HELISTAT®

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® 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® 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®, the practitioner can expect uniform behavior from this topical hemostat from one application to the next.

INDICATIONS

HELISTAT® 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® provides a three-dimensional matrix for the additional strengthening of the clot.

HELISTAT® effectively controls bleeding usually within two to five minutes when applied directly to the bleeding site. Excess HELISTAT® should be removed from the site after hemostasis is achieved. Long term effects of leaving HELISTAT® 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® may be recovered after hemostasis is accomplished using dry forceps. Implant studies in animals have demonstrated HELISTAT® 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® also elicits a similar foreign body reaction.

HELISTAT® 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® 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® did not produce irritation or contact sensitization. A chemical assay of HELISTAT® compared to one other collagen hemostat showed significantly less specific glycoprotein immunoreactive substances in HELISTAT®. 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® be left in an infected or contaminated space.

HELISTAT® is not intended to be used to treat systemic coagulation disorders.

Only the amount of HELISTAT® 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® 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® should be used in pregnant women only when the benefit outweighs the risk.

Long term effects of leaving HELISTAT® *in situ* are unknown.

ADVERSE REACTIONS

Adverse reactions reported with a microfibrillar collagen hemostatic agent (not HELITENE®) 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® is a collagen-based product, adverse reactions experienced with other collagen hemostatic agents may be related.

ADMINISTRATION

HELISTAT® should be placed directly on the bleeding surface with pressure applied using a dry gauze. **Either side of HELISTAT® 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® necessary to achieve hemostasis will depend on the nature and amount of bleeding to be controlled.

Dry forceps should be used to apply HELISTAT® to facilitate handling and placement of the material.

HELISTAT® may be left *in situ* whenever necessary. However, the surgeon should remove any excess HELISTAT® 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.**

SYMBOLS USED ON LABELING


See instructions for use

Lot number


Expiration date

Sterile unless package is opened or damaged. Method of sterilization–ethylene oxide


Do not reuse after opening

Manufacturer:

INTEGRA LIFESCIENCES CORPORATION
105 Morgan Lane • Plainsboro, NJ 08536 • USA
(800) 654-2873 • Facsimile (609) 275-5363

RMS# 21600-1208-0

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℞ **ONLY**

FDA Approved