Chemical Dissolution of Abdominal Adhesions
Product Design Specifications
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Function: To remove mature adhesions in patients who have received many surgeries and have resulting symptoms due to large adhesions. The solution must be less-invasive than current techniques.

Client Requirements:

- Must be able to remove adhesions after the adhesions are mature and well-developed (not a preventative measure)
- Must be non-invasive to reduce the risk of further adhesion development and other issues associated with large surgeries

Design Requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: The product is to assist in adhesion degradation or removal without the need for major surgical procedures. It should cause less of a risk of adhesion reformation than current removal methods, and it should reduce the overall adhesion volume by greater than 50%.

b. *Safety*: The product is to attack formed adhesions without negatively affecting functioning organs or causing adverse reactions in the body. This includes potential for chemical contamination to non-targeted tissues, induced toxicity to organs, and development of adverse side effects to patient or surgeon due to delivery method or MMP type. The product must maintain FDA standards through clinical testing for safety.

c. *Accuracy and Reliability*: This product must be able to target a localized region without seeping into other parts of the body. It must also be able to remove the adhesion without subsequent major surgery for device removal once the solution has acted on the adhesion. No more than 2% of the introduced MMP solution should seep out of the area containing the adhesion.

d. *Life in Service*: The solution should ideally be fast acting and with a short half-life to optimize its activity at the site of the adhesion before possible diffusion to other parts of the body. Half life should be as short as short as possible, while still allowing for destruction of collagen.

e. *Shelf Life:* The device itself should last for 1 year in appropriate storage, but the actual enzyme solution will be made within days to hours of administration.

f. *Operating Environment*: The product is to be administered in an operating/procedure room where all FDA sterility standards apply [2].

g. *Ergonomics*: The product must be user friendly for those in an operating/procedure room. According to OSHA's Sections 1910.103, 1910.106 through 1910.111, and 1910.119, 1910.120, and 1910.122 through 1910.126, which declare the standards for hazardous materials.

h. *Size*: The product should be small enough to be conveniently inserted into the abdominal area of an adult patient without creating problems for neighboring organs. The design must also be able to be surgically implanted with laparoscopy techniques, and must not require a major surgery. Most laparoscopy tools are between 3-10mm so our tool will not exceed this range.

i. Weight: The device must not be too heavy that it will cause the patient uncomfort once implanted; it also should not cause unnecessary stress to the adhesion and surrounding tissue once implanted. The final weight of the design will be on the scale of grams, and no more than 20 grams maximum.

j. *Materials*: The materials currently include a collagenase solution (most likely a derivative of Collagenase Clostridium Histolyticum). The other materials are not yet known and will depend greatly upon the team's choice of delivery method. However, materials chosen must not cause adverse reactions to the body, and will ideally be bioabsorbable.

k. *Aesthetics*, *Appearance, and Finish*: This product is intended to dissolve adhesions within the body, and thus will not be seen once implanted in the patient. As a result, its appearance and finish are not of great concern.

2. Production Characteristics

a. *Quantity*: Since the team's target customers are patients with unique complications, the product will most likely be produced on a relatively small scale with the possibility of individualization.

b. *Target Product Cost*: The product should not cost substantially more for the patient or hospital than the current surgery used to remove mature adhesions. Specific material and procedural costs will depend greatly upon the final design chosen.

3. Miscellaneous

a. *Standards and Specifications*: The product must comply with all hospital and FDA regulations regarding sterility for critical items [2]. It must also reduce patient discomfort as compared to the patient's comfort levels prior to the operation.

b. *Customer*: The intended customers are patients who have matured adhesions and resulting bowel obstructions. They are most likely to be older patients who had abdominal surgeries before preventative methods were implemented.

c. *Patient-related concerns*: The patient should experience minimal discomfort and no further adhesion development as a result of the treatment. The patient should not have any additional discomfort other than the discomfort associated with laparoscopy. The patient should also subjectively report increased comfort postop.

d. *Competition*: Although there are numerous products focusing on adhesion prevention, no major products target the removal of already-matured adhesions in the abdominal cavity. Our design may incorporate aspects of current preventative methods (suprafilms, surgical techniques), however, it must be able to degrade a mature adhesion.

PDS References:

[1]"Draft guidance for sponsors, industry, researchers, investigators, and food and drug administration staff: Certifications to accompany drug, biological product, and device applications/submissions," *Biotechnology Law Report*, vol. 27, no. 4, pp. 336–337, Aug. 2008.
[2] CDC, "Guideline for Disinfection and sterilization in healthcare facilities, 2008," CDC, 2009. [Online]. Available: http://www.cdc.gov/hicpac/Disinfection_Sterilization/17_00Recommendations.html. Accessed: Oct. 19, 2016.