TERUMO
INTERVENTIONAL
SYSTEMS

R2P™ Misago®

RX Self-expanding Peripheral Stent

PATIENT GUIDE

NOTE – The individuals depicted are not actual patients.

Peripheral Arterial Disease affects 8-10 million Americans. It becomes more common as we get older.

Your physician has determined that you may benefit from receiving an R2P™ MISAGO® RX Self-expanding Peripheral Stent System.

This guide will help you better understand Peripheral Arterial Disease (PAD) in the Superficial Femoral Artery (SFA) and its treatment with a stent. You should read this guide carefully and ask your physician if you have questions or would like additional information. The information in this booklet is provided to help you make a decision about whether or not the R2P™ MISAGO® RX Self-expanding Peripheral Stent System is right for you.

TERUMO INTERVENTIONAL SYSTEMS

About Peripheral Arterial Disease in the Superficial Femoral Artery 6

Risk Factors 8

Diagnosis 9
Ankle-Brachial Index (ABI) 9
Vascular Ultrasound 9
Angiogram 9

Treatment Options 10
Diet Changes and Exercise 10
Medical Management 10
Balloon Angioplasty 10
Stenting 11
Bypass Surgery 11

About the R2P™ MISAGO® RX Self-expanding Peripheral Stent System 12
When the device should not be used (contraindications) . . . 12

The Procedure 14
Potential Benefits of the R2P™ MISAGO® RX Self-expanding Peripheral Stent System 14
Risks of the Procedure 15

Frequently Asked Questions 16
What is the purpose of the Patient Implant Card? 16
Can the stent move or rust? 16
How soon can I go back to work? 16
Do I need to inform the security screener at the airport that I have a stent implanted? 16
Can the disease in my leg get worse or the stent not work? 16
After my stent procedure, are there times when I should call my doctor? 17
Can I have an MRI (Magnetic Resonance Imaging) or x-ray? 17

Useful Definitions 18

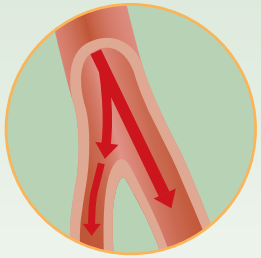
TERUMO INTERVENTIONAL SYSTEMS

About Peripheral Arterial Disease in the Superficial Femoral Artery

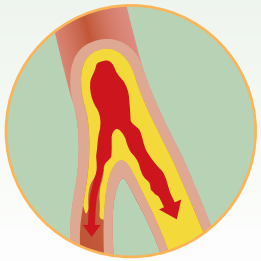
Arteries are blood vessels that carry oxygen-rich blood from the heart throughout your body. Peripheral Arterial Disease (PAD) is a disease where cholesterol, fatty deposits and/or calcium known as plaque, narrow or block arteries limiting blood flow. A common area affected by PAD is found in a major thigh artery called the Superficial Femoral Artery (SFA). See figures at right.

PAD affects 8-10 million Americans. It becomes more common as we get older. PAD occurs in 4.3% of people over 40 years old, but increases to 14.5% in people over 70. While a person can have PAD without even knowing, the following are common signs of PAD:

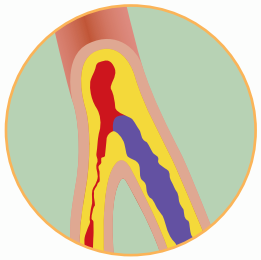
- The most common symptoms of PAD are cramping and pain or tiredness in the leg or hip muscles while walking or climbing stairs (claudication). Typically, this pain goes away with rest and returns when you walk again.
- Hair loss, skin discoloration, coldness and/or numbness of the leg between the knee and the ankle
- Leg pain at rest
- Sores or open wounds (tissue loss) to the foot or toes (late stage of PAD)



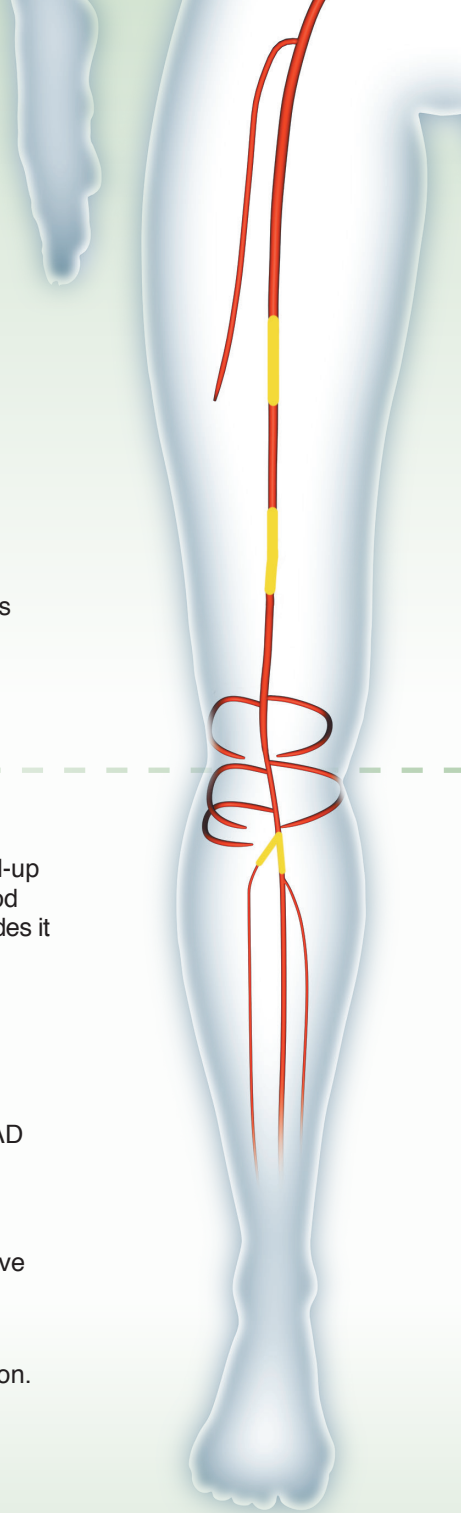
Healthy Vessel
In healthy vessels, blood flows freely



Narrowed Vessel
Plaque build-up in vessel walls reduces blood flow



Blocked Vessel
Severe plaque build-up further reduces blood flow and even occludes it



Important facts:

- Many people mistake the symptoms of PAD for something else.
- PAD often goes undiagnosed.
- People with peripheral arterial disease have four to five times more risk of heart attack or stroke.
- Left untreated, PAD may lead to amputation.

Risk Factors

Both PAD and cardiovascular risk factors include:

- Family History
- Smoking
- Obesity
- High Blood Pressure
- High Cholesterol
- Diabetes
- Inactivity
- Age

Diagnosis

Diagnosis of PAD begins with a physical examination. Your healthcare provider will check for weak blood flow in your legs. Your physical examination may include the following:

- **Ankle-Brachial Index (ABI):**

  The Ankle-Brachial Index is a simple test that can possibly show PAD in the legs. The test is conducted by measuring and comparing the blood pressure in your arms with the blood pressure in the lower leg. Normally, these pressures should be about the same. If the blood pressure in the legs is lower than in the arm, the ABI will be low. Low ABI may be a sign of decreased blood flow in the legs, an indication of PAD.

- **Vascular Ultrasound:**

  A vascular ultrasound is an examination that uses ultrasound scanning (similar to sonar waves, and known as sonography) to see the blood vessels and the speed of blood as it moves through the vessels. Ultrasound imaging is a safe medical test that helps physicians diagnose and treat medical conditions.

- **Angiogram:**

  In this procedure, a physician enters an artery via a small needle and injects an x-ray dye into the blood vessels so they are seen on x-ray. During the test to image your arteries (angiogram) your physician may identify narrowed vessels in your leg that require treatment.

Other technologies that may be used for the diagnosis of PAD are Computed Tomography (CT) and Magnetic Resonance Imaging (MRI).

Treatment Options

There are a number of lifestyle steps that you can take to help prevent and/or control further worsening of your disease:

Diet Changes and Exercise

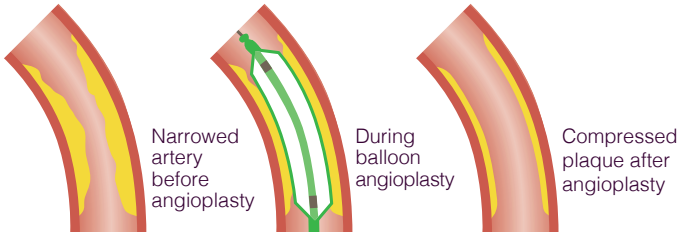
- If you smoke, stop.
- Control your blood pressure.
- Lower your cholesterol.
- Control your blood sugar.
- Follow healthy eating habits.
- Exercise regularly.
- Maintain ideal weight.

Medical Management

A physician may prescribe medications for you to help control PAD risk factors. However, as PAD progresses, there may be a need for other procedures or surgery. Your physician will discuss the options with you in detail.

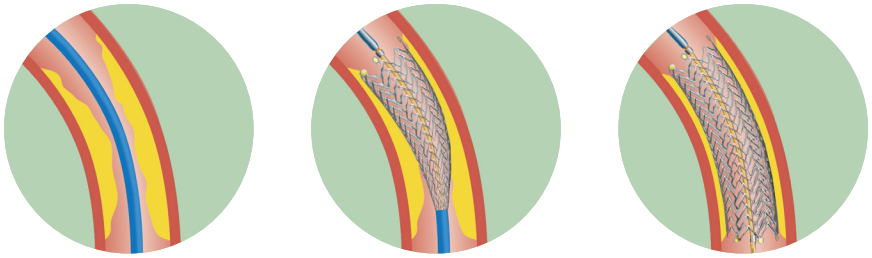
Balloon Angioplasty

Balloon angioplasty, also known as Percutaneous Transluminal Angioplasty (PTA), is a procedure that uses a catheter with a small balloon mounted on the end. When the balloon is placed through the narrowed portion of the artery and inflated, the balloon opens the narrowed vessel to restore blood flow to the leg.



Stenting

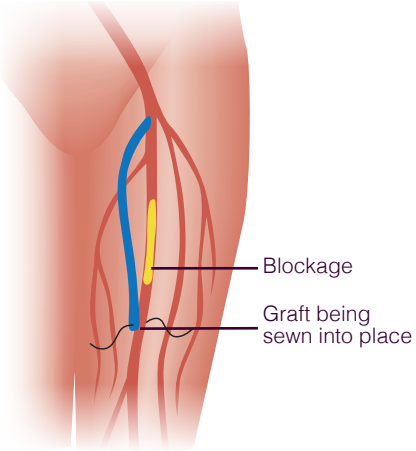
A stent is a tiny mesh tube. It is mounted on the tip of a catheter similar to a balloon. When the stent is placed in the narrowed portion of the artery, it provides a scaffolding to keep the narrowed blood vessel open. The stent remains in the vessel to minimize the risk that the vessel will become narrowed or blocked again.



Placement of stent system across plaque — Deployment of stent — Implanted stent

Bypass Surgery

Surgical bypass of the blocked or narrowed artery may be performed by re-routing the blood supply in your leg. See figure to the right.



Talk with your physician about your situation and what medications and therapies best apply to you.

About the R2P™ MISAGO® RX Self-expanding Peripheral Stent System

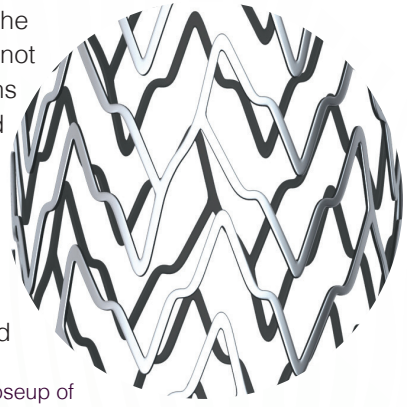
The R2P™ MISAGO® RX Self-expanding Peripheral Stent System consists of a self-expanding wire mesh tube, called a stent, made from a special metal alloy called nitinol (nickel and titanium), and a catheter that delivers the stent to the area of disease.

R2P™ MISAGO® RX Self-expanding Peripheral Stent System

The R2P™ MISAGO® RX Self-expanding Peripheral Stent System is used to try to keep a narrowed or closed-off blood vessel open. Essentially, the purpose of the stent is to open the narrowed or blocked vessel and lower the risk that the blood vessel will narrow or become blocked again.

When the device should not be used:

- If you have severe blood clots in your thigh arteries before or after undergoing a balloon angioplasty procedure
- If you have allergies to nitinol (which contains nickel and titanium), gold, or x-ray dye
- If the physician decides that the diseased vessel walls will not be able to sufficiently stay open after the balloon inflation or stent delivery
- If you cannot take antiplatelet medication, platelet aggregation inhibitors, and/or anticoagulation medications, you should not receive an R2P™ MISAGO® RX Self-expanding Peripheral Stent System. Antiplatelet medications such as aspirin, and platelet aggregation inhibitors such as Plavix® or Effient™ (prasugrel), are very important and are routinely given to patients after a stent is placed to make blood cells slippery; this lowers the risk that the stent will suddenly clot off or narrow. Heparin is a common type of blood thinner that is used during the placement of a stent to also reduce the risk of sudden clotting of the stent or the surrounding blood vessels. If you are not able to take these types of medications that thin your blood or make the blood cells less sticky, it is not safe for you to receive an R2P™ MISAGO® RX Self-expanding Peripheral Stent System. Please ask your physician if you have questions about these or other medications you may be required to take.



Closeup of R2P™ MISAGO® RX Self-expanding Peripheral Stent System

The Procedure

If your physician determines that you may benefit from the R2P™ MISAGO® RX Self-expanding Peripheral Stent System, your physician will give you details on how the procedure will be performed. Here is a summary of the procedure:

The procedure will most likely take place in a special imaging room at your local hospital. Prior to the physician sticking the skin above your artery with a needle, anesthetics or numbing medicines will be given to lessen the pain at the puncture site. A small flexible wire and catheter are then inserted to access the blood vessel (arteries). Your physician will then inject x-ray dye into your arteries to find the blockage. Using current standards of practice, several pictures of the artery will be taken using an x-ray, called an angiogram, to determine the condition of your artery. After your physician evaluates the blockage in your leg, a decision may be made to fix the blockage with a special balloon that compresses the blockage and reopens the vessel (balloon angioplasty). At times, the balloon angioplasty can be performed alone without the need for any further treatment. If your physician decides that the artery needs a stent, you will undergo a stent placement procedure. The way the stent is placed in your artery and the medicines used during and/or after the procedure are standard regardless of the stent you get.

These procedures, tests, and medications are how your physician would normally treat a narrowed thigh artery (SFA – superficial femoral artery).

Potential benefits of the R2P™ MISAGO® RX Self-expanding Peripheral Stent System:

- Blood vessel re-opening and increased blood flow through the legs
- Decreased pain in the legs
- Ability to walk longer distances

Potential Complications (Risks) of Stent Placement

Minimally invasive procedures (procedures and treatments that use only small incisions) such as endovascular procedures (small tubes in the arteries versus open surgical repair) have been associated with shorter recovery times, reduced hospital stay, less pain and decreased blood loss. However, they also have risks. All risks will be described by your physician prior to the procedure.

Generally, complications of the procedure are also complications for stent placement. Complications include, but are not limited to: Allergic reaction, amputation of treated limb, arrhythmia, arterial dissection/perforation/rupture/injury, arterial embolism/thrombosis/occlusion, arterial spasm, arteriovenous fistula, bleeding/hematoma, bradycardia/palpitation, cerebral vascular accident, death, distal embolization, femoral pseudoaneurysm/pseudoaneurysm formation, fever, hemorrhage, hypotension/hypertension, infection and pain at puncture site, leg pain/claudication, myocardial infarction, renal failure, restenosis, sepsis, stent fracture, stroke, target lesion revascularization, and thrombosis of target vessel.

Summary of Clinical Information*

The MISAGO® stent was evaluated in the OSPREY Clinical Study. The OSPREY study enrolled 261 patients. Overall, the study provided reasonable assurance of safety and effectiveness of the stent for treating superficial femoral or popliteal artery stenosis. Following treatment with the MISAGO® stent, many patients had improved blood flow to their legs. Within 30 days after the procedure, there were two patients who required re-treatment of their superficial femoral artery because of re-narrowing. There were no patient deaths or amputations of the treated limb within 30 days after the procedure.

* Results of this study are based on clinical data using access through an artery in the patient's groin (femoral artery), and are not based on data specifically related to access through an artery in the patient's wrist (radial artery).

At 12 months after the procedure, 34 out of 261 (13.0%) patients treated with the MISAGO® stent needed to have their superficial femoral or popliteal arteries treated again because of re-narrowing.

The results of this study showed that the MISAGO® stent is safe and effective for treating superficial femoral or popliteal artery stenosis.

Frequently Asked Questions

1. **What is the purpose of the Patient Implant Card?**
   If you have a stent implanted, you will be provided with a Patient Implant Card. It is important that you carry this card at all times. The card provides information about your stent that will be important for your health care providers to be aware of, especially if you are getting an MRI after receiving the stent. At that time, please show the card to the technologist performing your MRI.

2. **Can the stent move or rust?**
   Once positioned by a physician, this stent should not move, rust, or deteriorate on its own.

3. **How soon can I go back to work?**
   Most people return to work within a few days of the procedure. Please check with your physician.

4. **Do I need to inform the security screener at the airport that I have a stent implanted?**
   No, the stent is a very small amount of metal embedded in your body and will not set off the metal detectors used for airport security.

5. **Can the disease in my leg get worse or the stent not work?**
   Yes, the disease can progress and the stent may not remain open. However, making lifestyle changes such as the following will increase the chances of the stent remaining open: If you smoke, stop; control your blood pressure; lower your cholesterol; control your blood sugar; follow healthy eating habits; exercise regularly; maintain ideal weight; follow up with your physician; and stay on your prescribed medication.

6. **After my stent procedure, are there times when I should call my doctor?**

   Call your doctor if you have any of the following symptoms:

   - Pain in your leg
   - Your leg is colder than your unaffected one
   - Your leg becomes unusually pale or blue
   - You have numbness in your leg
   - Your procedure entry site starts to bleed or swell
   - You start having increasing pain when walking
   - You develop a fever

   Your physician may ask you to call for other symptoms as well.

7. **Can I have an MRI (Magnetic Resonance Imaging) or x-ray?**

   The R2P™ MISAGO® Self-expanding Peripheral Stent System is considered MRI conditional, which means that it can be scanned safely under certain conditions that are described on your Patient Implant Card. When you meet with radiologists or MRI technologists, be sure to present your Patient Implant Card to provide them with the necessary information.

The information provided in this section of the booklet is not intended to be used for medical diagnosis or treatment, or as a substitute for professional medical advice or physician's orders and/or standard of care. Individual symptoms, situations, circumstances, and treatment requirements may vary. Please consult your physician or qualified health care provider regarding your condition and appropriate medical treatment.

Useful Definitions

Angiogram A study where special fluid is injected in the blood vessels in order to see them under x-ray.

Angioplasty A procedure where a balloon is inflated in a blood vessel and used to reopen narrowed or closed blood vessels.

Catheter A tiny flexible tube inserted in the blood vessel. A physician may inject dye, measure pressures, use it to assist in the delivery of other equipment, assist with the removal of blood clots or give medications.

Claudication The name given to severe, cramp-like pain of the legs (and sometimes of the arms) that happens with exercise or walking. The pain is caused by insufficient blood flow to the muscles. The cramping or pain is usually relieved with rest.

Computed Tomography A test that uses special x-ray equipment to get very detailed pictures of blood vessels, organs and bone.

Endovascular Procedure Inside (endo) a blood vessel (vascular). A procedure designed to access a region in the body via major blood vessels through a very small puncture in the skin.

Fluoroscopy Real time x-ray pictures.

Lesion The area of a blood vessel that is narrowed or closed due to a build-up of plaque. (see definition)

Magnetic Resonance Imaging (MRI) MRI uses powerful magnets to take detailed pictures of the body.

R2P™ MISAGO® RX Self-expanding Peripheral Stent System This system is composed of a stent made from nitinol (see definition) and a delivery tube (catheter).

Nitinol The common name for a metal made of nickel and titanium frequently used in self-expanding stents.

Percutaneous Generally refers to a procedure where the entry to the body is through a small nick or puncture in the skin.

Peripheral Arterial Disease (PAD) A common disorder that occurs in arteries where the artery wall linings slowly become narrowed and rough clots form due to built-up plaque (see definition). It is a major predictor of a patient's overall health due to the fact that a patient with PAD is more likely to have blockages in the heart and brain with potential for death from heart attack or stroke.

Plaque The built-up material on the inner lining of an artery made up of cholesterol, fatty substances, and/or calcium.

Stent A wire mesh tube that is placed within the artery via a catheter. The stent is opened to form a scaffolding. This holds the clogged artery open and potentially prevents re-narrowing.

Superficial Femoral Artery (SFA) The SFA is the large artery in the thigh that supplies blood to the leg.

Thrombus A blood clot.

Vascular Usually refers to the structures and vessels that transport and pump blood.

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