Artiss Easyspray
Quick Setup Guide

ARTISS
[Fibrin Sealant (Human)]

Instructions for Scout Nurse

Connect Spray Set filters to Easyspray device. Connect blue filter to the blue female luer connector and the clear filter to the male luer connector.

Turn the on/off switch on the front side of the EASYSPRAY to the ON position.

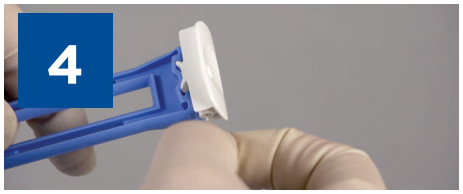
Check the gauge on the EASYSPRAY device for the appropriate pressure range of 1.5-2.0 bars (21.5-28.5 psi). Adjust pressure setting by turning the black pressure control knob.[1]

Instructions for Scrub Nurse

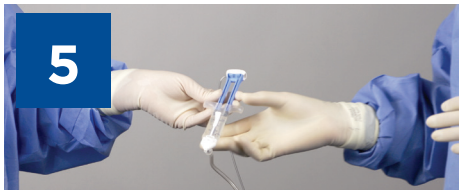
Firmly attach the spray head to the nozzle of the syringe.

Fasten the pull strap to the ARTISS syringe holder to assure the spray head is tightly Secured.

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



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

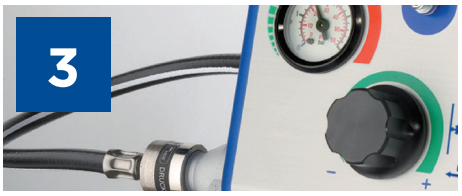


Pass the end of the connector tube with sterile filters to the circulating nurse. Pass the syringe to the surgeon for spray application.

Set-up Guide

Insert 9V battery into the EASYSPRAY pressure regulator device.

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



Use suitable connection tube to connect EASYSPRAY device to compressed medical air. (Ranging 3.5-7 bar, 50-100psi).

Important Points

- Spray from a distance of 10-15cm for optimum results (minimum spraying distance being 10cm).[1]
- To activate the flow of gas, occlude the opening in the clip center with thumb. To begin application, gently depress the syringe plunger.

References: 1. Tisseel/Artiss sprayset Instructions for Use

Baxter

ARTISS [Fibrin Sealant (Human)]

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Two-Component Fibrin Sealant, Deep-Frozen, Vapour Heated (VH) and Solvent Detergent (S/D) treated.

Indications

ARTISS is indicated to adhere autologous skin grafts in burn patients.

ARTISS is indicated to adhere tissue flaps during facial rhytidectomy surgery (face-lift).

ARTISS is not indicated for haemostasis.

Contraindications

ARTISS is contraindicated in the case of hypersensitivity to the active substances or to any of the excipients.

ARTISS is contraindicated for intravascular application. Intravascular application may result in life-threatening thromboembolic events.

Soft tissue injection of ARTISS carries the risk of local tissue damage.

Precautions

ARTISS alone is not indicated for the treatment of massive and brisk arterial or venous bleeding. As with any proteincontaining product, allergic type hypersensitivity reactions are possible. Hypersensitivity or allergic/ anaphylactoid reactions may occur with the use of 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 plasma 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 vapor 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

Adverse Reactions from Clinical Trials

In a phase 3, multi-centered, 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 eight non-serious adverse reactions occurred in six patients. Five of these reactions were skin graft failures, 4 were graft detachment/nonadherence, and 1 was graft necrosis. The remaining nonserious adverse reactions were pruritus (2) and dermal cyst (1).

Post marketing Adverse Reactions

There are limited post-marketing data available for ARTISS.

Adverse reactions reported from clinical studies as well as from postmarketing surveillance of Baxter´s other fibrin sealants are summarized in the full Product Information.

Dosage and Administration

ARTISS should be administered topically. Do not inject. ARTISS may be denatured by antiseptics (see Interactions with other medicines). Similar to comparable products or Thrombin solutions, the product may be denatured after exposure to solutions containing alcohol, iodine or heavy metals (e.g. antiseptic solutions). Such substances should be removed to the greatest possible extent before applying the product.

The skin graft should be attached to the wound bed immediately after ARTISS has been applied. The surgeon has approximately 60 seconds to manipulate and position the graft prior to polymerization.

After the graft or flap has been positioned, hold in the desired position by gentle compression for at least 3 minutes to ensure ARTISS sets properly and the graft or flap adheres firmly to the underlying tissue.

Please review full Product Information before prescribing. Available from Baxter Medical Information 1300 302 409 or onecall@baxter.com

To order call Baxter Customer Support:

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PBS Information: This product is not listed on the PBS

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