Patient Information for AMDS™ Hybrid Prosthesis

Device Name
AMDS Hybrid Prosthesis

Device Models
There are four AMDS™ configurations: AMDS40, AMDS4030, AMDS55, AMDS5540

Purpose of the AMDS
The AMDS is intended for use by a physician for aortic repair, aortic remodeling and re-expansion of the dissected flap within the ascending aorta, aortic arch, and into the descending aorta. Patients receiving the AMDS are adults with acute DeBakey Type I aortic dissection undergoing open surgical repair within 0-14 days of diagnosis.

Material Information
The AMDS consists of a nitinol braided stent, a polytetrafluoroethylene felt collar (PTFE), and "expanded" polytetrafluoroethylene (ePTFE) sutures. Manufacturing residuals have been assessed and do not pose a risk.

How your AMDS works
The AMDS uses the distal uncovered component of the device implanted distal to the aortic anastomosis, to expand the true lumen and support the intimal flap, thereby promoting remodeling in the aortic arch. In addition, the stent will expand the true lumen and improve the blood flow through the aorta and its tributaries. Because the stent component is uncovered, it will allow uninhibited flow to the aortic side branches.

MRI Safety
You are able to undergo a Magnetic resonance imaging (MRI) procedure while implanted with the AMDS *under certain conditions.* Talk to your doctor and/or radiologist prior to undergoing any imaging studies.

You can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 2,000-gauss/cm (20-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Potential Side Effects/Device Related Risks
Contact your doctor if you experience any of these potential side effects which may occur with the use of AMDS:

- Allergic reaction (to contrast media, antithrombotic agents, prosthesis material)
- Amputation
- Aortic enlargement (e.g. persisting flow in the false lumen)
- Aortic rupture
- Arterial or venous thrombosis and/or pseudoaneurysm
- Cardiac complications and subsequent problems (e.g., arrhythmia, tachycardia, tamponade, myocardial infarction, hypotension, hypertension)
- Cardiac failure (e.g. congestive heart failure)
- Death
- Dissection, perforation, or rupture of the aortic vessel & surrounding vasculature
- Embolism (e.g. thromboembolism)
- Fistula (e.g. aorto-esophageal, aorto-tracheal, aorto-bronchial)
- Gastrointestinal symptoms complications and subsequent problems (e.g. visceral ischemia/infarction, nausea, vomiting)
- Hemorrhage/bleeding
- Hepatic failure
- Infection (e.g. local, systemic, prosthesis) or fever
- Ischemia or infarction (e.g. cerebral, visceral, renal, organ, peripheral)
- Neurological complications and subsequent problems (e.g. transient ischemic attack, stroke, neuropathy)
- Occlusion (venous or arterial, incl. prosthesis occlusion)
- Pain and inflammation
- Pulmonary complication (e.g. edema, embolism, pneumonia, respiratory failure)
- Renal insufficiency
- Spinal cord ischemia, including paraparesis and paraplegia
- Stenosis (arterial or venous)
- Wound complications and subsequent problems (e.g., dehiscence, infection)
- Sepsis

Warnings and Precautions
Only doctors (or qualified healthcare providers working for a doctor) may use AMDS. The warnings and precautions in the IFU instruct the doctor or health care provider how to use the device safely and correctly. The AMDS should not be implanted in patients with mycotic aneurysms, patients who exhibit sensitivity to polytetrafluoroethylene (PTFE), or nitinol, nickel or titanium, patientswith aortic fistulous communication with non-vascular structures, or in patients with uncontrolled systemic infection. Ask your physician to assess your suitability for the treatment.

Comply with the recommendations of your physician, including precautions and post-surgical medical appointments. Before any medical procedure, it is important to let your physician know you have an AMDS implanted.

Device Lifetime
The AMDS is intended to be implanted in the body for the patient lifetime.

Post-Operative Monitoring
Follow the physician's instructions for post-operative care and attend regular follow-up imaging and checks on your health and the performance of the device as scheduled by your physician.

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.

Please report any serious device related incident to the manufacturer at www.ascyrus.com or 800-438-8285, and the competent authority of the Member State or Territory in which the patient is established. For patients in Australia, report any serious adverse events to the Therapeutic Goods Administration, https://www.tga.gov.au, click on the "Report a problem" link.