Arista™ AH Absorbable Hemostatic Particles

Discover the powder hemostat surgeons rely on

BD

Arista™ AH Absorbable Hemostatic Particles

Adjunctive hemostatic device for capillarly, venous or arteriolar bleeding[1]

Simple

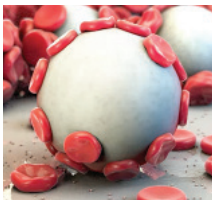
- Ready on demand
- Simply pop the cap and apply powder directly to the bleeding site[1]
- No mixing and no refrigeration
- Five-year shelf life[2]

Safe

- Synthesized from a purified plant starch
- Thrombin-free, biocompatible and nonpyrogenic[2]
- Typically absorbed and cleared within 24–48 hours[3] by amylases[4]
- Cell-saver compatible hemostat[3]

Effective

- Clotting process begins on contact, regardless of patient's coagulation status[3]
- Complete hemostasis can be achieved in minutes[5]
- Provides broad area coverage



Proprietary MPH™ Technology– a unique approach to achieving hemostasis

The power of Arista™ AH lies in its proprietary MPH™ (microporous polysaccharide hemospheres) technology. Consisting of microporous particles with a controlled pore size, the spheres are designed to act as a molecular sieve. The powerful osmotic action dehydrates and gels the blood on contact to accelerate the natural clotting process.

FlexiTip™ Delivery System– add flexibility to your technique

With the FlexiTip™ spray applicator, applying Arista™ AH accurately and directly is fast and simple. The delivery system features a lightweight, plastic device with a long, flexible tube. The FlexiTip™ and FlexiTip™ XL extended reach applicator tips provide the precise and accurate delivery of Arista™ AH hemostatic powder from a simple, single-use device.

FlexiTip™ XL-R Applicator

The FlexiTip™ XL-R applicator makes the delivery of Arista™ AH in minimally invasive surgery easy.

- Provides the advantage of delivering Arista™ AH through a 5 mm or larger trocar
- 38 cm length to access hard-to-reach areas, with little to no residual Arista™ AH lost in the tip[2]
- Rigid applicator body can be manipulated to target the site of bleeding directly

Hemostasis within minutes[5] Reabsorption within hours[4]

Arista™ AH initiates the clotting process on contact with blood. The MPH™ particles concentrate blood solids such as platelets, red blood cells and blood proteins to form a gelled matrix. By providing a barrier to further blood loss, the normal clotting process is enhanced, regardless of the patient's coagulation status.[3] Arista™ AH is absorbed within 24–48 hours[4] after application.

Proven safety and efficacy in a variety of surgical areas and procedure types[5]

Examples include:

- Cardiothoracic and cardiovascular
- Vascular
- Gynecological
- Urology
- Orthopedic surgery
- General surgery
- Plastic surgery
- Ear, nose and throat (ENT) surgery

Use of Arista™ AH in neurological or ophthalmic surgical procedures is excluded from its approved indication.

Cell saver compatible hemostat

Arista™ AH is a cell saver compatible hemostat. When Arista™ AH is used in conjunction with autologous blood salvage circuits, a 40-µ cardiotomy reservoir, cell washing and 40-µ transfusion filter must be used.

Ordering Information		
Cat. no.	Description	Qty.
SM0005-USA	Arista™ AH 1 g box (absorbable hemostatic particles)	5/cs.
SM0002-USA	Arista™ AH 3 g box (absorbable hemostatic particles)	5/cs.
SM0007-USA	Arista™ AH 5 g box (absorbable hemostatic particles)	5/cs.
AM0004	Arista™ AH FlexiTip™ Applicator, 14 cm (includes [2] applicators)	5/cs.
AM0005	Arista™ AH FlexiTip™ XL Applicator, 38 cm (includes [1] applicator)	10/cs.
AM0010	Arista™ AH FlexiTip™ XL-R Applicator, rigid, 38 cm	10/cs.

Accelerate the clotting process with Arista™ AH

Following appropriate surgical techniques for the control of bleeding

Remove
Remove all excess blood

Apply
Apply Arista™ AH liberally to the bleeding site

Pressure
Administer wound-appropriate pressure until hemostasis is achieved

Irrigate
Irrigate and remove excess Arista™ AH from the site

Done
Hemostasis is achieved—quickly, safely and effectively

1. See Arista™ AH full Instructions for Use for detailed application instructions. **2.** Data on file. **3.** Arista™ AH Instructions for Use. **4.** Data generated in a preclinical model. Data may not correlate to performance in humans. 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. **5.** Arista™ AH PMA Clinical Study, P050038 Approval date September 26, 2006.

Arista™ AH FlexiTip™ Applicators: FlexiTip™, FlexiTip™ XL and FlexiTip™ XL-R
Indications. The Arista™ AH FlexiTip™ Applicators are intended for use in delivering Arista™ AH Absorbable Hemostatic Particles to the treatment site in surgical procedures. **Contraindications.** Do not inject Arista™ AH into the lumen of blood vessels as potential for embolization and death may exist. **Warnings.** The FlexiTip™ Applicators are supplied as a sterile (single use only) product and cannot be resterilized. The FlexiTip™ Applicators in conjunction with Arista™ AH are not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis. **Precautions.** Do not use the FlexiTip™ Applicators if the product packaging has been opened or damaged. To prevent product contamination prior to application, always follow aseptic techniques. The safety and efficacy of the combined use of a FlexiTip™ Applicator with other hemostatic agents has not been clinically evaluated and is therefore not recommended. If the FlexiTip™ XL-R is placed through a trocar during endoscopic/laparoscopic procedures, a 5 mm inner diameter or larger trocar is recommended. The FlexiTip™ XL-R is not designed to fit through a trocar smaller than 5 mm. Avoid an insufflation gas leak.

Arista™ AH
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 **bd.com.**

Caution: Federal (U.S.) law restricts this device to sale by or on order of a licensed physician or properly licensed practitioner.
Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.

Contact a BD sales representative to schedule an appointment or visit **bd.com** for more information.

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