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# 4EVER

Investigator-initiated trial investigating the safety of the full 4F EndoVascular trEatment appRoach of infra-inguinal arterial stenotic disease at 24-months[1]

## Conclusions

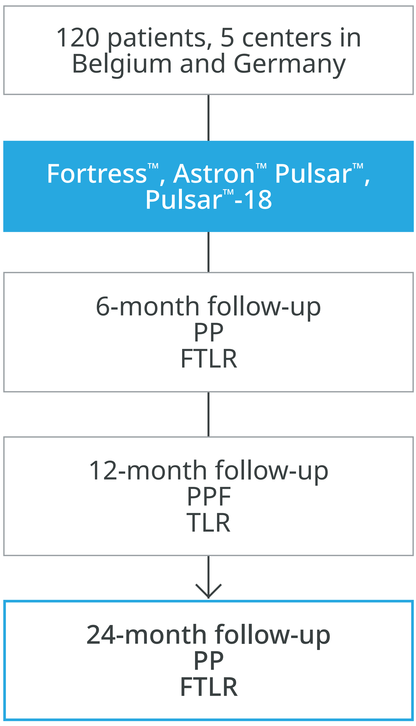
Pulsar™ stents are safe and effective for treating SFA disease with excellent performance and clinical outcomes:

- Primary Patency (PP)* and Freedom from Target Lesion Revascularization (FTLR) are in line with other documented bare metal/passive coated stents in lesions with similar characteristics[2]
- PP is in line with Zilver PTX (drug-eluting stent) despite longer average lesion length
- Sufficient chronic outward force and compression resistance demonstrated by the favorable 24-month PP, even in calcified lesions and total occlusions

## Study design

Prospective, non-randomized, multi-center, controlled study.

120 patients with 6, 12, 24-month follow-up. Devices: Fortress™, Astron™ Pulsar™, Pulsar™-18, Passeo™-18 and Cruiser™-18.




## Endpoints

**Primary endpoint**

- PP* at 12 months

**Secondary endpoints (selected)**

- PP* at 6 and 24 months
- FTLR 6, 12 and 24 months
- Technical success
- Puncture site complication rate
- Stent fracture rate at 12 and 24 months
- Clinical success at 6, 12 and 24 months

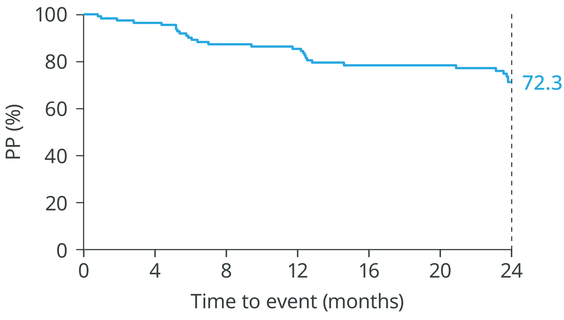
| PATIENT CHARACTERISTICS | | N=120 |
|---|---|---|
| Age, yrs** | 71±9.7 | 47–90 |
| Male | 82 | 68.3 % |
| Nicotine abuse (current) | 50 | 41.7 % |
| Hypertension (controlled) | 78 | 65.0 % |
| Diabetes mellitus | 43 | 35.8 % |
| Renal insufficiency | 13 | 10.8 % |
| Hypercholesterolemia | 66 | 55.0 % |
| Obesity | 39 | 32.5 % |

| LESION CHARACTERISTICS | | N= 120 |
|---|---|---|
| Lesion length (mm)** | 71±45.9 | 10–220 |
| Popliteal involvement | 5 | 4.17 |
| Total occlusions | 25 | 20.8 % |
| Ulcerated lesion | 3 | 2.5 % |
| Calcified lesion | 37 | 30.8 % |
| Presence of thrombus | 2 | 1.7 % |

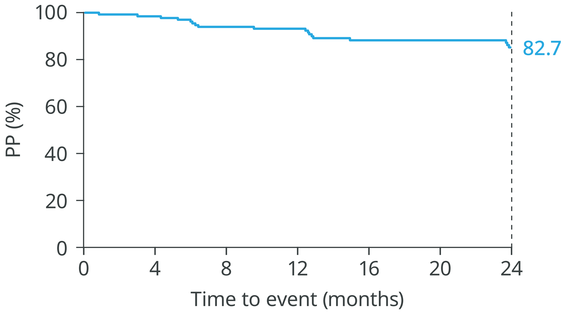
** Defined as freedom from >50 % restenosis as indicated by duplex ultrasound PSVR <2.5*
*** Data shown as mean±SD*

| RESULTS | 12 MONTHS[1] | 24 MONTHS[3] | P-VALUE |
|---|---|---|---|
| **PP (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 % | 0.659 0.485 |
| **FTLR** | 89.3 % | 82.7 % | |
| Astron™ Pulsar™ | 91.1 % | 82.3 % (Δ–8.8 %) | |
| Pulsar™-18 | 85.2 % | 85.1 % (Δ–0.1 %) | |
| Rutherford Classification change (+/0/-) | (2/3/91) of 96 patients | n/a | |

## 24-month PP




## 24-month FTLR




## 24-month PP and FTLR in perspective

| | A.L.L. | PP | FTLR | TOTAL OCCLUSIONS |
|---|---|---|---|---|
| ZILVER PTX[4] | 6.6 cm | 74.8 % | 86.6 % | 32.8 % |
| **4EVER (Pulsar™-18)[1]** | **10.8 cm** | **69.7 %** | **85.1 %** | **32.6 %** |
| **4EVER (Astron™ Pulsar™, Pulsar™-18)[3]** | **7.1 cm** | **72.3 %** | **82.7 %** | **20.8 %** |
| STROLL[5] | 7.7 cm | 74.9 % | 80.3 % | 23.6 % |
| DURABILITY II[6] | 8.9 cm | 66.0 % | n/a | 48.1 % |
| SUPERA[7] | 9.0 cm | 84.7 % | n/a | 30.8 % |

## Key points

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

## Key outcomes

24-m **72.3 %** PP

24-m **82.7 %** FTLR

**Principal investigator:** Dr. M Bosiers, A.Z. Sint-Blasius, Dendermonde, Belgium.


**References:**

1 Bosiers M et al. 4-French -compatible endovascular material is safe & effective in the treatment of femoropopliteal occlusive disease: Results of the 4EVER Trial. J Endovasc Ther 2013; 20: 746-756.
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