

Improved Method of Securing Surgical Drains

Preliminary Product Design Specifications

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Function:

Surgical drains are used to keep certain fluids and air from accumulating in a dead space that is created during surgery [1]. These are attached to patients using sutures which are stitches that attach and hold the tube in the patient's skin [1]. However, these sutures cause pain and discomfort due to tension at the suturing site [2][3]. The created device will address this problem by reducing the amount of tension produced at the suturing site. This problem will be addressed by developing a device that improves the attachment of the surgical drains to the skin. As a result, the patient will have a more comfortable experience with decreased irritation while the surgical drain is in place.

Client requirements:

- The device will need to work effectively in various environments including normal physiological conditions as well as exposure to water.
- The device should be able to work for any type of surgical drain and be placed in any location.
- The device should maintain function and provide comfort when the patient is performing various movements and daily activities including walking, sleeping, stretching, and exercising.
- The drainage wound site should be accessible for sanitizing using alcohol or various soaps.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:*

The device should be replaceable and removable for sanitary reasons until the surgical drain collects less than 25 - 30 cc of fluid, which can take 1 to 5 weeks [2][4]. Once the drainage amount is consistently below 25 - 30 cc of fluid, the drain can be removed. The device should also prevent displacement of the surgical drain tube, especially during patient movement or when pulled on. In addition, the device should relieve the tension created at the attachment site of the surgical drain tube. It will also be necessary that the device is biocompatible with the skin to avoid irritation when in use. Lastly, the device will need to follow certain FDA protocols highlighted in section 3a.

b. *Safety:*

This attachment device should not cause any additional irritation or inflammation to the patient. It should not inhibit drainage flow or cause the tube to be displaced. The site should also be able to be cleaned to ensure that it is sanitary and will not cause any infections.

c. *Accuracy and Reliability:*

The attachment device should be able to hold the surgical drain in place without irritating the patient's skin. This device should not allow for displacement greater than 3.16 +/- 1.0 mm [5]. It should also be adjustable to ensure it is adequately secured and for patient comfort.

d. *Life in Service:*

This product should be able to last for the duration that the surgical drain is attached to the patient, up to one week. This device should be able to withstand all of the activities that accompany a normal life without any impact on its function or how secure it is.

e. *Shelf Life:*

While not in use, this device will be stored in a standard healthcare storage closet at room temperature. If properly stored, the attachment device should be able to be kept for 36 to 40 months [6].

f. *Operating Environment:*

The attachment device will be placed near the exit site of a surgical drain and will have to maintain its function while exposed to body temperatures, cleansing and showering, and stripping of the drain to ensure the drain does not become clogged. The design will likely be attached to the patient's skin and should be able to maintain its function at body temperatures ranging from 98.3 +/- 4.0°F [7]. This range accounts for the temperatures the patient's body might get to if they are instructed to do light exercises while the drains

are still in place. Patients are instructed to shower while their surgical drains are in place so the design should not lose its integrity when exposed to water [8]. Drains also need to be regularly stripped to ensure they remain functional, so the design should not detach or displace during this process [2].

g. Ergonomics:

The design should not detach from the patient's skin after accidental tugging or movement [2]. The housing design should allow the patient to move around and attend their daily activities without interruption. The housing design will incorporate a way to easily hide or wrap this extra tubing. The patient should also be able to access their drain site for the duration they need the drain which can range from 1 to 5 weeks [9].

h. Size:

Most surgical drain diameters range from 0.25 inches to 1 inch and are 14-18 inches long [4][10]. The attachment device will be able to accommodate this range of diameters.

i. Weight:

The design should weigh less than 1 oz as this competes with current devices on the market and will not cause increased discomfort on the patient's skin [11].

j. Materials:

The design must use sterile materials that do not interfere with natural wound healing. The materials should not evoke an immune response at the drainage site. Water-soluble materials cannot be used, as the site must be washed frequently [12]. The material should not notably expand or contract. The design must also use durable materials to withstand use for up to several weeks, but must be easy to remove in as little as a few days [13]. Drains are used for varying durations of time, and the design must be versatile to represent this.

k. Aesthetics, Appearance, and Finish:

The final design must have a smooth finish to avoid any unnecessary catching on clothing [2]. In addition to this, it should conceal the appearance of the drains. Ideally, the design will have various skin tone options for a more discreet appearance [14]. The design should also be able to be used in conjunction with an existing method of securing tubing and drainage bulbs so that the design accounts for all portions of the drainage process, not just at the drain-skin contact point [15].

2. Production Characteristics

a. *Quantity:*

Only one or two units will be needed to show proof of concept. The design should be easily scalable to large quantities to match the rapidly growing need for surgical drains [16].

b. *Target Product Cost:*

Various other products on the market typically fall in the range of \$25 to \$35 [14]. Our design should fall within this range, however, it will ideally be lower in cost than similar products on the market. If scaled up to match market demand, the price will ultimately be lower than the initial cost of production.

3. Miscellaneous

a. *Standards and Specifications:*

The FDA classifies surgical sutures [17], topical adhesives [18], and surgical drains [19] as class II medical devices. Therefore, new attachment methods must follow the FDA's general and special controls. All equipment must be sterilized following FDA sterilization guidelines [20].

b. *Customer:*

The device should prevent tugging on the drain, a source of pain and discomfort for the patient. Additionally, it should be concealed under normal clothing or be designed to appeal to all customers.

c. *Patient-related concerns:*

New attachment methods must be sterilizable prior to use and must allow visual access to the insertion site. The housing device should be machine washable and avoid kinking the drain tube.

d. *Competition:*

Many variations of surgical drain bulb holders have been patented including:

- Medical drainage pouch [21]
- Post-surgical drainage bulb support sling [22]
- Post-surgical drainage container carrier [23]
- Drain tube belt and shower pack kit [24]
- Surgical recovery brassiere [25]
- Drainage reservoir support assembly [26]

- Surgical drainage device [27]
- Abdominal binder with improved drainage bulb holding system [28]
- Apparatus and method for carrying and storing medical drains [29]
- Drain pouch caddy [30]
- Post-operative compression bra and drain apron [31]
- Surgical drain management apparatus [32]
- Drain tube holder system [33]
- Ostomy pouch holding system [34]
- Surgical drainage reservoir support [35]
- Medical drain carrier [36]
- ** This is a non-exhaustive list **

Methods for surgical drain attachment include:

- Sutures with Tie-Lok [37]
- Adhesive device [38]
- Prolene suture with beads [39]
- Centurion sandal [5]
- Centurion sandal with two locking plastic ties [5]
- Centurion sandal with Steristrips [5]
- Double loop sutures [5]
- Multiple loop sutures [5]
- Classical suture loop and knot [40]
- Roman Gaiter suture technique [40]
- Locking-Turns suture technique [40]
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