Same functionality, improved performance with lower risk for infection.

Single-use protective disk with CHG to reduce microbial impact on the site dressing on patients with IV and other catheters. Improved absorbency, better wound healing, and superior disk design over market-leading product.

LEARN MORE

Designing for Healthcare

HaloGUARD™ Protective Disc with CHG (Chlorhexidine Gluconate) has demonstrated in-vitro antimicrobial efficacy against a broad range of organisms known to cause Catheter Related Blood Stream Infections (CRBSI's).

Blood stream infections associated with IV catheters and similar are a common cause of death in US hospitals. The Center for Disease Control (CDC) has recommended the use of 0.5% Chlorhexidine Gluconate on skin at the catheter exit site for the prevention of catheter-related blood stream infections.

HaloGUARD™ is a sterile, single-use disposable disc infused with the antimicrobial agent chlorhexidine gluconate (CHG) to reduce contamination of the dressing by inhibiting microbial growth and colonization of the dressing.

HaloGUARD™ is intended to cover and protect insertion sites on adult patients. Common applications include IV catheters, central venous lines, suction catheters, epidural catheters, PICCs, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices. HaloGUARD™ prevents contamination of the dressing by inhibiting microbial growth and colonization of the dressing.

HaloGUARD™ has undergone applicable in vitro, biocompatibility, sterility, and performance testing for safety and effectiveness.

Same Functionality as the Competition

- Vascular insertion sites
- Preventing contamination of the wound dressing for 7 days (168 hours)
- Biocompatible circular foam disk with center hole and radial slit for ease of placement
- Chlorhexidine gluconate (CHG) Antimicrobial agent consistent with CDC and DOQI guidelines
- Incorporation/infusion through soaking foam in CHG solution
- Broad-spectrum of antimicrobial agent
- 5 log CFU/ml reduction of 8 different target pathogens
- Pyrogen and latex free
- Multiple product sizes
- Sterility assurance level: 10-6
- Film adhesive: Pressure sensitive acrylic

Improved Performance

We asked clinical professionals how to improve disks currently used for this. HaloGUARD™ was designed on the basis of the feedback:

- Beveled edges to reduce potential for catheter kinking and securement
- Softer material to reduce skin irritation/abrasion
- Higher absorbency of foam (38% higher than market-leading product)
- Performed tests of In-Vitro Cytotoxicity, irritation and skin sensitization, and chemical characterization
- Better in-vivo wound healing results (by day 21, HaloGUARD compared to BioPatch showed a 63% reduction in observed signs of infection; a 15% smaller wound circumference; 20% less eschar formation and 50% greater re-epithelialization)

Contact us for clinical study, FDA clearance summaries and more details!

HaloGUARD™ Protective Disc with CHG (Chlorhexidine Gluconate) has demonstrated in-vitro antimicrobial efficacy against a broad range of organisms known to cause Catheter Related Blood Stream Infections (CRBSI's)

VIEW FOCUS GROUP RESULTS

Same Great Device.....

Description	HaloGuard 	Competing Brand 
PATIENT ANATOMICAL SITE FOR USE OF DEVICE Vascular insertion sites of other devices (i.e. catheters, etc.) outside the body	✓	✓
MODE OF OPERATION Antimicrobial foam disc with antimicrobial agent CHG to protect device-related vascular insertion sites	✓	✓
GEOMETRY OF DEVICE Circular foam disc with center hole and radial slit	✓	✓
TEMPERATURE REQUIREMENTS: 15 to 30°C (59 to 86°F)	✓	✓
ANTIMICROBIAL AGENT: Chlorhexidine gluconate (CHG)	✓	✓
FUNCTION/PURPOSE OF ANTIMICROBIAL AGENT Prevents contamination of the dressing by inhibiting microbial growth and colonization of the dressing	✓	✓
PHARMACOLOGY OF ANTIMICROBIAL AGENT CHG provides antiseptic and antimicrobial effect with rapid bactericidal action. CHG has a positive charge that reacts with the negatively charged microbial cell surface and destroys the integrity of the cell membrane.	✓	✓
ANTIMICROBIAL AGENT APPLICATION METHOD TO MEDICAL DEVICE Incorporation/infusion through soaking foam in CHG solution	✓	✓
SPECTRUM OF ACTIVITY OF ANTIMICROBIAL AGENT Broad spectrum (works against a wide range of gram-positive and gram-negative bacteria, yeast and mold) antimicrobial agent	✓	✓
TARGET PATHOGENS • Staphylococcus aureus (MRSA) • Pseudomonas aeruginosa • Staphylococcus epidermidis (MRSE) • Candida albicans • Vancomycin-Resistant Enterococci (VRE) • Candida tropicalis • Enterobacter cloacae • Klebsiella pneumoniae	✓	✓
AVERAGE CHG CONCENTRATION Industry standard concentration across sizes	✓	✓
PRODUCT SIZE CONFIGURATIONS • 1 inch (2.5 cm) disc, 4.0 mm center hole with radial slit • 1 inch (2.5 cm) disc, 7.0 mm center hole with radial slit • 0.75 inch (1.9 cm) disc, 1.5 mm center hole with radial slit	✓	✓
PYROGEN & LATEX FREE	✓	✓
SINGLE USE & DISPOSABLE	✓	✓
STERILITY ASSURANCE LEVEL (SAL): 10^{-6}	✓	✓
FILM ADHESIVE: Pressure-sensitive acrylic	✓	✓

....with better features

	HaloGuard	Competing Brand
DESIGN FEATURES	HaloGUARD™ Protective Disc with CHG is a chlorhexidine gluconate (CHG) infused sterile hydrophilic absorptive foam dressing (disc)	Protective Disk with CHG is a hydrophilic polyurethane absorptive foam with chlorhexidine gluconate (CHG)
DEVICE MATERIALS	Medical grade hydrophilic polyurethane foam impregnated with chlorhexidine gluconate (CHG) with a polyether polyurethane film with print	Polyurethane foam impregnated with chlorhexidine gluconate with a nylon reinforced urethane film with print
ABSORBENCY	11 times its own weight in fluid	8 times its own weight in fluid
STERILIZATION METHOD	E-beam Radiation	Ethylene Oxide
MICROBIAL REDUCTION	5 log reduction or greater	4 log reduction
PRODUCT EDGE FINISH	Pinched (beveled)	Straight
PACKAGING	LLDPE film and aluminum foil laminate, non-breathable (suitable for E-beam)	Tyvek/lid is spun bound polyolefin with an adhesive coating, breathable (suitable for ethylene oxide)
MEM ELUTION CYTOTOXICITY	Moderately cytotoxic	Severely cytotoxic

Summary of ISO 10993 Biocompatabilty Testing and Wound Healing Studies for HaloGUARD vs. BioPatch

HaloGUARD was evaluated according to recommended ISO biocompatibility tests for safety and compared with the predicate BioPatch. Upon completion of the testing FDA requested further in-vivo testing designed to evaluate the effect both HaloGUARD and BioPatch may have on wound healing. This test is not the standard required for this type of device, but was asked for by FDA due to the presence of MDR's related to patch devices and wounds.

- Summary of ISO 10993 Testing Completed
- Wound Healing Study Day 7 Evaluation Data Summary
- Wound Healing Study Day 14 Evaluation Data Summary
- Wound Healing Study Day 21 Evaluation Data Summary
- Wound Healing Study Day 28 Evaluation Data Summary
- Microbial Simulated Use Challenge Results (Day 7)

Note From:Robin - the above are buttons they will link to results table pop-ups

CONTACT US

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HaloGUARD™