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 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 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 (clottable protein) and 300 KIU/ml aprotinin. Thrombin Solution contains 500 IU/ml human thrombin and 40μmol per ml calcium chloride. Presentations of 1, 2 or 5ml in each chamber resulting in total volume of 2ml, 4ml or 10ml of sealant. Indications: Supportive treatment where standard surgical techniques are 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. 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 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 with 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 notes. 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. Overdose: Not reported. Legal category: POM Basic NHS price: TISSEEL Lyo 2 ml kit - £83.46; 4 ml kit - £166.92; 10 ml kit - £379.85. TISSEEL Ready to use 2ml - £97.50; 4ml - £195; 10ml - £443.75. Marketing Authorisation Number and Holder: TISSEEL Lyo - PL 00116/0321. TISSEEL Ready to use - PL 00116/0627 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 206360, or by email to vigilanceuk@baxter.com