

SHEATHLESS INTERVENTION FOLLOWING ANGIOGRAPHY WITH A SHEATH PROCEDURE GUIDE

For procedures that start with a coronary angiogram, remove the sheath and use the RAILWAY System to advance the guide catheter and perform a sheathless intervention.

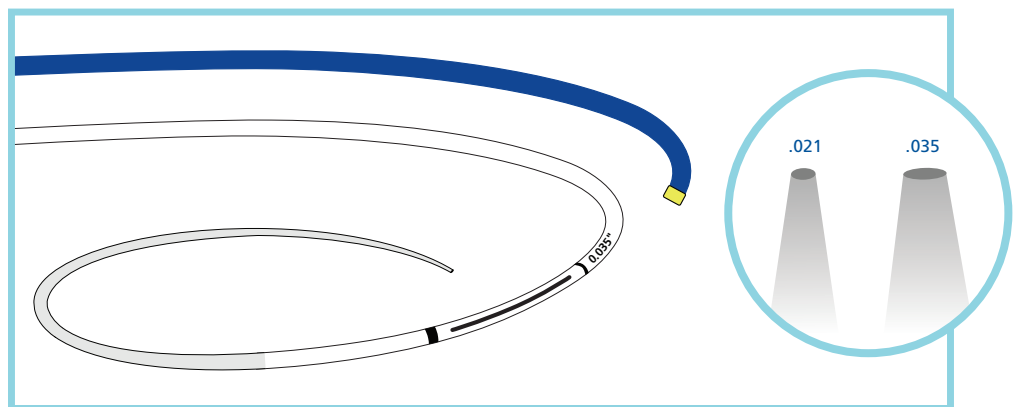
This procedure guide assumes an introducer sheath is in place over an exchange-length (260 cm) .035" wire.

STEP 1

Select the .035" RAILWAY dilator.

Flush the .035" dilator and the selected guide catheter.

Hydrate the hydrophilic coating on the tapered end of the dilator.

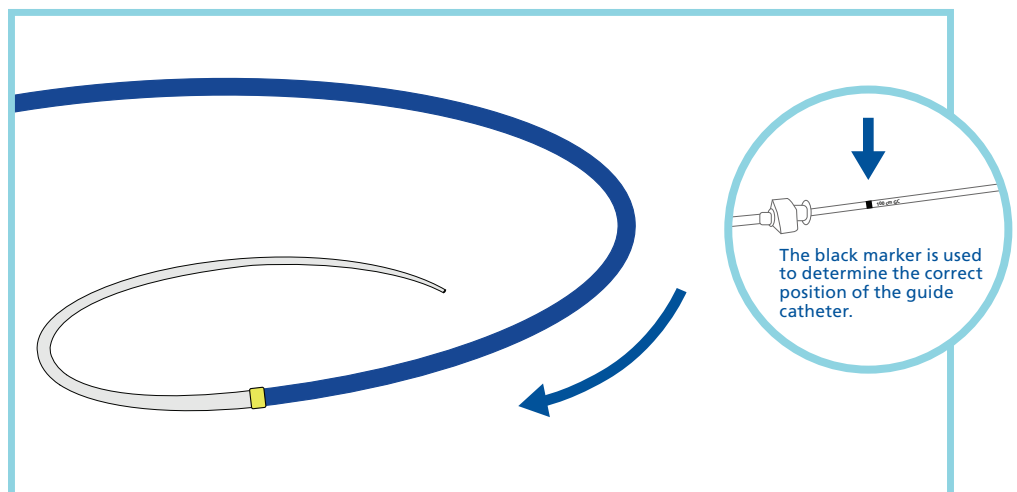


STEP 2

Load the guide catheter onto the proximal end of the .035" dilator. Use the black marker to position the catheter.

The wire port is not used in this procedure because there is no wire exchange through the port.

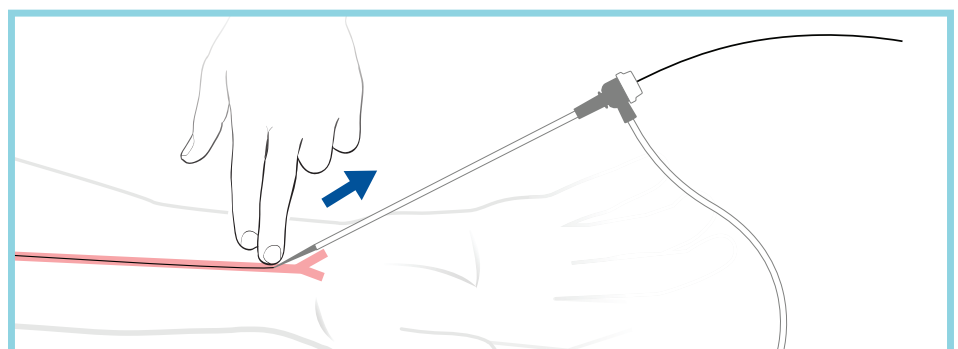
NOTE: The black markers are used to determine the position where the transition from the guide tip to the dilator is optimal. When using a 90 cm catheter, use the 90 cm marker. When using a 100 cm catheter, use the 100 cm marker.



STEP 3

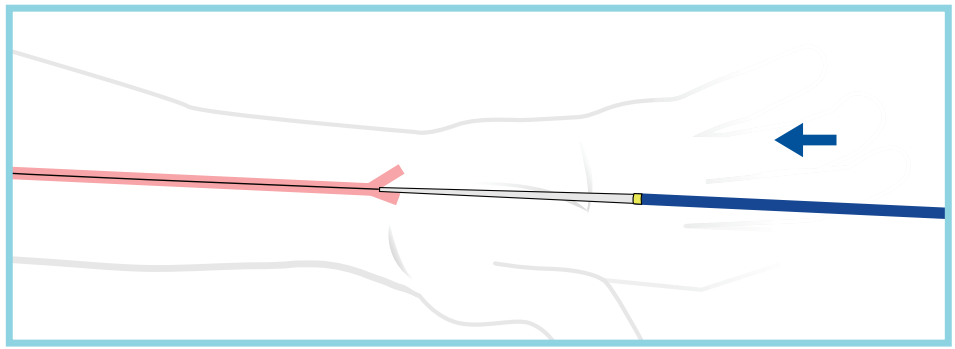
Remove the introducer sheath over the exchange-length .035" wire.

Apply pressure as sheath is removed per standard interventional techniques.



STEP 4

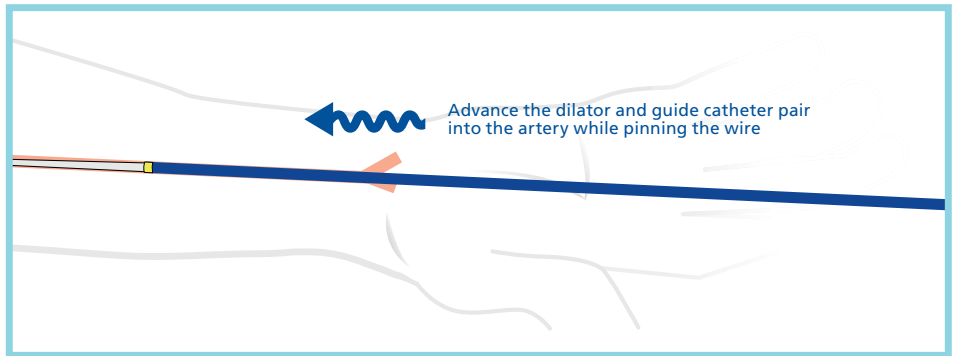
Advance the .035" dilator and guide catheter pair over the guidewire and up to the wrist and feed the wire into the dilator until it exits the proximal end of the dilator. Straighten out the system so that the wire doesn't snag on the wire port. If the wire snags, straighten out the system and try again. The catheter may be pulled back to view the port.



STEP 5

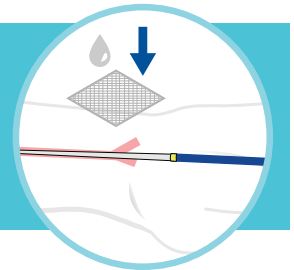
Pin the proximal end of the wire and advance the dilator and guide catheter pair into the artery. Both the dilator and catheter should be straight and taut during this maneuver, which may require a second set of hands.

Rotate the guide catheter while advancing it into the artery per standard interventional techniques.



TIP

The dilator and guide catheter can be continuously hydrated to facilitate insertion. Use a piece of gauze soaked with heparinized saline to hydrate the dilator and guide catheter tip to reactivate the hydrophilic coating.

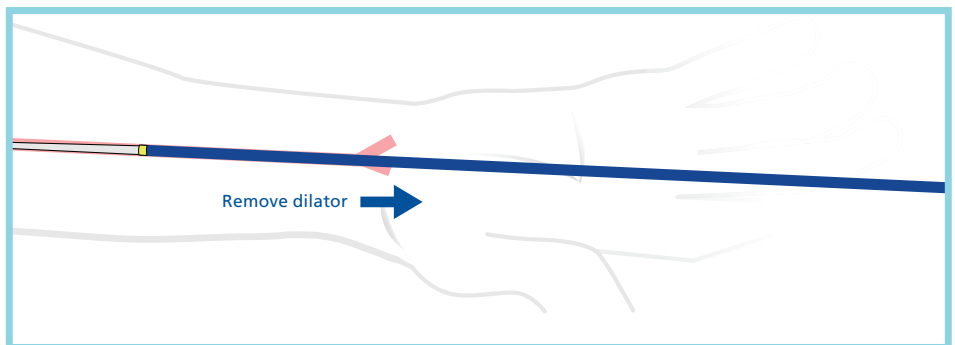


OPTIONAL STEP

Use the dilator and guide catheter pair to assist with tracking up to the subclavian artery.

STEP 6

Remove the dilator and guidewire from the guide catheter, then insert the wire of choice to perform the sheathless intervention.



The RAILWAY™ Sheathless Access System is indicated for use in radial arterial procedures requiring percutaneous introduction of intravascular devices.

Contraindications

Avoid the use of the RAILWAY Sheathless Access System in vasculature with extreme tortuosity, calcified plaque or thrombus.

Radial access is contraindicated in patients with:

- Inadequate circulation to the extremity as evidenced by signs of artery occlusion or absence of radial pulse.
- Hemodialysis shunt, graft or arterio-venous fistula involving the upper extremity vasculature.

Warnings

- Prior to radial access procedures, it is recommended to verify adequate collateral flow through the ulnar artery, such as with an Allen test. If collateral blood supply to the hand is considered inadequate, an alternate access site should be considered.
- Do not use Ethiodol™ or Lipiodol™ contrast media, or other such contrast media which incorporates components of these agents, as solvents used in these media may have a deleterious effect on the device.
- For the Introcath Safety® IV Catheter needle, do not reinsert the needle into the IV catheter at any time. The needle could damage the IV catheter, resulting in an IV catheter embolus.
- If using a hydrophilic wire, do not use with a bare needle or metal torque device, as this may damage the integrity of the coating.
- Use of alcohol, antiseptic solutions, or other solvents should be avoided, as they may adversely affect the device.
- Manipulate the mini-guidewire slowly and carefully to avoid damage to the vessel wall, while monitoring tip position and movement under fluoroscopy.
- Failure to follow the procedural steps when exchanging a guiding catheter may result in loss of vessel access.
- Do not manually re-shape the distal tip of the dilator or the mini-guidewire by applying external force intended to bend or affect the shape of the dilator or mini-guidewire.
- The dilator must only be advanced while over a guidewire. Advancing the dilator without a wire in place may cause vascular complications.
- Persons with allergic reactions to nickel may suffer an allergic response to components of this device.

Important information: Prior to use, refer to the instruction for use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions.

CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician

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