



# PTA Dilatation Catheter

## RIVAL® PTA Dilatation Catheter

Catheter Shaft Length		Balloon Size		Sheath Size (F)	Nominal Pressure* (ATM)	RBP** (ATM)
80 cm	135 cm	Diameter (mm)	Length (cm)			
RV8032	RV13532	3	2	5	8	16
RV8034	RV13534	3	4	5	8	16
RV80310	RV135310	3	10	5	8	16
RV8042	RV13542	4	2	5	8	14
RV8044	RV13544	4	4	5	8	14
RV80410	RV135410	4	10	5	8	12
RV80415	RV135415	4	15	5	8	12
RV8052	RV13552	5	2	5	8	14
RV8054	RV13554	5	4	5	8	14
RV8056	RV13556	5	6	5	8	14
RV8058	RV13558	5	8	5	8	14
RV80510	RV135510	5	10	5	8	12
RV80515	RV135515	5	15	5	8	12
RV8062	RV13562	6	2	5	8	14
RV8064	RV13564	6	4	5	8	14
RV8066	RV13566	6	6	5	8	14
RV8068	RV13568	6	8	5	8	14
RV80610	RV135610	6	10	5	8	12
RV80615	RV135615	6	15	6	8	12
RV8072	RV13572	7	2	6	8	14
RV8074	RV13574	7	4	6	8	14
RV8076	RV13576	7	6	6	8	14
RV8078	RV13578	7	8	6	8	14
RV8082	RV13582	8	2	6	6	14
RV8084	RV13584	8	4	6	6	14
RV8086	RV13586	8	6	6	6	14
RV8088	RV13588	8	8	6	6	14
RV8092	RV13592	9	2	6	6	12
RV8094	RV13594	9	4	6	6	12
RV80102	RV135102	10	2	7	6	10
RV80104	RV135104	10	4	7	6	10

REPRESENTATIVE NAME
CONTACT PHONE NO.

PHYSICIAN'S SIGNATURE
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\* 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.

### RIVAL® PTA Balloon Dilatation Catheter

**Indications for Use:** The RIVAL® PTA Balloon Dilatation Catheter is intended to dilate stenosis in the peripheral arteries, treat obstructive lesion of native or synthetic A-V fistulae, and/or re-expand endoluminal stent graft elements in the iliac 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. 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 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 that 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 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 RIVAL® PTA Balloon Dilatation 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)** Use the recommended balloon inflation medium (30-50% contrast medium/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. **5)** 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. **6)** If resistance is felt during post-procedure withdrawal of the catheter, it is recommended to remove the balloon catheter, introducer sheath and guidewire (as necessary) as a single unit. **7)** Do not continue to use the balloon catheter if the shaft has been bent or kinked. **8)** 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 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.

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.

**Please consult product labels and package inserts for indications, contraindications, hazards, warnings, cautions and instructions for use.**

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S11705 Rev 3



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# RIVAL<sup>®</sup>

## PTA Dilatation Catheter



First-line PTA Balloon with  
Unmatched Trackability



## Superior Trackability for Everyday and Challenging Cases

The RIVAL® PTA Dilatation Catheter's performance, size offering and value make it the optimal standard .035" balloon choice.

# dependable

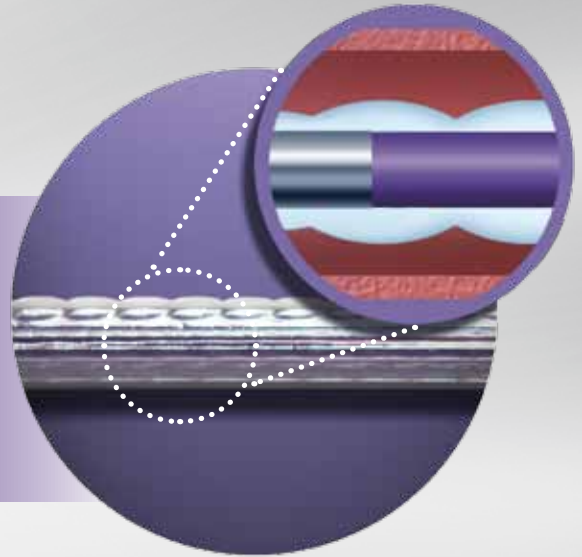
## FIRST-LINE PTA BALLOON

- Provides dilation of obstructive lesions of native or synthetic fistulae
- Wide range of lengths for treatment of long, diffuse lesions
- Dual-lumen catheter decreases inflation and deflation times for procedural efficiency



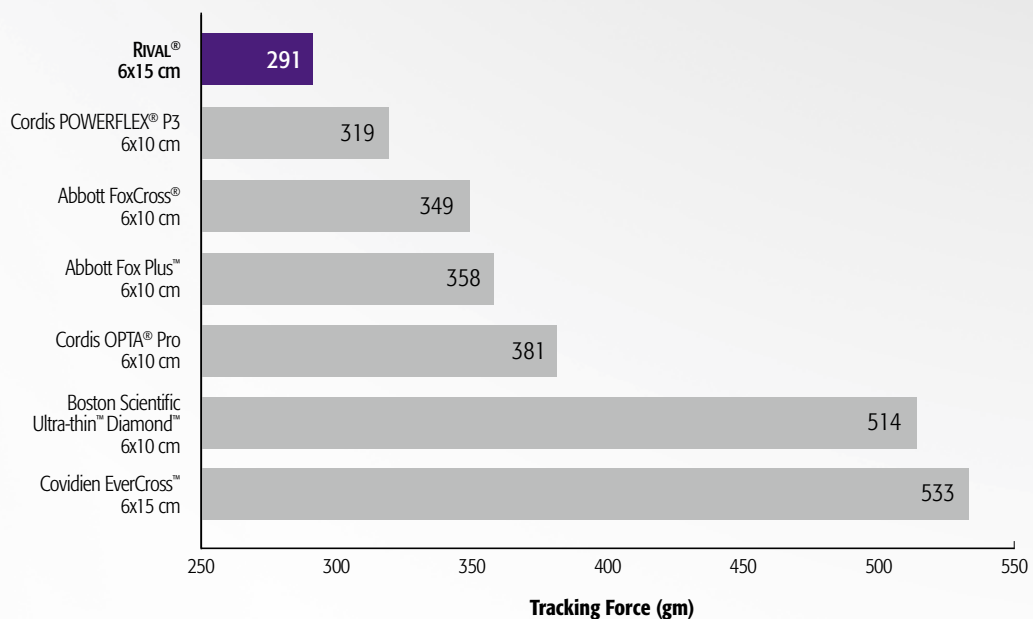
# unmatched TRACKABILITY

- **CHECKER™ Flex Points** increase balloon flexibility for enhanced trackability
- **Tapered, low-profile tip** creates reduced profile design and promotes improved deliverability



# effortless DELIVERY THROUGH TORTUOUS ANATOMY

Force Required to Track: RIVAL<sup>®</sup> PTA Dilatation Catheter vs. Competitors<sup>1</sup>



Tracking Force is the peak force required to track through an anatomical model.

1. Data on file.