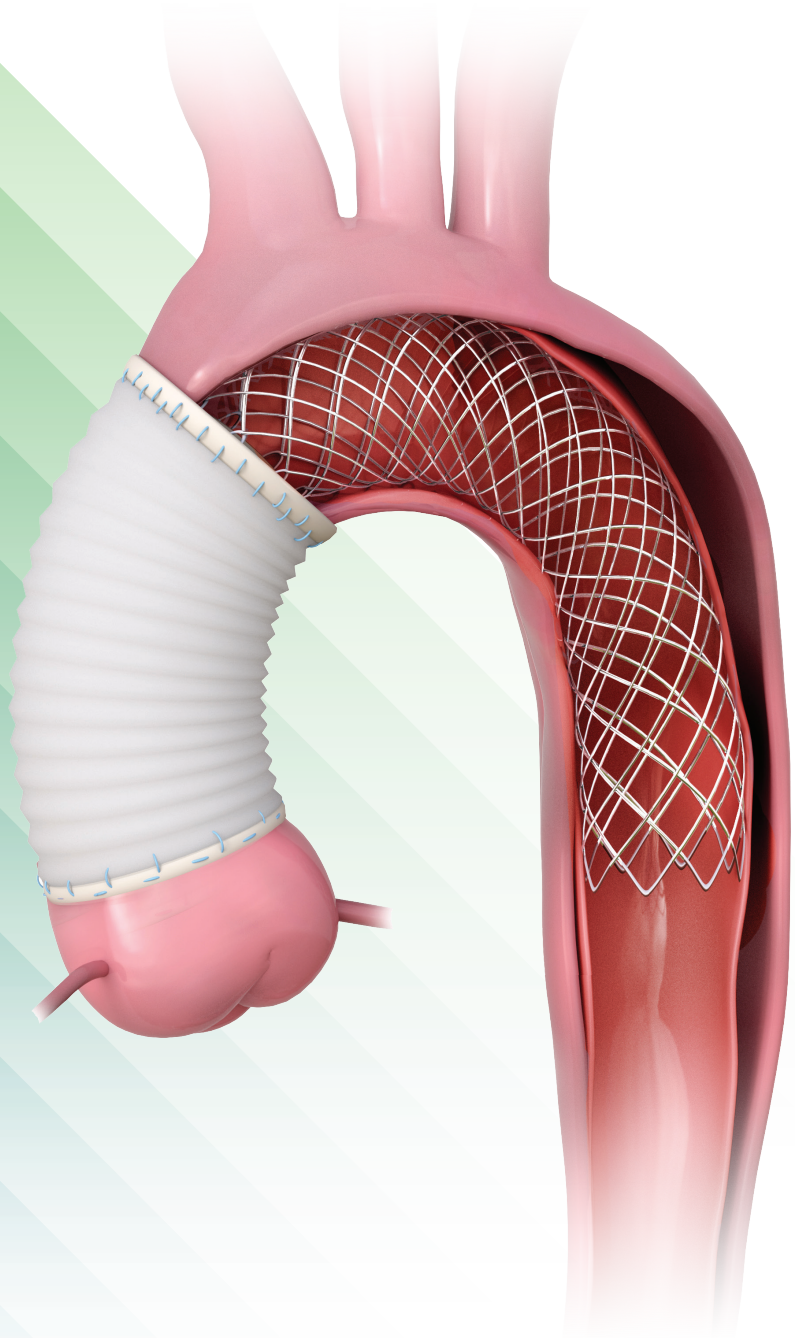
The Role of the AMDS™ Hybrid Prosthesis in Improving Outcomes for Patients with Acute DeBakey I Dissections

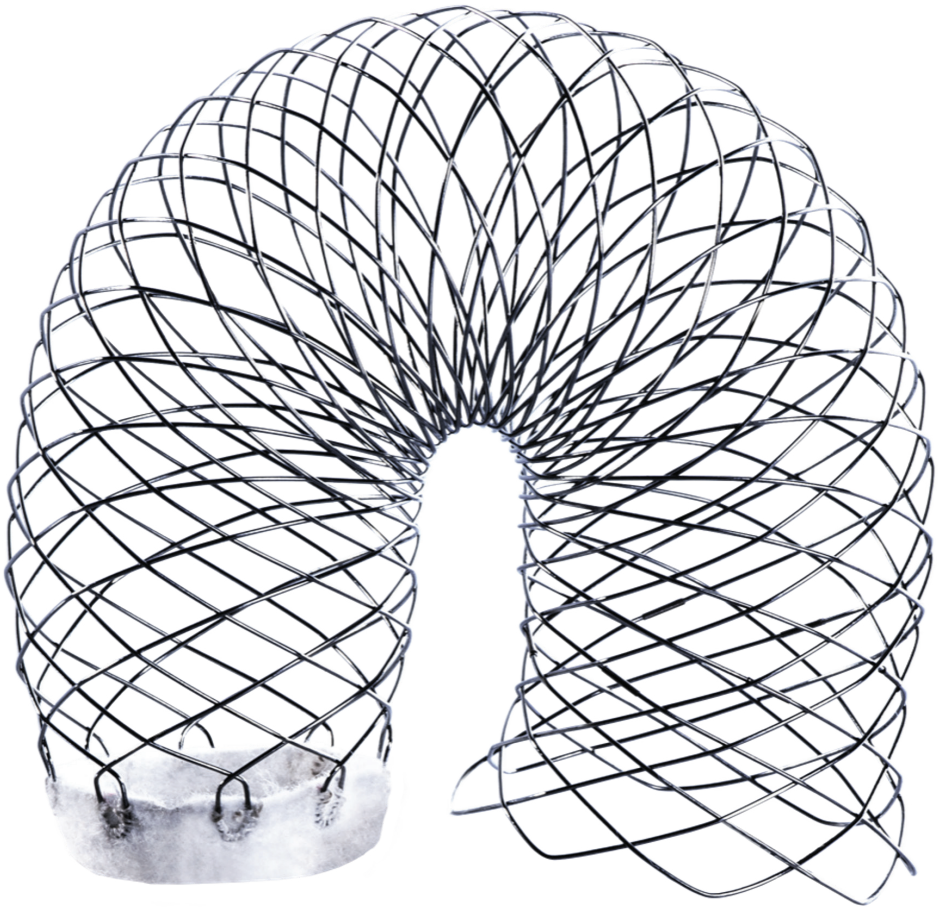


ARTIVION | AMDS™ Hybrid Prosthesis

Elevate the Standard

AMDS Hybrid Prosthesis

The world's first device designed specifically to address the unique challenges of ATAD I.



Artivion is dedicated to the collection and dissemination of data to better understand ATAD I and specifically the use of AMDS in this complex patient population.

DARTS

A prospective multi-center study of 47 patients receiving AMDS with published data out to 3 years.

PERSEVERE

Prospective multi-center IDE study actively enrolling across 20 US centers targeting enrollment of 93 patients with AMDS.

PROTECT

Post-market global registry targeting enrollment of 300 patient with AMDS.

Acute Dissection, One of the Greatest Clinical Challenges

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 0.5% per hour and approximately 24% in the first 48 hours.[1] 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.

Limitations of Hemiarch Procedure

Creation of Distal Anastomotic New Entry Tear (DANE)

DANEs have been reported in up to 70% of patients following standard surgical repair of ATAD I.[2] It's considered to be 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 (Figure 1).[3]

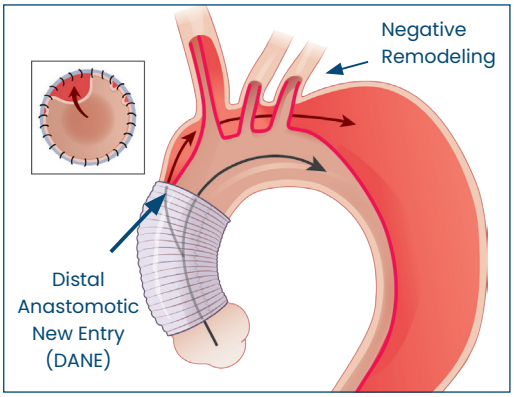


Figure 1

Negative Remodeling

Continued antegrade pulsatile flow in the false lumen can lead to continued false lumen patency and aneurysmal dilatation of the aorta after the index repair (Figure 1).[21,22]

Inability to Resolve Malperfusion

Up to 56% of ATAD I patients present with malperfusion which can lead to significant downstream effects if not resolved.[4,5,6]

Risk of Mortality

Early mortality rates are up to 22% and patients presenting with malperfusion are at even higher risk of up to 44%.[4, 6, 7, 8, 9, 10]

Required Reintervention

Reintervention rates vary significantly across centers; reintervention occurs in both the acute setting, to address persistent malperfusion, and in the longer-term setting to address negative remodeling.

Key Outcome Measures After Open Surgical Repair for Acute Dissection	Rate
Presence of DANE[2,11]	70%
Post-op malperfusion[4]	26%
Early mortality*[,4,6,7,8,9, 10]	16 – 22%
Early mortality in patients with pre-op malperfusion[6,9]	29 – 44%
Continued False Lumen Patency[21,22]	79 - 81%
Early reintervention[13]	20%
Late redo arch re-operation[15,20]	8 – 25%

*Early mortality includes 30-day mortality and in-hospital mortality

AMDS Prevents DANE and Resolves Malperf Inducing Positive Aortic Remodeling

Proven Results

DANE Prevention

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.[16,18]

Malperfusion Resolution

AMDS-induced expansion of the true lumen demonstrates over 95% resolution of vessel malperfusion.[16]

Uninhibited Flow to Supra-Aortic Vessels (SAVs)

The novel stent design of AMDS allows for uninterrupted flow into the native SAVs without surgical manipulation (i.e., bypass)(Figure 2).[16]

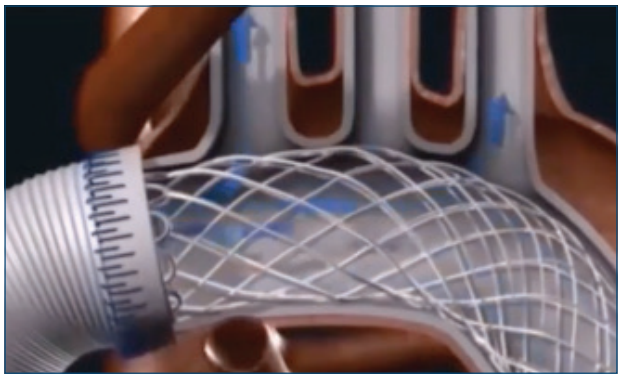


Figure 2

Reintervention Options

The open cell design of AMDS allows for minimally invasive reintervention options if necessary, with the ability to access the SAVs.

Minimal Time Added to Operation

AMDS prolongs the circulatory arrest time of the hemiarch procedure by only a few minutes without adding significant technical complexity.[17]

Key Outcome Measures After AMDS	DARTS[16,18]	Berlin 100 Patient Series[17]
Presence of DANE	0%	NR
Malperfusion resolution	96%	80%
Average deployment time*	3 min	8 min
Early mortality	13%	18%
Reintervention	13%**	13%***
Spinal Cord Injury (SCI)	0%	NR

*Does not include suture time. **Average. 3 year follow up. *** 30 day follow up. NR = not reported

fusion,

Positive Aortic Remodeling:

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

1. True Lumen (TL) Expansion

2. False Lumen (FL) Reduction

3. Total Aortic Diameter Stabilization

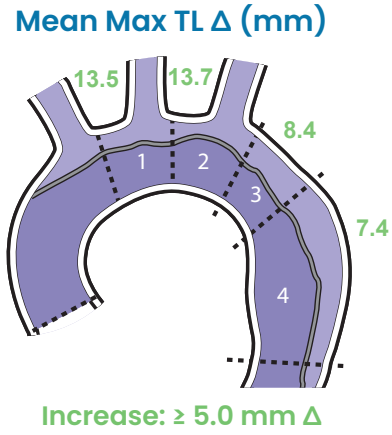


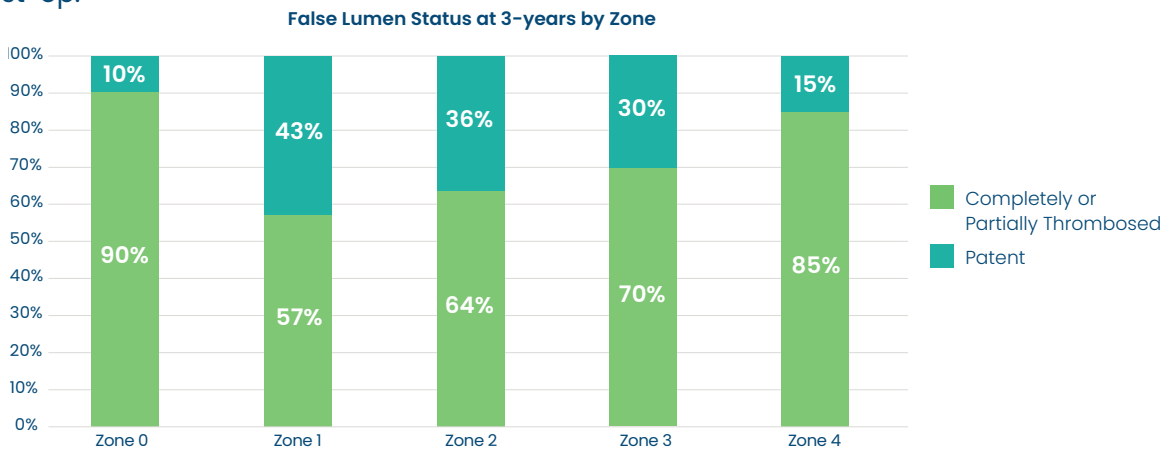
Figure 3

True Lumen Expansion

DARTS study demonstrated sustained true lumen expansion ≥ 5.0 mm in aortic Zones 1 – 4 from pre-op to 3 years, post-op (Figure 3).[19]

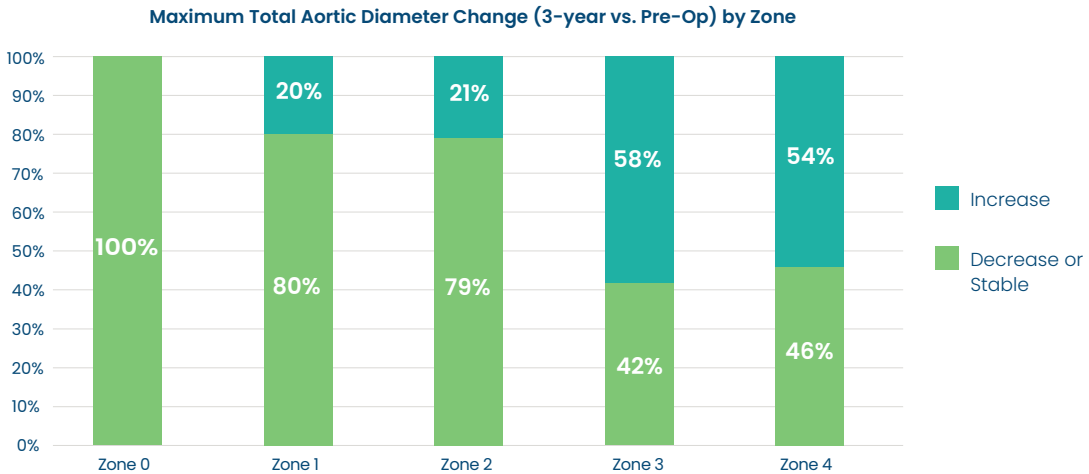
False Lumen Reduction

DARTS study demonstrated complete or partial false lumen thrombosis in the majority of patients in Zones 0 – 4 at 3 years, post-op.[19]



Total Aortic Diameter Stabilization

DARTS study demonstrated total aortic diameter stability or decrease in a majority of patients in Zones 0 – 2 and half of patients in Zones 3 and 4 at 3 years, post-op.[19]



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To View the Full Clinical Compendium on AMDS, Scan the QR Code.

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