

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 II⁵ 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 mm⁶
- 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 pressure¹
 - Quicker ambulatory rates²
 - Reduced vascular access complications^{3,4}

150 cm catheter length

Long catheter allows for an extended reach

Triaxial design

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

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

¹Buchler, 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.

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

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

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

⁵Rocha-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. ⁶Matsumura J. DURABILITY II 12-month data. ISET 2012.

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