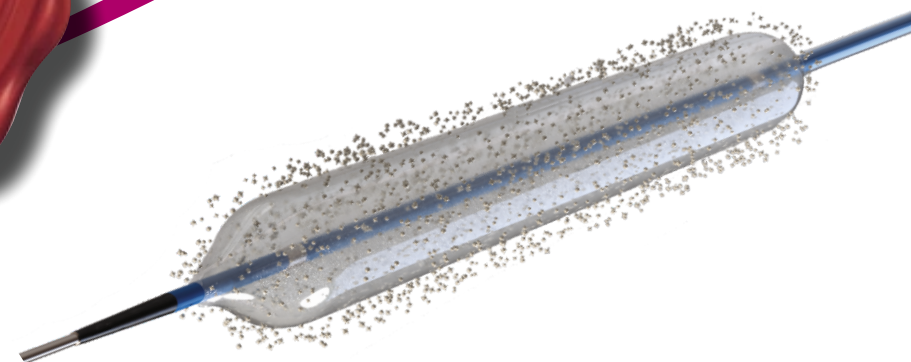


Protégé

Paclitaxel Coated Coronary
Balloon Dilatation Catheter



Taking **DCB Technology**
to a New High



Protégé

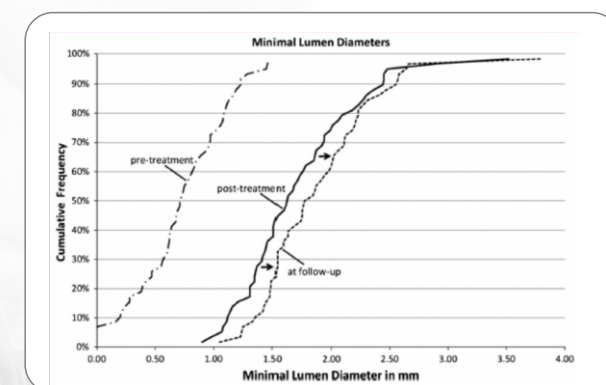
Paclitaxel Coated Coronary Balloon Dilatation Catheter

PACLITAXEL – Drug of Choice for DCB in Coronary Interventions with Large Clinical Evidence*

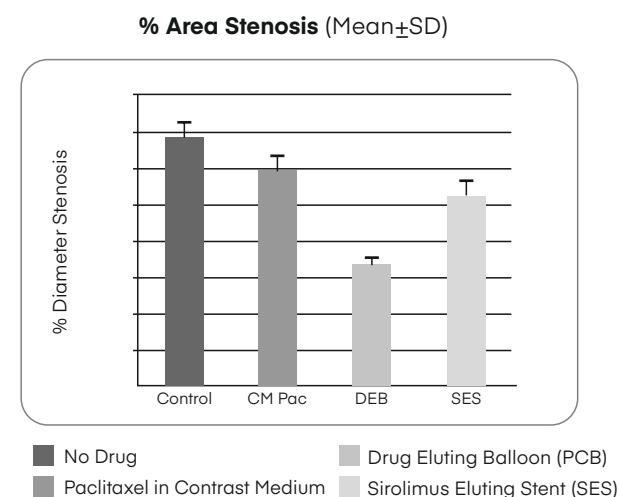


Paclitaxel proven more Efficacious than Limus as a choice of Drug in DCB

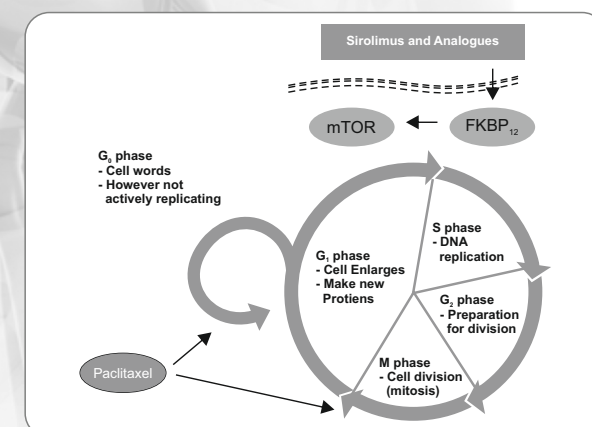
- Positive vessel remodeling with late lumen enlargement**



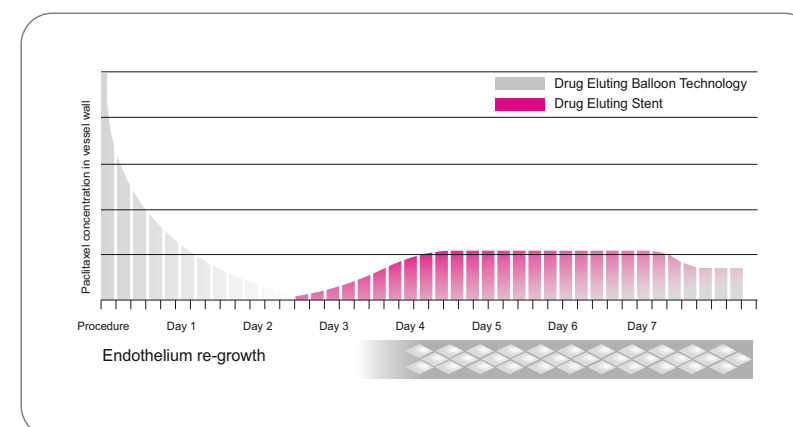
- Quicker vessel healing and faster reendothelialization***



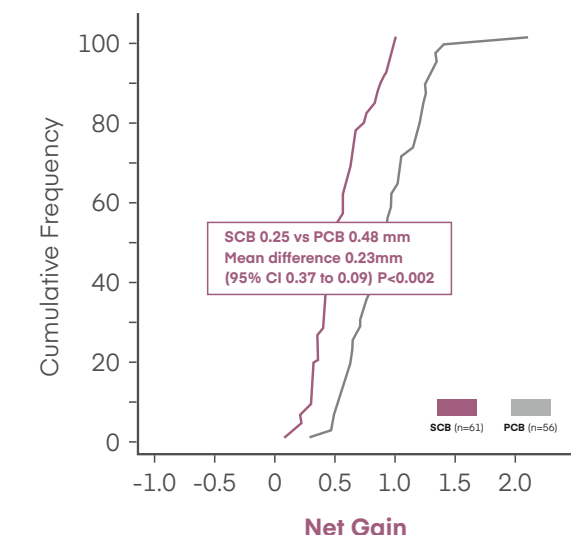
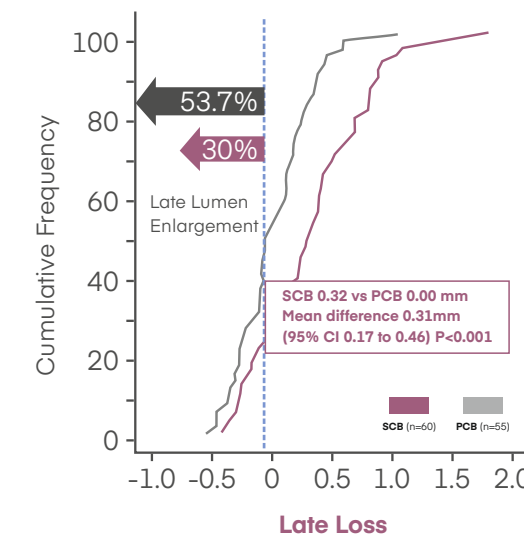
- Apoptotic effect of Paclitaxel reduces toxicity****



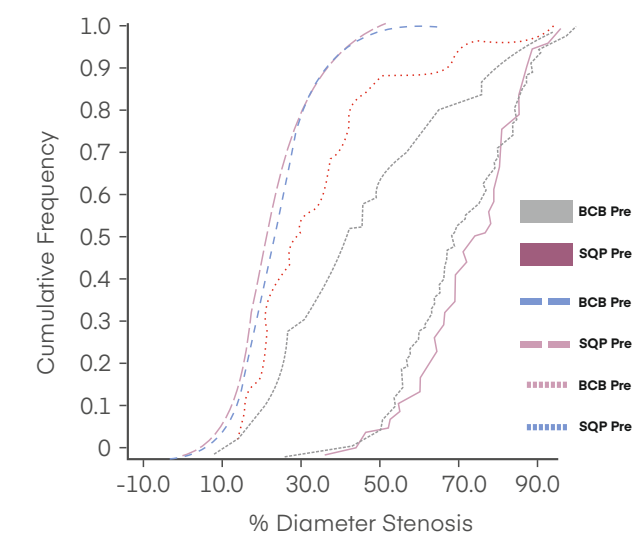
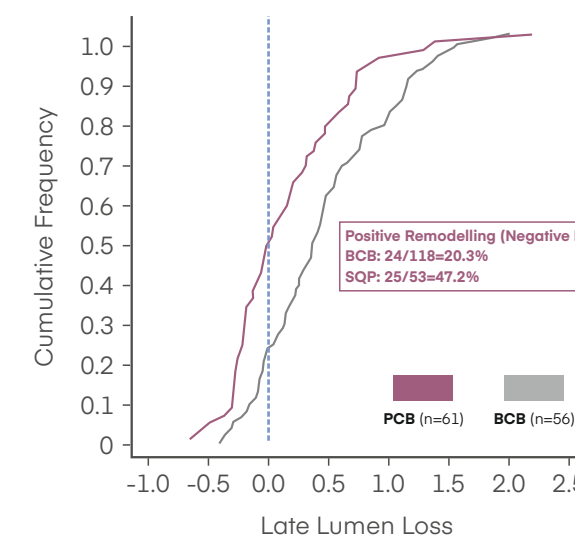
- Higher absorption into vessel wall



- Paclitaxel Coated Balloon (PCB) showed superiority over Sirolimus Coated Balloon (SCB) in a Randomized Controlled Trial*



- PCB demonstrated superior anti restenotic efficacy than Biolimus Coated Balloon (BCB)**



*European Heart Journal (2018)00, 1-23 Doi:10.1093/eurheartj/ehy394 **Clin Res Cardiol. 2015; 104: 217-25

***Speck, U., et al. (2006). "Neointima Inhibition: Comparison of Non-Stent-based Local Drug Delivery and a Drug-eluting Stent in Porcine Coronary Arteries." RSNA.

****Biotechnology and Bioprocess Engineering 17: 912-924 (2012) DOI 10.1007/s12257-011-0571-z,

Scheller B, Vukadinovic D, Jeger R, et al. Survival After Coronary Revascularization With Paclitaxel-Coated Balloons. J Am Coll Cardiol. 2020;75(9):1017-1028.

*Ninomiya, K. et al. (2023). Sirolimus-Coated vs. Paclitaxel-Coated Balloon in Small Vessels. J Am Coll Cardiol Intv, 16(23), 2884-2896. doi:10.1016/j.jcin.2023.09.026

**Raynor, B. P. et al. (2023). Biolimus A9™ DCB for In-Stent Restenosis: REFORM Trial Design. Cardiovasc Revasc Med, 56, 75-81. doi:10.1016/j.carrev.2023.06.004

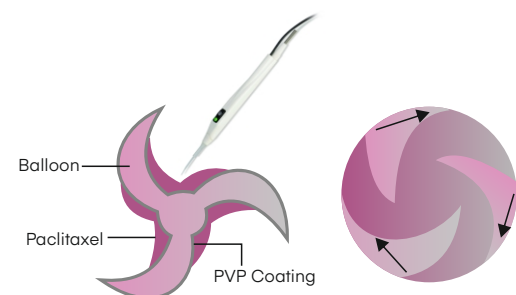
Protégé

Paclitaxel Coated Coronary Balloon Dilatation Catheter

UNIQUE DRUG APPLICATION

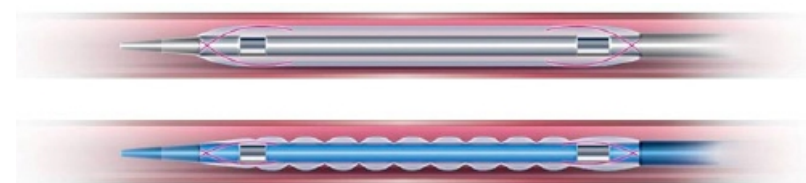


- During the production process the balloon material is inflated & folded



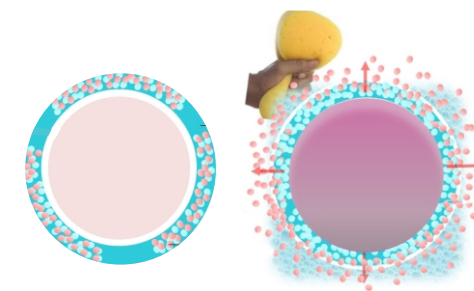
- Paclitaxel is applied within the folds of a PVP-coated (hydrophilic) balloon, reducing exposure and preventing loss prior to inflation

WING SEAL TECHNOLOGY



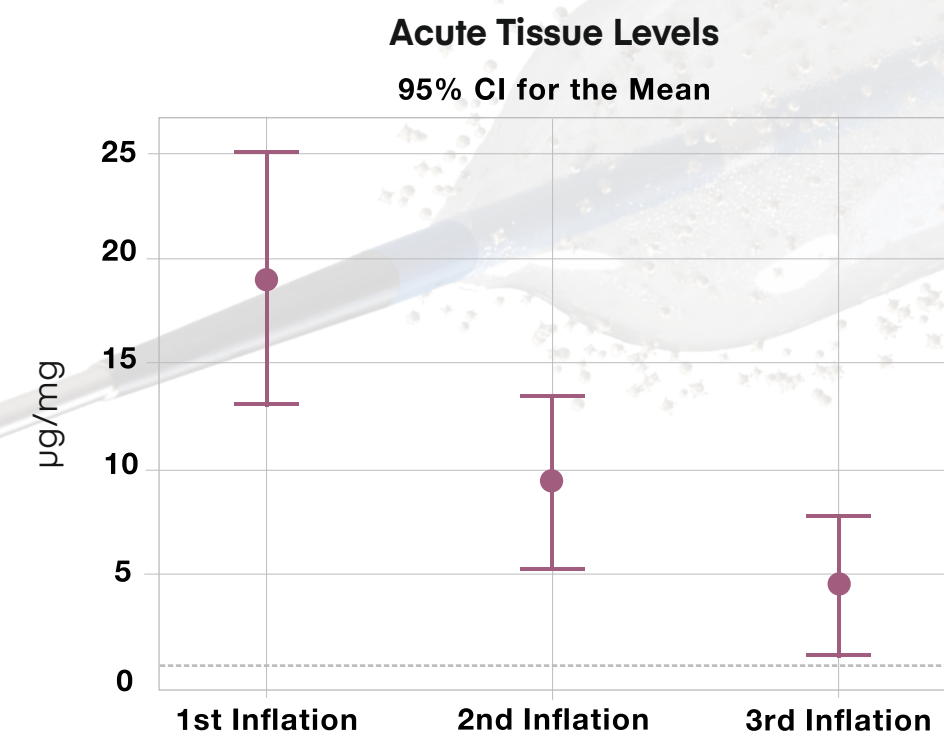
- **Protects the drug between the balloon folds** during advancement, resulting in negligible drug loss prior to inflation
- **The corrugation increases flexibility of the balloon** ensuring better trackability & crossability
- **Tight wrapping prevents the balloon unfolding** during advancement

DRUG RELEASE



- The coating acts as sponge which elutes the drug only when pressure is applied
- Paclitaxel is released from the coating after first inflation to the target vessel

M3i TECHNOLOGY



- **Multiple Drug Release***
Drug release up to 3 times with the same device when clinically indicated
- Interval Plot of Acute tissue levels of Paclitaxel over multiple inflations

Protégé

Paclitaxel Coated Coronary Balloon Dilatation Catheter

PEARL STUDY*

Proven safety and efficacy of the Protégé in real-world PCI of In-Stent Restenosis (ISR) and De Novo Lesions

>500
Complex Patient
Subset Including
ACS

- Highly Complex Lesion classified type C - **36%**
- Prior PCI - **86.4%**
- ISR DES - **60.4%**
- Diabetes - **28.3%**

Conclusions: at 2 Years Follow-Up

Protege Paclitaxel DCB is proven safe and effective in patients treated for ISR and De Novo Lesions

At 2 years MACE rates after DCB for De Novo Lesions was **9.7%** showing better efficacy and safety

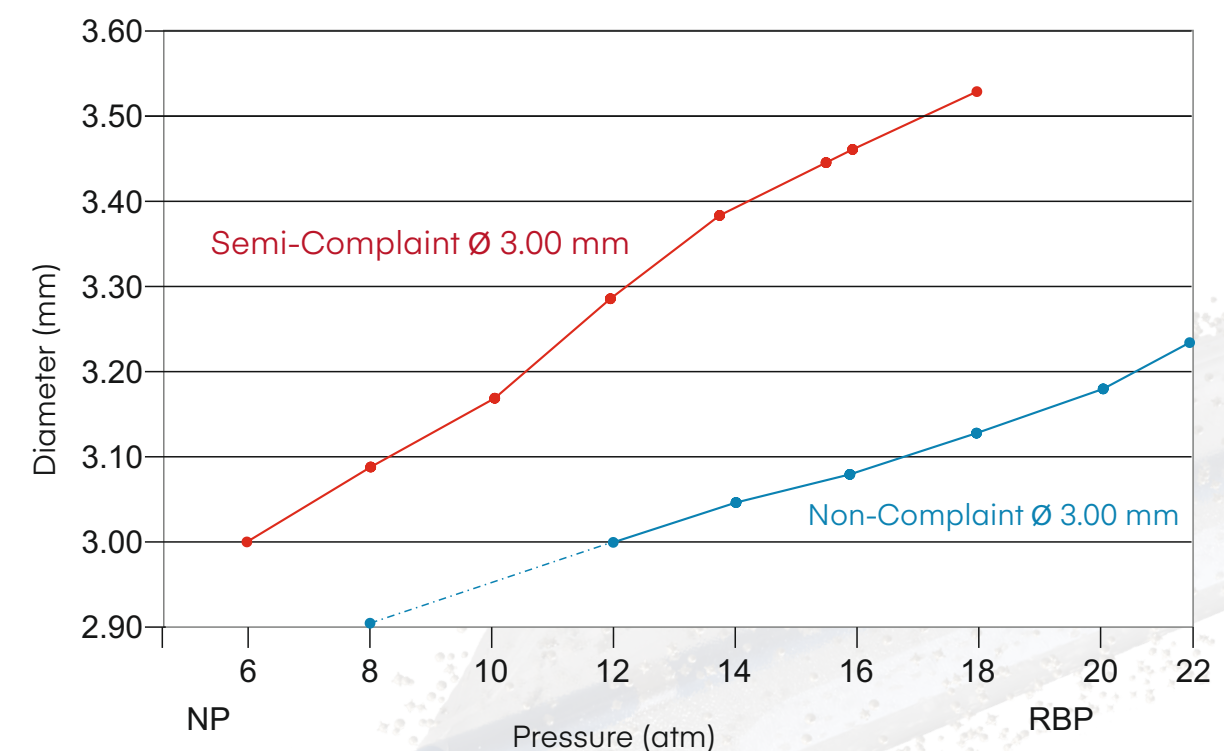
At 2 years MACE driven by TLR in patients treated for ISR was **(11.7%)** & for De Novo Lesions **(2.9%)** which is lower compared to the reported incidence rates in ISR patients (>15%)

*Cheng et al., 2022, J. Invasive Cardiol. 34(6) – Pearl Registry: Paclitaxel-coated balloon in PCI practice.

Protégé NC

Paclitaxel Coated Coronary Balloon Dilatation Catheter

- **World's Only** Non-Complaint Drug Coated Balloon Catheter
- Linear Expansion with no over growth at high pressure
- NC balloons minimize dissection in complex lesion subset compared to SC balloons*
- For the treatment of ISR and lesions difficult to dilate
- Higher strength than Semi-Compliant DCB**



*Desmet, W. J., De Scheerder, I. K., Barrios, L., & Piessens, J. H. (1997). Catheter Cardiovasc Diagn, 41(1), 5–11.
**Amstutz, C., Behr, J., Krebs, S., Haeberlin, A., Vogel, R., Zurbuchen, A., & Burge, J. (2023). BioMedical Engineering OnLine, 22(94)

SIZE CATHETER

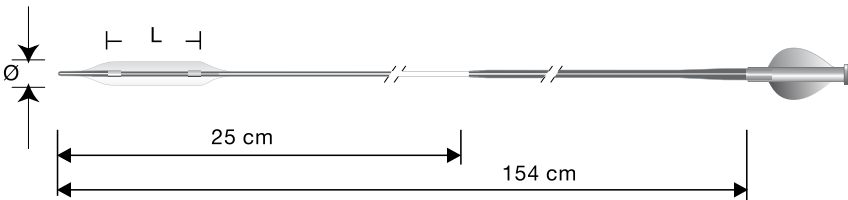
PROTÉGÉ - DCB CATHETER

L \ Ø	2.00	2.50	3.00	3.50	4.00
10	PRO2010	PRO2510	PRO3010	PRO3510	PRO4010
15	PRO2015	PRO2515	PRO3015	PRO3515	PRO4015
20	PRO2020	PRO2520	PRO3020	PRO3520	PRO4020
30	PRO2030	PRO2530	PRO3030	PRO3530	PRO4030

PROTÉGÉ NC - DCB CATHETER

L \ Ø	2.50	2.75	3.00	3.25	3.50	4.00	4.50
10	PNC2510	PNC2710	PNC3010	PNC3210	PNC3510	PNC4010	PNC4510
15	PNC2515	PNC2715	PNC3015	PNC3215	PNC3515	PNC4015	PNC4515
20	PNC2520	PNC2720	PNC3020	PNC3220	PNC3520	PNC4020	PNC4520

(Ø = Diameter, L = Length)



TECHNICAL SPECIFICATIONS

	PROTÉGÉ - DCB CATHETER	PROTÉGÉ NC - DCB CATHETER
Nominal Pressure	6 bar	12 bar
Rated Burst Pressure	16 bar (Ø 4,0= 13 bar)	Ø 2.50 - 2.75: 22 bar Ø 3.00 - 3.50: 20 bar Ø 4.00 - 4.50: 18 bar
Folding	3-folds WingSeal	3-folds WingSeal
Drug	Paclitaxel 3 µg/mm ² (drug loaded balloon surface)	Paclitaxel 3 µg/mm ² (drug loaded balloon surface)
Guiding catheter compatibility	5F	5F
Guide wire compatibility	0.014" (0.36mm)	0.014" (0.36mm)
Catheter type	Rapid Exchange	Rapid Exchange
Usable length	154 cm	154 cm
Catheter Coating	Hydrophilic coating	Hydrophilic coating