

MILTEX® HI-LIGHT

WOUND DRESSING PRODUCTS



Miltex® collagen wound dressing products are used to help control bleeding, develop blood clots and to protect the wound site in order for the healing process to begin. The Miltex® product offering includes HeliCOTE®, HeliPLUG® and HeliTAPE® collagen wound dressing products. Heli products are reabsorbed by the body within 10 to 14 days after placement.

These collagen products are packaged in individual clam shells with an easy to peel backing, reducing tray set up time and making it easy for clinicians to open packages during procedures. The product is sterile and is sold in packs of 10.

REF	Description	Qty/Box
62-200	HeliTAPE Collagen Wound Dressing, 1" X 3" (2.5cm X 7.5cm)	10
62-201	HeliCOTE Collagen Wound Dressing, 3/4" X 1.5" (1.9cm X 3.8cm)	10
62-202	HeliPLUG Collagen Wound Dressing, 3/8" X 3/4" (1cm X 2cm)	10

See Reverse For More Details

Illustrations and content provide general description only and may be subject to change. For additional information, an in-office demonstration, or to place an order, please contact your local Miltex, Inc. authorized Distributor or Miltex Customer Service at 1-866-854-8300, email customerservice@miltex.com, or visit us at www.miltex.com.

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HeliTAP[®]

Indications

- Used for dressing minor wounds
- Used to aid in the closure of graft sites
- Used to help repair the Schniderian Membrane

HeliCOTE[®]

Indications

- Used in palatal donor sites
- Used in mucosal flaps

HeliPLUG[®]

Indications

- Used to control bleeding and to develop blood clots in extraction sites
- Used to control bleeding and to develop blood clots in biopsy sites

DIRECTIONS FOR USE

DESCRIPTION

The Absorbable Collagen Wound Dressings for Dental Surgery (HeliTAP[®], 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 dressings retain their structural integrity even when wet. Unwanted dispersal from the site is not encountered. The Absorbable Collagen Wound Dressings for Dental Surgery are very porous. Greater than 90% of the dressing consists of open pores, which can fill with fluid. The dressings are highly absorbent, holding many times their own weight of saline solution. The basic material from which the Absorbable Collagen Wound Dressings for Dental Surgery are fabricated is 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. Because of the high initial purity and further processing achieved during manufacture, the sponges are safe and effective wound dressings that exhibit very consistent behavior. The Absorbable Collagen Wound Dressings for Dental Surgery are nontoxic and nonpyrogenic, and each dressing is packaged individually. The sterility of the dressing is guaranteed unless the package is opened or damaged.

INDICATIONS

The Absorbable Collagen Wound Dressings for Dental Surgery are indicated for application to moist or bleeding clean oral wounds created during dental surgery, to control bleeding and protect the surface 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. The Absorbable Collagen Wound Dressings for Dental Surgery, 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. 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. 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. Since the Absorbable Collagen Wound Dressings can be easily removed without damaging the wound bed, they can be used as temporary dressings prior to surgical closure.

INFORMATION FOR USE

The Absorbable Collagen Wound Dressings for Dental Surgery have been shown to have good adherence to moist wounds. The highly porous sponge structure absorbs blood and wound exudate. An inherent property of native collagen is the ability to promote hemostasis. In contact with blood, collagen is known to cause aggregation of platelets, which bind in large numbers to the collagen fibrils. The aggregated platelets degranulate, releasing coagulation factors that enable, together with plasma factors, the formation of Fibrin. The sponge structure of the Absorbable Collagen Wound Dressings provides a three-dimensional matrix for additional strengthening of the blood clot. In vivo studies using guinea pigs showed that the incidence of infection (abscess) of incision sites inoculated with *Staphylococcus aureus* was not enhanced by the presence of the Absorb-

able Collagen Wound Dressings when compared to another collagen hemostatic agent. However, extent of wound infection tended to be greater than control with the Absorbable Collagen Wound Dressings and another collagen hemostatic agent tested. This tendency is observed with many foreign substances. The Absorbable Collagen Wound Dressings for Dental Surgery have been tested for potential allergenic sensitivity and cytotoxicity. The sponges contain no toxic leachables, do not produce tissue irritation, and show no contact sensitization upon repeat challenge. Passive hemagglutination, which is a sensitive test for potential antigenicity, was used with the Absorbable Collagen Wound Dressings as the antigen. There was no agglutination observed. The Absorbable Collagen Wound Dressings for Dental Surgery are tested and certified as nonpyrogenic.

PRECAUTIONS

The Absorbable Collagen Wound Dressings for Dental Surgery should not be used on infected or contaminated wounds. Although the Absorbable Collagen Wound Dressings will promote hemostasis, they are not intended for use in treating systemic coagulation disorders. Store the Absorbable Collagen Wound Dressings in sealed packages at room temperature. Avoid excessive heat or humidity. Discard all open but unused dressings. Do not attempt to re-sterilize. The material has not been tested on pregnant women. The risk to health has not been established. The long-term effects of leaving the Absorbable Collagen Wound Dressings in situ are presently unknown.

ADMINISTRATION

A sufficiently large Absorbable Collagen Wound Dressing should be selected so as to completely cover the oral wound. The wound should be rinsed clean and excess fluid removed. The dressing should be applied over the wound and held in place with moderate pressure. The period of time necessary to apply pressure will vary with the degree of bleeding. In general, two to five minutes should be sufficient to achieve hemostasis. At the end of the procedure, the Absorbable Collagen Wound Dressing can be removed, replaced or left in situ. If desired, the Absorbable Collagen Wound Dressing can be covered with a periodontal packing to help hold the sponge in place. The Absorbable Collagen Wound Dressing may be left in situ, when necessary. However, the dentist should remove any excess dressing prior to wound closure.

ADVERSE REACTIONS

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. The Absorbable Collagen Wound Dressings for Dental Surgery differ substantially in source, method of processing, and purity from other microfibrillar and macrofibrillar forms of collagen commercially distributed for hemostatic and wound care applications.



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