

# 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.

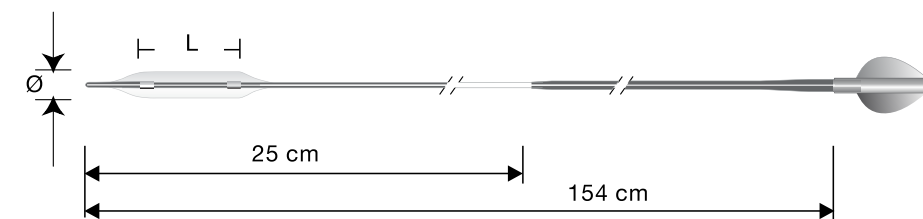
## SIZE CATHETER

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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 NC - DCB CATHETER	
Nominal Pressure	12 bar
Rated Burst Pressure	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
Drug	Paclitaxel 3 µg/mm <sup>2</sup> (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

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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# Protégé NC

Paclitaxel Coated Coronary Balloon Dilatation Catheter



Taking **DCB Technology** to a New High



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# Protégé NC

Paclitaxel Coated Coronary Balloon Dilatation Catheter

## WORLD'S ONLY NON-COMPLAINT 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\*\*

## PACLITAXEL

- > Drug of Choice for DCB with Large Clinical Evidence<sup>1</sup>
- > Positive vessel remodelling with late lumen enlargement<sup>2</sup>
- > Quicker vessel healing and faster reendothelialization<sup>3</sup>
- > Apoptotic effect of Paclitaxel reduces toxicity<sup>4</sup>
- > Higher absorption into vessel wall



1. European Heart Journal (2018)00, 1-23 Doi:10.1093/eurheartj/ehy394

2. Clin Res Cardiol. 2015; 104: 217-25

3. 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.

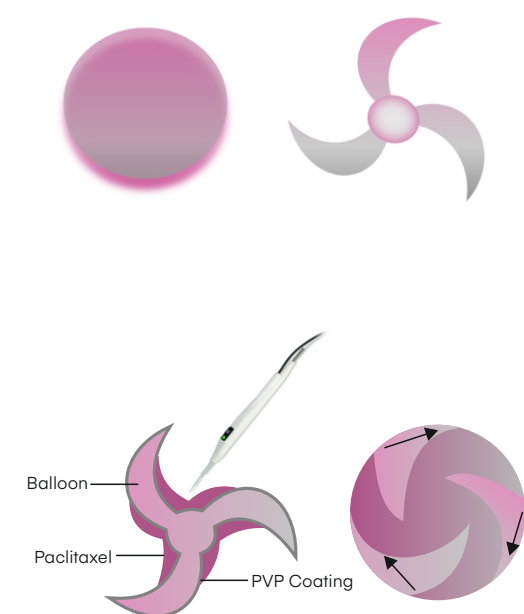
4. Biotechnology and Bioprocess Engineering 17: 912-924 (2012) DOI 10.1007/s12257-011-0571-z.

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.

\*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., Hoerberlin, A., Vogel, R., Zurbuchen, A., & Burge, J. (2023). BioMedical Engineering OnLine, 22(94)

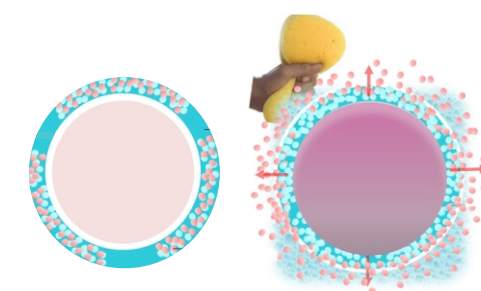
## UNIQUE DRUG APPLICATION



> 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

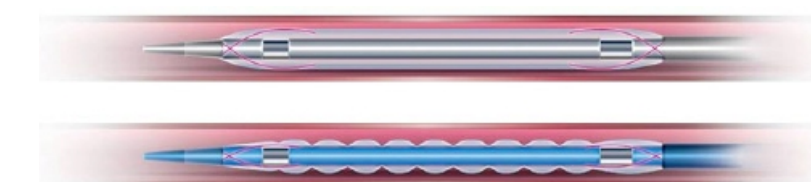
## DRUG RELEASE



> 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

## WINGSEAL TECHNOLOGY



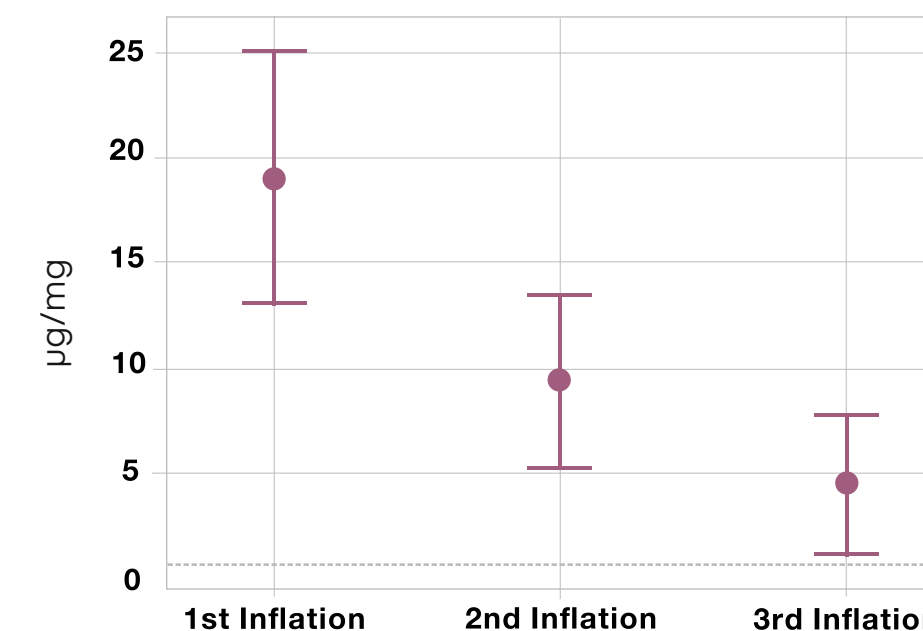
> Protects the drug between the balloon folds during advancement, resulting in negligible drug loss prior to inflation

> The corrugation increases flexibility of the balloon ensuring better trackability & crossability

> Tight wrapping prevents the balloon unfolding during advancement

## M3i TECHNOLOGY

Acute Tissue Levels  
95% CI for the Mean



> 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

Minimum Effective Dose (1µg/mol/l)

\*Internal Data