Product Design Specifications

Autofocus Microscopy

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Function:

During a neurosurgery, a surgeon operates in a cavity which may measure up to six inches in depth. Navigation within this cavity is aided by an operating microscope which exhibits a depth of field of approximately half an inch. Consequently, the surgeon may only observe, and therefore operate within, a relatively small fraction of the cavity at any given time. In order to change the depth of operation, a task which most surgeries require be carried out frequently, the surgeon must halt the surgery and refocus the microscope by hand to the desired depth. The refocusing process not only consumes valuable time but also disrupts the surgeon's train of thought and any maneuvers which require continuous movement of an instrument from one depth to another. Our product will function to eliminate the need to refocus the microscope as the surgeon transitions from one depth of field to the next by allowing the microscope to alter its focus in response to changes in the position of the surgeon's instrument tip.

Client Requirements:

- The device must not interfere with any surgical maneuvers
- Must be lightweight
- Must be compatible with current microscopes and other surgical equipment
- Must hold up to sterilization
- Must keep instrument in depth of field at all times
- Must not interfere with other instrumentation
- Must not harm patient or medical personnel

1. Physical and Operational Characteristics

a.) Performance Requirements: The device must track the position of the tip of a surgical implement and refocus accordingly. It should refocus without any significant lag time (<1sec.) and should work with any surgical implements.

b.) Safety Requirements: The device must not interfere with the surgeon's ability to perform to his or her best abilities. It must not release any harmful substances during surgery. All electronics must be housed appropriately. Any components which will come in contact with the patient during surgery must be easily sterilized.

c.) Accuracy and Reliability: The device must track the position of the implement tip to within one centimeter (initially) of its actual position and refocus the microscope to the same degree of accuracy. It must retain this degree of accuracy throughout its lifetime.

d.) Life in Service: Provided it is regularly serviced along with the microscope and does not undergo unnecessary abuse, the device should last three to five years.

e.) Shelf Life: Long periods of inactivity should have no effect on the performance of the device.

f.) Operating Environment: The device will function in an operating environment. This suggests it will not encounter extreme temperatures or humidity. The device is intended to be used in a clean, dust-free environment in order to optimize the performance of electronics. It will also be designed to withstand continuous UV light exposure.

g.) Ergonomics: The device should be easy to use for any surgeon with minimal electronics background. It will be user friendly such that someone skilled in the art of surgery could use it without problems.

h.) Size: The device will be used in an operating room, where space is at a premium. For this reason, the footprint of the entire device should be minimized, with a maximum of 6" X 6".

i.) Weight: The component mounted on the surgical instrument should not inhibit fine adjustments by the surgeon. The entire device must not exceed 5 pounds.

j.) Materials: Any materials are welcome, provided they are safe for use in an operating room.

k.) Aesthetics: Aesthetics should not affect any aspect of our design as our client prefers function over appearance.

2. Production Characteristics

a.) Quantity: One complete prototype will be fabricated.

b.) Target Cost: Firm guidelines for cost have yet to be established, but there will be refinance allowance of $500.00.