PRESCRIBING INFORMATION - TISSEEL
Lyo Two-Component Fibrin Sealant
Ready to use Solutions for Sealant
(Please consult the Summary of Product Characteristics before prescribing)
Name and composition: 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.
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 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.
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:** 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.*
Hypersensitivity/anaphylactic/anaphylactoid reactions may occur, especially in patients who have previously received Tisseel repeatedly or known to be hypersensitive to aprotinin. Early symptoms of allergic reactions include, but are not limited to, angioedema, burning and stinging at the application site, bradycardia, bronchospasm, chills, dyspnoea, flushing, generalized urticaria, headache, hives, hypotension, lethargy, nausea, pruritus, restlessness, tachycardia, tightness of the chest, tingling, vomiting, wheezing. Postoperative wound infection, fibrin degradation products increased, paresthesia, erythema, axillary vein thrombosis, haematoma, cerebral artery embolism, cerebral infarction, air embolism, intestinal obstruction, impaired healing, procedural pain, oedema, sensory disturbance, pain, increase in body temperature, rash, pain in extremity and seroma have been reported. Do not inject – risk of thromboembolic complications. Risk of arterial embolism. **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 Number and Holder:** TISSEEL Lyo - PA 167/129/6. TISSEEL Ready to use - PA 167/129/005 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE **Date of preparation:** March 2016 **Further information is available on request.**

Baxter Healthcare encourages healthcare professionals to continue to be vigilant and to report suspected adverse reactions to the Health Products Regulatory Authority (online at www.hpra.ie or via email at medsafety@hpra.ie).
Any adverse events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on +44 (0) 1635 206360, or by email to vigilanceuk@baxter.com