A Closer Look at Abdominal Aortic Aneurysms and Potential Treatment Options

A patient information guide from Cordis

[Mouse Type] Published on DATE
TABLE OF CONTENTS

1. INTRODUCTION
2. WHAT IS AN ABDOMINAL AORTIC ANEURYSM (AAA)?
3. WHO IS AT RISK FOR AN AAA?
4. HOW IS AN AAA DIAGNOSED?
5. HOW IS AN AAA TREATED?
6. WHAT ARE THE DIFFERENT TYPES OF AAA SURGERY?
7. WHAT IS THE INCRAFT® AAA STENT GRAFT SYSTEM?
8. WHO SHOULD NOT RECEIVE THE INCRAFT® AAA STENT GRAFT SYSTEM?
9. HOW IS THE INCRAFT® AAA STENT GRAFT SYSTEM INSERTED?
10. WHAT ARE SOME OF THE RISKS ASSOCIATED WITH THE INCRAFT® AAA STENT GRAFT SYSTEM?
11. WHAT SHOULD YOU EXPECT AFTER RECEIVING THE INCRAFT® AAA STENT GRAFT SYSTEM?
12. GLOSSARY
13. ADDITIONAL INFORMATION
14. NOTES
1. INTRODUCTION

A Closer Look at Abdominal Aortic Aneurysms and Potential Treatment Options

You may have questions if you or a member of your family has been diagnosed with a condition called an abdominal aortic aneurysm (also called AAA or “triple-A”).

This guide is designed to help you learn more about AAA, including some of the risk factors that can cause the condition. This guide also explains some of the potential treatment options, including a treatment called endovascular aneurysm repair (EVAR).

As with any medical procedure, your doctor and healthcare team are the best sources of information. Your doctor will do a thorough examination to determine which treatment(s) are best suited to your needs and your specific medical condition(s). EVAR may be just one of these treatment options.

At the end of this guide, you will find a glossary of medical terms and space where you can make some notes. You may find it helpful to review these terms before reading this guide. It is also recommended to write down any questions you may have so that you can discuss them with your doctor and healthcare team.

The information in this guide does not replace any information provided to you by your doctor and is not intended to diagnose any medical condition.
2. WHAT IS AN ABDOMINAL AORTIC ANEURYSM (AAA)?

An AAA is an enlarged area in the lower part of the aorta. Before getting into more detail, it is important to understand a little more about this area of the body.

The Aorta

An artery is a type of blood vessel, which carries blood throughout the body. The aorta is the largest artery in the human body and is connected directly to the heart. When the heart beats, it pumps oxygen-rich blood into the aorta, which helps transport blood to the rest of the body. The lower portion of the aorta is known as the abdominal aorta, because it helps to supply blood to many organs in the abdomen like the stomach, kidneys, and liver.

Abdominal Aortic Aneurysm

If the walls of the abdominal aorta become weakened, a bulge, called an aneurysm, can occur in the aorta. Over time, the bulge can continue to enlarge, stretching and thinning the wall of the abdominal aorta.

[Risk] The difference between a normal aorta and an abdominal aortic aneurysm

Rupture of the AAA

The majority of AAAs tend to grow slowly over time, sometimes over the course of several years. In many cases, there are no symptoms to warn someone that an AAA is present. The main concern for a person with an AAA is that the thinning wall of the abdominal aorta could burst, or rupture. A rupture can quickly cause a large amount of internal bleeding, resulting in a life-threatening emergency.
3. WHO IS AT RISK FOR AN AAA?

It is not fully understood why AAAs occur, though there are certain risk factors that may lead to the condition.

**Age**
The risk of developing an AAA increases as a person gets older.

**Gender**
AAAs occur in both men and women; however, the condition appears to be up to 4 times more common in men.

**Race**
AAAs can affect persons of any race or ethnicity.

**Other Risk Factors**
These additional factors also may increase the risk of an AAA.

- Tobacco use
- High blood pressure
- High cholesterol
- Obesity
- Severe heart disease
- People who have had a stroke
- People who have had a heart or liver transplant
- Family history of AAA

[Callout box]
The US Preventive Services Task Force, an independent volunteer panel of national experts in prevention and evidence-based medicine, recommends that men aged 65–75, who have smoked at least 100 cigarettes in their lifetime, have a one-time screening for AAA.
4. HOW IS AN AAA DIAGNOSED?

Detecting an AAA can sometimes be difficult. Often, there are no symptoms. In many cases, the AAA is discovered when a doctor is performing tests for another unrelated condition and happens to find the AAA.

The signs and symptoms that may warn an AAA is occurring are vague and not specific. These signs and symptoms include back pain, side pain, and abdominal pain. Individuals with risk factors for an AAA, who experience any of these signs or symptoms, should consult with their doctor to determine the most appropriate course of action. The doctor may then run certain tests that can help detect an AAA.

**Ultrasound**

An *ultrasound* is a safe, *noninvasive* test that allows the doctor to use sound waves to look at certain organs inside the body. An ultrasound examination is a useful test that can help your doctor see if an AAA is present.

![Caption] A person getting an ultrasound

**CT Scan**

A *computerized tomography (CT) scan* is another noninvasive test that doctors use to diagnose an AAA. An abdominal CT scan uses x-rays to create many pictures of the belly area. By stacking the pictures together, a 3-dimensional model of the belly area can be made, allowing doctors to see if an AAA exists or not. This test can also help doctors decide on recommended treatment options.

![Caption] Abdominal CT scan of an AAA
5. HOW IS AN AAA TREATED?

Once an AAA is diagnosed, there are a number of treatment options from which doctors may choose. The type of treatment depends upon a number of factors, including the size of the aneurysm, how quickly it is growing, and the size and shape of a person’s arteries. Be sure to discuss all the benefits and risks of any treatment or procedure with your doctor.

Small Aneurysms
If the aneurysm is considered small and is not accompanied by symptoms, doctors may decide to observe the AAA over time. It may be necessary to have an ultrasound performed every 6 to 12 months to monitor the progression of the aneurysm.

Larger Aneurysms
Aneurysms that are large, growing quickly, or of a certain shape have a higher risk for rupture. These types of AAAs typically require treatment, which usually involves some form of surgery.

[Callout box]
If you have been diagnosed with an AAA and at any time you start having abdominal tenderness or back pain, you should report these symptoms to your doctor immediately. These may be signs of a worsening condition, which can become serious or even life threatening.
6. WHAT ARE THE DIFFERENT TYPES OF AAA SURGERY?

The goal of surgery is to repair the AAA, to prevent rupture. For an AAA that requires surgery, doctors consider the size, shape, and location of the AAA along with a person’s general health to decide which surgical procedure is the best course of action. Typically, doctors will choose between one of two types of surgery, open surgical repair or endovascular aneurysm repair (EVAR).

[Callout box]
There are risks and benefits associated with any surgery to repair an AAA. Individuals should speak with their doctor and healthcare team to fully understand all of the risks and benefits of surgery.

Open Surgical Repair
This form of AAA repair involves making an incision in a person's abdomen or side so that the affected portion of the aorta can be replaced with a synthetic tube called a graft, which is sewn into place.

Open surgical repair is performed in a hospital using general anesthesia and usually takes 2 to 4 hours to complete. With this type of surgery, it is common to spend several days in the hospital after the procedure. Full recovery may take a month or more.

Endovascular Aneurysm Repair (EVAR)
EVAR is a minimally invasive form of surgery in which a tube(s) is placed inside the aorta to reinforce the weakened aneurysm and allow it to shrink over time. Small incisions are made in a person’s groin to allow delivery systems (a series of thin tubes called catheters) containing collapsed stent grafts to be inserted.

A stent graft is a long cylinder-like tube made of a thin metal framework (stent), covered by a woven fabric-like material (graft).

The delivery systems containing the stent graft are guided from the arteries of a person’s groin to the location of the aneurysm in the aorta. Once at the proper
location, the stent graft is carefully expanded and fastened in place with small hooks or pins. The stent graft is designed to reinforce the weakened section of the aorta and will remain permanently inside the body.

EVAR can be performed in a hospital operating room, radiology department, or catheterization laboratory with either general or local anesthesia. The procedure usually takes 1 to 3 hours to perform. Individuals who undergo EVAR surgery generally leave the hospital after 1 or 2 days.

[Callout box]
Not all individuals are candidates for EVAR. Your doctor and healthcare team will do a thorough examination to determine which treatment(s) are best suited to your needs and your specific medical condition(s).

Benefits
There are a number of benefits\(^1\) to having an abdominal stent graft procedure. Some of these are listed below.

- The procedure is less invasive than open surgical aneurysmal repair.
- The procedure can sometimes be performed with local anesthesia.
- There is a lower rate of surgical complications.
- The patient may lose less blood during the procedure. This reduces the risk related to blood transfusion.
- The patient may spend less time in the intensive care unit after the procedure, and may have a shorter hospital stay.

\(^1\) Based on clinical study data for the Cordis\(^\text{®}\) INCRAFT\(^\text{®}\) AAA Stent Graft. The long-term results for the INCRAFT\(^\text{®}\) AAA Stent Graft have not yet been established.
7. WHAT IS THE INCRAFT® AAA STENT GRAFT SYSTEM?

The INCRAFT® AAA Stent Graft System is a stent graft device used in EVAR procedures to repair an AAA. The device is designed to be implanted inside the aorta to allow blood to pass through the device, removing pressure from the weakened aortic wall.

The INCRAFT® AAA Stent Graft System consists of two main components.

- One Aortic Bifurcate Prosthesis (also called the Main Body)
- Two Iliac Limb Prostheses

These prostheses are placed in the aneurysm using catheters referred to as delivery systems.

The metallic support components, called stents, of the INCRAFT® AAA Stent Graft System are made of a strong, thin metal called nitinol. The outer covering (called the graft), which allows blood to flow through the tube without leaking, is made from a seamlessly woven polyester fabric.
8. WHO SHOULD NOT RECEIVE THE INCRAFT® AAA STENT GRAFT SYSTEM?

The INCRAFT® AAA Stent Graft System is not right for everyone. Only a doctor can recommend the best course of treatment for each individual.

Individuals who should not receive the INCRAFT® AAA Stent Graft System include the following.

- People with certain AAA anatomies that are not compatible with the INCRAFT® AAA Stent Graft System.
- People who have a condition that threatens to infect the graft.
- People with a known allergy or intolerance to nickel titanium (nitinol) polyethylene terephthalate (PET), or polytetrafluoroethylene (PTFE).
9. HOW IS THE INCRAFT® AAA STENT GRAFT SYSTEM INSERTED?

The INCRAFT® AAA Stent Graft System is inserted in the body using a minimally invasive procedure called EVAR. This means that small incisions are made in a person’s groin to allow the INCRAFT® AAA Stent Graft delivery systems to be inserted.

[Caption] X-ray view of the INCRAFT® AAA Stent Graft in the abdominal aorta

Each component of the INCRAFT® AAA Stent Graft is compressed into the end of a long and thin delivery system.

Two small incisions or punctures are made in the groin area to access the arteries near the top of each leg called the femoral arteries.

Using a real-time x-ray system called fluoroscopy, a doctor carefully guides the delivery systems up the femoral artery to the location of the AAA.

The delivery systems containing the compressed INCRAFT® AAA Stent Graft System are delivered to the abdominal aorta in 3 stages.

First, the delivery system containing the compressed Aortic Bifurcate (or Main Body) is carefully positioned and then expanded.

Once the proper position of the Aortic Bifurcate has been confirmed, the doctor will then use another delivery system to place and expand one of the Iliac Limbs and attach it to the Aortic Bifurcate.

The other Iliac Limb is then attached and expanded to form the complete INCRAFT® AAA Stent Graft System.

Once proper placement of the INCRAFT® AAA Stent Graft System has been confirmed, the surgeon will make sure the device is correctly implanted and working properly. Once confirmed, the delivery systems are removed from the body.
10. WHAT ARE SOME OF THE RISKS ASSOCIATED WITH THE INCRAFT® AAA STENT GRAFT SYSTEM?

As with any medical procedure, endovascular repair involves risks of experiencing complications and side effects related to the implanted device and/or the procedure.

A small number of patients in the clinical study for the INCRAFT® AAA Stent Graft System experienced some of the complications listed below. The clinical study included patients between the ages of 51 and 90 years old. Many of these patients had high blood pressure, high cholesterol, heart disease, and a history of smoking. However, patients who had a recent surgery, infection, heart attack, bleeding disorder, kidney failure, or stroke were not included in the study. You should talk to your doctor about how your situation may be different or similar.

The clinical study patients who received the INCRAFT® AAA Stent Graft System had these major side effects within 30 days after their endovascular repair. The INCRAFT® clinical studies are ongoing so that we can collect and better understand the risks with this device.

<table>
<thead>
<tr>
<th>All Clinical Study Patients</th>
<th>Major Side Effects within 30 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer than 3 out of 100 people (2.1%)</td>
<td>Significant blood loss</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.5%)</td>
<td>Heart attack</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.5%)</td>
<td>Stroke</td>
</tr>
<tr>
<td>Fewer than 1 out of 100 people (0.5%)</td>
<td>Death for any reason</td>
</tr>
</tbody>
</table>

While most people who receive the INCRAFT® AAA Stent Graft System do not experience major side effects, it is important to be familiar with potential risks associated with the procedure and to discuss those risks with your doctor. If side effects occur, your doctor can decide what treatment, if any, is required.

Some side effects may require additional endovascular procedures. In the INCRAFT® AAA Stent Graft System clinical study, fewer than 7 out of 100 people (6.9%) required a second procedure for any reason through 1-year.

The major risks associated with AAA stent grafts include, but are not limited to the following.

- Complications from anesthesia
- Aneurysm growth or rupture
- Damage to the arteries or blood vessels during the procedure
- Formation of an abnormal passage between the blood vessels and intestines
- Blood clots that can travel through the arteries or veins and block the flow of blood
• Bleeding through the medical devices used to complete the procedure
• Bowel complications including severe damage to a portion of your bowel tissue requiring surgical removal
• Heart or lung complications such as abnormal heartbeat or heart attack
• Pain, cramping or weakness in the legs
• Migration or movement of the stent graft components over time
• Swelling, infection, pain or bleeding at the treatment site
• Leaking of blood around the stent graft into the aneurysm sac (referred to as an Endoleak)
• Death
• Fever
• Complications with the gastrointestinal system
• Complications of the reproductive and urinary organs including infection or severe tissue damage.
• Damage to the stent graft such as fractured stents, wear/puncture/damage to the implant fabric or broken sutures that connect the stents to the fabric
• Kinking or twisting of the stent graft system
• Kidney Failure or complications related to the dye (called contrast) used as part of the x-ray imaging during the procedure
• Impotence
• Inflammation
• Nervous system complications
• Conversion from an endovascular procedure to open surgery
• Occlusion or blocking of blood flow within the stent graft
11. WHAT SHOULD YOU EXPECT AFTER RECEIVING THE INCRAFT® AAA STENT GRAFT SYSTEM?

Individuals who receive the INCRAFT® AAA Stent Graft typically spend 1 to 2 days in the hospital after surgery for observation and recovery. It is recommended that regular follow-up examinations are scheduled after the procedure. Timing of the follow-up evaluations is best determined in consultation with your doctor and healthcare team.

Stent Implant Card
Individuals who receive the INCRAFT® AAA Stent Graft will be provided with a Stent Implant Card prior to leaving the hospital. This card contains information about the implanting physician, the hospital, and the specific device that was implanted.

The purpose of this card is to provide important information to healthcare providers who may be unfamiliar with the INCRAFT® AAA Stent Graft, including information on the magnetic resonance imaging (MRI) safety and compatibility of the device. This card should be carried at all times.

Device Tracking
US Federal Law, Title 21 Code of Federal Regulations, Part 821, requires the tracking of all AAA stent grafts at all stages of distribution. As required by this federal regulation, once you receive an INCRAFT® AAA Stent Graft System, the hospital staff will forward the device tracking information to Cordis Corporation that will include, only with your consent, your personal contact information. Cordis Corporation will also attempt to contact you to ensure that your device tracking record is up to date.

Follow-up Examinations
Lifelong follow-up examinations are required following the implantation of the INCRAFT® AAA Stent Graft System. The purpose of these regular examinations is to check the position of the device, to assess the flow of blood through the device, and to look for changes in the aneurysm (shrinking or growing). The frequency of these routine follow-up examinations will be determined by your doctor, and may include the following:
- A physical examination
- Abdominal x-rays
- Ultrasound
- CT scan
Magnetic Resonance Imaging (MRI) Safety
After the implantation of the INCRAFT® AAA Stent Graft, it is still safe to have MRI procedures under certain conditions. The Stent Implant Card provides guidance to healthcare professionals regarding these conditions.

Lifestyle Changes
To help stay as healthy as possible, individuals who have received the INCRAFT® AAA Stent Graft System are encouraged to make important diet, exercise, and lifestyle changes. Some individuals may need few modifications, while others may need to make several changes.

A diet low in fat and cholesterol can reduce the levels of fat in the blood and ward off other health risks. Choosing to eat healthy foods in the right proportions can also help to achieve and maintain a healthy weight. Smoking should always be avoided.
12. GLOSSARY

**Abdomen**: The part of the body between the chest and the hips, also known as the belly.

**Abdominal aorta**: The large artery (aorta) that passes through the belly.

**Abdominal aortic aneurysm (AAA)**: A bulge in the wall of the abdominal aorta caused by weakening of the blood vessel wall.

**Aneurysm**: A bulging of the wall of a blood vessel.

**Aorta**: The main artery of the heart that carries oxygen-rich blood to the rest of the body.

**Aortic Bifurcate**: The main component of the INCRAFT® AAA Stent Graft System that is placed inside the aorta.

**Artery**: Vessels carrying oxygen-rich blood from the heart to the rest of the body.

**Catheter**: A hollow, flexible tube that can be guided into a vessel or space in the body.

**Computerized tomography (CT) scan**: An x-ray technique for examining internal structures of the body by creating accurate pictures of organs and tissues.

**Endovascular aneurysm repair (EVAR)**: A type of minimally invasive surgery performed to repair an abdominal aortic aneurysm by placing a stent graft to reinforce the weakened part of the aorta.

**Femoral artery**: A blood vessel located in the groin area.

**Fluoroscopy**: A technique used for creating a real-time x-ray.

**Graft**: A tube made of fabric.

**Iliac Limb**: The 2 smaller parts of the INCRAFT® Stent Graft System, which connect to the Aortic Bifurcate.

**INCRAFT® AAA Stent Graft System**: A type of stent graft.

**Magnetic resonance imaging (MRI)**: A technique to make pictures of the internal structures and reactions of the body.

**Nitinol**: A strong, flexible metal alloy made from nickel and titanium.

**Noninvasive**: A type of test or procedure that does not require the introduction of instruments into the body.

**Open surgical repair of AAA**: A type of surgery performed to repair an aneurysm where a cut is made on a person’s belly or the side to access the aneurysm. The surgeon repairs the aorta by sewing a graft into place to act as a replacement blood vessel.

**Rupture**: The potentially life-threatening tear or burst of a blood vessel.

**Stent**: A tube made of metal to support a blood vessel.

**Stent graft**: A fabric tube supported by metal wire stents that reinforces the weak spot in a blood vessel.

**Stent Implant Card**: An important identification card that can provide healthcare professionals with vital information about the person’s stent implant.

**Ultrasound**: A technique that uses sound waves to create images of the internal structures of the body.
13. ADDITIONAL INFORMATION

You can find additional information about AAAs and available treatment options from the following sources:

**Aneurysm Screening**
Medicare.gov
www.medicare.gov/coverage/ab-aortic-aneurysm-screening.html
The official U.S. Government site for Medicare. Medicare and Medicaid have been covering health care for 50 years. Medicare’s official website contains details regarding the screening benefit provided for those patients who may be at increased risk of developing an abdominal aortic aneurysm.

**Aneurysms**
American Heart Association www.heart.org
Founded in 1924, the American Heart Association is the nation’s oldest, largest voluntary organization devoted to fighting cardiovascular diseases and stroke.

Mayo Clinic www.mayoclinic.com
Mayo Clinic is a nonprofit worldwide leader in medical care, research, and education for people from all walks of life.

**Treatment Options**
Society of Interventional Radiology www.sirweb.org
The Society of Interventional Radiology is a national organization of physicians, scientists, and allied health professionals dedicated to improving public health through disease management and minimally invasive, image-guided therapeutic interventions.

MedlinePlus is the National Institutes of Health’s Web site for patients and their families and friends. Produced by the National Library of Medicine, it brings you information about diseases, conditions, and wellness issues in language you can understand. MedlinePlus offers reliable, up-to-date health information, anytime, anywhere, for free.

**Product Information**
US Department of Health and Human Services
Food and Drug Administration www.fda.gov
A US 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.
Cordis Corporation [www.cordis.com]
Cordis is a leading worldwide medical device company that has been developing and manufacturing products to treat individuals who suffer from cardiovascular disease for more than 50 years. Cordis works to identify solutions to provide the best possible outcomes for both physicians and patients.
14. NOTES

You are encouraged to use this space to write down questions or concerns that you wish to discuss with your healthcare team.

[Fill the page with lines]
Caution: Federal law restricts this device to sale by or on the order of a physician.

Indications for Use
The INCRAFT® Stent Graft System is intended for the endovascular treatment of patients with infrarenal abdominal aortic aneurysms with the following characteristics:

- Adequate iliac or femoral vessel morphology that is compatible with vascular access techniques, devices and accessories
- Proximal neck length ≥ 10mm
- Aortic neck diameters ≥ 17mm and ≤ 31mm
- Aortic neck suitable for suprarenal fixation
- Infrarenal and suprarenal neck angulation ≤ 60°
- Iliac fixation length ≥ 15mm
- Iliac diameters ≥ 7mm and ≤ 22mm
- Minimum overall AAA treatment length (proximal landing location to distal landing location) ≥ 128mm

Safety information is found in the Instructions for Use.

Cordis
1820 McCarthy Blvd
Milpitas, CA 95035
USA
T: 408-273-3700
http://www.cordis.com