Product Design Specification (PDS)

Project Title: **Universal Surgical Drain**

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Function: The universal surgical drain will be used to drain pus from boils and abscesses that form underneath the skin. When inserted into a surgical incision made upon an abscess, the drain will keep the cavity of the abscess open by physically preventing the healing and closing of the skin, allowing the pus to drain. This device will be an improvement upon the existing Penrose drain. It will eliminate the need to suture the drain to the wound, and it will be simple to reinsert into the abscess cavity. This will eliminate the need for costly outpatient nursing visits. Additionally, it should be simple, cheap, and easy to produce so that it remains a viable competing product. The drain will be made in several different sizes to accommodate all size of abscess incisions.

Design requirements:

Dr. Ramzi Shehadi has several requirements he would like us to meet. First, the drain must be able to physically prevent the incision from healing and closing without having to be sutured to the skin. Second, the drain must be able to passively maintain its position within the abscess cavity without falling out/being easily removed and without putting excessive pressure on the wound. Third, the patient should be able to easily remove and reinsert the drain into the wound at home without the aid of a nurse or physician. Fourtho, the drain must be made of a cheap, flexible and medical grade non-latex material, preferably the material of the non-latex rubber finger tourniquet given to us by Dr. Shehadi. The drain must be made in different sizes to accommodate all size of abscess incisions, which generally range from 1.5 - 4 cm in length. Our client would like the drain to be made as cheaply and simply as possible to allow for easy mass production.

1. Physical and Operational Characteristics

a. *Performance requirements*: The drain will be used to hold open a surgical incision leading to a subcutaneous abscess for the duration of the healing process (2 weeks to 2 months). The drain should not impede the drainage of fluid from the abscess cavity nor should it place excessive pressure on the inside or outside of the abscess. The drain is intended to be passive with no active components, other than an irrigation port for saline washes, and should be resilient enough to flex and bend without causing structural damage.

b. *Safety*: The drain should be non-toxic and should be made from a medical grade polymer that will not leach toxic products. The drain should not cause an adverse foreign body reaction or lead to a heightened inflammatory response. The drain should be comfortable for extended patient wear and should not cause irritation. The drain should be easy to put in place by a patient if necessary, given instructions are provided. Lastly, the drain will likely need sterile packaging and will be intended as a one-time use product.

c. *Accuracy and Reliability*: The drain should reliably allow an infected abscess cavity to drain. See *Safety* section above.

d. *Life in Service*: The drain will be in place for the duration of the abscess closure process which can range from 2 weeks to 2 months depending on a number of factors (age, original insult, severity, diseases, etc.), but is ultimately disposable and one-time use. The drain should have a shelf-life of at least 2 years.

e. *Operating Environment*: The drain will be inserted into an abscess cavity through a surgical incision and covered by gauze. It will be used by a patient during normal day-to-day activities. As such it should be resistant to external stress and movements by the patient. Additionally it should have a low profile at the incision site to minimize snagging, accidental dislodgement, and further wounding. The device will be originally put in place by a trained physician but will be maintained, and replaced as needed, by the patient.

f. *Ergonomics*: The drain should require minimum force to insert and should remain securely in place for the duration of the wound healing process. It should be comfortable for extended patient wear and should not cause any additional irritation. A cognizant patient should be able to use the drain in an instructed manner.

g. *Size*: The drain will be designed in 3 stock sizes that will cover a range of incision sizes from 1.5 – 4 cm. The drain will need to span 0.5 cm across the dermis and epidermis layers from the external environment into the abscess cavity. The drain should not extend more than 2 cm from the surface of the incision to minimize and prevent accidental snags.

h. *Materials*: The drain should be made of a medical grade polymer such as PDMS, PTFE, or PVC that does not contain toxic, leachable byproducts or additives. If metal is needed for structural reinforcement, stainless steel will be used.

i. *Aesthetics, Appearance, and Finish*: The drain should have a smooth finish to promote patient comfort. The drain should exude safety and efficacy.

2. Production Characteristics

a. *Quantity*: One prototype is needed for proof of concept; however, the design should be engineered to be injection moldable.

b. *Target Product Cost*: The drain cost should be kept to a minimum and be kept as simple as possible to manufacture. Per unit cost should be comparable to the Bard Penrose Drain, which retails at ~$1.50.

3. Miscellaneous

a) *Standards and Specifications:* FDA approval would be required for this device before clinical use. The device would at a minimum have to be proven substantially similar to current drainage devices (i.e. Penrose Drain) and could possibly fall under a class three device.

b) *Customer:* This surgical drain is made to be used by patients under the direction and supervision of a licensed physician. The customers (both the physicians and patients) prefer that the product be latex free, flexible, and easy to manipulate into place. Products that are low in cost and easy to manufacture have been shown to do well in this market.

c) *Patient-Related Concerns:* The device should be stored in its original package at room temperature away from direct exposure to light. The device is designed to be used on a single use basis and sterilization is not required unless directed to do so by a physician. Patients are suggested to consult their doctors prior to removing or changing the drain.

d) *Competition:* There are currently many surgical drains on the market. Specifically we are looking to compete with surgical drains that require no suction and have no added wound healing characteristics. Examples include:

   a. **Surgical drain** - **Patent** 5053021
   b. FLAT **DRAIN** - **Patent** 3860008
   c. SURGICAL **DRAIN** - **Patent** 3823720
   d. Method and device for **draining abscess** - **Patent** 5232440