

IMED GUARD COMPARISON

The IMed Guard was designed in attempt to address several shortcomings seen with clinical use of the BioPatch. By using a softer foam with specific porosity characteristics, the IMed Guard can help alleviate some of the irritation issues associated with BioPatch. Product characteristics for both IMed Guard and BioPatch are outlined below:

	IMED GUARD	BIOPATCH
Design Features	IMED Guard Protective Disc with CHG is a chlorhexidine gluconate (CHG) infused sterile hydrophilic absorptive foam dressing (disc)	BIOPATCH 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 polyether polyurethane film with print	Polyurethane foam impregnated with chlorhexidine gluconate with nylon reinforced urethane film with print
Absorbency	11x its own weight in fluid	8x 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

In-vivo testing was completed to evaluate the effect both IMed Guard and BioPatch may have on wound healing. Artificial wounds were created of specific size and depths bi-laterally on test subjects. Wounds on one side were covered with IMed Guard; wounds on the opposite side were covered with BioPatch. Observations took place over a 28 day period and recorded in the table below:

TABLE: Wound Healing Study Day 28 Evaluation Data Summary

Characteristic	Test Average+	Control Average+	Results
Mean Wound Circumference (cm)	3.6	4.2	15% smaller
Granulation Tissue	1.8	1.8	equivalent
Signs of Infection*	0.3	0.8	63% less
Erythema*	0.1	0.1	equivalent
Hair Regrowth*	0.2	0.1	equivalent
Eschar Formation**	0.6	0.7	20% less
Estimate of Re-epithelialization*	1.2	0.6	50% greater
Photos Taken	Yes	Yes	equivalent

Observational Summary

The results suggest that wound healing was substantially equivalent until Day 21, where IMed Guard showed a 63% reduction in observed signs of infection; a 15% smaller wound circumference; 20% less eschar formation and 50% greater re-epithelialization than the predicate BioPatch.

*Scored as 0 = none; 1 = mild; 2 = moderate; 3 = severe

**Scored as 0 = absent; 1 = present

+Averages calculated as total observational scores divided by total sites in test or control group

Source: ATTWILL Medical Solutions, 2024