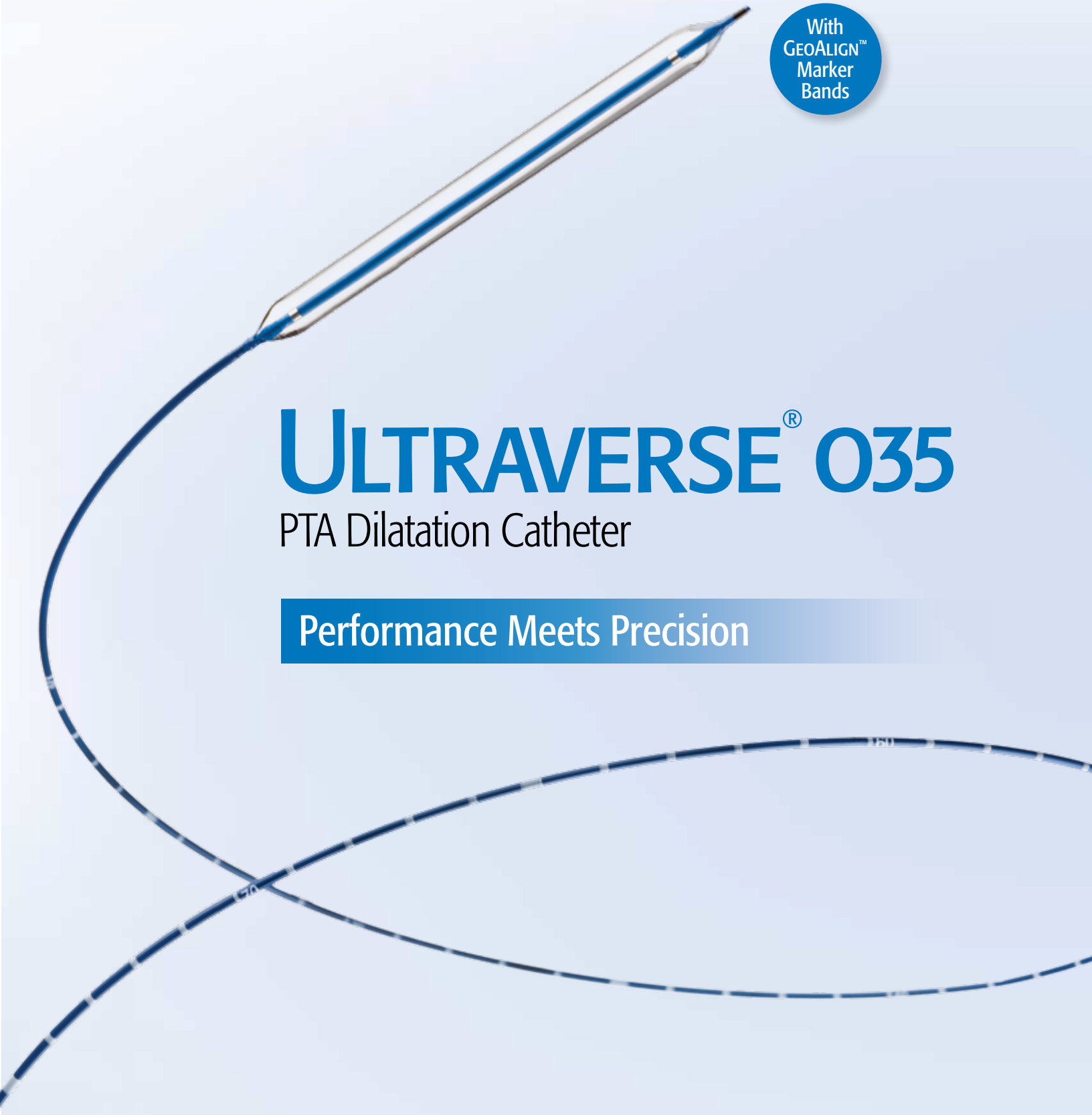
With GeoAlign™ Marker Bands



# 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†

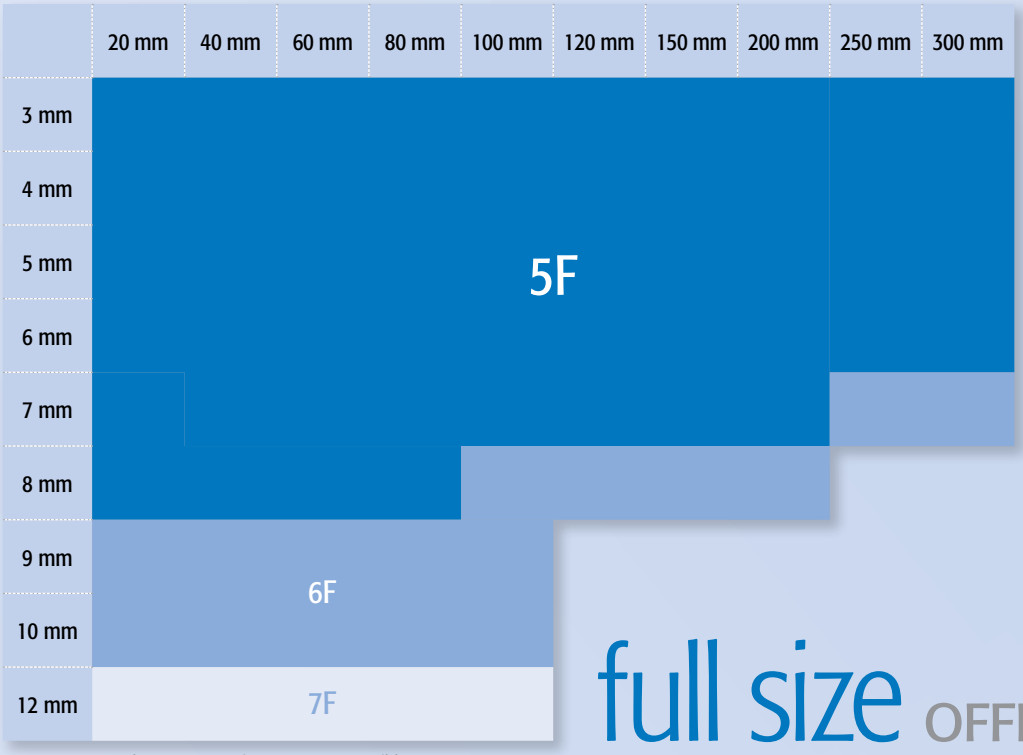
† When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation

# ULTRAVERSE® 035
PTA Dilatation Catheter

With GEOALIGN™ Marker Bands

## 5F COMPATIBLE UP TO 8 x 80 MM*

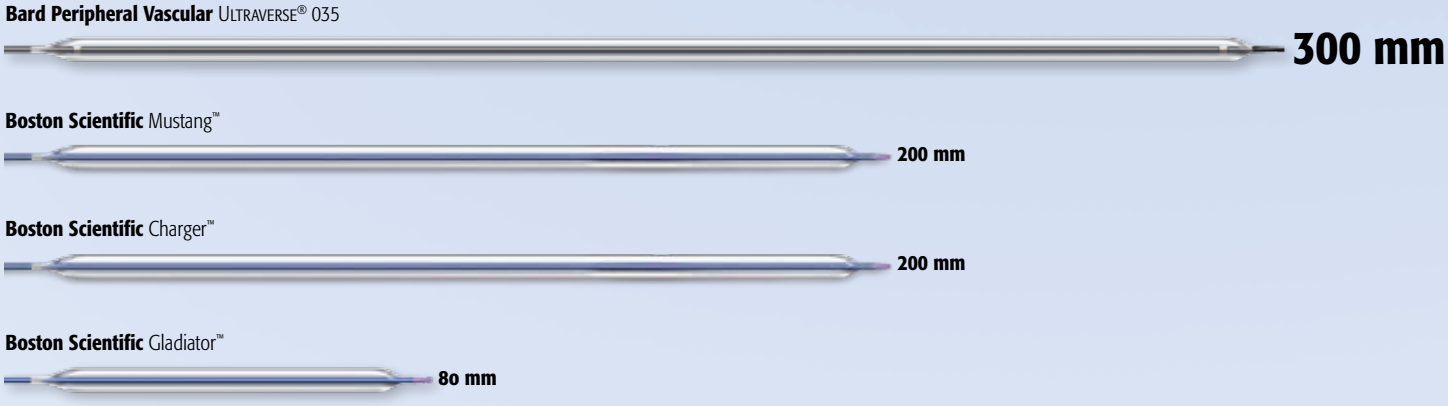
ULTRAVERSE® 035 Offers more sizes that are 5F compatible than Boston Mustang™ or Charger™




*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

Bard Peripheral Vascular, Inc.
1625 W. 3rd Street
Tempe, AZ 85281 USA
Tel: 1 480 894 9515 / 1 800 321 4254
Fax: 1 480 966 7062 / 1 800 440 5376
www.bardpv.com