



**TISSEEL**  
[Fibrin Sealant]

**EASY** as ① ② ③

# Premixed, Pre-filled, Preferred\*

(\*versus Lyophilized version of TISSEEL)



FOR TOPICAL USE ONLY



- **No reconstitution required**
- **Consistent product volume**
- **Consistent product formulation**

TISSEEL requires no preparation time after thawing the frozen pre-filled syringe, and warming between (33°C-37°C). Then, TISSEEL is ready when you need it - helping your team work more efficiently.

No more mixing, no more drawing up and no more vials. And it is compatible with the full line of application and delivery devices currently available for TISSEEL.

### **Important Risk Information for TISSEEL**

Do not expose to temperatures above 37°C.

Keep the product at 33°C-37°C until needed.

Do not microwave.

Do not refrigerate or re-freeze.

The application of TISSEEL must be completed within 4 hours of opening the pre-filled frozen syringe.

**Please see the TISSEEL Indications and full Important Risk Information on the back, and the accompanying full Prescribing Information for details.**



# TISSEEL

[Fibrin Sealant]

## TISSEEL [Fibrin Sealant] Indications

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.

TISSEEL has been shown to be an effective sealant as an adjunct in the closure of 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 rare 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.

| <b>Product</b>                         | <b>Codes</b>   |
|--|----------------|
| <b>TISSEEL [Fibrin Sealant] Frozen</b> |                |
| 2 mL                                   | 1501261        |
| 4 mL                                   | 1501262        |
| 10 mL                                  | 1501263        |
| <b>EASYSpray Pressure Regulator</b>    | <b>0600012</b> |
| <b>EASYSpray SET (case of 10)</b>      | <b>0600013</b> |

To order, call 1-800-423-2090  
[www.baxterbiosurgery.com](http://www.baxterbiosurgery.com)

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