

Incremental Orthopedic Incremental Drill Stop Device

Product Design Specification Report

Team Members

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Problem Statement

Our client, Dr. Tim O'Connor is a resident in the department of Orthopedic Surgery at the University of Wisconsin Hospital. While performing an operation that requires a surgeon to drill through a bone, it is necessary to control over penetration of the drill bit into the soft tissue behind the bone. Currently, surgeons often drill by feel and attempt to stop precisely when the bit penetrates the posterior of the bone, but this is often difficult. Our team has been asked to create a device that can accurately stop within a 2mm tolerance and can easily be used by one surgeon while drilling.

Client Requirements

- Accurate to within 2 mm of the posterior of the bone
- Bit must be held firm in device when pressure applied
- Easily reset
- Quickly adjustable to minimize heat transfer to bone

Design Requirements

1. Physical and Operational Characteristics

a. *Performance requirements:*

- Needs to hold up to repeated use during surgery

b. *Safety*

- The device must decrease the plunge depth past the bone during surgery

c. *Accuracy and Reliability*

- Must advance accurately in 1-2 mm increments without slipping

d. *Life in Service*

- Prototype must last through testing planned by client
- Final device should not need to be replaced

e. *Shelf Life*

- There should be no major requirements to meet regarding shelf life

f. *Operating Environment*

- Device must withstand 15 N normal force from drill

- Should account for potential of bone dust to get on/in device

g. *Ergonomics*

- Should be able to be held and used with one hand
- Should be able to be used in right or left hand

h. *Size*

- Should be handheld, operated by one person

i. *Weight*

- Should be comfortably held without need for excessive force

j. *Materials*

- Should not break down easily
- Prototype can be made in plastic

k. *Aesthetics*

- Not important

2. Production Characteristics

a. *Quantity*

- One unit needed

b. *Target Product Cost*

- Cost should not exceed \$200

3. Miscellaneous

a. *Standards and Specifications*

- Class 1 medical device, so it is thusly subject to general controls
- Must follow US Medical device standards

b. *Customer*

- Customer has mentioned preference towards modification of current prototype or design of thumb wheel device

c. *Patient-related concerns*

- Final device needs to be able to be sterilized

d. *Competition*

- Although other similar devices exist, should enter new niche of market by allowing for variable depth control while drilling at a low cost