4EVER

Long-term follow-up with 24 months results[1]
Physician-initiated trial investigating the safety of the full 4F EndoVascular trEatment appRoach of infra-inguinal arterial stenotic disease[1]

Conclusions

- Pulsar stents are safe and effective for treating SFA disease with excellent performance and clinical outcomes:
  - PP and FTLR in line with other documented bare metal/passive coated stents in lesions with similar characteristics
  - PP in line with Zilver PTX (Drug Eluting Stent) even though longer average lesion length in 4EVER study
  - Sufficient chronic outward force and compression resistance demonstrated by the favorable 24m PP, even in calcified lesions and occlusions
- Astron Pulsar and Pulsar stents are safe and effective for treating SFA disease
- Clinical outcomes in line with other documented studies including Zilver PTX
- Sufficient radial force and compression resistance

Study design

- C.C.I. Dr. M Bosiers, A.Z. Sint-Blasius, Dendermonde, Belgium
- 120 patients with 6, 12, 24m follow-up2
- BIOTRONIK devices: Fortress, Astron Pulsar, Pulsar-18
- 1^0 endpoint: Primary Patency (PP) at 12m3
- 2^0 endpoints: PP at 6 & 24m; Freedom from Target Lesion Revascularization (FTLR) 6, 12 & 24m; Technical success; Puncture site complication rate; Stent fracture rate at 12 & 24m; Clinical success at 6, 12 & 24m

Participating centers

- P.I. Dr. P Peeters, Bonheiden, Belgium
- P.I. Dr. O d'Archambeau, Antwerp, Belgium
- P.I. Prof. D Scheinert, Leipzig, Germany
- P.I. Prof. G Torsello, Münster, Germany

[1] Bosiers M, Deloose K, Callaert J, et al. 4-French–compatible endovascular material is safe and effective in the treatment of femoropopliteal occlusive disease: results of the 4-EVER trial. J Endovasc Ther. 2013;20:746–756.

Not available for sale in the USA. CAUTION - Investigational Device.
Limited by United States Law to Investigational Use.

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Patient demographics

	Baseline
Mean Rutherford class	2.81 ± 0.50
CLI	16.7 %
Smoker	59.2 %
of which ex-smoker	17.5 %
Diabetes	35.8 %
Hypercholesterolemia	55.0 %
Hypertension	65.0 %

Lesion characteristics

	Baseline
Occlusions	20.8 %
Calcification	30.8 %
Average lesion length (cm)	7.1 ± 4.6[4]
Astron Pulsar (cm)	4.25 ± 2.05[4]
Pulsar-18 (cm)	10.8 ± 4.08[4]
TASC A / B / C / D	70.0 % / 22.5 % / 7.5 % / 0.0 %

Key points

Average lesion length (ALL) **in line** with several published or presented studies[4]

Results

	12m	24m	p-value
Primary patency (overall)	81.4 %	**72.3 %**	
Astron Pulsar	85.2 %	76.2 % (Δ -9.0 %)	
Pulsar-18	73.4 %	69.7 % (Δ -3.7 %)	
Calcified vs. non-calcified	80.2 % vs. 82.0 %	66.8 % vs. 76.7 %	p = 0.659 / p = 0.485
Freedom from TLR	89.3 %	**82.7 %**	
Astron Pulsar	91.1 %	82.3 % (Δ -8.8 %)	
Pulsar-18	85.2 %	85.1 % (Δ -0.1 %)	
Change Rutherford (+/0/-)	(2/3/91) of 96 patients	n/a	

Key points

PP and FTLR at 24m **similar** to other published or presented studies[4]

No significant difference between calcified vs. non-calcified lesions at both 12m and 24m

Pulsar-18 PP and FTLR shows **less Δ** from 12m to 24m than Astron Pulsar

24m primary patency and freedom from TLR in perspective

	ALL	PP	FTLR	Occlusions
DURABILITY II	8.9 cm	66.0 %	n/a	48.0 %
SUPERA	9.0 cm	76.1 %	n/a	31.0 %
STROLL	7.7 cm	74.9 %	80.3 %	23.6 %
ZILVER PTX	6.6 cm	74.8 %	86.6 %	30.0 %
4EVER (Astron Pulsar, Pulsar-18)	**7.1 cm**	**72.3 %**	**82.7 %**	**20.8 %**
4EVER (Pulsar-18)	**10.8 cm**	**69.7 %**	**85.1 %**	**30.8 %**

Key points

Pulsar stent seems to provide **similar** PP as other studies at 24m including Zilver PTX (longer lesion length in 4EVER)

12m fracture rates in perspective

12m	SUPERA	SUMMIT	DURABILITY II	ZILVER PTX	STROLL	ABSOLUTE	MISAGO II	RESILIENT	4EVER	COMPLETE SE	DURABILITY 200	DURABILITY I	FAST
PP	84.7 %	85.1 %	77.9 %	83.1 %	81.7 %	63.0 %	87.6 %	81.3 %	81.4 %	78.3 %	64.8 %	72.2 %	68.3 %
# rate %	0.0 %	0.0 %	0.4 %	0.9 %	1.5 %	2.0 %	3.1 %	3.1 %	4.2 %	4.6 %	6.0 %	8.1 %	12.0 %

[2] If patients received both an Astron Pulsar and Pulsar stent
[3] PSVR < 2.5 by Duplex Ultrasound
[4] DURABILITY II, SUPERA, STROLL, ZILVER PTX

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