Bone Quality Indenter

Click to add text

Team Introductions
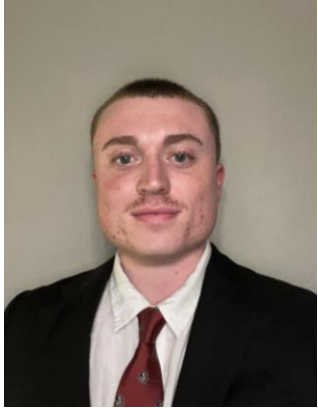
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Orthopedic Bioengineer

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

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.
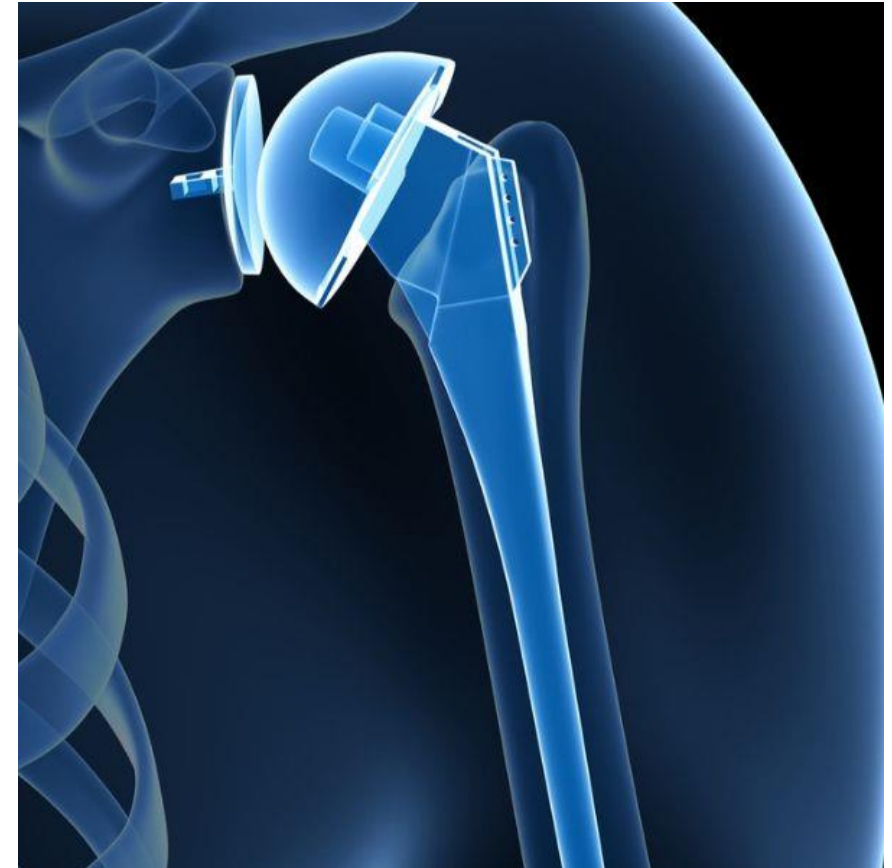
Tessany Schou

Total Shoulder Arthroplasty

Purpose

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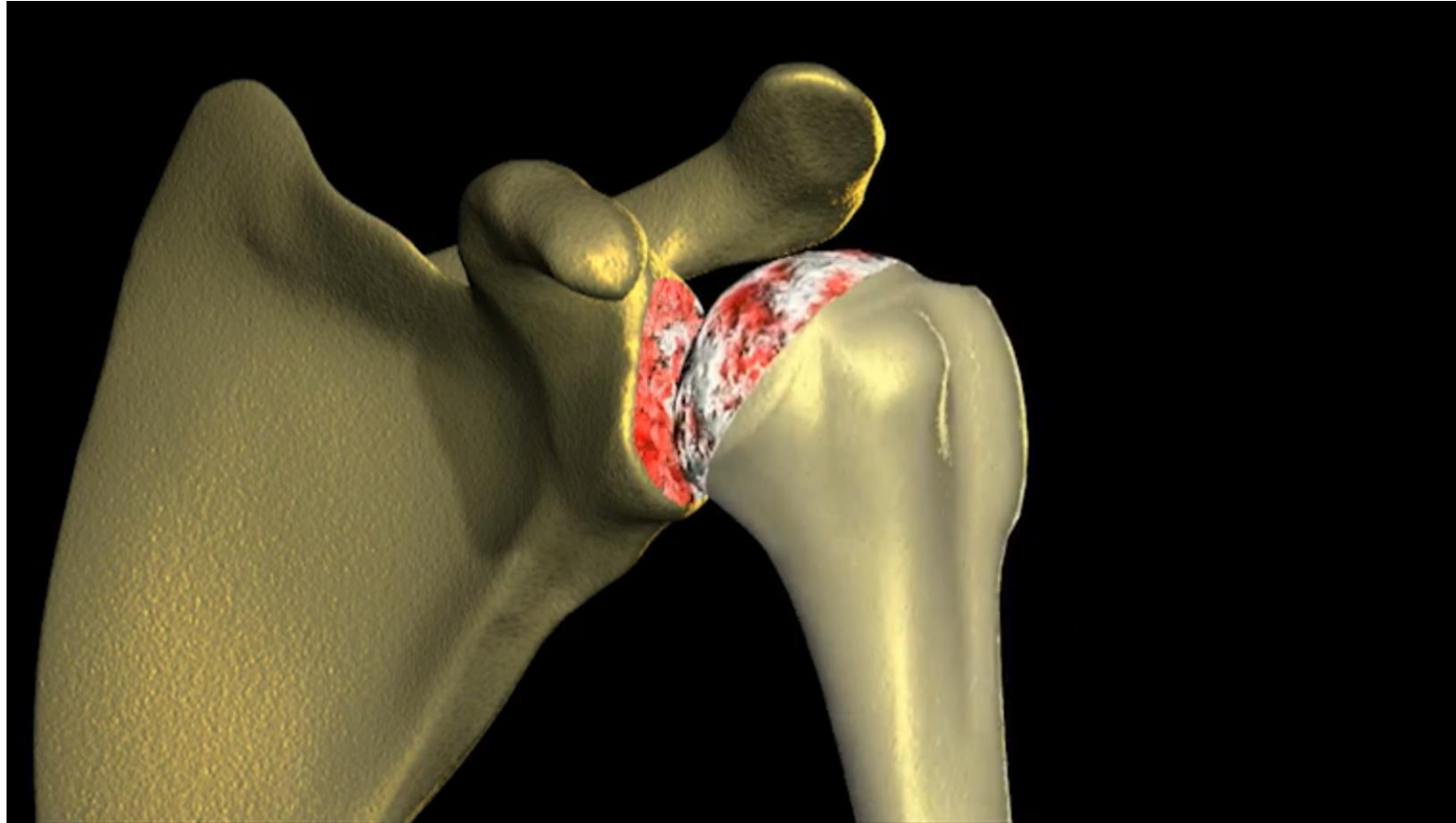
Erin Petkus

Types of Implants

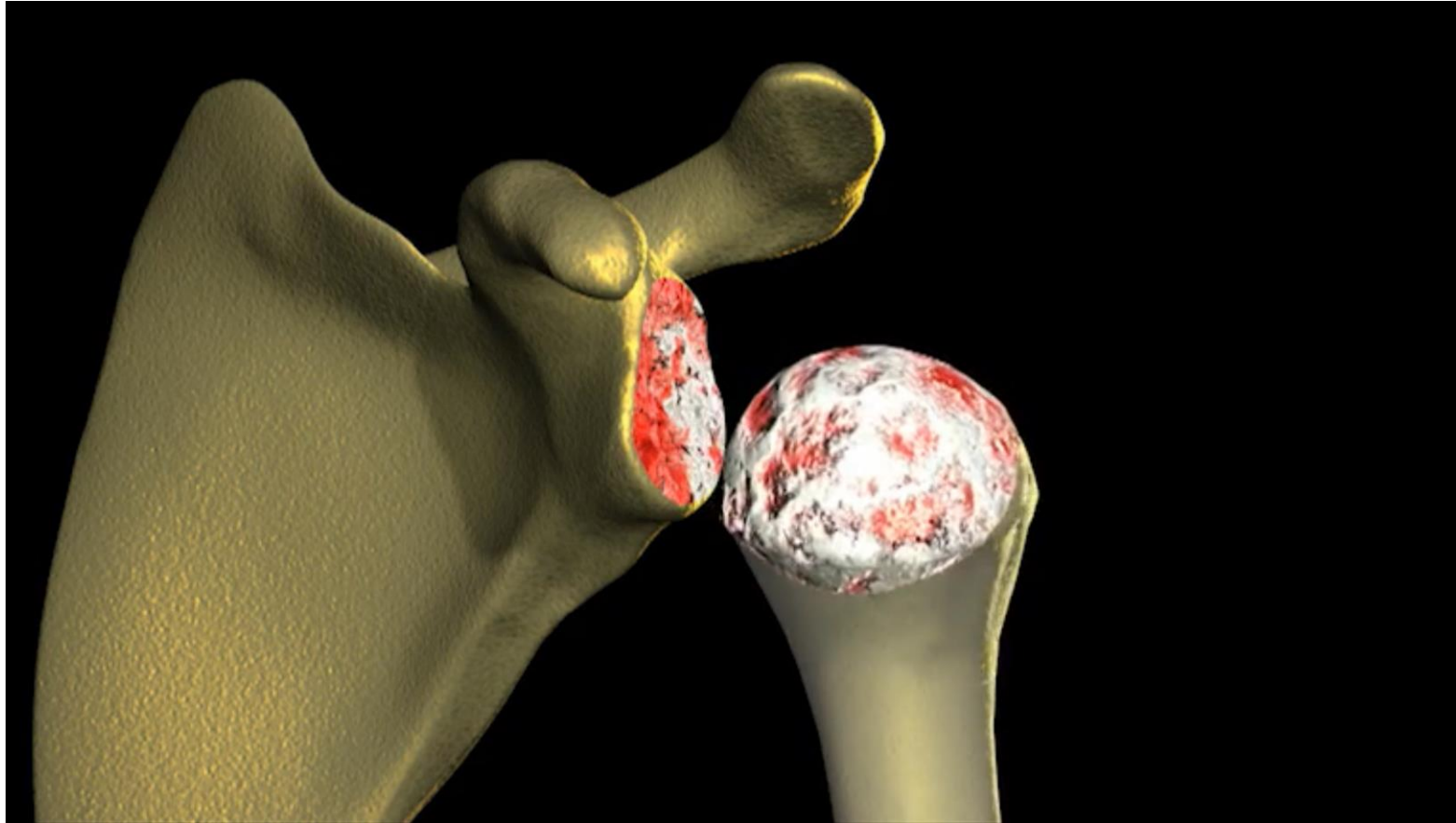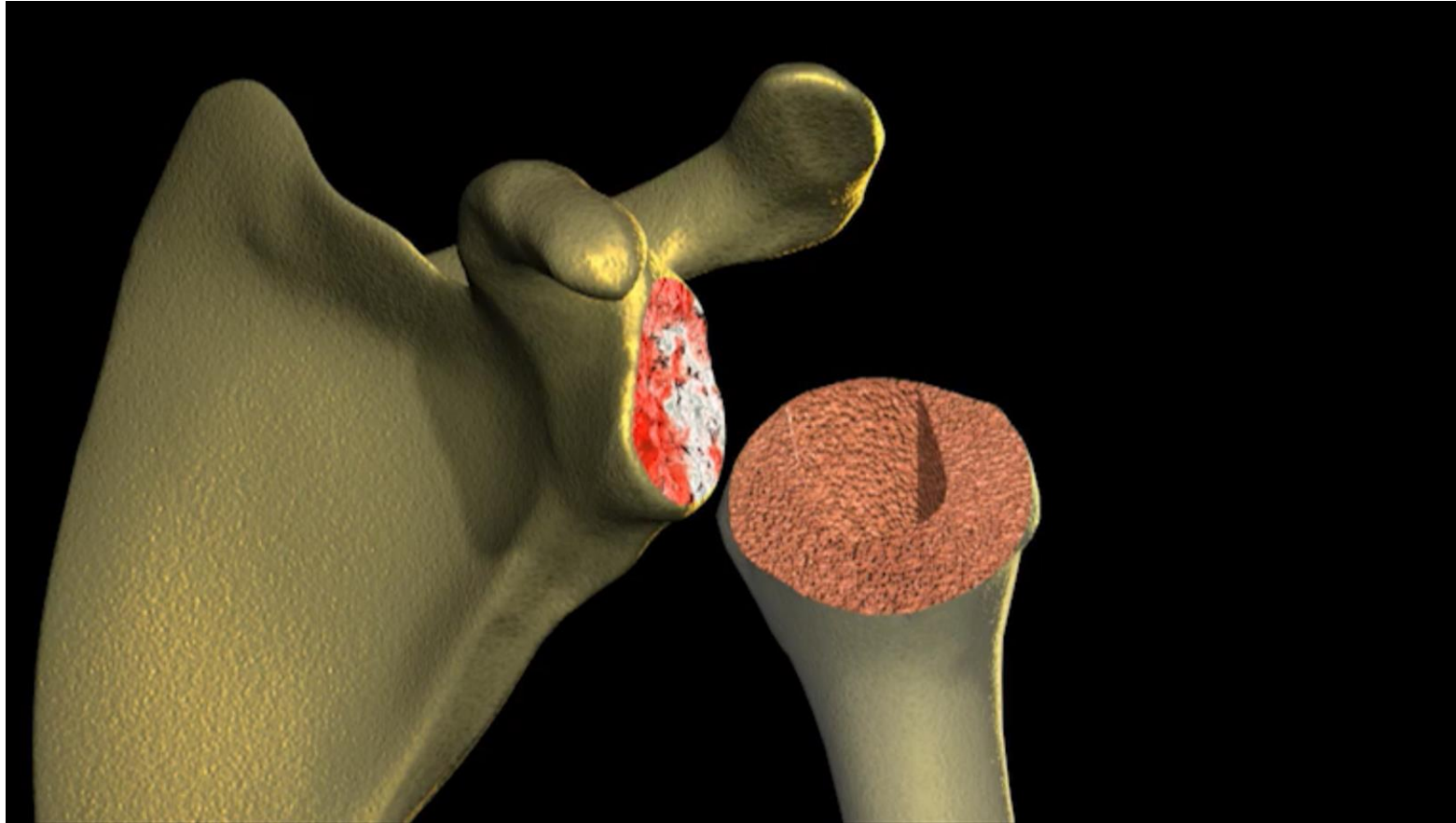Stemmed Implant

Stemless Implant

Erin Petkus

FAMU-FSU Engineering

The "Thumb Test"

Erin Petkus

The "Thumb Test"

Erin Petkus

The "Thumb Test"

Erin Petkus

Levels of Bone Density/Quality

12.5 PCF
Osteoarthritic

15 PCF
Good

30 PCF
Excellent

Pounds per Cubic Foot

Erin Petkus

Targets

Compliant with FDA regulations

Device withstands temperatures up to 284°F

Creates indentation less than or equal to 1 in.

Weighs less than or equal to 5 lbs.

Length of device is smaller than 6 in.

Lifespan greater than 50 uses
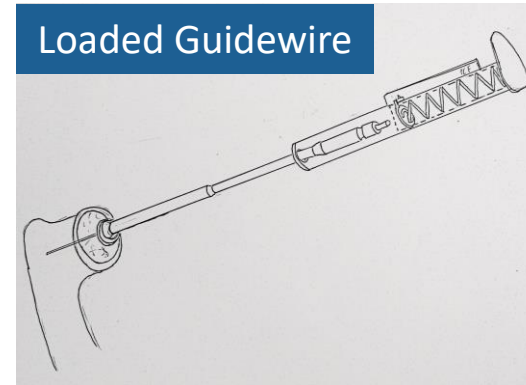
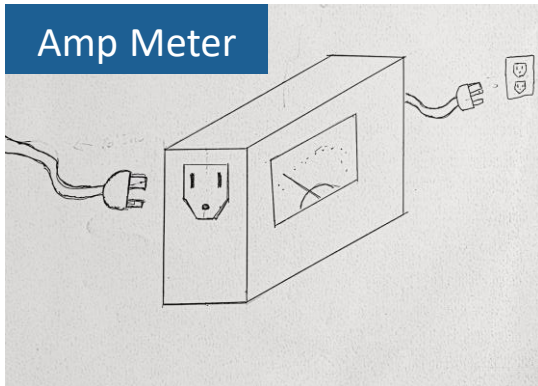Reports results with 95% accuracy

Abrea Green

Concepts

Linear Spring
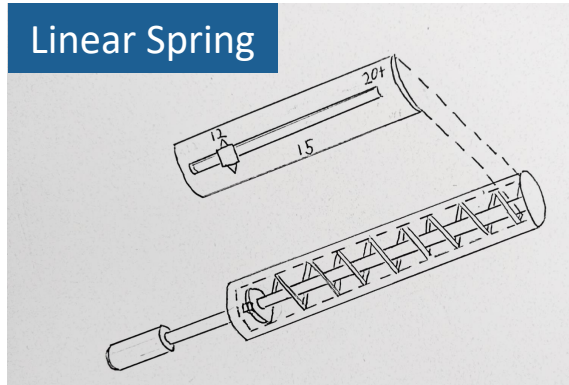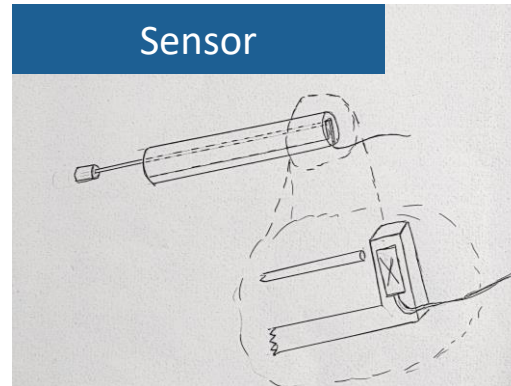

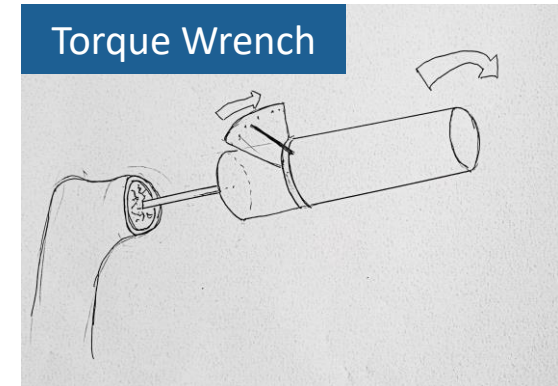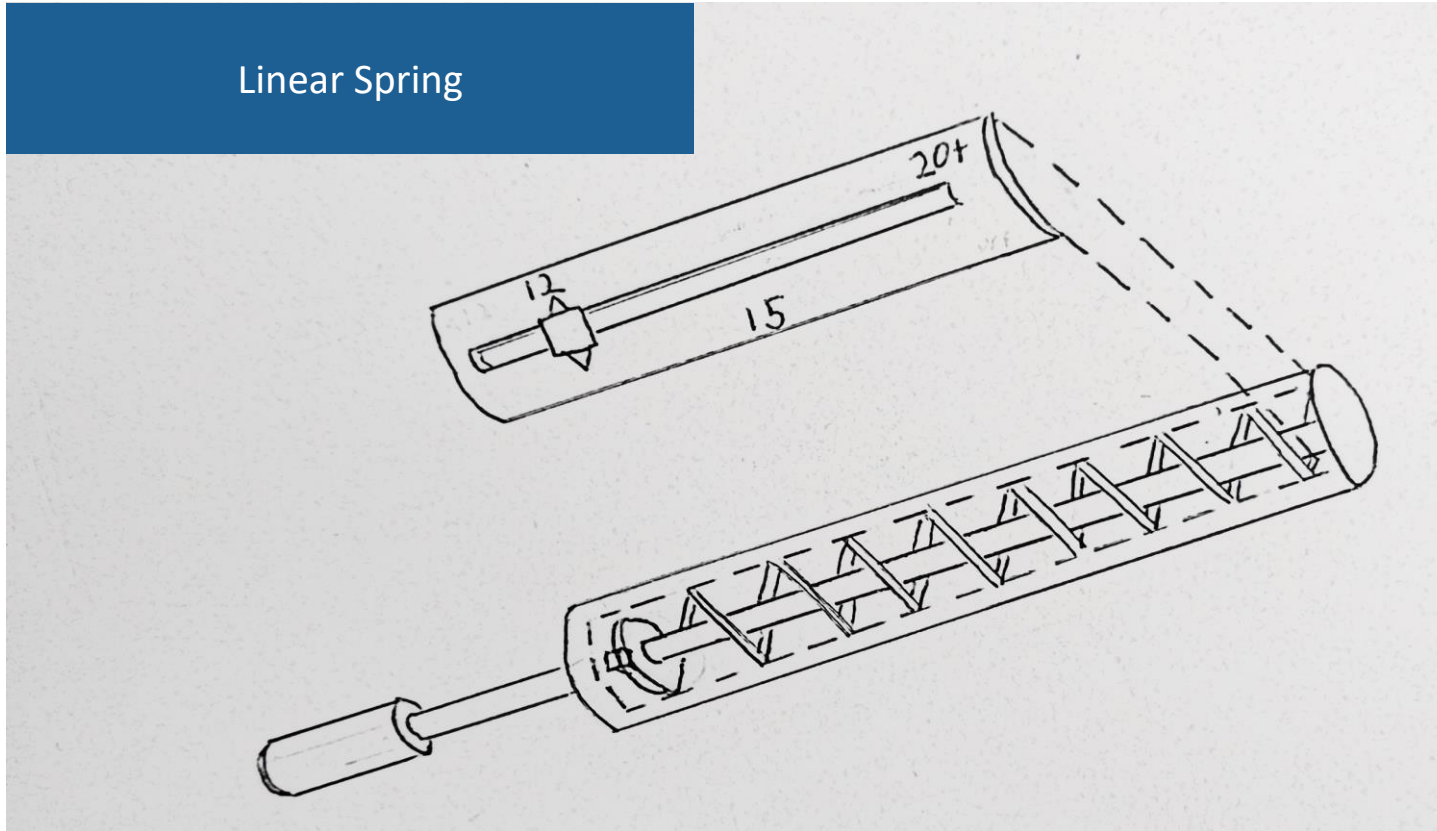Loaded Guidewire

Amp Meter

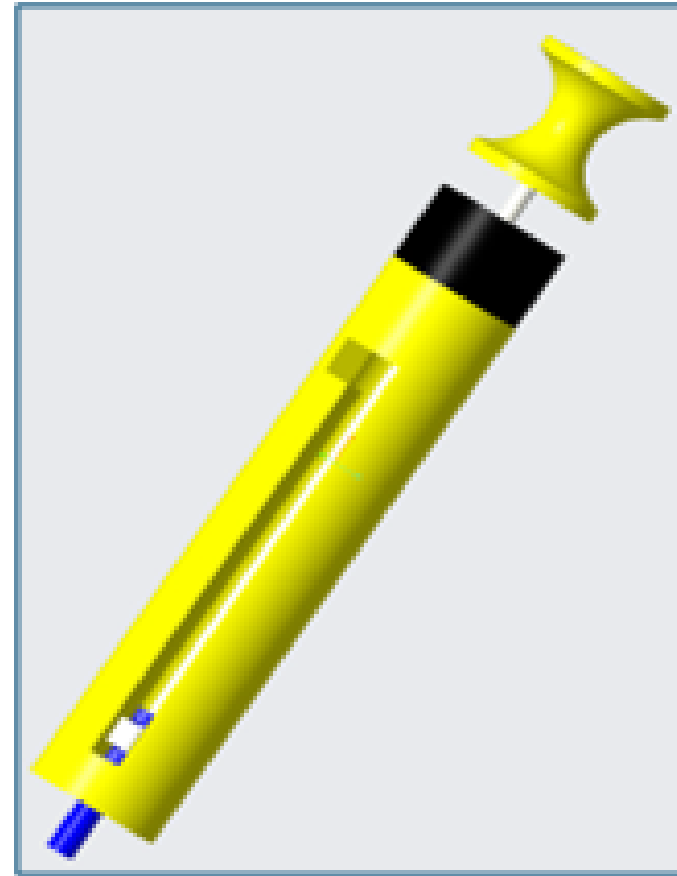Sensor

Torque Wrench

Tessany Schou

Concept Selection

Linear Spring

Tessany Schou

Rework and 3D Model

Tessany Schou

Classification & Applicable Standards
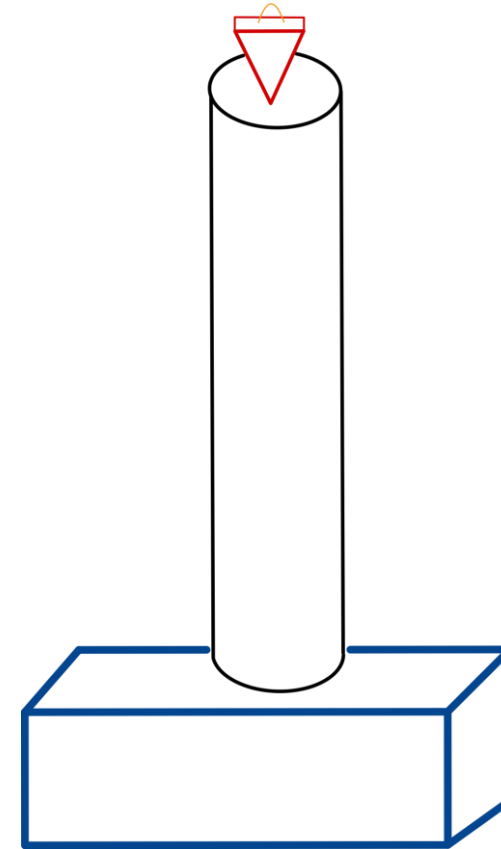

- Class I medical device
  - Exempt or 510K
- Relevant Standards
  - ASTM D-1621
  - ISO 10993-20
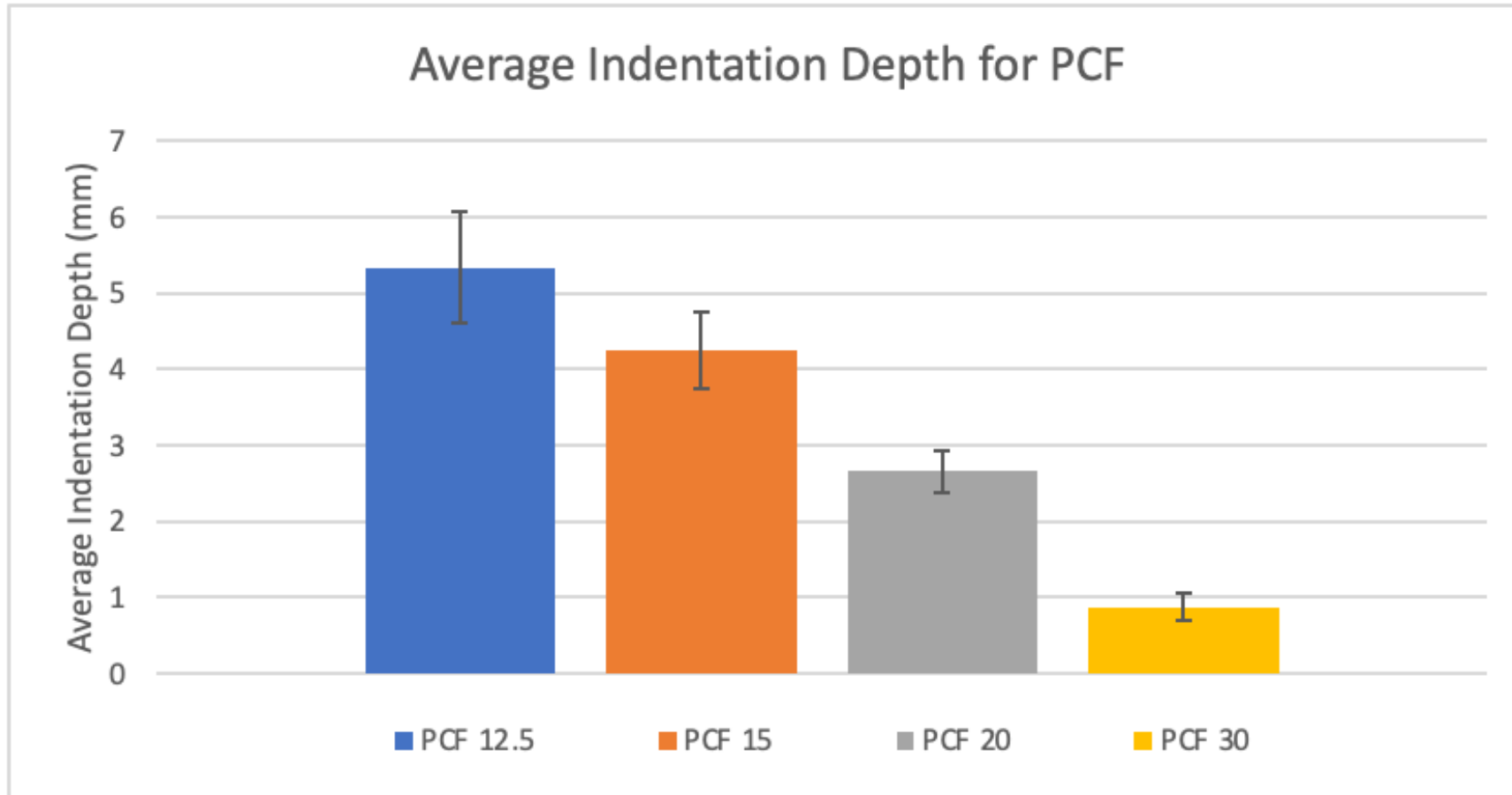 - ISO 17665-1 and -2

Abrea Green

Pyramid 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

Pyramid Drop Testing Results

Nick Vastano
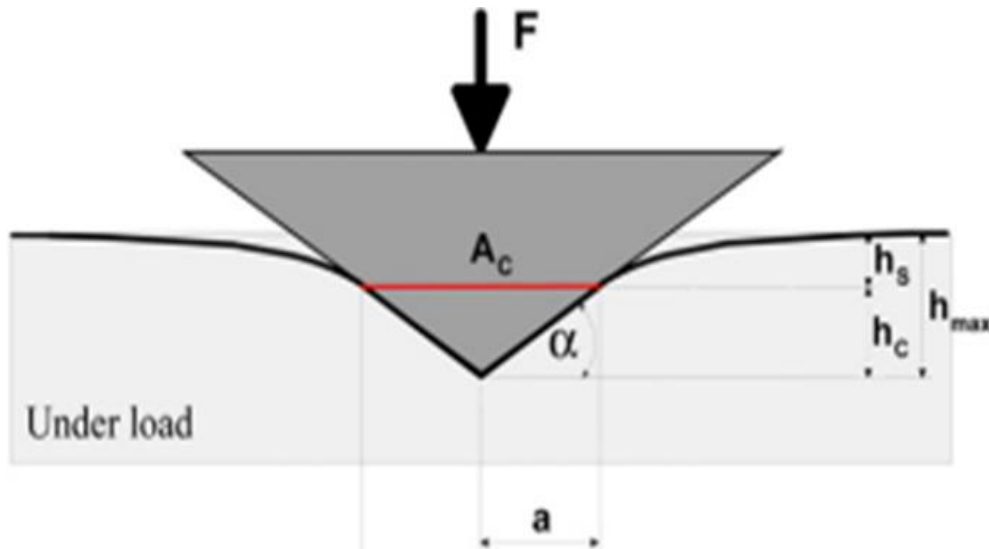
Pyramid Drop Testing Results

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

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

- F: Force (176.9±10% N)

- E*: Young's Modulus of sawbone related to Poisson's ratio

- ν: Poisson's ratio for polyurethane foam = 0.25

- α: Angle of incidence (78 Degrees)

- h: Indentation depth

Nick Vastano

Flat Point Testing Results

Indentation in Sawbone of Variable Hardness
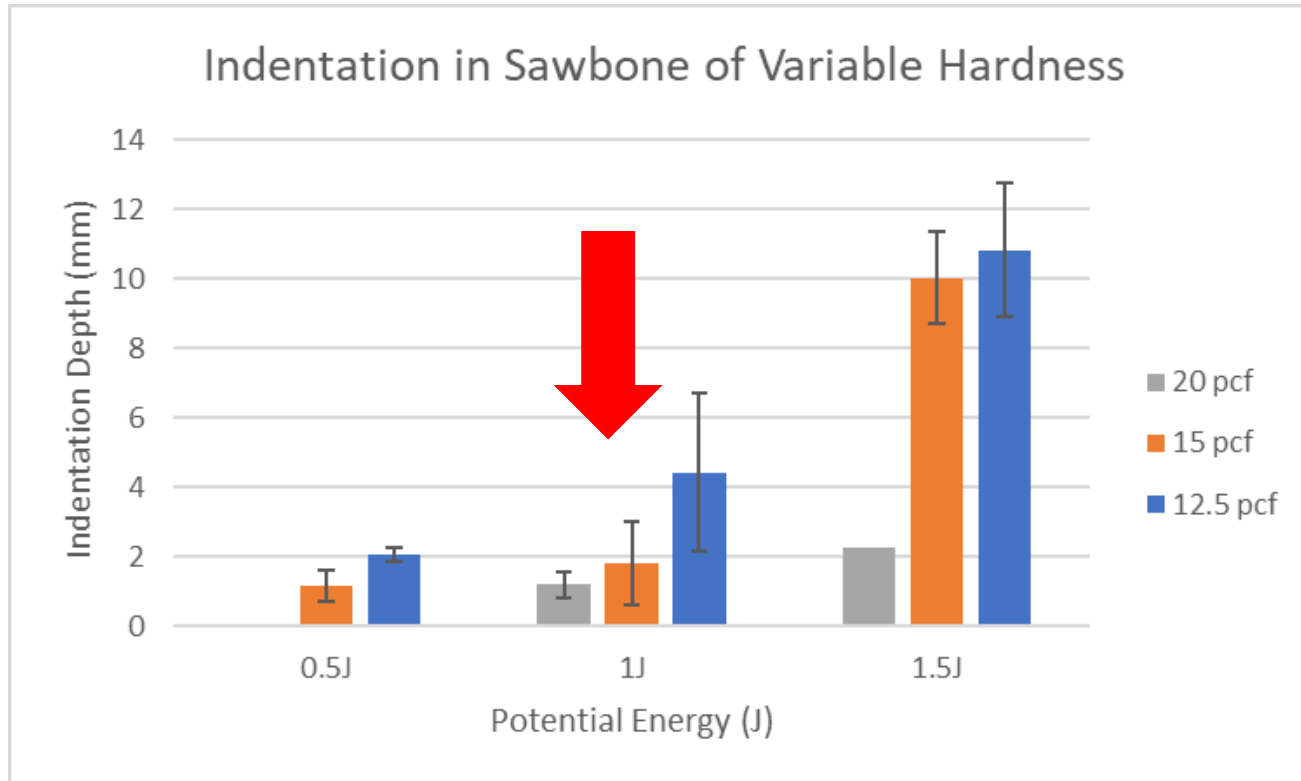
$$PE = \frac{1}{2}kx^2$$

- Largest indentation depth at 1.5J

- No indentation of 20 PCF at 0.5J

- Target PE = 1J

Abrea Green

Design Refinement
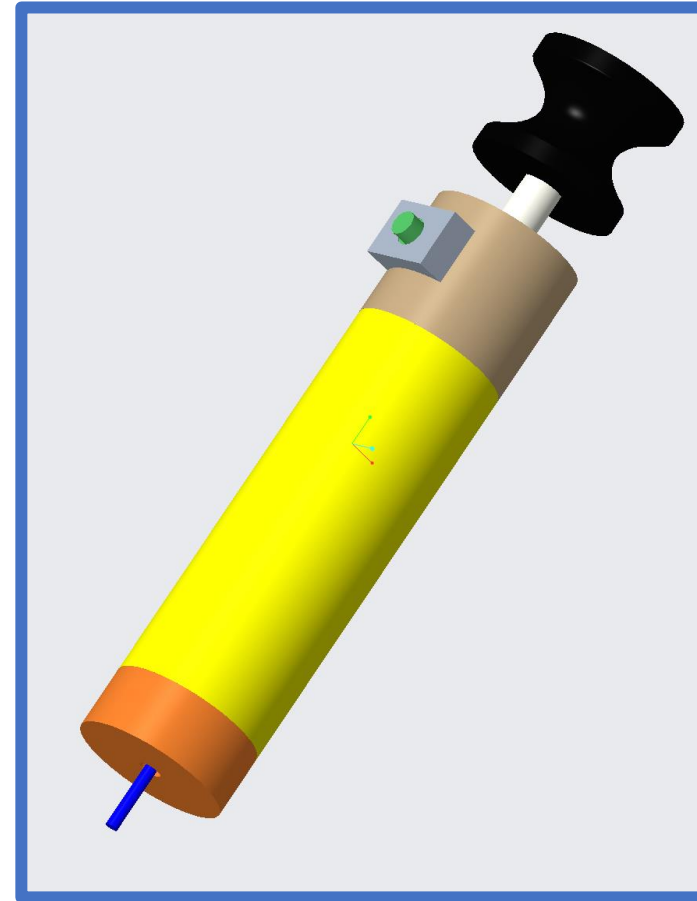
Tessany Schou

Current Method of Release

Free Position
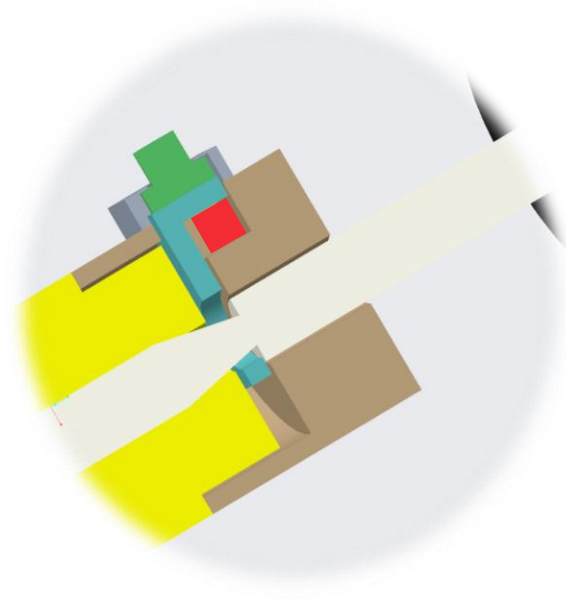
Loaded Position

Tessany Schou

Current Method of Release

Free Position
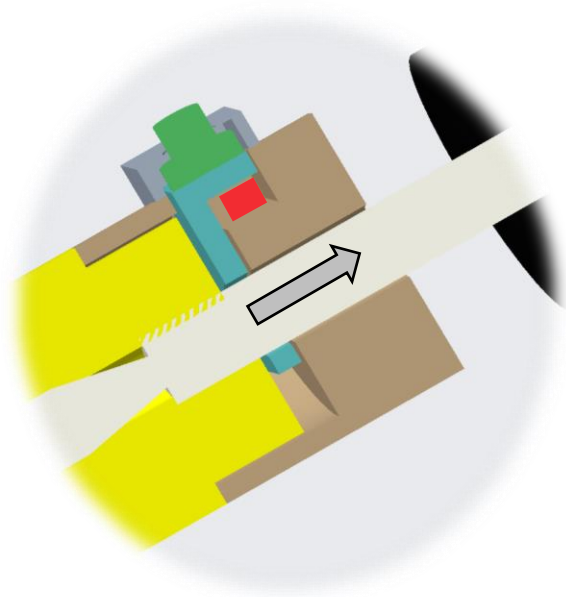
Loaded Position
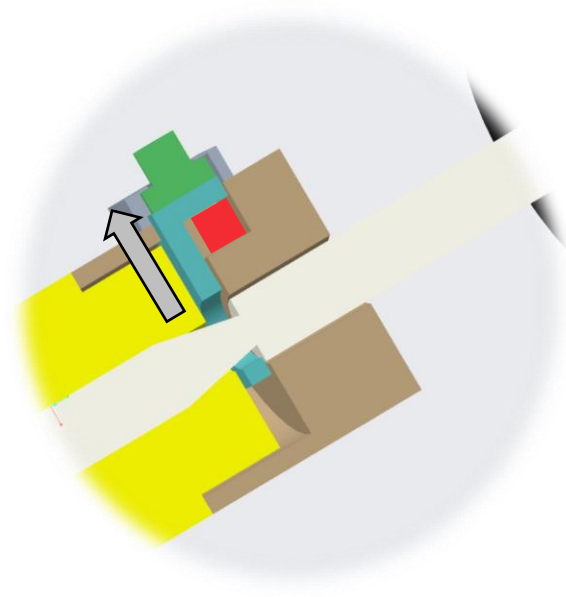
Tessany Schou

Internal Design
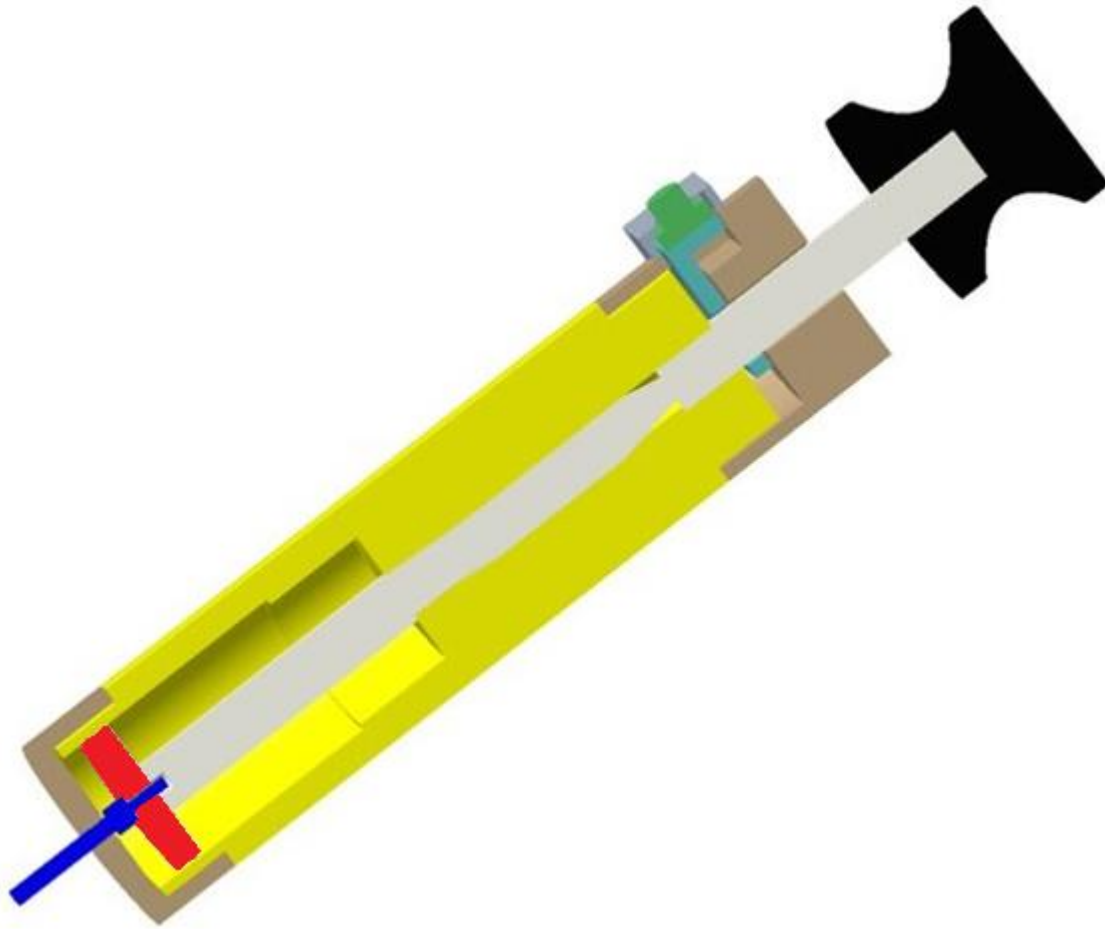
- Visit to Machine shop
  - Feedback on design

- Changes
  - Removable tip
  - "Washer"
  - Sealing
  - Welding

Timothy Surface

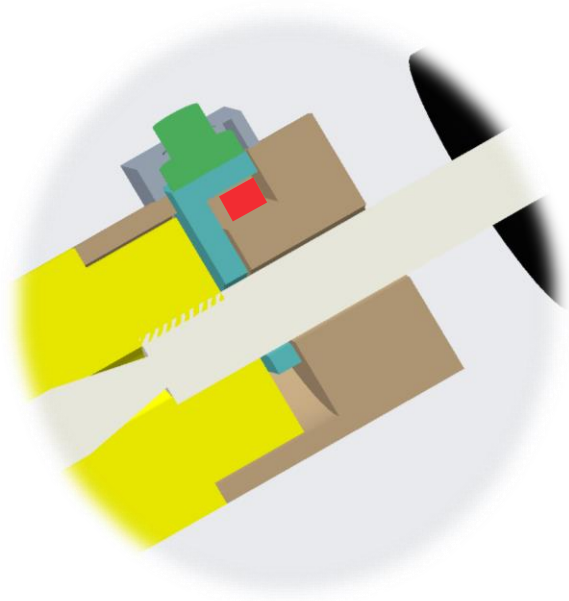# Readout
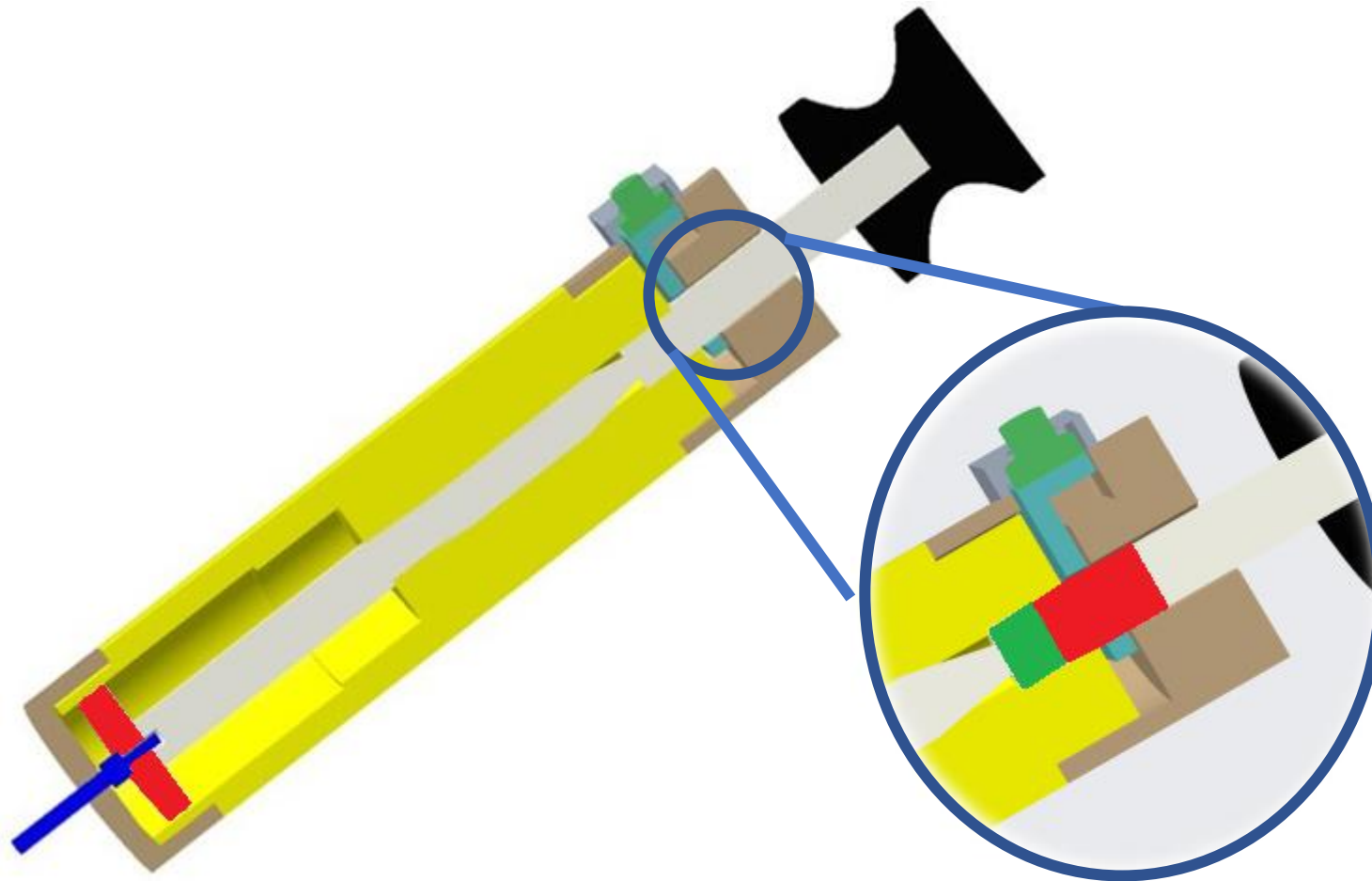
Timothy Surface

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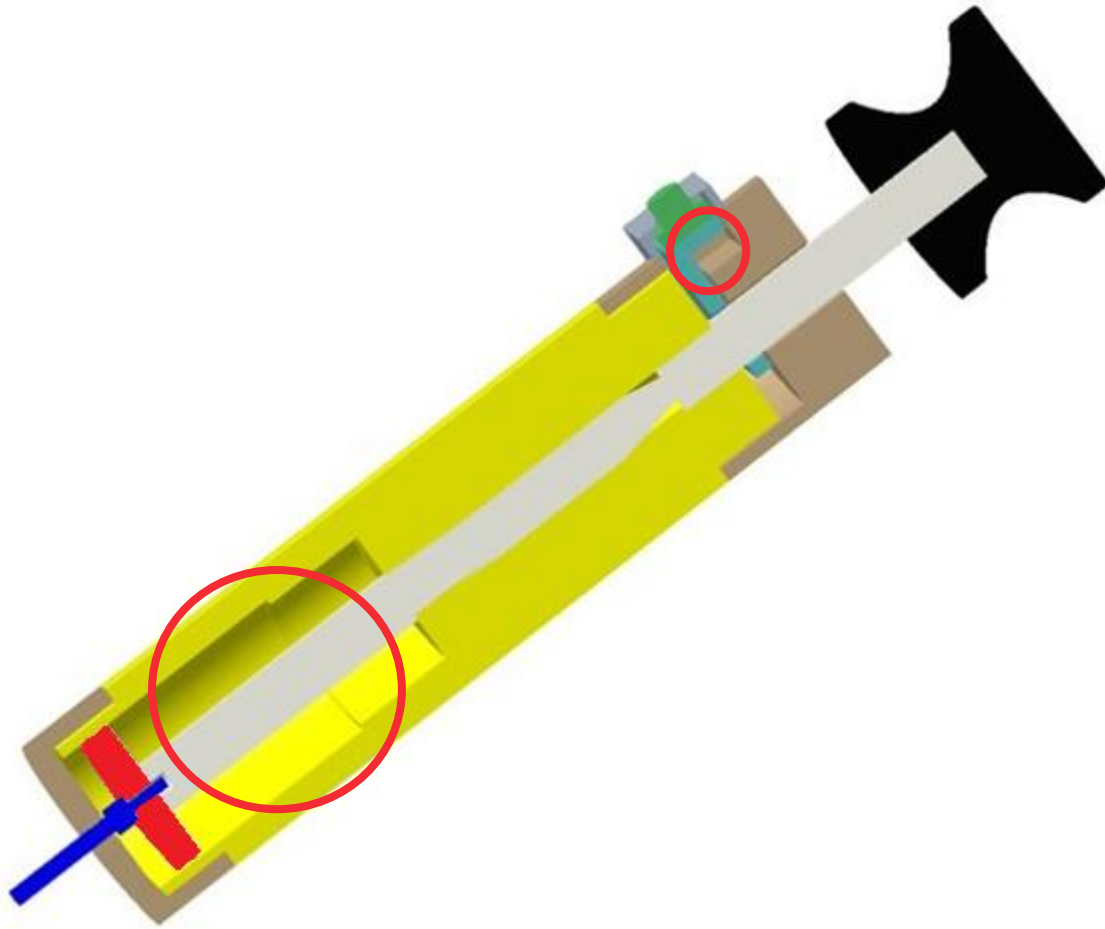
- Housing and Caps
- Rod
- Tip
- Button Components
- Spring

Timothy Surface

Validation Testing

Physical specifications

Repeatability and wear on device

Design Verification

Indentation depth and sawbone damage

Sterilization
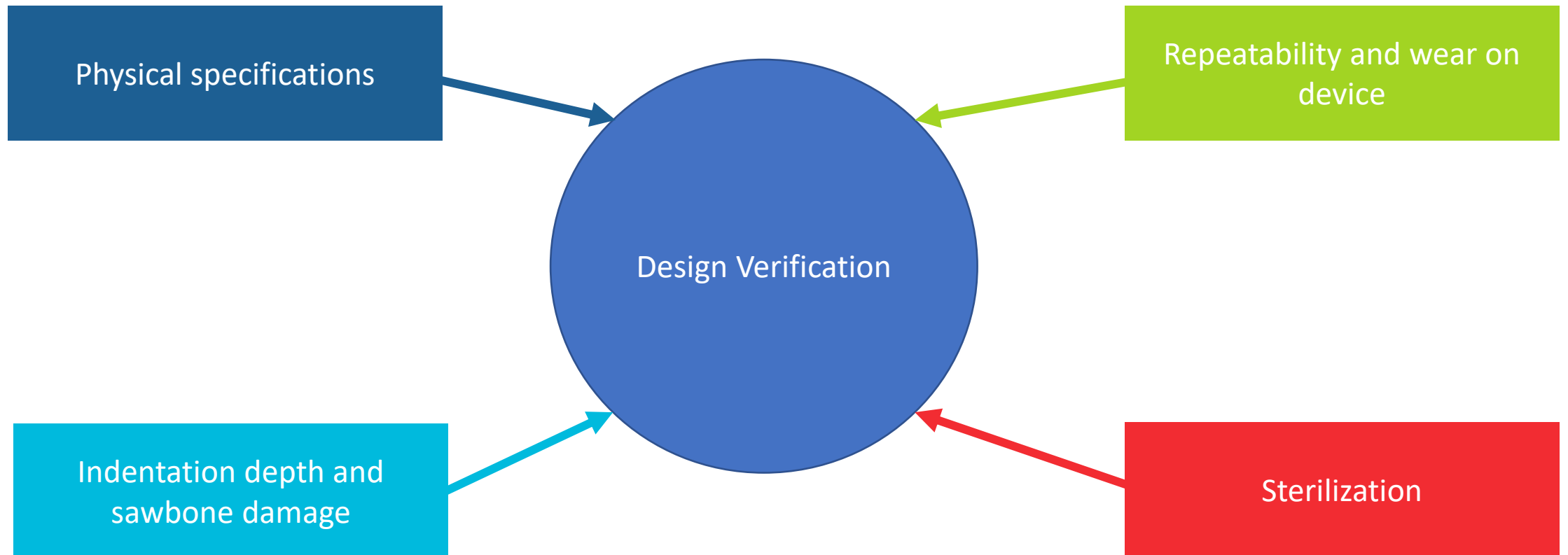
Timothy Surface

Validation Testing

1. Loaded spring into completed prototype
2. Fired into 4 different PCF sawbone blocks with 3 different orientations:
   - Horizontal
   - 45° Angle
   - Vertical
3. Indentation depth was measured using calipers

Grant Giorgi

FAMU-FSU
Engineering

Validation Testing Results

Average Indentation Depths for Angle of Incidence
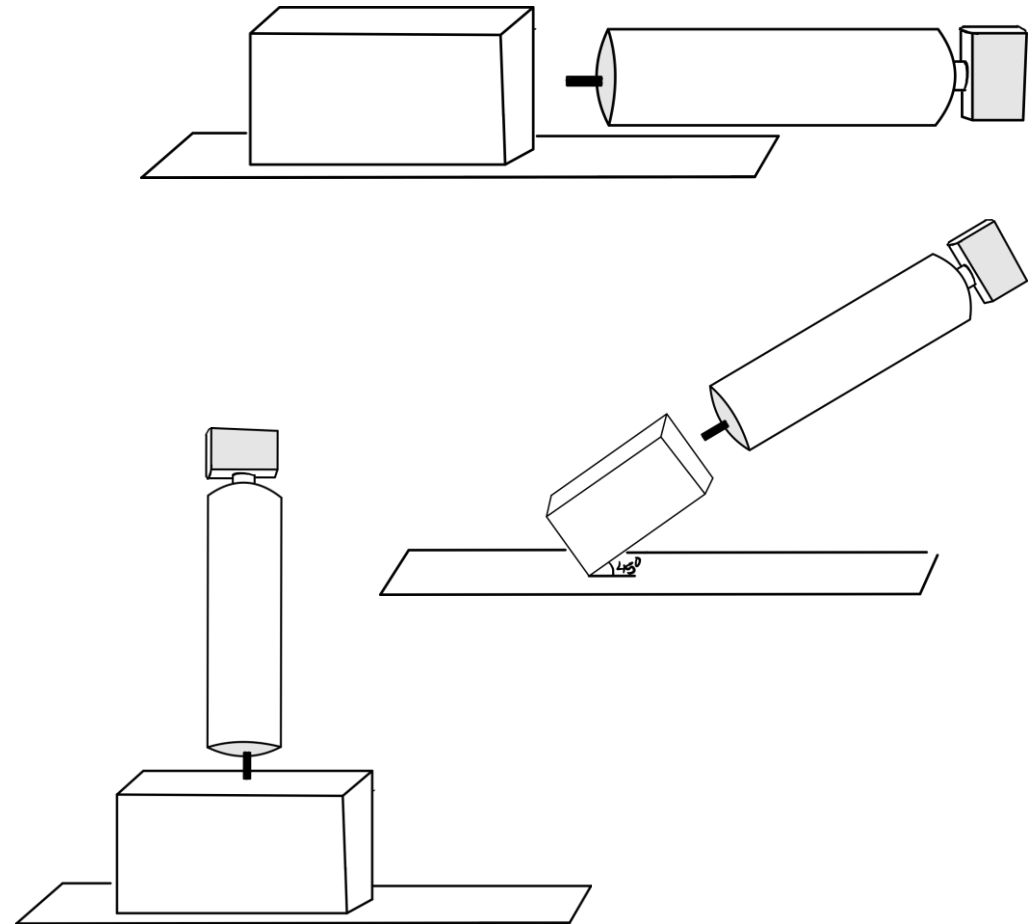
Grant Giorgi

Validation Testing Results

Nick Vastano
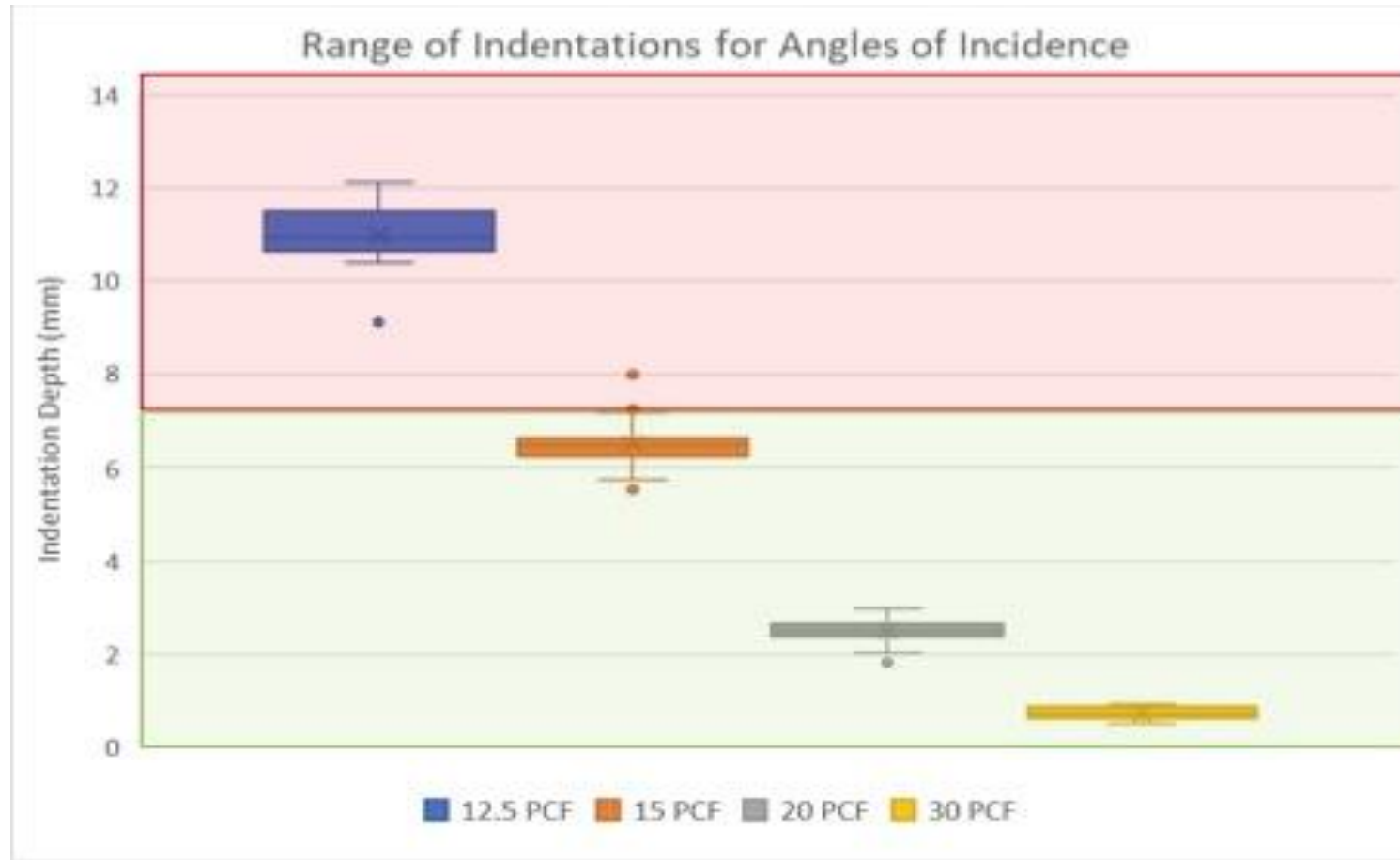
Depth Gauge
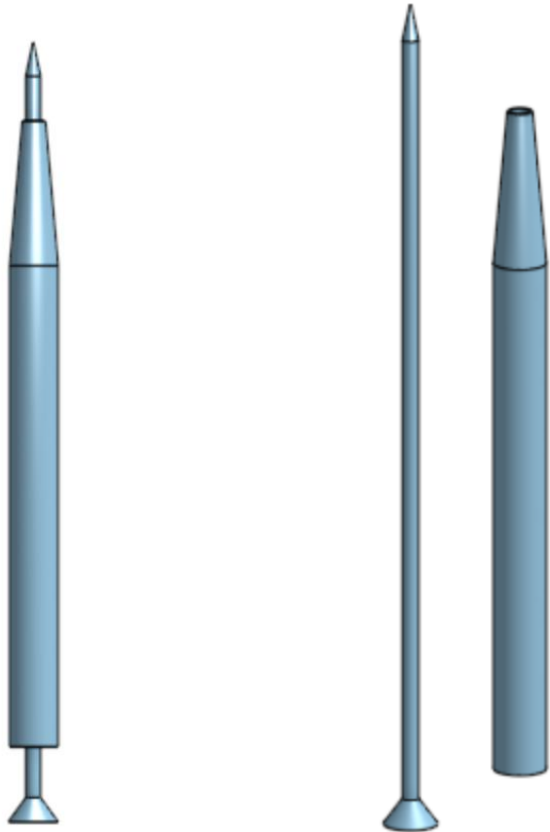
- Diameter is small enough to provide measurements from the device

- Simplistic and cost-efficient design

- Sterilizable

Erin Petkus

Validation Testing Results

Target	Validation
Compliant with FDA regulations	Exempt or 510k
Device withstands temperatures up to 284 °F	Yes
Creates indentation less than or equal to 1 in.	Yes
Weighs less than or equal to 5lbs	Yes
Length of device is smaller than 6 in.	Yes
Lifespan greater than 50 uses	Yes
Reports results with 95% accuracy	Yes

Timothy Surface

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Future Work

Detailed Validation Data Review

Improvements to Design

Design for Production
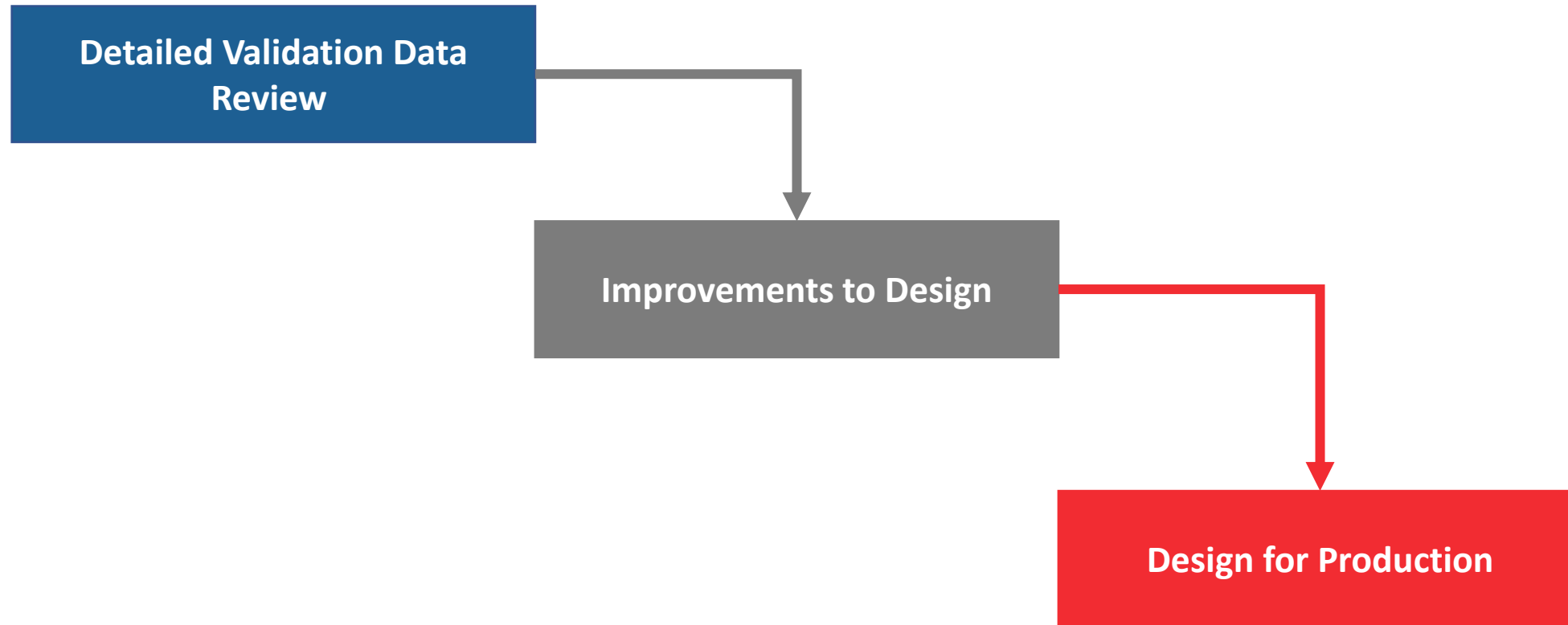
Timothy Surface

Lessons Learned

Nothing works correctly the first time

Everything takes longer than you expect

Spending time planning early on saves time later

Talk to experts

Timothy Surface

4 Most Important Points

1. Project is to develop a device to measure bone quality.

2. Prototype completed

3. Conducting validation testing

4. Incorporating changes into a final design

Timothy Surface

Department of Mechanical Engineering
Department of Biomedical Engineering

FAMU-FSU
Engineering

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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Reeves, J. M., Vanasse, T., Roche, C., Athwal, G. S., Johnson, J. A., Faber, K., & Langohr, D. G. (2017). *Proximal Humeral Density Correlations: Are We "Thumb Testing" in the Right Spot?* ORS.
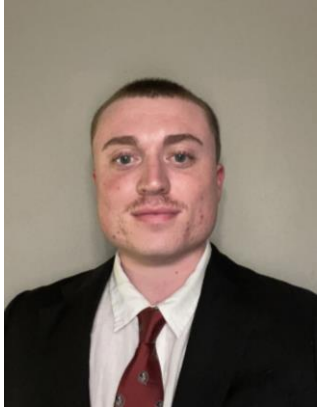
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Reference

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

Timothy Surface

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