

Information for Patients

COMBO Bio-Engineered Sirolimus Eluting Stent

COMBO Plus Dual Therapy Stent

Note: for the purpose of this document together referred to as: COMBO Stent

Introduction

This document gives you information about your implanted device. We will call your stent “COMBO Stent” in this document. This document includes these topics:

- Description of COMBO Stent and what it does
- Important safety and follow-up information
- Warning and precautions
- Product details (materials and sizes)
- How long COMBO Stent will last
- Contact information

Talk to your healthcare provider if you have any questions.

About COMBO Stent

COMBO Stent is used to treat heart disease (coronary artery disease). It does this by helping to restore adequate blood flow to your heart. COMBO stent is implanted in a blocked vessel(s) in your heart (coronary arteries) to expand the artery wall. The expanded artery allows blood flow to the heart muscle.

COMBO Stent is made of metal and covered with a medicine (called sirolimus) to help reduce the chance of blood vessel(s) becoming narrow or blocked again. The sirolimus medicine is contained in a coating that is slowly dissolved by the body (biodegradable). The COMBO Stent is also coated with antibodies (called anti-CD34) that help with blood vessel healing to protect against blood clots near the stent.

A catheter is a long, thin, hollow tube. During your implant procedure, a catheter was used to place the stent in your artery. A small balloon on the catheter was inflated to push open the artery wall to restore blood flow. Then the balloon was deflated, and the catheter was withdrawn. The stent was left behind to help keep the artery open. For some patients, more than one stent may be needed. This depends on the length of the vessel and the blockage.

Safety information and follow-up care

This section gives some safety precautions and follow-up care related to COMBO Stent. Be sure to follow your healthcare provider’s advice for your specific situation.

When to contact your healthcare provider

There are some risks associated with having an implanted COMBO Stent. Even with a successful implant, there is a chance that your coronary artery will narrow again. This may require additional treatments. It is possible to experience irregular heartbeats, chest pain, or discomfort after the procedure. You should have received information about the benefits and potential risks of your implant from your healthcare provider. You should also have received information about when you should call for help. If you have any bleeding or pain at the incision site, shortness of breath, or severe chest pain, contact your healthcare provider right away.

Patient implant card

You received a patient implant card with information about you and COMBO Stent. It is important to carry your patient implant card at all times. When you visit the dentist or receive other medical care, show your patient implant card. This will notify them that you have an implanted medical device.

Allergies or sensitivities

If you develop any new allergies or sensitivities, contact your healthcare provider. If you develop a skin rash or hives around your incision, or if you are extremely tired after you receive COMBO Stent, notify your healthcare provider.

Metal detector or security scan

COMBO Stent contains metal, which may be detected by certain scanning systems. It is unlikely that COMBO Stent will set off a metal detector or security system. Always notify security staff that you have a medical device. Always carry your patient implant card.

MRI scan

An MRI scan is a type of medical imaging. MRI uses magnetic fields to create an internal view of the body. If you need an MRI scan, tell your healthcare provider that COMBO Stent is MR Conditional. When your healthcare provider follows the safety instructions provided by OrbusNeich, you can safely receive an MRI scan.

Other medical scans and tests

Most medical tests like mammograms, CT scan, and x-rays are safe for people with stents. Before you have any tests, be sure to tell your healthcare provider that you have an implanted stent. Show them your patient implant card.

At-home care and medications

After your procedure, your healthcare provider will give you instructions about at-home care. Follow all care instructions to ensure the best possible results.

- Follow guidelines about diet, medications, and physical activity.
- You should be able to return to normal activities soon after your procedure. Be sure to discuss this with your healthcare provider.
- Take all medications as instructed. Stopping prescribed medication early could result in medical issues. Do not stop taking any prescribed medications unless instructed to do so by the doctor who implanted COMBO Stent.

Follow-up appointments

Keep all follow-up appointments, even if you are feeling healthy. Follow-up visits with your healthcare provider allow you to ask questions. Visits are important for assessing your recovery.

WARNINGS

Use of COMBO Stent may be associated with the following risks:

- Blood clot that forms on the surface of a stent (coronary or stent thrombosis)
- Increased vessel and/or bleeding complications (due to a problem with blood clotting)
- Increased length of hospital stay
- Infection due to contamination of the stent which may lead to a blood clot inside a vessel, leaking blood from a vessel, or vessel bursting.
- Implantation of the stent may cause spasm, blood clot, and/or obstruction. The stent could move from the site of implantation.
- Excessive stretching of the vessel may cause rupture and life-threatening bleeding.
- Stents can be partially deployed in particularly resistant blockages.
- Stent dislodgment and/or movement from the target site during or after implantation.
- Patients with an unknown allergy to stainless steel alloy may suffer an allergic reaction to this implant.
- Use of this product may be associated with developing allergic reaction towards murine antibodies.
- Long term clinical outcome for this permanent implant is unknown at present.
- Talk to your healthcare provider about stent risks and benefits.

Product details

The COMBO Stent's key material/substances in direct contact with the patient's blood or tissues are listed below. Some of the materials could cause sensitization or an allergic reaction in some patients. If you have any questions or concerns, contact your healthcare provider.

Table 1. COMBO Stent materials

Component	Materials in contact with your body	Mass*
Stent	316L stainless steel alloy	12-48mg
Stent coating	Drug- sirolimus	45-190µg
	biodegradable polymer	83-352µg
	anti-human CD34 antibody	0.63-2.6µg

*Mass values represent a range of material amounts that may be present. The specific amount depends on the size of the implanted stent.

The appropriate stent length and diameter are selected based on the patient's specific anatomy and heart condition. The following table shows the available sizes for the COMBO Stent.

Table 2. COMBO Stent measurements

Measurement	Value
Available stent diameters	2.5mm to 4.0mm
Available stent lengths	9, 13, 15, 18, 23, 28, 33, 38mm

How long will COMBO Stent last?

The stent is a permanent implant. The stent has a minimum expected lifetime of 10 years. Talk to your healthcare provider about stent risks and benefits. Discuss any necessary follow-up.

Contact information

If you have any concerns, discomfort, or questions, contact your healthcare provider. To contact OrbusNeich, use the address provided on this document.



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