Adjunctive Hemostats and Sealants

	Absorbable Adjunctive Hemostats			Biologically Active Absorbable Adjunctive Hemostats			Synthetic
	Gelatin/ Collagen	**ORC** (Oxidized Regenerated Cellulose)	**Hemostatic Powders**	**Flowable With Thrombin**	**Fibrin Sealant**	**Fibrin Patch**	**Vascular Sealants**
Ethicon	**SURGIFOAM®** Absorbable Gelatin Family 	**SURGICEL®** Family of Absorbable Hemostats 	**SURGICEL®** Powder Absorbable Hemostat 	**SURGIFLO®** Hemostatic Matrix Kit* 	**VISTASEAL™** Fibrin Sealant (Human) 	**EVARREST®** Fibrin Sealant Patch 	
Baxter				FLOSEAL Hemostatic Matrix	TISSEEL [Fibrin Sealant]	TACHOSIL® Fibrin Sealant Patch	COSEAL Surgical Sealant
Bard/BD	Avitene™ Microfibrillar Collagen Hemostat		Arista™ Absorbable Hemostatic Particles				
Other	Gelfoam® Absorbable Gelatin Powder and Pads Pfizer Inc.		Hemoblast Bellows Hemostatic Agent Biom'up	GEL-FLOW® Absorbable Gelatin Powder + JMI Thrombin Pfizer Inc.			BioGlue® Surgical Adhesive CryoLife

*When used with thrombin.

Product attributes sourced from the prescribing information for each product and not based on head-to-head studies.
Not intended to convey comparative safety or efficacy.
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SURGIFOAM® Essential Product Information

DESCRIPTION

SURGIFOAM® is a sterile, water-insoluble, malleable, porcine gelatin absorbable sponge or powder intended for hemostatic use by applying to a bleeding surface.

ACTIONS

When used in appropriate amounts, SURGIFOAM® is absorbed completely within 4 to 6 weeks. When applied to bleeding mucosal regions, it liquefies within 2 to 5 days.

INTENDED USE/INDICATION

SURGIFOAM®, used dry or saturated with sterile sodium chloride solution, is indicated for surgical procedures (except ophthalmic) for hemostasis, when control of capillary, venous and arteriolar bleeding by pressure, ligature and other conventional procedures is ineffective or impractical. Although not necessary, SURGIFOAM® can be used with thrombin to achieve hemostasis

CONTRAINDICATIONS

- Do not use SURGIFOAM® in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.
- Do not use SURGIFOAM® in intravascular compartments because of the risk of embolization. Do not use SURGIFOAM® in patients with known allergies to porcine collagen

WARNINGS

- SURGIFOAM® should not be used in the presence of infection and should be used with caution in contaminated areas of the body
- SURGIFOAM® should not be used in instances of pumping arterial hemorrhage
- SURGIFOAM® will not act as a tampon or plug in a bleeding site.
- SURGIFOAM® should be removed if possible once hemostasis has been achieved because of the possibility of dislodgment of the device or compression of other nearby anatomic structures.
- SURGIFOAM® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm.
- The safety and effectiveness of SURGIFOAM® for use in ophthalmic procedures have not been established.
- SURGIFOAM® should not be used for controlling post-partum bleeding or menorrhagia.
- The safety and effectiveness of SURGIFOAM® have not been established in children and pregnant women.

PRECAUTIONS

- Safe and effective use of this product has been reported in a published neurologic retrospective study involving 1700 cases in Europe. Safe and effective use has not been proven through randomized, controlled clinical studies in the United States.
- SURGIFOAM® is supplied as a sterile product and cannot be resterilized. When placed into cavities or closed tissue spaces, care should be exercised to avoid overpacking. SURGIFOAM® Sponge may swell to its original size on absorbing fluids, creating the potential for nerve damage.
- SURGIFOAM® should not be used for packing a cavity unless excess product not needed to maintain hemostasis is removed.
- Once hemostasis is achieved, any excess SURGIFOAM® should be carefully removed.
- SURGIFOAM® should not be used in conjunction with autologous blood salvage circuits.
- SURGIFOAM® should not be used in conjunction with methyl methacrylate adhesives. The safety and effectiveness for use in urological procedures have not been established through a randomized clinical study.
- In urological procedures, SURGIFOAM® should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

ADVERSE EVENTS

A total of 142 patients received SURGIFOAM® Gelatin Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge. In general, the following adverse events have been reported with the use of absorbable porcine gelatin-based hemostatic agents:

- Gelatin-based hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth.
- Giant cell granulomas have been observed at implant sites when used in the brain.
- Compression of the brain and spinal cord resulting from the accumulation of sterile fluid has been observed.
- Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminectomy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.
- The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations has been associated with fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence and paresis.
- The use of absorbable gelatin-based hemostatic agents has been associated with paralysis, due to device migration into foramina in the bone around the spinal cord, and blindness, due to device migration in the orbit of the eye, during lobectomy, laminectomy and repair of a frontal skull fracture and lacerated lobe.
- Foreign body reactions, “encapsulation” of fluid, and hematoma have been observed at implant sites.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
- Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostats in nasal surgery.
- Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

063763-161128

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™, SURGICEL® NU-KNIT®, and SURGICEL® SNoW™ Absorbable 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, such as encapsulation of the product, which may mimic artifacts on radiographic images, resulting in diagnostic errors and possible reoperation.

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 section of the complete product package insert).

• 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. For complete product information including indications, contraindications, warnings, precautions, and adverse reactions, please reference the individual product package inserts.

063768-200213

SURGICEL® Powder Absorbable Hemostat Essential Product Information

INDICATIONS

SURGICEL® Powder (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® Powder can also be applied in laparoscopic or other endoscopic procedures when used with the SURGICEL™ Endoscopic Applicator.

The SURGICEL™ Endoscopic Applicator is intended for use in delivering SURGICEL® Powder absorbable hemostat to bleeding surgical sites through a 5 mm or larger trocar.

CONTRAINDICATIONS

- Do not inject or place SURGICEL® Powder into an open blood vessel. Do not use to treat bleeding from large defects in arteries or veins.
- SURGICEL® Powder should not be used to control hemorrhage from large arteries or veins.
- The SURGICEL® Powder and the SURGICEL™ Endoscopic Applicator devices were not designed for intraluminal procedures.
- When SURGICEL® Powder is used to help achieve hemostasis in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, or the optic nerve and chiasm, it must always be removed after hemostasis is achieved since it will swell and could exert unwanted pressure.
- SURGICEL® Powder should not be used for implantation in bone defects, such as fractures, since there is a possibility of interference with callus formation and a theoretical chance of cyst formation.

WARNINGS

- SURGICEL® Powder is not intended for use on dry (non-bleeding) surfaces or for prevention of bleeding.
- Closing with SURGICEL® Powder in a contaminated wound without drainage may lead to complications and should be avoided.
- SURGICEL® Powder should not be impregnated with anti-infective agents or with other materials such as buffering or hemostatic substances.
- SURGICEL® Powder is dry and there may be difficulties in precise delivery under certain circumstances. Unintentional device placement may result in powder scattering and device migration that may increase the risk of adhesion formation. In preclinical in vivo animal studies it was demonstrated that SURGICEL® Powder does not increase the incidence of remote adhesions in laparoscopic procedures.
- Although SURGICEL® Powder is bactericidal against a wide range of pathogenic microorganisms, it is not intended as a substitute for systemically administered therapeutic or prophylactic antimicrobial agents to control or to prevent postoperative infections.
- To prevent clogging with the SURGICEL™ Endoscopic Applicator Tip, do not touch the tip to wet surface. Be careful to avoid damaging tissue with the rigid tip.
- Do not attempt to trim the applicator tip. Replace the tip if it becomes clogged.

PRECAUTIONS

- SURGICEL® Powder should not be used in conjunction with autologous blood salvage circuits, because its fragments may pass through the transfusion filters of blood-scavenging systems.
- Use only as much SURGICEL® Powder (oxidized regenerated cellulose) as is necessary and apply only where needed for hemostasis. Remove any excess before surgical closure in order to facilitate absorption and to minimize the possibility of foreign body reaction.
- Use minimal amount of SURGICEL® Powder required to achieve hemostasis, and remove excess powder in the area of drains to prevent clogging. In urological procedures, minimal amounts of SURGICEL® Powder 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® Powder could be prevented in chemically cauterized areas, its use should not be preceded by application of silver nitrate or any other escharotic chemicals.

SURGICEL® Powder Absorbable Hemostat Essential Product Information (cont'd)

- If SURGICEL® Powder is used temporarily to line the cavity of open wounds, it should be removed by irrigation with sterile water or saline solution after bleeding has stopped.
- Precautions should be taken in otorhinolaryngologic surgery to ensure that none of the material is aspirated by the patient (e.g., controlling hemorrhage after tonsillectomy and controlling epistaxis).
- The applicator tip provided on the SURGICEL® Powder device is not intended for laparoscopic or other endoscopic use. If laparoscopic or other endoscopic use is desired, remove the existing applicator tip from the SURGICEL® Powder device, and replace with the SURGICEL™ Endoscopic Applicator tip (supplied separately). In laparoscopic or other endoscopic procedures, SURGICEL® Powder should only be applied using the SURGICEL™ Endoscopic Applicator. Consult the SURGICEL™ Endoscopic Applicator Instructions for Use (IFU) for proper assembly and directions for use with the SURGICEL® Powder device.
- The SURGICEL Endoscopic Applicator is supplied with a flexible inner tip inside a rigid cannula. The rigid cannula cannot be used independently.
- The SURGICEL Endoscopic Applicator should only be used by persons having adequate training and familiarity with endoscopic techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any endoscopic procedure.
- To prevent inadvertent device spillage, or unintended contact with tissue, organs, or blood, maintain visualization of the SURGICEL™ Endoscopic Applicator tip at all times.
- Do not compress or excessively bend the flexible inner tip of the SURGICEL Endoscopic Applicator which could obstruct the application of the powder. It is possible that the powder accumulated in the applicator could disperse beyond the target bleeding site upon compression of the bellows, which may require additional irrigation and aspiration.

ADVERSE EVENTS

- Paralysis and nerve damage have been reported when other SURGICEL® products were 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 other SURGICEL® products were placed in the anterior cranial fossa (see WARNINGS and PRECAUTIONS).
- Foreign body reactions have been reported with other products from the SURGICEL® Family of Absorbable Hemostats.
- Burning has been reported when other SURGICEL® products were applied after nasal polyp removal. Headache, burning, stinging, and sneezing in epistaxis and other rhinological procedures, and stinging when SURGICEL® product was applied on surface wounds (varicose ulcerations, dermabrasions, and donor sites) have also been reported.
- For more information and technical questions, call 1-800-795-0012. For complete information including indications, contraindications, warnings, precautions, adverse reactions, and directions for use, consult the product package insert.

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

071582-190227

SURGIFLO® Hemostatic Matrix Kit Essential Product Information (Made from Absorbable Gelatin Sponge, USP) with Thrombin

DESCRIPTION

SURGIFLO® with Thrombin (SURGIFLO® Hemostatic Matrix Kit) is intended for hemostatic use by applying to a bleeding surface.

ACTIONS

When used in appropriate amounts SURGIFLO® is absorbed completely within 4 to 6 weeks.

INTENDED USE/INDICATIONS

SURGIFLO®, mixed with thrombin solution, is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.

CONTRAINDICATIONS

- Do not use SURGIFLO® in intravascular compartments because of the risk of embolization.
- Do not use SURGIFLO® in patients with known allergies to porcine gelatin.
- Do not use SURGIFLO® in closure of skin incisions because it may interfere with the healing of skin edges. This interference is due to mechanical interposition of gelatin and is not secondary to intrinsic interference with wound healing.

WARNINGS

- SURGIFLO® should not be used in the presence of infection and should be used with caution in contaminated areas of the body• SURGIFLO® should not be used in instances of pumping arterial hemorrhage. SURGIFLO® will not act as a tampon or plug in a bleeding site.
- SURGIFLO® should be removed from the site of application when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, and/or the optic nerve and chiasm because it may swell resulting in nerve damage.
- Excess SURGIFLO® should be removed once hemostasis has been achieved.
- The safety and effectiveness of SURGIFLO® for use in ophthalmic procedures has not been established.
- SURGIFLO® should not be used for controlling post-partum intrauterine bleeding or menorrhagia.
- The safety and effectiveness of SURGIFLO® has not been established in children and pregnant women.
- The blue flexible applicator tip should not be trimmed to avoid exposing internal guidewire.
- The white straight applicator tip should be trimmed away from the surgical area. Cut a square angle to avoid creating a sharp tip.

PRECAUTIONS

- Safe and effective use of SURGIFOAM® Sponge has been reported in a published neurologic retrospective study involving 1700 cases in Europe. Safe and effective use in neurosurgery has not been proven through randomized, controlled clinical studies in the United States.
- SURGIFLO® is supplied as a sterile product and cannot be resterilized.
- SURGIFLO® should not be used for packing unless excess product that is not needed to maintain hemostasis is removed. SURGIFLO® may swell up to 20% upon contact with additional fluid.
- SURGIFLO® should not be used in conjunction with autologous blood salvage circuits.
- SURGIFLO® should not be used in conjunction with methylmethacrylate adhesives.
- In urological procedures, SURGIFLO® should not be left in the renal pelvis or ureters to eliminate the potential foci for calculus formation.

ADVERSE EVENTS

A total of 142 patients received SURGIFOAM® Sponge during a clinical trial comparing SURGIFOAM® Sponge to another absorbable gelatin sponge. In general, the following adverse events have been reported with the use of absorbable porcine gelatin-based hemostatic agents:

SURGIFLO® Hemostatic Matrix Kit Essential Product Information (Made from Absorbable Gelatin Sponge, USP) with Thrombin (cont'd)

- Gelatin-based hemostatic agents may serve as a nidus for infection and abscess formation and have been reported to potentiate bacterial growth.
- Giant cell granulomas have been observed at implant sites when used in the brain.
- Compression of the brain and spinal cord resulting from the accumulation of sterile fluid have been observed.
- Multiple neurologic events were reported when absorbable gelatin-based hemostatic agents were used in laminectomy operations, including cauda equina syndrome, spinal stenosis, meningitis, arachnoiditis, headaches, paresthesias, pain, bladder and bowel dysfunction, and impotence.
- The use of absorbable gelatin-based hemostatic agents during the repair of dural defects associated with laminectomy and craniotomy operations, has been associated with fever, infection, leg paresthesias, neck and back pain, bladder and bowel incontinence, cauda equina syndrome, neurogenic bladder, impotence, and paresis.
- The use of absorbable gelatin-based hemostatic agents has been associated with paralysis, due to device migration into foramina in the bone around the spinal cord, and blindness, due to device migration in the orbit of the eye, during lobectomy, laminectomy, and repair of a frontal skull fracture and lacerated lobe.
- Foreign body reactions, "encapsulation" of fluid, and hematoma have been observed at implant sites.
- Excessive fibrosis and prolonged fixation of a tendon have been reported when absorbable gelatin-based sponges were used in severed tendon repair.
- Toxic shock syndrome was reported in association with the use of absorbable gelatin-based hemostats in nasal surgery.
- Fever, failure of absorption, and hearing loss have been observed when absorbable hemostatic agents were used during tympanoplasty.

EVITHROM® Thrombin, Topical (Human) for Topical Use Only
Lyophilized Powder for Solution

EVITHROM® is a topical thrombin indicated as an aid to hemostasis whenever oozing blood and minor bleeding from capillaries and small venules is accessible and control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

EVITHROM® may be used in conjunction with an Absorbable Gelatin Sponge, USP.

Important Safety Information

- For topical use only.
- Do not inject.
- Apply EVITHROM® on the surface of bleeding tissue only.
- The amount of EVITHROM® required depends upon the area of tissue to be treated and the method of application. In clinical studies, volumes up to 10 ml were used in conjunction with Absorbable Gelatin Sponge.
- Do not use for the treatment of severe or brisk arterial bleeding.
- Do not use in individuals known to have anaphylactic or severe systemic reaction to human blood products. Hypersensitivity reactions, including anaphylaxis, may occur.
- There is a potential risk of thrombosis if absorbed systemically.

SURGIFLO® Hemostatic Matrix Kit Essential Product Information (Made from Absorbable Gelatin Sponge, USP) with Thrombin (cont'd)

- May carry a risk of transmitting infectious agents such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite manufacturing steps designed to reduce the risk of viral transmission.
- The most common adverse reactions during clinical trial (reported in at least 2% of subjects treated with EVITHROM®) were prolonged activated partial thromboplastin time, increased INR, decreased lymphocyte count, prolonged prothrombin time and increased neutrophil count.
- None of the patients treated with EVITHROM developed antibodies to human thrombin or to human Factor V/Va. The clinical significance of these findings is unknown.

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

150669-200820

VISTASEAL™ Fibrin Sealant (Human) IMPORTANT SAFETY INFORMATION

INDICATION

VISTASEAL™ is indicated as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. VISTASEAL is effective in heparinized patients.

CONTRAINDICATIONS

Do not inject directly into the circulatory system.

Do not use for the treatment of severe or brisk arterial bleeding.

Do not use in patients with history of anaphylaxis or severe systemic reactions to human blood products.

Do not use VISTASEAL for spraying unless the minimum recommended distance from the applicator tip to the bleeding site can be achieved.

WARNINGS AND PRECAUTIONS

Thromboembolic events may occur if VISTASEAL is administered intravascularly.

Only spray VISTASEAL if it is possible to accurately judge the distance from the spray tip to the tissue surface.

Hypersensitivity reactions can occur.

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.

ADVERSE REACTIONS

The most common adverse reactions (reported in >1% of clinical trial subjects) were nausea and procedural pain.

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

115517-190529

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: Safety and effectiveness in pediatric patients have not been established. 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.

030813-171115

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