

**WHEN PRECISE  
PLACEMENT  
IS CRITICAL**



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

## OSTIAL PRO®

Stent Positioning System

# OSTIAL PRO® Stent Positioning System Facilitates More Accurate Stent Positioning in AO Lesions

OSTIAL PRO® Stent Positioning System allows easier assessment of coronary or renal ostia, improving the accuracy of stent positioning in AO lesions:

- Unique design provides three dimensional visual and tactile feedback
- Excellent pushability and strong pullback capabilities
- Compatible with 6, 7, and 8 French guiding catheters

OSTIAL PRO® Stent Positioning System helps avoid potential complications. Once positioned against the ostium, the OSTIAL PRO® Stent Positioning System:

- Helps prevent deep seating of the guide catheter<sup>1</sup>
- May decrease risk of dissection by minimizing guide catheter tip trauma
- Facilitates precise stent positioning in the ostium to help reduce the risk of distal and proximal lesion stent deployment and the need for more costly reinterventions

The OSTIAL PRO® Stent Positioning System enables more accurate stent placement, which can help reduce:

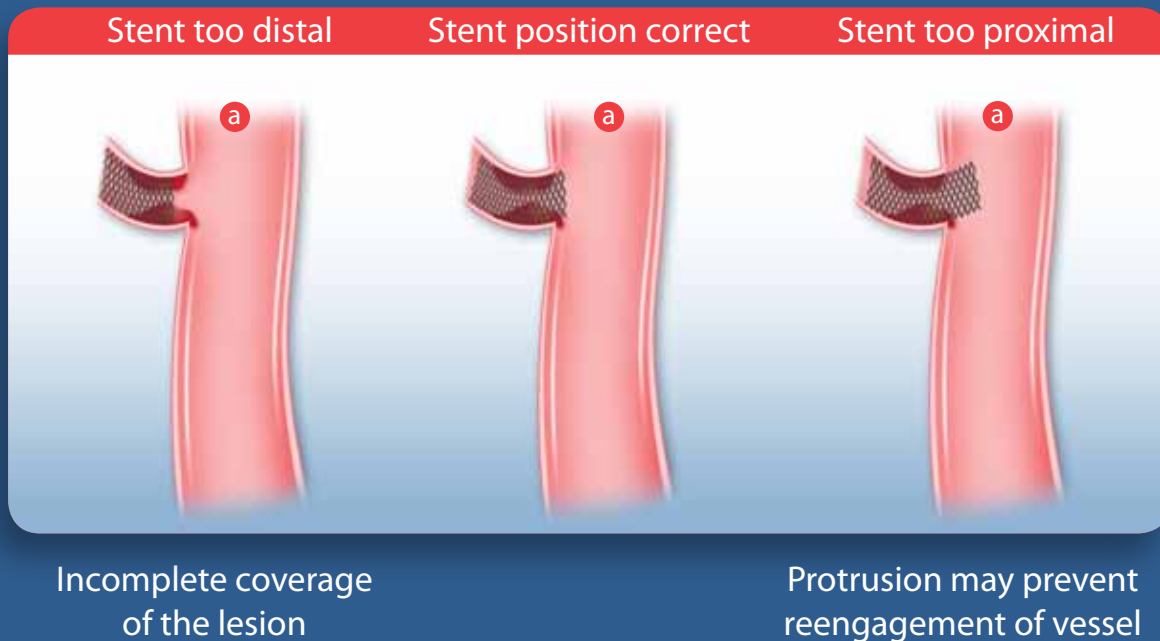
- The length of procedures
- Fluoroscopy and radiation exposure
- Use of contrast (important for preserving renal function)

**References:** 1. 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. 2. Kobo O et al. Screening, diagnosis, and treatment of renal artery stenosis by percutaneous transluminal renal angioplasty with stenting. *Isr Med Assoc J.* 2010;12(3):140-3. 3. Zähringer M et al. Sirolimus-eluting versus bare-metal low-profile stent for renal artery treatment (GREAT Trial): angiographic follow-up after 6 months and clinical outcome up to 2 years. *J Endovasc Ther.* 2007;14(4):460-8. 4. Chin K. An approach to ostial lesion management. *Curr Interv Cardiol Rep.* 2001;3(2):87-9. 5. Jokhi P, Curzen N. Percutaneous coronary intervention of ostial lesions. *EuroIntervention.* 2009;5(4):511-4. 6. 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. 7. Kaplan S 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. 8. Sakamoto H et al. Angiographic and clinical outcomes after sirolimus-eluting stent implantation to de novo ostial lesion of the right coronary artery: a retrospective study. *Circ J.* 2008;72(6):880-5. 9. Dishmon DA et al. CRT 2011 abstract. 10. Wertman BM et al. Characterization of complex coronary artery stenosis morphology by coronary computed tomographic angiography. *JACC Cardiovasc Imaging.* 2009;2(8):950-8. 11. Mavromatis K et al. Comparison of outcomes of percutaneous coronary intervention of ostial versus nonostial narrowing of the major epicardial coronary arteries. *Am J Cardiol.* 2004;94(5):583-7.

## The Challenge of Stenting Aorto-Ostial Lesions

- Aorto-ostial (AO) stenting accounts for an estimated 5%-7% of coronary interventions<sup>1</sup> and more than 90% of renal artery interventions.<sup>9</sup>
- AO lesions are more likely to be associated with suboptimal angiographic results due to lesion rigidity and elastic recoil<sup>4</sup>, and have higher rates of target lesion revascularization.<sup>5</sup>
- Conventional angiographic landmarks used during stenting of AO lesions are often ambiguous and/or misleading, making accurate stent positioning extremely difficult.<sup>7</sup>
- In a retrospective study of 100 patients in whom stents were placed using angiographic landmarks, correct stent positioning was achieved in only 46% of cases.<sup>9</sup>
- This device was associated with decreased procedure time, radiation exposure and reduced use of contrast.<sup>1</sup>

### Stent Positioning at Aorto-Ostial Sites

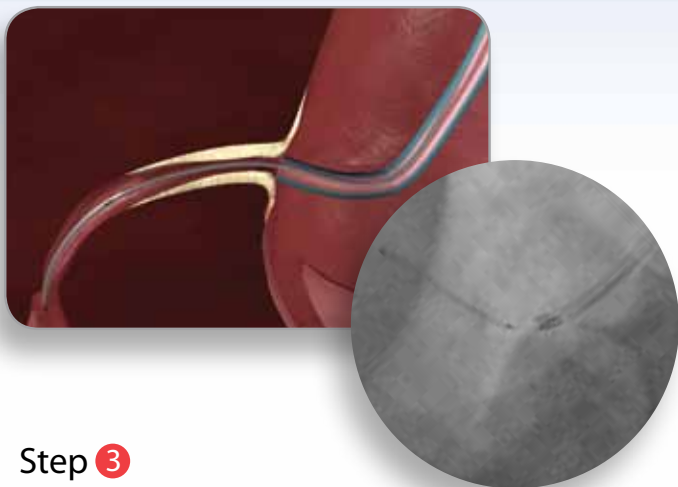


# OSTIAL PRO<sup>®</sup>

## Stent Positioning System

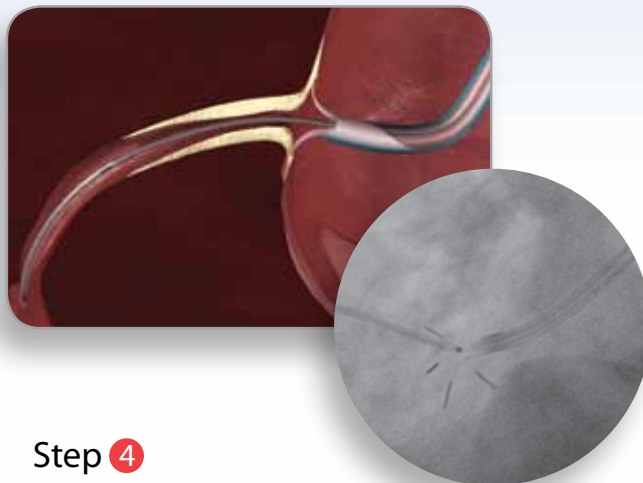
### Step 1

Advance the Stent Past the Lesion



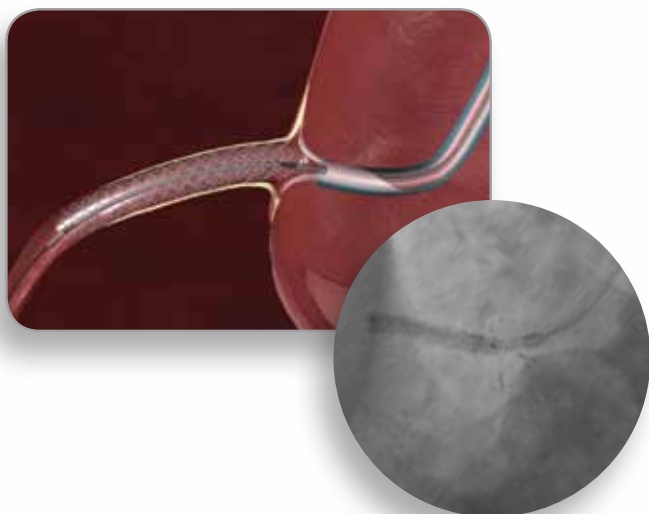
### Step 2

Position OSTIAL PRO<sup>®</sup> Stent Positioning System at the AO Junction



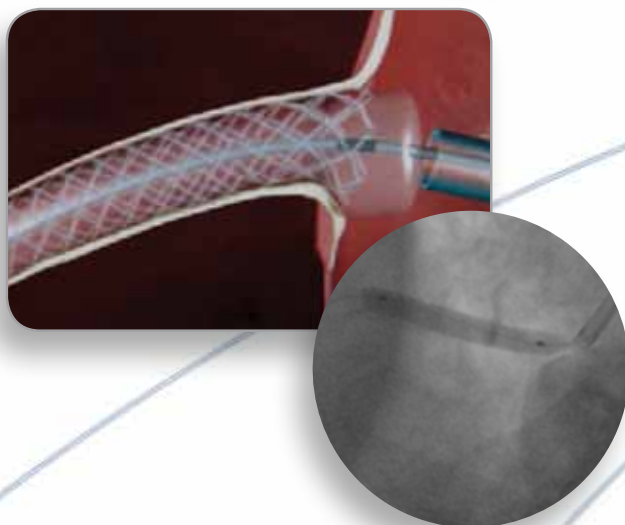
### Step 3

Retract Stent and Deploy



### Step 4

Stent Flaring



**Yellow marker** permits positive identification and differentiation of the OSTIAL PRO<sup>®</sup> Stent Positioning System from other wires.

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

NOTE: Please read full Instructions for Use for more detailed information prior to use.

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

**15 mm leg span**  
accommodates ostia.

**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, while retaining push/pull characteristics.

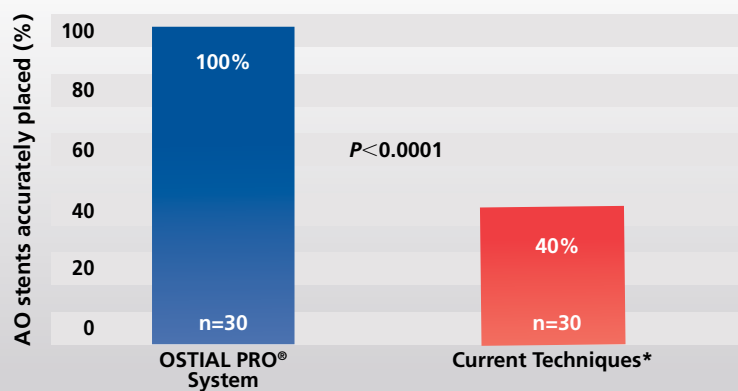
**Flexible cylinder**  
Longitudinal opening allows use with 6, 7, or 8 French guiding catheters.

**Cylinder/wire connection**

**Tapered cylinder**  
permits easy pullback into the guide.

**Overall length of 127 cm**  
permits use with any guide that is  $\leq 100$  cm in length.

### In a Clinical Study, OSTIAL PRO® Stent Positioning System Significantly Increased the Accuracy of AO Stent Placement<sup>1</sup>



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

# OSTIAL PRO<sup>®</sup>

## Stent Positioning System

### Ordering Information

Catalog Number 3011

Packaged 5 per box.

#### Essential Prescribing Information

##### OSTIAL PRO<sup>®</sup> Stent Positioning System

###### Indications For Use

The OSTIAL PRO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Stent Positioning System introduction into the guiding catheter.
- If the OSTIAL PRO<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> Stent Positioning System with great force.
- In the event the cylinder and feet of the OSTIAL PRO<sup>®</sup> Stent Positioning System are advanced too far distally from the tip of the guide causing the OSTIAL PRO<sup>®</sup> 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<sup>®</sup> Stent Positioning System into guiding catheter before stent delivery system has been withdrawn.
  - Retract OSTIAL PRO<sup>®</sup> Stent Positioning System into guiding catheter until feet collapse.
  - Re-cross ostial lesion with stent delivery system.
  - Advance OSTIAL PRO<sup>®</sup> Stent Positioning System until feet "pop out."
- Stent crossing profile must be less than Ostial Pro<sup>®</sup> Stent Positioning System effective ID to prevent stent or Ostial Pro<sup>®</sup> 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.

The third party trademarks used herein are trademarks of their respective owners

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"



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