SAN DIEGO STATE UNIVERSITY

ME 683 - Group Design Project

Ayleen Mendoza, Sahithi Lingala, Kevin Medici

Mechanical Engineering Department, San Diego State University

5500 Campanile Drive, San Diego, CA 92182

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DESIGN INPUT

Background, Medical Need, Anatomy, Function & Medical conditions that require the device solution

Intramedullary rods (IM rods) are long metal rods inserted into the medullary canal of a bone to stabilize fractures. Arm movement and structural support are greatly aided by the humerus, the long bone of the upper arm that connects the shoulder to the elbow. Along its length, it shields important blood arteries and nerves, forms a portion of the elbow and shoulder joints, and gives muscles places to connect. For humeral fractures, IM rods offer several advantages, including less invasive surgical techniques, reduced soft tissue trauma, quicker recovery times, and the ability to maintain alignment in diaphyseal fractures. Humerus fractures account for approximately 5-10% of all fractures, with proximal humerus fractures alone making up about 4-5%. The need for IM rods is driven by the rising incidence fracture especially from accidents and sports and an aging population. The global orthopedic trauma device market is projected to reach $12-14 billion by 2030, growing at 6-8% annually. The rods will be especially important in regions experiencing high trauma rates and healthcare advancements.

Identification of predicate device

A. Predicate Device: Tornier IM Nail Humeral Fracture System
B. 510 (K) Number: K241484
C. Device Class: II
D. Product Code: HSB
    a. Comparing the Devices: Accurod's design will differ from the predicate device because of the variation in the proximal bend angle. By doing this, the chance of irritation will be reduced because there will be less contact between the rod and the tissue. We will have the same number of holes on the proximal and distal ends as the predicate device to allow for the same fixation possibilities in both, and the technological features will be identical to those of the rod. Accurod's design will also have a smaller diameter as compared to the Stryker model to further reduce tissue contact and irritation.
    b. Substantial Equivalence: The AccuRod has the same intended use and technological characteristics as the predicate device and therefore can be deemed substantially equivalent

Engineering specifications

A. List of Components and their Critical Dimensions
    a. Intramedullary Rod: Titanium Alloy Ti-6Al-V4
    b. Length: 250 mm (Adult Male Humerus: ~304 mm)
    c. Proximal Diameter: 8.9mm (Medullary Canal of Humerus: ~12 mm)
    d. Distal Diameter: 8.5 mm
    e. Proximal Screw: Titanium Alloy Ti-6Al-V4
    f. Length: 33.59 mm
    g. Diameter: 5mm
    h. Distal Screw: Titanium Alloy Ti-6Al-V4
    i. Length: 25.53 mm
    j. Diameter: 4mm
B. Desired Material and Mechanical Characteristics
    a. **Titanium Alloy Ti-6Al-V4 (Grade 5)**
    b. Young Modulus: 113.8 GPa
    c. Flexural Modulus: 110 GPa
    d. Tensile Strength, Yield: 880 MPa

e. Biocompatible, Low stress-shielding

C. Proposed manufacturing and assembly
    a. Manufacturing:
        i. The material, Titanium Grade 5, will undergo a forging process to achieve the rough shape of the intramedullary rod. Forging occurs by heating the metal to a high temperature allowing the titanium to mold into the desired shape. During the heating stage, the material is more malleable and easier to shape, reducing the stress during deformation. Once cooled, the metal will recrystallize allowing for smaller grains to form. This new grain structure improves the mechanical properties, such as the strength, demonstrating that forging is an ideal manufacturing process for this application.
        ii. Machining techniques such as turning, drilling, and milling are then utilized on the forged titanium to remove any excess material. The device is mounted on a lathe where turning is used to achieve a uniform diameter along the shaft. Milling occurs on a cutting tool where the device can be customized to the design. This is where specific shapes, contours, or geometries will be cut into the design. Drilling is used to cut holes into the rod. The holes are typically cut using a drill and positioned for the screws to be placed securely.
        iii. The rod is then polished to remove any irregularities or imperfections from the machining process. A smooth surface optimizes the device by minimizing wear, friction, and tissue irritation.
        iv. To complete the machining process, the rod will go through a final heat treatment step. This will include a technique such as stress-relief annealing, eliminating residual stress introduced during machining. This will further enhance the mechanical strength, fatigue resistance, and durability of the material, ensuring its safety for medical applications.
    b. Proposed Assembly:
        i. The IM rod is a single part that will be held in place using screws or bolts.

    c. <u>Proposed sterilization</u>
        i. Sterilization will be Ethylene Oxide. EtO gas is effective at low temperatures. It can penetrate complex geometries, ensuring the sterility of the entire device. However, strict adherence to aeration procedures is required to remove residual gas.

<u>List of design constraints and assumptions</u>

A. Geometric (based on anatomy, dimensions)
    a. Compatible with the anatomy (humerus dimensions) of a range of patients. The length of the rod must match the length of the typical humerus. The diameter must fit within the medullary canal
    b. Must accommodate all screws on proximal and distal ends
    c. The rod is for comminuted, transverse, oblique, and spiral fracture
B. Materials (hard vs soft, avoid mismatch with native tissue; biocompatible, durable for application)
    a. The design must be biocompatible. Must be non-toxic and not elicit an immune reaction
    b. The rod should mimic the bone characteristics so as not to disrupt bone growth/damage the bone plates.

    c. The material must be strong enough to bear the physiological loads of humerus without breaking
    d. Must have a smooth finish to minimize irritation
    e. Must be designed to last for the intended duration of healing
C. Function (motion/deformation)
    a. Effectively transfer load across fracture site to ensure proper healing
    b. Designed to allow normal shoulder movements post-implantation
    c. Should be able to tolerate minor deformations from bearing load on humerus
D. Include all components (list separately)
    a. Rod body: Provides structural stability and maintains alignment of the fractured segments
    b. Distal and Proximal Screws: Provides stability to the rod in the bone to maintain alignment at the top of the bone
E. Safety
    a. The device must meet FDA regulations.
    b. The Intramedullary Rod will meet the ASTM F1264 standard
    c. The rod will be tested alongside the predicate to ensure durability

DESIGN OUTPUT

Features of the device solution (degree change)

A. Accurod's design will differ from the predicate device because of the variation in the proximal bend angle. By doing this, the chance of irritation will be reduced because there will be less contact between the rod and the tissue. Accurod will also have a smaller diameter which will further reduce the contact with tissue reducing the irritation.

List of materials and possible sources

A. Table 1. Bill Of materials

IM Rod Part	**Material**	**Amount**	**Vendor**	**Description**
Main Rod (Body)	Titanium Alloy Ti-6Al-4V	1	Magellan Metals	Provides structural stability and maintains alignment of the fractured segments.
Proximal Screws	Titanium Alloy Ti-6Al-4V	4	Magellan Metals	Provides stability to the rod in the bone to maintain alignment at the top of the bone
Distal Screws	Titanium Alloy Ti-6Al-4V	3	Magellan Metals	Provides stability to the rod in the bone to maintain alignment at the bottom of the bone

Component and assembly drawings Analysis of the device under appropriate loading conditions

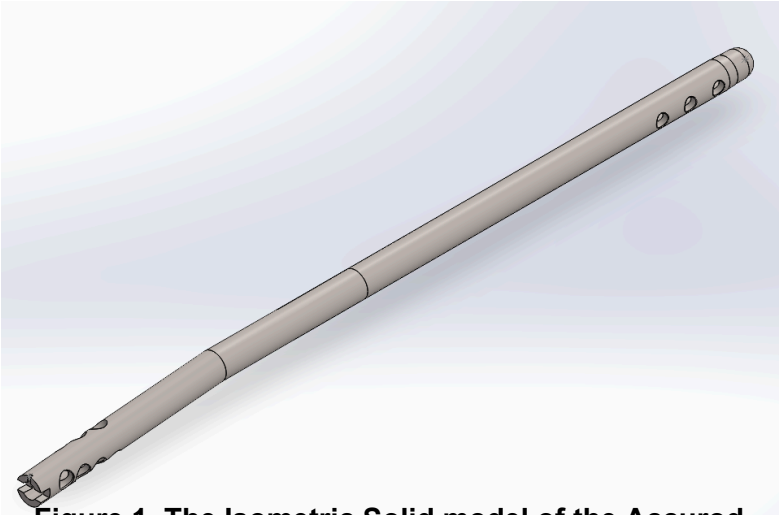

Figure 1. The Isometric Solid model of the Accurod

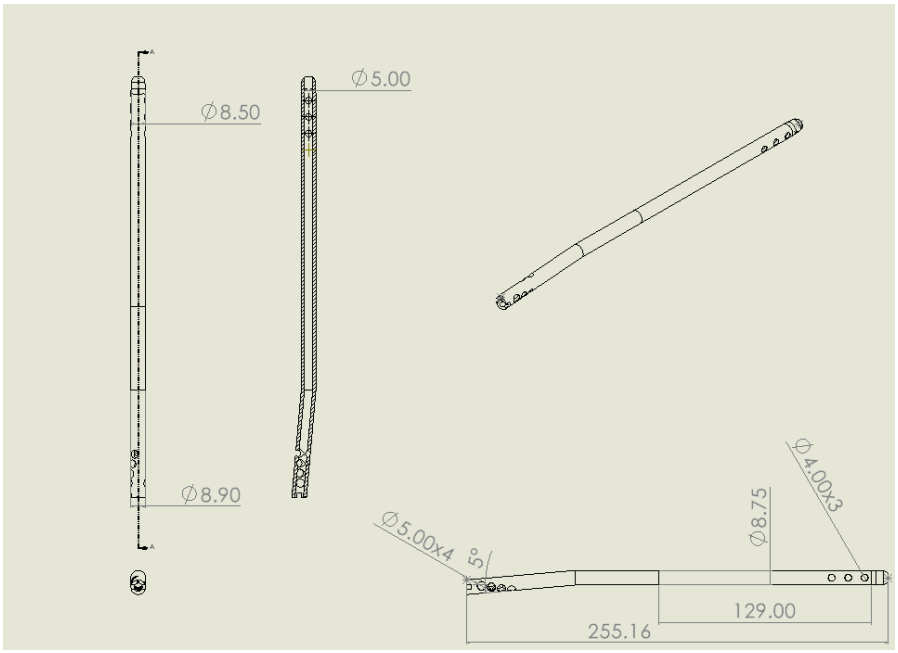

Figure 2. Units in Millimeters. Dimensions of the Accurod

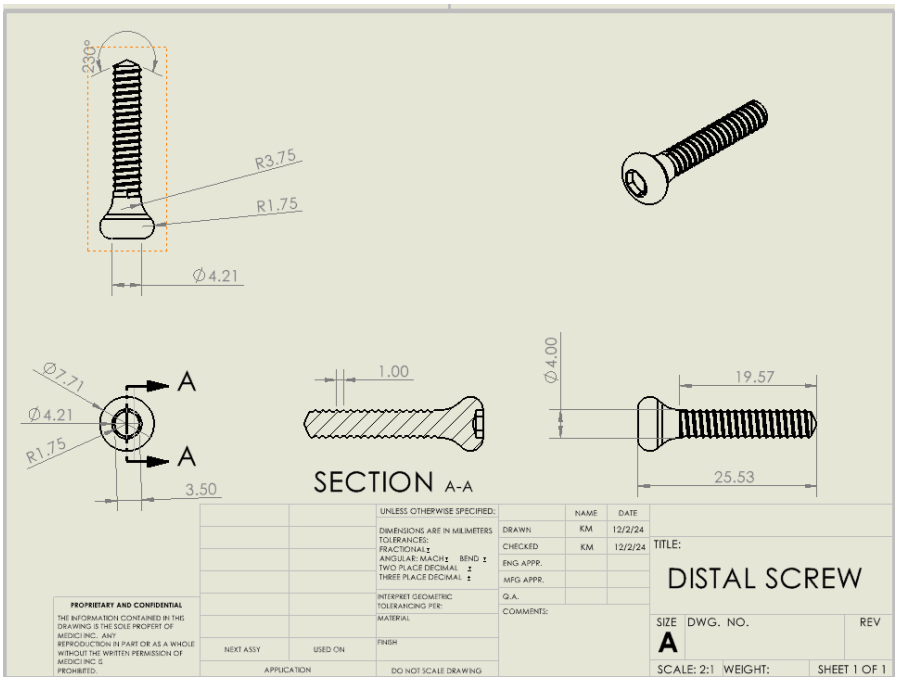

Figure 3. Units in Millimeters. Dimensions of the Distal Screws

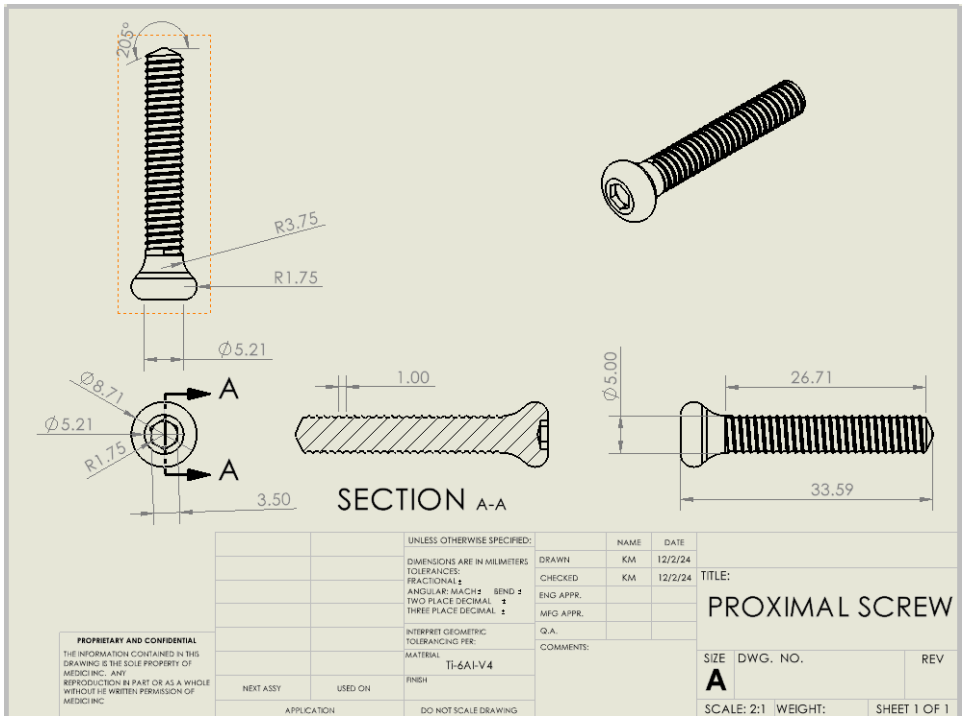

Figure 4. Units in Millimeters. Dimensions of the Distal Screws

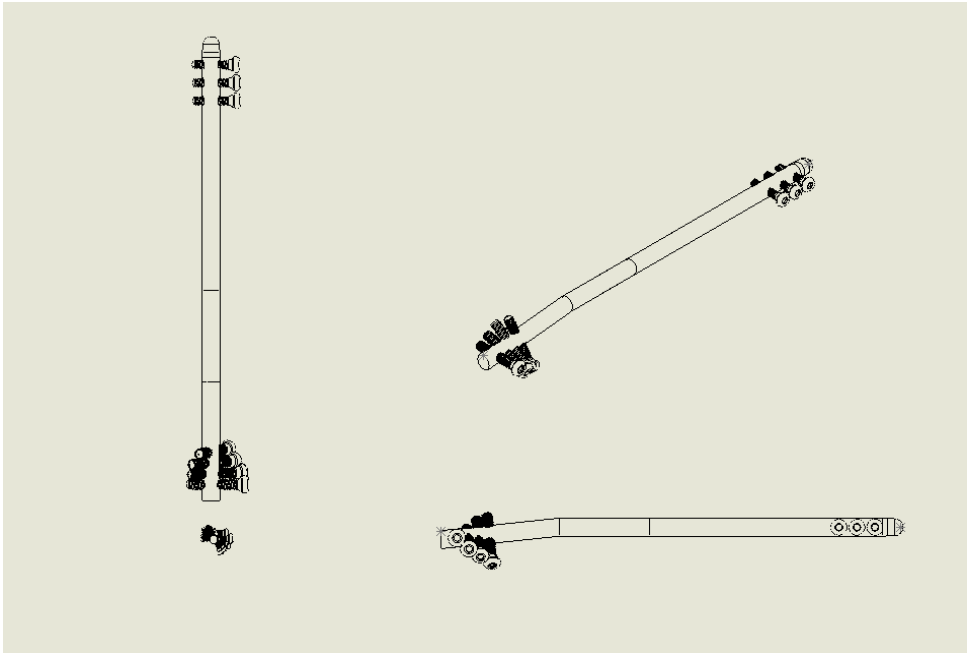

Figure 5. Assembly drawing of the Accurod and screws

Analysis of the device under appropriate loading conditions

A. Define conditions based on native structures/tissues
    a. The assumptions about the finite element analysis (FEA) is that the rod will be simplified to be able to create a rough estimate of how the forces will act on the rod to ensure the rod can maintain proper shape. The rod is bent at a 5 degree angle to fit the humerus bone relatively, but it is decreased relative to the predicate device to reduce the amount of irritation of the humerus bone. The humerus bone has an average diameter of 19.3mm and the bend on the humerus will vary but it has an angle of 5-10 degrees.
B. Consider each type of loading separately and combined (e.g. compression, torsion, flexion, extension)

Three point bending test

The intramedullary rod is assumed to increase the strength of the overall humerus bone when inserted. To observe the strength of the rod a finite element analysis (FEA) is done to determine how much the rod can bend. The points of fixation for the three point test were followed by the ASTM standard F1264-16 for the range of spans to be at three points where one fixation point was 13.5mm away from the top and one fixation point was 13.5mm away from the bottom of the Intramedullary rod; therefore, the fixtures are 218mm apart. This was more logical to test the force acting on it for the accuracy of seeing where the whole rod would have a force acting on it to calculate the maximum moment.

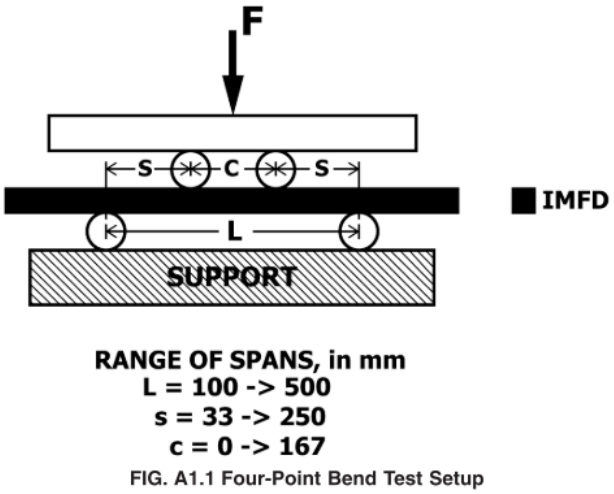

Figure 6. ASTM F1264-16 standard Four Point Bend Test

A. Two scenarios were analyzed:
    1. The worst case scenario where the rod should break is where the yield stress is used to calculate the force.
    2. The case where the average torque to break the human humerus bone is used to calculate the force.

Scenario 1.

The worst case scenario where the rod will break is calculated by the following:

$$\sigma_{yield} = \frac{FL}{\pi(R_o^3 - R_i^3)}$$ equation 1.

Where
F is the force applied to the middle of the intramedullary rod.
L is the support span of the rod at 0.228m.
R_o is the outer radius of the rod at 0.00445m.
R_i is the inner radius of the rod at 0.0025m.
σ_{yield} is the yield strength of the titanium rod at 880×10^6pa

We can rearrange this equation to obtain the force:

$F = \frac{\sigma_{yield}\pi(R_o^3 - R_i^3)}{L}$ equation 2.

This yields $F = 785.97N$. Therefore when we apply a force along the middle of the rod to get a displacement that will show the most displacement will be within the middle of the rod until it breaks.

The bending moment can then be calculated as follows:

$M = \frac{F \cdot s}{2}$ equation 3.

Where,
M is the maximum bending moment.
F is the maximum force applied at 785.97N.
s is the span where the fixtures are applied at 0.076m.

The bending moment is calculated to be 29.87Nm to break the rod.

TABLE A1.4 Precision Statistics for Ultimate Bending Moment, M_{MAX}

Specimen Group	Mean (N-m)	S_r^A	S_R^B	r^C	R^D	No. of Labs
A	237.22	1.75	2.77	4.90	7.76	7
B	107.15	1.44	4.15	4.04	11.61	7
C	12.75	0.18	0.27	0.49	0.75	7

[A] S_r = within-laboratory standard deviation of the mean.
[B] S_R = between-laboratories standard deviation of the mean.
[C] $r = 2.83\ S_r$.
[D] $R = 2.83\ S_R$.

Figure 7. ASTM F1264-16 Maximum Bending Moment

From the figure above the mean maximum moment will vary for each specimen studied from 12.75-237.22Nm; this implies that the rod will be between the mean ultimate bending moment, ensuring a safe design abiding by the ASTM standard F1264-16.

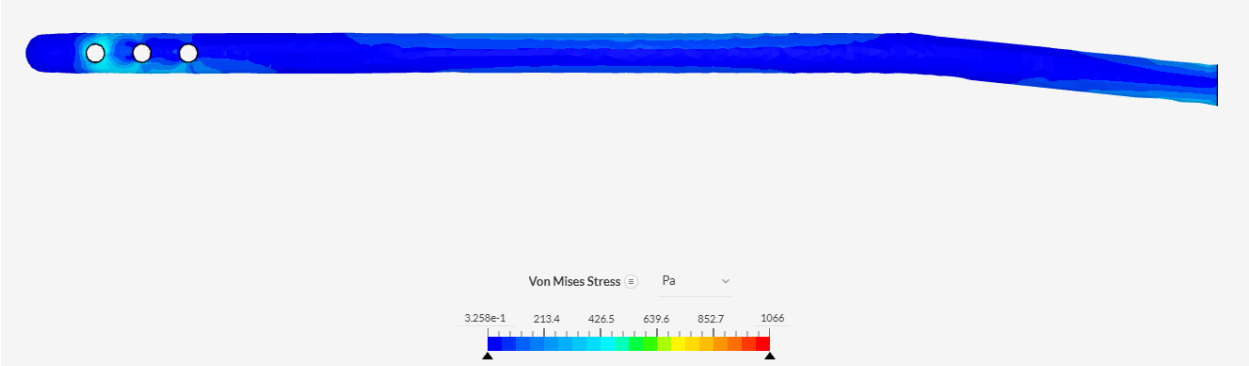

Figure 8. Von Mises Stress for a Three Point Bending Test

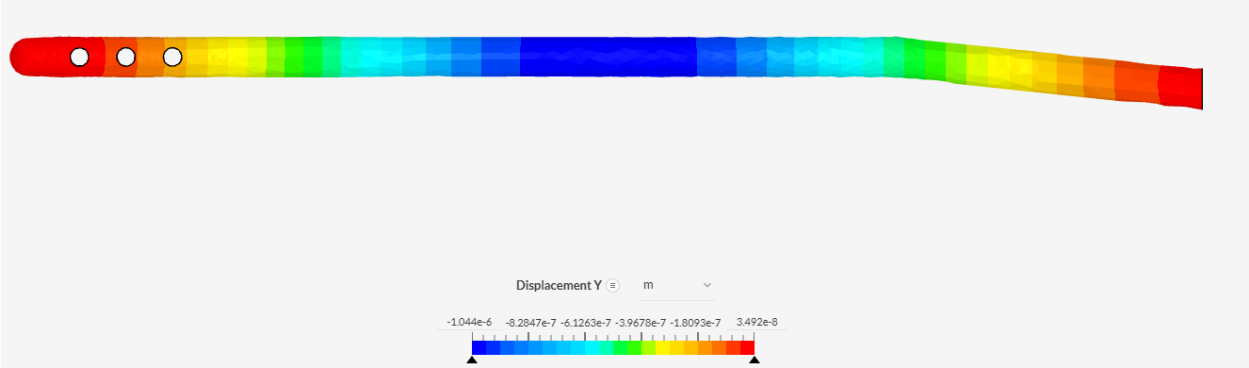

Figure 9. Displacement in the y direction for a Three Point Bending Test

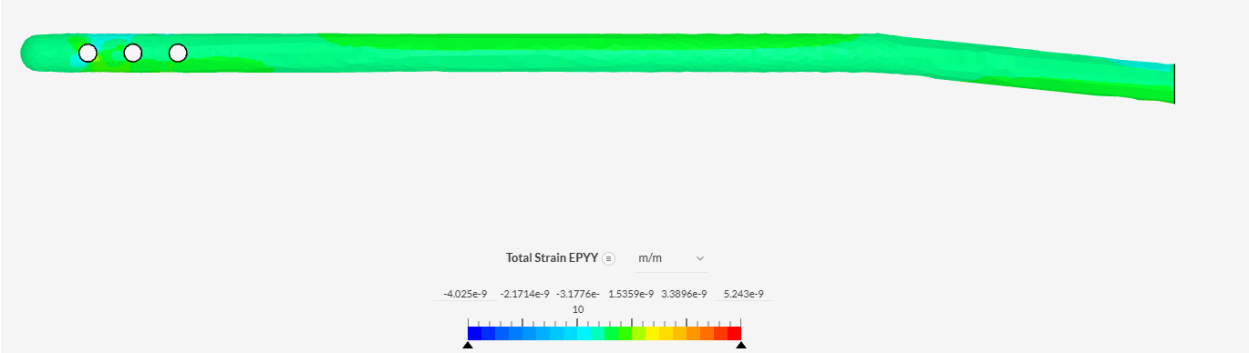

Figure 10. Total Strain in the yy direction for a Three Point Bending Test

From figure x we can see that the maximum strain (S_{max}) is approximately $1.37 \times 10^{-8} \frac{mm}{mm}$.

Scenario 2.

The case scenario where the bone will break is calculated by the following:

The average symmetrical torque necessary to break the bone of a female tester is around 88.04 Nm.

The equation for the Torque is the following:

$T = r \cdot F \cdot sin(\theta)$ equation 4.

Where,

T is the average torque to break the humerus at 88.04Nm

F is the average force needed to break the humerus.
r is the average moment arm for the humerus at 0.23m
θ is the angle where the force is applied at 90 degrees
This implies the force is determined as:

$F = \frac{T}{r \cdot sin(\theta)}$ equation 5.

This implies the force will be 3.83N.

The bending moment can then be calculated from equation 3. as follows:
$M = \frac{F \cdot s}{2}$
Where,
M is the maximum bending moment.
F is the maximum force applied at 3.83N
s is the span where the fixtures are applied at 0.076m.

The bending moment is calculated to be 0.146 Nm to break the humerus bone.

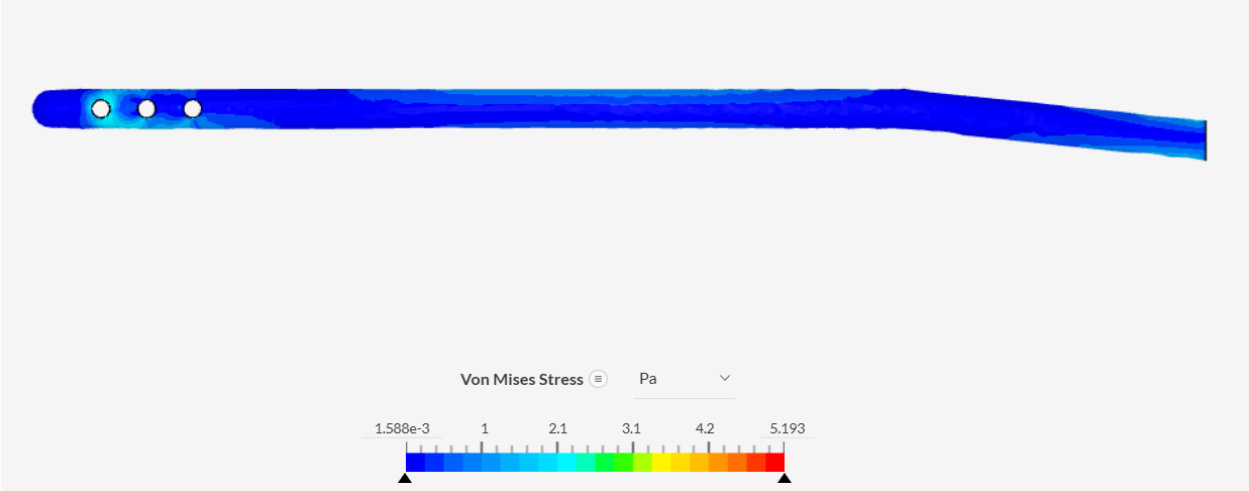

Figure 11. Von Mises Stress for a Three Point Bending Test

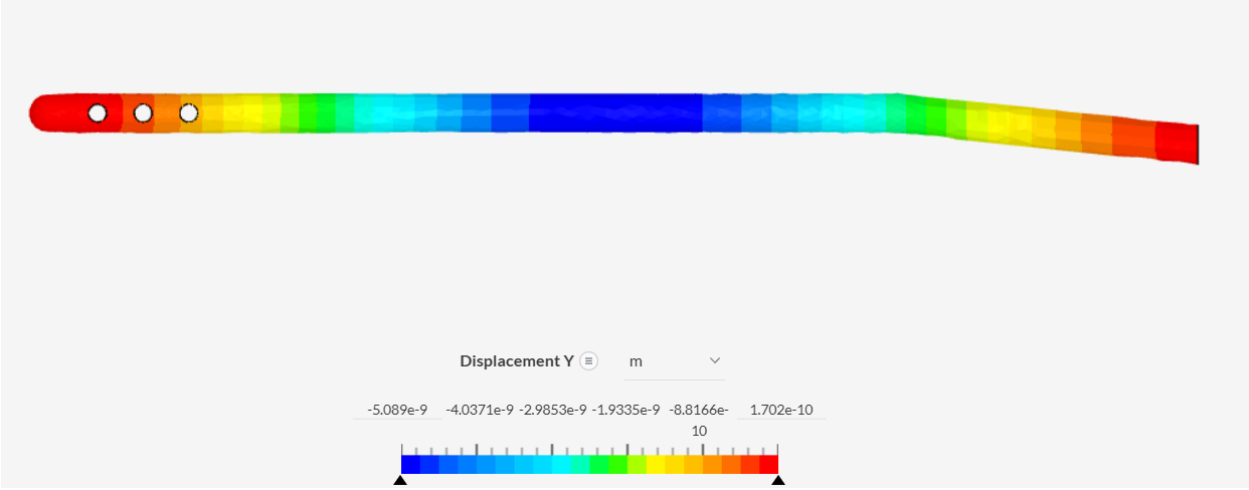

Figure 12. Displacement in the y direction for a Three Point Bending Test

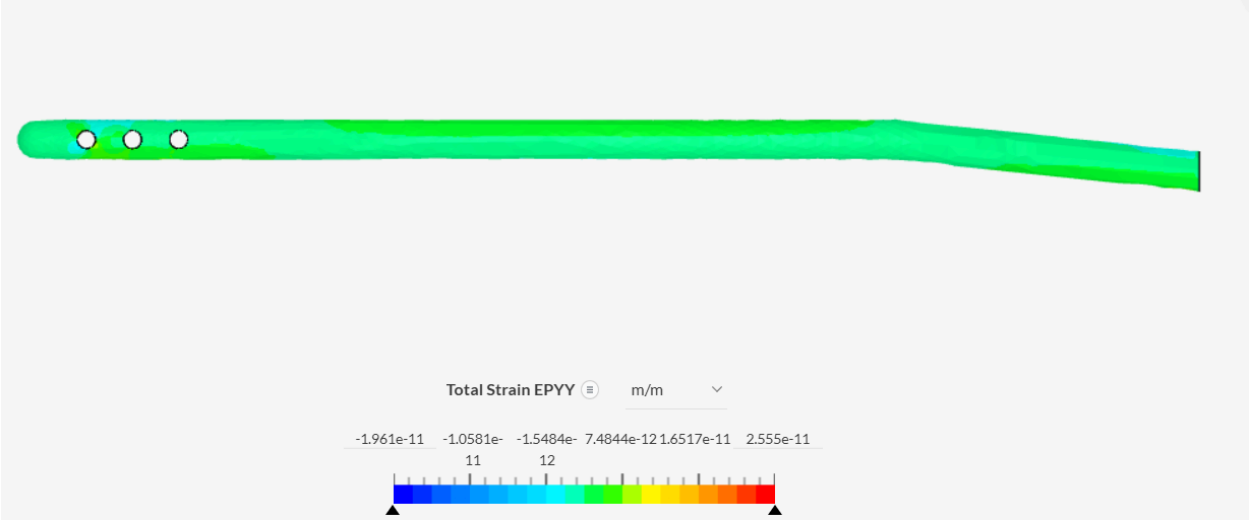

Figure 13. Total Strain in the yy direction for a Three Point Bending Test

Compressive Strength Test

To do a compressed strength test there is a fixed support on the lowest distal hole and a force is applied to the diameter of the rod on the proximal side.

To determine the maximum amount of stress until breaking the rod from a force acting perpendicular to the hole; the equation is as follows:

$F_{yield} = \sigma_{yield} \cdot A$ equation 6.

Where,

$A = \pi((\frac{D_{outer}}{2})^2 - (\frac{D_{inner}}{2})^2)$ equation 7.

$D_{outer} = 0.0089m$

$D_{inner} = 0.005m$

$\Rightarrow A = 42.6 \times 10^{-6} m^2$

σ_{yield} is the yield strength of the titanium rod at 880×10^6pa

F_{yield} is the maximum force applied.

The F_{yield} yields 37,467.26N to break the rod.

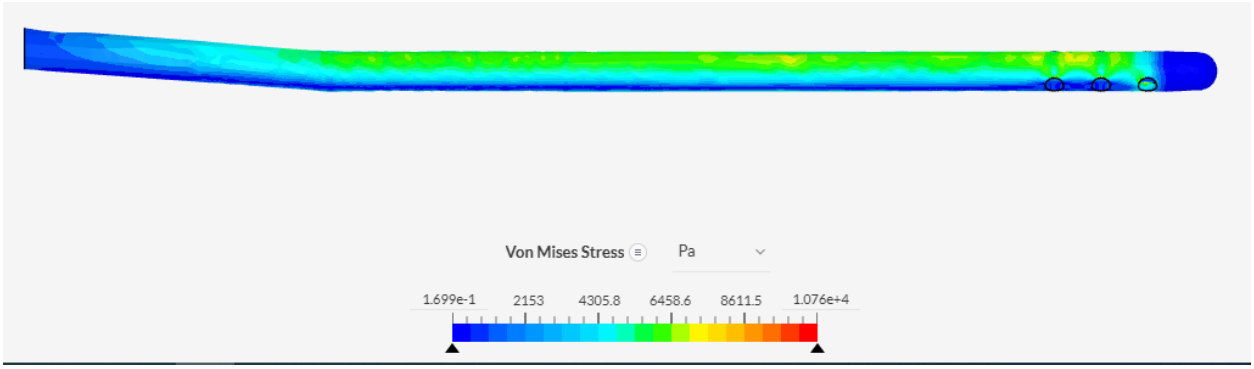

Figure 14. Von Mises Stress for a Compression Strength Test

The figure 14 shows that the rod stress would be along the side where the bend is.

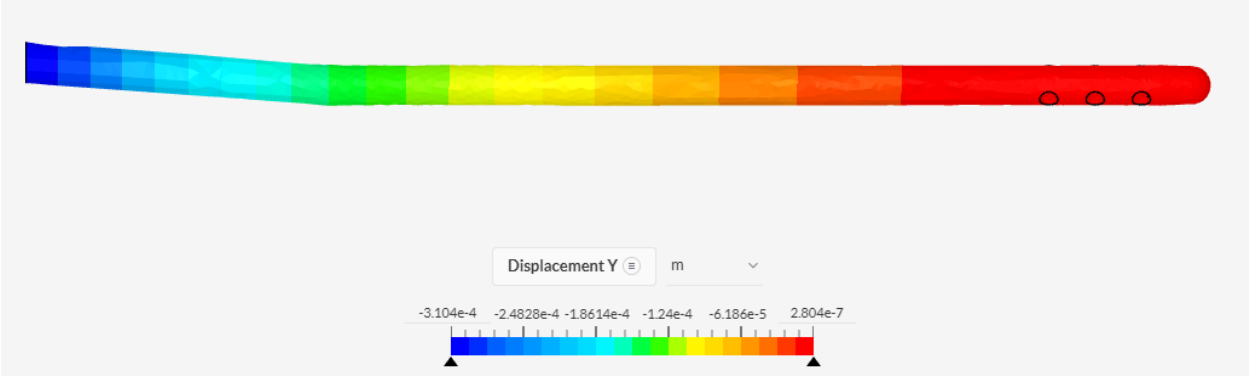

Figure 15. Displacement in the y direction for a Compression Strength Test

The figure 15. Shows that the displacement is mostly at the distal end.

Torsional Strength Test

The torsional strength test will abide by the ASTM standard F1264-16 where the fixed supports were at the distal hole and the proximal diameter face for the torque applied to the rod.

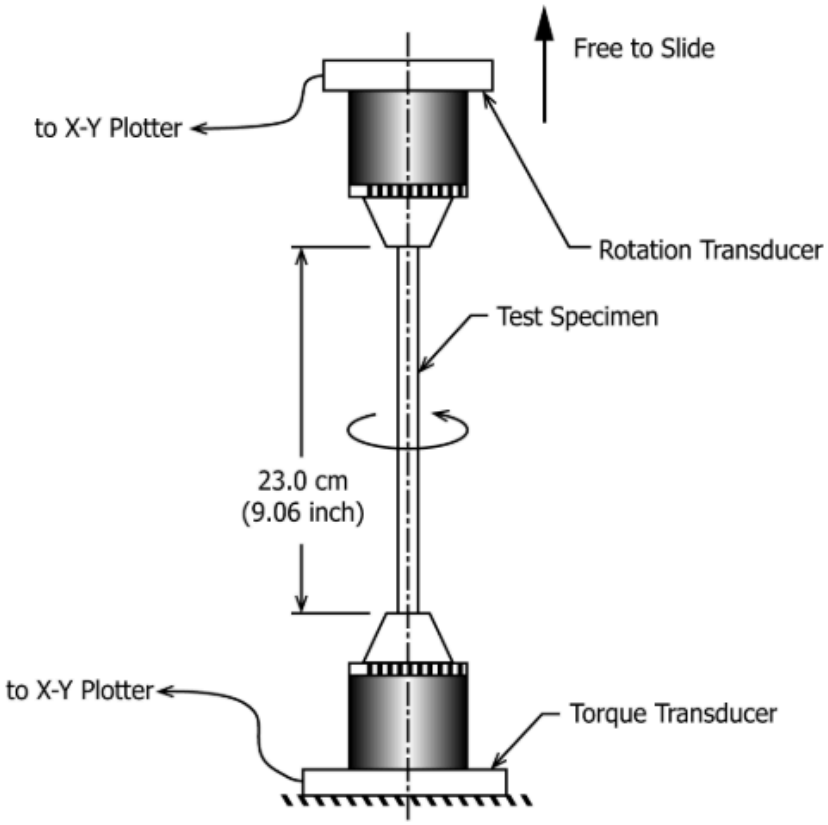

Figure 16. ASTM F1264-16 standard Torsional Test

To determine the amount of torsion needed to break the rod the following equation will be used:

$T = \frac{\tau J}{r_o - r_i}$ equation 8.

T is the torque to break the rod.

τ is the shear stress needed to break the rod at $550 \times 10^6 pa$.

r_o is the outer radius of the rod at .00445m.

r_i is the inner radius of the rod at .0025m.

J is the polar moment of inertia $J = \frac{\pi}{2}((\frac{D_{outer}}{2})^4 - (\frac{D_{inner}}{2})^4)$ equation 9.

$D_{outer} = 0.0089m$

$D_{inner} = 0.005m$

$\Rightarrow J = 5.55 \times 10^{-10} m^4$

This implies that the Torque to break the rod would be 156.42Nm

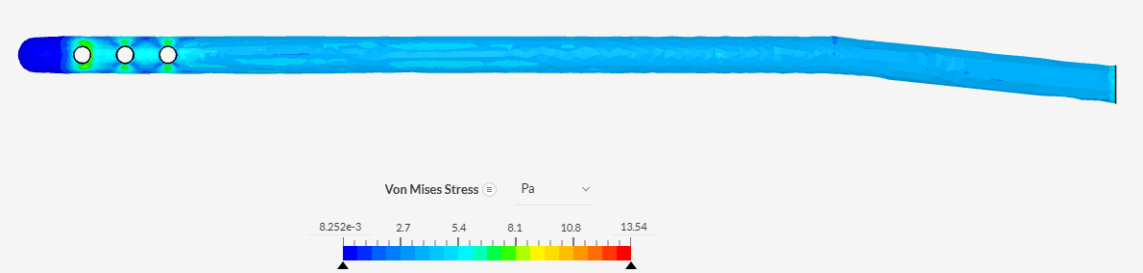

Figure 17. Von Mises Stress for a Torsion Test

This FEA implies that the most stress applied would be at the distal tip relative to the rest and the strong points with less stress acting on it would be at the holes.

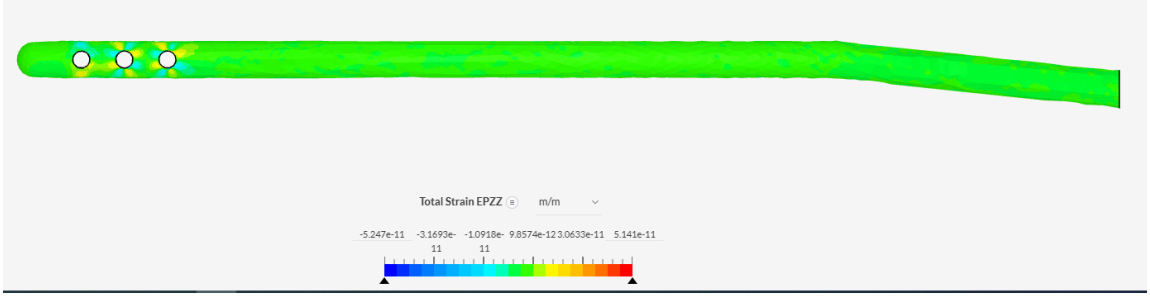

Figure 18. Strain in the ZZ direction for a Torsion Test

The Strain acting on this torsion test was evenly distributed across the rod.

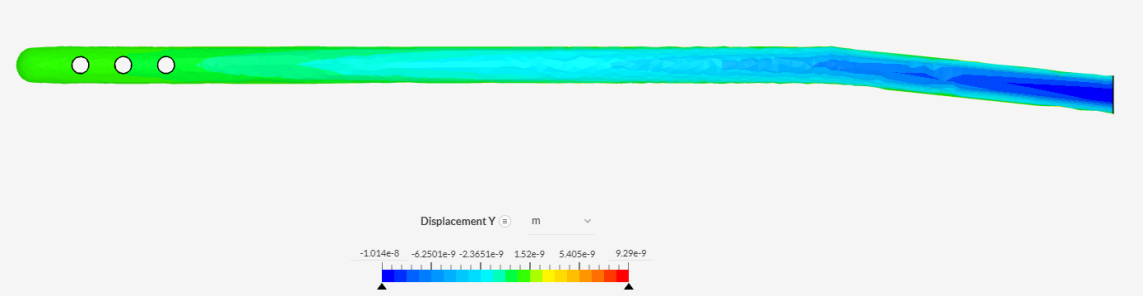

Figure 19. Displacement in the y direction for a Torsion Test

The most displacement of the rod from the rod would be at the proximal end of the rod.

Structural Stiffness
The structural stiffness is the structure or materials resistance to deformation under applied loads. To calculate the structural stiffness is the following:

$k = EI$ equation 10.
Where,
k is the structural stiffness.
E is the young's modulus of the material $1.14 \times 10^{11} pa.$
I is the moment of $I = \frac{\pi}{4}((\frac{D_{outer}}{2})^4 - (\frac{D_{inner}}{2})^4)$
$D_{outer} = 0.0089m$
$D_{inner} = 0.005m$
$\Rightarrow I = 2.77 \times 10^{-10} m^4$
This implies the structural stiffness is $31.56Nm^2$; this falls within the range of typical bending structural stiffness testing the ASTM standard.

TABLE A1.2 Precision Statistics for Bending Structural Stiffness, EI_e

Specimen Group	Mean (N/m^2)	S_r^A	S_R^B	r^C	R^D	No. of Labs
A	179.59	2.16	7.82	6.04	21.89	6
B	396.49	17.56	41.47	49.16	116.13	6
C	25.30	0.73	1.05	2.04	2.95	6

$^A S_r$ = within-laboratory standard deviation of the mean.
$^B S_R$ = between-laboratories standard deviation of the mean.
$^C r = 2.83\ S_r$.
$^D R = 2.83\ S_R$.

Figure 20. The Bending Structural Stiffness ASTM F1264-16

The Load-Displacement slope
The Load displacement for the Accurod can be calculated by the following:

$$\frac{F}{y} = \frac{EI \cdot 12}{s^2(3L - 4s)}$$

Where,
EI is the structural stiffness at $31.56Nm^2$
s is the span where the fixtures are applied at 0.076m.
L is the support span of the rod at 0.228m.
$\Rightarrow \frac{F}{y} = 172.53 \frac{N}{mm}$
This falls within the standard of the Load-displacement Slope for the ASTM Standard which shows the Accurod is above the minimum load displacement slopes mean on a tested sample.

TABLE A1.1 Precision Statistics for Load-Displacement Slope, *F/y*

Specimen Group	Mean (N/mm)	S_r[A]	S_R[B]	r[C]	R[D]	No. of Labs
A	905.23	9.03	28.15	25.28	78.81	8
B	1667.63	59.11	127.34	165.51	356.56	8
C	132.20	4.02	11.18	11.26	31.32	8

[A] S_r = within-laboratory standard deviation of the mean.
[B] S_R = between-laboratories standard deviation of the mean.
[C] $r = 2.83\ S_r$
[D] $R = 2.83\ S_R$

Figure 21. The Load-Displacement Slope ASTM F1264-16

Stress Shielding Test

The bone needs about 4000 newtons to break the humerus according to discovery.com. We can calculate the amount of stress that is absorbed by the IM Rod. The average Diameter of the Humerus is 19.3mm.

The equation to determine the stress to break the bone is as follows:

$$\sigma_{bone} = \frac{F_{max}}{A} \qquad \text{equation 11.}$$

Where,

F_{max} is the maximum force needed to break the humerus at 4000N.

A is the area at $A = \pi r^2$ where in this case $r = \frac{0.0193}{2} m$

$\Rightarrow A = 0.00029 m^2$

σ_{bone} equates to 13.67Mpa.

The stress needed to break the rod is $F = 37,467.26N$ and $A = 42.6 \times 10^{-6} m^2$

By using the equation 11 but for the rod would yield the following:

$\sigma_{rod} = \frac{F_{max}}{A} \Rightarrow \frac{37,467.26N}{42.6\times10^{-6} m^2} \Rightarrow \sigma_{rod}$ equates to 88.0Mpa.

We can then calculate the combined stress as the following:

$$\sigma_{combined} = \frac{\sigma_{bone}\cdot E_{bone}\cdot A_{bone} + \sigma_{rod}\cdot E_{rod}\cdot A_{rod}}{E_{bone}\cdot A_{bone} + E_{rod}\cdot A_{rod}} \qquad \text{equation 12.}$$

E_{rod} is 113.8Gpa.

E_{bone} is 19.09Gpa.

$\sigma_{combined} = 19.58 Mpa$

Then we can calculate the amount of force taken by the rod as follows:

$$F_{rod\ combined} = F_{max} \cdot \frac{E_{rod}\cdot A_{rod}}{E_{bone}\cdot A_{bone} + E_{rod}\cdot A_{rod}}$$

$\Rightarrow F_{rod\ combined} = 317.90N$ which is the force absorbed by the rod from the maximum force acting on it.

Summarize results in a table

Table 2. Accurod vs ASTM Standard

	Accurod	ASTM Minimum Standard (mean)
Ultimate Bending Moment ($N \cdot m$)	29.87	12.75
Structural Stiffness($N \cdot m^2$)	31.56	25.30
Load Displacement Slope ($\frac{N}{mm}$)	172.53	132.2

The results show that the Accurod has complied with the standards for the ASTM F1264-16.

Manufacturing, Assembly and Bonding methods

A. Manufacturing
    a. The material, Titanium Grade 5, will undergo a forging process to achieve the rough shape of the intramedullary rod. Forging occurs by heating the metal to a high temperature allowing the titanium to mold into the desired shape. During the heating stage, the material is more malleable and easier to shape, reducing the stress during deformation. Once cooled, the metal will recrystallize allowing for smaller grains to form. This new grain structure improves the mechanical properties, such as the strength, demonstrating that forging is an ideal manufacturing process for this application.
    b. Machining techniques such as turning, drilling, and milling are then utilized on the forged titanium to remove any excess material. The device is mounted on a lathe where turning is used to achieve a uniform diameter along the shaft. Milling occurs on a cutting tool where the device can be customized to the design. This is where specific shapes, contours, or geometries will be cut into the design. Drilling is used to cut holes into the rod. The holes are typically cut using a drill and positioned for the screws to be placed securely.
    c. The rod is then polished to remove any irregularities or imperfections from the machining process. A smooth surface optimizes the device by minimizing wear, friction, and tissue irritation.
    d. To complete the machining process, the rod will go through a final heat treatment step. This will include a technique such as stress-relief annealing, eliminating residual stress introduced during machining. This will further enhance the mechanical strength, fatigue resistance, and durability of the material, ensuring its safety for medical applications.
B. Assembly and Bonding
    a. The IM rod is a single part that will be held in place using screws or bolts.
    b. A thin layer of titanium nitride will be applied to the surface to ensure corrosion resistance and increase long-term durability.

Sterilization procedure

A. Conditioning Phase
    a. The chamber is normally pre-conditioned to a regulated relative humidity (30–60%) and temperature (45°C to 55°C). Because EtO works better in the presence of moisture, which improves the gas's penetration, enough humidity is

essential. To balance the moisture content, the gadgets stay in the conditioning environment.

B. Gas Exposure Phase
    a. Ethylene oxide gas is added after the chamber's temperature and humidity are at the appropriate levels. EtO concentrations usually range from 450 to 1,200 mg/L, depending on the apparatus and load capacity. Although the length of EtO exposure varies, it typically lasts one to six hours, it's recommended to use 2 to 3 hours. In order to increase gas penetration into the device packaging and internal catheter regions, EtO sterilization frequently entails a sequence of vacuum and pressure cycles.
C. Aeration Phase
    a. Eliminating any remaining EtO gas from the catheters is crucial after the exposure phase. In order to accomplish this, the products are aerated in a regulated chamber, usually at a high temperature (normally between 40°C and 50°C). Depending on the material and legal restrictions, the aeration duration can vary from 12 hours to several days. The exhaust mechanism of the chamber safely ventilates the gas, guaranteeing that no hazardous EtO is left on the equipment.
D. Post-Sterilization Inspection
    a. Ensure that EtO residues (ethylene oxide, ethylene chlorohydrin, and ethylene glycol) on the catheters are within safe limits as per ISO 10993-7 standards. Inspect the packaging and the devices for any damage during sterilization.

VERIFICATION AND VALIDATION

<u>510(k) Regulatory Submission Plan</u>

A. Purpose of submission:
    a. The purpose of this 510(k) submission is to notify the U.S. Food and Drug Administration (FDA) of the introduction of a new Intramedullary rod designed for humerus fractures intended for physician use. This device will be implanted to stabilize the fracture and enhance bone growth during the healing period. This submission is intended to demonstrate that the new Intramedullary rod (AccuRod) is substantially equivalent to the legally marketed predicate device IM Rod with product code HSB. These devices can be deemed substantially equivalent because they have the same intended use and technological characteristics.
B. Regulatory Pathway:
    a. Intramedullary Rod is classified as a class II medical device under FDA regulations. It will be submitted for approval via the 510(k) premarket notification process because it is intended for the same use as the predicate device. The predicate device is also cleared under 510(K) K241484.
C. Predicate Device:
    a. Predicate Device: Tornier IM Nail Humeral Fracture System
        i. 510 (K) Number: K241484
            1. Device Class: II
                a. Comparing the Devices: Our Intramedullary Rod design will differ from the predicate device because of the variation in the proximal bend angle. By doing this, the chance of irritation will be reduced because there will be less contact between the rod and the tissue. We will have the same number of holes on the proximal and distal ends

as the predicate device to allow for the same fixation possibilities in both, and the technological features will be identical to those of the rod. Accurod will also have a smaller diameter further reducing tissue contact and irritation.

2. Device Classification: The Intramedullary rod will be classified as a Class II device. The Predicate device also has a Class II designation.
3. Regulatory Requirements: The following FDA regulations and standards apply to the new Intramedullary Rod:

- 11-197 ASTM F983-86 (Reapproved 2018)
  Standard Practice for Permanent Marking of Orthopaedic Implant Components
- 11-199 ASTM F565-04 (Reapproved 2018)
  Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- 11-310 ASTM F1611-00 (Reapproved 2018)
  Standard Specification for Intramedullary Reamers
- 11-316 ASTM F1264-16
  Standard Specification and Test Methods for Intramedullary Fixation Devices
- 11-326 ASTM F384-17
  Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
- 11-355 ISO 15142-1 First edition 2003-08-01
  Implants for surgery - Metal intramedullary nailing systems - Part 1: Intramedullary nails
- 11-356 ISO 15142-2 First edition 2003-08-01
  Implants for surgery - Metal intramedullary nailing systems - Part 2: Locking components
- 11-357 ISO 15142-3 First edition 2003-08-01
  Implants for surgery - Metal intramedullary nailing systems - Part 3: Connection devices and reamer diameter instruments

A. Submission Team:

The following team members will be responsible for the preparation of the 510(K) submission:
Sahithi Lingala: Regulatory Affairs Manager: Responsible for overall submission preparation, FDA communication and compliance.
Kevin Medici: R&D Engineer: Responsible for device design, testing plans and preparing performance evaluations.
Ayleen Mendoza:Quality Assurance Engineer: Responsible for testing and documentation meets FDAs standards.

510(k) summary

A. Device Name:
   a. Trade name: AccuRod
   b. Common name: Intramedullary rod
   c. Classification name: Rod, Fixation, Intramedullary and Accessories
   d. Product Code: HSB
B. Predicate Device:
   a. Predicate Device: Rod, Fixation, Intramedullary and Accessories

b. 510 (K) Number: K241484
c. Device Class: II

C. Device Description:

The AccurRod is an Intramedullary Rod designed for the stabilization of humerus fractures. The rod is surgically implanted into the medullary canal, stabilizing the fracture and promoting alignment during the healing process. It consists of a Ti-6Al-4V rod with a smooth finish, proximal and distal fixation holes for screws, and a modified proximal bend angle. The proximal bend angle, with a minimized diameter, will reduce tissue irritation by minimizing tissue contact and essentially improving patient comfort.

The AccuRod will have a length of 250 mm, a proximal diameter of 8.9 mm, and a distal diameter of 8.5 mm. It is designed using titanium grade 5 (Ti-6Al-4V) due to its biocompatibility, corrosion resistance and strength. The rod is manufactured through a series of forging, machining, polishing and stress-relief annealing. The finished product is then sterilized using Ethylene Oxide (EtO) and finalized for use.

D. Intended Use

The AccuRod (IM rod) is a long metal rod that is inserted into the medullary canal of the humerus to stabilize fractures. The rod is intended for comminuted, transverse, oblique, and spiral fractures, and is surgically implanted to support, align and facilitate bone healing in a wide range of patients.

Intramedullary Rods (IM rod) offer several advantages for treating humeral fractures. These include less invasive surgical techniques, reduced soft tissue trauma, quicker recovery times, and the ability to maintain alignment in diaphyseal fractures. Humerus fractures account for approximately 5-10% of all fractures, with the demand of IM rods rising from accidents, sports and an aging population. Globally, the orthopedic trauma device market is growing at an annual rate of 6-8%. The AccuRod will play a vital role in addressing these concerns, especially in regions experiencing high trauma rates.

The AccurRod shares a series of characteristics with the predicate, deeming it substantially equivalent. They share the same function (stabilization and fixation of fractures), material (Ti-6Al-V4), and design (long metal rod with proximal and distal screw placements). The key difference is the introduction of a modified proximal bend angle and a smaller diameter. This modification reduces tissue irritation by minimizing soft tissue contact, enhancing patient comfort without compromising the device's performance.

E. Technological Characteristics

The AccuRod is substantially equivalent to the predicate device. Both devices share the same intended use (stabilization and fixation of fractures), material (Ti-6Al-V4), and design (long metal rod with proximal and distal fixation holes for secure screw placement).

The main difference is the modification of the proximal bend angle, which minimizes tissue irritation and contact. Despite this modification, the design improvement does not alter the safety, effectiveness or function of the device.

F. Non-Clinical Performance Testing

Performance evaluation included the following tests:

- Bending strength: Four-point bending test to determine the stress distribution and deflection under physiological loads.
- Torsional Strength test: Assessing the amount of torque applied to the rod before failure.
- Structural Stiffness: Calculating the material's resistance to deformation under applied loads.

All test were conducted and were in compliance per ASTM and ISO standards:

- 11-197 ASTM F983-86 (Reapproved 2018)
  Standard Practice for Permanent Marking of Orthopaedic Implant Components
- 11-199 ASTM F565-04 (Reapproved 2018)
  Standard Practice for Care and Handling of Orthopedic Implants and Instruments
- 11-310 ASTM F1611-00 (Reapproved 2018)
  Standard Specification for Intramedullary Reamers
- 11-316 ASTM F1264-16
  Standard Specification and Test Methods for Intramedullary Fixation Devices
- 11-326 ASTM F384-17
  Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
- 11-355 ISO 15142-1 First edition 2003-08-01
  Implants for surgery - Metal intramedullary nailing systems - Part 1: Intramedullary nails
- 11-356 ISO 15142-2 First edition 2003-08-01
  Implants for surgery - Metal intramedullary nailing systems - Part 2: Locking components
- 11-357 ISO 15142-3 First edition 2003-08-01
  Implants for surgery - Metal intramedullary nailing systems - Part 3: Connection devices and reamer diameter instruments

The tests demonstrated sufficient bending strength, torsional strength, and structural stiffness. Additionally, Finite Element Analysis (FEA) confirmed the structural integrity under worst-case loading conditions. The results, when compared to the predicate, confirm that the AccuRod is as safe and effective, in accordance with ASTM and ISO standards.

G. Conclusion Drawn from testing

The AccuRod has demonstrated substantial equivalence to the predicate device based on the mechanical tests and compliance with ASTM standards. The device is deemed equally safe and effective as the predicate device. Additionally, the AccuRod meets the same performance standards for its equivalent intended use.

Verification testing plan

A. Static/dynamic; compression/tension/torsion

For static tests, the intramedullary rod will be subjected to compression, tension, and bending forces using a universal testing machine equipped with appropriate fixtures using the Finite Element Analysis software Simscale. The rod will be aligned and secured within the machine, ensuring even distribution of forces. Compression and tension tests will measure the rod's ability to withstand forces applied along its length, assessing its structural integrity under conditions that mimic in vivo loading. The magnitude of the force applied will be increased

gradually until the rod reaches its yield point or fails, with data recorded on deformation and load resistance.

Dynamic testing involves applying cyclic loads to simulate the repeated stresses that the rod would experience during normal activities. This test assesses the fatigue life of the rod by subjecting it to bending forces at various frequencies and amplitudes until failure occurs. The testing apparatus will record the number of cycles the rod withstands before showing signs of fatigue or structural failure, providing insights into its long-term durability and performance.

Torsion tests will be conducted to evaluate the rod's resistance to twisting forces, which are critical in scenarios where the rod might experience rotational stresses. The rod will be clamped at one end, and a torsional force will be applied at the other using a torsion tester. The angle of twist and the torque required to cause deformation or fracture will be measured. This test helps determine the rod's torsional stiffness and strength, ensuring it can withstand physiological torsional loads without compromising its structural integrity.

The four-point bend test will assess the rod's bending strength and stiffness. The rod will be placed on two supports, and loads will be applied at two points located symmetrically between the supports. This setup reduces the shear forces at the point of load application, focusing the stress on bending the rod. The force will be gradually increased while measuring the deflection and stress distribution along the rod. This test is crucial for determining how the rod will behave under bending loads, simulating conditions such as falls or impacts that could occur in vivo.

B. Geometry of test (including fixtures)

The geometry of the test setup for the intramedullary rod, including fixtures, is designed to accurately simulate real-world loading conditions while ensuring precise measurement and control during testing. For compression, tension, and torsion tests, the rod will be secured in fixtures that allow for uniform application of forces along its length or around its circumference, as appropriate. In compression and tension tests, the rod will be aligned vertically between two plates of a universal testing machine, ensuring that forces are applied axially along the longitudinal axis of the rod to prevent bending or buckling unless specifically testing for such outcomes.

For the torsion test, the rod will be held firmly at one end, with the torsional force applied at the other. This setup will include chucks or clamps designed to grip the rod securely without slipping or damaging it. In the four-point bending test, the rod will be supported on two lower supports spaced at a specified distance, with the load applied via two upper loading points equidistant from the center and supports. This arrangement minimizes shear forces at the point of load application and focuses stress on bending the rod, crucial for assessing bending strength and flexibility.

These fixtures are typically made from high-strength, rigid materials that do not deform under testing loads, providing stability and repeatability in results. The precise geometry of the test setup, including the distances between supports and load points, will be determined based on the dimensions of the rod and the specific requirements of ASTM F1264, ensuring that all tests are compliant with

industry standards and yield reliable, relevant data for evaluating the performance characteristics of the intramedullary rod.

C. Loading conditions (magnitude and time)

The loading conditions for testing the intramedullary rod, including the magnitude and duration of the applied loads, are meticulously defined to ensure the accuracy and relevance of the test outcomes. For static tests, such as compression and tension, the loads will be gradually applied to the rod until a predetermined value or until failure occurs. The magnitude of these loads is determined based on the mechanical properties of the material (e.g., yield strength, ultimate tensile strength) and the cross-sectional area of the rod. For example, the load might be set to achieve a stress level near the material's yield strength, typically ranging from 70% to 100% of this value, to assess the rod's deformation and failure characteristics under realistic physiological conditions.

In dynamic tests, particularly for fatigue testing under cyclic loading, the rod will be subjected to repeated loading and unloading cycles to evaluate its endurance. The magnitude of these loads will generally be less than the yield strength to simulate everyday stresses, with the frequency and number of cycles defined based on expected usage conditions. The load might be applied cyclically at a frequency that mimics physiological activities, with durations extending to millions of cycles to evaluate long-term performance and durability.

For torsion tests, torque will be applied incrementally until the rod either twists to a specified angle or fails. The rate of torque application is controlled to avoid dynamic effects unless testing specifically for such conditions. The magnitude of torque corresponds to the calculated shear strengths, ensuring the rod's rotational integrity is assessed under expected service conditions. These controlled loading conditions are critical for determining how the rod will perform under various mechanical stresses, providing essential data for its validation and eventual clinical use.

D. Apparatus, Procedures

For the four-point bending test, the apparatus consists of a universal testing machine equipped with two pairs of rollers or supports. The rod will be placed horizontally across these supports. The two lower supports are spaced at a specified distance according to ASTM standards, and the loads will be applied through two upper loading points that are also spaced symmetrically but closer together compared to the lower supports. This configuration focuses bending stresses at the center section of the rod, between the upper loading points, reducing shear forces at the point of load application. The force is applied incrementally using a hydraulic or electromechanical actuator, and the displacement and bending moment are continuously recorded. A dial gauge or a more sophisticated electronic displacement transducer measures the deflection at the center of the rod. The apparatus is calibrated before each test to ensure accuracy, and all data are logged for analysis to determine the bending strength and stiffness of the rod.

The torsion test utilizes a torsion testing machine, which securely clamps one end of the rod while applying a rotational force or torque to the other end. The rod is held by specialized fixtures that prevent slippage and damage during testing. The torsional force is applied through a motor-driven actuator capable of generating and measuring torque. The angle of twist and the torque are recorded

using angular displacement transducers and torque sensors, respectively. This setup helps in evaluating the rod's torsional stiffness and the torque that causes yielding or failure. The rate of torque application is controlled carefully to simulate physiological conditions, and the entire procedure is monitored to ensure that no axial loading is unintentionally applied.

In the compression test, the intramedullary rod is positioned vertically between the compression plates of a universal testing machine. Each end of the rod rests against a hardened steel plate designed to distribute the compressive load uniformly. The lower plate is fixed, while the upper plate is connected to a load cell that applies the compressive force downward. The force is increased gradually, and the deformation of the rod is measured using displacement sensors attached to the plates. This test determines the maximum compressive load the rod can withstand before failure, and data on load versus displacement are collected to assess the rod's compressive strength and stiffness. The setup ensures that the load is axial to prevent any bending effects, and the procedure is conducted under controlled environmental conditions to mimic the in vivo thermal and humidity conditions.

E. Template for test reports

1. Four-Point Bending Test

Apparatus Description: The test utilizes a universal testing machine with four adjustable supports. Two supports are configured to act as the reaction points and the other two to apply the load, minimizing shear stress at the point of load application.
Procedure:
Position the intramedullary rod horizontally on the two lower supports.
The upper two loading points are symmetrically placed between the supports to apply loading forces.
Gradually increase the load using a hydraulic or electromechanical actuator while continuously recording the force and corresponding deflection.
Measure the rod's response to bending until failure or up to a predetermined deformation limit to assess its mechanical integrity and stiffness.

2. Torsion Test

Apparatus Description: A torsional tester equipped with fixtures to clamp the rod securely at one end, while the opposite end is twisted using a motorized torque applicator.
Procedure:
Secure the intramedullary rod within the clamping fixture.
Apply torsional force gradually at the free end and measure the angle of twist and the torque required to induce deformation.
Continue to increase the torque until the rod yields or breaks, documenting the torque and angular displacement to determine torsional stiffness and strength.

3. Compression Test

Apparatus Description: Compression testing is performed using a universal testing machine that applies a compressive force through aligned platens that interface with the rod.
Procedure:
Place the rod vertically between the compression platens of the testing machine.
Apply compressive force incrementally from one platen, while the opposite end remains static.
Record the force and displacement until the rod fails or reaches the deformation criteria.

The goal is to ascertain the maximum compressive load the rod can withstand and its deformation characteristics under load.

Validation testing plan

A. Design validation

The design validation ensures that the AccuRod will perform safely and effectively for its intended use. Testing included the static four-point bending test, static torsion test, and bending fatigue test, based on ASTM F1264-16 standards. These tests were performed to ensure that the design can withstand physiological loads and stresses. Finite Element Analysis (FEA) simulated the forces on the rod and deformation behavior under different loading conditions, validating the rod's structural integrity. Biocompatibility testing (ISO 10993) is performed to ensure the materials are corrosion-resistant, non-toxic and safe for human tissue use. Lastly, sterilization validation confirmed the device is free from any manufacturing residue and ready to use.

i. Test equipment

Test equipment is selected based on the required testing for the AccuRod per ASTM standards. The AccuRod is tested using the same methods as the predicate device. Universal testing equipment is utilized to conduct mechanical tests, ensuring the rod can withstand physiological loading conditions. Additional equipment includes a torsional tester to evaluate the rod's strength and resistance to twisting forces, a fatigue testing machine to assess long-term durability and cycle loading resistance, biocompatibility testing equipment to verify material safety in accordance with ISO 10993 standards, and sterilization equipment to validate the use of ethylene oxide, ensuring the device is properly sterilized and ready for use.

All equipment used is properly calibrated and has undergone installation and operational qualification to ensure reliability. A maintenance log is kept to document a detailed list of maintenance and repairs conducted on the apparatus. Testing protocols are followed and recorded to ensure accuracy and repeatable results.

B. Process validation

The AccuRod is manufactured in compliance with Good Manufacturing Practices (GMP), ensuring consistency in the specifications and functionality of the devices produced.

This process includes that the manufacturing, assembly and sterilization are validated and GMP-compliant. The manufacturing process is validated to ensure consistency and precision in production. The assembly is verified to ensure that the screws are correctly applied for proper performance. The sterilization validation includes documentation of controlled environmental conditions to ensure the device undergoes proper EtO sterilization.

i. Prospective validation

1. All manufacturing equipment and processes have been validated to ensure they meet regulatory criteria. A side-by-side testing of the AccuRod and predicate device has been performed to confirm that the same machines and standards were applied.

ii. Equipment and Process
    1. The equipment meets the installation qualification, verifying proper calibration, installation and functionality. The manufacturing process is confirmed through the process performance qualification. This verifies that the machining, and heat treatment, application produces compliant devices. The product performance qualification verifies the consistency of the final device and its ability to perform as intended. The results are supported by meeting the mechanical and biocompatibility requirements. Furthermore, all tests adhere to ASTM and ISO standards, ensuring compliance.

iii. System to assure timely revalidation
    1. To ensure ongoing compliance of the system, revalidation of the equipment and process is implemented. Following the manufacturer's instructions, regular maintenance and calibration of the equipment should be performed to ensure accurate testing. Periodic evaluations are conducted to maintain compliance with GMP requirements. Data analysis of device performance is collected to validate the continued safety and effectiveness of the device.

iv. Documentation
    1. All validation and verification protocols will adhere to the FDA requirements. Every step of the process will be clearly documented and easily traceable for all tests performed.

C. Retrospective process validation

A side-by-side test comparison of the current device and the predicate has been evaluated to confirm that the performance of the new design meets ASTM standards. The difference in the device does not affect its safety or intended use compared to the predicate. This test plan ensures that the manufactured product meets the safety, effectiveness and performance requirements necessary for implantation.

Resources

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