ULTRAVERSE® RX

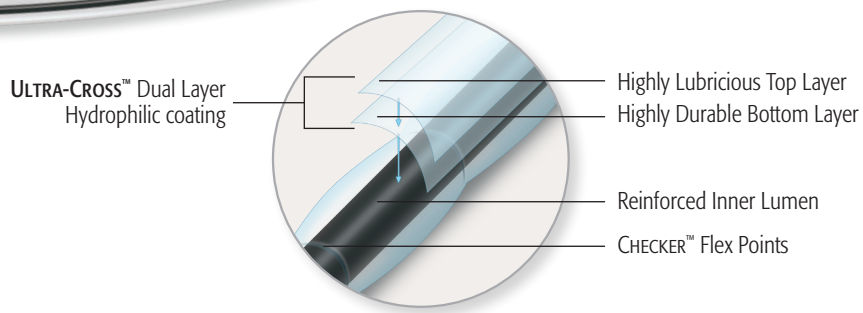
PTA Dilatation Catheter

Going the Distance

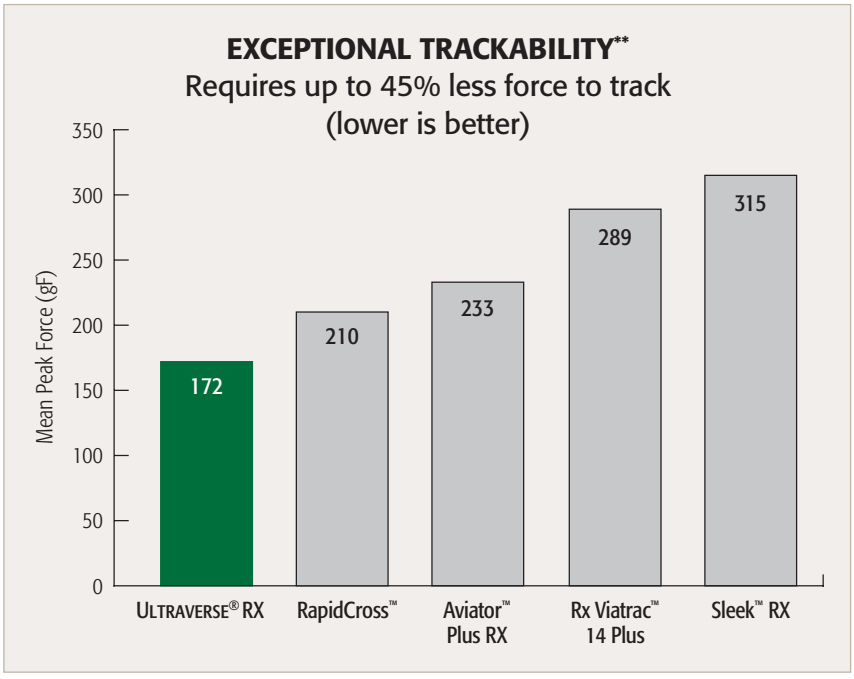
BARD | PERIPHERAL VASCULAR

NAVIGATING THE extremes

- **ULTRA-CROSS™ Dual Layer Hydrophilic Coating and CHECKER™ Flex Points enhance trackability**
- **Broadest diameter range* - 1.25 mm to 7 mm**



- 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



**4 mm x 40 mm x 150 cm ULTRAVERSE® RX - N=20; 4 mm x 40 mm x 170 cm RapidCross™ - N=20; 4 mm x 40 mm x 140 cm Aviator™ Plus RX - N=20; 4 mm x 40 mm x 135 cm Rx Viatrac™ 14 Plus - N=40; 4 mm x 40 mm x 150 cm Sleek™ RX - N=40. $p<.05$. Bench data on file. Results may not necessarily be indicative of clinical performance. Different tests may yield different results.

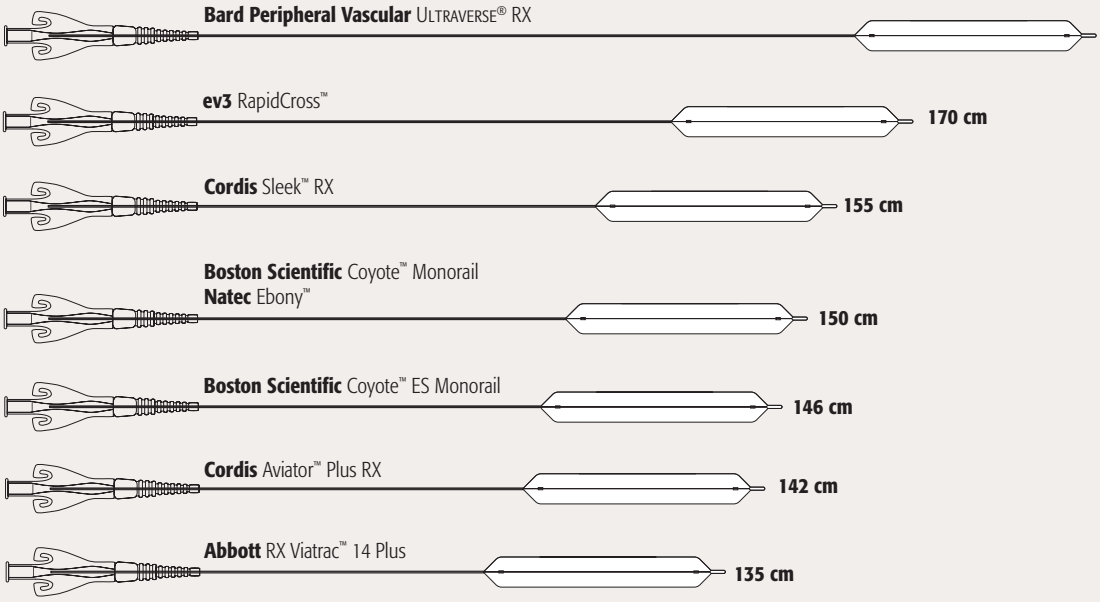
ULTRAVERSE® RX .014"

PTA Dilatation Catheter

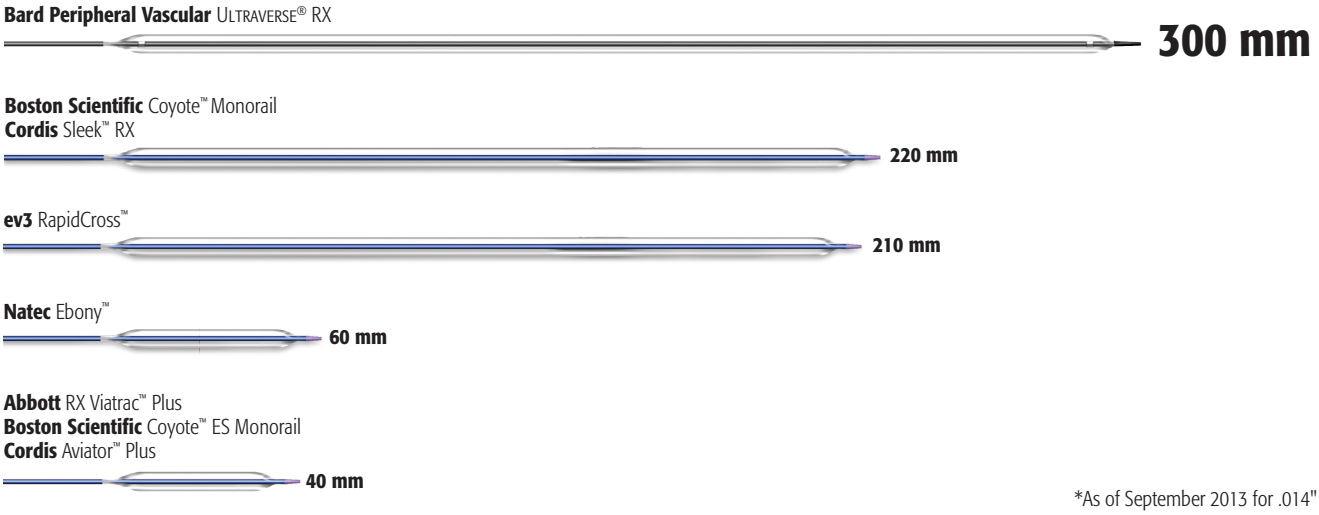
MANEUVER PAST THE boundaries

- **200 cm shaft - longest on the market***
- **Longest balloon available* - 300 mm**

LONGEST SHAFT*



LONGEST BALLOONS*



*As of September 2013 for .014" RX PTA Balloons.

ULTRAVERSE® RX PTA Dilatation Catheter

Ordering Information

150 cm Shaft Length .014" Guidewire Compatible

Diameter (mm)	Length (mm)	RBP† (ATM)	Product Code
1.25	15	16	U41501Q1HRX
	20	16	U41501Q2RX
	40	16	U41501Q4RX
1.5	15	16	U41501H1HRX
	20	16	U41501H2RX
	40	16	U41501H4RX
	80	16	U41501H8RX
	120	16	U41501H12RX
2	15	16	U415021HRX
	20	16	U415022RX
	40	16	U415024RX
	60	16	U415026RX
	80	15	U415028RX
	100	15	U4150210RX
	120	15	U4150212RX
	150	15	U4150215RX
	200	15	U4150220RX
	250	15	U4150225RX
	300	15	U4150230RX
2.5	15	16	U41502H1HRX
	20	16	U41502H2RX
	40	16	U41502H4RX
	60	16	U41502H6RX
	80	15	U41502H8RX
	100	15	U41502H10RX
	120	15	U41502H12RX
	150	15	U41502H15RX
	200	15	U41502H20RX
	250	15	U41502H25RX
	300	15	U41502H30RX
3	15	16	U415031HRX
	20	16	U415032RX
	40	16	U415034RX
	60	16	U415036RX
	80	15	U415038RX
	100	15	U4150310RX
	120	15	U4150312RX
	150	15	U4150315RX
	200	15	U4150320RX
	250	15	U4150325RX
	300	15	U4150330RX

150 cm Shaft Length .014" Guidewire Compatible (continued)

Diameter (mm)	Length (mm)	RBP† (ATM)	Product Code
3.5	15	16	U41503H1HRX
	20	16	U41503H2RX
	40	16	U41503H4RX
	60	16	U41503H6RX
	80	15	U41503H8RX
	100	15	U41503H10RX
	120	15	U41503H12RX
	150	15	U41503H15RX
	200	15	U41503H20RX
	250	15	U41503H25RX
	300	15	U41503H30RX
4	15	16	U415041HRX
	20	16	U415042RX
	40	16	U415044RX
	60	16	U415046RX
	80	15	U415048RX
	100	15	U4150410RX
	120	15	U4150412RX
	150	15	U4150415RX
	200	15	U4150420RX
	250	15	U4150425RX
	300	15	U4150430RX
5	15	14	U415051HRX
	20	14	U415052RX
	40	14	U415054RX
	60	14	U415056RX
	80	13	U415058RX
	100	13	U4150510RX
	120	13	U4150512RX
	150	13	U4150515RX
	200	13	U4150520RX
	250	13	U4150525RX
	300	13	U4150530RX
6	40	14	U415064RX
	60	14	U415066RX
7	40	12	U415074RX
	60	12	U415076RX

200 cm Shaft Length .014" Guidewire Compatible

Diameter (mm)	Length (mm)	RBP† (ATM)	Product Code
1.25	15	16	U42001Q1HRX
	20	16	U42001Q2RX
	40	16	U42001Q4RX
1.5	15	16	U42001H1HRX
	20	16	U42001H2RX
	40	16	U42001H4RX
	80	16	U42001H8RX
	120	16	U42001H12RX
2	15	16	U420021HRX
	20	16	U420022RX
	40	16	U420024RX
	60	16	U420026RX
	80	15	U420028RX
	100	15	U4200210RX
	120	15	U4200212RX
	150	15	U4200215RX
	200	15	U4200220RX
	250	15	U4200225RX
	300	15	U4200230RX
2.5	15	16	U42002H1HRX
	20	16	U42002H2RX
	40	16	U42002H4RX
	60	16	U42002H6RX
	80	15	U42002H8RX
	100	15	U42002H10RX
	120	15	U42002H12RX
	150	15	U42002H15RX
	200	15	U42002H20RX
	250	15	U42002H25RX
	300	15	U42002H30RX
3	15	16	U420031HRX
	20	16	U420032RX
	40	16	U420034RX
	60	16	U420036RX
	80	15	U420038RX
	100	15	U4200310RX
	120	15	U4200312RX
	150	15	U4200315RX
	200	15	U4200320RX
	250	15	U4200325RX
	300	15	U4200330RX

200 cm Shaft Length .014" Guidewire Compatible

Diameter (mm)	Length (mm)	RBP† (ATM)	Product Code
3.5	15	16	U42003H1HRX
	20	16	U42003H2RX
	40	16	U42003H4RX
	60	16	U42003H6RX
	80	15	U42003H8RX
	100	15	U42003H10RX
	120	15	U42003H12RX
	150	15	U42003H15RX
	200	15	U42003H20RX
	250	15	U42003H25RX
	300	15	U42003H30RX
4	15	16	U420041HRX
	20	16	U420042RX
	40	16	U420044RX
	60	16	U420046RX
	80	15	U420048RX
	100	15	U4200410RX
	120	15	U4200412RX
	150	15	U4200415RX
	200	15	U4200420RX
	250	15	U4200425RX
	300	15	U4200430RX
5	15	14	U420051HRX
	20	14	U420052RX
	40	14	U420054RX
	60	14	U420056RX
	80	13	U420058RX
	100	13	U4200510RX
	120	13	U4200512RX
	150	13	U4200515RX
	200	13	U4200520RX
	250	13	U4200525RX
	300	13	U4200530RX

Nominal Pressure (ATM)		Guide Catheter Size (F)	
All Codes	6	All Codes	6

Sheath Size for All Shaft Lengths (F)	
1.25 mm x 15 mm – 4 mm x 120 mm	4
4 mm x 150 mm – 7 mm x 60 mm	5

REPRESENTATIVE NAME

CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE

ULTRAVERSE® RX PTA Dilatation Catheter

Indications for Use: ULTRAVERSE® RX PTA Dilatation Catheter is indicated for use in Percutaneous Transluminal Angioplasty of the renal, femoral, popliteal and infra-popliteal arteries. This catheter is not for use in coronary arteries.

Contraindications: None known.

Warnings: **1.)** Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened or damaged. Do not reuse, reprocess or resterilize. **2)** 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. **3.)** 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. **4.)** 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. **5.)** 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 or catheter breakage, catheter kink, or balloon separation. **6.**) 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. **7.)** 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: 1.) 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. **2.)** ULTRAVERSE® RX Catheter shall only be used by physicians experienced in the performance of percutaneous transluminal angioplasty. **3.)** The minimal acceptable introducer sheath/guide catheter French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size introducer sheath/guide catheter than indicated on the label. **4.)** 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. **5.)** If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath/guide catheter, determine if contrast is trapped in the balloon with fluoroscopy. If contrast is present, push the balloon out of the introducer sheath/guide catheter and then completely evacuate the contrast before proceeding to withdraw the balloon. **6.)** If resistance is still felt during post procedure withdrawal of the catheter, it is recommended to remove the balloon catheter and introducer sheath/guide catheter as a single unit. **7.**) Do not continue to use the balloon catheter if the catheter shaft has been bent or kinked. **8.)** Prior to re-insertion through the introducer sheath/guide catheter, the balloon should be wiped clean with gauze and rinsed with sterile normal saline. **9.**) Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire or stylet. **10.)** In order to activate the hydrophilic coating, it is recommended to wet the ULTRAVERSE® RX Catheter with sterile saline solution immediately prior to its insertion in the body.

Potential Adverse Reaction: The complications which 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

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

S120261 Rev. 3

BARD | PERIPHERAL VASCULAR

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