













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

HealiAid® Dental Collagen Wound Dressing

GRAPHICAL SYMBOLS

| | | | |
|---|------------------------------|---|---|
|  | Single use only |  | Lot number |
|  | Read instructions before use |  | Store at room temperature |
|  | Sterilization by irradiation |  | Keep away from sunlight |
|  | Do not re-sterilize |  | Do not use if package is damaged |
|  | Use by expiry date |  | Federal law(USA) restricts this device to sale by or on the order of a licensed healthcare practitioner |
|  | Manufacturer | | |
|  | Catalog number | | |

Description

HealiAid® Dental Collagen Wound Dressing is a white, porous, pliable and absorbable collagen wound dressing. HealiAid® Dental Collagen Wound Dressing is fabricated by fibrous collagen matrix purified from bovine origin. HealiAid® Dental Collagen Wound Dressing is pliable and can be applied easily to oral wounds to protect the wound bed. The product is supplied in a sterile, non-pyrogenic package, and is indicated for single use only.

Indications

HealiAid® Dental Collagen Wound Dressing is indicated for the management of oral wounds and sores, including:

- Denture sores
- Oral ulcers (non-infected or viral)
- Periodontal surgical wounds
- Extraction sites
- Surgical wounds
- Traumatic wounds

Instructions for using HealiAid® Dental Collagen Wound Dressing

HealiAid® Dental Collagen Wound Dressings should be applied over the wound site and held in place until adherence has been achieved. At the end of the procedure, HealiAid® Dental Collagen Wound Dressings can be removed if not spontaneously degraded within 30 days, or replaced.

1. Cleanse the wounded area: Make sure the wounded part is clean and dry. Use any appropriate cleaning agents to remove debris from the area to eliminate possibilities of infection.
2. Prepare the dressing: Open the package and take the dressing out. Size the dressing appropriately for covering the wound.
3. Apply the dressing: Cover the wound with the sized

dressing. Apply moderate pressure to the dressing to make sure it can adhere to the wound. Take care not to apply too much pressure on the wound to avoid further damage. It takes approximately 2-5 minutes for the dressing to adhere properly to the wound.

4. Monitor the dressing: Ensure the dressing remains in the right place and that it is providing appropriate protection to the wound. Adjust or replace the dressing if necessary.
5. Offer follow-up care: Provide post-operative care to the patient, pay a close attention to the signs of infection.

Contraindications

- HealiAid® Dental Collagen Wound Dressing should not be applied to acutely or chronically infected area of a wound site.
- The safety of HealiAid® Dental Collagen Wound Dressing on pregnant women is not clinically evaluated. Surgeon should evaluate the application of HealiAid® Dental Collagen Wound Dressing in pregnant women.
- Patients with severe allergy history or hypersensitivity to bovine collagen are not recommended to use HealiAid® Dental Collagen Wound Dressing.
- HealiAid® Dental Collagen Wound Dressing is contraindicated to patients undergoing desensitization therapy to meat products.
- Large tissue defects should not be filled with several layers of HealiAid® Dental Collagen Wound Dressings.
- This product is contraindicated for patients with clinically significant kidney, liver, heart, endocrine, blood, autoimmune or systemic diseases under the judgment of physicians. Safety and efficacy of HealiAid® Dental are not guaranteed for patients diagnosed with the above-mentioned diseases.

Precaution

- Clean the contamination area carefully before applying HealiAid® Dental Collagen Wound Dressing onto the wound site to prevent infection.
- Check the expiration date of each individual product before use. Do not use expired products. Use immediately after opening.
- Do not use HealiAid® Dental Collagen Wound Dressing when packaging is damaged, as sterility of the contents cannot be assured.
- HealiAid® Dental Collagen Wound Dressing is limited to single use only.
- Do not re-sterilize or re-use HealiAid® Dental Collagen Wound Dressing.
- Discontinue use of HealiAid® Dental Collagen Wound Dressing and notify your doctor if excessive redness, pain, swelling or blistering occurs.
- Pay attention if applying to the following patients:
 - Chronically infection in the application sites

- Uncontrolled metabolism diseases (E.g. diabetes, Osteomalacia, Thyroid disease)
- Taking long-term adrenocortical hormones treatments
- Autoimmune disease
- Receiving radiotherapy
- Severe smoking
- Taking long-term steroid therapy
- Currently taking anticoagulant drugs

Adverse Reactions

- Hypersensitivity reactions have been noted with the use of other products containing collagen.
- Any adverse events may occurs including but not restrict to swelling, bleeding, local inflammation/necrosis and infection.
- Since HealiAid® Dental Collagen Wound Dressing are collagen-based products, adverse reactions experienced with another microfibrillar collagen may be related.

Specifications

HealiAid® Dental Collagen Wound Dressing is a collagen wound dressing. Each product is well-packed in sterile (gamma-irradiation) packaging. The specifications of HealiAid® Dental Collagen Wound Dressing products are listed below:

| Product type | Specification |
|-------------------------------|-----------------------|
| HealiAid® Dental-Sheet | |
| HAD204030 | 20mm x 40mm x 3.0mm |
| HAD505030 | 50mm x 50mm x 3.0mm |
| HAD100100 | 100mm x 100mm x 3.0mm |
| HAD152005 | 15mm x 20mm x 0.5mm |
| HAD203005 | 20mm x 30mm x 0.5mm |
| HAD253005 | 25mm x 30mm x 0.5mm |
| HAD304005 | 30mm x 40mm x 0.5mm |
| HADB152030 | 15mm x 20mm x 3.0mm |
| HADB253030 | 25mm x 30mm x 3.0mm |
| HADB304030 | 30mm x 40mm x 3.0mm |

HealiAid® Dental-Plug

| | |
|-----------|--------------|
| HAD001020 | ø10mm x 20mm |
| HAD001520 | ø15mm x 20mm |

Storage

HealiAid® Dental should be stored at room temperature in a dry place. Do not freeze or expose HealiAid® Dental to extreme environmental conditions. Avoid excessive heat or humidity.

Warning

HealiAid® Dental Collagen Wound Dressing cannot be sutured in place. HealiAid® Dental Collagen Wound Dressing cannot be autoclaved because the collagen fibrous structure as well as the packaging will be damaged. Residual portions of HealiAid® Dental Collagen Wound Dressing should be discarded after use. HealiAid® Dental Collagen Wound Dressing contains bovine collagen and must not be use in patients with a history of allergies to any bovine collagen products. Hypersensitivity reactions reported when using bovine collagen products including erythema, swelling, induration, and/or urticaria. HealiAid® Dental Collagen Wound Dressing should be stored at room temperature in a dry place. Do not use after expiration date.

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