



Interwoven Self-Expanding Nitinol Stent

Peripheral Vascular System

A Different Class of Stent



inspiration • innovation • intervention



Interwoven Self-Expanding Nitinol Stent

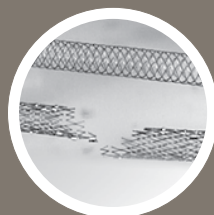
Peripheral Vascular System

SUPERA® Flexibility

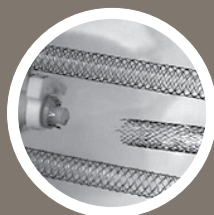
Flexibility is directly related to fracture resistance

Zero fractures observed in any SUPERA stent tested after 10 million cycles of 120° of flexion and extension.¹

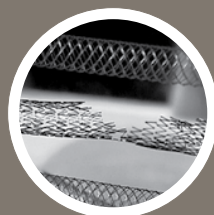
All standard nitinol stents (SNS) tested fractured - and the fractures occurred in less than 100 thousand cycles.¹



SNS 1: 21,087 cycles



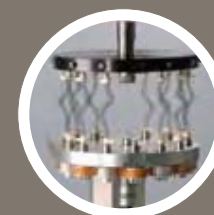
SNS 2: 92,415 cycles



SNS 3: 21,087 cycles

Tests were stopped at random intervals to observe fracture rates.

Zero fractures observed in any SUPERA stent tested after 20 million cycles of torsion.¹



The SUPERA stent completely resisted kinking, crushing and crimping.¹



SUPERA®

A different class of stent

SUPERA interwoven self-expanding nitinol stent

Materials

Super-elastic nitinol wire for high loading and unloading plateau stresses.

Woven Design

6 pairs of interwoven wires in a helical design combine strength with flexibility.



Standard Nitinol Stents (SNS)

Materials

Cold-formed nitinol tube, laser cut to form the resulting stent.

Cell Design

Open cell geometry provides flexibility, closed cell geometry provides strength, one must be sacrificed for the other.



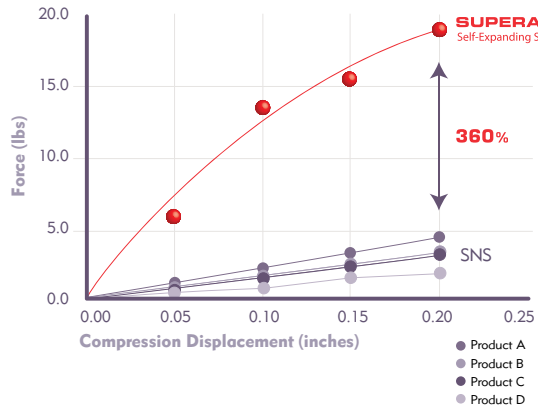
SUPERA® Strength

Stent geometry supports anatomy

Radial strength provides true circumferential lumen.

- SUPERA has a minimum of **4 times the radial strength** of standard nitinol stents.¹
- SUPERA has **360% stronger crush resistance** than standard nitinol stents.¹

Crush compression data for 6 mm stents



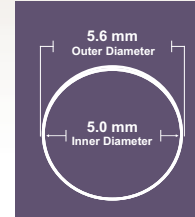
SUPERA® Simplicity

The **only** stent with 1-to-1 sizing

The unique characteristics of the SUPERA stent require balloon inflation to match the stent outer diameter (OD).

Clinical Guidelines

- Longer inflation times can generate less recoil and create an optimal tract for SUPERA.
- Entire lesion length should be prepped to the OD of the stent.
- Do not overly elongate or stack the stent during deployment.



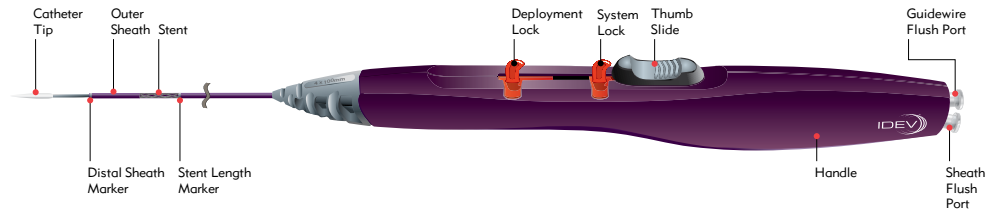
Predilation and Sizing Table		
Labeled Stent Diameter (mm)	Stent Outer Diameter (mm)	Inflated Balloon Diameter* (recommended) (mm)
4.0	4.6	4.6
5.0	5.6	5.6
6.0	6.7	6.7
7.0	7.7	7.7
8.0	8.8	8.8

Please refer to and follow stent sizing guidelines per the IFU.

Delivering a Better Solution

- 6Fr and 7Fr systems available in 2 working lengths.
- Embedded distal marker improves tip radiopacity.
- Hydrophilic, atraumatic tip enhances crossability.
- Fewer strokes for full deployment.¹

The **only** stent with the SUPERA VERITAS® Delivery System



SUPERA® Results

Promising clinical data,
even in the most challenging cases

In challenging anatomy, and even in severely diseased arteries, SUPERA has been shown to deliver excellent patency – with no stent fractures.

SUPERA Registry Results

	SFA (107 patients)	Popliteal (101 patients)
6 month patency	93.1%	95.7%
12 month patency	84.7%	87.4%
18 month patency	76.1%	76.5%
24 month patency	76.1%	76.5%
Observed stent fractures	Zero	Zero

The SUPERA Registry is conducted at Park Hospital and Heart Center in Leipzig, Germany. SFA patient follow-up completed through 24 months; popliteal patient follow-up completed through 12 months. SFA data published in *Journal of Endovascular Therapy* December 2011.² Popliteal data presented at the 2011 Leipzig Interventional Course (LINC) by Andrej Schmidt, M.D.

Long Lesion SUPERA Analysis

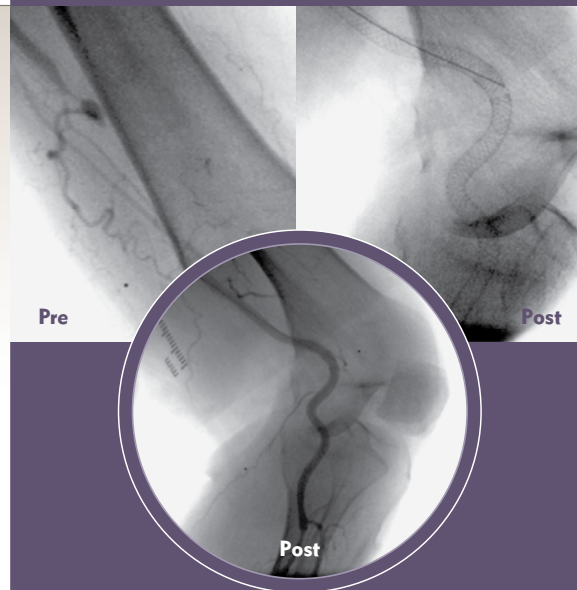
(182 patients)

12 month patency	73.7%
Average stent length	240 mm
Stents per patient	1.7
% Patients Fontaine 3 or 4	71%
% Patients TASC C or D	65%
Observed stent fractures	Zero

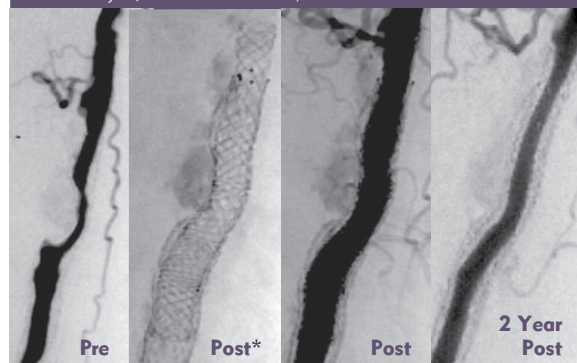
Data presented at Vaatdagen 2011 Conference based on a study by Andre Molenaar, M.D. and Peter Haarbrink, M.D., Canisius-Wilhelmina Ziekenhuis (CWZ) Hospital in Nijmegen, Netherlands.

Case Images

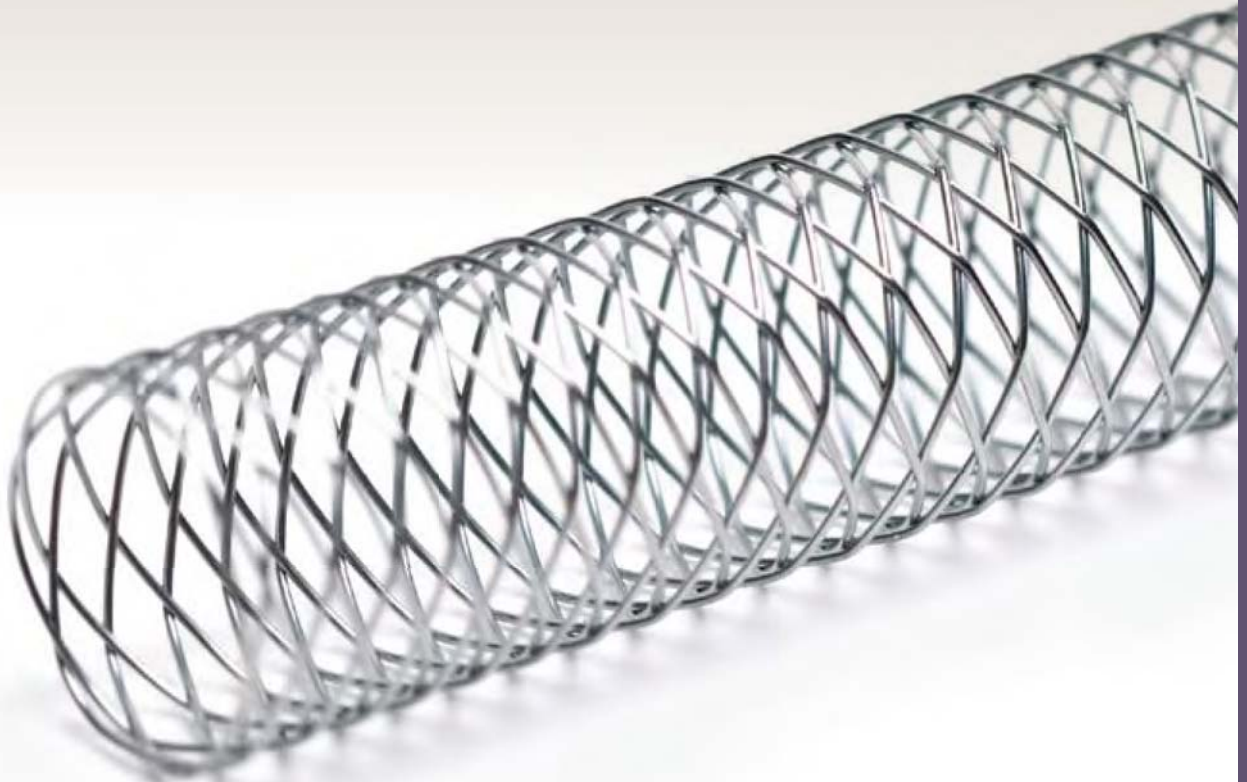
Courtesy of Thomas Zeller, M.D.



Courtesy of David E. Cohen, M.D.



*SUPERA inside a collapsed standard nitinol stent



Nothing Performs Like SUPERA VERITAS®



Interwoven Self-Expanding Nitinol Stent

Peripheral Vascular System

IDEV is leading the way in developing minimally invasive medical technologies to protect and preserve anatomical function.

IDEV is focused on products that are truly differentiated and deliver clear patient benefits.

IDEV is investing in research and development.

IDEV - Architects of Intervention.



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SUPERA VERITAS®

	Stent Diameter (mm)	Stent Length (mm)									
		20	30	40	60	80	100	120	150	180	200
6 Fr, 80 cm	4	SE-04-020-080-6F	SE-04-030-080-6F	SE-04-040-080-6F	SE-04-060-080-6F	SE-04-080-080-6F	SE-04-100-080-6F	SE-04-120-080-6F	SE-04-150-080-6F		
	5	SE-05-020-080-6F	SE-05-030-080-6F	SE-05-040-080-6F	SE-05-060-080-6F	SE-05-080-080-6F	SE-05-100-080-6F	SE-05-120-080-6F	SE-05-150-080-6F	SE-05-180-080-6F	SE-05-200-080-6F
	6	SE-06-020-080-6F	SE-06-030-080-6F	SE-06-040-080-6F	SE-06-060-080-6F	SE-06-080-080-6F	SE-06-100-080-6F	SE-06-120-080-6F	SE-06-150-080-6F	SE-06-180-080-6F	SE-06-200-080-6F
	7	SE-07-020-080-6F	SE-07-030-080-6F	SE-07-040-080-6F	SE-07-060-080-6F	SE-07-080-080-6F	SE-07-100-080-6F				
6 Fr, 120 cm	4	SE-04-020-120-6F	SE-04-030-120-6F	SE-04-040-120-6F	SE-04-060-120-6F	SE-04-080-120-6F	SE-04-100-120-6F	SE-04-120-120-6F	SE-04-150-120-6F		
	5	SE-05-020-120-6F	SE-05-030-120-6F	SE-05-040-120-6F	SE-05-060-120-6F	SE-05-080-120-6F	SE-05-100-120-6F	SE-05-120-120-6F	SE-05-150-120-6F	SE-05-180-120-6F	SE-05-200-120-6F
	6	SE-06-020-120-6F	SE-06-030-120-6F	SE-06-040-120-6F	SE-06-060-120-6F	SE-06-080-120-6F	SE-06-100-120-6F	SE-06-120-120-6F	SE-06-150-120-6F	SE-06-180-120-6F	SE-06-200-120-6F
	7	SE-07-020-120-6F	SE-07-030-120-6F	SE-07-040-120-6F	SE-07-060-120-6F	SE-07-080-120-6F	SE-07-100-120-6F				
7 Fr, 120 cm	4			SE-04-040-120-G3	SE-04-060-120-G3	SE-04-080-120-G3	SE-04-100-120-G3	SE-04-120-120-G3	SE-04-150-120-G3		
	5			SE-05-040-120-G3	SE-05-060-120-G3	SE-05-080-120-G3	SE-05-100-120-G3	SE-05-120-120-G3	SE-05-150-120-G3	SE-05-180-120-G3	SE-05-200-120-G3
	6			SE-06-040-120-G3	SE-06-060-120-G3	SE-06-080-120-G3	SE-06-100-120-G3	SE-06-120-120-G3	SE-06-150-120-G3	SE-06-180-120-G3	SE-06-200-120-G3
	7			SE-07-040-120-G3	SE-07-060-120-G3	SE-07-080-120-G3	SE-07-100-120-G3				
	8	SE-08-020-120-G3	SE-08-030-120-G3	SE-08-040-120-G3	SE-08-060-120-G3	SE-08-080-120-G3	SE-08-100-120-G3				

Product Specifications

- 0.014" or 0.018" guidewire
- 6 pairs of super-elastic nitinol wires interwoven in a helical pattern with a closed cell geometry
- Self-expanding stent

Catheter Size	Stent Size	Sheath Size	Working Length
6 Fr	4 mm - 7 mm	6 Fr	80 cm or 120 cm
7 Fr	4 mm - 8 mm	7 Fr - 0.100" minimum	120 cm

Contact Us

For a product demonstration or for more information on SUPERERA VERITAS®, please contact your IDEV representative:

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INDICATIONS FOR USE: The SUPERERA VERITAS® Interwoven Self-Expanding Nitinol Stent System is indicated for palliative treatment of biliary strictures produced by malignant neoplasms and peripheral vascular use following failed percutaneous transluminal angioplasty (PTA). **WARNINGS: GENERAL WARNINGS/PRECAUTIONS:** DO NOT resterilize or reuse this device. For single use only. Sterilized with ethylene oxide gas. DO NOT use the device if the device or the device package is open or damaged. Use this device prior to the "use-before" ("expiration") date as specified on the device package label. DO NOT expose the device to organic solvents. DO NOT use with Ethiodol or Lipiodol contrast media. This device is not designed for use with contrast media or power injection systems. DO NOT oversize stent. Size stent to vessel reference diameter. Refer to Section 3b under Preparation Procedures of the "Instructions for Use". Flush the device prior to use. This device is not compatible with "back loading" (loading guidewire through proximal end). Never advance the device without the guidewire extending from the tip. Do not rotate the handle during the procedure. Take care to avoid unnecessary handling, which may kink or damage the delivery system. DO NOT use if device is kinked. The SUPERERA VERITAS® Interwoven Self-Expanding Nitinol Stent System is not designed for repositioning or recapturing. Implantation of the SUPERERA® Interwoven Self-Expanding Nitinol Stent should be performed only under fluoroscopic observation with radiographic equipment providing high-resolution images. This device is intended for use by physicians that have received appropriate training. Use caution when crossing a partially or fully deployed stent with adjunct devices. When multiple stents are used, they should be of similar composition. Long term outcomes following repeat dilatation of endothelialized stents are unknown. CAUTION: This device is not yet approved by the FDA for distribution in the United States for peripheral vascular disease. ©IDEV Technologies, Inc. All rights reserved. MKT00108 (12/12/11)

Reference

- ¹ Data on file. IDEV Technologies, Webster, Texas.
- ² Dierk Scheinert, MD; Lars Grummt, MD; Michael Piorkowski, MD; Jacqueline Sax; Susanne Scheinert, MD; Matthias Ulrich, MD; Martin Werner, MD; Yvonne Bausback, MD; Sven Braunlich, MD; and Andrej Schmidt, MD. "Novel Self-Expanding Interwoven Nitinol Stent for Complex Femoropopliteal Lesions: 24-Month Results of the SUPERERA SFA Registry." *Journal of Endovascular Therapy*, Volume 18, Issue 6 (December 2011): 745-752, DOI: 10.1002/ccd.22811.