

OSTIAL PRO[®] STENT POSITIONING SYSTEM

1 Preparation

Steps Before Use of the OSTIAL PRO[®] System

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|--|---|--|--|
| <ul style="list-style-type: none"> • The artery is engaged with guiding catheter and the appropriate guide wire. - Cannulate the ostium with the guide. Guide selection is important; choose a shape that provides the best coaxial alignment. | <ul style="list-style-type: none"> • When making a guiding catheter selection, consider the following guidelines: <ul style="list-style-type: none"> - Choose a shape that provides the best coaxial alignment. - Use a 6F guide for most coronaries with a stent of 4.5 mm or smaller. | <ul style="list-style-type: none"> • Use a 7F guide for peripherals up to a 6.0mm peripheral stent. • For larger 7.0mm diameter peripheral stents, use of the OSTIAL PRO[®] would require an 8F guiding catheter. | <ul style="list-style-type: none"> • Just prior to loading the stent, prepare the OSTIAL PRO[®] System device by loading it onto the guide wire. |
|--|---|--|--|

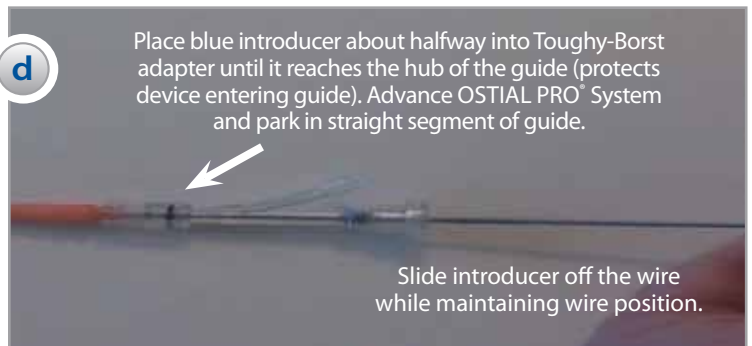
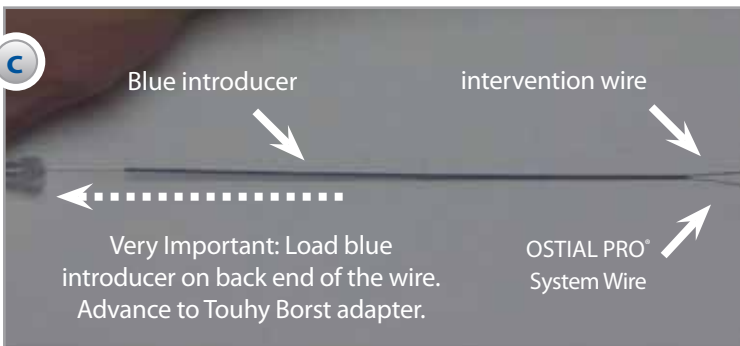
Load the OSTIAL PRO[®] System Into the Guiding Catheter



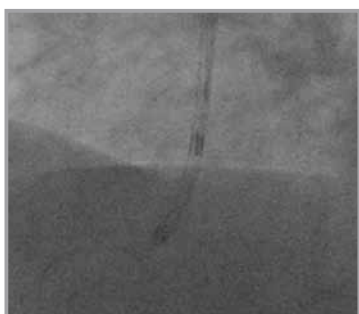
- Remove the OSTIAL PRO[®] System and introducer from the protective coil.
- Load the OSTIAL PRO[®] System (yellow end first) into the introducer.



- Continue to advance the OSTIAL PRO[®] System through the introducer until the gold-plated feet retract inside the introducer.



Pass Stent Through OSTIAL PRO[®] System in Straight Segment of the Guide



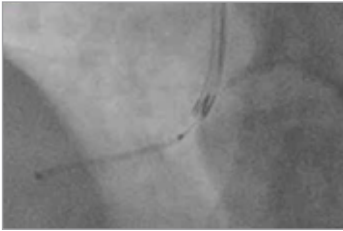
- Place OSTIAL PRO[®] System in straight segment of guide.
- Load the stent onto the guidewire and move it past the OSTIAL PRO[®] System.

OSTIAL PRO[®] STENT POSITIONING SYSTEM

This is intended as an overview or a reminder only. Please read full Instructions For Use for more detailed information.

2 Advancement

Advance Stent Into Vessel, Past Lesion



- Advance the stent into the vessel, 4 to 5 mm past the ostial lesion.

Disengage Guide Into Aorta

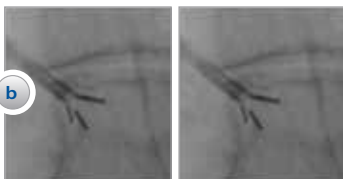


- Hold guidewire position and stent shaft in place.
- Disengage guide catheter 3 to 5 mm into aorta to allow room for the OSTIAL PRO[®] System to fully deploy.
- Confirm position in aorta with small contrast injection.

Deploy the OSTIAL PRO[®] System

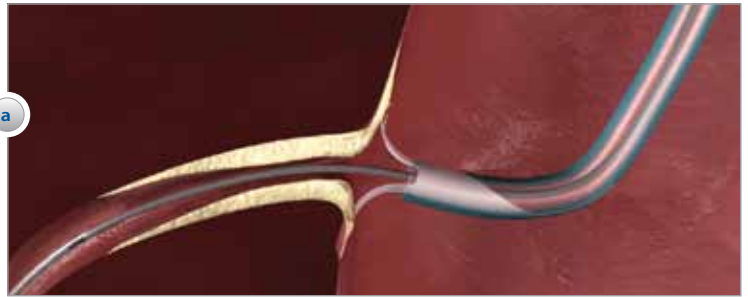


- Hold the stent shaft and guide wire stationary.
- Gently push the OSTIAL PRO[®] System forward until the gold plated distal feet expand into an open position, using fluoroscopic guidance.
- Do not advance the OSTIAL PRO[®] System cylinder distal to the guiding catheter tip.

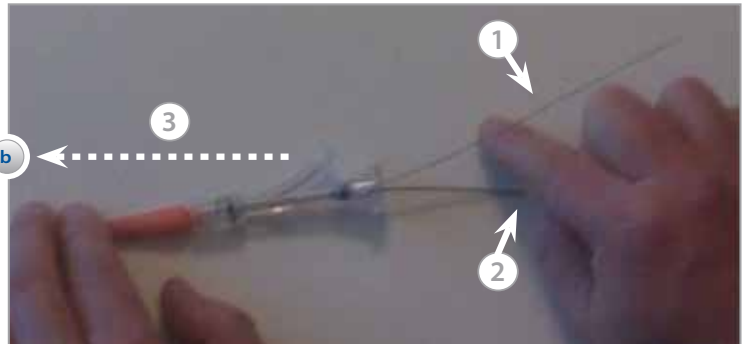


3 Positioning

Advance the OSTIAL PRO[®] System Back to the Ostium—the “Power Position”



- Push the guiding catheter forward until gold plated feet are clearly in contact with the aortic wall.



- Leave the OSTIAL PRO[®] System free to move with guide forward toward ostium. Don't pin. ①
- Pin 0.014" guidewire and stent shaft to maintain position. ②
- Advance guide and the OSTIAL PRO[®] System (as a unit) over stent shaft to ostium. ③



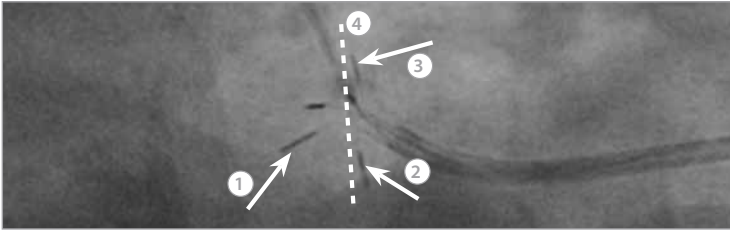
- Advance until at least 2 legs of the OSTIAL PRO[®] System “flex”.
- You will be able to “feel” the feet touching the aortic ostium.
- Inject contrast to confirm position.

Information on proper use, indications, contraindications, warnings, precautions, and adverse events.

4

Stent Deployment

Ensure the OSTIAL PRO® System is in the "Power Position"

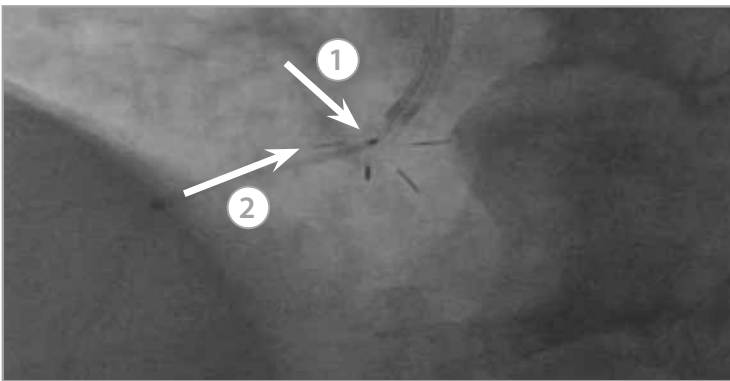


• To identify whether the OSTIAL PRO® System is in the "Power Position" follow 1 through 4 (defining the true ostium).

- ① Leg "flexed" on aortic cusp
- ② Leg on aortic wall
- ③ Leg on aortic wall
- ④ Ostial plane is defined by the OSTIAL PRO® System

• Stent can now be properly aligned.

Pull Back Stent and Align With the OSTIAL PRO® System



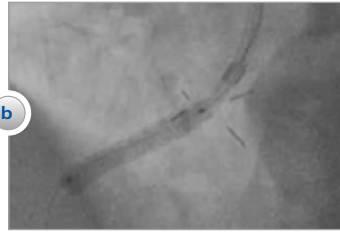
• The stent is pulled back until the proximal marker band on the stent balloon is just proximal to the gold plated feet of the OSTIAL PRO Stent Positioning System.

• Inject contrast medium to confirm the stent position. The proximal stent delivery system marker band should typically be just distal to the distal tip of the guiding catheter.

Stent Deployment



• With the OSTIAL PRO® System in place (feet in the expanded position and the correct alignment confirmed), deploy the stent.



• Deflate the stent delivery balloon before removing the OSTIAL PRO® System from the guiding catheter.

5

Retraction

Final Steps



• Retract the OSTIAL PRO® System into the distal end of the guiding catheter.

• You can now remove the OSTIAL PRO® System from the guide.



• Re-inflate the balloon several mm proximal to the original inflation to "flare" the proximal end of the stent.

• Remove the stent delivery catheter.

• Precise stent placement at the ostium.



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