PRODUCT DESIGN SPECIFICATIONS **FEBRUARY 3, 2011**

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A common technique to facilitate a percutaneous thermal ablation is hydrodissection. During hydrodissection, fluid is injected between the target ablation site and any surrounding tissues which require thermal protection. The hydrodissection fluid creates a physical, thermal and, in the case of non-ionic fluids, electrical barrier to protect such vulnerable tissues. Current fluids are relatively non-viscous, prone to migration in the abdominal cavity, and readily absorbed by the body. As a result, large fluid volumes are often required (~1 L) to create an effective barrier. Even with large volumes, the fluid barrier can degrade substantially during a procedure.

Previously, a 19.0% poloxamer 407 solution in DI water was formulated and tested to prevent fluid migration and barrier degradation while retaining the useful characteristics of currently used hydrodissection fluids. Poloxamer 407 could be injected as a fluid, then form a thermoreversible gel in vivo at body temperature. This does solve the main problem with other hydrodissection fluids; however, it also presents new problems to solve. The main issue with the current design is that it is too viscous of a fluid to readily inject through a 21 gauge needle. In addition, initial animal testing has shown that excessive motion between the ablation site and surrounding tissue can inhibit and even prevent gelation in vivo.

Client Requirements:

- The fluid must prevent migration of solution within the body cavity during hydrodissection and ablation.
- The fluid will be used in minimally invasive procedures and must be able to inject easily through a 21 gauge needle
- The designed fluid must retain the favorable characteristics of the current product:
    - 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 the 19.0% poloxamer solution is minimal, approximately ten dollars per unit.

Design Requirements:

1. Physical and Operational Characteristics
    a. *Performance requirements:* The product must retain all favorable characteristics of current hydrodissection methods: biocompatibility, thermal and electrical insulation, fluid migration prevention, and reasonable cost. In addition, it must be easier to inject

and form a stronger gel not prone to breakdown upon excessive motion between tissues.

b. *Safety:* Since the fluid is to be introduced into the body cavity, the final design must be non-toxic, biocompatible, bioabsorbable, and hypo-allergenic.
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 to three hours.
d. *Life in Service:* The product is to be used for hydrodissection during radiofrequency ablation lasting approximately one to three hours. Prior to treatment, the fluid will be stored in 250 mL IV bags at room temperature, though refrigeration would be ideal.
e. *Shelf Life:* The fluid will be packaged in 250 mL IV bags and should 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, 35-37oC. It should also be isotonic to the peritoneal fluid.
g. *Ergonomics:* The final design must have a low enough viscosity to inject through a 21 gauge needle. The ability of the fluid to be introduced through a 21 gauge needle is imperative for successful, minimally invasive operations.
h. *Size:* A single effective treatment should require one 250 mL unit or less.
i. *Weight:* Weight requirements are not applicable to this product.
j. *Materials:* All the materials used in this design must meet the standards of the Food and Drug Administration (FDA) for class III medical devices, as it is designed for use on human subjects.
k. *Aesthetics, Appearance, and Finish:* Requirements for the design necessitate distinction between the fluid and the malignant tissue during procedural imaging.

2. Production Characteristics
    a. *Quantity:* A volume of 250 mL or less should be sufficient for treatment.
    b. *Target Product Cost:* Less than $200 per unit. Minimizing cost is essential to market success of the product.
3. Miscellaneous
    a. *Standards and Specifications:* The final product will require the approval of the FDA for class III medical devices for use in the human body.
    b. *Customer:* Prospective customers of this product would require it to produce effective hydrodissection, be ergonomically efficient, have a reasonable cost, and be biocompatible. The primary customers are medical personnel performing radiofrequency or cryoablation procedures. This product will be an alternative to current hydrodissection techniques during patient consults.
    c. *Patient-related concerns:* Patient safety is the primary concern; the prevention of non-targeted tissue damage is essential. Additionally, patient comfort should be maximized during and after treatment.
    d. *Competition:* Five percent dextrose in water (D5W) is the most commonly used hydrodissection fluid, and fulfills many requirements for an ideal hydrodissection fluid. Though it is only $2.50 per 250 mL unit, large volumes (> 1L) are often required to prevent ablation damage due to migration within the peritoneal cavity. Saline solutions have also been used in similar quantities; however, they conduct electricity and do not see as much use.