DURABILITY II
QUICK REFERENCE GUIDE

DURABILITY II is the first controlled study to focus on treating long, complex lesions with a single stent and to specifically test the performance of a 200 mm stent in the superficial femoral artery. After 36 months, DURABILITY II evidence supports a single stent strategy — implanting one long stent reduces fracture rates and increases vessel patency.

STUDY OBJECTIVE

The study objective was to compare PTA and primary stenting using the EverFlex™ self-expanding peripheral stent system for the treatment of lesions in the native SFA or SFA and proximal popliteal arteries.

STUDY DESIGN

- U.S. FDA IDE study
- Prospective, multicenter, non-randomized, single-arm study
- 287 subjects
- Independently adjudicated

PRIMARY ENDPOINTS

Safety: Major adverse events at 30 days
Effectiveness: Primary patency at 1 year

STUDY PARAMETERS

PARAMETER	Lesion Characteristics (n = 287)
Mean Lesion Length (core lab)	89.1 mm
Total Occlusions	48.1%
Calcification (moderate to severe)	70.0%
Moderate	26.8%
Severe	43.2%

STUDY RESULTS

The 36-month results offer evidence that even in long, complex lesions, the EverFlex stent is able to sustain patency and durability.

DURABILITY II	RESULTS		
	12-mo[1]	24-mo[2]	36-mo[3]
Freedom from loss of primary patency (PSVR < 2.0)[†]	77.2%	66.0%	60.0%
Patency in lesions ≤ 80 mm	86.2%	80.8%	71.0%
Patency in lesions > 80 mm	69.6%	53.1%	50.5%
Fracture rate	0.4%	0.9%	0.9%

FREEDOM FROM TLR	12-mo[1]	24-mo[2]	36-mo[3]
All Subjects (n = 287)	86.0%	75.0%	70.0%
Lesions ≤ 80 mm (n = 133)	92.0%	89.0%	80.0%
Lesions > 80 mm (n = 154)	81.0%	64.0%	61.0%

[†]Kaplan-Meier analysis.

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PERIPHERAL BARE METAL STENTS FOR FEMOROPOPLITEAL DISEASE
CLINICAL DATA QUICK REFERENCE GUIDE†

	DURABILITY II[1,2]	RESILIENT[3,4]	STROLL[5,6]	SuperNOVA[7]	SUPERB[8]	OSPREY[9,10]
Stent	EverFlex™ Peripheral Stent	LifeStent™* Vascular Stent	S.M.A.R.T.™* Vascular Stent	Innova™* Self-expanding Stent	Supera™* Peripheral Stent	R2P™* MISAGO™* Stent
Mean Lesion Length (mm)	89.1	70.5	77.3	93.2	77.7	83.8
Calcification (moderate to severe)	70.0% (43.2% severe)	35.3% (24.5% severe)	19.3% (severe only)	Not Reported (35.6% severe)	72.8% (44.9% severe)	66.6% (31.4% severe)
CTOs	48.1%	17.0%	23.6%	44.7%	24.7%	Not Reported
Patency	77.2% (12 months) 66.0% (24 months) 60.0% (36 months) Lesions ≤ 80 mm: 86.2% (12 months) 80.8% (24 months) 71.0% (36 months)	81.3% (12 months) Lesions ≤ 80 mm: 85.0% (12 months)	87.9% (12 months) 80.5% (24 months) 72.7% (36 months)	66.4% (12 months)	86.1% (12 months)	82.9% (12 months)
Fracture Rate	0.4% (12 months) 0.9% (24 months) 0.9% (36 months)	3.1% (12 months) 4.1% (18 months)	2.0% (12 months) 2.3% (24 months) 3.6% (36 months)	1.9% (12 months) 2.2% (24 months)	0% (12 months) 0% (24 months) 0.6% (36 months)	0.5% (12 months) 2.0% (24 months) 2.0% (36 months)
Key Message**	Long, complex lesions, PSVR < 2.0	Shorter, less complex lesions, PSVR < 2.5	Shorter, less complex lesions, PSVR < 2.5	Failed primary efficacy endpoint, PSVR < 2.4	Shorter lesions, fewer CTOs, only 36% of stents deployed nominally, PSVR < 2.0	Shorter, less complex lesions, PSVR < 2.5

†For IDE clinical trials with 2 years or more published data as of August, 2020. Results are not directly comparable. Primary patency rates may be defined differently. Information provided is for illustration purposes only, and may differ in head-to-head comparison.

**Higher PSVR thresholds may yield higher patency rates. Higashimori A, Kawarada O, Morioka N, et al. Impact of changing PSVR thresholds on the patency rates of SFA recanalisation with self-expanding nitinol stents. *EuroIntervention*. 2013;9(8):964-967.

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Indication: The EverFlex™ Self-expanding Peripheral Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 180 mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5–7.5 mm. **Contraindications:** Use of the EverFlex™ Self-expanding Peripheral Stent System is contraindicated in patients with known hypersensitivity to nickel titanium; patients contraindicated for anticoagulant and/or antiplatelet therapy; patients who have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system. **Potential Adverse Events:** Potential adverse events which may be associated with the use of a stent in the SFA and proximal popliteal arteries include, but are not limited to: allergic reaction, amputation, arterial dissection/perforation, bleeding disorders (including GI, lymphatic), infection (local or systemic including bacteremia or septicemia), pseudoaneurysm, restenosis, stent/vessel thrombosis, surgical orendovascular intervention.

See the Instructions for Use provided with the product for a complete list of warnings, precautions, adverse events, and device information.

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

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