

## Avitene™ Microfibrillar Collagen Hemostat

A legacy of proven performance





# The power of Avitene MCH lives in proven reputation, versatile technology and economic value.

Every product in the Avitene™ MCH family of hemostats is made from 100% collagen,¹ which is proven to accelerate clot formation across surgical specialties.²

Acceptable for use in all procedures where a topical hemostat is indicated, including neurosurgery.

Avitene™ MCH's five formats provide versatile options to fit each specific procedure.²

Avitene™ MCH is made in the United States, and is trusted by surgeons across the globe.⁴

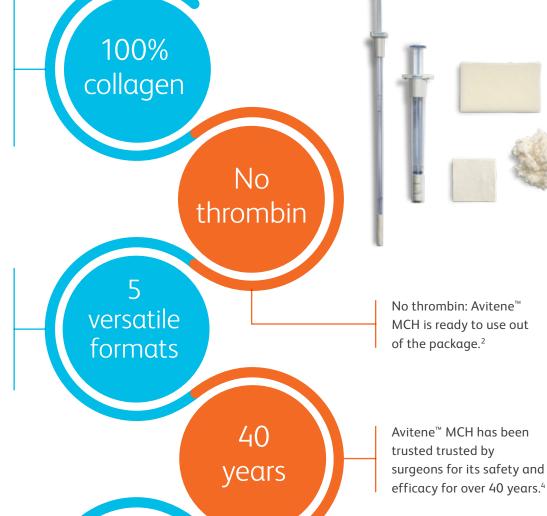
Acceptable for use in all procedures where a topical hemostat is used—including neurology, urology, cardiovascular and general surgery.<sup>2</sup>

Patient savings

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Reduced dependence on thrombin equals better health economics. As an active hemostatic agent, the Avitene™ Ultrafoam™ Collagen Sponge achieves effective hemostasis without adding thrombin. As a result, using the Avitene™ Ultrafoam™ Collagen Sponge versus a gelatin sponge with thrombin delivers economic

benefits.3



Avitene™ MCH's acceptability for use in all procedures where a topical hemostat is indicated and five versatile formats provides an effective and simple solution for hemostasis.²

#### Avitene™ Ultrafoam™ Collagen Sponge

- Easy, effective solution for hemostasis
- In an animal study, the Avitene<sup>™</sup> Ultrafoam<sup>™</sup>
  Collagen Sponge without thrombin was as
  effective as the Gelfoam<sup>®</sup> Sponge
  with thrombin<sup>3</sup>
- Reduced thrombin usage may lower cost
- Soft, pliable sponge is ready to use out of the package
- No soaking, no waste
- Does not swell, providing predictable placement of Ultrafoam™



### Avitene™ Microfibrillar Collagen Hemostat Flour

- Effective in controlling arterial bleeding<sup>2</sup>
- Conforms and adheres to irregular spaces
- Easy removal with irrigation and suction
- Available in 0.5 g, 1.0 g and 5.0 g sizes



#### Avitene™ Sheets (Nonwoven web)

- Avitene<sup>™</sup> Sheets provide the same efficacy expected from Avitene<sup>™</sup> Flour
- Cut to any shape or size
- Clings tenaciously to hemorrhage
- Ideal for use on flat surfaces or to wrap vessels and anastomosis sites
- Available in 3.5 cm x 3.5 cm, 7.0 cm x 3.5 cm and 7.0 cm x 7.0 cm



#### EndoAvitene™ Applicators

- Preloaded sheets for endoscopic delivery
- 10-mm diameters pass easily through trocars



#### SyringeAvitene™ Collagen Hemostat

- Preloaded 1 gm SyringeAvitene™ Applicator
- Collagen flour used in trauma, oncology, general and cardiovascular surgery

## How it works<sup>2</sup>

Avitene™ MCH adheres tightly to bloody surfaces and begins working on contact.

Collagen in Avitene™ MCH activates platelets, which bind strongly and specifically.

Platelets aggregate and proteins release to form fibrin.

The result: fast induction of hemostasis, regardless of the patient's coagulation status and without the need for thrombin.

Avitene™ Microfibrillar Collagen Hemostat Flour			
Product item ID	Product item name	Packaging (SKU)	Dimensions
1010010	Avitene™ Microfibrillar Collagen Hemostat	6/cs	0.5 g
1010020	Avitene™ Microfibrillar Collagen Hemostat	6/cs	1.0 g
1010590	Avitene™ Microfibrillar Collagen Hemostat	2/cs	5.0 g

SyringeAvitene™ Applicαtors			
Product item ID	Product item name	Packaging (SKU)	Dimensions
1010340	SyringeAvitene™ Applicators	6/cs	1 g flour preloaded applicator; 2 cm (0.8") diameter, 16 cm (6.5") usable length

Avitene™ Sheets			
Product item ID	Product item name	Packaging (SKU)	Dimensions
1010080	Avitene™ Sheets	6/cs	3.5 cm x 3.5 cm (1.4" x 1.4")
1010090	Avitene™ Sheets	6/cs	7.0 cm x 3.5 cm (2.75" x 1.4")
1010110	Avitene™ Sheets	6/cs	7.0 cm x 7.0 cm (2.75" x 2.75")

EndoAvitene™ Applicators			
Product item ID	Product item name	Packaging (SKU)	Dimensions
1010150	EndoAvitene™ Applicators	6/cs	10 mm diameter–42 cm length (50 mm x 15 mm x 1 mm preloaded sheet)

Avitene™ Ultrafoam™ Collagen Sponge			
Product item ID	Product item name	Packaging (SKU)	Dimensions
1050020	Avitene™ Ultrafoam™ Collagen Sponge	12/cs	12.5 sq cm 2 cm x 6.25 cm x 7 mm (3/4" x 2 1/2" x 1/4")
1050030	Avitene™ Ultrafoam™ Collagen Sponge	6/cs	50 sq cm 8 cm x 6.25 cm x 1 cm <i>(3 1/8" x 2 1/2" x 3/8")</i>
1050040	Avitene™ Ultrafoam™ Collagen Sponge	6/cs	100 sq cm 8 cm x 12.5 cm x 1 cm (3 1/8" x 5" x 3/8")
1050050	Avitene™ Ultrafoam™ Collagen Sponge	6/cs	100/thin 8 cm x 12.5 cm x 3 mm <i>(3 1/8" x 5" x 1/8")</i>

#### Indications

Avitene™ Microfibrillar Collagen Hemostat (MCH) and Avitene™ Ultrafoam™ Sponge are indicated in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.

#### Contraindications

- Avitene™ MCH and Avitene™ Ultrafoam™ Sponge should not be used in the closure of skin incisions as they 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.
- It has been reported with other collagen hemostatic agents that by filling porosities of cancellous bone, they may significantly reduce the bond strength of methylmethacrylate adhesives. Avitene™ MCH and Avitene™ Ultrafoam™ Sponge should not, therefore, be employed on bone surfaces to which prosthetic materials are to be attached with methylmethacrylate adhesives.

#### Warnings

- Avitene™ MCH and Avitene™ Ultrafoam™ Sponge are inactivated by autoclaving.
- Ethylene oxide reacts with bound hydrochloric acid to form ethylene chlorohydrin.

- These devices have 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 devices 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 devices may lead to injury, illness or death of the patient or end user. Opened, unused product should be discarded.
- Moistening Avitene™ MCH or wetting with saline or thrombin impairs its hemostatic efficacy. It should be used dry.
- As with any foreign substance, use of Avitene™ MCH and Avitene™ Ultrafoam™ Sponge in contaminated wounds may enhance infection.
- Avitene™ Ultrafoam™ Sponge should not be used in instances of pumping arterial hemorrhage.
- Avitene™ Ultrafoam™ Sponge should not be used where blood or other fluids have pooled, or in cases where the point of hemorrhage is submerged as it may mask an underlying source of bleeding, resulting in hematoma.

- Avitene™ Ultrafoam™ Sponge 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.
- Avitene™ Ultrafoam™ Sponge is not intended to treat systemic coagulation disorders.
- Avitene™ MCH and Avitene™ Ultrafoam™ Sponge are not for injection, intraocular or intravascular use.

#### Adverse reactions

- The most serious adverse reaction reported that may be related to the use of Avitene™ MCH or other collagen products 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) and increased incidence of alveolalgia when used for packing of dental extraction sockets.
- Transient laryngospasm due to aspiration of dry material has been reported following use of Avitene™ MCH in tonsillectomy.

Please consult package insert for more detailed safety information and Instructions for Use.

- 1. Price P, et al. Surgical technology for the surgical technologist: a positive care approach. 2nd ed. Clifton Park, NY: Thomson-Delmar Learning, 2004.
- 2. For complete information regarding the use of Avitene<sup>™</sup> Microfibrillar Collagen Hemostat in procedures where a topical hemostat is used please refer to the Instructions for Use included with the product or found on our website at www.bd.com. BD. Clinical data on file.
- 3. Connolly, Raymond. A comparison of Avitene™ UltraFoam™ versus GELFORM® with and without thrombin to effectively control bleeding. 1999. BD. In vitro testing. Data on file. Preclinical test results may not correlate to clinical performance.
- 4. Data on file.

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