

APIS® Instructions for Use

Description

APIS® is a wound management device comprised of a highly purified collagen derivative (gelatin), Manuka honey and hydroxyapatite. The intended use of APIS® 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, APIS® 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
- traumatic wounds (healing by secondary intention)
- donor site wounds
- surgical wounds

Contraindications

APIS® 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

Precautions

- APIS® is sterile if the package is unopened and undamaged. Do not use if package seal is open or if there are any visual damage to any part of the package.
- Do not re-sterilize. Any opened and unused APIS® materials must be disposed of.
- APIS® should not be applied until bleeding, infection, excessive exudate, and acute swelling is controlled.
- Do not use APIS® 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 APIS® and discontinue use if signs of sensitivity appear.

Adverse reactions

Due to APIS® composition, individuals with known sensitivity to collagen, porcine-derived materials or honey may experience an allergic reaction.

Instructions for Use

Users should follow the most recent procedures and best practices for wound management to complete wound preparation, application of APIS®, 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 APIS® device

- Measure the wound in size and select the appropriate size and number of APIS® devices.
 - Adults:
 - up to 44 of the small dressings may be applied weekly, OR
 - up to 18 of the medium dressings may be applied weekly, OR
 - up to 4 of the large dressings may be applied weekly, OR
 - up to 2 of the extra-large dressings may be applied weekly.
 - Children (above 10kg / 22 lbs):
 - up to 23 of the small dressings may be applied weekly, OR
 - up to 9 of the medium dressings may be applied weekly, OR
 - up to 2 of the large dressings may be applied weekly, OR
 - 1 of the large dressings may be applied weekly.

3. Application of APIS®

- For a wound with low or no exudate, hydrate APIS® on both sides using sterile saline for up to 2 minutes, or until fully hydrated. It should be noted that upon hydration, APIS® may expand slightly in length and width.
- For highly exudating wounds, hydration prior to application of APIS® may not be needed.
- If needed, cut or fold APIS® to fit the wound size and shape.
- Place APIS® directly onto the wound

4. Application of Secondary Dressing

- To ensure APIS® 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. Frequency of secondary dressing change will depend on 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 APIS® as required.
- APIS® devices are biodegradable and completely absorbable, thus removal of APIS® is not necessary.
- Do not forcibly remove parts of APIS® that have adhered to the wound.

Sterility

APIS® is sterilized using gamma irradiation. APIS® should be removed from its packaging following aseptic technique.

Storage

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

Disposal

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

Product Availability

Size	Reference Number	Width and length (cm)	Sterile barrier
Small	APIS-16x16-1	1.6 x 1.6	Double
	APIS-16x16-2		Single
Medium	APIS-25x25-1	2.5 x 2.5	Double
	APIS-25x25-2		Single
Large	APIS-50x50-1	5.0 x 5.0	Double
	APIS-50x50-2		Single
Extra Large	APIS-60x80-2	6.0 x 8.0	Single

Caution

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

The material of APIS® is developed under US Patent No. 10258717

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Manufactured for:












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Symbols used in labelling:

	Manufacturer		Consult instructions for use
	Lot number		Do not use if package is damaged
	Catalog number		Do not reuse
	Use by / expiration date		Sterilized using radiation
	Temperature limits for storage		Do not resterilize
	For Prescription use Only		