Inspiron Stent

Clinical Research Program

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All faculty disclosures are available on the CRF Events App and online at www.crf.org/tct

Potential conflicts of interest. In the last 36 months:

Institutional Research/Educational Grant
BSC
Cordis
Medtronic
Scitech

Medical Advisory Board
BSC
Medtronic
Scitech

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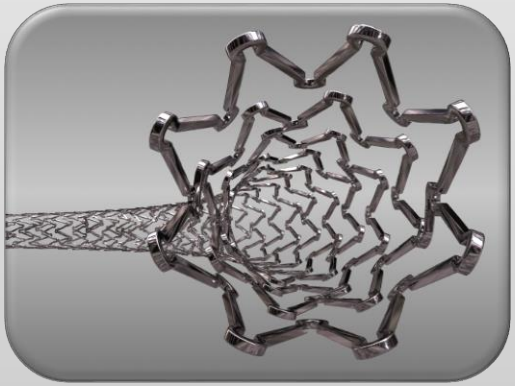
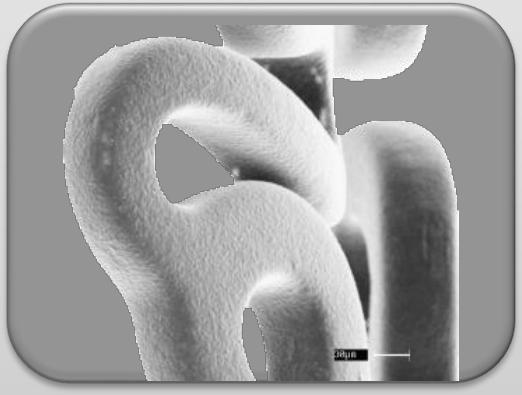
Inspiron™ Sirolimus-Eluting Stent

Thin-Strut Plataform
CoCr – L605



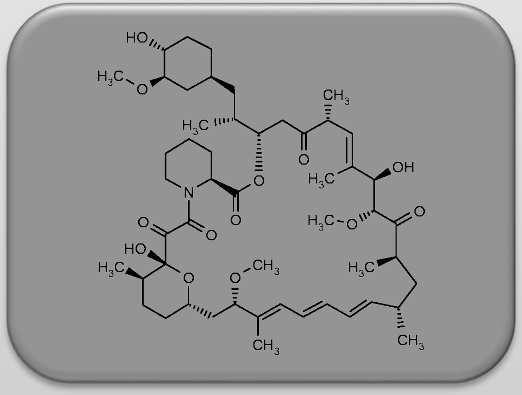
Cronus NE™
75 µm strut thickness

Abluminal Coating
Biodegradable Polymer



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

Low Drug
Sirolimus



Low dose

Inspiron™	**Cypher™**
3.5 x 13 mm	3.5 x 13 mm
56 µg	129 µg

Inspiron SES – Clinical Validation Program

- INSPIRON I
  - Randomized (Inspiron vs. BMS)
  - 2-year follow-up completed
- DESTINY
  - Non-inferiority
  - Randomized (Inspiron vs. Biomatrix)
  - 9-month primary EP completed
- INSPIRON Real Life Study
  - Dynamic registry

INSPIRON I Trial

Study Design (n=60 pts)

1 or 2 *de novo* lesions
2.5 mm to 3.5 mm
Treated with a single 16 or 19mm stent

Randomization 1:2
(Cronus BMS vs. Inspiron SES)

1EP: IS – Late Loss
at 6 months

5 years
Clinical FUP

Angiographic and IVUS Core Lab

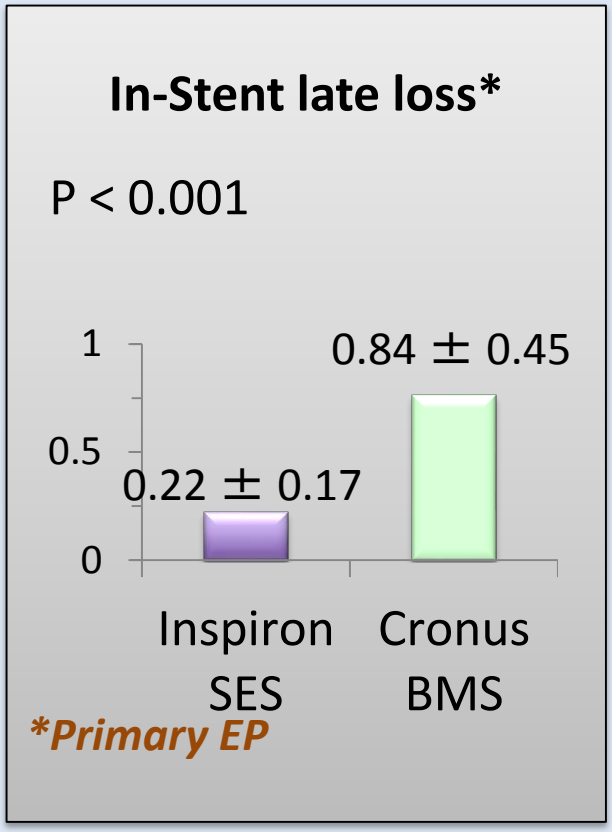
Clopidogrel 1 mo in BMS and 6 mos in DES group

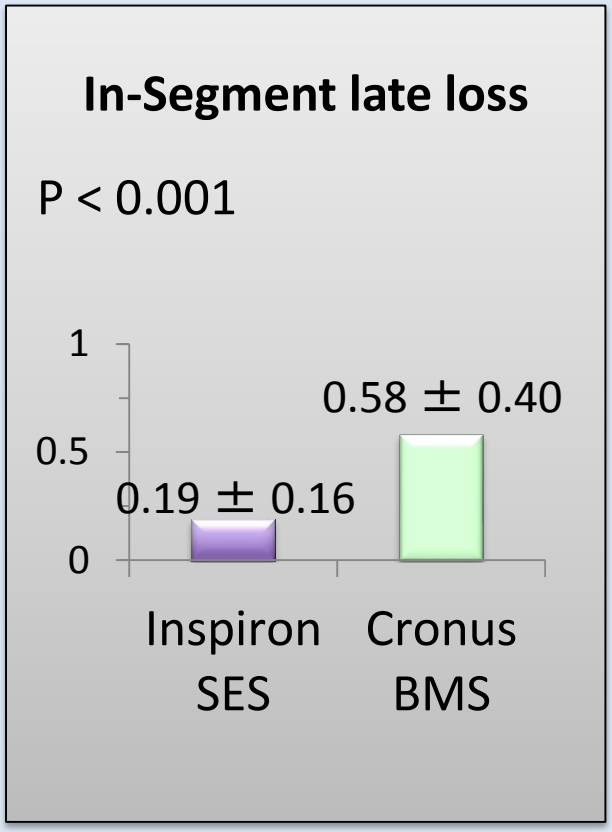
PI Expedito Ribeiro MD PhD

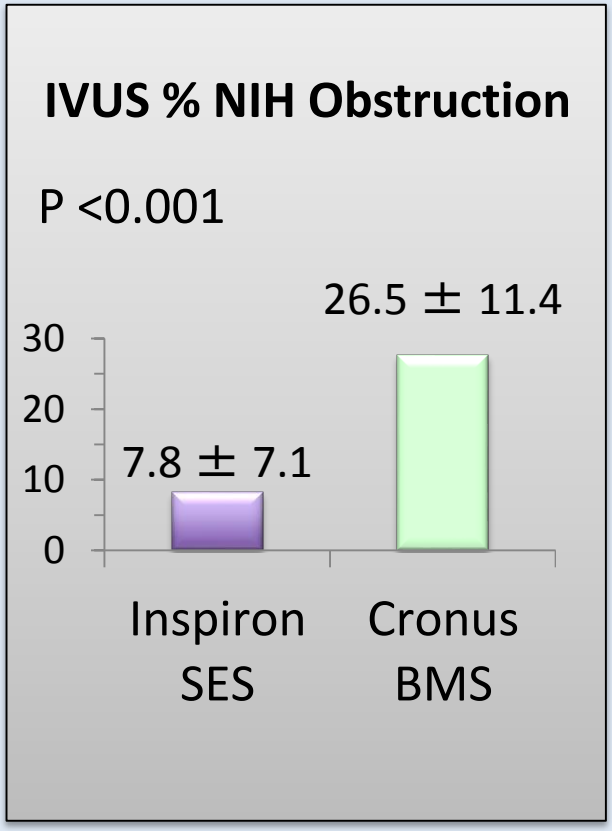
EuroIntervention 2014;9:1380-1384

INSPIRON I Trial

6-month angiographic and IVUS outcomes







EuroIntervention 2014;9:1380-1384

DESTINY Trial

Study Design (Multicenter in 10 Brazilian Institutions)

Primary EP
IS LL at 9 months
Non-inferiority

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

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])

PI: Pedro Lemos MD PhD
Angiographic, IVUS and OCT corelab: CRC

DESTINY Trial
Trial Organization

Steering Committee and Participating Centers

1. Pedro A. Lemos (InCor – SP. Chairman)
2. Alexandre Abizaid (IDPC – SP)
3. Expedito Ribeiro (InCor – SP)
4. Marco Perin (Sta Marcelina – SP)
5. Jose Mariani Jr. (Sta Casa SP – SP)
6. Costantino Costantini (H.C. Costantini – PR)
7. M. Cantarelli (H. Bandeirantes – SP)
8. Mauricio Prudente (ENCORE – GO)
9. Rogério Sarmento-Leite (IC – RS)
10. Adriano Dourado (Sta Casa BA – BA)
11. George Meireles (IAMSPE – SP)

1. **Contract Research Organization**
   - Cardiovascular Research Center (Sao Paulo-SP)
2. **Angiographic, IVUS & OCT Core Laboratory**
   - Cardiovascular Research Center (Sao Paulo-SP)
3. **Study Coordinator**
   - Maria Auxiliadora Ferraz RN
4. **Database Management and Statistical Analysis**
   - Coreware (São Paulo – SP)
5. **Independent Adjudication Committee**
   - J. A. Mangione (RBBP – SP. Chairman)
6. **Independent Data Safety and Monitoring Board**
   - J. C. Nicolau (InCor – SP. Chairman)
7. **Study sponsor**
   - Scitech, Goiania, Brazil

DESTINY Trial

Main baseline and procedural characteristics

	Inspiron (N= 114 pts; 132 les)	*Biomatrix Flex* (N= 56 pts; 62/les)	*P-Value*
Age, years	59.9 ± 9.4	59.9 ± 9.8	>0.9
Male	57.9	48.2	0.2
Hypertension	86.0	82.1	0.5
Diabetes Mellitus	36.6	36.4	>0.9
Insulin dependent	7.9	8.9	>0.9
Current smoker	18.4	25.0	0.3
Prior MI	45.1	41.1	0.6
Prior PCI	17.5	8.9	0.1
Prior CABG	3.5	1.8	>0.9
Stable CAD	60.5	57.1	0.7
Target vessel LAD	45.5	43.5	0.8
Post-dilatation	81.1	85.5	0.5

DESTINY Trial

9-month QCA

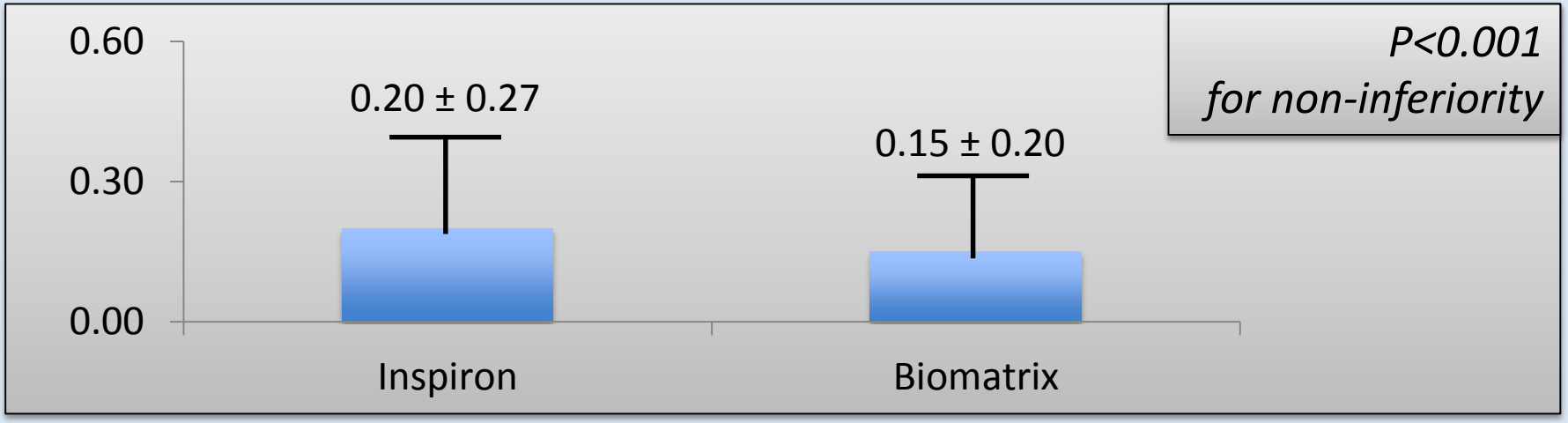
	Inspiron *(n= 132 les)*	*Biomatrix Flex* *(n= 62 les)*	*P-Value*
In-stent			
MLD, mm	2.44 ± 0.44	2.55 ± 0.40	0.1
DS, %	11.2 ± 11.3	9.7 ± 6.6	0.3
Late loss, mm*	0.20 ± 0.27	0.15 ± 0.20	0.1
Binary restenosis	3.2	1.7	0.6
In-segment			
MLD, mm	2.33 ± 0.44	2.43 ± 0.45	0.2
DS, %	17.1 ± 10.5	14.9 ± 8.1	0.2
Late loss, mm	0.17 ± 0.28	0.14 ± 0.21	0.4
Binary restenosis	3.2	3.3	>0.9

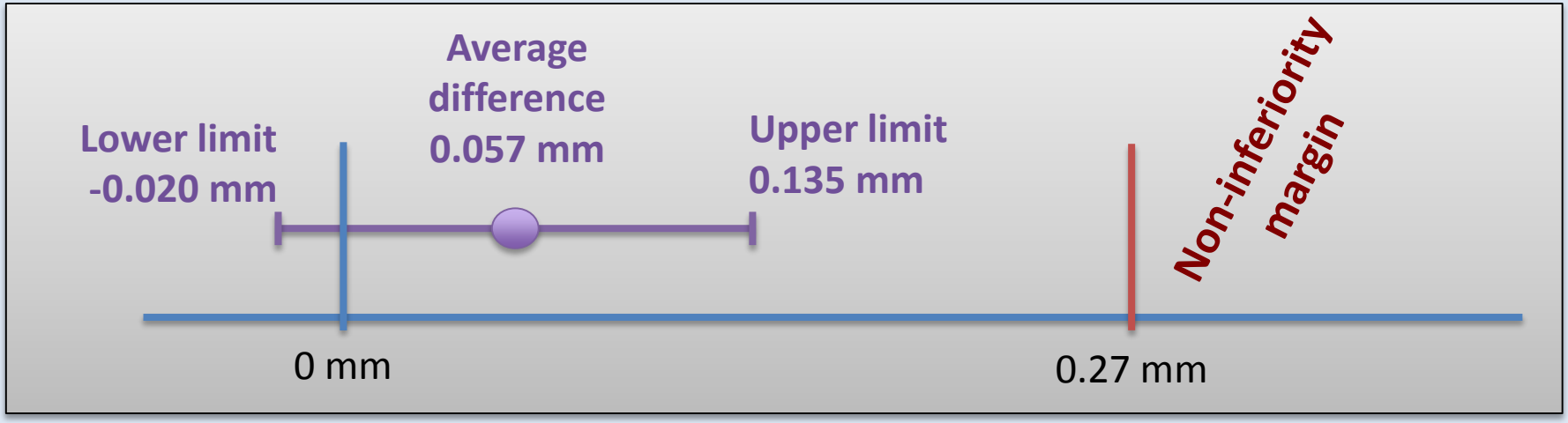
*Study primary end-point

DESTINY Trial

Primary Endpoint – In-stent Lumen Loss

Non-Inferiority Analysis

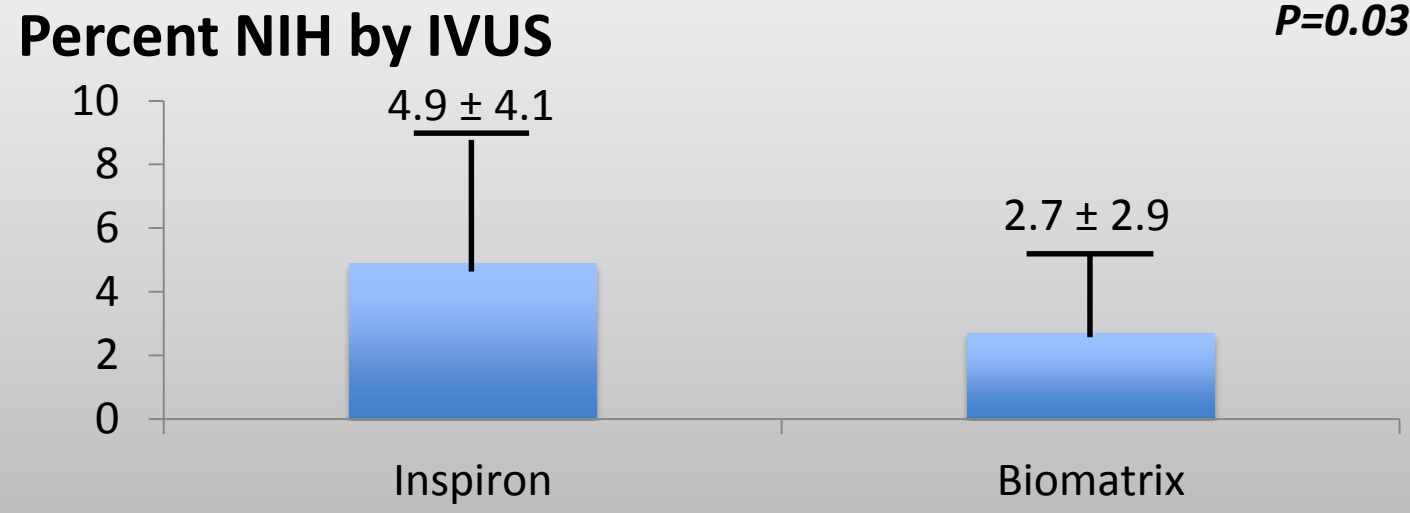




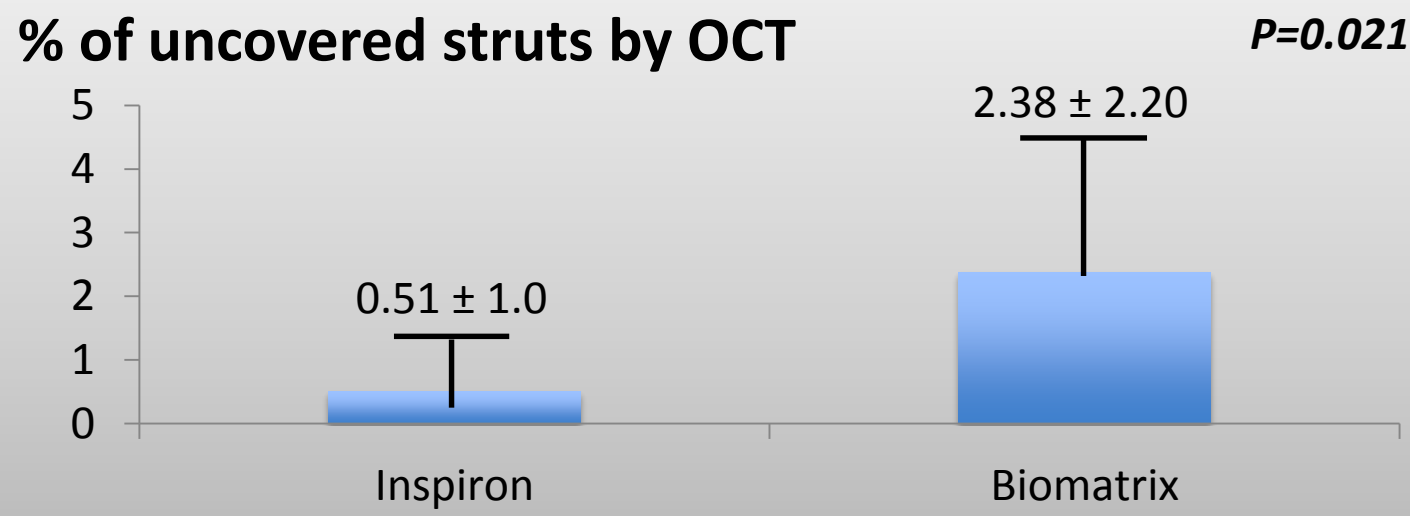
DESTINY Trial

Main IVUS and OCT findings

9-month IVUS
(n=86)



9-month OCT
Strut Level
(n=8,944)



DESTINY Trial

Clinical adverse events (up to 270 days)

	Inspiron *(n= 111 pts)*	*Biomatrix Flex* *(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
TLR / TVR	5.4	1.8	0.7
MACCE	6.3	7.3	0.7
MACE	6.3	7.3	0.7
Stent thrombosis	0	0	-

Inspiron Real Life Study

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 → *Jul 2014*

371 patients

Inspiron Real-Life Registry

Important Baseline & Procedural Characteristics (n=371 pts; 574 Inspiron™ SES)

Diabetes	50.7 %
Insulin-requiring DM	14.6 %
Multivessel disease	69.2 %
3-vessel CAD	33.4 %
Heart failure	15.6 %
Previous CAD treatment (PCI and/or CABG)	48.5 %
Bifurcation	36.4 %
In-stent restenosis	19.9 %
Lesion type B2 / C	83.8 %
Number of Inspiron SES	1.6 ± 0.7
Inspiron SES summed length	34.3 ± 17.2 mm

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

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

In summary,

- The Inspiron™ is a new formulation of low-dose SES, abluminally coated with a thin layer of biodegradable polymers that has shown efficacy in reducing neointimal growth compared to BMS.
- Results of the DESTINY RCT have shown non-inferiority of Inspiron™ SES compared to Biomatrix™ BES.
- IVUS and OCT substudies from DESTINY demonstrate that the Inspiron™ stent has slightly higher NIH growth associated with a slightly higher strut coverage, compared to Biomatrix™.
- In clinical practice, the Inspiron™ has shown excellent mid-term safety and efficacy profile for the treatment of highly complex patients.