Endovascular Stent Grafts:
A treatment for abdominal aortic aneurysms
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Introduction

If you, or a loved one, have been diagnosed with an abdominal aortic aneurysm (a bulge that occurs in the part of the aorta that passes through the abdomen as a result of the weakening of the arterial wall), this guide will help answer some of the questions that you may have. This guide contains information on how abdominal aortic aneurysms are treated with the TriVascular endovascular stent graft and what to expect after surgery.

This information is being provided to you on behalf of TriVascular, Inc. It is not intended to diagnose a medical condition. The treatment of abdominal aortic aneurysms may vary according to patient’s needs and a doctor’s assessment. Only a doctor can determine if you or your loved one is a good candidate for this treatment. As with any medical procedure, the best source for information and advice is your doctor.

This guide contains definitions of the medical terms used. All of the medical terms in bold letters are explained in the Glossary section on the following page.
Glossary

Abdominal aortic aneurysm: Sometimes referred to as “AAA.” This is a bulge that occurs in the part of the aorta that passes through the abdomen. The bulge occurs due to weakening of the arterial wall.

Aneurysm rupture: A burst or tear in the vessel wall near or at the location of the bulging or “ballooning” of the weakened area of the blood vessel (i.e., abdominal aortic aneurysm).

Angiography: An x-ray method that uses a liquid dye called “contrast” (see definition below) which is injected into the bloodstream to see blood flow through vessels.

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

Contrast: A liquid dye injected into the bloodstream to show blood vessels under x-ray or CT scan.

CT (Computed Tomography) Scan: A series of computerized x-rays that form a picture of your aneurysm.

Complication: An occasional problem that occurs as a result of a medical treatment.

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

Delivery Catheter: A long, thin tube-like device that the doctor uses in delivering and positioning the stent graft during the endovascular repair procedure.

Endoleak: Blood flow into the abdominal aortic aneurysm after placement of a stent graft.

Endovascular Stent Graft: A stent graft placed within a diseased vessel to seal off the aneurysm without the use of open surgical repair.

Endovascular Repair: Involves the placement of an endovascular stent graft to seal off an aneurysm and create a new blood flow path within the weakened artery.

Femoral Arteries: Two blood vessels (one in each leg) that carry blood to the thigh region. Doctors can use the femoral arteries as a path to reach the iliac arteries and the aorta during endovascular repair.

Fluoroscopy: A real time x-ray image that is viewed on a monitor. The doctor generally uses fluoroscopy to visualize the placement of the endovascular stent graft during an endovascular repair procedure.
**Iliac Arteries:** Two large blood vessels (one on each side) that connect the lower end of the aorta to the upper end of the femoral arteries.

**Imaging:** The use of Angiography, CT Scans, Fluoroscopy, MRI, Ultrasound, x-rays and/or other techniques to obtain pictures of the inside of the body.

**(Iliac) Limb:** The two smaller parts of the stent graft that are placed inside the iliac arteries and connect to the **main body** of the stent graft.

**Main Body:** The largest part of the stent graft that is placed inside the aorta.

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

**Migration:** The movement of the graft away from the desired location.

**Minimally Invasive:** A surgical technique involving a puncture or cut of the skin without exposing the internal organs.

**Open Surgical Repair:** A type of surgery performed to repair an aneurysm. To reach the aneurysm, a doctor makes a large cut through the abdomen of the patient. The doctor repairs the aorta by replacing the aneurysm section with a fabric tube called a “graft.” The “graft” is sewn into place and acts as a replacement blood vessel.

**PTFE:** A polymer of tetrofluoroethylene (commonly known as Teflon). The fabric used in the TriVascular endovascular stent graft. PTFE is used widely in medical applications.

**Polyethylene Glycol (PEG):** The base material used in the “soft material” injected into the TriVascular endovascular stent graft during implantation.

**Stent:** Metal part of the stent graft that provides anchoring of the graft to the aorta.

**Stent Graft:** A type of endovascular device with both metallic and graft components.

**Ultrasound:** An imaging technique used in follow-up of Endovascular Repair that creates an image through the use of high-frequency sound waves.

**X-ray:** An imaging method used to create a picture of the structures within the body.
Product Description: Endovascular Stent Graft for Abdominal Aortic Aneurysms

An endovascular stent graft system is intended for permanent implant. Each stent graft is enclosed in a small catheter (a long, flexible tube) that is inserted using each of your femoral arteries (blood vessels that supply the blood to your legs) for placement of the graft in your aorta and iliac arteries.

The stent graft is made of metal stents and fabric. The metal portion of the stent is made from nitinol, a common metal used in many implantable medical devices. The fabric used in the device is also a material (PTFE) that is commonly used in many implantable medical devices.

There is a channel in the aortic part of the stent graft which is injected with a soft material (polyethylene glycol – or PEG- based). The soft material is a special material designed to ensure the stent graft is tight against the wall of the aorta. The size of the device portion that is placed in your aorta and contains the soft material-filled rings is 20mm (less than 1 inch) to 34mm (less than 1 ½ inches) in diameter, depending on the size of your aorta.

The iliac limbs are the two smaller parts of the stent graft that are placed inside the iliac arteries and connect to the main body of the stent graft.

The stent graft has been successfully laboratory tested for a 10-year device life. The clinical device life is expected to be at least 10-years but this length of time has not been tested in humans.

FIGURE 1: Abdominal Aorta with the TriVascular Endovascular Stent Graft
THE AORTA

The main artery that carries blood from the heart to the rest of the body (aorta) is the largest artery in the body. The abdominal aorta is the part of the aorta just below the stomach, in the abdomen (see Figure 2).

FIGURE 2: The Aorta

The aorta branches into two large blood vessels, one on each side (iliac arteries). The iliac arteries carry blood to the lower parts of the body and legs. The iliac arteries become the femoral arteries as the blood vessels extend into your thighs.

ABDOMINAL AORTIC ANEURYSM

An abdominal aortic aneurysm (or AAA) is caused by weakening of the wall of the aorta due to age, disease or other conditions (see Figure 3). As the bulge grows, the wall of the aorta becomes weaker. This condition, if left untreated, could cause the aorta to rupture or burst. A rupture of the aorta leads to serious internal bleeding or death.
ABDOMINAL AORTIC ANEURYSM CAUSE, SYMPTOMS AND DIAGNOSIS

The likelihood of having an abdominal aortic aneurysm is increased if you have a family history of aneurysms, smoking and/or high blood pressure. Abdominal aortic aneurysms are more commonly found in men over 50 years of age, although younger people and women may also have them. Often an abdominal aortic aneurysm is found during an examination being done for other unrelated health reasons. In other cases, symptoms may include mild to severe pain in the abdomen, chest or back. Some patients might feel the aneurysm as a throbbing mass in their abdomen. Your doctor may feel a bulge or pulsation (thrumming) in your abdomen.

Abdominal aortic aneurysms can be detected through special tests including: CT Scan, MRI, Angiography, Ultrasound and x-ray.
ABDOMINAL AORTIC ANEURYSM TREATMENT

Not all abdominal aortic aneurysms require surgery. If your doctor recommends treatment of your abdominal aortic aneurysm because of the risk that your aneurysms will rupture (burst), he or she may discuss Open Surgical Repair and Endovascular Repair.

Endovascular repair is described later in this booklet. In an open surgical repair, the doctor makes a cut in the abdomen or side of the patient. The doctor replaces the aneurysm section with a fabric tube called a “graft”. The “graft” is sewn into place and acts as a replacement blood vessel. This surgery is performed under general anesthesia and takes about three to four hours to complete. Patients typically stay overnight in intensive care and then remain in the hospital for an additional 5 to 7 days. It can take at least 3 months to fully heal from this surgery. Open surgical repair is commonly used and often works well.

Risks and benefits are associated with both endovascular repair and open surgical repair. Patients should talk with their doctors about which option is best for them.

PATIENTS THAT ARE NOT CANDIDATES FOR ENDOVASCULAR REPAIR (CONTRAINDICATIONS)

Not all patients are candidates for endovascular repair. The stent graft is not right for you if:

- You have a condition that could create an infection to the stent graft, and/or
- You have sensitivities or are allergic to the device materials (such as nitinol, PTFE, or PEG-based materials) or contrast imaging dye.

Allergies and potential infection can cause problems during the follow up imaging exams or long term implant of the device, possibly requiring removal by an open surgical procedure. It is important to tell your doctor about any condition that could create an infection to the stent graft or if you have any sensitivities or allergies. The information will help your doctor decide if the stent graft is not right for you.
WARNINGS

The TriVascular endovascular stent graft has not been evaluated in patients who:

- Are pregnant or nursing;
- Are less than 18 years old;
- Have traumatic aortic injury or aneurysm rupture or require other emergent aorta/aneurysm treatment;
- Have aneurysms in places other than the abdominal aorta and iliac arteries;
- Have a bleeding problem;
- Have connective tissue problems;
- Have other artery disease that would interfere with the stent graft treatment.

Your physician will need to help you decide whether it is appropriate for you to get an endovascular stent graft if any of these situations apply to you.

If you have poor kidney function, you should ask your doctor about the dyes used in some of these imaging studies as they may further decrease kidney function.

If you have any of the following items, the TriVascular endovascular stent graft is not recommended for you

- Body infection;
- Allergy to the device materials;
- Allergy to the dyes that are used in follow up imaging exams;
- Allergy to the medicines used during the operation (antiplatelets or anticoagulants);
- Stroke within 6 months before the operation.

PRECAUTIONS

If you have endovascular repair of your abdominal aortic aneurysm, it is very important that you attend regularly scheduled follow-up appointments with your doctor. Your doctor needs to find out if your stent graft is working right. If you don’t go, your doctor won’t know if:

- your blood is leaking from your stent graft
- your stent graft has moved (migrated)
- your stent graft is not working right

Only your doctor can tell if you have these problems or some of the problems that are listed in the Risks section. Any of these problems could seriously harm you or cause your death.
Treatment with the TriVascular endovascular stent graft may not be recommended if you cannot have regular follow-up imaging and/or have bleeding disorders, have kidney disease, cannot use blood thinners or cannot tolerate imaging dyes.

As described in the Magnetic Resonance Imaging (MRI) section below, you will receive a patient implant card that will provide guidance to healthcare providers regarding these conditions. After implant with the endovascular stent graft, it is still safe to have MRI procedures under certain conditions, but show the implant card prior to having MRI exams so that your healthcare providers are aware of these conditions.

In between follow up visits to check the endovascular stent graft, call your doctor immediately or visit the nearest emergency room if you experience any of the following symptoms:

- Pain, numbness, or weakness in the legs, back, chest, or abdomen
- Discoloration or coldness in the leg
- Dizziness
- Fainting
- Rapid heartbeat
- Sudden weakness

If you don’t seek medical attention for these symptoms, they could seriously harm you or cause your death.

RISKS

As with any medical procedure, endovascular repair involves risks of complications. As mentioned in the Clinical Studies section, a small number of patients experienced some of the complications listed below. The Clinical Studies included patients between the ages of 54 and 95 years old. Almost all patients had high blood pressure. Many had indications of other heart disease and/or smoking history. However, patients who had a recent surgery, infection, heart attack or stroke were not included in the studies. You should talk to your doctor about how your situation may be different or similar.

The clinical study patients had these major complications within 30 days after their endovascular repair:
## TRIVASCULAR PATIENT INFORMATION

<table>
<thead>
<tr>
<th>POSSIBILITY (%)</th>
<th>MAJOR COMPLICATIONS WITHIN 30 DAYS&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer than 2 out of 100 people (1.2%)</td>
<td>Heart attack</td>
</tr>
<tr>
<td>Fewer than 2 out of 100 people (1.2%)</td>
<td>Kidney failure</td>
</tr>
<tr>
<td>Fewer than 2 out of 100 people (1.2%)</td>
<td>Significant blood loss</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.6%)</td>
<td>Death for any reason</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.6%)</td>
<td>Breathing problems or failure (respiratory failure)</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.6%)</td>
<td>Decreased blood flow to the intestine</td>
</tr>
</tbody>
</table>

The device studies are continuing so that we can collect and better understand the risks with this device.

### POSSIBLE RISKS AFTER 30 DAYS

After your endovascular repair, there is a chance than an **endoleak** may cause your **abdominal aortic aneurysm** to begin to grow again. If this happens, your doctor may recommend a second **endovascular repair** procedure to fix it. If the aneurysm continues to grow and is not repaired, it could **rupture**. In the TriVascular clinical trial, 3% of patients had a second procedure to treat **endoleak**. None of these patients experienced aneurysm growth or an **aneurysm rupture**.

Ask your doctor about the possible risks of **endovascular repair** as they relate to your own health.

### POSSIBLE BENEFITS

The biggest benefit of having your **abdominal aortic aneurysm** treated is a decreased chance of **rupture**. If left untreated, your aneurysm may continue to grow which can lead to **rupture**. If your **abdominal aortic aneurysm** grows to 5.5 cm in diameter, annual **rupture** risk may be 3-15%<sup>2</sup> (3 to 15 out of 100 people).

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1. Average rates of Major Adverse Events within 30 days of procedure with the TriVascular endovascular stent graft for treatment of AAA disease.
There are a number of benefits to having an **endovascular repair** as compared to an **open surgical repair**. Some of these are listed below:

- The procedure is **minimally invasive**.
- Although not always performed, the procedure can be performed under local anesthesia.
- The patient may lose less blood during the procedure.
- The patient may spend less time in the intensive care unit after the procedure and have a shorter hospital stay.

**ENDOVASCULAR STENT GRAFT PROCEDURE DESCRIPTION**

Prior to the procedure, **imaging** tests are performed. These tests allow the doctor to assess your **aneurysm**.

**Endovascular repair** is **minimally invasive** compared to **open surgical repair**. **Endovascular repair** usually has a shorter recovery period. The procedure usually lasts about 1 – 3 hours.

Instead of making a large cut in the abdomen, the doctor makes a small cut or puncture where your lower abdomen and the top of your leg meet (groin area) to access the **femoral arteries** (see Figure 4). The **delivery catheter** delivers the **stent graft** through the **femoral arteries** to put the **stent graft** in your **aorta** and **iliac arteries**. The procedure is performed under local, regional or general anesthesia according to the following steps:

- The **delivery catheter** is inserted and pushed up from the **femoral artery** (Figure 4) into position in the **aorta**. The **stent graft** is positioned using **fluoroscopy**.
- When the **stent graft** is in the correct position, your doctor places the **main body** in the **aorta**. Channels in the **main body** are then filled with the soft material to create a seal against the **aorta** and provide support for the graft.
- Your doctor then inserts the **iliac limbs** into the **main body** through both **femoral arteries**. The **iliac limbs** are deployed in position. This completes the **stent graft** and creates a new path for the blood to flow.
- The **delivery catheters** are removed from the body.
- Your doctor will confirm the position of the **stent graft** and the flow of blood through the **stent graft** (and not in the **aneurysm**) using **angiography**.
- The cuts in your groin are closed with sutures and the procedure is complete.
- Patients may have a hospital stay of only a few days. Patients usually recover in 4 to 6 weeks.
After Procedure Information: Follow-up and What to Expect After Treatment with an Endovascular Stent Graft

Please also refer to the Risks section of this patient information booklet.

Immediately after recovery from the stent grafting procedure you may be required to lie flat for 4 to 6 hours. This allows for the healing to begin in your groin. Some patients experience mild discomfort (such as swelling of the groin area or fever), but this usually resolves in two days. Other side effects may include numbness of the legs, nausea, vomiting, leg pain or throbbing, lack of appetite, endoleak and/or absence of bowel movement for one to three days. Your doctor will provide you with specific care and follow up instructions.

It is important to schedule regular follow-up visits with your doctor. Long-term results of this stent graft have not yet been established. Most problems with endovascular repair do not have symptoms. Follow-up visits with your physician are 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, CT scans will be performed to look at your 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.
When to Call Your Doctor After Endovascular Repair:
In between follow up visits to check the endovascular stent graft, call your doctor immediately or visit the nearest emergency room if you experience any of the following symptoms:

- Pain, numbness, or weakness in the legs, back, chest, or abdomen
- Discoloration or coldness in the leg
- Dizziness
- Fainting
- Rapid heartbeat
- Sudden weakness

If you don’t seek medical attention for these symptoms, they could seriously harm you or cause your death.

CLINICAL STUDIES
In the TriVascular clinical study, 161 patients were studied in the United States, Germany and Chile. The patients were studied to a minimum of 1 year. In the study, a few patients experienced some of the complications listed in the Risks section of this brochure, but all patients were successfully implanted with the device.

The rates below are from the TriVascular clinical study. Information for procedure time, blood loss and hospital stay are average values.

<table>
<thead>
<tr>
<th>COMPLICATION</th>
<th>TRIVASCULAR CLINICAL STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death in the first 30 days</td>
<td>Fewer than 1 out of 100 people (0.6%)</td>
</tr>
<tr>
<td>Major complications in the first 30 days</td>
<td>Fewer than 3 out of 100 people (2.5%)</td>
</tr>
<tr>
<td>Procedure information</td>
<td></td>
</tr>
<tr>
<td>Procedure time</td>
<td>1 to 2 ½ hours</td>
</tr>
<tr>
<td>Blood loss during procedure</td>
<td>150 cc (1/2 pint)</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>1 to 2 days</td>
</tr>
</tbody>
</table>

It is important to note that the long-term results of endovascular stent grafts have not yet been established as the studies are ongoing.
TRIVASCULAR PATIENT INFORMATION

IMPLANTED DEVICE IDENTIFICATION CARD
Prior to leaving the hospital, you will be provided a patient implant card: keep this card in your wallet and show the card to your health care providers so that they know you have been treated for this disease with this device. If asked, the card will show that it is safe to have most MRI procedures after the implant of the stent graft.

MAGNETIC RESONANCE IMAGING (MRI)
After implant with the endovascular stent graft, it is still safe to have MRI procedures under certain conditions. Your patient implant card will provide guidance to healthcare providers regarding these conditions. Show this card to your healthcare providers.

LIFESTYLE CHANGES AND TRAVEL
• 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 endovascular stent graft is not expected to interfere with or trigger a response in passenger screening devices such as airport security scanners. Please consult your doctor if your follow up visit needs to be rescheduled as a result of travel.

QUESTIONS YOU MAY WANT TO DISCUSS WITH YOUR DOCTOR
• Is the TriVascular endovascular stent graft an appropriate treatment for my AAA?
• What are the other options for treating my AAA?
• Which stent grafts are approved for treating AAA?
• What are all of the risks with open surgical repair / stent graft treatment?
• What are the risks of rupture with a stent graft?
• What if my AAA continues to grow after endovascular treatment?
• Would I have to limit activities after either kind of treatment? If so, for how long?
• How long could my stent graft remain implanted in the body?
• Will health insurance pay part or all of the costs associated with this procedure?
• After the procedure, how often will you require to see me for follow up?
• Which tests will be performed for follow up?
• How many stent graft procedures has this facility performed?
WHERE TO FIND OUT MORE

Aneurysms
Background Information on Abdominal Aortic Aneurysms:
VascularWeb Patient Information
Website: www.vascularweb.org

VascularWeb is a World Wide Web (WWW) based global resource of information and service for individuals interested in improving vascular health worldwide. VascularWeb is sponsored and owned by the American Association for Vascular Surgery (AAVS) and the Society for Vascular Surgery (SVS), both non-profit organizations.

Endovascular Therapy
Society of Interventional Radiology
Website: www.sirweb.org

The Society of Interventional Radiology (SIR) is a professional society for doctors who specialize in interventional or minimally invasive procedures. SIR is a non-profit, national organization deeply committed to its mission to improve health and the quality of life through the practice of cardiovascular and interventional radiology.

U.S. National Library of Medicine
Website: www.medlineplus.gov

The National Library of Medicine (NLM), on the campus of the National institutes of Health in Bethesda, Maryland, is the world’s largest medical library. The library collects materials in all areas of biomedicine and health care, as well as works on biomedical aspects of technology, the humanities, and the physical, life and social sciences.

Product Information
US Department of Health and Human Services, Food and Drug Administration
Website: www.fda.gov
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/
DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm
(reference TriVascular Ovation Abdominal Stent Graft System HDE H100008)

A U.S. government agency intended to promote and protect the public health by helping safe and effective products reach the market in a timely way and monitoring products for continued safety after they are in use.