VERIS™

Instructions For Use

Description

VERIS™ is a wound management device comprised of a highly purified collagen derivative (gelatin), Manuka honey and hydroxyapatite. The intended use of VERIS™ in the management of wounds is to cover and protect the wound, absorb wound exudate, and provide and maintain a moist wound environment.

Indications

Under the supervision of a healthcare professional. VERIS™ is indicated for use in management of wounds, including:

- · Full and partial thickness wounds
- · Pressure ulcers (stages I-IV)
- · Venous stasis ulcers
- Diabetic ulcers
- Abrasion
- Surface wounds
- · Donor site wounds
- · Surgical wounds
- Traumatic wounds (healing by secondary intention)
- · Donor Site Wounds
- Surgical Wounds

Contraindications

VERIS™ is not indicated for:

- · Patients with sensitivity to collagen and its derivatives
- · Patients with sensitivity to porcine-derived products
- · Patients with sensitivity to honey
- Third-degree burns
- · Infections or contamination in the wound site
- · Control of bleeding
- · Children and infant patients under 10kg / 22lbs

Adverse Reactions

 Due to VERIS[™] composition, individuals with known sensitivity to collagen, porcine-derived materials, or honey may experience an allergic reaction.

Precautions

- VERIS[™] is sterile if the package is unopened and undamaged. Do not use if the package seal is open or if there is any visual damage to any part of the package.
- Do not re-sterilize. Any opened and unused VERIS™ materials must be disposed of.
- VERIS[™] should not be applied until bleeding, infection, excessive exudate, and acute swelling is controlled.

Precautions (Continued)

- Do not use VERIS™ after the expiration date stated on the product label.
- Contact a health care professional if (1) signs of infection occur (e.g. increased pain), (2) there is a change in wound color and/or odor, (3) the wound does not begin to show signs of healing, or (4) any other unexpected symptoms occur.
- Remove VERIS[™] and discontinue use if signs of sensitivity appear.

Instructions for Use

Users should follow the most recent procedures and best practices for wound management to complete wound preparation, application of VERIS™, and application of secondary dressings.

1. Wound Bed Preparation

Prior to application, prepare the wound bed per standard wound care protocols, and debride if necessary.

2. Selection of VERIS™ device

Measure the wound in size and select an appropriately sized VERIS™ device

Adults

- · up to 6 of the small dressings may be applied daily, OR
- · up to 2 of the medium dressings may be applied daily, OR • up to 1 of the large dressings may be applied every 2 days.

Children (above 10kg / 22 lbs):

- up to 3 of the small dressings may be applied daily, OR
- · up to 1 of the medium dressings may be applied daily, OR • up to 1 of the large dressings may be applied every 3 days.

3. Application of VERIS™

- For a wound with low or no exudate, wet VERIS™ with several drops of sterile saline. It should be noted that upon hydration, VERIS™ may expand slightly in length and width.
- For highly exudating wounds, hydration prior to application of VERIS™ may not be needed.
- If needed, cut or fold VERIS™ to fit the wound size and shape.
- Place VERIS[™] directly onto the wound.

4. Application of Secondary Dressing

To ensure VERIS™ adherence to the wound and to provide wound protection, cover and secure with a suitable secondary dressing.

5. Dressing Changes + Wound Assessment

- Secondary dressing changes should be performed as needed depending on wound type and per standard protocols. The frequency of secondary dressing change will depend on the level of exudation, secondary dressing type, patient condition, patient movements, and other factors.
- Per standard protocols, inspect the wound for healing or any signs of adverse reactions, infection, or other possible complications and reapply VERIS™ as required.
- VERIS[™] devices are biodegradable and completely absorbable, thus removal of VERIS™ is not necessary.
- . Do not forcibly remove parts of VERIS™ that have adhered to the wound.

Sterility

- VERIS™ is sterilized using gamma irradiation.
- VERIS[™] should be removed from its packaging following the aseptic technique.

Storage

- VERIS[™] should be stored at controlled room temperature, which is considered 15°-25° C (59°-77° F), otherwise product performance cannot be quaranteed.
- Do not use VERIS[™] after the expiration date stated on the packaging.

Disposal

Product Availability

Size

Small

Medium

Large

Reference

Number

VERIS-16x16-1

VERIS-16x16-2

VERIS-25x25-1

VERIS-25x25-2

VERIS-50x50-1

VERIS-50x50-2

Width and

length (cm)

1.6 x 1.6

2.5 x 2.5

 5.0×5.0

VERIS™ is not considered hazardous to the environment and can be disposed of in regular household waste.

Symbols Used in Labeling



For prescription use only

Use by / Expiration Date

 $\mathcal{R}_{\mathcal{L}}$



Consult instructions for use



Temperature storage limits



Manufacturer







Sterilized using radiation



Do not resterilize

Do not reuse



Catalog Number



Caution

Do not use if packageis damaged

Sterile

Barrier

Double

Single

Double

Single

Double

Single

Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner. The material of VERIS™ is developed under US Patent No. 10258717

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VERIS™ is a pending trademark of SweetBio, Inc.

Manufactured By

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