TISSEEL
[Fibrin Sealant]

# **Duplospray MIS** Quick Setup Guide

## **Instructions for Scout Nurse** – Duplospray MIS Regulator


Position DUPLOSPRAY System so the foot switch is placed next to the surgeon's foot at time of application.


Attach the supply hose located at the back of the regulator to a source of medical grade $CO_2$.


While depressing the foot switch, adjust the gas flow to 1.0-2.0 litres per minute. Check the gas flow by noting the height of the ball in the gas gauge while stepping on foot switch.

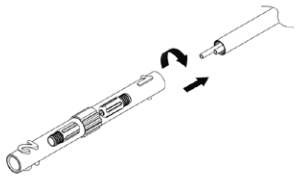

Attach the spray set to the DUPLOSPRAY. Connect the clear hooded luer connector on the tubing set to the male clear gas port on the regulator. Connect the blue male luer connector on the tubing set to the female luer blue vent port on the regulator.

## **Instructions for Scrub Nurse** – Duplospray MIS Applicator


Prepare TISSEEL [Fibrin Sealant] according to the instructions in the package insert.


Remove the DUPLOSPRAY applicator, the tubing and **tip alignment tool*** from the package using sterile technique.*tip alignment tool not part of DUPLOSPRAY 360 applicator


Use the tip alignment tool to thread a sterile replaceable tip onto the applicator until seated against the end of the applicator shaft.



Retain the tip alignment tool, which holds a second replaceable tip provided for use if the first tip becomes occluded.

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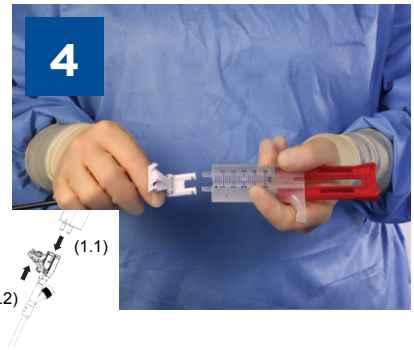
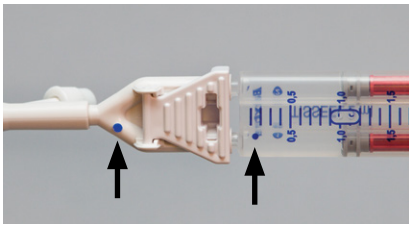



Match the single blue dot on the syringe's calibrated side with the blue dot on the applicator.

Push the male syringe set luers all the way into the female luer cones on the applicator.



If multiple syringes are required in a procedure, inconsistent orientation of syringes may cause the dual-chamber applicator to clog.


Push the snap lock all the way down to securely fasten the applicator to the syringe luers.


Connect the clear female luer connector on the tubing set to the male luer gas port on the applicator.


Connect the red male luer connector on the tubing set to the female luer connector on the trocar vent value. Ensure vent valve is fully open.

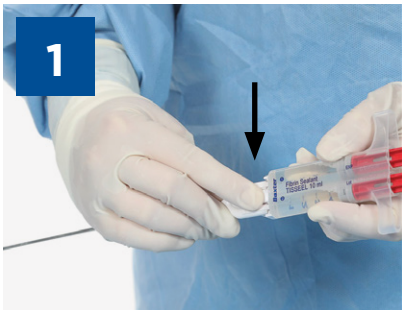
## Dispense


Check the gas flow meter on regulator before inserting applicator into trocar. Maximum flow rate = 2.0L/ min; recommended spray distance 3cm (range 2-5cm).

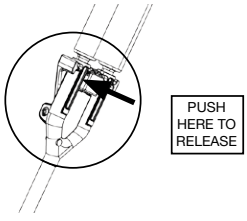

Press the foot switch of the DUPLOSPRAY MIS Regulator to start the gas flow prior to applying TISSEEL.

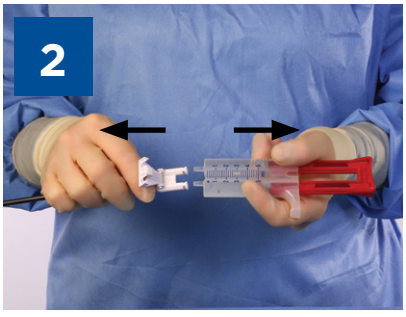

While activating the foot switch, dispense TISSEEL into the applicator by depressing syringe plungers using SLOW STEADY PRESSURE. To stop spray delivery, release pressure on syringe plungers while maintaining gas flow by holding foot switch down for 3-5 seconds after applying TISSEEL to clear the applicator's tip.

## Release Applicator




Press the release button on the back of the snap lock.




Detach applicator from syringe. Dispose of as biohazard waste.

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TISSEEL
[Fibrin Sealant]

# **Duplospray MIS** Quick Setup Guide

## INTENDED USE

The DUPLOSPRAY MIS Applicator is intended for the application of TISSEEL [Fibrin Sealant].

## WARNINGS/PRECAUTIONS

Only qualified personnel should operate this device. Use only with approved DUPLOSPRAY MIS Regulators. Connect DUPLOSPRAY regulator to down-regulated $CO_2$ gas source; maximum input pressure not to exceed 100 psi (7 bar). See regulator IFU for more information.

Caution must be used when applying product using pressurized gas.

- Air or gas embolism has occurred with the use of spray devices employing 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 in close proximity to the tissue surface. When applying sealants using a spray device, be sure to use the flow rate recommended in the Instructions for Use.
- To avoid possible gas embolism, do not spray directly into circulatory pathways. Any application of pressurized gas is associated with a potential risk of air embolism, tissue rupture or gas entrapment with compression, which may be life threatening.

Be sure to take appropriate measures to address these risks by observing these recommendations:

- Do not spray at a distance closer to the surface of tissues than 2 cm (3 cm is recommended) at a maximum flow rate of 2.0 liters per minute (L/min).

| **FLOW RATE** | 1.0 - 2.0 Liters per minute (L/min) | | |
|---|---|---|---|
| **DISTANCE** | 2cm | **3cm** | 5cm |
| | | **recommended** | |

- When using pressurized spray devices, changes in blood pressure, pulse, oxygen saturations, and end tidal should be monitored because of the possibility of occurrence of air gas embolism.

## TISSEEL [Fibrin Sealant]

**NAME OF THE DRUG - TISSEEL [Fibrin Sealant]**
Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated, TISSEEL VH S/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 containers:
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:
- Chapter number (1): Sealer Protein Solution (with aprotinin) deep frozen
- Chapter numnber (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

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

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