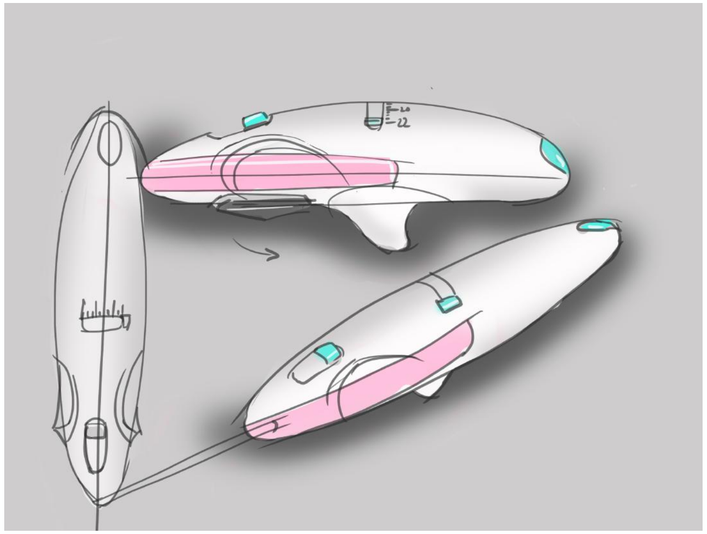


the second prototype is shown to different people mostly designers for the feedback and the form is still explored to make it look more clinical and simple.



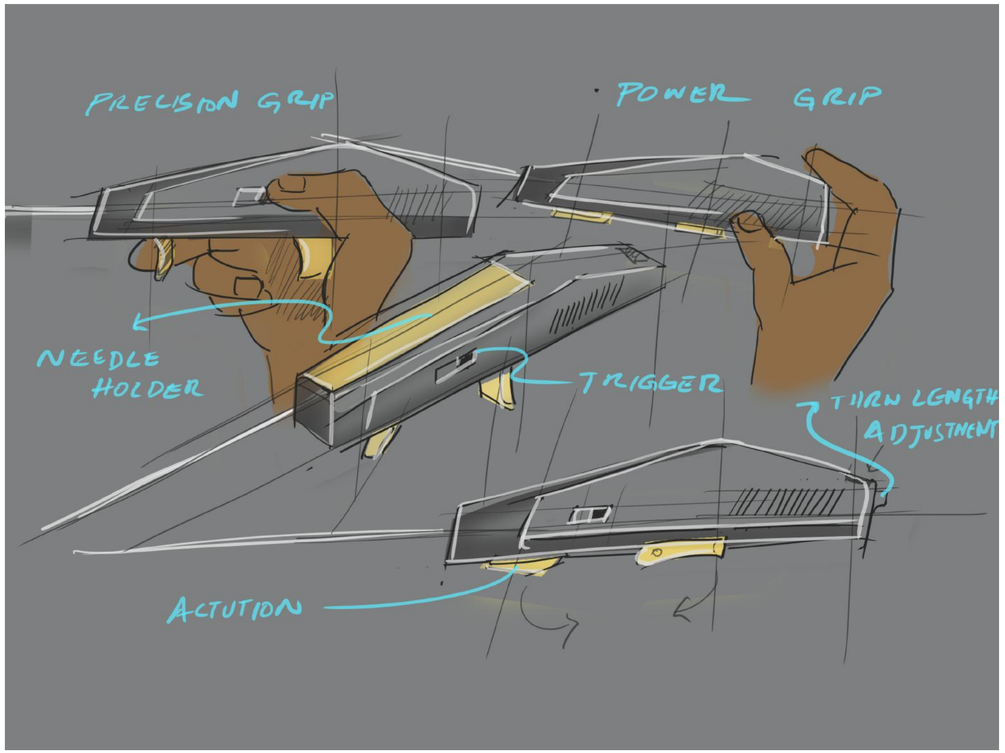
From studying the ergonomics during the use of device during different subfuctions, the design is further improved to much simple and ergonomic.

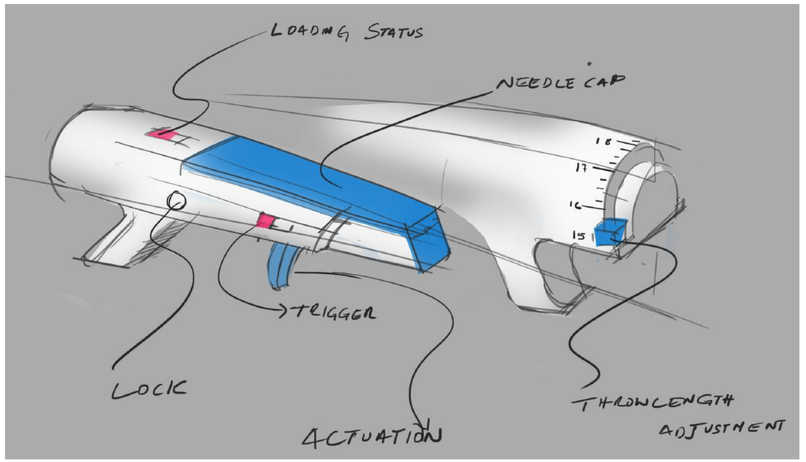




once the design is made simple and cleaner , different ideations are tried for the actuation button and grip. A final form is finalised and again feedback is taken from different people(mostly designers). Though the feedback is positive in terms of clinical look , the device looks much feminine.

5.11 Form ideation 5



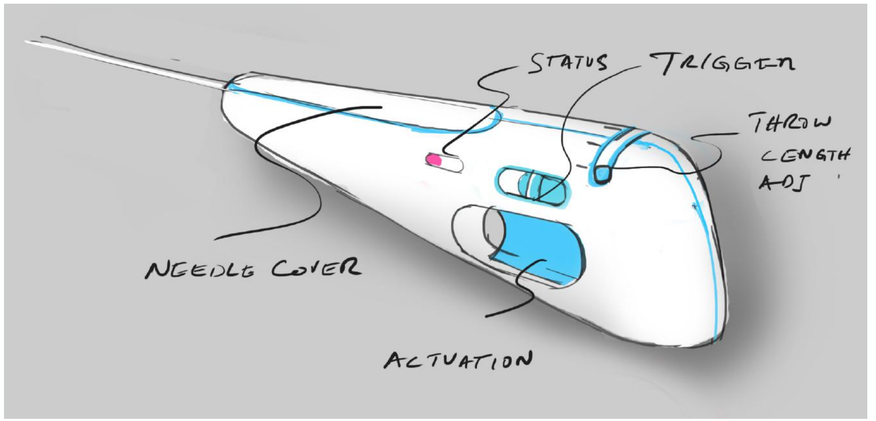


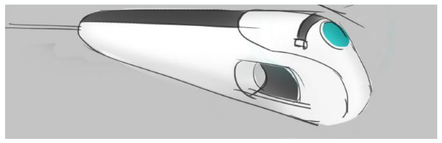
The trigger is moved from the front to the middle by changing the mechanism so that the device can be handled in other alternative holding postures. It is also observed that the earlier design only allows to hold the device in precision grip. But when the tumour location is obvious it device will be handled casually. so the design is further improved such that the interactions are comfortable in both precision and casual grip.

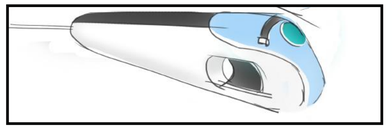
5.12 Prototype three

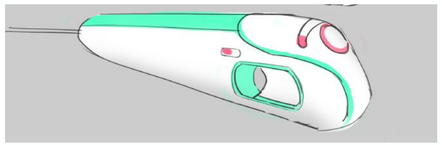
Precision grip

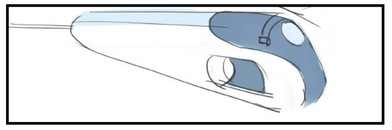
casual grip







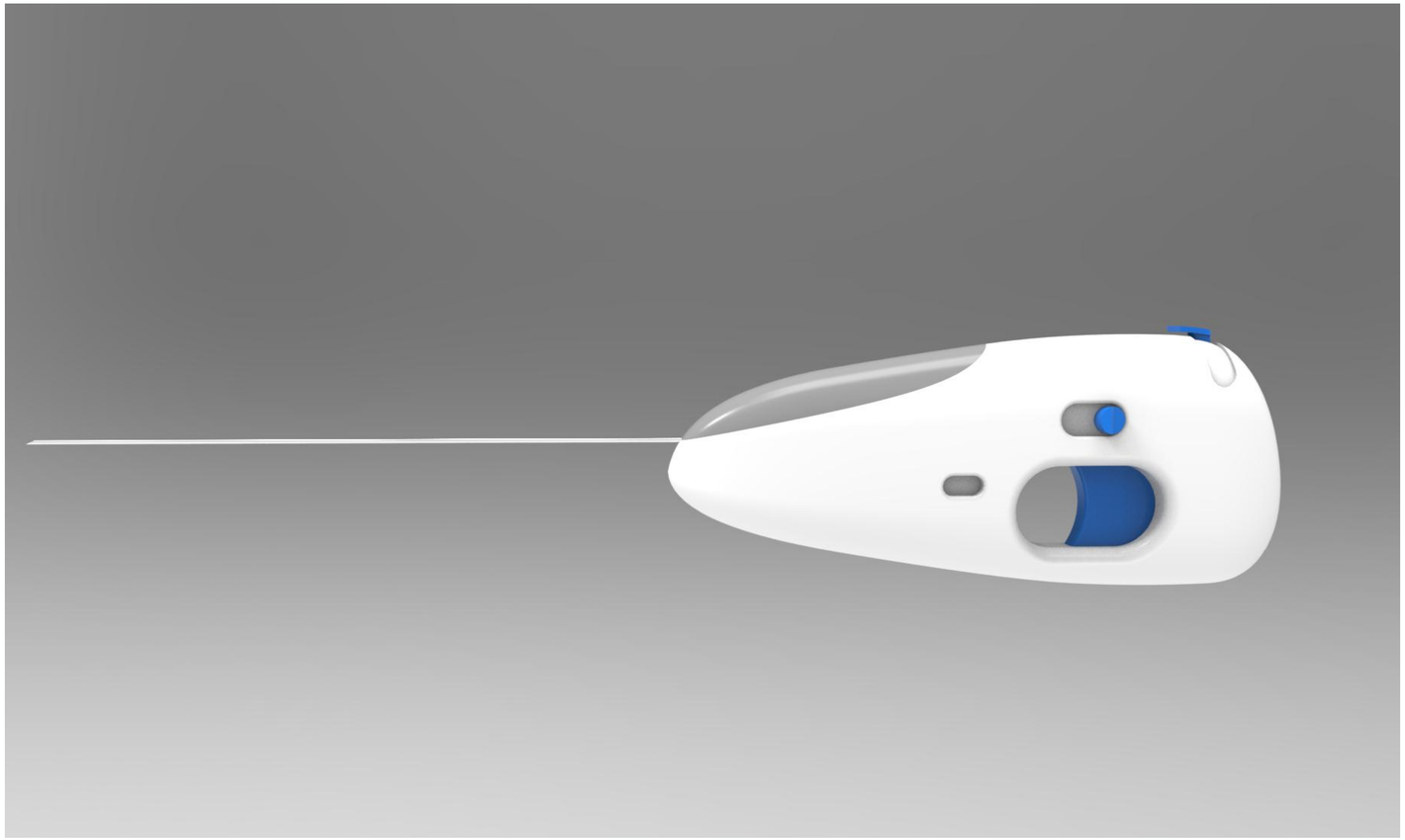




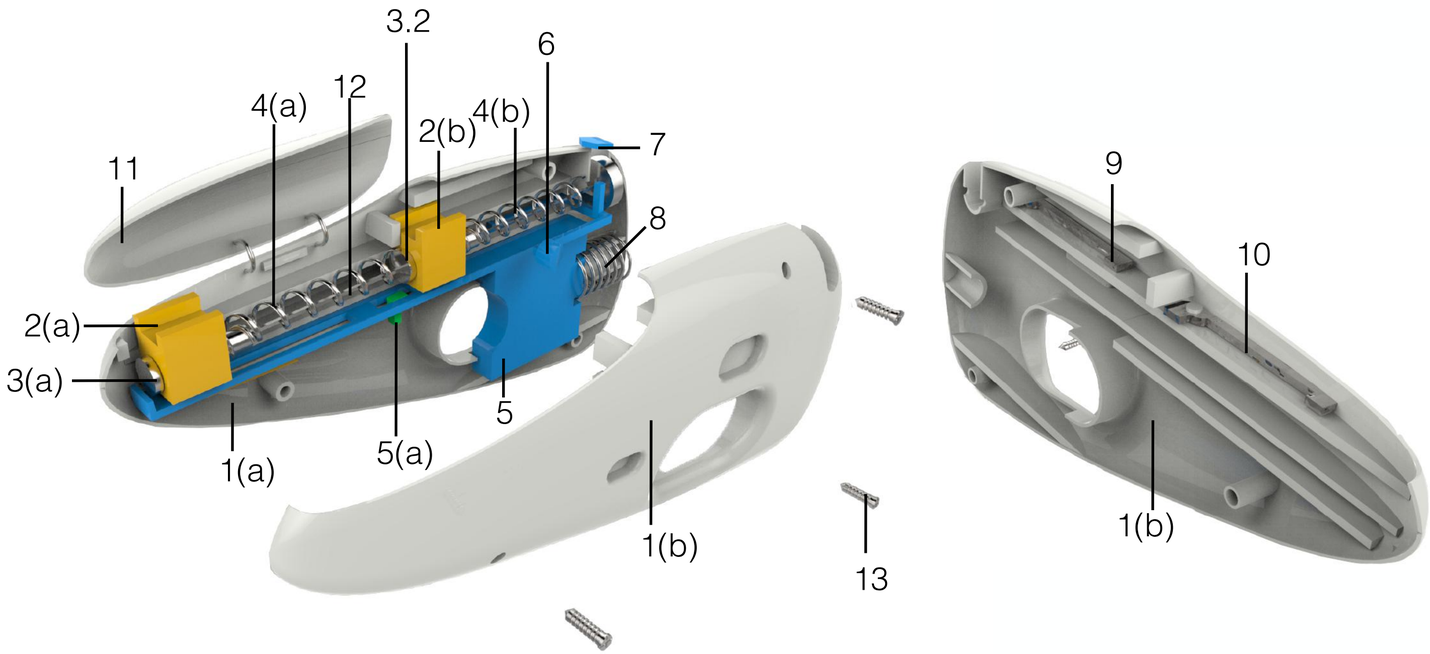
Interactions of the device

. As the form looks much cleaner and simple and the interactions are comfortable in both the precision and casual holding posture the design is finalised.

5.13 Final Design



5.14 Exploded view



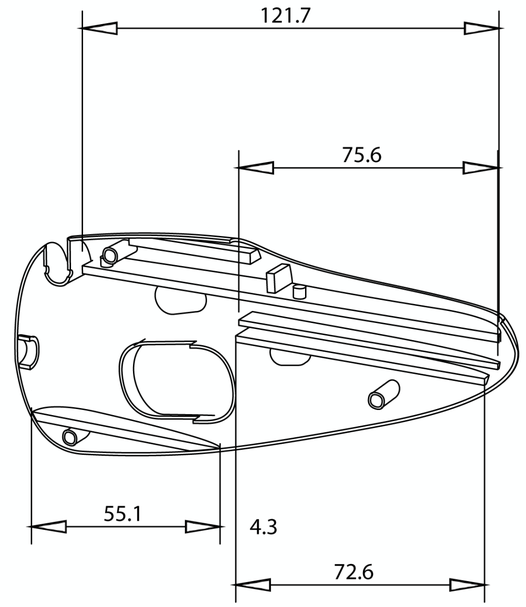
Parts

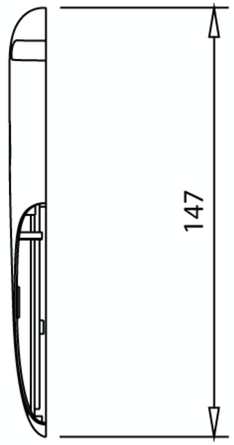
1(a)	Outer case 1
1(b)	Outer case 2
2(a)	Outer needle holder
2(b)	Inner needle holder
3(a)	Outer needle bolt
3(b)	Inner needle bolt
4(a)	Outer needle spring
4(b)	Inner needle spring
5	Actuation button
5(a)	Lever
6	Trigger
7	Throw adjustment button
8	Trigger spring
9	Inner needle L lever lock
10	Outer needle L lever lock
11	Needle cap
12	Rod to rotate the bolts
13	Screws

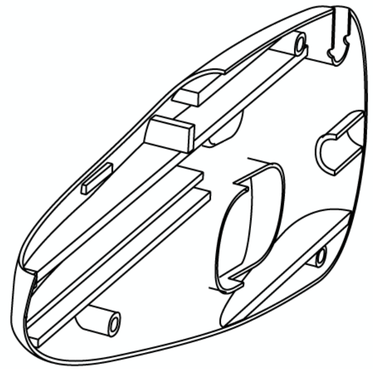
5.15 Manufacturing drawings

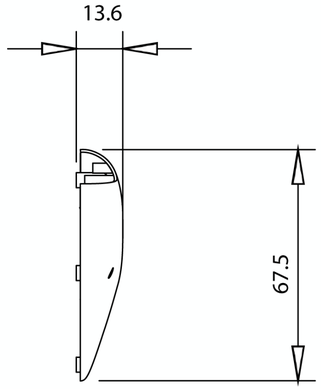
Part 1(a)

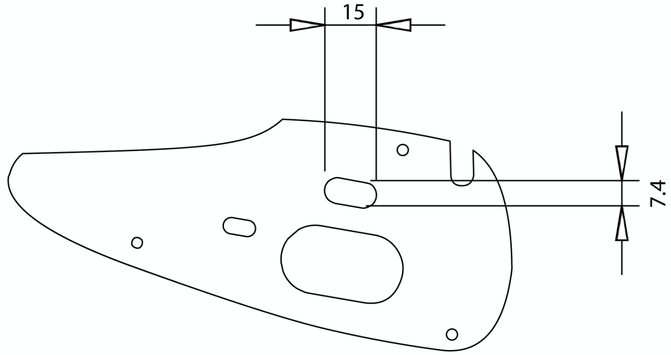
Part 1(b)

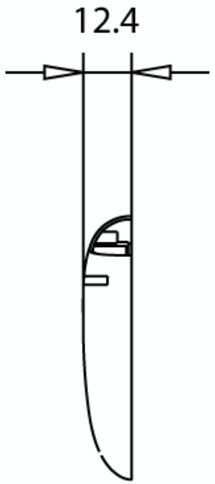


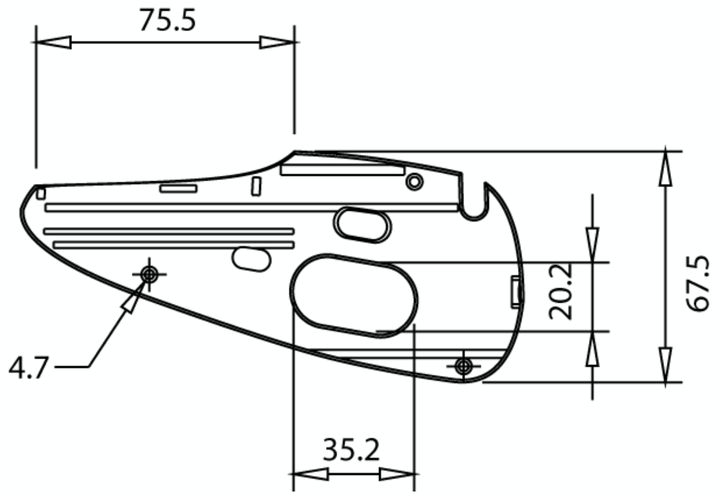






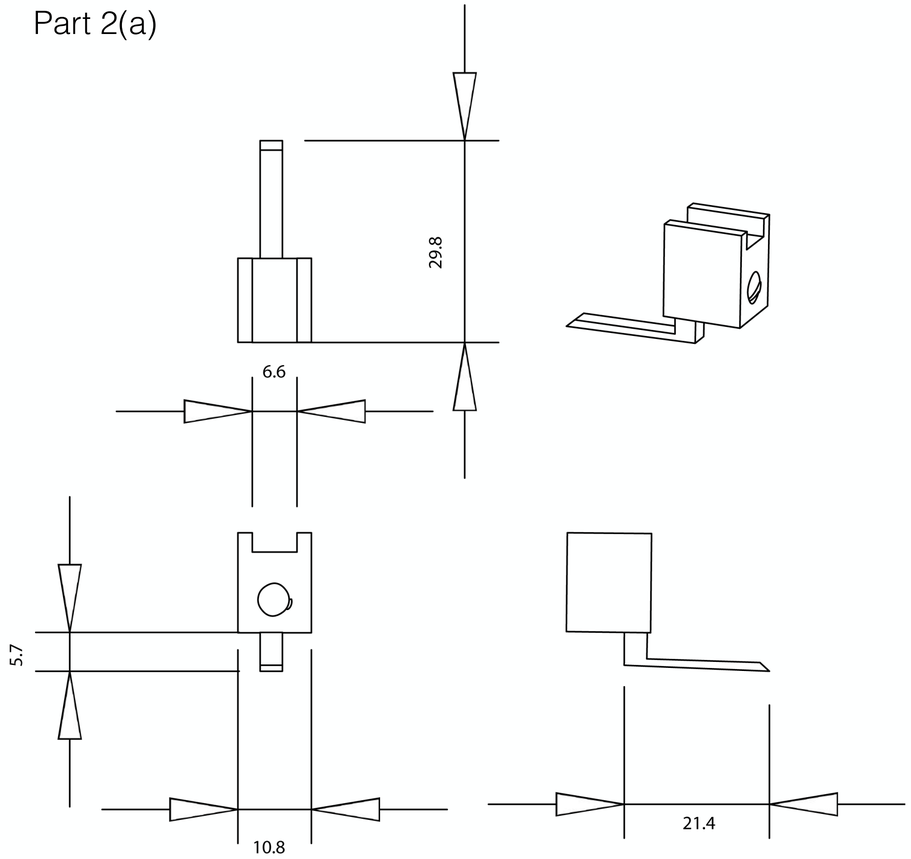




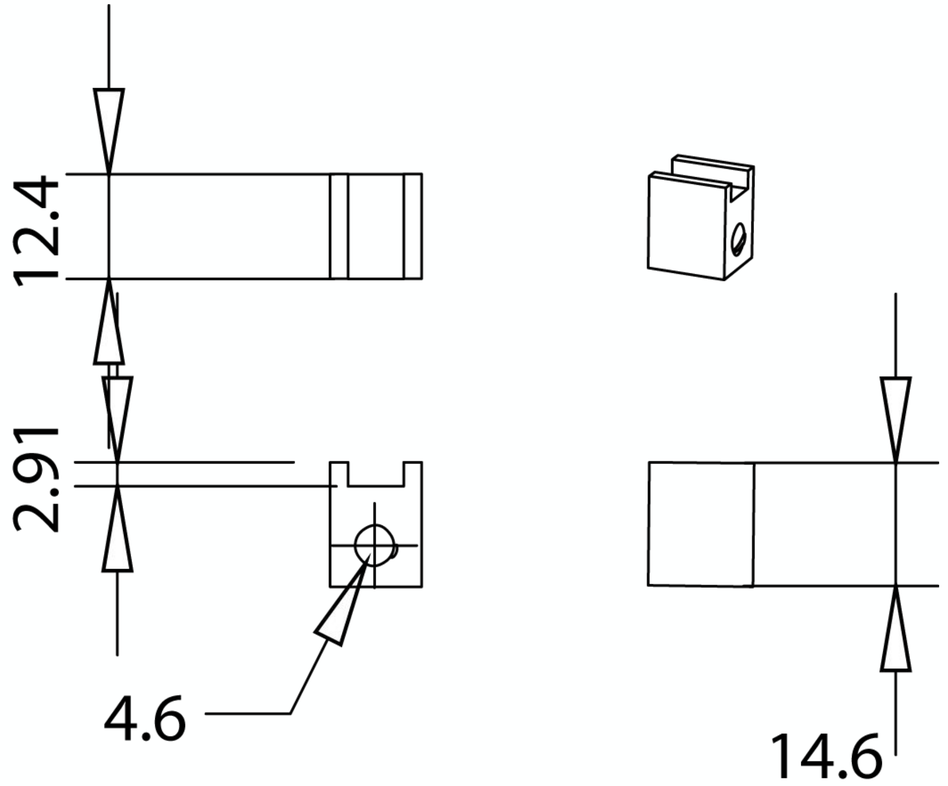


Manufacturing drawings

Part 2(a)

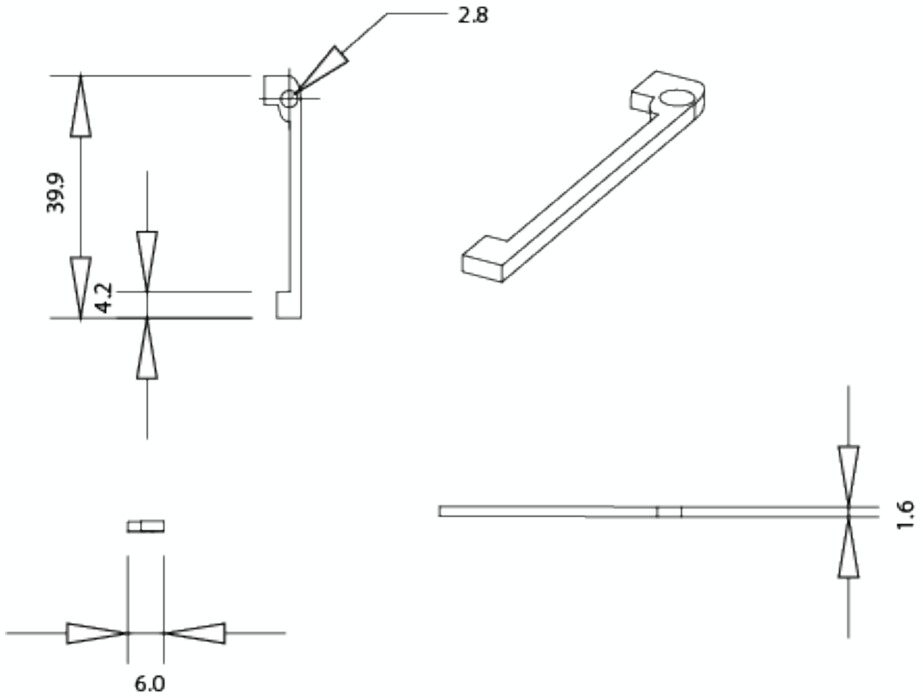


Part 2(b)

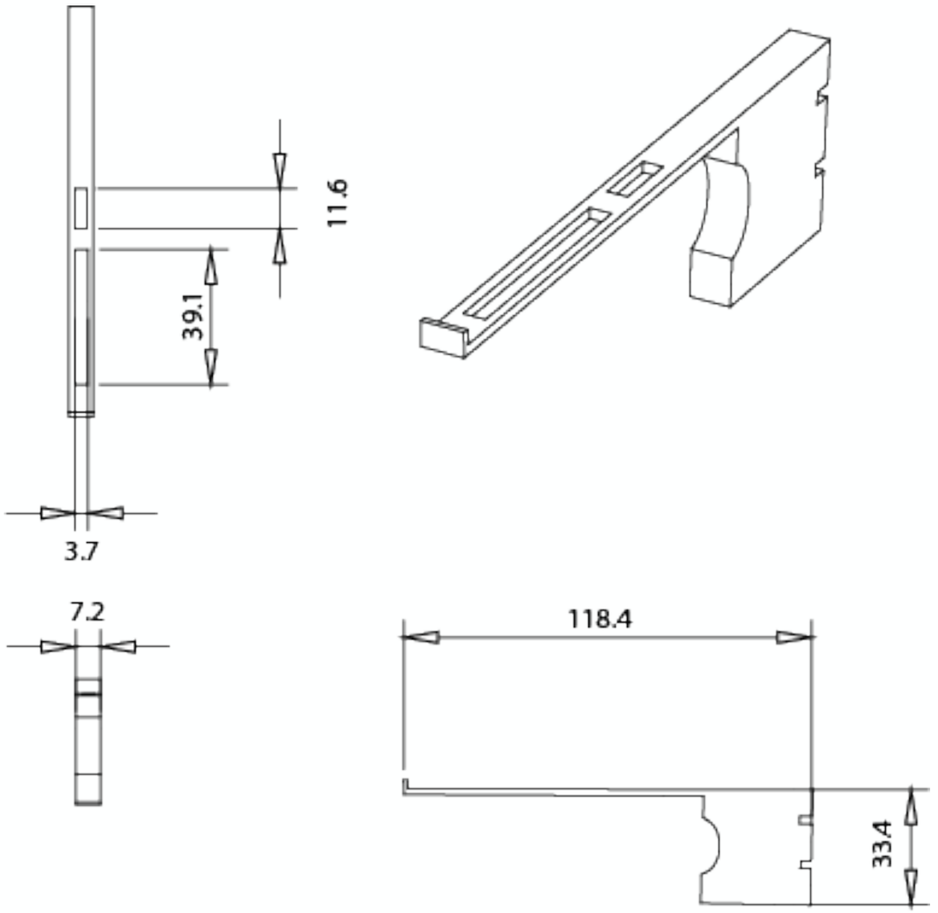


5.7 Manufacturing drawings

Part 9, 10

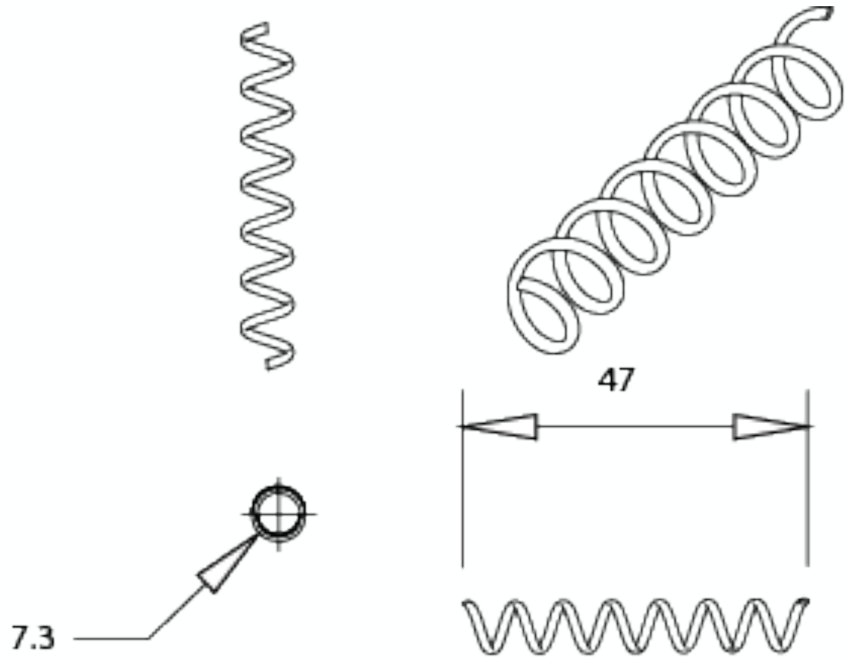


Part 5

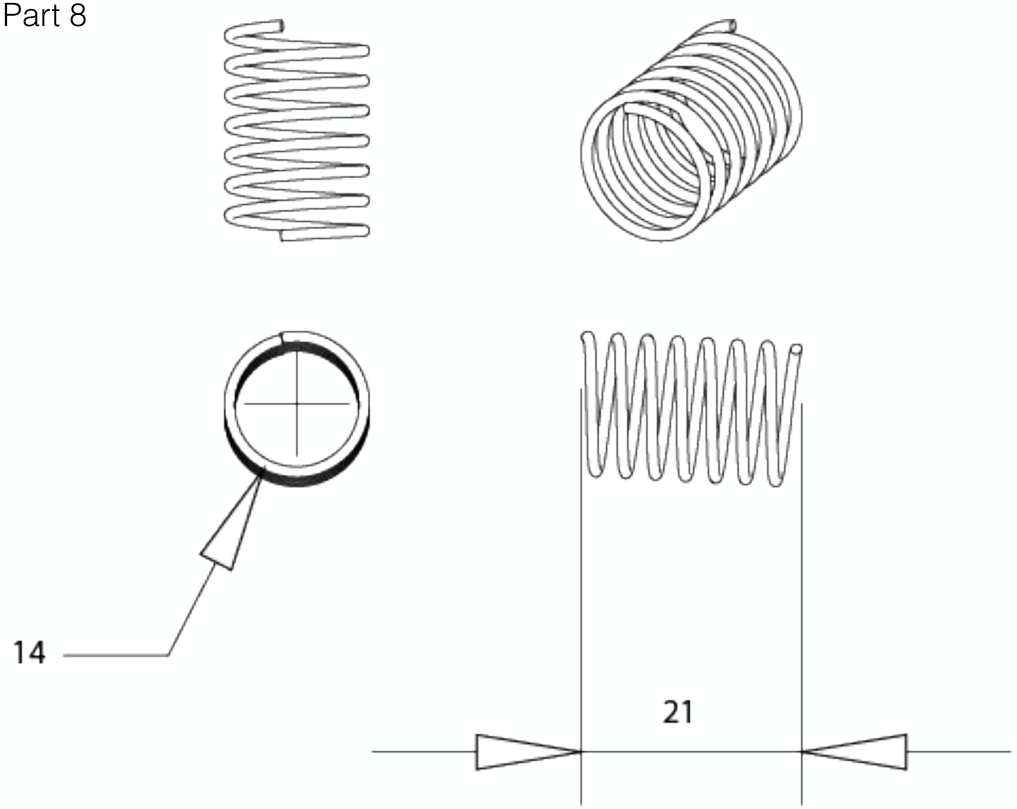


Manufacturing drawings

Part 4(a), 4(b)

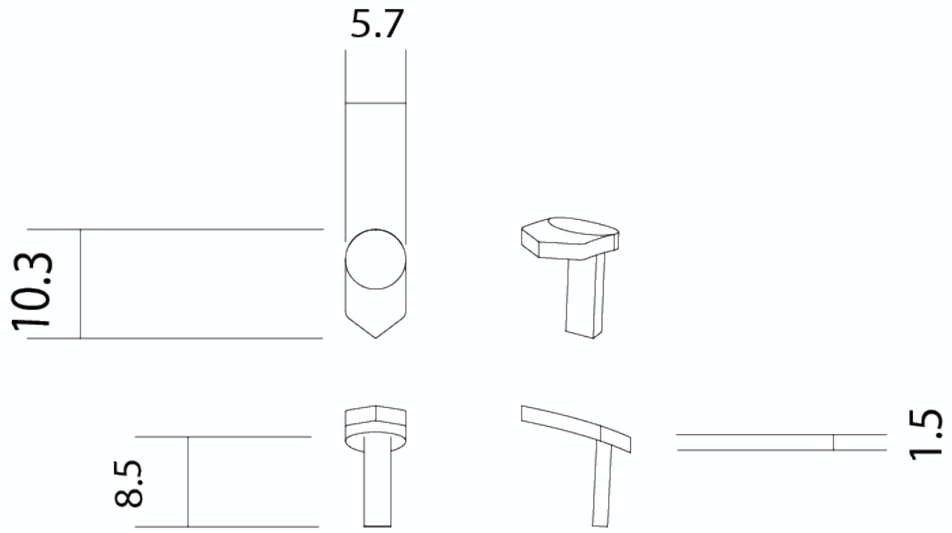


Part 8

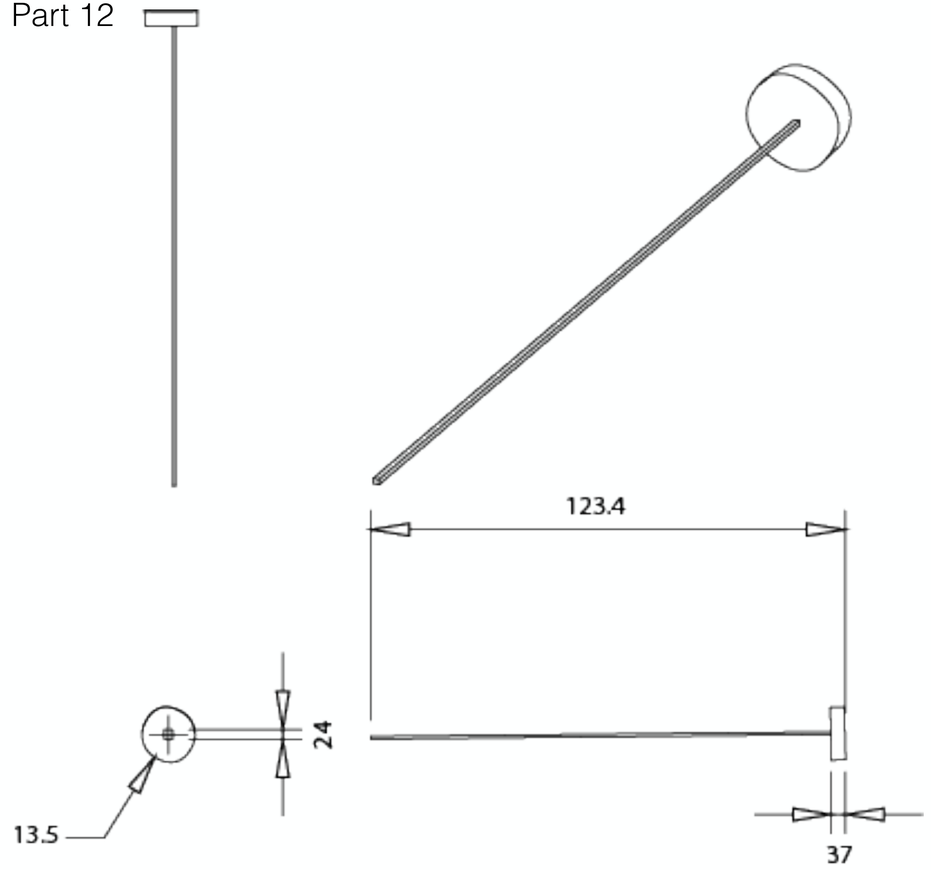


Manufacturing drawings

Part 7

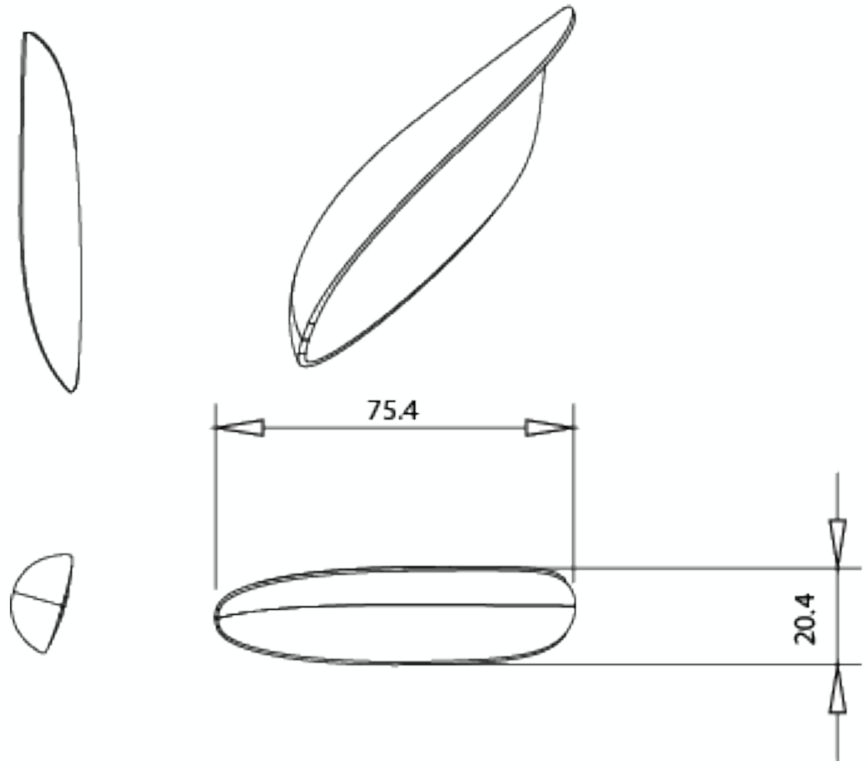


Part 12

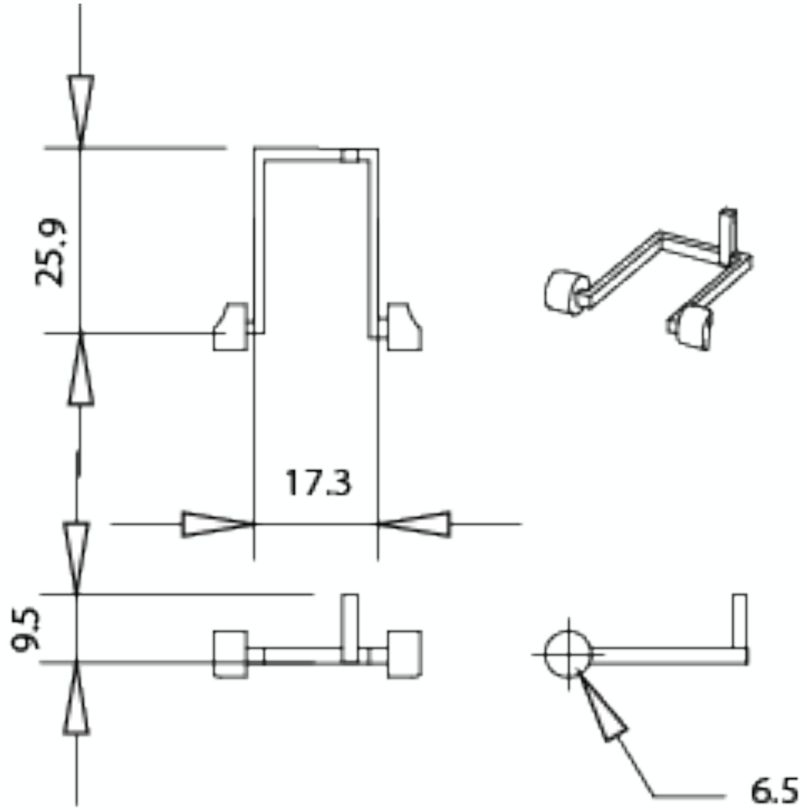


Manufacturing drawings

Part 11

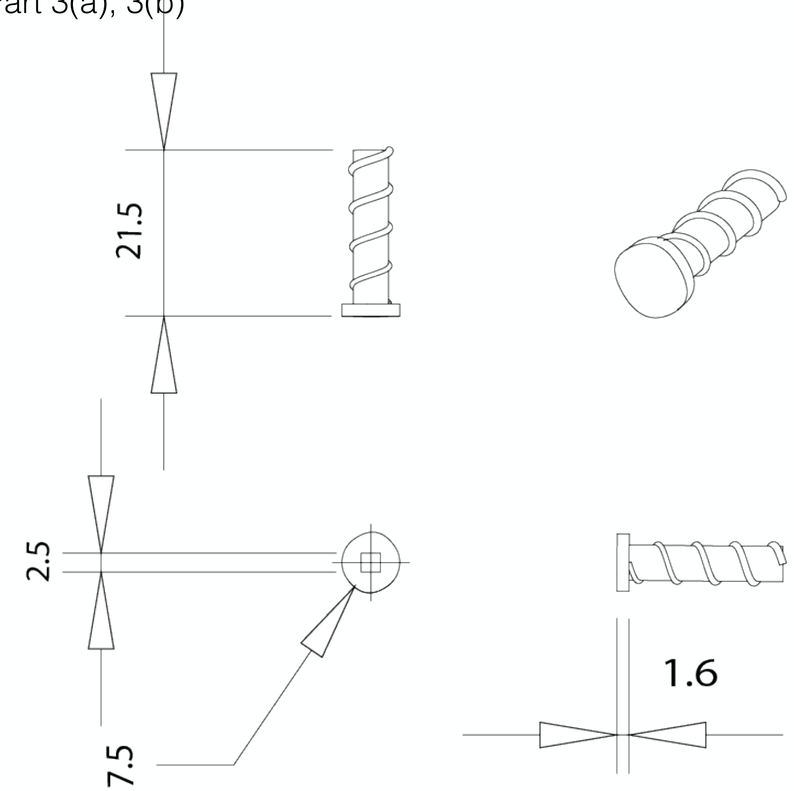


Part 6

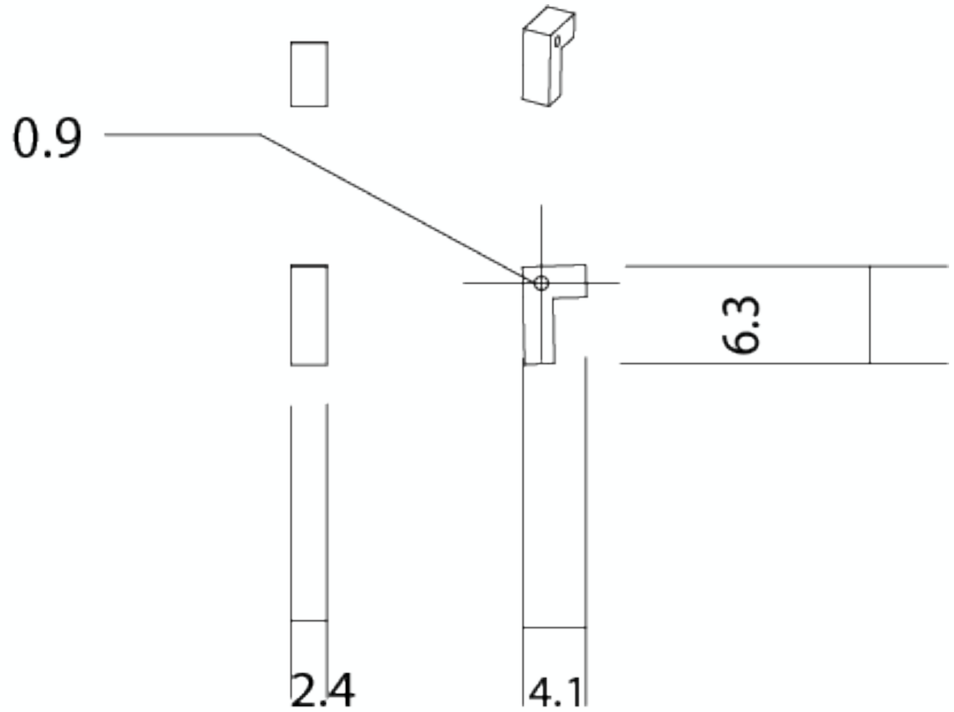


Manufacturing drawings

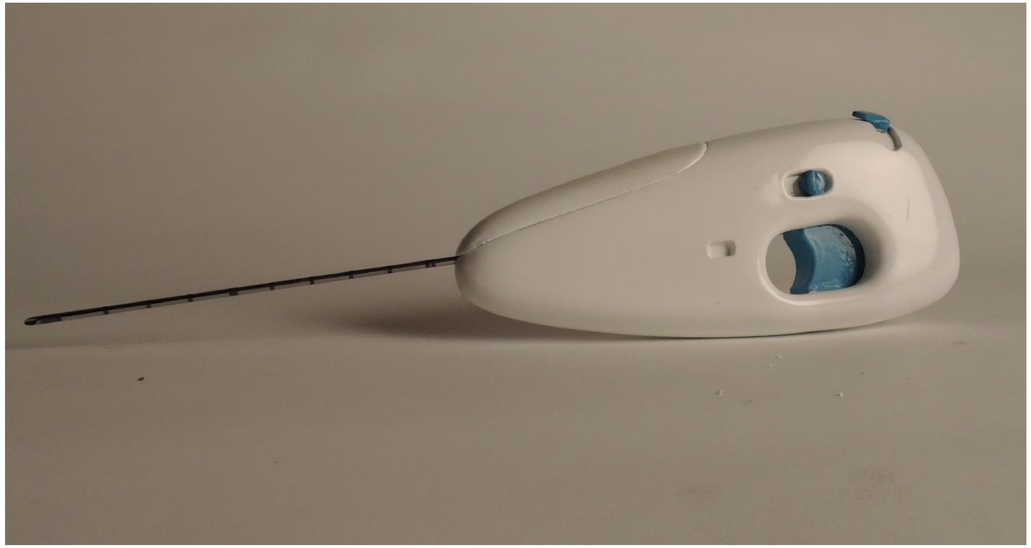
Part 3(a), 3(b)

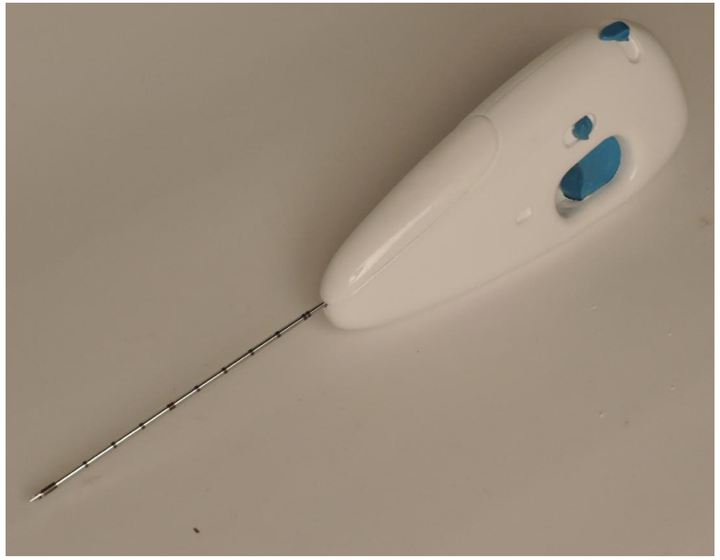


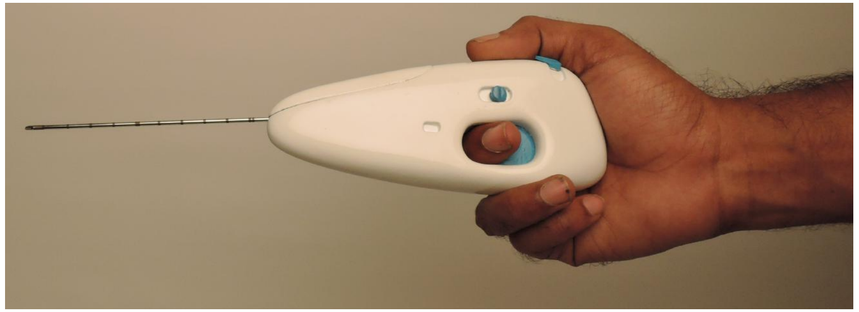
Part 5(a)



5.16 Final design prototype







6. Tissue collection system design

6.1 Analysing the problem

Once the sample is taken out, surgeon inserts the needle in the bowl to remove the sample. Most of the times sample sticks to the needle as the sample is palpable soft tissue. Usually surgeon shakes the device to remove the sample. Still if the sample not gets removed, nurse will remove the sample using other needle.

6.2 Separating sample from the needle

Separating the tissue from the needle needs some external force. Current practice is a gentle shake of the handle by the doctor till the tissue falls into the bowl. If that doesn't work, nurse uses an another needle to remove the tissue.

1. Rotating the bowl creates a centrifugal force, this force separates the tissue from the needle the moment it is placed in the bowl.

2. In another approach a force jet of water from a small pump is used to separate the sample from the needle. Since the force required to remove the sample is low, a 6v pump is used.

3. Another approach for separating the tissue is by vibrating the needle. When the needle touches the vibration in the tissue collection device it vibrates the needle and separates the tissue.

6.3 Tissue collection bowl design

At present a normal steel bowl is used to collect the sample. some of the problems with this method are

1. carefully drain the water such that the tissue wont fall in to the trash
2. care fully transfer the samples using tweezer to the formalin bottle such that the samples wont be missed
3. since the bowl is opaque sample cant be seen until the water is drained completely.

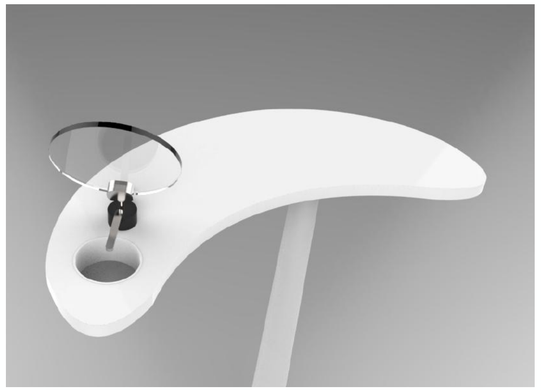
6.4 Tissue collection system design

Two approaches were considered to design tissue collection device. One handheld and another integrating tissue collection device in the trolley.

Hand held device

1. Desired features
2. One hand operable
3. Separates samples from needle
4. Easy transfer of samples
5. Easy cleaning

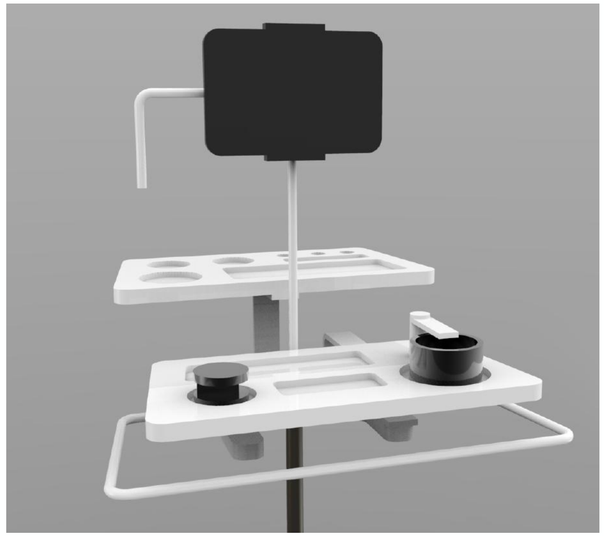
6.5 Trolly design ideation



Approach 1: Minimalistic

In this approach the base will have three castor wheels giving minimum ground clearance such that the trolly can be easily the patients bed to the necessary position. Height adjustable stand. The top is a clean curved shape space , enough to keep the equipment. A hole to keep the bowl and small vibrating setup is provided which is used for tissue separation. A concave mirror to view the enlarged sample reflection.

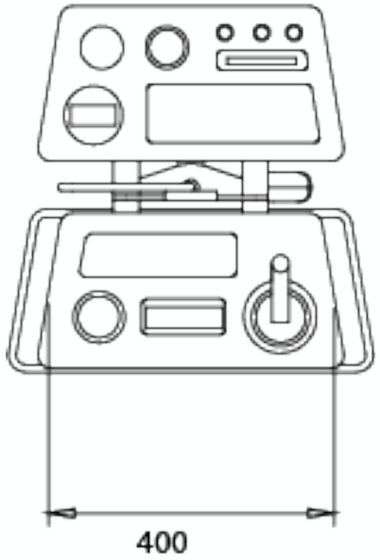
Trolly design ideation

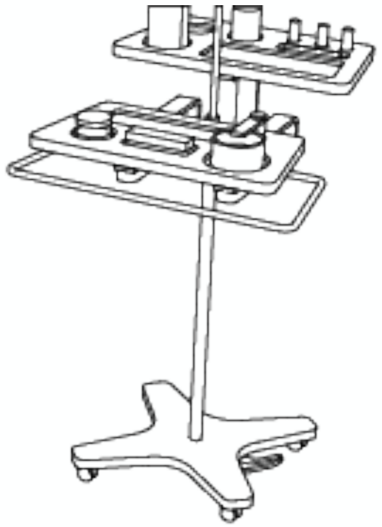


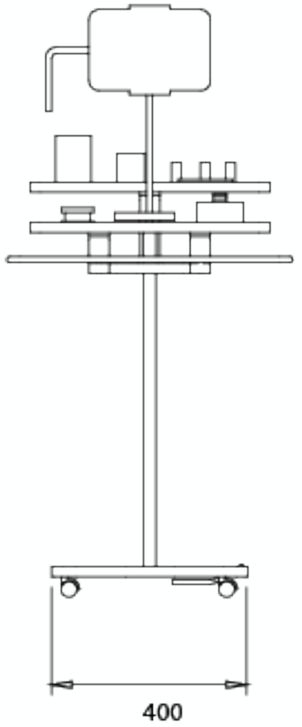
Approach 1: Sophisticated and Futuristic

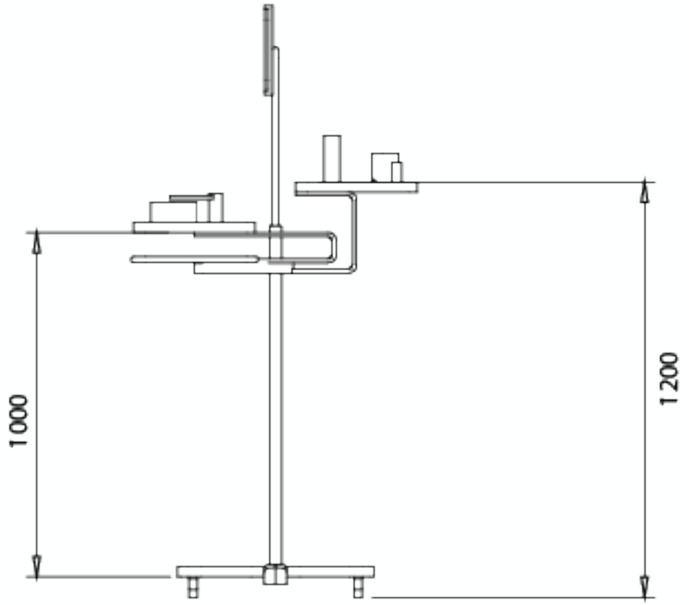
The design of the trolly is designed more functional depending on the observation from the field visit. The front top is accessible to the doctor and the back part is accessible to the nurse. The front and back are provided with spaces for the devices they need during the biopsy. The trolly is provided with a provision to attach a tablet so that the doctor can view the sample collected during the biopsy more clearly and enlarged. The future applications like connecting the tablet to wifi and sending the sample images live to the pathologist for a instant feedback for the sample quality.

Trolly design

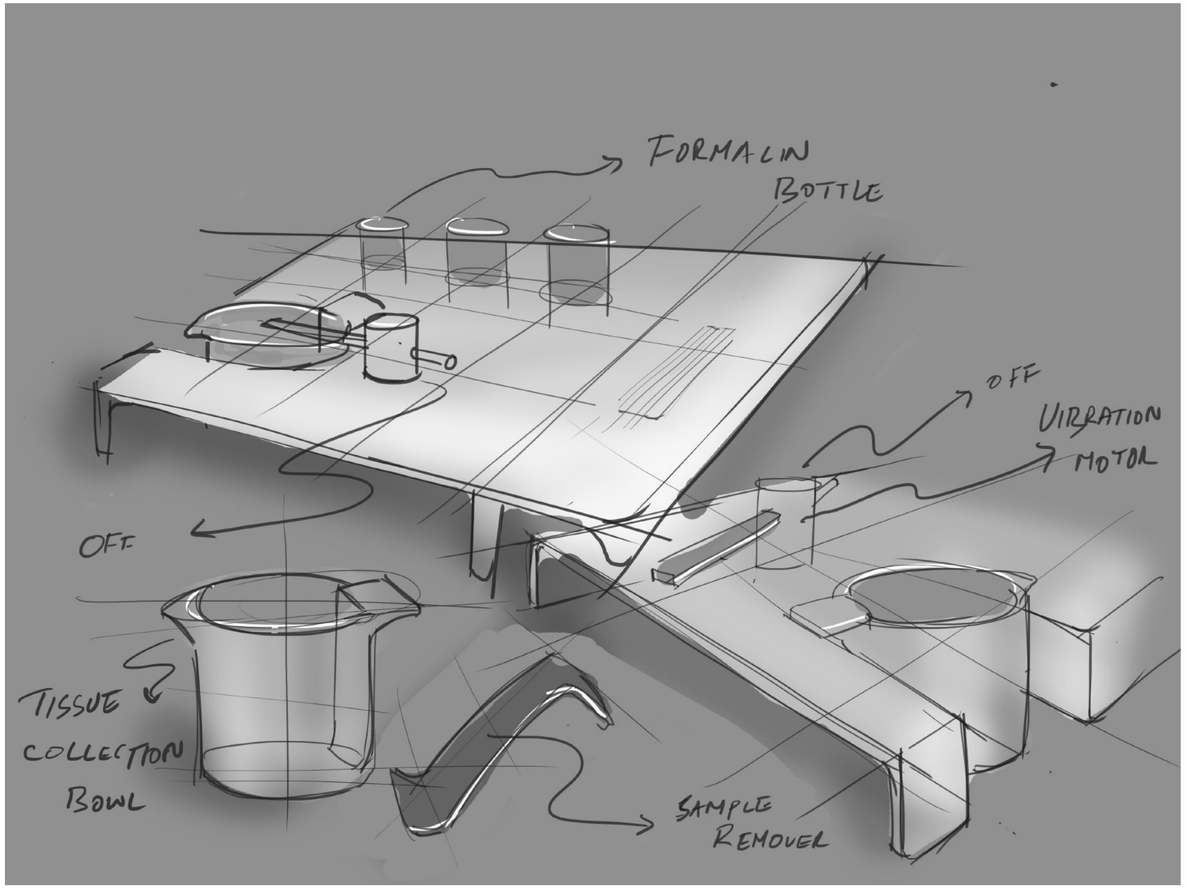






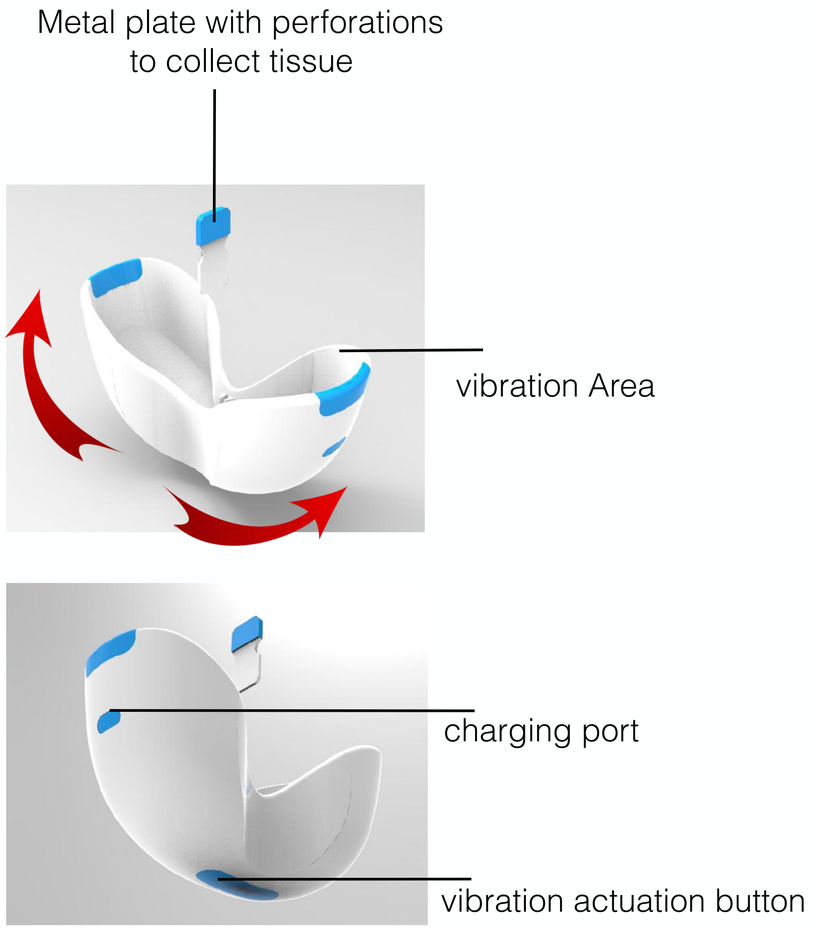


6.6 Feedback from Doctor and final design ideation



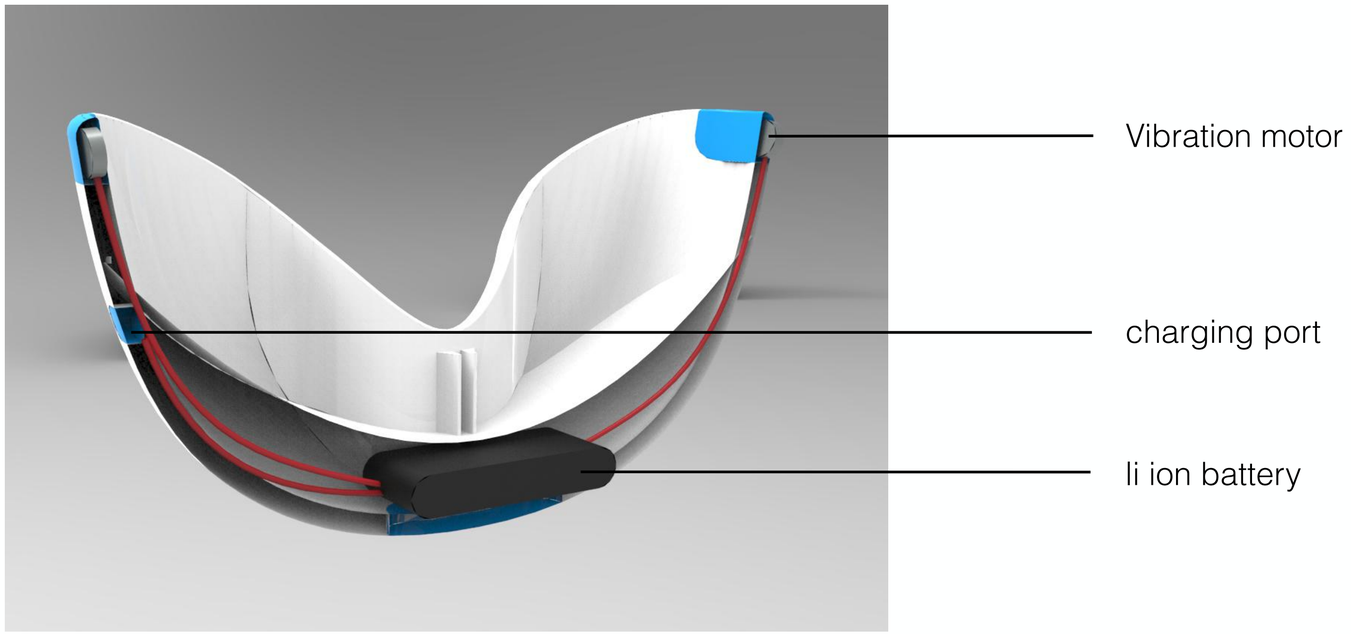
After the feed back from the doctor, as space is a major issue the tissue collection device should be small and can be used in all possible scenario's. so the final design is a tray with transparent tissue collection bowl and which will have formalin bottles on the tray to transfer at one go.

6.7 Final design

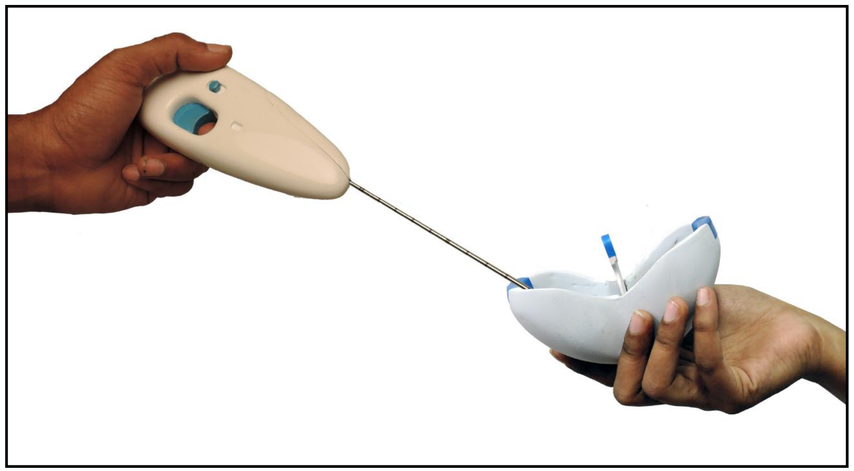


This electronic tissue collection bowl simply replaces the existing steel bowl. It is embedded with small vibration motors on either side , helps in removing tissue when the needle touches the blue space. A small removable metal piece in the centre that separated the bowl has perforations to allow water to pass water from one side to other when the bowl is tilted. When the water in passes from one side to other the tissue get collected on the separator, makes the tissue collection easy. The wide open mouth of the bowl is easy to clean. The rechargeable battery works for days on a single charge.

6.8 Cross-section view



6.9 Final model prototype

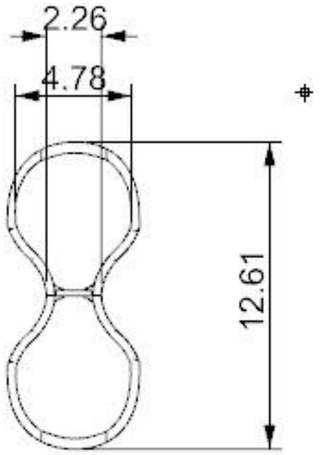


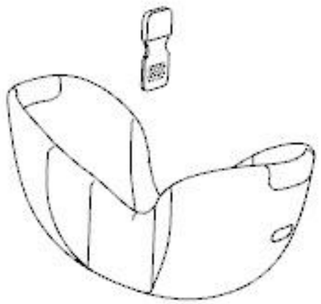
1. When needle touches the vibrating portion of the bowl, tissue gets separated and falls in the bowl.

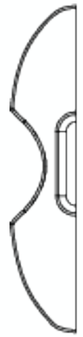
2. When the water moves from one side the other, the tissue gets collected on the middle removable part.

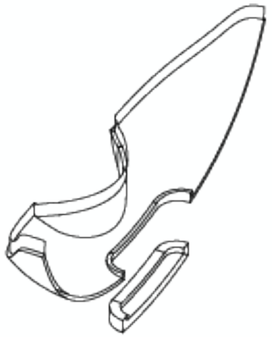
3. Remove the middle part to collect the sample.

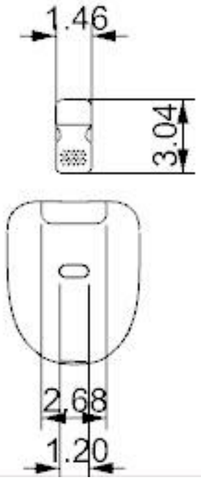
6.10 Manufacturing drawings

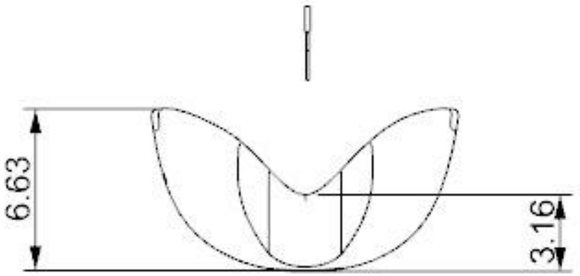


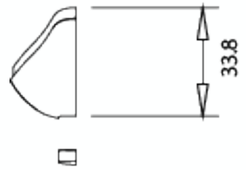


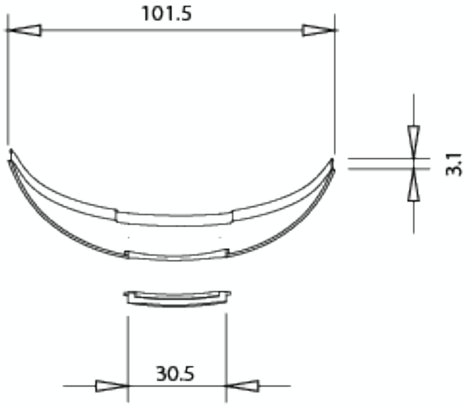












7 Reference

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- Fig 23: http://www.bardmedical.com/media/3224/Magnum_biopsy_instructions.pdf
- Patents : us 4944308, EP 1135065, US 20120253230
- Biopsy . wikipedia, https://en.wikipedia.org/wiki/Biopsy
- http://www.cancer.org/treatment/understandingyourdiagnosis/examsandtestdescriptions/forwomenfacingabreastbiopsy/breast-biopsy-biopsy-types
- http://www.mayoclinic.org/diseases-conditions/cancer/in-depth/biopsy/art-20043922
- Fig 2: Bolt and Nut mechanism, Designed by Shivam mital, IIT Bombay , 2013-15

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