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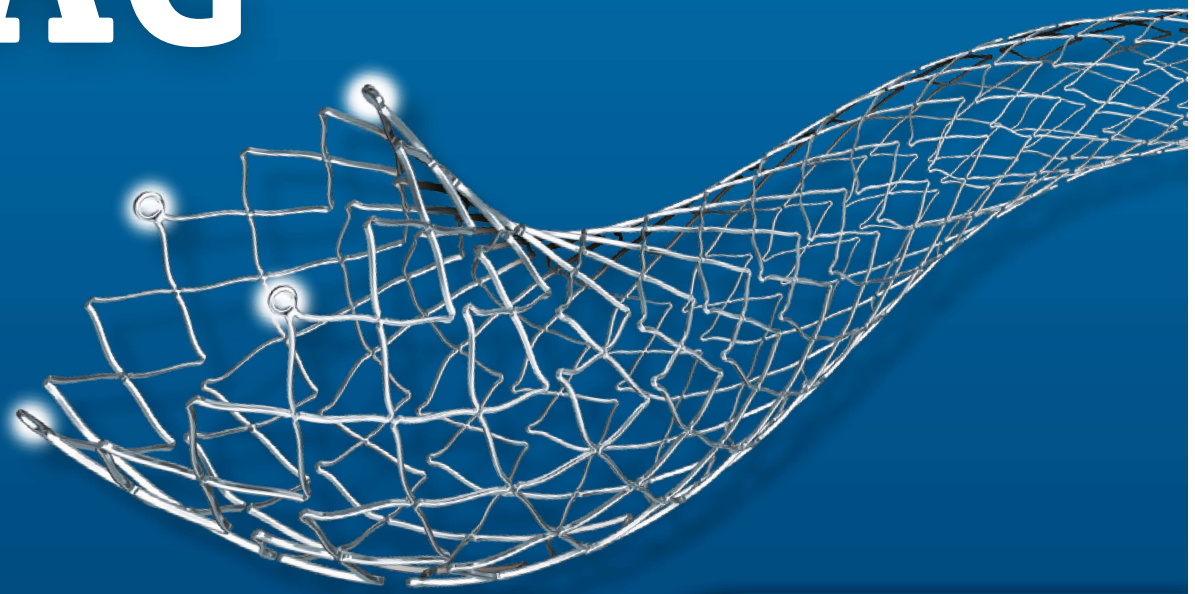
EPIC™ Vascular Self-Expanding Stent System

IDEAL FOR THE ILIAC



Roadmap for Discussion

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Introduction & Description

The Epic™ Stent

The Epic Stent Delivery System

Product Specifications & Size Matrix

Stent Deployment Steps

ORION Clinical Trial Data

Introduction

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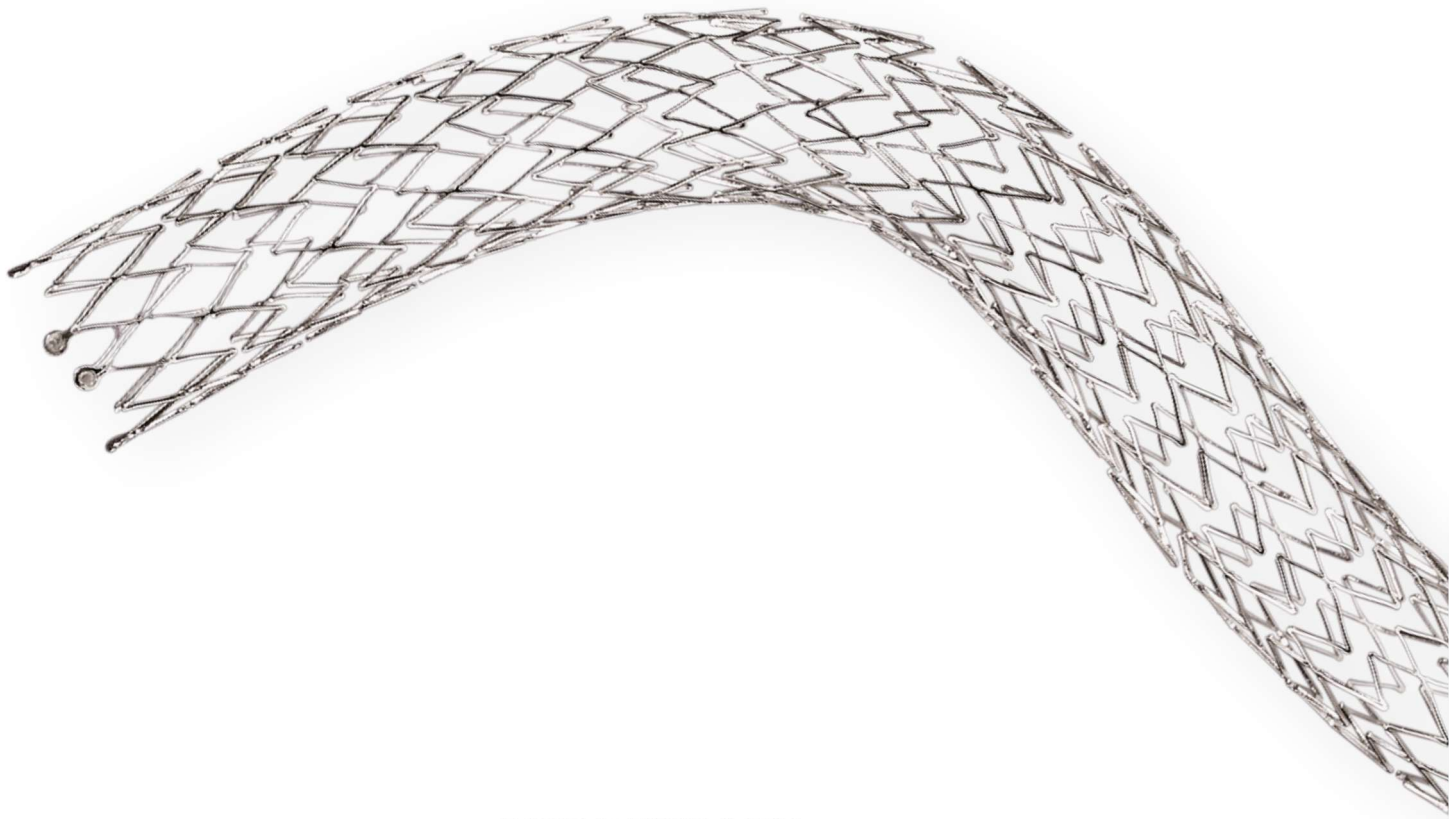
The Epic™ Vascular Self-Expanding Stent is third-generation Nitinol technology, designed for an optimal balance between **flexibility, radial force, deployment accuracy and fracture resistance** providing versatility throughout the size matrix—without compromise.

The Epic Stent is indicated for use in the treatment of iliac artery stenosis.*

*Please see 'Directions for Use' for complete indication description.



Epic™ Device Description

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- Laser-cut self-expanding Nitinol stent
- Distal and proximal radiopaque stent markers (Tantalum)
- 6 F coaxial design delivery system offered in two shaft lengths for all sizes (75 cm and 120 cm)
- 0.035" guidewire compatible

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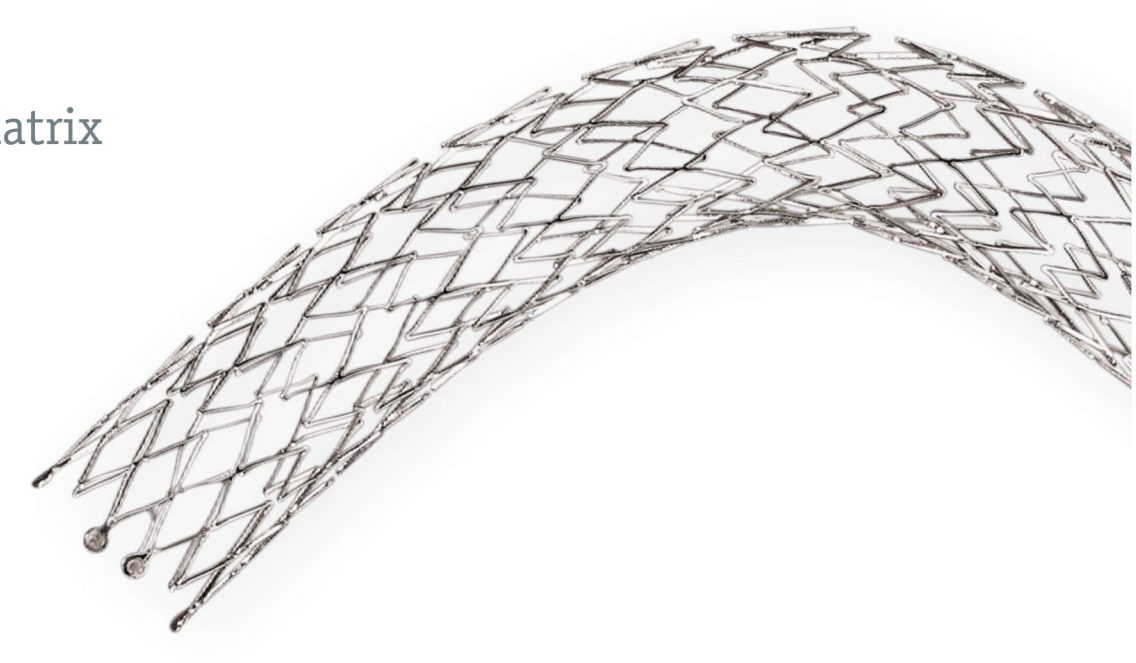

The Stent

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The Epic™ Stent is designed for total performance from a balanced platform.

- EXCEPTIONAL FLEXIBILITY
- FRACTURE RESISTANCE
- BALANCED RADIAL FORCE
- EXCELLENT DEPLOYMENT ACCURACY

Tandem Architecture™ Stent Design

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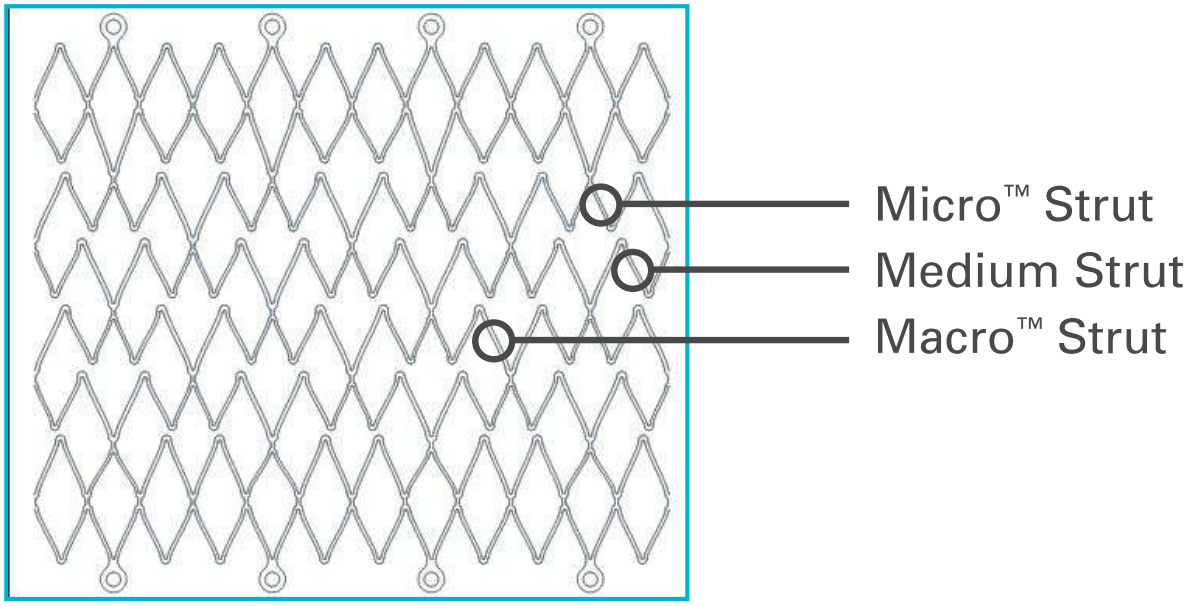
The Tandem Architecture stent design combines struts of varying lengths that are arranged in a manner intended to optimize flexibility, radial strength and scaffolding.



Hybrid Stent Architecture

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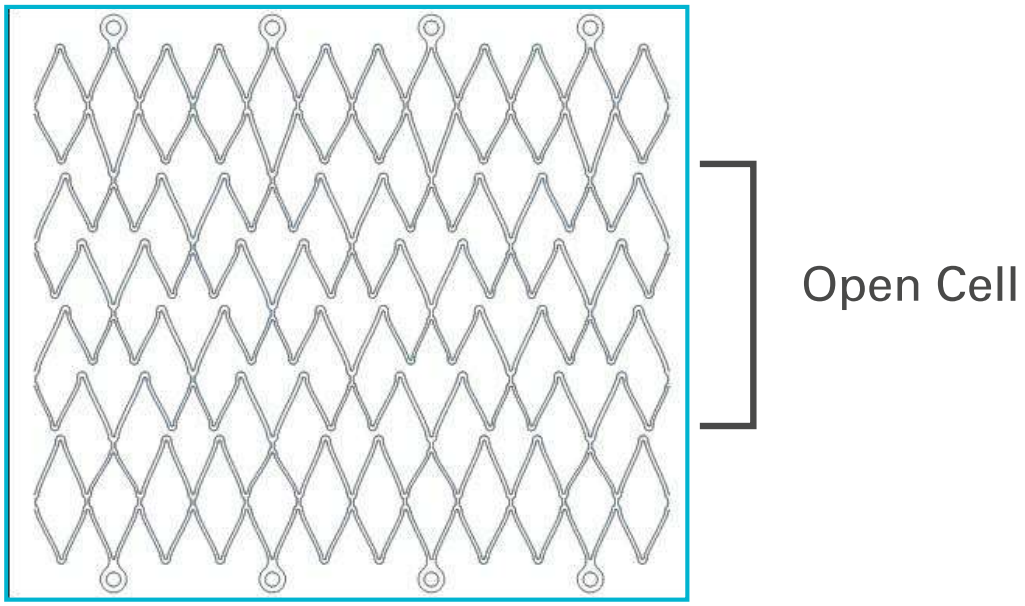
The Epic™ Stent is a hybrid design, with open cell geometry (defined as the absence of connections of peaks between rows) in the mid-section, intended to enhance flexibility.



Hybrid Stent Architecture

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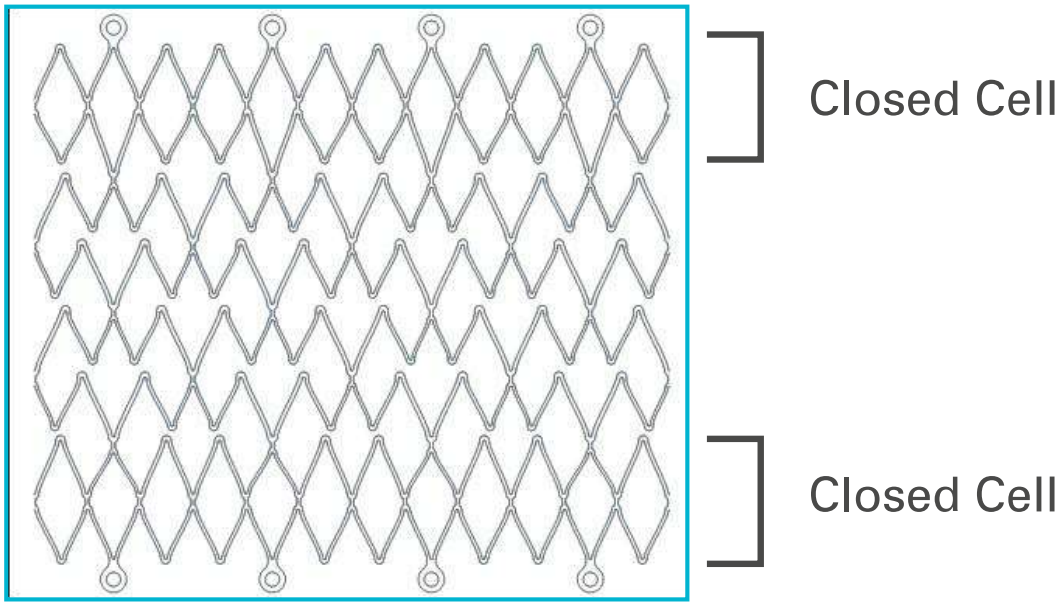
The end rows of the stent are closed cell geometry (defined as having connections between rows from peak-to-peak) which is intended to aid in the uniform deployment of the stent.



Radiopacity

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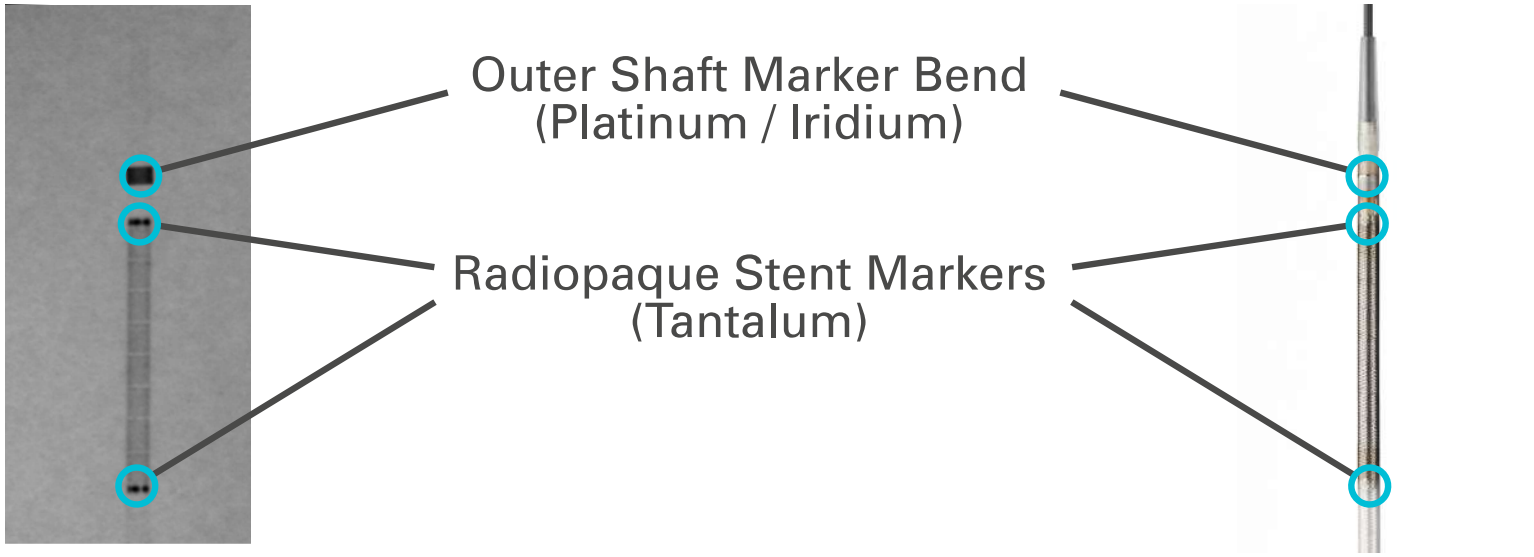
Tantalum markers on the stent enhance visualization under fluoroscopy, facilitating precise placement.



Epic™ Stent System
Under Fluoroscopy

Epic Stent System

Radiopaque Markers

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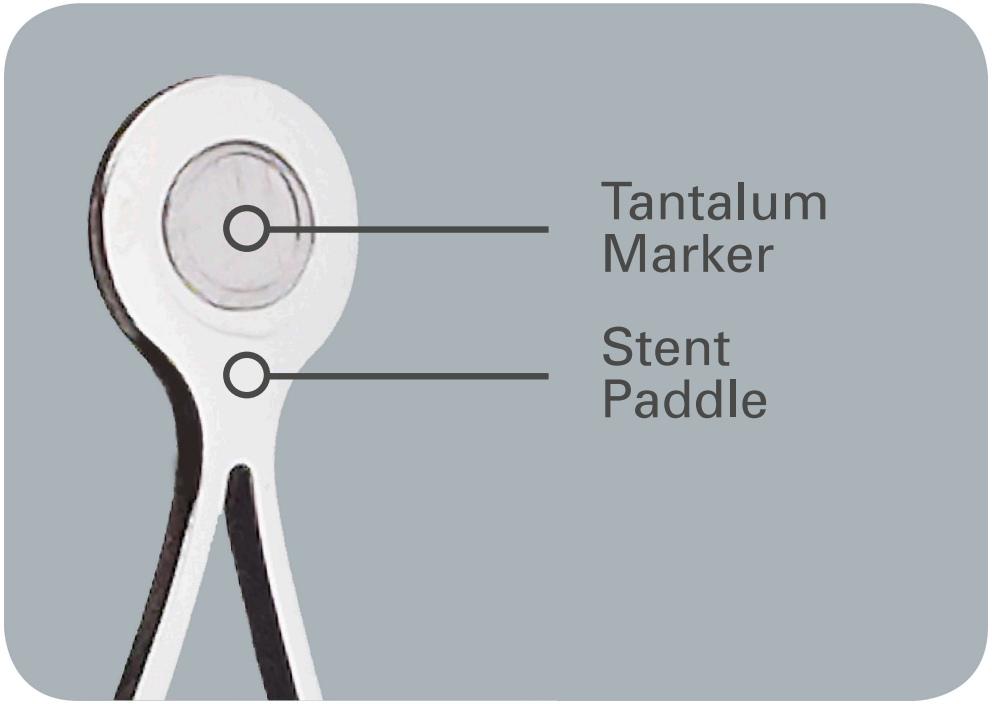
Stent Diameter	Number of radiopaque markers at each end
6 - 7 mm	4
8 - 12 mm	5



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The Stent Delivery System

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The Epic™ Stent System is designed to deliver accurately.

- Ergonomic Handle
- 6 F Compatible
- Robust Catheter
- Quick-Flush Luer

Stent Delivery System Schematic

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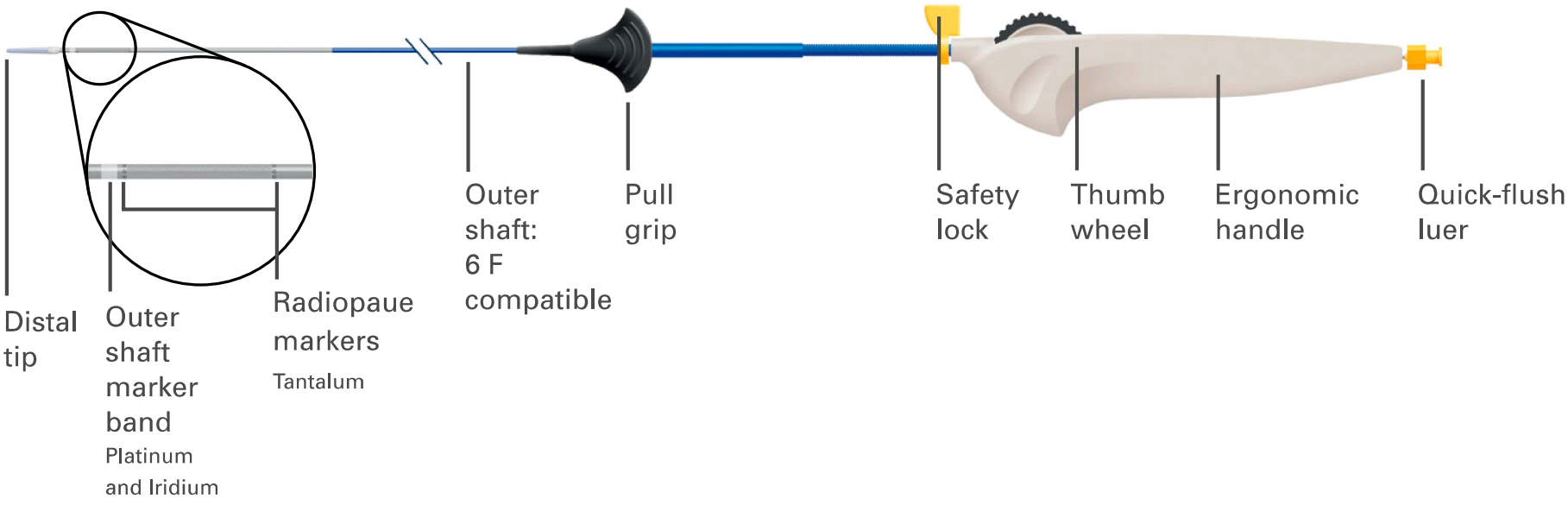

Note: Schematic not to scale.

Deployment Handle

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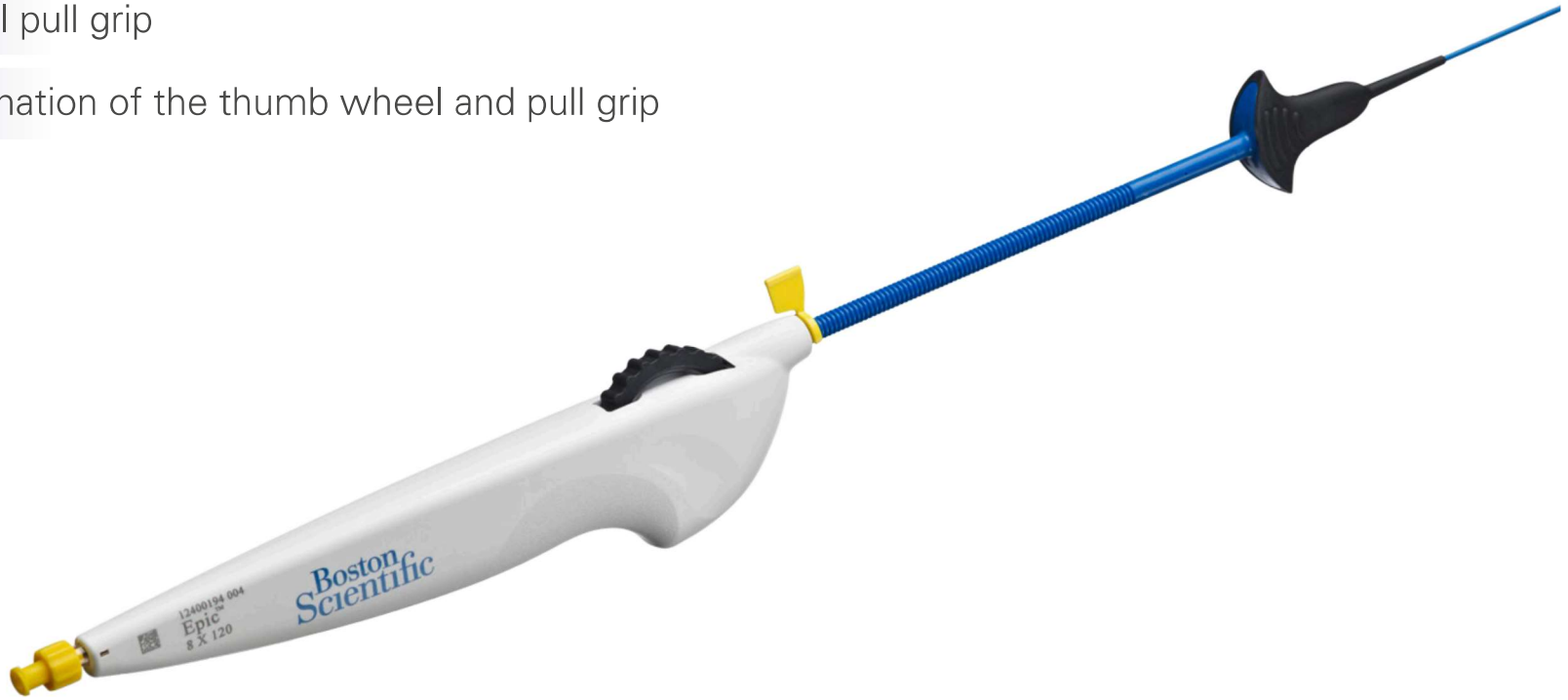
The ergonomic handle offers multiple options for deployment.

1. Thumb wheel
2. Manual pull grip
3. Combination of the thumb wheel and pull grip



Thumb Wheel

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The thumb wheel enables precise control over stent deployment.

- Emits audible ‘clicks’ as it is rolled
- Automatically rolls as the pull-grip is pulled proximally
- Rolls in the proximal direction (as indicated on the handle). Once the stent is partially deployed, it cannot be “re-captured” or “re-sheathed” using the stent delivery system

Pull Grip

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The pull grip enables more rapid stent deployment.

- Emits audible ‘clicks’ as it is pulled back
- Once the stent is anchored, the pull grip can be used to complete stent deployment
- Pull the grip in a proximal direction toward the handle

Quick-Flush Luer

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The quick-flush port enables simultaneous flushing of the guidewire lumen and stent lumen with a single flush.

To flush catheter:

- Attach a 10 mL (cc) syringe filled with saline to the luer
- Apply positive pressure. Continue to flush until saline appears at the distal end of both the guidewire lumen and the sheath-tip junction
- Remove the flushing luer

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Product Specifications

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Stent Diameters	6 - 12 mm
Stent Lengths	20 - 120 mm
Catheter Lengths	75, 120 cm
Guide Wire System	0.035" OTW
Introducer Sheath Compatibility	6 F
Catheter Nominal O.D.	0.079" → 0.077" distal → proximal
Stent Alloy	Nitinol

Product Size Matrix

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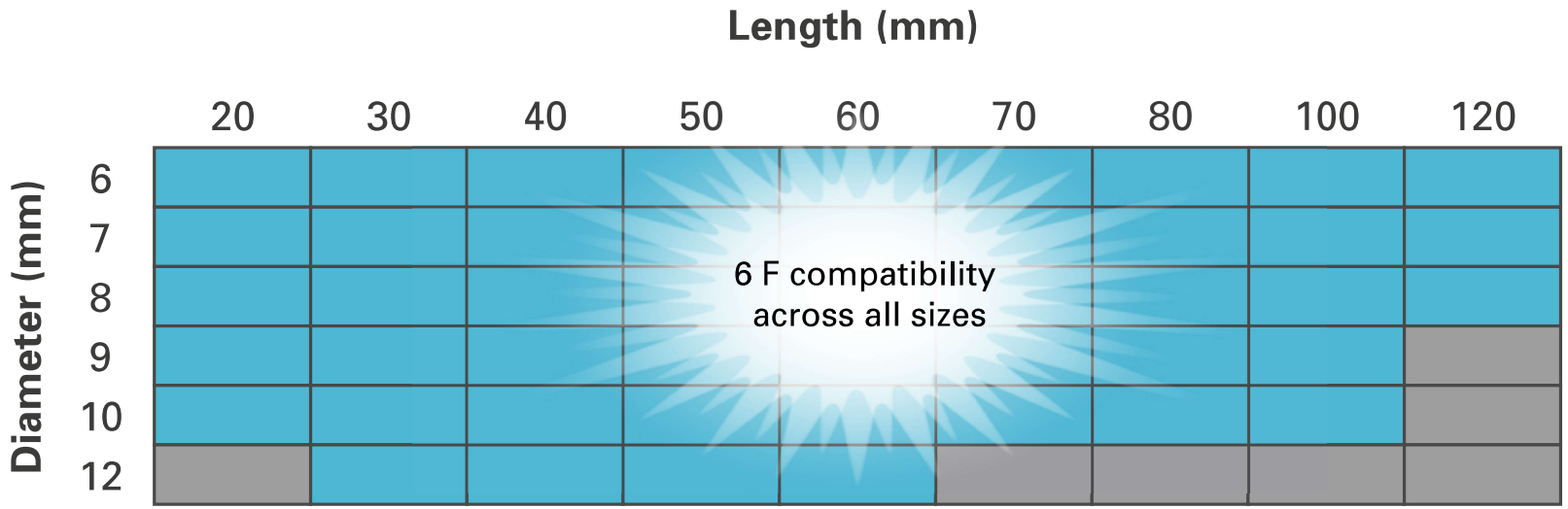
Expansive size matrix; all compatible with a 6 F introducer sheath.



Catheter lengths: 75 cm, 120 cm
Guidewire system: 0.035" OTW

Roadmap for Discussion

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Stent Deployment

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1. **Remove** all slack from the catheter prior to stent deployment. Excessive slack may result in stent jumping or the stent length being reduced.
2. **Remove** the safety lock (5) positioned on the rack by pulling vertically to the axis of the stent delivery system (SDS). Confirm that the radiopaque markers (2) and (3) are still properly positioned across the target lesion.
3. **Keep** the entire length of the delivery system as straight as possible, and maintain slight backward tension on the delivery system during deployment.

Deployment Technique

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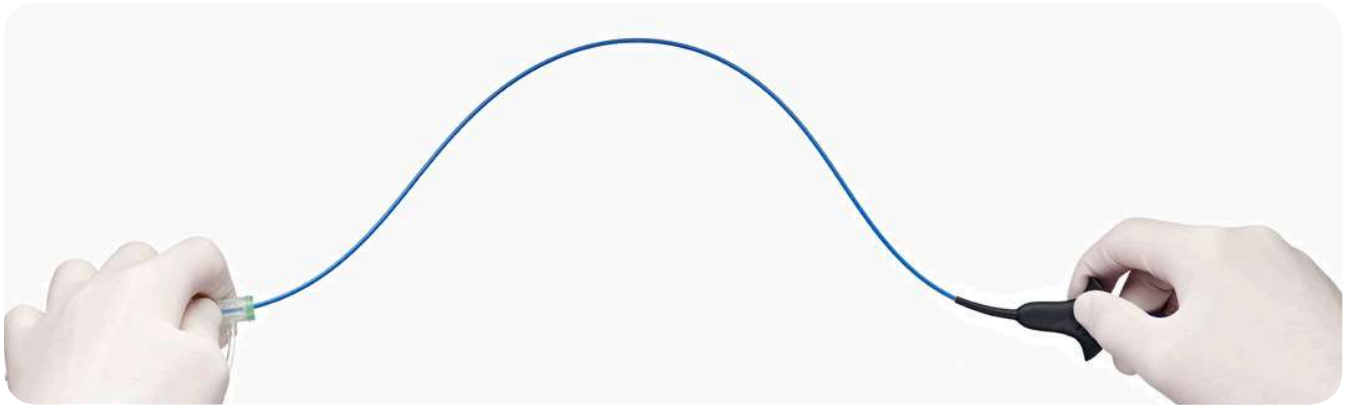

Incorrect deployment technique

Correct deployment technique

Stent Deployment

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4 **Stent deployment:** Start deploying the stent by slowly rotating the thumb wheel 6. Allow the stent to contact and anchor to the vessel wall.

5 **Continue** to deploy the stent with one of the following methods:

- Roll the thumb wheel 6 of the deployment handle in a proximal direction. Continue to roll thumbwheel until the radiopaque marker of the exterior shaft 1 passes the proximal radiopaque markers of the stent 3 resulting in full deployment.
- Grasp the manual pull grip 4 and pull toward the deployment handle. Continue to pull back until the radiopaque marker of the exterior shaft 1 passes the proximal radiopaque markers 3 of the stent resulting in full deployment.

Stent Deployment

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As the outer shaft retracts proximally during deployment, the stent will begin to flower outward.

Pre-deployment

Beginning stent deployment

Beginning stent anchoring

Stent flowering

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ORION Clinical Trial

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DESIGN:

- Prospective, single-arm, multicenter

PRIMARY ENDPOINT:

Device- and/or procedure-related major adverse events (MAE) at 9 months

- Death within 30 days, or
- MI that occurs during index hospitalization, or
- Target vessel revascularization through 9 months, or
- Amputation of index limb through 9 months

COMPARATOR:

- Predefined performance goal (MAE) of 17.0%, based on a literature-derived expected rate of 8.0% for iliac stenting plus a margin of 9.0%

Baseline Characteristics

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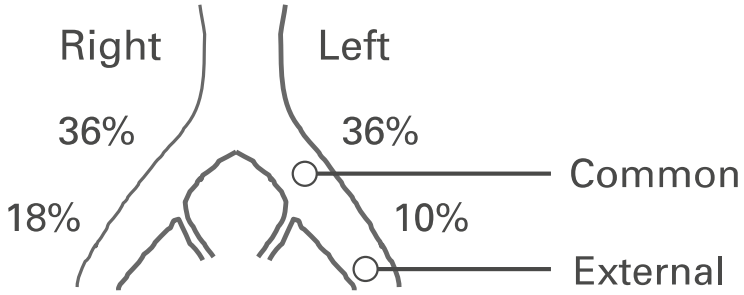
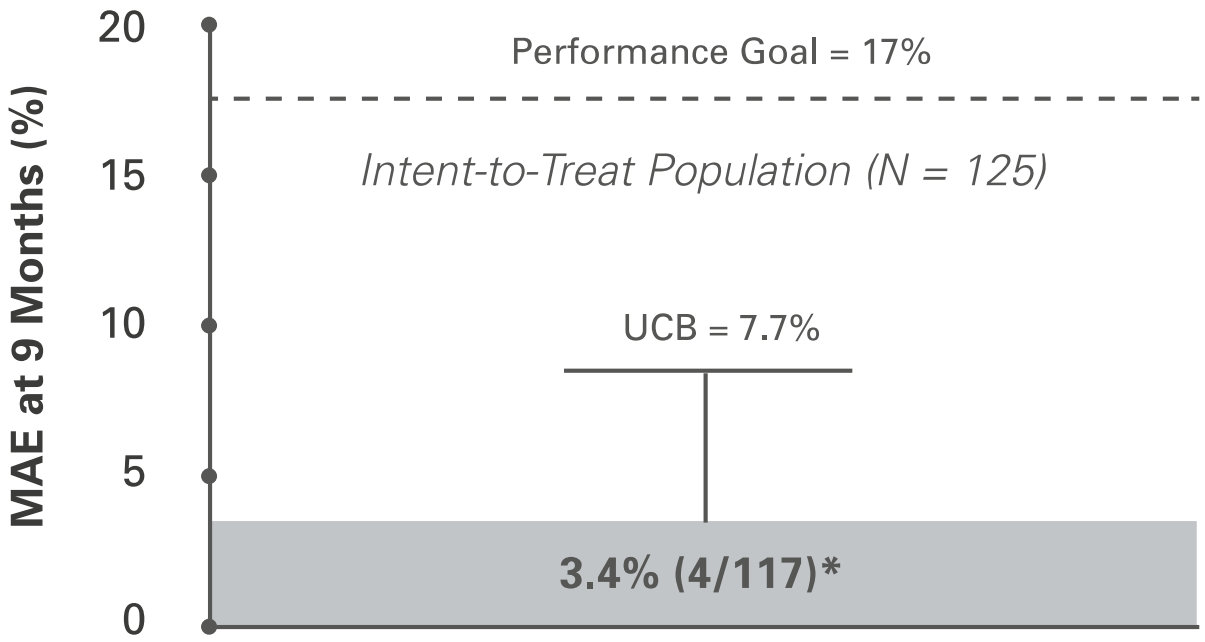
125 Patients
166 Iliac Artery Lesions



Male	64.8%	RVD (mm)	7.69 ± 1.79
Age (years)	61.1 ± 9.3	Lesion length (mm)	31.04 ± 22.13
Diabetes	33.6%	MLD (mm)	2.20 ± 1.34
- Insulin	12.0%	DS (%)	71.51 ± 16.27
Smoking (ever)	96.0%	Severe calcification	48.8%
Hyperlipidemia	78.4%	Ostial lesion	62.5%
Hypertension	76.0%	Occlusion	16.3%

Primary Endpoint



* Value of 3.4% with a 95% upper confidence bound (UCB) of 7.7% is significantly less ($P < 0.001$) than the performance goal.

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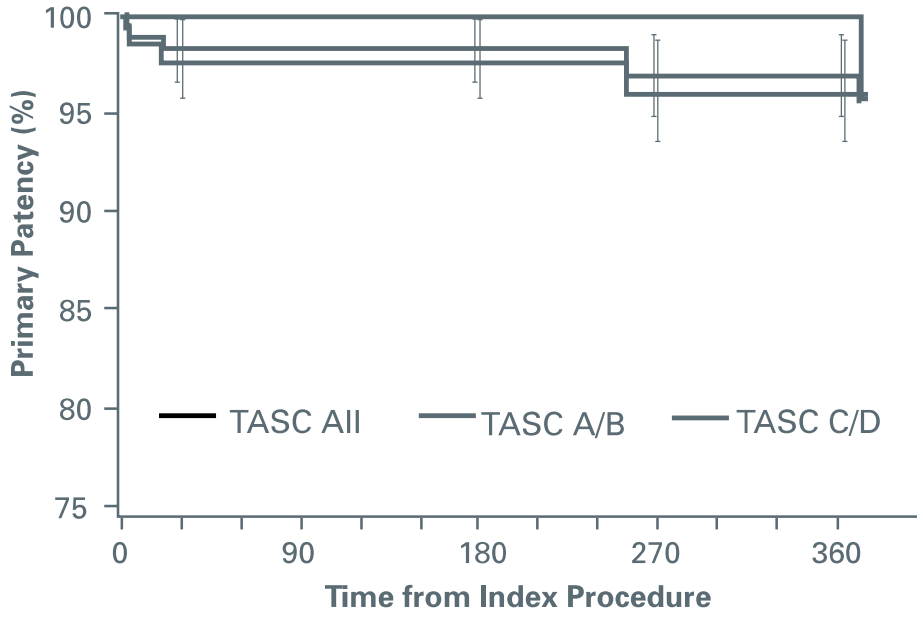
The Only US IDE Clinical Trial to demonstrate similar patency across all TASC classifications

12-Month Primary Patency by TASC Classification



Lesions at Risk	AII	163.5	155	153	152.5	132
	A/B	132.5	124	123	122.5	104
	C/D	27	27	26	26	25

12-month Primary data

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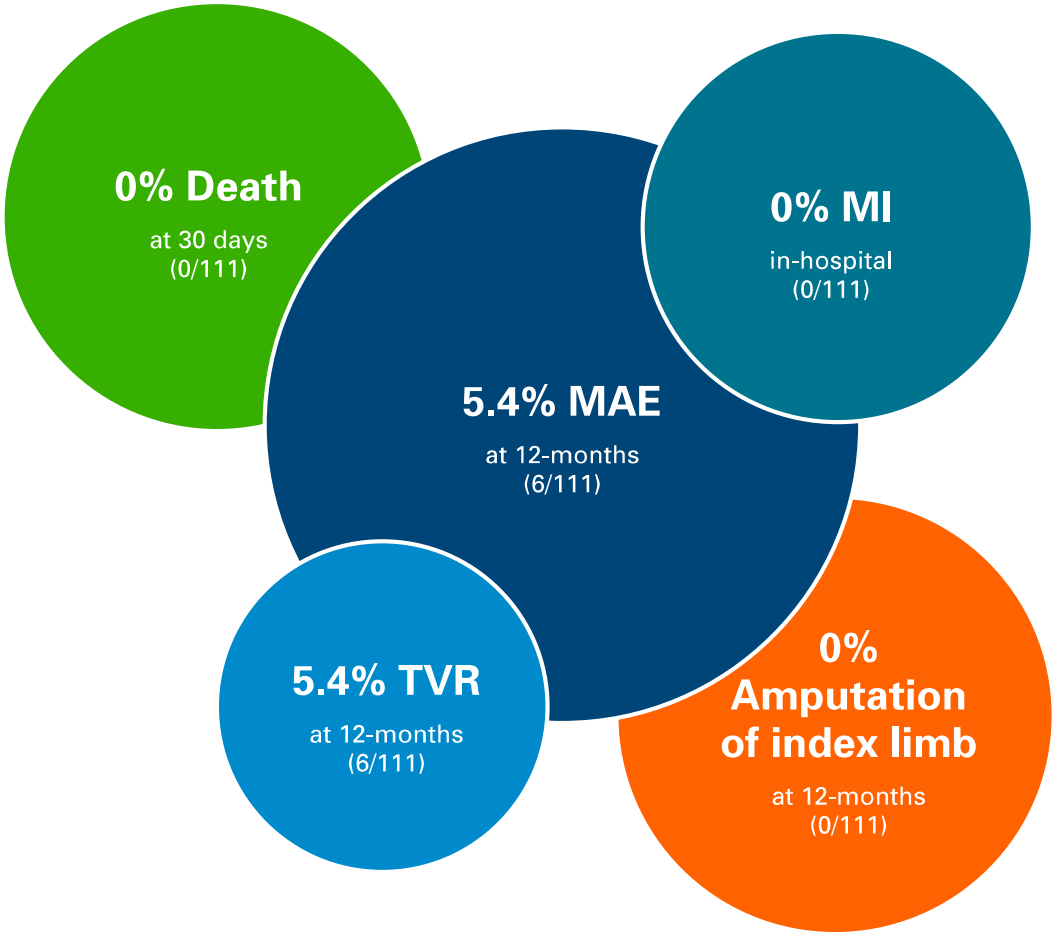

Composite Success Rates

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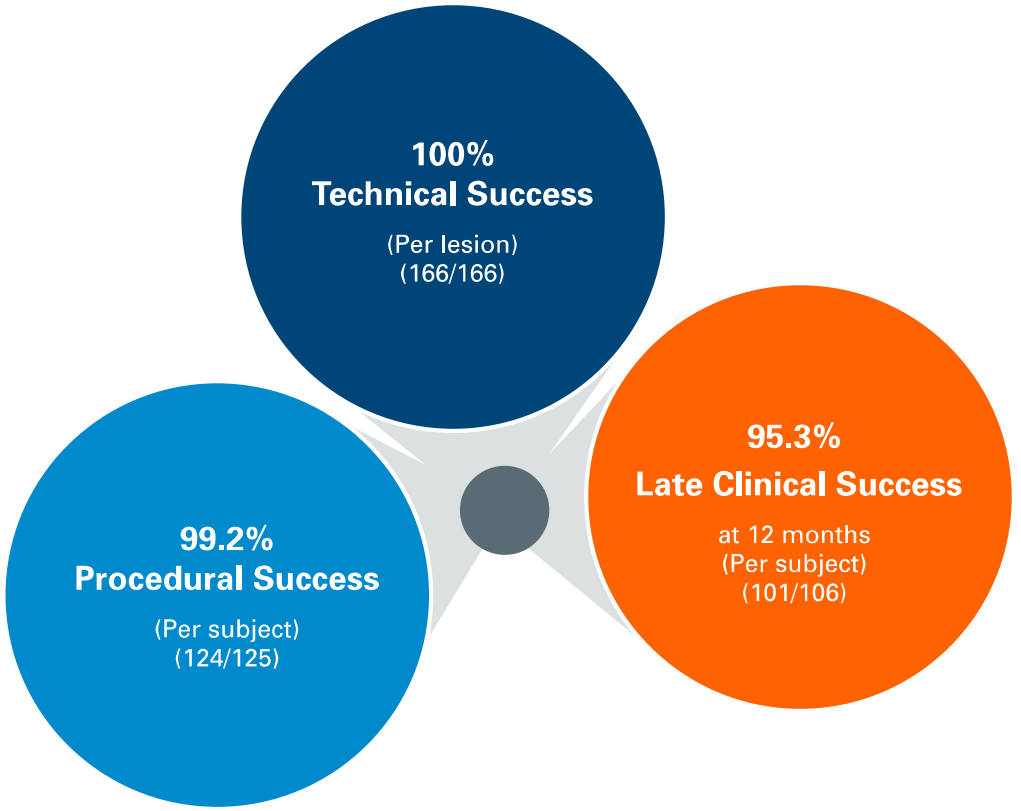

Technical: stenosis ≤ 30% post procedure; Procedural: technical success and no in-hospital MAE (death, MI, TVR, index limb amputation); Clinical: Rutherford classification improved by ≥ 1 class versus baseline; MAE = major adverse events; MI = myocardial infarction; TVR = target vessel revascularization.

12-month Stent Patency and Restenosis

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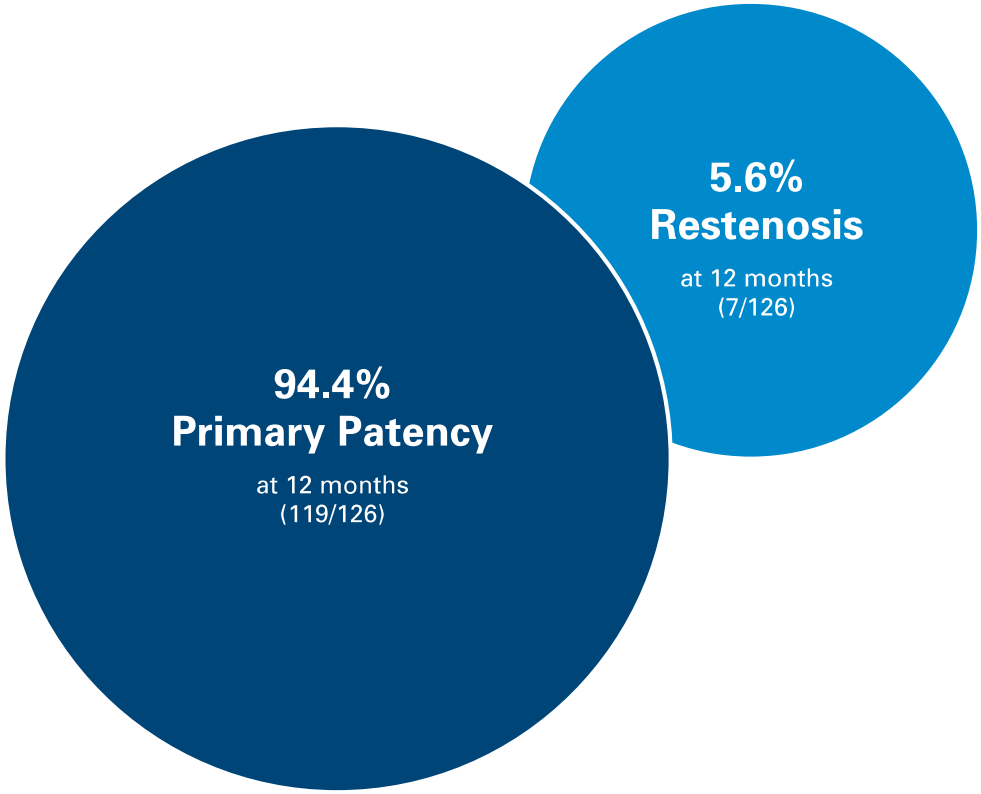

Thank You!

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DINPER4699EA