



TISSEEL
[Fibrin Sealant]



Ready to use* Tisseel - Quick Reference Guide

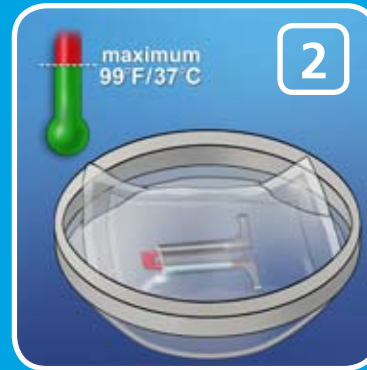
*3 Ways To Thaw The Frozen Pre-Filled Syringe | *Plan Ahead: Thaw up to 48 hours before use.



Thawing / warming - ON sterile field:
Thawing/warming times 33°C-37°C

- 2 mL in bath without pouch approximately 5 min.
- 4 mL in bath without pouch approximately 5 min.
- 10 mL in bath without pouch approximately 12 min.

(Ensure the contents of the syringe remain submerged throughout thawing.)



Thawing / warming - OFF sterile field:
Thawing/warming times 33°C-37°C

- 2 mL in bath with pouches approximately 30 min.
- 4 mL in bath with pouches approximately 40 min.
- 10 mL in bath with pouches approximately 80 min.

(Ensure the pouches remain submerged throughout thawing.)



Thawing / warming - OFF sterile field (Incubator):
Thawing/warming times 33°C-37°C

- 2 mL in pouches approximately 40 min.
- 4 mL in pouches approximately 85 min.
- 10 mL in pouches approximately 105 min.

DO NOT microwave.

Application of Tisseel must be completed within 4 hours after removal of protective caps on syringe hubs. Discard any unused product.

Product Storage



Long term: Store at $\leq -20^{\circ}\text{C}$
Short term: Thawed, unopened pouches may be stored for up to 48 hours at room temperature (15°C-25°C) after removal from the freezer.



If not used immediately:
Tisseel is stable after thawing for 48 hours at room temperature in the unopened, undamaged sterile pack. After 48 hours Tisseel cannot be used.



DO NOT REFRIGERATE.
Once thawed, DO NOT refrigerate or re-freeze. DO NOT expose to temperatures above 37°C. DO NOT use after the expiration date.



Quick Reference Guide

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.

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.

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

Use caution when applying with pressurized gas. Any application of pressurized gas may be associated with a potentially life-threatening risk of air embolism, tissue rupture or gas entrapment with compression.

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.

Please see accompanying full Prescribing Information

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For Tech Support Call:

1-877-TISSEEL

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select option #1