

PROFILER[®]

Balloon Dilatation Catheter

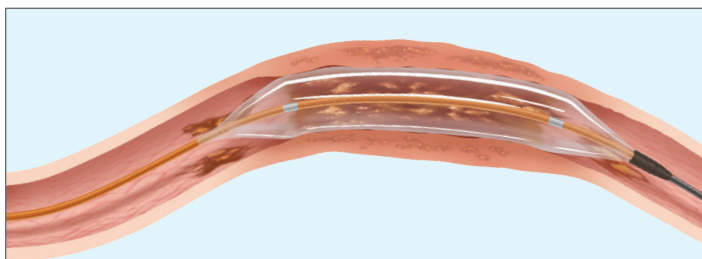
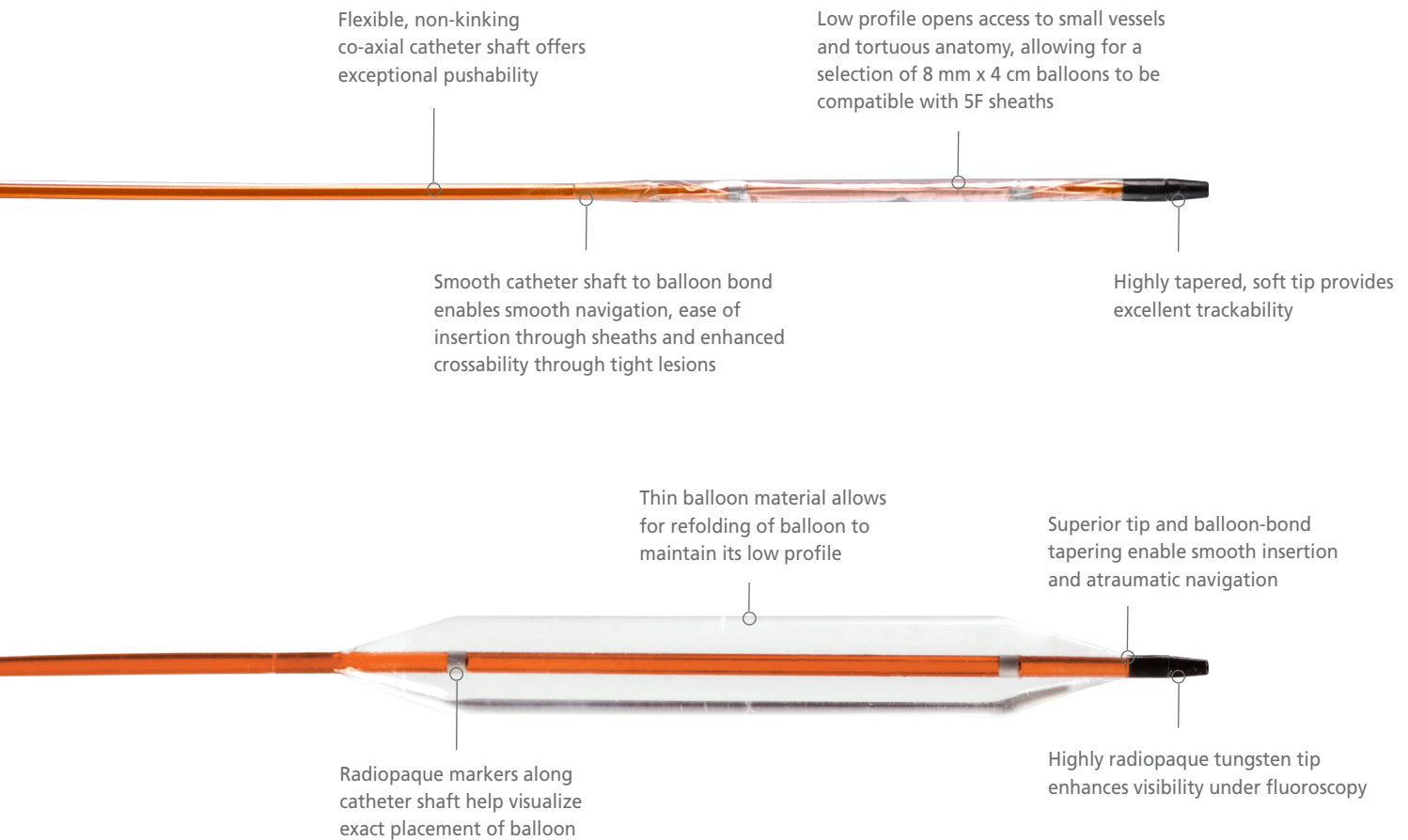


ANGIODYNAMICS[®]

PROFILER[®]

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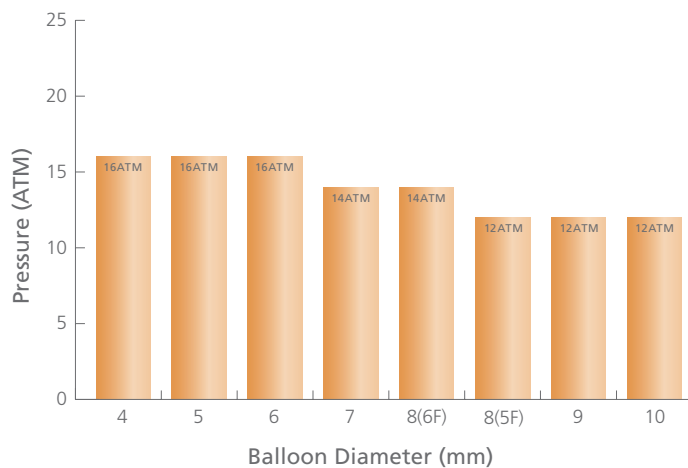
The low-profile design of the Profiler[®] balloon supports the most demanding angioplasty needs. Its agility, visibility and versatility help ensure it gets to where it needs to be every time.



The low-profile of the Profiler balloon catheter allows access to small vessels and tortuous anatomy while the highly tapered tip ensures consistent and smooth navigation through the vasculature and lesions.

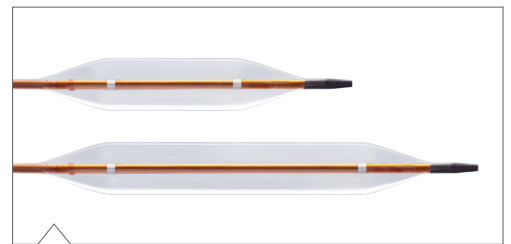
Rated Burst Pressure

for Profiler Balloons



SPECIFICATIONS

- Balloon Material: Non-compliant PET
- Balloon Construction: Proprietary polymer blend that is smooth and scratch resistant
- Balloon Outer Diameters: 4 mm–10 mm
- Balloon Lengths: 2 cm, 4 cm, 6 cm, 8 cm
- Shaft Lengths: 40 cm, 75 cm, 120 cm
- Recommended Sheath Sizes: 5F, 6F
- Rated Burst Pressure:
 - 4–6 mm: 16 atm
 - 7 mm and 8 mm x 2 cm, 8 mm x 4 cm: 14 atm
 - 8–10 mm: 12 atm



Balloons also available in 8 mm x 2 cm and 8 mm x 4 cm at a higher rated burst pressure through a 6F sheath.

IMPORTANT RISK INFORMATION

INDICATION FOR USE: The PROFILER® 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: Exceeding the rated burst pressure can 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.

PROFILER® BALLOON DILATATION CATHETER

Part #	Balloon Outer Diameter	Balloon Length	Catheter Length	Recommended Sheath Size	Rated Burst Pressure
16801101	4 mm	2 cm	40 cm	5F	16 atm
16801102	4 mm	4 cm	40 cm	5F	16 atm
16801103	4 mm	6 cm	40 cm	5F	16 atm
16801104	5 mm	2 cm	40 cm	5F	16 atm
16801105	5 mm	4 cm	40 cm	5F	16 atm
16801106	5 mm	6 cm	40 cm	5F	16 atm
16801107	6 mm	2 cm	40 cm	5F	16 atm
16801108	6 mm	4 cm	40 cm	5F	16 atm
16801109	6 mm	6 cm	40 cm	5F	16 atm
16801110	7 mm	2 cm	40 cm	5F	14 atm
16801111	7 mm	4 cm	40 cm	5F	14 atm
16801112	7 mm	6 cm	40 cm	5F	14 atm
16801113	8 mm	2 cm	40 cm	5F	12 atm
16801114	8 mm	4 cm	40 cm	5F	12 atm
16801166	8 mm	2 cm	40 cm	6F	14 atm
16801167	8 mm	4 cm	40 cm	6F	14 atm
16801115	8 mm	6 cm	40 cm	6F	12 atm
16801116	9 mm	2 cm	40 cm	6F	12 atm
16801117	9 mm	4 cm	40 cm	6F	12 atm
16801118	9 mm	6 cm	40 cm	6F	12 atm
16801119	10 mm	2 cm	40 cm	6F	12 atm
16801120	10 mm	4 cm	40 cm	6F	12 atm
16801121	10 mm	6 cm	40 cm	6F	12 atm
16801122	4 mm	2 cm	75 cm	5F	16 atm
16801123	4 mm	4 cm	75 cm	5F	16 atm
16801124	4 mm	6 cm	75 cm	5F	16 atm
16801125	5 mm	2 cm	75 cm	5F	16 atm
16801126	5 mm	4 cm	75 cm	5F	16 atm
16801127	5 mm	6 cm	75 cm	5F	16 atm
16801128	6 mm	2 cm	75 cm	5F	16 atm
16801129	6 mm	4 cm	75 cm	5F	16 atm
16801130	6 mm	6 cm	75 cm	5F	16 atm
16801131	7 mm	2 cm	75 cm	5F	14 atm
16801132	7 mm	4 cm	75 cm	5F	14 atm
16801133	7 mm	6 cm	75 cm	5F	14 atm

Part #	Balloon Outer Diameter	Balloon Length	Catheter Length	Recommended Sheath Size	Rated Burst Pressure
16801134	8 mm	2 cm	75 cm	5F	12 atm
16801135	8 mm	4 cm	75 cm	5F	12 atm
16801168	8 mm	2 cm	75 cm	6F	14 atm
16801169	8 mm	4 cm	75 cm	6F	14 atm
16801136	8 mm	6 cm	75 cm	6F	12 atm
16801137	8 mm	8 cm	75 cm	6F	12 atm
16801138	9 mm	2 cm	75 cm	6F	12 atm
16801139	9 mm	4 cm	75 cm	6F	12 atm
16801140	9 mm	6 cm	75 cm	6F	12 atm
16801141	10 mm	2 cm	75 cm	6F	12 atm
16801142	10 mm	4 cm	75 cm	6F	12 atm
16801143	10 mm	6 cm	75 cm	6F	12 atm
16801144	4 mm	2 cm	120 cm	5F	16 atm
16801145	4 mm	4 cm	120 cm	5F	16 atm
16801146	4 mm	6 cm	120 cm	5F	16 atm
16801147	5 mm	2 cm	120 cm	5F	16 atm
16801148	5 mm	4 cm	120 cm	5F	16 atm
16801149	5 mm	6 cm	120 cm	5F	16 atm
16801150	6 mm	2 cm	120 cm	5F	16 atm
16801151	6 mm	4 cm	120 cm	5F	16 atm
16801152	6 mm	6 cm	120 cm	5F	16 atm
16801153	7 mm	2 cm	120 cm	5F	14 atm
16801154	7 mm	4 cm	120 cm	5F	14 atm
16801155	7 mm	6 cm	120 cm	5F	14 atm
16801156	8 mm	2 cm	120 cm	5F	12 atm
16801157	8 mm	4 cm	120 cm	5F	12 atm
16801170	8 mm	2 cm	120 cm	6F	14 atm
16801171	8 mm	4 cm	120 cm	6F	14 atm
16801158	8 mm	6 cm	120 cm	6F	12 atm
16801159	8 mm	8 cm	120 cm	6F	12 atm
16801160	9 mm	2 cm	120 cm	6F	12 atm
16801161	9 mm	4 cm	120 cm	6F	12 atm
16801162	9 mm	6 cm	120 cm	6F	12 atm
16801163	10 mm	2 cm	120 cm	6F	12 atm
16801164	10 mm	4 cm	120 cm	6F	12 atm
16801165	10 mm	6 cm	120 cm	6F	12 atm

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