

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.

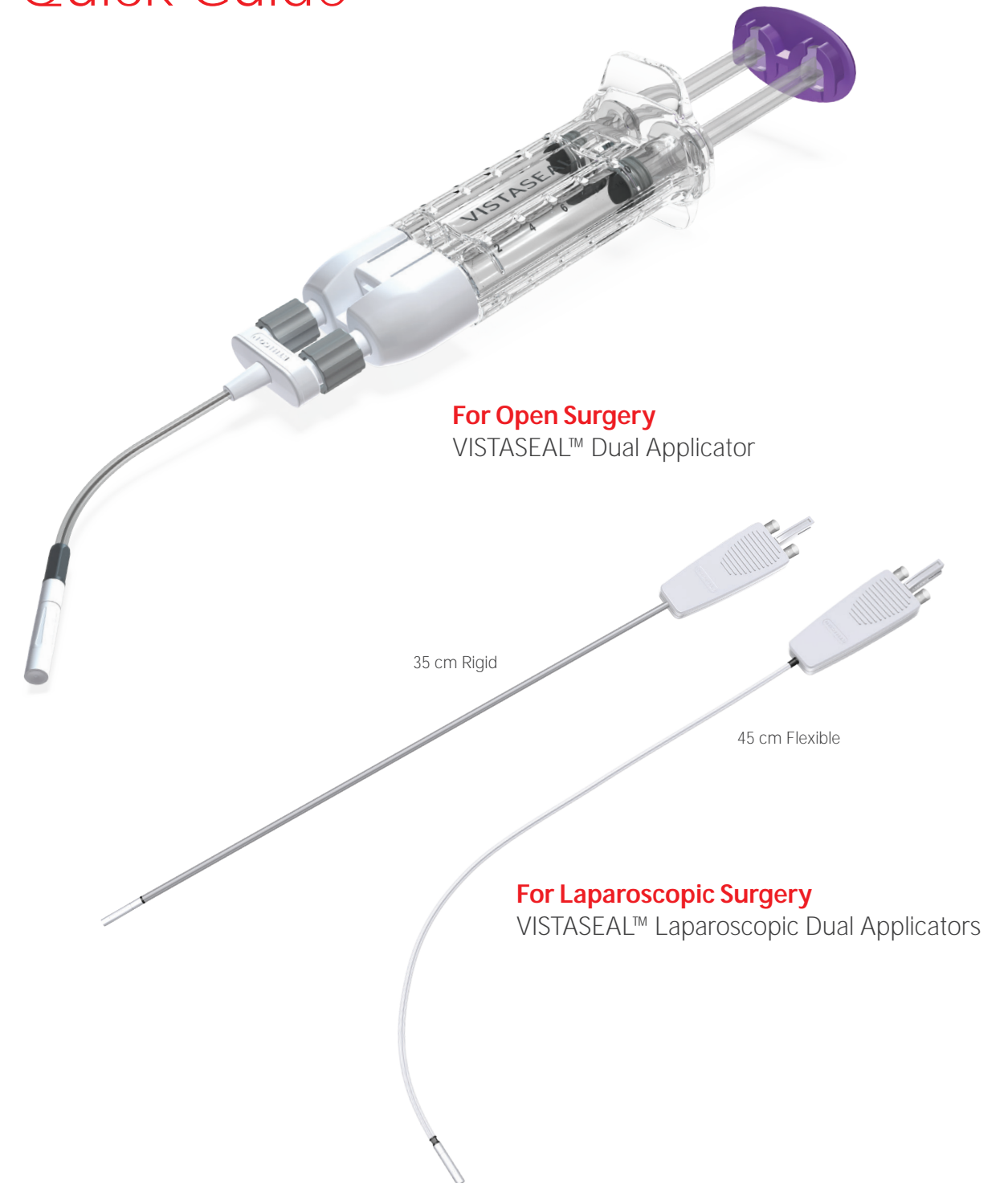
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For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

References: 1. VISTASEAL™ Fibrin Sealant (Human). [Highlights of Prescribing Information] Instituto Grifols, S.A. 2018. 2. Bjelovic M, Ayguasonosa J, Kim RD, et al. A prospective, randomized, phase III study to evaluate the efficacy and safety of fibrin sealant Grifols as an adjunct to hemostasis as compared to cellulose sheets in hepatic surgery resections. *J Gastrointest Surg.* 2018;22:1939-1949. 3. VISTASEAL™ Laparoscopic Dual Applicator Assembly Guide, LAB100621384v2, 2019. Ethicon, Inc.

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VISTASEAL™ Fibrin Sealant (Human) Optimized Device Performance Quick Guide



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