

restore[®]

DEB

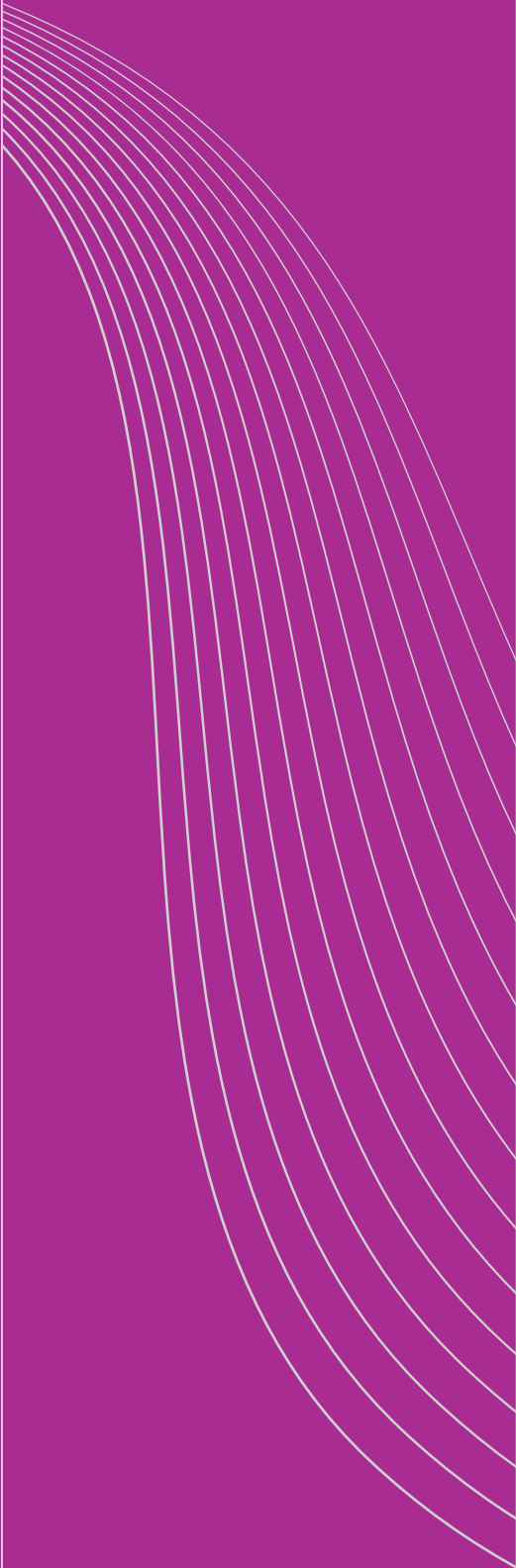
Paclitaxel Releasing PTCA
Balloon Catheter

Specifically designed
for ease of handling,
high safety and precise
drug delivery



Coating technology

Paclitaxel releasing PTCA Balloon Catheter



With clinical evidences in the treatment of In-Stent Restenosis (ISR), Small Vessel Disease (SVD), Diffuse Long Lesions and Bifurcations.

- Procedural success rates > 98% in both ISR and SVD patients¹⁻³;
- Restore SVD RCT demonstrated **non-inferiority vs Resolute™ DES** in terms of % Diameter Stenosis at 9 months in SVD¹;
- **5-Year** data for Restore SVD RCT confirmed no difference in terms of clinical outcomes between Restore® DEB and Resolute™ DES²;
- 2-Year data from Restore ISR RCT showed **non-inferiority to SeQuent® Please** in terms of Late Lumen Loss in the treatment of ISR⁴;
- Results from the HYPER study confirmed that the combined use of Restore® DEB with modern DES in the context of De-Novo diffuse CAD is safe and effective, and associated with a low incidence of 2-Year DOCES⁵.



Restore SVD RCT Results

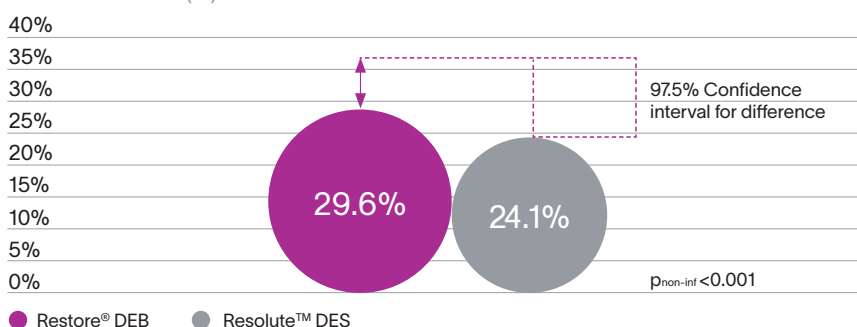
Restore[®] DEB vs Resolute[™] DES
in De-Novo small and
Very Small Vessels (VSV).

Clinical evidences and results

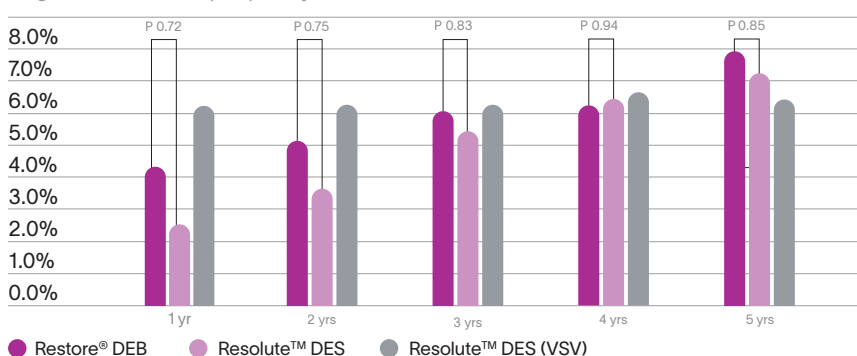
Data from 230 patients
showed that:

At 9 months Restore[®] DEB showed to be non-inferior to
Restore[®] DES in terms of in-segment % Diameter Stenosis¹;
5-year data confirmed that Restore[®] DEB has equivalent
long-term safety and efficacy compared to Resolute[™] DES in
De-Novo small and VSV².

Diameter Stenosis (%) at 9 months



Target Lesion Failure (TLF) at 5 years

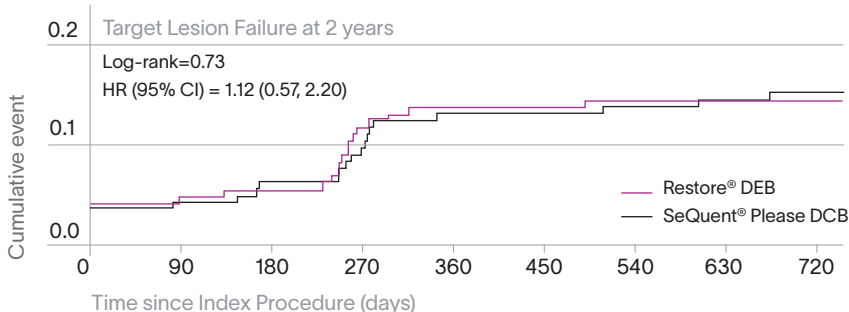
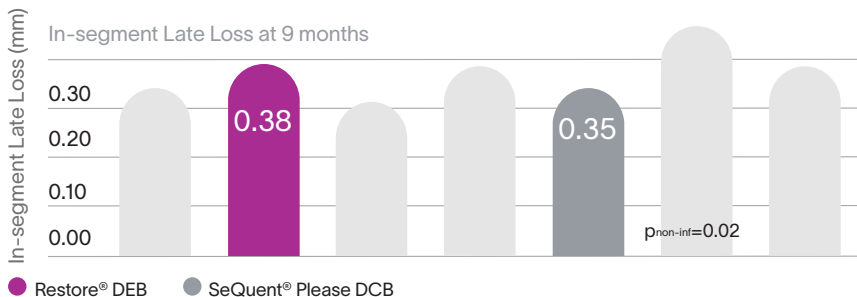


Restore ISR RCT Results

Restore[®] DEB vs SeQuent[®] Please
in the treatment of ISR.

Data from 230 patients
showed that:

At 9 months, Restore[®] DEB was non-inferior to SeQuent[®]
Please in terms of Late Lumen Loss in the treatment of ISR³;
At 2 years, both groups had similar Target Lesion Failure (TLF)⁴:
14.8% vs 15.0%; $p = \text{ns}$.



Restore[®] is indicated
for the treatment of:

Technical specifications



Technical Data

Shaft material	Plastic tube and a stainless steel hypotube
Balloon material	Nylon
Usable catheter length	140 cm
Max. recommended guidewire	0.014"
Length of guide wire lumen	25 cm
Entry profile	0.016"
Guiding catheter compatibility	5F
Nominal Pressure	6 bar
Rated Burst Pressure	16 bar (14 bar for balloons Ø 4.00 mm with length higher than 20 mm)
Paclitaxel coating	3.0 µg/mm ² balloon surface

Ordering information

Balloon Ø (mm)	Balloon Length (mm)			
	15 mm	20 mm	25 mm	30 mm
2.00 mm	R2.00-15	R2.00-20	R2.00-25	R2.00-30
2.25 mm	R2.25-15	R2.25-20	R2.25-25	R2.25-30
2.50 mm	R2.50-15	R2.50-20	R2.50-25	R2.50-30
2.75 mm	R2.75-15	R2.75-20	R2.75-25	R2.75-30
3.00 mm	R3.00-15	R3.00-20	R3.00-25	R3.00-30
3.50 mm	R3.50-15	R3.50-20	R3.50-25	R3.50-30
4.00 mm	R4.00-15	R4.00-20	R4.00-25	R4.00-30

Innovative Technology.
Proven Performance.

Not All DCBs Are The Same



Amorphous vs
Crystalline

References

The 3rd generation, unique amorphous paclitaxel matrix system with the highest coating stability on the market.

- **No Distal Embolization**

Designed with an amorphous and no-crystalline coating technology to prevent distal particles embolization ensuring safer outcomes, especially in high-risk and fragile patients.

- **No Slow Coronary Flow (SCF)**

Effectively eliminates the risk of Slow Flow and No-Reflow phenomena, promoting uninterrupted coronary perfusion.

- **Unmatched Drug Retention**

Features the lowest drug wash-off rate and particle release among current DCBs, guaranteeing precise and sustained drug delivery directly to the target lesion.

- **Clinically Proven Performance**

Exceptional safety and efficacy demonstrated in thousands of patients, supported by robust randomized controlled trials (RCTs) with follow-up extending up to 5 years.



Comparison between Safepax®'s innovative no-crystalline coating (top) and traditional crystalline coatings used by competitors*

* Cardionovum® data on file

1 Tang Y, et al., Drug-Coated Balloon Versus Drug-Eluting Stent for Small-Vessel Disease: The Restore SVD China Randomized Trial. JACC Cardiovasc Interv. 2018 Dec 10;11(23):2381-2392;

2 Shao Liang Chen, Data presented at TCT 2022;

3 Chen Y, et al., "Comparison of 2 Different Drug-Coated Balloons in In-Stent Restenosis: The Restore ISR China Randomized Trial. JACC Cardiovasc Interv. 2018 Dec 10;11(23):2368-2377;

4 Cai X, et al., Comparing the efficacy and safety of two different drug-coated balloons in in-stent restenosis: Two-year clinical outcomes of the Restore ISR China randomized trial. J Cardiol. 2023

5 Ielasi A., HYPER EXTEND: 2-Year Follow-up Following a Hybrid Strategy Using Drug-eluting Stent and Drug-Coated Balloon in Diffuse Coronary Artery Disease, data presented at EuroPCR 2023.



Manufacturer, Headquarter and International Sales Office

CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn – Germany
phone +49 (0) 228-90 90 59-0
fax +49 (0) 228-90 90 59-20

CARDIONOVUM Schweiz
GmbH c/o BDO AG
Feldmoosstrasse 12
8853 Laachen – Switzerland
phone +41 79 560 91 93

E-MAIL info@cardionovum.com
WEB www.cardionovum.com

