

PRODUCT INFORMATION

Product Code: ISEPT-450-USA



- CONTENTS INCLUDE:**
- (1) 450 mL bottle of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP)
 - (1) Irriprobe® applicator
 - (1) Convenience Cap

PACKAGING CONSIDERATIONS:

Irrisept Antimicrobial Wound Lavage is sterile packaged and aseptically-filled in a Blow-Fill-Seal (BFS) bottle. Contents are wrapped in two sequential (CSR) wraps and sealed in a Tyvek® pouch.



Remove TYVEK® strip to open pouch. For aseptic practice, product may be transferred onto the sterile field by unwrapping the outer CSR wrap and allowing sterile personnel to handle product wrapped in the inner CSR wrap. Because components may be loose together inside second CSR wrap, it is recommended to place the wrapped bottle on a flat surface to open.

*In-servicing video available for further assistance.

DIRECTIONS FOR USE:



Remove Irriprobe® applicator from cap.



Place cap on bottle and apply slight pressure to cap and twist quickly in **ONLY ONE** direction, until bottle top snaps off.



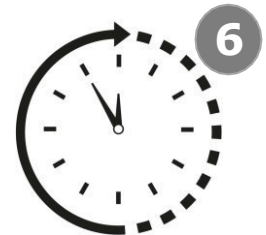
Discard the cap and bottle top.



Attach applicator to bottle.



Invert bottle. Using manual compression, direct stream into wound ensuring complete coverage.



Wait approximately one minute, rinse with normal saline for irrigation. Discard any unused solution.

OPTIONAL WARMING INSTRUCTIONS

Irrisept may be warmed in packaging to 40°C (104°F) for up to 7 days before use. Once removed from a temperature warming cabinet, Irrisept should be used within 24 hours or discarded.

INDICATIONS FOR USE

Irrisept Antimicrobial Wound Lavage is intended for mechanical cleansing and removal of debris, dirt, and foreign materials, including microorganisms from wounds.

WARNINGS

- Do not use this product if the patient is allergic to chlorhexidine gluconate.
- Discontinue use immediately if irritation, sensitization, or allergic reaction occurs.

CAUTIONS

- Do not use unless solution is clear and bottle twist seal is intact.
- When using this product, keep away from the eyes and ear canals. If the solution inadvertently contacts these areas, rinse out promptly and thoroughly with water and/or normal saline.
- Not for injection.
- Single patient use only.
- Irrisept is intended for use by healthcare professionals only.
- Irrisept solutions meet biocompatibility guidelines for ≤24 hours contact with breached or compromised surfaces (ISO 10993-1).
- Do not use if the package is damaged.
- Rx only.

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This product is non-pyrogenic and is not made with natural rubber latex. Refer to labeling for product information.

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