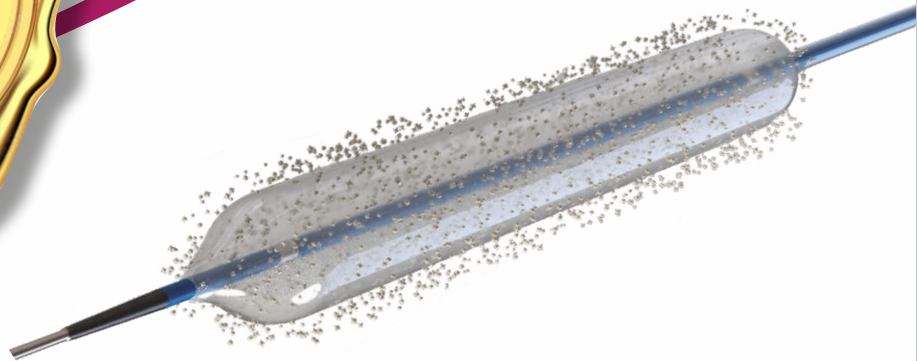


Protégé

Paclitaxel Coated Coronary
Balloon Dilatation Catheter



Taking **DCB Technology**
to a New High

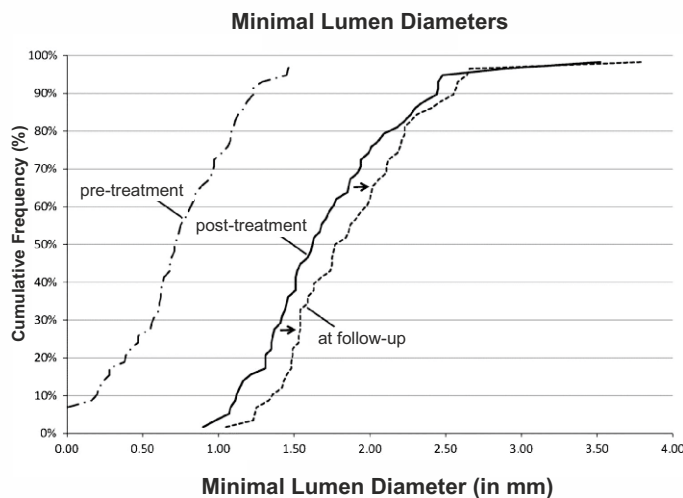
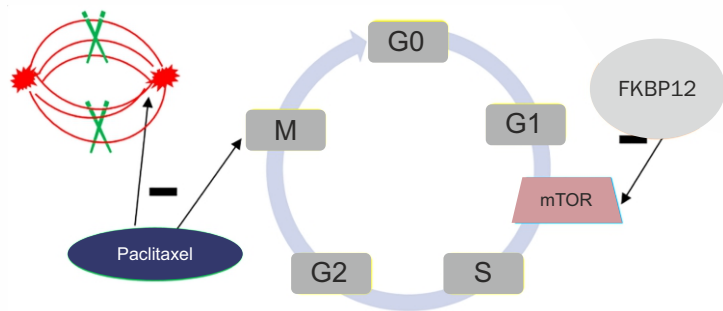
Protégé

Paclitaxel Coated Coronary Balloon Dilatation Catheter

PACLITAXEL

Drug of Choice for DCB in Coronary Interventions with Large Clinical Evidence¹

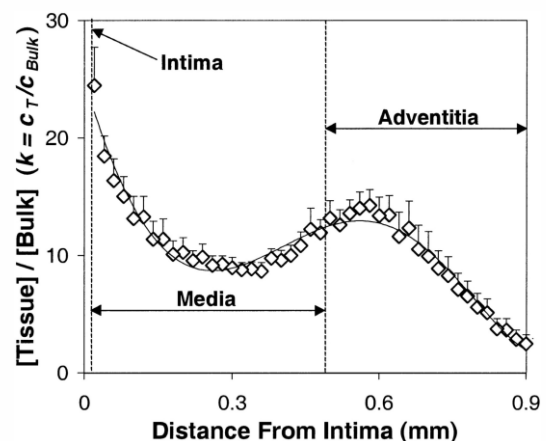
Apoptotic effect of Paclitaxel reduces toxicity²



(Paclitaxel-induced luminal changes following drug-coated balloon (DCB) angioplasty to treat coronary de novo lesions without additional stenting)

Positive vessel remodelling with late lumen enlargement³

Higher absorption into vessel wall⁴

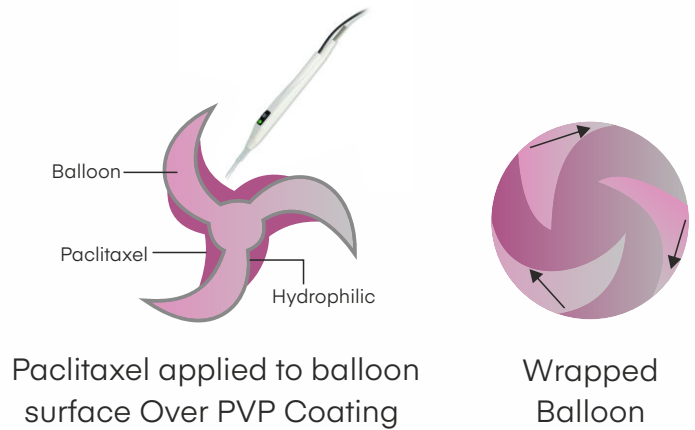


1. European Heart Journal (2018)00, 1-23 Doi:10.1093/eurheartj/ehy394 2. Rev. Cardiovasc. Med. 2021vol.22(4),1323-1330

3. Clin Res Cardiol (2015) 104:217-225 4. Circ Res. 2000;86:879-884

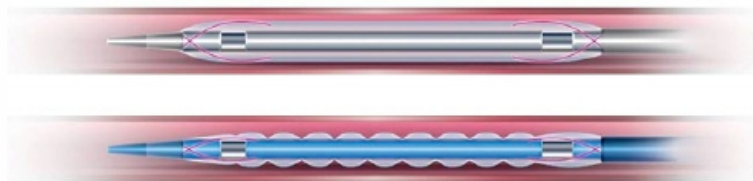
UNIQUE DRUG APPLICATION

Drug is applied through auto pipette technology with in the balloon folds ensuring minimum drug loss



WING SEAL TECHNOLOGY

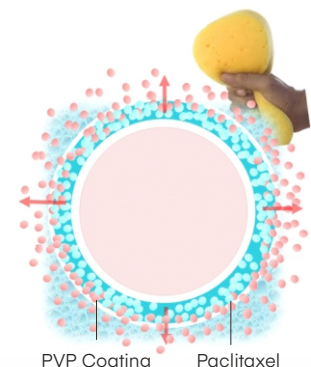
Wrapped balloon is crimped & then subjected to a process that creates corrugation



- Crimping prevents balloon unfolding during advancement and minimizes drug loss
- Surface corrugation creates low balloon profile for better flexibility & deliverability even in complex anatomy
- Corrugation reduces frictional abrasion during balloon advancement

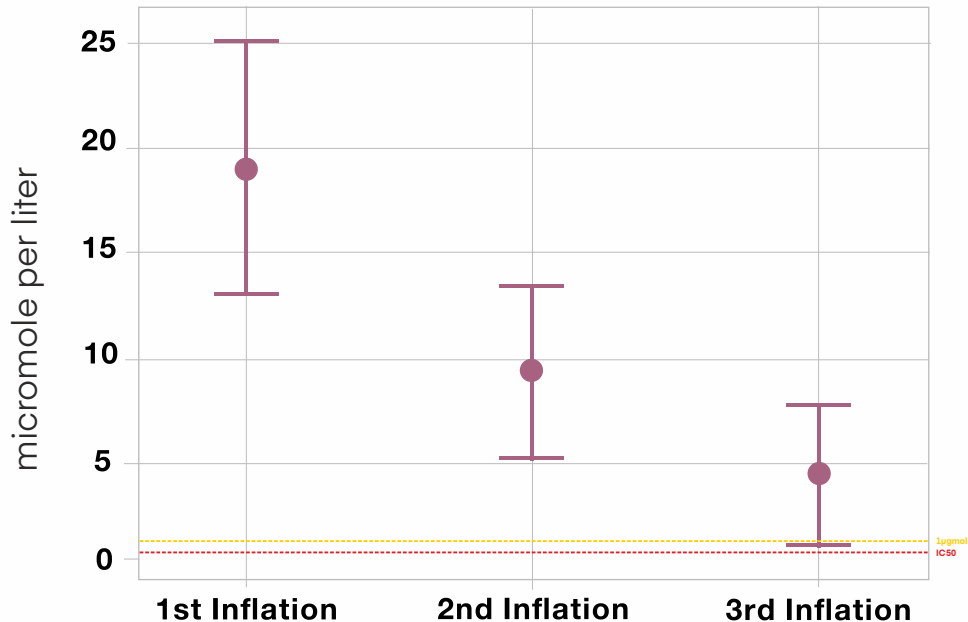
DRUG RELEASE

- 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



Acute Tissue Levels

95% CI for the Mean



Multiple Drug Release*

Multiple inflations were performed at a different location, the difference in tissue bound paclitaxel was found to be greater. This was attributed to diffusion characteristics.

3rd Inflation provides 1µmol/l of tissue bound paclitaxel which is minimal optimal dosage to as efficiently as possible inhibit the SMC's

*Data on File

Protégé NC

Paclitaxel Coated Coronary Balloon Dilatation 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)

Protégé

Paclitaxel Coated Coronary Balloon Dilatation Catheter

Proven safety and efficacy of the Protégé*

In real-world PCI of In-Stent Restenosis (ISR) and De Novo Lesions

>500

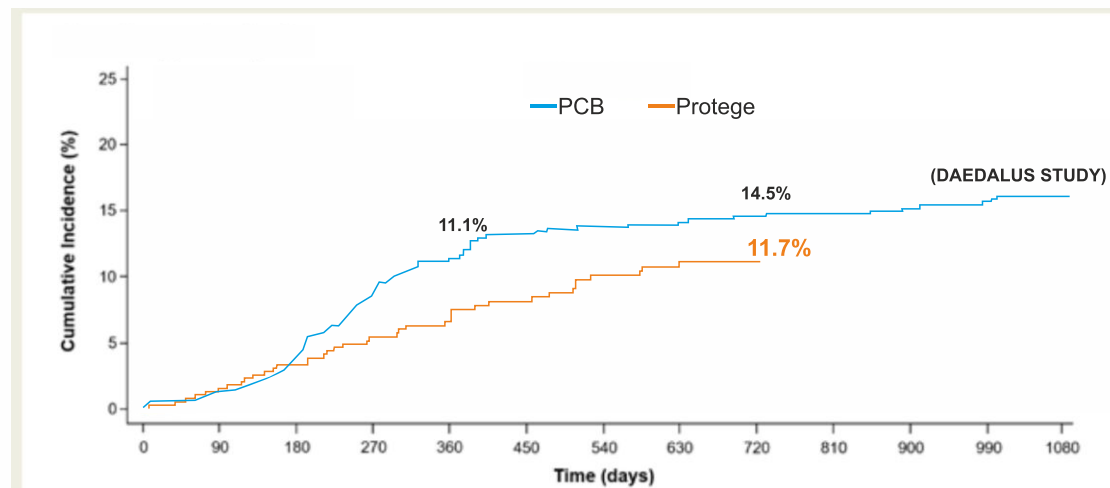
Complex Patient
Subset Including
ACS

➤ 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%)

SIZE CATHETER

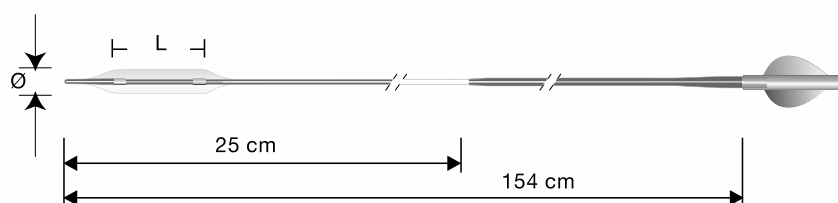
PROTÉGÉ - DCB CATHETER

$\begin{matrix} \diagup \\ L \end{matrix} \diagdown \emptyset$	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

$\begin{matrix} \diagup \\ L \end{matrix} \diagdown \emptyset$	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

($\emptyset$ = Diameter, L = Length)



TECHNICAL SPECIFICATIONS

PROTÉGÉ - DCB CATHETER

Nominal Pressure	6 bar
Rated Burst Pressure	16 bar ($\emptyset$ 4,0= 13 bar)
Folding	3-folds WingSeal
Drug	Paclitaxel 3 $\mu\text{g}/\text{mm}^2$ (drug loaded balloon surface)
Guiding catheter compatibility	5F
Guide wire compatibility	0.014" (0.36mm)
Catheter type	Rapid Exchange
Usable length	154 cm
Catheter Coating	Hydrophilic coating

PROTÉGÉ NC - DCB CATHETER

12 bar
$\emptyset$ 2.00 - 2.75: 22 bar $\emptyset$ 3.00 - 3.50: 20 bar $\emptyset$ 4.00 - 4.50: 18 bar
3-folds WingSeal
Paclitaxel 3 $\mu\text{g}/\text{mm}^2$ (drug loaded balloon surface)
5F
0.014" (0.36mm)
Rapid Exchange
154 cm
Hydrophilic coating

CE 2797

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