

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

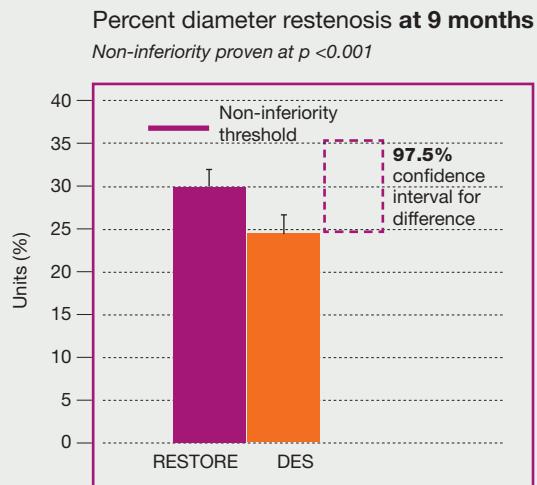


Controlled trials confirm the excellent safety profile of **RESTORE®**

- ◆ Procedural success rates **>98%** in both ISR and SVD patients¹⁻³
- ◆ 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
- ◆ Low complication rates in patients with very small vessels²
- ◆ There is no statistically significant difference between RESTORE DCB and RESOLUTE DES in terms of cumulative clinical outcomes rate at **2 years follow up.**⁴

RESTORE® DEB

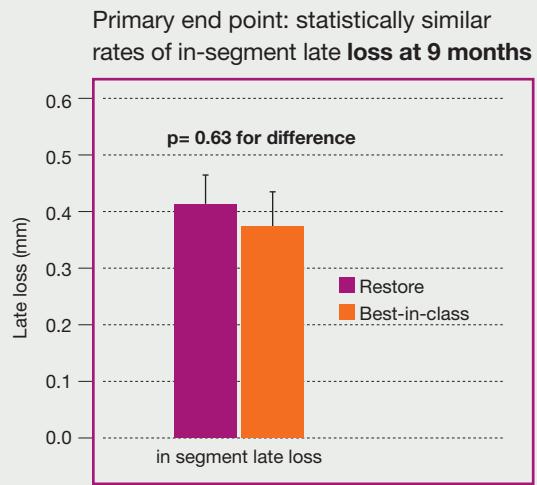
RESTORE SVD China: RESTORE® is a proven equal alternative to zotarolimus-eluting stent in patients with coronary small vessel lesions²



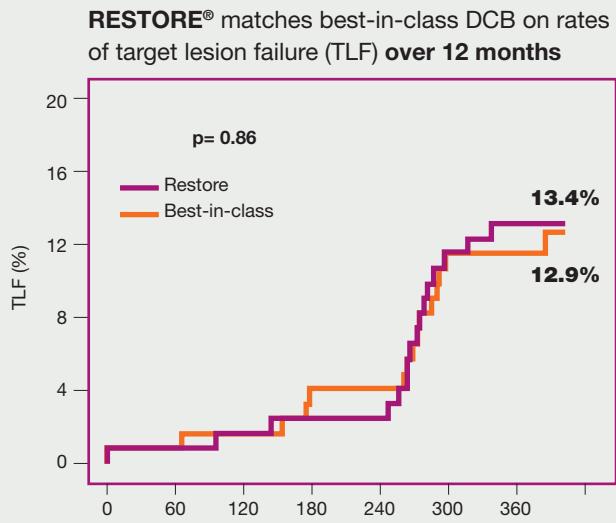
No difference in 12-months rates of target lesion failure between RESTORE and zotarolimus-eluting stent ($p=0.47$)

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 restenosis³



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



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 Ø < 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 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 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 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 SAFEPAK®

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

Dr YunDai Chen

- Locally delivered 3 $\mu\text{g}/\text{mm}^2$ 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

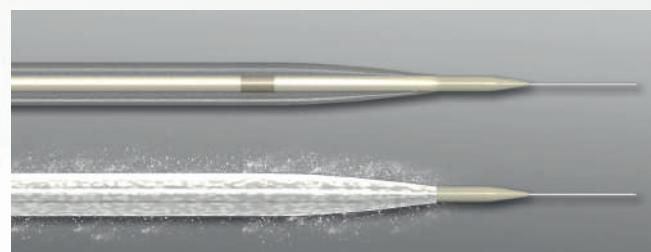
No need for a loading tool

- 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 SAFEPAK® 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>.
- ⁴ 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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