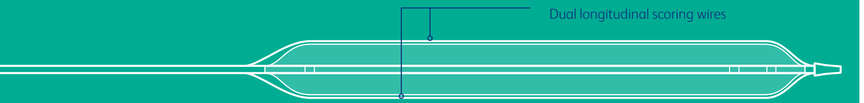
Designed to fracture plaque longitudinally at lower inflation pressures compared to standard PTA

Ultrascore™ Focused Force PTA Balloon Design



24 x Force

Ultrascore® Balloon

The two longitudinal wires of the Ultrascore® Focused Force PTA Balloon provide **greater concentrated force** against the plaque at lower inflation pressures, which may allow for a more controlled fracture compared to dilatation with a standard PTA balloon of the same size.[1,2] As a result, before nominal pressure is achieved, approximately **24 times** more force is exerted at the point of contact between the wires and the vessel wall.[3]

Standard PTA

Standard PTA Balloon

A standard PTA balloon distributes force to the entire surface area of the vessel wall. At the same nominal inflation pressure as the Ultrascore® Focused Force PTA Balloon, a standard PTA balloon generates less force against the lesion.[1,2]

1 Based on a simulated finite element analysis. Data on File, Bard Peripheral Vascular, Inc., Tempe, AZ. May not be predictive of clinical performance. Different test methods may yield different results.

2 For purposes of this analysis, initiation of plaque failure was deemed to occur when the strain exceeds 18%. Ultrascore™ Focused Force PTA Balloon was predicted to initiate failure at .32 ATM, while a standard semi-compliant PTA balloon was predicted to initiate failure at 10.3 ATM. Data on file, Bard Peripheral Vascular, Inc., Tempe, AZ. Simulated analyses may not be predictive of actual clinical performance. Different test methods may yield different results.

3 Based on theoretical calculation using equation P=F/A. Data on File, Bard Peripheral Vascular, Inc., Tempe, AZ. May not be predictive of clinical performance. Different test methods may yield different results.

Ultrascore™ Focused Force PTA Balloon

Ordering information

150 cm Shaft I .014" Guidewire Compatible

Diam. (mm)	RBP (ATM)	Sheath Compatibility	Balloon Length 20 mm	40 mm	80 mm	100 mm	120 mm	150 mm	200 mm	300 mm
2	14	4F	US1415022	US1415024	US1415028	US14150210	US14150212	US14150215	US14150220	US14150230
2.5	14	4F	US141502H2	US141502H4	US141502H8	US141502H10	US141502H12	US141502H15	US141502H20	US141502H30
3	14	4F	US1415032	US1415034	US1415038	US14150310	US14150312	US14150315	US14150320	US14150330
3.5	14	4F	US141503H2	US141503H4	US141503H8	US141503H10	US141503H12	US141503H15	US141503H20	US141503H30
4	14	5F	US1415042	US1415044	US1415048	US14150410	US14150412	US14150415	US14150420	US14150430
5	12	5F	US1415052	US1415054	US1415058	US14150510	US14150512	US14150515	US14150520	US14150530
6	12	5F	US1415062	US1415064	US1415068	US14150610	US14150612	US14150615	US14150620	US14150630
7	10	5F	US1415072	US1415074	US1415078	US14150710	US14150712	US14150715	US14150720	-

130 cm Shaft I .035" Guidewire Compatible

Diam. (mm)	RBP (ATM)	Sheath Compatibility	Balloon Length 20 mm	40 mm	80 mm	100 mm	120 mm	150 mm	200 mm	300 mm
4	14	5F	US3513042	US3513044	US3513048	US35130410	US35130412	US35130415	US35130420	US35130430
5	14	5F	US3513052	US3513054	US3513058	US35130510	US35130512	US35130515	US35130520	US35130530
6	14	5F	US3513062	US3513064	US3513068	US35130610	US35130612	US35130615	US35130620	US35130630
7	10	6F	US3513072	US3513074	US3513078	US35130710	US35130712	US35130715	US35130720	-
8	10	6F	US3513082	US3513084	US3513088	US35130810	US35130812	US35130815	US35130820	-

Ultrascore® Focused Force PTA Balloon

Indications for Use

The ULTRASCORE® Focused Force PTA Balloon is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also recommended for post dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

Contraindications

The ULTRASCORE® Focused Force PTA Balloon is contraindicated: • Where there is the inability to cross the target lesion with a guidewire • For use in the coronary or neuro vasculature

Warnings

1. Contents supplied STERILE using ethylene oxide (EO). Non-Pyrogenic. Do not use if sterile barrier is opened, damaged or contamination is evident. Do not reuse, reprocess or re-sterilize. Use the catheter prior to the "Use By" date specified on the package label. 2. This device has been designed for single patient use. 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. Additionally, re-use and/or repackaging may compromise the structural integrity and/or material and design characteristics of the device, which may lead to device failure, and/or lead to patient injury. 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 or difficulty in deflating, 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, the location of the balloon should be confirmed 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 or difficulty in deflation may occur if the RBP rating is exceeded. To prevent over pressurization, use of a pressure monitoring device is recommended. 7. After contact with blood or use, this product is a biohazard. Handle and dispose as a biohazard 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.

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. The ULTRASCORE® Focused Force PTA Balloon should only be used by physicians experienced in the performance of percutaneous transluminal angioplasty. 3. 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. 4. For ULTRASCORE® .014 guidewire sizes only, in order to activate the hydrophilic coating, wet the ULTRASCORE® balloon and catheter with sterile saline or wipe the balloon catheter with sterile saline saturated gauze immediately prior to its insertion in the body. Avoid excessively wiping the coated portions of the device, or wiping with dry gauze, as this may damage the hydrophilic coating. 5. ULTRASCORE® .014" guidewire sizes are coated with a hydrophilic coating at the distal segment of the shaft and 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. 6. 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. 7. Use the recommended balloon inflation medium (25% contrast medium/75% sterile saline solution). Never use air or other gaseous medium to inflate the balloon. 8. The ULTRASCORE® Focused Force PTA Balloon should be used with caution for procedures involving calcified lesions, stents or synthetic vascular grafts due to the abrasive nature of these lesions. 9. Fully evacuate the balloon prior to withdrawing the system. Larger sizes of ULTRASCORE® Focused Force PTA Balloons may exhibit slower deflation times. 10. If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath, determine if contrast medium 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. 11. 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. 12. 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. 13. For ULTRASCORE® .014 guidewire sizes only, prior to re-insertion through the introducer sheath, re-activate the hydrophilic coating, and clean the balloon catheter by wiping the balloon catheter with sterile saline saturated gauze and rinsing with sterile saline. Using different media other than the recommended solution could affect the hydrophilic coating and its performance. 14. 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 coating which could affect the device safety and performance. 16. Avoid pre-soaking devices for extended periods, as this may impact the coating performance.

Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions and instructions for use.

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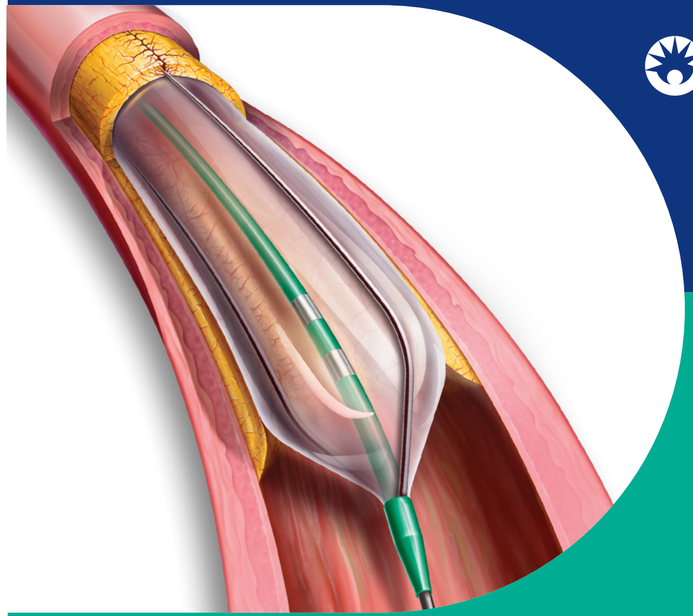


Designed for Controlled Plaque Modification: The UltraScore Scoring Balloon

Ultrascore™

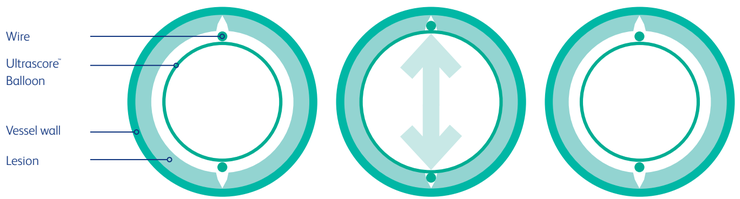
Focus Forced PTA Balloon

Controlled Plaque Modification

Compared to a standard PTA balloon of the same size, the Ultrascore™ Focused Force PTA Balloon:

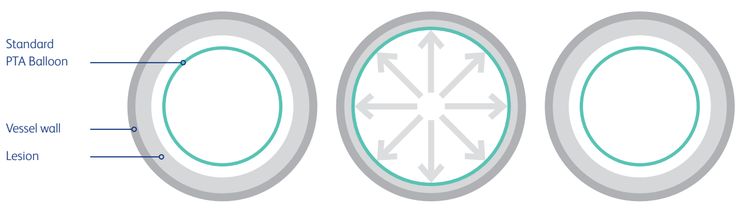
- Is designed to **longitudinally fracture plaque at lower inflation pressures**
- May allow for a more **controlled plaque fracture and less vessel recoil,** even in calcified lesions

How Ultrascore™ Focused Force PTA Balloon Works



Ultrascore™ Balloon

Force is focused where the wire contacts the lesion



Standard PTA Balloon

Force is distributed along entire surface area of lesion

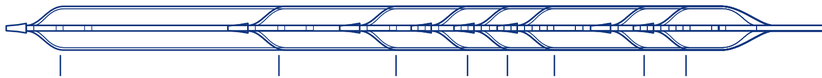
Low profile, over-the-wire design

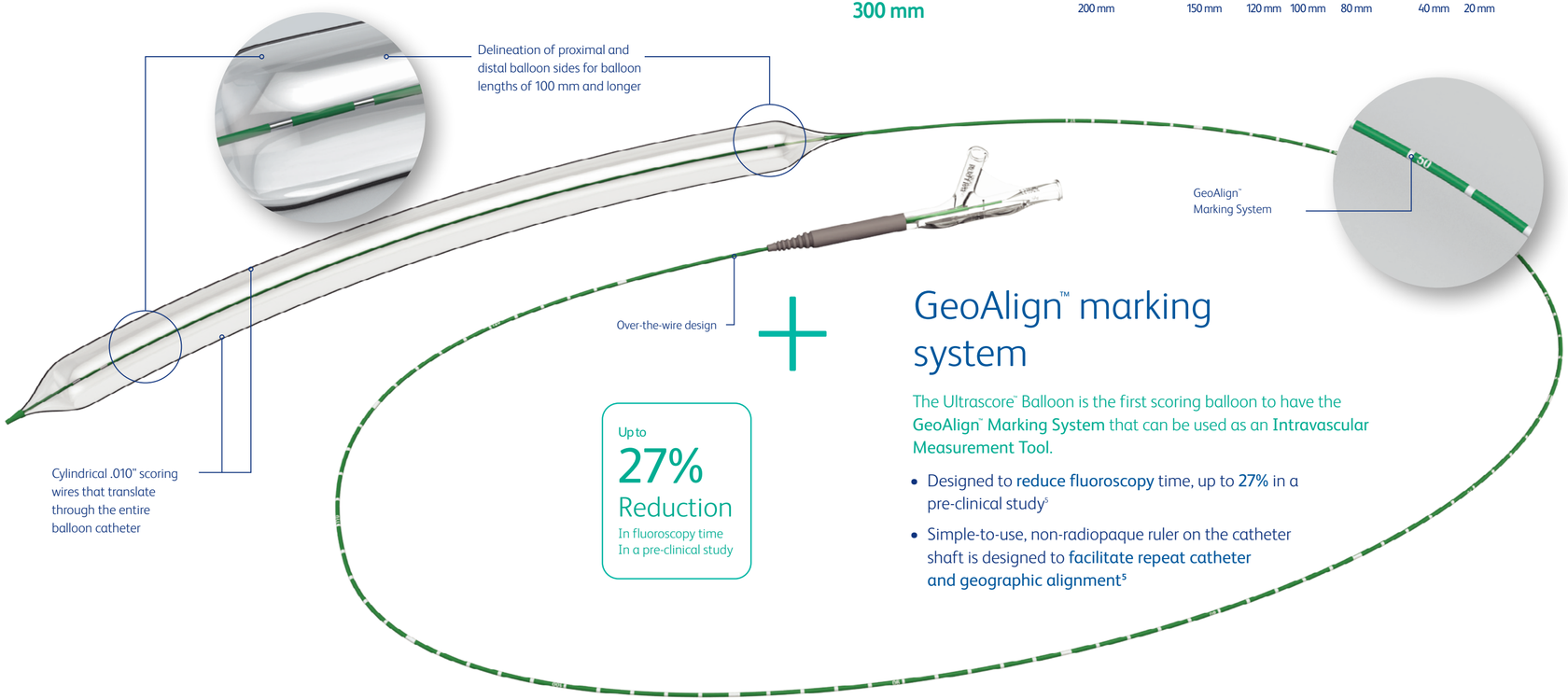
Ultrascore™ Focused Force PTA Balloon is available on a **.035" and .014"** platform, and and offers low profile scoring balloon.

- **4F sheath** compatibility.
- **Hydrophillic coating** for optimized deliverability on .014" platform[4]

Broad scoring balloon portfolio[4]

Long scoring balloon length.





Up to
27%
Reduction
In fluoroscopy time
In a pre-clinical study

GeoAlign™ marking system

The Ultrascore™ Balloon is the first scoring balloon to have the **GeoAlign™ Marking System** that can be used as an **Intravascular Measurement Tool.**

- Designed to **reduce fluoroscopy** time, up to **27%** in a pre-clinical study[5]
- Simple-to-use, non-radiopaque ruler on the catheter shaft is designed to **facilitate repeat catheter and geographic alignment**[5]

1 As of March 2018.

2 When the catheter is exposed to the vascular system, the location of the balloon should be confirmed while under high quality fluoroscopic observation. GeoAlign™ Markers are not a replacement for fluoroscopy. Animal study (repeat PTA in swine artery) was performed by 3 physicians who tested the Lutonix™ 035 DCB (no drug) and the Ultraverse™ 035 PTA Catheter, both with GeoAlign™ Markers, to POBA with no GeoAlign™ Markers [n=112, test n = 96 (with and average placement time of 66 seconds), control n = 16 (with an average placement of 90 seconds)]. Animal data on file, Bard Peripheral Vascular, Inc., Tempe, AZ. Animal test results may not be indicative of clinical performance. Different test methods may yield different results.

Ultrascore™

Focus Forced PTA Balloon