# Supera<sup>™</sup> Peripheral Stent System

# RESULTS MATTER. PLATFORM MATTERS.

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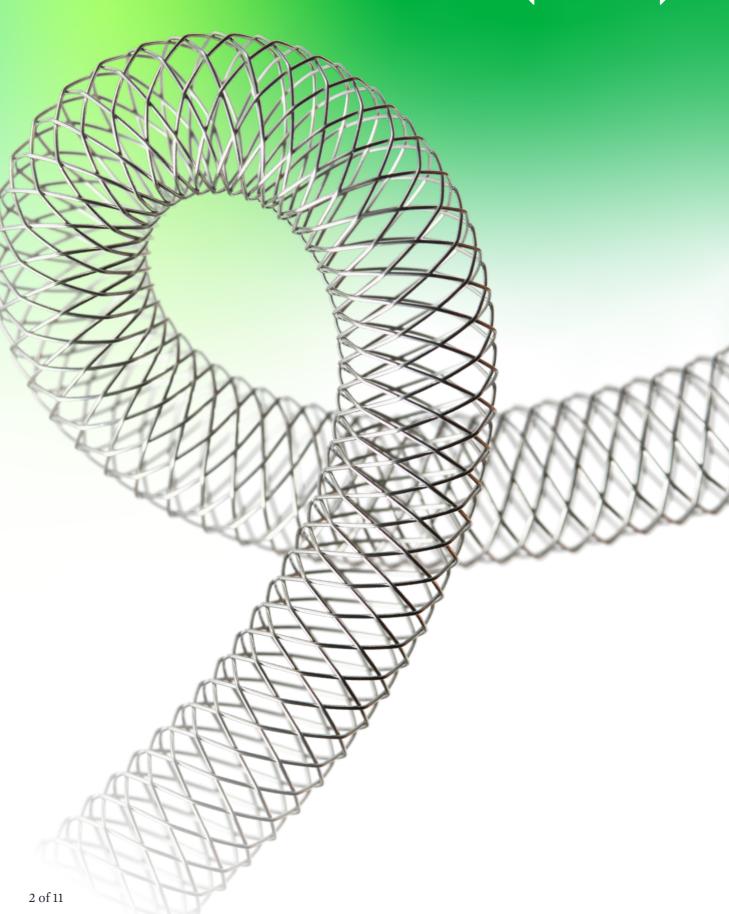


## THE ONLY VASCULAR MIMETIC IMPLANT

Supera<sup>™</sup> Stent is an SFA/Popliteal workhorse stent which provides physician with confidence to achieve unparalleled clinical outcomes from simple to complex lesions<sup>1-4</sup>.

Treitl, K.M., et al. *European Radiology*. 2017; 10.1007.
 Garcia L. et al. *Circ Cardiovasc Interv*. 2015;8:e000937.
 Brescia A. et al. *J Vasc Surg*. 2015 Mar 6. pii: S0741-5214(15)00132-9.
 Palena L.M. et al. *Catheterization and Cardiovascular Interventions* 2016.

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# SUPERA<sup>™</sup> STENT IS LIKE NO OTHER STENT





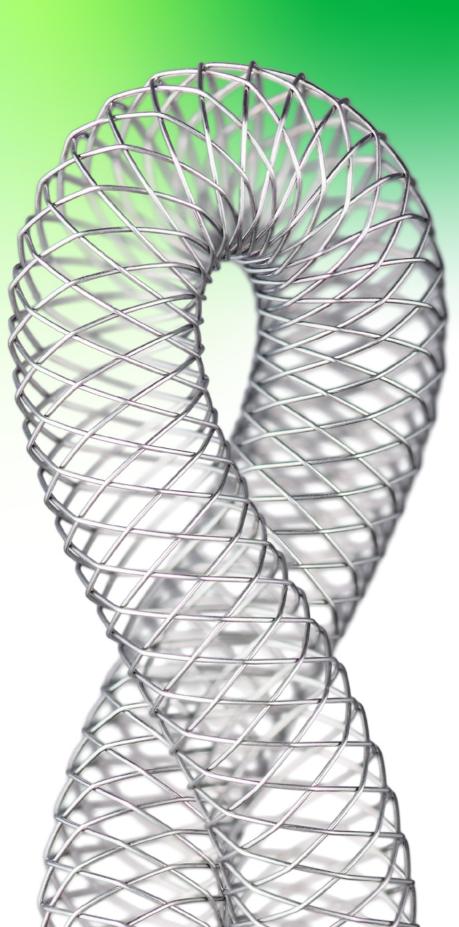
LOW CHRONIC **OUTWARD FORCE<sup>1</sup>** 



 Test(s) performed by and data on file at Abbott.
 Garcia, Lawrence A. et al., SUPERB Final 3-Year Outcomes Using Interwoven Nitinol Biomimetic Supera Stent. Catheterizationand Cardiovascular Interventions 2017.

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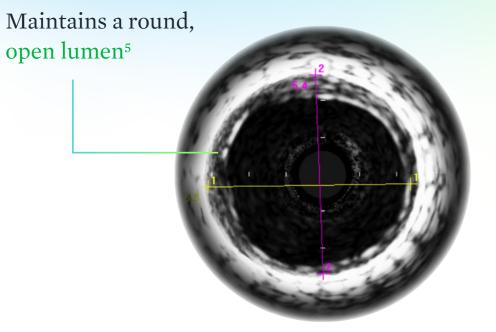


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# MIMICS THE NATURAL STRUCTURE AND MOVEMENT OF THE ANATOMY

The natural environment of the SFA and popliteal anatomy is highly dynamic and characterized by torsion, bending, shortening, and compression. The native vasculature reacts seamlessly to these forces to maintain unhindered blood flow<sup>1-4</sup>.

The Supera<sup>™</sup> Vascular Mimetic Implant supports the natural movement of the vessel:



Results in normal, healthy blood flow in challenging anatomy<sup>5,6</sup>

Image courtesy of Dr. Hans Biemans, Rivas Hospital Gorinchem, the Netherlands.

- 1. Range of 23-25% shortening for 90 degree bend. See Jonker et al., Dynamic Forces in the SFA and Popliteal Artery During Knee Flexion, *Endovascular Today*. Buyer's Guide 2009, pp. 54-59.
- Cheng, C.P., Wilson, N.M., Hallett, R.L., Herfkens, R.J., Taylor, C.A. In Vivo MR Angiographic Quantification of Axial and Twisting Deformations of the Superficial Femoral Artery Resulting from Maximum Hip and Knee Flexion. J Vasc Interv Radiol. 2006;17(6):979-987.
- 3. Nikanorov, A., Schillinger, M., Zhao, H., Minar, E., Schwartz, L.B. Assessment of Self-Expanding Nitinol Stent Deformation After Chronic Implantation into the Femoropopliteal Arteries. *J Vasc Surg.* 2008;48(2):435-440.
- 4. Scholten, F.G., Warnars, G.A., Mali, W.P., van Leeuwen, M.S. Femoropopliteal Occlusions and the Adductor Canal Hiatus, Duplex Study. *Eur J Vasc Surg*. 1993;7(6):680-683.
- 5. Characteristically round lumens supported by Arena, F.J., Arena, F.A. Intravascular Ultrasound Evaluation of Interwoven Nitinol Stents at Implant. *J Vasc Med Surg.* 2013:1;116.
- 6. Test(s) performed by and data on file at Abbott.

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## THE MOST STRENGTH AND FLEXIBILITY<sup>1,2</sup>

SFA lesions are often heavily calcified<sup>3</sup>. The closed-end interwoven wires of the Supera<sup>™</sup> implant move independently and distribute external forces across the entire implant. This mimetic design provides the strength needed to treat highly calcified lesions with the lowest chronic outward force<sup>4</sup>.



Image from Chan, Y-C. Single-Centre Results of Femoro-Popliteal Revascularisation Using Helical Interwoven Nitinol Stents. LINC Asia Pacific 2013.
Flexibility is defined as kink resistance. The Supera<sup>™</sup> sizes with the lowest kink resistance, as compared to 6.0 x 100 mm standard nitinol stents, are the 5.0 x 100 and 6.0 x 100 mm implants. Competitors tested include Absolute Pro, Astron Pulsar-18, Complete SE, Epic, EverFlex, Innova, LifeStent, Maris Deep, Misago, S.M.A.R.T., and Zilver. Data on file at Abbott.

- The compression resistance for a 5.0 x 100 mm Supera<sup>™</sup> implant is 9 kg at 53% compression. This is four times the compression resistance of all other competitors. All other products compressed 53% with less than 2.25 kg applied. Competitors tested include Absolute Pro, Astron Pulsar-18, Complete SE, Epic, EverFlex, Innova, LifeStent, Maris Deep, Misago, S.M.A.R.T., and Zilver. Test(s) performed by and data on file at Abbott.
- 3. Herisson, F. et al., Carotid and femoral atherosclerotic plaques show different morphology. *Atherosclerosis*, 2011;216(2):348-54
- 4. Competitors tested include Astron Pulsar-18<sup>‡</sup>, Complete<sup>‡</sup> SE, EverFlex<sup>‡</sup>, Innova<sup>‡</sup>, LifeStent<sup>‡</sup>, Misago<sup>‡</sup>, S.M.A.R.T., and Zilver<sup>‡</sup> PTX. Test(s) performed by and data on file at Abbott.

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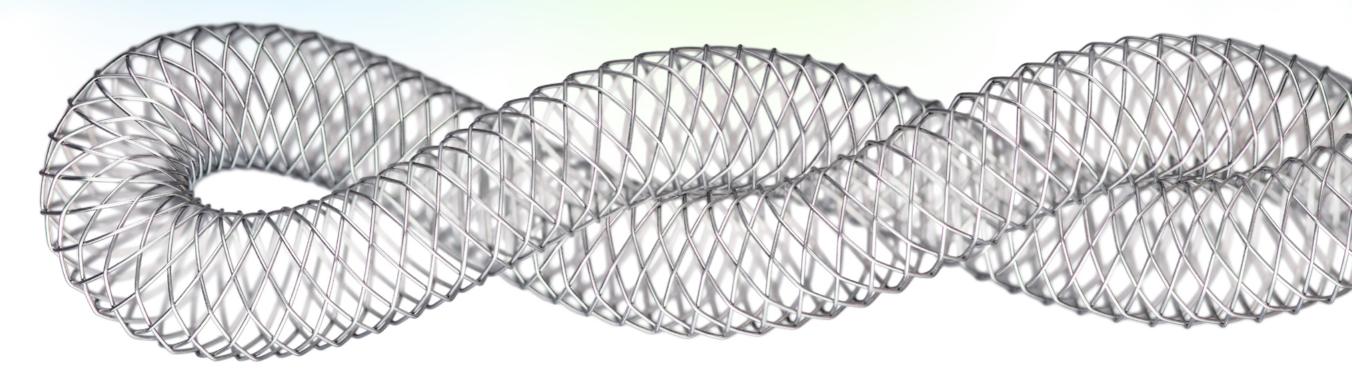
## SUPERATIN STENT IS CLINICALLY PROVEN AND WIDELY STUDIED WITH EXCELLENT OUTCOMES

# > 2,000 PATIENTS

published in 17 studies worldwide as early as 2011<sup>1-17</sup>

# **O** FRACTURES

at 1 year across all studies<sup>1-17</sup>



1. Brescia AA. et al., *J Vasc Surg*. 2015 Jun;61(6):1472-8. 2. Chan YC. et al., *J Vasc Surg*. 2015 Nov;62(5):1201-9. 3. Dumantepe M. *Vasc Endovascular Surg*. 2017 Jul;51(5):240-246. 4. Garcia L. et al., *Catheterization and Cardiovascular Interventions* 2017 Jun 1;89(7):1259-1267. 5. George JC. et al., *J Vasc Interv Radiol*. 2014 Jun;25(6):954-61. 6. Goltz JP. et al., *J Endovasc Ther*. 2012 Jun;19(3):450-6. 7. León LR Jr. et al., *J Vasc Surg*. 2013 Apr;57(4):1014-22. 8. Montero-Baker M. et al., *J Vasc Surg*. 2016 Oct;64(4):1002-8. 9. Myint M. et al., *J Endovasc Ther*. 2016 Jun;23(3):433-41. 10. Palena LM. et al., *J Endovasc Ther*. 2018 Oct;25(5):588-591. 11. Scheinert D. et al., *J ACC Cardiovasc Interv*. 2013 Jan;6(1):65-71. 12. Scheinert D. et al., *J Endovasc Ther*. 2011 Dec;18(6):745-52. 13. Steiner S. et al., *J Endovasc Ther*. 2016 Apr;23(2):347-55. 14. Werner M. et al., *EuroIntervention*. 2014 Nov;10(7):861-8. 15. San Norberto EM. et al., *Ann Vasc Surg*. 2017 May;41:186-195. 16. Teymen B. et al., *Vascular*. 2018 Feb;26(1):54-61. 17. Bhatt H. et al., *Cardiovasc Med*. 2018 Jul;19(5 Pt A):512-515.

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# UNMATCHED CLINICAL OUTCOMES IN SIMPLE LESIONS\*

## SUPERB TRIAL<sup>1</sup>

## **U.S. IDE TRIAL RESULTS**

		1-YEAR P	ATENCY (KM)	3-YEAR FREEDOM FROM T			
	91%	91%	SUPERA <sup>™</sup> STENT Nominal <sup>™1</sup>	94%	SUPERA™ STENT Nominal**1		
	<b>Patency (K-M) at 1 year</b> When nominally deployed <sup>*</sup>	86%	SUPERA <sup>™</sup> STENT All deployment types <sup>1</sup>	82%	SUPERA <sup>™</sup> STENT All deployment types <sup>1</sup>		
		89%	Eluvia <sup>‡2</sup>	NOT REPORTED	Eluvia <sup>‡</sup>		
	O 40/	84%	Zilver <sup>‡</sup> PTX <sup>‡3</sup>	84%	Zilver <sup>‡</sup> PTX <sup>‡3</sup>		
	94%	83%	Misago <sup>‡12</sup>		Misago <sup>‡</sup>		
	Freedom from TLR at 3 years	81%	LifeStent <sup>‡4</sup>	76%	LifeStent <sup>‡5</sup>		
		80%	S.M.A.R.T. <sup>‡6</sup>	79%***	S.M.A.R.T. <sup>‡7</sup>		
	When nominally deployed*	77%	EverFlex <sup>‡8</sup>	70%	EverFlex <sup>‡9</sup>		
		74%	Innova <sup>‡10</sup>	NOT REPORTED	Innova <sup>‡</sup>		
		67%	Pulsar <sup>‡11</sup>	NOT REPORTED	Pulsar <sup>‡</sup>		

\*Study reported with a majority as TASC A&B lesion and/or majority as Rutherford Class 2 and 3.

\*\* Nominal deployment is defined as the stent length upon deployment being within +/- 10% of the

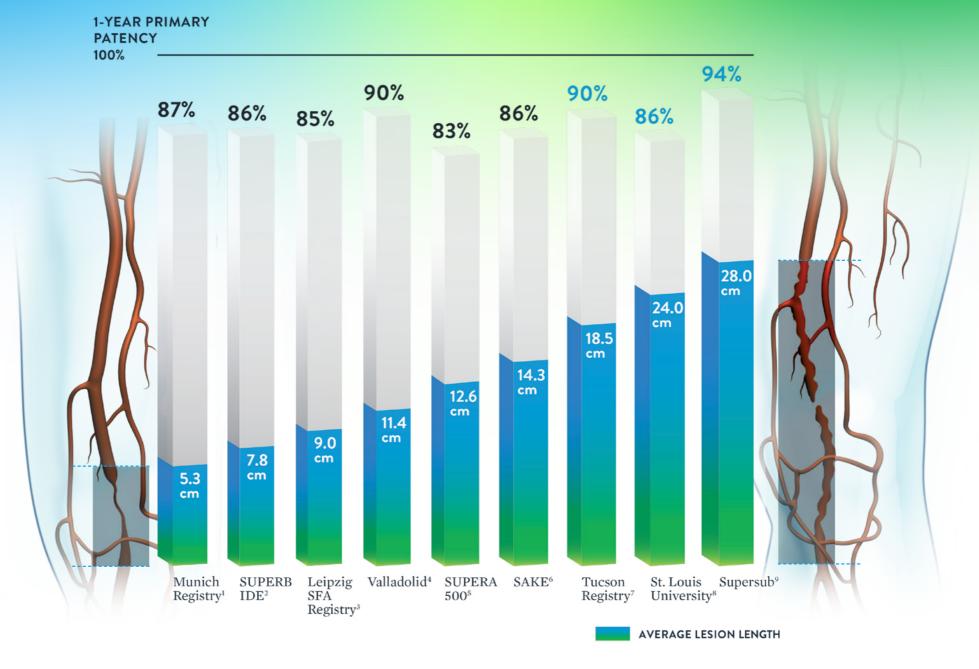
labeled stent length. This data is from a non-powered post-hoc analysis.

\*\*\* 3-year freedom from TLR rate for SMART refers to clinically-driven TLR.

1. Garcia L. et al., *Catheterization and Cardiovascular Interventions* 2017 Jun 1;89(7):1259-1267. 2.Gray W. et al., *Lancet* 2018;392:1541-51. 3. Dake M. et al., *Circulation*. 2016;133:1472-1483. 4. Laird J. et al., *Circ Cardiovasc Interv*. 2010;3:267-276. 5. Laird J et al., *J Endovasc Ther*. 2012;19:1–9. 6. S.M.A.R.T. Control IFU 7. Jaff, M., SMART Nitinol Self-Expanding Stent in the Treatment of Obstructive Superficial Femoral Artery Disease: Three-year Clinical Outcomes from the STROLL Trial. ISET 2014. 8. Matsumura J et al., *J Vasc Surg* 2013;58:73-83. 9. Rocha-Singh, K., 3-Year Results of the DURABILITY II Study. VIVA 2013. 10. US Innova IFU 11. US Pulsar IFU 12. Ohki T. et al., *J Vasc Surg*. 2016 Feb;63(2):370-6.

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## SUPERB DATA EVEN IN LONG LESIONS



1. Treitl, K.M., et al. *European Radiology*. 2017; 10.1007. 2. Garcia L. et al. *Circ Cardiovasc Interv*. 2015;8:e000937. 3. Scheinert D. et al., *J Endovasc Ther*. 2011 Dec;18(6):745-52. 4. San Norberto EM. et al., *Ann Vasc Surg*. 2017 May;41:186-195. 5. Werner M. et al., *EuroIntervention*. 2014 Nov;10(7):861-8. 6. George JC. et al., *J Vasc Interv Radiol*. 2014 Jun;25(6):954-61. 7. Montero-Baker M. et al., *J Vasc Surg*. 2016 Oct;64(4):1002-8. 8. Brescia A. et al. *J Vasc Surg*. 2015 Mar 6. pii: S0741-5214(15)00132-9. 9. Palena L.M. et al. *Catheterization and Cardiovascular Interventions* 2016.

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## VASCULAR MIMETIC TECHNOLOGY

Unlike current SFA treatment options, the Supera<sup>™</sup> implant maintains a visibly round, open lumen for normal, healthy blood flow in challenging anatomy<sup>1</sup>.

## **STANDARD NITINOL STENT/COVERED STENT**<sup>2</sup>

- Constrains vessel movement due to limited axial flexibility<sup>3</sup>
- Liable to kink and fracture under extreme bending or in calcification

## **PTA/ATHERECTOMY**

• Provides temporary lumen gain while allowing future treatment options

CURRENT TREATMENT LIMITATIONS Supports the natural movement of the vessel<sup>4</sup> Mimics the natural anatomy<sup>4,5</sup>

1. Arena F. et al., *J Vasc Med Surg*. 2013:1;116. Test(s) performed by and data on file at Abbott. 2. Metzger, C., A Mechanical Problem Should Be Treated Mechanically. LINC 2013.

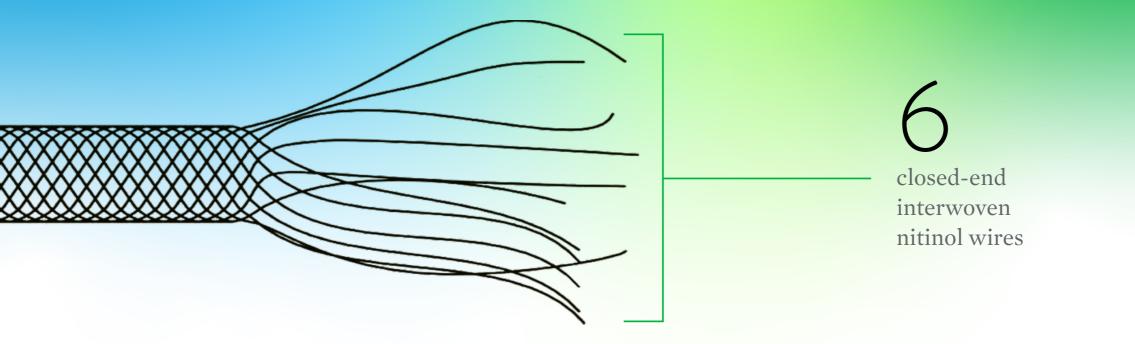
- 3. Garcia, L., Rosenfield, K., et al., SUPERB Pivotal IDE Trial, 12-Month Results, TCT 2012.
   4. Arena F. et al., *J Vasc Med Surg*. 2013:1;116. Chen Y. et al., *J Vasc Surg* 2014;59:384-91. Test(s) performed by and data on file at Abbott.
- 5. Competitors tested include Astron Pulsar-18<sup>‡</sup>, Complete<sup>‡</sup> SE, EverFlex<sup>‡</sup>, Innova<sup>‡</sup>, LifeStent<sup>‡</sup>, Misago<sup>‡</sup>, S.M.A.R.T., and Zilver<sup>‡</sup> PTX. Test(s) performed by and data on file at Abbott.

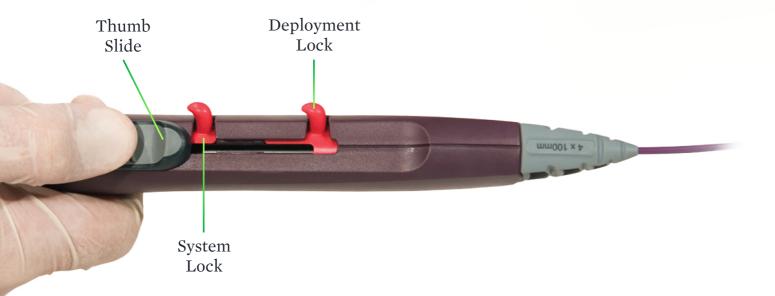
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## SUPERA<sup>™</sup> VASCULAR MIMETIC IMPLANT





### **DELIVERY SYSTEM**

- Unique Thumb Slide design
- 0.014" and 0.018" guide wire compatible
- Over-the-Wire delivery system

Data on file at Abbott.

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## SIZE MATRIX AND PART NUMBERS

CE	STENT OUTER	STENT LENGTH (mm)									
	DIAMETER - (mm)	20	30	40	60	80	100	120	150	180	200
<b>80</b> cm 6F	4.5	N/A	N/A	42045040- 080	42045060- 080	42045080- 080	42045100- 080	42045120- 080	42045150- 080	N/A	N/A
	5.0*	N/A	N/A	42050040- 080	42050060- 080	42050080- 080	42050100- 080	42050120- 080	N/A	N/A	N/A
	5.5	N/A	N/A	42055040- 080	42055060- 080	42055080- 080	42055100- 080	42055120- 080	42055150- 080	42055180- 080	42055200- 080
	6.0*	N/A	N/A	42060040- 080	42060060- 080	42060080- 080	42060100- 080	42060120- 080	42060150- 080	N/A	N/A
	6.5	N/A	N/A	42065040- 080	42065060- 080	42065080- 080	42065100- 080	42065120- 080	42065150- 080	42065180- 080	42065200- 080
	7.5	N/A	N/A	42075040- 080	42075060- 080	42075080- 080	42075100- 080	N/A	N/A	N/A	N/A

<b>120</b> cm 6F	4.5	42045020- 120	42045030- 120	42045040- 120	42045060- 120	42045080- 120	42045100- 120	42045120- 120	42045150- 120	N/A	N/A
	5.0*	42050020- 120	42050030- 120	42050040- 120	42050060- 120	42050080- 120	42050100- 120	42050120- 120	N/A	N/A	N/A
	5.5	42055020- 120	42055030- 120	42055040- 120	42055060- 120	42055080- 120	42055100- 120	42055120- 120	42055150- 120	42055180- 120	42055200- 120
	6.0*	42060020- 120	42060030- 120	42060040- 120	42060060- 120	42060080- 120	42060100- 120	42060120- 120	42060150- 120	N/A	N/A
	6.5	42065020- 120	42065030- 120	42065040- 120	42065060- 120	42065080- 120	42065100- 120	42065120- 120	42065150- 120	42065180- 120	42065200- 120
	7.5	42075020- 120	42075030- 120	42075040- 120	42075060- 120	42075080- 120	42075100- 120	N/A	N/A	N/A	N/A

\*5.0 mm and 6.0 mm diameters available in select countries only. Check with your local Abbott representative for local availability.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *eifu.abbottvascular.com* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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