BioSurgery

Proven Science.
Excellent Outcomes.

BARD
DAVOL INC.

ARISTA™ AH
Absorbable Hemostatic Particles

PROGEL™
Pleural Air Leak Sealant

AVITENE™
Microfibrillar Collagen Hemostat

Complement surgical technique with the BARD BioSurgery family of products.

BIOSURGERY
Proven Science. Excellent Outcomes.

BioSurgery Family of Products

Discover a unique family of sealing and hemostatic solutions designed to meet your surgical needs.

BARD is the market leader in comprehensive soft tissue reconstruction. In addition to this extensive suite of products, our BioSurgery franchise is delivering a growing line of sealants and hemostatic products to complement surgical techniques across thoracic, cardiovascular, and other surgical specialties. This franchise is committed to serving our surgeons and clinicians by leveraging unique and proprietary materials-science and continuing Bard's focus on improving clinical outcomes for optimal patient care.

PROVEN SCIENCE. EXCELLENT OUTCOMES.

PROGEL™

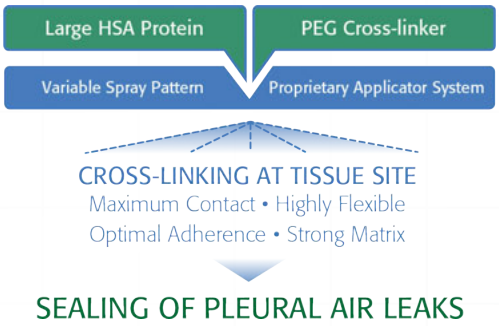
Pleural Air Leak Sealant

Adherence. Strength. Flexibility.

The only product FDA-approved as an adjunct for treatment of pleural air leaks during open thoracotomy, PROGEL™ Pleural Air Leak Sealant (PALS) forms a highly-flexible hydrogel specifically designed for use on the lung.

Designed for Thoracic Surgery[1]

The PROGEL™ Sealing Cascade



[1] Progel™ Pleural Air Leak Sealant is a single use device intended for application to visceral pleura during an open thoracotomy after standard visceral pleural closure with, for example, sutures or staples, of visible air leaks (≥ 2 mm) incurred during open resection of lung parenchyma.

ARISTA™ AH

Absorbable Hemostatic Particles

Simple. Safe. Effective.

When experiencing capillary, venous or arteriolar bleeding, surgeons turn to ARISTA™ AH as an adjunct to their primary methods of closure. This plant-based, absorbable hemostatic powder enhances the clotting process to quickly and effectively achieve hemostasis in minutes[1].

Used in a variety of surgical areas and procedure types. Examples include:

- Cardiothoracic & Cardiovascular
- Vascular
- Gynecological
- Urology
- General Surgery
- Plastic Surgery
- Orthopedic Surgery

Proprietary MPH™ Technology:

A unique approach to achieving hemostasis

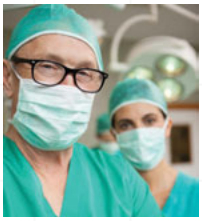
[1] Arista™ AH PMA P050038 Clinical Study

AVITENE™

Microfibrillar Collagen Hemostat

The Proven Active Hemostat

AVITENE™ Microfibrillar Collagen Hemostat is an active collagen hemostat, proven to help accelerate clot formation. AVITENE™ effectively enhances platelet aggregation and the release of proteins to form fibrin, resulting in hemostasis.



The Proven Solution: For Controlling Bleeding in All Surgical Applications

THE POWER OF AVITENE™ HEMOSTATS

- Active absorbable topical hemostatic agent
- 100% collagen: help accelerate patient's own clotting mechanism
- Trusted by surgeons for over 40 years
- A collagen hemostat acceptable for all procedures where a topical hemostat is indicated, including urologic and neurosurgery
- Complete line of sizes and forms

Product Ordering

PROGEL™ Pleural Air Leak Sealant

Catalog Number	Quantity	Description	
PGPS002	4/cs.	PROGEL™ Pleural Air Leak Sealant (4 ml)	☐
PGST009	10/cs.	PROGEL™ Applicator Spray Tips (Pack of 2)	☐
PGEN005-11	4/cs.	PROGEL™ Extended Spray Tip 29 cm (11")	☐
PGEN005-06	4/cs.	PROGEL™ Extended Spray Tip 16 cm (6")	☐

ARISTA™ AH Absorbable Hemostatic Particles

Catalog Number	Quantity	Description	
SM0005-USA	5x1 g	ARISTA™ AH 1 g Box (absorbable hemostatic particles)	☐
SM0002-USA	5x3 g	ARISTA™ AH 3 g Box (absorbable hemostatic particles)	☐
SM0007-USA	5x5 g	ARISTA™ AH 5 g Box (absorbable hemostatic particles)	☐
AM0004	Box of 10	ARISTA™ AH FlexTip™ Applicator 14 cm (absorbable hemostatic particles)	☐
AM0005	Box of 10	ARISTA™ AH FlexTip™ Applicator 38 cm	☐

AVITENE™ Microfibrillar Collagen Hemostat

AVITENE™ Flour

Catalog Number	Quantity	Description	
1010010	6/cs.	0.5 gram	☐
1010020	6/cs.	1 gram	☐
1010590	2/cs.	5 gram	☐

AVITENE™ Sheets (Non-woven web)

Catalog Number	Quantity	Description	
1010080	6/cs.	3.5 cm x 3.5 cm (1.4" x 1.4")	☐
1010090	6/cs.	7.0 cm x 3.5 cm (2.8" x 1.4")	☐
1010110	6/cs.	7.0 cm x 7.0 cm (2.8" x 2.8")	☐

AVITENE™ ULTRAFOAM™ Collagen Sponge

Catalog Number	Quantity	Description	
1050020	12/cs.	2.0 cm x 6.25 cm x 7 mm (12.5 sq cm ¾" x 2½" x ¼")	☐
1050030	6/cs.	8.0 cm x 6.25 cm x 1 cm (50 sq cm 3⅛" x 2½" x ⅜")	☐
1050040	6/cs.	8.0 cm x 12.5 cm x 1 cm (100 sq cm 3⅛" x 5" x ⅜")	☐
1050050	6/cs.	8.0 cm x 12.5 cm x 3 mm (100 sq cm/Thin 3⅛" x 5" x ⅛")	☐

SYRINGEAVITENE™ Collagen Hemostat

Catalog Number	Quantity	Description	
1010340	6/cs.	1 gram SYRINGEAVITENE™ Collagen 1 gram preloaded flour 2 cm (0.8") diameter, 16.5 cm (6.5") usable length	☐

ENDOAVITENE™ Collagen Hemostat

Catalog Number	Quantity	Description	
1010150	6/cs.	10 mm ENDOAVITENE™ Collagen 50 mm x 15 mm x 1 mm preloaded sheet 1 mm diameter, 42 cm usable length	☐
1010260	6/cs.	5 mm ENDOAVITENE™ Collagen 50 mm x 5 mm x 1 mm preloaded sheet 5 mm diameter, 42 cm usable length	☐

Order Form

☐ Please add these marked products to my preference card.

☐ I would like to have these marked products in stock.
(Reference sizes checked above)

☐ I would like to trial these marked products.

Purchase Order Number _____ Date _____

Catalog Number(s) _____ Quantity _____

Surgeon's Signature _____

BARD
DAVOL INC.

PROGEL™ Pleural Air Leak Sealant

Intended Use / Indications For Use

PROGEL™ Pleural Air Leak Sealant (PALS) is a single use device intended for application to visceral pleura during an open thoracotomy after standard visceral pleural closure with, for example, sutures or staples, of visible air leaks (≥ 2 mm) incurred during open resection of lung parenchyma.

Contraindications

- Do not use PROGEL™ PALS in patients who have a history of an allergic reaction to Human Serum Albumin or other device components.
- Do not use PROGEL™ PALS in patients who may have insufficient renal capacity for clearance of the PROGEL™ PALS polyethylene glycol load.
- Do not apply PROGEL™ PALS on open or closed defects of main stem or lobar bronchi due to a possible increase in the incidence of broncho-pleural fistulae, including patients undergoing pneumonectomy, any sleeve resection or bronchoplasty.
- Do not apply PROGEL™ PALS on oxidized regenerated cellulose, absorbable gelatin sponges or any other surface other than visceral pleura as adherence and intended outcome may be compromised.
- Do not use more than 30 ml of PROGEL™ PALS per patient.

Warnings

PROGEL™ PALS safety and effectiveness was evaluated in 5 patients with FEV1 ≤ 40%, providing limited data about PROGEL™ PALS use in patients with FEV1 ≤ 40%. For patients with preop FEV1 ≤ or > 40%, mean (median) chest tube placement duration for patients with FEV1 ≤ 40% was 8.3 (7.0) days for PROGEL™ PALS and 5.8 (4.5) days for Control subjects; for patients with FEV1 > 40%, the mean (median) chest tube placement duration was 6.8 (5.0) days for PROGEL™ PALS and 6.2 (5.5) days for the Control cohort.

Precautions

The safety and effectiveness of PROGEL™ PALS has not been established in patients with the following conditions:

- Less than 18 years of age, pregnant or nursing women.
- Contaminated or dirty pulmonary resection cases.
- The presence of an active infection.
- In the presence of other sealants, hemostatic devices or products other than sutures and staples used in standard visceral pleural closure.
- Visceral pleural air leak due to spontaneous pneumothorax, any non resective pulmonary tissue trauma, or malignancy as well as congenital or acquired functional or anatomic defect.
- Patients receiving PROGEL™ PALS in more than one application session (surgery) before and/or after resorption of PROGEL™ PALS that was applied in any previous surgical session.
- In any area or tissue other than the visceral pleural surface as indicated.

Adverse Events

There were 3 subjects in the PROGEL™ PALS group with AEs that were considered by the investigator to be possibly or probably related to the device. The AEs reported were: chest pain, constipation, gastroesophageal reflux, nausea, cough, dyspnea, pneumothorax, and subcutaneous emphysema. All were reported as a single occurrence in the PROGEL™ PALS group. Two of the AEs, dyspnea and chest pain, were reported as "severe" and "serious", respectively and occurred in the same subject. All others were reported as mild or moderate.

In a clinical trial there were reports of renal dysfunction, urinary system disorders and deaths within the study population. None of these have been confirmed to be associated with PROGEL™. The details of these clinical trial adverse events can be reviewed in the IFU supplied with the product and also available at www.davol.com.

Caution: Federal (USA) law restricts this device to sale by or on order of a licensed physician or properly licensed practitioner.

AVITENE™ Microfibrillar Collagen Hemostat

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.

Caution: Federal (USA) law restricts this device to sale by or on order of a licensed physician or properly licensed practitioner.

Arista™ AH Absorbable Hemostatic Particles

Indications
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.

Contraindications
Do not inject or place Arista™ AH into blood vessels as potential for embolization and death may exist.

Warnings
Arista™ AH is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.

Once hemostasis is achieved, excess Arista™ AH should be removed from the site of application by irrigation and aspiration particularly when used in and around foramina of bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm. Arista™ AH swells to its maximum volume immediately upon contact with blood or other fluids. Dry, white Arista™ AH should be removed. The possibility of the product interfering with normal function and/or causing compression necrosis of surrounding tissues due to swelling is reduced by removal of excess dry material.

Safety and effectiveness of Arista™ AH have not been clinically evaluated in children and pregnant women. Because there have been reports of decreased amylase activity in newborns up to 10 months, absorption rates of Arista™ AH in this population may be longer than 48 hours.

Arista™ AH should be used with caution in the presence of infection or in contaminated areas of the body. If signs of infection or abscess develop where Arista™ AH has been applied, re-operation may be necessary in order to allow drainage.

Safety and effectiveness in neurosurgical and ophthalmic procedures has not been established.

Arista™ AH should not be used for controlling post-partum bleeding or menorrhagia.

Precautions
When Arista™ AH is used in conjunction with autologous blood salvage circuits, carefully follow instructions in the Administration section of the IFU regarding proper filtration and cell washing.

Arista™ AH is intended to be used in a dry state. Contact with saline or antibiotic solutions prior to achieving hemostasis will result in loss of hemostatic potential.

Arista™ AH is not recommended for the primary treatment of coagulation disorders.

No testing has been performed on the use of Arista™ AH on bone surfaces to which prosthetic materials are to be attached with adhesives and is therefore not recommended.

Arista™ AH is supplied as a sterile product and cannot be resterilized. Unused, open containers of Arista™ AH should be discarded.

Do not apply more than 50g of Arista™ AH in diabetic patients as it has been calculated that amounts in excess of 50g could affect the glucose load.

In urological procedures, Arista™ AH should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

Adverse Reactions
None of the adverse events that occurred in a randomized prospective, concurrently controlled clinical trial were judged by the Data Safety Monitoring Board to be related to the use of Arista™ AH. The most common recorded adverse events were pain related to surgery, anemia, nausea, lab values out of normal range, arrhythmia, constipation, respiratory dysfunction and hypotension - all reported in greater than 10% of the Arista™ AH treated patients. The details of this clinical trial's adverse events can be reviewed in the IFU supplied with the product and are also available at www.davol.com.

Caution: Federal (USA) law restricts this device to sale by or on order of a licensed physician or properly licensed practitioner.

To order, call your local representative or our customer service department at 1.800.556.6275 or visit us on the web at www.davol.com

Contact a BARD representative to schedule an appointment or visit Davol.com for more information.

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.

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