DORADO®

PTA Dilatation Catheter

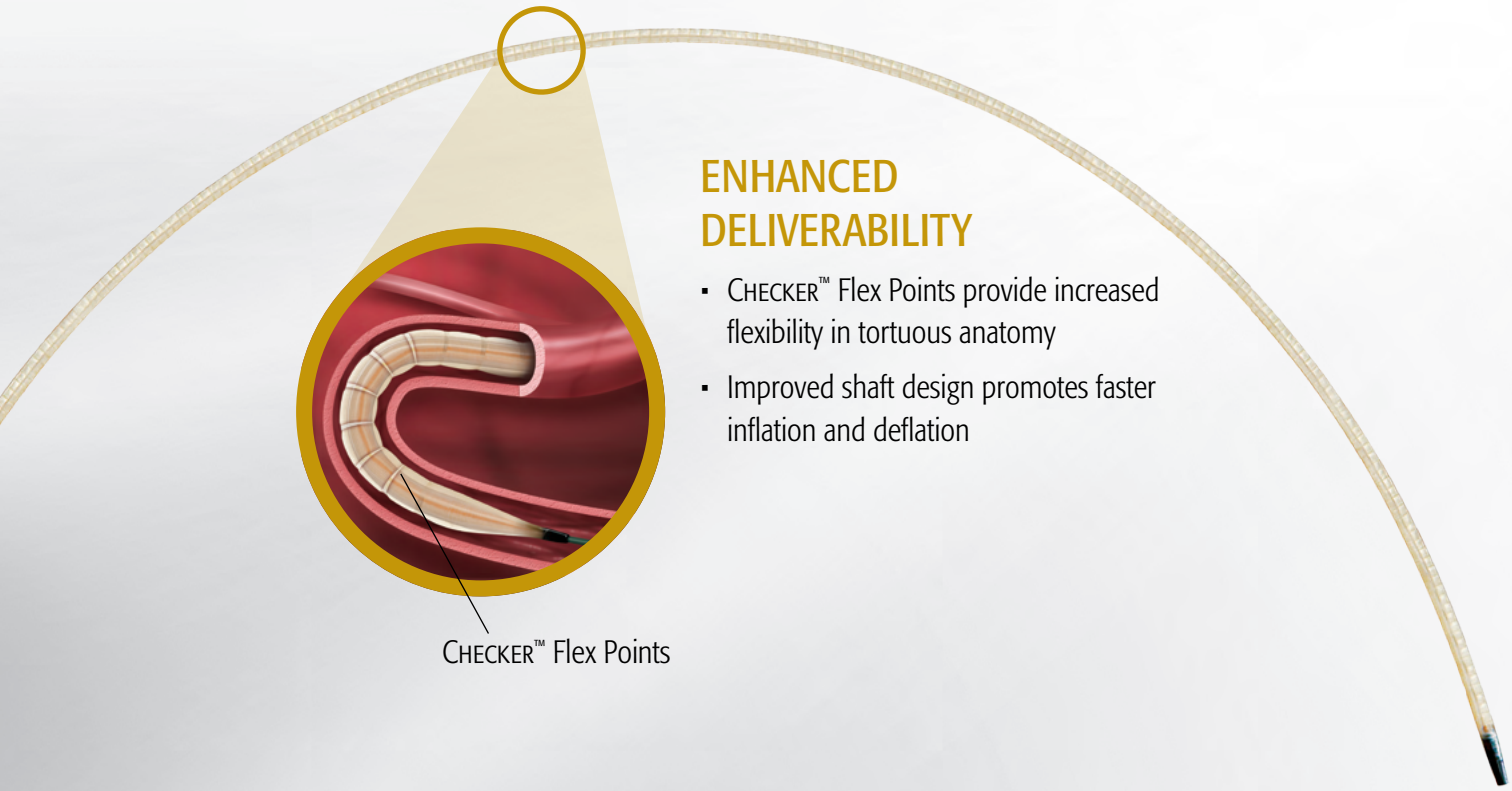
Resistance Is Futile

BARD | PERIPHERAL VASCULAR

DORADO®
PTA Dilatation Catheter

Confidence and precision for challenging cases

The DORADO® PTA Dilatation Catheter provides strength and versatility with enhanced deliverability, making this ultra non-compliant balloon the optimal choice for challenging lesions and in-stent restenosis.



ENHANCED DELIVERABILITY

- CHECKER™ Flex Points provide increased flexibility in tortuous anatomy
- Improved shaft design promotes faster inflation and deflation

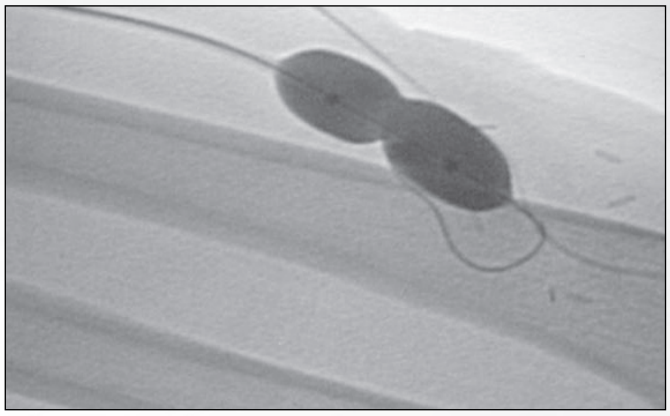
LONGER LENGTHS

For treatment of long stenosis or post-dilatation of long stents with fewer inflations.

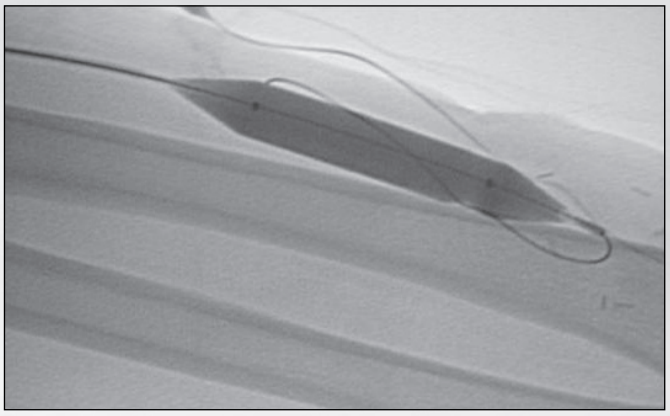
Balloon Lengths to 20 cm

ULTRA NON-COMPLIANCE

- Concentrates maximum dilatation force at the resistant lesion
- Allows for inflation without the risk of overexpansion
- Strong balloon material promotes consistent post-stent dilatation
- Provides treatment of in-stent restenosis

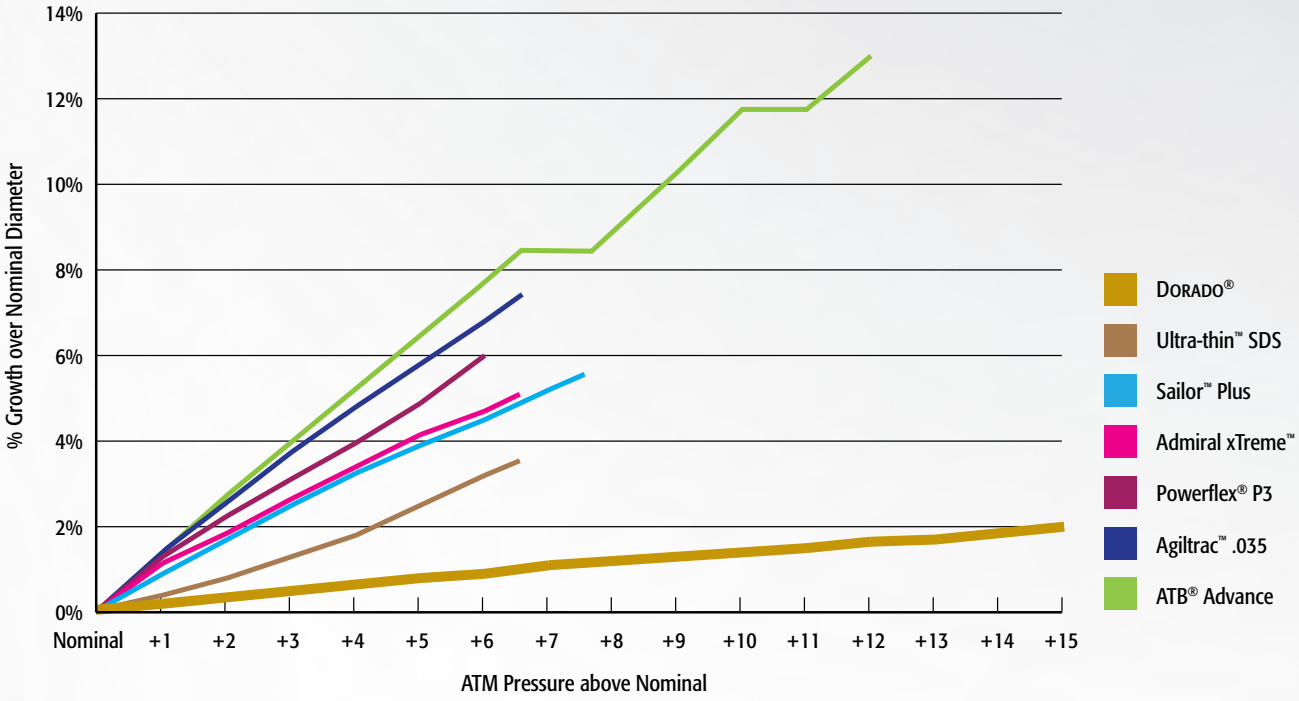


Semi-compliant balloon in a resistant stenosis.



BARD® ultra non-compliant balloon in a resistant stenosis.

Balloon Compliance Comparison*
(7 mm Balloons)



*Competitive compliance data taken from each manufacturer's product labeling.
DORADO® PTA Dilatation Catheter compliance data on file.

DORADO®

PTA Dilatation Catheter

Balloon Size		Catheter Shaft Length				Sheath Size (F)	Nominal Pressure* (ATM)	RBP** (ATM)
Diameter (mm)	Length (cm)	40 cm	80 cm	120 cm	135 cm			
3	2		DR8032		DR13532	5	8	24
3	4		DR8034		DR13534	5	8	24
3	10		DR80310		DR135310	5	8	24
4	2	DR4042	DR8042		DR13542	5	8	24
4	4	DR4044	DR8044	DR12044	DR13544	5	8	24
4	10		DR80410	DR120410	DR135410	5	8	24
4	12				DR135412	6	8	24
4	15				DR135415	6	8	24
4	17				DR135417	6	8	24
4	20				DR135420	6	8	24
5	2	DR4052	DR8052	DR12052	DR13552	5	8	24
5	4	DR4054	DR8054	DR12054	DR13554	5	8	24
5	6		DR8056		DR13556	5	8	24
5	8		DR8058		DR13558	5	8	24
5	10		DR80510	DR120510	DR135510	5	8	24
5	12				DR135512	6	8	24
5	15				DR135515	6	8	24
5	17				DR135517	6	8	24
5	20				DR135520	6	8	24
6	2	DR4062	DR8062	DR120062	DR135062	6	8	24
6	4	DR4064	DR8064	DR12064	DR13564	6	8	24
6	6		DR8066		DR13566	6	8	24
6	8		DR8068		DR13568	6	8	24
6	10		DR80610	DR120610	DR135610	6	8	22
6	12		DR80612		DR135612	6	8	22
6	15		DR80615		DR135615	6	8	22
6	17		DR80617		DR135617	6	8	22
6	20		DR80620		DR135620	6	8	22
7	2	DR4072	DR8072		DR13572	6	8	22
7	4	DR4074	DR8074	DR12074	DR13574	6	8	22
7	6		DR8076			6	8	22
7	8		DR8078			6	8	22
7	10		DR80710	DR120710	DR135710	6	8	22
7	12		DR80712		DR135712	6	8	22
7	15		DR80715		DR135715	6	8	22
7	17		DR80717		DR135717	6	8	22
7	20		DR80720		DR135720	6	8	22
8	2	DR4082	DR8082		DR13582	6	8	22
8	4	DR4084	DR8084	DR12084	DR13584	6	8	22
8	6		DR8086			6	8	22
8	8		DR8088			6	8	22
8	10		DR80810		DR135810	6	8	20
9	2		DR8092			6	8	20
9	4	DR4094	DR8094		DR13594	6	8	20
9	8		DR8098			6	8	20
10	2		DR80102		DR135102	6	8	20
10	4		DR80104	DR120104	DR135104	6	8	20
10	8		DR80108			7	8	20

*Nominal pressure: The pressure at which the balloon reaches its labeled diameter.

**RBP (Rated Burst Pressure): The pressure at which Bard has 95% confidence that 99.9% of the balloons will not burst upon single inflation.

DORADO® BALLOON DILATATION CATHETER

Indications for Use: Dorado® Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty (PTA) of the renal, iliac, femoral, popliteal, tibial, peroneal, and subclavian 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 and self expanding stents in the peripheral vasculature. This catheter is not 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 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, 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, 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. 6) Do not exceed the RBP recommended for this device. Balloon rupture may occur if the RBP rating is exceeded. To prevent overpressurization, 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 Dorado® 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. Never use air or other gaseous medium to inflate the balloon. 6) 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. 7) 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. 8) Do not continue to use the balloon catheter if the shaft has been bent or kinked. 9) 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 • Stroke • Thrombosis • Vessel dissection, perforation, rupture, or spasm.

AUSTRIA Bard Medica SA, Thaliastrasse 125A/1/5, 1160 Wien, Austria. Tel: +43 14 949130. Fax: +43 14 94913030.
BENELUX Bard Benelux n.v., Hagelberg 2, 2250 Olen, Belgium. Tel: +32 14 286950. Fax: +32 14 286955.
CZECH REPUBLIC Bard Czech Republic s.r.o., Taborska 619, 140 00 Prague, Czech Republic. Tel: +420 242 408620. Fax: +420 242 408621.
FRANCE Bard France SAS, Av. Joseph Kessel 164-166, Parkile P14, 78960 Voisins-le-Bretonneux, France. Tel: +33 1 39305858. Fax: +33 1 39305859.
GERMANY C. R. Bard GmbH, Wachhausstrasse 6, 76227 Karlsruhe, Germany. Tel: +49 721 94450. Fax: +49 721 9445111.
GREECE Bard Hellas SA, 22, Alkiviadou St & 72, Vouliagmenis Av, 16675 Glyfada, Greece. Tel: +30 210 9690770. Fax: +30 210 9628810.
ITALY Bard S.p.A., Via Cina 444, 00144 Roma, Italy. Tel: +39 06 524931. Fax: +39 06 5295852.
NORDIC Bard Norden AB, Karbingatan 22, 254 67 Helsingborg, Sweden. Tel: +46 42 386000. Fax: +46 42 386010.
POLAND Bard Poland sp. z o.o., ul. Cybernetyki 7b, 02-677 Warszawa, Poland, Tel: +48 22 3210930, Fax: +48 22 3210938
PORTUGAL C. R. Bard Portugal, LDA, Rua Castilho 13D-2A, 1250-066 Lisboa, Portugal. Tel: +351 21 3190330. Fax: +351 21 3190339.
SPAIN Bard de Espana S.A., Avda. Diagonal 652-656, Edificio A, 4a planta, 08034 Barcelona, Spain. Tel: +34 93 2537800. Fax: +34 93 2537834.
SWITZERLAND Bard Medica SA, Seestrasse 64, 8942 Oberrieden/Zürich, Switzerland. Tel: +41 44 7225360. Fax: +41 44 7225370.
UK Bard Limited, Forest House, Tilgate Forest Business Park, Brighton Road, Crawley, West Sussex RH11 9BP, UK. Tel: +44 1293 527888. Fax: +44 1293 552428.

CE 0086

BARD | PERIPHERAL VASCULAR