YOUR GUIDE TO

Understanding Abdominal Aortic Aneurysms

Patient Information Guide

TERUMO

Table of Contents

Helpful hints

To help you learn more about your Abdominal Aortic Aneurysm, you'll notice some words and terms highlighted with a dotted underline, so you'll know you can find their meanings in the Glossary section near the back of this guide.

Introduction

This educational information is provided by Terumo Aortic to help you make an informed decision about the TREO® Abdominal Aortic Stent-Graft System to treat your Abdominal Aortic Aneurysm (AAA).

Since gaining initial European approval in 2015, the TREO® Abdominal Stent-Graft System has been implanted in about **5,700 patients**, in over **38 countries**.

The TREO® Abdominal Stent-Graft System is manufactured by Terumo Aortic, a global medical device company focused on addressing every patient's aortic needs. Our goal is to work together with your doctor to find solutions that best fit your anatomy.

While you are reading this information, it may be helpful to write down any questions you may have so you can discuss them with your doctor and healthcare team. Only your doctor can decide if you are a good candidate for an abdominal aortic stent-graft procedure.

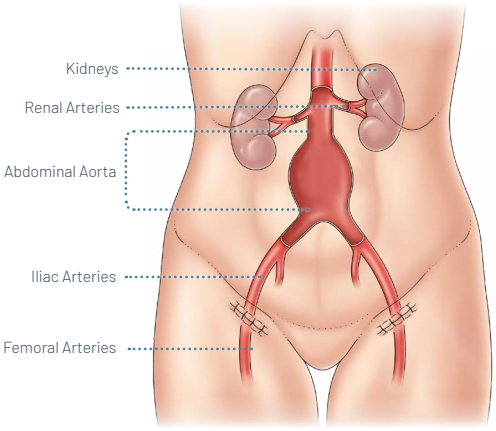
Abdominal Aortic Aneurysm

What is an Abdominal Aortic Aneurysm or AAA?

The aorta is your body's largest artery and carries oxygen-filled blood from your heart to all parts of your body. In your abdomen, the aorta splits into the iliac arteries, which carry blood to your legs and lower areas of your body and normally ranges in diameter from 3/4" to 1" (2–2.5 cm).

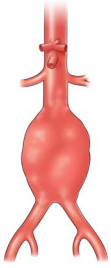
When an abnormal bulge or swelling occurs in your abdominal aorta, it is called an Abdominal Aortic Aneurysm or AAA. An aneursym can increase in size. The larger the size of an aneursym, the greater risk it could burst or rupture.

A rupture can lead to severe internal bleeding and possibly death.



Abdominal Aortic Aneurysm


Normal Aorta


Aorta with Aneurysm

Prevalence and Causes

What causes an Abdominal Aortic Aneurysm?

Each year approximately 15,000 people in the United States die of a ruptured aneurysm, making it a leading cause of death.* Fortunately, abdominal aneurysms generally grow slowly and can be electively repaired with an operation so they do not rupture.

Abdominal Aortic Aneurysms are most often caused by a weakening in the aorta, often resulting from vascular disease, traumatic injury, or a genetic defect. In addition, as you age, continuous high blood pressure can cause the aorta to bulge out, thin and/or weaken, thus resulting in an aneurysm.

Your risk for an Abdominal Aortic Aneurysm increases if you:

- Are male over the age of 60
- Have high cholesterol
- Are overweight
- Have high blood pressure
- Smoke
- Have a family history of aneurysms, cardiovascular or peripheral vascular disease (a narrowing of the blood vessels)

Symptoms

What are the symptoms of an Abdominal Aortic Aneurysm?

Abdominal Aortic Aneurysms may go unnoticed initially because patients may not feel any symptoms, AAA are usually detected when doctors are ordering tests for other reasons. When symptoms are experienced, the most common are:

- Pain in the chest, abdomen, flank or lower back, possibly spreading to the groin, buttocks, or legs. The pain may be deep, aching, gnawing and/or throbbing and may last for hours or days. It is generally not affected by movement, although certain positions may be more comfortable than others.
- A pulsating sensation in the abdomen
- Coldness, bruising or pain in your lower leg or foot can occur if the AAA produces a blood clot that breaks off and blocks blood flow
- Fever or weight loss, if it is an inflamed/infected Abdominal Aortic Aneurysm

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

* EMedicineHealth Online 2011.

Treatment

How is an Abdominal Aortic Aneurysm treated?

Treatment for an Abdominal Aortic Aneurysm depends on its size, location and your overall health. Together with your doctor, you will decide on the best option for treating your abdominal aneurysm.

If your doctor feels the aneurysm is at risk to burst or rupture, the treatment is generally either open surgery or Endovascular Aneursym Repair (EVAR), which is a less invasive treatment.

Conventional/Open Surgery

In conventional or open surgery, the surgeon reaches the aneurysm through a large incision in the abdomen. The weakened section of the vessel, where the aneurysm has formed, is usually surgically replaced with a synthetic material.

Open surgery is usually performed under general anesthesia and takes about several hours to complete. Repairing the aneurysm surgically requires an experienced vascular surgical team.

After your surgery, you normally stay in the Intensive Care Unit (ICU) a day or two and then another five to seven days in the hospital, depending on how your body heals. Your recovery time may be about three to six months before you feel able to resume your normal activities.

Benefits of Open Surgical Repair

- Well-proven surgical procedure seen as a standard method of treatment
- With lasting results, the likelihood of having additional interventions decreases over time
- While long term follow-up with your surgeon is recommended, the imaging needed is not as frequent as required after EVAR
- There is less radiation and contrast dye exposure thus decreasing the risk from imaging requirements

Risks of Open Surgical Repair

As with any major operation there are potential risks of medical complications. Your surgeon will only recommend treatment for your aneurysm if he/she believes the risk of the aneurysm bursting is higher than the potential risk of an operation. Discuss with your surgeon the risk of:

- Heart attack
- Stroke
- Kidney failure
- Incision related complications
- Loss of circulation in the legs or bowel
- Infection in the graft used to replace your aorta
- general anesthesia
- Major abdominal surgery/long abdominal cut
- the surgical complication rate being higher than minimally invasive EVAR
- a longer hospital stay and recovery time than EVAR
- Blood loss during the procedure
- Deep vein thrombosis (DVT)
- Death

Endovascular Aneursym Repair (EVAR)

An alternate treatment known as Endovascular Aneurysm Repair (EVAR) or Stent-Grafting has been developed. It involves two small incisions in the groin area, where stent-grafts are inserted into the femoral artery via a catheter to reline the abdominal aorta.

By avoiding major surgery, this less invasive procedure may result in less blood loss, less trauma, fewer days of hospitalization and potentially a faster recovery time. Your recovery time may be about two to six weeks before you feel able to resume your normal activities.

Benefits of EVAR

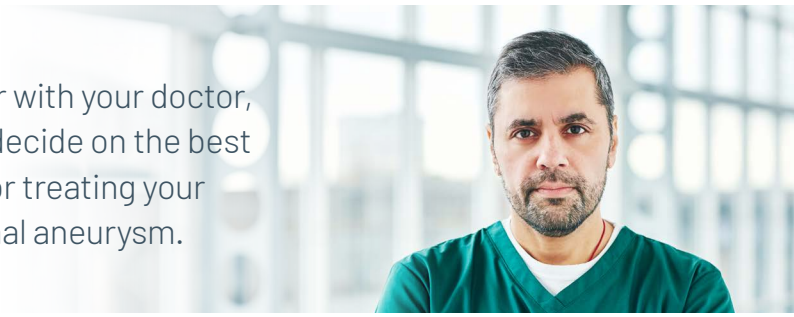
There are a number of potential benefits to having an abdominal stent-graft procedure. Some of these are listed below:

- Minimally invasive procedure
- May be performed under local anesthesia
- Lower procedural complication rate as compared to open surgery
- May reduce the risk of a blood transfusion being required
- Less time may be spent in the intensive care unit after surgery
- Shorter average hospital stay
- Quicker recovery time than open surgical repair

Risks of EVAR

As with any endovascular stent-graft, the abdominal stent-graft comes with potential risks. Please discuss all risks with your doctor. Major risks associated with abdominal endovascular stent-grafts include, but are not limited to:

- Endoleak – when blood continues to flow into the aneurysm
- Migration – Movement of the stent-graft from its original position
- Device-related issues such as breaking of the sutures or metal portion of the stent-graft, fabric defects/tears or component separation
- Continued growth of the aneurysm
- Aneurysm rupture
- Additional endovascular or surgical procedures
- Heart attack
- Stroke
- Kidney failure
- Access site incision complications
- Conversion to open surgical repair
- Death



The Terumo Aortic difference

Abdominal Stent-Grafting with the TREO® Abdominal Stent-Graft System

The TREO® Abdominal Stent-Graft is a woven polyester graft (fabric tube), supported by a series of stents made from a strong, thin metal called Nitinol. The TREO® Abdominal Stent-Graft is placed inside the abdominal aortic aneurysm, using a delivery system (thin tubes that contain and deliver collapsed stent-grafts), thus preventing the need for a major surgical incision.

The TREO® Abdominal Stent-Graft consists of two main components: a main bifurcated stent-graft and a leg extension stent-graft. The struts and barbs at the top of the stent-graft enable the device to stay in-place within the anatomy.

TREO® Abdominal Stent-Graft System

Each patient receives at least three stent-grafts by design (one main Bifurcated Stent-Graft and two Leg Extension Stent-Grafts). The TREO® Abdominal Stent-Graft is intended to seal off the aneurysm by allowing blood to flow through the graft, away from the diseased aorta.

Prior to the procedure, your doctor will require you to undergo an imaging procedure called "Computed Tomography", commonly referred to as a "CT" or "CAT" Scan. It is important to understand that there is a small amount of radiation and contrast dye associated with CT imaging. You should discuss the potential risks associated with radiation and contrast dye with your doctor.

Once you and your doctor agree to proceed, the doctor will determine the exact size of the device to implant. The delivery of the TREO® Abdominal Stent-Graft to the location of the aneurysm occurs in three stages.

The procedure begins with the delivery system containing the compressed Main Bifurcated Stent-Graft being inserted in the aorta through a small incision made in the groin. The main Bifurcated Stent-Graft is positioned and expanded in the aorta with the top edge of the fabric just below the renal arteries.

Secondly, the doctor will then use two separate delivery systems to individually attach the two Leg Extension Stent-Grafts to the main Bifurcated Stent-Graft. The Leg Extension Stent-Grafts connect the main Bifurcated Stent-Graft to your iliac arteries. Unlike other abdominal stent-grafts, the TREO® Abdominal Stent-Graft has a proprietary feature called Lock Stent that is designed to minimize the possibility of the Leg Extension Stent-Graft separating from the main Bifurcated Stent-Graft.

TREO® Abdominal
Stent-Graft delivery system

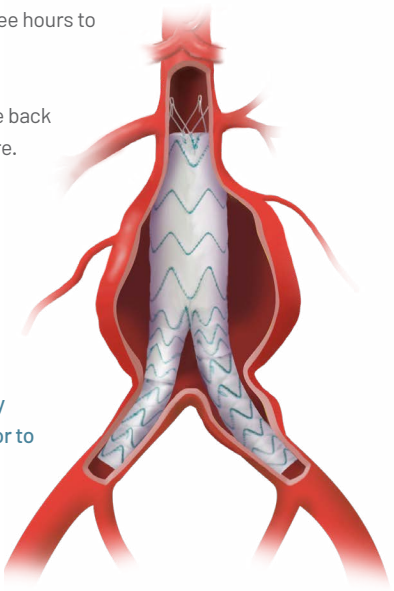
Finally, once the TREO® Abdominal Stent-Graft is implanted, your doctor will verify that your device is positioned and working properly. All delivery systems are then removed completely, leaving only the stent-grafts in place.

The TREO® Abdominal Stent-Graft procedure can be done under local, regional or general anesthesia and typically takes one to three hours to complete.

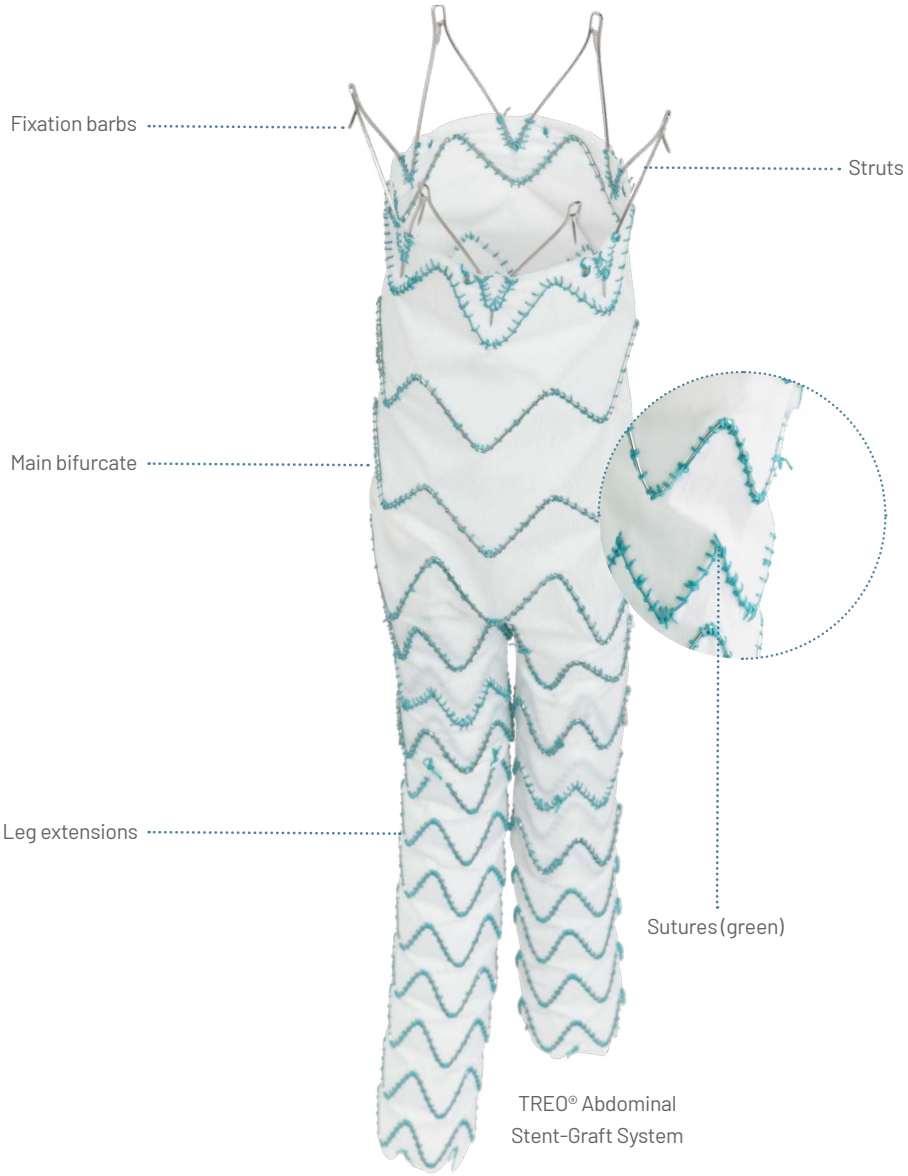
Your hospital stay may only last a few days and you should be back to your normal activities two to six weeks after the procedure. You will need to follow up regularly with your doctor, so they may determine if your device is working properly over time.

The TREO® Stent-Graft System is manufactured by Terumo Aortic, a global established medical device manufacturer with U.S. operations based in Sunrise, Florida.

At Terumo Aortic, we are 100% focused on addressing every patient's aortic needs and working together with your doctor to find solutions that best fit your anatomy.



Final implanted TREO® Abdominal
Stent-Graft system



TREO® Abdominal
Stent-Graft System

TREO® Clinical Study Summary

The TREO® Study was a 150-Subject study conducted in the United States to assess the safety and effectiveness of the TREO® Abdominal Stent Graft System.

Patients enrolled in this study will be followed for five years, some will continue to be followed for 10 years. Currently three-year data is available on 98 subjects. Safety success was defined as absence of Major Adverse Events through 30 days. Of the 150 Subjects evaluated at 30 days, 149 (99.3%) had a successful safety outcome. Effectiveness success was defined as successful aneurysm treatment through 1 year. Of the 131 Subjects evaluated at 1 year, 122 (93.1%) had the device successfully placed and did not experience device-related events. The remaining 19 Subjects lacked adequate information to evaluate the effectiveness endpoint.

Although the types of risks are similar to other EVAR procedures and AAA stent grafts, please talk to your doctor to better understand how the TREO® Abdominal Stent Graft System compares to the other EVAR devices.

One year of Subject follow-up has detected the following:

- 3 out of 137 Subjects (2.2%) experienced leakage of blood around the stent graft into the aneurysm that was related to the device
- 4 out of 135 Subjects (3.0%) had breaks (2 with struts and 2 with barbs) in their device
- 11 out of 144 Subjects (7.6%) had additional procedures to treat the aneurysm or related to the stent graft
- 9 out of 137 Subjects (6.6%) experienced device effectiveness failures.
- No Subjects in the study have had a rupture/burst of the aneurysm or aneurysm-related death.
- No Subjects in the study experienced unintended device movement or need to replace the device.

Longer term data through three years showed the following:

- 16.2% of Subjects experienced at least one Major Adverse Event (i.e. Death, Stroke, Heart Attack) but most were not related to the device.
- 9 Subjects had breaks in their device but no adverse events related to breaks or need for secondary surgery.
- 16 Subjects had additional procedures to treat the aneurysm or related to the stent graft.

Your risk of having these events may be higher or lower.

You should discuss the likely risk of these events throughout your life with your doctor and discuss how the risks and benefits of the TREO® Abdominal Stent Graft System may apply to you.

Your recovery

What should I expect after the procedure?

Immediately after treatment

Immediately after recovery from the stent-graft procedure you may be required to lie flat for 4 to 6 hours. This allows for the healing to begin in your groin. Some patients experience mild discomfort such as swelling of the groin area or fever, but this usually resolves in a few days.

Other side effects may include:

- Numbness of the legs
- Nausea
- Vomiting
- Leg pain or throbbing
- Lack of appetite
- Endoleak (blood flow into the abdominal aortic aneurysm after placement of a stent-graft)
- Absence of bowel movement for 1 to 3 days

When to Call Your Doctor

Call your doctor immediately or visit the nearest emergency room if you experience any of the following symptoms:

- Pain, numbness, or weakness in the legs, back, chest, or abdomen
- Discoloration or coldness in the leg
- Dizziness
- Fainting
- Rapid heartbeat
- Pain or swelling at the access site incision

If you do not seek medical attention for these symptoms, they could seriously harm you or cause your death.

Follow up

Your doctor will discuss your follow-up plan, which will include check-ups at one month, six months, twelve months and annually thereafter. Endovascular repair requires that you maintain regular lifelong follow-up with your doctor to ensure that the device is working properly. Some problems do not show symptoms and are not felt by the patient.

During your follow-up examinations, you may routinely receive:

- X-rays
- CT Scans
- Physical examinations
- Blood tests
- Ultrasound or MRI scans

Maintaining regularly scheduled follow-up examinations is necessary for your doctor to find out if your stent-graft is working properly and to monitor any changes in your condition over time.

If you do not go, your doctor will not know if:

- blood is leaking into your aneurysm (endoleak)
- the stent-graft has moved (migrated)
- the stent-graft has other issues

During examination, if the size of the aneurysm shows an increase and/or it is identified that blood flow has returned to the aneurysm, your doctor may also request evaluations to see if additional treatment may be required.

Implant Card

Before leaving the hospital, you will be given a patient implant card. Along with your personal information, the following is included:

- Your implant(s) model and ID number
- Hospital name
- Doctor's name
- Nurse's name
- Date of implant
- Manufacturers name and contact information
- MRI safety conditions

Keep this card with you at all times. Please share this information with your health care providers and make them aware you have been treated with a TREO® Abdominal Stent-Graft.

Questions to ask your doctor

- Are you familiar and comfortable performing an Endovascular Aortic Repair (EVAR) procedure and how many EVAR procedures have you conducted?
- What are my best treatment options for addressing my aneurysm?
- Am I a candidate for open surgery or an EVAR procedure?
- What are the benefits and risks of performing an open repair procedure?
- Could an endovascular approach be an alternative option for me?
- Am I a candidate to use the TREO® Abdominal Stent-Graft System to treat my aneurysm? If so, what are the benefits and risks? How do they compare to other products on the market?
- What should I expect after my procedure and how often do I need to follow up with you?
- How critical is it for me to continue the prescribed treatment plan?
- How long will the stent-graft be implanted in my body?
- What should I expect if my aneurysm continues to grow?
- How much of the cost of my procedure will be covered by my health insurance?
- Will I have to change my lifestyle activities after the procedure? If so, for how long?

Your questions

Where can I get more information?

Aneurysms

American Heart Association

www.americanheart.org

Founded in 1924, today the American Heart Association is the largest voluntary health organization fighting cardiovascular diseases and stroke.

Mayo Clinic

www.mayoclinic.com

MayoClinic.com is the latest chapter in a long and successful consumer health publishing history of the Mayo Clinic. This presence on the Web is a natural extension of Mayo's long-standing commitment to provide health education to patients and the general public.

Interventional Therapy

Society of Interventional Radiology

www.sirweb.org

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

Society for Vascular Surgery

www.vascular.org/patients

The Society for Vascular Surgery® (SVS) is a not-for-profit professional medical society, seeking to advance excellence and innovation in vascular health through education, advocacy, research and public awareness. SVS is the national advocate for more than 5,800 specialty-trained vascular surgeons and other professionals dedicated to the prevention and cure of vascular disease.

US National Library of Medicine

www.medlineplus.gov

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

Product Information

Terumo Aortic

www.terumoaortic.com

Terumo Aortic is a global medical device company dedicated to developing solutions for aortic and peripheral vascular disease.

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.

US Department of Health and Human Services

www.hhs.gov

HHS helps families and individuals stay safe and informed about food, drugs, medical devices, and more. Information is available about medical device safety for consumers, healthcare providers and regulated industry, including device recalls.

Glossary

Aorta
The main artery that carries blood away from the heart distributing it to the rest of the body.

Abdominal Aortic Aneurysm (AAA)
Enlargement and thinning of the abdominal region of the aorta due to a weakening in the arterial wall. This term is often abbreviated as "AAA" and referred to as "triple A."

Aneurysm
Occurs when part of an artery wall weakens, allowing it to balloon out or widen abnormally - resulting in the weakening of the vessel wall. Aneurysms can occur anywhere. An Aortic Aneurysm occurs in the major artery from the heart.

Angiography/Angiogram
Angiography is a method whereby dye is injected into the bloodstream to view blood flow through the blood vessels under X-ray. Angiography utilizes contrast (dye) and small doses of radiation. The resulting images are angiograms.

Contrast (dye)
A liquid injected into the vascular system that allows a doctor to see a patient's blood flow when the patient is exposed to X-ray.

Computed Tomography Scan (CT/CAT Scan)
An imaging technique that creates very precise, thin, cross-sectional views of the human body. For patients under consideration for AAA treatment, this scan will focus on the abdomen and aorta. This technique often utilises contrast (dye) and always requires limited radiation exposure.

Delivery Catheter
A medical tool that resembles a long thin tube used by a doctor to enter the body through the vascular system and enables placement and positioning of an endovascular device.

Endoleak
Unintended blood flow into the Abdominal Aortic Aneurysm after placement of an endovascular graft.

Endovascular Graft
A synthetic graft implanted within a diseased vessel intended to relieve blood pressure on the weakened vessel walls. Endovascular grafts are placed into the blood vessel using a delivery catheter, which enables the doctor to avoid needing to make a large incision on the patient.

Endovascular grafts are compacted within the delivery system. While still small-in-size, they are able to enter the body through the vascular system. Once in proper position, they are then deployed or expanded to the required size based on the blood vessel being treated.

Endovascular Repair
A less invasive option for the repair of an Abdominal Aortic Aneurysm as compared to open surgery. It involves the use of an endovascular graft that excludes (seals off) an aneurysm of a diseased aorta, thereby creating a new path for blood to flow.

The technique uses real time X-rays allowing the doctor to visualise the location of the device and disease to ensure proper device placement. The doctor will also use a variety of other temporarily placed devices (such as guidewires) to perform the treatment.

Femoral Artery
The main artery within each leg between the area of the hip and knee that brings blood to the lower extremities. Doctors perform many endovascular procedures, including treatment of Abdominal Aortic Aneurysms, using the femoral artery as the primary access site.

Fluoroscopy
A live X-ray image viewed on a monitor by the doctor which is used to view both the patient's blood vessels and the endovascular graft.

Guidewire
A long flexible wire used by the doctor to provide a path for the delivery system to move through the patient's vasculature.

Iliac Artery
The main artery on each side of the body that takes blood from the Abdominal Aorta to the femoral artery. In addition to bringing blood to the lower extremities, the iliac artery also provides blood to the pelvic regions of the body.

Iliac arteries are often included in the treatment of Abdominal Aortic Aneurysms.

Intravascular Ultrasound (IVUS)
An ultrasound probe on a device temporarily placed inside arteries to determine diameters and lengths of arteries.

Magnetic Resonance Imaging (MRI)
A diagnostic technique that uses magnetic fields and radio waves to visualize structures inside the body.

Occlusion
The blocking of a vessel that causes blood flow to be reduced or stop completely.

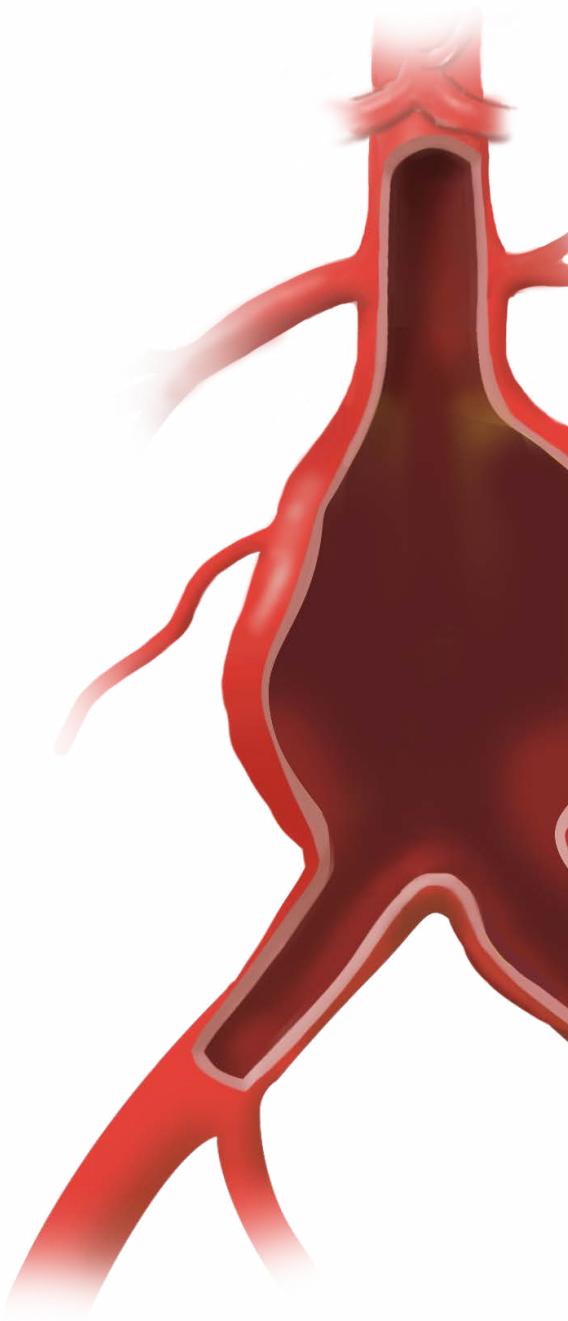
Renal Artery
The main artery on each side of the body that brings blood to the kidneys.

Rupture
A tear in the wall of an artery that allows blood to exit the blood vessel and could be a potential life-threatening event. The common term for this is hemorrhage.

Synthetic Graft
A graft manufactured to replace the vessel. They are created by using man-made materials such as polyester.

Ultrasound
Imagery of the anatomy created using high-frequency sound waves.

X-Ray
A form of energy allowing medical providers to see anatomical structures in the body, as well as the stent-graft components in your body.



Your notes

Indications For Use

The TREO® Abdominal Stent-Graft System is indicated for use in the endovascular treatment of patients with infrarenal abdominal aortic and aorto-iliac aneurysms with the following characteristics:

- Adequate iliac or femoral access compatible with the required delivery systems and accessories
- Proximal aortic landing zone with:
  - Infrarenal landing neck length of ≥ 15mm
  - Aortic neck diameters ≥ 17 mm and ≤ 32 mm
  - Suprarenal neck angle of ≤ 45 degrees
  - Infrarenal neck angle of ≤ 60 degrees
- Distal iliac landing zone with:
  - an inside diameter of 8 mm – 13 mm and a length of ≥ 10 mm or
  - an inside diameter of > 13 mm – 20 mm and a length of ≥ 15 mm
- Minimum overall AAA treatment length (proximal landing location to distal landing location) of 13 cm
- Minimum overall length from the lowest renal artery to the aortic bifurcation of 9 cm

Contraindications of Use for the TREO® System

The TREO® Abdominal Stent-Graft System is contraindicated for the following:

- Patients with a known allergy or intolerance to device materials listed

Implant Component	Material
Stent	Nitinol (including Nickel)
Graft	Woven Polyester
Sutures	Braided Polyester
Radiopaque Markers	Platinum (90%) – Iridium (10%)

- Patients with a condition that threatens to infect the graft

MRI Safety Information

Non-clinical testing demonstrated that the TREO® Abdominal Stent-Graft is MR Conditional. A person with this device can be safely scanned in an MR system meeting the following conditions:

MR Conditional

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient magnetic field of 4,000 gauss/cm (40 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

Under the scan conditions defined above, the TREO® Abdominal Stent-Graft is expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 5 mm from the TREO® Abdominal Stent-Graft when imaged with a gradient echo pulse sequence and a 3 T MRI system. This artifact does not obscure the device lumen.

Our goal is to work together with your doctor to find solutions that best fit your anatomy.

This leaflet gives only general information for patients.
Your medical practitioner will be able to answer any specific questions you may have on your condition.
This information was produced as a service to medicine by Terumo Aortic.

terumoaortic.com

Discover solutions for every segment of the aorta

Refer to Instructions for Use for more information concerning indications, contraindications, warnings, precautions and adverse events.

Rx Only. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured by: Bolton Medical Inc, 799 International Parkway, Sunrise, Florida 33325, USA

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