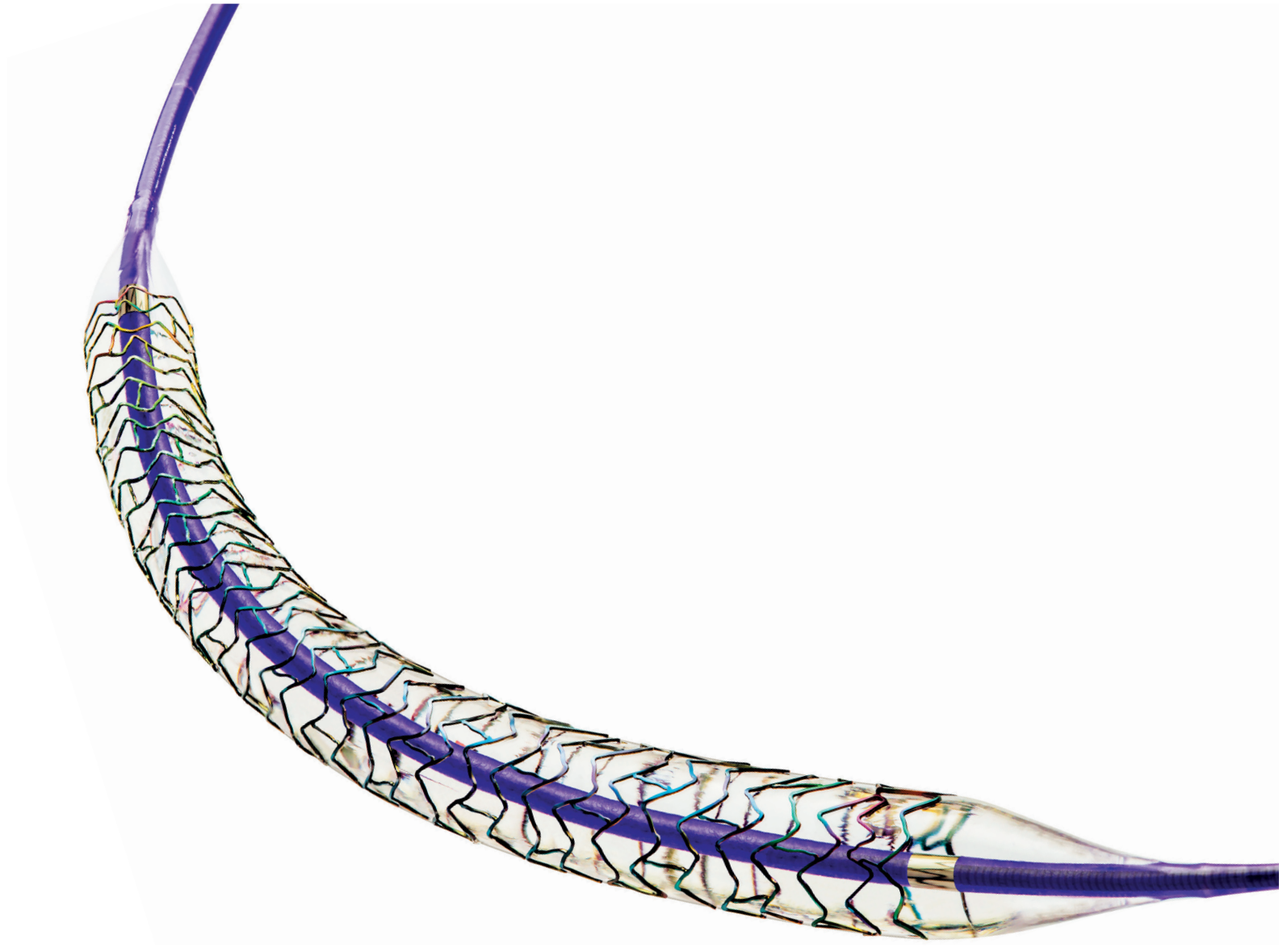
Vascular Intervention // Coronary
Sirolimus Eluting Coronary Stent System

Orsiro®

INFORMATION FOR PATIENTS / PATIENT INFORMATION LEAFLET



BIOTRONIK
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This guide answers questions that you may have about coronary stents.

Understanding Coronary Artery Disease

The circulatory system carries vital oxygen, water, nutrients and hormones through our bodies. Your "engine" – the heart – keeps this system running. In one minute, the heart muscle pumps all of our blood through the entire body with rhythmic contractions. Over one's lifetime, the heart beats three billion times and transports 250 million litres of blood – an astonishing performance that no other engine can compete with. Coronary arteries are blood vessels that carry oxygen and nutrient-rich blood to the heart muscle so that it can function properly.

Coronary Artery Stenting

Your physician may have informed you that one or more of the arteries supplying your heart 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 coronary 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.

Orsiro® Sirolimus Eluting Coronary Stent System

The Orsiro® Sirolimus Eluting Coronary Stent System has a drug-eluting 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 is coated with BIOlute®, a special bioabsorbable drug matrix (drug and poly-l-lactide polymer) to help reduce the chance of the artery becoming blocked again. The drug is called sirolimus, and it is released from the stent over a period during which re-blockage is most likely to occur. The stent is designed to be very flexible, allowing it to fit the shape of your artery. The stent stays in your body permanently to support the vessel and improve blood flow.

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 of the incision 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 heart problems developing in the future. Follow the instructions from your physician regarding medication and precautions to be taken after implantation and any follow-up examinations.

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

The Orsiro 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

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 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Orsiro 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 7 mm from the Orsiro stent when imaged with a gradient echo pulse sequence and a 3.0 T MR 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:

- Heart events: heart attack or reduced blood flow to your heart, abrupt closure of an artery, re-closing or re-narrowing of the treated artery (greater than 50% blockage) due to re-growth of tissue, cardiogenic shock (damage to your heart where it cannot supply enough blood to the rest of your body), chest pain, fluid build-up in the lining around the heart causing pressure which may result in a decreased blood flow and pumping, hole or tear in an artery or in your heart muscle, need for emergency heart surgery, widening/expansion of an artery in your heart or enlarged heart muscle.
- Abnormal heart rates or rhythms, such as a rapid heart rate, slow heart rate, or an irregular heart rate that can cause a quivering sensation in your chest, shortness of breath, dizziness, fatigue or weakness.
- Stent system events: stent placed in a different part of the vessel or unplanned location, stent falling off the balloon catheter during the procedure, stent deformation (bending or twisting), stent embolization, stent thrombosis (blood clot) or occlusion (closed artery), stent fracture (break), stent movement, stent is not fully positioned against the vessel wall, balloon inflation difficulties, rupture or pinhole of the balloon, balloon deflation difficulties, difficulty removing the balloon catheter, embolization of balloon catheter material (may enter the bloodstream and cause damage or clotting).
- Breathing or lung events: a build-up of fluid around your lungs, heart failure (a disease that may cause heart muscle weakness), difficulty breathing or inability to breathe.
- Blood vessel system events: access site bruising and/or pooling of blood under the skin, low blood pressure, high blood pressure, pooling of blood that forms as the result of a leaking hole in an artery, arteriovenous fistula formation (an abnormal connection between an artery and a vein), retroperitoneal bruising and/or pooling of blood under the skin, vessel dissection or perforation (hole or tear in a blood vessel wall), re-narrowing of blood vessels, blood clot formation or closure of a vessel, closure or narrowing of vessels connected to the artery, spasm or injury of a blood vessel, deficient blood distribution in the limbs due to narrowing or closed arteries, tear in a vessel, distal embolization (air, tissue, debris or blood clot may enter the bloodstream and cause damage or clotting).
- Neurological/nervous system events: stroke, transient ischemic attack (TIA), nerve damage, or pain.
- Bleeding events: bleeding from the site where the stent system was inserted into the skin, requiring special medication or blood transfusions (severe bleeding).
- Allergic reaction to the contrast media, antiplatelet medications or anticoagulants (drugs used to thin the blood) during the procedure, or stent material.
- Death.
- Infection and sepsis (a life-threatening complication of an infection).

The potential adverse events related to the oral administration of sirolimus are provided for information only. The amount of sirolimus circulated in your bloodstream will be significantly lower for stent implants than when obtained in oral doses. They include, but are not limited to:

- Abnormal liver function tests.
- Allergic reaction to the drug which can include an itchy rash or a more severe reaction of difficulty breathing, throat swelling, and low blood pressure.
- Anemia (low red blood cell count).
- Cancer of the lymph nodes or other types of cancer.
- Diarrhea.
- Diseases that affect the tissues and space around the air sacs of the lungs.
- Increased levels of cholesterol and triglycerides (fat or lipids) in the blood.
- Joint pain.
- Low level of potassium in the blood.
- Low platelet count in the blood.
- Low white cell count in the blood.

Inform and discuss the stent procedure with your doctor if you are:

- Taking immunosuppressive medications.
- Pregnant (as there is also potential harm to the fetus).

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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