Vascular Intervention // Peripheral Self-Expanding Stent System





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With more than 10,000¹ implantations of the Pulsar-18 T3 self-expanding stent system, physicians from around the globe shared their case experiences, highlighting why they choose Pulsar-18 T3 in their daily practice for both routine and challenging patient presentations.

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With 140 µm struts – thinner than leading brands² – there is minimal metal burden and an optimal amount of chronic outward force (COF), which is clinically proven to keep the vessel open while lowering the risk of restenosis.^{3,4}

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Thin struts, low COF

With 140 µm struts—thinner than leading brands² – there is minimal metal burden and an optimal amount of chronic outward force (COF), which is clinically proven to keep the vessel open while lowering the risk of restenosis.^{3,4}



- Lower risk of restenosis³
- Reduced vessel injury and inflammation³
- Faster endothelialization^{6,7}

*As demonstrated in pre-clinical studies

Thinner struts for lower COF⁸





Vessel response on SE stent 1 mm oversizing showing neointimal hyperplasia at 90 days⁹



BIOTRONIK

Low COF



Lifestent XL BARD High COF





Stenting 400 mm of SFA Dissection

Author

Gianluca Cangiano, MD, Resp. UOS Interventistica Vascolare, UOC Radiologia Vascolare e Interventistica, Cardarelli Hospital, Naples, Italy

1. Patient history

- A 62-year-old patient suffering from diabetes for 40 years and a previous fempop bypass presented with necrosis of the second, third and fourth toes of the right foot
- Stenosis of the external iliac, ostial occlusion of the superficial femoral artery (SFA) and bypass, popliteal infiltration, occlusion of the anterior and posterior tibial, and peroneal and plantar arteries was confirmed (Figures 1-3)





Fig. 2



Fig. 1

Fig. 4

Fig. 6

Fig. 3

2. Procedure description

- Recanalization of the iliac artery was performed with standard PTA and stenting
- Subintimal crossing of SFA occlusion with re-entry point at the popliteal level (Figure 4)
- Angioplasty with 3 x 150 mm balloon for successful recanalization of the tibioperoneal trunk and peroneal artery
- SFA pre-dilation with 5 x 150 mm balloon
- Severe dissection visible along the full SFA (Figure 5)
- Full stenting of the SFA with two 5 x 200 mm Pulsar®-18 T3 stents to cover the long dissection





Fig. 5b



- Pulsar-18 T3 was chosen for its 200 mm length availability, flexibility, and thin-strut design to minimize metal burden despite the large amount of scaffolding needed to support the artery (Figures 6-9)
- Despite the long 200 mm length, stent could be placed precisely ending proximally right at the ostium to the SFA
- At 6 month follow-up, the artery was fully open on duplex ultrasound

"When implanting long stent lengths, Pulsar 18-T3 is an optimal choice due to its minimal metal burden and precise placement."

Gianluca Cangiano, MD, Resp. UOS Interventistica Vascolare, UOC Radiologia Vascolare e Interventistica, Cardarelli Hospital, Naples, Italy



Fig. 7







Stenting of 35 cm Femoropopliteal Total Occlusion for CLI

Author

Gianluca Cangiano, MD, Resp. UOS Interventistica Vascolare, UOC Radiologia Vascolare e Interventistica, Cardarelli Hospital, Naples, Italy

1. Patient history

• An 83-year-old patient suffering from persistent atrial fibrillation (treated with coumadin), hypertensive cardiomyopathy and previous stroke presented with critical limb ischemia (CLI) and recent infection at the level of the left heel

2. Procedure description

- Antegrade femoral access achieved with short 5F introducer sheath
- Occlusion of the proximal superficial femoral artery (SFA), popliteal and below-the-knee (BTK) arteries (Figures 1-3)
- Extremely late filling of posterior tibialis (10 sec without use of image subtraction) (Figure 4)
- Antegrade lesion crossing and preparation performed using 4 x 80 mm and 5 x 150 mm Passeo®-18 balloon
- The post-PTA result showed that, despite the initial angiography findings, not all the lower artery lesions were real total occlusions, but instead were likely the result of a thromboembolic event that occurred over an atheromatous plaque (atrial fibrillation patient), thus causing the rapid clinical worsening (heel necrosis)
- Multiple dissections required stenting of femoropoliteal arteries (Figures 5-6)
- Two Pulsar®-18 T3 self-expanding stents were placed, one 5 x 200 mm and one 6 x 150 mm (Figures 7-8)
- BTK arteries did not require angioplasty and showed nice blood flow to the foot after SFA stenting



3. Final result

• Final angioplasty showed nice flow into the BTK and pedal arteries (Figures 9-10)







Total Occlusion of Proximal Popliteal

Author

Luis Carlos Silva Corten, MD; Vincent Scavee, MD; Jean-Paul Haxhe, MD, Clinique Saint-Pierre, Ottignies-Louvain-La-Neuve, Belgium

1. Patient history

• A 66-year-old man with a history of multiple vascular interventions of both legs presented with complaints of left-side claudication, which progressed to severe ischemic rest pain (Rutherford 5), and some pressure points on the foot were at risk of developing wounds

2. Procedure description

- CT angiography showed a short proximal popliteal occlusion in the left leg (Figure 1)
- Anterograde puncture was performed, but due to inguinal fibrosis it was not possible to introduce a 4F sheath
- A small access to the fibrotic tissue was required to place a heavier 6F sheath
- Easy lesion crossing and pre-dilation was performed with a 5 x 60 mm Passeo®-18 balloon (Figure 2)
- Control angiography still showed some recoil (Figure 3)
- A 5 x 40 mm **Pulsar®-18 T3** was deployed over the culprit lesion (Figure 4) and post-dilatated with a 5 mm balloon (Figure 5)
- Final angiography showed a nicely corrected caliber of the popliteal artery and good runoff (known posterior tibial artery disease) (Figure 6)











Fig. 5





3. Final results

- Immediately post-operatively, dorsalis pedis pulsations were restored and the pain was relieved
- The patient was able to leave the hospital the next day

"We chose the **Pulsar-18 T3** stent as a strategy to treat the culprit site because of its nice flexibility and acceptable outward force in the femoropopliteal position.

Furthermore, **Pulsar-18 T3** is generally preferred because of its possibility to keep the puncture size as small as possible."

Luis Carlos Silva Corten, MD; Vincent Scavee, MD; Jean-Paul Haxhe, MD, Clinique Saint-Pierre, Ottignies-Louvain-La-Neuve, Belgium



Thin-Strut Stenting for a Calcified SFA Total Occlusion

Author

Jordi Villalba Aunon, MD; Josep María Romero, MD, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain

1. Patient history

- A 67-year-old man with moderate claudication of the left leg was admitted to the angiology department with complaints of pain in his left thigh at 100 meters
- Risk factors included smoking, hypertension, hypercholesterolemia and hyperlipoproteinemia
- Duplex ultrasound demonstrated a high-grade stenosis from the mid-distal superficial femoral artery (SFA) to the P1 segment of the popliteal artery
- Ankle-brachial index (ABI) was 0.64 on the left side, and no wounds were present

2. Procedure description

- Diagnostic angiography confirmed a total occlusion of the SFA from the origin to the P1 segment (Figures 1 and 2)
- Crossover was performed with a 5F Fortress[®] reinforced introducer sheath
- After several attempts, an 0.018" guidewire crossed the lesion with some difficulty due to the high calcium burden in some areas
- Pre-dilatation was performed with a 6 x 170 mm Passeo®-18 balloon (3 minutes at 9 atm) over the entire length of the lesion (Figure 3), followed by placement of a 6 x 200 mm Pulsar®-18 T3 self-expanding stent
- Angiography revealed residual stenosis, so postdilatation was performed with a 6 x 40 mm **Passeo-18** to 12 atm at different levels of the stent





Fig. 1

Fig. 2



Fig. 3

3. Final result

- After **Pulsar-18 T3** implantation, rapid flow was seen through the full length of the left SFA with direct flow to the popliteal arteries (Figure 4)
- The next day, ABI was 0.9 on the left side and there was a significant improvement in pain-free walking distance



"The low profile design and crossing profile of the **Pulsar-18 T3** stent system offers excellent delivery. Despite the thin 140 µm struts, the stent has great radial strength and offers excellent flexibility and adaptation to the lesion." Jordi Villalba Auñón, MD, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain



Tri-axial system with braided shaft

The outer stabilizing shaft isolates the retractable shaft from friction caused by the introducer valve, ensuring accurate stent deployment.

Accurate stent deployment

The outer stabilizing shaft isolates the retractable shaft from friction caused by the introducer valve to ensure accurate stent deployment.







Stenting Total Occlusion of the SFA

Author

Gianluca Cangiano, MD, Resp. UOS Interventistica Vascolare, UOC Radiologia Vascolare e Interventistica, Cardarelli Hospital, Naples, Italy

1. Patient history

• A 55-year-old patient with previously implanted nitinol stent in the proximal popliteal

2. Procedure description

- Upon presentation, there was a total occlusion of the superficial femoral artery (SFA) from the ostium to the distal occluded stent (Figures 1-2), with no visible SFA stump and poor runoff to the foot (Figure 3) with additional occlusions in the posterior tibial, peroneal, and plantar arteries
- Antegrade access was achieved via the femoral artery
- Angioplasty was performed over the entire length of the SFA with incrementally increasing balloon diameters, which resulted in a dissection at the ostium of the SFA (Figure 4, arrow)
- The SFA was stented with a 6 x 200 mm **Pulsar®-18 T3** self-expanding stent, which positioned perfectly despite the difficult positioning needed at the ostium (Figure 5)





Fig. 1

Fig. 2



Fig. 3



Fig. 4

Fig. 5



3. Final results

• After additional angioplasty in the below-the-knee vessels, completion angiography showed excellent runoff to the foot (Figure 6)

Precise Stenting at the Ostium

Author

Gianluca Cangiano, MD, Resp. UOS Interventistica Vascolare, UOC Radiologia Vascolare e Interventistica, Cardarelli Hospital, Naples, Italy

1. Patient history

- A 71-year-old diabetic patient presented with a calcified total occlusion of the superficial femoral artery (SFA) all the way from the ostium, with no available stump
- Imaging was misleading, with the appearance of a duplicate deep femoral artery (Figure 1)



Fig. 1

3. Final results

• After post-dilation with Passeo-18 (5 mm) result shows a good runoff below-the-knee (Figure 7)





2. Procedure description

- Crossover antegrade lesion crossing was impossible due to the highly calcified occlusion, so retrograde recanalization was performed, which resulted in a slight improvement to SFA flow (Figure 2)
- A distal puncture was performed at the distal SFA with a micropuncture access set (21 G, 7 cm needle; Cook Medical)
- Retrograde crossing was successful with Command ES Hi-Torque (Abbott) and additional support of a support catheter
- Subintimal rendez-vous into the antegrade 5F diagnostic catheter
- Angioplasty was performed via an antegrade approach with incrementally increasing balloon diameters (Figure 4)
- A dissection occurred at the ostium, most likely caused by the subintimal rendez-vous (Figure 5, arrow)
- A 6 x 120 mm **Pulsar®-18 T3** self-expanding stent was placed precisely at the ostium (Figure 6, markers)





Fig. 4

Fig. 2











Low-Profile Crossing and Stenting of a Long SFA Occlusion

Author

Michael Lichtenberg, MD, FESC, Arnsberg Vascular Center, Arnsberg, Germany

1. Patient history

• A 78-year-old man presented with severe claudication of the right leg, and imaging revealed a 30-cm-long occlusion of the superficial femoral artery (SFA) from the origin to the popliteal segment 1 (Figure 1)



- A crossover approach from the left groin was performed using a 6 F crossover **Fortress**® reinforced introducer sheath
- The flush occlusion of the SFA was penetrated with a guidewire and Carnelian[®] Support 18 microcatheter, followed by pre-dilatation and drug-coated balloon angioplasty (Figure 2)
- A persistent long type C dissection was revealed, so a 6 x 150 mm **Pulsar®-18 T3** self-expanding stent was placed (Figure 3)

3. Final results

• Final angiography showed brisk flow within the full length of the target lesion and into the foot via the patent posterior tibial artery (Figure 4)









Fig. 2





Precise Stenting for a Long Occlusion

Author

João Albuguerque e Castro, MD, Angiology and Vascular Surgery Department, Hospital CUF Descobertas, Lisboa, Portugal

1. Patient history

- A 66-year-old postman with severe claudication of both legs admitted with complaints of pain in both thighs after < 30 meters
- Cardiac risk factors included previous smoking habit, hypertension, dyslipidemia and a minor stroke 1 year prior
- Duplex ultrasound revealed a long occlusion of the last third of the left superficial femoral artery (SFA) and a stenotic preocclusive lesion of the right popliteal artery; CT angiography confirmed both lesions
- No wounds were present on either extremity

2. Procedure description

- For recanalization of the left side (Figure 1), crossover was performed via right femoral artery access using a pigtail catheter over a 0.035" Glidewire (Terumo) and a 6F Fortress® reinforced introducer sheath
- A stiff 300 cm guidewire and an angled NaviCross 0.035" support catheter (Terumo) passed the left SFA occlusion • Lesion preparation was performed with a 5 x 150 mm Passeo®-35 Xeo angioplasty balloon inflated at 10 atm for
- 3 minutes over the length of the lesion, noting outstanding crossing capacity and deflation time
- Angiography revealed residual stenosis and a mild dissection (Figure 2), so bailout stenting was performed with a 6 x 150 mm Pulsar®-18 T3 self-expanding stent, which tracked easily to the target lesion and was precisely implanted (Figure 3)
- Post-dilatation was performed using a 6 x 150 mm Passeo®-18 balloon to achieve full stent expansion
- On the right side, after accessing via the left femoral artery with a crossover technique, the lesion was treated with a Passeo-18 angioplasty balloon followed by a 5 x 120 mm Passeo®-18 Lux® drug-coated balloon (DCB) with an excellent angiographic result (Figure 4)
- Both puncture holes were closed with Angio-Seal (Terumo)



Fig. 1



Fig. 2





Fig. 4

3. Final results

- After Pulsar-18 T3 implantation, brisk flow was seen within the full length of the target lesion and there was straight flow into the left popliteal artery (Figure 5)
- The Passeo-18 Lux DCB strategy was also very effective, with brisk flow seen within the full length of the target lesion and straight flow to the right tibial-peroneal trunk
- The next day, there were pedal pulses on both sides and a significant improvement in pain-free walking distance with no pain in the target limbs







Low profile delivery system

The 4F low profile improves acute outcomes, with the potential for safer, faster and simpler procedures compared to 6F.⁵

4F low profile - improved acute outcomes* vs. 6F⁵

Potential for safer, faster and simpler procedures than 6F

- Clinically proven lower access site complication rates⁵
- Shorter compression time⁵
- 45% smaller puncture site than 6F¹
- No need for a closure device⁵
- Potential for ambulatory treatment



4F access – who may benefit?^{5,10}

Patient

Smaller puncture hole means:

- Less wound complications
- Day case intervention
- Vessel preservation for future intervention

Physician

- Technical success may be improved low crossing profile
- Potential for reduced risk of distal thrombo-embolization due to low crossing profile
- May permit ambulatory treatment potentially reducing hospital costs
- May reduce need for Vascular Closure Devices

Smaller puncture hole reducing access site complications.⁴



Direct Stenting of a Pre-Occlusive SFA Stenosis

Author

Giorgio Loreni, MD; Marco Doddi, MD; Germano Scevola, MD, UOSD Radiologia Interventistica, Pertini Hospital, Rome, Italy

1. Patient history

• A 78-year-old woman with a history of cardiovascular disease, type 2 diabetes mellitus and hyperlipidemia presented with rest pain and an acral ulcer of the right toe, which hadn't healed for 6 months

2. Procedure description

- Pre-procedural imaging showed a pre-occlusive superficial femoral artery (SFA) stenosis caused by unstable fibrous plaque (Figure 1)
- A 4-F antegrade approach was used to provide pushability, control and low-profile lesion crossing without the need for pre-dilatation
- Direct stenting was performed to reduce the risk of distal plaque embolization and protect the downstream circulation
 A 6 x 80 mm Pulsar®-18 T3 self-expanding stent was selected for its very low profile and easy and accurate placement
- with the simple delivery system (Figure 2) • After postdilation of the start, final application control showed complete lesion recapalization with direct flow to the
- After postdilation of the stent, final angiographic control showed complete lesion recanalization with direct flow to the below-the-knee vessels and no elastic recoil (Figure 3)





Fig. 1

Fig. 2



3. Final results

• The patient experienced immediate pain relief

"The **Pulsar 18-T3** stent is preferred thanks to a very low profile and precise release. **Pulsar-18 T3** is a stent with an excellent profile, compatible with a 4F sheath. In our experience, the delivery system is simple, and the wide range in stent diameters and lengths offers many solutions for all kinds of SFA, proximal popliteal, and infrapopliteal lesions."

Giorgio Loreni, MD; Marco Doddi, MD; Germano Scevola, MD, UOSD Radiologia Interventistica Pertini Hospital, Rome, Italy



4F Stenting of Long Femoral Artery Total Occlusion

Author

Eszter M. Végh, MD, PhD, Cardiovascular Center, Bács-Kiskun Country Hospital, Kecskemét, Hungary

1. Patient history

- A 62-year-old man with a history of hypertension and multiple previous interventions including thrombolysis, bypass, stenting and angioplasty in both legs
- Presented with progressing claudication of the left leg, and a long occlusion of the left femoral artery was diagnosed (Figure 1)







- Crossover catheterization was to be avoided because of the presence of an elongated aortobifemoral graft
- Ipsilateral femoral puncture was not possible because of the total occlusion of the femoral artery
- A transtibial approach was selected via the distal anterior tibial artery
- After balloon dilation, the new lumen was still insufficient, and stenting was necessary (Figure 2)
- Because of the slender sheath in the tibial artery, exchange for 6F was not an option
- A 4F **Pulsar®-18 T3** was successfully implanted (Figure 3), postdilated and resulted in a good outflow

3. Final results

- Very good outflow and runoff to the tibial arteries (Figure 4)
- Strict follow up is planned





Fig. 2







4F Treatment of Multiple SFA Stenoses and Recurrent CLI

Author

Luis Mariano Palena, MD; Marco Manzi, MD, Interventional Radiology Unit, Foot & Ankle Clinic, Policlinico Abano Terme, Abano Terme (PD), Italy

1. Patient history

• A 77-year-old man presented with recurrent critical limb ischemia (CLI) and a history of diabetes, hypertension, dyslipidemia, chronic renal failure and a previous transmetatarsal amputation that was not healing

2. Procedure description

- Imaging revealed multiple stenoses in the superficial femoral artery (SFA), including a medium occlusion in the distal SFA, heavy calcification and a Texas University class 3D lesion in the previous amputation (Figure 1)
- Antegrade access was achieved via the common femoral artery, and balloon angioplasty was performed with gradual increasing of balloon diameters and pressures
- Due to the calcification, unmodified plaque, recoiling and dissections remained, so three **Pulsar®-18 T3** self-expanding stents were placed (two 7 x 150 mm, one 7 x 100 mm) due to the 4F low profile, minimal metal burden and precise tri-axial deployment (Figure 2)

• After postdilatation, the stent performed very well even

in the curved area of the vessel (Figure 3)





Fig. 1

Fig. 2





3. Final results



Redo Stenting With Pulsar-18 T3 in Previous SFA Spot Stenting

Author

Nicola Troisi, MD, Department of Surgery, Vascular and Endovascular Surgery Unit, San Giovanni di Dio Hospital, Florence, Italy

1. Patient history

- A 55-year-old man suffering from recurrent critical limb ischemia (CLI) in the left lower limb
- Heavy smoker (40 cigarettes a day for 30 years), coronary artery disease, insulin-dependent diabetes and previous hemodialysis treatment
- Ten months before presenting again, the patient underwent recanalization with paclitaxel-coated balloon angioplasty and spot stenting of left superficial femoral artery (SFA) with 6F antegrade approach
- Clinical examination revealed the absence of popliteal and tibial femoral pulses
- Duplex scan showed severe restenosis of left SFA

2. Procedure description

- Open surgical bypass was considered, but a redo endovascular approach was chosen because of the high-level comorbidities
- Antegrade ultrasound-guided puncture of left SFA (ostium) was performed and a 4F, 11 cm sheath was placed
- Preoperative angiograms showed a tight tandem restenosis immediately below two short previously placed 6 mm stents, as well as a long occlusion of the anterior tibial artery (ATA) (Figure 1)
- After crossing the SFA and ATA with a 0.018" 300 cm V-18 ControlWire (Boston Scientific) and a 4F Ber II catheter, ATA was treated with a 0.018" 3 x 150 mm balloon, and SFA was predilated with a 5 x 80 mm balloon
- Two **Pulsar®-18 T3** stents (6 x 80 mm and 6 x 40 mm) were inserted and deployed to cover both restenotic lesions
- Postdilatation of stents was performed with the same 5 x 80 mm balloon used for the pre-dilatation (Figure 2)



Fig. 1



Fig. 2



- Final angiography showed good patency of the stents without residual stenosis or flow-limiting dissections, and patency of ATA with improvement of foot circulation (Figure 3)
- Femoral access was closed by manual compression
- Immediately after the procedure, pedal pulses were palpable, and Duplex scan the following day showed good patency of the popliteal and below-the-knee arteries
- Patient was discharged on first postoperative day with aspirin 100 mg/day and clopidogrel 75 mg/day



Fig. 3

"**Pulsar-18 T3** is safe and effective to treat restenosis after spot stenting. Antegrade ultrasound-guided 4F approach was enough to perform the procedure. Knowledge of materials and puncture technique are key points for a successful procedure."

Nicola Troisi, MD, Department of Surgery, Vascular and Endovascular Surgery Unit, San Giovanni di Dio Hospital, Florence, Italy

References

- 1. BIOTRONIK data on file.
- 2. BIOTRONIK data on file. 6.0 mm diameters.
- 3. Zhao HQ. Late stent expansion and neointimal proliferation of oversized nitinol stents in peripheral arteries. Cardiovasc. Interv Radiol. 2009; 32(4); 720-6.
- 4. Funovics M. Differences in clinical outcomes of low COF stent vs high COF stent proven in clinical practice. Presented at: CIRSE, Sep 8, 2019; Barcelona, Spain.
- 5. 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.
- 6. Koskinas C. Role of endothelial shear stress in stent restenosis and thrombosis: pathophysiologic mechanisms and implications for clinical translation. JACC. 2012 10;59(15):1337-49.
- 7. Koppara T. Thrombogenicity and early vascular healing response in metallic biodegradable polymer-based and fully bioabsorbable drug-eluting stents. Circ Cardiovasc Interv. 2015 8(6):e002427.
- 8. BIOTRONIK data on file. 6.0 mm diameters. Supera stent not possible to test due to its design and applied test method.
- 9. Funovics M. Correlation between chronic outward force (COF) and neointimal hyperplasia in self-expanding nitinol stents in swine in clinically relevant oversizing ranges. Presented at: LINC, Jan 26, 2017; Leipzig, Germany.
- 10. Bosiers M. 4EVER 24 month results: long-term results of 4F Pulsar stent in femoropopliteal lesions. Presented at: CIRSE 2013; Barcelona, Spain.

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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_10.10240301-15264000785. FTLR for stent only group. Clinical data obtained with Pulsar-18, a predecessor of Pulsar-18 T3 using the same stent.

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FTLR=Freedom from Target Lesion Revascularization; COF=Chronic Outward Force. Pulsar is a trademark or registered trademark of the BIOTRONIK Group of Companies.

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