

1. Desired Needs

- A non-invasive physical barrier to prevent environmental contaminant entry into the mammary ducts, addressing a pathway untargeted by existing prevention strategies
- A device safe for repeated skin contact and comfortable for extended daily wear
- A research platform to investigate whether ductal occlusion reduces inflammation biomarkers associated with carcinogen exposure
- An accessible, low-cost design manufacturable without specialized equipment

2. Major Constraints

- Safety/Regulatory: All materials required biocompatibility for repeated skin contact
- Risks: Skin irritation or allergic response from silicone or adhesive; inadequate seal allowing water or contaminant penetration; device displacement during wear
- Global Impact: Device must be manufacturable at low cost to remain accessible
- Manufacturability: Fabrication was constrained to budget and equipment available
- Quality Control/Marketability: Silicone casting quality could not be fully standardized without industrial degassing equipment, necessitating careful material selection

3. Engineering Standards

- ISO 10993-1, -5, -10, -23: biocompatibility (cytotoxicity, sensitization, irritation)
- ASTM F2255, F2256, F2258: adhesive strength (lap-shear, T-peel, and tension loading)
- ISO 13485 / ISO 14971: quality management and risk management for medical devices

4. Ethical, Environmental, and Societal Concerns

- Coercion risk in recruitment required multiple IRB revisions to remove incentive structures; informed consent and participant comfort were prioritized throughout
- Claims of cancer prevention must be communicated carefully to avoid false assurance prior to clinical validation
- Single-use adhesive generates waste; silicone cover reusability was a core design goal to minimize environmental footprint

5. Teamwork and Leadership

- Subprojects assigned by interest: IRB analysis and prototype fabrication
- Goals tracked against IRB milestones and prototype cycle deadlines, revised iteratively
- Peer and mentor feedback incorporated after each cycle; Dr. Schmid-Schoenbein and Dr. Taylor shaped adhesive selection and testing methodology

6. Motivating Factors

- New knowledge: IRB development required learning human subjects regulations, biocompatibility standards, and statistical methodology from scratch
- Self-initiating: The team independently sourced materials, designed the peel force testing apparatus, and developed all evaluation logs and recruitment materials
- Persistence: Six prototype cycles and multiple IRB revision rounds required continued iteration; air bubble failures in early prototypes drove the material pivot that produced the breakthrough in water seal performance

7. Innovative and Entrepreneurial Ideas

- HUNEES is the first device designed specifically to physically occlude the mammary ductal openings as a carcinogen barrier (no commercial equivalent exists)
- Dual function as a consumer prevention product and a clinical research platform creates a novel pathway to generate mechanistic evidence while delivering immediate user value
- Low-cost construction supports a realistic commercialization pathway, with potential for anatomical size variants and skin-tone colorways to serve diverse populations