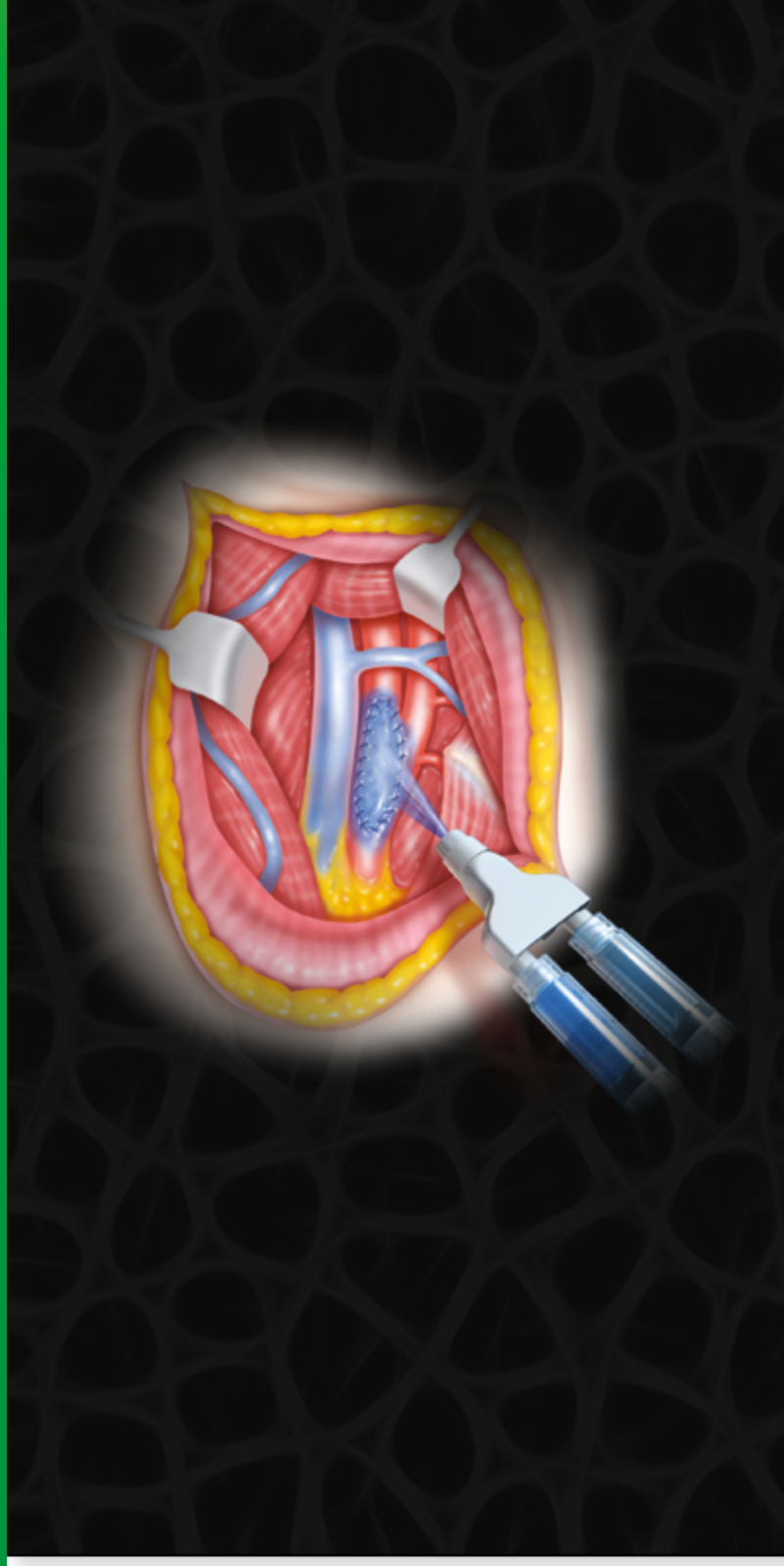
Integra®

VascuSeal® Vascular Sealant System

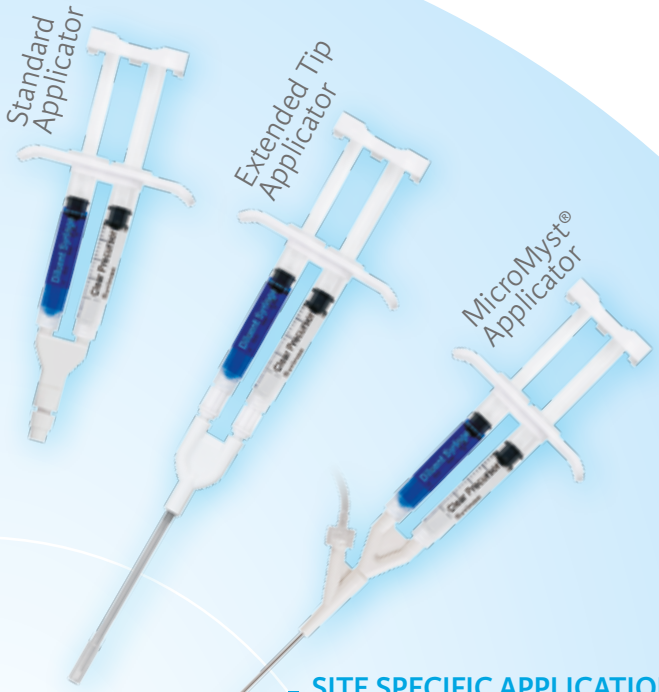
Limit uncertainty with VascuSeal® System, hydrogel technology for vascular surgery.

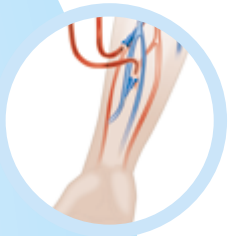


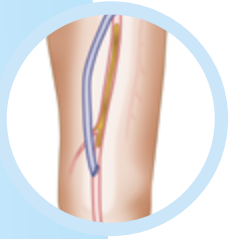
INTEGRA®
LIMIT UNCERTAINTY

Integra®
VascuSeal® Vascular Sealant System

The VascuSeal® Vascular Sealant System provides vascular surgeons with a polyethylene glycol hydrogel sealant that allows rapid hemostasis along suture lines in arterial and venous reconstruction procedures aiming at preventing intraoperative and postoperative complications associated with suture line bleeding. The VascuSeal® Vascular Sealant System consists of components for preparation and delivery of a synthetic absorbable surgical sealant.







SITE SPECIFIC APPLICATION
- Instant polymerization for effective sealing
- Blue color for visualization

SYNTHETIC & ABSORBABLE
- 100% synthetic
- Hydrolizes over 7 days and is cleared by the kidneys[1]

OPTIMIZED ADHERENCE & FLEXIBILITY
- Adherence properties to tissues to withstand critical vessel pressure

EASY TO USE
- Less than 2 minute preparation time
- Choice of standard, MicroMyst® or Extended Tip Applicator

Sealant Facts

Visualization

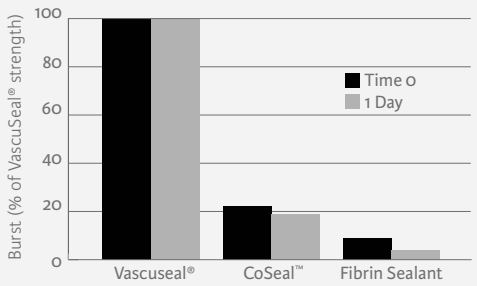
- Distinctive blue colorant provides a visual cue to assess sealant coverage and thickness.

Polyethylene Glycol (PEG) Inert Properties[1]

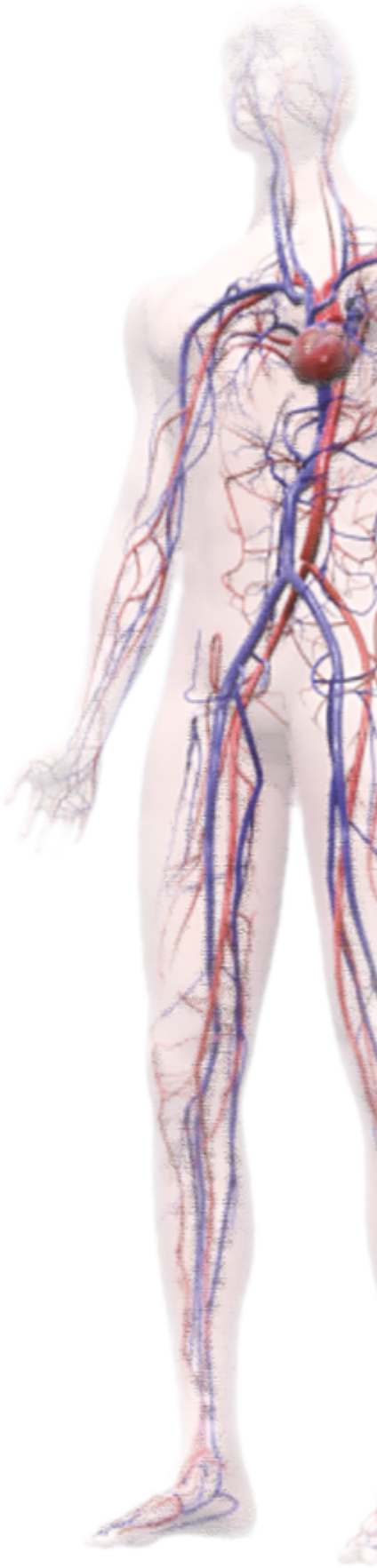
- Polymerization gentle on tissue
- No exothermic reaction
- Biocompatible

Strength[1]

- Strong adherence properties allow the sealant to withstand critical pressures.



Normalized burst strength of CoSeal® and fibrin sealant, relative to the normalized VascuSeal® burst strength at time zero and after 24 hours in 37°C PBS.



VascuSeal® Vascular Sealant System vs. Fibrin products

Criteria	VascuSeal® Sealant System	Fibrin Sealant[2]
Synthetic	Yes	No
Potential risk of viral transfer and anaphylactic reaction	No	Yes
Easily visualized	Yes - Blue colorant	No - Clear
Resorption Time	7 days	10 - 14 days
Preparation time	< 2 minutes	10 - 15 minutes
Storage temperature	At or below 77 °F (25 °C)	Refrigerate/or room temperature
Storage location	Operating Room	Pharmacy

1. Patrick K. Campbell, PhD, Steve Bennett, PhD, Next-Generation Vascular Sealants: How They Compare to Traditional Methods, 2009

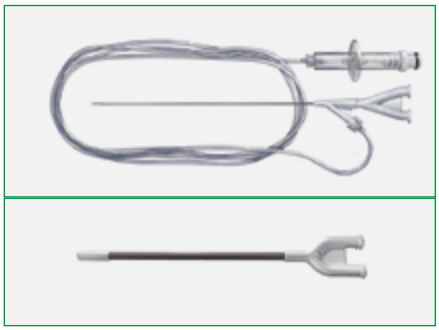
2. TISSEEL (Fibrin Sealant) Instructions For Use (0707074). Baxter Healthcare Corporation, Westlake Village, CA.

Integra®
VascuSeal® Vascular Sealant System

Ordering Information

VascuSeal® Vascular Sealant System

Reference	Description	Reference
VAS-RA001	VascuSeal® Sealant System 5 mL, sterile, single-use	1/box



Applicators (to be ordered separately)

Reference	Description	Reference
20-5000	MicroMyst® Air Assist Applicator, 14 cm length, malleable shaft	5/box
205115	Extended Tip Applicator, 15 cm length, malleable shaft	5/box

Other Accessories (to be ordered separately)

Reference	Description	Reference
FR-6065	Flow Regulator for use in conjunction with MicroMyst® Applicator	1 unit

Indications For Use

The **VascuSeal® system** is intended for use as a surgical sealant during arterial and venous reconstructions to seal suture lines.
The **Extended Tip Applicator** is intended for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.
The **MicroMyst® Applicator** is intended for use in the delivery of two non-homogenous solutions onto a surgical site.
The **Flow Regulator** is intended to provide pressurized gas air or nitrogen) to gas-assisted applicators.

Contraindications

Do not use the **VascuSeal® system**, **Extended Tip Applicator**, **MicroMyst® Applicator** and **Flow Regulator** for other indications than ones provided in the instructions for use.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Please read carefully the instructions for use.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

Products mentioned in this document are CE class IIa or III devices. Please contact Integra customer service should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED".

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