A patient information guide for acute DeBakey Type I aortic dissections and treatment options

Humanitarian Device.

Authorized by Federal law for use in the treatment of acute DeBakey Type I aortic dissections. The effectiveness of this device for this use has not been demonstrated.

Important terms and explanations

Words and terms used in this guide are explained below to help you learn more about your acute DeBakey Type I aortic dissection and treatment options.

1. *Aorta* – Main artery that carries blood from the heart to the organs and limbs.
2. Angiography/Angiogram – Imaging technique using a dye injected into your bloodstream to visualize inside arteries and blood vessels.
3. *Computed Tomography Scan (CT/CAT Scan)* - Imaging technique using x-rays to produce cross-sectional images of the body.
4. *Delivery Catheter* – A device which facilitates navigation and positioning of the stent into the aorta by a doctor or surgeon.
5. *Dissection* – A serious and possibly life-threatening condition which occurs when the inner layer of the aorta tears, and blood flows into the layers of the aorta, leading to separation of the layers and reduced blood flow to the organs and limbs.
6. *DANE* – Distal Anastomotic New Entry (DANE) tear. A ‘DANE’ tear occurs when there is a leak between the layers of the aorta and the hemiarch repair graft which allows blood flow back into the false lumen.
7. *dSINE* – Distal stent-graft induced new entry tear. A dSINE tear is damage to the aorta during placement of the stent graft. The metal stent may tear the aortic wall during initial placement or over time (due to rubbing or friction between the stent and aorta).
8. *False Lumen* – In aortic dissection, this refers to the section of aorta that is dissected, where blood flows between the layers of the aortic wall. Over time this can lead to the development of an anuerysm and potential for rupture.
9. *Graft* – Tube-shaped device made of synthetic material (such as polyester) which is used to restore blood flow between two sections of the aorta.
10. *Magnetic Resonance Imaging (MRI)* – An imaging technique which uses magnetic fields and raido waves to visualize structures within the body.
11. *Malperfusion* – Inadequate blood flow to your organs and limbs due to aortic dissection.
12. *Paraplegia* – Inability to move the lower parts of your body.
13. *Paraparesis* – Limited ability to move the lower limbs due to disrupted nerve signals between the brain and muscles.
14. *Spinal Cord Injury* – Physicial damage to any part of the spinal cord or nerves at the end of the spinal cord, which results in permanent changes in strength, feeling, and body functions below the site of the injury.
15. *True Lumen* – In aortic dissection, the true lumen is lined by the innermost layer of the blood vessel.

Table of Contents

Introduction

The information in this leaflet is provided by Artivion, Inc. to help you make an informed decision on the treatment of your acute DeBakey Type I aortic dissection.

The AMDS™ Hybrid Prosthesis was first approved for commercial use in Canada in November of 2018 and marketed as the 'Ascyrus Medical Dissection Stent'). Since then, the AMDS™ Hybrid Prosthesis has been implanted in approximately 1,500 patients in over 20 countries worldwide.

While you are reviewing this information guide, you may find it helpful to write down questions about your condition and treatment options to discuss with your doctor. Your doctor will determine if you are a good candidate for open repair of your ascending aorta, which is the first section of your aorta, with the AMDS™ Hybrid Prosthesis.

What is an aorta?

The aorta is a main artery and the largest blood vessel in the human body which extends from the aortic valve within your heart. The aorta carries oxygen-rich blood pumped by your heart to your organs (e.g., brain, stomach, kidneys, liver, etc.), arms and legs. Doctors refer to the aorta in sections – the ascending aorta which delivers blood pumped from the heart to the coronary arteries, the aortic arch which contains vessels which deliver blood to the torso and head, and the descending aorta, which travels down the body through the chest to each leg and delivers blood to vital organs (e.g., stomach, liver, kidneys, etc.) and the lower limbs. The aortic wall is made of three layers – the adventitia, the media, and the intima. The intima is the inner layer in contact with blood (***Figure 1***).

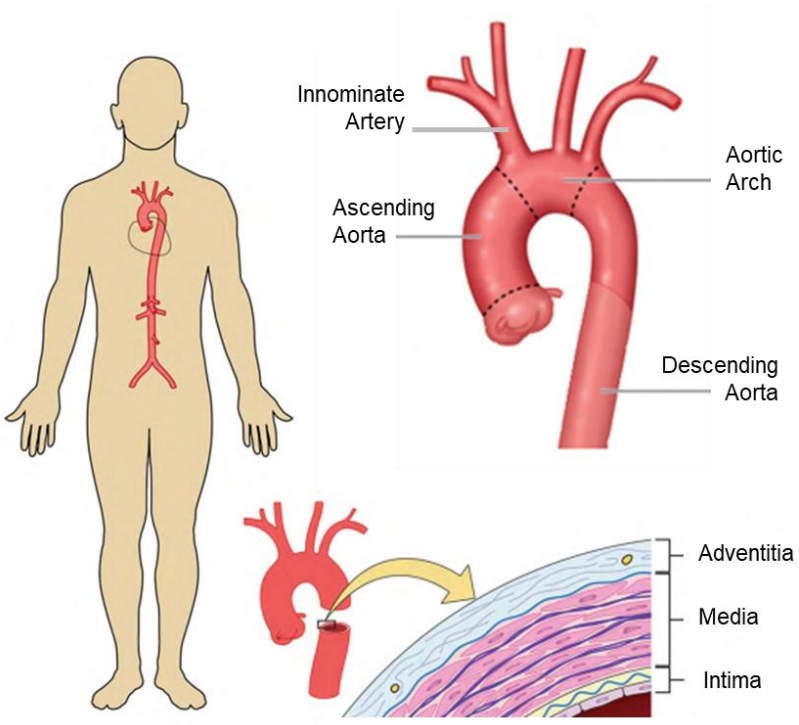

Figure 1 – Aortic Anatomy

What is an acute DeBakey Type I aortic dissection?

An acute DeBakey Type I aortic dissection is an urgent, life-threatening medical condition which involves the ascending aorta down to the descending aorta. The dissection develops when there is tear in the layers of the aortic wall. The layers separate as blood is able to flow between them, which may weaken the wall and lead to decreased blood flow to your organs and legs, as well as risk of aneurysm and rupture if left untreated (***Figure 2***).

An aortic dissection can occur if you have had high blood pressure for a long period of time, if you have genetic traits and family history of aortic dissection, or if you have experienced trauma to your torso (i.e., a car accident).

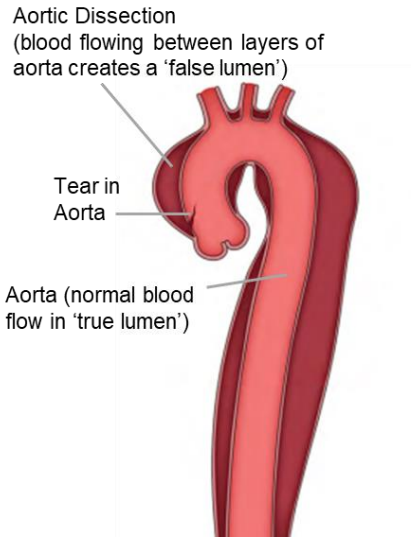

Figure 2 – Aortic Dissection

What risks are associated with my aortic dissection?

Aortic dissection weakens the wall of the aorta, which may lead to organ damage (such as kidney failure or life-threatening intestinal damage), stroke, aortic valve damage or rupture, or death due to rupture of the aorta and severe internal bleeding.

https://www.mayoclinic.org/diseases-conditions/aortic-dissection/symptoms-causes/syc-20369496

What symptoms are associated with my aortic dissection?

Aortic dissection symptoms may be similar to those of other heart problems, such as a heart attack. Typical signs and symptoms include:

- Sudden severe chest or upper back pain, often described as a tearing or ripping sensation, that spreads to the neck or down the back
- Sudden severe stomach pain
- Loss of consciousness
- Shortness of breath
- Symptoms similar to those of a stroke, including sudden vision problems, difficulty speaking, and weakness or loss of movement (paralysis) on one side of your body
- Weak pulse in one arm or thigh compared with the other
- Leg pain or paralysis
- Difficulty walking

https://www.mayoclinic.org/diseases-conditions/aortic-dissection/symptoms-causes/syc-20369496

What are my treatment options?

Your doctor will determine your best method of treatment based on your age, overall state of health, your symptoms and the extent of your aortic dissection. An acute DeBakey Type I aortic dissection is a medical emergency typically requiring immediate surgical treatment to avoid rupture. If you have symptoms of organ failure, immediate treatment is necessary to avoid worsening of your condition. The method for repair of an aortic dissection is an open surgical technique, which may vary depending on the location and extent of your dissection and the current state of your health.

An acute DeBakey Type I aortic dissection is typically treated by removing the section of the ascending aorta where aortic dissection tear is located and replacing it with a graft (***Figure 3***). Before the procedure, you will be placed under general anesthesia with pain control and connected to a heart-lung machine during the surgery to keep blood flowing to your organs and limbs. You will remain unconscious during the procedure. The surgeon will make an incision (cut) into your chest in order to access the aorta and remove the section of the aorta with the dissection tear. The surgeon then sews a tubular graft (or multiple grafts) to reconnect the healthy parts of your ascending aorta and aortic arch to repair blood flow within the aorta. The surgeon will then sew up your incision site.

Figure 3 – Hemiarch Repair for Acute DeBakey I Dissection

As with all surgical procedures, there are associated risks. Your doctor will discuss the risks and benefits with you. Only your doctor can determine the most appropriate treatment for you.

Treatment with the AMDS™ Hybrid Prosthesis

What is the *AMDS™* Hybrid Prosthesis?The AMDS™ Hybrid Prosthesis is an implantable, uncovered stent constructed from braided Nitinol wire which is attached to a polytetrafluoroethylene (PTFE) felt cuff with polyester (PET) sutures (***Figure 4***). The AMDS stent is secured onto a delivery catheter (***Figure 5***). The delivery catheter is inserted into the body through the aorta and once the stent is inserted into the correct position and the AMDS™ Hybrid Prosthesis is in the aorta, the catheter is removed.

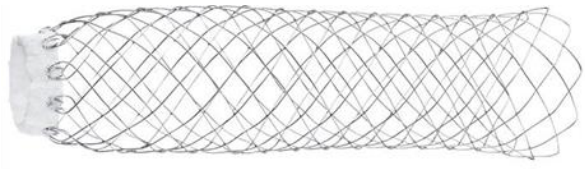

Figure 4. Stent

Figure 5. Delivery Catheter

What is the AMDS™ Hybrid Prosthesis procedure?

The AMDS™ Hybrid Prosthesis is implanted during the standard surgical procedure for patients with acute DeBakey Type I aortic dissections and malperfusion (including cerebral, visceral, renal, and peripheral malperfusion) undergoing open surgical repair within 0-14 days of diagnosis.

Once the surgeon has removed the diseased part of the ascending aorta, the AMDS™ Hybrid Prosthesis is positioned in the aortic arch and the stent is deployed from the delivery catheter so that it can expand against the inner layer of the aortic wall (***Figure 6***). The AMDS stent expands the aorta 'true lumen' (where blood is supposed to flow) and puts pressure on the 'false lumen' (where blood is not supposed to flow) so that the aortic layers can heal. A tubular graft is sewn into the ascending aorta to replace the dissected section of aortic tissue. The AMDS stent is sutured to the tubular graft (***Figure 7***) to close the aorta and restore blood flow. Implantation of the AMDS™ Hybrid Prosthesis adds approximately 5 minutes for deployment, with additional time needed for suturing to complete the standard procedure.

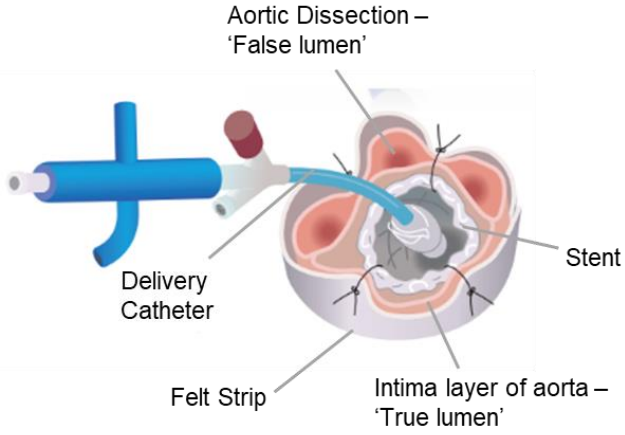

Figure 6. Insertion into the aorta

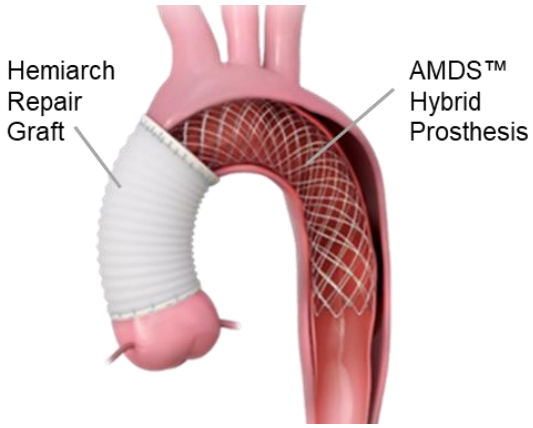

Figure 7. Standard Repair with AMDS™

How does the AMDS™ Hybrid Prosthesis work?

The AMDS™ Hybrid Prosthesis is intended to be used in patients with a primary dissection tear localized in the ascending aorta (e.g., only distal to the innominate artery). *During a standard hemiarch repair procedure without the AMDS™ Hybrid Prosthesis, distal anastomotic new entry (DANE) tears can occur when blood leaks through the layers of the aorta and the hemiarch repair graft back into the false lumen. Increased blood flow into the false lumen leads to aortic growth, risk of rupture, and reintervention. Decreased blood flow into the true lumen leads to persistent malperfusion after treatment (**Figure 8**).*

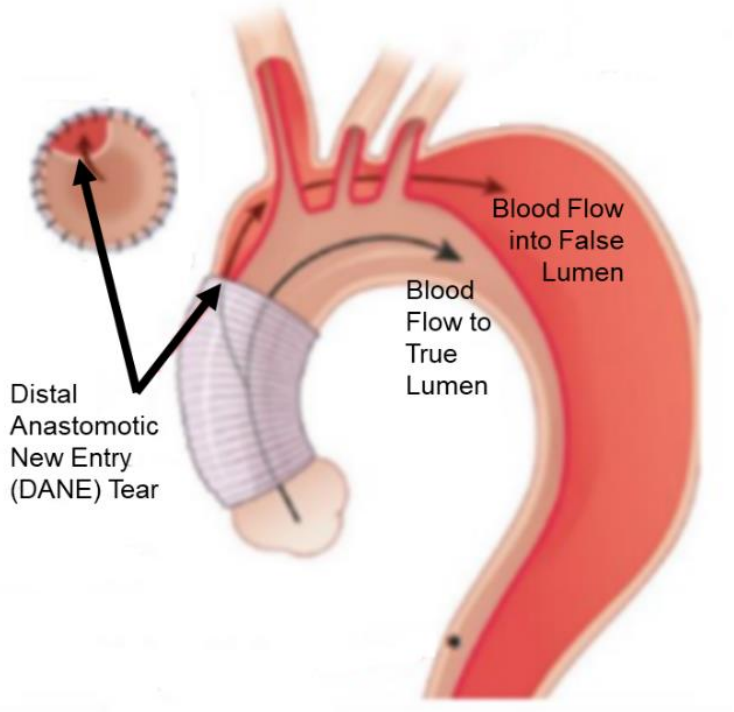

Figure 8. Distal Anastomosis New Entry (DANE) Tear

The AMDS™ Hybrid Prosthesis stent expands the true lumen and closes the dissection tear, and the cuff and felt strip placed on the outside of the aorta strengthen the sutured connection (anastomosis) between the hemiarch repair graft by the aorta, which prevent DANE tears by creating a seal between the hemiarch repair graft and AMDS™ Hybrid Prosthesis cuff to improve the blood flow through the true lumen of the aorta.

What risks are associated with the AMDS™ Hybrid Prosthesis?

The AMDS Hybrid™ Prosthesis is not meant to be used in patients who have a primary dissection tear at or beyond the innominate artery (e.g., throughout the aortic arch). The AMDS™ Hybrid Prosthesis cannot be used to treat patients with sensitivity to the implant materials (Polytetrafluoroethylene [PTFE] or Nitinol [e.g., Nickel or Titanium]), or patients with mycotic aneurysms, aortic fistulous communication with non-vascular structures, or uncontrolled systemic infection. As with any surgery, repair of your dissection comes with potential risks that should be discussed with your doctor.

The risks associated with the use of the AMDS™ Hybrid Prosthesis include, but are not limited to:

- Allergic reaction to the device, imaging dyes, or medication given during the procedure
- Growth of the aorta/false lumen leading to increased risk of rupture of the aortic wall, dissection, perforation or other disease progression which may require surgical or minimally invasive reintervention
- Cardiac complications or heart failure
- Complications at the surgical site
- Occlusion (narrowing) or stenosis (blockages) in the aorta, thrombosis (flow-restricting blood clots in the aorta) , and/or pseudoaneurysm,(false aneurysms from blood leaking through the aortic wall and pooling)
- Continued symptoms of malperfusion after the procedure
- Pulmonary complications (e.g., edema [fluid accumulation in lungs]embolism [blood clot], pneumonia, respiratory failure)
- Stroke or temporary stroke-like symptoms, =, nerve pain, or spinal cord injury with possible paralysis.
- Stomach, liver, kidney or gastrointestinal symptoms (e.g., nausea/vomiting, liver failure, renal failure)
- Potential difficulties in performing future catheter-based or surgical procedures due to location of AMDS stent within the aorta,
- Stent compression, or kinking of the stent, which may lead to the stent not fully expanding in sections of the aorta

Summary of Complication Rates for Hemiarch Repair

The 30-day rate of complications from hemiarch repair procedures (without AMDS) in patients with malperfusion are reported in the literature are shown in ***Table 1*** below.

Table 1. Major Complications in Hemiarch Repair (without AMDS) from Literature

Complication	Total # of Complications*
Death from any cause (within 30 days)	13.4 – 43.7%
New stroke	12.5 – 47.9%
New Kidney (renal) Failure Requiring Dialysis	11 – 43%
Heart Attack (Myocardial Infarction)	6.8 – 16.1%
DANE Tear¥	43.3 – 70%

*Literature: Bossone et al. 2002, Geirsson et al. 2007, Girdauskas et al. 2009, Pacini et al. 2013, Zindovic et al. 2019.

¥ Literature: Bing et al. 2014, Ergin et al 1994; Rylski et al 2017, Tamura et al. 2017.

Summary of Key Results from AMDS Clinical Studies

The AMDS was evaluated in two clinical studies in the United States (PERSEVERE) and in Canada and Germany. A summary of the key results from each study is presented below.

30-Day Results from the PERSEVERE IDE Study

The PERSEVERE Study included 93 patients with malperfusion who were treated with AMDS for acute DeBakey type I dissection at multiple sites within the United States. The objective of the study was to evaluate the number of patients who experienced a major complication (death for any reason, new stroke, new kidney (renal) failure requiring dialysis, and heart attack), as well as the number of patients with a DANE tear. The major complications occurring in patients treated with AMDS within 30 days of the procedure is presented in Table 2 below; the PERSEVERE study is ongoing.

Table 2. Major Complications in the PERSEVERE Study

Complication	Total # of Complications*	Total # of Patients with ≥ 1 Major Complication
Death from any cause	9 (9.7%)	26 (28.0%)
New stroke	11 (11.8%)	
New Kidney (renal) Failure Requiring Dialysis	18 (19.4%)	
Heart Attack (Myocardial Infarction)	0 (0%)	
DANE Tear	0 (0%)	0 (0%)

3-Year Results from the DARTS I Study

The DARTS I Study included 46 patients with or without malperfusion at 5 sites in Canada and 1 site in Germany who were implanted with AMDS to treat an acute DeBakey type I dissection. The objective of the study was to evaluate the number of patients who experienced a major complication (death for any reason, death due to the AMDS procedure, stroke, or other neurologic issue). The major complications occurring in patients treated with AMDS within 30 days of the procedure and through 3-year follow-up is presented in *Table 3*. No patients experienced DANE through 3-year follow-up. The DARTS study is ongoing through 5-year follow-up.

Table 3. Major Complications in the DARTS I Study

Major Adverse Events	Total # of Patients with Complications within 30-Days (%)	Total # of Patients with Complications within 3 Years (%)
Death from any cause	6 (13.0%)	10 (21.7%)
Procedure-related death	1 (2.2%)	2 (4.3%)
All Neurological Events (Stroke, mini-stroke, paralysis)	10 (21.7%)	11 (23.9%)
New Stroke or Mini-stroke	6 (13.0%)	7 (15.2%)
DANE Tear	0 (0%)	0 (0%)

The anticipated benefit to a patient treated with AMDS include reduced 30-day mortality in patients with preoperative malperfusion, complete closure of the intimal flap, and reduction of DANE tears and associated reoperations, when compared with patients treated with a standalone hemiarch repair procedure.

Recovery after the AMDS procedure

What can I expect after the procedure?

Before being discharged from the hospital, your doctor or nurse will explain your post-operative care needs and medication, and address any remaining questions or concerns you have. Regular follow-up appointments will be scheduled with your surgeon and doctor to monitor your healing progress – it is important to attend these appointments.

Will I need more surgery later?

The AMDS™ Hybrid Prosthesis is intended to remain permanently implanted in your aorta to treat your acute DeBakey Type I aortic dissection. The AMDS™ Hybrid Prosthesis has demonstrated long-term durability through benchtop testing. Your physician should confirm with you the requirement for commitment and compliance to life long post-operative follow-up with imaging as necessary to ensure your implant continues to function as required. Some patients may experience disease progression into the descending thoracic aorta after initial treatment of the dissection in the ascending aorta and aortic arch, which may require additional surgery. It is important to attend your annual follow-up visits so that your doctor can monitor your condition. Contact your physician if you begin feeling any side effects, such as abdominal pain, bloody stool, tenderness to palpitation, absence of pulse or decreased mobility in your arms or legs.

Post-operative care

After Surgery

The first follow-up examination usually occurs prior to leaving the hospital. After discharge, further imaging is recommended at 30 days, 6 months, and 1 year post-surgery, and then annually thereafter.

Follow-up

The first year following your surgery, post-operative care is necessary to monitor the outcome of your procedure and review of any complications you experience after surgery. Beyond one year, follow-up appointments and imaging (CT angiography scans or Magnetic Resonance Imaging (MRI)) are used to monitor your aorta and AMDS™ Hybrid Prosthesis.

Lifestyle and wellness

The healing process is different for each person. After completing the recovery and rehabilitation plan as instructed by your doctor, you should be able to continue daily life or work as you did before your surgery. Your chest incision should be healed within 6 to 8 weeks after surgery, with complete healing of your breastbone within approximately 3 months.

Exercises such as walking, swimming, and moderate strength training are suitable once you have healed – avoid excessive physical activity until you have steadily built back your endurance. Enjoyment of a sauna or jacuzzi should occur no earlier than three months after surgery.

Driving and Travel

You should avoid driving a car for the first six weeks after your surgery, as motions while driving (such as looking over your shoulder, turning the steering wheel, etc.) may cause chest pain.

Flying home after being discharged from the hospital is possible – arrangements should be made to minimize physical activity during travel (e.g., wheelchair, luggage assistance, transportation).

Please consult with your doctor regarding travel after your surgery. Long trips can be taken no earlier than three months after surgery. Ensure to bring an adequate supply of medication and a copy of your medical report. Use caution when carrying luggage.

Medication

There is no specific anti-platelet or anticoagulant therapy recommended for patients who have received the AMDS device. After treatment, you may need to take medication to control your blood pressure for the rest of your life. Your postoperative medication will be prescribed per standard medical practice at the discretion of your doctor.

Implant Card

The AMDS™ Hybrid Prosthesis is a metal stent which requires special information for safe MRI scanning; you have been given an implant card which provides the details of safe MRI scanning conditions to be presented to medical practitioners prior to any imaging procedure.

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 healthcare providers and make them aware you have been treated with the AMDS™ Hybrid Prosthesis.

Questions to ask your doctor

- Are you familiar and comfortable treating aortic dissections and how many patients have you implanted with the AMDS™ Hybrid Prosthesis?
- What are the options for treating my acute DeBakey Type I aortic dissection and what are the benefits and risks of each?
- What should I expect after my procedure and how often do I need to follow up with you or my family doctor?
- How critical is it for me to continue the prescribed treatment plan?
- How long will the device be implanted in my body?
- What should I expect if my acute DeBakey Type I aortic dissection is not fixed?
- 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?
- Where can I get more information?

Where can I get more information?

The following websites and academic societies will provide additional information about acute DeBakey Type I aortic dissections, treatment guidelines, information on FDA-approved treatment options and their clinical outcomes. Report any adverse event that occurs during the AMDS procedure or after the AMDS implantation to Artivion Field Assurance at 1-800-438- 8285 or by email to fieldassurance@artivion.com, and to FDA as applicable.

American Heart Association	*americanheart.org*
Mayo Clinic	*mayoclinic.com*
American Association for Thoracic Surgery	*aats.org*
Society of Thoracic Surgeons	*sts.org*
Society for Vascular Surgery	*vascular.org/patients*
Food and Drug Administration	*fda.gov*
US Department of Health and Human Services	*hhs.gov*
US National Library of Medicine	*medlineplus.gov*

Artivion, Inc. is a global medical device company committed to developing solutions which address the challenges that cardiac and vascular surgeons face in treating patients with aortic disease. More information about the AMDS™ Hybrid Prosthesis is available at www.artivion.com.

Indications for Use

The AMDS™ Hybrid Prosthesis is indicated for use in patients with acute DeBakey Type I aortic dissections with malperfusion (including cerebral, visceral, renal and peripheral malperfusion) and a primary entry tear within the ascending aorta proximal to the innominate artery, who are undergoing open surgical repair within 0-14 days of diagnosis.

Contraindications for Use

The AMDS™ Hybrid Prosthesis is contraindicated in the following:

- Patients who exhibit sensitivity to the implant materials (Polytetrafluoroethylene [PTFE] or Nitinol [e.g., Nickel or Titanium]),
- Patients with mycotic aneurysms, aortic fistulous communication with non-vascular structures, uncontrolled systemic infection.

Magnetic Resonance Imaging (MRI) Safety

Conditions for MR Safety

The AMDS™ Hybrid Prosthesis is MR Conditional. A patient with an AMDS implant can be scanned safely in an MR system under the following conditions. Failure to follow these conditions may result in injury. If information about a specific parameter is not included, there are no conditions associated with that parameter. Physicians can consult the IFU for additional details on MR safety.

MR Conditional

Static Magnetic Field Strength (B_0)	1.5-T or 3-T
Maximum Spatial Field Gradient	20-T/m (2,000-G/cm)
RF Excitation	Circularly Polarized (CP)
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration and Wait Time	Up to 60 minutes of scan duration
MR Image Artifact	In non-clinical testing, the image artifact caused by the device extends approximately 12mm from the AMDS™ Hybrid Prosthesis when imaged with a gradient echo pulse sequence and a 3.0-Tesla MR system. The lumen of this stent cannot be visualized on the gradient echo pulse sequence.

Our priority is to collaborate with your doctor to ensure you receive the treatment option that best suits your condition and anatomy.

This leaflet gives an overview of information intended for patients.
Please consult with your doctor for any questions you may have related to your condition or the AMDS procedure.

Artivion, Inc.
1655 Roberts Blvd. NW
Kennesaw, GA 30144
USA
+1-770-419-3355
www.artivion.com

JOTEC GmbH
Lotzenäcker 23
72379 Hechingen,
GERMANY
+49 7471 922-0
www.jotec.com

Australian Sponsor
CryoLife Medical (Australia) Company Pty Ltd.
Level 16, 201 Elizabeth Street
Sydney NSW 2000
AUSTRALIA

OMCS Medical GmbH
Aegeristrasse 5
6300 Zug.
SWITZERLAND

UK Responsible Person
OMC Medical Ltd.
Planet House
North Heath Lane, Horsham
West Sussex, RH12 5QE
UNITED KINGDOM

L09475.001 (2024-12-10)