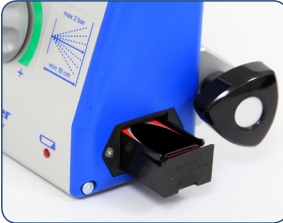




EASYSpray Quick Reference Guide (for open wound surgery)





Instructions for Circulating Nurse | EasySpray Pressure Regulator


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1 Insert 9V battery into the EASYSpray pressure regulator device.
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2 Connect EASYSpray device to IV pole or cart rail using the clamps on the back of the device.
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3 Use suitable connection tube to connect the EASYSpray device to medical air (ranging 3.5 – 7 bar / 50 – 100 psi).
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4 Connect Spray Set filters to EASYSpray device. Connect the blue filter (pressure line) to the blue female luer connector and the clear filter (sensor line) to the male luer connector.
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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 pressure control knob.


Instructions for Scrub Nurse | Spray Set


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1 Prepare TISSEEL Fibrin Sealant according to the instructions in the package insert.
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2 Firmly attach the spray head to the nozzle of the syringes.
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3 Fasten the pull strap to the double syringe system to assure the spray head is tightly secured.
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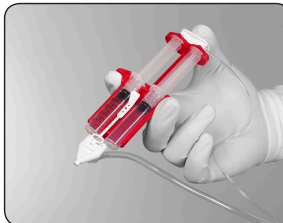
4 Fit the connection tube of the spray set to the luer-lock connector on the underside of the spray head.
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5 Attach the clip (on the end of the sensor line) by sliding it into the grooves located on the top of the syringe plunger.
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6 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

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1 Confirm (verbally) the actual pressure with OR personnel.
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2 Spray from a distance of 10 – 15 cm for optimum results.
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3 To activate the flow of gas occlude the opening in the clip center with thumb. To begin application, gently depress the syringe plunger.

The use of TISSEEL Fibrin Sealant is restricted to experienced surgeons who have been trained in the use of TISSEEL.

In order to ensure optimal safe use of TISSEEL by spray application, apply a minimum spray distance of 10 cm and a maximum spray pressure of 2.0 bar (28.5 psi) to minimize 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.

For full prescribing information about Tisseel, contact your local sales representative

Caution: 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. 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.

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 TISSEEL/TISSUCOL Fibrin 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 CO₂ 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.

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

Recommended pressure, distance and devices for spray application of TISSEEL					
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	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		
	DUPLOJECT Spray Set	n.a.	TISSOMAT		
	TISSEEL/TISSUCOL Spray Set	n.a.	EASYSpray		

When spraying the TISSEEL, changes in blood pressure, pulse, oxygen saturation and end tidal CO₂ should be monitored because of the possibility of occurrence of air or gas embolism.

WARNINGS AND PRECAUTIONS

Caution: Pressurized 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: Spray application requires appropriate safety measures as described in the pertinent Summary of Product Characteristics and Instructions for Use of the spray devices to make sure that the risks mentioned in this reference guide will be avoided

NOTE: Do not use with rechargeable batteries. The use of accessories of other manufacturers is not permitted.

Baxter

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For detailed information please contact your local representative

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