DUPLOSPRAY MIS Applicator

SNAP LOCK ATTACHMENT QUICK REFERENCE GUIDE

TISSEEL [Fibrin Sealant]

Instructions for **CIRCULATING NURSE**

SET UP REGULATOR

1

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

2

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

3

Attach spray set to regulator. Connect the blue vent line filter to the blue female luer and the clear gas line filter to the male luer on the regulator.

4

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 the foot switch.

5

Hand applicator over to scrub nurse using sterile technique.

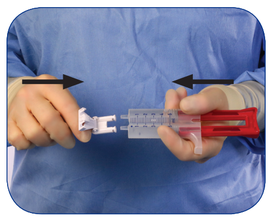
Instructions for **SCRUB NURSE**

ASSEMBLE APPLICATOR

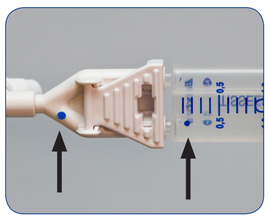
1

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.

2



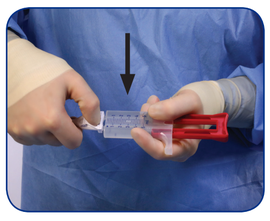
Push the male syringe set luers all the way into the female luer cones on the applicator.



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

If multiple syringes are required in the procedure, inconsistent orientation my cause the dual-chamber to clog.

3



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

4

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

5

Connect the red male luer connector on the tubing set to the female luer connector on the trocar vent valve.

Instructions for **SURGEON**

DISPENSE

1

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).

2

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

3

While activating the foot switch, dispense TISSEEL into the applicator by depressing syringe plungers using VERY 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.

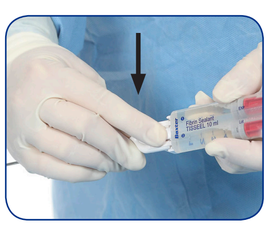
NOTE: If using DUPLOSPRAY 360 Degree, angle the flexible tip at the end of the applicator by grasping and turning with an endoscopic grasper.

NOTE: Spray application precaution: any application of pressurised gas may be 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 the recommended minimum spraying distance and the maximum pressure provided in the appropriate spray set instructions for use, or the TISSEEL SPC.

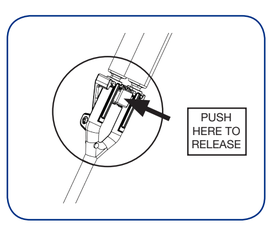
Instructions for **SCRUB NURSE**

RELEASE APPLICATOR

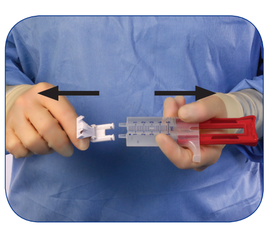
1



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



2



Detach applicator from syringe. Dispose as biohazard waste.

TROUBLESHOOTING – **OCCLUDED TIP**

1

If the replaceable tip becomes occluded during use, as indicated by no spray or by no movement of the ball in the regulator flow meter, use the tip alignment tool to remove the occluded tip by unscrewing it in a counterclockwise motion. These steps should be at the end of the assembly steps including connection to gas source etc.

2

Using a sterile sponge, wipe any clotted material or fluid from the exposed metal tube ends.

3

Use the opposite chamber of the tip alignment tool to install a new tip by screwing it in a clockwise motion.

Ensure replacement tip is secured firmly to prevent accidental tip detachment.

Baxter

DUPLOSPRAY MIS Applicator

SNAP LOCK ATTACHMENT QUICK REFERENCE GUIDE

TISSEEL [Fibrin Sealant]

DUPLOSPRAY MIS and 360 Endoscopic Applicator Product Codes
with SNAP LOCK ATTACHMENT

DESCRIPTION	EA PER PACK	CODES
DUPLOSPRAY MIS APPLICATOR WITH SNAP LOCK 20cm	5/PK	0601133
DUPLOSPRAY MIS APPLICATOR WITH SNAP LOCK 30cm	5/PK	0601129
DUPLOSPRAY MIS APPLICATOR WITH SNAP LOCK 40cm	5/PK	0601130
SPRAY SET 360 ENDOSCOPIC APPLICATOR WITH SNAP LOCK	5/PK	0611128

SNAP ON and USE!

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 pressurised 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 pressurised 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 pressurised spray devices, changes in blood pressure, pulse, oxygen saturations, and end tidal CO_2 should be monitored because of the possibility of occurrence of air gas embolism.

TISSEEL [Fibrin Sealant]

PRESCRIBING INFORMATION TISSEEL Ready to use Solutions for Sealant / Lyo Powder and Solvent for Sealant
(Please consult the Summary of Product Characteristics before prescribing)

Name and composition: Tisseel Ready to use – prefilled double chamber syringe containing Sealer Protein Solution (with aprotinin) deep frozen in one chamber and Thrombin Solution (with Calcium Chloride) deep frozen in the other chamber. Sealer Protein Solution contains 91mg/ml Human Fibrinogen (as clottable protein), 0.6-5 IU/ml Human Factor XIII and 3000 KIU/ml Aprotinin. Thrombin Solution contains 500 IU/ml Human Thrombin and 40µmol/ml Calcium Chloride. Presentations of 1, 2 or 5ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of sealant. Tisseel Lyo - powders and solvents for fibrin sealant. 1) Sealer protein concentrate, after reconstitution 1 ml contains 91 mg Human Fibrinogen (as clottable protein); 0.6-5 IU Human Factor XIII and 3000 KIU Aprotinin; 2) Thrombin solution, after reconstitution, 1 ml contains 500 IU of Human Thrombin and 40µmol Calcium Chloride. **Indications:** As a coagulant producer for use as a tissue sealant and haemostatic, for surgical incisions, plastic surgical repairs, orthopaedic, traumatic, and dental surgery. **Dosage and Route:** For epilesional (topical) use only. The use of TISSEEL is restricted to experienced surgeons who have been trained in the use of TISSEEL. A thin layer is applied to the tissue surface where required. Dose depends on the indication, application method and number of applications. As a guideline for the gluing of surfaces, 1 pack of TISSEEL 2 ml (i.e. 1 ml Sealer Protein Solution plus 1 ml Thrombin Solution) will be sufficient for an area of at least 10 cm^2. Apply topically – tissue surface should be as dry as possible before application. Application can be repeated if necessary. Apply by drops or spray as needed depending on indication. Safety and efficacy in paediatric population not established. **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: Apply with care in coronary artery bypass surgery due to increased risk of inadvertent intravascular application. TISSEEL and/or Thrombin Solution should only be applied topically. Do not inject in soft tissue – risk of local tissue damage. When spraying TISSEEL, changes in blood pressure, pulse, oxygen saturation and end tidal CO_2 should be monitored because of the possibility of occurrence of air or gas embolism. See SmPC for further details. Air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life-threatening or fatal, have occurred with the use of spray devices with air or gas employing a pressure regulator to administer fibrin sealant. These events appear to be related to the use of the spray device at higher than recommended pressures and in close proximity to the tissue surface. Must not be used with Easyspray/spray set in enclosed areas. When applying by spray, follow the instructions provided with the spray device, with particular reference to gas pressure and distance from the tissue surface. After TISSEEL has been applied, allow at least 2 minutes to achieve sufficient polymerization. Do not use pressurized air or gas for drying the site. TISSEEL must be sprayed only onto application sites that are visible. TISSEEL must not be applied intravascularly. 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. The effect of Tisseel on fertility has not been established. **Contraindications:** Do not apply intravascularly – can be life threatening. Hypersensitivity to active substances or other components. Not for the treatment of massive and brisk arterial or venous bleeding. Do not use to replace skin sutures intended to close surgical wounds. **Interactions:** No formal interaction studies have been performed. Thrombin component may be denatured by alcohol, iodine or heavy metals (e.g. antiseptic solutions). **Overdose:** Not reported. **Legal category:** POM. **Marketing Authorisation Holder and Number:** Baxter Holding B.V. Kobaltweg 49, 3542CE Utrecht, Netherlands. Tisseel Ready to use PA2299/025/001. Tisseel Lyo PA2299/025/002. **Date of preparation:** April 2019

Suspected Adverse Reactions to medicines and any drug or medical device product quality complaints (including suspected defective medicines or medical device adverse incidents) should be reported to the Health Products Regulatory Authority (HPRA) using a Yellow Card obtained from the HPRA, via the online system (www.hpra.ie) or by telephone on 01-6764971.

Adverse Events relating to Baxter products should also be reported direct to Baxter Healthcare Ltd, by email (vigilanceuk@baxter.com) or by phone (+44 1635 206360).

Drug or medical device product quality complaints relating to Baxter products can be reported directly to Baxter Healthcare Ltd by email (shs_complaints_dublin@baxter.com) or by phone (01-2065500).

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