APPENDIX

APPENDIX A: ABREVIATION LIST

SNN: Samenwerkingsverband Noord-Nederland (The Northern Netherlands Provinces Alliance)
TEDD: Total Epicardial Device Delivery
VATS: Video Assisted Thoracic Surgery
UMCG: Universitair Medisch Cenrtum Groningen (Academic Medical Centre Groningen)
LV: Left Ventricle
RV: Right Ventricle
POP: Proof of Principle
AV: Atrio-Ventricular
LBBB: Left bundle block
CS: Coronary Sinus
CRT: Cardiac resynchronization therapy
POP1: The shooting concept (Proof of Principle 1)
POP2: Subxipoid concept (Proof of principle 2)

APPENDIX B: MEDICAL TERMS LIST

Epicardial: On the outside of the heart.
Thorax: The part of the human body between the neck and the diaphragm. The chest.
Minithoracotomy: Incision in the chest wall, involving les muscle division that classic thoracotomy.
Lead: Electric wire that connects the pacemaker to the heart.
Trans-venous: Performed or inserted through a vein.
Atrium: Upper chamber of the heart that receives blood from the veins and forces it into the ventricle.
Ventricle: Muscular chamber of the heart that receives blood from the atrium and pumps into the arteries.
Myocardium: The middle and thickest layer of the heart wall.
Septum: Wall or partition deciding a body pace or cavity.
Endocardial: On the inside of the heart.
Vein: Blood vessel containing oxygen depleted blood.
Phrenic nerve: The motor nerve to the diaphragm
Trocar: Sharp-pointed instrument equipped with a cannula. Used to puncture the wall of a body cavity and to introduce a scope or medical tool
Pericardium: Fibroserous sac enclosing the heart and the roots of the great vessels.
Intercostal: Between two ribs.
Double lumen: Duplication of a vessel or tubular structure.
Right Lateral Decubitus: Position where the patient is lying on its right side.
Scapula: Shoulder blade.
Posterior: Director toward, or situated at the back.
Posterolateral wall: Wall of the heart situated on the side and toward the posterior aspect.
Anterolateral wall: Wall of the heart situated on the front and to one side.
Pleural space: Potential space. In this case between the lungs and the ribs.
Supine: Positioned on his back.
Blunt Dissection: Separating Tissues along natural lines of cleavage without cutting.
Hematoma: A localized swelling that is filled with blood caused by a break in the wall of a blood vessel.

APPENDIX C: ACTION PLAN AND PLANNING

Actor analysis

This bachelor assignment will be executed commissioned by Demcon. The goal of the assignment is to improve one of the evaluated points of the by Demcon developed Proof of Principle (POP) of a Total Epicardial Delivery Device. This improvement will be tested with a new POP which is also realized during the assignment. The TEDD is a device which will be used for pacemaker lead placement on the left ventricle (LV) with a minimal invasive surgery. Minimal invasive surgery means that there will be no open chest, but small incisions in which a camera and instrument are inserted to perform the surgery. After the leads have been placed on the LV they will be connected to the pacemaker. Demcon is cooperating closely with the Universitair Medisch Centrum Groningen (UMCG) and with the surgeons that work there for insights from the field. Those doctors will be using the TEDD in the future so it is of great importance that they are able to use it very well in order to treat the patient as good as possible. The patient does also have an important role in the development of this product. The entire product is developed in order to reduce the recovery period afterwards. The purpose of the device is to make it possible for the patient to receive a pacemaker with a minimal invasive surgery instead of an open chest surgery. It is unacceptable if the success rate of the operation will be reduced or the change of implications will increase with the TEDD. What is more, the TEDD has to make it easier for the doctor to place the lead, and also to place the lead on the desired location. Therefore the change of a successful lead placement should increase. Demcon is developing the TEDD from a POP to a certified medical product. At the moment they are at the phase were they delivered a POP. However, there are some components that need improvement in order to reach maximum functionality. The functionality and usability have to be improved to assure that doctors can use it safely and easily.

Demcon is a company which works on many mechatronic projects. Within Demcon there are three major directions: Hightech Systems, Industrial Systems and Medical Systems. This assignment will be executed at the Mechatronic Systems Engineering department for the business unit Medical Devices. Examples of products and projects from Medical Devices are a special device which is able to pump sterile fluid through the eye, and a hand scanning device which measures within two and a half minutes by scanning with red and infrared light whether the patient has rheumatism. Within Demcon there are three employees with a background as Industrial Designer.

Project Framework

The ultimate goal of the commissioning company is to put an optimal functioning product on the market. In order to achieve this goal the current POP has be improved. The evaluation of the present POP resulted in the following four points that need improvement:

- The technique that moves the tip of the TEDD.
- The technique that places the pacemaker lead on the hart.
- The way in which the tip of the TEDD gets temporary fixated on the heart.
- The way in which the pericardium is opened.

For this assignment one of the four problems is chosen to be improved. This is done when more knowledge of the TEDD and the minimal invasive surgery procedure is gained. Besides Demcon, the UMCG also plays an important role in this. In the end it will be the doctors who will be using the TEDD in practice. This means they will be able to give useful information about the reason why something would or would not work. The commissioning company is looking for solutions in the technical operating of the device. Demcon thinks that the functionality of the TEDD will increase when the technology behind it is being improved.

Goal

Demcon wants put a new TEDD, developed by themselves, on the market. Demcon has been working on this project for a couple of years now and has delivered different POPs. Based on these POPs some points of improvement surfaced which Demcon wants to tackle. The goal of this assignment is to pick one of these points, improve it, build a POP and test this POP.
This will be achieved by beginning with an analysis of the POP that Demcon already has. This should clarify why some things have to be improved and there will arise a better understanding which makes it possible to make a conscious choice about which point of improvement will be tackled. When that has been done, research will be performed on the specific point of improvement. This research probably provides a lot of medical information. This research will be performed by reading literature and by using the field specific knowledge other employees have about this project. This analysis should result in the system requirements which will be used to create several concepts in which the operation of the TEDD will be improved. A morphological scheme can

be used to combine several sub solutions into different concepts. The best concept will be chosen with the help of the system requirements and this concept will be implemented and realized into a POP. These results will be used to improve the functionality and usability of the TEDD. Everything described above will be executed in three months. Implementing one of the four points of improvement into a POP with improved functionality and usability with respect the current POP seems feasible within three months.

Phrasing of questions

Why are the current solutions not optimal?

- How does the current solution work?
- What performance is expected from the chosen point of improvement of the TEDD?
- How could the required performances be achieved?
- What kind of techniques are used in similar products which fulfill the same goal.
- What kind of ideas can be made up to achieve the required performances?
- How will the chosen point of improvement operate within the total system of the TEDD?
- How is the chosen point of improvement integrated within the TEDD?

Strategy

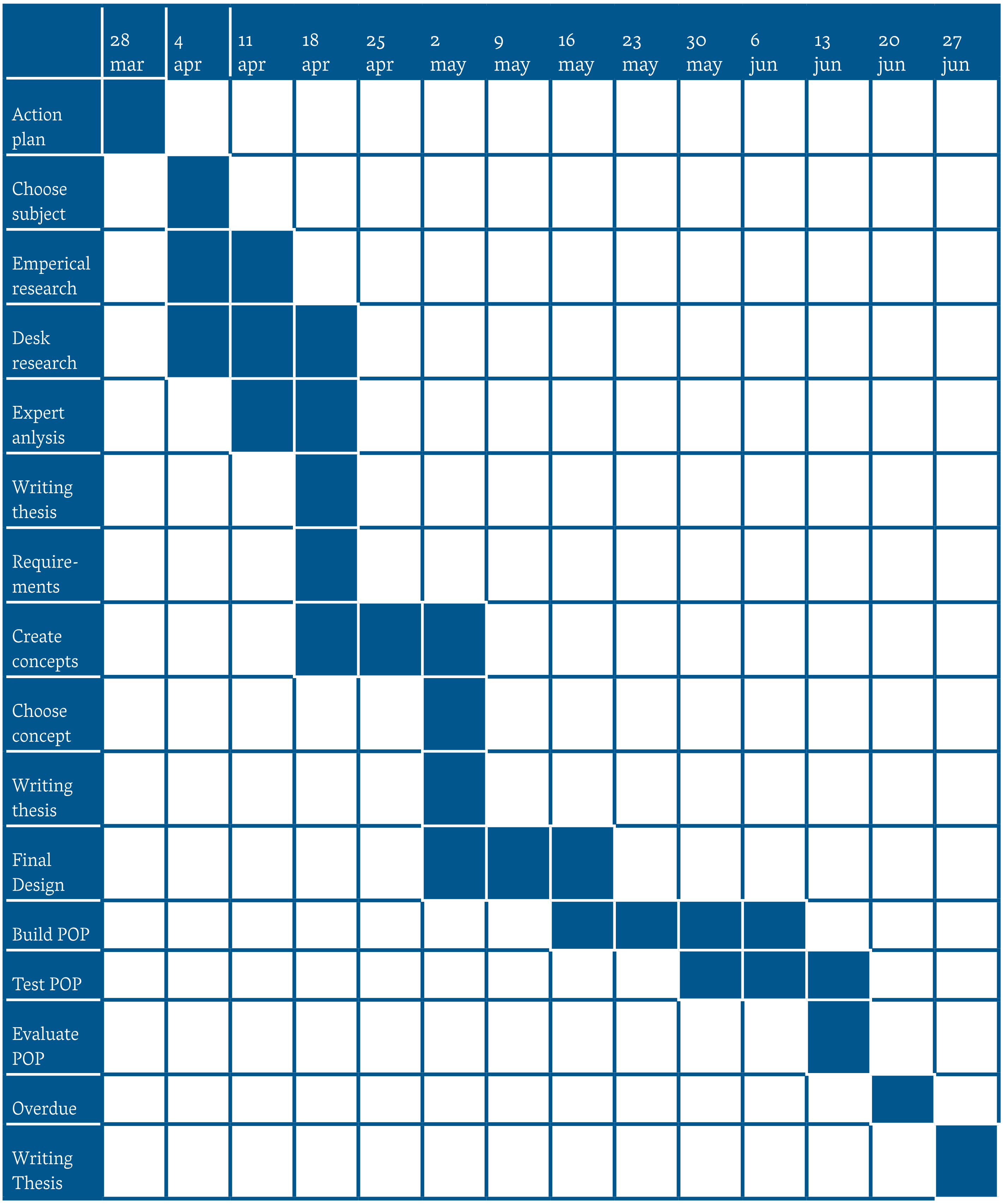
This bachelor assignment will focus on a small part of the total TEDD. First of all a better understanding of the product itself and the procedure of the surgery has to be gained. Secondly the working environment has to be examined and it needs to be known what is important in that environment for the chosen point of improvement of the TEDD. Thirdly, it has to be investigated how this optimization can be accomplished. In the end the final design has to be tested to check if the point of improvement is indeed improved.
The first analysis will mainly consist of empirical research. With this empirical research the current POP principle op will be understood and more knowledge will be gained about the procedure of lead placements and the environment in which the TEDD will be used. Besides empirical research, literature research will also play a viable roll in the analysis. As well as for understanding the procedure and the environment as in gaining information about similar techniques used in different product which fulfill the same goal literature plays an important role. For example, techniques in products that are used to cut through a film or to transform translation into rotation. Besides looking at similar techniques, expert reviews will be used. These experts have lots of knowledge about the TEDD and can provide help in some design choices based on what they think will and will not work. Eventually, an experiment will be needed to test the final design on its performance. The results of this experiment should show that the functionality and usability of the chosen point of the TEDD is optimized and improved.

The required materials for the empirical research are the doctors and the operation rooms in which the TEDD will be used. To gain a better understanding of the TEDD an overview can be made of comparable products. There are some comparable product for sale, but none of them are especially developed for minimal invasive surgery and none of them is able to fixate the TEDD temporarily on the heart, measure if the lead in positioned in the correct spot and automatically place the lead. The shortcomings of these products can provide insights which can improve the TEDD. It is also an option, depending of the chosen point of improvement, to compare the TEDD with the not minimal invasive method. What controls do doctors use there and what movements or gestures are they familiar with? To acquire the literature that is needed Scopus and other sites the University of Twente is affiliated with will be used. The documentation which was the result of developing a POP principle will also provide a lot of information about the TEDD. Demcon has their own prototyping department and there has to be checked whether it can be used to realize the POP. If that is not the case, it might be a possibility to build the POP in the workshop at the University of Twente.

Disclosure of material

Different preparations are needed for each of these different methods. It is important to take a look in de the operation room and to witness a LV lead placement as quickly as possible. By that time it could also be possible to talk to the doctors. It that turns out to be possible, some questions have to be prepared in order to gain the right and much information. The POP will be used to gain a better understanding of the TEDD. Demcon has developed this POP in-house so this won't cause major issues. In order to start with the literature research, a choice of point of improvement has to be made. After that choice is made it will be possible to start searching for literature for that point specific. In order to make a POP the design has to be made and masterminded based on one concept or a combination of several concepts which will be the result of the empiric research and the literature research.

Planning



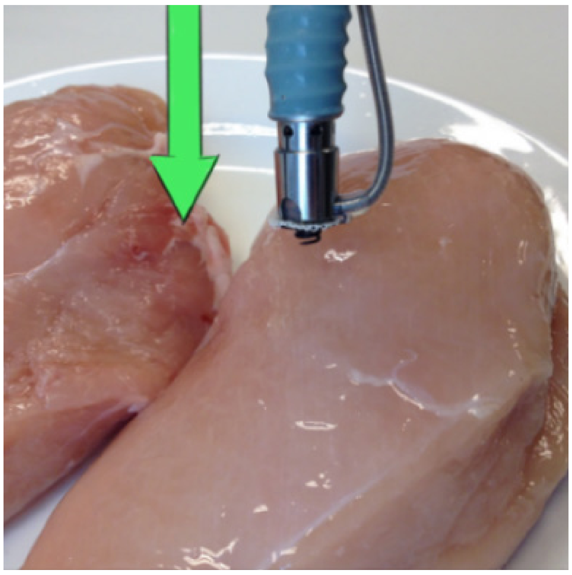
Bottlenecks

Empirical research: It is possible that it turns out to be harder than expected to witness a LV lead placement and/or to talk with the doctors. In order to make the chance of witnessing a LV lead placement as high as possible, there has to be checked as soon as possible if it is possible.

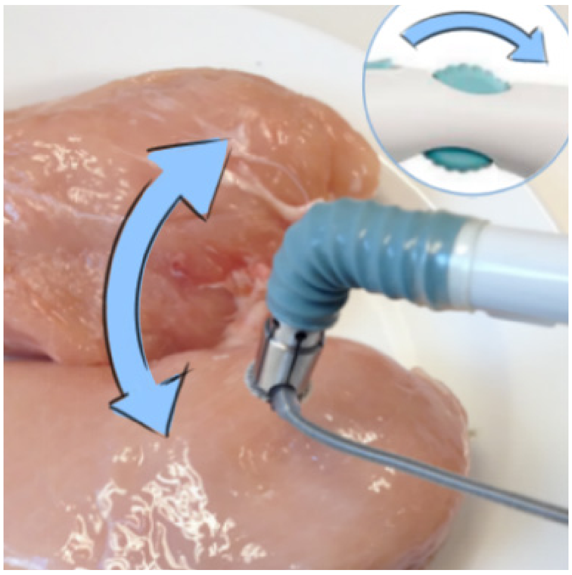
Manufacturing of POP: It is a possibility that manufacturing the final design will take more time as expected. When that is happening there has to be searched for the possibility of getting extra manpower or if the design can be simplified. Besides there also is a week extension which can be used for this purpose.

APPENDIX D:
WORKFLOW OF THE FASTAC

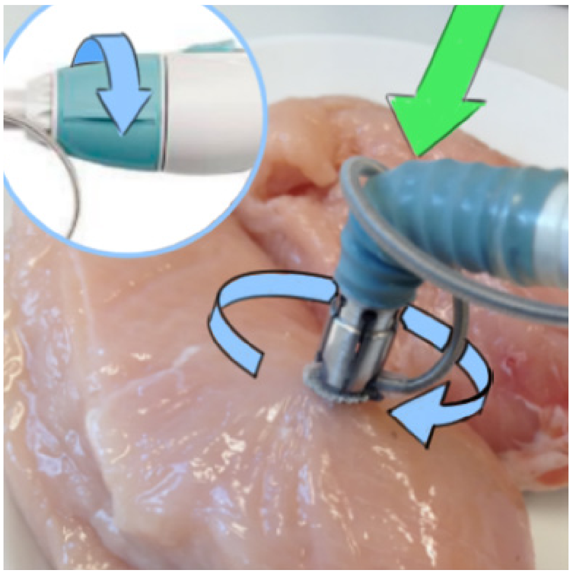
Attach the lead to the FasTac



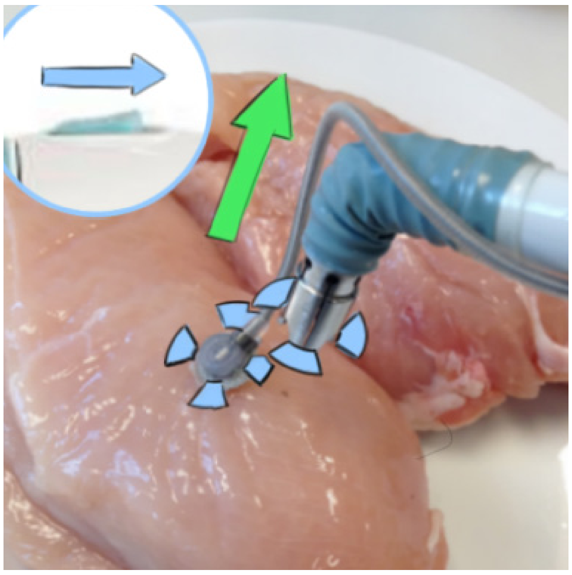
Move to the tool to the heart



Bend the tip in the desired angle

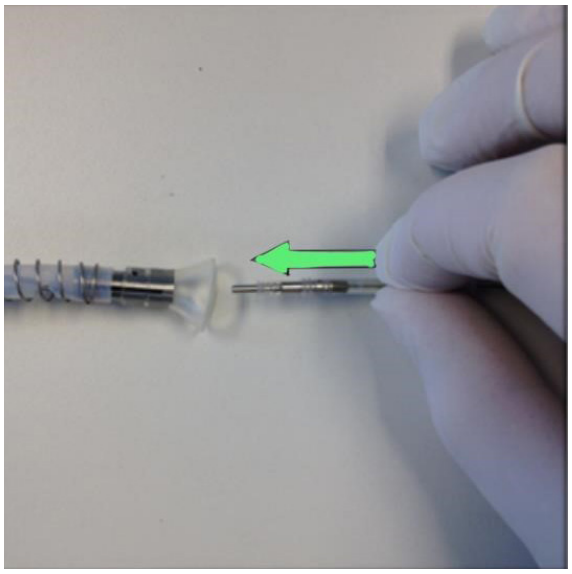


Screw in the lead by turning the knob

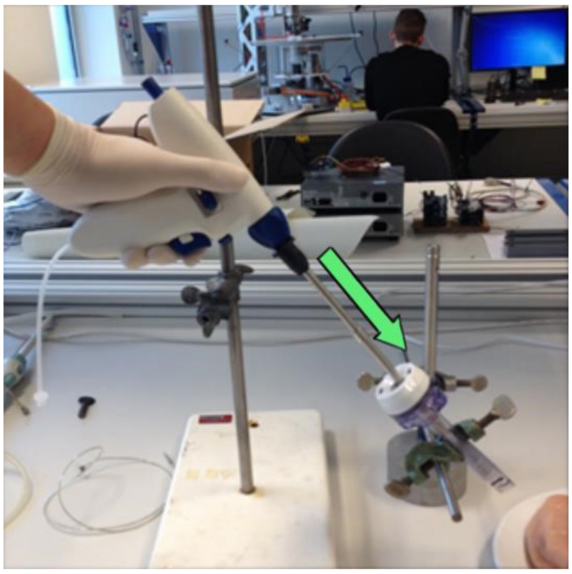


Release the lead by pressing the button forward

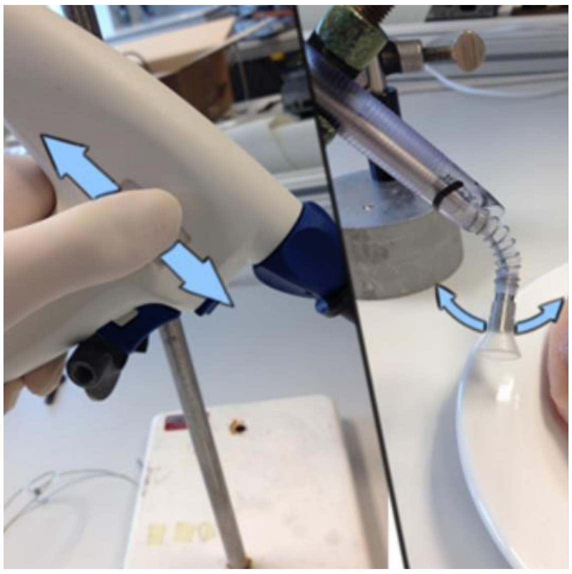
APPENDIX E: WORKFLOW OF THE FASTAC



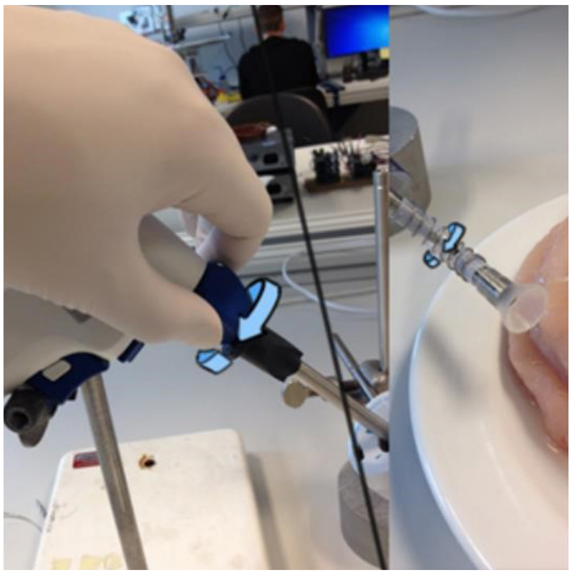
Loading the lead



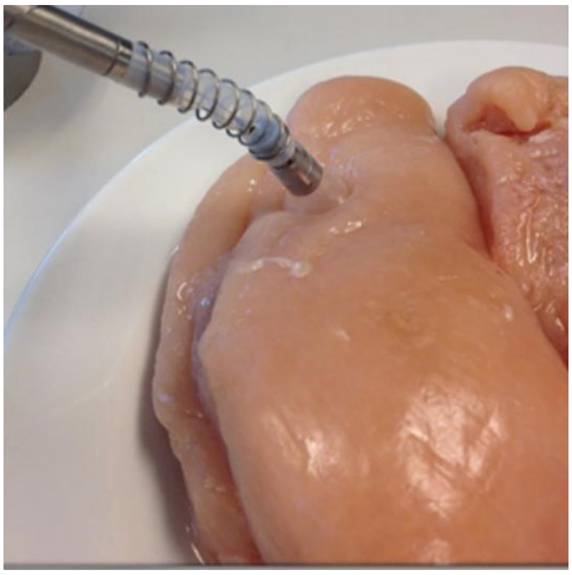
Entering the body through a trocar



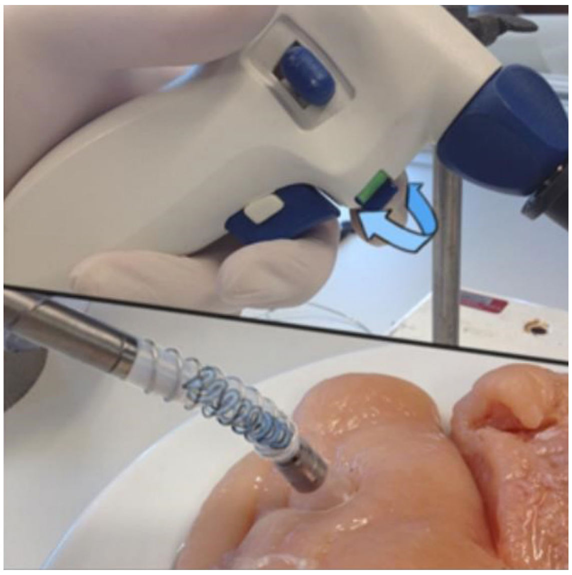
Bend the tip in the desired angle



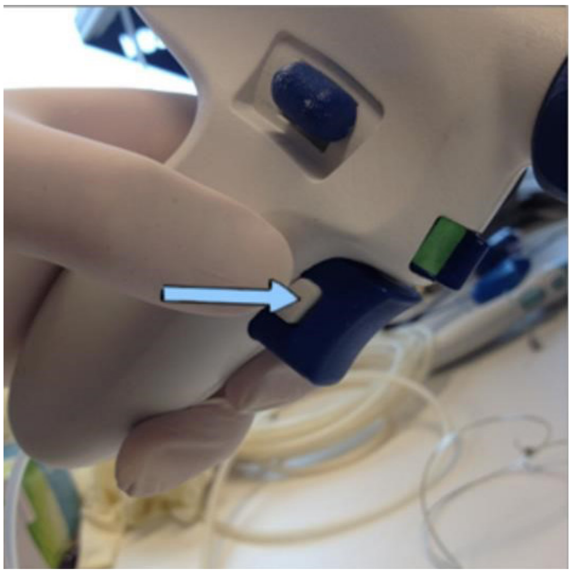
Rotate the shaft in the desired angle

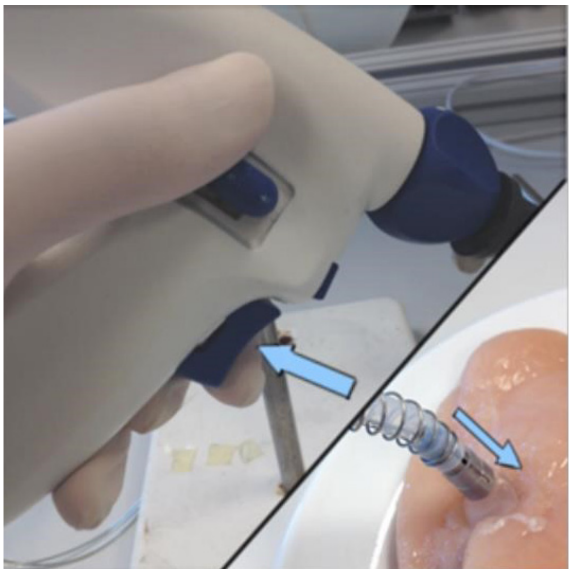


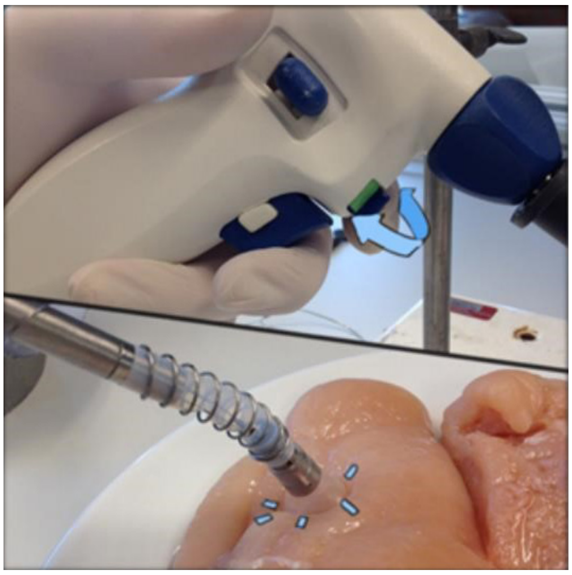
Put the vacuum pad on the heart

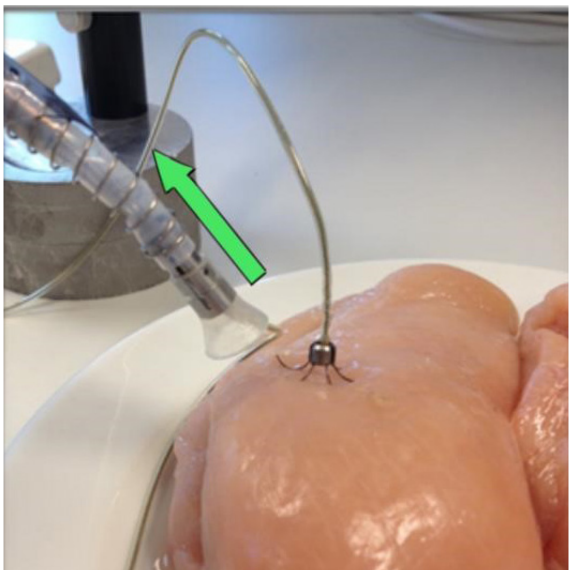


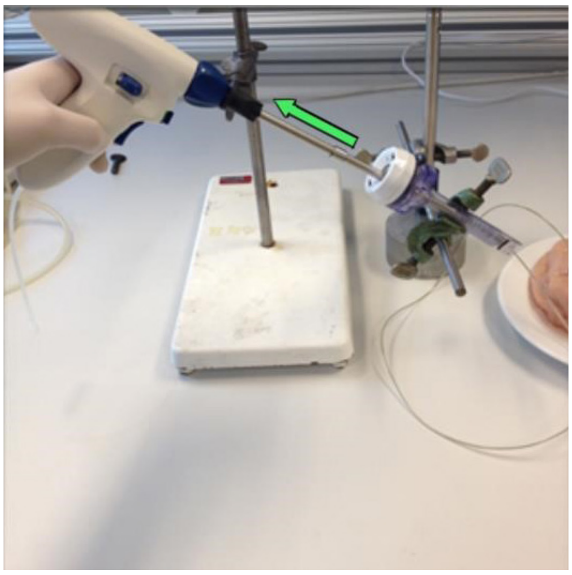
Turn on the vacuum

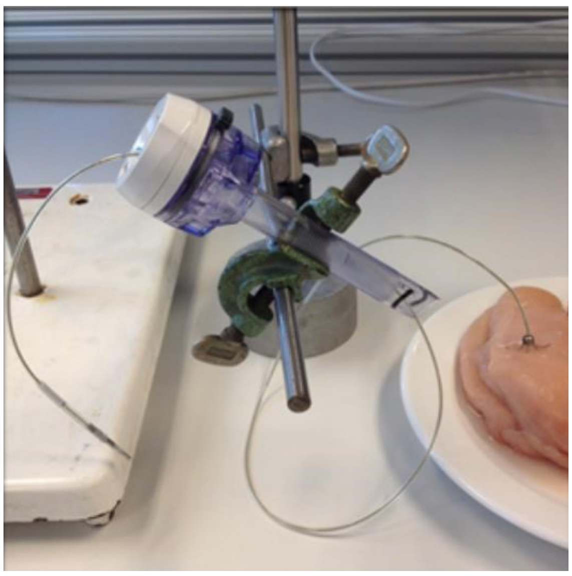

Push the safety pawl


Shoot the lead into the heart

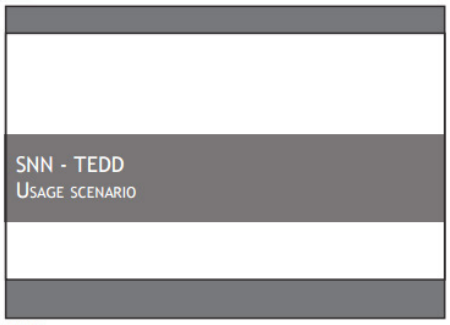

Turn off the vacuum


Bend the nozzle back and retract the device

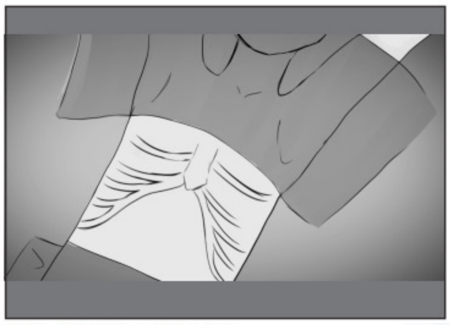




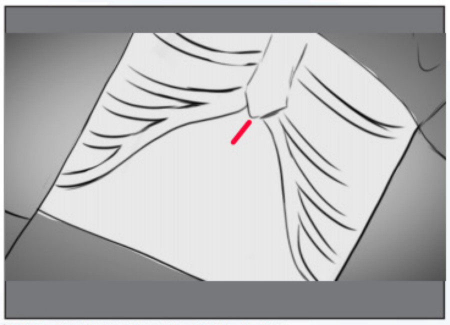
APPENDIX F:
WORKFLOW OF POP2



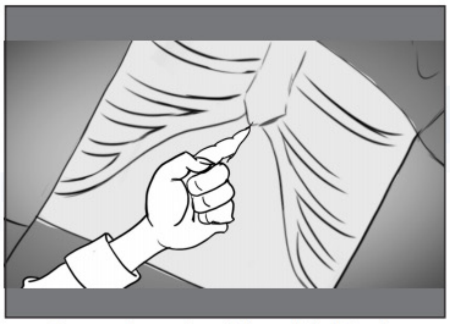
01



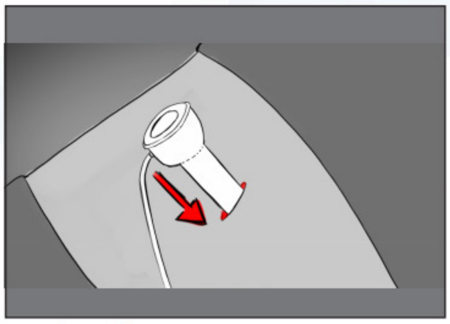
02 Patient lies on his/her back.



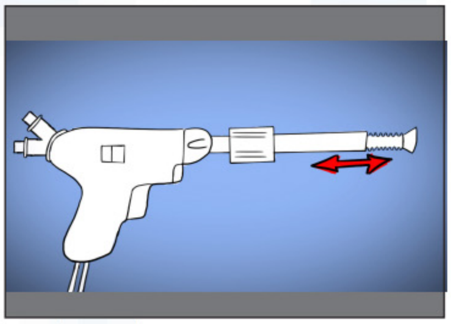
03 Create incision sub-xiphoid,+/- 2cm.



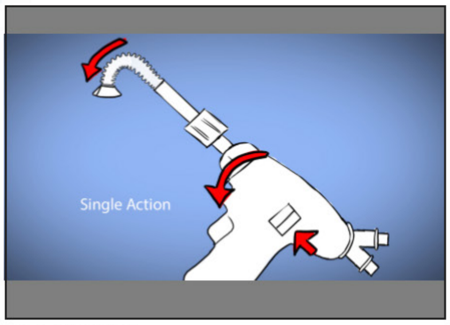
04 Insert one finger underneath the xyphoid, feeling the sternum on the fingertip, thus creating a space for the trocar



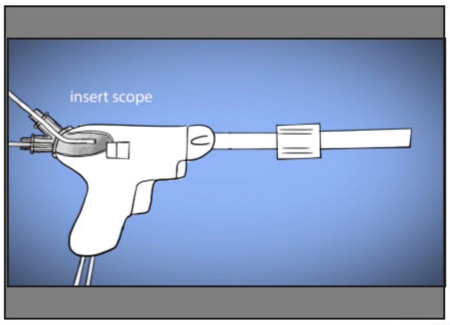
05 Insert single-entry trocar.
Insufflate CO2 to create space.



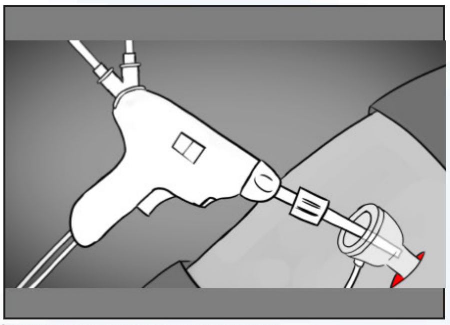
06 Demcon-tool.



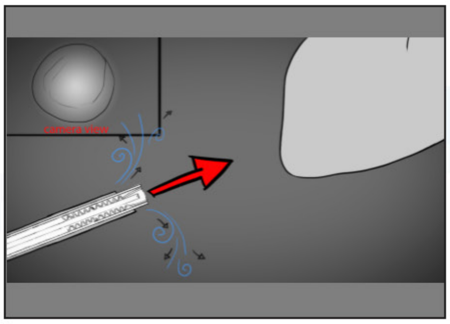
07 Demcon-tool.



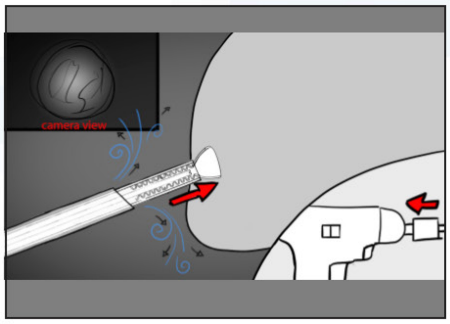
08 Insert flexible scope in channel of the Demcon-tool.



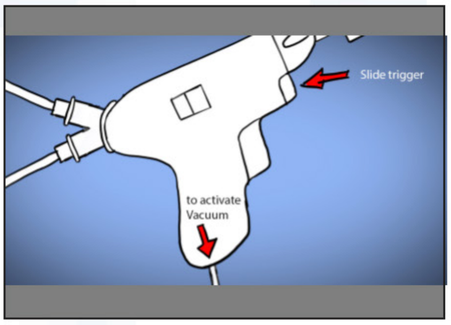
09 Insert Demcon-tool throught trocar.



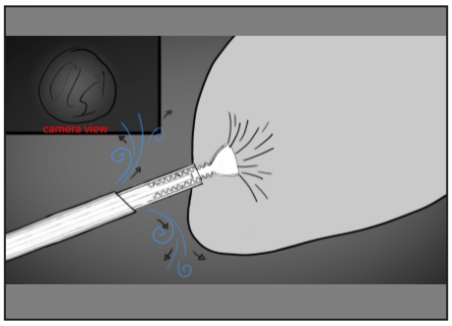
10 Navigate to heart.



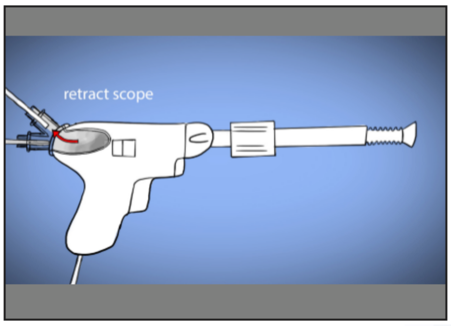
11 Expand vacuumpad and place on pericard.
Insufflate CO2 to create space.



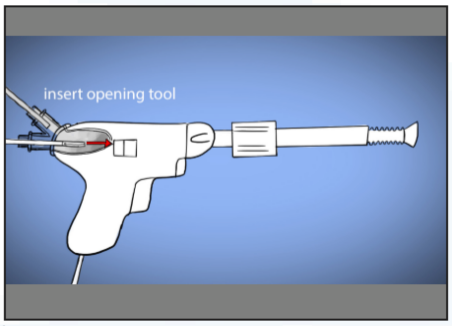
12 Ativate vacuum.



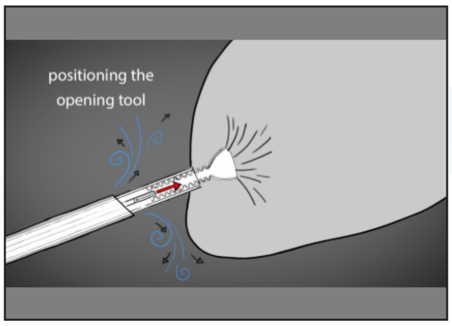
13 Attach tool on pericard using vacuum.



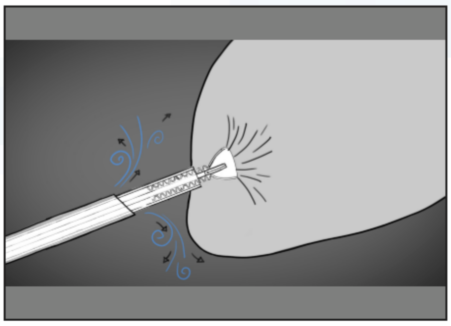
14 Retract scope out of the channel.



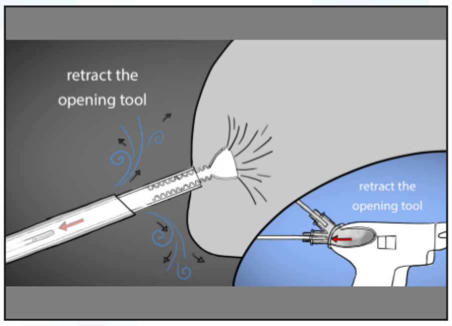
15 Insert the opening tool in the channel to open the pericard.



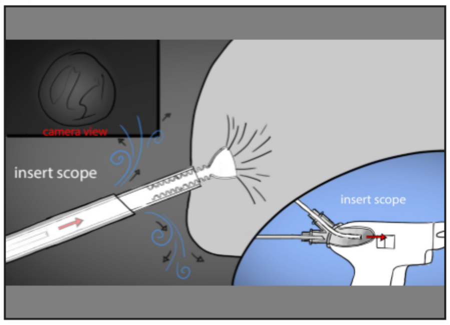
16 Insert the opening tool close to the pericard.



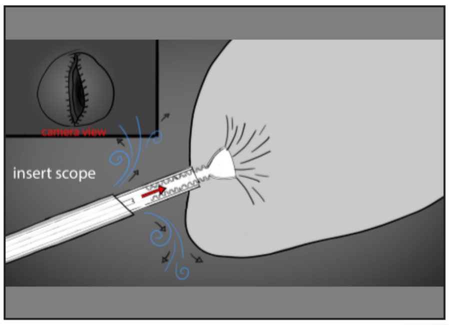
17 Open the pericard with the opening tool



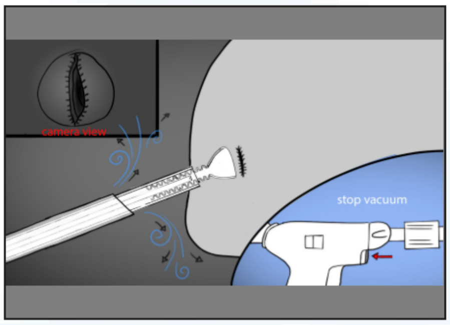
18 Retract the opening tool out of the channel.



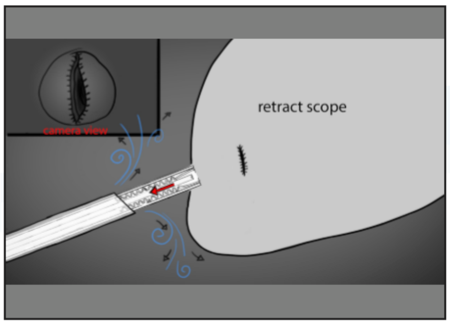
19 Insert the scope in the channel.



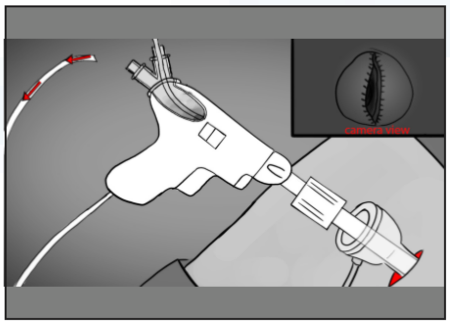
20 Insert scope and inspect the opening of the pericard.



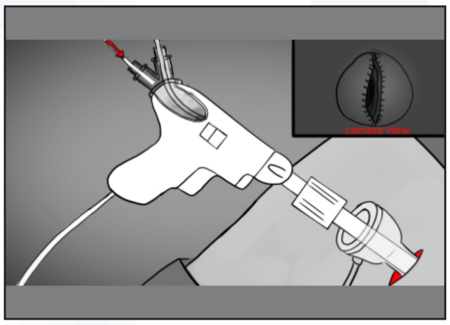
21 Stop the vacuum and detach the vacuumpad.



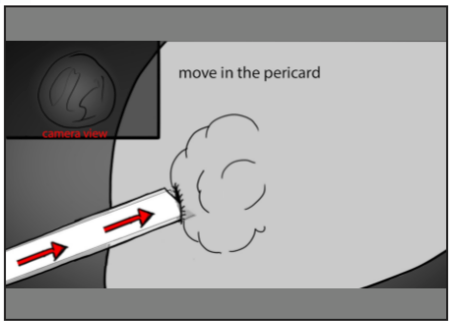
22 Fold vacuumpad and retract the Demcon-tool.



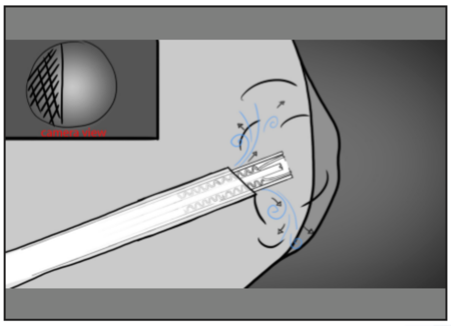
23 Remove the opening tool from the second bay in the Y connector



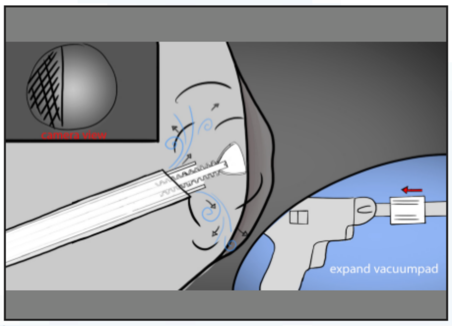
24 Replace it with the flexible catheter.



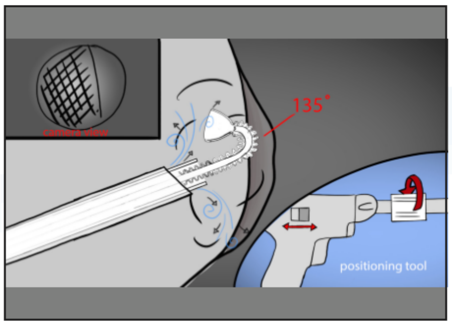
25 Enter the opening with the trocar and blow CO_2 with the trocar.



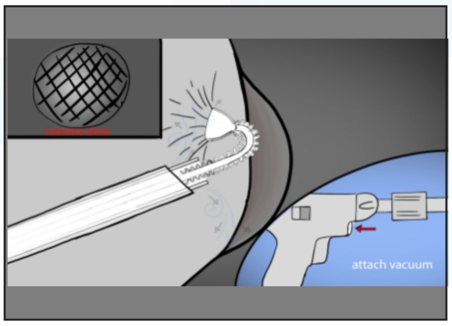
26 Navigate to the target area wile you insufflate CO_2 to create more space.



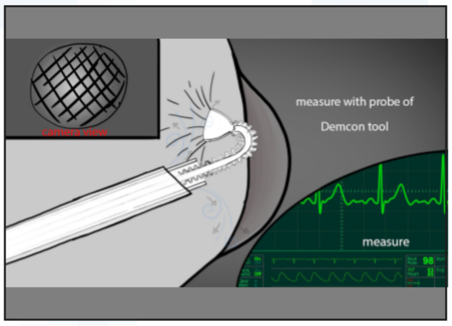
27 Expand vacuumpad.



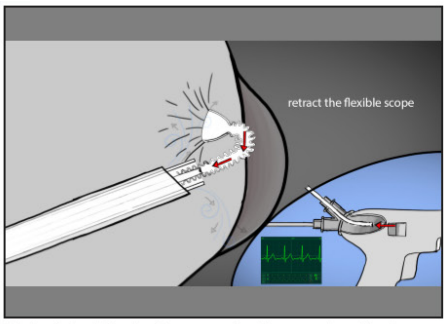
28 Positioning tool.



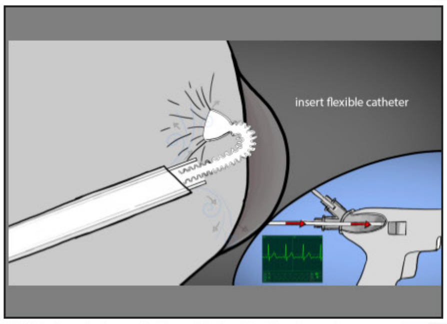
29 Attch using vacuum on the target area.



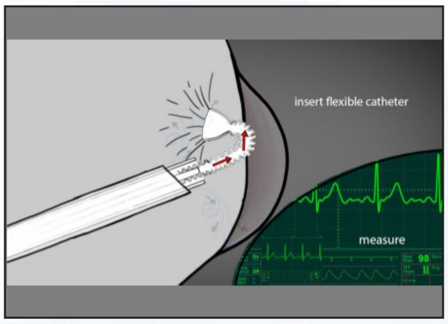
30 Measure the epicard with the tip of the Demcon-tool and reposition when location is found inadequate for stimulation.



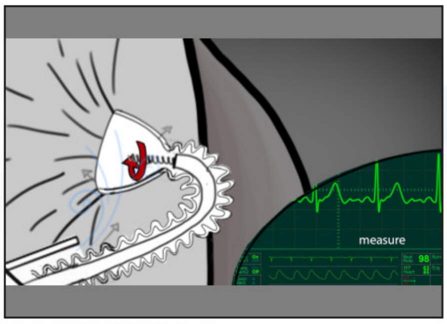
31 Retract the flexible scope when the correct position is found based on measurement.



32 Insert the catheter with lead in the channel

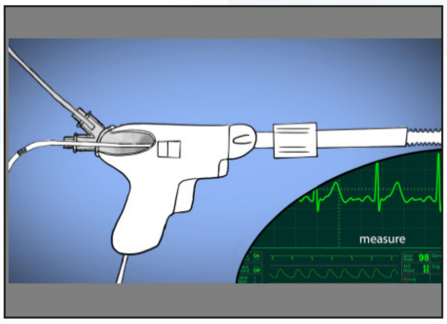


33 Advance it to the target area.

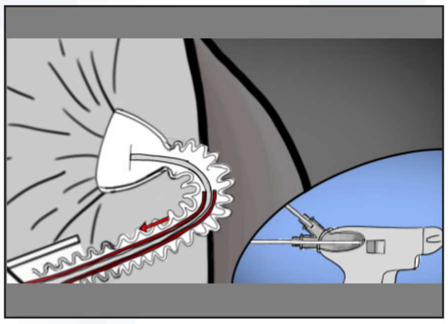


34 Secure the lead manually.

(in the final version securing the lead can be done automatically)

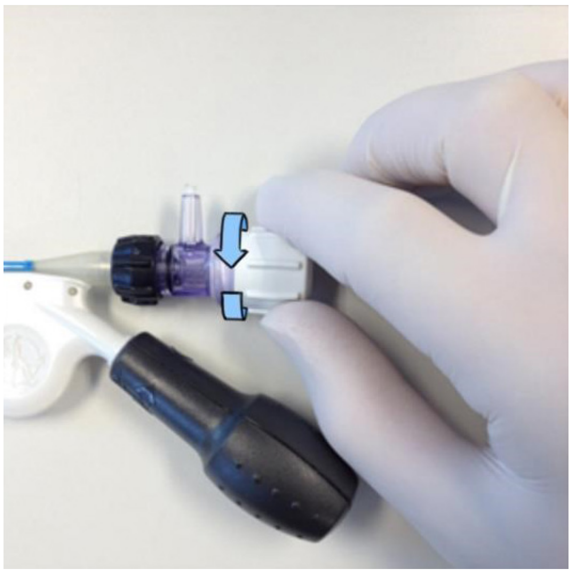


35 Verify whether the lead is working correctly.

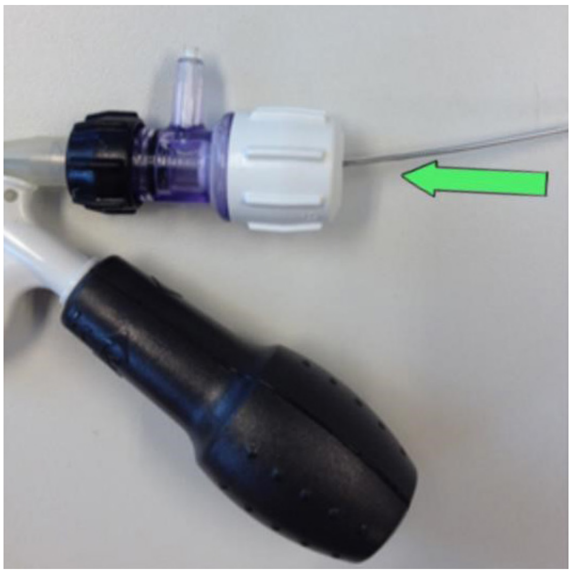


36 Remove the catheter.

APPENDIX G:
WORKFLOW OF POP2 INTERCOSTAL

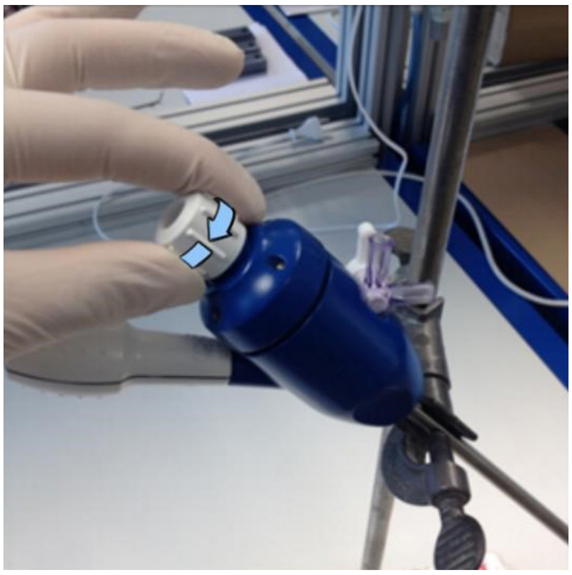


Open the vacuum valve of the catheter



Insert the lead in the catheter

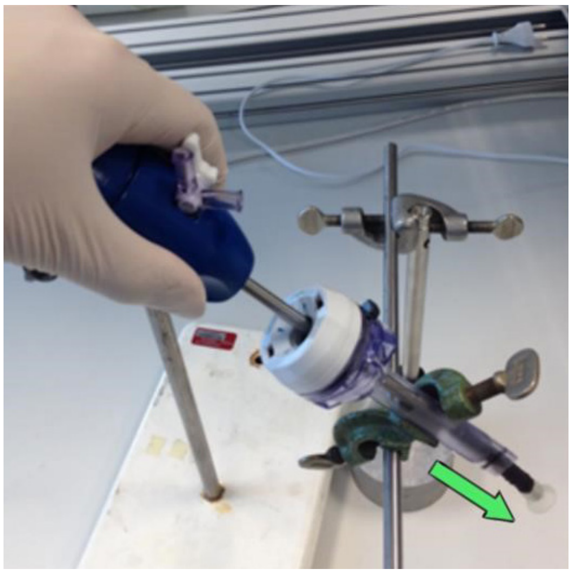
Close the vacuum valve of the catheter



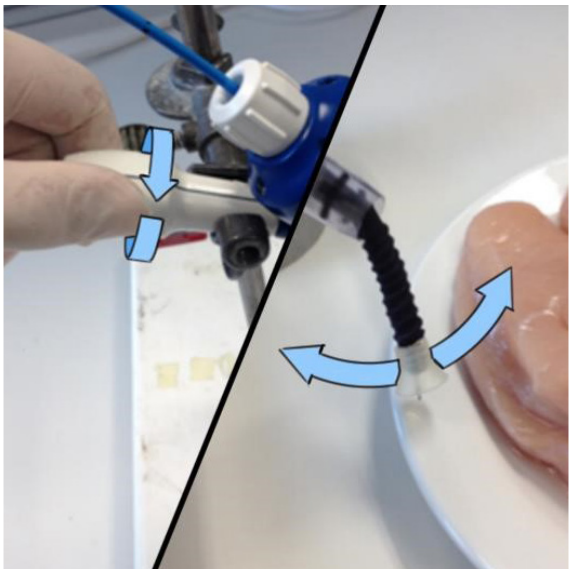
Open the vacuum valve of the TEDD

Insert the catheter into the TEDD

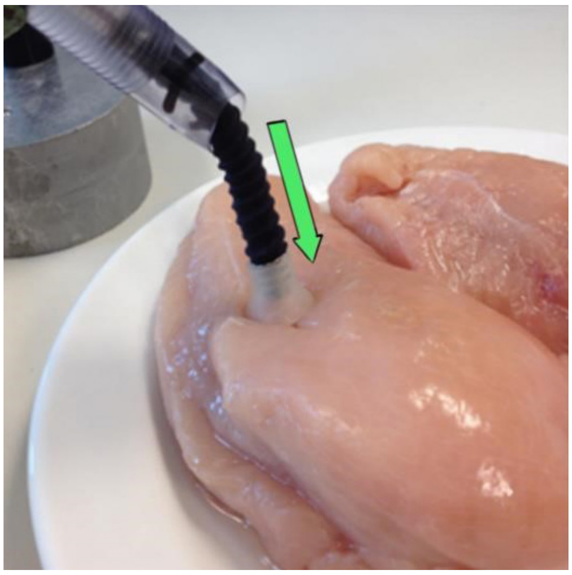
Close the vacuum valve of the TEDD



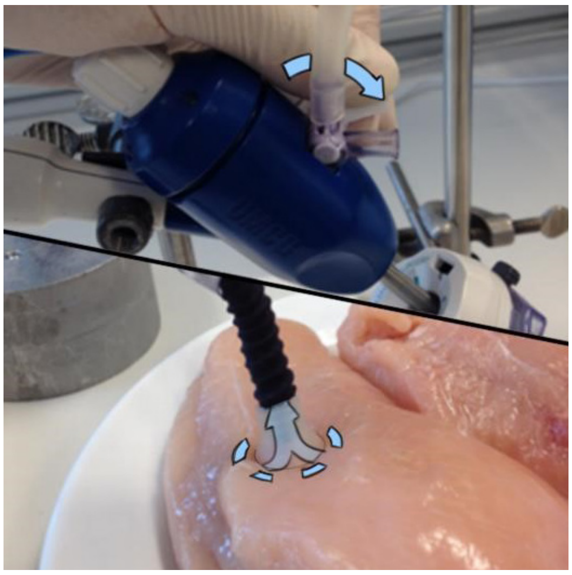
Insert the TEDD into the trocar



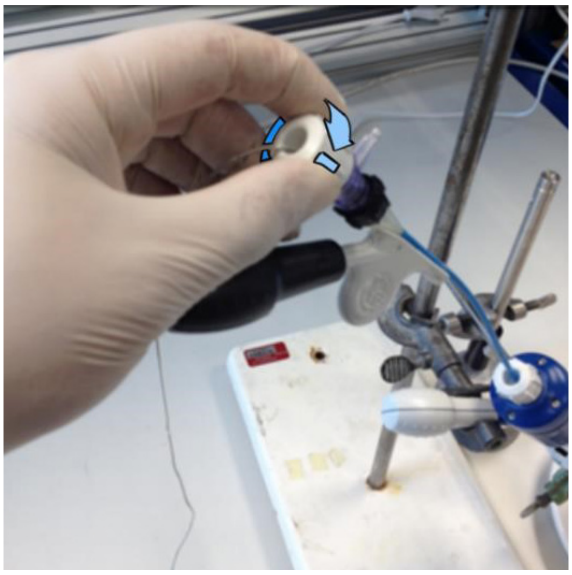
Bend the tip in the desired angle



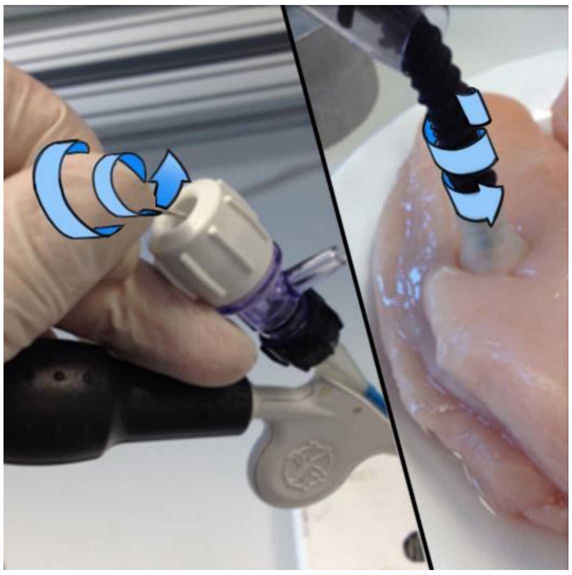
Push the vacuum pad to the heart



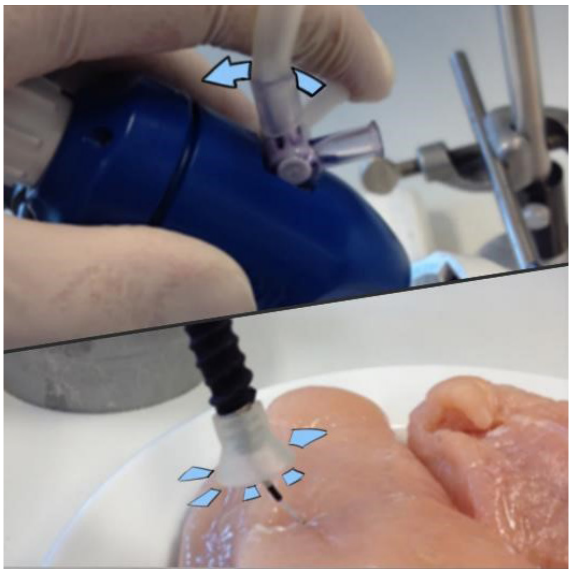
Turn on the vacuum



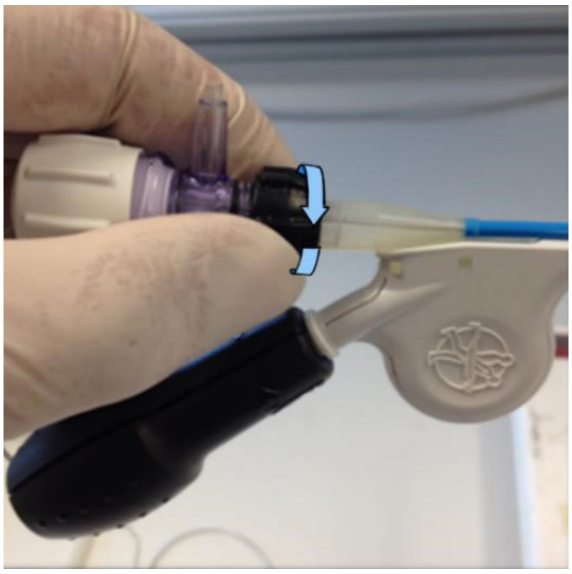
Loosen the vacuum valve of the catheter



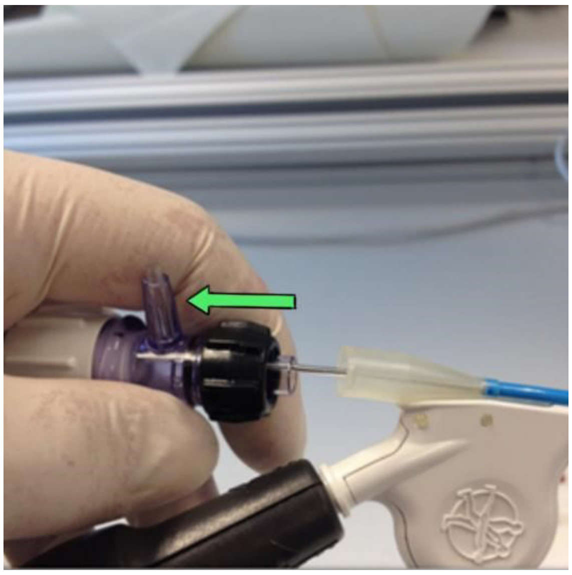
Screw in the lead by hand



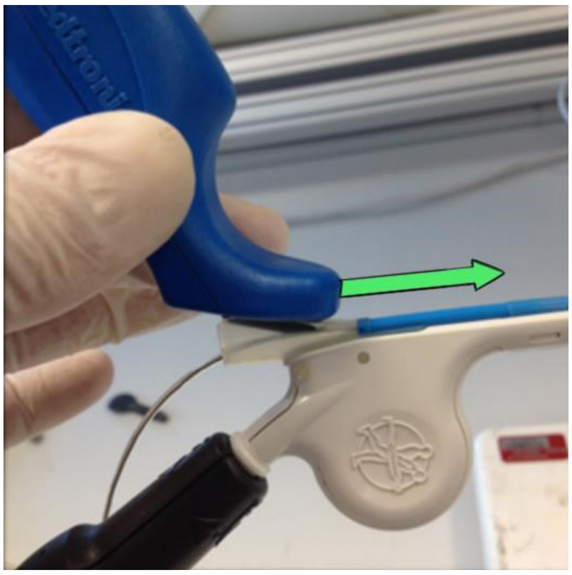
Turn off the vacuum



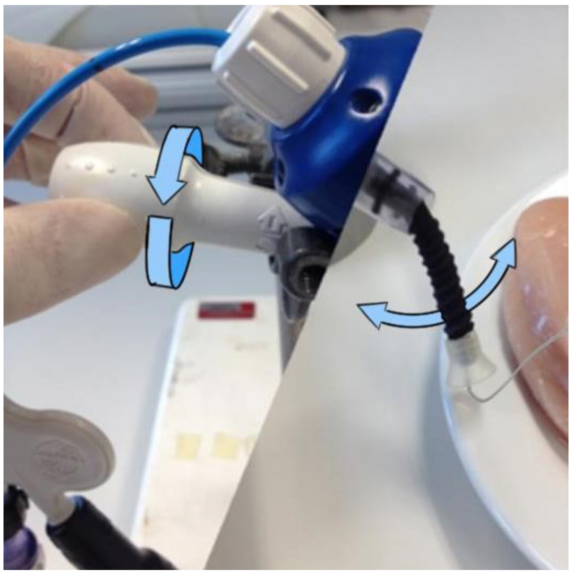
Unscrew the vacuum valve from the catheter



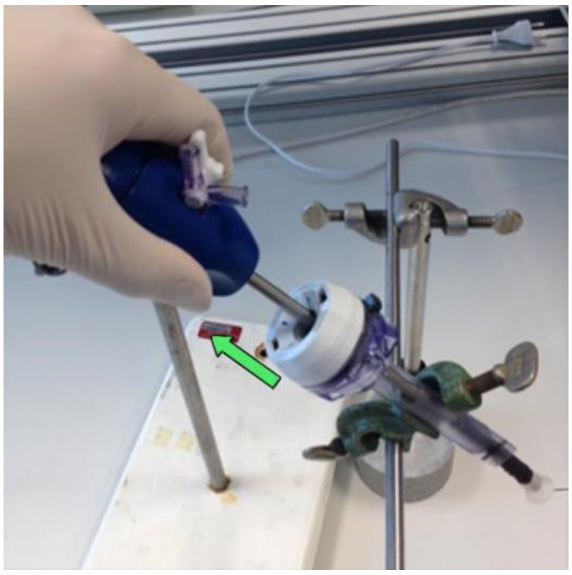
Retrieve the vacuum valve



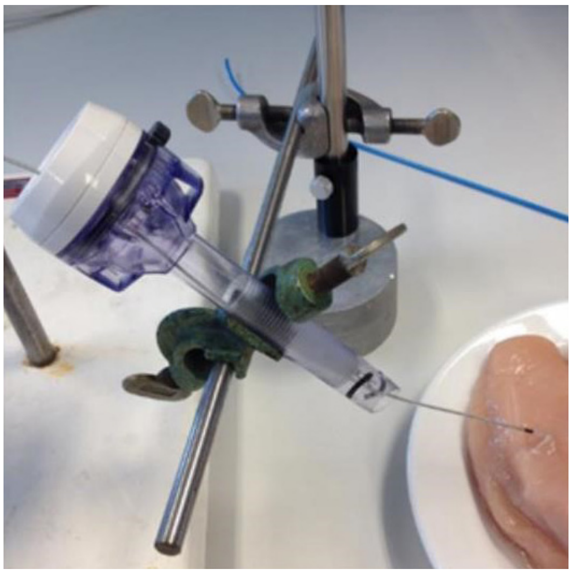
Cut the catheter open using a slitter

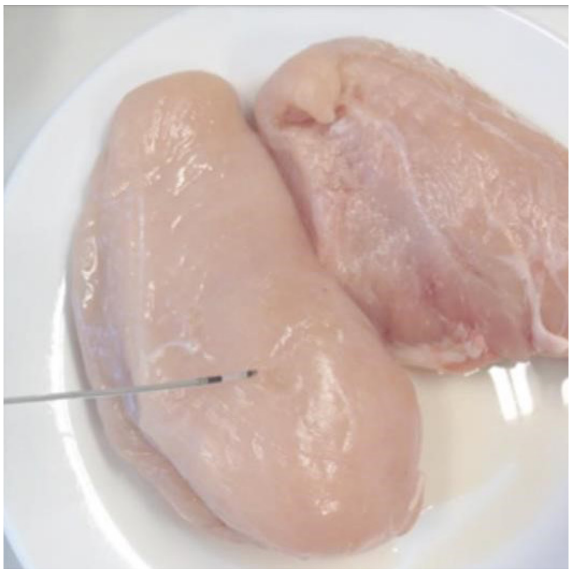


Bend the nozzle back straight



Retrieve the TEDD from the body





APPENDIX H:
STRESS IN THE CLICK FINGERS

The click fingers have to shrink their diameter from 4mm to 1.3mm in order to grab the lead, and still let the connector fit through. This calculation shows the amount of stress in one finger and checks whether it is lower than the tensile strength of the material. Since the fingers have an odd shape, some assumptions have been made. The width and height of the intersection have been estimated as can be seen on the image below and are taken on the smallest part of the finger. Therefore this calculation provides a worst case scenario. Also the young modulus of PET has been taken as young modulus for the printing material (Base) since this is unknown.

$$y = \frac{FL^3}{3EI} \quad => \; F = \frac{y \cdot 3EI}{L^3}$$

$$y = \frac{(4-1.3)}{2} = 1.35\text{mm}$$

$$L = 10.9mm$$

$$I = \frac{1}{12} bh^3$$

$$b = 2mm \qquad h = 0{,}45mm$$

$$I = \frac{1}{12} \cdot 2 \cdot 0.45^3 = 0.015\, mm^2$$

$$E = 2 \cdot 10^3\ (PET)$$

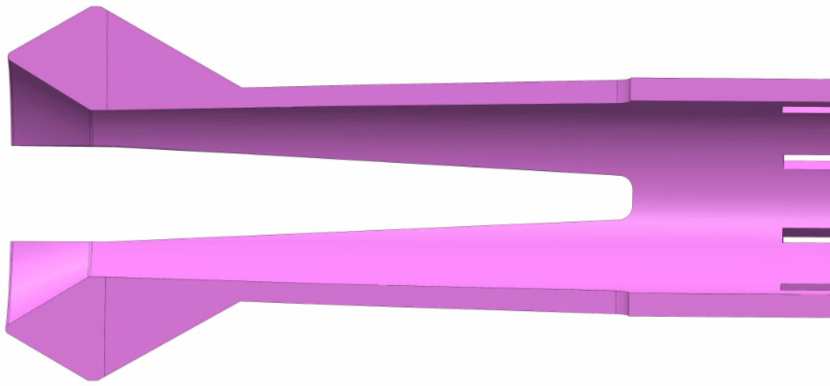
$$F = \frac{1.35 \cdot 3 \cdot 2 \cdot 10^3 \cdot 0.015}{10.9^3} = 0.09N$$

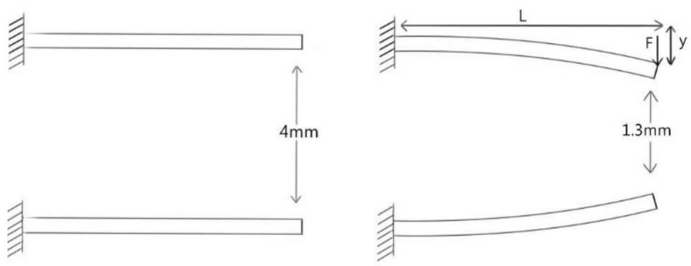
$$\sigma = \frac{Mb}{Wb}$$

$$Mb = F \cdot L = 0.09 \cdot 10.9 = 0.981\ Nmm$$

$$Wb = \frac{I}{e} = \frac{0.015}{0.225} = 0.067$$

$$\sigma = \frac{0.981}{0.067} = 14.6N/mm^2 = 14.6 \text{ MPa}$$





The yield strength for PET is 55MPa, so the fingers should not break off.