Tisseel
FIBRIN SEALANT

DUPLOSPRAY Regulator Preparation Guide
FOR TECH SUPPORT CALL 1-888-229-0001, OPTION 4

Circulating Nurse
DUPLOSPRAY Regulator Set Up

1

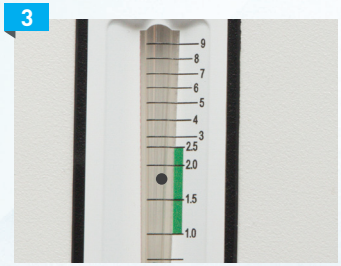
Attach supply hose (connected to DUPLOSPRAY Regulator) to medical grade CO2. Confirm CO2 tank is open (LEFT to OPEN; RIGHT to CLOSE).

RIGHT gauge should increase upon opening if tank is full. Use knob to set CO2 pressure (LEFT gauge) to 100 PSI (+/- 5).

2

Attach spray set to the regulator. Connect blue to blue and clear to clear.

3



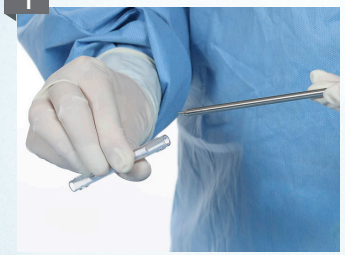
Step on foot pedal to adjust gas flow. The black ball should be near 2 L/min in the green area; if it isn't, use the knob to adjust the black ball.

4

Ensure 3 pieces (tubing set, metal cannula, and orange tip alignment tool) are passed to the sterile field.

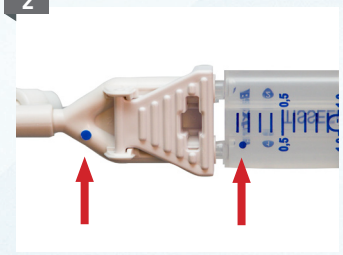
Scrub Nurse
Applicator Assembly

1



Slide tip alignment tool over metal cannula and thread a tip onto the applicator until seated. Save housing, which holds a second replacement tip if the first tip gets clogged.

2



OPEN the snap lock and connect spray head to the syringe, ensuring blue dots align, and fasten snap lock to the applicator.

3

Attach CLEAR connector on the tubing set to the Luer-lock connector on the underside of the spray head and screw down the WHITE collar.

Connect the RED connector on tubing set to the trocar vent valve.

4

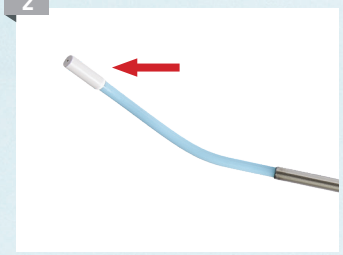
Check the gas flow meter on regulator before inserting applicator into trocar. Maximum flow rate = 2.0L/min; Recommended spray distance = 3 cm (range 2-5 cm).

Application Tips

1

Depress pedal THEN push TISSEEL syringe plunger. Use SLOW, STEADY pressure when depressing syringe plunger. To stop application, release pressure on syringe plunger THEN remove pressure on foot pedal 3-5 seconds after to clear the applicator tip.

2



If using DUPLOSPRAY 360 Degree, angle the flexible tip by grasping the white tip with an endoscopic grasper to prevent clogging.

3

If tip becomes clogged, signaled by no movement of the black ball in the flow meter, use orange tip alignment tool to remove the clogged tip. Use a sterile sponge to wipe any clogged material from end and use the opposite chamber of the tip alignment tool to install new tip, ensuring it is secured firmly.

*Maintain a distance of 3cm from targeted tissue. Do not touch tissue with applicator tip.

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.

Aprotonin 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.

DUPLOSPRAY Warnings and Precautions

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.

For questions or ordering information, please contact your Baxter representative or call 888-229-0001.
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 DUPLOSPRAY Regulator Instructions for Use.

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