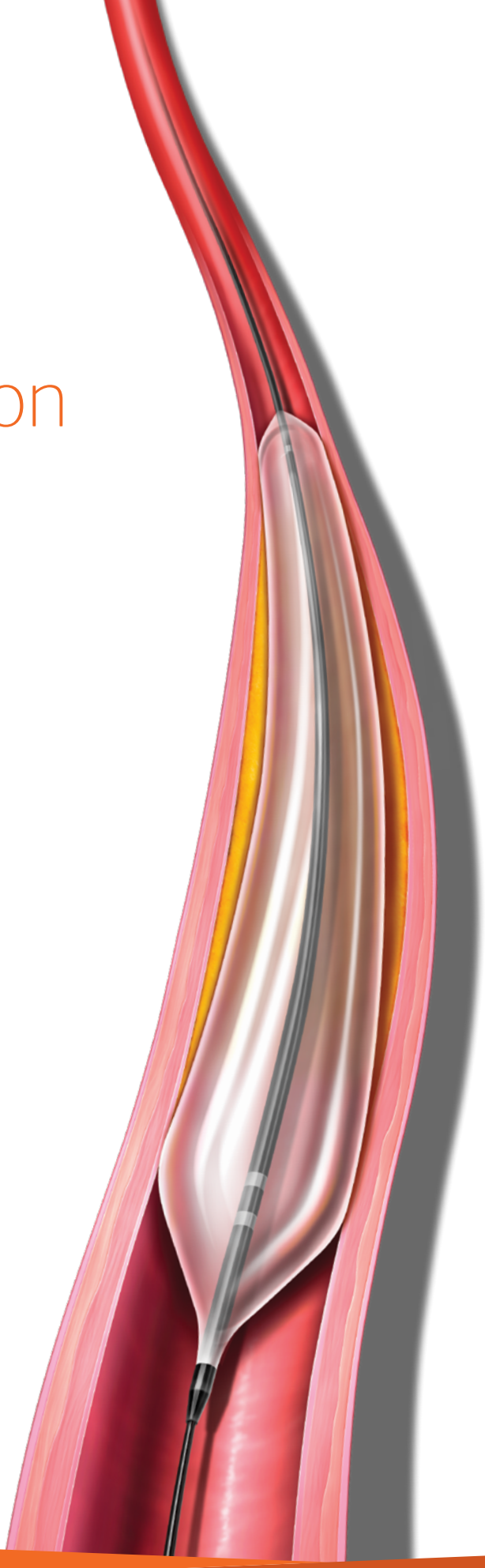
Ultraverse™ 014

PTA Balloon Dilatation Catheter

Advanced innovation for **exceptional performance**



BD

Long .014" OTW balloon lengths on the market

Bard Peripheral Vascular Ultraverse™ 014 **300 mm**

Cordis Sleek™ 280 mm

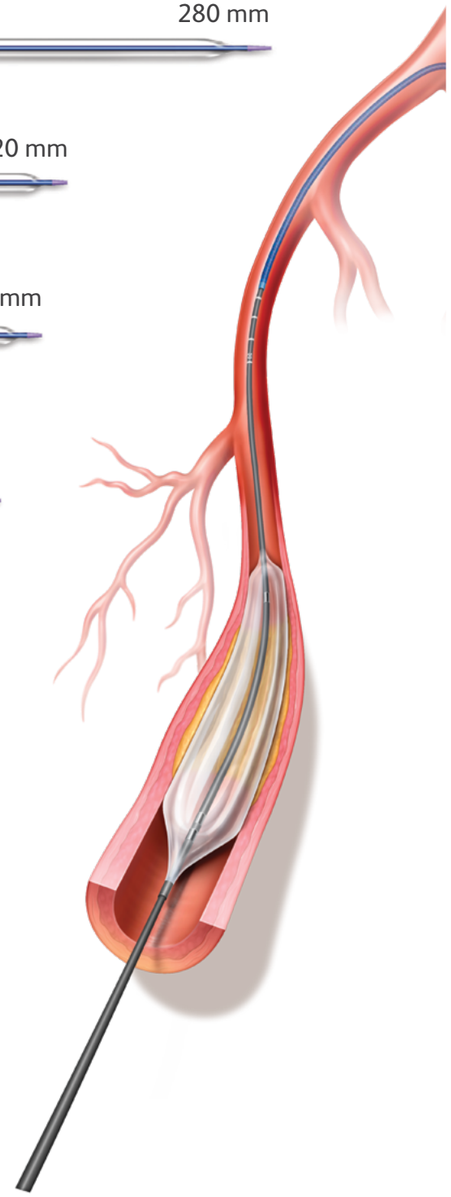
Boston Scientific Coyote™ 220 mm

EV3 Nanocross™
Medtronic Amphirion™ Deep 210 mm

Abbott Armada™ 14
Cook Advance™ I 4LP
TriReme GliderfleX™ 200 mm

Cook Advance™ Micro 14
Medtronic Amphirion™ Plus 120 mm

Boston Scientific Sterling™ ES
Boston Scientific Coyote™ ES
40 mm

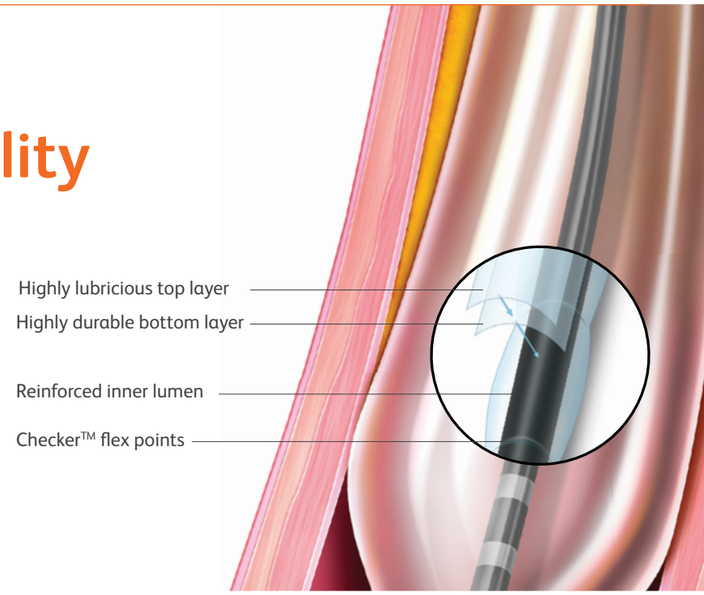


Long balloons **reduce the need for multiple inflations,** potentially **reducing procedure times**

Advanced innovation for exceptional performance
Ultraverse™ 014 PTA Balloon Dilatation

Optimal **deliverability**

- **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



Proprietary Ultra-Cross™ Dual Layer Hydrophilic Coating

Excellent **trackability**

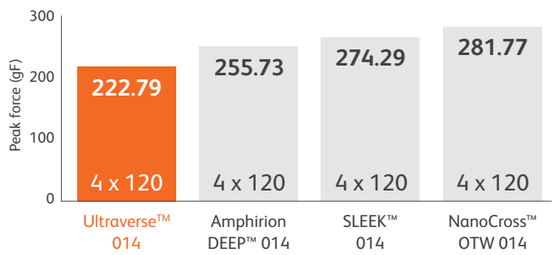
Ultra -Cross Hydrophilic Coating and Checker™ Flex Points provide excellent trackability when treating long, diffuse lesions in challenging anatomies.

Superior **pushability**

vs. competitive OTW Balloons

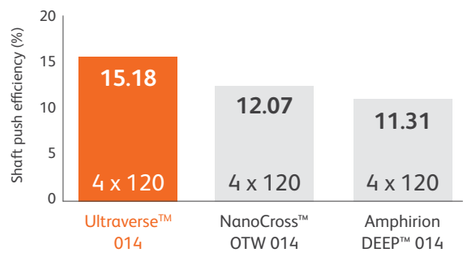
Innovative, reinforced inner lumen promotes improved axial strength for crossing tight lesions.

Excellent trackability**
Lower is better



The trackability test measures the peak force necessary to track a catheter though a tortuous anatomical model.

Superior pushability**
Higher is better



The pushability test measures the percent of longitudinal force transferred from the hub to the tip of the catheter in an anatomical model.

**4xl20 mm Ultraverse™ 014- N=5; 4xl20 mm Amphirion DEEP™ N=5; 4xl20 mm SLEEK™ N=5; 4xl20 mm NanoCross™ 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™ 014

PTA Balloon Dilatation Catheter

Ultraverse™ 014 PTA Balloon Dilatation Catheter

Ordering information

150 cm catheter length

Order code	Balloon diameter (mm)	Balloon length (mm)	Nominal pressure (atm)	Rated burst pressure (atm)	Sheath size (F)
U41501H2	1.5	20	6	16	4
U41501H4		40	6	16	4
U41501H8		80	6	16	4
U41501H10		100	6	16	4
U41501H12		120	6	16	4
U41501H15		150	6	16	4
U415022	2	20	6	16	4
U415024		40	6	16	4
U415028		80	6	15	4
U4150210		100	6	15	4
U4150212		120	6	15	4
U4150215		150	6	15	4
U4150222		220	6	15	4
U4150230		300	6	15	4
U41502H2	2.5	20	6	16	4
U41502H4		40	6	16	4
U41502H8		80	6	15	4
U41502H10		100	6	15	4
U41502H12		120	6	15	4
U41502H15		150	6	15	4
U41502H22		220	6	15	4
U41502H30		300	6	15	4
U415032	3	20	6	16	4
U415034		40	6	16	4
U415038		80	6	15	4
U4150310		100	6	15	4
U4150312		120	6	15	4
U4150315		150	6	15	4
U4150322		220	6	15	4
U4150330		300	6	15	4

Order code	Balloon diameter (mm)	Balloon length (mm)	Nominal pressure (atm)	Rated burst pressure (atm)	Sheath size (F)
U41503H2	3.5	20	6	16	4
U41503H4		40	6	16	4
U41503H8		80	6	15	4
U41503H10		100	6	15	4
U41503H12		120	6	15	4
U41503H15		150	6	15	4
U41503H22		220	6	15	4
U41503H30		300	6	15	4
U415042	4	20	6	16	4
U415044		40	6	16	4
U415048		80	6	15	4
U4150410		100	6	15	4
U4150412		120	6	15	4
U4150415		150	6	15	4
U4150422		220	6	15	4
U4150430		300	6	15	5
U415052	5	20	6	14	5
U415054		40	6	14	5
U415058		80	6	13	5
U4150510		100	6	13	5
U4150512		120	6	13	5
U4150515		150	6	13	5
U4150522		220	6	13	5
U4150530		300	6	13	5

Ultraverse™ 014 PTA Balloon Dilatation Catheter

Indications for Use: Ultraverse™ 014 PTA Dilatation Catheter is 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: 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 breakage 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. **8)** The safety and effectiveness of the device has not been established, or is unknown, in vascular regions other than those specifically indicated.

Precaution: 1) Refer to accessory IFU for potential access site warnings, precautions, and adverse events. **2)** 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. **3)** The Ultraverse™ 014 PTA Balloon Dilatation Catheters shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty. **4)** 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. **5)** 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. **6)** 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. **7)** 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. **8)** 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, and replace the previously used balloon catheter with a new balloon. Exercise caution when removing the device. **9)** Do not continue to use the balloon catheter if the shaft has been bent or kinked. Do not excessively bend, twist, or alter the shape of the device as it may compromise the integrity of the hydrophilic coating. **10)** Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with wet gauze and rinsed with sterile normal saline. Avoid excessively wiping the coated portions of the device, or wiping with dry gauze, as this may damage the hydrophilic coating. **11)** Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire or stylet. **12)** This device is coated with a hydrophilic coating at the distal segment of the shaft and the balloon. Please refer to the Directions for Use section for further information on how to prepare and use this device to ensure it performs as intended. Failure to abide by the warnings in this labeling might result in damage to the hydrophilic coating, which may require intervention or result in serious adverse events. **13)** 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. Using different media other than the recommended solution could affect the hydrophilic coating and its performance. **14)** The GEOALIGN™ Marking System is designed to be used as an additional reference tool to accompany the interventionalist standard operation procedure. The use of fluoroscopic imaging is recommended following positioning of the catheter to the target lesion and prior to balloon deployment. **15)** Avoid using alcohol, antiseptic solutions, or other solvents to pre-treat the device because this may cause unpredictable changes in the hydrophilic coating which could affect the device safety and performance. **16)** Avoid pre-soaking devices for extended periods, as this may impact the hydrophilic coating performance. **17)** It is recommended to consider the use of anti-coagulants, anti-platelet agents, and/or vasodilators in conformance with the accepted standard of practice or institutional guidelines surrounding peripheral endovascular procedures.

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 • Compartment Syndrome • 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 product labels and insrtuction for use for indications, contraindications, hazards, warnings, and precautions.

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