Understanding Abdominal Aortic Aneurysms: A Patient Information Guide for Minimally Invasive Repair
Lombard Medical Technologies Inc. is pleased to present this Patient Information Guide to help you learn more about your Abdominal Aortic Aneurysm and possible treatment options, including a new, minimally invasive procedure using the Aorfix™ AAA Flexible Stent Graft System.

This guide is designed for information only and is not intended to diagnose a medical condition. As with any surgery or medical procedure, the best resource 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.

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GLOSSARY OF KEY TERMS

AAA or Abdominal aortic aneurysm: 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 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.

Delivery System: 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.

Guide wire: A thin metal wire which is pushed into your arteries from the cut in your groin to beyond your Aneurysm. All the parts of the Stent graft slide over the top of the Guide wire and this makes sure they are accurately positioned.

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.

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

Nitinol: A metal made from nickel and titanium that is often used to make stents and stent grafts because it is unusually springy.

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.

Polyester: A type of plastic widely used in regular and medical applications.

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.
INTRODUCTION

1. 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 grow. Left untreated, the aneurysm may grow to several times the size of a normal vessel and could eventually rupture or burst.

Aneurysms may occur in any blood vessel but are most common in the aorta and the iliac arteries. The aorta is your largest blood vessel and carries blood from your heart to the lower portion of your 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. When the aneurysm (bulge) occurs in the abdomen, it is called an Abdominal Aortic Aneurysm or commonly abbreviated as AAA.

2. What causes an AAA?

AAA risk increases with age and generally affects individuals over the age of 50. AAAs occur more often in men than they do in women. The weakening aorta itself may be caused by a vascular disease, some form of trauma or injury, or by a genetic (hereditary) defect in the blood vessel wall tissue. Continuous blood pressure against the weakened area can cause that part of the blood vessel to balloon and eventually burst.

Aneurysm risk factors include family history, smoking, heart disease, high blood pressure, and poor diet. If you have these risk factors, most doctors will advise lifestyle changes and recommend periodic check-ups before an aneurysm develops or to detect an aneurysm that does develop as soon as possible. These changes may include keeping your blood pressure under control, quitting smoking, and reducing cholesterol levels. Making these changes may also prevent additional problems in the future.
3. What are some symptoms? How are AAAs discovered?

In most cases, AAA patients feel no symptoms. For those who do have symptoms, pain is most common and can be in the abdomen, back, or chest. This pain may be mild to severe or simply be tenderness in the mid to upper abdomen or lower back. Some patients feel a pulsing or throbbing mass in their abdomen. Unfortunately, many patients feel none of these symptoms but still have a AAA.

A AAA is often discovered during a routine examination for other purposes. Common medical tests such as an ultrasound or a CT scan (also known as a CAT scan) are used to confirm the presence, location, size, and shape of your aneurysm.

4. Are AAAs serious?

In early AAA stages, the immediate health risk is small. However, your doctor will want to see you on a regular basis to assure that your aneurysm is either not growing or growing very slowly. Rupture risk increases with aneurysm size, age, and other risk factors such as high blood pressure. When your aneurysm grows to an unacceptable size, your doctor will want to repair it before a critical situation develops. Most AAAs have a significantly higher chance of rupturing when they exceed 2 inches (5 cm) in size or if they expand rapidly. Much less commonly, an AAA can cause blood clots to pass into the legs, which can lead to additional complications. If an aneurysm ruptures, it can be very serious or fatal. Approximately 200,000 new aneurysms are diagnosed each year in the U.S. and are a leading cause of death.

ABDOMINAL AORTIC ANEURYSM TREATMENTS

5. What are the treatments for AAA?

Your general health and the size and location of your AAA will determine how your aneurysm is treated. Smaller aneurysms may be closely monitored by your doctor.

If surgery is not required, your doctor may recommend an ultrasound or CT scan every 6-12 months to carefully monitor the aneurysm 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. A AAA may be treated with either open surgical repair or by less invasive endovascular repair techniques.
6. Open Surgical Repair

Until recently, open surgical repair has been the most common procedure for AAAs. During this surgery, your doctor will make a cut in your abdomen or side, move your internal organs, and locate the portion of the aorta with the weakened wall. The affected area will be removed and the artery repaired with a fabric tube called a graft which is permanently sewn into place. The new graft acts as a replacement blood vessel.

The open surgical repair procedure typically lasts between 3-4 hours, requires general anesthesia, and blood flow in the aorta must be stopped while the graft is being inserted. Afterwards, an overnight stay in the hospital intensive care unit is usually required plus another 5-9 days in the hospital. Some patients are unable to eat normally for several days after surgery and overall recovery may take up to three months before normal activities may be resumed.

Open repair is a proven medical procedure that works. However, not all patients can tolerate a major operation. As with any medical procedure, the possible risks should be discussed with your doctor.
7. Endovascular Repair

**Endovascular repair** is a newer procedure for repairing AAAs. It is much less invasive than **open surgical repair** and 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. Rather than making a large cut in your abdomen, your physician makes smaller cuts in your groin area.

Through these cuts, they insert a *Guide wire* and then the *stent graft* pieces, which are contained in a small tube called a *delivery system*, are pushed through your *femoral arteries* and into the *Aneurysm* by sliding along the *Guide wire*. The final *stent graft* is held in place through the use of metal hooks acting as anchors.

The **endovascular repair** procedure typically lasts between 1-3 hours and may be performed under general, regional, or local anesthesia. Patients normally have a few days of hospital stay, may begin normal activities within a week, and can usually return to full physical activity within 4-6 weeks of the procedure. As a result, stent graft patients typically recover more quickly and experience less pain than those who have open surgery.

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 doctor.**
8. What are the advantages and disadvantages for each type of repair procedure?

OPEN SURGICAL REPAIR ADVANTAGES

• Traditional treatment

• Proven surgical procedure

• Generally a permanent solution for the current aneurysm (other weakened areas could develop in the future)

• Long term follow-up generally not required (other than to assure no new aneurysms)

OPEN SURGICAL REPAIR DISADVANTAGES

• Requires general anesthesia

• Considered to be major abdominal surgery with a long abdominal cut

• Surgical complication rate is generally higher than with Endovascular Repair procedure

• Requires a longer and more intense hospital stay and recovery times can be longer than with Endovascular Repair procedure

ENDOVASCULAR REPAIR ADVANTAGES

• Minimally invasive procedure

• Local anesthesia preferred

• No large abdominal cuts, only small groin area cuts

• Surgical complication rate generally lower than with Open Surgical Repair procedure

• Generally, requires a shorter hospital stay and has a shorter recovery time than with Open Surgical Repair procedure

ENDOVASCULAR REPAIR DISADVANTAGES

• Long term results less certain

• Potential for blood leaking around the graft (called endoleaking) and possible aneurysm rupture

• Long term follow-up examinations required

• Possibility of additional endovascular and surgical procedures after the initial repair
9. What is the Aorfix™ Implant?

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

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 and then to insert the plug-in leg and connect it to the main body in the other iliac artery. The entire stent graft extends from just beneath the renal arteries (leading to the kidneys) down the aorta and into both iliac arteries.

Placing the Aorfix™ AAA Flexible Stent Graft System is a minimally invasive surgical procedure. Before the procedure, your doctor will usually examine CT scan pictures of your aorta. These pictures will be used to locate the exact position of your aneurysm and to help select the proper size for each part of the stent graft. A small incision is then made at the top of the thigh in the groin area under local, epidural, or general anesthetic to locate a major artery called the femoral artery. The femoral artery is close to the skin and leads to the aorta. A guidewire is fed into the femoral artery, into the iliac artery and finally into the aorta past the aneurysm. The stent graft delivery system is a long tube-like device that carries the stent graft to the aorta. It is slid over the guidewire inside the femoral artery and onwards into
AORTIC ANEURYSM IMPLANTED AORFIX™ AAA FLEXIBLE STENT GRAFT SYSTEM

the portion of the aorta that has the AAA. Your doctor will observe the placement of the stent graft using x-ray guidance and assure correct positioning using dye. Once the stent graft is in the correct position, the delivery system will release the stent graft which is held in place using small hooks. The delivery system is then withdrawn from your groin and the steps repeated from the opposite groin to attach the plug-in leg. The blood in your aorta will flow through the stent graft and exclude the aneurysm from your main blood circulation.

The Aorfix™ AAA Flexible Stent Graft System was designed to cope with 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, and 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 minimize this risk by reviewing your pre-surgery CT scan. 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.

10. How was the Aorfix™ Implant Tested?

The Aorfix™ implant was tested in a clinical trial performed at 41 hospitals in the U.S., 3 in Canada and 1 in Europe. 210 patients received the implant. At the time of data were reported, 171 of these patients had been clinically evaluated for at least 12 months since their surgery. Patients were also evaluated at 30 days, 6 months, and continued to be followed with a clinical visit and imaging every year until 5 years after the operation.
After 12 months, the results of the implant were analyzed in terms of how safe it is and how well it works. The safety analysis showed that 24.3% of patients who received the Aorfix™ device had a complication at the end of 1 month. The safety analysis showed that 40.8% of patients who had open surgery also had a complication at the end of 1 month. The majority of complications were caused by patients who needed to be given blood during or after surgery.

To test how well the stent graft works, three different types of failure were analyzed 1 year after the operation:

1) The number of patients where the graft did not seal completely into the aorta.

2) The number of patients where the graft moved by 10mm (a little less than ½”) from where it was first placed.

3) The number of patients where the metal part of the Aorfix™ had broken. Analysis showed that 9.3% of patients had a leak, graft movement, or metal components of the graft break.

Many other measurements were also analyzed and an important outcome was that in 1.2% of patients, the aneurysm continued to enlarge after 1 year. In 98.8% of patients, the aneurysm either stopped growing or started to shrink.

RISKS

11. The First 30 days
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 52 and 94 years old. Most patients studied had a very bent aorta because Aorfix™ is designed to be able to treat this kind of disease. Almost all patients had high blood pressure. Many had indications of other heart disease and 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:

<table>
<thead>
<tr>
<th>All Patients</th>
<th>Major Complications within 30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer than 13 out of 100 people (12.4%)</td>
<td>Significant blood Loss</td>
</tr>
<tr>
<td>Fewer than 5 out of 100 people (4.1%)</td>
<td>Surgical wound complication</td>
</tr>
<tr>
<td>Fewer than 4 out of 100 people (3.2%)</td>
<td>Heart failure</td>
</tr>
<tr>
<td>Fewer than 4 out of 100 people (3.2%)</td>
<td>Poor blood flow in graft</td>
</tr>
<tr>
<td>Fewer than 3 out of 100 people (2.3%)</td>
<td>Heart attack</td>
</tr>
<tr>
<td>Fewer than 2 out of 100 people (1.8%)</td>
<td>Need for another operation</td>
</tr>
<tr>
<td>Fewer than 2 out of 100 people (1.8%)</td>
<td>Death for any reason</td>
</tr>
<tr>
<td>Fewer than 2 out of 100 people (1.4%)</td>
<td>Breathing problems or failure(ventilator failure)</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.9%)</td>
<td>Kidney failure</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.5%)</td>
<td>Decreased blood flow to the intestine</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.5%)</td>
<td>Serious Infection</td>
</tr>
</tbody>
</table>
For every type of complication, patients in the study who had a straighter aorta had fewer complications out of every 100 people and none had kidney failure, breathing problems, decreased blood flow to the intestine or serious infection.

12. 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 operation to fix it. If the aneurysm continues to grow and is not repaired, it could rupture. In the Aorfix™ clinical trial, 4.3% of patients had a second procedure to treat endoleak. Only two of these patients experienced aneurysm growth. Ask your doctor about the possible risks of endovascular repair as they relate to your own health. Fewer than 17 out of 100 people (16.2%) required a 2nd procedure for any reason.

ABOUT YOUR HEALTH

13. 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 or
- You have sensitivities or are allergic to the device materials (such as Nitinol and Polyester) 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. You should tell your doctor:

- If you have a kidney problem
- If you have had a problem with X-rays of your arteries in the past
- If you have had a problem with ‘blood thinning’ drugs in the past
- If you have an infection
- If you are allergic to nickel
- If you have had a heart attack in the last 6 months

14. What follow-up Lifestyle Changes are necessary after surgery?

Endovascular repair requires lifelong, regular follow-up to assess the health and performance of the implanted endovascular stent graft. During the first year after receiving the Aorfix™, you are likely to be asked to see your doctor and have a CT scan one month after your operation and again on the anniversary of your operation. You may also be asked to visit your doctor more often. Since most stent graft problems do not have symptoms, only your doctor can assess possible long term problems and this requires the use of special medical tests (ultrasound, CT Scans, etc.).
Possible risks that may require observation and additional treatment include the following:

- **Endoleak**: an endoleak may occur when blood from the aorta continues to leak around the stent graft into your AAA. Most endoleaks do not cause medical problems but a small number do require additional surgical treatment.

- Aneurysm growth or rupture: there is a small chance that your AAA may continue to grow despite the implanted stent graft. You may not have any symptoms but, if you do, the most common will be pain and possibly numbness and leg weakness. If your aneurysm ruptures, symptoms will include dizziness, fainting, rapid heartbeat, or sudden weakness. Regular follow-ups can identify aneurysm changes and help eliminate developing symptoms.

- **Stent graft** movement or fracture: over time, it is possible that your stent graft could move from its original position or the reinforcing wire could break. Your doctor can decide if any additional treatment is required.

- Reduced blood flow to the hips and legs: if your stent graft reduces blood flow, you may be required to undergo additional surgical procedures. Symptoms may include leg or hip pain during walking or discoloration or coolness in the leg. Your doctor will help identify these potential problems and recommend appropriate treatment if necessary.

As with any surgery or medical procedure, there may be other potential complications with the treatment of your AAA. Please discuss these risks and benefits with your doctor.

15. **MR Safety Information you may need to pass on to doctors after your operation**

**Patient Implant Card**: If you receive the Aorfix™ AAA Flexible Stent Graft System, you will be given a Patient Implant Card. This card provides valuable information on the type of your implanted device, the implant date, your implanting doctor’s name and telephone number, and MRI information. You should carry this card with you at all times and always show it to your health care providers.

**Magnetic Resonance Imaging (commonly called an MRI)**: If you receive the Aorfix™ AAA Flexible Stent Graft System, it is still safe to have most MRI procedures. MRI safety information is provided on your Patient Implant Card. Be sure to show your Patient Implant Card to all your health care providers. Your Aorfix™ stent graft should not interfere with airport security scanners. Non-clinical testing has demonstrated that the Aorfix™ Stent Graft implants are MR Conditional. Patients can be scanned safely immediately after implantation under the following conditions:

- Static magnetic field of 1.5 Tesla (1.5T) or 3.0-Tesla (3.0T).
- Maximum spatial gradient field less than or equal to 10 T/m.
- Normal Operating Mode: Maximum whole-body specific absorption rate (SAR) of:
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5T.
  - 2.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0T.
16. After the operation, you should call your doctor if you have these symptoms:
If you have any of the following symptoms, you should contact your doctor as soon as possible:

- If you feel faint or suddenly weak, dizzy or if you have a rapid heartbeat
- If your legs or buttocks are painful, numb or feel cold or weak
- If you feel pain in your abdomen, back or chest, or groin pain

You should also call your doctor if you need to change your next follow-up appointment.

17. Questions you may want to ask your doctor
- Is the Aorfix™ AAA Flexible Stent Graft System an appropriate treatment for my AAA?
- What are the other options for treating my AAA?
- What are all the risks with open surgical repair?
- 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 of all 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?

18. Additional Information
If you have additional questions regarding aneurysms, the following websites may be of help:

Vascular Web Patient Information www.vascularweb.org
Vascular Web is a web based global resource of information and services for individuals interested in improving vascular health worldwide. Vascular Web is sponsored and owned by the Society for Vascular Surgery (SVS) and is governed by a Board of Directors and managed by an Editorial Board.

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

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.

Food and Drug Administration www.fda.gov
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.
CONTACTING LOMBARD MEDICAL

If you have specific questions regarding the Aorfix™ AAA Flexible Stent Graft System, you should discuss them with your doctor. If there is anything that Lombard Medical Technologies Inc. can do to assist you, please feel free to contact us at the following:

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Federal (USA) law restricts this device to sale by or on the order of a physician
Refer to product IFU for full indications, contraindications, warnings and precautions