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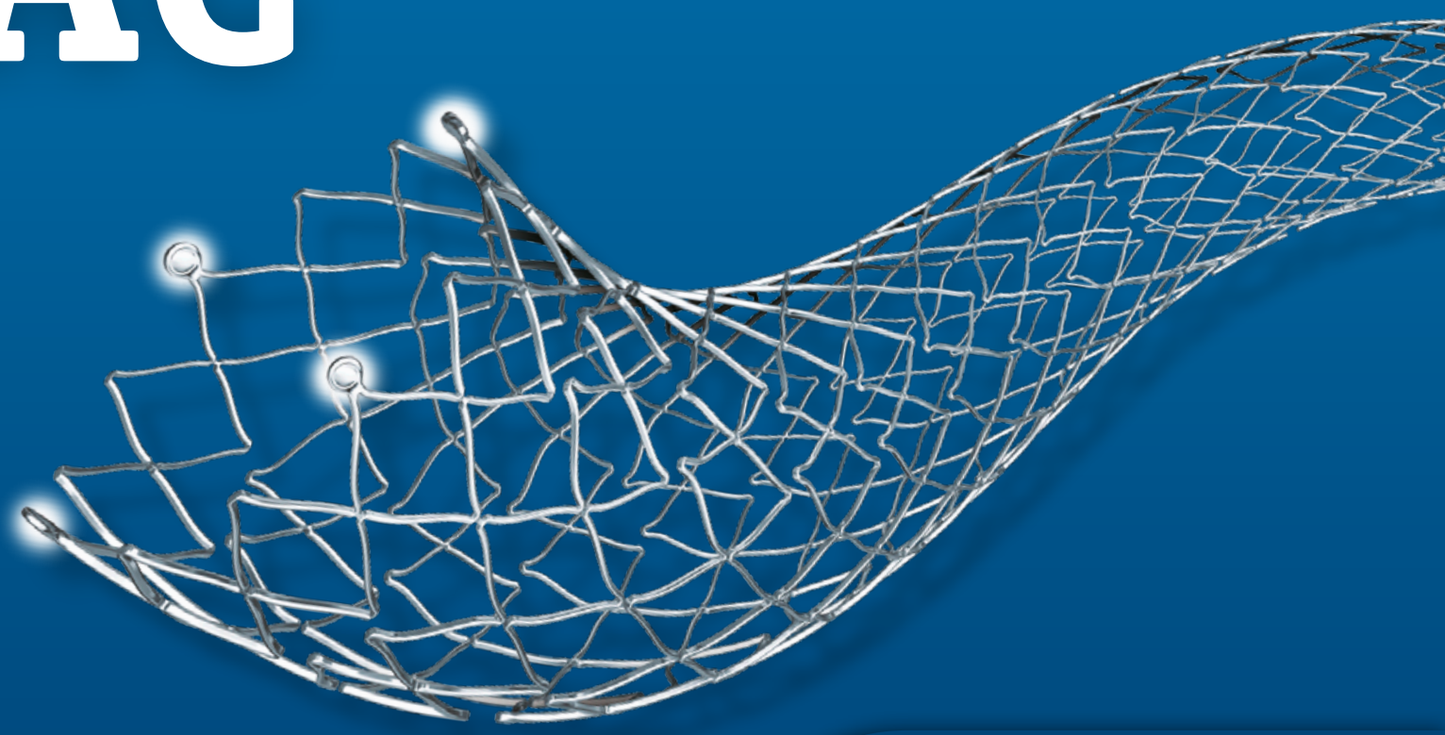
EPIC™ Vascular Self-Expanding Stent System

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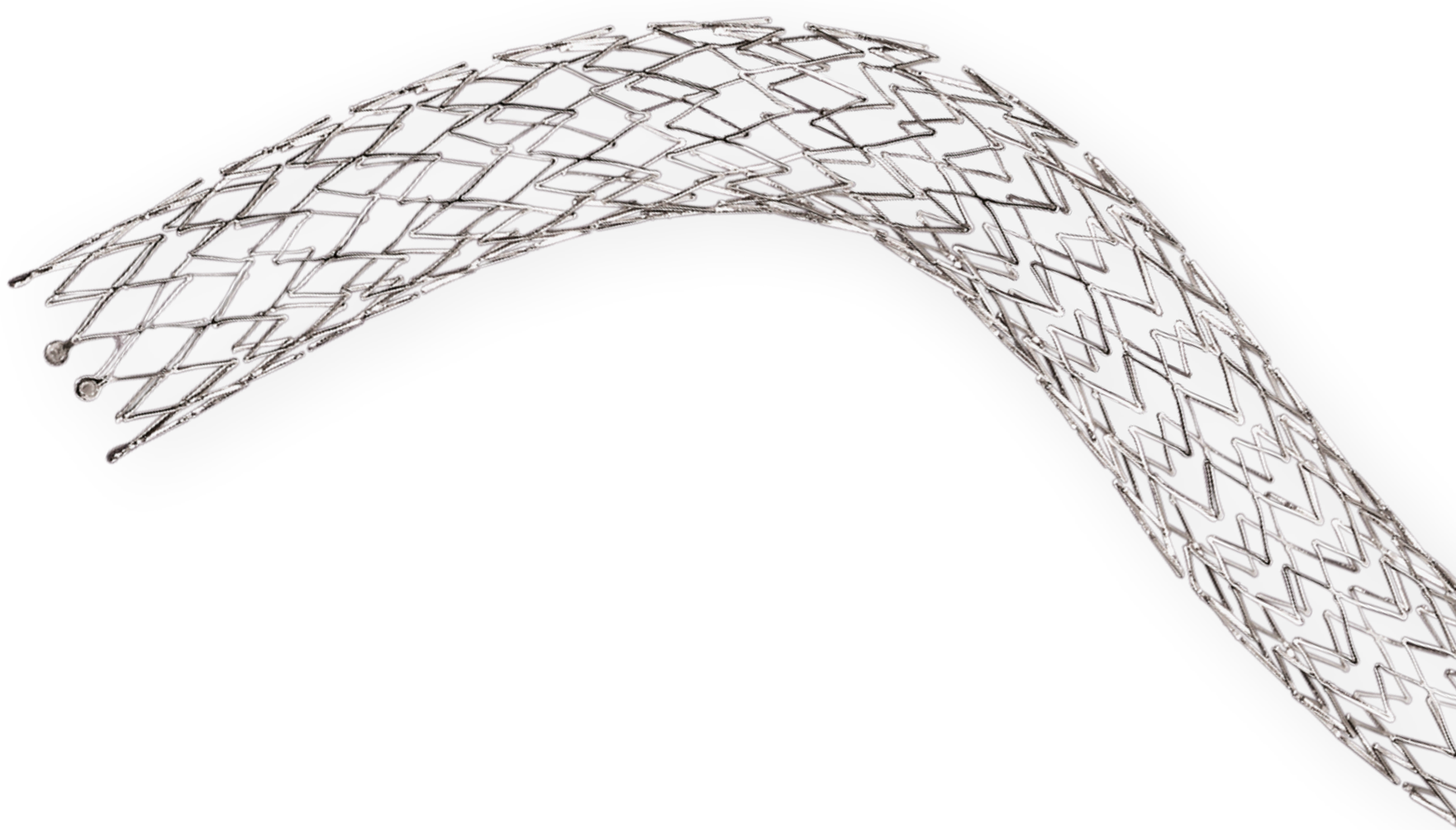
The Epic™ Vascular Self-Expanding Stent is third-generation Nitinol technology, designed for an optimal balance between **flexibility, radial force, deployment accuracy and fracture resistance** providing versatility throughout the size matrix—without compromise.

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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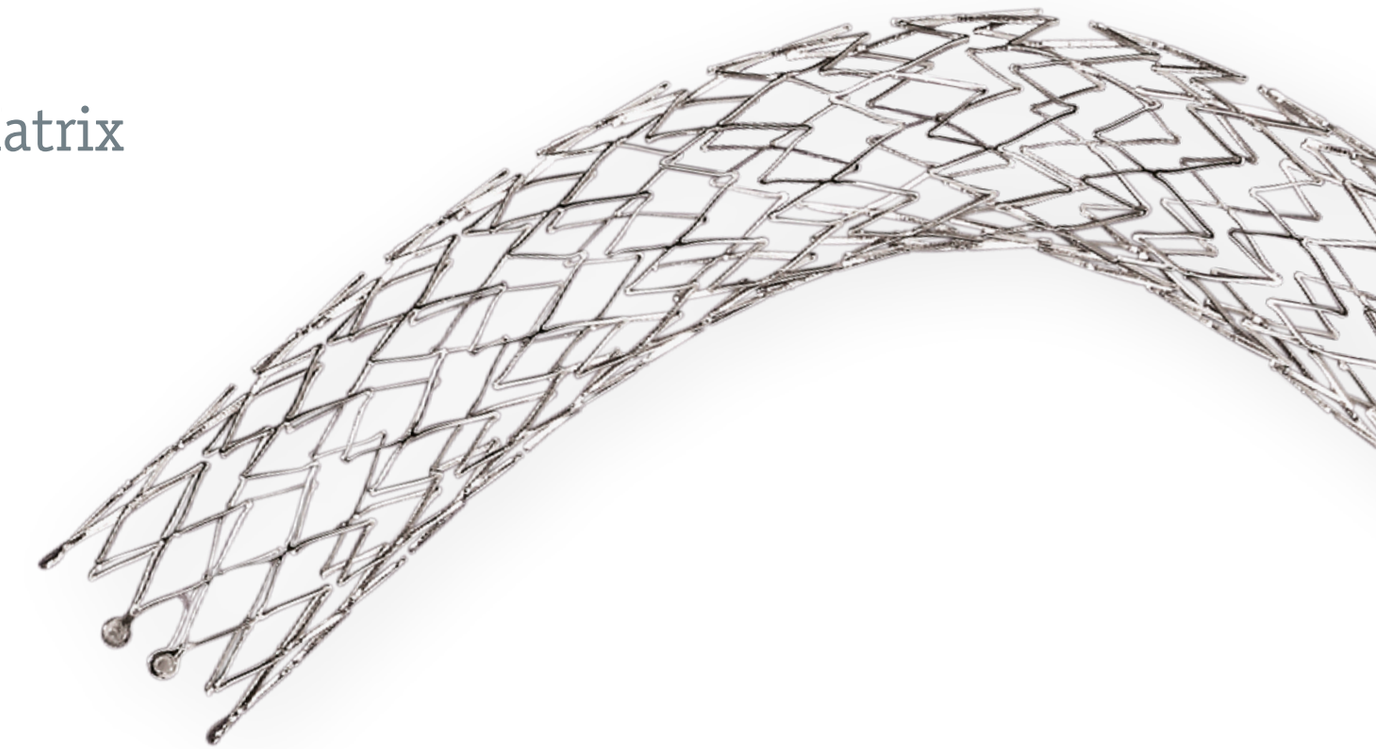

The Stent

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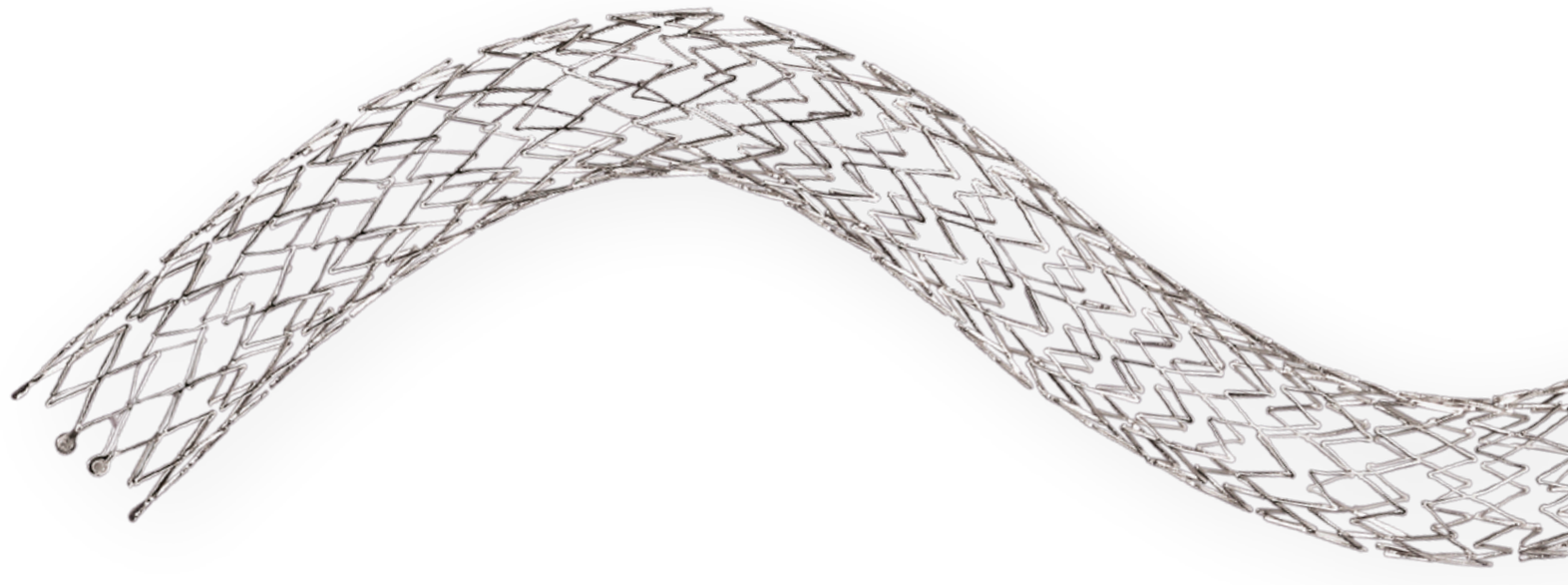
The Epic™ Stent is designed for total performance from a balanced platform.

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



Tandem Architecture™ Stent Design

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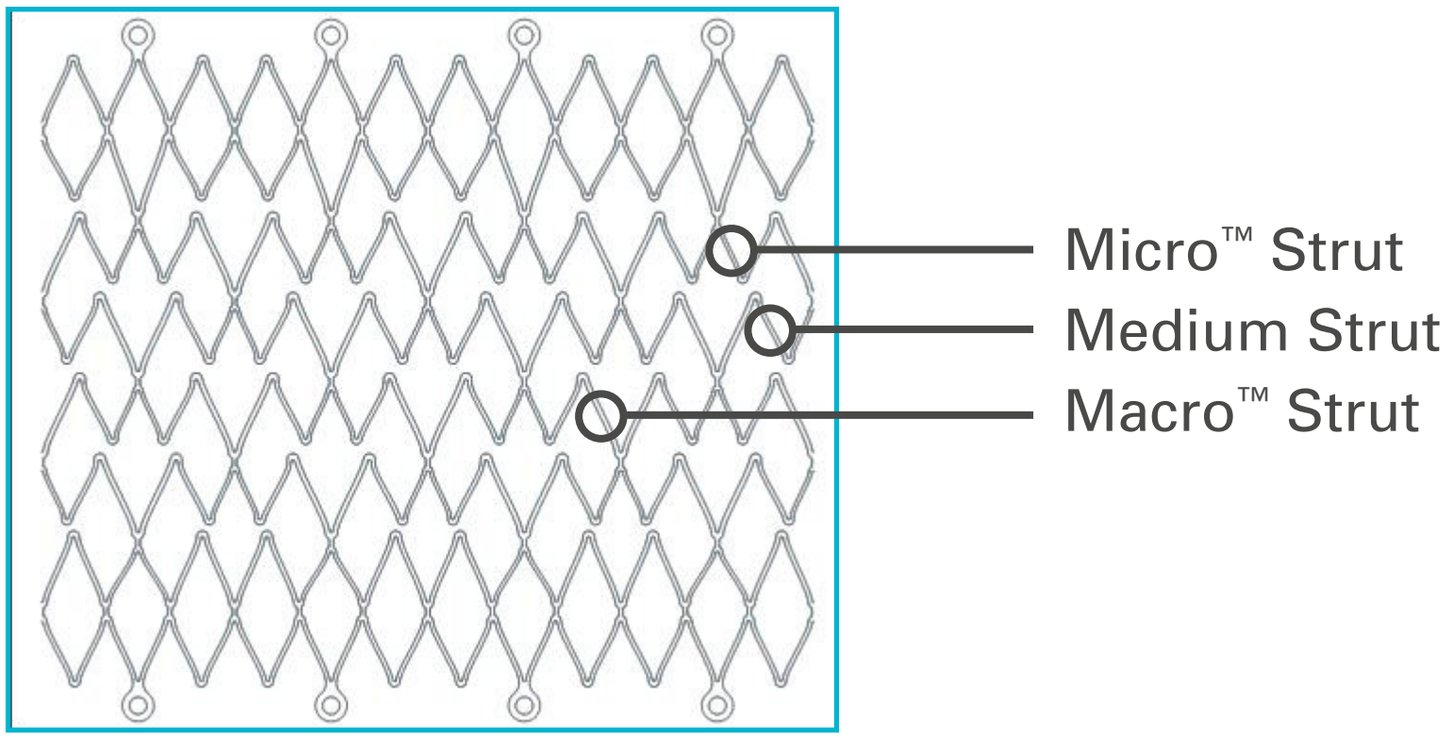
The Tandem Architecture stent design combines struts of varying lengths that are arranged in a manner intended to optimize flexibility, radial strength and scaffolding.



Hybrid Stent Architecture

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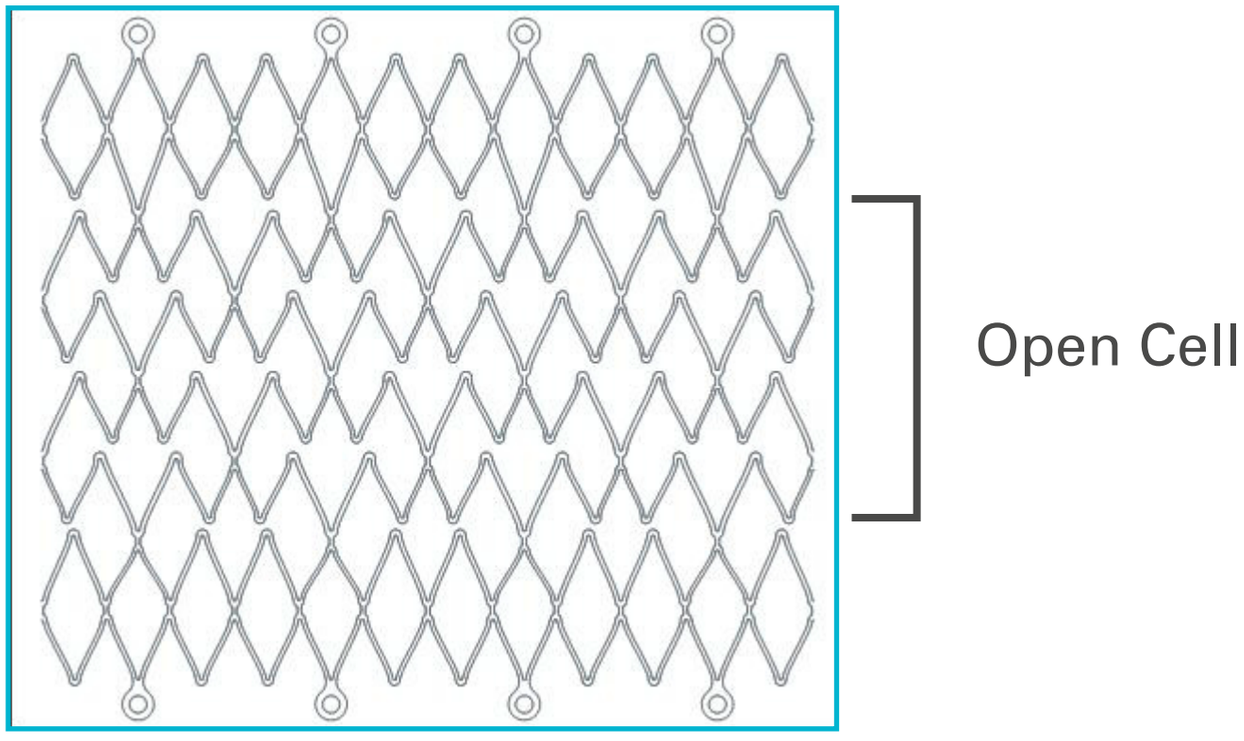
The Epic™ Stent is a hybrid design, with open cell geometry (defined as the absence of connections of peaks between rows) in the mid-section, intended to enhance flexibility.



Hybrid Stent Architecture

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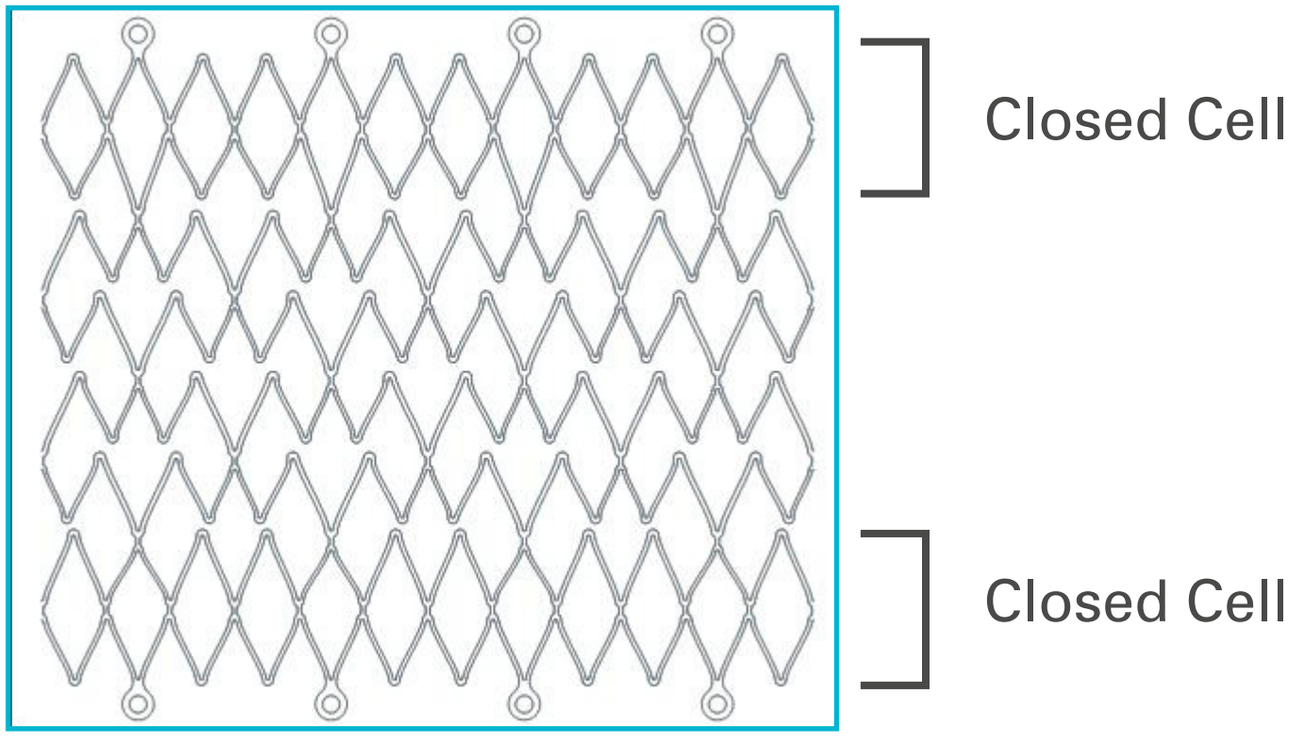
The end rows of the stent are closed cell geometry (defined as having connections between rows from peak-to-peak) which is intended to aid in the uniform deployment of the stent.



Radiopacity

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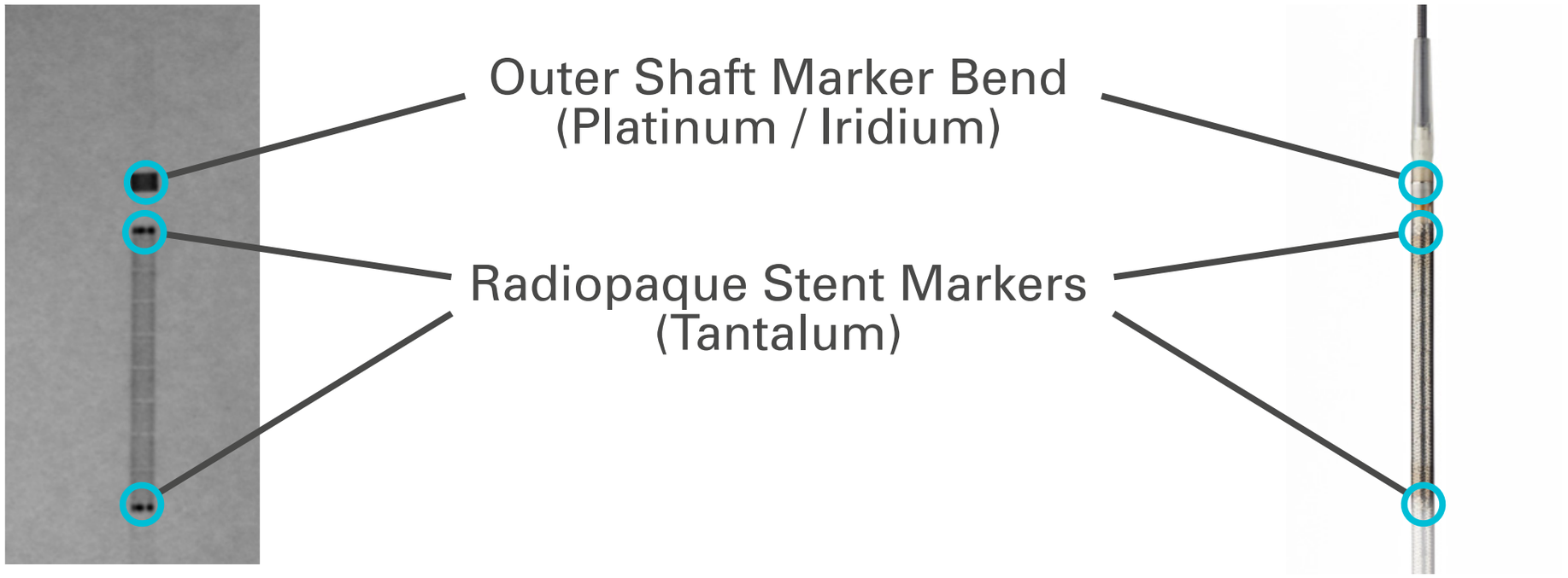
Tantalum markers on the stent enhance visualization under fluoroscopy, facilitating precise placement.



Epic™ Stent System
Under Fluoroscopy

Epic Stent System

Radiopaque Markers

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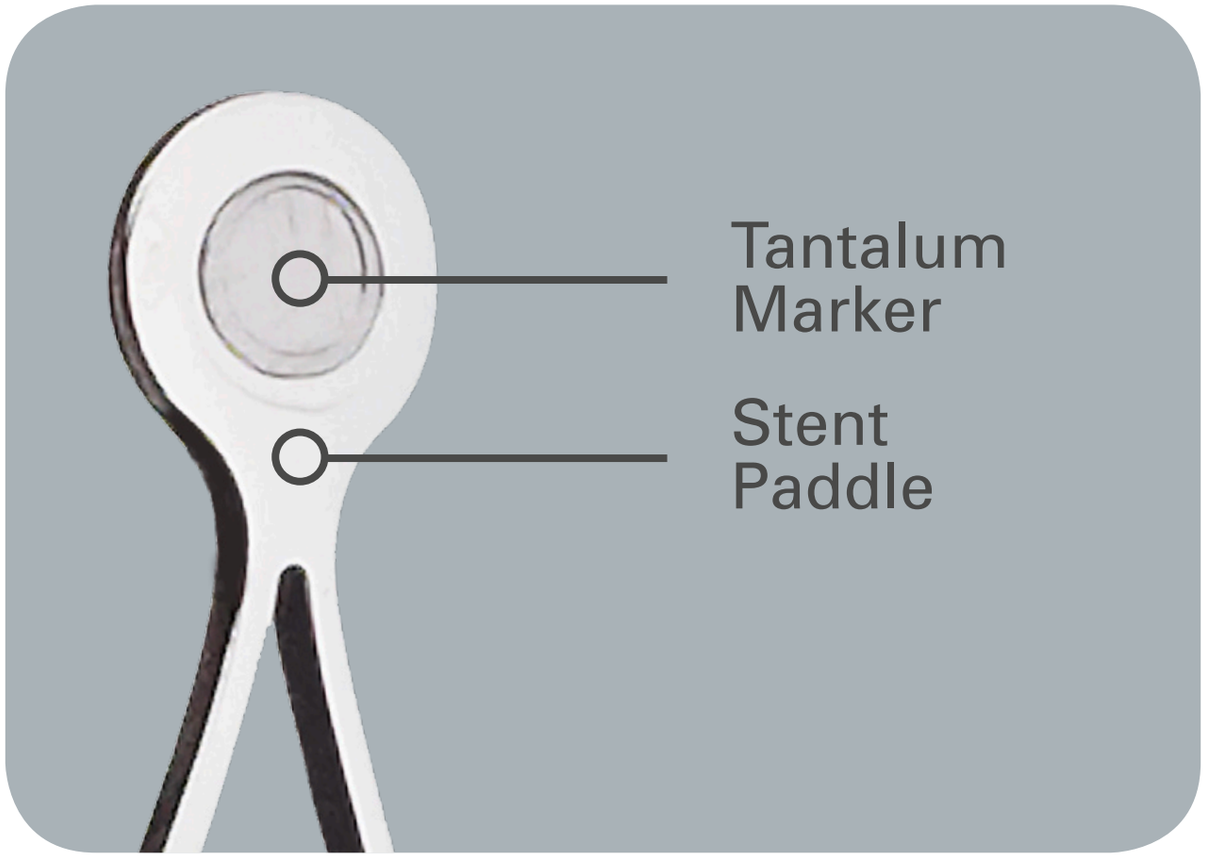
Stent Diameter	Number of radiopaque markers at each end
6 - 7 mm	4
8 - 12 mm	5



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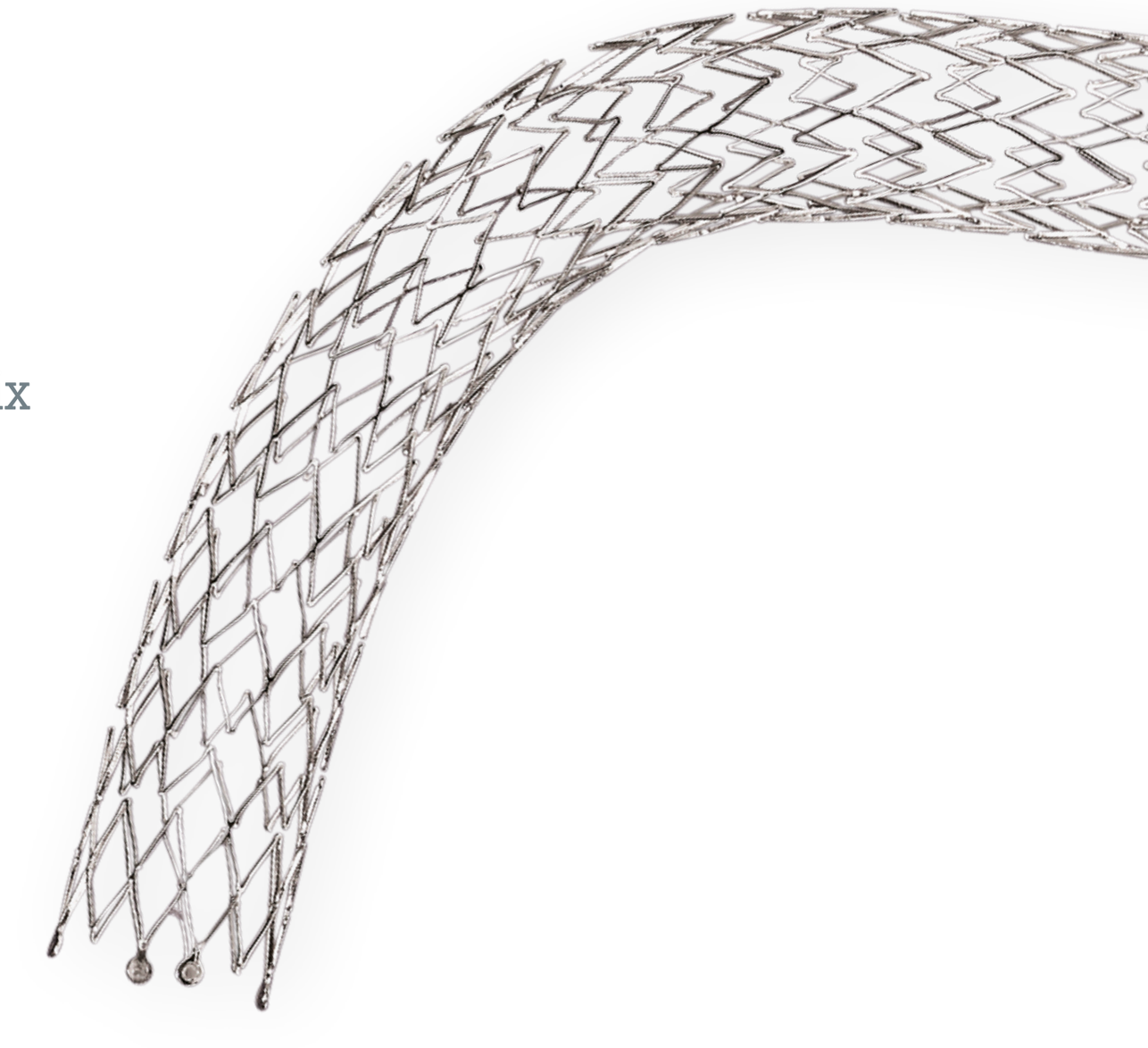

The Stent Delivery System

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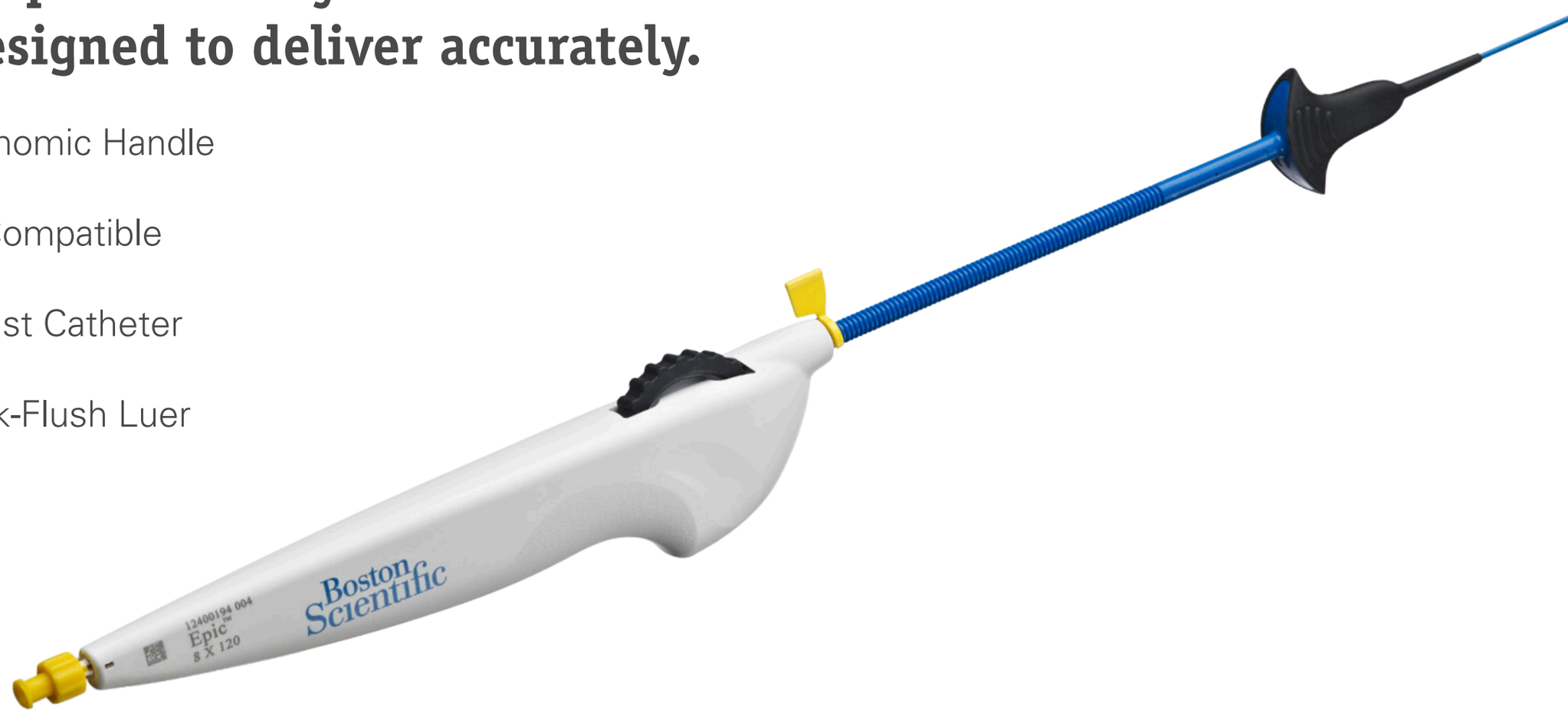
The Epic™ Stent System is designed to deliver accurately.

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



Stent Delivery System Schematic

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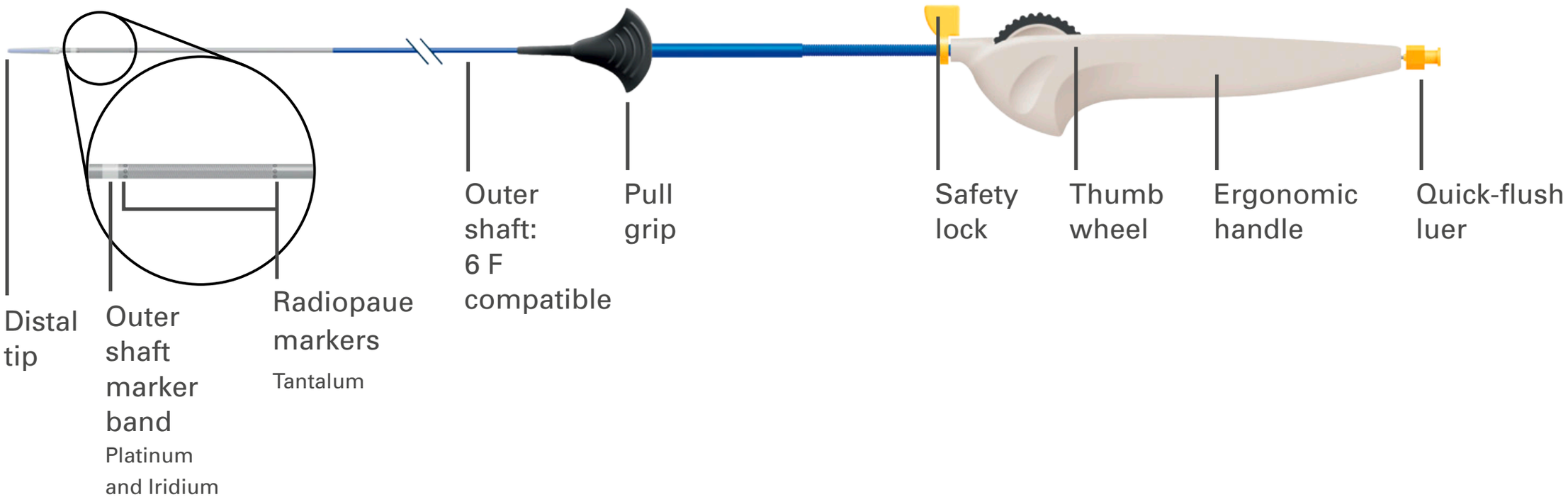

Note: Schematic not to scale.

Deployment Handle

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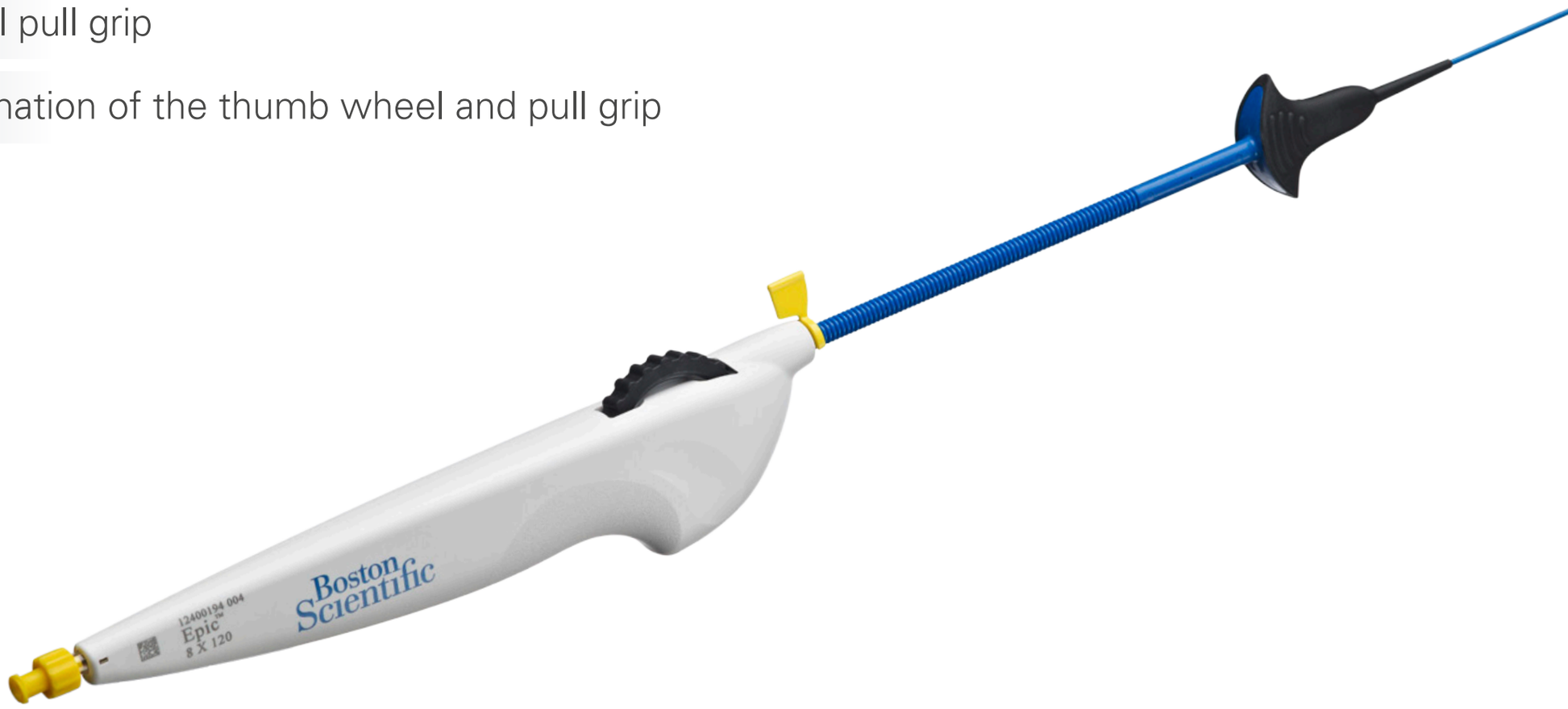
The ergonomic handle offers multiple options for deployment.

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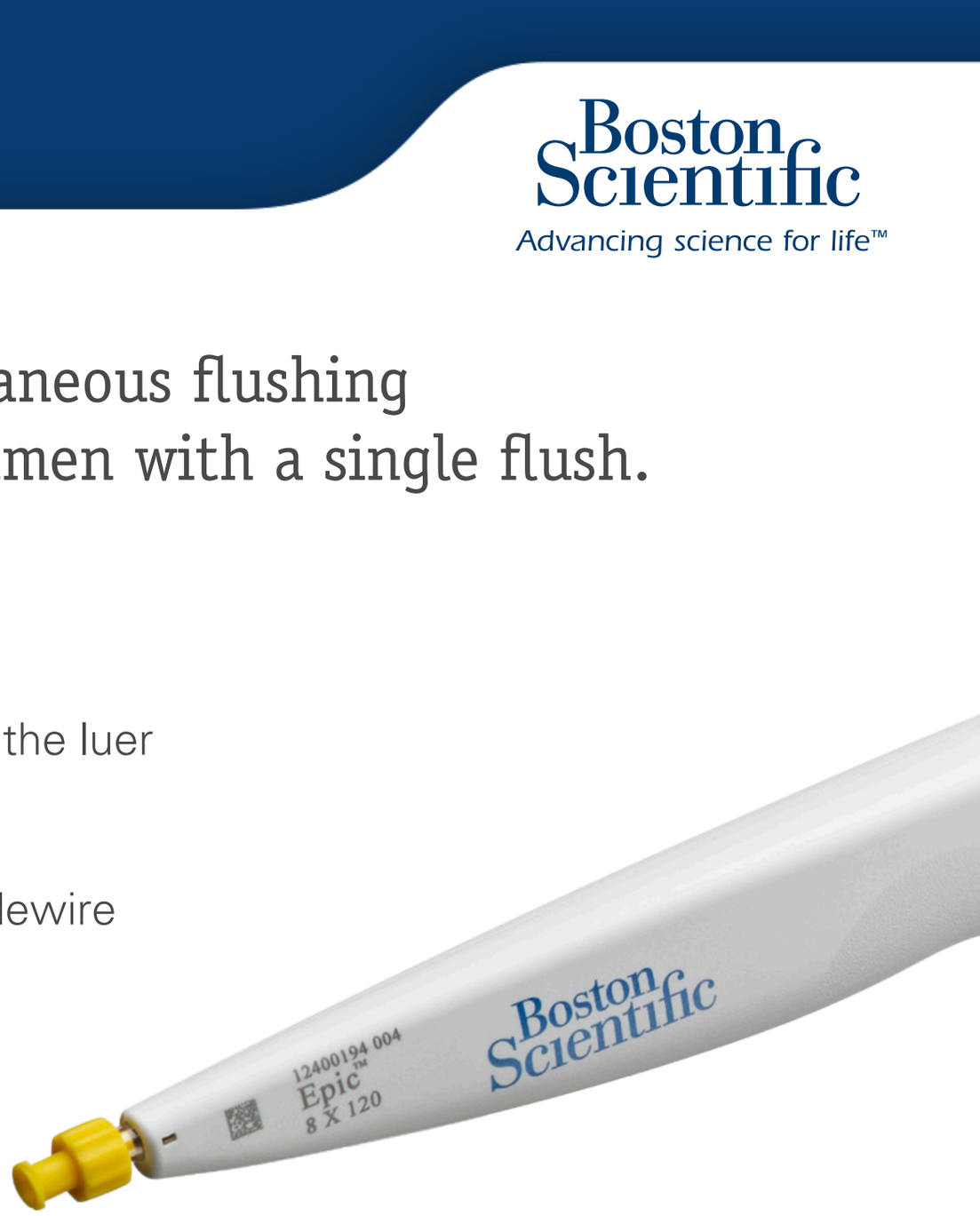
The quick-flush port enables simultaneous flushing of the guidewire lumen and stent lumen with a single flush.

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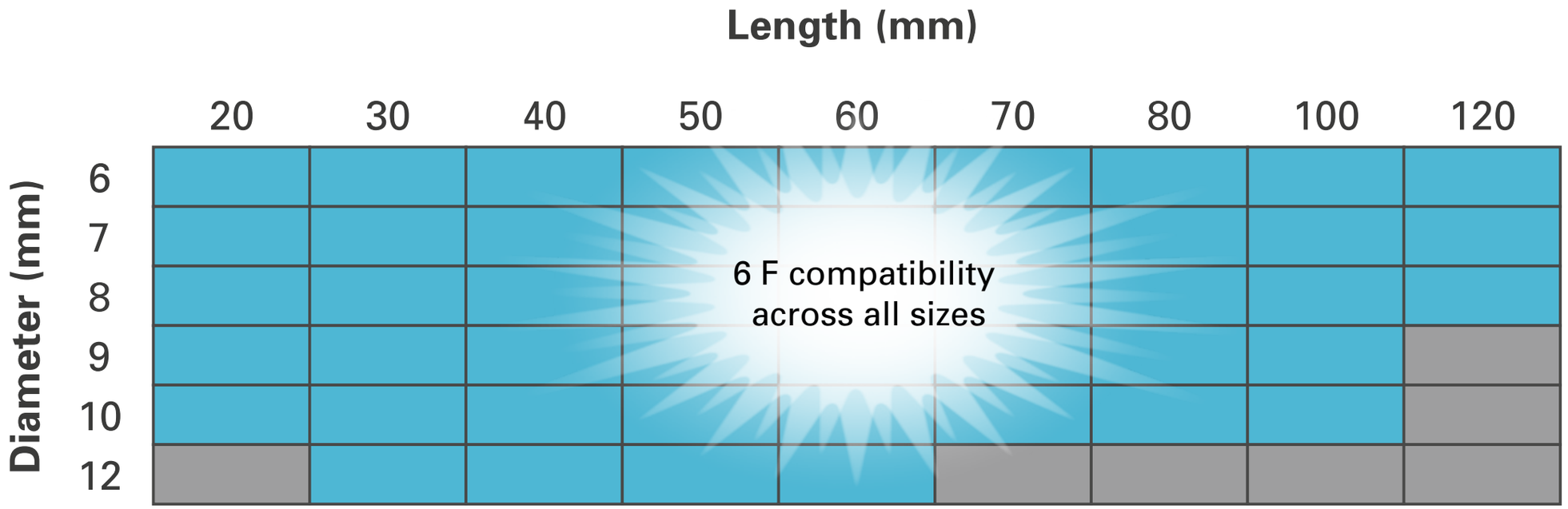
Expansive size matrix; all compatible with a 6 F introducer sheath.



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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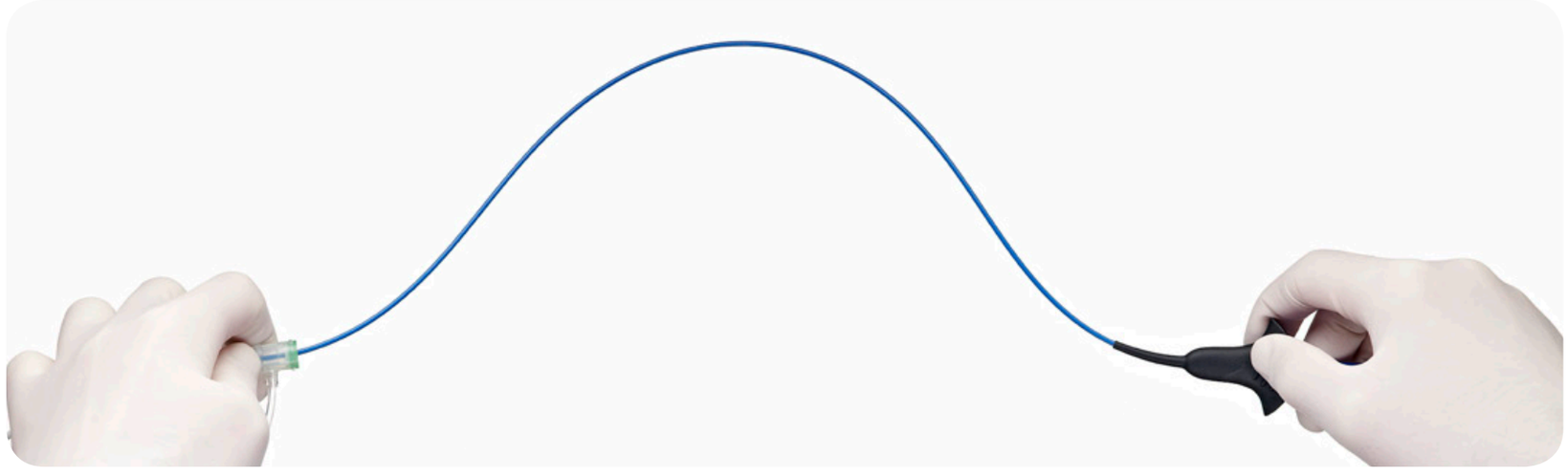

Incorrect deployment technique

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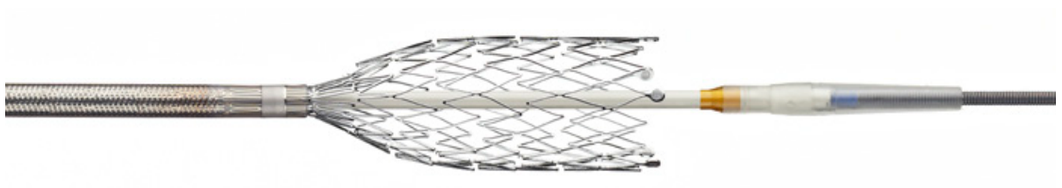
As the outer shaft retracts proximally during deployment, the stent will begin to flower outward.

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

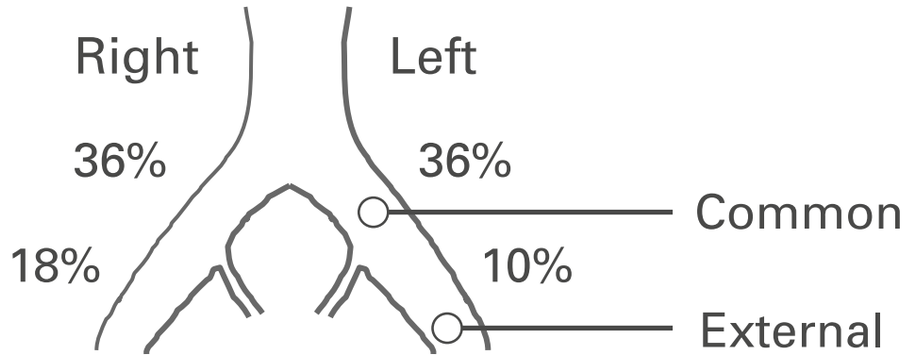
- Death within 30 days, or
- MI that occurs during index hospitalization, or
- Target vessel revascularization through 9 months, or
- Amputation of index limb through 9 months

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%

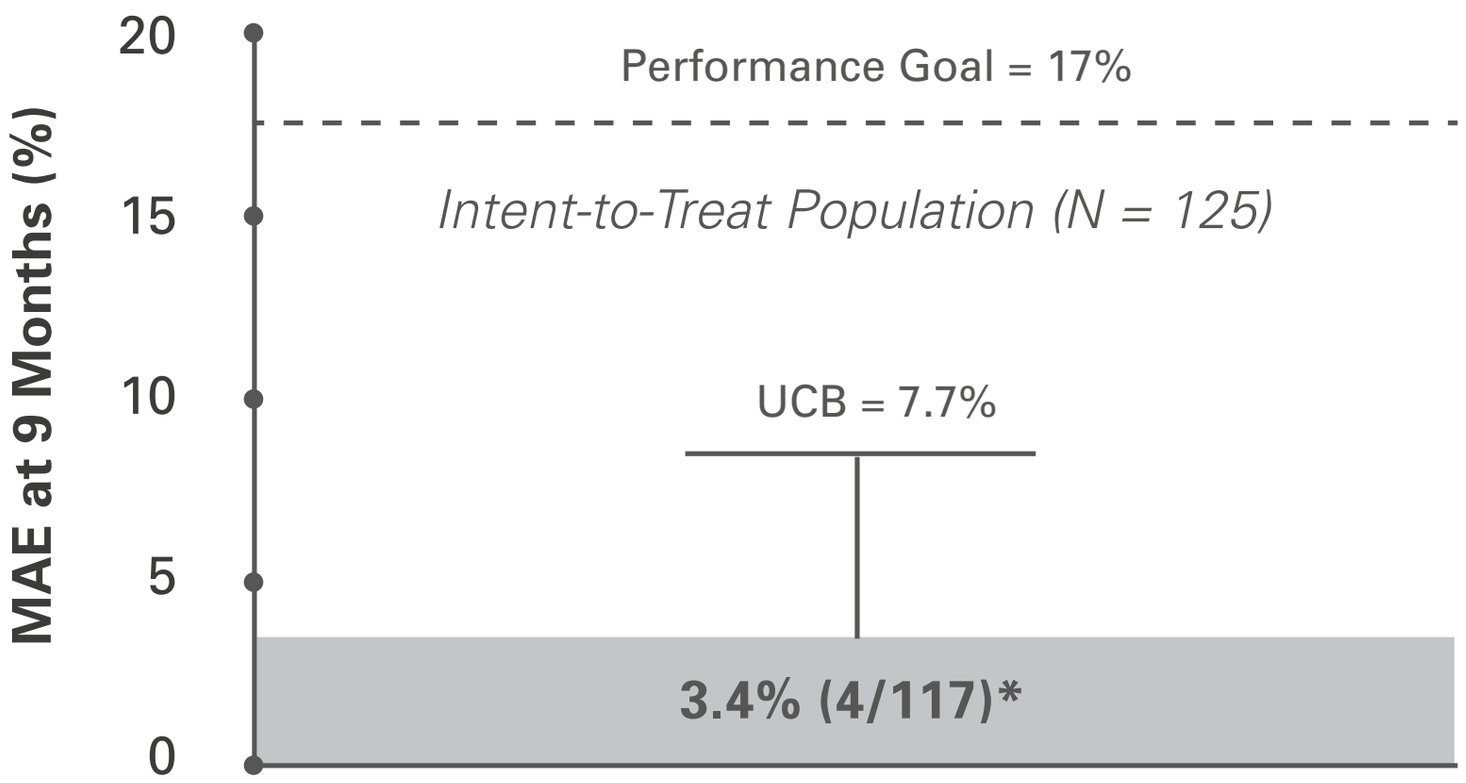
Baseline Characteristics

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.

ORION Clinical Trial

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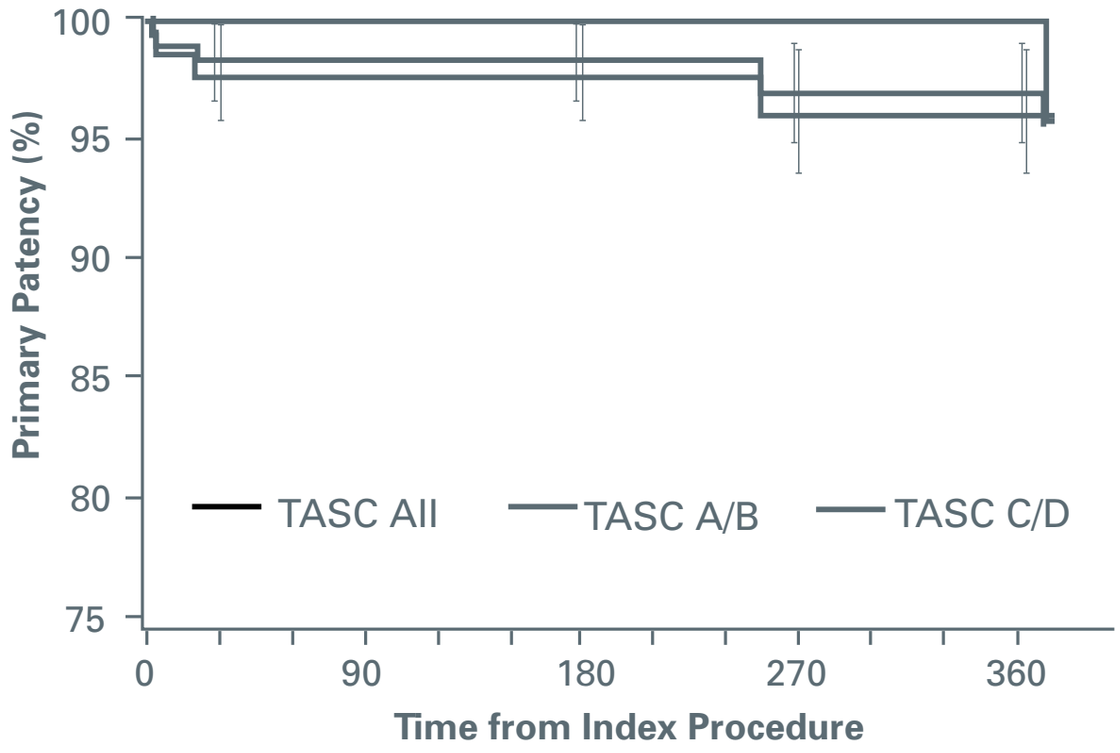
The Only US IDE Clinical Trial to demonstrate similar patency across all TASC classifications

12-Month Primary Patency by TASC Classification



Lesions at Risk	All	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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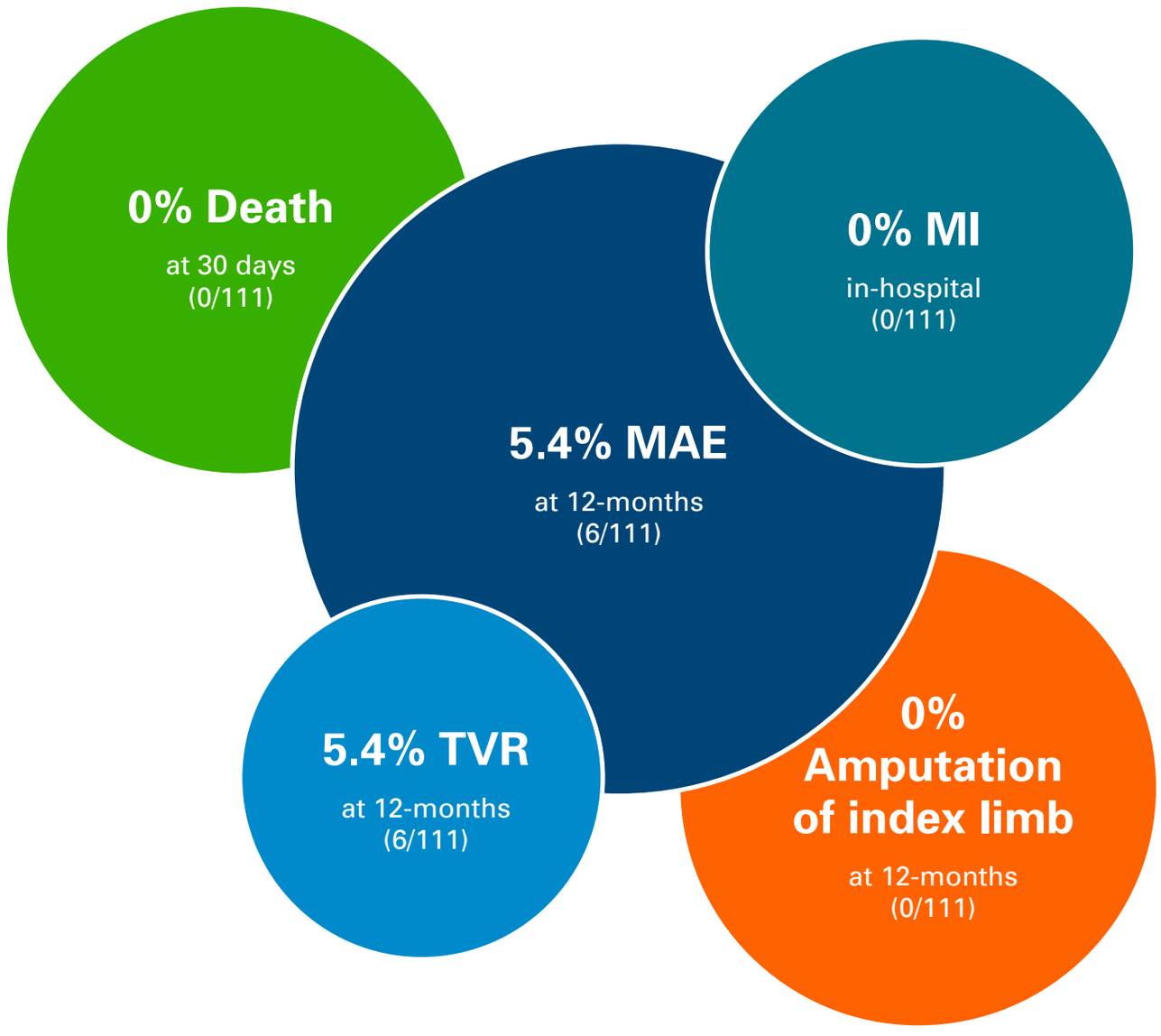

Composite Success Rates

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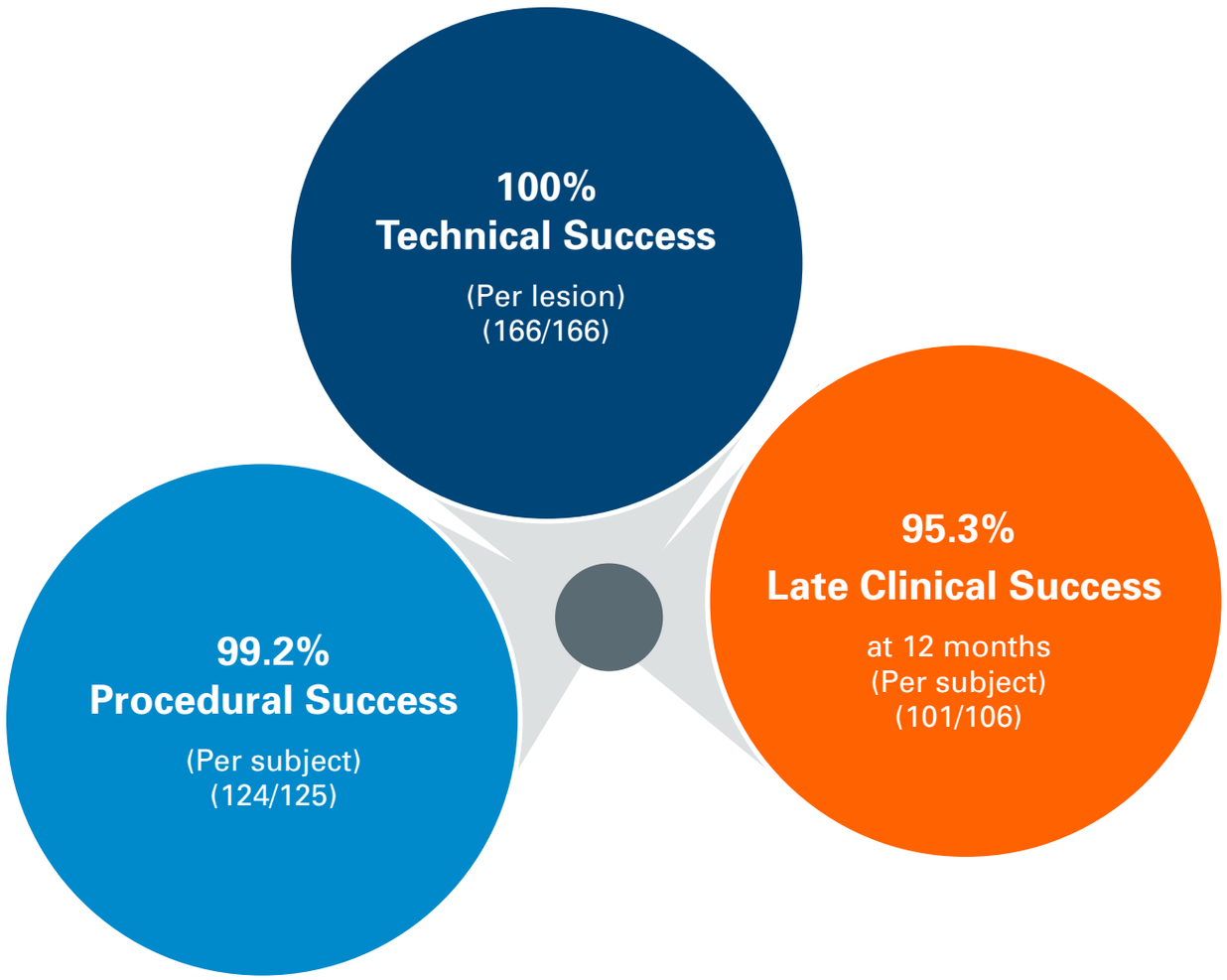

Technical: stenosis ≤ 30% post procedure; Procedural: technical success and no in-hospital MAE (death, MI, TVR, index limb amputation); Clinical: Rutherford classification improved by ≥ 1 class versus baseline; MAE = major adverse events; MI = myocardial infarction; TVR = target vessel revascularization.

12-month Stent Patency and Restenosis

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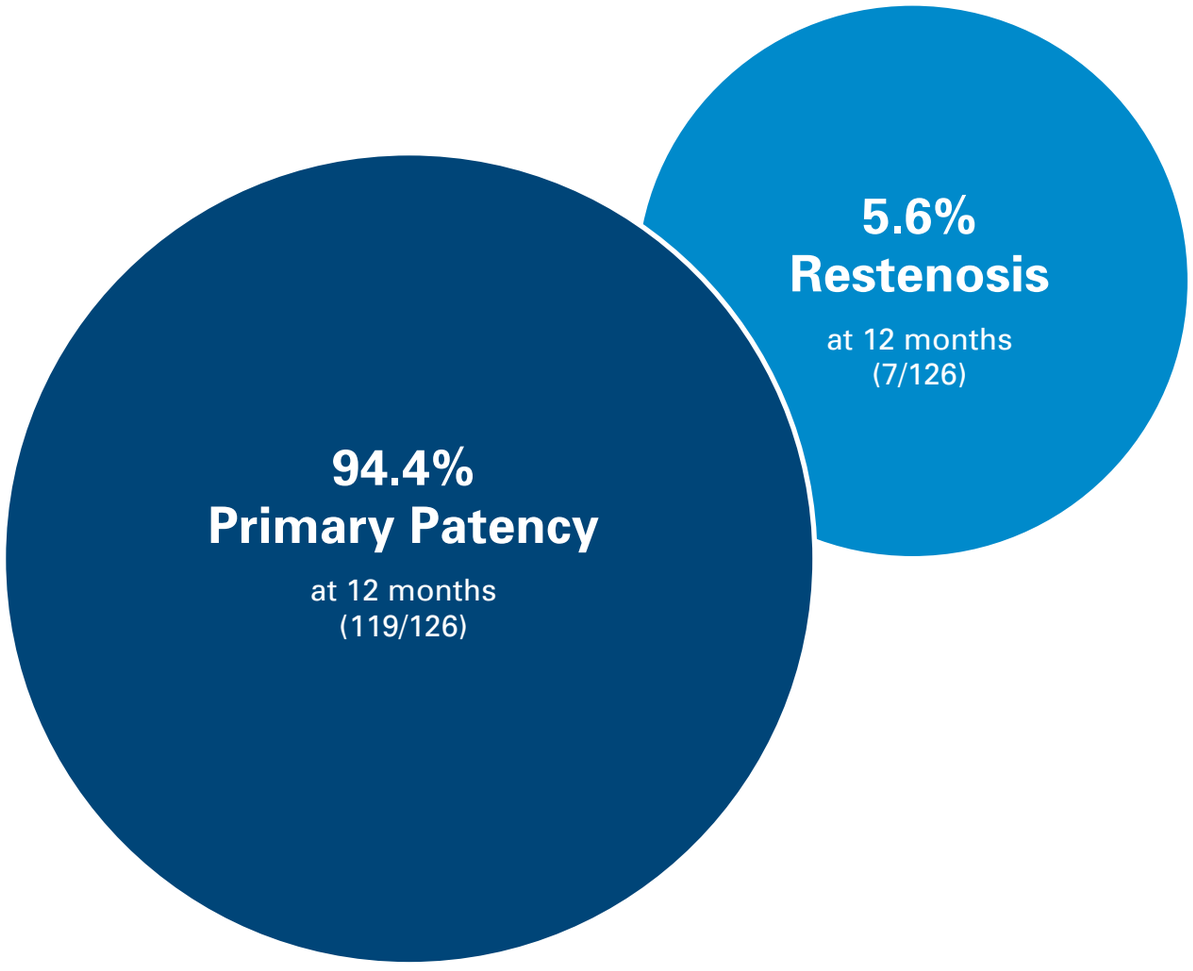

Thank You!

Epic™ Vascular Self-Expanding Stent System

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DINPER4699EA