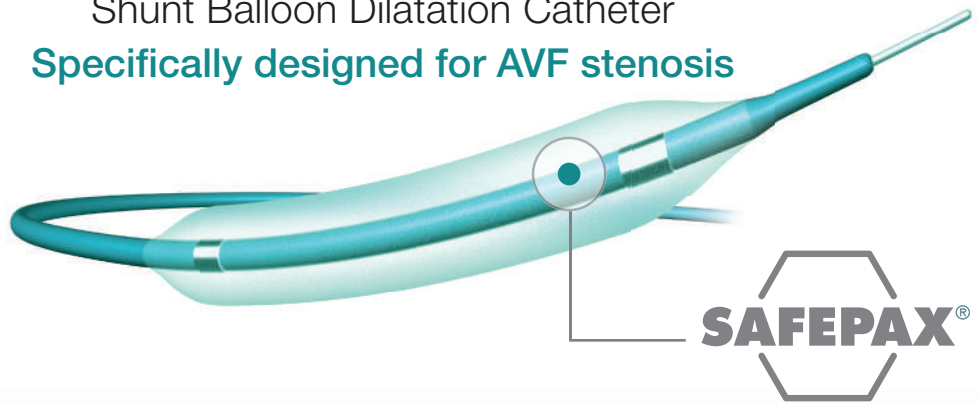


APERTO® OTW

High-Pressure Paclitaxel Releasing Hemodialysis
Shunt Balloon Dilatation Catheter
Specifically designed for AVF stenosis



Powered by SAFEPAX® Technology
The 3rd generation, unique amorphous
paclitaxel matrix system with the highest
coating stability on the market

APERTO® OTW: High-Pressure 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 and 80 cm shaft lengths** for the treatment of native and prosthetic stenosis.
- ◆ **Now available** up to 12 mm balloon diameter.

APERTO® OTW

The Paclitaxel Matrix of the Future

Powered by SAFEPAX® technology: the 3rd generation, unique, virtually loss-less matrix.



Locally delivered 3 $\mu\text{g}/\text{mm}^2$ paclitaxel dose to **prevent restenosis and neointimal proliferation** without compromising safety.

Proprietary ammonium salt solution excipient for **minimal wash-off** during introduction to target site and **drug release** into the vessel wall.

Amorphous coating for an **homogeneous** and **stable** drug layer on the balloon's surface with a **minimal mass effect**.

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*

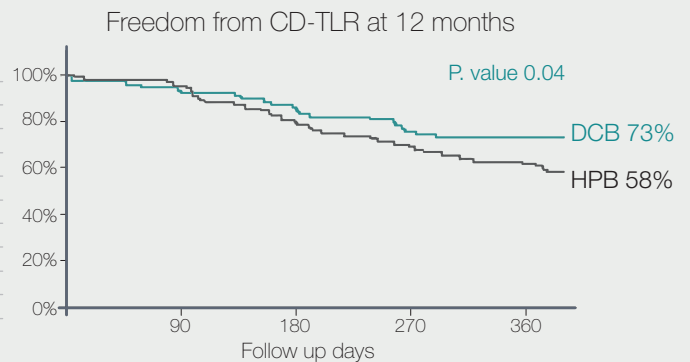
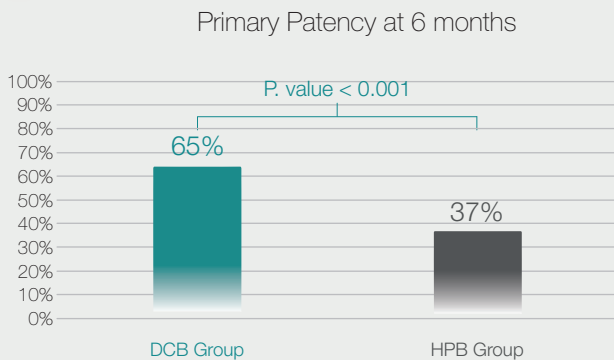
APERTO® OTW: Clinical evidences and results

APERTO® OTW Randomized Clinical Trial Results¹

APERTO® OTW vs High-Pressure balloon and 90% of De-Novo lesions

Data from 161 patients showed APERTO®'s statistical superiority in:

- Primary Patency at 6 months equal to **65%** rather than 37% of the HPB group;
- Freedom from CD-TLR at 12 months equal to **73%** rather than 58% in the HPB group.

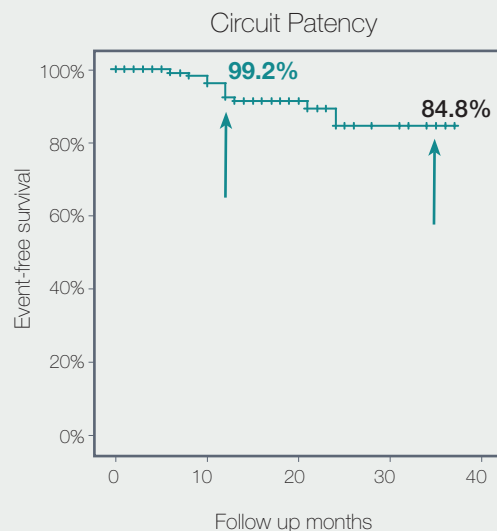
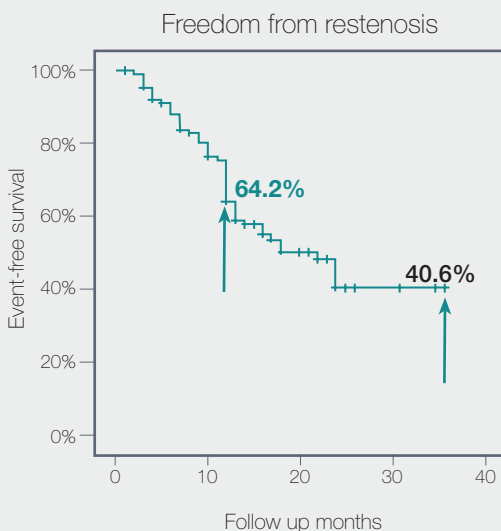


APERTO® OTW Italian Registry results²

Evaluation of APERTO® OTW in arteriovenous grafts and arteriovenous fistulas

Data from 200 patients and 311 angioplasty procedures confirmed:

- APERTO®'s **freedom from restenosis** after single angioplasty with rates equal to **64.2%** at 12 months and **40.6%** at 36 months;
- APERTO®'s **circuit patency** including multiple angioplasty with rates of **99.2%** at 12 months and **84.8%** at 36 months



¹ Yanqi Y. et al., "Efficacy and Safety of Paclitaxel-Coated Balloon Angioplasty for Dysfunctional Arteriovenous Fistulas: A Multicenter Randomized Controlled Trial", American Journal of Kidney Diseases, Volume 78, Issue 1, 2021, Pages 19-27.e1, ISSN 0272-6386, <https://doi.org/10.1053/j.ajkd.2020.11.022>;

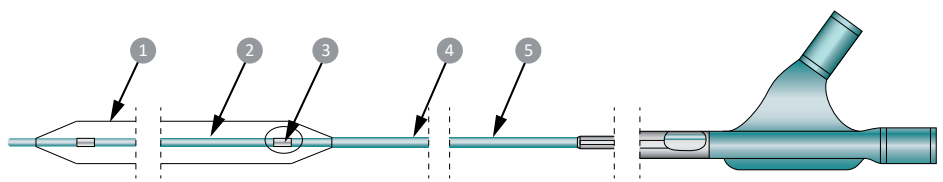
² Tozzi M. et al., "Drug-coated balloon angioplasty in failing haemodialysis arteriovenous shunts: 12-month outcomes in 200 patients from the Aperto® Italian registry", The Journal of Vascular Access. 2019;20(6):733-739. doi:10.1177/1129729819848609

Technical Data

Drug releasing balloon	
Balloon & shaft material	Polyamide
Usable catheter length	40 cm: for Ø 4.00 mm - 8.00 mm 80 cm: for Ø 9.00 mm - 12.00 mm
Max. recommended guidewire	0.035"
Tip length	5.0 mm
Rated burst pressure	20 bar: for Ø 4.00 mm - 7.00 mm 18 bar: for Ø 8.00 mm 12 bar: for Ø 9.00 mm - 10.00 mm 10 bar: for Ø 12.00
Nominal pressure	12 bar: for Ø 4.00 mm - 8.00 mm 6 bar: for Ø 9.00 mm - 12.00 mm
Introducer sheath compatibility	6 F: for Ø 4.00 mm - 6.00 mm 7 F: for Ø 7.00 mm - 10.00 mm 8 F: for Ø 12.00 mm

Drug coating technology	
Drug	Paclitaxel
Drug dose	3.0 µg/mm ²
Delivery matrix	SAFEPAX®
Coated area	Cylindrical section of the balloon, exceeding the proximal and distal markers

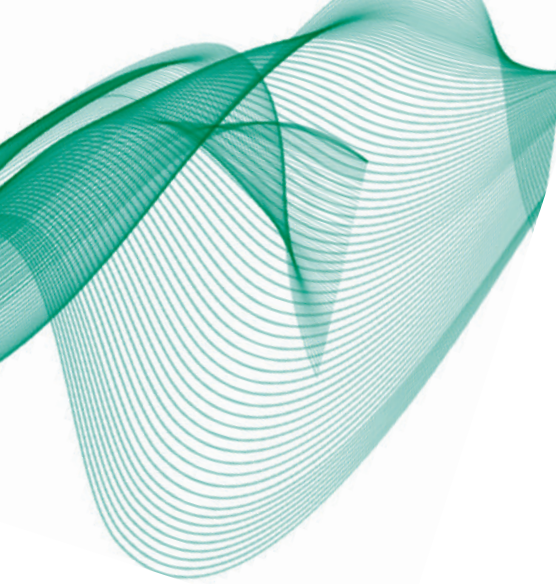
Components and materials



- 1. 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)	Catheter Shaft length 40 cm				Catheter Shaft length 80 cm			
	Balloon Ø (mm)							
	4.00 mm	5.00 mm	6.00 mm	7.00 mm	8.00 mm	9.00 mm	10.00 mm	12.00 mm
20mm	APS 4.00-20 OTW	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	-
40mm	APS 4.00-40 OTW	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	APL 12.00-40 OTW
60mm	APS 4.00-60 OTW	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	-



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APERTO® OTW:

