# Applications and Evidence for minimally invasive stenting

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**Disclosure**

Speaker name: Dr. Jingjun Jiang

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I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ■ I do not have any potential conflict of interest

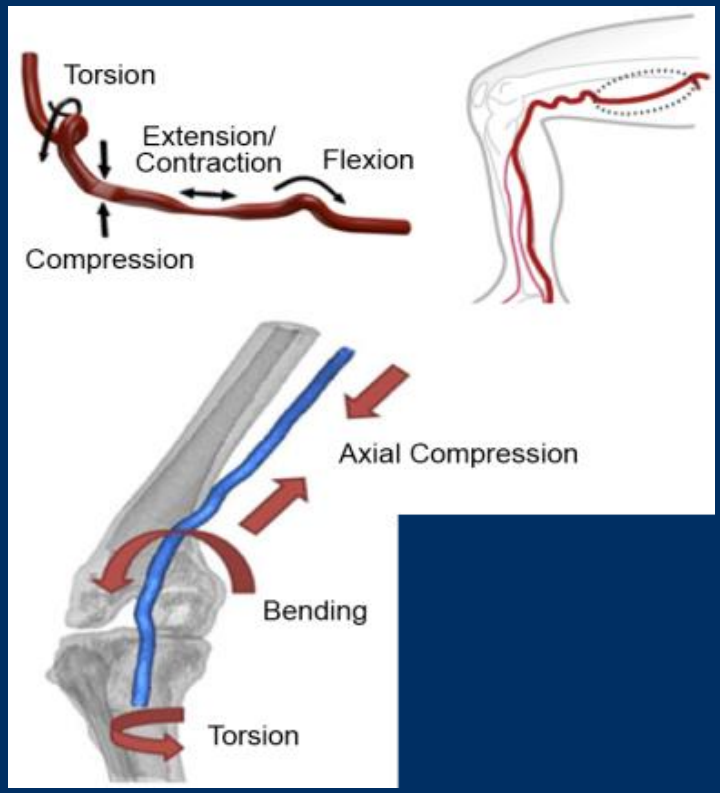
# The SFA is a challenge to treat

**Shortening 23-25%[1]**

**Compression > 1kg[2]**

**Torsion 60°[3]**

**Bending 64°[4]**




SFA, superficial femoral artery.*Catheter Cardiovasc Interv.* 2009;74(5):787-98.
1. Jonker et al., Dynamic Forces in SFA/Popliteal Artery During Knee Flexion, Endovascular Today. Buyer's Guide 2009, pp. 54–59
2. Supinski, G.S. et al. Effect of Diaphragmatic Contraction on Intramuscular Pressure and Vascular Impedance. J Appl Physiol.1990;68(4):1486–1493.
3. Cheng, C.P. et al. In Vivo MRA Quantification of Axial/Twisting Deformations of the SFA Resulting from Maximum Hip and Knee Flexion. J Vasc Interv Radiol. 2006;17(6):979–987
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Slide curtesy of Dr. Koen Deloose

# «Dedicated stents» needed to tackle SFA lesions

## Properties of an ideal SFA stent

- Accurate deployment
- High multidirectional flexibility
- Low Chronic Outward Force (COF)
- Sufficient Radial Resisitive Force (RRF)
- Sufficient Crush Resistance (CR)
- Low profile

Source: SUPERB Study 12m data presented by Lawrence Garcia, MD at VIVA 2014.

# Is Pulsar an ideal SFA stent?

### Pulsar-18 Specifications

- 0.018” OTW Nitinol Stent
- Ø: 4.0-5.0-6.0-7.0 mm
- **Strut thickness 140µm**
- L: 30-40-60-80-100-120-150 mm
- proBIO coated (a-SiC:H)
- 4F Introducer Sheath compatible

### Pulsar-18 key features

- Thin Struts and Low COF
- Low Profile 4F Delivery System
- Stent with multi-directional flexibility and peak-to-valley design
- Accurate stent deployment - one-handed stent release handle

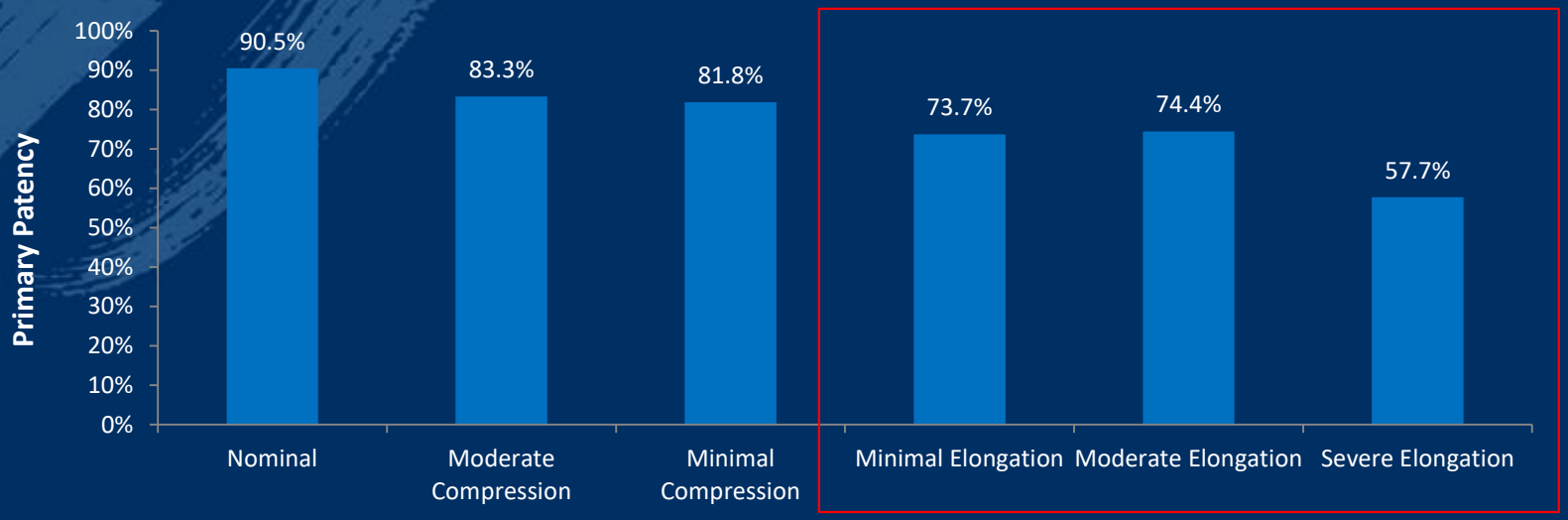
**Thin Struts**

**Low COF**

**Clinically Proven**

# Properties of an ideal SFA stent

## Elongation/compression can impact patency




**Pulsar has one-handed & accurate & easy stent release**

Source: SUPERB Study 12m data presented by Lawrence Garcia, MD at VIVA 2014.

# Properties of an ideal SFA stent

High multidirectional flexibility depends on the strut thickness and stent design

**BIOTRONIK Pulsar 6/100**

**Boston Innova 6/100**

**BARD LifeStent XL 6/100**

**Cook Zilver Flex 6/100**

**MDT EverFlex Entrust 6/100**

**Medtronic Complete SE 6/100**

Source: 1. BIOTRONIK Data on file test report IIB(P)79/2016

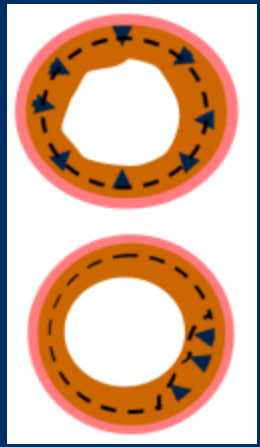
# Properties of an ideal SFA stent

- **Low Chronic Outward Force (COF)**
- High multidirectional flexibility
- Sufficient Radial Resisitive Force (RRF)
- Sufficient Crush Resistance (CR)

- **Accurate deployment**
  Elongation/compression can impact patency

**RRF**
(resistance to **concentric** compression)

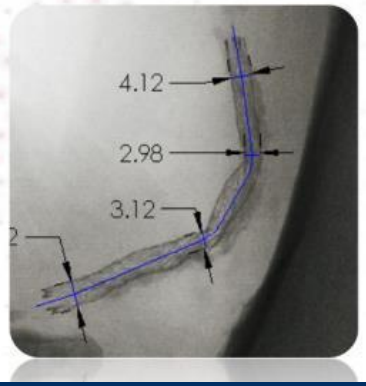
**CR**
(resistance to **eccentric** compression)



TOO low...

Impossibility to open the lesion

Residual Stenosis




TOO high...

Chronic stent-vessel irritation

Intimal Hyperplasia

LABORATORY INVESTIGATION

Late Stent Expansion and Neointimal Proliferation of Oversized Nitinol Stents in Peripheral Arteries

Intramural Stress Increases Exponentially with Stent Diameter: A Stress Threshold for Neointimal Hyperplasia

A link between stent radial forces and vascular wall remodeling: The discovery of an optimal stent radial force for minimal vessel restenosis

Joseph W. Freeman[1], Patrick B. Snowhill[2], John L. Nosher[3]

Slide curtesy of Dr. Koen Deloose

# Pulsar vs. LifeStent® in animals

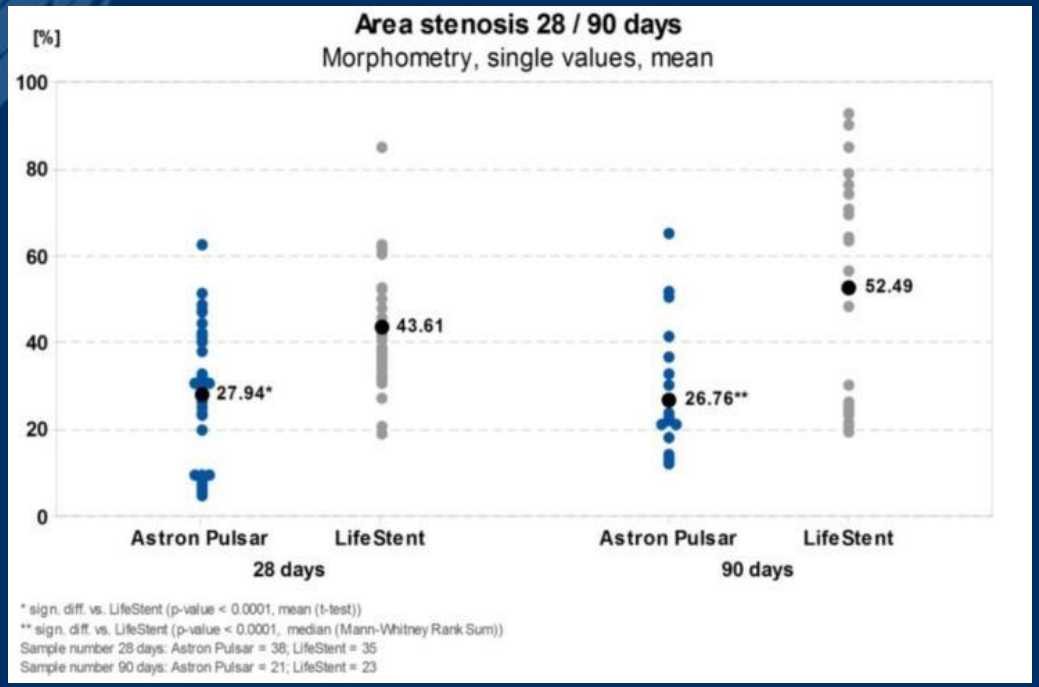
**LOW COF** stent shows significantly **smaller area stenosis** vs. **HIGH COF** stent

**28 days FUP**

Astron Pulsar
8.78mm²

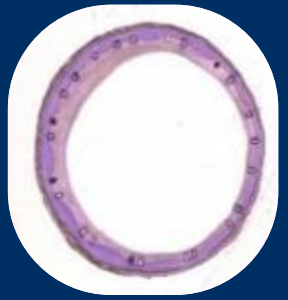
Lifestent
17.02mm²

## Area stenosis @ 28 and 90 days




**90 days FUP**

Astron Pulsar
6.9mm²



Lifestent
19.32mm²

Funovic M. Oral presentation at LINC 2017

# Pulsar shows long term durability with sufficient Radial Resisitive Force (RRF)

2011

2014


2011

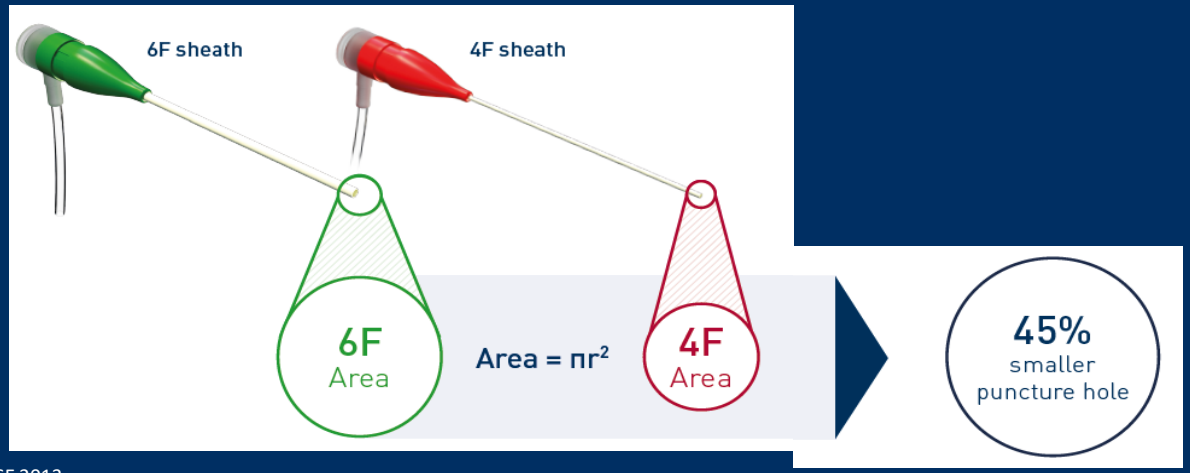
2016

Images curtesy of Prof van den Berg

# Pulsar-18 is less invasive 4F device

## Benefits of 4F intervention

| Patient | Physician |
|---|---|
| ▪ **Smaller puncture hole:**<br>▪ Less wound complications<br>▪ Day case intervention<br>▪ Vessel better preserved for future intervention | ▪ Technical success may be improved – low crossing profile<br>▪ Potential for reduced risk of distal thrombo-embolization -low crossing profile may reduce need for pre-dilation<br>▪ May permit Ambulatory treatment- potentially reducing hospital costs<br>▪ May reduce need for Vascular Closure Devices |




Source: 4EVER 24m CIRSE 2013

# Technical Success Rate

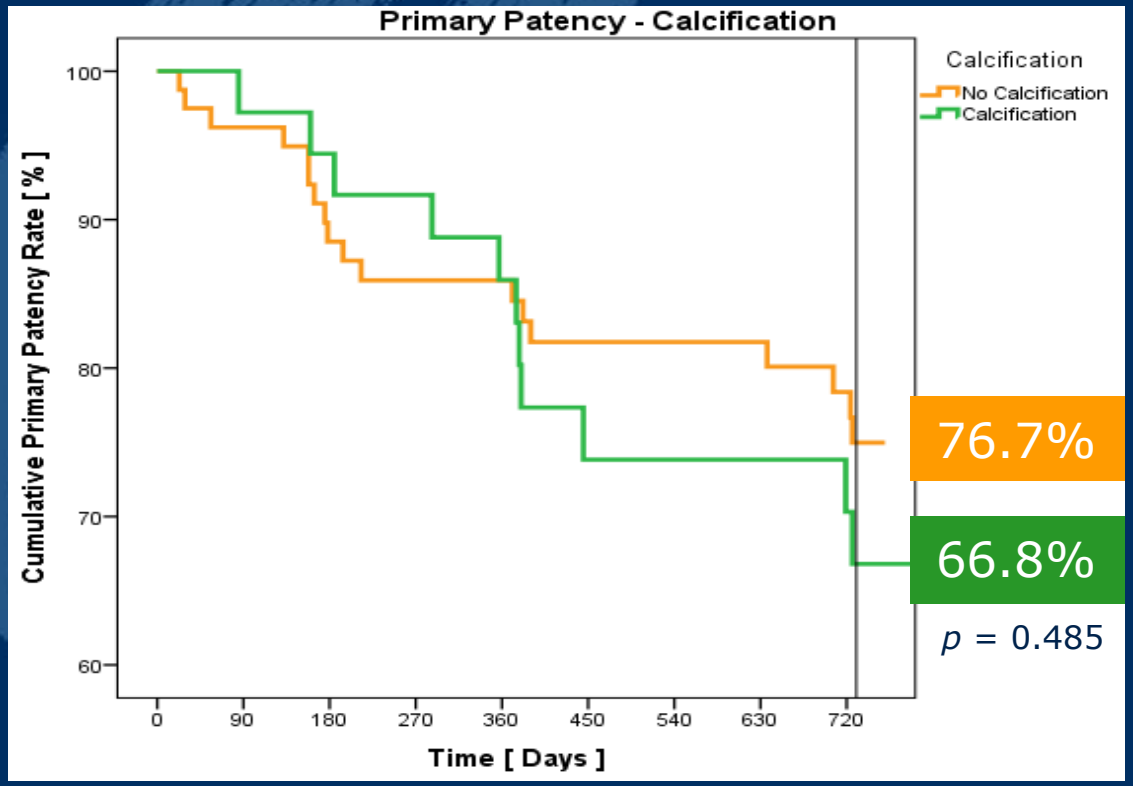
**Pulsar Clinical Studies: complex lesion rates**

| | |
|---|---|
| **4EVER[1]** | **100% technical success rate**<br>**31% calcified lesion** |
| **PEACE[2]** | **100% technical success rate**<br>**56.7% CTO** |
| **TASC D[3]** | **100% technical success rate**<br>**100% CTO**<br>**Long lesions – Long stents** |

Despite thin strut, low COF design, high technical success[4] can be achieved with Pulsar

1. Bosiers M. 4EVER, JEVT 2013;20:746–756 . 2. Lichtenberg M. PEACE 12m results, J ENDOVASC THER 2014;21:373–380 . 3. Lichtenberg M; TASC D,
- J. Cardiovasc Surg 2013; 54: 433-9 . 4. Technical success: defined as the ability to cross and stent the lesion and achieve angiographic residual stenosis,
- 30% and residual stenosis, 50% by duplex imaging

# Pulsar-18 in calcified lesions: 4EVER 24m results




| Patients at risk (n) | | |
|---|---|---|
| | **Baseline** | **24m** |
| **Calcification** | 37 | 27 |
| **No calcification** | 83 | 62 |

**Pulsar demonstrated a non-significant difference in long-term (24m) results in calcified vs. non-calcified arteries**

Source: Deloose K. Oral presentaion at LINC 2014. 4EVER Bosiers M. JEVT 2013;20:746–756.

# Pulsar-18 in patients with CLI TASC D 12m results

**DESIGN:**
Single Center, prospective registry,

22 patients

**PRINCIPAL INVESTIGATOR:**
Dr. M. Lichtenberg (Arnsberg, Germany)

**ENDPOINTS:**
Primary Patency (PP) at 6 and 12 months

Freedom from Target Lesion Revascularization (TLR) at 6 and 12 months

| Lesion Characteristics | N= 22 |
|---|---|
| Mean Ankle Brachial Index (ABI) | 0.44 ± 0.18 |
| Average lesion length | 24.5 cm (21.5 – 31.5 cm) |
| Chronic Total Occlusion | 100% |
| Sub-intimal recanalizations | 81.8% |
| Stent ration per patient | 2.4 |

| Results | 12 months |
|---|---|
| Primary Patency | 77% |
| Freedom from TLR | 86% |
| Mean ABI | 0.85 ± 0.2 |

Source: Lichtenberg M; J. Cardiovasc Surg 2013; 54: 433-9

# BIOFLEX PEACE - evaluating Pulsar in a real world setting

**DESIGN:**
**All-Comers registry. Prospective, multicenter, for the treatment of atherosclerotic disease of the femoropopliteal arteries using the 4F Pulsar-18 stent.**

**PRINCIPAL INVESTIGATOR:**
**Dr. M. Lichtenberg (Arnsberg, Germany)**

**PRIMARY ENDPOINT:**
**Primary Patency (PP) at 12 months**

**SECONDARY ENDPOINT:**

**Primary Patency at 6 & 24 months**

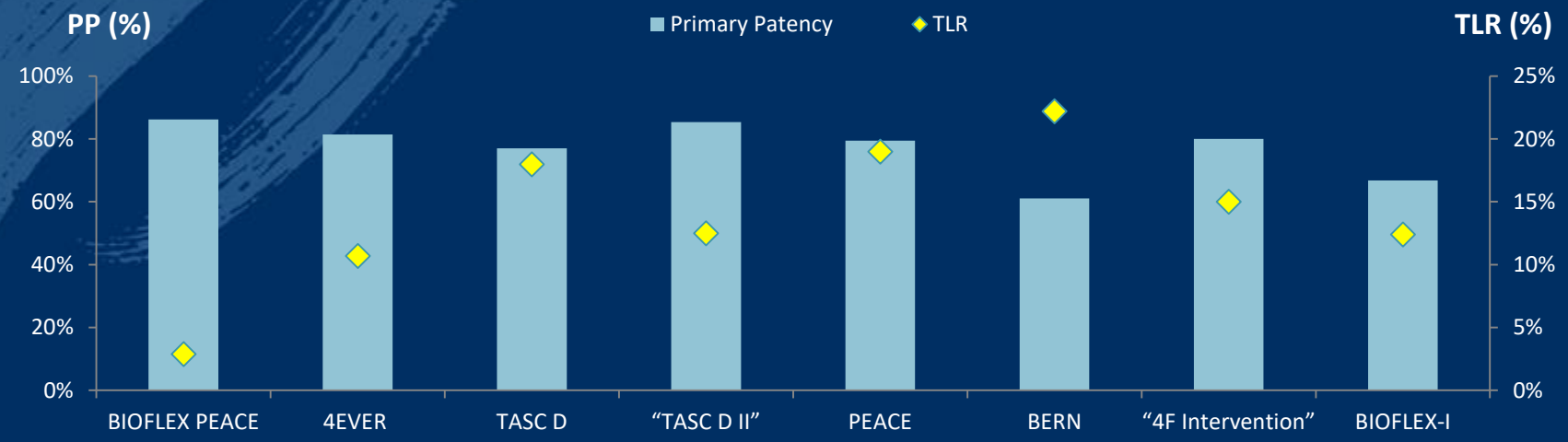
**Freedom from clinical driven Target Lesion Revascularization (cd-TLR) at 6, 12 & 24 months**

| Lesion Characteristics | N=160 |
|---|---|
| Lesion length, cm (mean ± SD) | 11.6 ± 10.3 |
| Mean ref. vessel diameter | 4.97 mm |
| Mean implanted stent diameter | 5.77 mm |
| TASC C | 34 (18.3%) |
| TASC D | 40 (21.5%) |

| Results | 24 months |
|---|---|
| Primary Patency | 78.0 % |
| Freedom from TLR | 92.4 % |

# Pulsar clinical results

| | Short/med lesions | Long lesions | Popliteal | Dissection | Occlusion | Low/Mod. Calcification | High Calcification | Adjunct to DCB |
|---|---|---|---|---|---|---|---|---|
| **Pulsar-18** | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ | ☑ |




| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| A.L.L. (cm) | 11.6 | 7.1 | 24.5 | 18.2 | 11.2 | 16.4 | 8 | 8.2 |

- Pulsar has demonstrated consistent clinical performance in several clinical studies.
- Results are consistent across a range of lesion lengths.

Source: BIOFLEX PEACE (interim). Lichtenberg M. Presented at CIRSE 2017. 4EVER Bosiers M. JEVT 2013;20:746–756; PEACE Lichtenberg M. JEVT, 2014, 21:373-380; BERN registry Baumann F. JCS 2012:52;475-80; TASC D registryLichtenberg M. JCS 2013: 54; 433-9; "TASC D II" registry Lichtenberg M. Clin Med Insights 2014: 8; 37-42; 4F intervention" Sarkadi H, Eur J Vasc Endovasc Surg (2015) 49, 199-204. US Food and Drug Administration, Center for Devices and Radiological Health. FDA Summary of Safety and Effectiveness Data – Astron Pulsar and Pulsar-18 Stent, P160025. www.fda.gov (accessed, May 5, 2017). Trial comparison is for illustration only.

# Conclusions

- Pulsar stent is specifically designed for the SFA treatment
- High multidirectional flexibility and low COF are given by very thin strut thickness and special stent design
- Pulsar as a low COF stent shows significantly smaller area stenosis then high COF LifeStent in animal study
- Pulsar shows long term durability with sufficient Radial Resisitive Force which has been demonstrated in several clinical studies
- Pulsar outcomes are consistent across a range of lesion lengths

# Applications and Evidence for minimally invasive stenting

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