

## **Bactericidal drain tube attachment for the prevention of surgical site infections**

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Surgical site infections (SSI's) represent a significant portion of healthcare associated infections, with between 1 and 3% of all surgeries developing an SSI, totaling somewhere between 500,000 and 750,000 per year (Perencevich et al., 2003). Mastectomies, the removal of one or both breasts, have a disproportionately high rate of SSI's. Because this surgery is relatively destructive, excess blood and fluid need to be drained, resulting in the need for installation of a surgical drain tube. Between 12 and 26% of mastectomy patients who undergo reconstruction with tissue expanders develop an SSI while drain tube is present (Olsen, et al., 2008). One study has shown mean additional costs of SSI's at \$25,546 (Stone et al., 2005). Assuming 26% of the 114,000-mastectomy patients/year will develop an SSI, approximately \$757 million will be spent per year to treat mastectomy-related SSI's alone. Additionally, SSI's are common across almost all surgical specialties, including orthopedic, thoracic, cardiovascular, neurological, and plastic surgery.

To drain the excess fluid, a surgical drain tube is used. A drain tube is normally made of silicone and is connected to a bulb on the outside of the body that collects the fluid. The device inserts in a 5 mm incision at the surgical site. The surgeon then places a suture from the skin to the drain tube to prevent the tube from sliding at the surgical site. These tubes are typically left in the body for up to 14 days.

Currently, two commercially available devices are in use to prevent SSI's associated with drain tubes. BIOPATCH® is a polyurethane foam disc impregnated with chlorhexidine gluconate (CHG), a common bactericidal agent, to fight infection on the surface of the skin for only 7 days. Additionally, the BIOPATCH® does not have a method of attachment, leading to the use of dressing. Bacterin International, Inc. has released the Elutia Coated Silicone Surgical Wound Drain™, a channel drain enhanced with a silver sulfadiazine coating. Like the BIOPATCH®, however, this tube can only be used for 7 days and must be replaced, causing additional discomfort for the patient.

The CidalSeal™ has been developed to account for the shortcomings of these products. The device consists of a protective platinum-cured silicone cap covering a pair of polyurethane bactericidal sponges. A circular sponge is impregnated with CHG (3%) and is surrounded by a ring of sponge impregnated with silver sulfadiazine (1%), both clinically effective and safe antimicrobial agents. The system was tested in a controlled environment over a period of 14 days. The two microcidal agents were proven efficacious at inhibiting growth of Methicillin-resistant *Staphylococcus aureus* (MRSA), *Staphylococcus epidermidis*, *Streptococcus pyogenes*, and *Pseudomonas aeruginosa*. The CidalSeal™ design exhibits greater protection from a variety of bacterial species than the BIOPATCH, and is effective for a full two weeks. Thus, the CidalSeal™ is a promising development for use in post-surgical patients requiring insertion of a drain tube.