

**Product Design Specifications:
Ergonomic Redesign of a Surgical Stapling Device
February 3, 2017**

Client: Dr. Amy Liepert, liepert@surgery.wisc.edu

Advisor: Beth Meyerand, memeyerand@wisc.edu

Team:

Andrew Fugate - afugate@wisc.edu, Team Leader

Albert Anderson - afanderson2@wisc.edu, Communicator

Therese Besser - tmbesser@wisc.edu, BSAC

Ellen Restyanszki, restyanszki@wisc.edu, BWIG & BPAG

Function:

Surgical staplers have undergone many design modifications including the recent addition of powered devices. Stapling devices are used both for intestinal resections and anastomoses as well as for vascular control. The users of these devices have changed overtime with both the increase in female surgeons as well as an aging surgeon population. Opportunities for improvements in device design for the increasingly diversified surgeon users are multiple. This project provides the opportunity for lab based and field study investigation of the ergonomic implications for the device users as well as potential for novel design modifications and/or solutions.

Dr. Liepert performs laparoscopic surgeries and utilizes a surgical stapler to separate and seal tissues. Her procedures require her to fire the stapler approximately five times. The existing stapler, the Ethicon Echelon Flex, is too large for her hand and the force required to fire causes excess stress and strain on her hand and elbow. The goal of this project is to either design a new stapler, or update an existing device, to be compatible for Dr. Liepert.

Client Requirements:

- Fabricate a prototype for a disposable laparoscopic surgical stapler
- Reduce stress and strain on arm and elbow upon firing
- Compatible with client's hand size

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

The stapler will be designed to be disposable after one surgery, approximately 5-10 staples. It is not feasible to design a device that can be sterilized and reused. It will be preloaded with staples.

b. Safety:

Patient:

The stapler will puncture the desired tissue without harming any surrounding tissue of the patient. The ISO standards focus on the physical implant, the staplers, which will not be augmented by the team.

Surgeon:

The device aims to minimize the strain on the clinician's wrist and elbow, minimizing injury such as Musculoskeletal Disorders from repeated use.

c. Accuracy and Reliability:

The stapler will reliably supply a minimum of 5 staples into the desired tissue location. The ergonomic redesign will not affect the accuracy or reliability of the existing device, the Ethicon Echelon Flex.

d. Life in Service:

The stapler will only be employed once before disposal. The single use will supply a maximum of 10 staples. It is not within the specifications of the project to design a device that can be autoclaved for multiple surgical uses.

e. Shelf Life:

The shelf life of the prototype will be 5 years. The electronics within the device will remain viable for the entirety of the shelf life. The device will be sterilized during the manufacturing process and cannot be contaminated before it is used in the operating room.

f. Operating Environment:

The device will remain in the original packaging until use. Therefore, the device should be stored at room temperature, away from any liquids, and handled with care until the packaging is opened in the operating room. For this reason set-up and opening of the package must be fast and simple so as to not hold up the surgery. The stapler can be reused multiple times on the same patient during a single operation, but must be disposed of as hazardous material following the operation.

g. Ergonomics:

The goal of the project is to improve the ergonomics of the Ethicon Echelon Flex 45 Endopath Stapler. Currently, the grip of the device is too large for our client's hand. The prototype will be compatible with Dr. Liepert's grip. The device will also be designed to be held in a comfortable position by the clinician during operations, minimizing strain on the user's wrist and elbow. The force required to fire a staple will be minimized for ease of use in the female and elderly population.

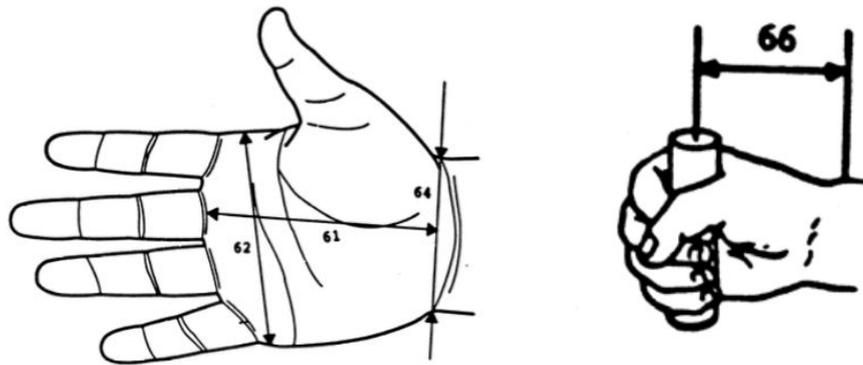


Figure 1 and 2: Hand dimensions from US Army Anthropometry tables

Dr. Liepert's hand measurements are as follows: palm length (61) is 4in, hand breadth from digitizer (62) is 3.25in, wrist-center of grip length (66) is 2.5in, and hand length from digitizer (58) is 7in.

h. Size:

Portability and storage space are not primary concerns of the design of the tool or of the tool itself. Ideally, the product will be smaller than the current surgical stapler used by Dr. Liepert and will be comfortably held in one hand.

i. Weight:

While no specific weight was set by Dr. Liepert, the weight of the stapler is one of the key aspects of the design that must be considered. The product must weigh less than the current surgical stapler used by Dr. Liepert and, ideally, have a more even distribution of weight for more comfortable and convenient operation and handling with one hand.

j. Materials:

The product will likely be made of a plastic alloy; this is in keeping with the designs of current disposable surgical staplers on the market. The material should comply with current FDA guidelines and other relevant requirements.

k. Aesthetics, Appearance, and Finish:

Dr. Liepert did not specify a preference of aesthetic, appearance, or finish. The example surgical stapler shown featured a standard white and blue plastic color scheme and finish; many surgical staplers seen on the market feature a similar appearance and style.

2. Production Characteristics

a. Quantity:

The goal of the semester is to create one working prototype.

b. Target Product Cost:

In the current market the going rate for a laparoscopic surgical stapler ranges from \$600-800. For our purposes this semester, we will work with a budget of \$100.

a. Standards and Specifications:

ISO standards regulate specifications for the implanted device (the staples), but not the stapler. [1] We will not be augmenting the staples, therefore this is not a concern for our project.

b. Customer:

Our customer would prefer a small and easy to pick up and handle machine. The design is for a customer with a smaller hand size or weaker grip strength. Eventually this product could be marketed not only to female surgeons but surgeons who are losing hand strength and dexterity to age-related problems.

c. Patient-related concerns:

The product will be used on a one per procedure basis. The product will be delivered to the Operating Room sterile, and be disposed of post procedure, therefore sterilization is not a concern. Stapler malfunction, however, is a concern for the patient. Every year, there are 8000-9000 adverse events reported to the FDA as a result of stapler malfunction, approximately 1% of which result in death. The primary patient problems as a result of a stapler malfunction are prolonged surgery, excess bleeding, and infection. [2]

d. Competition:

The market of surgical staplers is quite large and diverse, as evidenced by searches through online marketplaces. Available staplers vary wildly in price, design, quality, sophistication, and application; staplers of nearly all shapes, sizes, and colors are available with a wide variety of options and design considerations, including how the device is powered, if it is reusable, and several other key factors. These staplers range from \$10 for a single, plastic, disposable device to several hundred dollars for metal alloy, reusable staplers. Additionally, each disposable Ethicon stapler used by Dr. Liepert and the UW Hospital costs between \$500 and \$600.

Sources:

[1] "Implants for surgery -- Staples with parallel legs for orthopaedic use -- General requirements ISO 8827:1988," *International Organization for Standardization*. [Online]. Available: http://www.iso.org/iso/catalogue_detail.htm?csnumber=16301. [Accessed: 02-Feb-2017].

[2] "Surgical Staplers," in *US Food and Drug Administration*, Center for Devices and Radiological Health, 2015. [Online]. Available: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/ucm110739.htm>. Accessed: Feb. 3, 2017.