Medtronic
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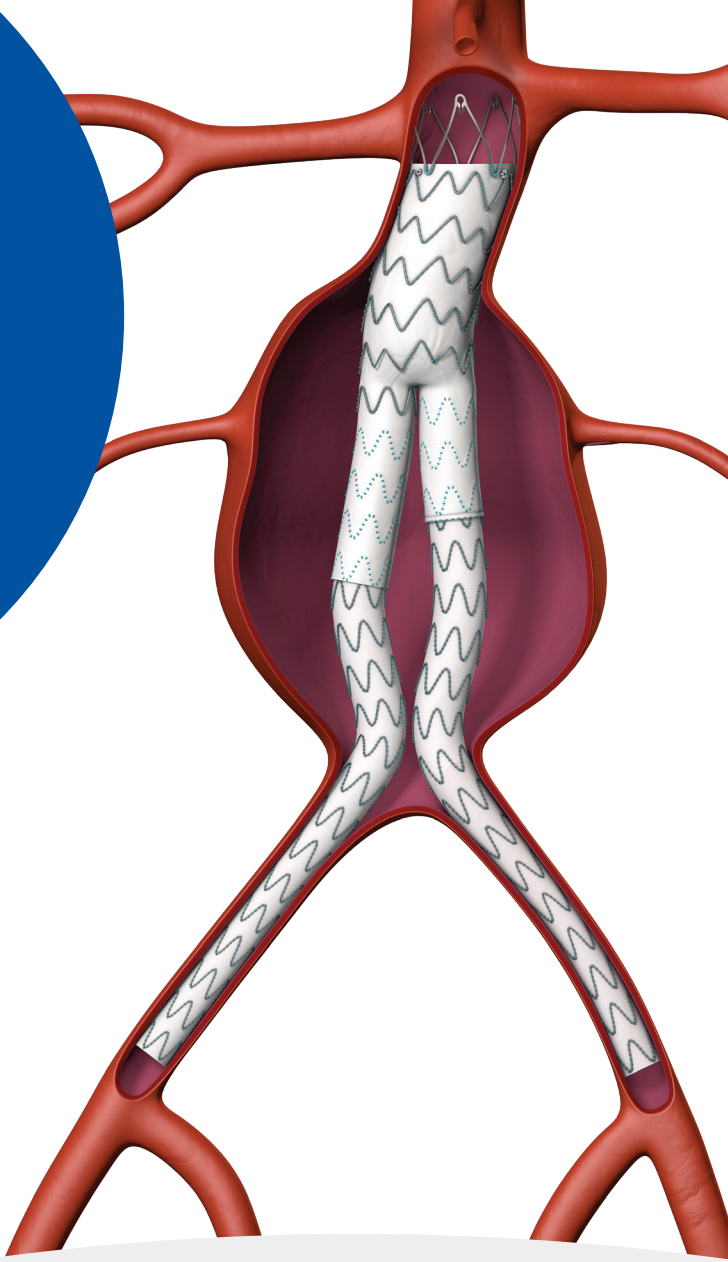
# Patient information booklet



## Endovascular stent grafts:
a treatment for abdominal aortic aneurysms

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The image on the cover is the Endurant™ Stent Graft.
This booklet applies to all Medtronic abdominal aortic stent grafts.

# Introduction

You have discussed having a stent graft procedure to treat an abdominal aortic aneurysm (AAA) with your doctor. Your doctor has given you this guide to help you further understand the device and procedure. Only a doctor can determine if you are a good candidate for an abdominal stent graft procedure.

A Glossary is provided in the next section to help you understand the medical terms used in this book. Words that are bolded in the text are defined in the Glossary.

There are two stent graft types available: bifurcated and aorto-uni-iliac (AUI). Your physician will determine which stent graft is best for you but in general, an AUI stent graft is used when a bifurcated stent graft cannot be used. This booklet will provide you with more information about the stent graft types. Please note that additional procedures may be needed with the use of an AUI stent graft, which you should discuss with your doctor.

# Glossary

Abdominal aortic aneurysm (AAA): A bulging or "ballooning" of a weakened area of the abdominal aorta. This term is often called "AAA."

Anatomy: The study of parts of the body.

Aneurysm rupture/Rupture: A tear in the blood vessel wall near or at the location of the weakened area of the blood vessel.

Aorta: The main artery that carries blood from the heart to the rest of the body.

Aorto-uni-iliac (AUI) stent graft: A type of stent graft used to treat abdominal aortic aneurysms. This type of stent graft extends from the aorta down to one of the two iliac arteries that supply blood to the legs. Refer to Figure 5 for illustration of the AUI stent graft.

Bifurcated stent graft: A type of stent graft used to treat abdominal aortic aneurysms. This type of stent graft extends from the aorta down to the two iliac arteries that supply blood to the legs. Refer to Figure 5 for illustration of the bifurcated stent graft.

Computed Tomography (CT) scan: A scan that creates a series of X-rays that form a picture of the aneurysm and nearby blood vessels.

Endoleak: Blood flow into the aneurysm (bulge or ballooning of the weakened area of the blood vessel) after placement of a stent graft.

Endovascular: Inside or within a blood vessel.

Endovascular stent grafting: A procedure in which a tube-shaped device is placed inside a diseased vessel without surgically opening the tissue surrounding the diseased vessel.

Exclude: Shutting off or removing from the main part.

Femoral arteries: Blood vessels that carry blood to the thigh region of each leg. Doctors can use these arteries as pathways to reach the aorta. Refer to Figures 4 and 6 for an illustration of the location of the femoral arteries.



Femoral-femoral artery bypass: A type of surgery that is performed as part of some endovascular stent graft procedures. A portion of one iliac artery on one side of the patient is intentionally blocked if required and if not already blocked. Blood flow to the leg on this side is preserved by surgically connecting the femoral artery that is below the blocked portion to the femoral artery of the other leg, using a fabric graft. Refer to Figure 8 for illustration of the femoral-femoral artery bypass.

Fluoroscopy: A real-time X-ray image that is viewed on a monitor. This is an imaging technique generally used by doctors to see the placement of the stent graft during endovascular procedures.

Iliac arteries: Blood vessels that carry blood to the lower back, groin, and buttocks. Refer to Figures 1 and 2 for an illustration of the location of the iliac arteries.

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

Minimally invasive: Involving a puncture or cut of the skin without exposing the internal organs.

Magnetic resonance imaging (MRI): A technique that uses magnetic fields to form images of structures within the body.

Occlusion device: Device used during some endovascular procedures to stop or prevent backward flow of blood into an artery.

Open surgery/open surgical repair: A type of surgery performed to repair an aneurysm. The doctor repairs the aorta by making a large cut in the abdomen. The weakened area of the aorta is removed and replaced with a fabric graft. The graft is sewn into place and acts as a replacement blood vessel.

Stent graft/abdominal stent graft: A woven polyester tube supported by a tubular metal web that is placed inside of a diseased vessel without surgically opening the surrounding tissue. After being placed in the artery, the stent graft expands and relieves the pressure on the aneurysm by providing a new pathway for blood flow.

Ultrasound: An imaging technique that creates an image through the use of high-frequency sound waves.

# Abdominal aorta

The aorta is the largest blood vessel in the body. It carries blood away from the heart to the rest of the body. The abdominal aorta is the part of the aorta located in the abdomen (see Figure 1).

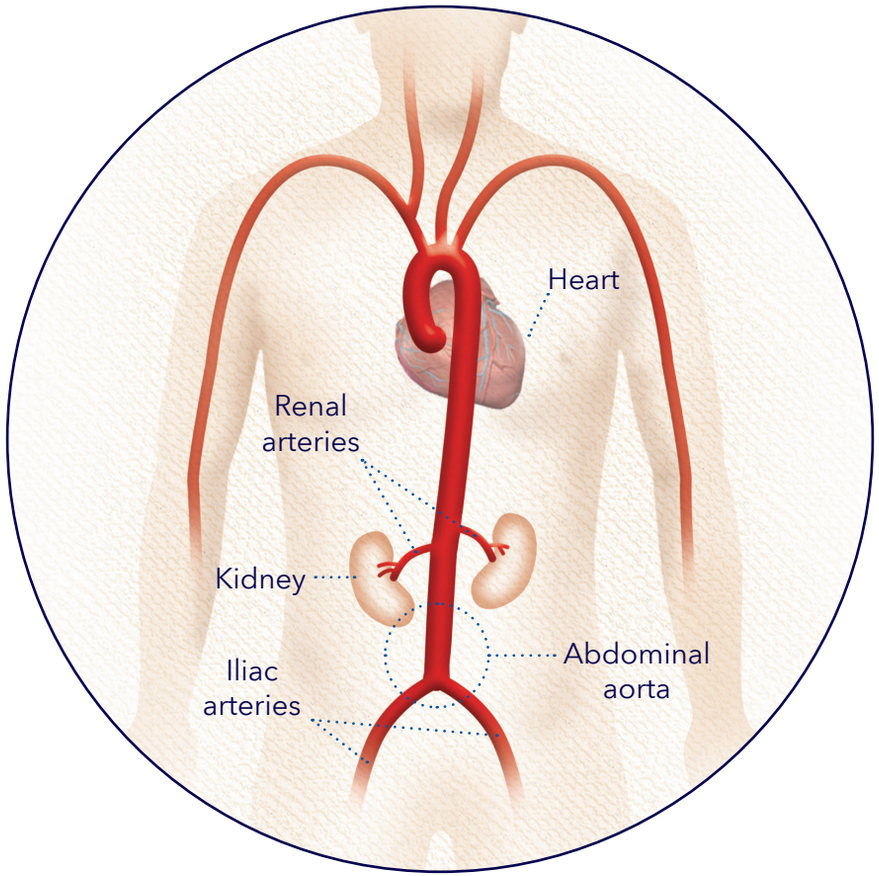


Figure 1
Abdominal aorta (normal)



# Abdominal aortic aneurysm

An aneurysm is the bulging or ballooning of a weakened area of a blood vessel. The wall of the aorta can become weak due to age, disease, or trauma. This may cause the aortic wall to bulge, leading to an AAA (see Figure 2). As the bulge grows, the wall of the aorta becomes weaker. This may cause the aorta to rupture and lead to massive internal bleeding. An aneurysm rupture can cause death and needs immediate medical attention.

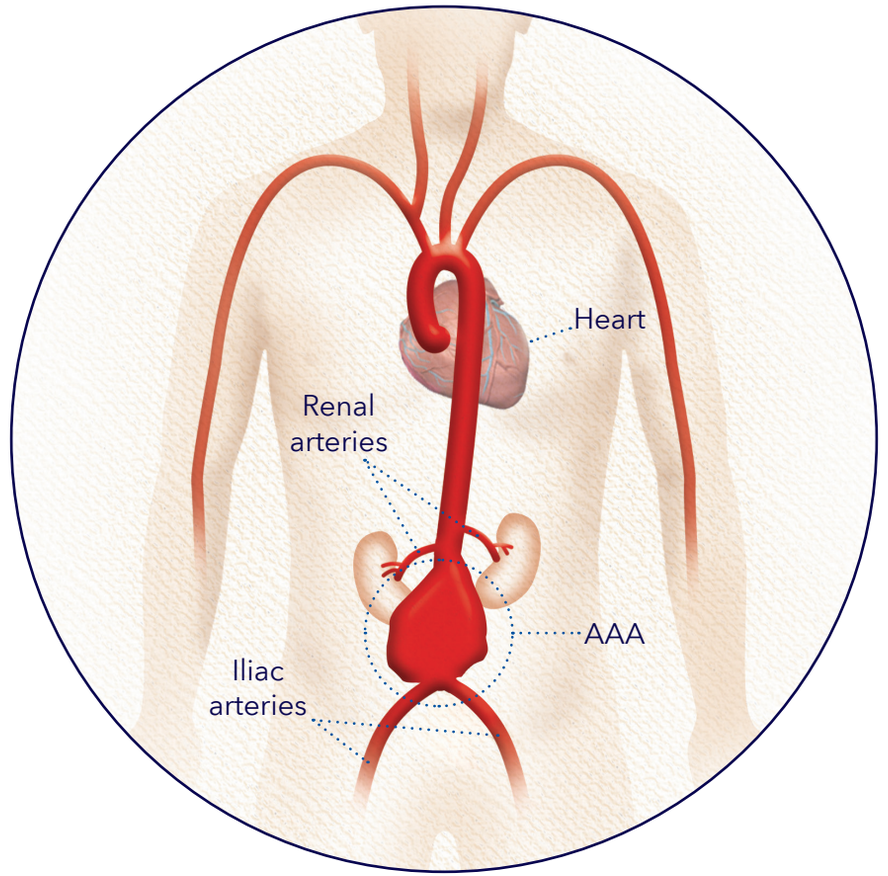


Figure 2
Abdominal aorta aneurysm

## Causes

The risk of developing an AAA increases with age. AAA usually affects people over 50 years of age and is more common in men than in women. Other risks include smoking and high blood pressure. A patient with a family history of AAA is at higher risk and should consult a doctor.

## Symptoms

In most cases, patients have no symptoms of an AAA. However, for those patients with symptoms, the most common one is pain in the abdomen, back, or chest. The pain may range from mild to severe. Some patients might feel the aneurysm as a throbbing mass in their abdomen. An AAA is often discovered during an examination being done for other unrelated health reasons. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen. Most often, aneurysms are found during a medical test such as a CT scan or ultrasound.

## Treatment options

If your doctor thinks there is a risk that your AAA may rupture, he or she may recommend treatment. There are two primary treatment options available depending on your doctor's diagnosis:

**Open surgery or endovascular stent grafting**



## Open surgery

In this treatment option, the doctor repairs the aorta by making a large cut in the abdomen (see Figure 3). The aneurysm section of the aorta is removed and replaced with a fabric graft.

The fabric graft is sewn into place and acts as a replacement blood vessel. The blood flow through the aorta is stopped while the graft is put in place.

Open surgery is typically performed under general anesthesia. It takes about three to four hours to complete. Patients typically spend one to two days in an intensive care unit and typically remain in the hospital for one week. Patients may require two to three months to recover completely. Open repair is a proven medical procedure.

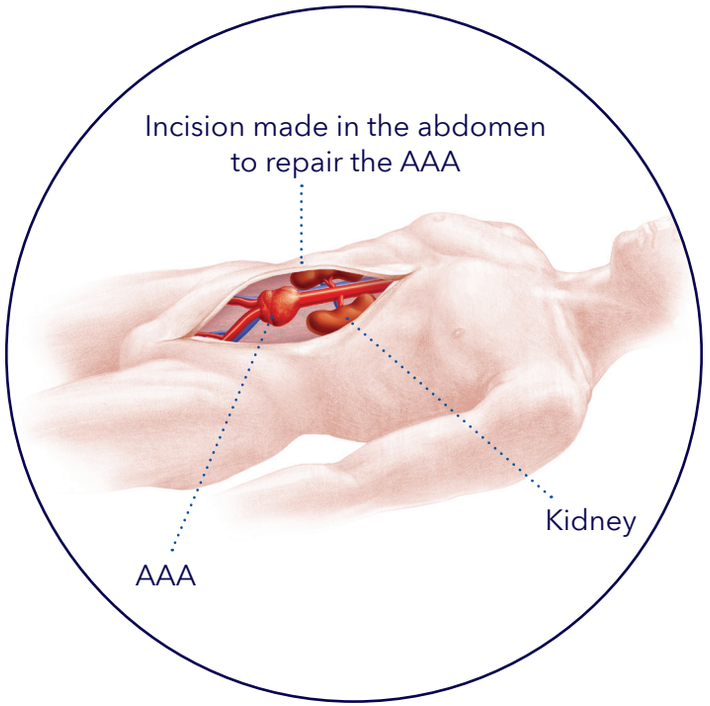


Figure 3
Abdominal aorta aneurysm

## Endovascular stent grafting

This is a minimally invasive procedure. A stent graft (such as the abdominal stent graft) is placed inside the aneurysm without surgically opening the tissue surrounding it (see Figure 4). The stent graft is a fabric tube supported by a metal framework. The placement of an AUI stent graft may require an additional procedure, such as femoral-femoral artery bypass and/or placement of an occlusion device in your iliac artery (see Figure 8).

This procedure is typically performed under local, regional, or general anesthesia. It takes about one to three hours to complete. Patients typically spend a few hours in the intensive care unit and typically remain in the hospital for one to two days. Patients may require four to six weeks to recover completely.

The recovery time for a patient who receives an AUI stent graft device along with a femoral-femoral artery bypass would be different than if you received a bifurcated stent graft device because of the additional femoral-femoral artery bypass being performed. The typical hospital stay would be approximately 4–7 days for a patient receiving an AUI stent graft device and a femoral-femoral artery bypass, with the full recovery lasting as long as the bypass incisions take to fully heal which could be about 4–6 weeks.

Your medical history in combination with your arterial anatomy may make you a better candidate for an AUI stent graft rather than a bifurcated stent graft and/or open surgical repair.

**Risks and benefits are associated with both treatment options. Patients should talk with their doctors about which option is best for them.**

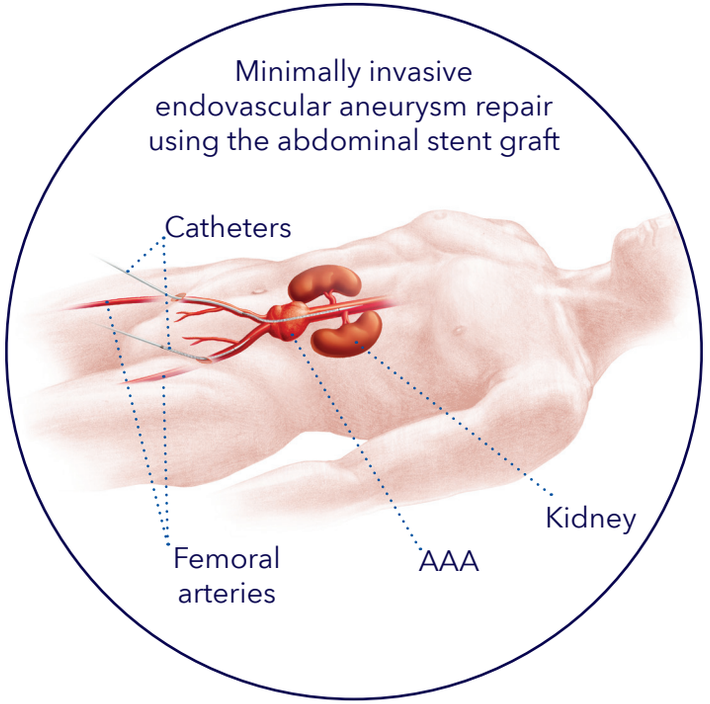


Figure 4
Endovascular stent grafting

## Abdominal stent graft

The abdominal stent graft is a fabric tube supported by a metal framework (see Figure 5). It is placed in the aorta using a catheter. The stent graft is designed to exclude the aneurysm. The stent graft reduces the pressure on the aneurysm and provides a new pathway for blood flow. This reduces the risk of rupture.

The abdominal stent grafts manufactured by Medtronic are typically made from nitinol (nickel-titanium), polyester, and platinum-iridium.

Do not get the abdominal stent graft if:
- You have a condition that can infect the stent graft
- You are allergic to the stent graft materials

There are two stent graft types available: Bifurcated and AUI. Your medical history in combination with your arterial anatomy may make you a better candidate for an AUI stent graft rather than a bifurcated stent graft and/or an open surgical repair. Your doctor can help determine if the abdominal stent graft is suitable for you.

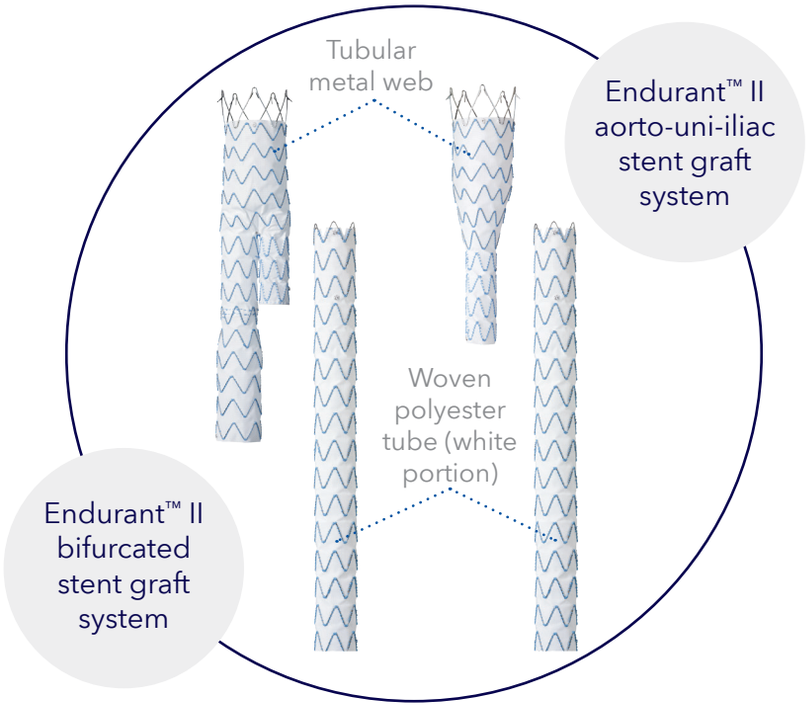


Figure 5
Endurant™ II AAA stent graft system†

In some cases, your physician may choose to implant EndoAnchor™ implants at one end of the stent graft to help keep it in place and reduce the potential for endoleaks. EndoAnchor™ implants are a series of small metallic coils that hold the stent graft to the artery wall to keep the stent graft from moving. If this occurs, you can expect the same basic risks and benefits from the treatment and the same precautions and follow-up instructions would apply.

†Note: The stent grafts shown in the figure above are not representative of the actual size. The bifurcated stent grafts manufactured by Medtronic range in length from 124 mm (4.88 in.) to 166 mm (6.54 in). The aorto-uni-iliac (AUI) stent grafts manufactured by Medtronic have a length of 102 mm (4.02 in).



## Risks

As with any endovascular stent graft, the abdominal stent graft comes with risks. Please discuss all risks with your doctor. Major risks associated with abdominal endovascular stent grafts include, but are not limited to:

- Endoleaks – An endoleak is the leaking of blood around the graft into the aneurysm. Endoleaks can be detected using CT scans. Most endoleaks do not require treatment. Your doctor can decide if you need any treatment.
- Stent graft movement – This is the movement of the stent graft from its original position over time. This can be assessed using imaging techniques like CT scans. Your doctor can decide if you need any treatment.
- Device-related issues (for example, breaking sutures or the metal portion of the stent graft or the EndoAnchor™ implant [if used]) – These issues may be detected using imaging techniques such as X- rays. Your doctor can decide if you need any treatment.
- Aneurysm rupture
- The use of this device requires fluoroscopy and use of dyes for imaging. Patients with kidney problems may be at risk of kidney failure due to the use of dyes.
- Swelling of the groin area
- Nausea and vomiting
- A hole or a tear of the blood vessels are risks associated with any catheter-based procedure. These risks may increase with the use of large-sized catheters.
- Formation of an abnormal passage between your arteries and veins
- Bowel complications including death of a portion of your bowel tissue requiring surgical removal
- Cramping pain and weakness in the legs and especially the calves
- Formation of blood clots that block the flow of blood to your organs
- Fever and inflammation
- Problems affecting your urinary and reproductive organs including infection and tissue death

- Impotence
- Infection of the aneurysm and device access site
- Complications of the nervous system including total or partial paralysis of the lower half of the body with involvement of both legs, confusion, stroke, and transient ischemic attack
- Blockage of the device or blood vessel
- Kidney problems
- Liver problems
- Additional endovascular procedures
- Surgical conversion to open surgical repair
- Infection, pain, or bleeding in wounds
- Reduced blood flow to the legs resulting from complications of the femoral-femoral artery bypass or any device used during the endovascular procedure
- Death

## Benefits

There are a number of benefits[1] to having an abdominal stent graft procedure. Some of these are listed below:

- The procedure is minimally invasive.
- The procedure can be performed under local anesthesia.
- There is a lower surgical complication rate.
- The patient may lose less blood during the procedure. This reduces the risk of blood transfusion.
- The patient may spend less time in the intensive care unit after the procedure, and have a short hospital stay.

[1]Based on clinical study data for abdominal stent grafts manufactured by Medtronic. The long-term results of the abdominal stent graft have not yet been established.



## Abdominal stent graft procedure

**Before the procedure:**

Prior to the procedure, imaging tests like CT scans are performed. These tests allow the doctor to assess the aneurysm. Your physician will determine which stent graft is best for you based on your pre-procedure imaging.

**During the procedure:**

This procedure is performed using anesthesia. A small cut is made on both sides of the groin to prepare for the stent grafting procedure.

Fluoroscopy is used to guide the catheter to the AAA. The catheter is a long, thin tube-like device used to place the stent graft in the aorta. The catheter is advanced through the large vessel in the patient's groin (femoral artery) to reach the abdominal aneurysm (see Figure 6).

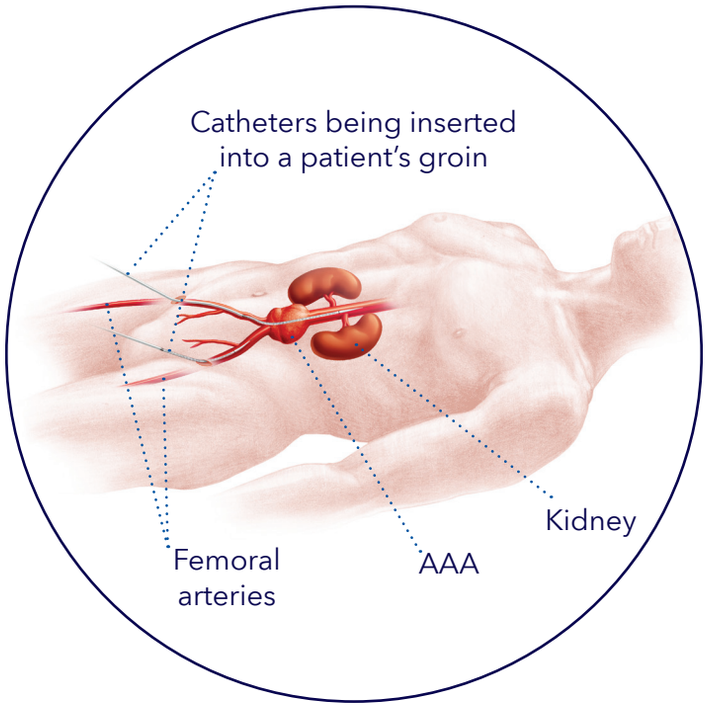


Figure 6
Insertion of the catheters

The stent graft is slowly released from the catheter into the aorta. As the stent graft is released, it expands to its proper size so that it snugly fits into the aorta both above and below the aneurysm. The catheter is then removed from the body. The stent graft remains inside the aorta permanently (see Figure 7). Additional stent grafts may be required to completely exclude the aneurysm. Imaging procedures are often performed to check whether the stent graft is properly placed.

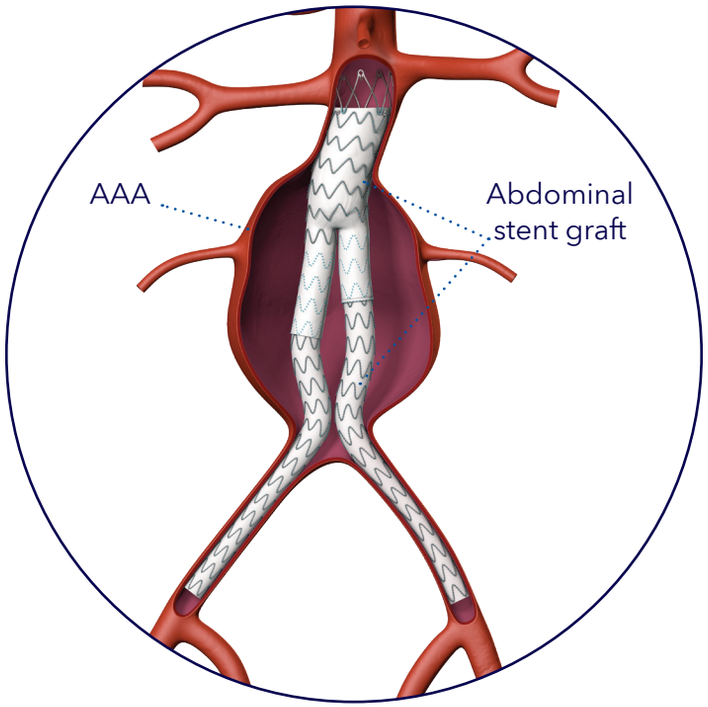


Figure 7
Abdominal stent graft inside the aneurysm

In situations where only one iliac artery is available, your doctor may decide to use an AUI stent graft. This device may treat the aneurysm without requiring two open iliac arteries. In this situation, an occlusion device is typically placed in one iliac artery (if it is not already blocked) and a femoral-femoral artery bypass is performed to maintain blood flow to both legs.



**After the procedure:**

Immediately after recovery from the stent grafting procedure, you may be required to lay flat for four to six hours. This will allow the leg wounds to start healing. Some mild discomfort may be felt at the wounds in the groin. This usually resolves in two days. Side effects may include swelling of the groin area, numbness of the legs, nausea, vomiting, leg pain or throbbing, lack of appetite, fever and/or absence of bowel movement for one to three days.

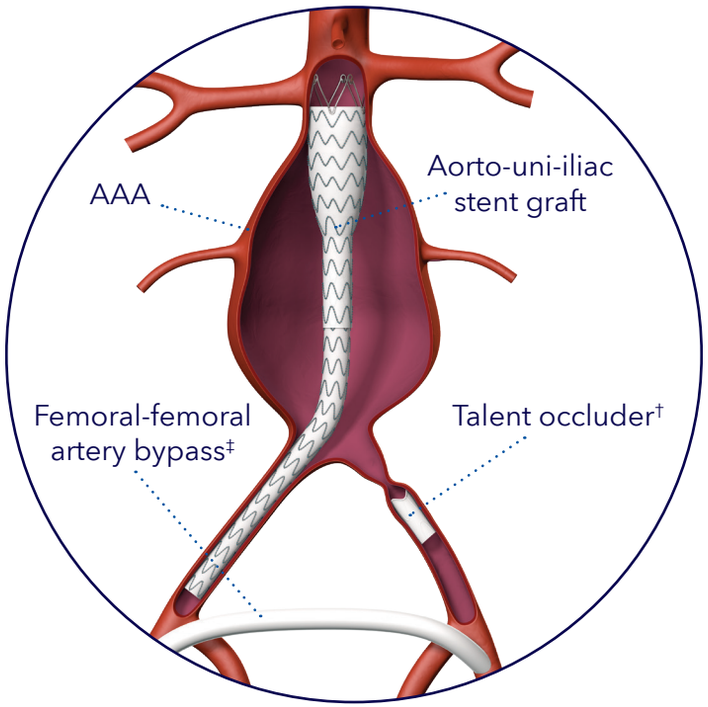


Figure 8
Abdominal AUI stent graft inside the aneurysm with a femoral-femoral artery bypass

†Any commercialized occluding devices or occluding technique can be used.
‡Femoral-femoral Artery Bypass is an additional surgical procedure which may be required in some cases based on physician's discretion.

## What symptoms should prompt you to call your doctor after the procedure?

If you experience any of the following symptoms, contact your doctor immediately:

- Pain, numbness, coldness, or weakness in the legs or buttocks
- Any back, chest, abdominal, or groin pain
- Dizziness, fainting, rapid heartbeat, or sudden weakness

A doctor should also be called if you need to reschedule a follow-up visit for any reason.

## Follow-up

It is important to schedule regular follow-up visits with your doctor. Long-term results of the stent graft have not yet been established. Most problems with endovascular repair do not have symptoms. Thus, follow-up is important to determine the success of your stent graft.

Follow-up visits will help the doctor to check your aneurysm and stent graft on a regular basis. Some problems that might occur are listed in the Risks section of this booklet. Your doctor will schedule follow-up visits depending on your condition. Most often these will occur at one month, one year, and annually thereafter. At each visit, imaging such as CT scans will be carried out to determine the performance of the stent graft. If you have poor kidney function, you should ask your doctor about the dyes used in some of these imaging studies, as they may be harmful.

Along with other imaging to assess the stent graft device type, your physician will ask you to have an ultrasound to assess the femoral-femoral artery bypass. Your physician will work with you to provide you with the appropriate timing and frequency of follow-up imaging for both the femoral-femoral artery bypass and the stent graft device.



## Implanted device identification card

After your abdominal stent graft procedure, your doctor will give you a temporary implanted device identification (ID) card. The temporary implanted device ID card will tell you the size and number of your abdominal aortic stent graft implants.

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
- Magnetic resonance imaging (MRI) information

Be sure to tell all of your healthcare providers that you have the stent graft and show them your implanted device ID card. You should keep your patient ID card available at all times.

## Magnetic resonance imaging

After being implanted with the abdominal stent graft manufactured by Medtronic, it is still safe to have MRI procedures, under certain conditions. MRI information is provided on your implanted device ID card. Show this ID card to your healthcare providers.

## Lifestyle changes

- You will need to go for regular follow-up visits to check your stent graft.
- Please consult your doctor about your ability to perform strenuous physical activities.

The abdominal stent graft is not expected to trigger any passenger screening devices such as airport security scanners. Please consult your doctor to reschedule any follow-up visits if you are traveling.

## Questions you may want to discuss with your doctor

- What are the other options for treating AAA?
- Which stent grafts are approved for treating AAA?
- What are all of the risks associated with an abdominal stent graft procedure?
- What are all of the risks associated with open surgical repair?
- Will health insurance pay part or all of the costs associated with this procedure?
- After the procedure, how often must a doctor follow up with the patient, and which tests will be performed?
- Does a patient have to limit activities after treatment? If so, for how long?
- How long can the stent graft remain implanted in the body?
- How many stent graft procedures has this facility performed?
- If I am having an AUI stent graft procedure, what additional procedures might be required?
- If a femoral-femoral artery bypass is required, when will this be done and what are the risks associated with this procedure?
- If an occlusion device is required, what does this procedure involve and what are the risks associated with this procedure?

**This guide is not a substitute for detailed discussions between you and your doctor. Only your doctor can decide if this procedure is suitable for you. This therapy is not for everyone. Please consult your doctor. Prescription is required.**



## Additional information

Additional information regarding AAA can be found at:
www.medlineplus.gov
www.fda.gov
www.medtronic.com/AAApatient

**Contacting Medtronic:**
If you have any questions concerning an abdominal stent graft manufactured by Medtronic, 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:

Medtronic
3576 Unocal Place
Santa Rosa, CA 95403
USA

CardioVascular LifeLine
Customer Support
Tel: 877.526.7890
Tel: 763.526.7890

## Notes



## Notes

**medtronic.com/aortic**

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