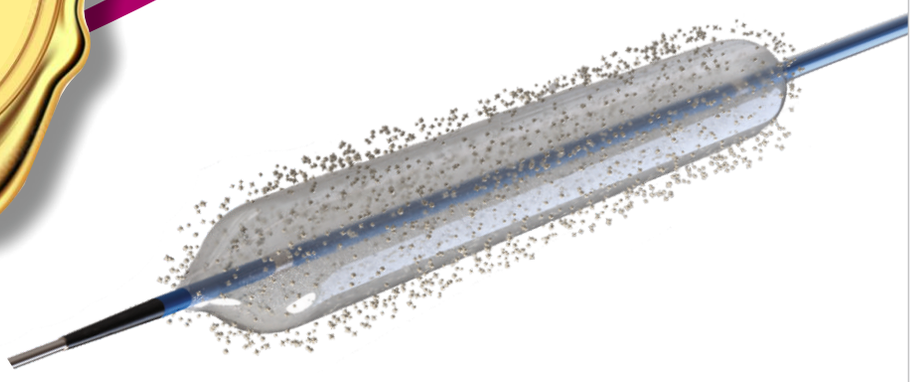
translumina
LIMITLESS POSSIBILITIES

Protégé

Paclitaxel Coated Coronary Balloon Dilatation Catheter

EU-MDR CERTIFIED



Taking **DCB Technology to a New High**

BLUEMEDICAL
A Translumina Group Company

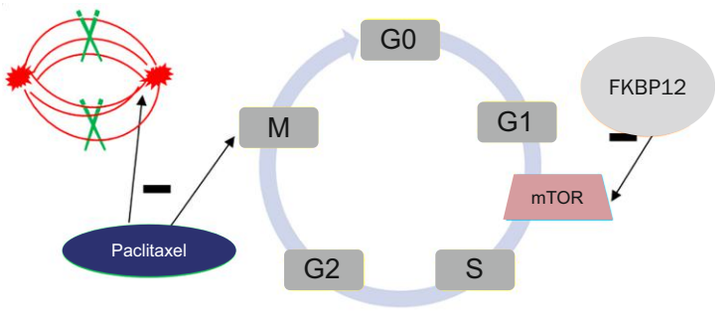
Protégé

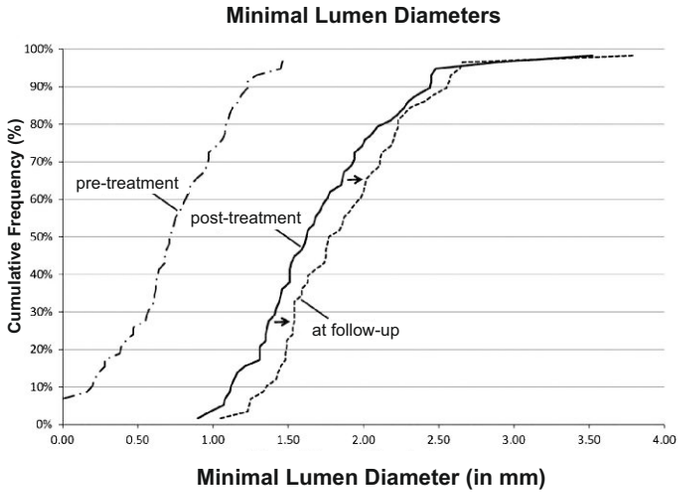
Paclitaxel Coated Coronary Balloon Dilatation Catheter

PACLITAXEL

Drug of Choice for DCB in Coronary Interventions with Large Clinical Evidence[1]

Apoptotic effect of Paclitaxel reduces toxicity[2]

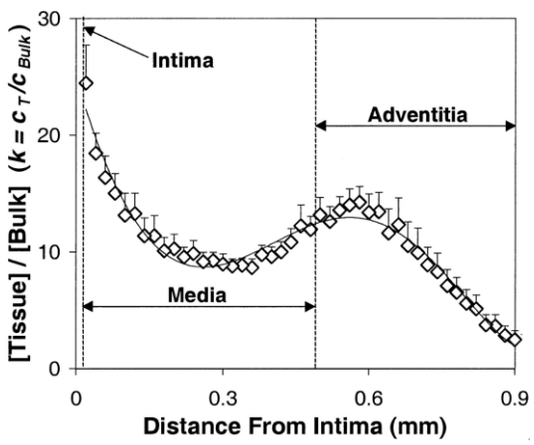




(Paclitaxel-induced luminal changes following drug-coated balloon (DCB) angioplasty to treat coronary de novo lesions without additional stenting)

Positive vessel remodelling with late lumen enlargement[3]

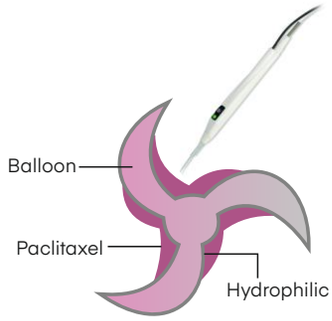
Higher absorption into vessel wall[4]



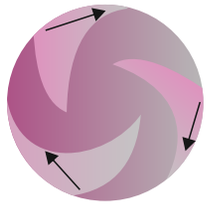
1. European Heart Journal (2018)00, 1-23 Doi:10.1093/eurheartj/ehy394 2. Rev. Cardiovasc. Med. 2021vol.22(4),1323-1330
3. Clin Res Cardiol (2015) 104:217–225 4. Circ Res. 2000;86:879-884

UNIQUE DRUG APPLICATION

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



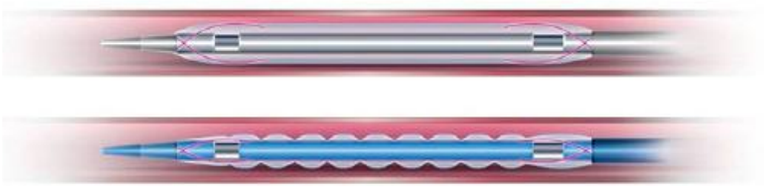
Paclitaxel applied to balloon surface Over PVP Coating



Wrapped Balloon

WING SEAL TECHNOLOGY

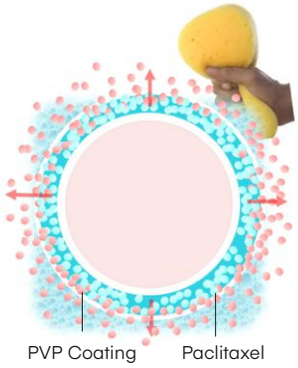
Wrapped balloon is crimped & then subjected to a process that creates corrugation



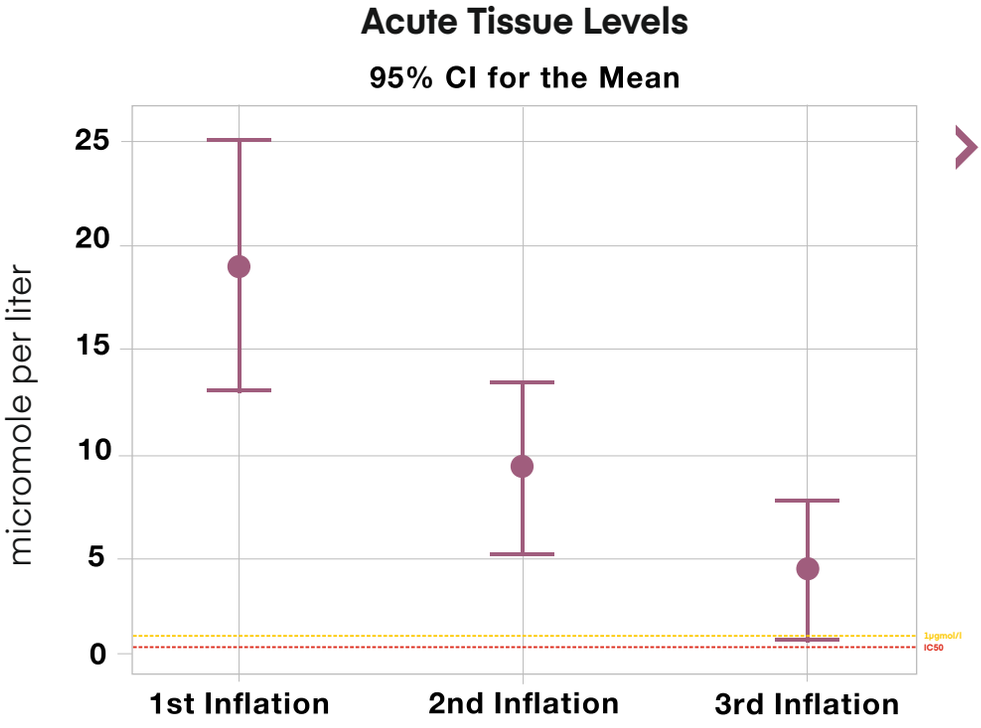
- Crimping prevents balloon unfolding during advancement and minimizes drug loss
- Surface corrugation creates low balloon profile for better flexibility & deliverability even in complex anatomy
- Corrugation reduces frictional abrasion during balloon advancement

DRUG RELESE

- 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 STUDY



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

★ ★ ★
World's First and
Only
Non-Compliant
DCB
★ ★ ★

- 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

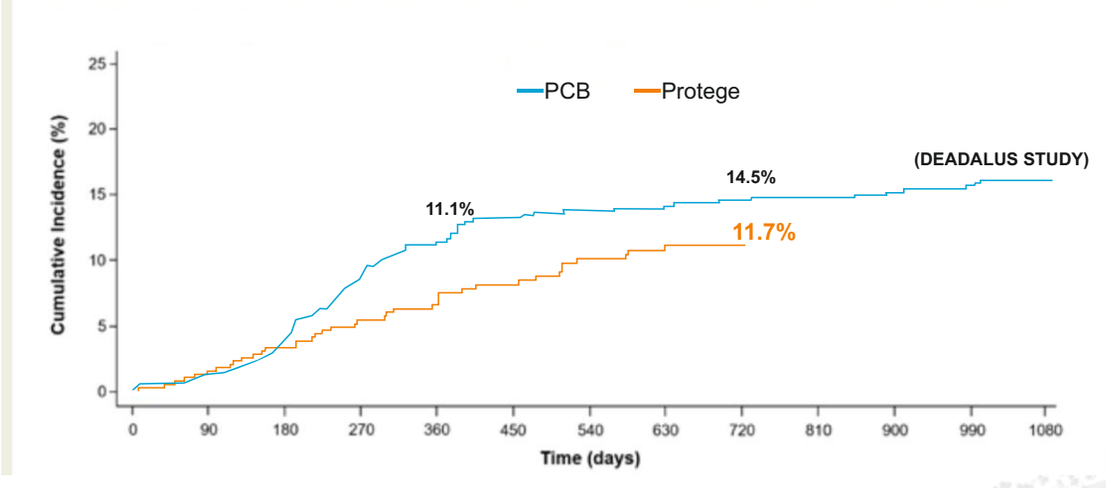
Proven safety and efficacy of the Protégé*

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%)

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

SIZE CATHETER

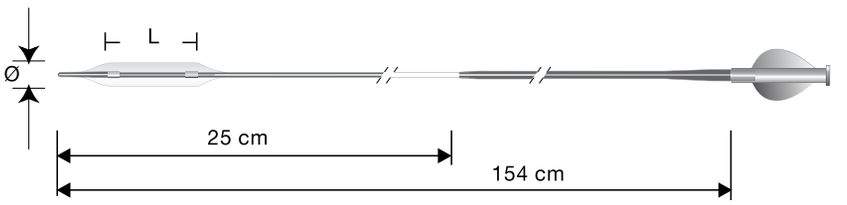
PROTÉGÉ - DCB CATHETER

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 2.00 - 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/mm²(drug loaded balloon surface)	Paclitaxel 3 µg/mm²(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

CE 2797

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Indications, contraindications, warnings and instruction for use can be found in the product labeling

⚠ Caution- Restricted to sale by or on the order of a physician

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LIMITLESS POSSIBILITIES

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