Skysong Innovations

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# Invention Disclosure Form

**PRIVILEGED AND CONFIDENTIAL**

| SI Use Only | |
|---|---|
| Tech ID: | Date Received: |
| Director of Intellectual Assets: | |

**Title of the Invention:** (should be brief and descriptive)
Home use Electric Stimulation device for patients with chronic weakness of hand due to stroke or spinal cord injury.

Is the disclosure of this invention regulated by **ANY U.S. export laws and regulations** pertaining to the export of technical data, services and commodities [i.e. International Traffic in Arms Regulations (**ITAR**) and/or Export Administration Regulations (**EAR**)]?
☐ Yes ☒ No

## Potential Inventor(s):

(subject to legal review) *Please use additional copies of this page for more than four names*

| | | | |
|---|---|---|---|
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Which of the above should be the primary contact for correspondence? Atharva Ajay Wani

| | |
|---|---|
| University Lab(s)/resources used to develop this technology: | HIDA electronics and fabrication lab, Tech Center<br>Innovation hub, Hayden Makerspace |

| | |
|---|---|
| Are all inventors listed above employees, officers or students of Arizona State University? ☐ Yes ☒ No (*If No, provide details*) | Dr. Joelly Lobato is an occupational therapist at Barrow Neurological Institute |
| Are any inventors listed above undergraduate students? | ☐ Yes ☒ No |
| Was any material or equipment provided by a third party? ☐ Yes ☒ No (*If Yes, provide details*) | |

## Federal Grant/Contract or Subcontract Funding

Was the invention conceived or first actually reduced to practice in the performance of work funded, in whole or in part, by any federal grant(s), contract(s) or subcontract(s)? (If yes, list below) ☐ Yes ☐ No

| Sponsor(s): | Grant/Contract Number(s): | Principal Investigator: | ORSPA Account Number(s): |
|---|---|---|---|
| Barrow Neurological Institute | | | |
| | | | |
| | | | |

**ANY PRIOR OR PENDING PUBLICATIONS, DISCLOSURES, OR OTHER ACTIVITIES (WHETHER BY YOU OR A THIRD PARTY) RELATING TO OR INVOLVING THE INVENTION CAN ADVERSELY AFFECT PATENT RIGHTS IN THE INVENTION.**

## Publication, Public Disclosure & Other Activities:

| | |
|---|---|
| Has the invention been described in any publication(s) *(including abstracts)*? | ☐ Yes ☒ No |
| Name of Publication, journal or website: | |
| Date of each publication: | |
| Has a manuscript describing the invention been submitted for publication? | ☐ Yes ☒ No |
| If yes, has it been **accepted** for publication at this time? | ☐ Yes ☒ No |
| Has a description of the invention appeared online (including conferences and abstracts)? | ☐ Yes ☒ No |
| Was a grant application describing the invention submitted for review? | ☐ Yes ☒ No |
| Was the invention disclosed publicly, such as in a poster session, presentation or lecture? | ☐ Yes ☒ No |
| Was the invention or any derivative product sold, offered for sale, or used in public? | ☐ Yes ☒ No |
| **Are any of the above disclosures or activities contemplated in the near future?** | ☐ **Yes** ☒ **No** |
| If yes to ANY of the above, please provide details: | |

*If the answer to any of the above questions is **YES**, please provide detailed information and attach any grants, abstracts, manuscripts, articles, presentations, etc., including any earlier publications (by you or anyone else) or other prior art that may be relevant to the patentability of the invention. Please keep our office informed of any future submission or acceptance for publication or other possible disclosure of any manuscripts, abstracts or oral presentations describing the invention.*

## Conception/Disclosure:

*Conception is defined as: "the act of forming a general idea or notion" Please fill in the following dates:*

| | |
|---|---|
| Conception of discovery: | 02/25/2023 |
| First disclosure to another: | 02/28/2023 |
| First experiment demonstrating discovery: | 03/17/2023 |

If the discovery or a significant aspect of the discovery is not supported by written records, briefly describe how the date of discovery can be established and identify earliest written record: Photographs of the experiment. earliest written record - 04/23/2023

## Type of Invention: (*Check all that apply*)

| | | |
|---|---|---|
| ☐ Agriculture/Animal Science | ☐ Environmental | ☒ Medical Devices & Imaging |
| ☐ Bio-Technology | ☐ Fuel Cells & Energy | ☐ Networks, I/T, Software & Communication |
| ☐ Drug Screening | ☒ Materials & Electronics | ☒ Therapeutics |
| ☐ Educational | ☒ Mechanical/Manufacturing | Other: (please specify) |

## Abstract/Brief Summary of the Invention:

*Give an overview of the invention's concept and chief objective(s) or purpose(s).*

The invention is a medical device designed for patients with chronic hand weakness resulting from conditions such as stroke or spinal cord injury. The primary objective is to create ergonomic e-stim pads that exhibit exceptional durability by preventing corrosion. Additionally, these e-stim pads eliminate the necessity of adhering them to the patient's skin, thereby enhancing safety during usage.
The device operates through voice and touch commands, making it accessible to a broad spectrum of patients. It also incorporates self-tightening mechanisms and boasts a compact design to enable independent usage.

## Introduction/Background of the Invention:

*Give context to the invention. Describe the field(s) to which the invention pertains and the developments that led to the invention.*

Upon speaking with a therapist from Barrows Neurological Institute and using their therapy device, we realized the need for a better solution. The primary complaint from the patients was about the sticky, wet e-stim pads that needed to be stuck to the skin and changed frequently. The primary complaint from the therapist's perspective was the bulky, expensive, and non-portable design of the devices they use and the scarcity of well-integrated home-use devices for patients. This sparked the thought process to come up with new designs for pads and a device around them to make the device accessible, ergonomic, and easy to use.

## Detailed Description of the Invention:

*Give a thorough description of the invention as well as how it is made/executed and used. The description should be so detailed that a person skilled in the field would be able to make and use the invention as a result of reading it. Please be as clear, exact and thorough as possible in your description, and please be sure to clearly identify which element of your research is "the invention."*

The device is an electric stimulation device used to stimulate the muscles in the hands of patients with chronic weakness due to stroke or spinal cord injury. The prototype is built using readily available technologies and components such as a wrist brace glove, NMES e-stim device, Arduino micro-controller, touch screen module, thin-film pressure sensor, ratcheting mechanism, nylon/elastic laces, and various CAD, manufacturing, and programming software. The innovation in this device lies in the design of the e-stim pads and their placement to make them more comfortable and induce a more natural gripping style compared to other devices on the market.

To design the e-stim pads, the anatomy of the hand is thoroughly studied, and the motion of the fingers and palm is observed to create a profile that puts pressure on the thenar and hypo-thenar muscles of the hand. These pads are then 3D modeled in SolidWorks. The pad design consists of two parts that clip into each other. The top piece is made from stainless steel, and the base of the pad is made from PLA plastic. Spiral grooves with a 1mm diameter are incorporated on the bottom of the top piece and the top of the base to facilitate wire routing. The base also features a swept hole to conceal the wire.

The top piece of the pads is manufactured using a Selective Laser Sintering (SLS) metal 3D printer with Stainless Steel (SS-306). After printing, the pads are finished by grinding the surface that comes in contact with the user's skin to achieve a smooth, shiny finish. The base of the pad is manufactured using a plastic extrusion 3D printer with PLA plastic filament.

Copper tape is embedded into the grooves on the bottom of the top piece of the pad to allow for soldering wires. A section of thin electrical wire is stripped of its sheath and routed through the holes in the base. The wire is carefully soldered into the groove, and excess solder is ground to create a flush interface between the top piece and the base.

A third pad is designed in the shape resembling a button and is placed along the forearm. This pad also features spiral grooves for wire routing, and the wire is soldered in the same way as in the previous case. The wire from one of the previous pads is split, and the two pads are connected in series. The other end of the wire is connected to the e-stim device, which is a Neuro Muscular Electric Stimulation (NMES) device made by Balego. It is set to a 40Hz frequency (adjustable range: 2-150Hz) with a 250uS pulse width (adjustable range: 50-300uS) for the safety of the patient, but these values can be changed by the therapist remotely based on the patient's profile. These settings are only accessible to the therapist due to safety concerns related to improper use of electricity through the body. The current has an adjustable range of 0-100 mA at 0-50 V, which the user can change locally on the touch screen. This setting is user-accessible.

The e-stim device is modified so that it can be controlled by an Arduino micro-controller and a touch screen. The e-stim device is set to continuous mode, and the Arduino controls the power going to the device to induce muscle stimulation when the user needs it.

The device is controlled by an Arduino Nano RP2040 Connect microcontroller, which uses the Arduino voice recognition library to recognize voice commands. To activate the device, the user says the phrase "RIGHT GLOVE," which can be modified to "LEFT GLOVE" for gloves worn on the left hand. After the activation phrase, an LED lights up to indicate that the device is ready to receive commands from the user. The action words used to control the device are "GRASP," "GRAB," "HOLD," "RELEASE," "LEAVE," "DROP," "WEAR," and "REMOVE." The Arduino stays awake for 20 seconds after activation, and multiple commands can be given within that span. After 20 seconds have passed, the user must reactivate the device by saying "RIGHT GLOVE." Upon receiving the command "GRASP," "GRAB," or "HOLD," the Arduino sends a signal to a relay to provide power to the e-stim device. When the command "RELEASE," "LEAVE," or "DROP" is received, the Arduino stops the power to the e-stim device.

Using the command "WEAR" initiates the self-tightening mechanism. A continuous rotation servo motor starts reeling in the nylon strings with a ratchet mechanism, tightening the glove. Two thin-film pressure sensors are placed under the pads and halt the self-tightening mechanism when they register a pressure of 1-2 kg/cm2 on both pads. The command "REMOVE" causes the motor to rotate in the opposite direction, opening the glove.

The device can also be controlled using Electromyography signals. The same pads used to deliver e-stim are also used as EMG sensors. The Arduino controller employs a machine learning algorithm to detect these signals and classify them into categories: GRAB, RELEASE, WEAR, and REMOVE.

A wireless charging pad is mounted on the underside of the glove, and the wires from it run directly to the battery, charging it when placed on a wireless charger. An emergency stop button is provided on the touch screen to completely halt the device's operation in case the user encounters any trouble.

A case is designed to house all the electronics with a mesh opening for the microphone to receive voice commands. The components fit inside, and the cables from the pads and wireless charger enter through dedicated holes in the case. The self-tightening strings are also connected to the motor inside the case. Once assembled, the case is affixed to the glove and is manufactured using a plastic extrusion 3D printer with PLA plastic filament.

The placement of the pads is crucial, with one pad permanently affixed under the thenar muscle of the palm and another under the hypo-thenar muscle of the palm, both on the glove. These pads incorporate thin-film pressure sensors. The third pad is stitched along the forearm on the glove. The pad design accommodates hands of all shapes and sizes and serves as EMG sensors to detect signals from the hand.

The device was tested by the inventors on themselves and verified the functionality of the device. Verified the correct muscle groups were getting activated and the hand was making a grasping motion. Checked the strength of grip by lifting common household items like coffee mug, water bottle, books etc

## Figures and Descriptions:

*If you wish to submit documents, presentations, figures, charts or other supporting materials, please list them here and include them with this disclosure.*

Concept designs and 3D CAD screen captures of the pads and device.

## Non-Confidential Summary of the Invention:

*This should be one to two paragraphs in length and should not contain any proprietary information. The non-confidential summary should include an overview of the invention and its impact/commercial potential and may be shared with companies interested in licensing the rights to the invention.*

The device aims to bridge the gap between the products available on the market and the need for a more comfortable and "independent" product by consumers. E-stim pads can be moisture-controlled, requiring them to be wet under operation, or they can be gel, which is highly uncomfortable for the users. The invention of the new device, which consists of e-stim pads along with several additional attachments, solves the problem of pads that need to be changed frequently. The new ergonomic design ensures natural grip and provides robust control of actuation by implementing voice and touch sensing.

## Novel Aspects of the Invention:

*Specifically identify those properties of the invention (or the process by which it is made or used) that are novel and that distinguish it from existing technologies.*

The current e-stim pads using the TENS method require to be stuck to the skin and pose a risk of injury if the pads are dry and not conducting. Our device, being compact, portable, and easy-to-use, solves these problems faced by users. The novel e-stim pads are ergonomic, developed using SLS metal 3D printing procedures, and made of stainless steel SS-306. They utilize the natural curvature of the hand with stainless steel to work as electrodes, inducing current through the NEMS method, giving more freedom to the users, and providing a "natural" grip. Another novel aspect of the device is the use of IOT, AWS, and sensors to connect the users with the therapists in real time. Additional touch screen and voice activation offer a wide range of operating principles.

Self-tightening is achieved by a new method using a combination of motors and a rachet mechanism. To make it easier for the user and allow for different palm sizes, the unique pad design targets a larger section of the muscle to be more effective for most hand sizes. Two pads in the device are located in approximately the middle of the thenar and hypothenar muscles of the palm, respectively, whereas the third pad is located along the forearm to assist in achieving the primary objective. This specific placement ensures a more natural and functional grip, allowing the user to manipulate any item with ease.

## Advantages Over Current Technology and Impact:

*Please identify the invention's advantages over existing alternative products, processes or services.*

This device uses e-stim pads that do not need to be changed or stuck to the skin. Along with this crucial novel pad design, the voice and touch activation, larger area of contact for the pads, and self-tightening mechanism make this device unique from the current products. Additionally, functional aspects like self-charging and easy donning and doffing make this device more suitable for independent use.

| Which Companies or Investors are most likely to be interested in this invention? | | | |
|---|---|---|---|
| **Company** | **Contact** | **Phone** | **Email Address** |
| Medtronic | | | |
| Johnson & Johnson | | | |
| Intuitive surgical | | | |
| Rehabtronics | | | |

## Commercial Potential:

*Please describe the invention's commercial potential, in terms of potential products and services, and describe its competition/available alternatives.*

This device makes the life of patients much more comfortable and gives them more independence and control over their lives. This is very important as improving quality of life of patients with chronic ailments is essential to their families and themselves. Using this invention many people will be able to get a device that is affordable, easy to use and maintain, comfortable and can make the users more independent.

*Per ABOR 6-908 and ASU RSP 604, the creator's share of "Net income" received by ASU from commercialization of intellectual property is divided equally among all inventors unless each and every inventor agrees in writing to a different distribution of the creator's share. Please contact SI if the creators wish to enter into a sharing arrangement for the creator's share that is different from that provided under university policies.*

## Related Publications:

*Please list any papers, patents and other published material that you are currently aware of that either relate to your invention or describe similar technology. Please include links and/or submit copies of the publications when possible. (add supplemental sheet if necessary)*

Rehabtronics Regrasp - https://rehabtronics.com/product/regrasp-rehabilitation-glove/
Bioness H200 - https://encompasshealth.com/inpatient-rehabilitation/irf-our-technology/bioness-h200
Restorative therapies Xcite2 - https://restorative-therapies.com/ifes-systems/xcite2/

## Certification and Acknowledgement: *(please use additional copies of this page if more signatures are required)*

I certify that the information contained in this Invention Disclosure Form is true, accurate and complete. I acknowledge and agree that the Arizona Board of Regents (ABOR) on behalf of ASU owns the discovery and intellectual property disclosed herein pursuant to ABOR Intellectual Property Policy #6-908. I hereby assign all rights in the invention disclosed herein, including any patent applications related hereto, to ABOR on behalf of Arizona State University. I understand that Arizona Technology Enterprises (SI) is the intellectual property management organization for ASU.

If SI determines to seek patent or other appropriate protection for the technology described herein, I shall cooperate with SI in its efforts to do so and shall sign such documents as may be required for this purpose, including but not limited to an assignment of the discovery to ABOR in a form that may be recorded, a declaration as to inventorship, and power of attorney. I understand that ASU will adhere to the terms of ABOR policy #6-908, as amended from time to time, and will distribute any proceeds from licensing or assigning the technology in accordance with such policy and ASU RSP #604.

If it is determined that I am an inventor, I acknowledge that SI will need my contact information to facilitate the prosecution and commercialization of this invention. I agree to promptly provide SI with any changes to my contact information. My failure to provide current contact information may affect SI's ability to prosecute and/or commercialize this invention and my ability to share in any commercialization revenue.

| Signatures | Date |
|---|---|
| | 11/07/2023 |
| Ishan Swaminathan Vyas (Nov 8, 2023 11:18 MST) | 11/08/2023 |
| S.P. Joglekar | 11/08/2023 |
| Joelly Lobato de Faria<br>Joelly Lobato de Faria (Nov 8, 2023 10:19 MST) | 11/08/2023 |

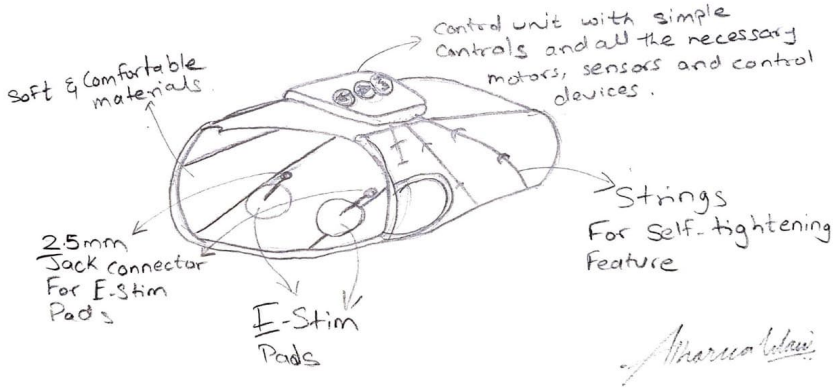


Fig 1. Overall Concept design

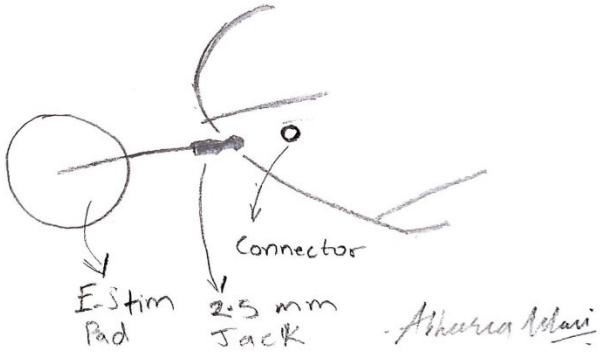


Fig 2 Pad Connection concept

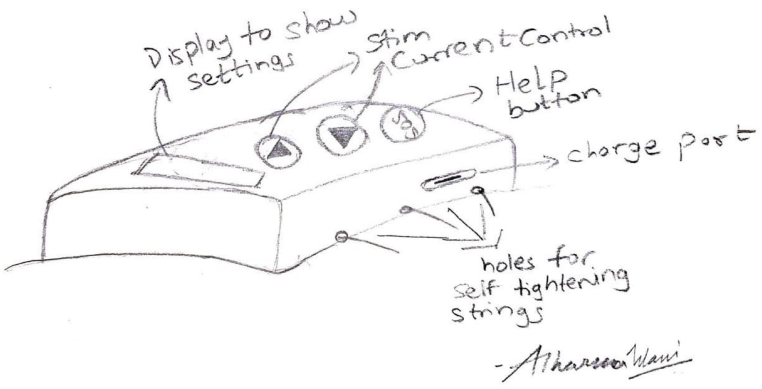


Fig 3. Control unit concept design

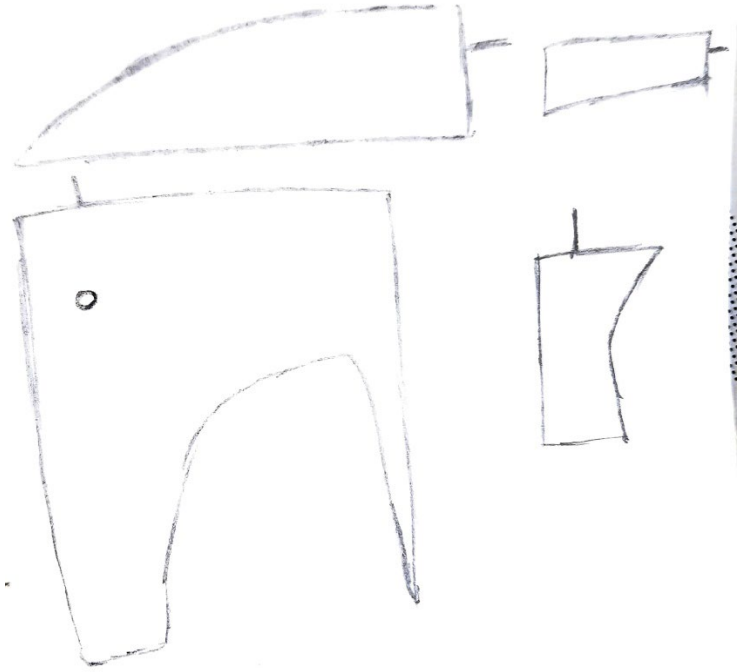

Fig 4. New pad design concept

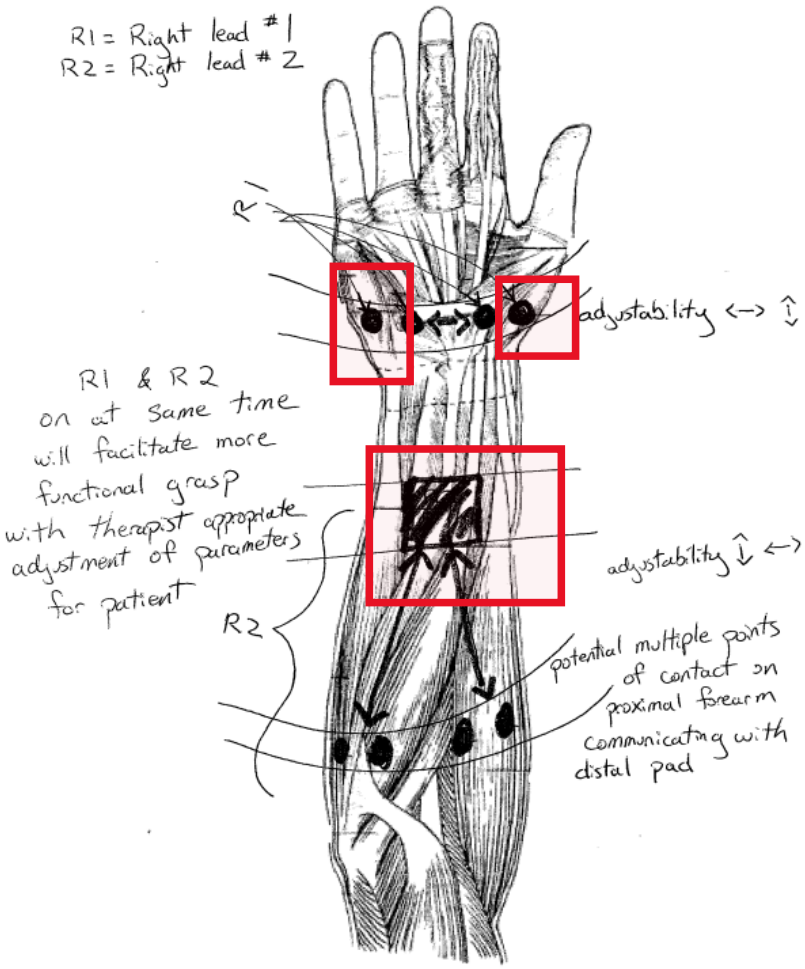


Fig 5. Pad placement

Fig 6a – 6e. Different CAD views of the top piece of the thenar pad

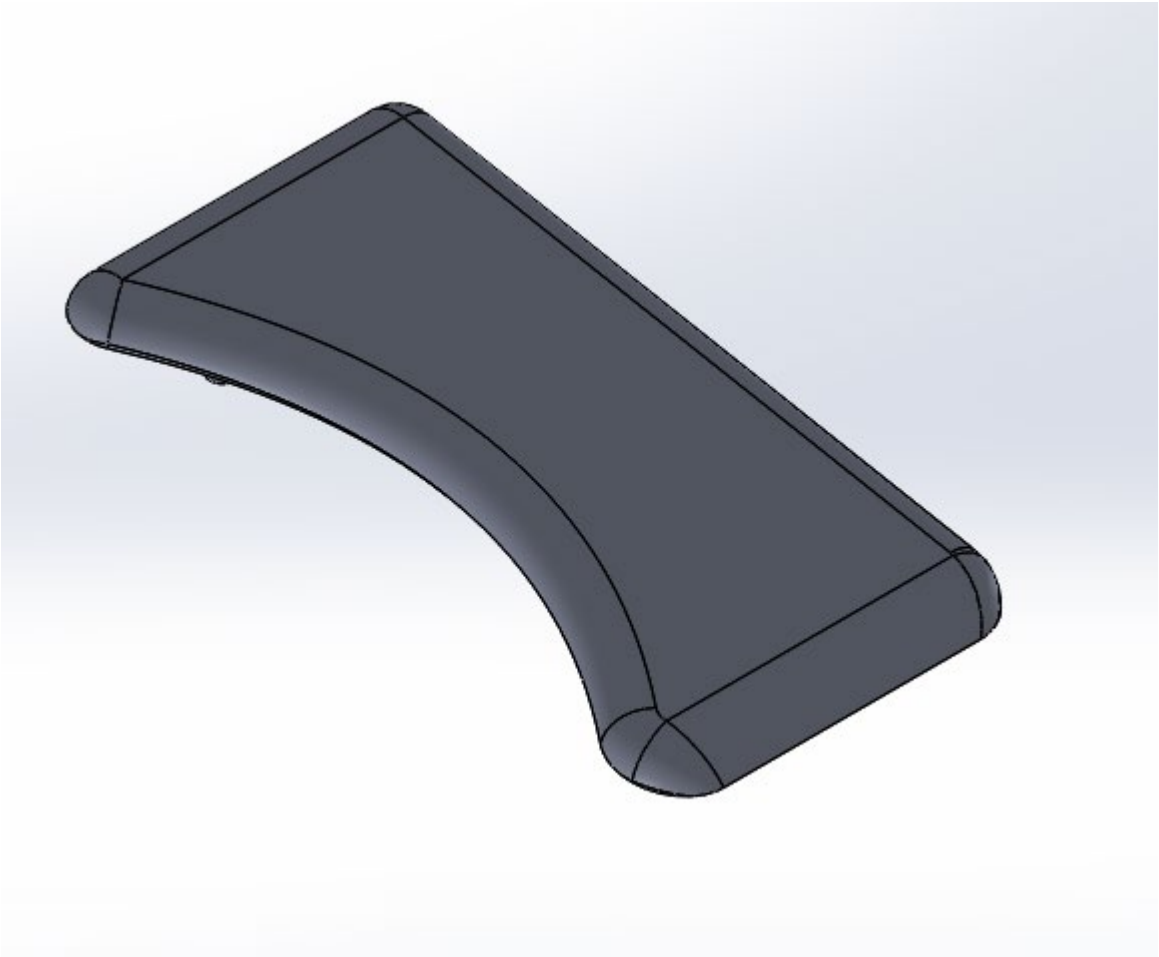

Fig 6a

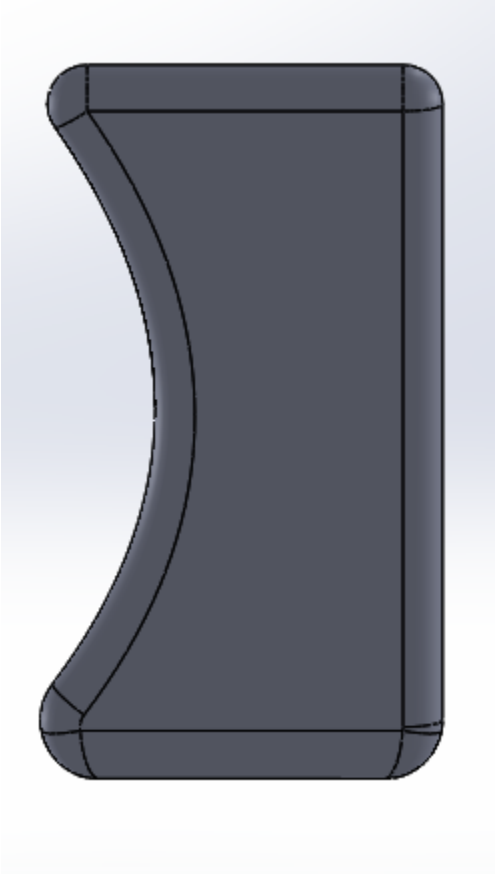

Fig 6b

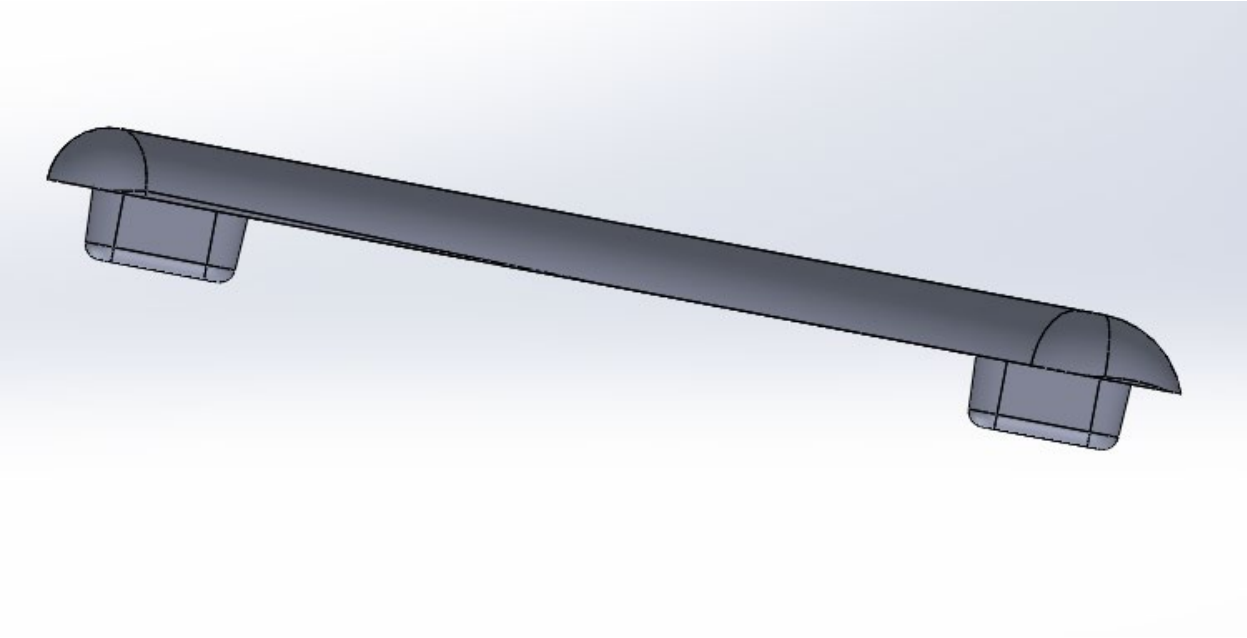

Fig 6c

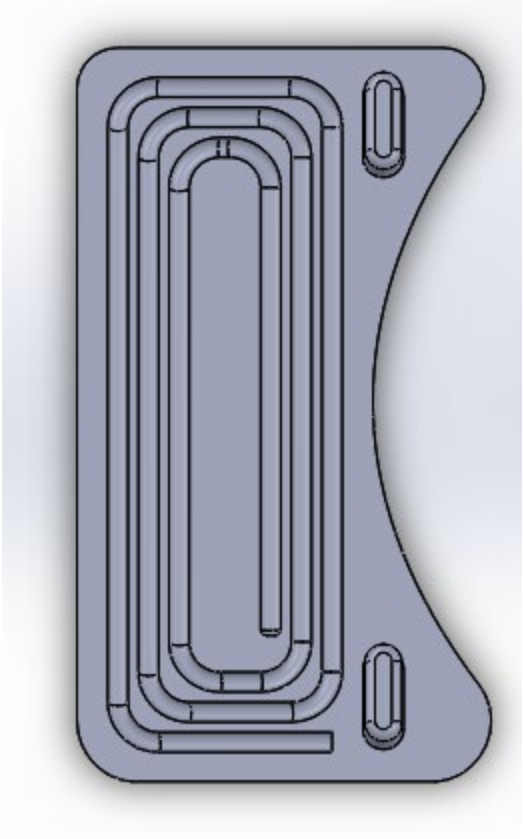

Fig 6d

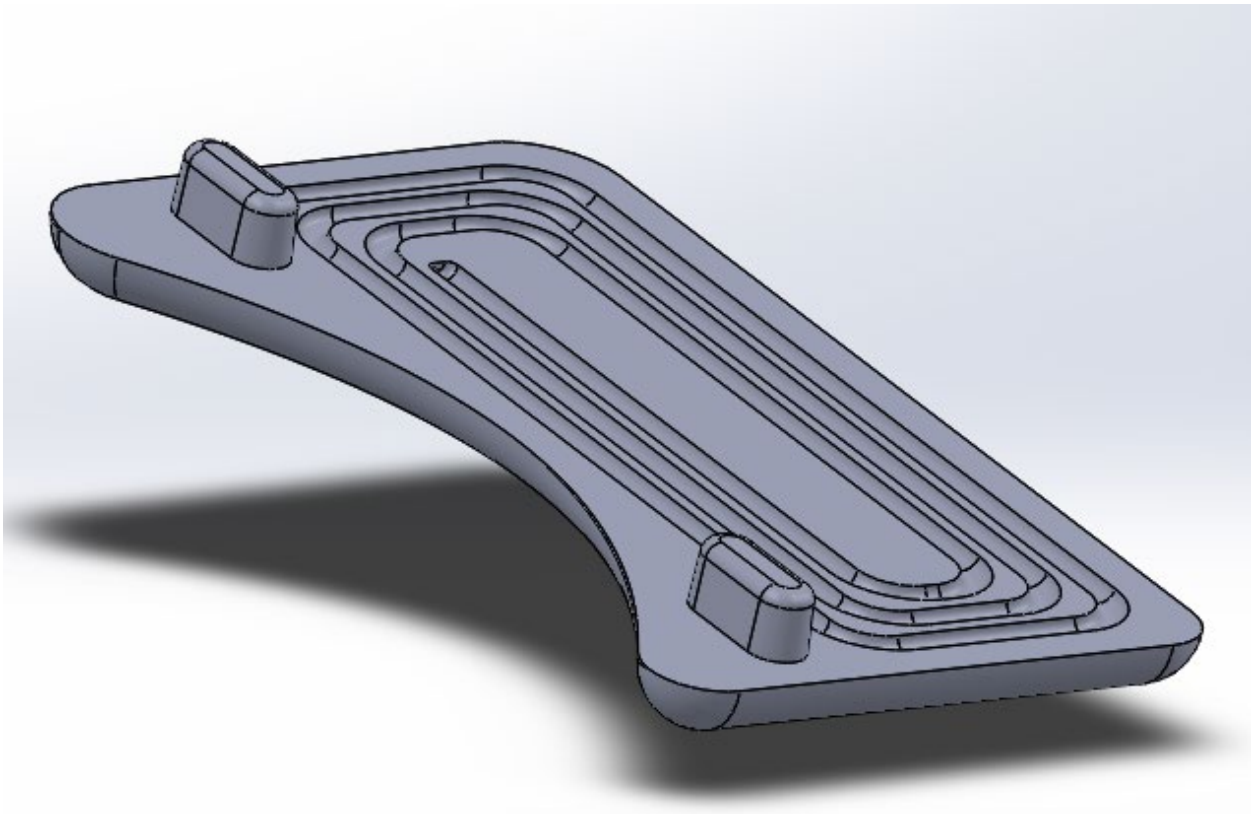

Fig 6e

Fig 7a – 7e. Different CAD views of the base of the thenar pad

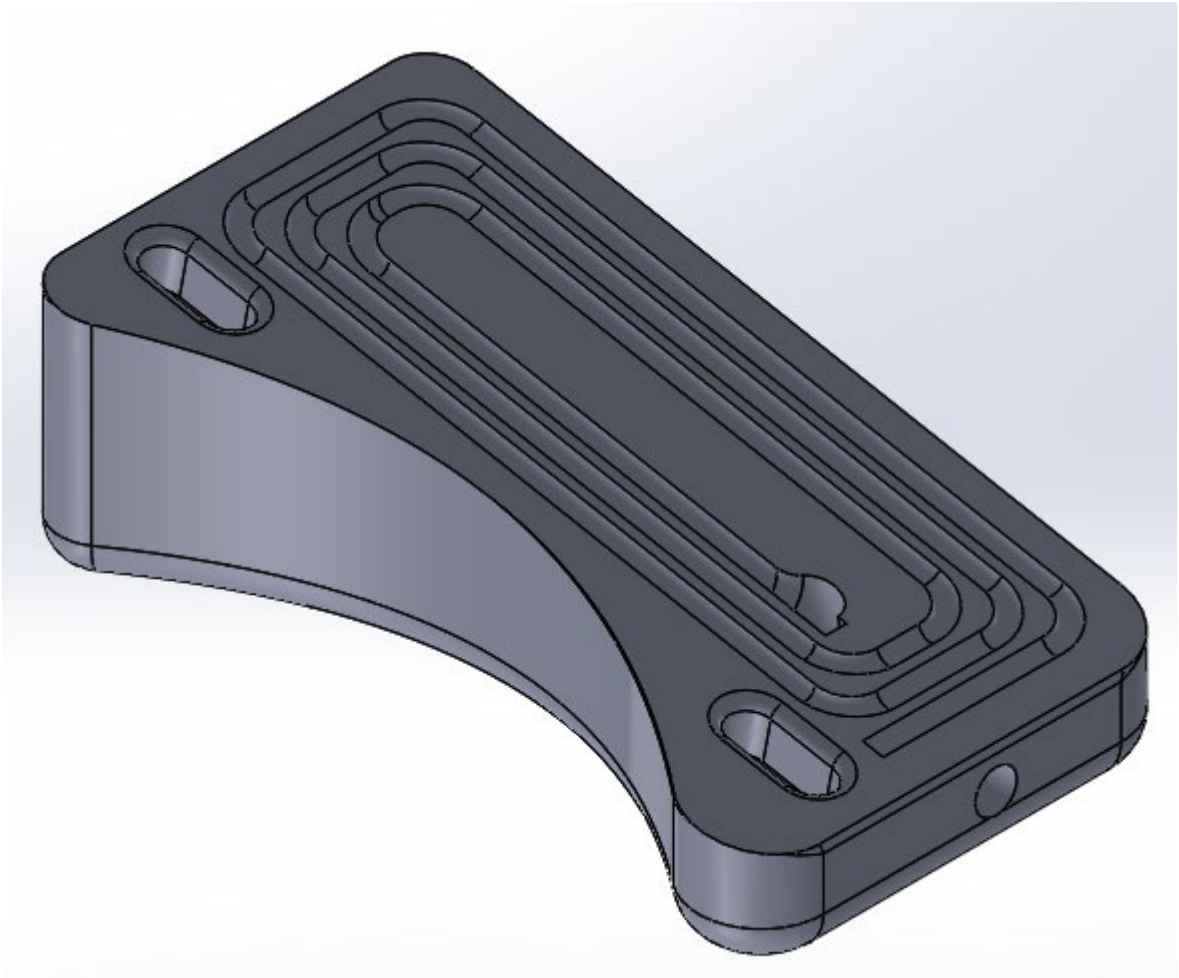

Fig 7a

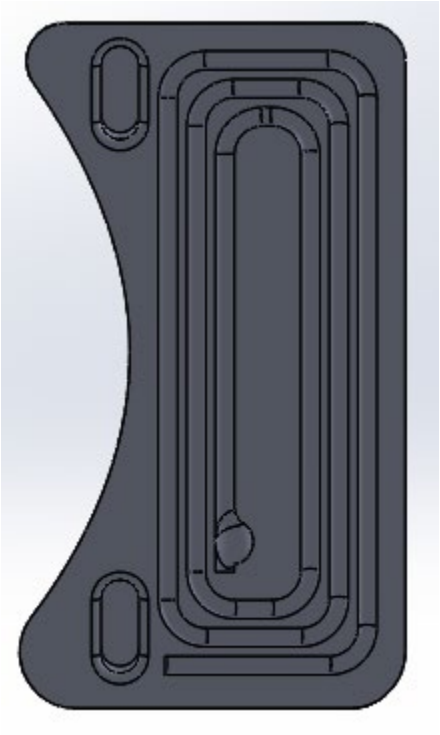

Fig 7b

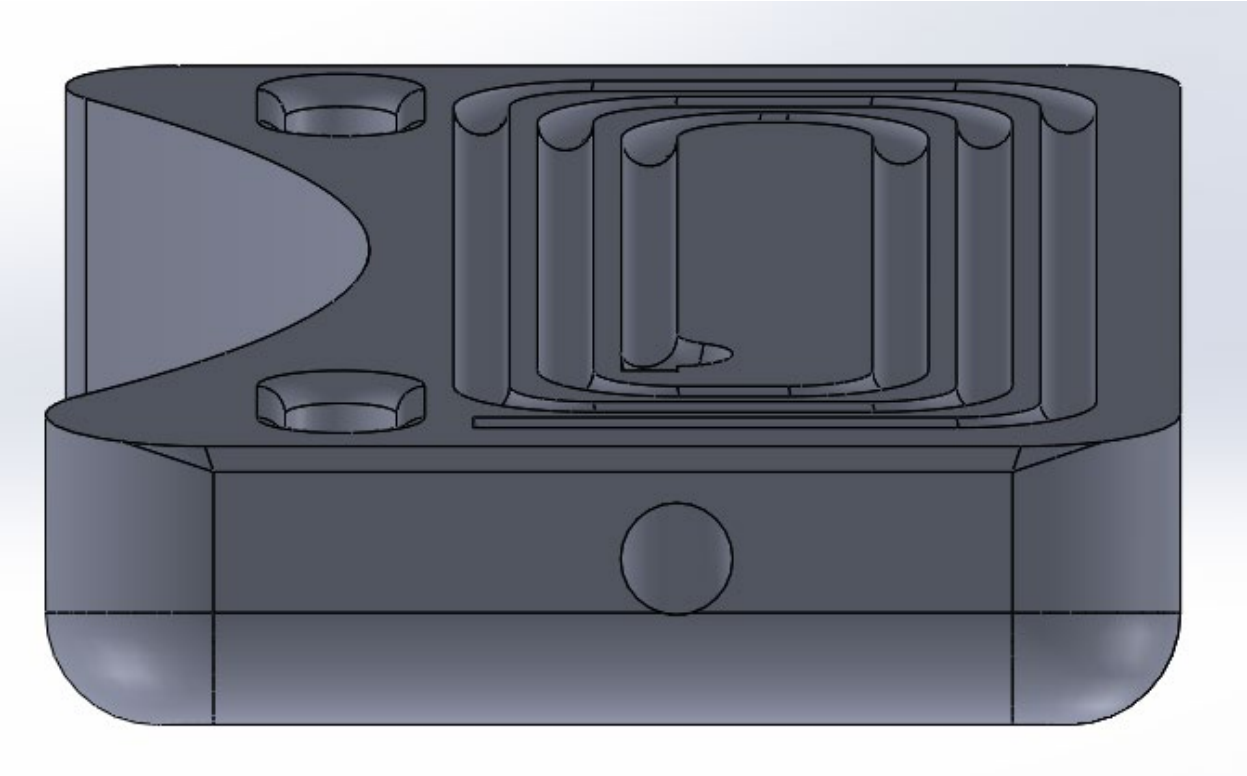

Fig 7c

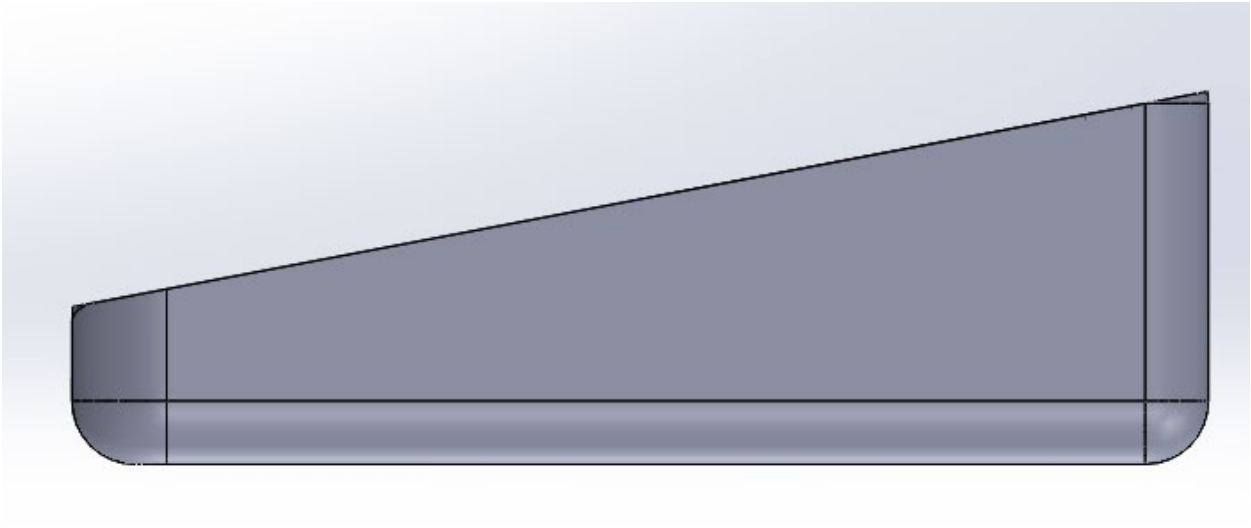

Fig 7d

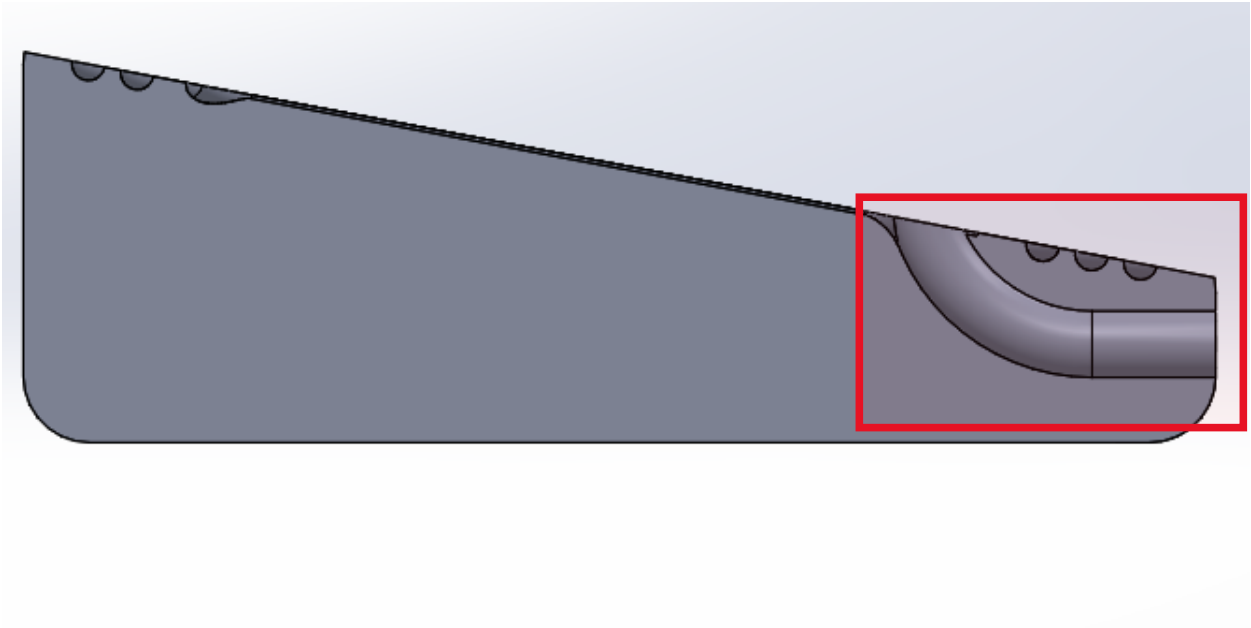

Fig 7e. The highlighted portion shows the swept hole to route the wires.

Fig 8a – 8e. Different CAD views of the top piece of the hypo-thenar pad

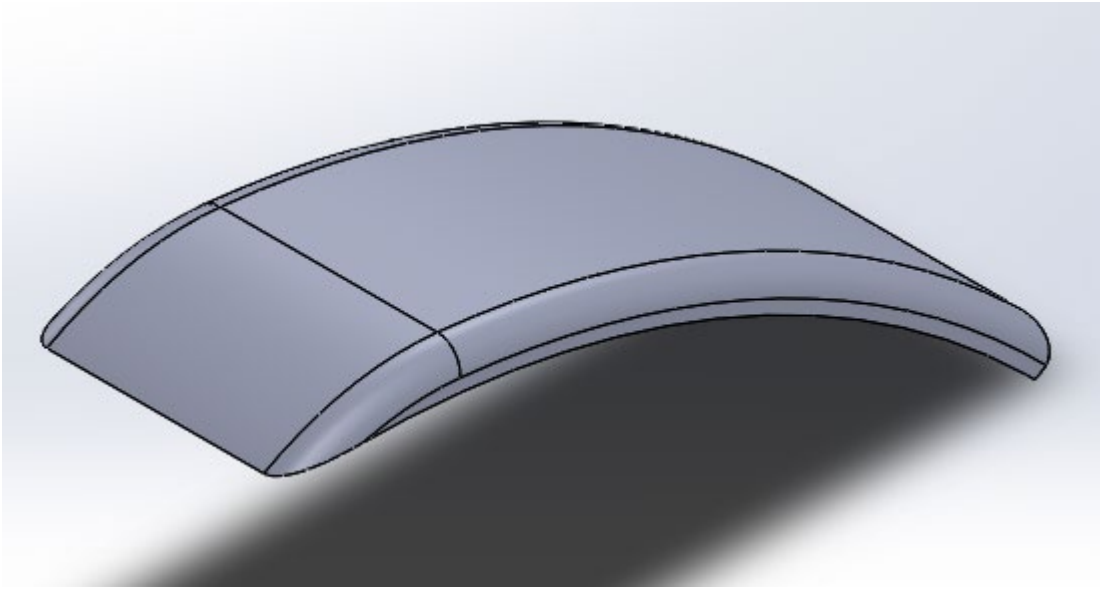

Fig 8a.

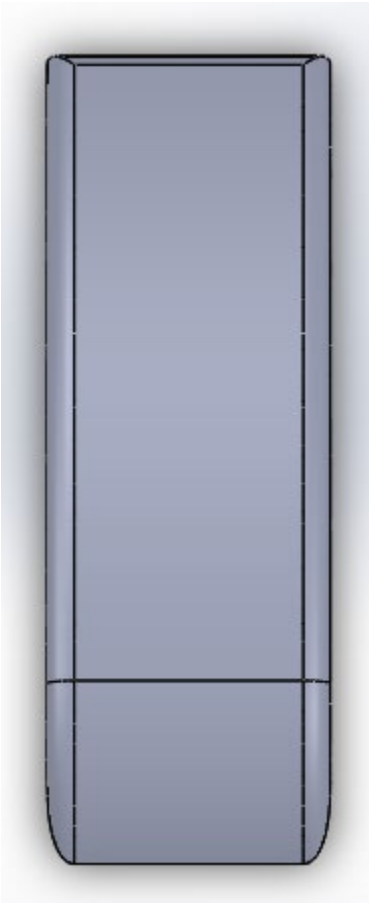

Fig 8b.

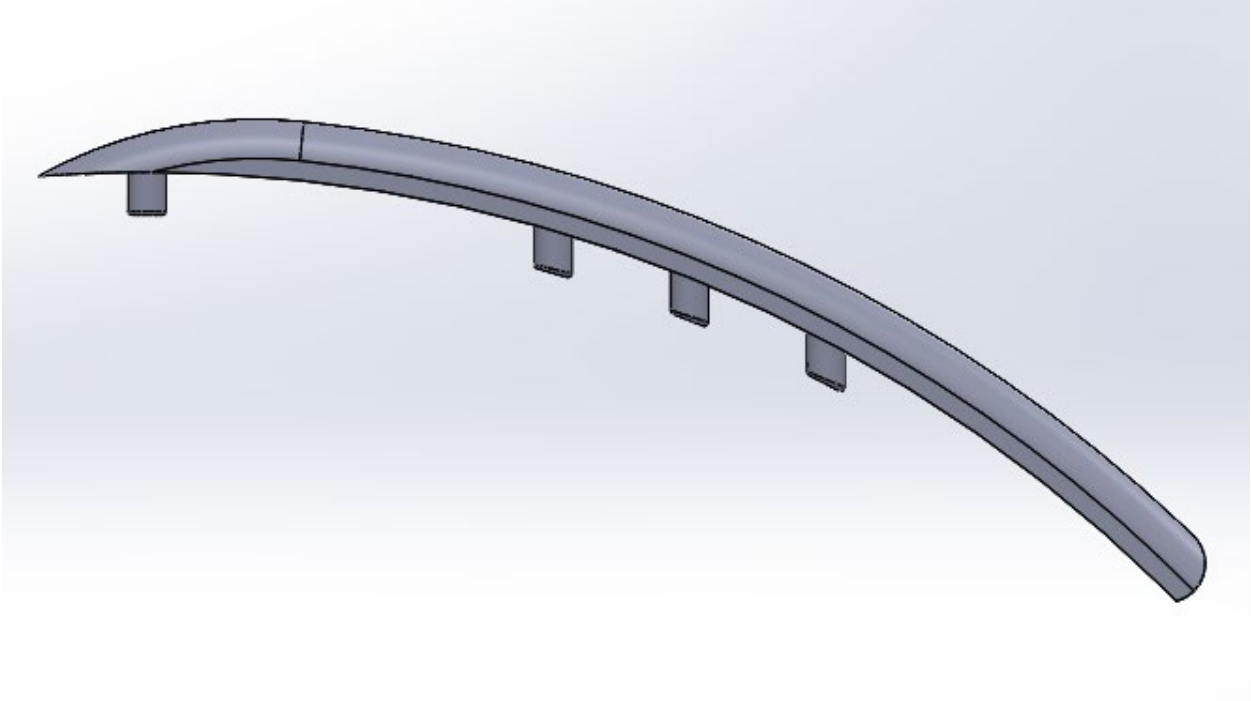

Fig 8c.

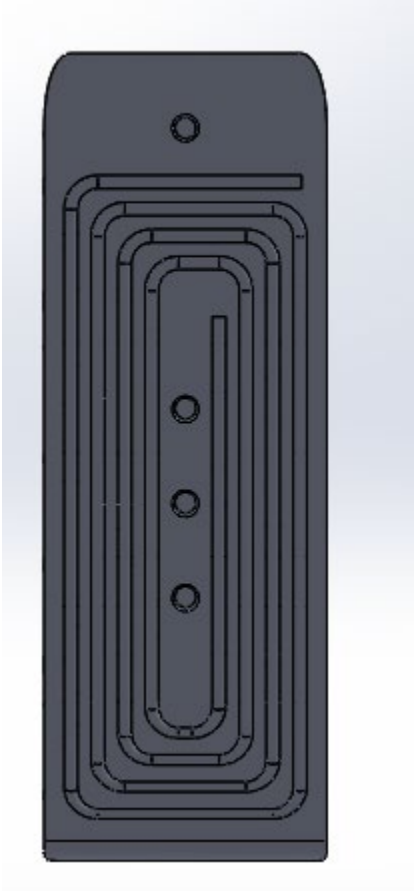

Fig 8d.

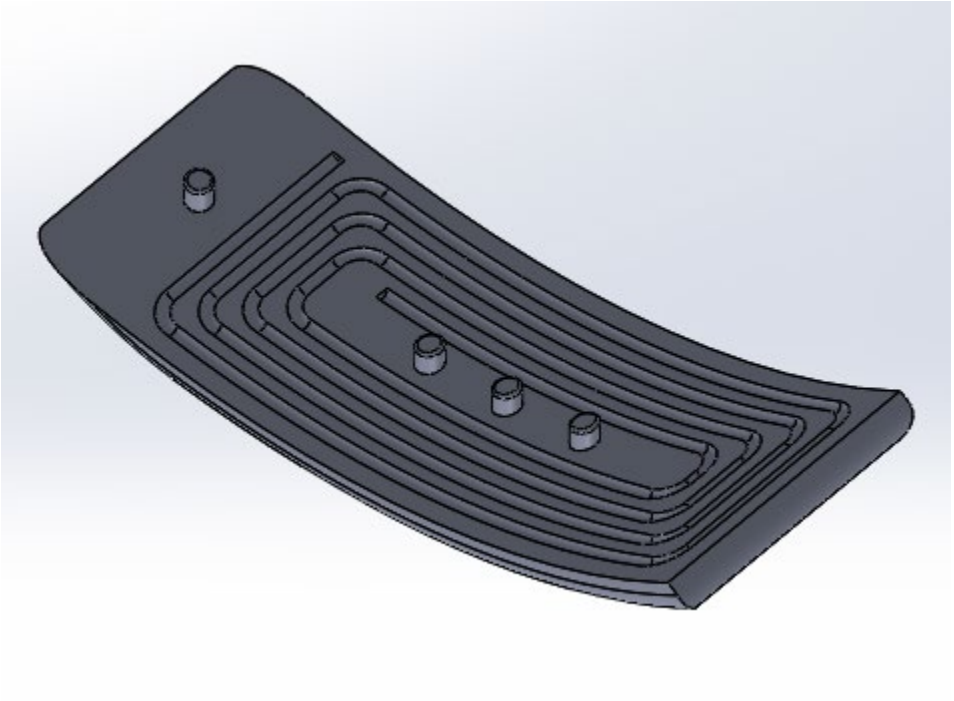

Fig 8e.

Fig 9a – 9e. Different CAD views of the top piece of the hypo-thenar pad

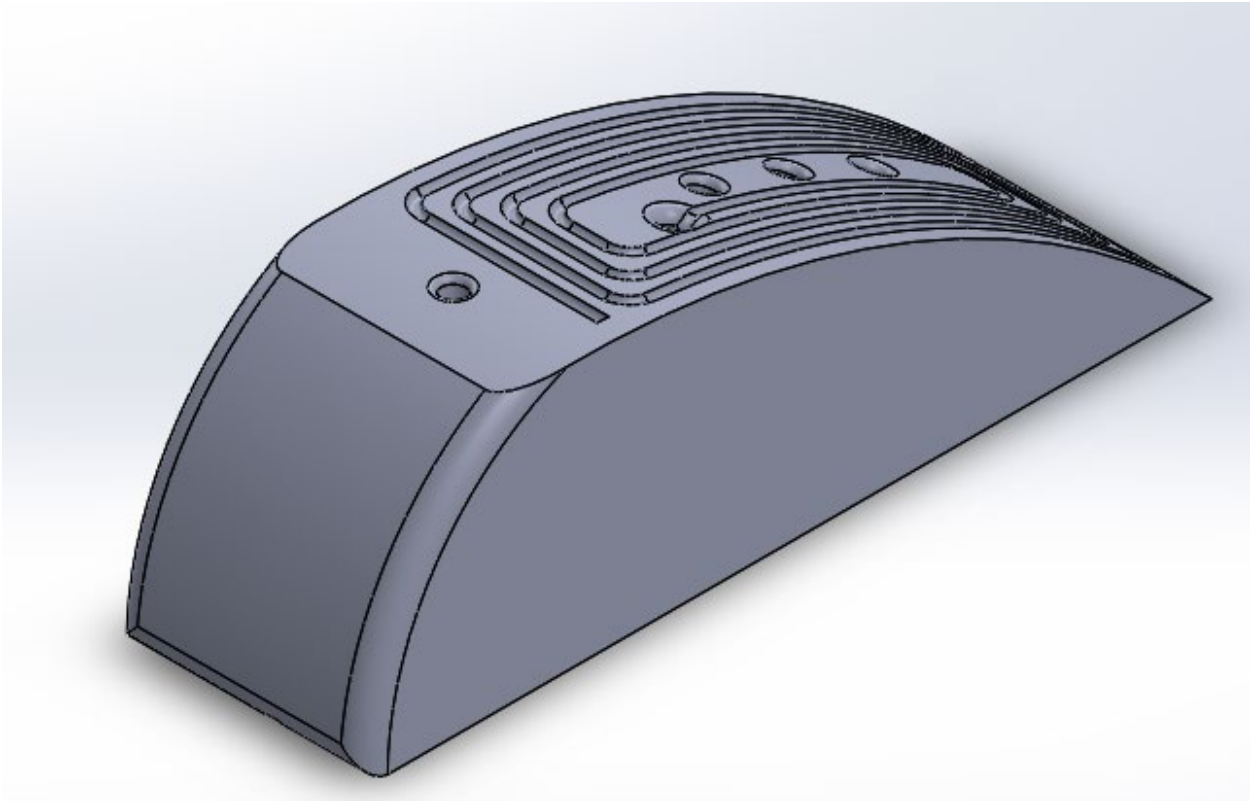

Fig 9a.

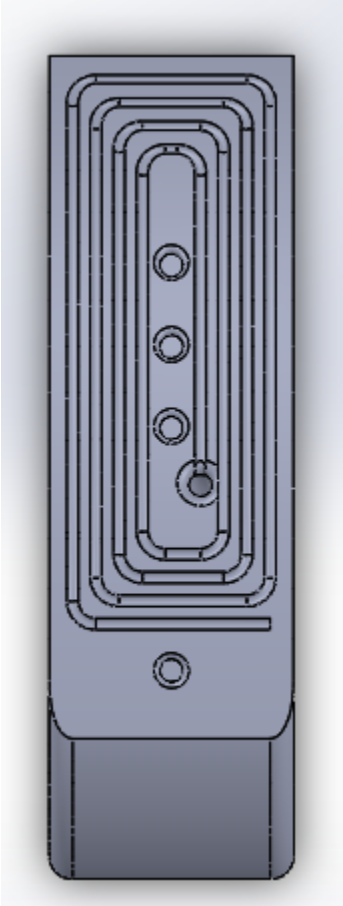

Fig 9b.

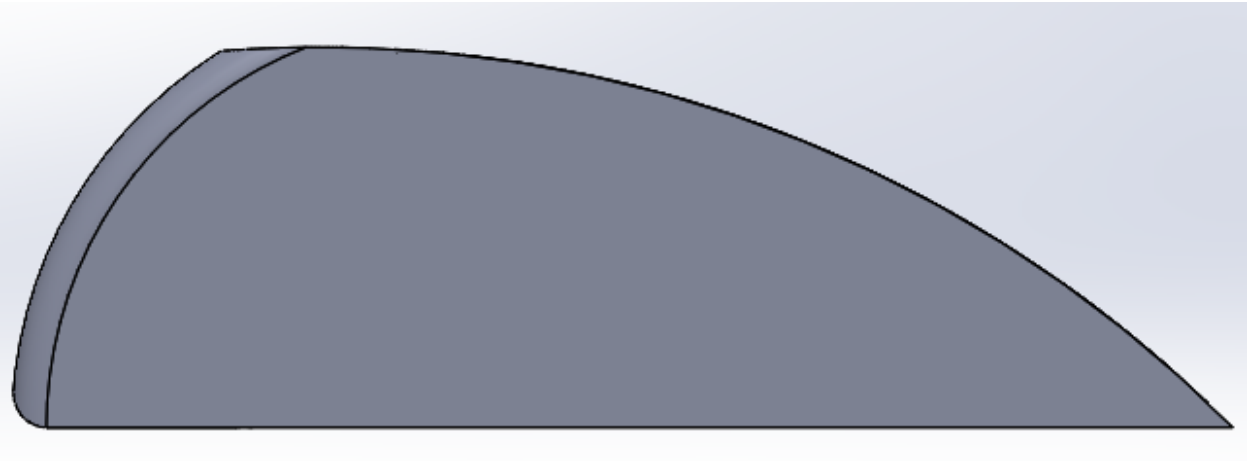

Fig 9c.

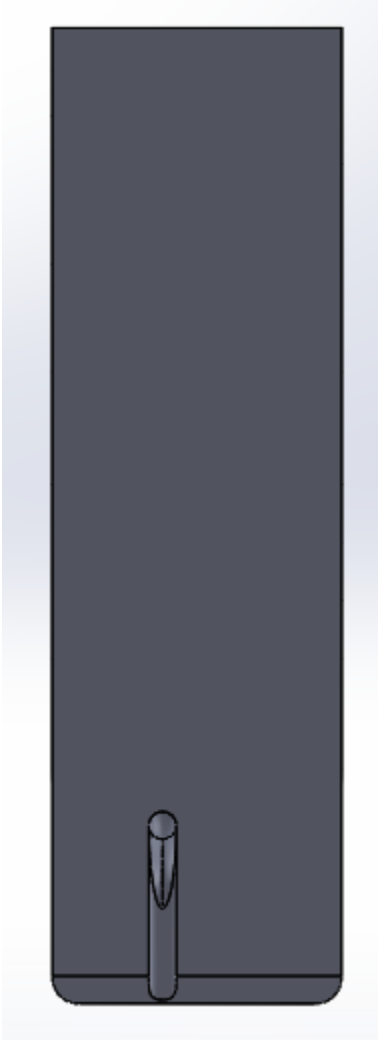

Fig 9d.

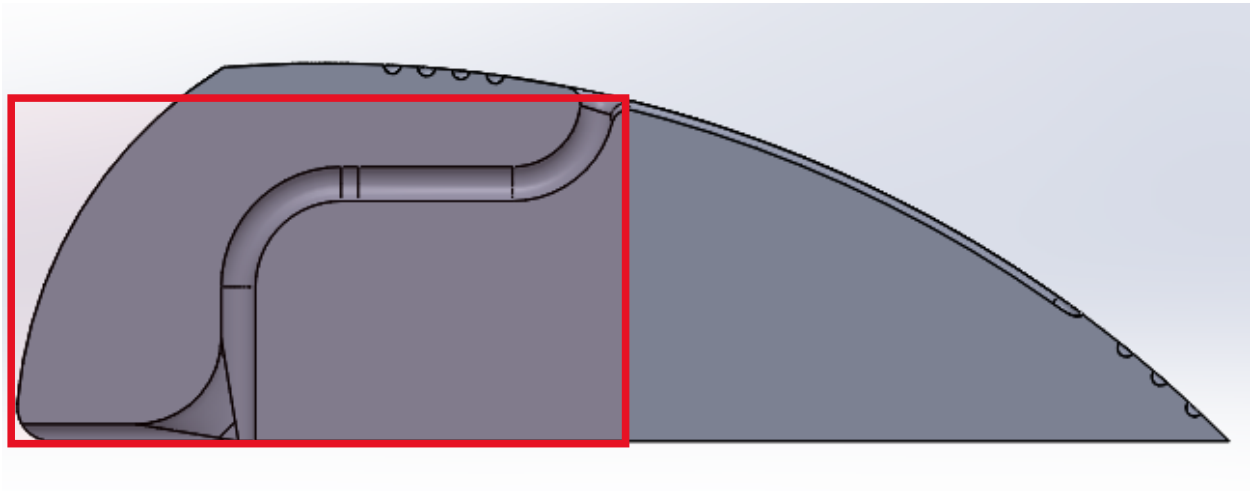

Fig 9e. The highlighted portion shows the swept hole to route the wires.

Fig 10a – 10b. Different CAD views of the top piece of the forearm pad

Fig 10a.

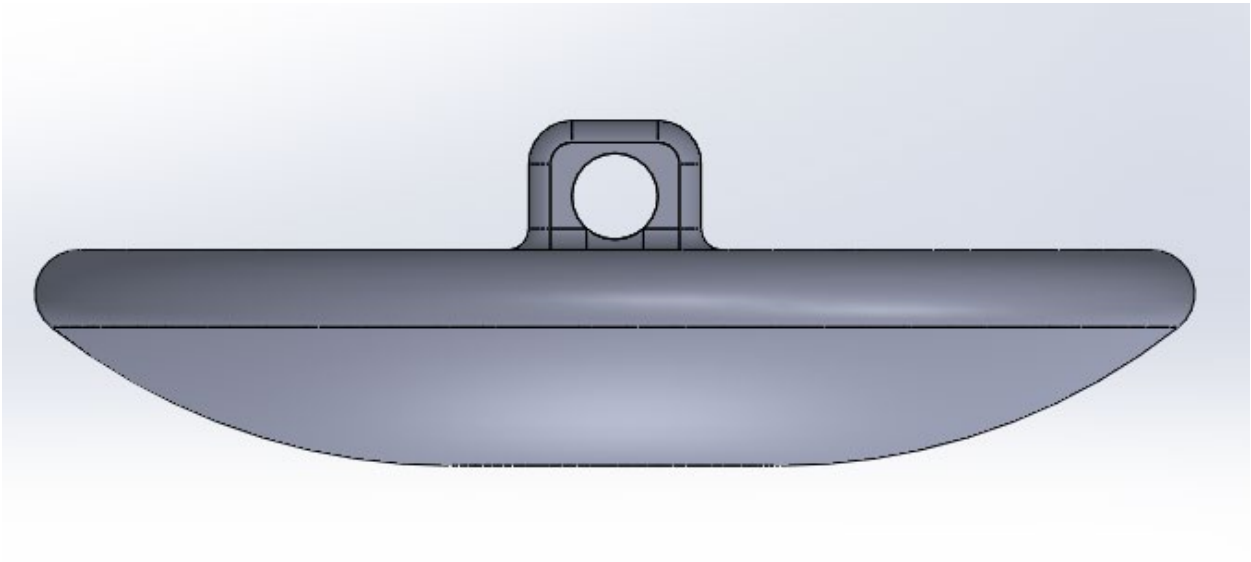

Fig 10b.