



ASSIST SILVER

Instructions for Use

(Read carefully before using the device)

Description

ASSIST Silver is a sterile, single-use, antimicrobial graft cover. The graft cover is a multi-component substrate containing a controlled-release silver ion antimicrobial throughout and provides a favorable wound healing environment by combining Active Fluid Management® technology with an effective barrier to microbes.

The Active Fluid Management properties of ASSIST Silver allow use on graft sites throughout all stages of healing.

The silver ion antimicrobial kills microbes within the graft cover. The graft cover demonstrates in vitro antimicrobial activity for up to 7 days against microbial strains that can be detrimental to wound healing such as, but not limited to:

S. auerus (including MRSA), *S. epidermidis* (including MRSE), *E. faecalis* (including VRE), and *A. baumannii*, and *P. aeruginosa*.

Directions for Use

ASSIST Silver can be used throughout the healing process. Prepare the graft site, and apply the graft according to clinical protocol. Remove ASSIST Silver graft cover from the package, taking note of the printing.

The printed side of the graft cover should be applied away from the graft, and an absorbent secondary layer may be applied on top. Secure with an appropriate fixative such as roll gauze, adhesive bordered gauze, transparent film or tape.

Optimal performance of ASSIST Silver requires direct contact with the graft. ASSIST Silver can be cut as necessary. The secondary layer may be changed as often as needed without disturbing the ASSIST Silver primary graft cover.

ASSIST Silver is MRI compatible. There is no thermal or mechanical response. There is no image distortion.

Directions for Removal

ASSIST Silver should be changed when clinically indicated or as prescribed by a healthcare professional. Carefully remove the secondary layer and the ASSIST Silver from the graft. The graft cover can be moistened with sterile saline or water to ease removal if necessary.

Indications

ASSIST Silver provides an antimicrobial barrier to microbial colonization in the graft cover and reduces microbial penetration through the graft cover.

ASSIST Silver is indicated for management of acute and chronic wounds: partial thickness burns, incisions, skin grafts, donor sites, laceration, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).

Contraindications

ASSIST Silver should not be used on patients with a known sensitivity to silver. In case of suspected allergic reaction, discontinue use immediately and contact your healthcare provider.

Precautions and Observations

The Active Fluid Management performance of ASSIST Silver may be impaired with petrolatum-based ointments.

The use of ASSIST Silver during radiation treatment or examinations such as X-rays, ultrasonic treatment, diathermy, microwaves, or HBO has not been demonstrated.

The use of ASSIST Silver during pregnancy, lactation and for pediatric use has not been demonstrated.

Storage

ASSIST Silver should be stored at temperatures less than 131°F. Keep dry.

Sterilization

ASSIST Silver is sterile as provided. Do not use ASSIST Silver if the primary package is visibly damaged or broken. Do not resterilize ASSIST Silver. For single use only.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner (U.S.A. only).





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