**Instructions for Circulating Nurse | DUPLOSPRAY MIS Regulator**

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

2. Attach gas supply hose, located at back of regulator, to source of medical grade CO₂.

3. Attach spray set to regulator. Connect the blue vent line filter to the blue female luer and the clear gas line filter to the male luer on the regulator.

4. While depressing foot pedal, adjust gas flow rate to 1.0-2.0 litres per minute. Check gas flow by noting height of ball in flow gauge while stepping on foot pedal.

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**Instructions for Scrub Nurse | DUPLOSPRAY MIS Applicator**

1. Thread sterile replaceable tip onto applicator using tip alignment tool.

2. Firmly attach the applicator to the nozzles of the double syringe.

3. Fasten the pull strap to the double syringe holder to assure the spray applicator is tightly secured.

4. Attach gas supply line (clear luer connector) to sterile applicator. Turn white locking collar to secure connection.

5. Pass assembled double syringe and spray applicator to surgeon for spray application.

6. Attach patient vent line (red luer connector) to available female luer on trocar vent valve. Ensure vent valve is fully open.

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**Instructions for Surgeon**

1. Confirm actual flow of max 2 litres/min with theatre personnel.

2. Depress foot pedal to start gas flow prior to applying TISSEEL Fibrin Sealant. Check gas flow gauge on regulator before inserting applicator. If flow level ball does not move when foot pedal is depressed, the applicator tip is occluded and should be replaced.

3. While activating foot pedal dispense TISSEEL Fibrin Sealant through applicator tip by depressing double syringe plungers using very slow, steady pressure. To stop spray delivery release pressure on plungers while maintaining gas flow by holding down foot pedal for an additional 3-5 seconds to clear applicator tip.

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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 2 cm and a maximum spray pressure of 1.5 bar (22 psi/maximum gas flow rate 2.0 litres per minute) to minimise the potential risk of air or gas embolism, tissue rupture, or air or gas entrapment with compression.

**TIPS**

- The patient vent line attached to the trocar cannula vent valve will only vent gas out when foot pedal is depressed. After connection to trocar cannula, ensure vent valve is fully open on trocar cannula prior to spray application.

- If tip becomes occluded during use, remove plugged tip by unscrewing it counterclockwise. Using a sterile cloth, wipe any clotted material off exposed tube ends. Screw on new tip and tighten with finger pressure.

- The twin-tube assembly can be easily separated as necessary to allow freedom of movement. Please see the TISSEEL SmPC provided together with this material.
CAUTION BOX

Any application of pressurised 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 TISSUECOOL Fibrin Sealant
• 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 (e.g., 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 laparoscopic procedures: Use CO₂ only when using spray application. When applying the product as a spray using a CO₂ pressure regulator device, the maximum pressure should be 1.5 bar (22 psi) maximum gas flow rate 2.0 liters per minute. The product should be sprayed at a distance at least 2 cm (recommended range 2-5 cm) from the tissue surface.

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**

<table>
<thead>
<tr>
<th>Surgery</th>
<th>Spray set to be used</th>
<th>Pressure regulator to be used</th>
<th>Pressure regulator to be used</th>
<th>Recommended distance from target tissue</th>
<th>Recommended spray pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopic/ minimally invasive procedures</td>
<td>n.a.</td>
<td>DUPLOSPRAY MIS Applicator 20cm</td>
<td>DUPLOSPRAY MIS Applicator</td>
<td>2-5 cm</td>
<td>1.2-1.5 bar (18-22 psi)</td>
</tr>
<tr>
<td>Laparoscopic/ minimally invasive procedures</td>
<td>n.a.</td>
<td>DUPLOSPRAY MIS Applicator 40cm</td>
<td>DUPLOSPRAY MIS Applicator</td>
<td>2-5 cm</td>
<td>1.2-1.5 bar (18-22 psi)</td>
</tr>
<tr>
<td>Replaceable tip</td>
<td>n.a.</td>
<td>Duplospray MIS Regulator</td>
<td>Duplospray MIS Regulator</td>
<td>2-5 cm</td>
<td>1.2-1.5 bar (18-22 psi)</td>
</tr>
</tbody>
</table>

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.

Connect to regulated CO₂ gas source only; maximum input pressure not to exceed 100 psi ± 5 (6.89 bar ± .35). To avoid possible air or gas embolism, do not directly spray into circulatory pathways.

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 of 2 cm (optimal working distance 3 cm) and the maximal flow rate of 2.0 standard liters per minute.

For detailed information please contact your local representative.

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