

PATIENT INFORMATION BOOKLET

Endovascular Stent Grafts:
A treatment for
Abdominal Aortic Aneurysms

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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.

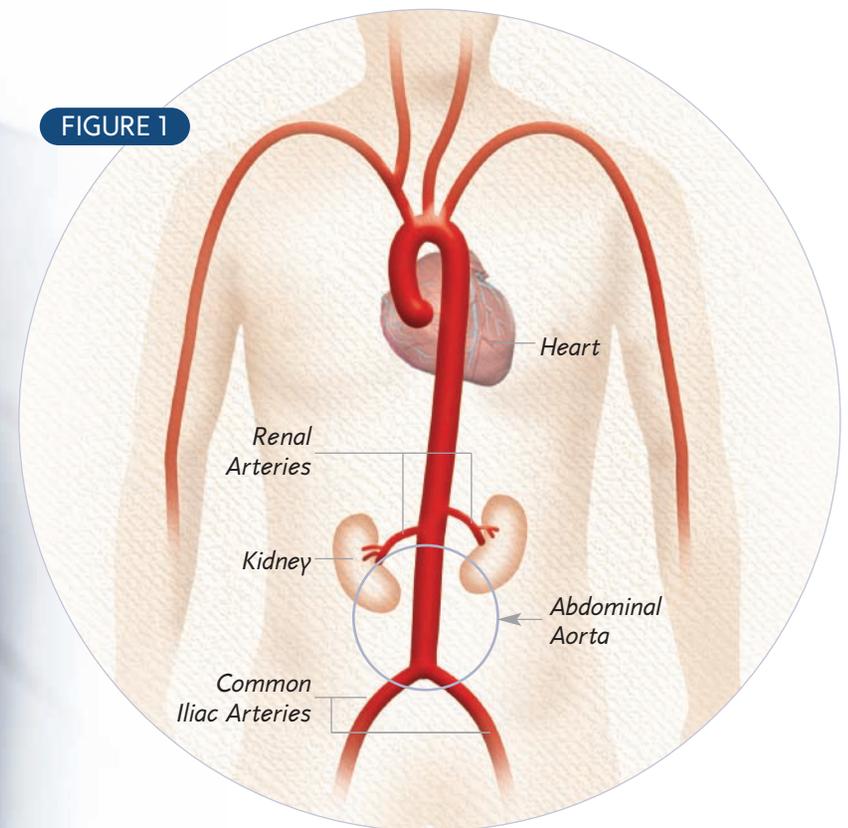
Only a doctor can determine if the patient is a good candidate for a **stent graft** procedure.

A Glossary is provided on Page 16 to help you understand the medical terms used in this book. Words that are bolded in the text are defined in the Glossary.



What is the 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).

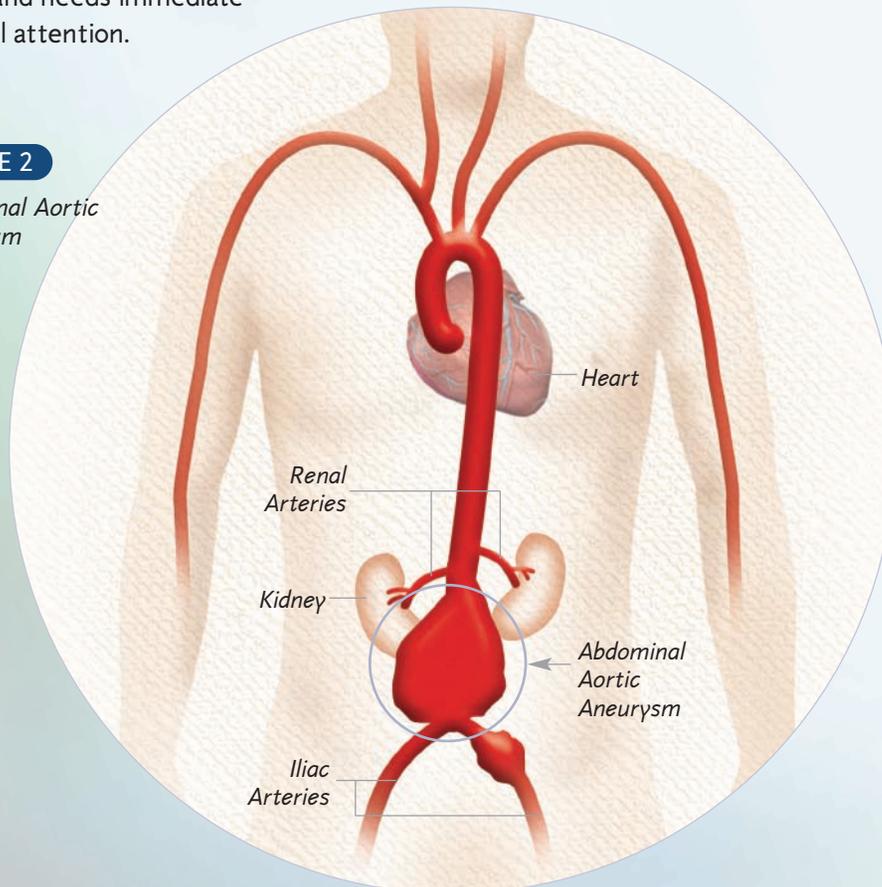


What is an Abdominal Aortic Aneurysm (AAA)?

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 **abdominal aortic aneurysm (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. A ruptured aneurysm can cause death and needs immediate medical attention.

FIGURE 2

Abdominal Aortic Aneurysm



What causes an AAA?

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.

What symptoms are associated with AAAs?

In most cases, patients have no symptoms of an **AAA**. However for those patients that have 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**.

What are the treatment options for repair of AAAs?

If your doctor thinks there is a risk that your **AAA** may rupture, he 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 usually spend three days in an intensive care unit and remain in the hospital for at least one week. Patients may require two to three months to recover completely. Open repair is a proven medical procedure. However, since it requires major surgery, it is not well tolerated by all patients.

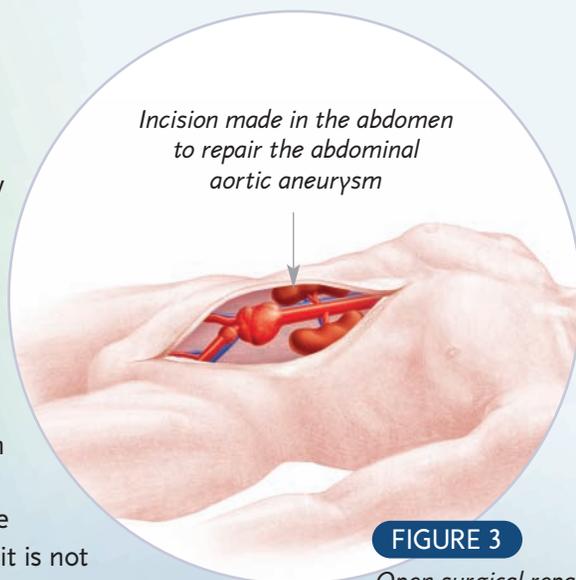


FIGURE 3

Open surgical repair

ENDOVASCULAR STENT GRAFTING:

This is a **minimally invasive** procedure. A **stent graft** (such as the **Talent™ 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.

This procedure usually takes about two hours and is performed under local, regional or general anesthesia.

A patient may not have to spend time in the intensive care unit. The hospital stay is typically two to four days. Recovery time is typically four to six weeks.

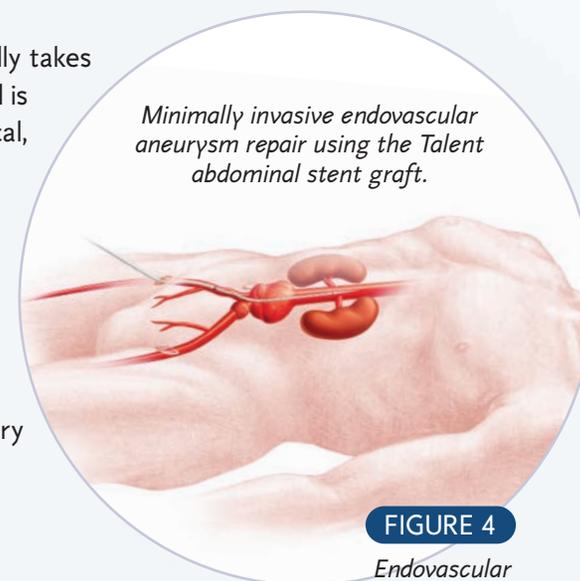


FIGURE 4

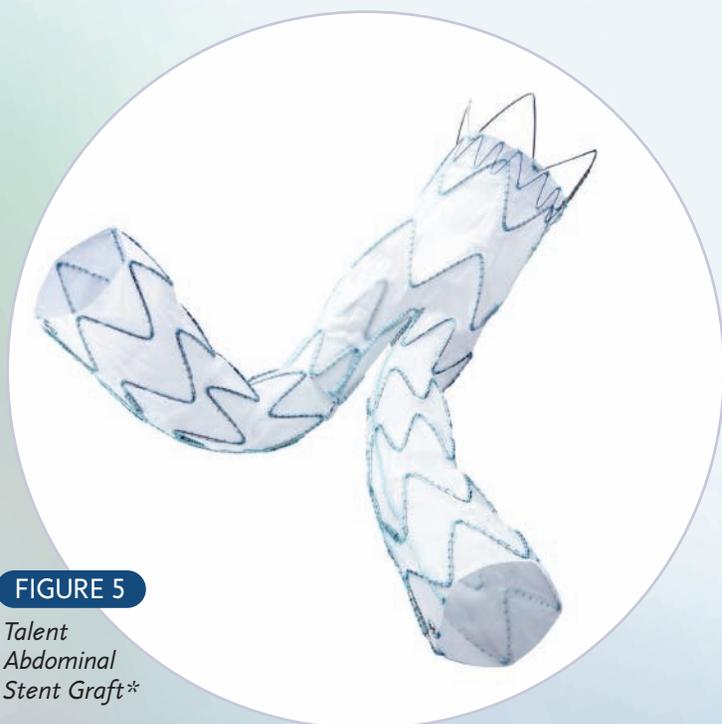
Endovascular Stent Grafting

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

What is the Talent Abdominal Stent Graft?

The **Talent Abdominal Stent Graft** is a fabric tube supported by a metal framework (Figure 5). The **stent graft** is designed to **exclude** the **aneurysm** and reinforce the weakened wall of the **aorta**. The **stent graft** reduces the pressure on the **aneurysm** and provides a new pathway for blood flow. This reduces the risk of rupture.

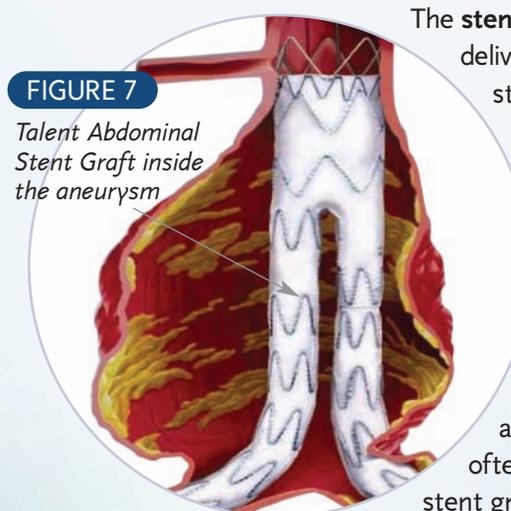
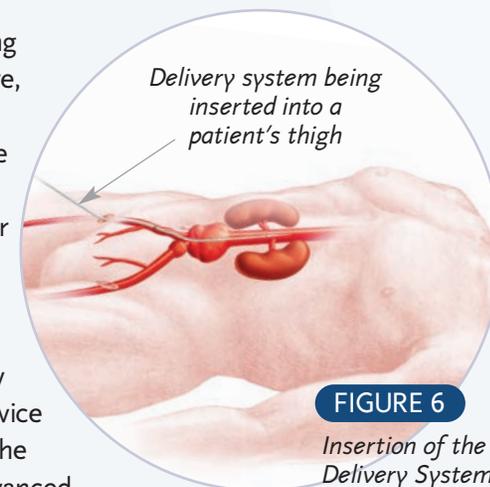
The **stent graft** is placed in the **aorta** using a device called a **delivery system**. The delivery system is a long thin tube-like device that contains the compressed stent graft.



*NOTE: The stent graft shown in the figure above is not representative of the actual size. The actual size of the Talent Abdominal Stent Grafts range from 154mm to 186mm in length.

How is the Talent Abdominal Stent Graft procedure performed?

This procedure is performed using anesthesia. Prior to the procedure, **imaging** tests like **CT scans** are performed. These tests allow the doctor to assess the **aneurysm**. A small cut is made in both upper thighs to prepare for the stent grafting procedure. **Fluoroscopy** is used to guide the **delivery system** to the **AAA**. The delivery system is a long thin tube like device used to place the **stent graft** in the **aorta**. The delivery system is advanced through the large vessel in the patient's thigh (**femoral artery**) to reach the abdominal aneurysm (see Figure 6).



The **stent graft** is slowly released from the delivery system into the **aorta**. As the stent graft is released, it expands to its proper size so that it snugly fits into aorta both above and below the **aneurysm**. The delivery system 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.

What are the Risks of the Talent Abdominal Stent Graft?

As with any **endovascular stent graft**, the **Talent 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 sac**. 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** (example: breaking of sutures or metal portion of the **stent graft**): Device related issues can be detected using **imaging** techniques such as X- rays. Your doctor can decide if you need any treatment.
- **Aneurysm Rupture**
- Additional **endovascular** or surgical procedures may be required

What are the Benefits of the Talent Abdominal Stent Graft Procedure?*

There are a number of benefits to having a **Talent Abdominal Stent Graft** procedure, some of which are listed below:

- The procedure is **minimally invasive**
- Procedure can be performed under local anesthesia
- Lower surgical complication rate compared to **open surgery**[†]
- The patient may lose less blood during the procedure[†]
- The patient may spend less time in the intensive care unit after the procedure[†]
- The patient may have a shorter hospital stay with faster recovery time compared to **open surgery**[†]

Are you a good candidate for the Talent Abdominal Stent Graft?

Based on your **anatomy**, your doctor can decide if you are a good candidate for this procedure. Anyone who is considering the **Talent Abdominal Stent Graft** procedure should:

- Be able to undergo a procedure that typically lasts between one to three hours
- Be able to go for regular follow-up visits after the procedure
- Be fully informed about the risks and benefits of the **Talent Abdominal Stent Graft** procedure.

[†]Talent Abdominal Clinical Study Data

*Long term results of this stent graft have not yet been established

What can you expect after a stent graft 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 upper thighs, 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.

What kind of follow-up will you need after a stent graft procedure?

It is important to schedule regular follow-up visits with your doctor. Long-term results of this **stent graft** have not been yet established. Thus follow-up is important to determine the success of your stent graft.

Most problems with **endovascular** repair do not have symptoms. 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 "What are the Risks of the Talent Abdominal Stent Graft?" section of this booklet, page 10.

Your doctor will schedule follow-up visits depending on your condition, most often these will occur at 1 month, 1 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.

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 the patient needs to reschedule a follow-up visit for any reason.

What is the Patient Identification Card?

After your **Talent Abdominal Stent Graft** procedure, your doctor will give you a temporary patient identification (ID) card. The temporary patient ID card will tell you the size and number of your abdominal aortic **stent graft** implants.

Medtronic will mail you a permanent patient ID card to carry in your wallet. Your permanent ID card will list information about:

- Type of device implanted
- Date of implant
- Your doctor's information
- **Magnetic Resonance Imaging (MRI)** information

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

Can I undergo Magnetic Resonance Imaging (MRI)?

After being implanted with the Talent **stent graft**, it is still safe to have most **MRI** procedures, under certain conditions. MRI information is provided on your patient ID card. Show your patient ID card to your health care providers.

What are the Contraindications?

A **contraindication** is a specific situation in which a drug, procedure, or surgery should not be used, because it may be harmful to the patient. The Talent Abdominal Stent Graft is contraindicated in patients who have a condition that can infect the stent graft and in patients who are allergic to the stent graft materials¹. Your doctor can help determine if the Talent Abdominal Stent Graft is safe for you.

Warnings

- Warning:** All patients with **endovascular aneurysm** repair must undergo periodic imaging to evaluate the **stent graft** and **aneurysm** size. (**Imaging** is defined as the use of **X-rays, CT scans, MRI scans** or other techniques in order to obtain pictures of the inside of the body).
- Warning:** The use of this device requires use of dyes used for **imaging**. Patients with kidney problems may be at risk of kidney failure after procedure
- Warning:** The long-term risks of prolonged **fluoroscopy** have not been established
- Warning:** Perforation and/or dissection of the blood vessels is a risk with any catheter-based procedure. This risk may increase with the use of large-sized catheters.

¹The Talent Abdominal Stent Graft is made up of the following materials: nitinol, polyester and platinum-iridium wire.

Questions you may want to discuss with your doctor

- What are the other options for treatment of **AAA**?
- Which stent grafts are approved for treatment of **AAA**?
- What are the risks (including **rupture**) with a **stent graft**?
- Will health insurance pay for part or all of the cost associated with this procedure?
- After the procedure, how often must a doctor follow up with the patient, and which types of tests will need to be performed?
- Does a patient have to limit activities after the treatment? If yes, for how long?
- How long can the **stent graft** remain implanted in the body?
- How many **stent graft** procedures has this facility performed?

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.



Glossary

Abdominal Aortic Aneurysm (AAA): A bulging or “ballooning” of a weakened area of the abdominal aorta. This term is often abbreviated to “AAA”.

Anatomy: The study of the structure of the body and the relationship between its body parts.

Aneurysm: A bulging or “ballooning” of a weakened area of a blood vessel.

Aneurysm rupture: A tear in the vessel wall near or at the location of the bulging or “ballooning” of the weakened area of the blood vessel.

Aneurysm Sac: A pouch or bulge formed in the blood vessel due to the aneurysm.

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

CT scan: An imaging technique that creates a series of computerized X-rays that form a picture of the aneurysm and adjacent blood vessels.

Contraindications: A specific situation in which a drug, procedure, or surgery should not be used, because it may be harmful to the patient.

Delivery system: A long, tube-like device that assists in the placement of the stent graft within the 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 minimally invasive procedure in which a tube shaped device is placed inside a diseased vessel without surgically opening the tissue surrounding the diseased vessel.

Exclude/exclusion: 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 the femoral arteries as a path to reach the iliac arteries and the aorta.

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

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

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

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

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 aneurysm section of the aorta is removed and replaced with a fabric graft. The graft is sewn into place and acts as a replacement blood vessel.

Rupture: A tear in the vessel wall near or at the location of the bulging or “ballooning” of the weakened area of the blood vessel.

Stent graft / Talent Abdominal Stent Graft: A woven polyester tube (graft) supported by a tubular metal web (resilient springs commonly referred to as stents) that is placed inside of a diseased (aneurysmal) vessel without surgically opening the surrounding tissue. After being placed in the artery, the stent graft expands to a pre-established diameter. The stent graft 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.

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