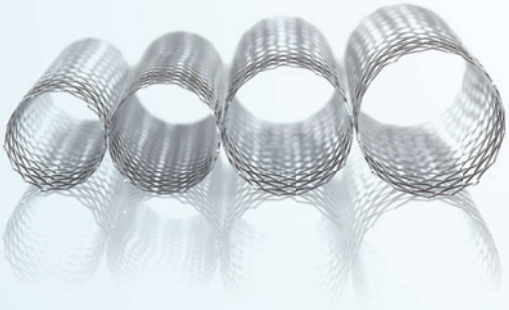
MEDTRONIC PERIPHERAL STENT FAMILY

Visi-Pro™
Balloon-expandable Peripheral Stent System



Protégé™ GPS™
Self-expanding Peripheral Stent System

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

Medtronic
Further, Together

ENTRUST™

PERFORMANCE YOU CAN TRUST

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

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 than Protege Everflex™
- Less time applying pressure[1]
- Quicker ambulatory rates[2]
- Reduced vascular access complications[3,4]

0.035" guidewire compatible
Guidewire provides greater support for SFA procedures

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

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

DISTINCTIVE DESIGN

- EverFlex™ Self-expandable stent flatform
- 5F Delivery System
- 0.035" guide wire compatible
- 150 cm catheter length available
- Triaxial design
- One-handed ease of use
- Rotating thumb wheel

PROVEN PERFORMANCE

The Entrust system delivers the EverFlex Self-expanding Peripheral Stent, which is backed by clinical evidence in the DURABILITY II[5] 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[6]
- 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%

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

[1] 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.

[2] 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.

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

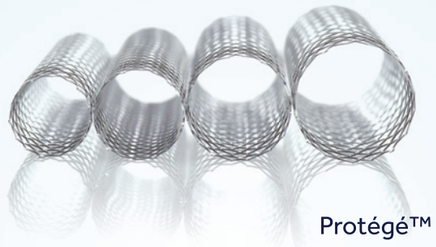
[4] Zahn R, et al, Do 5-F Catheters reduce the incidence of a pseudoaneurysm?, Internal Angiology, 1995; Vol 15, No.

[5] 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.

[6] Matsumura J. DURABILITY II 12-month data. ISET 2012.

PROTÉGÉ GPS™

LARGE DIAMETER
LOW PROFILE



Protégé™ GPS™
Self-expanding Peripheral Stent System

Compact delivery

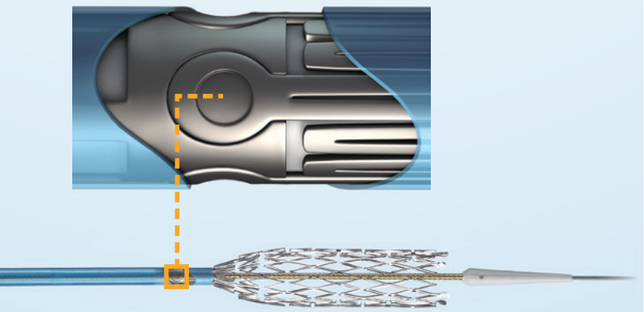
- Diameters up to 14 mm
- Full line is 6 F compatible

Precision

- Propietary EX.P.R.T.™ deployment system secures the stent to eliminate premature deployment or "jumping"[2]
- Tantalum GPS markers enhance visibility for easier, precise positioning

Radial strength and flexibility

Designed for radial strength without sacrificing flexibility.



DURABILITY ILIAC[1] Clinical Trial Summary (nine-month data)

STUDY OBJECTIVE

To confirm the safety and effectiveness of primary stenting using the EverFlex™ and Protégé™ GPS™ self-expanding stent systems for the treatment of lesions in the common and external iliac arteries.

STUDY DESIGN

- Prospective, multicenter, nonrandomized
- 75 subjects enrolled
- Primary outcome: major adverse event (MAE) rate at nine months
- Clinical follow-up at predischarge; 30 days; nine months; 1,2 and 3 years post procedure
- Independent Clinical Events Committee (CEC) and core laboratory analysis

PRIMARY OUTCOME (N = 75)

EverFlex™ and Protege™ GPS™ Stents
The MAE rate at nine months defined as a composite of periprocedural death, in-hospital myocardial infarction (MI), clinically driven target lesion revascularization (TLR), and amputation of the treated limb through nine months post procedure.

1.3% **Nine-month MAE**

0.0%	Peripocedure death
0.0%	In-hospital MI
1.3%	Clinically driven TLR
0.0%	Amputation of the treated limb

CONCLUSION

Nine-month results of the DURABILITY Iliac study showed favorable safety and efficacy, with a MAE rate of 1.3% and **A PRIMARY PATENCY RATE OF 95.8%.**

Protégé™ GPS™

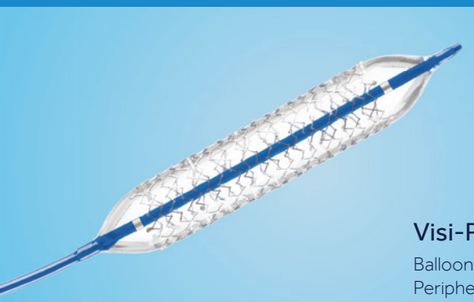
Self-expanding Peripheral Stent System

USABLE SHAFT LENGTH		STENT SIZE		COMPATIBILITY		
Product catalog number 80 cm	Product catalog number 120 cm	Diameter (mm)	Length (mm)	Recommended introducer sheath (F)	Guidewire (in)	Recommended lumen size (mm)
SERP65-09-20-80	SERP65-09-20-120	9	20	6	0.035	7.5 - 8.5
SERP65-09-30-80	SERP65-09-30-120	9	30	6	0.035	7.5 - 8.5
SERP65-09-40-80	SERP65-09-40-120	9	40	6	0.035	7.5 - 8.5
SERP65-09-60-80	SERP65-09-60-120	9	60	6	0.035	7.5 - 8.5
SERP65-09-80-80	SERP65-09-80-120	9	80	6	0.035	7.5 - 8.5
SERP65-10-20-80	SERP65-10-20-120	10	20	6	0.035	8.5 - 9.5
SERP65-10-30-80	SERP65-10-30-120	10	30	6	0.035	8.5 - 9.5
SERP65-10-40-80	SERP65-10-40-120	10	40	6	0.035	8.5 - 9.5
SERP65-10-60-80	SERP65-10-60-120	10	60	6	0.035	8.5 - 9.5
SERP65-10-80-80	SERP65-10-80-120	10	80	6	0.035	8.5 - 9.5
SERP65-12-20-80	SERP65-12-20-120	12	20	6	0.035	9.5 - 11.0
SERP65-12-30-80	SERP65-12-30-120	12	30	6	0.035	9.5 - 11.0
SERP65-12-40-80	SERP65-12-40-120	12	40	6	0.035	9.5 - 11.0
SERP65-12-60-80	SERP65-12-60-120	12	60	6	0.035	9.5 - 11.0
SERP65-12-80-80	SERP65-12-80-120	12	80	6	0.035	9.5 - 11.0
SERP65-14-20-80	SERP65-14-20-120	14	20	6	0.035	11.5 - 13.0
SERP65-14-30-80	SERP65-14-30-120	14	30	6	0.035	11.5 - 13.0
SERP65-14-40-80	SERP65-14-40-120	14	40	6	0.035	11.5 - 13.0
SERP65-14-60-80	SERP65-14-60-120	14	60	6	0.035	11.5 - 13.0
SERP65-14-80-80	SERP65-14-80-120	14	80	6	0.035	11.5 - 13.0

[1] Faries, P. Nine-month outcomes of DURAVILITY Iliac Trial. VIVA 2014.
[2] Protege™ GPS™ IFU

VISI-PRO™

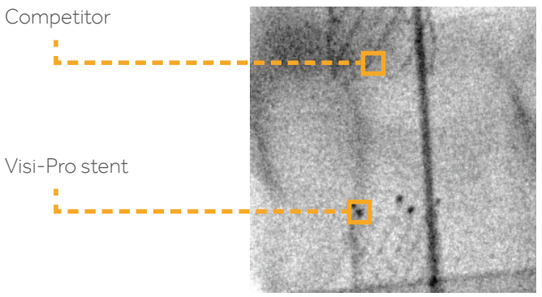
VISIBLE
PRECISION



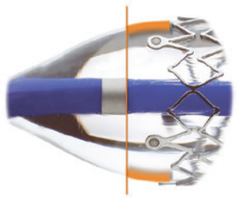
Visi-Pro™
Balloon-expandable
Peripheral Stent System

A difference you can see

Distinct 0.035" balloon-expandable stent with radiopaque markers ensures visibility during and after stent placement.[1]



Precision



- Minimal dilation of healthy tissue because of balloon to stent placement
- Accurate catheter marker alignment to balloon taper
- Progressive stent design delivers minimal shortening

VISIBILITY ILIAC Clinical Trial Summary (nine-month data)

STUDY OBJECTIVE

To confirm the safety and effectiveness of primary stenting using the Visi-Pro™ balloon-expandable peripheral stent system for the treatment of lesions in the common and external iliac arteries.

STUDY DESIGN

- Prospective, multicenter, nonrandomized
- Seventy-five subjects enrolled
- Primary outcome: major adverse event (MAE) rate at nine months
- Clinical follow-up at predischarge: 30 days; 9 months; 1,2 and 3 years post procedure
- Independent Clinical Events Committee (CEC) and core laboratory analysis

STUDY RESULTS (N = 75)

The MAE rate at nine months defined as a composite of periprocedural death, in-hospital myocardial infarction (MI), clinically driven target lesion revascularization (TLR), and amputation of the treated limb through nine months post procedure.

4.0% **Nine-month MAE**

0.0%	Peripocedure death
0.0%	In-hospital MI
4.0%	Clinically driven TLR
0.0%	Amputation of the treated limb

CONCLUSION

Nine-month results of the VISIBILITY Iliac study showed favorable safety and efficacy, with a MAE rate of 4.0% and **A PRIMARY PATENCY RATE OF 95.8%.**[2]

Visi-Pro™

Balloon-expandable Peripheral Stent System

ORDERING INFORMATION

Product number catheter length 80 cm	Product number catheter length 135 cm	Stent diameter (mm)	Stent length (mm)	Balloon length (F)	Sheath size (mm)
PXP35-05-12-080	-	5	12	15	6*
PXP35-05-17-080	PXP35-05-17-135	5	17	20	6
PXP35-05-27-080	PXP35-05-27-135	5	27	30	6
PXP35-05-37-080	PXP35-05-37-135	5	37	40	6
PXP35-05-57-080	PXP35-05-57-135	5	57	60	6
PXP35-06-12-080	-	6	12	15	6
PXP35-06-17-080	PXP35-06-17-135	6	17	20	6
PXP35-06-27-080	PXP35-06-27-135	6	27	30	6
PXP35-06-37-080	PXP35-06-37-135	6	37	40	6
PXP35-06-57-080	PXP35-06-57-135	6	57	60	6
PXP35-07-12-080	-	7	12	15	6
PXP35-07-17-080	PXP35-07-17-135	7	17	20	6
PXP35-07-27-080	PXP35-07-27-135	7	27	30	6
PXP35-07-37-080	PXP35-07-37-135	7	37	40	6
PXP35-07-57-080	PXP35-07-57-135	7	57	60	6
PXP35-08-17-080	PXP35-08-17-135	8	17	20	6
PXP35-08-27-080	PXP35-08-27-135	8	27	30	6
PXP35-08-37-080	PXP35-08-37-135	8	37	40	6
PXP35-08-57-080	PXP35-08-57-135	8	57	60	6
PXP35-09-17-080	PXP35-09-17-135	9	17	20	7
PXP35-09-27-080	PXP35-09-27-135	9	27	30	7
PXP35-09-37-080	PXP35-09-37-135	9	37	40	7
PXP35-09-57-080	PXP35-09-57-135	9	57	60	7
PXP35-10-17-080	PXP35-10-17-135	10	17	20	7
PXP35-10-27-080	PXP35-10-27-135	10	27	30	7
PXP35-10-37-080	PXP35-10-37-135	10	37	40	7
PXP35-10-57-080	PXP35-10-57-135	10	57	60	7

*6 F = 0.085" ID

COMPLIANCE CHART*

Visi-Pro diameter (mm)	Inflation pressure (atm)				
	8	9	10	11	12
5.0	5.00	5.09	5.16	5.22	5.28
6.0	6.00	6.11	6.22	6.31	6.39
7.0			7.00	7.09	7.17
8.0			8.00	8.15	8.26
9.0			9.00	9.15	9.28
10.0			10.00	10.11	10.21

Diameter at nominal pressure
Diameter at rated burst pressure (RBP)

* Data on Visi-Pro™ IFU

[1] Comparison testing performed by Medtronic. Data on file. Bench results not intended to indicate clinical performance.
[2] Rundback, J. Nine-month outcomes of VISIBILITY Iliac Trial. EuroPCR 2014.

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