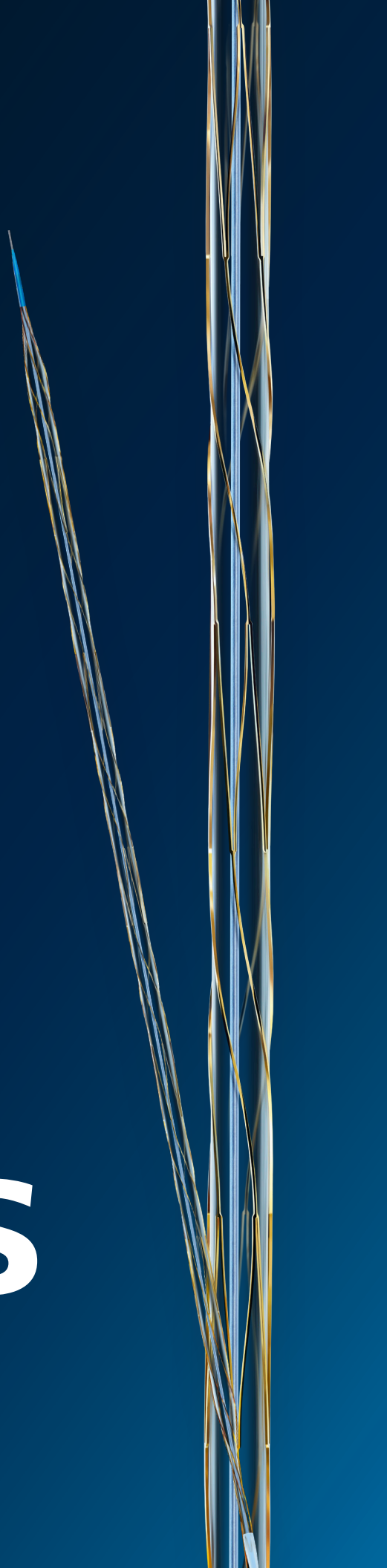
PHILIPS

*Angio**Sculpt** XL*

PTA scoring
balloon catheter

Scoring means **results**



Big score...

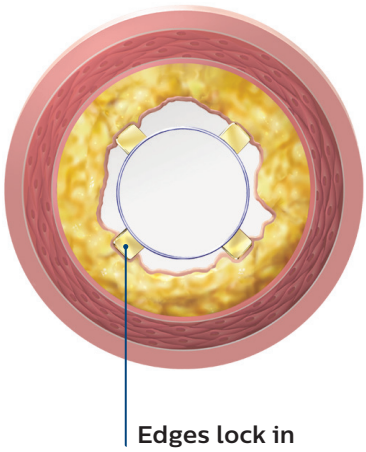
in longer lengths

Designed specifically to address long, diffuse lesions commonly found in infrainguinal arteries, the AngioSculpt XL PTA scoring balloon catheter, now available in 100mm and 200mm lengths, offers 360˚ of precise and effective dilatation. AngioSculpt's smart scoring balloon technology delivers a unique combination of controlled, effective dilatation and predictable device safety.

Scoring means results.

The longer length of AngioSculpt XL provides more coverage and convenience for infrainguinal artery procedures, but it's the unique advantage of the AngioSculpt scoring technology that really delivers.

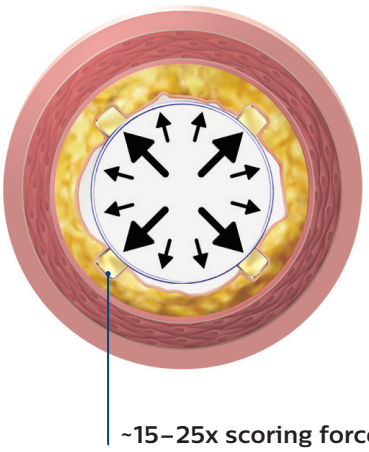
Precision



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[1,2]

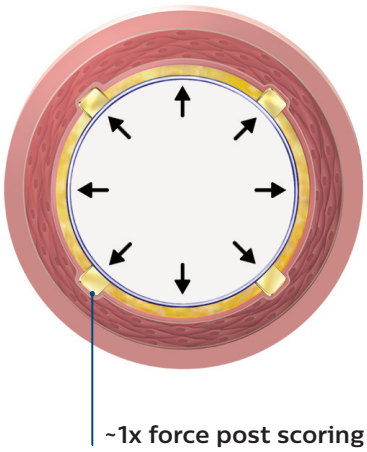
Power



More dilatation force

- The leading edges are designed to drive outward expansion with up to ~15–25 times the force of a conventional balloon[3]
- AngioSculpt's helical nitinol element creates a uniform initial luminal enlargement

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[1,2]
- Low rate of adjunctive stenting[1,2]
- Zero (0) flow-limiting dissections[5-6]

Advanced technology. **Proven benefits.**

Circumferential scoring across the entire length

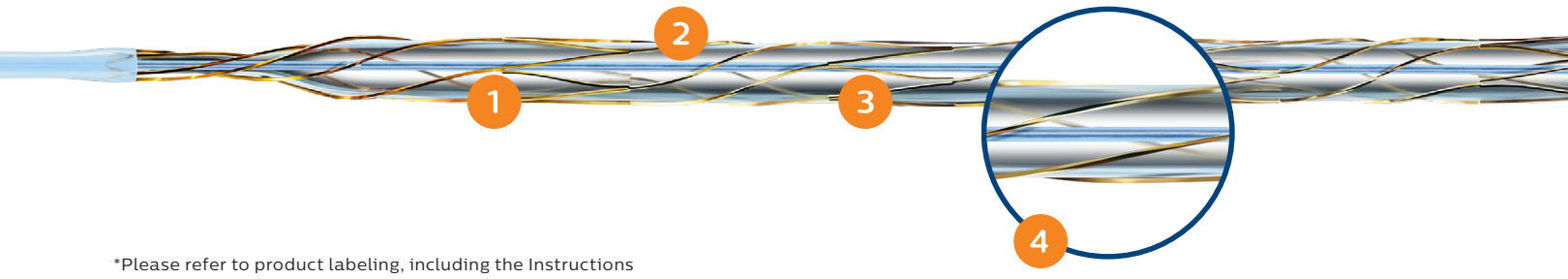
AngioSculpt XL features a nitinol scoring element arranged in a helical configuration, leading to uniform scoring and a procedure that is safe, predictable and precise—it's the only long balloon to offer the distinct AngioSculpt benefits:

1. Large working range (2–up to 20 atm) allows physician to tailor device to vessel size*
2. Nitinol-enhanced balloon deflation for excellent rewrap and recross capabilities
3. Electropolished, helical scoring element safely scores lesion circumferentially[4]

Scoring element

4. Smooth electropolished struts provide a margin of safety resulting in low dissection rates and no significant device slippage[1, 2]

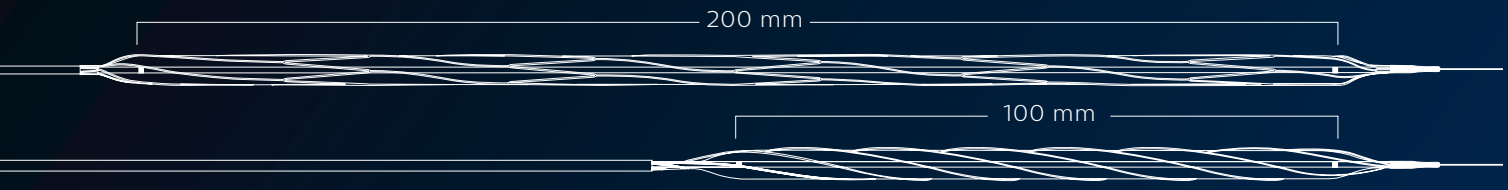
   Rectangular edges provide a predictable dilatation resulting in low dissection rates and minimal device slippage[1]



*Please refer to product labeling, including the Instructions For Use, to select the appropriate device size.

The AngioSculpt XL is now available in even longer lengths, providing a greater array of sizes to meet the needs of treating diffuse disease in the lower extremities.

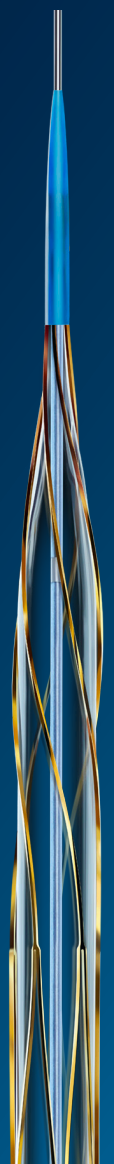
- **Longer balloon length can lead to fewer inflations and reduced procedure times**
- **Only 100mm and 200mm devices to feature the proprietary AngioSculpt scoring technology**
- **Available in a wide range of balloon sizes**



Compliance chart

	Pressure (atm)										
Balloon size	**2**	**4**	**6**	**8**	**10**	**12**	**14**	**16**	**18**	**20**	**22**
2.0 x 10	1.88	1.91	1.95	2.01	2.08	2.15	2.22	2.28	2.32	2.37	2.39
2.0 x 20	1.88	1.91	1.95	2.01	2.08	2.15	2.22	2.28	2.32	2.37	2.39
2.0 x 40	1.86	1.90	1.94	1.98	2.03	2.07	2.10	2.14	2.17	2.20	2.23
2.0 x 100	1.80	1.85	1.90	1.94	1.99	2.03	2.06	2.10	2.13	-	-
2.5 x 20	2.28	2.35	2.40	2.49	2.59	2.69	2.77	2.85	2.89	2.95	2.99
2.5 x 40	2.24	2.31	2.39	2.46	2.52	2.57	2.61	2.65	2.68	2.72	2.76
2.5 x 100	2.26	2.32	2.38	2.44	2.50	2.55	2.60	2.64	2.68	-	-
3.0 x 20	2.73	2.79	2.88	3.01	3.16	3.27	3.36	3.43	3.50	3.57	3.63
3.0 x 40	2.57	2.67	2.79	2.91	3.00	3.07	3.12	3.16	3.20	3.24	-
3.0 x 100	2.70	2.78	2.88	2.97	3.05	3.12	3.20	3.28	3.37	-	-
3.5 x 20	3.19	3.26	3.37	3.51	3.65	3.73	3.81	3.86	3.91	3.97	-
3.5 x 40	3.06	3.19	3.35	3.46	3.55	3.61	3.67	3.73	3.79	-	-
3.5 x 100	3.15	3.25	3.37	3.46	3.55	3.59	3.66	3.72	3.78	-	-
4.0 x 20	3.52	3.69	3.85	3.96	4.03	4.10	4.16	4.23	4.29	-	-
4.0 x 40	3.52	3.67	3.82	3.94	4.02	4.09	4.16	4.22	-	-	-
4.0 x 100	3.60	3.76	3.94	4.07	4.17	4.25	4.32	4.40	4.47	-	-
4.0 x 200	3.65	3.80	3.97	4.10	4.19	4.27	-	-	-	-	-
5.0 x 20	4.25	4.48	4.74	4.92	5.05	5.14	5.23	5.33	5.41	-	-
5.0 x 40	4.23	4.55	4.80	4.98	5.09	5.19	5.29	5.42	-	-	-
5.0 x 100	4.43	4.60	4.79	4.94	5.05	5.13	5.20	5.28	-	-	-
5.0 x 200	4.57	4.77	5.00	5.18	5.30	5.42	-	-	-	-	-
6.0 x 20	5.12	5.42	5.74	5.93	6.06	6.16	6.27	6.37	-	-	-
6.0 x 40	5.36	5.57	5.80	5.96	6.07	6.17	6.26	6.35	-	-	-
6.0 x 100	5.42	5.62	5.86	6.03	6.17	6.27	6.36	6.44	-	-	-
6.0 x 200	5.43	5.68	5.95	6.16	6.31	6.45	-	-	-	-	-
7.0 x 40	6.21	6.46	6.74	6.96	7.13	7.27	7.41	-	-	-	-
8.0 x 40	6.86	7.22	7.63	7.96	8.19	8.40	8.60	-	-	-	-

Nominal pressure Rated burst pressure



Ordering information

Number	Balloon diameter (mm)	Balloon length (mm)	Catheter length	Guidewire compatibility	Sheath size (F)
2039-2010	2	10	137	.014"	5F
2039-2020	2	20	137	.014"	5F
2155-2040	2	40	155	.014"	5F
2216-20100	2	100	155	.014"	6F
2039-2520	2.5	20	137	.014"	5F
2155-2540	2.5	40	155	.014"	5F
2216-25100	2.5	100	155	.014"	6F
2039-3020	3	20	137	.014"	5F
2155-3040	3	40	155	.014"	5F
2216-30100	3	100	155	.014"	6F
2039-3520	3.5	20	137	.014"	5F
2155-3540	3.5	40	155	.014"	5F
2216-35100	3.5	100	155	.014"	6F
2076-4020	4	20	137	.018"	6F
2092-4040	4	40	90	.018"	6F
2076-4040	4	40	137	.018"	6F
2290-40100	4	100	90	.014"	6F
2237-40100	4	100	137	.014"	6F
2249-40200	4	200	137	.014"	6F
2076-5020	5	20	137	.018"	6F
2092-5040	5	40	90	.018"	6F
2076-5040	5	40	137	.018"	6F
2290-50100	5	100	90	.014"	6F
2237-50100	5	100	137	.014"	6F
2249-50200	5	200	137	.014"	6F
2105-6020	6	20	50	.018"	6F
2092-6020	6	20	90	.018"	6F
2076-6020	6	20	137	.018"	6F
2105-6040	6	40	50	.018"	6F
2092-6040	6	40	90	.018"	6F
2076-6040	6	40	137	.018"	6F
2290-60100	6	100	90	.014"	6F
2237-60100	6	100	137	.014"	6F
2249-60200	6	200	137	.014"	6F
2332-7040	7	40	50	.018"	6F
2333-7040	7	40	90	.018"	6F
2334-7040	7	40	137	.018"	6F
2332-8040	8	40	50	.018"	6F
2333-8040	8	40	90	.018"	6F
2334-8040	8	40	137	.018"	6F

References

1. 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.
2. Scheinert D, Peeters P, Bosiers M, et al. Results of the multicenter first-in-man study of a novel scoring balloon catheter for the treatment of infra-popliteal peripheral arterial disease. Catheter Cardiovasc Interv. 2007;70:1034-1039.
3. AngioSculpt Test Plan ST-1197 (2008), on file at AngioScore, Inc.
4. Fonseca A, Costa JR, Abizaid A, et al. Intravascular ultrasound assessment of the novel AngioSculpt Scoring Balloon Catheter for the treatment of complex coronary lesions. J Invasive Cardiol. 2008;20:21-27.
5. Bosiers et al, Use of the AngioSculpt Scoring Balloon for Infrapopliteal Lesions in Patients with Critical Limb Ischemia: 1-year Outcome Vascular, Vol. 17. No. 1, pp. 29-35. 2009.
6. MASCOT Presented at Veith 2009 (NYC, NY) and CRT 2010 (Washington, DC)

Summary of safety and effectiveness—PTA catheter

CE mark granted for peripheral applications

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, total occlusion of the treated artery, arterial dissection or perforation, arterial spasm, pseudoaneurysm, restenosis of the dilated artery, embolism, thrombus, retained device components, hemorrhage or hematoma, arteriovenous fistula.

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