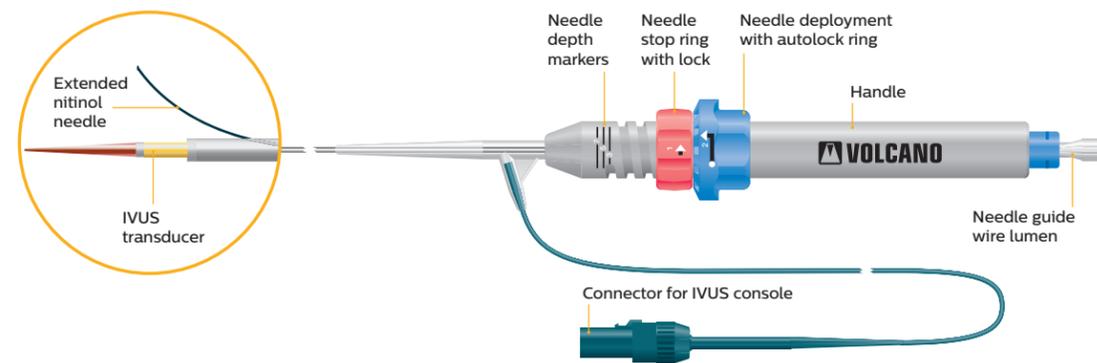


Product features



Indications for use

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

For further information, please call Philips at 800-228-4728 and/or consult Philips website at www.philips.com/IGTdevices.

Technical information

| | |
|----------------------|---------------------|
| Sheath compatibility | 6F (0.087", 2.2 mm) |
| Tracking guidewire | 0.014" |
| Needle guidewire | 0.014" |
| Catheter length | 120 cm |

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.

Ordering information

Product name

Pioneer Plus catheter PPLUS120

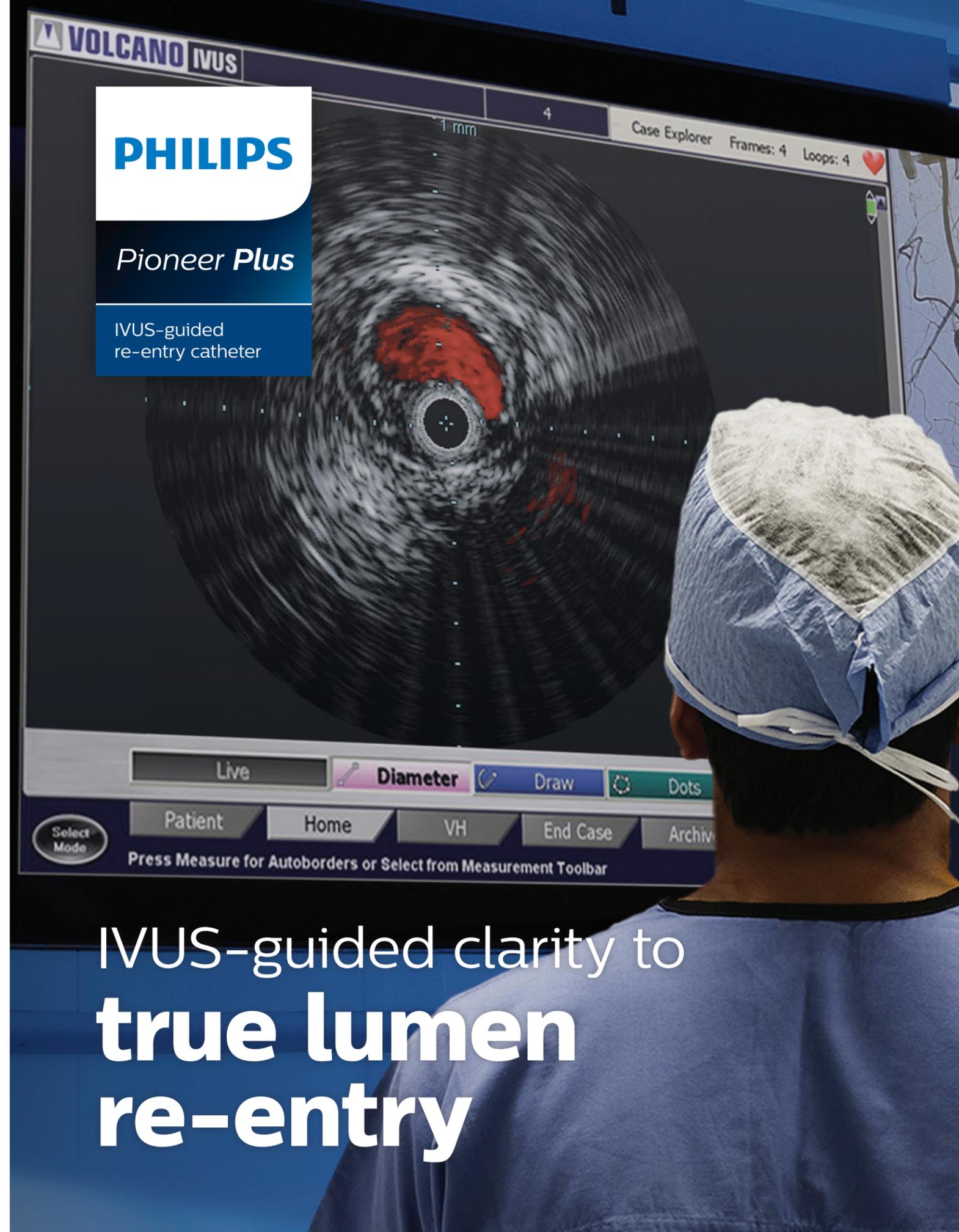


PPLUS120

1. Saket R., Razavi, M., Padidar A., et al. Novel Intravascular Ultrasound-Guided Methods to Create Transintimal Arterial Communications: Initial Experience in Peripheral Occlusive Disease and Aortic Dissection. *J Endovasc Ther.* 2004; 11: 274-280.
2. Al-Ameri, H et al. Peripheral Chronic Total Occlusions Treated with Subintimal Angioplasty and a True Lumen Re-Entry Device. *Journal of Invasive Cardiology.* 2009; 21(9): 468-472.
3. Saketkhoo RR, Razavi MK, Padidar A, Kee ST, Sze DY, Dake MD. Percutaneous bypass: subintimal recanalization of peripheral occlusive disease with IVUS guided lumen re-entry. *Tech Vasc Interv Radiol.* 2004; 7: 23-27.

* Saket et al., Novel Intravascular Ultrasound-Guided Method to Create Transintimal Arterial Communications, *J Endovascular Therapy*, 11:274-280, 2004. Krishnamurthy et al., Intravascular ultrasound-guided true lumen reentry device for recanalization of unilateral chronic total occlusion of iliac arteries: technique and follow-up. *Ann Vasc Surg.* 24:487-97, 2010.

† The Pioneer Plus catheter can only be used with Philips s5, s5i, or Core Imaging System. The catheter will not operate if connected to other imaging systems. Philips s5, s5i, and Core Intravascular Ultrasound Systems are manufactured by Philips.



IVUS-guided clarity to true lumen re-entry

The Pioneer Plus

IVUS-guided re-entry catheter

The **only** re-entry device with IVUS and ChromaFlo



Procedural time for effective re-entry ranging from **6-10 minutes¹**



Subintimal angioplasty procedural success rate from **95 to 100%²**

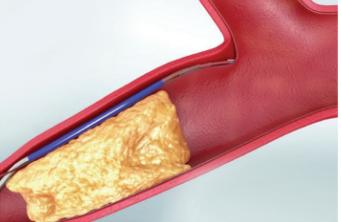


IVUS guidance and direction **minimizes** potential procedural complications³



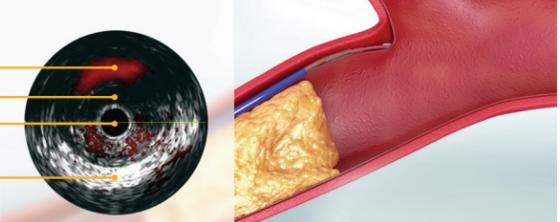
IVUS-guided true lumen return

1



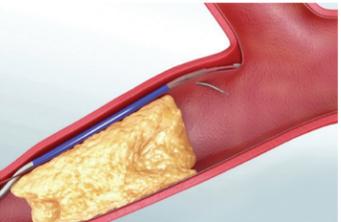
Insert the Pioneer Plus catheter over the 0.014" subintimal guidewire.

2



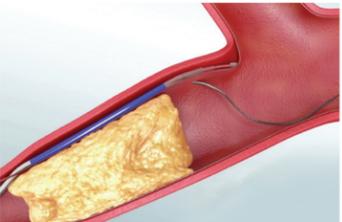
Use IVUS to precisely target reentry. IVUS is used in order to localize the true lumen by the presence of flow. The Pioneer Plus catheter should be rotated so the true lumen (identified by the ChromaFlo feature) is at the 12 o'clock position.

3



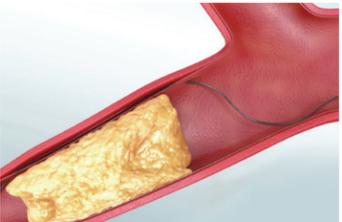
Deploy the nitinol needle to create a pathway to the true lumen.

4



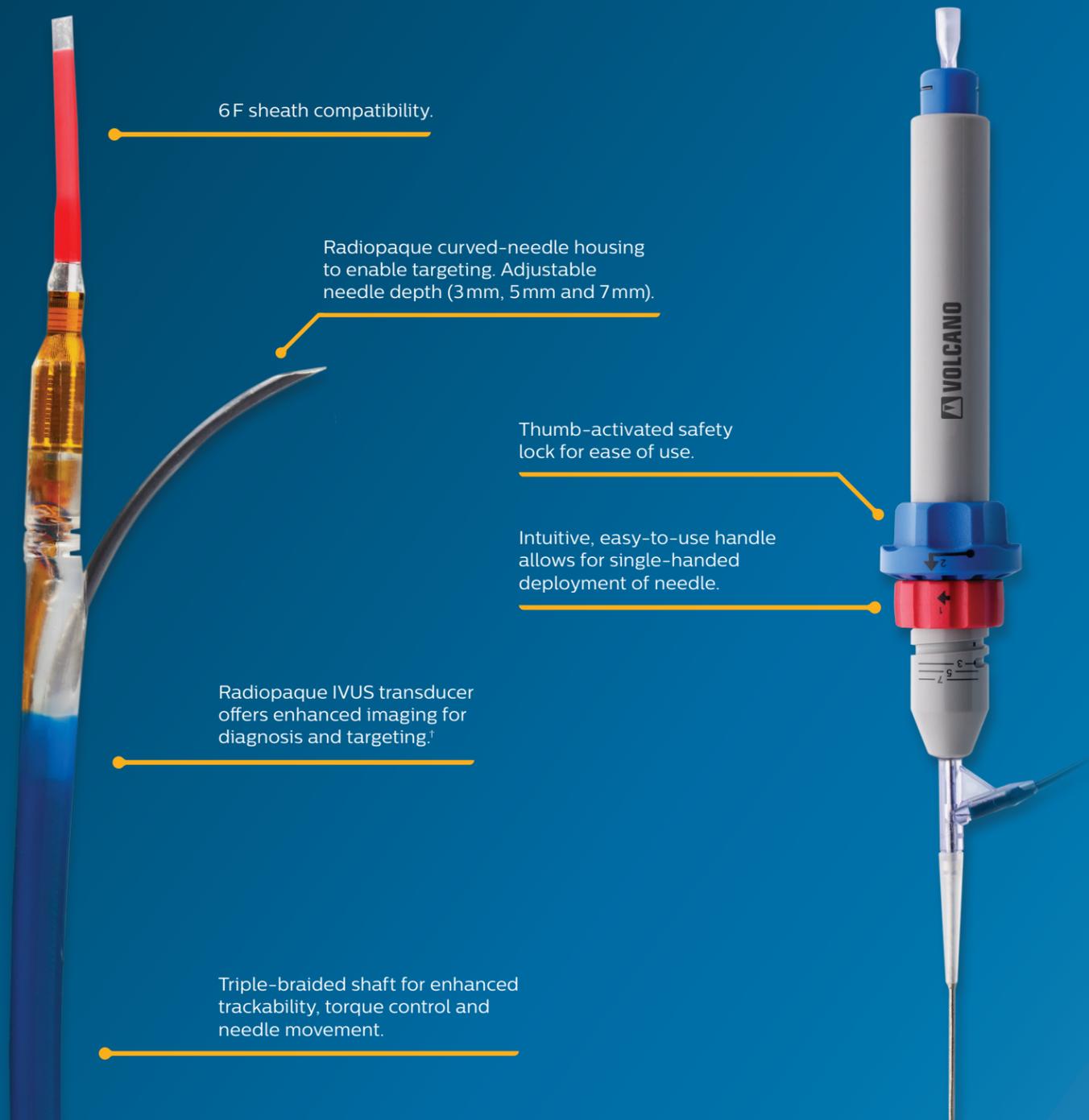
Advance a non-hydrophilic 0.014" guidewire through the needle into the true lumen. This guidewire will be used to facilitate the placement of subsequent catheters after the Pioneer Plus catheter is removed.

5



Retract the needle and remove the Pioneer Plus catheter. The vessel is now ready for additional interventions.

Delivering quick, confident and controlled true lumen re-entry*



- 6 F sheath compatibility.
- Radiopaque curved-needle housing to enable targeting. Adjustable needle depth (3 mm, 5 mm and 7 mm).
- Thumb-activated safety lock for ease of use.
- Intuitive, easy-to-use handle allows for single-handed deployment of needle.
- Radiopaque IVUS transducer offers enhanced imaging for diagnosis and targeting.[†]
- Triple-braided shaft for enhanced trackability, torque control and needle movement.