HEMOBLAST™ Bellows

HIGH-PERFORMANCE
HEMOSTASIS MADE SIMPLE.

THAT'S REAL STOPPING POWDER.

A NEW SOLUTION FOR TODAY'S BLEEDING CHALLENGES

Dilon Technologies®

This material is intended for Health Care Professionals in the US.

THE POWDER TO BE VERSATILE

NOW HIGH-PERFORMANCE HEMOSTASIS IS SIMPLER THAN EVER:

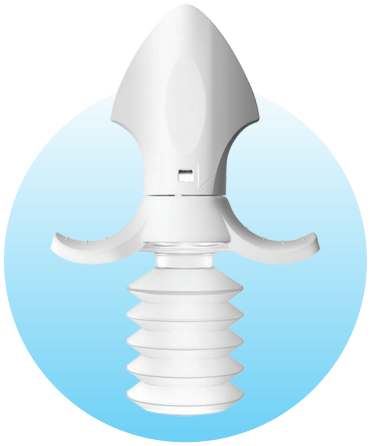
PROVEN
The only hemostatic agent clinically proven effective on the validated SPOT GRADE™ scale for minimal, mild, and moderate bleeding.[1-13]

READY TO USE
No reconstitution, mixing, or thawing.[1]

CONTAINS HUMAN-DERIVED THROMBIN[1]
In the physiologic coagulation cascade, thrombin converts fibrinogen into fibrin.[14]

VERSATILE
- Effective for focal (pooling/flowing) bleeding*[1]
- Allows broad coverage to treat large area bleeding without the need for a power source or spray kit[1]
- Effective on bony and soft tissue[1]

*as evaluated on the SPOT GRADE™ scale

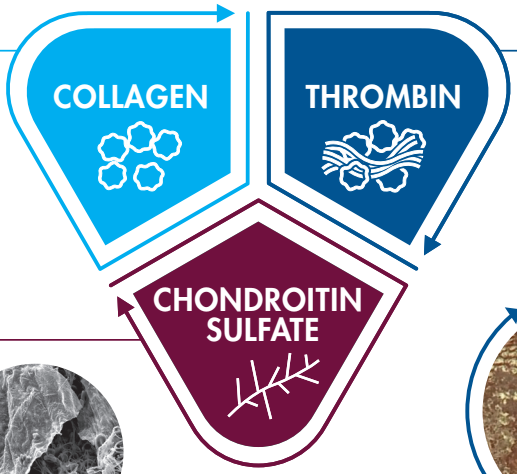


THE FORMULA FOR SUCCESS:

3 SYNERGISTIC COMPONENTS + 1 SIMPLE BELLOWS APPLICATOR = HIGH-PERFORMANCE HEMOSTASIS

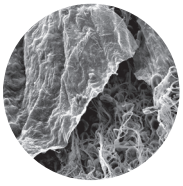
FOR A COHESIVE AND STABLE CLOT

MECHANICAL HEMOSTASIS
The (porcine-derived) collagen in HEMOBLAST™ Bellows supports a controlled swell.[1] Additionally, in the coagulation cascade, collagen is known to induce platelet aggregation and coagulation.[14]

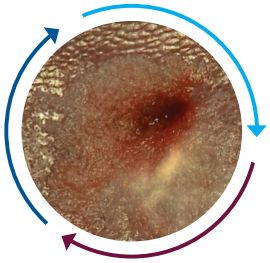


PHYSIOLOGIC HEMOSTASIS
HEMOBLAST™ Bellows contains (human-derived) thrombin.[1] Thrombin converts fibrinogen to fibrin, a basic element in a blood clot.[14]

COHESION
HEMOBLAST™ Bellows is the only hemostat that contains (bovine-derived) chondroitin sulfate,[1] included for the purpose of providing cohesion between the wound and surrounding tissue.



SEM photo showing chondroitin sulfate



HEMOBLAST™ Bellows clot in a porcine liver model

The clot formed by HEMOBLAST™ Bellows offers visibility of the wound site after application. The hemostatic powder resorbs within 4 weeks.

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. Refer to the back for additional Important Risk Information.

THE ONLY PRODUCT INDICATED AS AN ADJUNCT TO HEMOSTASIS FOR MINIMAL, MILD, AND MODERATE BLEEDING ON THE SPOT GRADE™ SCALE[1-13]

Biom'up developed the SPOT GRADE™ scale or the Surface Bleeding Severity Scale (SBSS) to quantitatively determine the amount of bleeding from a surgical wound and standardize bleeding definitions across surgical specialties and procedures. HEMOBLAST™ Bellows performed impressively in our FDA-approved pivotal trial, in controlling SPOT GRADE™ bleeding levels 1 through 3, covering oozing to flowing bleeding.[1]

HEMOBLAST™ BELLOWS
Effective hemostasis on SPOT GRADE™ levels 1 through 3:
minimal, mild, and moderate bleeding
for approved indications.[1]

SPOT GRADE™ SCALE

SPOT GRADE™	0	1	2	3	4	5
Maximum Expected ACS-ATLS* Shock Risk Class	1	1	1	2	3	4
Verbal Descriptor	None	Minimal	Mild	Moderate	Severe; not immediately life-threatening	Extreme; immediately life-threatening
Visual Descriptor	Dry	Oozing	Pooling	Flowing	Streaming	Gushing
Expected Intervention(s)	None	Manual pressure, cautery, adjuvant hemostat(s)	Manual pressure, cautery, suture, adjuvant hemostat(s)	Manual pressure, cautery, suture, adjuvant hemostat(s)	Manual pressure, cautery, suture, staples, tissue repair	Manual pressure, cautery, suture, staples, tissue repair
Flow Rate (mL/min) Ranges for Target Bleeding Site[16]						
1 (cm^2)	0	[0;4.8]	[4.8; 12.0]	[12.0; 25.3]	[25.3; 102.0]	[102.0; +∞]
10 (cm^2)	0	[0;9.1]	[9.1; 20.0]	[20.0;71.3]	[71.3; 147.4]	[147.4; +∞]
50 (cm^2)	0	[0;13.5]	[13.5; 28.0]	[28.0;117.3]	[117.3; 192.7]	[192.7; +∞]

EFFICACY THAT'S PROVEN[1]

The US pivotal study evaluating the safety and efficacy of HEMOBLAST™ Bellows against absorbable gelatin sponge and thrombin involved 242 patients randomized across 16 sites and found HEMOBLAST™ Bellows statistically superior at achieving hemostasis:

- 71.1% vs. 45.8% at 3 minutes (p=0.0001)[1]
- 93.1% vs. 73.5% at 6 minutes (p=0.0001)[1]
- No clinical signs or symptoms of postoperative bleeding with HEMOBLAST™ Bellows within 24 hours[1]
- Lower rate of surgical rescue treatment (2.9% vs. 13.3%) (p=0.0129)[1]

POSTOPERATIVE BLEEDING DATA

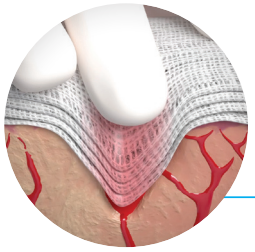
0% ***SIGNS OR SYMPTOMS OF POSTOPERATIVE BLEEDING[1]***

0% ***REOPERATIONS DUE TO BLEEDING[1]***

*American College of Surgeons – Advanced Trauma Life Support.

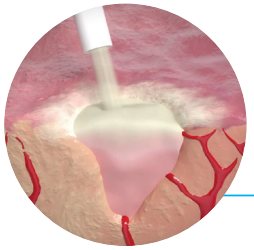
THE POWDER TO PERFORM

APPLICATION THAT'S EASY[1]



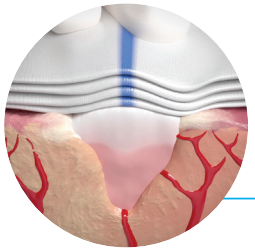
1 Blot Excess Blood

Blot excess blood from the target bleeding site with a laparotomy pad/gauze or suction. The wound surface should be as dry as possible just before application.



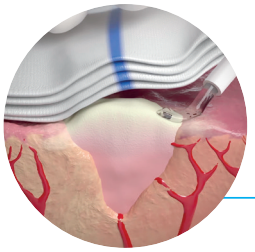
2 Apply HEMOBLAST™ Bellows

Apply HEMOBLAST™ Bellows to the source of bleeding by compressing the bellows. Enough implant material should be applied to cover the entire source of bleeding.



3 Hold Soaked Laparotomy Pad/Gauze

Immediately apply wound-appropriate pressure using a soaked laparotomy pad/gauze. Hold for approximately 3 minutes. Gently lift the laparotomy pad/gauze and inspect the area.



4 Once Hemostasis is Achieved, Irrigate Excess

Once hemostasis is achieved, excess powder not incorporated in the hemostatic clot should be removed by gentle irrigation.

Please refer to the Instructions for Use for full prescribing information.[1]

THE ONLY POWDER WITH THROMBIN[1,2,4-6]

HEMOBLAST™ Bellows contains thrombin for efficacy on minimal, mild, and moderate bleeding on the SPOT GRADE™ scale.[1]

Handles Oozing, Pooling, and Flowing Bleeding[1]*

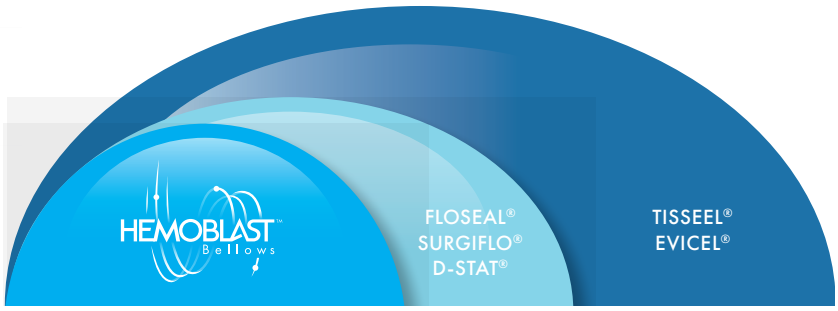
MINIMAL, CAPILLARY, VENOUS, AND SMALL ARTERIAL/ ARTERIOLAR BLEEDING

MILD AND MODERATE (POOLING AND FLOWING BLEEDING)

READY WHEN YOU NEED IT[1]

Because it does not require advance preparation, HEMOBLAST™ Bellows optimizes hospital staff time and provides a possible solution to avoid waste from unused product.[1]

Stay Ready for Unexpected Bleeding



READY TO USE

REQUIRES RECONSTITUTION

REQUIRES THAWING OR RECONSTITUTION AND ASSEMBLY

LESS COST & HASSLE[1,7,8]

Unlike fibrin sealants, HEMOBLAST™ Bellows is proven effective on moderate bleeding, including pooling and flowing bleeding,* while possibly eliminating the extra cost, hassle, and risk of air gas embolism of a spray set and external gas set-up.[1,7,8]

Covers Pooling and Flowing Bleeding[1]*

No Spray Sets or Known Risk of Air Gas Embolism

*as evaluated on the SPOT GRADE™ scale

THE POWDER TO SIMPLIFY

APPLICATION VERSATILITY[1]

Compared to flowable hemostats, only HEMOBLAST™ Bellows easily allows coverage of focal and large area bleeding and does not require reconstitution.[1]

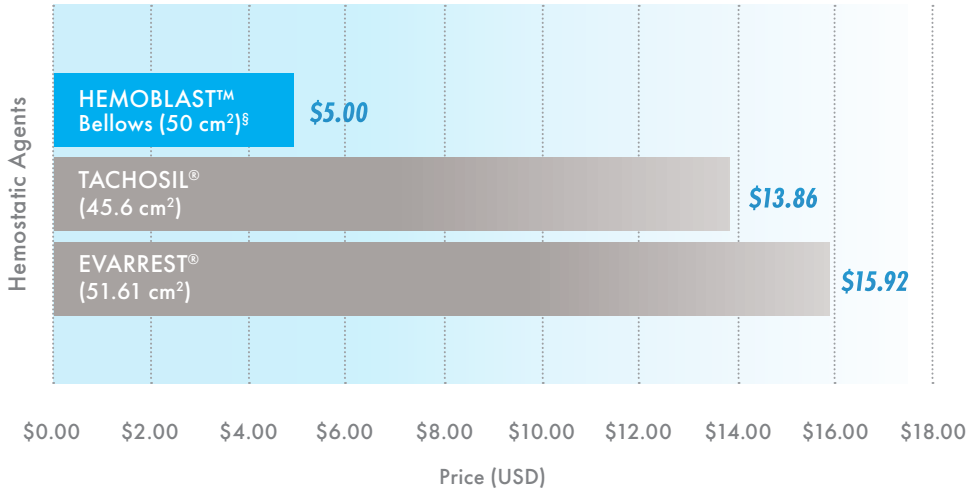
Handles Focal and Large Area Bleeding[1]

Applied Dry, No Reconstitution Required[1]

MORE COVERAGE, MORE SAVINGS[1,12,13,17-19]

With up to 50 cm^2 coverage per unit, HEMOBLAST™ Bellows provides more coverage for less cost than fibrin sealant patches.[1,12,13,17-19]

COST PER AREA COVERED (CM^2) PER UNIT[1,12,13,17-19]

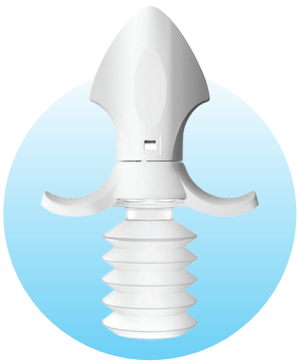


Covers More Bleeding Area for Less[1,12,13,17-19]

†Other Powder Hemostats, including ARISTA™ AH, GELFOAM® POWDER, SURGICEL® POWDER, SURGIFOAM® POWDER were not evaluated using the SPOT GRADE™ scale. Their efficacy under this grading is unknown.

§For larger areas, more than 1 HEMOBLAST™ Bellows may be needed.

With excellent versatility and coverage, HEMOBLAST™ Bellows is designed to simply and effectively meet your bleeding challenges.[1]



HIGH-PERFORMANCE HEMOSTASIS MADE SIMPLE.

HEMOBLAST™ Bellows is supplied as a preloaded bellows that:

- Contains 1.65 g of powder, including a maximum of 1,500 units of thrombin
- Includes a 10 cm nozzle extension to assist with application where a slightly longer tip is desired to reach the target bleeding site in open procedures
- Is biocompatible and non-pyrogenic

APPLICATION VERSATILITY[1]

The HEMOBLAST™ Bellows Laparoscopic Applicator is:

- Intended for delivering HEMOBLAST™ Bellows hemostatic powder to bleeding surgical sites
- Compatible with a 5 mm diameter or larger trocar
- Sold separately from HEMOBLAST™ Bellows*

*Please see the HEMOBLAST™ Bellows and HEMOBLAST™ Bellows Laparoscopic Applicator Instructions for Use for complete information on the hemostatic agent.

PART NUMBER	DESCRIPTION	MINIMUM ORDER QTY
BQF02-US	1 EA. HEMOBLAST™ BELLOWS AND 1 EA. 10 CM NOZZLE EXTENSION	1 CASE/12 EA.
LAP01-US	1 EA. INDIVIDUALLY PACKAGED LAPAROSCOPIC APPLICATOR	1 CASE/12 EA.

REQUEST A CLINICAL EVALUATION OR DEMONSTRATION AT:

1-877-GO-DILON (1-877-403-4566)

Hemoblast.com/us/evaluation

ORDER HEMOBLAST™ BELLOWS AT:

1-877-GO-DILON (1-877-403-4566)

orders@dilon.com

Dilon Technologies®

1. HEMOBLAST™ Bellows Hemostatic Agent [instructions for use]. Dilon Technologies, Inc. **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 sales brochure. 074300-170608. Somerville NJ; Ethicon Inc. **6.** Surgifoam Absorbable Gelatin Powder package insert. Somerville NJ; Ethicon Inc. **7.** TISSEEL Fibrin Sealant [prescribing information]. Deerfield, IL: Baxter Healthcare. **8.** Evicel Fibrin Sealant [prescribing information]. Somerville NJ; Ethicon Inc. **9.** FLOSEAL Hemostatic Matrix [instructions for use]. Deerfield, IL: Baxter Healthcare. **10.** SURGIFLO Hemostatic Matrix Kit [instructions for use]. Somerville, NJ; Ethicon Inc. **11.** D-Stat Flowable Hemostat Instructions for Use. Vascular Solutions, Inc. **12.** TachoSil Fibrin Sealant Patch [prescribing information]. Takeda AS. **13.** Evarrest Fibrin Sealant Patch [prescribing information]. Somerville, NJ; Ethicon Inc. **14.** Spotnitz, W. Hemostats, Sealants, and Adhesives: A Practical Guide for the Surgeon. Am Surg. 2012;78:1305-1321. **15.** Dilon Technologies, Inc., internal data. Data derived from clinical use of 186 cases in Germany and France (PME report). **16.** Spotnitz, WD; Zielske, D; Centis, V; et al. The SPOT GRADE: A New Method for Reproducibly Quantifying Surgical Wound Bleeding. Spine. 2018;43(11):E664-E671. **17.** 2016 IMS Hemostat Revenue, Unit, and ASP Sales Data. **18.** Dilon Technologies, Inc., company data. ET-2015-001-PC-019. **19.** Dilon Technologies, Inc., company data.

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

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. For safe and proper use of this device, refer to the full Instructions for Use.

Important Risk Information for HEMOBLAST™ Bellows 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. Rx Only: For safe and proper use of this device, please refer to full device Instructions for Use.

E-MKT-098-V1