Helistat®

ABSORBABLE COLLAGEN HEMOSTATIC SPONGE

Rx ONLY

FDA Approved

ABSORBABLE COLLAGEN HEMOSTATIC AGENT

DESCRIPTION

Helistat® Absorbable Collagen Hemostatic Sponge is a soft, white, pliable, non-friable absorbent sponge. Because of its non-friable coherent sponge structure, the application of Helistat hemostatic sponge to the site where hemostasis is desired is easily controlled. Unwanted dispersal over the operative site is not encountered.

The basic material from which Helistat hemostatic sponge is fabricated is collagen obtained from bovine deep flexor (Achilles) tendon. The tendon is known to be one of the purest sources of collagen that can be readily obtained and processed in commercial amounts. Helistat hemostatic sponge being derived from this tendon, is expected to be very consistent material.

Because of the initial purity of the collagen source and the further purification steps during processing of Helistat hemostatic sponge, the practitioner can expect uniform behavior from this topical hemostat from one application to the next.

INDICATIONS

Helistat hemostatic sponge is indicated in surgical procedures (other than ophthalmological and urological surgery) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

INFORMATION FOR USE FOR HELISTAT® ABSORBABLE COLLAGEN HEMOSTATIC SPONGE

On contact with blood, collagen is known to cause aggregation of platelets. Platelets deposit in large numbers on the collagen structure, degranulate, and release coagulation factors that, together with plasma factors, enable the formation of fibrin. The structure of Helistat hemostatic sponge provides a three-dimensional matrix for the additional strengthening of the clot.

Helistat hemostatic sponge effectively controls bleeding usually within two to five minutes when applied directly to the bleeding site. Excess Helistat hemostatic sponge should be removed from the site after hemostasis is achieved. Long term effects of leaving Helistat hemostatic sponge collagen hemostatic agents *in situ* are unknown.

Helistat absorbable collagen hemostatic agents are designed to be totally absorbable if left *in situ* after hemostasis. If desired, Helistat hemostatic sponge may be recovered after hemostasis is accomplished using dry forceps. Implant studies in animals have demonstrated Helistat hemostatic sponge collagen hemostatic agents to be absorbed with tissue reaction similar to that observed with other absorbable hemostatic agents.

The collagen hemostatic agent absorption was evaluated after subcutaneous and intrahepatic implantation in rats. In one out of five animals, complete subcutaneous absorption was observed by day 14, and by day 56, three out of four animals had complete absorption. Complete intraperitoneal absorption was not observed by day 56.

As shown with other hemostatic agents, the implantation of Helistat hemostatic sponge also elicits a similar foreign body reaction.

Helistat hemostatic sponge Absorbable Collagen Hemostatic Sponge has been evaluated *in vitro* for the enhancement of bacterial growth of *Staphylococcus aureus* and *Escherichia coli.* Enhancement of bacterial growth did not occur for either organism.

In vivo studies using guinea pigs showed that incidence of infection (abscess) of incision sites inoculated with *Staphylococcus aureus* was not enhanced by the presence of the collagen hemostatic agent when compared to another collagen hemostatic agent. However, extent of wound infection tended to be greater than control with Helistat hemostatic sponge and another collagen hemostatic agent tested. This tendency is observed with many foreign substances.

Helistat Absorbable Collagen Hemostatic Sponge was evaluated for potential allergenic sensitivity. A guinea pig maximization study showed that Helistat hemostatic sponge did not produce irritation or contact sensitization. A chemical assay of Helistat hemostatic sponge compared to one other collagen hemostat showed significantly less specific glycoprotein immunoreactive substances in Helistat hemostatic sponge. A hemagglutination study was conducted evaluating Helistat Absorbable Collagen Hemostatic Sponge as the antigen. There was no agglutination observed.

PRECAUTIONS

As with other hemostatic agents, it is not recommended that Helistat hemostatic sponge be left in an infected or contaminated space.

Helistat hemostatic sponge is not intended to be used to treat systemic coagulation disorders.

Only the amount of Helistat hemostatic sponge necessary to produce

hemostasis should be used. After approximately 10-15 minutes, excess material should be removed. This is usually possible by lifting the Helistat hemostatic sponge using dry forceps. In otolaryngological surgery, precaution against aspiration should include removal of excess dry material.

There are no well-controlled studies in pregnant women; therefore, Helistat hemostatic sponge should be used in pregnant women only when the benefit outweighs the risk.

Long term effects of leaving Helistat hemostatic sponge *in situ* are unknown.

SINGLE-USE DEVICE

The Helistat hemostatic sponge agent is supplied in a single-use package and is guaranteed to be sterile and non-pyrogenic unless opened or damaged. The product is intended for use as an absorbable implant and is not to be reused. Reuse of the device can result in contamination and/or disease transmission. Any attempt to resterilize or reuse the product/components will damage the matrix and impair its ability to function as intended. All unused pieces must be discarded.

ADVERSE REACTIONS

Adverse reactions reported with a microfibrillar collagen hemostatic agent (not Helistat hemostatic sponge) that were possibly related to its use were adhesion formation, allergic reaction, foreign body reaction, and subgaleal seroma (report of a single case). The use of microfibrillar collagen in dental extraction sockets has been reported to increase the incidence of alveolalgia.

Other microfibrillar collagens have been reported to cause interference with the healing of skin edges when used in the closure of skin incisions and to reduce the strength of methyl-methacrylate adhesive when used to attach prosthetic devices to bone surfaces. Transient laryngospasm due to aspiration of dry material has been reported following the use of another microfibrillar collagen in tonsillectomy procedures.

Since Helistat hemostatic sponge is a collagen-based product, adverse reactions experienced with other collagen hemostatic agents may be related.

ADMINISTRATION

Helistat hemostatic sponge should be placed directly on the bleeding surface with pressure applied using a dry gauze. **Either side of Helistat hemostatic sponge may be applied to the bleeding site.** The period of time necessary to apply pressure will vary with the type and amount of bleeding to be controlled. In general, one to five minutes should be sufficient. It has been shown that hemostasis usually occurs within two to five minutes. The amount of Helistat hemostatic sponge necessary to achieve hemostasis will depend on the nature and amount of bleeding to be controlled.

Dry forceps should be used to apply Helistat hemostatic sponge to facilitate handling and placement of the material.

Helistat hemostatic sponge may be left *in situ* whenever necessary. However, the surgeon should remove any excess Helistat hemostatic sponge prior to wound closure.

HOW SUPPLIED

Sterile Helistat Absorbable Collagen Hemostatic Sponge is supplied in the following sizes:

REF	Size	Quantity
1210-ZW	1 in x 2 in x 5.0 mm* (2.5 cm x 5.0 cm x 5.0 mm*) 2 sq in (12.5 sq cm)	10/box
3410-ZX	3 in x 4 in x 5.0 mm* (7.5 cm x 10.0 cm x 5.0 mm*) 12 sq in (75 sq cm)	10/box
1690-ZZ	1/2 in x 1 in x 7.0 mm* (1.27 cm x 2.54 cm x 7.0 mm*) 0.5 sq in (3.2 sq cm)	18/box
1910-ZM	1 in x 9 in x 5.0 mm* (2.5 cm x 22.5 cm x 5.0 mm*) 9 sq in (56.2 sq cm)	4/box

*nominal thickness

Contents of the package are guaranteed sterile and non-pyrogenic unless the package is opened or damaged. **Avoid excessive heat and humidity.**

PRODUCT INFORMATION DISCLOSURE

INTEGRA HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. INTEGRA INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS HAVING RECEIVED PROPER TRAINING IN THE USE OF THE DEVICE.

SYMBOLS USED ON LABELING

	Consult Instructions for Use
	Expiration date
	Do not re-use
	Lot number
	Do Not Use if package is damaged
	Sterilized Using Ethylene Oxide.
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner
	Manufacturer
	Catalog number
	Do Not re-sterilize
	Peel here

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