

EVARREST™ Fibrin Sealant Patch

Important Safety Information

Indications and Usage

EVARREST™ Fibrin Sealant Patch is indicated for use with manual compression as an adjunct to hemostasis for soft tissue bleeding during open retroperitoneal, intra-abdominal, pelvic, and non-cardiac thoracic surgery when control of bleeding by standard surgical methods of hemostasis (e.g., suture, ligature, cautery) is ineffective or impractical.

Limitations for Use:

- Not for use in children under one month of age.
- Cannot safely or effectively be used in place of sutures or other forms of mechanical ligation in the treatment of major arterial or venous bleeding.

Important Safety Information

For topical use on soft tissue bleeding only. Do not apply intravascularly.

Do not use to treat bleeding from large defects in arteries or veins.

Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products.

Thrombosis can occur if absorbed systemically. Apply topically to soft tissue bleeding only.

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 closed spaces (e.g., in, around, or in proximity to, foramina in bone or areas of bony confine) where swelling may cause compression.

Use the least number of patches required to cover the entire bleeding area. 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 per single surgical procedure.

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 during clinical trials ($\geq 1\%$) were abdominal distension, blood fibrinogen increased, post procedural and intra-abdominal hemorrhage, and pulmonary embolism.

Please see package insert for EVARREST™ Full Prescribing Information.