Pioneer Plus Re-entry Catheter Certification Guide for Reps

The trainee should be able to verbalize the following:

Identify Indications per IFU

* 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 guide wires 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

Device Description

* 6 Fr sheath compatible
* Catheter is dual-wire system containing both an RX and OTW lumen
* Both lumens accept 0.014” guide wires
* RX guide wire is the “subintimal” or “tracking” wire and may be 190 or 300 cm in length
* OTW guide wire is the “re-entry” or “needle” wire and must be 300 cm in length and non-hydrophilic
* Distal catheter incorporates 64 element phased array IVUS component
* Catheter can only be used with the Volcano s5, s5i, or CORE system, Core M2
* Catheter incorporates a 24 gauge Nitinol re-entry needle
* Needle depth is determined using graticules on IVUS image
* Pre-determined needle depths are 3, 5 and 7 mm. Needle depth is “set” using needle deployment ring on the proximal end of the catheter
* Needle exits catheter approximately 7 mm proximal to the IVUS transducer

Device Prep

* Confirm valid device expiration date
* In a sterile fashion, open device pouch and place PIM connector in the small plastic pouch and close
* Evaluate needle function:
* Set the needle deployment distance by rotating the Stop Ring clockwise to 7mm
* Rotate the Needle Deployment Ring in a clockwise direction and advance it up to the Stop Ring to test the needle for proper advancement and retraction
* Return both the Stop and Needle Deployment Rings to their original positions before proceeding further
* Attach a rotating hemostasis valve to the proximal luer of the catheter and flush the valve and catheter with heparinized saline
* Flush the distal end of the catheter with heparinized saline using the Flushing Tool; be careful to not damage the tip of the catheter
* Slide the sterile Probe Cover over the Patient Interface Module (PIM)
* Remove the plastic pouch from the PIM connector. Connect the Pioneer Plus catheter to the PIM-turn IVUS console on and assure a properly functioning connection
* Insert a 300 cm long 0.014” non-hydrophilic guide wire into the needle lumen (do not leave the distal tip of the wire exposed outside the needle tip- place it within the needle). Carefully tighten the rotating hemostasis valve around the needle guide wire

Procedural Steps

* Using a percutaneous technique, place 0.035” guide wire beyond target lesion by creating a small “loop” in the distal guide wire and enter the sub-intimal space
* Using an exchange-type catheter, exchange 0.035” guide wire for supportive 0.014” guide wire
* Back-load the distal tip of the catheter onto the supportive 0.014” guide wire and advance catheter into the vasculature
* Turn on the ChromaFlo feature to verify an IVUS image is obtained
* Advance catheter to desired site using fluoroscopy
* Using ChromaFlo, orient the catheter such that the true lumen is located at the 12 o’clock position, visualized on the IVUS console screen
* Determine proper needle depth by utilizing the graticules on the IVUS image
* Rotate Stop Ring to desired needle depth
* Rotate the Needle Deployment Ring clockwise and quickly advance it to deploy the re-entry needle into the true lumen of the vessel
* Loosen hemostatic valve and advance the non-hydrophilic needle guide wire into the lumen of the vessel
* Return Needle Deployment and Stop Rings to their original positions
* Remove the subintimal tracking wire
* Disconnect Pioneer Plus from the PIM
* Under fluoroscopy and using a catheter exchange technique, remove the catheter, assuring the needle guide wire remains straight
* Now the 0.014” guide wire (previously the needle guide wire) may be used to treat the intended target lesion

General Information

* Do not attempt to perform an angiogram through the Pioneer Plus catheter (at the rotating hemostasis valve)
* Assure needle guide wire does not have a hydrophilic coating
* If user meets significant resistance when initially placing Pioneer Plus catheter at desired site do not force catheter advancement but remove catheter and pre-dilate the desired site using small PTA balloon, 2.0-2.5 mm diameter. Afterward re-advance Pioneer Plus catheter and proceed as planned

Practice Grade: \_\_\_\_ Pass: \_\_\_\_\_\_ Fail: \_\_\_\_\_\_