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Product Design Specifications

Title: Interpenetrating Networks for delivery systems

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Function : Interpenetrating networks (IPNs) are a type of biomaterials that polymerize in situ and have been used in drug delivery, wound healing, and tissue engineering applications. This design project involves the development of novel delivery mechanisms that should be clinically easy to use with improved storage life. Our device should safely, efficiently, and accurately aid in the administration of IPNs to a specific region.

Client requirements: Our client, Dr. John Kao, would like us to build on our research from last semester by further exploring the delivery mechanism for IPNs. This may involve both mechanical and chemical components, so throughout the semester our team will integrate both to streamline the mixing and application of the final solution. A few topics to consider throughout the semester may be compartments for IPN components, delivery vessel shapes, uniform consistency of solution, ergonomics of spraying, ability to sterilize, and post-reconstitution shelf life.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*
Isolating liquid and powder components will be desired. Mixing procedures should be relatively straightforward and produce a uniform spray pattern, resulting in a uniformly cured IPN. Final solution should be cured within 60 seconds under UV light after application.

b.*Safety*
Chemical properties of the original IPN should not be compromised. The final solution or any of the initial chemical components should not inflict any harm on the patient or medical personnel making or applying the IPN. Sterilization of all components should be possible

c. *Accuracy and Reliability*

Mixing procedures should be relatively straightforward to minimize human error. Composition should be standardized between bottles. Final solution should have a uniform consistency and an even spray.

d. *Life in Service*
Each package will be single use.

e. *Shelf Life*
The useful life of the reconstituted product will be explored, with a goal of two hours.

f. *Operating Environment*
Product will only be used in a sterile environment such as hospital operating rooms and emergency rooms.

g. *Size*
The product's volume will be standardized to accommodate different-sized wounds. Possible sizes might be 20 mL, 60 mL, and 100 mL.

j. *Materials*
Components of the formula will include gelatin, PEG-dA, solvent, photoinitiator, and pharmaceuticals. Materials for vessel fabrication should be biocompatible, easily sterilized, and of low-cost. Pieces that are currently commercially will also be favored.

k. *Aesthetics, Appearance, and Finish*
Possibly color-coded for varied applications. Product must be well-labeled. A capacity to shield the photoinitiator from UV light is essential.

l. *Ergonomics*
Application must minimize fatigue and work required from the user. Final delivery system must be comfortable to use. User should be able to control the rate of application.

2. Production Characteristics

a. *Quantity*
Only one unit is desired.

b. *Target Product Cost*
Pharmaceutical components should be the largest percentage of the total product's cost.

3. Miscellaneous

a. *Standards and Specifications*

FDA re-approval may be necessary.

b. *Customer*
Various medical institutions.

c. *Patient-related concerns*
Proper wound debridement will be necessary prior to application. Sterile packaging is essential.

d.*Competition*
Inter-Vial, Clip'n'ject, U-Mix travel bottle, and Hasplast.