

CID

Carbostent & Implantable Devices



Adhere to patient care



OPTIMA
Tacrolimus eluting Carbostent

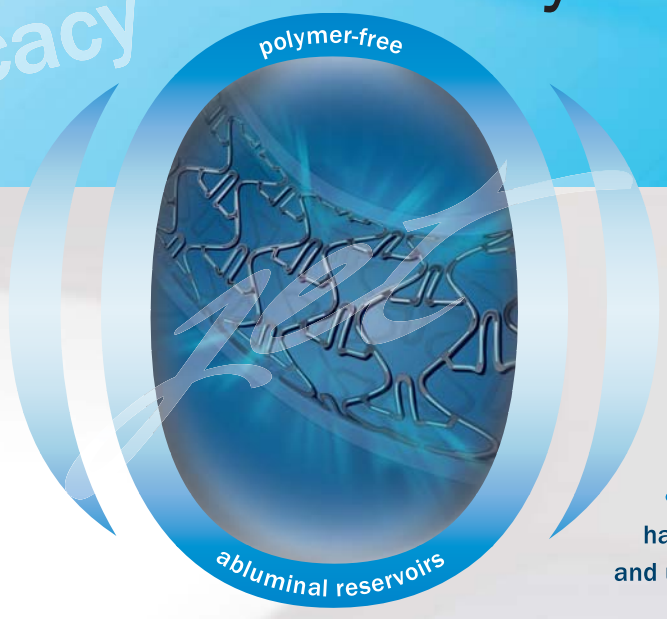


The most technologically simple solution to optimal safety and efficacy

Unique device technology

Proprietary Abluminal Reservoir Technology

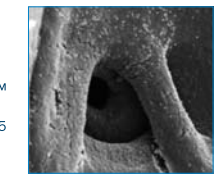
- Slow, controlled and complete (100%) elution of the drug
- Targeted drug release only towards the vessel wall
- Drug protected during stent delivery without additional profile to the stent strut



Years of experience

Carbofilm™: for over 30 years, Pyrolytic carbon (same chemical structure of Carbofilm™) is the only coating used in mechanical heart valves

- Stents coated with Carbofilm™ have shown fast endothelialization⁵ and unbeatable safety results¹

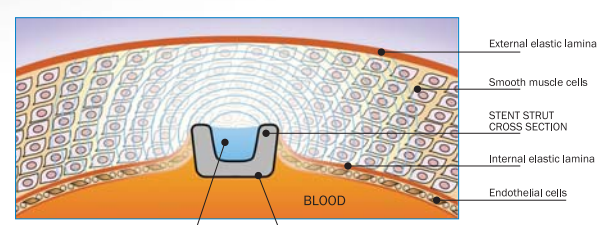


Endothelialization of Carbostent™ DES located over the ostium of a side branch⁹

Tacrolimus: a worldwide drug of reference in organ transplants³

- Tacrolimus has shown a selective action in reducing the proliferation of smooth muscle cells rather than endothelial cells⁴

Polymer-Free drug release

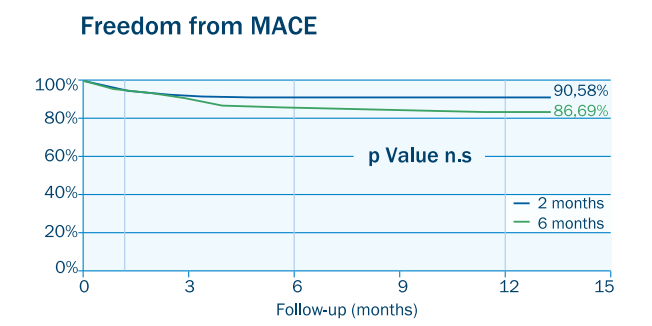


- Lack of inflammatory/thrombogenic components, thus eliminating the shortcomings often associated with polymers
- No drug or polymer in contact with the bloodstream
- The bio & haemo-compatible¹ Carbofilm™ coating is the only surface in contact with the blood and vessel wall

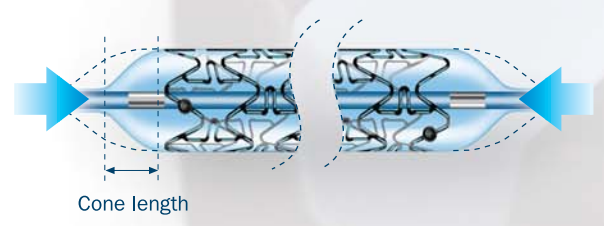
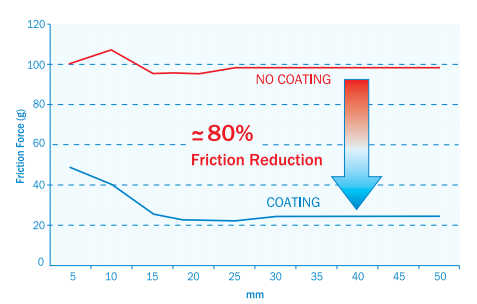
Clinical evidences

- 0% thrombosis rate⁶ at 24 months in randomized trial with all patients' DAT ≤ 6 months
- Matrix registry⁷ at 1 year highlights Carbostent™ DES safety and efficacy with 2 months of DAT regimen duration

	Months	190 Pts 2 Months DAT	382 Pts 6 Months DAT	Total %
Acute Thrombosis	1	0	1	0.17%
Sub-Acute Thrombosis	2	0	0	0%
Late Thrombosis (up to 6 months)	3			
	4	0	0	0%
	5			
	6			
	7			
Late Thrombosis (up to 12 months)	8			
	9	0	0	0%
	10			
	11			
	12			



A further step ahead in stent delivery system performance



- Friction-free hydrophilic coating² for a gold-standard performance in deliverability
- Extremely short balloon tapers for improved stent strut apposition

- The results obtained from Carbostent™ DES allow physicians to treat AF (Atrial Fibrillation) patients, that should benefit from DES efficacy, without increasing the risk of bleeding⁸
- Optima Carbostent™ is the only DES to allow 2 months DAT⁹

¹ Hurricane (Antoniucci et al; Cathet Cardiovasc Intervent 2001;54:420-426), Antares (Bartorelli et al; Cathet Cardiovasc Intervent 2002;55:150-156) and Safe (Bartorelli et al; Am J of Cardiol April 2007) studies
² ComfortCoat™ manufactured by DSM Biomedical
³ Prograf® - Immunosuppressant used to prevent rejection in organ transplants

⁴ C. Matter, T. Luscher - J Cardiovasc Pharmacol. 2006 Dec;48(6):286-92
⁵ Dr. Perez De Prado; Journal of Interventional Cardiology, June 2009
⁶ Prospective randomized clinical trial results at 24 months
⁷ MATRIX analysis presented during GISE09
⁸ ESC Guide lines - Thromb Haemost. 2010 Jan;103(1):13-28
⁹ Product IFU



Technical data

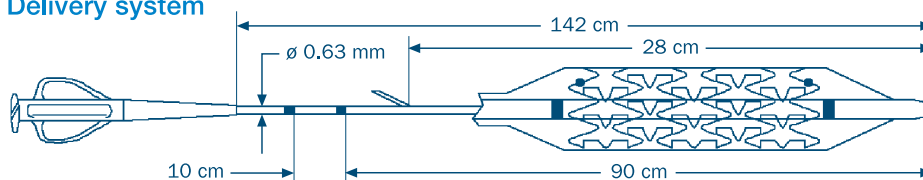
Coronary stent

- Stent material: Stainless steel AISI 316 LVM
- Slotted tube multicellular architecture with unique abluminal reservoirs for drug loading
- Integral turbostratic carbon coating (Carbofilm™)
- Polymer-free drug release device
- Strut thickness = 110µm
- Metal to artery ratio: 16-19%
- Recoil: 1-4%
- 2 radiopaque markers
- Negligible stent foreshortening upon expansion

Tacrolimus*

- Cytostatic immunosuppressive drug
- Highly lipophilic drug
- Specific dose by vessel treated equivalent to 2.3µg/mm²

Delivery system



Device specifications

- Guiding catheter compatibility: 5F (0.058")
- Nominal Pressure (NP): 8 ATM
- Rated Burst Pressure (RBP): 16 ATM
- Average Burst Pressure (ABP): 22 ATM



Ordering information

Size \ Length	12mm	15mm	19mm	25mm	31mm
2.5mm	ICV8605	ICV8606	ICV8607	ICV8608	-
2.75mm	ICV8609	ICV8610	ICV8611	ICV8612	-
3.0mm	ICV8613	ICV8614	ICV8615	ICV8616	ICV8617
3.5mm	ICV8618	ICV8619	ICV8620	ICV8621	ICV8622
4.0mm	ICV8623	ICV8624	ICV8625	ICV8626	ICV8627

Please contact your local sales representative for product availability

NOT FOR SALE IN USA AND JAPAN

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 Astellas Pharma Inc.



 Tacrolimus eluting CarboStent

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