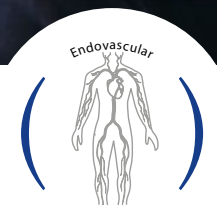


Carotid self-expanding stent MER
with delivery system, Rapid Exchange



PATIENT INFORMATION LEAFLET



This guidebook is designed to help you and your family understand carotid artery disease and its treatment with *Carotid self-expanding stent MER with delivery system RX*.

For your convenience, a glossary of medical terms is included at the end of this booklet. Words that are in bold throughout the text are defined in the glossary.

This booklet is only a guideline. It is not intended to diagnose a medical condition. The treatment of carotid artery disease may vary according to everyone's unique needs and doctor assessments. As with any medical procedure, the best source for information and advice is your doctor.

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Carotid self-expanding stent MER

with delivery system RX

INTRODUCTION

This guidebook is designed to help you and your family to understand vascular disease of the **carotid arteries** of your neck and treatment with a vascular stent. If you have any questions as you read, please write them down and discuss them with your doctor.

CAROTID ARTERIES DISEASE

Carotid artery disease occurs when fatty deposits (**plaques**) clog the blood vessels that deliver blood to your brain and head (**carotid arteries**).

THE CAROTID ARTERIES

The carotid arteries are the blood vessels that carry oxygen-rich blood to the head, brain and face. They are located on each side of the neck. You can easily feel them by placing your fingers gently either side of your windpipe.

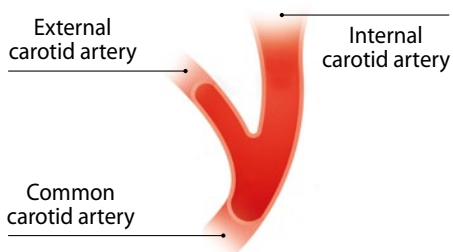


Fig. 1. Carotid arteries



Fig. 2. Carotid arteries disease

CAROTID ARTERY STENOSIS

Severe narrowing of the carotid artery is known as atherosclerosis and it is carotid artery disease. Fatty material which builds up in the artery is called **plaque**. It may cause partial or total blockage of blood flow to the brain which may lead to mini-strokes (Transient Ischemic Attack – TIA) and cause a stroke.

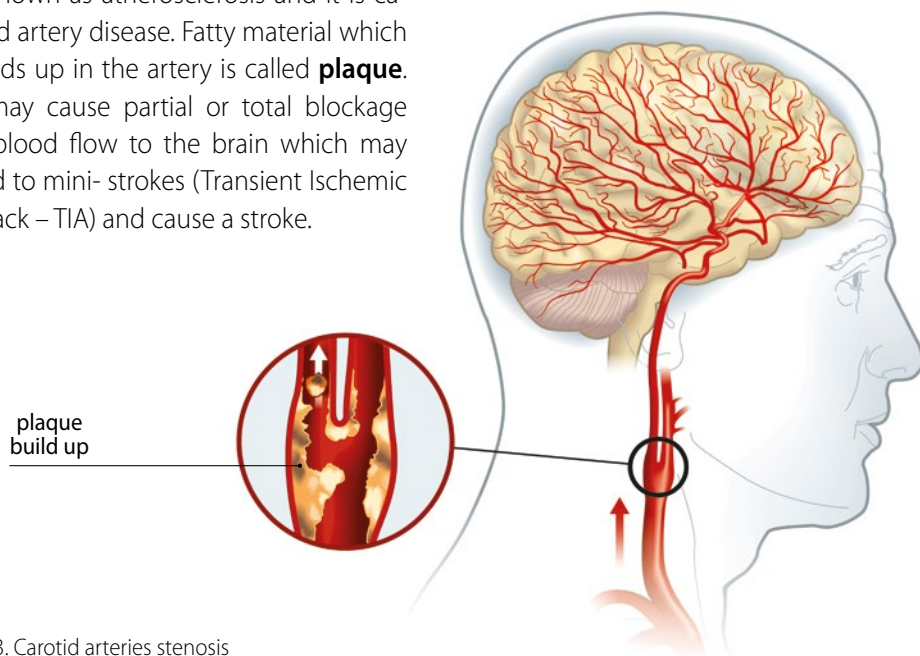


Fig. 3. Carotid arteries stenosis

DIAGNOSIS

You should be screened for carotid artery **stenosis** if you have:

Sudden weakness or numbness in the face, arms, or legs
(usually on one side of the body)

Trouble speaking (garbled speech) or understanding

Sudden vision problems in one or both eyes

Dizziness, fainting

Sudden, severe headache

Drooping on one side of your face

Sometimes, patients are screened for carotid artery **stenosis** if the doctor knows the patient has vascular disease elsewhere in the body.

The following tests may be performed if carotid artery disease is suspected.

Carotid artery ultrasound, which uses sound waves to produce pictures of the carotid arteries in the neck

Carotid angiography is a diagnostic imaging tool that uses dye, or contrast, and a special X-ray machine to study the health of veins, arteries and blood flow.



Fig. 4. Carotid artery ultrasound

TREATMENT OPTIONS

Treatment of the carotid artery disease is proposed to prevent a stroke in the future.

It is important to inform your doctor about your entire medical history. Follow your doctor's recommendations. These may vary greatly depending on your case and may include:

MEDICATION

Your doctor may prescribe medications to help you reduce your cholesterol, lower blood pressure, manage your diabetes, or help you stop smoking. You may also be prescribed an anti-platelet or anticoagulant medication.

Both above options do not require any surgery, but each of them may not be enough to manage your disease completely. If neither of the above options is sufficient to manage your disease, one of the following interventional options, which consist in restoration or widening of the artery, may be recommended.

SURGICAL PROCEDURE

Carotid artery disease may be treated in conventional surgery. **Carotid endarterectomy (CEA)** is an open surgery operation. This surgical procedure removes **plaque** from inside of your carotid artery to restore normal blood flow to your brain. You are usually put to sleep for

this procedure using general anesthesia. The surgeon exposes your carotid artery through an incision (cut) in the side of the neck. The **plaque** inside of the artery is then removed and the artery is sewn back together.

MINIMALLY INVASIVE ENDOVASCULAR PROCEDURE

Carotid artery stenting (CAS) is an endovascular treatment which means it's performed through a blood vessel mostly under the local anesthetic. During this procedure interventional Doctor implants stent into the carotid artery to open up narrowed or blocked artery and to improve blood flow. A small incision is made in your groin or arm and small tubes or **catheters** containing the medical devices used for the procedure are introduced to the carotid artery in your neck. A filter basket is placed beyond the area of your blockage to help prevent any **embolic material** from traveling to your brain during the stenting procedure. A **balloon catheter** is then inflated to open the blockage before stenting. Then the **stent** is placed at the area of your blockage. The stent holds the artery open to allow normal blood flow to the brain.

CAROTID SELF-EXPANDING STENT MER WITH DELIVERY SYSTEM RX

The Carotid Self-Expanding Stent MER® is indicated for the treatment of atherosclerotic lesions in **carotid arteries**. MER® stent is made of nitinol, which is a well-studied and biocompatible material. In other words, the device can be used to help open a blocked area of the **carotid artery** of the neck.

The outline of the stent was obtained by means of laser work. A stent is placed inside the delivery system for passage into the body to the **carotid arteries**. After being released from the delivery system, the stent opens up, taking the form of a cylinder. Thanks to its properties, it restores the desirable shape of the lumen of the vessel.

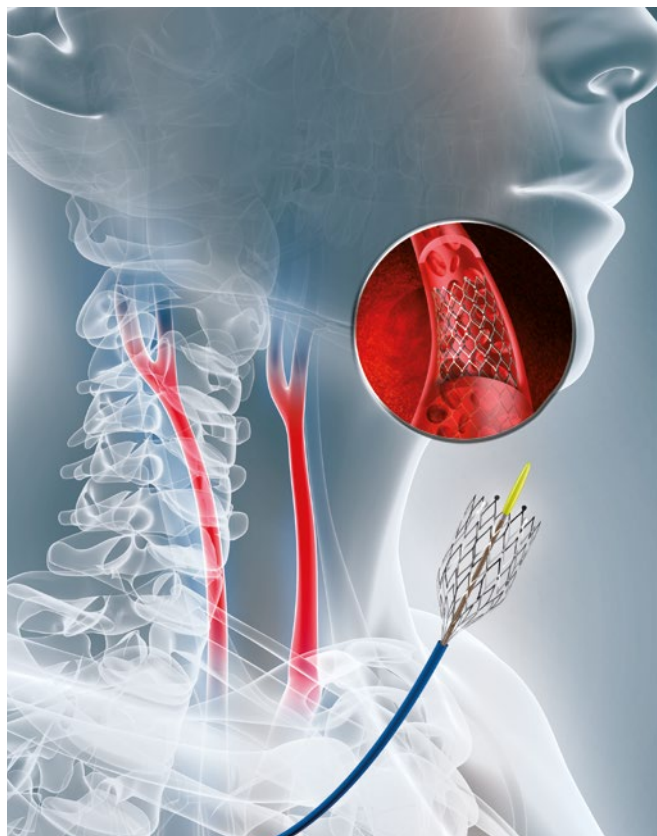


Straight Carotid Stent



Tapered Carotid Stent

Fig. 5. Carotid stent MER®



PREPARING FOR YOUR PROCEDURE

The benefit of implantation of the Carotid Self-Expanding Stent MER is the reduction of **carotid artery stenosis**. However, as with any intervention, the implantation procedure involves some risks and contraindications.

Upon admission to the hospital, you may have tests such as angiography, carotid artery ultrasound and blood tests. Remember to tell your doctor about all the medications you are currently taking and any allergies you may have. You may be asked not to drink or eat from midnight before the procedure.

Your doctor should have discussed the procedure in detail with you and explained the possible risks and potential benefits of the device. Please do not hesitate to ask any questions. As with any intervention, the angioplasty and stenting procedure involves some risks. These risks are uncommon, but are important to be aware of.

CONTRAINDICATIONS

- Contraindications against taking antiplatelet or antithrombotic medicines,
- Uncorrected bleeding disorders or active/recent intracranial or gastrointestinal bleeding,
- Known hypersensitivity to nickel-titanium or contrast media,
- Severe vascular tortuosity or anatomy or heavy calcifications that would preclude the safe introduction of a guide catheter, sheath, embolic protection system, or stent system,
- Lesions located in the ostium of the common carotid artery,
- Fresh thrombus,
- Total occlusion of target carotid artery,
- Pregnant women or during lactation.

POTENTIAL COMPLICATIONS

(in alphabetical order)

- Allergic/ anaphylactoid reaction (including to antiplatelet agents, contrast medium or stent materials)
- Arrhythmia (including bradycardia requiring need for a temporary or permanent pacemaker)
- Carotid artery complications
 - abrupt closure
 - dissection
 - embolism (air, atherosclerotic plaque, thrombotic material or device)
 - perforation
 - restenosis
 - spasm
 - thrombosis (acute, subacute, late, very late)
- Cerebral edema
- Death

- Emergent or urgent carotid endarterectomy
- Fever
- Filter thrombosis/occlusion
- Headache
- Hemorrhage (including GI bleeding from anticoagulation/antiplatelet medications)
- Hyperperfusion syndrome
- Hypotension/ hypertension
- Infection or sepsis
- Myocardial infarction
- Renal failure
- Seizures
- Stent deformation/fracture
- Stent malaposition
- Stent migration
- Stent restenosis
- Stent thrombosis
- Stroke
- Transient Ischemic Attack (TIA)
- Vascular access complications which may require blood transfusion or vessel repair:
 - bleeding (ecchymosis, hematoma, hemorrhage, retroperitoneal hemorrhage)
 - embolism (air, atherosclerotic plaque, thrombotic material or device)
 - peripheral ischemia
 - peripheral nerve injury
 - pseudoaneurysm, dissection, perforation, arteriovenous fistula

STENT IMPLANTATION PROCEDURE

The **carotid artery** stenting a procedure performed in catheterization laboratory or a radiology suite.

You will enter the room equipped with special instruments and will be laying on the X-ray table. You will be covered with sterile sheets and the area where the catheter will be inserted will be shaved and washed with antiseptic solution to prevent infection.

During the procedure you will be awake and medical and nursing staff will be monitoring you closely. Local anaesthet-

ic will be injected through the skin into the groin or arm (it depends on decision of your operator). When the medication takes effect, you should only feel dull pressure where the operator is working with the catheter. The operator will insert a fine tube (introducer) into the artery and it will provide passageway through which the doctor can insert catheters with necessary devices and dye. A dye injected through the catheter will allow seeing the area of blockage in your artery.

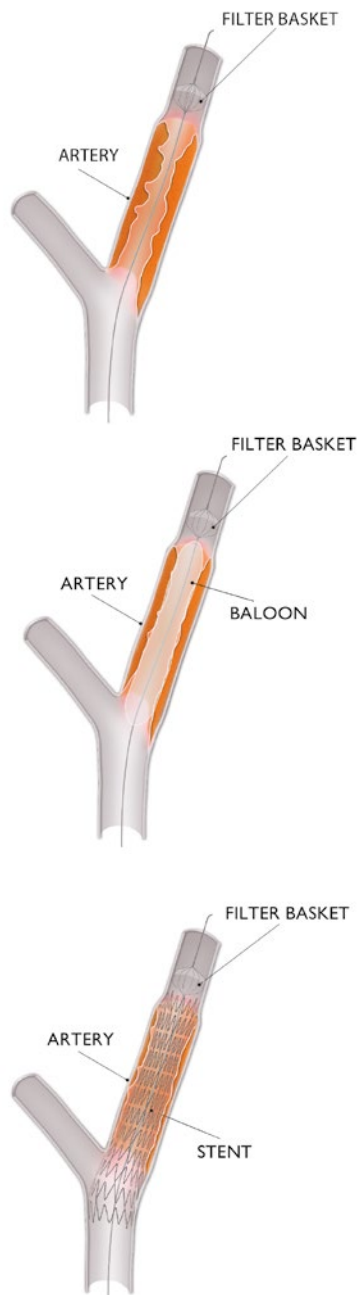


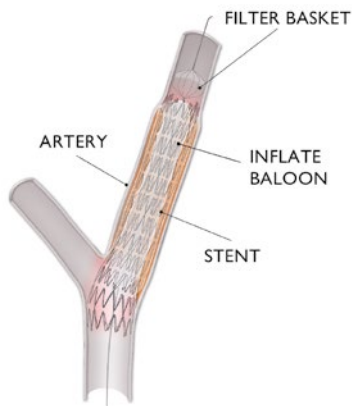
Fig. 6. Catheterization laboratory

The operator may insert a filter basket to lower the risk of stroke during the procedure.

The operator also may insert balloon to prepare artery for **stent** implantation.

Then the stent is advanced into the **carotid artery** in a delivery system and deployed in the blocked area of the artery. The stent will be placed in the proper position in you artery.





The delivery system is withdrawn from your body. Once again the doctor may insert the balloon to ensure the stent is in full contact with the artery wall.

The MER stent stays in place permanently, holding the artery open.

The operator also may insert balloon to the artery after **stent** implantation.

Fig. 7. Carotid artery stenting procedure

After the stent implantation procedure is completed, the filter basket is closed and removed from the body.

The introducer is usually removed at the end of procedure, but if the physician feel the necessity it may sometimes be left in place temporarily.



Carotid artery **before** stent implantation



Carotid artery **after** stent implantation

Fig. 8. The appearances before and after the endovascular placement of a stent

AFTER YOUR PROCEDURE

Once the procedure is finished you will be moved to the special care unit where you will be closely monitored by hospital staff. Your heart rhythm and blood pressure will be monitored continuously.

If the groin was used as an access site for the procedure you will have to lie flat in bed and not move your leg for up to six hours and a sandbag may be placed over the puncture site to keep pressure on it. In some cases, the puncture site may be closed with a closure device that will be described to you by your doctor.

If an access to the procedure was through the arm it will be stitched closed and you may be allowed to sit up afterwards.

Once you return to the ward you will have regular observations of your conscious

level, heart rate, blood pressure, puncture site and pulses in your feet. You may also have a drip to make sure you are not getting dehydrated. When the drip will be removed you should drink around 2 litres of water to help to wash out the contrast (dye) used during the procedure.

Notify to hospital staff if you feel anything disturbing like trouble with seeing, swallowing, feeling lightheaded or dizzy, weakness, tingling or numbness in limbs, face or side of your body.

Mostly after 1-3 days after the procedure you will be allowed to go home. Before you leave the hospital your neuroradiologist will give you information about medications, diet and activity.

YOUR RECOVERY

You will be informed when you can resume normal activity and return to work. You should avoid strenuous activities like lifting for at least a week. Remember to take all prescribed medications as your doctor tells you to do. Notify your doctor if these medications cause unpleasant reactions.

To help yourself staying in health in the future you should pay attention on the healthy diet and exercises. It will be easier and safer if you get help from a professional dietician and physiotherapist. It is extremely important to avoid smoking. If you need help quitting, please notify your healthcare provider.

Special monitoring or maintenance doctor's visits are not required, but you should discuss with your doctor your post-operative care plan. See your doctor immediately if you have concerns or questions about your implant.

The MER stent is inert and does not degrade. It is permanently implanted in your body.

The following symptoms might suggest stent failure/stent narrowing:

- Sudden weakness or numbness in the face, arms, or legs (usually on one side of the body)
- Trouble speaking (garbled speech) or understanding
- Sudden vision problems in one or both eyes
- Dizziness, fainting
- Sudden, severe headache
- Drooping on one side of your face





If such symptoms occur/re-occur you should consult your doctor.

PATIENT IMPLANT CARD

Be sure your doctor gives you a completed Patient Implant Card that you can keep as a record of your procedure. Carry the card with you always and show it to any doctors or health care workers who

may be treating you. The card will have the date of the stent procedure, location of the stent in your body, the name of the doctor who performed the procedure and other important information.

<p>MD</p> <p>MER</p> <p>(UA) Саморозширний стент мер для сонної артерії з системою доставки (KZ) Мойынның қуретамырларына арналған, RX енгізу жүйесі бар, өздігінен кеңейетін стент (TR) RX salını sistemine sahip, kendiliğinden genişleyen karotid stent</p>	<p>05/2021</p> <p>BALTON Sp. z o.o. Nowy Świat 7/14, 00-496 Warszawa, Poland Tel. (+48) 22 597 44 00, fax (+48) 22 597 44 44 email: balton@balton.pl, www.balton.pl</p> <p></p> <p style="text-align: center;"><i>Put the sticker from the product label here</i></p>	<p>BALTON®</p> <p>INTERNATIONAL IMPLANT CARD</p> <p> _____</p> <p> _____</p> <p> _____</p> <p> www.balton.pl</p>	<p>MD</p> <p>MER</p> <p>(EN) Carotid self-expanding stent with delivery system RX (PL) Stent samorozprężalny do tętnic szyjnych z systemem wprowadzającym RX (FR) Stent auto-extensible carotidien avec système de pose RX (IT) Stent autoespandibile carotideo con sistema di rilascio RX – stent cilindrico (ES) Stent de carótida autoexpansible con sistema de liberación de intercambio rápido (DE) Selbstexpandierender karotistent mit Rapid-Exchange-katheter (PT) Stent carotídeo auto-expansível com sistema de colocação system RX (RU) Саморасширяющийся стент для сонной артерии с системой доставки RX</p>
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SAFETY DURING MAGNETIC RESONANCE IMAGING (MRI)

If you require MRI after carotid artery stenting, tell your health care providers that you have a stent.

MRI SAFETY INFORMATION:

A patient with this device can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 3.0 T or 1.5 T
- Maximum spatial field gradient of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 1.0 W/kg

CONCLUSION

You have a very important role to play to ensure that your stent implantation is successful. It is essential that you cooperate with your doctor and follow through with your responsibilities as part of the patient/medical team. You will need to see the doctor who implanted your stent for routine follow-up examinations. During these visits, your doctor will monitor your progress and evaluate your medications, the status of your disease, and how the stent is working for you. If you have any questions or concerns please contact your doctor to discuss them.

GLOSSARY

Term	Definition
Angiogram	A procedure in which contrast dye is injected into the arteries to diagnose a narrowing or blockage of the artery.
Angioplasty	A procedure whereby a balloon dilation catheter is passed through the blood vessel to the blocked area of an artery. Once the balloon on the tip of the catheter is inflated, the blocked area in the artery is opened. Also called PTA (Percutaneous Transluminal Angioplasty).
Anticoagulant	A medicine that slows or prevents the clotting of blood.
Atherosclerosis	The process of fatty deposits and/or calcium build-up (plaque) on the inside of the arteries.
Balloon Catheter	A long tube that passes through your arteries with a tiny balloon on its tip. The balloon is inflated after it is in place to open a blockage and press the stent against the artery wall.
Carotid Arteries	Arteries are vessels that carry blood away from the heart. The carotid arteries extend from the main artery (aortic arch) coming directly from the heart and supply oxygen-rich blood to the brain.
Carotid artery stenting (CAS)	An endovascular treatment during which interventional neuroradiologist implants stent into the carotid artery to open up narrowed or blocked artery and to improve blood flow.

GLOSSARY

Carotid endarterectomy (CEA)	An open surgery operation, which removes plaque from inside of a carotid artery to restore normal blood flow to your brain/
Catheter	A long hollow tube used to introduce a device, drug, or dye into a blood vessel.
Catheterization	A procedure that involves passing a tube (catheter) through blood vessels and injecting dye to detect blockages.
Cholesterol	A substance that circulates in the blood and when deposited in the artery, plays a role in the formation of blockages. Cholesterol originates in foods that are rich in animal fat
Embolic material	Small clots or pieces of plaque that travel in the bloodstream and lodge in a blood vessel, blocking blood flow.
MRI (Magnetic Resonance Imaging)	A diagnostic test that uses magnetic waves to obtain images of the inside of your body.
Plaque	An accumulation or build-up of fatty deposits, calcium and/or cell debris in an artery that leads to narrowing of the artery.
Restenosis	The recurrence of a narrowing or blockage in an artery after treatment.
Stent	An expandable, metallic, tubular shaped device that provides structural support for a vessel.
Stenosis	A narrowing in your arteries caused by plaque build-up, which restricts blood flow.
Ultrasound	A non-invasive test using sound waves to determine the presence of arterial narrowing.

CONTACT INFORMATION

Your doctor or nurse will review this material with you. We encourage you to ask them any questions regarding your treatment and recovery.

Additionally, your doctor may recommend that you join a support group to speak with others who have undergone similar procedures. Ask your doctor for contact information about these groups and possible web site addresses.



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