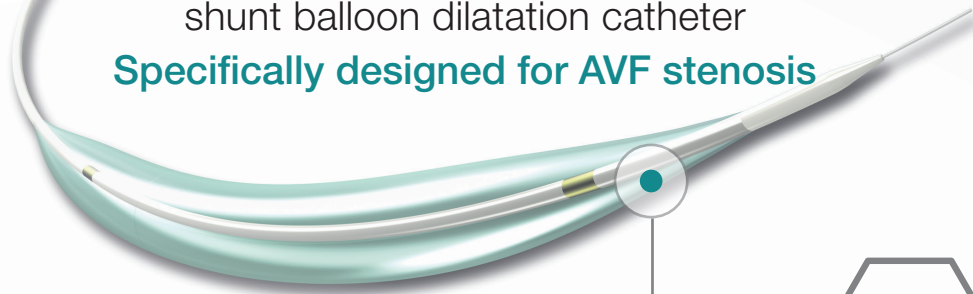


APERTO[®] OTW

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



Powered by SAFEPAX[®] Technology

The 3rd generation, unique paclitaxel matrix
system with the highest coating stability
on the market

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 survival¹

“Thoughtful use of various endovascular techniques can improve access longevity and patients’ quality of life.”²

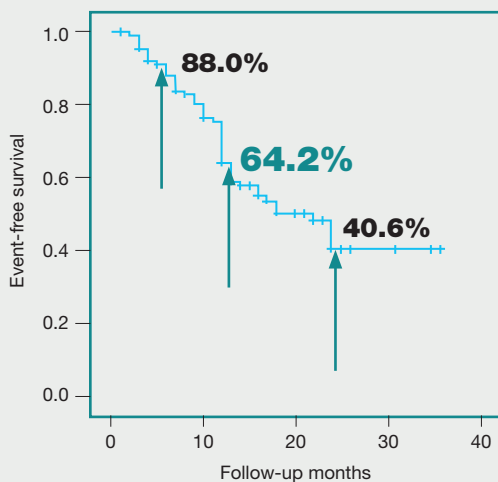
Data from 200 patients and 311 angioplasty procedures¹ confirm:

- 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

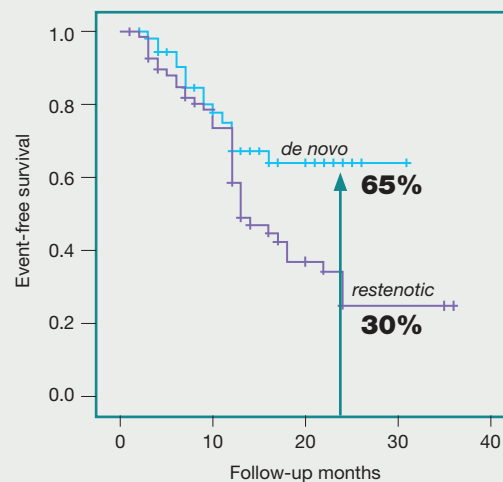
“DCB should not be a second option, but first line treatment for all AVF stenosis”
Prof. Matteo Tozzi

APERTO® OTW Italian Registry results

High rates of freedom from restenosis after single angioplasty with APERTO® OTW



Sub analysis of survival estimator primary patency 24m **40.6%**



¹Tozzi 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.

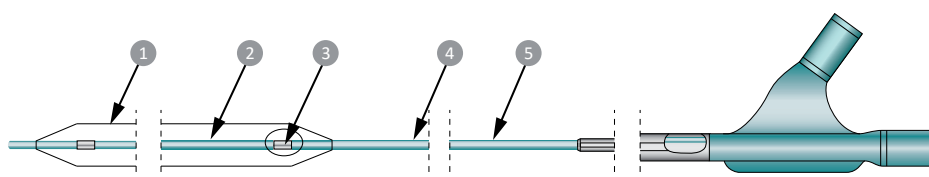
²Horikawa M, Quencer KB. “Central Venous Interventions”, *Tech Vasc Interv Radiol.* 2017 Mar;20(1):48-57.

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 ² |
| Delivery matrix | SAFEPA [®] |
| 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 3rd generation, unique paclitaxel matrix system with the highest coating stability on the market*

Powered by

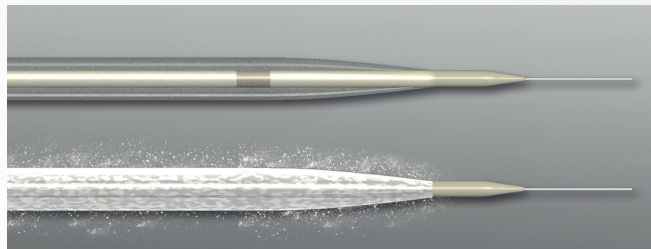


Locally delivered 3 µg/mm² paclitaxel dose for consistent inhibition of neointimal proliferation without compromising safety

Virtually loss-less matrix 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

Stable vs Unstable



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

* *Cardionovum data on file*



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