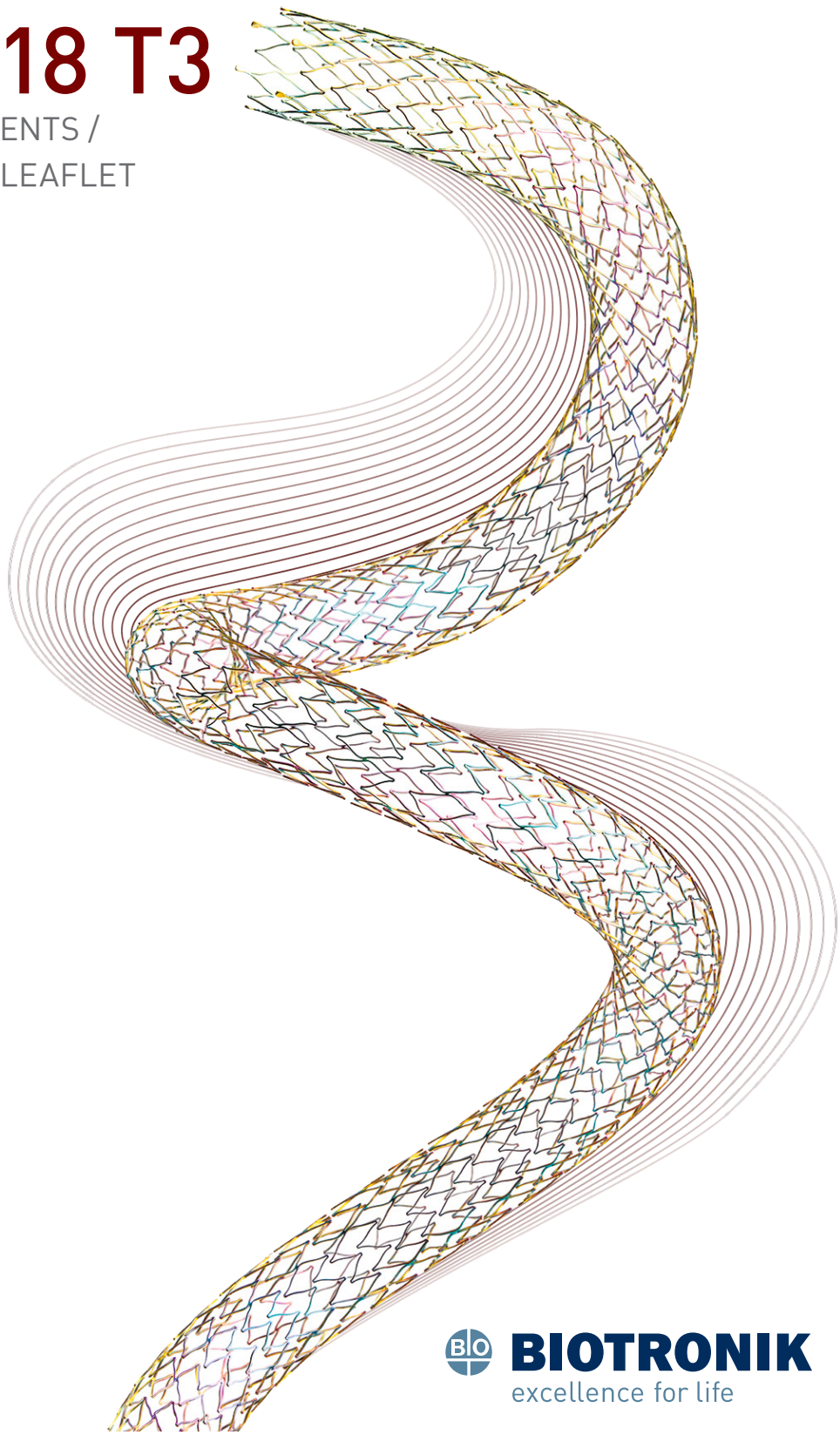
Vascular Intervention // Peripheral
Self-Expanding Nitinol Stent System

Pulsar®-18 T3

INFORMATION FOR PATIENTS /
PATIENT INFORMATION LEAFLET



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Pulsar®-18 T3

Peripheral Stent System

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This guide answers questions that you may have about peripheral stents.

Peripheral Artery Stenting

Your physician may have informed you that one or more of the arteries supplying your lower body with oxygen-rich blood has significant narrowing and may be suitable for treatment with a stent. A stent is a tiny, metal mesh-like tube used to hold open the walls of an artery and allow blood to flow through. The stent is delivered into your peripheral arteries with a stent delivery system.

Once positioned within the narrowed section of the artery, the stent is deployed. The stent expands and pushes against the flow-limiting material, opening the artery. The stent delivery system is completely removed from your body, while the stent is left in the artery to keep it open and helps to prevent further narrowing of the artery. Over time, the artery wall will heal around the stent as it continues to support the artery.

Pulsar®-18 T3 Peripheral Self-Expanding Nitinol Stent System

The Pulsar®-18 T3 Peripheral Nitinol Stent is a self-expandable stent made from a laser-cut nitinol tube completely covered with a thin layer of proBIO amorphous silicon carbide coating. The stent is delivered into your peripheral arteries with a stent delivery system. The stent stays in your body permanently to support the vessel and improve blood flow. The stent is designed to be strong to keep the artery open and also very flexible, allowing it to fit the shape of your artery.

After the Procedure

After the stent is implanted, you will rest in a unit where nurses and doctors can monitor you closely as you begin to recover. You may be asked to stay in bed for several hours. You may have some bruising and soreness at the area where the catheter was inserted, which is normal. If you received a sedative, you might feel sleepy or forgetful. You will gradually begin to feel normal. Pressure may be applied to the area where the catheter was inserted to promote healing and prevent bleeding. It may be one or more days before you are discharged from the hospital.

Consider the following:

- Follow your doctor's guidelines.
- Return to normal activities gradually. Pace yourself with resuming activities as you feel better. Ask your doctor about specific exercise or strenuous activities.
- Report any side effects immediately to your doctor.
- Let your doctor know about any changes in lifestyle you make during your recovery period.
- Keep up with all follow-up appointments, including any laboratory blood tests.
- Carry your Patient Implant Card at all times and show it to any medical professional who treats you, e.g., for dental work, medical care or when reporting to an emergency center.
- This device carries an associated risk of thrombosis, vascular complications, or bleeding events. Compliance with antiplatelet/anticoagulation medication as prescribed by the physician is very important.

Frequently Asked Questions

What do I need to do about follow-up examinations or medications?

Maintaining a healthy lifestyle after a procedure is vital as it helps to reduce the risk of developing arterial problems in the future. Follow the instructions from your physician regarding medication and precautions to be taken after stent implantation and any follow-up examinations.

What should I do if I am undergoing an MRI scan?

The Pulsar-18 T3 stent is MR conditional (MRI: Magnetic Resonance Imaging, a medical imaging technique using magnetic fields). The MRI safety information as described below is given on the Patient Implant Card. Carry the Patient Implant Card with you at all times and show it to any medical professional who treats you. The conditions described below ensure your safety as a patient undergoing an MRI scan.

MRI safety information:

Non-clinical testing has demonstrated that the Pulsar-18 T3 stent is MR Conditional for single and overlapping lengths up to 385 mm. A patient with this stent can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 and 3.0 Tesla (T).
- Maximum spatial field gradient of 3000 gauss/cm (30 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of:
  - 1 W/kg for landmarks below the umbilicus, and
  - 2 W/kg (Normal Operating Mode) for landmarks above the umbilicus.

Under the scan conditions defined above, the Pulsar-18 T3 stent is expected to produce a maximum temperature rise of less than 5.7 °C after 15 minutes of continuous scanning.

In non-clinical tests, the image artifact caused by the device extended approximately 4 mm from the Pulsar-18 T3 stent when imaged with a gradient echo sequence and 3 mm when imaged with a spin echo pulse sequence in a 3.0 Tesla MRI system. The artifact may obscure the device lumen.

Undesirable side effects that could be caused

Potential adverse events that may be associated with stent placement include:

- Stent system events: failure to deliver the stent to the intended site, stent misplacement, stent deformation, stent or delivery system material embolization (i.e., detached stent or delivery system material may enter the blood stream and decrease or interrupt blood flow in the subsequent artery section or artery), stent thrombosis (formation of blood clots in the stent) or occlusion, stent fracture, stent migration, inadequate apposition (i.e., not all stent struts have contact with the vessel wall) or compression of stent(s), withdrawal difficulties.
- Vascular events: access site hematoma, hypotension/ hypertension, pseudoaneurysm (collection of blood that forms between two of the three layers of an artery), arteriovenous fistula formation, retroperitoneal hematoma, vessel dissection or perforation, restenosis (recurrence of the narrowing of the treated blood vessel, leading to restricted blood flow), thrombosis or occlusion, vasospasm, peripheral ischemia, dissection and distal embolization (air, tissue debris and thrombus).
- Infection and sepsis.
- Embolization of air, thrombotic or atherosclerotic material (air, blood clots or plaque from the vessel may enter the blood stream and decrease or interrupt blood flow in the subsequent artery section or artery).
- Allergic reactions to contrast media, antiplatelets, anticoagulants, and amorphous silicon carbide.
- Emergency surgery to correct vascular complications.
- Tissue necrosis (cell injury which results in the premature death of cells) and limb loss due to distal embolization.
- Bleeding events: bleeding from the site where the stent system was inserted into the skin, requiring special medication or blood transfusions (severe bleeding).
- Death.

Your doctor can inform you about these potential adverse events.

Furthermore, all procedure-related events as described in the national and international guidelines of the respective medical associations apply.

There may be other potential adverse events that are unforeseen at this time.

Reporting of Serious Incidents

Report any serious incident that has occurred with the device to the manufacturer and the Therapeutic Goods Administration (https://www.tga.gov.au).

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