Deliver a clot even when your patient can’t.¹

VistaSeal™ Fibrin Sealant (Human)
Patient factors increase the risk of surgical bleeding

Consequences of post-operative bleeding

The risk of potential bleeding complications calls for a reliable fibrin clot that is effective independent of the patient coagulation profile – especially in high-risk patients.

Postoperative bleeding lengthens hospital stays by nearly 4 days and adds over $21K in total cost, and unfortunately some of these cases may be fatal.
VISTASEAL mimics the clot formation process regardless of the patient’s coagulation profile.1 When applied to the surgical site, these biologic components generate a cross-linked fibrin clot in a process that recreates the last stage of the coagulation cascade... and is effective even in heparinized patients.1

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VISTASEAL contains human fibrinogen and human thrombin1. Formation of the VISTASEAL fibrin clot begins to form as soon as the the biologics mix.1

VISTASEAL provides a rapid, adherent, and durable clot at the bleeding site².

Proven sustained hemostasis²

Durable hemostasis demonstrated in over 300 patients across randomized controlled trials².¹

VISTASEAL demonstrated a significant reduction in time to hemostasis compared to the control arm for vascular and parenchyma surgery in pivotal trials².¹

Safety and efficacy were evaluated in patients with a wide range of coagulation profiles.1

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 suturing, 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.

Please see page 11 for important safety information. For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

1 Safety and efficacy were demonstrated in a pivotal vascular randomized controlled trial (VISTASEAL) and shown to be superior to the control group in achieving hemostasis by direct observation. Safety and efficacy were documented in a pivotal parenchyma randomized controlled trial (VISTASEAL) and shown to be superior to the control group in achieving hemostasis by direct observation.

2 Safety and efficacy were documented in a pivotal brain surgery randomized controlled trial (VISTASEAL) and shown to be non-inferior to the control group in achieving hemostasis by direct observation.
No other fibrin sealant preps faster

* Based on number of set-up steps and thawing time required for VISTASEAL™ Dual Applicator vs competition.

† Refers to 10 mL TISSEEL device.

- No CO₂ needed
  Airless Spray Technology eliminates the need for external spraying equipment

- Once thawed
  no additional warming needed vs TISSEEL
  (4 minutes to warm)†

- Pre-filled syringes
  with click-on dual applicator; all in one box

**Designed for performance**

- **Flexibility** to drip or spray - narrow to broad

- **Malleable tip** provides precise application to challenging anatomy

- **Broader range of working temperature** for clinical use (2°C to 37°C) vs TISSEEL
  (33°C to 37°C)†

**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.

Please see page 11 for important safety information. For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

**VistaSeal™ Fibrin Sealant (Human)**
The malleable Dual Applicators are offered as 35 cm Rigid and 45 cm Flexible tips and can be used for spraying or dripping. Each comes with an airless spray tip attached and 2 replacement airless spray tips.

**Application precautions**

- Before administration of VISTASEAL, protect (cover) parts of the body outside the desired application area to prevent tissue adhesion at undesired sites.
- Apply VISTASEAL as thin layer. Excessive clot thickness may negatively interfere with the product’s efficacy and the wound healing process.
- Only spray VISTASEAL if it is possible to accurately judge the distance from the spray tip to the tissue surface.

**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.

**VISTASEAL™ Laparoscopic Dual Applicators for your minimally invasive procedures**

The malleable Dual Applicators are offered as 35 cm Rigid and 45 cm Flexible tips and can be used for spraying or dripping. Each comes with an airless spray tip attached and 2 replacement airless spray tips.
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.
Potential re-bleeding risk

Bleeding may be addressed intraoperatively, but could later develop into more serious complications.3,4

VISTASEAL

Part of the Ethicon Hemostasis Optimization Program – a systemic approach to bleeding management

The next generation device awaits you.

For more information, visit ethicon.com/vistaseal or contact your sales representative.

References:
1. VISTASEAL™ Fibrin Sealant (Human). Full Prescribing Information. April 2019.
5. AHQR. Postoperative hemorrhage or hematoma (provider-level): rate per 1,000 surgical discharges. Measure Summary NQMC-8088.

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