

Surgical Drain Tube (PDS)

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Function: Dr. Samuel Poore would like a surgical drain tube that consists of a standard round, fluted tube to prevent surgical site infections. He would like the tube to have a microcidal agent, such as chlorhexidine gluconate, in it in some form.

Client requirements:

- Must interface with currently available drain tubes
- Must be able to be left in the body and fight infection for 2 weeks
- Reduce amount of dressing on wound
- Material must be biocompatible
- Have ability to be mass produced

Design requirements:

1. Physical and Operational Characteristics

- a. *Performance requirements:*
 - i. Must fight infection
 - ii. Must fit tightly around the wound
 - iii. Must be disposable
- b. *Safety:*
 - i. Materials cannot harm patient, must be inert
 - ii. Microcidal agent must not enter deeper anatomy
 - iii. Must be sterile
- c. *Accuracy and Reliability*
 - i. Deliver microcidal agent to only the skin
 - ii. Microcidal agent should fight infection
- d. *Life in Service:*
 - i. Microcidal agent should fight infection for 2 weeks
- e. *Shelf Life:*
 - i. 2 years
 - ii. Easily stored
- f. *Operating Environment:*
 - i. Tube
 1. Inside the body, between the skin and pectoralis major
 - ii. Cap and Foam
 1. On skin
 - iii. Room Temperature and Body Temperature- 15-40 degrees Celsius
- g. *Ergonomics:*
 - i. Comfortable for the patient to wear for 2 weeks
 - ii. Easy to use for surgeons
 - iii. Decrease infection rates
- h. *Size*
 - i. Tubing
 1. 3 mm diameter
 2. 1 m total length
 3. 0.3 m of fluted tube
 - ii. Cap

1. 30 mm diameter
2. 2-5 mm suture tabs
3. 4 mm height
4. 3 mm diameter opening
5. 6 mm tube extension

iii. Foam

1. 25 mm diameter
2. 4 mm height
3. 3 mm diameter opening
4. 2 concentric rings

i. *Materials:*

i. i. Silicone

1. Tubing, cap

ii. Polyurethane foam

1. Impregnated foam

iii. Chlorhexidine Gluconate

1. Microcidal agent

iv. Silver Sulfadiazene

1. Microcidal agent

j. *Aesthetics, appearance, and finish:*

- i. Function over aesthetics

2. Production Characteristics

- a. *Quantity:*
 - i. One prototype
 - ii. Possibly mass produce
- b. *Target Product Cost:*
 - i. \$2 each

3. Miscellaneous

- a. *Standards and Specifications:*
 - i. Follow hospital regulations, FDA regulations
 - ii. Must be safe and comfortable for patients
 - iii. Must decrease infection rates
- b. *Customer:*
 - i. Easy to use for surgeons
- c. *Patient-related concerns:*
 - i. Cannot get microcidal agent too deep into tissue
 - ii. Must be comfortable for entire use (2+ weeks)
 - iii. Whole tube must be sterile
- d. *Competition:*
 - i. Existing drain tube with Biopatch
 - ii. Catheters with microcidal agents
 - iii. Elutia drain tube with silver sulfadiazine hydrogel