Topical Pharmaceutical Application Device for Scalp

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Problem Statement:

Human cancer patients receiving a 30-day course of radiotherapy for head and neck cancer must have solvent containing drug applied topically to their scalps to prevent alopecia. This is done using a hollow comb applicator that applies a specific amount of solvent to a specific area of the scalp. The client desires a device that will accurately dispense the drug and have a professional appearance so that it complies with the Institutional Review Board (IRB) standards for use in clinical trials.

Client Requirements:

- Applicator must deliver drug solution to the scalp while minimizing amount wasted on the hair
- Deliver 2.0 mL ± 5% to a 50 cm^2 area of scalp
- One-time use and completely disposable
- Limit the amount of dead space to 1.0 mL to minimize costs associated with wasted drug
- Application process must be quick and clean

Design Restraints:

1. **Physical and Operational Requirements**
    a. *Performance requirements:* The device should be designed for single use in a clinical trial setting to deliver 30% water/70% ethanol solution with drug directly to a patient's scalp. The application process should be comfortable and take between 60-90 seconds. The device should limit the amount of dead space to 1.0 mL.
    b. *Safety:* The applicator must pass the standards of the Institutional Review Board (IRB).
    c. *Accuracy and Reliability:* The applicator should uniformly deliver 2.0 mL ± 5% to a 50 cm^2 area of scalp and minimize dripping of the solution.
    d. *Life in Service:* The device will be disposable for one-time use.
    e. *Shelf life:* Since the clinical trials will take approximately 1-2 months, the device should last at least 3-6 months.
    f. *Operating Environment:* The device will be used in a clinical study by a clinical research assistant.
    g. *Ergonomics:* The device should be comfortable for a nurse to hold and use. The comb attachment should not cause any discomfort when used repeatedly on the scalps of patients with sensitive, irradiated skin. A flexible comb with a slightly curved shape arrangement of tips would follow the contours of the scalp better than a rigid comb and would therefore be more comfortable for the patient.
    h. *Size:* The device should be hand-held.
    i. *Weight:* The device weight should be less than 0.5 kg.
    j. *Materials:* The materials used in the device should be compatible with a 70% ethanol solution containing drug. Natural latex should not be used due to potential patient allergies. The client suggests that glass, stainless steel, or plastic is used.

k. *Aesthetics, Appearance, and Finish:* The device should look professional enough to be accepted by the IRB and FDA for clinical trials.

2. Product Characteristics

a. *Quantity:* The client requires one device as a proof of concept. Ideally, 300-400 would be required for clinical trials.
b. *Target Product Cost:* $200-400, could be increased with client approval

3. Miscellaneous

a. *Standards and Specifications:* The applicator must pass the standards of the Institutional Review Board (IRB).
b. *Customer:* The device will be used in a clinical trial at the UW Hospital.
c. *Patient concerns:* Other than general safety concerns, there are no special considerations for the device since it is one-time use.
d. *Competition:* Due to the fact that the device is custom to this specific research lab, there is no foreseen competition; however, there is the potential to integrate current hair dye applicator combs into our design.