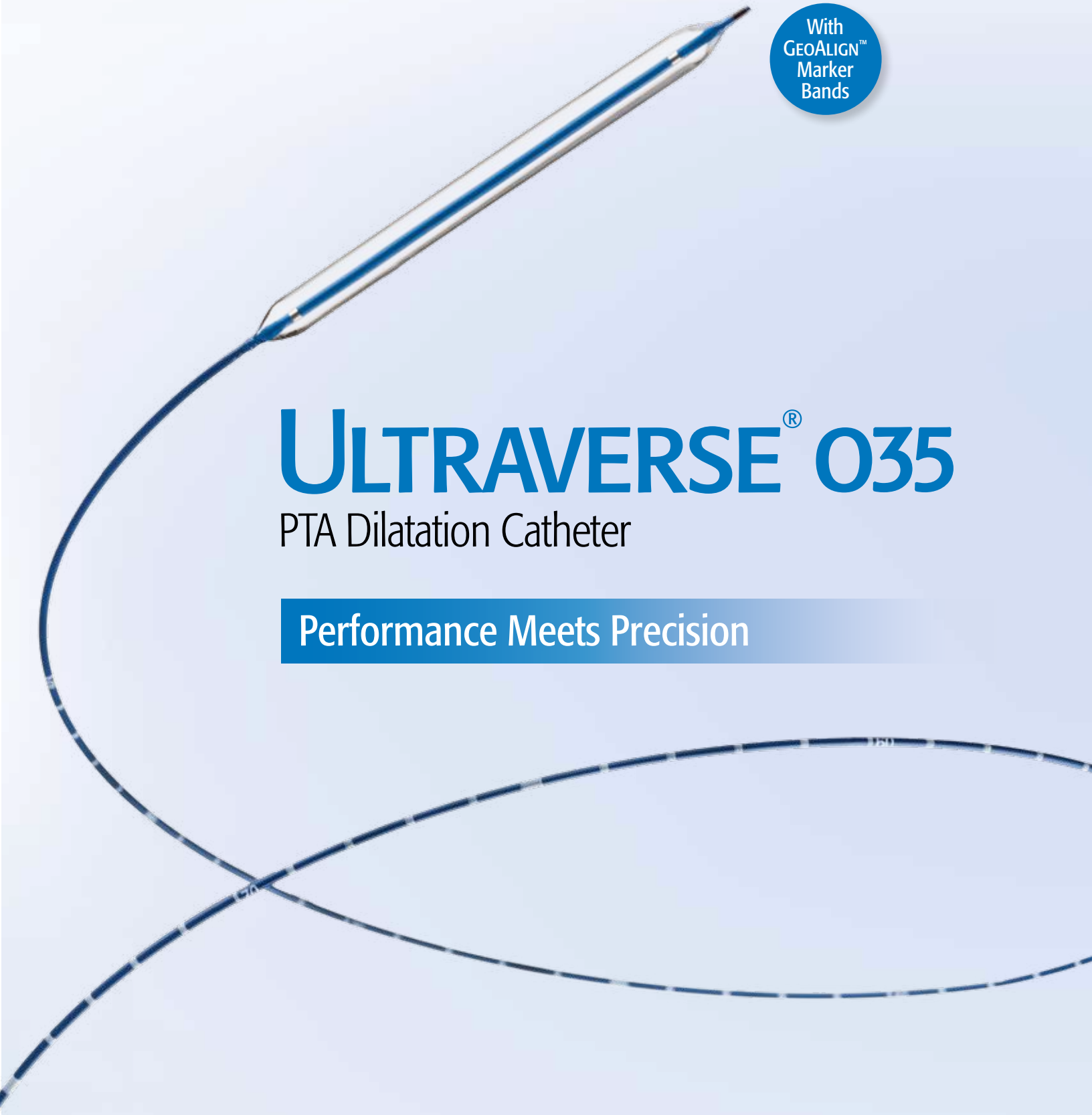
With GeoAlign™ Marker Bands



Ultraverse® 035

PTA Dilatation Catheter

Performance Meets Precision

BARD | PERIPHERAL VASCULAR

GeoAlign™ Marker Bands are designed to be used as a reference tool to help enable precise balloon placement at the treatment zone

GeoAlign™ Marker Bands are designated on the catheter shaft by **1 cm increment bands**

Each 10 cm increment is labeled with the **distance from the distal balloon tip**

GeoAlign™ Marker Bands are non-radiopaque

GeoAlign™ Marker Bands are designed to increase procedure efficiency by minimizing fluoroscopy exposure†

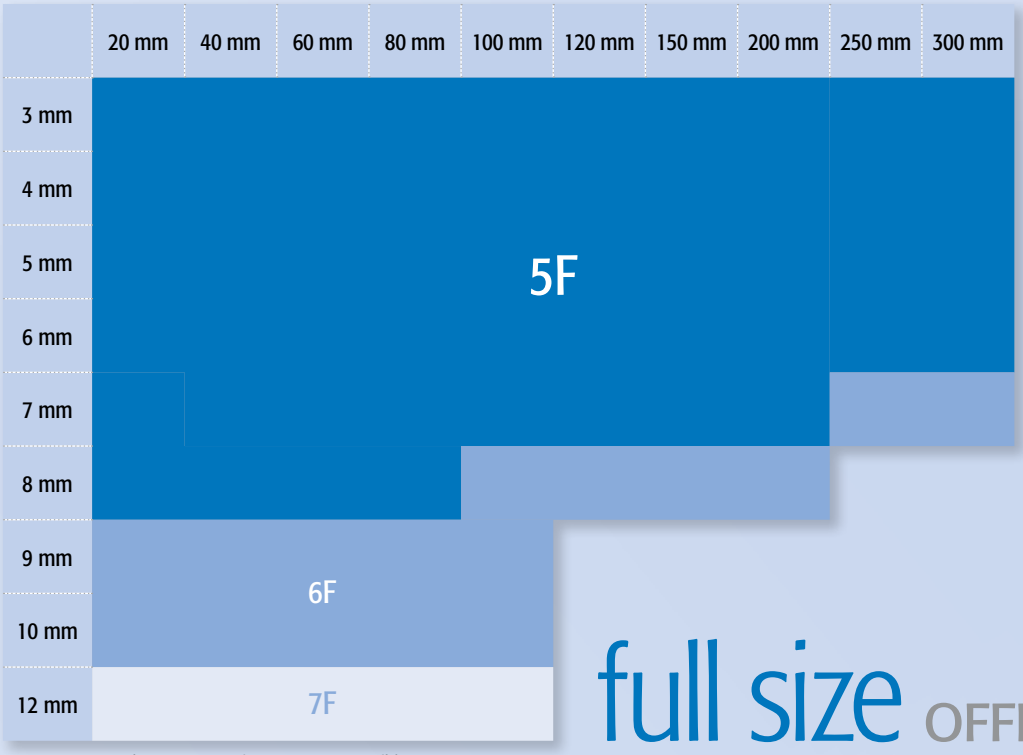
† When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation

ULTRAVERSE® 035
PTA Dilatation Catheter

With GEOALIGN™ Marker Bands

5F COMPATIBLE UP TO 8 x 80 MM*

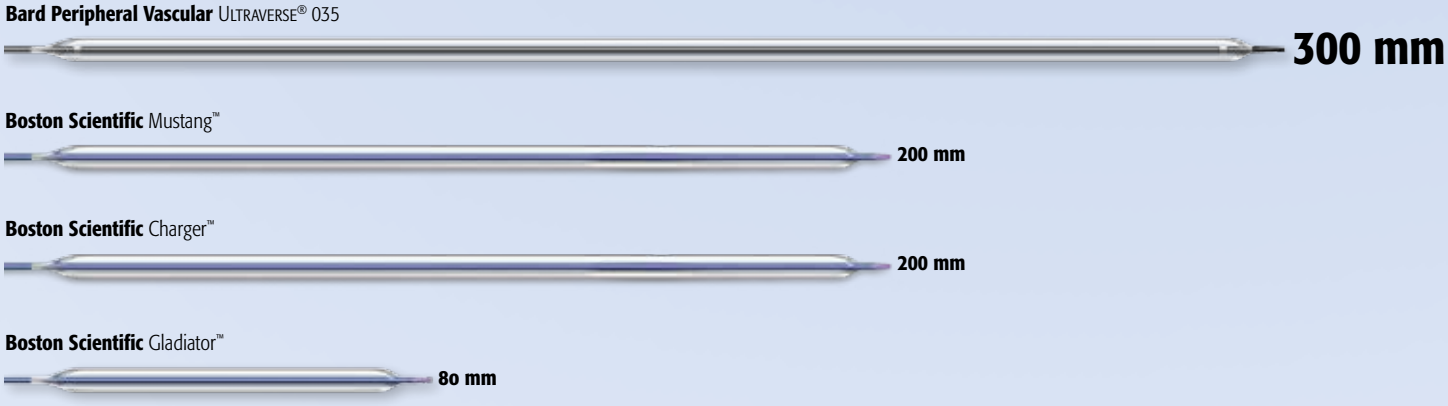
ULTRAVERSE® 035 Offers more sizes that are 5F compatible than Boston Mustang™ or Charger™



*7 x 250 mm and 7 x 300 mm sizes are 6F compatible

full size OFFERING

BALLOON LENGTHS UP TO 300 mm‡



Depending on lesion type and length, longer balloons may require fewer inflations, potentially reducing procedural and fluoroscopy time

‡ As of July 2014 for .035" PTA Balloons

ULTRAVERSE® 035 PTA Dilatation Catheter

Ordering Information

75 cm Catheter Length			
Dia. (mm)	Length (mm)	RBP† (ATM)	Product Code
3	20	21	U357532
	40	21	U357534
	60	21	U357536
	80	21	U357538
	100	19	U3575310
	120	19	U3575312
	150	19	U3575315
	200	19	U3575320
	250	19	U3575325
	300	19	U3575330
4	20	20	U357542
	40	20	U357544
	60	20	U357546
	80	20	U357548
	100	19	U3575410
	120	19	U3575412
	150	19	U3575415
	200	19	U3575420
	250	19	U3575425
	300	19	U3575430
5	20	17	U357552
	40	17	U357554
	60	17	U357556
	80	17	U357558
	100	16	U3575510
	120	16	U3575512
	150	16	U3575515
	200	16	U3575520
	250	16	U3575525
	300	16	U3575530
6	20	15	U357562
	40	15	U357564
	60	15	U357566
	80	15	U357568
	100	14	U3575610
	120	14	U3575612
	150	14	U3575615
	200	14	U3575620
	250	14	U3575625
	300	14	U3575630

75 cm Catheter Length			
Dia. (mm)	Length (mm)	RBP† (ATM)	Product Code
7	20	14	U357572
	40	14	U357574
	60	14	U357576
	80	14	U357578
	100	11	U3575710
	120	11	U3575712
	150	11	U3575715
	200	11	U3575720
	250	11	U3575725
	300	11	U3575730
8	20	10	U357582
	40	10	U357584
	60	10	U357586
	80	10	U357588
	100	13	U3575810
	120	13	U3575812
	150	13	U3575815
	200	13	U3575820
9	20	12	U357592
	40	12	U357594
	60	11	U357596
	80	11	U357598
	100	11	U3575910
10	20	11	U3575102
	40	11	U3575104
	60	10	U3575106
	80	10	U3575108
	100	10	U35751010
12	20	11	U3575122
	40	11	U3575124
	60	9	U3575126
	80	9	U3575128
	100	9	U35751210

Sheath Profile (F)	
3 mm x 20 mm - 7 mm x 200 mm	5F
7 mm x 250 mm - 7 mm x 300 mm	6F
8 mm x 20 mm - 8 mm x 80 mm	5F
8 mm x 100 mm - 8 mm x 200 mm	6F
All 9 mm and 10 mm	6F
All 12 mm	7F

130 cm Catheter Length			
Dia. (mm)	Length (mm)	RBP† (ATM)	Product Code
3	20	21	U3513032
	40	21	U3513034
	60	21	U3513036
	80	21	U3513038
	100	19	U35130310
	120	19	U35130312
	150	19	U35130315
	200	19	U35130320
	250	19	U35130325
	300	19	U35130330
4	20	20	U3513042
	40	20	U3513044
	60	20	U3513046
	80	20	U3513048
	100	19	U35130410
	120	19	U35130412
	150	19	U35130415
	200	19	U35130420
	250	19	U35130425
	300	19	U35130430
5	20	17	U3513052
	40	17	U3513054
	60	17	U3513056
	80	17	U3513058
	100	16	U35130510
	120	16	U35130512
	150	16	U35130515
	200	16	U35130520
	250	16	U35130525
	300	16	U35130530
6	20	15	U3513062
	40	15	U3513064
	60	15	U3513066
	80	15	U3513068
	100	14	U35130610
	120	14	U35130612
	150	14	U35130615
	200	14	U35130620
	250	14	U35130625
	300	14	U35130630

Nominal Pressure*	
3 mm - 7 mm	8 ATM
8 mm - 12 mm	6 ATM

130 cm Catheter Length			
Dia. (mm)	Length (mm)	RBP† (ATM)	Product Code
7	20	14	U3513072
	40	14	U3513074
	60	14	U3513076
	80	14	U3513078
	100	11	U35130710
	120	11	U35130712
	150	11	U35130715
	200	11	U35130720
	250	11	U35130725
	300	11	U35130730
8	20	10	U3513082
	40	10	U3513084
	60	10	U3513086
	80	10	U3513088
	100	13	U35130810
	120	13	U35130812
	150	13	U35130815
	200	13	U35130820
9	20	12	U3513092
	40	12	U3513094
	60	11	U3513096
	80	11	U3513098
	100	11	U35130910
10	20	11	U35130102
	40	11	U35130104
	60	10	U35130106
	80	10	U35130108
	100	10	U351301010
12	20	11	U35130122
	40	11	U35130124
	60	9	U35130126
	80	9	U35130128
	100	9	U351301210

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

† 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.

Please contact your local Bard Peripheral Vascular Sales Representative for availability of sizes.

Indications for Use
The ULTRAVERSE® 035 PTA Balloon Dilatation Catheter is intended to dilate stenoses in the peripheral arteries, to treat obstructive lesions of native or synthetic A-V fistulae and/or re-expand endoluminal stent graft elements in the iliac arteries. This device is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. 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® 035 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)** GeoAlign™ Marker Bands are designed to be used only as an additional reference tool to accompany the interventionalist standard operation procedure.

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

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

S120491 Rev. 0

BARD | PERIPHERAL VASCULAR

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