Needle OCT
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Product Design Specification

Needle OCT

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Function:

Our project involves creating a needle with imaging capabilities via optical coherence tomography (OCT). The needle has several optical components which include a fiber lens and a diffraction optic. These components have several parameters that may be optimized. Because of the complex nature of the project, our focus is to design a diffraction optic with optimal imaging capabilities. Parameters we will consider include spatial and spectral resolution, as well as biological requirements.

Client requirements:

- Maximum diameter of needle 500µm.
- No loss of information because of encoding overlap. Wavelengths cannot overlap in same order, or in separate intensity orders.
- Prefer no moving parts, illustrates need for diffraction optics.
- Image field made up of micro and macro-sweeps. Macro-sweeps result from optical coherence tomography imaging techniques. Micro-sweeps result from diffraction optic.
- At least 20 µm spatial and spectral resolution.

Design Requirements:

1. **Physical and Operational Characteristics.**

a) Performance requirements:

Needle must be mechanically robust since it will be implemented in various biological tissues. The needle must be strong and flexible to allow optimum penetration into the tissue, with a depth resolution of 20 um. The needle will be used only once before being discarded.

b) Safety:

The optics composing the needle may be composed of glass rods with a maximum diameter of 500 µm. Given the mechanical instability of these thin glass rods, a coating substance must be applied to further strengthen the optical probe. In the case that the glass rod breaks, the coating must contain all the glass, protecting the tissue from infection. The needle design should allow standard sterilization procedure before use. Additionally, the external surface of the needle should not induce an immune response.

c) Accuracy and Reliability:

Optical components involved must ensure the repeatability of obtaining images.

d) Life in Service:

A single needle must be able to function for an entire imaging session.

e) Shelf Life:

Assuming needle is in sterile packaging, the needle has an indefinite shelf life.

f) Operating Environment:

During use the needle must withstand biological tissue temperature (98.6^0F), pH 5.5 to 7.45. The needle will be stored in ambient temperatures.

g) Ergonomics:

The needle should be user-friendly and simple to operate.

h) Size:

The optical needle must have an outer diameter of 200 μm or less. A single needle can be used in one of the following applications: research, clinical, and surgical.

i) Materials:

The needle must be composed of substances acceptable for use in biological tissues by the FDA.

k) Aesthetics, Appearance, and Finish:

The external coating must be smooth.

1. **Production Characteristics**
    - **a) Quantity:**
        A single diffraction optic should be constructed for this semester.
    - **b). Target Product Cost:**
        When commercialized, $10; for design purposes, $100
2. **Miscellaneous**
    - **a). Standards and Specifications:**
        FDA approval necessary.
    - **b). Customer:**
        The concept of no moving parts and a live front view image.
    - **c). Patient Related Concerns:**
        The packaging of the needle must have approved sterilization requirements. The fiber carrying the wavelength encoded information from the needle to the processing area must a separate network so patient imaging information is hacked into. Each needle must be discarded after every use.
    - **d). Competition:**
        Optical coherence needle patent number 6564087 has moving parts forms a washer image from side viewing port.

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Forward Scanning Imaging Optical Probe, patent number US 7,261,687 B2, front viewing probe which uses two moving prisms.