

PDS

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Problem statement:

Our client desires a more efficient surgical instrument for minimally invasive surgery. The instrument must be operable by hand and optimally will mimic the motions of the human wrist. Improvements of various factors for convenience are necessary and include, but are not limited to: applied force feedback, reusability, and simple operation for new users.

Physical and Operational Characteristics

- a. *Performance requirements:* The instrument, used for surgical operation, should simulate human wrist motion while being capable of ambidextrous use. Operational conditions require a device sensitive to movement and touch that precisely replicates tensions and pressures applied.
- b. *Safety:* The surgical instrument should maintain the current safety precautions that don't allow the instrument to slip, allow it to lock into place, and minimize uncontrolled motion. There must be simple sterilization techniques for instrument if not disposable.
- c. *Accuracy and Reliability:* The device must maintain the reliability of current product. It must be extremely reliable and durable. The new mechanism should improve the inadequate current accuracy due to poor visual images in 2-D.
- d. *Life in Service:* The product will have a temporary life in service; it will be either disposed of after its operation, or after number of years.
- e. *Shelf Life:* The product's energy source, if operated robotically, is an outlet. Simultaneously, it can be manually used.
- f. *Operating Environment:* The product will experience various surgical operative conditions. All device mechanisms will be exposed to patient's anatomy.
- g. *Ergonomics:* One essential feature of our product will be convenience. The device must have clear instructions, simple to use, and single-arm operation in the case surgeon needs to use other equipment simultaneously.

- h. *Size*: The current length and radius of the device, which is submerged into the patient, should be maintained; handle and parts not exposed to patient's anatomy can be increased in size.
- i. *Weight*: Lighter products are favorable.
- j. *Materials*: Durability, strength, and sterility are the only limitations on material. Steel is currently used for reusable model, but its prices are again rising; it may be worthwhile to explore other options.
- k. *Aesthetics, Appearance, and Finish*: Not of importance but different colors between handle and parts that are inserted into patient could be used.

Production Characteristics

- a. *Quantity*: It will be mass produced; however, our goal is to achieve a working prototype.
- b. *Target Product Cost*: Maintain prices at or near cost currently used.

3. Miscellaneous

- a. *Standards and Specifications*: Convenient for surgeons. There should be no confusion over instrument instructions.
- b. *Customer*: None currently known; this requires further research.
- c. *Patient-related concerns*: None.