

Product Design Specification for BME 200/300 Group 1: Pelvic Prolapse Model

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Problem Statement:

Dr. Tova Ablove needs a dynamic model to teach the pelvic organ prolapse quantification exam (POP-Q). Currently, there is no easy way to teach the different types of prolapse including cystoceles, rectoceles, and vault prolapse. Our objective is to design and fabricate a dynamic, to-scale model, which will accomplish these teaching goals.

Client Requirements:

The model must meet all of the requirements set forth by the client:

- Model dimensions must be to scale.
- Model must contain the bladder, uterus, rectum, vagina, endopelvic fascia.
- Model must show central and lateral prolapse as well as the different stages.
- Model must not include labels.
- Model must be easy to manipulate and reset.

1. Design Requirements

- Performance requirements:* Model must accomplish the teaching goals set by the client.
- Safety:* Model must not be harmful to humans in any way.
- Accuracy and Reliability:* Model needs to have the proportional dimensions of a human pelvis. It must display structural support as well as the bladder, uterus, rectum, and inner walls of the vagina. It must be able to move accurately to demonstrate different types (cystocele, rectocele, uterine, and vaginal vault) and stages (0, I, II, III, IV) of prolapse.
- Life in Service:* Model must be durable and able to be reused for as long as the POP-Q exam is relevant.
- Operating Environment:* Must be able to operate in room temperature (30-40°C) and normal humidity (40-60%).
- Ergonomics:* Model will be fabricated with no rough edges or points and it must be easy to manipulate.
- Size:* Model must be at least three times the size of an average female pelvis.
- Weight:* Must be light enough to be transported easily.
- Materials:* Model must be made of both flexible and rigid materials.
- Aesthetics, Appearance, and Finish:* Model must be able to function as a teaching model for the different stages of prolapse. It does not need to look exactly like a human female pelvis as long as it serves its purpose effectively.

2. Product Characteristics

- a. *Quantity*: One working prototype.
- b. *Target Product Cost*: \$1000.

3. Miscellaneous

- a. *Standards and Specifications*: FDA approval is not required.
- b. *Customer*: Physicians who need a model to teach the POP-Q exam to residents.
- c. *Patient Related Concerns*: Model will not be used on humans; it is solely for teaching purposes.
- d. *Competition*: There are static anatomical models, but few dynamic. One dynamic involves an inverted Santa Claus hat with a wooden embroidery frame and buttons.