

Tisseel

FIBRIN SEALANT

Ready to use*

TISSEEL [Fibrin Sealant]

Quick Reference Guide



*2 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 (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 $\leq -20^{\circ}\text{C}$

Short term:

Unopened pouches may be stored for up to 72 hours at room temperature (not more than 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.

72 hours after thawing, Tisseel [Fibrin Sealant] must be disposed of.



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.

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PRESCRIBING INFORMATION - TISSEEL Ready to use Solutions for Sealant (Please consult the Summary of Product Characteristics before prescribing)

Composition: prefilled double chamber syringe containing deep frozen Sealer Protein Solution (with aprotinin) and Thrombin Solution (with Calcium Chloride Dihydrate). Sealer Protein Solution contains 91mg/ml human fibrinogen (clottable protein) and 3000 KIU/ml aprotinin. Thrombin Solution contains 500 IU/ml human thrombin and 40µmol per ml calcium chloride. Presentations of 1, 2 or 5ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of sealant. **Indications:** Supportive treatment where standard surgical techniques are insufficient, for improvement of haemostasis, as a tissue glue to promote adhesion, sealing or as suture support, in gastrointestinal anastomoses, in neurosurgery where contact with cerebrospinal fluid or dura mater may occur and for mesh fixation in hernia repair, as an alternative or adjunct to sutures or staples. **Dosage and Route:** For epilesional (topical) use only. Use of TISSEEL is restricted to experienced surgeons who have been trained in the use of TISSEEL. A thin layer is applied under direct vision to the tissue surface where required. Dose depends on the indication, application method and number of applications. For tissue adherence, it is recommended that the initial application cover the entire intended application area. As a guideline for the gluing of surfaces, 1 pack of TISSEEL 2 ml will be sufficient for an area of at least 10 cm². Tissue surface should be as dry as possible before application. Do not use pressurized air or gas for drying the site. Application can be repeated if necessary but avoid reapplication of TISSEEL to pre-existing polymerized TISSEEL. Apply by drops or spray as needed depending on indication. **Side effects:** See Summary of Product Characteristics for detail. Postoperative wound infections. Fibrin degradation products increased. Hypersensitivity/anaphylactic reactions, anaphylactic shock, paresthesia, bronchospasm, wheezing, pruritus, erythema. Sensory disturbance. Bradycardia, tachycardia. Axillary vein thrombosis, hypotension, haematoma, embolism arterial, air embolism, cerebral artery embolism, cerebral infarction. Dyspnoea. Nausea, Intestinal obstruction. Rash, urticaria, impaired healing. Pain in an extremity. Procedural pain, pain, increased body temperature, flushing, oedema. Seroma, angioedema. **Class reaction:** Air or gas embolism, see Precautions. **Precautions:** Life threatening thromboembolic complications may occur if unintentionally applied intravascularly. Apply with care in coronary artery bypass surgery due to increased risk of inadvertent intravascular application. Must not be injected into highly vascularized tissue, such as nasal mucosa. 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. Air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life-threatening, have occurred with the use of spray devices employing a pressure regulator to administer fibrin sealant at higher than recommended pressures and in close proximity to the tissue surface. When applying by spray, follow the instructions provided with the spray device, with particular reference to gas pressure and distance from the tissue surface. Do not administer with spray devices in enclosed body areas. Take risk of compressive complications into account when applying in confined spaces. Use with caution in patients with prior exposure to aprotinin. Caution in patients with bovine protein allergies. Infectious diseases due to the transmission of infective agents cannot be totally excluded. Use of Tisseel and batch number should be recorded in patient's notes. Excessive clot thickness may negatively interfere with product efficacy and the healing process. Oxidised cellulose-containing preparations should not be used with TISSEEL. **Contraindications:** Do not apply intravascularly. Hypersensitivity to active substances or other components. Not for the treatment of active or spurting arterial or venous bleeding. Not for replacement of skin sutures intended to close surgical wounds. **Interactions:** Avoid solutions containing alcohol, iodine and heavy metals. **Overdose:** Not reported. **Legal category:** POM. **Basic NHS price:** 2ml - £97.50; 4ml - £195.00; 10ml - £443.75. **Marketing Authorisation Number and Holder:** PL 00116/0627 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, UK. **Date of preparation:** Jan 2019

Adverse Events and any suspected defective medicines should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse Events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on +44 (0)1635 206360, or by email to vigilanceuk@baxter.com

Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com.

Alternatively please report directly to your Baxter Representative, who will take the details and forward to the Baxter Country Quality Assurance Team.

Ordering Information

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

Description	Product Code
TISSEEL PRIMA Syringe, 2ml	5500387
TISSEEL PRIMA Syringe, 4ml	5500388
TISSEEL PRIMA Syringe, 10ml	5500389

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

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Baxter Healthcare Ltd.,
Wallingford Road,
Compton,
Newbury
RG20 7QW