

1. Desired Needs

- The fixation screw securely keeps the FDL tendon to the navicular bone.
- Developed designs that maximize surface area and incorporate a porous scaffold to promote osseointegration.
- Maintain compatibility with standard sizing without compromising the core design.

2. Constraints

- *Safety/Regulatory Affairs*: The final design must not have any sharp edges that may damage the patient's tendon or surrounding area.
- *Risks*: Possibility of poor biocompatibility/osseointegration, leading to mechanical failure, rejection by the patient, and/or a revision surgery.
- *Global Impact*: Device is aimed to be more customizable to each individual patient and accommodate those with unique anatomy or certain circumstances.
- *Manufacturability*: Difficulty in increasing scalability since 3D-printing using titanium powder with Renishaw RenAM 500Q is both expensive and has limited space, along with the extended time required to print each screw.
- *Quality Control/Marketability*: Design should be similar to existing competitors so surgeons are familiar with the product, yet still produce improved attributes.

3. Engineering Standards

- ASTM F3001-14: Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Infusion
- ASTM F543: Standard Specification and Test Methods for Metallic Medical Bone Screws

4. Ethical, Environmental, or Societal concerns

- Material and design may incur high costs which may produce disparities in treatment based on affordability. Titanium is expensive to extract, maintain, and shape, while the processing requires a great deal of power.

5. Active Teamwork and Leadership

- Weekly meetings with the project group and mentor to discuss progress and used Messages for easy communication. Goals and deadlines were discussed and established together during these meetings. Constructive feedback was given to us by our mentor, in which we implemented improvements into our designs.
- Each design was done by the respective member and other assignments were delegated on a rotational basis.

6. Most significant motivating factors

- The main motivation was the opportunity to learn about the production of medical devices in industry, along with the considerations that must be factored in to ensure the product obtains FDA approval.

7. Most innovative and/or entrepreneurial ideas

- Our project leveraged 3D printing to create patient-specific designs while utilizing titanium, a material with a well-established record of biocompatibility and safety.