

# RESTORE<sup>®</sup> DEB

Paclitaxel Releasing PTCA Balloon Catheter  
Specifically designed for ease of handling, high safety  
and precise drug delivery



## Powered by SAFEPAX<sup>®</sup> Technology

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

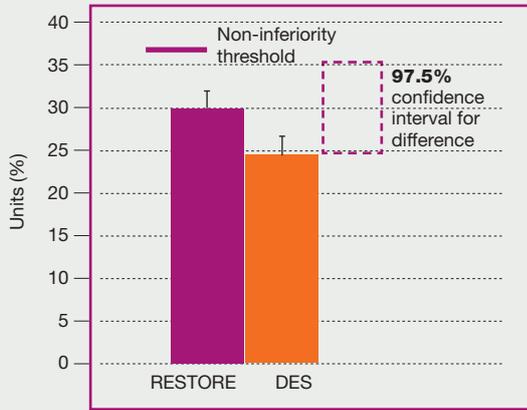
Controlled trials confirm the excellent safety profile of **RESTORE®**

- Procedural success rates **>98%** in both ISR and SVD patients<sup>1-3</sup>
- No procedure-related complications with RESTORE in two ISR trials and 160 patients: **<1%** complication rates<sup>1, 3</sup>
- Similar complication rates to DES in vulnerable SVD patients (p=0.19 for comparison)<sup>2</sup>
- Low complication rates in patients with very small vessels<sup>2</sup>
- There is no statistically significant difference between RESTORE DCB and RESOLUTE DES in terms of cumulative clinical outcomes rate at **2 years follow up.**<sup>4</sup>

**RESTORE SVD China:** RESTORE® is a proven equal alternative to zotarolimus-eluting stent in patients with coronary small vessel lesions<sup>2</sup>

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

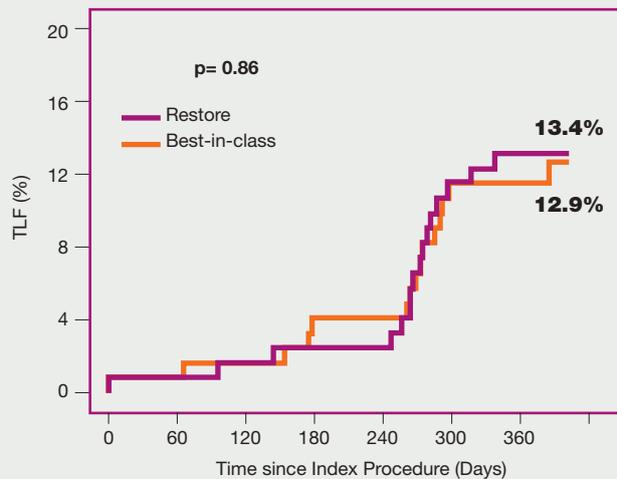
**RESTORE ISR China:** RESTORE® is a proven equal alternative to the best-in-class DCB in the treatment of patients with coronary in-stent restenosis<sup>3</sup>

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  $\geq 70\%$  diameter on visual assessment, or  $\geq 50\%$  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® DEB

RESTORE® is indicated for the treatment of:

- Coronary in-stent restenosis
- Small vessel lesions  $\varnothing < 3.0$  mm
- De-novo lesion dilation

### 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 $\varnothing 4.00$ mm with length higher than 20 mm)
Paclitaxel coating	3.0 $\mu\text{g}/\text{mm}^2$ 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 2.75-15	R 2.75-20	R 2.75-25	R 2.75-30
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



*The 3<sup>rd</sup> generation, unique, virtually loss-less matrix. For improved homogeneity of drug transfer and highest coating stability on the market*

## RESTORE<sup>®</sup>: Leveraging all the benefits from SAFEPAX<sup>®</sup>

“With RESTORE<sup>®</sup> I am in control of drug delivery to the target site with minimal risk for embolisation”  
Dr YunDai Chen

⬡ **Locally delivered 3 µg/mm<sup>2</sup> 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

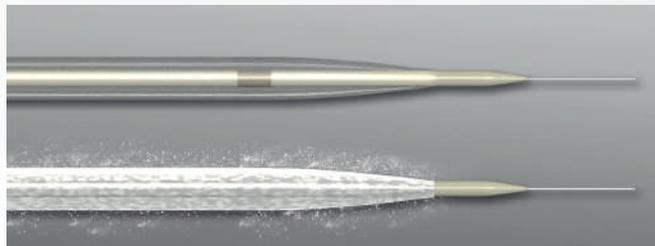
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⬡ **Designed for maximal procedural safety**

No major adverse procedural complications reported in two clinical trials of in-stent restenosis<sup>1,3</sup> - the lowest rates reported to date

Low mass-related risk of distal embolisation

## Stable vs Unstable



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

\* Cardionovum<sup>®</sup> data on file

## References

- <sup>1</sup> 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.
- <sup>2</sup> 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>.
- <sup>3</sup> 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>.
- <sup>4</sup> Jan Tian, poster TCT 259 presented at TCT congress 2019. "A 2-year follow-up of a randomized multicenter study comparing a drug-coated balloon with a drug-eluting stent in small coronary vessels the RESTORE SVD China randomized trial"



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