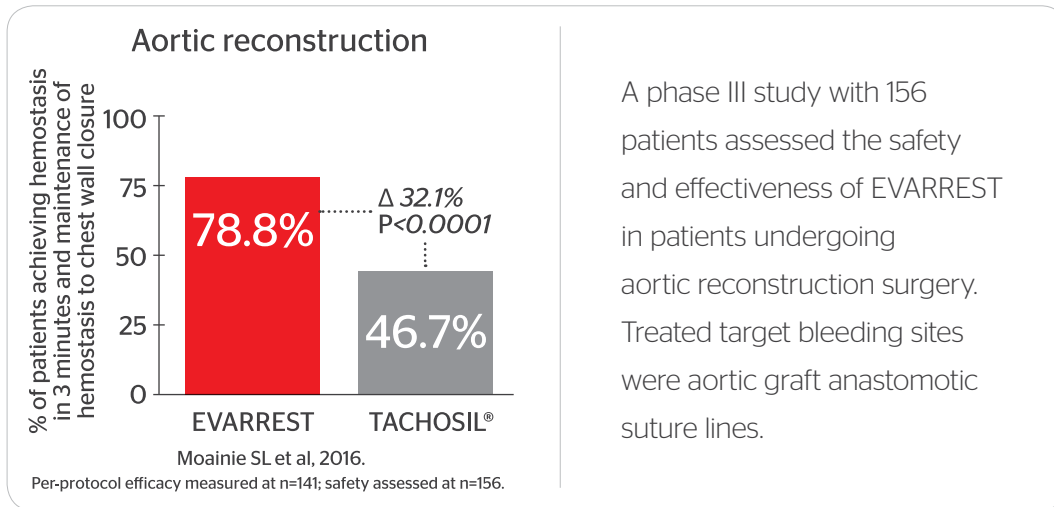




EVARREST® Fibrin Sealant Patch demonstrated superior hemostatic efficacy on the **1st attempt** in aortic reconstruction surgery¹



A phase III study with 156 patients assessed the safety and effectiveness of EVARREST in patients undergoing aortic reconstruction surgery. Treated target bleeding sites were aortic graft anastomotic suture lines.

The PP results are similar to the intention-to-treat results from the randomized controlled clinical trials. The PP results represent patients treated with no major violations to the clinical study protocol.

- EVARREST delivered positive results under the most challenging circumstances, such as application to a vascular prosthetic graft for hypothermic patients undergoing cardiopulmonary bypass surgery¹
- Studies demonstrated no increased risk of thromboembolic events in patients treated with EVARREST^{2,3}

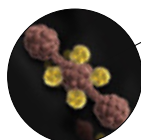
EVARREST was studied in the following cardiovascular procedures¹:

- ✓ Aortic aneurysm repair
- ✓ Aortic reconstruction
- ✓ Aortic valve and root repair

Disclaimer: The primary endpoints of these studies did not include an evaluation of the safety and efficacy of EVARREST in these specific procedures.



Combining thousands of woven fibers and active human biologics.¹⁴



EVARREST is ready to use, right out of the box⁴

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. 030813-161020

References: **1.** Moainie S, Chen E, Al-Attar N, et al. A phase III, randomized, controlled superiority trial evaluating EVARREST® Fibrin Sealant Patch versus Tachosil Fibrin Sealant Patch in controlling bleeding in aortic reconstruction surgery. Abstract presented at The Houston Aortic Symposium; March 3 - 5, 2016. **2.** Fischer CP, Bochicchio G, Shen J, Patel B, Batiller J, Hart JC. 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 (Oxford)*. 2013;15(1):61-70. **4.** EVARREST® Fibrin Sealant Patch [prescribing information]. Somerville, NJ: Ethicon, Inc.