

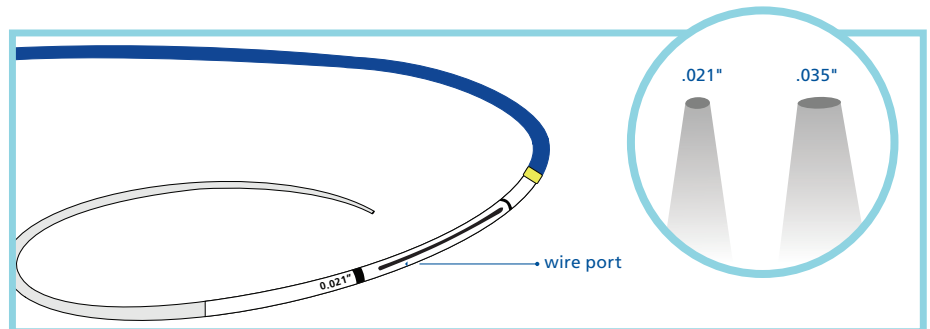
PURELY SHEATHLESS ACCESS FOR PLANNED INTERVENTIONS

PROCEDURE GUIDE

When a diagnostic catheter isn't necessary for your planned procedure, use the RAILWAY System for a completely sheathless intervention – from access to closure.

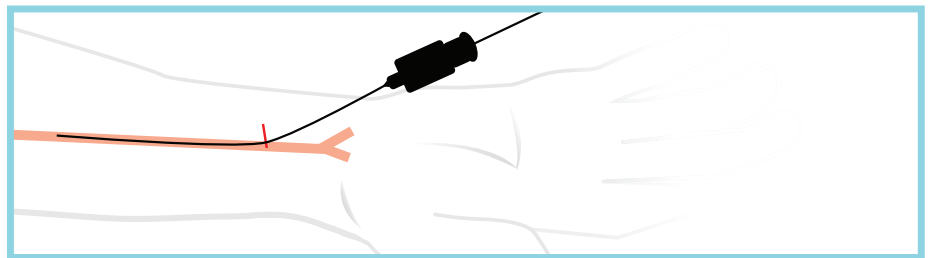
STEP 1

- Select the .021" RAILWAY System dilator.
- Flush the .021" dilator and the selected guide catheter.
- Hydrate the hydrophilic coating on the tapered end of the dilator.
- Load the guide catheter onto the proximal end of the .021" dilator up to the wire port.



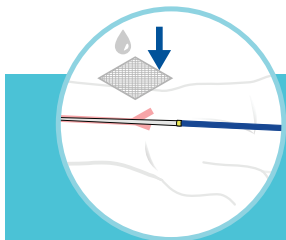
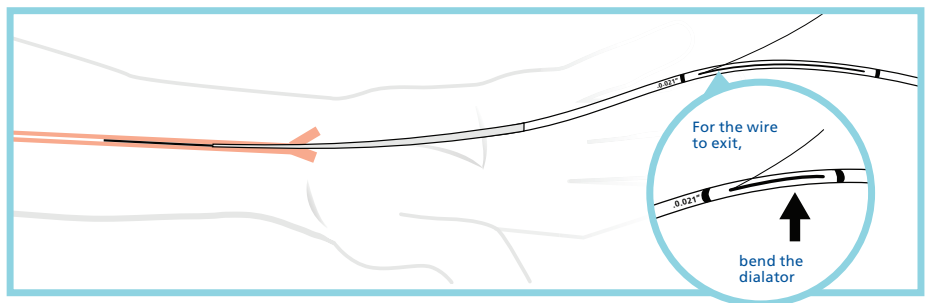
STEP 2

- Initiate the needle puncture and achieve access with the .021" mini guidewire.



STEP 3

- Advance the .021" dilator and guide catheter pair into the vessel over the mini guidewire, bending the wire port of the dilator slightly to allow the wire to exit the port as the system is advanced.

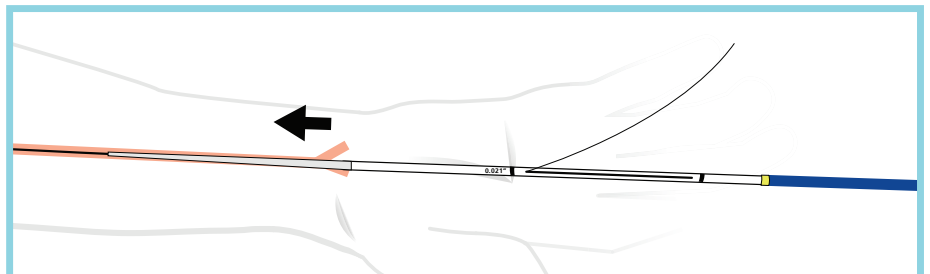


TIP

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.

STEP 4

- Continue advancing the dilator into the vessel until the wire port reaches the access site.

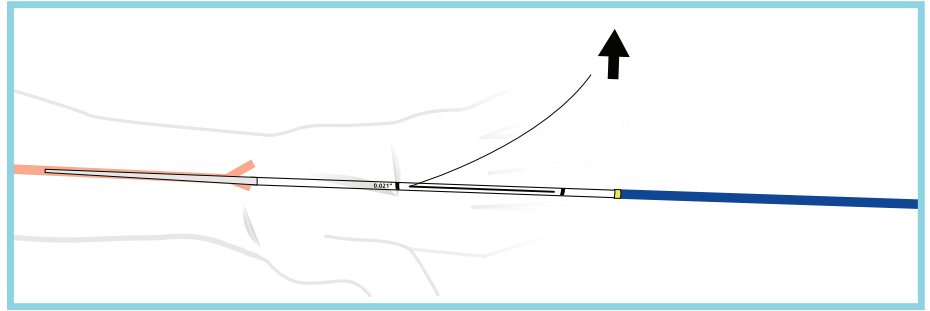


TIP

If needed, use a surgical scalpel to make a superficial skin nick at the skin puncture site.

STEP 5

Remove the mini guidewire from the artery through the wire port.

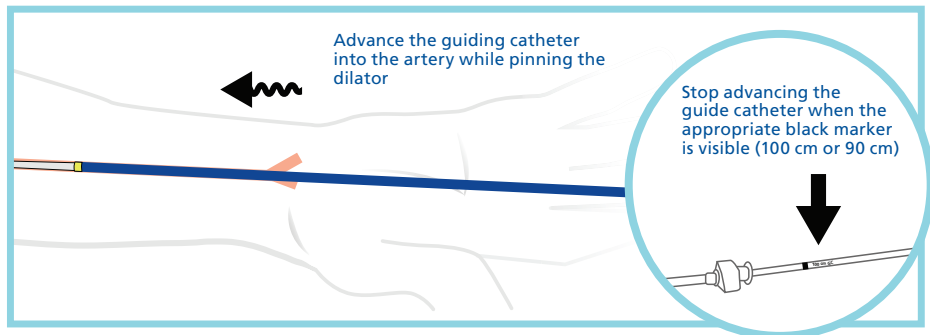


STEP 6

Advance the guide catheter into the artery while pinning the proximal end of the dilator to keep it fixed. Both the dilator and catheter should be straight and taut during this maneuver, which may require a second set of hands.

It is important to maintain the fixed position of the dilator as forward motion of the dilator may cause vascular complications.

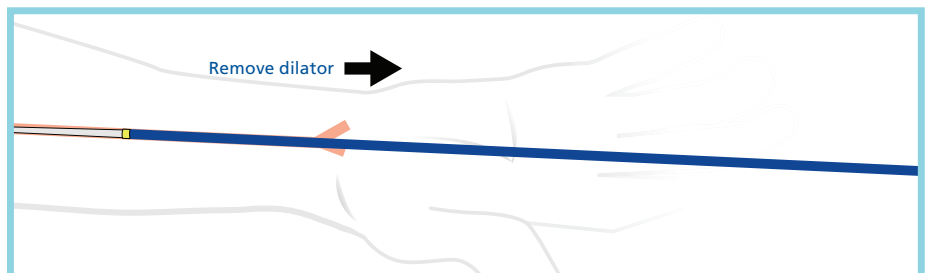
Rotate the catheter while advancing it into the artery per standard interventional techniques. Stop advancing the catheter when the appropriate black marker is visible on the proximal end of the dilator.



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 7

Access is achieved and you may now remove the RAILWAY™ dilator to perform a sheathless intervention.



OPTIONAL STEP

The RAILWAY System may be used to support tracking of the guiding catheter to the subclavian artery.

First, insert a .035" guidewire into the .035" dilator of the RAILWAY System. Advance the guidewire-dilator pair together into the guiding catheter already in position in the radial artery. Advance until the appropriate black marker is visible near the hub of the guiding catheter.

Then, advance the dilator-guiding catheter pair over the guidewire no further than the subclavian artery. Then, remove the dilator and wire, reinsert the wire in the guiding catheter, and proceed to the target site.

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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