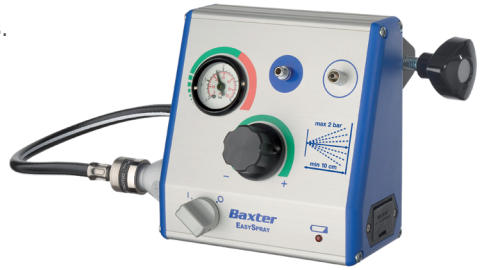
ARTISS
[Solutions for Sealant]

Recommended Guidelines when Spraying ARTISS with a Pressurised Spray Regulator

Open Procedures – Easyspray

- ✓ The surface area of the surgical site has been dried using standard techniques.
- ✓ The gauge on the Easyspray device shows a pressure range of 1.5 – 2.0 bar.
- ✓ ARTISS should be sprayed at a minimum of 10cm from the surface tissue.



ARTISS is for subcutaneous use only.

ARTISS is not recommended for laparoscopic surgery.

Caution: 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. Be sure to take appropriate measures to address these risks by observing the recommended minimum spraying distance and the maximum pressure.

BioSurgery-Advancing Surgery, Enhancing Life

Baxter

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PRESCRIBING INFORMATION – ARTISS

(Please consult the Summary of Product Characteristics before prescribing)

Name and composition: ARTISS Solutions for Sealant – one 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 3000 KIU/ml aprotinin. Thrombin Solution contains 4 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 total volume of product ready for use. Contains human factor XIII co-purified with human fibrinogen in a range of 0.6 – 5 IU/ml. **Indication:** Hospital use only. A tissue glue to adhere / seal subcutaneous tissue in plastic, reconstructive and burn surgery, replacement or adjunct to sutures or staples. Adjunct to haemostasis on subcutaneous tissue surfaces. **Dosage and Route:** The use of ARTISS is restricted to experienced surgeons who have been trained in the use of ARTISS. For epilesional use. Dose individualised and governed by indication, application methods and number of applications. Guide – 1 pack ARTISS 2ml sufficient for an area at least 10 cm2. Avoid excess granulation by applying only a thin layer. Surface of the wound should be as dry as possible. **Side effects:** *See summary of product characteristics for detail.* Risk of anaphylactic reaction. Intravascular injection may lead to life-threatening thromboembolic events. Hypersensitivity or allergic reactions. Pruritus, skin graft failure **Precautions:** Caution applying ARTISS using pressurised gas, not to be used with Easy Spray / Spray Set system in enclosed body areas - risk of air or gas embolism, tissue rupture or gas entrapment. Use spray device pressure within manufacturers recommended range, not exceeding 2.0 bars. Do not spray closer than 10-15 cm from tissue surface. Monitor blood pressure, pulse, oxygen saturation, end tidal CO2 for possibility of occurrence of air or gas embolism. Not indicated for use where a fast clotting sealant is required, especially in cardiovascular surgery. Not for use in neurosurgery or gastrointestinal or vascular anastomoses. Excessive clot thickness may interfere with efficacy and wound healing. Care to prevent adhesion at undesired sites. Signs of hypersensitivity include hives, urticaria, tightness of chest, wheezing, hypotension, anaphylaxis. Risk of anaphylaxis increased if previous exposure to aprotinin. In event of hypersensitivity or anaphylaxis discontinue use and remove polymerised product from surgical site. Oxycellulose containing preparations may reduce ARTISS efficacy. Infectious diseases due to transmission of infective agents cannot be totally excluded. Use of ARTISS and batch number should be recorded in patients' notes. Carefully evaluate in patients with allergies to bovine proteins. **Contra-indications:** Not indicated to replace sutures intended to close surgical wound. Not for treatment of massive and brisk arterial or venous bleeding. Not for intravascular use. Hypersensitivity to active substances or excipients. **Interactions:** Avoid solutions containing alcohol, iodine and heavy metals. **Overdose:** No cases of overdose have been reported. **Legal Category:** POM **Marketing Authorisation Number and Holder:** ARTISS – PA 167/131/001, Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk. IP24 3SE. **Date of Preparation:** March 2013

Any adverse event relating to Baxter products should be reported to Baxter Healthcare directly by calling 01-206-5500 and asking for the Quality Department.

Baxter Healthcare encourages healthcare professionals to continue to be vigilant and to report suspected adverse reactions with ARTISS to the Irish Medicines Board (online at www.imb.ie, telephone 01-6764971 or using the yellow card system).

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