HARMONIC ACE®+7 Shears — unprecedented precision¹ with stronger large vessel sealing²,³

Uniting unmatched precision¹ with powerful sealing ability²,³ HARMONIC ACE®+7 Shears are designed for gynecologic surgical procedures to reduce the number of surgical devices needed to achieve hemostasis.⁴

**Stronger large vessel sealing**

- HARMONIC ACE+7 had durable seals in 94% of the vessels encountered in laparoscopic hysterectomy.²
- HARMONIC ACE+7 had 100% hemostasis when sealing the ovarian pedicle during oophorectomies, as shown in an observational study.²

**Multifunctionality**

- Majority of surgeons surveyed reported fewer instrument exchanges when using HARMONIC ACE+7 in laparoscopic hysterectomy procedures.⁶
- HARMONIC ACE®+7 can reduce the need for alternate energy sources in laparoscopic hysterectomy procedures.⁴

Clinical utility of a novel ultrasonic vessel sealing device in transecting and sealing large vessels during laparoscopic hysterectomy using advanced hemostasis mode


Read full article
Committed to surgical gynecologic procedures. Dedicated to a **complete solution no matter your surgical approach.**

**HARMONIC ACE+7** unites the precision\(^1\) of HARMONIC\(^\circ\) with optimal sealing capability\(^7\) for uterine vessels up to 7mm\(^8\) and hemostatic dissection of adhesions\(^9\) and lymph nodes\(^10\)

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**Addressing surgical bleeding with adjunctive hemostats**

**Surgicel Family of Absorbable Hemostats**—50-plus years of the proven safety and efficacy surgeons trust\(^11\,12\)

**SURGIFLO**\(^\circ\) Hemostatic Matrix Kit— the bioresorbable gelatin matrix with proven efficacy, safety and convenience that stops bleeding in less than 2 minutes when mixed with thrombin

**EVICEL**\(^\circ\) Fibrin Sealant—provides sustained hemostasis for bleeding that may be addressed intraoperatively, but could later develop into more serious complications especially in high-risk patients

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**Secure closure to address risk factors associated with infection**

**STRATAFIX**\(^\text{TM}\) Knotless Tissue Control Devices—delivers more consistency, more security and more efficiency than traditional sutures\(^13\,14\,15\,17\,18\,19\)

**DERMABOND**\(^\circ\) PRINEO** Skin Closure System—uncompromised strength and protection for excellent wound closure\(^20\)

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Ethicon provides a complete solution for gynecological surgery. To learn more, contact your sales representative or visit ethicon.com.
EVITHROM® Thrombin, Topical (Human) for Topical Use Only

Lyophilized Powder for Solution

EVITHROM® is a topical thrombin indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

EVITHROM® may be used in conjunction with an Absorbable Gelatin Sponge, USP.

Important safety information

- For topical use only
- Do not inject
- Apply EVITHROM® on the surface of bleeding tissue only
- The amount of EVITHROM® required depends upon the area of tissue to be treated and the method of application. In clinical studies, volumes up to 10 ml were used in conjunction with Absorbable Gelatin Sponge.
- Do not use for the treatment of severe or brisk arterial bleeding.
- Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products. Hypersensitivity reactions, including anaphylaxis, may occur.
- There is a potential risk of thrombosis if absorbed systemically.
- May carry a risk of transmitting infectious agents such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite manufacturing steps designed to reduce the risk of viral transmission.
- The most common adverse reactions during clinical trial (reported in at least 2% of subjects treated with EVITHROM®) were prolonged activated partial thromboplastin time, increased INR, decreased lymphocyte count, prolonged prothrombin time and increased neutrophil count.
- None of the patients treated with EVITHROM developed antibodies to human thrombin or to human Factor V/Va. The clinical significance of these findings is unknown.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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EVICEL® Fibrin Sealant (Human)

Important safety information

Indication

EVICEL® Fibrin Sealant (Human) is indicated as an adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques (such as suture, ligature, or cautery) is ineffective or impractical.

Contraindications

- Do not inject directly into the circulatory system. Intravascular application of EVICEL® may result in life-threatening thromboembolic events.
- Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products.
- Do not use for the treatment of severe or brisk arterial bleeding.
- Do not use EVICEL® for spraying in endoscopic or laparoscopic procedures where the minimum recommended distance from the applicator tip to the target site cannot be ensured.

Warnings and precautions

- Life-threatening air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer EVICEL®. This event appears to be related to the use of the spray device at pressures higher than recommended and/or at distances closer than recommended to the surface of the tissue.
- Monitor changes in blood pressure, pulse, oxygen saturation, and end-tidal CO₂ when spraying EVICEL® because of the possibility of gas embolism.
- To reduce the risk of potentially life-threatening gas embolism, spray EVICEL® using only pressurized CO₂ gas at the pressures and distances recommended for the specific tips.
- Use EVICEL® spray application only if it is possible to accurately judge the spray distance, especially during endoscopic or laparoscopic procedures.
- Prior to applying EVICEL®, dry surface areas of the wound by standard techniques (e.g. intermittent application of compresses, swabs, use of suction devices). Prepare and administer EVICEL® according to the instructions and with only devices recommended for this product.
- May carry a risk of transmitting infectious agents, e.g. viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The most common adverse reactions reported in clinical trials are peripheral edema, abdominal abscess, infection, hematoma, incision site hemorrhage, vascular graft occlusion, postoperative wound complication and decreased hemoglobin.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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SURGIFLO® Hemostatic Matrix Kit

**Essential Product Information**
(Made from Absorbable Gelatin Sponge, USP) with Thrombin

**Description**
SURGIFLO® with Thrombin (SURGIFLO® Hemostatic Matrix Kit) is intended for hemostatic use by applying to a bleeding surface.

**Actions**
When used in appropriate amounts SURGIFLO® is absorbed completely within 4 to 6 weeks.

**Intended use/indications**
SURGIFLO®, mixed with thrombin solution, is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.

**Contraindications**
- Do not use SURGIFLO® in intravascular compartments because of the risk of embolization.
- Do not use SURGIFLO® in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

**Warnings**
- SURGIFLO® should not be used in the presence of infection and should be used with caution in contaminated areas of the body. SURGIFLO® should not be used in instances of pumping arterial hemorrhage. SURGIFLO® will not act as a tampon or plug in a bleeding site.
- SURGIFLO® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.
- Excess SURGIFLO® should be removed once hemostasis has been achieved.
- The safety and effectiveness of SURGIFLO® for use in ophthalmic procedures has not been established.
- SURGIFLO® should not be used for controlling post-partum intrauterine bleeding or menorrhagia.
- The safety and effectiveness of SURGIFLO® has not been established in children and pregnant women.
- The blue flexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.

**Precautions**
- Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurologic retrospective study involving 1700 cases in Europe. Safe and effective use in neurosurgery has not been proven through randomized, controlled clinical studies in the United States.
- SURGIFLO® is supplied as a sterile product and cannot be resterilized.
- SURGIFLO® should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® may swell up to 20% upon contact with additional fluid.
- SURGIFLO® should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.
- In urological procedures, SURGIFLO® should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

**Adverse events**
A total of 142 patients received SURGIFOAM® Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge. In general, the following adverse events have been reported with the use of absorbable porcine gelatin-based hemostatic agents:
- Gelatin-based hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth.
- Giant cell granulomas have been observed at implant sites when used in the brain.
- Compression of the brain and spinal cord resulting from the accumulation of sterile fluid have been observed.
- Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminectomy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.
- The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations, has been associated with fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.
- The use of absorbable gelatin-based hemostatic agents has been associated with paralysis, due to device migration into foramina in the bone around the spinal cord, and blindness, due to device migration in the orbit of the eye, during lobectomy, laminectomy, and repair of a frontal skull fracture and lacerated lobe.
- Foreign body reactions, "encapsulation" of fluid, and hematoma have been observed at implant sites.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
- Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostats in nasal surgery.
- Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

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Precautions

- Use only as much SURGICEL® Absorbable Hemostat as is necessary for hemostasis, holding it firmly in place until bleeding stops. Remove any excess before surgical closure in order to facilitate absorption and minimize the possibility of foreign body reaction.
- In urological procedures, minimal amounts of SURGICEL® Absorbable Hemostat should be used and care must be exercised to prevent plugging of the urethra, ureter, or a catheter by dislodged portions of the product.
- Since absorption of SURGICEL® Absorbable Hemostat could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.
- If SURGICEL® Absorbable Hemostat is used temporarily to line the cavity of large open wounds, it should be placed so as not to overlap the skin edges. It should also be removed from open wounds by forceps or by irrigation with sterile water or saline solution after bleeding has stopped.
- Precautions should be taken in otolaryngologic surgery to assure that none of the material is aspirated by the patient. (Examples: controlling hemorrhage after tonsillectomy and controlling epistaxis.
- Care should be taken not to apply SURGICEL® Absorbable Hemostat too tightly when it is used as a wrap during vascular surgery (see Adverse Reactions).

Adverse events

- "Encapsulation" of fluid and foreign body reactions have been reported.
- There have been reports of stenotic effect when SURGICEL® Absorbable Hemostat has been applied as a wrap during vascular surgery.
- Paralysis and nerve damage have been reported when SURGICEL® Absorbable Hemostat was used around, in, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm.
- Blindness has been reported in connection with surgical repair of a laceraed left frontal lobe when SURGICEL® Absorbable Hemostat was placed in the anterior cranial fossa.
- Possible prolongation of drainage in cholecystectomy and difficulty passing urine after prostatectomy have been reported.
- For more information, please consult your doctor or for product quality and technical questions, call 1-800-795-0012.

References:

1. As compared to HARMONIC™ devices without Adaptive Tissue Technology (C1949).
3. As shown in an observational study hemostasis achieved and maintained in 19 (94.4%) transactions (both L and R sides of the uterine artery/uterine pedicle and ovarian pedicle) (n=40 cases). Neboer TE, et al. Clinical utility of a novel ultrasonic vessel sealing device in transecting and sealing large vessels during laparoscopic hysterectomy using Advanced Hemostasis Mode. Euro J of Obstetrics and Gyn and Reproductive Biology (2016) (C1903).
5. As shown in an observational study hemostasis achieved and maintained in 19 (94.4%) transactions (both L and R sides of the uterine artery/uterine pedicle and ovarian pedicle) (n=40 cases). Neboer TE, et al. Clinical utility of a novel ultrasonic vessel sealing device in transecting and sealing large vessels during laparoscopic hysterectomy using Advanced Hemostasis Mode. Euro J of Obstetrics and Gyn and Reproductive Biology (2016) (C1901).
7. As per IFU (C1585).
8. As shown in a case series of 16 VATS patients in whom the HARMONIC® scalpel was used for adhesiotomy, cutting lung parenchyma and division of lymphatic tissue (lymphatic dissection and sampling) Yamada S et al. New-model ultrasonically activated shears for hemostatic sectioning during video-assisted thoracic surgery. General Thoracic and Cardiovascular Surgery. 2007 Volume 55 Pages 518-520. (C1887)
9. As per IFU (C1585).
10. Based on a case series of 16 VATS patients in whom the HARMONIC® scalpel was used for adhesiotomy, cutting lung parenchyma and division of lymphatic tissue (lymphatic dissection and sampling) Yamada S et al. New-model ultrasonically activated shears for hemostatic sectioning during video-assisted thoracic surgery. General Thoracic and Cardiovascular Surgery. 2007 Volume 55 Pages 518-520. (C1887)
11. As shown in a case series of 16 VATS patients in whom the HARMONIC® scalpel was used for adhesiotomy, cutting lung parenchyma and division of lymphatic tissue (lymphatic dissection and sampling) Yamada S et al. New-model ultrasonically activated shears for hemostatic sectioning during video-assisted thoracic surgery. General Thoracic and Cardiovascular Surgery. 2007 Volume 55 Pages 518-520. (C1887)
12. As shown in a case series of 16 VATS patients in whom the HARMONIC® scalpel was used for adhesiotomy, cutting lung parenchyma and division of lymphatic tissue (lymphatic dissection and sampling) Yamada S et al. New-model ultrasonically activated shears for hemostatic sectioning during video-assisted thoracic surgery. General Thoracic and Cardiovascular Surgery. 2007 Volume 55 Pages 518-520. (C1887)
17. Based on a case series of 16 VATS patients in whom the HARMONIC® scalpel was used for adhesiotomy, cutting lung parenchyma and division of lymphatic tissue (lymphatic dissection and sampling) Yamada S et al. New-model ultrasonically activated shears for hemostatic sectioning during video-assisted thoracic surgery. General Thoracic and Cardiovascular Surgery. 2007 Volume 55 Pages 518-520. (C1887)
18. Based on a case series of 16 VATS patients in whom the HARMONIC® scalpel was used for adhesiotomy, cutting lung parenchyma and division of lymphatic tissue (lymphatic dissection and sampling) Yamada S et al. New-model ultrasonically activated shears for hemostatic sectioning during video-assisted thoracic surgery. General Thoracic and Cardiovascular Surgery. 2007 Volume 55 Pages 518-520. (C1887)
19. Based on a case series of 16 VATS patients in whom the HARMONIC® scalpel was used for adhesiotomy, cutting lung parenchyma and division of lymphatic tissue (lymphatic dissection and sampling) Yamada S et al. New-model ultrasonically activated shears for hemostatic sectioning during video-assisted thoracic surgery. General Thoracic and Cardiovascular Surgery. 2007 Volume 55 Pages 518-520. (C1887)