

Product Design Specifications
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Adhesion Dissolution

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Problem Statement:

In many patients with past surgical histories abdominal adhesions are common. In elderly patients, these adhesions can become painful and cause further complications such as small bowel obstructions. Currently, surgery is the only viable non-preventative method for removing adhesions. However, this invasive technique can lead to more adhesion formation. Therefore, the team has been tasked with developing an alternative non-invasive solution for adhesion removal.

Function: To remove mature adhesions in patients who have received many surgeries and have resulting symptoms due to these 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.

b. *Safety:* The product is to attack formed adhesions without negatively affecting functioning organs or causing adverse reactions in the body.

c. *Accuracy and Reliability:* This product must be reliable and trustworthy, as it is ideally to be used to treat people who have developed large adhesions.

d. *Life in Service:* Solution should be able to function in vivo and degrade the collagen in the adhesion.

e. *Shelf Life*: The product should last for 1 year, but the shelf life may vary depending upon the final solution chosen.

f. *Operating Environment*: The product is to be administered in a clinical setting.

g. *Ergonomics*: Must be user friendly for those in an operating/procedure room.

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.

i. *Weight*: The solution should not be unnecessarily heavy.

j. *Materials*: Currently an issue the team is examining as materials will ultimately guide our solution. The material must work to rid the body of the adhesions and prevent further development.

k. *Aesthetics, Appearance, and Finish*: This product is intended to solve adhesions within the body, and thus the aesthetics, appearance, and finish are not of great concern.

2. Production Characteristics

a. *Quantity*: Currently an issue dependent upon the type of solution chosen by the team.

b. *Target Product Cost*: The product should be affordable to be used in a medical facility as an alternative for surgical removal of adhesions. The current budget for this project is \$200.

3. Miscellaneous

a. *Standards and Specifications*: The product must comply with all hospital and FDA regulations regarding sterility. It must also not cause harm to the patient that would outweigh its benefit.

b. *Customer*: The intended customers are patients with already-formed adhesions that cause them bowel obstructions.

c. *Patient-related concerns*: The patient should experience minimal discomfort and no further adhesion development as a result of the treatment.

d. *Competition*: Although there are numerous products focusing on adhesion prevention, no major products target the removal of already-matured adhesions.