

EASYSPRAY Quick Reference Guide









For Tech Support Call 1-877-TISSEEL


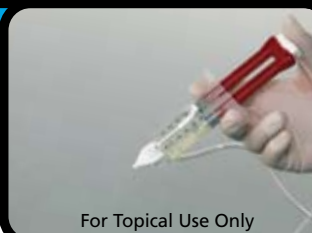
Instructions for Circulating Nurse – EASYSPRAY Pressure Regulator

<p>1</p>  <p>Connect EASYSPRAY device to IV pole or cart rail using the clamps on the back of the device.</p>	<p>2</p>  <p>Set wall unit pressure between 3.5 and 7 bar (51-100 psi).</p>	<p>3</p>  <p>Connect the black tube, located at the side of the EASYSPRAY device, to a propellant gas source. Use medical compressed air or nitrogen only.</p>	<p>4</p>  <p>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.</p>	<p>5</p>  <p>Turn the on/off switch on the front side of the EASYSPRAY to the ON position.</p>	<p>6</p>  <p>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.</p>
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Instructions for Scrub Nurse – Spray Set for TISSEEL [Fibrin Sealant]

<p>1</p>  <p>For Topical Use Only</p> <p>Prepare TISSEEL [Fibrin Sealant] according to the instructions in the package insert.</p>	<p>2</p>  <p>For Topical Use Only</p> <p>Firmly attach the spray head to the nozzle of the syringes.</p>	<p>3</p>  <p>For Topical Use Only</p> <p>Fasten the pull strap to the syringe to assure the spray head is tightly secured.</p>	<p>4</p>  <p>For Topical Use Only</p> <p>Fit the connection tube of the spray set to the luer-lock connector on the underside of the spray head.</p>	<p>5</p>  <p>Attach the clip (on the end of the sensor line) by sliding it into the grooves located on the top of the syringe plunger.</p>	<p>6</p>  <p>Pass the assembled TISSEEL syringe to the surgeon for spray application.</p> <p>Pass the end of the connection tube with the sterile filters to the circulating nurse.</p>
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Instructions for Surgeon

<p>1</p>  <p>For Topical Use Only</p> <p>Spray from a distance of 10-15 cm for optimum results. Avoid spraying from a distance of less than 5cm. For a distance of less than 10cm the pressure must be reduced appropriately. For Topical Use Only</p>	<p>2</p>  <p>For Topical Use Only</p> <p>To activate the flow of gas, occlude the opening in the clip center with thumb. To begin application, gently depress the TISSEEL syringe plunger.</p>
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 Do Not connect to an oxygen source. Do Not use rechargeable batteries.

TIPS

- 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 *Indications and Important Risk Information on the back.*
- Rx Only: For safe and proper use of the EASYSPRAY device, please refer to full device Instructions for Use included.





For Tech Support Call 1-877-TISSEEL (1-877-847-7335)

TISSEEL [Fibrin Sealant] Indications

Hemostasis: TISSEEL is a fibrin sealant indicated as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and treatment of splenic injuries. TISSEEL is satisfactory for use in fully heparinized patients undergoing cardiopulmonary bypass

Sealing: TISSEEL is indicated as an adjunct to prevent leakage from colonic anastomoses following the reversal of temporary colostomies

Important Risk Information for TISSEEL

For Topical Use Only. Do not inject TISSEEL directly into the circulatory system. Intravascular application of TISSEEL may result in life-threatening thromboembolic events. Caution should be exercised to minimize any risk of inadvertent intravascular application.

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

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

Hypersensitivity or allergic/anaphylactoid reactions may occur with the use of TISSEEL. Symptoms associated with allergic reactions include: flush, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnea, severe hypotension and anaphylactic shock. Such reactions may also occur in patients receiving TISSEEL for the first time.

Discontinue administration of TISSEEL in the event of hypersensitivity reactions.

Apply as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process.

Air or gas embolism has occurred with the use of spray devices employing pressure regulator to administer fibrin sealants. This event appears to be related to use of the spray device at higher than recommended pressures and in close proximity to the tissue surface.

The information presented here has been taken directly from the TISSEEL/ARTISS Spray Set Instructions for Use, 6208400ZA06 and the EASYSpray Pressure Regulator Instructions for Use, 6299610EH04.

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When applying fibrin sealants using a spray device, be sure to use the pressure within the pressure range recommended by the spray device manufacturer.

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

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.


There have been rare reports of serious adverse events such as paralysis and other compressive complications possibly related to the use of fibrin sealant in combination with resorbable hemostatic agents.

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

Please see accompanying full Prescribing Information.

Do not exceed pressure range of 1.5 - 2 bars (21.5 - 28.5 psi).

To achieve an optimal result, a spraying distance of 10-15 cm is recommended. In specific situations where spraying less than 10 cm is necessary, the gas pressure must be reduced appropriately .

 **Do Not connect to an oxygen source.
Do Not use rechargeable batteries.**

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