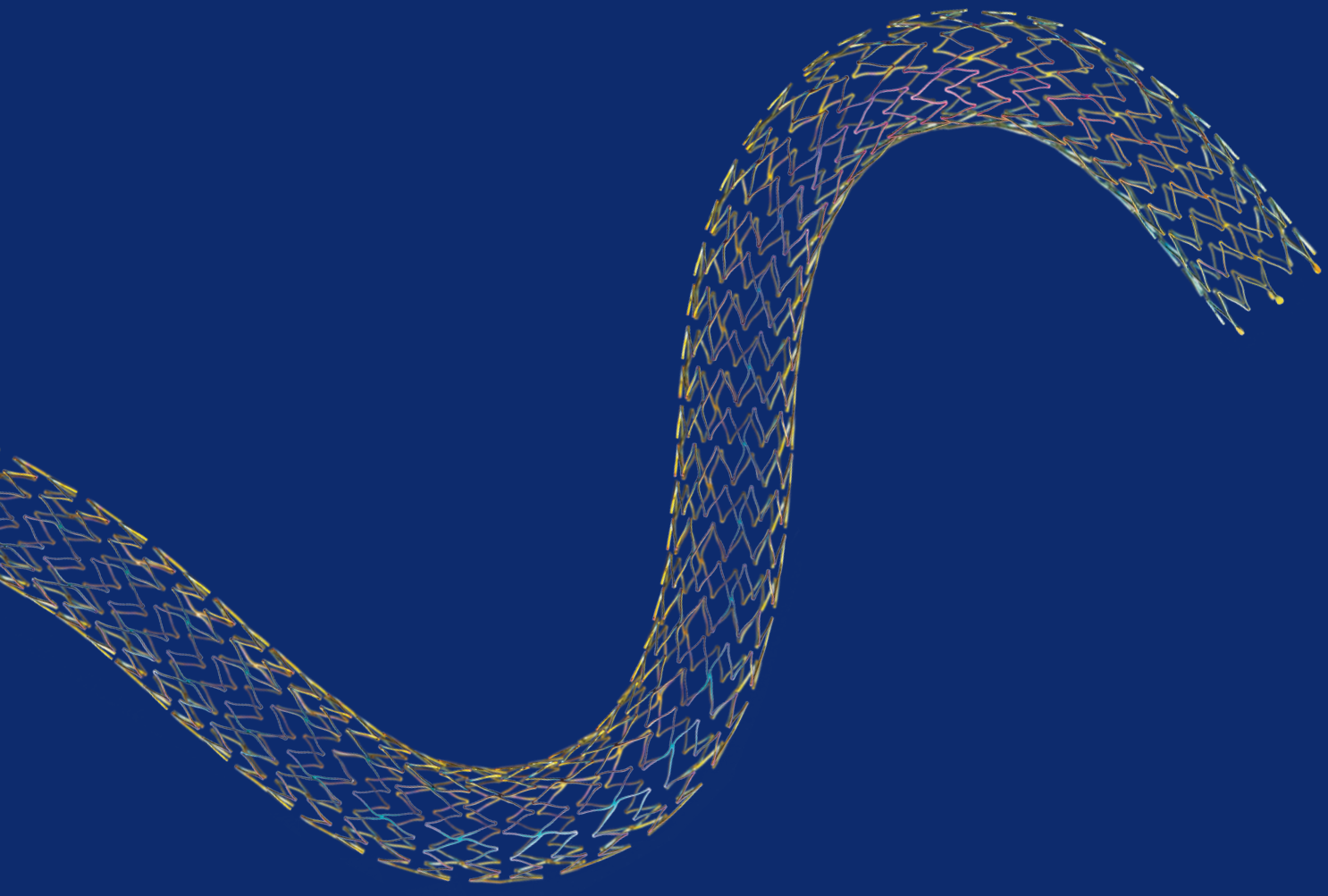
Teleflex™
Empowering the future of healthcare

Pulsar™

Self-Expanding Stent System

Thin struts, low chronic outward force (COF).

36-month results confirm the excellent
12- and 24-month outcomes of the Pulsar™ stent.

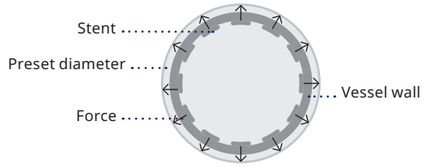


Thinner struts and low COF make a difference

140 µm thin struts – thinner than the leading brands[1]

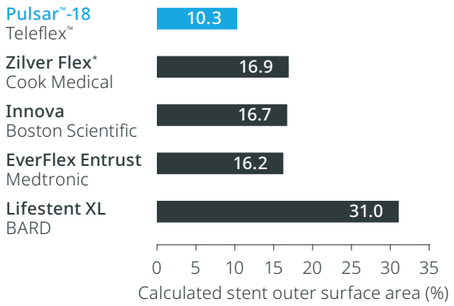
Chronic outward force (COF)

Chronic outward force (COF) is the force exerted on the vessel wall by a self-expanding (SE) stent to achieve its preset diameter.



SE Stent 1 mm oversized in vessel

Minimal metal burden[1]



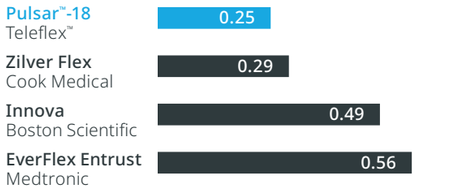
**Bare metal platform for Zilver PTX drug eluting stent*

Thinner struts for low chronic outward force (COF)[2]

With low COF the natural response of the body is much lower when compared to high COF stents**:

- less inflammation[3]
- less neointimal hyperplasia[3]
- lower risk of restenosis[3]

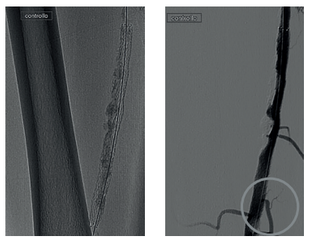
***As demonstrated in pre-clinical studies*



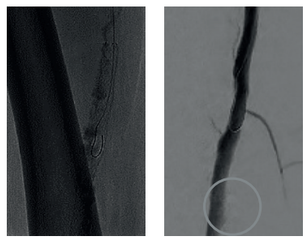
Sufficient radial force for long-term vessel support, even in calcified lesions

The following figure shows a fluoroscopic image after stent implantation (6 × 80 mm Pulsar™-18 in 2011) in a severely calcified lesion, with lack of full expansion of the stent in an area of focal calcification, and an angiographic residual stenosis of less than 30 % (circle; with a high COF stent the stress exerted on the vessel wall would be significant, potentially leading to neo-intimal hyperplasia).

A fluoroscopic image that was obtained 5 years later when the patient came back for treatment of an ipsilateral iliac lesion shows full expansion of the stent, and angiographically a full patency of the stented segment. This figure illustrates nicely the chronic impact of the Pulsar™ stent and its COF on long-term clinical outcome. With a constant low chronic outward force applied to the vessel, patency can be achieved and maintained over a long term follow-up.



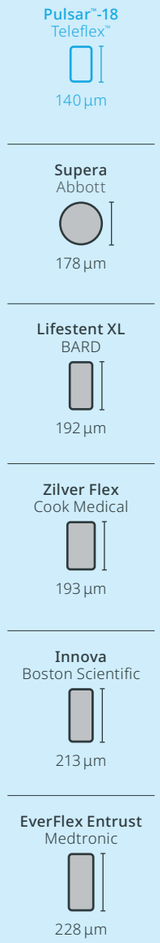
After the treatment 2011



2016

(Courtesy of Prof. van den Berg)

Stent strut thickness in perspective[1]

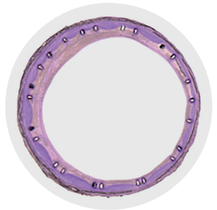


Benefits of low COF proven in animal studies

Stents with higher COF show more neointimal hyperplasia**

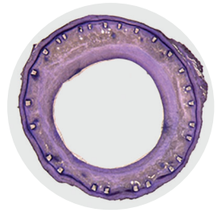
Pulsar™ stent causes less neointimal hyperplasia[4,**]

Pre-clinical study results indicate that the low COF Pulsar™ stent causes less neoinitmal hyperplasia at 90 days compared to the high COF Lifestent stent.



Pulsar™ Stent
Teleflex Low COF

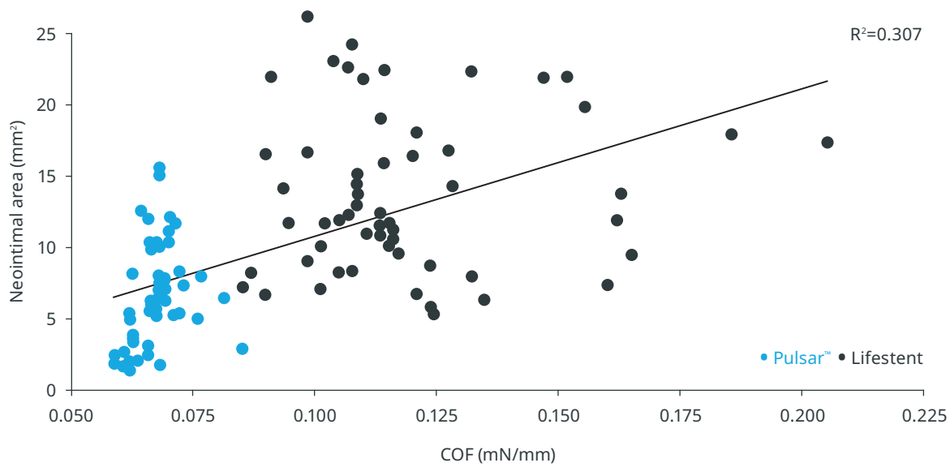
1 mm stent oversizing at 90 days



Lifestent XL
BARD High COF

Neointimal area vs. COF[3,**]

Stents with higher COF show more neointimal area.



Thinner struts and lower COF make a difference:**

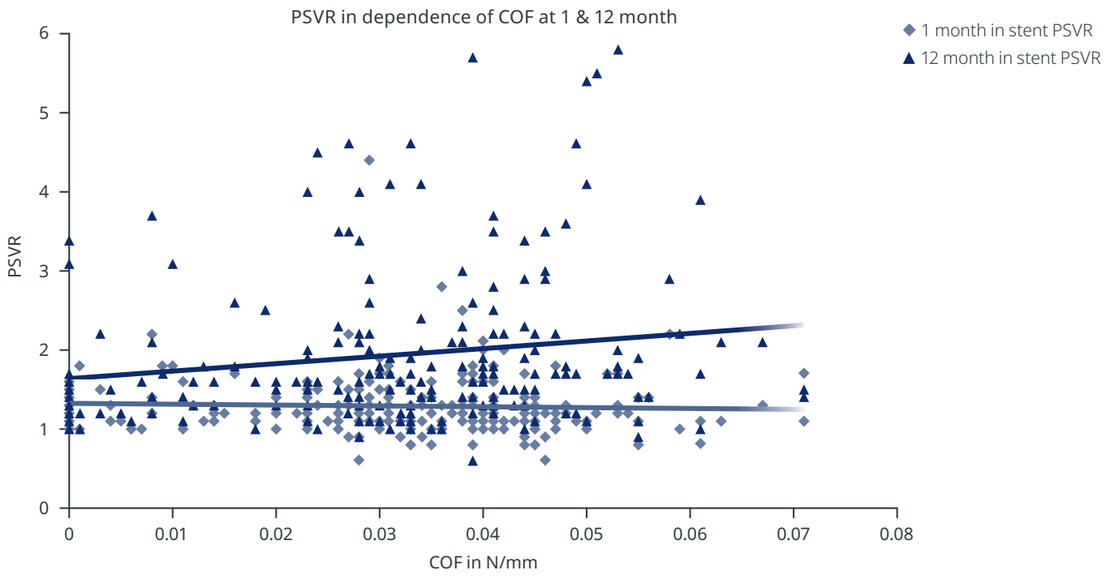
- Lower risk of restenosis[3]
- Reduced vessel injury and inflammation[3]
- Faster endothelialization[5,6]

***As demonstrated in pre-clinical studies*

Pre-clinical study results showed significantly smaller area stenosis, lower injury and inflammation scores for the Pulsar™ stent compared to the high COF stent Lifestent.**

Benefits of low COF shown in clinical study

BIOFLEX-I[7]: COF correlation to peak systolic velocity ratio (PSVR)



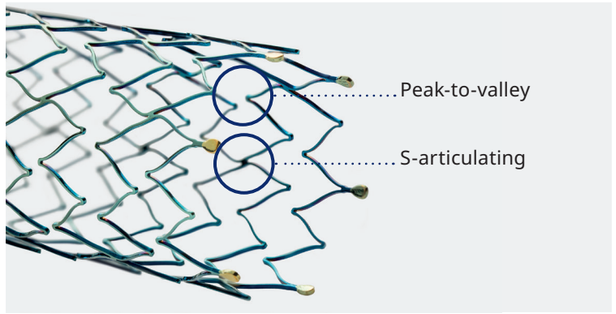
- At 1 month COF shows minimal impact on blood flow
- At 12 months blood flow worsens with the increasing COF

Conclusion
In the long term, vessel reaction on high COF might lead to a higher risk of restenosis.

Risk factors for increased PSVR

MODEL	SIG.
Radial outward force	0.024

COF was one of the most significant predictors for deterioration of PSVR.



Bending

Peak-to-valley design and S-articulating connecting bars provide multi-directional flexibility and avoid fish scaling in mobile vessel architecture.[1]

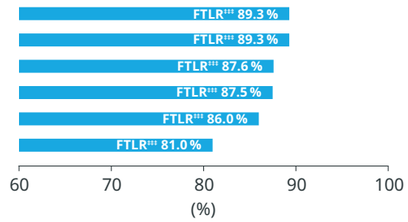
0.25 N/mm
low chronic outward force[2]

Clinical evidence

Low COF, thin struts – proven in extensive clinical program

Consistent 12-month outcomes across different lesion length

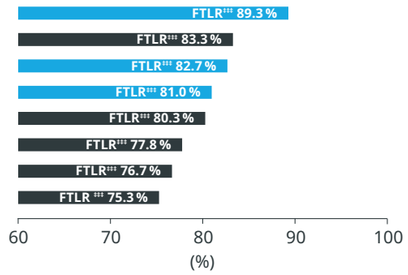
STUDY	PRODUCT	ALL[‡]	PP[‡‡]
BIOFLEX PEACE[8]	Pulsar™ (stent only)	8.2 cm	84.7 %
4EVER[9]	Pulsar™	7.1 cm	81.4 %
BIOFLEX-I[10]	Pulsar™	8.2 cm	70.6 %
TASC D II[11]	Pulsar™	18.2 cm	85.4 %
TASC D[12]	Pulsar™	24.5 cm	77.0 %
PEACE[13]	Pulsar™	11.2 cm	79.5 %



Excellent outcomes after 2 years

24-month data in perspective

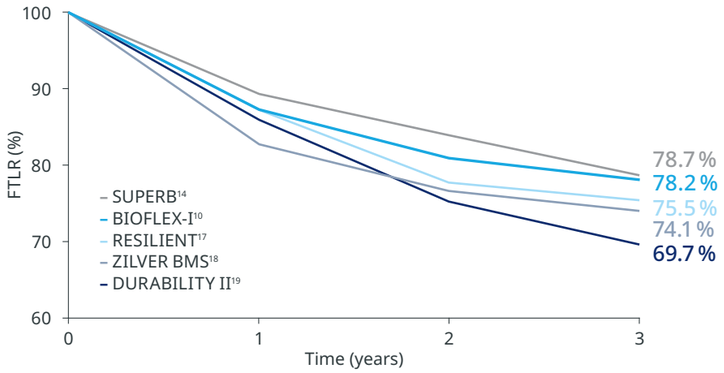
STUDY	PRODUCT	ALL[‡]	PP[‡‡]
BIOFLEX PEACE[8]	Pulsar™ (stent only)	8.2 cm	78.4 %
SUPERB[14]	Supera	7.8 cm	n/a
4EVER[15]	Pulsar™	7.1 cm	72.3 %
BIOFLEX-I[10]	Pulsar™	8.2 cm	n/a
STROLL[16]	S.M.A.R.T. Control	7.7 cm	74.9 %
RESILIENT[17]	Lifestent	7.0 cm	n/a
ZILVER PTX[18]	Zilver BMS provisional	6.3 cm	65.8 %
DURABILITY II[19]	EverFlex	10.9 cm	66.1 %



[‡]Average Lesion Length [‡‡]Primary Patency [‡‡‡]Freedom from Target Lesion Revascularization

Results from different trials are not directly comparable. Differences in outcomes may be the result of differences in protocol design, patient populations or other factors. Astron Pulsar™, Pulsar™-18, Pulsar™-18 T3 and Pulsar™-35 have equivalent stent platforms, therefore the clinical results are valid for the Pulsar™ range.

3-year outcomes in perspective



After 3-years fTLR is still in line with competitor bare metal stent studies.

Low COF – Less is more.

Pulsar™ stent's thin strut and low COF efficiency are proven throughout stable outcomes over the long term.

Key studies

Outcomes of key Teleflex studies

	TASC D[12]	4EVER[9]	BIOFLEX PEACE[8]	BIOFLEX-I[10]
STUDY	LONG AND OCCLUDED LESIONS IN HIGH RISK POPULATION	ENDOVASCULAR TREATMENT WITH 4F DEVICES	STENT ONLY GROUP	IDE-TRIAL
Selected Demographics	– 100 % CLI[§] patients – 72.7 % Diabetics – 100 % Occlusion	– 16.7 % CLI[§] patients – 35.8 % Diabetics – 20.8 % Occlusions	– 15.8 % CLI[§] patients – 40.0 % Diabetics – 76.7 % Smokers	– 40.7 % Diabetics – 30.1 % Total occlusion
Patient Number	22	120	60/160#	302
Average Lesion Length	24.5 cm	7.1 cm	8.2 cm	8.2 cm

	TASC D[12]	4EVER[9]	BIOFLEX PEACE[8]	BIOFLEX-I[10]
12-MONTH RESULTS				
Primary Patency	77.0 %	81.4 %	84.7 %	70.6 %
FTLR[‡‡‡]	86.0 %	89.3 %	89.3 %	87.6 %
Additional Outcomes	– Limb Salvage: 100 %	– Access site complication: 0.9 % (excludes patients on coumarin) – Mean Compression Time: 8.1 minutes	– Oversizing of 0.8 mm – 81.7 % Improvement of Rutherford classification	– Study results are similar to the results ofother US IDE trials

	TASC D[12]	4EVER[15]	BIOFLEX PEACE[8]	BIOFLEX-I[10]
24-MONTH RESULTS				
Primary Patency	n/a	72.3 %	78.4 %	n/a
FTLR[‡‡‡]	n/a	82.7 %	89.3 %	81.0 %
36-MONTH RESULTS				
FTLR[‡‡‡]	n/a	n/a	n/a	78.2 %

Key Messages	– Pulsar™ stent has shown excellent outcomes for long occluded lesions (100 % TASC D lesions) in TASC D study. – Pulsar™ stent has shown to reduce the risk of foot loss – Pulsar™ stent has shown its efficacy in a high risk patients population (Mean Rutherford class by 100 % CLI patients)	– Improved acute outcomes of 4F vs. 6F[†] – Less access site complication rates may permit ambulatory treatment – Shorter compression time with 4F compared to 6F – 30.8 % Calcification: No significant difference between calcified vs. non-calcified lesions at both 12 m and 24 m	– Pulsar™ stent is very efficient under All-comers condition – Pulsar™ stent shows excellent results in mixed population	– FDA approved – Pulsar™ stent systems are the only US SFA stents that are compatible with 4F sheaths[††] – The study results are similar to the results of other competitor stents for use in patients with femoropopliteal lesion – 36 m results confirm Pulsar™ stent safety and efficiency on the long term

[§]CLI–Critical Limb Ischemia [†]Less access site complications [††]when compared to leading US brands [‡‡‡]Freedom from Target Lesion Revascularization

References

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Refer to IFU

Refer to QR code for a copy of the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

About Teleflex

As a global provider of medical technologies, Teleflex is driven by our purpose to improve the health and quality of people's lives. Through our vision to become the most trusted partner in healthcare, we offer a diverse portfolio with solutions in the therapy areas of anesthesia, emergency medicine, interventional cardiology and radiology, surgical, vascular access, and urology. We believe that the potential of great people, purpose driven innovation, and world-class products can shape the future direction of healthcare.

Teleflex is the home of Arrow™, Barrigel™, Deknatel™, LMA™, Pilling™, QuikClot™, Rüsch™, UroLift™ and Weck™ – trusted brands united by a common sense of purpose.

At Teleflex, we are empowering the future of healthcare. For more information, please visit teleflex.com.

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