ABSORBABLE HYDRODISSECTION FLUID

PRODUCT DESIGN SPECIFICATIONS
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Hydrodissection is used to protect adjacent organs during percutaneous thermal ablation. Current techniques involve the injection of 5% dextrose with water (D5W) or saline. Although effective in protecting surrounding tissue, these solutions tend to migrate into the body cavity. To remain effective, large amounts of fluid are necessary (approximately one liter). The goal of this project is to develop a solution/gel that encompasses favorable aspects of the current solutions: easy to introduce, ultrasound transparent, visible on CT/MRI, biocompatible, absorbable, thermally and electrically insulating, and relatively low cost; but also puts a stop to solution migration into the body cavity.

Client Requirements:

- The designed fluid must prevent the migration of solution within the body cavity during hydrodissection and ablation.
- The designed fluid must be comparable with the current favorable characteristics of D5W. These include:
    - Easy to introduce/inject – The product must be able to be introduced through 20 gauge needle (0.6 mm inner diameter).
    - Ultrasound transparent and visible on CT/MRI – The product should not reduce tumor visibility or imaging capabilities.
    - Biocompatible/absorbable – The product must be well tolerated by the body cavity and leave no post treatment residue.
    - Thermal /electrical insulator – In order for the product to effectively protect adjacent tissue, it must be a thermal and electrical insulator.
    - Comparable cost – The current cost of D5W is minimal, approximately five dollars per one liter unit.

Design Requirements:

1. Physical and Operational Characteristics

A. *Performance requirements:* The product must contain all favorable characteristics of current hydrodissection methods: ease of injection, biocompatibility, thermal and electrical insulator, and reasonable cost. In addition, it must prevent the migration of fluid into the peritoneal cavity.

B. *Safety:* Since the fluid is to be introduced into the body cavity, the final design must be non-toxic, biocompatible, and hypoallergenic.

C. *Accuracy and Reliability:* Failure of the product could result in serious complications to the patient; therefore, the product must be completely reliable. The accuracy of fluid retention time is imperative to the effectiveness of the treatment. Efficient hydrodissection must persist for at least one hour.

D. *Life in Service:* This product is to be used for hydrodissection during radiofrequency ablation lasting approximately one hour. Prior to treatment, the fluid will be stored in a 250 ml IV bag.
E. *Shelf Life:* The fluid is to be packaged in 250 ml IV bags and must have at least a one year shelf life; this is necessary to be competitive with currently used products.
F. *Operating Environment:* The product is designed to be injected into the body cavity and should function predictably within the body's normal thresholds: approximately 7.3 pH, 35-37^{o}C, and should be isotonic to the peritoneal fluid.
G. *Ergonomics:* The final design must be comparable to D5W for ease of injection. The ability of the fluid to be introduced through a 20 gauge needle is necessary for patient safety.
H. *Size: A* single effective treatment should require less than one IV bag, 250mL of fluid.
I. *Weight:* Weight requirements are not applicable for this product.
J. *Materials:* All the materials used in this design must meet the standards of the Food and Drug Administration (FDA), as it is designed for use on human subjects.
K. *Aesthetics, Appearance, and Finish:* Requirements for the design necessitate distinction between the fluid and tumor during procedural imaging.

2. Production Characteristics

A. *Quantity:* A volume of 250mL or less should be sufficient for one treatment.
B. *Target Product Cost:* Less than $200 per unit. Minimizing the cost is essential to market success of this product. Ideally the unit price would be comparable to D5W.

3. Miscellaneous

A. *Standards and Specifications:* The final product will require the approval of the Food and Drug Administration for use in the human body.
B. *Customer:* Prospective customers of this product would require effective hydrodissection, ease of use, reasonable cost, and biocompatibility. The primary customers are medical personnel performing hydrodissection procedures, this product will be an alternative to current hydrodissection techniques during patient consults.
C. *Patient-related concerns:* Patient safety is the first concern; the prevention of non-targeted tissue damage is essential. Additionally, patient comfort should be maximized during and after treatment.
D. *Competition:* D5W is most commonly used in hydrodissection procedures and fulfills most requirements for an ideal hydrodissection fluid. Also, 0.9% saline is used for hydrodissection; however, because of the ionic characteristic of saline, it is less common than D5W.