

# PERFORMANCE YOU CAN TRUST

Low profile.  
Extended reach.  
No compromises.

EverFlex™ Self-expanding Peripheral Stent with  
Entrust™ Delivery System



**Medtronic**  
Further, Together

# DISTINCTIVE DESIGN

The Entrust™ delivery system is a one-handed stent delivery system with a low 5 F profile. This low profile was achieved without compromising the design of the EverFlex™ stent or the 0.035" guidewire compatibility. The device was engineered specifically for control and accuracy based on physician feedback provided during extensive interviews and procedural observations.

# PROVEN PERFORMANCE

The Entrust system delivers the EverFlex Self-expanding Peripheral Stent, which is backed by clinical evidence in the DURABILITY II<sup>5</sup> study. DURABILITY II is the first controlled study to focus on treating long, complex lesions and to specifically test the performance of a single long stent in the superficial femoral artery.

### The study enrolled 287 patients:

- The mean stenosed lesion length was 89.1 mm
- 70.0% of patients had moderate to severe calcification
- 48.1% of lesions were totally occluded
- 73.0% of patients received stents ≥ 100 mm<sup>6</sup>
- 95% of patients received a single stent

### DURABILITY II Results

Three years later, the results continue to offer evidence that even in long, complex lesions, the EverFlex stent is able to sustain patency and durability.

	12-month	24-month	36-month
Freedom from loss of primary patency (PSVR < 2.0)	77.9%	66.1%	60.0%
Patency in lesions ≤ 80 mm	87.5%	80.9%	71.0%
Patency in lesions > 80 mm	69.6%	53.3%	50.5%
Fracture rate	0.4%	0.9%	0.9%

### Redesigned tip

Tip attached to outer catheter eliminates risk of tip catching the stent upon removal of delivery system

### 5 F delivery system

- Low profile may allow for:
- Smaller puncture site
  - Less time applying pressure<sup>1</sup>
  - Quicker ambulatory rates<sup>2</sup>
  - Reduced vascular access complications<sup>3,4</sup>

### Triaxial design

Isolation sheath reduces friction from the system for increased accuracy and more predictable outcomes

### 150 cm catheter length

Long catheter allows for an extended reach

### 0.035" guidewire compatible

Guidewire provides greater support for SFA procedures

### EverFlex stent

- DURABILITY II study proves strong stent performance
- Broad stent matrix minimizes need to place multiple stents
- Second-generation design for flexibility and durability in the SFA

### Rotating thumb wheel

Auditory and tactile feedback enable greater control during stent flowering

### One-handed ease of use

Comfortable grip designed for improved control during one-handed deployment



# EverFlex™ Self-expanding Peripheral Stent with Entrust™ Delivery System

Catheter			Stent dimensions		Size compatibility		
80 cm Product catalog	120 cm Product catalog	150 cm Product catalog	Unconstrained stent diameter (mm)	Unconstrained stent length (mm)	Sheath/guide compatibility (F)	Guidewire acceptance (in)	Recommended vessel size (mm)
EVX35-05-020-080	EVX35-05-020-120	EVX35-05-020-150	5	20	5	0.035	3.5-4.5
EVX35-05-040-080	EVX35-05-040-120	EVX35-05-040-150	5	40	5	0.035	3.5-4.5
EVX35-05-060-080	EVX35-05-060-120	EVX35-05-060-150	5	60	5	0.035	3.5-4.5
EVX35-05-080-080	EVX35-05-080-120	EVX35-05-080-150	5	80	5	0.035	3.5-4.5
EVX35-05-100-080	EVX35-05-100-120	EVX35-05-100-150	5	100	5	0.035	3.5-4.5
EVX35-05-120-080	EVX35-05-120-120	EVX35-05-120-150	5	120	5	0.035	3.5-4.5
EVX35-05-150-080	EVX35-05-150-120	EVX35-05-150-150	5	150	5	0.035	3.5-4.5
EVX35-06-020-080	EVX35-06-020-120	EVX35-06-020-150	6	20	5	0.035	4.5-5.5
EVX35-06-040-080	EVX35-06-040-120	EVX35-06-040-150	6	40	5	0.035	4.5-5.5
EVX35-06-060-080	EVX35-06-060-120	EVX35-06-060-150	6	60	5	0.035	4.5-5.5
EVX35-06-080-080	EVX35-06-080-120	EVX35-06-080-150	6	80	5	0.035	4.5-5.5
EVX35-06-100-080	EVX35-06-100-120	EVX35-06-100-150	6	100	5	0.035	4.5-5.5
EVX35-06-120-080	EVX35-06-120-120	EVX35-06-120-150	6	120	5	0.035	4.5-5.5
EVX35-06-150-080	EVX35-06-150-120	EVX35-06-150-150	6	150	5	0.035	4.5-5.5
EVX35-07-020-080	EVX35-07-020-120	EVX35-07-020-150	7	20	5	0.035	5.5-6.5
EVX35-07-040-080	EVX35-07-040-120	EVX35-07-040-150	7	40	5	0.035	5.5-6.5
EVX35-07-060-080	EVX35-07-060-120	EVX35-07-060-150	7	60	5	0.035	5.5-6.5
EVX35-07-080-080	EVX35-07-080-120	EVX35-07-080-150	7	80	5	0.035	5.5-6.5
EVX35-07-100-080	EVX35-07-100-120	EVX35-07-100-150	7	100	5	0.035	5.5-6.5
EVX35-07-120-080	EVX35-07-120-120	EVX35-07-120-150	7	120	5	0.035	5.5-6.5
EVX35-07-150-080	EVX35-07-150-120	EVX35-07-150-150	7	150	5	0.035	5.5-6.5
EVX35-08-020-080	EVX35-08-020-120	EVX35-08-020-150	8	20	5	0.035	6.5-7.5
EVX35-08-040-080	EVX35-08-040-120	EVX35-08-040-150	8	40	5	0.035	6.5-7.5
EVX35-08-060-080	EVX35-08-060-120	EVX35-08-060-150	8	60	5	0.035	6.5-7.5
EVX35-08-080-080	EVX35-08-080-120	EVX35-08-080-150	8	80	5	0.035	6.5-7.5
EVX35-08-100-080	EVX35-08-100-120	EVX35-08-100-150	8	100	5	0.035	6.5-7.5
EVX35-08-120-080	EVX35-08-120-120	EVX35-08-120-150	8	120	5	0.035	6.5-7.5
EVX35-08-150-080	EVX35-08-150-120	EVX35-08-150-150	8	150	5	0.035	6.5-7.5

<sup>1</sup>Buchler, J et al. A Randomized Trial of 5 versus 7 French Guiding Catheters for Transfemoral Percutaneous Coronary Stent Implantation. Journal of Interventional Cardiology, Vol. 21, No. 1, 2008.

<sup>2</sup>Rodriguez A and Katz S, The Use of the Starclose Device for Obtaining Femoral Artery Hemostasis, Vascular and Endovascular Surgery, 2011; 45(7)627-630.

<sup>3</sup>Meis A, et al, Sonographic Follow-up of the Access Site After Arterial Angiography, J Ultrasound Med 1009: 28:1151-1157.

<sup>4</sup>Zahn R, et al, Do 5-F Catheters reduce the incidence of a pseudoaneurysm?, Internal Angiology, 1995; Vol 15, No.

<sup>5</sup>Rocha-Singh KJ, Bosiers M, Schultz G et al. A single stent strategy in patients with lifestyle limiting claudication: 3-year results from the Durability II trial. Catheter Cardiovasc. Interv. 2015. <sup>6</sup>Matsumura J. DURABILITY II 12-month data. ISET 2012.

## Medtronic

**Invatec S.p.A.**  
Via Martiri della Libertà 7  
25030 Roncadelle (BS)  
Italy  
Tel: +39.030.2589311

**Medtronic**  
710 Medtronic Parkway NE  
Minneapolis, MN 55432  
USA  
Tel: +1.763.514.4000

**Medtronic International  
Trading Sàrl**  
Route du Molliau 31  
CH-1131 Tolochenaz  
Switzerland  
Tel: +41.21.802.7000

**Medtronic of Canada Ltd.**  
99 Hereford Street  
Brampton, Ontario L6Y 0R3  
Canada  
Tel: +1.905.460.3800

**Medtronic Latin America**  
3750 NW 87th Avenue, Suite 700  
Miami, FL 33178  
USA  
Tel: +1.786.709.4200

**Medtronic International Ltd.**  
49 Changi South Avenue 2  
Singapore 486056  
Tel: +65.6436.5000

**Medtronic Australasia Pty Ltd.**  
97 Waterloo Road  
North Ryde, NSW 2113  
Australia  
Tel: +61.29857.9000

**Medtronic New Zealand**  
Unit N16, Mezzanine Level 5  
Gloucester Park Road  
Onehunga  
Auckland  
New Zealand

**Medtronic Korea Co., Ltd.**  
5F, Sajoo Building  
1001 Daechi-dong, Kangnam-ku  
Seoul, 135-280  
Korea  
Tel: +82.2.3404.3600

**Medtronic META FZ-LLC**  
Office Park, Block D, 2nd Floor  
PO Box 500638  
Dubai Internet City | Dubai,  
United Arab Emirates  
Tel: +971.4.818.2666

[medtronic.com/apv](http://medtronic.com/apv)