Reducing the Risk of Bleeding Complications in Colorectal Procedures

Bleeding situations, burden, risk factors, management of complications, and how Ethicon can help.

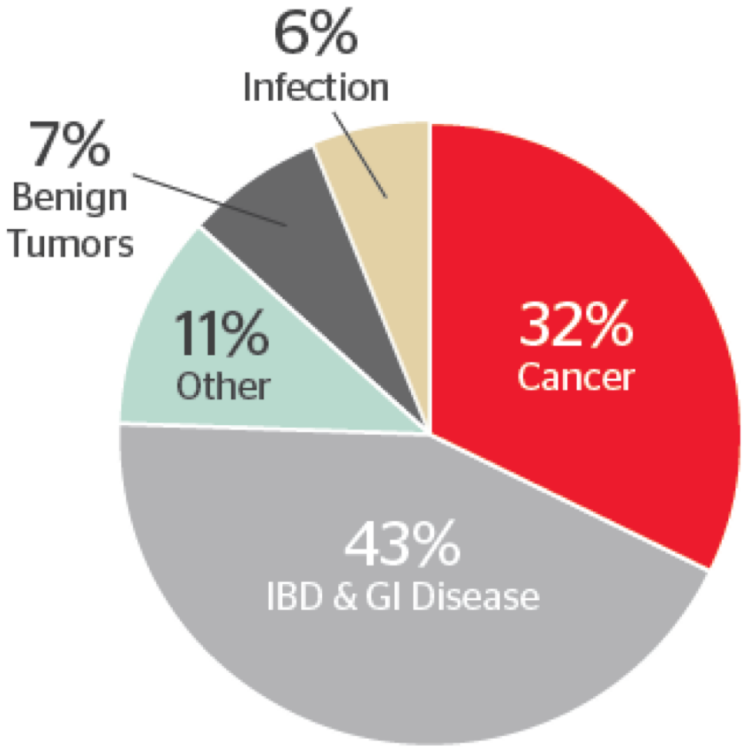
OR Team/Resident Training Program

The purpose of this presentation is to provide information for surgeons to share with their OR teams, residents, or with other surgeons who may be interested in discussing colorectal procedures. The presentation is intended to facilitate discussion that may identify opportunity for improvement.

Agenda

- Reasons for colorectal procedures
- Colorectal complications
- What bleeding complications can occur?
- Key steps to managing bleeding
- Incidence of bleeding complications
- Impact and cost of bleeding complications
- Bleeding risk factors
- Bleeding risk reducing activities
- How Ethicon can help

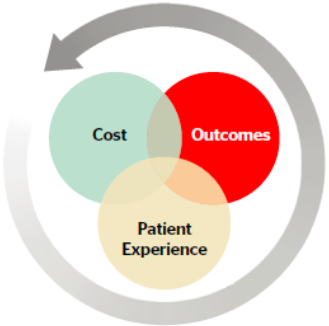
Reasons for Colorectal Procedures[1]



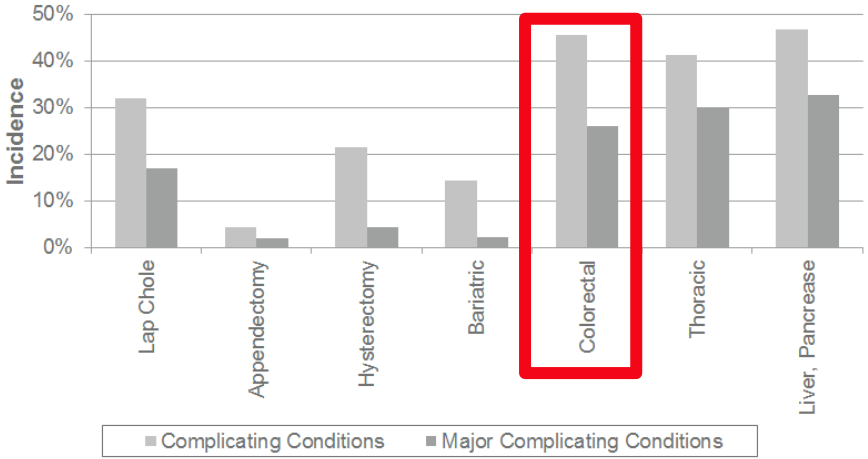
Complications May Create Barriers to Achieving Hospital Goals

Hospital Goals:

- Improve Outcomes
- Improve Patient Experience
- Reduce Total Cost



Complicating Conditions Across Many Procedures[2]



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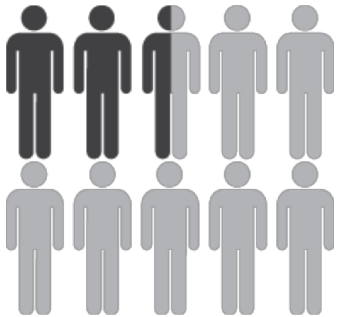
Colorectal Complications

- Colorectal surgeries have high rates of complications and readmissions.
- Leading reasons for readmissions include **staple line leaks, perioperative bleeding, and surgical site infections.**[3]

Adverse outcomes in colorectal surgery

Complications



30.5%

of patients
have complications[4]

Readmissions

11%

of patients
are readmitted within 30 days[3]

23%

of patients
are readmitted within 90 days[5]

Costs

$9K

average readmission costs[5]

Perioperative Bleeding

Cost of bleeding complications [4]

Complication	Incidence	Mean incremental cost difference	Average Length of Stay (LOS)
Bleeding	10.5%	$12,081	2.5 days incremental

Risk factors

- Anticoagulant or antiplatelet use[6,7]*
- Congenital bleeding disorders[8]

*Risk factors that are potentially modifiable.

The incidence of bleeding complications

Surgical bleeding can adversely affect patient outcomes, hospital costs and resources

- Challenging and uncontrollable bleeding during surgery is associated with high mortality rates[9]
- High risk patients are more likely to experience rebleeding events[9-11]

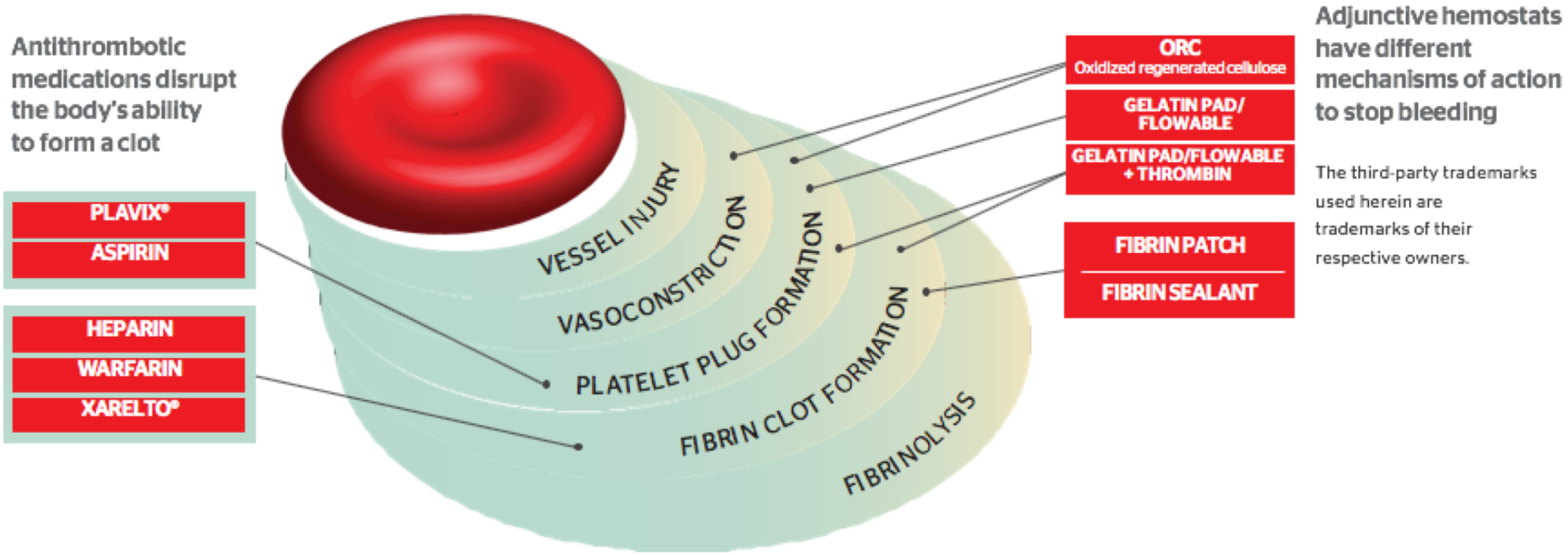
32 - 68% of all cases in open procedures experience major bleeding events.[6]

Bleeding as an Anastomotic Complication[12]

- Minor and major bleeding are two of the most common anastomotic complications
  - **Minor bleeding** – bleeding that does not require blood transfusion and/or intervention and that usually ceases within 24 hours.
    - It is hypothesized that anastomotic bleeding occurs secondary to inadequate clearance of the mesentery prior to division and/or stapling of the bowel.
  - **Major bleeding** – bleeding that is a result of hemodynamic instability, requires a blood transfusion or an emergency procedure.
    - The reported rate of major bleeding from an anastomosis following colorectal surgery ranges in most studies from 0.5 to 4.2%.

The Hemostatic Cascade

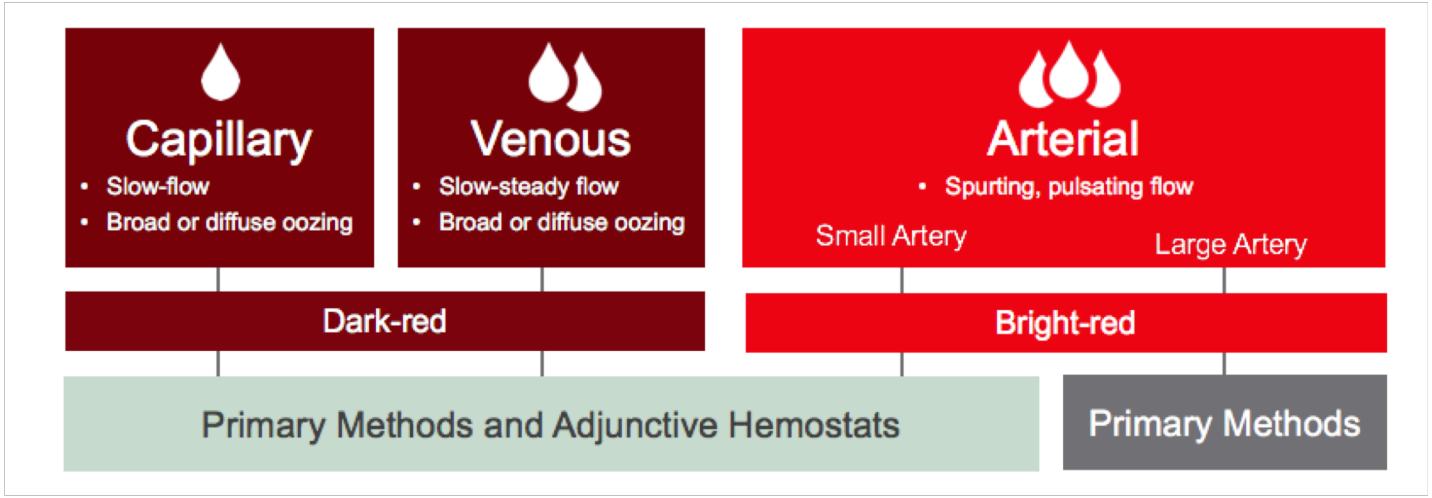
Understanding the steps of hemostasis is important in achieving the right solution.



Important Risk Information: Adjunctive hemostats are not intended for use on nonbleeding tissue or for prophylactic use. The bleeding situations identified reflect customer insights/market research on optimal adjunctive hemostat utilization. The product solutions should only be used in accordance with their instructions for use. Product recommendations should not supplant medical judgment. Surgeon preference, experience, and patient needs may dictate alternate technique. Review all relevant precautions, especially the indications, contraindications, warnings, and information for use. Please see package inserts for Full Prescribing Information.

Types of Bleeding

There are different types of bleeding (eg, capillary, venous, arterial). Each type may require different methods to achieve hemostasis



Hemostasis Primary methods of hemostasis may not always allow achievement of complete hemostasis. Using an adjunctive hemostat may result in faster time to achieve and sustain hemostasis.

Different bleeding situations require different solutions

Primary Methods

Mechanical

- Sutures
- Ligating clips
- Staples
- Clamps
- Manual compression

Energy

- Traditional electrocautery
- Advanced technology (ultrasonic or bipolar)

Adjunctive Methods

Topical Hemostats and Sealants

- Oxidized regenerated cellulose
- Flowable gelatin
- Fibrin sealants
- Fibrin patches
- Bone wax
- Collagen based

Comprehensive Bleeding Management Solution

Bleeding Situation		Suggested Hemostat
 Continuous oozing	Will not stop with compression/simple packing. The solution for this bleeding is more time consuming than it is difficult.	Oxidized regenerated cellulose (ORC)
 Problematic	Even though the bleeding is accessible, it could be trouble. It is more than routine and likely to be resistant to conventional means and requires immediate attention causing disruption to the normal progression of surgery.	Fibrin patch
 Difficult to access	Bleeding that occurs in tight and irregular spaces and you cannot see the exact source of the bleed. You are concerned accessing a tight space will cause more harm.	Flowable gelatin
 Potential rebleeding risk	Bleeding may be addressed intraoperatively, but could later develop into more serious complications, especially in high-risk patients.	Fibrin sealant
 High-pressure vessel bleeding	A leak in high-pressure vessel (aortic orperipheral vascular suture line) that has been stopped but if it leaks post-op, could be catastrophic.	Vascular sealant

How Ethicon Can Help

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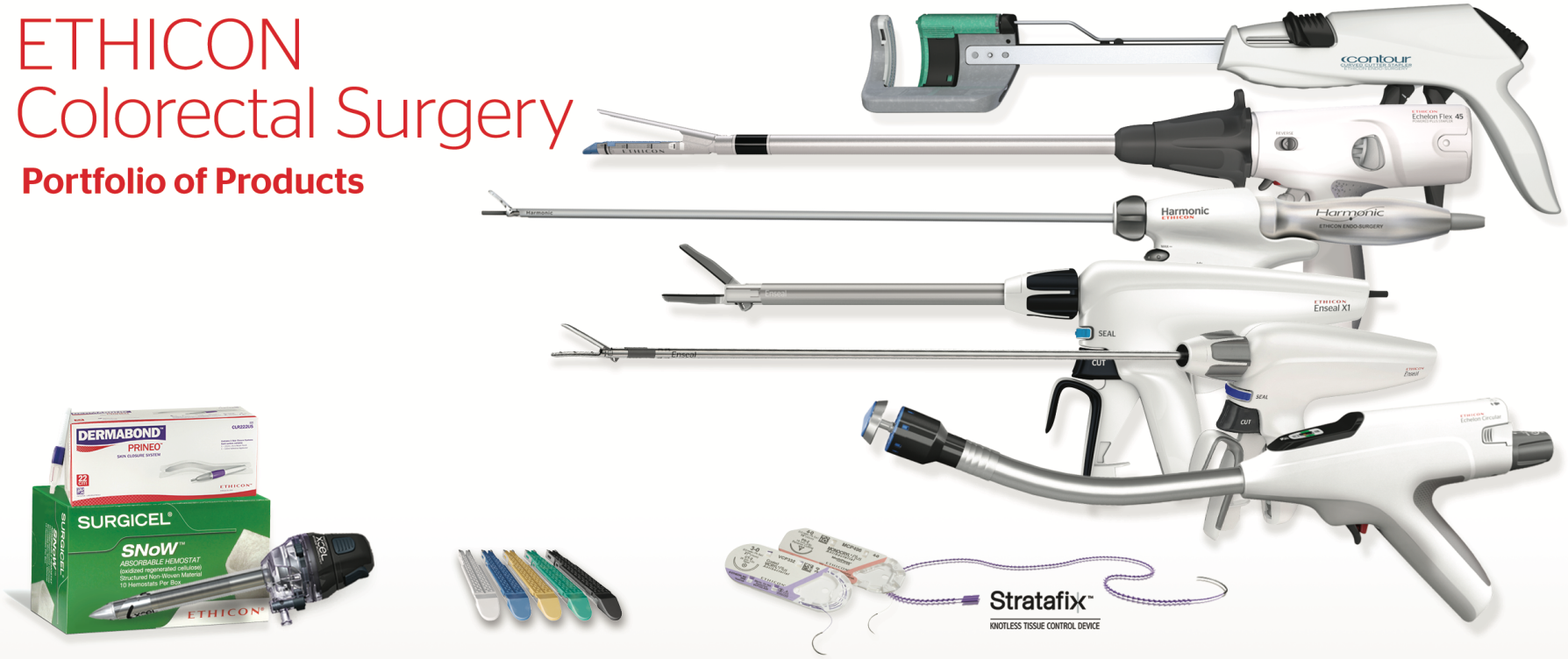
Colorectal Surgery

Portfolio of Products



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“Why bleeding matters” Dr. Konstantin Zakashansky

SURGICEL® Powder Absorbable Hemostat

Gets to the source of the bleed[13,17]

- The next generation of the #1 brand of absorbable adjunctive hemostats is built to stop continuous, broad-surface oozing fast — even on friable or raw tissues[13,14]
- Efficiently and effectively controls continuous oozing on broad surfaces and fully absorbs within 7 to 14 days[15,16]
- The structure of the powder penetrates the surface of the blood[13,17]

SURGICEL SNoW™ Absorbable Hemostat

Enhanced Hemostasis*[18,19]

- One layer of SURGICEL SNoW is more effective than 4 layers of SURGICEL® Original Absorbable Hemostat[20]
- Greater conformability and adherence to the bleeding site compared with SURGICEL® Original Absorbable Hemostat[21]
- Fully absorbable 7-14 days[22,23]

*Compared to SURGICEL® Original Absorbable Hemostat.

SURGIFLO® Hemostatic Matrix Kit

Stays in place even during active bleeding* [24,25]

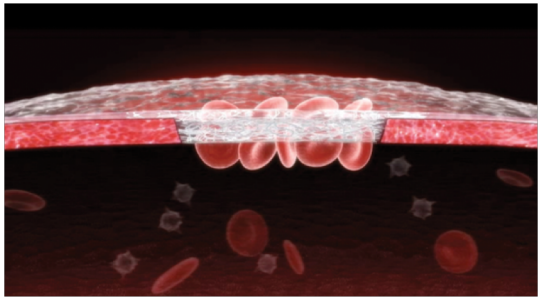
- Achieves hemostasis within approximately 60 seconds[26]
- Proven efficacy, safety and convenience[27,28]
- In blind testing, surgeons prefer the consistency of SURGIFLO over Floseal†[29]

*In animal models.
†Testing conducted with 101 US surgeons.

EVICEL® Fibrin Sealant (Human)

Provides sustained hemostasis, demonstrated in high-risk patients[30]

- Designed to deliver a rapid, adherent, and lasting fibrin clot[31*]
- No reoccurrence or treatment site bleeding was found for up to 4 weeks post-operative[32]



*Evicel Airless Spray Accessory

HARMONIC® ACE+7 Shears with Advanced Hemostasis

The use of HARMONIC® technology has been shown to significantly reduce blood loss when compared to conventional electrosurgery in laparoscopic colorectal surgery*

- 100% hemostasis when sealing the inferior mesenteric artery (IMA) (n=40)†
- 98% hemostasis when sealing the inferior mesenteric vein (IMV) (n=40)‡

*In a prospective randomized study (n=23),the use of the HARMONIC® Scalpel 5mm ultrasonic shears resulted in less blood loss versus the monopolar electrosurgery scissors (100mL, 200mL, respectively) (P<0.01). Targarona E, Balague C, Marin, J, et al. Energy Sources for Laparoscpic Colectomy: A Prospective Randomized Comparison of Conventional Electrosurgery, Bipolar controlled Electrosurgery, and Ultrasonic Dissection. Operative Outcome and Costs Analysis. Surgical Innovation 2005; 12(4): 339-344.

†As shown in an observational study. First pass hemostasis on IMA (100%). Plasencia G, et al. Large-Vessel Sealing in Laparoscopic Colectomy with an Ultrasonic Device. JSLS. 2016 Apr-Jun; 20(2)

‡As shown in an observational study. First pass hemostasis on IMV (97.5%). Plasencia G, et al. Large-Vessel Sealing in Laparoscopic Colectomy with an Ultrasonic Device. JSLS. 2016 Apr-Jun; 20(2)

ENSEAL® X1 Portfolio

Enseal® X1 Large Jaw Tissue Sealer

More secure

- Better sealing with less bleeding at the distal tip vs. LigaSure Impact™ in thick tissue*

ENSEAL® X1 Curved Jaw Tissue Sealer

More efficient

- Captures more tissue per bite with a 16% longer jaw and 40% wider jaw aperture compared to LigaSure™ Maryland†

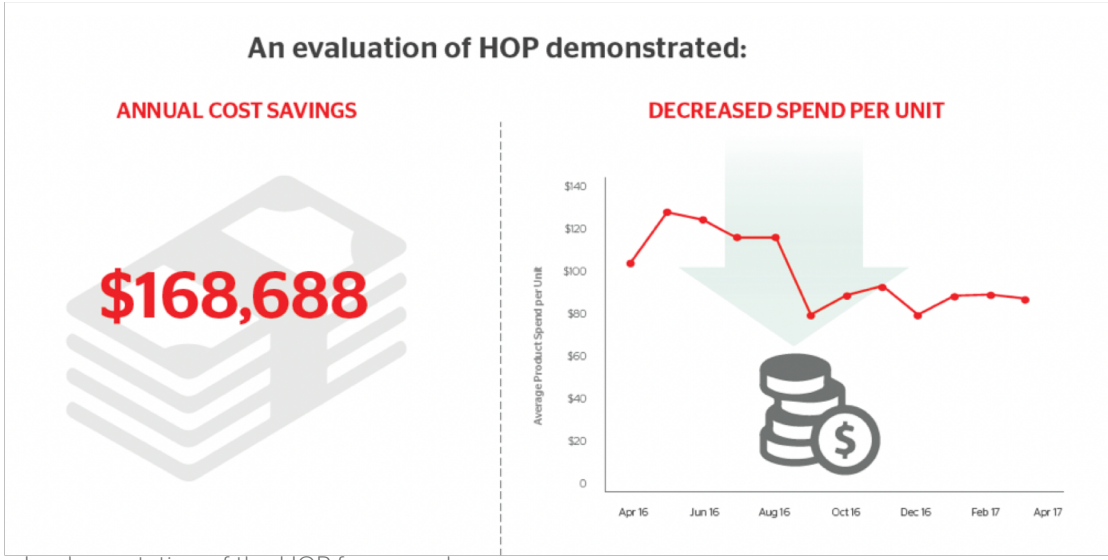
*Preclinical test of distal tip bleeding (ENSEAL® vs. Impact-LF4318) in thick porcine mesentery base (p=0.001).
†Based on metrology data, ENSEAL® X1 Curved Jaw Tissue Sealer has a 16% (or 3.4mm) longer jaw than LigaSure™ Maryland (LF1937) ($p < 0.001$) and ENSEAL® X1 Curved Jaw Tissue Sealer has a 40% (or 5.0mm) wider unbiased jaw aperture than LigaSure™ Maryland (LF1937) ($p < 0.001$).

Hemostasis Optimization Program

A systematic approach to surgical bleeding management

Implementation of the Hemostasis Optimization Program (HOP) at a large US teaching hospital as part of a portfolio conversation, resulted in[33]:

- Substantial cost savings without sacrificing patient outcomes
- OR and supply chain efficiencies
- High surgeon and staff satisfaction



Implementation of the HOP framework resulted in annual cost savings of $168,688, not including contractual savings from switching to a full-line supplier

Spend per hemostat until trended downward 15%

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Hemostasis Optimization Program Steps

Step	Action	Role of Facility	Role of Ethicon
Step 1: Data Collection 	Observe procedures and gather data to ultimately offer suggestions for improvement	❑ Enable access to representative for case observations ❑ Provides usage by code, procedure, and surgeon (if applicable) ❑ Clinical team(s) to provide overview of current adjunctive hemostat usage by specialty and review procedural preference cards	❑ Collect and summarize data and use market research insights to provide guidance on current hemostat usage and how to gain optimal utilization within your facility

Hemostasis Optimization Program Steps

Step	Action	Role of Facility	Role of Ethicon
Step 2: Data Review & Action Plan Meeting 	Review case observations and summary of findings, and develop a plan	❑ Include members of hemostasis project team in this meeting. Team should include OR director, nurse educator, specialty managers, and surgeon liaison	❑ Present cross reference and cost analysis ❑ Provide summary of findings ❑ Establish action plan for education and evaluation

Hemostasis Optimization Program Steps

Step	Action	Role of Facility	Role of Ethicon
Step 3: Education 	Meet with clinical teams to determine appropriate product recommendations for the evaluation	❑ Schedule in-service and department meeting times (as applicable) ❑ Communicate upcoming initiatives to surgeons and hospital staff	❑ Deliver Hemostasis Education Sessions (surgeons and surgical staff) about optimally managing bleeding

Hemostasis Optimization Program Steps

Step	Action	Role of Facility	Role of Ethicon
Step 4: Evaluation 	Period of time to evaluate recommended solutions	❑ Confirm evaluation parameters with staff ❑ Provide case schedule to Ethicon representative ❑ Gather evaluation forms and feedback for discussion	❑ On site support for all appropriate cases ❑ Conduct ongoing check-ins to review progress ❑ Ensure product supply and availability

Hemostasis Optimization Program Steps

Step	Action	Role of Facility	Role of Ethicon
Step 5: Follow-Up Meeting 	Share feedback on clinical performance observations from procedures, surgeon, and staff	❑ Share feedback from surgeons and nursing staff on the effectiveness of the program ❑ Discuss obstacles and any concerns needing to be addressed ❑ Determine as a group if objectives have been met and when to move into next phase	❑ Share feedback on clinical performance observations from procedures from surgeons and staff ❑ Provide additional resources if needed: for example, meeting with R&D, resident or surgeon training in lab setting, etc ❑ Continue to cover cases and provide ongoing education and in servicing

Medicare Dashboard

This Ethicon designed dashboard provides Medicare outcomes based information by hospital or IDN regarding colorectal procedures:

- Length of stay (LOS),
- Readmissions
- Complications of bleeding, infection, leaks and pneumonia.

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Ethicon Professional Education Support

- Resident/fellow training
- Animate labs focusing on all platforms – stapling; energy; wound closure; biosurgery
- National, local and tailored courses
- Customer Education Visits
- Webinars
- Conference presentations
- Customized programs

Colorectal National Courses

Optimizing Minimally Invasive Colectomy: An O.R. Team Approach

Minimally invasive colorectal surgical techniques continue to advance. This course helps colorectal teams performing minimally invasive colectomy procedures expand their knowledge and skills of Ethicon Energy and Endo-mechanical products. The course has a didactic portion that addresses patient selection, surgical techniques and device technology utilized and provides hands-on lab experiences.

Optimizing the Anastomosis: A Comprehensive Overview

This program provides a review of anastomotic techniques and management of leaks with primary focus on the safe and effective use of Ethicon products used to manage colorectal anastomosis. It covers causes, associated factors, and measures taken to minimize anastomotic leaks.

Complex Open Colorectal Surgery Procedure Course

This course focuses on the management of complex open colorectal procedures with an emphasis on the prevention of injuries to essential anatomical structures. A comprehensive review of complex open colorectal procedures is given, as is an overview of all aspects of open surgery from rationale of surgical techniques, unique patient issues, re-operative surgery and enhanced recovery protocols.

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For further information or help

- Go to Ethicon.com/colorectal
- Contact your local sales representative

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 CO_2 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 CO_2 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

021323-170803

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SURGICEL® Powder Absorbable Hemostat Essential Product Information

INDICATIONS

SURGICEL® Powder (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective.

CONTRAINDICATIONS

- Do not inject or place SURGICEL® Powder into an open blood vessel. Do not use to treat bleeding from large defects in arteries or veins.
- SURGICEL® Powder should not be used to control hemorrhage from large arteries or veins.
- When SURGICEL® Powder is used to help achieve hemostasis in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm, it must always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.
- SURGICEL® Powder should not be used for implantation in bone defects, such as fractures, since there is a possibility of interference with callus formation and a theoretical chance of cyst formation.

WARNINGS

- Closing with SURGICEL® Powder in a contaminated wound without drainage may lead to complications and should be avoided.
- SURGICEL® Powder should not be impregnated with anti-infective agents or with other materials such as buffering or hemostatic substances.
- SURGICEL® Powder is dry and there may be difficulties in precise delivery under certain circumstances. Unintentional device placement may result in powder scattering and device migration that may increase the risk of adhesion formation.
- Although SURGICEL® Powder is bactericidal against a wide range of pathogenic microorganisms, it is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or to prevent postoperative infections.
- Do not attempt to trim the applicator tip.

PRECAUTIONS

SURGICEL® Powder should not be used in conjunction with autologous blood salvage circuits, because its fragments may pass through the transfusion filters of blood-scavenging systems.

Use only as much SURGICEL® Powder (oxidized regenerated cellulose) as is necessary and apply only where needed for hemostasis. Remove any excess before surgical closure in order to facilitate absorption and to minimize the possibility of foreign body reaction.

In urological procedures, minimal amounts of SURGICEL® Powder 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® Powder 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® Powder is used temporarily to line the cavity of open wounds, it should be removed by irrigation with sterile water or saline solution after bleeding has stopped.

Precautions should be taken in otorhinolaryngologic surgery to ensure that none of the material is aspirated by the patient (e.g., controlling hemorrhage after tonsillectomy and controlling epistaxis).

This applicator tip is not intended for laparoscopic or other endoscopic use.

ADVERSE EVENTS

Paralysis and nerve damage have been reported when other SURGICEL® products were 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 lacerated left frontal lobe when other SURGICEL® products were placed in the anterior cranial fossa (see WARNINGS and PRECAUTIONS).

Foreign body reactions have been reported with other products from the SURGICEL® Family of Absorbable Hemostats.

Burning has been reported when other SURGICEL® products were applied after nasal polyp removal. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when SURGICEL® product was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) have also been reported.

For more information and technical questions, call 1-800-795-0012. For complete information including indications, contraindications, warnings, precautions, adverse reactions, and directions for use, consult the product package insert.

071582-180827

SURGICEL Essential Product Information

INDICATIONS
SURGICEL® Absorbable Hemostat (oxidized regenerated cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when ligation or other conventional methods of control are impractical or ineffective. SURGICEL® ORIGINAL, SURGICEL® FIBRILLAR™, SURGICEL® NU-KNIT®, and SURGICEL® SNoW™ Absorbable Hemostats can be cut to size for use in endoscopic procedures.

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 otorhinolaryngologic 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 section of the complete product package insert).

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 lacerated left frontal lobe when SURGICEL® Absorbable Hemostat was placed in the anterior cranial fossa.

Possible prolongation of drainage in cholecystectomies and difficulty passing urine per urethra after prostatectomy have been reported.

For more information, please consult your doctor or for product quality and technical questions, call 1-800-795-0012. For complete product information including indications, contraindications, warnings, precautions, and adverse reactions, please reference the individual product package inserts.

063768-180827

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.
• 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.
•

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.

063756-161128

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.

021328-180430

References

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