

PATIENT INFORMATION BOOKLET

Complete® SE Vascular Stent System:
A Treatment for Peripheral Arterial Disease
in the Superficial Femoral and Popliteal Arteries

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*See pages 12 to 15 for important safety information.

INTRODUCTION

An **endovascular repair** procedure is one option to treat blocked arteries, or **atherosclerosis**, of the leg. Your doctor has given you this booklet to help you further understand the device and procedure. Only your doctor can determine if you are a good candidate for **endovascular repair**.

A glossary is in the next section to help you understand the medical terms used in this booklet. Words that are in bold text are defined in the glossary.

GLOSSARY

Access site: The location in the groin where the introducer sheath is placed during a minimally invasive procedure.

Amputation: Surgical removal of a body part.

Anatomy: The study of parts of the body.

Angiogram: A special X-ray test that indicates the number, exact location and extent of narrowed or blocked arteries.

Angioplasty: A procedure used to open narrow arteries using a small balloon-tipped catheter.

Aorta: The primary artery that delivers blood from the heart to the rest of the body.

Artery (arteries): A blood vessel that carries blood away from the heart to the rest of the body.

Atherosclerosis: A disease process involving the buildup of a fatty substance called plaque on the inside of the arteries.

Blood vessel (vessel): An artery or a vein.

Bypass: See **Open bypass**.

Bypass graft: A fabric tube or blood vessel taken from another part of the patient's body used to restore blood flow in an open bypass.

Catheter: A thin, hollow tube that is inserted through a small opening in the body.

Claudication: Leg pain, cramping, or severe tiredness while exercising.

CT scan: A scan that uses X-rays to see inside the body.

Delivery catheter: A catheter used to implant another device, such as a stent.

Diabetes: A health condition where the body is unable to properly break down blood sugar (glucose) in the blood. Symptoms may include hunger, thirst, excessive urination, dehydration and weight loss.

Endarterectomy: A surgical procedure intended to clean out the plaque in an artery.

Endovascular: Inside or within a blood vessel.

Endovascular repair: A procedure in which a small balloon attached to a catheter (angioplasty) or a small metallic mesh tube called a stent may be placed inside an artery without cutting open the leg.

Femoral artery: Artery that carries blood from the pelvis to the leg. Doctors can use this artery as a path to reach other arteries such as the iliac, superficial femoral and popliteal arteries.

Fever: Higher than normal body temperature.

Fluoroscopy: A live X-ray image that allows doctors to see inside patients.

General anesthesia: A state of sleep induced by the doctor with medication during the procedure.

Glucose: Blood sugar.

Hematoma: A pocket of clotted blood that forms in tissue.

Hypertension: High blood pressure.

Hypotension: Low blood pressure.

Iliac artery: Artery that carries blood to your pelvis.

Imaging: The use of X-rays, CT scans, MRI scans, ultrasound, or other techniques to get pictures of the inside of the body.

Infection: Attack of tissue due to the presence of tiny organisms, such as bacteria.

Introducer sheath: A tube that inserts into an artery, such as the femoral artery, allowing passage of minimally invasive instruments through the arteries to diseased arteries and plaques.

Local anesthesia: The numbing of a select region of the body, such as the access site of an endovascular repair.

Medical therapy: The use of medication, such as aspirin to treat atherosclerosis.

Minimally invasive: Involving a small cut of the skin without exposing the organs.

Magnetic Resonance Imaging (MRI): A technique that uses magnetic fields to get pictures of the inside of the body.

Non-invasive: Not involving cuts through the skin, as in a procedure.

Occlusion: A complete blockage of an artery due to plaque.

Open bypass: An open surgical repair that uses either a fabric tube or a blood vessel taken from another part of the patient's body to redirect blood around a narrowed or blocked artery and restore blood flow.

Open surgery/Open surgical repair: A procedure in which a doctor makes a large cut in the leg to cut out or bypass the plaque in the artery.

Percutaneous Transluminal Angioplasty (PTA): See Angioplasty

Peripheral Arterial Disease (PAD): Atherosclerosis of the peripheral arteries, such as arteries of the pelvis and legs.

Plaque: Buildup of fat and cholesterol on the inner lining of arteries.

Popliteal artery: A continuation of the superficial femoral artery that crosses behind the knee to carry blood to the lower leg.

Recoil: Contraction of an artery to its diseased diameter immediately following angioplasty or stent placement.

Rest pain: Steady aching or pain of the foot or toes while at rest.

Restenosis: Re-narrowing of an artery at the site of angioplasty and/or stent placement.

Smoking cessation: The process of quitting smoking nicotine cigarettes.

Spasm: Contraction of an artery.

Stenosis: A narrowing on the inside of an artery due to plaque.

Stent: A small metallic mesh tube that is permanently placed in the vessel to outwardly push the disease and artery open and restore blood flow.

Stent fracture: Breakage of the stent within the artery.

Superficial Femoral Artery (SFA): Artery that carries blood to the knee and lower leg. The SFA transitions to the popliteal artery near the knee.

Target lesion revascularization (TLR): An endovascular repair or open surgical repair performed on the same plaque within an artery that was already treated, such as with angioplasty or a stent.

Target limb loss: An amputation that occurs on the treated leg of a patient.

Target vessel revascularization (TVR): An endovascular repair or open surgical repair performed on the same artery that was already treated, such as with angioplasty or a stent.

Tissue loss: Skin breakdown and tissue death due to loss of blood supply.

Transfusion: Transfer of blood to a patient.

Ulcer: A wound in the skin involving the breakdown of skin tissue.

Ultrasound: A non-invasive imaging technique that creates a picture through the use of sound waves.

Vein: A blood vessel that returns blood from the body's limbs and organs to the heart.

SUPERFICIAL FEMORAL AND POPLITEAL ARTERIES

The **superficial femoral artery (SFA)** carries blood from the **femoral artery** through the thigh to the knee and lower leg. Near the knee, the **SFA** becomes the **popliteal artery** which continues below the knee to supply the lower leg with blood (Figure 1).

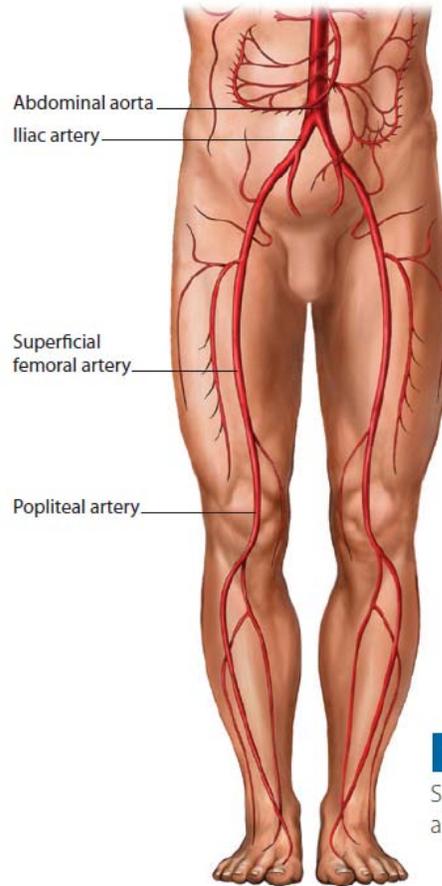
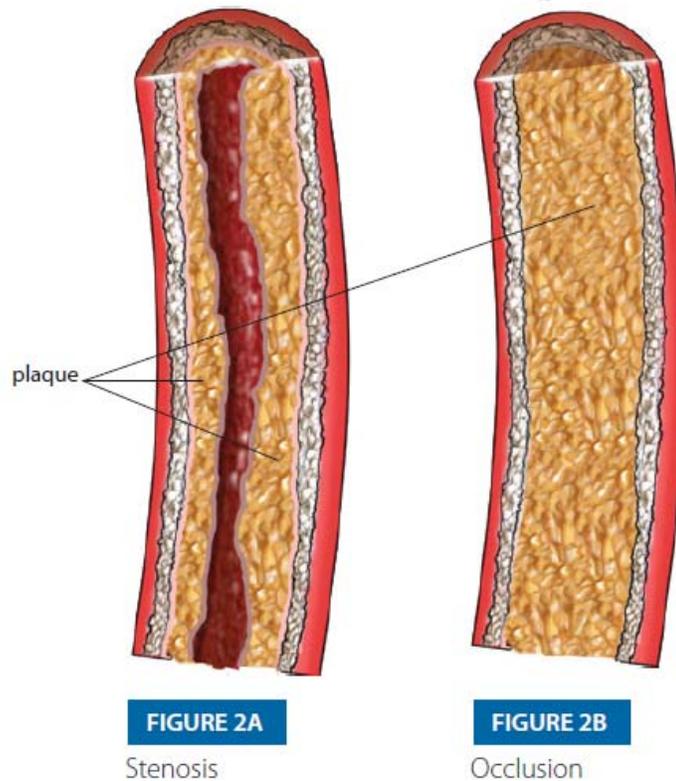


FIGURE 1

Superficial femoral
and popliteal arteries

PERIPHERAL ARTERIAL DISEASE

Peripheral Arterial Disease (PAD) is a disease that occurs when the naturally smooth walls of **arteries** in the arms, legs, and some organs become hardened and narrowed due to the buildup of **plaque**. The process of **plaque** buildup is known as **atherosclerosis**. **Plaque** from **atherosclerosis** may cause a narrowing of the **artery** called a **stenosis** (Figure 2A). This narrowing can become so severe that the **artery** becomes completely blocked, causing an **occlusion** (Figure 2B). Blood flow through an **artery** may decrease due to a **stenosis** or completely stop in the case of an **occlusion**. When **PAD** affects the **SFA** or **popliteal artery**, blood flow to the leg may decrease. The loss of blood flow may result in pain of the leg or foot while performing activities, or may occur even at rest. In more advanced cases, the loss of blood flow may be severe enough to result in **tissue loss**.



CAUSES

PAD occurs slowly over time due to smoking, **diabetes**, high cholesterol, and aging.

SYMPTOMS

Symptoms of **PAD** may include difficulty in walking, or pain, discomfort, or tiredness in the legs. Depending on the disease severity, these symptoms may occur while performing an activity or even at rest. In more severe cases, skin **ulcers**, non-healing wounds, and **tissue loss** may occur.

TREATMENT OPTIONS

Several treatment options exist for **PAD**, depending on your doctor's diagnosis:

- lifestyle alterations, such as exercise and **smoking cessation**;
- **medical therapy**;
- **open surgical repair** (described below);
- **endovascular repair** (described below).

Additionally, **PAD** may be treated with a combination of these options.

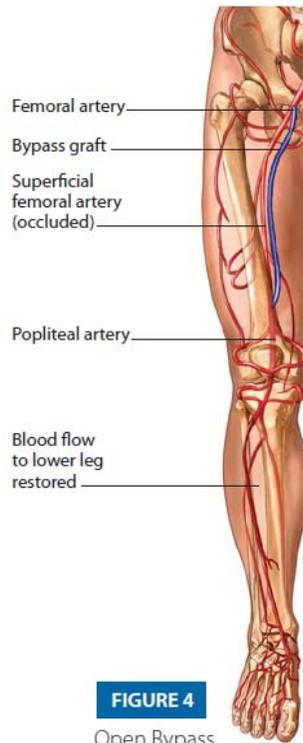
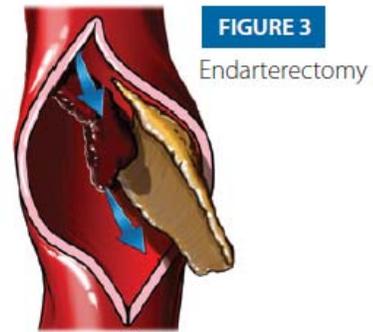
*Since all treatment options have possible complications and benefits, you should talk to your doctor about which option is best for you. See pages 12 to 15 for important safety information about **endovascular repair**.*

OPEN SURGICAL REPAIR

Open surgical repair may be an **endarterectomy** or a **bypass**, depending on the severity and location of the **plaque**. In an **endarterectomy**, the doctor makes a cut at the location of the diseased **artery** (Figure 3). After making a lengthwise cut through the **artery** wall, the doctor can then remove the **plaque**. Once the **plaque** is removed, the **artery** may be sewn closed. Sometimes, the closure is completed with a patch of the patient's own **vein** or a fabric material. After closure, blood flows normally through the **artery**.

In an **open bypass** procedure, a large cut down the inside of the leg is performed to provide access to the diseased **artery** (Figure 4). Once exposed, the doctor can then **bypass** the diseased **artery** with a **bypass graft**, made from either another **vessel** taken from the patient's body or a fabric tube. The **bypass** is performed by sewing the **bypass graft** to **arteries** above and below the diseased **vessel**. The **bypass graft** re-routes blood around the diseased **artery** to restore blood flow.

After **open surgical repair**, patients typically stay in the hospital for a few days.² Recovery at home may take two months or more.



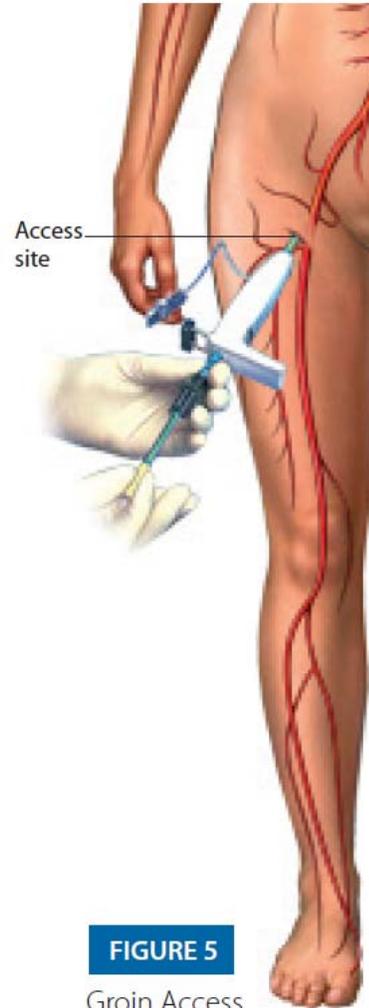
ENDOVASCULAR REPAIR

Endovascular repair is a newer **minimally invasive** medical procedure. This treatment option typically includes **percutaneous transluminal angioplasty (PTA** or commonly just **angioplasty**) often performed in conjunction with a permanently-placed metallic mesh tube called a **stent**. Because **plaque** often forms in the **SFA** and **popliteal artery**, causing symptoms such as **claudication** and **rest pain**, these arteries are common sites of **PTA** and **stent** placement.

The doctor begins the **endovascular repair** with a small cut, commonly at the patient's groin (Figure 5). This cut allows the doctor to insert an **introducer sheath** into the patient's **artery**. The **introducer sheath** allows the doctor to pass **minimally invasive** instruments through the **arteries** in order to treat the **plaque**. A common **minimally invasive** instrument is a **guidewire**, which the doctor threads beyond the **plaque** in order to provide treatment. Once the **guidewire** is in place, the doctor may direct an **angioplasty catheter** or a **stent** over the **guidewire** to the site of the **plaque**. Here, the doctor may use **angioplasty** or place a **stent** to open the vessel. While **angioplasty** is used temporarily within the **artery**, a **stent** is intended to be placed permanently within the **artery**.

After **endovascular repair**, patients often stay overnight in the hospital, and sometimes go home the day of the procedure.² Recovery at home may still take several weeks.

The long-term results of **endovascular repair** of the **SFA** and **popliteal artery** have not been established.



COMPLETE® SE VASCULAR STENT SYSTEM

The Complete® SE Vascular Stent System is a **minimally invasive** device that includes a **delivery catheter** and **stent** (Figure 6). Using **endovascular repair**, the doctor may thread the Complete® SE Vascular Stent System over a **guidewire** to the **plaque**. Here, the doctor may permanently place the **stent** component of the Complete® SE Vascular Stent System. Once the **stent** has been placed, the **delivery catheter** is removed. The doctor may use **PTA** or other **minimally invasive** instruments with the Complete® SE Vascular Stent System during the procedure.



FIGURE 6

Complete® SE
Vascular Stent
System

IS ENDOVASCULAR REPAIR RIGHT FOR YOU?

If you have the right **anatomy**, an **endovascular repair** procedure may be an option to treat your **PAD** due to flow blockages of the **SFA** and **popliteal artery**.

WHEN ENDOVASCULAR REPAIR IS NOT AN OPTION

If you have a condition that can infect the **stent** or are allergic to **stent** materials, an **endovascular repair** with a stent should not be performed because you could get infected or have an allergic reaction, both of which could be life-threatening. Also, if you cannot receive medication required for **endovascular repair**, such as aspirin or blood thinners, this procedure may not be an option for you.

Only your doctor can decide which treatment option is right for you.

WARNINGS

The use of the Complete® SE Vascular Stent System has not been studied in patients who:

- are less than 18 years old;
- are pregnant or breast feeding;
- have any condition that does not allow safe use of **endovascular** devices;
- have received a previous **stent** in the same area of their **SFA** or **popliteal artery**;
- have known untreatable reactions to any component of the **stent** system, drugs, such as aspirin or blood thinners, or **imaging** dyes;
- have bleeding disorders;
- refuse blood **transfusions**;
- have kidney disease.

The Complete® SE Vascular Stent System is not intended for use in patients that cannot or will not comply with their doctors' instruction before and after the procedure. Your doctor will need to help you decide whether it is appropriate to use a Complete® SE Vascular Stent System if any of these situations apply.

WHAT SYMPTOMS SHOULD PROMPT YOU TO CALL YOUR DOCTOR AFTER THE PROCEDURE?

Call your doctor immediately if you experience any of the following symptoms after your **endovascular repair**: pain, numbness, coldness, or weakness in your legs or buttocks, or bleeding from the groin.

IMPORTANT SAFETY INFORMATION

To better understand the complications and benefits of **endovascular repair** of the **SFA** and **popliteal artery**, Medtronic conducted a clinical trial within the US, Belgium, and Germany³. This trial enrolled 196 patients between the ages of 40 and 93 years old. These patients had **plaques** in their **SFAs** and **popliteal arteries** that contributed to their **claudication**, and in some cases, **rest pain** and **tissue loss**. Your doctor can discuss how your situation compares to this clinical trial population.

Some problems experienced after **endovascular repair** of the **SFA** and **popliteal artery** do not have symptoms associated with them. You will have to schedule regular follow-up visits with your doctor. This will allow your doctor to check on your progress.

POSSIBLE COMPLICATIONS

During the clinical trial of the Complete® SE Vascular Stent System, some patients had complications³. These complications were counted at the time of the **endovascular repair** and at 12 months after the **endovascular repair**. Within 30 days of their **endovascular repair**, one patient had a complication. The complication was an **ulcer** on the foot of the treated leg that resulted in partial **amputation** of the foot. By the time 12 months had passed, 11% of patients received an additional procedure on their artery that had been treated with the **stent** (a **target vessel revascularization** or **TVR** for short). One of these patients received an **open surgical bypass**. The table below shows these complications along with the percentage of patients affected.

When considering **endovascular repair** with the Complete SE Vascular Stent System, there is a risk of these complications happening to you.

Complications Observed in Clinical Trial³

During the procedure	
Complication	0.0%
Death through 30 Days	0.0%
Death (Device and/or Procedure Related)	0.0%
Device Related	0.0%
Procedure Related	0.0%
Target Limb Loss (amputation)	0.0%
TLR	0.0%
PTA	0.0%
Open Bypass Graft	0.0%
TVR	0.0%
PTA	0.0%
Open Bypass Graft	0.0%

Out to 12 months after the procedure	
Complication	11.0%
Death through 30 Days	0.0%
Death (Device and/or Procedure Related)	0.0%
Device Related	0.0%
Procedure Related	0.0%
Target Limb Loss (amputation)	0.5%
Clinically Driven TLR	8.4%
PTA	8.4%
Open Bypass Graft	0.5%
TVR	11.0%
PTA	10.5%
Open Bypass Graft	0.5%

RISKS OF ENDOVASCULAR REPAIR

Risks of **endovascular repair** of the **SFA** and **popliteal artery** with a **stent** may also include:

- Abrupt **stent** closure
- Allergic reaction to components of the **stent** system, drugs, or **imaging** dyes
- **Amputation**
- Bleeding complications
- Emergency **open bypass** to restore blood flow to the leg or foot
- Death
- Detachment of a part of the **stent** system
- Weakening or tearing of blood vessel
- **Fever**
- **Hematoma** at **access site**, which may require surgical repair
- **Hypotension** or **hypertension**
- **Infection**
- Kidney failure
- **Occlusion** of **SFA** or **popliteal artery**
- Pain (at the insertion site or in the treated limb)
- **Stent** placed at unintended location or placed in the wrong position
- **Stent fracture**, which may lead other complications
- **Restenosis** of **artery** portion where the **stent** was placed
- Vascular complications (for example, blood clot)
- Vessel **spasm** or **recoil**
- Wound healing complications

After your **endovascular repair** of the **SFA** or **popliteal artery**, there is a chance that a **restenosis** may occur. If this happens, your doctor may recommend a second **endovascular repair** procedure to fix the **restenosis**. If the **restenosis** is not repaired, **claudication** may return or **tissue loss** or **amputation** may occur.

Complications may be different for each patient. You should ask your doctor to help you understand and use this information.

POSSIBLE BENEFITS OF TREATMENT

In comparison to **open surgery**, **endovascular repair** of the **SFA** or **popliteal artery** may come with a smaller chance of infection, wound healing complications, and vascular complications.¹ Also, **endovascular repair** may result in fewer days spent in the hospital and shorter recovery time compared to **open surgery**.^{2,3} For the clinical trial of the Complete® SE Vascular Stent System, patients on average reported improvement of their symptoms.

All patients began the clinical study with symptoms involving their legs. After 30 days following their **endovascular repair**, 56.2% of patients reported no symptoms with their legs. At 12 months following their **endovascular repair**, 54.5% of patients continued to report no symptoms with their legs. Patients also reported the ability to walk faster, farther, and climb stairs with less difficulty 12 months after their **endovascular repair**. Overall at 12 months, 90.9% of patients reported an improvement in their symptoms.

The results of the clinical trial support that the Complete® SE Vascular Stent System safely improves symptoms in patients experiencing **claudication**.

Other benefits of an **endovascular repair** may include:

- Possible reduction of procedure-related illness and death in patients who have other severe disease (for example, heart disease);^{1,3}
- Improved monitoring of the patient's health status during the procedure, because **general anesthesia** is not required to perform an **endovascular repair**;
- Optional treatment for **PAD** of the leg **arteries** in patients who are not suitable candidates for **open bypass** or do not wish to have an **open surgical repair**;
- An increase in patient comfort over **open surgical repair**.

For detailed clinical study information, go to www.ClinicalTrials.gov and search for "Complete SE SFA Study" or contact Medtronic at 877-526-7890.

ENDOVASCULAR STENTING PROCEDURE

Before the procedure:

Prior to the procedure, you may be given medication to help calm you and maintain proper blood clotting times.

During the procedure:

Typically, the **endovascular repair** takes around 2 hours to complete. During this time, you are sedated.

1. Using **local anesthesia**, a small cut is made on one side of your groin.
2. An **introducer sheath** is inserted into your **femoral artery** to help the doctor pass **endovascular** instruments to the diseased **artery**.
3. A **catheter** holding the **stent** is inserted through the **introducer sheath** and advanced through your **arteries** to the location of disease within your **SFA** or **popliteal artery**.
1. *Note: **Fluoroscopy** is used to guide the **catheter** to the proper location. This requires the use of **imaging** dyes. If you have kidney problems, the doctor should be notified.*
4. Once the **catheter** is placed, the **stent** is released into your **artery** (Figure 7).



FIGURE 7

Stent deploying
in artery

5. When the **stent** is released, it expands to push the **plaque** out of the way and hold you **artery** open (Figure 8).
6. The **delivery catheter** is removed and the doctor will test to make sure the **stent** is working properly.
7. **Angioplasty** may be used with the **stent** during the **endovascular repair**.
8. Once the doctor has ensured that the **artery** is properly opened, the **introducer sheath** may be removed.
9. The cut in your groin is then closed and the procedure is complete.

After the procedure:

After the **endovascular repair**, you will go to a recovery room to recover. Your doctor may discuss with you the medications you may be required to take after the procedure as well as your follow-up visits.



FIGURE 8

Expanded Stent

FOLLOW-UP

It is important to schedule regular follow-up visits with your doctor. These follow-up visits often occur at one month, six months, and then yearly after your procedure.

Imaging tests may be required to monitor **stent** performance. Since the long-term effects of **endovascular repair** of the **SFA** and **popliteal artery** are not known and some problems with **endovascular repair** may not have symptoms, you will need to let your doctor check on your progress regularly. See pages 12 to 15 for important safety information.

IMPLANTED DEVICE IDENTIFICATION CARD

After your procedure, your doctor will give you a temporary implanted device identification (ID) card. This card will tell you the details about the **stent** placed in your **artery**.

Medtronic will mail you a permanent implanted device ID card to carry in your wallet. Your permanent ID card will list the following information:

- Type of device implanted
- Date of implant
- Your doctor's information

Be sure to tell all of your healthcare providers that you have a **stent** and show them your implanted device ID card. You should keep your ID card with you at all times since it tells healthcare providers important details of your stent, which may be necessary in the case of an emergency.

MAGNETIC RESONANCE IMAGING

After being implanted with a Medtronic Complete® SE Vascular Stent System, it is safe to have **MRI** procedures, under certain conditions. Show your implanted device ID card to your healthcare providers to help them determine proper **MRI** conditions.

LIFESTYLE CHANGES

- You will need to go for regular follow-up visits to check your **stent**. Please consult your doctor to reschedule any follow-up visits if you are traveling.
- The **stent** is not expected to trigger any passenger screening devices such as airport security scanners.
- Please consult your doctor about your ability to perform strenuous physical activities.

QUESTIONS YOU MAY WANT TO DISCUSS WITH YOUR DOCTOR

- What are the other options for treating my **PAD**?
- Which stents are approved for treatment of **PAD** of the **SFA** and **popliteal artery**?
- What are all of the possible complications of an **endovascular repair** of the **SFA** or **popliteal artery**?
- What are all of the possible complications of an **open surgical repair** or **open bypass** of the **SFA** or **popliteal artery**?
- Will my health insurance pay part or all of the cost of my **endovascular repair** procedure?
- After the **endovascular repair**, how often must I follow-up with a doctor?
- After the **endovascular repair**, what tests will be done?
- Do I have to limit activities after treatment? If yes, for how long?
- How long can the **stent** remain implanted in my body?
- How many **endovascular repair** procedures has this facility performed?

This guide is not a substitute for detailed talks with your doctor. Only your doctor can decide if this procedure is right for you. This therapy is not for everyone. Please consult your doctor. A prescription is required.

ADDITIONAL INFORMATION

Additional information regarding treatment can be found at:

www.medlineplus.gov

www.fda.gov

www.vascularweb.org

CONTACTING MEDTRONIC

If you have any questions concerning the Medtronic Complete® SE Vascular Stent System, you should contact your doctor. It is Medtronic's mission to alleviate pain, restore health and extend life. If there is anything that we as a company can do to assist you, please feel free to contact us at:

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CardioVascular LifeLine
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REFERENCES

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- ³PMA P110040: Complete SE for superficial femoral and proximal popliteal arteries, Summary of Safety and Effectiveness Data.
- ⁴Hunink MGM, et al., "Revascularization for femoropopliteal disease: A decision and cost-effectiveness analysis", *Journal of the American Medical Association* 274: 165-71 (1995).

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➤ www.peripheral.medtronicendovascular.com

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