



TISSEEL
[Fibrin Sealant]

EASYSpray Pressure Regulator Quick Reference Guide

Instructions for Circulating Nurse EASYSpray Device



- **For first time usage:** 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.



- Connect the adapter attached to the black tubing, located at the side of the EASYSpray device, to an appropriate gas source. Pressurized gas supply must be set between 3.5 and 7 bar (51-100 psi).



- 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.



- Turn the on/off switch on the front side of the EASYSpray device to the ON position. The low-battery indicator light will only illuminate when the battery is weak and when the gas flow is activated. If the battery is completely dead, the low battery indicator will not illuminate.



- 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.

***Switch OFF the EASYSpray Device after the surgeon is finished spraying TISSEEL**

Instructions for Scrub Nurse Spray Set for TISSEEL [Fibrin Sealant]



- Prepare TISSEEL [Fibrin Sealant] according to the instructions in the package insert.



- Firmly attach the spray head to the nozzle of the syringes by aligning the blue dot on the spray head to the blue dot on the syringes.



- Fasten the pull strap to the double syringe system 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 syringe plunger.



- Pass the assembled TISSEEL syringe to the surgeon for spray application. Pass the end of the connection tube with the sterile filters to the circulating nurse.

Instructions for Surgeon



- A spraying distance of 10 –15 cm is recommended. Note that the spraying distance should not be less than 10 cm (3.9") and the maximum pressure should not exceed 2 bars (29.5psi).



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

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.

Selected Important Risk Information

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.

Rx Only: For safe and proper use of these devices, please refer to the appropriate full device Instructions for Use included.



Do Not connect to an oxygen source.



Do Not use rechargeable batteries.

TISSEEL [Fibrin Sealant] Indications

Supportive treatment where standard surgical techniques appear insufficient

- For improvement of haemostasis
- As a tissue glue to improve wound healing or to support sutures
- For tissue sealing, to improve adhesion of the separated tissue

The efficacy in fully heparinised patients has been proven. The use of TISSEEL is restricted to experienced surgeons who have been trained in the use of TISSEEL.

For epilesional use only.

Contraindications:

- TISSEEL alone is not indicated for the treatment of massive or brisk arterial or venous bleeding
- TISSEEL is not indicated to replace skin sutures intended to close surgical wounds
- TISSEEL must never be applied intravascularly. Intravascular application may result in life-threatening thromboembolic events
- TISSEEL must not be applied in case of hypersensitivity to the active substances or to any of the excipients
Special warnings and precautions for use.
- Do not apply intravascularly
- Life-threatening thromboembolic complications may occur if the preparation is unintentionally applied intravascularly
- Caution must be used when applying fibrin sealant using pressurised gas

- Any application of pressurised gas is associated with a potential risk of air or gas embolism, tissue rupture, or gas entrapment with compression, which may be life-threatening
- Apply TISSEEL as a thin layer. Excessive clot thickness may negatively interfere with the product's efficacy and the wound healing process
- Life-threatening/fatal air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer fibrin sealants. This event appears to be related to the use of the spray device at higher than recommended pressures and/or in close proximity to the tissue surface. The risk appears to be higher when fibrin sealants are sprayed with air, as compared to CO2 and therefore cannot be excluded with TISSEEL when sprayed in open wound surgery
- When applying TISSEEL using a spray device, be sure to use a pressure within the pressure range recommended by the spray device manufacturer
- TISSEEL 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
- When spraying 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 Reporting of suspected adverse reactions. Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via your national reporting system.

For Posology, method of administration, incompatibilities, interactions and undesirable effects, please refer to the full SPC.

Medicinal products are subject to medical subscription. In some countries TISSEEL [Fibrin Sealant] is licensed under the trademark TISSUCOL Fibrin Sealant.

Rx Only: For safe and proper use of the DUPLOSPRAY device, please refer to the full Instructions for Use.

This abbreviated summary of product characteristics (SPC) is intended for international use. Please note that it may differ from the licensed SPC in the country where you are practicing. Therefore, please always consult your country-specific SPC or package leaflet.

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 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 Tisseel in open surgery.

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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GLBL/90/20-0010 3/2020

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