SFA STENTING STUDIES

Study	Sponsor	Sample Size	Devices	Study Design
COMPLETE SE	Medtronic, Inc.	N = 178	Complete SE	Prospective, multicenter, single-arm study of Complete SE stents in SFA/proximal popliteal lesions or occlusions vs PTA Objective Performance Criteria. Primary endpoints of MAEs and stent patency at 12 months.
DURABILITY II (US)	ev3 Inc.	N = 287	Protégé EverFlex	Prospective, multicenter, single-arm study of single Protégé EverFlex stents in long SFA/proximal popliteal lesions vs PTA Objective Performance Criteria.
FAST	Bard Peripheral Vascular	N = 244	Luminexx	Randomized, prospective, multicenter study of PTA vs stenting in proximal SFA lesions. Primary endpoint of ultrasound-assessed binary restenosis at 12 months with fracture follow-up.
RESILIENT	Bard Peripheral Vascular	N = 206	LifeStent	Randomized, prospective, multicenter study of PTA vs PTA plus stenting in SFA and proximal popliteal lesions.
STROLL	Cordis Corporation	N = 250	Smart	Prospective, multicenter, single-arm study of Smart stents in SFA lesions vs PTA Objective Performance Criteria.
SUPERB	IDev Technologies, Inc.	N = 258	Supera	Prospective, multicenter, single-arm study of Supera SE stents in SFA lesions vs PTA Objective Performance Criteria.
VIABAHN	W. L. Gore & Associates	N = 244	Viabahn	Randomized, prospective multicenter study of PTA vs Viabahn stents in SFA lesions. Efficacy endpoint: primary patency of the target vessel at 1 year, treatment success, technical success, clinical success.
VIBRANT	W. L. Gore & Associates	N = 148	Viabahn	Randomized, prospective, multicenter study of Viabahn stents in SFA lesions vs nitinol stent of choice. Efficacy endpoint: primary patency at 3 years defined by color Doppler ultrasonography peak systolic velocity < 2 for target lesion.
VIPER	W. L. Gore & Associates	N = 120	Viabahn	Prospective, single-arm, multicenter study of Viabahn Endoprosthesis with Heparin Bioactive Surface. Efficacy endpoint: primary patency of the target vessel at 1 year (> 2.5 peak systolic velocity determined by duplex).
ZILVER PTX (US phase 1)	Cook Medical	N = 60	Zilver PTX (DES)	Randomized, prospective multicenter study of PTA with provisional stenting vs DES stenting in SFA and proximal popliteal. Efficacy endpoint: 12-month patency determined by duplex.
ZILVER PTX (US phase 2)	Cook Medical	N = 420	Zilver PTX (DES)	Randomized, prospective multicenter study of PTA with provisional stenting vs DES stenting in SFA and proximal popliteal. Efficacy endpoint: 12-month patency determined by duplex.
ZILVER PTX (OUS)	Cook Medical	N = 792	Zilver PTX (DES)	Prospective, multicenter registry. Indication: treatment of symptomatic disease of the above-the-knee femoropopliteal artery. Rutherford category 2 and higher, no lesion length limitations, up to four stents per patient, multiple lesions per leg, stenosis, occlusion, restenosis, in-stent restenosis. Endpoint: safety (event-free survival), stent integrity at 6 and 12 months, effectiveness (freedom from TLR at 6, 12, and 24 months).

DES, drug-eluting stent; MAE, major adverse event; OUS, outside United States; PMA, Premarket Approval; PTA, percutaneous transluminal angioplasty; SFA, superficial femoral artery; TLR, target lesion revascularization.
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Lesion Lengths	Results	Core Lab Adjudicated?	Status
≥ 4 to ≤ 14 cm	Not available.	Yes	Enrolling (began November 2008).
≥ 4 to ≤ 18 cm	Not available.	Yes	Enrolling (began October 2007).
≤ 10 cm	No statistically significant difference between treatment groups at 12 months. Properly powered trials in individual subgroups appears warranted.	Yes	Results presented and paper accepted for publication.
≤ 15 cm	Freedom from TLR rate at 2 years: 78% vs 42% for PTA alone. Fracture rate at 18 months: 3.8%.	Yes	FDA PMA, February 2009.
4 to 15 cm	Not available.	Yes	Enrolling (began August 2008).
4 to 14 cm	Not available.	Yes	Enrolling.
≤ 13 cm	When compared to PTA, Viabahn resulted in higher rates of treatment success, technical success, and 12-month patency as defined by current clinical standards.	Yes	FDA PMA, June 2005.
≥ 8 cm	148 randomized subjects enrolled (mean lesion length, 19 cm). MAE at 30 days: 0.7%	Yes	Enrollment closed.
≥ 5 cm	Not available.	No	Enrolling.
≤ 7 cm	Primary patency at 9 months: PTA = 52%, DES = 90%. 0% fracture rate for 41 lesions at 6 months and 18 lesions at 1 year. Event-free survival: PTA = 91%, DES = 89%.	Yes	Enrollment complete. Interim 9-month trial data presented at ISET 2007.
≤ 14 cm	Not available.	Yes	Enrollment complete.
No lesion length restrictions.	Interim data presented at Charing Cross 2009, 12-month follow-up on 592 patients (673 lesions) and 24-month follow-up on 177 patients (221 lesions). Stent integrity: 1.4% at 6 months and 1.8% at 12 months. Effectiveness: 89% at 12 months and 82% at 24 months. Event-free survival: 87% at 12 months and 78% at 24 months.	Yes, for stent fractures.	Interim data presented at Charing Cross 2009.