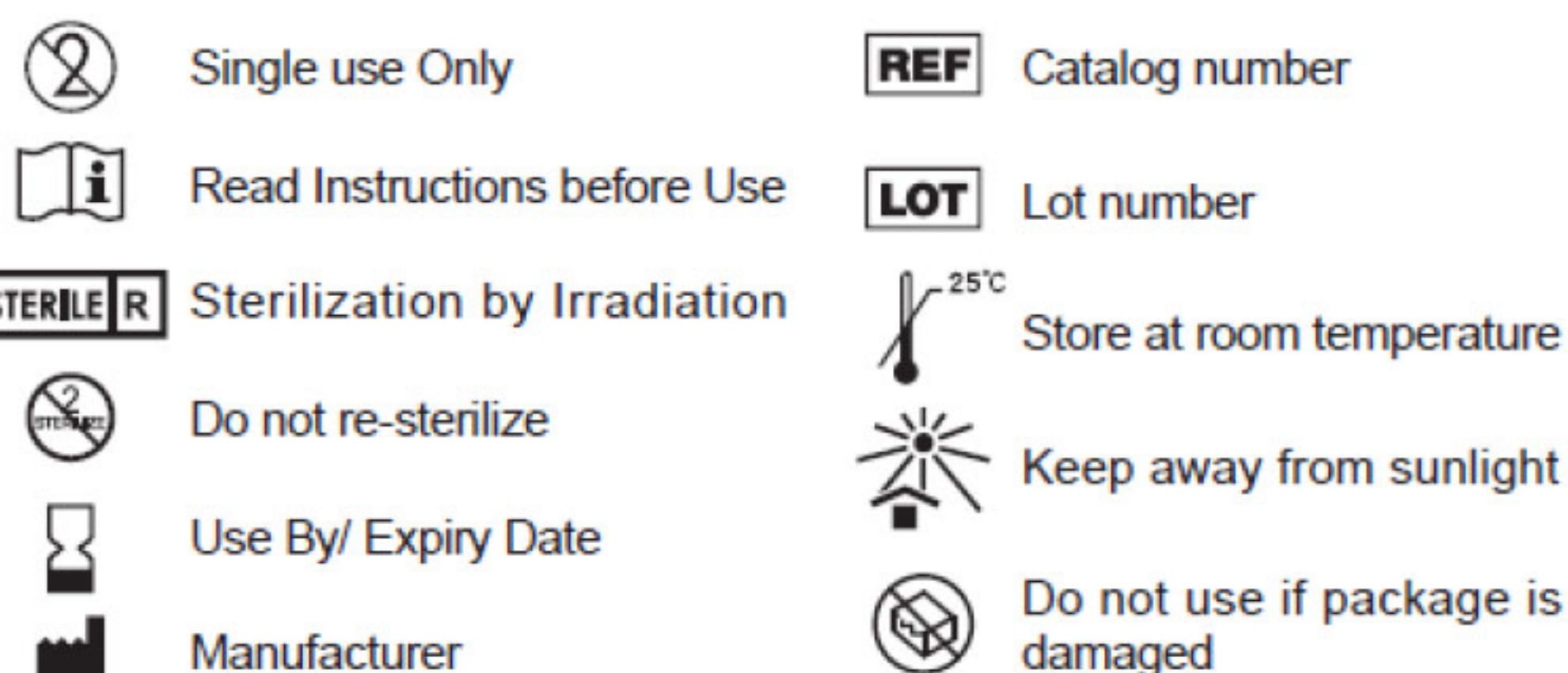


Read this package insert completely before use and comply with the instructions for use.

# FormaAid<sup>®</sup> Collagen Membrane

DOH-MD-No. 003195

## GRAPHICAL SYMBOLS



## Description

FormaAid<sup>®</sup> Collagen Membrane is a white, pliable membrane consisting of natured fibrous collagen matrix purified from bovine Achilles tendon.

## Intended Use

FormaAid<sup>®</sup> Collagen Membrane is indicated for use in surgical treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration (GTR) procedures to enhance wound healing.

## Indications for Use

FormaAid<sup>®</sup> Collagen Membrane can be served as GTR membrane and be used in the following treatments:

- Ridge augmentation;
- Bone Regeneration;
- Sinus window;
- Extraction sites;
- Periodontal defects.

## Instructions for Use

Open the blister trays, and then open the plastic board containing the FormaAid<sup>®</sup> Collagen Membrane. Take the FormaAid<sup>®</sup> Collagen Membrane out from the blister tray and trim it with sterilized scissors or instruments to the desired size and shape of the defect.

FormaAid<sup>®</sup> Collagen Membrane should be hydrated in sterile water or normal saline solution for minutes before placing it over the wound close to the tooth. After the clinician perform through debridement and/or further fill the defect with bone replacement graft material, the hydrated FormaAid<sup>®</sup> Collagen Membrane is placed over the wound close to the tooth. Finally, FormaAid<sup>®</sup> Collagen Membrane is sutured with the epithelial tissue of gingival with absorbable sutures.

## Precaution

- FormaAid<sup>®</sup> Collagen Membrane should not be applied to infected area of a wound site.
- Clean the contaminated area carefully before applying FormaAid<sup>®</sup> Collagen Membrane onto the wound site to prevent infection.
- The safety of FormaAid<sup>®</sup> Collagen Membrane on pregnant women is not clinically evaluated. Surgeon should evaluate the application of FormaAid<sup>®</sup> Collagen Membrane in pregnant women.
- Patients with severe allergy history or hypersensitivity to bovine collagen are not recommended to use FormaAid<sup>®</sup> Collagen Membrane.
- FormaAid<sup>®</sup> Collagen Membrane is contraindicated to patients undergoing desensitization injections to meat products, as these

injections may contain bovine collagen.

- Check the expiration date of each individual product before use. Do not use expired products.
- Do not use FormaAid<sup>®</sup> Collagen Membrane when packaging is damaged, as sterility of the contents cannot be assured.
- FormaAid<sup>®</sup> Collagen Membrane is limited to single use only. Do not re-sterilize or re-use FormaAid<sup>®</sup> Collagen Membrane.

## Specifications

FormaAid<sup>®</sup> Collagen Membrane is a fibrillar collagen membrane. Each product is well-packed in sterile (γ-irradiation) condition.

The specifications of FormaAid<sup>®</sup> Collagen Membrane products are listed below:

| Product type | Specifications         | Quantity/Box |
|--------------|------------------------|--------------|
| FA-1520      | 15 mm × 20 mm × 0.5 mm | 1            |
| FA-2530      | 25 mm × 30 mm × 0.5 mm | 1            |
| FA-3040      | 30 mm × 40 mm × 0.5 mm | 1            |
| FA-T1520     | 15 mm × 20 mm × 0.3 mm | 1            |
| FA-T2530     | 25 mm × 30 mm × 0.3 mm | 1            |
| FA-T3040     | 30 mm × 40 mm × 0.3 mm | 1            |

## Storage

FormaAid<sup>®</sup> Collagen Membrane should be stored at room temperature below 25°C in a dry place. Do not expose FormaAid<sup>®</sup> Collagen Membrane to extreme environmental conditions. Do not use after expiration date.

## Warnings

FormaAid<sup>®</sup> Collagen Membrane cannot be autoclaved because the collagen fibrous structure as well as the packaging will be damaged. FormaAid<sup>®</sup> Collagen Membrane cannot be re-used, the patients may expose to the risk of diseases and have the possibility of cross-infection may lead to death. In addition, FormaAid<sup>®</sup> Collagen Membrane should not be re-sterilized. Residual portions of FormaAid<sup>®</sup> Collagen Membrane should be discarded after use. FormaAid<sup>®</sup> Collagen Membrane contains bovine collagen and must not be used to patients with a history of allergy to any bovine collagen products. Hypersensitivity reactions may include erythema, swelling, induration, and/or urticaria.

MDA Reg. No: 0000

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