AVITENE™

Microfibrillar Collagen Hemostat

Instructions for Use

Mode d'emploi • Gebrauchsanweisung
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℞ Only

STERILE

Single Use

BARD

DAVOL INC.

DESCRIPTION: Avitene™ (Microfibrillar Collagen Hemostat, or MCH), is an absorbable topical hemostatic agent prepared as a dry, sterile, fibrous, water insoluble partial hydrochloric acid salt of purified bovine corium collagen. It is prepared in a loose fibrous form and in a compacted "non-woven" web form. In its manufacture, swelling of the native collagen fibrils is controlled by ethyl alcohol to permit non-covalent attachment of hydrochloric acid to amine groups on the collagen molecule and preservation of the essential morphology of native collagen molecules. Dry heat sterilization causes some cross-linking which is evidenced by reduction of hydrating properties, and a decrease of molecular weight which implies some degradation of collagen molecules. However, the characteristics of collagen, which are essential to its effect on the blood coagulation mechanisms, are preserved.

ACTIONS: Avitene™ (MCH), in contact with a bleeding surface, attracts platelets which adhere to the fibrils and undergo the release phenomenon to trigger aggregation of platelets into thrombi in the interstices of the fibrous mass. The effect on platelet adhesion and aggregation is not inhibited by heparin *in vitro*. It has been found effective in heparinized dogs and in eight of nine fully heparinized human subjects. Platelets of patients with clinical thrombasthenia do not adhere to MCH *in vitro*. However, in clinical trials it was effective in 50 of 68 patients receiving aspirin. MCH cannot control bleeding due to systemic coagulation disorders. Appropriate therapy to correct the underlying coagulopathy should be instituted prior to use of the product. MCH is tenaciously adherent to surfaces wet with blood but excess material not involved in the hemostatic clot may be removed by teasing or irrigation, usually without causing rebleeding. In animal and human studies, it has been shown to stimulate a mild, chronic cellular inflammatory response. When implanted in animal tissues, it is absorbed in less than 84 days. In human studies of hemostasis in osteotomy cuts, it has been shown not to interfere with bone regeneration or healing. In animal studies, it has been demonstrated that MCH does not predispose to stenosis at vascular anastomotic sites. These findings have not been confirmed in human use. Studies have been performed using MCH (fibrous form) in experimental wounds contaminated with hemolytic *Staphylococcus* aureus. The presence of MCH does not enhance or initiate *Staphylococcus* wound infections to a greater or lesser extent than control agents employed for the same purpose.

INDICATIONS: Avitene™ (MCH) is used in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

CONTRAINDICATIONS: Avitene™ (MCH) should not be used in the closure of skin incisions as it may interfere with the healing of the skin edges. This is due to simple mechanical interposition of dry collagen and not to any intrinsic interference with wound healing. By filling porosities of cancellous bone, MCH may significantly reduce the bond strength of methylmethacrylate adhesives. MCH should not, therefore, be employed on bone surfaces to which prosthetic materials are to be attached with methylmethacrylate adhesives.

WARNINGS: Avitene™ (MCH) is inactivated by autoclaving. Ethylene oxide reacts with bound hydrochloric acid to form ethylene chlorohydrin. This device has been designed for single use only. Reuse, reprocessing, resterilization or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient.
Reuse, reprocessing, resterilization or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness or death of the patient or end user. MCH is not for injection or intraocular use. *Moistening MCH or wetting with saline or thrombin impairs its hemostatic efficacy*. It should be used dry. Discard any unused portion. As with any foreign substance, use in contaminated wounds may enhance infection.

PRECAUTIONS: Only that amount of Avitene™ (MCH) necessary to produce hemostasis should be used. After several minutes, excess material should be removed; this is usually possible without the reinitiation of active bleeding. Any excess Avitene™ (MCH) not removed at the time of surgery may either present itself as a (recurring) mass or a (space occupying) lesion or it may lead to a foreign body reaction that may present with or without clinical signs and symptoms as a recurring mass or lesion or postoperative abscess formation upon imaging. Imaging may initially not be capable of distinguishing the difference. Removal of excess material, ideally performed upon conclusion of the initial procedure, typically resolves all signs and symptoms. Failure to remove excess MCH may result in bowel adhesion or mechanical pressure sufficient to compromise the ureter. In otolaryngological surgery, precautions against aspiration should include removal of all excess dry material and thorough irrigation of the pharynx. MCH contains a low, but detectable, level of intercalated bovine serum protein which reacts immunologically as does beef serum albumin. Increases in anti-BSA titer have been observed

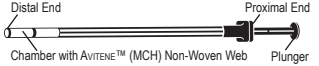
following treatment with MCH. About two-thirds of individuals exhibit antibody titers because of ingestion of food products of bovine origin. Intradermal skin tests have occasionally shown a weak positive reaction to BSA or MCH but these have not been correlated with IgG titers to BSA. Tests have failed to demonstrate clinically significant elicitation of antibodies of the IgG class against BSA following MCH therapy. Care should be exercised to avoid spillage on nonbleeding surfaces particularly in abdominal or thoracic viscera. Avitene™ (MCH) should not be used in conjunction with autologous blood salvage circuits, as Avitene™ may pass through the filters of such systems. It has been suggested that fragments of MCH may pass through filters of blood scavenging systems, therefore the reintroduction of blood from operative sites treated with MCH should be avoided. Teratology studies in rats and rabbits have revealed no harm to the animal fetus. There are no well-controlled studies in pregnant women, therefore, MCH should be used in pregnant women only when clearly needed. Avitene™ non-woven web should not be used as a surface dressing except for immediate control of bleeding. Avoid packing Avitene™ tightly in cavities, especially within the bony enclosure of the CNS or within other relatively rigid cavities where swelling may interfere with normal function or possibly cause necrosis. Avitene™ is not recommended for use in patients sensitive to bovine derived collagen.

ADVERSE REACTIONS: The most serious adverse reactions reported which may be related to the use of Avitene™ (MCH) are potentiation of infection including abscess formation, hematoma, wound dehiscence and mediastinitis. Other reported adverse reactions possibly related are adhesion formation, allergic reaction, foreign body reaction and subgaleal seroma (report of a single case). The use of MCH in dental extraction sockets has been reported to increase the incidence of alveolalgia. Transient laryngospasm due to aspiration of dry material has been reported following use of MCH in tonsillectomy.

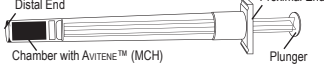
DOSAGE AND ADMINISTRATION: Avitene™ (MCH) must be applied directly to the source of bleeding. Because of its adhesiveness, it may seal over the exit site of deeper hemorrhage and conceal an underlying hematoma as in penetrating liver wounds. When possible, surfaces to be treated should be compressed with dry sponges immediately prior to application of the dry Avitene™. It is then advantageous to apply pressure over the Avitene™ with a dry sponge for a period of time which varies with the force and severity of bleeding. A minute may suffice for capillary bleeding (e.g., skin graft donor sites, dermatologic curettage) but three to five or more minutes may be required for brisk bleeding (e.g. splenic tears) or high pressure leaks in major artery suture holes. For control of oozing from cancellous bone, it should be firmly packed into the spongy bone surface. After five to ten minutes, excess MCH may be teased away (see Precautions); this can usually be accomplished with blunt forceps and is facilitated by wetting with sterile 0.9% saline solution and irrigation. If breakthrough bleeding occurs in areas of thin application, additional Avitene™ may be applied. The amount required depends, again on the severity of bleeding. In capillary bleeding, one gram will usually be sufficient for a 50 cm² area. Thicker coverage will be required for more brisk bleeding. MCH will adhere to wet gloves, instruments, or tissue surfaces. To facilitate handling, use dry, smooth forceps or a pre-loaded Avitene™ applicator device (SyringeAvitene™ or EndoAvitene™). In neurosurgical and other procedures the non-woven web may conveniently be used by applying small squares to bleeding areas and then covering the sites with moist cottonoid “patties”. After five to ten minutes excess MCH may be removed by teasing and irrigation.

Avitene™ Pre-loaded Applicators

EndoAvitene™ 5mm and 10mm diameters



SyringeAvitene™ 1gram



1. Follow accepted sterile technique when removing from foil pouch and introducing into sterile field.
2. Position the distal end of applicator at the bleeding site.
3. Depress the syringe plunger to deliver Avitene™ to the site of application.
4. Excess Avitene™ can be irrigated away.

After use, the applicators are potentially biohazardous products due to exposure to blood and body fluids. Dispose of any potentially biohazardous products in accordance with accepted medical practice and applicable local, state and federal regulations and the institutions' written policy for the disposal of potentially biohazardous material.

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