

Take control.
Even in unpredictable
situations.

Ethicon Bariatric Revision Solution



ETHICON
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES

Shaping
the future
of surgery

Bariatric revision surgeries demand predictable performance.

A bariatric revision surgery is unpredictable. It involves complex patient variables such as adhesions, fragile tissue, disruptive bleeding, challenging access and more. Assessing surgical challenges preoperatively is difficult.

When faced with the unpredictable during your next revision surgery, rely on Ethicon.

Surgical challenges

need to capture all tissue in one staple line

varying tissue type and thickness **impaired vision due to bleeding**

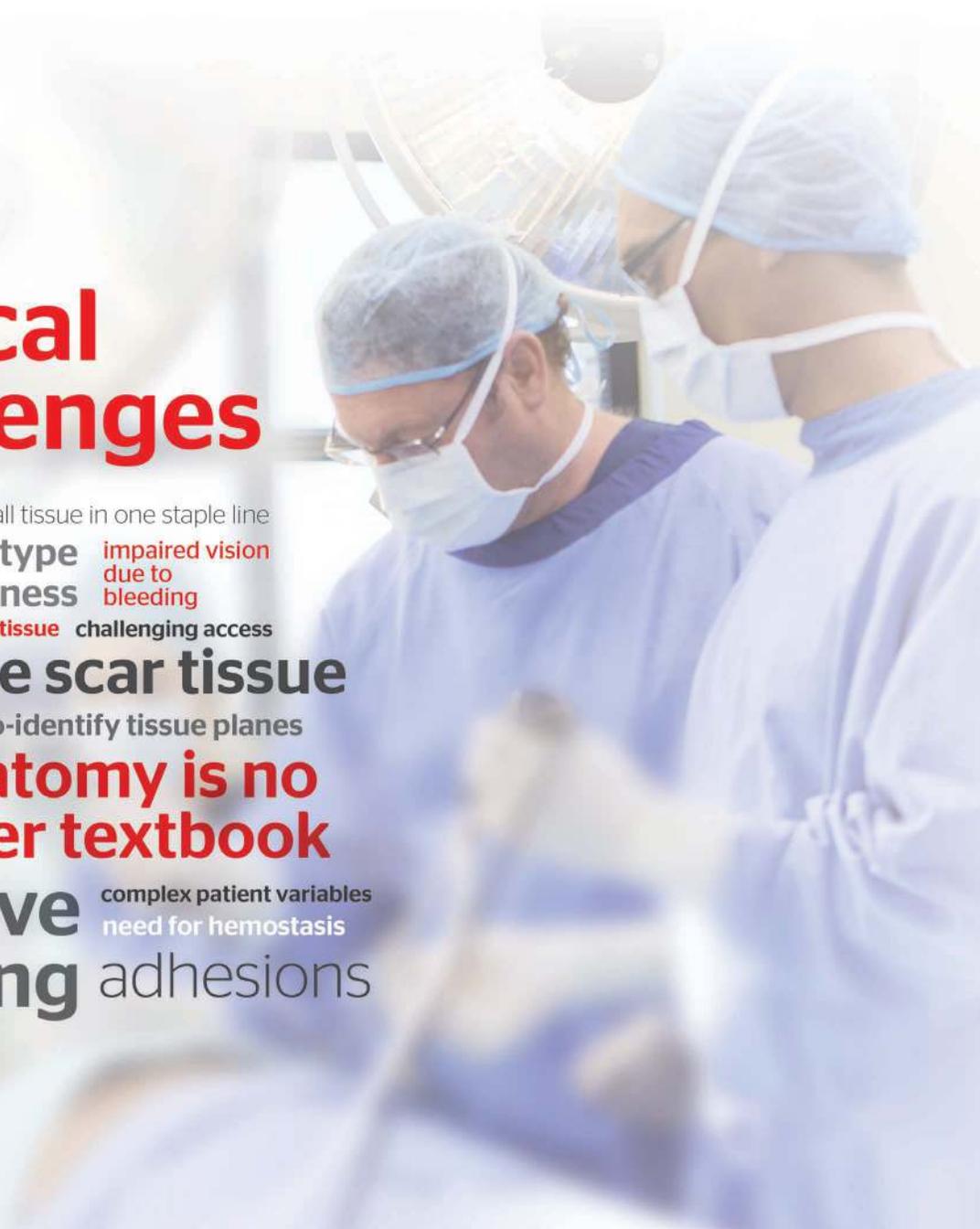
delicate and fragile tissue **challenging access**

thick or dense scar tissue

change in **hard-to-identify tissue planes**

thickness of the fundus **anatomy is no longer textbook**

disruptive bleeding **complex patient variables**
adhesions **need for hemostasis**



The control you want.

The Ethicon Bariatric Revision Solution offers a portfolio of products from a company you know and trust to provide precision, efficiency and hemostasis. These products give you the control you want and the flexibility you need.

HARMONIC® HD 1000i Shears

Unmatched precision¹



ECHELON FLEX™ GST System

Superior staple line integrity²



SURGICEL SNoW™ Absorbable Hemostat (for adjunctive use)

Conformability and handling³



STRATAFIX™ Knotless Tissue Control Devices

More consistent control⁴



Ethicon Bariatric Revision Procedure Kit

Increased efficiency

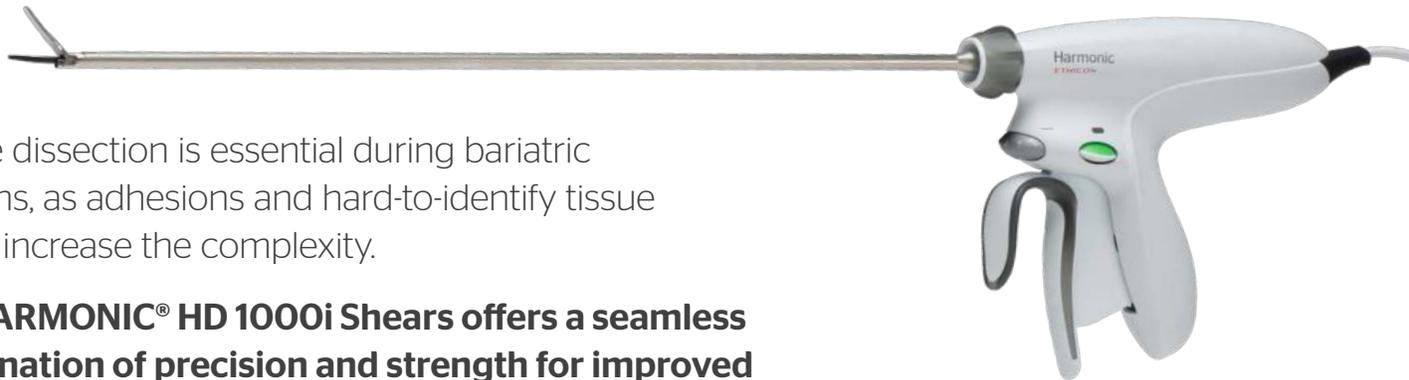


Meet the highest demands in your most challenging procedures.

¹ Design Validation Study with surgeons (n=33) operating in simulated procedures in an animate porcine laboratory model (33/33). ² The ECHELON FLEX™ GST System was designed and tested to meet rigorous design requirements for staple line integrity. The GST System accommodates a tissue thickness range of 1.0mm to 4.0mm (measured at 8g/mm², tissue comfortably compressed to closed staple height during firing per IFU) while the Medtronic Tri-Staple™ portfolio is intended for a tissue thickness range of 0.75mm to 3.0mm (per IFU & materials downloaded from Medtronic website on Nov 16, 2016). ³ VOC Final Report (J. Helms). ⁴ Moran ME, Marsh C, Perrotti M. Bidirectional-barbed sutured knotless running anastomosis v classic Van Velthoven suturing in a model system. J Endourol. 2007;21(10):1175-1178.

HARMONIC® HD 1000i Shears

Unmatched precision⁵



Precise dissection is essential during bariatric revisions, as adhesions and hard-to-identify tissue planes increase the complexity.

The HARMONIC® HD 1000i Shears offers a seamless combination of precision and strength for improved dissection, faster transection and more secure sealing.

Improved access

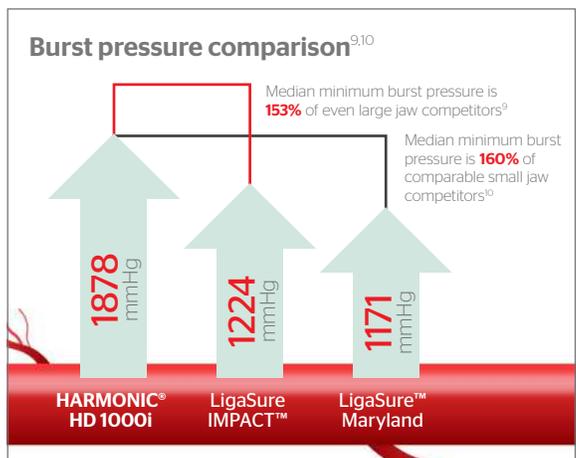
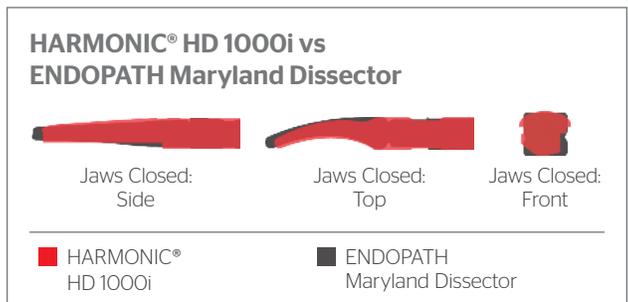
- More tapered jaw designed to enable more precise access to tissue planes⁵
- Curved, tapered blade geometry mirrors a mechanical dissector, delivering superior dissection among advanced energy devices⁵

Optimized efficiency

- Increased sealing speed, multifunctionality and simplified steps for use allow for optimal efficiency⁶
- Strong tip grasping is designed to minimize tissue slippage and may aid in tissue manipulation and control⁷

Reliable hemostasis

- Produces consistent and reliable hemostasis⁸



⁵ Design Validation Study with surgeons (n=33) operating in simulated procedures in an animate porcine laboratory model (33/33). ⁶ Based on a benchtop study ⁷ Based on average device tip grasping force (distal 5 mm of the jaw). ⁸ The supporting evidence for this claim can be found in Evidence #E810, "PSB004423A HARMONIC HD 1000i Laparoscopic Shears (HARHD36): Design Verification Chronic (30 day) Survival Study in the Pig", page 10 & 11 of 20 of PDF and Evidence #E811 "Software Version Comparison - John Schulte 041416" page 1 of 1 of PDF. ⁹ In a benchtop study with 5-7 mm porcine carotid arteries that compared median burst pressure, HARMONIC® HD 1000i (1878 mmHg) vs. LigaSure Impact™ (1224 mmHg) (p<0.0001). ¹⁰ In a benchtop study with 5-7 mm porcine carotid arteries that compared median burst pressure, HARMONIC® HD 1000i (1878 mmHg) vs. LigaSure™ Maryland (1171 mmHg) (p<0.0001).

ECHELON FLEX™ GST System

Transect as intended even in challenging tissue



Unpredictable tissue type and thickness are common during bariatric revision surgeries. You may encounter different tissue thicknesses within one staple line. Superior staple line integrity is a must.

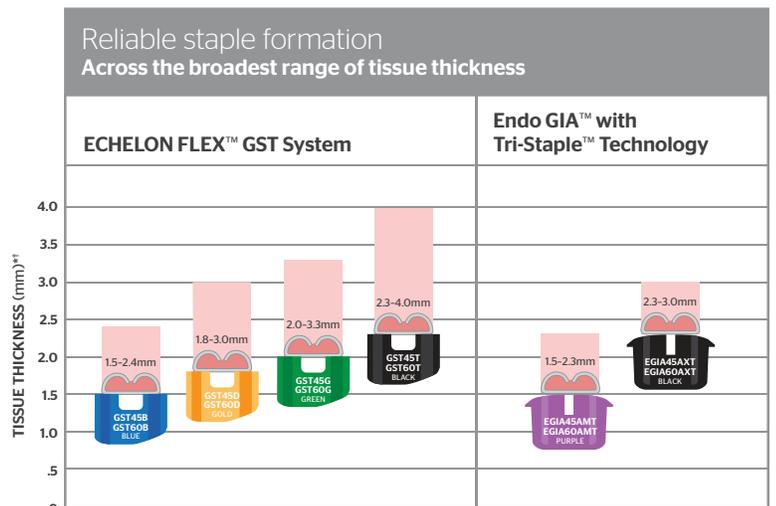
The ECHELON FLEX™ GST System¹¹ controls tissue movement to enable you to transect as you intend even on the most challenging tissue.

Superior staple line integrity

- Exceptional staple line integrity across the broadest range of tissue thicknesses¹²
- The ECHELON FLEX™ GST System provides the largest indicated range of tissue thickness to provide more confidence in revision surgery¹³
- Consistent compression and uniform staple heights optimize hemostasis and perfusion in targeted tissue¹⁴
- Enables surgeon choice with reload options designed to meet the specific needs of tissue

Improved outcomes

- ECHELON FLEX™ Powered Staplers are associated with fewer bleeding complications¹⁵ and reduced costs¹⁶ in bariatric procedures



* GST - Porcine tissue thickness measured at 8g/mm² prior to firing, tissue comfortably compressed to closed staple height during firing per IFU

† EGIA - Intended tissue thickness range per manufacturer IFU

¹¹ System components include ECHELON FLEX™ Powered Plus Stapler and ENDOPATH ECHELON™ Reloads with Gripping Surface Technology compared to Medtronic manual staplers. ¹² The ECHELON FLEX™ GST System was designed and tested to meet rigorous design requirements for staple line integrity. The GST System accommodates a tissue thickness range of 1.0mm to 4.0mm (measured at 8g/mm², tissue comfortably compressed to closed staple height during firing per IFU) while the Medtronic Tri-Staple™ portfolio is intended for a tissue thickness range of 0.75mm to 3.0mm (per IFU & materials downloaded from Medtronic website on Nov 16, 2016). ¹³ Porcine gastric tissue testing ¹⁴ Closed staple heights of ENDOPATH ECHELON™ Reloads with Gripping Surface Technology per the IFU compared to mean closed staple heights of Endo GIA™ Ultra Handle (EGIAUSTND) and Endo GIA™ Reloads with Tri-Staple™ Technology from benchtop firings in porcine stomach measured at specified tissue thicknesses, based on a minimum of 150 closed staple height measurements from each staple row: Green Reload with GST (GST60G) 2.0mm vs Tri-Staple Purple (EGIA60AMT) at 2.5mm tissue thickness; outer row 2.09mm, middle row 1.79mm, inner row 1.59mm and at 3.3mm tissue thickness; outer row 2.11mm, middle row 1.81mm, inner row 1.61mm. Black Reload with GST (GST60T) 2.3mm vs Tri-Staple Black (EGIA60AXT) at 2.5mm tissue thickness; outer row 2.24mm, middle row 2.03mm, inner row 1.93mm and at 4.0mm tissue thickness; outer row 2.29mm, middle row 2.08mm, inner row 1.99mm. (C1952) ¹⁵ Use of Ethicon powered staplers was associated with fewer bleeding/transfusion complications (1.61%) compared to Medtronic non-powered staplers (3.05%), p=0.010, in laparoscopic Sleeve Gastrectomy and Roux-en-Y Gastric Bypass procedures. Based on retrospective analysis of 21,466 cases from the Premier Perspective® Hospital Database. ¹⁶ Use of Ethicon powered staplers was associated with lower overall hospital costs (\$12,261) compared to Medtronic non-powered staplers (\$14,038), p=0.022, in laparoscopic Sleeve Gastrectomy and Roux-en-Y Gastric Bypass procedures. Based on retrospective analysis of 21,466 cases from the Premier Perspective® Hospital Database.

SURGICEL SNoW™ Absorbable Hemostat (for adjunctive use)

Enhanced speed, handling and performance¹⁷

Bariatric revision surgeries require flexible options to manage disruptive bleeding. Scarred, twice-impacted tissue bleeds more, impairing your vision and progress. It's critical to control continuous oozing without harming tissue to keep the surgical field as clear as possible.



SURGICEL SNoW™ Absorbable Hemostat (for adjunctive use) helps you focus on the procedure, not the bleed.

Faster time to hemostasis¹⁷

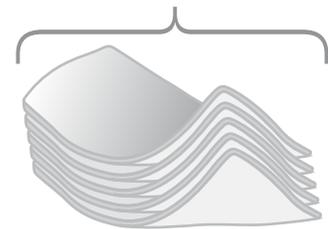
- Superior hemostasis compared to SURGICEL® Original Absorbable Hemostat (43% faster time to hemostasis [TTH]) with reproducible performance among specialties and procedures¹⁸
- One layer of SURGICEL SNoW Hemostat is more effective than 4 layers of SURGICEL Original Hemostat¹⁸



4x more effective¹⁸



SURGICEL SNoW™ Absorbable Hemostat



SURGICEL Original Absorbable Hemostat

Superior conformability and handling¹⁷

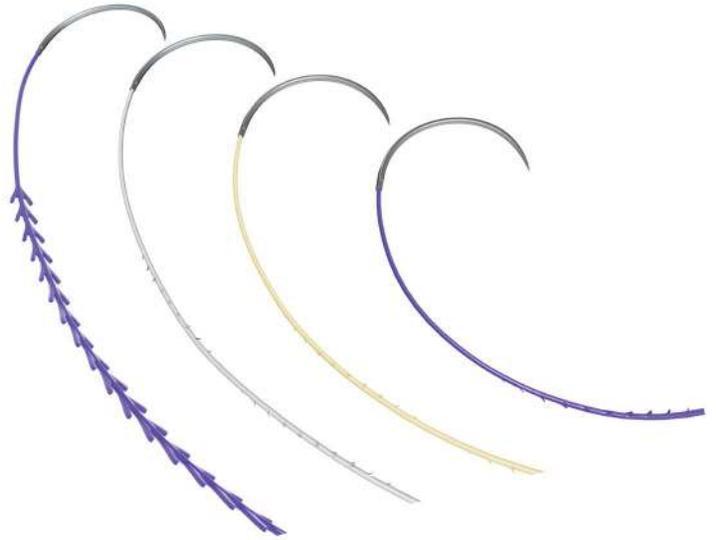
- Structured non-woven fabric conforms to irregular surfaces—provides optimal conformability and adherence to the bleeding site^{17,19}

STRATAFIX™ Knotless Tissue Control Devices

Efficient and secure without compromise

Suturing can be complicated in bariatric revision surgeries. You need a suture that's secure.

STRATAFIX™ Knotless Tissue Control Devices with antibacterial protection give surgeons more consistent control over every pass. They combine the strength and security of interrupted closure with the efficiency of continuous closure.

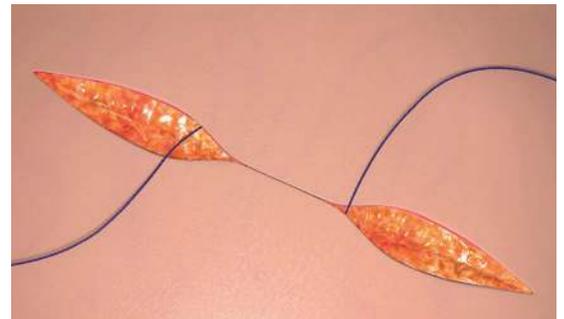


More security

- STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Devices and STRATAFIX™ Spiral PDO Knotless Tissue Control Devices provide 6 weeks of tissue support, while V-Loc™ 180 Absorbable Wound Closure Devices only provide 3 weeks^{20,21,22}

More consistency

- Compared with traditional sutures, STRATAFIX™ Knotless Tissue Control Devices help you easily manage tension and control approximation during closure^{23,24,25}
- STRATAFIX™ Spiral Knotless Tissue Control Devices pull through tissue easily, like traditional monofilament sutures, but provide the security of knotless tissue control devices^{23,30}



More efficiency

- Closure with STRATAFIX™ Knotless Tissue Control Devices is more efficient than continuous closure with traditional sutures because there is no need to tie knots or to have an assistant follow the suture^{23,28,31}

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

20 STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device Instructions for Use. Ethicon, Inc. **21** STRATAFIX™ Spiral PDO Knotless Tissue Control Device Instructions for Use. Ethicon, Inc. **22** V-Loc™ 180 Absorbable Wound Closure Device Instructions for Use. Medtronic. **23** Moran ME, Marsh C, Perrotti M. Bidirectional-barbed sutured knotless running anastomosis v classic Van Velthoven suturing in a model system. *J Endourol.* 2007;21(10):1175-1178. **24** Vakili JJ, O'Reilly MP, Sutter EG, Mears SC, Belkoff SM, Khanuja HS. Knee arthroscopy repair with a continuous barbed suture: a biomechanical study. *J Arthroplasty.* 2011;26(5):710-713. **25** Levine BR, Ting N, Della Valle CJ. Use of a barbed suture in the closure of hip and knee arthroplasty wounds. *Orthopedics.* 2011;34(9):e473-e475. doi: 10.3928/01477447-20110714-35. **26** For "pulls through tissue easily," this is based on the handling imparted by the design of the anchor and how it can collapse during passage through tissue. **27** Eickmann T, Quane E. Total knee arthroplasty closure with barbed sutures. *J Knee Surg.* 2010;23(3):163-167. **28** Einarsson JI, Chavan NR, Suzuki Y, Jonsdottir G, Vellinga TT, Greenberg JA. Use of bidirectional barbed suture in laparoscopic myomectomy: evaluation of perioperative outcomes, safety, and efficacy. *J Minim Invasive Gynecol.* 2011;18(1):92-95. **29** Data on file, Ethicon, Inc.: 100326296: Time Zero Tissue Holding - Competitive Claims Comparisons for STRATAFIX Knotless Tissue Control Devices vs Various Products. 2015. **30** Data on file, Ethicon, Inc. Ethicon study AST-2012-0331. Tissue gapping under tension of porcine cadaveric skin incisions closed with Stratafix Spiral in comparison to Monocryl in both interrupted and continuous stitching patterns. Approved on August 24, 2012. **31** Warner JP, Gutowski KA. Abdominoplasty with progressive tension closure using a barbed suture technique. *Aesthet Surg J.* 2009;29(3):221-225.

Ethicon Bariatric Revision Procedure Kit

Redefining success in bariatric surgery

Ethicon is committed to shaping the future of surgery in the fight against obesity and metabolic diseases. We are helping to elevate the standard of care with innovative products that not only provide predictable performance but also improve the OR experience.

The Bariatric Revision Procedure Kit increases efficiencies both before and during surgery.



Streamline inventory ordering and standardize procedure costs—all in one box with one SKU code



Reduce OR set-up time—increase efficiency from the very beginning



Experience fewer procedure interruptions because the right products are already pulled

Ethicon provides a comprehensive product solution for bariatric revision surgeries.

To learn more, contact your Ethicon sales representative.

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™ and SURGICEL® NU-KNIT® 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).

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.