



TISSEEL [Fibrin Sealant]



Ready to use* TISSEEL [Fibrin Sealant] - 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.)



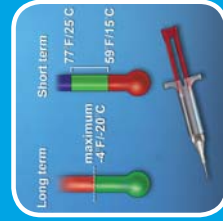
Thawing / warming - OFF sterile field (Incubator):
Thawing/warming times 33°C-37°C

- 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 [Fibrin Sealant] must be completed within 4 hours of warming to 33°C-37°C or opening the package. Discard any unused product.

Product Storage



Long term: Store at ≤ 20°C
Short term: 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 [Fibrin Sealant] total thawing and warming time cannot exceed 48 hours.
After 48 hours TISSEEL [Fibrin Sealant] 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.



TISSEEL [Fibrin Sealant] Indications

Hemostasis: TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in adult and pediatric patients (> 1 month of age) undergoing surgery when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. TISSEEL is effective in heparinized patients.

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 [Fibrin Sealant]

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, can result in life-threatening thromboembolic events, and can increase the likelihood and severity of acute hypersensitivity reactions in susceptible patients. To minimize the risk of intravascular application, exercise caution when using TISSEEL in surgery.

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

Do not use TISSEEL for 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.

Do not spray TISSEEL where the minimum recommended distance from the applicator tip to the target site cannot be assured.

Hypersensitivity or allergic/anaphylactoid reactions can occur with the use of 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.

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 when fibrin sealant was administered using pressurized gas. This can occur if a spray device is used at higher than recommended pressures and in closer than recommended proximity to the tissue surface.

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.

TISSEEL is denatured when exposing to solutions containing alcohol, iodine or heavy metals. 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 by dripping or spraying using cannula or spray set. Excess clot thickness can negatively interfere with wound healing.

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, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Please see accompanying full Prescribing Information.

The information here is taken from the TISSEEL [Fibrin Sealant] full Prescribing Information.

For Tech Support Call 1-888-229-0001

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