BIOFLEX-I

36 months SFA/PPA results overview

Conclusions

- The study results are similar to the results of other competitor stents for use in patients with Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) lesions
- Freedom from Clinically-Driven Target Lesion Revascularization (Fcd-TLR) rate at 36-month is at 78.2% and shows stable long term outcomes for Pulsar-18

Study design

Prospective, non-randomized, multi-center study with two treatment cohorts, iliac lesion treatment and SFA/PPA lesion treatment. Only the SFA/PPA lesion treatment cohort is applicable to the Pulsar stents (Astron Pulsar and Pulsar-18 Stent Systems).

Endpoints

Primary safety endpoint

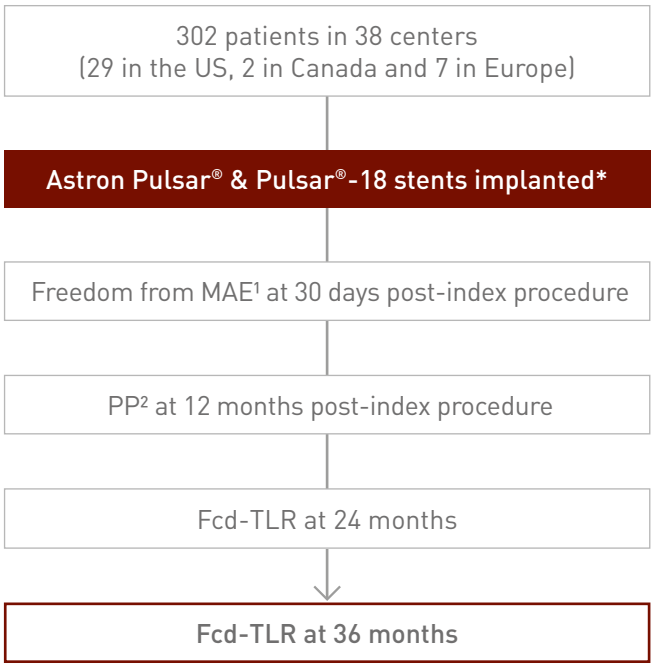
- Freedom from procedure- or stent-related Major Adverse Events[1] (MAE) at 30 days post-index procedure

Primary efficacy endpoint

- The primary effectiveness endpoint for the Pulsar stent group is the Primary Patency[2] (PP) rate at 12 months (395 days) post-index procedure

Secondary endpoints (selected)

- Compare the primary and secondary endpoint results between evaluable subjects in the Pulsar stent group with lesions from 20 mm to 140 mm in length and evaluable subjects with lesions from 141 mm to 190 mm in length



Patient characteristics	n = 302	
Age, yrs‡	67.3 ± 10.3	
Diabetes mellitus	123	40.7%
Hypertension[3]	255	84.4%
Hyperlipidemia[3]	245	81.1%
Current smoker	122	40.4%
Cerebrovascular disease[4]	48	15.9%
Congestive heart failure[5]	27	8.9%
Ischemic heart disease[6]	124	41.1%
Coronary revascularization	110	36.4%
Renal insufficiency[7]	17	5.6%

Lesion characteristics	n = 302	
Total occlusion	91	30.1%
Average lesion length (cm)‡	8.2 ± 4.7	
Lesion location		
Ostial SFA	2	0.7%
Proximal SFA	38	12.6%
Mid SFA	156	51.7%
Distal SFA	99	32.8%
Proximal popliteal	7	2.3%
Stent ratio per patient[8]	1.22	
TASC[9] A	166	55.1%
B	106	35.2%
C	26	8.6%
D	3	1.0%

* Angiogram
‡ Data shown as mean ± SD

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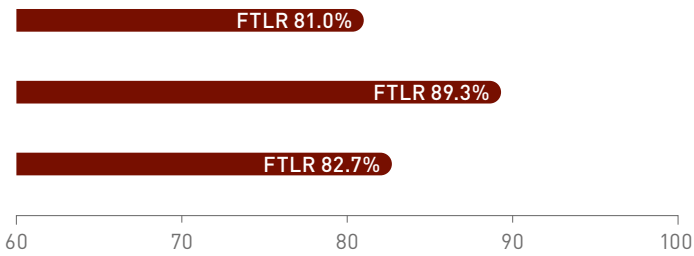
24-months outcomes of Pulsar-18

Study, Product	Manufacturer	A.L.L.	PP
BIOFLEX-I[10] Pulsar	**BIOTRONIK**	8.2 cm	N/A
BIOFLEX PEACE[11] Pulsar-18 – stent only	**BIOTRONIK**	8.2 cm	78.4%
4EVER[12] Pulsar	**BIOTRONIK**	7.1 cm	72.3%



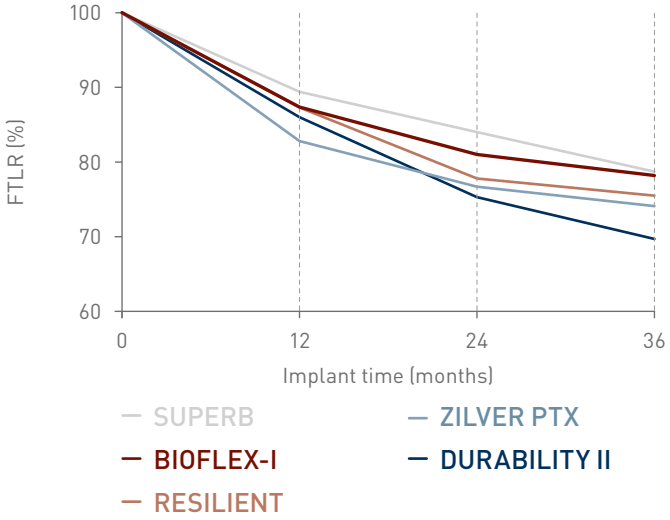
BIOFLEX-I outcomes confirm the excellent outcomes of BIOFLEX PEACE and 4EVER after 24 months

36-months outcomes in perspective

Study, Product	Manufacturer	A.L.L.	TLR
BIOFLEX-I[10] Pulsar	**BIOTRONIK**	8.2 cm	21.8%
SUPERB[13] Supera	Abbott	7.8 cm	21.3%
RESILIENT[14] Lifestent	BD/Bard	7.0 cm	24.5%
ZILVER PTX[15] Zilver BMS provisional	Cook Medical	6.3 cm	25.9%
DURABILITY II[16] EverFlex	Medtronic	10.9 cm	30.3%

BIOFLEX-I results are similar to the results of other competitor stents

Long term FTLR in perspective



Principal investigators

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Independent Core Lab and CEC adjudication

1. Major Adverse Event (MAE) is a composite of device and procedure related mortality through 30 days post index procedure, major target limb amputation and clinically-driven Target Lesion Revascularization (cd-TLR). MAE are adjudicated by an independent Clinical Events Committee (CEC); 2.Primary Patency (PP) is freedom from >50% restenosis in the target lesion as indicated by a duplex ultrasound peak systolic velocity ratio (PSVR) >2.5 or by visual; 3. Hypertension and Hyperlipidemia - requiring treatment with a prescription medication; 4. Cerebrovascular disease - carotid artery disease and history of stroke or TIA; 5. Congestive heart failure - ejection fraction <40% or heart failure diagnosis; 6. Ischemic heart disease - myocardial infarction, angina pectoris, percutaneous or surgical coronary revascularization, positive exercise test or anti-anginal therapy; 7. Renal insufficiency - creatinine ≥1.5 mg/dL (last measurement prior to baseline); 8. A total of 367 stents were implanted; 9. TASC II: TransAtlantic Inter-Society Consensus ; 10. BIOFLEX-I Pulsar 2018 Post Approval Clinical Report_Final_36m; 11. Lichtenberg et al. Effectiveness of the Pulsar-18 self-expanding stent with optional drug-coated balloon angioplasty in the treatment of femoropopliteal lesions - the BIOFLEX PEACE All-Comers Registry.Vasa (2019), 1-9. doi_10.10240301-1526a000785; 12. Bosiers M. 4EVER 24 month results: long-term results of 4F Pulsar stent in femoropopliteal lesions. Presented at: CIRSE 2013; Barcelona, Spain; 13. Supera IFU, EL2100430 (2016-03-23); 14. Laird J et al. Nitinol Stent Implantation vs. Balloon Angioplasty for Lesions in the Superficial Femoral and Proximal Popliteal Arteries of Patients With Claudication: Three-Year Follow-up From the RESILIENT Randomized Trial (Feb 2012),doi10.1583/11-3627.1; 15. Dake et al. 5-Year Results of the Zilver PTX Randomized Trial, 2016;133:1472–1483; 16. Rocha-Singh et al. DURABILITY II Three-Year Follow-up. Catheterization and Cardiovascular Interventions 2015; 86:164-170.

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