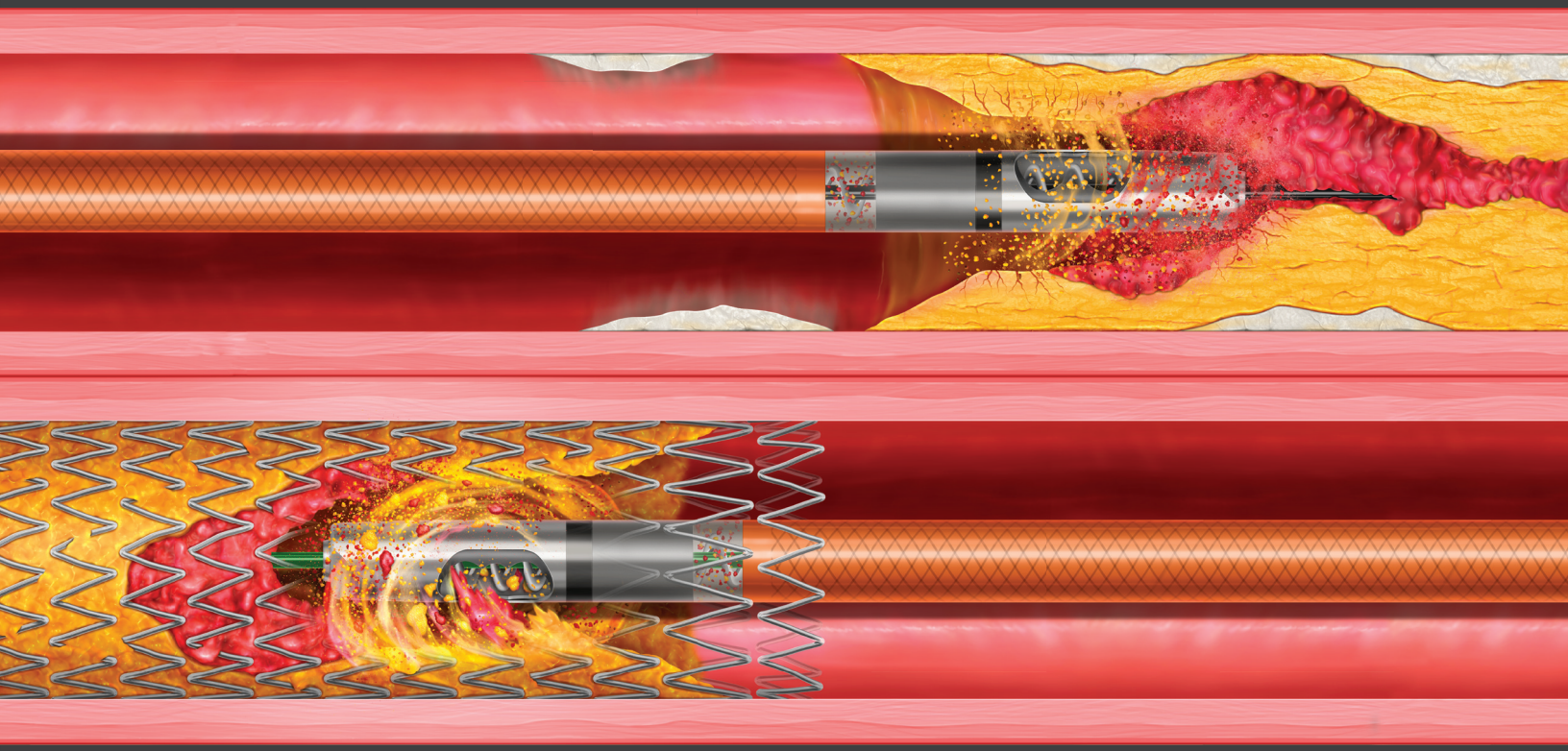
REFINED ATHERECTOMY
BUILT TO REMOVE

Rotarex™S
Endovascular System

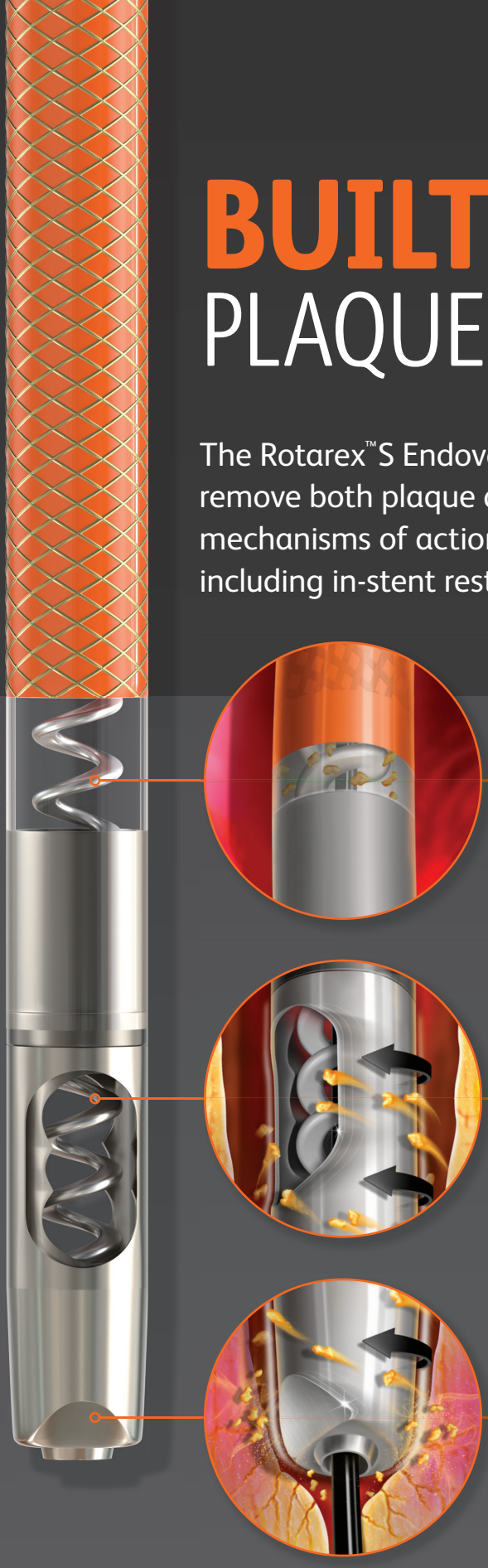
ATHERECTOMY + THROMBECTOMY



BD

BUILT TO REMOVE PLAQUE AND THROMBUS[1]

The Rotarex™ S Endovascular System is designed to efficiently remove both plaque and thrombus by utilising three distinct mechanisms of action to treat peripheral artery disease lesions including in-stent restenosis.



CONTINUOUS ACTIVE ASPIRATION

- Internal helix creates negative pressure at the tip to actively aspirate and transport material away

ROTATING ABRADING VORTEX

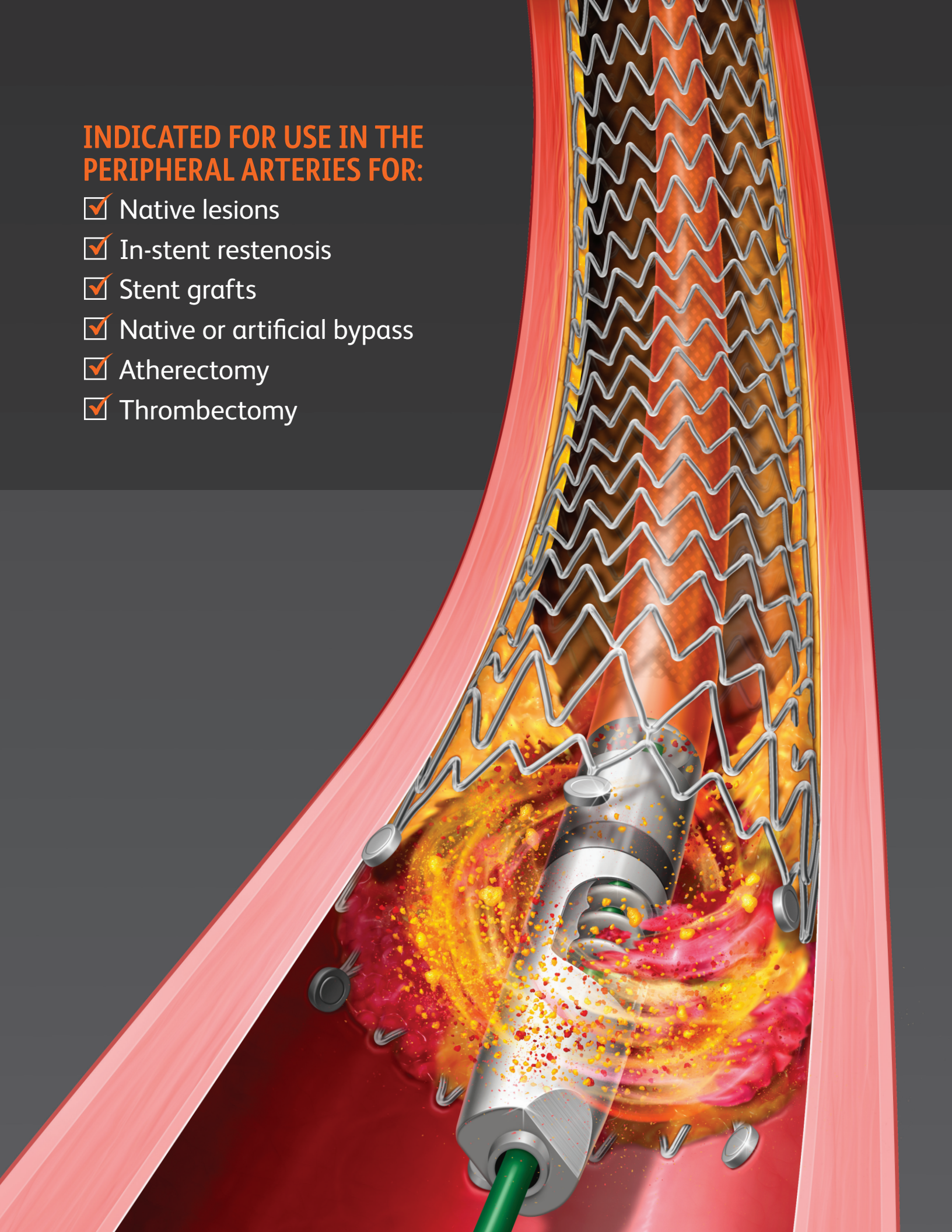
- Vortex creates additional luminal gain around the cylinder
- Large side windows further break down and efficiently remove detached material

MODIFYING BEVELED TIP

- Catheter head and helix rotate at approximately 40,000-60,000 RPMs

INDICATED FOR USE IN THE PERIPHERAL ARTERIES FOR:

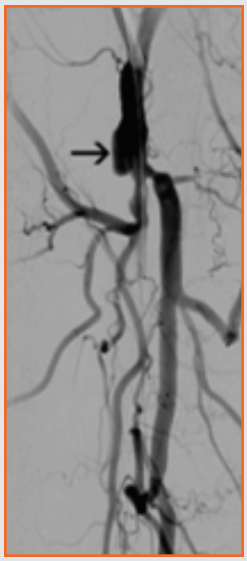
- ☑ Native lesions
- ☑ In-stent restenosis
- ☑ Stent grafts
- ☑ Native or artificial bypass
- ☑ Atherectomy
- ☑ Thrombectomy



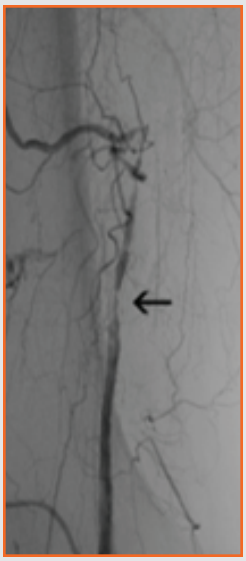
REAL WORLD **CLINICAL EXPERIENCE**

Bypass case: 61-year-old male presented with subacute ischemia of the left lower limb, Rutherford 4, proximal, prosthetic bypass thrombosis (antegrade approach)[2]

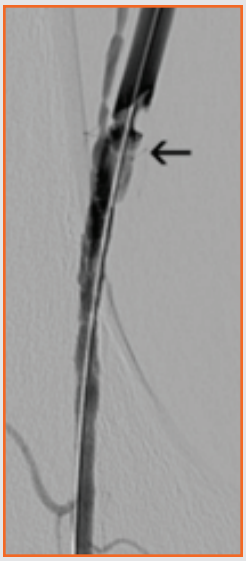
Dr. Bulvas, MD, PhD, Associate Professor Miroslav



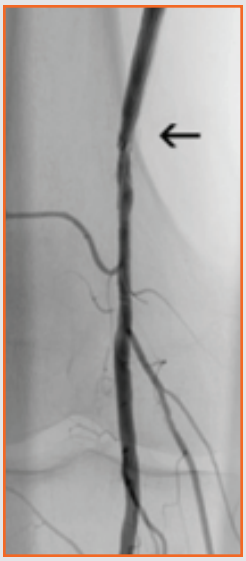
Occluded prosthetic bypass insertion, stenosis of DFA



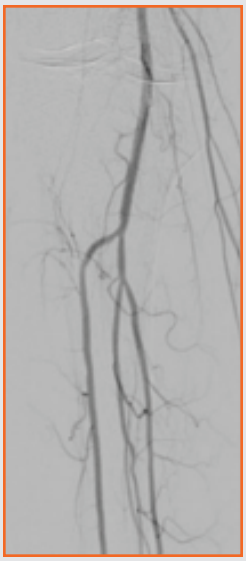
PA filled via collaterals: distal anastomosis



Distal anastomosis after bypass debulking with Rotarex™S Endovascular System



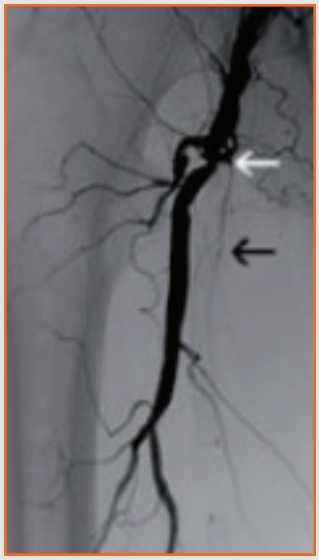
Distal anastomosis after Percutaneous Transluminal Angioplasty and stenting

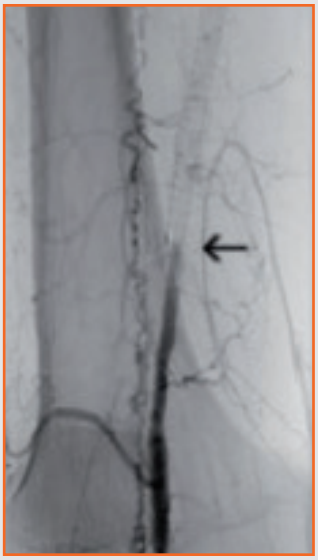


Tibial vessels

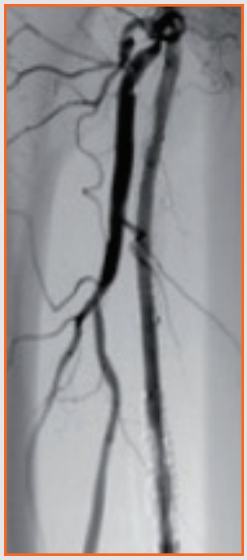
In-stent restenosis case: 59-year-old male presented with acute ischemia of the right lower limb, Rutherford IIb[3]

Dr. Bulvas, MD, PhD, Associate Professor Miroslav

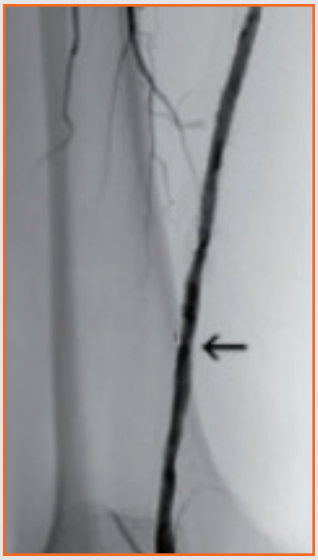




Before treatment the SFA is occluded at its origin (white arrow), proximal margin of stented area is depicted by black arrow. The popliteal artery is filled via collaterals.



After treatment of Rotarex™S Endovascular System alone



After adjunctive PTA

The clinical experiences presented herein are for informational and educational purposes only. The results presented may not be predictive for all studies and patients. Results may vary depending on a variety of experimental and clinical parameters, as well as patient specific attributes. Please consult product labeling for appropriate use.

SFA (Superficial Femoral Artery); PTA (Percutaneous Transluminal Angioplasty); DFA (deep femoral artery); PA (popliteal artery)

The Rotarex™S Endovascular System has been studied in over 2,100 patients.[4]

A meta-analysis of 8 clinical studies comprising data obtained from 2,107 patients studied from 2002 to 2015 was performed to*:

- Establish Rotarex™S Endovascular System clinical performance
- Provide a quantitative review and synthesis of the results of related but independent studies of the Rotarex™S Endovascular System.

Measure/outcomes	Mean (95% CI)
Age	68.1 (66.4, 69.7)
Gender (% male)	65.3% (60.6%, 70.0%)
Treatment time (minutes)	3.0 (1.3, 4.7)
Lesion length (mm)	153.96 (115.24, 192.69)
Technical success	95.8% (94.3%, 97.3%)
Clinical success	79.9% (75.2%, 84.5%)
TLR at 6 months	7.8% (1.0%, 14.5%)
TLR at 12 months	11.3% (7.4%, 15.3%)
Restenosis at 6 months	16.9% (0.0%, 35.3%)
Restenosis at 12 months	35.5% (19.6%, 51.4%)

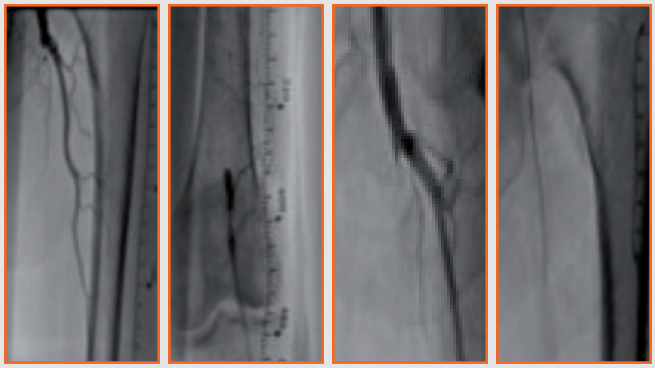
Measure/outcomes	Mean (95% CI)
ABI at baseline	0.33 (0.18, 0.47)
ABI at 6 months	0.83 (0.78, 0.88)
ABI at 12 months	0.77 (0.71, 0.82)
Rutherford score at baseline	3.54 (3.42. 3.67)
Rutherford score at 6 months	1.51 (1.03, 2.00)
Rutherford score at 12 months	2.13 (1.83, 2.42)
Procedure-related dissection	5.9% (3.3%, 8.6%)
Procedure-related embolisation	7.5% (4.7%, 10.4%)
Procedure-related perforation	2.2% (0.9%, 3.4%)
Procedure-related pseudo-aneurysm	1.5% (0.6%, 2.4%)
Procedure-related abrupt reocclusion	2.4% (1.0%, 3.7%)

* The statistical treatment of the data summarised in the table above endpoints with an adequate number of data points (>2). SAS v9.3 (SAS Institute, Cary, NC) was used to pool data and calculate all estimates. For each clinical outcome, a random effects model was executed to calculate pooled estimates per group, as well as the corresponding confidence intervals (CI): there was no adjustment for multiplicity, despite multiple analyses.

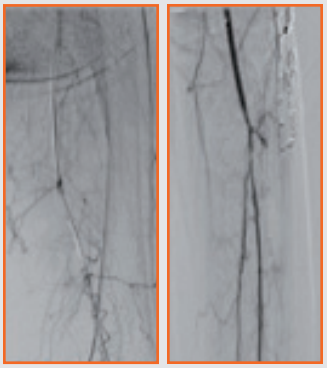
ABI (Ankle Brachial Index); TLR (Target Lesion Revascularisation)

CTO Left SFA: 64-year-old male patient presented with left-sided CLI[5]

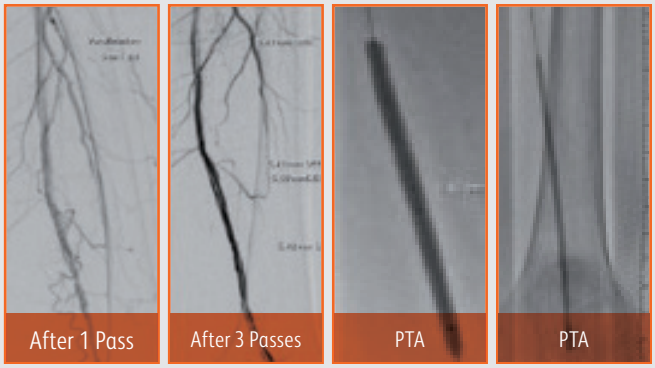
Dr. Bruno Freitas, MD, Prof. Santa Casa de Maceió, Federal University of Alagoas



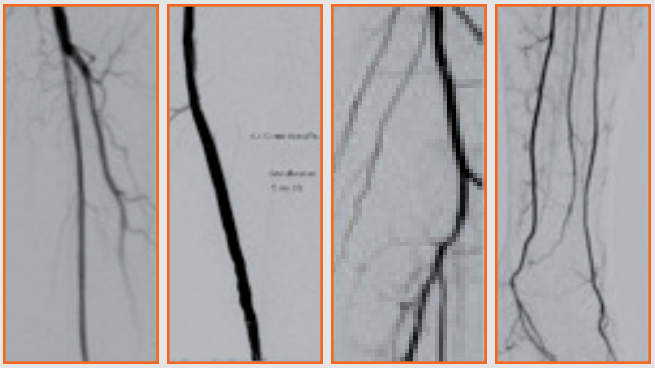
Before treatment. Flush occlusion of left SFA to PII segment. Crossed intraluminally with guidewire.



Extensive collaterals of SFA reconstituting at PII segment, with 2 vessel run-off BTK.



Angiogram after 1 and 3 passes with Rotarex™S Endovascular System Catheter. DCB follows Rotarex™S Endovascular System Atherectomy treatment.



Final angiogram showing restored flow in SFA and 3 vessel run-off BTK.

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CTO (Chronic total occlusion); CLI (Critical limb ischemia); DCB (Drug Coated Balloon); Below the Knee (BTK)

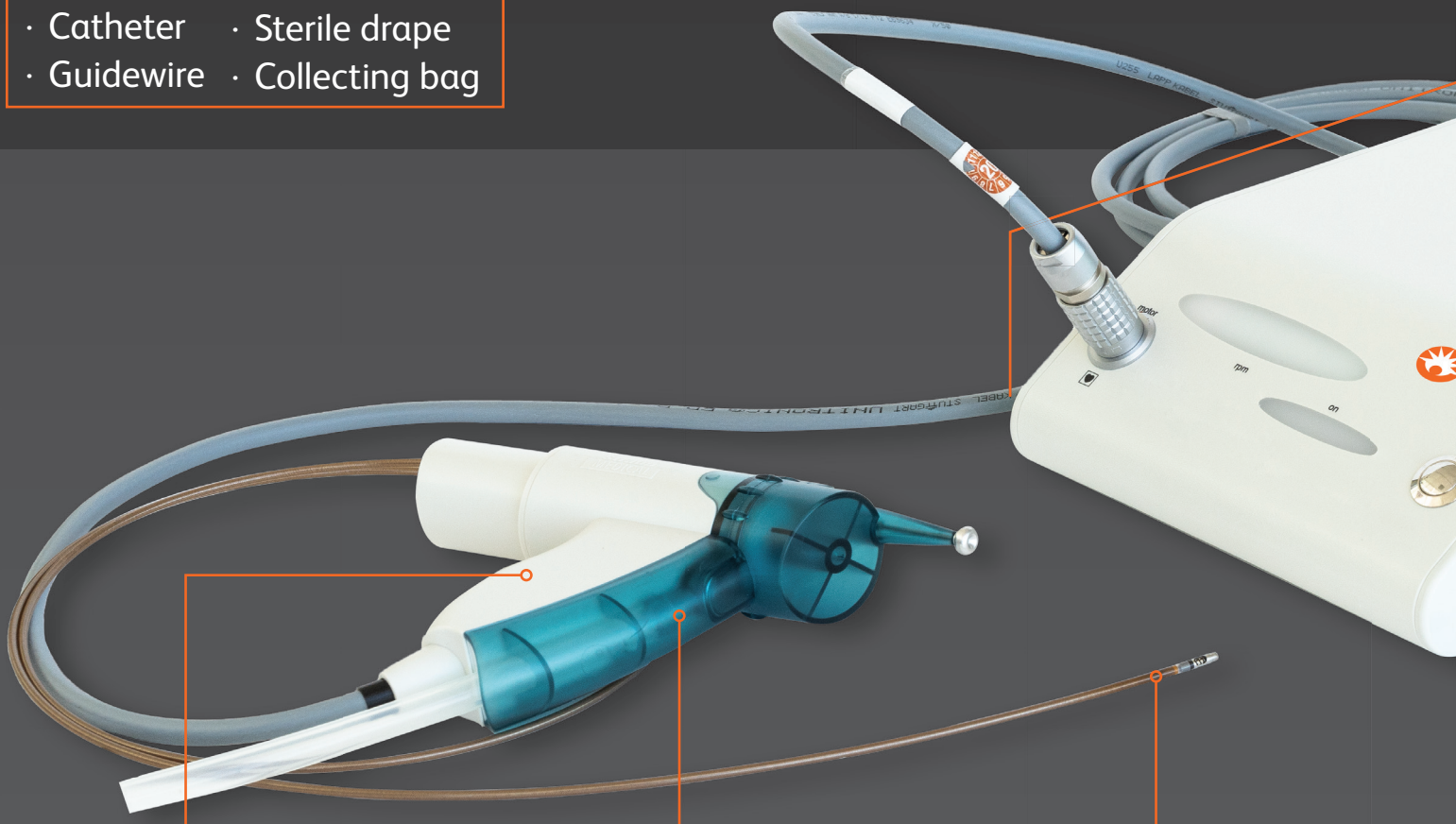
SMALL FOOTPRINT

SIMPLE TO SETUP[6]

- No warm up, infusion or repeated catheter clean out required
- Plug and play capital component

Catheter Set includes:

- Catheter
- Guidewire
- Sterile drape
- Collecting bag



SWITCH

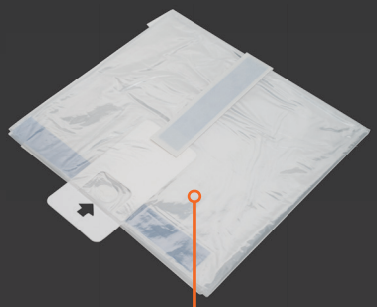
- Operated by hand or optional use foot switch to facilitate single or multiple operator scenarios
- Magnetic coupling facilitates ease of use while in the sterile environment

ERGONOMIC HANDLE

- Easy to use handle designed for single operator control
- Disposable catheter simply clips to reusable portion of the handle
- Included with catheter set

CATHETER

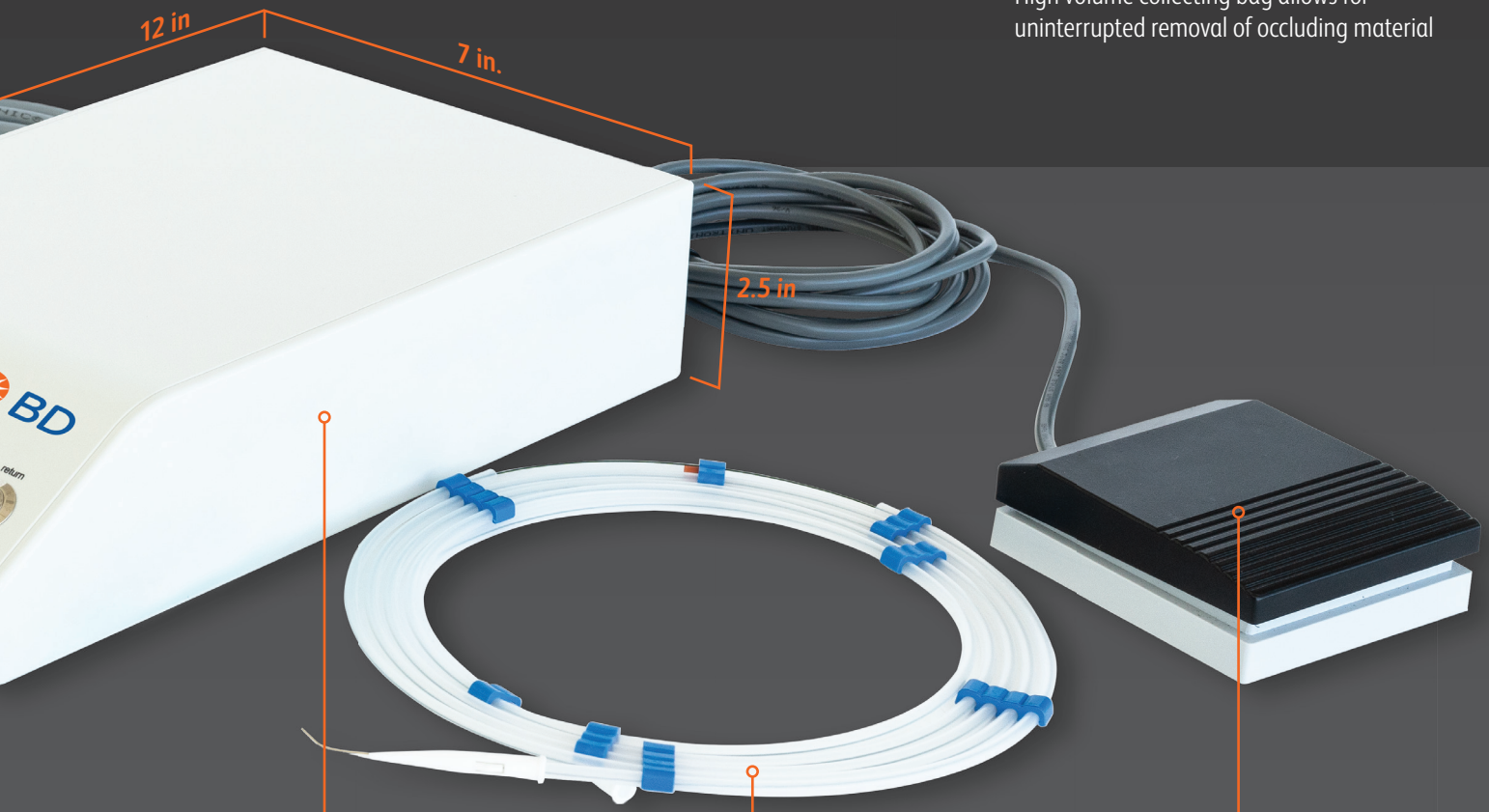
- Designed to perform in a variety of lesions, including complex, mixed morphology occlusions
- No defined limitation on treatable lesion length



STERILE DRAPE

COLLECTING BAG

- High volume collecting bag allows for uninterrupted removal of occluding material



DRIVE SYSTEM

- Small, portable design
- Easy set-up, plug-in and switch on
- System is auto-aspirating, without the need for a separate pump

GUIDEWIRE

- Nitinol core shaft with polytetrafluoroethylene coating for catheter support
- Hydrophilically-coated with a flexible, angled tip to enable lesion crossing
- Gold-plated tungsten coil to enhance visualisation under fluoroscopy

OPTIONAL FOOT SWITCH

- Operated by foot switch or by handle to facilitate single- or multiple-operator scenarios

Rotarex™S

Endovascular System

Rotarex™S Endovascular Catheter set

Size	Length (cm)	Product codes
6F	110	☐ 80219
	135	☐ 80202
8F	85	☐ 80223
	110	☐ 80224
10F	85	☐ 80277

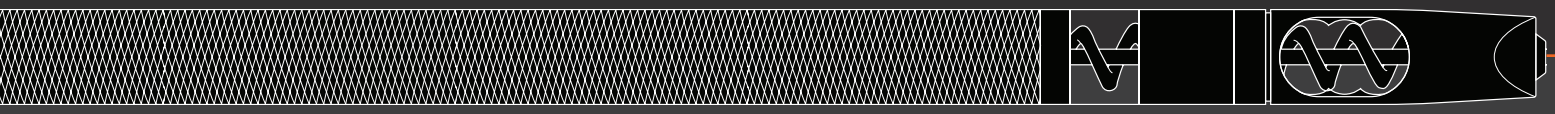
Spare Rotarex™S Endovascular Guidewires (5-Pack)

Diameter	Length (cm)	Tip	Flexible tip	Hydrophilic coating	Product codes
0.018"	220	Angled	40 mm	9.5 cm	☐ 80270
	270	Angled	40 mm	9.5 cm	☐ 80271
	320	Angled	40 mm	9.5 cm	☐ 80272
0.025"	220	Angled	60 mm	8.5 cm	☐ 80304
	270	Angled	60 mm	8.5 cm	☐ 80305

Rotarex™S Drive System

Description	Product code
Drive System	☐ 80300

› Rotarex™S Catheter set includes catheter, guidewire, sterile drape and collecting bag



Rotarex™S Endovascular System

Indication For Use: Rotarex™S catheters catheters in combination with the Straub Medical Drive System (REF SRS-Set/80300) are intended for the percutaneous transluminal removal of thrombotic, thromboembolic and atherothrombotic material from fresh, subacute and chronic occlusions of blood vessels outside the cardiopulmonary, coronary and cerebral circulations; Indicated for: Native blood vessels or vessels fitted with stents, stent grafts or native or artificial bypasses outside the cardiopulmonary, coronary and cerebral circulations.

Contraindications: · In patients not suitable for thrombectomy · In the cardiopulmonary, coronary or cerebral circulations · In vessels that are undersized or oversized for the device used ·

Warnings: · Do not use in anatomical locations with persistent vasospasm · The Rotarex™S family of catheters may only be used with the BD supplied guidewire with which they are packaged · The catheter must always be guided via the supplied guidewire, which has been correctly positioned according to the instructions for use. Do not use the catheter without the supplied guidewire or over the supplied guidewire which is incorrectly placed · If the supplied guidewire is in a subintimal position of any length, reposition and ensure it is intraluminal before proceeding · Do not use the catheter if the supplied guidewire has become threaded or entangled in the wire mesh of a stent, stent graft or the lining of a stent graft · Position the flexible tip of the supplied guidewire as far distally as possible from the vessel occlusion being treated to avoid the tip being aspirated into the rotating helix. Recommended distance is at least 10 cm. Operators should take care that manipulations of the catheter do not alter the desired position of the supplied guidewire · Do not use inside or via narrow vessel radii or in tortuous vessel courses (bending radius of catheter shaft < 2 cm) · Do not use in calcified vessel segments with presence of radiopacities on both sides of the arterial wall and extending more than 1 cm of length prior to contrast injection or digital subtraction angiography · Do not use this device at or near locations with pre-existing damage to the vessel wall from prior surgery, aneurysms, or other disease · Remove catheter and supplied guidewire from patient before employing magnetic resonance imaging (MRI) or using a defibrillator · Do not use Rotarex™S Atherectomy Catheters when product damage is evident, whose packaging is damaged, or where the sterilisation expiration date has passed · This device is intended for use only by suitably qualified medical personnel experienced in the diagnosis and treatment of peripheral vascular disease by percutaneous methods · This device may only be used in conjunction with the Drive System · This device is supplied sterile for single-use only. Do not reprocess or resterilise. Resterilisation or reconditioning may severely impair the function of the device · Risk of distal embolisation is greatly increased if the operator attempts to advance the catheter faster than the recommendations in these instructions, especially near the distal end of the occlusion · Failure to ensure sufficient blood flow to the catheter head could result in vessel collapse · Monitor the blood flow to the collecting bag continuously throughout the procedure · Do not operate near fractured areas of broken stents or stent grafts. If a protruding stent strut penetrates into the side window of the catheter head, the stent, stent graft or vessel may become severely damaged, destroyed and/or dislodged, or the catheter head may become entrapped in the stent or stent graft in such a manner that the catheter and the stent or stent graft must be surgically recovered · This device should only be used under adequate visual monitoring with suitable radiographic techniques

Precautions: · This device does not contain any parts that can be maintained or serviced by the end-user. Do not repair or change the configuration of the device · Use of the device through a kinked or damaged introducer or where the catheter itself has become kinked or bent, may cause erratic function and/or device failure · Catheters must not be allowed to operate "dry" and must be primed and flushed using heparinised saline before and during use per the instructions in this IFU. Throughout catheter use, always ensure there is a sufficient blood flow to the catheter head. Allowing the catheter to operate without heparinised saline solution priming and flushing or without adequate amounts of aspirated blood, will cause the device to operate erratically and/or cease functioning · Failure to manipulate the catheter slowly in a back and forth motion as described in these instructions may result in fracture of the helix and/or supplied guidewire · Insufficient blood flow through the catheter may result in intra-catheter clotting, slow or absent therapeutic function, fracture of the helix and/or supplied guidewire, and/or overheating of the catheter · The guidewire adaptor must be in the working position (pulled back) when the motor is active · When active, the handle of the Rotarex™S Catheter and the portion of the catheter outside the patient's body must be kept at he same height as the introducer sheath and straight at all times with the outlet tube to the collecting bag hanging vertically below the motor in a straight line. Failure to position the catheter and outlet tube in this manner may result in catheter blockage, helix fracture and/or supplied guidewire fracture · If the supplied guidewire begins to rotate with the helix, which may occur if the helix and supplied guidewire become bonded with fibrin, the procedure must be immediately stopped; the catheter thoroughly flushed and the supplied guidewire changed

Potential Adverse Effects: Potential adverse events include, but are not limited to: · Embolisation, especially distal embolisation · Pulmonary embolisms of all degrees of severity · Thrombosis · Re-occlusion · Vessel wall injury · Vessel dissection / perforation / rupture · Perforation as a result of mural calcium being torn out of the vessel wall · Arteriovenous fistula / pseudo-aneurysm · Hematoma, bleeding, hemorrhage · Organ perforation · Implants such as stents / stent grafts / bypass grafts getting damaged, caught or dislodged · Disruption of the catheter: debris remaining in the body · Allergic reactions, including allergic reactions to device components · Infections or necrosis at the puncture site · Catheter-induced sepsis · Death

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

1. Straub Medical AG Rotarex S. Instructions for Use. ZE11120 B3
2. Bulvas M. Endovascular Debulking in Therapy of Occluded Lower Limb Bypass.*OJCR*(2),1-4
3. Straub Medical. 2022. Rotarex Case Reports. Accessed on February 15, 2022, at http://www.straubmedical.com/userdata/uploads/pr-bulvas-rotarex-and-in-stent-occlusion.pdf
4. Rotarex S Clinical Study. Instructions for Use. ZE10895 B6 02/21
5. Data on file at BD.
6. Straub Medical AG Drive System. Instructions for Use. ZE11407 A5

Becton Dickinson Pty Ltd T/A Bard Australia Pty Ltd. Customer Service: 1800 257 232.