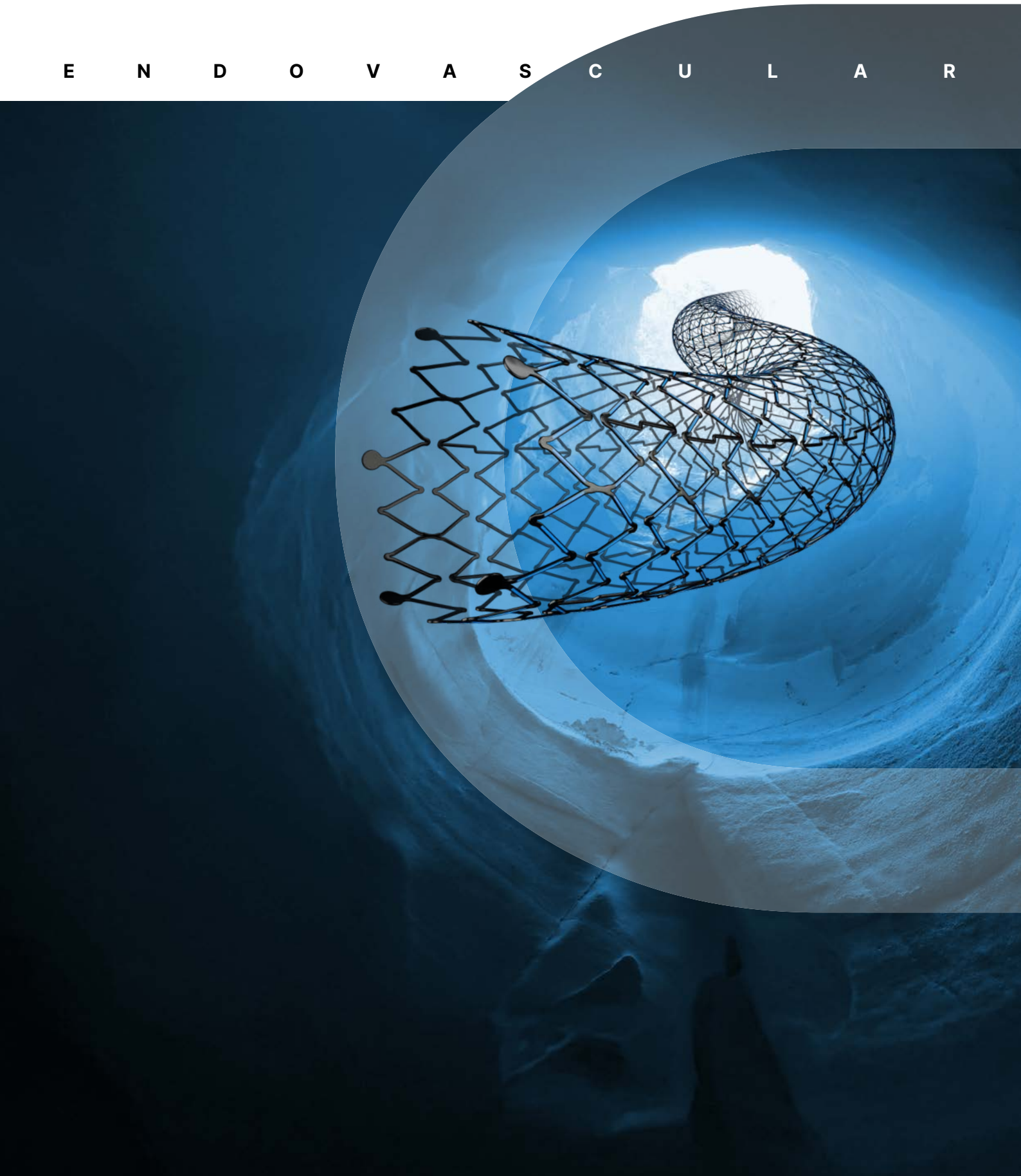
NiTiDES™

SFA | P1 AMPHILIMUS™ ELUTING SX STENT

E N D O V A S C U L A R

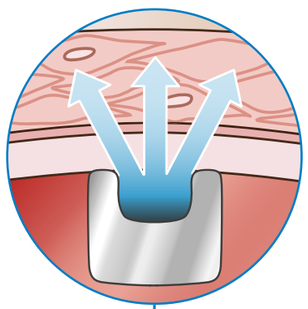


NiTiDES™

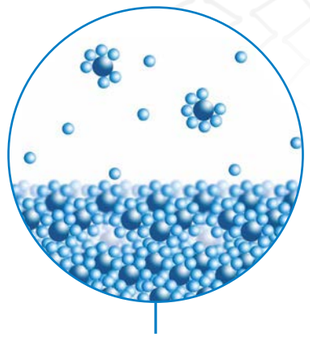
SFA | P1 AMPHILIMUS™ ELUTING SX STENT

Polymer-free Amphilimus™ (Sirolimus + Fatty Acid) eluting stent for lesions in the SFA | P1 region. The absence of polymer minimizes the risk of inflammation/thrombosis, while the proprietary formulation enhances drug absorption

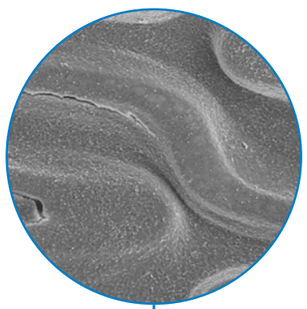
UNIQUE FEATURES



The Abluminal Reservoir Technology allows a sustained drug release, exclusively towards the vessel wall, up to 3 months



The Amphilimus™ formulation (Sirolimus + Fatty Acid) enhances drug bioavailability, permeability and maximizes safety and efficacy



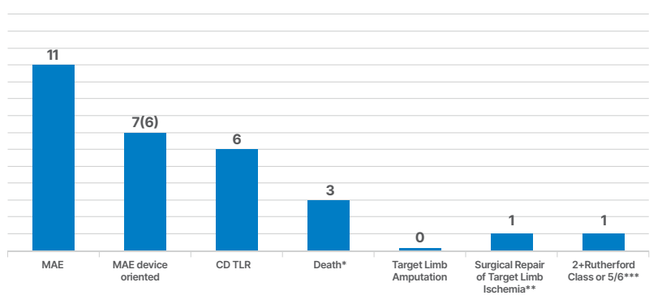
BIS coating accelerates endothelialization, reduces thrombogenicity and seals against heavy metal ions release

CLINICAL PROOF

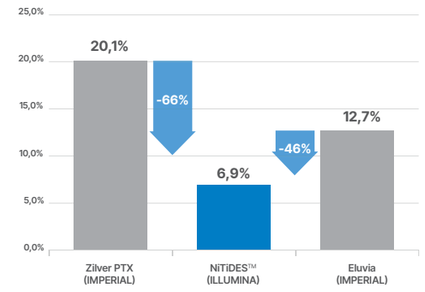
ILLUMINA is the First In Human study designed to prove NiTiDES™ Safety and Efficacy in the treatment of SFA | P1. The study enrolled 100 patients in 10 centers across Germany, France and Italy.

ILLUMINA STUDY - 24 MONTHS RESULTS

Primary Safety Endpoint - MAE - and components @ 24m



cd-TLR @ 2 years

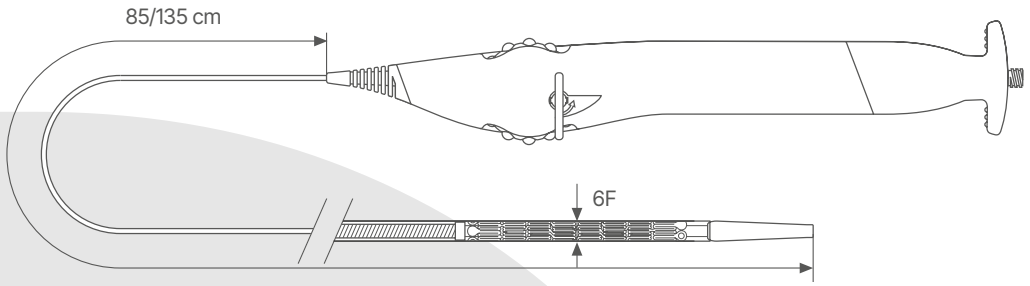


**3 deaths non stent or procedural related (CEC adjudicated): 1 due to MI @ 5 months; 1 due to severe septic shock @ 13 months; 1 due to lung cancer @ 17 months*
***1 thrombo-endo-aterectomy (in CFA, far proximal to the lesion) @ 18 months - non stent related (CEC adjudicated)*
****1 patient, asymptomatic at 1year, had femoral bone fracture 5months before 2years FU visit (Rutherford classes are not CEC adjudicated)*

J Am Coll Cardiol 2019 Oct 29;74(17):2216-2218 | JACC Cardiovasc Interv 2022 Mar 28;15(6):618-626

The **ILLUMINA** study results stand NiTiDES™ at the top of excellence in today peripheral **DES** scenario

TECHNICAL DATA



CATHETER SPECIFICATIONS	
Category	Over The Wire (OTW) delivery system
Guiding catheter compatibility	6F
Guidewire compatibility	0.035"
Usable catheter length	85 - 135 cm
External Sheath	Braided Polyamide
Dual Release System	Thumbwheel for micrometric release Pull back for rapid release
Category	Over The Wire (OTW)
Guiding catheter compatibility	6F

DES SPECIFICATIONS	
Category	Bio Inducer Surfaced Self Expanding Polymer-free DES
Material	Nickel Titanium alloy (Nitinol)
Drug eluting technology	Abluminal Reservoir Technology Sustained elution up to 2-3 months
Drug releasing	Amphilimus™ Formulation Sirolimus + Fatty Acid
Stent diameters	6 - 8 mm
Stent lengths	20 - 150 mm
X-ray visibility	Six dot Tantalum markers

ORDER INFORMATION

USABLE CATHETER LENGTH	Ø (mm) \ L (mm)	20	40	60	80	100	120	150
85 cm	6	ICNI6020S	ICNI6040S	ICNI6060S	ICNI6080S	ICNI60100S	ICNI60120S	ICNI60150S
	7	ICNI7020S	ICNI7040S	ICNI7060S	ICNI7080S	ICNI70100S	ICNI70120S	ICNI70150S
	8	ICNI8020S	ICNI8040S	ICNI8060S	ICNI8080S	ICNI80100S	ICNI80120S	ICNI80150S
135 cm	6	ICNI6020L	ICNI6040L	ICNI6060L	ICNI6080L	ICNI60100L	ICNI60120L	ICNI60150L
	7	ICNI7020L	ICNI7040L	ICNI7060L	ICNI7080L	ICNI70100L	ICNI70120L	ICNI70150L
	8	ICNI8020L	ICNI8040L	ICNI8060L	ICNI8080L	ICNI80100L	ICNI80120L	ICNI80150L

Manufactured by
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