THE VALUE

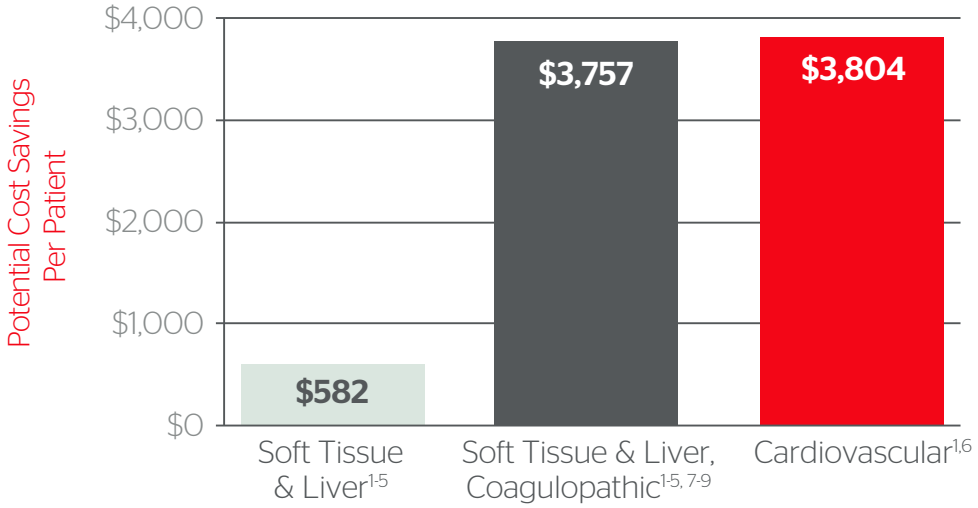
Clinically proven cost-effective data in problematic bleeding situations

Economic value based on superior hemostatic efficacy in clinical trials of EVARREST® Fibrin Sealant Patch versus conventional adjunctive hemostats or TachoSil® Fibrin Sealant Patch[1-6]

EVARREST demonstrated potential perioperative cost savings in indicated patients across a broad range of surgical procedures and specialties, including:

✓ Cardiovascular ✓ Oncology ✓ Trauma ✓ Urology/Gynecology ✓ General Surgery

POTENTIAL PERIOPERATIVE COST SAVINGS*



- 4-Trials, All Patients (n=400)
- 4-Trials, Coagulopathic Patients† (n=98)
- Cardiovascular Trial‡ (All Patients Anticoagulated) (n=156)

*Perioperative costs included operating time, retreatment, and transfusions.

†Patients potentially coagulopathic, defined by a coagulation parameter outside of normal reference range.

‡Cardiovascular surgery efficacy claims refer to a head-to-head study of EVARREST and TachoSil® Fibrin Sealant Patch.

EVARREST may reduce both perioperative and postoperative costs

Surgeons need an innovative solution that can achieve 1st-attempt efficacy to minimize the clinical and economic impact of problematic bleeding[10]

- Economic data was collected in 5 randomized, controlled clinical trials (n=556)[1-6]
- Even in challenging bleeding situations, EVARREST showed clinical superiority and potential cost savings over standard of care and TachoSil® Fibrin Sealant Patch[1-6‡]
- EVARREST demonstrated additional cost savings with postoperative costs such as length of hospital stay and ventilator use[1]

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

EVARREST® Fibrin Sealant Patch
IMPORTANT SAFETY INFORMATION

Indications and Usage

EVARREST® is a fibrin sealant patch indicated for use with manual compression as an adjunct to hemostasis in adult patients undergoing surgery, when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical.

Limitations for Use

- Cannot be used in place of sutures or other forms of mechanical ligation in the treatment of major arterial or venous bleeding.
- Not for use in children under one month of age.
- Laparoscopic and other minimally invasive surgeries where manual compression would be difficult to achieve.

Important Safety Information

For topical use only. Apply immediate manual compression over the entire surface of the patch and maintain contact pressure for 3 minutes to control the bleeding.

Do not apply intravascularly. This can result in life threatening thromboembolic events.

Do not use to treat bleeding from large defects in arteries or veins where the injured vascular wall requires conventional surgical repair and maintenance of vessel patency or where there would be persistent exposure of EVARREST® to blood flow and/or pressure during absorption of the product. Thrombosis can occur if absorbed systemically.

Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products. EVARREST ® can cause hypersensitivity reactions including anaphylaxis.

Avoid application to contaminated areas of the body or in the presence of active infection. Infection can occur.

EVARREST contains oxidized regenerated cellulose which adheres to bleeding surfaces. Inadvertent adhesions can occur.

Avoid use in, around, or in proximity to, foramina in bone or areas of bony confines where swelling may cause compression.

Use the least number of patches required to cover the entire bleeding area. Portions of excess patch material can become dislodged and migrate to other areas of the body.

Do not use more than eight 2x4 inch (5.1 x 10.2 cm) or more than four 4x4 inch (10.2 x 10.2 cm) patches.

Use in patients who have been previously exposed to EVARREST® has not been studied.

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 adverse reactions reported during clinical trials occurred in less than 1% of all cases and included deep venous thrombosis, pulmonary embolism, blood fibrinogen increase, anastomotic hemorrhage, post procedural and intra-abdominal hemorrhage, abdominal distension, anemia, gastrointestinal hemorrhage, thoracic cavity drainage, pleural effusion, abdominal abscess, ascites, localized intra-abdominal fluid collection, cardiac failure, operative hemorrhage, and ischemic bowel.

Pediatrics: Use in children under the age of one month may be unsafe or ineffective due to small size and limited ability to apply the patch as recommended.

Please see package insert for EVARREST® Full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact ETHICON Customer Support Center at 1-877-384-4266 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: **1.** Data on file. Ethicon Inc. EVARREST Economic Cost Analysis. Aug 2016. **2.** Fischer CP, Bochicchio G, Shen J, et al. A prospective, randomized, controlled trial of the efficacy and safety of fibrin pad as an adjunct to control soft tissue bleeding during abdominal, retroperitoneal, pelvic, and thoracic surgery. *J Am Coll Surg.* 2013;217(3):385-393. **3.** Koea JB, Batiller J, Patel B, et al. A phase III, randomized, controlled, superiority trial evaluating the fibrin pad versus standard of care in controlling parenchymal bleeding during elective hepatic surgery. *HPB.* 2013;15(1):61-70. **4.** Koea J, Baldwin P, Shen J, et al. Safety and hemostatic effectiveness of the fibrin pad for severe soft-tissue bleeding during abdominal, retroperitoneal, pelvic, and thoracic (non-cardiac) surgery: a randomized, controlled, superiority trial. *World J Surg.* 2015;39(11):2663–2669. **5.** Koea J, Batiller J, Aguirre N, Shen J, Kocharian R, Bochicchio G, Garden OJ. A multicentre, prospective, randomized, controlled trial comparing EVARREST fibrin sealant patch to standard of care in controlling bleeding following elective hepatectomy: anatomic versus non-anatomic resection. *HPB (Oxford).* 2016;18(3):221–228. **6.** Data on file. Ethicon Inc. Moainie SL, Chen E, Al-Attar N, Batiller J, Aguirre N, Kocharian R. EVARREST Fibrin Sealant Patch as a hemostatic adjunct in aortic reconstruction surgery. The Houston Aortic Symposium. Houston, Texas, March 2016. **7.** Prothrombin Time (PT). U.S. National Library of Medicine website. http://www.nlm.nih.gov/medlineplus/ency/article/003652.htm. Accessed September 13, 2016. **8.** Partial Thromboplastin Time (PTT). U.S. National Library of Medicine website. http://www.nlm.nih.gov/medlineplus/ency/article/003653.htm. Accessed September 13, 2016. **9.** Fibrinogen blood test. U.S. National Library of Medicine website. http://www.nlm.nih.gov/medlineplus/ency/article/003650.htm. Accessed September 13, 2016. **10.** Data on file. Ethicon, Inc. EVARREST® Fibrin Sealant Patch, Dossier.

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