RADIANZ
RADIAL PERIPHERAL SYSTEM™

Procedure Guide

Cordis®

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Cordis Radianz Radial Peripheral System™ Procedure Guide

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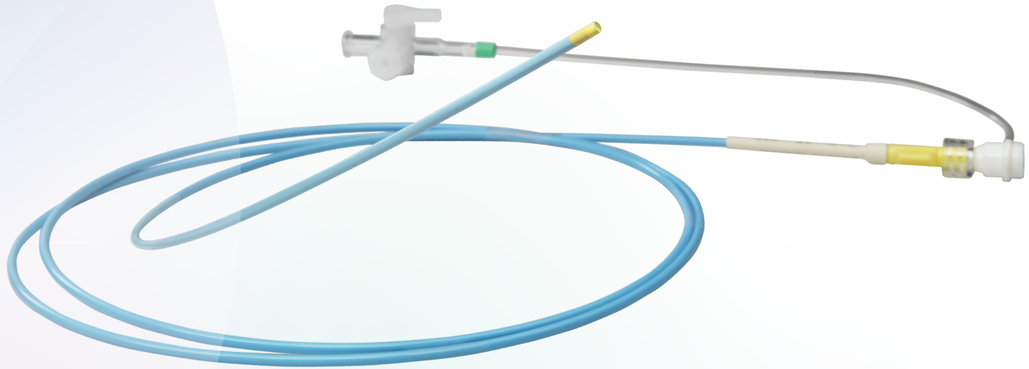
01

Introduction to the Radianz Radial Peripheral System™



Why Radial?

Drive Patient Satisfaction.

Multiple studies demonstrate an overwhelming **patient preference** for radial access due to its manifold benefits over femoral access.[1,2]

80% preferred

80% of patients who underwent both access methods **strongly preferred radial.**[1]

Increase Efficiency.

Adoption of radial access may improve **procedural efficiencies** compared to femoral access.

65% reduction

Radial access resulted in a **65% reduction in time to discharge.**[1]

95% reduction

Improve recovery room patient turnover with **+95% reduction in time to ambulation** from 2–4 hours to minutes.[1,3]

Reduce the Total Cost of Care.[4]

A systematic review of 14 randomized controlled trials found radial access **lowered hospital costs.**[4]

$1,116 saved

Saved $1,116 per procedure in duration of stays costs compared to femoral access.[5]

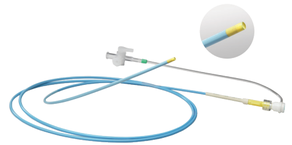
1. Cooper CJ, El-Shiekh RA, Cohen DJ, et al. Effect of transradial access on quality of life and cost of cardiac catheterization: A randomized comparison. Am Heart J. 1999 Sep;138(3 Pt 1):430–6.
2. Kok MM, Weernink MGM, von Birgelen C, Fens A, van der Heijden LC, van Til JA. Patient Preference for Radial versus Femoral Vascular Access for Elective Coronary Procedures: The PREVAS Study. Catheter. Cardiovasc. Interv. 2018;91(1):17–24.
3. Kern MJ. Radial Access in Practice. Tips for starting a successful program. Cardiac Interventions Today. September/October 2015.
4. Mitchell MD, Hong JA, Lee BY, et al. Systematic Review and Cost–Benefit Analysis of Radial Artery Access for Coronary Angiography and Intervention. Circ Cardiovasc Qual Outcomes. 2012;5:454–462.
5. Ansaarie I, Goldfaden RF, Hardy J, et al. A Retrospective Cohort Study to Evaluate the Efficacy, Safety, and Cost of MäLEI via Transradial vs Transfemoral Peripheral Revascularizations. Vascular Disease Management. 2021.

The Radianz Radial Peripheral System™

Another best-in-class radial offering from Cordis, the Radianz Radial Peripheral System™ is the only radial peripheral system purposely engineered to deliver exceptional outcomes and a high level of patient satisfaction with tools optimized for radial access and treatment—including the first stent indicated for iliac lesions.

BRITE TIP RADIANZ™ Guiding Sheath

The BRITE TIP RADIANZ™ Guiding Sheath is comprised of the catheter sheath, dilator, and removable hemostasis valve.



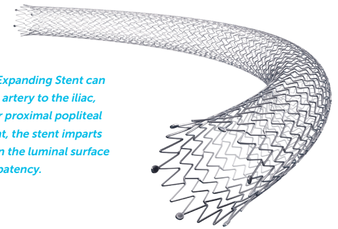
SABERX RADIANZ™ PTA Dilatation Catheter

The SABERX RADIANZ™ PTA Dilatation Catheter has the most clinically comprehensive radial peripheral PTA size matrix that facilitates broader treatment of lesions and delivers exceptional performance.

S.M.A.R.T. RADIANZ™ Vascular Stent System

S.M.A.R.T. RADIANZ™ Vascular Stent System is the first stent indicated to treat iliac lesions. It is purposely engineered to treat superficial femoral artery and proximal popliteal lesions, all from a radial approach.

Now the S.M.A.R.T.® Self-Expanding Stent can be delivered via the radial artery to the iliac, superficial femoral and/or proximal popliteal arteries. Upon deployment, the stent imparts an outward radial force on the luminal surface of the vessel to establish patency.



Enhanced Quality of Life via S.M.A.R.T.® Vascular Stents

Backed by the numbers, a strong foundation of clinical evidence validates the performance and value of S.M.A.R.T.® Vascular Stents.

>85% Favorable patient outcomes: >85% of patient-reported PAD-related quality-of-life improvements were sustained to 3 years.[1]

>3k *The stent with the stats*: 3,000+ patients studied with 10-year follow-up data*

1. Bunte MC, Cohen DJ, Jaff MR, et al. Long term clinical and quality of life outcomes after stenting of femoropopliteal artery stenosis: 3 year results from the STROLL study. Catheter Cardiovasc Interv. 2018;92:106 114.
*Clinical data was collected using the S.M.A.R.T.® Vascular Stent System via femoral access. The stent delivered and its indications for use is identical to the S.M.A.R.T. RADIANZ™ Vascular Stent System.

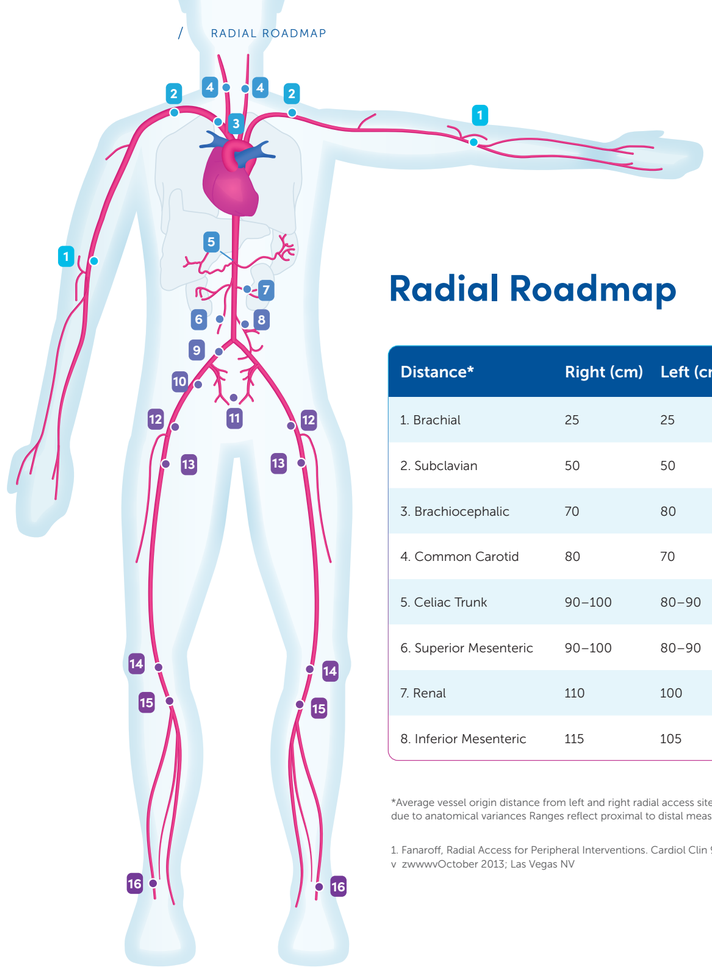
02
Case Planning

Procedural Considerations

- ◯ Intervention Room Size and Setup
- ◯ Interventional Tools
- ◯ Plan for Treatment
- ◯ Patient Selection
- ◯ Patient Height
- ◯ Radial Artery Characteristics
- ◯ Alternative Access
- ◯ Complexity and Location of Disease State
- ◯ Complex CTO Cases

Equipment Picklist

- ◯ Radial Arm Board (if desired)
- ◯ RAIN Sheath™ Transradial Thin-Walled Introducer Kit
- ◯ .035" STORQ®, .018" SV, or .014" STABILIZER® Interventional Guidewires
- ◯ INFINITI® and TEMPO AQUA® Diagnostic Catheters
- ◯ BRITE TIP RADIANZ™ Guiding Sheath
- ◯ Support Catheters
- ◯ SABERX RADIANZ™ PTA Dilatation Catheters
- ◯ S.M.A.R.T. RADIANZ™ Vascular Stent System
- ◯ ZEPHYR® Vascular Compression Device



Radial Roadmap

Distance*	Right (cm)	Left (cm)
1. Brachial	25	25
2. Subclavian	50	50
3. Brachiocephalic	70	80
4. Common Carotid	80	70
5. Celiac Trunk	90–100	80–90
6. Superior Mesenteric	90–100	80–90
7. Renal	110	100
8. Inferior Mesenteric	115	105

Distance*	Right (cm)	Left (cm)
9. Common Iliac	130	120
10. External Iliac	140	130
11. Uterine	140	130
12. Common Femoral Artery (CFA)	145	135
13. Superficial Femoral Artery (SFA)	150	140
14. Popliteal	190	180
15. Tibioperoneal Trunk	200–210	190–200
16. Dorsalis Pedis	210–240	200–230

*Average vessel origin distance from left and right radial access sites based on 5'11" (180.34cm) patient height. All measurements are approximations and may vary due to anatomical variances Ranges reflect proximal to distal measurements of the target vessels.[1]

1. Fanaroff, Radial Access for Peripheral Interventions. Cardiol Clin 9 (2020) 53–61 Chowdhury, Contemporary Use of Radial to Peripheral, CTOCM, 2021 (1)[41] vvff v zwwwvOctober 2013; Las Vegas NV

Product Portfolio

Thin-Walled Hydrophilic Sheaths

Product name	Length (cm)	Size (Fr)
RAIN Sheath™ Transradial Introducer	10, 16	4, 5, 6, 7
BRITE TIP RADIANZ™ Guiding Sheath	110, 135	6

Wires

Product name	Length (cm)	Size (in)	Shape
STORQ® Steerable Guidewire	180, 300	0.035	Modified J, Straight, Angled
SV-5 & SV-8 Steerable Guidewire	180, 300	0.018	Straight/Shapeable
STABILIZER® Steerable Guidewire	180, 300	0.014	Angled/Straight

Diagnostic Catheters

Product name	Length (cm)	Size (Fr)	Shape
INFINITI® Catheter	110	4, 5, 6	Pig
TEMPO AQUA® Catheter	100, 125	4, 5	Bern, Vert, Str, MPA1, SIM1–2, H1, RBL

Product Portfolio (continued)

Balloons

Product name	Diameter (mm)	Length (mm)	Shaft Length (cm)	Size (Fr)
SABERX RADIANZ™ PTA Dilatation Catheter – RX .018"	2–10	20–300	190	4–6

Self-Expanding Stents

Product name	Diameter (mm)	Length (mm)	Shaft Length (cm)	Size (Fr)
S.M.A.R.T. RADIANZ™ Vascular Stent System (SFA Indication)	6–8	20–150	190	6
S.M.A.R.T. RADIANZ™ Vascular Stent System (Iliac Indication)	8–10	10–150	150	6

Closure

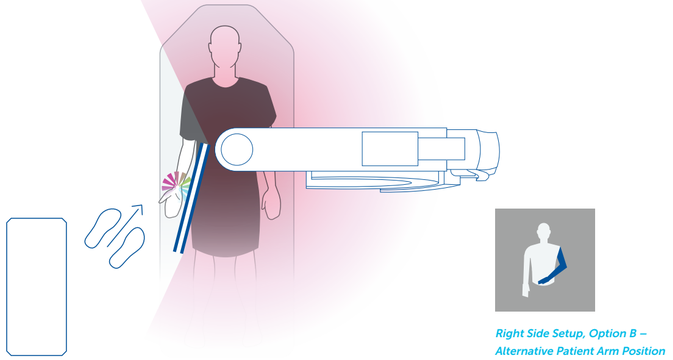
Product name	Length (cm)	Size
ZEPHYR® Vascular Compression Band	30	Large

Patient Positioning and Room Setup

Each patient positioning option helps ensure an optimized room setup based on your team's preferred access to entry and positions.

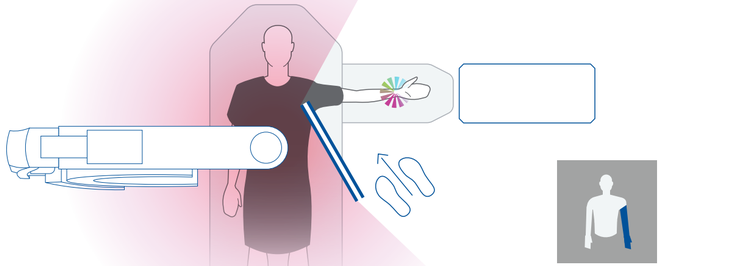
		Right Side Setup	Left Side Setup
1	Choose Patient Arm Position	 *Option a*	 *Option a*
		 *Option b*	 *Option b*
2	Choose Operator Position		
3	Choose C-Arm Position (Intervention)		
4	Choose Back Table Position		

Right Side Setup, Option A

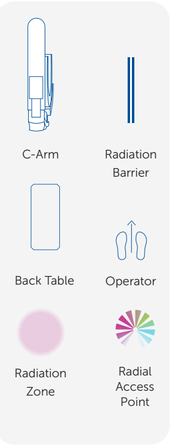


Right Side Setup, Option B – Alternative Patient Arm Position

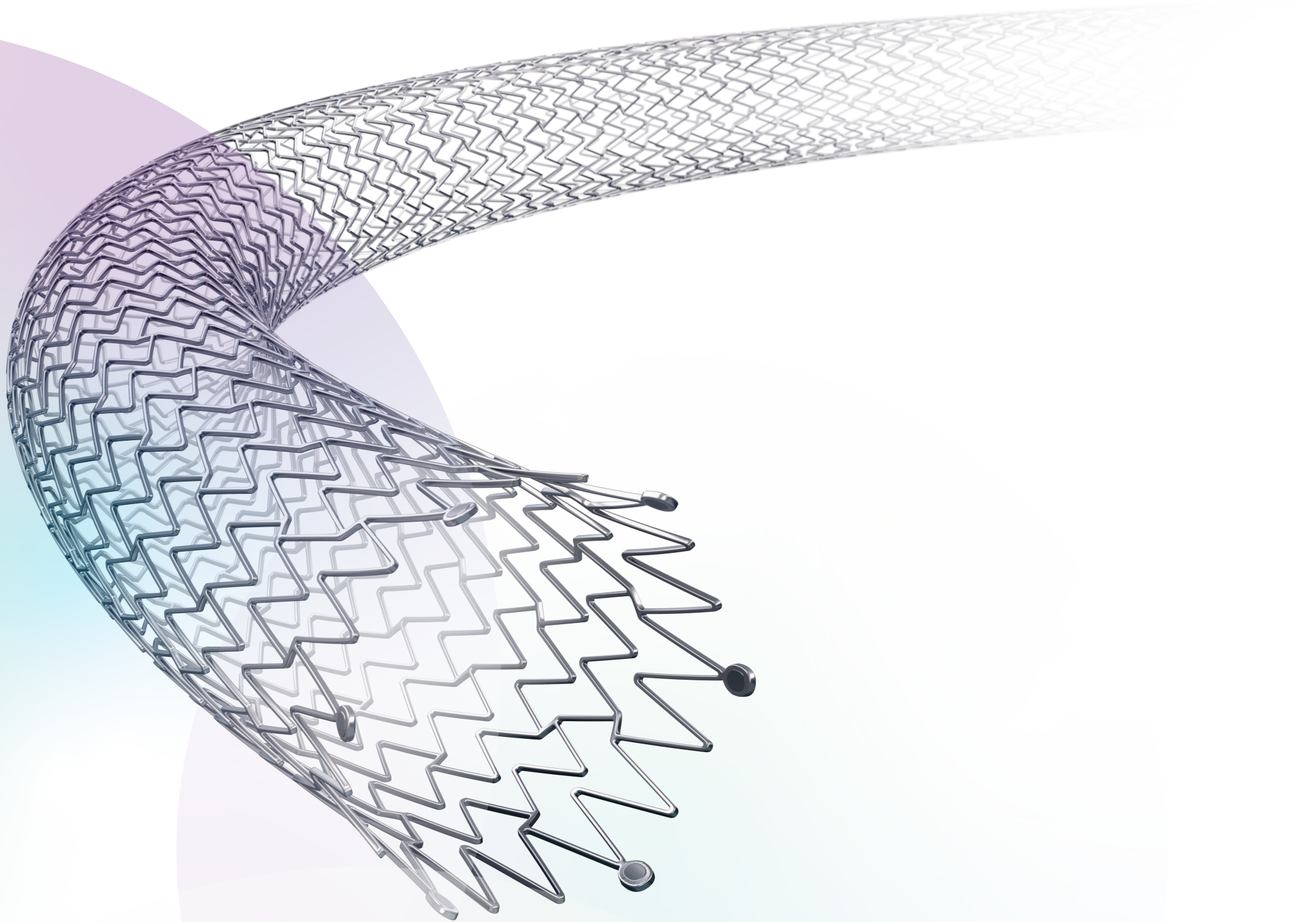
Left Side Setup, Option A



Left Side Setup, Option B – Alternative Patient Arm Position



03
Device Delivery



Pre-Procedure

1. The patient may be started on 81–325mg of enteric-coated or non-enteric-coated aspirin one or two days prior to the procedure and 300–375mg of Clopidogrel bisulfate, if deemed appropriate by the physician.
2. The percutaneous placement of the stent in a stenotic or obstructed artery should be done in an angiography procedure room. Angiography should be performed to map out the extent of the lesion(s) and the collateral flow. If thrombus is present or suspected, thrombolysis should precede stent deployment using standard acceptable practice. Access vessels must be sufficiently patent, or sufficiently recanalized, to proceed with further intervention. Patient preparation and sterile precautions should be the same as for any angioplasty procedure.
3. Ensure patient is appropriate for radial access by assessing the radial artery is the dominant artery for hand perfusion.

Procedure

1. Initial Angiogram

A. Use the appropriate selection criteria for radial access (e.g. Allen test or Barbeau test).

B. After local anesthesia is administered, the radial artery is entered under ultrasound guidance with a puncture needle in either a single or double wall technique. A guidewire is introduced into the radial artery through the needle.

C. The needle is then exchanged for a dedicated radial sheath with a tapered dilator and hydrophilic coating.

D. The sheath is then flushed with an anti spasmolytic cocktail.

E. A guidewire and pigtail diagnostic catheter are then advanced into the abdominal aorta where a diagnostic angiogram is performed.

F. After an aortogram is performed, an angled diagnostic catheter may be introduced and directed in the appropriate direction to perform a lower extremity angiogram.

G. This demonstrates the location of the lesion as well as its length and approximate diameter.

H. The diagnostic catheter and radial sheath are then exchanged for a long dedicated radial sheath to the level of the aorta.

I. Select and prep BRITE TIP RADIANZ™ Guiding Sheath.

J. Place a 6Fr guiding sheath of an appropriate length (110cm for a 150cm long device and a 135cm for a 190cm long device) with an internal diameter of at least 2.00mm.

2. Preparation of the BRITE TIP RADIANZ™ Guiding Sheath

A. Select an appropriately sized catheter guiding sheath, remove it from the package and inspect for any signs of damage. (Figure 1)

Figure 1

B. Check to make sure the hemostasis valve is securely connected to the guide sheath hub.

C. Soak the guide sheath in a sterile heparinized saline or a similar isotonic solution to activate hydrophilic coating before use.

D. To remove any air, flush with heparinized saline or a similar isotonic solution through the 3-way stopcock. (Figure 2)

Figure 2

E. Carefully insert the dilator through the guide sheath and snap it into place. (Figure 3)

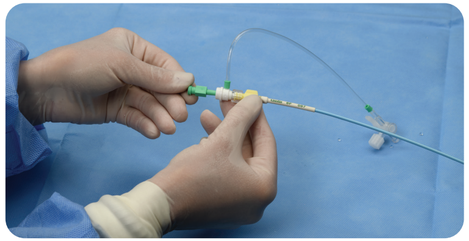


Figure 3

F. Flush the dilator with the same solution.

3. Insertion and delivery of BRITE TIP RADIANZ™ Guiding Sheath

A. Activate the hydrophilic coating. (Figure 4)

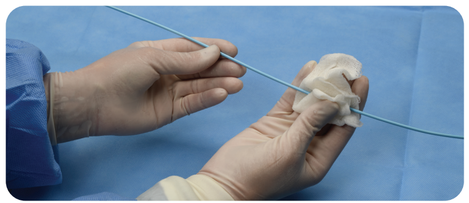


Figure 4

B. Insert the guidewire and load distal tip dilator with guide sheath over the guidewire and advance into the vessel.

C. Advance the guidewire and guide sheath to the target site.

D. Once in position, remove the dilator and guidewire from guide sheath by releasing the snap fit at the hemostasis valve hub and carefully withdraw dilator and guidewire while maintaining the position of the guide sheath. (Figure 5)

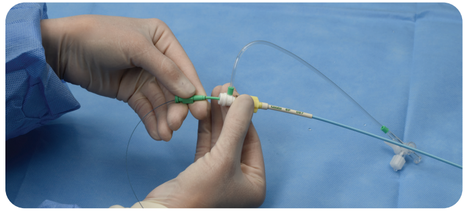


Figure 5

E. If the dilator needs to be reinserted, wipe with moistened gauze, flush and immerse in heparinized saline until use.

F. Verify proper position of the guide sheath under fluoroscopy.

G. Carefully introduce selected compatible interventional or diagnostic devices.

H. Place an .018" (0.46mm) guidewire of sufficient length across the lesion to be treated via the guiding sheath.

I. An injection of contrast media through the catheter should be done in order to confirm the intraluminal position.

4. Select Stent Size

A. Using diagnostic images, measure the length of the target lesion to determine the length of stent(s) required. Size the stent length(s) to extend slightly proximal and distal to the lesion.

B. The appropriate stent length(s) should be selected to cover the entire length of the lesion.

▶ *Note: Should more than one stent be required, placement of the stent most distal from the puncture site should be completed first, followed by placement of the proximal stent in tandem.*

C. Determine the diameter of the vessel (by visual estimation using angiography or as determined by intravascular ultrasound). (Table 1)

Stent Size Selection Guide	
Vessel Lumen Dia. (mm)	Unconstrained Stent Dia. (mm)
4–5	6
5–6	7
6–7	8
7–8	9
8–9	10
Note: Refer to product labeling for stent length information	

Table 1

▶ *Note: Because of the behavior of Nitinol, which imparts an outward radial force, the stents are indicated for placement into vessels that are 1–2mm smaller than the unconstrained diameter of the stent.*

5. Preparation of Stent Delivery System

A. Open the outer box to reveal the pouch containing the stent and delivery system.

B. Check the temperature exposure indicator on the pouch to confirm that the black dotted pattern with a grey background is clearly visible.

C. After careful inspection of the pouch to look for damage to the sterile barrier, carefully peel open the pouch and extract the stent delivery system from the tray. Examine the device for any damage. If it is suspected that the sterility or performance of the device has been compromised, the device should not be used. (Figure 6)

Figure 6

D. Flush the delivery system with heparinized saline to expel air:

Attach a 3cc syringe filled with a heparinized saline to the Luer Hub. Apply positive pressure to the syringe until fluid weeps from the guidewire exit port. While covering the guidewire exit port with thumb and forefinger, apply positive pressure until saline weeps from the catheter tip and the space between the tip and the Outer Sheath. (Figures 7, 8)

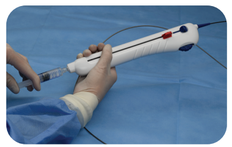


Figure 7

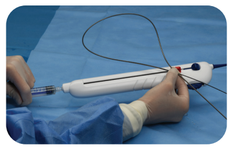


Figure 8

E. Evaluate the distal end of the catheter to ensure that the stent is contained within the outer sheath. Do not use if the stent is partially deployed.

F. Inspect the catheter distal tip of the device to ensure it is within the distal end of the outer sheath. Do not use if there is a gap between the end of the catheter distal tip and the outer sheath.

6. Dilation of Lesion

A. If appropriate, pre-dilate the lesion using standard PTA balloon catheter techniques.

7. Preparation of the SABERX RADIANZ™ PTA Dilatation Catheter

A. Open the pouch, grasp the hub and gently remove the catheter.

B. Remove the flushing needle from the tray. (Figure 9)

Figure 9

C. Without twisting, slide the forming tube off the balloon.

D. Remove the protection sheath from the flushing needle.

E. Insert the needle into the tip of the catheter.

F. Attach a syringe filled with sterile heparinized saline or similar isotonic solution to the flushing needle.

   1. Flush the guidewire lumen. (Figure 10)

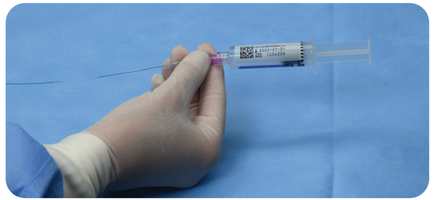


Figure 10

G. Attach a 3-way stopcock to the inflation port, which is marked "BALLOON".

H. Attach a partially filled syringe with heparinized saline to the stopcock:

   1. Open the stopcock to the balloon.
   2. Induce negative pressure.

I. Hold the syringe and proximal end of the catheter above the distal end of the catheter and hold the balloon vertically with the balloon tip pointing down.

J. While maintaining negative pressure close the stopcock to the inflation port.

   1. Remove the syringe and purge the air.

K. To ensure air contained in the balloon and inflation lumen is removed.

   1. Apply negative pressure twice as instructed.
   2. Repeat steps H–J. (Figure 11)

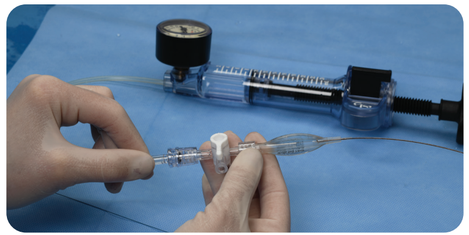


Figure 11

L. Prepare an angioplasty inflation system with a 50% solution of contrast medium in sterile saline or similar solution.

M. Purge the air from the inflation device.

N. Connect the inflation device to the 3-way stopcock that is connected to the catheter inflation port.

   1. Open the stopcock to the catheter.
   2. Slowly fill the inflation lumen and the balloon will slowly fill with diluted contrast medium.

▶ *Note: The SABERX RADIANZ™ PTA Catheters are coated with a hydrophilic material. Prior to insertion, wipe down the catheter with a saline soaked gauze to activate the coating.*

! *Caution: Do not wipe down the catheter surface with dry gauze.*

8. Insertion, Inflation and Withdrawal of the SABERX RADIANZ™ PTA Dilatation Catheter

A. Place the prepared catheter over a prepositioned guidewire and advance the tip to the introduction site.

▶ *Note: To preserve the folded balloon shape during insertion and catheter manipulation, maintain a vacuum on the inflation lumen.*

! *Caution: Fully deflate the balloon by inducing negative pressure with the inflation system whenever the PTA catheter is advanced or withdrawn. Do not advance or withdraw the PTA catheter within the vasculature unless the catheter is preceded by a guidewire.*

B. Carefully advance the catheter through a guide sheath through the percutaneous entry site. (Figure 12)

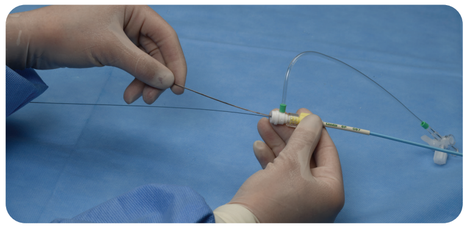


Figure 12

C. Carefully advance the catheter to the selected stenosis.

! *Caution: If strong resistance is met during advancement or withdrawal of the catheter, discontinue movement and determine the cause of resistance before proceeding. If the cause of resistance cannot be determined, withdraw the entire system.*

▶ *Note: If a PTA catheter is torqued more than twice, the guidewire will wrap around the catheter thereby affecting the procedure or damaging the guidewire or catheter.*

D. Using fluoroscopy and the radiopaque marker bands, position the catheter at the appropriate location.

E. When an acceptable position has been obtained, inflate the balloon to achieve the desired dilatation.

! *Caution: Do not exceed the rated burst pressure. Higher pressures may damage the balloon or catheter or overdistend the selected artery.*

F. Deflate the balloon by pulling vacuum on the inflation syringe or inflation device. Apply negative pressure to the balloon for about 30–85 seconds until the balloon is deflated.

G. Remove the vacuum (do not apply pressure) and carefully withdraw and remove the catheter.

▶ *Note: Gentle counterclockwise rotation of the balloon may ease withdrawal from the sheath or from the percutaneous entry site. If the balloon cannot be withdrawn through the sheath, withdraw the catheter and sheath as a unit.*

9. Remove the PTA balloon catheter from the patient while maintaining lesion access with the guidewire.

▶ *Note: Stent placement is not indicated if the primary angioplasty is not technically successful. A technically successful angioplasty is one in which the guidewire and dilation catheter are passed through the lesion and dilatation of the lesion produces a lumen adequate to accommodate introduction of the stent delivery system.*

10. Stent Advancement

A. Ensure the safety lock is still in place.

B. Advance the device over the guidewire through the hemostatic valve and guiding sheath to the lesion site. (Figure 13)

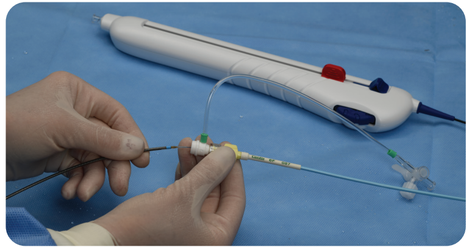


Figure 13

▶ *Note: If resistance is met during delivery system introduction, the system should be withdrawn, and another system should be used. The handle should not be rotated during insertion or removal.*

! *Caution: Always use a guiding sheath for the implant procedure to protect puncture site. A guiding sheath of a 6Fr (2.0mm) or larger size is recommended.*

11. Slack Removal

A. Advance the stent delivery system past the lesion site.

B. Pull back the stent delivery system until the radiopaque stent markers (leading and trailing ends) move in position so that they are proximal and distal to the target lesion site.

C. Ensure the device outside the patient remains flat and straight.

! *Caution: Slack in the catheter shaft, either outside or inside the patient, may result in deploying the stent beyond the target lesion site.*

12. Stent Deployment

A. Verify that the delivery system's radiopaque stent markers (leading and trailing ends) are proximal and distal to the target lesion.

B. Ensure that the guiding sheath or guiding catheter does not move during deployment.

C. Remove the safety lock from the handle. (Figure 14)

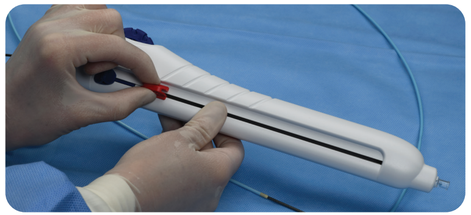


Figure 14

▶ *Note: Do not rotate the thumbwheel prior to removing the safety lock from handle.*

D. Initiate the stent deployment by rotating the thumbwheel in a clockwise direction while holding the handle in a fixed position. (Figure 15)

Figure 15

▶ *Note: Failure to maintain a fixed handle position or constraining the catheter shaft during deployment may result in stent compression (shortening) or elongation.*

E. While using fluoroscopy, maintain position of the radiopaque stent markers relative to the target lesion site. Watch for the distal radiopaque markers to begin separating. Separation of the distal stent markers signals that the stent is deploying. Continue turning the tuning dial to cause further separation of the distal radiopaque markers until the distal end of the stent obtains full wall apposition.

F. With the distal end of the stent apposing the vessel wall while maintaining a fixed handle position, pull back the deployment slide to deploy the remainder of the stent. (Figures 16, 17)

Figure 16

Figure 17

G. Deployment is complete when the proximal markers oppose the vessel wall and the outer sheath radiopaque marker crosses the proximal stent marker.

▶ *Note: When more than one stent is required to treat the lesion, the more distal stent should be placed first. Overlap of sequential stents is necessary but the amount of overlap should be kept to a minimum.*

13. Post-Deployment

A. While using fluoroscopy, withdraw the entire delivery system as one unit, over the guidewire, into the guiding sheath and out of the body. Remove the delivery device from the guidewire. Do not rotate the handle during withdrawal.

▶ *Note: The guidewire lumen will be exposed upon removal of the device from the sheath. Be sure that distal tip is visible outside of the hemostasis valve before attempting to grasp the guidewire.*

B. Using fluoroscopy, visualize the stent to verify full deployment. If incomplete expansion exists within the stent at any point along the lesion, post deployment balloon dilatation (standard PTA technique) can be performed.

▶ *Note: Only areas within the stent length should receive post-deployment balloon dilatation.*

C. Select an appropriate size PTA balloon catheter and dilate the lesion with conventional technique. The inflation diameter of the PTA balloon used for post-dilatation should approximate the diameter of the reference vessel. Remove the PTA balloon from the patient.

Post-Procedure

A. Remove the guidewire and sheath from the body.

B. Close the entry wound as appropriate.

C. After use, all components used, and packaging materials may be a potential biohazard. Handle and dispose of in accordance with the accepted medical practice and with applicable local, state and federal laws and regulations.

▶ *Note: Physician experience and discretion will determine the appropriate post-procedure drug regimen for each patient.*

Instructions for Use

For more information and to access BRITE TIP RADIANZ™ Guide Sheath, SABERX RADIANZ™ PTA Dilatation Catheter, and S.M.A.R.T. RADIANZ™ Vascular Stent System instructions for use (IFU), please visit **https://www.cordislabeling.com**

Disclaimer

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Important information: Prior to use, refer to the instructions for use supplied with this device for indications, contraindications, side effects, suggested procedure, warnings and precautions.

ZEPHYR Band is manufactured by Advanced Vascular Dynamics and distributed by Cordis.

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