

PrTISSEEL (Fibrin Sealant (Human), Vapor Heated, Solvent/Detergent Treated)

Important Risk Information

Indications and Clinical Use:

TISSEEL (Fibrin Sealant (Human), Vapor Heated, Solvent Detergent Treated) is used in addition to standard measures, to achieve hemostasis, to seal or glue tissue, and to support wound healing.

Indications include: abdominal surgery, cardiovascular surgery, orthopedic surgery, thoracic surgery, urology

Geriatrics (>65 years of age): Efficacy and safety in use of Fibrin Sealant has been evaluated in clinical trial involving a number of geriatric patients. No overall differences in safety or effectiveness were observed between these subjects and younger subjects

Pediatric (1.1-16 years of age) or (<16 years of age): Efficacy and safety in use of Fibrin Sealant has been evaluated in a clinical trial involving also a group of pediatric patients and was not found to be different from an adult population

Contraindications:

- TISSEEL should not be used in individuals with a known hypersensitivity to Aprotinin
- Intravascular application
- Treatment of massive and brisk arterial or venous bleeding

Most Serious Warnings and Precautions:

- **Intravascular Coagulation:** Intravascular application of TISSEEL can lead to intravascular coagulation, may result in life threatening thromboembolic events.
- **Anaphylactic Reactions:** TISSEEL contains aprotinin, a monomeric polypeptide, which is known to be associated with anaphylactic reactions. In the event of hypersensitivity reactions, administration of TISSEEL is to be discontinued. If possible, remove any applied, polymerized product from the surgical site.
- **Air or gas embolism:** Caution must be used when applying fibrin sealant using pressurized air or gas. Life-threatening/fatal air or gas embolism has been related to the use of spray device at higher than recommended pressures and in close proximity to the tissue surface.
- **Protein Denaturation:** Solutions containing alcohol, iodine or heavy metals will interfere with the product performance.

Other Relevant Warnings and Precautions:

- TISSEEL is made from human plasma. It 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.
- Apply TISSEEL as a thin layer. Excessive thickness may interfere with the products efficacy and the wound healing process.
- In the submucous injection of fibrin sealant into hollow organs to stop GI-bleeding (stomach, duodenum), the following points are to be considered: Insertion of the needle into the organ wall may result in accidental perforation, which in rare cases may injure adjoining organs or vessels. Injection into the

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submucous membrane may cause a mechanical dissection between the tunica mucosa and the tunica muscularis propria, which in rare cases may lead to vessel injury or the formation of an intramural hematoma. Injection into the nasal mucosa must be avoided, as severe allergic-anaphylactoid reactions have been seen and thromboembolic events may occur.

- TISSEEL with the EasySpray Set must not be used in enclosed body areas.
- When spraying TISSEEL, changes in blood pressure, pulse, oxygen saturation and end tidal CO₂, should be monitored because of the possibility of occurrence of air or gas embolism.
- The safety and effectiveness of TISSEEL used alone or in combination with biocompatible carriers in neurosurgical procedures or other surgeries involving confined spaces have not been evaluated.

For more information:

Please consult the product monograph at

[http://www.baxter.ca/en_CA/assets/downloads/monographs/\(13\)Tisseel_EN.pdf](http://www.baxter.ca/en_CA/assets/downloads/monographs/(13)Tisseel_EN.pdf) for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece.

The product monograph is also available by calling us at 1-888-719-9955.
