

ARISTA™ AH

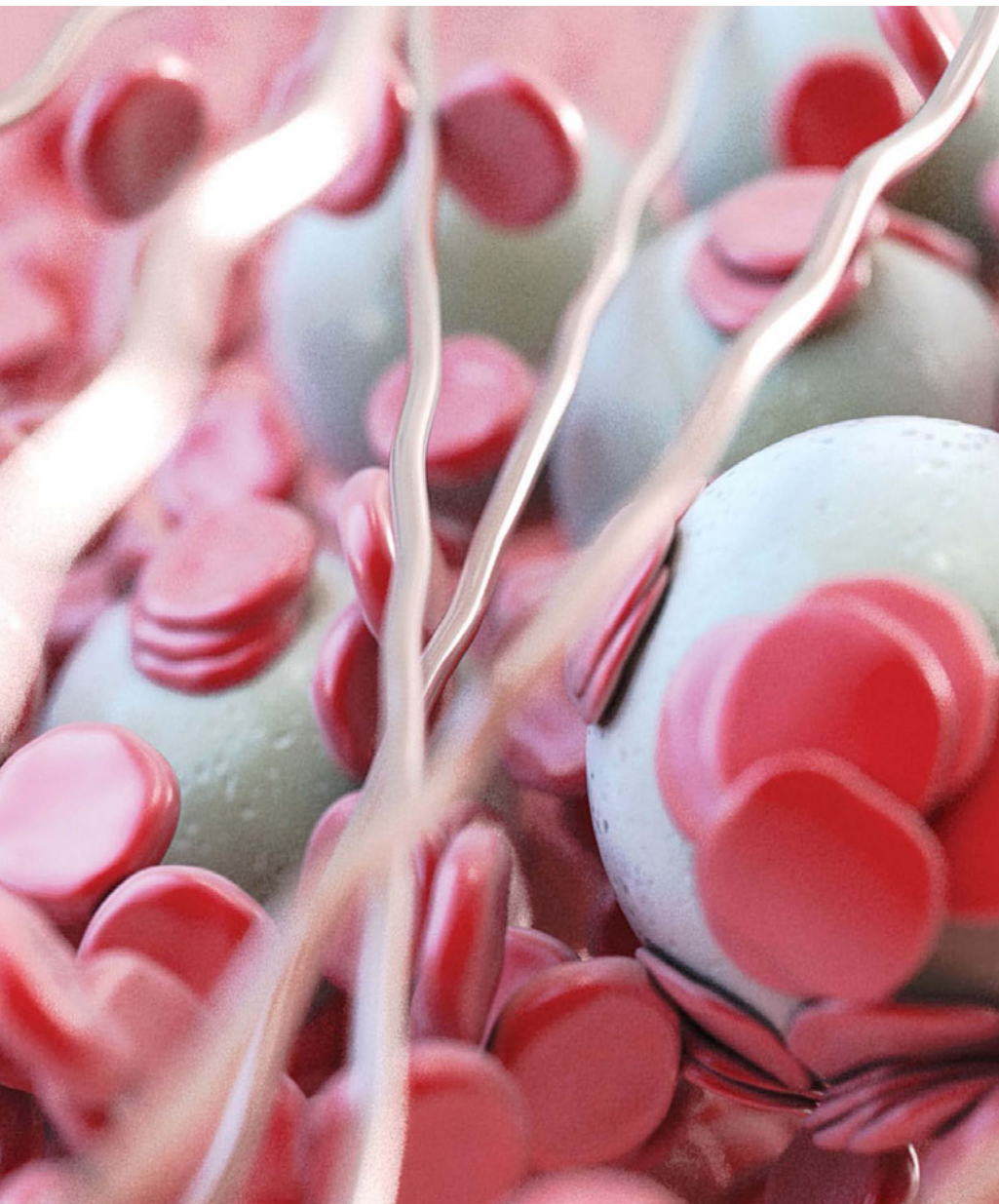
Absorbable Hemostatic Particles

Simple. Safe. Effective.

The latest generation in
hemostasis from BARD.

BARD

DAVOL INC.



BIOSURGERY

Proven Science. Excellent Outcomes.

Complement Your Surgical Technique with ARISTA™ AH: The Latest Generation Hemostat

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 accelerates the clotting process to quickly and effectively achieve hemostasis in minutes¹.

Simple

- No mixing and no refrigeration
- The product is ready on demand, with a 5 year shelf life
- Simply pop the cap and apply powder directly to the bleeding site²

Safe

- Synthesized from a purified plant starch
- Thrombin-free, biocompatible and non-pyrogenic
- Typically absorbed and cleared within 24-48 hours³ by amylases

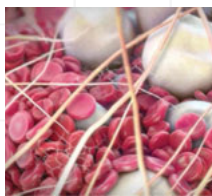
Effective

- Clotting process begins on contact, regardless of patient's coagulation status⁴
- Complete hemostasis is achieved in minutes¹
- Provides broad area coverage on rough surfaces and in hard-to-reach areas



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's hemostatic powder from a simple, single-use device.

Simple. Safe. Effective.

Hemostasis Within Minutes. Reabsorption Within Hours.

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 status¹. Unlike some products, ARISTA™ AH is easily absorbed within 24-48 hours³ after application.

Proven Safety and Efficacy in a Variety of Surgical Areas and Procedure Types

Examples Include:

- Cardiothoracic and Cardiovascular
- Vascular
- Gynecological
- Urology
- General Surgery
- Plastic Surgery

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

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



FDA-Approved Cell Saver Hemostat

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

¹ ARISTA™ AH PMA P050038 Clinical Study.

² See full Instructions for Use for detailed application instructions.

³ 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.

⁴ ARISTA™ AH Instructions for Use.

ARISTA™ AH Absorbable Hemostatic Particles

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Catalog Number	Size	Description
SM0005-USA	5/cs.	ARISTA™ AH 1 g Box (absorbable hemostatic particles)
SM0002-USA	5/cs.	ARISTA™ AH 3 g Box (absorbable hemostatic particles)
SM0007-USA	5/cs.	ARISTA™ AH 5 g Box (absorbable hemostatic particles)
AM0004	5/cs.	ARISTA™ AH FlexiTip™ Applicator 14 cm (includes 2 applicators)
AM0005	10/cs.	ARISTA™ AH FlexiTip™ XL Applicator 38 cm

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.

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

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Davol Inc. • Subsidiary of C. R. Bard, Inc.
100 Crossings Boulevard • Warwick, RI 02886
1.800.556.6275 • www.davol.com
Medical Services & Support 1.800.562.0027

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