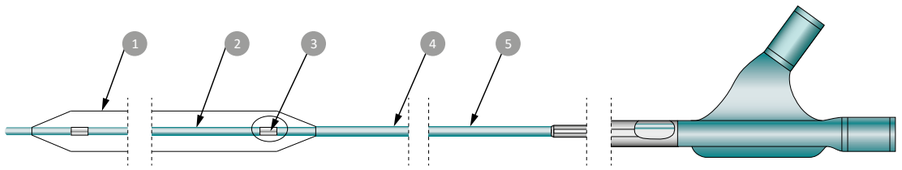
Technical Data

APERTO® OTW

Drug releasing balloon	
Shaft material	Polyamide
Balloon material	Polyamide
Usable catheter length	40 cm
Max. recommended guidewire	0.035"
Tip lenght	5.0 mm
Rated burst pressure	20 bar for Ø 5.00 mm - 7.00 mm 18 bar for Ø 8.00 mm
Nominal pressure	12 bar for Ø 5.00 mm - 8.00 mm
Introducer sheath size	6F for Ø 5.00 mm - 6.00 mm 7F for Ø 7.00 mm - 8.00 mm

Drug coating technology	
Drug	Paclitaxel
Drug dose	3.0µg/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 shaft Polyamide OTW 3) Marker band embedded
4) Hydrophilic coated middle shaft 5) Distal shaft Polyamide OTW

Ordering Information

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

*20 mm balloon length available on request

CARDIONOVUM®
Life deserves the best

International Sales Office

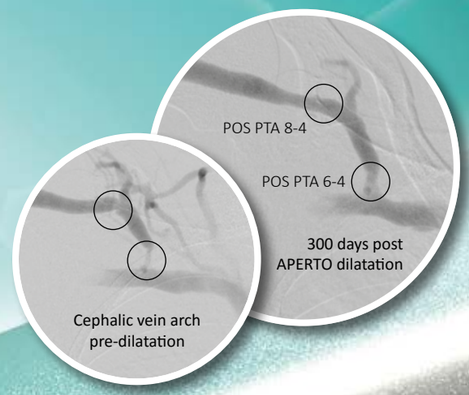
CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn
Germany

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

Legal Manufacturer

CARDIONOVUM Sp. z o.o.
ul. Panska 73
00-834 Warsaw
Poland

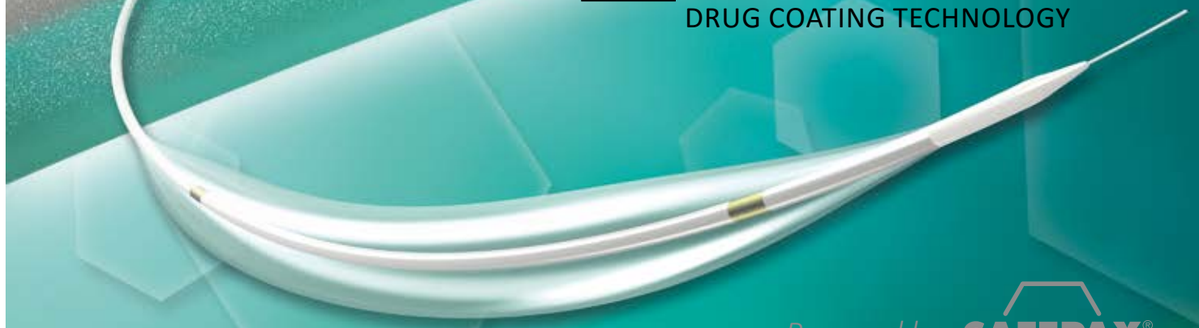
Rev.no.: AP-04014EN



APERTO®
OTW

Paclitaxel Releasing Hemodialysis Shunt Balloon Dilatation Catheter

WITH UNIQUE ‘SAFEPAX’
DRUG COATING TECHNOLOGY



Powered by SAFEPAX®

LESS SHUNT RESTENOSIS IMPROVES HEMODIALYSIS PATIENTS’ QUALITY OF LIFE!

APERTO HIGH PRESSURE SHUNT DCB protects AV fistulas and shunt grafts from early restenosis. For the prevention and successful dilatation of intimal hyperplasia.

CARDIONOVUM®
Life deserves the best

APERTO®OTW

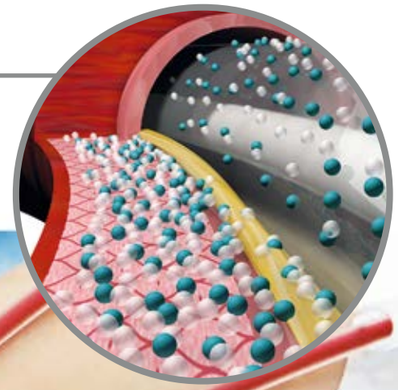
Paclitaxel Releasing Hemodialysis High Pressure Shunt Balloon Dilatation Catheter

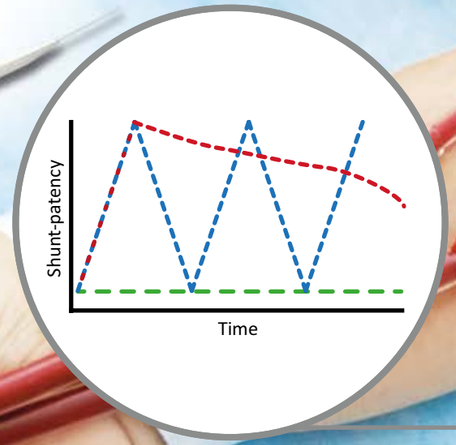
The new prohealing treatment of shunt stenosis. Long-term shunt patency with anti-proliferative vessel wall protection.

Conventional Mechanical Balloon Angioplasty	APERTO Angioplasty with Prohealing Local Drug Delivery
Trauma	Trauma
Inflammation	Anti-Inflammatory Action !
Neointimal Hyperplasia	Anti-Proliferative Action !
Restenosis	Healing !
Short-Term Repeat Intervention	Long-Term Shunt Patency !
High Patient Cost	Cost Saving !

Unsurpassed invisibly small and translucent PTX particles.

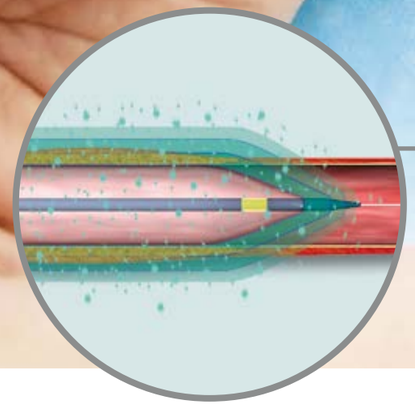
SAFEPAX, the coating used for the APERTO OTW is safely kept on the balloon during the catheter preparation, which guarantees clean and safe working conditions for physicians as no particles are lost prior to insertion of the DCB.





Long-term shunt-patency.

- Patency after conventional therapies
- Patency after DCB-high pressure dilatation
- Minimal required patency



Paclitaxel release from balloon surface for clinically effective PTX transfer into vessel wall.

APERTO optimizes the long-term anti-proliferative vessel wall protection, combined with a anti-inflammatory healing effect.

APERTO OTW promises a prolonged dialysis access survival.

Less shunt re-interventions for a better patient life quality.

Shunt restenosis represents a common threat to the function of arteriovenous fistulas (AVFs) and shunt grafts in patients on hemodialysis. Patients often develop a consecutive neointimal hyperplasia in hemodialysis access vessels as well as along the needle puncture site.

The new APERTO OTW Paclitaxel releasing, high pressure balloon dilatation catheter provides a dual shunt treatment quality for the prevention and dilatation of intimal hyperplasia. AVF or PTFE shunt graft venous outflow lesions can be treated very successfully by the new APERTO OTW leading to a substantial reduction of hemodialysis shunt restenosis, for a prolonged dialysis access survival.

APERTO OTW provides 2 x vessel protection!

Anti-inflammatory & Anti-proliferative!

Hemodialysis vessel stenosis is typically treated by using a high pressure PTA dilatation balloon or alternatively a cutting balloon, which is applied to cut into highly calcified and fibrotic lesions. By applying the APERTO OTW, your shunt balloon dilatation is optimized by a 2 fold clinically important vessel wall protection.

1 APERTO OTW Study, Groene Hart Hospital , Gouda, Prof. Pattynama, MD, PhD: A randomized trial of APERTO Paclitaxel-eluting shunt dilatation catheter compared to POBA in AV-fistula.

2 APERTO OTW Study, University of Insubria, Varese (Italy), Dr. M.Tozzi et al.: Initial expirience with a new drug-eluting balloon for the treatment of critical shunt stenosis.