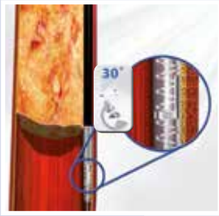
Quick Reference Procedural Guide

This is intended as a quick reference guide only. Prior to use, please read the full Instructions For Use for complete information.

Step 1 - Preparation

- REMOVE cannula tip cover
- FLUSH device at the flush and guidewire exit port, then repeat
- Ensure proper function by
  1) RETRACTING and ADVANCING the cannula tip via proximal and distal movement of the deployment slide, and
  2) ROTATING the Rotating Knob which rotates the catheter shaft/nosecone.
- If cannula does not fully retract back into shaft after initial preparation, **REPEAT flush sequence**
- SELECT recommended 0.014" guidewire

Step 2 - Position Catheter



- ADVANCE the catheter over the wire to the desired site.
- RETRACT the 0.014" guidewire into the catheter approximately 5 cm.
- ROTATE the image Intensifier so the catheter appears adjacent to the **target vessel under fluoroscopy**.
- ORIENT the "L" marker to point toward the target vessel by rotating the **Rotator Knob**.

- ROTATE the image intensifier so the catheter appears superimposed **over the target vessel under fluoroscopy (90° orthogonal view)**.
- ADJUST the catheter by rotating the Rotator Knob such that the **radiopaque marker appears as a "T"**.
- RELEASE any stored torque in the catheter.

Step 3 - Re-Entry

- ROTATE the image intensifier back to the previous **position to confirm "L" marker**.
- DEPLOY cannula into the target vessel by advancing the Deployment **Slide**.
- ADVANCE the 0.014" guidewire into the target vessel.
- RETRACT the cannula and remove catheter over the guidewire.

Ordering Information

OTB59080A	OUTBACK™ Elite Re-Entry Catheter	80 cm
OTB59120A	OUTBACK™ Elite Re-Entry Catheter	120 cm

Wire Compatibility List

The following guide wires are recommended for use with the **OUTBACK™ Elite Re-Entry Catheter**. Failure to use a recommended guide wire may result in damage to the guide wire, such as, abrasion of the hydrophilic coating, release of polymer fragments, separation of the wire, or inability to withdraw the **OUTBACK™ Elite Re-Entry Catheter** over the guide wire.

0.014" ATW (Cordis, A Cardinal Health company)
0.014" STABILIZER™ Plus (Cordis, A Cardinal Health company)
0.014" STABILIZER™ XS (Cordis, A Cardinal Health company)
0.014" Choice Extra Support (Boston Scientific/Scimed)
0.014" Mailman (Boston Scientific/Scimed)
0.014" Luge (Boston Scientific/Scimed).

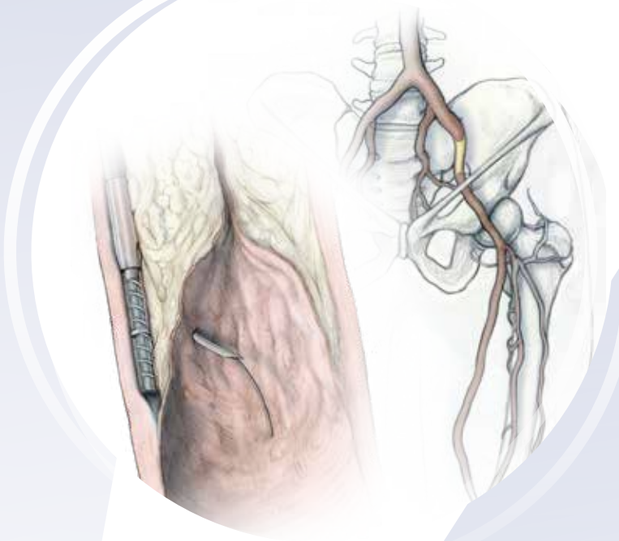
Protected under one or more of the following U.S. Patents: 6,719,725; 6,235,000; 6,217,527 and other patents pending in the U.S. and other countries.

For more information please visit
www.cardinalhealth.co.uk

OUTBACK™ Elite

Re-Entry Catheter

True Precision.
True Control.
True Lumen.

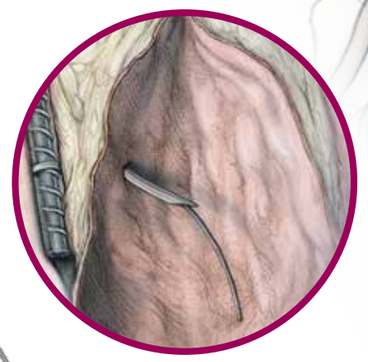


Cordis™
A Cardinal Health company

OUTBACK™ Elite
Re-Entry Catheter

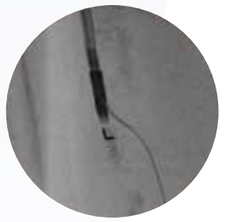
The **OUTBACK™ Elite Re-Entry Catheter** enables faster and more precise re-entry into the true lumen in the most challenging cases.[1]

- 80 cm and 120 cm shaft lengths
- Ergonomic handle for greater control
- Robust Nitinol Cannula

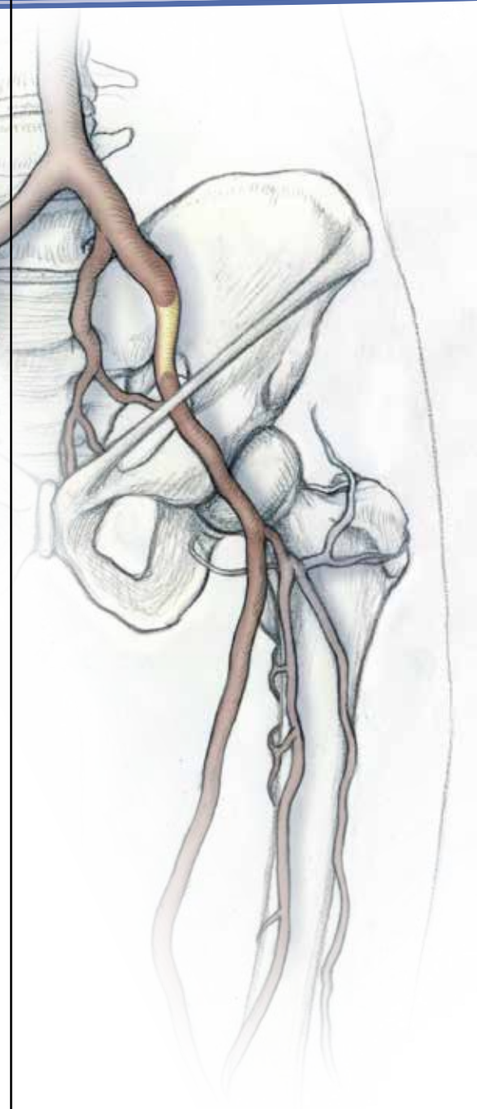


More Ergonomic Handle

True Precision.
True Control.
True Lumen.

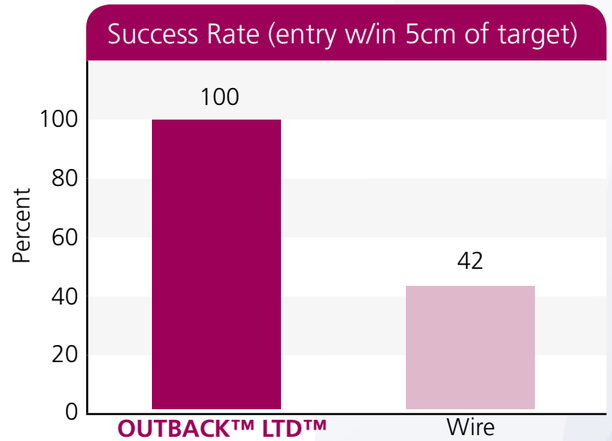


An “LT” marker (radiopaque directional marker) housed within the nosecone assists in visualization of the catheter tip and is used to fluoroscopically align the cannula tip towards the site of reconstitution, thus providing a conduit for guide wire placement.

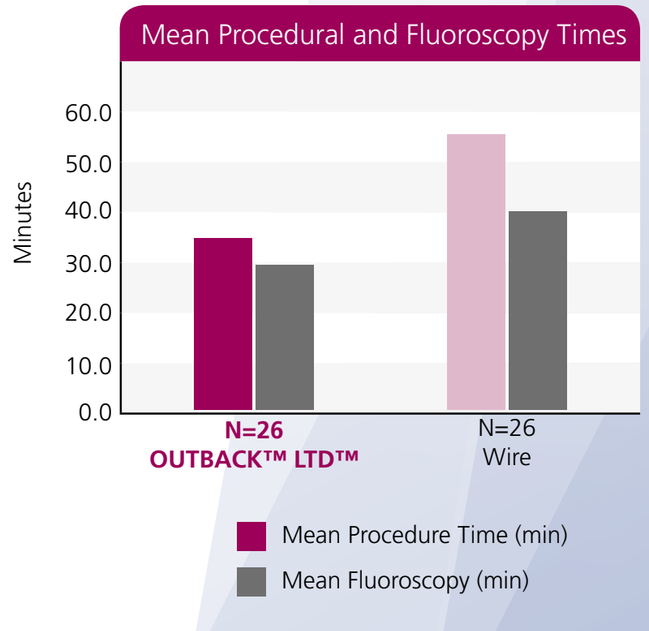


Clinical Performance[1]

The device included in the randomized study was OUTBACK™ LTD™ Re-Entry Catheter



In a study by Gandini et al., the OUTBACK™ LTD™ Re-Entry Catheter was shown to have a higher success rate of precision re-entry. Use of the device also saved the operator and the patient from additional fluoroscopy and procedure time.



1 Gandini, R., Fabiano, S., Spano, S., Volpi, T., Morosetti, D., Chiaravalloti, A., Nano, G. and Simonetti, G. (2013), - Randomized control study of the outbackTM LTD reentry catheter versus manual reentry for the treatment of chronic total occlusions in the superficial femoral artery. Cathet. Cardiovasc. Intervent., 82: 485–492. doi: 10.1002/ccd.24742. Compared with manual re-entry.