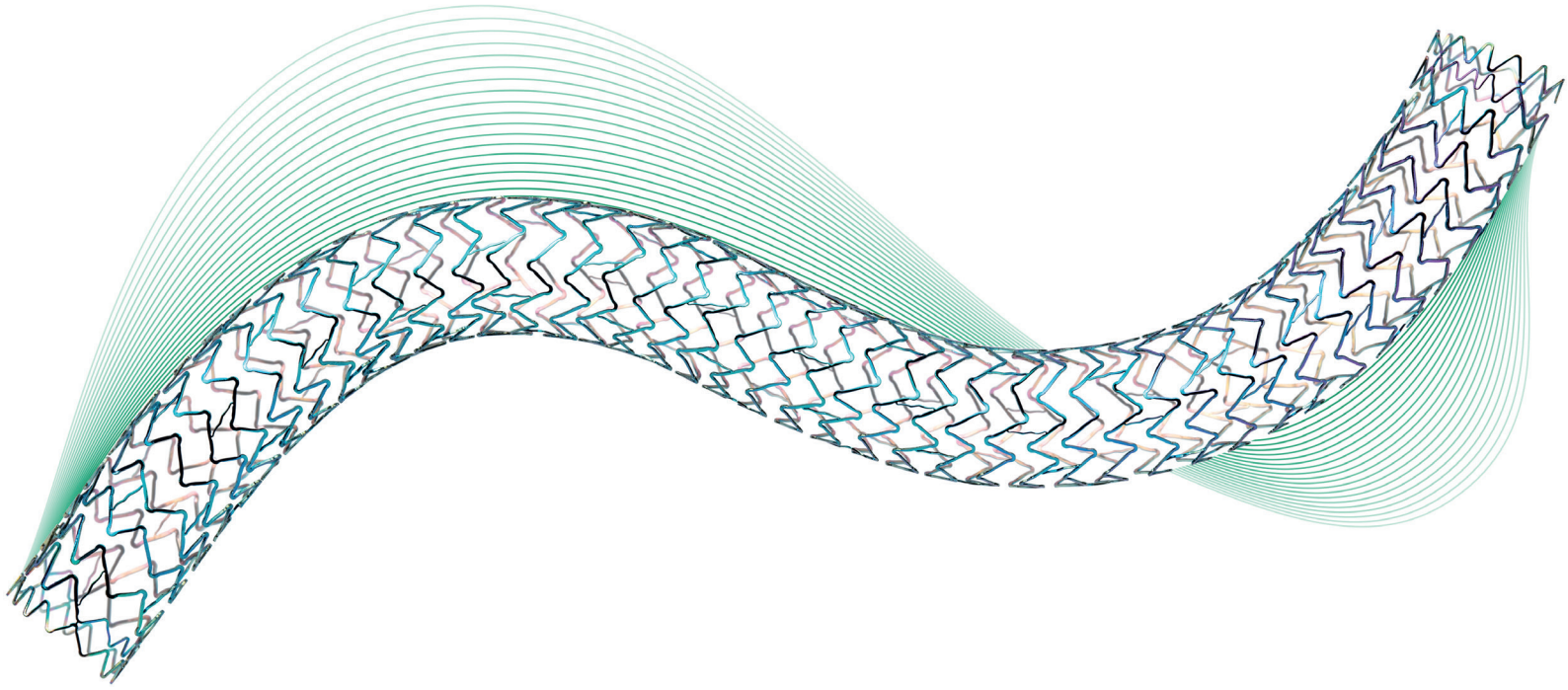
Vascular Intervention // Peripheral
Balloon-Expandable Cobalt-Chromium Stent System

Dynetic®-35

INFORMATION FOR PATIENTS / PATIENT INFORMATION LEAFLET



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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 on a balloon catheter. Once positioned within the narrowed section of the artery, the stent is expanded with the inflation of the balloon. The stent and balloon push the flow-limiting material aside, widening the artery. The balloon is deflated and completely removed from your body, while the stent is left in the artery to keep it open and help prevent further narrowing of the artery. Over time, the artery wall will heal around the stent as it continues to support the artery.

Dynetic®-35 Peripheral Balloon-Expandable Stent System

The Dynetic®-35 Peripheral Balloon-Expandable Stent System has a cobalt chromium stent that is delivered to the artery using the balloon catheter. The cobalt chromium stent is covered with a thin layer of the proBIO amorphous silicon carbide coating. 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 Dynetic-35 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 Dynetic-35 stent is MR Conditional up to total stented length of 151 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 2500 gauss/cm (25 T/m).
• Maximum MR system reported, whole body averaged specific absorption rate (SAR) of:
- 1 W/kg for scans with the stent positioned in the isocenter, and
- 2 W/kg (Normal Operating Mode) for scans with the nearest part of the stent positioned at least 20 cm out of the isocenter.

Under the scan conditions defined above, the Dynetic-35 stent is expected to produce a maximum temperature rise of less than 5.6 °C after 15 minutes of continuous scanning. In non-clinical tests, the image artifact caused by the device extended approximately 8 mm from the Dynetic-35 stent when imaged with a gradient echo pulse sequence and a 3.0 T 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 dislodgement from the delivery system (i.e., from the balloon catheter), stent misplacement, stent deformation, stent material or catheter material embolization (i.e., detached stent or catheter 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), balloon inflation difficulties during the procedure, rupture or pinhole of the the delivery system balloon, withdrawal difficulties of the balloon catheter.
• Puncture site hematoma or bleeding.
• Hemorrhage (escape of blood from a damaged or ruptured vessel) or hematoma.
• Injury to the artery wall, dissection (formation of a tear along the inside arterial wall), perforation, rupture, intimal tear.
• Vessel spasm (vessel constriction).
• Arteriovenous fistula (abnormal connection between artery and vein).
• 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).
• Pseudoaneurysm formation (collection of blood that forms between two of the three layers of an artery).
• Total occlusion of the artery.
• Restenosis of the stented artery (recurrence of the narrowing of the treated blood vessel, leading to restricted blood flow).
• Acute or subacute stent thrombosis (formation of blood clots in the stent with rapid onset of symptoms).
• Infection.
• Allergic reactions to contrast media, antiplatelets, anticoagulants, amorphous silicon carbide or other compounds of the system.
• Emergency surgery to correct vascular complications.
• Tissue necrosis (cell injury which results in the premature death of cells) and limb loss.
• 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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