

Cre8™ EVO

AMPHILIMUS™ ELUTING CORONARY SYSTEM ON RX BALLOON CATHETER

Manufacturing Company	CID S.p.A. 13040 Saluggia VC - Italy
CE Mark released by	NB 0373
Shelf life	24 months

Stent Technical Characteristics

Stent type	Balloon expandable stent
Material	L605 (Cobalt-Chromium alloy)
Permanent Coating	Bio Inducer Surface (<i>i</i> Carbofilm™) – integral and permanent pure carbon thin film impermeable to metallic ions responsible of possible allergic reaction (See additional information)
Ferromagnetism	MRI Conditional Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T) Maximum spatial field gradient of 2,890 G/cm (28.90 T/m) MR system reported, whole body averaged SAR: 1.5 T = 2.9 W/kg; 3 T = 2.9 W/kg
Visibility	Two Platinum markers at stent edges
Stent Design	Multicellular architecture, laser micromachined tube
Drug	Amphilimus™ Formulation: Sirolimus + fatty acid, placed in abluminal reservoirs
Specific Dose	0.9 µg/mm ²
Drug release system	The drug is released from reservoirs placed on the external surface of the stent, in direct contact with the vessel wall
Polymer Free	Yes
Strut Thickness	70 µm (diameter 2.00 – 2.25 mm) 80 µm (diameters from 2.50 to 4.50)
Metal to artery ratio [%]	~18%
Foreshortening upon expansion [%]	0
Elastic Recoil [%]	~3%
Stent Crimping	“Clasp Care Crimping +” (Proprietary process)

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Delivery System

Catheter Design	Rapid exchange (RX) catheter
Catheter Length	142 cm
Compatibility	
Guidewire	0.014"
Guiding Catheter	5 F
Proximal Shaft	
Material	Stainless Steel Hypotube PTFE coated
Diameter	0.63 mm (1.9 French)
Length	114 cm
Brachial and Femoral Markers	90 and 100 cm
Distal Shaft	
Material	Polyamide
Diameter	0.89 mm (2.7 French)
Length	28 cm
Coating	Hydrophilic coating
Balloon Characteristics	
Tip Material	PEBA
Entry Profile	0.17"
Material	Polyamide
Nominal Pressure NP	9 atm
Rated Burst Pressure RBP	18 atm
Average Burst Pressure ABP	24 atm
Radiopaque markers	2 ring markers

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Stent Technical Specifications

Stent ø (mm)	Stent struts thickness (mm)	Stent crossing profile (mm/inches)
2.00	0.070	0.84 / 0.033
2.25	0.070	0.84 / 0.033
2.50	0.080	0.89 / 0.035
2.75	0.080	0.91 / 0.036
3.00	0.080	0.99 / 0.039
3.50	0.080	1.02 / 0.040
4.00	0.080	1.10 / 0.043
4.50	0.080	1.18 / 0.046

Stent model	Available stent diameters (mm)	Maximum Cell expansion for Side Branch Access* (mm)
3 cells mod.	2.00 - 2.25	2.75
3 cells	2.50 - 3.00	3.5
4 cells	3.50 - 4.50	4.0

*According to calculation based on cell perimeter

Stent model	Available stent diameters (mm)	Maximum tested stent diameter with maintained mechanical performance (mm)	Largest achievable stent diameter# (mm)
3 cells mod	2.00 - 2.25	3.05	3.20
3 cells	2.50 – 3.00	3.85	4.05
4 cells	3.50 - 4.50	5.05	5.50

#According to geometry

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COMPLIANT CHART

	Balloon diameter [mm]							
Pressure [atm]	2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50
6	1.85	2.08	2.31	2.54	2.77	3.26	3.74	4.15
7	1.89	2.13	2.37	2.61	2.85	3.35	3.84	4.27
8	1.95	2.19	2.43	2.68	2.93	3.43	3.92	4.38
9 NP	2.00	2.25	2.50	2.75	3.00	3.50	4.00	4.50
10	2.05	2.31	2.55	2.83	3.08	3.58	4.09	4.61
11	2.10	2.36	2.61	2.90	3.15	3.66	4.17	4.68
12	2.13	2.40	2.65	2.95	3.20	3.71	4.25	4.74
13	2.17	2.44	2.70	3.01	3.25	3.77	4.32	4.80
14	2.20	2.48	2.74	3.06	3.29	3.82	4.37	4.86
15	2.23	2.51	2.77	3.09	3.32	3.86	4.41	4.92
16	2.27	2.55	2.80	3.12	3.36	3.90	4.46	4.98
17	2.30	2.59	2.83	3.15	3.39	3.94	4.50	5.04
18 RBP	2.33	2.62	2.86	3.19	3.43	3.98	4.54	5.11
19	2.36	2.65	2.89	3.23	3.47	4.03	4.59	5.19
20	2.38	2.68	2.93	3.27	3.51	4.08	4.65	5.27
21	2.41	2.71	2.96	3.30	3.55	4.12	4.69	5.33
22	2.44	2.74	2.99	3.34	3.60	4.18	4.74	5.40

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ORDERING INFORMATION

	STENT LENTGH							
DIAMETER	9 mm	13 mm	16 mm	20 mm	26 mm	33 mm	40 mm	46mm
2.00 mm	ICLX20009	ICLX20013	ICLX20016	ICLX20020	ICLX20026	ICLX20033		
2.25 mm	ICLX22509	ICLX22513	ICLX22516	ICLX22520	ICLX22526	ICLX22533	ICLX22540	-
2.5 mm	ICLX2509	ICLX2513	ICLX2516	ICLX2520	ICLX2626	ICLX2533	ICLX2540	ICLX2546
2.75 mm	ICLX27509	ICLX27513	ICLX27516	ICLX27520	ICLX27526	ICLX27533	ICLX27540	ICLX27546
3.0 mm	ICLX3009	ICLX3013	ICLX3016	ICLX3020	ICLX3026	ICLX3033	ICLX3040	ICLX3046
3.5 mm	ICLX3509	ICLX3513	ICLX3516	ICLX3520	ICLX3526	ICLX3533	ICLX3540	ICLX3546
4.0 mm	ICLX4009	ICLX4013	ICLX4016	ICLX4020	ICLX4026	ICLX4033		-
4.5 mm	-	ICLX4513	ICLX4516	ICLX4520	ICLX4526	ICLX4533	-	-

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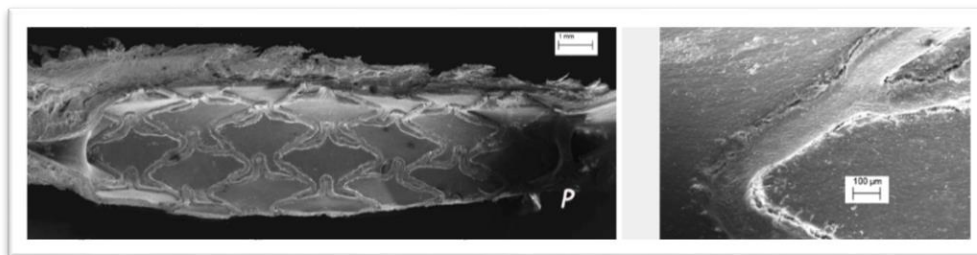
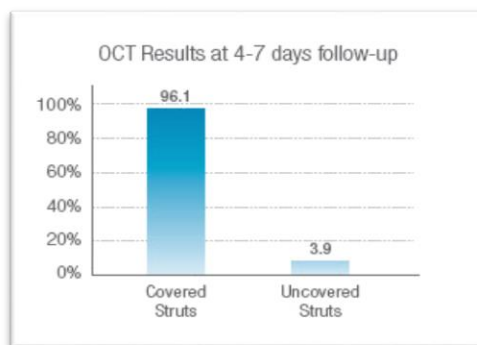
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ADDITIONAL INFORMATION

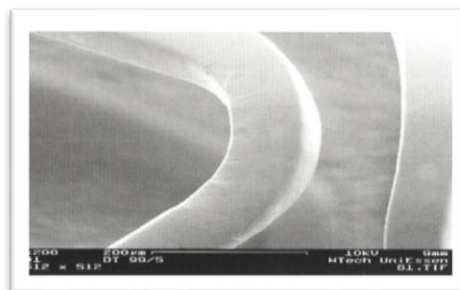
Bio Inducer Surface (*i* Carbofilm™), commercially known as BIS, is Alvimedica 2nd generation pure carbon coating with a crystalline structure extremely close to diamond.

Thanks to an extremely good bio & haemo compatibility, the clinical benefits of the Bio Inducer Surface are:

- 1) Reduced thrombogenicity & reduced inflammatory trigger (through accelerated endothelialization).
In the On-Guarde Study (STEMI patients), an OCT study presented by Prof. Prati at Euro PCR 2010, the Bio Inducer Surface has shown excellent results in terms of stent endothelialization and struts coverage in CID BMS platform – Avantgarde.



- 2) Reduced inflammatory process (effective barrier versus heavy metal ions release).
Results after immersion in Ringer's solution for 3 months of dilated stents (coated with CID pure carbon coatings) have demonstrated that BIS is impermeable to metallic ions responsible of possible allergic reaction.



- 3) Reduced foreign body reaction (inert physical / chemical surface)
Excellent in-stent Late Lumen Loss results have been obtained with all the CID stents coated with pure carbon coatings stating that the foreign body reaction (directly connected to neo-intima thickness) is highly reduced.

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