

## A Microcidal Drain Tube Attachment

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### Motivation

- Post-surgical drain tube required for mastectomy patients with expander for reconstruction [1]
- 114,000 mastectomies/year performed in United [4]
  - 12 – 26% of these patients develop surgical site infections (SSI) [5]
  - 5% require second operation due to SSI [1]
  - Expensive end effect: \$757 million spent/year to treat [6]
  - More negative effects: longer recovery, more complications
- The drain-tube related SSI problem extends beyond mastectomy patients



Figure 1. Close up view of a fluted drain tube with exploded cross-section  
<<http://www.ctsnet.org/peterssurgical>>

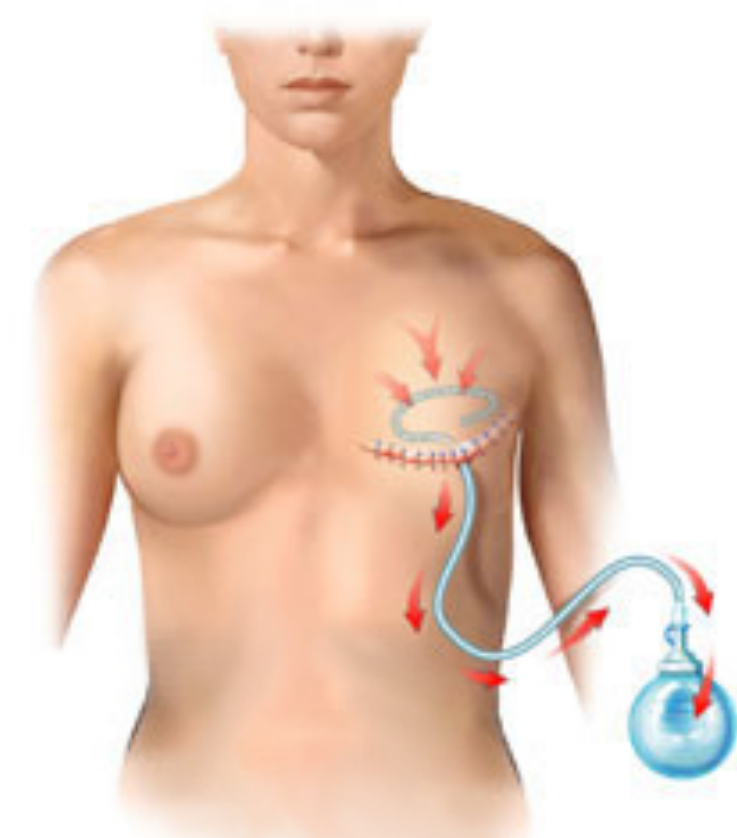


Figure 2. Diagram of a surgical drain tube.  
<[http://www.cancer.sutterhealth.org/information/bc\\_notebook/postoperative\\_care.html](http://www.cancer.sutterhealth.org/information/bc_notebook/postoperative_care.html)>

### Current Technologies

#### The Competition

- Biopatch®**
- Releases CHG up to 7 days [2]
  - Tailored for catheters, *not* drain tubes
  - Lacks attachment mechanism
- Elutia®**
- Tested for 7 days
  - Silicone drain tube
  - Silver hydrogel coating [4]

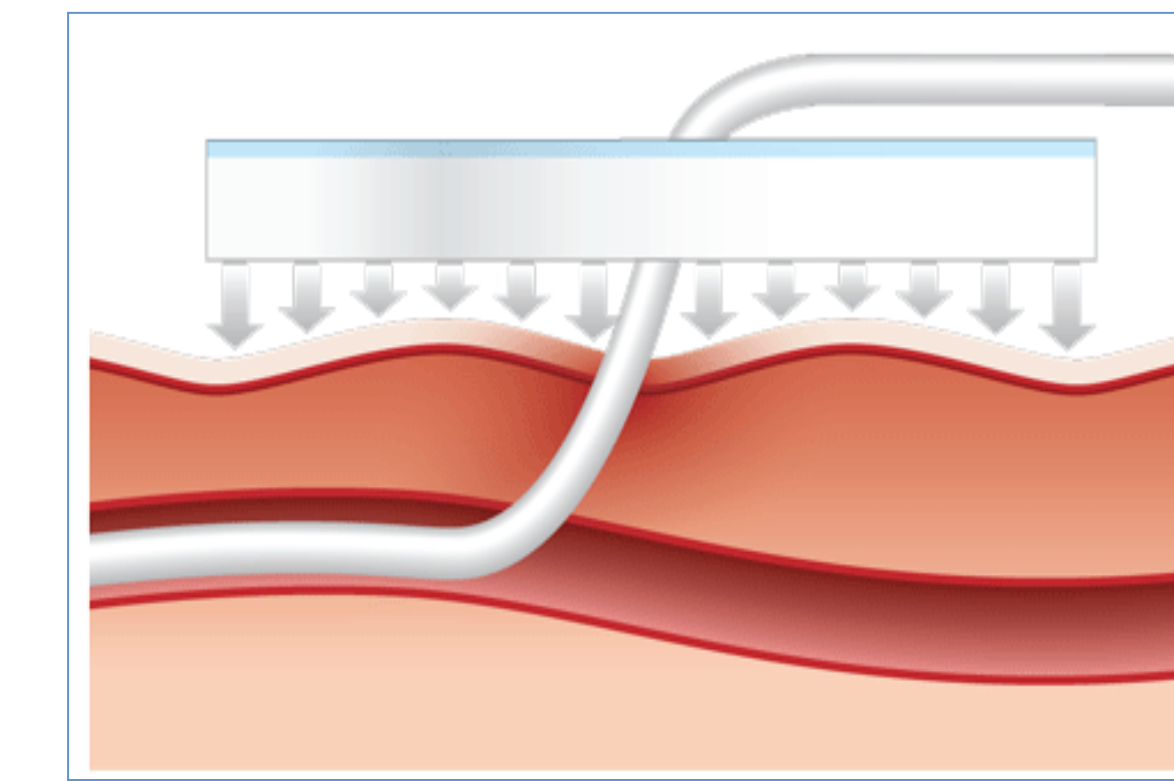


Figure 3. Diagram of a Biopatch® used on skin with a catheter. <<http://www.ethicon360.com/products/biopatch-protectedisk-chg>>

#### Design Criteria for Improved Solution

- Operate *in vivo* for 2 weeks
- Easy interface to currently available surgical drains
- Reduce wound dressing
- Biocompatible
- Easily manufactured

### Proposed Solution

#### Chlorhexidine Gluconate Impregnated Foam Disc

- Primary Antibacterial Agent
- 3% CHG Solution

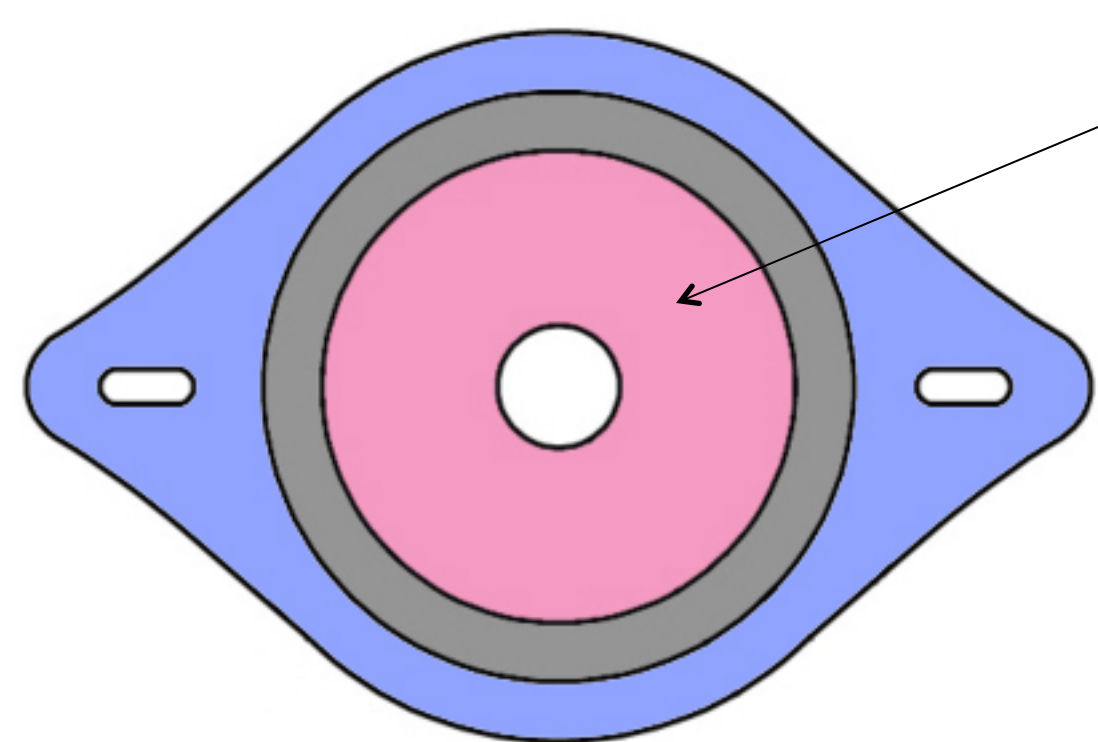


Figure 4: Bottom view of CidalSeal

#### Silicone Extension

- Facilitates Attachment of CidalSeal™ to Drain Tube
- Provides Extra Friction Forces to Prevent Slipping

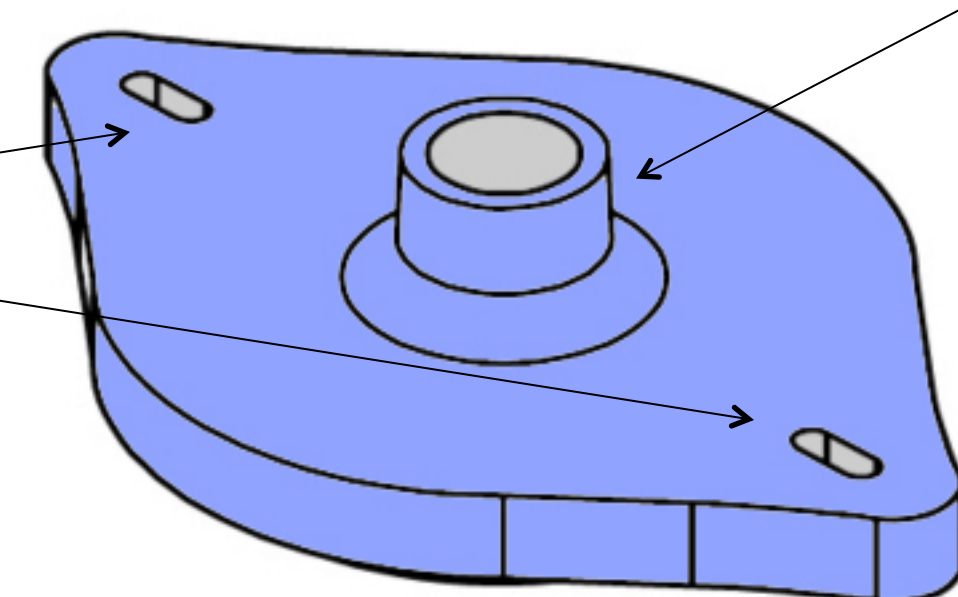


Figure 5: Top Isometric view diagram of the CidalSeal

#### Suture Tab

- Facilitates Attachment of CidalSeal™ to Skin
- Ovoid Shape for Mechanical Strength

#### Silver Sulfadiazine Impregnated Foam Band

- Secondary Microcidal Agent
- Protects Against Different Bacterial Infections than CHG

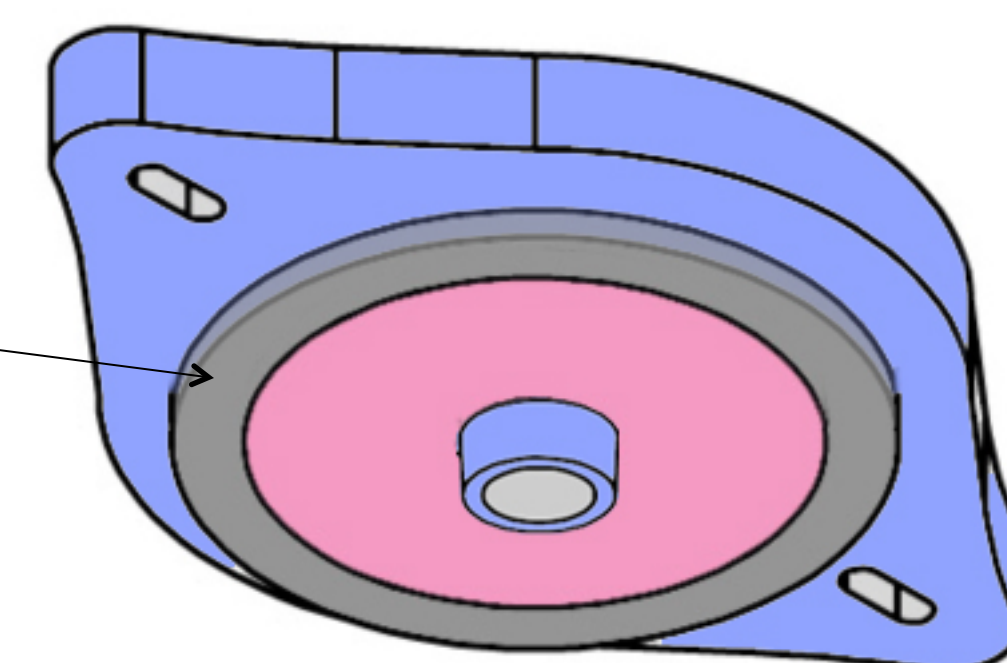
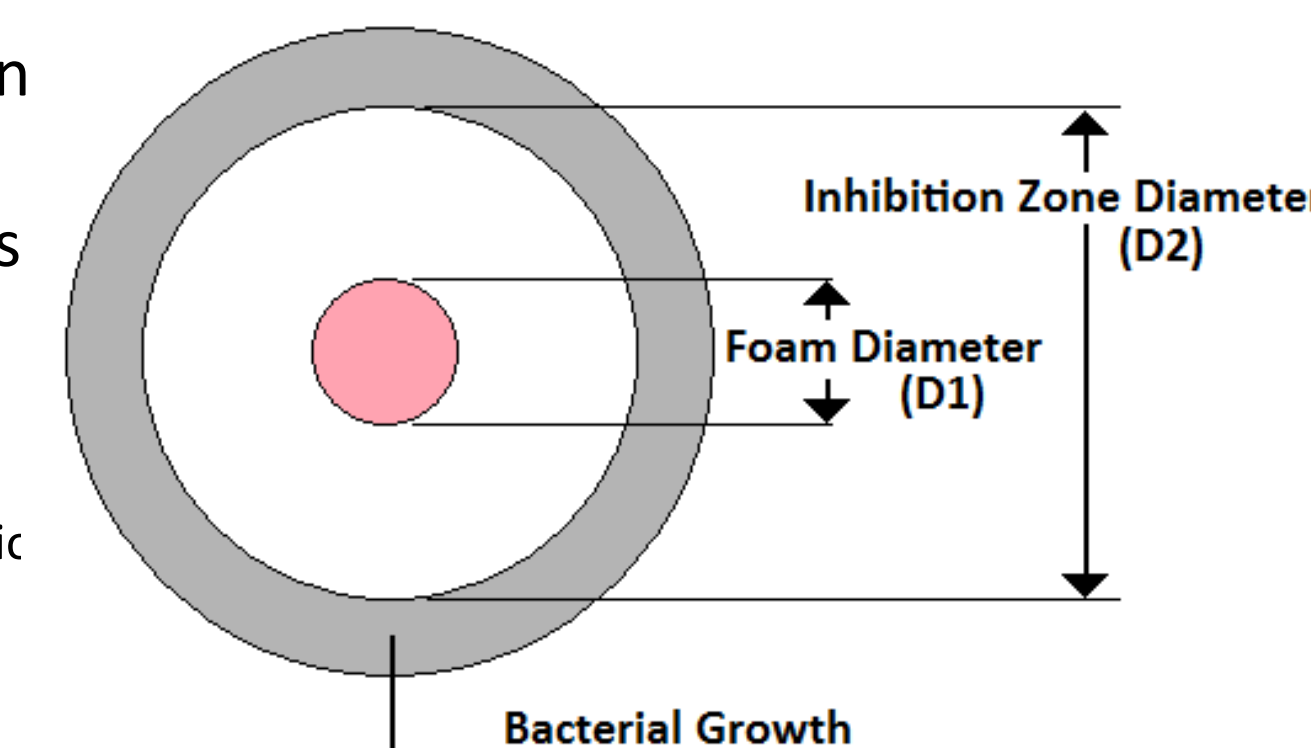


Figure 6: Bottom Isometric view diagram of the CidalSeal

### Quantitative Analysis

- Tested Inhibition against 4 bacterial species

Figure 7: An example showing the method of measurement for inhibitory zone



#### 14 days of bacterial infection protection

- Competing products only last 7 days
- Protection of 4 common infections

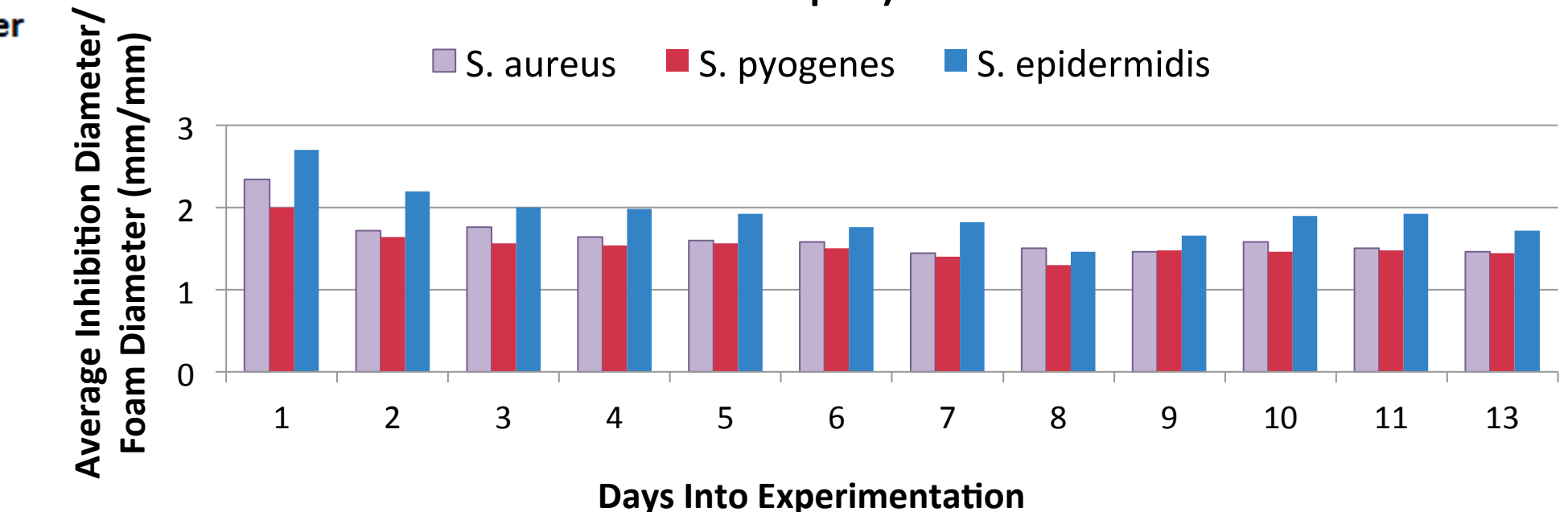
#### Protection against Pseudomonas aeruginosa

- Failure after 6 days with CHG foam
- Biopatch only microcidal agent is CHG
- Full 14 days protection with Silver sulfadiazine foam

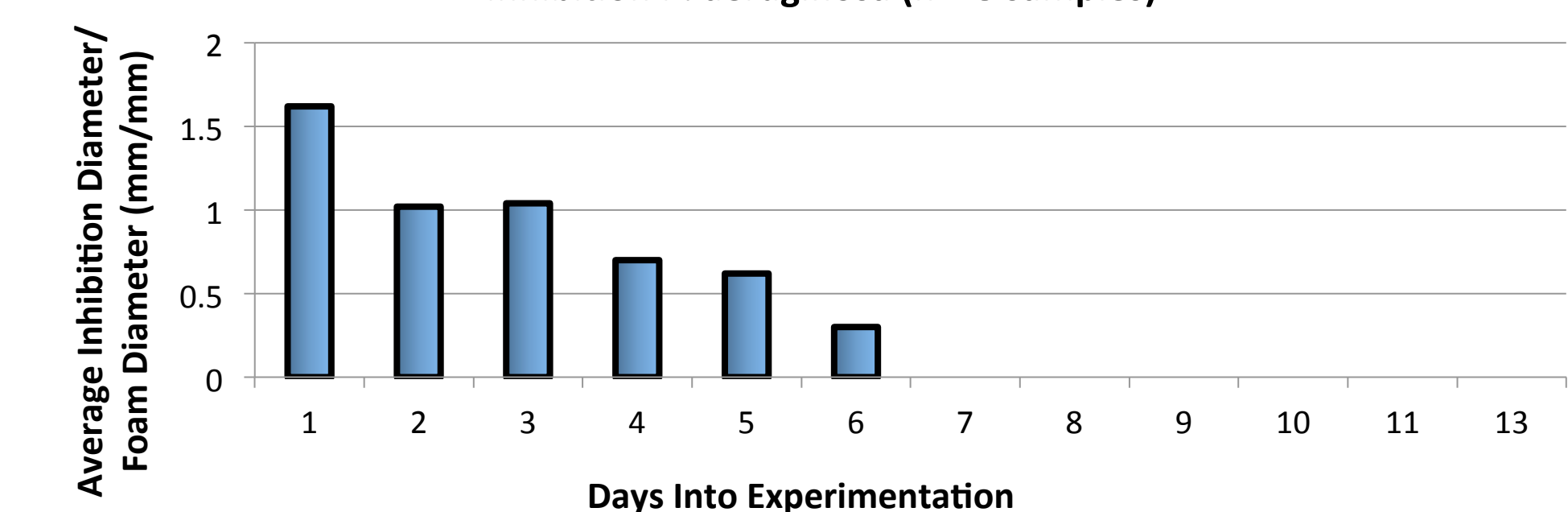
#### Improvement of attachment/removal process

- Only 2 sutures needed for attachment
- Reducing dressings/tape decreases pain for patient upon removal

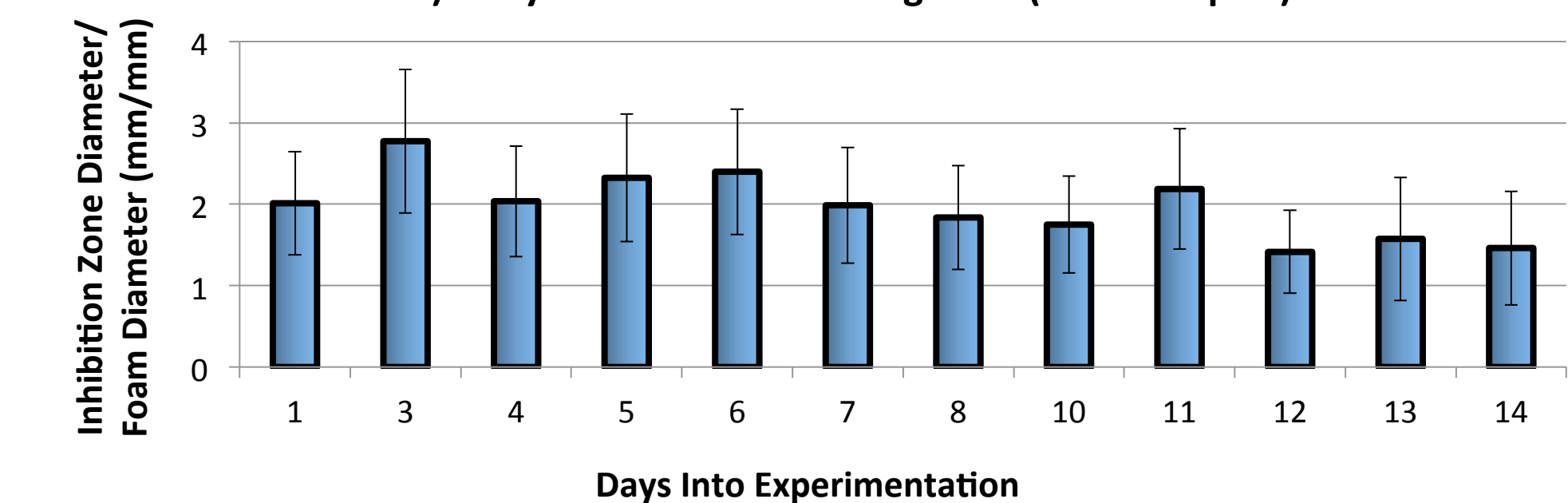
#### Impregnated PU Foam (1.8 lb/ft³) Daily Bacterial Inhibitions (n = 8 samples)



#### CHG Impregnated Polyurethane Foam (1.8 lb/ft³) Daily Bacterial Inhibition P. aeruginosa (n = 8 samples)



#### Silver Sulfadiazine Impregnated Black Polyurethane Foam (2 lb/ft³) Daily Inhibition of P. aeruginosa (n = 6 samples)



### Cost Analysis

#### Clinical impact:

- **\$757 million** spent per year to treat SSI's from mastectomy patients alone [6]
- Drain tubes also used in plastic, orthopedic, and other cardiothoracic surgeries

#### Manufacturing Costs:

- An initial tooling cost estimated at \$1445.00

Product	Price Per Unit
Biopatch®	\$11.30
CidalSeal™	\$1.90

### Moving Forward

#### Testing: In vitro testing

#### Manufacturing:

- Scale up from in lab to industry
- Possibility of injection molding for silicone
- Improve pressure clip

#### Companies of interest:

- Johnson & Johnson
- Cardinal Health
- Jackson Pratt drain
- BARD Medical
- Plus others

### References

#### References

- [1] "Postoperative Care; Wound Dressing and Drain Care." Cancer Services at Sutter Health. Web. 07 Mar. 2011. <[http://www.cancer.sutterhealth.org/information/bc/notebook/postoperative\\_care.html](http://www.cancer.sutterhealth.org/information/bc/notebook/postoperative_care.html)>.
- [2] BioPatch: Protective disk with CHG. Ethicon 360. [online] Referenced Feb 27, 2011. <<http://www.ethicon360.com/products/biopatch-protectedisk-chg>>.
- [3] <http://www.ctsnet.org/peterssurgicalTestingFinal>
- [4] Habermann, E., B., Abbott, A., Parsons, H., M., Virnig, B., A., Al-Refaie, W., B., Tuttle, T., M. (2010). Are Mastectomy Rates Really Increasing in the United States? Journal of Clinical Oncology. 28, 3437-3441.
- [5] Olsen MA, Lefta M, Dietz JR, et al. Risk factors for surgical site infection after major breast operation. J Am Coll Surg. September 2008; 207 (3): 326-335
- [6] Stone PW, Braccia D, Larson E. Systematic review of economic analyses of health care-associated infections. Am. J. Infect. Control. 2005;33(9):501-509. 3 ICT

#### Acknowledgements

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