**Product Name:** Pulsar-18 Self Expanding Nitinol Stent

*(Peripheral Vascular Therapeutics - In Development, Lower Limb Advanced Arterial Therapeutics, Pathway Clinical Trial MarketTracks, Medtronic PV Lower Limb Advanced Arterial Therapeutics, Lower Limb Critical Limb Ischemia - CLI)*

### Description:

The next generation of the Astron Pulsar stent with the following features: longer lengths of 100 mm up to 200 mm, optimized radial force and improved flexibility in diameters from 4 mm to 7 mm, delivery system features a friction-reducing handle for smooth stent deployment, is compatible with a 0.018-in. guidewire, and is the world's first 4F-sheath.

### Company/Sponsor:

- BIOTRONIK

### Vessels:

- Lower Limb Arteries
- Femoral-Popliteal Arteries (FemPop)

### General Modality:

- Medical Devices

### Specific Modality:

- Stents

### General Product Type:

- Bare Metal

### Clinical Trials:

- BIOFLEX I Study - Investigational Device
- Exemption Study to Determine the Safety and Efficacy of the Astron and Pulsar Stents
- BIOFLEX PEACE Registry - Pulsar Efficacy: an All Comers Registry
- BIOFLEX-COF Study - Self-expanding Nitinol Stents of High vs. Low Chronic Outward Force in De-novo Femoropopliteal Occlusive Arterial Lesions
- BIOFLEX-I EU - The Treatment of Iliac and Femoral Atherosclerotic Lesions Using the Self-expanding Astron and Pulsar-18 Stents
- BIOLUX 4EVER Trial - Physician-Initiated Trial Investigating the Efficacy of Endovascular Treatment of Femoropopliteal Arterial Stenotic Disease With the Biotronik Passeo-18 Lux Drug Releasing Balloon and the Biotronik Pulsar-18 Stent
- DEBAS EXPAND Study - Self Expanding Nitinol Stent Versus PTA With Optional Bailout Stenting in Case of PTA Failure in Patients With Symptomatic Critical Limb Ischemia or Severe Intermittent Claudication
- Superficial femoral artery TASC D Registry: twelve-month effectiveness analysis of the Pulsar-18 SE nitinol stent in patients with critical limb ischemia
- Treatment for long-segment femoro-popliteal obstructions: initial experience with a 4-F compatible self-expanding nitinol stent and review of the literature

### Commercial Approval:

- On May 15, 2018 Biotronik Inc received PMA approval for Pulsar 18 Self Expanding Stent for Multiple changes to the measurement and laser cutting processes for the stent component.
- On May 16, 2018 Biotronik Inc received PMA approval for Pulsar 18 Self Expanding Stent for change to replace an extrusion machine used to produce various component tubes with a new extrusion machine.
- On August 07, 2017 Biotronik Inc received PMA approval for Pulsar 18 Self Expanding Stent for final PMA PAS Protocol Administrative Addendum approval.

### Development Status - Commercial Events:

- On November 10, 2010 BIOTRONIK announced the international full market release of the Pulsar-18 stent for treatment of long lesions in the superficial femoral and infrapopliteal arteries.
- On August 23, 2017 Getinge has announced the full US market release of the Pulsar 18 stent from Biotronik.

### Development Status - Clinical Trials:

- On 14 November, Biotronik announced the first US implant of their Pulsar-18 self-expanding stent in the BIOFLEX-I investigational device exemption clinical trial.


