




















# HEMOSTATIC AGENT BLEEDING INDICATIONS

HEMOBLAST™ Bellows is the only product indicated as an adjunct to hemostasis for minimal, mild, and moderate bleeding based on the SPOT GRADE™ (Surface Bleeding Severity Scale).<sup>1-14</sup>

	No Descriptor of Bleeding Severity <sup>3,9-14</sup>	Capillary, Venous, and Arteriolar Bleeding <sup>1,2,4-8</sup>	Oozing Blood and Minor Bleeding <sup>7,8</sup>	Surface Bleeding Severity Scale (SBSS)		
				Minimal (Oozing) <sup>1</sup>	Mild (Pooling) <sup>1</sup>	Moderate (Flowing) <sup>1</sup>
<b>Combination Powdered Hemostats</b>						
						
<b>Mechanical Hemostats<sup>†</sup></b>						
ARISTA™ AH						
AVITENE™						
GELFOAM® POWDER						
SURGICEL® POWDER						
SURGIFOAM® POWDER						
<b>Topical Thrombin<sup>†</sup></b>						
RECOTHROM®						
THROMBIN-JMI®						
<b>Flowables<sup>†</sup></b>						
FLOSEAL®						
SURGIFLO®						
<b>Fibrin Sealants<sup>†</sup></b>						
TISSEEL®						
EVICEL®						
<b>Fibrin Sealant Patches<sup>†</sup></b>						
EVARREST®						
TACHOSIL®						

\* Products are indicated for adjunctive hemostasis of capillary, venous, small artery, and/or arteriolar bleeding.

† Products are indicated for adjunctive hemostasis when control of bleeding by conventional methods is ineffective or impractical.

1. HEMOBLAST™ Bellows Hemostatic Agent [Instructions for Use]. Biom'up France SAS. 2. ARISTA™ AH Absorbable Hemostatic Particles Instructions for Use. CR Bard, Inc. 3. Avitene™ Microfibrillar Collagen Hemostat [Instructions for Use]. CR Bard, Inc. 4. Gelfoam® Absorbable Gelatin Powder [Instructions for Use] Pharmacia and Upjohn Co. 5. SURGICEL® Powder Absorbable Hemostat. Ethicon, [www.ethicon.com/na/products/adjunctive-hemostasis/absorbable-hemostats/surgicel-powder-absorbable-hemostat](http://www.ethicon.com/na/products/adjunctive-hemostasis/absorbable-hemostats/surgicel-powder-absorbable-hemostat). Accessed August 22, 2018. 6. SURGIFOAM® Absorbable Gelatin Powder Package Insert. Somerville NJ; Ethicon Inc. 7. RECOTHROM® [Package Insert]. Hazelwood, MO: Mallinckrodt Hospital Products Inc; 2016. 8. THROMBIN-JMI® [Prescribing Information]. New York, NY; Pfizer Inc; 2018. 9. FLOSEAL® Hemostatic Matrix [Instructions for Use]. Deerfield, IL: Baxter Healthcare. 10. SURGIFLO® Hemostatic Matrix Kit [Instructions for Use]. Somerville, NJ; Ethicon Inc. 11. TISSEEL® Fibrin Sealant [Prescribing Information]. Deerfield, IL: Baxter Healthcare. 12. EVICEL® Fibrin Sealant [Prescribing Information]. Somerville NJ; Ethicon Inc. 13. EVARREST® Fibrin Sealant Patch [Prescribing Information]. Somerville, NJ; Ethicon Inc. 14. TachoSil® Fibrin Sealant Patch [Prescribing Information]. Takeda AS.



# HEMOSTATIC AGENT INDICATIONS

## Indications

### Combined Powdered Hemostats



HEMOBLAST™ Bellows is indicated in surgical procedures as an adjunct to hemostasis when control of minimal, mild, and moderate bleeding by conventional procedures is ineffective or impractical, except in neurosurgical, ophthalmic, and urological procedures.

### Mechanical Hemostats

ARISTA™ AH	ARISTA™ AH is indicated in surgical procedures (except neurological and ophthalmic) as an adjunctive hemostatic device to assist when control of capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is ineffective or impractical.
AVITENE™	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.
GELFOAM® POWDER	GELFOAM® Sterile Powder, saturated with sterile sodium chloride solution, is indicated in surgical procedures, including those involving cancellous bone bleeding, as a hemostatic device, when control of capillary venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is either ineffective or impractical. Although not necessary, GELFOAM® can be used either with or without thrombin to obtain hemostasis.
SURGICEL® POWDER	SURGICEL® Powder (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective.
SURGIFOAM® POWDER	SURGIFOAM® Powder saturated with sterile sodium chloride solution, is indicated for surgical procedures (except ophthalmic) for hemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical. Although not necessary, SURGIFOAM® Powder can be used with thrombin to achieve hemostasis.

### Topical Thrombin

RECOTHROM®	RECOTHROM®, Thrombin topical (Recombinant), is a topical thrombin indicated to aid hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical in adults and pediatric populations greater than or equal to one month of age.
THROMBIN-JMI®	THROMBIN-JMI® is indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible.

### Flowables

FLOSEAL®	FLOSEAL® Matrix is indicated in surgical procedures (other than in ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical.
SURGIFLO®	SURGIFLO® Hemostatic Matrix, mixed with sterile saline or thrombin solution, is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.

### Fibrin Sealants

TISSEEL®	Hemostasis: TISSEEL® is a fibrin sealant indicated for use as an adjunct to hemostasis in adult and pediatric patients (>1 month of age) undergoing surgery when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. TISSEEL® is effective in heparinized patients. Sealing: TISSEEL® is a fibrin sealant indicated as an adjunct to standard surgical techniques (such as suture and ligature) to prevent leakage from colonic anastomoses following the reversal of temporary colostomies.
EVICEL®	EVICEL® is a fibrin sealant (human) indicated as an adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

### Fibrin Sealant Patches

EVARREST®	EVARREST® is a fibrin sealant patch indicated for use with manual compression as an adjunct to hemostasis in adult patients undergoing surgery, when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. Limitations for Use: Cannot be used in place of sutures or other forms of mechanical ligation in the treatment of major arterial or venous bleeding. Not for use in children under one month of age. Not for use in laparoscopic and other minimally invasive surgeries where manual compression would be difficult to achieve.
TACHOSIL®	TACHOSIL®: Indicated for use with manual compression in adult and pediatric patients as an adjunct to hemostasis in cardiovascular and hepatic surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical. Not for use in place of sutures or other forms of mechanical ligation in treatment of major arterial or venous bleeding. Not for use in children under one month of age.

**Indication:** HEMOBLAST™ Bellows is indicated in surgical procedures as an adjunct to hemostasis when control of minimal, mild, and moderate bleeding by conventional procedures is ineffective or impractical, except in neurosurgical, ophthalmic, and urological procedures.

**Important Risk Information for HEMOBLAST™ Bellows:** Do not inject HEMOBLAST™ Bellows into a vessel or tissue. There is a risk of allergic-anaphylactoid reaction and/or thromboembolic events, which may be life-threatening. Do not apply HEMOBLAST™ Bellows in the absence of active blood flow, e.g., while the vessel is clamped or bypassed. Extensive intravascular clotting and even death may result. Do not administer to patients with known allergies or hypersensitivity to materials of porcine or bovine origin. Because HEMOBLAST™ Bellows is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent. HEMOBLAST™ Bellows contains chondroitin sulfate from bovine origin which is associated with a remote risk for Transmissible Spongiform Encephalopathies (TSE), which has been minimized in accordance with regulatory guidelines by a manufacturing process with demonstrated TSE inactivation capacity. When applied to a bleeding site, HEMOBLAST™ Bellows swells up to 60% within about 5 minutes. Do not attempt to trim the applicator tip. HEMOBLAST™ Bellows should not be used at the site of a valve replacement or repair as valvular dysfunction could occur. HEMOBLAST™ Bellows should not be applied at the site of a synthetic graft or patch implant due to potential for decreased effectiveness. The product should not be in contact with circulating cerebrospinal fluid (CSF). The material has not been tested on children and pregnant or lactating women. Rx Only.

**Important Safety Information for the Laparoscopic Applicator:** Do not use the applicator to manipulate or retract organs or tissue. The product must be manipulated and used by qualified personnel according to the general principles of sterility and pre-medication. The tip of the laparoscopic applicator must be directly visualized at all times to minimize potential for unintended contact with tissue, organs, or blood as well as any possible unintended spillage of residual powder.

This material is intended for Health Care Professionals in the U.S. Please refer to the Instructions for Use accompanying each device for further information.

Caution: Federal law restricts this device to sale on or by the order of a physician.

The trademark of HEMOBLAST™ Bellows and SPOT GRADE™ are the property of Biom'up France SAS. The trademarks of the products listed herein are trademarks of their respective manufacturer.

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