


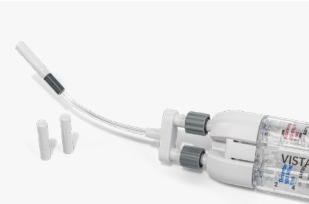


DEVICE SPECS

VISTASEAL™ Fibrin Sealant (Human) & Accessories

	 <p>VISTASEAL™ Fibrin Sealant (Human)</p>	 <p>VISTASEAL™ Rigid Laparoscopic Dual Applicator</p>	 <p>VISTASEAL™ Flexible Laparoscopic Dual Applicator</p>	 <p>VISTASEAL™ Dual Applicator</p>
Codes	VST02, VST04, 04VST04, 12VST04, VST10, 04VST10, 12VST10	VSTL35	VSTL45	VSTAS1E
Description	Fibrin Sealant (Human) in 2ml (single), 4ml (single, 4-pack, 12-pack), or 10ml (single, 4-pack, 12-pack)	35cm Rigid Laparoscopic Dual Applicator	45cm Flexible Laparoscopic Dual Applicator	Dual Applicator
Indication	VISTASEAL™ is a fibrin sealant (human) indicated as an adjunct to hemostasis for use in patients undergoing surgery, when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical	--	--	--
Size	2mL (VST02), 4mL (VST04, 04VST04, 12VST04), 10mL (VST10, 04VST10, 12VST10)	35cm	45cm	--
Hemostatic Agent/Accessory	Hemostatic Agent	Accessory	Accessory	Accessory
Absorption Time	10-14 days	--	--	--
Storage Requirements	Store frozen vials at -18°C or colder for up to 2 years. Store VISTASEAL at 2°C to 8°C for up to 48 hours. The two VISTASEAL components, Fibrinogen and Thrombin, have been shown to be stable for up to 24 hours at room temperature	Store at room temperature. Do not freeze.	Store at room temperature. Do not freeze.	--
Preparation Time	5 minute thawing time in sterile water bath at temperature of no higher than 37C (99F). 70 minute thaw time at room temperature for 2mL and 4mL sizes , 90 minute thaw time at room temperature for 10mL size	--	--	--
Shelf Life	2 years	3 years	3 years	2 years
Material/Composition	Human Fibrinogen and Human Thrombin	--	--	Dual Applicator Tip
Mechanism of Action	VISTASEAL™ fibrin clot is formed when thrombin activates conversion of fibrinogen into fibrin	--	--	--
NDC/Distributor Code	Carton: 61953-0011-1, 61953-0012-1, 61953-0014-1 Blister label: 61953-0011-2, 61953-0012-2, 61953-0014-2	--	--	--
Qty./Box	1 (VST02, VS04, VST10) 4 (04VST04, 04VST10) 12 (12VST04, 12VST10)	3	3	3

IMPORTANT SAFETY INFORMATION

VISTASEAL™ Fibrin Sealant (Human)

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.

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.

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