

IRRISEPT® PRODUCT INFORMATION

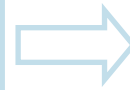
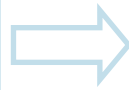
Jet lavage containing low concentration Chlorhexidine Gluconate (CHG) 0.05% in sterile water for irrigation. CHG acts as a preservative to help inhibit microbial growth in the solution.

Irrisept Wound Debridement & Cleansing System includes:

- (1) Irrisept®, 450mL bottle, 0.05% CHG in sterile water, USP (99.95%)
- (1) Irriprobe® applicator

Contents are wrapped in two sequential CSR wraps and sealed in TYVEK® pouch.

Cleared as a Class II Medical Device and an unclassified combination product (K080779).

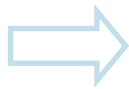


Remove TYVEK® strip to open pouch. Recommend placing double wrapped CSR on flat surface to open. Irrisept bottle and Irriprobe applicator are loose together inside 2nd CSR wrap.

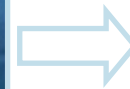
(Please remove and discard the clear protective sleeve, it is not a component of the device.)



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



Attach applicator to bottle.



Wait approximately one minute, rinse with normal saline for irrigation.

Customer Service direct: 770-807-8445

cs@irrisept.com

www.irrisept.com

See reverse for important information

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INDICATIONS FOR USE

Irrisept Wound Debridement and Cleansing system is a wound cleansing delivery system. The mechanical action effectively loosens and removes wound debris.

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. 0.05% chlorhexidine gluconate sterile water for irrigation, USP

When using this product keep away from eyes and ear canals. If the solution should contact these areas, rinse out promptly and thoroughly with water and/or normal saline.

Federal law restricts this device to sale by or on the order of a licensed physician.

Not for injection.

Do not re-use. Single patient use only.

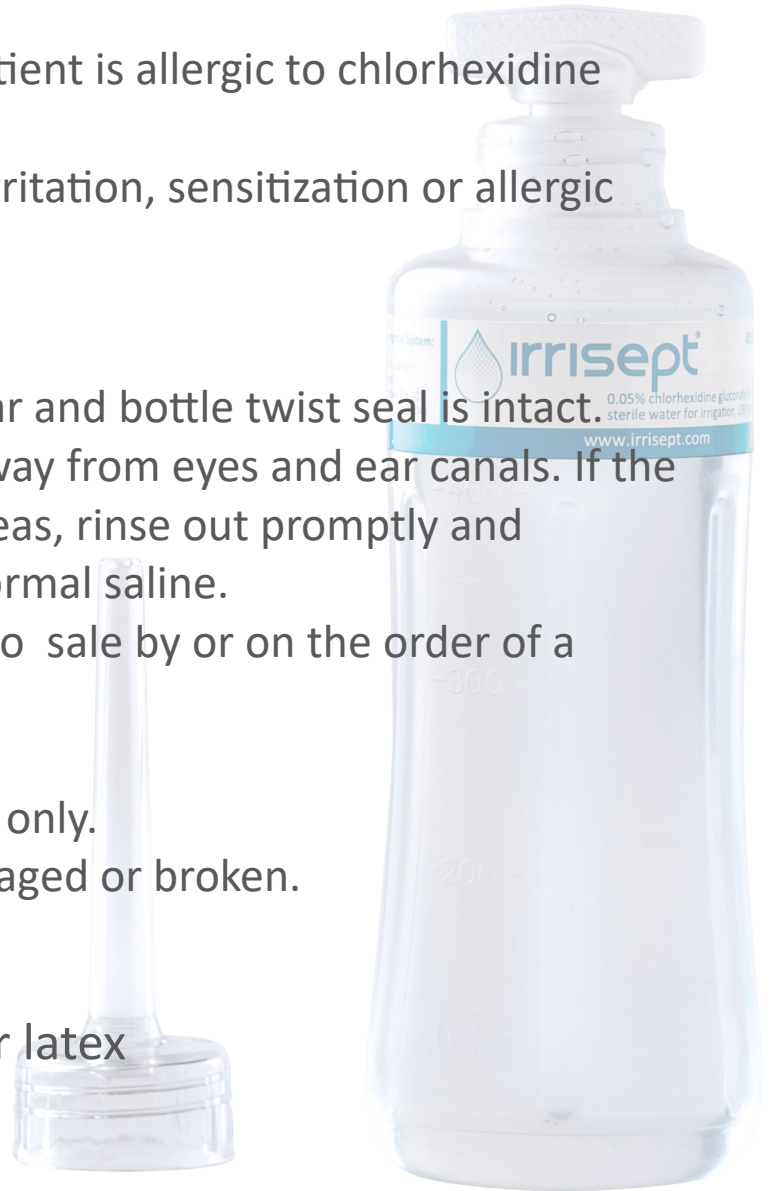
Do not use if the package is damaged or broken.

FEATURES

Not made with natural rubber latex

Single use, disposable

Self-contained, portable



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