

RESTORE[®] Plus

PACLITAXEL RELEASING PTCA BALLOON CATHETER

SPECIFICALLY DESIGNED FOR THE TREATMENT
OF THE MOST **COMPLEX LESIONS** AND
TORTUOUS ANATOMIES

Powered by SAFEPAX[®]
coating technology



 **CARDIONOVUM[®]**
Life deserves the best

RESTORE® PLUS

EFFORTLESS NAVIGATION, MORE SIZES:
REDEFINING DCB ACCESSIBILITY.

RESTORE® PLUS

Paclitaxel Coronary DCB powered by clinically proven with Safepax® coating technology

- In-Stent Restenosis;
 - Small Vessel Disease;
 - Diffuse Long Lesions and Bifurcations.
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- ▶ **RESTORE® Plus:** Enhanced Trackability;
 - ▶ **Enhanced navigability;**
 - ▶ **Expanded Treatment:** Diameters from 1,5 mm and lengths up to 40 mm;
 - ▶ **Clinical evidences*** in different anatomical scenarios with Safepax®;
 - ▶ Clinical data up to 5-Year **available from Restore SVD RCT;**
 - ▶ **Optimized size matrix** for the treatment of long diffuse and distal lesions.

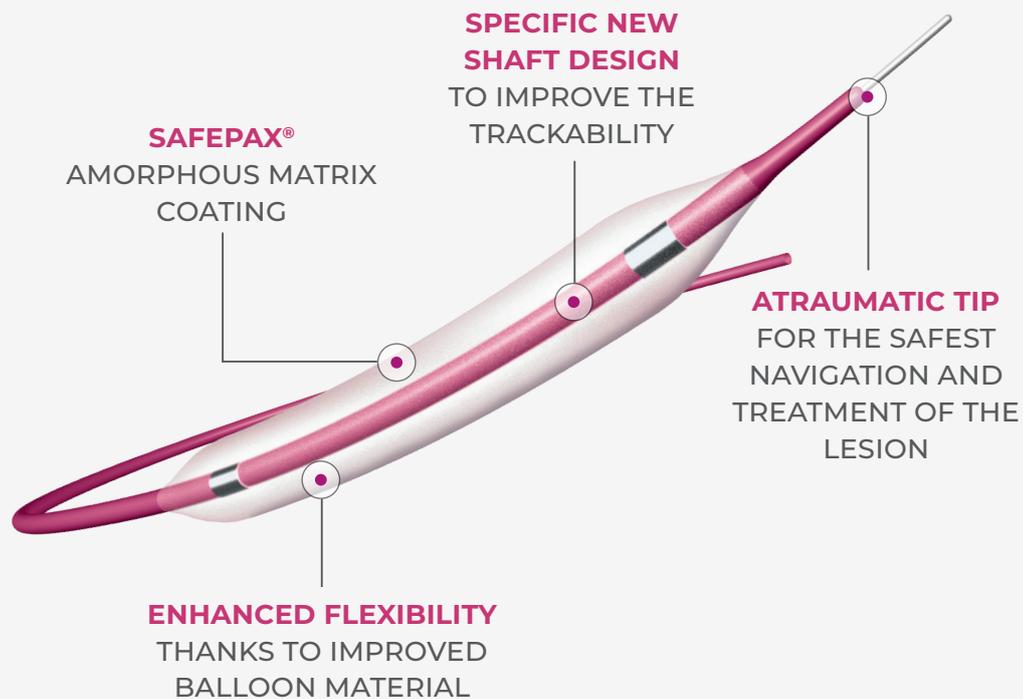
*NAVIGATE EASILY, DISCOVER
BOUNDLESS SIZES:
EMPOWERING YOUR CHOICES!*

*Cardionovum data on file

PERFORMANCES

RESTORE® PLUS

Designed with a **New Platform** that improves the delivery performances



RESTORE® PLUS MAIN ADVANTAGES

Restore® Plus demonstrates:

- Enhanced **trackability**;
- **More controlled Compliance**;
- **Expanded** size matrix.

This combination ensures reliability in drug delivery, leading to optimal therapeutic outcomes.

Experience unparalleled control and versatility with Restore® Plus for superior patient care.

CLINICAL EVIDENCES

SAFEPA[®] CLINICAL EVIDENCES IN CORONARY LESIONS

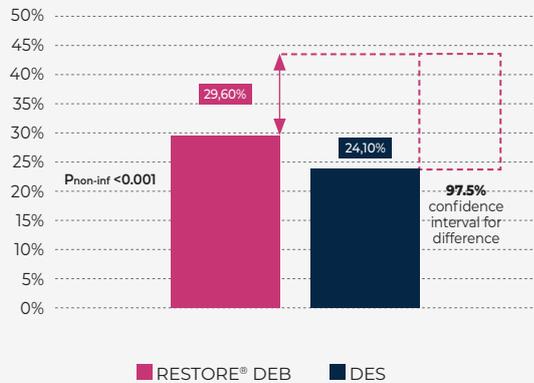
RESTORE SVD Randomized Clinical Trial Results

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

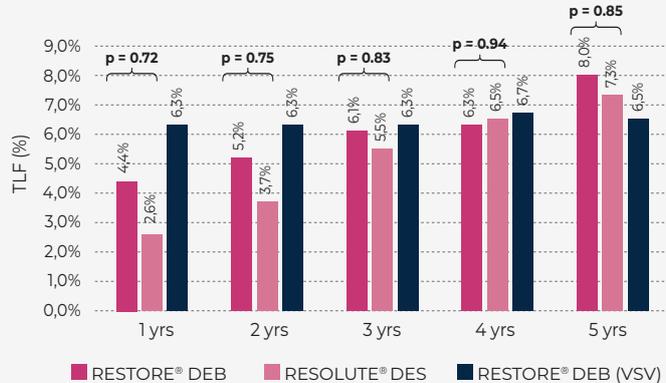
Data from 230 patients showed that:

- At 9 months RESTORE[®] DEB showed to be **non-inferior to RESOLUTE[™] DES** in terms of in-segments % 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



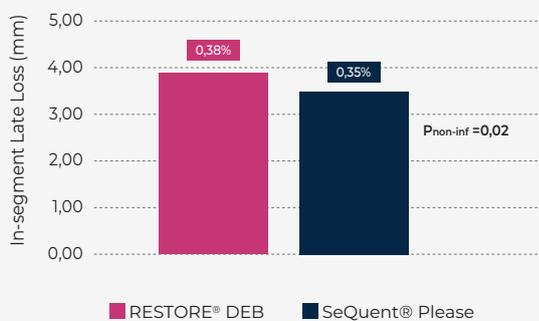
RESTORE ISR Randomized Clinical Trial Results

RESTORE[®] DEB vs SeQuent[®] Please in the treatment of In-Stent Restenosis (ISR).

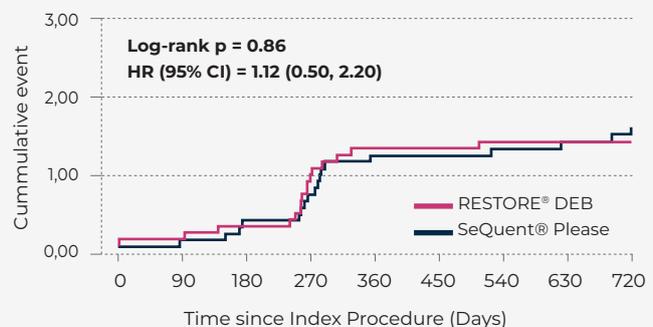
Data from 230 patients showed that:

- 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=ns.

IN-SEGMENT LATE LOSS AT 9 MONTHS



TARGET LESION FAILURE AT 2 YEARS



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 Jan;81(1):76-82.
⁵ Ielasi A., data presented at EuroPCR 2023.

TECHNOLOGY

RESTORE® PLUS: MORE NAVIGABILITY WITHOUT COMPROMISING EFFICACY.



SAFEPAX® **THE MOST ADVANCED COATING TECHNOLOGY** AVAILABLE

- ▶ **No distal embolization** thanks to **No flacking** effect for the treatment of the most fragile patients;
- ▶ **No Reflow** and **No Slow Flow** phenomena;
- ▶ **Lowest Wash-Off** effect among contemporaneous DCBs ensuring the optimal therapeutic treatment;
- ▶ **Highest deliverability** for an unmatched navigability, even in the most complex and distal districts;
- ▶ **Safety** and **Efficacy** clinically proven on thousands of patients including RCTs* with F.U. up to 5 years.

SAFEPAX® VS CRYSTALLINE COATING TECHNOLOGY**: STABLE VS UNSTABLE.



Safepax® vs Crystalline

- ▶ **Precise and Reliable**, regardless of anatomical or complexity of the lesion.
- ▶ **Negligible «Wash Off»**: Ensuring lesion's treatment, without concerns about time to reach the lesion.
- ▶ Absence of **Distal Embolization**, reducing No-Reflow or Slow Flow risks with the most critical patients.
- ▶ **High trackability**, thanks to the elastic properties of the coating.

*Cardionovum data on file.

**Frames taken from deployment video at the same moment

TECHNICAL SPECIFICATIONS

RESTORE® PLUS: PROVIDING EXCELLENCE, EMBRACING PATIENT'S NEEDS!

Designed to treat the most complex lesions and anatomies.

TECHNICAL SPECIFICATIONS

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

Bonn
Lachen

 **CARDIONOVUM®**
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