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Peripheral Field Training Guide

ABSTRACT

As you progress through the Philips IGTD Clinical Pathway on the road towards competence and confidence, you will have opportunity to supplement your foundational learnings from the Distance Learning Program through Field Training. Use this guide with your Field Trainer to facilitate and document your field experiences.

- Clinical Sales Training Team

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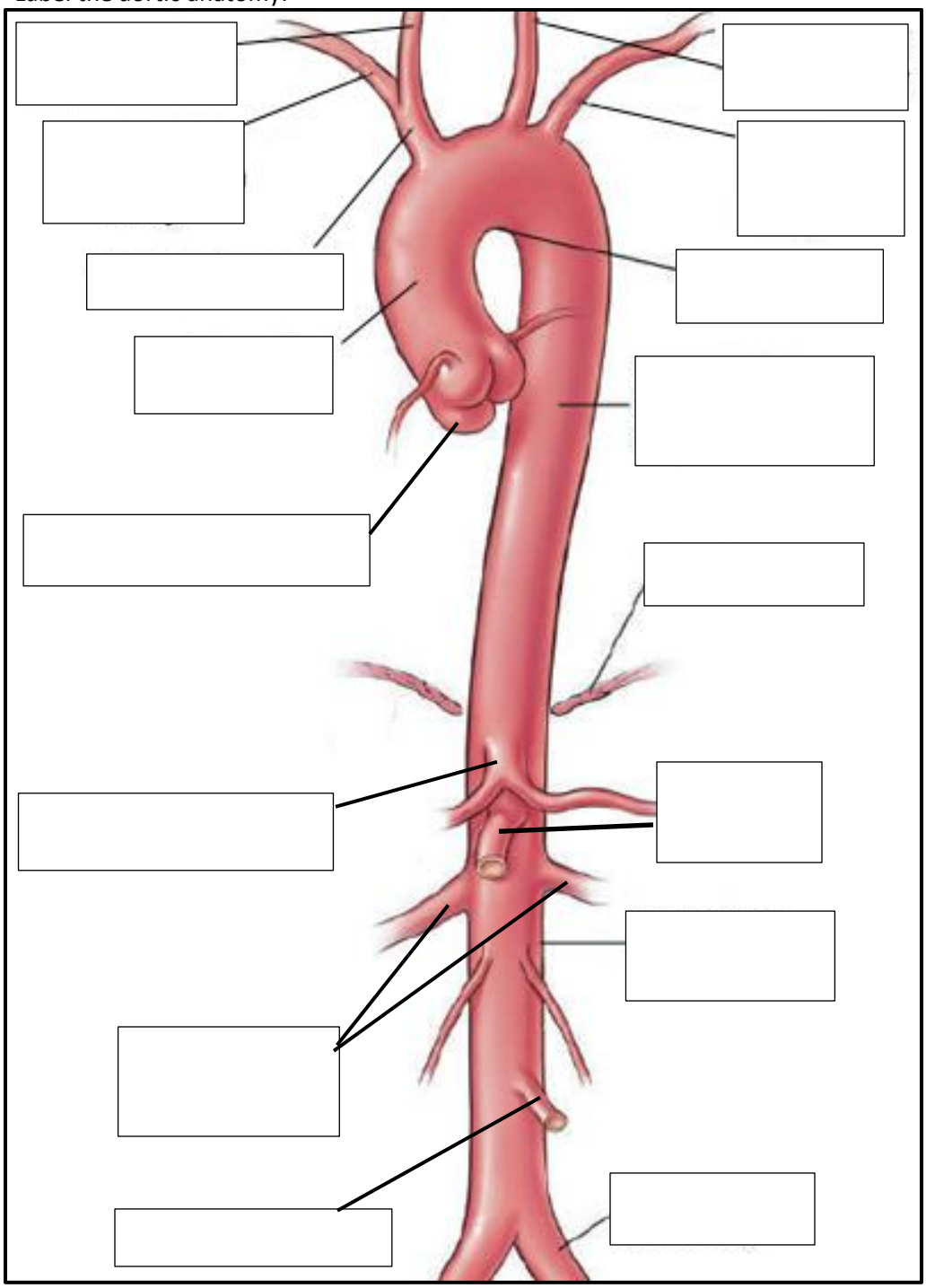
Anatomy review

Aortic anatomy quiz

Label the aortic anatomy.



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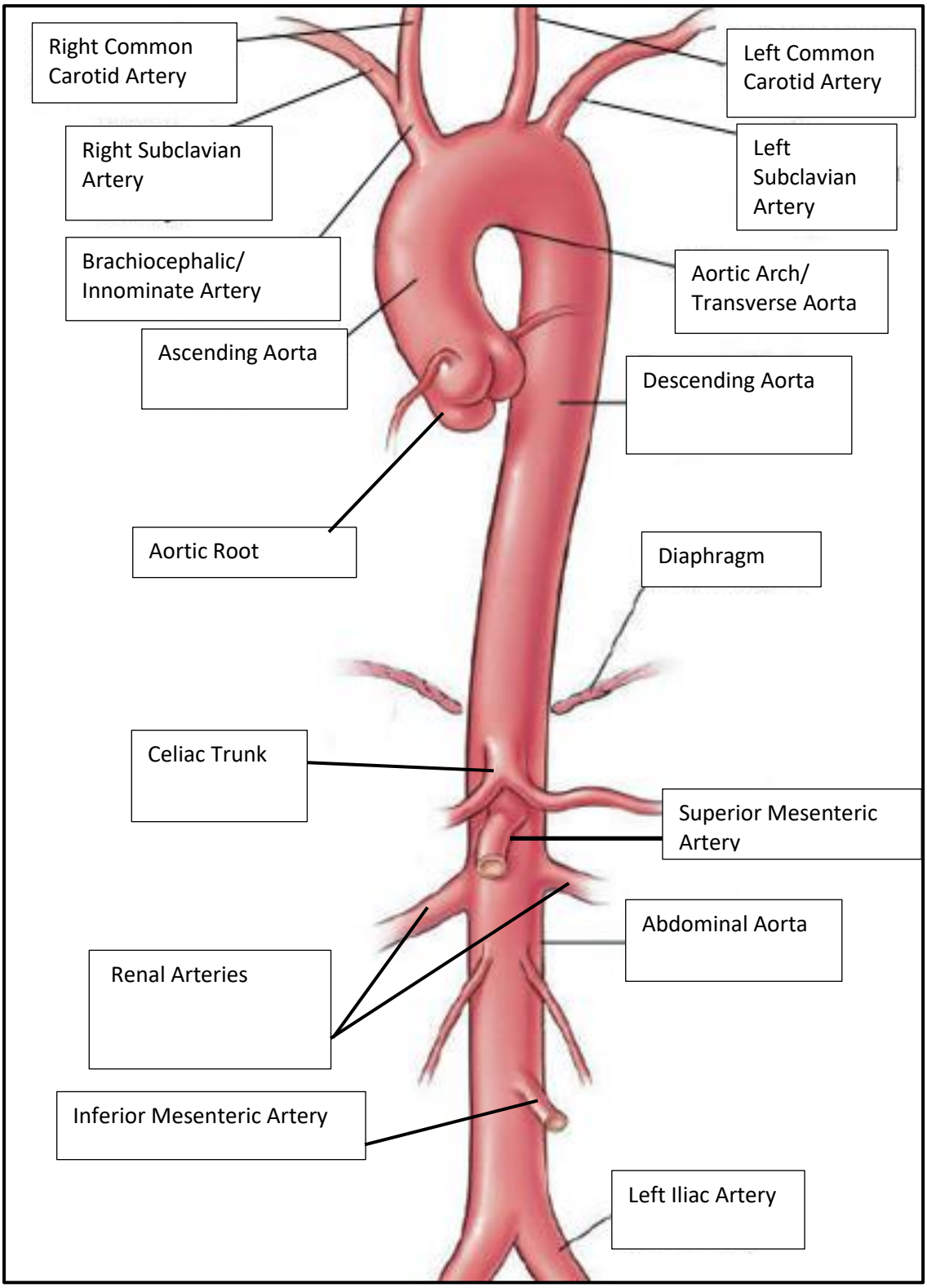
Aortic anatomy answer key



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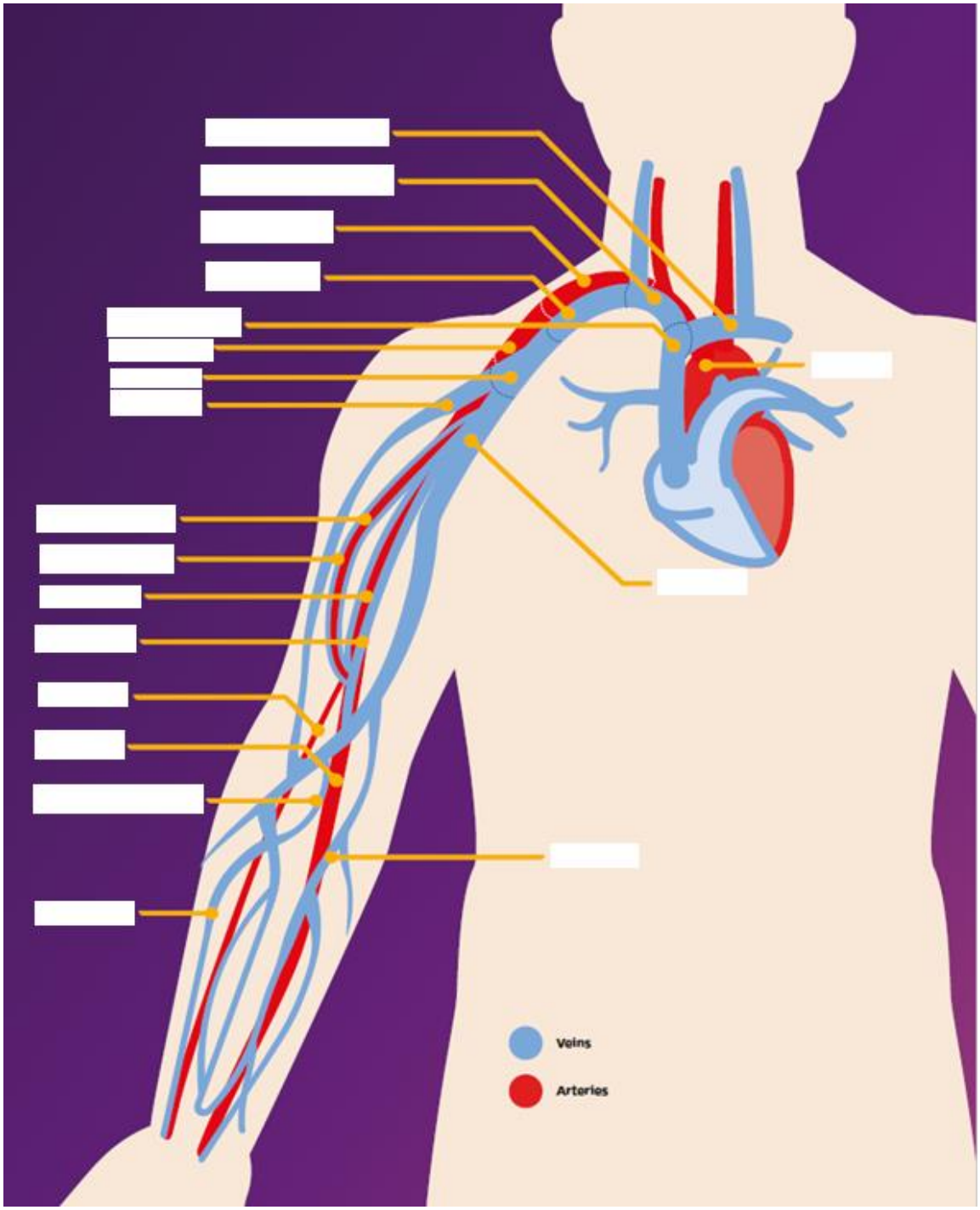
AV access quiz

Label the anatomy.



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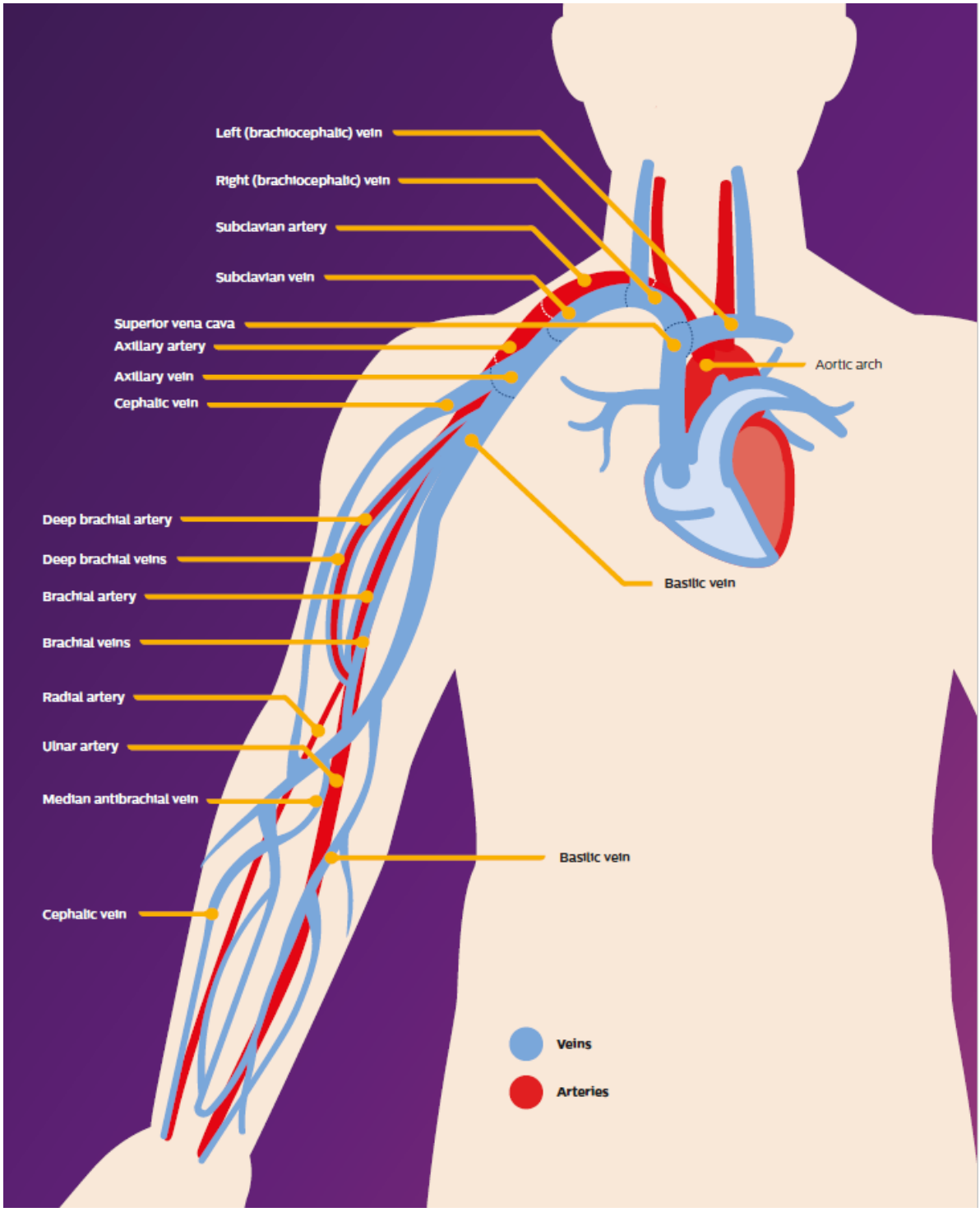
AV access answer key



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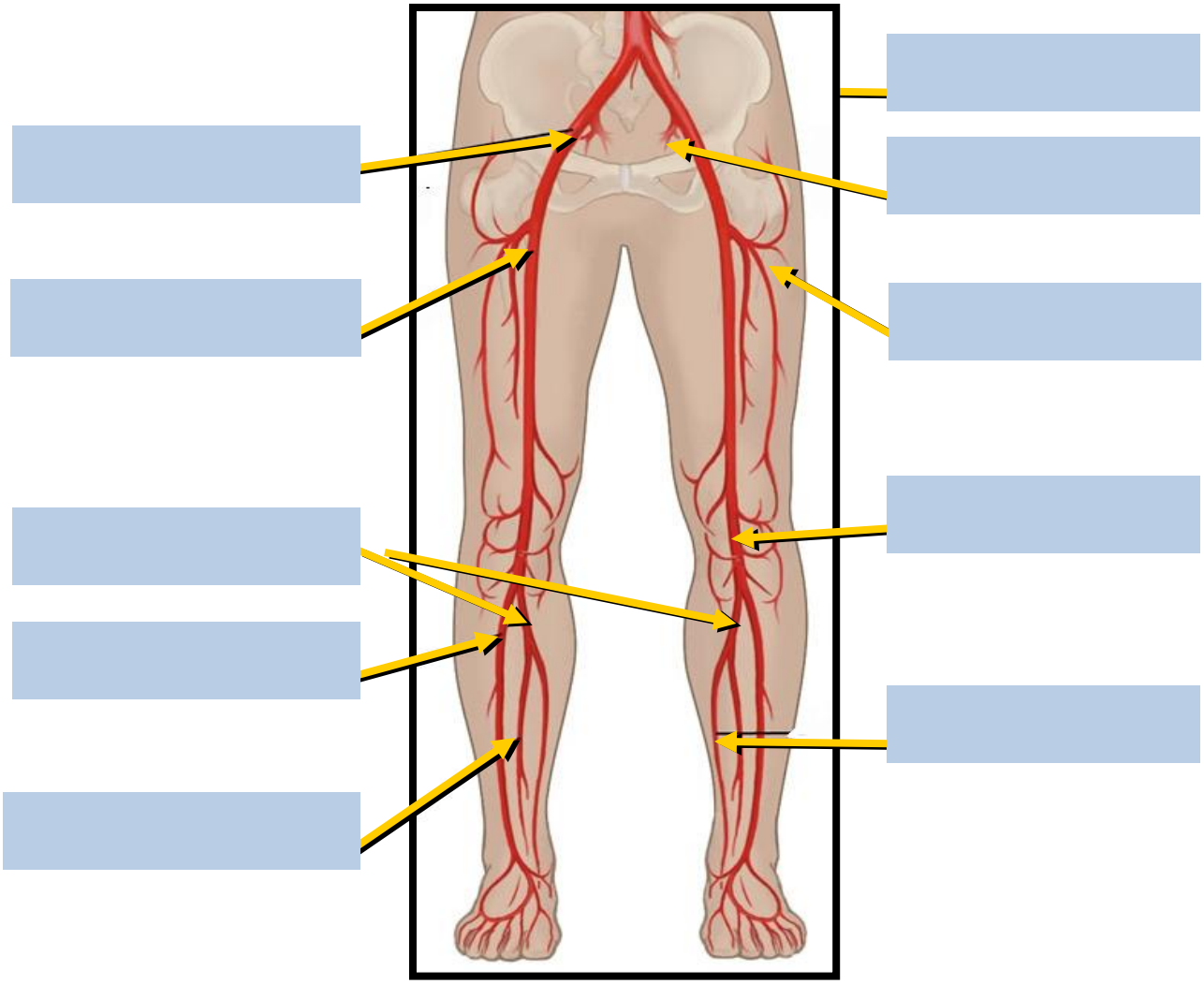
Aorto-iliac and lower extremity anatomy quiz

Label the anatomy.



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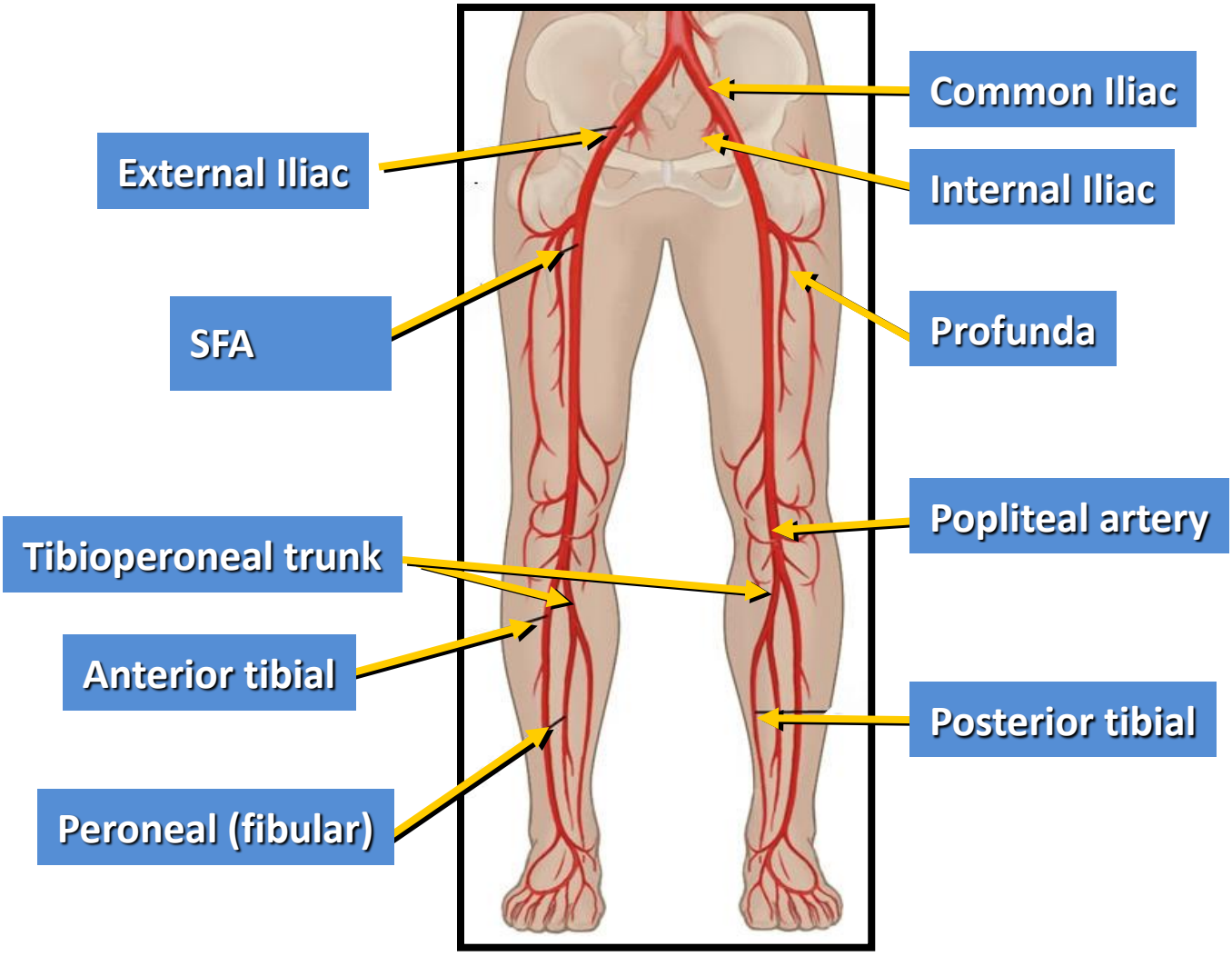
Aorto-iliac and lower extremity anatomy answer key



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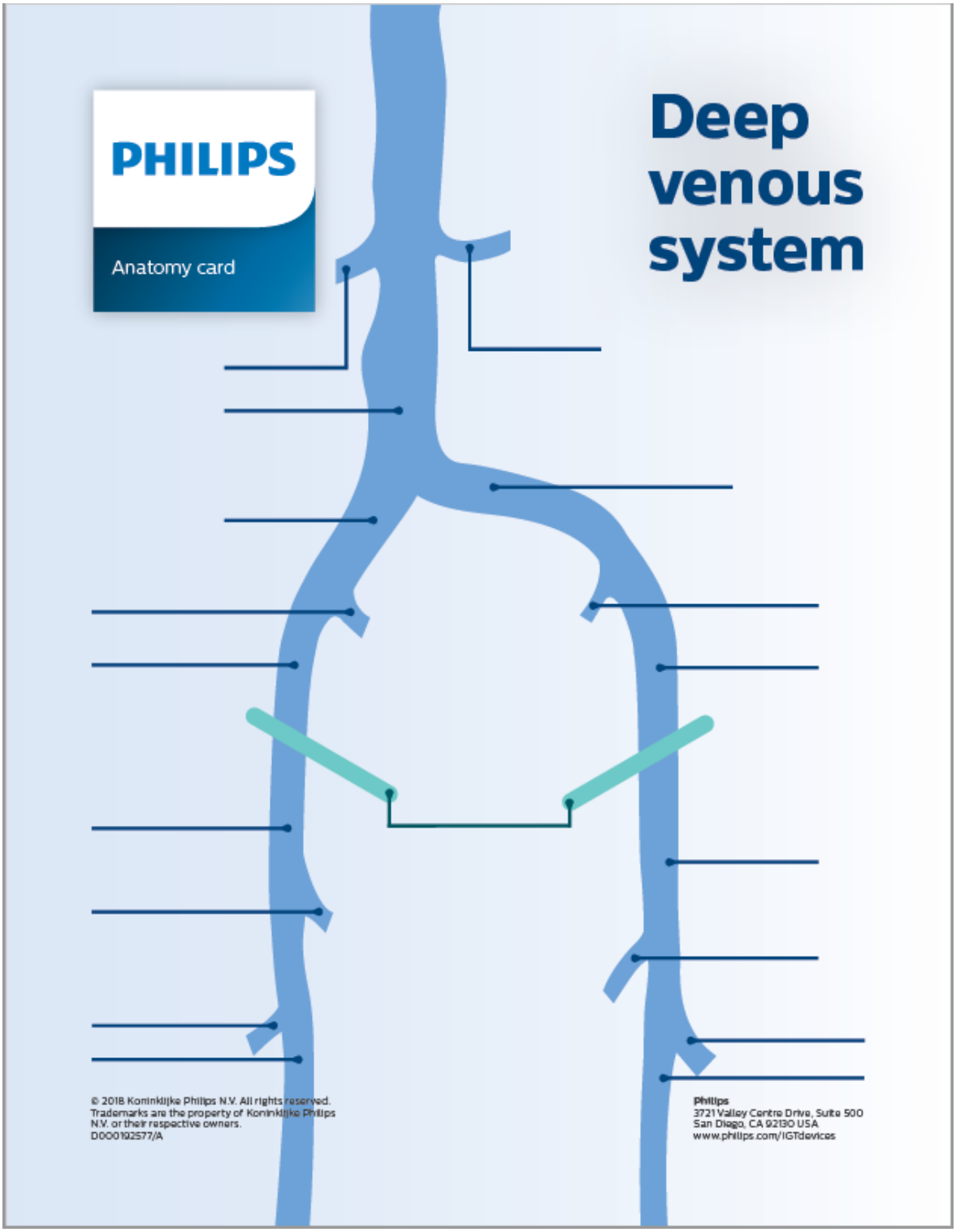
Deep venous IVUS anatomy

Label the anatomy.



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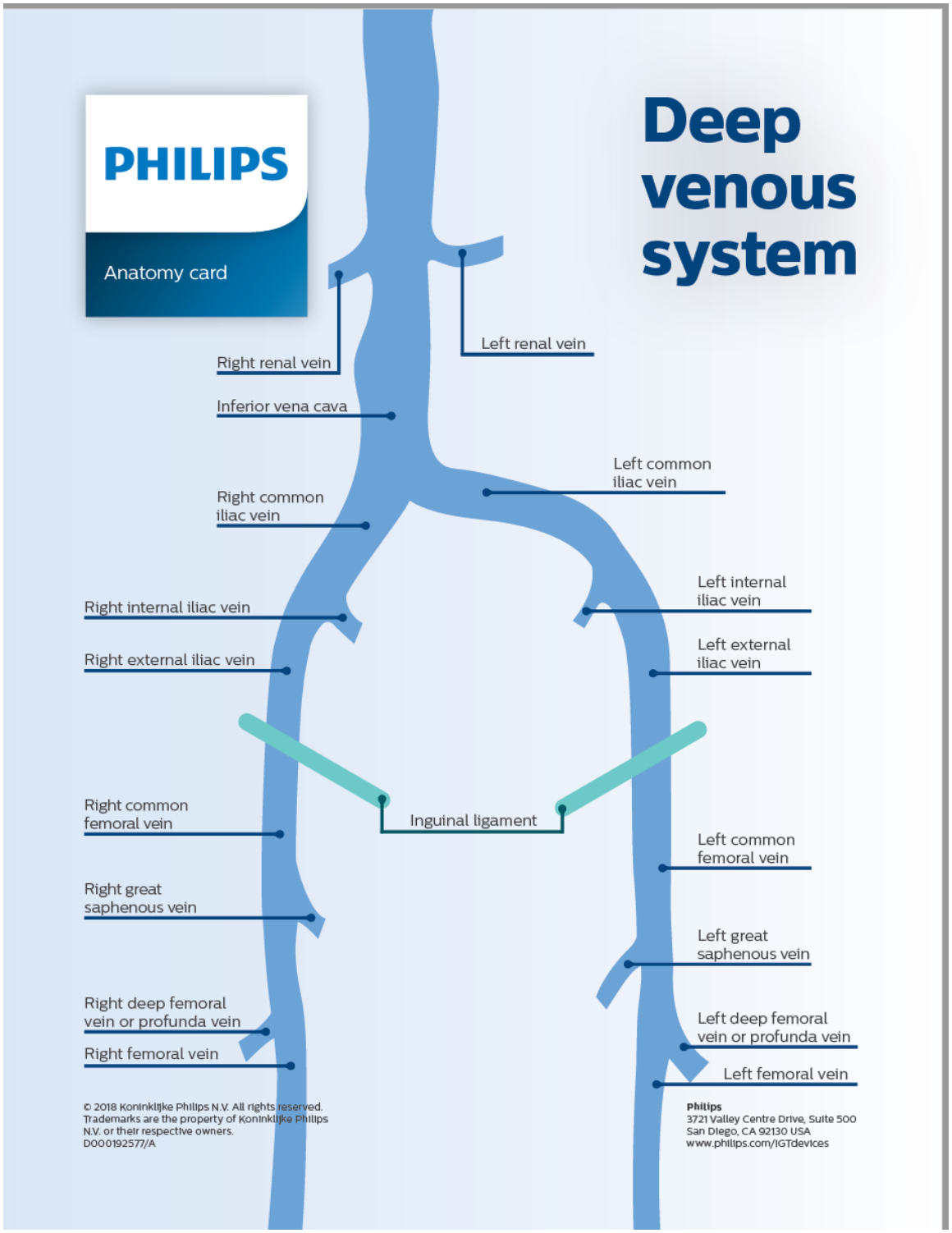
Deep venous IVUS anatomy



REVIEW THE OBJECTIVES BY PRODUCT LINE/TREATMENT AREA WHICH WILL GUIDE YOU AND YOUR FIELD SALES TRAINER (FST) THROUGHOUT YOUR FIELD TRAINING EXPERIENCE.

DOCUMENT FIELD ACTIVITIES ON YOUR CASE OBSERVATION FORM, AS IT WILL COMPLIMENT YOUR INDIVIDUAL LEARNING PLAN.

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IVUS objectives

Basic IVUS objectives

Clinical	Technical	Sales
1. Practice basic image interpretation skills with Field Sales Trainer (FST) using system images inclusive of border recognition, geometry and morphology interpretation and anatomy references on IVUS. 2. Complete image interpretation exercises with FST on System in the field. 3. Observe cases while FST guides the IVUS portion. Utilize your field competency checklist to enhance system proficiency and be sure to submit case observation forms.	1. Practice System competency and functionality. 2. Review product specifications with FST. Inclusive of: • Visions PV .014P RX • Visions PV .018 RX • Reconnaissance PV .018 OTW • Visions PV .035 • Pioneer Plus 3. Practice product demonstration with FST. Trainee should be able to perform a tip to tail product in-service on each catheter provided. Utilize product quizzes and IFU to enhance product knowledge and training.	1. Discuss FST's targeting strategy that drives utilization and adoption. 2. Discuss competition and defense strategy. 3. Review and discuss IVUS Competitive Messaging. 4. Review iPad and identify key marketing tools available.

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Peripheral IVUS (Arterial) objectives

Clinical	Technical	Sales
1. Review and identify: • Thoracic Aortic Anatomy • Abdominal Aortic Anatomy • Iliac and Pelvic Arterial Anatomy • Lower Extremity Arterial Anatomy 2. Review with FST clinical procedures where peripheral IVUS may be utilized: • Iliac Artery • SFA • Popliteal Artery • Tibial Arteries • Thoracic Aorta (Dissection / Aneurysm Endovascular Repair) • Abdominal Aorta (Dissection / Aneurysm Endovascular Repair) 3. Observe cases for the above when available and complete your case observation forms. 4. Identify and discuss key studies supporting peripheral arterial IVUS. Utilize your field competency checklist to enhance system proficiency.	1. Continue to review and identify the specifications, indications, features and benefits of the PV IVUS Catheters. 2. Present information from product spec sheets and IFU's for each product to FST. 3. Review the REACT Campaign and resources: REACT CAMPAIGN	1. Discuss FST's targeting strategy that drives utilization and adoption. 2. Discuss competition and defense strategy. 3. Review Aortic iPad App. 4. Discuss economic impact/reimbursement strategy in Office based practice vs. Hospital.

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Peripheral IVUS (Venous) objectives

Clinical	Technical	Sales
1. Review and identify Venous anatomy with FST. 2. Review, with FST, Venous procedures where IVUS may be utilized: • Iliac Venous Compression • AV access sites • IVC Filters • Nut Cracker/Pelvic Congestion Syndrome • Thoracic Outlet Syndrome 3. Observe cases for the above. 4. Identify and articulate key takeaways from 4 pertinent Venous studies supporting the use of IVUS. 5. Identify key anatomical landmarks on IVUS: • IVC • Confluence • Internal Iliac Vein • Hypogastric Artery • Common Femoral Vein Utilize your field competency checklist to enhance system proficiency.	1. Review and identify the Imaging Catheters and features that facilitate diagnosis and treatment in Venous Cases (ChromaFlo and Marker bands). 2. Present information from product spec sheet for each imaging catheter to FST. 3. Identify and articulate workflow for an Iliac Venous Compression case with FST and send in workflow with case observation form.	1. Discuss essential components to successful Venous market development (key studies, sales collateral, and medical education). 2. Discuss economic and reimbursement in Office-based practice vs. Hospital. 3. Work through the Venous iPad App.

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Product IFUs

PV.014P Rx

PV .018 RX

PV .018 OTW

PV .035

Pioneer Plus

Phoenix Atherectomy System

QuickClear

Tack endovascular system – 6F, 4F

Click HERE to access these IFUs:

- AngioSculpt PTA
- CVX-300
- Quick-Cross Support Catheter
- Turbo-Elite LASER Catheter
- Turbo-Power 7Fr LASER Catheter
- Turbo-Power 6 Fr LASER Catheter
- Stellarex DCB

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S5/CORE IVUS System Competency for Peripheral Sales Personnel

WEEK: **TRAINER:**

Power on System (if not already on) • How do you manage a power failure during the case? • How does powering on differ between the S5/Core tower and the S5i/Core Integration System?
VGA/Display Port Output • What is it used for? • When would it be useful?
Attach PIM Cable if not attached • Hang PIM Tableside
Ethernet Port • What is it used for?
Enter Patient Name • Explain which information is required to start a case
Demonstrate going to LIVE before inputting patient data • Explain why this is useful
Acknowledge and explain worklist functionality
Phased Array Catheter vs Rotational • Describe the differences in Phased array and Rotational technologies • Review Specs of the PV Phased Array Catheters • Demonstrate Prep • Discuss proper Handling • Connect to PIM & Confirm Connection
Acknowledge LIVE mode
Ring Down • Explain Ring Down Artifact • Demonstrate Ring Down Process (Why, When & How) • Explain when not to ring down (PV .035)

Adjust Setting Menu
• FOV (Field of View)
  ○ Explain Benefits of this feature
  ○ Discuss when, how & why to adjust
• Gain
  ○ Discuss feature and its benefit
  ○ Adjust and discuss recommended settings

• Revolve
  ○ Explain Benefits of this feature
  ○ Discuss when, how & why to adjust
• ChromaFlo Explain & Demonstrate Sensitivity settings
  ○ Explain Region of Interest & adjust (when & why)
  ○ How does ChromaFlo work?
  ○ When is ChromaFlo useful?
  ○ When can/should ChromaFlo be activated?
  ○ Which catheters have ChromaFlo as a feature?

Demonstrate Freeze Feature • When is this useful? • Measure during Freeze
Save Frame from Live image
Record a Video Loop • Bookmark several places • Identify the Distal & Proximal end of the ILD dependent on anatomy
Stop the Recording
Record a second video loop • Identify Video Loop capacity per case
Access the first video loop • Navigate Bookmarks (demonstrate several methods)
Retrieve a case from Hard Drive or DVD-R

MEASUREMENTS
• Diameter (when & why?)
  ○ Demonstrate 2 diameter measurements
  ○ Edit Diameter Measurements
  ○ Speak on the location of the measurements

• Dots (when & why?)
  ○ Demonstrate Lumen and vessel measurements
  ○ Demonstrate editing
  ○ Speak on the location of the measurements
  ○ Speak on what each measurement represents
  ○ Lock Measurement of Lumen
  ○ Explain this feature and ability to measure % stenosis

• Draw (when & why?)
  ○ Demonstrate Measuring or editing in draw mode
  ○ Edit measurements

• Rapid Review (when & why?)
  ○ Utilize rapid review feature
  ○ Measure when in rapid review
  ○ Explain how this feature can aid in interpretation

• Annotations on screen (when & why?)
  ○ Demonstrate annotations and editing
  ○ Save frame post annotation

• Auto Measure (when & why?)
  ○ Demonstrate Auto Measure feature
  ○ Explain need for editing and pitfalls of this feature

• PRINT IMAGE
IN-LINE DIGITAL • Demonstrate Rotation of the ILD   o Explain benefits of this feature • Demonstrate compression and expansion of the ILD • Articulate the ability to perform length measurements • Change pullback speed and demonstrate how to measure length

ACCESS CASE EXPLORER
• Access Video Loops
  ○ Name video Loop
  ○ Delete (or talk through) a video loop
• Access Saved Frame
  ○ Name Saved Frame
• Change Pullback Speed (also can be done in step 5 above)
• Access Properties
  ○ Explain what each feature under properties reveals

END CASE • Demonstrate editing patient information • End Case • Identify hard drive capacity • Delete case from hard drive • Explain how to delete several cases at once
ARCHIVE A CASE • Archive to DICOM   o Explain how to archive several cases at one time • Archive to DVD-R • Explain how to review case on PC (viewer software)

- Access Settings Menu
    - Change date and time
    - Explain Power options
- Change Acquisition Rate
    - Explain benefits of this feature
    - When would this change
- Compress ILD on default
- Demonstrate DICOM / Worklist set up
- Adjust rapid review settings
- Measure
    - Customize measurement options
    - Change Auto Measure to lumen only
    - Display Auto Borders
    - Change edit mode to dots only

Be able to define/demonstrate/locate the following:

- CONCENTRIC Vs. ECCENTRIC PLAQUE MORPHOLOGIES
- FIBROUS (SOFT PLAQUE) Vs. CALCIUM
- SUPERFICIAL Vs. DEEP CALCIUM
- ARC DEGREE OF CALCIUM
- ADVENTITIAL CUTS
- SUBIMITMAL PLACEMENT OF GUIDEWIRE WIRE
- TRUE LUMEN Vs. FALSE LUMEN
- DISSECTION FLAPS
- SIDE BRANCH ANATOMIES

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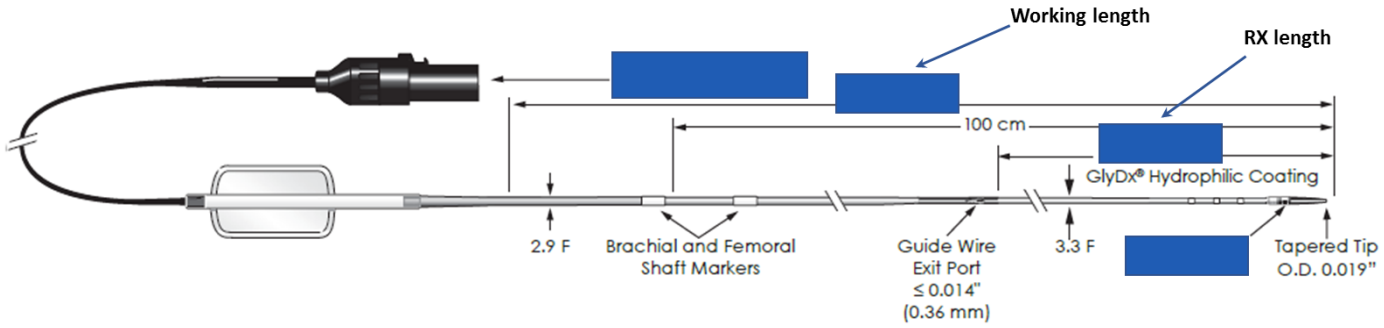
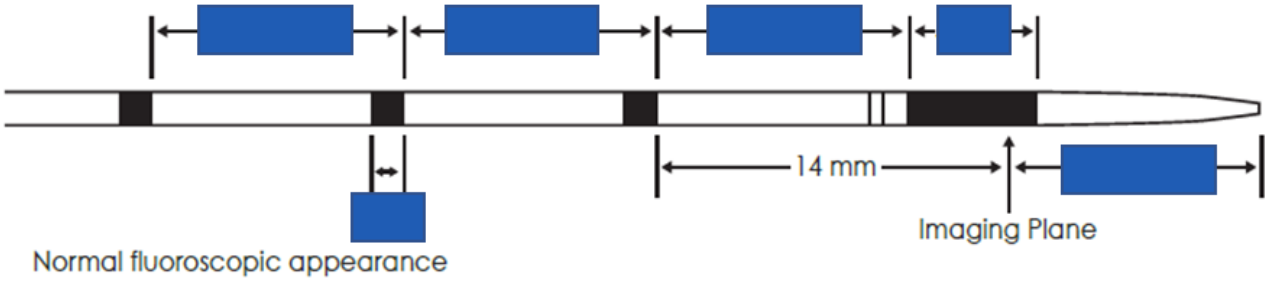
Visions PV .014p Rx, PV .018 RX, PV .018 OTW specifications quiz

Label the PV IVUS Catheter Specs according to the IFU and fill in the chart below.

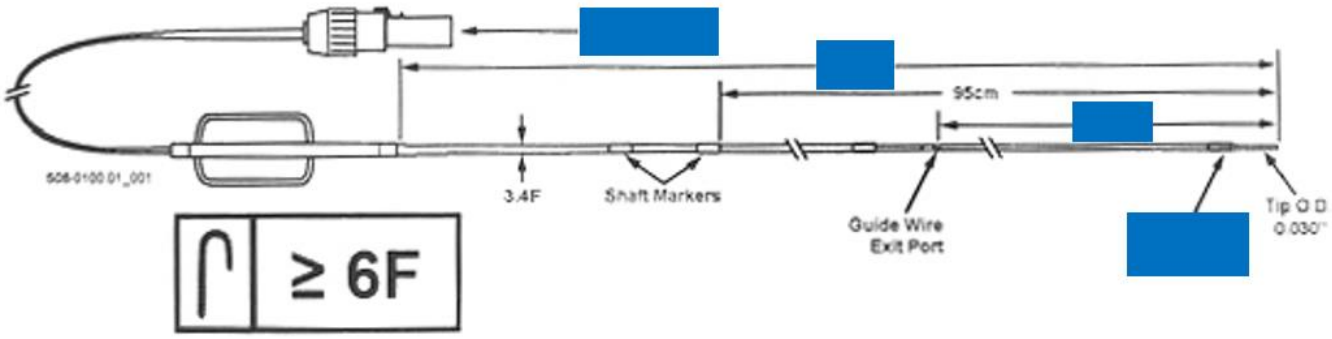
PV .014p RX Catheter



Distal Tip and RO Marker Detail



PV .018 RX Catheter



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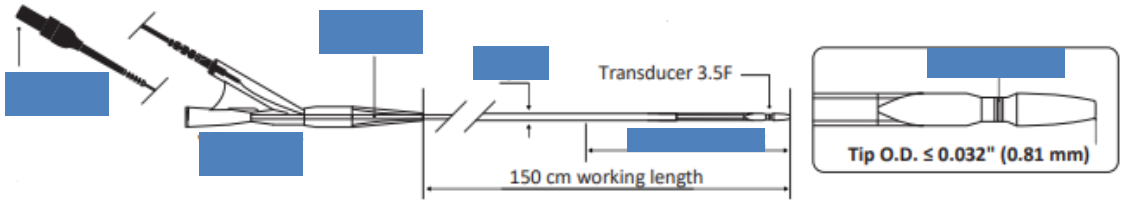
Reconnaissance PV .018 Digital IVUS catheter



PV .014p Rx, PV .018, PV .018 OTW Catheter specs

	Minimum Guide Catheter Size	ChromaFlo Ability?	Tip to Transducer Length (mm)	Crossing Profile of Transducer	IVUS MHz/Elements	RX Length	Max Guidewire	Working Length (cm)	Maximum Field of View (mm)
Visions PV .014P Rx									
Visions PV .018									
Reconnaissance PV .018 Digital IVUS									

Proper device prep for RX catheters

1. Remove Winged Flush Tool from _____.
2. Attach Winged Flush Tool to a _____filled with heparinized saline.
3. Carefully insert distal tip of catheter into open end of_____.
4. Flush the _____ end of the catheter with _____ using the Winged Flush Tool until fluid exits the _____ exchange port; be careful to not damage the ___ of the catheter.
5. Catheter is now flushed, wipe with _____, and load _____.

Note – PV .014P Rx has a _____, inside _____, that must be removed prior to flushing.

Briefly describe the flush procedure of the .018 Digital IVUS Catheter

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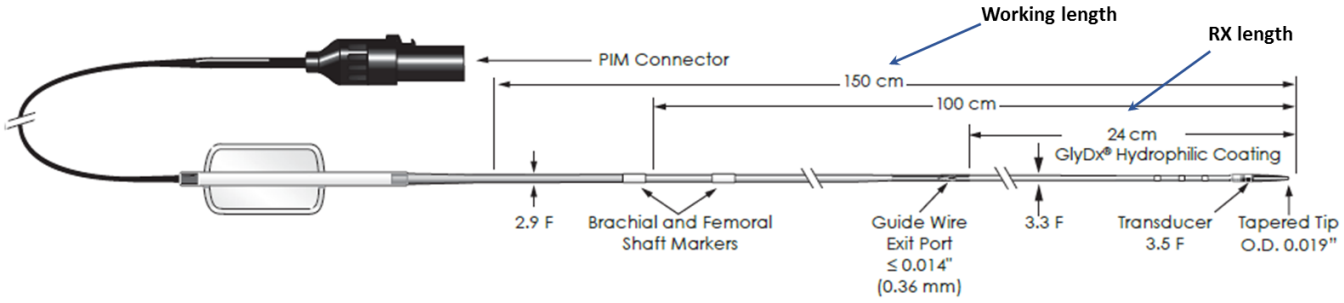
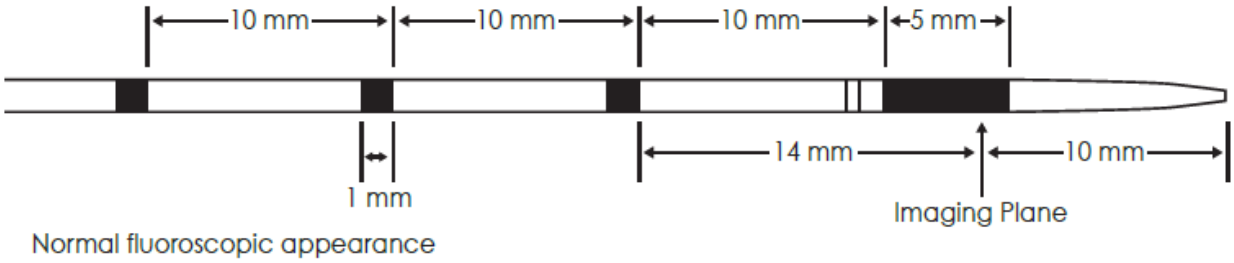
Visions PV .014p Rx, PV .018 RX, PV .018 specifications answer key

Check your answers on the PV IVUS Catheter Specs.

PV .014p Catheter

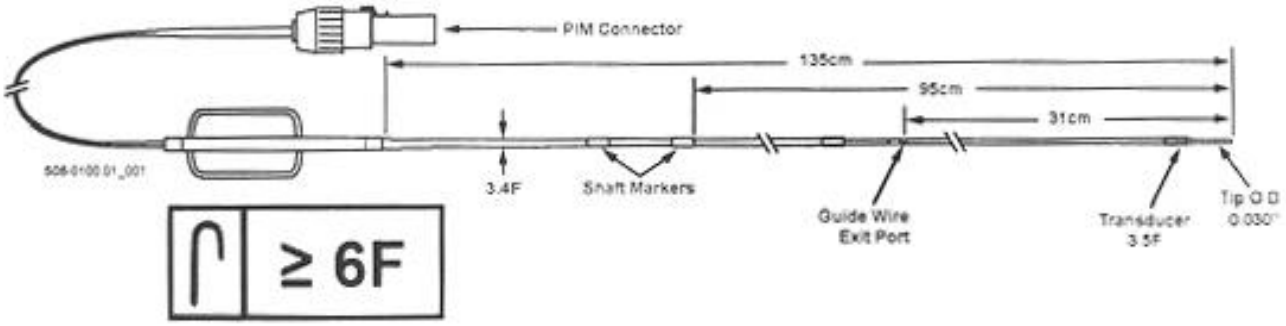


Distal Tip and RO Marker Detail



Normal fluoroscopic appearance

PV .018 Catheter



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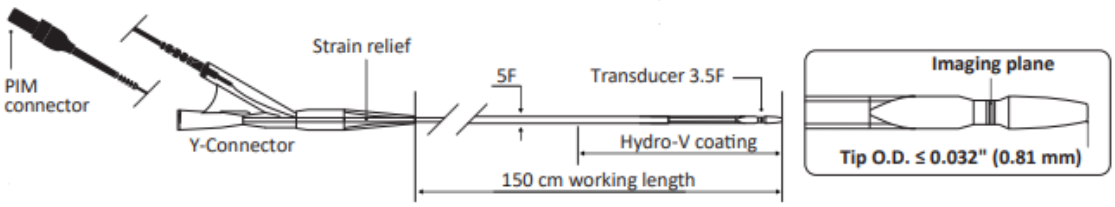
Reconnaissance PV .018 Digital IVUS catheter



PV .014p RX, PV .018 RX , PV .018 OTW Catheter specs

	Minimum Guide Catheter Size	ChromaFlo Ability?	Tip to Transducer Length (mm)	Crossing Profile of Transducer	IVUS MHz/Elements	RX Length	Max Guidewire	Working Length (cm)	Maximum Field of View (mm)
Visions PV .014P Rx	5F	Y	10mm	3.5F	20MHz 64 Elements	24cm	.014	150cm	20mm
Visions PV .018	6F	Y	10-13mm	3.5F	20MHz 64 Elements	31cm	.018	135cm	24mm
Reconnaissance PV .018 Digital IVUS	5F	Y	2.5mm	3.5F	20MHz 64 Elements	N/A	.018	150cm	20mm

Proper device prep for RX catheters

1. Remove Winged Flush Tool from catheter hoop.
2. Attach Winged Flush Tool to a 10cc syringe filled with heparinized saline.
3. Carefully insert distal tip of catheter into open end of Winged Flush Tool.
4. Flush the distal end of the catheter with heparinized saline using the Winged Flush Tool until fluid exits the proximal exchange port; be careful to not damage the tip of the catheter.
5. Catheter is now flushed, wipe with wet 4x4, and load on the wire.

Note – PV .014P Rx has a stylet, inside the exchange rail, that must be removed prior to flushing.

Briefly describe the flush procedure of the .018 Digital IVUS Catheter

Flush the guidewire lumen through the port at the catheter's Y connector, and then wipe down the entire working length with sterile heparinized normal saline.

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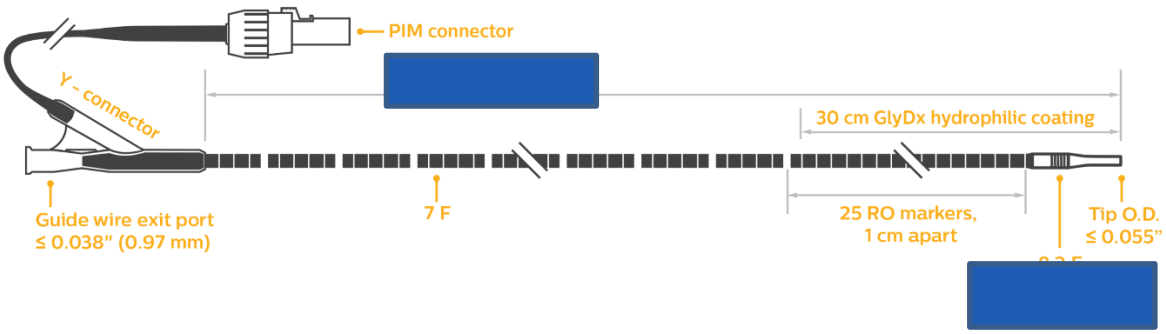
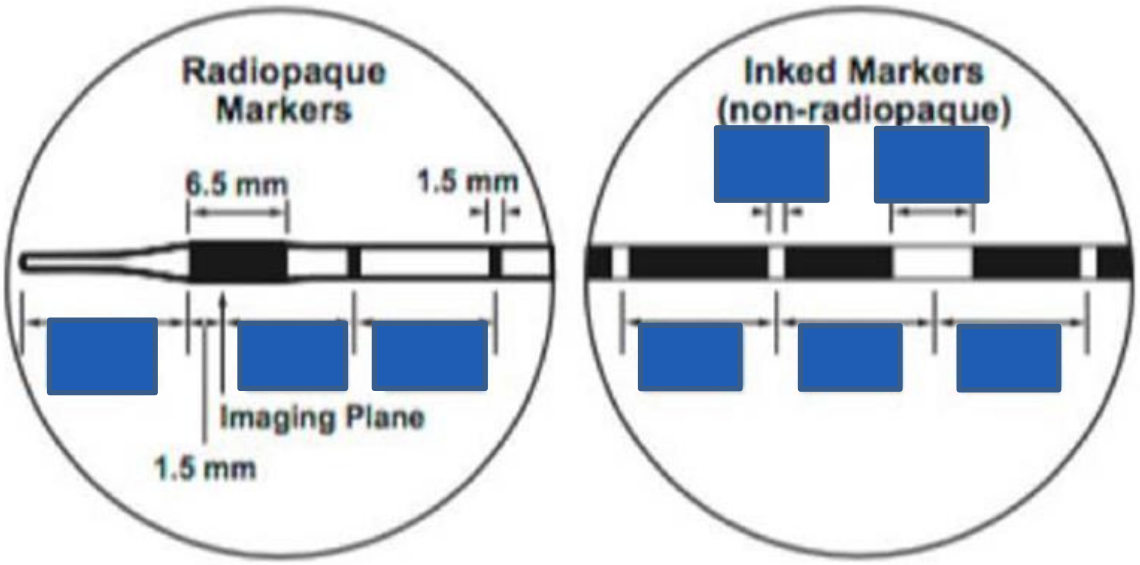
Visions PV .035 specifications quiz

Label the PV IVUS Catheter Specs according to the IFU and fill in the charts below.

PV .035 Catheter





Briefly describe the flush procedure of the PV .035 IVUS Catheter.

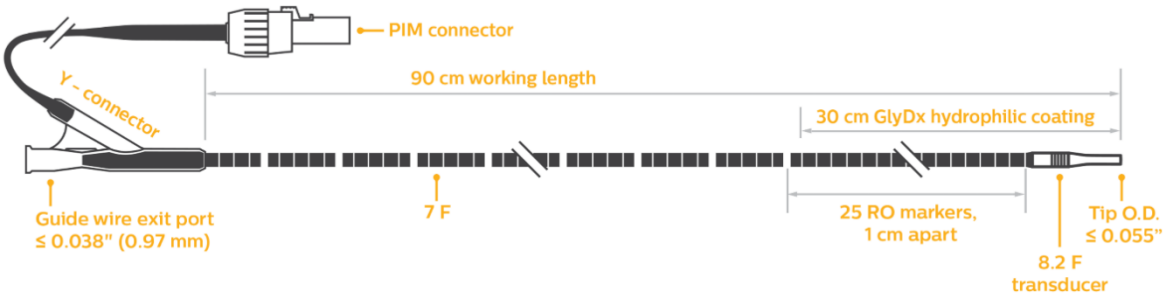
PV .035 Catheter Specs

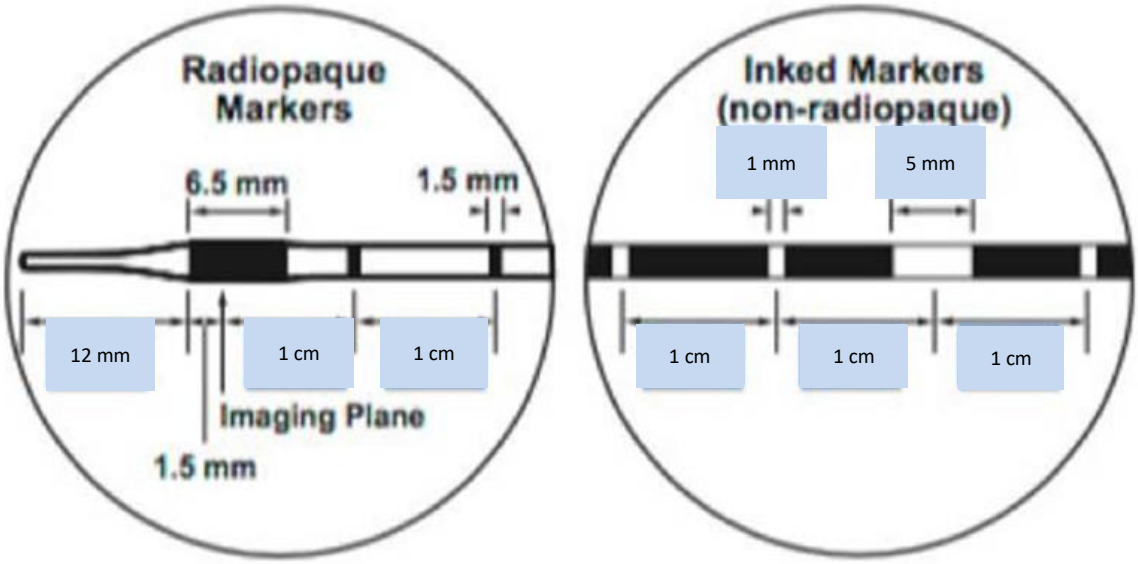
	Minimum Guide Catheter Size	ChromaFlo Ability?	Tip to Transducer Length (mm)	Crossing Profile of Transducer	IVUS MHz/Elements	Max Guidewire	Working Length (cm)	Maximum Field of View (mm)
Visions PV .035								

Visions PV .035 specifications answer key

Check your answers on the PV IVUS Catheter Specs.

PV .035 Catheter





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Briefly describe the flush procedure of the .035 IVUS Catheter

Flush the guidewire lumen through the port at the catheter's Y connector, and then wipe down the entire working length with sterile heparinized normal saline.

PV .035 Catheter Specs

	Minimum Guide Catheter Size	ChromaFlo Ability?	Tip to Transducer Length (mm)	Crossing Profile of Transducer	IVUS MHz/Elements	Max Guidewire	Working Length (cm)	Maximum Field of View (mm)
Visions PV .035	8.5F	N	12mm	8.2F	10MHz 64 Elements	.038	90cm	60mm

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Pioneer Plus IVUS Guided Re-Entry Catheter objectives

Clinical	Technical	Sales
1. Articulate Indications for Use. 2. Discuss Clinical Indications for Pioneer Plus. • Identify Competitors • Demonstrate knowledge of device performance compared to competition 3. Identify and discuss appropriate clinical applications of Pioneer Plus. • Identify clinical scenarios that are inappropriate/ contraindicated 4. Complete Image Interpretation exercises with the FST on the system. Be able to discuss: • ChromaFlo and benefits of this feature • True lumen vs. False lumen 5. Observe 3-5 Cases. • Discuss clinical scenario of each case with FST.	1. Describe the product specifications and features of Pioneer Plus. 2. Discuss and demonstrate Pioneer Plus device set-up, prep and case workflow. 3. Demonstrate knowledge of sheath selection. • Identify recommend sheath size. 4. Demonstrate knowledge of Guidewire Management. • Identify compatible wires, length, size and coatings. • Identify guide wire lumens and appropriate wire for each lumen – Tracking wire vs. Sub Intimal Wire. • Proper insertion/removal of device.	1. Discuss key factors to successful Pioneer Plus launch strategy with Field Trainer: • Discuss setting appropriate expectations for Physicians • Role play talk tracks • Practice objection handling • Discuss and demonstrate use of data 2. Discuss Competitive Positioning of Pioneer Plus against other Re-Entry Devices on the market: • What is the value of controlled Re-Entry? • Articulate the value proposition of Pioneer Plus. • Articulate the synergies of IVUS, Pioneer Plus and Phoenix Atherectomy. 3. Develop Launch plan with RSM: • Identify Targets within territory. • Refine talk tracks and objection handling. • Set-up account visits. • Initiate Physician and staff product training via product demonstration.

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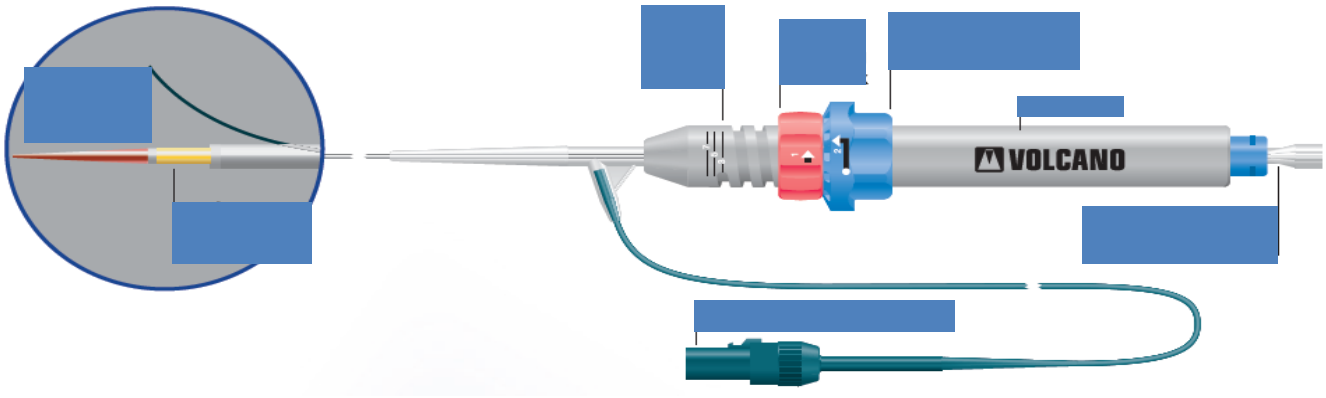
Pioneer Plus IVUS Guided Re-Entry Catheter quiz

Label the Pioneer Plus IVUS Catheter components per IFU and fill in the chart below.



Pioneer Plus IVUS Guided Re-Entry Catheter Specs

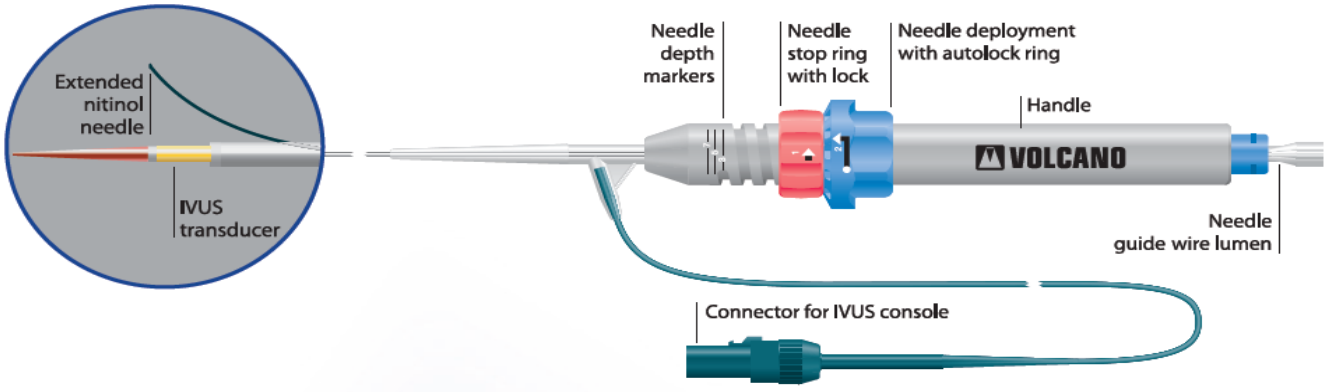
Sheath	GW Diameter(s)	GW Length(s)	Working Length (cm)	Needle Depths (mm)	IVUS MHz/Elements	Needle exits ___mm proximal IVUS transducer

Briefly describe indication for use:

Briefly describe the prep of the Pioneer Plus Catheter:

Pioneer Plus IVUS Guided Re-Entry Catheter answer key

Check your answers on the components of the Pioneer Plus IVUS Catheter.



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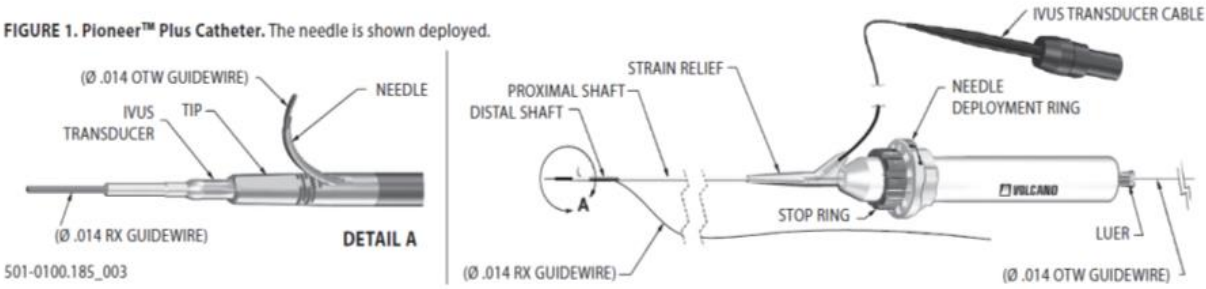
INSTRUCTIONS FOR USE
PIONEER™ PLUS
CATHETER

REF PPLUS120 ENGLISH

FIGURE 1. Pioneer™ Plus Catheter. The needle is shown deployed.



Pioneer Plus IVUS Guided Re-Entry Catheter Specs

Sheath	GW Diameter(s)	GW Length(s)	Working Length (cm)	Needle Depths (mm)	IVUS MHz/Elements	Needle exits ___mm proximal IVUS transducer
6F	014 (Both) *OTW must be non-hydrophilic	190cm(Rx) 300cm(OTW)	120cm	3,5,7	20MHz 64 elements	7

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Pioneer Plus IVUS Guided Re-Entry Catheter procedure steps

VOLCANO

Pioneer Plus re-entry Catheter

STERILE CONTENTS

- Pioneer-Plus re-entry catheter
- Large sterile PIM drape (on inner box wall)
- Small 2x2 plastic bag for IVUS connector
- White "winged" RX flush adapter

*Requires (2) **NON**-hydrophilic 300 x .014 wires*
Suggest Miracle Bro or Grand Slam wires

PIONEER PREP

1. **Place 2x2 bag over IVUS connector**
2. **Attach "winged" adapter to 10cc syringe and flush RX lumen tip**
3. **Attach a Tuohy-Borst to proximal luer on Pioneer handle and flush needle lumen**
4. **Dry-Fire needle (confirm it's working)**
   Remove catheter from plastic hoop. Set needle stop (red collar) to '7', unlock blue deployment collar (a right ¼ turn) and deploy needle with quick continuous fwd thrust until Blue collar hits Red collar
5. **Create "wire-tip-bend" on needle wire**
   insert 300 cm NON-hydrophilic wire into proximal needle lumen, advance out deployed needle tip, put 90° bend on the wire tip, retract needle, then retract wire & re-flush lumen.

IVUS PREP

1. **Power On** *(system takes couple min to boot)*
2. **Enter patient info** *(Patient ID# is the minimum info required to save procedure data)*
3. **Place sterile cover over PIM**
4. **Connect Pioneer connector to PIM** *(IVUS screen indicates catheter is detected)*
5. **Press ChromoFlo button on console to activate ChromoFlo feature**

GENERAL INFO

- Only use 300 x .014 ***NON***-hydrophilic wires
- "**Needle in > Wire in**" (Always retract needle *before* retracting needle-wire)
- "**Needle out > Wire out**" (Always deploy needle *before* advancing needle-wire)
- **Needle Deployment** (Always use a firm continuous motion - do not pause)
- For easier advancement, under fluoro, ensure the curved needle housing is aligned with curve of the bifurcation
- After using Pioneer for re-entry, keep in sterile field - can still be used as standard IVUS catheter during procedure

VOLCANO

Pioneer-Pus re-entry Catheter

PROCEDURE STEPS

1. **Backload Pioneer over subintimal .014 wire and advance to sheath**
   If resistance, wipe down wire or flush RX lumen

2. **Advance Pioneer beyond lesion**
   Align curve of needle with curve of aortic bifurcation
   Slight rotation of Pioneer or balloon pre-dilatation may be needed when advancing into subintimal space

3. **Identify ChromoFlo image of true lumen, then rotate Pioneer so true lumen image is orientated to 12 o'clock location on IVUS screen**

4. **Under Floro, identify curvature of needle housing**

5. **Use gradicules on IVUS screen to aid in determining needle throw length**

6. **Set Red needle depth collar to desired depth, then rotate Blue deployment collar ¼ turn Rt. to unlock, then fully advance Blue collar in a single quick forward motion to deploying needle**

7. **Slowly advance guide wire, exiting needle and into true lumen**
   *If resistance, stop, retract needle **slightly** and try advancing wire again*
   *(If unsuccessful, then **fully** retract needle, then retract wire, then reposition Pioneer - and repeat step #5 again)*

8. **Once in true lumen, *fully retract needle* and remove (RX) subintimal wire**

9. **Disconnect Pioneer from PIM**

10. **While pinning true lumen wire, remove Pioneer off wire**
    Retract Pioneer using short smooth strokes (walking it off the wire). Ensure .014 wire remains in true lumen

    Proceed with intervention…

Pioneer Plus Catheter True Lumen Re-Entry Animation

Watch the Pioneer Plus Animation.

PHILIPS

Pioneer Plus IVUS Guided Re-Entry Catheter Certification Evaluation

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: _____

PHILIPS

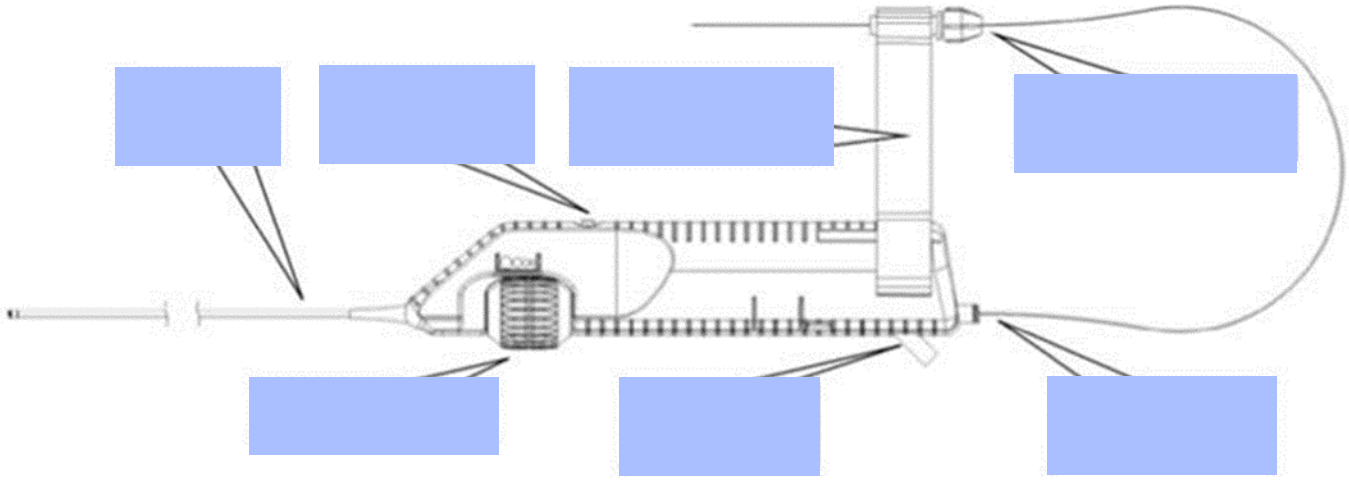
Phoenix Atherectomy System objectives

Clinical	Technical	Sales
1. Articulate Phoenix Atherectomy System Indications for Use. 2. Discuss Clinical Indications for Phoenix Atherectomy System. • Identify Competitors • Demonstrate knowledge of device performance compared to competition 3. Identify and discuss appropriate clinical applications of Phoenix Atherectomy System • Identify clinical scenarios that are inappropriate/ contraindicated 4. Complete Phoenix Atherectomy System inservice with assigned FST on the system and catheters. Be able to discuss: • Proper preparation, setup of catheters, and process to activate deflection • Identify the Components of Phoenix Atherectomy System • Describe mechanism of action • Describe the difference between Tracking and Deflecting Catheters 5. Observe 5 -7 Cases using Tracking Catheters and 2 cases using Deflecting Cases • Discuss clinical scenario of each case with FST.	1. Describe the product specifications and features of Phoenix Atherectomy System 2. Discuss and demonstrate Phoenix Atherectomy System device set-up, prep, deflection and case workflow. 3. Demonstrate knowledge of appropriate catheter sizing. • Identify recommend sheath 4. Demonstrate knowledge of Guidewire Management. • Identify compatible wires, length, size and coatings. • Proper insertion/removal of device.	1. Discuss key factors to successful Phoenix Atherectomy System launch strategy with Field Trainer: • Discuss setting appropriate expectations for physicians • Role play talk tracks • Practice objection handling • Discuss and demonstrate use of data 2. Discuss Competitive Positioning of Phoenix Atherectomy System against other atherectomy devices on the market: • What is unique to Phoenix Atherectomy System? • Articulate the value proposition of Phoenix Atherectomy System • Articulate the synergies of IVUS, Pioneer Plus, and our Therapies solutions. 3. Develop Launch plan with RSM: • Identify Targets within territory. • Refine talk tracks and objection handling. • Set-up account visits. • Initiate physician and staff product training via product demonstration.

Phoenix Atherectomy System specifications quiz

Review and practice identifying the components of the Phoenix Atherectomy System.

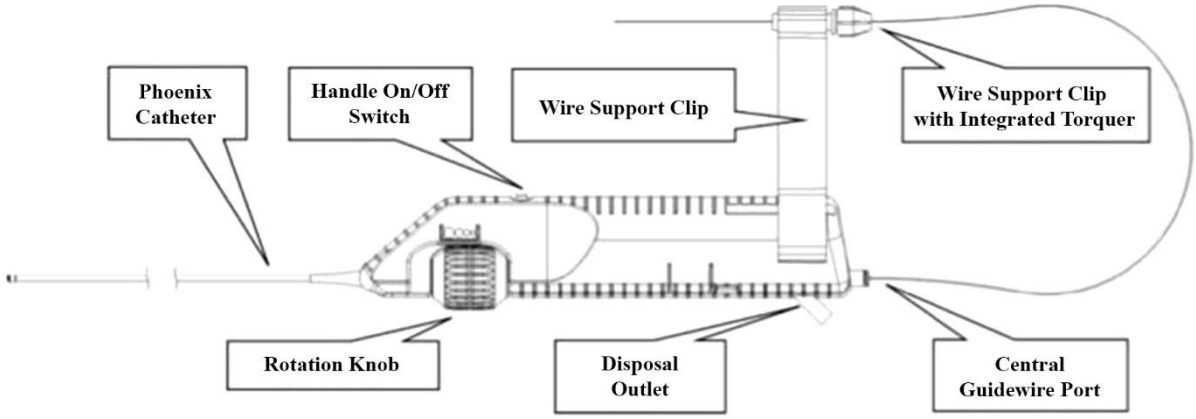
Label the components of the Phoenix Atherectomy Catheter System per IFU.



PHILIPS

Phoenix Atherectomy System specification answer key

Check your answers on the components of the Phoenix Atherectomy Catheter System.



The trainee should be able to verbalize the following:

Identify Indications per IFU

- ☐ The Phoenix Atherectomy System is intended for use in atherectomy of the peripheral vasculature.
- ☐ The Phoenix Atherectomy System is not intended for use in the coronary, carotid, iliac, or renal vasculature.

Device Description

- ☐ Phoenix system components include Atherectomy Catheter, Atherectomy Handle, Wire Support Clip and Disposal Bag. All system components are sterile, single-use devices designed for atherectomy of the peripheral vasculature
- ☐ The Phoenix Catheter is a flexible double-lumen catheter that contains a torque shaft that is attached to a metal cutting element at the distal tip and a centralized guidewire lumen. An Archimedes Screw is fixed on the outer surface of the torque shaft. The distal cutter head is a true front cutting design incorporating 2 helical shaped blades on the distal tip, 4 blades within the cutter head which further macerates excised plaque. When activated, the torque shaft rotates, causing the cutting element to cut, capture and continuously clear plaque through passive conveyance via the Archimedes Screw.
- ☐ The Phoenix Handle includes a battery – operated motor/handle that drives rotation of the cutter at a nominal speed of 10,000 to 12,000 RPM. The Phoenix System is activated by sliding the ON/OFF slider switch on the top of the Handle
- ☐ The Phoenix Wire Clip is an accessory which can help support and secure the guidewire position during the procedure.
- ☐ Phoenix Atherectomy Catheter sizes, lengths and sheath compatibility include:
  - 1.8mm tracking, 130 and 149cm, 5fr sheath
    - Minimum vessel diameter 2.5mm
  - 2.2mm tracking, 130 and 149cm, 6fr sheath
    - Minimum vessel diameter 3.0mm
  - 2.4 tracking, 130cm,7 fr sheath
    - Minimum vessel diameter, 3.0mm
  - 2.2mm deflecting, 130 cm,6 fr sheath
    - Minimum vessel diameter 3.0mm
  - 2.4mm deflecting, 127cm straight -125cm deflected, 7fr sheath
    - Minimum vessel diameter 3.0mm
- ☐ Catheter is OTW system
  - Accommodates 300cm 0.014” guidewires
  - Refer to approved guidewires listed on IFU

PHILIPS

Device Prep

- □ Confirm valid device expiration date
- □ Examine the packaging for cuts, tears, or other breach of the sterile barrier.
- □ Examine the Phoenix Atherectomy Catheter for bends, kinks or other damage.
- □ Examine the Handle for sign of damage.
- □ Turn ON the Handle and ensure that it can be activated. Do not use any defective equipment
- □ In a sterile fashion, open sterile packages containing Phoenix catheter, handle, wire support clip and disposal bag
- □ Priming the Phoenix Catheter
  - Attach 10cc syringe filled with heparinized saline onto the disposal outlet and flush slowly with gentle pressure until saline drips out of the guidewire port.
  - Cover the centralized guidewire port with a finger and continue to flush until saline drips out of the distal tip of the catheter
  - Attach handle
- □ Assembly of Phoenix Catheters
  - Remove white tape covering on/off switch
  - Snap catheter into handle matching “C” in handle with sweep knob
  - Verify that Catheter is completely inserted into handle, listen for 2 clicks
  - Snap handle on from front to back, remove from back to front
- □ Use of Wire Support Clip
  - Slide or snap 0.014 compatible torque device into Wire Support Clip
  - Snap Wire Support Clip onto handle
    - Feed the proximal end of the wire into the torque device and form a support loop of about 10-15cm that spans from the central guidewire exit port of the Catheter to the Wire Support Clip
    - Tighten the torque device onto the guidewire
    - Verify that the torque device does not spin in the Wire Support Clip. Replace torque device if it is not firmly secured in the Wire Support Clip
  - Attach disposal bag to disposal port
  - Post Procedure Flushing
  - **When removing device from patient, if additional use is remotely possible, submerge tip of catheter in heparinized saline and activate motor drive unit to flush debris from internal components. Avoid contact with bowl and contents within bowl.**
- □ Help prevent debris in internal components from clotting
- □ Debulked material will be forced out of Archimedes Screw into device catheter shaft and laser cuts. This can create perforations in catheter shaft PTFE coating

- **Verbalize:** If the Phoenix System is used to treat multiple lesions in the same patient, where the Catheter is removed and re-inserted through the Introducer Sheath, the Catheter must be flushed between re-insertions using the Catheter Preparation Method for System Test where the System is turned ON with the Catheter tip completely submerged in heparinized saline to actively clear blood and/or debris that may be within the catheter lumen.
  - It is important that we reinforce this more strongly because common practice is to flush lumen for all devices before going back in and we need to reinforce this message as the proper procedure is to flush.

Procedural Steps

- Insertion
  - Insert the appropriately –sized sheath with a cross cut hemostasis valve using standard techniques
  - Advance an approved 300cm 0.014" guidewire through the sheath beyond the lesion to be treated, taking care to remain intraluminal
  - Backload the end of the guidewire into the distal tip and out of the proximal end of the Phoenix Atherectomy Catheter guidewire lumen. Insert the distal tip of the Phoenix Atherectomy Catheter into the introducer sheath with the Phoenix System OFF until the tip exits the Introducer Sheath with the Phoenix System OFF until the tip exits the Introducer Sheath.
- Guidewire Preparation
  - While holding the guidewire stationary and using fluoroscopic guidance, advance the Phoenix Atherectomy Catheter distal tip over the guidewire to within a few millimeters proximal to the target lesion
  - Confirm that the guidewire is intraluminal. A second angiographic viewing angle to confirm wire placement is recommend
  - Confirm that the distal tip of the guidewire is positioned a minimum of 20cm from the distal tip of the Catheter
  - Apply torque device tightly to the guidewire approximately 20 cm to 30 cm from central guidewire port.
  - Monitor the smooth tracking of Catheter over guidewire during operation .If resistance is encountered during the procedure, remove Catheter and flush guidewire lumen by running the Catheter within a heparinized saline bowl where the System is turned ON with the Catheter tip completely submerged in heparinized saline to actively clear blood and/or debris that may be within the catheter lumen.
- Crossing the Lesion and Debulking
  - Under fluoroscopic guidance, turn ON the Phoenix Atherectomy Catheter using the switch on the Handle. Advance the Catheter slowly at a rate of 1mm/sec through the lesion. In highly stenotic lesions or lesions > 10 cm in length, periodically pause and withdraw the Catheter to allow improved blood flow and plaque removal during cutting. Continue to advance distal tip of Catheter until it has crossed the lesion

- The Phoenix Atherectomy System must remain ON to remove plaque
- Withdraw the Catheter until the distal tip is proximal to the lesion. Image the lumen and repeat cutting through the lesion if desired (Flush the catheter before repeating).

□ Phoenix Atherectomy Catheter Removal

- Removal of the Catheter should be accomplished by running the device off the wire in ON mode
- Use a standard over-the-wire guidewire management technique to remove the Catheter out of the sheath under fluoroscopic guidance.
- Utilize Wire Support Clip with torque device while removing Catheter to prevent wire spinning. Adjust position of torque device, while device is off, to feed wire into the handle until the Catheter tip exits the Introducer Sheath
- Turn OFF the Phoenix Atherectomy System with the switch on the Handle
- Perform a post- atherectomy angiogram

□ Debulking to Larger Diameter (Deflected Cutting) Phoenix 2.2mm Deflecting

- When moving to deflected cutting, the use of a flexible (“light”) guidewire allows maximum deflection of the Catheter tip. Exchange guidewire if desired.
- While holding the guidewire stationary and using fluoroscopic guidance, advance the Phoenix Atherectomy Catheter distal tip to within a few millimeters proximal to the target lesion.
- To Rotate: Adjust the position of the Catheter tip by turning the knob on the Catheter Handle clockwise or counterclockwise. As the knob is rotated, a tactile click will be felt by the user. A 360 degree rotation of the Catheter tip can be achieved with 24 clicks of the knob.
- Under fluoroscopic guidance, turn ON the Phoenix Atherectomy System.
- **Warning: When the catheter is deflected and the System is ON, do not leave the cutter head stationary or perforation may occur.**
- Advance the Catheter slowly and carefully while debulking. Always monitor the Catheter tip deflection position during cutting Rotate and/or reposition the Catheter tip as desired during cutting or between passes.
- The Phoenix Atherectomy System must remain ON in order to effectively remove plaque.
- Once the lumen is opened up to the maximum diameter desired, turn OFF the Phoenix Atherectomy System.
- Retract the Catheter at least 1 cm proximal to the lesion.
- Perform an angiogram to assess the lumen.
- Continue debulking if desired and reassess the lumen with an angiogram.

□ Debulking to Larger Diameter (Deflected Cutting) Phoenix 2.4mm Deflecting

- When moving to deflected cutting, the use of a flexible guidewire allow maximum deflection of the Catheter tip. Exchange guidewire if desired.
- While holding the guidewire stationary and using fluoroscopic guidance, advance the Phoenix deflecting Catheter distal tip to within a few millimeters proximal to the target lesion.

- To Deflect: Using the Slider, slide the Outer Sheath distal to increase deflection (bend tip) and backward to decrease deflection (straighten tip). The Slider features a trigger lock to maintain selected position.
- To Rotate: Adjust the position of the Catheter tip by turning the knob on the Outer Sheath clockwise or counter clockwise. As the knob is rotated, a tactile click will be felt by the user. 360-degree rotation of the Catheter tip can be achieved with 8 clicks of the knob. If there is resistance to rotating the tip, decrease deflection (straighten tip) prior to rotating and then re-adjust to desired deflection
- Under fluoroscopic guidance, turn ON the Phoenix Atherectomy System.
- **Warning: When the catheter is deflected and the System is ON, do not leave the cutter head stationary or perforation may occur.**
- The Catheter may be advanced and retracted while at a fixed deflection setting to debulk.
- Always monitor the Catheter tip deflection position during cutting, to ensure the setting does not need to be adjusted as debris is removed and there is less resistance to deflection.
- Rotate and/or reposition the Catheter tip as desired during cutting or between passes.
- If there is resistance to rotating the tip, decrease deflection (straighten tip).
- The Phoenix Atherectomy System must remain ON in order to effectively remove plaque.
- Once the lumen is opened up to the maximum diameter desired, turn OFF the System.
- Retract the Catheter at least 1 cm proximal to the lesion.
- Perform an angiogram to assess the lumen.
- Continue debulking if desired and reassess the lumen with angiogram.

□ Phoenix Atherectomy Catheter Removal

- Stabilize the guidewire across the lesion, straighten the Catheter tip by sliding the Outer Sheath to the fully proximal position, and carefully remove the Catheter out of the sheath under fluoroscopic guidance using standard over- the wire technique.
- Hold the guidewire firmly during the Catheter removal process by manually securing the guidewire or securing (“locking”) a torque device to the guidewire.
- Removal of the Catheter should be accomplished by running the device off the wire in ON mode per the following steps:
  - Lock a torque device on the proximal end of the guidewire a distance back from the Introducer Sheath.
  - Hold the torque device manually or with the Wire Support Clip to prevent guidewire rotation and turn ON the Phoenix Atherectomy System using the switch on the handle
- Under fluoroscopy, remove the Catheter by feeding the wire into the handle until the Catheter tips exits the Introducer Sheath.
- Turn OFF the Phoenix Atherectomy System with the switch on the Handle
- Perform a post-atherectomy angiogram

Grade:_____ Pass:_____ Fail:_____
Trainer Signature:_____ Date:_____
Trainee Signature:_____ Date:_____

Comments:

PHILIPS

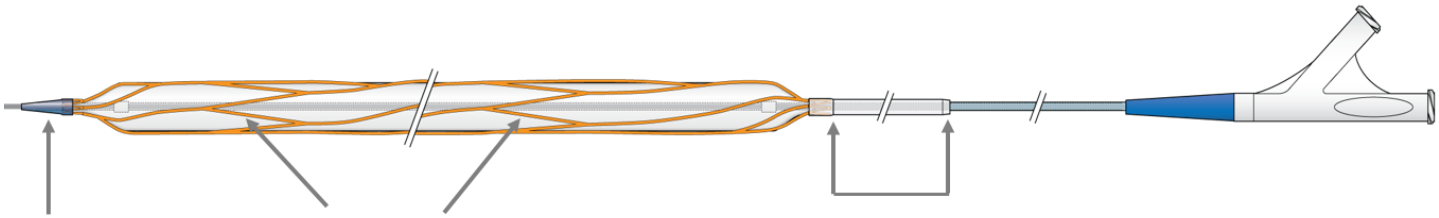
AngioSculpt & Stellarex objectives

Clinical	Technical	Sales
1. Articulate Indications for Use. 2. Discuss Clinical Indications for AngioSculpt and Stellarex. • Identify Competitors • Demonstrate knowledge of device performance compared to competition 3. Identify and discuss appropriate clinical applications of AngioSculpt and Stellarex. • Identify clinical scenarios that are inappropriate/ contraindicated 4. Complete AngioSculpt and Stellarex in-services with assigned FST. Be able to discuss: • Key talking points of the data and clinical studies • Reference key studies and important statistics • How each device works in calcium 5. Observe 2-5 Cases. • Discuss clinical scenario of each case with FST.	1. Describe the product specifications and features of AngioSculpt and Stellarex. 2. Discuss and demonstrate AngioSculpt and Stellarex device packaging considerations, prep and case workflow. 3. Demonstrate knowledge of appropriate device sizing. • Identify recommend sheath • Identify proper Stellarex overlap with use of multiple balloons 4. Demonstrate knowledge of Guidewire Management. • Identify compatible wires • Identify inflation hold times • Proper insertion/removal of device.	1. Discuss key factors to successful AngioSculpt and Stellarex launch strategy with Field Trainer: • Discuss setting appropriate expectations for physicians • Role play talk tracks • Practice objection handling • Discuss and demonstrate use of data 2. Discuss Competitive Positioning of AngioSculpt and Stellarex against other scoring devices/cutting balloons or DCBs on the market: • What is the value of each? • Articulate the value proposition of both AngioSculpt and Stellarex. • What makes our technologies • Articulate the synergies of IVUS, Pioneer Plus, and our Therapies solutions. 3. Develop Launch plan with RSM: • Identify Targets within territory. • Refine talk tracks and objection handling. • Set-up account visits. • Initiate physician and staff product training via product demonstration.

PHILIPS

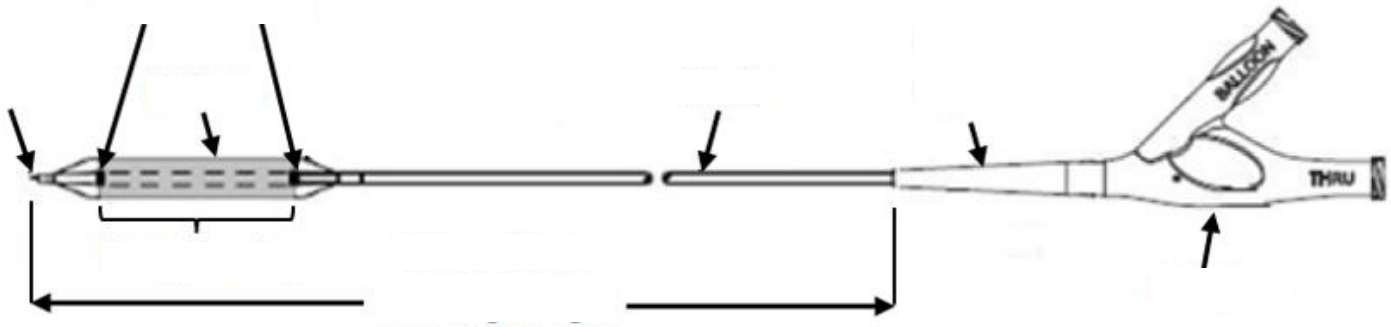
AngioSculpt specifications quiz

Label the components of the AngioSculpt catheter.

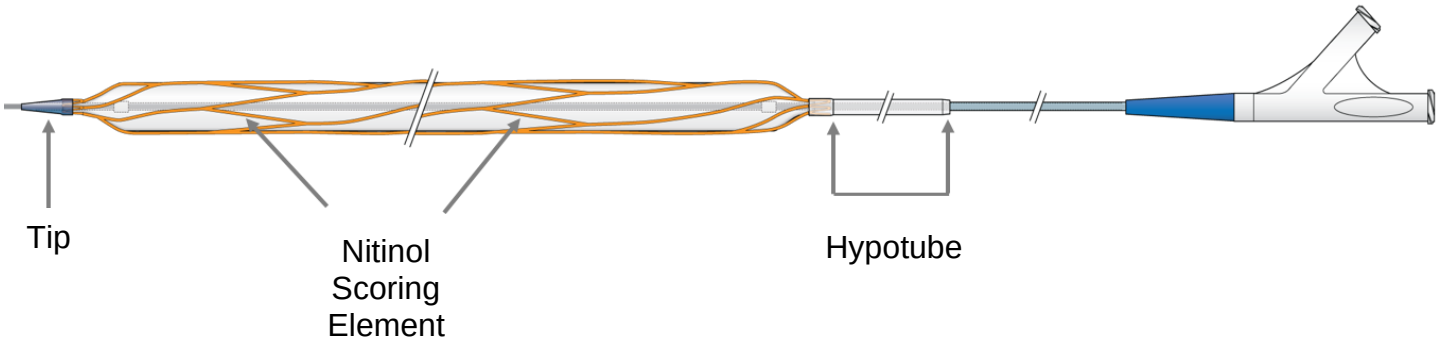


Stellarex specifications quiz

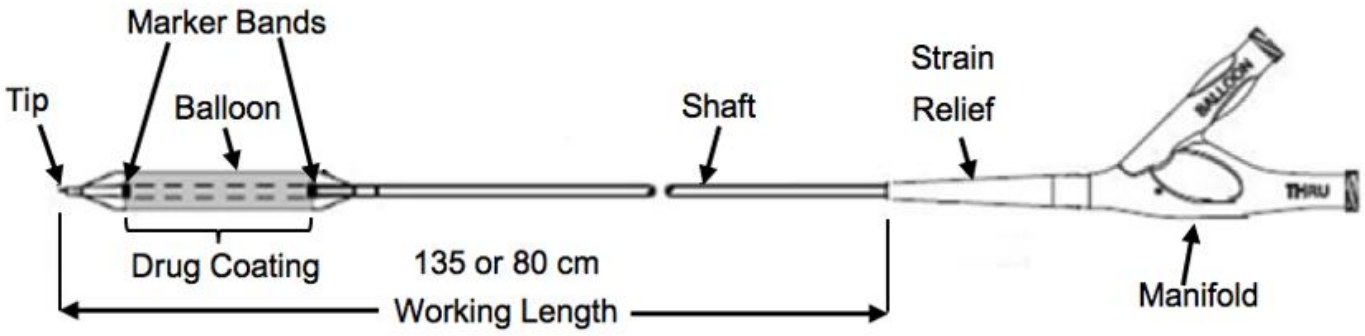
Label the components of the Stellarex catheter.



AngioSculpt Specifications answer key



Stellarex Specifications answer key



PHILIPS

Stellarex In-Service Checklist and IFU

INDICATIONS FOR USE AND MECHANISM OF ACTION

Indications for Use

1.	Percutaneous transluminal angioplasty after appropriate vessel preparation of de novo or restenotic lesions up to 180 mm in length in native SFA or popliteal arteries with reference diameters of 4-6 mm	

Mechanism of Action

1.	Mechanical dilatation of de novo or restenotic lesions by PTA and transfer of Paclitaxel drug to the vessel wall	
2.	Active drug inhibits restenosis caused by the proliferative response from vessel injury due to PTA	

PRODUCT FAMILIARIZATION

Carton, Labeling & IFU

1.	Outer Carton - Stellarex brand color is orange; green colored hexagon denotes 6Fr.	
2.	Sizing and SKU information is listed on the back and two sides of the spine; bar code is listed on the right spine only; 3 peel-off patient stickers on back; expiration date	
3.	IFU is located at www.spectranetics.com/IFU	

Balloon Components

4.	Catheter – 80 cm and 135 cm lengths to support all access approaches and to reach distal lesions; compatible with over-the-wire 0.035" guide wires; 135 cm working length	
5.	Semi-compliant balloon - for mechanical dilatation of de novo or restenotic lesions	
6.	Low entry profile tapered tip for high pushability and trackability through severely stenosed tortuous anatomy and previously deployed stents	
7.	Radiopaque Marker Bands – placed distally and proximally, indicates working length of balloon and facilitates fluoroscopic visualization during delivery and placement	
8.	Protective Sheath – protects drug-coated balloon prior to use	

Coating: EnduraCoat™ Technology

1.	Paclitaxel – is the active drug intended to inhibit restenosis; originally indicated for treatment of multiple cancers	
2.	Hybrid Paclitaxel - blend of amorphous and crystalline paclitaxel; low drug dose of 2µg/mm^2 and low particulate	
3.	Excipient – promotes adhesion and transfer of paclitaxel from the balloon to the vessel wall when exposed to blood	
4.	Polyethylene Glycol (PEG) – a hydrophilic polymer with a large molecular weight and mechanical properties for increased durability during handling, tracking and inflation	
5.	PEG may limit drug wash-out in calcified lesions due to its affinity to hydroxyl apatite	

Stellarex Balloon Sizes

1.	6 French introducer sheath compatible – sized for most SFA procedures	
2.	Balloon diameters: 4, 5, 6 mm; Balloon Lengths: 40, 60, 80, 120 mm	
3.	Nominal Pressure – the pressure that is needed to achieve the nominal diameter of the balloon when inflated	
4.	Rated Burst Pressure – high pressure for more challenging lesions; do not exceed RBP; refer to compliance card	
5.	Dose Density – multiple balloons with a total drug dose greater than 14,200 µg has not been evaluated	

PHILIPS

IMPORTANT SAFETY INFORMATION

Contraindications, Adverse Events, Warnings, Cautions and Precautions

1.	Refer to Stellarex IFU for full list	

PREPARATION

Balloon Prep

1.	Packaging and Labeling – single carton with two pouches; do not contact sterile field with either pouch	
2.	Use sterile gloves to handle DCB prior to use	
3.	Remove inner Tyvek pouch from outer foil pouch and carton, remove hoop and then catheter	
4.	Remove and discard protective sheath from balloon; avoid fluid contact with coating	
5.	Flush guidewire with saline though the lumen marked "THRU"	
6.	Evacuate air from balloon by attaching syringe to lumen marked "BALLOON"	

Sizing to Lesion

1.	Select the appropriate Stellarex DCB size for the lesion: nominal balloon diameter should match the diameter of the vessel distal to the lesion; balloon length must exceed the lesion by 5mm on each end	
2.	Refer to nominal and rated burst pressures to size to vessel	
3.	If lesion is longer than longest Stellarex DCB, use multiple Stellarex DCBs; overlap balloons 10mm	
4.	Approved to treat lesion lengths of up to 180mm	

PROCEDURE

Insertion, Dilatation, and Removal

1.	Place guidewire; if needed, first cross lesion with Quick-Cross™ Catheter or similar	
2.	Choose appropriate vessel prep for lesion (e.g. PTA, Laser Atherectomy, AngioSculpt® Scoring Balloon)	
3.	Introduce Stellarex through 6 French sized introducer sheath and guidewire; advance to lesion	
4.	Use marker bands to position balloon at treatment area	
5.	Inflate balloon for at least 60 seconds per compliance chart—do not exceed RBP; longer dilation times may be optimal – greater than 3 minutes was typically used in the ILLUMENATE Pivotal clinical study	
6.	Deflate balloon, apply negative pressure and withdraw catheter	
7.	Do not reinsert; dispose of according to accepted medical practice	

ILLUMENATE Trials: Patency and CD-TLR

1.	Patency = length of time an artery maintains efficient blood flow after DCB treatment (absence of target lesion restenosis determined by duplex ultrasound peak systolic velocity (PSVR) of ≤ 2.5 and freedom from clinically-driven target lesion revascularization)	
2.	Stellarex has the highest reported patency at 1 year of any DCB RCT: 89% patency in common patients (KM estimate, EU RCT); 82.3% in complex patients (KM estimate, Pivotal); only DCB RCT studied in highly complex patients	
3.	Complex patients = highest percentage of female patients and patients with severe calcium, diabetes, renal insufficiency, and clinical obesity	
4.	Stellarex enrolled highest percentage of severely calcified patients in a DCB RCT after adequate pre-dilatation with PTA	
5.	Clinically Driven Target Lesion Revascularization (CD-TLR) = Treated lesion needs to be retreated for clinical reasons (showed a PSVR ≥ 2.5 by duplex ultrasound or >50% stenosis by angiography and had worsening in Rutherford classification or ABI (0.015))	
6.	Stellarex demonstrated top-tier CD-TLR as low as 5.9% (EU RCT); CD-TLR of 7.9% (Pivotal)	

PHILIPS

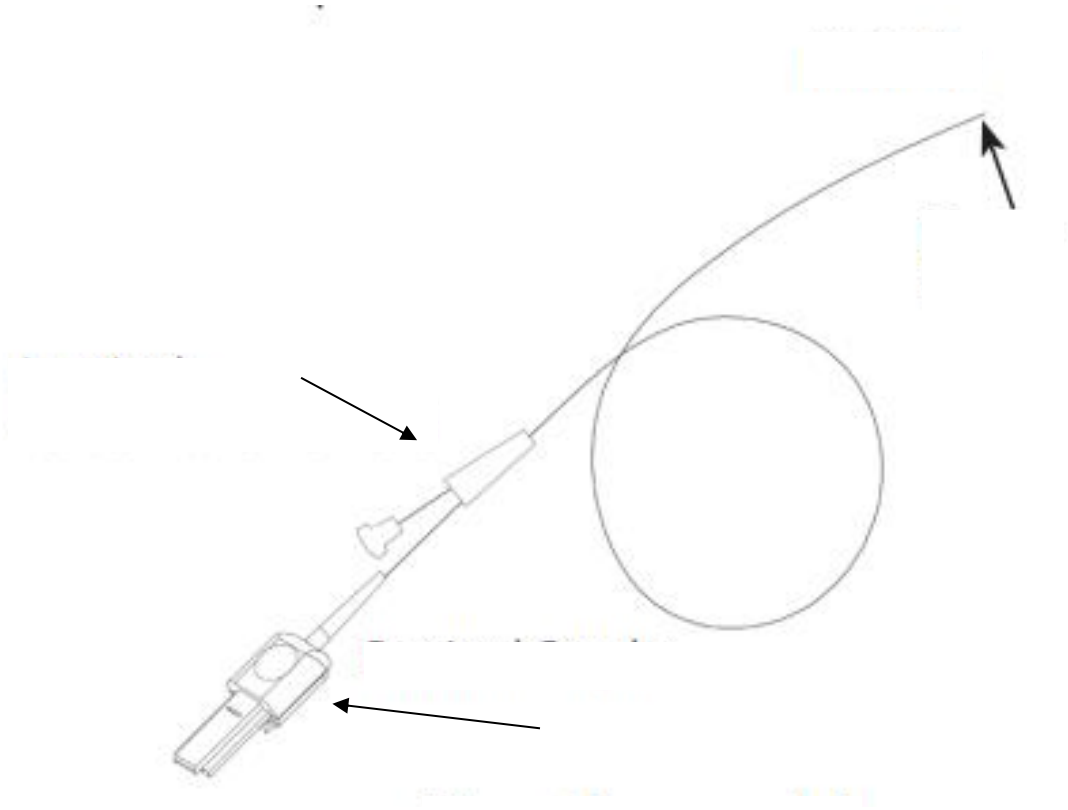
CVX-300 and Turbo-Elite & Turbo-Power objectives

Clinical	Technical	Sales
1. Articulate Indications for Use. 2. Discuss Clinical Indications for Turbo-Elite and Turbo-Power. • Identify Competitors • Demonstrate knowledge of device performance compared to competition 3. Identify and discuss appropriate clinical applications of Turbo-Elite and Turbo-Power. • Identify clinical scenarios that are inappropriate/ contraindicated 4. Complete CVX-300 with Turbo-Elite and Turbo-Power in-services with assigned FST on the system and catheters. Be able to discuss: • Proper catheter calibration and prep • Components of CVX-300 • Brief summary of what LASER is and how it works (LASER Science) 5. Observe 5 Cases. • Discuss clinical scenario of each case with FST.	1. Describe the product specifications and features of Turbo-Elite and Turbo-Power. 2. Discuss and demonstrate CVX-300, Turbo-Elite and Turbo-Power device set-up, prep and case workflow. 3. Demonstrate knowledge of appropriate catheter sizing. • Identify recommend sheath 4. Demonstrate knowledge of Guidewire Management. • Identify compatible wires, length, size and coatings. • Proper insertion/removal of device.	1. Discuss key factors to successful CVX-300, Turbo-Elite and Turbo-Power launch strategy with Field Trainer: • Discuss setting appropriate expectations for physicians • Role play talk tracks • Practice objection handling • Discuss and demonstrate use of data 2. Discuss Competitive Positioning of Turbo-Elite and Turbo-Power against other atherectomy devices on the market: • What is the value of LASER atherectomy? • Articulate the value proposition of Turbo-Elite and Turbo-Power. • Articulate the synergies of IVUS, Pioneer Plus, and our Therapies solutions. 3. Develop Launch plan with RSM: • Identify Targets within territory. • Refine talk tracks and objection handling. • Set-up account visits. • Initiate physician and staff product training via product demonstration.

PHILIPS

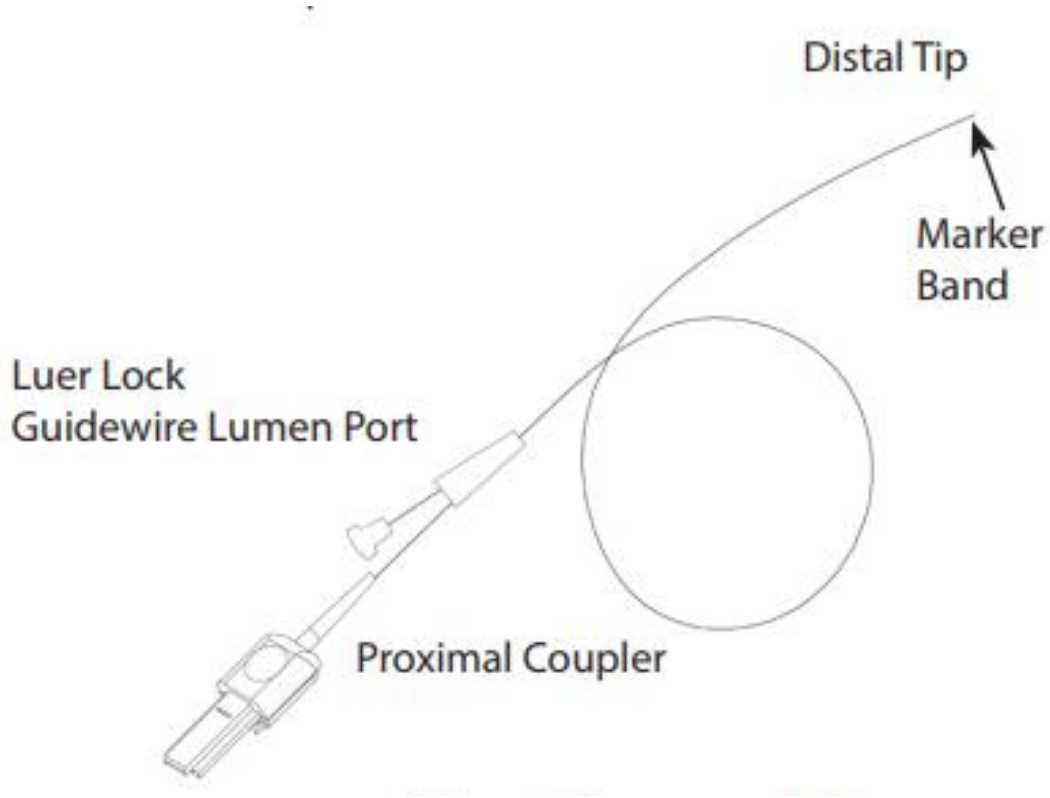
Turbo-Elite OTW specifications quiz

Label the missing components.



PHILIPS

Turbo-Elite OTW specifications answer key



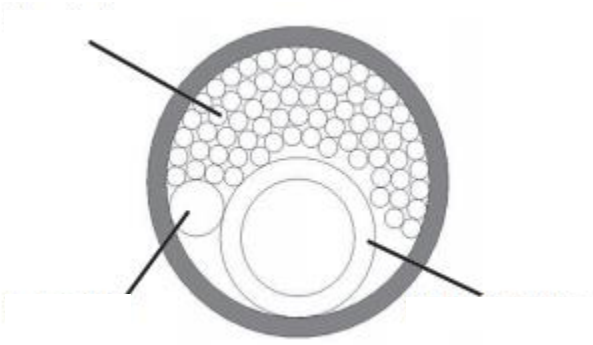
PHILIPS

Turbo-Power specifications quiz

Label the missing components.

Figure 1. Turbo-Power Laser Atherectomy Catheter

Figure 2. Turbo-Power User Interface

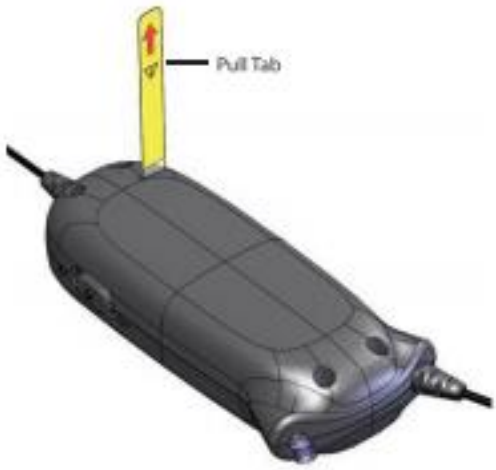


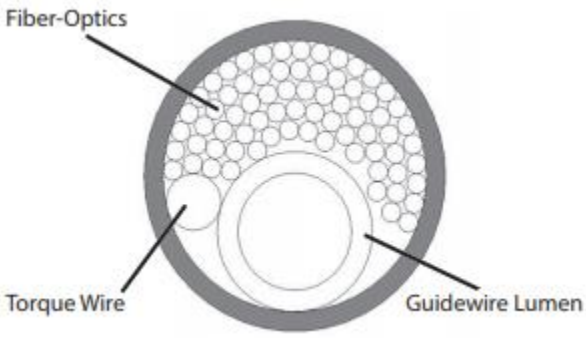
PHILIPS

Turbo-Power specifications answer key

Figure 1. Turbo-Power Laser Atherectomy Catheter

Figure 2. Turbo-Power User Interface





PHILIPS

Turbo-Elite sizes and specs

Fill in the Specs for Turbo Elite

OTW Turbo Elite Catheters

Catheter	0.9mm	1.4mm	1.7mm	2.0mm	2.3mm	2.3mm
Model #						
Minimum Vessel Diameter						
Max. Guidewire Compatibility						
Sheath Compatibility						
Working Length						
Fluence (mJ/mm^2)						
Rate (Hz)						

RX Turbo Elite Catheters

Catheter	0.9mm	1.4mm	1.7mm	2.0mm
Model #				
Minimum Vessel Diameter				
Max. Guidewire Compatibility				
Sheath Compatibility				
Working Length				
Fluence (mJ/mm^2)				
Rate (Hz)				

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Turbo-Elite sizes and specs answer key

OTW peripheral over-the-wire catheters

Catheter diameter	0.9mm	1.4mm	1.7mm	2.0mm	2.3mm	2.5mm	2.3mm	2.5mm
Model number	410-152	414-151	417-152	420-006	423-001	425-011	423-135	425-135
Vessel diameter	≥1.4mm	≥2.1mm	≥2.6mm	≥3.0mm	≥3.5mm	≥3.8mm	≥3.5mm	≥3.8mm
Max guidewire compatibility	0.014"	0.014"	0.018"	0.018"	0.018"	0.018"	0.035"	0.035"
Sheath compatibility	4F	5F	5F	6F	7F	8F	7F	8F
Max tip outer diameter	0.038"	0.055"	0.068"	0.080"	0.091"	0.101"	0.091"	0.101"
Max shaft outer diameter	0.047"	0.056"	0.069"	0.081"	0.091"	0.102"	0.091"	0.102"
Working length	150cm	150cm	150cm	150cm	120cm	110cm	125cm	112cm
Fluence (mJ/mm2)	30-80	30-60	30-60	30-60	30-60	30-45	30-60	30-60
Repetition rate (Hz)	25-80	25-80	25-80	25-80	25-80	25-80	25-80	25-80

RX peripheral rapid exchange catheters

Catheter diameter	0.9mm	1.4mm	1.7mm	2.0mm
Model number	410-154	414-159	417-156	420-159
Vessel diameter	≥1.4mm	≥2.1mm	≥2.6mm	≥3.0mm
Max guidewire compatibility	0.014"	0.014"	0.014"	0.014"
Sheath compatibility	4F	5F	6F	7F
Max tip outer diameter	0.038"	0.057"	0.069"	0.080"
Max shaft outer diameter	0.049"	0.062"	0.072"	0.084"
Working length	150cm	150cm	150cm	150cm
Fluence (mJ/mm2)	30-80	30-60	30-60	30-60
Repetition rate (Hz)	25-80	25-80	25-80	25-80

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Turbo-Power sizes and specs

Fill-in the missing information.

6Fr Turbo Power

Feature	Dimension
Working length	
Wire Compatibility	
Sheath Compatibility	
Laser Catheter	

7Fr Turbo Power

Feature	Dimension
Working length	
Wire Compatibility	
Sheath Compatibility	
Laser Catheter	

PHILIPS

Turbo-Power sizes and specs answer key

Turbo-Power 6Fr

Feature	Dimension
Working length	150cm
Wire Compatibility	0.018" (0.46mm)
Sheath Compatibility	6F
Laser Catheter	2.0mm Over The Wire (OTW)

Turbo-Power 7Fr

Feature	Dimension
Working length	125cm
Wire Compatibility	0.018" (0.46mm)
Sheath Compatibility	7F
Laser Catheter	2.3mm Over The Wire (OTW)

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CVX-300 In-Service Checklist

Safety

☐ Laser signs

- Post laser "Danger" warning signs on all entrances to the room where the laser system is being used.
- Signs have the following information:
  - Visible and invisible laser radiation
  - Avoid eye or skin exposure
  - Eye protection required
  - 308 nm Excimer Laser - Class IV Laser
  - 670nm Diode Laser – Class IIIa
- Signs can be ordered from Customer Service.

☐ Eye Protection

- Protective laser safety eyewear will always have the Optical Density (OD) rating at a specific wavelength or range of wavelengths printed on the lens.
  - An OD rating of at least 5 at 308nM is required when operating the CVX-300.
  - Philips laser eyewear has an OD rating of 9+ and can be ordered from Customer Service, part number 4110-0223.
- Everyone in the room including the patient must wear the appropriate laser safety eyewear at all times when in the operating room or cath lab.
- The red aiming laser is a class IIIa laser and does not require any additional eye protection.

Set-Up

☐ Moving the CVX-300

- The CVX-300 is heavy. Use caution when moving the system to avoid injury to you and others around you.
- Use the rear handle and/or front hand inserts when moving the CVX-300.
- Do not attempt to lift the system with the rear handle.
- Avoid jarring the CVX-300 or running it into walls or other equipment. Move the laser system slowly over bumps such as elevator thresholds.
- Always disconnect and store the footswitch when moving the CVX-300.
- Always ensure the power cord is disconnected from the wall and properly stored before moving the CVX-300.
- Once the CVX-300 is in the required location lock the front wheels using the foot brake located in the front of the laser system.

☐ CVX-300 Power-Up

- Power cord connected to wall receptacle, main circuit breaker in ON position, interlock plug installed
  - Ensure the power cord strain relief on the CVX-300 is locked into position.
  - Safely route the power cord to eliminate tripping hazards.
- On initial power up the CVX-300's display panel will:
  - Complete a lamp test
  - Indicate the software version in the display window
  - Complete a self-test (approx. 30 seconds)
  - Count down of the 5:00 minute warm-up starts

☐ Footswitch Connection

- Connect the footswitch to the connector located at the rear of the CVX-300.
  - Align the red dot on the footswitch connector and the red dot on the footswitch receptacle then insert.

☐ Warm-Up Mode

- The CVX-300 requires a 5:00 minute warm-up in order to operate properly.
- If the laser system is accidentally turned off, the warm-up mode can be by-passed if the laser system has already completed an initial 5:00 minute warm-up and was without power for less than 30 seconds before power was turned back on.
  - To by-pass the warm-up mode, allow the system to complete the self-test mode and re-enter the 5:00 minute warm-up, then simultaneously depress the Standby and Reset buttons. The Warm-Up lamp will turn out.

Catheter Calibration

☐ The front surface of the energy detector can be cleaned using an alcohol prep.

☐ Catheter Connection

- Open the catheter connection door. Raise the energy detector if using a CVX-300-P.
- Insert the proximal end of the catheter completely.

☐ CVX-300 Operation Verification (Reference Catheter)

- Proper operation of the CVX-300 should be verified by calibrating the Reference Catheter prior to calibration of a clinical catheter(s). Follow the instructions to calibrate all catheters.

☐ Catheter Calibration

- After connecting the catheter, depress the Calibrate button, then aim the distal tip of the catheter at the center of the energy detector. Use the red aiming beam for centering.
- Using the catheter alignment guide, label distance the tip of the catheter between the min and max lines. Catheter should be pointed directly at the center of the detector and not at an angle.

- Depress the footswitch and hold it down until the CVX-300 automatically stops lasing and the Cal OK lamp illuminates.

Warning: System faults may occur during the procedure if the catheter is not perpendicular to and/or at the proper distance from the detector surface during calibration.

Operation

☐ Adjust the Fluence and Rate settings per the physician's instructions.

☐ Depress the Ready button.

- Depressing the footswitch will cause the CVX-300 to operate for a period of time, as described in the catheter's Instructions For Use (IFU).
- A wait period may be imposed at the end of a lasing train depending on the type of catheter; refer to the IFU. The footswitch must be released during the wait period.
    - An audible beep will be heard at the end of the wait period indicating the CVX-300 is ready to complete another lasing train.

☐ Pulses Delivered Counter

- Depressing the Pulses Delivered button will display the total number of pulses delivered during the procedure.
    - The total pulses will be stored in memory until a catheter is calibrated again or the system is turned off.
- The counter can be reset by simultaneously depressing the Pulses Delivered and Reset buttons.

☐ Treatment Time Counter

- Depressing the Treatment Time button will display the total lasing time delivered during the procedure.
    - The treatment time will be stored in memory until a catheter is calibrated again or the system is turned off.
- The counter can be reset by simultaneously depressing the Treatment Time and Reset buttons.

Troubleshooting

☐ CVX-300 will not turn on.

- Verify the power cord is properly connected to the CVX-300 and the wall receptacle.
- Verify the main circuit breaker on the CVX-300 is in the ON position.
- Verify the interlock plug is installed.
- Have the facilities bio-med department verify there is power at the wall receptacle.

☐ CVX-300 buzzes when plugged in and will not turn on.

- Release the red emergency button located on the rear of the CVX-300 by turning it clockwise.

☐ Fault Codes 1 – 4.

- Ensure the energy detector face is clean. Use an alcohol prep to clean.
- Ensure the distal tip of the catheter is clean and dry.
- Try to re-calibrate again.
  - If calibration is unsuccessful attempt to calibrate with the reference catheter first and then try the disposable catheter again.
  - If calibration is un-successful, turn the CVX-300 OFF and then ON again, by-pass warm-up and then attempt to calibrate the Reference Catheter. If successful, open a new clinical catheter. Record the Fault Code and report incident to Philips Customer Service.
  - If calibration of the Reference Catheter is unsuccessful, record the Fault Code and report the incident to Philips Customer Service.

☐ Fault Code 5.

- Remove the proximal end of the catheter from the CVX-300 and firmly reinsert.
  - If Fault occurs again, report incident to Philips Customer Service.

☐ Fault Codes 10 – 50.

- Turn the CVX-300 OFF and then ON again, by-pass warm-up and then attempt to calibrate the catheter. If calibration is successful, proceed.
- Record the Fault Code and report the incident to Philips Customer Service.

☐ Power Error lamp flashing or on continuously.

- Ensure that the 5:00 minute warm-up has been completed.
- Stop use of the CVX-300 and call Philips Customer Service so a service call can be scheduled.

CVX-300 Shutdown and Storage

☐ Press the Standby button.

☐ Turn the keyswitch to the OFF position

☐ Disconnect the catheter from the CVX-300.

☐ Disconnect the power cord from the wall receptacle.

- Wrap power cord around cord wrap on located at the rear of the CVX-300.

☐ Disconnect and store the footswitch in the front storage compartment.

☐ Clean the energy detector face with an alcohol prep.

☐ Lower the energy detector on a CVX-300-P. Close the catheter connector door.

☐ Cover the laser system.

PHILIPS

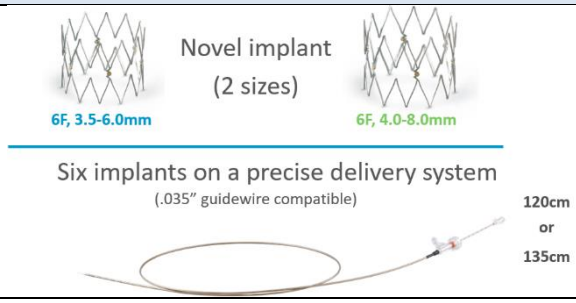
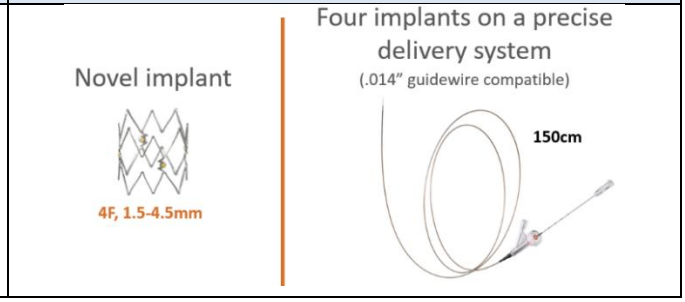
Tack Endovascular System In-Service Checklist

The trainee should be able to verbalize the following:

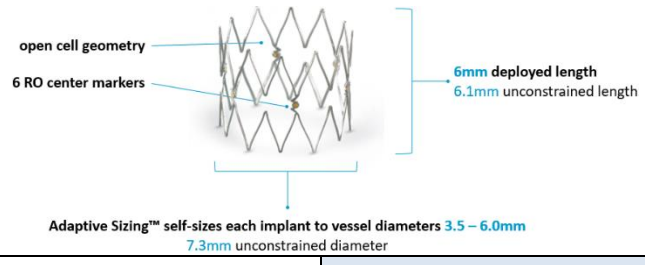
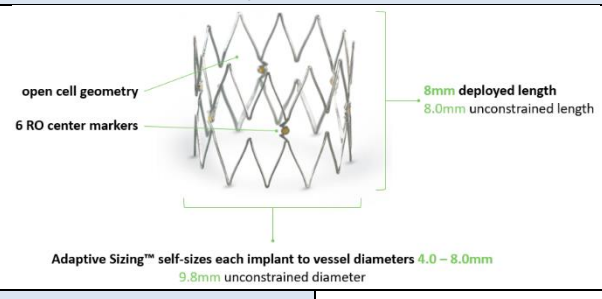
Tip to tail walk through on device

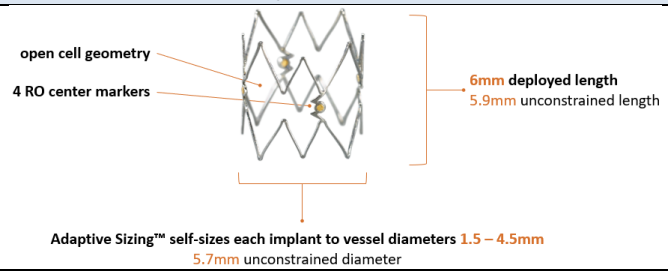
- □ All parts, markers, names, measurements, sizing, etc. Refer to product IFU.

Tack Endovascular System Components

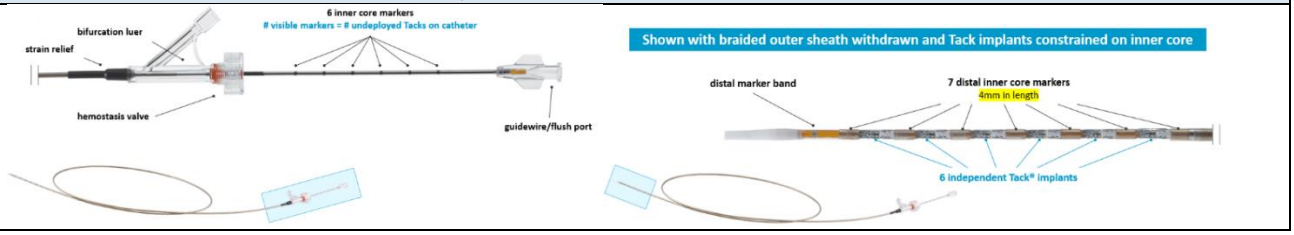
6F	4F
	

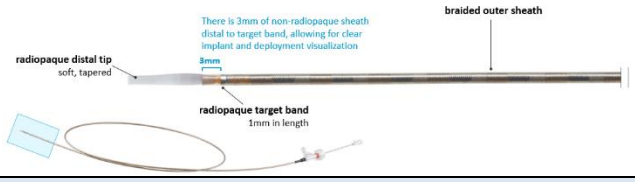
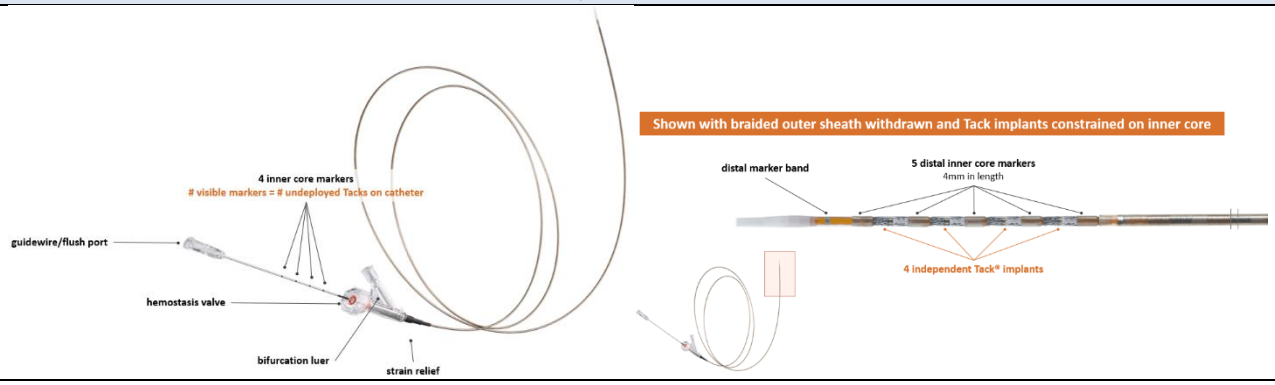
Tack Implant

6F, 3.5-6.0mm	6F, 4.0-8.0mm
	

4F, 1.5-4.5mm


Delivery System

6F, 3.5-6.0mm and 4.0-8.0mm


6F, 3.5-6.0mm and 4.0-8.0mm

4F, 1.5-4.5mm


Mark or identify areas to place Tack with physician

- □ Dry-erase on monitor, ruler, roadmap, dry-erase with IVUS catheter and/or ruler with IVUS catheter, etc.

Deploy 2 Tacks

- □ 1 regular “as-is” deployment
- □ 1 “custom-spaced” deployment (demonstrate ability to make slight adjustments to the system, positioning either slightly proximal or slightly distal (“dancing” for second deployment)
- □ Make appropriate target marks on demo deployment tube)

Demonstrate how to appropriately and completely re-sheath the device. Why is this important?

- □ Prevents accidental, unwanted deployment of additional Tacks

Identify when Tacks should be placed in the course of treatment in the case.

- □ We always want to Tack last
- □ We always want to Tack distal first, then work distal to proximal if more Tacks are needed
    - This is to minimize the chance that we need to cross fresh Tacks with devices to treat distal

Identify how to approach Tack in a dissection.

- □ Trailing edge, then middle area (if needed), then leading edge
- □ Work distal to proximal, based on access point

Should Tacks be overlapped?

- □ No. No benefit is gained in radial force, and the is possible increased risk for restenosis

List the key factors to post dilation.

- □ Mag up, go slow, and visualize balloon crossing each Tack
- □ Match balloon to guidewire

- □ Use a new balloon
- □ Post dilate with same size balloon as pre-treatment, utilizing same or reduced ATMs pressure

Describe what to do if the balloon looks to be contacting or moving the Tack.

- □ Stop
- □ Adjust wire bias
- □ Adjust balloon (rotation, etc)
- □ New balloon? Does balloon match guidewire?
- □ If Tacks look good/physician satisfied and not able to safely cross to post dilate, pass on post dilation

What do we do if Tack fails to resolve dissection and/or physician unsatisfied with result?

- □ Attempt to re-dilate Tacks if possible
- □ Attempt to re-dilate Tacks with larger balloon if possible
- □ Utilize a bail-out stent to address/cover Tack(s) in-question

Walk through the process for a live Tack deployment under fluoro video.

1. Play the Tack Deployment under fluoroscopy video.

2. Identify the following on the video
   - □ Distal marker band
   - □ Target band (on sheath)
   - □ Inner core markers, and how many are seen (3)
   - □ Tacks
   - □ Middle markers of Tacks

3. Talk through deployment on the video
   - □ Pull back of target marker band
   - □ Notes slow technique
   - □ Flowering of Tack (once target band has advanced to the next inner core marker)
   - □ When a Tack is fully deployed, and confirmed as deployed (previous Tack fully deploys once the target marker band is over the next Tack)

4. Click here to view the video answer key.

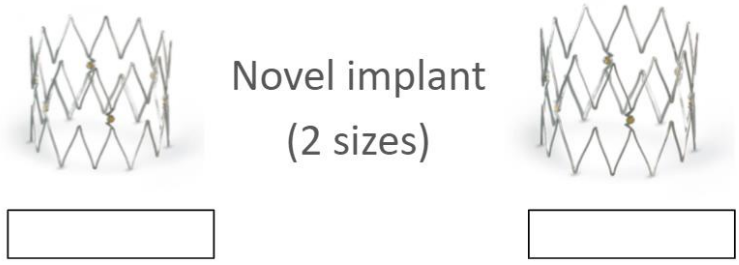
Practice Grade: ____ Pass: _____ Fail: _____

PHILIPS

Tack Endovascular System components quiz

Label the components.

Tack Endovascular System (6F) Components



intact vascular

MKT-0215 Rev04

Fill in the blanks.

Tack Endovascular System (6F) Components

intact vascular

MKT-0215 Rev04

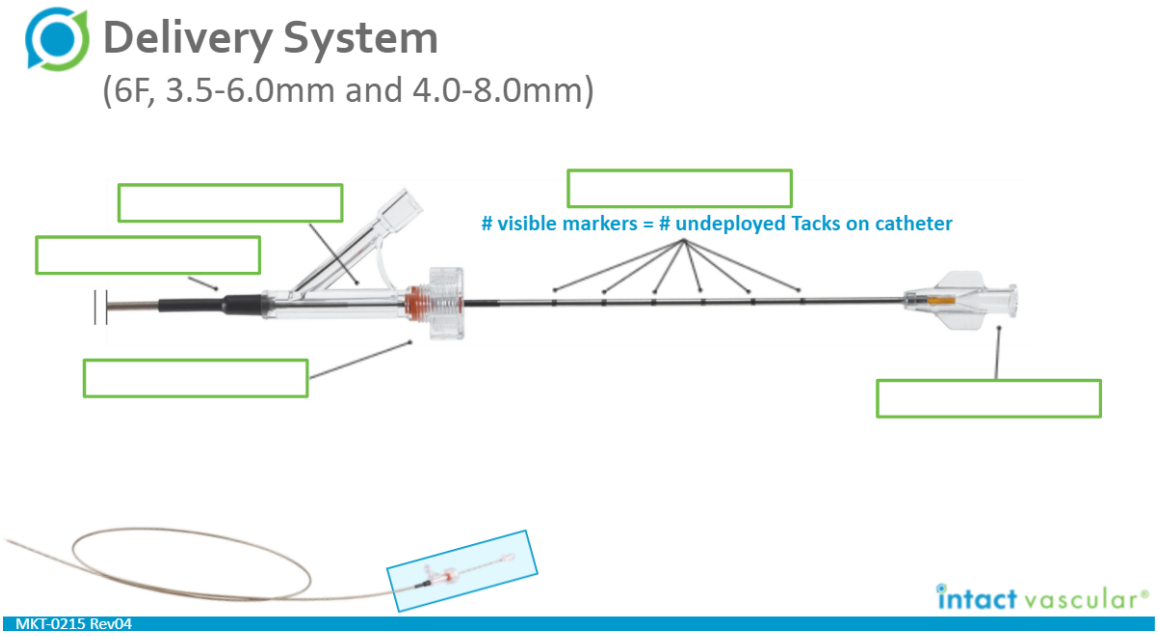
Tack Endovascular System components answer key

Check your answers.

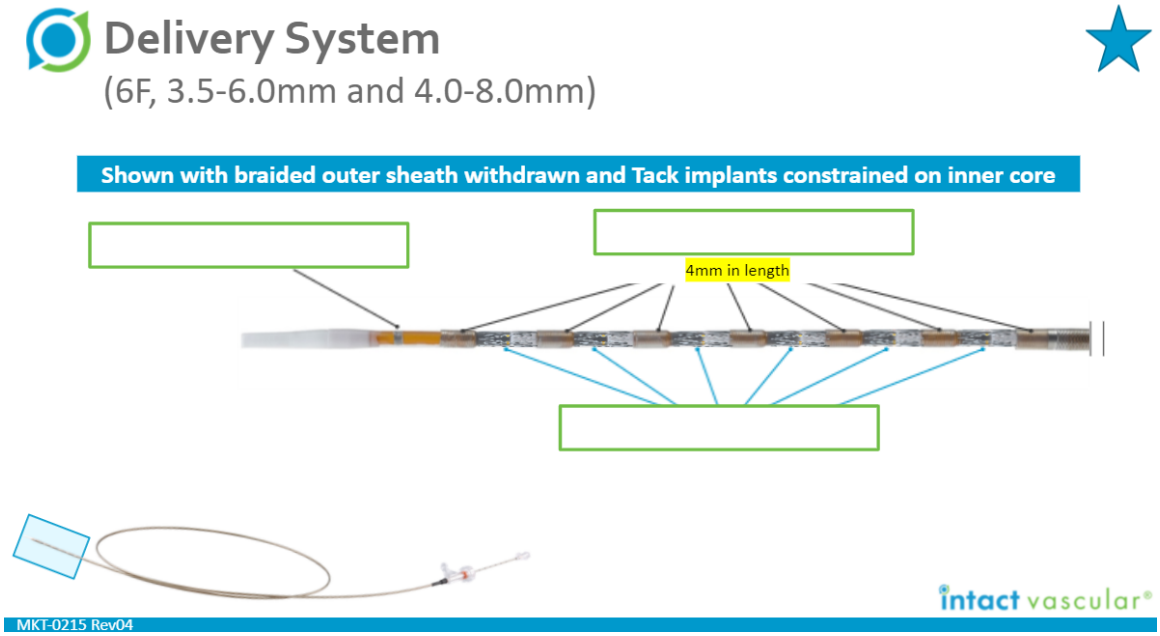
PHILIPS

Tack Endovascular System quiz

Label the components.



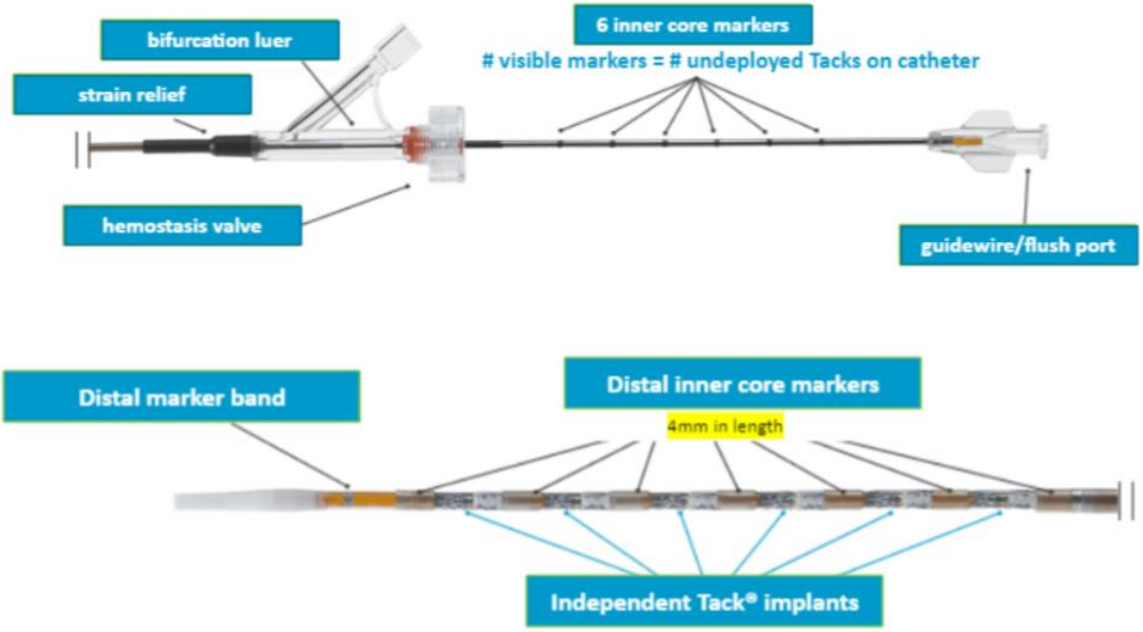
Label the components.



PHILIPS

Tack Endovascular System answer key

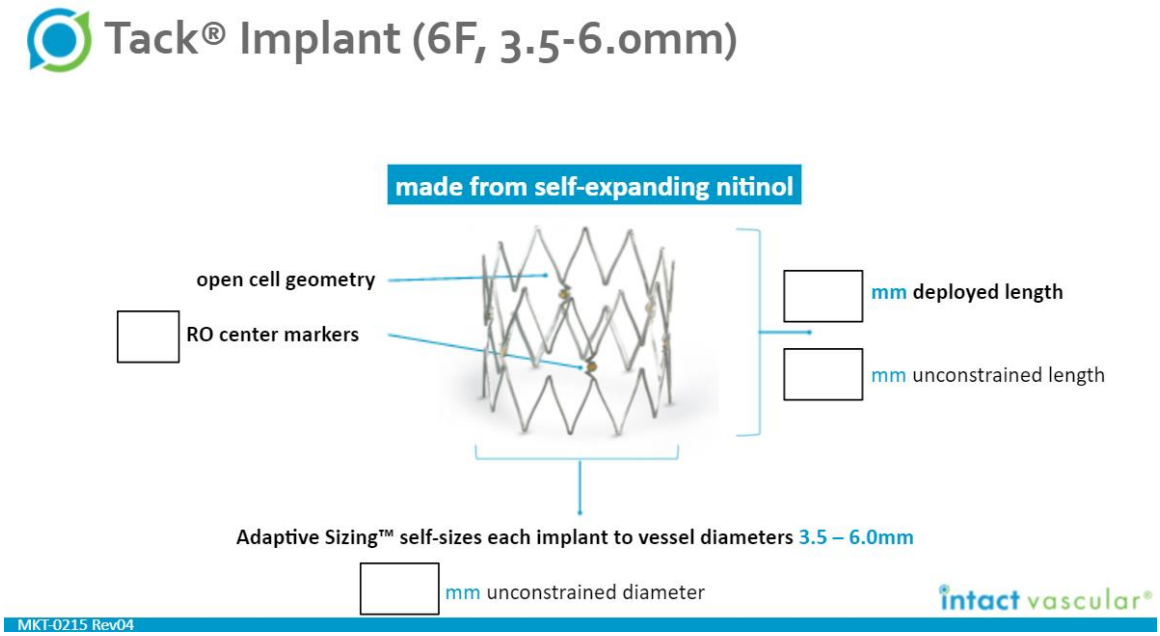
Check your answers.



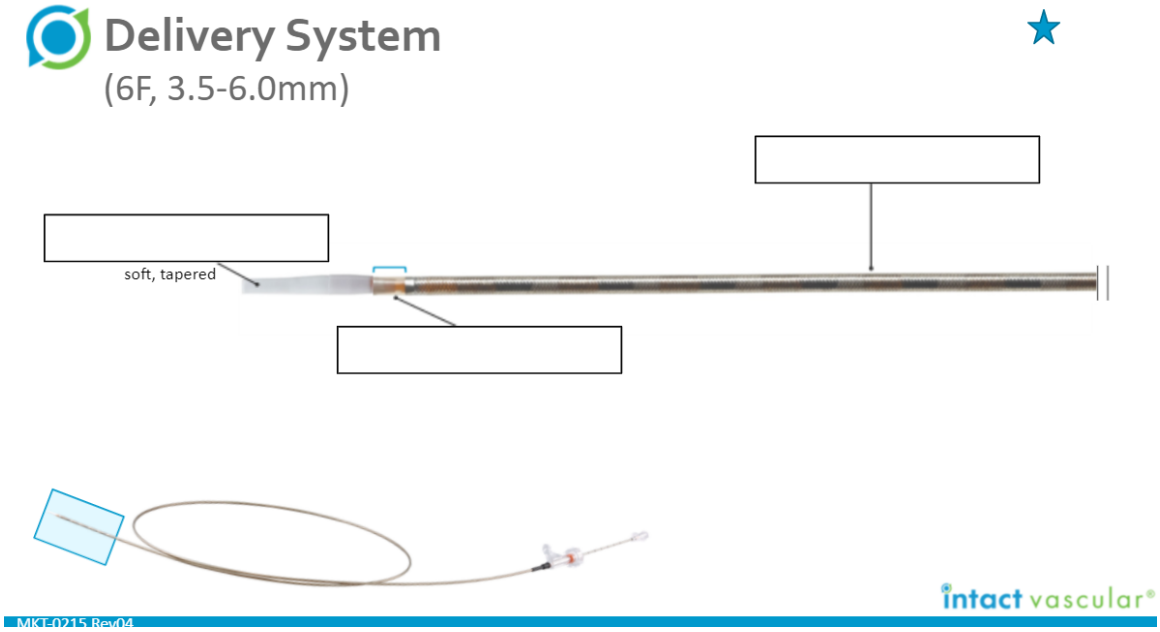
PHILIPS

Tack Implant (6F, 3.5-6.0mm) and Delivery System quiz

Fill in the blanks.



Label the components.



Select the best answer.

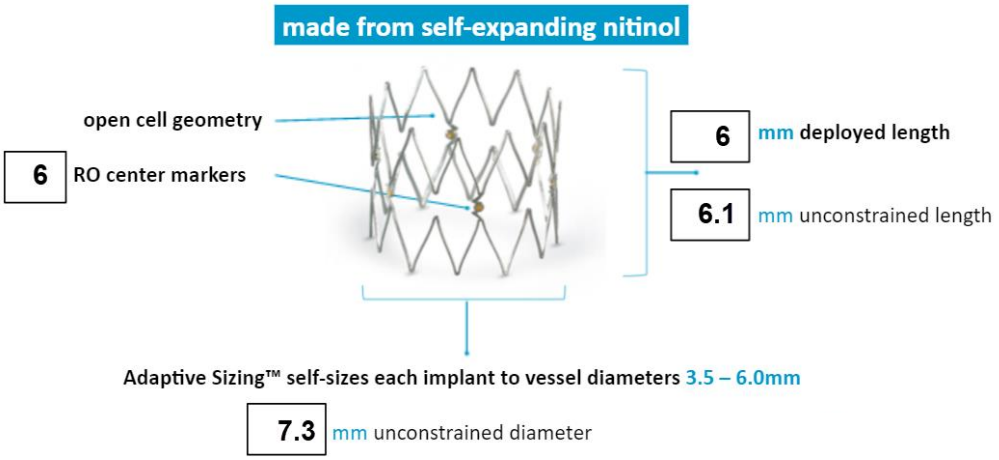
Delivery System
(6F, 3.5-6.0mm)

There is _____mm of non-radiopaque sheath distal to target band, allowing for clear implant and deployment visualization.

- 2mm
- 3mm
- 4mm
- 6mm

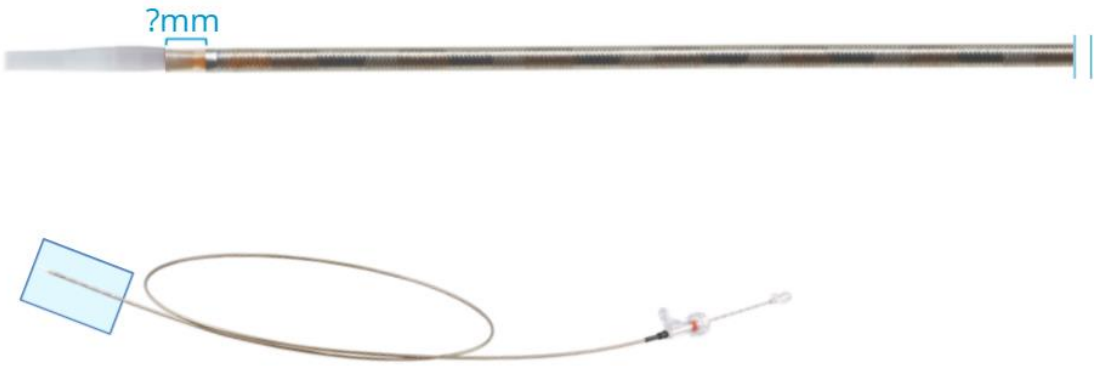
Tack Implant (6F, 3.5-6.0mm) and Delivery System answer key

Check your answers.



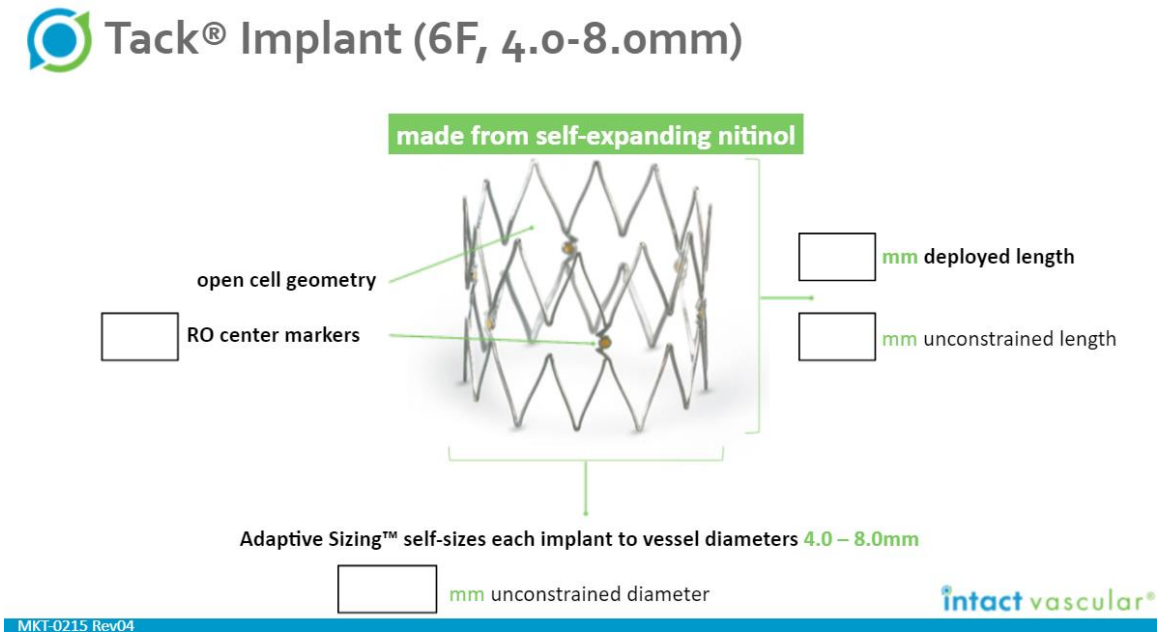
There is _____mm of non-radiopaque sheath distal to target band, allowing for clear implant and deployment visualization.

- 2mm
- 3mm
- 4mm
- 6mm

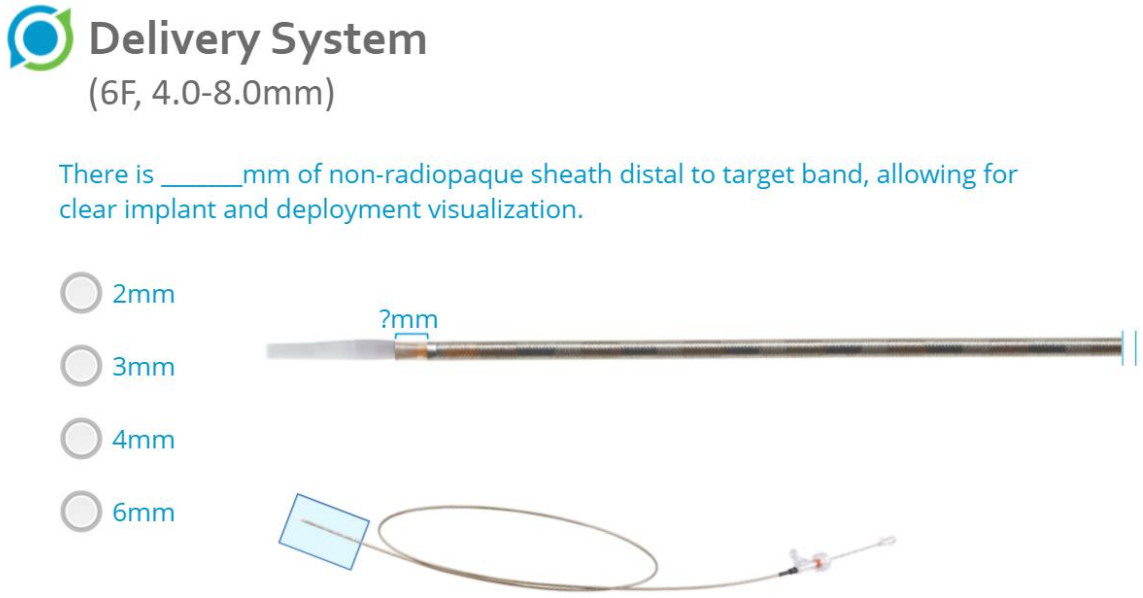


Tack Implant (6F, 4.0-8.0mm) and Delivery System quiz

Fill in the blanks.

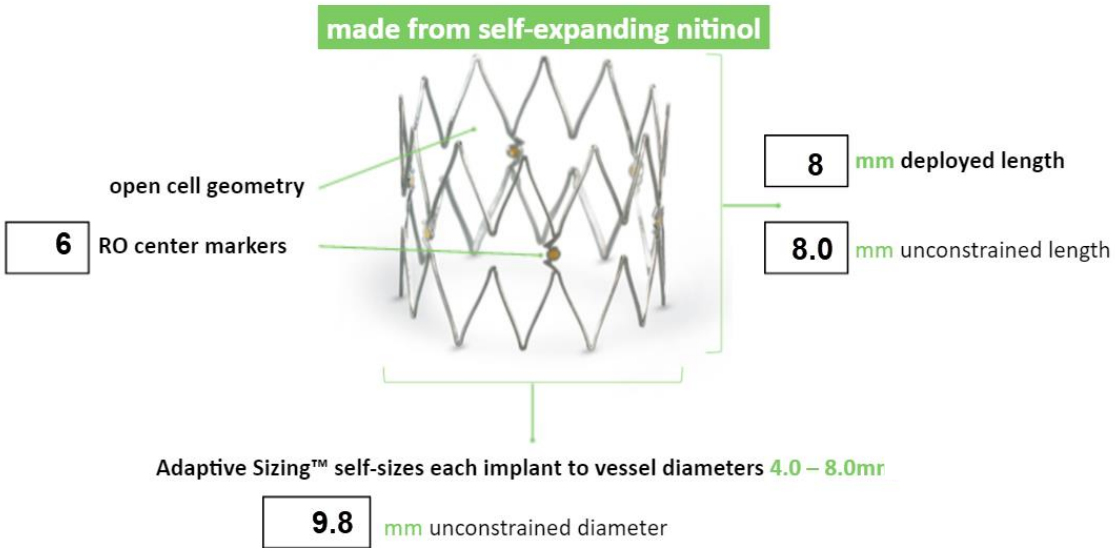


Select the best answer.



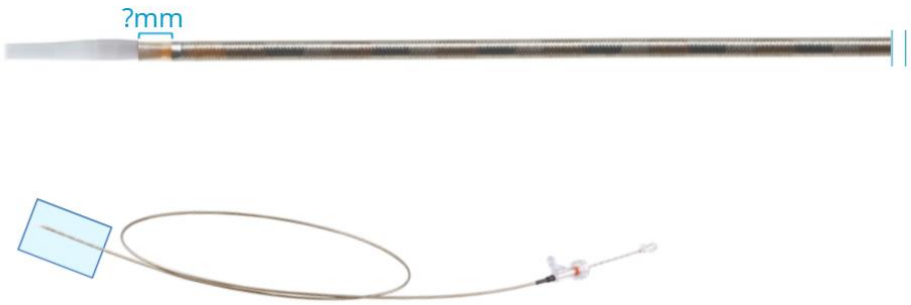
Tack Implant (6F, 3.5-6.0mm) and Delivery System answer key

Check your answers.



There is _____mm of non-radiopaque sheath distal to target band, allowing for clear implant and deployment visualization.

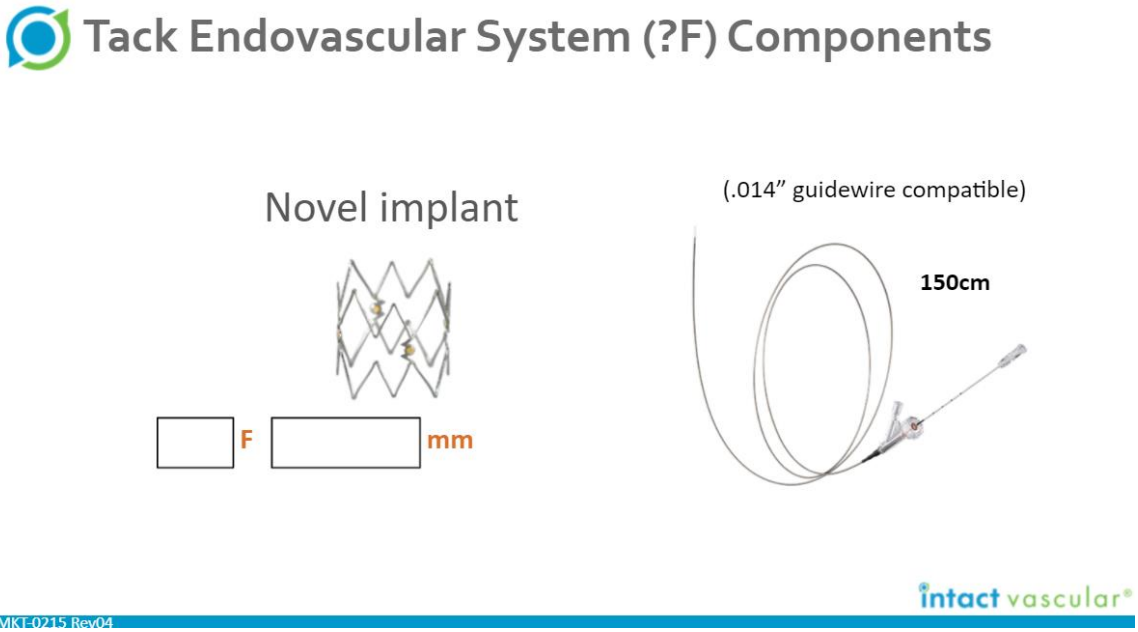
- 2mm
- 3mm
- 4mm
- 6mm



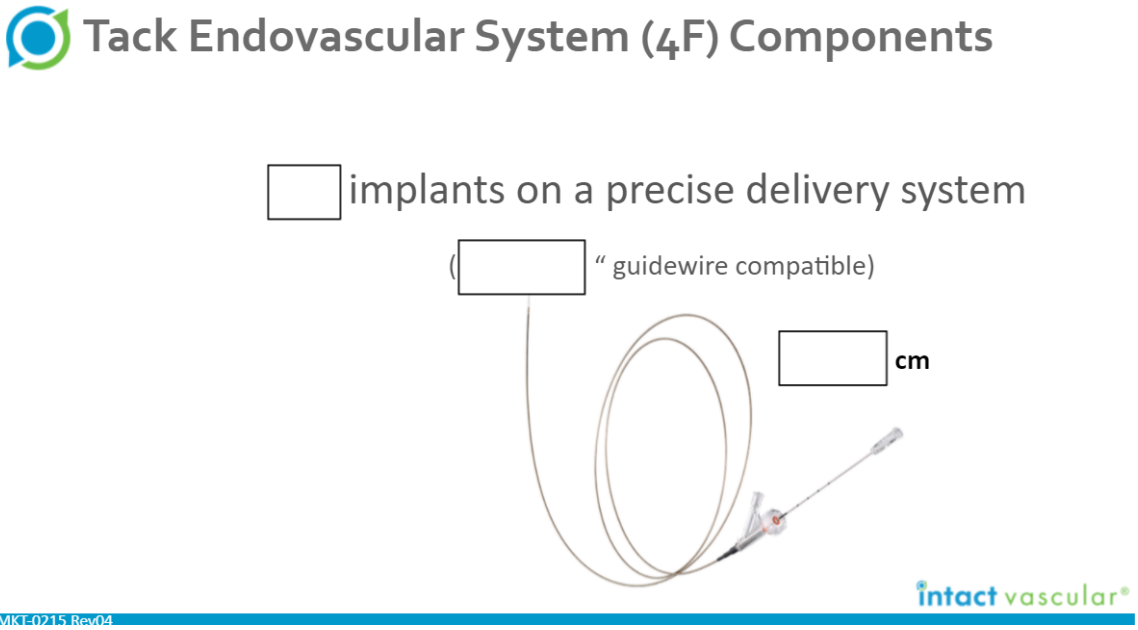
PHILIPS

Tack Implant (4F) and Delivery System components quiz

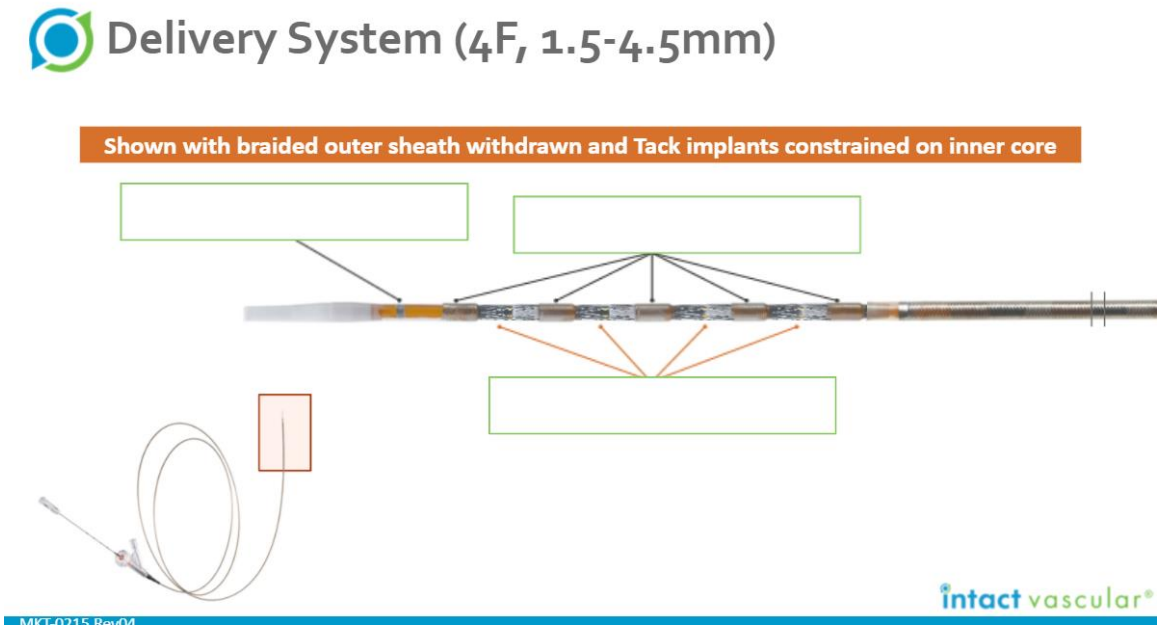
Fill in the blanks.



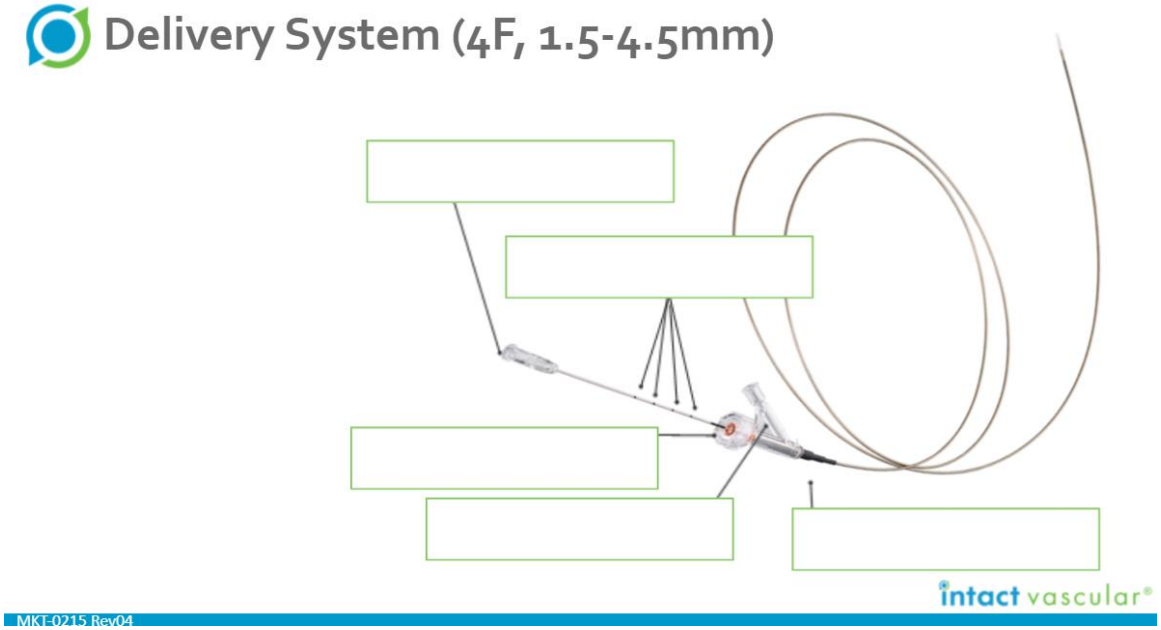
Fill in the blanks.



Label the components.

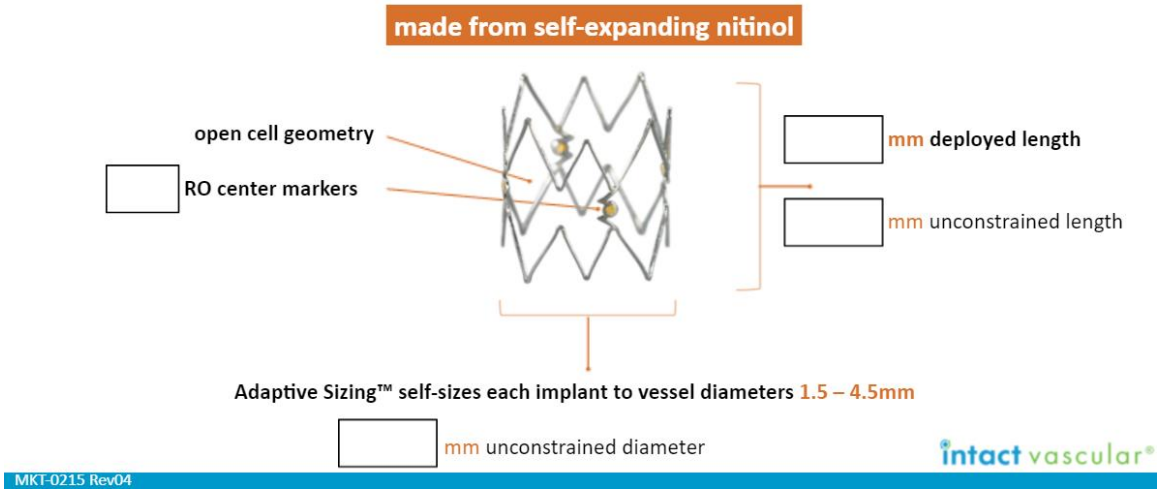


Label the components.



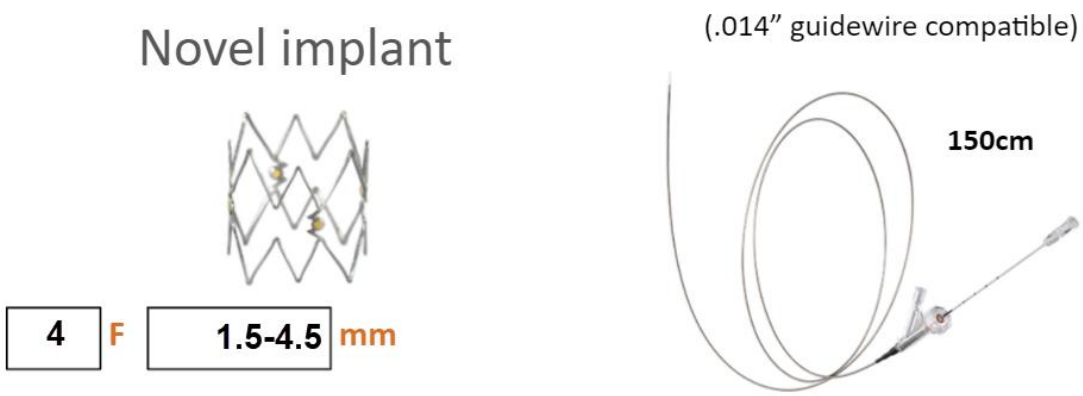
Fill in the blanks.

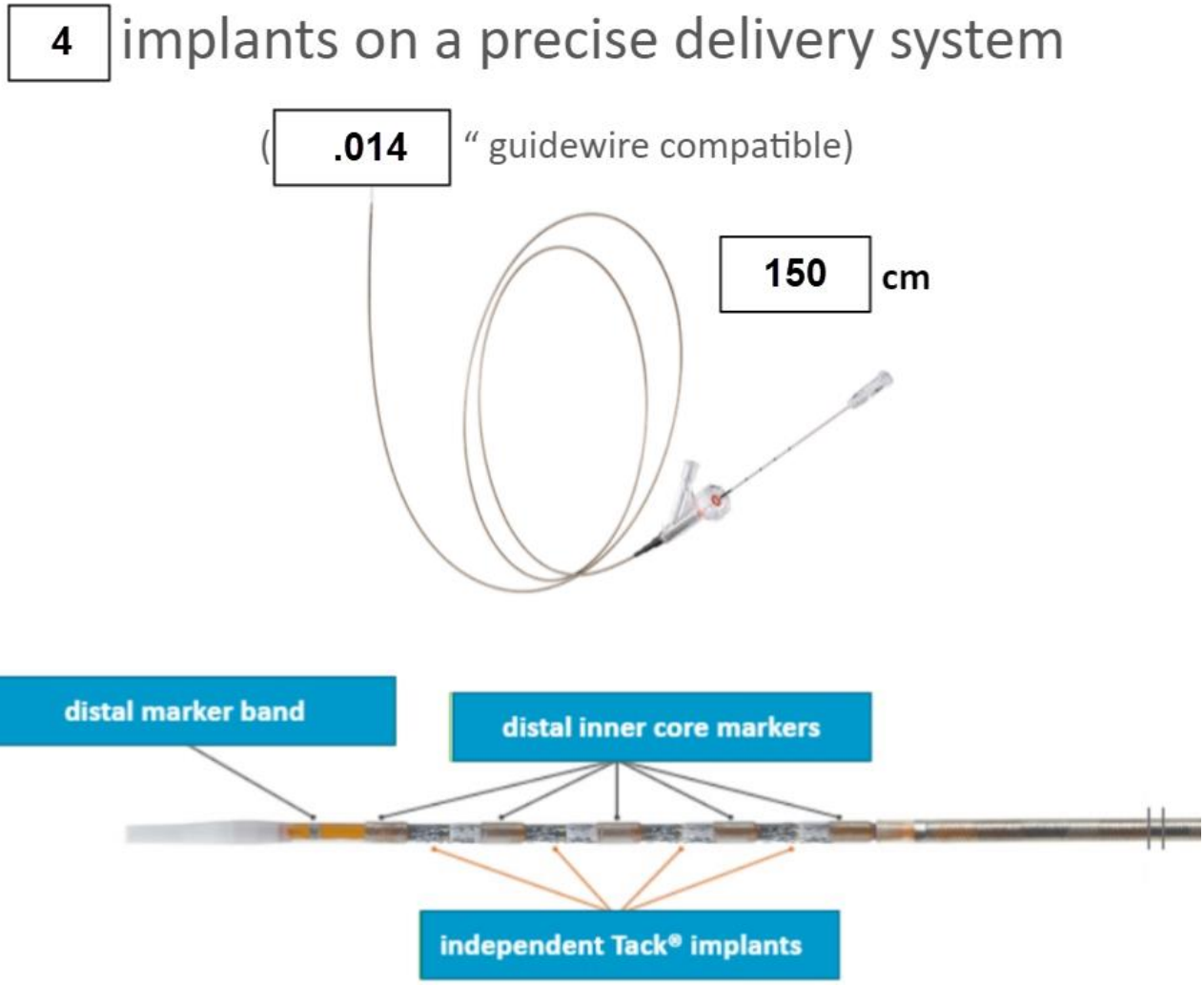
Tack® Implant (4F, 1.5-4.5mm)

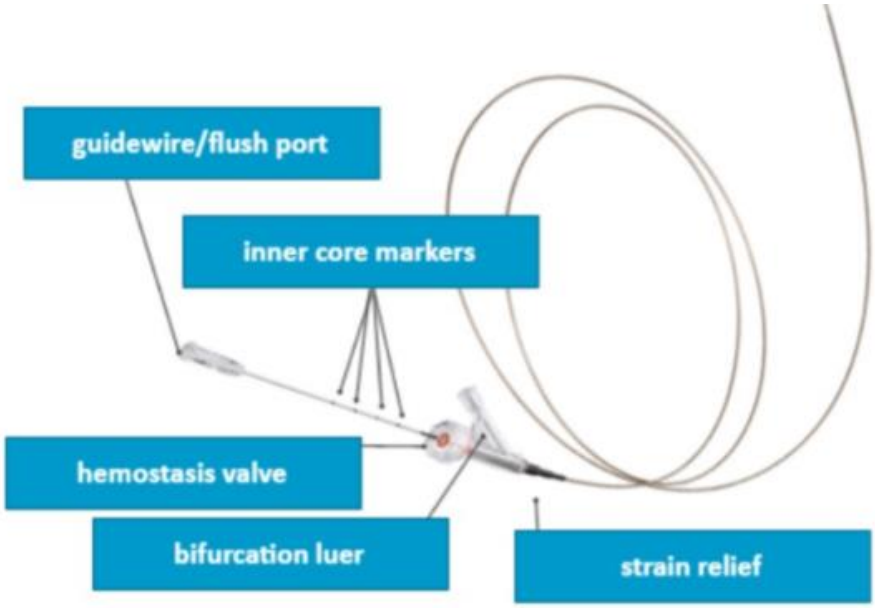


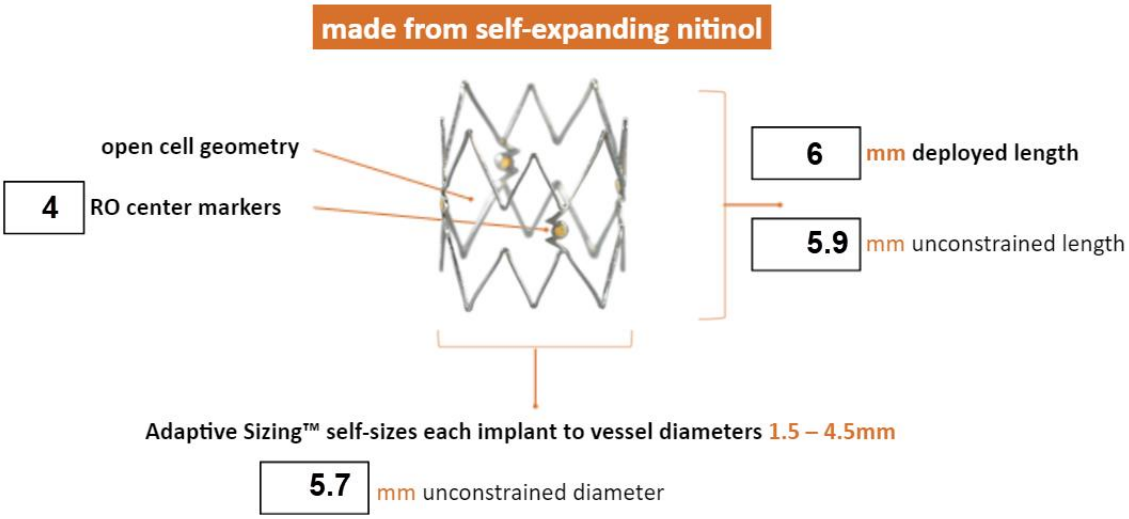
Tack Implant (4F) and Delivery System Components answer key

Check your answers.





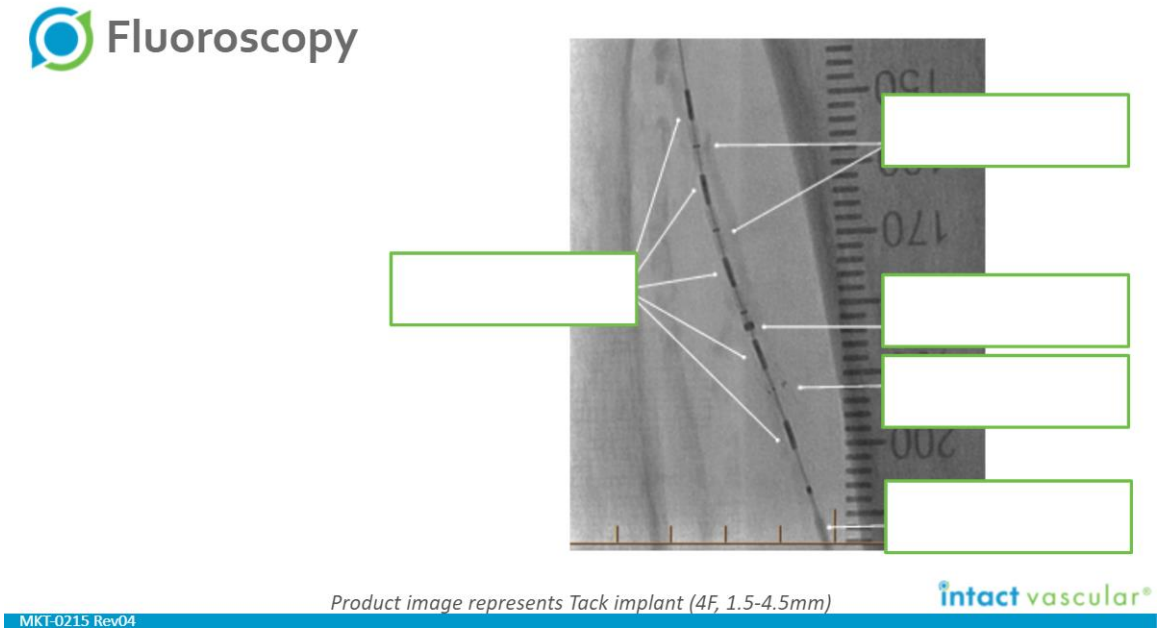




PHILIPS

Fluoroscopy quiz

Label the components.



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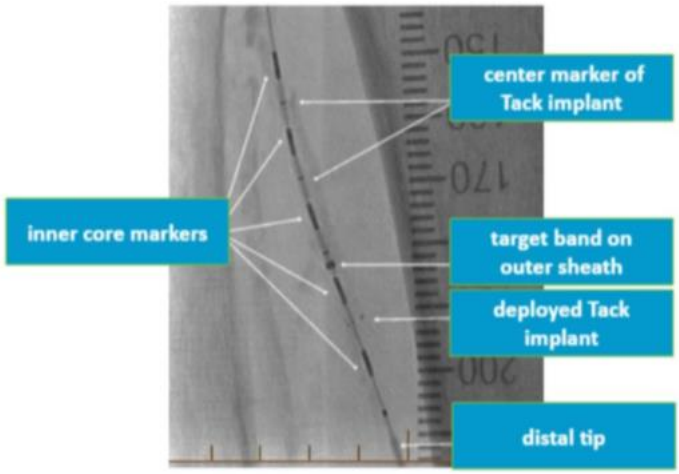
Fluoroscopy answer key

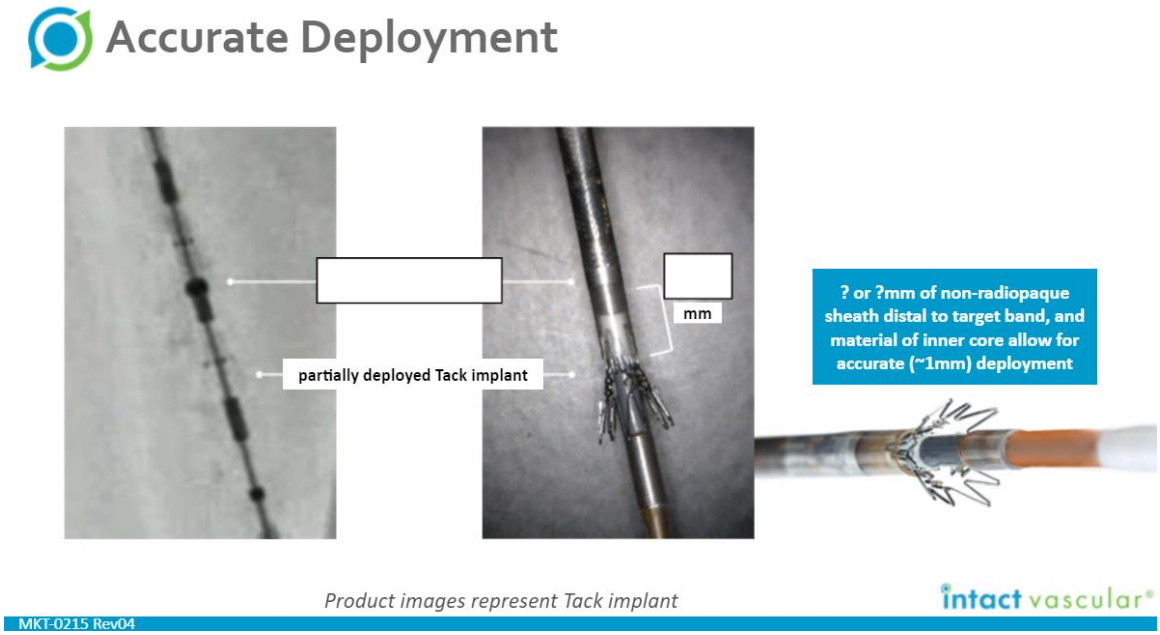
Check your answers.



PHILIPS

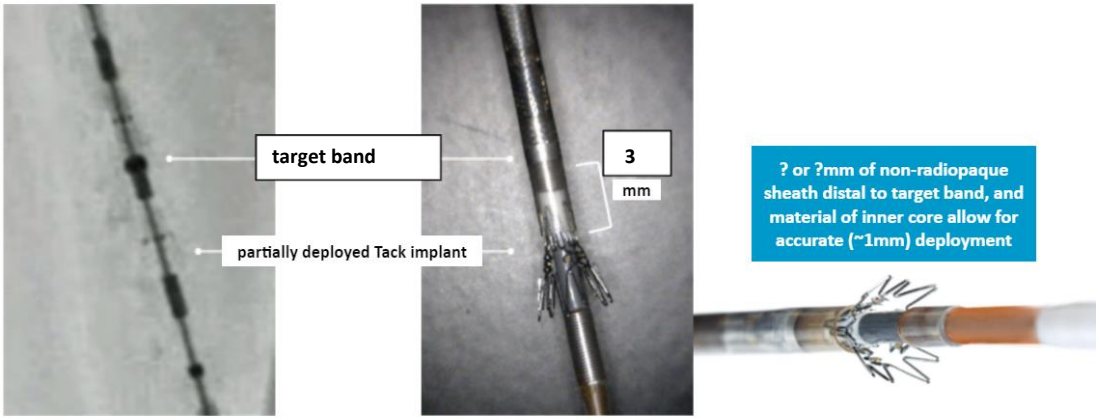
Accurate Deployment quiz

Fill in the boxes.



Accurate Deployment answer key

Check your answers.



The trainee should be able to verbalize the following:

Indications and contraindications for using QuickClear.

- □ **Indication:** Removal of fresh, soft emboli and thrombi from vessels of the arterial and venous systems
- □ **Contraindication:** Use in the coronary or neuro vasculature

Which sizes are indicated for both arterial and venous vasculature?

- □ Both 6fr and 8fr indicated for arterial and venous vasculature
- □ Only 10fr indicated for venous vasculature.

Provie a quick overview of the QuickClear Mechanical Thrombectomy System.

- □ Two main components:
    1. QuickClear Aspiration Catheter Kit
    2. QuickClear Aspiration Pump Kit
- □ **Aspiration catheter:**
    - Sterile, single use, single lumen sheath that is 0.035" guidewire (GW) compatible with various tip configurations including straight tip for 6F & shaped tip for 8F&10F catheters
    - The distal 30 cm of the aspiration catheter has a lubricious hydrophilic coating to allow ease of delivery to the target site; a radiopaque (RO) distal marker band is located at the distal tip to allow for visibility under fluoroscopic guidance
- □ **Obturator:** Provided with the 8F and 10F aspiration catheter sizes to provide support for insertion into the introducer sheath and aide the catheter to track over a 0.035" guidewire while accessing the target peripheral vessel(s)

What do you need to validate when opening the QuickClear Mechanical Thrombectomy System?

- □ Packaged and **sterilized** individually—each device/kit is sterile if the sealed pouch is unopened and undamaged
- □ Examine the packaging for cuts, tears, or other breach of the sterile barrier—do not use open or damaged package
- □ Examine the QuickClear Aspiration Catheter, in particular the catheter tip for **bends, kinks or other damage**
- □ Intended for single use only and should not be reused or re-sterilized
- □ Verify the "Use Before Date" dated printed on the package labels

List the equipment required per the IFU.

- □ The appropriately sized QuickClear Aspiration Catheter Kit
- □ QuickClear Aspiration Pump Kit
- □ Appropriately Sized introducer sheath with cross-cut valve
- □ Sterile heparinized (10,000 IU/L) 0.9% normal saline and 10cc or larger slip-tip syringe for priming device
- □ Compatible 0.035" sized, exchange length guidewire (260 cm length minimum for 6F; 180 cm length for 8F & 10F)

List the steps to prepare the catheter for insertion.

- □ Withdraw the Aspiration Catheter from the sterile protective packaging by carefully removing the tip and any tip holder from the backing card and set the Catheter on the sterile table. Ensure not to damage the catheter tip.
- □ Prime the Aspiration Catheter
- □ For the 8F and 10F aspiration catheter, flush the obturator with sterile saline and insert the obturator through the Hemostasis Valve Y Connector through to the tip of the aspiration catheter.

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Describe the pump priming process.

- □ Turn ON the Aspiration Pump and ensure that it can be activated. Do not use any defective equipment. Return all damaged devices with packaging to the manufacturer/distributor. Ensure that the inline flow control switch is in the open position.
- □ Attach the 60cc syringe partially filled (approximately 20-30cc) with sterile heparinized normal saline into the t-connector on the aspiration pump tubing.
- □ Flush slowly with gentle pressure until saline drips out of the valve at the end of the tubing.
- □ Close the flow control switch and flush slowly with gentle pressure until fluid exits out the proximal end of the pump tubing.
- □ Keep the 60cc syringe attached to the aspiration tubing set after priming.
- □ Attach the waste collection bag to the proximal end of the pump tubing.

Describe the steps for insertion.

- □ Insert an appropriately sized introducer sheath with a cross-cut hemostasis valve using standard techniques.
- □ Advance the catheter and obturator, if used, into the target vessel over a guidewire taking care not to damage the catheter tip during insertion into the introducer sheath.
- □ Close the introducer hemostasis valve tight enough to prevent blood leakage around the catheter shaft, but still allow axial movement of the catheter through the valve.
- □ Connect the Aspiration Pump to the Aspiration Catheter via the aspiration tubing to the side port of the hemostasis valve.
- □ Close the inline flow control switch prior to intervention

List the steps for aspirating/removing a thrombus.

- □ Verify the position of the aspiration catheter relative to the lesion site through fluoroscopic visualization of the radiopaque tip.
- □ Remove the guidewire from the catheter once catheter is placed in the target area and adjacent to the blockage intended for removal.
- □ Under fluoroscopic guidance, turn ON the Aspiration Pump and open the inline flow control switch connected to the Y-connector to initiate removal of thrombus.
    - Verify that thrombus is being removed by monitoring blood being collected in the Waste Collection Bag.

  WARNING: Do not operate the Aspiration System across venous valves; **CLOSE** the Inline Flow Control Switch before crossing the valve.

- □ In highly thrombotic regions of vessels > 10 cm in length, periodically pause and withdraw the catheter slightly to allow improved blood flow and clot removal during aspiration. Additionally, cycle the inline flow control switch (open/close) to enhance thrombus removal and/or assess clot aspiration.
    - Additional vacuum may be generated by pulling the plunger on the 60cc syringe connected to the T-connector.
- □ The 8F and 10F shaped tip catheters may be rotated and advanced slowly to aspirate thrombus from a larger diameter vessel. Reposition the catheter tip as desired during or between aspiration passes. If there is resistance to rotating the tip, stop rotating the tip.

List the steps you should perform if the flow of aspirated material ceases during the procedure.

- □ Turn OFF the aspiration pump.
- □ Pull the aspiration catheter back gently under fluoroscopy to verify the catheter tip is not caught in the vessel wall.

- □ **If the tip appears to be caught**, disconnect the aspiration line/aspiration pump from the catheter to allow catheter pressure to open and gently retract the catheter proximal to the lesion to re-establish blood flow. Turn Pump ON to aspirate/clear blood through the catheter and resume aspiration.
- □ **If due to a clogged shaft or if flow of aspirated material is not re-established**, disconnect the aspiration pump from the catheter. Remove the catheter from the patient. Flush the catheter within a sterile heparinized normal saline bowl with the catheter tip completely submerged in the saline to actively clear blood and/or aspirated material that may be within the catheter lumen.
- □ Obtain a post procedure angiogram/venogram by injecting contrast media through the guide catheter or introducer.
- □ Periodically monitor the Waste Collection Bag for air and vent bag as required.

List the steps you should take if the QuickClear Aspiration Catheter is used to treat multiple thrombotic occlusions where the catheter is removed and re-inserted through the introducer sheath.

- □ The catheter must be flushed between re-insertions by flushing the catheter within a sterile heparinized normal saline bowl with the catheter tip completely submerged in the saline to actively clear blood and/or aspirated material that may be within the catheter lumen.

Describe how to dispose of the used device.

- □ **Aspiration Catheter:** Disposable per hospital biohazard procedures
- □ Aspiration Pump:
    - Contains Lithium batteries
    - Is NOT disposable per standard biohazard procedures
    - Should be disposed per standard hospital hazardous waste procedures

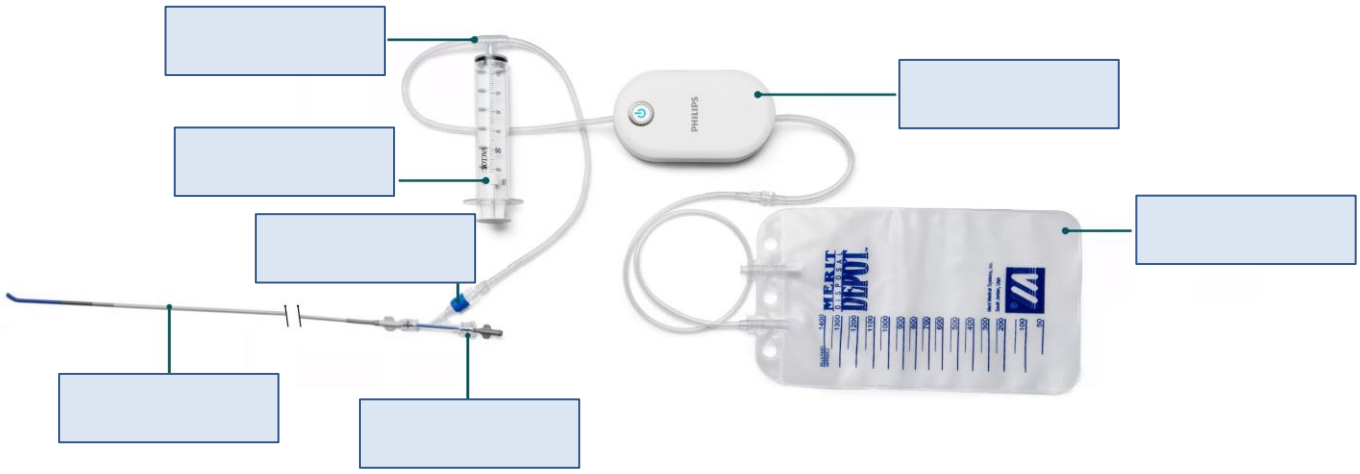
Caution: Do not incinerate the Aspiration Pump.

WARNING: Portable RF communications and electrical equipment, such as those for diathermy, lithotripsy, electrocautery, RFID, and electromagnetic anti-theft systems, can affect any medical electrical equipment including the Aspiration Pump.

Practice Grade: ____ Pass: _____ Fail: _____

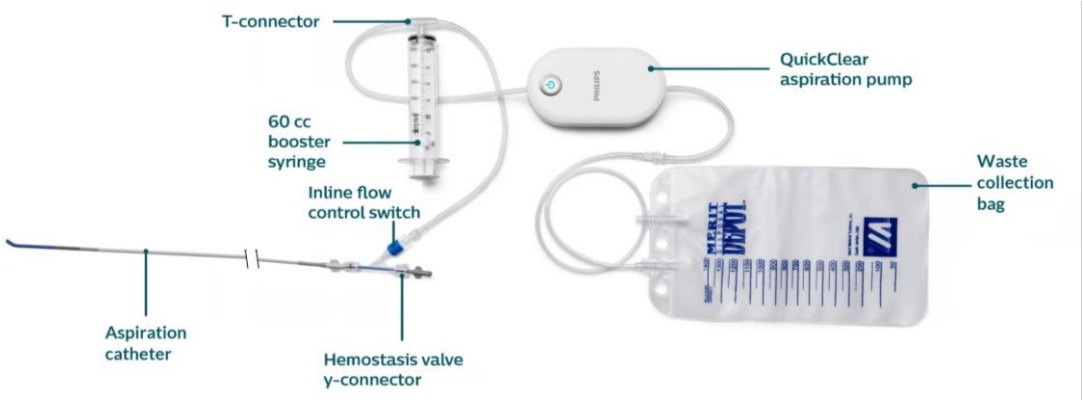
QuickClear quiz

Identify the components of the QuickClear System.



QuickClear answer key

Check your answers.



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Appendix

Vessel prep Devices and Lesion characteristics table

PAD Lesion Education

Lesion Description → Clinical Challenge → Mechanism of Action/Treatment Considerations → Philips Device

NOTE: These are general considerations and suggestions for educational purposes. Every clinical scenario is unique and requires individual assessment and is subject to the operating physician's experience and comfort level.

Morphology Type/Location	Lesion Description	Clinical Challenges	Devices that may not perform well	Treatment Considerations: Devices that may perform well	Philips Devices (Assumes Quick-Cross & Stellarex included)
Fatty	• Gelatinous and very compliant due to water content	• More likely to shift or embolize • Can be pushed downstream • Could inhibit drug transfer from DCB/DES -	• POBA pushes plaque against the wall without debulking and may stretch the vessel • Mechanical devices that cut, spin or sand without aspiration may lead to more embolization	• Use a device that will debulk the soft lesion material reducing risk of embolization • Cutting device that has aspiration capability may be beneficial • PTA/stent: choose a longer device to account for the longitudinal shift that may occur • Prep to limit potential drug barriers	• Turbo-Power or Turbo-Elite Laser – Works at the tip; no moving parts; will debulk/ablate • Phoenix – cuts, captures and clears • IVUS post treatment to confirm treated entire lesion
Fibrous	• Organized, tough mesh-like • May be chronic	• May be tough to get through or eliminate • Could require multiple atherectomy passes and multiple devices for debulking • POBA could create a channel without debulking • May be just as non-compliant as calcium particularly if it is concentric and chronic • Vessel may be very stiff and rigid. Dissection major concern if not adequately prepped • Appropriate balloon sizing is critical • More likely to see wires go subintimal	• POBA pushes plaque against the wall without debulking and stretches the vessel • Sanding atherectomy may lead to more embolization	• Restore flow and avoid dissection • If more fibrous, use mechanical atherectomy to cut and capture; laser to debulk and ablate • Pre-treatment with a scoring or cutting balloon • Prep to limit potential drug barriers	• Turbo-Power or Turbo-Elite Laser – debulks to reduce risk of embolization • Phoenix – cuts, captures and clears • AngioSculpt - score fibrotic plaque also helps to reduce dissections • IVUS post treatment to interrogate for potential dissections
Mixed (Most common)	• Mix of soft/fatty, fibrous, thrombus, calcium to varying degrees	• May be tough to get through (cross) or eliminate • Could require multiple atherectomy passes and multiple devices for debulking • POBA could create a channel (dissections) without debulking • May be just as non-compliant as calcium particularly if it is concentric and chronic • Could recoil if not stenting • Could inhibit drug from DCB/DES • High embolic risk/runoff • Appropriate balloon sizing is critical • More likely to see wires go subintimal	• If more soft, mechanical may not best choice • If more calcium, mechanical could cause embolization • Blunt tipped devices could get caught on superficial calcium • One atherectomy device will not likely serve as best option for all morphologies represented	• If more soft, laser because it ablates • If more fibrous, use mechanical atherectomy to cut and capture; laser to debulk and ablate • If more calcium, use mechanical atherectomy with capture capability • If equal amounts of all, laser is a great choice because it can ablate most morphologies while being very safe • Prep to limit potential drug barriers	• IVUS-use here showcases the degree of lesion composition to confidently direct the appropriate atherectomy devices • Turbo-Elite or Turbo-Power laser – debulks and ablates to reduce risk of embolization; no moving parts to minimize embolization risk • Phoenix – cuts, captures and clears • AngioSculpt to dilate in resistant areas while minimizing slippage • IVUS post treatment to interrogate for potential dissections
Luminal Calcium	• Hard and extremely organized, uniform, very brittle • Thrombus is usually created as calcium forms	• May be tough to get through (cross) or eliminate • When treated, it could cause dissections • Calcium can lift and act like a knife into the vessel wall cutting it causing dissections and perforations • Risk of embolizing (bits of calcium or thrombus) • Calcium may act as a barrier to drug absorption • Calcium can work as a hindrance to full vessel luminal expansion	• Angioplasty may watermelon seed and slip • If the arc of calcium is not 360-degrees there may be a chance that utilizing an exposed cutter or sander will cause significant flow limiting dissections and or adventitial cuts cutting into media/adventitia starts the restenosis cascade • Blunt tipped devices may get caught on calcium • Resistance to balloon inflation may occur; may rupture	• Devices that spin and cut or sand or ablate • Scoring balloons, cutting balloons that prevent slippage seen in POBA • Prep to limit potential drug barriers	• Quick-Cross Select with its 45-degree tip to cross tougher lesions • Phoenix deflecting front facing to cut, capture and clear calcium in 3mm sized vessels or larger • AngioSculpt – scores calcium to reduce dissection by more controlled dissection; restores flow at lower atmospheres • Turbo-Power with its rotation can ablate rigid lesions (ATK) • Turbo-Elite can create a channel (ATK/BTK) • Stellarex DCB proven to work well in severely calcified lesions • IVUS post treatment to interrogate for dissections • Tack if dissections exist
Medial Calcium	• Concentric sheets of calcium hardening the vessel • May present like railroad tracks on angiogram	• This calcium is behind the leading edge of the medial wall; should avoid cutting though the medial wall • Decreases the elasticity of the vessel (stiffens the vessels) • Lack of vessel compliance does limit some therapies • There may be soft/fibrous plaque in the lumen • Aids as a hindrance to full vessel expansion • Likely to be judged as superficial calcium if detected on angiograph alone	• No cutting devices will reach past the media layer • Orbital may not work well in soft luminal plaque or thrombus that may accompany medial calcium • Resistance to balloon inflation may occur	• Orbital/sanding claims to disturb through vibration • Shockwave may work as they use lithotripsy or sounds waves on a balloon • Treat soft/fibrous luminal plaque • Prep to limit potential drug barriers	• The laser acoustic wave may affect medial calcium • Turbo-Power laser to treat soft/fibrous luminal plaque • Turbo-Power and Turbo-Elite laser may affect vessel compliance where medial calcium is present
Thrombus	• Blood, fibrin and water	• More likely to shift or embolize • Can be pushed downstream • Must be removed	• Mechanical devices that cut or spin may lead to more embolization	• Suction devices like mechanical aspiration catheters capture thrombus • Manual aspiration, drug-infusion catheters • Prep to limit potential drug barriers	• QuickClear thrombectomy will suction acute thrombus • Turbo-Power or Turbo-Elite lasers ablates thrombus mixed with other morphologies

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PAD Lesion Education

Morphology Type/Location	Lesion Description	Clinical Challenges	Devices that may not perform well	Treatment Considerations: Devices that may perform well	Philips Devices
CTO	• Hard calcific caps • Long dense lesions, with calcium and thrombus layers; may have fibrous areas • Extensive collaterals	• When treated, without adequate prep, it could cause dissections • May embolize the thrombus layer • Could be challenging to cross due to collaterals • CTO cap composition may impact ability to cross and stay true lumen • May require alternative access points • Vessel takeoff may be difficult to find if ostium occluded • Lack of vessel reconstitution could make knowing your location challenging • Most likely scenario to go subintimal • Procedure time is often greatly increased	• POBA may not get through • Mechanical atherectomy could be a risk if wire went sub-intimal • Mechanical atherectomy could be an embolic risk with the potential thrombus makeup of the morphology • Devices with large profile • Devices with less than optimal tracking features • Side cutting devices are risky if the wire is subintimal • Directional cutting devices can be hard to steer in occlusive vessels	• Important to cross the hard, calcific cap • Laser will work to create a channel where crossing a CTO is a challenge • Laser can treat different morphologies of a CTO • Creating a uniform channel is needed to minimize dissection/vessel trauma	• Quick-Cross Extreme or Select with its 45-degree tip to cross tougher lesions • Turbo-Elite step-by-step technique shown to be effective in uncrossable CTOs; ablate through hard proximal cap; distal access through concave cap works well; also removes thrombus layers • Pioneer Plus re-entry catheter can help facilitate true lumen re-entry if necessary • Turbo-Power laser if wire is true lumen • QuickClear for thrombus • IVUS post treatment to interrogate for dissections • Tack if dissections exist
CLI/BTK	• High CTO prevalence • Long diffuse and mixed morphology • Isolated calcium deposits in the lumen • Heavy calcium in medial layers of diabetics & end-stage renal failure	• Really small, stiff vessels so limited treat options • Vessels prone to acute recoil • Vessel tortuosity • More collateral beds • Lesions difficult to reach; may need pedal access • May have multiple occluded vessels • Increased case time • Increased risk of dissection and limited good options to treat if this is the result • Higher need for filters to protect frequent single vessel runoff	• Conventional stents should not be used below the knee because vessels are already small in diameter so may increase rate of restenosis with already lower flow • Mechanical devices with long nose cones • Devices with large profile • Devices with large profile • Devices with less than 150cm working length	• Laser • Front cutters with capture ability • Scoring balloons • POBA • Devices with small profiles • Orbital • Dissection repair	• Quick-Cross Select with its 45-degree tip designed for branched anatomy • AngioSculpt can crack or modify calcium with controlled scoring power with low dissection rates • Turbo-Elite works well BTK • Phoenix 1.8 is a great option with calcium and in smaller vessels • IVUS post treatment to interrogate for potential dissections • Tack if dissections exist
Neo-intimal hyperplasia (NIH)	• Water-laden, spongy, slippery, rubbery, stringy = scar tissue (aqueous collagen) • May occur in stents or after medial cuts or in AV Fistulas	• Rehydrates & recoils quickly after POBA • High embolic risk/runoff • High restenosis rate • Highly occlusive and recurring • Paclitaxel has limited solubility in water and in highly hydrated tissues	• POBA may slip in NIH • Devices with moving parts may not work well here because the tissue is spongy so higher risk of embolization • Front cutters struggle here	• Laser works well • Scoring balloons, cutting balloons that prevent slippage seen in POBA • Prep to limit potential drug barriers	• Turbo-Elite or Turbo-Power debulks/ablates • AngioSculpt minimizes slippage
Restenotic Native Vessel	• Dominated by neo-intimal hyperplasia (NIH) with areas of thrombus • Aqueous collagen	• High water content • High embolic risk/runoff • High restenosis rates • Paclitaxel has limited solubility in water and in highly hydrated tissues	• POBA may allow lesion to rehydrate & recoil quickly after use	• Laser ablate NIH, modify compliance and limit recoil prior to POBA, DCB or Stent (improves wall apposition) • Remove thrombus • Scoring balloons minimizes slippage in NIH • Prep to limit potential drug barriers	• Turbo-Elite or Turbo-Power ablates NIH, modify compliance and limit recoil prior to POBA, DCB or Stent (improves wall apposition) • QuickClear to remove thrombus • AngioSculpt minimizes slippage in NIH
In-stent Restenosis (ISR)	• Dominated by NIH in a stent & thrombus if occluded • Aqueous collagen • Rarely calcified in the lumen	• Rehydrates & recoils quickly after POBA • High embolic risk/runoff • High restenosis rate • Highly occlusive and recurring • Paclitaxel has limited solubility in water and in highly hydrated tissues • Stent crossing may be challenging • Limited treatment options	• POBA may slip in NIH • Mechanical atherectomy, specifically spinning and cutting devices are in danger of stent interaction; many are contraindicated	• Laser is only indicated atherectomy device in ISR • Scoring balloons may work because of minimizing slippage	• Turbo-Power atherectomy indicated for ISR • Turbo-Power – vaporize NIH to create pilot channel • AngioSculpt – can score NIH and minimize slippage in NIH post laser; (But not in a newly placed stent)
Concentric	• Plaque is located throughout diameter of vessel	• Non-compliant lesions are really difficult to disrupt • May be non-compliant regardless of plaque type due to 360° plaque of constant force inward from the lesion (napkin ring)	• A concentric lesion may often be more unyielding to conventional ballooning because the 360° plaque will push back.	• Device that delivers equal diameter force • A device that debulks or scores the plaque would be a good treatment option • Prep to limit potential drug barriers	• Concentric tied to calcium→ laser to debulk and creates a channel • AngioSculpt scores calcium • Concentric with fibrous→ Turbo-power with continuous rotation packs added punch • Deflecting Phoenix to maximize debulking in 3mm sized vessels or larger
Eccentric	• Plaque built up unevenly on one side of the vessel (crescent moon shape) • Often includes area of healthy vessel (not covered by plaque)	• Concern is that an exposed blade from any device may cause injury to the vessel wall significantly impacting patency rates and restarting the restenosis cascade • Luminal gain can be from compressing the plaque and stretching the vessel.	• Cutting and spinning devices could come in contact with healthy tissue • Drug-coated devices would introduce paclitaxel to healthy tissue	• Devices that allow directed treatment • Prep to limit potential drug barriers	• Turbo-Power has eccentric direction allowing it to steer to one area of the vessel • Deflecting Phoenix if plaque area is clearly identified in 3mm sized vessels or larger
Sub-intimal	• Area that is created between the lumen of the artery and the media or adventitia or beyond (a tear; false channel)	• Occurs in CTOs and calcium; created as path of least resistance • May want to create a channel around the lesion • Limited treatment options; may dissect	• No mechanical atherectomy because moving parts • Mechanical atherectomy device in this area carries a high risk of perforation or adventitial injury	• Use a re-entry device to regain entry	• Pioneer Plus to regain true lumen • Pioneer Plus is only IVUS-guided re-entry device