TISSEEL
[Fibrin Sealant]

New Zealand Customer Support Website
https://www.baxterprofessional.co.nz/as-product-guides

VISIT NZ SITE

INDICATIONS[1]:

- An adjunct to haemostasis during surgical procedures, when control of bleeding by conventional surgical techniques is ineffective or impractical
- As a sealant as an adjunct for closure of colostomies
- As a sealant and/or adhesive for use in autologous chondrocyte implantation (ACI) or matrix-induced autologous chondrocyte implantation (MACI) procedures
- For mesh fixation in inguinal, femoral and incisional hernia repair, as an alternative or adjunct to sutures, staples or tacks.

WHEN TO USE

- **Diffuse oozing as a haemostat**
- For mesh fixation in inguinal, femoral and incisional hernia repair, as an alternative or adjunct to sutures, staples or tacks.

WHY USE

- Stop **diffuse** bleeding.
- Adhere hernia mesh. Can be used as an alternative to tacks

WHO PREPARES

- Scrub (Sterile)- **Thawed at room temperature** and immerse Tisseel in 37°C sterile water or saline container and connect selected applicator.

HOW IT WORKS

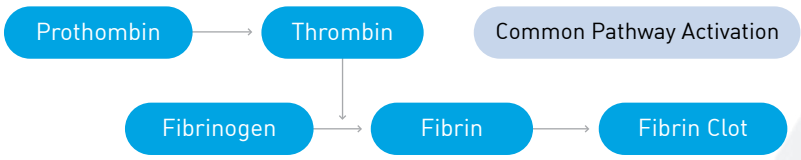
- **Fibrinogen** and **thrombin** polyermerise and form a stable fibrin clot. **Mimics final stage** of the clotting cascade

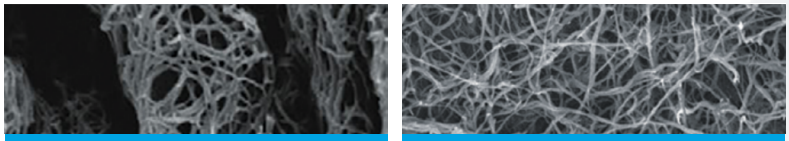
- Once thawed TISSEEL may be used for up to 72 hours if stored at 25°C or below
- On the sterile field TISSEEL must be used within 4 hours
- TISSEEL is totally absorbed in 7-10 days[3]

MECHANISM OF ACTION:

TISSEEL Clot is Similar to Physiological Clot[1,3,4]

Upon mixing Sealer Protein (human) and Thrombin (human), soluble fibrinogen is transformed into fibrin, that polymerises into a net-like matrix and firmly adheres to exposed collagen[3]. This **achieves haemostasis** and or **gluing of tissue**.





Normal fibrin clot without TISSEEL | Fibrin clot with TISSEEL

Tisseel clot similar to the Physiological clot[1,3,4]

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[Fibrin Sealant]

ORDERING INFORMATION

Description	Qty	Order Code	Rebate Code
Tisseel PRIMA VHSD Synthetic Aprotinin 2mL	1 Each	5500378	BX214
Tisseel PRIMA VHSD Synthetic Aprotinin 4mL	1 Each	5500379	BX215
Tisseel PRIMA VHSD Synthetic Aprotinin 10mL	1 Each	5500380	BX216

Please see Applicator Catalogue for Applicator options or contact your Sales Representative

References:
1. Tisseel VH S/D Product Information, Apr 2019
2. Sierra DH. Fibrin sealant adhesive systems: a review of their chemistry, material properties and clinical applications. J Biomater Appl. 1993;7:309-352
3. Seelich T.J. Tissucol: Biochemistry & Methods of Application. J. Head & Neck Pathol. 1982; 3:65-70
4. Baxter Healthcare Corporation. How TISSEEL works. http://www.tisseel.com/us/tisseel_performance_how_tisseel_works.html. Accessed March 1, 2018.

TISSEEL [Fibrin Sealant] Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated, TISSEEL VH S/D. **INDICATIONS: (NZ) TISSEEL** is indicated as adjunct to haemostasis during surgical procedures, when control of bleeding by conventional surgical techniques is ineffective or impractical: and as a sealant as an adjunct for closure of colostomies: as a sealant and/or adhesive for use in autologous chondrocyte implantation (ACI) or matrix-induced autologous chondrocyte implantation (MACI) procedures: for mesh fixation in inguinal, femoral and incisional hernia repair, as an alternative or adjunct to sutures, staples or tacks. CONTRAINDICATIONS Known hypersensitivity to aprotinin or any other component of TISSEEL. Injection of TISSEEL into tissues is contraindicated. Such use has been associated with inadvertent intravascular injection which may result in life-threatening thromboembolic complications, can lead to intravascular coagulation which may increase likelihood and severity of acute hypersensitivity reactions in susceptible patients. TISSEEL should be applied with caution to minimise any risk of intravascular application, for example in coronary bypass surgery. TISSEEL should only be applied topically. Soft tissue injection of TISSEEL carries the risk of an anaphylactic reaction and/or local tissue damage. PRECAUTIONS Viral and prion risk due to human plasma derived sealer protein concentrate and thrombin. Products made from human plasma may contain infectious agents which can cause disease. Standard measures are taken to prevent infection but when medicinal products are prepared from human blood or plasma, the possibility of transmitting infective agents cannot be totally excluded and this also applies to unknown or emerging viruses and other pathogens. Administration of TISSEEL may result in allergic reactions. For patients with a known allergic diathesis, history of hypersensitivity to medical products or has previously received aprotinin-containing products (including previous use of TISSEEL) a careful risk-benefit assessment should be carried out prior to administration. Risk of immunisation against proteins such as aprotinin is increased if repeated exposure occurs within six months. TISSEEL contains synthetic aprotinin which is structurally identical to bovine aprotonin so use in patients with allergies to bovine proteins should be carefully evaluated. Life threatening air or gas embolism, tissue rupture, or gas entrapment with compression have occurred with the use of spray devices employing a pressure regulator to administer TISSEEL, relating to the use of spray devices at higher than recommended pressures and/or in close proximity to the tissue surface. The risk appears to be higher when Tisseel is sprayed with air, compared to CO2 and therefore cannot be excluded with Tisseel when sprayed in open wound surgery. TISSEEL alone is not indicated for severe or brisk arterial or venous bleeding. Should not be used for sealing neuroanastomoses. Do not inject into nasal mucosa. TISSEEL alone is not indicated for the treatment of massive and brisk arterial or venous bleeding. If fibrin sealants are applied in confined bodily spaces, the risk of compressive complications should be taken into account. INTERACTIONS/INCOMPATIBILITIES: There are no known interactions between TISSEEL and other drugs. Efficacy has been demonstrated in fully heparinised patients undergoing cardiopulmonary bypass. Solutions containing alcohol, iodine or heavy metals (e.g. disinfectants) or any such substance should be thoroughly rinsed off wound area before TISSEEL application. Oxidised cellulose-containing preparations may reduce the efficacy of TISSEEL and should not be used as carrier material. Do not mix TISSEEL with other medicinal products. ADVERSE EFFECTS: Anaphylactic and anaphylactoid reactions may occur in patients who have previously received a fibrin-based sealant, in those with a known hypersensitivity to aprotinin and those who have previously received aprotinin systemically. Even if the second treatment with TISSEEL was well tolerated, a subsequent administration of TISSEEL or systemic administration of aprotinin may result in severe anaphylactic reactions. Symptoms associated with allergic/anaphylactic reactions include flushing, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnoea, severe hypotension, and anaphylactic shock. In the event of hypersensitivity reactions, administration of TISSEEL should be discontinued, the topical clot removed, and appropriate treatment instituted. In rare cases, these reactions may also occur in patients receiving aprotinin or TISSEEL for the very first time. Common adverse reactions in clinical trial: fibrin degradation products increased,post-procedural pain. Fibrin sealant/haemostatic class reactions: manifestations of hypersensitivity such as application site irritation, chest discomfort, chills, headache lethargy, restlessness, vomiting. DOSAGE AND METHOD OF USE - TISSEEL should only be administered topically. Do not inject. Tisseel must not be applied intravascularly. See full PI. NAME AND ADDRESS SPONSOR- Baxter Healthcare Pty Ltd, 1 Baxter Drive, Old Toongabbie, NSW 2146. Review Product Information before prescribing. Full Product Information is available from Baxter Medical Information on 1300 302 409 or onecall@baxter.com

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