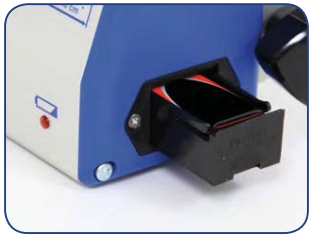
EASYSPRAY Quick Reference Guide (for open surgery)

Instructions for Circulating Nurse | EasySpray Pressure Regulator

1. 

Insert 9V battery into the EASYSPRAY pressure regulator device.

2. 

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

3. 

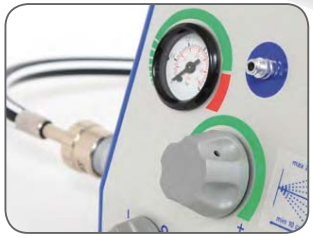
Use suitable connection tube to connect the EASYSPRAY device to medical air (ranging 3.5 – 7 bar / 51 – 100 psi).

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 to the ON (I) position.

6. 

Check the gauge on the EASYSPRAY device for the appropriate pressure range of 1.5-2.0 bars (21.5-28.5 psi). Adjust pressure setting by turning the grey pressure control knob.

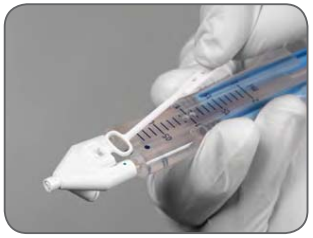
Instructions for Scrub Nurse | Spray Set

1. 

Prepare ARTISS Solution for Sealants according to the instructions in the package insert.

2. 

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

3. 

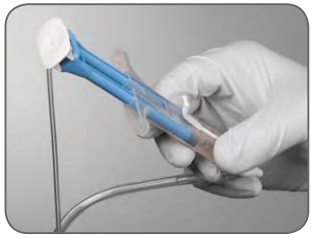
Fasten the pull strap to the double syringe system to assure the spray head is tightly secured.

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.

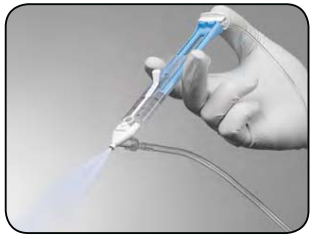
Instructions for Surgeon

1. 

Confirm (verbally)the actual pressure with OR personnel.

2. 

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

3. 

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

The use of ARTISS Solutions for Sealant 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 bar 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 provided together with this material.

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.

Baxter

EASYSPRAY Quick Reference Guide

CAUTION BOX

Any application of pressurized 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 if the product is sprayed incorrectly

Precautions
For ARTISS Solutions for Sealant

- In open-wound surgery: when applying sprayable fibrin solutions for sealant using a pressure regulator device, the maximum pressure should be 2.0 bar (28.5 psi). The product should be sprayed at a distance at least 10 cm from the tissue surface.
- Spray application should only be used if it is possible to accurately judge the spray distance as recommended by the manufacturer. Do not spray closer than the recommended distances.
- Prior to applying sprayable fibrin solutions for sealant, the surface area of the wound should only be dried using standard techniques (eg, intermittent application of compresses, swabs, use of suction devices).
- Blood pressure, pulse rate, oxygen saturation and end tidal CO_2 should be monitored closely when spraying fibrin solutions for sealant using a pressure regulator device, because of the possibility of occurrence of air or gas embolism.
- Regulators should be used in line with manufacturer recommendations and the SmPC and Instruction for Use.
- ARTISS is recommended for subcutaneous use only. ARTISS is not recommended for laparoscopic use.

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

Recommended pressure, distance and devices for spray application of ARTISS

Surgery	Spray set to be used	Applicator tips to be used	Pressure regulator to be used	Recommended distance from target tissue	Recommended spray pressure
Open wound of subcutaneous tissue	Tisseel / Artiss Spray Set	n.a.	EASYSPRAY	10 – 15 cm	1.5-2.0 bar (21.5-28.5 psi)
	Tisseel / Artiss Spray Set 10 pack	n.a.	EASYSPRAY		

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.

WARNINGS AND PRECAUTIONS

Caution: Pressurised gas supply must be between 3.5 and 7 bar (51-100 psi).
Caution: DO NOT connect to an oxygen source. Failure to follow these instructions can lead to explosion, which could result in serious injury or death.
Prior to operation make sure that the pressure range of the device is adjusted to the range specified in the appropriate spray set instructions for use.
Caution: Spraying into enclosed body cavities requires appropriate safety measures to make sure that the above mentioned risks will be avoided.
NOTE: Do not use with rechargeable batteries. The use of accessories of other manufacturers is not permitted.

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 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. 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: April 2018.

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 (0) 1604 704603).

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http://www.baxterspraysafety.com/index.html
For detailed information please contact your local representative.

July 2019 UKI/107/19-0001