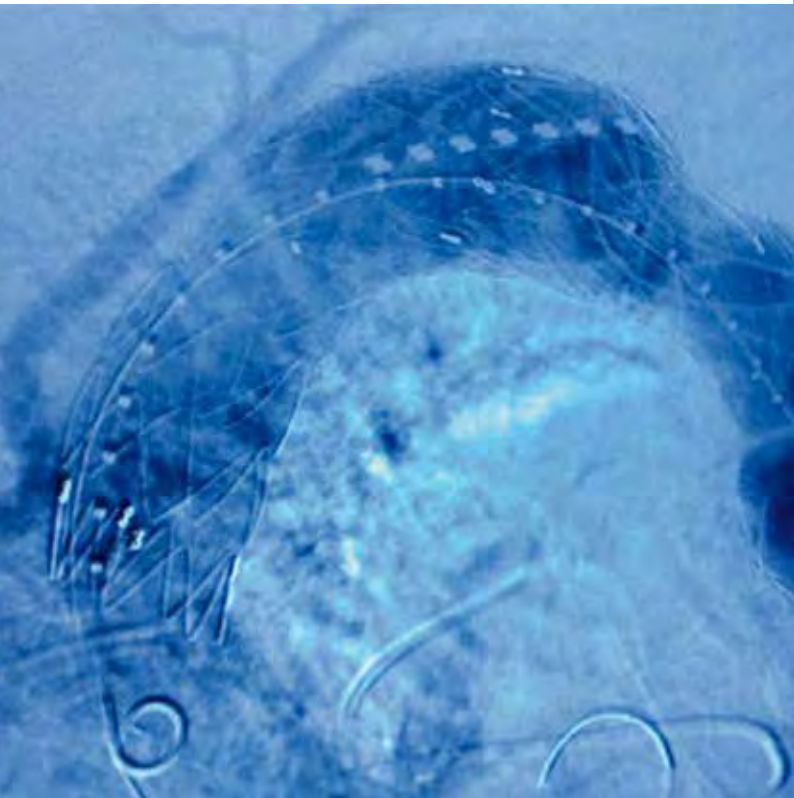


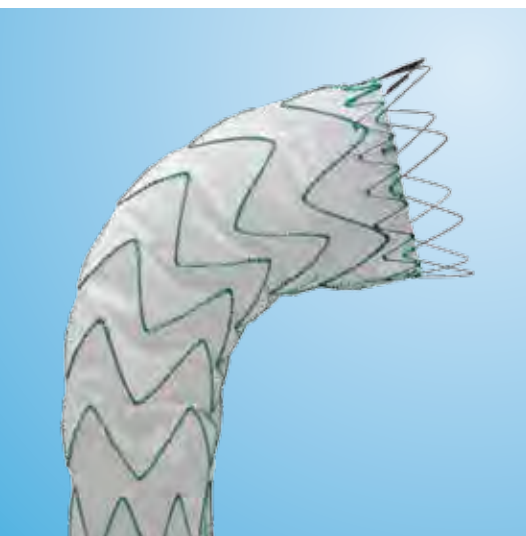
**Valiant™** Thoracic Stent Graft  
with the **Captivia™** Delivery  
System



# PROVEN DESIGN

The proven design and performance of the **Valiant™ Captivia™ system** offers a broad set of options to treat a wide range of patient anatomies.<sup>1-4</sup>

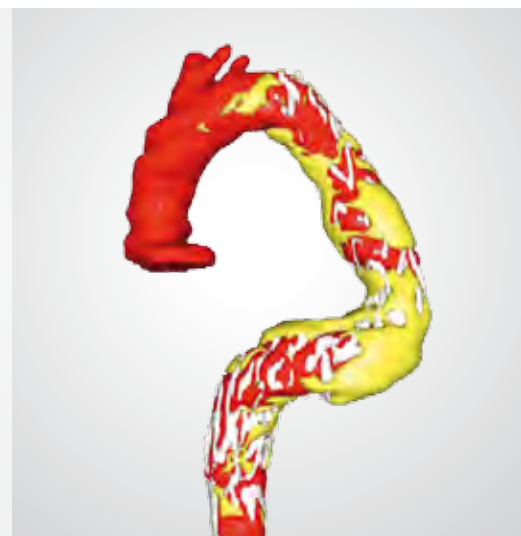
Proven design with enhanced conformability and kink resistance

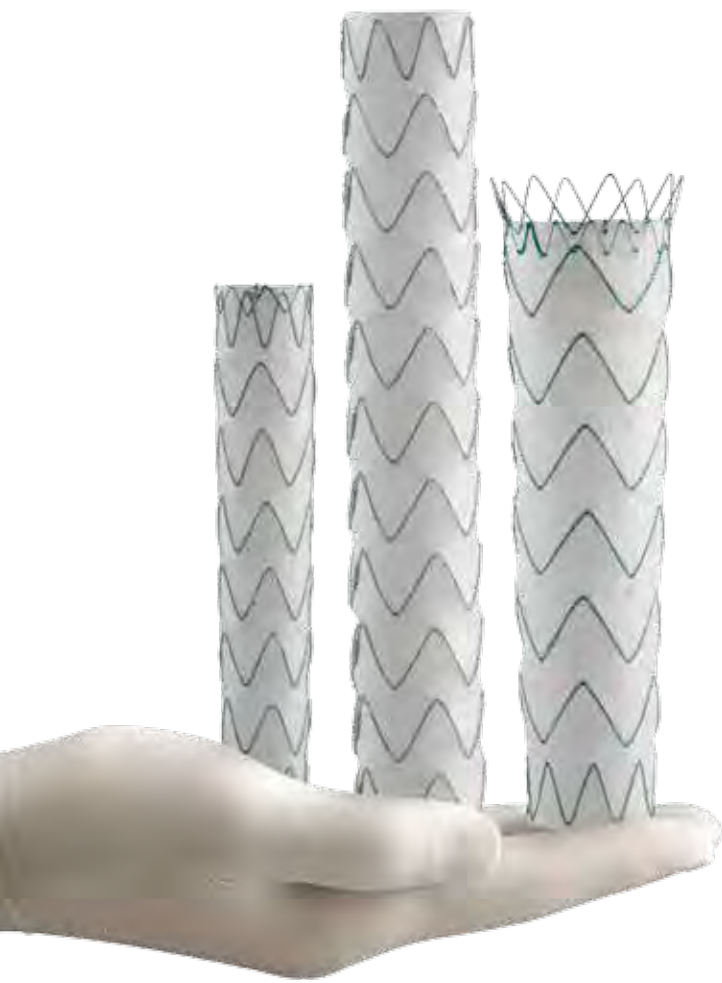


Additional components to treat a wide range of anatomies



Consistent clinical performance across a variety of pathologies





The Valiant™ Captivia™ system with proximal FreeFlo tapers continues to deliver proven performance with additional components for broad patient suitability.

**A tapered stent graft should be preferred for the majority of patients with dissection.<sup>1</sup>**

The Valiant™ Captivia™ system with proximal FreeFlo tapers helps you treat more anatomies with confidence.

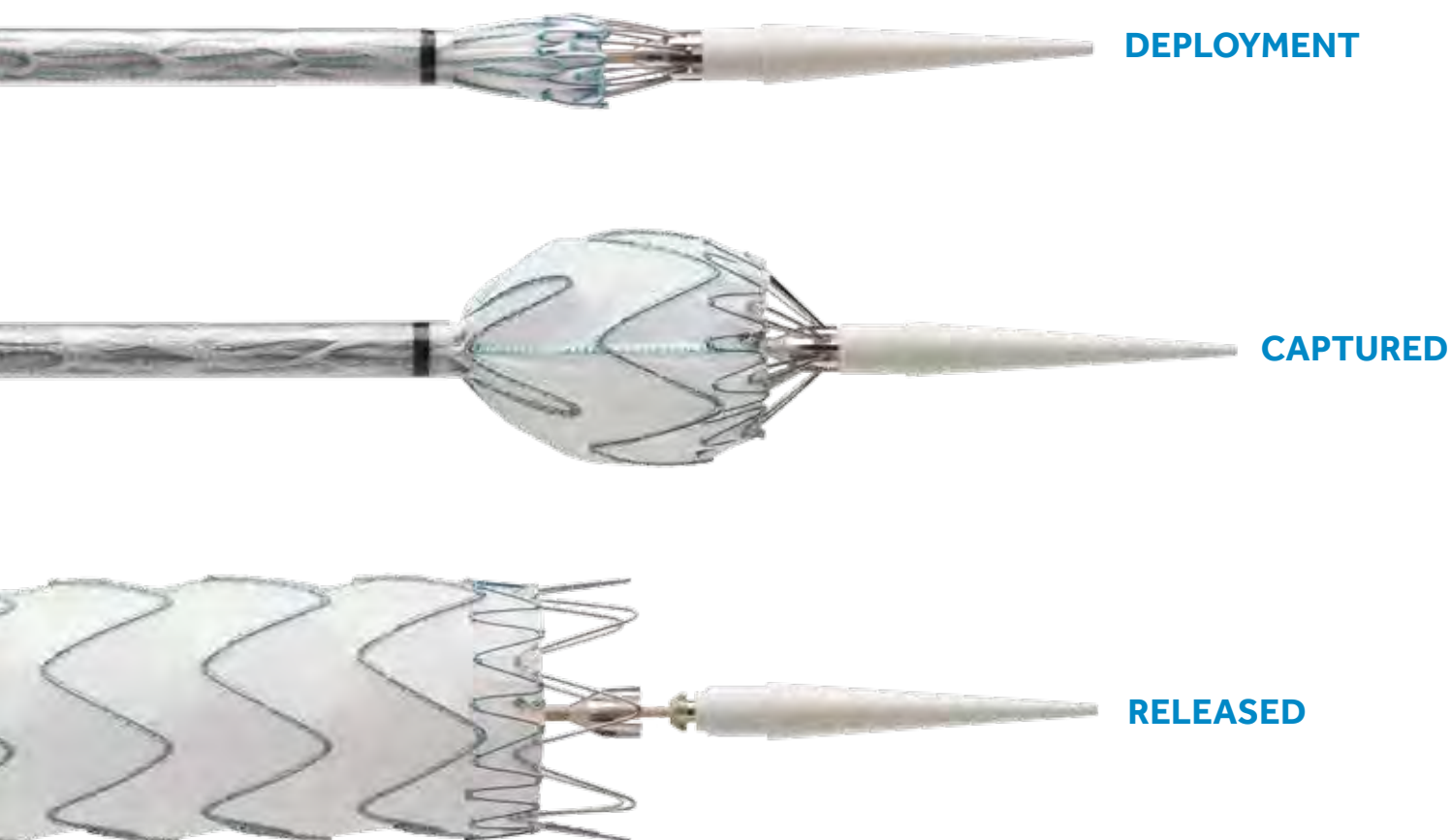


Tip capture for accuracy of positioning

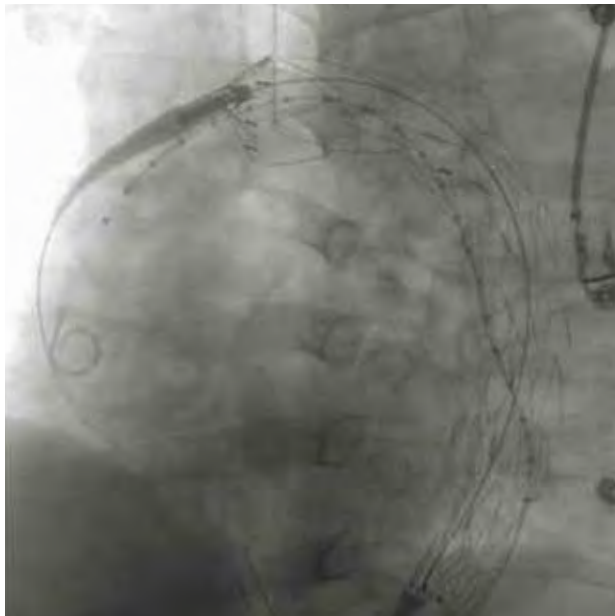
<sup>1</sup>Pantaleo A, Jafrancesco G, Buia F, et al. Distal Stent Graft-Induced New Entry: An Emerging Complication of Endovascular Treatment in Aortic Dissection. *Ann Thorac Surg.* 2016;102(2):527-532.

# PRECISE DEPLOYMENT

Controlled Deployment  
with Tip Capture

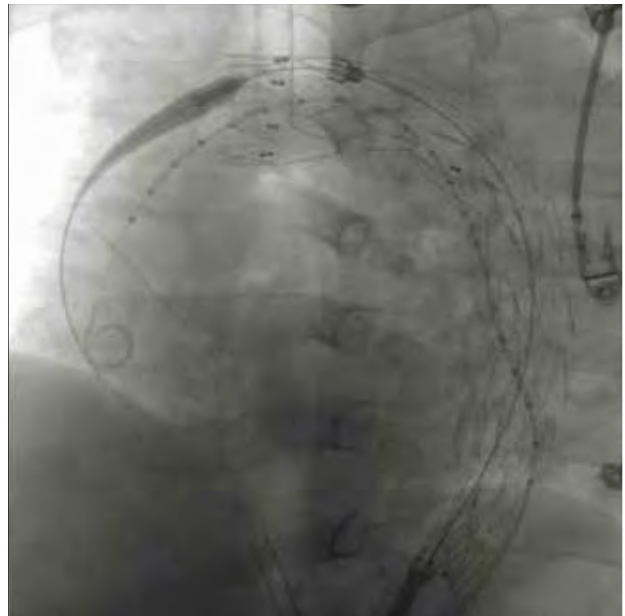


The Valiant™ Captivia™ system features tip capture of the proximal stent. Tip capture provides controlled deployment and placement when navigating the thoracic aorta.



### **PLACEMENT**

Tip capture provides accurate stent graft placement



### **RELEASE**

After tip capture is released, the Valiant™ Captivia™ system conforms to the patient's anatomy

# OPTIMAL SEAL

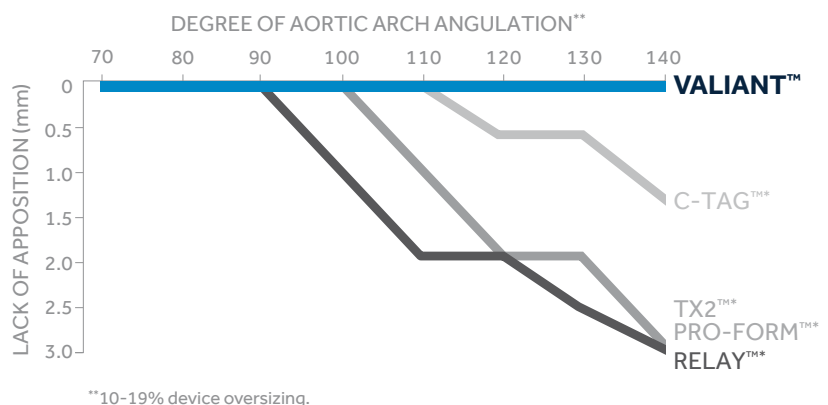
The Valiant™ Captivia™ system is designed to conform to the thoracic aorta. The sinusoidal shape and placement of nitinol springs provide flexibility and conformability to the anatomy. The Valiant™ stent graft is the only device that maintains complete apposition regardless of angulation and oversizing.<sup>2</sup>

## RESULTS

The Valiant™ stent graft remained apposed to the aortic wall at each increment of neck angulation and degree of oversizing in a simulated environment.

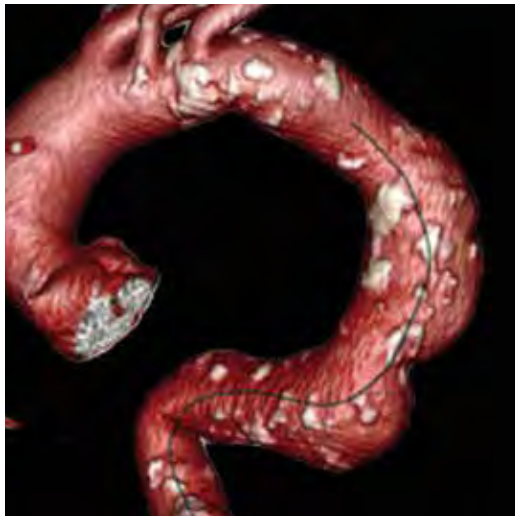
For the other stent grafts tested, lack of device wall apposition was observed between the proximal anchorage segment and the inferior aortic wall.

### Angular Flexibility and Radial Strength Give the Valiant™ Captivia™ Stent Graft Conformability and Optimal Seal<sup>2</sup>

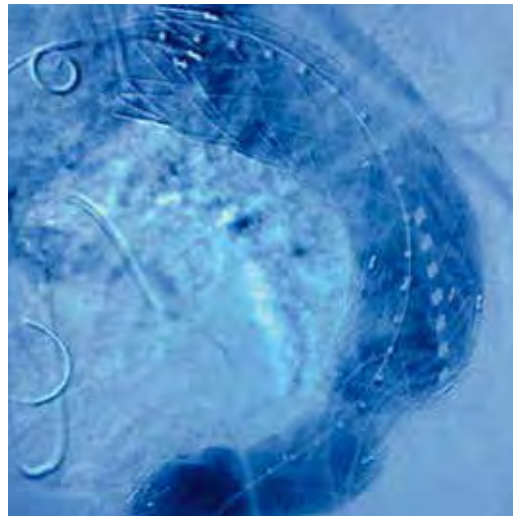


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<sup>2</sup>Canaud L, Cathala P, Joyeux F, Branchereau P, Marty-Ané C, Alric P. Improvement in conformability of the latest generation of thoracic stent grafts. *J Vasc Surg.* April 2013;57(4):1084-1089.



**PRE** — 3-D reconstruction of patient anatomy<sup>†</sup>



**POST** -index procedure result<sup>†</sup>

PRODUCT TESTED	Proximal Apposition at Different Landing Zone Angulation	Body Apposition at Different Landing Zone Angulation
Medtronic Valiant™	No lack of apposition (remained apposed)	No lack of apposition (remained apposed)
Gore™ C-TAG™*	Lack of apposition above 120°	No lack of apposition (remained apposed)
Bolton Relay™*	Lack of apposition above 110°	No lack of apposition (remained apposed)
Cook Zenith™ TX2™ Pro-Form™*	No lack of apposition (remained apposed)	Lack of apposition above 110°

Test data not indicative of clinical performance.

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

†Images courtesy of The Heart Hospital Baylor Plano.

# EASE OF ACCESS

The Valiant™ Captivia™ system features a crossing profile similar to or lower than other thoracic stent grafts for ease of access. Tip capture release means control across a broad range of pathologies.



## TIP CAPTURE RELEASE HANDLE

Simple turn-and-pull motion for tip release

## DEVICE OUTER DIAMETER PROFILES

	Medtronic Valiant™	Bolton Relay™ Plus	Cook Zenith™* TX2™* Pro-Form™*	Gore™* C-TAG™*
Crossing Profile (OD) <sup>†</sup>	24 F	24 F	26 F	27 F
Hydrophilic Coating	Yes	Yes	No	No
Sheath Required	No	No	Yes	Yes

System OD for Gore C-TAG and Cook Zenith list the OD of sheath as their IFUs recommend the use of a sheath. The System OD for Medtronic Valiant and Bolton Relay list the OD of the delivery catheter as the use of a sheath is not required per the respective IFUs.

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<sup>†</sup>36 mm diameter graft used for comparison for all manufacturers except Gore. A 37 mm diameter graft used for Gore since no 36 mm diameter graft exists.



## EASY THREE-STEP DEPLOYMENT PROCESS



### Step 1

Slow, controlled deployment for precise stent graft placement



### Step 2

Quick deployment option if desired



### Step 3

Tip capture release

## HYDROPHILIC COATING

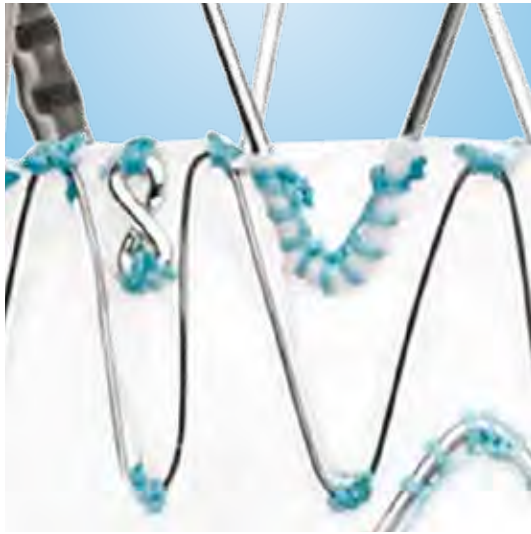
to facilitate stent graft delivery



# PROVEN DESIGN



The Valiant™ Captivia™ system is built on 12 years of worldwide experience and is proven in more than 100,000 implants. Our advanced design enhances confidence.†



**Figur8 Markers for Accurate Placement.** Platinum-iridium markers provide high visibility.



**Proximal 8-peak FreeFlo Configuration.** Evenly distributes radial force over multiple apices.



**Broad Selection of Pieces.** Broad selection of proximal and distal components leads to many combinations to customize for a variety of patients.



**Enhanced Conformability.** Absence of longitudinal bar allows for enhanced flexibility and kink resistance.

<sup>†</sup>Bench test results may not be indicative of clinical performance with reference M333320F001DOC1, TR11570.

# PROVEN CLINICAL TRACK RECORD

Proven performance across a variety of thoracic pathologies

## U.S. Medtronic Dissection Trial<sup>3</sup>

Prospective, nonrandomized, multicenter

Long-term Outcomes of TEVAR in Acute Type B Aortic Dissection: Results from the Valiant™ U.S. IDE Trial

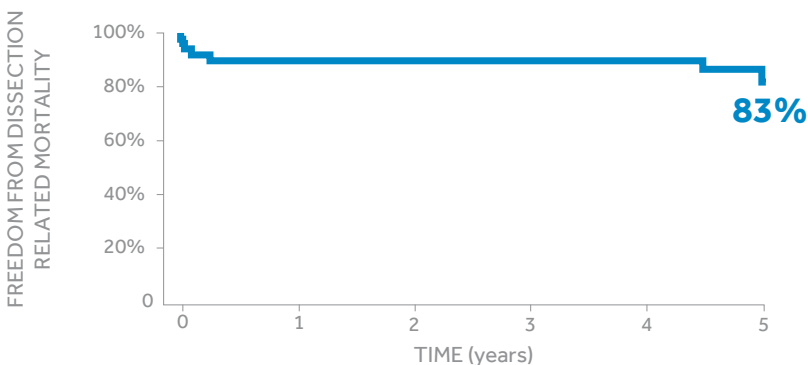
### FIVE-YEAR RESULTS

The Valiant™ Captivia™ system effectively treated acute complicated Type B aortic dissections with positive aortic remodeling through five years

### FIVE-YEAR EVIDENCE HIGHLIGHTS

- **94%** (16/17) true lumen diameter increase/stable
- **100%** (50/50) proximal entry tears fully excluded<sup>4</sup>
- **89%** (16/18) complete false lumen thrombosis
- **94%** (46/49) presented with DeBakey class IIIB dissections

### FREEDOM FROM DISSECTION-RELATED MORTALITY



“The majority of patients with acute Type B dissection will fail medical therapy over time... Patients who underwent any aortic intervention had a significant survival advantage over those who were treated with medical management alone.”<sup>5</sup>

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> Any aortic intervention compared to medical management alone (76.4% +/- 4.7% vs 59.3% +/- 3.8%; p<0.05). Further study is necessary to determine who will benefit most from early intervention. Durham CA, Cambria RP, Wang LJ, et al. The natural history of medically managed acute type B aortic dissection. *J Vasc Surg.* May 2015;61(5):1192-1198.

## The Valiant™ Captivia™ System Successfully Treats

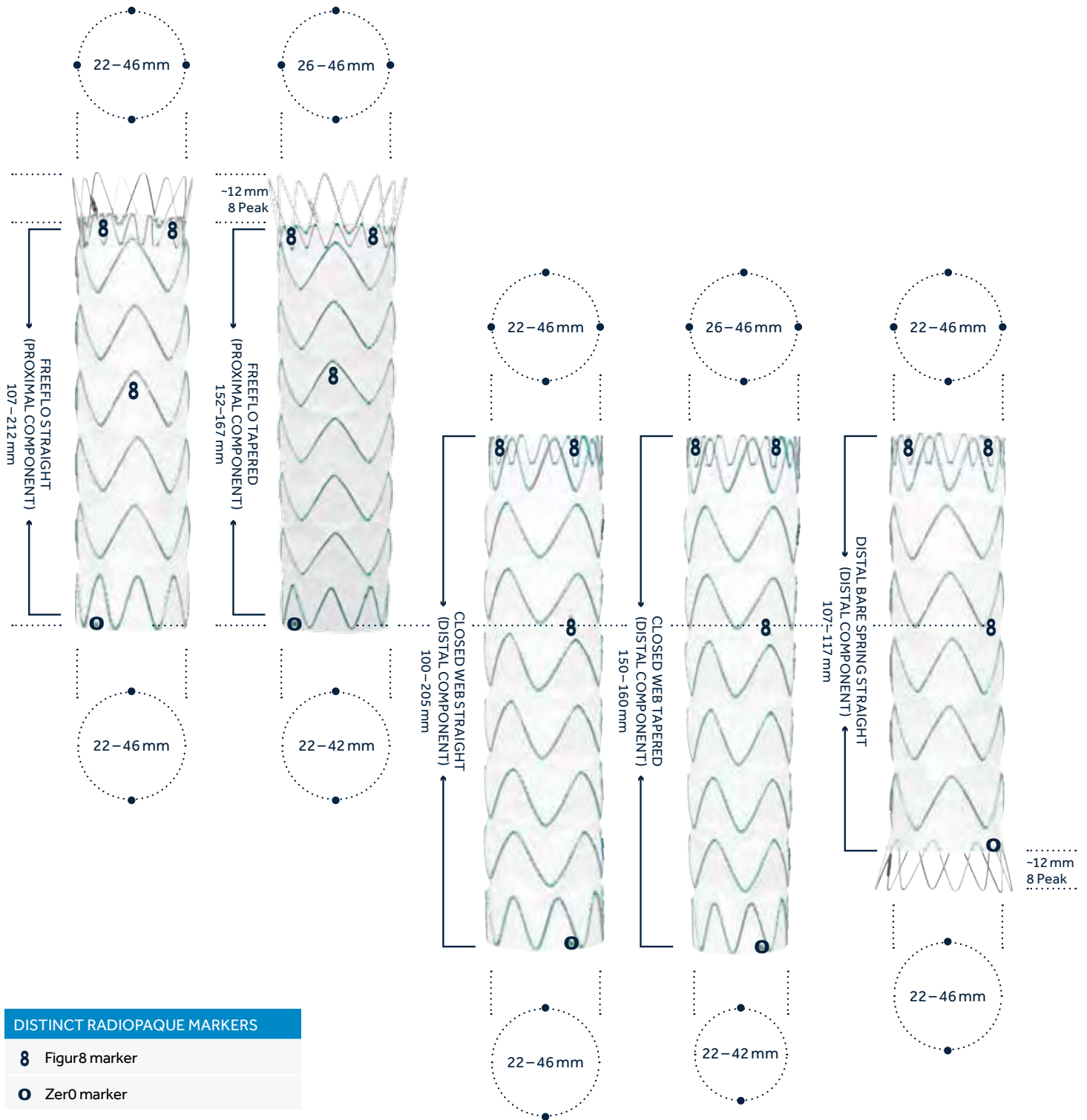
### Broad Range of Pathologies and Anatomies

Comprehensive clinical studies and registries support the use of TEVAR with Valiant™ Captivia™ in patients with aortic dissections

## MEDTRONIC CLINICAL DATA SUPPORTS THE USE OF TEVAR ACROSS MULTIPLE PATHOLOGIES

CLINICAL TRIAL/STUDY	# PATIENTS ENROLLED	TRIAL STUDY DESIGN
<b>VALOR II</b> (Valiant™ stent graft)	160	Prospective, nonrandomized, multicenter U.S. IDE study conducted to evaluate the safety and effectiveness of the Valiant™ stent graft system in patients with descending thoracic aneurysms
<b>VIRTUE</b> (Valiant™ stent graft)	100	Prospective, nonrandomized, multicenter European registry evaluating Valiant™ in Type B aortic dissections
<b>VALIANT™ CAPTIVIA™ REGISTRY</b> (Valiant™ Captivia™ system)	100	Multicenter, noninterventional, single arm registry, mid- to high-risk all comer cohort
<b>RESCUE</b> (Valiant™ Captivia™ system)	50	Prospective, nonrandomized, multicenter U.S. IDE trial to evaluate device performance in blunt thoracic aortic injury
<b>Medtronic U.S. DISSECTION Trial</b> (Valiant™ Captivia™ system)	50	Prospective, nonrandomized, multicenter U.S. IDE trial to evaluate device performance in acute, complicated Type B aortic dissections

# COMPONENT PLACEMENT GUIDE AND PRODUCT CODES



**PROXIMAL FREEFLO STRAIGHT**

Product Code						Catheter Outer Diameter (F)	Stent Graft Covered Length (mm)
Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design					
VAMF	22	22	C	100	TU	22	112
VAMF	24	24	C	100	TU	22	112
VAMF	26	26	C	100	TU	22	112
VAMF	28	28	C	100	TU	22	117
VAMF	30	30	C	100	TU	22	117
VAMF	32	32	C	100	TU	22	117
VAMF	34	34	C	100	TU	24	107
VAMF	36	36	C	100	TU	24	107
VAMF	38	38	C	100	TU	24	107
VAMF	40	40	C	100	TU	24	107
VAMF	42	42	C	100	TU	25	112
VAMF	44	44	C	100	TU	25	112
VAMF	46	46	C	100	TU	25	112
VAMF	22	22	C	150	TU	22	152
VAMF	24	24	C	150	TU	22	152
VAMF	26	26	C	150	TU	22	152
VAMF	28	28	C	150	TU	22	157
VAMF	30	30	C	150	TU	22	157
VAMF	32	32	C	150	TU	22	157
VAMF	34	34	C	150	TU	24	167
VAMF	36	36	C	150	TU	24	167
VAMF	38	38	C	150	TU	24	167
VAMF	40	40	C	150	TU	24	167
VAMF	42	42	C	150	TU	25	157
VAMF	44	44	C	150	TU	25	157
VAMF	46	46	C	150	TU	25	162
VAMF	30	30	C	200	TU	22	192
VAMF	32	32	C	200	TU	22	192
VAMF	34	34	C	200	TU	24	212
VAMF	36	36	C	200	TU	24	207
VAMF	38	38	C	200	TU	24	207
VAMF	40	40	C	200	TU	24	212
VAMF	42	42	C	200	TU	25	207
VAMF	44	44	C	200	TU	25	212
VAMF	46	46	C	200	TU	25	212

**CLOSED WEB STRAIGHT**

Product Code						Catheter Outer Diameter (F)	Stent Graft Covered Length (mm)
Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design					
VAMC	22	22	C	100	TU	22	105
VAMC	24	24	C	100	TU	22	105
VAMC	26	26	C	100	TU	22	105
VAMC	28	28	C	100	TU	22	110
VAMC	30	30	C	100	TU	22	110
VAMC	32	32	C	100	TU	22	110
VAMC	34	34	C	100	TU	24	100
VAMC	36	36	C	100	TU	24	100
VAMC	38	38	C	100	TU	24	100
VAMC	40	40	C	100	TU	24	100
VAMC	42	42	C	100	TU	25	105
VAMC	44	44	C	100	TU	25	105
VAMC	46	46	C	100	TU	25	105
VAMC	22	22	C	150	TU	22	145
VAMC	24	24	C	150	TU	22	145
VAMC	26	26	C	150	TU	22	145
VAMC	28	28	C	150	TU	22	150
VAMC	30	30	C	150	TU	22	150
VAMC	32	32	C	150	TU	22	150
VAMC	34	34	C	150	TU	24	160
VAMC	36	36	C	150	TU	24	160
VAMC	38	38	C	150	TU	24	160
VAMC	40	40	C	150	TU	24	160
VAMC	42	42	C	150	TU	25	150
VAMC	44	44	C	150	TU	25	150
VAMC	46	46	C	150	TU	25	155
VAMC	30	30	C	200	TU	22	185
VAMC	32	32	C	200	TU	22	185
VAMC	34	34	C	200	TU	24	205
VAMC	36	36	C	200	TU	24	200
VAMC	38	38	C	200	TU	24	200
VAMC	40	40	C	200	TU	24	205
VAMC	42	42	C	200	TU	25	200
VAMC	44	44	C	200	TU	25	205
VAMC	46	46	C	200	TU	25	205

**PROXIMAL FREEFLO TAPERED**

Product Code						Catheter Outer Diameter (F)	Stent Graft Covered Length (mm)
Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design					
VAMF	26	22	C	150	TU	22	152
VAMF	28	24	C	150	TU	22	157
VAMF	30	26	C	150	TU	22	157
VAMF	32	28	C	150	TU	22	157
VAMF	34	30	C	150	TU	24	167
VAMF	36	32	C	150	TU	24	167
VAMF	38	34	C	150	TU	24	167
VAMF	40	36	C	150	TU	24	167
VAMF	42	38	C	150	TU	25	157
VAMF	44	40	C	150	TU	25	157
VAMF	46	42	C	150	TU	25	162

**DISTAL BARE SPRING STRAIGHT**

Product Code						Catheter Outer Diameter (F)	Stent Graft Covered Length (mm)
Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design					
VAMC	22	22	B	100	TU	22	112
VAMC	24	24	B	100	TU	22	112
VAMC	26	26	B	100	TU	22	112
VAMC	28	28	B	100	TU	22	117
VAMC	30	30	B	100	TU	22	117
VAMC	32	32	B	100	TU	22	117
VAMC	34	34	B	100	TU	24	107
VAMC	36	36	B	100	TU	24	107
VAMC	38	38	B	100	TU	24	107
VAMC	40	40	B	100	TU	24	107
VAMC	42	42	B	100	TU	25	112
VAMC	44	44	B	100	TU	25	112
VAMC	46	46	B	100	TU	25	112

**CLOSED WEB TAPERED**

Product Code						Catheter Outer Diameter (F)	Stent Graft Covered Length (mm)
Proximal Graft Diameter (mm)	Distal Graft Diameter (mm)	Distal Design					
VAMC	26	22	C	150	TU	22	150
VAMC	28	24	C	150	TU	22	150
VAMC	30	26	C	150	TU	22	150
VAMC	32	28	C	150	TU	22	150
VAMC	34	30	C	150	TU	24	160
VAMC	36	32	C	150	TU	24	160
VAMC	38	34	C	150	TU	24	160
VAMC	40	36	C	150	TU	24	160
VAMC	42	38	C	150	TU	25	150
VAMC	44	40	C	150	TU	25	150
VAMC	46	42	C	150	TU	25	155

**HELI-FX™ THORACIC RECOMMENDED NUMBER OF ENDOANCHOR™ IMPLANTS**

- The following is recommended based on internal testing
- Additional or fewer EndoAnchor implants may be placed at physician discretion

Aortic Neck Diameter (Proximal or Distal)	Recommended Minimum Number of EndoAnchor Implants		
	Graft Angulation		
	≤ 60°	> 60° and < 75°	> 75° and < 90°
≤ 29 mm	4	4	4
30–32 mm	4	4	5
33–36 mm	4	5	7
37–40 mm	5	6	8
> 40 mm	5	7	9

Sizing of the anatomy and EndoAnchor decisions are the responsibility of the physician

The approved name of Valiant™ Captivia™ system is Valiant™ Thoracic Stent Graft with the Captivia™ Delivery System.

#### References

1. Conrad, M., Tucheck, J., Freezor, R., Bavaria, J., White, R., Fairman, R. Results VALOR II Medtronic Valiant TSG. Journal of Vascular Surgery. 2017.
2. Bavaria J, Brinkman, W., Hughes, C., et al. "Five-year outcomes of endovascular repair of complicated acute type B aortic dissections". J Thorac Cardiovasc Surg. 2020; S0022-5223(20)31092-8. doi: 10.1016/j.jtcvs.2020.03.162.
3. Patel, H., Azizzadeh, A., Matsumoto, A., Five-Year Outcomes From the United States Pivotal Trial of Valiant Captivia Stent Graft for Blunt Aortic Injury, Ann Thorac Surg 2020;110:815-20
4. Heijmen, RH, et al. Valiant thoracic stent-graft deployed with the new Captivia delivery system: procedural and 30-day results of the Valiant Captivia registry. J Endovasc Ther. 2012 Apr;19(2):213-25.

See the device manual for detailed information regarding the instructions for use, 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](http://medtronic.eu).

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