# Tibial Stent: Designing a novel fixation device for pediatric orthopaedic tibia fractures

*Product Design Specifications*

***Client:*** *Dr. Matthew Halanski, MD*

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**Function:**
Rigid intramedullary devices have been used in adults with complete fractures of the bone; however, this method cannot be used in pediatric patients due to the presence of epiphyseal growth plates at either end of the bone. Therefore the purpose of this project is to design and fabricate a device similar to a rigid intramedullary device which can be used in pediatric patients. A previous design team developed a device that is flexible enough to be inserted into the bone at a 45˚ angle, yet can be made rigid enough to provide adequate structural support to the bone. This semester's work will center around improving the fixation properties of this existing device specifically focusing on limiting axial rotation of the device within the medullary canal without negatively affecting radial force and flexibility properties.

**Client Requirements**
- No axial rotation or lateral movement after implantation in canal
- Flexible enough to be inserted into the bone at a 45˚ angle
- Rigid enough to stabilize fracture
- All components of design must be biocompatible/hemocompatible

**Design Requirements**
1. Physical and Operational Characteristics
    a. *Performance Requirements*: The device must have a narrow flexible state, and a rigid expanded state. The flexible state must be able to bend to at least a 45˚ angle for insertion into the bone. In the expanded state, the device must be able to be fixed in the tibia bone canal and handle all mechanical forces normally experienced by a casted limb. The device must also be able to compress back to the flexible state for easy surgical removal after the fracture is healed.

    b. *Safety*: This device must be able to be sterilized easily, should be made of biocompatible materials, and should not plastically deform or fail while inside the tibial canal of the patient.

    c. *Accuracy/Reliability*: This device must be very reliable, as it will be implanted into a patient to assist with bone fracture healing.

d. *Life in Service*: The device must to be able withstand implantation lasting anywhere from 2 to 9 months.

e. *Shelf Life*: The device should have as infinite shelf life if kept in place and not tampered with before surgical implantation.

f. *Operating Environment*: The device will be inserted inside the medullary canal of the tibia, which is normally full of fat and blood; however, this is not a concern as the canal is emptied as part of the surgical procedure. In addition, the inside of the ends of the canal are soft bone tissue, while the tissue near the midpoint of the bone is rough and hard. This device will be used primarily near the midpoint of the tibia since this is the place where complete fractures are most common.

g. *Ergonomics*: The device should be intuitive for a trained surgeon to use, and should be designed to maximize the ease of implantation. The device must also be able to be arranged with the other tools of the surgical set up to provide intuitive placement to avoid confusing the surgeon, which could lead to error or complications.

h. *Size*: The device must be cylindrical in shape, no wider than 7 mm, and 115 mm long to match the previous design.

i. *Weight Materials*: The device weight should be kept to a minimum. With the current design, total weight should not be a problem and due to its very small size, the weight of the materials will not have a significant effect on leg function and motion.

j. *Aesthetics*: There are no aesthetic requirements for this device because it is an implant. Function takes precedence to form.

**2. Production Characteristics**

a. Quantity: There was no requested quantity of devices, we would like to be able to fabricate at mass quantities if possible.

b. Target Product Cost: For this project we have been given a budget of $4,500 but we would like to keep the total fabrication cost of the device to under $500.

**3. Miscellaneous**

a. Standards and Specifications: The device must comply with FDA standards and specifications for implantable medical devices.

b. Customer: Dr. Matthew Halanski, Department of Orthopedics, UW Health is

hoping this will eventually be a commercial product that other orthopaedic surgeons and their respective hospitals will use for their pediatric patients. The highest priority is the safety of the patients, both the surgeon and the patient must be comfortable using the device to help heal bone fractures in pediatric patients. Inability to convince the patient that the device is reliable would result in target patient rejection of the design.

c. Patient Related Concerns: There have not been any patient-related concerns that have been brought to our attention.

d. Competition: Current designs include elastic nails, which have few points of contact with the bone and hence little fixation is seen anywhere other than points at the top, middle and bottom of bone. In addition, adult patients may undergo surgery in which an intramedullary rod is implanted through the top of the bone, through the growth plate, and then screwed in place once in the tibial canal.