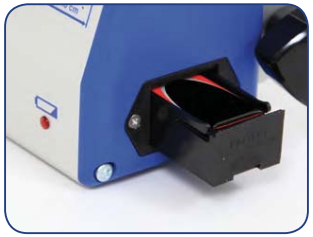
EASYSPRAY Quick Reference Guide (for open wound surgery)

Instructions for Circulating Nurse | EASYSPRAY Pressure Regulator

1. 
Insert 9V battery into the EASYSPRAY pressure regulator device.

2. 
Connect EASYSPRAY device to IV pole or trolley rail using the clamps on the back of the device.

3. 

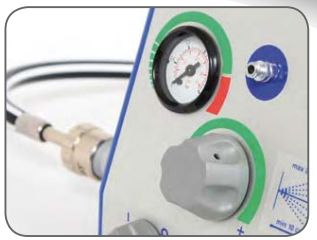
Use suitable connection tube to connect the EASYSPRAY device to medical air (ranging 3.5 – 7 bar / 51 – 100 psi).

4. 

Connect Spray Set filters to EASYSPRAY device. Connect the blue filter (pressure line) to the blue female luer connector and the clear filter (sensor line) to the male luer connector.

5. 

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

6. 
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 grey pressure control knob.

Instructions for Scrub Nurse | Spray Set

1. 
Prepare TISSEEL Fibrin Sealant according to the instructions in the package insert.

2. 
Firmly attach the spray head to the nozzle of the syringes.

3. 
Fasten the pull strap to the double syringe system to assure the spray head is tightly secured.

4. 
Fit the connection tube of the spray set to the luer-lock connector on the underside of the spray head.

5. 
Attach the clip (on the end of the sensor line) by sliding it into the grooves located on the top of the syringe plunger.

6. 
Pass the assembled applicator to the surgeon for spray application. Pass the end of the connection tube with the sterile filters to the circulating nurse.

Instructions for Surgeon

1. 
Confirm (verbally) the actual pressure with theatre personnel.

2. 
Spray from a distance of 10 – 15 cm for optimum results.

3. 
To activate the flow of gas occlude the opening in the clip center with thumb. To begin application, gently depress the syringe plunger.

The use of TISSEEL Fibrin Sealant is restricted to experienced surgeons who have been trained in the use of TISSEEL.

In order to ensure optimal safe use of TISSEEL by spray application, apply a minimum spray distance of 10 cm and a maximum spray pressure of 2 bar to minimise the potential risk of air or gas embolism, tissue rupture, or air or gas entrapment with compression.

The EASYSPRAY device will continue to emit gas for a brief period after the thumb is removed from the clip/plunger. This delay helps to avoid clogging of the spray head.

Please see the TISSEEL SmPC provided together with this material.

Caution: Any application of pressurised gas may be associated with a potential risk of air or gas embolism, tissue rupture or air 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.

Baxter

EASYSPRAY Quick Reference Guide

CAUTION BOX

Any application of pressurized gas may be associated with a potential risk of air or gas embolism, tissue rupture or air or gas entrapment with compression, which may be life threatening if the product is sprayed incorrectly

Precautions

For TISSEEL/TISSUCOL Fibrin Sealant

- In open-wound surgery: when applying sprayable fibrin solutions for sealant using a pressure regulator device, the maximum pressure should be 2.0 bar (28.5 psi). The product should be sprayed at a distance at least 10 cm from the tissue surface.
- Spray application should only be used if it is possible to accurately judge the spray distance as recommended by the manufacturer. Do not spray closer than the recommended distances.
- Prior to applying sprayable fibrin solutions for sealant, the surface area of the wound should only be dried using standard techniques (eg, intermittent application of compresses, swabs, use of suction devices).
- Blood pressure, pulse rate, oxygen saturation and end tidal CO_2 should be monitored closely when spraying fibrin solutions for sealant using a pressure regulator device, because of the possibility of occurrence of air or gas embolism.
- Regulators should be used in line with manufacturer recommendations and the SmPC and Instruction for Use.

In order to ensure optimal safe use of TISSEEL by spray application the following recommendations should be followed:

Recommended pressure, distance and devices for spray application of TISSEEL

Surgery	Spray set to be used	Applicator tips to be used	Pressure regulator to be used	Recommended distance from target tissue	Recommended spray pressure
Open wound	TISSEEL / ARTISS Spray Set	n.a.	EASYSPRAY	10-15 cm	1.5-2.0 bar (21.5-28.5 psi).
	TISSEEL / ARTISS Spray Set 10 pack	n.a.	EASYSPRAY		
	TISSEEL/TISSUCOL Spray Set	n.a.	EASYSPRAY		

When spraying the 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.

WARNINGS AND PRECAUTIONS

Caution: Pressurized gas supply must be between 3.5 and 7 bar (51-100 psi).
Caution: DO NOT connect to an oxygen source. Failure to follow these instructions can lead to explosion, which could result in serious injury or death.
Prior to operation make sure that the pressure range of the device is adjusted to the range specified in the appropriate spray set instructions for use.
Caution: Spray application requires appropriate safety measures as described in the pertinent Summary of Product Characteristics and Instructions for Use of the spray devices to make sure that the risks mentioned in this reference guide will be avoided
NOTE: Do not use with rechargeable batteries. The use of accessories of other manufacturers is not permitted.

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 cm2. 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 CO2 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

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin: Tel:+353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie Email: medsafety@hpra.ie .

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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Baxter Healthcare Ltd
Unit 7 Deansgrange Business park
Blackrock
Co. Dublin

http://www.baxterspraysafety.com/index.html

For detailed information please contact your local representative.

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