



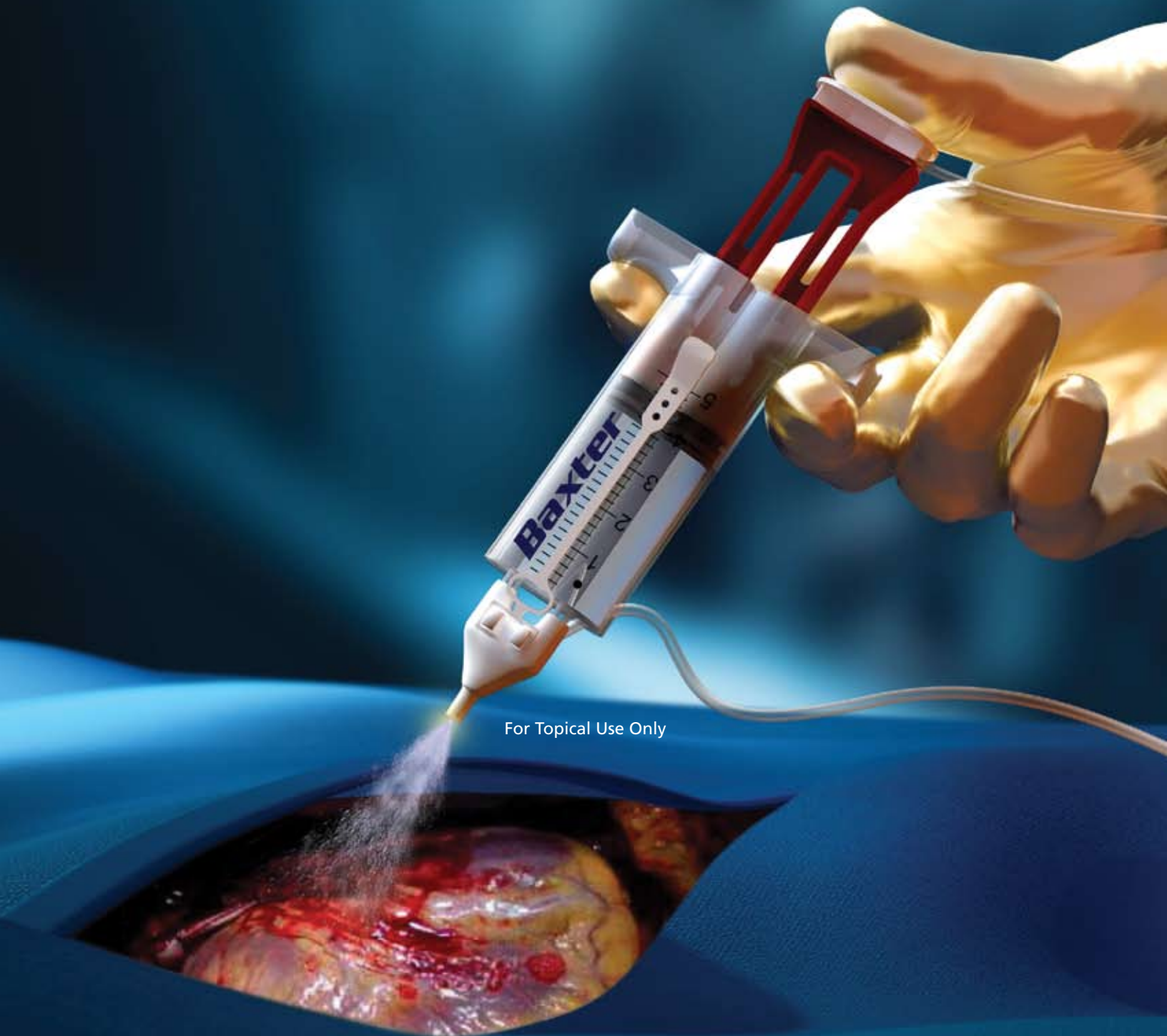
TISSEEL

[Fibrin Sealant]

Proven Hemostasis. Easy To Use.*

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

TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass.



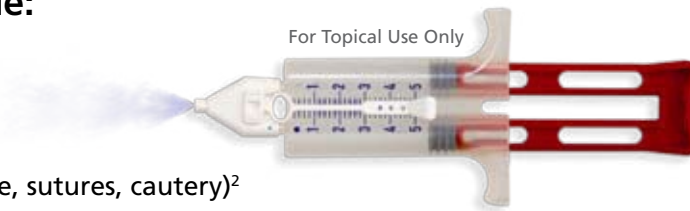
For Topical Use Only

DIFFUSE OOZING ACROSS BROAD, RAW SURFACES

Proven Hemostasis

Cardiac surgery is associated with significant blood loss.¹
Potential causes of blood loss may include:

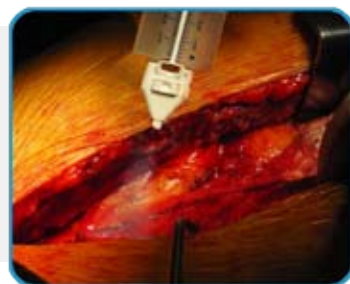
- Coagulopathy²
- Poor tissue characteristics (such as friable tissue)²
- Inaccessibility of bleeding sites to “surgical” control (ie, sutures, cautery)²
- Invasiveness of the procedure¹



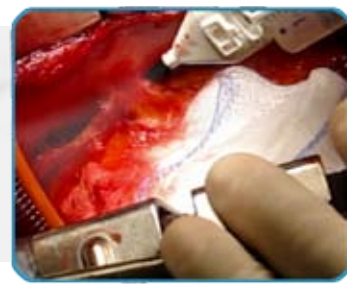
Proven efficacy in controlling hemostasis in surgeries involving cardiopulmonary bypass

- TISSEEL is indicated as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass, when control of bleeding by conventional surgical techniques, including suture, ligature, and cautery, is ineffective or impractical.
- Two pivotal studies with over 800 patients undergoing cardiac surgeries involving cardiopulmonary bypass demonstrated TISSEEL safely and effectively provided adjunctive hemostasis^{1,2}
- TISSEEL achieved hemostasis in 5 minutes and maintained until surgical closure^{1,3}
- TISSEEL was found to be a satisfactory hemostatic agent in fully heparinized patients undergoing cardiopulmonary bypass^{2,3}
- 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 layer³
- Do not use for the treatment of severe or brisk arterial bleeding³

TISSEEL provides hemostasis across broad, raw oozing surfaces



For Topical Use Only
Sternal Edge



Mammary Bed



Epicardium

Easy To Use

EASYSpray system allows efficient application over broad surfaces

- The EASYSpray regulator controls and releases pressurized gas provided by a propellant gas source
- Enables an aerosolized spray application at the control of the surgeon’s fingertips
- 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
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 appropriately⁴
DO NOT connect the spray set directly to the pressurized gas supply⁴

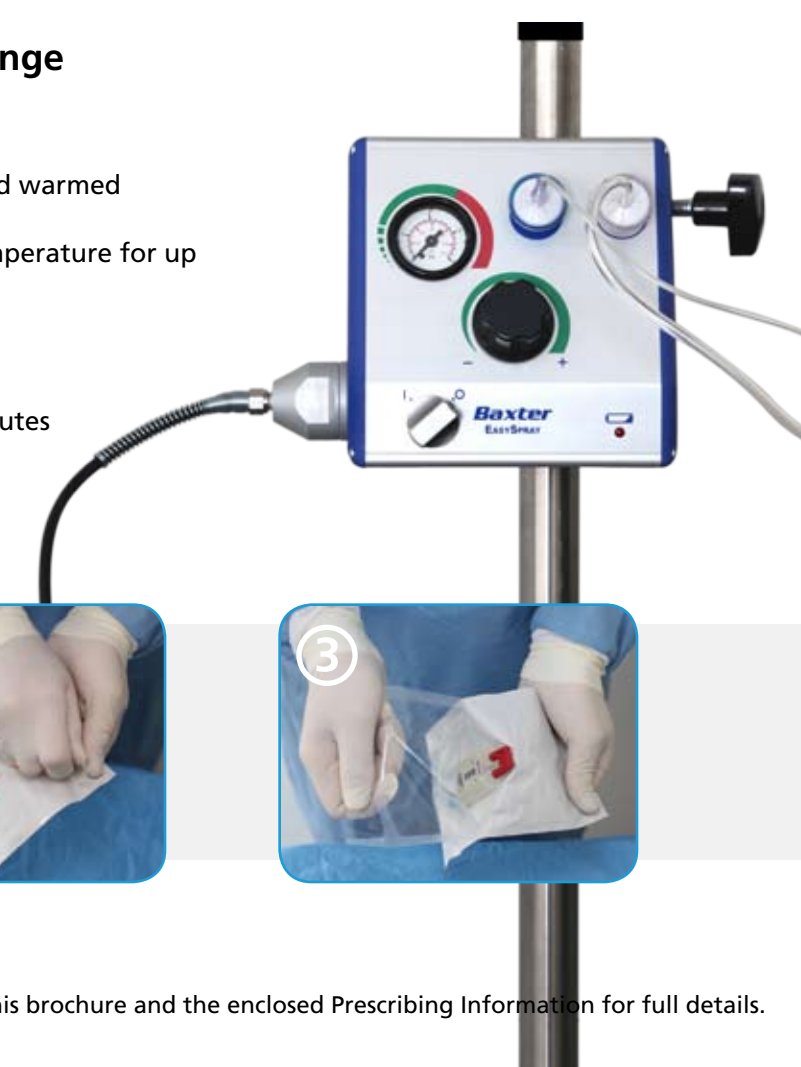
Available in a convenient pre-filled syringe

- No mixing or reconstitution required
- Do not use TISSEEL until it is completely thawed and warmed
- Thawed, unopened pouches are stable at room temperature for up to 48 hours after removal from freezer³
- Keep product 33°- 37°F until needed
- Once thawed, can be ready to use in just a few minutes

Easy as 1-2-3



For Topical Use Only





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.

www.baxterbiosurgery.com

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

Baxter, Tisseel, and Easyspray are trademarks of Baxter International, Inc.

References:

1. Lowe J, Luber J, Levitsky S, et al. Evaluation of the topical hemostatic efficacy and safety of TISSEEL VH SD 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.
2. Rousou J, Gonzalez-Lavin L, Cosgrove D, et al. Randomized clinical trial of fibrin sealant in patients undergoing resection or reoperation after cardiac operations. *J Thorac Cardiovasc Surg.* 1989;97:194-203.
3. TISSEEL [Fibrin Sealant] full Prescribing Information, 10/2010.
4. EASYSpray Set Instructions For Use; 62084006H07.

Baxter

Baxter International Inc.
One Baxter Parkway
Deerfield, Illinois 60015

www.baxter.com