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LESS IS MORE

Maximizing results for SFA stenting.

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What Defines the Ideal Self-Expanding Stent for Lower Limb Interventions?

Optimal engineering to achieve optimal results.

BY KOEN R. DELOOSE, MD

Bare-metal stent (BMS) design and its clinical implications for treating infrainguinal peripheral artery disease have returned to the spotlight for a variety of reasons. One of the most notable is driven by the infamous Katsanos et al publication and the resulting questions surrounding paclitaxel-eluting devices.[1] Several authorities, scientific organizations, and professional societies are still advocating the avoidance of paclitaxel, making nondrug-based treatments particularly valuable. Regardless, for all interventionalists—both paclitaxel believers and nonbelievers alike—there is still a strong need for modern-generation stents to perform well in increasingly demanding clinical scenarios. In extreme calcium, lesions in highly flexible areas such as the superficial femoral and popliteal arteries, chronic total occlusions, and common femoral artery disease, an especially complex demand is placed on a BMS's mechanical performance. With renewed interest, the scientific community is looking to see if the clinical outcomes of these modern devices in these challenging scenarios are overruling the current gold standard.

THE EFFECTS OF STENT DESIGN PARAMETERS

The late complication of in-stent restenosis (ISR) is clearly the Achilles' heel of BMSs, especially in difficult anatomic and pathologic areas. This late healing phenomenon leads to loss of patent vessel lumen and recurrence of claudication and chronic limb-threatening ischemia symptoms. Target lesion revascularization is a logical sequence in this setting.

During the last decade, it became clear that ISR is associated with many self-expanding BMS design features, such as longer stent lengths, smaller stent diameters, nonadapted strut thicknesses, high metal-to-artery ratios, lack of flexibility, and suboptimal radial forces.[2]

Mechanical engineering is a science of compromise. Therefore, altering any single characteristic of a stent inevitably affects other properties. There is a very complex interaction between every feature of stent design and how the device behaves in clinical practice.[3]

Radial Forces

One potential predictor of good stent performance is an ideal amount and balance of the three radial forces: chronic outward force (COF), the radial force that a self-expanding stent exerts at expansion on the vessel wall; radial resistive force (RRF), the force the stent resists under circumferential compression; and crush resistance (CR), the force the stent resists under focal compression.[4-7] Influencing the programming of hysteresis curves of nitinol can influence the radial forces in one or another direction (Figure 1). Complex engineering techniques, such as programming the fully open stent diameter higher than the normal nominal diameter, can also manipulate the different radial forces of the device.

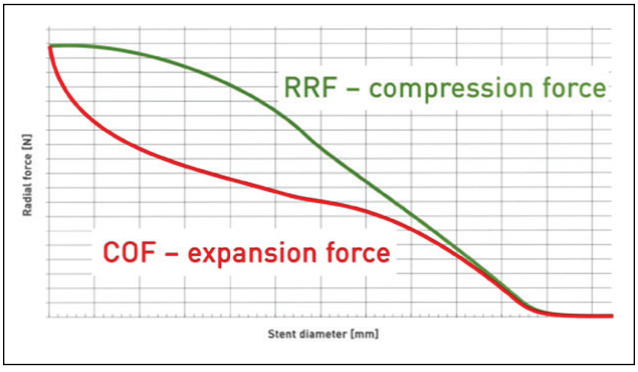

Figure 1. The programming of hysteresis curves can impact the expansion and compression forces of a stent.

Accomplishing the right amount of these forces is crucial. For example, on one hand, the COF needs to be high enough to restore the vessel lumen to near-normal diameter. On the other hand, too much COF (eg, from higher oversizing ratios) can cause a significant chronic increase in wall shear and structural stress to the arterial wall, inflammatory response, deep vascular injury with internal elastic lamina fracture, and finally, the development of myointimal hyperplasia. Animal studies have demonstrated the negative effect of too much COF on the occurrence of restenosis,[5,6] which is also supported by clinical evidence.[7,8]

Strut Thickness and Width

Strut thickness is defined as the wall thickness of the nitinol tube from which the stent is laser cut, while strut width is defined as the width of the struts that remain after the laser nitinol cutting process (Figure 2). Surface treatments such

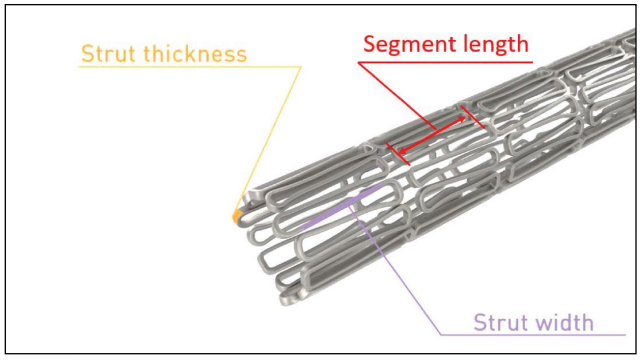

Figure 2. Strut thickness, segment length, and strut width are some of the most important influencers on COF.

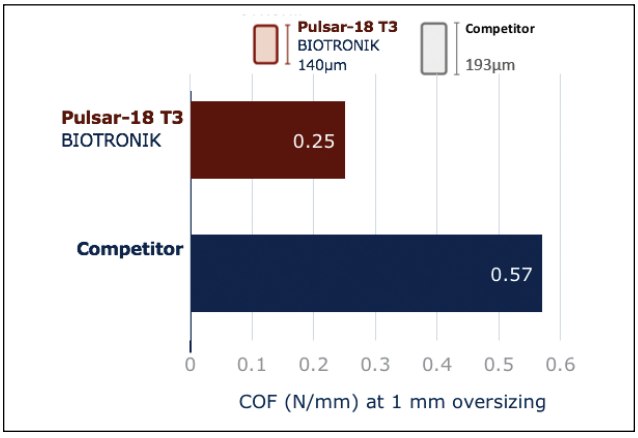

Figure 3. Thinner struts create lower COF. A comparison between the thin-strut Pulsar-18 T3 stent and a thick-strut competitor.

as cleaning and polishing may further decrease the final strut thickness and width.

If a stent is created with thin and small struts, such as the Pulsar®-18 T3* self-expanding stent (BIOTRONIK), the resulting COF will be sufficiently low. If the struts are large and thick, the stent will have extremely high COF. For example, the Pulsar-18 T3 stent with a 6-mm diameter has a strut thickness of 140 µm and creates a COF of 0.25 N/mm when it is 1-mm oversized.[9] A 6-mm competitor stent with a strut thickness of 193 µm creates a COF of 0.57 N/mm when 1-mm oversized (Figure 3).[9]

When struts are too thin and small, the RRF and CR will decrease tremendously and will be insufficient to prevent recoil and collapsing. If the struts are large and thick, the stent will be highly recoil resistant (circular or eccentric) but unfortunately will have extremely high COF, which can result in damage of the intima, inflammation, and neointimal hyperplasia.[5-8]

Strut thickness also plays a role in the development of the inflammatory response and injury to the internal elastic lamina: the thinner the struts, the less they induct trauma and inflammation.[10] Deep trauma in vessels with high plaque burden results in myointimal hyperplasia and earlier restenosis. Thinner struts provide greater stent flexibility, avoiding bigger flow disturbances and areas of high shear stress, while allowing for faster endothelialization.[9†]

TABLE 1. MECHANICAL ENGINEERING FACTORS' RESULTING INFLUENCE ON STENT FORCES

	Strut Thickness	Strut Width	Segment Length
Lower COF	↓	↓	↑
Higher RRF	↑	↑	↓
Higher CR	↑	↑	↓

NOTE: Arrow sizes correlate with degree of impact: the larger the arrow, the greater the influence.
Abbreviations: COF, chronic outward force; CR, crush resistance; RRF, radial resistive force.

Segment Length

Stent segment length, defined as the length from crown to crown (Figure 2), is determined by the stent design and programming of the laser cutting process. Segment length affects stent flexibility and the radial forces: the shorter the segment length, the lower the COF and vice versa.[10] The segment length is handling two directions, with an opposite effect on the different radial forces (Table 1).

DELIVERY SYSTEM PROFILE

Beyond the stent itself, the delivery system's profile will also have potential clinical impact. As was demonstrated by the 4EVER trial, a 4-F approach, as is possible with the low-profile Pulsar-18 T3 system, provides the potential for safer, faster, and simpler procedures compared to a 6-F approach, with lower access site complication rates and shorter compression time.[11] When comparing the puncture site size, a 4-F intervention will result in a 45% smaller puncture site when compared to that with 6-F sheaths (Figure 4). The mean compression time with a 4-F puncture of 8 minutes is about half the time needed after a 6-F intervention.[12]

As more lower limb interventions move to the outpatient setting, data support the use of 4-F devices to deliver an equivalent safety profile to that of the established 6-F devices, while eliminating the need for a vascular closure device.[13]

CONCLUSION

It is essential that endovascular specialists are intimately familiar with the stents' properties and corresponding pros and cons in order to select the correct one for the appropriate clinical situation. Understanding the biomechanical differences between stents is becoming more important as lesion complexity increases. Selecting the right device is the key to achieving a good clinical outcome for the patient. At the

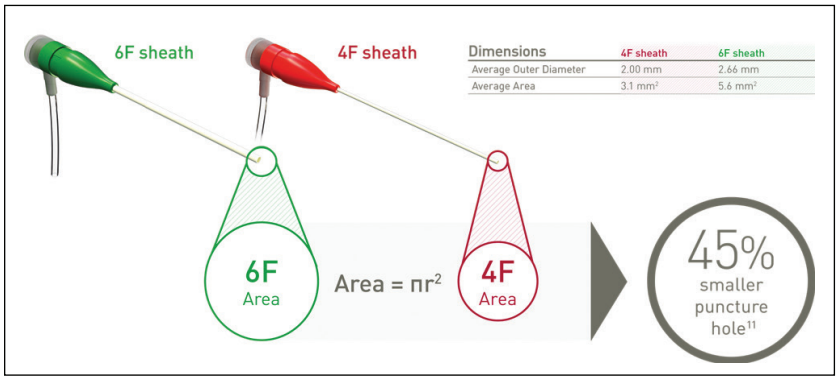

Figure 4. A 4-F intervention will result in a 45% smaller puncture size compared to 6-F devices.

same time, it is essential to compare apples with apples and randomize the best of classes to each other in well-designed head-to-head trials.

The evolution of stents' role in endovascular treatment of peripheral artery disease has resulted in a significant change in stent designs. Stent design is crucial for acute and long-term outcomes of our patients. Well-designed stent systems like the Pulsar-18 T3 stent, with minimal metal burden, low-profile sheath compatibility, and an appropriate balance of radial forces, will continue to demonstrate high primary patency rates and event-free follow-up consistent with the device's extensive clinical program in more than 1,000 patients.[7,8,11-22‡] ■

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*Also applicable to Pulsar-18, the predecessor of Pulsar-18 T3 that uses the same stent.
†As demonstrated in preclinical studies using comparable stents.
‡Some clinical data obtained with Astron Pulsar and Pulsar-18, predecessors of Pulsar-18 T3; stent of Pulsar-18 is identical compared to Pulsar-18 T3.

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How Does Stent Size Selection Play a Role in SFA Stenting Outcomes?

Findings from the BIOFLEX-I evaluation of COF.

BY MARIANNE BRODMANN, MD

A self-expanding stent's chronic outward force (COF) is dependent on the stent's design and materials, the structure of the lesion, as well as the implanted stent's selected size for the target vessel diameter. Self-expanding stents should generally be at least one size larger than the vessel diameter to ensure adequate contact with the vessel wall; however, the greater the size ratio, the more COF is exerted onto the vessel wall, which can result in

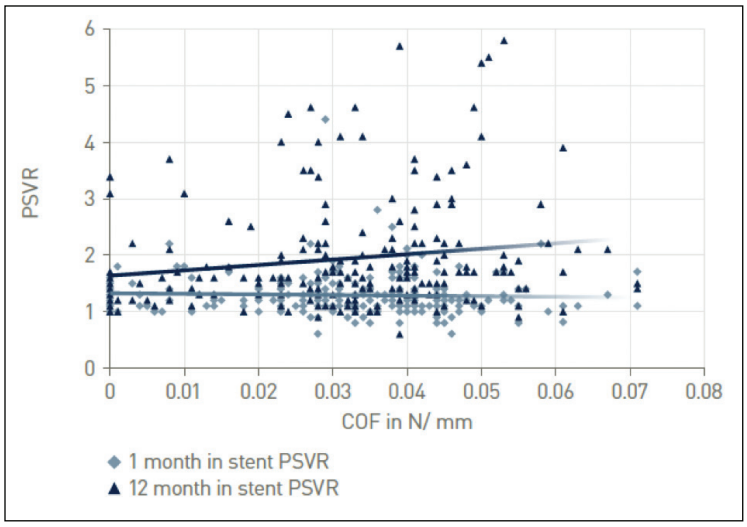

Figure 1. PSVR in dependence of COF at 1 and 12 months.

mechanical stress that may increase neointimal hyperplasia and restenosis.[1*] To evaluate the role of stent sizing and the resulting COF in clinical outcomes, a secondary evaluation was performed from a cohort of patients in the BIOFLEX-I study.[2]

BIOFLEX-I was a prospective, nonrandomized, multicenter, core lab–adjudicated study that evaluated the safety and efficacy of the Pulsar® self-expanding stent† (BIOTRONIK) in 302 patients with superficial femoral artery and proximal popliteal peripheral artery disease lesions. Duplex ultrasound was performed at 30-day and 6- and 12-month follow-up. These measurements were then used to do a secondary evaluation to explore the clinical impact of COF.

BIOFLEX-I EVALUATION OF COF

Available core lab–adjudicated angiographic imaging taken immediately after Pulsar stent implantation were analyzed to determine each individual vessel diameter and stent oversizing. Identified stent oversizing was then correlated with COF as measured in bench testing, and this determined amount of COF was correlated with measured peak systolic velocity ratio (PSVR) at 1, 6, and 12 months (Figure 1).

Pearson's correlation coefficient showed significance at 1 and 12 months (−0.196; $P = .008$). At 1 month, the PSVR was lower in those stents sized to exert greater COF; however, the sign of correlation was swapped at 12 months, with the lower COF stents showing lower PSVR. Thus, it was found that COF (in addition to smoking) was one of the most significant predictors for deterioration of PSVR ($P = .024$).

DISCUSSION

The data gathered from BIOFLEX-I show a trend that supports previous studies suggesting that oversizing can have a negative impact on clinical results. While theoretically it would seem likely that substantially increasing luminal diameter via oversized stent implantation would optimize outcomes, there has been a demonstrated threshold for when the resulting intramural stress from oversizing will trigger neointimal hyperplasia and subsequently may cause early restenosis.[3] Another study demonstrated that higher oversizing is associated with a significant increase in wall shear stress but resulted in no significant increase in luminal gain.[4] Particularly in calcified lesions, oversizing has been found to be associated with risk of tissue failure and is advised to be avoided.[5] The Zilver PTX global clinical program also showed that stent oversizing > 30% was a significant factor impacting target lesion revascularization ($P = .043$).[6]

CONCLUSION

As suggested by secondary evaluation from BIOFLEX-I, at 12 months, high COF appears to be a significant risk factor for restenosis (shown as high PSVR; $P = .024$). Long-term, low COF seems to result in less restenosis and potentially fewer reinterventions.[2] This should be considered when selecting size and stent for implantation in the lower limb to optimize the amount of exerted radial force; avoiding oversizing could potentially improve clinical outcomes.[3] The Pulsar stent, which has shallow expansion curves and low COF, has been associated with better outcomes compared to higher COF alternatives.[7] Further research is needed to clarify the relationship between stent forces, size selection, and clinical outcomes. ■

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*As demonstrated in preclinical studies using comparable stents.
†Clinical data obtained with Astron Pulsar and Pulsar-18, predecessors of Pulsar-18 T3; stent of Pulsar-18 is identical compared to Pulsar-18 T3.

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Comparison of High Versus Low Chronic Outward Force Nitinol Stents in the SFA

Clinical and preclinical data provide insight as to how mechanical forces impact outcomes.

BY PROF. MARTIN A. FUNOVICS, MD

The endovascular treatment of peripheral artery disease (PAD) in the superficial femoral artery (SFA) today offers several options that reflect astounding technologic advances and ingenuity. After plain balloon angioplasty came nitinol stents, stent grafts, drug-eluting stents, and more recently, drug-coated balloons, some in conjunction with various atherectomy devices. These devices have all been heralded at some point as safe, effective, and able to give better results compared with "previously published cohorts." However, given this plethora of options, surprisingly little high-quality evidence is available as to which method is in fact superior to another and how exactly and in which lesions or patients this benefit can be obtained.

Nitinol stents have been advocated as the therapy of choice in intermediate or longer SFA lesions, especially after failed plain or drug-coated balloon angioplasty. Thus, regardless of whether a primary or provisional use of stents is preferred, the nitinol stent in the SFA will remain a part of every endovascular armamentarium for the foreseeable future.

However, every implanted self-expanding stent will exert a continuous force onto the surrounding vessel wall, termed chronic outward force (COF), for the remainder of its functional life. COF can be made higher by choosing a larger stent size for a given vessel size and by choosing a stiffer stent that exerts a higher expansive force when implanted in a vessel even slightly below the stent's nominal diameter. Although high COF was previously thought to be beneficial to overcome external compression and stent collapse, there is now anecdotal evidence that too much COF triggers inflammation and neointimal proliferation in the vessel, leading to early restenosis and occlusion. This evidence is available in animal studies as well as in clinical subgroup analyses from past randomized controlled trials.[1-5]

PRECLINICAL DATA

To assess the effect of COF in an animal experiment, nitinol stents were implanted in the peripheral arteries in porcine models.[6] Either high-COF (LifeStent, BD Interventional) or low-COF stents (Astron® Pulsar®*, BIOTRONIK) were used. After 28 and 90 days, the treated arteries were histopathologically evaluated. In the high-COF group, neointimal area was significantly larger at both time points compared to the low-COF stent. Angiographic evaluation revealed a trend for lower lumen narrowing for the low-COF group at 28 and 90 days.

CLINICAL DATA

The aforementioned animal results have been partly confirmed in a retrospective analysis of patients who received de novo nitinol stent implantation and had an available follow-up CT 12 to 24 months after the index procedure (Funovics et al, unpublished data). A correlation between relative amount of stent oversizing and restenosis could be detected with a correlation coefficient (R^2) of 0.216 for male patients and 0.329 for female patients (Figure 1).

To further investigate the effect of COF on restenosis, the BIOFLEX-COF randomized controlled trial was designed to prospectively assess the influence of stent COF on patency at 1 and 2 years after implantation.

Patients with de novo SFA lesions were randomized in two groups. The high-COF group

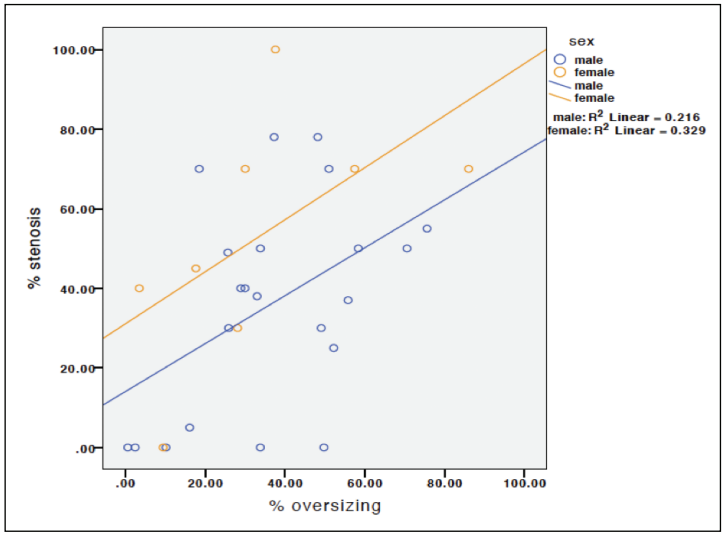

Figure 1. Correlation between stent oversizing and restenosis after 12 to 24 months in a retrospective data set of patients after de novo nitinol stent implantation in the SFA. The correlation coefficients for men (blue line) and women (brown line) are 0.216 and 0.329, respectively.

TABLE 1. STENT SIZE SELECTION BY VESSEL DIAMETER			
Vessel diameter	4.6-5.5 mm	5.6-6.5 mm	6.6-7.0 mm
Predilatation	4	5	6
Postdilatation	5	6	7
LifeStent size (high COF)	6	7	8
Pulsar-18 size (low COF)	5	6	7

received a LifeStent stent with generous oversizing, while the low-COF group received a Pulsar®-18 stent (BIOTRONIK) with minimal oversizing. In the high-COF group, the stents are not only stiffer but also sized approximately 1-mm larger at a given vessel diameter (Table 1). This was done to create the highest difference in COF to feasibly test the force's effect. The relation between COF and diameter of the stent is shown in Figure 2.

After implantation, the diameter of the implanted stent was measured at every millimeter along its longitudinal axis in two planes; from the curves shown in Figure 2, the COF could be calculated at every millimeter. The outcome variable is the amount of neointima in the stent measured at CTA after 1 and 2 years. Similarly, the in-stent restenosis is measured at every millimeter along the stent axis and the percentage of lumen loss is calculated (Figure 3).

A total of 89 patients are included in the study (high COF, n = 44; low COF, n = 45), and their demographics represent a typical cohort of PAD patients, with main comorbidities of diabetes (51% and 37%), smoking (58% and 43%), hypertension (88% and 98%), and hyperlipidemia (88% and 91%) in the high- and low-COF groups, respectively.

Mean lesion length was 127 and 167 mm in the high- and low-COF groups, respectively, and a second lesion was treated in three cases for each group. Occlusions were treated in 12 patients and 17 patients, with a mean length of 98 and 100 mm, respectively in the high- and low-COF groups.

The preliminary comparison of COF shows that the study could meet its technical goal in creating two groups of otherwise similar characteristics that differ markedly

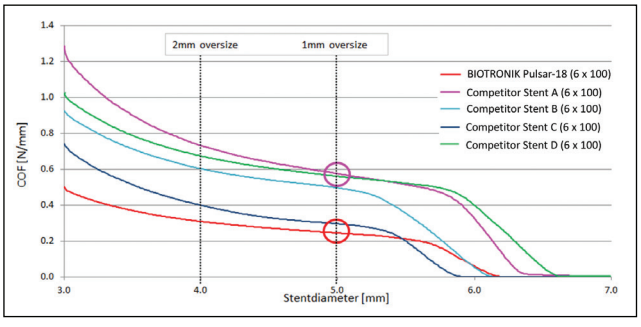

Figure 2. Relation between COF (N/mm, y axis) and stent diameter (mm, x axis) of Pulsar-18 and competitor stents.

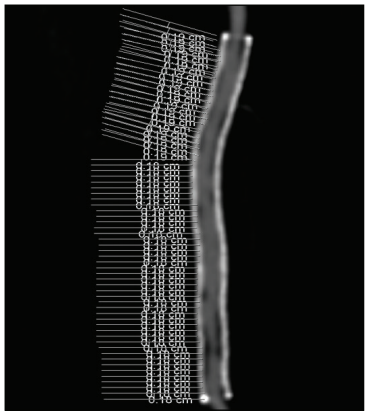

Figure 3. CTA (coronal reformation) of an implanted stent at 1-year follow-up. The bright white lines represent the stent surface, and the grey area inside the stent is the perfused lumen. Adjacent to the inner stent wall, there are black neointima formations that narrow the perfused lumen to a various extent.

in the stent COF.[7] While the high-COF group showed a median total COF of 55.69 N per patient, the low-COF group showed only 14.89 N, a 3.7-fold lower COF ($P < .001$). The preliminary results show lower restenosis in the low-COF group by a clinically relevant amount.

One-year results are expected to be published in the coming months, and we are confident that our approach to measure neointima on CTA will prove more sensitive in detecting early changes in lumen loss, even before clinical events are noted.

CONCLUSION

BIOFLEX-COF represents the first prospective randomized trial to assess COF of nitinol stents in the SFA, and we believe we will gain valuable insight as to which sizing and design can be recommended in the future of SFA stenting. ■

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*Data generated for Astron Pulsar and Pulsar-18; Astron Pulsar, Pulsar-18, Pulsar-18 T3 and Pulsar-35 have equivalent stent platforms; therefore, the preclinical and clinical results are valid for the Pulsar range.

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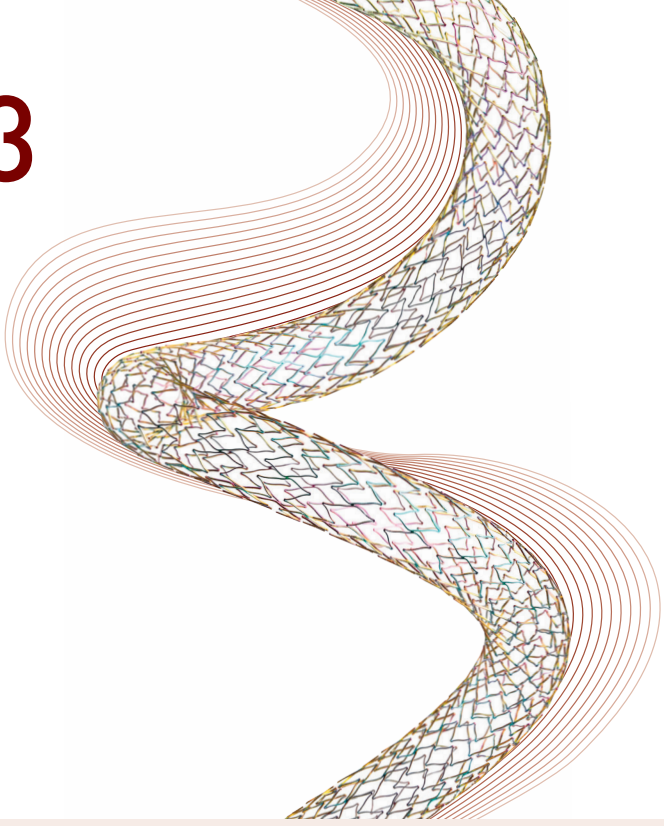
Self-Expanding Stent System

A unique combination of 3 technologies



TRI-AXIAL 1st 4F SYSTEM

4F

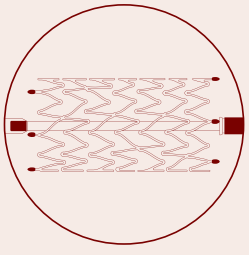
Low profile delivery system

Smaller puncture site area

45%
Smaller puncture site area vs. 6F[1]

Tri-axial system with braided shaft

Accurate stent deployment



Thin struts, low COF

Lower risk of restenosis[2,3]

89.3%
24-m FTLR BIOFLEX PEACE[4]

Easy to use, ergonomically designed handle.

1. BIOTRONIK data on file; 2. Zhao HQ. Late stent expansion and neointimal proliferation of oversized nitinol stents in peripheral arteries. Cardiovasc Intervent Radiol. 2009 Jul;32(4):720-6; 3. Funovics M._Differences in clinical outcomes of low COF stent vs high COF stent proven in clinical practice_BIOFLEX COF_CIRSE_Sep8_2019; 4.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. FTLR for stent only group. Clinical data obtained with Pulsar-18, a predecessor of Pulsar-18 T3 using the same stent.

FTLR=Freedom from Target Lesion Revascularization; COF=Chronic Outward Force.

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