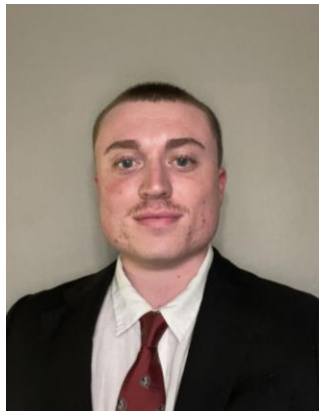
Bone Quality Indenter

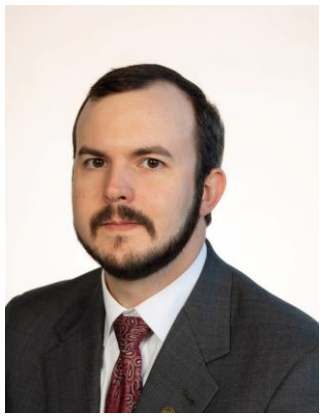
Click to add text

Team Introductions



Grant Giorgi
Orthopedic Bioengineer

Erin Petkus
Biomaterials and Biopolymers Engineer



Timothy Surface
Manufacturing Engineer

Abrea Green
Clinical Engineer

Tessany Schou
Materials Engineer

Nicholas Vastano
Bioinstrumentation Engineer

Sponsor and Advisor

Exactech®
Surgeon focused. Patient driven.™

Project Sponsor
Tom Vanasse
Director of Engineering, Exactech

Academic Advisor
Stephen Arce, Ph.D.
Professor, FAMU-FSU Engineering

Tessany Schou

Objective

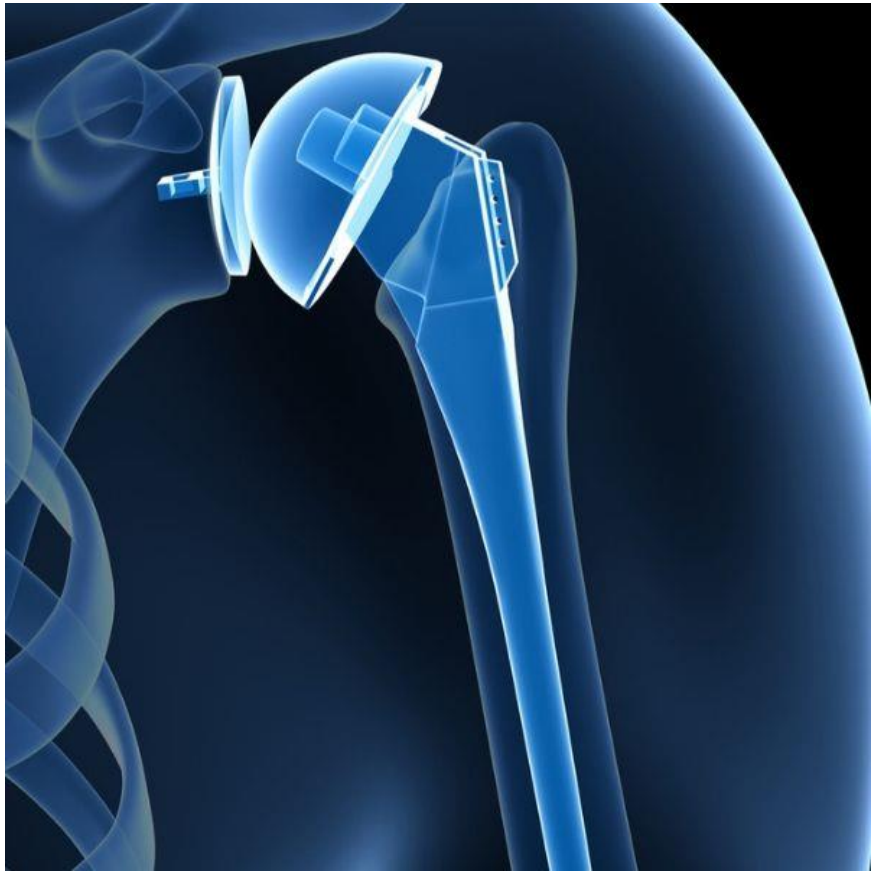
The objective of this project is to create a functional prototype and complete feasibility testing of a device that assists the surgeon's selection in type of implant used during Total Shoulder Arthroplasty.

Tessany Schou

Total Shoulder Arthroplasty

Purpose

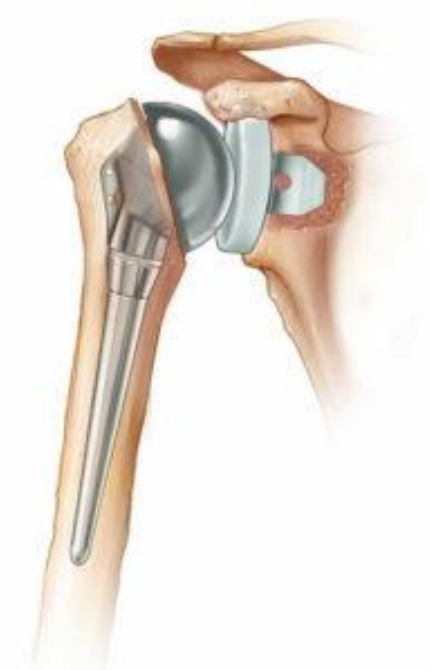
- Eliminate source of pain and dysfunction by replacing shoulder joint with artificial components



Erin Petkus

Types of Implants

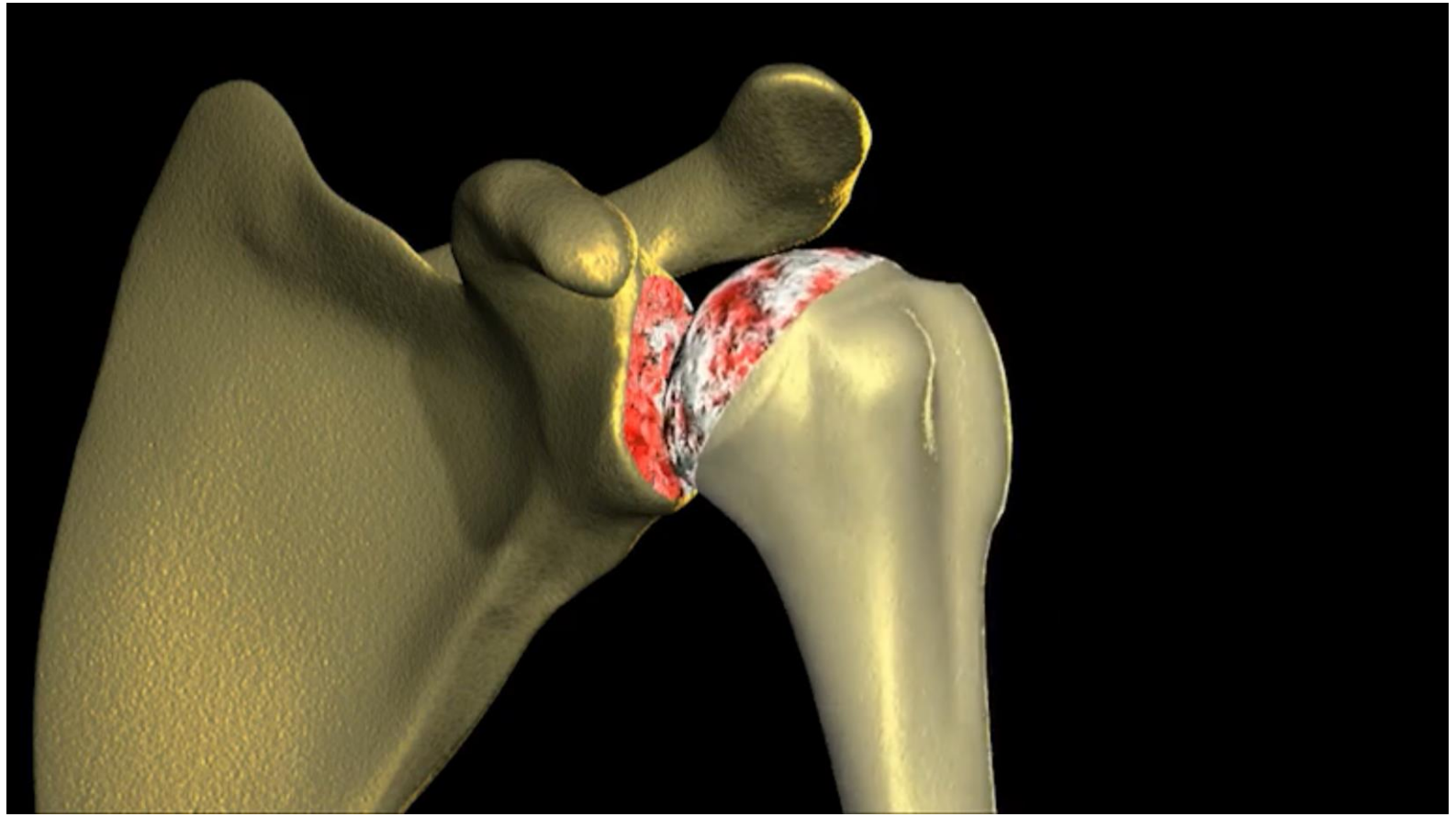
Stemmed Implant



Stemless Implant

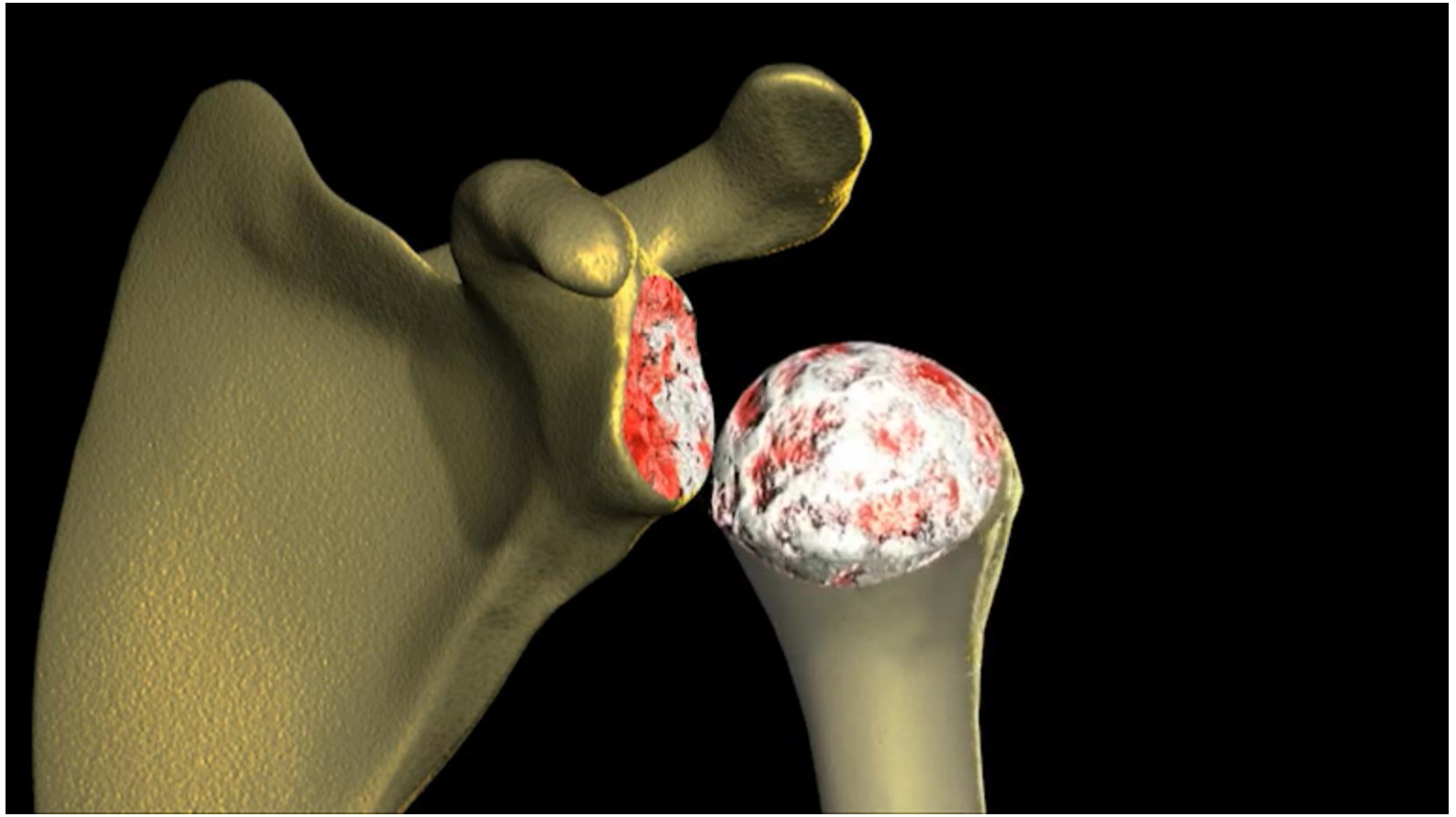
Erin Petkus

The “Thumb Test”



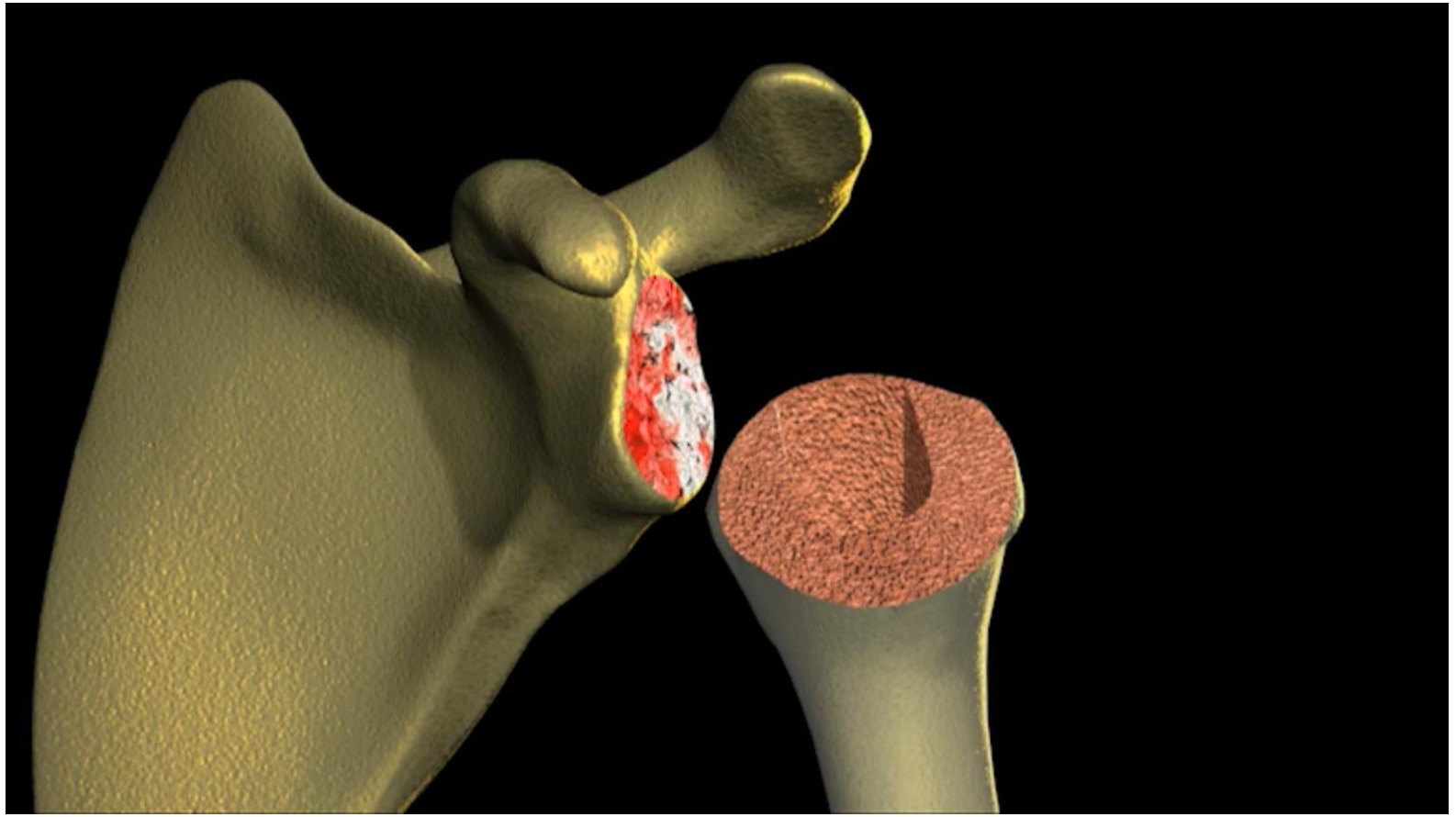
Erin Petkus

The “Thumb Test”



Erin Petkus

The “Thumb Test”



Erin Petkus

Levels of Bone Density/Quality

Erin Petkus

Functional Decomposition

SAFETY

- Adheres to codes
- Survives cleaning
- Prevents harm

EASE OF USE

- Endures multiple uses
- Allows easy manipulation

MEASUREMENT

- Displays measurement
- Provides accuracy
- Demonstrates speed

Tessany Schou

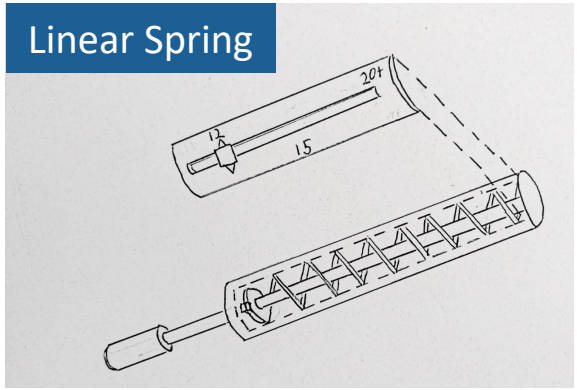
Targets

- Compliant with FDA regulations
- Creates indentation less than or equal to 1 in.
- Width of device is smaller than 6 in.
- Reports results with 95% accuracy
- Device withstands temperatures up to 284 °F
- Weighs less than or equal to 5 lbs.
- Lifespan greater than 50 uses

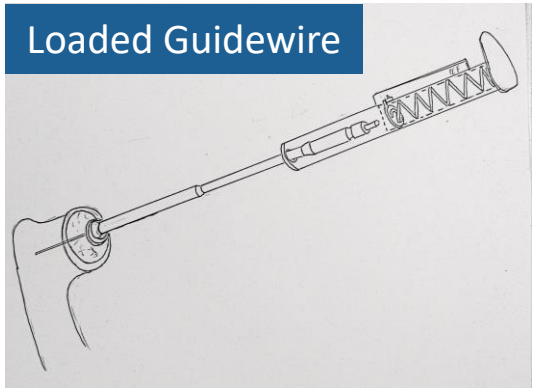
Tessany Schou

Concepts

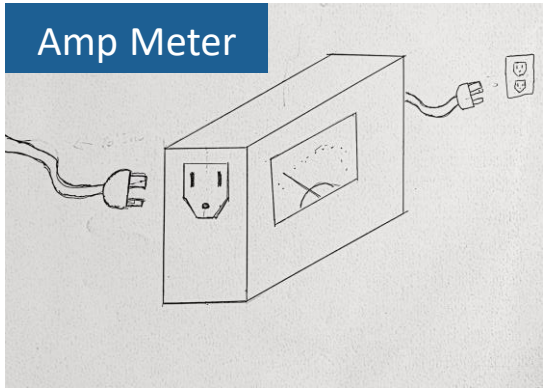
Linear Spring



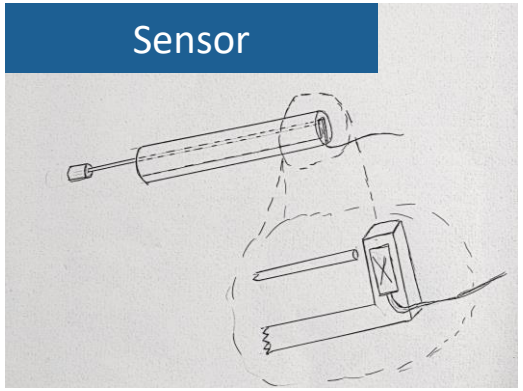
Loaded Guidewire



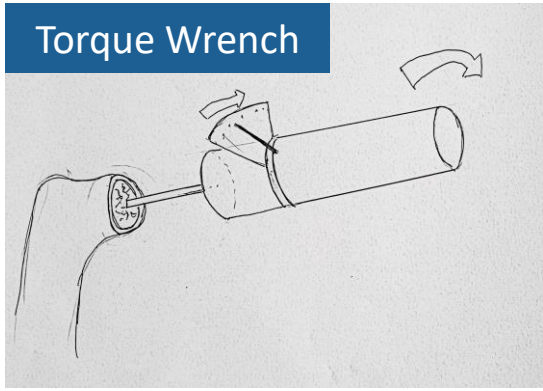
Amp Meter



Sensor

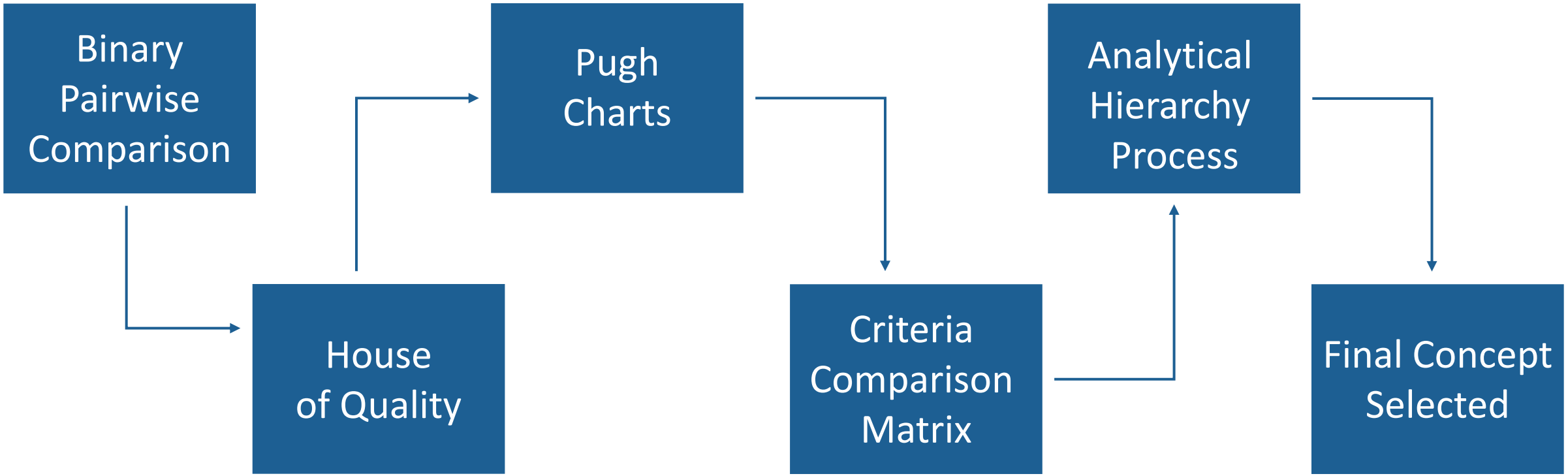


Torque Wrench



Tessany Schou

Concept Selection



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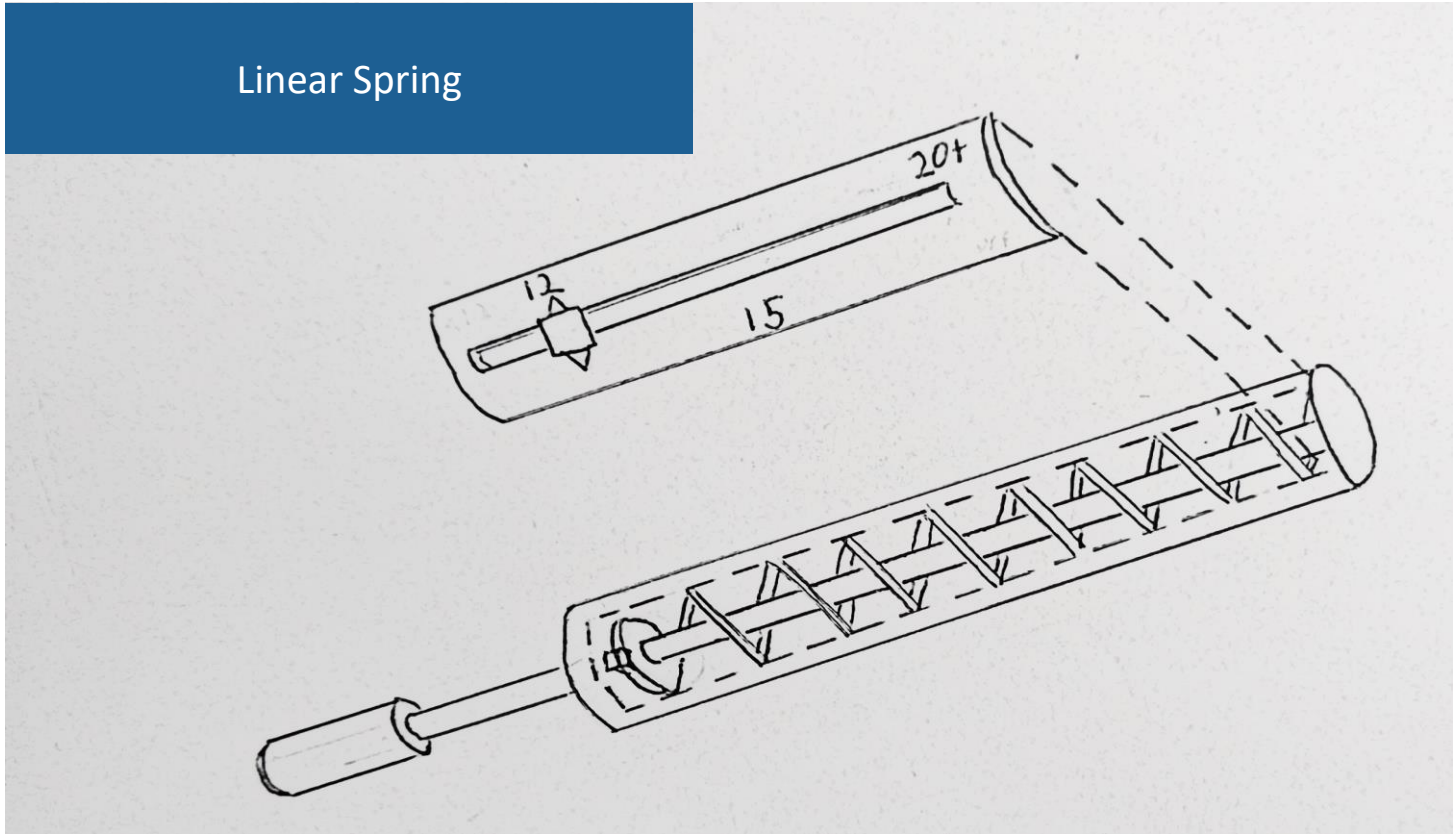
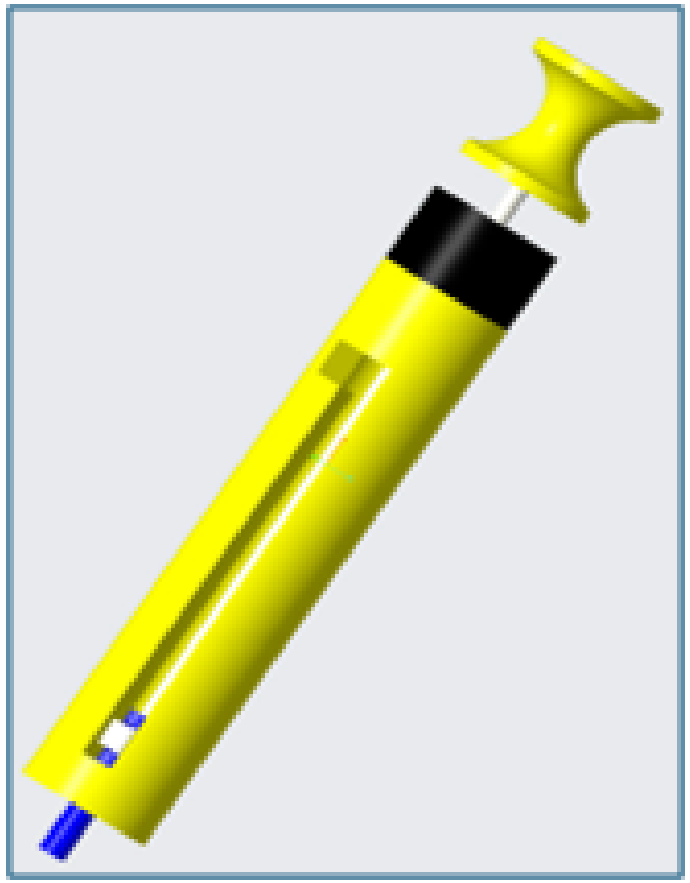
Concept Selection

Linear Spring



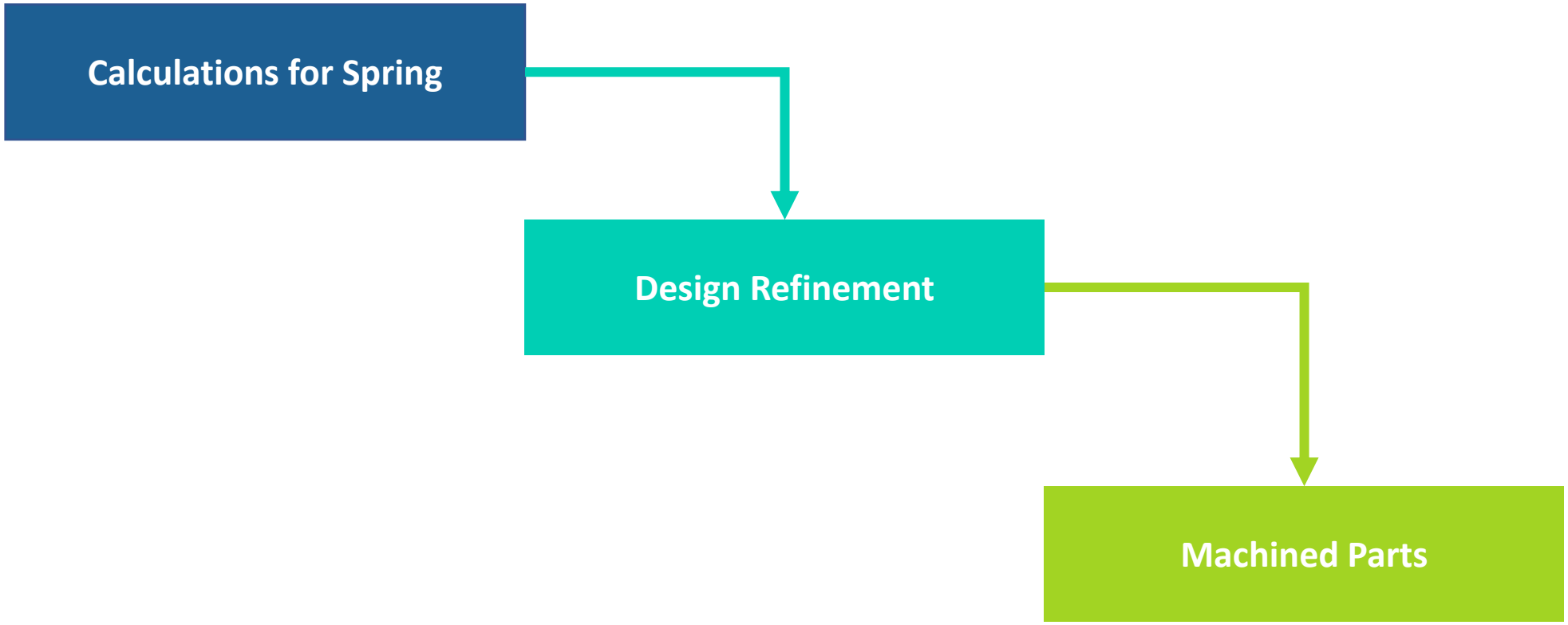
Tessany Schou

Rework and 3D Model



Tessany Schou

DR5



Abrea Green

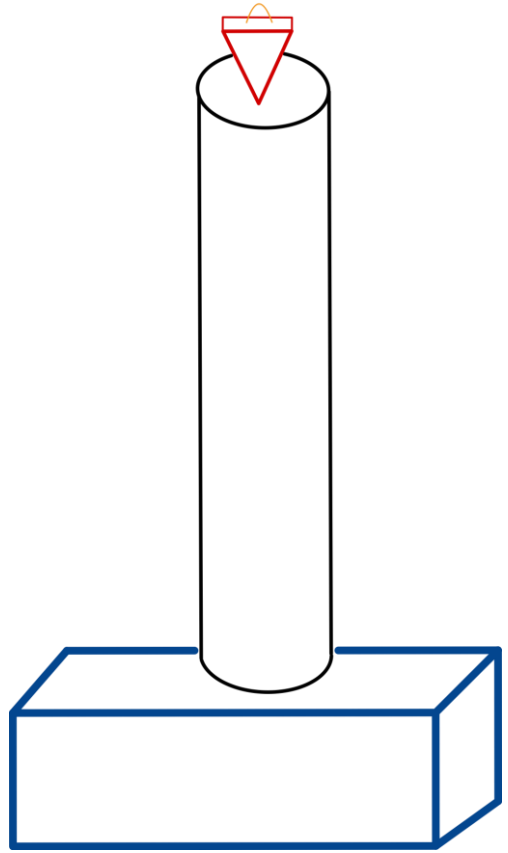
Classification & Applicable Standards

- Class I medical device
  - PMA versus 510K
- Relevant Standards
  - ISO 17665-1 and -2
  - ISO 10993-20
  - ASTM D-1621

Abrea Green

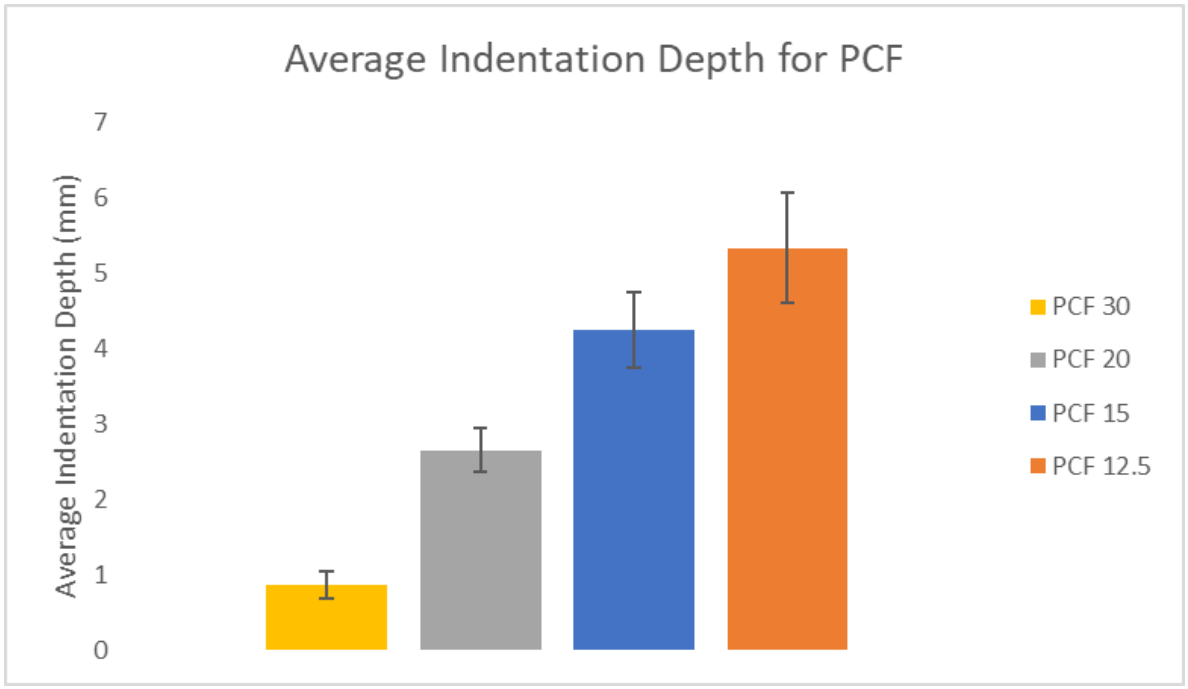
Drop Testing Procedure

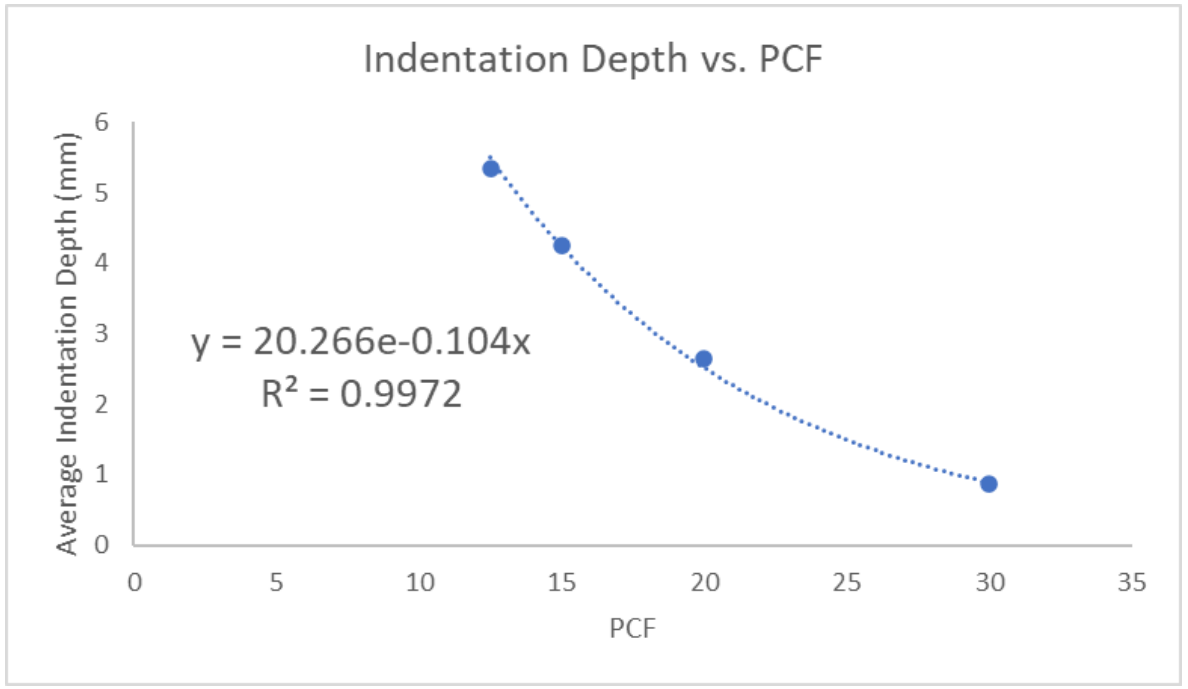
- Pyramid shaped fishing weights through PVC pipe
  - 3 ounces and 50.75 inches
- Depth measured with calipers
- Force back-calculated for varied PCF



Grant Giorgi

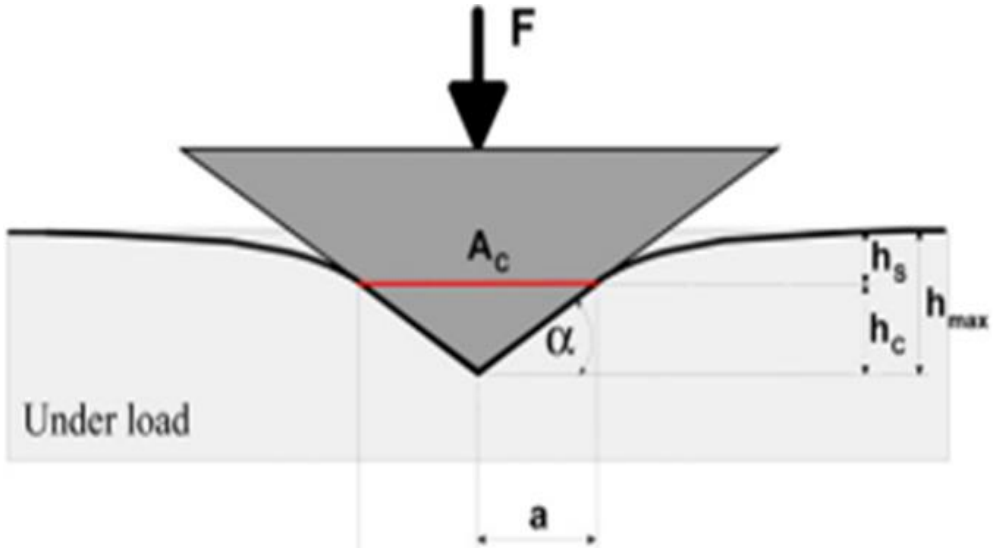
Drop Testing





Nick Vastano

Drop Testing



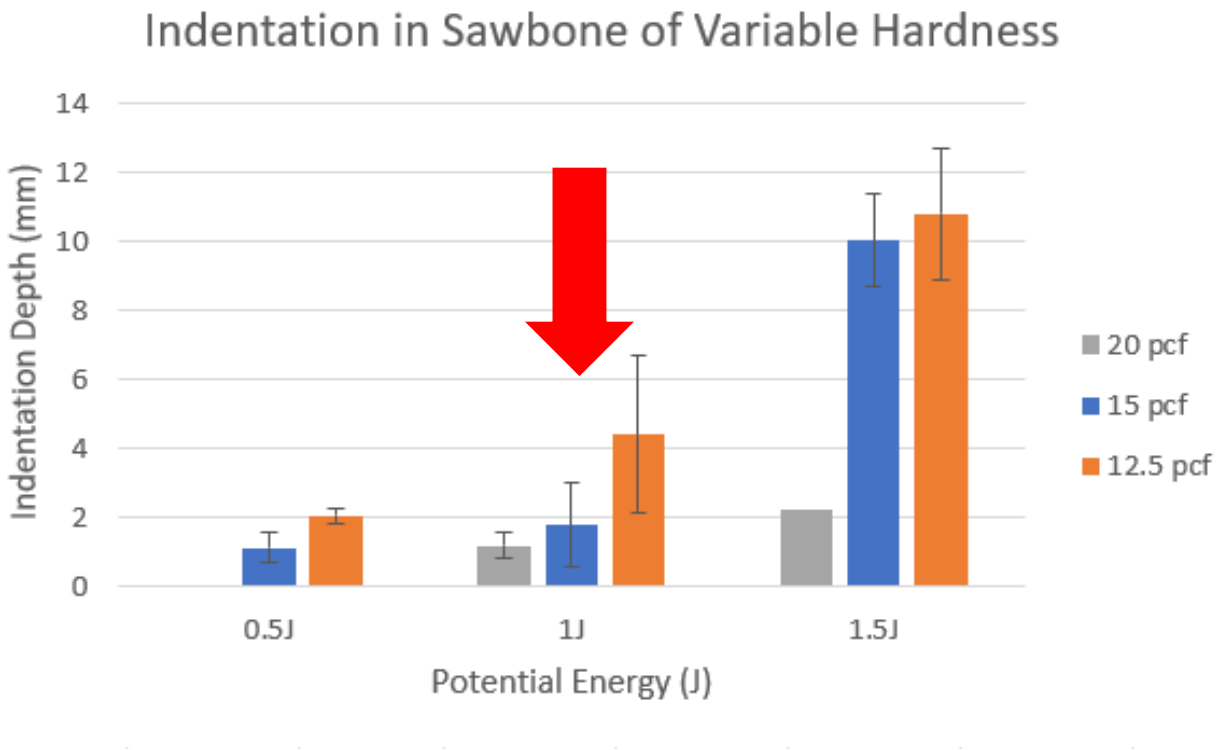
$$F = \frac{2}{\pi} \cdot \frac{E^*}{\tan \alpha} \cdot h^m, \qquad \text{where}$$

$$E^* = \frac{E}{(1 - \nu^2)} \quad \text{and} \quad m = 2$$

- F: Force (176.9±10% N)
- E*: Young's Modulus of sawbone related to Poisson's ratio
- v: Poisson's ratio for polyurethane foam = 0.25
- α: Angle of incidence (78 Degrees)
- h: Indentation depth

Nick Vastano

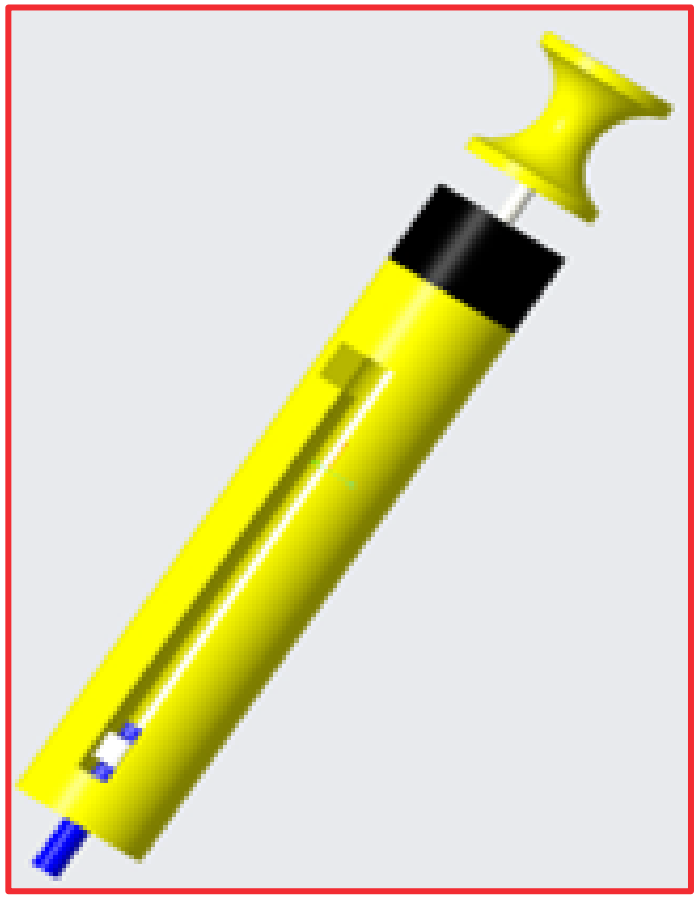
Flat Point Testing

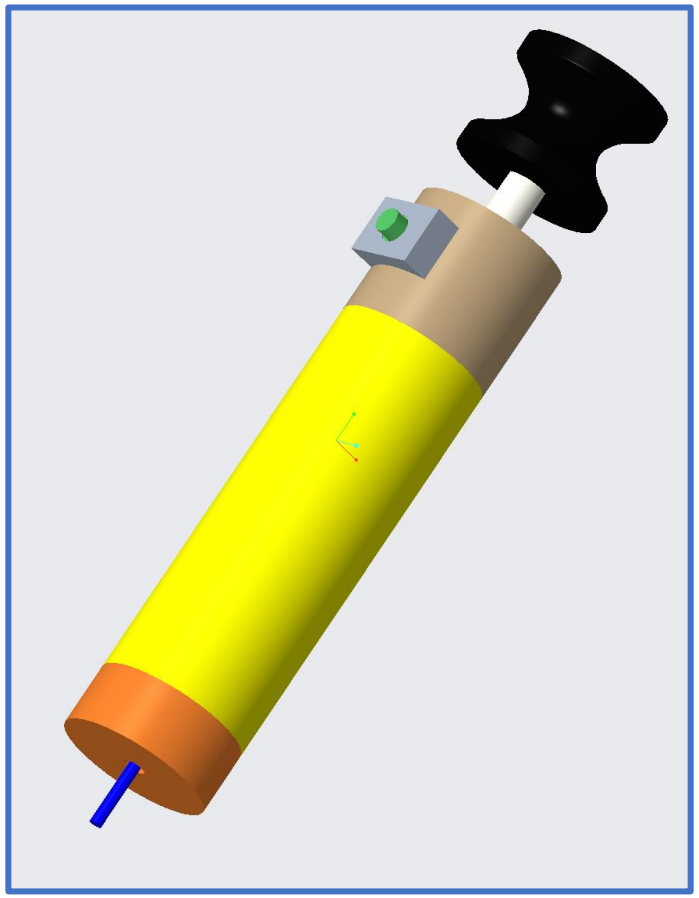


- PE = ½ * kx^2
- Largest indentation depth at 1.5J
  - 15 vs 12.5 PCF
- No indentation of 20 PCF at 0.5J

Abrea Green

Design Refinement

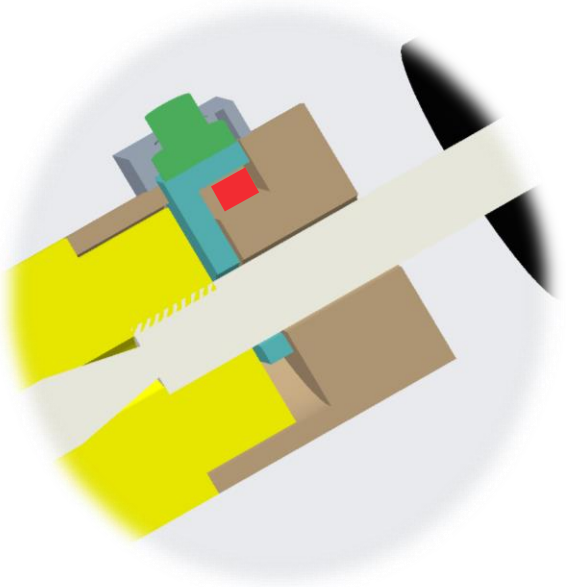




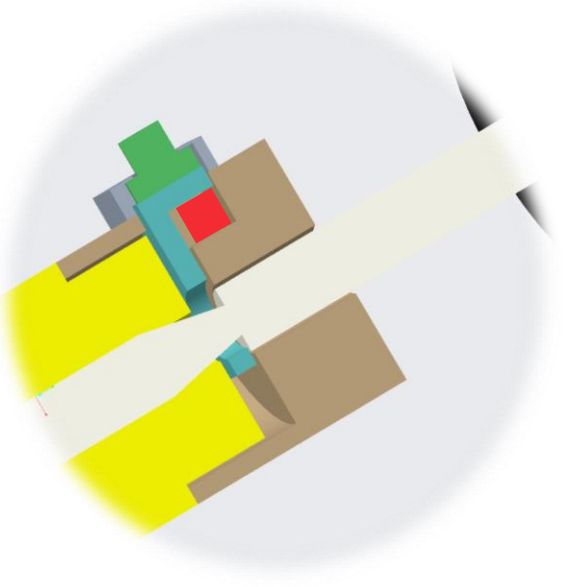
Tessany Schou

Current Method of Release

Free Position



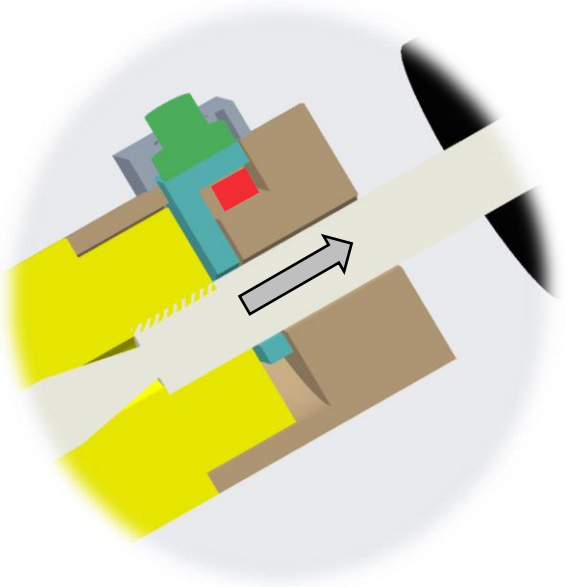
Locked Position



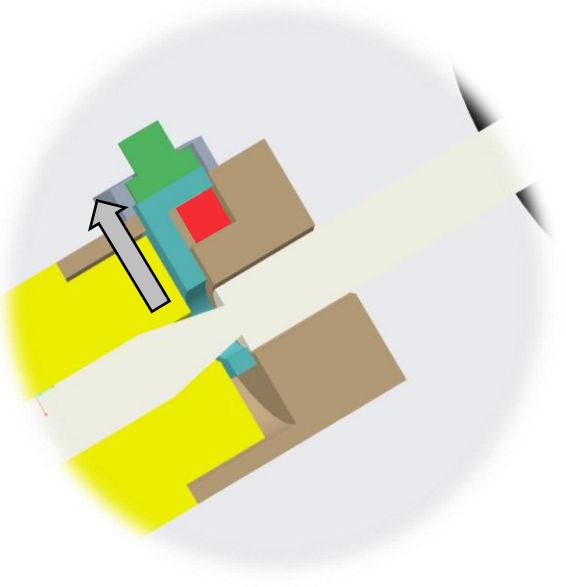
Tessany Schou

Current Method of Release

Free Position

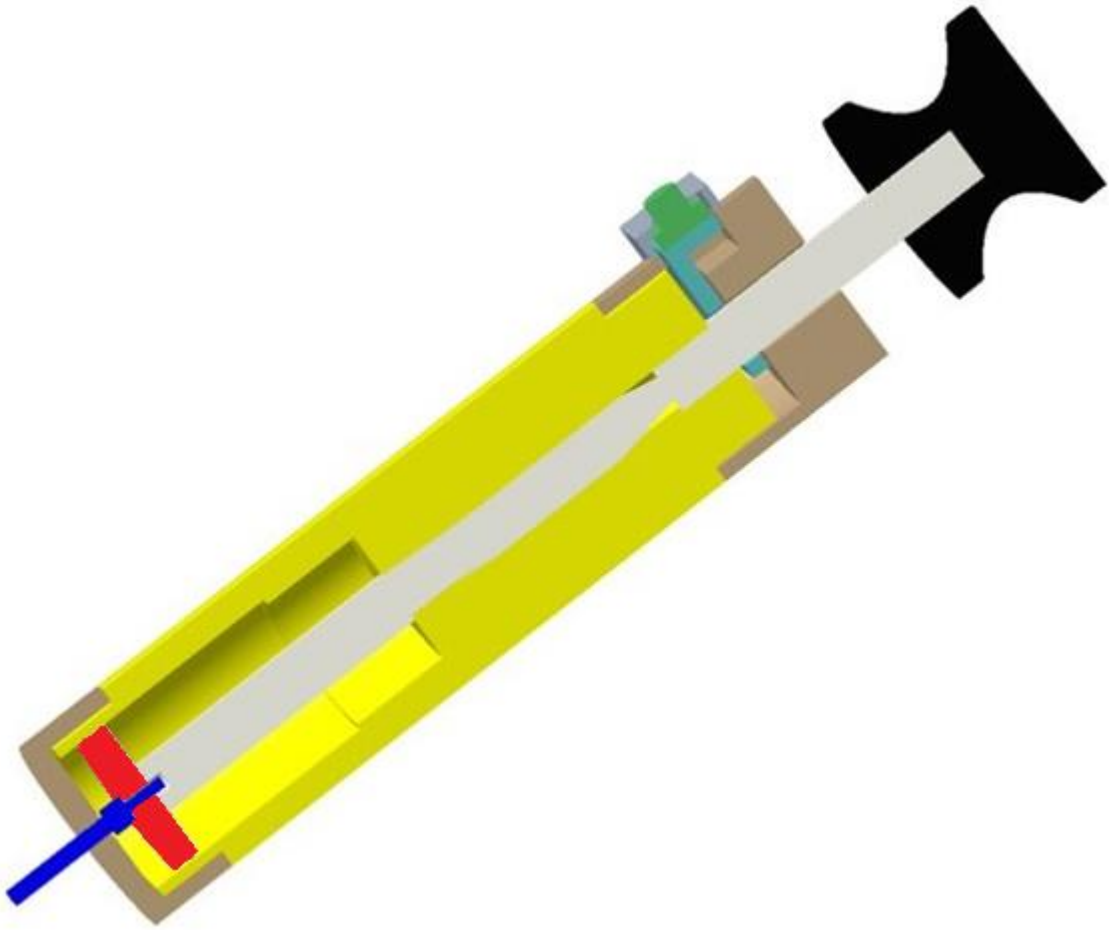


Locked Position



Tessany Schou

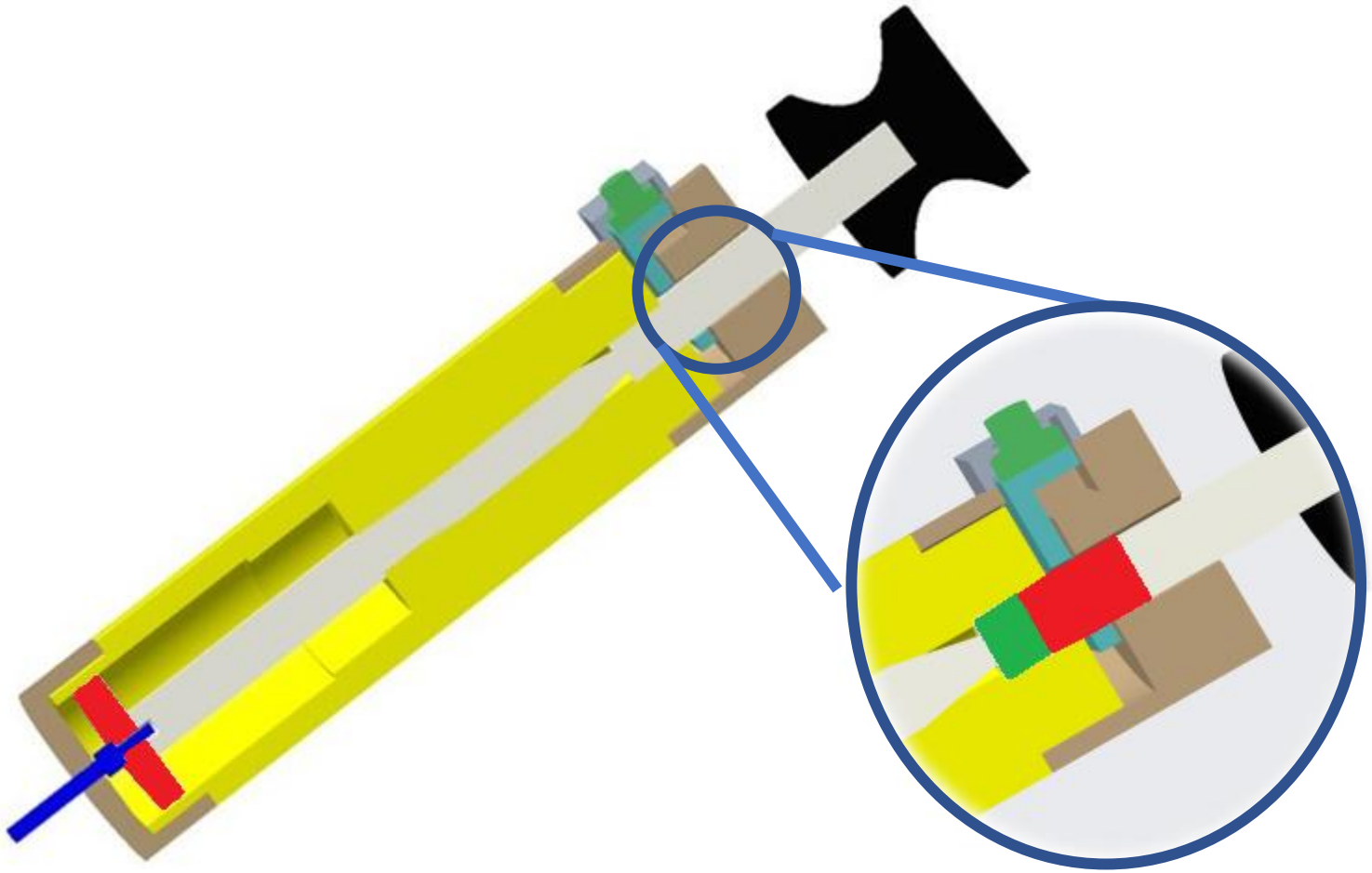
Internal Design



- Visit to Machine shop
  - Feedback on design
- Changes
  - Removable tip
  - "Washer"
  - Sealing
  - Welding

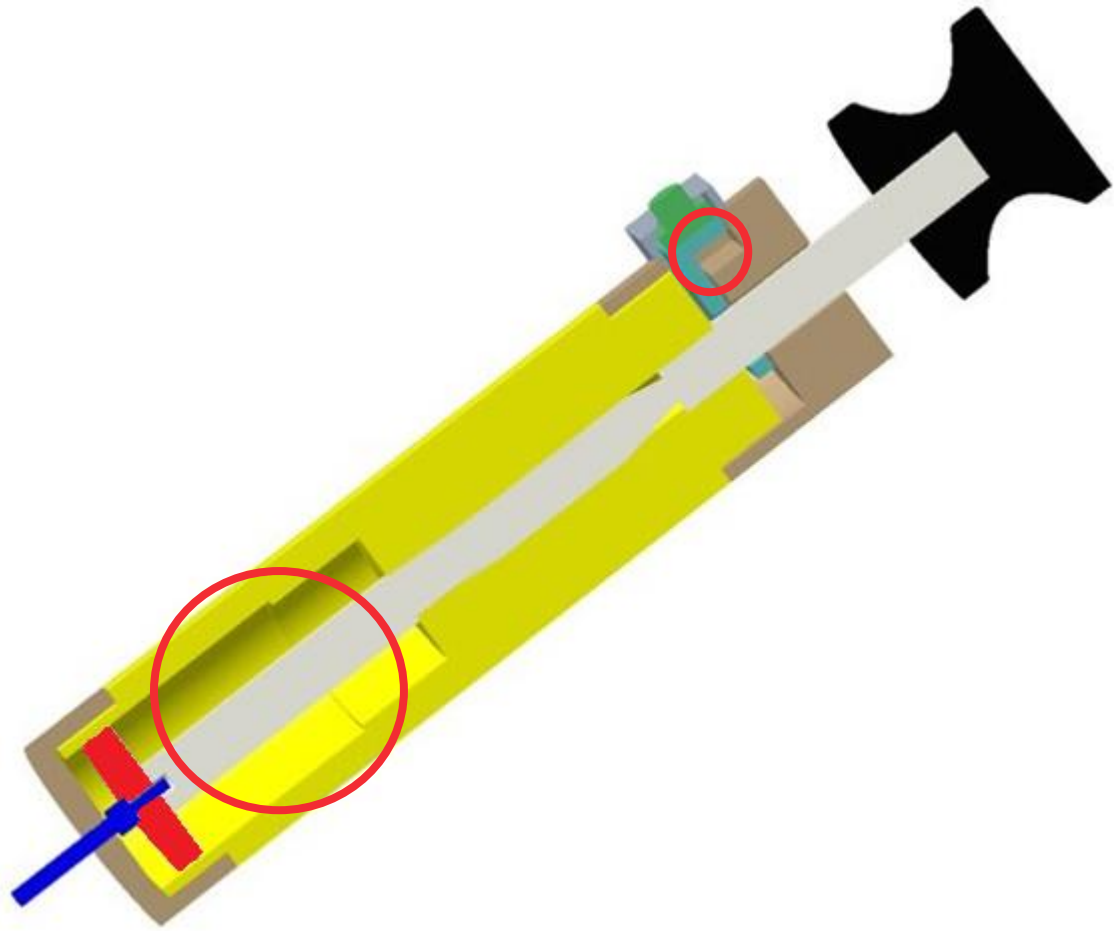
Timothy Surface

Readout



Timothy Surface

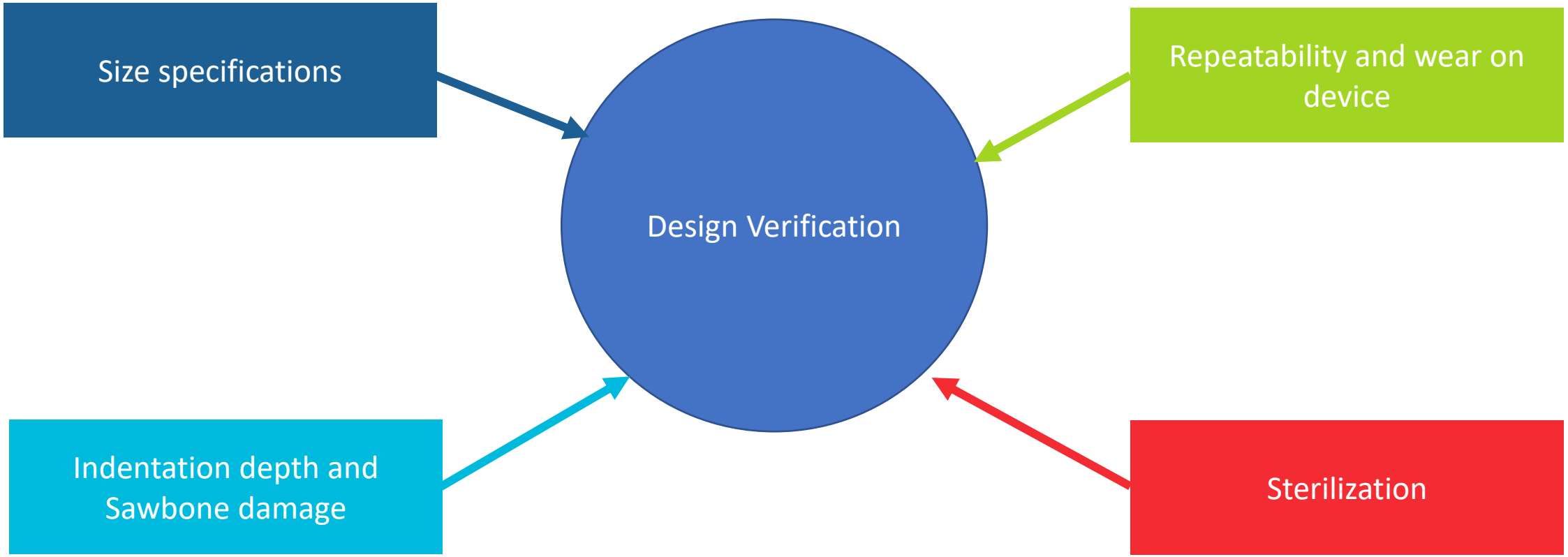
Components and Ordering



- Housing and Caps
- Rod
- Tip
- Button Components
- Spring

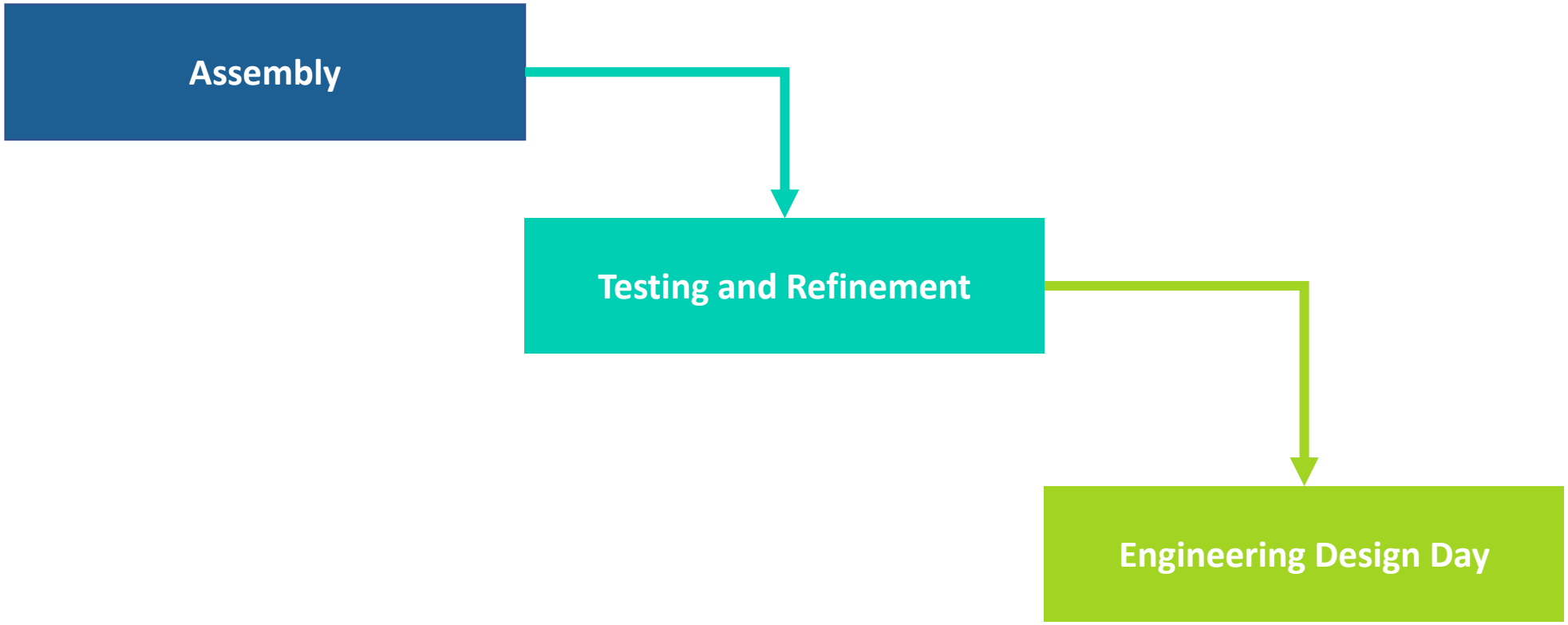
Timothy Surface

Validation Testing



Timothy Surface

Looking Ahead



Timothy Surface &
Grant Giorgi

4 Most Important Points

1. Project is to develop a device to measure bone quality.
2. Machined parts are finished.
3. Assembly is in progress.
4. Moving to complete validation testing next week.

Timothy Surface

Reference

Anastasio, Okafor, C., Garrigues, G. E., Klifto, C. S., Lassiter, T., & Anakwenze, O. (2021). Stemmed versus stemless total shoulder arthroplasty: a comparison of operative times. Seminars in Arthroplasty, 31(4), 831–835. https://doi.org/10.1053/j.sart.2021.05.013

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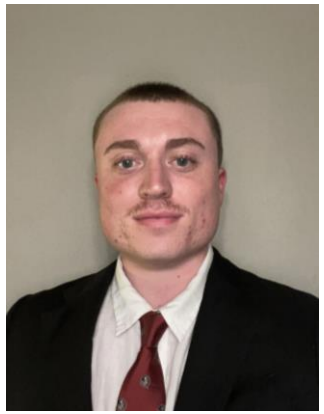
Timothy Surface

Reference

Zdravkovic, Kaufmann, R., Neels, A., Dommann, A., Hofmann, J., & Jost, B. (2020). Bone mineral density, mechanical properties, and trabecular orientation of cancellous bone within humeral heads affected by advanced shoulder arthropathy. Journal of Orthopaedic Research, 38(9), 1914–1919. https://doi.org/10.1002/jor.24633

Contact the Team



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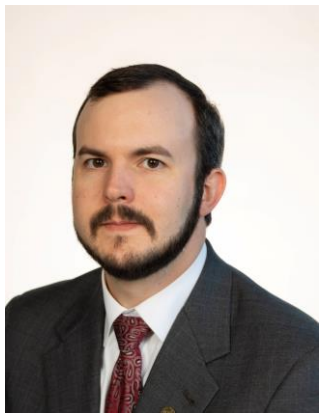

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