

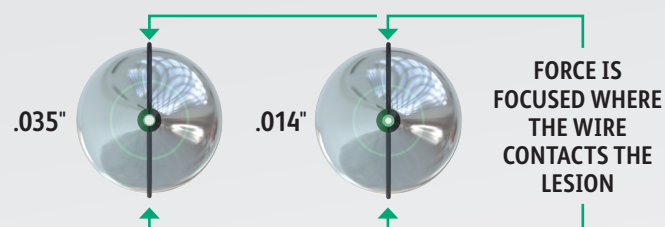
Engineered to Provide Focused Force

The UltraScore™ Focused Force PTA Balloon is the **first commercially available .035" scoring balloon** on the U.S. market*, with sizes available on both .014" and .035" guidewire platforms. Compared to a standard PTA balloon of the same size, the UltraScore™ Balloon:

- Provides approximately **24 times more force** where the wire contacts the lesion**
- Is designed to **longitudinally fracture plaque** at **lower inflation pressure**
- May allow for a **more controlled plaque fracture** and **less vessel recoil**, even in calcified lesions

UltraScore™

Focused Force PTA Balloon



* As of July 2021

** Based on theoretical calculation using equation $P=F/A$ comparing UltraScore™ Balloon to POBA. Data on file, Becton, Dickinson and Company. Different tests may yield different results. May not be predictive of clinical performance.

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. 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. 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.

UltraScore™

Focused Force PTA Balloon

Ordering Information

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

130 cm Shaft .035" Guidewire Compatible										
Diam. (mm)	RBP (ATM)	Balloon Length								Sheath Compatibility
		20 mm	40 mm	80 mm	100 mm	120 mm	150 mm	200 mm	300 mm	
4	14	<input type="checkbox"/> US3513042	<input type="checkbox"/> US3513044	<input type="checkbox"/> US3513048	<input type="checkbox"/> US35130410	<input type="checkbox"/> US35130412	<input type="checkbox"/> US35130415	<input type="checkbox"/> US35130420	<input type="checkbox"/> US35130430	5F
5	14	<input type="checkbox"/> US3513052	<input type="checkbox"/> US3513054	<input type="checkbox"/> US3513058	<input type="checkbox"/> US35130510	<input type="checkbox"/> US35130512	<input type="checkbox"/> US35130515	<input type="checkbox"/> US35130520	<input type="checkbox"/> US35130530	6F
6	14	<input type="checkbox"/> US3513062	<input type="checkbox"/> US3513064	<input type="checkbox"/> US3513068	<input type="checkbox"/> US35130610	<input type="checkbox"/> US35130612	<input type="checkbox"/> US35130615	<input type="checkbox"/> US35130620	<input type="checkbox"/> US35130630	
7	10	<input type="checkbox"/> US3513072	<input type="checkbox"/> US3513074	<input type="checkbox"/> US3513078	<input type="checkbox"/> US35130710	<input type="checkbox"/> US35130712	<input type="checkbox"/> US35130715	<input type="checkbox"/> US35130720	—	
8	10	<input type="checkbox"/> US3513082	<input type="checkbox"/> US3513084	<input type="checkbox"/> US3513088	<input type="checkbox"/> US35130810	<input type="checkbox"/> US35130812	<input type="checkbox"/> US35130815	<input type="checkbox"/> 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 indeterminate 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 indeterminate 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, antiplatelet 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.