Harmonic®

HEPATO-BILIARY SURGERY

HARMONIC® Technology in open surgery: **Superior clinical advantages** in hepatectomy

HARMONIC® Technology vs. Conventional techniques

HARMONIC® Technology has demonstrated significant benefits compared to conventional techniques in open hepatectomy procedures as shown in the following studies.

Reduced blood loss

55%
decrease[1]

Decreased intraoperative time

73
minutes[2]

Fewer complications

19%
reduction in complications[3]

Shorter length of stay

1.5
days[4]

Skeletonization and Isolation of the Glissonean and venous branches in liver surgery with an ultrasonic scalpel technology, Aoki T et al., *International Surgery* 2015;100:1048-1053

Key conclusions: The HARMONIC Scalpel group had less blood loss (389 versus 871 mL; p=0.034) and shorter total operative times (285 versus 358 minutes; p=0.01).[1,2]

A prospective randomized controlled trial: comparison of two different methods of hepatectomy, Hanyong S, et al., *European Journal of Surgical Oncology*, (2015) 243-248

Key conclusion: The postoperative complication rate was significantly higher in the Pringle maneuver group (41.3% versus 22.5% in the HARMONIC Scalpel group, $p < 0.05$).[3]

"Technological" approach versus clamp crushing technique for hepatic parenchymal transection: a comparative study, Aldrighetti L et al., *Journal of Gastrointestinal Surgery*, (2006) Vol(10), No.7

Key conclusion: Median hospital stay was 7 days (range, 5-53) in the HARMONIC Scalpel + Ultrasonic Dissector group and 8.5 (range, 5-60) in the conventional clamp crush group (p=0.02).[4]

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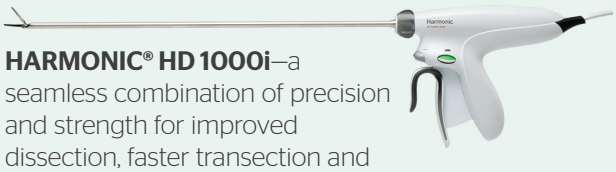
Shaping the future of surgery

HARMONIC® Technology: Committed to hepato-biliary procedures, dedicated to **flexible solutions** for treating advanced disease with less risk for complications[3,4]

Precise dissection with efficient sealing capability to minimize collateral damage

HARMONIC FOCUS®+ Long Shears with Adaptive Tissue Technology—brings greater efficiency to open procedures with an unparalleled level of access, visibility, controlled dissection and sealing consistency compared to traditional techniques[5]



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

Ethicon offers a **broad portfolio** that enables optimized hemostasis at every critical step.

Managing bleeding situations with adjunctive hemostats

SURGICEL® Family of Absorbable Hemostats—50-plus years of the proven safety and efficacy surgeons trust[6,7]

Confidently sealing difficult to access or fragile vessels and ducts

ETHICON ENDO-SURGERY™ Linear Cutter—designed to deliver optimal compression and superior hemostasis[8]

ECHELON FLEX™ GST System[9]—greater stability for potentially less tissue trauma

ECHELON FLEX™ Powered Vascular Stapler—enables the most precise placement on isolated fragile vessels

Secure closure that addresses risk factors associated with infection

STRATAFIX™ Knotless Tissue Control Devices—delivers more consistency, more security and more efficiency than traditional sutures[10,11,12,13,14,15,16]

DERMABOND® PRINEO® Skin Closure System—uncompromised strength and protection for excellent wound closure[17]

Learn more from 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.

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References:

1 In a clinical study comparing HARMONIC® ACE devices to conventional techniques (p=.001). Skeletonization and Isolation of the Glissonean and Venous Branches in Liver Surgery With an Ultrasonic Scalpel Technology. Aoki, Takeshi et al. Int Surg 2015; 100(6):1048-53 (C1927) **2** In a clinical study comparing HARMONIC® ACE devices to conventional techniques 285 min for HARMONIC® vs. 358 min for conventional (p=.001). Skeletonization and Isolation of the Glissonean and Venous Branches in Liver Surgery With an Ultrasonic Scalpel Technology. Aoki, Takeshi et. al, Int Surg 2015. 100(6):1048-53 (C1925) **3** Postoperative complication rate for HARMONIC® (22.5%) vs. Pringle maneuver (41.3%) (n=80/group; p<0.05). Hanyong S, et al. A prospective randomized controlled trial: Comparison of two different methods of hepatectomy. EJSO 41 (2015) 243-248. (C2005) **4** Ultrasonic dissector combined with Harmonic scalpel vs. clamp crush (n=100/group); 7 vs. 8.5 days, respectively (p=0.020). Aldrighetti L. "Technological" Approach Versus Clamp Crushing Technique for Hepatic Parenchymal Transection: A Comparative Study. J Gastrointest Surg. 2006 Jul-Aug;10(7):974-9. (C2002) **5** In a pre-clinical study, 100% (32/32) of porcine blood vessels remained hemostatic over a 30 day survival period. **6** A Compendium of Scientific Literature. Evidence Supporting the Efficacy and Safety of the Surgicel Family of Absorbable Hemostats **7** Hong Y, Loughlin K. The use of hemostatic agents and sealants in urology. J Urol. 2006;176:2367-2374. **8** Pre-clinical porcine study comparing the NTLC75, TLC75 and DST Series™ GIA™ 80 (3.8mm cartridge). Hemostasis was evaluated against a 5-point scale, with lower scores representing better hemostasis. Mean scores by instrument: NTLC-2.9, TLC-3.9, and DST Series GIA-3.6. The NTLC demonstrated superior hemostasis when compared to the TLC and DST Series GIA, p>0.05. **9** System components include ECHELON FLEX™ Powered Plus Stapler and ENDOPATH ECHELON™ Reloads with Gripping Surface Technology **10** Eickmann T, Quane E. Total knee arthroplasty closure with barbed sutures. J Knee Surg. 2010;23(3):163-167. **11** 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. **12** 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. **13** 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. **14** Rodeheaver GT, Pineros-Fernandez A, Salopek LS, et al., Barbed sutures for wound closure: in vivo wound security, tissue compatibility and cosmesis measurements. In: Transactions from the 30th Annual Meeting of the Society for Biomaterials; Mount Laurel, NJ; p. 232. **15** Vakil JJ, O'Reilly MP, Sutter EG, Mears SC, Belkoff SM, Khanuja HS. Knee arthrotomy repair with a continuous barbed suture: a biomechanical study. J Arthroplasty. 2011;26(5):710-713. **16** Warner JP, Gutowski KA. Abdominoplasty with progressive tension closure using a barbed suture technique. Aesthet Surg J. 2009;29(3):221-225. **17** Data on file, Ethicon, Inc.: DERMABOND PRINEO Skin Closure System Matrix. PRI-044-13. 2015.

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