


Novelrad Percutaneous Endovascular Suturing Device: How Does It Work And Clinical Experience

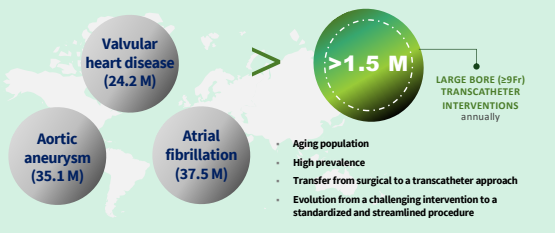


Veith Symposium 2024
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Disclosure Consultant to NovelRad

Minimally invasive interventions are on the rise

- New procedures such as valve implantation, aneurysm repair and structural heart repair expected to increase the number of large bore procedures by 3-6x



Valvular heart disease (24.2 M)

Aortic aneurysm (35.1 M)

Atrial fibrillation (37.5 M)

>1.5 M LARGE BORE (≥9Fr) TRANSCATHETER INTERVENTIONS annually

- Aging population
- High prevalence
- Transfer from surgical to a transcatheter approach
- Evolution from a challenging intervention to a standardized and streamlined procedure

The Need

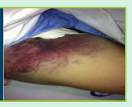
- Closing large-bore access site, in many cases as large as the vessel diameter, is challenging
- Existing devices are associated with high rate of vascular and bleeding complications (~20%)

+5 DAYS Length of hospital stay

50-60% Increase in cost of care

JAMA Cardiology | Brief Report
Mortality, Length of Stay, and Cost Implications of Procedural Bleeding After Percutaneous Interventions Using Large-Bore Catheters

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CONTEMPORARY REVIEWS IN INTERVENTIONAL CARDIOLOGY

Femoral Large Bore Sheath Management: How to Prevent Vascular Complications From Vessel Puncture to Sheath Removal

Lazaro Paraggio, MD, Francesco Bianchini, MD, Cristina Aurigemma, MD, PhD, Enrico Romagnoli, MD, PhD, Emiliano Bianchini, MD, Andrea Zito, MD, Mattia Lunardi, MD, Carlo Tranì, MD, Francesco Burzotta, MD, PhD


ABSTRACT: Transfemoral access is nowadays required for an increasing number of percutaneous procedures, such as structural heart interventions, mechanical circulatory support, and interventional electrophysiology/pacing. Despite technological advancements and improved techniques, these devices necessitate large-bore (2-12 French) arterial/venous sheaths, posing a significant risk of bleeding and vascular complications, whose occurrence has been related to an increase in morbidity and mortality. Therefore, optimizing large-bore vascular access management is crucial in endovascular interventions. Technical options, including optimized preprocedural planning and proper selection and utilization of vascular closure devices, have been developed to increase safety. This review explores the comprehensive management of large-bore accesses, from optimal vascular puncture to sheath removal. It also discusses strategies for managing closure device failure, with the goal of minimizing vascular complications.

Key Words: femoral artery • heart assist device • peripheral artery disease • transcatheter aortic valve replacement • vascular access devices

Paraggio L, Bianchini F, Aurigemma C, Romagnoli E, Bianchini E, Zito A, Lunardi M, Tranì C, Burzotta F. Femoral Large Bore Sheath Management: How to Prevent Vascular Complications From Vessel Puncture to Sheath Removal. *Circ Cardiovasc Interv.* 2024 Sep;17(9)

Surgical Suturing


The "gold standard" for vessel and tissue repair



- Preserves Natural Anatomy
- Oblivates Risk of Implant Related Complications
- Tissue Approximation Promotes Healing
- Reliable With Minimal Side Effects or Complications

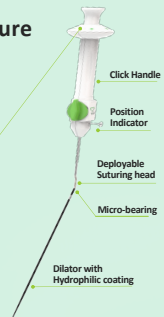
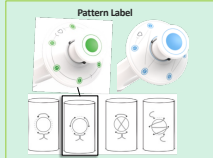
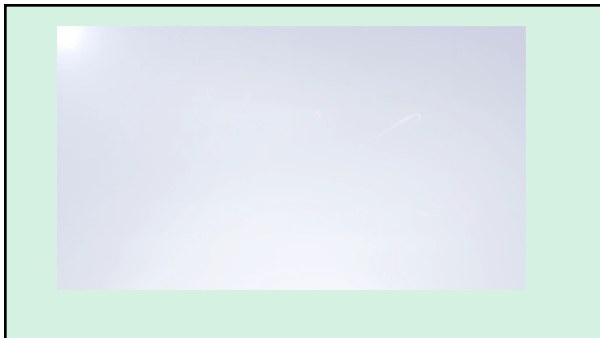
Core Technology

A micro stitching-tip that deploys a continuous running suture by transferring a micro needle, back and forth, through the tissue



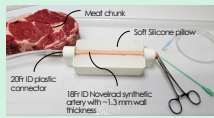
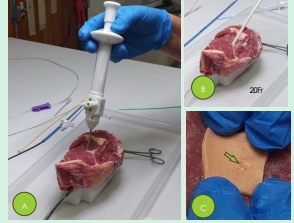
Our solution for large bore closure

- Multipoint purse-string suture – ideal for expansion and closure
- Single device for large access closure
- Simple and intuitive, ballpoint pen, 'Click' design

Bench Testing - Full system

Test	Method
Usability demo	Demo kit operations
Bench testing demo kit	'Fat layer' (perfused)
Pre-clinical	Acute, Chronic Histology (30d)

Pre-clinical | Animal


STUDY DATA

- Study type: Chronic with 30-day follow-up
- Animal model: Swine (100kg)
- Approach type: Laparotomy with 22Fr dilation

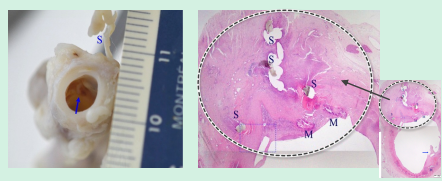
RESULTS

- Freedom from major lower limb complications after 30d
- Rapid TTH
- No vessel deformation
- Unobstructed blood flow

FLUOROSCOPY AFTER 30-DAYS



Pre-clinical | Animal

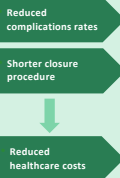


HISTOLOGY RESULTS (after 30-days follow up)

- The suture was intact and in place
- Closed the arteriotomy of 22Fr and the vessel is intact
- Appropriate inflammatory reaction and signs of healing

All the **ADVANTAGES** of MIS procedure.
All the **BENEFITS** of suturing.

	Surgical suturing	Plugs		Suture-based	
		Manta/Perqseal	Proglide	N-VCD	
Minimally invasive	X	✓	✓	✓	✓
Perform by interventionalist	X	✓	✓	✓	✓
Artery and Vein	✓	X	✓	✓	✓
One device for all sizes	✓	X	X	✓	✓
Multipoint continuous suturing	✓	X	X	✓	✓
Tissue approximation	✓	X	✓	✓	✓
Single point of closure	✓	✓	X	✓	✓
Real-time access control	✓	X	X	✓	✓
Re-enter / Revision	✓	X	✓	✓	✓
Extra-large bore (>24Fr)	✓	X	X	✓	✓



Development plan and regulatory path

	H1 25	H2 25	H1 26	H2 26	H1 27	H2 27	H1 28	H2 28
V&V	█							
FIH Study		█	█					
CE Study				█	█			
CE Mark							█	█

N-VCD Regulatory Path:

- CE: Class IIb
- FDA: PMA (MGB)

Pivotal Clinical Study Characteristics

- Prospective, Multi-Center, Single Arm
- # patients*: CE 80-100, FDA 120-150
- Patient population: patients undergoing large-bore transcatheter intervention

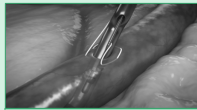
Primary End Point

- Freedom from access site major adverse event at 30d

*Based on predicate devices with similar intended use.

Current pipeline

Vascular closure device
Multipoint continuous purse string suture



- Arterial closure – up to 21F
- Venous closure
- VCD extended range

Intracardiac repair
Replacing occluders with multipoint continuous suture



- Patent Foramen Ovale (PFO)
- [LAA, ASD]