EN Instructions for Use

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.

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1.0 OVERVIEW OF THE AMDS HYBRID PROSTHESIS

1.1 INTENDED USE

The AMDS™ Hybrid Prosthesis (AMDS) is intended for use in combination with standard surgical hemiarch repair for the treatment of patients with acute DeBakey Type I aortic dissections to re-expand the intimal flap within the ascending aorta and encourage positive remodeling through the aortic arch and descending aorta in patients with malperfusion. The AMDS is intended to be used by trained cardiothoracic surgeons with experience in performing standard hemiarch repair procedures in a surgical suite or the operating room.

1.2 DEVICE DESCRIPTION

AMDS is an implantable, uncovered stent constructed from braided Nitinol wire, attached proximally to a polytetrafluoroethylene (PTFE) felt cuff with polyester (PET) suture (***Figure 1***), which is mounted on a single-use Delivery System using an expanded polytetrafluoroethylene (ePTFE) suture (***Figure 2***).The delivery system consists of a catheter shaft with a pigtail tip that can accommodate insertion of a 0.035" guidewire through the port at the proximal handle. The stent is compressed to the diameter of the catheter shaft, and constrained just proximal to the delivery system tip by:

- An ePTFE suture which is circumferentially knotted around the entire length of the stent to stabilize the stent on the catheter. The ePTFE suture is passed through a skive in the catheter lumen and connected to the green cap (deployment mechanism),
- A clear, protective sheath located on the proximal end of the stent near the cuff, to reduce the profile of the proximal stent for atraumatic insertion of the AMDS system into the transected aorta, which is removed immediately upon stent insertion.

The ePTFE suture constrains the stent during implantation; the green cap is pulled to deploy the stent (proximally, then distally) at the time of implantation. The red cap is non-functional. The AMDS is packaged in a sealed Tyvek® tray within a single unit carton, and provided sterile (Ethylene Oxide), non-pyrogenic, for single use only.

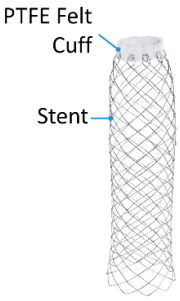


Figure 1. AMDS Stent

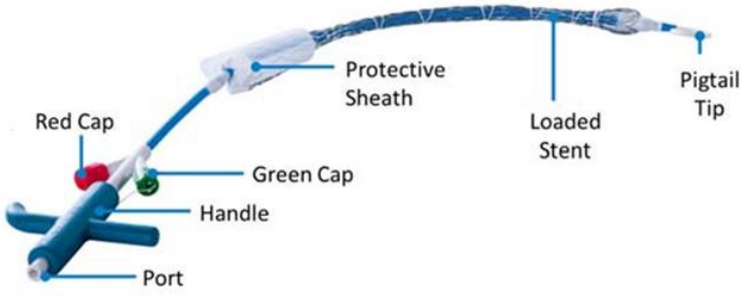


Figure 2. AMDS Delivery System

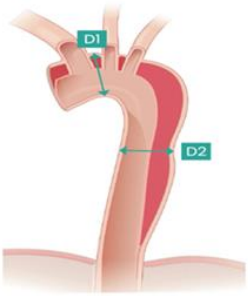


Figure 3. AMDS Sizing

The AMDS uses the uncovered stent component of the device implanted distal to the aortic anastomosis, to expand the true lumen and support the intimal flap, with the goal of promoting remodeling in the aortic arch. In addition, the stent is intended to expand the true lumen and improve the blood flow through the aorta and its tributaries. The AMDS cuff is used to strengthen the distal aortic anastomosis created between a conventional polyester graft and the transected aorta. The main function of the AMDS cuff is to assist in closing the false lumen at the site of the conventional graft to the aorta anastomosis. The entire procedure is performed utilizing an open chest approach while on cardiopulmonary bypass.

The AMDS device is offered in eight configurations based on the stent sizing to fit a range of aortic diameters and lengths (see ***Table 1***). The AMDS stent is available in four straight models (diameters of 40mm and 55mm) and four tapered models (stent diameters tapered from 40mm to 30mm and 55mm to 40mm). The PTFE felt cuff is available in three diameters (24mm diameter for AMDS40 and AMDS4030; 28mm diameter for AMDS40c, AMDS4030c, AMDS55c, and AMDS5540c; and 32mm diameter for AMDS55 and AMDS5540). The AMDS stent is a braided design, resulting in its length being a function of its expanded diameter (i.e. the device lengthens or shortens as its diameter is reduced or increased). The AMDS has an expanded stent free surface area of >95% in all indicated aorta diameters.

Table 1. The AMDS Stent Sizing and Catheter Length

REF	Stent Shape	Aortic Diameter Stent Sizing		Aortic Length Stent Sizing		Cuff Diameter (mm)	Catheter Length (mm)	Minimum Deployment Suture Length (cm)
		D1 Proximal Diameter (mm)	D2 Distal Diameter (mm)	Stent Min Length (mm)*	Stent Max Length (mm)**			
AMDS 40	Straight	20-35	25-35	153	207	24	527	135
AMDS 40c						28		
AMDS 4030	Tapered		20-24	159	203	24		
AMDS 4030c						28		
AMDS 55	Straight	36-45	36-45	187	215	32	565	150
AMDS 55c						28		
AMDS 5540	Tapered		27-35	185	211	32	546	145
AMDS 5540c						28		

* Represents the minimum stent length when stent is expanded to the largest indicated aorta diameter
** Represents the maximum stent length when stent is expanded to the smallest indicated aorta diameter

2.0 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.

3.0 CONTRAINDICATIONS

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

4.0 WARNINGS

- **Professional use only.** The AMDS procedure shall only be performed by physicians trained in cardiac surgery and hemiarch repair. Device sizing must be selected by the physician based on the patient-specific anatomy, utilizing guidelines provided in the AMDS Sizing Chart in ***Table 1*****.** Sizing must be based on measurement of the outer aortic diameter (adventitia to adventitia) based on preoperative imaging. Implantation of the AMDS in anatomy beyond the recommended guidelines may result in patient injury or death. The device has not been studied in patients with a primary entry tear located distal to the innominate artery.
- **For single use only. DO NOT reuse, reprocess, or re-sterilize.** Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which may result in deterioration of health or death of patients. Reuse, reprocessing or re-sterilization may lead to contamination of the device and/or cause patient infection or transmission of infectious disease leading to injury, illness or death of the patient or user.
- **DO NOT** use the device if the labeled expiration date has passed, the packaging is opened or damaged, or the product has been dropped, damaged, or otherwise inappropriately handled. The tray must be intact at the time of use; damage to the seal renders the AMDS non-sterile. If the device or packaging is damaged, return the product to the manufacturer.
- **DO NOT** use the AMDS device in pediatric patients.
- **DO NOT** use a clamp on the PTFE Felt Cuff, Stent, or Delivery System. Clamping may damage the device and result in patient injury.
- **DO NOT** cut the AMDS stent wires; due to the braided wire design, cutting a wire within the stent may cause stent malfunction or vascular damage.
- **DO NOT** deploy the AMDS in the false lumen of the aortic dissection.
- **DO NOT** preclot; the AMDS device; the PTFE felt collar does not require pre-clotting.
- **DO NOT** oversize. Some degree of oversizing is inherently built into the sizing guidance as device selection is based on total aortic diameter adventitia-to-adventitia, while the native true lumen is known to be smaller than this. Device sizing must be selected by the physician based on the patient-specific anatomy, according to the AMDS Sizing Chart in ***Table 1***. Sizing must be based on measurement of the outer aortic diameter (adventitia to adventitia) based on preoperative CT scan imaging. Implantation of the AMDS in anatomy beyond the sizing recommendations (e.g., oversizing) may result in unexpected device conformability (such as stent narrowing).

5.0 PRECAUTIONS

- Physicians should exercise discretion during patient selection for treatment with the AMDS device. Patients with secondary entry tears may present challenging deployment where there is an opportunity for the AMDS to mis-deploy or malposition within the false lumen.
- The AMDS cuff should not be used as a graft to replace the aorta. The AMDS cuff is solely used to buttress and strengthen the anastomosis between the polyester graft and the aorta.
- Differences between the diameter of the AMDS cuff and the diameter of the transected aorta are expected due to the broad range of aortic diameters covered. Malalignment when creating this anastomosis may result in gaps or folds in aortic tissue leading to continued pulsatile flow into the false lumen and/or twisting of the AMDS device.
- Use care to not cut the deployment suture.
- If the AMDS stent is inadvertently mis-deployed in an undesired position within the true lumen, the physician may consider carefully removing the AMDS stent by cutting the tacking sutures and slowly pulling the AMDS stent from the aorta. Withdrawal of the AMDS stent after deployment may lead to vascular damage. A new AMDS stent may then be implanted, taking care to deploy the stent in the desired location. See §13.0, Summary of Clinical Studies and Clinical Benefit for information related to occurrence of mis-deployment in the AMDS clinicals studies.
- Extensive thrombus or calcification in the aortic arch may increase the risk of stroke.
- Excessive aortic tortuosity may preclude safe passage of the device within the aorta.
- Pregnant or breastfeeding women need to be counseled on the radiation risks associated with follow-up CT scans.
- The long-term performance of the AMDS has not yet been established; therefore, patients should be monitored on a regular basis for adverse events, for example false lumen growth.
- The safety and effectiveness of the AMDS has not been clinically studied for use in patients with connective tissue disorders, or subacute or chronic dissections (>14 days after the index event).
- A conventional aortic graft must be anastomosed to the aorta and the conventional graft, aortic wall and the PTFE felt must be incorporated in each suture bite. DO NOT apply tension to the AMDS cuff or proximal graft while suturing the anastomosis, as this may result in stent malposition. When completing the proximal anastomosis, leave the ascending graft long enough to avoid putting tension on the AMDS at the distal anastomosis.
- Device not studied in combination with other hybrid or endovascular stents (e.g., TEVAR endovascular stent).
- The AMDS has not been tested to establish potential of genetic toxicity. Prolonged exposure to genetic toxicants may lead to long term mutagenic and carcinogenic affects. The risks of these potential harms from the product have not been established clinically.

6.0 POTENTIAL ADVERSE EVENTS AND UNDESIRABLE SIDE EFFECTS

Potential adverse effects associated with the hemiarch repair procedure with the use of the AMDS device include, but are not limited to:

- Allergic reaction to device, contrast media, or antithrombotic agents administered during the procedure
- Aortic enlargement or rupture, dissection, perforation or other disease progression requiring future total arch replacement
- Cardiac complication or failure (e.g., arrhythmia, fast heartbeat, cardiac tamponade, heart attack, irregular blood pressure)
- Complications at the surgical site (e.g., infection, fever, pain, or inflammation), hemorrhage and/or bleeding, fistula
- Distal anastomotic new entry (DANE) tears leading to persistent malperfusion or requiring re-operation
- Distal stent-induced new entry tears (dSINE) leading to aortic dissection or requiring reoperation
- Occlusion, stenosis, thrombosis, thromboembolism, and/or pseudoaneurysm (arterial or venous)
- Post-operative malperfusion leading to multi-system organ failure, limb amputation, or death
- Pulmonary complications (e.g., edema, embolism, pneumonia, respiratory failure)
- Neurological, local, or systemic complications (e.g., stroke, transient ischemic attack (TIA), neuropathy, or spinal cord injury with possible paralysis
- Visceral ischemia or gastrointestinal symptoms (e.g., nausea/vomiting, liver failure, renal insufficiency)
- Patients may become unstable under hypothermic circulatory arrest during cardiac procedures

Potential adverse effects that may be associated with the AMDS procedure include, but are not limited to:

- Exposure to contrast media and/or radiation during follow-up visits to visualize the AMDS stent
- Malposition of the AMDS stent in the false lumen of the aorta leading to required reintervention
- Potential difficulties in accessing the arch branch vessels during future interventional procedures
- Overly tortuous arch anatomy, leading to incomplete stent expansion in sections of the aorta

7.0 MAGNETIC RESONANCE IMAGING SAFETY AND COMPATIBILITY INFORMATION

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.

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.

Patients who have other MR Conditional devices can be scanned as long as all the MR Conditional scan parameters for each of the devices are met. Do not conduct an MRI scan if any conditions for safe scanning for any device cannot be met. Nonclinical testing was performed using the thorax as the landmark position for MRI scanning; there are no exclusions. Under the scan conditions defined, an implant from the AMDS Hybrid Prosthesis is expected to produce a maximum temperature rise of 5°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

8.0 PATIENT SELECTION AND TREATMENT

8.1 PATIENT SELECTION

Each patient should be evaluated by their physician to determine if hemiarch repair with the AMDS™ Hybrid Prosthesis is the most appropriate treatment for their acute DeBakey Type I aortic dissection. Consideration should be given to the individual patient condition, including age and life expectancy, comorbidities, patient tolerance for general anesthesia, cardiopulmonary bypass and hypothermic circulatory arrest, presence of secondary entry tears that may necessitate future procedures (e.g., a more extensive total arch repair with or without a frozen elephant trunk device), and the ability and willingness of the patient to complete the recommend clinical and imaging follow-up visits after the procedure.

8.2 DEVICE SIZING GUIDELINES

The aorta is sized based on a contrast enhanced CT scan or MR- Angiography of the chest using 2D and/or 3D imaging. Using the pre-op CT scan, measure the aortic vessel diameters (defined by adventitia-to-adventitia [outer wall to outer wall] measurements):

- D1: Measure the proximal diameter at the level between the innominate and left common carotid artery.
- D2: Measure the distal diameter at the level of the tracheal or pulmonary artery bifurcation to determine the tapered or straight configuration.

The operator can also estimate the ultimate length of the AMDS using **Table 1 and Figure 3** to approximate distal landing zone.

8.3 PATIENT COUNSELING

The physician should counsel the patient on all associated risks and benefits of the AMDS™ Hybrid Prosthesis and its associated procedures, preferably in written form, including but not limited to:

- Patient age, risks, and benefits of the procedure with respect to the patient condition and comorbidities, and life expectancy
- Risks related to other treatment options (e.g., medical management, alternative surgical options, non-intervention)
- Safety and probable benefit of the AMDS™ Hybrid Prosthesis with the possibility of future reinterventions for disease progression
- Long-term follow-up and periodic imaging appointments needed to assess the status of the patients' health and device performance
- Symptoms of specific clinical sequelae (e.g., continued perfusion to the false lumen through secondary tears)

9.0 DEVICE STORAGE, RETURNS AND DISPOSAL

The AMDS, in its protective packaging, should be stored at room temperature, specifically not less than 0°C and not more than 25°C, and in a dry location. At the end of the procedure, care must be taken to ensure safe disposal of the AMDS delivery system. The surgical team should dispose of the AMDS delivery system in a biohazard waste disposal per hospital procedures.

Prior authorization from Artivion Customer Service is required for the return of any product. For any questions regarding AMDS or for return authorization, please contact Customer Service.

10.0 EQUIPMENT

- Surgical instruments for standard hemiarch repair
- Conventional ascending aorta polyester graft
- Sterile drape
- Sterile surgical sutures
- Standard PTFE Surgical Felt
- 0.035" stiff guidewire intended for cardiac procedures (Optional)

11.0 DIRECTIONS FOR USE – AMDS PROCEDURE

11.1 Preparation of the Aorta and Distal Anastomosis

The ascending aorta is transected and removed in a routine manner utilizing hypothermic circulatory arrest. The operator must ensure to leave at least 10 mm (1.0 cm) aortic tissue proximal to the native arch branch vessels that will be preserved in order to leave room for the 10mm PTFE felt portion of AMDS and avoid interruption of flow to the supra-aortic vessels. Initially the lesser curvature should be left longer to simplify the attachment of the AMDS to the aorta. The excess aortic tissue should be resected up to the level of the AMDS PTFE graft after the AMDS is secured to the aorta and prior to performing the anastomosis to the conventional graft. More than 1.0 cm of aortic tissue should be left in place proximal to the innominate artery or any of the arch branches that are intended to be preserved (***Figure 4***). Visually inspect the aorta to identify the true and false lumen prior to AMDS insertion.

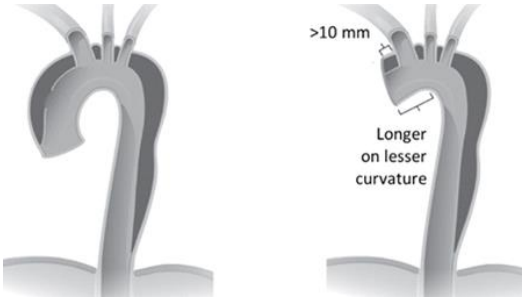


Figure 4. Preoperative intact ascending aorta (Left) and transected aortic prepared for the AMDS (Right)

11.2 AMDS System Preparation

Visually inspect the device packaging. If the package has been previously opened or the seal is damaged, discard and replace with a new package. Pre-soak the AMDS in saline. After soaking, flush the catheter with saline through the port using a 10mL sterile syringe until saline exits the pigtail tip.

WARNING: Do not remove the protective sheath until the device is advanced in the vessel. Premature removal of the protective sheath may result in device damage or early expansion, which may result in patient injury.

11.3 AMDS Insertion and Positioning

11.3.1 Insert the AMDS into the true lumen through the open distal aorta until the PTFE Felt Cuff is in the same plane; use of a stiff 0.035" guidewire (e.g. Lunderquist or alternative) is optional to ensure insertion into the true lumen. If a guidewire is used, it should be inserted via transfemoral approach prior to placing the patient on cardiopulmonary bypass (CPB) or while on CPB prior to inducing hypothermic arrest. Confirm guidewire position within the true lumen using TEE or IVUS.

11.3.2 Insert AMDS into the true lumen of the aorta until the cuff of the device is in the same plane as the transected distal aorta. The device is symmetrical and therefore does not require rotational orientation (***Figure 5***).

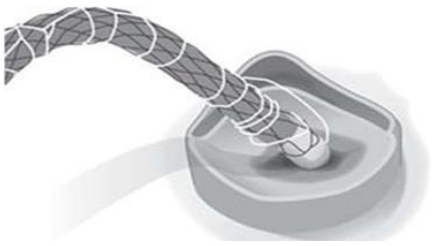


Figure 5. Insertion of the AMDS into transected aorta

CAUTION: Avoid twisting the system when inserting and deploying the stent to ensure complete expansion.

11.3.3 Following insertion of the delivery system into the aorta, confirm the AMDS stent is located in the true lumen prior to deployment.

CAUTION: Failure to deploy the stent in the true lumen may result in device malposition, persistent false lumen malperfusion or persistent malperfusion of the visceral organs, prolonged procedure time, and/or explant of the AMDS stent with or without a second AMDS implantation.

11.4 AMDS DEPLOYMENT

11.4.1 After the AMDS is positioned in the aorta and the edge of the AMDS collar is at the level of the transected edge of the aorta, retract the protective sheath to fully expose the cuff (see **Figure 6**). Remove the protective sheath and discard.

11.4.2 Stabilize the cuff by placing interrupted sutures to tack the cuff to the proximal-most inner aspect of the transected aorta (***Figure 7***). Use of a surgical PTFE felt strip external to the aorta is highly recommended to avoid excessive tension on or tearing of the aorta. Align the AMDS cuff with the adjacent section of the aorta and place 4 tacking sutures respectively approximately 90° apart. Repeat across the entire 360-degree circumference of the aorta. Once the AMDS cuff is tacked to the aorta, visually inspect the supra- aortic branches to ensure to avoid any inadvertent blockage of these vessels by the PTFE felt component

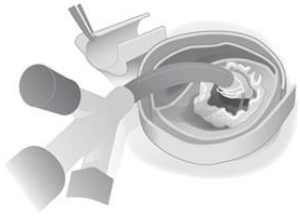


Figure 6. Position cuff at edge of transected aorta

Figure 7. Suture cuff to transected aorta

CAUTION: While placing the tacking sutures, use care to ensure that the tacking suture is not looped around the deployment suture as this may cause damage to the deployment suture.

11.4.3 If a guidewire was used, it should be removed prior to deployment of the AMDS stent. While an assistant stabilizes the AMDS cuff to the aorta using gentle vascular pickups, unscrew the green cap in a counterclockwise fashion to release the green cap in preparation to pull the deployment suture. Pulling the deployment suture will open the stent from a proximal to a distal direction on the delivery system. The operator should then:

- maintain grip of the AMDS handle to prevent rotation of the delivery system
- pull the deployment suture back until it is completely free of the delivery system and AMDS stent is fully deployed

CAUTION: Avoid forward pressure or rotation on the delivery system during deployment of the stent.

11.4.4 Following the deployment of the device (pulling of the green cap), ensure the entire deployment suture is removed, confirming that the device is in a fully deployed position. The minimum deployment suture length for each configuration is referenced in **Table 1**.

CAUTION: If mis-deployment occurs (e.g., the stent is mal-positioned or fails to expand within the aorta), the implant may be carefully removed by cutting the tacking sutures (e.g., sutures previously placed to attach the cuff to the aorta) and slowly pulling the AMDS stent (with or without the delivery system) from the aorta. Withdrawal of the AMDS stent may lead to vascular damage.

11.4.5 Once the stent is released and disengaged from the delivery mechanism, remove the delivery system, making sure the tip of the delivery system is free from the distal end of the stent. If resistance is felt during delivery system removal after the AMDS is deployed, a guidewire may be placed through the delivery system to uncurl the tip to straighten the delivery system.

CAUTION: Do not forcefully pull on the delivery system after deployment of the AMDS, as the tip may be caught within the stent struts which may result in stent malposition or dislodgement.

CAUTION: Balloon dilatation of the AMDS stent is not recommended and should not be used to dilate the stent frame under normal use or in the event of limited stent expansion; balloon dilatation of the stent may lead to vascular trauma, stent migration, or aortic rupture.

11.5 ANASTOMOSES

11.5.1 Once the delivery system is removed, confirm successful deployment through visual inspection by looking within the aorta to see that the stent is fully deployed and then prepare the aortic anastomosis.

11.5.2 Completely secure the aortic layers by running a continuous suture layer circumferentially around the transected aorta, attaching the AMDS cuff through the aorta and to the external PTFE felt strip (see ***Figure 8A*** and ***Figure 8B***). There should be no folding of the inner felt as it may allow blood flow to find its way to the false lumen once flow is established. It may be helpful for an assistant to stretch the inner AMDS felt layer while completing the anastomosis.

11.5.3 Once this suture line is complete, any of the approved aortic replacement grafts may be chosen and the graft to aorta distal anastomosis performed in a conventional way. All dissected aortic tissue should be removed proximal to the AMDS. The anastomosis between the conventional polyester graft and the AMDS-aorta complex should be performed with each suture bite incorporating the conventional graft and the surgical felt-aorta- AMDS cuff complex creating a meticulously tight seal between the PTFE felts and the dissected aorta. This technique in essence allows the operator to anastomose the conventional graft to the AMDS "washer" created from surgical felt-aorta-AMDS cuff to create a sealed and secure anastomosis (***Figure 8C***). Routine intra-op and/or post-op imaging may be performed to confirm deployment and/or position of the device.

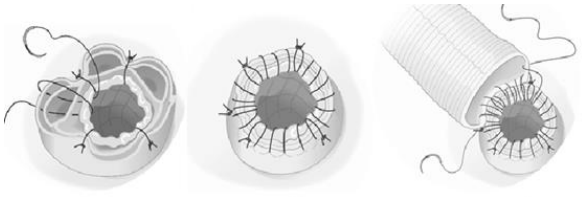


Figure 8. Complete the sequential anastomoses steps

CAUTION: The conventional aortic graft must be anastomosed to the aorta incorporating the conventional graft, aortic wall and the PTFE felt in each suture bite.

12.0 PATIENT FOLLOW-UP

All patients should undergo periodic imaging as advised by their physician. Patients experiencing reduced blood flow through the true lumen or dilation of the false lumen may need additional interventions.

No specific anti-platelet or anticoagulant therapy is recommended for patients who have received the AMDS device. Hence, postoperative anti-platelet or anticoagulant therapy should be instituted in accordance with standard practice following surgical repair of ATAD and at the discretion of the treating medical team.

13. SUMMARY OF CLINICAL STUDIES AND CLINICAL BENEFIT

Clinical studies were performed in the United States (PERSEVERE, NCT # NCT05174767) and in Canada and Europe (DARTS I Study, NCT # NCT03397251, NCT03035643) to establish a reasonable assurance of safety and probable benefit for treatment of patients with Acute DeBakey I dissections with the AMDS as an adjunct to conventional surgery (e.g., ascending/hemiarch repair). A summary of the PERSEVERE Pivotal IDE and DARTS I investigational clinical study is presented below, along with additional supplemental clinical data supporting the safety of the AMDS in real-world use.

13.1. SUMMARY OF CLINICAL STUDY (PERSEVERE)

The PERSEVERE Study is a prospective, single-arm, multi-center pivotal IDE study of the AMDS for treatment of patients with Acute DeBakey I dissections with clinical or radiographic malperfusion. A total of 93 patients were included in the study; the first patient was enrolled in July 2022 and the last patient was enrolled in November 2023 and 26 sites participated within the United States. Patients were consented pre-operatively and were considered enrolled only after AMDS implantation. The intended study follow-up period is 5 years after AMDS surgery. Data used in this analysis was exported on 22-Dec-2023. This includes complete, 30-day adjudicated follow-up data of 78 subjects for the primary endpoint analysis; secondary endpoint data and longer term data is not yet completely adjudicated.

The PERSEVERE study has two co-primary endpoints to establish safety and effectiveness which are defined below:

- Patients experiencing at least one of the following major adverse events (MAEs) occurring ≤ 30-days post-procedure: all-cause mortality, new disabling stroke, new onset renal failure requiring dialysis, and myocardial infarction.

  The results were tested against a performance goal of 58% derived from published clinical outcomes after the standard of care (hemiarch procedure), calculated as the average of the 5 estimations for the total number of patients with at least one in-hospital MAE in the malperfusion reference cohort[1]. Sample size was calculated assuming enrollment of 93 patients with an expected drop-out rate of 10% at 30-days, which would leave 84 patients required to achieve the statistical assumptions under an assumed true AMDS 30-day MAE rate of 40%.

- Patients with Distal Anastomotic New Entry (DANE) tears documented by the independent Core Lab on a post-operative CTA ≤ 30 days post-procedure. The results will be tested against a performance goal of 45% derived from the weighted average of published DANE rates after the standard of care (hemiarch procedure) as reported in the DANE reference cohort[2]. Sample size was calculated assuming a minimum of 21 patients required to achieve the statistical assumptions under an assumed true AMDS 30-day rate of 10%.

For each co-primary endpoint, a one-sided exact binomial test will be used to construct the 95% exact (Clopper-Pearson) confidence interval ($\alpha = 0.025$).

A preliminary analysis was conducted to establish an assurance of safety and probable benefit based upon the co-primary endpoints stated above using 30-day follow-up data in all 93 patients enrolled in the PERSEVERE study. External evaluation groups used during the PERSEVERE study included:

- A Core Laboratory was used to perform independent assessments of computed tomography (CT)/computed tomography with angiography (CTA), X-Ray and duplex ultrasound (DUS) imaging submitted by clinical sites. The Core Laboratory assessments were used in the 30-day analysis.
- An external Clinical Events Committee (CEC) adjudicated co-primary endpoint events and select adverse events.

13.1.1 Inclusion and Exclusion Criteria

The patient population included patients who were ≥18 years of age or ≤80 years of age at time of surgery, with acute DeBakey type I dissection based on computed tomography angiography (CTA) and diagnosed ≤14 days from of the index event, with the presence of malperfusion (cerebral, visceral, renal, spinal cord, and/or peripheral). Patients were not permitted to enroll in the study if they met any of the following key exclusion criteria (this is not a comprehensive list):

- A primary entry tear that extends into the aortic arch or distal to the left subclavian artery
- Need for a total aortic arch replacement and/or repair or reconstruction of any part of the arch and branch vessels (including extra-anatomic bypass of the branch vessels), for any reason, as deemed necessary by the Investigator
- Aortic fistulous communication with non-vascular structure (e.g., esophagus, bronchial)
- Extensive thrombus or calcifications in the aortic arch as defined by CTA
- Excessive tortuosity precluding safe passage of AMDS as defined by CTA
- Descending thoracic aneurysm involving the proximal third (one-third) of the descending aorta and measuring >45 mm in diameter
- Aortic arch aneurysm >50 mm in diameter
- Coronary malperfusion
- In circulatory shock (i.e., systolic blood pressure <90 mmHg) at time of screening
- In extreme hemodynamic compromise requiring cardiopulmonary resuscitation at time of screening
- Suspicion of bowel necrosis (as determined by the implanting physician based on imaging observations, peritoneal signs, surgical exploration, elevated serum lactate levels, low pH , and/or acidosis)
- Clinical or radiographic signs of bowel infarction or gastrointestinal hemorrhage
- Base deficit > -10 mmol/L or -10 mEq/L
- Previous placement of a thoracic endovascular graft
- Interventional and/or open surgical procedures 30 days prior to the dissection repair
- Planned major interventional and/or open surgical procedures 30 days post the dissection repair
- Previously diagnosed with Marfan syndrome, Ehlers-Danlos syndrome, or Loeys-Dietz syndrome based on laboratory genetic testing
- Diagnosed with acute myocardial infarction in the 30 days prior to the dissection diagnosis
- Diagnosed with severe and catastrophic neurological complications in the 30 days prior to the dissection diagnosis (i.e., obtundation or coma)
- Current Stage 5 End stage chronic kidney disease (estimated Glomerular Filtration Rate [eGFR] ≤ 15 mL/min)

13.1.2 Schedule of Assessments

[1] Bossone et al., Geirsson et al., Girdauskas et al., Pacini et al, Zindovic et al.
[2] Bing et al., Ergin et al., Rylski et al., Tamura et al.

Patients were evaluated at baseline for study eligibility, monitored from the start of the procedure through discharge, and followed per the study protocol as shown in ***Table 2***.

Table 2. PERSEVERE Study Visit Schedule of Assessments

PROTOCOL ACTIVITY	Visit 1	Visit 2		Visit 3	Visit 4	Visit 5	Visits 6-9
	Pre-Op	Procedure	Discharge	30-days	3-6 months	1 year	2- 5 years
	⩽14 days from procedure	<24 hrs post-op	⩾ 24 hrs post-op	+/-14 days	+/-7 days	+/- 8 wks	+/- 12 wks
Informed Consent, Eligibility and Baseline Assessments	X						
Concomitant Medication and Patient Exam	X		X	X	X	X	X
Blood tests	X	X	X	X	X	X	X
CT /CTA Imaging Evaluation (chest/ abdomen & pelvis)	X			X	X	X	X
Brain Imaging (CT and/ or MRI) and NIHSS in patients with stroke per site procedure	*	*	*	*	*	*	*
Electrocardiogram (ECG)			X				
mRS	X		X		*	*	*
Procedure & Device Sizing and Technical Success		X					
Adverse Events and additional Post-Op Procedures		X	X	X	X	X	X
Quality of Life Assessment (SF-12v2)			X	X	X	X	X
Procedural /Treatment Success				X	X	X	X

X=Study Specific Activity [includes data collection only]

*Abbreviations: mRS =modified Rankin Score; NIHSS = National Institutes of Health Stroke Scale; Pre-op = preoperative; Post-op= post-operati wks = weeks; hrs=hours; SF-12 = 12-item Short Form Survey; * indicates per site based on standard of care*

13.1.3 Clinical Endpoints

The co-primary endpoints include the following:

- Patients experiencing at least one of the following major adverse events (MAEs): all-cause mortality, new disabling stroke, new onset renal failure requiring dialysis, myocardial infarction ≤ 30-days post-procedure. The co-primary endpoint was compared to a performance goal of 58%.
- Patients with DANE tears documented by the independent Core Lab on a post-operative CTA ≤ 30-days post-procedure. The co-primary endpoint was compared to a performance goal of 45%.

The PERSEVERE pivotal study preliminary main analysis was considered successful if the lower limit of the 95% confidence interval, associated with the proportion of patients who experience at least one MAE (all-cause mortality, new disabling stroke, new onset renal failure requiring dialysis, or myocardial infarction) at 30-days post procedure is less than 58%, and the lower limit of the of the 95% confidence interval associated with the proportion of patients who experience a DANE tear at 30-days post procedure is less than 45%.

The secondary safety endpoints included are assessed at all post-discharge visits:

- Analysis of rates of MAEs, mortality, additional aortic procedures, device related events, false lumen response, and branch vessel patency and their corresponding 95% exact (Clopper-Pearson) confidence intervals will be reported. Additional major adverse events included in the secondary endpoint analysis are listed below:
    - Aortic rupture
    - Bowel ischemia
    - Hypersensitivity
    - Myocardial infarction
    - New disabling and non-disabling stroke
    - New postoperative paraplegia/paraparesis
    - New postoperative organ malperfusion, including cerebral, coronary, visceral, renal, spinal cord, and peripheral
    - New onset renal failure requiring dialysis
    - Pseudoaneurysm
    - Recurrent laryngeal or phrenic nerve injury
    - Respiratory failure (need for reintubation or ventilator dependence >48 hours)
    - Severe heart failure requiring mechanical circulatory support
    - Thromboembolic adverse events

The secondary effectiveness endpoints included:

- Remodeling outcomes (measurement and change in total aortic diameter, true lumen diameter, false lumen diameter, clinically meaningful (≥ 6.0mm) true lumen expansion, and false lumen response were summarized descriptively at each post-discharge visit.
- Analysis of Secondary Composite Endpoints of technical and procedural success rates and their corresponding 95% exact (Clopper-Pearson) confidence intervals were reported, as defined below:
    - *Technical Success at conclusion of the index procedure*: Delivery and accurate placement of the device at the intended implantation site and retrieval of the device delivery system, patency of the device and aortic arch vessels at the conclusion of the procedure, and no need for unanticipated or emergency surgery to correct a device malfunction or reintervention due to device-related complications.

- *Procedural Success at 30-days post-procedure*: Death, major adverse ischemic events, including new disabling stroke (modified Rankin Score [mRS] > 2 with change from baseline > 1), new postoperative paraplegia or paraparesis, new ischemia due to branch vessel compromise related to the procedure, and distal procedure-related thromboembolic events, and any additional unplanned surgical or interventional procedures related to the device since completion of the original procedure.

13.1.4 Patient Accountability and Compliance to Follow-Up

At the time of analysis, pre-procedure and procedure data was available for all 93 enrolled patients, with 30-day post-operative data available for 78 patients. Currently, 15 patients have died and one patient withdrew from the study. Subject status and data availability is shown in ***Table 3***.

Table 3. PERSEVERE Subject Status, Follow-Up Compliance and Imaging Quality Summary

Visit Details		Subjects with Data for Visit and Subject Status						Imaging Compliance and Quality to Assess Parameters of Interest[5]		
Visit #	Visit Description	Eligible for follow-up[1]	Subjects with Data for Visit	Subjects with Visit Missed or Pending	Death Prior to Indicated Visit	LTF/ Withdrawn Prior to Indicated Visit	Not due for next visit[4]	CT/CTA read by Core Lab	TL Diameter at Zone 3	DANE
		#	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
1	Pre-Op	93	93/93 (100%)	0/93 (0%)	NA	NA	NA	91/93 (97.8%)	89/93 (95.7%)	NA
2	Procedure	93	93/93 (100%)	0/93 (0%)	0/93 (0%)	0/93 (0%)	0 (0%)	NA	NA	NA
3	30-days[2]	93	78/93 (83.9%)	6/93 (6.5%)	9/93 (9.7%)	0/93 (0%)	9/93 (9.7%)	68/93 (73.1%)	63/93 (67.7%)	61/93 (65.6%)
4	31-180 days[3]	75	54/75 (72.0%)	18/75 (24.0%)	3/75 (4.0%)	0/75 (0%)	54/75 (72.0%)	43/75 (57.3%)	41/75 (54.7%)	41/75 (54.7%)
5	181-365 days	18	9/18 (50%)	5/18 (27.8%)	3/18 (16.7%)	1/18 (5.6%)	9/18 (50.0%)	6/18 (33.3%)	6/18 (33.3%)	5/18 (27.8%)

[1] Eligible for follow-up = eligible for follow-up from the previous interval – [death+LTF+not due for next visit]

[2] This time period includes >24 hours post-procedure through 30-days; the CTA data indicates data available within the 30-day visit window.

[3] Subjects pending includes those within the window who did not have data entry at time of data export.

[4] Those subjects that are "Not due for next visit" are those subjects that are not within the follow-up window for the next interval.

[5] The data represents the existence of available data; these numbers do not reflect incidence of reported events.
Abbreviations: EFU=Eligible for Follow-up, NA=Not applicable, CT=computed tomography, CTA=computed tomography angiography, TL=true lumen, LTF=lost-to-follow-up, DANE= distal anastomotic new entry

13.1.5 Study Population and Baseline Characteristics

A total of 93 patients with acute DeBakey Type I dissection were enrolled in PERSEVERE. Patients were mostly male (78.5%) with a mean age of 58.6 ± 9.45 years and average body mass index (BMI) of 29.69 ± 7.18 kg/m^2). All patients presented with preoperative clinical (80%) or radiographic (20%) malperfusion syndrome in at least one organ system. Comorbidities most commonly included history of coronary artery disease (CAD) (11.8%), cardiac arrhythmia (20.4%) and prior myocardial infarction (3.2%), diabetes (15.1%), and chronic obstructive pulmonary disease (COPD) (10.8%) (see ***Table 4***).

Table 4. Patient Baseline Characteristics (PERSEVERE)

Characteristics	Total Patients (n=93)
Demographics and Baseline Characteristics	
Age	58.6 ± 9.45
% Male	78.5%
Preoperative Clinical / Radiographic Malperfusion	80% clinical / 20% radiographic
Race	
Asian	1 (1.1%)
Black or African American	21 (22.6%)
White	56 (60.2%)
Unknown or missing	14 (15.1%)
Ethnicity	
Non-Hispanic	73 (78.5%)
Hispanic or Latino	10 (10.8%)
Unknown or missing	10 (10.8%)
Aortic Arch Anatomy	
Normal (3 great vessels)	66 (71.0%)
Bovine Arch	21 (22.6%)
Isolated Vertebral	5 (5.4%)
Not documented/assessed	2 (2.2%)
Primary entry tear in Zone 0 documented by Core Lab	92.5% (86)
Primary entry tear beyond Zone 0 documented by Core Lab	4.3% (4)
Primary entry tear data missing	3.2% (3)
Risk Factors – No of Patients (%)	
Cardiac Arrhythmia	20.4% (19)

Table 4. Patient Baseline Characteristics (PERSEVERE)

Characteristics	Total Patients (n=93)
Congestive Heart Failure (CHF)	4.3% (4)
Coronary Artery Disease (CAD)	11.8% (11)
Chronic Pulmonary Obstructive Disease (COPD)	10.8% (10)
Peripheral Arterial Disease	0% (0)
Hypertension	45 (48.4%)
Liver Disease	5 (5.4%)
Cancer	11 (11.8%)
Chronic Renal Insufficiency requiring dialysis	1 (1.1%)
Diabetes	14 (15.1%)
Prior Stroke	5 (5.4%)
Prior TIA	5 (5.4%)
Prior Myocardial Infarction	3 (3.2%)
Prior Thromboembolic Event (DVT)	4 (4.3%)
Prior CABG	0% (0)
Prior PCI	5 (5.4%)
Previous Cardiac Intervention – Other	4 (4.3%)

13.1.6 Procedural Characteristics

Hemiarch repair was performed in 100% of patients, with concomitant procedures performed in 85% of patients. The duration for the total procedure and AMDS implantation is shown in ***Table 5***.

Table 5. Procedural Characteristics (PERSEVERE)

Procedural Characteristics		% Patients
Concomitant Procedures	None (Hemiarch + AMDS only)	13 (14.0%)
	Aortic Root Repair or Replacement	35 (37.6%)
	Aortic Valve Repair or Replacement	21 (22.6%)
	Coronary Artery Bypass Surgery (CABG)	5 (5.4%)
	Other	24 (25.8%)
		Median (Range)
Procedure Times (minutes)	AMDS Deployment Time (min)	4 (0-11)
	Cardiopulmonary Bypass (CPB) Duration Time (min)	175.5 (91-403)
	Hypothermic Circulatory Arrest (min)	28 (0-168)
	Cerebral Perfusion Time (min)	28 (10-230)
	Total AMDS Implantation Time (min)	15 (5-277)

13.1.7 Co-Primary Endpoints

Complete, adjudicated data included in the co-primary endpoint for major adverse events (MAE) occurring within 30 days post-procedure are shown in ***Table 6***. The imaging Core Lab found 0 DANE tears (95% CI: 0%, 3.9%) in any of the 61 CTAs which were evaluated at Visit 3 (30-days) and had sufficient quality to analyze the image and which met the minimum sample size (21 patients) required to meet the statistical assumptions (compared to a performance goal of 45% (95% CI: 18.7%, 37.2%) compared to the performance goal of 58% (95% CI: 49.95%, 66.63%). The co-primary endpoints were met based upon the 30-day data.

Table 6. Primary Endpoint Events (PERSEVERE)

Major Adverse Events	Total Number of Events Adjudicated (% Patients)
All-cause Mortality	9 (9.7%)
New Disabling Stroke	11 (11.8%)
New Onset Renal Failure Requiring Dialysis	18 (19.4%)
Myocardial Infarction	0 (0%)
Co-Primary Endpoint: Total # of Patients with ≥ 1 MAE	**26 (28.0%)**
Co-Primary Endpoint: # of Patients with Distal Anastomotic New Entry (DANE) Tear	0 (0%)

*New disabling stroke (defined as a change in the modified Rankin Score (mRS) > 2, with a change from baseline > 1).

13.1.8 Results of the Secondary Endpoints

The following MAEs were observed at any point in follow-up (listed from most to least observed, with adjudicated rates where applicable): new onset of renal failure requiring dialysis (18.3%), respiratory failure (18.3%), new post-operative organ malperfusion (14%), new disabling stroke (8.6%), thromboembolic events (8.6%), new non-disabling stroke (3.2%), bowel ischemia (2.2%), and myocardial infarction (2.2%). Aortic rupture, pseudoaneurysm, hypersensitivity, new post-operative paraplegia or paraparesis, recurrent laryngeal or phrenic nerve injury, and severe heart failure requiring mechanical circulatory support were not observed. There were no unanticipated device-related reoperations and no explants. Considering all CTAs evaluated by the imaging Core Lab, there was no radiographic evidence of DANE, d-SINE, device migration, stent fracture, kink, or twist.

Technical success (delivery, deployment, catheter retrieval, AMDS and aortic arch vessel patency, freedom from device-related malfunction or reintervention) was reported in 98.9% of patients; in one patient the AMDS stent was inadvertently implanted in the false lumen through a distal secondary entry tear false lumen with no injury or clinical sequelae.

Procedural success was achieved in 80.9% (n=72 of 89 patients) of complete cases or those patients who had a 30-day visit completed and/or patients who had an MAE ≤ 30 days from the AMDS procedure. Four patients were missing data. Seventeen patients did not achieve procedural success for the following reasons: 9 patients died, 7 patients had new disabling stroke (including one patient who failed technical success), and 1 patient who had new ischemia due to branch vessel complication. There were no cases of new paraplegia or paraparesis or distal procedure-related thromboembolic event. There were also no additional unplanned procedures related to the device within 30-days. Procedural success information was not available for 4 patients at the time of data export. There were no subgroup analyses conducted for the PERSEVERE study.

13.1.9 Aortic Remodeling through 30-Day Follow-Up

The aorta was analyzed at zones 1-3 to evaluate the change in maximal total aortic diameter, true lumen and false lumen diameter (***Table 7***), as well as false lumen status (***Table 8***). Aortic zones were defined by the Society of Thoracic Surgeons (STS)/Society of Vascular Surgeons (SVS) Aortic Zone Classification (see ***Figure 9***). The number of scans for each endpoint at each timepoint varied due to CTA quality issues, as well as anatomical and implant variations.

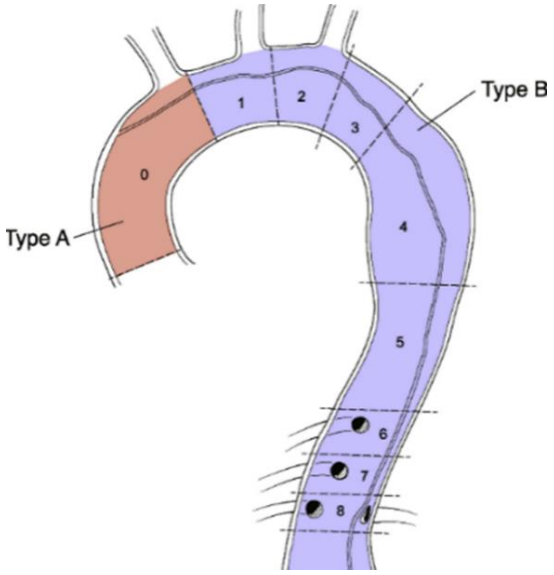


Figure 9. STS/SVS Aortic Zone Classification

Table 7. Aortic Remodeling – Change from Baseline through 30-Day Follow-Up [Mean (SD)]

Aortic Zone	Total Aortic Diameter (mm)		True Lumen Diameter (mm)		False Lumen Diameter (mm)	
	Discharge (n=48)	30-Days (n=68)	Discharge (n=48)	30-Days (n=68)	Discharge (n=48)	30-Days (n=68)
Zone 1	0.50 (2.923)	0.47 (3.331)	11.22 (4.973)	12.21 (4.931)	10.74 (4.259)	-11.34 (6.207)
Zone 2	0.86 (3.057)	1.34 (3.651)	11.34 (4.361)	12.08 (4.901)	-10.39 (4.790)	-10.69 (5.426)
Zone 3	1.73 (2.290)	3.32 (3.319)	5.92 (4.527)	6.72 (5.376)	-4.27 (4.716)	-3.37 (5.921)

Table 8. Aortic Remodeling – Change from Baseline at Discharge and 30-Day Follow-Up [n (%)]

Aortic Zone	Discharge (n=71)				30-Days (n=69)			
FL Status	Completely Thrombosed	Partially Thrombosed	Patent	Not Assessed	Completely Thrombosed	Partially Thrombosed	Patent	Not Assessed
Zone 1	9 (9.7%)	21 (22.6%)	1 (1.1%)	40 (43.0%)	11 (14.1%)	29 (37.2%)	10 (12.8%)	19 (24.4%)
Zone 2	8 (8.6%)	27 (29.0%)	6 (6.5%)	30 (32.3%)	7 (9.0%)	41(52.6%)	12 (15.4%)	9 (11.5%)
Zone 3	6 (6.5%)	28 (30.1%)	7 (7.5%)	30 (32.3%)	4 (5.1%)	46 (59.0%)	10 (12.8%)	9 (11.5%)
Zone 4	2 (2.2%)	35 (37.6%)	5 (5.4%)	29 (31.2%)	0 (0.0%)	50 (64.1%)	9 (11.5%)	10 (12.8%)
Zone 5	2 (2.2%)	31 (33.3%)	8 (8.6%)	30 (32.3%)	0 (0.0%)	45 (57.7%)	13 (16.7%)	11 (14.1%)

13.2. Summary of Additional Clinical Study (DARTS I)

The DARTS I Study is a prospective, single-arm, multi-center study of the AMDS for treatment of patients with Acute DeBakey I dissections. A total of 46 patients met the protocol eligibility criteria and were enrolled at 5 sites in Canada (n=39) and 1 site in Germany (n=7) over a period spanning approximately 2 years (between March 2017 and January 2019). Patients are to be followed for 5 years. The results of the study were compared to literature-based results reported for ascending/ hemiarch repair using descriptive statistics. An independent core laboratory evaluated the imaging obtained during the study, including true lumen and total aortic diameter measurements, false lumen status, and the presence of re-entry tears. The study did not include a Clinical Events Committee nor a Data Safety Monitoring Board.

13.2.1 Inclusion and Exclusion Criteria

The study population included patients with acute DeBakey Type I aortic dissection. Patients were not permitted to enroll in the study if they met any of the following exclusion criteria:

- ≤18 years of age or over 80 years of age
- Life expectancy less than 2 years
- Patient in extreme hemodynamic compromise requiring cardiopulmonary resuscitation (CPR)
- Inability to obtain CT angiograms for follow-up
- Patients previously diagnosed with Marfan syndrome, Ehlers- Danlos syndrome or Loeys- Dietz syndrome based on laboratory genetic testing on a date prior to the diagnosis of the dissection
- Any pathology of mycotic origin
- Subacute or chronic dissection (>14 days after the index event)
- Aortic fistulous communication with non-vascular structure (e.g. esophagus, bronchial)
- Extensive thrombus or calcifications in the aortic arch
- Excessive tortuosity precluding safe passage of the AMDS
- Descending thoracic aneurysm involving the proximal third (1/3) of the descending aorta and measuring > 45 mm in diameter.
- Aortic arch aneurysm > 45 mm in diameter (Germany only)

13.2.2 Schedule of Assessments

Patients were evaluated at baseline for study eligibility, monitored from the start of the procedure through discharge, and followed per the study protocol as shown in ***Table 9***. Imaging included CT/CTA scans.

Table 9. DARTS I Study Visit Schedule of Assessments

PROTOCOL ACTIVITIES	Pre-Op[1]	Procedure	Post-Procedure (Discharge)	4-6 Weeks Post-Op[2] (+/- 2 weeks)	12 Weeks Post-Op (+/-2 weeks)	24 Weeks Post-Op (+/- 4 weeks)	1-5 Years (+/- 8 weeks)
Informed Consent	X						
Inclusion/Exclusion	X						
Demographics	X						
Medical History	X						
Risk Assessment	X						
Device Sizing	X						
Assessment Diagnostic[3]	X		X	X	X	X	X
Procedure		X					
Length of Hospital Stay			X				
Neurological Assessment			X	X	X	X	X
Imaging Evaluation	X		X	X	X	X	X
Adverse Events			X[4]				
Device Removal			X[4]				
Study Exit			X[5]				

[1]The pre-op information is collected within 14 days of the procedure
[2]The 4-6 weeks visit was only applicable to sites in Canada
[3]The Assessment Diagnostic form includes the following information: Medications, Blood Pressure, and Blood Work
[4]An adverse event or device removal (i.e., an explant) could happen at any point after the AMDS procedure
[5]Study exit is anticipated to occur at 5-years, post-procedure, but can happen at any point if the patient withdraws, is lost-to-follow, or dies

13.2.1 Clinical Endpoints

The primary safety endpoints included device- and procedure-related mortality, neurological complications (stroke, transient ischemic attack, paraparesis, paraplegia), aortic injury associated with AMDS implantation, and aortic arch vessel patency at 30-day and 3-month follow-up. The primary effectiveness endpoints included successful reattachment of the intimal flap (absence of DANE), thrombosis (partial or complete) of the false lumen, radiographic evidence of false lumen exclusion at all post-operative visits. Successful device deployment was documented at the conclusion of the procedure. Secondary endpoints included explant rate, device-related reintervention rate, and long-term follow-up of the primary safety endpoints, and device performance assessment evaluated by an imaging Core Lab (e.g., fracture, compression, kink, twist, DANE tears, and d-SINE tears and were assessed at all follow-up visits.

13.2.2 Patient Accountability and Compliance to Follow-Up

Data was available for all 47 enrolled patients for 30-day safety assessment and 46 in the intent to treat group (e.g., the patients who received the AMDS device). Subject status and data availability is shown in ***Table 10***. All evaluable patients have completed three-year follow-up.

Table 10. DARTS I Study Follow-Up and Compliance Table

Visit Details			Subjects with Data for Visit and Subject Status					Imaging Adequate to Assess Parameters of Interest[7]		
Visit #	Visit Description	Eligible for follow-up[1]	Subjects with Data for Visit	Subjects with Visit Missed or Pending	Death Prior to Indicated Visit	LTF / Withdrawn Prior to Indicated Visit	Not due for next visit[6]	CT/CTA read by Core Lab	TL Diameter at Zone 3	DANE
		#	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)	# (%)
1	Pre-Op	47	47/47 (100%)	0/47 (0%)	0/47 (0%)	0/47 (0%)	0/47 (0%)	44/47 (93.6%)	40/47 (85.1%)	NA
2	Procedure[2]	47	47/47 (100%)	0/47 (0%)	0/47 (0%)	0/47 (0%)	0/47 (0%)	NA	NA	NA
	Pre-Discharge	39	38/39 (97.4%)	1/39 (2.6%)	7/39 (17.9%)	1/39 (2.6%)	0/39 (0%)	35/39 (89.7%)	33/39 (84.6%)	30/39 (76.9%)
3	4-6 weeks[3]	39	32/39 (82.1%)	7/39 17.9%)	0/39 (0%)	0/39 (0%)	0/39 (0%)	27/39 (69.2%)	26/39 (66.7%)	25/39 (64.1%)
4	3-months	38	36/38 (94.7%)	2/38 (5.3%)	1/38 (2.6%)	0/38 (0%)	0/38 (0%)	32/38 (84.2%)	31/38 (81.6%)	28/38 (73.7%)
5	6-months[4]	37	30/37 (81.1%)	7/37 18.9%)	1/37 (2.7%)	0/37 (0%)	0/37 (0%)	25/37 (67.6%)	25/37 (67.6%)	24/37 (64.9%)
6	1-year[5]	36	35/36 (97.2%)	1/36 (2.8%)	1/36 (2.8%)	0/36 (0%)	0/36 (0%)	34/36 (94.4%)	26/36 (72.2%)	26/36 (72.2%)
7	2-years	35	34/35 (97.1%)	1/35 (2.9%)	1/35 (2.9%)	0/35 (0%)	0/35 (0%)	28/35 (80.0%)	27/35 (77.1%)	25/35 (71.4%)
8	3-years	33	33/33 (100%)	0/33 (0%)	0/33 (0%)	2/33 (6.1%)	0/33 (0%)	30/33 (90.9%)	29/33 (87.9%)	28/33 (84.8%)

[1] Eligible for follow-up = eligible for follow-up from the previous interval - (death + LTF + not due).
[2] Procedure considered as time 24 hours from implant.
[3] The protocol in Germany didn't include a 4-6 week visit; 7 patients without data were from the Berlin Site and # with CTA for this visit consider just the patients from Canada
[4] 2 additional patients had an X-ray at 6-months
[5] The death prior to Visit 1 is LON-004, who is not included in the per protocol cohort
[6] The data represents the existence of available data; these numbers do not reflect incidence of reported events. TL diameter measurement at Zone 3 selected due to importance in the PERSEVERE IDE study.
[7] Those subjects that are "Not due for next visit" are those subjects that are not within the follow-up window for the next interval
Abbreviations: NA=Not applicable, CT=computed tomography, CTA=computed tomography angiography, TL=true lumen, LTF=lost-to-follow-up, DANE= distal anastomotic new entry, d-SINE= distal stent induced new entry

13.2.3 Study Population and Baseline Characteristics

A total of 45 patients (97.8%) were enrolled and treated for acute DeBakey type I dissection; one patient with an intramural hematoma was treated. Patients were mostly male (67.4%) with a mean age of 60 ± 12.4 years and average body mass index (BMI) of 29.1 ± 7.1 kg/m^2. Due to the nature of this disease, comorbidities were anticipated (***Table 11***); patients most commonly presented with hypertension (61%), coronary artery disease (CAD) (15%), cardiac arrhythmia (13%), diabetes (13%), and chronic obstructive pulmonary disease (COPD) (13%), reflecting a sick patient population. A minority of patients had a history of cardiothoracic surgery (2.2%), and 35% self-reported any history of smoking.

Table 11. Patient Baseline Characteristics (DARTS I)

Characteristics	Total Patients (n=46)
Demographics and Baseline Characteristics	
Age	60 ± 12.4
% Male	67.4%
Preoperative Clinical / Radiographic Malperfusion	56.5%
Race and Ethnicity	
Asian	1 (2.2%)
Black or African American	1 (2.2%)
White	34 (73.9%)
Not reported (not collected in Germany)	10 (21.7%)
Aortic Arch Anatomy	
Normal (3 great vessels)	71.7%
Bovine Arch	15.2%
Primary entry tear in Zone 0	78.3%*
Presence of secondary entry tears	69.6%
Risk Factors – No of Patients (%)	
Cardiac Arrhythmia	6 (13.0%)
Congestive Heart Failure (CHF)	1 (2.2%)
Coronary Artery Disease (CAD)	7 (15.2%)
Chronic Pulmonary Obstructive Disease (COPD)	6 (13.0%)
Peripheral Vascular Disease	1 (2.2%)
Hypertension	28 (60.9%)
Aneurysm	4 (8.7%)
Liver Disease	1 (2.2%)
Cancer	4 (8.7%)
Chronic Renal Insufficiency requiring dialysis	1 (2.2%)

Table 11. Patient Baseline Characteristics (DARTS I)

Characteristics	Total Patients (n=46)
Diabetes (Insulin Dependent)	1 (2.2%)
Prior Stroke	3 (6.5%)
Prior TIA	1 (2.2%)
Prior Myocardial Infarction	4 (8.7%)
Prior Thromboembolic Event (DVT)	3 (6.5%)
Prior CABG	2 (2.2%)
Prior PCI	2 (2.2%)
Previous Cardiothoracic Surgery	2 (2.2%)

*17% of patients had missing data on the primary entry tear.

13.2.4 Procedural Characteristics

Concomitant procedures (considered anything other than the hemiarch repair and AMDS device implantation procedures) were performed in 57% of cases, most commonly aortic valve repair (30%) or aortic root repair or replacement (20%). AMDS implantation was performed with a mean time of 3 minutes, and the majority of devices were implanted without the need for fluoroscopy (98%) and without intravascular ultrasound to identify the true lumen (96%). Successful device deployment was reported in 100% of patients, with no incidence of aortic injury in any patient. A majority (96%) of AMDS devices were implanted proximal to the innominate artery, with 3 patients (7%) requiring supra-aortic branch vessel bypass. The average Intensive Care Unit (ICU) stay was 10 days; time in the ICU was prolonged for 39% of the cohort. ICU stay was considered prolonged, in the opinion of the investigator. The average hospital stay was 23 days. A summary of procedural outcomes is provided in ***Table 12.***

Table 12. Procedural Characteristics (DARTS I)

Procedural Characteristics		Patients (%)
Concomitant Procedures	None (Hemiarch + AMDS only)	20/46 (43.5%)
	Aortic arch replacement	2/46 (4.3%)
	Aortic Root Repair or Replacement	9/46 (19.6%)
	Aortic Valve Repair or Replacement	14/46 (30.4%)
	Coronary Artery Bypass Surgery (CABG)	3/46 (6.5%)
	Other	3/46 (6.5%)
		Median (Range)
Procedure Times (minutes)	AMDS Deployment Time	*3.2 (1 – 15)*
	CPB Duration Time	*227.7 (8-1035)*
	Hypothermic Circulatory Arrest	**13.7** *(0-322)*

13.2.6 Results of the Primary Endpoints – Major Adverse Events through 3-Year Follow-Up

There were 6 deaths within 30 days of the procedure; one death was attributed to the procedure and no deaths were considered device related (***Table 13***). All event relationships were determined by the investigators. There were 4 additional deaths beyond thirty days, of which one was considered possibly related to the procedure and none were considered device-related.

Table 13. Cumulative Major Adverse Events (DARTS I)

Major Adverse Events	30-Days Total Number of Events (%)	3-Years Total Number of Events (%)
All-cause Mortality	6/46 (13.0%)	10/46 (21.7%)
Procedure-related mortality	1/46 (2.2%)	2/46 (4.3%)
All Neurological Events (Stroke or TIA, paraparesis/paraplegia)	10/46 (21.7%)	11/46 (23.9%)
New Stroke or TIA	6/46 (13.0%)	7/46 (15.2%)

A total of 10 patients (23.9%) experienced neurological complications within the first 30 days, including 6 patients who had new stroke (defined as a new disabling or non-disabling stroke in a patient absent of prior stroke or stroke symptoms pre- or peri-procedure). One additional patient had a new ischemic stroke beyond 30 days. No patients experienced DANE through 3-year follow-up.

13.2.7 Results of the Secondary Endpoints

Late mortality, aortic branch vessel patency, thrombosis of the false lumen, and aortic remodeling (true lumen and false lumen diameter change) were assessed prior to discharge, 3-months, 6-months 1-year and 3-years. The number of subjects with imaging adequate to assess imaging-based endpoints was variable given CTA quality issues and/or patient anatomy (e.g., bovine arch patients did not have data for Zone 1). The change in true lumen and false lumen diameter, and change in false lumen thrombosis, were reported based on the maximum number of measurements available in all zones for all available patients at that visit.

- *Other Major Adverse Events through 3-Year Follow-Up*

The most frequently occurring events (out of 184 adverse events) were atrial fibrillation (6%), pleural effusion (6%), acute kidney injury (5%), and stroke (4%). Treatment was provided for 77% of the observed MAEs and was predominately non-interventional medical treatment (63%), such as pharmaceuticals; Some intervention was required in most events (77%), predominately medical treatment (63%); 27 events were resolved with surgery (open or percutaneous) and a subset of events (22%) required hospitalization (new or prolonged). Only a small percentage of events were considered as possibly related to the procedure (10%) or to the AMDS (3%), including posterior reversible encephalopathy syndrome, anemia, hypoxic encephalopathy, cerebellar ischemic injury, and severe upper left arm pain. Late mortality rates at 3-years were 21.7% for all patients, 15.3% for malperfusion patients, and 28.6% for no malperfusion patients). In lieu of event adjudication by a Clinical Events Committee (CEC) or Data Safety Monitoring Board (DSMB), all events were assessed for relatedness to the device and/or procedure by the site investigators.

- *Arch vessel branch patency*

Pre-operative orifice stenosis or occlusion was documented in 2 of the 7 patients (38%). A majority of patients (85%) had patent arch vessels at all follow-up visits; seven (7) patients (15%) had evidence of orifice stenosis (>50%) in at least 1 vessel during follow-up potentially caused by chronic conditions leading to calcification build up, coverage by the dissection flap, thrombus related to the dissection, and obstruction by an implanted device. There were no adverse events that were documented in relationship to the observed arch branch vessel orifice stenosis. No arch branch vessels were occluded through

3-year follow-up.

- *Aortic Remodeling through 3-Year Follow-Up*

The AMDS is implanted in Zones 1-3 and may also extend into the distal section of the descending thoracic aorta (Zones 4 and 5). Radiographic assessment of aortic remodeling (defined as change in true lumen and false lumen diameter) was completed in Zones 1-6 (***Figure 9***). Aortic remodeling was assessed based on total aortic diameter (TAD), which was measured at distinct anatomical benchmarks: the innominate artery (IA), the left common carotid artery (LCCA), the left subclavian artery (LSA), and 2 cm distal to the LSA. Measurements were compared to pre-op measurements. A negative change indicates that the TAD decreased from pre-op. On average, there was a reduction in the aortic diameter just proximal to the edge of the IA at all post-operative visits, with only 1 case of increase > 5.0 mm (at 1-year), which was sustained through 3-years.

On average there was a small reduction and overall stability of the aortic diameter just proximal to the LCCA through 3-years. Aortic diameter growth ≥ 5.0 mm just proximal to the LCCA was observed in 1 patient (5.0%) at discharge and 4 patients (19.0%) at 3-years. On average, the aortic diameter just proximal to the edge of the LSA artery was stable with < 5.0 mm of growth through 3-years.

Aortic diameter growth ≥ 5.0 mm just proximal to the LSA was observed in 1 patient (4.2%) at discharge and 4 patients (18.2%) at 3-years. On average, there was aortic diameter stability 2 cm distal to the LSA at early visits. True lumen expansion (≥ 5.0 mm) was demonstrated as early as pre-discharge, remaining stable and/or expanding through 3-years (***Table 14***).

Table 14. Change in Total Aortic Diameter (TAD) from Baseline (mm)

Zone	Pre-Op (n=43)	Pre-Discharge (n=34)		3 Months (n=31)		1-year (n=31)		3-years (n=29)	
	Mean (SD)	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline
Innominate Artery	42.4 (4.4)	38.9(5.6)	-3.9 (5.8)	39.4 (4.5)	-3.3 (3.9)	39.3 (5.3)	-3.5 (4.5)	39.3 (4.7)	-3.4 (4.7)
Left Common Carotid Artery	39.3 (4.4)	38.5 (5.0)	-0.9 (5.0)	39.0 (5.0)	0.1 (4.2)	39.9 (4.9)	0.6 (4.2)	39.9 (5.6)	0.3 (4.7)
Left Subclavian Artery	34.8 (3.9)	35.3 (3.9)	0.4 (3.2)	36.2 (4.5)	1.4 (2.8)	36.5 (4.2)	1.3 (3.9)	37.3 (4.3)	1.8 (3.6)
2 cm distal to LSA	33.1 (4.4)	35.3 (4.4)	2.1 (2.7)	37.9 (7.5)	4.7 (5.2)	39.1 (6.7)	5.4 (5.0)	40.8 (8.9)	7.2 (7.7)

True lumen expansion (≥ 5.0 mm) was demonstrated as early as pre-discharge, remaining stable and/or expanding through 3-years (***Table 15***).

Table 15. Change in True Lumen Diameter (mm)

Zone	Pre-Op (n=41)	Pre-Discharge (n=32)		3 Months (n=31)		1-year (n=31)		3-years (n=29)	
	Mean (SD)	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline
1	19.2 (7.4)	30.4 (5.2)	12.2 (8.1)	31.8 (5.2)	13.8 (6.8)	31.9 (6.3)	14.6 (6.9)	31.6 (6.1)	13.8 (7.2)
2	19.4 (7.3)	29.9 (5.4)	10.8 (8.0)	28.6 (5.5)	11.2 (7.6)	29.9 (5.8)	13.1 (5.1)	30.4 (5.8)	13.3 (5.3)
3	18.5 (6.9)	23.8 (6.6)	5.1 (6.9)	23.7 (5.3)	6.2 (6.4)	24.9 (5.2)	7.3 (5.8)	25.2 (6.1)	8.2 (5.6)
4	18.1 (8.7)	23.6 (6.7)	5.4 (5.9)	23.2 (4.7)	5.9 (6.4)	24.6 (5.5)	7.6 (7.1)	24.8 (5.1)	7.2 (7.2)
5	14.3 (8.5)	24.7 (4.5)	9.5 (8.4)	23.1 (5.9)	8.4 (8.6)	23.3 (5.2)	9.4 (7.2)	23.2 (6.6)	9.9 (9.4)
6	13.7 (8.1)	16.8 (5.3)	2.6 (5.5)	15.4 (5.4)	0.5 (6.9)	15.7 (4.7)	0.6 (7.0)	16.7 (5.4)	2.9 (7.9)

Reported as mean (Standard Deviation or SD) diameter (mm).

Additionally, CT scan data was analyzed to evaluate the change in true lumen diameter at baseline and after AMDS implantation prior to discharge, 1-year, and 3-year nominal timepoints. Time was calculated for each subject based on the actual number of days between visits. The change in true-lumen diameter was modeled in aortic Zones 1-6 for pre-operative baseline to pre-discharge, (2) baseline to 1-year follow-up, and (3) baseline to 3-year follow-up, to evaluate the effect of AMDS on true lumen remodeling over time (***Figure 10***).

The results indicate that the change in true lumen diameter after initial implantation of AMDS was not clinically meaningful or statistically significant in longer-term follow-up. An immediate increase in true lumen diameter was observed upon AMDS implantation with only a marginal mean increase in true lumen diameter (3.0mm) between pre-discharge and three years in Zones 1-3.

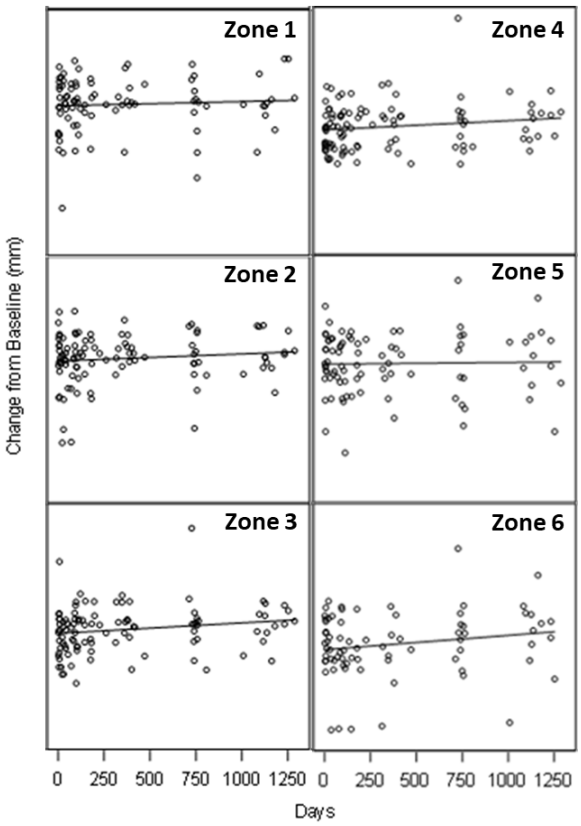


Figure 10. True Lumen diameter change from Baseline to 3-Year Follow-Up

False lumen reduction (≤ 5.0 mm) was also demonstrated in most patients as early as patient discharge (***Table 16***). False lumen response in Zone 3 was variable and susceptible to continued FL flow if communications were present in the left subclavian artery or visceral segment near the infrarenal aorta.

Table 16. Change in False Lumen Diameter (mm) through 3-Years (DARTS I)

Zone	Pre-Op (n=41)	Pre-Discharge (n=32)		3 Months (n=31)		1-year (n=31)		3-years (n=29)	
	Mean (SD)	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline	Mean (SD)	Change from Baseline
1	20.1 (7.7)	8.1 (4.4)	-12.7 (8.5)	7.4 (4.8)	-13.8 (7.8)	7.6 (5.2)	-14.5 (8.0)	8.6 (6.5)	-13.3 (8.2)
2	16.6 (6.9)	6.6 (4.4)	-10.7 (7.6)	8.5 (5.3)	-9.8 (8.6)	7.7 (5.4)	-11.8 (5.0)	7.8 (6.4)	-11.9 (6.6)
3	15.3 (6.6)	11.9 (5.4)	-3.1 (6.8)	14.9 (6.6)	-1.3 (7.4)	14.4 (7.8)	-2.3 (7.0)	16.0 (11.1)	-1.2 (8.8)
4	16.8 (8.7)	12.9 (5.8)	-3.1 (5.9)	17.2 (7.6)	0.1 (6.4)	16.3 (7.8)	-1.4 (7.6)	17.4 (11.6)	-0.2 (9.8)
5	16.4 (9.0)	7.1 (5.1)	-7.4 (8.4)	12.6 (6.4)	-3.8 (8.3)	13.2 (6.9)	-3.1 (8.1)	15.8 (9.9)	-1.7 (10.9)
6	13.8(8.5)	11.2 (6.6)	-1.9 (5.5)	14.8 (6.2)	2.2 (6.6)	15.6 (7.5)	3.6 (7.1)	16.1 (8.7)	2.4 (9.5)

Reported as mean (Standard Deviation or SD) diameter in mm.

Thrombosis of the false lumen (partial or complete, shown in **Table 17**) was observed in a majority of the patients at discharge through 3-year follow-up.

Table 17. False Lumen Thrombosis Status through 3-Year Follow-Up (DARTS I)

Aortic Zone	False Lumen Thrombosis Status	Discharge		3-months		1-years		3-years	
		Total # of Patients	# (%)	Total # of Patients	# (%)	Total # of Patients	# (%)	Total # of Patients	# (%)
Zone 1	Completely Thrombosed	23	6 (26.1%)	25	5 (20.0%)	24	7 (29.2%)	21	7 (33.3%)
	Partially Thrombosed		8 (34.8%)		7 (28.0%)		5 (20.8%)		5 (23.8%)
	Patent		9 (39.1%)		13 (52.0%)		12 (50.0%)		9 (42.9%)
Zone 2	Completely Thrombosed	25	4 (16.0%)	26	6 (23.1%)	26	8 (30.8%)	23	8 (34.8%)
	Partially Thrombosed		10 (40.0%)		10 (38.5%)		7 (26.9%)		7 (30.4%)
	Patent		11 (44.0%)		10 (38.5%)		11 (42.3%)		8 (34.8%)
Zone 3	Completely Thrombosed	25	4 (16.0%)	26	3 (11.5%)	26	5 (19.2%)	24	6 (25.0%)
	Partially Thrombosed		12 (48.0%)		14 (53.8%)		11 (42.3%)		11 (45.8%)
	Patent		9 (36.0%)		9 (34.6%)		10 (38.5%)		7 (29.2%)

- *Assessment of Device Performance through 3-Year Follow-Up*

Radiographic secondary endpoints also included assessment of the device (***Table 18***). In total, 4 patients (9%) had evidence of device compression on ≥ 1 follow-up CTA; 1 patient (2%) had a twist noted, along with compression. Compression was defined by the Core Lab as 50% reduction in device diameter in comparison to diameters directly proximal or distal to the measurement area. In all cases of compression, there was no clinical sequelae reported. The Core Lab also evaluated for evidence of communications between the true lumen and false lumen throughout the aorta, specifically noting if DANE or d-SINE was present. There was no DANE or d-SINE noted in any discharge, 3-month, 1-year or 3-year CTAs.

Table 18. Device Assessment (DARTS I)

Device Characteristic	Discharge (n=26)	3-months (n=26)	1-year (n=29)	3-years (n=23)
Absence of stent fracture	100.0%	100.0%	100.0%	100.0%
Absence of stent compression	91.7%	90.9%	91.2%	89.7%
Absence of stent kinking	100.0%	100.0%	100.0%	100.0%
Absence of stent twist	97.2%	97.0%	97.1%	96.6%
Absence of Distal anastomotic new entry DANE tears	100.0%	100.0%	100.0%	100.0%
Absence of distal stent-induced new entry (d-SINE) tears	100.0%	100.0%	100.0%	100.0%

14. ADVERSE EVENT REPORTING

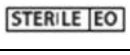
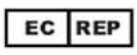
Any adverse event that occurs during the AMDS procedure or after the AMDS implantation should be reported to Artivion Field Assurance at 1-800-438-8285 or by email to fieldassurance@artivion.com, and to the national regulatory authority as applicable.

15. DISCLAIMER OF WARRANTIES; LIMITS OF LIABILITY

ARTIVION DISCLAIMS ALL EXPRESS AND IMPLIED WARRANTIES WITH RESPECT TO THIS SURGICAL ADHESIVE, INCLUDING BUT NOT LIMITED TO THE EXPRESS AND IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT

SHALL ARTIVION BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES. In the event that such disclaimer is found invalid or unenforceable for any reason: (I) any action for breach of warranty must be commenced within one year after any such claim or cause of action accrued and (ii) the remedy for any such breach is limited to the replacement of the product.

16. SYMBOLS USED ON LABELING

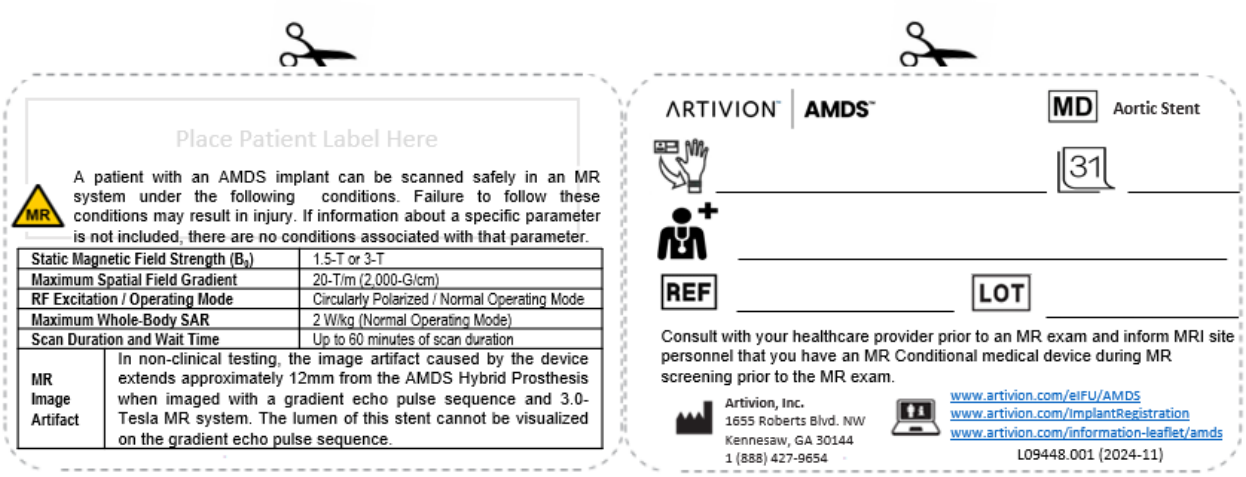
	Manufacturer		Use By Date		Keep Dry		Patient Name
	Date of Manufacture		Consult Instruction for Use		Temperature Limit		Date of implantation
	Catalog Number		Sterilized Using Ethylene Oxide		MR Conditional		Name and Address of the implanting healthcare institution/provider
	Batch Code		Do not reuse		Information website for patients		
	Medical Device		Do Not Use If Package Is Damaged		UDI as AIDC format		Do not re-sterilize
	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician		Sterile barrier system/sterile packaging		Single sterile barrier system with protective packaging outside		Country of Manufacture
	European Authorized Representative		Swiss Authorized Representative		UK Authorized Representative		Importer

17. PATIENT IMPLANT CARD

Instructions for completion of Patient Implant Card (to be completed by the healthcare institution/provider):

1. Patient name (first, middle, last) or patient ID
2. Date of implantation (YYYY-MM-DD)
3. Name and address of the implanting healthcare institution/provider (two lines)
   Physician's name (last line)
4. Attach one of the device courtesy labels to the implant card

The instructions and form for completing the patient implant registration is provided on the Artivion website at: www.artivion.com. The AMDS Hybrid Prosthesis is packaged with an implant card, all patients should be instructed to keep this card in their possession at all times.



Place Patient Label Here

MR

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.

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 / Operating Mode	Circularly Polarized / 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 3.0-Tesla MR system. The lumen of this stent cannot be visualized on the gradient echo pulse sequence.

ARTIVION | AMDS™

MD Aortic Stent

31

REF

LOT

Consult with your healthcare provider prior to an MR exam and inform MRI site personnel that you have an MR Conditional medical device during MR screening prior to the MR exam.

Artivion, Inc.
1655 Roberts Blvd. NW
Kennesaw, GA 30144
1 (888) 427-9654

www.artivion.com/eIFU/AMDS
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