Medtronic

Valiant™ Thoracic Stent Graft
with the Captivia™ Delivery System

Deploy durability

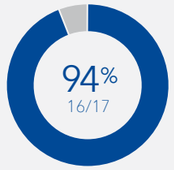
Five-year results: Dissection Trial
TEVAR in Acute, Complicated Type B Dissection[1]

89%

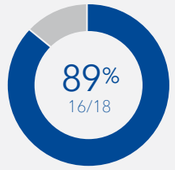
of patients treated with Valiant Captivia system achieved positive and sustained aortic remodeling through five years

89% (16/18) achieved sustained aortic remodeling, with false lumen thrombosis and true lumen expansion increasing over time in this challenging patient cohort (94% DeBakey class IIIB)

Sustained aortic remodeling



true lumen diameter increase/stable and true lumen volume increase – with 92.3% (24/26) true lumen diameter increase/stable already achieved at three years[2]



complete false lumen thrombosis[1]

proximal entry tears fully excluded[3]

Key highlights through five years

No instances of postimplant rupture

No conversions to open repair for the descending aortic dissection

No aortic ruptures

No core lab reported type Ib endoleaks

Low RTAD incidence through one year in complicated TBAD*

Medtronic
Dissection Trial[3]
(2/50)

4.0%

Cook™*
Stable Trial[4]
(3/40)

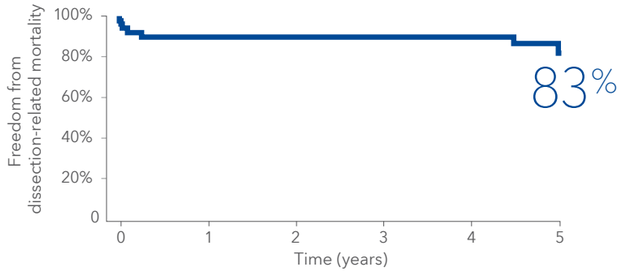
7.5%

Gore™*
Dissection IDE[5]
(5/50)

10.0%

Results are taken from independent clinical studies for illustration purposes only and are not based on statistical analysis. Results may differ in a head-to-head comparison; multiple factors contribute to clinical study outcomes and need to be considered in making assessments across different studies.

Five-year freedom from dissection-related mortality



94%

freedom from type Ia endoleak through 5 years

Three core lab reported type Ia endoleaks over the 5 years: two were detected at six-month follow-up and neither needed reintervention

86%

freedom from secondary endovascular procedures related to the dissection

Trial quick facts

Objective

Evaluate the clinical performance of the Valiant Captivia thoracic stent graft system for the treatment of acute, complicated Type B aortic dissections.

Study design

Prospective, non-randomized, multicenter trial with the Valiant Captivia Thoracic Stent Graft System

16 U.S. centers

n = 50 patients with acute, complicated (malperfusion, rupture) Type B aortic dissection

Primary endpoint: all-cause mortality within 30 days of index procedure

Clinical status at onset

94% DeBakey class IIIB dissections (46/49)

86% Malperfusion (43/50)

20% Rupture (10/50)

References

™*Third party brands are trademarks of their respective owners.

*RTAD incidence from leading competitor stent grafts is not intended for cross-study comparison of different stent grafts or patient cohorts.

[1] Bavaria JE, Brinkman WT, Hughes GC, et al. Five-year outcomes of endovascular repair of complicated acute type B aortic dissections. *J Thorac Cardiovasc Surg*. Published online May 13, 2020.

[2] Lim CY, et al. Endovascular Repair in Acute Complicated Type B Aortic Dissection: 3-Year Results from the Valiant US Investigational Device Exemption Study. *Korean J Thorac Cardiovasc Surg*. 2017 June;50(3):137-143.

[3] Bavaria J, Brinkman W, Hughes C, et al. Outcomes of Thoracic Endovascular Aortic Repair in Acute Type B Aortic Dissection: Results From the Valiant United States Investigational Device Exemption Study. *Ann Thorac Surg*. September 2015;100(3):802-808.

[4] Lombardi JV, Cambria RP, Nienaber CA, et al. Prospective multicenter clinical trial (STABLE) on the endovascular treatment of complicated type B aortic dissection using a composite device design. *J Vasc Surg*. 2012 Mar;55(3):629-640.e2.

[5] Gore Dissection IDE: Gore cTAG IFU pages 56 and 69

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

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