



The Challenge of Accurately Stenting Aorto-Ostial Lesions

- In a retrospective study of 100 patients in whom stents were placed using angiographic landmarks, correct stent positioning was achieved in only 48% of cases.¹
- Conventional angiographic landmarks used during stenting of aorto-ostial lesions are often ambiguous and/or misleading, making accurate stent positioning extremely difficult.²
- The accuracy of stent placement at the ostium by the Szabo technique was reported in 78 out of 257 cases of Medina (010-001) or aorto-ostial lesions.³



Where is the ostium?



The Ostial PRO at the "true" ostium.

The Ostial PRO Stent Positioning System is an alignment tool with gold-plated "feet" that engage the aortic wall and allow easier assessment of the coronary or renal ostia, improving accuracy of stent positioning in aorto-ostial lesions.

References:

1. Dishmon DA, Elhaddi A, Packard K, et al. High incidence of inaccurate stent placement in the treatment of coronary aorta-ostial disease. *J Invasive Cardiol* 2011; 23:322-326.
2. Kaplan S, Barlis P, Tanigawa J, et al. Unconventional treatment of aorto-ostial in-stent restenosis with marked protrusion into the aorta. *J Cardiovasc Med (Hagerstown)*. 2008;9(2):184-6.
3. Gutiérrez-Chico JL, Villanueva-Benito I, Villanueva-Montoto L, et al. Szabo technique versus conventional angiographic placement in bifurcations 010-001 of Medina and in aorto-ostial stenting: angiographic and procedural results. *EuroIntervention* 2010 Feb;5:801-808.



Stent Positioning System

Ordering Information

Catalog Number **3011**

Essential Prescribing Information Ostial PRO® Stent Positioning System

Indications For Use

The Ostial PRO® Stent Positioning System is intended for use in aorta-ostial procedures to introduce and position stents and other interventional devices within the coronary and peripheral vasculature. In addition, the Ostial PRO® Stent Positioning System is intended to facilitate the alignment of interventional devices and function as an alignment tool.

Contraindications

If other interventional devices are used in conjunction with the Ostial PRO® Stent Positioning System, refer to specific manufacturer's product labeling for intended use, contraindications and potential complications associated with that device.

Warnings and Precautions

- For Single Use Only. Do Not Resterilize.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- The device must be used prior to the expiration date.
- Discard device if mishandling has caused possible damage or contamination.
- It is recommended that the patient must have received therapeutic dosage of Heparin to achieve ACT > 200.
- If extended procedure is required (greater than 30 minutes), it is recommended to not load the Ostial PRO® Stent Positioning System into the guiding catheter until it is needed to aid in the placement of the stent. For these procedures, utilize the "Front Loading" steps for the Ostial PRO® Stent Positioning System introduction into the guiding catheter.
- If the Ostial PRO® Stent Positioning System feet and cylinder is advanced out of the distal end of the guiding catheter, gently pull on the proximal end of the Ostial PRO® Stent Positioning System until the cylinder has retracted into the distal end of the guiding catheter leaving only the gold-plated feet exposed or retract both components in the distal end of the guiding catheter. Never pull back the Ostial PRO® Stent Positioning System with great force.
- In the event the cylinder and feet of the Ostial PRO® Stent Positioning System are advanced too far distally from the tip of the guide causing the Ostial PRO® Stent Positioning System to become "derailed" from the stent delivery system, perform the following steps:
 - Retract stent delivery system into guiding catheter. Never retract Ostial PRO® Stent Positioning System into guiding catheter before stent delivery system has been withdrawn.
 - Retract Ostial PRO® Stent Positioning System into guiding catheter until feet collapse.
 - Re-cross ostial lesion with stent delivery system.
 - Advance Ostial PRO® Stent Positioning System until feet "pop out."
- Stent crossing profile must be less than Ostial Pro® Stent Positioning System effective ID to prevent stent or Ostial Pro® Stent Positioning System damage.

Potential Complications

The following complications can occur: emboli, hemorrhage, ischemia, vasospasm, and neurological defects including stroke and death.

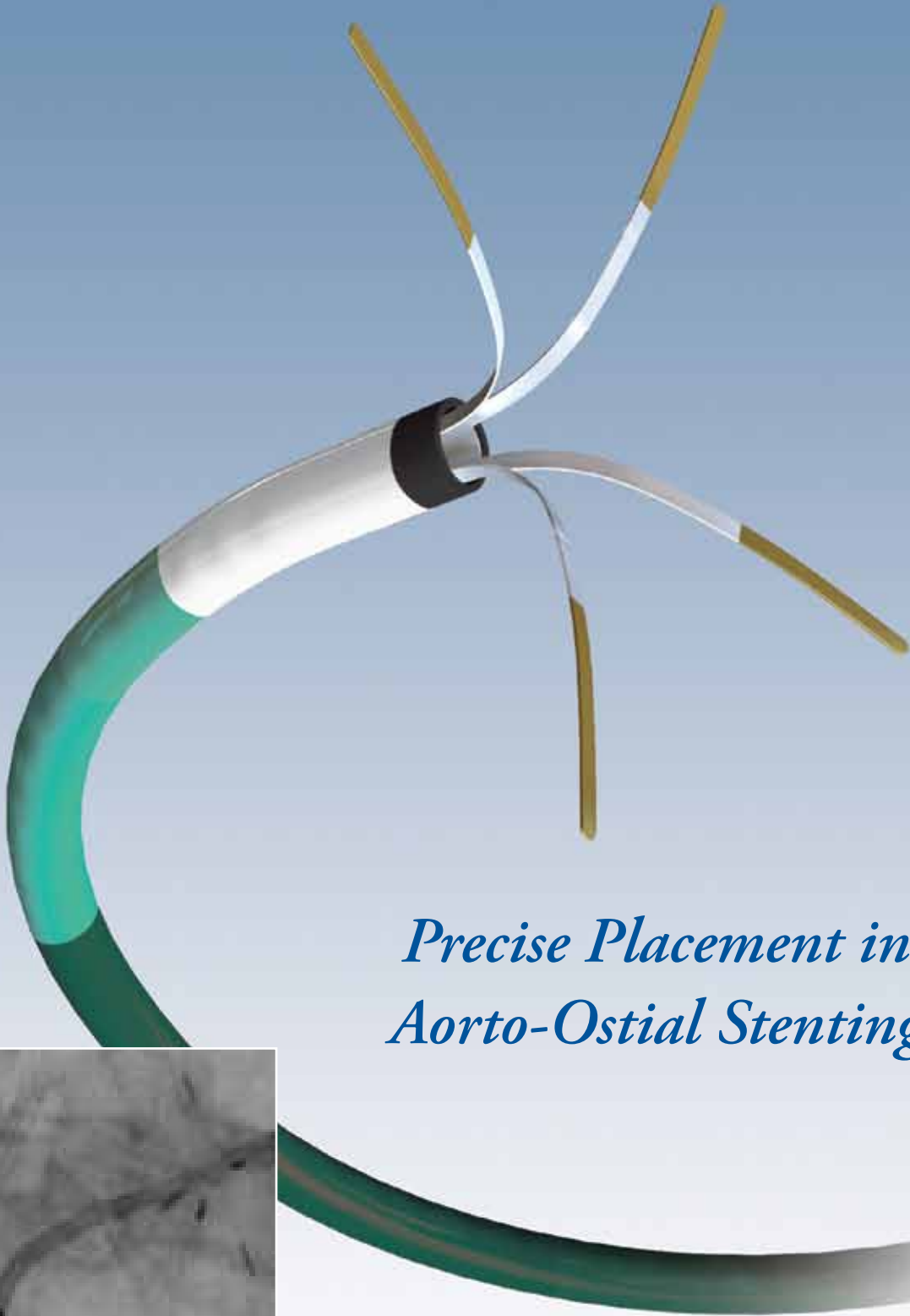
Caution

Federal (USA) law restricts this device to sale by or on order of a physician.

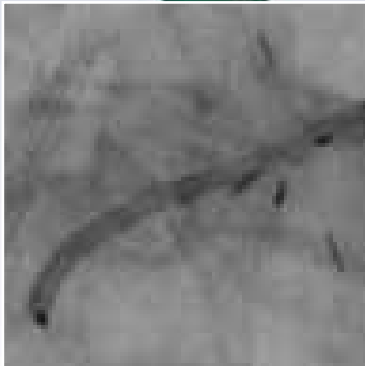
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Guide Catheter Compatibility		
French Size	Estimated Catheter ID	Effective ID
6 F	0.070"	0.050"
7 F	0.078"	0.058"
8 F	0.088"	0.068"





*Precise Placement in
Aorto-Ostial Stenting*



 **stia** **PRO**®
Stent Positioning System

*15 mm leg span
accommodates ostia.*

*Flexible cylinder
Longitudinal opening allows use
with 6, 7, or 8 French guiding
catheters.*

Cylinder/wire connection

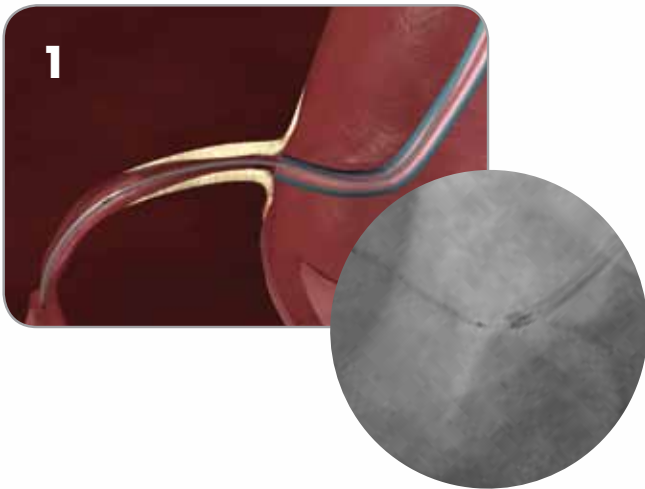
*Tapered cylinder
permits easy pullback
into the guide.*

*Nitinol gold-plated legs
allow greater opacification to help
identify the plane of the ostium.*

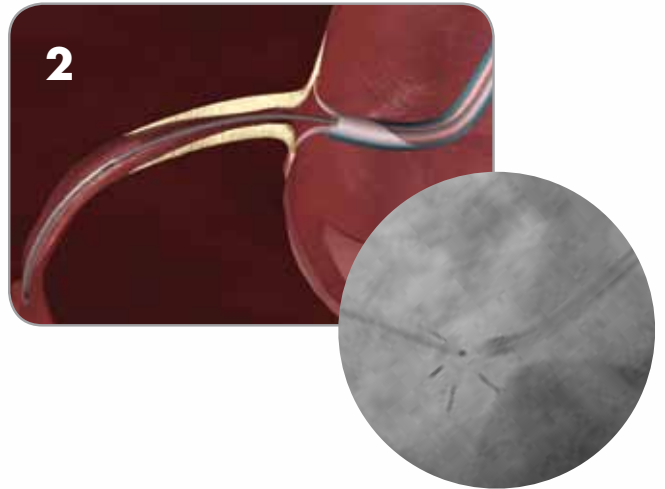
*Flexible distal wire
The 4 cm distal end is ground down to
0.014 inches and heat treated to allow
more flexibility to prevent straightening of
the guiding catheter curve, yet retains
push/pull characteristics.*

*Overall length
127 cm permits use with any guide
that is ≤ 100 cm in length.*

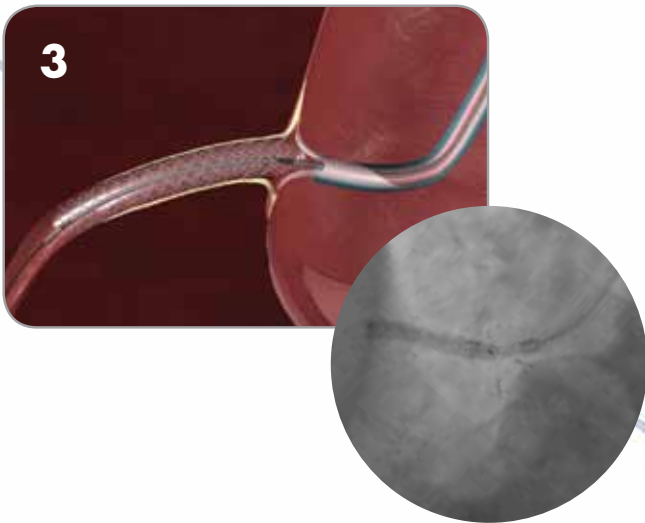
Stent Advances Past the Lesion



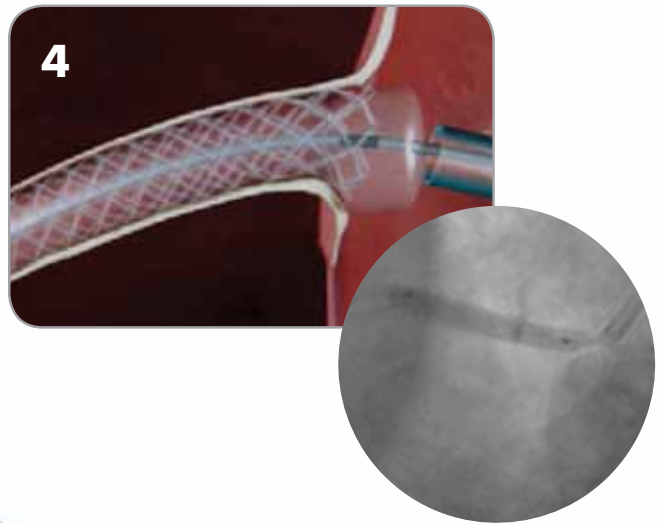
Ostial PRO Positioned at the Aorto-Ostial Junction



Stent Deployed at the Vessel Ostium



Stent Flaring



Nitinol wire
 0.018 inch wire allows
 greater pushability and
 strong pullback capabilities.

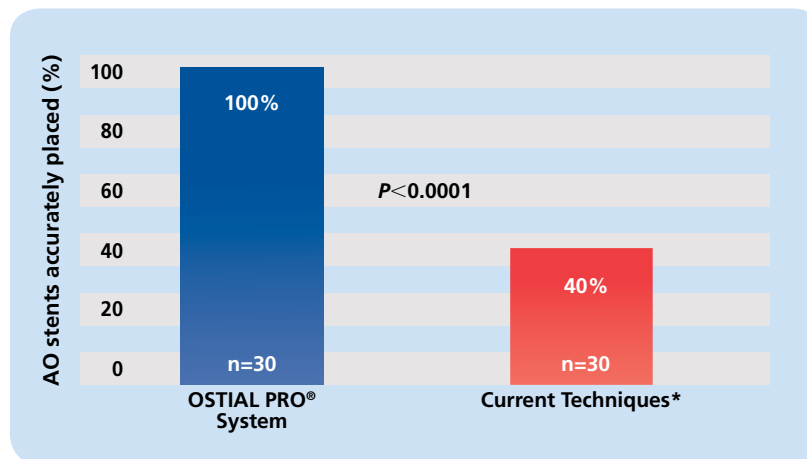
Yellow marker
 permits positive identification
 and differentiation of the
 OSTIAL PRO® Stent
 Positioning System
 from other wires.



Stent Positioning System

In clinical studies, the Ostial PRO significantly increased the accuracy of aorto-ostial stent placement.

- Compared to the Ostial PRO group, which had accurate stent placement in 30/30 cases without any issues related to reengagement or a need for a second stent placement, the control group had significant stent misplacement observed in 60% (18/30) of cases ($p < 0.0001$ versus Ostial PRO results).⁴
- The Ostial PRO was associated with decreased procedure time, radiation exposure and reduced use of contrast.⁵



*Historical controls prior to use of the Ostial PRO® Stent Positioning System

Additional Benefits of the Ostial PRO Stent Positioning System:

- Reduces the risk of distal and proximal lesion stent deployment and the need for more costly re-interventions⁵
- Increases cost savings by reducing the length of procedures, reducing fluoroscopy and radiation exposure, and reducing the use of contrast (important for preserving renal function)⁵
- Prevents deep seating of the guide catheter, decreasing risk of dissection by minimizing guide catheter tip trauma⁶

References:

4. Fischell TA et al. A new ostial stent positioning system (Ostial Pro) for the accurate placement of stents to treat aorto-ostial lesions. *Catheter Cardiovasc Interv.* 2008;71(3):353-7.
5. Fischell TA et al. Initial clinical experience using an ostial stent positioning system (Ostial Pro) for the accurate placement of stents in the treatment of coronary aorto-ostial lesions. *J Invasive Cardiol.* 2009;21(2):53-9.
6. Kwan TW et al. What is the price for perfection for precise aorto-ostial stent placement? *J Invasive Cardiol.* 2011;23(8):327.