

**PHILIPS**

**VOLCANO**

*Pioneer Plus*

IVUS-guided  
re-entry catheter



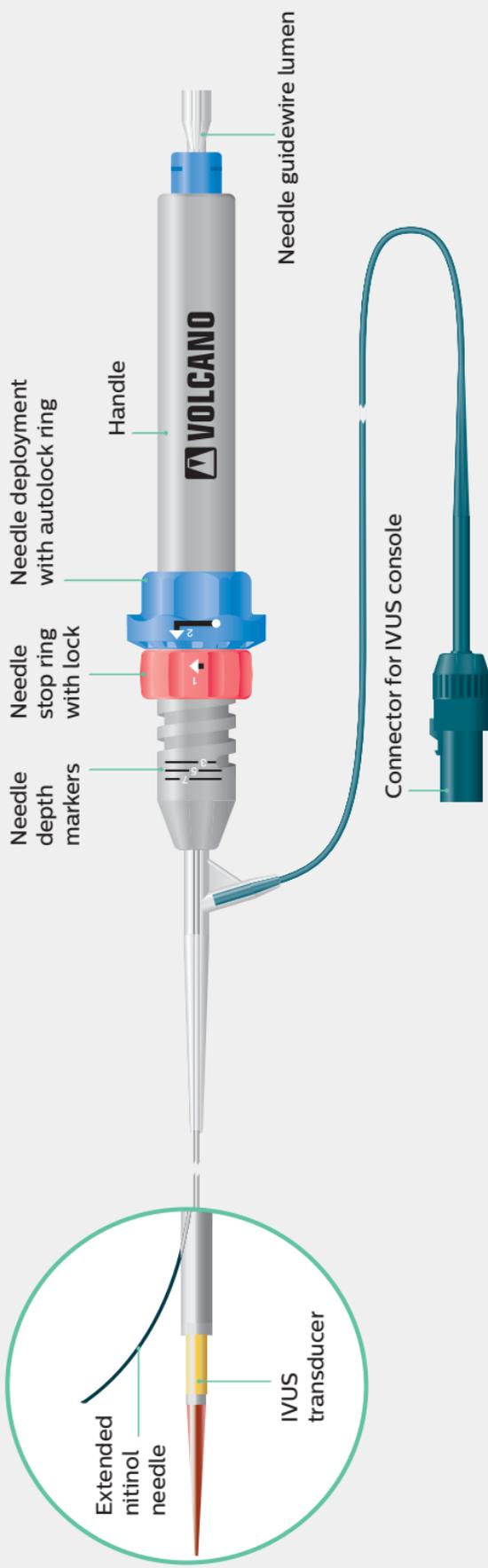
## Quick reference

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# System setup

## System setup



Confirm all necessary devices and equipment are in the lab before starting the procedure:

- 1 Pioneer Plus catheter.
- 2 Philips Volcano IVUS console and Patient Interface Module (PIM).
- 3 Sterile cover/bag for IVUS PIM.
- 4 10-cc syringe and RHV or Tuohy-Borst.
- 5 0.014" nonhydrophilic guidewires with long-coil transition (300 cm and 190 cm ipsilateral/two 300 cm contralateral).

Plug in and turn on Philips Volcano IVUS unit at start of procedure—system initialization takes ~2 min.

- IVUS settings:
  - **Gain:** 52–58
  - **Diameter:**
    - SFA: 10–12
    - ILIAC: 14–16
  - **ChromaFlo:** 3–5

Confirm vascular sheath size is appropriate for Pioneer Plus catheter use (6F or larger).

# Prepping the Pioneer Plus catheter

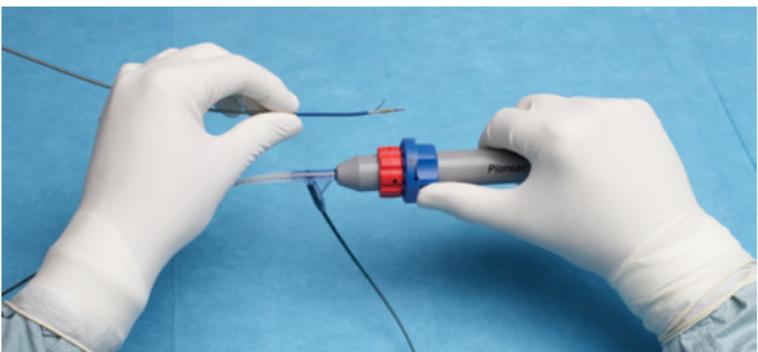
Prepping the  
Pioneer Plus catheter

# Prepping the Pioneer Plus catheter

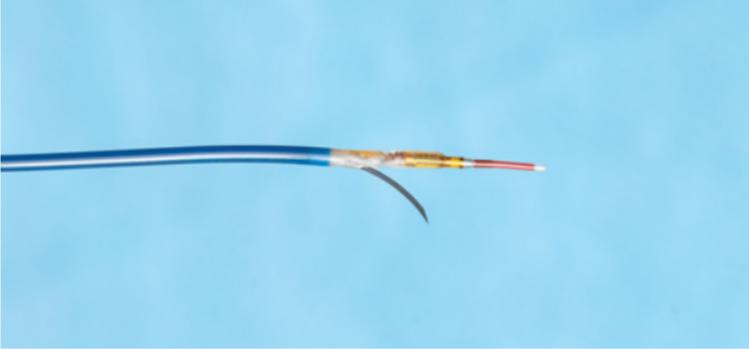
- 1 Remove the Pioneer Plus catheter from the box.



- 2 Place plastic tray on sterile prep table. Carefully remove the Pioneer Plus catheter and all contents from the plastic tray.
- 3 Inspect catheter for any manufacturing defects or damage that may have resulted from shipping.
- 4 Attach the white “winged” rapid exchange flush adapter to a 10-cc syringe.
- 5 Place the sterile plastic bag over the IVUS connector.
- 6 Attach a Tuohy-Borst adapter or rotating hemostasis valve to the proximal luer on the handle.
- 7 Set the needle stop to “7” and deploy the needle to confirm needle movement.



Verify needle movement in and out of catheter shaft.



- 8 Flush both lumens with heparinized saline as illustrated below:
- a. The rapid exchange lumen requires the use of the white “winged” adapter. Gently insert tip of catheter into adapter until a snug fit is achieved and flush. Repeat before use, if necessary.



**a. Flushing rapid exchange lumen**

- b. Needle lumen is flushed through the proximal handle luer with a 10-cc syringe. Use a stopcock or luer cap after flushing



**b. Flushing needle lumen**

- 9 Insert PIM into the sterile bag. Connect Pioneer Plus catheter to the PIM and verify system recognizes catheter.

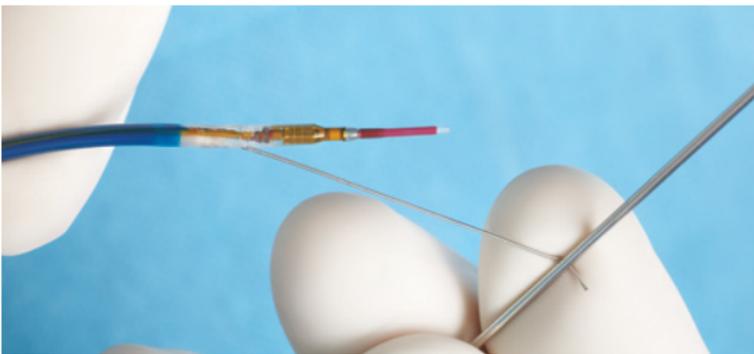


The Pioneer Plus catheter works with the Philips Volcano s5 Series or CORE series of Philips Volcano systems. If an IVUS image is not obtained or is unsatisfactory, consult the Philips Volcano s5 Series or CORE Series of Systems Operator's Manual supplied by Philips Volcano.

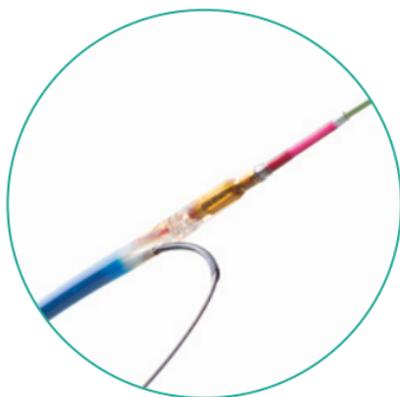
- 10 Insert 300 cm guidewire\* into needle lumen; place a 90° angle on wire tip. **Retract needle first**, then retract wire and reflush needle lumen.

Carefully tighten the rotating hemostasis valve around the needle guidewire and close off the side port with a closed end cap of stopcock.

**Warning:** ensure that the needle, Stop Ring and Deployment Ring are fully retracted prior to and during the introduction of the catheter into the peripheral vascular system.



\*Needle wire must be nonhydrophilic with long-coil transition.

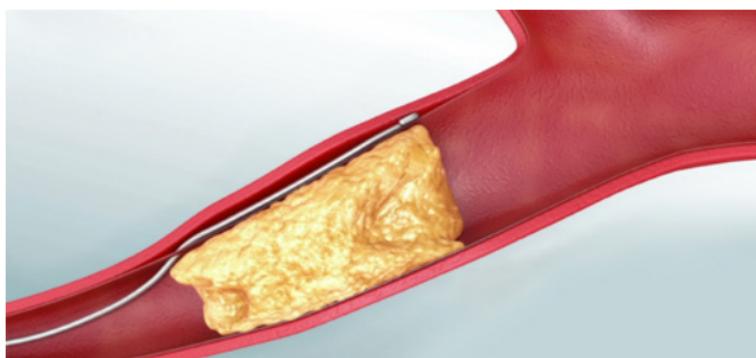




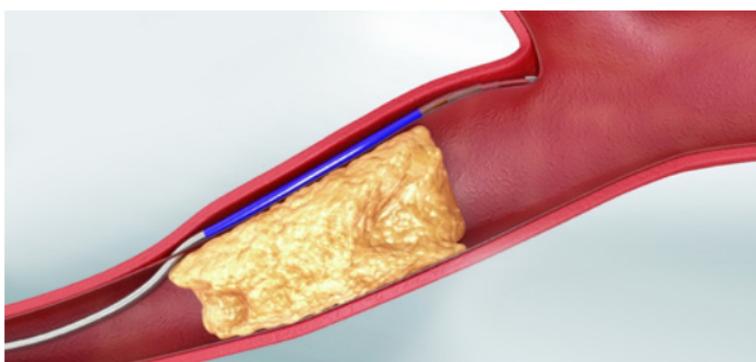
# Step-by-step procedure

## Step-by-step procedure

### Introducing and advancing the Pioneer Plus catheter to the lesion



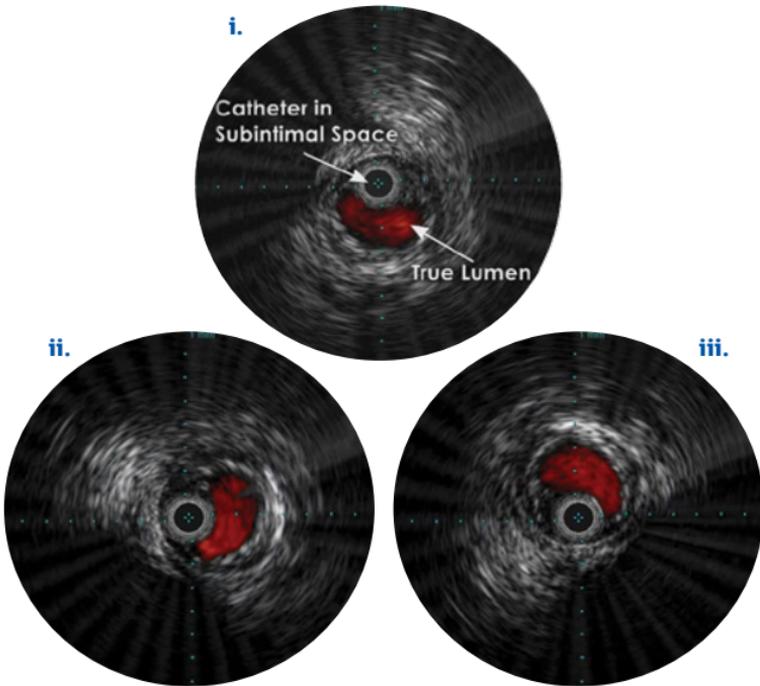
- 1 Introduce the Pioneer Plus catheter into the peripheral vascular system using clinically accepted percutaneous techniques. Guide the catheter over the previously placed support 0.014" (0.36mm) tracking guidewire already in the vessel by "back-loading" the tracking guidewire into the guidewire lumen in the distal tip.



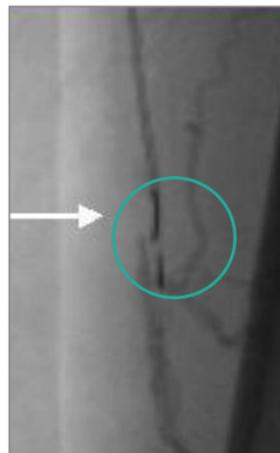
- 2 Introduce Pioneer Plus catheter into vascular sheath and advance to the lesion. If tracking over the aortic bifurcation, make sure the curvature of the needle housing is in line with the curvature of the sheath.
  - Slight rotation of the Pioneer Plus catheter or balloon dilatation may be required to advance the Pioneer Plus catheter.

- 3 Use IVUS to precisely target re-entry into the true lumen
- Once past the lesion, turn on the ChromaFlo feature and rotate the Pioneer Plus catheter so the true lumen is at the 12 o'clock position.

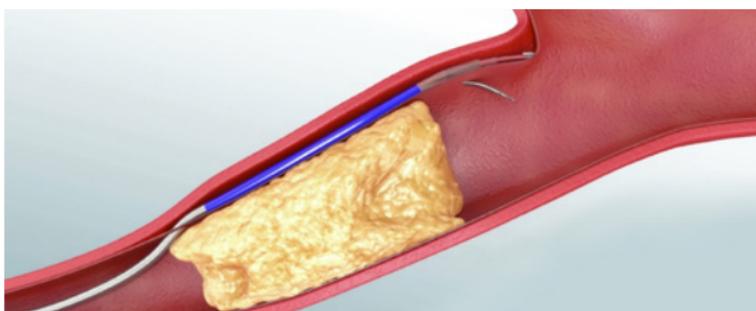
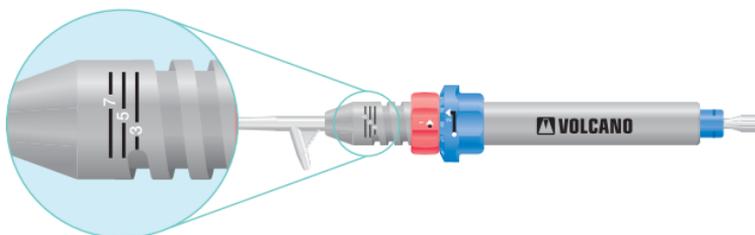
**Tip:** to ensure continuity of imaging, support the PIM connector extension with the hand that is rotating the Pioneer Plus catheter.



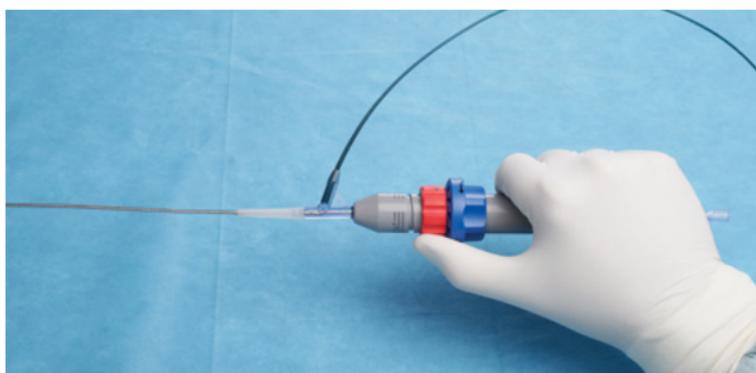
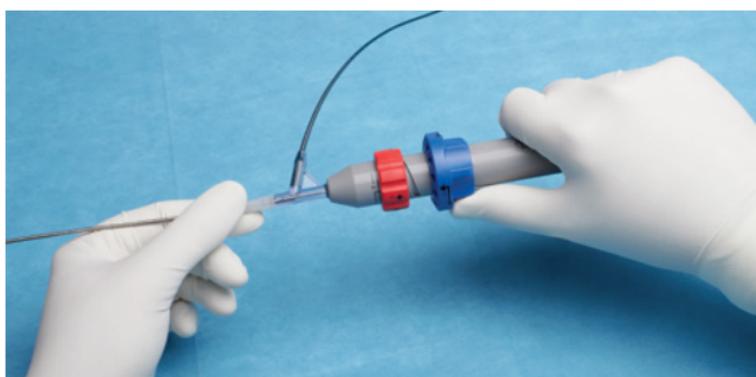
- Confirm catheter position is correct using fluoroscopy to identify curvature of needle housing.

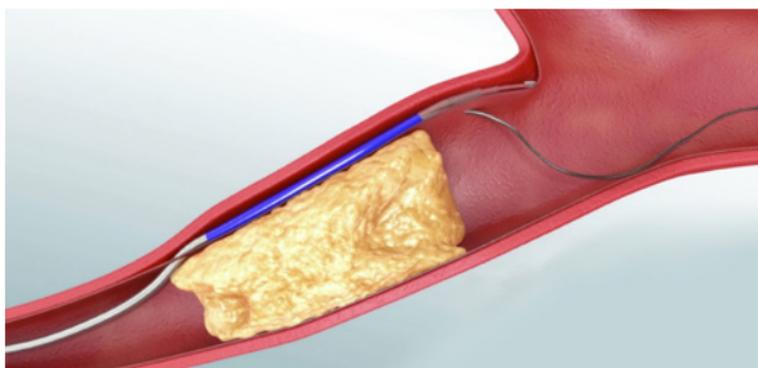


- 4 After confirming catheter orientation, set the needle stop (“3” for popliteal, “5” for SFA, “7” for iliac).



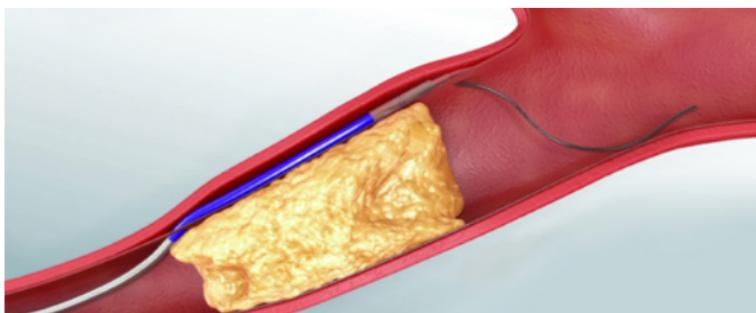
- 5 Thumb-activated safety lock: Rotate needle deployment ring clockwise and deploy needle.





- 6 Under fluoro, slowly advance needle guidewire out of needle—if you feel no resistance to wire movement, continue advancing wire into target vessel lumen. However, if resistance is felt, stop wire movement. Retract needle slightly and advance wire.
  - If unsuccessful, **retract the needle**, then needle guidewire and repeat the steps in this section. The catheter may require slight advancement before additional attempts to deploy needle.  
(**Note:** the needle must be retracted before retracting the needle guidewire.)

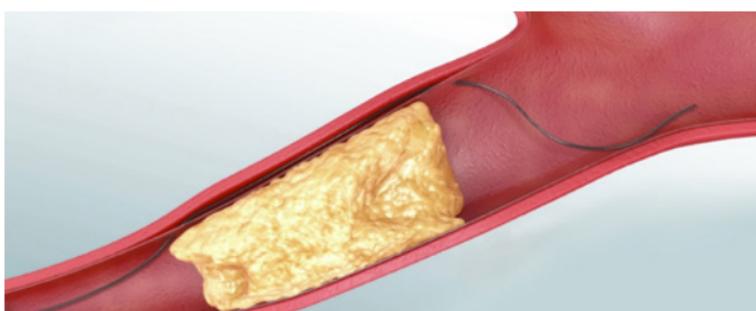
## Exchanging Pioneer Plus catheter



- 7 Following successful true lumen access, retract the needle. Remove the subintimal tracking wire.



- 8 Disconnect the Pioneer Plus catheter from the PIM.



- 9 Back the Pioneer Plus catheter off of needle wire using short, smooth strokes. This will leave the 0.014" needle guidewire in the true lumen.

# Trouble- shooting guide

Catheter tracking  
challenges

## Catheter tracking challenges

- 1 Shortly after introducing the Pioneer Plus catheter into the femoral sheath, you feel significant resistance. What are the most likely causes?
  - The wrong sheath size may be in place—the system requires a 6F (2.2 mm) sheath. Although the catheter tip may pass through a smaller sheath size, at the point where the tracking wire exits the Pioneer Plus catheter, the combined volume of the catheter shaft and guidewire will fit only through a 6F or larger sheath.
  - The catheter orientation may be such that resistance to tracking is maximized. The needle housing has a fixed curvature; significant resistance may occur if the curvature of the needle housing is opposite that of the vascular sheath.
  - The tracking guidewire may need to be wiped clean or the tracking lumen may need to be flushed. Any buildup of blood or other foreign matter on the tracking guidewire can induce resistance to movement.
  - The tracking guidewire or sheath may be kinked and should be replaced.

- 2 After the Pioneer Plus catheter has been advanced past the distal end of the sheath, significant resistance is felt while tracking through tissue, and the Pioneer Plus catheter has reached a point where further forward movement seems impossible. What are the possible causes?
- The tracking wire may be kinked.
  - The Pioneer Plus catheter handle may be caught on a rigid section of the table.
  - The tissue morphology may be such that there is resistance to the catheter, inhibiting forward movement. This is especially true in highly calcified occlusions. If tissue resistance is believed to be the cause, a small-diameter balloon may be used to dilate the tissue. Remember, this is a technique commonly utilized in subintimal angioplasty, and if the Pioneer Plus catheter is advanced through significant resistance without adequate predilatation, the IVUS component may be terminally damaged and/or the needle may kink.



# Trouble- shooting guide

Guidewire challenges

# Guidewire challenges

- 1 While loading the needle guidewire into the needle lumen, significant resistance is met. What are the most likely causes?

  - The needle guidewire tip may be caught on a joint within the lumen. Try spinning gently or loading a straight-tip guidewire (unshaped) to advance past the joint. Use of a guidewire introducer is recommended.
  - The needle guidewire size may be too large for the lumen. The needle lumen is compatible only with a 0.014" guidewire.
  - The needle lumen may be blocked with a clot or other foreign debris. While still *ex vivo*, reflush the lumen with a 10-cc syringe or smaller to clear any blockages.
  - The needle guidewire may need to be wiped clean. Any buildup of blood or other foreign matter on the needle guidewire can induce resistance to movement.
  - The needle guidewire may be kinked and needs to be replaced.
- 2 Following needle deployment, the needle guidewire will not pass into the target vessel. What are the potential causes?

  - The needle tip could be against the far wall of the vessel. Retract the needle slightly while attempting to gently push the wire forward until the wire freely moves into the vessel or the needle is completely retracted.

- Angiographic interpretation utilizing orthogonal views with the wire advanced to the point of resistance (for visualization purposes) may demonstrate if the needle is short of the target. In the latter case, the needle should be advanced farther.
- The wrong target may have been elected. Verify location of the needle/guidewire with IVUS and multiple fluoro views.
- Although the IVUS shows a patent vessel, the needle exits the catheter approximately 7 mm behind the IVUS transducer, so the needle may be just proximal to the patent target vessel.
- The target must be parallel to the Pioneer Plus catheter for the IVUS imaging plane to match the needle exit 7 mm proximal. In some instances, the catheter is positioned in a spiral dissection, so the imaging is in a different plane than the target. Advance the catheter so that the target and catheter are parallel throughout the IVUS transducer/needle exit separation. If necessary, remove the catheter completely and create a more ideal dissection plane with the Glidewire/Glidecatheter.
- Severe calcification, generally visible under fluoro and/or IVUS, may inhibit intimal needle penetration and subsequent guidewire advancement. If this appears to be the case, advance or retract the Pioneer Plus catheter to a different location along the patent true lumen in an attempt to find a less calcific “window.”

- 3 Exchanging the Pioneer Plus catheter seems to be difficult. What are the likely causes?
- The long needle lumen and the tight tolerances between the needle lumen and the needle guidewire make the exchange difficult.
  - If the catheter is still connected to the PIM, exchanging the catheter can be difficult. Therefore, make sure the IVUS connector is disconnected from the PIM before exchanging the catheter. Make sure that the Pioneer Plus connector is replaced in the sterile bag provided.
  - The presence of the tracking wire can make the exchange confusing. Some physicians use tape to identify the different guidewires. Once the position of the secondary guidewire (needle guidewire) is confirmed to be in the true lumen, the tracking wire can be removed.
  - If the Pioneer Plus catheter binds on the needle guidewire, stop and advance the needle wire as far as possible, then pull the Pioneer Plus catheter with the needle guidewire back slightly, and try to exchange again. If the problem persists stop immediately to prevent further binding of the needle guidewire. If the issue is not resolved, the needle wire may be kinked. Remove the system (Pioneer Plus catheter together with needle wire) for inspection. Remove the needle guidewire, and re-prepare the catheter with a new wire before repeating the true lumen return procedure.

## Indications

The Pioneer Plus catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Pioneer Plus catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total, or chronic total occlusions) prior to additional intervention (i.e., PTA, stent, etc.).

## Warning

The Pioneer Plus catheter is not indicated for use in the coronary or cerebral vasculature.

## Adverse events

Possible adverse events associated with use of the Pioneer Plus catheter include, but are not limited, to the following:

- Hemorrhage or hematoma
- Injury to the vessel wall (e.g., perforation, dissection)
- Infection
- Peripheral embolization
- Thrombosis of the vessel
- Vessel spasm

## Caution

Federal (USA) law restricts this device to sale by or on the order of a physician. For further information, please call Philips Volcano at 800-228-4728 or consult Philips Volcano's website at [www.volcanocorp.com](http://www.volcanocorp.com).



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