

Instructions for **CIRCULATING NURSE**

SET UP REGULATOR



Position DUPLOSPRAY System so the foot switch is placed next to the surgeon's foot at time of application.



Attach the supply hose located at the back of the regulator to a source of medical grade CO₂.



Set CO₂ pressure to 100 psi (+/-5).



Attach the spray set to regulator. Connect the clear hooded luer connector on the tubing set to the male clear gas port on the regulator. Connect the blue male luer connector on the tubing set to the female luer blue vent port on the regulator.



While depressing the foot switch, adjust the gas flow to 1.0-2.0 liters per minute. Check the gas flow by noting the height of the ball in the gas gauge while stepping on foot switch.



Hand applicator over to scrub nurse using sterile technique.

Instructions for **SCRUB NURSE**

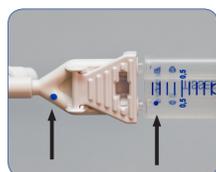
ASSEMBLE APPLICATOR



Use the tip alignment tool to thread a sterile replaceable tip onto the applicator until seated against the end of the applicator shaft. Retain the tip alignment tool, which holds a second replaceable tip provided for use if the first tip becomes occluded.



Push the male syringe set luer all the way into the female luer cones on the applicator.



Match the blue dot on the syringe's calibrated side with the blue dot on the applicator. If multiple syringes are required in the procedure, inconsistent orientation may cause the dual-chamber to clog.



Push the snap lock all the way down to securely fasten the applicator to the syringe luer.



Connect the clear female luer connector on the tubing set to the male luer gas port on the applicator.



Connect the red male luer connector on the tubing set to the female luer connector on the trocar vent valve.

Instructions for **SURGEON**

DISPENSE



Check the gas flow meter on regulator before inserting applicator into trocar. Maximum flow rate = 2.0L/min; recommended spray distance 3cm (range 2-5cm).



Press the foot switch of the DUPLOSPRAY MIS Regulator to start the gas flow prior to applying TISSEEL [Fibrin Sealant].



While activating the foot switch, dispense TISSEEL into the applicator by depressing syringe plungers using VERY SLOW STEADY PRESSURE. To stop spray delivery, release pressure on syringe plungers while maintaining gas flow by holding foot switch down for 3-5 seconds after applying TISSEEL to clear the applicator's tip.

NOTE: If using DUPLOSPRAY 360 Degree, angle the flexible tip at the end of the applicator by grasping and turning with an endoscopic grasper.



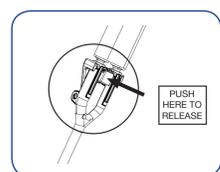

NOTE: Spray application precaution: any application of pressurized gas may be associated with a potential risk of air embolism, tissue rupture or gas entrapment with compression, which may be life-threatening. Be sure to take appropriate measures to address these risks by observing the recommended minimum spraying distance and the maximum pressure provided in the appropriate spray set instructions for use, or the TISSEEL SPC.

Instructions for **SCRUB NURSE**

RELEASE APPLICATOR



Press the release button on the back of the snap lock.



Detach applicator from syringe. Dispose as biohazard waste.



If the replaceable tip becomes occluded during use, as indicated by no spray or by no movement of the ball in the regulator flow meter, use the tip alignment tool to remove the occluded tip by unscrewing it in a counterclockwise motion. These steps should be at the end of the assembly steps including connection to gas source etc.



Using a sterile sponge, wipe any clotted material or fluid from the exposed metal tube ends.



Use the opposite chamber of the tip alignment tool to install a new tip by screwing it in a clockwise motion. Ensure replacement tip is secured firmly to prevent accidental tip detachment.

TROUBLESHOOTING – **OCCLUDED TIP**



DUPLOSPRAY MIS and 360 Endoscopic Applicator Product Codes with NEW SNAP LOCK ATTACHMENT

EXISTING CODES	DESCRIPTION	EA PER PACK	NEW CODES
0600033	DUPLOSPRAY MIS APPLICATOR WITH SNAP LOCK 20cm	5/PK	0601133
0600029	DUPLOSPRAY MIS APPLICATOR WITH SNAP LOCK 30cm	5/PK	0601129
0600030	DUPLOSPRAY MIS APPLICATOR WITH SNAP LOCK 40cm	5/PK	0601130
0600128	SPRAY SET 360 ENDOSCOPIC APPLICATOR WITH SNAP LOCK	5/PK	0611128

INTENDED USE

The DUPLOSPRAY MIS Applicator is intended for the application of TISSEEL [Fibrin Sealant].

WARNINGS/PRECAUTIONS

Only qualified personnel should operate this device. Use only with approved DUPLOSPRAY MIS Regulators. Connect DUPLOSPRAY regulator to down-regulated CO₂ gas source; maximum input pressure not to exceed 100 psi (7 bar). See regulator IFU for more information.

Caution must be used when applying product using pressurized gas.

- 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 the use of the spray device at higher than recommended pressures and in close proximity to the tissue surface. When applying sealants using a spray device, be sure to use the flow rate recommended in the Instructions for Use.
- To avoid possible gas embolism, do not spray directly into circulatory pathways. Any application of pressurized gas is 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 these recommendations:

- Do not spray at a distance closer to the surface of tissues than 2 cm (3 cm is recommended) at a maximum flow rate of 2.0 liters per minute (L/min).

FLOW RATE	1.0 - 2.0 Liters per minute (L/min)		
DISTANCE	2cm	3cm	5cm
		recommended	

- When using pressurized spray devices, changes in blood pressure, pulse, oxygen saturations, and end tidal should be monitored because of the possibility of occurrence of air gas embolism.

TISSEEL [Fibrin Sealant]

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.

TISSEEL [Fibrin Sealant] Indications

Supportive treatment where standard surgical techniques appear insufficient

- For improvement of hemostasis
- 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 heparinized patients has been proven

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

For epislonal use.

Contraindications:

- TISSEEL alone is not indicated for the treatment of massive and brisk arterial or venous bleeding.
- TISSEEL is not indicated to replace skin sutures intended to close surgical wound.
- 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 pressurized gas.
- Any application of pressurized 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 authorization 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 full device instructions for use.