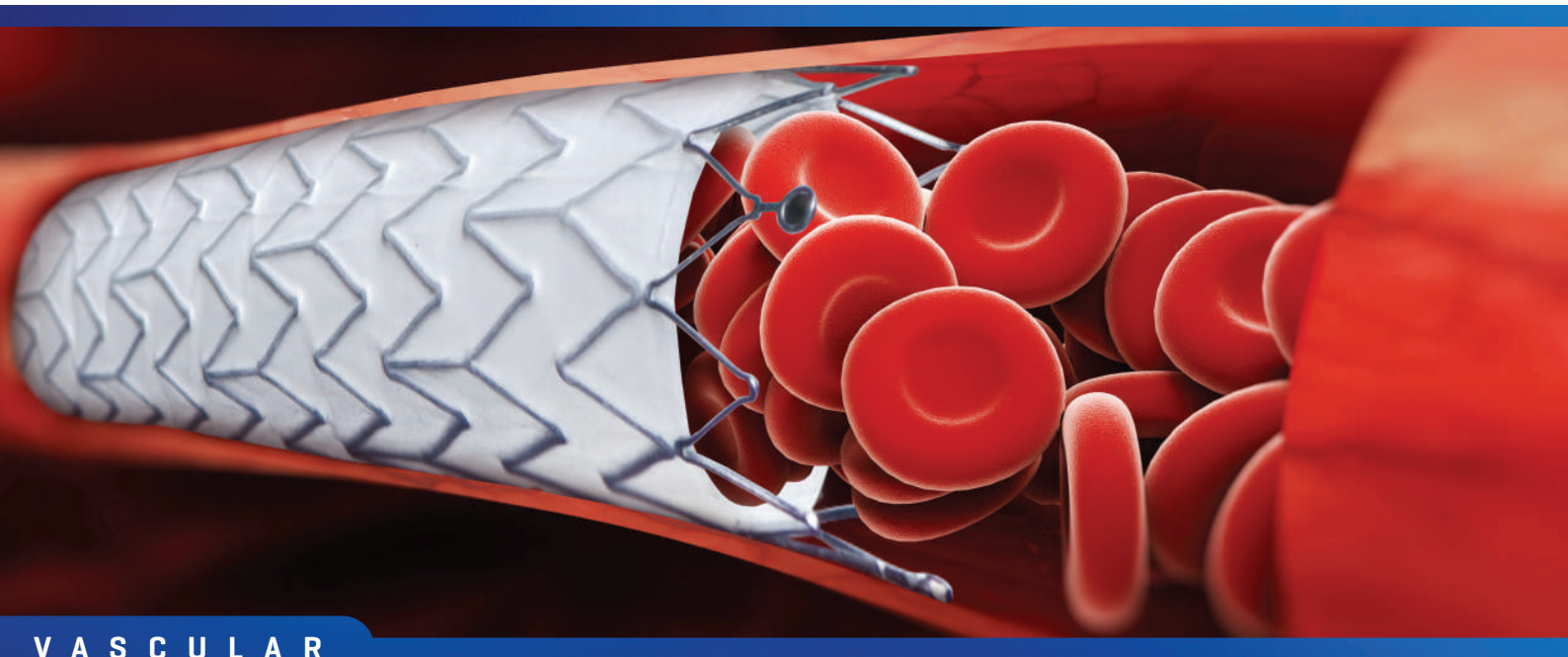
SCITECH®

Innovation for Life

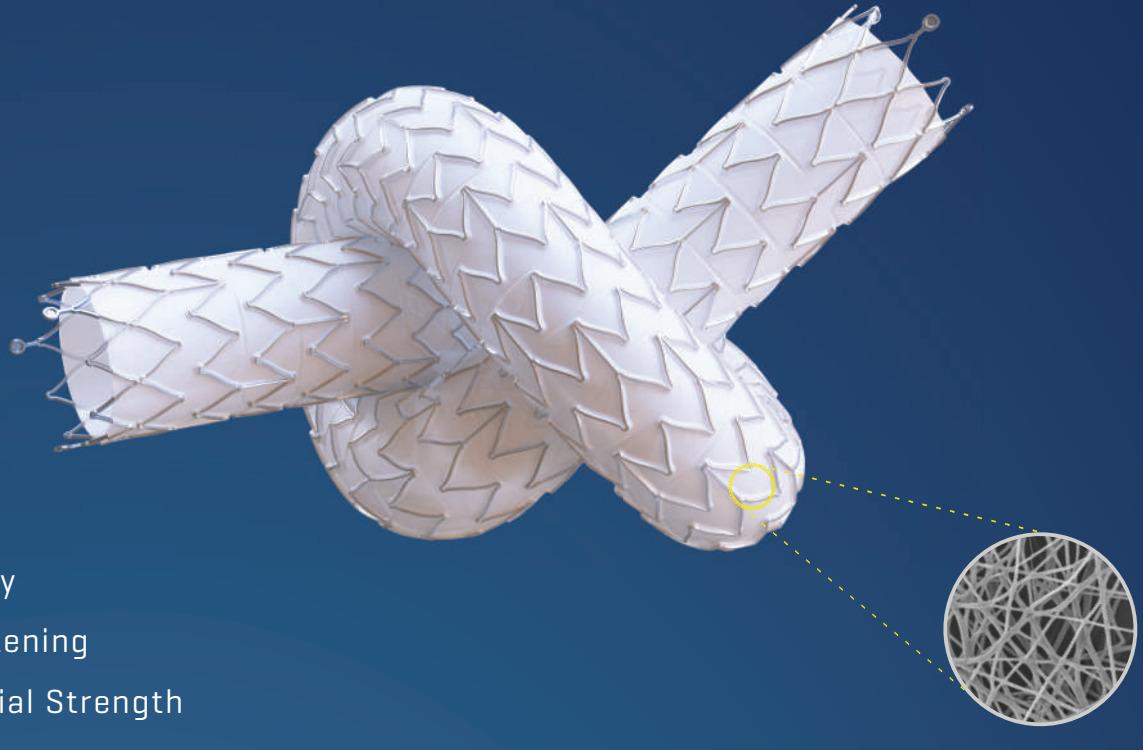


VASCULAR

SOLARIS

SOLARIS

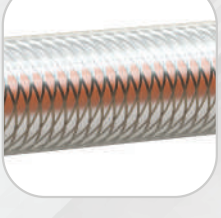
SOLARIS is a flexible self-expanding stent-graft, comprised of a durable electrospinning **PTFE** membrane encapsulating a **Nitinol** stent structure.



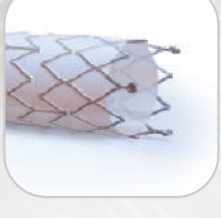
- Precision
- High Flexibility
- Minimal Shortening
- Balanced Radial Strength

Electrospinning PTFE membrane:

Multidirectional Resistance Force with Instantaneous Sealing



Hydrophilic Coating



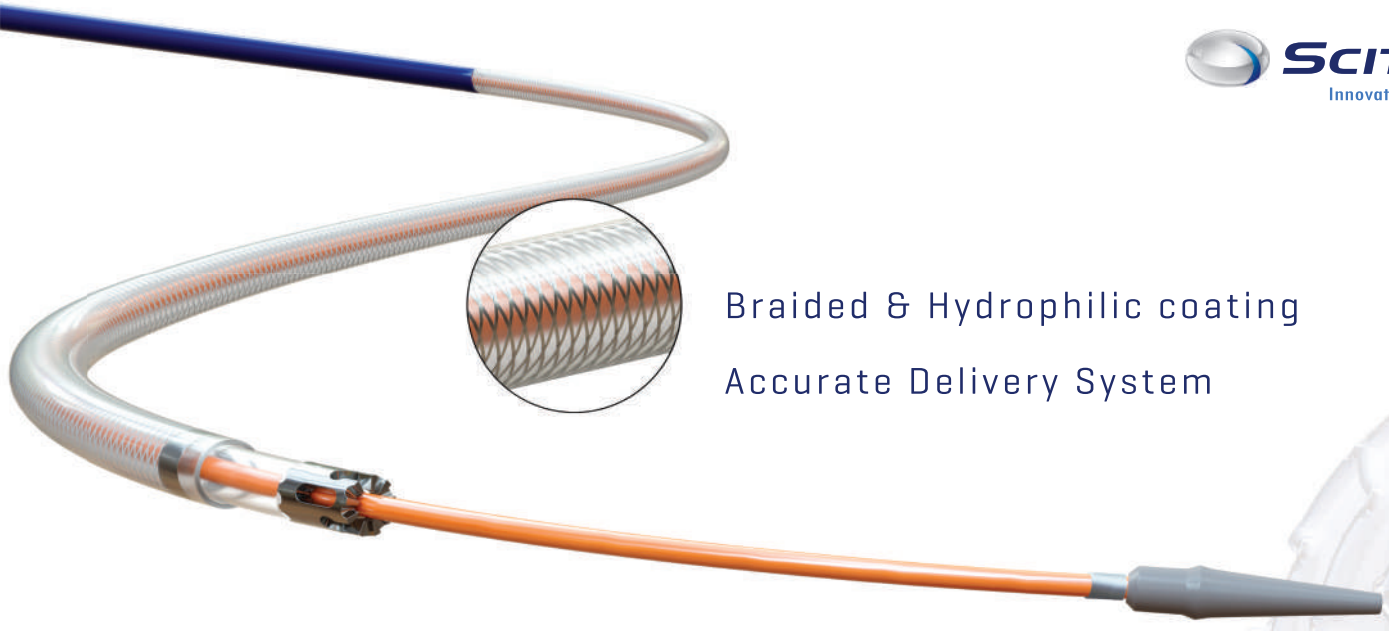
3 Tantalum Marker Bands [Distal/Proximal]

Anti-Jump Feature

Pullback Delivery System

Atraumatic Flexible Tip

SCITECH®
Innovation for Life

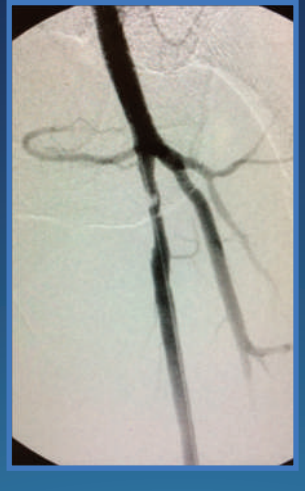


Braided & Hydrophilic coating

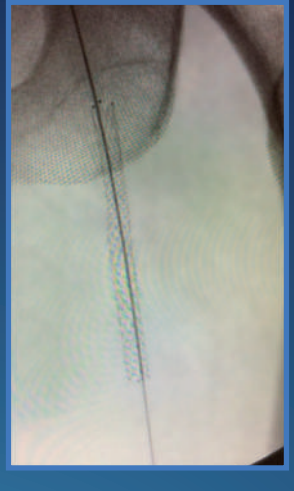
Accurate Delivery System

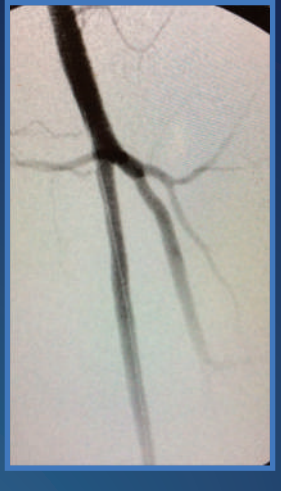
SOLARIS: Clinical Case, SFA Lesion.

PRE



POST



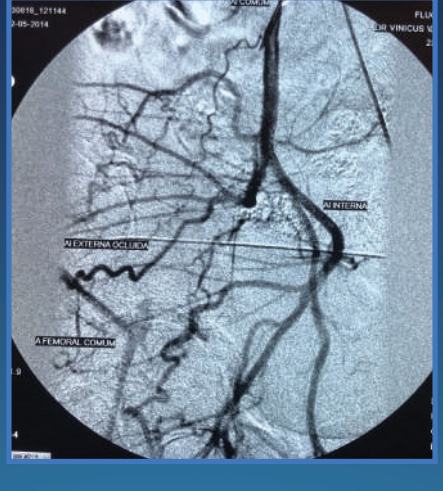


SOLARIS 6x60mm

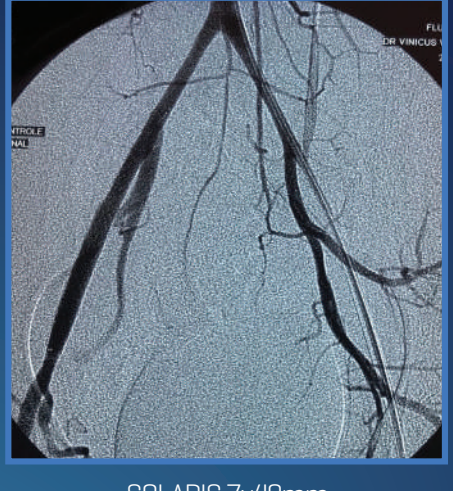
Images courtesy of Marcus Vinicius Cury, MD, PhD.

SOLARIS: Clinical Case, EIA lesion.

PRE



POST



SOLARIS 7x40mm

Images courtesy of Vinicius Fornazari, MD, PhD.

Optical Coherence Tomography and Histopathological Preclinical Evaluation of an Enhanced Polytetrafluoroetylene (PTFE) Covered Stent in a Peripheral Swine Animal Model: Addressing the Anatomical Challenges of the Lower Limb Stenting Procedure

Armando Tellez, Krista N. Dillon, Dane A. Brady, Luciano Curado, Eduardo Cordeiro, Alexander Moreira,
Serge D. Rousselle Alizée Pathology; Thurmont, Maryland; Scitech Medical, São Paulo Brazil

Introduction

Covered stents are widely used to address numerous areas of need in peripheral intervention including degenerated vein grafts, iatrogenic arterial perforations, aneurysm exclusion, iliac artery graft extension, and the chimney/snorkel technique to treat aortic aneurysm. However, PTFE-covered stents have a known relative inflexibility which makes deliverability difficult in complex, tortuous, and heavily calcified anatomy. Additionally, current technologies tend to produce kinks resulting in device collapse. This, in turn, can be associated with a high restenosis rate post-implantation, particulary stent-edge restenosis, acute, and subacute thrombosis. In this study we aim to evaluate the performance and vascular response of a new, peripheral covered stent in a large animal model as compared to a commercially available PTFE-covered stent.

Methods

Six domestic swine were included in this study (45±1kg). Based on angiographic QVA, the superficial femoral arteries were randomized for either the implantation of Solaris (Scitech, São Paulo, Brazil) or Competitor A.
Stents utilized were 40mm long for both groups and implanted aiming for a 1.1:1 ratio. Following implantation, animals were recovered and followed for 30 days. At 30 days post-implantation all stents were evaluated under optical coherence tomography (OCT), explanted and subjected to stent integrity analysis and histopathological evaluation.

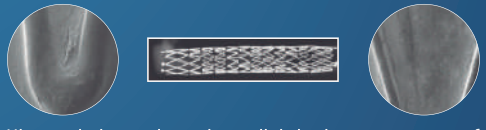
Animal Model	Naïve Domestica Swine n=6	
Target Vessel	Peripheral Arteries (Superficial Femoral Arteries) n=12	
Test Groups	Solaris PTFE Nitinol Stent Graft n=6	Control Article (Competitor A) n=6
30 Days End Points	Optical Coherence Tomography and Histopathology Evaluation	

Results

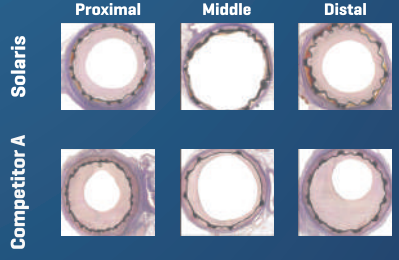
A total of 11 stents were evaluated (Solaris n=6, Competitor A n=5), The operator described the Solaris stents as demonstrating a higher navigability when compared to the Competitor A stent. The hydrophilic coated delivery system of the Solaris stent allowed a smoother release of the device without any sudden jump and greater geogr phical precision at implantation. At 30 days, OCT revealed a similar stent area for groups (Solaris 25.8±4,7 vs Competitor A 24.7±5mm2) with a lower neointimal area (Solaris 7.8±1.8 vs Competitor A 10.8±2.4mm2) compared to control. This led to a higher percentage stenosis in the control group (Solaris 31.9±7 vs Competitor A 44.8±6%).

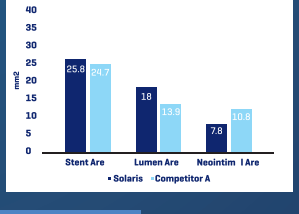
Device description

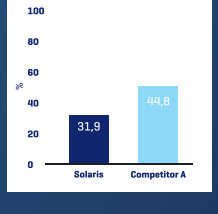
Low profile (5-7 mm diameter x 40-100 mm in length) self-expandable nitinol peripheral stent. Due to the cell design, the Solaris stent provides superior, ultidirectional flexibility and easy navigability. Three tantalum markers on the extremities allow for precision in delivery. The stent is covered by an ultra-thin, polytetrafluoroethylene (PTFE) membrane. The representative images above illustrate the SEM of the membrane at 170x (left) and 60x (right) objective magnification.



Histopathology showed a slightly lower amount of neointima formation in the Solaris (area percent stenosis ~ 30%) compared to the controls (~37%). There was optimal local biocompatibility in both groups. The Solaris and Competitor A stent grafts showed optimal biocompatibility. Both groups showed instances of increased mural inflammation (in the media and adventitia) primarily due to stent expansion.







Conclusion

The Solaris PTFE-covered peripheral stent demonstrated a resistance to fracture with increased flexibility and navigability and better conformability to artery curvature. The release system allowed for an accurate geographical delivery and the components of the device produced a lower OCT morphometrically - assessed neointimal response when compared to the control group.

References Guide

Diameter (mm)	Length (mm)							
	40		60		80		100	
	Ref	Ø	Ref	Ø	Ref	Ø	Ref	Ø
5	112429	8F	112430	8F	112431	8F	112432	8F
6	112434	8F	112435	8F	112436	8F	111715	9F
7	112439	8F	112440	8F	112441	8F	111720	9F
8	112444	8F	112445	8F	112446	8F	111725	9F
9	111727	9F	111728	9F	111729	9F	111730	9F
Delivery System (Length): 130cm								

*Solaris - BR / Asia / LATAM

SCITECH®
Innovation for Life

www.scitechmed.com
E-mail: scitech@scitechmed.com
Phone: +55 62 3625-5000

R. 01 - 06-21