

Integra® Miltex®

ULTRA PURE COLLAGEN™
FOR DENTAL APPLICATIONS

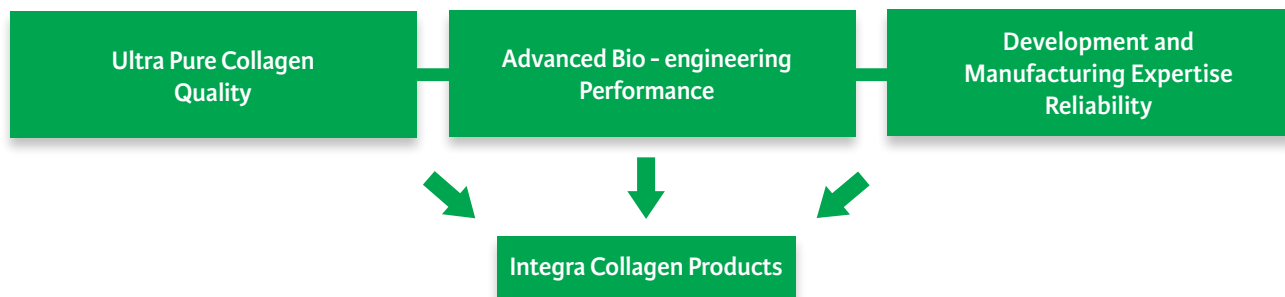


INTEGRA®
LIMIT UNCERTAINTY

What Makes Integra's Collagen Unique?

Ultra Pure Collagen™ provides high quality and Clinical differentiation

- Limits the risk of foreign body reaction
- Reduces the chance of encapsulation by fibrous tissue
- Mitigates the possibility of immunological response



Ultra Pure Collagen: Integra LifeSciences exposes its collagen to a proprietary purification process which mitigates the risk of inflammatory response. Bovine tendon is known to be one of the purest sources of Type 1 collagen that is commercially available.

Advanced Bio-Engineering: The Ultra-Pure Collagen is specifically engineered for each clinical application

Development & Manufacturing Expertise: Integra has been a leader in developing and manufacturing high quality collagen for more than 30 years.

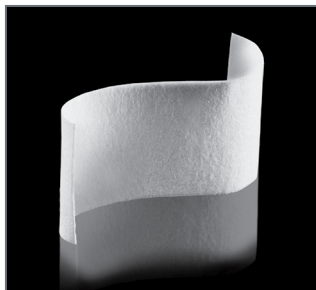
Absorbable Collagen Wound Dressings for Dental Surgery

Integra absorbable collagen wound dressing products are soft, white, pliable, non-friable, absorbent sponges made from collagen obtained from bovine deep flexor (Achilles) tendon. The tendon is one of the purest sources of collagen that can be readily obtained and processed in commercial quantities.

These dressings are intended for use on moist or bleeding wounds where a stabilized blood clot can help protect the surface of the wound from further injury. Collagen wound dressing products are typically reabsorbed by the body within 2 to 4 weeks after placement.

Collagen Wound Dressings

Indications: For application to moist or bleeding clean oral wounds created during dental surgery, to control bleeding and to protect the surface of the wound from further injury.



Collagen Tape Wound Dressing:

- Minor oral wounds
- Closure of grafted sites
- Repair of Schneiderian Membranes



Collagen Cote Wound Dressing:

- Palatal donor sites
- Mucosal flaps



Collagen Plug Wound Dressing:

- Extraction sites
- Biopsy sites

See instructions for use for full prescribing information

Features and Benefits

- Dressings retain their structural integrity even when wet
- Very porous. The dressings are highly absorbent, holding many times their own weight of saline solution
- Controls bleeding usually within two to five minutes
- In situations where frequent aspiration is required to remove accumulated blood and exudate, the Absorbable Collagen Wound Dressings can be used to dress bleeding or oozing wounds and thereby improve patient comfort
- Easily removed without damaging the wound bed, they can be used as temporary dressings prior to surgical closure
- The structure of the Dressings provides a three-dimensional matrix for additional strengthening of the blood clot
- Designed to be totally absorbable when left in situ after hemostasis
- Require no preparation time and are easy to handle

Absorbable Collagen Membranes

Integra absorbable collagen membranes are white, compressed, non-friable matrices fabricated from collagen derived from bovine-deep flexor (Achilles) tendon. These collagen products provide wound stabilization and create space during guided tissue regeneration procedures where an extended resorption profile is desired. These membranes are completely absorbable, eliminating the need for the second surgery that is often required to remove a non-resorbable membrane. The HeliMend® membrane incorporates into the surrounding tissue and is generally reabsorbed within 4-8 weeks, and the HeliMend® advanced collagen membrane is generally reabsorbed within 18 weeks.



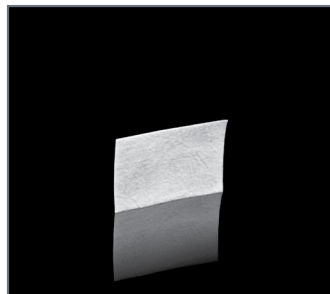
Integra collagen membrane has excellent handling characteristics.

Features and Benefits

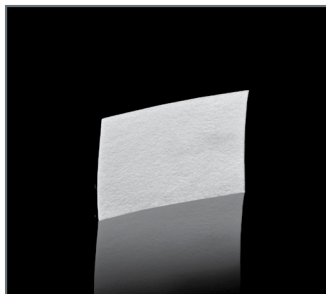
- Can be cut to any size or shape in the wet or dry state, without tearing or fragmenting
- Textured surface for easy handling, non-slippery when wet
- Wet characteristics greatly facilitate the positioning and handling of the device during surgical procedures
- Semi-occlusive, it allows essential nutrients to pass through the membrane
- Have mechanical strength to be sutured in place
- Prevents epithelial cell migration and maintains space for periodontal ligament and enhances clinician's ability to promote bone regeneration
- Functions as a barrier during the critical period of wound healing

Absorbable Collagen Membranes

Indications: Absorbable collagen membranes are absorbable, implantable material that is indicated for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.



15mm x 20mm



20mm x 30mm



30mm x 40mm

See instructions for use for full prescribing information

Absorbable Collagen Wound Dressings

Reference	Description	Sizes
62-200	HeliTape® Absorbable Collagen Wound Dressing	1" x 3" (2.5cm x 7.5cm)
62-201	HeliCote® Absorbable Collagen Wound Dressing	¾" x 1 ½" (2cm x 4cm)
62-202	HeliPlug® Absorbable Collagen Wound Dressing	3/8" x ¾" (1cm x 2cm)

Absorbable Collagen Membranes

Reference	Description	Sizes
62-203	HeliMend® Absorbable Collagen Membrane	15mm x 20mm
62-204	HeliMend® Absorbable Collagen Membrane	20mm x 30mm
62-205	HeliMend® Absorbable Collagen Membrane	30mm x 40mm

Advanced Collagen Membrane

Reference	Description	Sizes
62-206	HeliMend® Advanced Collagen Membrane	15mm x 20mm
62-207	HeliMend® Advanced Collagen Membrane	20mm x 30mm
62-208	HeliMend® Advanced Collagen Membrane	30mm x 40mm

HeliMend® and HeliMend® Advanced

Indications

HeliMend® absorbable collagen membrane is a absorbable, implantable material that is indicated for guided tissue regeneration of the periodontal apparatus.

Description

HeliMend® absorbable collagen membrane is a white, compressed, non-friable matrix fabricated from collagen derived from bovine deep flexor (Achilles) tendon.

Possible complications which can occur with any periodontal surgery includes swelling of the intraoral tissue, thermal sensitivity, gingival recession, excessive gingival bleeding, flap sloughing, resorption or ankylosis of the treated root, some loss of the crestal bone height, infection, pain or complications associated with the use of anesthesia.

As with any type of surgical therapy, the patient may experience minor discomfort for a few days.

Spontaneous exfoliation of the material may occur in the immediate postoperative period if the HeliMend® membrane is not adequately covered by the mucogingival flap.

HeliCoat®, HeliTape®, HeliPlug® Absorbable Collagen Wound Dressing

Indications

Absorbable Collagen Wound Dressings for Dental Surgery are indicated for application to moist bleeding clean oral wounds created during dental surgery, to control bleeding and protect the face of the wound from further injury. Topical administration of the Absorbable Collagen Wound Dressings directly over the wound effectively controls bleeding usually within two to five minutes.

Absorbable Collagen Wound Dressing for Dental Surgery, are indicated for use on moist or bleeding wounds where a stabilized blood clot can help protect the surface of the wound from further injury. The Absorbable Collagen Wound Dressings are indicated during prolonged dental procedures where maintaining a clear surgical field and ease of use are beneficial factors in treating oral wounds.

Situations where frequent aspiration is required to remove accumulated blood and execute, the Absorbable Collagen Wound Dressings can be used to dress bleeding or oozing wounds and thereby improve patient comfort. Since the Absorbable Wound Dressings can be easily removed without damaging the wound bed, they can be used as temporary dressing prior to surgical closure.

Description

Absorbable Collagen Wound Dressings for Dental Surgery HeliTape®, HeliCote®, HeliPlug® are soft, white, pliable, nonfriable sponges. Because of the coherent sponge structure, application of the dressings to the wound is easily controlled. The dressing retain their natural structural integrity when wet. Unwanted dispersal from the site is not encountered.

Adverse reactions reported with another microfibrillar collagen hemostatic agent that were possibly related to its use were adhesion formation, allergic reaction, foreign body reaction and subgaleal seroma (report of a single case)

Since the wound dressings are collagen based products, adverse reactions experienced with another microfibrillar collagen may be related.

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