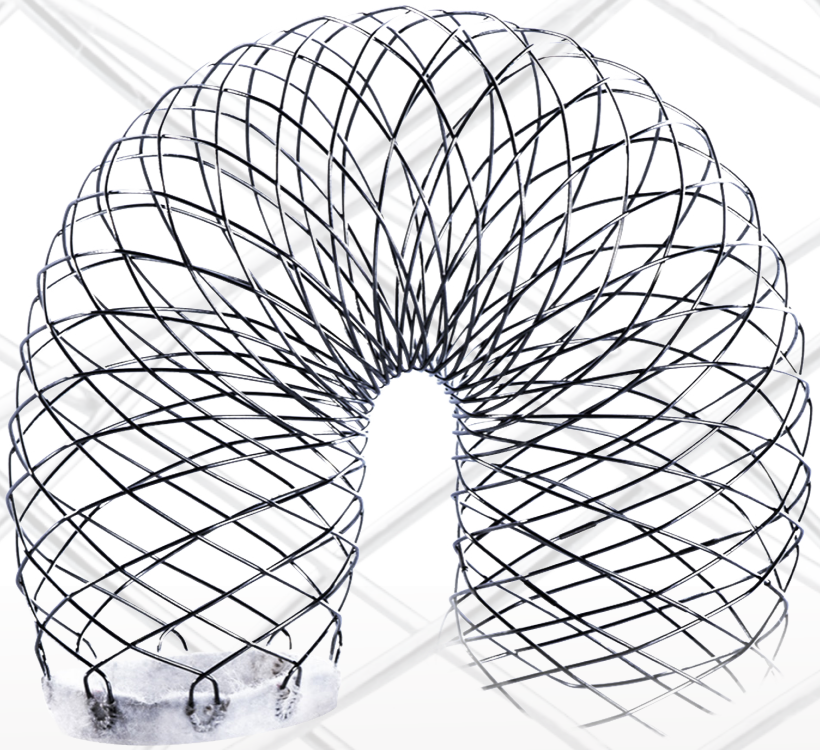
PERSEVERE US IDE Study
Early and Midterm Results

A Landmark Prospective, Multi-Center Study to Evaluate the Safety and Effectiveness of AMDS™ in the Treatment of Acute DeBakey Type I Dissection

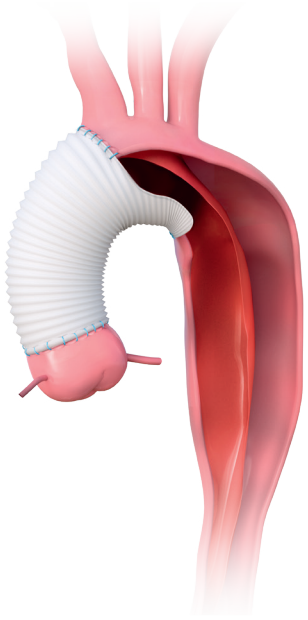


Rethink the Repair

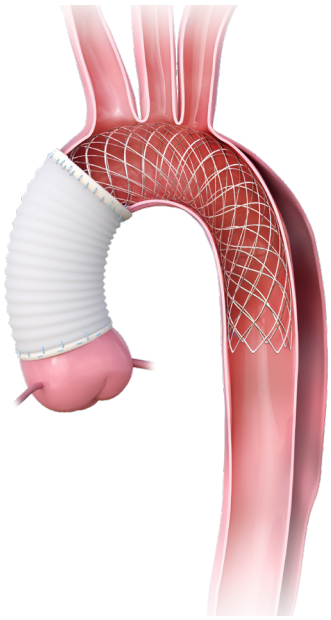
ARTIVION™ | AMDS™ Hybrid Prosthesis

30-Day[1-6] and 1-Year Results[7]

Primary Endpoints: MAE and DANE Rates



Hemiarch Reference Cohort Average[1-5] (n=790 combined)		PERSEVERE[6] (n=93)
34.6%	All Cause Mortality	**9.7%**
20.9%	Stroke	**10.8%** (new disabling)
24.1%	New Onset Renal Failure Requiring Dialysis	**19.4%**
10.5%	Myocardial Infarction	**0%**
58%	≥ 1 MAE	**26.9%**



Peri-Operative Data[6]

98.9% Technical Success

28 min Total Hypothermic Circulatory Arrest*

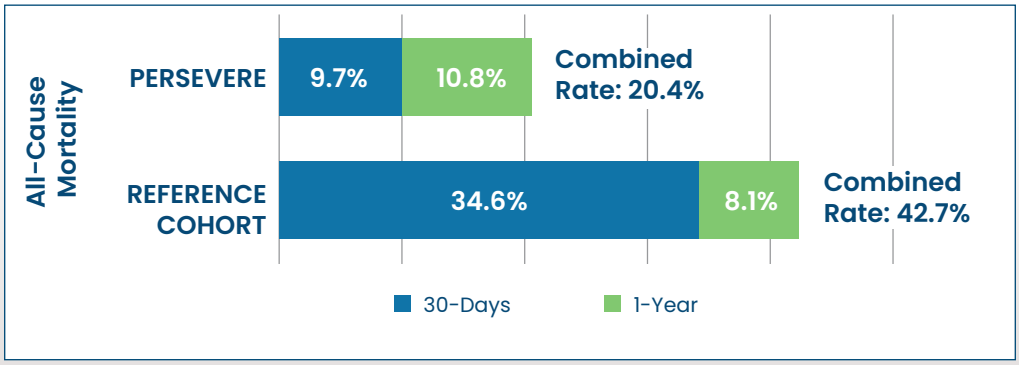
4 min AMDS Deployment Time*

6 days Time in ICU*

* Median Data

1-Year Results[7]

AMDS demonstrated **> 50% lower 1-year all-cause mortality rate** of **20.4%** in comparison to a hemiarch-alone cohort of **42.7%.**



Proven Performance

AMDS demonstrated durable aortic remodeling, prevention of distal anastomotic new entry (DANE) tears, and stable long-term outcomes following repair of acute DeBakey Type I dissection complicated by malperfusion.[8]

Dane Prevention

By preventing DANE at the distal anastomosis, AMDS will encourage false lumen reduction over time.[8]

Malperfusion Resolution

Postoperative imaging demonstrated significant true lumen expansion in the innominate and left carotid arteries, supporting the remodeling mechanism of AMDS.[9]

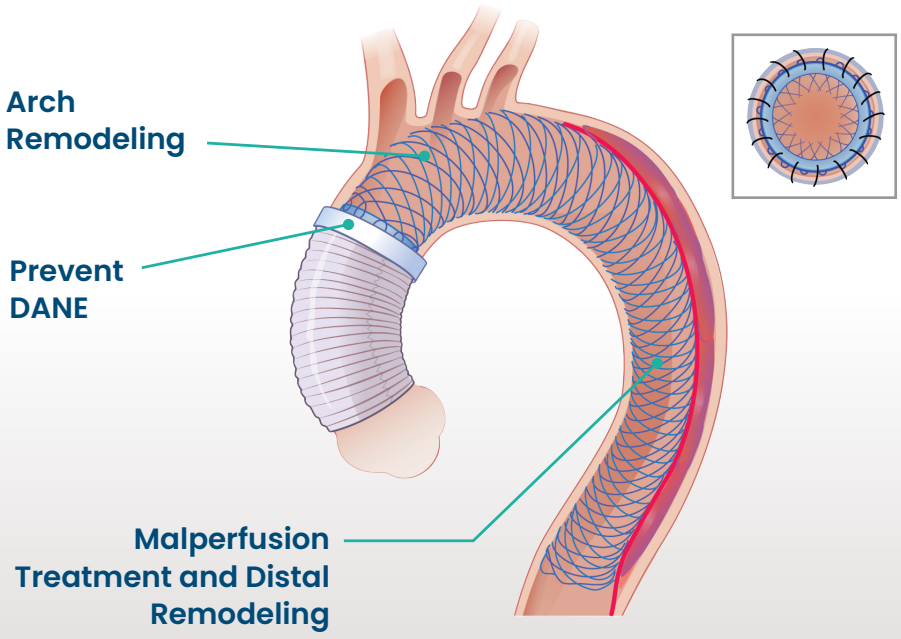
AMDS effectively resolved malperfusion in vascular territories distal to the area treated by the stent in the majority of patients.[10]

Positive Aortic Remodeling

Positive aortic remodeling and stability contributed to low intervention rates.[8]

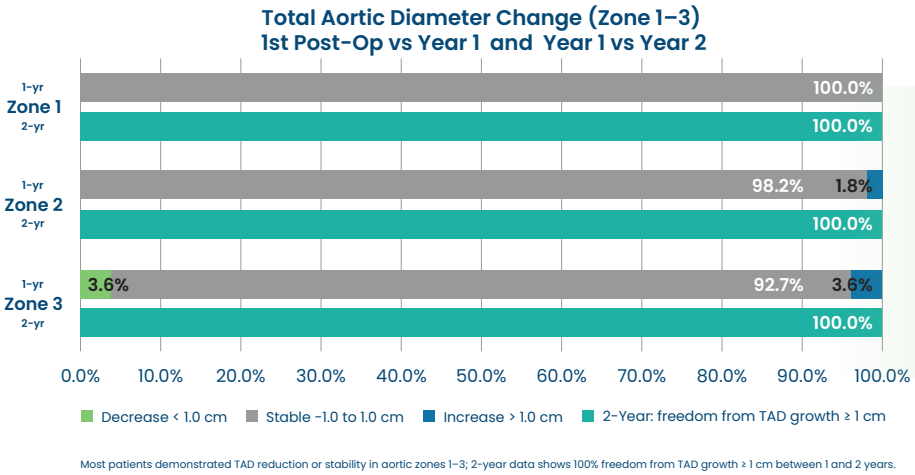
Future Intervention

Open and endovascular reinterventions are feasible, with 4.3% unanticipated reoperation through 2 years.[8]



2-Year Results[7-8]

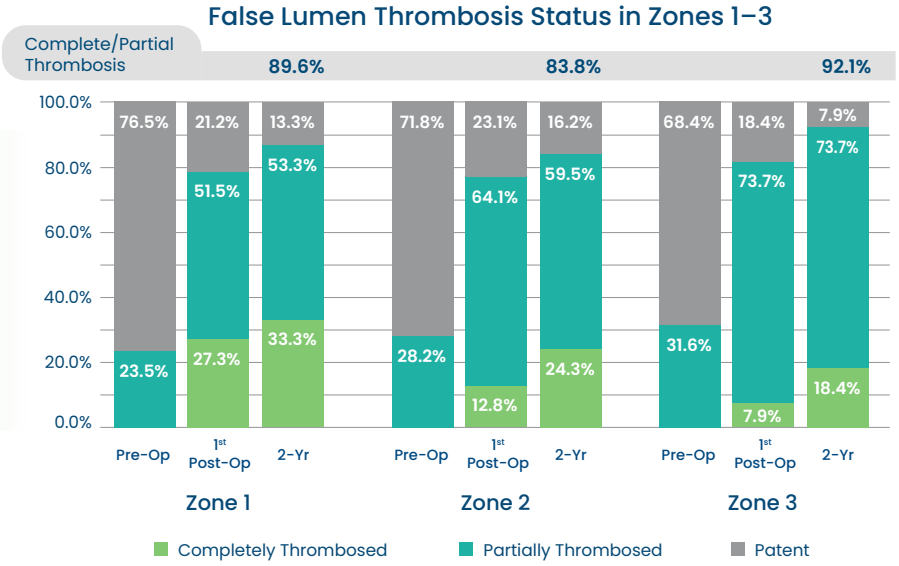
AMDS Promotes Positive Aortic Remodeling Through 2 Years as Assessed by Independent Core Lab



Most patients demonstrated TAD reduction or stability in aortic zones 1–3; 2-year data shows 100% freedom from TAD growth ≥ 1 cm between 1 and 2 years.

Total Aortic Diameter Remained Stable Through 2 Years

Freedom from TAD growth ≥ 1 cm between 1 and 2 years was 100% in zones 1, 2, and 3



False Lumen Thrombosis Continued to Improve Between 1 and 2 Years

Up to 92.1% complete or partial false lumen thrombosis was observed across zones 1—3

0%

Instances of Distal Anastomotic New Entry (DANE) Tear[8]

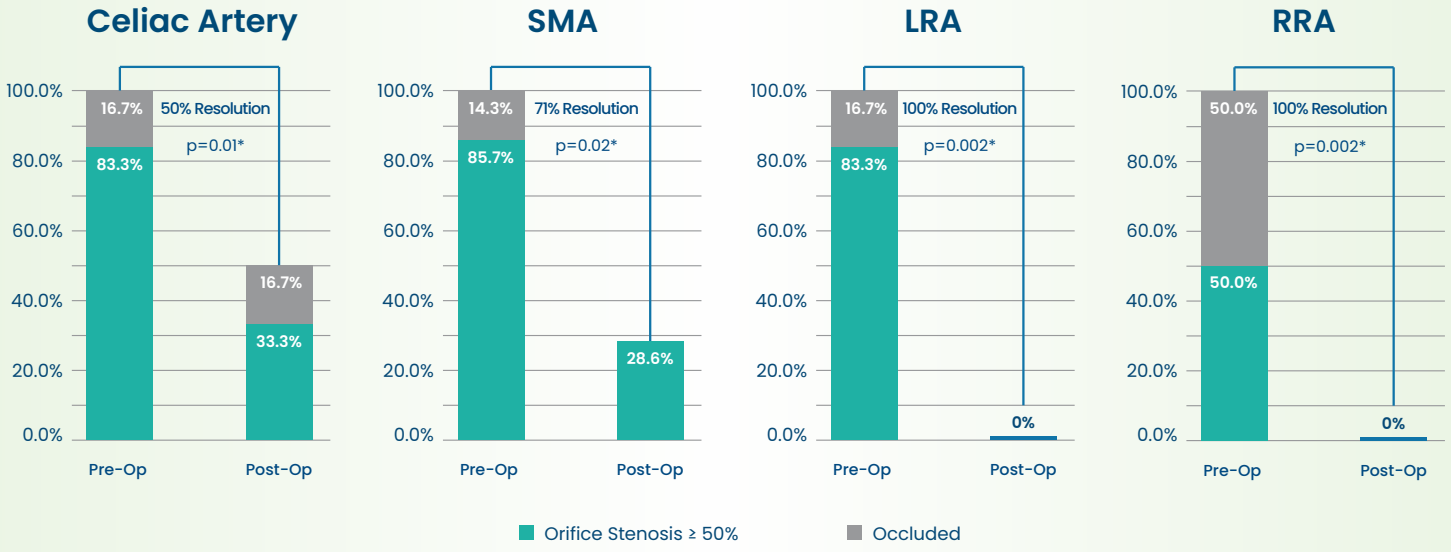
AMDS demonstrated limited deaths, stroke, and renal failure between 1 and 2 years[8]

Both open and endovascular reinterventions were feasible, with low rates of unanticipated reoperation through 2 years, 4.3% (n=4/93)[8]

Malperfusion Resolution

≤ 30-Day Radiographic Malperfusion Results[10]

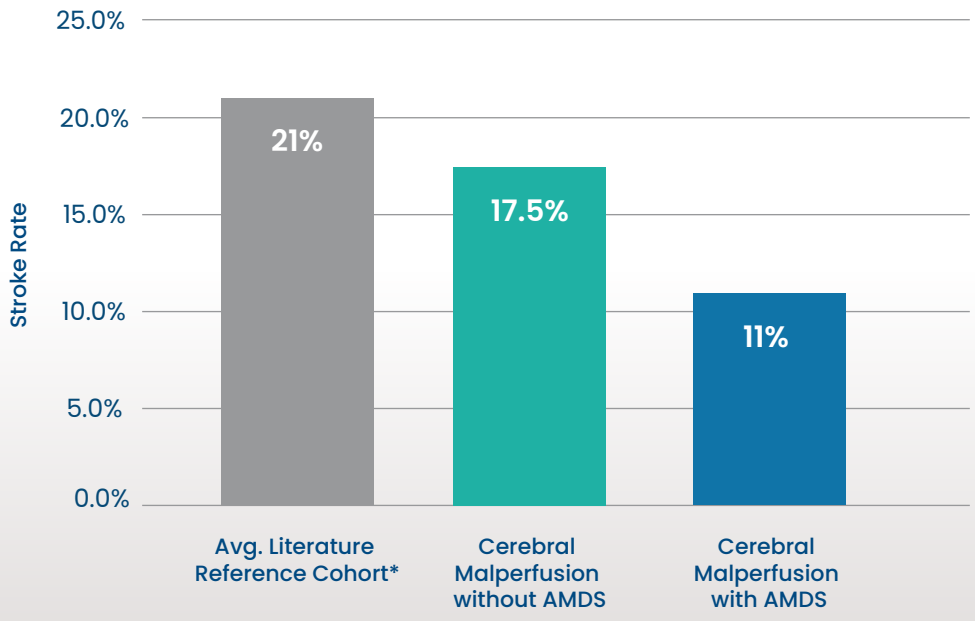
AMDS effectively resolved malperfusion in vascular territories distal to the area treated by the stent in the majority of patients.



30-Day Cerebral Malperfusion Results[9]

Cerebral malperfusion patients treated with AMDS had similar stroke rates following implant compared to patients who presented without cerebral malperfusion.

- 89% (16/18) of patients had resolution or stability of presenting clinical symptoms of cerebral malperfusion at 30 days



Pre-Op[11]

Post-Op[11]

ARTIVION™

Learn more at **artivion.com**

To watch the AMDS animation, scan the QR code.

References: 1. Zindovic I, G. T., Ahlsson A, Fuglsang S, Gunn J, Hansson EC, Hjortdal V, Jarvela K, Jeppsson A, et al. (2019). Malperfusion in acute type A aortic dissection: an update from the Nordic Consortium for Acute Type A Aortic Dissection. J Thorac Cardiovasc Surg.,157, 1324-1333. **2.** Geirsson A, S. W., Pochettino A, McGarvey ML, Keane MG, Woo YJ, Augoustides JG, Bavaria JE. (2007). Significance of malperfusion syndromes prior to contemporary surgical repair for acute type A dissection: outcomes and need for additional revascularizations. Eur J Cardiothorac Su, 32, 255-262. **3.** Pacini D, L. A., Belotti LM, Fortuna D, Gabbieri D, Zussa C, Contini A, Di Bartolomeo R, et al. (2013). Acute type A aortic dissection: significance of multiorgan malperfusion. Eur J Cardiothorac Surg, 43, 820-826. **4.** Girdauskas E, K. T., Borger MA, Falk V, Mohr FW. (2009). Surgical risk of preoperative malperfusion in acute type A aortic dissection. J Thorac Cardiovasc Surg, 138, 1363-1369. **5.** Bossone E, R. V., Nienaber CA, Trimarchi S, Ballotta A, Cooper JV, Smith DE, Eagle KA, Mehta RH. (2002). Usefulness of Pulse Deficit to Predict In-Hospital Complications and Mortality in Patients With Acute Type A Aortic Dissection. Am J Cardiol, 89, 851-855. **6.** Szeto WY, Fukuhara S, Fleischman F, Sultan I, Brinkman W, Arnaoutakis G, Takayama H, Eudailey K, Brinster D, Jassar A, DeRose J, Early results from the PERSEVERE trial. J Thorac Cardiovasc Surg. 2024 Aug 6:S0022-5223(24)00677-9. **7.** Szeto, W. Y., et al. One-Year Results of Novel Aortic Arch Hybrid Prosthesis for Repair of Acute DeBakey Type I Dissection with Malperfusion: PERSEVERE Study. The Annals of thoracic surgery, S0003-4975(25)01111-7. Advance online publication. https://doi.org/10.1016/j.athoracsur.2025.10.036. **8.** Eudailey, K. (2026, February 1). Using a Novel Hybrid Aortic Arch Prosthesis for Open Repair of Acute DeBakey Type I Dissection with Malperfusion: Two-Year Results from the PERSEVERE Trial. Presented at STS, New Orleans, LA. **9.** Brinkman W, Squiers JJ, Jassar A, et al. Cerebral malperfusion resolution after repair of acute DeBakey type I dissection with a novel hybrid prosthesis: early results of the PERSEVERE Study†. Eur J Cardiothorac Surg. 2025;67(7):ezaf199. doi:10.1093/ejcts/ezaf199. **10.** Jassar, A. (2025, October 10). Effectiveness of AMDS Hybrid Prosthesis in Resolving Visceral and Renal Malperfusion in Acute DeBakey Type I Dissection- Results from the PERSEVERE Study . EACTS, Coperhagen, Denmark. **11.** Artivion images on file.

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