RESTORE® DEB

Paclitaxel Releasing PTCA Balloon Catheter

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

Powered by SAFEPAX® Technology

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

CARDIONOVUM®

Life deserves the best

RESTORE® DEB: Paclitaxel releasing PTCA Balloon Catheter with clinical evidences in the treatment of In-Stent Restenosis (ISR), Small Vessel Disease (SVD), Diffuse Long Lesions, Bifurcations.

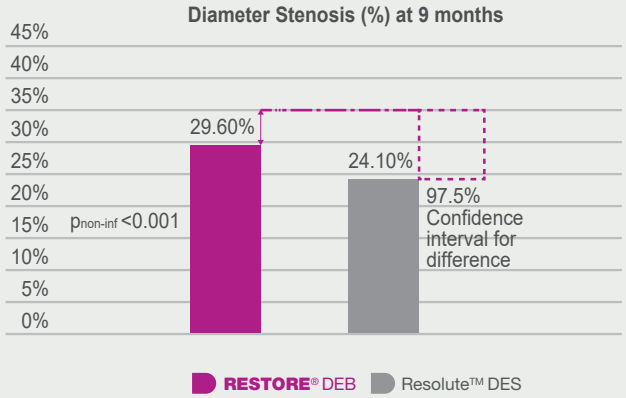
- Procedural success rates **>98%** in both ISR and SVD patients[1-3];
- Restore SVD Randomized Clinical Trial demonstrated **non-inferiority vs RESOLUTE™ DES** in terms of % Diameter Stenosis at 9 months in SVD[1];
- **5-Year** data for RESTORE SVD RCT confirmed no difference in terms of clinical outcomes between RESTORE® DEB and RESOLUTE™ DES[2];
- 2-Year data from Restore ISR Randomized Clinical Trial showed **non-inferiority to SeQuent® Please** in terms of Late Lumen Loss in the treatment of ISR[3];
- 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 DOCEs[5].

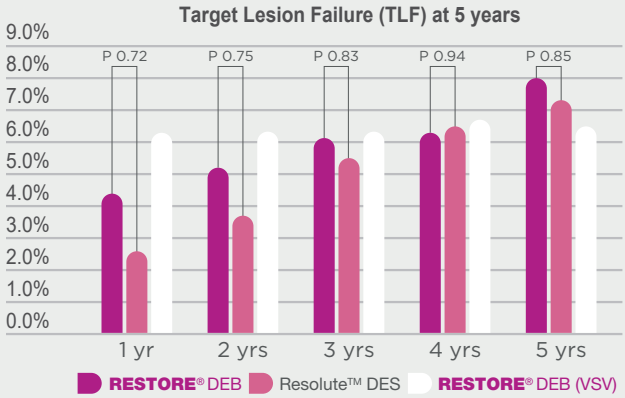
RESTORE® DEB
Clinical evidences and results

RESTORE SVD Randomized Clinical Trial Results
RESTORE® DEB vs RESOLUTE™ DES in De-Novo small and Very Small Vessels (VSV).

Data from 230 patients showed that:

- At 9 months RESTORE® DEB showed to be **non-inferior to RESOLUTE™ DES** in terms of in-segment % Diameter Stenosis[1];
- 5-year data confirmed that RESTORE® DEB has equivalent long-term safety and efficacy compared to RESOLUTE™ DES in De-Novo small and VSV[2].

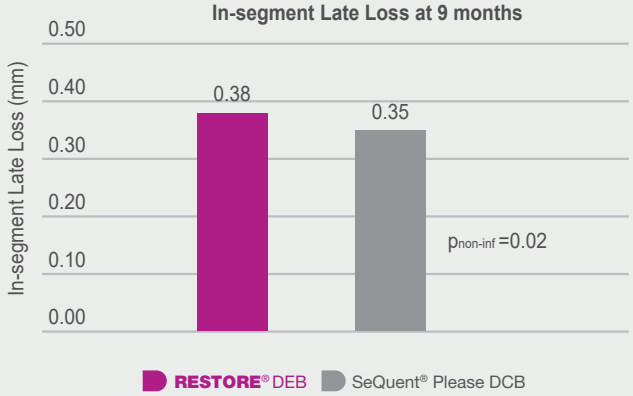


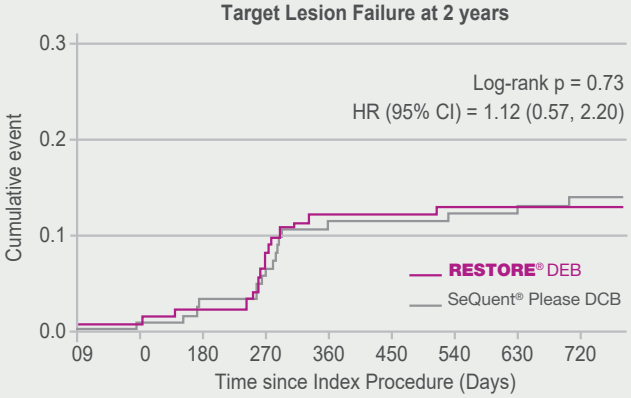


RESTORE ISR Randomized Clinical Trial Results
RESTORE® DEB vs SeQuent® Please in the treatment of In-Stent Restenosis (ISR).

Data from 230 patients revealed that:

- At 9 months, RESTORE® DEB was **non-inferior to SeQuent® Please** in terms of Late Lumen Loss in the treatment of ISR[3];
- At 2 years, both groups had similar Target Lesion Failure (TLF)[4]: 14,8% vs 15.0%; p=ns.





RESTORE® DEB

RESTORE® is indicated for the treatment of:

- Coronary in-stent restenosis
- Small vessel lesions Ø < 3.0 mm
- De-novo lesion

Technical specifications

Drug releasing balloon	
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
Rated Burst Pressure	16 bars (14 bars for balloons Ø 4.00 mm with length higher than 20 mm)
Paclitaxel coating	3.0 µg/mm^2 balloon surface

Ordering Information

Balloon diameter (mm)	Balloon lengths (mm)			
	15 mm	20 mm	25 mm	30 mm
2.00 mm	R 2.00-15	R 2.00-20	R 2.00-25	R 2.00-30
2.25 mm	R 2.25-15	R 2.25-20	R 2.25-25	R 2.25-30
2.50 mm	R 2.50-15	R 2.50-20	R 2.50-25	R 2.50-30
2.75 mm	R 275-15	R 275-20	R 275-25	R 275-30
3.00 mm	R 3.00-15	R 3.00-20	R 3.00-25	R 3.00-30
3.50 mm	R 3.50-15	R 3.50-20	R 3.50-25	R 3.50-30
4.00 mm	R 4.00-15	R 4.00-20	R 4.00-25	R 4.00-30

Powered by

SAFEPAX®

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

RESTORE® DEB: Leveraging all the benefits from SAFEPAX®

SAFEPAX®

- **Paclitaxel dose equal to 3 µg/mm²**
- **Virtually loss-less matrix**
- **Patented technology with Ammonium Salt excipient**
- **Highly stable coating, with low surface friction**

  Excellent manoeuvrability for maximal control: smooth pushability and optimised tensile resistance;

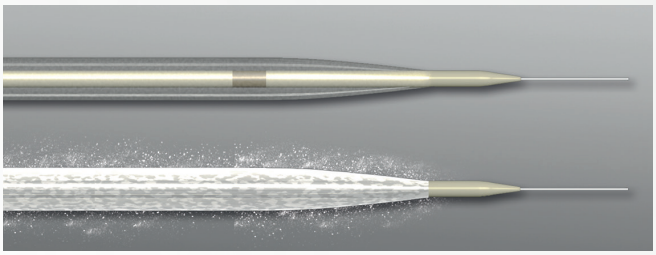
  Enhanced crossability and trackability;

  No need for a loading tool.

- **Designed for maximal procedural safety**

  No major adverse procedural complications reported in ISR Randomized Controlled Trials[3].

Stable vs Unstable



Comparison between the virtually loss-less SAFEPAX® DCB PTX Balloon Coating (top) and a first-generation DCB coating (bottom) *

* Cardionovum® data on file

References

[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; Ielasi A., data presented at EuroPCR 2023

[2] TShao 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] JCai 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 Jan;81(1):76-82.

[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.

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Life deserves the best

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