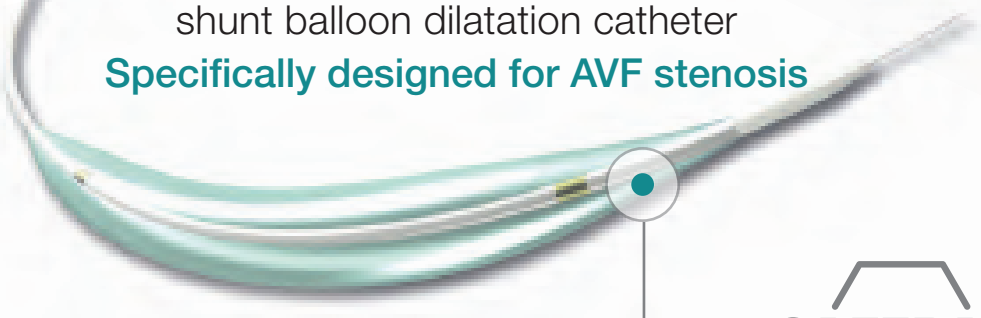
APERTO® OTW

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



SAFEPAX®

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

CARDIONOVUM®
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.

Prospective Randomised Controlled Trial Confirms Superior performance of **APERTO** vs. High-Pressure Balloon in Arteriovenous Fistulae Stenosis

"Thoughtful use of various endovascular techniques can improve access longevity and patients' quality of life."[2]

Data from 161 patient confirm[1]:

- Significantly more patients treated with APERTO were free of restenosis at 6 months (primary endpoint) compared with high-pressure balloon treatment (p<0.001; Figure 1) after D.U.S. examination.
- Target lesion primary patency rates* at 12 months (secondary end point) were **26%** higher with APERTO than with control. The difference was **statistically** significant (p=0.042; Figure 1).
- The investigators calculated that after APERTO treatment patients would maintain patency **three months longer** (262 vs 172 days) than with high-pressure balloon treatment (Figure 2).

> *The results from APERTO AVF China are aligned with what we see in the Italian registry. Together these investigations provide a high-grade evidence for APERTO in VA stenosis*
>
> *Prof. Matteo Tozzi*

APERTO AVF China trial

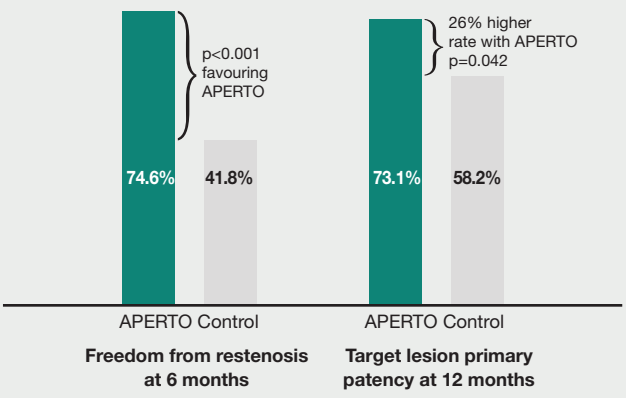


Figure 1. Main efficacy results from APERTO AVF China

How long before a patient needs a re-intervention?

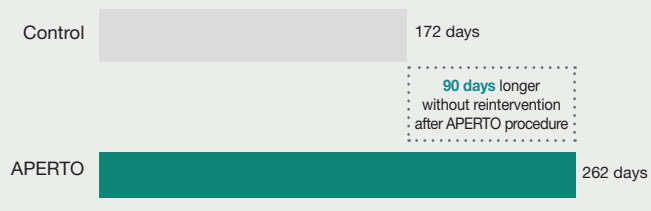


Figure 2. Average time to re-intervention after treatment with APERTO or high-pressure balloon

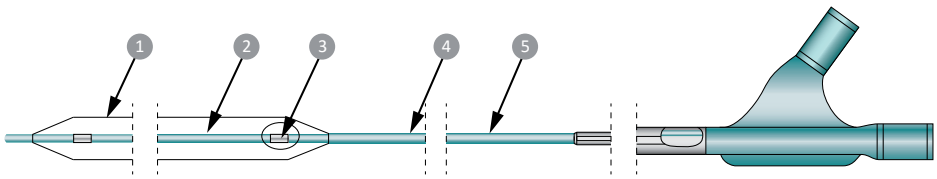
[1] **Jos van den Berg,** *CIRSE 2019.*
[2] **Horikawa M,** *Quencer KB. "Central Venous Interventions", Tech Vasc Interv Radiol. 2017 Mar;20(1):48-57.*

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 lenght	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/mm²
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	APL10.00-60 OTW

20 bar RBP | 18 bar RBP | 12 bar RBP

The Paclitaxel Matrix of the Future

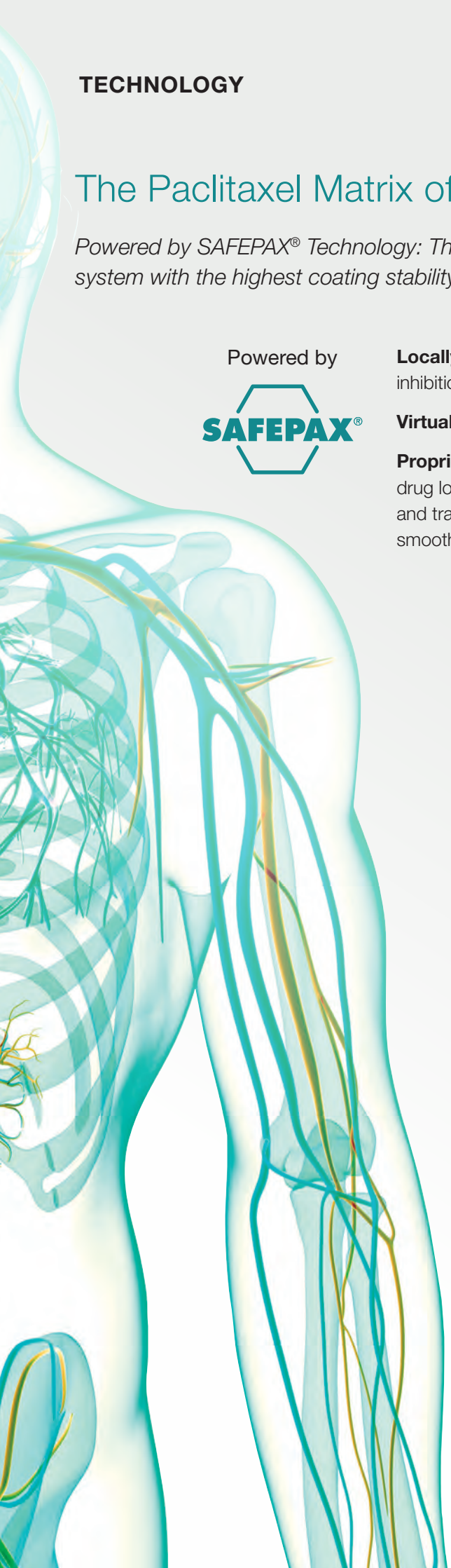
*Powered by SAFEPAX® Technology: The 3rd generation, unique paclitaxel matrix system with the highest coating stability on the market**

Powered by SAFEPAX®

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*

CARDIONOVUM®

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International Sales Office and Legal Manufacturer

CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn
Germany

Phone +49 (0) 228 - 90 90 59 - 0
Fax +49 (0) 228 - 90 90 59 - 20
E-Mail info@cardionovum.com
Web www.cardionovum.com

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