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, virtually loss-less matrix. For improved homogeneity of drug transfer and highest coating stability on the market

CARDIONOVUM®

Life deserves the best

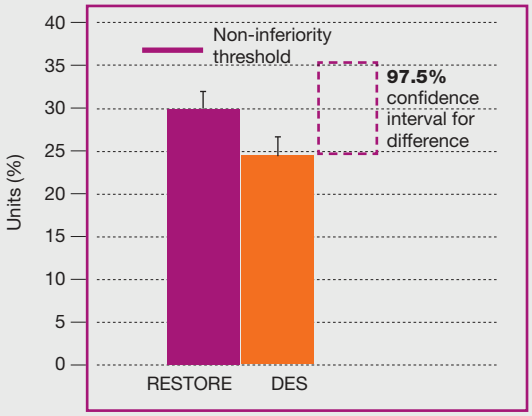
Controlled trials confirm the excellent safety profile of **RESTORE®**

- Procedural success rates **>98%** in both ISR and SVD patients[1-3]
- No procedure-related complications with RESTORE in two ISR trials and 160 patients: **<1%** complication rates[1, 3]
- Similar complication rates to DES in vulnerable SVD patients (p=0.19 for comparison)[2]
- Only DCB with demonstrated low complication rates **(~3%)** in patients with very small vessels[2]

RESTORE SVD China: RESTORE is a proven equal alternative to zotarolimus-eluting stent in patients with coronary small vessel lesions[2]

Percent diameter restenosis **at 9 months**

Non-inferiority proven at p <0.001



No difference in 12-months rates of target lesion failure between RESTORE and zotarolimus-eluting stent (p=0.47)

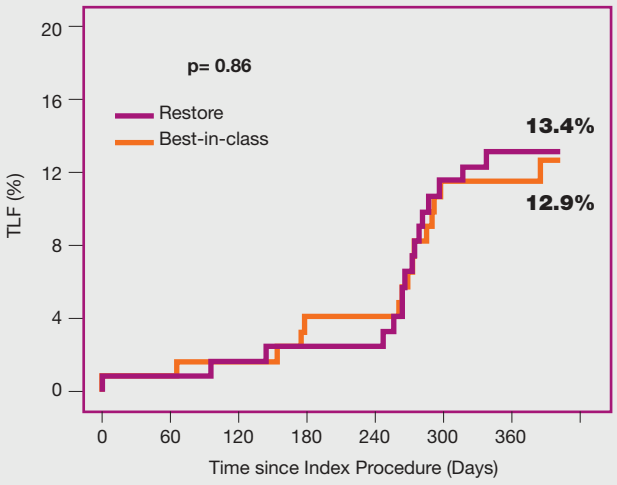
Multi-centre, randomised, controlled clinical trial in 262 subjects at 12 sites in China. The primary end point was in-segment diameter stenosis after 9 months follow-up. Major adverse events were evaluated at 1, 6, 9 and 12 months and will be collected up to 5 years

RESTORE ISR China: RESTORE is a proven equal alternative to the best-in-class DCB in the treatment of patients with coronary in-stent restenosis[3]

Primary end point: statistically similar rates of in-segment late **loss at 9 months**

Results were valid for both in-segment and in-device late loss at one year

RESTORE matches best-in-class DCB on rates of target lesion failure (TLF) **over 12 months**



TLF rates with RESTORE and the best-in-class DCB

Multi-centre, randomised, controlled clinical trial in 240 subjects at 12 sites in China. Patients had in-stent restenosis ≥70% diameter on visual assessment, or ≥50% diameter stenosis and with ischaemic symptoms on coronary angiography. The primary endpoint was in-segment late lumen loss of the target lesion at 9 months after the procedure. Major adverse events were evaluated at 1, 6, 9 and 12 months.

RESTORE® is indicated for the treatment of:

- Coronary in-stent restenosis
- Small vessel lesions Ø < 2.5 mm
- Side branch dilation of bifurcated coronary artery lesions
- De-novo lesion dilation

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”
Length of guide wire lumen	25 cm
Entry profile	0.016”
Guiding catheter compatibility	5F
Rated Burst Pressure	16 bar (14 bar for balloons > 4,0-20)
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, virtually loss-less matrix. For improved homogeneity of drug transfer and highest coating stability on the market

RESTORE: Leveraging all the benefits from SAFEPAX

With RESTORE I am in control of drug delivery to the target site with minimal risk for embolisation

Dr YunDai Chen

- **Locally delivered 3 µg/mm² paclitaxel dose**
- **Virtually loss-less matrix**
- **Proprietary ammonium salt solution excipient**
- **Highly stable coating, with low surface friction**

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

  Enhanced crossability and trackability

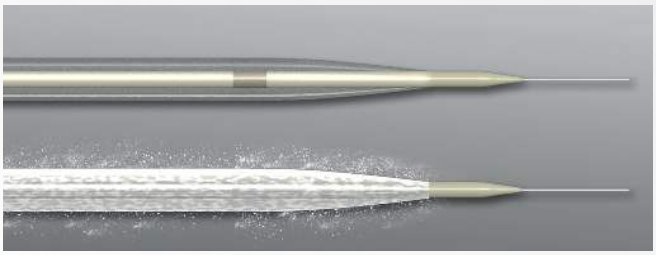
  No need for a loading tool

- **Designed for maximal procedural safety**

  No major adverse procedural complications reported in two clinical trials of in-stent restenosis[1, 3] - the lowest rates reported to date

  Low mass-related risk of distal embolisation

Stable vs Unstable



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

References

[1] Miglionico M, Mangiacapra F, Nusca A, et al. Efficacy and Safety of Paclitaxel-Coated Balloon for the Treatment of In-Stent Restenosis in High-Risk Patients. Am J Cardiol 2015; 116: 1690-4.

[2] Tang Y, Qiao S, Su X, Chen Y, Jin Z, Chen H, Xu B, Kong X, Pang W, Liu Y, Yu Z, Li X, Li H, Zhao Y, Wang Y, Li W, Tian J, Guan C, Xu B, Gao R, for the RESTORE SVD China Investigators, Drug-Coated Balloon Versus Drug-Eluting Stent for Small Vessel Disease: The RESTORE SVD China Randomized Trial, JACC: *Cardiovascular Interventions* (2018), doi: https://doi.org/10.1016/j.jcin.2018.09.009.

[3] Chen Y, Gao L, Qin Q, Chen S, Zhang J, Chen H, Wang L, Jin Z, Zheng Y, Zhang Z, Li H, Li X, Fu G, Chen L, Sun Z, Wang Y, Jin Q, Cao F, Guo J, Zhao Y, Guan C, Li W, Xu B, for the RESTORE ISR China Investigators, Comparison of Two Different Drug-Coated Balloons in In-Stent Restenosis: The RESTORE ISR China Randomized Trial, JACC: *Cardiovascular Interventions* (2018), doi: https://doi.org/10.1016/j.jcin.2018.09.010.

CARDIONOVUM®
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