VISTASEAL™ Fibrin Sealant (Human)

IMPORTANT SAFETY INFORMATION

INDICATION
VISTASEAL™ is indicated as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. VISTASEAL™ is effective in heparinized patients.

CONTRAINDICATIONS
- Do not inject directly into the circulatory system.
- Do not use for the treatment of severe or brisk arterial bleeding.
- Do not use in patients with history of anaphylaxis or severe systemic reactions to human blood products.
- Do not use VISTASEAL for spraying unless the minimum recommended distance from the applicator tip to the bleeding site can be achieved.

WARNINGS AND PRECAUTIONS
- Thromboembolic events may occur if VISTASEAL is administered intravascularly.
- Only spray VISTASEAL if it is possible to accurately judge the distance from the spray tip to the tissue surface.
- Hypersensitivity reactions can occur.
- 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.

ADVERSE REACTIONS
The most common adverse reactions (reported in >1% of clinical trial subjects) were nausea and procedural pain.

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

References:
1. VISTASEAL™ Fibrin Sealant (Human) (Highlights of Prescribing Information) Instituto Grifols, S.A. 2018
Spray or Drip Application Quick Tips

Spraying VISTASEAL

- Position the Airless Spray Tip 2 cm or more from the target tissue.
- Apply firm, even pressure to the plunger to spray the fibrin sealant. Increase distance accordingly to achieve desired coverage of the target area.
- VISTASEAL is designed to deliver a rapid, adherent, and durable clot; and the tip can clog if continuous pressure is not maintained.

If expression is stopped and the tip clogs, change the Airless Spray Tip:

1. Remove the old Airless Spray Tip by twisting counter-clockwise.
2. Wipe and pull away any clots from the end of the tip with sterile gauze. Purge clot from tip connector, if needed.
3. Connect a new Airless Spray Tip by twisting clockwise, ensuring it is securely tightened before use.

Dripping VISTASEAL

- Remove the Airless Spray Tip of the VISTASEAL Dual Applicator by unscrewing it from the tip connector.
- Keep the end of the tip as close to the tissue surface as possible without touching the tissue during application.

If expression is stopped and the tip clogs, change the Airless Spray Tip:

1. Remove the old Airless Spray Tip by twisting counter-clockwise.
2. Apply individual drops to the surface area to be treated. To prevent uncontrolled clotting, allow the drops to separate from each other and from the end of the tip.

VISTASEAL is shipped and stored frozen and must be thawed before use

<table>
<thead>
<tr>
<th>Storage</th>
<th>Shelf Life</th>
<th>Thawing Procedure</th>
<th>Thawing Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤-18°C (freezer)</td>
<td>2 years</td>
<td>Room temperature (20-25°C)</td>
<td>70 min. for 24 mL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sterile water bath (37°C) inside sterile field</td>
<td>90 min. for 10 mL</td>
</tr>
<tr>
<td>2-8°C (refrigerator)</td>
<td>48 hr</td>
<td>No thawing needed</td>
<td></td>
</tr>
<tr>
<td>20-25°C (room temperature)</td>
<td>24 hr</td>
<td>No thawing needed</td>
<td></td>
</tr>
</tbody>
</table>

OPEN SURGERY – Assembly

1. Open the blister packs for the pre-filled syringes and VISTASEAL™ Dual Applicator and transfer to the sterile field.

2. Tighten the grey Luer nuts on the VISTASEAL Dual Applicator by twisting counter-clockwise.

3. Unscrew and discard the syringe luer caps, making sure to keep the syringe holder pointed upright.

4. While keeping it in an upright position, gently strike the side of the syringe holder one or two times and lightly depress the plunger to evert excess air.

5. Attach the VISTASEAL Dual Applicator to the syringe holder with pre-filled syringes. An audible click will indicate the device is assembled. The device is now ready to use.

LAPAROSCOPIC SURGERY – Assembly

1. Open the blister packs for the pre-filled syringes and VISTASEAL™ Dual Applicator and transfer to the sterile field. Next, transfer the VISTASEAL™ Laparoscopic Dual Applicator into the sterile field.

2. Loosen the grey Luer nuts on the VISTASEAL™ Laparoscopic Dual Applicator and remove the open tip (Spray and Drip Tip).

3. Attach the VISTASEAL Laparoscopic Dual Applicator to the adapter by tightening the Luer nuts by twisting counter-clockwise.

4. Unscrew and discard the syringe luer caps. While keeping it in an upright position, gently strike the side of the syringe holder one or two times and lightly depress the plunger to evert excess air.

5. Attach the VISTASEAL™ Laparoscopic Dual Applicator and adapter to the syringe holder with pre-filled syringes. An audible click will indicate the device is assembled. The device is now ready to use.

Pressure-sensitive Plunger

- Do not depress plunger during attachment or prior to intended use; the two biologic components will pre-mix in the Airless Spray Tip, which may clog the tip.
- Ensure the Airless Spray Tip is securely tightened.
- The red indicator will not be visible if the Airless Spray Tip is securely tightened.

NOTE: Do not discard the syringe luer caps. An audible click will indicate the device is assembled. The device is now ready to use.

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