

# IMed® Guard

## PROTECTIVE DISC WITH CHG



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PK-xxxx Rev A

### PRODUCT DESCRIPTION

IMed® Guard Protective Disc with CHG is a sterile, single use disposable disc infused with the antibacterial agent chlorhexidine gluconate (CHG).

### INDICATIONS FOR USE:

IMed® Guard Protective Disc with CHG is patients. Common applications include IV catheters, central venous lines, epidural catheters, PICCs, hemodialysis catheters, orthopedic pins, other intravascular catheters and percutaneous devices.

### In-vitro Performance Testing

IMed® Guard Protective Disc with CHG prevents contamination of the dressing only by inhibiting bacterial growth within the dressing.

In-vitro studies have shown that IMed® Guard Protective Disc with CHG is effective at inhibiting bacterial growth by a 4-log reduction after 4 hours of exposure to the following pathogens:

- *Staphylococcus aureus* (MRSA)
- *Pseudomonas aeruginosa*
- *Staphylococcus epidermidis* (MRSE)
- *Candida albicans*
- *Candida tropicalis*
- *Vancomycin-Resistant Enterococci* (VRE)
- *Enterobacter cloacae*
- *Klebsiella pneumoniae*

### Labelling Symbols

	Do not re-use	<b>QTY</b>	Quantity
	Caution! See instructions for use		Use by Date
	Do not use if package is damaged		Manufacturer
	Do not re-sterilize using radiation	<b>REF</b>	Catalogue number
	Not made with natural rubber latex		
	Temperature limits		
			Sterilized using E-Beam
<b>Rx ONLY</b>			Caution: Federal law (USA) restricts this device to sale on the order of a physician.

### INSTRUCTIONS FOR USE

#### (Read Carefully Before Use)

1. Prepare injection site per hospital protocol. Ensure skin is clean and dry.
2. Remove IMed® Guard Protective Disc with CHG from package using sterile technique.
3. Place IMed® Guard Protective Disc with CHG around compatible device. Ensure print side faces upward.
4. Ensure compatible device rests upon slit portion of IMed® Guard Protective Disc with CHG. Do not compress disc with compatible device connector. The disc must remain in contact with skin to maximize efficacy.
5. Secure compatible device and IMed® Guard Protective Disc with CHG to skin, using a biocclusive dressing. Ensure complete skin contact.
6. Change IMed® Guard Protective Disc with CHG according to hospital protocol. Antibacterial efficacy of IMed Guard Protective Disc with CHG was evaluated for up to 7 days in-vitro, therefore, dressing changes should occur at least once every 7 days. Highly exuding wounds require more frequent dressing changes.
7. To remove IMed® Guard Protective Disc dressing. Peel and stretch the biocclusive with CHG, lift a corner of the dressing away from the compatible device, while holding the device in place. Continue to peel and stretch until it is easy to remove. IMed® Guard Protective Disc with CHG will remain attached to the biocclusive dressing.

## CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

- Imed® Guard Protective Disc with CHG is intended for prescription use by clinicians and healthcare practitioners in a healthcare setting, as a sterile, single use disposable device.
- Do not use Imed® Guard Protective Disc with CHG on premature infants. Use of similar products on premature infants has resulted in hypersensitivity reactions and necrosis of the skin.
- The safety and effectiveness of Imed® Guard Protective Disc with CHG has not been established in children under 22 years of age. Use with pediatric populations is not recommended.
- Although it is not likely that other drugs or substances will interact with CHG as found in Imed® Guard Protective Disc with CHG, the clinician should verify if any other substances used by the patient may interact with CHG before using Imed® Guard Protective Disc with CHG.
- For external use only. Do not allow this product to contact the eyes, ears, mouth, or mucous membranes.
- Do not use Imed® Guard Protective Disc with CHG directly over a burn injury or on patients with a known sensitivity to CHG. Hypersensitivity reactions associated with the topical use of CHG have been reported in several countries. The most serious reactions have included anaphylaxis.
- Do not use Imed® Guard Protective Disc with CHG if patient is allergic to CHG. CHG may cause severe allergic reactions including wheezing, difficulty breathing, hives, shock, rash and facial swelling.
- Patient should stop use of Imed® Guard Protective Disc with CHG if irritation, sensitization, or allergic reaction occurs as these may be signs of a serious condition. Adverse reactions to CHG such as dermatitis, hypersensitivity, and generalized allergic reactions are rare, but if any such reactions occur, discontinue use of the dressing immediately.
- Imed® Guard Protective Disc with CHG is not intended to treat infections. Clinical studies on CHG to evaluate reduction in infections have not been performed.
- Imed® Guard Protective Disc with CHG is not intended to be used as a treatment of percutaneous device-related infections.
- Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

## STORAGE AND HANDLING INFORMATION:

- Do not re-sterilize Imed® Guard Protective Disc with CHG using radiation.
- Imed® Guard Protective Disc with CHG is supplied sterile. Each unit package contains a single disc for single use only. Do not use if the package is opened or damaged. Do not use if seal is broken or compromised.
- Store between 15°C and 30°C (59°F and 86°F) in its original packaging.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations. Discard any open and unused portions of the device.
- NOTE: Imed® Guard Protective Disc with CHG may appear yellow in color. This coloration does not reduce the antibacterial efficacy of the dressing.

## SUMMARY OF SAFETY AND EFFECTIVENESS

Imed® Guard Protective Disc with CHG has undergone applicable in vitro, biocompatibility, sterility, and performance testing for safety and effectiveness.

AVERAGE CONCENTRATION PER DISC		
Model Number	Description	CHG Amount (mg)
IM36026	1 in disc, 4 mm hole	90