

Product Design Specifications for BME 200/300 group 9: Grasping Instrument

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Problem Statement: During laparoscopic surgery, small clips are used to hold tissue away from the site of surgical procedure. Current clips concentrate greater pressure on the area of tissue closest to the joint. This sometimes causes the tissue to be expelled from the grasping instrument with possibility of traumatizing the tissue. The goal of this project is to equalize the pressure across the length of the clip. Due to the small entrance incision, the prospective device must have a diameter less than 5 mm. The grasping instrument must be designed for internal use, thus precautions must be taken to minimize moving parts and safety hazards.

Client requirements:

- Equalize pressure across grasper head
- Limit bulkiness
- Small (5 mm in diameter)
- Must be reusable and easily sterilized
- Possibly attach pressure/force sensor
- Cost limit \$100

Design requirements: Since the device is relatively expensive and multiple graspers could be required for surgery, the device will be used often. The device should provide equal force across the entire surface of the tissue to which it is grasping. The jaws of the clip must lay flat together in order to be inserted or removed from the body. Moving and/or sharp parts must be minimized to protect the interior of the bowel on which the surgery is being performed. These conditions must be met in conjunction with a design that is sturdy, easy to sterilize and produce a good grip.

a. *Performance requirements:* The device could be required at multiple points throughout one surgery and possibly several times a day. Most of the force applied to the grasper will be applied and controlled by the surgeon.

b. *Safety:* The device is meant for internal use and therefore must not contain sharp or moving points that could damage the tissues. Sterilization should occur between every use of the device. The possible sterilization techniques used on this device are ultrasonic cleaning and steam autoclave. Ultrasonic cleaning involves placing the instrument in a neutral pH solution where it will be bombarded by bubbles created by high frequency sound waves. Steam autoclave utilizes high pressured steam to clean the instrument.

c. *Accuracy and Reliability:* The grasper must be capable of opening 55 to 65 degrees such that it can maximize the range in which it can grasp the intended tissue. The grasper must also effectively grip the tissue without damage. When the grasper is completely open, the vertical distance of the opening must be 10mm.

d. *Life in Service*: Due to the relatively high cost for such a small device we would like to optimize the life in service. The high rate of use may cause the grasper to be worn out; however, it is more likely that the mechanical components will wear out before the clip itself would. The clip will be manufactured from 300 to 400 series surgical stainless steel, because this material is stress resistant, yet operatively feasible.

e. *Shelf Life*: The shelf life of the clip is not completely dependent on the material alone, but rather proper care of the surgical instrument, as well. The stainless steel can become stained if the surgical instrument is not cleaned after use. Blood, pus, and tissue can cause pitting, staining, and discoloration to occur on the instrument. Surgical stainless steel contains a chromium alloy which acts to prevent corrosion and scratches.

f. *Operating Environment*:

Temperature range: Room Temperature (25°C) - Autoclave (121°C).

Pressure: Room Pressure (101.3kPa) - Autoclave Pressure (103kPa).

Corrosion from fluids: Exposed to Nitrogen or CO₂, Water, Blood, Bodily Fluids, Steam.

Must withstand Torque through the entirety of the shaft from head to handle 48 cm in length. Head must have enough force to grip a specimen and must withstand wear and tear of surgery.

g. *Ergonomics*: Scissors motion on handle in connection with the gripping head. Withstand torque from the clamping force of the scissor handles through the wires in the shaft to the grasping head. The device must have a long narrow shaft with a gripping head at the end. The shaft must be able to connect and fit to the current handle used.

h. *Size*: Head and shaft must fit through a 5mm-10mm canula. Handle size will correspond to finger and hand size of surgeon. The handle uses a scissor configuration.

i. *Weight*: Grasper weights may vary between 200g and 500g.

j. *Materials*: Surgical Stainless Steel/autoclave tolerant. Prototype: steel, various alloys

k. *Aesthetics, Appearance, and Finish*:

Texture: Smooth, no sharp edges that could catch on innards.

2. Production Characteristics

a. *Quantity*: The client wants one prototype made by the end of the semester.

b. *Target Product Cost*: Currently the device is typically marketed between \$300 and \$1,000. However, only \$100 is available for the production of a prototype.

3. Miscellaneous

a. *Standards and Specifications*: FDA approval is required for the device since it will be directly used on a patient. The device must be safe to use inside a human body and the

parts must be secure such that they will spontaneously decompose while working on a patient. Surgical stainless steel will be used, which has already been FDA approved. The ridges on the grasper must be soft enough that it will not tear or damage the bowel lining (lumen), yet provide a strong enough grip to hold tissue when the device is being used.

b. *Customer*: The client wants a design that can fit through a 5 mm port and will be compatible with the current surgical technique.

c. *Patient-related concerns*: The device will need to be reusable. Therefore, it is imperative that the device can effectively undergo the sterilization process used on surgical tools.

d. *Competition*: There are similar devices that exist. However, no device has been found which incorporates our client's idea. The change in the mechanism of the hinge would produce an entirely unique grasper design. Current designs all involve the angular closure of the grasper, similar to scissors. The client wants a device that will close in a vertical motion, with the grasper ends parallel to one another to equally distribute the forces across the jaw planes.