Tisseel Easyspray
Quick Setup Guide

TISSEEL
[Fibrin Sealant]

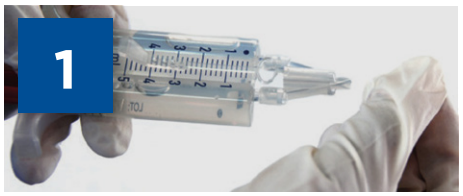
Instructions for Scout Nurse

Connect Spray Set filters to Easyspray device. Connect blue filter to the blue female luer connector and the clear filter to the male luer connector.

Turn the on/off switch on the front side of the EASYSPRAY to the ON position.

Check the gauge on the EASYSPRAY device for the appropriate pressure range of 1.5-2.0 bars (21.5-28.5 psi). Adjust pressure setting by turning the black pressure control knob.[1]

Instructions for Scrub Nurse



Firmly attach the spray head to the nozzle of the syringe.

Fasten the pull strap to the Tisseel syringe holder to assure the spray head is tightly Secured.

Fit the connection tube of the spray set to the luer-lock connector on the underside of the spray head.

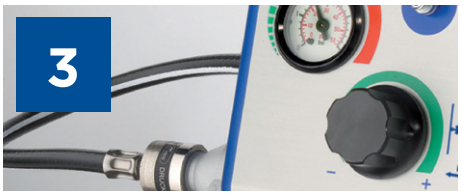
Attach the clip (on the end of the sensor line) by sliding it into the grooves located on the top of the TISSEEL plunger.

Pass the end of the connector tube with sterile filters to the circulating nurse. Pass the syringe to the surgeon for spray application.

Set-up Guide

Insert 9V battery into the EASY-SPRAY pressure regulator device.

Connect EASYSPRAY device to IV pole or cart rail using the clamps on the back of the device.



Use suitable connection tube to connect EASYSPRAY device to compressed medical air. (Ranging 3.5-7 bar, 50-100psi).

Important Points

- Spray from a distance of 10-15cm for optimum results (minimum spraying distance being 10cm).[1]
- To activate the flow of gas, occlude the opening in the clip center with thumb. To begin application, gently depress the syringe plunger.

References: 1. Tisseel Product Information 2018

Baxter

Tisseel [Fibrin Sealant]

Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated, TISSEEL VHS/D.

Indications

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 known hypersensitivity to any other component of TISSEEL. Injection of TISSEEL into tissues is contraindicated. Such use has been associated with inadvertent intravascular injection, with thromboembolic complications. Especially in coronary bypass surgery, TISSEEL should be applied with caution to minimise any risk of intravascular application. TISSEEL should only be applied topically.

Precautions

General

Administration of TISSEEL may result in allergic reactions in some patients. For patients with a known allergic diathesis, a history of hypersensitivity to medical products or a history of having previously received aprotinin-containing products (including previous use of TISSEEL) a careful risk-benefit assessment should be carried out prior to administration. The risk of immunisation against bovine-derived proteins such as aprotinin is increased if repeated exposure occurs within six months. If it is decided to proceed with treatment in such patients, prior administration of antihistamines should be considered.

TISSEEL alone is not indicated for the treatment of massive and brisk arterial or venous bleeding.

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 flush, 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.

Dosage and Administration

Dosage

TISSEEL should only be administered topically. The required dose depends upon the size of the surface to be covered. To avoid the formation of excess granulation tissue, and to ensure gradual absorption of the solidified fibrin sealant, only a thin layer of TISSEEL should be applied.

Do not Microwave TISSEEL

TISSEEL should only be used when, after thawing, the Sealer Protein Solution has a viscous consistency similar to honey (air bubbles in the syringe chamber holding the Sealer Protein Solution slowly rise to the top when the double chamber syringe is tilted or turned upside down). If the Sealer Protein Solution has the consistency of a gel, it must be assumed to have become denatured due to an interruption of the cold storage chain. In this case, the fibrin sealant must not be used.

The protective syringe cap should not be removed until thawing is complete and application tip is ready to be attached. Do not use TISSEEL unless it is completely thawed and warmed (liquid consistency).

The solutions must be used within 72 hours after thawing and stored at or below 25°C.

Any unused product and/or devices should be disposed of in accordance with local requirements.

Method of Application

Application of TISSEEL must be completed within 4 hours after opening the preloaded frozen double chamber syringe. Discard any unused product.

After the two components have been applied, fix or hold the sealed parts in the desired position for at least three to five minutes to ensure the setting TISSEEL adheres firmly to the surrounding tissue.

Device Set Instructions: firmly connect the double chamber syringe nozzles to the Y-piece and secure it by fastening the tether strap to the syringe. Fit an application cannula onto the Y-piece. To avoid clogging, do not expel the air remaining inside the Y-piece or application cannula until application.

Presentation

Nature and Contents of Container

Nature of Container

Both Sealer Protein Solution and Thrombin Solution are contained in two separate chambers of a single use double chamber syringe made of polypropylene.

Contents

Each pack TISSEEL contains:

- One single use double chamber syringe, each chamber containing:
- Chamber number [1]:Sealer Protein Solution (with aprotinin) deep frozen
- Chamber number [2]: Thrombin Solution (with calcium chloride) deep frozen
- One set of devices

TISSEEL is available in the following pack sizes:

- TISSEEL, 2.0 mL (containing 1.0 mL of Sealer Protein Solution and 1.0 mL of Thrombin Solution)
- TISSEEL, 4.0 mL (containing 2.0 mL of Sealer Protein Solution and 2.0 mL of Thrombin Solution)
- TISSEEL, 10.0 mL (containing 5.0 mL of Sealer Protein Solution and 5.0 mL of Thrombin Solution)

TISSEEL, Two component Fibrin Sealant, deep frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated, is manufactured by Baxter AG, Vienna, Austria, and supplied in Australia by: Baxter Healthcare Pty Ltd, 1 Baxter Drive, Old Toongabbie, NSW 2146. Ph: 9848 1111, Fax: 9848 1123

Full Product Information is available from Baxter Medical Information on 0800 556 682 or onecall@baxter.com Please review full Product Information before prescribing.

Date of Medsafe approval: 22 June 2011

To order call Baxter Customer Support:
New Zealand 0800 229 837

NEW ZEALAND

Baxter Healthcare Ltd
33 Vestey Drive, Mt Wellington, Auckland 1060, New Zealand
0800 229 837

PBS Information: This product is not listed on the PBS

ANZ/9/19-0026.

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