LEGFLOW® RX/OTW

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter

Powered by SAFEPAX® Technology:

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

Excellent Deliverability:

The elastic coating ensures smooth and easy crossing of complex anatomies and the optimised PTA hypotube shaft secures kink resistance and pushability

No Compromise:

Unsurpassed range of paclitaxel releasing peripheral balloon dilatation catheters

CARDIONOVUM®

Life deserves the best

SAFEPAX®:

the Paclitaxel Matrix of the Future

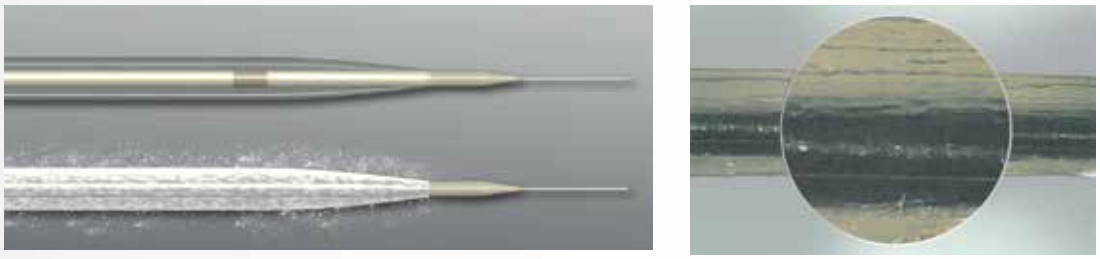
With SAFEPAX® CARDIONOVUM is leading the way in matrix technology. SAFEPAX® is a third-generation paclitaxel balloon matrix coating, developed exclusively for the CARDIONOVUM family of DCBs for maximal safety and optimised drug delivery.

Locally delivered 3 µg/mm² paclitaxel dose
for consistent inhibition of neointimal proliferation without compromising safety

Virtually loss-less matrix
Invisibly small 0.1 µm paclitaxel particles for improved homogeneity of drug transfer

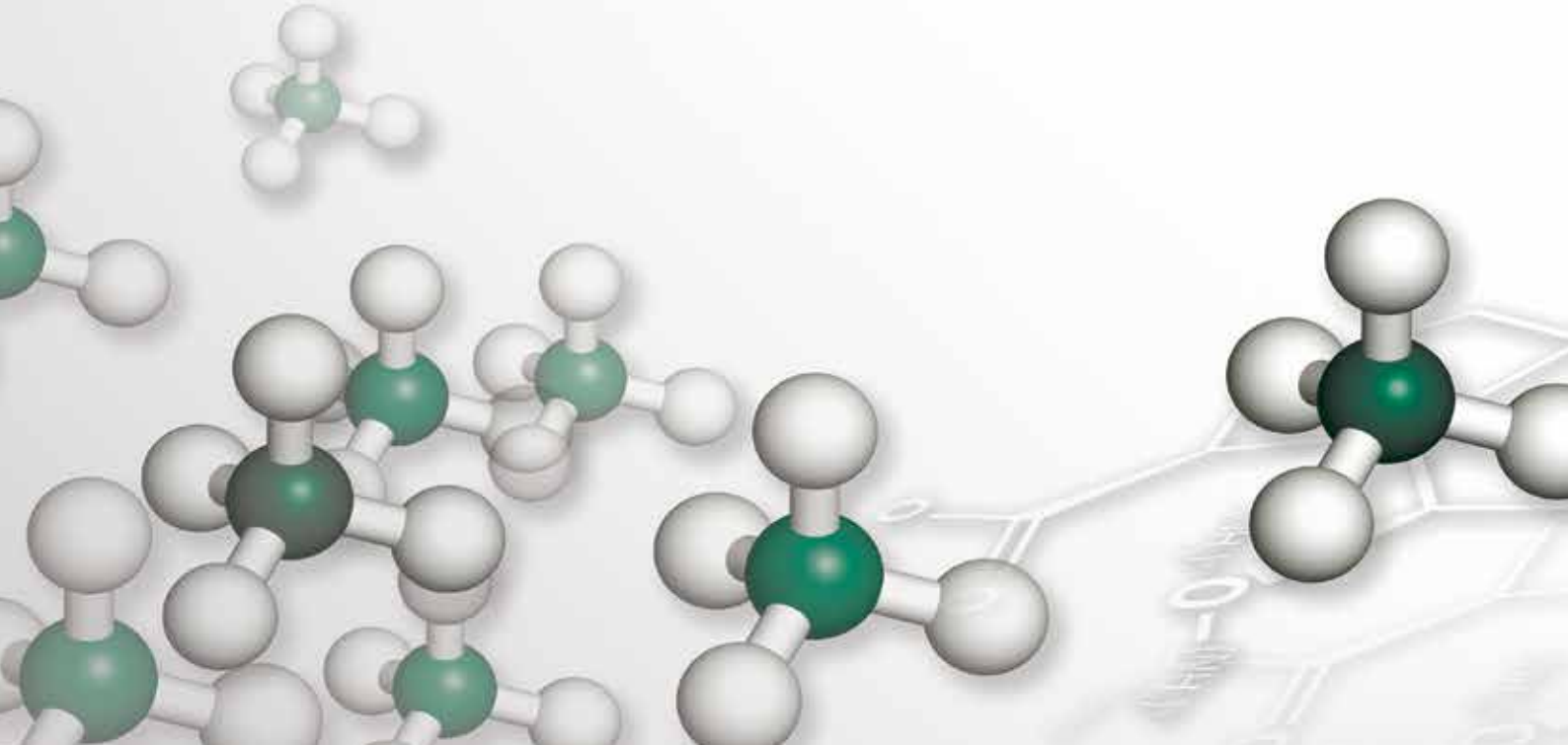
Proprietary ammonium salt solution excipient

- **Hydrophobic during catheter tracking**
  Minimal drug loss during introduction to target site
- **Lipophilic when inflated**
  Reliable drug release and transfer into the vessel wall
- **Elastic**
  Low surface friction; consistent smoothness and minimised risk of dissection



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

Michael Lichtenberg, Arnsberg DE: "Because of its stable coating, LEGFLOW is the only balloon that easily survives crossing a haemostatic valve."



The Result:

Consistent, predictable drug delivery to target lesions, with the lowest paclitaxel wash-off rates of currently available DCBs, as demonstrated in independent tests*

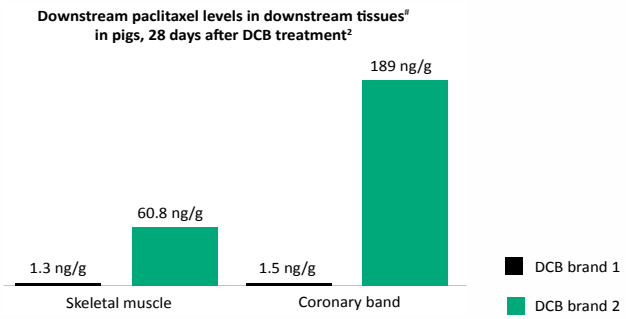
Laboratory tests under simulated blood conditions† show paclitaxel **wash-off rates <0.2%***

There have been no safety issues in LEGFLOW® clinical trials and registries to date (2017).

Mohamad Hamady, London UK: "The virtual lack of drug leakage with Legflow is a very promising development. It would be exciting to investigate reduced need for predilation in BTK with this DCB."

Particle size and wash-off rates matter! Studies in non-SAFEPAX® DCBs show:

Paclitaxel can leak into the systemic circulation after lower limb DCB angioplasty.[1]
With non-SAFEPAX DCBs, animal experiments have identified paclitaxel in non-target organs far downstream from the DCB treated SFA, even in the coronary band.[2]
Type of excipient and method of balloon coating affect the efficiency of drug transfer.[3]



Local drug leakage leading to higher concentration of paclitaxel and crystalline embolic materials in downstream tissues is associated with fibrinoid necrosis and possibly reduced survival in animal experiments.[2]

Vasculitic rash related to particulate embolisation of paclitaxel coating has been reported in the literature.[4]
All studies demonstrating paclitaxel leakage and particulate embolisation were performed with DCBs that have proven higher rates of leakage than SAFEPAX® DCBs.

* CARDIONOVUM data on file. Reports are available upon request
† DCBs were incubated with agitation for 1 minute in 4 mL ultra-pure water at 37°C. The process was repeated 10 times and the total amount of paclitaxel in the 10 samples was measured by HPLC.
# In pigs, SFAs were treated with DCB or standard balloon angioplasty. Downstream non-target organs (skeletal muscle and coronary band) were examined by histology after 28 days (reference 2)

LEGFLOW® RX/OTW:

Reliable Complex Lesion Crossing with all Benefits from SAFEPAX® Matrix

LEGFLOW® was developed to facilitate complex lesion crossing and deliver the advantages of the third-generation virtually loss-less SAFEPAX® matrix.

The catheter design combined with the high elasticity of the SAFEPAX® matrix ensures low stickness, kink resistance and smooth pushability.

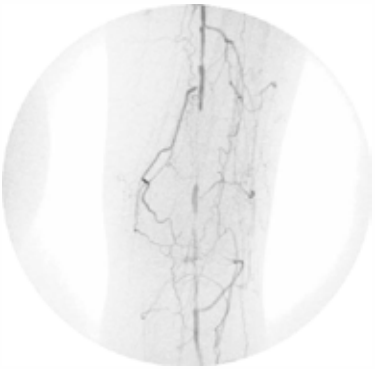
Guidewire friction is further reduced by an extruded guidewire lumen and an atraumatic tip.

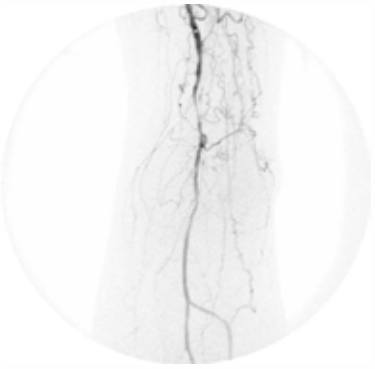
The PTA balloon was specifically designed for maximal synergy with the unique SAFEPAX® matrix.

The Result:

Unsurpassed ease of handling and safety, and precise drug delivery

Peter Goverde, Antwerp BE: "LEGFLOWs design, wide portfolio and different platforms makes it an ideal DCB to treat arteries from iliac to tibial level."





LEGFLOW® RX/OTW Portfolio:

Performance without Compromise

CARDIONOVUM offers an unsurpassed range of DCBs for the widest application:

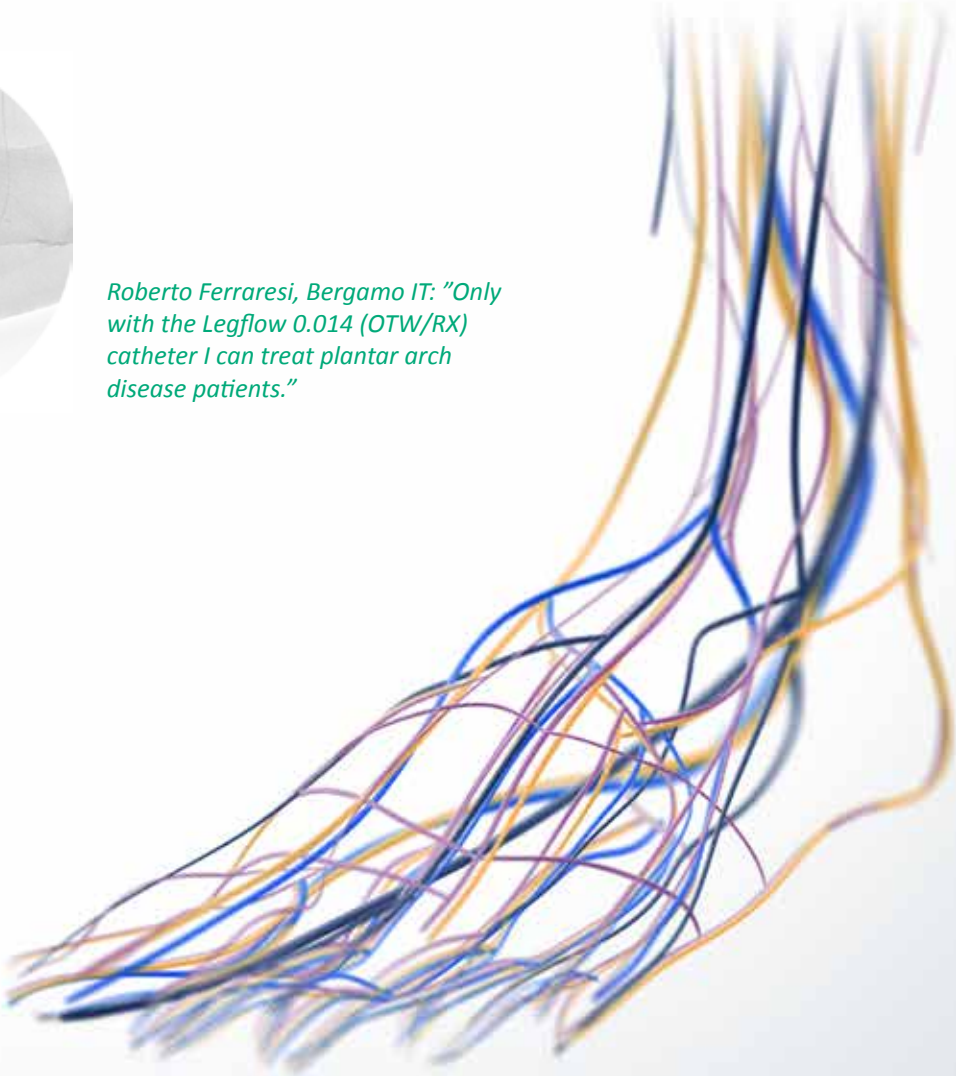
- Balloons 2-10 mm diameter; lengths 20-200 mm
- Balloons in RX and OTW configuration
- LEGFLOW® OTW in three platforms: 014", 018", 035"
- Introducer sheaths down to 4Fr (Ø 2.0-4.0 mm)

The range guarantees physicians the widest choice to ensure that patients benefit from **SAFEPAX®** technology **without compromise.**

LEGFLOW® RX/OTW is indicated for the treatment of:

- Critical limb ischaemia (CLI)
- De-novo and restenotic lesions of the SFA
- Popliteal artery (BTK) and (BTA) artery lesions
- In-stent restenosis

Roberto Ferraresi, Bergamo IT: "Only with the Legflow 0.014 (OTW/RX) catheter I can treat plantar arch disease patients."

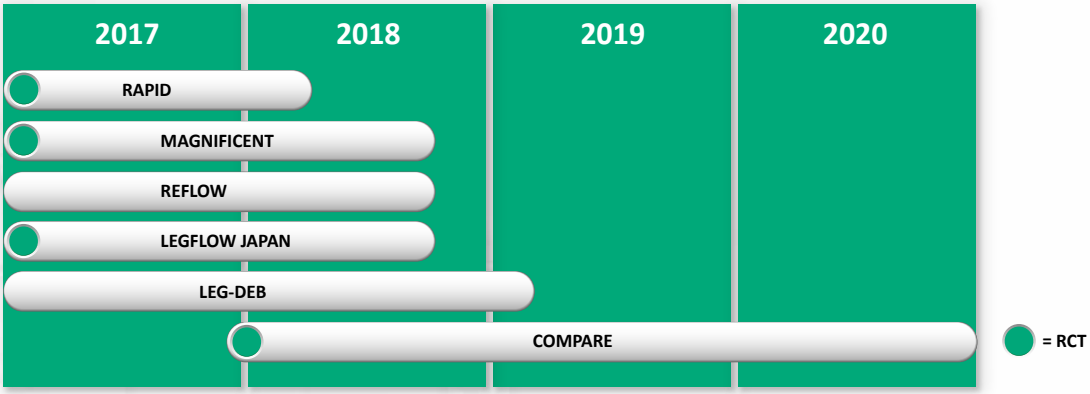


Clinical Programme

On-going clinical trials are expanding the evidence base in support of the safety and effectiveness of LEGFLOW® in various conditions of real life treatment:

- RAPID: long (>15 cm) and intermediate (5-15 cm) lesions
- MAGNIFICENT: absence of binary restenosis
- REFLOW: femopopliteal long lesions >15cm
- LEGFLOW JAPAN: Patients with CLI and de-novo stenosis or embolisation in arteries below the popliteal artery
- LEG-DEB: Infrainguinal arterial disease in real-world patients (including claudication and CLI)
- COMPARE: Head-to-head comparison of LEGFLOW® vs. DCB in real-world SFA patients

Clinical timeline



Eugenio Stabile, Naples IT: "LEGFLOW is the only DCB on the market with consistent and reliable data for patients with CLI."

Technical Summaries

Ordering Information and Technical Data

LEGFLOW OTW 0.035

Usable catheter length 80 cm	Usable catheter length 135 cm	Balloon Ø (mm)	Balloon length (mm)	Introducer sheath size (F)	RBP
LS 4.0-20 OTW	L 4.0-20 OTW	4	20	6	16
LS 4.0-40 OTW	L 4.0-40 OTW	4	40	6	16
LS 4.0-60 OTW	L 4.0-60 OTW	4	60	6	16
LS 4.0-80 OTW	L 4.0-80 OTW	4	80	6	16
LS 4.0-100 OTW	L 4.0-100 OTW	4	100	6	16
LS 4.0-120 OTW	L 4.0-120 OTW	4	120	6	16
LS 4.0-150 OTW	L 4.0-150 OTW	4	150	6	16
LS 5.0-20 OTW	L 5.0-20 OTW	5	20	6	16
LS 5.0-40 OTW	L 5.0-40 OTW	5	40	6	16
LS 5.0-60 OTW	L 5.0-60 OTW	5	60	6	16
LS 5.0-80 OTW	L 5.0-80 OTW	5	80	6	14
LS 5.0-100 OTW	L 5.0-100 OTW	5	100	6	14
LS 5.0-120 OTW	L 5.0-120 OTW	5	120	6	14
LS 5.0-150 OTW	L 5.0-150 OTW	5	150	6	14
LS 6.0-20 OTW	L 6.0-20 OTW	6	20	6	16
LS 6.0-40 OTW	L 6.0-40 OTW	6	40	6	16
LS 6.0-60 OTW	L 6.0-60 OTW	6	60	6	16
LS 6.0-80 OTW	L 6.0-80 OTW	6	80	6	14
LS 6.0-100 OTW	L 6.0-100 OTW	6	100	6	14
LS 6.0-120 OTW	L 6.0-120 OTW	6	120	6	14
LS 6.0-150 OTW	L 6.0-150 OTW	6	150	6	14
LS 7.0-20 OTW	L 7.0-20 OTW	7	20	7	14
LS 7.0-40 OTW	L 7.0-40 OTW	7	40	7	14
LS 7.0-60 OTW	L 7.0-60 OTW	7	60	7	14
LS 7.0-80 OTW	L 7.0-80 OTW	7	80	7	12
LS 7.0-100 OTW	L 7.0-100 OTW	7	100	7	12
LS 7.0-120 OTW	L 7.0-120 OTW	7	120	7	12
LS 7.0-150 OTW	L 7.0-150 OTW	7	150	7	12
LS 8.0-20 OTW	L 8.0-20 OTW	8	20	7	14
LS 8.0-40 OTW	L 8.0-40 OTW	8	40	7	14
LS 8.0-60 OTW	L 8.0-60 OTW	8	60	7	14
LS 8.0-80 OTW	L 8.0-80 OTW	8	80	7	12
LS 8.0-100 OTW	L 8.0-100 OTW	8	100	7	12
LS 8.0-120 OTW	L 8.0-120 OTW	8	120	7	12
LS 8.0-150 OTW	L 8.0-150 OTW	8	150	7	12
LS 9.0-20 OTW	L 9.0-20 OTW	9	20	7	12
LS 9.0-40 OTW	L 9.0-40 OTW	9	40	7	12
LS 9.0-60 OTW	L 9.0-60 OTW	9	60	7	12
LS 10.0-20 OTW	L 10.0-20 OTW	10	20	7	12
LS 10.0-40 OTW	L 10.0-40 OTW	10	40	7	12
LS 10.0-60 OTW	L 10.0-60 OTW	10	60	7	12

LEGFLOW OTW 0.018

Usable catheter length 150 cm	Balloon Ø (mm)	Balloon length (mm)	Introducer sheath size (F)	RBP
L18 2.0-40	2	40	4	14
L18 2.0-60	2	60	4	14
L18 2.0-80	2	80	4	14
L18 2.0-100	2	100	4	14
L18 2.0-120	2	120	4	14
L18 2.0-150	2	150	4	14
L18 3.0-40	3	40	4	14
L18 3.0-60	3	60	4	14
L18 3.0-80	3	80	4	14
L18 3.0-100	3	100	4	12
L18 3.0-120	3	120	4	12
L18 3.0-150	3	150	4	12
L18 4.0-40	4	40	4	14
L18 4.0-60	4	60	4	14
L18 4.0-80	4	80	4	14
L18 4.0-100	4	100	4	12
L18 4.0-120	4	120	4	12
L18 4.0-150	4	150	4	12
L18 5.0-40	5	40	5	14
L18 5.0-60	5	60	5	14
L18 5.0-80	5	80	5	14
L18 5.0-100	5	100	5	12
L18 5.0-120	5	120	5	12
L18 5.0-150	5	150	5	12
L18 6.0-40	6	40	5	14
L18 6.0-60	6	60	5	14
L18 6.0-80	6	80	5	14
L18 6.0-100	6	100	5	12
L18 6.0-120	6	120	5	12
L18 6.0-150	6	150	5	12
L18 7.0-40	7	40	5	14

LEGFLOW OTW 0.014

Usable catheter length 150 cm	Balloon Ø (mm)	Balloon length (mm)	Introducer sheath size (F)	RBP
L 2.0-40 OTW	2	40	4	16
L 2.0-80 OTW	2	80	4	16
L 2.0-120 OTW	2	120	4	16
L 2.0-150 OTW	2	150	4	16
L 2.5-40 OTW	2.5	40	4	16
L 2.5-80 OTW	2.5	80	4	16
L 2.5-120 OTW	2.5	120	4	16
L 2.5-150 OTW	2.5	150	4	16
L 3.0-40 OTW	3	40	4	14
L 3.0-80 OTW	3	80	4	14
L 3.0-120 OTW	3	120	4	14
L 3.0-150 OTW	3	150	4	14
L 3.5-40 OTW	3.5	40	4	14
L 3.5-80 OTW	3.5	80	4	14
L 3.5-120 OTW	3.5	120	4	14
L 3.5-150 OTW	3.5	150	4	14

LEGFLOW RX 0.014

Usable catheter length 140 cm	Balloon Ø (mm)	Balloon length (mm)	Introducer sheath size (F)	RBP
L 2.0-20 RX	2	20	5	16
L 2.0-40 RX	2	40	5	16
L 2.0-60 RX	2	60	5	14
L 2.0-80 RX	2	80	5	14
L 2.0-100 RX	2	100	5	14
L 2.0-120 RX	2	120	5	14
L 2.0-150 RX	2	150	5	14
L 2.0-200 RX	2	200	5	14
L 2.5-20 RX	2.5	20	5	16
L 2.5-40 RX	2.5	40	5	16
L 2.5-60 RX	2.5	60	5	14
L 2.5-80 RX	2.5	80	5	14
L 2.5-100 RX	2.5	100	5	14
L 2.5-120 RX	2.5	120	5	14
L 2.5-150 RX	2.5	150	5	14
L 2.5-200 RX	2.5	200	5	14
L 3.0-20 RX	3	20	5	16
L 3.0-40 RX	3	40	5	16
L 3.0-60 RX	3	60	5	14
L 3.0-80 RX	3	80	5	14
L 3.0-100 RX	3	100	5	14
L 3.0-120 RX	3	120	5	14
L 3.0-150 RX	3	150	5	14
L 3.5-20 RX	3.5	20	5	16
L 3.5-40 RX	3.5	40	5	16
L 3.5-60 RX	3.5	60	5	14
L 3.5-80 RX	3.5	80	5	14
L 3.5-100 RX	3.5	100	5	14
L 3.5-120 RX	3.5	120	5	14
L 3.5-150 RX	3.5	150	5	14
L 4.0-20 RX	4	20	5	16
L 4.0-40 RX	4	40	5	14
L 4.0-80 RX	4	80	5	14
L 4.0-120 RX	4	120	5	14

References

1. P. Freyhardt et al., ROFO. Fortschr. Geb. Rontgenstr. Nuklearmed. 183, 448–455 (2011).
2. F. D. Kolodgie et al., J. Vasc. Interv. Radiol. JVIR 27, 1676–1685.e2 (2016).
3. T. Heilmann et al., Eur. Cardiol. Rev. 6, 40 (2010).
4. S. D. Thomas, R. R. A. McDonald, R. L. Varcoe, J. Vasc. Surg. 59, 520–523 (2014).

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