Osteochondral Graft Delivery System
Preliminary Product Design Specifications

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Date: September 20, 2016

Function: Osteochondral allografting is a common procedure performed on patients that require replacement of diseased bone. Current methods of implantation require the application of mechanical forces that have a detrimental effect on the live chondrocytes present on the implant. Maximizing the amount of viable tissue during and after the surgery is a crucial factor for the success of the procedure. Hence, the client requests a delivery system that will reduce the amount of mechanical forces required to securely place the implant into the donor site.

Client Requirements:

- Budget must not exceed $TBA
- Must be placed into donor site with minimal exertion of forces from surgeon
- Must securely fit into donor site while maximizing tissue viability during and after the procedure
- Delivery system must only require the use of sterile tools available in a surgery room, or must be made to to fit surgical standards.

Design Requirements:

- *Performance Requirements:*
    - Application of bone graft should result in _____ damage to chondrocytes
    - Procedure must be simple enough to be done in operating room where time is of the essence
    - Bone graft and vice must be held to lie perpendicular so screws on bone graft remain straight
    - Device must be capable of turning a bone sample clockwise and counterclockwise
- *Safety:*
    - Device should be biocompatible and should not create any adverse responses through the duration of the surgical procedure and thereafter.
    - Our device has failed if postoperatively the graft does not exhibit proper integration into the native tissue, if the hyaline cartilage is not properly maintained, if an associated cartilage disorder develops, or if significant fissuring, fibrillation, or fibrous tissue infiltration occurs.

- *Accuracy and Reliability:*
    - The device should have a success rate that exceeds that of current devices (20-25% failure)
    - The device should also allow for successful graft implantation as graded according to the aforementioned characteristics in the safety section
- *Life in Service*:
    - The device should be capable of reuse and sterilizable - another option is a disposable design
- *Shelf Life:*
    - The device should be capable of indefinite storage at normal room temperature
    - No corrosion should be observed on the device and must be compliant with hospital regulations
- *Operating Environment:*
    - Product has to be sterile while in use
    - Should operate in temperatures typical of an operating room (20-23 C), with humidity of 20-60%
    - All pieces will have to withstand rotational forces
    - Must be able to be used in conjunction with other orthopedic tools, including supports, water, bone glue...etc.
    - Must be able to be operated by an orthopedic surgeon
- *Ergonomics:*
    - Device should contain a significant safety factor from foreseeable forces or torques during operation. Should be able to be used without much force by surgeon.
- *Size:*
    - Device will be sized appropriately based on the size of the defect.
    - Range of 5mm-20mm diameter for threading device
    - Depth of at least 10 cm
- *Weight:*
    - Device should be easily held by one person as they assist the surgeon
- *Materials:*
    - Must comply with orthopedic surgical standards
- *Aesthetics, Appearance, and Finish:*
    - No color or aesthetics

    - Function over form

Production Characteristics:

- *Quantity:*
    - 1 final product, preferably multiple prototypes for testing
- *Target Product Cost:*
    - TBD
- *Standards and Specifications:*
    - Device should be to FDA standards for surgical devices

Characteristics:

- Device should consist of a tap, die, and a bone screwdriver and vices
- Must be made of surgery-grade material
- Various devices to stabilize tools will be necessary
- *Patient-related concerns:*
    - Completed bone graft must not cause pain
- *Customer:*
    - Orthopedic surgeons implanting an osteochondral graft
- *Patient-related concerns:*
    - Allergies, immune response hemocompatibility, and biocompatibility
    - Device should not release unwanted fragments of bone
    - Required surgery with device should not be more invasive than current procedures