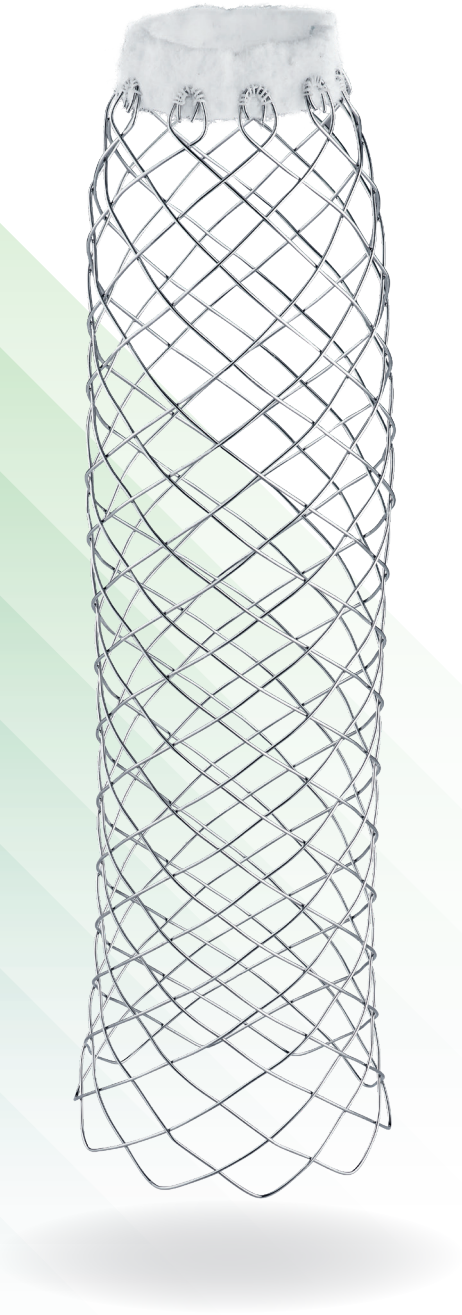
Elevate the Standard With

AMDS™



ARTIVION™ | AMDS™ Hybrid Prosthesis

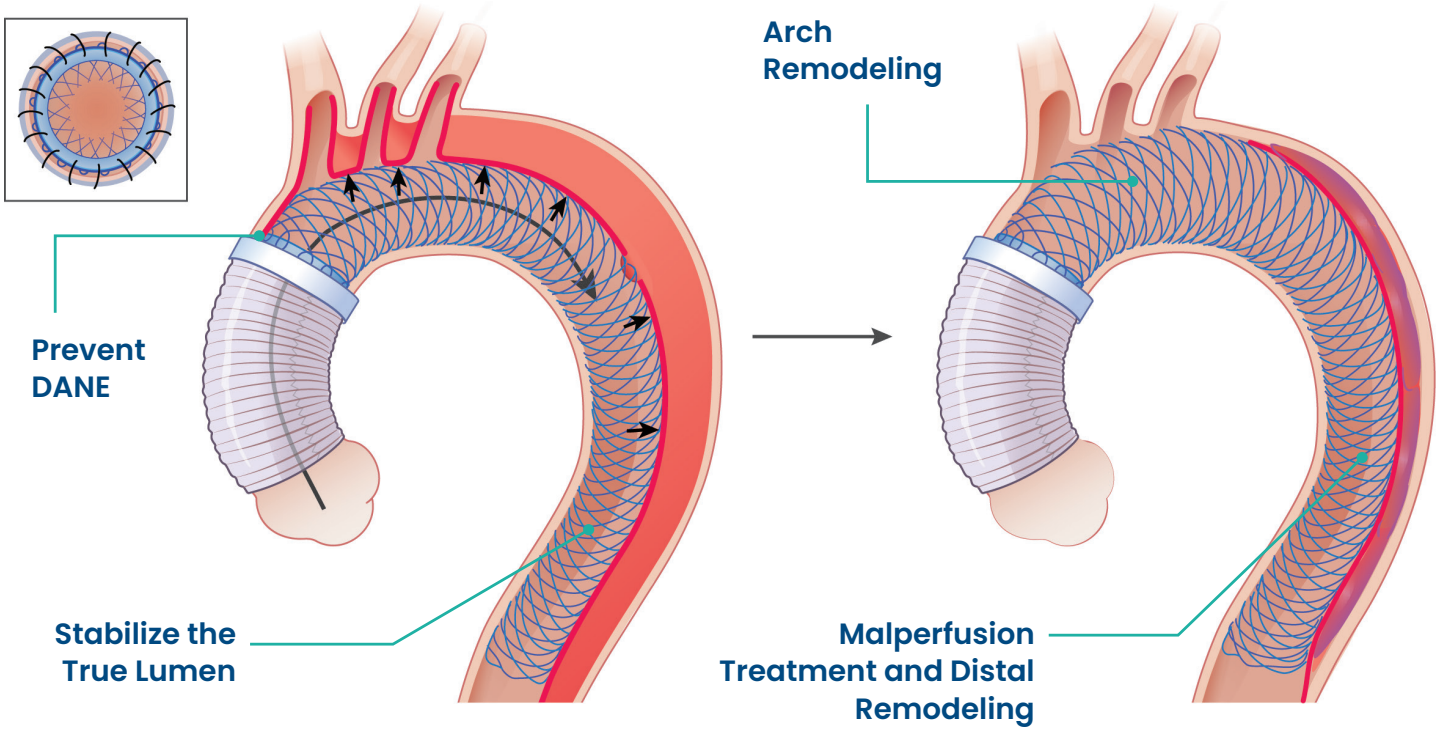
AMDS: An Elegant Solution

Nedengtas hibridinis stentas/protezas indikuotas DeBakey I tipo aortos lanko ir nusileidžiančios aortos disekacijoms gydyti

An acute type A aortic dissection, specifically DeBakey Type I (ADTI), is a life-threatening, emergent condition. Left untreated mortality is reported to be approximately 1% per hour and approximately 50% in the first 48 hours.[3] 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.

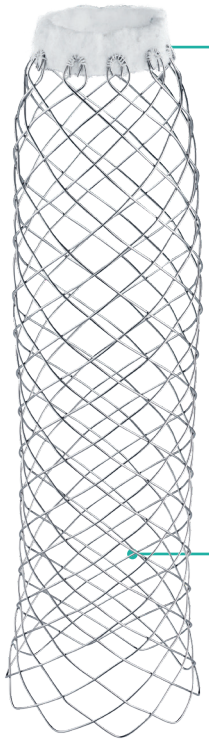
AMDS Mode of Action

AMDS is delivered in an antegrade fashion during standard open repair of a type A dissection. The stent supported felt cuff is incorporated into the distal anastomosis to prevent distal anastomotic new entry (DANE) tears. The uncovered stent stabilizes the true lumen, helping to resolve dynamic malperfusion and induce positive aortic remodeling.



Design Features

Stento proksimalus galas turi PTFE medžiagos žiedą, skirtą prisiūti prie rekonstruotos aortos lanko



PTFE felt cuff component is used to buttress and strengthen the aortic tissue at the distal anastomosis.

Pinto nitinolio konstrukcija

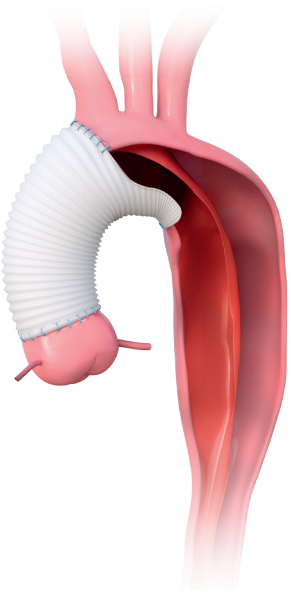
Uncovered nitinol wire braided stent expands the true lumen and stabilizes the dissection flap across the arch and descending thoracic aorta.

Stentas implantuojamas su įvedimo sistema

Proven Performance

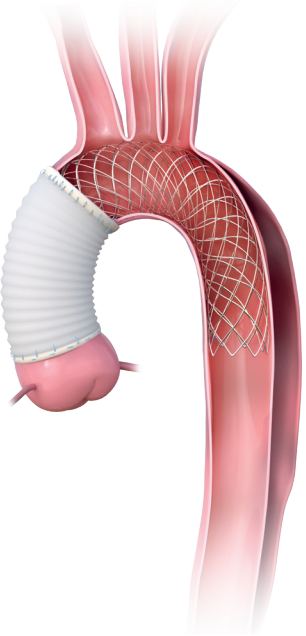
Reduction in Major Adverse Events (MAE's)

In the PERSEVERE IDE trial, the largest prospective study of acute type A dissections to date, AMDS demonstrated the ability to significantly reduce mortality and the occurance of MAE's compared to hemiarch control group in patients with pre-op malperfusion.[1]



ADTI with Malperfusion

Hemiarch Reference Cohort Average[4] (n=790 combined)		PERSEVERE[5] (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	**0.0%**
58.0%	≥ 1 MAE	**26.9%**



Prevention of DANE

0%

Instances of DANE in **PERSEVERE** (n=93) and **DARTS** (n=46)

The stent supported cuff of the AMDS and expansion of the device from the arch distally, elevates and supports the intimal flap. This reduces tension on the intima, media, and the suture line, avoiding the formation of DANEs in the friable anastomosis.[1,2]

Promotion of Positive Remodeling

By avoiding DANE and stabilizing the true lumen, AMDS induces positive aortic remodeling, defined by 3 key measures:[2]

1. True Lumen Expansion

2. False Lumen Reduction

3. Total Aortic Diameter Stabilization

Resolution of Malperfusion

In the DARTS study, AMDS demonstrated over 95% resolution of vessel malperfusion.[2]

- **Image 1:** Pre-op acute DeBakey type I aortic dissection with cerebral, celiac artery and renal malperfusion with radiographic occlusion of the innominate artery and right common carotid artery.
- **Image 2:** 1-year follow-up CTA with fully restored flow to innominate, right carotid, celiac artery and left renal artery flow.

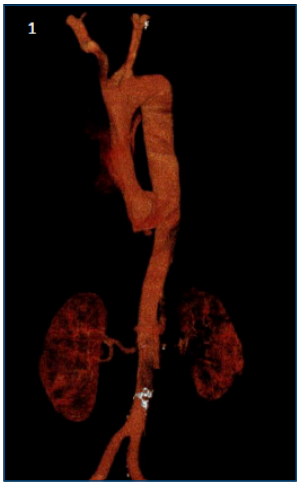


Image 1

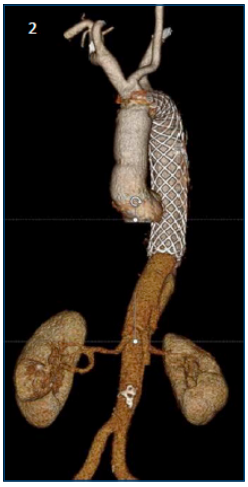


Image 2

Ease of Use

AMDS prolongs the circulatory arrest time of the standard hemiarch procedure by only a few minutes without adding significant technical complexity.

Surgical Approach: Requires minimal change to standard procedure
- 99% technical success*

Clinical Requirements: No X-ray room or hybrid room required
- 8.6% use of fluoroscopy*

Procedural Access: No additional vascular access is required with AMDS
- 9.7% use of guidewire*

Device Sizing: Simplified sizing methodology, with two simple measurements
- D1: Large or small AMDS configuration
- D2: Straight or tapered AMDS configuration

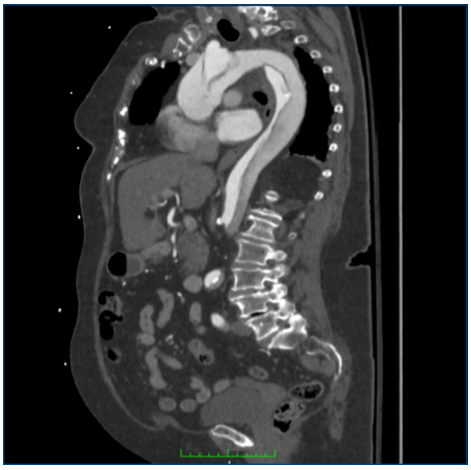
Added Time: AMDS adds minimal time to procedure
- Mean AMDS deployment time = 4 min*
- Mean AMDS implant time including distal anastomosis = 15 min*

*PERSEVERE 30-day data

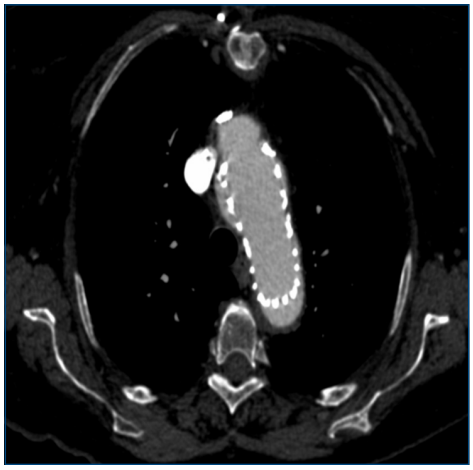
Case Examples

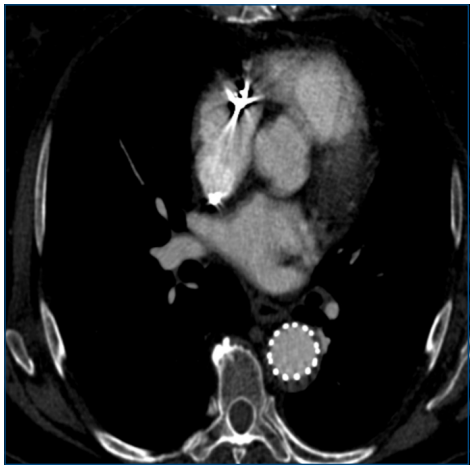
AMDS was first implanted in March of 2017, and now is available in over 30 countries worldwide. Data from the DARTS and PERSEVERE studies, among others, continue to assess and prove the efficacy of AMDS in treating this very challenging patient population.

Ex. 1: Complete Obliteration of False Lumen in the Arch and Proximal DTA



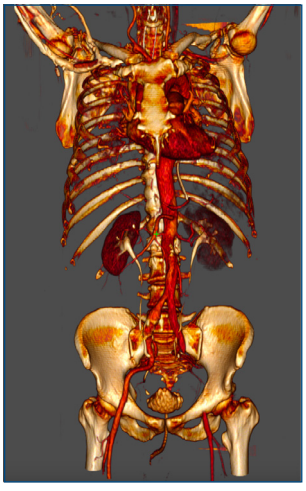
Pre-op



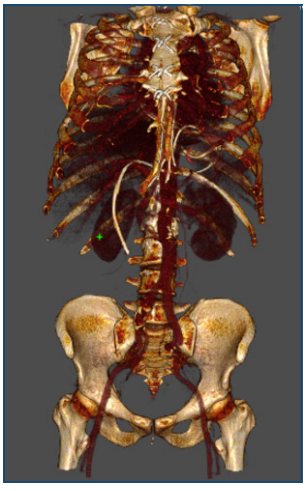


Post-op

Ex. 2: Malperfusion Resolution of Left Renal Artery and Left Iliac



Pre-op

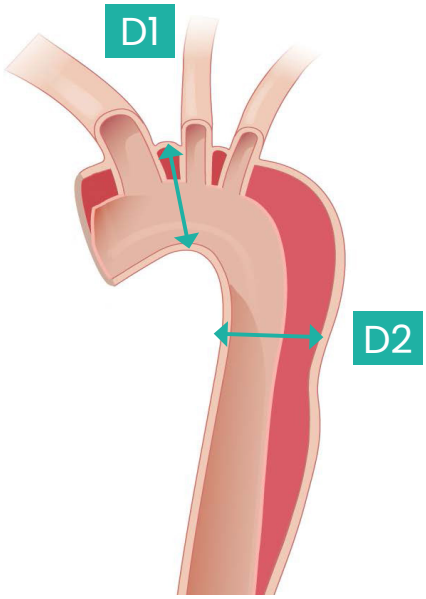


Post-op

Ordering Information

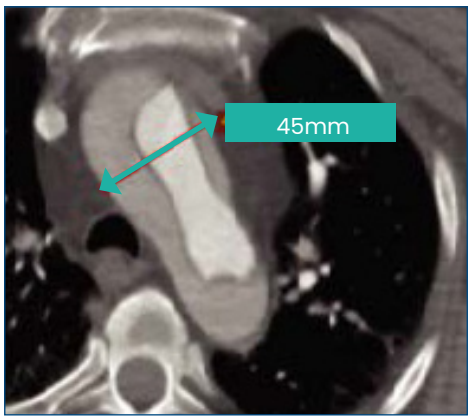
Sizing Guidance

Measure the aortic vessel diameter (adventitia to adventitia) at the D1 and D2 anatomical landmarks as shown below. It is recommended to take measurements in axial view.



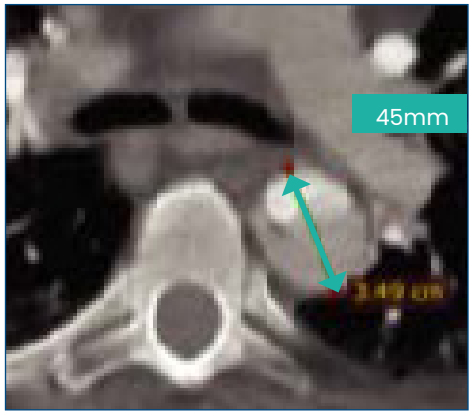
D1 Example

At the level between the innominate and left common carotid artery



D2 Example

At the level of the tracheal bifurcation of the pulmonary artery



Reference sizing chart below, when selecting the appropriate AMDS do not oversize, when in-between sizes, please select the smaller size device.

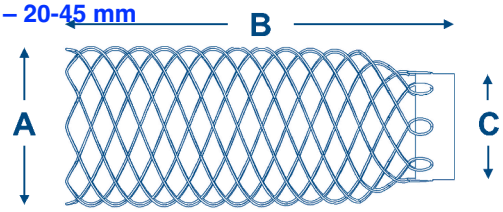
Pasirinktinai dvi stento formos – tiesi ir kūgiška **Stento ilgis 153 – 215 mm** **Žiedo diametras 24 – 32 mm**

REF	Stent Shape	Aortic Diameter Stent Sizing (A)		Aortic Length Stent Sizing (B)		(C) Felt Cuff (mm)
		D1 Proximal Diameter (mm)	D2 Distal Diameter (mm)	Stent Min Length (mm)*	Stent Max Length (mm)**	
AMDS 40c	Straight	20-35	25-35	153	207	24
AMDS 4030c	Tapered		20-24	159	203	24
AMDS 55	Straight	36-45	36-45	187	215	32
AMDS 5540	Tapered		27-35	185	211	32

Proksimalus aortinis diametras – 20 – 45 mm **Distalus aortinis diametras – 20-45 mm**

* 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



ARTIVION™

Learn more at **artivion.com**

To watch the AMDS animation, scan the QR code.

References:
1. Adjudicated data as presented at STS Jan 2024 by Dr. Wilson Szeto on behalf of corresponding authors, Results of a Novel Aortic Arch Hybrid Prosthesis for Open Repair of Acute DeBakey Type I Dissection with Malperfusion: 30-day Results from the PERSEVERE Study/Saturday 27 January 2024/3:00pm -4:00 pm. Manuscript pending publication. **2.** Bozso SJ, N. J., Chu MWA, Kiaii B, El-Hamamsy I, Ouzounian M, Forcillo J, Kempfert J, Stark C, Moon MC. (2022). 3-Year Outcomes of the Dissected Aorta Repair Through Stent Implantation Trial. J Thorac Cardiovasc Surg. doi:https://doi.org/10.1016/j.jtcvs.2022.08.040. **3.** Isselbacher EM, Preventza O, Hamilton Black J 3rd, Augoustides JG, Beck AW, Bolen MA, Braverman AC, Bray BE, Brown-Zimmerman MM, Chen EP, Collins TJ, DeAnda A Jr, Fanola CL, Girardi LN, Hicks CW, Hui DS, Schuyler Jones W, Kalahasti V, Kim KM, Milewicz DM, Oderich GS, Ogbechie L, Promes SB, Gyang Ross E, Schermerhorn ML, Singleton Times S, Tseng EE, Wang GJ, Woo YJ. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Circulation. 2022 Dec 13;146(24):e334-e482. doi: 10.1161/CIR.0000000000001106. Epub 2022 Nov 2. PMID: 36322642; PMCID: PMC9876736. **4**. Zindovic I, 2019. Pacini D, 2013. Girdauskas E, 2009. Geirsson A, 2007. and Bossone E, 2002. **5.** Szeto WY, Fukuhara S, Fleischman F, Sultan I, Brinkman W, Arnaoutakis G, Takayama H, Eudailey K, Brinster D, Jassar A, DeRose J, Brown C, Farrington W, Moon MC. A novel hybrid prosthesis for open repair of acute DeBakey type I dissection with malperfusion: Early results from the PERSEVERE trial. J Thorac Cardiovasc Surg. 2024 Aug 6:S0022-5223(24)00677-9.

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