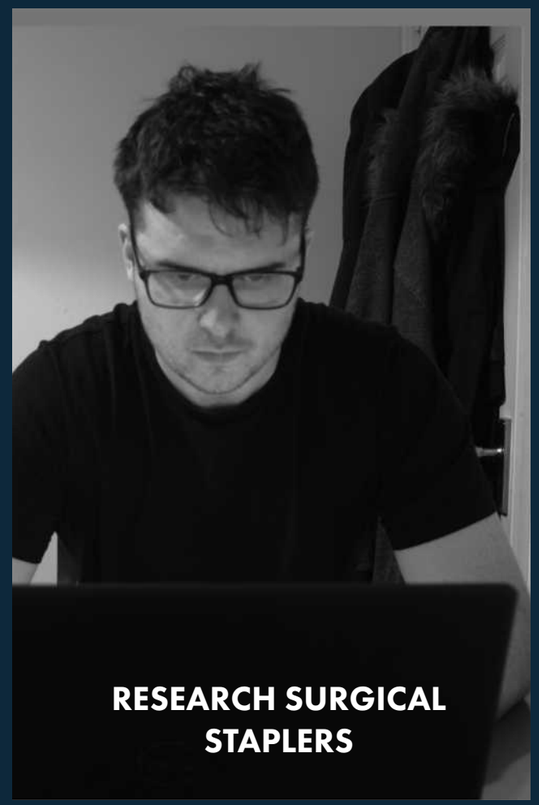
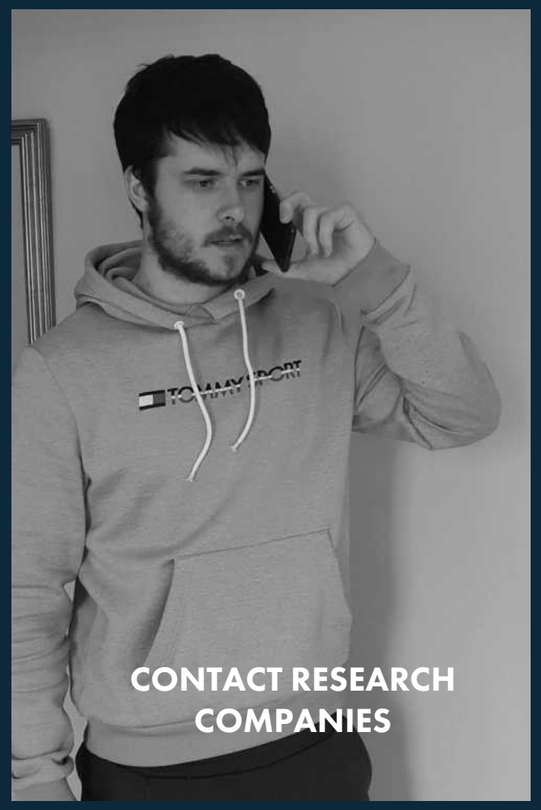
SUBFLEX

THOMAS HEAGNEY
16781575
FINAL YEAR PROJECT PROCESS BOOK
MAYNOOTH UNIVERSITY





JOURNEY TO FIND A PROBLEM WORTH SOLVING

Research Surgeries

I began by researching which surgeries had low satisfaction outcomes, detailed by either the patient or operator using resources found online.

Choose Surgical Stapler

The surgical stapler was a device that seemed to reoccur throughout my research as a root cause for different abdominal surgeries that failed.

Research Surgical Staplers

After selecting the surgical stapler I researched more into the medical aspect of the device, researching what it is used for, how it is used and it's effects on different organs and tissue it comes into contact with.

Contact Research Companies

Upon gathering as much information and data I could on surgical staplers, I reached out to research companies with databases of analysis and statistics on surgical staplers. Being a student many companies released data for me and I was invited to attend a webinar from one of the companies which I did.

MAUDE Analysis

An analysis was carried out on the last 1000 adverse events including surgical staplers on the FDA's "manufacturer and user facility device experience" website and a table was created with the data.

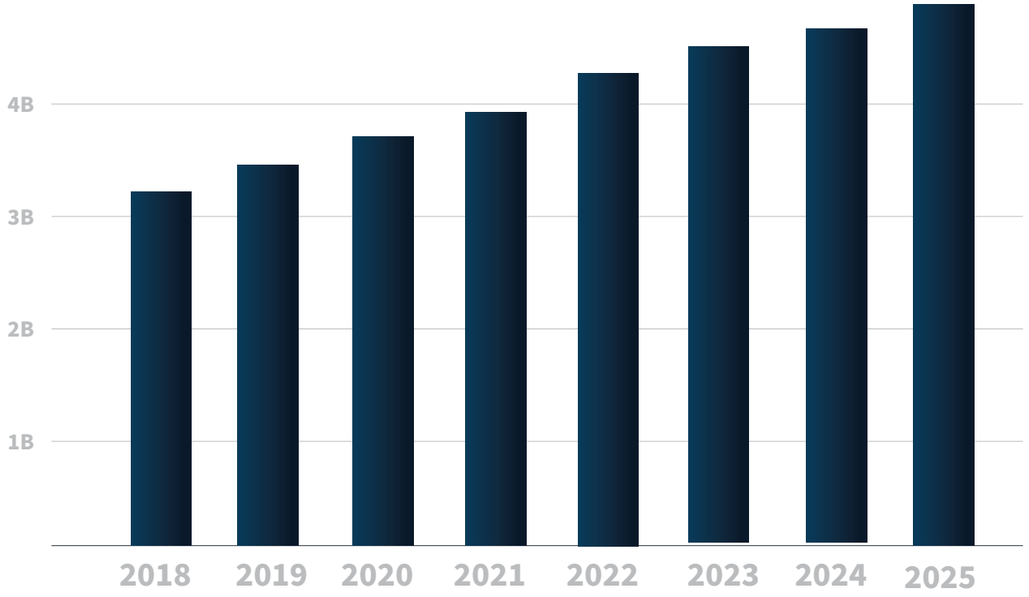
Surgical Stapler Market

In 2018 the surgical stapler market was valued at 3.3 billion USD , and is anticipated to reach 4.9 billion USD by 2025, with an anticipated compound annual growth rate of 6.7%, during the forecast period.

Current Surgical Staplers Issues

Since 2011, more than 100,000 surgical stapler complications and malfunctions have resulted in 412 deaths, 11,181 serious injuries and 98,404 malfunctions, according to the U.S. Food and Drug Administration.

“Injuries and deaths from the misuse of surgical staplers are substantial and preventable,” Marcus Schabacker, M.D., president and CEO of the ECRI Institute.

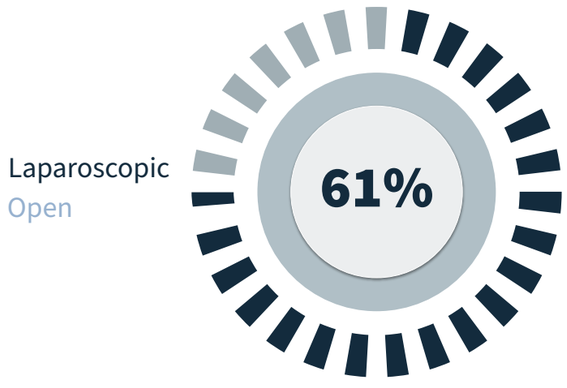


U.S Surgical Stapling Device Market Size, 2018 - 2025

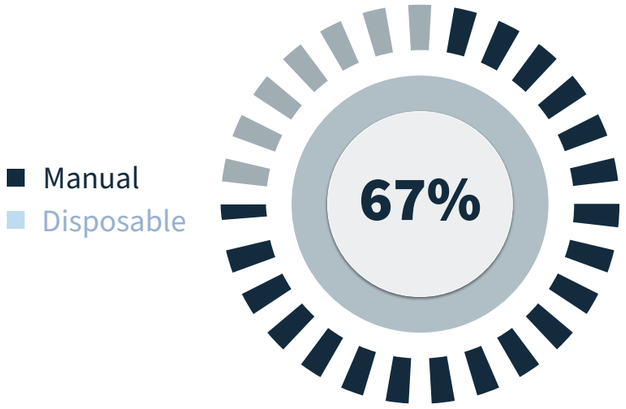
Surgical Stapler Market Growth Rate by Region (2018 - 2015)

Target Market

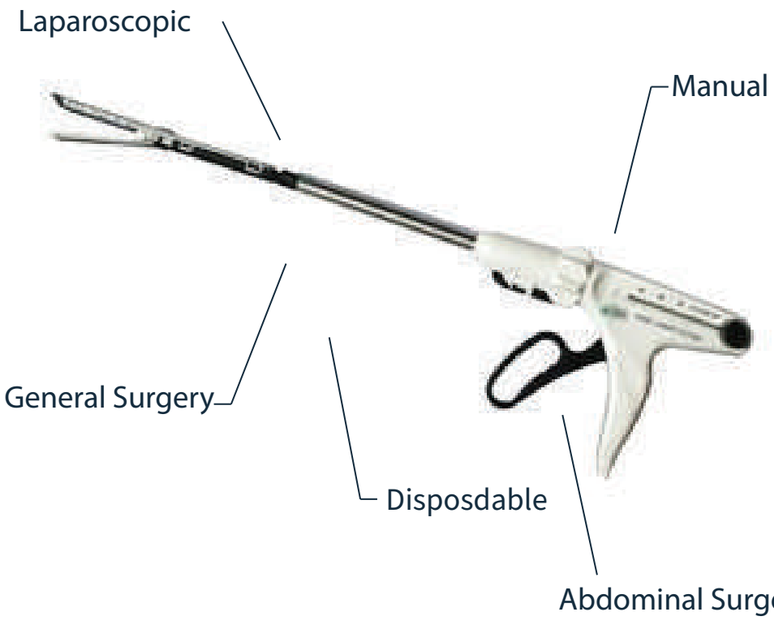
Given the provided statistics, the surgical stapler that projects the most potential in the future is the disposable, laparoscopic, surgical stapler market.

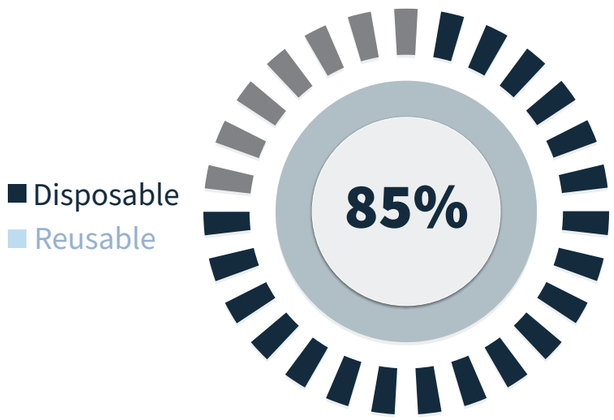


Forecast Market Share Based on Invasiveness (2025)

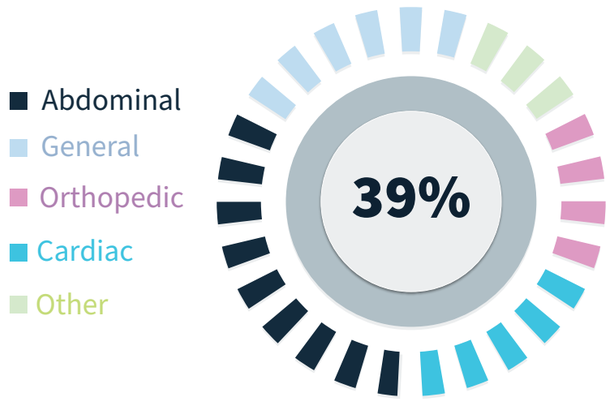


Market Share Based on Type



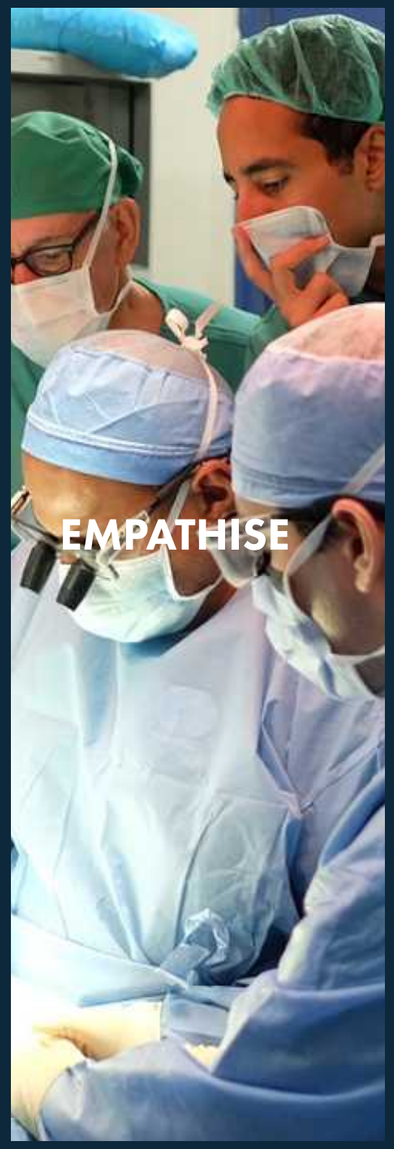


Market Share Based on Reusability

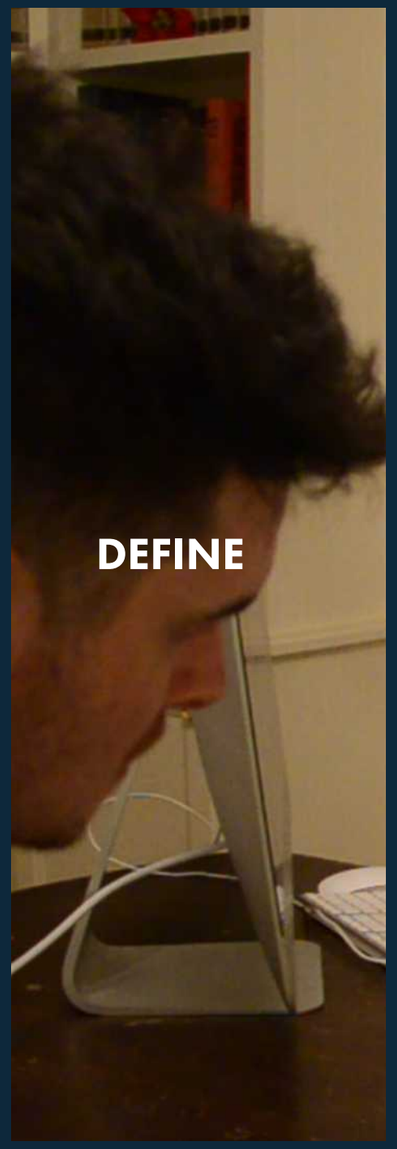


Market Share Based on Application

MY DESIGN PROCESS



EMPATHISE



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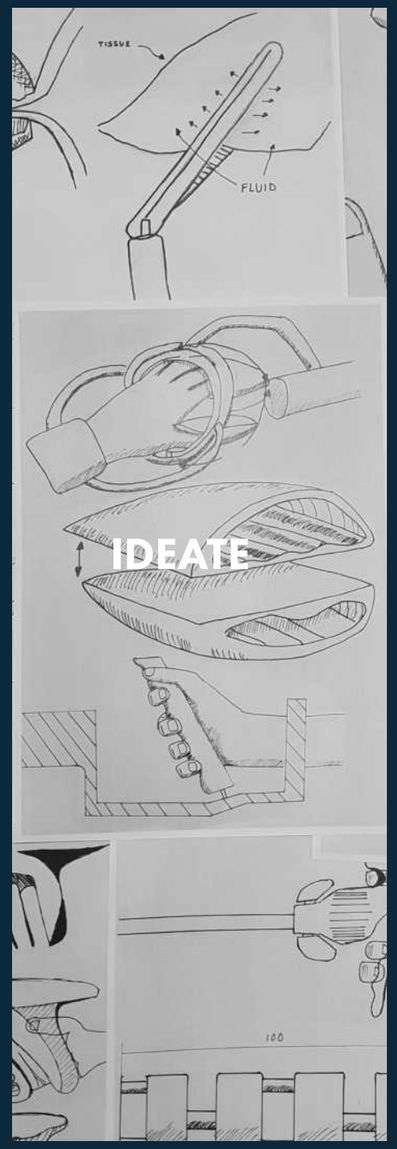
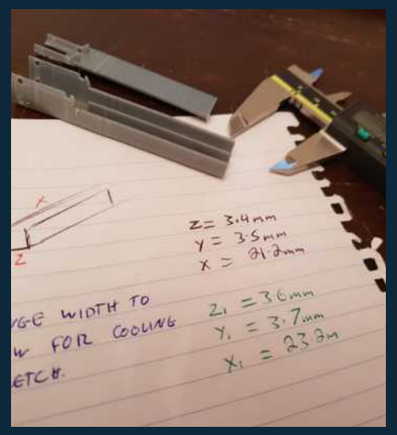


IDEATE

CAD MODEL



TEST

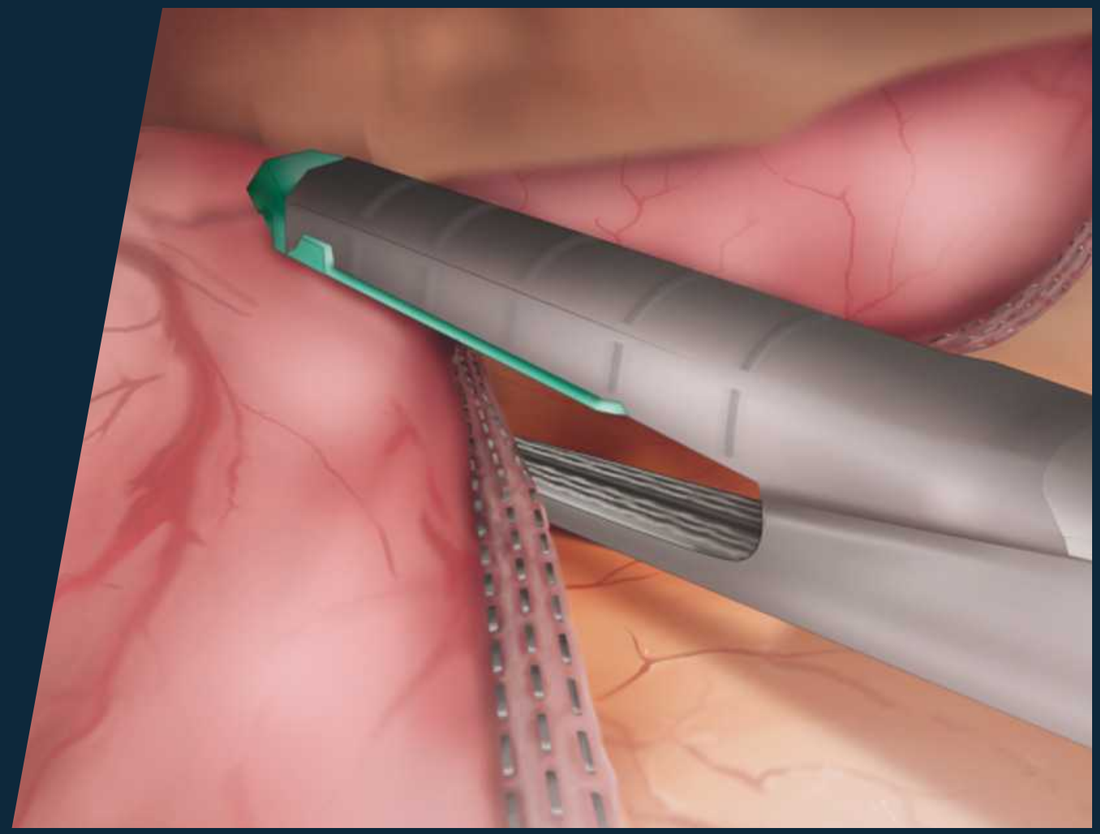
3D PRINT

ITERATIVE PROTOTYPING

Backround to Problem

In most cases when using a laparoscopic linear cutters, the surgeon must make a number of transections to fully cut/staple the tissue.

These transections are consecutively formed to create a row of multiple interlocking staple lines. The risk of the staple line as a whole failing rises with the number of staple lines used to create a transection.



Potential Failures

1. Increased risk of leakage at intersection points.

2. Increased risk of staple malfunction at intersection points.

3. Increased general risk of staple line failure.

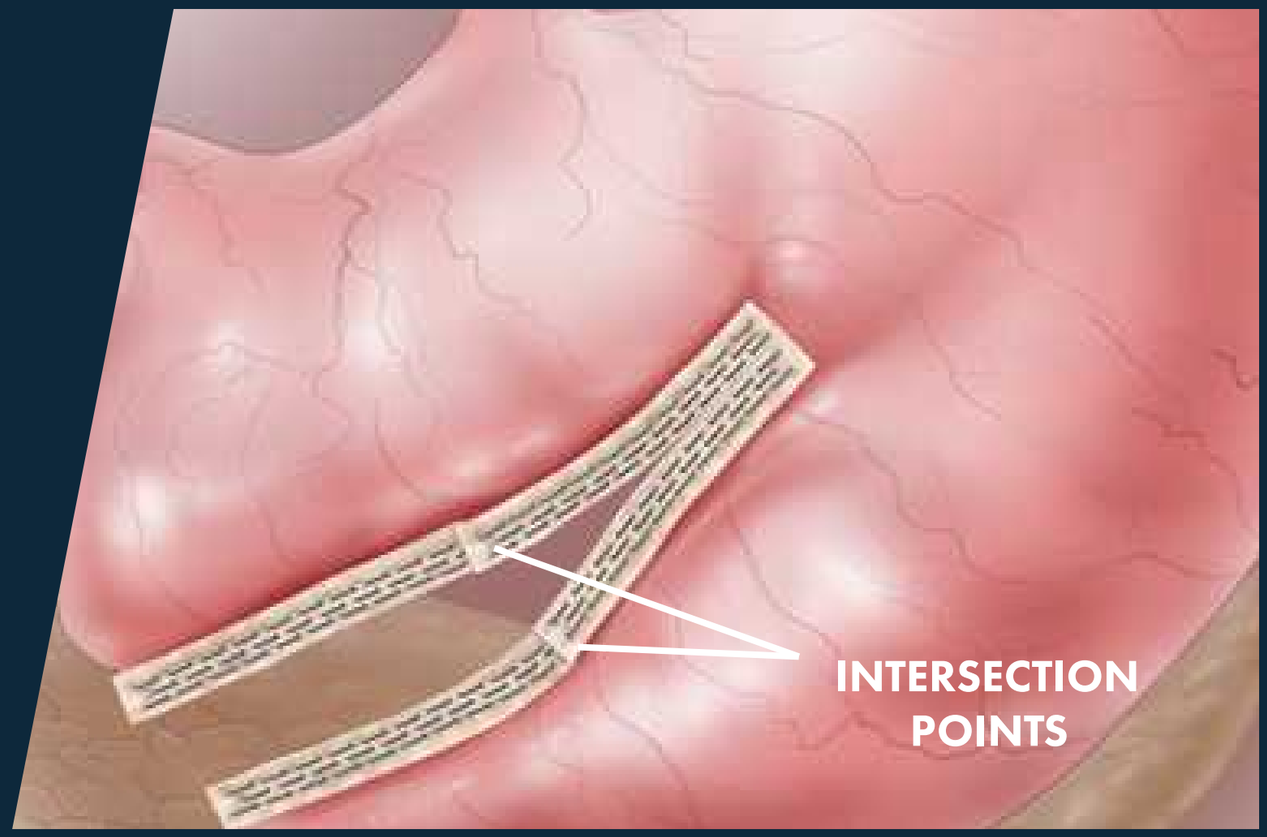
Potential Failure effects

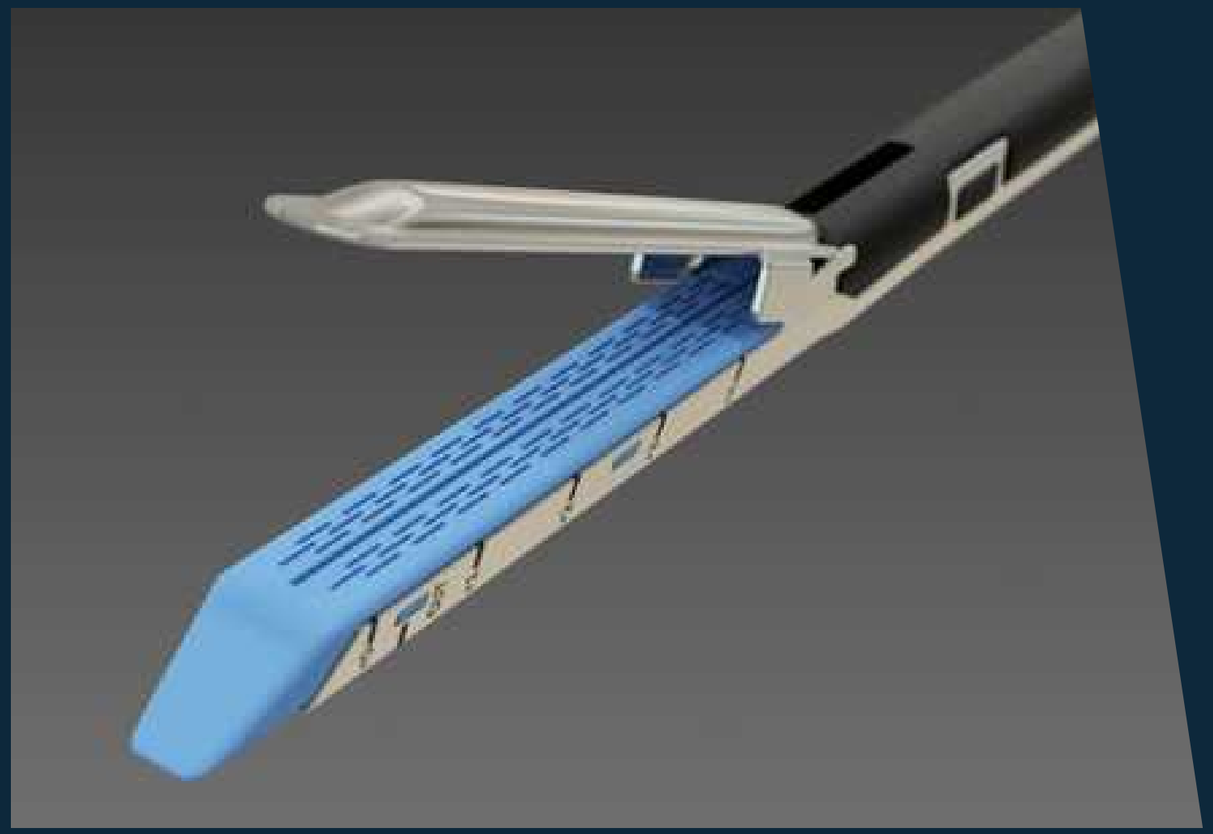
1. Immediate laceration to tissue causing leakage potentially resulting in patient harm or death.

2. Immediate leakage of vital fluids from organ potentially reulting in serious patient harm or death.

3. Delayed post-operative leakage potentially resulting in serious patient harm or death.

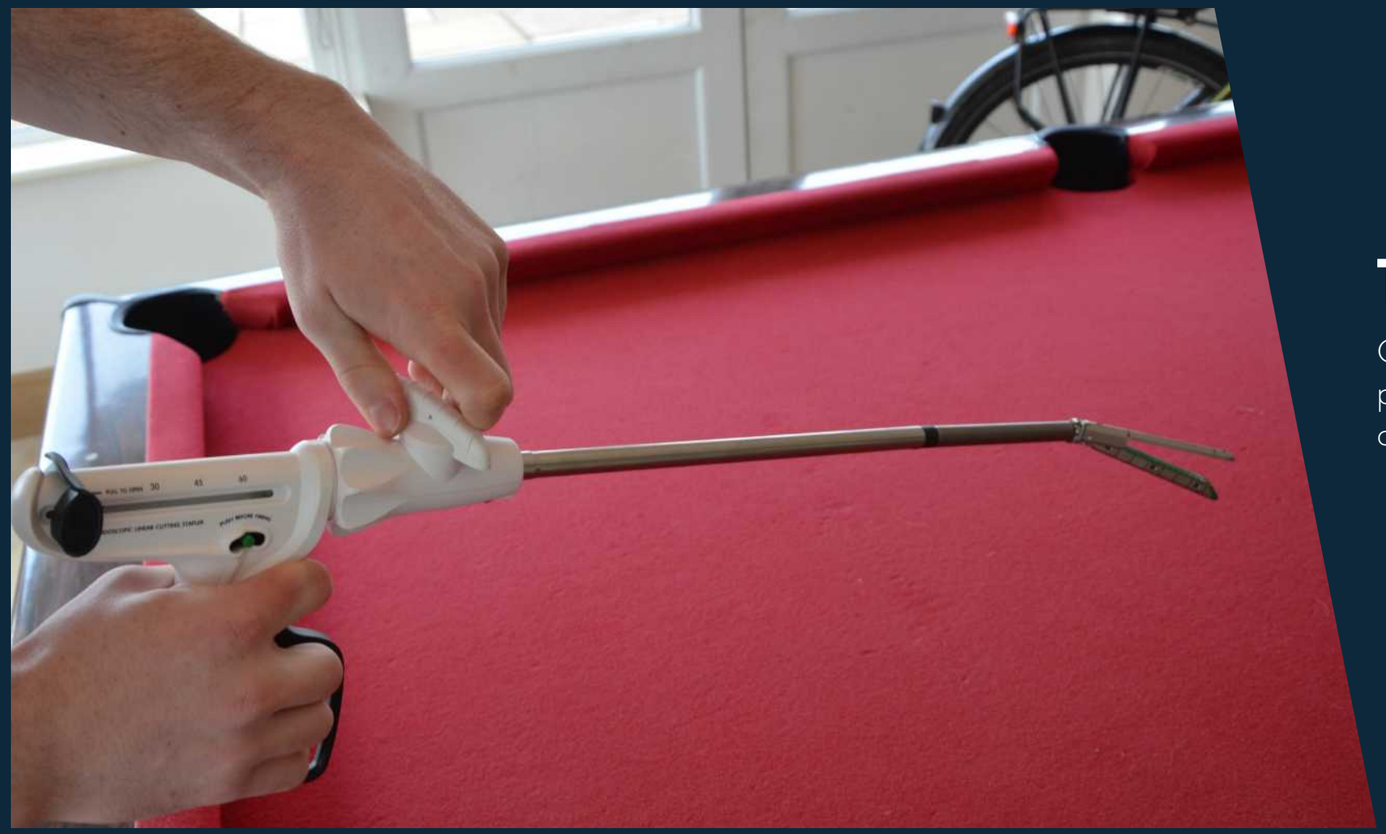
4. Delayed post operative failure of staple line potentially resulting in serious patient harm or death.





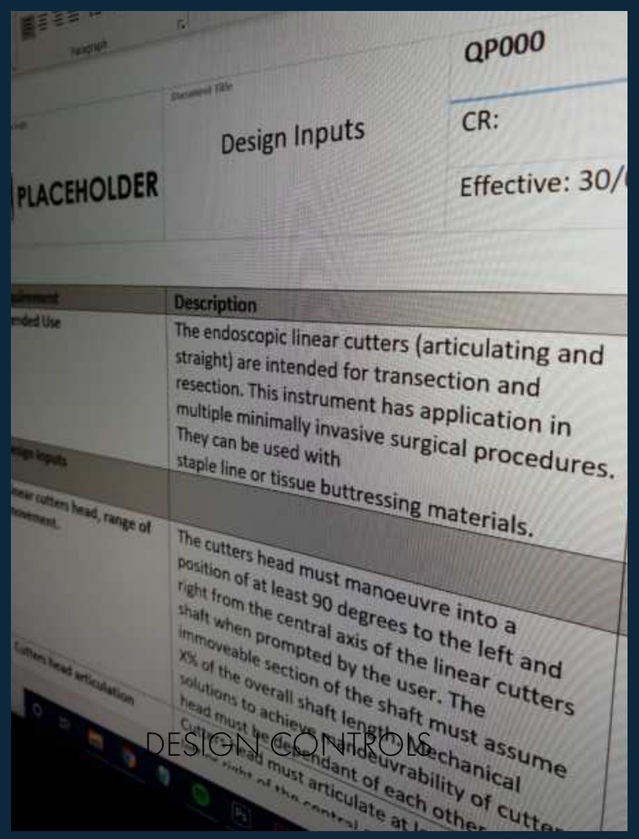
Cost

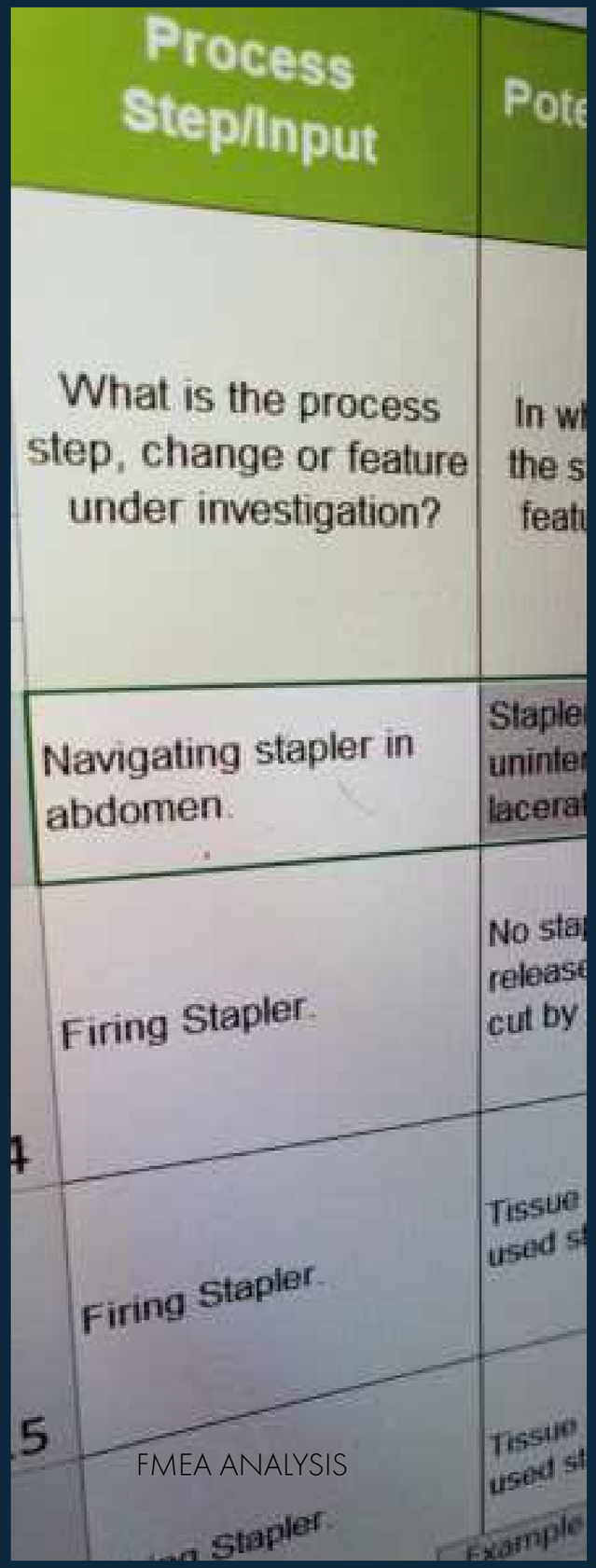
Cost of procedure rises with number of staple lines used to crete a complete transection, as a new staple cartridge is required for each individual staple line. Each new cartridge used costs on average €67.42.



Two-Handed Operation

Current models of linear cutters require two hands to operate, preventing the surgeon from utilizing two instruments during the entire course of the procedure.





FDA & ISO Regulation

Current FDA and ISO standard regulations were studied and documented. Both regulations contain similar parameters surrounding the laparoscopic surgical stapler which falls under a class 2 medical device and would be tested under the conditions outlined in this device category. To ensure proper procedure and compliance steps were taken place during the development process a similarc, currently marketed stapler was used as a predicate device.

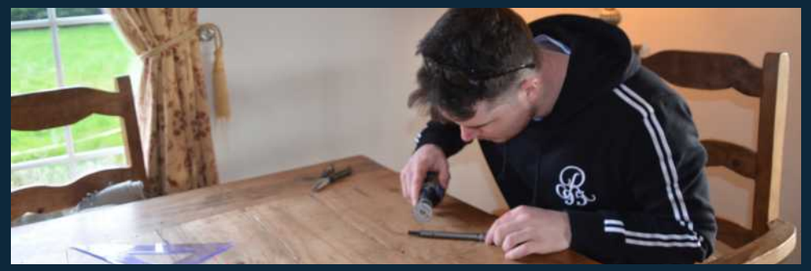
Design Controls

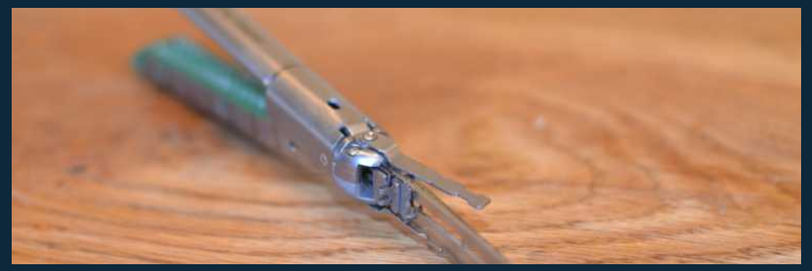
To aid in compliance with regulatory body parameters, a digital filing system to document the research and design process was created. The design controls system was updated throughout the duration of the project and was vital in offering clarity to the project.

FMEA Analysis

An FMEA analysis was carried out on current linear cutters already on the market to create an accurate risk assesment of different design aspects of the device.

TESTING FUNCTION AND ERGONOMICS OF CURRENT LINEAR CUTTERS





PRODUCT TEARDOWN

T.H

SHAFT CAP

SHAFT

SHAFT

ROTATOR HANDLE

MAIN BODY (RIGHT)

KNIFE RETRACT HANDLE

SHAFT LINER

TOP JAW (ANVIL)

KNIFE DRIVER

BOTTOM JAW

SHAFT LINER

COMPLETE PRODUCT TEARDOWN

SHAFT LINER

KNIFE DRIVER (PLASTIC)

ROTATOR HANDLE LINER

ARTICULATING KNOB

ARTICULATING KNOB MECHANISM

ARTICULATING KNOB

ROTATOR HANDLE

MAIN BODY (LEFT)

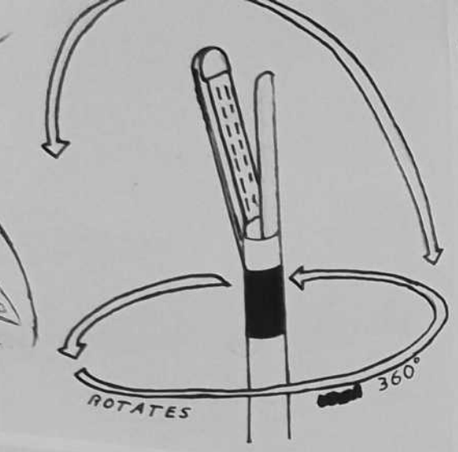
SHAFT CAP

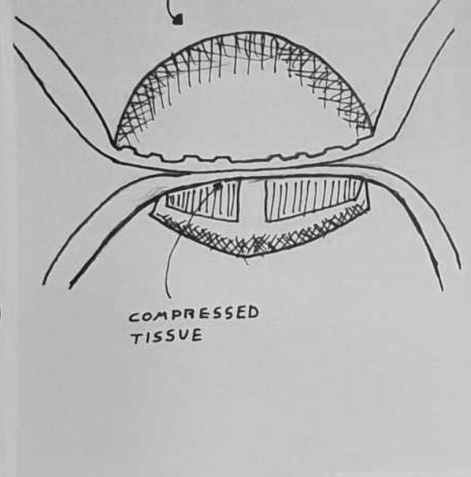
SHAFT

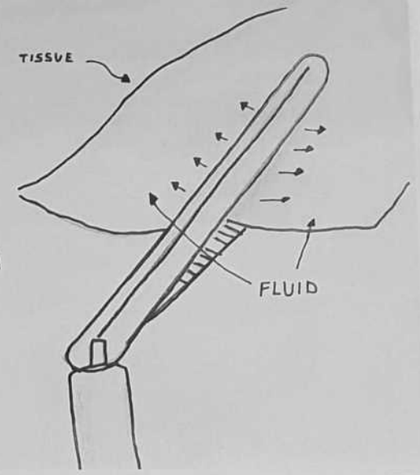
KNIFE RETRACT HANDLE

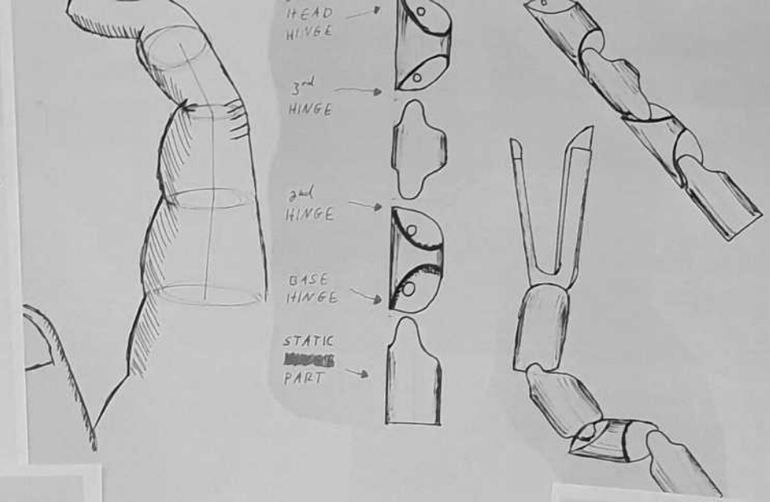
IDEATION

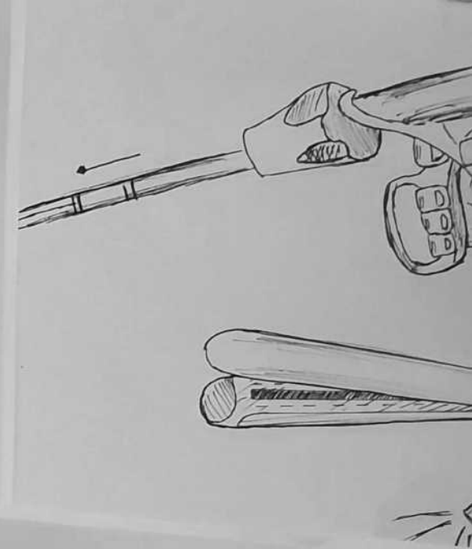
DESIGN SKETCHING

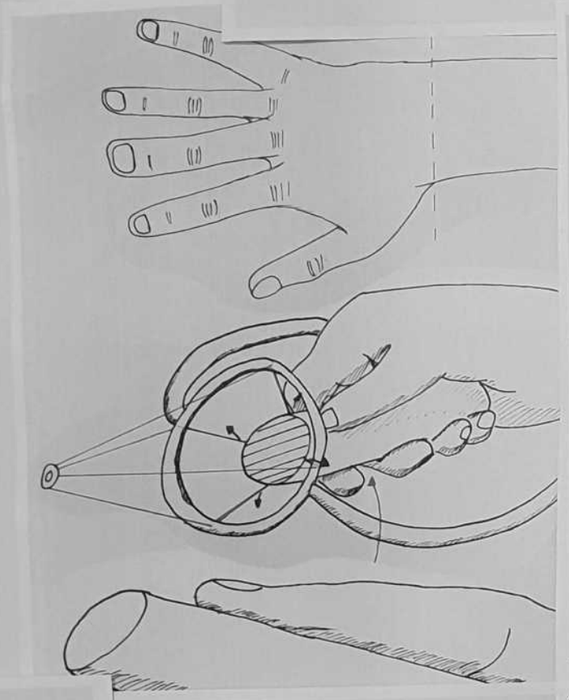


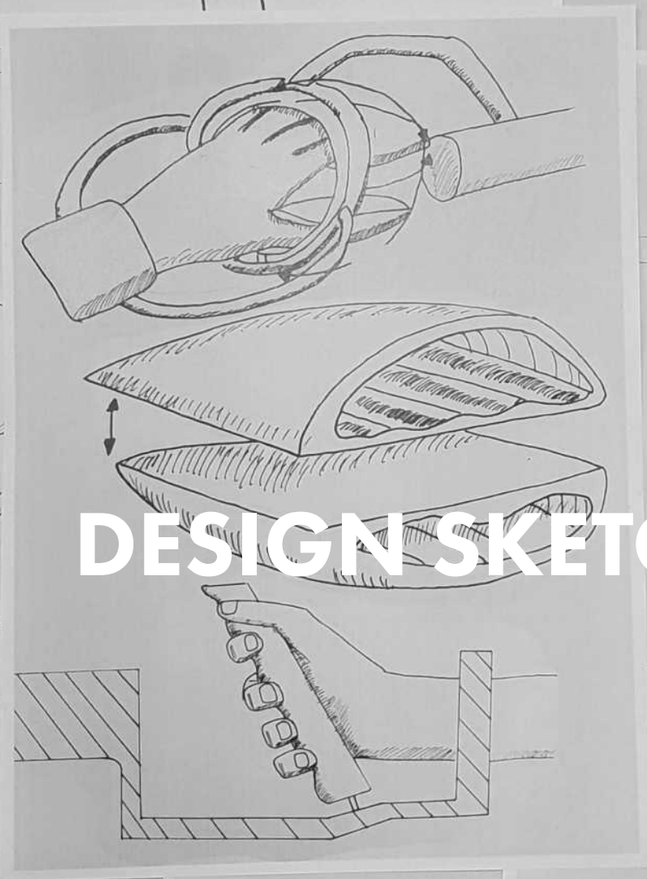


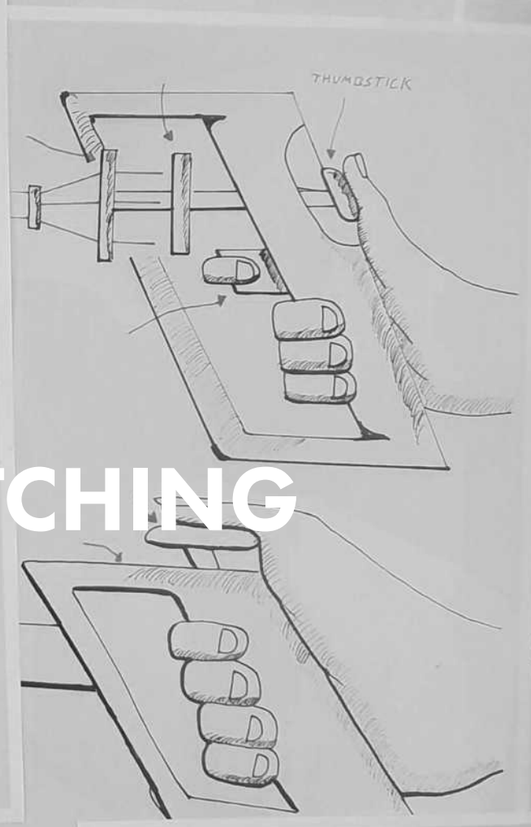


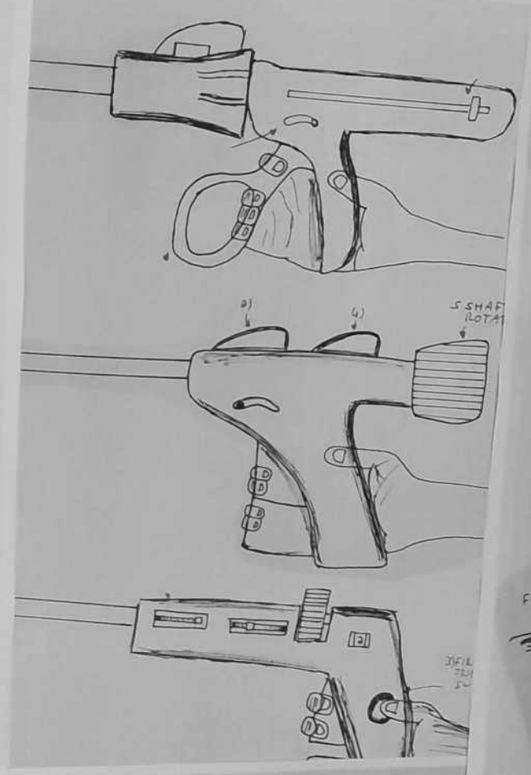


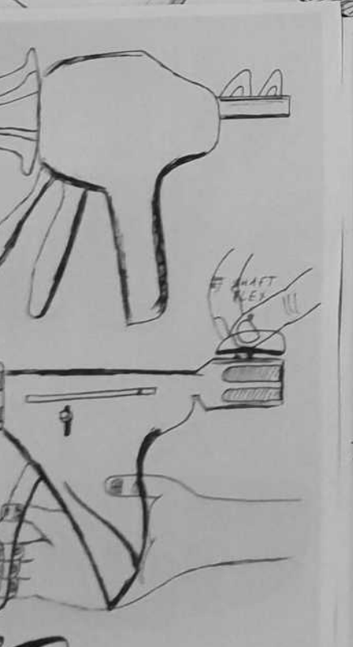


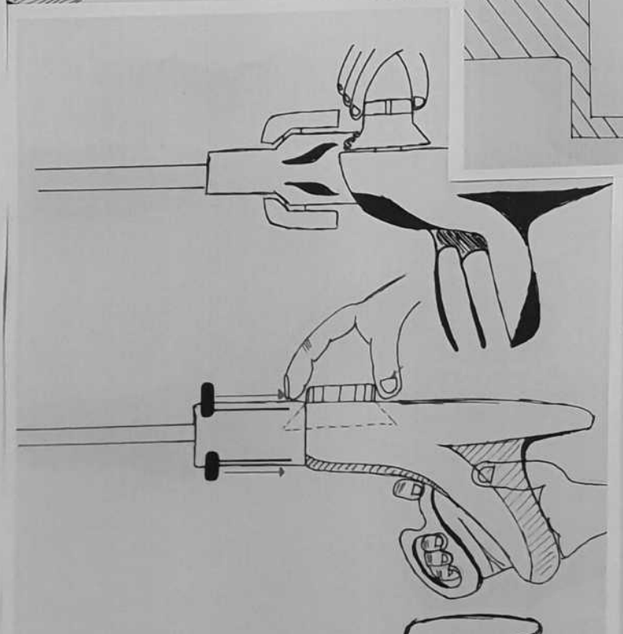


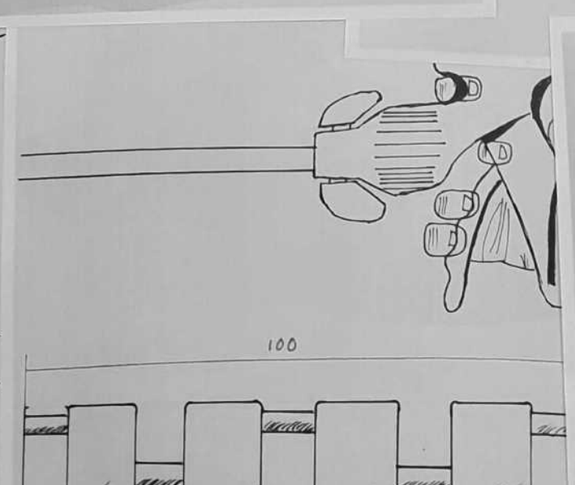


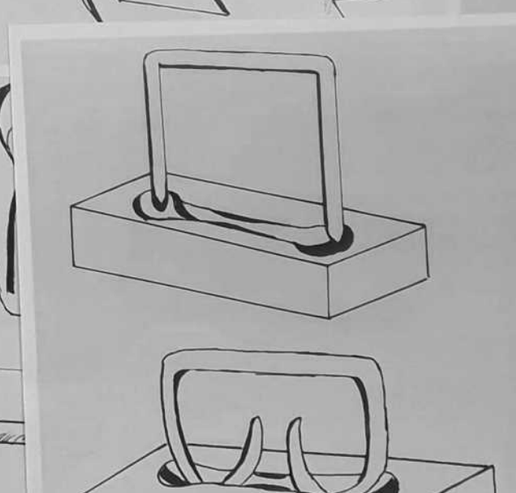


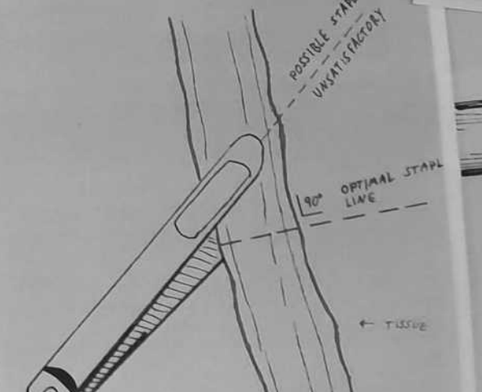










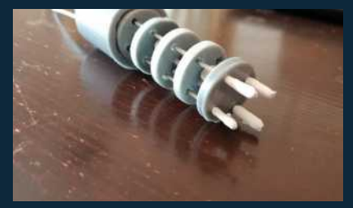


ENGINEERING DESIGN

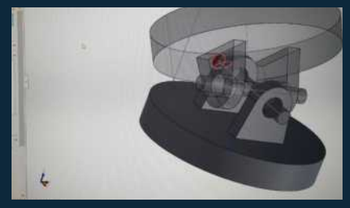
CONCEPT GENERATION

PROTOTYPE PHASE



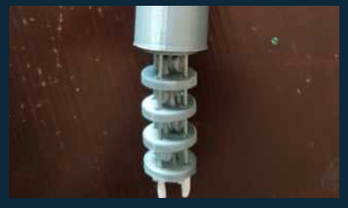
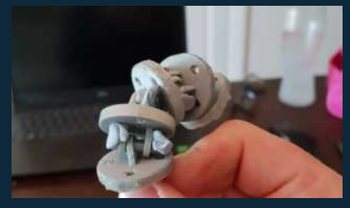

Helix






Ultimaker

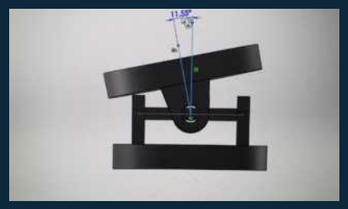
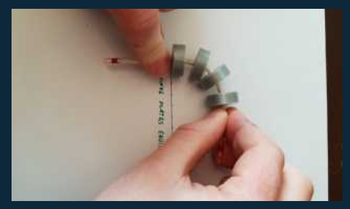









PLATES EQUI





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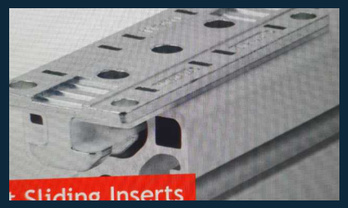
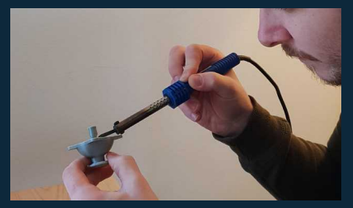

Sliding Inserts





DELL

PROTOTYPED PARTS


SUBFLEX


SUBFLEX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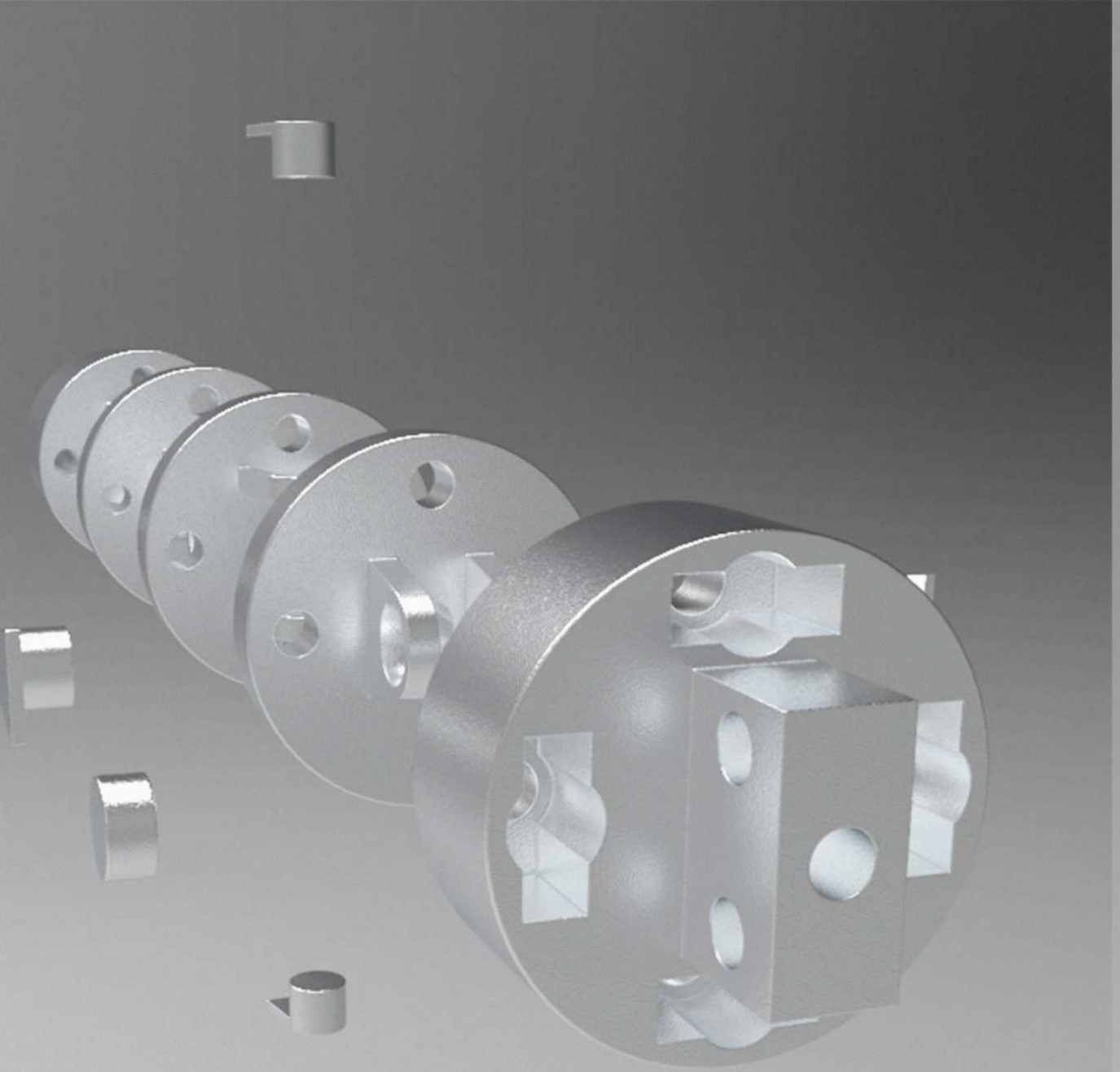

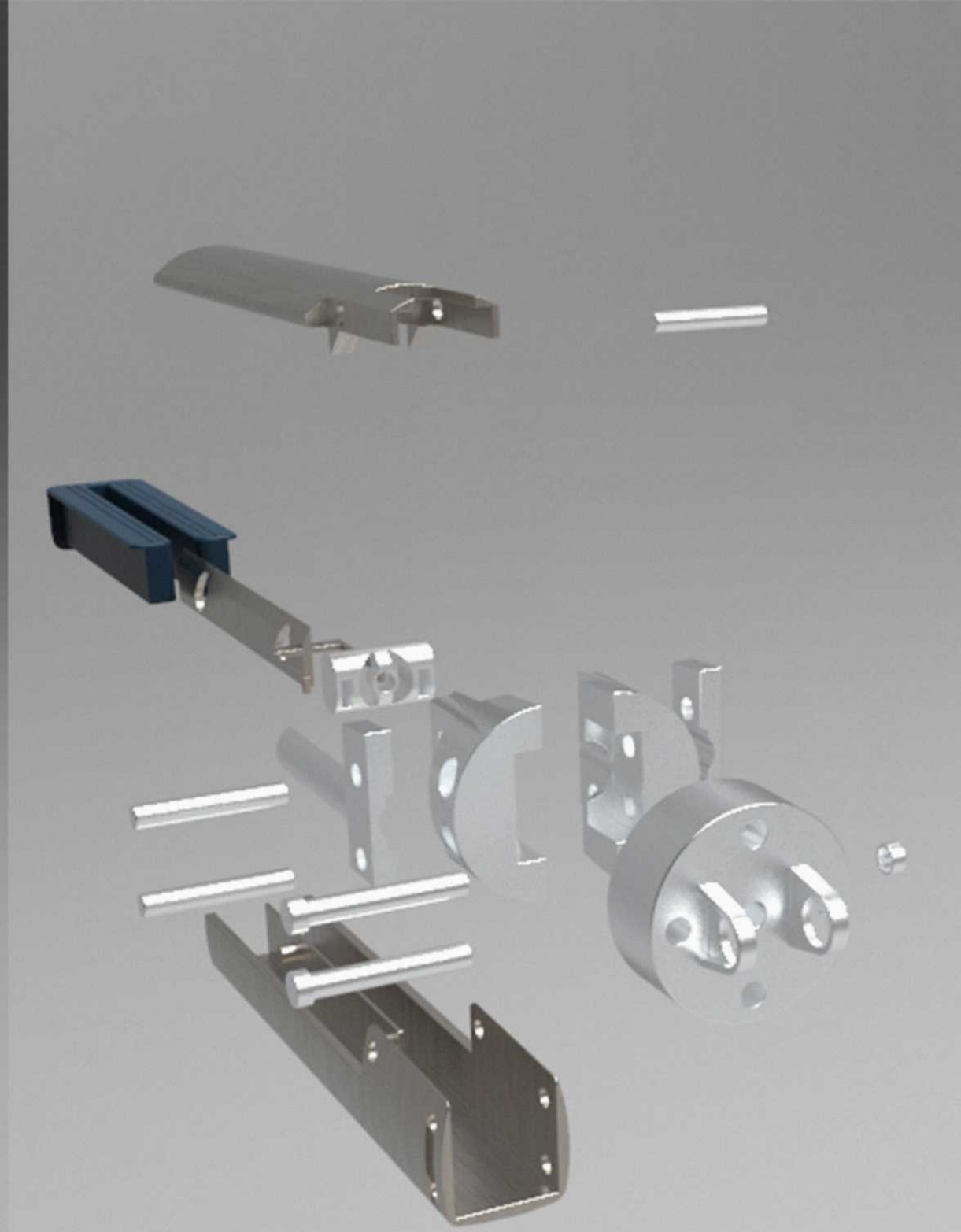

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THANK YOU