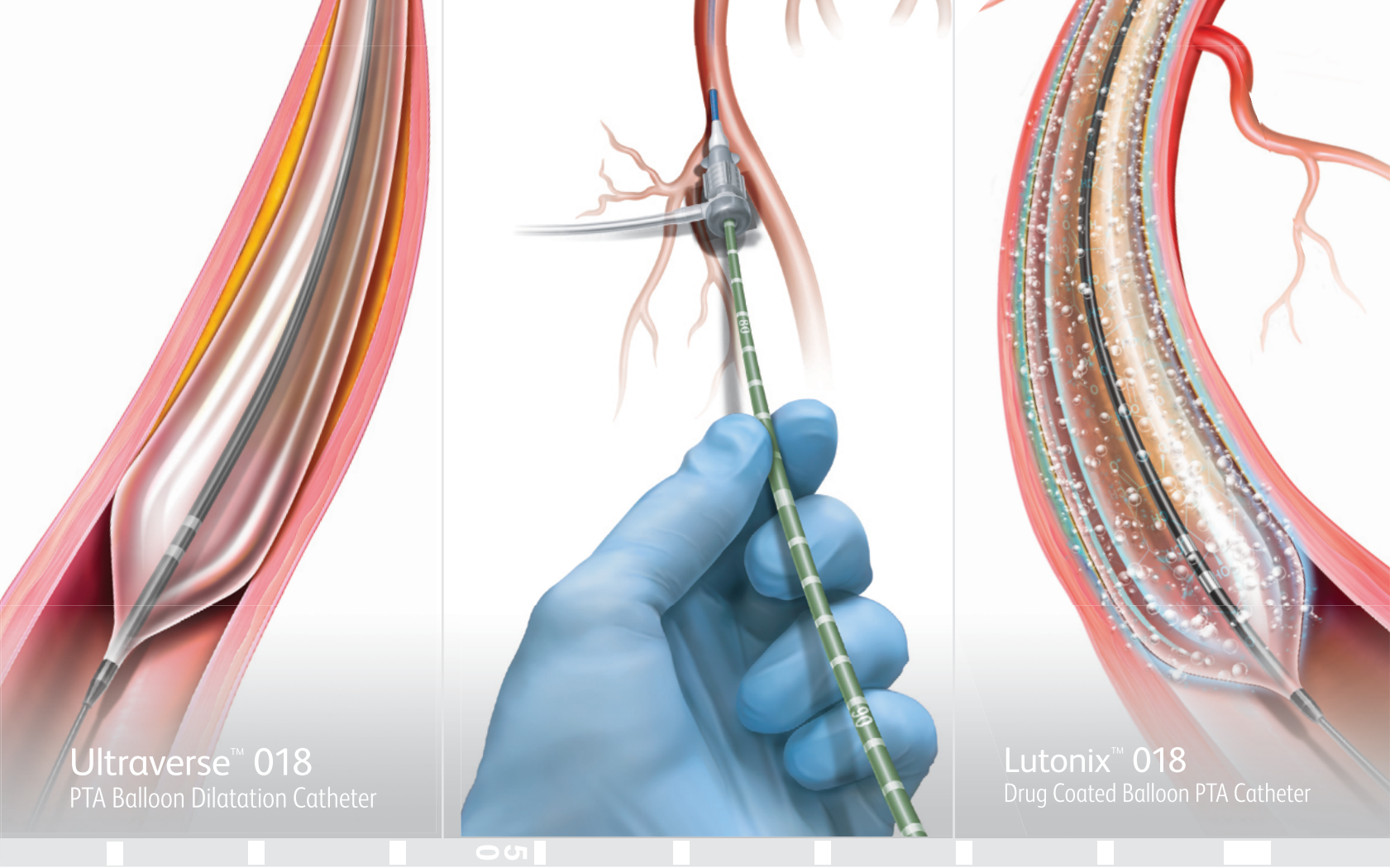
Ultraverse™ 018

PTA Balloon Dilatation Catheter

Advanced Innovation for Exceptional Performance

BD



Designed to:

Optimize pre-dilatation

Reduce fluoroscopy exposure

Facilitate repeat catheter alignment

GeoAlign™ Marking System is now available on the Ultraverse™ 018 PTA Balloon Dilatation Catheter designed to be utilized for geographic alignment with the Lutonix™ 018 Drug Coated Balloon PTA Catheter.*

*The Ultraverse PTA Balloon Dilatation Catheter and the Lutonix DCB both feature the GeoAlign® Marking System, allowing for optimized pre-dilatation angioplasty with geographic alignment when used in combination.

Ultraverse™ 018

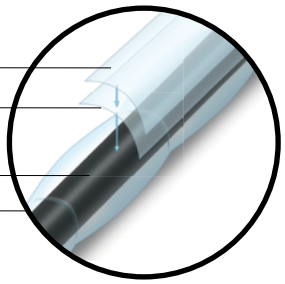
PTA Balloon Dilatation Catheter

Optimal deliverability

Proprietary Ultracross™ Dual Layer Hydrophilic Coating

· Highly lubricious top layer
· Highly durable bottom layer

· Reinforced inner Lumen
· Checher™ Flex Points



- Ultracross™ Dual Layer Hydrophilic Coating designed to reduce friction
- Checher™ Flex Points engineered to allow the balloon to f1ex in tortuous anatomy
- Reinforced Inner Lumen provides improved axial strength constructed to cross tight lesions

Excellent Trackability

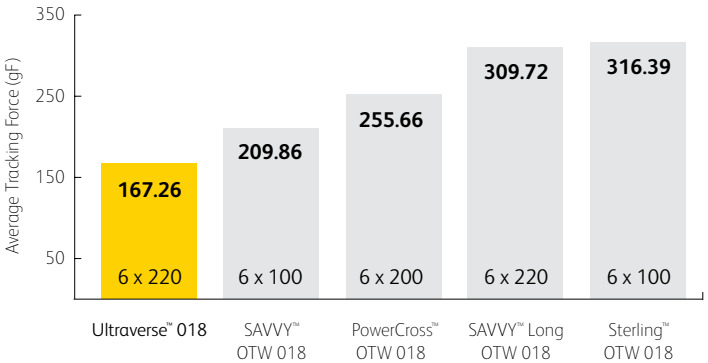
At least a 20% reduction in tracking force supports outstanding performance in challenging anatomies.

Superior Pushability

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

Excellent Trackability**

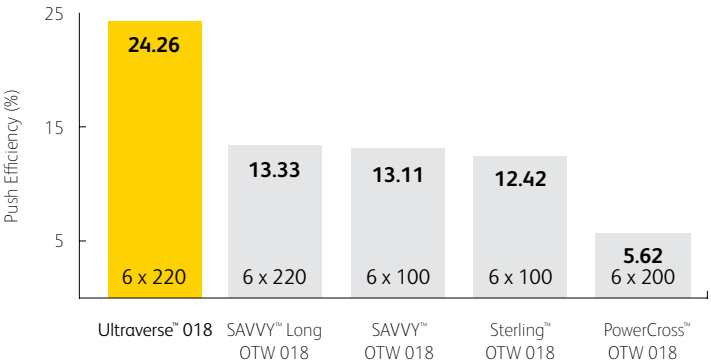
Lower is better



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; 6x200mm 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 Balloon Dilatation Catheter
Ordering information

Ultraverse™ 018
PTA Balloon Dilatation Catheter

75 cm Catheter Length

Order code	Balloon diameter (mm)	Balloon lenght (mm)	Rated burst pressure (atm)
U87522	2	20	16
U87524		40	16
U875210		100	15
U875215		150	15
U875222		220	15
U875230		300	15
U8752H2	2.5	20	16
U8752H4		40	16
U8752H10		100	15
U8752H12		120	15
U8752H15		150	15
U8752H22		220	15
U87532	3	20	16
U87534		40	16
U875310		100	15
U875315		150	15
U875322		220	15
U875330		300	15
U87542	4	20	16
U87544		40	16
U875410		100	15
U875415		150	15
U875422		220	15
U875430		300	15
U87552	5	20	14
U87554		40	14
U875510		100	13
U875515		150	13
U875522		220	13
U875530		300	13
U87562	6	20	14
U87564		40	14
U875610		100	12
U875615		150	12
U875622		220	12
U87574	7	40	12
U87584	8	40	12
U87594	9	40	11

130 cm Catheter Length

Order code	Balloon diameter (mm)	Balloon lenght (mm)	Rated burst pressure (atm)
U813022	2	20	16
U813024		40	16
U813026		60	16
U813028		80	15
U8130210		100	15
U8130212		120	15
U8130215		150	15
U8130222		220	15
U8130230		300	15
U81302H2	2.5	20	16
U81302H4		40	16
U81302H6		60	15
U81302H8		80	15
U81302H10		100	15
U81302H12		120	15
U81302H15		150	15
U81302H22		220	15
U81302H30		300	15
U813032	3	20	16
U813034		40	16
U813036		60	16
U813038		80	15
U8130310		100	15
U8130312		120	15
U8130315		150	15
U8130322		220	15
U8130330		300	15
U81303H2	3.5	20	16
U81303H4		40	16
U81303H6		60	16
U81303H8		80	15
U81303H10		100	15
U81303H12		120	15
U81303H15		150	15
U81303H22		220	15
U81303H30		300	15

130 cm Catheter Length

Order code	Balloon diameter (mm)	Balloon lenght (mm)	Rated burst pressure (atm)
U813042	4	20	16
U813044		40	16
U813046		60	16
U813048		80	15
U8130410		100	15
U8130412		120	15
U8130415		150	15
U8130422		220	15
U8130430		300	15
U813052	5	20	14
U813054		40	14
U813056		60	14
U813058		80	13
U8130510		100	13
U8130512		120	13
U8130515		150	13
U8130522		220	13
U8130530		300	13
U813062	6	20	14
U813064		40	14
U813066		60	14
U813068		80	12
U8130610		100	12
U8130612		120	12
U8130615		150	12
U8130622		220	12
U8130630		300	12
U813072	7	20	12
U813074		40	12
U813076		60	12
U813078		80	11
U8130710		100	11
U8130712		120	11
U8130715		150	11
U8130722		220	11

200 cm Catheter Length

Order code	Balloon diameter (mm)	Balloon lenght (mm)	Rated burst pressure (atm)
U820044	4	40	16
U820046		60	16
U820048		80	15
U8200410		100	15
U8200412		120	15
U8200415		150	15
U8200420		200	15
U8200422		220	15
U8200430		300	15
U820054		40	14
U820056	5	60	14
U820058		80	13
U8200510		100	13
U8200512		120	13
U8200515		150	13
U8200520		200	13
U8200522		220	13
U8200530		300	13
U820064	6	40	14
U820066		60	14
U820068		80	12
U8200610		100	12
U8200612		12	12
U8200615		150	12
U8200620		200	12
U8200622		220	12
U8200630		300	12
U820074	7	40	12
U820076		60	12
U820078		80	11
U8200710		100	11
U8200712		120	11
U8200715		150	11
U8200720		20	11
U8200722		220	11
U820084	8	40	11
U820086		60	11
U820094	9	40	11
U820096		60	11

Nominal pressure	
All Codes	6 ATM
Sheath	
2 mm x 2 cm - 4 mm x 22 cm	4F
4 mm x 30 cm - 7 mm x 30 cm	5F
8 mm x 4 cm - 9 mm x 6 cm	6F

ULTRAVERSETM 018 PTA Balloon Dilatation Catheter

Indications for Use: ULTRAVERSE™ 018 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). Nonpyrogenic. 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™ 018 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 instruction for use for indications, contraindications, hazards, warnings, and precautions.

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