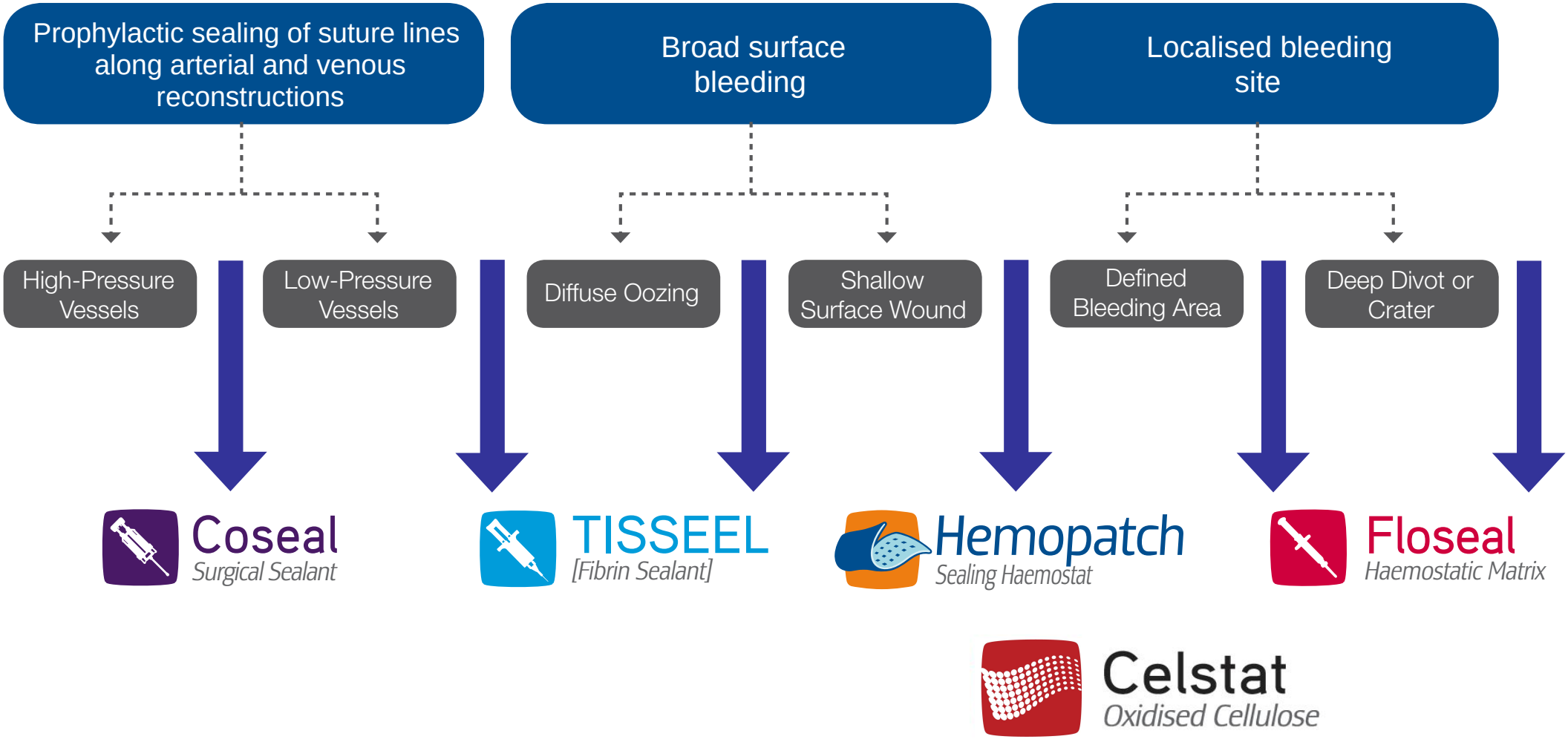
Positioning & Portfolio Brand Choice

Hemopatch
Sealing Haemostat



Celstat
Oxidised Cellulose

Baxter

Hemopatch
Sealing Haemostat

PRESCRIBING INFORMATION - TISSEEL Ready to use Solutions for Sealant

(Please consult the Summary of Product Characteristics before prescribing)

Composition: prefilled double chamber syringe containing deep frozen Sealer Protein Solution (with aprotinin) and Thrombin Solution (with Calcium Chloride Dihydrate). Sealer Protein Solution contains 91mg/ml human fibrinogen (clottable protein) and 3000 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:** For epilesional (topical) use only. Use of TISSEEL is restricted to experienced surgeons who have been trained in the use of TISSEEL. A thin layer is applied under direct vision to the tissue surface where required. Dose depends on the indication, application method and number of applications. For tissue adherence, it is recommended that the initial application cover the entire intended application area. As a guideline for the gluing of surfaces, 1 pack of TISSEEL 2 ml will be sufficient for an area of at least 10 cm^2. Tissue surface should be as dry as possible before application. Do not use pressurized air or gas for drying the site. Application can be repeated if necessary but avoid reapplication of TISSEEL to pre-existing polymerized TISSEEL. Apply by drops or spray as needed depending on indication. **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:** Life threatening thromboembolic complications may occur if unintentionally applied intravascularly. Apply with care in coronary artery bypass surgery due to increased risk of inadvertent intravascular application. Must not be injected into highly vascularized tissue, such as nasal mucosa. 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. 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 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. Do not administer with spray devices in enclosed body areas. Take risk of compressive complications into account when applying in confined spaces. 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. **Contraindications:** Do not apply intravascularly. Hypersensitivity to active substances or other components. Not for the treatment of active or spurting arterial or venous bleeding. Not for replacement of skin sutures intended to close surgical wounds. **Interactions:** Avoid solutions containing alcohol, iodine and heavy metals. **Overdose:** Not reported. **Legal category:** POM. **Basic NHS price:** 2ml - £97.50; 4ml - £195.00; 10ml - £443.75. **Marketing Authorisation Number and Holder:** PL 00116/0627 Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk IP24 3SE, UK. **Date of preparation:** Jan 2019

Adverse Events and any suspected defective medicines should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

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

Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on +44 (0)1604 704603, or by email to UK_SHS_QA_Complaints@baxter.com. Alternatively please report directly to your Baxter Representative, who will take the details and forward to the Baxter Country Quality Assurance Team.

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