

1. Desired Needs

- a) Develop a device which seals off the mammary ducts from external environments in which carcinogens are present, as to lower the risk of mammary duct inflammation and subsequent ductal carcinoma in situ (DCIS)**
- b) Create a design biocompatible with multiple nipple anatomies which is safe for usage over extended wear periods**
- c) The device should be reusable to lower costs and improve accessibility to users**

2. Constraints

- a) All materials used had to be biocompatible over extended wear periods**
- b) Water infiltration from an improper seal; potential skin irritation from device removal if the adhesive was too strong**
- c) The device had to be relatively cheap and reusable as to improve accessibility**
- d) Prototype development was limited to a \$400 budget; access to small-scale FDM printing hindered development of multiple molds**
- e) We were unable to standardize silicone casting process, causing slight differences between prototypes**

3. Engineering Standards

- a) ISO 10993-1, -5, -10, -23: Biocompatibility (cytotoxicity, irritation, and sensitization testing for skin-contact materials)**
- b) ASTM F2244, ASTM F2256, ASTM F2258: Adhesion Strength Testing**
- c) ISO 13485 / ISO 14971: Quality/risk management for medical devices**

4. Ethical, Environmental, and Societal Concerns

- a) Ethical: Duty to not claim the device prevents breast cancer, as carcinogen entrance via mammary ducts has not been proven**
- b) Environmental: The device should be reusable, as it's intended to be primarily plastic which can generate increased waste if single-use**
- c) Societal: There may be stigmas/fears associated with using a device associated with breast cancer, even if it's preventative in nature**

5. Active Teamwork and Leadership

- a) Individuals signed up for IRB and design subgroups based on interest; rotation of leadership roles**
- b) IRB subgroup aimed to complete items to align with UCSD IRB committee reviewal days; design subgroup aimed to complete each design iteration within one to two weeks**
- c) The team incorporated feedback from Dr. Taylor and Dr. Schmid-Schoenbein in regards to timelines and design choices; the team utilized testing logs to inform each design iteration**

6. Motivating Factors

- a) Currently, there is no consensus on the specific environmental factors which cause DCIS**
- b) No device currently exists for the purpose of breast cancer prevention; the team had to determine the most effective materials which provided adequate adhesivity and cause no adverse effects**
- c) The team developed six unique prototypes over six testing cycles, each with targeted design choices that gradually decreased water infiltration over extended wear periods**

7. Entrepreneurial Ideas

- a) Hunees has the ability to function as a device with the potential to prevent breast cancer, serve as a research platform to expand on the current knowledge of breast cancer, and provide cosmetic outcomes similar to nipple covers currently on the market**