Artiss
FIBRIN SEALANT (HUMAN)

EASYSPRAY Preparation Guide (for Open Wound Surgery)

Instructions for Circulating Nurse
EASYSPRAY Pressure Regulator

1

For first time usage:
Insert 9V battery into the EASYSPRAY pressure regulator device.

2

Connect EASYSPRAY device to IV pole or cart rail using the clamps on the back of the device.

3

Connect the adapter attached to the black tubing, located at the side of the EASYSPRAY device, to an appropriate gas source. Pressurised gas supply must be set between 3.5 and 7 bar (51-100 psi).

4

Connect Spray Set filters to EASYSPRAY device. Connect the blue filter to the blue female Luer connector and the clear filter to the male Luer connector.

5

Turn the on/off switch on the front side of the EASYSPRAY device to the ON position. The low-battery indicator light will only illuminate when the battery is weak and when the gas flow is activated. If the battery is completely dead, the low battery indicator will not illuminate.

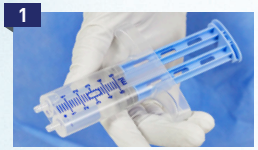
6

Check the gauge on the EASYSPRAY device for the appropriate pressure range of 1.5-2.0 bars (21.8-29 psi). Adjust pressure setting by turning the black pressure control knob.

***Switch OFF the EASYSPRAY Device after the surgeon is finished spraying ARTISS.**

Instructions for Scrub Nurse
Spray Set for ARTISS Fibrin Sealant (Human)

1



Prepare ARTISS according to the instructions in the package insert.

2

Firmly attach the spray head to the nozzle of the syringe.

3

Fasten the pull strap to the syringe to assure the spray head is tightly secured.

4

Fit the connection tube of the spray set to the luer-lock connector on the underside of the spray head.

5

Attach the clip (on the end of the sensor line) by sliding it into the grooves located on the top of the syringe plunger.

6

Pass the assembled applicator to the surgeon for spray application. Pass the end of the connection tube with the sterile filters to the circulating nurse.

Instructions for Surgeon

1

Confirm (verbally) the actual pressure with OR personnel.

2

To activate the flow of gas occlude the opening in the clip center with thumb. To begin application, gently depress the syringe plunger.

3

Spray from a distance of 10 – 15 cm for optimum results.

Tips

The use of ARTISS is restricted to experienced surgeons who have been trained in the use of ARTISS.

In order to ensure optimal safe use of ARTISS by spray application, apply a minimum spray distance of 10 cm and a maximum spray pressure of 2.0 bar (28.5 psi) to minimise the potential risk of air or gas embolism, tissue rupture, or air or gas entrapment with compression.

The EASYSPRAY device will continue to emit gas for a brief period after the thumb is removed from the clip/plunger. This delay helps to avoid clogging of the spray head.

Please see the ARTISS SmPC for further information.

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 provided in the appropriate spray set instructions for use.

Please see Prescribing Information on the reverse side.

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In order to ensure optimal safe use of ARTISS by spray application, the following recommendations should be followed:

SURGERY	SPRAY SET TO BE USED	PRESSURE REGULATOR TO BE USED	RECOMMENDED SPRAY DISTANCE	RECOMMENDED SPRAY PRESSURE
Open wound surgery of subcutaneous tissue	TISSEEL / ARTISS Spray Set 10 pack	EASYSPRAY	10 – 15 cm	1.5 – 2.0 bar (21.5 – 28.5 psi)

When spraying the ARTISS, 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.

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 dihydrate. 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 cm^2. 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. In isolated cases these reactions have progressed to severe anaphylaxis. Pruritus and skin graft failure.

Precautions: Caution applying ARTISS using pressurised air or gas, not to be used with Easy Spray / Spray Set system in enclosed body areas. Any application of pressurised air or gas is associated with a potential risk of air or gas embolism, tissue rupture or gas entrapment with compression, which may be life threatening or fatal. 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 CO_2 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 patient's 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. Spray application should not be used in endoscopic procedures. **Interactions:** Avoid solutions containing alcohol, iodine and heavy metals. The effects of ARTISS on fertility have not been established. **Overdose:** No cases of overdose have been reported. **Legal Category:** POM Basic NHS price: 2ml kit - £97.50; 4ml kit £195.00; 10ml kit £443.75 **Marketing Authorisation Number and Holder:** ARTISS – PL 00116/0634, Baxter Healthcare Limited, Caxton Way, Thetford, Norfolk. IP24 3SE. **Date of Preparation:** May 2021.

Adverse Events and any drug or medical device product quality complaints (including suspected defective medicines or medical device adverse incidents) should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse Events should also be reported to Baxter Healthcare Ltd, by email (vigilanceuk@baxter.com) or by phone (+44 (0)1635 206360).
Drug or medical device product quality complaints relating to Baxter products can be reported directly to Baxter Healthcare Ltd by email (UK_SHS_QA_Complaints@baxter.com) or by phone (+44 1604 704603).

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The information presented here has been taken directly from the ARTISS Summary of Product Characteristics, the TISSEEL/ARTISS Spray Set Instructions for Use, and the EASYSPRAY Pressure Regulator Instructions for Use.

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