

## Product Design Specifications (PDS)

**Project:** Skin Applicator

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### I. Function

The goal of this project is to design a disposable applicator for a topical, drug-containing solution. The device should be able to apply the topical solution to a cancer patient receiving radiotherapy over the course of 30 days. There is a current study under way which could make use of such a device.

### II. Client Requirements

- The device must be able to apply 10 mL of the solution per use
- The device should release the drug-containing solution in a controlled, consistent manner
- The device should be able to apply the solution to approximately 250 cm<sup>2</sup> of skin
- The device should be disposable after one use
- The device should function as well as or better than current devices on the market
- The device should be similar in size to the ChloroPrep™ 10.5 mL applicator
- The applicator should be slightly abrasive to increase skin porosity for drug absorption

### III. Design Requirements

#### 1. Physical and Operational Characteristics

- a) Performance Requirements:** The device should be able to successfully apply the solution in a controlled, consistent manner. The device should be disposable after one use.
- b) Safety:** The device must not harm the patient to which the drug is administered, nor should it harm the individual administering the drug. If a glass ampoule is incorporated into the design, there should be no significant possibility of injury from glass shards. The safety of the device is irrespective of the safety of the drug which it is intended to administer (which is determined by the clinician and other regulatory entities).
- c) Accuracy and Reliability:** The device should be able to administer  $10 \pm 0.5$  mL of solution (i.e. within 5% of the desired value). The device should be able to administer the drug to a 250 cm<sup>2</sup> area of skin (or larger).
- d) Life in Service:** The device is intended for a single use.
- e) Shelf Life:** The shelf life is dependent on the half-life of the drug (norepinephrine).
- f) Operating Environment:** The device should be able to function correctly in a typical clinical setting (i.e. 25 °C, 1 atm). The device should be able to withstand stresses and strains imposed by the individual using the applicator.
- g) Ergonomics:** The device should be handheld, portable, and easily used by a single individual with minimal effort.

- h) Size:** The device will consist of two main components: the handle (approximately 15 cm x 4 cm x 2 cm) and the foam applicator (approximately 8 cm x 4 cm x 2 cm).
- i) Weight:** The device will weigh approximately 100 to 200 g.
- j) Materials:** The device will consist mainly of glass (i.e. borosilicate or soda lime glass ampoule) and polymer (i.e. plastics, foam).
- k) Aesthetics:** The device should be aesthetically pleasing and should not induce excessive discomfort or fear in the patient. The plastic handle should be reasonably transparent to monitor the solution. The foam should be slightly abrasive in texture to promote application of the solution onto the skin.

## 2. Production Characteristics

- l) Quantity:** Initially, one functional, disposable device is desired. If the device is successful, then larger scale production may be desired.
- m) Target Product Cost:** The initial prototype should cost under \$200-\$300 to produce. If the prototype is successful, then a lower per-unit cost would be desired.

## 3. Miscellaneous

- n) Standards and Specifications:** Currently there are no significant concerns with University, state, national, or international standards, as the device will initially be tested with the drug vehicle (i.e. a 70:30 solution of ethanol/water).
- o) Customers:** The device should be appealing to and easy to use by clinicians applying radiotherapy to cancer patients.
- p) Patient-Related Concerns:** The cancer patients should not be concerned or harmed by application of the solution by using the device.
- q) Competition:** There are several similar proprietary devices on the market (e.g. CareFusion ChloraPrep™ applicators).