

Artiss

FIBRIN SEALANT (HUMAN)

EASYSpray Preparation Guide

FOR TECH SUPPORT CALL 1-888-229-0001, OPTION 4

Circulating Nurse
EASYSpray Device



1 Connect the adapter* attached to the black tubing, located at the side of the EASYSpray device, to an appropriate gas source (medical grade air, nitrogen or CO₂ depending on adapter). Pressurized gas supply must be set between 3.5 and 7 bar (51-100 psi).



2 Connect spray set filters to EASYSpray device, ensuring to remove the packaging caps from filters. Connect blue to blue and clear to clear.



3 Turn ON/OFF switch to the ON Position. If the battery is completely dead, the low battery indicator will not illuminate and no gas flow will occur. Ensure device is turned OFF after spraying to prevent risk of gas tank emptying and battery drainage.



4 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.

Scrub Nurse
Spray Set



1 Firmly attach the spray head to the syringe, ensuring blue dots align, and fasten the pull strap to the syringe.



2 Attach clear connector to the Luer-lock connector on the underside of the spray head.



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

Surgeon
Application Tips



1 To activate the flow of gas, occlude the opening in the clip center with thumb. To begin application, gently depress the ARTISS syringe plunger. The EASYSpray device will continue to emit gas shortly after thumb is removed from clip to help avoid clogging of the spray head.



2 A spraying distance of 10 - 15 cm is recommended. Note that the spraying distance should not be less than 10cm and the maximum pressure should not exceed 2bars (29.5psi).

Selected Important Risk Information

The EasySpray pressure regulator is only intended for open surgery. Air or gas embolism has occurred when fibrin sealant was administered using pressurized gas. This can occur if a spray device is used at higher than recommended pressures and in closer than recommended proximity to the tissue surface.

Please see detailed risk information on the back or prescribing information for additional information.

 **Do Not connect to an oxygen source.**

 **Do Not use rechargeable batteries.**

*The EasySpray device has no adapter installed from the factory due to multiple possible configurations, and should be installed by the hospital's biomedical engineering dept.

ARTISS [Fibrin Sealant (Human)] Indication

ARTISS is a fibrin sealant indicated to adhere autologous skin grafts to surgically prepared wound beds resulting from burns in adult and pediatric populations greater than or equal to 1 year of age. ARTISS is indicated to adhere tissue flaps during facial rhytidectomy surgery (face-lift).

ARTISS is not indicated as an adjunct to hemostasis

Important Risk Information for ARTISS

- For Topical Use Only. Do not inject directly into the circulatory system or into highly vascularized tissue. Intravascular application can result in life-threatening thromboembolic events and can increase the likelihood and severity of acute hypersensitivity reaction in susceptible patients.
- Do not use in individuals with a known hypersensitivity to aprotinin and/or hypersensitivity to any of the active substances or excipients of ARTISS.
- Do not spray where the minimum recommended distance from the applicator tip to the target site cannot be assured.
- Hypersensitivity reactions, including anaphylaxis, can occur. Should symptoms occur, discontinue and administer appropriate treatment. Such reactions may especially be seen if product is applied repeatedly over time or in the same setting, or if systemic aprotinin has been administered previously; however, these reactions may also occur in patients receiving ARTISS for the first time.

- Aprotinin is known to be associated with anaphylactic reactions. Even in the case of strict local application of aprotinin, there is a risk of anaphylactic reactions to aprotinin, particularly in the case of previous exposure.
- Discontinue administration in the event of hypersensitivity reactions. Remove the already applied, polymerized product from the surgical field.
- Life threatening/fatal air or gas embolism has occurred with the use of spray devices employing pressure regulator to administer fibrin sealants. This can occur if a spray device is used at higher than recommended pressures and in closer than recommended proximity to the tissue surface. To reduce the risk of potential life-threatening gas embolism, spray using only the appropriate pressurized gas at the recommended pressure (21.8-29.0 psi) and distance (10-15 cm). Use the EASYSpray device, or an equivalent spray device cleared by FDA, connected to a Medical grade CO₂, Compressed Air or Nitrogen. The risk appears to be higher when fibrin sealants are sprayed with air, as compared to CO₂. Spray only onto visible application sites, not in enclosed body cavities.
- ARTISS may denature when exposed to solutions containing alcohol, iodine or heavy metals. If these substances have been used to clean the wound area, the area should be thoroughly rinsed and dried before application of ARTISS.
- ARTISS is made from human plasma, it may carry the risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) and theoretically, the classic Creutzfeldt-Jakob disease agent.
- Adverse reactions reported in ≥ 1% of clinical trial subjects with the use of ARTISS were: Skin graft failure, hematoma and pruritus in burn studies, and hematoma/seroma in rhytidectomy studies.

Please see the accompanying full PI, or download it at: https://baxterpi.com/pi-pdf/Artiss_PI.pdf

EASYSpray Indications For Use

The EASYSpray Pressure Regulator controls and releases pressurized gas provided by a propellant gas source. The EASYSpray Pressure Regulator is to be used only with spray sets specified for use with this pressure regulator.

CAUTION: Pressurized gas supply must be between 3.5 and 7 bar.

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.

WARNING: Any application of pressurized gas may be associated with a potential risk of air embolism, tissue rupture 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 maximum pressure provided in the appropriate spray set instructions for use.

CAUTION: Spraying into enclosed body cavities is not permitted with ARTISS.

CAUTION: Do not use rechargeable batteries.

Please see the full instructions for use for additional information.



Do Not connect to an oxygen source.



Do Not use rechargeable batteries.

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

APPLICATOR TIPS TO BE USED	PRESSURE REGULATOR TO BE USED	GAS	RECOMMENDED DISTANCE FROM TARGET TISSUE	RECOMMENDED SPRAY PRESSURE / GAS FLOW RATE
TISSEEL / ARTISS Spray Sets	EASYSpray Regulator	CO ₂ * Medical Air or Nitrogen	10 - 15 cm	1.5 - 2 bar (21.8 - 29psi)

* CO₂ is the preferred gas for application, however Medical Air or Nitrogen are acceptable gasses for administration of ARTISS in open surgery.

For questions or ordering information, please contact your Baxter representative or call 888-229-0001.
www.advancedsurgery.baxter.com

Advancing the art of healing

The information presented here has been taken directly from the ARTISS Fibrin Sealant (Human) Prescribing Information, the TISSEEL/ARTISS Spray Set Instructions for Use, and the EASYSpray Pressure Regulator Instructions for Use.

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Baxter Healthcare Corporation
1 Baxter Parkway
Deerfield, IL 60015
USA

Baxter