

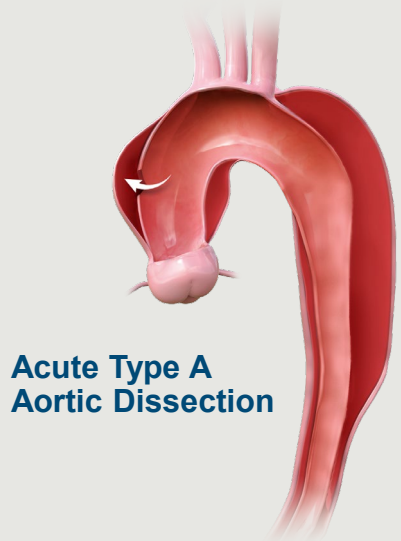
ARTIVION™

Formerly CryoLife | Jotec

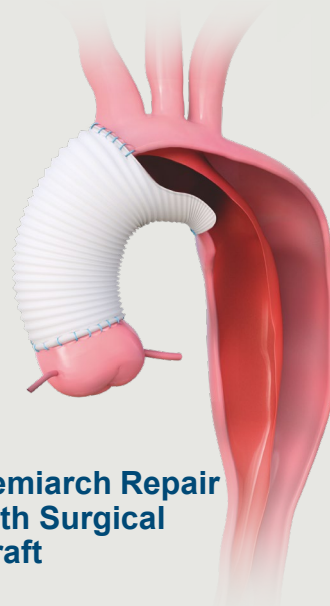
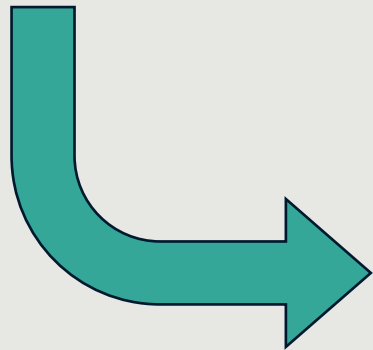
Restriction of the Thoracic Aorta with a Hybrid Intraluminal Device

ICD-10-PCS Code Request
Spring 2025

Acute Type A Aortic Dissection is an Emergent, Life-Threatening Disease if Left Untreated



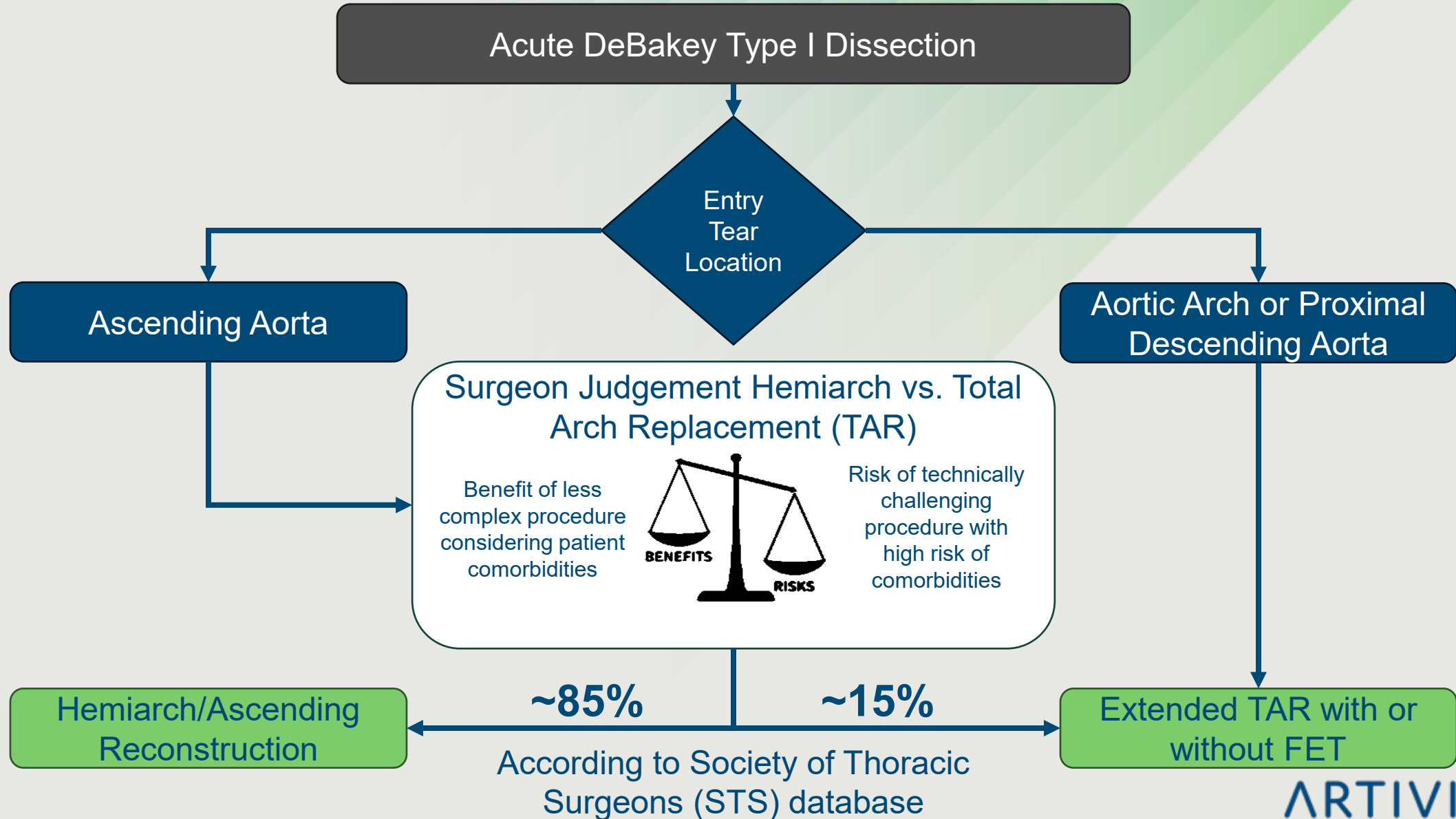
Acute Type A
Aortic Dissection



Hemiarch Repair
with Surgical
Graft

- An acute type A aortic dissection, specifically DeBakey Type I (ATAD I) is a life-threatening, emergent condition.
 - Left untreated mortality is reported to be approximately 1% per hour after onset on symptoms and can lead to 50% mortality in the first 48 hours.
- Today the standard of care is an ascending replacement or hemiarch repair.
 - While this procedure can successfully remove the primary entry tear, it fails to adequately address the remainder of the diseased aorta, resulting in complications in both the acute and long-term phases.

Therapy Algorithm Today



AMDS Hybrid Prosthesis Indication for Use

Indications:

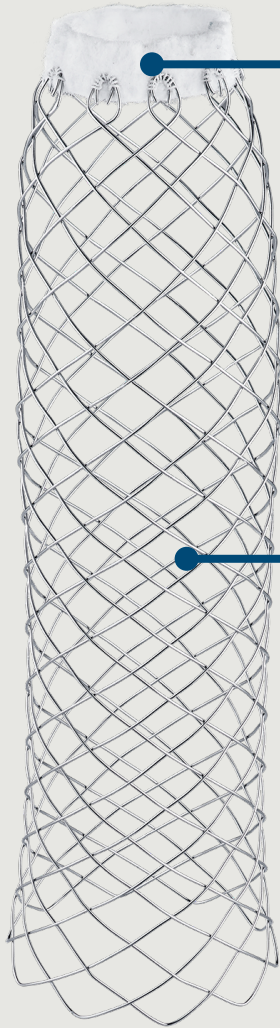
- The AMDS Hybrid Prosthesis is indicated for use in patients with acute DeBakey Type I aortic dissections with malperfusion (including cerebral, visceral, renal, and peripheral malperfusion) and a primary entry tear within the ascending aorta proximal to the innominate artery, who are undergoing open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

Application: adjunct to standard ascending aorta/hemiarch reconstruction

Contraindications:

- The AMDS should not be implanted in patients who exhibit sensitivity to PTFE or Nitinol (e.g. Nickel or Titanium), patients with mycotic aneurysms, aortic fistulous communication with non-vascular structures, or patients with uncontrolled systemic infection.

AMDS Hybrid Prosthesis



PTFE felt cuff component made of a PTFE felt tube is used to buttress and strengthen the aortic tissue in preparation to perform the conventional polyester graft to aorta anastomosis.

28mm Cuff for 40mm stents

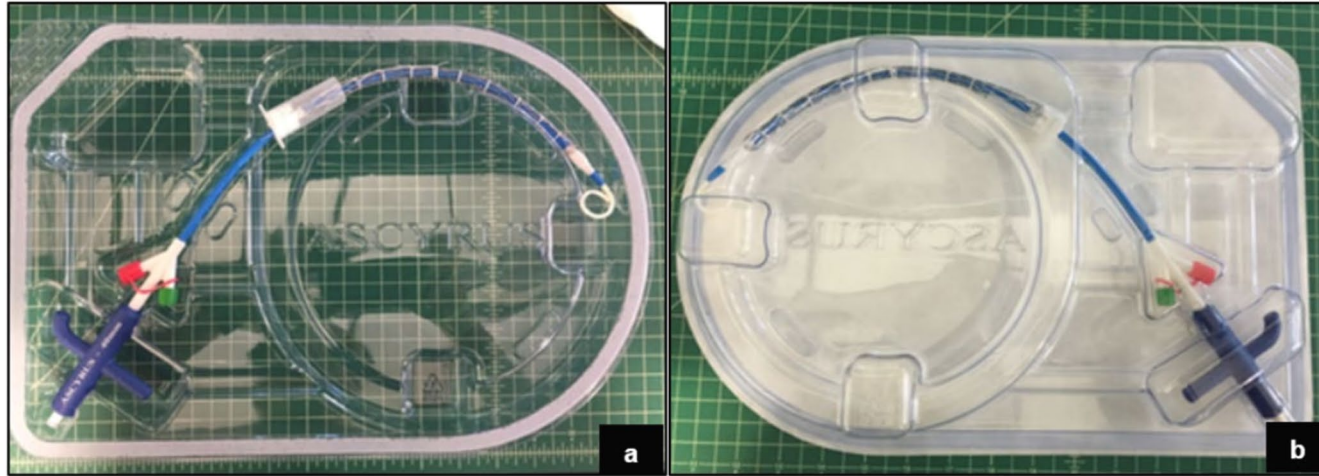
32mm Cuff for 55mm diameter stents

Uncovered nitinol wire braided stent enables the stabilization of the dissection flap within the aortic arch and descending aorta thereby stabilizing the structure of the aortic wall and promoting its healing.

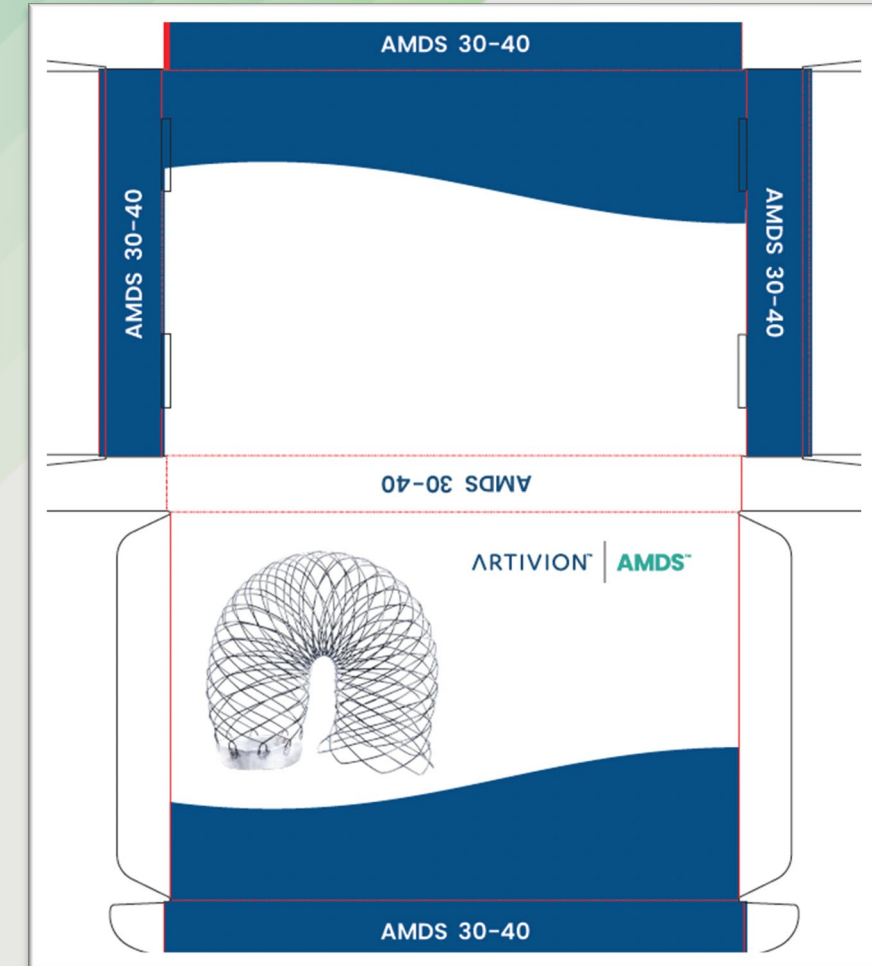
Four sizes available covering a proximal aortic diameter of 20-45mm and distal aortic diameter of 25-45mm. All sizes come in either a tapered or straight configuration.

Packaging & Device Components

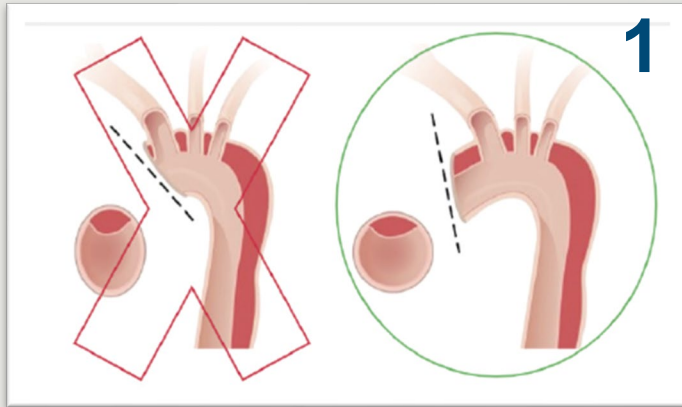
Figure 1: Thermoformed Tray with Device (a) and Packaged Device with Tyvek Lid (b)



- Only inside the Tyvek lid is sterile, the packaging within the box is not.
- 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.



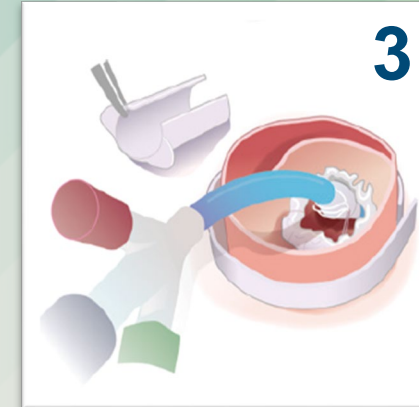
AMDS Hybrid Prosthesis Simplified Procedure Steps



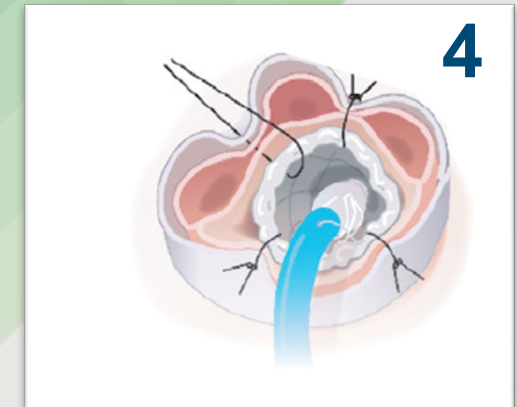
1
Transect perpendicularly to the ascending aorta & introduce device into open distal aorta until cuff aligns



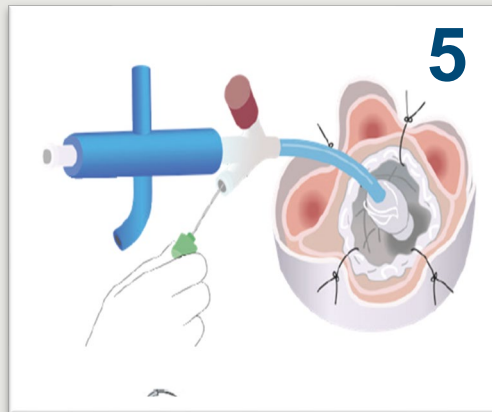
2
Introduce AMDS Hybrid Prosthesis into the true lumen of the thoracic aorta



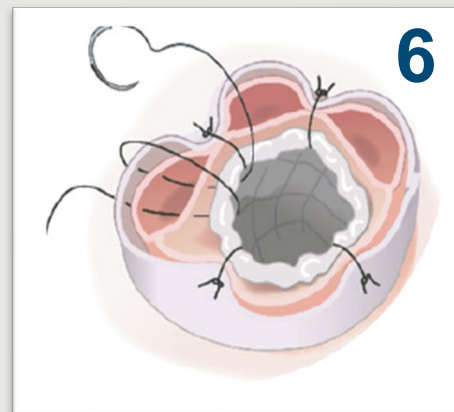
3
Retract and remove the protective sheath to fully expose the PTFE felt



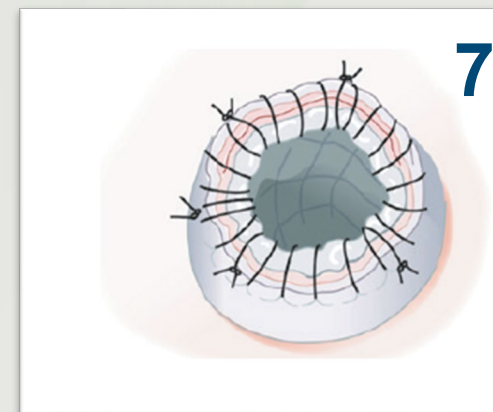
4
Place sutures at the 3, 6, 9 & 12 o'clock positions using a felt strip external to aorta for added support



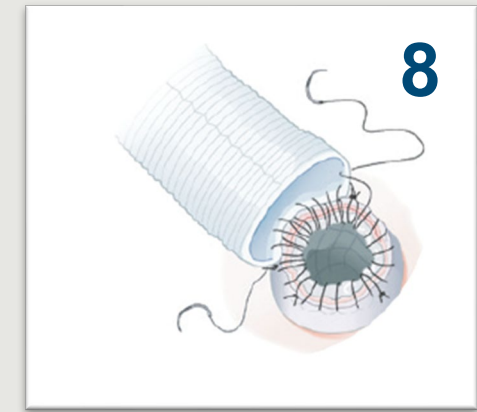
5
Unscrew green cap & pull back the cap and connecting ePTFE suture to deploy the stent



6
Remove the delivery system, making sure the tip is free from the distal end of the stent.



7
The anastomosis secures the inner AMDS felt cuff through the aorta and to the outer PTFE felt.



8
Complete end-to-end anastomosis with a conventional surgical graft or valved conduit

Additional Questions & Answers

1.) How many devices are required per procedure?

- Only one AMDS Hybrid Prosthesis is implanted per patient.

2.) Potential diagnoses associated with AMDS Hybrid Prosthesis?

- AMDS Hybrid Prosthesis is intended for use in patients diagnosed with Acute Type I DeBakey Aortic Dissection.

3.) Where is the device documented in the medical record for individuals (e.g., medical coders) to identify?

- Surgeon or nurse operative report
- The Implant Registration should be digitally completed by the hospital staff via the URL: www.artivion.com/ImplantRegistration. The information required to initiate the registration, such as Serial Number, Catalog Number, etc. can be found on the product label.

Key Takeaways and Summary

- An acute type A aortic dissection, specifically DeBakey Type I (ATAD I) is a life-threatening, emergent condition.
 - Left untreated mortality is reported to be approximately 1% per hour after onset on symptoms and can lead to 50% mortality in the first 48 hours.
- Today the standard of care is an ascending replacement or hemiarch repair with surgical graft.
 - While this procedure can successfully remove the primary entry tear, it fails to adequately address the remainder of the diseased aorta, resulting in complications in both the acute and long-term phases
 - Published data reports high rates of early Major Adverse Events (MAEs) due to malperfusion.
 - A common post-surgical complication of the standard hemiarch procedure is the creation of a distal anastomotic new entry tear (DANE)
 - DANE is one of the causes of false lumen patency after surgery and results in higher rates of aortic growth in the arch and descending aorta, compared to patients without DANE and those with thrombosed false lumen.
- Combining the less complicated standard hemiarch repair with the AMDS Hybrid Prosthesis gives a surgeon a more effective alternative to the standard hemiarch procedure addressing the main cause of DANE while avoiding the complexity and risk associated with a total arch replacement.
- Current ICD-10-PCS coding does not adequately or uniquely identify the combined open hybrid procedure using a surgical graft for replacing the ascending aorta and AMDS Hybrid Prosthesis for the restriction of the thoracic aorta for patients with Acute DeBakey Type I Aortic Dissection.