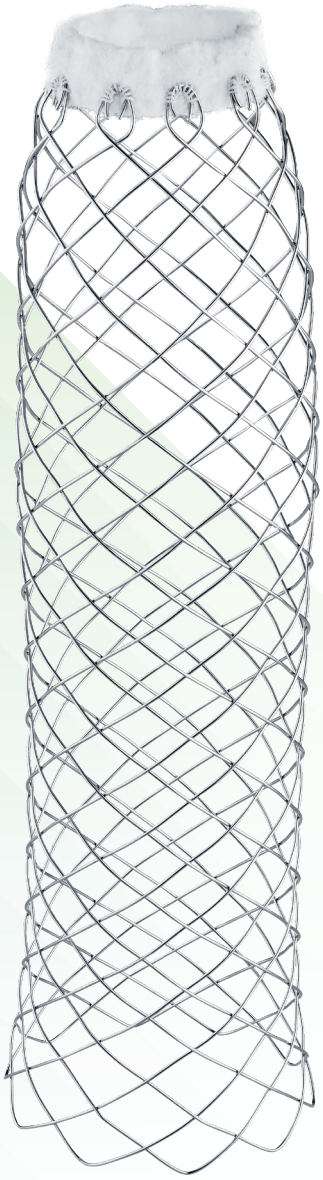
Elevate the Standard.
Rethink Prevention.

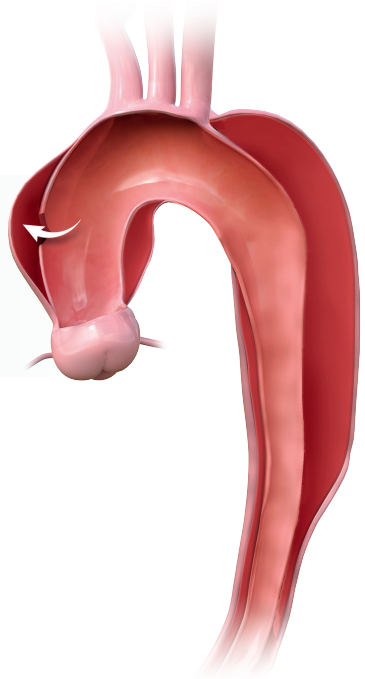


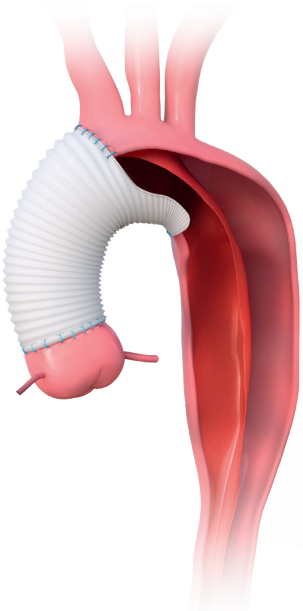
ARTIVION™ | AMDS™
Hybrid Prosthesis

Today's Standard Treatment for Acute Type A Aortic Dissection Isn't Enough.

Type A Aortic Dissection (TAAD) presents itself emergently. Left untreated, mortality of type A dissection is reported to be approximately 1% to 2% per hour after onset of symptoms[1] and can lead to 50% mortality in the first 48 hours.[2]

Approximately 70% of entry tears occur in the ascending area.[3] Surgical repair remains high-risk, with both mortality and neurological complication rates of 15% to 30%.[1]





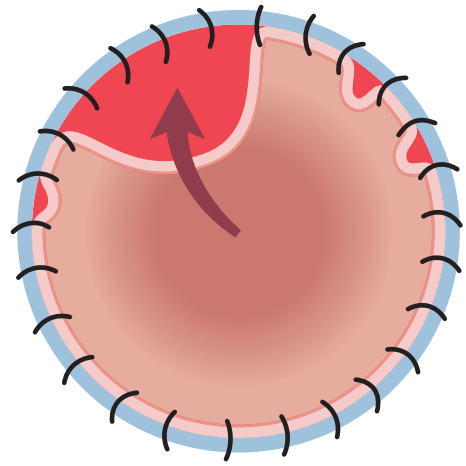
Aortic dissection is complex and difficult to treat.[4,5] Hemiarch repair alone isn't enough to stop a dissection from causing significant complications[4-7] including:

- High Mortality[5,8] + Re-intervention[6,8]
- Aortic Growth[6,9]
- Malperfusion[4,6]

Elevate the Standard. Rethink Prevention.

Consider the Implications of Distal Anastomotic New Entry (DANE) following a Standard Repair for Acute TAAD.

Distal anastomotic new entry (DANE) in the standard hemiarch repair for TAAD is considered to be one of the causes of patent false lumen (PFL) after acute type I aortic dissection repair.[9-12] DANE is observed in 40-70% of patients post hemiarch repair.[6,10]



An untreated DANE can lead to:

High Mortality

Survival with a patent false lumen gets significantly worse over the years, with a reduced actuarial survival by over 10% at 5 years and over 30% at 10 years compared to patients with occluded false lumen.[11]

Aortic Growth

A patent false lumen with DANE is associated with significantly greater aortic growth compared not only to a thrombosed false lumen, but also patent false lumen without DANE.[9]

Malperfusion

Between 30-55% of all acute TAAD patients present with malperfusion.[4,13,14] In-hospital mortality rate can be 5X higher in patients presenting with any malperfusion vs. patients presenting without malperfusion.[13] At least 25% of patients have post-operative malperfusion syndrome.[4]

A Simple Elegant Solution to Address DANE.

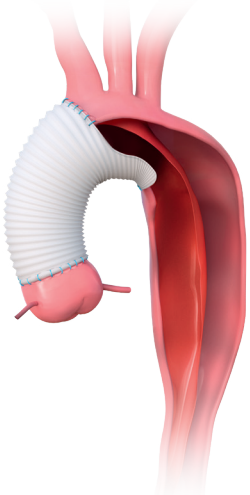
PTFE felt graft component made of a PTFE felt tube is used to buttress and strengthen the aortic tissue in preparation to perform the conventional polyester graft to aorta anastomosis.[15]

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 healing of the wall.[15,16]

The AMDS device comes **pre-mounted on a delivery system**. There is no need for X-Ray, fluoroscopy or hybrid room to use the AMDS system.[15]

The AMDS Hybrid Prosthesis Simply Elevates the Standard of Care for Acute TAAD

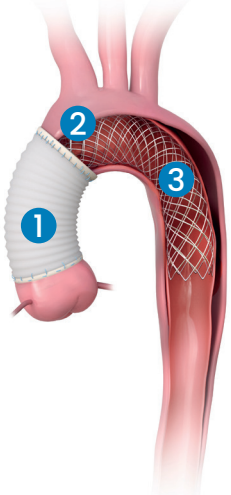
Hemiarch Repair



1. Replace the ascending aorta
2. Seal the distal anastomotic entry tear (DANE)[16]
3. Stabilize the true lumen[16]

Induce Remodeling[6,9,12]

Surgical Repair + AMDS

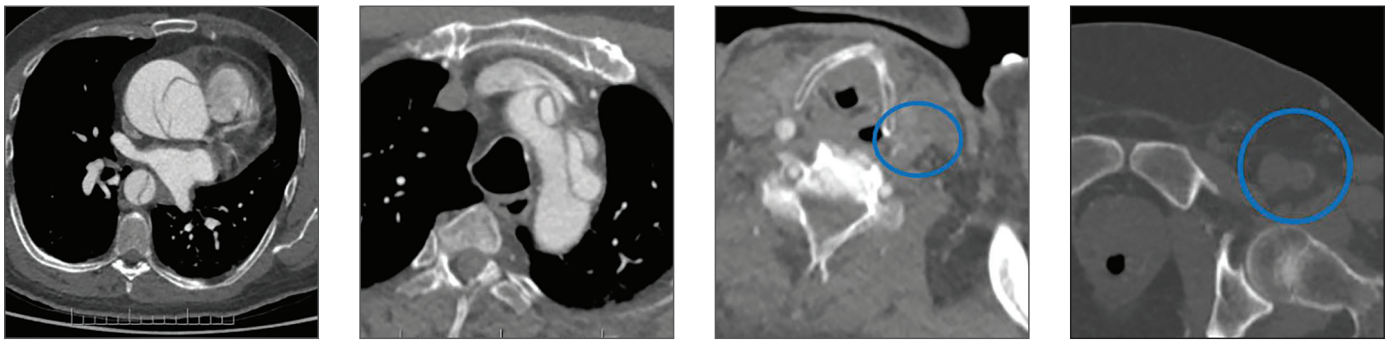


Comparison of Standard Surgical Repair vs. Surgical Repair with AMDS.

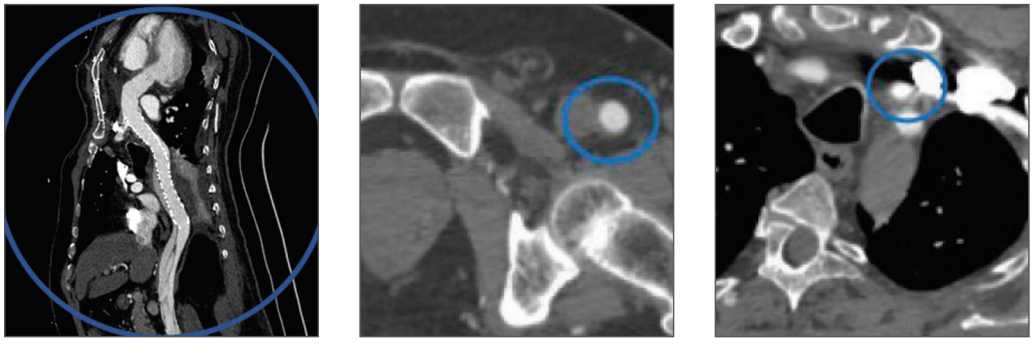
	Standard Surgical Repair	Surgical Repair with AMDS[16]
Pre-Op Malperfusion	33.6%[14] - 55.6%[4]	56.5%
Overall Operative Mortality	17%[17] - 18.7%[18]	13.0%
Malperfusion Related Mortality	21.3%[14] - 47.3%[4]	7.7%
One-Stage Malperfusion Resolution	58.1%[19]	95.5%
Paralysis	2.9%[17]	0%
New Post-Op Stroke	12.9%[20] - 13.6%[18]	6.5%
Aortic Arch Remodeling (Absence of Aortic Expansion)	24%[6]	100%

Case Example

Pre-operative images of dissection and malperfusion of left common carotid and common femoral arteries

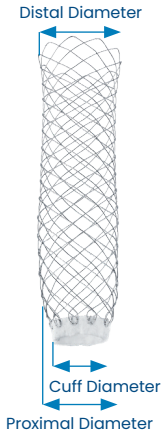


Remodeling and complete resolution of malperfusion post AMDS implantation



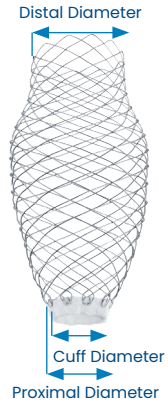
Sizes and Configuration

Straight



Item	Ø Stent (mm)	Ø Proximal Aortic (mm)	Ø Distal Aortic (mm)	Device Length (mm)	Ø Felt Cuff (mm)
AMDS 40-40	40	20-35	25-35	155-208	24
AMDS 55-55	55	36-45	36-45	195-231	32

Tapered



Item	Ø Stent (mm)	Ø Proximal Aortic (mm)	Ø Distal Aortic (mm)	Device Length (mm)	Ø Felt Cuff (mm)
AMDS 40-30	40 prox. 30 dist.	20-35	20-24	170-210	24
AMDS 55-40	55 prox. 40 dist.	36-45	27-35	190-225	32

ARTIVION™

Learn more at **artivion.com**

1. Bonser et al. J Am Coll Cardiol 2011;58:2455–74. 2. Pepper J et al. Ann Cardiothorac Surg 2016;5(4):360-367. 3. Chin et al. J Am Coll Cardiol. 2018 June 19; 71(24): 2773–2785. 4. Nardi et al. Vessel Plus 2017;1:77-83. 5. Merkle et al. Ther Adv Cardiovasc Dis 2018, Vol. 12(12) 327–340. 6. Rylski et al. Eur J Cardiothorac Surg 2017;51:1127–34. 7. Czerny et al. J Vis Surg 2018;4:14. 8. Shrestha et al.. Eur J Cardiothorac Surg 2017;51:i34–i39. 9. Tamura et al Eur J Cardiothorac Surg 2017;52:867–73. 10. Bing et al Vascular and Endovascular Surgery 2014, Vol. 48(3) 239-245. 11. Fattouch et al Ann Thorac Surg 2009;88:1244–50. 12. Evangelista et al. Circulation. 2012;125:3133-3141. 13. Geirsson A, et al. Eur J Cardio-Thorac Surg, 2007;32(2):255-262. 14. Czerny M, et al. JACC 2015;65(24):2628-2635. 15. Instructions for Use (IFU), Ascyrus Medical Dissection Stent. 16. Journal Pre-proof of Bozso SJ et al. "Midterm Outcomes of the Dissected Aorta Repair Through Stent Implantation Trial", The Annals of Thoracic Surgery (2020), doi: https://doi.org/10.1016/ j.athoracsur.2020.05.090. 17. Lee TC et al. J Card Surg. 2018;33:7–18. 18. Easo J et al. J Thorac Cardiovasc Surg 2012;144:617-23. 19. Grimm JC et al. Ann Cardiothorac Surg 2016;5(3):202-208. 20. Dumfarth J et al. Eur J Cardiothorac Surg 2018;53:1013–2.

Artivion, Inc.
1655 Roberts Blvd., NW
Kennesaw, GA 30144 USA
Phone: +1-888-427-9654
Fax: +770-590-3753
E-mail: inquiries@artivion.com
For contact information by region, please visit. www.artivion.com/contact

JOTEC GmbH, Lotzenäcker 23, 72379 Hechingen, Germany

JT-BR-0980200-EN V03 06/2022