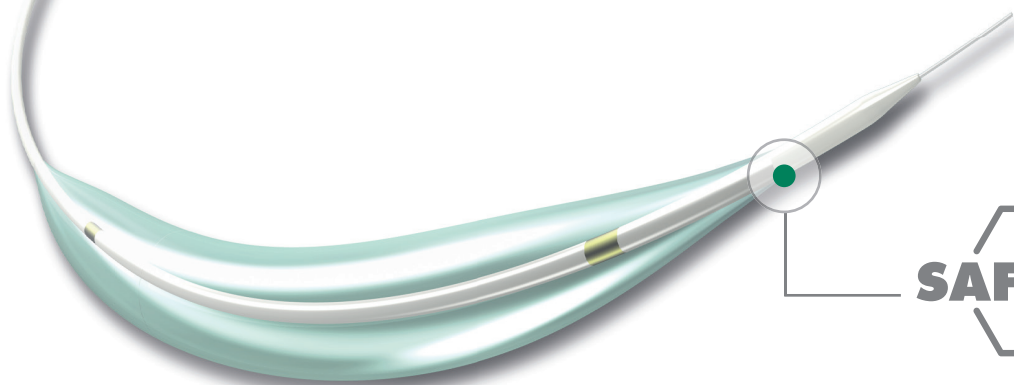


LEGFLOW[®] RX/OTW

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter
Specifically designed for SFA & BTK complex lesions



Powered by SAFEPAX[®] Technology

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

Locally delivered 3 µg/mm² 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**.



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

- **Widest choice without compromise**, with 163 codes in total;
- Elastic coating ensures **excellent deliverability** and **easy crossing of complex lesions**;
- **Excellent pushability** and **kink resistance** thanks to the unique catheter design.

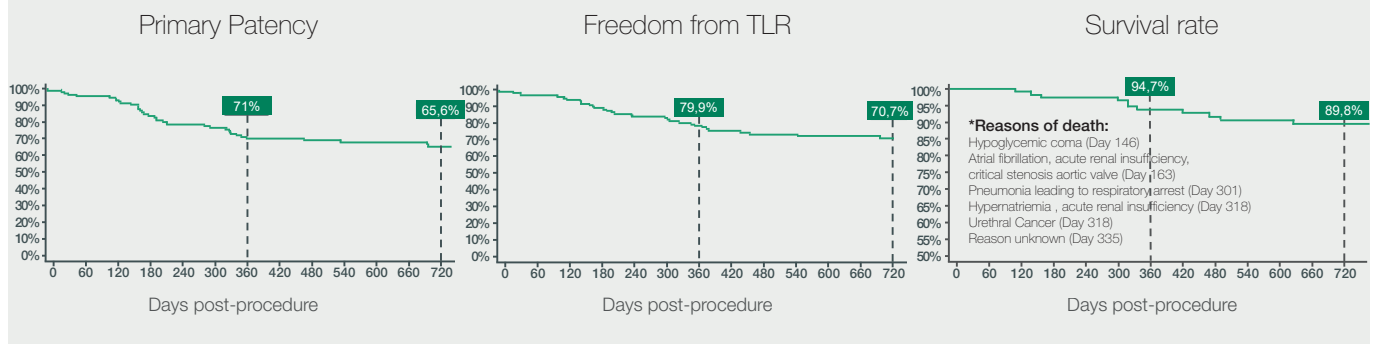
LEGFLOW® RX/OTW: Real life patients' clinical outcomes

ReFlow Study: International multicenter registry in long and complex lesions¹

LEGFLOW®'s performances in the treatment of long (>20 cm) TASC C&D lesions

Clinical results demonstrated great LEGFLOW®'s safety and efficacy showing:

- 🟩 **Primary Patency: 71,1%** at 12 months and **65,6%** at 24 months;
- 🟩 **Freedom from TLR: 79,9%** at 12 months and **70,7%** at 24 months;
- 🟩 **Survival rate*** of **94,7%** at 12 months and **89,8%** at 24 months.



LegDEB Study: International multicenter registry in real life population²

LEGFLOW®'s advantages in complex patients with femoropopliteal lesions

Clinical outcomes confirmed LEGFLOW®'s excellent safety and efficacy in the treatment of endovascular lesions in all-comer settings. Results showed:

- 🟩 **Primary Patency of 81,1%** and **Freedom from TLR of 83,3%** at 12 months;
- 🟩 Advantages of in terms of **efficacy at 12 months** in the treatment of femoropopliteal obstructions in **different clinical settings**.



¹ Dr. Bosiers data presented @ Charing Cross 2021

² Stabile E. et al., Journal of Endovascular Therapy 2019, Vol.26(1) 26-30.

Technical Data

A total of 163 options with:

- 0.035", 0.018" and 0.014" guidewires compatibility;
- Balloon's diameters from 2.00 to 10.00 mm;
- Balloon's lengths from 20 to 200 mm;

LEGFLOW® RX/OTW	OTW – 0.035"	OTW – 0.018"	OTW – 0.014"	RX – 0.014"
Type	OTW	OTW	OTW	RX
Shaft material	Polyamide	Polyamide	Polyamide	Stainless Steel
Balloon Material	Polyamide	Polyamide	Polyamide	Polyamide
Usable catheter length	80 or 135 cm	150 cm	150 cm	140 cm
Max. Recomm. Guidewire	0.035"	0.018"	0.014"	0.014"
Tip Length	5.0 mm	5.0 mm	3.5 mm	5.0 mm
Rated Burst Pressure	<p>16 bar Ø 4.0 mm all lengths; Ø 5.0 and 6.0 mm with lengths 20-60 mm;</p> <p>14 bar Ø 5.0 and 6.0 mm with lengths 80-150 mm; Ø 7.0 and 8.0 mm with lengths 20-60 mm;</p> <p>12 bar Ø 7.0 and 8.0 mm with lengths 80-150 mm; Ø 9.0 and 10.00 mm with lengths 20-60 mm;</p>	<p>14 bar Ø 2.0 mm all lengths; Ø 3.0-6.0 mm with lengths 40-80 mm; Ø 7.0 mm with 40 mm length</p> <p>12 bar Ø 3.0-6.0 mm with lengths > 80 mm;</p>	<p>16 bar Ø 2.0-2.5 mm with lengths 40-150 mm</p> <p>14 bar Ø 3.0-3.5 mm with lengths 40-150 mm;</p>	<p>16 bar Ø 2.0-3.5 mm with lengths 20-40 mm; Ø 4.0 mm with 20 mm length;</p> <p>14 bar Ø 2.0-2.5 mm with lengths 60-200 mm; Ø 3.0-3.5 mm with lengths 60-150 mm; Ø 4.0 mm with lengths 40-120 mm;</p>
Nominal Pressure	6 bar	6 bar with lengths from 100 to 150 mm; 8 bar with lengths ≤ 80 mm	6 bar	6 bar
Introducer sheath compatibility	6 F Ø 4.00 to Ø 6.00 mm 7 F Ø 7.00 to Ø 10.00 mm	4 F Ø 2.0 to 4.0 mm with all lengths; 5 F Ø 5.0 to 7.0 mm with all lengths.	4 F	5 F

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

LEGFLOW® RX/OTW

Ordering informations

LEGFLOW® OTW 0.035"

Balloon length (mm)	Balloon Ø (mm) 0.035" OTW							
	Catheter length 80 cm (LS) or 135 cm (L)							
	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	L 5.0-20 OTW	L 6.0-20 OTW	L 7.0-20 OTW	L 8.0-20 OTW	L 9.0-20 OTW	L 10.0-20 OTW	
	LS 4.0-20 OTW	LS 5.0-20 OTW	LS 6.0-20 OTW	LS 7.0-20 OTW	LS 8.0-20 OTW	LS 9.0-20 OTW	LS 10.0-20 OTW	
40 mm	L 4.0-40 OTW	L 5.0-40 OTW	L 6.0-40 OTW	L 7.0-40 OTW	L 8.0-40 OTW	L 9.0-40 OTW	L 10.0-40 OTW	
	LS 4.0-40 OTW	LS 5.0-40 OTW	LS 6.0-40 OTW	LS 7.0-40 OTW	LS 8.0-40 OTW	LS 9.0-40 OTW	LS 10.0-40 OTW	
60 mm	L 4.0-60 OTW	L 5.0-60 OTW	L 6.0-60 OTW	L 7.0-60 OTW	L 8.0-60 OTW	L 9.0-60 OTW	L 10.0-60 OTW	
	LS 4.0-60 OTW	LS 5.0-60 OTW	LS 6.0-60 OTW	LS 7.0-60 OTW	LS 8.0-60 OTW	LS 9.0-60 OTW	LS 10.0-60 OTW	
80 mm	L 4.0-80 OTW	L 5.0-80 OTW	L 6.0-80 OTW	L 7.0-80 OTW	L 8.0-80 OTW	-	-	
	LS 4.0-80 OTW	LS 5.0-80 OTW	LS 6.0-80 OTW	LS 7.0-80 OTW	LS 8.0-80 OTW	-	-	
100 mm	L 4.0-100 OTW	L 5.0-100 OTW	L 6.0-100 OTW	L 7.0-100 OTW	L 8.0-100 OTW	-	-	
	LS 4.0-100 OTW	LS 5.0-100 OTW	LS 6.0-100 OTW	LS 7.0-100 OTW	LS 8.0-100 OTW	-	-	
120 mm	L 4.0-120 OTW	L 5.0-120 OTW	L 6.0-120 OTW	L 7.0-120 OTW	L 8.0-120 OTW	-	-	
	LS 4.0-120 OTW	LS 5.0-120 OTW	LS 6.0-120 OTW	LS 7.0-120 OTW	LS 8.0-120 OTW	-	-	
150 mm	L 4.0-150 OTW	L 5.0-150 OTW	L 6.0-150 OTW	L 7.0-150 OTW	L 8.0-150 OTW	-	-	
	LS 4.0-150 OTW	LS 5.0-150 OTW	LS 6.0-150 OTW	LS 7.0-150 OTW	LS 8.0-150 OTW	-	-	

LEGFLOW® OTW 0.018"

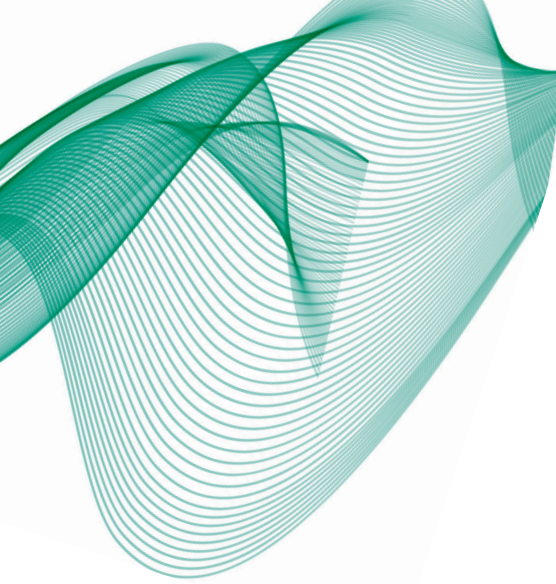
Balloon length (mm)	Balloon Ø (mm) 0.018" OTW					
	Catheter length 150 cm					
	2.0 mm	3.0 mm	4.0 mm	5.0 mm	6.0 mm	7.0 mm
40 mm	L 18 2.0-40	L 18 3.0-40	L 18 4.0-40	L 18 5.0-40	L 18 6.0-40	L 18 7.0-40
60 mm	L 18 2.0-60	L 18 3.0-60	L 18 4.0-60	L 18 5.0-60	L 18 6.0-60	-
80 mm	L 18 2.0-80	L 18 3.0-80	L 18 4.0-80	L 18 5.0-80	L 18 6.0-80	-
100 mm	L 18 2.0-100	L 18 3.0-100	L 18 4.0-100	L 18 5.0-100	L 18 6.0-100	-
120 mm	L 18 2.0-120	L 18 3.0-120	L 18 4.0-120	L 18 5.0-120	L 18 6.0-120	-
150 mm	L 18 2.0-150	L 18 3.0-150	L 18 4.0-150	L 18 5.0-150	L 18 6.0-150	-

LEGFLOW® OTW 0.014"

Balloon length (mm)	Balloon Ø (mm) 0.014" OTW			
	Catheter length 150 cm			
	2.0 mm	2.5 mm	3.0 mm	3.5 mm
40 mm	L 2.0-40 OTW	L 2.5-40 OTW	L 3.0-40 OTW	L 3.5-40 OTW
80 mm	L 2.0-80 OTW	L 2.5-80 OTW	L 3.0-80 OTW	L 3.5-80 OTW
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

LEGFLOW® RX

Balloon length (mm)	Balloon Ø (mm) 0.014" RX				
	Catheter length 140 cm				
	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm
20 mm	L 2.0-20 RX	L 2.5-20 RX	L 3.0-20 RX	L 3.5-20 RX	L 4.0-20 RX
40 mm	L 2.0-40 RX	L 2.5-40 RX	L 3.0-40 RX	L 3.5-40 RX	L 4.0-40 RX
60 mm	L 2.0-60 RX	L 2.5-60 RX	L 3.0-60 RX	L 3.5-60 RX	-
80 mm	L 2.0-80 RX	L 2.5-80 RX	L 3.0-80 RX	L 3.5-80 RX	L 4.0-80 RX
100 mm	L 2.0-100 RX	L 2.5-100 RX	L 3.0-100 RX	L 3.5-100 RX	-
120 mm	L 2.0-120 RX	L 2.5-120 RX	L 3.0-120 RX	L 3.5-120 RX	L 4.0-120 RX
150 mm	L 2.0-150 RX	L 2.5-150 RX	L 3.0-150 RX	L 3.5-150 RX	-
200 mm	L 2.0-200 RX	L 2.5-200 RX	-	-	-



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