

SETTLE  
FOR  
**NOTHING  
LESS**



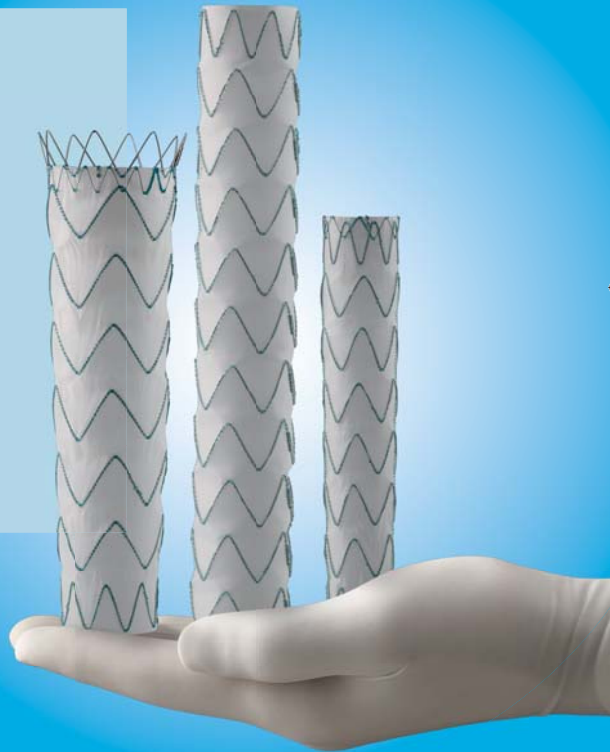
VALIANT™  
Thoracic Stent Graft

CAPTIVIA™  
Delivery System

**Medtronic**  
Further. Together

The **Valiant Captivia System with proximal FreeFlo tapers** continues to deliver the proven performance with additional components for **broad patient suitability**.

21% (n = 160) of patients in VALOR II trial presented tapered aortas. The Valiant Captivia System with proximal FreeFlo tapers helps you treat more anatomies with confidence.\*

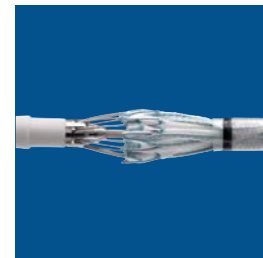


\*Data on file at Medtronic, Inc.

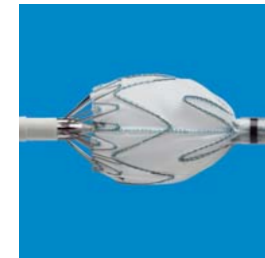
## CONFIDENCE IN CONTROL

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

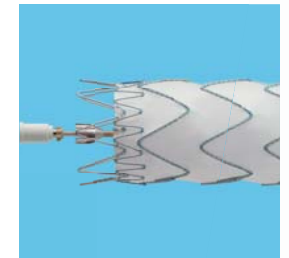
### CONTROLLED DEPLOYMENT WITH TIP CAPTURE



▲ Deployment

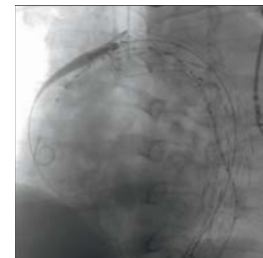


▲ Captured



▲ Released

### PLACEMENT



◀ Tip capture provides accurate stent graft placement

### RELEASE

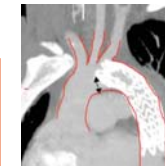
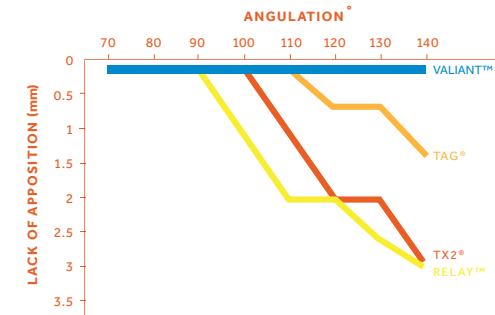


▶ After tip capture is released, the Valiant Captivia System conforms to the patient's anatomy

# CONFORMABILITY & 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>1</sup>

## ANGULAR FLEXIBILITY AND RADIAL STRENGTH GIVE THE VALIANT CAPTIVIA STENT OPTIMAL SEAL<sup>1-2</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.

Product tested	Proximal apposition at different landing zone angulation	Body apposition at different landing zone angulation
<b>Medtronic Valiant™</b>	No lack of apposition (remained apposed)	No lack of apposition (remained apposed)
<b>Gore® C-TAG®</b>	Lack of apposition above 120°	No lack of apposition (remained apposed)
<b>Bolton Relay™</b>	Lack of apposition above 110°	No lack of apposition (remained apposed)
<b>Cook® Zenith® TX2® Pro-Form</b>	No lack of apposition (remained apposed)	Lack of apposition above 110°

Test data not indicative of clinical performance

<sup>1</sup>Ludovic Canaud, Pierre Alric, Martrille Laurent, Thierry-Pascal Baum, Pascal Branchereau, Charles Henri Marty-Ané, Jean-Philippe Berthet. Proximal Fixation of Thoracic Stent-Grafts as a Function of Oversizing and Increasing Aortic Arch Angulation in Human Cadaveric Aortas. *Journal of Endovascular Therapy*; 2008;15:326-334

<sup>2</sup>Ludovic Canaud, Philippe Cathala, Pierre Alric, Pascal Branchereau, Charles Henri Marty-Ané. (2013) Improvement in conformability of the latest generation of thoracic stent grafts. *Journal of Vascular Surgery*; April 2013, Vol. 57, No. 4

## PRE



▲ 3D reconstruction of patient anatomy

## POST



▲ Fluoro shot of post index procedure result

Pre and post-procedure images courtesy of dr.Carbonari, AOU O.R. Ancona

# OPTIMISED ACCESS

Hydrophilic coating to facilitate stent graft delivery

The **Valiant Captivia System** features a crossing profile similar to or lower than other thoracic stent grafts. Ease of access means control at every step, across a broad range of anatomies.



### TIP CAPTURE RELEASE HANDLE

Simple turn-and-pull motion for tip release

## DEVICE OUTER DIAMETER PROFILES

	Medtronic Valiant™	Bolton Relay™	Cook® Zenith® TXz® Pro-Form	Gore® C-TAG®
Crossing profile (OD)	24F	24F	26F	28F
Hydrophilic coating	Yes	Yes	Yes	No
Sheath required	No	No	Yes	Yes

System OD for Gore C-TAG & 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.

## EASY THREE-STEP DEPLOYMENT PROCESS



### STEP 1

Slow, controlled deployment for precise stent graft placement.



### STEP 2

Quick deployment option if desired.



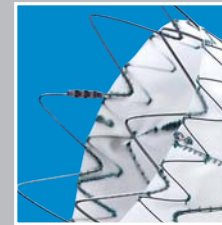
### STEP 3

Tip capture release.

## DURABLE DESIGN

The **Valiant Captivia System** is built on Medtronic's 15 years of thoracic stent graft experience and is proven in more than 50,000 implants. Our advanced design enhances confidence.\*

1. **Proximal 8-peak FreeFlo configuration** — evenly distributes radial force over multiple apices



3. **Enhanced conformability** — absence of longitudinal bar allows for enhanced flexibility and kink resistance







2



2. Figur8 markers for accurate placement — platinum iridium markers provide high visibility

3



4. Broad selection of pieces — broad selection of proximal and distal components leads to many combinations to customise for a variety of patients

\* Test data on file at Medtronic, Inc. Bench test results may not be indicative of clinical performance.

# CLINICAL DATA BUILDING CONFIDENCE

Proven performance across a variety of thoracic pathologies

## U.S. IDE VALOR II TRIAL

Prospective, multi-center, single-arm trial

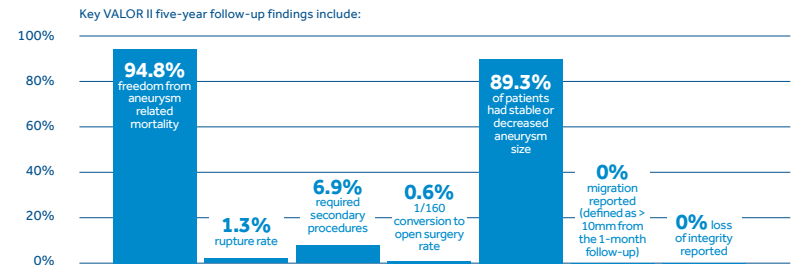
THE EVALUATION OF THE CLINICAL PERFORMANCE OF THE VALIANT THORACIC STENT GRAFT SYSTEM IN THE TREATMENT OF DESCENDING THORACIC ANEURYSMS (N=160)

### 5-YEAR RESULTS

Valiant proves to be effective and durable in treating descending thoracic aneurysms of degenerative etiology in subjects who are candidates for endovascular repair.

#### TEVAR FOR AORTIC ANEURYSM

Cumulative clinical results: year 0 through year 5



### EVIDENCE HIGHLIGHTS

Valiant provides an effective and durable treatment of descending TAA with outstanding long term results and no integrity issues

Effective in preventing ruptures and conversions, with a limited incidence of reinterventions

Stable, with no migration reported thanks to the FreeFlo fixation system, also in challenging anatomies

Source: Conrad M.F. NESVS 2015

# U.S. DISSECTION IDE TRIAL

Prospective, multi-center, single-arm trial

OUTCOMES OF VALIANT™ STENT GRAFT IN AORTIC DISSECTION (N=50)

## 2-YEAR RESULTS

Valiant proves to be effective and durable in treating complicated type B dissections in patients with suitable anatomy

INDEPENDENT U.S. DISSECTION IDE TRIAL DATA <sup>1</sup>		cTAG
VALIANT	Study Design	Prospective, multi-center, single-arm, evaluation of cTAG in acute, complicated type B dissection (n=50)
109 minutes	Median procedure Time at implant	168 minutes
6%	CVA, CVI or stroke through 30 days	18%
0%	Ruptures through 12 months	4%
4%	Retrograde type A dissections through 12 months	6%

A track record of success.

## EVIDENCE HIGHLIGHTS

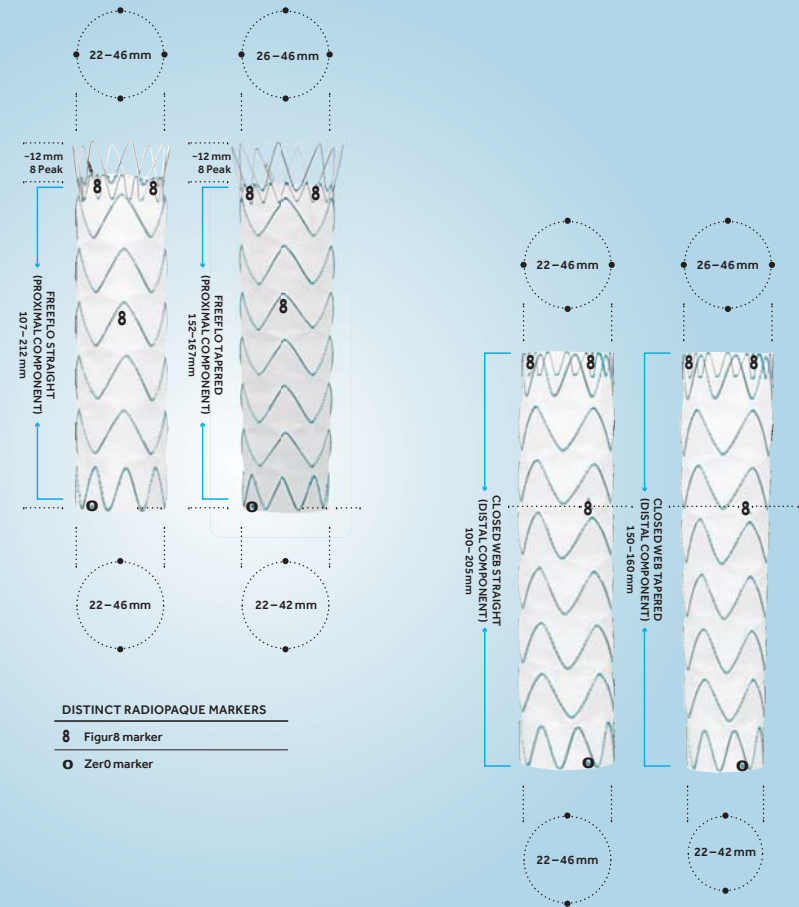
Valiant proves to be:

Easy to be implanted with a median implant time of 109 minutes

Safe in preventing dissection related ruptures, with no events at 12 months and with a limited incidence of retrograde type A dissection

<sup>1</sup> Data not directly comparable. Data obtained from pivotal studies reported in the most recent IFU for each of the TEVAR systems.

# 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						
VAMP	22	22	C	100	TE	22	112	
VAMP	24	24	C	100	TE	22	112	
VAMP	26	26	C	100	TE	22	112	
VAMP	28	28	C	100	TE	22	117	
VAMP	30	30	C	100	TE	22	117	
VAMP	32	32	C	100	TE	22	117	
VAMP	34	34	C	100	TE	24	107	
VAMP	36	36	C	100	TE	24	107	
VAMP	38	38	C	100	TE	24	107	
VAMP	40	40	C	100	TE	24	107	
VAMP	42	42	C	100	TE	25	112	
VAMP	44	44	C	100	TE	25	112	
VAMP	46	46	C	100	TE	25	112	
VAMP	22	22	C	150	TE	22	152	
VAMP	24	24	C	150	TE	22	152	
VAMP	26	26	C	150	TE	22	152	
VAMP	28	28	C	150	TE	22	157	
VAMP	30	30	C	150	TE	22	157	
VAMP	32	32	C	150	TE	22	157	
VAMP	34	34	C	150	TE	24	167	
VAMP	36	36	C	150	TE	24	167	
VAMP	38	38	C	150	TE	24	167	
VAMP	40	40	C	150	TE	24	167	
VAMP	42	42	C	150	TE	25	157	
VAMP	44	44	C	150	TE	25	157	
VAMP	46	46	C	150	TE	25	162	
VAMP	30	30	C	200	TE	22	192	
VAMP	32	32	C	200	TE	22	192	
VAMP	34	34	C	200	TE	24	212	
VAMP	36	36	C	200	TE	24	207	
VAMP	38	38	C	200	TE	24	207	
VAMP	40	40	C	200	TE	24	212	
VAMP	42	42	C	200	TE	25	207	
VAMP	44	44	C	200	TE	25	212	
VAMP	46	46	C	200	TE	25	212	

**PROXIMAL FREEFLO TAPERED**

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

**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	TE	22	105	
VAMC	24	24	C	100	TE	22	105	
VAMC	26	26	C	100	TE	22	105	
VAMC	28	28	C	100	TE	22	110	
VAMC	30	30	C	100	TE	22	110	
VAMC	32	32	C	100	TE	22	110	
VAMC	34	34	C	100	TE	24	100	
VAMC	36	36	C	100	TE	24	100	
VAMC	38	38	C	100	TE	24	100	
VAMC	40	40	C	100	TE	24	100	
VAMC	42	42	C	100	TE	25	105	
VAMC	44	44	C	100	TE	25	105	
VAMC	46	46	C	100	TE	25	105	
VAMC	22	22	C	150	TE	22	145	
VAMC	24	24	C	150	TE	22	145	
VAMC	26	26	C	150	TE	22	145	
VAMC	28	28	C	150	TE	22	150	
VAMC	30	30	C	150	TE	22	150	
VAMC	32	32	C	150	TE	22	150	
VAMC	34	34	C	150	TE	24	160	
VAMC	36	36	C	150	TE	24	160	
VAMC	38	38	C	150	TE	24	160	
VAMC	40	40	C	150	TE	24	160	
VAMC	42	42	C	150	TE	25	150	
VAMC	44	44	C	150	TE	25	150	
VAMC	46	46	C	150	TE	25	155	
VAMC	30	30	C	200	TE	22	185	
VAMC	32	32	C	200	TE	22	185	
VAMC	34	34	C	200	TE	24	205	
VAMC	36	36	C	200	TE	24	200	
VAMC	38	38	C	200	TE	24	200	
VAMC	40	40	C	200	TE	24	205	
VAMC	42	42	C	200	TE	25	200	
VAMC	44	44	C	200	TE	25	205	
VAMC	46	46	C	200	TE	25	205	

**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	TE	22	150	
VAMC	28	24	C	150	TE	22	150	
VAMC	30	26	C	150	TE	22	150	
VAMC	32	28	C	150	TE	22	150	
VAMC	34	30	C	150	TE	24	160	
VAMC	36	32	C	150	TE	24	160	
VAMC	38	34	C	150	TE	24	160	
VAMC	40	36	C	150	TE	24	160	
VAMC	42	38	C	150	TE	25	150	
VAMC	44	40	C	150	TE	25	150	
VAMC	46	42	C	150	TE	25	155	

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