

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

HealiAid[®] Collagen Wound Dressing DOH-MD-No. 003197

GRAPHICAL SYMBOLS



Description

HealiAid[®] Collagen Wound Dressing is a white, porous, pliable and absorbable collagen wound dressing. HealiAid[®] Collagen Wound Dressing is fabricated by native fibrous collagen matrix purified from Achilles bovine tendons. HealiAid[®] Collagen Wound Dressing is pliable and can be applied easily to

bleeding wounds. The product is supplied in a sterile, non-pyrogenic package, and is indicated for single use only.

Indications

HealiAid[®] Collagen Wound Dressing is a white, pliable sheet material which consists native fibrous collagen matrix purified from bovine Achilles tendon. HealiAid[®] Collagen Wound Dressing is flexible for easily application to wound HealiAid[®] Collagen Wound Dressing has better bio-compatibility with positive cosmetic effects, and can better stimulate wound healing when compared to other wound dressing products.

 ${\sf HealiAid}^{\circledast}$ Collagen Wound Dressing can be used in the following treatments:

- Periodontal Surgery
- Implantology
- Sinus Elevation
- Defect Surgery
- Stop Bleeding after an Odontectomy.

Instructions for using HealiAid[®] Collagen Wound Dressing

- 1. After dental extraction, press HealiAid[®] Collagen Wound Dressing on the wound site to stop bleeding for two to five minutes.
- 2. Fill wound site with HealiAid® Collagen Wound Dressing.
- 3. Suture the wound site.

Precaution

- HealiAid[®] Collagen Wound Dressing should not be applied to infected area of a wound site.
- Clean the contaminated area carefully before applying HealiAid[®] Collagen Wound Dressing onto the wound site to prevent infection.
- Even though HealiAid[®] Collagen Wound Dressing promotes blood clotting, HealiAid[®] Collagen Wound Dressing is not intended to apply to patients with abnormal blood clotting.
- The safety of HealiAid[®] Collagen Wound Dressing on pregnant women is not clinically evaluated. Surgeon should evaluate the application of HealiAid[®] Collagen Wound Dressing in pregnant women.
- Patients with sever allergy history or hypersensitivity to bovine collagen not recommended to use HealiAid[®] Collagen Wound Dressing.

- HealiAid[®] Collagen Wound Dressing 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 HealiAid[®] Collagen Wound Dressing when packaging is damaged, as sterility of the contents cannot be assured.
- HealiAid[®] Collagen Wound Dressing is limited to single use only. Do not re-sterilize or re-use HealiAid[®] Collagen Wound Dressing.

Specifications

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

Product type	Specification
HealiAid®-Sheet	
SA204030	20mm x 40mm x 3.0mm
SA505030	50mm x 50mm x 3.0mm
SA100100	100mm x 100mm x 3.0mm
SA152005	15mm x 20mm x 0.5mm
SA203005	20mm x 30mm x 0.5mm
SA253005	25mm x 30mm x 0.5mm
SA304005	30mm x 40mm x 0.5mm
HealiAid®-Plug	
SA001020	ø10mm x 20mm
SA001520	ø15mm × 20mm
HealiAid [®] -Particle	
SA-G01	1cc
SA-G02	2cc
SA-G05	5cc
SA-G10	10cc
SA-G20	20cc

Storage:

HealiAid[®] should be stored at room temperature in a dry place. Do not freeze or expose HealiAid[®] to extreme environmental conditions.

Warning

HealiAid[®] Collagen Wound Dressing cannot be autoclaved because the collagen fibrous structure as well as the packaging will be damaged. HealiAid[®] Collagen Wound Dressing should not be re-sterilized. Residual portions of HealiAid[®] Collagen Wound Dressing should be discarded after use.

HealiAid[®] Collagen Wound Dressing contains bovine collagen and must not be use to patients with a history of allergy to any bovine collagen products. Hypersensitivity reactions reported when using bovine collagen products including erythema, swelling, induration, and/or urticaria.

HealiAid[®] Collagen Wound Dressing should be stored at room temperature in a dry place. Do not expose HealiAid[®] Collagen Wound Dressing to extreme environmental conditions. Do not use after expiration date.

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