

INSTAT

Collagen Absorbable Hemostat

DESCRIPTION:

INSTAT Collagen Absorbable Hemostat is a purified and lyophilized bovine dermal collagen. The material, prepared as a sponge-like pad, is lightly cross-linked, sterile, non-pyrogenic, and absorbable. Hemostatic activity, which is an inherent property of collagen, is largely dependent on the basic helical structure of this protein. The helical structure of native collagen is preserved during the manufacture of INSTAT Hemostat. When collagen comes into contact with blood, platelets aggregate on the collagen and release coagulation factors which, together with plasma factors result in the formation of fibrin, and finally in the formation of a clot.

INDICATIONS:

INSTAT Hemostat is indicated in surgical procedures (other than in neurosurgical and ophthalmological surgery) for use as an adjunct to hemostasis when control of bleeding by ligation or other conventional methods is ineffective or impractical. INSTAT Hemostat can be cut to size for use in endoscopic procedures.

CONTRAINDICATIONS:

INSTAT Hemostat should not be used in the closure of skin incisions as it may interfere with the healing of skin edges. This interference is due to simple mechanical interposition of dry collagen and not due to any intrinsic interference with wound healing. It has been reported with another absorbable collagen hemostat that, in filling porosities of cancellous bone, collagen may reduce the bonding strength of methylmethacrylate. Therefore, INSTAT Hemostat should not be applied on bone surfaces to which prosthetic materials are to be attached with methylmethacrylate adhesives.

WARNINGS:

INSTAT Hemostat is inactivated by autoclaving. It should not be resterilized. As with any foreign substance, use in contaminated wounds may enhance infection.

INSTAT Hemostat should not be used in instances of pumping arterial hemorrhage.

INSTAT Hemostat should not be used where blood or other fluids have pooled or in cases where the point of hemorrhage is submerged. INSTAT Hemostat will not act as a tampon or plug in a bleeding site nor will it close off an area of blood collecting behind a tampon.

Only the amount of INSTAT Hemostat necessary to provide hemostasis should be used. The long-term effects of leaving INSTAT Hemostat in situ are unknown. Opened, unused INSTAT Hemostat should be discarded because it cannot be resterilized.

PRECAUTIONS:

As with other hemostatic agents, it is not recommended that INSTAT Hemostat be left in an infected or contaminated space, nor is it recommended for use in persons known to be sensitive to materials of bovine origin. When placed into cavities or closed spaces, care should be exercised to avoid overpacking INSTAT Hemostat as it may absorb fluid and expand and press against neighboring structures. In urological procedures, INSTAT Hemostat should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

Safety of this product has not been established in children and pregnant women; therefore, INSTAT Hemostat should only be used when benefit to risk clearly warrants its use.

INSTAT Hemostat is not intended to be used to treat systemic coagulation disorders.

Endoscopic procedures should be performed only by persons having adequate training and familiarity with endoscopic techniques. Consult medical literature relative to techniques, complications and hazards prior to performance of any endoscopic procedure.

A thorough understanding of the principles and techniques involved in laparoscopic laser and electrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Refer to appropriate electrosurgical system users manual for use indications and instructions to ensure that all safety precautions are followed.

When endoscopic instruments and accessories from different manufacturers are employed together during a procedure, verify their compatibility prior to initiation of the procedure and ensure that isolation or grounding is not compromised.

ADVERSE REACTIONS:

INSTAT Hemostat is a collagen product. Although several types of post-operative complications were observed in INSTAT Hemostat treated patients, none were attributed to INSTAT Hemostat except one case of fibrotic reaction where INSTAT Hemostat involvement could not be ruled out. Adverse reactions reported for other collagen hemostats include hematoma, potentiation of infection, wound dehiscence, inflammation and edema. Other reported adverse reactions that may be related to the use of collagen hemostats include adhesion formation, allergic reaction, foreign body reaction and subgaleal seroma (in a single case). The use of microfibrillar collagen in dental extraction sockets has been reported to increase the incidence of alveolgia. The possibility that all of the above reactions may occur with INSTAT Hemostat cannot be excluded.

ADMINISTRATION:

INSTAT Hemostat is applied directly to the bleeding surface with pressure. INSTAT Hemostat can be cut to size. The amount needed and the period of time necessary to apply pressure will vary with the type and amount of bleeding to be controlled. Hemostasis time depends upon the type of surgery and degree of pretreatment bleeding. It usually occurred between 2 to 5 minutes with INSTAT Hemostat. INSTAT Hemostat maintains its integrity in the presence of blood and is not dispersed when wet. It is easily removed from the site following hemostasis. It is most effective when used dry.

INSTAT Hemostat may be left in situ whenever necessary. However, the surgeon, at his discretion, should remove any excess of INSTAT Hemostat prior to wound closure. Animal implant studies have demonstrated that absorption and tissue reaction to INSTAT Hemostat are similar to those observed with another absorbable collagen hemostatic agent. In these studies, on visual examination, most of INSTAT Hemostat was found to be absorbed in 8 to 10 weeks after implantation.

CLINICAL STUDIES:

The safety, effectiveness and handling characteristics of INSTAT Hemostat were evaluated in a variety of surgical procedures. The median time to hemostasis for INSTAT Hemostat was 3 minutes. Passive Hemagglutination Assay (PHA) and Enzyme-Linked Immunoabsorbent Assay (ELISA) methods have been used to evaluate the immunologic potential for INSTAT Hemostat to produce antibodies in patients. These assays revealed mild elevation of antibody titers in both INSTAT Hemostat treated patients and patients treated with a collagen control hemostat, confirming that INSTAT Hemostat, like other collagen hemostats, is a weak antigen.

HOW SUPPLIED:

INSTAT Hemostat is supplied in a sponge-like form in peelable plastic envelopes in the following sizes:

Code No. 1981	1 in. x 2 in. (2.5 cm x 5.1 cm)
Code No. 1983	3 in. x 4 in. (7.6 cm x 10.2 cm)

The sterility of the product is guaranteed unless the individual envelope is damaged or opened.

STORAGE:

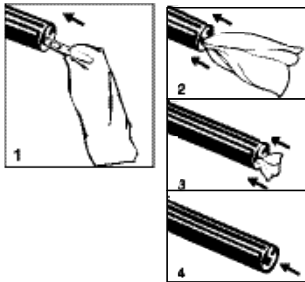
Store at controlled room temperature 59°-86°F (15°-30°C).

CAUTION:

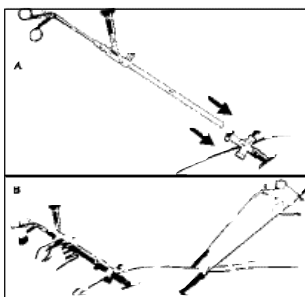
Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

DIRECTIONS FOR USING INSTAT COLLAGEN ABSORBABLE HEMOSTAT IN ENDOSCOPIC PROCEDURES:

INSTAT Hemostat should be cut to the appropriate size for endoscopic placement. Standard endoscopic procedures should be used up to the point of placement of the absorbable hemostat. Grasp INSTAT Hemostat at one corner. With a steady backward motion pull the material into the operating channel until the material is enclosed in the end of the laparoscope.



A. Place the laparoscope back into the patient via the sleeve and reposition the scope over the area of desired application. Slowly push the grasping instrument and material into the cavity.



B. With the use of grasping instruments in a 2nd and/or 3rd auxiliary site, placement can be made and the material positioned in place.

For product quality and technical questions, please call 1(877) 384-4266