**TISSEEL [Fibrin Sealant] Indications**

**Hemostasis:** TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in patients undergoing surgery when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. TISSEEL is effective in heparinized patients.

**Sealing:** TISSEEL is a fibrin sealant indicated as an adjunct to standard surgical techniques (such as suture and ligature) to prevent leakage from colonic anastomoses following the reversal of temporary colostomies.

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**Important Risk Information for TISSEEL**

For Topical Use Only. Do not inject TISSEEL directly into the circulatory system or into highly vascularized tissue. Intravascular application of TISSEEL can lead to intravascular coagulation, may result in life-threatening thromboembolic events, and may increase the likelihood and severity of acute hypersensitivity reactions in susceptible patients. Exercise caution to minimize the risk of intravascular application when using TISSEEL in surgery.

Do not use TISSEEL in individuals with a known hypersensitivity to aprotinin.

Do not use TISSEEL for the treatment of severe or brisk arterial or venous bleeding. In these situations, TISSEEL will be washed away in the flow of blood before hemostasis can be attained.

Hypersensitivity or allergic/anaphylactoid reactions may occur with the use of TISSEEL. Such reactions may especially be seen if TISSEEL is applied repeatedly over time or in the same setting, or if systemic aprotinin has been administered previously.

Aprotonin is known to be associated with anaphylactic reactions. Even in the case of strict local application of aprotinin, there is a risk of anaphylactic reactions to aprotinin, particularly in the case of previous exposure.

Discontinue administration of TISSEEL in the event of hypersensitivity reactions. Remove remaining product from the application site.

Air or gas embolism has occurred when fibrin sealant was administered using pressurized gas. This may occur if a spray device is used at higher than recommended pressures and in close proximity to the tissue surface.

When using the EASYSPRAY device, or an equivalent spray device for open surgical procedures cleared by FDA, TISSEEL must not be sprayed in enclosed body areas and must be sprayed onto only visible application sites.

TISSEEL is denatured when exposing to solutions containing alcohol, iodine or heavy metals. If any of these substances have been used to clean the wound area, the area must be thoroughly rinsed before the application of TISSEEL.

Apply TISSEEL as a thin layer by dripping or spraying using cannula or spray set. Excess clot thickness may negatively interfere with wound healing.

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; its use in this setting is not FDA approved.

TISSEEL is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Please see accompanying full Prescribing Information.