

LIBERTY 360° ORBITAL ATHERECTOMY LONG-TERM RESULTS

LIBERTY 360° is a real-world study designed to evaluate procedural and long-term clinical outcomes of endovascular device interventions in patients with symptomatic lower extremity peripheral artery disease. A total of 503 patients underwent endovascular treatment using the orbital atherectomy system (OAS) plus balloon angioplasty.

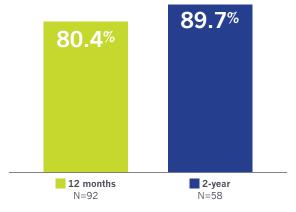
KEY TAKEAWAYS^{1,4}

The results of the LIBERTY 360° OAS subset show durable benefits across a wide range of Rutherford classes, lesion lengths and locations.



TLR/TVR = target lesion / vessel revascularization, RC = Rutherford Class, CLI = critical limb ischemia

HIGH PATENCY AT 2 YEARS IN RC 2-32-4





Patency determined using DUS (peak systolic velocity ratio ≤2.4)

KEY PATIENT DEMOGRAPHICS AND PROCEDURE CHARACTERISTICS

Real-world, all-comer study reflected by the diverse demographics and challenging lesions characteristics, including a high prevalence of current/former smoking, previous endovascular treatment (EVT) of target limb for peripheral artery disease and predominately calcified lesions across all groups.

	Rutherford Category		
Demographics	RC 2-3 (N=214)	RC 4-5 (N=233)	RC 6 (N=56)
Age (years)	70.4 ± 9.6	71.3 ± 10.9	67.9 ± 14.2
Current/Former smoker	72.4%	60.5%	64.3%
Diabetes	50.9%	67.4%	78.6%
Hyperlipidemia	91.1%	88.8%	67.9%
Hypertension	93.9%	93.6%	92.9%
Coronary artery disease	61.7%	67.4%	50.0%
Previous EVT of target limb	27.1%	30.5%	25.0%
Previous bypass surgery of target limb	4.2%	3.9%	7.1%
Lesion Characteristics	RC 2-3 (N=251)	RC 4-5 (N=289)	RC 6 (N=77)
ATK only	44.2%	24.6%	24.7%
ATK and BTK	12.7%	15.2%	7.8%
BTK only	43.0%	60.2%	67.5%
Mean treated target lesion length (mm)	78.7 ± 73.7 (N=240)	131.4 ± 119.0 (N=273)	95.2 ± 83.9 (N=73)
Chronic total occlusion	22.4%	35.7%	34.2%
Mean preprocedural MLD (mm)	0.8 ± 0.8 (N=245)	0.7 ± 0.9 (N=279)	0.6 ± 0.6 (N=76)
Target lesion preprocedural % stenosis	77.9 ± 19.4 (N=245)	80.7 ± 20.3 (N=280)	81.6 ± 17.9 (N=76)
Predominately calcified morphology	72.4%	67.4%	63.9%

KEY PERIPROCEDURAL COMPLICATIONS¹

Low rate of complications, even with complex patients and lesions. Low rates of bail-out stenting.

	Rutherford Category		
	RC 2-3 (N=251)	RC 4-5 (N=289)	RC 6 (N=77)
Severe dissection (Type C-F)	1.6%	2.4%	2.6%
Perforation	1.2%	2.1%	1.3%
Distal embolization	6.5%	5.6%	8.1%
Bail-out stenting	2.0%	2.8%	0.0%

- 1. Giannopoulos S, et al. J Endovasc Ther. 2020;27(5):714-725.
- 2. Mustapha J, et al. J Endovasc Ther. 2019;26(2):143-154.
- 3. Adams G, et al. J Vasc Surg. 2019;70(5, Suppl):e188-e189.
- 4. CSI data on file.

The detailed inclusion and exclusion criteria of the LIBERTY 360° study can be found at https://clinicaltrials.gov/ct2/show/NCT01855412

The Diamondback 360° and Stealth 360° Peripheral Orbital Atherectomy Systems are percutaneous orbital atherectomy systems indicated for use as therapy in patients with occlusive atherosclerotic disease in peripheral arteries and stenotic material from artificial arteriovenous dialysis fistulae. **Important Safety Information:** The Systems are contraindicated for use in coronary arteries, bypass grafts, stents, or where thrombus or dissections are present. Although the incidence of adverse events is rare, potential events that can occur with atherectomy include: pain, hypotension, CVA/TIA, death, dissection, perforation, distal embolization, thrombus formation, hematuria, abrupt or acute vessel closure, or arterial spasm.

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



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