



TISSEEL

[Fibrin Sealant]

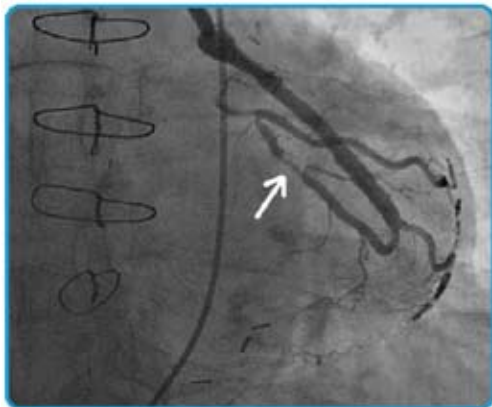
Proven Hemostasis.* Easy to Use.

Cases in Cardiovascular Surgery:

Redo CABG/Renal Insufficiency



*TISSEEL is indicated for adjunctive hemostasis in surgeries involving cardiopulmonary bypass



90% Stenosis of
Left Circumflex Artery

85 year-old patient presents with:

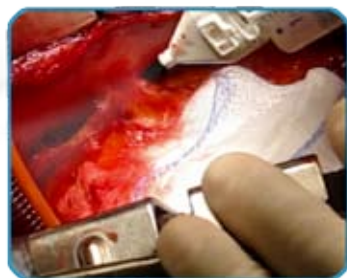
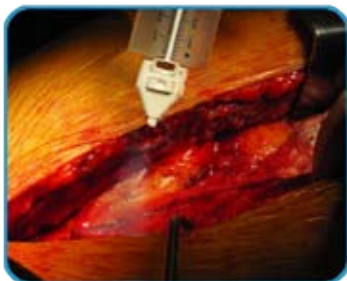
- History of previous CABG at 63 years-of-age for left coronary artery stenosis
- Complete occlusion of the posterior descending artery, 90% stenosis of left circumflex artery
- Severe aortic valve stenosis
- Renal Insufficiency

Operative Plan:

- Redo CABG using saphenous vein grafts
- Aortic valve replacement
- Fibrin sealant to control hemostasis

Why TISSEEL [Fibrin Sealant]?

- Proven efficacy in achieving adjunctive hemostasis in surgeries involving cardiopulmonary bypass¹⁻³
 - Statistically significantly superior to control topical hemostatic agents^{1,2}
 - Hemostasis achieved in 5 minutes and maintained until surgical closure^{1,3}
 - Satisfactory hemostatic agent in fully heparinized patients^{1,2}
 - 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
- Available in a prefilled (frozen) syringe for improved convenience
 - No mixing or reconstitution required
 - Improves speed to table
- EASYSpray Regulator allows efficient application over broad surfaces
 - 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.¹ Do not exceed pressure range of 1.5 - 2 bars (21.5 - 28.5 psi).⁴ To achieve an optimal result, a spraying distance of 10 - 15 cm is recommended. In specific situations where spraying less than 10 cm is necessary, the gas pressure must be reduced appropriately.⁴ DO NOT connect the spray set directly to the pressurized gas supply



For Topical Use Only

Please see reverse side for complete Important Risk Information

Baxter



TISSEEL

[Fibrin Sealant]

Reorder Number	Product Information
1501261	TISSEEL [Fibrin Sealant] Frozen, 2 mL
1501262	TISSEEL [Fibrin Sealant] Frozen, 4 mL
1501263	TISSEEL [Fibrin Sealant] Frozen, 10 mL
1501236	TISSEEL [Fibrin Sealant] Kit with DUPLOJECT System, 2 mL
1501237	TISSEEL [Fibrin Sealant] Kit with DUPLOJECT System, 4 mL
1501238	TISSEEL [Fibrin Sealant] Kit with DUPLOJECT System, 10 mL
0600065	EASYSpray Spray Set
0600012	EASYSpray Unit

TISSEEL [Fibrin Sealant] Indications and Usage

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

Sealing: TISSEEL is indicated as an adjunct 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. Intravascular application of TISSEEL may result in life-threatening thromboembolic events. Caution should be exercised to minimize any risk of inadvertent intravascular application.

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

Do not use TISSEEL for the treatment of severe or brisk arterial 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. Symptoms associated with allergic reactions include: flush, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnea, severe hypotension and anaphylactic shock. Such reactions may also occur in patients receiving TISSEEL for the first time.

Discontinue administration of TISSEEL in the event of hypersensitivity reactions.

Apply as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.

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 surface.

When applying fibrin sealants using a spray device, be sure to use the pressure within the pressure range recommended by the spray device manufacturer.

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.

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.

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.

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.

To order TISSEEL call 1-800-423-2090

www.baxterbiosurgery.com

References

1. TISSEEL [Fibrin Sealant] full Prescribing Information, 01/2010.
2. Rousou J, Gonzalez-Lavin L, Cosgrove D, et al. Randomized clinical trial of fibrin sealant in patients undergoing re sternotomy or reoperation after cardiac operations. *J Thorac Cardiovasc Surg.* 1989;97:194-203.
3. Lowe J, Luber J, Levitsky S, et al. Evaluation of the topical hemostatic efficacy and safety of Tisseel VH S/D fibrin sealant compared with currently licensed Tisseel VH in patients undergoing cardiac surgery: a phase 3, randomized, double-blind clinical study. *J Cardiovasc Surg.* 2007;48:323-31.
4. EasySpray Set Instructions for Use; 62084006H07.

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