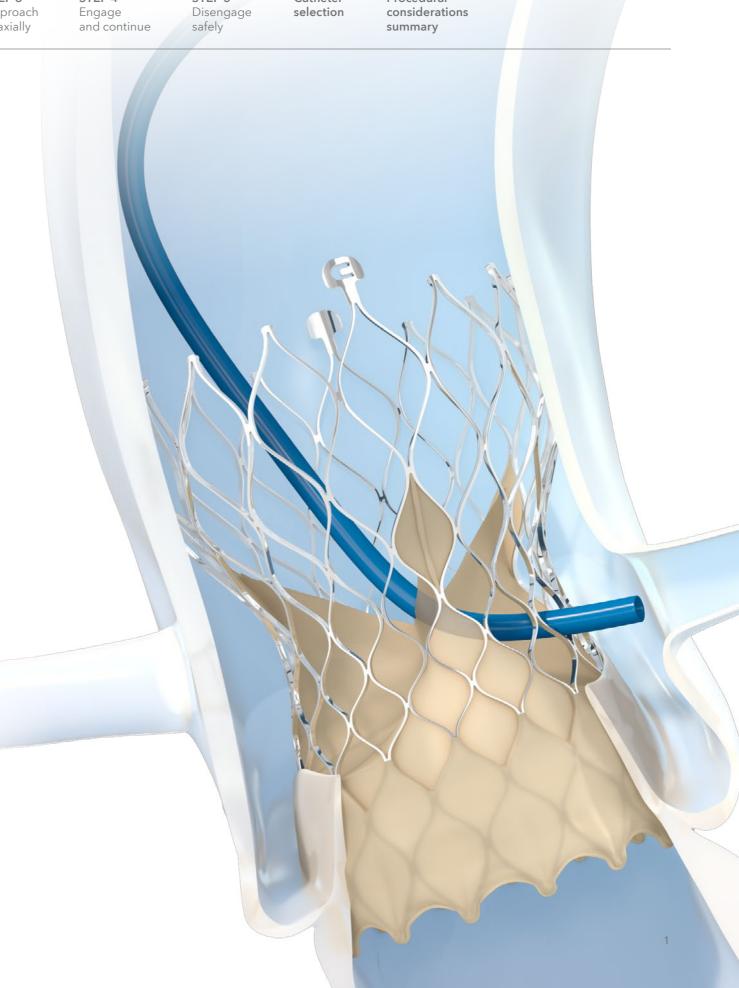
Post-TAVI coronary access

Updated procedural considerations

The following considerations for post-TAVI coronary access were created through a detailed review of available data, including publications and proctor input. These methods (including the use of accessory devices) have not been verified through bench testing.

The information in this document is intended for educational purposes based on an identified need, is not meant as a substitute for the instructions for use or product training, and is not intended to constitute medical advice or in any way replace the independent medical judgment of a trained and licensed physician with respect to any patient needs or circumstances. The physician is solely responsible for all decisions and medical judgments relating to the treatment of their patients. Please see the complete Instructions for Use for products discussed or demonstrated, including all product indications, contraindications, precautions, warnings, and adverse events. Practice, ease of use, and outcomes may vary based on clinical practice and judgment.



STEP 1
Perform
aortogram

STEP 2
Select
catheter

STEP 3
Approach coaxially

STEP 4
Engage
and continue

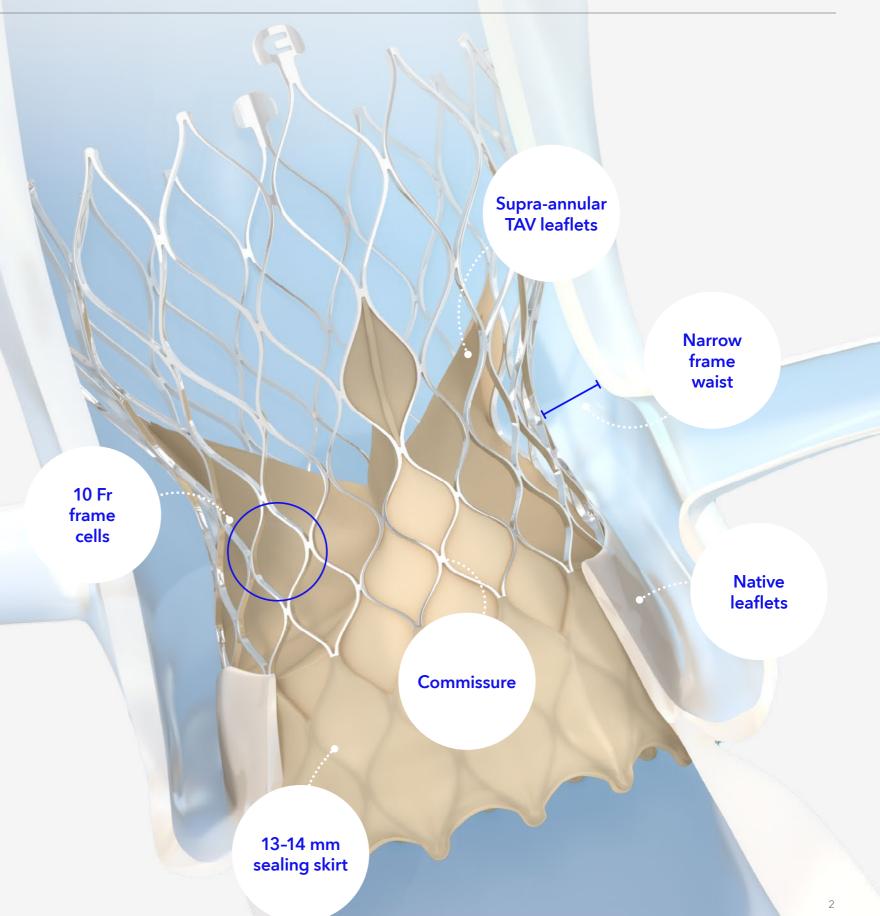
STEP 5
Disengage safely

Catheter selection

Procedural considerations summary

Evolut valve information

Structural factors to consider



Evolut valve information

Preprocedure: commissural position considerations

Confirm "C"-tab position

- Before beginning the procedure, image valve frame in 20-25° LAO projection.
- Note the position of the "C" tab of the valve frame. · ·
- Typical position is on the anterior portion of the lesser curve.

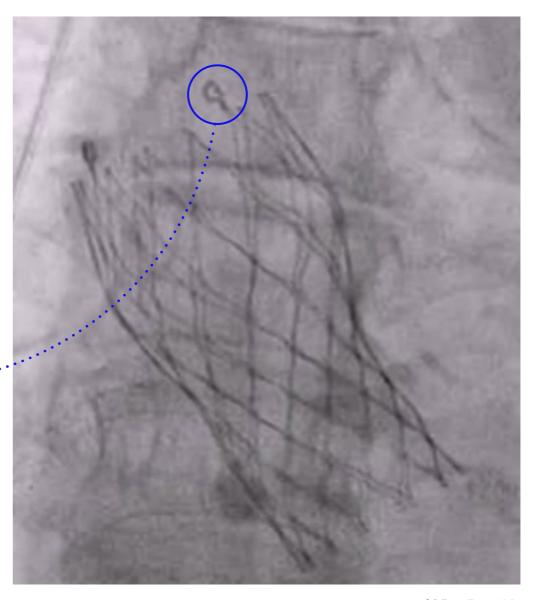


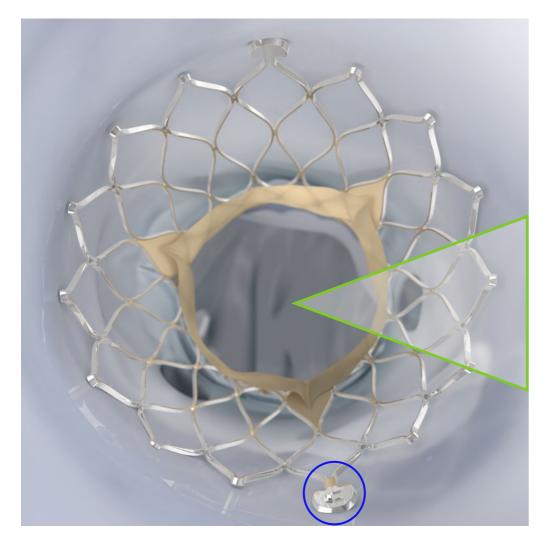
Image courtesy of Gilbert Tang, M.D.

- Compared to image at right, if the valve frame cells are not aligned at 20-25° LAO, consider adding a small amount of cranial or caudal angulation.
- If the "C"-tab is not located near the lesser curve, there is a higher likelihood that a tall commissure may be near a coronary ostium (see following page).

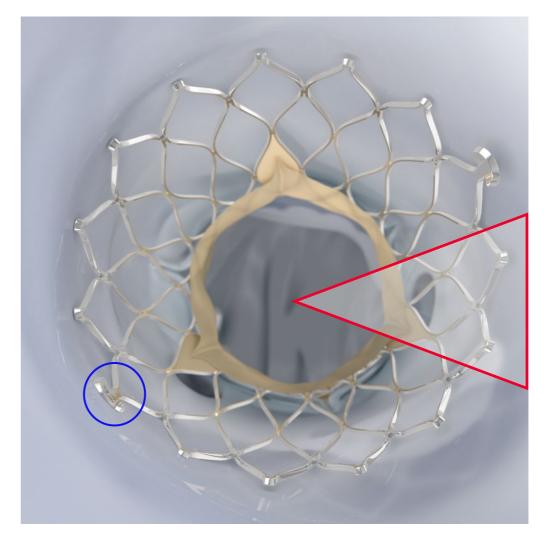
Evolut valve information

Preprocedure: commissural position considerations

C-tab located near lesser curve



C-tab NOT located near lesser curve



Perform aortogram

- Consider femoral access as it may provide easier access to the Evolut frame.
- Choose a C-arm angle with an orthogonal view of the coronary ostium of interest.
- Insert pigtail catheter to within the upper 1/3 of the Evolut frame.
- Perform an aortogram to delineate anatomy and frame cell adjacent to coronary.



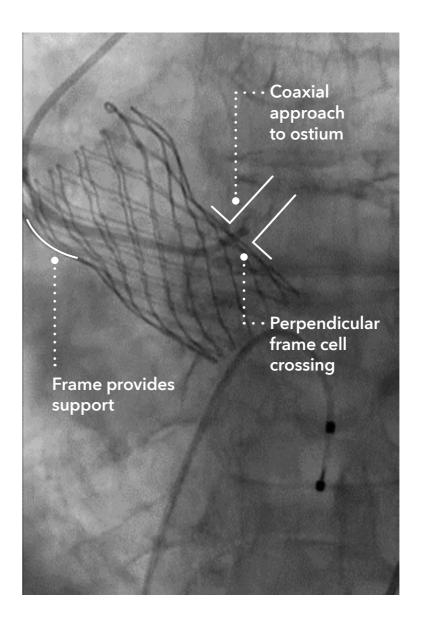
Considerations Note the following:

- Coronary height and angle of takeoff
- Sinus shape and width (e.g., effaced versus capacious, highly angulated aorta)
- Potential obstructions between frame and ostium

- Evolut frame cell adjacent to coronary ostium of interest
- Depth of Evolut implant consider position of 13-14 mm sealing skirt at inflow

Select catheter

- Choose a catheter shape that allows:
 - Perpendicular crossing of the frame and
 - Coaxial approach to ostium.
- Downsize catheter choice by 0.5 cm.

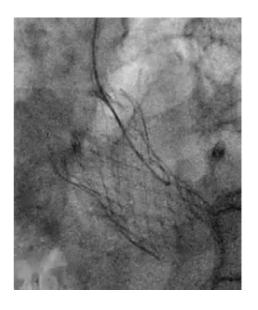


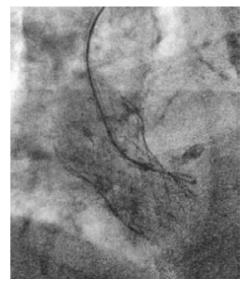
- The frame should provide significant catheter support. Consider a less aggressive shape (e.g., JL, JR, or Ikari). Use caution with EBU/XB guide catheters to avoid entanglement with the Evolut frame.¹
- For large/highly angulated aortic roots, consider longer tip lengths (e.g., AR [1/2] or MP).

- For smaller, more effaced roots, consider the following:
 - LCA: JR4, LCB, JL3 (guide)
 - RCA: AR1, 3DRC
- If "C"-tab is not near the typical location, commissure misalignment may be present consider longer tip catheter.

Approach coaxially

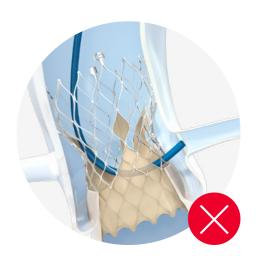
- Use exchange-length J-wire to select cusp of interest and exchange for selected catheter.
- Advance catheter to frame waist target the frame cell adjacent to ostium.
- Use J-wire and periodic contrast injections (if possible) to direct catheter through frame cell perpendicular to frame, engaging ostium coaxially.



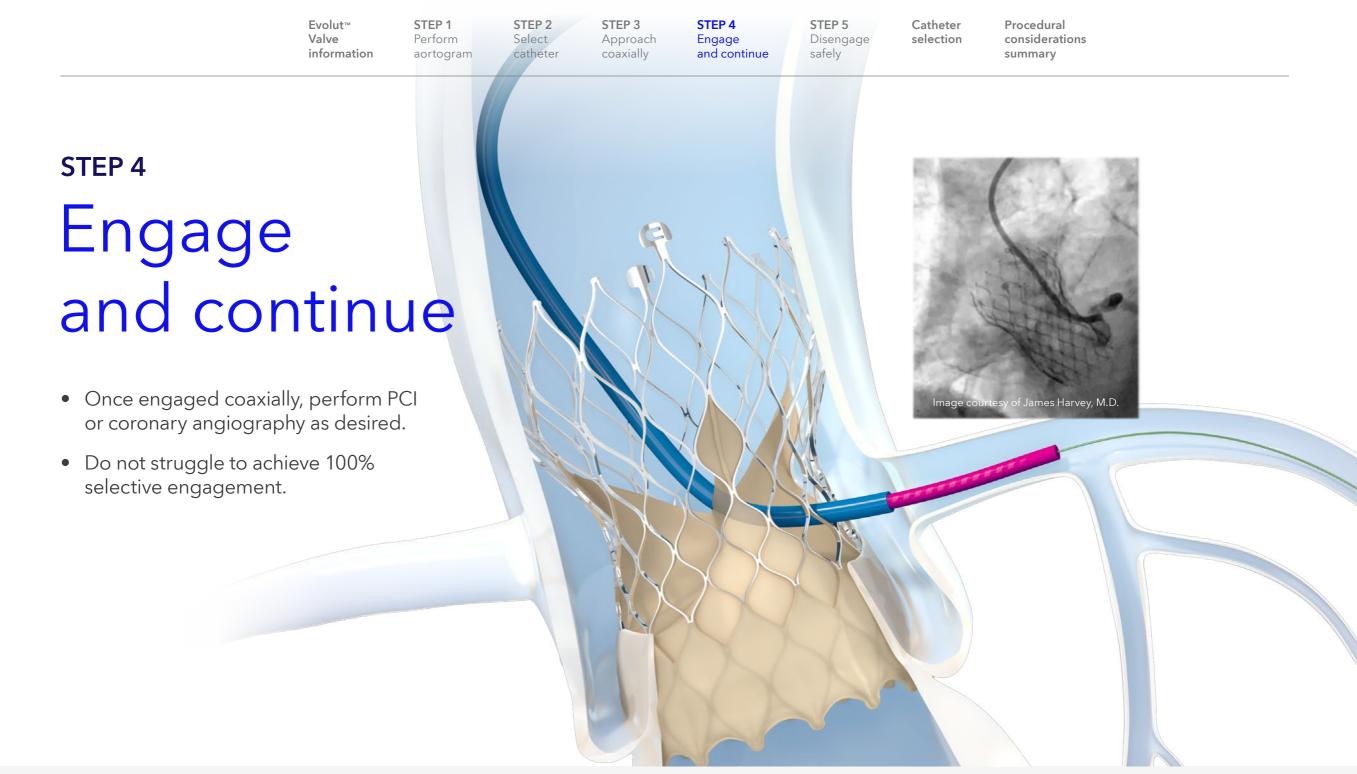


Images courtesy of James Harvey, M.D.





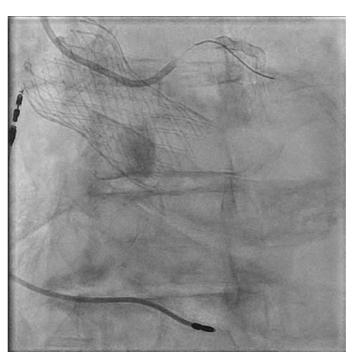
- Do not attempt to engage the ostium from below. Approach coaxially from the adjacent frame cell in order to avoid entanglement with the Evolut frame.
- Move one cell laterally or up if a commissure is obstructing a coaxial approach.

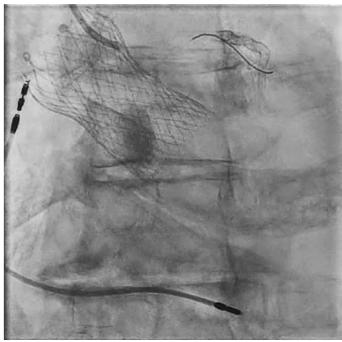


- If close to selective engagement, consider:
 - Nonselective angiography,
 - (For PCI) free-wire coronary with workhorse wire of choice, and bridge the gap with guide extension device.
- If unable to approach the ostium at all with current catheter, consider switching catheter as indicated by sinus shape, size, or presence of commissure interference (see catheter selection).

Disengage safely

- After PCI, remove the guide catheter over the guidewire to avoid becoming entangled with the Evolut frame.¹
 - Do not remove the 0.014" guidewire until the catheter is clear of the Evolut frame.
- For diagnostic only, remove the catheter over the J-wire.





Images courtesy of Harold Dauerman, M.D.

Considerations

If resistance from the Evolut frame is encountered when removing catheter:

- Utilize the stent or post-dilatation balloon to assist in disengaging the guide.
- Insert the J-wire through the guide catheter alongside the PCI guidewire for extra support. (Do not insert the J-wire into the coronary artery.)

Evolut™ Valve information **STEP 1**Perform aortogram

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STEP 3
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STEP 4
Engage
and continue

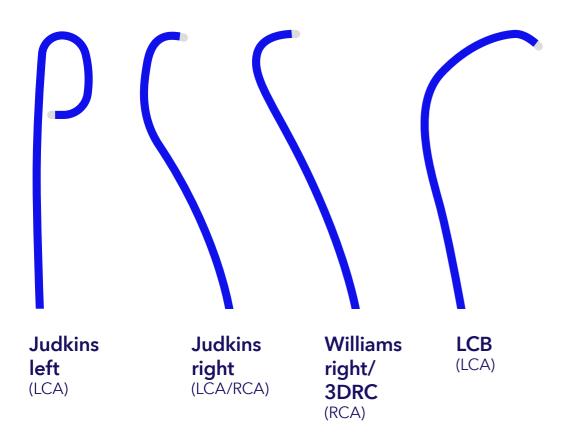
STEP 5Disengage safely

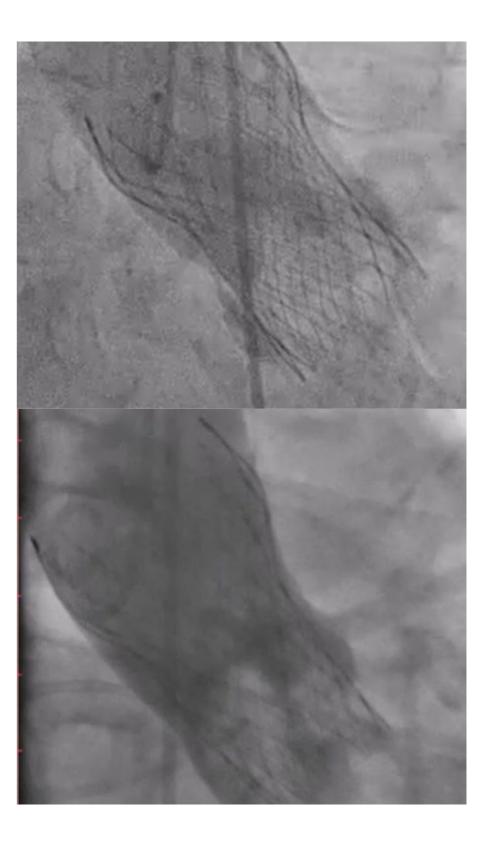
Catheter selection

Procedural considerations summary

Post-TAVI coronary access considerations

Catheter considerations for small, effaced root





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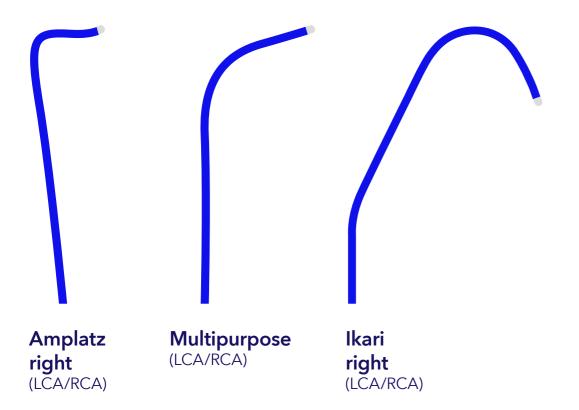
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Catheter considerations for capacious root





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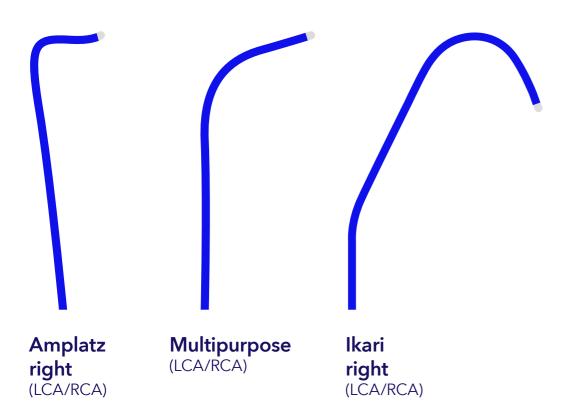
STEP 5
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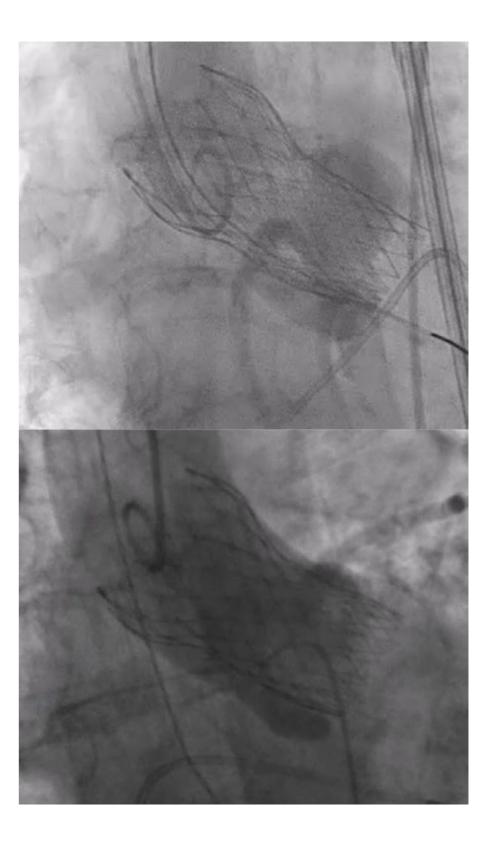
Catheter selection

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Post-TAVI coronary access considerations

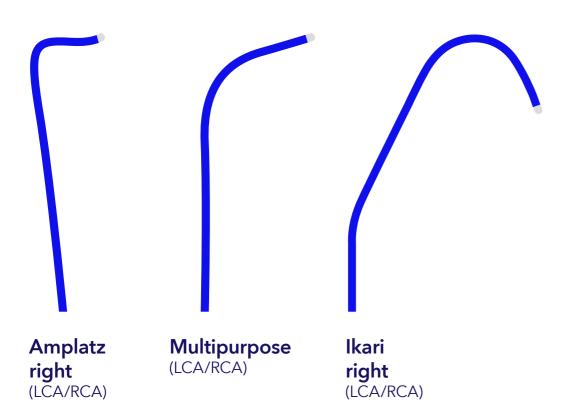
Catheter considerations for angulated root





Post-TAVI coronary access considerations

Catheter considerations to maneuver around commissures





Step 3

Procedural considerations

Summary

Step 1 Perform aortogram

Insert pigtail within Evolut frame, choose an orthogonal view of desired coronary, and perform an aortogram.



Approach coron

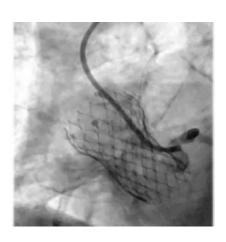
Approach coronary coaxially, remain perpendicular to frame. Do not approach from below. Use J-wire for aid.

Approach coaxially



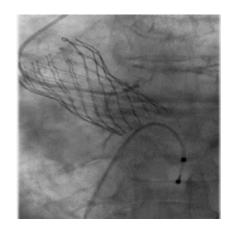
Step 4 Engage and continue

Perform nonselective angio/use guidewire and guide extension devices to reach ostium and perform diagnostic/PCI.



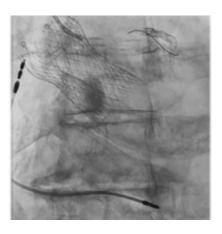
Step 2 Select catheter

Exchange to catheter shape based on root size/shape and location of commissure; downsize by 0.5 cm.



Step 5 Disengage safely

Always disengage catheter/guide over a guidewire.



Evolut™ STEP 1 STEP 2 STEP 3 STEP 4 STEP 5 Catheter Procedural Valve Perform Select considerations Approach Engage Disengage selection information catheter coaxially safely aortogram and continue summary

General Indication statements:

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. Consult instructions for use on this website http://manuals.medtronic.com/manuals/main/region. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

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