

VISTASEAL™ Fibrin Sealant (Human)

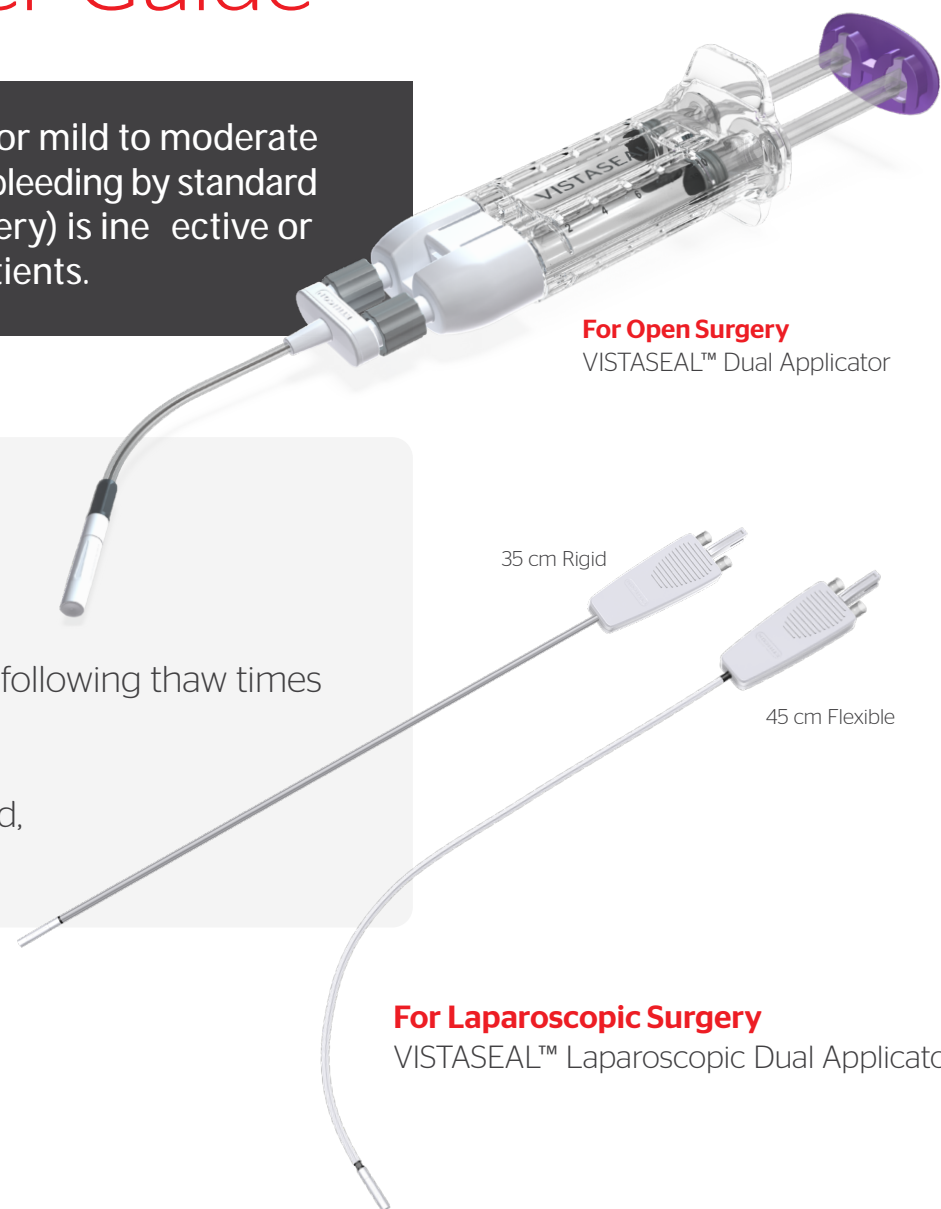
Interactive Device User Guide

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.

QUICK GUIDE FOR THAWING THE BIOLOGICS

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

- If thawing at room temperature (20-25°C), allow for the following thaw times
 - 2- and 4-mL devices - 70 minutes
 - 10-mL device - 90 minutes
- If thawing in a sterile water bath (37°C) inside sterile field, VISTASEAL™ is thawed in 5 minutes



For Open Surgery
VISTASEAL™ Dual Applicator

For Laparoscopic Surgery
VISTASEAL™ Laparoscopic Dual Applicators

TIPS AND TROUBLESHOOTING

Spraying VISTASEAL

Click the thumbnail for a video detailing how to spray VISTASEAL .



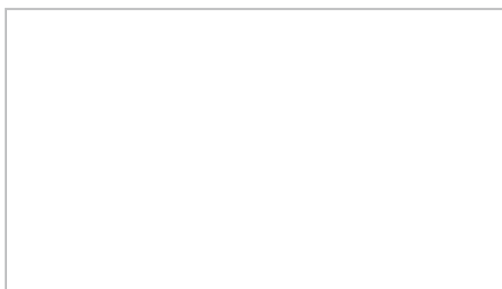
Position the Airless Spray Tip 2 cm or more from the target tissue

Apply firm, even pressure to the plunger to spray the fibrin sealant. Increase distance accordingly to achieve desired coverage of the target area

Tip can clog if continuous pressure is not maintained

Dripping VISTASEAL

Click the thumbnail for a video detailing how to drip VISTASEAL .



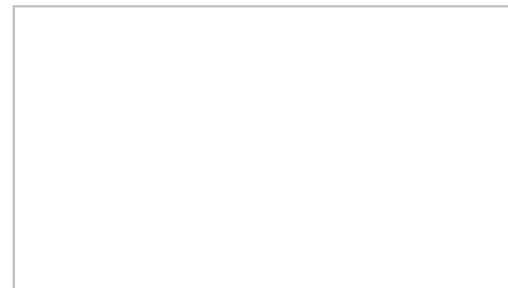
Remove the Airless Spray Tip of the VISTASEAL Dual Applicator by unscrewing it from the tip connector

Keep the end of the tip as close to the tissue surface as possible without touching the tissue during application

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

If expression is stopped, change the Airless Spray Tip

Click the thumbnail for a video detailing how to clear a clot.



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.

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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.

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

References: **1.** VISTASEAL™ Fibrin Sealant (Human). Full Prescribing Information. Instituto Grifols, S.A. 2019. **2.** VISTASEAL™ Laparoscopic Dual Applicator Assembly Guide, LAB100621384v2, 2019. Ethicon, Inc.