Conquest™ 40
PTA Dilatation Catheter

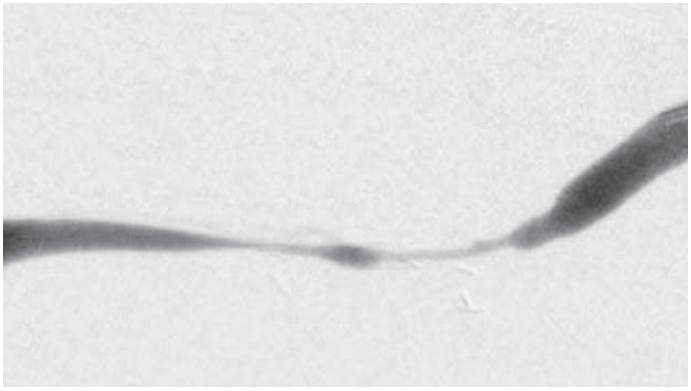
Strength That Explores New Atmospheres

BD

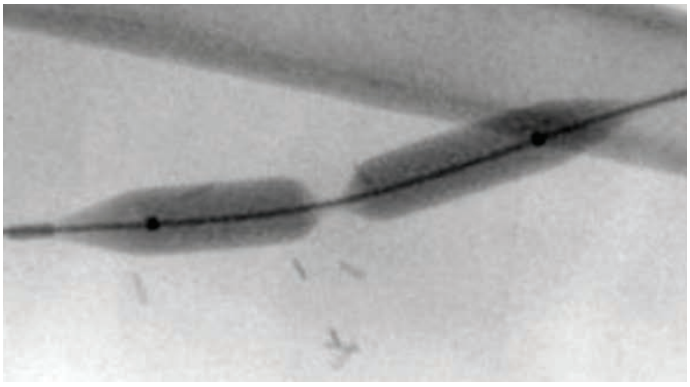
ENABLES A

Single-Balloon Strategy

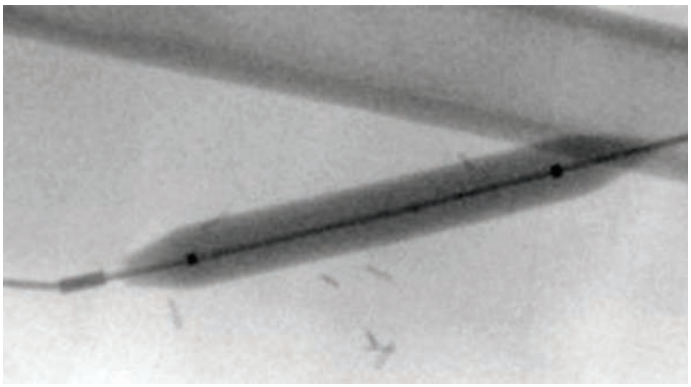
Literature Suggests That 99% of Stenoses in Hemodialysis Access can be Treated in the Range up to 40 ATM.†



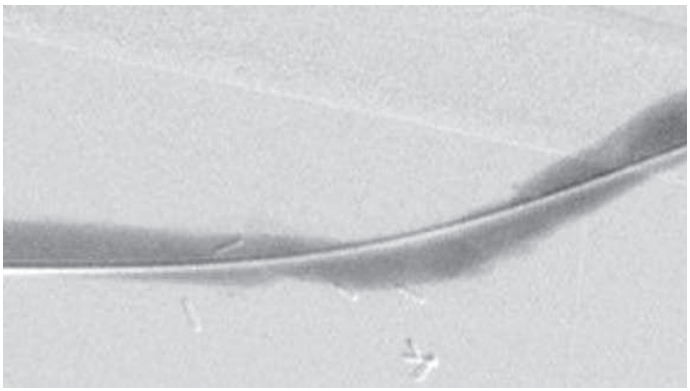
1 3cm long high-grade stenosis involving the upper basilic vein



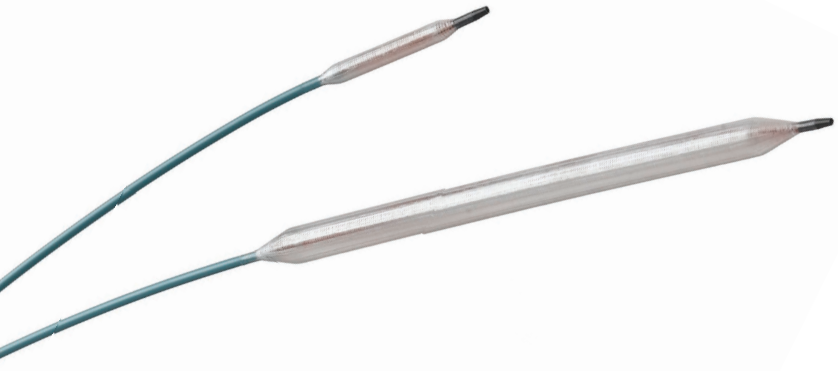
2 Unable to efface stenosis with standard, non-compliant balloon at 22 ATM



3 Ultra high pressure and ultra-non compliance were needed to efface lesion



4 Post angioplasty, the vessel is open and the patient can resume dialysis



Images courtesy of Thomas Vesely, MD.

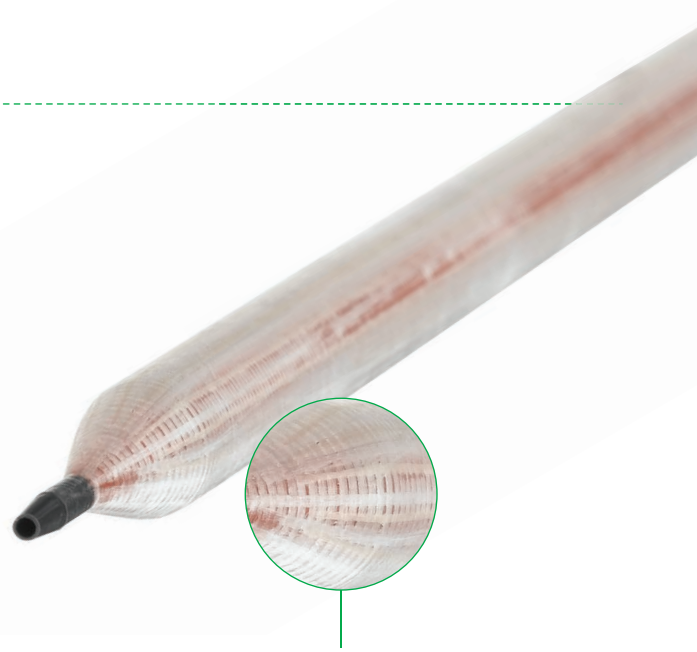
Results from this case may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.

† Foering K, Chittams JL, Trerotola SO, Percutaneous Transluminal Angioplasty Balloon Inflation with Syringes: Who Needs an Inflator? J Vasc Interv Radiol. 2009; 20:629-633
Trerotola SO, et. al. Prospective Study of Balloon Inflation Pressures and Other Technical Aspects of Hemodialysis Access Angioplasty. J Vasc Interv Radiol. 2005; 16:1613-1618

Incomparably

Ultra Non-compliant

- Delivers Maximum Dilatation Forces to Areas of Most Resistance
- True to Size from 8 ATM to 40 ATM - Allows Higher Pressures Without Vessel Overexpansion



Composite Balloon Material
with new stronger fiber design

	Ultra Non-Compliant Conquest™ 40	Non-Compliant Competitor
Diameter at Nominal	6.8 mm	6.5 mm
Diameter at Rated Burst	7.0 mm	7.2 mm
Compliance[‡]	2.2%	9.8%

[‡] Based on 7 mm x 4 cm balloons. p=.0012

DATA ON FILE. Bench testing using same test methods and sample sizes. Bench data may not be representative of clinical outcomes.

Advancements in Delivery

- New Tapered Tip
- New 4 mm Diameters and 10 cm Lengths
- Labeled for Syringe Inflation

Conquest™ 40
PTA Dilatation Catheter

Conquest™
PTA Dilatation Catheter

Ultra High Pressure PTA Dilatation Catheter - Ordering Information

.035" Guidewire Compatible						50 cm Shaft Lengths	75 cm Shaft Lengths
Diameter (mm)	Length (cm)	Syringe Inflation (cc)	RBP † (ATM)	Nominal Pressure* (ATM)	Sheath Size (F)	Product Code	
4	2	≥1	40	8	6	CQF5042	CQF7542
	4	≥1	40	8	6	CQF5044	CQF7544
	6	≥1	40	8	6	CQF5046	CQF7546
	8	≥1	40	8	6	CQF5048	CQF7548
	10	≥1	40	8	6	CQF50410	CQF75410
5	2	≥1	40	8	6	CQF5052	CQF7552
	4	≥1	40	8	6	CQF5054	CQF7554
	6	≥1	40	8	6	CQF5056	CQF7556
	8	≥1	40	8	6	CQF5058	CQF7558
	10	≥1	40	8	6	CQF50510	CQF75510
6	2	≥1	40	8	6	CQF5062	CQF7562
	4	≥1	40	8	6	CQF5064	CQF7564
	6	≥1	40	8	6	CQF5066	CQF7566
	8	≥1	40	8	6	CQF5068	CQF7568
	10	≥1	40	8	6	CQF50610	CQF75610
7	2	≥1	40	8	6	CQF5072	CQF7572
	4	≥1	40	8	6	CQF5074	CQF7574
	6	≥1	40	8	6	CQF5076	CQF7576
	8	≥1	40	8	6	CQF5078	CQF7578
	10	≥1	40	8	6	CQF50710	CQF75710
8	2	≥1	40	8	6	CQF5082	CQF7582
	4	≥1	40	8	6	CQF5084	CQF7584
	6	≥3	35	8	6	CQF5086	CQF7586
	8	≥3	35	8	6	CQF5088	CQF7588
	10	≥3	35	8	6	CQF50810	CQF75810
9	2	≥3	35	8	7	CQF5092	CQF7592
	4	≥3	35	8	7	CQF5094	CQF7594
	8	≥3	35	8	7	CQF5098	CQF7598
10	2	≥3	35	8	7		CQF75102
	4	≥3	35	8	7		CQF75104
	8	≥3	35	8	7		CQF75108
12	2	n/a	30	8	8		CQF75122
	4	n/a	30	8	8		CQF75124
Caliber™ Inflation Device REORDER CODE CL3030							

† 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.

* Nominal pressure: the pressure at which the balloon reaches its labeled diameter.
Please contact your local Bard Peripheral Vascular Sales Representative for availability of sizes.

Conquest™ 40 PTA Dilatation Catheter Instructions For Use

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. **Device Description:** The Conquest™ 40 PTA Dilatation Catheter is a high performance balloon catheter consisting of an over-the-wire catheter with a balloon fixed at the distal tip. The proprietary ultra non-compliant, low profile balloon is designed to provide consistent balloon diameters and lengths even at high pressures. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The coaxial catheter includes a tapered atraumatic tip to facilitate advancement of the catheter to and through the stenosis. The proximal portion of the catheter includes a female luer lock hub connected to the inflation lumen, and a female luer-lock hub connected to the guidewire lumen. The over-the-wire catheter is compatible with 0.035" guidewires and is available in 50cm and 75cm working lengths. Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use. A re-wrapping tool is also provided on the catheter shaft. A stylet is placed into the tip of the catheter to aid in balloon rewrap/refolding of the balloon. **This product is not manufactured with any latex. Indications for Use:** Conquest™ 40 PTA Dilatation Catheter is recommended for use in Percutaneous Transluminal Angioplasty of the femoral, iliac, 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 stents and stent grafts in the peripheral vasculature. This catheter isnot 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. Single patient use only. Do not reuse, reprocess or re-sterilize. 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 infectiouscomplications. 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.) To reduce the potential for stent or stent graft damage and/or vessel damage from the stent or stent graft, the diameter of the balloon should be no greater than the diameter of the stent or stent graft. Refer to the stent or stent graft IFU for safety information including the WARNINGS, PRECAUTIONS and potential ADVERSE EFFECTS regarding the use of balloon post-dilatation. 6.) 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 breakage or balloon separation. 7.) 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 or the use of indicated syringes. 8.) 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 Conquest™ 40 catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty. 3.) The minimal acceptable sheath French size is printed on the package label. Do not attempt to pass the PTA catheter through a smaller size sheath introducer than indicated on the label. 4.) Do not remove the guidewire in situ to shoot contrast through the wire lumen or perform a wire exchange. If the wire is removed while the balloon catheter is situated in tortuous anatomy, the risk of kinking the catheter is increased. 5.) Use the recommended balloon inflation medium (a range of 30-50% contrast medium/a range of 50-70% sterile saline solution). It has been shown that a 30/70% contrast / saline ratio has yielded faster balloon inflation/ deflation times. 6.) Never use air or other gaseous medium to inflate the balloon. 7.) If resistance is felt during post procedure withdrawal of the catheter through the introducer sheath, determine if contrast 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. 8.) 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. 9.) Do not continue to use the balloon catheter if the shaft has been bent or kinked. 10.) Prior to re-insertion through the introducer sheath, the balloon should be wiped clean with gauze, rinsed with sterile normal saline, and refolded with the balloon re-wrap tool. Balloon re-wrapping should only occur while the balloon catheter is supported with a guidewire or stylet. **Potential Adverse Reactions:** The complications which 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 • Thrombosis • Vessel dissection, perforation, rupture, or spasm **Warning:** 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 or indicated syringe is recommended. Please consult labels and IFU for indications, contraindications, hazards, warnings, cautions, and information for use.

바드코리아(주) 06236 서울시 강남구 테헤란로 142, 15층
T. 02-2188-2900 F. 02-539-3081

bd.com/ko-kr