

# Tisseel

## FIBRIN SEALANT

# EASYSPRAY Pressure Regulator 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 CO<sub>2</sub> 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 by turning the 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. **For Topical Use Only**



2 Attach clear connector to the Luer-lock connector on the underside of the spray head. **For Topical Use Only**



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. **For Topical Use Only**

Application Tips



1 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).



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

### 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.



## TISSEEL [Fibrin Sealant] Indications

**Hemostasis:** TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in adult and pediatric patients (> 1 month of age) undergoing surgery when control of bleeding by conventional surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. TISSEEL is effective in heparinized patients.

**Sealing:** TISSEEL is a fibrin sealant indicated as an adjunct to standard surgical techniques (such as suture and ligature) to prevent leakage from colonic anastomoses following the reversal of temporary colostomies.

## TISSEEL [Fibrin Sealant] Important Risk Information

**For Topical Use Only. Do not inject TISSEEL directly into the circulatory system or into highly vascularized tissue. Intravascular application of TISSEEL can lead to intravascular coagulation, can result in life-threatening thromboembolic events,** and can increase the likelihood and severity of acute hypersensitivity reactions in susceptible patients. To minimize the risk of intravascular application, exercise caution when using TISSEEL in surgery.

Do not use TISSEEL in individuals with a known hypersensitivity to aprotinin.

Do not use TISSEEL for treatment of severe or brisk arterial or venous bleeding. In these situations, TISSEEL will be washed away in the flow of blood before hemostasis can be attained.

Do not spray TISSEEL where the minimum recommended distance from the applicator tip to the target site cannot be assured.

Hypersensitivity or allergic/anaphylactoid reactions can occur with the use of TISSEEL. Such reactions may especially be seen if TISSEEL is applied repeatedly over time or in the same setting, or if systemic aprotinin has been administered previously.

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 of TISSEEL in the event of hypersensitivity reactions. Remove remaining product from the application site.

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.

When using the EASYSpray device, or an equivalent spray device for open surgical procedures cleared by FDA, TISSEEL must not be sprayed in enclosed body areas and must be sprayed onto only visible application sites.

TISSEEL is denatured when exposing to solutions containing alcohol, iodine or heavy metals. If any of these substances have been used to clean the wound area, the area must be thoroughly rinsed before the application of TISSEEL.

Apply TISSEEL as a thin layer by dripping or spraying using cannula or spray set. Excess clot thickness can negatively interfere with wound healing.

The safety and effectiveness of TISSEEL used alone or in combination with biocompatible carriers in neurosurgical procedures or other surgeries involving confined spaces have not been evaluated; its use in this setting is not FDA approved.

TISSEEL is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

Please see accompanying full Prescribing Information.

## 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 requires appropriate safety measures to make sure that the above mentioned risks will be avoided.

**CAUTION:** Do not use rechargeable batteries.

Please see full Indications for Use.



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



**Do Not use rechargeable batteries.**

**In order to ensure optimal safe use of TISSEEL 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 <sub>2</sub> * Medical Air or Nitrogen	10 - 15 cm	1.5 - 2 bar (21.8 - 29psi)

\* CO<sub>2</sub> is the preferred gas for application, however Medical Air or Nitrogen are acceptable gasses for administration of TISSEEL in open surgery.

**For questions or ordering information, please contact your Baxter representative or call 888-229-0001.**

**[www.advancedsurgery.baxter.com](http://www.advancedsurgery.baxter.com)**

# Advancing the art of healing

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

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