

Bioengineering Day Poster Addendum

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1. Desired Needs

- Develop a non-invasive, biocompatible, nipple barrier device that blocks the infiltration of foreign contaminants into the mammary ducts in order to reduce the risk of invasive ductal carcinoma development
- The device must be completely waterproof, sweat-resistant, and maintain adhesion during daily activities such as showering and light to heavy exercise.

2. Major Constraints

- Safety/Regulatory Affairs: all materials must be biocompatible, medical-grade, and hypoallergenic. The device must comply with international standards such as ISO 10993 for biocompatibility.
- Risks: skin irritation or allergic reactions during extended wear, water infiltration via lifting of adhesive, reduced adhesion due to extended water exposure or friction from clothing.
- Global Impact: the device provides a low-cost, non-invasive prevention strategy that could improve accessibility for women who do not want surgical or pharmacological interventions.
- Manufacturability: budget limitations restricted manufacturing methods, but future commercialization would require improved molding consistency, sterile packaging, and large-scale production methods.
- Quality Control/Marketability: Wear trials and adhesion peel testing provided means of evaluating comfort, adhesion strength, and quality of waterproof performance.

3. Engineering Standards

- ISO 10993-1, 5, 10, and 23: biocompatibility, cytotoxicity, skin sensitization, and irritation testing for all skin-contact materials.
- ASTM F2255, F2256, and F2258: adhesive performance and peel-force testing.

4. Ethical, Environmental, or Societal Concerns: with currently limited scientific evidence of carcinogen entry through mammary ducts, claims of the device's cancer-prevention potential must be evidence-based and carefully communicated.

5. Active Teamwork and Leadership

- The team was split into two subteams, the IRB team and the design team.
- Mentor feedback from Dr. Alyssa Taylor and Dr. Geert Schmid-Schoenbein also informed design decisions.

6. Significant Motivating Factors

- The project allowed the team to learn about breast cancer pathogenesis, biomaterials, biocompatibility standards, CAD design, silicone molding, and medical device testing.