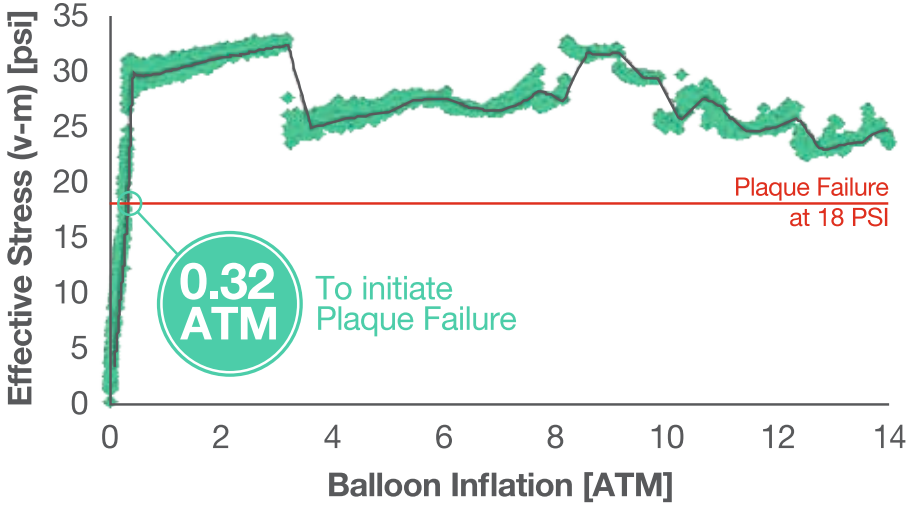
ULTRASCORE™ Outperforms PTA With Longitudinal Focused Force*

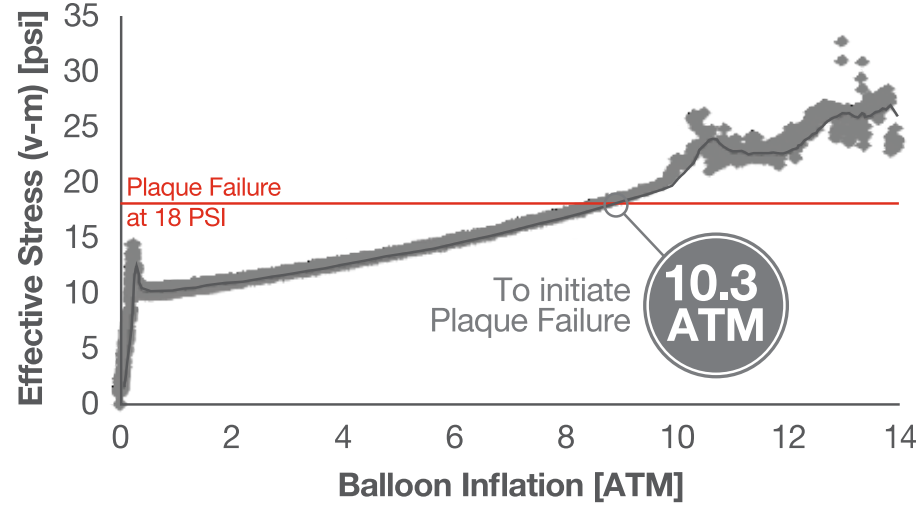
Testing Results: ULTRASCORE™ is designed to longitudinally fracture plaque at **lower inflation pressures** vs. Standard PTA.

ULTRASCORE™ Force (FEA)



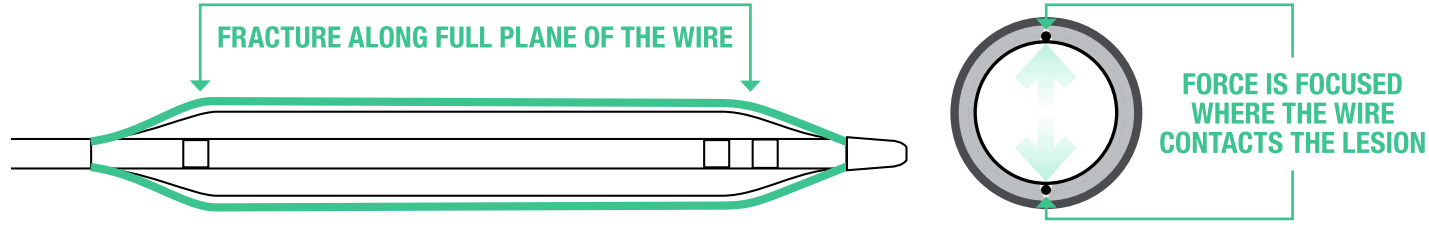
- ULTRASCORE™ requires 0.32 ATM or **32x less pressure** to initiate plaque failure

POBA Force (FEA)



- Standard PTA requires 10.3 ATM to initiate plaque failure

Scoring Mechanism:
The ULTRASCORE™ mechanism allows total wire engagement along the longitudinal plane at **lower inflation pressures.**



ULTRASCORE™
Focused Force PTA Balloon

BD BARD has joined BD

* 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.

ULTRASCORE™

Focused Force PTA Balloon

Ordering Information

0.014" - 150 cm Shaft

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

0.035" - 130 cm Shaft

Diameter (mm)	Length (mm)	Sheath (F)	RBP (ATM)	Product Codes
4	20	5	14	☐ US3513042
	40	5	14	☐ US3513044
	80	5	14	☐ US3513048
	100	5	14	☐ US35130410
	120	5	14	☐ US35130412
	150	5	14	☐ US35130415
	200	5	14	☐ US35130420
	300	5	14	☐ US35130430
5	20	5	14	☐ US3513052
	40	5	14	☐ US3513054
5	80	5	14	☐ US3513058
	100	5	14	☐ US35130510
	120	5	14	☐ US35130512
	150	5	14	☐ US35130515
	200	6	14	☐ US35130520
	300	6	14	☐ US35130530
6	20	5	14	☐ US3513062
	40	5	14	☐ US3513064
	80	6	14	☐ US3513068
	100	6	14	☐ US35130610
	120	6	14	☐ US35130612
	150	6	14	☐ US35130615
	200	6	14	☐ US35130620
	300	6	14	☐ US35130630
7	20	6	10	☐ US3513072
	40	6	10	☐ US3513074
	80	6	10	☐ US3513078
	100	6	10	☐ US35130710
	120	6	10	☐ US35130712
	150	6	10	☐ US35130715
	200	6	10	☐ US35130720
	300	6	10	☐ US35130730
8	20	6	10	☐ US3513082
	40	6	10	☐ US3513084
	80	6	10	☐ US3513088
	100	6	10	☐ US35130810
	120	6	10	☐ US35130812
	150	6	10	☐ US35130815
	200	6	10	☐ US35130820

CONTINUED

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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has joined BD

BD Switzerland Sarl, Route de Crassier 17,
Business Park Terre-Bonne, Batiment A4 1262 Eysins Switzerland.
Tel: +41 21 556 30 00. Fax: +4144 722 5370