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Improved Method of Securing Surgical Drains

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ABSTRACT

Developing a new and improved method for securing surgical drains can improve the lives of patients who need them after surgery to prevent accumulation of bodily fluids. The current method of securing surgical drains is to attach them to the body using a single suture. This method can be very uncomfortable for patients as the drain tends to get tugged on and pulled on the single suture site. Additionally, the tugging can lead to drain displacement, slowing down the overall healing process. After extensive research on current methods, three designs have been created that aim to distribute the pressure at the suture site and secure the surgical drain in place. The proposed final design must be comfortable for the patient and also effective at decreasing tension at the suture site for the duration that the drains need to be used. After evaluating the designs and deciding on moving forward with the adhesive bandage with clip design, tentative plans for fabrication and testing were created to evaluate the design's effectiveness. These plans include obtaining all materials and alternatives and creating a surgical drain site model. Once fabrication and testing begin, future changes will be considered to improve the design.

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1 INTRODUCTION

1.1 Motivation / Global Impact

Surgical drains are commonly used for a variety of purposes: therapeutically, palliatively, diagnostically, prophylactically, and for monitoring fluid output [1]. There were an estimated 75.5 million drains sold in 2020 with projections reaching 95.5 million by 2030 [2]. However, because of their current methods of fixation, surgical drains are reported to be uncomfortable, with tugging on the sutures that hold them in place. This is particularly relevant when the drain must be in place for extended periods of time, as drainage must consistently be less than 25-30 cc of fluid a day before removal, which can take up to 1-5 weeks [3], [4].

1.2 Existing Devices & Current Methods

Surgical drains are secured using many different methods based on the attending's preference and the equipment available. However, by and large, the most common method involves using sutures. Sutures are tied with various techniques (Figure 1) [5]–[9], but they will all encounter the same patient comfort issue of tugging on the sutures. Tape (Figure 2) [9] or disposable adhesive devices (Figure 3) [10]–[12] may be used instead to increase patient comfort. They function by attaching a locking mechanism (e.g., clip, locking tie, etc.) to an adhesive. The locking mechanism attaches to the drain tube, holding it in place while the adhesive fixes the device to the skin around the drain insertion site. These techniques, though, only last for approximately a week before requiring removal as the adhesive wears down.



Figure 1: A non-exhaustive diagram of suturing used to secure surgical drains including Purse String (PS), Roman Sandal (RS), Jo'burg (JO), through the tube (TH), one-pass locking tie (PT1), and two-pass locking tie (PT2) [9].



Figure 2: A tape fixation method for securing surgical drains using Leukoplast tape [9].



Figure 3: Disposable tube attachment devices from (A) Changzhou Haiers Medical Devices Co. Ltd. [9] and (B-D) Hollister Incorporated [12].

1.3 Problem Statement

Suturing is the most prevalent method of securing surgical drains after they are placed to prevent the accumulation of fluids and gasses [13]. These sutures, though, cause pain and discomfort due to the tension at the suturing site [3], [14]. However, alternative methods of attaching drains [9]–[12] are for short-term drain usage. Therefore, a new method of fixing surgical drains to the body will be developed to increase patient comfort when a long-term drain is placed.

2 BACKGROUND

2.1 Anatomy and Physiology

Surgical drains are generally needed after surgery in order to try and prevent a build-up of fluid, or a seroma, from forming in the body. Seromas occur when there is a collection or build-up of fluid in an open space or pocket below the skin [15]. They usually develop in areas where tissue has just been removed through surgery. An empty space between tissues can form if the wound does not heal correctly. This along with damage to the lymphatic system around the empty space can cause leakage of fluid, which results in a seroma forming in the skin [16]. Seromas can have a negative impact on the healing of the surgical wound. In the case of a mastectomy, the buildup of fluid causes the flaps of the chest wall to elevate and interferes with their adherence to the tissue bed. This can cause dangerous complications such as delayed wound healing, wound infection, hematoma, flap necrosis, wound reopening, longer hospitalization time, delayed recovery time, and are at risk of becoming infected which causes an abscess [17]. The most effective postoperative way that seromas can be prevented is by the use of surgical drains [18].

2.2 Client Information

Dr. Katie Kalscheur is a professor at the University of Wisconsin-Madison. She has her Ph.D. in Civil and Environmental Engineering and currently teaches the interdisciplinary freshman design course at the College of Engineering. She has tasked the team with developing an improved method for a more comfortable securement of surgical drains.

2.3 Product Design Specification

Since the drain is placed in an open wound, the device should be replaceable and removable until the drain collects less than 23-30 cc of fluid, this can take between 1-5 weeks [3] [4]. This device should also prevent any tube displacement that is caused by any tugging on the tubing and relieve the tension that is caused by sutures at the drain site. It should not cause any additional irritation or inflammation to the area nor should it inhibit the flow of the fluid that is passing through the tube. This device should hold the tube in place while preventing displacement greater than $3.6 \pm 1.0 \text{ mm}$ [7]. This device should be able to last for up to 1 week after it is installed on the patient and withstand typical, everyday activities such as walking, sleeping, stretching, and exercise. Since this device is placed near an open wound, it will need to maintain its function while exposed to body temperatures, this means that the device should remain secure at a body temperature of $98.3 \pm 4.0^{\circ}$ F [19]. The device should accommodate surgical drains with diameters ranging from 0.25-1 inch and should not weigh more than 1 ounce in order to remain competitive with other devices and not to increase discomfort on the patient's

skin [4][20]. In order for this device to be successful, it must not interfere with the natural wound-healing process or evoke an immune response [21]. This device should cost no more than \$35 in order to remain market competitive [22].

3 PRELIMINARY DESIGNS

3.1 Design 1 - Adhesive Bandage with Clip

One method for improving the fixation of surgical drains is to use a clip that will be attached to an adhesive bandage. This adhesive bandage with a clip design would be used alongside the suture placed by the surgeon to hold the drain in place. The adhesive would be made from a hydrocolloid bandage, as they are designed to be worn for up to a week [23]. The hydrocolloid bandage consists of an outer layer that acts as a barrier to protect the wound from bacterial contamination and foreign particles [23]. The hydrocolloid adhesive layer is used to absorb moisture from the wound and create a hydrogel that promotes healing [23]. This bandage would be placed right over the wound site and would encourage proper wound healing while the patient has to wear it. Since surgical drains are typically in place for 1-5 weeks, this bandage would need to be replaced weekly to ensure proper cleanliness at the drainage site [4]. To prevent irritation at the suture site, a gauze pad would be attached at the bottom of the bandage where the adhesive touches the skin. This would lead to less tugging directly at the suture site, and would also prevent any adhesive from pulling on the suture or drain during bandage replacement.

The clip would be made from high-density polyethylene since this material absorbs little water and is typically used as the plastic material for most medical devices [24]. The clip would be attached to a platform made from high-density polyethylene to allow for easy attachment to the adhesive portion of the design. The clip mechanism also allows for adaptability between different drain sizes, ranging from 0.25-1 inch in diameter [4]. This can be seen at the bottom of Figure 4.

Since this design would be made from a waterproof material, this would decrease the amount of time the patient would need to replace it. Replacing the design would be necessary and would increase the price of this product. The use of an adhesive material may irritate the patient's skin after multiple replacements.



Figure 4: Drawing of the adhesive bandage with clip design placed at the drainage site. The clip would wrap around the surgical drain tubing exiting the patient's skin.

3.2 Design 2 - Interior Pressure Distributing Flaps

Another method for securing the surgical drain would be to replace the use of sutures with another device. This device consists of a rigid tube that would be made from high-density polyethylene to fit the diameter of the surgical drain tubing. The high-density polyethylene was the chosen material since it is a rigid plastic that is biocompatible [24]. The flaps would be made from silicone since silicone is a flexible material that is also biocompatible [25]. Most implants are also made from silicone [25].

The device would be placed around the tubing of the surgical drain and implanted when the surgeon places the surgical drains. The flaps would be pulled up and flattened to allow them to be placed into the wound site as seen in Figure 5. Once under the skin, the rigid tube would be pulled up to allow the silicone flaps to flatten out underneath the skin as seen in Figure 6. Each flap would be used to distribute the pressure under the skin in different spots. A locking tie or clip would be wrapped along the edge of the tube outside the body to prevent the tube from getting pushed back further into the patient's body, and to prevent the displacement of the device. This device would remain in place for the entire duration the surgical drains would need to be in place. One drawback of this design would be that it could increase the chances of infection since the surgical drain tubing could not be stripped where the rigid tube is. It would also be difficult to remove this device and an extra incision would be needed to remove it. This device is also not adjustable as it would be slid on once the drain is in place and multiple sizes would need to be created to accommodate different drain sizes.



Figure 5: The silicone flaps in their upright position against the rigid tube for insertion at the wound site.



Figure 6: The silicone flaps are flattened underneath the skin with a tie around the rigid tube to hold the device in place outside the patient's skin.

3.3 Design 3 - Exterior Pressure Distributing Flaps

The third design would be used alongside the sutures that the surgeon typically uses to hold the drain in place. This design consists of pressure-distributing flaps made from a material similar to KT tape. KT tape is made from a cotton-woven base that allows for a more breathable bandage [26]. KT tape is very porous allowing for moisture to seep through the bandage,

preventing the degradation of the adhesive material [26]. This allows for KT tape to remain in place for up to a week at a time. This is ideal for this project as this will reduce the cost of the device and allow for the patient to continue to do their daily activities and physical therapy activities that may be assigned by their doctor without having to constantly replace the tape. Each flap would distribute the pressure evenly on the patient's skin away from the suture site.

The silicone ring of the design is used to hold the drain securely in place. Silicone was chosen for this as it is very flexible and will not compress the surgical tube enough to stop the flow of fluid out of the drain [27]. The gauze padding would be placed on the underside of the adhesive where the wound site and suture site are as can be seen in Figure 7. This ensures that the wound site and suture are not being tugged on by the adhesive material.

This design would be beneficial in distributing the pressure evenly on the patient's skin, except the KT tape material is not waterproof and the patient would need to replace it more often. This would increase the cost of this design.



Figure 7: The pressure-distributing adhesive flaps with a top and bottom view.

4 PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

The criteria for the designs are ranked in importance based on the client's needs. Effectiveness is ranked the highest because the design needs to be able to hold the surgical drain tubes in place and prevent any displacement from occurring. In addition, if effectiveness is low, it could bring up other problems relating to safety and comfort. Patient comfort is ranked next, as this is emphasized by the client as a problem with the current method of attaching surgical drains to a patient. This criterion is scored on how comfortably the design will be once it is installed on the patient. Additionally, it is rated on how well the design will ideally be able to alleviate the pain that occurs at the wound site. The next criterion used to score the designs is ease of use. Ease of use is described as how easily the design is able to be installed and the amount of maintenance required once it is installed. The cost is then used to assess the necessary expenses to fabricate and maintain the design. Lastly, adaptability analyzes how well the design is able to be used in various locations on the patient's body.

		Adhesive Bandage with Clip		Interior Pressure Distributing Flap		Adventer K. Tago Exterior Pressure Distributing Flap	
Criteria	Weight	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score	Score (10 max)	Weighted Score
Effectiveness	30	8	24	6	18	8	24
Patient Comfort	25	8	20	3	8	9	23
Ease of Use	20	7	14	9	18	6	12
Cost	15	8	12	9	14	6	9
Adaptability	10	10	10	7	7	8	8
Sum	100	Sum	80	Sum	66	Sum	76

Figure 8: The preliminary design matrix.

4.2 Evaluation of Preliminary Designs

The adhesive bandage with clip design and pressure-distributing flaps outside scored highest for effectiveness. This is because the two designs would still implement sutures to attach surgical drains [5]. Both designs would increase the stability and support of the surgical drains at the wound site. For patient comfort, the pressure distributing flaps scored the highest due to its use of KT tape which would help with comfortability and disperse the pressure when surgical tubes were tugged on. The second design scored low because some components would be under the skin, which could cause pain if the tubes were tugged on. In addition, inflammation could occur due to foreign body reactions of the silicone flaps going under the skin [28]. As for ease of use, the second design scored the highest since it does not require sutures to attach the tubes and requires little maintenance once it is installed. This is different from the first and second designs because these designs require the need for sutures and adhesives which would need to be changed on a daily basis. This reasoning is also applied to the cost criterion resulting in the

second design scoring the highest. Lastly, for the adaptability criterion, the first design scored the highest. This is because this design uses a clip mechanism that is adjustable for the use of different-diameter drains.

4.3 Proposed Final Design

After analyzing each design using the criteria generated above the adhesive bandage with clip design was chosen as the final design. This design was chosen because of its ability to provide added support for the surgical drain tubes at the wound site and prevent their displacement. In addition to the added support, this design is able to relocate the tension that occurs at the suture site to lessen the discomfort that the patient experiences. A gauze ring will also be implemented in this design to collect any fluid that is released from the wound. Lastly, the device is adaptable for different diameter drains and can be attached to different areas of the body.

5 DEVELOPMENT PROCESS

5.1 Materials

The materials used in the design may change as testing and fabrication progress forward. For initial fabrication purposes, various components will be incorporated, including a hydrocolloid adhesive layer, a gauze material, and a high-density polyethylene clip. The hydrocolloid adhesive has been selected for its ability to absorb moisture from the wound while simultaneously creating a hydrogel to promote successful wound healing. The cotton gauze sponge will prevent any unnecessary adhesion to the sutures or drain at the surgical site. The adhesive should not come into contact with the sutures, as there is added risk of drain displacement or premature suture removal, as well as the potential for added discomfort for the patient. The high-density polyethylene has been selected for the clip due to its hydrophobic nature. High-density polyethylene is also relatively lightweight and very durable [29]. These materials will be ordered and used for initial fabrication.

The team will also consider additional materials to substitute initial ones if testing results are insufficient. Kinesiology tape has been considered for its ability to stretch without rupture and its compatibility with skin in both dry and wet environments. A polyurethane adhesive has also been a potential consideration, as it exhibits good elastomeric properties and fatigue strength [30]. The materials the team has selected are relatively inexpensive and must be approved through the BME department to obtain funding. Materials will be ordered as needed to keep fabrication costs low.

5.2 Methods

To begin the fabrication process, the team will begin by finalizing the materials needed for constructing an initial prototype. Once the materials are finalized, they will be ordered and delivered to allow for fabrication to begin. The suture kit and surgical drains have already been obtained for testing, as detailed in <u>Section 5.3</u>. To begin, the team plans to test a few of the materials that best fit our application for maximum stretch, force to rupture, thickness, and adherence in wet and dry conditions [31].

Once a material has been selected, we will proceed with the fabrication of the prototype. The team will cut out the adhesive into a circle of proper diameter. Gauze will be added to the inner section of the adhesive in the shape of a circle of a smaller diameter. Both materials will be slit in one spot to allow for the bandage to be easily placed over the drain site without needing to disturb the drain tubing. The clip and attachment platform will be modeled using Solidworks to allow for 3D printing of the component using high-density polyethylene. The fabricated design will then be fixed to the testing apparatus for more comprehensive testing.

5.3 Testing

Our design will be tested to verify the ability to effectively minimize drain movement and disturbance. It will also be tested to ensure that the use of the design does not interfere with necessary drain care or cause any additional issues for the patient. The team will construct a testing apparatus to closely mimic the drain site when sutured into the patient. To fabricate the testing apparatus, the team will use a practice suture kit designed for medical students and first responders. The suture kit aims to mimic the layering of skin, fat, and tissue without the need to involve a real patient [32]. The team has also obtained several Jackson-Pratt drains with 100cc drain bulbs [33]. This is the same drain type that is used in mastectomy procedures and will be the starting point for testing.

To create the physical apparatus, the team will meet with Dr. Lee Wilke to have the drain professionally sutured into the suture kit. This will help remove potential sources of error in testing and can help conclude that drain dislodgement was due to a design error rather than suturing error. Once the design and testing apparatus are fabricated, the prototype will be tested by applying quick repetitive pulling forces or rotational forces to the drain, aiming to mimic the brushing of clothing or bumping during normal daily tasks. Measurements of drain displacement will be made.

To test the design based on interference with normal care, a wear test will need to be developed to ensure that the design is easily removable and replaceable as needed for daily drain site cleaning [21]. This will be tested on pig skin or untanned sheep skin to mimic the adhesion properties on human skin [31]. When using an adhesive, it will also be important to confirm there are no adverse effects in material choice, and that removal and reapplication of the design do not create unnecessary irritation to the patient's skin. A protocol for the removal of the design will be created if needed, and a potential topical removal solution may need to be considered, based on testing results.

6 CONCLUSIONS

Suturing is the most common method for securing surgical drains for the prevention of the accumulation of fluid in the body. These sutures are the single point on the patient's skin to hold the drain in place and may cause pain and discomfort. Alternative methods have been designed for attaching drains but commonly have to be replaced. A new and improved method of securing surgical drains to the body will be developed to increase patient comfort when a long-term drain is placed. The proposed final design works with the suture to secure the surgical drain in place using a clip mechanism attached to an adhesive bandage. This clip mechanism allows for an adaptable design that could incorporate the diameter of different drain sizes. By using a bandage design around the suture site, the pressure at the suture site should be reduced. Fabrication and testing plans for this device are described in detail in <u>Section 5</u>. The final goal of this design is to provide a more comfortable experience for the patient for the duration of time they need their drains in place.

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8 APPENDIX

8.1 Product Design Specifications

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 with two approaches. One approach will be to develop a device that improves the attachment of the surgical drains to the skin. The other approach will be to create a housing for the drain tubing and bulb. As a result, the patient will have a much more comfortable and painless experience with the surgical drains.

Client requirements:

- The device will need to work effectively in various environments including hot and cold temperatures 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 $98.3 + 4.0^{\circ}$ [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 patterned options as well as various skin tone options for a more discreet appearance [14]. The design should also incorporate a 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 housing 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]
- ** This is a non-exhaustive list **

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8.2 Material Expenses

			Part			Cost		
Item	Description	Manufacturer	Number	Date	QTY	Each	Total	Link
Complete								
Sterile Suture								
Practice Kit								
for First Aid								
Field								
Emergency								
and Medical								
Students	Practice Suture		MN-062	9/29/20				Practice
Training	Kit	NeoProMedical	719	22	1	27.99	27.99	Suture Kit
Jackson-Pratt								
flat silicone								
drain without								
trocar, 100cc								
bulb, 10mm								
drain, 3/4	Jackson-Pratt		SU130-1	10/6/20				<u>Surgical</u>
perforations	Surgical Drain	Cardinal Health	349	22	3	N/A	N/A	<u>Drain</u>
						TOTAL:	\$27.99	