

Treating your abdominal aortic and aortoiliac aneurysm

Zenith® Spiral-Z®
AAA Iliac Leg Graft

Zenith Flex®
AAA Endovascular
Graft

Zenith® Spiral-Z®
AAA Iliac Leg Graft

Zenith® Iliac Branch

Covered stent

Zenith®
ENDOVASCULAR GRAFTS

About this patient guide

This patient guide has been provided as a courtesy from Cook Medical and is intended to be a resource to learn more about **abdominal aortic aneurysms (AAA)**, **iliac aneurysms**, and potential treatment options. We hope this information will be helpful to you and your family.

For your convenience, a glossary of medical terms is included on pages 21-23. Words in **bold** throughout this text are defined in the glossary.

This patient guide is not intended to diagnose a medical condition. It provides basic information about **abdominal aortic** and **iliac aneurysms** and their treatment with the Cook **Zenith Flex AAA Endovascular Graft** and **Zenith Iliac Branch** devices. This information is not intended to diagnose a medical condition. The treatment of **abdominal aortic aneurysms** may vary according to an individual's unique needs and doctor assessments. As with any surgery or medical procedure, the best source of information and advice is your doctor.

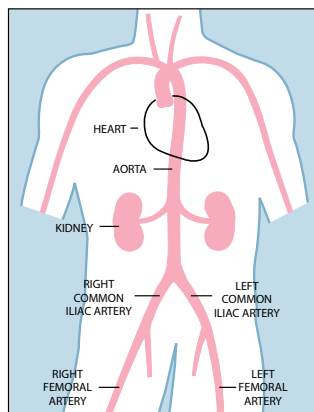
For further information regarding the indications for use and contraindications of these devices, please refer to the appropriate product's Instructions for Use.

US federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

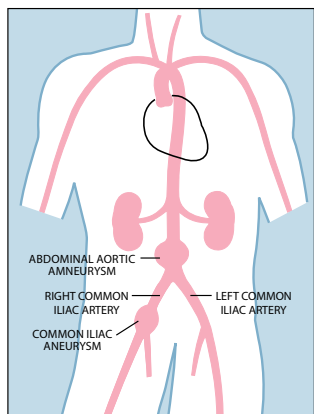
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Introduction



Aortic anatomy



Aortic anatomy with aneurysm

What is an abdominal aortic aneurysm (AAA)?

The **aorta** is the main blood vessel that carries blood from the heart to the rest of the body. It extends from the chest to the abdomen, where it branches into the common **iliac arteries**. The common **iliac arteries** carry blood to lower parts of the body and to the legs. Sometimes, because of aging or other changes, a section of the **aorta** may weaken and begin to bulge.

This bulge can enlarge over time as the walls of the **aorta** become thinner and stretch (like a balloon). This bulge in the **aorta** is called an **aneurysm**.

Sometimes an **aneurysm** occurs in the part of the **aorta** that runs through the abdomen. This is called an **abdominal aortic aneurysm (AAA)**.

What is an aortoiliac or iliac artery aneurysm?

Sometimes, an **abdominal aortic aneurysm** is not contained only within the **aorta**. The **aneurysm** can extend down into one or both of the common **iliac arteries**. Depending on where in the vessel the **aneurysm** is, the condition is called an **aortoiliac aneurysm** or **iliac artery aneurysm**. Up to 40% of patients with an **AAA** also have an **aortoiliac aneurysm** or **iliac artery aneurysm**.^{1, 2}

Are these serious conditions?

In its early stages, when an **AAA** or **iliac artery aneurysm** is small, it may not pose an immediate health risk. However, your doctor will want to check the conditions of the **aneurysm** regularly through follow-up visits and by taking pictures using special equipment.

In later stages, if the **AAA** or the **iliac artery aneurysm** continues to grow, the walls of the **aorta** or common **iliac arteries** can become thin and lose their ability to stretch. If these walls become too weakened by this, then the **aneurysm** could burst, causing serious internal bleeding.

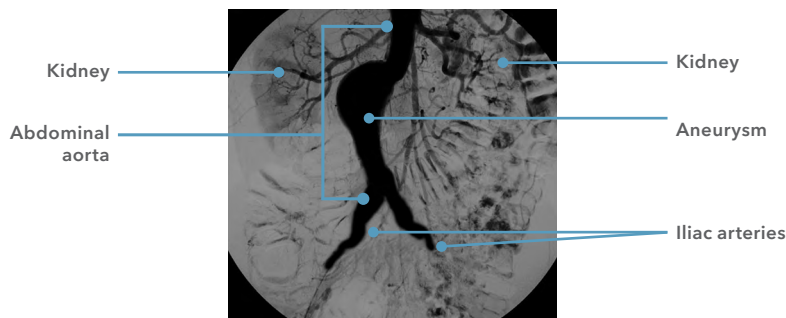
1. Giosdekos A, Antonopoulos CN, Sfyroeras GS, et al. The use of iliac branch devices for preservation of flow in internal iliac artery during endovascular aortic aneurysm repair. *J Vasc Surg.* 2020;71(6):2133-2144.
2. Isselbacher EM, Preventza O, Black JH 3rd, et al. 2022 ACC/AHA guideline for the diagnosis and management of aortic disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;146(24):e334-e482.

What are some of the symptoms of an aneurysm?

In most cases, patients have no symptoms of an **aneurysm**. For people who do have symptoms, the most common one is pain. For patients with an **AAA**, the pain can be in the abdomen, back, or chest. It could be anything from a mild pain to a severe pain or tenderness in the mid to upper abdomen or lower back. Some patients feel the **aneurysm** as a pulsating or throbbing mass in their abdomen. Patients with an **iliac artery aneurysm** may experience back pain, lower abdominal pain, or groin pain. Many patients feel none of these symptoms yet may still have an **aneurysm**.

An **aneurysm** is often discovered during an examination being done for other medical reasons. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen or groin. Most often, **aneurysms** are found during a medical test such as a **CT scan** or **ultrasound**.

If you know you have an **aneurysm** and you develop back pain, abdominal pain, or dizziness, call your doctor immediately.



What causes an aneurysm?

Over time, **vascular** disease, injury, or a hereditary defect in the wall of the blood vessel can cause a weakening of the **aorta** or common **iliac arteries**. Blood pressure against the weakened area can cause ballooning (enlarging and thinning) of the vessel.

Risk factors for developing an **aneurysm** include a family history of similar issues, smoking, heart disease, and high blood pressure. If you are at risk for developing an **aneurysm**, your doctor may recommend periodic checks. The checks could include a physical exam and possibly a **CT scan** or **ultrasound**.

Treatment of an abdominal aortic aneurysm

How do doctors treat an AAA?

When an **aneurysm** is small, your doctor may recommend periodic checkups to monitor it. If an **aneurysm** is larger, or is rapidly growing, it has a greater risk of bursting. If your doctor thinks there is a risk the **aneurysm** may burst, they may recommend treatment. There are two types of treatment for **AAA**:

- **Open surgical repair**
- **Endovascular repair**

The goal of all **AAA** and **iliac aneurysm** repair is to prevent the **aorta** or **iliac arteries** from bursting.

What is an open surgical repair?

In this treatment, surgery is performed to repair the section of the **aorta** or **iliac arteries** that has an **aneurysm**. To reach the **abdominal aortic aneurysm**, a doctor makes a cut through the abdomen or the side of the patient. The doctor repairs the blood vessel 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. The blood flow through the **aorta** is stopped while the graft is put in place. The surgery takes about two to four hours to complete.

Open surgical repair is a proven medical procedure that works. However, it also has a long recovery period. Patients usually stay overnight or several days in the intensive care unit and stay another 7 to 10 days in the hospital. Many patients are unable to eat normally for five to seven days after the surgery. The overall recovery period can last up to three months. **Open surgical repair** requires follow-up visits with your doctor to monitor the success of the repair.

As with any medical procedure, **open surgical repair** has a risk of complications. Discuss these with your doctor.

Important note: Not every patient is a candidate for **endovascular repair**. **Open surgical repair** and **endovascular repair** both have advantages and disadvantages based upon each patient's condition and needs. Discuss the advantages and disadvantages with your doctor.

What is an endovascular repair?

Endovascular means "inside or within a blood vessel." Instead of making a large incision in the abdomen, the doctor makes small cuts near the groin to get to the **femoral arteries** (blood vessels).

Through these small incisions, an **endovascular graft** is inserted through the **femoral artery** and positioned inside the **aorta** or **iliac arteries**. The **endovascular graft** is deployed and seals off the **aneurysm**. The graft makes a new path through which the blood flows. The graft remains inside the vessel permanently. **Endovascular repair** typically takes one to three hours to complete.

Because the incisions used for **endovascular repair** are much smaller than the cut used for **open surgical repair**, patients may experience less discomfort and faster recovery. Patients may have a hospital stay of only a few days. They can usually return to normal activity within four to six weeks after the procedure.

As with any medical procedure, **endovascular repair** has a risk of complications. These should be discussed with your doctor.

Endovascular repair also requires routine follow-up visits with your doctor. Tests will be done to evaluate the procedure and monitor the success of the treatment. There is also a possibility that additional treatment or surgery may be required after the **endovascular repair**. Refer to the "What follow-up should I expect?" section for more information.



About Zenith Flex AAA Endovascular Graft and Zenith Iliac Branch

What is Zenith Flex AAA Endovascular Graft?

The **Zenith Flex AAA Endovascular Graft** is made up of three parts: a **main body** and two “legs.” The **main body** is positioned in the **aorta**. The legs are positioned in the **iliac arteries** and connect to the **main body**. The graft extends from the **aorta** below the **renal arteries**, which lead to the kidneys, into both **iliac arteries**.

The graft itself is made of a polyester material like that used in **open surgical repair**. Stainless steel **stents** provide support for the attached graft material. The graft has several gold markers to help your doctor see it clearly during the procedure. All of these materials have a long history of use in medical implants.

What is Zenith Iliac Branch?

Zenith Iliac Branch is an **endovascular graft** specifically designed to ensure that blood is able to flow to the internal **iliac arteries**. This blood flow to the internal **iliac arteries** is important because those vessels allow blood flow to be maintained to the pelvic organs and the buttock muscles. The main graft is used with the Zenith Spiral-Z AAA Iliac Leg Graft in the common **iliac artery** and has a unique side branch that keeps blood flowing to the internal **iliac artery**.

Zenith Iliac Branch is made of polyester material, which is attached to a frame of stainless steel and nitinol **stents**. **Zenith Iliac Branch** also has gold markers to help your doctor see it clearly during the procedure.

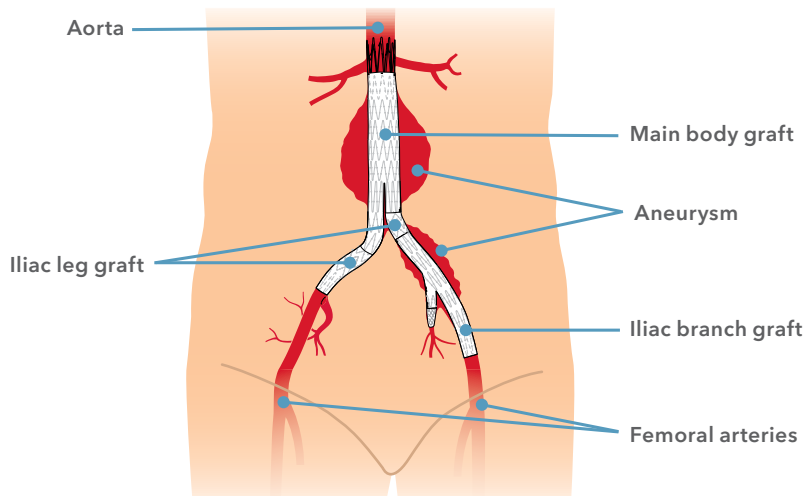
How are the grafts implanted?

Before the procedure, your doctor looks at pictures of your **aorta** and **iliac arteries** (from a **CT scan** and **angiogram**). From these pictures, the doctor can choose the proper size for each part of the **Zenith Flex AAA Endovascular Graft** so that it will fit in your blood vessels. The doctor may decide to use a **Zenith Iliac Branch** if the **aneurysm**

extends down into one or both of the common **iliac arteries**. This is done to keep blood flowing to the internal **iliac arteries**. During the procedure, the doctor uses x-rays to see the grafts and position them correctly.

Each of the grafts are contained in its own **sheath** (plastic tube). Each **sheath** is removed after the graft is put in place.

To place the graft, your doctor makes small cuts near the groin to get to the **femoral arteries** (blood vessels). Through these small cuts, each part of the graft is inserted separately. The **main body** of the **Zenith Flex AAA Endovascular Graft** is positioned in the **aorta**. The legs extend from the **main body** into the **iliac arteries**. When each part of the graft is released from its tube, it opens up to fill and reinforce the **aorta**. When both legs are connected to the **main body**, the graft seals off the **aneurysm**. If a **Zenith Iliac Branch** is being used as well, it is implanted first, followed by the **Zenith Flex AAA Endovascular Graft**, which is joined to it.



Before the procedure is finished, your doctor uses x-rays to confirm that the blood in the **aorta** and **iliac arteries** flows through the graft, not through the **aneurysm**. Your doctor then closes up the cut near the groin with a few stitches.

Zenith clinical study summary

Zenith Flex clinical study summary

The **Zenith Flex AAA Endovascular Graft** clinical study was a 432-subject study conducted in the United States to evaluate the safety and effectiveness of the **Zenith Flex** device. Of the total 432 subjects, 352 subjects were treated with the **Zenith Flex** and 80 were treated with **open surgery** as a control group.

Subjects enrolled in the study were followed for 2 years and all study-related activities are complete. The primary study analyses compared 200 of the **Zenith Flex** subjects to the 80 **open surgical repair** subjects. Results demonstrated reduced 30-day morbidity in the **Zenith Flex** group (20% vs. 43%) and equivalence between the two groups for 30-day survival (0.5% vs. 2.5%), 12-month survival (3.5% vs. 3.8%), and 12-month treatment success (89% vs. 85%).

Although the types of risks associated with the **Zenith Flex** are similar to other **endovascular** procedures for **aortoiliac** and **iliac aneurysms**, it is important to consult with your doctor to better understand if the **Zenith Flex** is right for you.

One year of follow-up for subjects treated with **Zenith Flex** resulted in the following:

- 7 out of 352 subjects (2%) experienced death related to their **aneurysm**.
- 1 out of 352 subjects (0.3%) experienced a **rupture** of their **aneurysm**.
- 18 out of 352 subjects (5.1%) experienced a leakage of blood around the endograft into the **aneurysm** sac that was related to the device.
- 3 out of 352 subjects (0.9%) experienced a growth (>5 mm) of their **aneurysm** at 1 year.
- 37 out of 352 subjects (10.5%) required additional procedures to treat their **aneurysm**.

Longer term follow-up through 2 years for subjects treated with the **Zenith Flex** showed the following:

- 9 out of 352 subjects (2.6%) experienced death related to their **aneurysm**.
- 11 out of 324 available subjects (3.4%) required additional procedures to treat their **aneurysm** between year 1 and 2 of follow-up.
- 9 out of 352 subjects (2.6%) experienced breakage of a device component (barbs), although no clinical symptoms were experienced by these subjects.

Zenith Iliac Branch clinical study summary

The PRESERVE-**Zenith Iliac Branch** clinical study was a 40-subject study conducted in the United States to evaluate the safety and effectiveness of the **Zenith Iliac Branch** device.

Subjects enrolled in the study were followed for five years and all study-related activities are complete. The primary study endpoint was 6-month freedom from patency-related intervention of the internal **iliac artery**. Of the 39 subjects with adequate data to evaluate, 39 (100%) had success on the primary outcome. The secondary safety endpoint was freedom from 30-day morbidity. Of the 40 subjects evaluated through 30 days, 34 (85%) had success on the secondary safety endpoint. The secondary effectiveness endpoint was branch vessel (i.e., internal **iliac artery**) patency at 6 months. Of the 37 subjects with adequate 6-month imaging, 37 (100%) had success on the secondary effectiveness endpoint.

Although the types of risks associated with the **Zenith Iliac Branch** are similar to other **endovascular** procedures for **aortoiliac** and **iliac aneurysms**, it is important to consult with your doctor to better understand if the **Zenith Iliac Branch** is right for you.

One year of subject follow-up resulted in the following:

- No subjects experienced death related to their **aneurysm**.
- No subjects experienced a **rupture** of their **aneurysm**.

- No subjects experienced growth (>5 mm) of their **iliac aneurysm** treated by the **Zenith Iliac Branch**.
- 1 out of 40 subjects (2.5%) experienced a leakage of blood around the devices into the **aneurysm** sac that was related to the device.
- 2 out of 40 subjects (5%) experienced **occlusion** of the external **iliac artery** segment of the **Zenith Iliac Branch** device.
- No subjects experienced breakage or separation of the device components.
- 4 out of 40 subjects (10%) required additional procedures to treat their **aneurysm**.

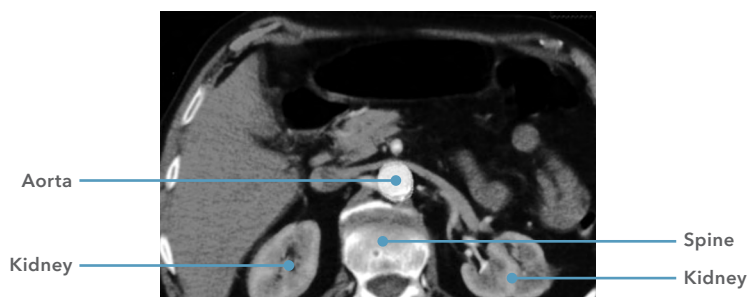
Longer-term follow-up through five years showed the following:

- No subjects experienced death related to their **aneurysm**.
- No subjects experienced a **rupture** of their **aneurysm**.
- 1 out of 40 subjects (2.5%) experienced growth (>5 mm) of their **iliac aneurysm** treated by the **Zenith Iliac Branch**.
- 1 out of 40 subjects (2.5%) experienced a leakage of blood around the endograft into the **aneurysm** sac that was related to the device.
- 2 out of 40 subjects (5%) experienced **occlusion** of the internal **iliac artery** segment of the **Zenith Iliac Branch** device.
- No subjects experienced breakage or separation of the endograft components.
- 9 out of 40 subjects (22.5%) required additional procedures to treat their **aneurysm**.

After the endovascular procedure

Why is follow-up important?

If you receive a **Zenith Flex AAA Endovascular Graft**, with or without a **Zenith Iliac Branch**, it is very important that you have regularly scheduled follow-up appointments with your doctor because the long-term results of an **endovascular repair** are not as well known as the short-term results. It is possible for problems to occur that do not cause noticeable symptoms. Therefore, your doctor needs to look at pictures (x-ray, **CT scan**) of your **aneurysm** and graft on a regular basis. If a problem occurs, your doctor may recommend additional procedures.



Some problems that might occur are:

Endoleak

An **endoleak** occurs when blood from the **aorta** or **iliac arteries** continues to leak into the **aneurysm**. Most **endoleaks** do not require treatment. However, a small number do require further treatment.

Graft movement

Because blood vessels can change over time with an **aneurysm**, it is possible for a graft to move over time. Because graft movement cannot be felt, it is important to keep your routine follow-up visits with your doctor. Graft movement, if it occurs, can be seen with a **CT scan**.

What symptoms should prompt you to call your doctor after the procedure?

Symptoms of **aneurysm** growth are not always present.

When symptoms of **abdominal aortic aneurysms** are present, the most common are:

- Pain in the legs, back, chest, or abdomen
- Numbness in the legs, back, chest, or abdomen
- Weakness in the legs, back, chest, or abdomen

Symptoms of an **aneurysm rupture** include:

- Pain
- Dizziness
- Fainting
- Rapid heartbeat
- Sudden weakness

Symptoms of device **occlusion** include:

- Leg, hip, or buttock pain during walking
- Leg discoloration
- Leg coolness

If you experience any of the symptoms listed above, call your doctor immediately.

What follow-up should I expect?

Follow-up exams are important and should be considered a lifelong commitment to your health and well-being.

Recommended follow-up includes checkups at:

- 1 month
- 6 months
- 12 months
- Every year afterward

Follow-up exams usually include routine blood tests, x-rays, a **CT scan**, and a physical exam.

These follow-up exams do have a small amount of risk. However, the benefits of these tests clearly outweigh any potential risks. There is a rare risk of allergic reaction related to the **contrast (dye)** used in the **CT scan**. Talk with your doctor if you have any concerns regarding these exams.

Follow-up exams are necessary to evaluate your treatment and any changes over time. Your doctor may request additional evaluations based on findings at the follow-up visits.

Possible risks if left untreated

Leaving an **abdominal aortic aneurysm (AAA)** untreated can result in **rupture**, which is a life-threatening condition. Therefore, the possible benefit of treatment is the prevention of **rupture**. However, as with any medical procedure, there are also risks associated with treating **AAAs**, as discussed in the section above.

What if I need magnetic resonance imaging (MRI)?

If you receive a **Zenith Flex AAA Endovascular Graft**, with or without a **Zenith Iliac Branch**, be sure to tell all of your healthcare providers that you have the graft. Show them your patient ID card(s). The card contains information related to **MRI** procedures for patients with these devices. Discuss the potential risks and benefits of an **MRI** with your healthcare providers if you have any concerns about this diagnostic test.

There may be potential risks (such as movement of the graft or injury to the blood vessel) that could be associated with magnetic forces affecting the metallic components of the **Zenith Flex AAA Endovascular Graft** or **Zenith Iliac Branch**. Therefore, your doctor will carefully assess these potential risks and potential benefits to you before an **MRI**. In addition, the facility for **MRI** should be appropriately selected to allow for healthcare providers to act quickly in the event that there has been a change to the graft that needs immediate attention.

What should I do with my patient ID card(s)?

This card(s) provide valuable information concerning:

- Type of device implanted
- Date of implant
- Your doctors
- **MRI** information

Be sure to tell all of your healthcare providers that you have the graft(s) and show them your patient ID card(s). You should keep your patient ID card(s) available at all times.

Front

MRI information on reverse side.

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Zenith Iliac Branch Endovascular Graft

COOK MEDICAL

This patient has received a

Implant date
 Patient name
 Implanting facility name
 Implanting physician
 Implanting physician phone number
 Follow-up physician
 Follow-up physician phone number
 Product catalog number ☐ Abdominal

Before MRI, you must show this card to your doctor who should assess potential risks and consider the MRI information in the device labeling on www.cookmedical.com. Because unforeseen variations in patient anatomy or scanners may increase risk, the MRI facility should allow for prompt intervention if necessary.

Back

It is recommended that patients register the conditions under which the implant can be safely scanned with the Medic Alert Foundation (medicalert.org) or an equivalent organization.

MR

A patient with the Zenith Iliac Branch (ZBIS) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

MRI SAFETY INFORMATION	
MR Conditional	
Item Name/Identification	Zenith Iliac Branch (ZBIS)
Normal Value(s) of Static Magnetic Field [T]	1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	7.2 T/m (720 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum whole body SAR [W/kg]	2.0 W/kg
Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
Image Artifact	The presence of this implant may produce an image artifact.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

PC-ZBIS-US-Rev001

Where can I find more information?

Aneurysm and procedure information

Society for Vascular Surgery

vascular.org

Vascular.org is an internet-based global resource of information and services for individuals interested in improving **vascular** health worldwide. It 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

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.

U.S. National Library of Medicine

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 healthcare, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences.

Product information

Cook Medical

cookmedical.com

With international headquarters in Bloomington, Indiana, privately held Cook is a leading designer, manufacturer, and global distributor of minimally invasive medical device technologies for diagnostic and therapeutic procedures. Since its founding in 1963, Cook has been a privately held company that creates innovative technologies for **stents** and stent grafts, catheters, wire guides, introducer needles and **sheaths**, embolization coils, medical biomaterials, vena cava filters, implanted cardiac lead extraction equipment, and other minimally invasive medical devices.

US Department of Health and Human Services

Food and Drug Administration

fda.gov

The FDA is a US government agency intended to promote and protect 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.

Notes

If you have any questions about your **abdominal aortic aneurysm** or treatment, we encourage you to talk to your doctor. They should always be your primary source of information. Talk to your doctor about the details of this procedure and its impact on your health.

- What is the best treatment option for my **aneurysm**?
- What are all of the potential risks and complications of an **open surgical repair** or an **endovascular repair**?
- When can I resume normal activity after my procedure?
- After my procedure, what will my follow-up include?
- How long will my medical treatment continue after my procedure?
- Is there a risk if I miss a follow-up?
- Will I need to consider any precautions in my daily life after my procedure (such as going through an airport security scanner)?
- What symptoms should prompt me to seek immediate medical attention after my procedure?

Use the space below to record your doctor’s name and phone number. You may also want to write down any questions, take notes, or keep a record of your discussions with your doctor.

Patient name:	
Implantation date:	
Device implanted	☐ Zenith Flex AAA Endovascular Graft ☐ Zenith Flex AAA Endovascular Graft and Zenith Iliac Branch ☐ Other – Please specify:
Implanting facility name (hospital):	
Implanting physician:	
Implanting physician phone #:	

Glossary

Abdominal Aortic Aneurysm (AAA) – a bulge that occurs in the part of the **aorta** that passes through the abdomen. The bulge (enlarging and thinning) of the **aorta** is due to a weakening in the arterial wall.

Aneurysm – a bulging or ballooning (enlarging and thinning) of a weakened area of a blood vessel.

Angiogram – an image taken by injecting dye into the bloodstream and taking an x-ray.

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

Aortoiliac Aneurysm – an enlarging and thinning of a weakened area of the abdominal **aorta** that also extends down into the common **iliac artery**.

Contrast (dye) – a liquid dye injected into the bloodstream to show blood vessels under x-ray or **CT scan**.

CT Scan – a series of computerized x-rays that form a picture of your body organs, your blood vessels, and your dissection. Formerly known as a CAT scan.

Endoleak – blood flow into the **abdominal aortic aneurysm** after placement of an **endovascular graft**.

Endovascular – inside or within a blood vessel.

Endovascular Graft – a graft placed inside a diseased vessel without the use of open surgical techniques. The graft makes a new path through which the blood flows.

Endovascular Repair – placement of an **endovascular graft** to

seal off (exclude) an **aneurysm**. Instead of making a large incision in the abdomen, the doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels). Through these small cuts, a graft (fabric tube) is inserted through the **femoral arteries**. The graft makes a new path through which the blood flows.

Femoral Arteries - two blood vessels (one in each leg) that carry blood to the thigh region of each leg. Doctors can use the **femoral arteries** as a path to reach arteries within the chest and abdomen.

Iliac Aneurysm - an enlarging and thinning of a weakened area of the common **iliac artery**.

Iliac Arteries (Common) - the two large blood vessels that extend from the lower end of the **aorta** to the internal **iliac**, external **iliac**, and **femoral arteries** in each leg.

Iliac Arteries (Internal) - two blood vessels that come off the **common iliac arteries** and supply blood to the pelvis and pelvic organs. If they are blocked off, complications can occur.

Main Body - the part of the **Zenith Flex AAA Endovascular Graft** that is placed in the **aorta**.

MRI (Magnetic Resonance Imaging) - a way of creating detailed pictures of the body. The **MRI** scanner uses magnetic fields and radio waves to create the pictures.

Occlusion - blockage of a blood vessel.

Open Surgical Repair (Open Surgery) - a type of surgery performed to repair an **aneurysm**. To reach the **aneurysm**, a doctor makes a cut through the abdomen or the side 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.

Renal Arteries - two blood vessels that come off the **aorta** and carry blood to the kidneys.

Rupture - a tear in the blood vessel wall that causes serious internal

bleeding.

Sheath – a long plastic tube that contains the **Zenith Flex AAA Endovascular Graft**. The **sheath** is advanced inside the blood vessel to the **aneurysm** site, and the graft is positioned in place.

Stents – surgical steel parts of the **endovascular graft** that provide support and hold it in place.

Ultrasound – a way to create pictures of parts of the body using high frequency sound waves.

Vascular – composed of, or pertaining to, the vessels that convey blood.

Zenith Flex AAA Endovascular Graft – a device placed within an **abdominal aortic aneurysm** to seal off the **aneurysm**. The graft is made of polyester graft material like that used in **open surgical repair**. Standard surgical suture is used to sew the graft material to a frame of stainless steel **stents**. These self-expanding **stents** provide support. The graft has three parts: a “**main body**” and two “legs.” The **main body** is positioned in the **aorta**. The legs are positioned in the **iliac arteries** and connect to the **main body**. The graft thus extends from the **aorta** below the **renal arteries**, leading to the kidneys, into both **iliac arteries**.

Zenith Iliac Branch – a device that is placed within a common **iliac artery** in order to preserve blood flow to the internal **iliac artery**. The graft is made of polyester material like that used in **open surgical repair**. Standard surgical suture is used to sew the graft material to a frame of stainless steel and nitinol **stents**. These self-expanding **stents** provide support. The graft has a “**main body**” component and a unique side branch that connects with an additional stent graft that goes into an internal **iliac artery**.

AI-ESC-IR-OHNS-PI-RH-SUR-A5

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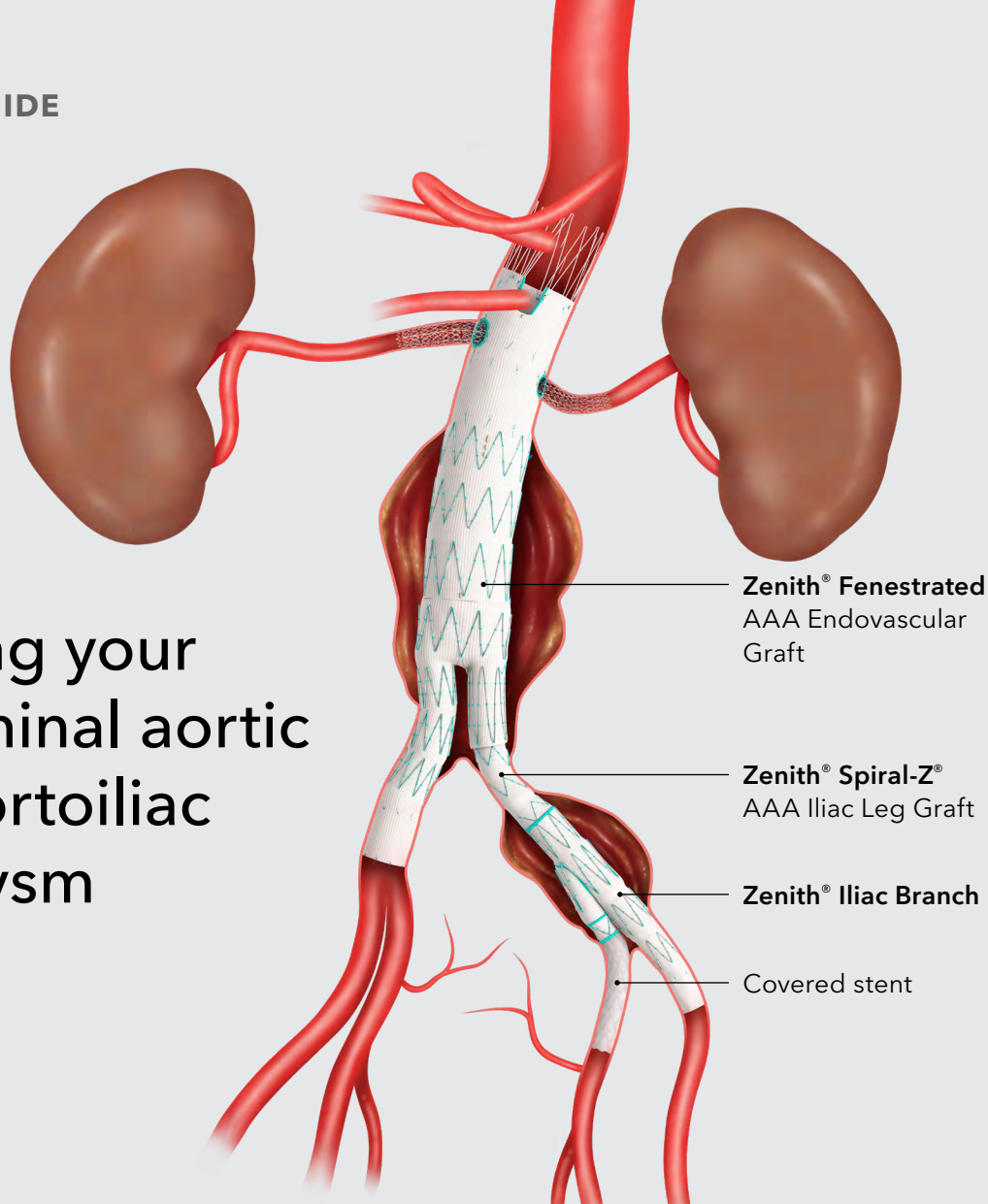
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Treating your abdominal aortic and aortoiliac aneurysm



Zenith®
ENDOVASCULAR GRAFTS

About This Patient Guide

This patient guide has been provided as a courtesy from Cook Medical and is intended to be a resource to learn more about **abdominal aortic aneurysms (AAA)**, **iliac aneurysms**, and potential treatment options. We hope this information will be helpful to you and your family.

For your convenience, a glossary of medical terms is included on pages 22-25. Words in **bold** throughout this text are defined in the glossary.

This patient guide is not intended to diagnose a medical condition. It provides basic information about **abdominal aortic** and **iliac aneurysms** and their treatment with the Cook **Zenith Fenestrated AAA Endovascular Graft**, the **Zenith Iliac Branch** devices, and a covered stent. The treatment of **abdominal aortic aneurysms** may vary according to an individual's unique needs and doctor assessments. As with any surgery or medical procedure, the best source of information and advice is your doctor.

For further information regarding the indications for use and contraindications of these devices, please refer to the appropriate product's Instructions for Use.

US federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

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Introduction

What is an abdominal aortic aneurysm (AAA)?

The **aorta** is the main blood vessel that carries blood from the heart to the rest of the body. It extends from the chest to the abdomen, where it branches into the common **iliac arteries**. The common **iliac arteries** carry blood to lower parts of the body and to the legs. Sometimes, because of aging or other changes, a section of the **aorta** may weaken and begin to bulge.

This bulge can enlarge over time as the walls of the **aorta** become thinner and stretch (like a balloon). This bulge in the **aorta** is called an **aneurysm**.

Sometimes an **aneurysm** occurs in the part of the **aorta** that runs through the abdomen. This is called an **abdominal aortic aneurysm (AAA)**.

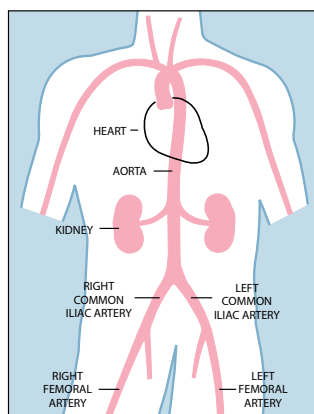
What is an aortoiliac or iliac artery aneurysm?

Sometimes, an **abdominal aortic aneurysm** is not contained only within the **aorta**. The **aneurysm** can extend down into one or both of the common **iliac arteries**. Depending on where in the vessel the **aneurysm** is, the condition is called an **aortoiliac aneurysm** or **iliac artery aneurysm**. Up to 40% of patients with an **AAA** also have an **aortoiliac aneurysm** or **iliac artery aneurysm**.^{1, 2}

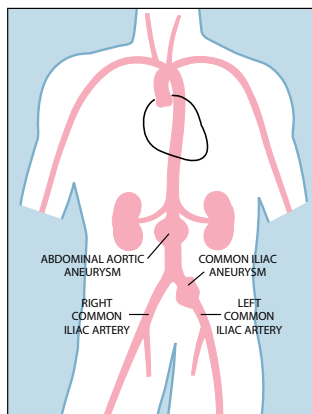
Are these serious conditions?

In its early stages, when an **AAA** or **iliac artery aneurysm** is small, it may not pose an immediate health risk. However, your doctor will want to check the condition of the **aneurysm** regularly through follow-up visits and by taking pictures using special equipment.

In later stages, if the **AAA** or the **iliac artery aneurysm** continues to grow, the walls of the **aorta** or common **iliac arteries** can become thin and lose their ability to stretch. If these walls become too weakened by this, then the **aneurysm** could burst, causing serious internal bleeding.



Aortic anatomy



Aortic anatomy with aneurysm

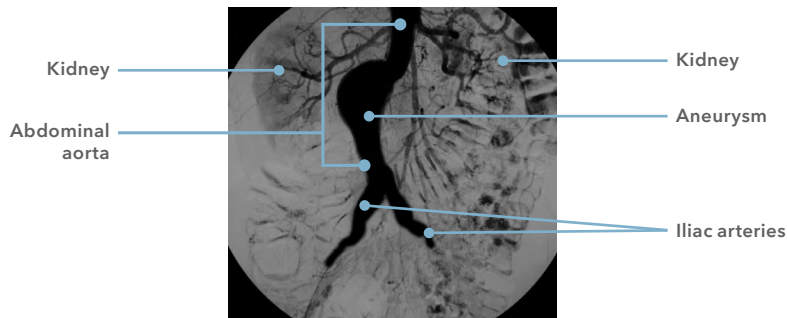
1. Giosdekos A, Antonopoulos CN, Sfyroeras GS, et al. The use of iliac branch devices for preservation of flow in internal iliac artery during endovascular aortic aneurysm repair. *J Vasc Surg.* 2020;71(6):2133-2144.
2. Isselbacher EM, Preventza O, Black JM 3rd, et al.; peer review committee members. 2022 ACC/AHA guideline for the diagnosis and management of aortic disease: a report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;146(24):e334-e482.

What are some of the symptoms of an aneurysm?

In most cases patients have no symptoms of an **aneurysm**. For people who do have symptoms, the most common one is pain. For patients with an **AAA**, the pain can be in the abdomen, back, or chest. It could be anything from a mild pain to a severe pain or tenderness in the mid to upper abdomen or lower back. Some patients feel the **aneurysm** as a pulsating or throbbing mass in their abdomen. Patients with an **iliac artery aneurysm** may experience back pain, lower abdominal pain, or groin pain. Many patients feel none of these symptoms yet may still have an **aneurysm**.

An **aneurysm** is often discovered during an examination being done for other medical reasons. Your doctor may feel a bulge or pulsation (throbbing) in your abdomen or groin. Most often, **aneurysms** are found during a medical test such as a **CT scan** or **ultrasound**.

If you know you have an **aneurysm** and you develop back pain, abdominal pain, or dizziness, call your doctor immediately.



What causes an aneurysm?

Over time, **vascular** disease, injury, or a hereditary defect in the wall of the blood vessel can cause a weakening of the **aorta** or common **iliac arteries**. Blood pressure against the weakened area can cause ballooning (enlarging and thinning) of the vessel.

Risk factors for developing an **aneurysm** include family history of similar issues, smoking, heart disease, and high blood pressure. If you are at risk for developing an **aneurysm**, your doctor may recommend periodic checks. The checks could include a physical exam and possibly a **CT scan** or **ultrasound**.

Treatment of an abdominal aortic aneurysm

How do doctors treat an AAA?

When an **aneurysm** is small, your doctor may recommend periodic checkups to monitor it. If an **aneurysm** is larger, or is rapidly growing, it has a greater risk of bursting. If your doctor thinks there is a risk the **aneurysm** may burst, they may recommend treatment. There are two types of treatment for **AAA**:

- **Open surgical repair**
- **Endovascular repair**

The goal of all **AAA** and **iliac aneurysm** repair is to prevent the **aorta** or **iliac arteries** from bursting.

What is an open surgical repair?

In this treatment, surgery is performed to repair the section of the **aorta** or **iliac arteries** that has an **aneurysm**. To reach the **abdominal aortic aneurysm**, a doctor makes a cut through the abdomen or the side of the patient. The doctor repairs the blood vessel 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. The blood flow through the **aorta** is stopped while the graft is put in place. The surgery takes about two to four hours to complete.

Open surgical repair is a proven medical procedure that works. However, it also has a long recovery period. Patients usually stay overnight or several days in the intensive care unit and stay another 7 to 10 days in the hospital. Many patients are unable to eat normally for five to seven days after the surgery. The overall recovery period can last up to three months. **Open surgical repair** requires follow-up visits with your doctor to monitor the success of the repair.

As with any medical procedure, **open surgical repair** has a risk of complications. Discuss these with your doctor.

Important note: Not every patient is a candidate for **endovascular repair**. **Open surgical repair** and **endovascular repair** both have advantages and disadvantages based upon each patient's condition and needs. Discuss the advantages and disadvantages with your doctor.

What is an endovascular repair?

Endovascular means "inside or within a blood vessel." Instead of making a large incision in the abdomen, the doctor makes small cuts in the groin to get to the **femoral arteries** (blood vessels).

Through these small incisions, an **endovascular graft** is inserted through the **femoral artery** and positioned inside the **aorta** or **iliac arteries**. The **endovascular graft** is deployed and seals off the **aneurysm**. The graft makes a new path through which the blood flows. The graft remains inside the vessel permanently. **Endovascular repair** typically takes one to three hours to complete.

Because the incisions used for **endovascular repair** are much smaller than the cut used for **open surgical repair**, patients may experience less discomfort and faster recovery. Patients may have a hospital stay of only a few days. They can usually return to normal activity within four to six weeks after the procedure.

As with any medical procedure, **endovascular repair** has a risk of complications. These should be discussed with your doctor.

Endovascular repair also requires routine follow-up visits with your doctor. Tests are done to evaluate the procedure and monitor success of the treatment. There is also a possibility that additional treatment or surgery may be required after the **endovascular repair**. Refer to the "What follow-up should I expect?" section for more information.

About Zenith Fenestrated AAA Endovascular Graft and Zenith Iliac Branch

What is the Zenith Fenestrated AAA Endovascular Graft?

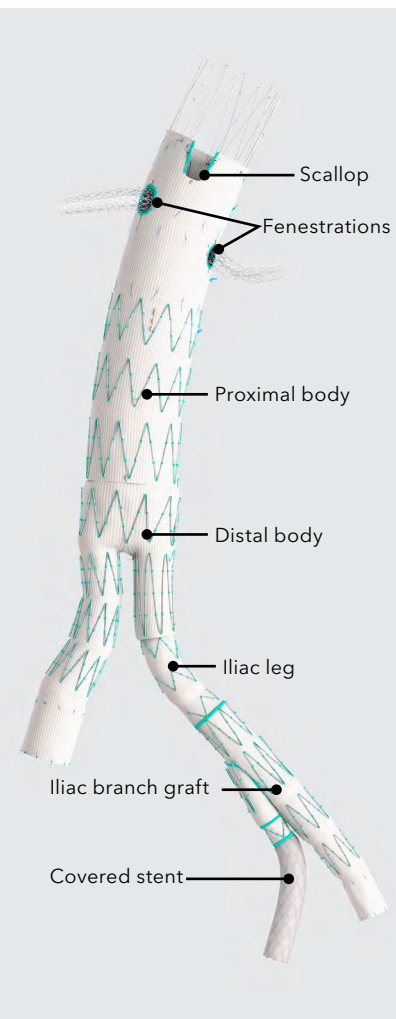
The **Zenith Fenestrated AAA Endovascular Graft** is a unique type of **endovascular graft** that was developed to provide an **endovascular repair** option for patients with a length of **aorta** above the **aneurysm** that is too short to form a seal using a standard (non-fenestrated) **endovascular graft**.

The **Zenith Fenestrated AAA Endovascular Graft** is made up of three parts: a proximal body, a distal body, and an **iliac leg**. The proximal body has carefully positioned **scallops** (u-shaped openings/cut-outs) or **fenestrations** (holes) in the graft material. The **scallops** and **fenestrations** allow the **endovascular graft** to achieve a seal of the **aneurysm** higher in the **aorta** while still permitting blood to continue flowing into the **branch vessels** (**renal arteries** and **superior mesenteric artery**). **Fenestration stents** are placed through the **scallops** or **fenestrations** into the **branch vessels**. These **stents** help to maintain blood flow to the **branch vessels** through the **scallops/fenestrations**. The distal body connects to the proximal body and provides a seal in one of the **iliac arteries**. The **iliac leg** graft connects to the distal body and provides a seal in the other **iliac artery**.

The graft itself is made of a polyester material like that used in **open surgical repair**. Standard surgical sutures are used to sew the graft material to a frame of stainless steel **stents**. These self-expanding **stents** provide support. The **fenestrations** (holes) are also supported by a ring of wire made of another type of metal (nitinol). The graft has several gold markers to help your doctor see the device during placement. All of these materials have a long history of use in medical implants.

What is the Zenith Iliac Branch?

The **Zenith Iliac Branch** is an **endovascular graft** specifically designed to ensure that blood is able to flow to the **internal iliac arteries**. This blood flow to the internal **iliac arteries** is important



because those vessels allow blood flow to be maintained to the pelvic organs and the buttock muscles. The main graft is used with the Zenith Spiral-Z AAA Iliac Leg Graft in the common **iliac artery** and has a unique side branch that keeps blood flowing to the internal **iliac artery**.

Zenith Iliac Branch is made of polyester material, which is attached to a frame of stainless steel and nitinol **stents**. **Zenith Iliac Branch** also has gold markers to help your doctor see it clearly during the procedure.

How are the grafts implanted?

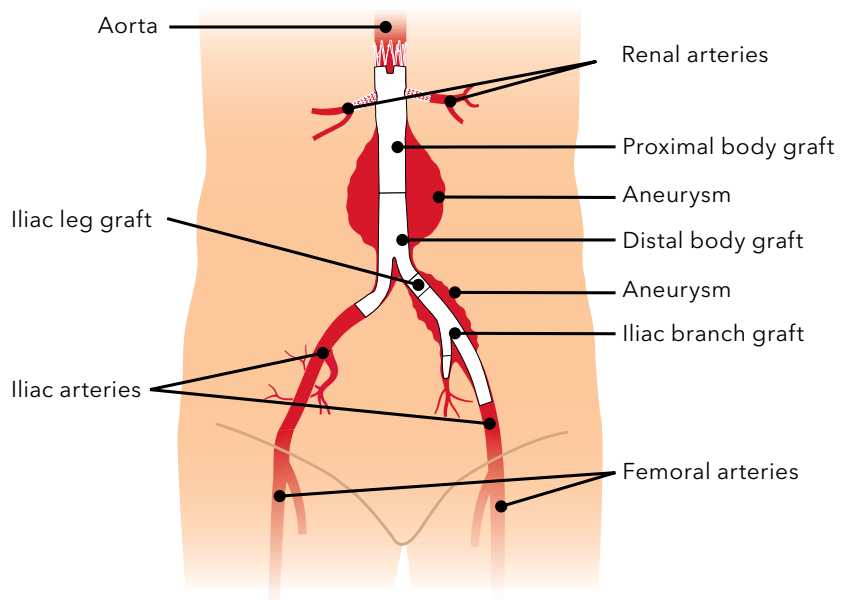
Before the procedure, your doctor looks at pictures of your **aorta** and **iliac arteries** (from a **CT scan** or **angiogram**). From these pictures, the doctor can choose the proper size for each part of the **Zenith Fenestrated AAA Endovascular Graft** so that it will fit in your blood vessels. These pictures are also used to determine the number, size, and location of the **fenestrations** and **scallops** so that the proximal body graft can be individually made to fit your specific anatomy.

The doctor may decide to use a **Zenith Iliac Branch** if the **aneurysm** extends down into one or both of the common **iliac arteries**. This is done to keep blood flowing to the internal **iliac arteries**. During this procedure, the doctor uses x-rays to see the grafts and position them correctly.

Each of the grafts is contained in its own **sheath** (plastic tube). Each **sheath** is removed after the graft is put in place.

To place the graft, your doctor makes small cuts near the groin to get to the **femoral arteries** (blood vessels). Through these small cuts, each part of the graft is inserted separately. The proximal body of the **Zenith Fenestrated AAA Endovascular Graft** is positioned in the **aorta** and contains **scallops** and **fenestrations** to maintain blood flow to **branch vessels**. To help maintain blood flow to **branch vessels**, **fenestration stents** may be placed through the **fenestrations** and **scallops** of the proximal body into the **branch vessels** (such as the **renal** and **superior mesenteric arteries**). The distal body connects the proximal body to one of the **iliac arteries**. The iliac leg connects the distal body to the other iliac artery. When

each part of the graft is released from its **sheath**, it opens up to fill and reinforce the **aorta**. When all pieces are in place, the graft seals off (excludes) the **aneurysm**. If a **Zenith Iliac Branch** is being used as well, it is implanted first, followed by the **Zenith Fenestrated AAA Endovascular Graft**, which is joined to it.



Before the procedure is finished, your doctor uses x-rays to confirm that blood is flowing to the **branch vessels** and **iliac arteries**, and also makes sure that blood is not flowing into the **aneurysm**. Your doctor then closes up the cut in each leg with a few stitches.

Zenith clinical study summary

Zenith Fenestrated AAA Endovascular Graft clinical study summary

The **Zenith Fenestrated AAA Endovascular Graft** (ZFEN) clinical study was a 42-subject study conducted in the United States to evaluate the safety and effectiveness of the ZFEN system.

Subjects enrolled in the study were followed for five years and all study-related activities are complete. The primary safety and effectiveness endpoint was treatment success at 6 months. Of the 40 subjects with adequate data at 6 months, 39 (97.5%) had success on the primary endpoint.

Although the types of risks associated with the **Zenith Fenestrated AAA Endovascular Graft** are similar to other **endovascular** procedures for **aortoiliac** and **iliac aneurysms**, it is important to consult with your doctor to better understand if the **Zenith Fenestrated** is right for you.

One year of subject follow-up resulted in the following:

- No subjects experienced death related to their **aneurysm**.
- No subjects experienced a **rupture** of their **aneurysm**.
- 1 out of 42 subjects (2.4%) experienced an **occlusion** of a **renal artery**.
- No subjects experienced a leakage of blood around the endograft into the **aneurysm** sac that was related to the device.
- 3 out of 42 subjects (7.1%) experienced breakage of the device (2 of a barb, 1 of a **stent**), although no clinical symptoms were experienced by these subjects.
- 6 out of 42 subjects (14.3%) required additional procedures to treat their **aneurysm**.

Longer-term follow-up through five years showed the following:

- 1 out of 42 subjects (2.4%) experienced death related to their **aneurysm**.
- No subjects experienced a **rupture** of their **aneurysm**.
- 2 out of 42 subjects (4.8%) experienced a renal (=kidney) event which required dialysis.
- 1 out of 42 subjects (2.4%) experienced an **occlusion** of a **renal artery**.
- 2 out of 42 subjects (4.8%) experienced a growth (>5 mm) of their **aneurysm**.
- No subjects experienced a leakage of blood around the endograft into the **aneurysm** sac that was related to the device.
- 11 out of 42 subjects (26.2%) required additional procedures to treat their **aneurysm**.

Zenith Iliac Branch clinical study summary

The PRESERVE-**Zenith Iliac Branch** clinical study was a 40-subject study conducted in the United States to evaluate the safety and effectiveness of the Zenith Iliac Branch device.

Subjects enrolled in the study were followed for five years and all study-related activities are complete. The primary study endpoint was 6-month freedom from patency-related intervention of the internal **iliac artery**. Of the 39 subjects with adequate data to evaluate, 39 (100%) had success on the primary outcome. The secondary safety endpoint was freedom from 30-day morbidity. Of the 40 subjects evaluated through 30 days, 34 (85%) had success on the secondary safety endpoint. The secondary effectiveness endpoint was **branch vessel** (i.e., internal **iliac artery**) patency at 6 months. Of the 37 subjects with adequate 6-month imaging, 37 (100%) had success on the secondary effectiveness endpoint.

Although the types of risks associated with the **Zenith Iliac Branch** are similar to other **endovascular** procedures for **aortoiliac** and

iliac aneurysms, it is important to consult with your doctor to better understand if the **Zenith Iliac Branch** is right for you.

One year of subject follow-up resulted in the following:

- No subjects experienced death related to their **aneurysm**.
- No subjects experienced a **rupture** of their **aneurysm**.
- No subjects experienced growth (>5 mm) of their **iliac aneurysm** treated by the **Zenith Iliac Branch**.
- 1 out of 40 subjects (2.5%) experienced a leakage of blood around the devices into the **aneurysm** sac that was related to the device.
- 2 out of 40 subjects (5%) experienced **occlusion** of the external **iliac artery** segment of the **Zenith Iliac Branch** device.
- No subjects experienced breakage or separation of the device components.
- 4 out of 40 subjects (10%) required additional procedures to treat their **aneurysm**.

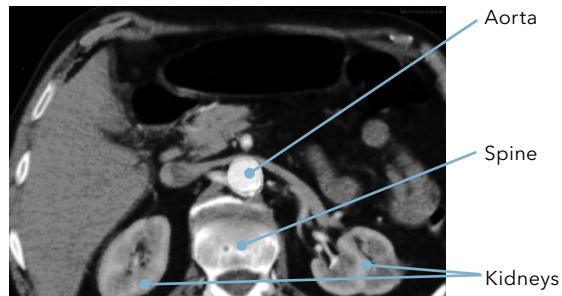
Longer-term follow-up through five years showed the following:

- No subjects experienced death related to their **aneurysm**.
- No subjects experienced a **rupture** of their **aneurysm**.
- 1 out of 40 subjects (2.5%) experienced growth (>5 mm) of their **iliac aneurysm** treated by the **Zenith Iliac Branch**.
- 1 out of 40 subjects (2.5%) experienced a leakage of blood around the endograft into the **aneurysm** sac that was related to the device.
- 2 out of 40 subjects (5%) experienced **occlusion** of the internal **iliac artery** segment of the **Zenith Iliac Branch** device.
- No subjects experienced breakage or separation of the endograft components.
- 9 out of 40 subjects (22.5%) required additional procedures to treat their **aneurysm**.

After the endovascular procedure

Why is follow-up important?

If you receive a **Zenith Fenestrated AAA Endovascular Graft**, with or without a **Zenith Iliac Branch**, it is very important that you have regularly scheduled follow-up appointments with your doctor because less information is known about this **endovascular graft** compared to standard (non-fenestrated) **endovascular grafts**, and the long-term results of this **endovascular graft** have not been confirmed by studies. It is possible for problems to occur that do not cause noticeable symptoms. Therefore, your doctor needs to look at pictures (x-ray, **CT scan**) of your **aneurysm** and graft on a regular basis. If a problem occurs, your doctor may recommend additional procedures.



Some problems that might occur are:

Endoleak

An **endoleak** occurs when blood from the **aorta** or **iliac arteries** continues to leak into the **aneurysm**. Most **endoleaks** do not require treatment. However, a small number do require further treatment.

Graft movement

Because blood vessels can change over time with an **aneurysm**, it is possible for a graft to move over time. Because graft movement cannot be felt, it is important to keep your routine follow-up visits with your doctor. Graft movement, if it occurs, can be seen with a **CT scan**.

What symptoms should prompt you to call your doctor after the procedure?

Symptoms of **aneurysm** growth are not always present. When symptoms of **abdominal aortic aneurysms** are present, the most common are:

- Pain in the legs, back, chest, or abdomen
- Numbness in the legs, back, chest, or abdomen
- Weakness in the legs, back, chest, or abdomen

Symptoms of an **aneurysm rupture** include:

- Pain
- Dizziness
- Fainting
- Rapid heartbeat
- Sudden weakness

Symptoms of limb device **occlusion** include:

- Leg, hip, or buttock pain during walking
- Leg discoloration
- Leg coolness
- Decreased urination

If you experience any of the symptoms listed above, call your doctor immediately.

What follow-up should I expect?

Follow-up exams are important and should be considered a lifelong commitment to your health and well-being.

Recommended follow-up includes checkups at:

- 1 month
- 6 months
- 12 months
- Every year afterward

Follow-up exams usually include routine blood tests, x-rays, a **CT scan**, and a physical exam.

These follow-up exams carry some minimal potential risk. However, the benefits of these tests clearly outweigh any potential risks. There is a rare risk of allergic reaction related to the **contrast dye** used in the **CT scan**. Talk with your doctor if you have any concerns regarding these exams.

Follow-up exams are necessary to evaluate your treatment and any changes over time. Your doctor may request additional evaluations based on findings at the follow-up visits.

Possible risks if left untreated

Leaving an **abdominal aortic aneurysm (AAA)** untreated can result in **rupture**, which is a life-threatening condition. Therefore, the possible benefit of treatment is the prevention of **rupture**. However, as with any medical procedure, there are also risks associated with treating **AAAs**, as discussed in the section above.

What if I need magnetic resonance imaging (MRI)?

If you receive a **Zenith Fenestrated AAA Endovascular Graft**, with or without a **Zenith Iliac Branch**, be sure to tell all of your healthcare providers that you have the graft. Show them your patient ID card(s). The card contains information related to **MRI** procedures for patients with these devices. Discuss the potential risks and benefits of an **MRI** with your healthcare providers if you have any concerns about this diagnostic test.

There may be potential risks (such as movement of the graft or injury to the blood vessel) that could be associated with magnetic forces affecting the metallic components of the **Zenith Fenestrated AAA Endovascular Graft** or **Zenith Iliac Branch**. Therefore, your doctor will carefully assess the potential risks and potential benefits to you before an **MRI**. In addition, the facility for **MRI** should be appropriately selected to allow for healthcare providers to act quickly in the event that there has been a change to the graft that needs immediate attention.

What should I do with my patient ID card(s)?

The card(s) provide valuable information concerning:

Type of device implanted

Date of implant

Your doctors

MRI information

Be sure to tell all of your healthcare providers that you have the graft(s) and show them your patient ID card(s). You should keep your patient ID card(s) available at all times.

Front

Zenith® Iliac Branch
Endovascular Graft

COOK MEDICAL

This patient has received a

Implant date

Patient name

Implanting facility name

Implanting physician

Implanting physician phone number

Follow-up physician

Follow-up physician phone number

Product catalog number ☐ Abdominal

Before MRI, you must show this card to your doctor who should assess potential risks and consider the MRI information in the device labeling on www.cookmedical.com. Because unforeseen variations in patient anatomy or scanners may increase risk, the MRI facility should allow for prompt intervention if necessary.

MRI information on reverse side.

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0009
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Back

It is recommended that patients register the conditions under which the implant can be safely scanned with the Medic Alert Foundation (medicalert.org) or an equivalent organization.

MRI SAFETY INFORMATION

	A patient with the Zenith Iliac Branch (ZBIS) may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
MR Conditional	
Item Name/Identification	Zenith Iliac Branch (ZBIS)
Normal Value(s) of Static Magnetic Field [T]	1.5 T or 3.0 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	7.2 T/m (720 Gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, head RF transmit-receive coil
Operating Mode	Normal Operating Mode
Maximum whole body SAR [W/kg]	2.0 W/kg
Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
Image Artifact	The presence of this implant may produce an image artifact.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

PC-ZBIS-US-Rev001

Where can I find more information?

Aneurysm and procedure information

Society of Vascular Surgery

vascular.org

Vascular.org is an internet-based global resource of information and services for individuals interested in improving **vascular** health worldwide. It is sponsored and owned by the Society of Vascular Surgery (SVS) and is governed by a board of directors and managed by an editorial board.

Society of Interventional Radiology

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.

US National Library of Medicine

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 healthcare, as well as works on biomedical aspects of technology, the humanities, and the physical, life, and social sciences.

Product information

Cook Medical Incorporated

cookmedical.com

With international headquarters in Bloomington, Indiana, Cook is a leading designer, manufacturer, and global distributor of minimally invasive medical device technologies for diagnostic and therapeutic procedures. Since its founding in 1963, Cook has been a privately held company that creates innovative technologies for stents and stent grafts, catheters, wire guides, introducer needles and sheaths, **embolization** coils, medical biomaterials, vena cava filters, implanted cardiac lead extraction equipment, and other minimally invasive medical devices.

US Department of Health and Human Services

Food and Drug Administration

fda.gov

The FDA is a US government agency intended to promote and protect 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.

Notes

If you have any questions about your **abdominal aortic aneurysm** or treatment, we encourage you to talk to your doctor. They should always be your primary source of information. Talk to your doctor about the details of this procedure and its impact on your health.

- What is the best treatment option for my **aneurysm**?
- What are all of the potential risks and complications of an **open surgical repair** or an **endovascular repair**?
- When can I resume normal activity after my procedure?
- After my procedure, what will my follow-up include?
- How long will my medical treatment continue after my procedure?
- Are there any risks if I miss a follow-up?
- Will I need to consider any precautions in my daily life after my procedure (such as going through an airport security scanner)?
- What symptoms should prompt me to seek immediate medical attention after my procedure?

Use the space below to record your doctor’s name and phone number. You may also want to write down your questions, take notes, or keep a record of your discussions with your doctor.

Patient Name	
Implantation Date	
Device Implanted	☐ Zenith Fenestrated AAA Endovascular Graft ☐ Zenith Fenestrated AAA Endovascular Graft and Zenith Iliac Branch ☐ Other—Please specify:
Implanting Facility's Name (Hospital)	
Implanting Physician	
Implanting Physician Phone #	

Glossary

Abdominal Aortic Aneurysm (AAA) - a bulge that occurs in the part of the **aorta** that passes through the abdomen (stomach area). The bulge (enlarging and thinning) of the **aorta** is due to a weakening in the arterial wall.

Aneurysm - a bulging or ballooning (enlarging and thinning) of a weakened area of a blood vessel.

Angiogram - the image taken during an angiography.

Angiography - an x-ray method that uses **contrast (dye)** injected into the bloodstream to see blood flow through blood vessels.

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

Aortoiliac Aneurysm - an enlarging and thinning of a weakened area of the abdominal **aorta** that also extends down into the common **iliac artery**.

Branch Vessels - blood vessels that come off the **aorta**, such as the **renal** and **superior mesenteric arteries**.

Contrast (dye) - a liquid dye injected into the bloodstream to show blood vessels under x-ray or **CT scan**.

CT Scan - a series of computerized x-rays that form a picture of your **aneurysm**. Formerly known as a CAT scan.

Embolization - the process of purposefully obstructing a blood vessel or organ with a material mass.

Endoleak - blood flow into the **abdominal aortic aneurysm** after placement of an **endovascular graft**.

Endovascular - inside or within a blood vessel.

Endovascular Graft - a graft placed inside a diseased vessel without the use of open surgical techniques. The graft makes a new path through which the blood flows.

Endovascular Repair – placement of an **endovascular graft** to seal off (exclude) an **aneurysm**. Instead of making a large incision in the abdomen, the doctor makes a small cut near each hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels). Through these small cuts, a graft (fabric tube) is inserted through the **femoral arteries**. The graft makes a new path through which the blood flows.

Femoral Arteries – two blood vessels (one in each leg) that carry blood to the thigh region of each leg. Doctors can use the femoral arteries as a path to reach arteries within the chest and abdomen.

Fenestration – a precisely placed hole (large or small) in the graft material to permit blood flow to a **branch vessel**.

Fenestration Stents – surgical steel mesh tubes that are deployed through the **scallops** or **fenestrations** to help maintain blood flow into the **branch vessels**.

Iliac Aneurysm – an enlarging and thinning of a weakened area of the common **iliac artery**.

Iliac Arteries (Common) – the two large blood vessels that extend from the lower end of the **aorta** to the internal **iliac**, external **iliac**, and **femoral arteries** in each leg.

Iliac Arteries (Internal) – two blood vessels that come off the common **iliac arteries** and supply blood to the pelvis and pelvic organs. If they are blocked off, complications can occur.

Iliac Leg(s) – the parts of the **Zenith Fenestrated AAA**

Endovascular Graft that extend from the main body (in the aorta) to the **iliac arteries**.

MRI (Magnetic Resonance Imaging) – a way of creating detailed pictures of the body. The MRI scanner uses magnetic fields and radio waves to create the pictures.

Occlusion – blockage of a blood vessel.

Open Surgical Repair – a type of surgery performed to repair an **aneurysm**. To reach the **aneurysm**, a doctor makes a cut through the abdomen or the side 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.

Renal Arteries – two blood vessels that come off the **aorta** and carry blood to the kidneys.

Renal Infarct – loss of blood flow to a portion of the kidney.

Rupture – a tear in the blood vessel wall that causes serious internal bleeding.

Scallop – a u-shaped opening or cutout from the proximal edge of the graft to permit blood flow to a **branch vessel**.

Sheath – a long plastic tube that contains the **endovascular graft**. The sheath is advanced inside the blood vessel to the **aneurysm** site, and the graft is put in place.

Stents – surgical steel parts of the **endovascular graft** that provide support and hold it in place.

Superior Mesenteric Artery – a blood vessel that comes off the **aorta** and carries blood to the intestine.

Ultrasound – a way to create pictures of parts of the body using high-frequency sound waves.

Vascular – composed of, or pertaining to, the vessels that convey blood.

Zenith Fenestrated AAA Endovascular Graft with the H&L-B One-Shot Introduction System – a device placed within an **abdominal aortic aneurysm** to seal off the **aneurysm**. The graft is a tube made of polyester graft material (fabric) like that used in **open surgical repair**. Standard surgical suture is used to sew the graft material to a frame of stainless steel **stents**. These self-expanding **stents** provide support. The Zenith Fenestrated AAA Endovascular Graft is made up of three parts: a proximal body, a distal body, and a leg. The proximal body is positioned in the **aorta** and has carefully positioned **scallops** (u-shaped openings/cut-outs) or **fenestrations**

(holes), so blood can continue to flow to the body's organs. The graft extends from the **aorta** around the **renal arteries**, which lead to the kidneys, into both **iliac arteries**. The Zenith Fenestrated AAA Endovascular Graft is placed within the **aneurysm** using the H&L-B One-Shot Introduction System.

Zenith Iliac Branch – a device that is placed within a common **iliac artery** in order to preserve blood flow to the internal **iliac artery**. The graft is made of polyester material like that used in **open surgical repair**. Standard surgical suture is used to sew the graft material to a frame of stainless steel and nitinol **stents**. These self-expanding **stents** provide support. The graft has a "main body" component and a unique side branch that connects with an additional stent graft that goes into an internal **iliac artery**.

AI-ESC-IR-OHNS-PI-RH-SUR-A5

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