

Laparoscopic Banding Device Product Design Specifications

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Function: Design a laparoscopic banding instrument for tubal sterilization that is less traumatic and more dependable than current, cumbersome, rough, inaccurate product.

Client Requirements:

- Load bands more easily
- Release bands safely, accurately
- Must work with existing trocan
- Training on device should be minimal

Design requirements:

1. Physical and Operational Characteristics

- Performance requirements:* Device must be accurate for one-time use, ergonomically similar to current product.
- Safety:* Device must not tear fallopian tubes while releasing bands and must be kept sterile before use.
- Accuracy and Reliability:* Device must release band onto bent tube the first (and only) attempt with a failure rate smaller than that of the current device (20%).
- Life in Service:* Entire product will only be used for one surgery before it is discarded.
- Shelf Life:* Device should be stored at room temperature (approximately 20-30 °C) in a clean and dry environment. Shelf life of materials (stainless steel, plastic) is many years, and as long as sterile package is not compromised, the device should last that long.
- Operating Environment:* The product is designed to enter the human body. Device must be able to withstand normal temperature range (approximately 15 – 50 °C) and exposure to internal organs and tissues without corroding within the given time frame.
- Ergonomics:* Device should be easy and intuitive for surgeon to handle. Grip must be easy to use within normal range of hand size which is approximately 150 – 250 mm in length. Product should indicate when band has been ejected from device, and the force exerted for ejection of band should not exceed the forces required on the current device.
- Size:* Device should measure approximately 360mm in length, with a handle of approximately 100mm. The outer diameter of the neck of the device to be

inserted into the body must not exceed 75mm. Current bands used have an outer diameter of 4mm and an inner diameter of 1mm.

- i. *Weight:* Weight of device should not exceed a few pounds because device should be easy for operator to handle and maneuver.
- j. *Materials:* Product should be made of stainless steel and plastic. Care should be taken that any other materials used in the device are not toxic. Bands used in the current device are made of silicone elastomer.
- k. *Aesthetics, Appearance, and Finish:* Device should be as similar to the old device as possible so that the surgeons do not have to learn a new procedure.



This is a picture of the current device. There is more information on it in US Patent 4,226,239.

2. Production Characteristics

- a. *Quantity:* The specific number requested is not specified, but we need to build at least one prototype.
- b. *Target Product Cost:* The target cost is as little as possible. The current product costs roughly \$400 and we hope to make a cheaper alternative. We also do not have funding at this time and will need to present a design before we can get funding.

3. Miscellaneous

- a. *Standards and Specifications:* FDA approval is required if the device is determined to be a plausible alternative to the current laparoscopic banding device. They approve all medical devices.
- b. *Customer:* Bands for device should load more easily, and ejected properly. Device should indicate when each band is ejected. Device should not tear the fallopian tube of the patient.
- c. *Patient-related concerns:* The current product is a single use device. If we create a multiple use device it will have to be sterilized at the hospital. For the patients' safety we should create a device that does not tear the fallopian tubes if possible to decrease the amount of unnecessary bleeding.
- d. *Competition:* The current product is produced by the ACMI Corporation and is the only mechanical device used in laparoscopic banding surgery that our client

has ever used or seen (US Patent 4,226,239). There are many other ways to permanently sterilize a woman. Our client prefers this method because of its simplicity and reversibility.