Total laparoscopic hysterectomy surgery

Using Arista™ AH Absorbable Hemostatic Particles to control intraoperative bleeding

Case report

Introduction

Preparation, planning, and practicing for intraoperative bleeding is essential for all surgeons and operating room teams. Uncontrolled bleeding can often prolong, interrupt, or complicate surgical procedures, reduce visualization of the surgical field, and increase morbidity and mortality rates (from 0.5% to 20%).[1–7] Conventional methods for hemostasis may not be appropriate if bleeding is diffuse, the source of bleeding is difficult to identify, the patient is coagulopathic, or if the patient had prior antiplatelet or anticoagulant medications. Significant bleeding during surgery is typically controlled through vessel ligation, suturing, and electrocautery; however, absorbable hemostatic products are useful adjunctive agents.[8] The introduction of different devices and topical agents has made it possible to perform more complex interventions during laparoscopic surgery.[8]

The following report presents Dr. Yera's surgical technique for total laparopscopic hysterectomy surgery using Arista™ AH Absorbable Hemostatic Particles as a broad field hemostat to control intraoperative bleeding during laparoscopic surgery.

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BD

Patient history

A 63 year old otherwise healthy female presented with a history of symptomatic uterine fibroids manifested by vaginal bleeding and pelvic pain. She has a history of a previous cesarean section.

Surgeon technique

Using standard set up and positioning, the patient was prepped and draped in the dorsal lithotomy position. After adequate induction of general anesthesia, a Foley catheter was placed into the bladder. A bivalve speculum was placed into the vagina and the anterior lip of the cervix was grasped with a single tooth tenaculum.

The cervical canal was then dilated, and the uterine cavity was sounded. The appropriate size Tip and Koh Cup™ of the RUMI® II uterine manipulator was then placed, and the manipulator was attached to the ALLY® uterine positioning system.

Attention shifted to the upper abdomen where a 5 mm intra-umbilical incision was made, after infiltration of 8 cc of 0.5% Marcaine with Epinephrine. A 5 mm trocar was placed through the incision and the abdomen was insufflated with CO_2 gas to a pressure of 15 mmHg. Two lateral 5mm trocars were then placed under direct visualization with a 5 mm, 30 degree scope. The incision was also infiltrated with 8 cc of 0.5% Marcaine with Epinephrine.

The patient was placed in steep Trendelenburg position. Inspection of the pelvis revealed anterior bladder and lower uterine segment adhesions due to the patient's previous history of a cesarean section. Pelvic adhesions from endometriosis were also present. Both ureters were identified and traced from the pelvic brim to the bladder. The bladder was filled with normal saline in a retro-grade fashion using the suction irrigator attached to the Foley catheter to demarcate its attachment to the lower uterine segment.

All vessel sealing and cutting was performed with the 5 mm Covidien LigaSure™ Retractable L-Hook, unless otherwise stated. The anterior uterine adhesions were taken down carefully using cautery and sharp dissection. The left tube was then removed. Following this, the left utero-ovarian ligament was sealed and divided. The left round ligament was then sealed and divided, and the broad ligament was opened. A bladder flap was created, and the left uterine vessels were skeletonized and sealed. The same procedure was then carried forth on the contralateral side. The right ovary was noted to be diseased with endometriosis, so it was removed by sealing and dividing the right infundibula-pelvic ligament. Both uterine vessels were then divided and colpotomy was performed with the monopolar L-Hook after insufflation of the colpo-occluder balloon on the RUMI®.

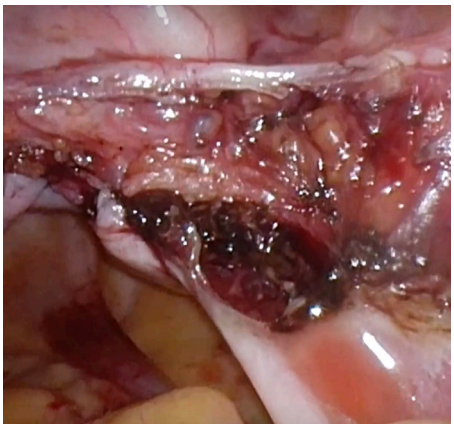
Intraoperative bleeding

The uterus and right ovary were then delivered through the vagina and the vaginal cuff was closed laparoscopically in two layers using a 2-0 V-Loc 180, 9 inch barbed suture. The tiny arteriole cuff bleeders were controlled using 3 g of Arista™ AH, applied using the Arista™ AH FlexiTip™ applicator.

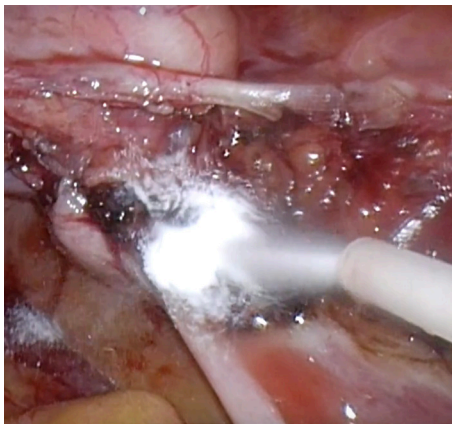
Cystoscopy was then performed with the 5 mm 30-degree laparoscope after retro-grade filling of the bladder with the suction irrigator. The patient was given Pyridium prior to the start of the case in order to facilitate visualization of the ureteral jets.

The abdomen was then desufflated. All cannulas were removed after five deep breaths were given in order to remove any trapped diaphragmatic CO_2 gas. The laparoscopic incisions were closed using simple interrupted sutures of 4-0 Monocryl. The patient was then awakened, successfully extubated, and taken to the recovery room. The patient was alert and in good condition. Estimated blood loss was 20 cc, there were no intraoperative complications and the patient made a full recovery.

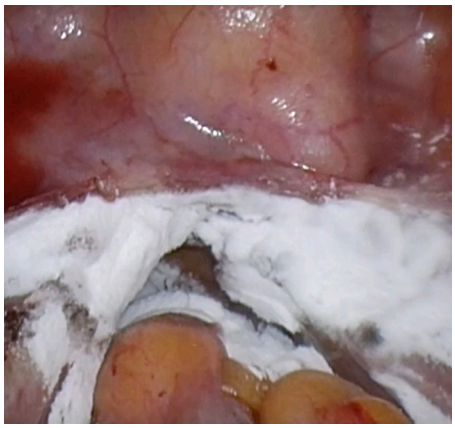
Photos provided by Dr. Yera



Before application of Arista™ AH



Application of Arista™ AH



Full Arista™ AH coverage

Potential bleeding scenarios during total laparoscopic hysterectomy

Bleed	Anatomy	Challenges based on Dr. Yera practice	Benefits of Arista™ AH
General tissue ooze from dissection	• Pelvic floor, on or around peritoneum	• Patients with endometriosis or who have adhesions from prior procedures • When energy use near vital organs is contraindicated • In areas that are difficult to suture	• Ready to use with no mixing[9] • Dehydrates and gels the blood on contact to accelerate the natural clotting[9] • Complete hemostasis can be achieved in minutes[13] • Provides broad area coverage[9] • Typically absorbed and cleared within 24–48 hours by amylases[9,10*] • Does not enhance infection of the wound site[9**]
Bleeding from adhesiolysis	• Intestinal and bladder adhesions • Large and small bowel adhesions to pelvic organs • Ovaries and tubes adhered to vital organs including uterus and pelvic side wall		
Vaginal Cuff, colpotomy	• Typically controlled with sutures or energy. Arista can be used as an adjunct for peritoneal oozing from the cuff.	• Energy can cause tissue necrosis • Healthy tissue oozes during colpotomy • Arista controls the oozing without tissue injury	
Broad oozing	• Pelvic organs	• May be caused by endometriosis or adhesions	
Pelvic floor	• Sacral promontory, posterior pelvic peritoneum, pouch of Douglas, paravaginal spaces	• Sacrocolpopexy dissection	

* 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 hemostat in this population may be longer than 48 hours.

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Arista™ AH works by dehydrating the blood[9]

It absorbs serum from the blood, creating a gel matrix that accelerates the clotting process.

Upon coming in contact with blood, the proprietary Microporous Polysaccharide Hemospheres™ (MPH™) of Arista™ AH rapidly absorb serum.

The porosity of the MPH™ excludes platelets, cellular components, and other clotting factors as well as large proteins.

These components become concentrated on the surface of the MPH™ particles and form a stable gel matrix.

The gel matrix supports the formation of a fibrin-rich clot.

By concentrating the patient's own clotting factors and platelets within the Arista™ AH gel matrix, clotting is accelerated.

Arista™ AH is then rapidly resorbed and cleared from the treatment site by endogenous alpha-amylase.

Covers a broad surface area quickly and effectively[14]

By broadly covering the surgical field with Arista™ AH, it is possible to identify localized areas of bleeding that may require additional suture placement.[14]

Controlled delivery with easy setup

Applicators can be attached to the ready-to-use bellows of Arista™ AH for a controlled delivery and extended reach.

The proprietary Arista™ AH powder achieves broad area coverage[14] on rough surfaces and in hard-to-reach areas,[14] for rapid control of bleeding.[9,13] Potential uses for Arista™ AH to control bleeding as an adjunctive hemostat may include:[9,13,15,16]

- Endometrial and cervical biopsy
- Hysterectomy (total abdominal or laparoscopically)
- Uterine fibroid/cyst removal
- Colporrhaphy
- Tubal ligation
- Ovarian lesion/cyst removal

Gynecologic surgeons and their patients may benefit from the unique features of Arista™AH

A prospective, multicenter, multi-surgical specialty, randomized, non-inferiority, controlled clinical study by Wisman et. al of 72 patients undergoing a surgical procedure in which a hemostatic agent may have been required suggests:

- Arista™ AH achieved hemostasis of the first treated lesion within five minutes in 94.4% (68/72) of patients (P< 0.0001).[13]
- Arista™ AH reduced time to hemostasis by one minute when compared to an absorbable gelatin control (P= 0.002).[13]

In a preclinical study:[11]

- Arista™ AH exhibited a lower rate of adhesion formation in a rat cecum compared to other hemostats and sealants.[12]

Preclinical data demonstrated that Arista™ AH helps form a 20% stronger clot than no treatment[11,17]

Ready to use with no mixing or refrigeration[9]

Preclinical testing demonstrated Arista™ AH is typically absorbed within 24–48 hours[9,10,11,*]

Derived from a plant-based material[9]

Arista™ AH profile

- Human and animal by-product free[9]

Based on preclinical studies:

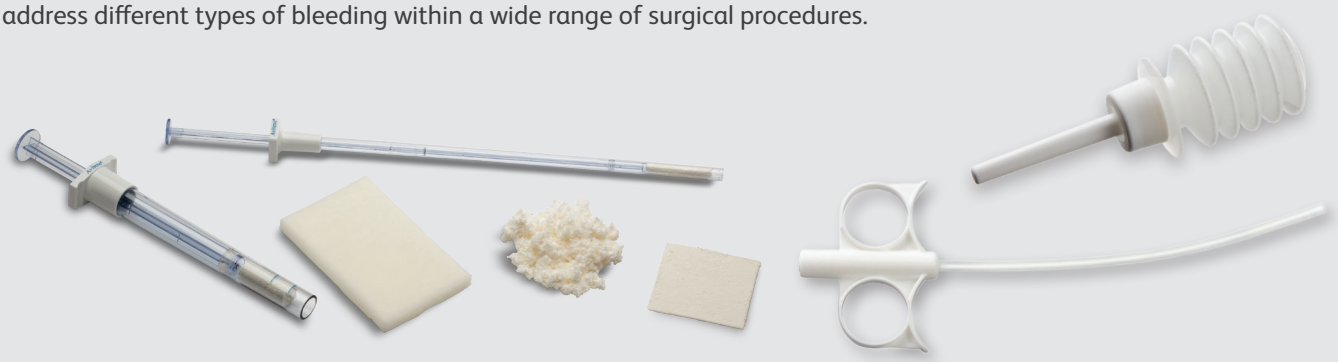
- Clotting process begins on contact, regardless of patient's coagulation status[9,11]
- Has shown no evidence of foreign body reaction and does not interfere with natural healing[9,11]
- Does not potentiate infection[9,11]
- Reaches maximum volume on contact with blood, with no additional swelling occurring as the powder absorbs[9,11]

* Data generated in 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.

BD family of hemostats

Hemostatic solutions you can rely on

BD offers a comprehensive range of hemostatic products in a variety of formats to help surgeons address different types of bleeding within a wide range of surgical procedures.



Ordering information

Cat. no.	Description	Qty.	
Arista™ AH Absorbable Hemostatic Particles			
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.	☐
Avitene™ Microfibrillar Collagen Hemostat Flour			
1010010	Avitene™ Microfibrillar Collagen Hemostat 0.5 g	6/cs	☐
1010020	Avitene™ Microfibrillar Collagen Hemostat 1.0 g	6/cs	☐
1010590	Avitene™ Microfibrillar Collagen Hemostat 5.0 g	2/cs	☐
EndoAvitene™ Applicators			
1010150	EndoAvitene™ Applicators 10 mm diameter–42 cm length (50 mm x 15 mm x 1 mm preloaded sheet)	6/cs	☐
Avitene™ Ultrafoam™ Collagen Sponge			
1050020	Avitene™ Ultrafoam™ Collagen Sponge 12.5 sq cm 2 cm x 6.25 cm x 7 mm (3/4" x 2 1/2" x 1/4")	12/cs	☐
1050030	Avitene™ Ultrafoam™ Collagen Sponge 50 sq cm 8 cm x 6.25 cm x 1 cm (3 1/8" x 2 1/2" x 3/8")	6/cs	☐
1050040	Avitene™ Ultrafoam™ Collagen Sponge 100 sq cm 8 cm x 12.5 cm x 1 cm (3 1/8" x 5" x 3/8")	6/cs	☐
1050050	Avitene™ Ultrafoam™ Collagen Sponge 100/thin 8 cm x 12.5 cm x 3 mm (3 1/8" x 5" x 1/8")	6/cs	☐
SyringeAvitene™ Applicators			
1010340	SyringeAvitene™ Applicators 1 g flour preloaded applicator; 2 cm (0.8") diameter, 16 cm (6.5") usable length	6/cs	☐
Avitene™ Sheets			
1010080	Avitene™ Sheets 3.5 cm x 3.5 cm (1.4" x 1.4")	6/cs	☐
1010090	Avitene™ Sheets 7.0 cm x 3.5 cm (2.75" x 1.4")	6/cs	☐
1010110	Avitene™ Sheets 7.0 cm x 7.0 cm (2.75" x 2.75")	6/cs	☐

1. Neveleff, D.J. Optimizing hemostatic practices: matching the appropriate hemostat to the clinical situation. AORN J96, S1-S17 (2012). **2.** Doria, C. & Vaccino, S. Topical hemostasis: a valuable adjunct to control bleeding in the operating room, with a special focus on thrombin and fibrin sealants. *Expert Opin Biol Ther.* 2009 Feb;9(2):243-7. **3.** Marietta, M., Facchini, L., Pedrazzi, P., Busani, S. & Torelli, G. Pathophysiology of bleeding in surgery. *Transplant Proc.* 2006 Apr;38(3):812-4. **4.** Shander, A. Financial and clinical outcomes associated with surgical bleeding complications. *Surgery.* 2007 Oct;142(4 Suppl):S20-5. **5.** Boucher, B.A. & Traub, O. Achieving hemostasis in the surgical field. *Pharmacotherapy.* 2009 Jul;29(7 Pt 2):2S-7S. **6.** Zimmerman, L.H. Causes and consequences of critical bleeding and mechanisms of blood coagulation. *Pharmacotherapy.* 2007 Sep;27(9 Pt 2):45S-56S. **7.** Despotis, G., Avidan, M. & Eby, C. Prediction and management of bleeding in cardiac surgery. *J Thromb Haemost.* 2009 Jul;7 Suppl 1:111-7. **8.** Vecchio R, Catalano R, Basile F, et al. Topical hemostasis in laparoscopic surgery. *G Chir.* Nov-Dec 2016;37(6):266-270. **9.** Arista™ AH Instructions for Use. Franklin Lakes, NJ; BD 2020. **10.** Because there have been reports of decreased amylase activity in newborns up to 10 months, absorption rates of Arista™ AH hemostat in this population may be longer than 48 hours. **11.** BD. Data on file. Preclinical data may not correlate to clinical performance in humans. **12.** Hoffmann NE, et al. Choice of hemostatic agent influences adhesion formation in a rat cecal adhesion model. *J Surg Res.* 2009 Jul;155(1):77-81. Arista™ AH was compared to N=10 for each of the following products: BioGlue®, FLOSEAL®, TISSEEL™, COSEAL®, and SURGICEL®. (P < 0.05). Preclinical data may not correlate to clinical performance in humans. **13.** Arista™ AH PMA P050038 clinical study: summary of safety and effectiveness. Available at https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050038b.pdf. Accessed October 15, 2020. **14.** Bruckner BA, Blau LN, Rodriguez L, et al. Microporous polysaccharide hemosphere absorbable hemostat use in cardiothoracic surgical procedures. *J Cardiothorac Surg.* 2014 Aug 2;9:134. **15.** The procedures listed are examples of surgeries where bleeding can occur and is not intended to replace clinical expertise. **16.** Based on a quantitative market research report internal user preference study. Data on file. **17.** In vitro TEG testing. Data on file.

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 50 g of Arista™ AH in diabetic patients as it has been calculated that amounts in excess of 50 g 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.**

Avitene™ Microfibrillar Collagen Hemostat

Indications Avitene™ Microfibrillar Collagen Hemostat (MCH) and Avitene™ Ultrafoam™ Sponge are indicated in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical. **Contraindications** • Avitene™ MCH and Avitene™ Ultrafoam™ Sponge should not be used in the closure of skin incisions as they 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. • It has been reported with other collagen hemostatic agents that by filling porosities of cancellous bone, they may significantly reduce the bond strength of methylmethacrylate adhesives. Avitene™ MCH and Avitene™ Ultrafoam™ Sponge should not, therefore, be employed on bone surfaces to which prosthetic materials are to be attached with methylmethacrylate adhesives. **Warnings** • Avitene™ MCH and Avitene™ Ultrafoam™ Sponge are inactivated by autoclaving. • Ethylene oxide reacts with bound hydrochloric acid to form ethylene chlorohydrin. • These devices have 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 devices 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 devices may lead to injury, illness or death of the patient or end user. Opened, unused product should be discarded. • Moistening Avitene™ MCH or wetting with saline or thrombin impairs its hemostatic efficacy. It should be used dry. • As with any foreign substance, use of Avitene™ MCH and Avitene™ Ultrafoam™ Sponge in contaminated wounds may enhance infection. • Avitene™ Ultrafoam™ Sponge should not be used in instances of pumping arterial hemorrhage. • Avitene™ Ultrafoam™ Sponge should not be used where blood or other fluids have pooled, or in cases where the point of hemorrhage is submerged as it may mask an underlying source of bleeding, resulting in hematoma. • Avitene™ Ultrafoam™ Sponge will not act as a tampon or plug in a bleeding site, nor will it close off an area of blood collecting behind a tampon. • Avitene™ Ultrafoam™ Sponge is not intended to treat systemic coagulation disorders. • Avitene™ MCH and Avitene™ Ultrafoam™ Sponge are not for injection, intraocular or intravascular use.
Adverse reactions • The most serious adverse reaction reported that may be related to the use of Avitene™ MCH or other collagen products 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)* and increased incidence of alveolalgia when used for packing of dental extraction sockets. • Transient laryngospasm due to aspiration of dry material has been reported following use of Avitene™ MCH in tonsillectomy. **Please consult package insert for more detailed safety information and Instructions for Use.**

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