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Tridyne™ Vascular Sealant

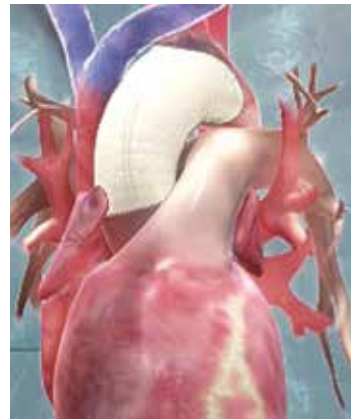
Clinically proven to perform under pressure¹

A strong elastic seal where it matters most



Tridyne™ Vascular Sealant is the latest addition to the BD family of hemostasis solutions, offering cardiovascular, cardiothoracic, and vascular surgeons a unique, easy-to-use solution to reinforce aortic anastomoses and control bleeding when adjunctive measures are required. By combining a proprietary formulation of polyethelyne glycol and human serum albumin, it forms a strong, flexible seal, even in anticoagulated patients.^{1,2} The Tridyne™ hydrogel is designed to adhere where it should – on both tissue and grafts.¹

Preclinical data demonstrates that Tridyne™ Vascular Sealant resorbs naturally to maintain its seal strength through the critical postoperative period without compromising tissue healing.²



- Strong²**
to reinforce anastomoses and adjunctively control bleeding³
- Elastic**
to support flexible movement of the aorta²
- Safe¹**
non-cytotoxic to support natural healing of aortic tissue²



Precise, controlled application—made easy

Tridyne™ Vascular Sealant provides application control without the need for pressurized gas.

The Tridyne™ applicator is designed to:

- Provide uniform, continuous coverage without clumping
- Control sealant application by varying hand pressure
- Easily transition from targeted application over the anastomosis to broader coverage to address more diffuse bleeding

Targeted application



Broad application



Clarity and coverage



The specialized Tridyne™ formulation is transparent and forms a completely clear hydrogel at the application site. With its unique combination of clarity and coverage, Tridyne™ Vascular Sealant allows for visual confirmation of hemostasis at the anastomotic suture line—making it an ideal choice for aortic surgery.

* The use of Tridyne™ Vascular Sealant with ePTFE grafts or vascular patches has not been studied clinically. Preclinical data on file. Preclinical test results may not correlate to clinical performance.

Performance under pressure



In a prospective, randomized, controlled multicenter study, Tridyne™ Vascular Sealant outperformed GELFOAM® PLUS Hemostasis Kit in several critical measures. The study included 156 patients from 18 different centers who underwent thoracic aortic surgery, with hemostasis evaluated at the aortic anastomotic suture line.¹

Immediate hemostasis¹

59.4%

Tridyne™
Vascular Sealant

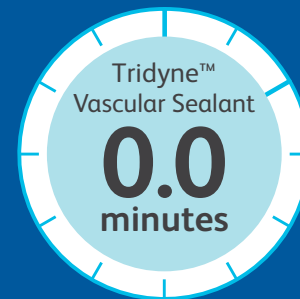
16.0%

GELFOAM® PLUS
Hemostasis Kit

$P < 0.0001$

Tridyne™ Vascular Sealant was significantly more effective at achieving hemostasis at the time of cross clamp removal (0 seconds).¹

Time to hemostasis¹



The median time to hemostasis was significantly lower in subjects in the Tridyne™ treatment group compared to subjects in the GELFOAM PLUS® treatment group.^{1,5}

Successful hemostasis¹

85.7%

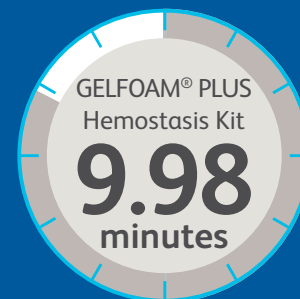
Tridyne™
Vascular Sealant

40.0%

GELFOAM® PLUS
Hemostasis Kit

$P < 0.0001$

Tridyne™ Vascular Sealant was significantly more effective at achieving hemostasis 5 minutes after cross-clamp removal.¹



$P < 0.0001$

The Tridyne™ treatment group had 0% reoperations due to aortic bleeding complications.^{1,4}

The proven solution during aortic repair¹

Tridyne™ Vascular Sealant offers surgeons a specialized, easy-to-use solution during aortic repair, with unique application control and clinically proven results.¹ With its demonstrated ability to provide fast, effective control of bleeding, it's clearly the sealant choice for aortic surgery.



1. Khoynzhad A, DelaRosa J, Moon M, et al. Facilitating Hemostasis After Proximal Aortic Surgery: Results of The PROTECT Trial. *Ann Thorac Surg.* 2018;105(5):1357-1364.

2. BD Inc. In vitro testing. Data on file. Preclinical test results may not correlate to clinical performance.

3. Tridyne™ Vascular Sealant is indicated for use in aortic surgery when adjunctive measures to achieve hemostasis are required by mechanically sealing areas of leakage.

4. One subject from the GELFOAM PLUS® treatment group required a reoperation for aortic bleeding complications following completed surgery through 30 days.

5. Mean time to hemostasis was 2.07 minutes for the Tridyne™ treatment group and 6.3 minutes for the GELFOAM PLUS® control treatment group ($P < 0.0001$).

Ordering information		
Cat. no.	Description	Qty.
TDVS004	Tridyne™ Vascular Sealant (4 mL)	4/cs.
TDST0020	Tridyne™ Applicator Spray Tips (pack of 2)	10/cs.
TDET0006	Tridyne™ Extended Spray Tip, 16 cm (6")	4/cs.



Indications

Tridyne™ Vascular Sealant (Tridyne™ VS) is indicated for use in aortic surgery when adjunctive measures to achieve hemostasis are required by mechanically sealing areas of leakage.

Contraindications

Tridyne™ VS is not for intravascular use.

Do not use Tridyne™ VS in patients who have a history of allergic reaction to Human Serum Albumin, Polyethylene Glycol, or other device components.

Do not apply Tridyne™ VS on oxidized regenerated cellulose, absorbable gelatin sponges, or any other surface or material other than the target tissue or graft as adherence and intended outcome may be compromised.

Do not use Tridyne™ VS in patients who have insufficient renal capacity for clearance of the Polyethylene Glycol load.

Warnings

Do not use Tridyne™ VS as a substitute for standard closure techniques.

Excessive pressure against the vessel/graft edges or surrounding tissue during application may result in separation of the vessel/graft edges, allowing sealant into the vessel.

Do not apply Tridyne™ VS when the vessel lumen is under negative pressure to avoid product from being drawn into the vessel (e.g., avoid applying in vessels that are not pressurized).

Do not use more than 30 mL of Tridyne™ VS per patient. Do not allow non-polymerized Tridyne™ VS to contact circulating blood.

Adverse Events

In a pivotal clinical trial, approximately half of the subjects in each treatment group experienced a Serious Adverse Event while in the study (51 subjects [48.1%] treated with Tridyne™ VS, 29 subjects [58.0%] treated with Control). Three Serious Adverse Events in the treatment group were considered by the Clinical Events Committee to be possibly device-related. These Serious Adverse Events included: cerebrovascular accident and serosanguineous pericardial effusion. None of the Serious Adverse Events were unexpected given the procedures performed.

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