



Product Information

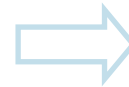
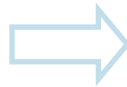
Product Code: ISEPT-450-USA

Contents include:

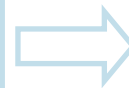
- (1) 450 mL bottle of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP)
- (1) Irriprobe[®] applicator

Irrisept Antimicrobial Wound Lavage is sterile packaged and aseptically-filled in a Blow-Fill-Seal (BFS) bottle. Contents are wrapped in two sequential Central Supply Room (CSR) wraps and sealed in a Tyvek[®] pouch. CHG acts as a preservative to inhibit microbial growth in the solution.

Directions for use:



Remove TYVEK[®] strip to open pouch. Recommend placing double-wrapped CSR on flat surface to open. Irrisept bottle and Irriprobe applicator are loose together inside second CSR wrap. *(Please remove and discard the clear protective sleeve, it is not a component of the device.)*



Grasp bottle top firmly and twist **quickly** in **ONLY ONE** direction, until seal cap snaps off.

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.

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 meets biocompatibility guidelines for ≤ 24 hours contact with breached or compromised surfaces (ISO 10993-1).
- Not made with natural rubber latex.
- Do not use if the package is damaged.
- Rx only.
- Non-pyrogenic.

Irrisept Antimicrobial Wound Lavage is a Class II Medical Device and an unclassified combination product.

Customer Service:

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