INTRODUCTION

You have been told by your doctor that you have a thoracic aortic aneurysm (TAA) and discussed different types of treatments for this disease, including Endovascular Repair with a thoracic stent-graft. This booklet will help you understand your disease and what Endovascular Repair is. This booklet can be used as a reference, but only your doctor can decide what type of procedure is right for you. Please consult your doctor prior to making any decisions regarding your TAA.

A glossary is provided in the next pages to help you understand the medical terms used in this booklet.
**GLOSSARY**

**Anatomy:** The study of the parts of the body.

**Aneurysm / Thoracic Aortic Aneurysm (TAA):** A widening or ballooning of a portion of the thoracic aorta caused by a weakness in the wall of the blood vessel.

**Aorta:** The largest vessel in the body that carries blood from the heart to the rest of the body.

**Artery:** A blood vessel that carries blood away from the heart.

**Contraindication:** A medical reason to withhold a certain medical treatment.

**CT Scan:** A series of X-ray views taken from different angles.

**Endoleak:** The presence of a persistent flow of blood into the aneurysm sac after a stent-graft is put into place.

**Endovascular:** Inside or within a blood vessel.

**Endovascular Repair:** A treatment in which a tube-shaped stent-graft is inserted into an aneurysm without opening the chest or stomach.

**Exclude:** To seal off.

**Femoral artery:** A large artery in the thigh which doctors use to reach the aorta in endovascular repair.

**Iliac artery:** One of the large arteries supplying blood to your pelvis and legs. Doctors can use these as pathways to reach your aorta.

**Imaging:** The use of X-rays, CT scans, MRI scans or other techniques to get pictures of the inside of the body.

**Minimally-invasive:** Involves tiny cuts to perform a procedure versus one large opening.

**Magnetic Resonance Imaging (MRI):** A type of scan that uses magnetic fields to see inside the body.

**Open Surgical Repair:** A procedure in which a doctor makes a large cut in the chest or stomach to remove an aneurysm and then replaces it with a fabric graft.

**Penetrating Ulcers:** A rare condition that most commonly develops in the aorta when plaque starts to penetrate the aortic wall putting it at risk for rupture.

**Plaque:** A deposit of fat, calcium and other substances on the inner lining of an arterial wall.

**Rupture:** A tear in the blood vessel wall near or in the diseased part of the vessel.

**Stent-graft / Thoracic stent-graft:** A fabric tube supported by a metal framework that a doctor uses to treat a TAA.

**Thoracic Aorta:** The section of the aorta located in the chest. It is the first part of the aorta that the blood enters when it leaves the heart to move throughout the body.
WHAT IS THE THORACIC AORTA?

The aorta is the largest artery in the body. The aorta is about the thickness of a garden hose and runs from your heart through the center of your chest and abdomen. The thoracic aorta is the section of the aorta that sits within your chest (see Figure 1) and is the first part of the aorta that the blood enters when it leaves the heart to move throughout the body.

[Image of aorta and thoracic aorta]

WHAT IS A THORACIC AORTIC ANEURYSM (COMMONLY CALLED TAA)?

A thoracic aortic aneurysm or TAA is a weakened and bulging area in the upper part of the aorta. Some TAAs are associated with penetrating ulcers. A TAA can continue to get larger, and it is possible for a TAA to burst, or rupture. Because the aorta is the body's main supplier of blood, a ruptured TAA can cause life-threatening bleeding.

Most small and slow-growing TAAs don't rupture, but large, fast growing TAAs may. Depending on the size and rate at which the TAA is growing, treatment may change from watchful waiting, to elective surgery, to emergency surgery. Once a TAA or penetrating ulcer is found, doctors will closely monitor it so that if surgery is needed it can be planned. An emergency surgery can be life-threatening.

WHAT CAUSES A TAA?

You have a greater chance of having a TAA if you:
/// Are over 60
/// Are male
/// Have smoked
/// Have high blood pressure
/// Have plaque build-up in your arteries
/// Have a family member with a TAA
/// Have certain diseases that may weaken the aortic wall (discuss with your doctor)

WHAT ARE THE SYMPTOMS OF A TAA?

Most people do not have symptoms of a TAA. For those with symptoms, the most common are:
/// Pain in the jaw, neck, chest, and back
/// Coughing, hoarseness, or difficulty breathing

If you have any of these symptoms, tell your doctor immediately. Your doctor may order imaging to see if a TAA is present.
WHAT ARE THE CURRENT TREATMENTS FOR TAA?

Medical Management
If your TAA is small and not causing any symptoms, your doctor may watch it for 6 months to make sure it’s not getting larger. Your doctor may also try medical or lifestyle changes to reduce the stress on the TAA, especially if it is small. This treatment may include: blood pressure medication and/or lifestyle changes such as quitting smoking.

Repair
If your doctor feels your TAA has reached a size that is at risk for rupture, he or she may recommend repairing it. There are two types of repair:

/// Open Surgical Repair
/// Endovascular Repair

Both TAA treatment options have possible complications and benefits. Patients should talk with their doctor about which option is best for them.

See pages 8 to 9 for important safety information about Endovascular Repair.

WHAT IS OPEN SURGICAL REPAIR?

During Open Surgical Repair, your doctor will make a cut to find your TAA and put a fabric tube (graft) in your aorta above and below your aneurysm. Blood will then flow through the graft. This surgery reduces the chance of vessel rupture.

Open Surgical Repair is performed under general anesthesia and typically takes four to six hours to complete. After surgery, you may stay in the hospital for 7 to 10 days. If your TAA is complicated, or if you have other conditions such as heart, lung, or kidney disease, you may require 2 to 3 months for a complete recovery.
WHAT IS ENDOVASCULAR REPAIR?

Endovascular Repair is a newer, minimally-invasive way to repair a TAA. During this procedure, a stent-graft that is compressed inside a narrow plastic tube called a delivery system is inserted through a small cut in your groin and threaded through your blood vessels. During the procedure, your doctor will use live x-ray pictures viewed on a video screen to guide the stent-graft to the site of your TAA. The stent-graft will open inside your aorta and become the new channel for blood flow. The stent-graft shields the TAA from receiving more blood that might make it grow and helps prevent more pressure from building on the TAA. This should keep your TAA from rupturing.

Following Endovascular Repair, you may stay 2 or 3 days in the hospital. You must speak to your doctor to understand if Endovascular Repair is the right treatment for you.

WHAT IS A THORACIC STENT-GRAFT?

A Thoracic Stent-Graft is a fabric tube supported by a metal frame which is placed in the diseased aorta through a small incision in the groin. This seals off the TAA by fitting inside the diseased part of the aorta and allows blood to flow normally through your aorta.

WHO SHOULD NOT HAVE ENDOVASCULAR REPAIR (CONTRAINDICATIONS)?

You should not have an Endovascular Repair if you:

/// Have an allergy to the materials used to make the stent-graft (polyester, nickel, titanium, or platinum-iridium)
/// Have a systemic infection

Only your doctor can say if Endovascular Repair is the right treatment for you.
IMPORTANT WARNINGS AND PRECAUTIONS

The following are general warnings and precautions. Please discuss with your doctor all warnings and precautions related to Endovascular Repair.

The use of stent-graft has not been studied in patients who:

/// Have a connective tissue disease
/// Have a torn, ruptured, or bleeding aorta
/// Have blood clotting diseases
/// Have a systemic infection
/// Are pregnant or breast-feeding
/// Are less than 18 years old

Your doctor will need to help you decide whether it is appropriate for you to get a stent-graft if any of these situations apply to you.

/// Cannot complete regular follow-up visit and imaging examinations
/// Cannot tolerate injectable dyes needed for imaging examinations
/// Have bleeding disorders
/// Cannot use blood thinners

CLINICAL STUDIES TO SUPPORT THE RELAYPLUS THORACIC STENT-GRAFT SYSTEM

In order to understand the risks and benefits of Endovascular Repair with the RelayPlus Thoracic Stent-Graft System as compared to open surgical repair, Bolton Medical conducted a clinical study in the United States with 120 patients.

The U.S. Relay Phase II Clinical Trial included 120 patients between the ages of 28 and 91. Most patients had high blood pressure, high cholesterol, or smoked. Many had mild heart, lung, or kidney disease. Patients who had recent surgery, heart attack, stroke, or infection were not included in these studies. Some of the risks and benefits to having Endovascular Repair are explained in the following sections.

RISKS OF HAVING ENDOVASCULAR REPAIR

Patients who were treated with a stent-graft in the U.S. clinical study experience the following complications up to 30 days after their endovascular repair:

<table>
<thead>
<tr>
<th>Complications up to 30 days</th>
<th>Likelihood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal healing of the incision</td>
<td>5 - 10%</td>
</tr>
<tr>
<td>Major blood loss</td>
<td></td>
</tr>
<tr>
<td>Difficulty breathing</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>3 - 5%</td>
</tr>
<tr>
<td>Fluid build-up in area around the lungs</td>
<td></td>
</tr>
<tr>
<td>Tearing or damage to a blood vessel</td>
<td></td>
</tr>
<tr>
<td>Heart attack</td>
<td>1 - 3%</td>
</tr>
<tr>
<td>Permanent loss of feeling and muscle function in the legs</td>
<td></td>
</tr>
<tr>
<td>Kidney failure</td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td></td>
</tr>
<tr>
<td>Mild to moderate difficulty breathing</td>
<td></td>
</tr>
<tr>
<td>Decreased blood flow to the intestines</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td></td>
</tr>
<tr>
<td>Aneurysm rupture</td>
<td>Less than 1%</td>
</tr>
<tr>
<td>Second procedure due to endoleak or continued TAA growth</td>
<td></td>
</tr>
<tr>
<td>Need for surgical repair of TAA</td>
<td></td>
</tr>
</tbody>
</table>

After your Endovascular Repair, there is a chance that an endoleak may cause your TAA to begin to grow again. If this happens, your doctor may recommend a second Endovascular Repair procedure to fix this. Depending on your condition, your doctor may decide that your TAA needs to be repaired by surgery. If the TAA continues to grow and is not repaired, it could rupture. In the U.S. clinical study, no patient had an endoleak up to 30 days after the procedure which required a second Endovascular Repair to treat this problem. Two patients had endoleaks after 30 days that required a second Endovascular Repair. One patient in the U.S. study required surgical repair of the TAA treated with a stent-graft due to an infection not related to the stent-graft. No patients in the U.S. study suffered ruptures of the TAA treated with stent-grafts.
POSSIBLE BENEFITS OF ENDOVASCULAR REPAIR

TAA repair may reduce the risk of rupture. As with any procedure, there are benefits and risks with either approach. Using Endovascular Repair to treat your TAA may have additional benefits. Please discuss the possible benefits and risks with your doctor.

In the U.S. clinical study, the results of patients treated by Open Surgical Repair were compared to the results of patients treated by Endovascular Repair. Clinical study results in the table below suggest advantages with Endovascular Repair.

<table>
<thead>
<tr>
<th>Complications</th>
<th>Endovascular Repair</th>
<th>Open Surgical Repair</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death (within 30 days)</td>
<td>5.8%</td>
<td>10%</td>
</tr>
<tr>
<td>Major complications (within 30 days)</td>
<td>21.7%</td>
<td>48.3%</td>
</tr>
<tr>
<td>Patients requiring blood transfusion (average)</td>
<td>8%</td>
<td>85%</td>
</tr>
<tr>
<td>Blood loss during procedure (average)</td>
<td>less than 1 pint</td>
<td>4.3 pints</td>
</tr>
<tr>
<td>Length of procedure (average)</td>
<td>2 hours, 23 minutes</td>
<td>4 hours, 35 minutes</td>
</tr>
<tr>
<td>Time in ICU (average)</td>
<td>2 days</td>
<td>8 days</td>
</tr>
<tr>
<td>Total time in hospital (average)</td>
<td>5.5 days</td>
<td>13 days</td>
</tr>
</tbody>
</table>

For more clinical study information, visit www.clinicaltrials.gov and search for RelayPlus or contact Bolton Medical at 855-7BOLTON (855-726-5866) or uscustomer@boltonmedical.com

OVERVIEW OF ENDOVASCULAR REPAIR

Before the procedure you will meet with your doctor to talk about the possible treatments for your TAA. These may include the endovascular repair, open surgery, medical therapy, or no treatment.

If endovascular repair is recommended, your doctor may ask you to have some further tests done before the procedure. These tests will allow the doctor to check your aneurysm and determine the proper size stent-graft that is needed for your procedure. The stent-graft selected will be sized to fit your aorta where the aneurysm is located.

THE PROCEDURE

Typically, the Endovascular Repair takes 2 to 3 hours to complete. You are usually asleep during the procedure and won’t feel any pain.

1. A small cut is made on one side of your groin.
2. A thin plastic tube, called a delivery system, holding your thoracic stent-graft is inserted into the opening and threaded through your femoral artery to reach your TAA. During the insertion, the doctor will view live x-ray pictures of your aorta to make sure the stent-graft is properly placed. This requires the use of dyes. (see warning section on page 11 regarding the use of dyes).
3. Once the delivery system reaches the correct location, the stent-graft is released into your aorta.
4. When your stent-graft is released, it expands to fit in your aorta, both above and below your TAA. 
   Note: The size and number of stent-grafts used will depend on your anatomy and your doctor’s preference.
5. Once the delivery system is removed, the doctor will recheck that your stent-graft is working properly.
6. The opening in the groin is closed and the procedure is complete.

THE STENT-GRAFT INSIDE THE TAA
AFTER THE PROCEDURE

After the Endovascular Repair, you will go to a recovery room where you will lay flat for a few hours. This will allow the cut in your groin to start healing. You may have some pain or discomfort for up to two days, and you will probably need to stay in the hospital 2 to 7 days. Your doctor will provide you with instructions on how to care for yourself after this procedure.

WHEN SHOULD I IMMEDIATELY CALL MY DOCTOR?

If you have any of the following symptoms after your Endovascular Repair and before your first follow up visit, call your doctor immediately.

/// Pain in your back, chest or groin
/// Dizziness
/// Fainting
/// Rapid heartbeat
/// Sudden weakness
/// Pain, numbness, coldness, or weakness in your legs or buttocks

WHEN DO I FOLLOW UP WITH MY DOCTOR?

The longterm performance of stent-grafts has not yet been confirmed. For this reason, lifelong, regular follow up to check the performance of your stent-graft and your overall health is important. Ask your doctor when you should schedule your first follow up visit. Most often these visits will occur at one month, one year, and then each year thereafter. Imaging tests are required at these visits to check device performance.

WHEN CAN I RESUME NORMAL ACTIVITIES?

Every patient and medical condition is different. Some patients can return to their normal activities more quickly than others after Endovascular Repair. You should consult your doctor about when you should return to normal activities.

QUESTIONS I MAY WANT TO ASK MY DOCTOR

/// What are all of my options for treating my TAA?
/// Is a thoracic stent-graft an appropriate treatment for my TAA?
/// What are the risks of rupture with a thoracic stent-graft?
/// Will I have any side effects from the RelayPlus Thoracic Stent-Graft?
/// After the procedure, how often will I need to see my doctor?
/// What follow up tests will be needed?
/// What if the TAA continues to grow after endovascular treatment?
/// Will I have to limit my activities after the treatment? If so, for how long?
/// How long can the stent-graft remain inside my body?
/// How many RelayPlus Thoracic Stent-Graft procedures has my doctor performed?
/// What are the advantages and disadvantages of Open Surgical Repair compared to Endovascular Repair of a TAA?
WHAT IS THE DEVICE IDENTIFICATION CARD?

After your procedure, your doctor will give you a Device Identification Card. This card will list the following information:
/// Type of device implanted
/// Date of implant
/// Your doctor’s information
/// Magnetic Resonance Imaging (MRI) information

You should keep this card in your wallet and with you at all times. Inform all your healthcare providers that you have a stent-graft and show them your Device Identification Card.

It is important to know that the RelayPlus Thoracic Stent-Graft is “MR Conditional.” This means that under specific conditions it is safe for you to undergo an MRI scan after receiving a RelayPlus Thoracic Stent-Graft. Show your Bolton Medical Device Identification Card to your doctor before having surgery or undergoing an imaging procedure.

WHERE CAN I FIND ADDITIONAL INFORMATION?

This booklet is only intended to provide you with basic information about TAA. It is not a substitute for consulting a doctor. Only your doctor can decide what procedure is best for you.

Additional information about TAA can be found at:
www.webmd.com/heart-disease/tc/aortic-aneurysm-overview
www.medlineplus.gov
www.fda.gov
www.vascularweb.org

CONTACTING BOLTON MEDICAL

If you have any questions concerning Bolton Medical’s RelayPlus Thoracic Stent-Graft System, you should contact your doctor. If for any reason you need to contact Bolton Medical, please feel free to contact us at:

Bolton Medical
799 International Parkway
Sunrise, FL 33325
USA
855-7BOLTON (855-726-5866)
954-324-8761 (fax)
uscustomer@boltonmedical.com

www.boltonmedical.com

ENDNOTES:
2. U.S. Phase II Clinical Trial to Determine the Safety and Efficacy of Relay® Thoracic Stent-Graft, 2/2012
Caution: Federal Law (US) restricts this device to sale by or on the order of a physician