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

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

HELITENE® Absorbable Collagen Hemostatic Agent is designed to be totally absorbable if left in situ after hemostasis. If desired, HELITENE® may be recovered after hemostasis is accomplished using dry forceps or irrigation. Implant studies in animals have demonstrated the Absorbable Collagen Hemostatic Agent 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 HELITENE® also elicited a similar foreign body reaction.

The Absorbable Collagen Hemostatic Agent 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 infection of incidence (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 the Absorbable Collagen Hemostatic Agent and another collagen hemostatic agent tested. This tendency is observed with many foreign substances.

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

It has been shown that fragments of microfibrillar hemostatic agents may be passed through the filter of blood saving devices and returned to the patient. The use of microfibrillar collagen in patients undergoing surgical procedures involving blood saving devices should be avoided.

As with other hemostatic agents, it is not recommended that HELITENE® be left in an infected or contaminated space. HELITENE® is intended not to be used to treat systemic coagulation disorders. Only the amount of HELITENE® necessary to produce hemostasis should be used. After approximately 10-15 minutes, excess material should be removed. This is usually possible by removing the HELITENE® using dry forceps or irrigation. In otolaryngological surgery, precaution against aspiration should include removal of excess dry material.

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

Long term effects of leaving HELITENE® in situ are unknown.

ADVERSE REACTIONS

Adverse reactions reported with another microfibrillar collagen agent that were possibly related to its use were adhesion formation, allergic reaction, foreign body reaction, and subglandular 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