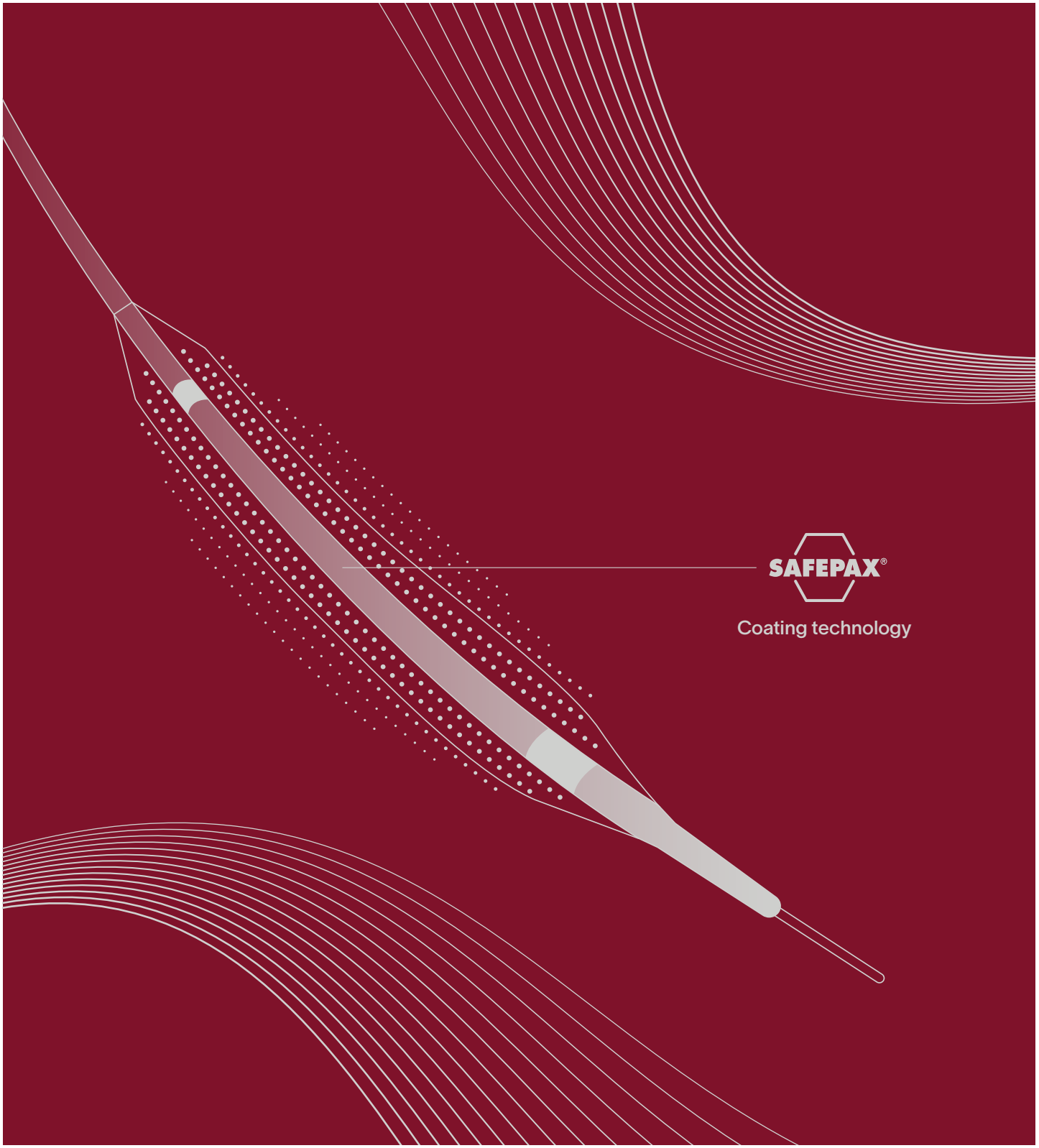
restore®
PLUS

Paclitaxel Releasing PTCA Balloon Catheter

Specifically designed for the treatment of the most complex lesions and tortuous anatomies



CARDIONOVUM®
life deserves the best

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 patients[1-3];
- Restore SVD RCT 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 RCT showed **non-inferiority to SeQuent® Please** in terms of Late Lumen Loss in the treatment of ISR[4];
- 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].

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Clinical evidences and results

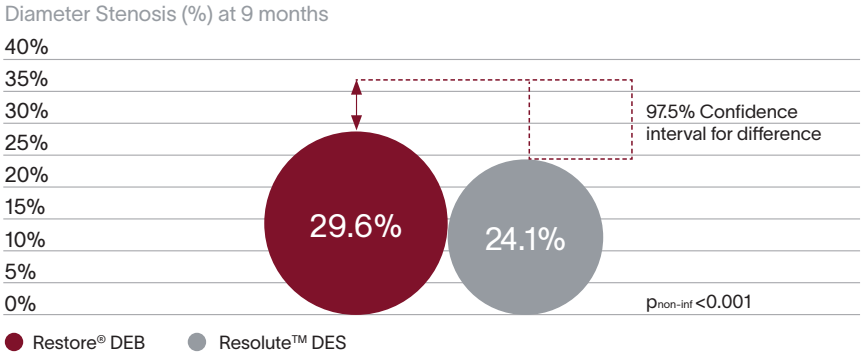
Restore **SVD** RCT Results

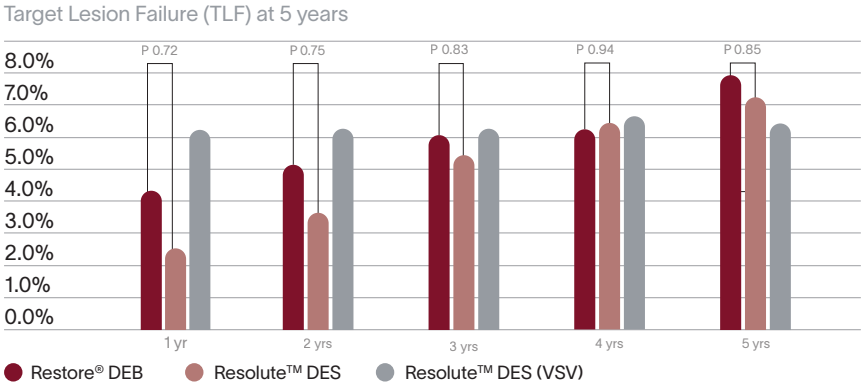
Restore® DEB vs Resolute™ DES in De-Novo small and Very Small Vessels (VSV).

Data from 230 patients showed that:

At 9 months Restore® DEB showed to be non-inferior to Restore® 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].





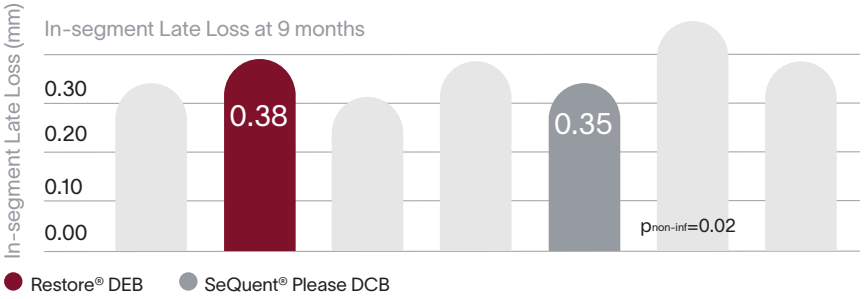
Restore **ISR** RCT Results

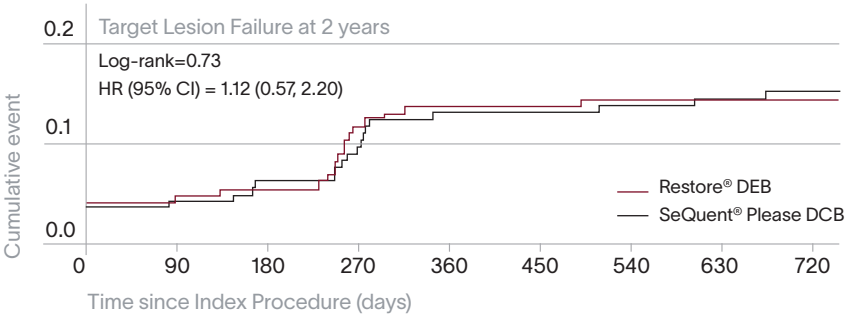
Restore® DEB vs SeQuent® Please in the treatment of ISR.

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 ISR[3];

At 2 years, both groups had similar Target Lesion Failure (TLF)[4]: 14,8% vs 15.0%; p=ns.





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Technical specifications

Restore® is indicated for the treatment of:

Technical Data

Shaft material	Plastic tube and a stainless steel hypotube
Balloon material	Polyamide blend / Nylon 12
Usable catheter lenght	140 cm
Max. recommended guidewire	0.014"
Entry profile	0.016"
Guiding catheter compatibility	5F
Rated Burst Pressure	16 bar (14 bar for balloons Ø 3.50 and 4.00 mm with length higher than 30 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	40 mm
1.50 mm	RP1.50-15	RP1.50-20	RP1.50-25	RP1.50-30	RP1.50-40
2.00 mm	RP2.00-15	RP2.00-20	RP2.00-25	RP2.00-30	RP2.00-40
2.25 mm	RP2.25-15	RP2.25-20	RP2.25-25	RP2.25-30	RP2.25-40
2.50 mm	RP2.50-15	RP2.50-20	RP2.50-25	RP2.50-30	RP2.50-40
2.75 mm	RP2.75-15	RP2.75-20	RP2.75-25	RP2.75-30	RP2.75-40
3.00 mm	RP3.00-15	RP3.00-20	RP3.00-25	RP3.00-30	RP3.00-40
3.50 mm	RP3.50-15	RP3.50-20	RP3.50-25	RP3.50-30	RP3.50-40
4.00 mm	RP4.00-15	RP4.00-20	RP4.00-25	RP4.00-30	RP4.00-40

Innovative Technology.
Proven Performance.

Not All DCBs Are The Same

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.

Powered by

SAFEPAX®

Amorphous vs Crystalline

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

* 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;

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.

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