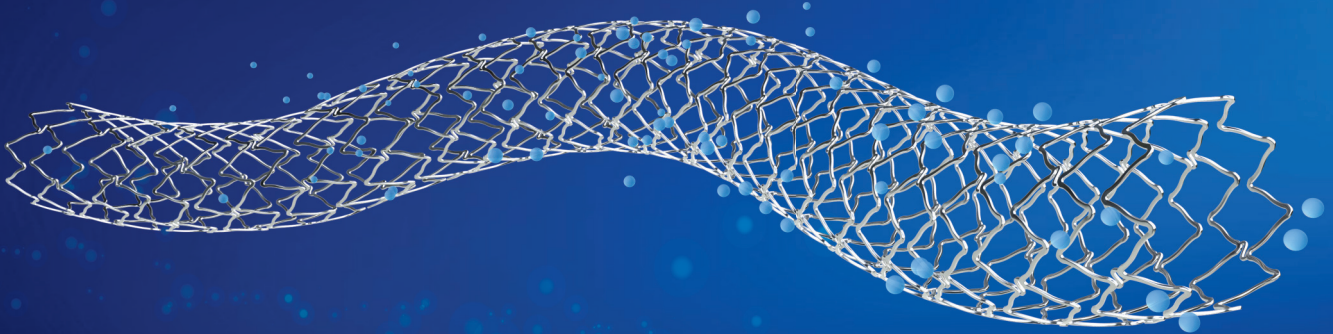




SCITECH[®]
Innovation for Life



C A R D I O L O G Y

SIROLIMUS DRUG ELUTING STENT

INSPIRON
— LEGACY —



SCITECH[®]
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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.

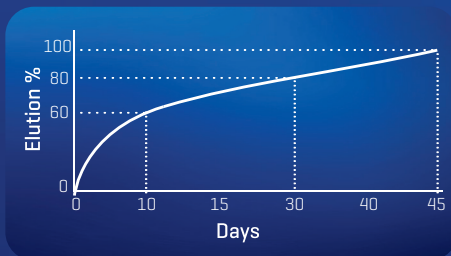
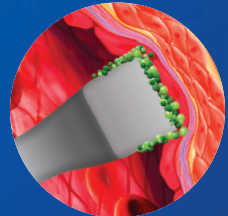
Coating thickness – 5µm

Abluminal Coating

Coating thickness – 5µm

Rounded structure to avoid artery injury.

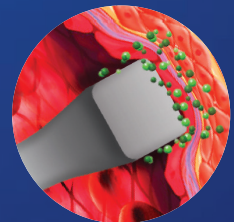
“S” connectors for high flexibility and navigability.



Sirolimus: Low dosage and moderate elution profile

100% Biodegradable Polymer

Complete degradation of polymers in CO₂ and H₂O within 9 months.



Design allows excellent lateral branch access

Excelent Lateral Branch Access for Bifurcation

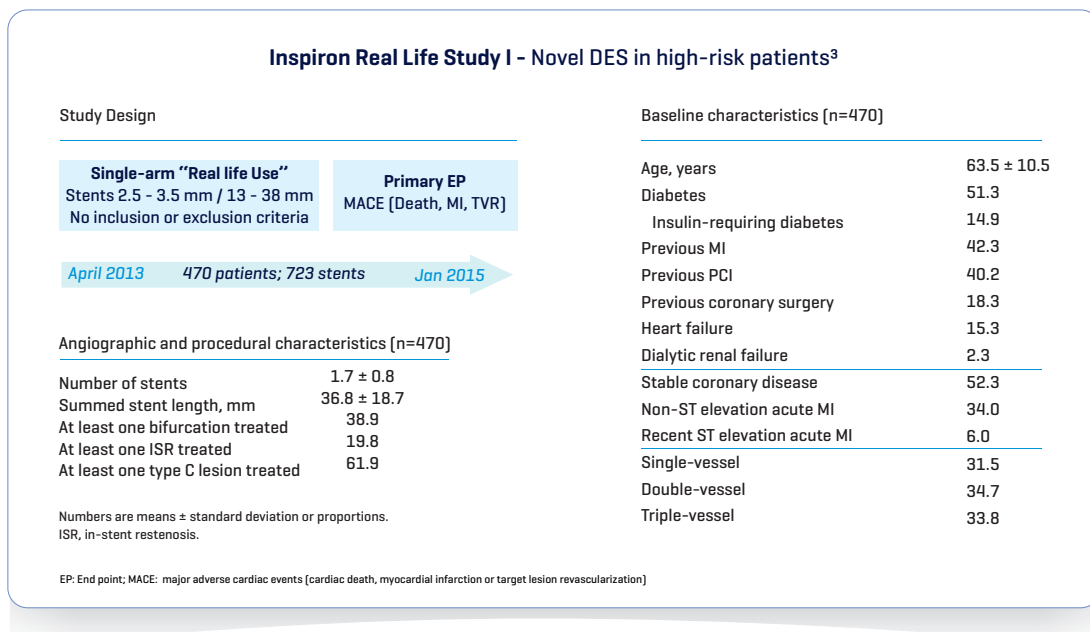
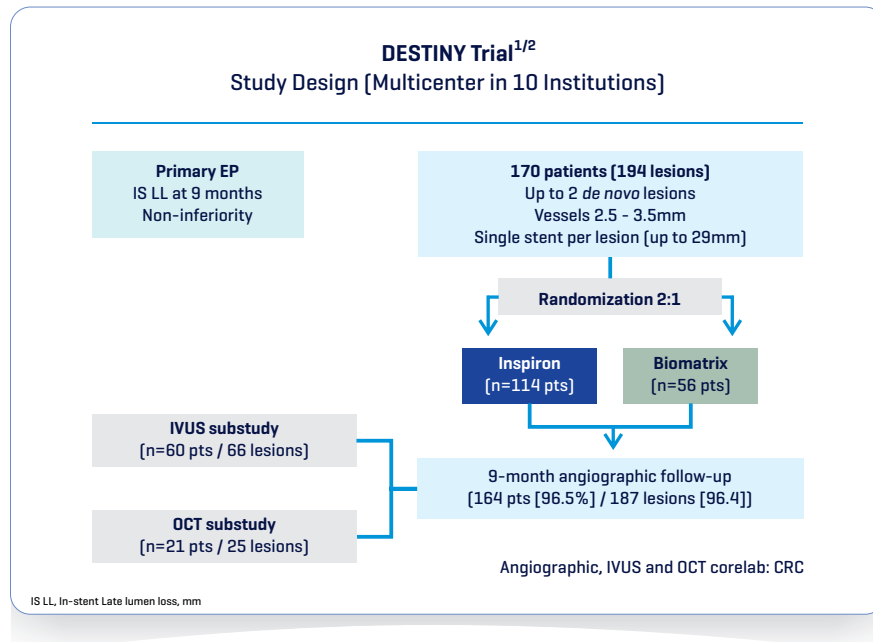
Image of a procedure performed in a simulator

Hydrophilic Delivery System High Rated Burst Pressure



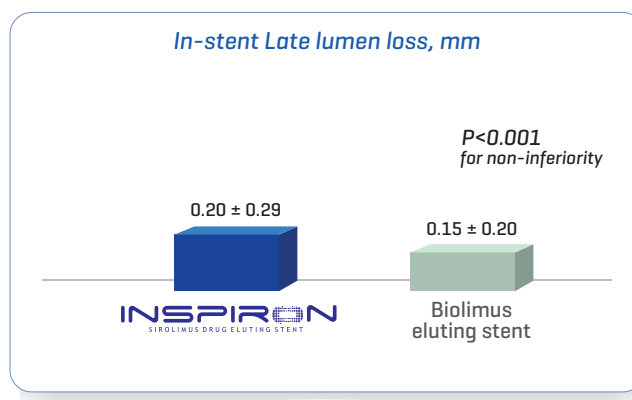
Length includes 48mm and 58mm

Clinical Trials

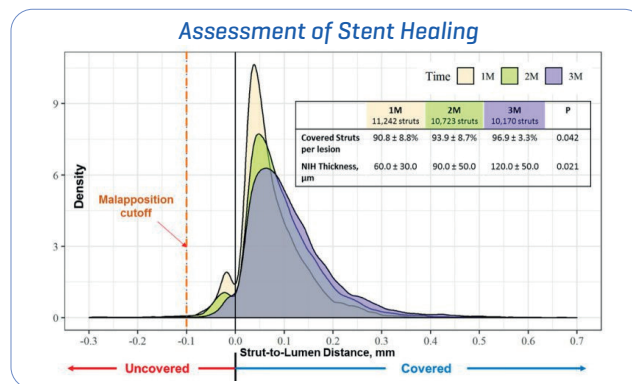
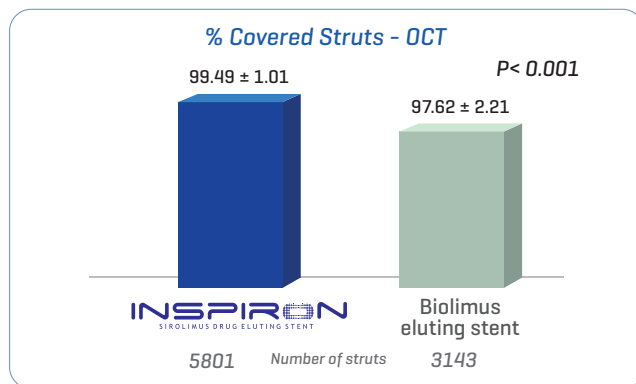


Clinical trials main conclusions

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

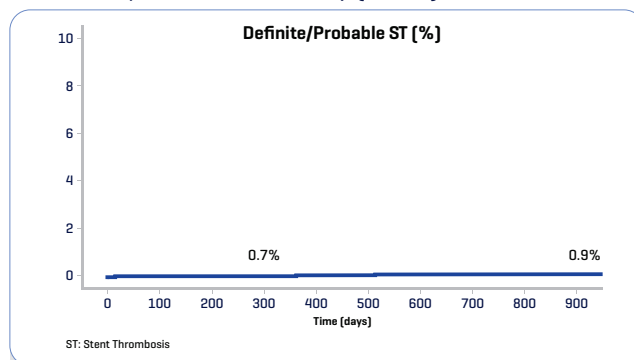
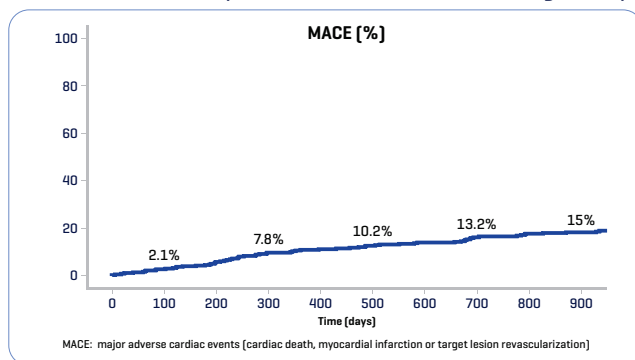


2 – OCT substudies demonstrate that INSPIRON has excellent strut coverage even at 3 months and higher strut coverage compared to Biolimus Eluting Stent with $p < 0.001$ at 9 months.



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

Inspiron Real Life I – Novel DES in high-risk patients³ – 900 days of median follow-up (n=470)*



*Dados publicados até 300 dias de seguimento.

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

Diameter	Length									
	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.

Technical Specifications

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



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