



## INSTRUCTIONS FOR USE

### HeliTape® / HeliCote® / HeliPlug®

Absorbable Collagen Wound Dressings for Dental Surgery

10571-731-02

#### DESCRIPTION

The 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 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 Absorbable 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, Dressing can be removed, replaced or left in situ. If desired, 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.

#### ORDERING INFORMATION

Sterile Absorbable Collagen Wound Dressings for Dental Surgery are supplied individually packaged in the following configurations:

| REF    | Dressing | Size                           | Quantity |
|--------|----------|--------------------------------|----------|
| 62-200 | HeliTape | 1" x 3"<br>(2.5 cm x 7.5 cm)   | 10/box   |
| 62-201 | HeliCote | 3/4" x 1 1/2"<br>(2 cm x 4 cm) | 10/box   |
| 62-202 | HeliPlug | 3/8" x 3/4"<br>(1 cm x 2 cm)   | 10/box   |

#### PRODUCT INFORMATION DISCLOSURE

THE MANUFACTURER HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND IN THE MANUFACTURE OF THESE PRODUCTS. MANUFACTURER AND DISTRIBUTOR EXCLUDE ALL WARRANTIES WHETHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NEITHER MANUFACTURER NOR DISTRIBUTOR SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSES, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. MANUFACTURER AND DISTRIBUTOR NEITHER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.



Manufacturer



Do not reuse

REF

Catalog Number



Expiration Date

LOT

Lot Number

STERILE EO

Method of Sterilization: ethylene oxide



Caution, see instructions for use

Rx ONLY

Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner.

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