RAILWAY™
SHEATHLESS ACCESS SYSTEM

TRACKING THE GUIDE CATHETER WITH THE RAILWAY SYSTEM AND A SHEATH IN PLACE
PROCEDURE GUIDE

To track through radial anatomy, the guide catheter can be paired with the RAILWAY dilator to facilitate tracking up to the subclavian artery.

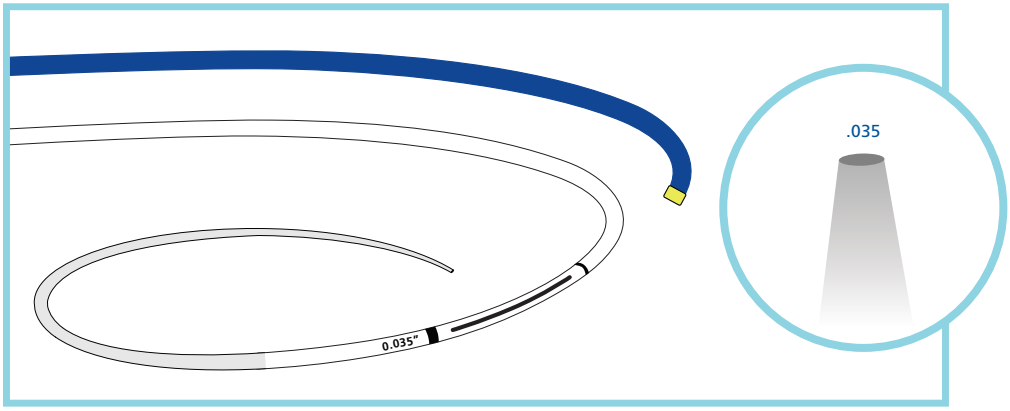
This procedure guide assumes an introducer sheath is in place over an exchange-length (260 cm) .035" wire.

STEP 1

Select the .035" RAILWAY System dilator.

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

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

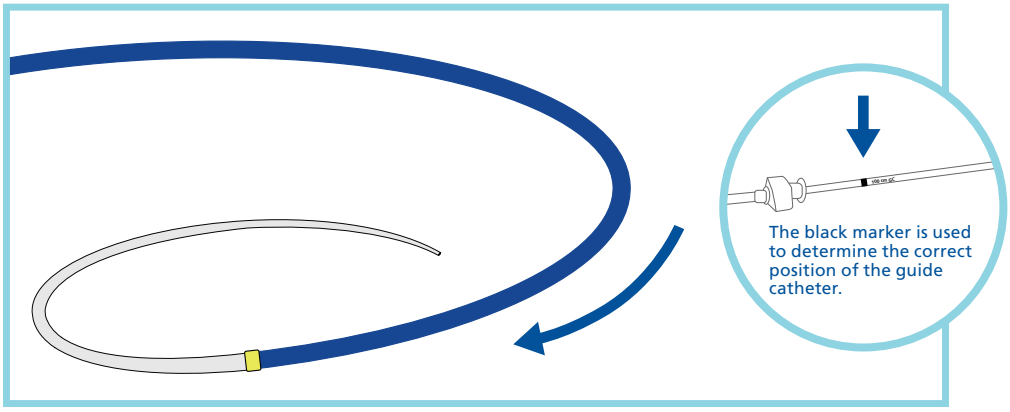


STEP 2

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

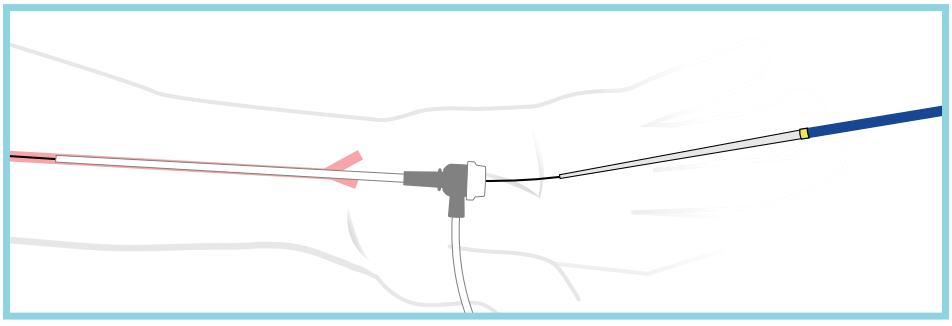
The wire port is not used in this procedure because there is no wire exchange through the port.

NOTE: The black markers are used to determine the correct position of the catheter. When using a 90 cm catheter, use the 90 cm marker. When using a 100 cm catheter, use the 100 cm marker.



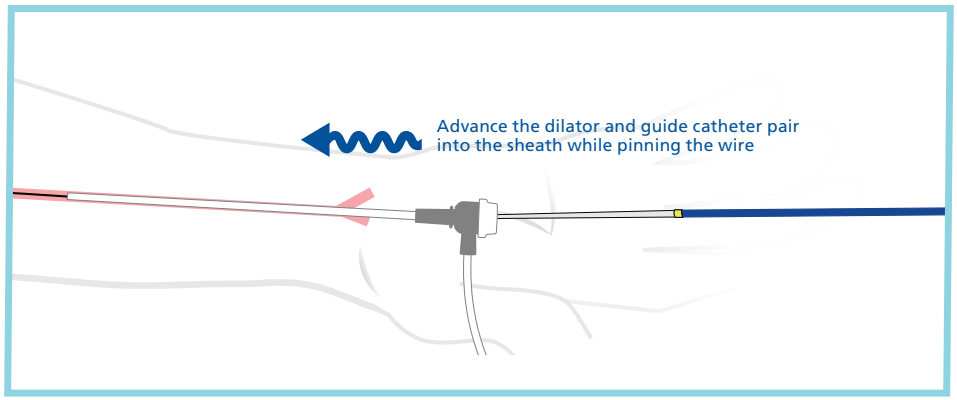
STEP 3

Advance the .035" dilator and guide catheter pair over the guidewire until the wire 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 guide catheter may be pulled back to view the port.



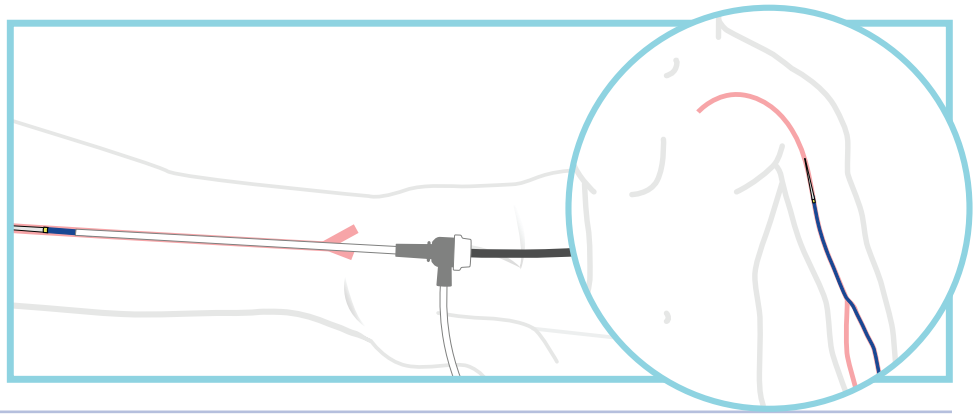
STEP 4

Maintaining the correct position of the catheter on the dilator as indicated by the marker band, pin the proximal end of the wire and advance the dilator and guide catheter pair into the sheath.



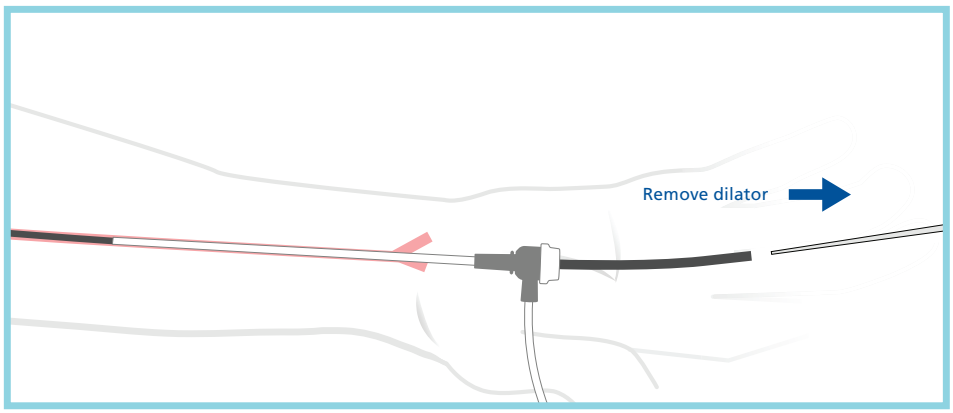
STEP 5

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



STEP 6

When tracking is complete, remove the dilator and guidewire from the guide catheter, then insert the wire of choice to continue with the procedure.



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 Introcan 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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