

# APERTO<sup>®</sup> OTW

Paclitaxel releasing hemodialysis  
shunt balloon dilatation catheter  
**Specifically designed for AVF stenosis**



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

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



Life deserves the best

**APERTO® OTW:** Paclitaxel releasing hemodialysis shunt balloon dilatation catheter **specifically designed for AVF stenosis**

*APERTO® OTW was developed specifically to solve unmet clinical needs in treatment of hemodialysis access stenosis and recanalization of AVF shunt grafts.*

**Variety of shaft and balloon sizes** for maximal adaptability to different stenosis situations

- **Up to 20 bar** balloon pressure for long-term patency.
- **40 cm shaft** for treatment of native and prosthetic AVF stenosis.
- **Up to 10 mm, 80 cm long shaft** to reach and treat central venous stenosis.

# APERTO® OTW: Clinically confirmed, excellent long-term rates of freedom from restenosis for extended dialysis access survival<sup>1</sup>

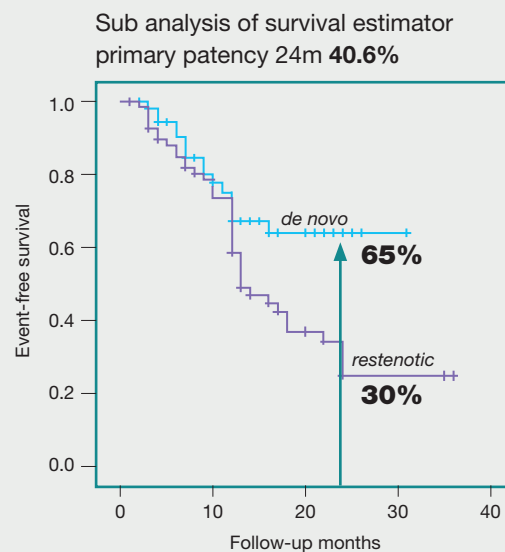
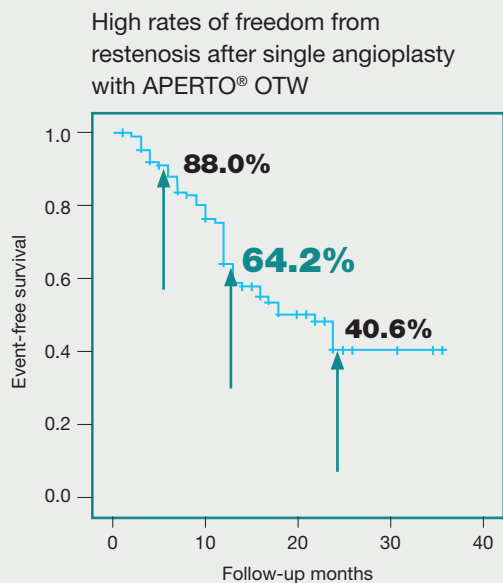
*“Thoughtful use of various endovascular techniques can improve access longevity and patients’ quality of life.”<sup>2</sup>*

Data from 200 patients and 311 angioplasty procedures<sup>1</sup> confirm:

- Single angioplasty procedures have achieved **64%** patency rates at 12 months and 41% at 24 months
- APERTO® OTW is successful with both autogenous and prosthetic vascular access

“DCB should not be a second option, but first line treatment for all AVF stenosis”  
Prof. Matteo Tozzi

## APERTO® OTW Italian Registry results



<sup>1</sup>Tozzi M. et al. “Drug-coated balloon angioplasty in failing haemodialysis AV shunts: 12-month outcomes in 200 patients from the Aperto Italian registry”, *Journal of Vascular Access JVA* 2018, in press.

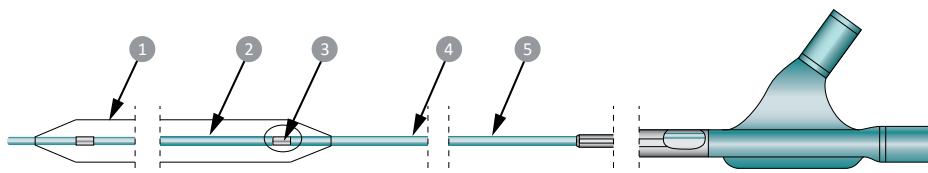
<sup>2</sup>Horikawa M, Quencer KB. “Central Venous Interventions”, *Tech Vasc Interv Radiol*. 2017 Mar;20(1):48-57.

## Technical Data

Drug releasing balloon	
Shaft material	Polyamide
Balloon material	Polyamide
Usable catheter length	40 cm, 80 cm for 9 mm and 10 mm
Max. recommended guidewire	0.035"
Tip length	5.0 mm
Rated burst pressure	From 12 bar to 20 bar (see table below)
Nominal pressure	12 bar for Ø 5.00 mm - 8.00 mm 6 bar for Ø 9.00 mm - 10.00 mm
Introducer sheath size	6F for Ø 5.00 mm - 6.00 mm 7F for Ø 7.00 mm - 10.00 mm

Drug coating technology	
Drug	Paclitaxel
Drug dose	3.0 µg/mm <sup>2</sup>
Drug coating formulation	0.1 µm nanocrystals
Delivery matrix	SAFEPAX®
Coated area	Cylindrical section of the balloon, exceeding the proximal and distal markers

## Components and materials



1. 0.035 PTA balloon Polyamide
2. Distal single lumen hypotube
3. Marker band embedded
4. Hydrophilic coated middle shaft
5. Proximal shaft Polyamide OTW

## Ordering Information

Balloon length (mm)	Balloon Ø (mm)					
	5.00 mm	6.00 mm	7.00 mm	8.00 mm	9.00 mm	10.00 mm
20 mm	APS 5.00-20 OTW	APS 6.00-20 OTW	APS 7.00-20 OTW	APS 8.00-20 OTW	APL 9.00-20 OTW	APL 10.00-20 OTW
40 mm	APS 5.00-40 OTW	APS 6.00-40 OTW	APS 7.00-40 OTW	APS 8.00-40 OTW	APL 9.00-40 OTW	APL 10.00-40 OTW
60 mm	APS 5.00-60 OTW	APS 6.00-60 OTW	APS 7.00-60 OTW	APS 8.00-60 OTW	APL 9.00-60 OTW	APL 10.00-60 OTW

20 bar RBP | 18 bar RBP | 12 bar RBP

## TECHNOLOGY

# The Paclitaxel Matrix of the Future

Powered by SAFEPAX® Technology: The 3<sup>rd</sup> generation, unique paclitaxel matrix system with the smallest particles and highest coating stability on the market\*

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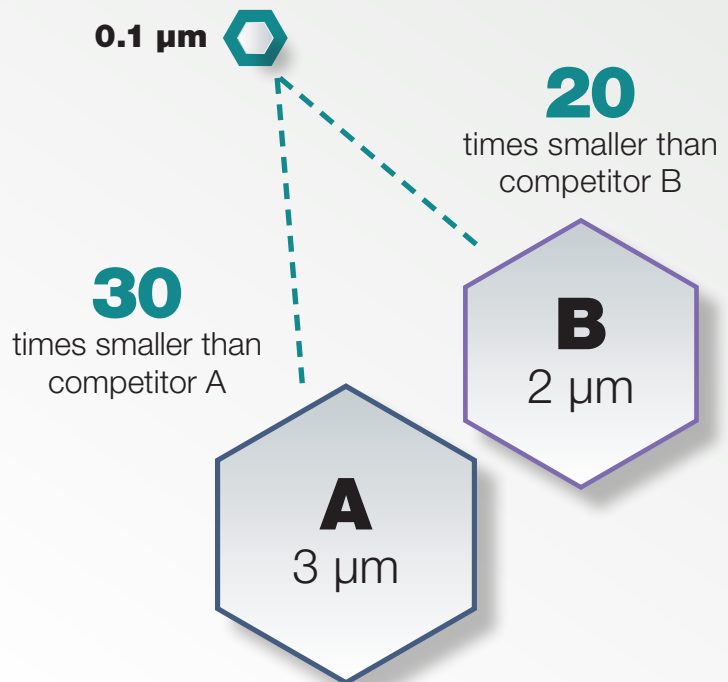


**Locally delivered 3 µg/mm<sup>2</sup> paclitaxel dose** for consistent inhibition of neointimal proliferation without compromising safety

**Virtually loss-less matrix** of invisibly small 0.1 µm paclitaxel particles for improved homogeneity of drug transfer

**Proprietary ammonium salt solution excipient** for minimal drug loss during introduction to target site; reliable drug release and transfer into the vessel wall; low surface friction; consistent smoothness and minimised risk of dissection

## Size matters



\* *Cardionovum data on file*



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