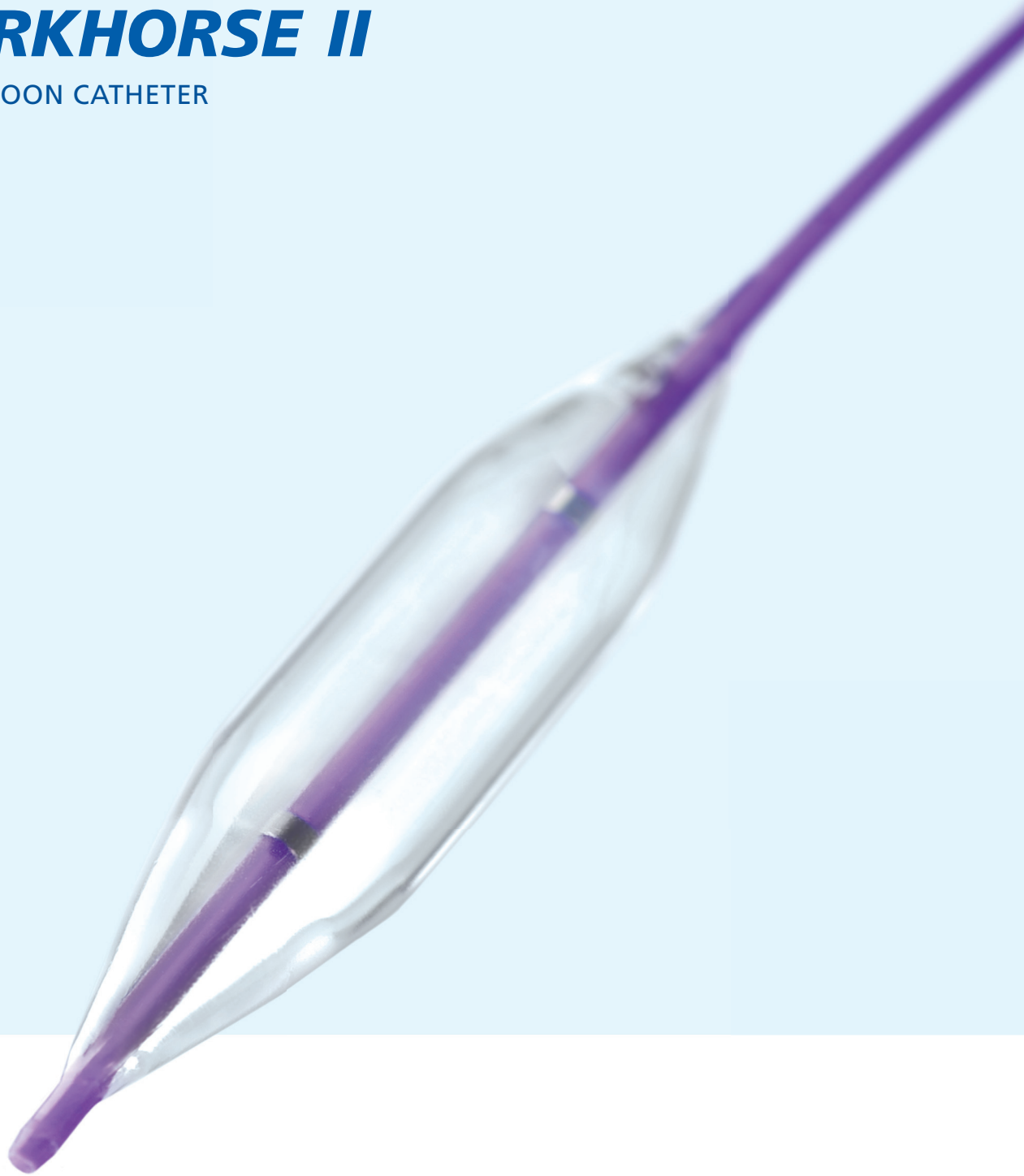


WORKHORSE II

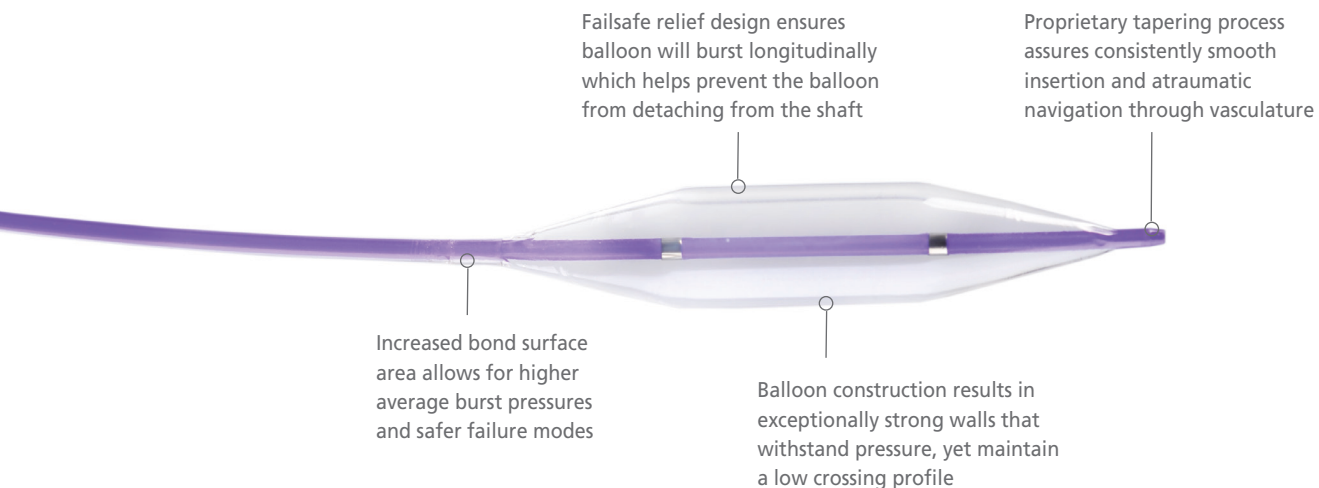
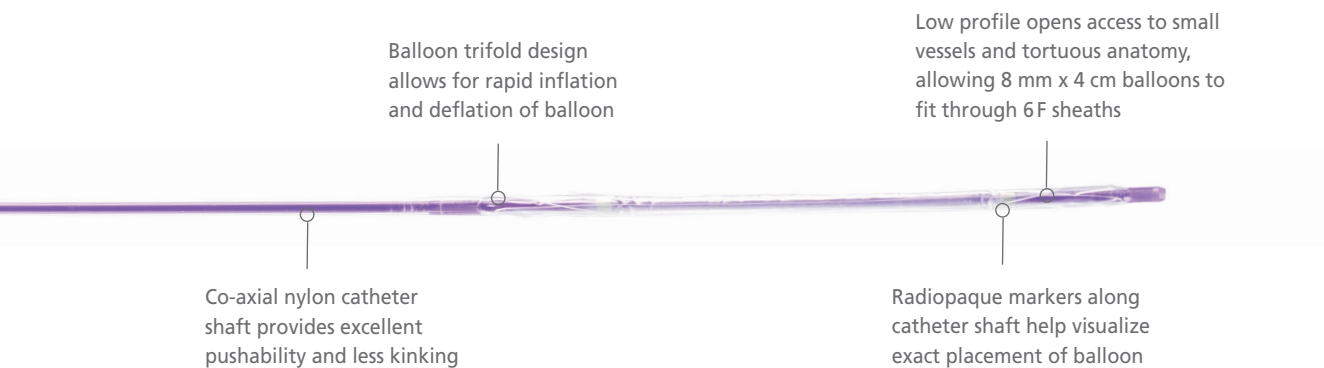
PTA BALLOON CATHETER



WORKHORSE II

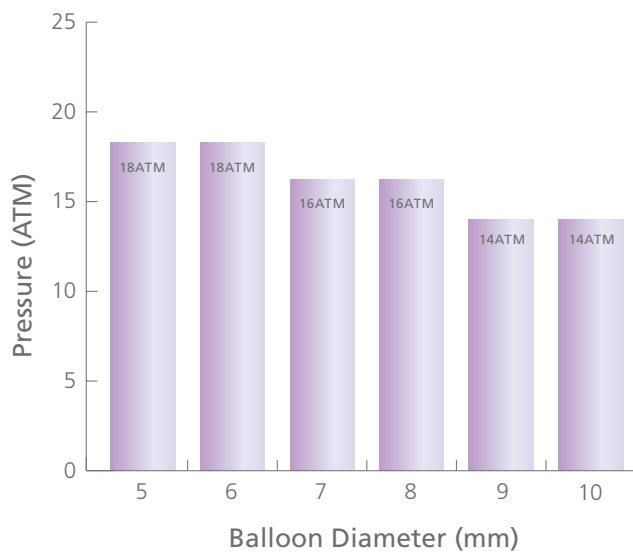
PTA BALLOON CATHETER

The WorkHorse II PTA balloon catheter is a durable, reliable balloon that is ideal for the majority of procedures. It is a cost-effective balloon that can withstand repeated usage during a procedure to deliver the desired results.



Rated Burst Pressure

for WorkHorse II Balloons



SPECIFICATIONS

- Design Description: Non-compliant, low profile, high pressure balloon
- Balloon Construction: Proprietary polymer blend that is smooth and scratch resistant
- Balloon Outer Diameters: 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm
- Balloon Lengths: 2 cm, 4 cm, 6 cm
- Shaft Lengths: 50 cm, 75 cm, 100 cm
- Recommended Sheath Sizes:
 - 5 mm–8 mm: 6F Sheath
 - 9 mm–10 mm: 7F Sheath
- Rated Burst Pressure:
 - 5 mm–6 mm: 18 atm
 - 7 mm–8 mm: 16 atm
 - 9 mm–10 mm: 14 atm

IMPORTANT RISK INFORMATION

INDICATION FOR USE: The WorkHorse II catheter is a coaxial designed catheter with a balloon mounted on its distal tip and is indicated for general Percutaneous Transluminal Angioplasty (PTA) of the iliac, femoral, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. These catheters are not designed for use in coronary arteries. **CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNINGS AND PRECAUTIONS: Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the device and/or lead to device failure. Contents sterile in unopened, undamaged package. Sterilized by ethylene oxide. **Caution:** Do not exceed the rated burst pressure, which

could cause balloon rupture and potential inability to withdraw the catheter through the introducer sheath. A syringe with pressure gauge is recommended to monitor pressure. In PTA, the dilated balloon should not markedly exceed the diameter of the vessel lying just proximal to the stenosis. Do not use air or any gaseous substance as a balloon inflation medium in PTA. Do not advance the guidewire, balloon dilation catheter, or any other component if resistance is met, without first determining the cause and taking remedial action. This catheter is not recommended for pressure measurement or fluid injection. This catheter is not intended for the expansion or delivery of stents. Please see package insert for complete list of warnings and precautions. Observe all instructions prior to use.

POTENTIAL COMPLICATIONS: Procedure-related complications may include, but are not limited to

vascular thrombosis; vessel spasm or perforation/dissection; hematoma or hemorrhage; hypotension; drug reactions or allergic reaction to contrast medium; pyrogenic reaction; pain and tenderness; arrhythmias; sepsis/infection; systemic embolization; endocarditis; short-term hemodynamic deterioration; death; arteriovenous fistula; and thromboembolic episodes. Potential balloon separation following rupture or abuse and the subsequent need to use a snare or other medical interventional techniques to retrieve the pieces. Note: There have been infrequent reports of larger diameter balloons bursting circumferentially, possibly due to combination of tight focal strictures in large vessels.

Indications, contraindications, warnings and instructions for use can be found in the instructions for use supplied with each device. Observe all instructions prior to use. Failure to do so may result in patient complications.

WORKHORSE PTA BALLOON CATHETER

Part #	Balloon Outer Diameter	Balloon Length	Catheter Length	Recommended Sheath Size	Rated Burst Pressure
16500401	5 mm	2 cm	50 cm	6F	18 atm
16500402	6 mm	2 cm	50 cm	6F	18 atm
16500403	7 mm	2 cm	50 cm	6F	16 atm
16500404	8 mm	2 cm	50 cm	6F	16 atm
16500437	9 mm	2 cm	50 cm	7F	14 atm
16500438	10 mm	2 cm	50 cm	7F	14 atm
16500405	5 mm	4 cm	50 cm	6F	18 atm
16500406	6 mm	4 cm	50 cm	6F	18 atm
16500407	7 mm	4 cm	50 cm	6F	16 atm
16500408	8 mm	4 cm	50 cm	6F	16 atm
16500443	9 mm	4 cm	50 cm	7F	14 atm
16500444	10 mm	4 cm	50 cm	7F	14 atm
16500425	5 mm	6 cm	50 cm	6F	18 atm
16500426	6 mm	6 cm	50 cm	6F	18 atm
16500427	7 mm	6 cm	50 cm	6F	16 atm
16500428	8 mm	6 cm	50 cm	6F	16 atm
16500449	9 mm	6 cm	50 cm	7F	14 atm
16500450	10 mm	6 cm	50 cm	7F	14 atm
16500409	5 mm	2 cm	75 cm	6F	18 atm
16500410	6 mm	2 cm	75 cm	6F	18 atm
16500411	7 mm	2 cm	75 cm	6F	16 atm
16500412	8 mm	2 cm	75 cm	6F	16 atm
16500439	9 mm	2 cm	75 cm	7F	14 atm
16500440	10 mm	2 cm	75 cm	7F	14 atm
16500413	5 mm	4 cm	75 cm	6F	18 atm
16500414	6 mm	4 cm	75 cm	6F	18 atm
16500415	7 mm	4 cm	75 cm	6F	16 atm

Part #	Balloon Outer Diameter	Balloon Length	Catheter Length	Recommended Sheath Size	Rated Burst Pressure
16500416	8 mm	4 cm	75 cm	6F	16 atm
16500445	9 mm	4 cm	75 cm	7F	14 atm
16500446	10 mm	4 cm	75 cm	7F	14 atm
16500429	5 mm	6 cm	75 cm	6F	18 atm
16500430	6 mm	6 cm	75 cm	6F	18 atm
16500431	7 mm	6 cm	75 cm	6F	16 atm
16500432	8 mm	6 cm	75 cm	6F	16 atm
16500451	9 mm	6 cm	75 cm	7F	14 atm
16500452	10 mm	6 cm	75 cm	7F	14 atm
16500417	5 mm	2 cm	100 cm	6F	18 atm
16500418	6 mm	2 cm	100 cm	6F	18 atm
16500420	8 mm	2 cm	100 cm	6F	16 atm
16500441	9 mm	2 cm	100 cm	7F	14 atm
16500442	10 mm	2 cm	100 cm	7F	14 atm
16500421	5 mm	4 cm	100 cm	6F	18 atm
16500422	6 mm	4 cm	100 cm	6F	18 atm
16500423	7 mm	4 cm	100 cm	6F	16 atm
16500424	8 mm	4 cm	100 cm	6F	16 atm
16500447	9 mm	4 cm	100 cm	7F	14 atm
16500448	10 mm	4 cm	100 cm	7F	14 atm
16500433	5 mm	6 cm	100 cm	6F	18 atm
16500434	6 mm	6 cm	100 cm	6F	18 atm
16500435	7 mm	6 cm	100 cm	6F	16 atm
16500436	8 mm	6 cm	100 cm	6F	16 atm
16500453	9 mm	6 cm	100 cm	7F	14 atm
16500454	10 mm	6 cm	100 cm	7F	14 atm



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