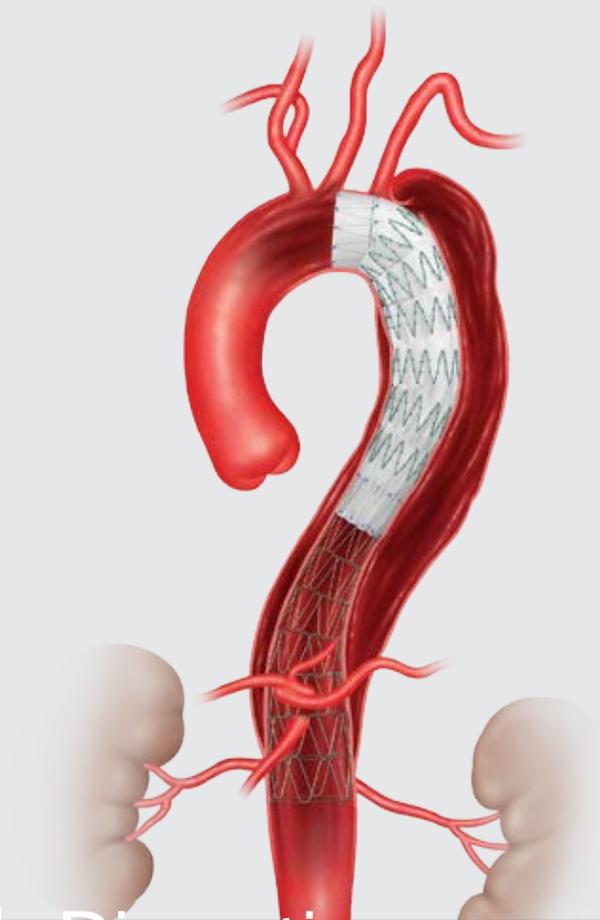


PATIENT GUIDE

# Treating Your Thoracic Aortic Dissection



## Zenith® Dissection

ENDOVASCULAR SYSTEM



## About this Patient Guide

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This patient guide has been provided as a courtesy from Cook Medical. It will help you learn more about **thoracic aortic dissections**. We hope this information will be helpful to you and your family.

For your convenience, a glossary of medical terms is included on pages 15-17. Words that are in **bold** throughout the text are defined in the glossary.

This patient guide is only a guideline. It provides basic information about **thoracic aortic dissections** and their treatment with the **Zenith®TX2® Dissection Endovascular Graft with Pro-Form® and the Z-Trak® Plus Introduction System combined with the Zenith® Dissection Endovascular Stent with the Z-Trak® Plus Introduction System**. It is not intended to diagnose a medical condition. The treatment of **thoracic aortic dissections** may vary according to an individual's unique needs and doctor assessments. As with any surgery or medical procedure, the best source for information and advice is your doctor.

# CONTENTS

## **4-5 INTRODUCTION**

What is aortic dissection?

Is this a serious condition?

What are some of the symptoms of a thoracic aortic dissection?

What causes a thoracic aortic dissection?

## **6-7 TREATMENT OF AORTIC DISSECTION**

How do doctors treat a thoracic aortic dissection?

What is an open surgical repair?

What is an endovascular repair?

## **8-9 ABOUT THE ZENITH TX2 DISSECTION ENDOVASCULAR GRAFT WITH PRO-FORM PROXIMAL COMPONENT AND THE ZENITH DISSECTION ENDOVASCULAR STENT**

What are the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent?

How are the graft and stent implanted?

## **10-14 AFTER THE ENDOVASCULAR PROCEDURE**

Why is follow-up important?

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

What follow-up should I expect?

Safety Information

Possible Benefits of Treatment

What if I need magnetic resonance imaging (MRI)?

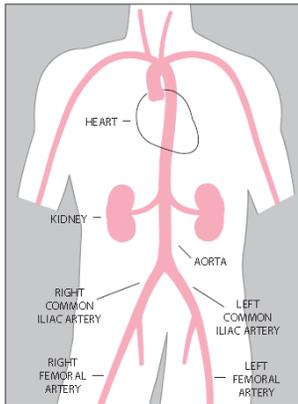
What should I do with my Patient I.D. Card?

## **15-17 GLOSSARY**

## **18-19 WHERE CAN I FIND MORE INFORMATION?**

## **20 NOTES**

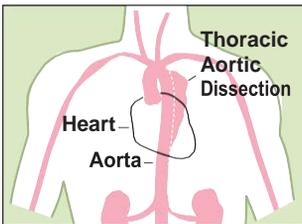
## Introduction



### *What is a thoracic aortic dissection?*

The **aorta** is the main blood vessel that carries blood from the heart to the rest of the body. The **aorta** has a thick wall that is made of three different layers of tissue, so it can withstand the high pressure that is generated when the heart pumps blood to the body. It extends from the chest to the lower abdomen, where it branches into the **iliac arteries**. The **iliac arteries** carry blood to lower parts of the body and to the legs through the **femoral arteries**.

Sometimes, with aging or other changes, a section of the **aorta** may weaken and tear, causing the layers of the **aorta** to come apart. As blood flows through the tear, between the layers of the aorta, the aortic wall splits. This tearing and separation in the layers of the **aorta** is called a **dissection**. Where the tear starts or originates is called the entry tear. Sometimes a dissection occurs in the part of the **aorta** that runs through the chest. This is called a **thoracic aortic dissection**.



### *Is this a serious condition?*

**Acute** (recent) **aortic dissection** is a potentially life-threatening condition. It requires prompt and accurate diagnosis immediately after symptoms appear in order to get the right treatment. All patients require medical management (with medications to control heart rate and blood pressure) and some may need surgical or endovascular treatment, depending on the severity and symptoms. If left untreated, there is a risk that the aorta could rupture or that important organs (e.g., kidneys, gut) would not get enough blood flow, which is associated with a high risk of death.

When an **aortic dissection** has been present for a longer time period, it is called a **chronic aortic dissection**. If blood continues to flow through the tear and between the layers of the **aorta**, a **chronic aortic dissection** could lead to the formation of an **aneurysm** (a localized bulging of the aorta), which may require additional treatment.

### *What are some of the symptoms of a thoracic aortic dissection?*

Symptoms of **aortic dissection** typically occur soon after the tear develops and can vary from one patient to the next. The most common symptom of **thoracic aortic dissection** is chest pain. Sufferers describe a very sharp or tearing pain in either the front or the back of their chest, most often between the shoulder blades. The pain occurs suddenly, and is commonly described as one's "worst pain ever." Other symptoms include, but are not limited to, severe back pain, severe abdominal pain, shortness of breath, pain in the arms or legs, and loss of consciousness.

**Thoracic aortic dissection** is most quickly confirmed with a **CT scan** of the chest. **Magnetic resonance imaging (MRI)** is another way of confirming that a **thoracic aortic dissection** is present.

*What causes a thoracic aortic dissection?*

**Thoracic aortic dissection** is a sudden event. It begins with a tear in the inner layer, of the **aorta**, and blood flows into the middle layer of the **aorta**. As blood flows in between the layers of the **aorta**, the **aorta** can bulge, and is at risk of **rupturing**, causing serious internal bleeding. The tear is thought to be caused by the pressure of blood on the diseased **aorta** combined with the repeated motion of 37-40 million heartbeats per year.

The tearing in the wall can move down the **aorta** and cut off flow to branches of the **aorta** that supply blood to the internal organs. Sometimes the **aorta** splits into two and becomes double-barreled, with neither of the two barrels providing blood to the organs.

Risk factors for developing a **dissection** include high blood pressure, family history, smoking, heart disease, trauma, and connective tissue disorders such as Marfan syndrome or Ehlers-Danlos syndrome. If you are at risk for developing a **dissection**, your doctor may recommend periodic checks. The checks could include a physical exam and possibly a **CT scan** or **MRI**.

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## Treatment of Aortic Dissection

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### *How do doctors treat a thoracic aortic dissection?*

Once diagnosed, **thoracic aortic dissection** should be treated promptly. The two main complications are **rupture** of the **aorta** or **malperfusion** (reduced blood flow from blockage of critical aortic branch arteries that supply blood to important organs such as the kidneys and gut), and both need prompt treatment. If nothing is done, the **aorta** is at risk of **rupturing** (bursting) or your internal organs may not get enough blood and die. There are three types of treatment for **thoracic aortic dissection**:

#### **Medical Management**

#### **Open Surgical Repair**

#### **Endovascular Repair**

All patients will receive **medical management**, or medications that help control heart rate and blood pressure.

If your doctor thinks that there is a risk of your **dissection rupturing**, or if blood flow to internal organs is blocked, he or she may recommend repair. The goal of all **thoracic aortic dissection** repair is to prevent the **aorta** from bursting or blocking the blood supply to other areas of the body.

**Important Note:** Not every patient is a candidate for **endovascular repair** or **open surgical repair**. **Open surgical repair** and **endovascular repair** have advantages and disadvantages, depending upon each patient's condition and needs. Discuss the advantages and disadvantages with your doctor.

### *What is an open surgical repair?*

In this approach, surgery is performed to repair the section of the **aorta** that has a **dissection**. To reach the **dissection**, a doctor makes a cut through the breastbone or the side of the chest. The doctor repairs the **aorta** by replacing the **dissection** section with a fabric tube called a graft.

The graft is sewn into place and acts as a replacement blood vessel. 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 surgical procedure. However, it has a long recovery period. Patients usually stay overnight or several days in the intensive care unit, and stay another seven 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. There is also a possibility that additional treatment or surgery may be required after the initial **open surgical repair**.

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

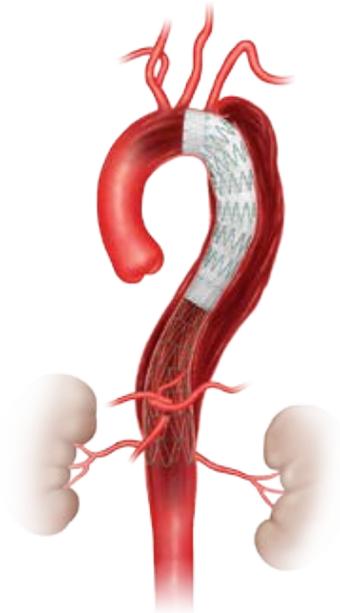
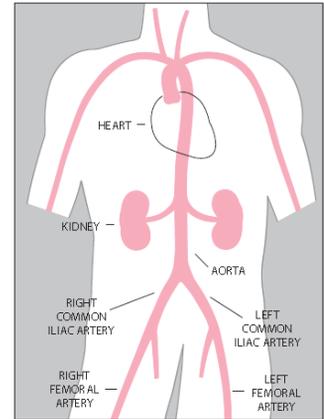
**What is an endovascular repair?**

**Endovascular repair** is a relatively new treatment. **Endovascular** means “inside or within a blood vessel.” Instead of making a large incision in the chest, the doctor makes a small incision near the hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels).

Through these small incisions, an **endovascular graft** is inserted into the femoral artery and positioned inside the **aorta**. The graft seals off the area where the tear in the **aorta** begins and makes a new path through which the blood flows. Below the **endovascular graft**, an **endovascular stent** (self-expanding steel tube) may be positioned. The **stent** is intended to gently reinforce and hold the layers of the **aorta** together. The graft and **stent** remain inside the **aorta** permanently. If there are blockages to critical blood vessels which persist after the endograft is delivered, other **stents** may be necessary. **Endovascular repair** typically takes one to three hours to complete.

Because the cuts 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 success of the treatment. There is also a possibility that additional treatment or surgery may be required after the initial **endovascular repair**. Refer to the “What follow-up should I expect?” section on page 11 for more information.



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## About the Zenith TX2 Dissection Endovascular Graft with Pro-Form Proximal Component and the Zenith Dissection Endovascular Stent

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### *What are the Zenith TX2 Dissection Endovascular Graft with Pro-Form and the Zenith Dissection Endovascular Stent?*

The **Zenith TX2 Dissection Endovascular Graft with Pro-Form** is a reinforced fabric tube. It is sized to the diameter and length of **aorta** that needs to be covered to seal off the **entry tear** and to exclude any aneurysmal segment of the **aorta** caused by the dissection. The graft is positioned in the **aorta** across the tear to prevent blood flow into the layers of the **aorta** and to reinforce the walls of the **aorta** when an **aneurysm** has formed.

The graft itself is made of a polyester material like that used in **open surgical repair**. Standard surgical suture is used to sew the graft material to a frame of self-expanding metal **stents**, which provide support. The **Zenith Dissection Endovascular Stent** is a bare metal tube that is introduced into the body collapsed. Its purpose is to gently hold the layers of the non-aneurysmal **aorta** together. When put into position, it expands to the vessel wall to reinforce it.

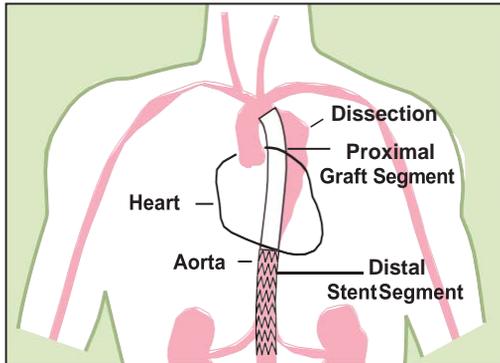
All of these materials have a long history of use in medical implants.

### *How are the graft and stent implanted?*

Before the procedure, your doctor looks at pictures of your **aorta** using **CT scans** and **angiograms**. From these pictures, the doctor can choose the proper size for the **Zenith TX2 Dissection Endovascular Graft with Pro-Form** and the **Zenith Dissection Endovascular Stent** so that they will fit your **aorta** where the **dissection** is located. During the procedure, the doctor uses X-rays to see the graft and **stent** in order to position them.

The graft and **stent** are each contained, or collapsed, in their own plastic tube (**sheath**). Each **sheath** is part of an introduction system. The two introduction systems allow the graft and **stent** to be inserted and placed in the correct position in the **aorta**. The plastic tubes are removed after the graft and **stent** are put in place.





To place the graft and **stent**, your doctor makes an incision near your hip (near the crease between the abdomen and thigh) to get to the **femoral arteries** (blood vessels). If the **femoral arteries** are too small, the doctor may use the arteries in the pelvis for delivery (**iliac arteries**).

The graft is placed first; if needed, the **stent** is placed second. The doctor inserts the graft through the incision and into your bloodstream. The graft is positioned in the **aorta** to seal off the **entry tear** of the dissected area, extending down the **aorta** in order to achieve a good seal. Once expanded, the graft prevents blood from flowing into the **dissection**. If an **endovascular stent** is placed, the **stent** introducer is positioned in the appropriate location in the **aorta**. The **stent** is placed in an area where the layers of the **aorta** have separated. The **stent** is intended to reinforce that section of **aorta**.

On occasion, an additional operation may be required to bypass vessels that may be covered over by the **endovascular stent graft**.

Before the procedure is finished, your doctor uses imaging to confirm that blood in the **aorta** is flowing through the graft and **stent**, not into the **dissection**. Your doctor will then close the incision in your leg with sutures.



**NOTE:** Image above is not to scale

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## After the Endovascular Procedure

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### *Why is follow-up important?*

If you receive a **Zenith TX2 Dissection Endovascular Graft with Pro-Form** and **Zenith Dissection Endovascular Stent**, it is very important that you have regularly scheduled follow-up appointments with your doctor, because the long-term results of **endovascular repair** have not been established. Problems could occur that do not cause noticeable symptoms. Therefore, your doctor needs to look at pictures (**CT scan**, **MRI**) of your **dissection**, graft and **stent** on a regular basis. Problems that may be identified on imaging include **entry flow** and **migration** (see page 12 for definitions). If a problem occurs, your doctor may recommend additional procedures.

### *What symptoms should prompt you to call your doctor following the procedure?*

Symptoms of dissection growth are not always present. When symptoms are present, the most common are:

- pain in the back, abdomen, legs or chest
- physical collapse

Symptoms of **aortic rupture** include:

- dizziness
- intensified pain in the chest or abdomen
- fainting
- rapid heartbeat
- sudden weakness

Symptoms of **malperfusion** include, but are not limited to the following and will depend on the branch vessels involved and the effect on nearby organs:

- Onset of pain in the chest, back, or abdomen
- Tingling/weakness/coldness in limbs
- Loss of sensation in limbs

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

**What follow-up should I expect?**

Recommended follow-up includes checkups at:

- 1 month
- 6 months
- 12 months
- yearly thereafter

Follow-up exams usually include routine blood tests a **CT scan** and a physical exam. These tests carry some minimal potential risk. There is a slight risk of allergic reaction to the **contrast dye** used in the **CT scan**. However, the benefits of these tests typically outweigh any potential risks. Talk with your doctor if you have any concerns about follow-up exams, as he or she may recommend special precautions.

These exams should be part of your lifelong commitment to health and well-being. They are necessary to evaluate your treatment and monitor any changes over time. Your doctor may request additional evaluations based on findings at the follow-up visits.

**Safety Information**

Cook conducted a clinical study on patients with **acute thoracic aortic dissection**. The study included patients between the ages of 34 and 81 years old, many of whom had a history of high blood pressure and smoking. Patients were treated for either **rupture** or reduced blood flow to organs as a result of their dissection. Most of the patients received both the **Zenith TX2 Dissection Endovascular Graft** and **Zenith Dissection Endovascular Stent**; some received only the graft.

Complications that occurred within 30 days of the procedure included the following:

Possibility	Complication within 30 days <sup>1</sup>
~ 20%	Respiratory complications Kidney complications
~10-15%	Cardiovascular complications Gastrointestinal complications
~5-10%	Wound complications Stroke Death Paraplegia / paraparesis
~1%	Extension of dissection Rupture

<sup>1</sup> Based on the event rates within 30 days during the clinical study for this device.

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Complications that occurred later in follow-up were similar to those listed above, but occurred less frequently. However, follow-up is important to ensure the device performs as it is intended and to identify potential complications such as device movement or continued blood flow into the dissection (entry-flow).

#### **Entry-Flow**

An **entry-flow** occurs when blood from the **aorta** continues to leak into the **thoracic aortic dissection** through the **entry tear**. Most sources of **entry-flow** do not require treatment. However, a small number require further treatment.

#### **Graft or stent movement**

Because blood vessels can change shape over time with **aortic dissection**, it is possible for a graft or stent to shift position. This graft movement may not be felt, but it can be seen with a **CT scan**. Movement can be caused by several factors such as changes in the anatomy over time, incorrect placement of the device, and incorrect size of the device. Movement may expose the **entry tear**, allowing blood to resume flow between the layers of the **aorta**, with risk of **rupture** and/or inadequate flow to organs.

Therefore, it is important to keep your routine follow-up appointment with your doctor.

#### ***Possible Benefits of Treatment***

Leaving a Type B aortic dissection untreated can result in aortic **rupture** or loss of blood flow to organs such as the kidneys, intestines, and liver (**malperfusion**) – all of which can be life-threatening conditions.

Therefore, the possible benefits of treatment are the prevention of **rupture** and **malperfusion**. However, as with any medical procedure, there are also risks associated with treating Type B aortic dissection, as discussed in section above. The possible benefits of treating Type B aortic dissection with this device compared to other treatment options cannot be anticipated as the clinical study for this device did not include this type of comparison.

***What if I need magnetic resonance imaging (MRI)?***

If you receive a **Zenith TX2 Dissection Endovascular Graft with Pro-Form** and **Zenith Dissection Endovascular Stent**, be sure to tell all of your health care providers that you have the graft and **stent** implanted. Show them your Patient I.D. Card. This card contains information related to **MRI** procedures for patients with this device. If you have any concerns about an **MRI**, discuss the potential risks and benefits of the test with your health care providers.

There may be potential risks (e.g., device migration or movement, vessel damage) that could be associated with forces applied to the metallic components of the **Zenith TX2 Dissection Endovascular Graft** and **Zenith Dissection Endovascular Stent**. Therefore, a careful assessment of these potential risks and potential benefits to you should be completed prior to use of MRI. In addition, the facility for MRI should be appropriately selected to allow for prompt intervention if necessary.

## What should I do with my Patient I.D. Cards?

You will receive a **Zenith Dissection Endovascular Stent** Patient I.D. Card. The card provides valuable information concerning:

- type of device implanted
- date of implant
- your doctors
- MRI information

Be sure to tell all your health care providers that you have the **graft** and **stent** and show them your Patient I.D. Card. You should keep the card available at all times.



Patient Name  Implant Date

Implanting Facility Name

Implanting Physician

Implanting Physician Phone #

Follow-up Physician

Follow-up Physician Phone Number

Product Catalog #

Product Catalog #

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



Cook recommends that the patient register the MR conditions with the MedicalAlert Foundation. The MedicalAlert Foundation can be contacted in the following manner:

Mai: MedicalAlert Foundation International  
2323 Colorado Avenue  
Tullock, CA 95382  
Phone: 888.633.4298 (toll free) or  
209.668.3333 (from outside the U.S.)  
Fax: 209.669.2450  
Web: [www.medicalert.org](http://www.medicalert.org)

- MR image artifact will extend throughout the anatomical region containing the device. Please refer to [www.medicalert.org](http://www.medicalert.org).
- A patient with this endovascular graft/stent can be scanned safely under the following conditions:

#### MRI Information

- Static magnetic fields of 1.5 or 3.0 Tesla
- Maximum spatial magnetic gradient of 720 Gauss/cm or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) < 2.0 W/kg (Normal Operating Mode) for 15 minutes of continuous scanning

Under the scan conditions defined above, the Zenith TX2 Dissection Endovascular Graft with Pro-Form overlapped with the nitinol Zenith Dissection Endovascular Stent (ZDES) is expected to produce a maximum temperature rise of less than 2.0°C after 15 minutes of continuous scanning.

In nonclinical testing, the image artifact extends approximately 80 mm from the Zenith TX2 Dissection Endovascular Graft with Pro-Form overlapped with the Zenith Dissection Endovascular Stent (ZDES) when imaged with a gradient echo pulse sequence and a 3.0 T MR system. The image artifact completely obscures the device lumen.

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## Glossary

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

**Angiography/Angiogram** – an X-ray method that uses contrast (dye) injected into the bloodstream to show blood flow through blood vessels. This type of image is called an angiogram.

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

**Aortic Dissection** – When there is a tear in the inner layer of the **aorta** and blood flows between the layers of the aortic wall, causing the layers to split.

- **Acute Aortic Dissection:** An aortic dissection which has been diagnosed soon after the dissection occurs, typically within the first few weeks. The initial line of treatment for acute aortic dissections is to control the blood pressure with medications. Based on severity and symptoms, surgical or endovascular treatment may also be required.
- **Chronic Aortic Dissection:** When an aortic dissection has been present for a longer time period (several weeks), it is called a chronic aortic dissection. If blood continues to flow through the entry tear and between the layers of the aorta, a chronic dissection may over time lead to the formation of an **aneurysm** or may cut off blood flow to organs, which may require additional treatment.

**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, blood vessels and your dissection. Formerly known as a CAT scan.

**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, to seal off (exclude) the diseased vessel.

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**Endovascular Repair** – placement of an **endovascular graft** to seal off (exclude) the **entry tear** in the dissected area of the aorta without the need for open surgical techniques. 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, the introduction system is inserted through the femoral arteries. The **endovascular graft** is deployed in the **aorta** and seals off the entry tear in the dissected area of the **aorta** and makes a new path through which the blood flows. Further, because in dissections it is common for the layers of the **aorta** to have separated below the **entry tear**, a **stent** may be placed in this area in order to reinforce the wall to hold the layers together.

**Endovascular Stent** – a stent placed inside of a diseased vessel without the need for open surgical techniques. In the case of a dissection, a stent may be placed to reinforce the wall of the aorta.

**Entry-Flow** – continued blood flow through the **entry tear** and between the layers of the **aorta** after placement of an **endovascular graft**. Most entry-flows do not require treatment. However, a small number require further treatment.

**Entry Tear** – a slit-like hole in the aortic lining that allows blood to enter into the layers of the **aorta**, causing the layers to split (dissect) and form an extra channel (**False Lumen**).

**False Lumen** – a channel between the layers of the wall of the aorta, as a result of an entry tear. Blood can flow into this channel, resulting in a "double-barreled aorta." There can potentially be multiple tears.

**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 Arteries** – the two large blood vessels that connect the lower end of the aorta to the femoral arteries in each leg. When the femoral arteries are too small, doctors can usually use the iliac arteries as a pathway to deliver an **endovascular graft** into the **aorta**.

**Malperfusion** means that organs and/or tissues are not being properly supplied with blood from the **aorta**. **Malperfusion** can occur if the **aortic dissection** is interrupting proper blood flow. Severity and symptoms of **malperfusion** depend upon how quickly the blood flow is interrupted and where it occurs.

**Medical Management** – treating patients with drug therapy. This can be supplemented with endovascular or **open surgical repair** if needed.

**Migration:** Movement of the graft and/or **stent** in the **aorta**. This can be caused by several factors such as changes in the anatomy over time, incorrect placement of the device and incorrect size of the device. This may expose the entry tear, allowing blood to resume flow between the layers of the **aorta**, with risk of **rupture** and/or inadequate flow to organs.

**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.

**Open Surgical Repair** – a type of surgery performed to repair a thoracic dissection. To reach the dissection, a doctor makes a cut through the patient's breastbone or side of the chest. The doctor repairs the aorta by replacing the dissection section with a fabric tube called a graft. The graft is sewn into place and acts as a replacement blood vessel.

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

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

**Stents** – self-expanding metal tubes that are placed inside the body to hold open and reinforce a vessel.

**Aneurysm** – a localized bulging of the aorta.

**Thoracic Aortic Dissection** – a dissection in the part of the aorta that runs through a person's chest.

**Zenith TX2 Dissection Endovascular Graft with Pro-Form and Zenith Dissection Endovascular Stent** – two stent-based devices that are placed within a dissection with the intent to seal off the dissection and reinforce the **aorta**. 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 metal stents. The bare **stent** component is a frame made from metal wire. Both **graft** and **stent** are introduced separately through long tubes called **sheaths**.

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## Where can I find more information?

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### *Dissections*

**VascularWeb Patient Information** [www.vascularweb.org](http://www.vascularweb.org)

VascularWeb is a World Wide Web (WWW) based global resource of information and services for individuals interested in improving vascular health worldwide. VascularWeb 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.

### *Interventional Therapy*

**Society of Interventional Radiology** [www.sirweb.org](http://www.sirweb.org)

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

**U.S. National Library of Medicine** [www.medlineplus.gov](http://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***

**Cook Medical Incorporated**

**[www.cookmedical.com](http://www.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 created 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.

***U.S. Department of Health and Human Services***

**Food and Drug Administration**

**[www.fda.gov](http://www.fda.gov)**

A U.S. government agency intended to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use. FDA approves research such as that being done in stent graft aneurysm and dissection clinical trials.

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## Notes

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If you have any questions about your **thoracic aortic dissection** or treatment, we encourage you to talk to your doctor. He or she 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 aortic dissection?
- 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 (e.g., when passing an airport security scanner)?
- What symptoms should prompt me to seek immediate medical attention after my procedure?

## TREATING YOUR THORACIC AORTIC DISSECTION

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:	
Implanting Date:	
Implanting Facility Name (Hospital):	
Implanting Physician:	
Implanting Physician Phone #:	

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