

 **CARDIONOVUM®**
Life deserves the best



LEGFLOW®

014 / 035

A UNIQUE PACLITAXEL ELUTING
PTA BALLOON DILATATION CATHETER
MAKES THE DIFFERENCE.

**Leading the Future of Drug-Eluting
Endovascular Balloon Technologies.**

 **CARDIONOVUM GmbH**
Am Bonner Bogen 2
53227 Bonn
Germany
Phone: +49 (0) 228 - 90 97 22 69
Fax: +49 (0) 228 - 18 09 19 09
E-Mail: info@cardionovum.eu
Web: www.cardionovum.eu

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

 **CARDIONOVUM Inc.**
29229 Canwood Street Suit 202,
Agoura Hills, CA 91301
USA

 **CARDIONOVUM®**
Life deserves the best

GRUPO
LEVBETH

LEVBETH™
MEDICAL 

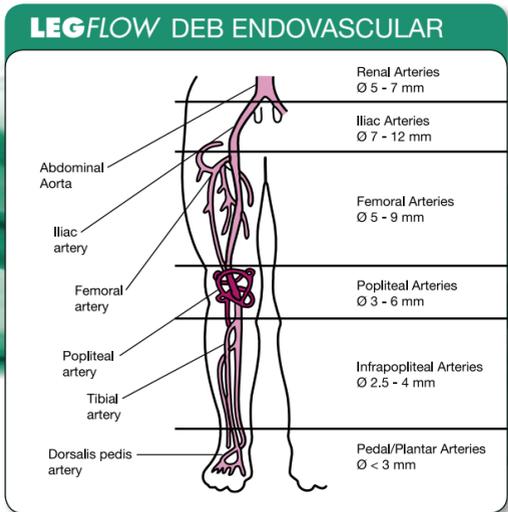
 (55) 6719 3014  info@levbethmedical.com



LEGFLOW[®]

PATIENTS WITH LESS RESTENOSIS
AFTER PERIPHERAL INTERVENTIONS.

A superior DEB technology makes an important clinical difference. A stable nano-crystalline PTX medication coating prevents Paclitaxel debonding during catheter manipulation for flawless implementation!



Groundbreaking SFA & BTK Revascularization Efficacy.

Through the highly effective antiproliferative supply of Paclitaxel to the target area during the angioplasty, LEGFLOW affords the most successful clinical option for the revascularization of the femoropopliteal arterial lesions. Amongst other advantages, the mitotic inhibitor, Paclitaxel suppresses the proliferation and migration of vascular smooth muscle cells (VSMC), fibroblasts and inflammatory cells. The ideal, easy-to-use LEGFLOW balloon catheter technology certifies a maximum MLD result and a significant long-term reduction in restenosis rates after the treatment.

The LEGFLOW DEB represents a durable, successful treatment for critical limb ischemia (CLI) and diabetic foot syndrome (DFS). Utilizing longer, Paclitaxel-eluting LEGFLOW balloon catheters to treat arterial lesions below the knee in particular, affords significantly superior clinical results when compared to stent implantations.

LEGFLOW drug-eluting angioplasty of

- ➔ SFA de novo and restenotic lesions
- ➔ Popliteal de novo and restenotic lesions
- ➔ BTK de novo and restenotic lesions

LEGFLOW[®]

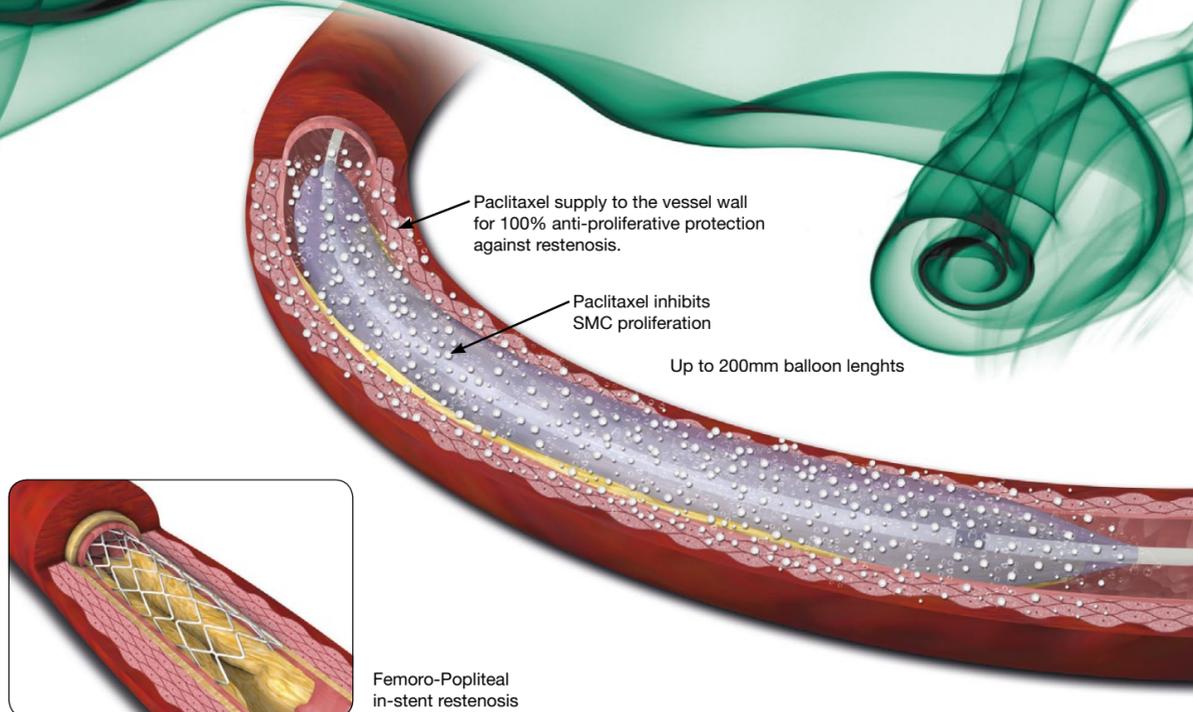
FOR LONG-TERM
RESTORATION
OF BLOOD FLOW.

For treatment of SFA – Superficial Femoral Artery

Treating peripheral artery disease (PAD) in the superficial femoral artery (SFA) is a difficult challenge. The anatomy is very dynamic and contains complex lesions, but also patient comorbidities such as diabetes require the clinically most-effective treatment. The new LEGFLOW Paclitaxel-eluting peripheral balloon dilatation provides the SFA with 100% anti-proliferative vessel wall treatment and promises long-term vessel patency.

For treatment of BTK – Below-The-Knee

The rate of recurrent stenosis after PTA and stenting is higher in the below-the-knee area than in femoropopliteal procedures. The absence of metal struts makes the LEGFLOW balloon dilatation suitable for treating long lesions, especially in small diameter vessels and areas in which flexion and compression of the stent may occur and result in stent fractures, particularly in the below-the-knee area. The clinically superior LEGFLOW drug-eluting lesion dilatation ensures complete vessel wall protection while the highly effective anti-proliferative drug of Paclitaxel minimizes the need for peripheral stenting, especially in small vessels.

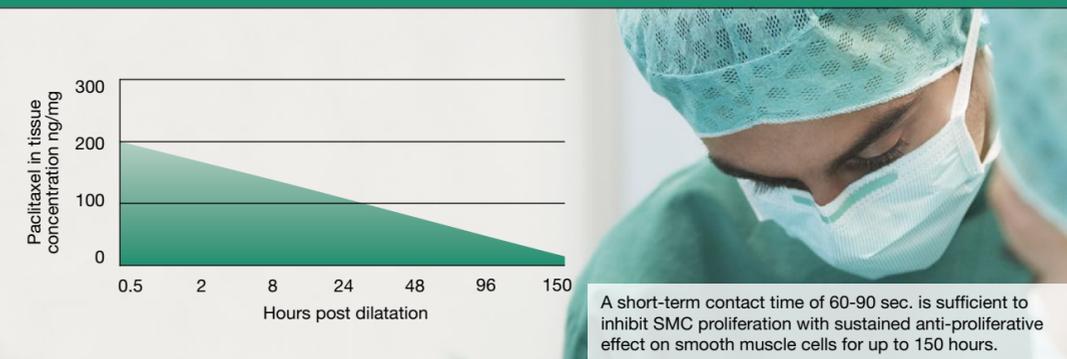


LEGFLOW®

THE MOST RELIABLE DEB DRUG COATING QUALITY.

For the highest patient safety and clinical efficacy!

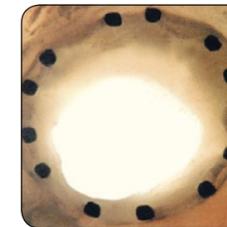
LEGFLOW BIOAVAILABILITY IN THE ARTERIAL TISSUE.



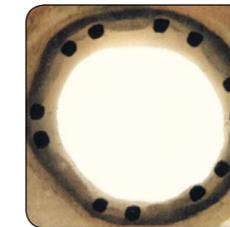
* Preclinical study results confirm a successful drug transfer into the vascular tissue, showing sustained drug effect up to 28 days. LEGFLOW treated arteries show no noticeable coating-induced micro emboli!
Source: R. Virmani MD, CV-PATH Institute, Gaithersbourg USA

LEGFLOW The key technology to clinical success.

The LEGFLOW DEB Drug-Coating Quality represents a new DEB generation and makes a clinically important difference compared to other DEBs coatings. A unique nanocrystalline Paclitaxel (PTX) drug formulation of 3.0µg of Paclitaxel per mm² of balloon surface is embedded underneath the surface as well as inside its newly designed, shelloic-acid drug-release matrix, which is coated onto the balloon surface. No white PTX is visible. First-generation DEBs were simply coated with a hydrophilic, water-soluble drug excipient, such as contrast media / PTX mixtures or other hydrophilic drug carriers. They provided much less surface-coating stability and functional integrity, as experienced in daily clinical practice.



Uncoated balloon dilatation

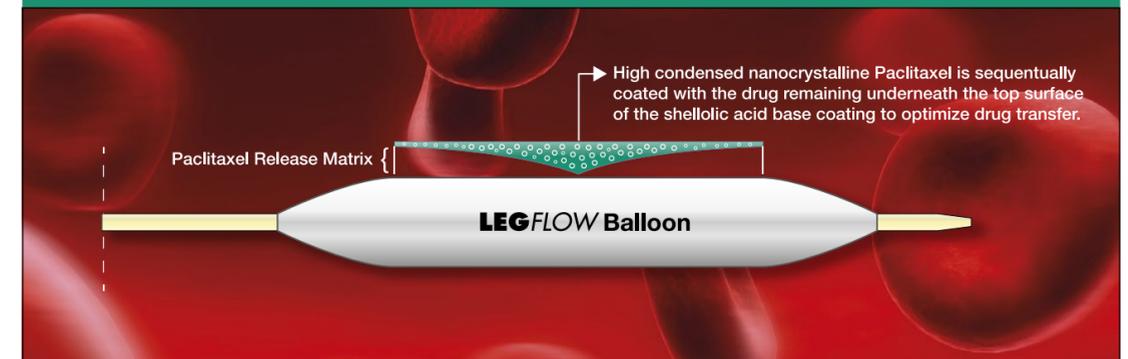


LEGFLOW: Significantly reduced in-stent neointima in porcine coronary artery



1. "Stable" LEGFLOW DEB PTX coating technology
2. "Unstable" DEB PTX coating showing PTX particles on top of the balloon coating surface

LEGFLOW PTX-BOLUS-DRUG COATING TECHNOLOGY.



* Preclinical study results confirm the clinically effective condensed PTX release from its carrier matrix and facilitates intra-cellular drug uptake and retention.
Source: R. Virmani MD, CV-PATH Institute, Gaithersbourg USA

"Unstable" balloon surface coatings cause PTX crystallization to form outside of the drug-release matrix on top of the coating surface, visible as unprotected white PTX particles, which easily detach. The LEGFLOW DEB Drug-Coating Technology protects both the physician and the patient against toxic PTX particles falling or being wiped off the balloon surface during catheter manipulation. Moreover, the "stable" LEGFLOW DEB Coating does not cause any significant micro emboli during DEB catheter positioning at the lesion site, and/or balloon dilatation ("Drug Wash Off Effect"). The safe PTX-protected balloon surface coating avoids the otherwise commonly experienced potential risk of uncontrollable drug loss and contamination with Paclitaxel in the cath lab environment.



LEGFLOW – 0.014“ Over the wire PTA - Technical Data	
Shaft Material	Polyamide
Balloon Material	Polyamide
Usable Catheter Length	150 cm
Max. Recommended Guidewire	0.014"
Tip Length	3.5 mm
Rated Burst Pressure	14 bar
Introducer Sheat size	4 F
Paclitaxel Coating	3.0µg/mm ²

LEGFLOW – 0.035“ Over the wire PTA - Technical Data	
Shaft Material	Polyamide
Balloon Material	Polyamide
Usable Catheter Length	135 cm or 80 cm (S)
Max. Recommended Guidewire	0.035"
Tip Length	5.0 mm
Rated Burst Pressure	14 bar
Introducer Sheat size	5 F Ø 4.0-6.0 mm 6 F Ø 6.0 > 100 mm balloon length 6 F Ø 7.0 to 8.0 mm 7 F Ø 9.0 to 10.0 mm
Paclitaxel Coating	3.0µg/mm ²
S - Ordersymbol	80 cm Catheter Length

Order Information

LEGFLOW OTW 0.035“



Balloon Length (mm)	Balloon Ø (mm) OTW 0.035“ Catheter Length 800 mm or 1350 mm						
	4.0 mm	5.0 mm	6.0 mm	7.0 mm	8.0 mm	9.0 mm	10.0 mm
20 mm	L 4.0-20 OTW LS 4.0-20 OTW	L 5.0-20 OTW LS 5.0-20 OTW	L 6.0-20 OTW LS 6.0-20 OTW	L 7.0-20 OTW LS 7.0-20 OTW	L 8.0-20 OTW LS 8.0-20 OTW	L 9.0-20 OTW LS 9.0-20 OTW	L 10.0-20 OTW LS 10.0-20 OTW
40 mm	L 4.0-40 OTW LS 4.0-40 OTW	L 5.0-40 OTW LS 5.0-40 OTW	L 6.0-40 OTW LS 6.0-40 OTW	L 7.0-40 OTW LS 7.0-40 OTW	L 8.0-40 OTW LS 8.0-40 OTW	L 9.0-40 OTW LS 9.0-40 OTW	L 10.0-40 OTW LS 10.0-40 OTW
60 mm	L 4.0-60 OTW LS 4.0-60 OTW	L 5.0-60 OTW LS 5.0-60 OTW	L 6.0-60 OTW LS 6.0-60 OTW	L 7.0-60 OTW LS 7.0-60 OTW	L 8.0-60 OTW LS 8.0-60 OTW	L 9.0-60 OTW LS 9.0-60 OTW	L 10.0-60 OTW LS 10.0-60 OTW
80 mm	L 4.0-80 OTW LS 4.0-80 OTW	L 5.0-80 OTW LS 5.0-80 OTW	L 6.0-80 OTW LS 6.0-80 OTW	L 7.0-80 OTW LS 7.0-80 OTW	L 8.0-80 OTW LS 8.0-80 OTW	-	-
100 mm	L 4.0-100 OTW LS 4.0-100 OTW	L 5.0-100 OTW LS 5.0-100 OTW	L 6.0-100 OTW LS 6.0-100 OTW	L 7.0-100 OTW LS 7.0-100 OTW	L 8.0-100 OTW LS 8.0-100 OTW	-	-
120 mm	L 4.0-120 OTW LS 4.0-120 OTW	L 5.0-120 OTW LS 5.0-120 OTW	L 6.0-120 OTW LS 6.0-120 OTW	L 7.0-120 OTW LS 7.0-120 OTW	L 8.0-120 OTW LS 8.0-120 OTW	-	-
150 mm	L 4.0-150 OTW LS 4.0-150 OTW	L 5.0-150 OTW LS 5.0-150 OTW	L 6.0-150 OTW LS 6.0-150 OTW	L 7.0-150 OTW LS 7.0-150 OTW	L 8.0-150 OTW LS 8.0-150 OTW	-	-

S - Ordersymbol: 80 cm Catheter Length

LEGFLOW OTW 0.014“

Balloon Length (mm)	Balloon Ø (mm) OTW 0.014“ Catheter Length 1500 mm			
	2.0 mm	2.5 mm	3.0 mm	3.5 mm
20 mm	-	L 2.5-20 OTW	L 3.0-20 OTW	L 3.5-20 OTW
40 mm	L 2.0-40 OTW	L 2.5-40 OTW	L 3.0-40 OTW	L 3.5-40 OTW
60 mm	-	-	-	-
80 mm	L 2.0-80 OTW	L 2.5-80 OTW	L 3.0-80 OTW	L 3.5-80 OTW
100 mm	-	-	-	-
120 mm	L 2.0-120 OTW	L 2.5-120 OTW	L 3.0-120 OTW	L 3.5-120 OTW
150 mm	L 2.0-150 OTW	L 2.5-150 OTW	L 3.0-150 OTW	L 3.5-150 OTW
200 mm	-	-	-	-

LEGFLOW RX 0.014“

Balloon Length (mm)	Balloon Ø (mm) RX-Rapid Exchange 0.014“				
	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm
20 mm	L 2.0-20	L 2.5-20	L 3.0-20	L 3.5-20	L 4.0-20
40 mm	L 2.0-40	L 2.5-40	L 3.0-40	L 3.5-40	L 4.0-40
60 mm	L 2.0-60	L 2.5-60	L 3.0-60	L 3.5-60	L 4.0-60
80 mm	L 2.0-80	L 2.5-80	L 3.0-80	L 3.5-80	L 4.0-80
100 mm	L 2.0-100	L 2.5-100	L 3.0-100	L 3.5-100	L 4.0-100
120 mm	L 2.0-120	L 2.5-120	L 3.0-120	L 3.5-120	L 4.0-120
150 mm	L 2.0-150	L 2.5-150	L 3.0-150	L 3.5-150	L 4.0-150
200 mm	L 2.0-200	L 2.5-200	-	-	-