Pocket Reference Guide For (CTO) Technologies

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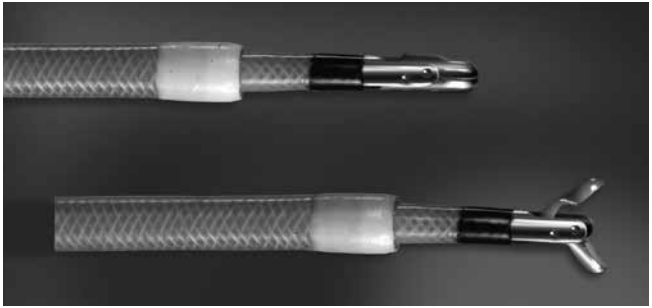
Table of Contents

Essential prescribing information for both FRONTRUNNER™ XP CTO Catheter and OUTBACK™ LTD™ Re-Entry Catheter can be found at the back of this pocket guide.



The FRONTRUNNER™ XP CTO Catheter is designed to cross chronic total occlusions in the peripheral vasculature by creating a pathway through the occluded vessel via controlled blunt micro-dissection.

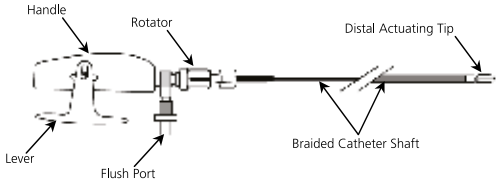
INDICATIONS

The FRONTRUNNER™ XP CTO Catheter is intended to facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

CONTRAINDICATIONS

The device is not intended for use in the cerebral vasculature.

Device Description



Consists of:

- A handle assembly with an integral rotator and a flush port for internal device flushing
- A proximal braided shaft for push and torque control
- A flexible distal shaft which may be manually shaped
- A radiopaque blunt-shaped distal actuating tip, comprised of a set of bilateral hinged pieces

Note: The FRONTRUNNER™ XP CTO Catheter DOES NOT have a guidewire lumen.

Device Specifications

FRONTRUNNER™ XP CTO Catheter

- .039" distal tip & crossing profile
- 2.3mm jaw opening
- Two lengths – 90cm & 140cm
- Not an over-the-wire system

Micro Guide Catheter

- Use with the FRONTRUNNER™ XP Catheter
- Stainless steel flat on flat braid
- Multi-segment nylon design
- PTFE liner
- 4.5F profile, 6F sheath compatible
- Peripheral – 82cm & 132cm lengths (76cm/126cm working lengths)
- Radiopaque tip

FRONTRUNNER™ XP CTO Catheter
Product Overview

Preparation of the Device

- Visually inspect for complete opening and closing of the distal tip – do not use if full closure cannot be achieved
- The distal shaft of the catheter may be manually shaped to facilitate its guidance through the vasculature – do not use tools of any kind to shape the catheter as this may compromise the hydrophilic coating
- Flush the catheter with heparinized saline through the proximal flush port located on the handle assembly
- Wipe the catheter with heparinized saline or submerge in heparinized saline to hydrate the hydrophilic coating just prior to use

Operation of the Device

- Push on the distal end of the handle lever to open the distal tip
- Push on the proximal end of the handle lever to close the distal tip
- Guidance and tracking of the catheter through the vasculature is accomplished by selective manual shaping of the flexible distal shaft, and controlled torquing of the handle rotator

* This section provides only an overview of product use. For more detailed use information, please read the Instructions for Use.

Introducing the device to the patient

- Advancement, manipulation, actuation (opening and closing the distal tip), and withdrawal of the catheter should always be performed under high-quality fluoroscopic guidance
- Ensure that the distal tip is closed prior to advancing the catheter to the lesion
- If a guidewire is in place in the patient, remove it
- Introduce the FRONTRUNNER® XP Catheter

For initial case success the following case and patient selection is recommended:

SFA cases are recommended and physicians should avoid aortic, subclavian and popliteal (below-the-knee) occlusions during initial experience with the FRONTRUNNER™ XP Catheter.

SFA Occlusions (Initial Experience)

- Best location for initial experience with FRONTRUNNER™ XP Catheter
- Antegrade or contralateral approach acceptable with mild tortuosity or minimally steep bifurcation
- In antegrade cases, proximal SFA should be patent and free of disease
- Mild calcium level in SFA and across CTO
- Focal to moderate occlusion length
- 5mm diameter vessel or greater

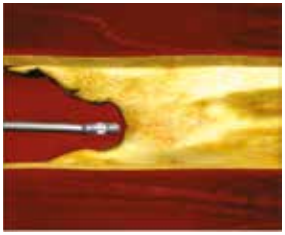
For initial iliac case we recommend:

- Should be focal to short occlusion length (1cm – 4cm)
- Should have visualization of true iliac lumen both distal and proximal to CTO
- 1cm or greater nub at iliac origin (proximal common iliac at aortic bifurcation) is recommended
- Minimal tortuosity
- Mild degree of calcium

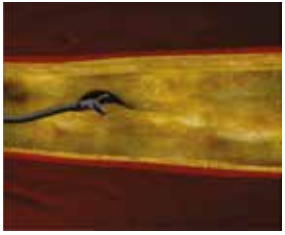
Imaging Suggestions:

- Perform a complete arteriogram to evaluate inflow and outflow
- Magnify the image where the device meets the lesion at the proximal cap and through the occluded segment
- Use of a roadmap may help to guide passage of the FRONTRUNNER™ XP Catheter

Technique 1 – 4 steps used by some physicians to engage and cross the lesion with the FRONTRUNNER™ XP Catheter

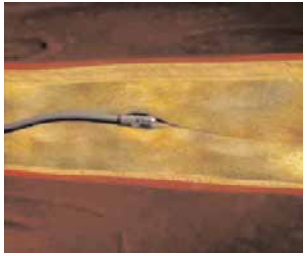


Step 1 – Advance with the distal tip in the closed position, advance the FRONTRUNNER™ XP Catheter to or through the lesion utilizing fluoroscopic guidance and steering the catheter's distal tip with the handle rotator. Advance the Micro Guide Catheter in tandem with the FRONTRUNNER™ XP Catheter. For optimal support position the Micro Guide Catheter 3 – 5cm proximal to the FRONTRUNNER™ XP Catheter jaws. When resistance is met proceed to step 2.



Step 2 – ***Open the Jaws.*** Continue to advance the closed distal tip into the lesion, then open the distal tip by pushing on the distal end of the handle lever. Hold open momentarily to help the blunt-micro-dissection of the CTO.

*** Note:** These physician techniques and cases are examples only, derived from interviews and case review with users. They are provided for information purposes only and not as a recommendation for use in any particular case. The technique chosen will be determined by the circumstances of each individual case.

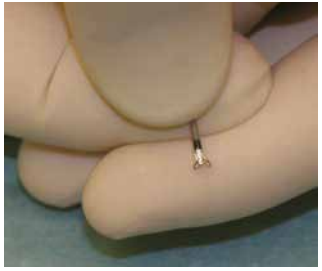


Step 3 – ***Close and Retract.*** Close the distal tip by pushing on the proximal end of the handle and retract the catheter slightly. If the catheter does not retract freely, continue to retract without torquing the catheter.

Step 4 – Repeat steps 2 and 3 and advance the catheter as needed. Advance the Micro Guide Catheter to facilitate placement of guidewire through the occlusion. Reorient the closed distal tip, as required, by turning the rotator on the handle assembly.

Technique 2 – Shaping the tip of the FRONTRUNNER™ XP Catheter

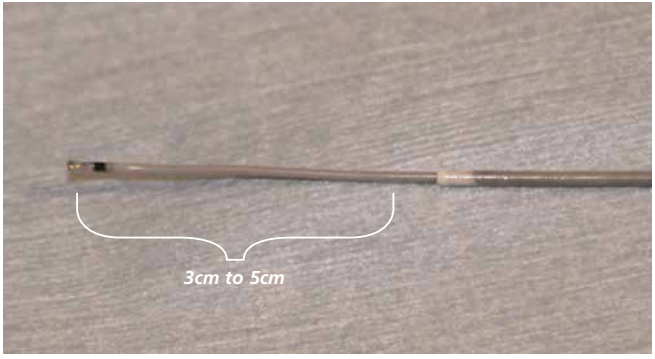
The FRONTRUNNER™ XP Catheter comes packaged straight. Sometimes users may choose to shape the tip of the catheter to facilitate steerability.



To shape the distal tip of FRONTRUNNER™ XP Catheter, first open the jaws by pushing on the distal end of the handle lever. Bend the distal tip right below the black marker band with one finger while holding the distal tip proximal to the black marker band between two fingers. Do not use metal tools to shape the catheter.

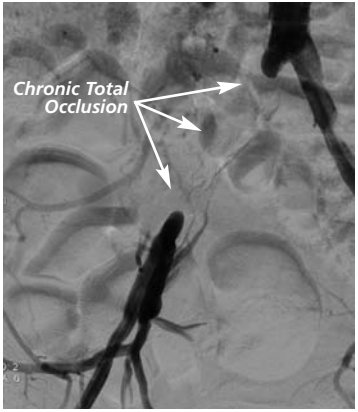
Technique 3 – Have the scrub tech hold the Micro Guide Catheter at the proximal sheath for additional support while the physician directs the FRONTRUNNER™ XP Catheter through the occlusion.

Technique 4 – Some physicians have found it helpful to have the Micro Guide Catheter approximately 3cm to 5cm behind the distal tip of the FRONTRUNNER™ XP Catheter. This relative distance allows the Micro Guide Catheter to provide adequate support and flexibility of the FRONTRUNNER™ XP Catheter to navigate through the occlusion.

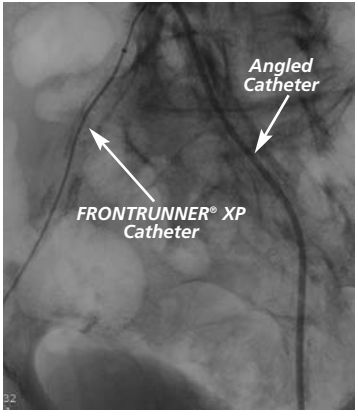


Case 1 – FRONTRUNNER™ XP Catheter in Iliac Occlusion (ipsilateral approach)

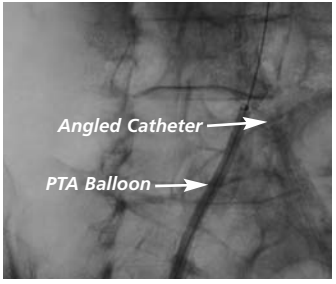
Patient has a mid-iliac occlusion on the right side.



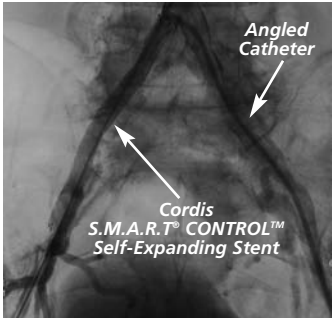
For iliac cases, dual access allows for easier visualization. Sheath access is obtained from both the left and right sides. From the left femoral artery, a diagnostic catheter is placed proximal to the occlusion providing a "target" for the physician. Initially, the physician attempts to cross the CTO with a guide wire ipsilaterally. The guidewire is not able to cross the CTO. From the right side the physician inserts the FRONTRUNNER™ XP Catheter and engages the iliac occlusion ipsilaterally.



- As needed the physician may choose to shape the tip
- The Micro Guide Catheter and FRONTRUNNER™ XP Catheter work as a system. There is more support for the FRONTRUNNER™ XP Catheter when the Micro Guide Catheter is advanced closer to the distal tip of the FRONTRUNNER™ XP Catheter and less support when it is proximal
- Do not inject contrast through the Micro Guide Catheter if the FRONTRUNNER™ XP Catheter is subintimal. The "contrast stain" in the subintimal space will make visualization of the reconstitution point difficult and can create a hydraulic dissection

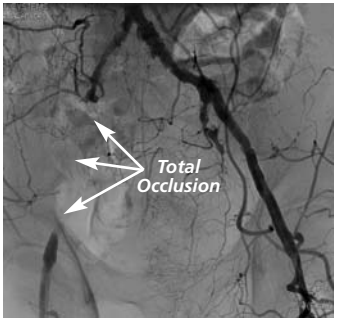


After the FRONTRUNNER™ XP Catheter creates a channel for the wire to cross the occlusion, the physician dilates the iliac vessel with a PTA balloon and places a S.M.A.R.T.™ CONTROL™ Self-Expanding Stent to maintain vessel patency. S.M.A.R.T.™ CONTROL™ Iliac Stent System has proven 95% patency at 12 months.[1]

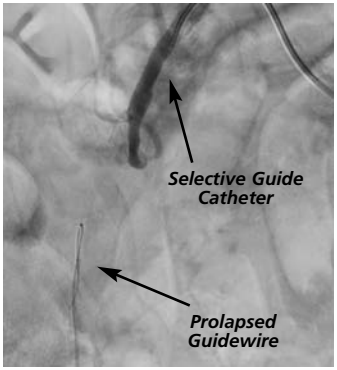


[1] Ponec et al. *The Nitinol S.M.A.R.T.™ Stent vs Wallstent for Suboptimal Iliac Artery Angioplasty: CRISP-US Trial Results. JVIR.* Vol 15, No 9

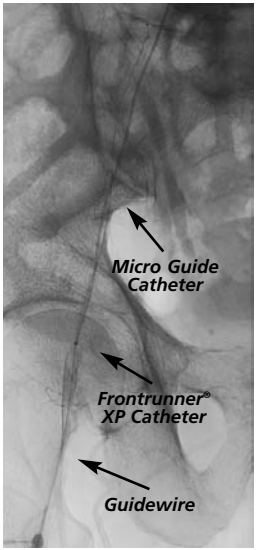
Patient has a mid-iliac occlusion on the right side.



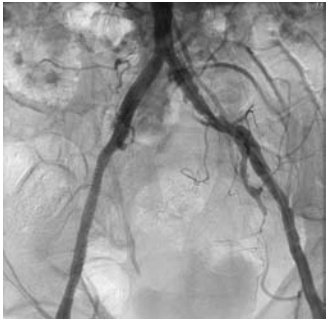
For iliac cases, dual access allows for easier visualization. Sheath access is obtained from both the left and right sides. The physician initially attempts to cross the CTO ipsilaterally using a guidewire. The guidewire is not successful in crossing the CTO. Placing a diagnostic catheter contralaterally from the left side into the iliac bifurcation provides a "target" for the physician to aim.



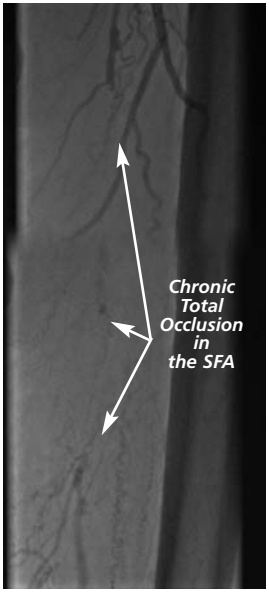
Using contralateral access from the left femoral artery across the aorto-iliac bifurcation, the physician inserts the FRONTRUNNER™ XP Catheter and engages the iliac occlusion. The physician leaves the guidewire distal to the CTO as a "target" for the FRONTRUNNER™ XP Catheter.



After the FRONTRUNNER™ XP Catheter creates a channel for the wire to cross the occlusion, the physician dilates the iliac vessel with a PTA balloon. After the iliac vessel is dilated with a PTA balloon, the physician places multiple self-expanding stents to maintain patency.

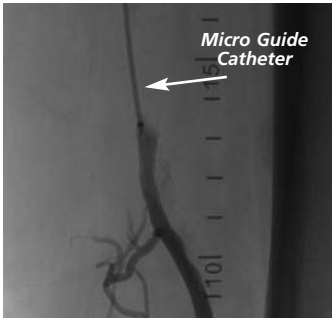


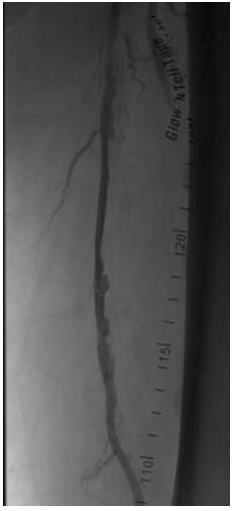
Patient has a mid-distal SFA occlusion on the left side.



For SFA cases, the occlusion can be approached either through contralateral (retrograde) or ipsilateral (antegrade) access. For visualization, keep the sheath proximal to the profunda allowing the contrast to fill the collateral vessels.

The FRONTRUNNER™ XP Catheter crosses the mid-distal SFA occlusion. The Micro Guide Catheter works with the FRONTRUNNER™ XP Catheter as a system. The Micro Guide Catheter helps maintain position during crossing and creates a channel for the guidewire to cross the CTO.

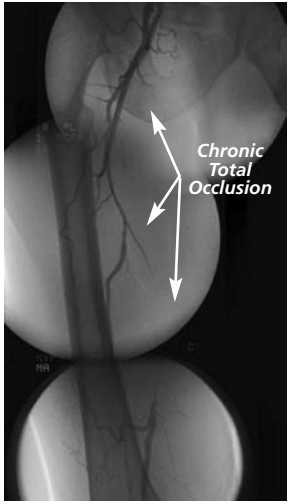




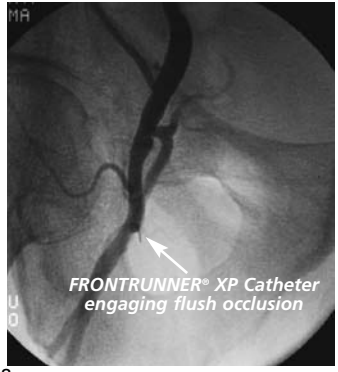
After the FRONTRUNNER™ XP Catheter creates a channel for the wire to cross the physician dilates the SFA with a PTA balloon to gain vessel patency.

Patient has a flush SFA occlusion on the right side.

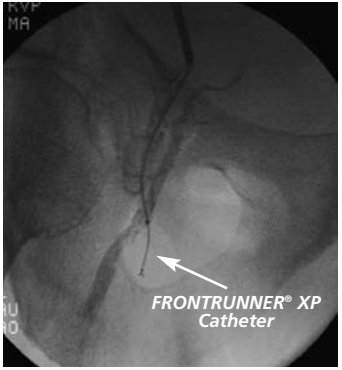
The physician approaches the occlusion contralaterally. For visualization, he keeps the sheath proximal to the profunda allowing the contrast to fill the collateral vessels. The physician pre-shapes the distal tip of the FRONTRUNNER™ XP Catheter to give it additional angle to engage the CTO.



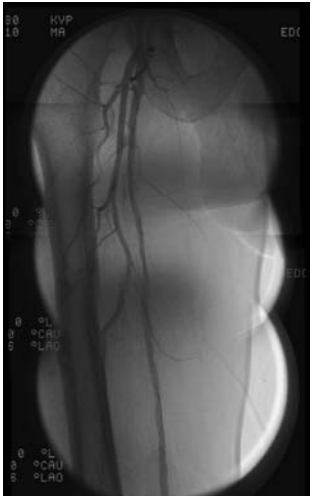
In flush occlusions, prior to retracting the FRONTRUNNER™ XP Catheter, ensure that the Micro Guide Catheter is embedded in the CTO.



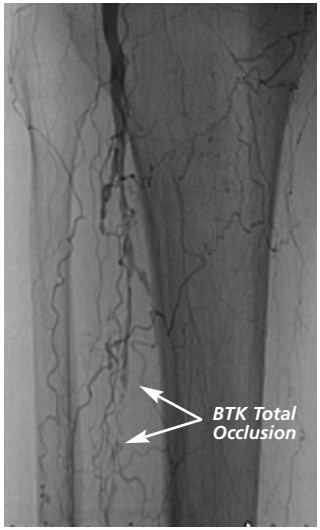
The physician continues to cross the SFA occlusion with the FRONTRUNNER™ XP Catheter (Please see Technique 1 on page 8 for additional technique). After penetrating the proximal cap, the physician continues to open and close the jaws of the FRONTRUNNER™ XP Catheter in areas where resistance is encountered.

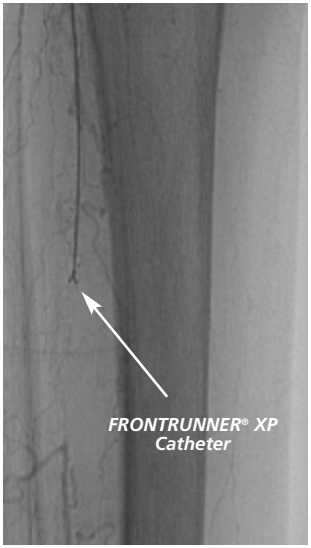


After the FRONTRUNNER™ XP Catheter and the Micro Guide Catheter create a channel for the wire to cross, the physician dilates the SFA with a PTA balloon.



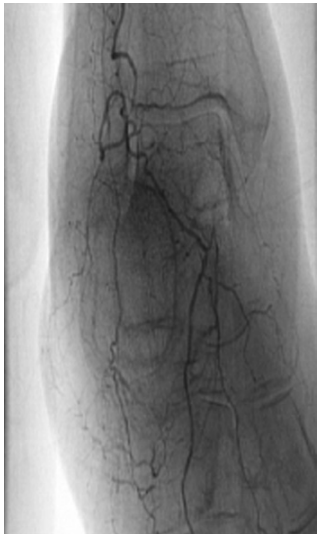
For a below-the-knee case, visualization of the distal reconstitution is recommended.

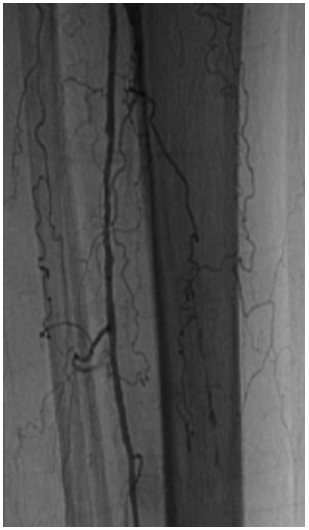




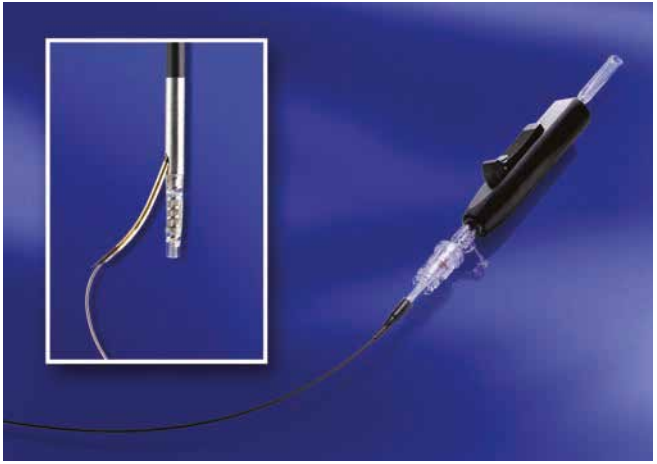
For below-the-knee cases, antegrade access and the 90cm FRONTRUNNER™ XP Catheter is recommended. The shorter FRONTRUNNER™ XP Catheter allows for more control and pushability. More caution should be used in cases in which the takeoff angle of the anterior tibial artery is more severe and the arteries are smaller.

After the FRONTRUNNER™ XP Catheter and Micro Guide Catheter create a channel for the wire to cross the physician dilates the tibial vessel with a small PTA balloon.





Post-PTA angiography shows single vessel run off and blood flow to the right foot.



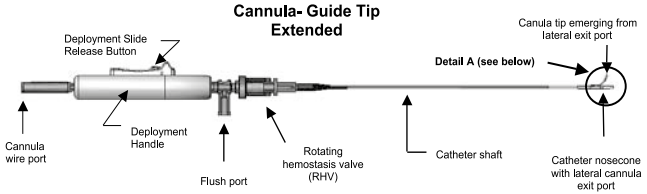
The OUTBACK™ LTD™ Re-Entry Catheter is a single lumen catheter designed to gain re-entry to the true lumen when stuck in the subintimal space.

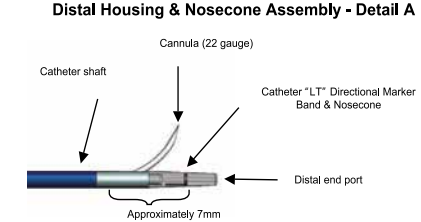
INDICATIONS
The OUTBACK™ LTD™ Re-Entry Catheter is intended to facilitate placement and positioning of guidewires and catheters within the peripheral vasculature. The OUTBACK™ LTD™ Catheter is not intended for use in the coronary or cerebral vasculature.

CONTRAINDICATIONS
The OUTBACK™ LTD™ Re-Entry Catheter is not intended for use in the coronary or cerebral vasculature.

* For complete list of WARNINGS, please see the IFU

Device Description





Consists of:

- A handle assembly with a Rotating hemostasis valve (RHV) and a flush port for internal device flushing
- A proximal braided shaft for push and torque control
- A nosecone with "LT" directional markers

Device Specifications

OUTBACK™ LTD™ Re-Entry Catheter

- 5.9 F profile
- 6F sheath compatible
- .014" guidewire compatible
- 120 cm length
- 22 gauge re-entry cannula

.014 Wire Compatibility

The following 300 cm length guidewires are recommended for use with the OUTBACK™ LTD™ Catheter*:

- ATW™ All Track Wire (Cordis Corporation)
- STABILIZER™ Plus Guidewire (Cordis Corporation)
- STABILIZER™ XS Guidewire (Cordis Corporation)
- Luge Guidewire (Boston Scientific-Scimed)
- Choice Guidewire (Boston Scientific-Scimed)
- Mailman Guidewire (Boston Scientific-Scimed)
- Platinum Plus Guidewire (Boston Scientific-Scimed)
- Hi-Torque Ironman Guidewire (Guidant Corporation)
- Hi-Torque SpartaCore Guidewire (Guidant Corporation)
- Hi-Torque Whisper Guidewire (Guidant Corporation)
- Hi-Torque All Star Guidewire (Guidant Corporation)

* LuMend, Inc. test results have shown these wires to be compatible with the OUTBACK™ LTD™ Catheter. Failure to use a recommended guidewire may result in damage to the guidewire, such as, abrasion of the hydrophilic coating, release of polymer fragments, separation of the wire, or inability to withdraw the OUTBACK™ LTD™ Catheter over the guidewire.

SFA Occlusions (Initial Experiences)

- Preferred location for initial experience with OUTBACK™ LTD™ Catheter
- Contralateral approach with mild tortuosity or minimally steep bifurcation
- Antegrade approach is only recommended if the proximal SFA is patent and free of disease.
- Mild calcium level in SFA, especially at distal reconstitution / re-entry site
- Focal to medium occlusion length
- 5mm diameter vessel or greater

Iliac Occlusions

- Should have visualization of true iliac lumen both distal and proximal to CTO
- 1cm or greater nub at iliac origin (proximal common iliac at aortic bifurcation) is recommended
- Minimal tortuosity with mild degree of calcium
- 6mm vessel diameter or greater

Avoid all below-the-knee vessels with OUTBACK™ LTD™ Catheter.

Imaging Suggestions

- Perform a complete arteriogram to evaluate inflow and outflow
- Magnify the image intensifier at the target zone (area of reconstitution)

7 Steps to OUTBACK™ LTD™ Catheter Success

Step 1: Visualize Distal Artery

Step 2: OUTBACK™ LTD™ Catheter Preparation

Step 3: Select and Load Guidewire

Step 4: Track Catheter Over Guidewire

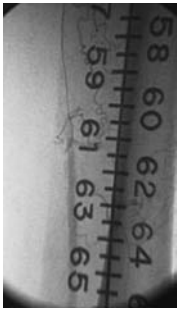
Step 5: Locate

Step 6: Tune

Step 7: Deploy

* This section provides only an overview of product use. For more detailed use information, please read the Instructions for Use.

Step 1: Visualize Distal Artery



- Inject contrast through sheath
- If contralateral, confirm sheath is proximal to profunda to visualize vessel reconstitution
- If ipsilateral, ensure visualization by allowing contrast to fill collateral branches
- Avoid contrast in subintimal space to prevent "staining" of subintimal space

Step 2: OUTBACK™ LTD™ Catheter Preparation

- Remove the silastic tube from the extended cannula
- Flush the catheter, at the flush port and the guidewire port
- Wait 30 seconds, then flush again
- Actuate cannula 2-3 times; retract cannula tip into nose cone
- Prior to insertion into the body, ensure cannula tip is fully retracted into the catheter lateral port and the handle deployment slide is locked in the most proximal position
- If not, repeat flushing sequence above

Step 3: Select and Load Guidewire

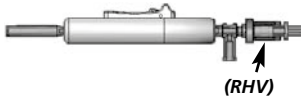
- Use smooth, transitionless guidewire
- Do not use wires with multiple external welds
- Recommended .014" guidewires (300cm length)
  - ATW™ All Track Wire (Cordis Corporation)
  - STABILIZER™ Plus Guidewire (Cordis Corporation)
  - STABILIZER™ XS Guidewire (Cordis Corporation)
  - Luge Guidewire (Boston Scientific-Scimed)
  - Choice Guidewire (Boston Scientific-Scimed)
  - Mailman Guidewire (Boston Scientific-Scimed)
  - Platinum Plus Guidewire (Boston Scientific-Scimed)
  - Hi-Torque Ironman Guidewire (Guidant Corporation)
  - Hi-Torque SpartaCore Guidewire (Guidant Corporation)
  - Hi-Torque Whisper Guidewire (Guidant Corporation)
  - Hi-Torque All Star Guidewire (Guidant Corporation)
- Load OUTBACK™ LTD™ Catheter onto .014" guidewire with the cannula tip retracted within the shaft

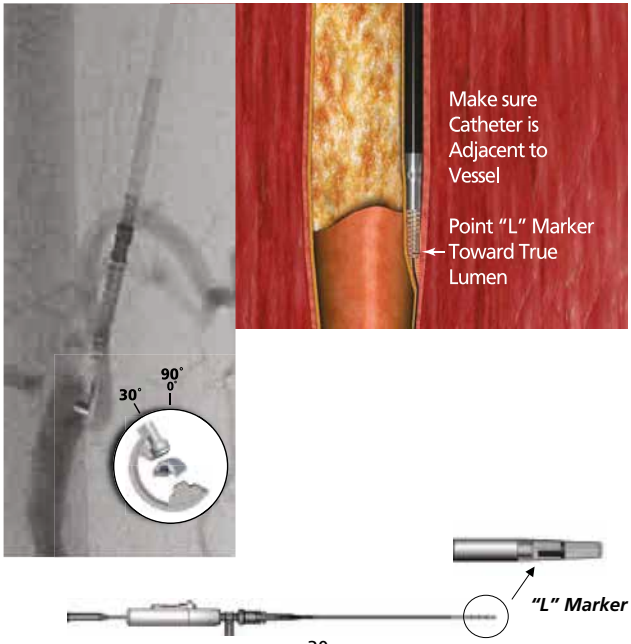
Step 4: Track Catheter Over Guidewire

- While tracking the catheter over a guidewire, always ensure the cannula tip is fully retracted inside catheter lateral port and the handle deployment slide is locked in the most proximal position
- Always track the catheter over a guidewire – do not track the catheter in the vasculature without a guidewire • Track the catheter over the guidewire to the desired vascular site – torque the catheter as needed during delivery via the handle RHV
- Rotate the image intensifier so the distal housing of the OUTBACK™ LTD™ Catheter is adjacent to the target re-entry site when visualized using fluoroscopy when visualized using fluoroscopy

Step 5: Tune the "L" Marker

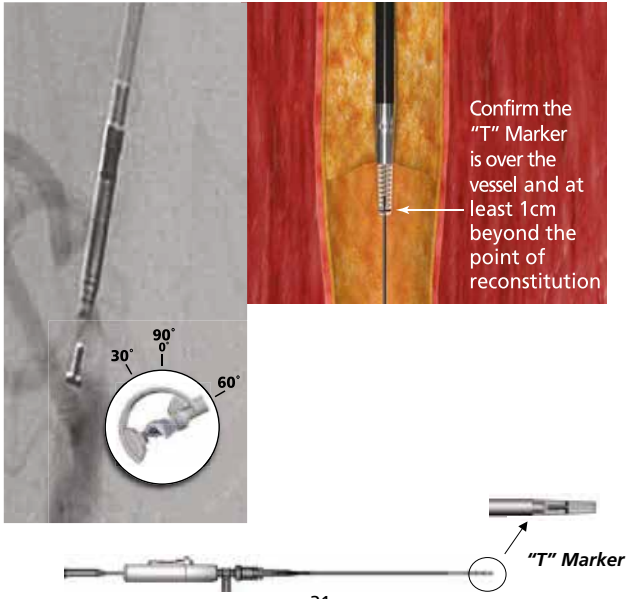
- Position image intensifier to show OUTBACK™ LTD™ Catheter adjacent to true lumen so that "L" marker is >1cm beyond point of reconstitution
- Point "L" marker toward the true lumen by turning the proximal rotating hub (rotating hemostasis valve – RHV)



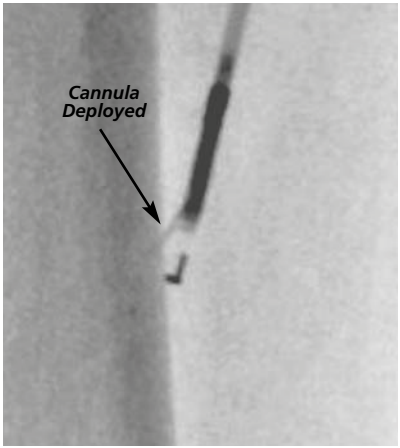


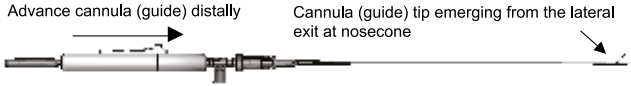
Step 6 – Tune the "T" Marker

- Move image intensifier to (90 degree) orthogonal view
- Ensure OUTBACK™ LTD™ Catheter is 'in line' with true lumen
- Fine tune OUTBACK™ LTD™ Catheter to display full "T" marker by rotating the rotating hemostasis valve (RHV)
- If additional orientation adjustments are necessary, this can be achieved via rotation of the RHV
- A confirming orthogonal view should be taken after each new adjustment of the catheter towards the re-entry target



Step 7 – Deploy the Cannula in the "L" View





- Release any stored torque in the catheter shaft once cannula tip is properly positioned
- Retract guidewire into tip approximately 5cm using fluoroscopic guidance to confirm guidewire position
- Depress handle deployment slide release button and advance the slide to extend the cannula tip
- Advance guidewire gently under fluoroscopy

Advancing the wire and removing the catheter

- If there is evidence of a kinked guidewire, it is recommended that a new guidewire is used for smoother advancement of the wire through the cannula
- Advance the guidewire through the cannula tip to position it as desired at the vascular target site
- Retract the cannula tip into the catheter by fully retracting the handle deployment slide until it hard stops – release the handle deployment slide button to lock the deployment slide in the retracted position
- Ensure the cannula tip is fully retracted into the catheter lateral port, and the handle deployment slide is locked, prior to withdrawing the catheter over the guidewire
- Carefully retract the catheter over the guidewire, leaving the guidewire in place for subsequent therapeutic procedures.
- Exchange the .014 wire for a larger diameter wire to treat the lesions as appropriate

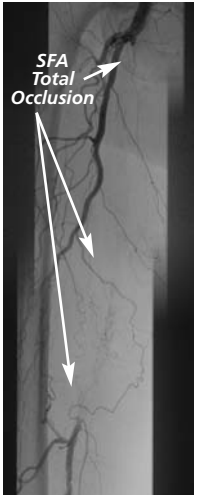
Technique 1 – Replace prolapsed or kinked wire with new guidewire prior to deploying cannula. For smooth deployment of the wire through the cannula, it is recommended a new guidewire be used prior to deploying the cannula if there is any evidence of wire kinking with any of the recommended .014" guidewires (please see page 25 for list of compatible wires).

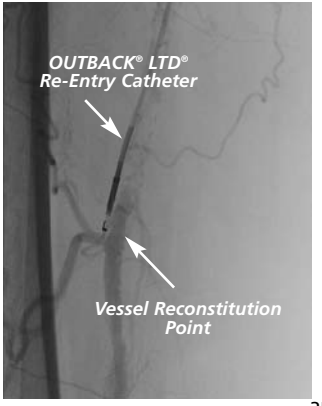
Technique 2 – Pre-dilation of the subintimal track. If strong resistance is felt during catheter manipulation/delivery, determine the cause of the resistance before proceeding further. Consider using a Cordis SAVVY™ PTA Dilatation Catheter at low ATM to dilate points of resistance, as needed, along delivery track. If the cause cannot be determined, withdraw the catheter. Excessive calcification at the site of reconstitution may impair performance.

Technique 3 – Upsize the sheath. Tight aortic bifurcation may make it difficult for the OUTBACK™ LTD™ Catheter to be tracked over the bifurcation. At times exchanging for a larger diameter sheath, 6F sheath exchanged for a 7F or 8F sheath may "layout" the aortic bifurcation.

Patient has an SFA occlusion on the right side. In attempting to cross the CTO with a guidewire the physician goes subintimal. Do not inject contrast into subintimal space.

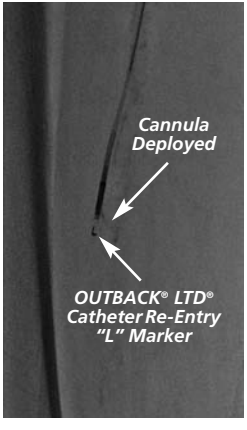
For SFA cases with contralateral approach, the sheath should remain in the common femoral, proximal to the profunda and SFA bifurcation.

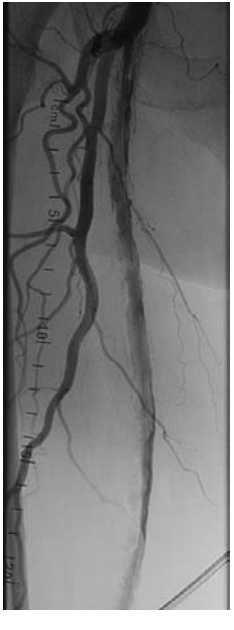




The physician tracks the OUTBACK™ LTD™ Catheter past the point of reconstitution in the subintimal space. Moving the image intensifier, the physician aligns the image so that the OUTBACK™ LTD™ Catheter is parallel and aligns to the vessel. The physician then directs the "L" marker toward the true lumen (at least 1cm distal to the reconstitution point).

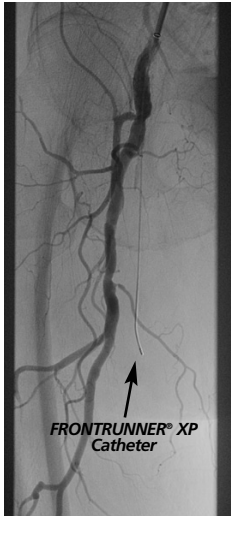
After aligning the "T" marker to be over the vessel, the physician returns the image intensifier to the "L" view to display the cannula. Remember: the cannula deploys approximately 7mm proximal to the "L" marker band.

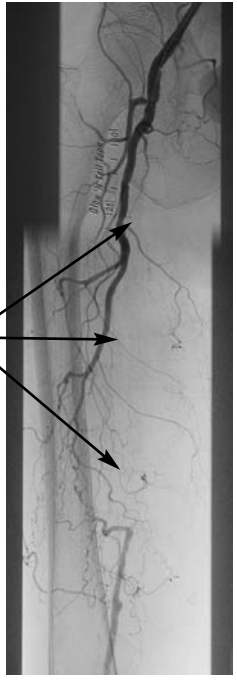




After the OUTBACK™ LTD™ Catheter re-enters the true lumen the physician dilates the re-entry point with a balloon. Dilation helps facilitate further intervention if necessary. The physician decides in this case to use a PTA Balloon to dilate the SFA. A Cordis SAVVY™ PTA Dilatation Catheter is recommended for its low profile and hydrophillic coating.

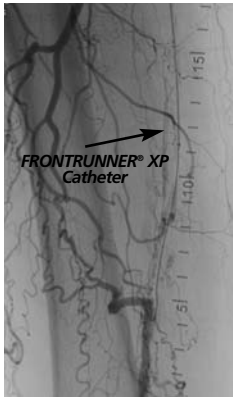
Patient has a flush SFA occlusion on the right side. The physician initially attempts to cross the CTO with a guide wire. Unable to cross, the physician uses the FRONTRUNNER™ XP Catheter.

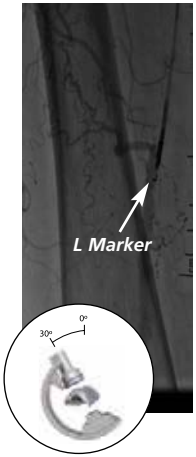


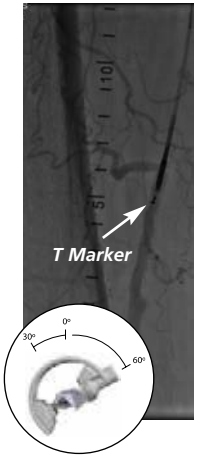


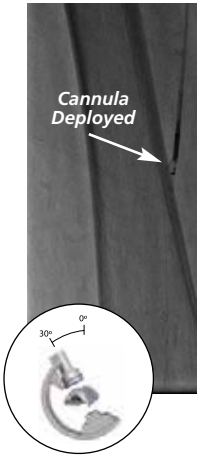
The physician is able to penetrate the proximal cap using blunt micro dissection. For SFA cases with antegrade approach, the sheath should remain in the proximal SFA.

The FRONTRUNNER™ XP CTO Catheter crosses through the CTO via subintimal approach.
The physician decides to use the OUTBACK™ LTD™ Catheter to re-enter the true lumen. The physician aligns the OUTBACK™ LTD™ Catheter so that it is adjacent to the vessel. The physician confirms the direction by aligning the "L" and "T" markers, and then deploys the cannula to re-enter the true lumen.

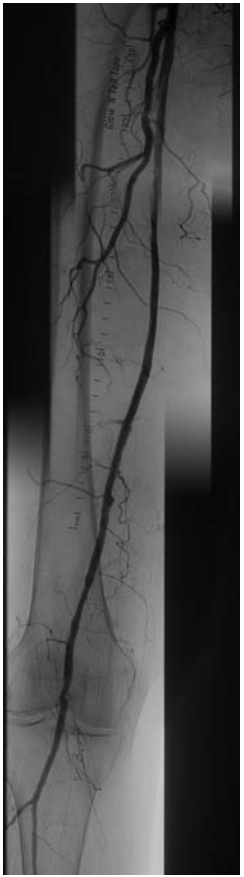




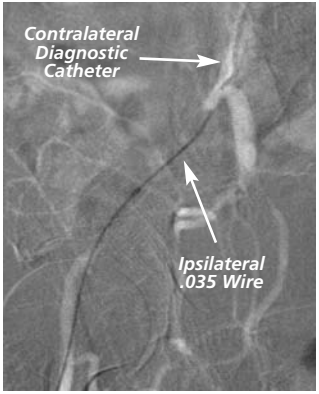


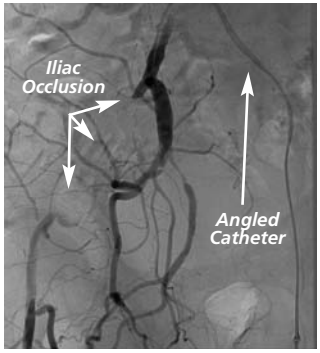


After the OUTBACK™ LTD™ Catheter re-enters the true lumen the physician dilates the re-entry point with a PTA balloon. Dilation helps facilitate further intervention if necessary. The Cordis SAVVY™ PTA Dilatation Catheter is recommended for its low profile and hydrophilic coating.



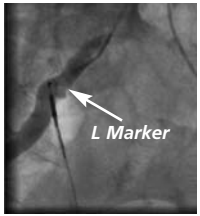
Patient has an iliac occlusion on the right side. For iliac cases, dual access allows for easier visualization. Sheath access is obtained from the other side; placing a diagnostic catheter contralateral from the left side into the iliac bifurcation. This allows for more visualization and a "target" for the physician. With iliac cases, be prepared with an 8mm-10mm occlusion balloon.

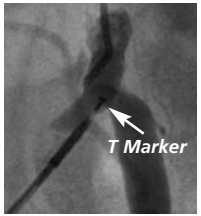


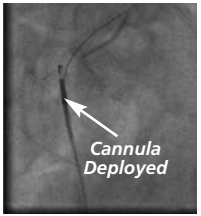


The physician crosses the iliac CTO with a .035 guidewire, however is not able to re-enter into the true lumen.

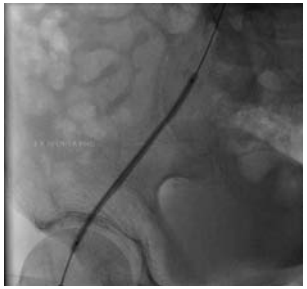
From the right side, the physician inserts the OUTBACK™ LTD™ Catheter and engages the lesion ipsilaterally. Do not inject contrast into subintimal space.

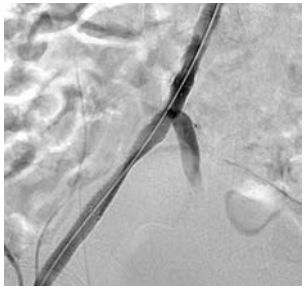






The OUTBACK™ LTD™ Catheter is tracked over a recommended .014" wire and is placed just past the point of reconstitution to avoid the distal CTO cap. Then the cannula is deployed.





After the OUTBACK™ LTD™ Catheter re-enters the true lumen the physician dilates the re-entry point with a Cordis SAVVY™ PTA Dilatation Catheter and dilates the iliac artery with a Cordis OPTA™ PRO PTA Catheter. To maintain patency in the vessel, the physician chose to deploy a S.M.A.R.T™ CONTROL™ Self-Expanding Stent. The S.M.A.R.T® Iliac Stent System has proven 95% patency at 12 months.[1]

Product Ordering Information

Product Code	Product Name	Overall Length (cm)	Usable Length (cm)	Sheath Compatibility (F)	Crossing Profile (F)
FBS3990	FRONTRUNNER™ XP CTO Catheter – 90 cm		90	6	3.1
MGC3990	Micro Guide Catheter (MGC)	82	76	6	4.5
FBP39140	FBP39140 FRONTRUNNER™ XP CTO Catheter – 140 cm		140	6	3.1
MGX39140	Micro Guide Catheter (MGX)	132	126	6	4.5
OTB42120	OUTBACK™ LTD™ Re-Entry Catheter		120	6	5.9

* FBS3990 and MGC3990 work together as a system
FBS39140 and MGC39140 work together as a system

Recommended OUTBACK™ LTD™ Re-entry Catheter compatible .014" guidewires (300 cm)

Wires with solder joints are not recommended for use with OUTBACK™ LTD™ Catheter

Product Code	Product Name	Total Length (cm)	Tip Flexibility	Tip Shape
507-300S	Cordis STABILIZER™ Support Guidewire	300	Supersoft	Straight
527-300E	Cordis STABILIZER™ Extra Support Guidewire	300	Supersoft	Straight

* For other recommended guidewires for the OUTBACK™ LTD™ Catheter, please refer to the list of recommended guidewires in the Instructions for Use (IFU).

STABILIZER™ Support and STABILIZER™ Extra Support Guidewires are packaged 5 per box – order in quantities of five each.

Essential Prescribing Information

FRONTRUNNER™ XP CTO Catheter

Indications for Use: Facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous interventions. Contraindications: Not intended for use in the cerebral vasculature. Warnings: Single use only. Do not resterilize, autoclave, or reuse. Do not use this device to cross a lesion within a stent. Do not use this device in the coronary vasculature. Precautions: Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Device intended for use by appropriately trained physicians. Inspect the catheter for functionality, integrity, size, and shape prior to use to ensure that it is undamaged and suitable for the specific procedure. Do not use if full distal tip closure cannot be achieved. Advancement, manipulation, actuation (opening and closing the distal tip), and withdrawal of the catheter should always be performed under highquality fluoroscopic guidance. In order to reduce the chance of inadvertently trapping tissue in the distal tip of the device, ensure that the distal tip is disengaged from the lesion and closed prior to advancing, rotating, or retracting the device. Torquing excessively may cause damage to the product. Withdraw the catheter should it become kinked. If strong resistance is felt during manipulation, determine the cause of the resistance before proceeding further. If the cause cannot be determined, withdraw the catheter. Do not expose the catheter to organic solvents (e.g., alcohol). Excessive bending or kinking may affect performance. Adverse Effects: Possible complications include, but are not limited to, the following: vessel dissection, perforation, or injury, vascular thrombosis, embolism, puncture site hemorrhage or hematoma, pseudoaneurysm, pyrogenic reaction, sepsis or infection, allergic reaction to contrast medium, pain and tenderness at the insertion site.

Micro Guide Catheter

Indications for Use: To be used with the FRONTRUNNER™ XP CTO Catheter. Facilitate the intraluminal placement of conventional guidewires beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. Contraindications: Not intended for use in the cerebral vasculature. Warnings: Single use only. Do no resterilize, autoclave, or reuse. Do not use to cross a lesion with a stent. Do not use to cross a saphenous vein graft (SVG). Do not torque or advance into a stenotic lesions (chronic total occlusion) without the appropriate use with the FRONTRUNNER™ XP CTO Catheter. Do not use in the coronary vasculature. Precautions: Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. This catheter should only be used by physicians trained in percutaneous interventional techniques in a fully equipped catheterization laboratory. Refer to FRONTRUNNER™ XP CTO Catheter IFU for proper usage. Inspect the device for functionality, integrity, size, and shape prior to use to ensure that they are undamaged and suitable for the specific procedure. Advancement, manipulation, and withdrawal of the device should always be performed under high-quality fluoroscopic guidance. Excessive torquing may cause damage to the product. Withdraw the FRONTRUNNER™ XP Catheter and/or Micro Guide Catheter if either one becomes kinked, or if binding occurs between the devices. Do not advance or torque the device unless the distal end is supported by the FRONTRUNNER™ XP Catheter. If strong resistance is felt during manipulation, determine the cause of the resistance before proceeding further. If the cause cannot be determined, withdraw the FRONTRUNNER™ XP Catheter and/or Micro Guide Catheter. Do not expose to organic solvents (e.g., alcohol). Excessive bending or kinking may affect performance. Removal of the FRONTRUNNER™ XP Catheter may introduce air into the Micro Guide Catheter. To minimize this effect, fully submerge the proximal hub of the Micro Guide Catheter in a bowl of sterile saline while removing the FRONTRUNNER™ XP Catheter from the Micro Guide Catheter. Adverse Effects: Possible complications include, but are not limited to, the following: Essential Prescribing Information vessel dissection, perforation or injury, vascular thrombosis, embolism, puncture site hemorrhage or hematoma, pseudoaneurysm, pyrogenic reaction, sepsis or infection, allergic reaction to contrast medium, pain and tenderness at the insertion site.

OUTBACK™ LTD™ Re-Entry Catheter

Indications for Use: Facilitate placement and positioning of guidewires and catheter within the peripheral vasculature. Not intended for use in the coronary or cerebral vasculature. Contraindications: Not intended for use in the coronary or cerebral vasculature. Warnings: Single use only. Do not resterilize, autoclave, or reuse. Precautions: Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. This catheter should only be used by physicians trained in peripheral percutaneous interventional techniques in a fully equipped catheterization laboratory. Confirm visualization of the targeted distal artery via contrast injection and fluoroscopy before using catheter. Avoid contrast injection in the sub-intimal space. Minimize sub-intimal dissection tract beyond point of reconstitution. Catheter must be well flushed at Rotating Hemostasis Valve (RHV) flush port and cannula wire port with sterile heparinized saline prior to use. Additional flushing may be necessary to maintain smooth guidewire movement. Inspect the catheter for functionality, integrity, size and shape prior to use to ensure that it is undamaged and suitable for the specific procedure. Inspect guidewires to be sure they are free from damage prior to using in conjunction with the OUTBACK™ LTD™ Catheter. Advancement, manipulation, actuation, and withdrawal of the catheter should always be performed under high-quality fluoroscopic guidance. To maintain guidewire position during device exchanges, an exchangeable length guidewire is recommended. Failure to use a recommended guidewire may result in damage to the guidewire, such as, abrasion of the hydrophilic coating, release of polymer fragments, separation of the wire, or inability to withdraw the OUTBACK™ LTD™ Catheter over the guidewire. Ensure that the cannula is fully retracted, and the cannula tip is positioned within the catheter lateral exit port, prior to and during advancement, withdrawal and rotation of the catheter. Failure to do so may result in damage to the guidewire, such as, abrasion of the hydrophilic coating, release of polymer fragments, or separation of the wire, or inability to withdraw the OUTBACK™ LTD™ Catheter over the guidewire. Do not advance the cannula tip without first retracting the guidewire tip into the catheter. Always track the catheter over a guidewire. Do not track the catheter in the vasculature without a guidewire. Always visualize tracking of the catheter tip over the femoral-aorta bifurcation. Use fluoroscopic visualization to verify that the catheter "LT" directional marker band located on the nosecone is oriented toward the desired vascular site prior to actuation of the deployment slide. Rotating excessively may cause damage to the product. Withdraw the catheter should it become excessively kinked. If strong resistance is felt during catheter manipulation/delivery, determine the cause of the resistance before proceeding further. Consider using a 3-4mm balloon at low ATM to dilate points of resistance, as needed, along delivery track. If the cause cannot be determined, withdraw the catheter. Excessive bending or kinking of the catheter may affect its performance. If the guidewire kinks while still inside of the catheter, carefully attempt to remove the wire and replace with a new one. Stop if any resistance is felt when removing wire from catheter. If resistance is encountered retract the cannula tip back into the shaft and then remove catheter and wire together from vasculature. Do not expose the catheter to organic solvents (e.g., alcohol). Excessive calcification at the site of reconstitution may impair performance. Adverse Effects: Possible complications include, but are not limited to, the following: vessel dissection, perforation, or injury, embolism, puncture site hemorrhage or hematoma, infection.

Cordis®
A Cardinal Health company