# *Wound Edge Approximation*

**Product Design Specification**


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**Team:**

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## Function:

Over 6 million laceration cases are treated in emergency departments each year; during such repairs, skin tension pulls the wound apart while the provider is attempting to approximate the wound edges [1]. Repair is therefore difficult, and imperfect approximation can lead to scarring and poor healing of the wound. This problem is often not an issue within operating rooms on larger wounds; however, it poses a challenge for physicians in emergency rooms, urgent care clinics, and office settings on smaller wounds ranging from 1-5 cm. A clinical tool will be developed to hold the wound edges together while the wound is either sutured or glued, acting as a "second pair of hands" for the physician. The device consists of two identical metal sides attached by two hinges and two springs. The hinges allow the device sides to pivot relative to one another, and the spring allows the sides of the device to be pulled apart by the physician and brought together once placed around the wound. The final design must be easy to use by physicians and must not impart any pain or markings onto the patient's skin during use.

## Client requirements:

- The device must hold the edges of the wound together for suturing or gluing; however, the tool must not interfere with the wound repair.
- The device must not harm healthy skin by leaving marks or causing pain for the patient during use.
- The device needs to be sterilizable since the tool will be used near open wounds, with the possibility of infection.
- The device should be effective to use for linear wounds 1-5 cm in length located typically on patient limbs or torso, not facial or scalp tissue.

- The device must be easy and simple to use, not cumbersome or difficult to handle.

**Design requirements**: The device the team will design must approximate the wound edges during wound closure. The prototype is a metal frame consisting of two identical stainless steel sides with three pieces: one long, thin segment and two rectangular slotted segments welded to opposite ends of the long segment at 45 degree angles. The segments of each half are connected via thumb screws at the top and hex nuts through the slots. Additionally, the sides are connected with tension springs near the bottom to hold the device in resting position while also allowing the sides to be pulled apart during use. To increase the effectiveness of the device, double-sided adhesive tape was included in the device operation procedure. A piece of tape is placed on each skin-contacting side of the device. The device is then pulled open by the clinician and placed on either side of the wound while pressing the edges against the skin to secure the tape in place. Those sides are then pulled together to approximate the wound edges via the force from the tension springs. Therefore, the clinician would be able to use two hands to suture or glue while the wound edges are approximated.

**1. Physical and Operational Characteristics**

a. *Performance requirements*: The device designed will be used daily in emergency rooms and office settings with sterilization in an autoclave taking place between uses. The device must withstand the temperatures (at least 121°C for 30 minutes) of the autoclave without deterioration in mechanical properties [2]. While in use, the device must provide skin tension forces between 6.5 and 7.8 N to allow efficient repositioning and eversion of the wound edges during wound closure [3].

b. *Safety*: The device must not cause further tissue damage during use or leave visible markings on the surrounding skin upon removal. Materials used must be hypoallergenic, non-toxic, medical grade and approved by the FDA. Wound edge approximation using the device must be possible without anesthetizing the surrounding tissues.

c. *Accuracy and Reliability*: During each use, the device must pull the wound edges into direct contact with each other to permit wound eversion. It must securely hold the wound edges in place while suturing or gluing occurs.

d. *Life in Service*: The device will be used daily for approximately 20 minutes at a time. The design must have a minimum lifetime of one year with repeated uses and sterilizations. One year of use with sterilization in between is estimated to be about 350

uses that the device must withstand.

e. *Shelf Life*: When in storage, the design must maintain its functionality when stored at room temperature of 20-25 °C. More specifically, the rectangle device should not weaken or corrode over time. Theoretically, it can be stored for at least a year.

f. *Operating Environment*: The design should be able to withstand basic sterilization procedures in an autoclave. Additionally, any tissue adhesive on the device should be able to be cleaned off in a timely manner. The prototype should also remain on dry skin without slipping for approximately 20 minutes in a typical clinic environment, 20-25 °C.

g. *Ergonomics*: The device should be easily and comfortably used by the administering physician or healthcare professional. Therefore, the size and shape of the device should be fabricated in a way that is appropriate for the shape of the average clinician's hand and easy to handle. The average hand length for males and females is 19.4 and 18.0 cm, respectively. The average hand breadth is 9.04 cm for males and 7.95 cm for females [4]. The team must consider this anthropometric data when designing the size and position of the metal pieces.

h. *Size*: The final design should function for a target wound size of 1-5 cm. Therefore, the sides of the device should be able to extend enough for the device to cover wounds ranging from 1-5 cm.

i. *Weight*: The final product should be light enough to allow the user to easily manipulate it with one hand as well as to avoid inflicting lasting discomfort to the patient. An ideal weight would be <0.23 kg (<0.5 lb).

j. *Materials*: For the design, the body of the device can be made of surgical-grade metal, most likely stainless steel. A plastic body could be an option; however, the device must be sterilized and plastic is often not allowed in autoclaves due to high heat. Originally, the team thought that the long sides of the rectangle design should consist of a softer component that contacts and grasps the skin. This could possibly be made of rubber. Rubber can be sterilized, but repeated cycles can accelerate the degradation of the rubber, so that aspect of the device may need to be replaced more frequently [5]. Silicone could also be used, as it would provide a firm frictional grip on the skin. The temperature and moisture resistant properties of silicone allow it to be sterilized through a variety of methods, including steam autoclaving and dry heat, without losing its physical properties [6]. The long sides of the rectangle could also be texturized to provide better frictional forces against the skin or possibly covered in a material with adhesive properties to maintain stable contact with the patient's skin. However, after preliminary fabrication and

testing, the team decided that a surgical grade adhesive should be used to keep the device on the patient's skin. When using the device, the double-sided adhesive will first be placed on the long metal edges that are to contact the skin. The device is then pulled open by the clinician and placed on either side of the wound while pressing the long edges against the skin to secure the tape in place. The forces from the tension spring then pull together the two long sides, while the connection between the metal and skin is maintained due to the adhesive.

k. *Aesthetics*, *Appearance, and Finish*: The product would likely be used with patients of all ages, including young children, so a non-threatening appearance is ideal in order to minimize patient discomfort. A simple, clean look should be sufficient for the device. In order to avoid user error, the texture of the rectangle device should not be too smooth or slippery.

**2. Production Characteristics**

a. *Quantity*: The team plans on fabricating one prototype for the client by the end of the semester time frame.

b. *Target Product Cost*: The client has not yet specified a budget, but the team hopes to fabricate the prototype with a budget of $300.

**3. Miscellaneous**

a. *Standards and Specifications*: The device will need to be registered with the FDA since it is a medical device, expected to classify as Class I, 510(k) exempt, indicating the device will not require pre-market approval [7].

b. *Customer*: The customers for this device are healthcare professionals that practice in urgent care clinics, emergency rooms, or office settings. From the commentary and opinions provided by the client, the device must be user-friendly for any healthcare provider with easy-to-understand instructions on device use. Additionally, the client made it clear that an overly complex or cumbersome device would be unfavorable to customers.

c. *Patient-related concerns*: Since the device will be used near open wounds with the possibility of infection, the device will need to be sterilized, using simple sterilization in an autoclave. Additionally, the device must not be uncomfortable to the patient or pinch the patient's skin to the point of harm.

d. *Competition*: Several products exist in the market that function to approximate wound edges and close the wound for healing. The device the team designs will only possess one of these functions: approximating wound edges. The device will not need to include a wound closure function. Currently, there is a lack of devices on the market that function solely for wound edge approximation; many healthcare professionals rely on a second person to push the wound edges together or attempt to use forceps to hold the wound while it is sutured or glued.

**DermaClip**: U.S. Pat. Nos. 8,157,839, 9,028,529, 9,301,760, and 9,603,596

The DermaClip is a skin closure device that allows for fast closure of skin surface wounds. The closure system is non-invasive and single use only. The design consists of plastic sutures with a hinge between two layers of adhesive. To use, the area between the adhesives is aligned with the wound. The plastic tabs are then pulled tightly to lock them in place and pull the edges of the wound together; the device is left on the skin during wound healing [8].

**microMend**: US20170333039A1

The wound closure system known as microMend has a design similar to a bandage, but the adhesive backing contains two arrays of micro-staples. The device is placed across the wound one side at a time, so the staples can insert into the skin, approximate the wound edges and close the wound. The holding strength is similar to that of sutures, and the staples are said to inflict minimal to no pain [9].

**Steri-Strip**: The adhesive skin closure system known as Steri-Strip is made of acrylate-based adhesive strips reinforced with polymer filaments for strong closure of skin lacerations. The strips offer a faster and non-invasive alternative to sutures and staples. The device is placed across the wound once the wound has been manually approximated, and stays in place during wound healing for around 7 days [10].

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