BAXTER

+dvantage

CHOOSING WITH CONFIDENCE

IS THERE BLEEDING?

YES

ACTIVE FOCAL BLEEDING

Floseal[1]
[HAEMOSTATIC MATRIX]

Hemopatch[5]
FLEXIBLE HEMOSTAT

DIFFUSE OOZING

Floseal[1]
[HAEMOSTATIC MATRIX]

Tisseel[2]
[FIBRIN SEALANT]

Hemopatch[5]
FLEXIBLE HEMOSTAT

Celstat[9]
OXIDISED CELLULOSE

Ostene[6]
BONE HAEMOSTASIS MATERIAL
**BONE BLEEDING*

NO

FIXATION

Tisseel[2]
[FIBRIN SEALANT]

Artiss[4]
[FIBRIN SEALANT (HUMAN)]

SEALING

Coseal[3]
[SURGICAL SEALANT]

Hemopatch[5]
FLEXIBLE HEMOSTAT

ADHESION REDUCTION

Coseal[3]
[SURGICAL SEALANT]
Site specific adhesion prevention

Seprafilm[8]
ADHESION BARRIER

adept®[7]
Broad Coverage
[Adhesion Reduction Solution]

Product information is available online at www.baxterprofessional.co.nz
or onecall medical information 0800 556 682 onecall@baxter.com

Please turn page over for more information
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Tisseel

MINIMUM PRODUCT INFORMATION: TISSEEL [Fibrin Sealant] Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated, TISSEEL VH S/D.

Indications: as adjunct to haemostasis during surgical procedures, when control of bleeding by conventional surgical techniques is ineffective or impractical; and as a sealant as an adjunct for closure of colostomies; as a sealant and/or adhesive for use in autologous chondrocyte implantation (ACI) or matrix-induced autologous chondrocyte implantation (MACI) procedures; for mesh fixation in inguinal, femoral and incisional hernia repair, as an alternative or adjunct to sutures, staples or tacks. Contraindications*: Known hypersensitivity to aprotinin or any other component of TISSEEL. Injection of TISSEEL into tissues is contraindicated. Such use has been associated with inadvertent intravascular injection which may result in life-threatening thromboembolic complications, can lead to intravascular coagulation which may increase likelihood and severity of acute hypersensitivity reactions in susceptible patients. TISSEEL should be applied with caution to minimise any risk of intravascular application, for example in coronary bypass surgery. TISSEEL should only be applied topically. Soft tissue injection of TISSEEL carries the risk of an anaphylactic reaction and/or local tissue damage. Precautions*: Viral and prion risk due to human plasma derived sealer protein concentrate and thrombin. Products made from human plasma may contain infectious agents which can cause disease. Standard measures are taken to prevent infection but when medicinal products are prepared from human blood or plasma, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. Administration of TISSEEL may result in allergic reactions. For patients with a known allergic diathesis, history of hypersensitivity to medical products or who have previously received aprotinin-containing products (including previous use of TISSEEL) a careful risk-benefit assessment should be carried out prior to administration. Risk of immunisation against proteins such as aprotinin is increased if repeated exposure occurs within six months. TISSEEL contains synthetic aprotinin which is structurally identical to bovine aprotonin so use in patients with allergies to bovine proteins should be carefully evaluated. 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 TISSEEL. These events appear to be related to the use of spray devices at higher than recommended pressures and/or in close proximity to the tissue surface. The risk appears to be higher when Tisseel is sprayed with air, compared to CO2 and therefore cannot be excluded with Tisseel when sprayed in open wound surgery. TISSEEL alone is not indicated for severe or brisk arterial or venous bleeding. TISSEEL S should not be used for sealing neuroanastomoses. Do not inject into nasal mucosa. If fibrin sealants are applied in confined bodily spaces, the risk of compressive complications should be taken into account. Interactions/Incompatibilities There are no known interactions between TISSEEL and other drugs. Efficacy has been demonstrated in fully heparinised patients undergoing cardiopulmonary bypass. Solutions containing alcohol, iodine or heavy metals (e.g disinfectants) should be thoroughly rinsed off wound area before TISSEEL application. Oxidised cellulose-containing preparations may reduce the efficacy of TISSEEL and should not be used as carrier material. Do not mix TISSEEL with other medicinal products. Adverse effects: Anaphylactic and anaphylactoid reactions may occur in patients who have previously received a fibrin-based sealant, in those with a known hypersensitivity to aprotinin and in those who have previously received aprotinin systemically. Even if the second treatment with TISSEEL was well tolerated, a subsequent administration of TISSEEL or systemic administration of aprotinin may result in severe anaphylactic reactions. Symptoms associated with allergic/anaphylactic reactions include flushing, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnoea, severe hypotension, and anaphylactic shock. In the event of hypersensitivity reactions, administration of TISSEEL should be discontinued, the topical clot removed, and appropriate treatment instituted. In rare cases, these reactions may also occur in patients receiving aprotinin or TISSEEL for the very first time. Common adverse reactions in clinical trial: fibrin degradation products increased, post-procedural pain. Fibrin sealant/haemostatic class reactions: manifestations of hypersensitivity such as application site irritation, chest discomfort, chills, headache lethargy, restlessness, vomiting. Dosage and Method of Use: TISSEEL should only be administered topically. Do not inject. Tisseel must not be applied intravascularly. The required dose depends upon the size of the surface to be covered. To avoid the formation of excess granulation tissue, and to ensure gradual absorption of the solidified fibrin sealant, only a thin layer of TISSEEL should be applied. Application can be repeated, if necessary, but avoid re-application of TISSEEL to a pre-existing polymerized TISSEEL layer. See PI for preparation details. Do not microwave TISSEEL. TISSEEL should only be used when, after thawing, the Sealer Protein Solution has a viscous consistency similar to honey. If the Sealer Protein Solution has the consistency of a gel, it must be assumed to have denatured and should not be used. The protective syringe cap should not be removed until thawing is complete and application tip is ready to be attached. Do not use TISSEEL unless it is completely thawed and warmed (liquid consistency). The solutions must be used within 72 hours after thawing at or below 25 °C. Prior to application, TISSEEL must be warmed to 33-37°C and must not be exposed to >37°C. Application of TISSEEL must be completed within 4 hours after opening the

Artiss

ARTISS [fibrin sealant (Human)], Two Component Fibrin Sealant, Deep Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated.

INDICATIONS: adherence of autologous skin grafts in burn patients, adherence of tissue flaps during facial rhytidectomy surgery (face lift). ARTISS is not indicated for haemostasis. CONTRAINDICATIONS: cases of hypersensitivity to the active substances or to any of the excipients. Intravascular application which may result in life threatening thromboembolic events. ARTISS should be applied with caution to minimise any risk of intravascular application. ARTISS should only be applied topically. Soft tissue injection of ARTISS caries the risk of an anaphylactic reaction and/or local tissue damage. PRECAUTIONS: ARTISS alone is not indicated for the treatment of massive and brisk arterial or venous bleeding. As with any protein-containing product, allergic type hypersensitivity reactions are possible. Hypersensitivity or allergic/anaphylactoid reactions may occur with the use of a fibrin sealant. In specific cases, these reactions have progressed to severe anaphylaxis. Sealer protein concentrate and thrombin are made from human plasma. When medicinal products prepared from human blood or plasmas are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses or other pathogens. The standard measures taken (including double virus inactivation by vapour heat treatment and solvent detergent treatment) are considered effective for enveloped viruses such as HIV, HBV, and HCV, and for the non-enveloped virus HAV. ADVERSE EFFECTS: In a phase 3, multi-centred, prospective, evaluator-blinded, randomized study, where ARTISS was used to affix split thickness sheet skin grafts to excised burn wounds, a total of 8 non-serious adverse reactions were reported. There were no serious reactions. The right non-serious adverse reactions occurred in six patients. Five of these reactions were skin graft failures, 4 were graft detachment/non-adherence, and 1 was graft necrosis. The remaining non-serious adverse reactions were pruritus and dermal cyst. There are limited post-marketing data available for ARTISS. Adverse reactions reported from clinical studies as well as from post-marketing surveillance of Baxter's other fibrin sealants are summarized in the full Product Information. Review full ARTISS Product Information before prescribing. Full PI available from Baxter Medical Information 0800 556 682

REFERENCES:

1. *Floseal Hemostatic Matrix, Instructions for Use. Baxter Healthcare SA*
2. *Tisseel VH S/D Product Information*
3. *Coseal Surgical Sealant. Instructions for Use. Baxter Healthcare Corp*
4. *Artiss (Fibrin Sealant(Human)) full Product Information*
5. *HEMOPATCH Sealing Hemostat Instructions for Use*
6. *Ostene, Bone Hemostasis material. Instructions for Use*
7. *Adept Instructions for Use*
8. *Seprafilm IFU*
9. *CELSTAT Oxidised Cellulose Sterile resorbable haemostatic reticulum IFU*

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