CRE8™

AMPHILIMUS ™ ELUTING CORONARY SYSTEM ON RX BALLOON CATHETER

Manufacturing Company	CID S.p.A. 13040 Saluggia VC - Italy
CE Mark	NB 0373
Shelf life	18 months

Stent Technical Characteristics

Stent type	Balloon expandable stent
Material	L605 (Cobalt-Chromium alloy)
Permanent Coating	*i* Carbofilm™ – integral and permanent pure carbon thin film impermeable to metallic ions responsible of possible allergic reaction
Ferromagnetism	MRI Conditional (static magnetic field of 3-Tesla or less, highest spatial gradient magnetic field of 720-Gauss/cm or less)
Visibility	Two Platinum markers at stent edge
Stent Design	Multicellular architecture, laser micromachined tube
Drug	Amphilimus™ Formulation: formulated Sirolimus with an organic acid, placed in reservoirs
Specific Dose	0,9 µg/mm^2
Drug release system	The drug is released from reservoirs placed on the external suface of the stent, in direct contact with vessel wall
Polymer Free	Yes
Strut Thickness [micron]	70 µm (2.25 mm) / 80 µm
Metal to artery ratio [%]	16÷19
Foreshortening upon expansion [%]	0
Elastic Recoil [%]	2÷7
Stent Crimping	“Clasp Care Crimping +” (Proprietary process)

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 “Comfort Coat™”
Balloon Characteristics	
Tip Material	Peba
Entry Profile	0.017”
Material	Polyamide
Nominal Pressure NP	9 atm
Rated Burst Pressure RBP	18 atm
Average Burst Pressure ABP	24 atm
Radiopaque markers	2 ring markers

Stent Technical Specifications

Stent ø (mm)	Stent struts thickness (mm)	Stent crossing profile (mm/inches)
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	Balloon ø	Diameter maximum circumference	Balloon ø	Diameter maximum circumference	Recommended maximum stent diameter
4 cells	2.25 mm	1.1 mm	2.62 mm	1.3 mm	2.55 mm
	2.5 mm	1.3 mm	2.86 mm	1.7 mm	3.05 mm
	2.75 mm	1.5 mm	3.19 mm	1.8 mm	
5 cells	3.0 mm	1.3 mm	3.43 mm	1.7 mm	3.85 mm
	3.5 mm	1.5 mm	3.98 mm	1.8 mm	
6 cells	4.0 mm	1.4 mm	4.54 mm	1.8 mm	5.05 mm
	4.5 mm	1.6 mm	5.11 mm	1.9 mm	
	Nominal Pressure (9 ATM)		**Rated Burst Pressure (18 ATM)**		

COMPLIANT CHART

	Balloon diameter [mm]						
Pressure [atm]	**2,25**	**2,50**	**2,75**	**3,00**	**3,50**	**4,00**	**4,50**
6	2,08	2,31	2,54	2,77	3,26	3,74	4,15
7	2,13	2,37	2,61	2,85	3,35	3,84	4,27
8	2,19	2,43	2,68	2,93	3,43	3,92	4,38
9 NP	*2,25*	*2,50*	*2,75*	*3,00*	*3,50*	*4,00*	*4,50*
10	2,31	2,55	2,83	3,08	3,58	4,09	4,61
11	2,36	2,61	2,90	3,15	3,66	4,17	4,68
12	2,40	2,65	2,95	3,20	3,71	4,25	4,74
13	2,44	2,70	3,01	3,25	3,77	4,32	4,80
14	2,48	2,74	3,06	3,29	3,82	4,37	4,86
15	2,51	2,77	3,09	3,32	3,86	4,41	4,92
16	2,55	2,80	3,12	3,36	3,90	4,46	4,98
17	2,59	2,83	3,15	3,39	3,94	4,50	5,04
18 RBP	*2,62*	*2,86*	*3,19*	*3,43*	*3,98*	*4,54*	*5,11*
19	2,65	2,89	3,23	3,47	4,03	4,59	5,19
20	2,68	2,93	3,27	3,51	4,08	4,65	5,27
21	2,71	2,96	3,30	3,55	4,12	4,69	5,33
22	2,74	2,99	3,34	3,60	4,18	4,74	5,40

ORDERING INFORMATION

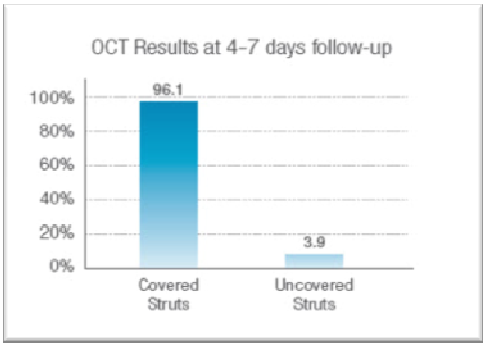
		STENT LENGTH						
NOMINAL STENT DIAMETER		**8 mm**	**12mm**	**16mm**	**20mm**	**25mm**	**31mm**	**38mm**
	2.25 mm	ICLI22508	ICLI22512	ICLI22516	ICLI22520	ICLI22525	ICLI22531	-
	2.5 mm	ICLI2508	ICLI2512	ICLI2516	ICLI2520	ICLI2525	ICLI2531	ICLI2538
	2.75 mm	ICLI27508	ICLI27512	ICLI27516	ICLI27520	ICLI27525	ICLI27531	ICLI27538
	3.0 mm	ICLI3008	ICLI3012	ICLI3016	ICLI3020	ICLI3025	ICLI3031	ICLI3038
	3.5mm	ICLI3508	ICLI3512	ICLI3516	ICLI3520	ICLI3525	ICLI3531	ICLI3538
	4.0mm	ICLI4008	ICLI4012	ICLI4016	ICLI4020	ICLI4025	ICLI4031	ICLI4038
	4.5mm	-	ICLI4512	ICLI4516	ICLI4520	ICLI4525	ICLI4531	-

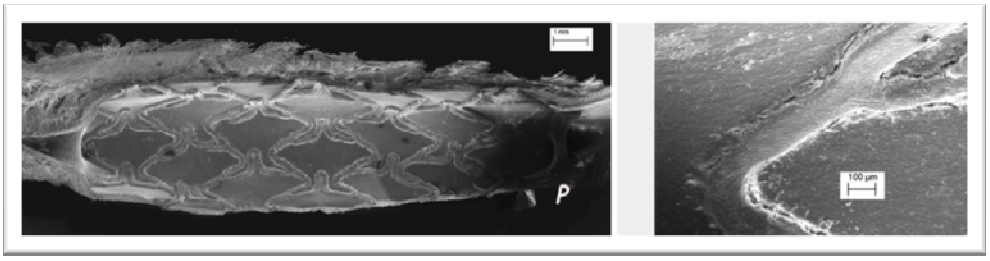
ADDITIONAL INFORMATION

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

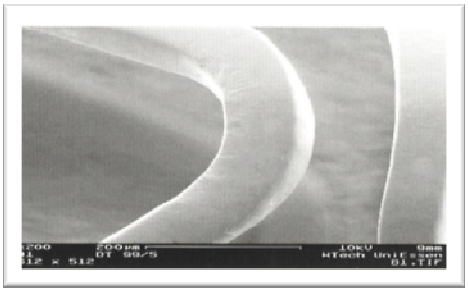
Thanks to an extremely good bio & haemo compatibility, the clinical benefits of the Bio Inducer Surface are:

1) Reduced thrombogenity & 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.