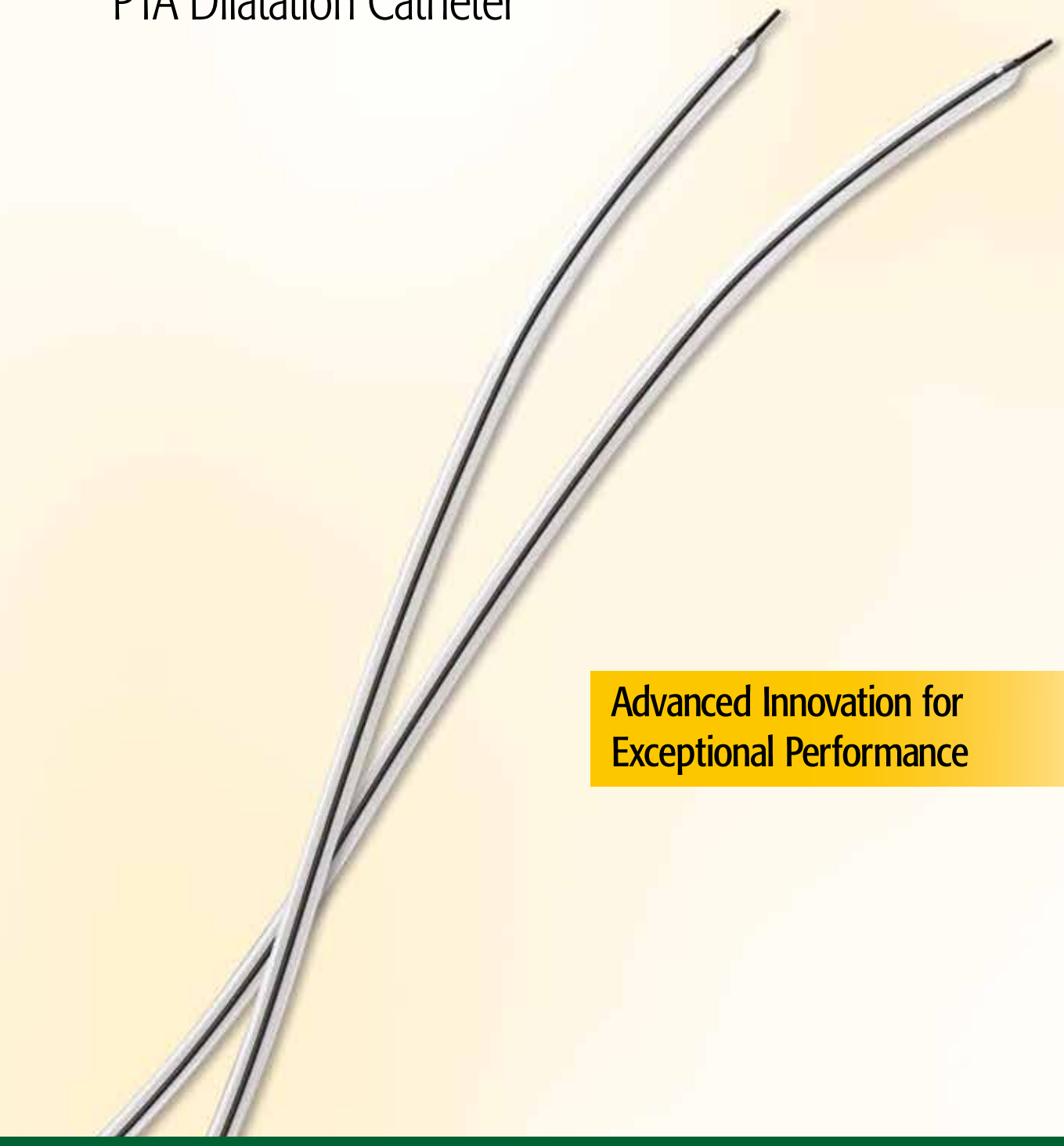
ULTRAVERSE® 018

PTA Dilatation Catheter



Advanced Innovation for Exceptional Performance

BARD | PERIPHERAL VASCULAR

longest .018" OTW BALLOON LENGTHS ON THE MARKET*

Bard Peripheral Vascular Ultraverse® 018 — **300 mm**

Medtronic Pacific Xtreme™ — **300 mm**

Cordis SAVVY™ Long — **220 mm**

Biotronik Passeo™ 18
Cook Advance™ 18LP
EV3 Powercross™
TriReme GliderfleX™ — **200 mm**

Boston Scientific Sterling™ SL
Medtronic Pacific Plus™ — **150 mm**

Abbott Fox™ SV
Medtronic Submarine Plus™ — **120 mm**

B. Braun Mini Ghost™
Boston Scientific Sterling™
Boston Scientific Symmetry™
Boston Scientific Symmetry™ Stiff
Cordis Savvy™ — **100 mm**

Medtronic Reef™ HP — **80 mm**

Cordis Slalom™ — **40 mm**

Long balloons **reduce the need for multiple inflations**, potentially **reducing procedure times**

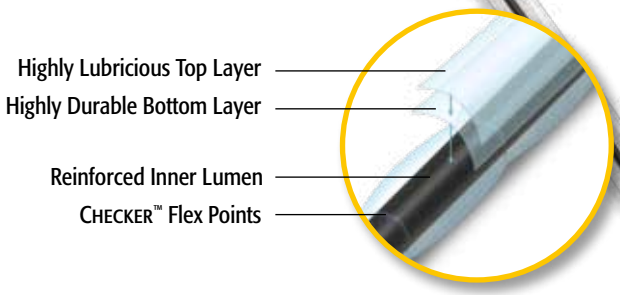
*As of September 2013.

ULTRAVERSE® 018

PTA Dilatation Catheter

OPTIMAL deliverability

Proprietary ULTRA-CROSS™ Dual Layer Hydrophilic Coating



- **ULTRA-CROSS™ Dual Layer Hydrophilic Coating** designed to reduce friction
- **CHECKER™ Flex Points** engineered to allow the balloon to flex in tortuous anatomy
- **Reinforced Inner Lumen** provides improved axial strength constructed to cross tight lesions

Excellent Trackability

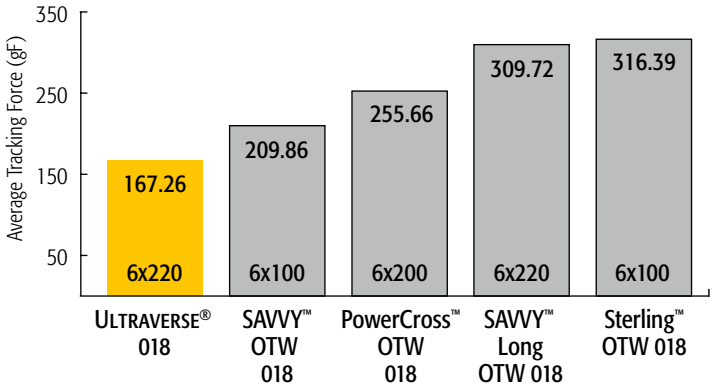
At least a 20% reduction in tracking force supports outstanding performance in challenging anatomies.

Superior Pushability

Innovative, reinforced inner lumen promotes improved axial strength for crossing tight lesions.

Excellent Trackability**

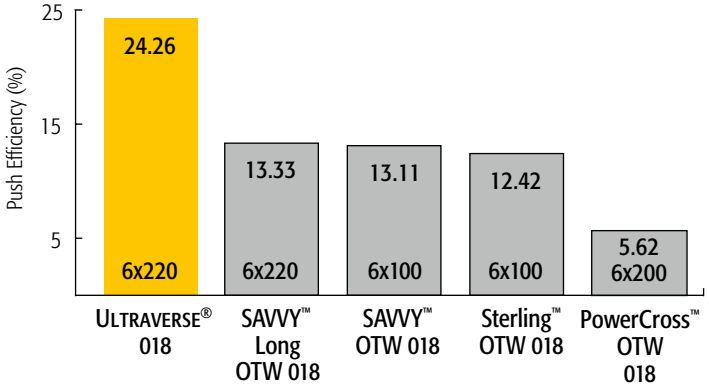
(Lower is better)



The Trackability Test measures the peak force necessary to track a catheter through a tortuous anatomical model.

Superior Pushability**

(Higher is better)



The Pushability Test measures the % of longitudinal force transferred from the hub to the tip of the catheter in an anatomical model.

**6x220 mm ULTRAVERSE® 018 – N=5; 6x200 mm PowerCross™ – N=5; 6x100 mm SAVVY™ – N=5; 6x220 mm SAVVY™ Long – N=5; 6x100 mm Sterling™ – N=5. $p < .05$. Data on file. Bench test results may not necessarily be indicative of clinical performance. Different tests may yield different results.

ULTRAVERSE® 018

PTA Dilatation Catheter

Scan with a Smart Phone and your local Bard Rep will contact you.

ULTRAVERSE® 018 PTA Dilatation Catheter Ordering Information

75 cm Catheter Length

Dia. (mm)	Length (cm)	RBP† (ATM)	Product Code
2	2	16	U87522
	4	16	U87524
	10	15	U875210
	12	15	U875212
	15	15	U875215
	22	15	U875222
2.5	2	16	U8752H2
	4	16	U8752H4
	10	15	U8752H10
	15	15	U8752H15
3	2	16	U87532
	4	16	U87534
	10	15	U875310
	12	15	U875312
	15	15	U875315
	22	15	U875322
3.5	2	16	U8753H2
	4	16	U8753H4
	10	15	U8753H10
	15	15	U8753H15
4	2	16	U87542
	4	16	U87544
	6	16	U87546
	10	15	U875410
	12	15	U875412
	15	15	U875415
	22	15	U875422
5	2	14	U87552
	4	14	U87554
	6	14	U87556
	10	13	U875510
	12	13	U875512
	15	13	U875515
	22	13	U875522
6	2	14	U87562
	4	14	U87564
	6	14	U87566
	10	12	U875610
	12	12	U875612
	15	12	U875615
	22	12	U875622
7	4	12	U87574
8	4	12	U87584
9	4	11	U87594

130 cm Catheter Length

Dia. (mm)	Length (cm)	RBP† (ATM)	Product Code
2	2	16	U813022
	4	16	U813024
	6	16	U813026
	8	15	U813028
	10	15	U8130210
	12	15	U8130212
	15	15	U8130215
	22	15	U8130222
	30	15	U8130230
2.5	2	16	U81302H2
	4	16	U81302H4
	6	16	U81302H6
	8	15	U81302H8
	10	15	U81302H10
	12	15	U81302H12
	15	15	U81302H15
	22	15	U81302H22
	30	15	U81302H30
3	2	16	U813032
	4	16	U813034
	6	16	U813036
	8	15	U813038
	10	15	U8130310
	12	15	U8130312
	15	15	U8130315
	22	15	U8130322
	30	15	U8130330
3.5	2	16	U81303H2
	4	16	U81303H4
	6	16	U81303H6
	8	15	U81303H8
	10	15	U81303H10
	12	15	U81303H12
	15	15	U81303H15
	22	15	U81303H22
	30	15	U81303H30
4	2	16	U813042
	4	16	U813044
	6	16	U813046
	8	15	U813048
	10	15	U8130410
	12	15	U8130412
	15	15	U8130415
	22	15	U8130422
	30	15	U8130430

130 cm Catheter Length

Dia. (mm)	Length (cm)	RBP† (ATM)	Product Code
5	2	14	U813052
	4	14	U813054
	6	14	U813056
	8	13	U813058
	10	13	U8130510
	12	13	U8130512
	15	13	U8130515
	22	13	U8130522
	30	13	U8130530
6	2	14	U813062
	4	14	U813064
	6	14	U813066
	8	12	U813068
	10	12	U8130610
	12	12	U8130612
	15	12	U8130615
	22	12	U8130622
	30	12	U8130630
7	4	12	U813074
8	4	12	U813084
9	4	11	U813094

150 cm Catheter Length

Dia. (mm)	Length (cm)	RBP† (ATM)	Product Code
2	2	16	U815022
	4	16	U815024
	6	16	U815026
	8	15	U815028
	10	15	U8150210
	12	15	U8150212
	15	15	U8150215
	22	15	U8150222
	30	15	U8150230
2.5	2	16	U81502H2
	4	16	U81502H4
	6	16	U81502H6
	8	15	U81502H8
	10	15	U81502H10
	12	15	U81502H12
	15	15	U81502H15
	22	15	U81502H22
	30	15	U81502H30

150 cm Catheter Length

Dia. (mm)	Length (cm)	RBP† (ATM)	Product Code
3	2	16	U815032
	4	16	U815034
	6	16	U815036
	8	15	U815038
	10	15	U8150310
	12	15	U8150312
	15	15	U8150315
	22	15	U8150322
	30	15	U8150330
3.5	2	16	U81503H2
	4	16	U81503H4
	6	16	U81503H6
	8	15	U81503H8
	10	15	U81503H10
	12	15	U81503H12
	15	15	U81503H15
	22	15	U81503H22
	30	15	U81503H30
4	2	16	U815042
	4	16	U815044
	6	16	U815046
	8	15	U815048
	10	15	U8150410
	12	15	U8150412
	15	15	U8150415
	22	15	U8150422
	30	15	U8150430
5	2	14	U815052
	4	14	U815054
	6	14	U815056
	8	13	U815058
	10	13	U8150510
	12	13	U8150512
	15	13	U8150515
	22	13	U8150522
	30	13	U8150530

REPRESENTATIVE NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

Nominal Pressure	
All codes	6 ATM

Sheath	
2 mm x 2 cm - 4 mm x 12 cm	4F
4 mm x 15 cm - 7 mm x 4 cm	5F
8 mm x 4 cm - 9 mm x 4 cm	6F

† RBP (Rated Burst Pressure): the pressure at which Bard has 95% confidence that 99.9% of the balloons will not burst at or below upon single inflation.

* Nominal pressure: the pressure at which the balloon reaches its labeled diameter.

ULTRAVERSE® 014/018 PTA Balloon Dilatation Catheters

Indications for Use: ULTRAVERSE® 014 and ULTRAVERSE® 018 PTA Dilatation Catheters are recommended for use in percutaneous transluminal angioplasty (PTA) of the renal, popliteal, tibial, femoral and peroneal arteries. These catheters are not for use in coronary arteries.

Contraindications: None known.

Warnings: Contents supplied sterile using ethylene oxide (EO). Non-pyrogenic. Do not use if sterile barrier is opened or damaged. Do not reuse, reprocess or re-sterilize. This device has been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes. To reduce the potential for vessel damage, the inflated diameter and length of the balloon should approximate the diameter and length of the vessel just proximal and distal to the stenosis. When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Applying excessive force to the catheter can result in tip breakage or balloon separation. Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent over-pressurization, use of a pressure monitoring device is recommended. After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practices and applicable local, state and federal laws and regulations.

Precautions: Carefully inspect the catheter prior to use to verify that catheter has not been damaged during shipment and that its size, shape and condition are suitable for the procedure for which it is to be used. Do not use if product damage is evident. The ULTRAVERSE® 014 and ULTRAVERSE® 018 PTA Balloon Dilatation Catheters shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty. The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath than indicated on the label. Do not remove the guidewire in situ to shoot contrast through the wire lumen or perform a wire exchange. If the wire is removed while the balloon catheter is situated in tortuous anatomy, the risk of kinking the catheter is increased. Use the recommended balloon inflation medium (25% contrast medium/75% sterile saline solution). It has been shown that a 25/75% contrast/saline ratio has yielded faster balloon inflation/deflation times. Never use air or other gaseous medium to inflate the balloon. If resistance is felt during post-procedure withdrawal of the catheter through the introducer sheath, determine if contrast is trapped in the balloon with fluoroscopy. If contrast is present, push the balloon out of the sheath and then completely evacuate the contrast before proceeding to withdraw the balloon. If resistance is still felt during post-procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and guidewire/introducer sheath as a single unit. Do not continue to use the balloon catheter if the shaft has been bent or kinked. Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze and rinsed with sterile normal saline. Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire or stylet. In order to activate the hydrophilic coating, it is recommended to wet the ULTRAVERSE® Catheter with sterile saline solution immediately prior to its insertion in the body.

Potential Adverse Reactions: The complications that may result from a peripheral balloon dilatation procedure include: • Additional intervention • Allergic reaction to drugs or contrast medium • Aneurysm or pseudoaneurysm • Arrhythmias • Embolization • Hematoma • Hemorrhage, including bleeding at the puncture site • Hypotension/hypertension • Inflammation • Occlusion • Pain or tenderness • Pneumothorax or hemothorax • Sepsis/infection • Shock • Short-term hemodynamic deterioration • Stroke • Thrombosis • Vessel dissection, perforation, rupture or spasm.

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

Please consult package insert for more detailed safety information and instructions for use.

S11742 Rev. 2

CE 0086

BARD | PERIPHERAL VASCULAR

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