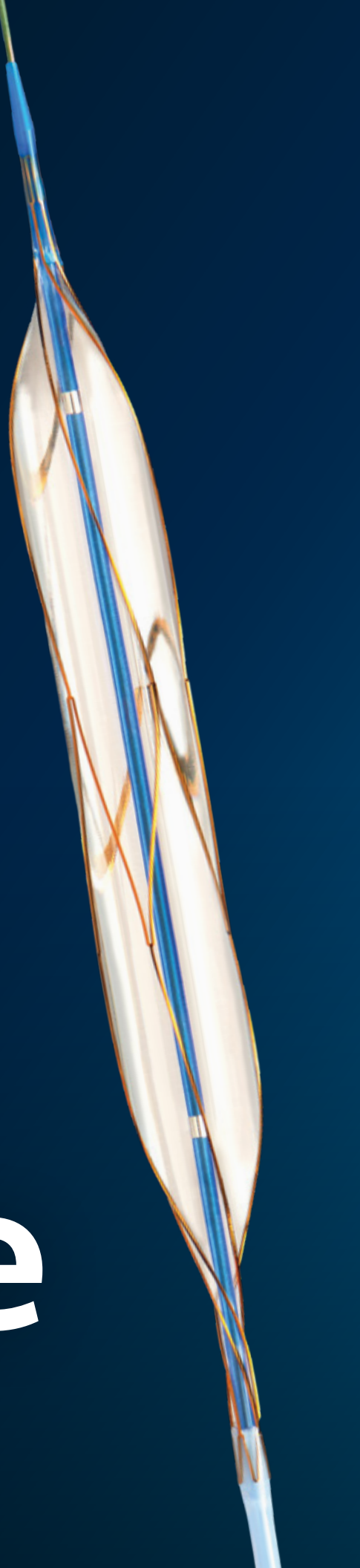
PHILIPS

AngioSculpt

PTA scoring
balloon catheter

7 and 8 mm diameters



Power
to score

AngioSculpt PTA scoring balloon catheter

Patients with hemodialysis access represent unique challenges:

Resistant stenoses
Lesions resistant to PTA are common and as many as 20% may require a high pressure dilatation (>20 atm)[1]

Recoil
Recoil and neointimal proliferation frequently lead to recurrent access dysfunction within several months of the angioplasty procedure[2]

Recurrent stenoses
~50% of all patients who undergo PTA will return with recurrent stenoses within 6 months[3,4]

The power to score with AngioSculpt scoring balloon catheter

More power
Dilate resistant lesions with 15-25 times the force of a conventional balloon[5]

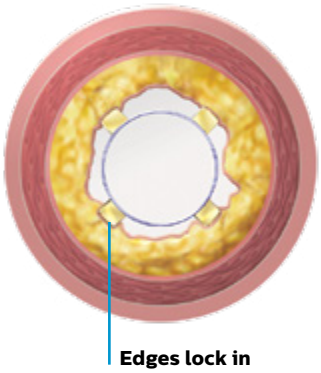
with less pressure
Effective dilatation at lower inflation pressures may reduce potential damage to vessel walls that trigger the cascade that can cause restenosis[5]

and minimal balloon slippage
In studies, AngioSculpt consistently exhibited no significant slippage, confirming that AngioSculpt's one-of-a-kind design improves performance[6]

Score with AngioSculpt

AngioSculpt's smart scoring balloon technology delivers a unique blend of controlled, effective dilatation and predictable device safety. A combination that can win in the most challenging cases.

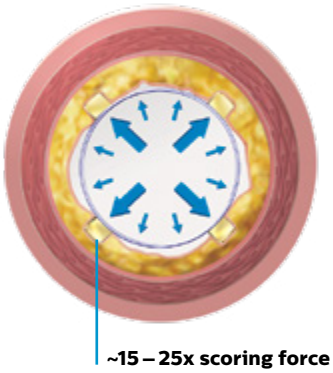
Precision



Minimal slippage

- Rectangular scoring edges lock the device in place
- No significant device slippage or "watermelon seeding" means less risk of damage to healthy tissue[6,7]

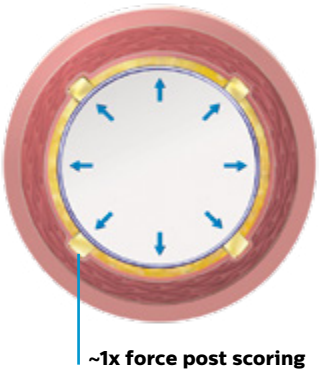
Power



More dilatation force

- The leading edges are designed to drive outward expansion with up to ~15-25 times the force of a conventional balloon[5]
- AngioSculpt's helical nitinol element creates a uniform initial luminal enlargement[8]

Safety



Low dissection rate

- Post scoring, outward forces are designed to be equivalent to that of a conventional balloon
- Low dissection rate and minimal perforations[6,7]
- Low rate of adjunctive stenting[6,7]

Ordering Information

Model number	Balloon diameter	Balloon length	Catheter length	Guidewire compatibility	Sheath size
2039-2010	2 mm	10 mm	137 cm	0.014″	5F
2039-2020	2 mm	20 mm	137 cm	0.014″	5F
2155-2040	2 mm	40 mm	155 cm	0.014″	5F
2216-20100	2 mm	100 mm	155 cm	0.014″	6F
2039-2520	2.5 mm	20 mm	137 cm	0.014″	5F
2155-2540	2.5 mm	40 mm	155 cm	0.014″	5F
2216-25100	2.5 mm	100 mm	155 cm	0.014″	6F
2039-3020	3 mm	20 mm	137 cm	0.014″	5F
2155-3040	3 mm	40 mm	155 cm	0.014″	5F
2216-30100	3 mm	100 mm	155 cm	0.014″	5F
2039-3520	3.5 mm	20 mm	137 cm	0.014″	5F
2155-3540	3.5 mm	40 mm	155 cm	0.014″	5F
2216-35100	3.5 mm	100 mm	155 cm	0.014″	6F
2076-4020	4 mm	20 mm	137 cm	0.018″	6F
2092-4040	4 mm	40 mm	90 cm	0.018″	6F
2076-4040	4 mm	40 mm	137 cm	0.018″	6F
2290-40100	4 mm	100 mm	90 cm	0.014″	6F
2237-40100	4 mm	100 mm	137 cm	0.014″	6F
2249-40200	4 mm	200 mm	137 cm	0.014″	6F
2076-5020	5 mm	20 mm	137 cm	0.018″	6F
2092-5040	5 mm	40 mm	90 cm	0.018″	6F
2076-5040	5 mm	40 mm	137 cm	0.018″	6F
2290-50100	5 mm	100 mm	90 cm	0.014″	6F
2237-50100	5 mm	100 mm	137 cm	0.014″	6F
2249-50200	5 mm	200 mm	137 cm	0.014″	6F
2105-6020	6 mm	20 mm	50 cm	0.018″	6F
2092-6020	6 mm	20 mm	90 cm	0.018″	6F
2076-6020	6 mm	20 mm	137 cm	0.018″	6F
2105-6040	6 mm	40 mm	50 cm	0.018″	6F
2092-6040	6 mm	40 mm	90 cm	0.018″	6F
2076-6040	6 mm	40 mm	137 cm	0.018″	6F
2290-60100	6 mm	100 mm	90 cm	0.014″	6F
2237-60100	6 mm	100 mm	137 cm	0.014″	6F
2249-60200	6 mm	200 mm	137 cm	0.014″	6F
2332-7040	7 mm	40 mm	50 cm	0.018″	6F
2333-7040	7 mm	40 mm	90 cm	0.018″	6F
2334-7040	7 mm	40 mm	137 cm	0.018″	6F
2332-8040	8 mm	40 mm	50 cm	0.018″	6F
2333-8040	8 mm	40 mm	90 cm	0.018″	6F
2334-8040	8 mm	40 mm	137 cm	0.018″	6F

Summary of safety and effectiveness — PTA Catheter

Caution

Federal (USA) Law restricts this device to sale by or on the order of a physician.

Indications

The AngioSculpt PTA scoring balloon catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature.

Contraindications

None known for percutaneous transluminal angioplasty (PTA) procedures.

Warnings

This device is intended for single (one) patient use only. Do not resterilize and/or reuse, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination. The inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis, in order to reduce potential vessel damage. 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 under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding. Balloon pressure should not exceed the rated burst pressure (RBP). Refer to product label for device-specific information. The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence level) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon. Proceed cautiously when using the AngioSculpt catheter in a freshly deployed bare metal or drug-eluting stent. The AngioSculpt catheter has not been tested for post-dilation of stents or in lesions distal to freshly deployed stents in clinical studies. Bench testing has shown no additional risk when inserting or withdrawing the AngioSculpt catheter through stents (no interference with stent struts, no retention of or damage to the AngioSculpt catheter). Use the catheter prior to the “Use Before” (expiration) date specified on the package.

Precautions

A thorough understanding of the principles, clinical applications and risks associated with PTA is necessary before using this product. Any use for procedures other than those indicated in these instructions is not recommended. The device is not recommended for use in lesions that may require inflation pressures higher than those recommended for this catheter. Do not use if package is opened or damaged. Prior to angioplasty, the catheter should be examined to verify functionality, device integrity and to ensure that its size and length are suitable for the specific procedure for which it is to be used. During and after the procedure, appropriate anticoagulants, antiplatelet agents and vasodilators should be administered to the patient according to institutional practice for peripheral angioplasty of similar arteries. Pass the AngioSculpt catheter through the recommended introducer sheath size or minimum size guiding catheter indicated on the product label.

Adverse effects

Possible adverse effects include, but are not limited to: vessel injury such as: dissection, perforation, rupture, spasm, or arteriovenous fistula; infection/sepsis; drug reactions; allergic reactions to contrast medium; restenosis/occlusion of the dilated artery; embolism; thrombus; hypertension/hypotension; hemorrhage; hematoma; pseudoaneurysm; need for blood transfusion; surgical repair of vascular access site; no or slow reflow of the treated vessel.

1. Trerotola, et al. Prospective study of balloon inflation pressures and other technical aspects of hemodialysis access angioplasty. JVIR. 2005 Dec;16(12):1613-8.
2. Dolmatch B. Maintenance of Hemodialysis Access With Stents and Covered Stents. Endovascular Today. June (2010): 55-59.
3. Conrad MF, Kang J, Cambria RP et al. Infrapopliteal balloon angioplasty for the treatment of chronic occlusive disease. J. Vasc. Surg. 50(4), 799–805 (2009).
4. Mwipatayi BP, Hockings A, Hofmann M et al. Balloon angioplasty compared with stenting for treatment of femoropopliteal occlusive disease: a meta-analysis. J. Vasc.Surg. 47(2), 461–469 (2008).
5. AngioSculpt Test Plan ST-1197 (2008), on file at Philips.
6. Scheinert D, Graziani L, Peeters P, Bosiers M, O’Sullivan G, Sultan S, Gershony G. Results of the Multi-Center First-in-Man Study of a Novel Scoring Balloon Catheter for the Treatment of Infra-Popliteal Peripheral Arterial Disease. Catheterization and Cardiovascular Interventions. 2007;70:1034-1039.
7. Kiesz RS, Scheinert D, Peeters PJ, et al. Results from the international registry of the AngioSculpt Scoring Balloon Catheter for the treatment of infra-popliteal disease. J Am Coll Cardiol. 2008;51:10 (suppl B);75.
8. Costa JR, Mintz GS, Carlier SG et al. Nonrandomized Comparison of Coronary Stenting Under IVUS Guidance of Direct Stenting Without Predilation Versus Conventional Predilation With a Semi-Link to reference: Compliant Balloon Versus Predilation With a New Scoring Balloon. Am J Cardiol, 2007; 100:812-817.

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