CE

SCITECH®

Innovation for Life

CARDIOLOGY

SIROLIMUS DRUG ELUTING STENT

INSPIRON LEGACY

SCITECH®

Innovation for Life

SCITECH Medical is a minimally invasive medical device company that was founded over 15 years ago and is currently present in more than 40 countries.
Its 6.000 sqm state-of-the-art ISO 13485 certified facility is located in Brazil.
Currently the company develops and manufactures a wide portfolio of products for the Interventional Cardiology, Peripheral Vascular, Endosurgery and Endoscopy markets.

For further information please access *www.scitechmed.com*

SIROLIMUS DRUG ELUTING STENT

INSPIRON LEGACY

EFFECTIVE HEALING

INSPIRON® is a 3rd generation Drug Eluting Stent designed to create a fast and homogeneous endothelialization. Its platform is the CRONUS NE® Stent, a stent which design, material (CoCr), thin struts (75 µm) and delivery system gives it good navigability, flexibility, good crossover profile, moderate radiopacity and high balloon rupture pressure. Its abluminal coating is composed of a mixture of PLA and PLGA polymers and a low Sirolimus dosage resulting in a moderate drug elution profile (60% in 10 days and 100% in 45 days), complete coating degradation between 6 and 9 months and in a fast and homogeneous endothelialization.

Advanced design with thin struts

Cobalt chromium alloy.

75µm strut thickness.

Coating thickness – 5µm

-limus klasės vaisto ir polimero storis ne daugiau 5 mikronų

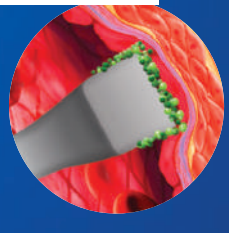
vaistu ir polimeru padengtas tik su arterijos sienele kontaktuojantis stento paviršius (abluminal coating, - angl.)

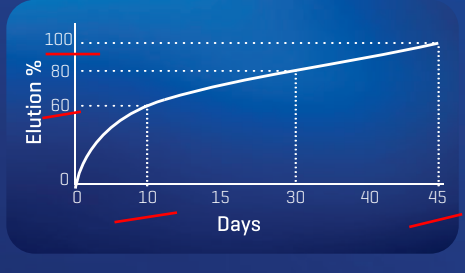
Abluminal Coating

Coating thickness – 5µm

Rounded structure to avoid artery injury.

"S" connectors for high flexibility and navigability.





Sirolimus: Low dosage and moderate elution profile

per pirmąsias 10 dienų nuo stento atsiskiria ne mažiau, nei 60% vaisto, o visas jis išsiskiria ne lėčiau, nei per 45 d.

100% Biodegradable Polymer

Complete degradation of polymers in CO_2 and H_2O within 9 months.

polimeras ištirpsta ne greičiau, nei per 9 mėn

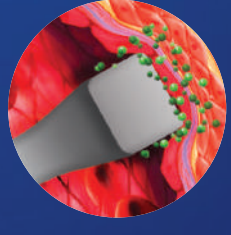


Image of a procedure performed in a simulator

Design allows excelent lateral branch access

Excelent Lateral Branch Access for Bifurcation

Hydrophilic Delivery System

High Rated Burst Pressure

Length includes 48mm and 58mm

Clinical Trials

DESTINY Trial[1/2]
Study Design (Multicenter in 10 Institutions)

Primary EP
IS LL at 9 months
Non-inferiority

170 patients (194 lesions)
Up to 2 *de novo* lesions
Vessels 2.5 - 3.5mm
Single stent per lesion (up to 29mm)

Randomization 2:1

Inspiron
(n=114 pts)

Biomatrix
(n=56 pts)

IVUS substudy
(n=60 pts / 66 lesions)

OCT substudy
(n=21 pts / 25 lesions)

9-month angiographic follow-up
(164 pts [96.5%] / 187 lesions [96.4])

Angiographic, IVUS and OCT corelab: CRC

IS LL, In-stent Late lumen loss, mm

Inspiron Real Life Study I - Novel DES in high-risk patients[3]

Study Design

Single-arm "Real life Use"
Stents 2.5 - 3.5 mm / 13 - 38 mm
No inclusion or exclusion criteria

Primary EP
MACE (Death, MI, TVR)

April 2013 — *470 patients; 723 stents* — *Jan 2015*

Angiographic and procedural characteristics (n=470)

Number of stents	1.7 ± 0.8
Summed stent length, mm	36.8 ± 18.7
At least one bifurcation treated	38.9
At least one ISR treated	19.8
At least one type C lesion treated	61.9

Numbers are means ± standard deviation or proportions.
ISR, in-stent restenosis.

Baseline characteristics (n=470)

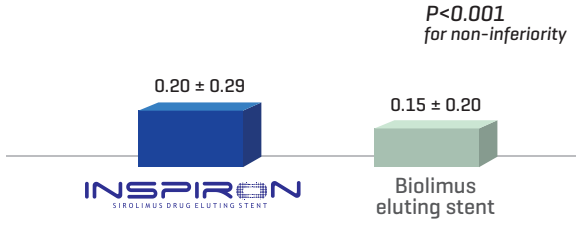
Age, years	63.5 ± 10.5
Diabetes	51.3
Insulin-requiring diabetes	14.9
Previous MI	42.3
Previous PCI	40.2
Previous coronary surgery	18.3
Heart failure	15.3
Dialytic renal failure	2.3
Stable coronary disease	52.3
Non-ST elevation acute MI	34.0
Recent ST elevation acute MI	6.0
Single-vessel	31.5
Double-vessel	34.7
Triple-vessel	33.8

EP: End point; MACE: major adverse cardiac events (cardiac death, myocardial infarction or target lesion revascularization)

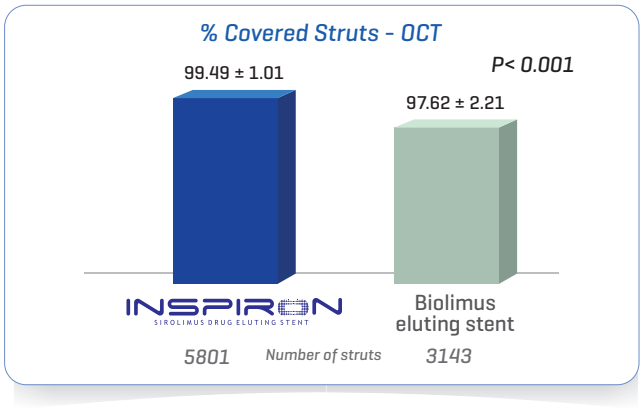
Clinical trials main conclusions

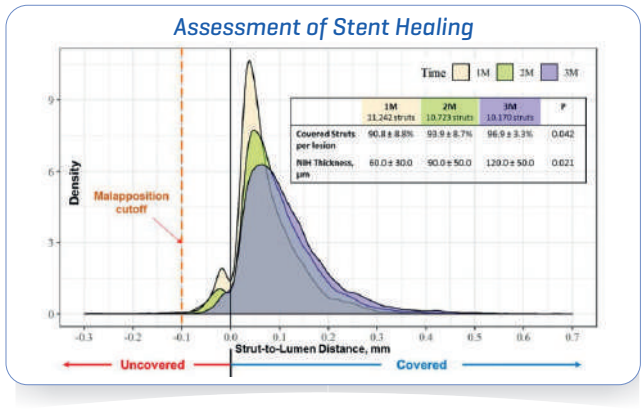
1 - Angiographically Non-inferiority vs. biolimus eluting stent at 9 months.[1]

In-stent Late lumen loss, mm



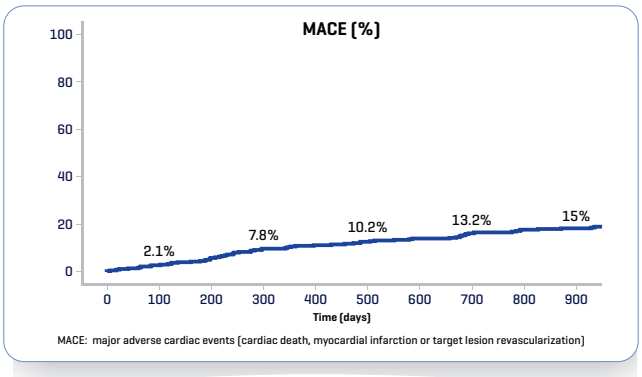
2 – OCT substudies demonstrate that INSPIRON has excellent strut coverage even at 3 months and higher strut coverage compared to Biolimus Eluting Stent with p<0.001 at 9 months.

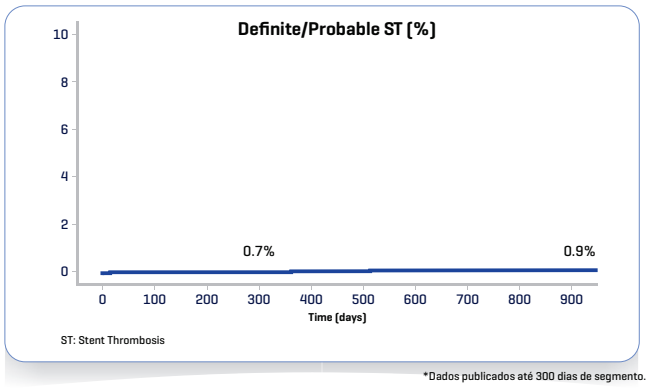




3 – Proven Safety and Efficacy with low rates of thrombosis in the long-term.

Inspiron Real Life I - Novel DES in high-risk patients[3] - 900 days of median follow-up (n=470)*





*Dados publicados até 300 dias de segmento.

DESTINY Trial Clinical adverse events (up to 270 days)

	Inspiron (n= 111 pts)	Biolimus Eluting Stent (n= 55 pts)	P-value
Death	0	0	-
Emergent CABG	0	0	-
MI	4.5	5.5	0.8
TLR	2.7	1.8	0.7
MACE	6.3	7.3	0.7
Stent thrombosis	0	0	-

MACE: major adverse cardiac events (death, MI, TLR); MI: myocardial infarction; TLR: target lesion revascularization

First in Human (4 years)[4/5]

Events	Inspiron (n= 38)	Cronus (n= 19)	P-value
Major adverse cardiac events	3 (7.9)	4 (23.5)	0.11
Death	1 (2.6)	0	0.50
Myocardian infarction	0	0	-
Target vessel revascularization	2 (5.3)	4 (23.5)	0.05
Stent thrombosis (definite or probable)	0	0	-

References

1. 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.
2. 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.
3. 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.
4. 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.
5. Study Inspiron trial I - EuroIntervention journal - April 2014; 9: 130-1384 pages.
6. Multicenter, prospective, randomized study to evaluate by OCT the healing score after stent implantation at 1, 2 and 3 months (NCT03269461).

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	105189	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	—	—	—	—

* Unavailable for CE Market.

stentų diametrai - 3,0 mm ir 3,5mm; tokių diametrų stentų ilgiai - 33, 38, 48 ir 58 mm;
stentų diametrai - 2,5 ir 2,75 mm; tokių diametrų stentų ilgiai - 33 ir 38 mm;

Technical Specifications

nominalus slėgis ne mažiau 10 atm

Material	CoCr L605	Delivery system length	145cm
Crossing profile	~1,05mm	Compatible guide wire	0,014"
Cateter guia compatível	minimum: 6F	Nominal pressure	10atm
Compatibility with MRI	Yes (non magnetic)	Rated burst pressure	18atm*
Design of the catheter	Rapid Exchange	Distal shaft (outside diameter)	2,8F
Balloon Compliance	Semi-Compliance	Proximal shaft (outside diameter)	2,1F
Strut thickness	75µm		

* For balloon up to 3,0

stento sienelės storis ne daugiau 75 mikronų

išbandytasis plyšimo slėgis ne mažiau 18 atm (3 mm ir plonesniems stentams)

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