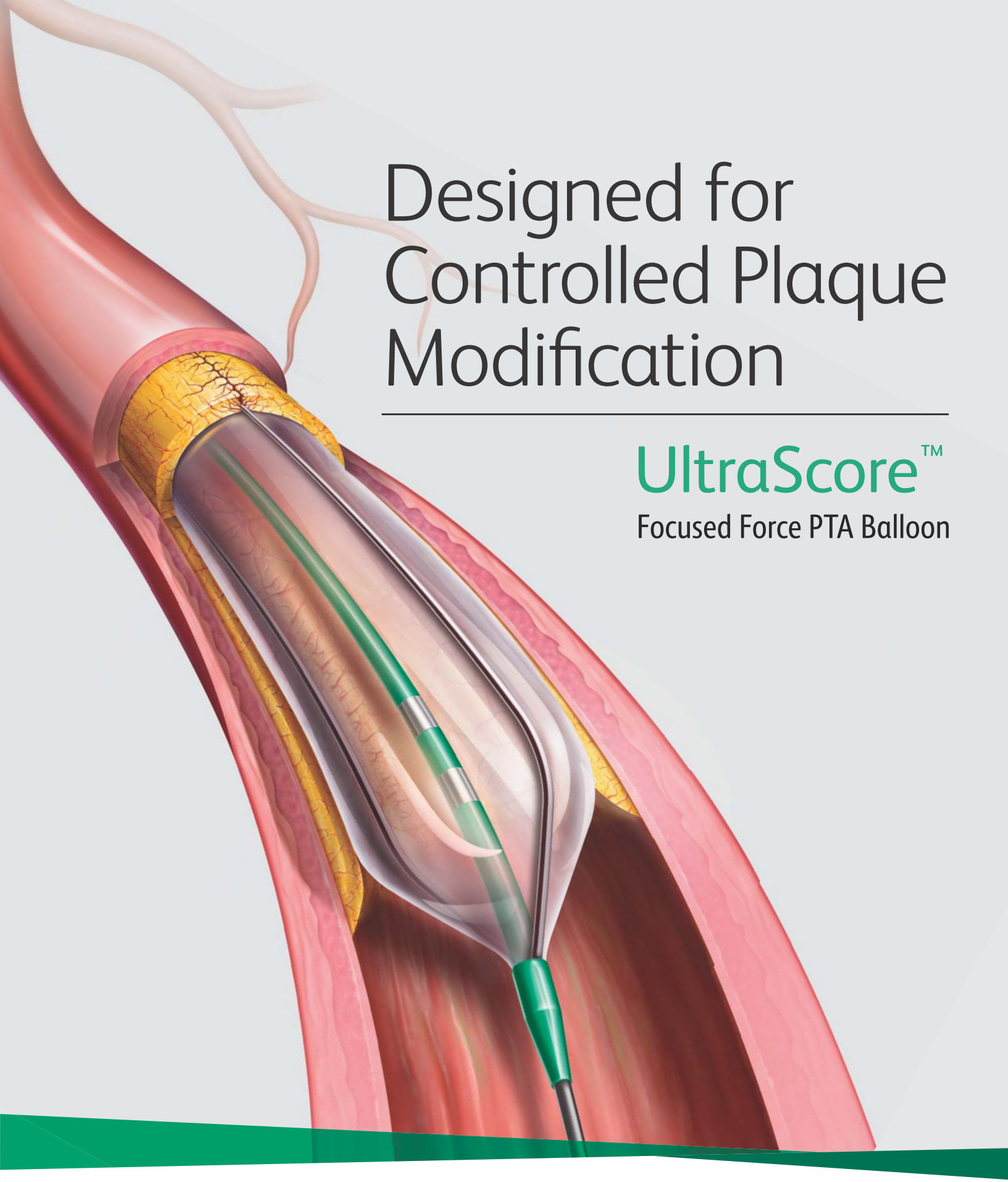


Designed for Controlled Plaque Modification

UltraScore™

Focused Force PTA Balloon

BD

Designed to **Fracture Plaque Longitudinally** at **Lower Inflation Pressures** Compared to Standard PTA

UltraScore™ Focused Force PTA Balloon Design

~24x 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 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.[1,3]

[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.

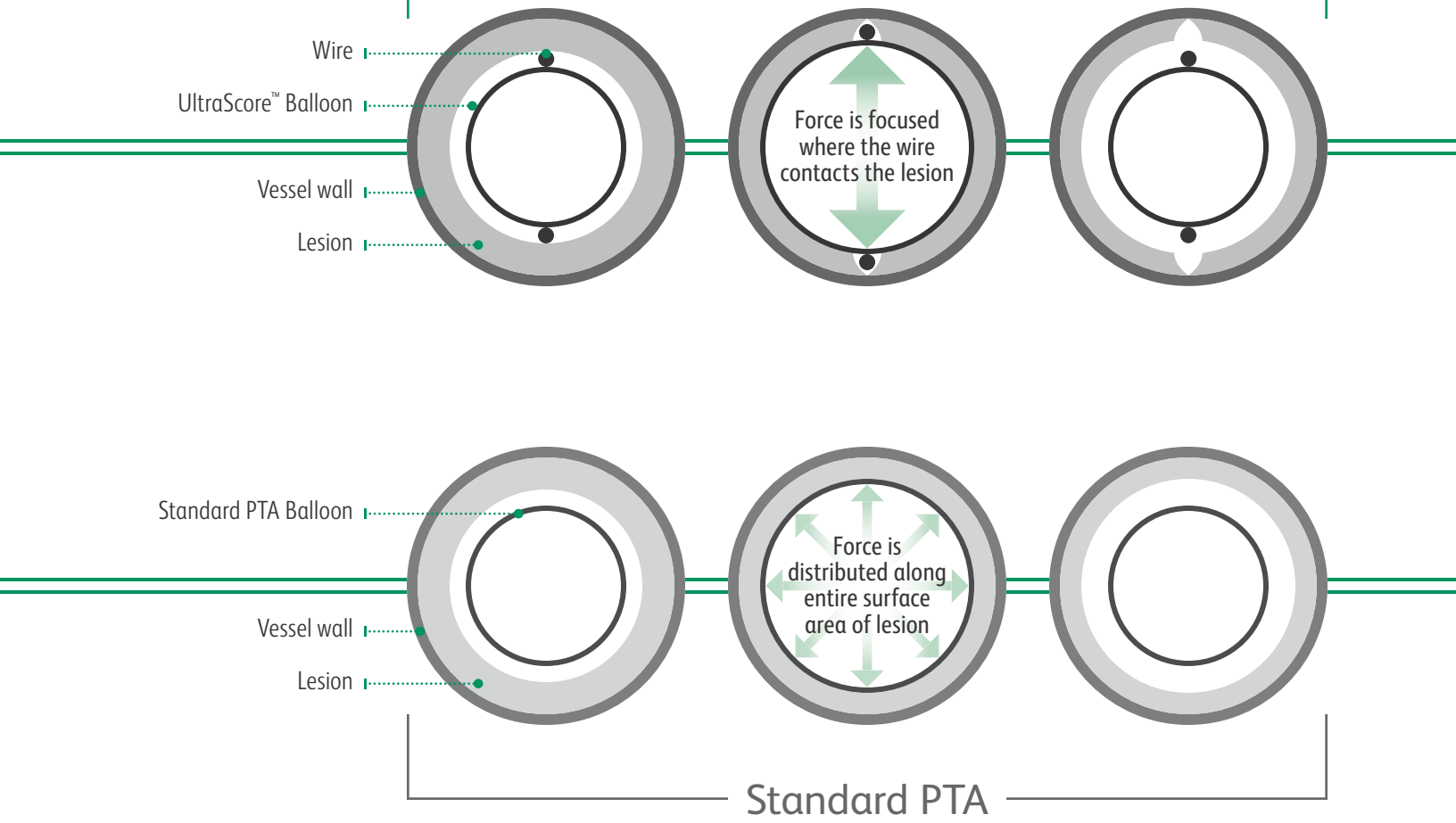
[3] Based on theoretical calculation using equation P=F/A. Data on File, Bard Peripheral Vascular, Inc., Tempe, AZ. May not be predictive of clinical performance. Different test methods may yield different results.

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

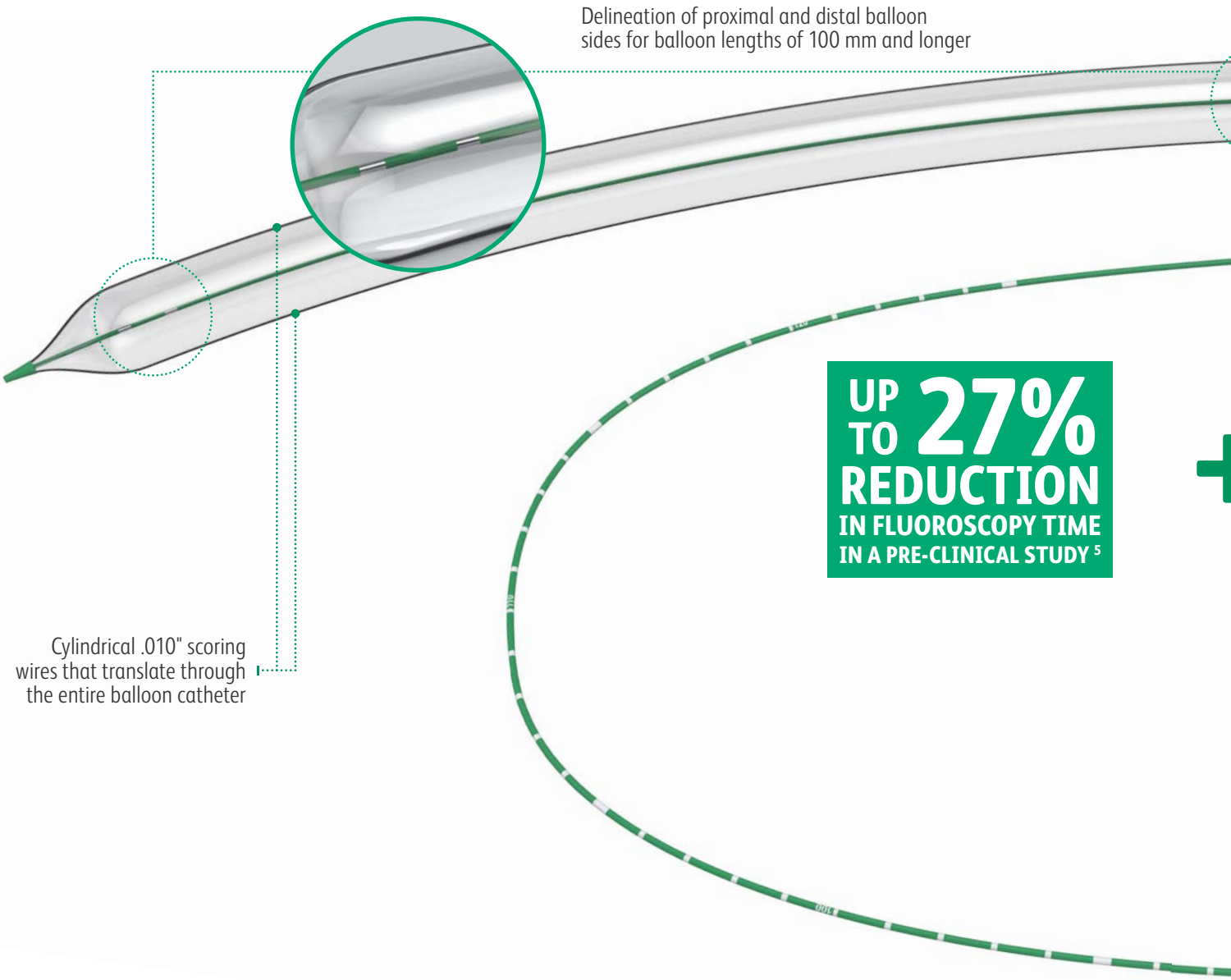
How UltraScore™ Focused Force PTA Balloon Works



Low Profile, Over-the-Wire Design

UltraScore™ Focused Force PTA Balloon is available on a **.035" and .014"** platform, and is the lowest profile scoring balloon on the U.S. market.[4]

- **Only 4F** scoring balloon on the U.S. market[4]
- **First .035"** scoring balloon commercially available on the U.S. market
- **Hydrophillic coating** for optimized deliverability on .014" platform



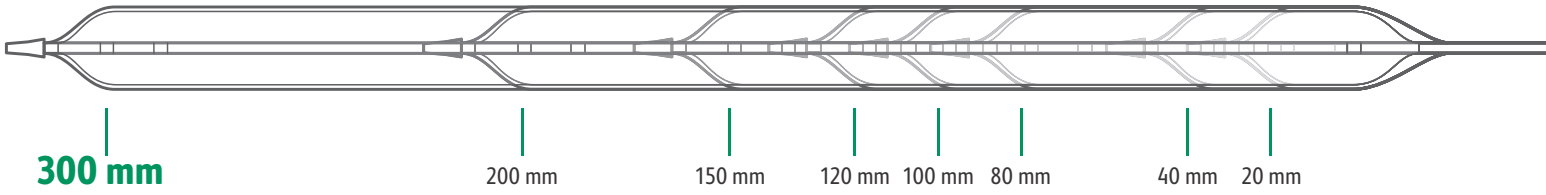
UP TO 27% REDUCTION IN FLUOROSCOPY TIME IN A PRE-CLINICAL STUDY [5]

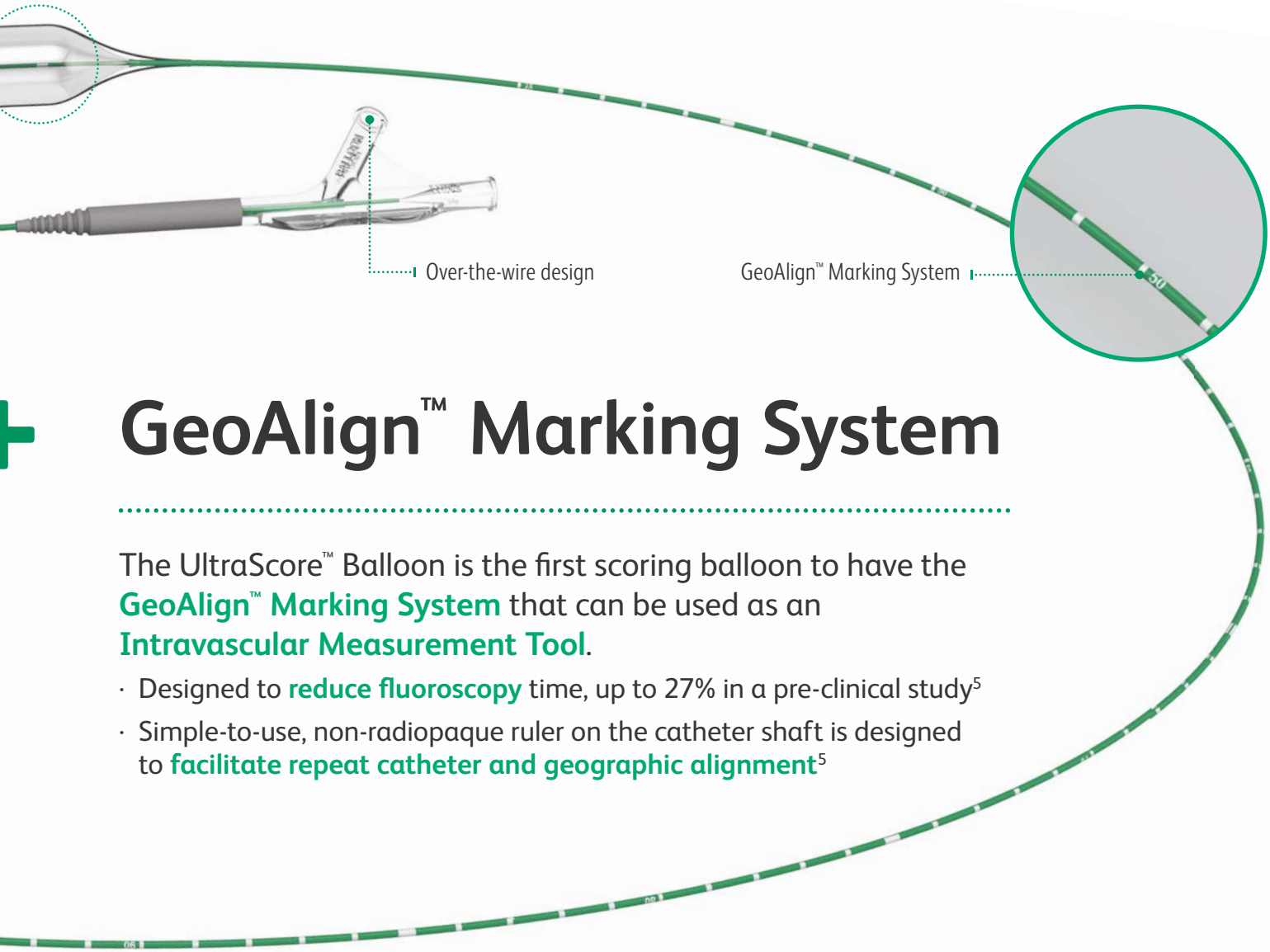
[4] As of January 2021.

[5] 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.

Broadest Scoring Balloon Portfolio[4]
on the U.S. Market

LONGEST SCORING BALLOON LENGTHS ON THE U.S. MARKET[4]





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]

UltraScore™
Focused Force PTA Balloon

UltraScore™

Focused Force PTA Balloon

150 cm Shaft	.014" Guidewire Compatible								
Dia. (mm)	RBP (ATM)	Balloon Length							Sheath (F)
		20 mm	40 mm	80 mm	100 mm	120 mm	150 mm	200 mm	300 mm	
2	14	☐ US1415022	☐ US1415024	☐ US1415028	☐ US14150210	☐ US14150212	☐ US14150215	☐ US14150220	☐ US14150230	4
2.5	14	☐ US141502H2	☐ US141502H4	☐ US141502H8	☐ US141502H10	☐ US141502H12	☐ US141502H15	☐ US141502H20	☐ US141502H30	
3	14	☐ US1415032	☐ US1415034	☐ US1415038	☐ US14150310	☐ US14150312	☐ US14150315	☐ US14150320	☐ US14150330	
3.5	14	☐ US141503H2	☐ US141503H4	☐ US141503H8	☐ US141503H10	☐ US141503H12	☐ US141503H15	☐ US141503H20	☐ US141503H30	
4	14	☐ US1415042	☐ US1415044	☐ US1415048	☐ US14150410	☐ US14150412	☐ US14150415	☐ US14150420	☐ US14150430	5
5	12	☐ US1415052	☐ US1415054	☐ US1415058	☐ US14150510	☐ US14150512	☐ US14150515	☐ US14150520	☐ US14150530	
6	12	☐ US1415062	☐ US1415064	☐ US1415068	☐ US14150610	☐ US14150612	☐ US14150615	☐ US14150620	☐ US14150630	
7	10	☐ US1415072	☐ US1415074	☐ US1415078	☐ US14150710	☐ US14150712	☐ US14150715	☐ US14150720	☐ US14150730	

130 cm Shaft	.035" Guidewire Compatible								
Diam. (mm)	RBP (ATM)	Balloon Length							Sheath (F)
		20 mm	40 mm	80 mm	100 mm	120 mm	150 mm	200 mm	300 mm	
4	14	☐ US3513042	☐ US3513044	☐ US3513048	☐ US35130410	☐ US35130412	☐ US35130415	☐ US35130420	☐ US35130430	5
5	14	☐ US3513052	☐ US3513054	☐ US3513058	☐ US35130510	☐ US35130512	☐ US35130515	☐ US35130520	☐ US35130530	6
6	14	☐ US3513062	☐ US3513064	☐ US3513068	☐ US35130610	☐ US35130612	☐ US35130615	☐ US35130620	☐ US35130630	
7	10	☐ US3513072	☐ US3513074	☐ US3513078	☐ US35130710	☐ US35130712	☐ US35130715	☐ US35130720	☐ US35130730	
8	10	☐ 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 or damaged. 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 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 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 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.)** 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. Do not wipe the balloon catheter with dry gauze. **5.)** 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. **6.)** Use the recommended balloon inflation medium (25% contrast medium/75% sterile saline solution). Never use air or other gaseous medium to inflate the balloon. **7.)** 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. **8.)** Fully evacuate the balloon prior to withdrawing the system. Larger sizes of UltraScore™ Focused Force PTA Balloons may exhibit slower deflation times. **9.)** 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. **10.)** 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. **11.)** Do not continue to use the balloon catheter if the shaft has been bent or kinked. **12.)** 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. Do not wipe the balloon catheter with dry gauze. **13.)** 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.

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 product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

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