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.

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 cart 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 / 50 – 100 psi).
4. Connect Spray Set filters to EASYSPRAY device. Connect the blue filter to the blue female luer connector and the clear filter 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 black 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 OR 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 minimize 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 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. 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.
**NOTE:** Do not use with rechargeable batteries. The use of accessories of other manufacturers is not permitted.

**Caution:** Spraying into enclosed body cavities requires appropriate safety measures to make sure that the above mentioned risks will be avoided.

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:** Pressurized gas supply must be between 3.5 and 7 bar (50-100 psi).

When spraying the 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.

**WARNINGS AND PRECAUTIONS**

Caution: Pressurized gas supply must be between 3.5 and 7 bar (50-100 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: Spraying into enclosed body cavities requires appropriate safety measures to make sure that the above mentioned risks will be avoided.

**N O T E:** Do not use with rechargeable batteries. The use of accessories of other manufacturers is not permitted.

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### EASYSPRAY Quick Reference Guide

**CAUTION BOX**

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 if the product is sprayed incorrectly.

**Precautions**

For TISSEEL Fibrin Sealant:

- In open surgery: when applying sprayable fibrin solutions for sealant using a pressure regulator device, the maximum pressure should be 2.0 bar (28.5 psi).
- 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, swards, use of suction devices).
- Blood pressure, pulse rate, oxygen saturation and end tidal CO₂ 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.

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### Recommended Pressure, Distance and Devices for Spray Application of TISSEEL

<table>
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<tr>
<th>Surgery</th>
<th>Spray set to be used</th>
<th>Applicator to be used</th>
<th>Pressure regulator to be used</th>
<th>Recommended distance from target tissue</th>
<th>Recommended spray pressure</th>
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<tr>
<td>Open wound</td>
<td>TISSEEL / ARTISS Spray Set</td>
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<td>EASYSPRAY</td>
<td>10-15 cm</td>
<td>1.5-2.0 bar (21.5-25.5 psi)</td>
</tr>
</tbody>
</table>

When spraying the 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.

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**PREScribing INFORMATION - TISSEEL**

**Lyo Two-Component Fibrin Sealant**

**Ready to use Solutions for Sealant**

(For detailed information please consult the Summary of Product Characteristics before prescribing)

**Name and composition:** TISSEEL Lyo - powders and solvents for fibrin sealant.

1. **Sealant protein concentrate:** After reconstitution 1 ml contains 96-125 mg total protein of which 72-110 mg is fibrinogen;
2. **Aprotinin Solution:** 3000 KIU per ml;
3. **Thrombin Powder:** 1 ml contains 500 IU of Thrombin in 45-55 mg total protein;
4. **Calcium chloride solution:** 40μmol per ml. TISSEEL Ready to use – prefilled double chamber syringe containing Sealant Protein Solution (with aprotinin) deep frozen in one chamber and Thrombin Solution (with Calcium Chloride) deep frozen in the other chamber. Sealant Protein Solution contains 919ng/ml human fibrinogen (dilutable protein) and 5000 KIU/ml aprotinin. Thrombin Solution contains 500 IU/ml human thrombin and 40μmol per ml calcium chloride. Presentations of 1, 2 or 5 ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of sealant. **Indications:** Supportive treatment for standard surgical techniques is insufficient, for improvement of haemostasis, as a tissue glue to promote adhesion, sealing or as suture support, in gastrointestinal anastomoses, in neurosurgery where contact with cerebrospinal fluid or dura mater may occur and for mesh fixation in hernia repair, as an alternative or adjunct to sutures or staples.

**Dose and Route:** 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. **Side effects:** See Summary of Product Characteristics for detail. Hypersensitivity / anaphylactic / anaphylactoid reactions may occur, especially in patients who have previously received aprotinin. Early symptoms of allergic reactions include flushing, urticaria, pruritus, nausea, hypotension, tachycardia or bradycardia, bronchospasm, tightness in chest and dyspnoea. Do not inject – risk of thromboembolic complications. **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. 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. Air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life threatening, have occurred, when the use of spray devices 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. When applying by spray, follow the instructions provided with the spray device, with particular reference to gas pressure and distance from the tissue surface. 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 records. Excessive clot thickness may negatively interfere with product efficacy and the healing process. **Contraindications:** Do not apply intravascularly. Hypersensitivity to active substances or other components. Not for the treatment of active or spurring arterial or venous bleeding. **Interactions:** Avoid solutions containing alcohol, iodine and heavy metals. **Ovcrdose:** Not reported. **Legal category:** POM Basic NHS prices: TISSEEL Lyo 2 ml - £33.46; 4 ml - £166.92; 10 ml - £379.85. TISSEEL Ready to use 2ml - £37.50; 4ml - £195; 10ml - £443.75. **Marketing Authorisation Number and Holder:** TISSEEL Lyo – PL 00116/0031, TISSEEL Ready to use - PL 00116/0027 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE. **Date of preparation:** March 2013. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Any adverse events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on 01635 206960, or by email to vigilanceuk@baxter.com

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For detailed information please contact your local representative.