



TISSEEL

[Fibrin Sealant]

Proven Sealing. Easy To Use.*

* Available in a pre-filled, pre-mixed syringe

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.

For Topical Use Only

*Available in a pre-filled, pre-mixed syringe

Proven Sealing

Risks associated with anastomotic leakage:²

- Anastomotic dehiscence
- Intra-abdominal abscess formation
- Re-operation
- Septic shock

Why TISSEEL [Fibrin Sealant]?

In a prospective, randomized trial TISSEEL was shown to be an effective tool for sealing colonic anastomoses and for reducing the incidence of intra-abdominal abscesses and re-operation following the closure of temporary colostomies²

» **TISSEEL's MECHANISM OF ACTION:** upon mixing Sealer Protein (Human) and Thrombin (Human), soluble fibrinogen is transformed into fibrin, forming a rubber-like mass that adheres to the wound surface and achieves hemostasis and sealing or gluing of tissues¹

- Do not inject directly into the circulatory system; thromboembolic events can occur. Do not use in individuals with a known hypersensitivity to aprotinin. Apply only as a thin layer¹
- Do not use for the treatment of severe or brisk arterial bleeding¹

TISSEEL provides leakage prevention through reinforcement

TISSEEL application to prevent leakage from colonic anastomoses following the reversal of temporary colostomies.



Please see the detailed Important Risk Information on the back of this brochure and the enclosed Prescribing Information for full details.



Easy To Use

The DUPLOSPRAY MIS system allows efficient application over broad surfaces

- Air or gas embolism has occurred with the use of spray devices employing pressure regulator to administer fibrin sealants. This event appears to be related to use of the spray device at higher than recommended pressures and in close proximity to the tissue surface¹

Unique Safety Features

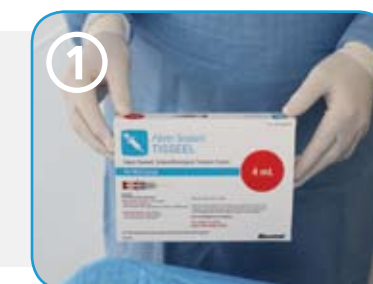
- Designed exclusively for use with CO₂ gas only – primary gas of choice to use in laparoscopic procedures
- Patient vent line – dynamically vents gas through the trocar vent valve, providing pressure stability during application
- Reduced gas flow rate – flow rate of DUPLOSPRAY MIS is approximately 2 L/min. Open gas spray systems (not designed for endoscopic use) can have flow rates as high as 20 L/min^{3,4}

High Performance*

- Thin, uniform spray enables consistent product utilization and broad area coverage.
- Rigid stainless steel cannula

*as compared to a manual spray device.

Easy as 1-2-3



For Topical Use Only



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TISSEEL
[Fibrin Sealant]

TISSEEL [Fibrin Sealant] Indications

Hemostasis: TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and treatment of blunt or penetrating splenic injuries when control of bleeding by conventional surgical techniques, including suture, ligature, and cautery, is ineffective or impractical. TISSEEL is a hemostatic agent that may be used in fully heparinized patients undergoing cardiopulmonary bypass.

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.

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. Caution should be exercised to minimize the risk of inadvertent intravascular application in cardiopulmonary bypass surgeries.

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. In specific cases, these reactions have progressed to severe anaphylaxis. Cases (less than one out of 10,000) have been reported in post marketing experience with 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. Even if the first treatment was well tolerated, this may not exclude the occurrence of an allergic reaction after a subsequent administration of TISSEEL or systemic aprotinin. Observed symptoms associated with allergic anaphylactic reactions to TISSEEL have included: bradycardia, tachycardia, hypotension, flushing, bronchospasm, wheezing, dyspnea, nausea, urticaria, angioedema, pruritus, erythema and paresthesia.

Aprotinin 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 with the use of spray devices employing a pressure regulator to administer fibrin sealants. This event appears to be related to use of the spray device at higher than recommended pressures and in close proximity to the tissue surface.

When applying TISSEEL using a spray device, be sure to use the pressure within the pressure range recommended by the spray device manufacturer. In the absence of a specific recommendation avoid using pressure above 20-25 psi. Do not spray closer than the distance recommended by the spray device manufacturer. In the absence of a specific recommendation avoid spraying closer than 10-15 cm from the surface of the tissue. 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. 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.

Exposure to solutions containing alcohol, iodine or heavy metals may cause TISSEEL to be denatured. 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. Excess clot thickness may delay the natural wound healing process.

The safety and effectiveness of the combined use of TISSEEL with other biocompatible materials has not been evaluated in controlled clinical trials. 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.

There have been reports of serious adverse events such as paralysis and other compressive complications possibly related to the use of fibrin sealant in combination with resorbable hemostatic agents.

Please see accompanying full Prescribing Information.

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For more information, contact your local sales representative or call 1-800-423-2090

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References:

1. TISSEEL [Fibrin Sealant] full Prescribing Information, 10/2010.
2. Schoemaker WC, Kram HB, Fleming AW. Randomized clinical trial of fibrin sealant in closure of temporary colostomies placed for trauma: effects on morbidity and mortality. Data on file, Baxter Healthcare Corporation, 1991:679-690.
3. DUPLOSPRAY MIS Instructions For Use; PN21281, Rev.A.
4. EASYSpray Set Instructions For Use; 62084006H07.

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