

A new thin-strut, low-dose, sirolimus-eluting stent with abluminal-only biodegradable polymeric coating: safety and efficacy clinical performance of the Inspiron™ stent in high-risk patients

Guy F A Prado Jr, Pedro H M Craveiro Melo, Gustavo M Alves, Welingson V Guimarães, Celso Takimura, Jose Mariani Jr, Luiz J Kajita, Carlos M Campos, Breno A Falcão, Marcus N Gama, Gilberto Marchiori, Antonio Esteves-Filho, Pedro E Horta, Micheli Z Galon, Andre G Spadaro, Silvio Zalc, Paulo R Soares, Marco A Perin, Expedito E Ribeiro, Roberto Kalil-Filho, Pedro A Lemos

Heart Institute - InCor, University of Sao Paulo Medical School, Sao Paulo, Brazil

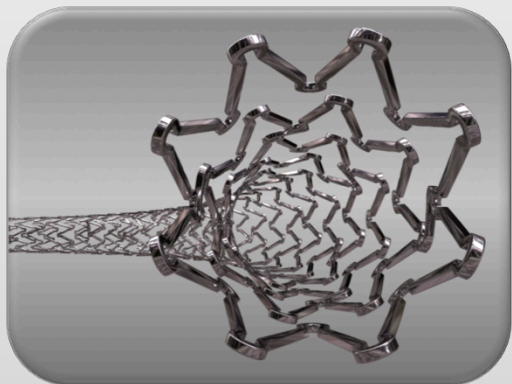


Disclosures

Author's disclosure: Institutional research grant

- The new Inspiron™ (Scitech, Brazil) is a thin-strut (75 μm) cobalt-chromium stent, abluminally coated with a thin PLA-PLGA polymeric layer (5 μm) , eluted with low-dose sirolimus (1.4 $\mu\text{g}/\text{mm}^2$).

Plataform
CoCr – L605



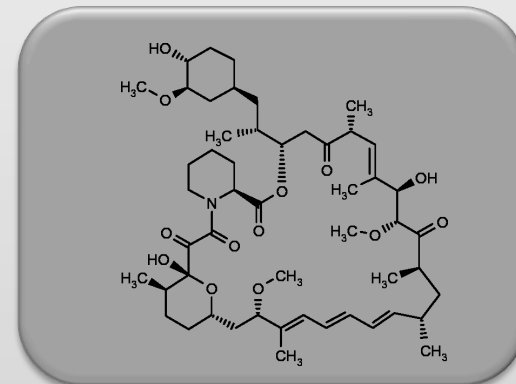
Cronus Plus™
75 µm strut thickness

Coating
Biodegradable Polymer



PLA + PLGA
Abluminal only
5 µm layer thickness
Complete degradation
in 6-9 months

Drug
Sirolimus



Low dose

Inspiron™
3.5 x 13 mm


56 µg

Cypher™
3.5 x 13 mm


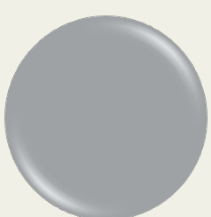
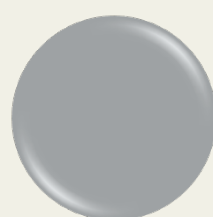
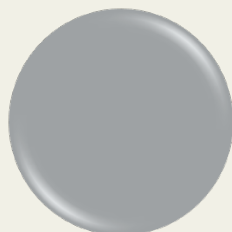


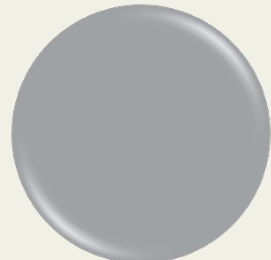
129 µg

Overview of current stent designs

Strut and coating thickness in perspective

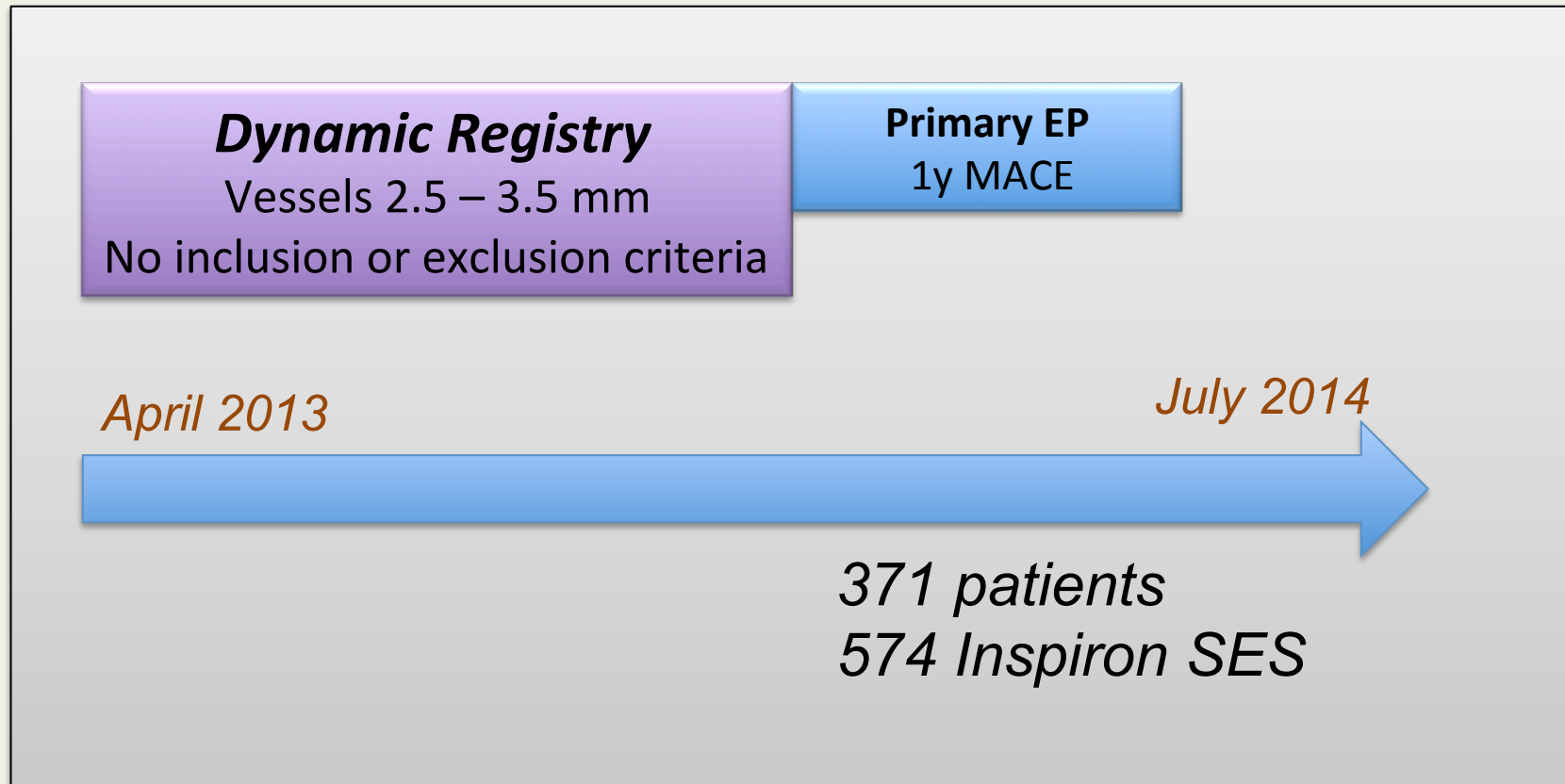
Durable Polymer Coated Stent		Bioabsorbable Polymer Coated Stent					Bioabsorbable Scaffold
Abbott/Boston	Medtronic	BIOSENSORS	Terumo	Boston	Scitech	BIOTRONIK	Abbott
Xience/ Promus¹	Resolute¹	BioMatrix¹	Ultimaster¹	Synergy¹	Inspiron	Orsiro¹	Absorb²
CoCr/PtCr-EES	CoNi-ZES	316L-BES	CoCr-SES	PtCr-EES	CoCr - SES	CoCr-SES	PLLA-EES
							
Strut thickness							
81 μm	91 μm	120 μm	80 μm	74 μm	75 μm	60 μm	150 μm
Polymer coating							
Circumferential 7-8 μm/side	Circumferential 6 μm/side	Abluminal 10 μm	Abluminal 15 μm	Abluminal 4 μm	Abluminal 5 μm	Circumferential 4-7 μm/side	Circumferential 3 μm/side

Overview of current generation stent crossing profiles

Durable Polymer Coated Stent			Bioabsorbable Polymer Coated Stent			Bioabsorbable Scaffold
Abbott	Boston Scientific	Medtronic	BIOSENSORS	BIOTRONIK	SCITECH	Abbott
Xience Xpedition 3.0/18 mm CoCr-EES	Promus Element 3.0/20 mm PtCr-EES	Resolute Integrity 3.0/18 mm CoNi-ZES	BioMatrix Flex 3.0/18 mm 316L-BES	Orsiro 3.0/18 mm CoCr-SES	Inspiron 3.0/19 mm CoCr-SES	Absorb 3.0 / 18 mm PLLA-EES
						
Crossing profile [mm]						
1.090	1.031	1.029	1.140	1.012	0.945	1.40

Inspiron Real Life Study

Study Design



Principal Investigator
P.I.: Pedro Lemos MD PhD

Inspiron Registry

- The study enrolled a complex population, with a large proportion of multivessel disease, diabetics, in-stent restenosis and bifurcation lesions, among other high-risk features.
- Patients were maintained in dual antiplatelet therapy for a minimum of 6 months and aspirin was prescribed indefinitely thereafter.

Inspiron Registry

Baseline Clinical Characteristics (n=371 pts)

Male	63.3
Age, years	62.9 ± 10.6
Diabetes	50.7
Insulin-requiring DM	14.6
Acute coronary syndrome	39.6
Multivessel disease	69.2
2-vessel CAD	35.8
3-vessel CAD	33.4
Heart failure	15.6
Previous coronary treatment	48.5
Previous PCI	39.6
Previous CABG	18.1

CABG = coronary artery bypass graft surgery; CAD = coronary artery disease; DM = diabetes mellitus; PCI = percutaneous coronary intervention

Inspiron Registry

Procedural Characteristics (n=371 patients; 574 Inspiron™ SES)

Bifurcation	36.4
In-stent restenosis	19.9
Lesion type B2 / C	83.8
Treated vessel	
Left main coronary	6.2
Left anterior descending	57.4
Left circumflex	33.2
Right coronary artery	27.8
Graft	3.5

Numbers are average \pm standard deviation or percentages at per patient level

Inspiron Registry

Procedural Characteristics (n=371 patients; 574 Inspiron™ SES)

Number of Inspiron SES	1.55 ± 0.74
Total number of stents*	1.68 ± 0.85
Direct stenting	28.6
Inspiron SES diameter, mm	2.96 ± 0.32
Inspiron SES summed length, mm	34.3 ± 17.2

*Additional stents were all BMS

Numbers are average ± standard deviation or percentages at per patient level

Inspiron Registry

Clinical Outcomes (n=371 pts; K-M estimates)

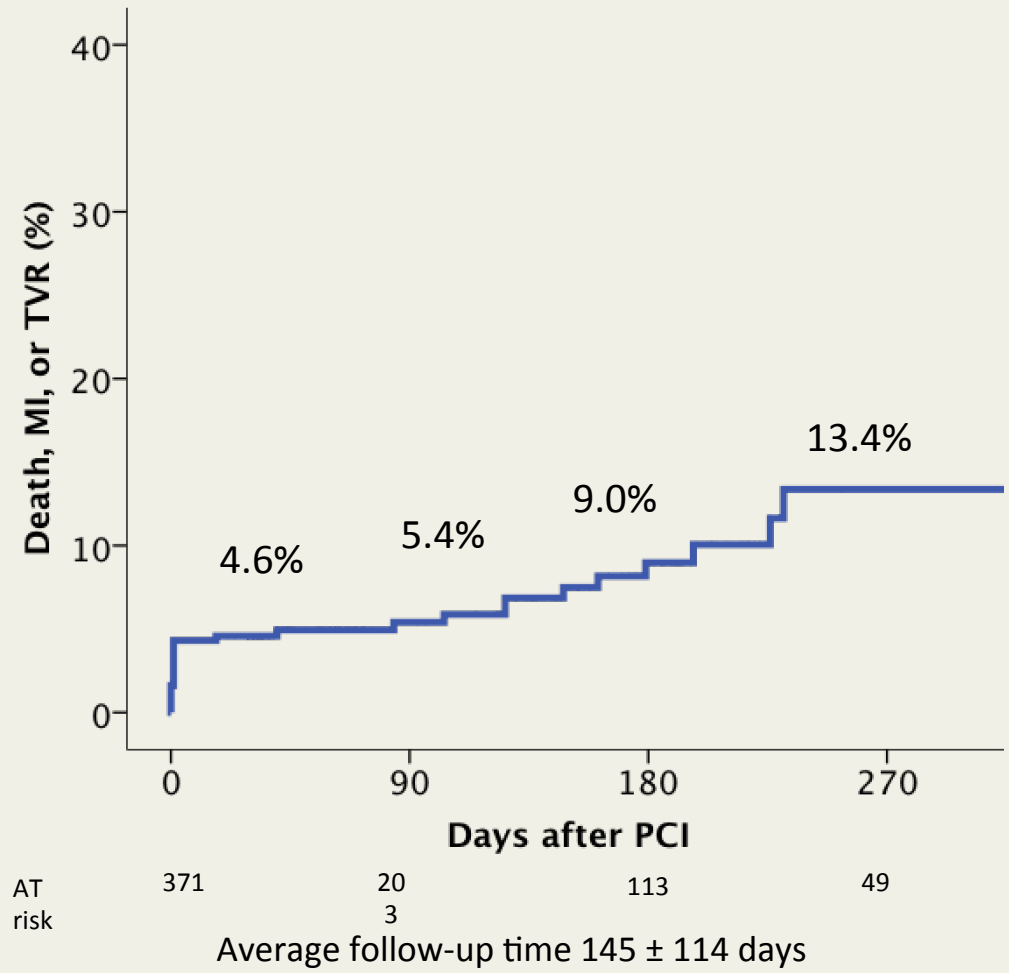
	30 days	180 days
Overall death	0.8	1.6
Myocardial infarction		
Peri-procedural	4.0	-
Non-peri-procedural	0	1.3
Target vessel revascularization	0	2.8
Any major cardiac adverse event	4.6	9.0
Stent thrombosis	0.5	0.5
Possible	0	0
Probable	0.5	0.5
Definite	0	0

Average follow-up time 145 ± 114 days

Numbers are percentages

Inspiron Registry

Clinical Outcomes (n=371 pts; K-M estimates)



Conclusion

- Our findings demonstrate excellent short- and mid-term safety and efficacy results for the novel Inspiron™ sirolimus-eluting stent in the treatment of highly complex patients.