Feminora: Redesign of the Vaginal Speculum

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INTRODUCTION AND PROBLEM

The **Vaginal Speculum** is a two-bladed medical device that gynecologists use to examine the vagina canal and cervix[1]

The current two-bill design **(Fig. 1)** results in great discomfort for patients because of the **limited sizing, discomforting clicking sounds, uneven pressure, pinching, and limited visibility when patient walls cave in on themselves[2]**

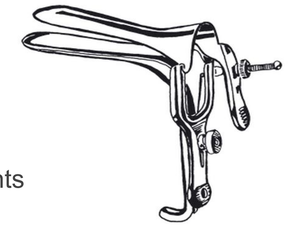


Figure 1. The current vaginal speculum[3]

PROJECT GOAL

Redesign the vaginal speculum

- Even pressure throughout vaginal canal
- Starting diameter size of a tampon for easy vaginal insertion
- Maintain ease of use for physicians
- Decrease discomfort for patients
- Cover a greater range of sizes
- Reduce purchasing costs with a reusable speculum and disposable outer sheath
- Increase visibility
- Soundless

TEAM ORGANIZATIONAL CHART

Mentors: Christine King, PhD & Dinh Vu, MD

- **Ashley Urrutia Avila** — BME — Tasks: Team Lead Business & Marketing
  - **Mei Jin** — BME — Tasks: Design & Prototyping
  - **Henry Nguyen** — BME — Tasks: Design & Prototyping
  - **Madhumita Kannan** — BME — Tasks: Val. Protocol & Testing
  - **Joshua Wang** — BME — Tasks: Matsci,, Business & Mktg.

DESIGN & DEVICE VALIDATION

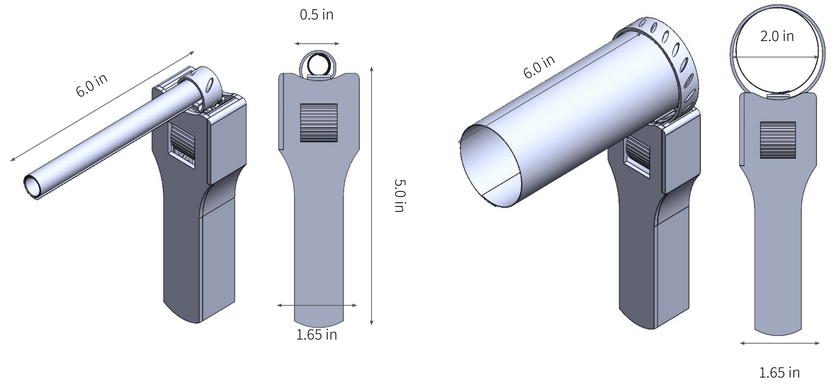


Figure 2. Redesigned vaginal speculum with starting size (left) of 0.5 inches in diameter, which is roughly the size of an average tampon, and the ending position (right) which is four times the starting position.

Design Concept:

- Create a 360-degree contact surface that effectively retracts all vaginal sidewall tissue
  - Similar size dimensions to an average tampon in the closed position
- Prioritize one-handed operation with addition of a smooth-action thumb scroll mechanism to expand the speculum
- Addition of an ergonomic handle that houses a gear train to actuate the opening mechanism

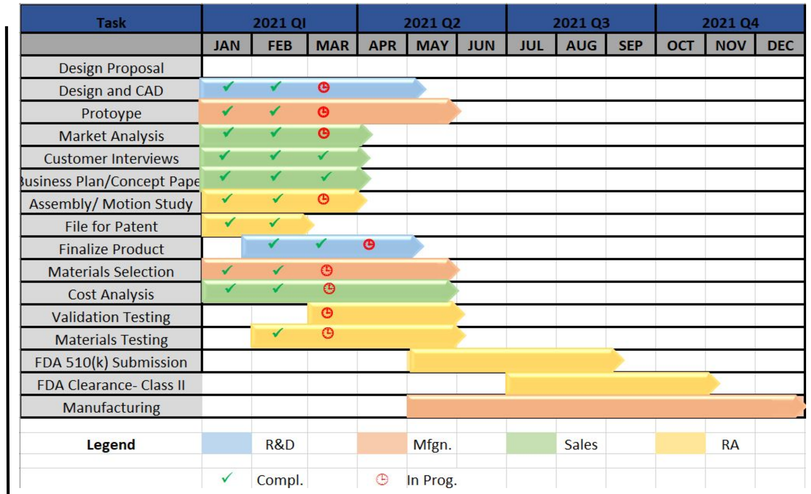
Testing:

- Sidewall force testing using pelvic trainers and small pressure transducers to determine material constraints.
- CES EduPack materials software used to optimize material (considering biocompatibility, surface smoothness, sterilizability, weight, cost, and sustainability).

FDA & ISO Standards:

- **FDA CFR Title 21**- Nonmetal Vaginal Speculum are classified as an Obstetrical and Gynecological Surgical Devices Class II
- **ISO 10993 Biocompatibility** - Characterized as a surface medical device with limited contact duration of less than 24 hours at the mucosal membrane. Biocompatibility standard to test for are Cytotoxicity, Sensitivity, and Irritation.
- **ISO 14971 Risk management of medical devices**- Must develop a plan for risk management with the mechanical components associated with our speculum. These include the collapsing of the instrument within the vaginal canal, and probably pinching of the tissue.
- **ASTM F04.15 Material test methods**- Our product has a reusable mechanical component which does need to be cleaned, thus need to test the materials of our reusable components and ensure that the cleaning processes for this are validated.

FEMINORA TIMELINE



FUTURE DIRECTIONS

- Finish building latest prototype
- Begin benchtop sidewall force testing to determine material constraints
  - Pelvic trainers
  - Small pressure sensors

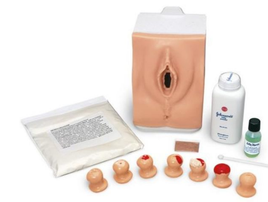


Figure 3. Pelvic trainer for cervical exam testing from 3B Scientific[4]

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CONTANT INFORMATION

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- ***Academic Mentor:*** Dr. Christine King, kingce@uci.edu

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[2] Bates, Carol K., et al. “The Challenging Pelvic Examination.” Journal of General Internal Medicine, vol. 26, no. 6, 2011, pp. 651–657.
[3] Tom King, Brent Edds. “Sklar Pederson Vaginal Speculum.” DRE Medical, www.dremed.com/sklar-pederson-vaginal-speculum/id/4769.
[4] Asiedu MN, Agudogo J, Krieger MS, Miros R, Proeschold-Bell RJ, Schmitt JW, et al. “Design and preliminary analysis of a vaginal inserter for speculum-free cervical cancer screening”, PLoS ONE 12(5), (2017)