

What is the benefit of the Aorfix™ Endovascular Stent Graft?

The Aorfix™ Endovascular Stent Graft is designed to be flexible and to treat AAAs with severe bends or angles. This flexibility allows some patients to be treated with a stent graft where open surgery was previously the only option. Aorfix is also appropriate for patients who have AAAs with less severe bends or angles.

The Aorfix stent graft was designed to adapt to bent or twisted arteries, but is also appropriate for straight arteries. It is a self-expanding implant made from the following materials:

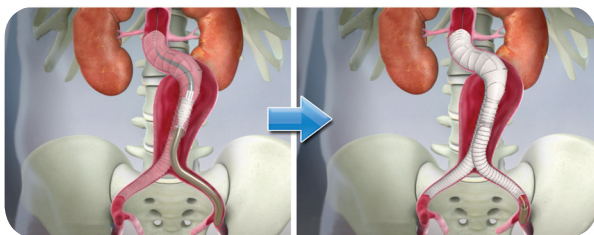
- Nickel and titanium, called Nitinol
- A woven polyester fabric

All components have been selected for maximum flexibility and to resist body rejection. The most common reason the implant procedure is not successful is because patient blood vessels are too small or not healthy enough to permit delivery of the stent graft. Your doctor will minimise this risk by reviewing your pre-surgery CT scan.

The stent graft consists of two parts: a main body and a separate plug-in leg. A delivery system is used to place the main stent graft body in the aorta and one iliac artery. The plug-in leg is then inserted through the other iliac artery and connected to the main body graft. The entire stent graft extends from just beneath the renal arteries (blood supply to the kidneys) down the aorta and into both iliac arteries.

Main Body Insertion

Contralateral Leg Insertion



Following the procedure, most patients can go home within a day or two. After a few days to a week of rest, patients can usually return to normal activities.

Please consult with your physician regarding AAA disease or treatment options.

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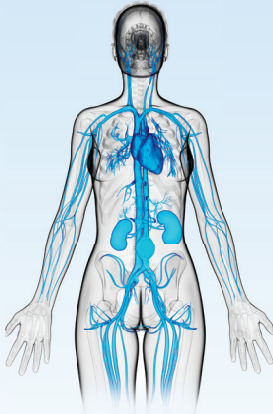
AORFIX™
Endovascular Stent Graft

Abdominal Aortic Aneurysm Patient Guide



What is an Abdominal Aortic Aneurysm (AAA)?

An aneurysm is a bulge in a blood vessel where the vessel wall has become weak or thin. As the wall weakens, that part of the vessel loses the ability to support the force of blood flow and begins to expand. Left untreated, the aneurysm may grow to several times the size of a normal vessel and could eventually rupture or burst. When the aneurysm occurs in the abdomen, it is called an Abdominal Aortic Aneurysm, commonly abbreviated as AAA.



The aorta is the body's main artery that carries oxygen-rich blood from the heart to the lower portion of the body. It extends from the chest to the abdomen where it divides into two arteries (the iliac arteries) that carry blood down into the legs. Aneurysms may occur in any blood vessel, but are most common in the aorta and iliac arteries.

What causes an AAA?

It is not fully clear why an aneurysm forms in the aorta. Aneurysms can affect men or women of any age. However, they are most common in men aged 65 and over. This can occur in about 1 out of 25 men. Not all aneurysms will be of a significant size; only 1 in 100 will be large enough (>5mm in diameter) to require surgery. Men are at higher risk than women, they are six times more likely to have an aneurysm.

As people age, they may lose some of the supporting tissue in the aortic wall. This explains why aneurysms are more common in older people. Your genetic make-up also plays a role as you have a much higher chance of developing an AAA if one of your immediate relatives (parent, brother or sister) has or had one. Other risk factors that increase the chance of getting an aneurysm include smoking, high blood pressure, high cholesterol, emphysema and obesity.

What is concerning about an AAA?

The main concern is that the aneurysm might rupture. The wall of the aneurysm is weaker than a normal artery wall and may not be able to withstand the pressure of blood inside. If a rupture does occur, it may lead to severe internal bleeding which is often fatal. Most AAAs do not rupture.

What are the symptoms of an AAA?

In most cases there are no symptoms with an AAA, when diagnosed, 7 in 10 people will not have had any symptoms due to the aneurysm. The expansion of the aneurysm does not cause any symptoms unless it becomes large enough to put pressure on nearby structures. Symptoms that do occur are likely to be mild abdominal or back pains. There are many other causes of these types of pains, which can lead to the delay in diagnosis unless the aneurysm is large enough to be felt by a doctor when he or she examines your abdomen.

What are the treatments for AAA?

Your general health as well as size and location of your AAA will determine how your aneurysm is treated. If surgery is not required, your doctor may recommend an ultrasound or computed tomography (CT) scan every 6-12 months to carefully monitor the aneurysm's size and shape. Your doctor may also prescribe certain medications to help keep the aneurysm stable and, if you smoke, advise you to stop. If your doctor feels there is aneurysm rupture risk, surgical repair may be recommended. An AAA may be treated with either open surgical repair or by less invasive endovascular repair techniques.

Open surgery

Your surgeon will open your abdomen to gain access to your aorta, then implant a graft into the weak area of your aorta. Blood will flow through the graft inside your aorta instead of going through the aneurysm and this will prevent the aneurysm from enlarging further.

Endovascular repair

Endovascular repair of AAAs is much less invasive than open surgical repair. The procedure involves placing a wire reinforced fabric tube graft (called a stent graft) inside your diseased aorta. The new stent graft is placed within the vessel and protects the AAA from blood pressure stress. Through a small incision in your groin, your physician will insert the stent graft parts over a guide wire. The graft is pushed through your femoral arteries and into the aneurysm by sliding along the wire. The stent graft is held in place through the use of metal hooks acting as anchors.



Insertion Of Stent Graft



Stent Graft Inside The Aneurysm

What are the possible risks of endovascular repair?

Not every patient is an endovascular repair candidate and there are possible complication risks. The risks and benefits of both the open surgical repair and endovascular repair procedures should be thoroughly discussed with your physician. Following your endovascular repair, it is important that you have regular scheduled follow-up appointments with your doctor. Most common complications can be identified early with a CT scan or X-ray.

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) — These issues may be detected using imaging techniques such as X-rays. Your doctor can decide if you need any treatment.
- Endovascular devices require fluoroscopy and use of dyes for imaging. Patients with kidney problems may be at risk of kidney failure due to the use of dyes.
- A hole or a tear of the blood vessels are risks associated with any catheter-based procedure.
- 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.
- Problems affecting your urinary and reproductive organs including infection and tissue death.

What are the benefits of endovascular repair?

There are a number of benefits to having an abdominal stent graft procedure versus undergoing open surgery. Some of these are listed below:

- The procedure is minimally invasive.
- The procedure can be performed under local anaesthesia.
- 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.