

Product Design Specifications - Orthopedic Drill

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Function:

Orthopedic surgery for the application of installing screws into bones requires precisely drilled holes through the diameter of the bone. The hole's depth must be measured afterwards, using a depth gauge, adding unnecessary time during surgery. Another problem occurs in this process as the surgeon must not drill too far into the soft tissue past the bone to minimize tissue damage (plunging). Currently this is gauged entirely on the surgeon's feel of where the bone ends and the soft tissue begins. A flesh protector is used during the drilling process to prevent soft tissue damage around the drill as it perforates the bone. A prototype of a flesh protector and drill bit interface system that is safe, cost effective and consistent in measuring the depth of the hole would be greatly beneficial to orthopedic surgeons in saving time during surgery. If this prototype is successful, it would allow the step involving the depth gauge to be removed entirely and decrease plunging, reducing pain and recovery time for the patient along with reducing cost to the hospital and patient.

Client Requirements:

- Accurate detection of depth
- Reduces plunging into soft tissue
- Interface between flesh protector and drill bit
- Cost efficient
- Autoclavable materials
- Does not compromise drill function or surgeon's vision

Design Requirements:

1) Physical and Operational Characteristics

- a. *Performance requirements* – Must retain drill's ability to drill through bone, remove the need for the depth gauge, and reduce plunging.
- b. *Safety* – Must be electrically safe to contact for both operator and patient. Must be made of sterilizable materials and not generate excessive heat that would burn bone or cause any irritation. Must also be non-toxic and corrosion-free.

The modified drill/drill bit must remain within current safety guidelines for drill orthopedic drill systems.

The added material must

- c. *Accuracy and Reliability* – Depth measurement resolution must be 2 mm's or less. The mechanism must reduce plunging into the soft tissue on the backside of the bone to less than 5 mm's.
- d. *Life in service* – The soft tissue protector must be reusable. The drill bit must be reusable until the cutting portion becomes dull.
- e. *Shelf Life* – Indefinite
- f. *Operating Environment* – The device will be used in a sterile operating environment and will come into contact with human blood, bone and soft tissue.
- g. *Ergonomics* - Must be able to be used comfortably in conjunction with the drill and must not block vision of the operator more than the current system.

- h. *Size* –The device must fit between the chuck and the drill bit and must not obstruct the surgeons view.
- i. *Weight* – The design must be light enough to not disturb the drilling accuracy. The weight of the device must be under 500 grams (if attached to the drill bit) to reduce any impact on drilling. Any extraneous components must be less than 1.5 kilograms for easy transportation.