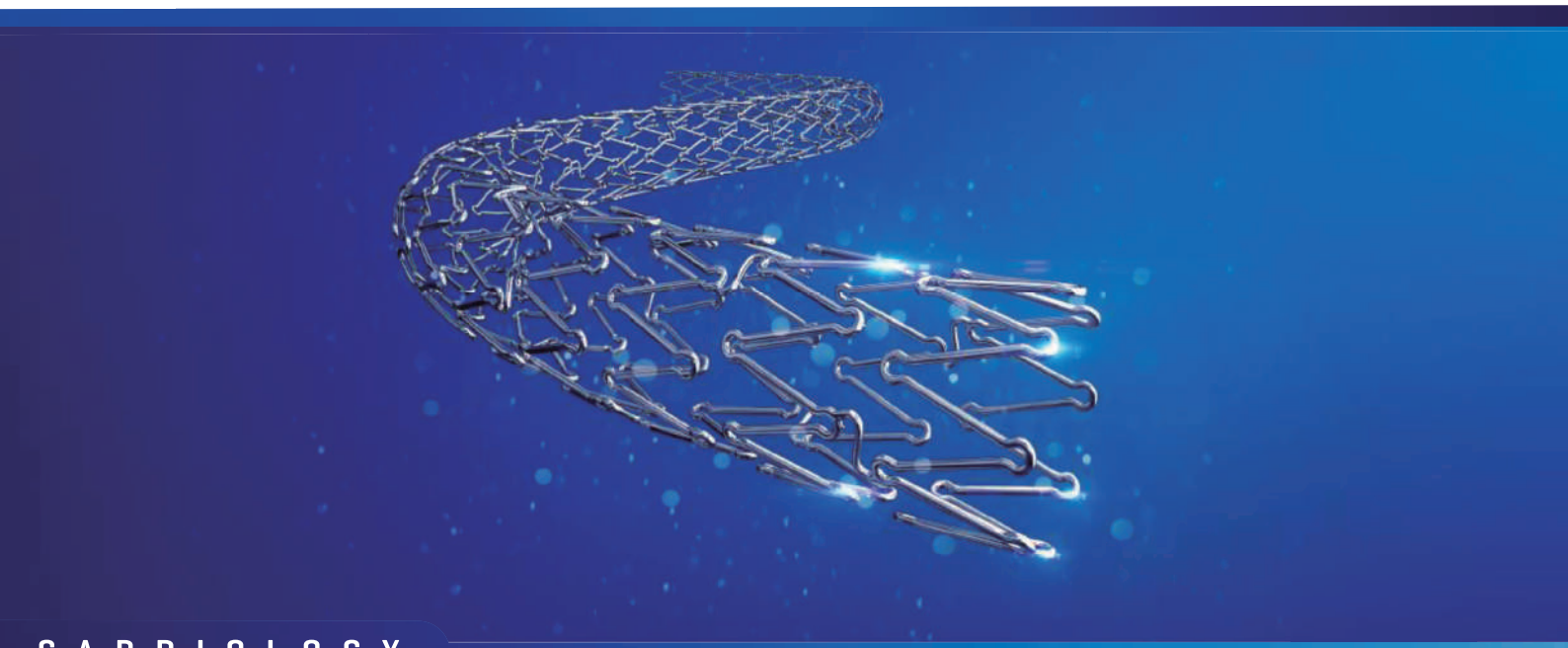
SCITECH®

Innovation for Life



CARDIOLOGY

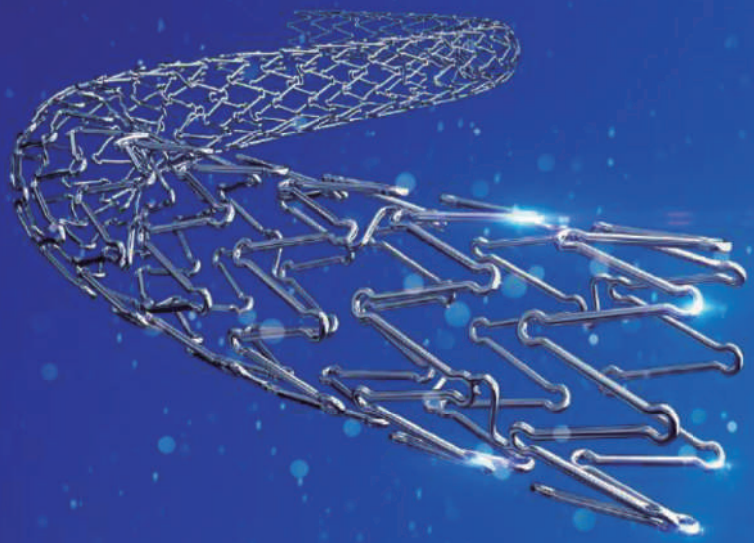
SIROLIMUS DRUG ELUTING STENT

INSPIRON

EFFECTIVE HEALING

SIROLIMUS DRUG ELUTING STENT

INSPIRON



EFFECTIVE HEALING

Publications:

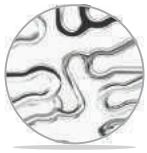
- Intravascular imaging comparison of two metallic limus-eluting stent abluminally coated with biodegradable polymers: IVUS and OCT results of the Destiny trial; October 2016; International Journal Cardiovascular Imaging.
- Metallic Limus-Eluting Stents Abluminally Coated with Biodegradable Polymers: Angiographic and Clinical Comparison of a Novel Ultra-Thin Sirolimus Stent Versus Biolimus Stent in the DESTINY Randomized Trial; November 2015; Cardiovascular Therapeutics 33 (2015) 367–371
- Clinical performance of a novel ultrathin strut, low-dose, sirolimus-eluting stent with abluminal-only biodegradable polymeric coating for patients undergoing percutaneous coronary intervention in the daily practice; Cardiovascular Diagnosis and Therapy. July 2015.
- Four-year clinical follow-up of the first-in-man randomized comparison of a novel sirolimus eluting stent with abluminal biodegradable polymer and ultra-thin strut cobalt-chromium alloy: the INSPIRON-I trial; September 2015; Cardiovasc Diagn Ther 2015;5(4):264-270.
- Study Inspiron trial I - EuroIntervention journal - April 2014; 9: 130-1384 pages - this is the first clinical study with 02 years follow up with Insprion stent. And it was presented at EuroPCR in 2011.

SCITECH®
Innovation for Life

Thin struts and advanced design

- Cobalt Chromium alloy
- 75µm strut thickness
- Excellent radial force

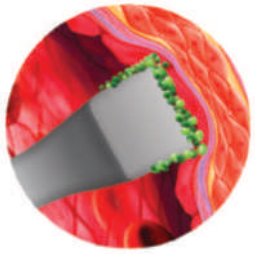
Rounded finishing of the strut structure



"S" shaped links allow high flexibility, improved trackability in tortuous anatomy and excellent side access in bifurcations

Abluminal coating

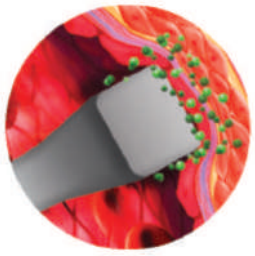
- Efficient endothelization



5µm - coating thickness

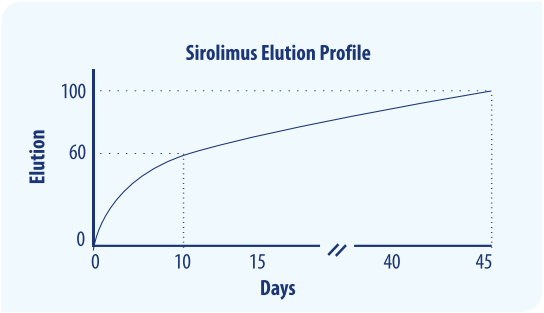
Biodegradable polymer

- PLA and PLGA biodegradable up to 9 months



Complete degradation into CO_2 and H_2O.

Sirolimus elution profile



Technical specifications

Material	CoCr L605	Delivery system length	145cm
Crossing profile	~1.05MM	Compatible guide wire	0.014"
Guiding catheter	minimum: 5F	Nominal pressure	10atm
Compatibility with MRI	Yes (non magnetic)	Rated burst pressure	18atm*
Design of the catheter	Rapid exchange	Distal shaft (outside diameter)	2.6F
Strut thickness	75µm	Proximal shaft (outside diameter)	2.1F

* For balloon up to 3,0

Configuration and ordering information

	Length									
Diameter	**9mm**	**13mm**	**16mm**	**19mm**	**23mm**	**29mm**	**33mm**	**38mm**	**48mm**	**58mm**
2.25mm		105181	105184	105186	105187	105188				
2.5mm	105024	105025	102633	102632	105028	105029	105030	104262		
2.75mm		105190	105191	105192	105193	105194	105195	105196		
3.0mm	105031	105032	102634	101335	105034	105037	105038	105041	113628	113632
3.5mm	105042	105044	102635	102636	105047	105048	105051	105052	113629	113633
4.0mm	105197	105198	105199	110964	110965	110966				

Inspiron™ Clinical Research Program:

DESTINY TRIAL is a multicenter, randomized study comparison between Inspiron™ SES from Scitech compared to Biomatrix™ BES from Biosensor. The primary objective is to evaluate the in-segment late loss at 9 months. Secondary endpoints included major adverse events (MACCE), percent in-stent obstruction as measured by intravascular ultrasound (IVUS) at nine months and percent of uncovered struts and neointimal coverage by optical coherence tomography (OCT) at nine months. One hundred and seventy patients were enrolled (194 lesions), 114 (132 lesions) for Inspiron™ and 56 (62 lesions) for Biomatrix™. Baseline clinical and angiographic characteristics of both groups were similar. At nine months, the in-segment LLL was 0,20 ± 0,27 for Inspiron™ versus 0,15± 0,20 for Biomatrix™ with P<0.001 for non-inferiority, as well as the percent neointimal obstruction by IVUS was 4,9 ± 4,1 for Inspiron™ and 2,7 ± 2,9 for Biomatrix™ with P=0,03. And the percent of uncovered struts by OCT was 0,51± 1,0 for Inspiron™ and 2,38 ± 2,20 for Biomatrix™ with P=0,021. At 270 days follow-up, incidence of MACCE was 6,3% for Inspiron™ and 7,3% for Biomatrix™ with p=0,7 with no deaths and no stent thrombosis at both groups.

INSPIRON REAL LIFE STUDY, single-arm "Real Life Use" with no inclusion or exclusion criteria. The primary objective was to evaluated major adverse cardiac events (MACCE). Three hundred and seventy one patients were enrolled (574 units of Inspiron™). At 30 days the MACE was 4,6% as well as at 180 days the MACCE was 9,0% with 1,6% overall death.

INSPIRON TRIAL I is a first in man, multicenter, randomized study (2:1) comparison between Inspiron™ and a stent with the same metallic structure but without polymer coating or drug eluting (Cronus). The primary objective was to evaluate the in-segment late loss (LLL) at six months. Secondary endpoints included percent in-stent obstruction as measured by intravascular ultrasound (IVUS) at six months and major adverse cardiac events (MACCE). Fifty-eight patients were enrolled (60 lesions), 39 for Inspiron™ and 19 for Cronus. Baseline clinical and angiographic characteristics of both groups were similar. At six months, the in-segment LLL was reduced in the Inspiron group compared to the control group (0.19±0.16 mm vs. 0.58±0.4 mm, respectively; p<0.001), as well as the percent neointimal obstruction (7.8±7.1% vs. 26.5±11.4%; p<0.001). At two-year follow-up, incidence of MACCE was similar between groups (7.9 vs. 21.1%, respectively; p=0.20), with lower target lesion revascularization for Inspiron™ (0 vs. 21.1%, respectively; p=0.01) and no stent thrombosis.

SCITECH®
Innovation for Life

Scitech Produtos Médicos Ltda
www.scitechmed.com
comercial@scitechmed.com
Rua 06 esq. c/ Rua 18 Qd. 21 Lt. 01 e 44
Polo Empresarial Goiás
Aparecida de Goiânia - GO - Brazil
ZIP Code: 74985-105
Export department
Phone: +55 (11) 2125-8953