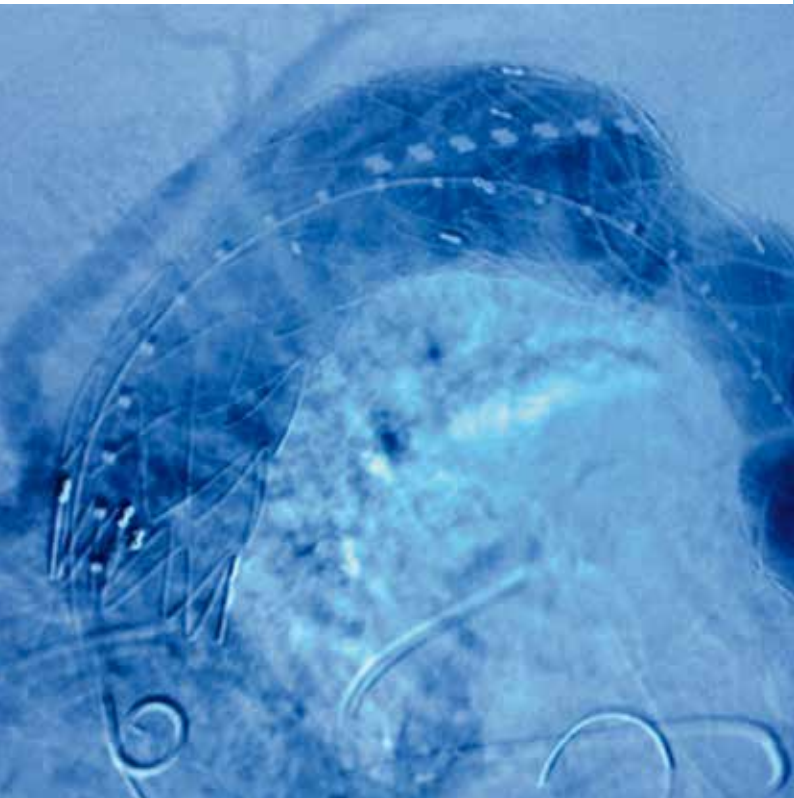
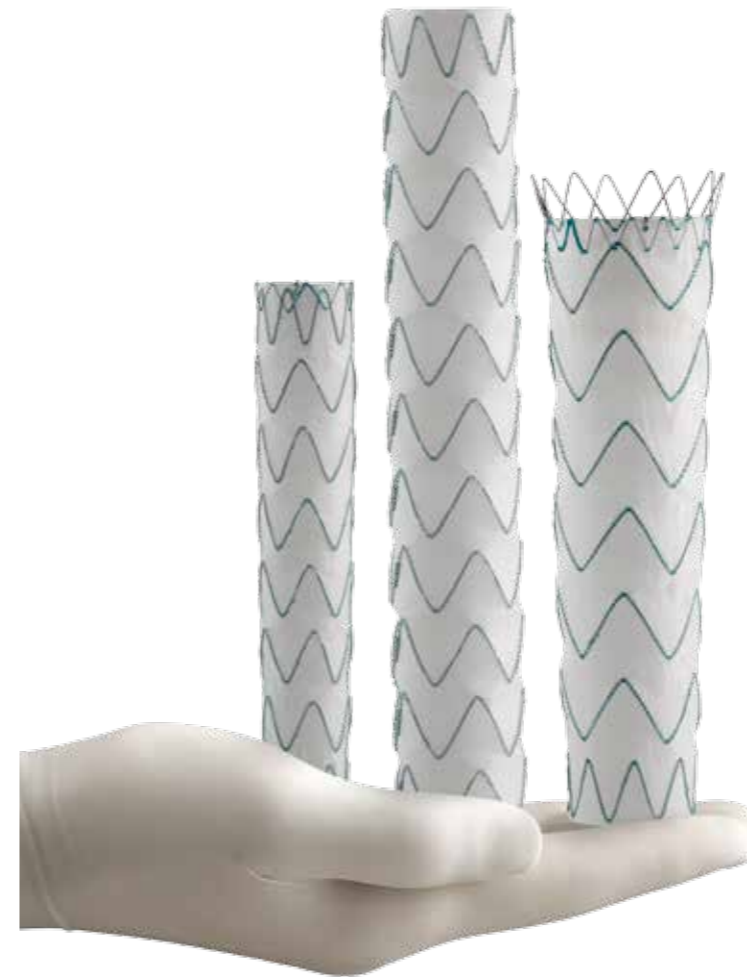


Valiant™ Thoracic Stent Graft
with the **Captivia™** Delivery
System



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.¹⁻⁴



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

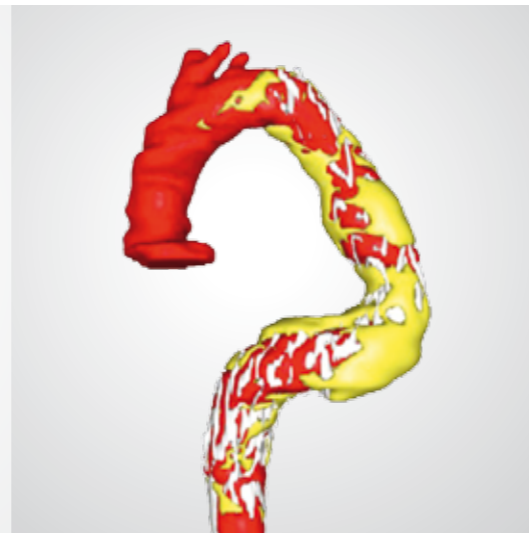
A tapered stent graft should be preferred for the majority of patients with dissection.¹

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

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

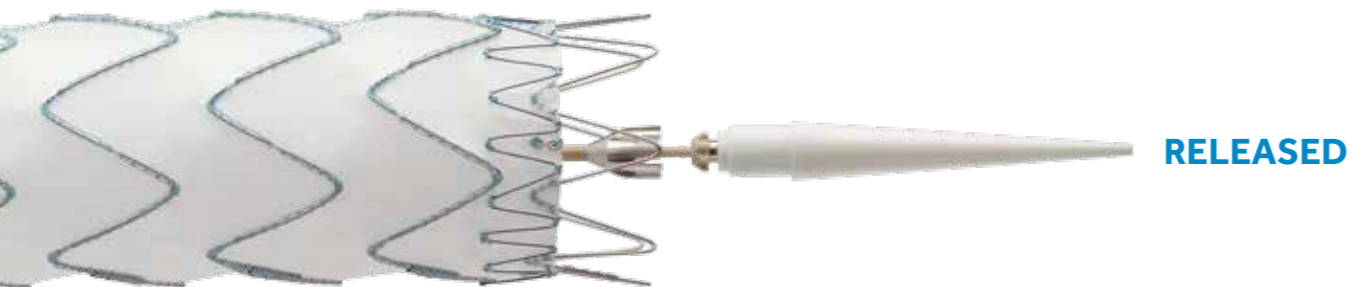
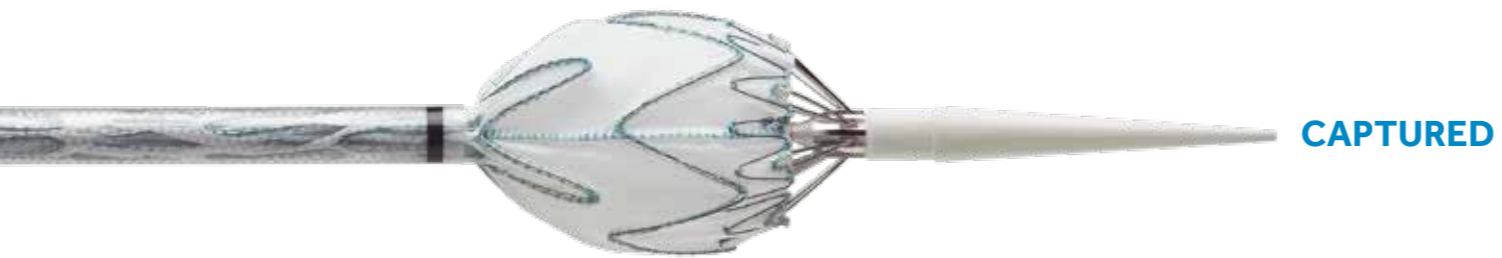


Tip capture for accuracy of positioning

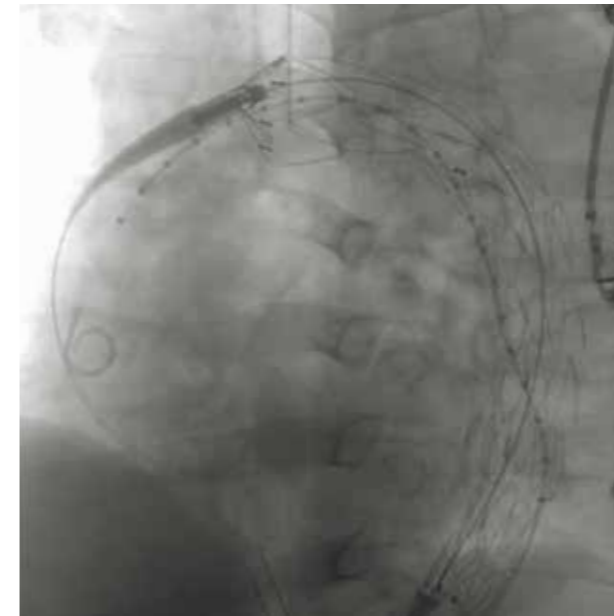
¹Pantaleo A, Jafrancesco G, Buia F, et al. Distal Stent Graft-Induced New Entry: An Emerging Complication of Endovascular Treatment in Aortic Dissection. *Ann Thorac Surg.* 2016;102(2):527-532.

PRECISE DEPLOYMENT

Controlled Deployment
with Tip Capture

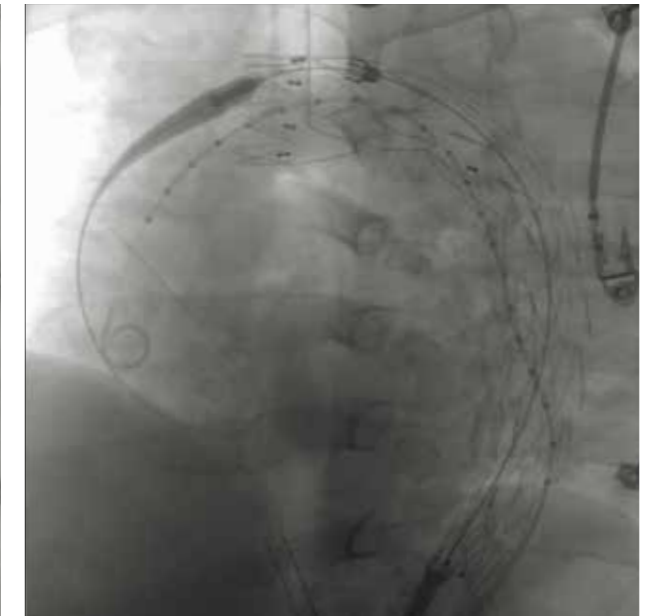


The Valiant™ Captivia™ system features tip capture of the proximal stent. Tip capture provides controlled deployment and placement when navigating the thoracic aorta.



PLACEMENT

Tip capture provides accurate stent graft placement



RELEASE

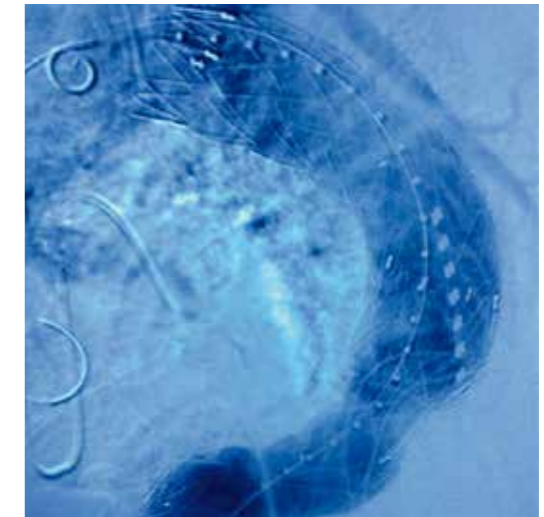
After tip capture is released, the Valiant™ Captivia™ system conforms to the patient's anatomy

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.²



PRE — 3-D reconstruction of patient anatomy†



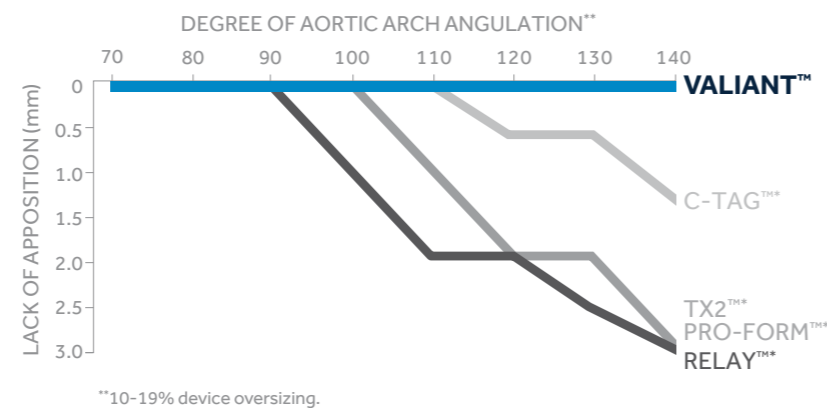
POST -index procedure result†

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 Seal²



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.

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²Canaud 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.

™™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) [†]	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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[‡]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

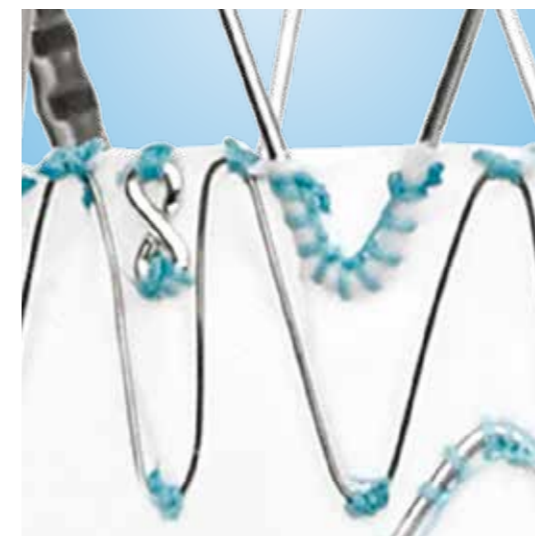
HYDROPHILIC COATING
to facilitate stent graft delivery



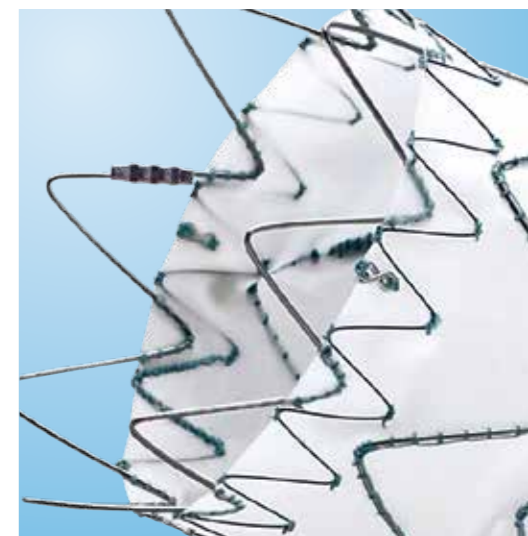
PROVEN DESIGN



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.

†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 Trial³

Prospective, nonrandomized, multicenter

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

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

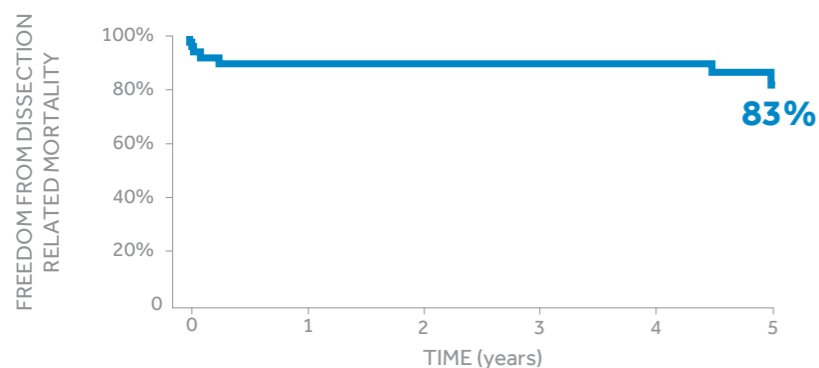
FIVE-YEAR RESULTS

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 excluded⁴
- **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.”⁵

MEDTRONIC CLINICAL DATA SUPPORTS THE USE OF TEVAR ACROSS MULTIPLE PATHOLOGIES

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

³ 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.

⁴ 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.

⁵ 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 approved name of Valiant™ Captivia™ system is Valiant™ Thoracic Stent Graft with the Captivia™ Delivery System.

References

1. Conrad, M., Tucek, 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.

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