



TISSEEL

[Fibrin Sealant]

Ready to use* TISSEEL [Fibrin Sealant] Quick Reference Guide



***3 Ways to Thaw The Frozen Pre-Filled PRIMA Syringe. | *Plan Ahead: Thaw up to 72 hours at room temperature before use.**



Thawing / warming - ON sterile field:

Thawing/warming times 33°-37°C

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

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



Thawing / warming - OFF sterile field:

Thawing/warming times 33°-37°C

- 2 mL in bath with pouches approximately 15 mins.
- 4 mL in bath with pouches approximately 20 mins.
- 10 mL in bath with pouches approximately 35 mins.

(Ensure the pouches remain submerged throughout thawing.)



Thawing / warming - OFF sterile field (Incubator):

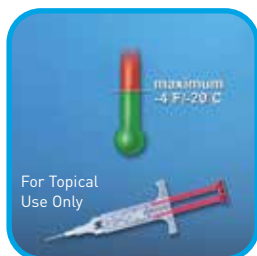
Thawing/warming times 33°-37°C

- 2 mL in pouches approximately 40 mins.
- 4 mL in pouches approximately 50 mins.
- 10 mL in pouches approximately 90 mins.

DO NOT microwave.

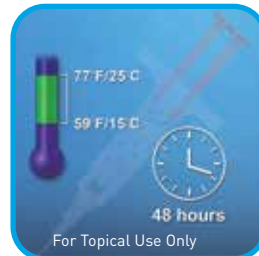
Application of TISSEEL [Fibrin Sealant] must be completed within 12 hours of warming to 33°C-37°C. Discard any unused product.

Product Storage



Long term: Store at <-20°C

Short term: Unopened pouches may be stored for up to 72 hours at room temperature (15°C-25°C) after removal from the freezer. Prior to application, the product must be warmed to 33-37°C.



If not used immediately:

TISSEEL [Fibrin Sealant] total thawing time cannot exceed 72 hours. After 72 hours TISSEEL [Fibrin Sealant] cannot be used. Prior to application, the product must be warmed to 33-37°C. TISSEEL [Fibrin Sealant] can be used for up to 12 hours at 33°C to 37°C.



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.

Please see Important Risk Information on reverse.

Baxter



TISSEEL

[Fibrin Sealant]

TISSEEL [Fibrin Sealant] Indications

Supportive treatment where standard surgical techniques appear insufficient

- For improvement of haemostasis
- As a tissue glue to improve wound healing or to support sutures
- For tissue sealing, to improve adhesion of the separated tissue

The efficacy in fully heparinised patients has been proven. The use of TISSEEL is restricted to experienced surgeons who have been trained in the use of TISSEEL.

For epislesional use only.

Contraindications:

- TISSEEL alone is not indicated for the treatment of massive or brisk arterial or venous bleeding
- TISSEEL is not indicated to replace skin sutures intended to close surgical wounds
- TISSEEL must never be applied intravascularly. Intravascular application may result in life-threatening thromboembolic events
- TISSEEL must not be applied in case of hypersensitivity to the active substances or to any of the excipients
Special warnings and precautions for use.
- Do not apply intravascularly
- Life-threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly
- Caution must be used when applying fibrin sealant using pressurised gas

- Any application of pressurised gas is associated with a potential risk of air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life-threatening
- Apply TISSEEL as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process
- Life-threatening/fatal 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 the use of the spray device at higher than recommended pressures and/or in close proximity to the tissue surface. The risk appears to be higher when fibrin sealants are sprayed with air, as compared to CO2 and therefore cannot be excluded with TISSEEL when sprayed in open wound surgery
- When applying TISSEEL using a spray device, be sure to use a pressure within the pressure range recommended by the spray device manufacturer
- TISSEEL spray application should only be used if it is possible to accurately judge the spray distance as recommended by the manufacturer. Do not spray closer than the recommended distances
- 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 Reporting of suspected adverse reactions. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via your national reporting system.

For Posology, method of administration, incompatibilities, interactions and undesirable effects, please refer to the full SPC.

Medicinal products are subject to medical subscription. In some countries TISSEEL [Fibrin Sealant] is licensed under the trademark TISSUCOL Fibrin Sealant.

Rx Only: For safe and proper use of the DUPLOSPRAY device, please refer to the full Instructions for Use.

This abbreviated summary of product characteristics (SPC) is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet.

Ordering Information

For more information or a demonstration of TISSEEL, please see your Baxter Sales Representative.

| Description | Product Code | |
|-----------------------------|--------------|-----|
| TISSEEL PRIMA Syringe, 2ml | 1506078 | NEW |
| TISSEEL PRIMA Syringe, 4ml | 1506079 | NEW |
| TISSEEL PRIMA Syringe, 10ml | 1506080 | NEW |

This quick reference guide is intended to provide an overview of select preparation steps. For complete instructions, refer to the Summary for Product Characteristics.

Baxter

Baxter International, Inc.
One Baxter Parkway
Deerfield, Illinois 60015
USA

www.baxter.com