Use of drill stop device for more accurate and efficient drilling in orthopedic surgery

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 and Clinics. He is concerned about over penetration of the drill bit into soft tissue during bicortical drilling in orthopedic surgery. The current method involves setting a pre-determined drill depth that is too cumbersome to adjust during the procedure. Our team has been asked to create a design that minimizes the plunge depth of the bit after penetrating the far side of the bone to prevent injury to soft-tissue.

Client Requirements

- Decrease plunge depth from 1.5-3.0cm to 1.0-3.0mm
- Operable by one person
- Reusable
- Able to adjust for varying bone depths during the procedure

Design Requirements

Physical and Operational Requirements

a) *Performance Requirements* – This design must be able to dynamically change the depth of the drill bit during the operation and decrease the amount that the drill bit passes into the soft tissue
b) *Safety* – The device must increase safety by decreasing the amount that the bit plunges into soft tissue. It must be strong enough to stop the advancement of the drill before it plunges into the soft tissue.
c) *Accuracy and Reliability* – +/-1mm
d) *Life in Service* – ??
e) *Shelf Life* – Indefinite
f) *Operating Environment* – This device will be used in a sterile operating room. Each device needs to be able to be sterilized so it can be used for multiple operations. It needs to be biocompatible such that it can come into contact with human tissue.
g) *Ergonomics* – This device needs to be operated by the user individually during a surgical procedure. It must not put any undue stress or strain on either the user or his environment during the operation.

h) *Size* – The model should be handheld and able to be operated by the surgeon during an operation without putting any undue pressure on the surgeon or the patient.
i) *Weight* – The design must be light enough to not disturb drilling accuracy. The weight must be below 1kg.
j) *Materials* – All of the materials used in this device must be sterile, non-flammable non-radioactive, and non-corrosive
k) *Aesthetics* – The aesthetics of this design and not important. It just needs to be clean and sterile.

Product Characteristics

a) *Quantity* – One product that would be able to be mass produced in the future
b) *Target Product Cost* – The target production cost for one product is under $100.

Miscellaneous

a) *Standards and Specifications* – This product would be a class I medical device and thus only subject to general controls, which requires good manufacturing techniques, proper branding and labeling, notification of the FDA before marketing the device, and general reporting procedures.
b) *Customer* – Our customer is an orthopedic surgeon who is looking for a way to increase patient safety and take the variability out of the hands of the surgeons. He is looking for a very simple device, similar to the drill sleeve that's currently used except with additional features such as dynamic adjustment during surgery.
c) *Patient-related concerns* – Since the product will be used during surgery, it must have an appropriate biomaterial interface to prevent injury or infection to the patient.
d) *Competition* – There has been research done in 1997 which has a drill that is connected to a computerized interface that is able to sense the force on the drill bit. However, this design is too complex for what our client is looking for, it requires additional equipment and an additional attendant to operate. Currently the surgeons are using drill guides, which the surgeons pre-set an estimated depth. However, these drill guides are not able to be adjusted during the procedure which makes them cumbersome to use.