INSTRUCTIONS FOR USE

CO₂ (Carbon Dioxide) Pressure Regulator for Use with EVICEL™ Application Device

DEVICE COMPONENTS
The pressure regulator (see diagram) is a pneumatic system consisting of the following parts:
1. Inlet pressure tubing
2. CO₂ connector for connection to a CO₂ gas supply (either a wall outlet or a pressurized container)
3. Pressure gauge
4. Sterile filter connector (male Luer lock connection) to the EVICEL™ Application Device
5. Pressure regulator (Knob)
6. Foot pedal
7. Stand clamp

The pressure regulator allows EVICEL® Fibrin Sealant to be applied by spraying using an EVICEL™ Application Device. The Application Device should be used only with an Omrix Pressure Regulator to achieve the recommended pressure for spray application.

To ensure safe and efficient operation, read the instructions for use and warnings carefully before attempting to operate the pressure regulator.

The pressure regulator has the following functions:
- It regulates the pressure of CO₂ obtained from either a wall outlet or a pressurized container to the recommended range.
- It allows CO₂ to be supplied to the Application Device at the recommended pressure, allowing sealant to be sprayed when the foot pedal is depressed.

As stated in the EVICEL® Fibrin Sealant package insert, EVICEL™ Application Device and Tip Assembly Guides:
- Do not use EVICEL® for spraying in endoscopic (intraluminal) procedures where the minimum required distance from the applicator tip to the target site cannot be assured. Please refer to Tables 1 & 2 for Spray Distance and Pressure for the minimum required distance for each tip.
- When applying EVICEL® Fibrin Sealant in open procedures, be sure to use a pressure and a distance from the tissue within the ranges recommended by the manufacturer:

Table 1: Recommended Spray Distances and Pressures for Open Surgery

<table>
<thead>
<tr>
<th>Tip Type</th>
<th>Distance</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 cm Tip</td>
<td>10-15 cm</td>
<td>1.4 – 1.7 bar (±20 – 25 psi)</td>
</tr>
<tr>
<td>35 cm Rigid Tip</td>
<td>1.0 – 1.4 bar (±15 – 20 psi)</td>
<td></td>
</tr>
<tr>
<td>45 cm Flexible Tip</td>
<td>1.0 – 1.4 bar (±15 – 20 psi)</td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Recommended Spray Distances and Pressures for Laparoscopic Surgery

<table>
<thead>
<tr>
<th>Tip Type</th>
<th>Distance</th>
<th>Pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>35 cm Rigid Tip</td>
<td>4–10 cm</td>
<td>1.0 – 1.4 bar (±15 – 20 psi)</td>
</tr>
<tr>
<td>45 cm Flexible Tip</td>
<td>4–10 cm</td>
<td>1.0 – 1.4 bar (±15 – 20 psi)</td>
</tr>
</tbody>
</table>

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WARNINGS

- Life-threatening air or gas embolism has occurred with the use of spray devices employing the pressure regulator to administer EVICEL® Fibrin Sealant. These events appear to be related to the use of the spray device at higher than recommended pressures and/or in close proximity to the tissue surface. In order to reduce the risk of air or gas embolism, do not exceed the recommended pressure or position the EVICEL® Tip closer than the recommended distance (see Tables 1 & 2).

- To reduce the risk of potentially life-threatening air embolism, EVICEL® should be sprayed using pressurized CO2 gas only, at the indicated pressures and distances.

- Ensure that the inlet pressure tubing does not cause any obstruction in the operating theatre.

- Do not allow any liquids to enter the unit.

- Clean the unit after use with a cloth soaked in warm water and an appropriate detergent.

- Replace the EVICEL™ Application Device tubing set after each surgery.

- Follow instructions for use in the EVICEL™ Application Device Assembly Guide and associated Accessory Tip Assembly Guides.

- The pressure regulator is for use only while spraying EVICEL® with its Application Device.

- When operation is completed, disconnect the pressure regulator from the gas source.

OPERATING INSTRUCTIONS

Make sure that the pressure regulator inlet connector is compatible with a pressurized CO2 gas source outlet before proceeding with the following steps.

1. Place the pressure regulator on the floor, on a flat surface, or mount on an IV pole using the provided clamp (no. 7 in diagram), where it does not obstruct the surgical staff.

2. Place the foot pedal on the floor, within easy reach of the surgeon.

3. Connect the inlet gas pressure from the CO2 gas supply source should be between 3–6 bar or 45–90 psi.

4. Pull up the regulator’s knob cap and adjust pressure reading by rotating the knob, while the foot pedal is being stepped on. Turn clockwise to increase and counterclockwise to decrease. Information about the pressure to be used is provided in Tables 1 & 2 and in the Device and Tip Assembly Guides.

5. Press the foot pedal to ensure gas discharge from the male Luer lock. Let gas flow for 15 seconds. Releasing the foot pedal will stop the gas discharge.

6. Pull up the knob cap of the regulator (5) and adjust pressure reading to 1 bar or 14.5 psi by rotation of the knob until the pointer on pressure gauge (3) is set to that pressure value.

7. The EVICEL™ Application Device kit contains 0.2 μm filter tubing. Connect the female Luer connector of the sterile filter tubing to the male Luer connector located on the panel of the pressure regulator unit. Connection of the female Luer connector to the male Luer connector should be done gently to avoid any damage to the unit and should be performed manually without the use of any tools.

8. The EVICEL™ Application Device kit contains 0.2 μm filter tubing. Connect the female Luer connector of the sterile filter tubing to the male Luer connector located on the panel of the pressure regulator unit. Connection of the female Luer connector to the male Luer connector should be done gently to avoid any damage to the unit and should be performed manually without the use of any tools.

9.Press gently on the foot pedal to activate gas flow through the EVICEL™ Applicator, then depress the Application Device plungers. This will allow sealant to be sprayed. Release the foot pedal to stop spraying. For guidance on the procedure, reference the instructions for use for the EVICEL™ Application Device.

10. When operation is completed, disconnect the pressure regulator from the gas source.

TECHNICAL SPECIFICATIONS

- Manually regulated gas pressure

- For nominal work pressures of up to 1.7 bar or 25 psi

- CO2 connector and tubing for source connection

- Stainless steel male Luer lock connector to fit the device

PRESSURE GAUGE VERIFICATION TESTING

The following testing should be performed at least once a year by a hospital medical engineer. In the event the device is dropped, subject to misuse, or suspected not to be working properly, verification testing should be performed prior to use on a patient according to the following directions:

1. Connect the pressure regulator to a CO2 source.

2. Connect a calibrated manometer, with a female Luer lock connector, to the sterile filter connector (no. 4 in diagram).

3. Pull up the knob cap of the regulator (5) and adjust pressure reading to 1 bar or 14.5 psi by rotation of the knob until the pointer on pressure gauge (3) is set to that pressure value.

4. Press the foot pedal (6) and verify that the pressure value, shown by the manometer, is within the range of 0.8–1.2 bar or 11.5–17.5 psi.

5. Adjust pressure reading to 1.5 bar or 22 psi by rotation of the knob until the pointer on pressure gauge (3) is set to that pressure value.

6. Press the foot pedal (6) and verify that the pressure value, shown by the manometer, is within the range of 1.3–1.7 bar or 19–24.5 psi.

The manufacturer guarantees that any fault in verification testing of the pressure regulator gauge, occurring within 2 years after the date of sale to the original purchaser, will be repaired or the device replaced free of charge.

If you have any questions or problems relating to the operation or verification testing of the pressure regulator gauge, please contact RA-OnelliComplaints@bles.inj.com.