CERTIFICATE

EC Certificate No. 1434-MDD-219/2020

Full Quality Assurance System
Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn
Germany

for the design, manufacture and final inspection of
medical devices, class III

LEGFLOW OTW Paclitaxel Releasing Peripheral Balloon Dilatation Catheter

The list of medical devices covered by this certificate is provided in the Annex no. 1, 2 and 3 to EC Design-examination Certificate No. 1434-MDD-218/2020

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 19.05.2020 to 27.05.2024

The date of issue of the Certificate: 19.05.2020

The date of the first issue of the Certificate: 30.06.2011

CE 1434

Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020
Module H2/3/4/5

mgr Anna Wyroba
Vice-President

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC Certificate No. 1434-MDD-218/2020

EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn
Germany

related to the medical device, class III

LEGFLOW OTW Paclitaxel Releasing Peripheral Balloon Dilatation Catheter

The list of medical devices covered by this certificate is provided in the Annex no. 1, 2 and 3

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 19.05.2020 to 27.05.2024

The date of issue of the Certificate: 19.05.2020

The date of the first issue of the Certificate: 30.06.2011

CE 1434

Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020
Module H1

mgr Anna Wyroba
Vice-President

ANNEX No. 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-218/2020

List of medical devices covered by the certificate:

OTW 0.035" Catheter length 800 mm (LS) or 1350 mm (L)							
Balloon Length (mm)	**Balloon Diameter (mm)**						
	4.00	**5.00**	**6.00**	**7.00**	**8.00**	**9.00**	**10.00**
20	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	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	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	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	L 9.0-80 OTW LS 9.0-80 OTW	L 10.0-80 OTW LS 10.0-80 OTW
100	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	L 9.0-100 OTW LS 9.0-100 OTW	L 10.0-100 OTW LS 10.0-100 OTW
120	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	L 9.0-120 OTW LS 9.0-120 OTW	L 10.0-120 OTW LS 10.0-120 OTW
150	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	-	-

CE 1434

Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020

mgr Anna Wyroba
Vice-President

ANNEX No. 2 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-218/2020

List of medical devices covered by the certificate:

OTW 0.018" Catheter length 1200 mm (LS) or 1500 mm (L)						
Balloon Length (mm)	Balloon Diameter (mm)					
	2.0	3.0	4.0	5.0	6.0	7.0
40	L 18 2.0-40 LS 18 2.0-40	L 18 3.0-40 LS 18 3.0-40	L 18 4.0-40 LS 18 4.0-40	L 18 5.0-40 LS 18 5.0-40	L 18 6.0-40 LS 18 6.0-40	L 18 7.0-40 LS 18 7.0-40
60	L 18 2.0-60 LS 18 2.0-60	L 18 3.0-60 LS 18 3.0-60	L 18 4.0-60 LS 18 4.0-60	L 18 5.0-60 LS 18 5.0-60	L 18 6.0-60 LS 18 6.0-60	L 18 7.0-60 LS 18 7.0-60
80	L 18 2.0-80 LS 18 2.0-80	L 18 3.0-80 LS 18 3.0-80	L 18 4.0-80 LS 18 4.0-80	L 18 5.0-80 LS 18 5.0-80	L 18 6.0-80 LS 18 6.0-80	L 18 7.0-80 LS 18 7.0-80
100	L 18 2.0-100 LS 18 2.0-100	L 18 3.0-100 LS 18 3.0-100	L 18 4.0-100 LS 18 4.0-100	L 18 5.0-100 LS 18 5.0-100	L 18 6.0-100 LS 18 6.0-100	L 18 7.0-100 LS 18 7.0-100
120	L 18 2.0-120 LS 18 2.0-120	L 18 3.0-120 LS 18 3.0-120	L 18 4.0-120 LS 18 4.0-120	L 18 5.0-120 LS 18 5.0-120	L 18 6.0-120 LS 18 6.0-120	L 18 7.0-120 LS 18 7.0-120
150	L 18 2.0-150 LS 18 2.0-150	L 18 3.0-150 LS 18 3.0-150	L 18 4.0-150 LS 18 4.0-150	L 18 5.0-150 LS 18 5.0-150	L 18 6.0-150 LS 18 6.0-150	L 18 7.0-150 LS 18 7.0-150

CE 1434

Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020

mgr Anna Wyroba
Vice-President

ANNEX No. 3 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-218/2020

List of medical devices covered by the certificate:

OTW 0.014" Catheter length 1500 mm				
Balloon Length (mm)	Balloon Diameter (mm)			
	2.0	2.5	3.0	3.5
8	L 2.0-8 OTW	L 2.5-8 OTW	L 3.0-8 OTW	L 3.5-8 OTW
10	L 2.0-10 OTW	L 2.5-10 OTW	L 3.0-10 OTW	L 3.5-10 OTW
20	L 2.0-20 OTW	L 2.5-20 OTW	L 3.0-20 OTW	L 3.5-20 OTW
30	L 2.0-30 OTW	L 2.5-30 OTW	L 3.0-30 OTW	L 3.5-30 OTW
40	L 2.0-40 OTW	L 2.5-40 OTW	L 3.0-40 OTW	L 3.5-40 OTW
60	L 2.0-60 OTW	L 2.5-60 OTW	L 3.0-60 OTW	L 3.5-60 OTW
80	L 2.0-80 OTW	L 2.5-80 OTW	L 3.0-80 OTW	L 3.5-80 OTW
100	L 2.0-100 OTW	L 2.5-100 OTW	L 3.0-100 OTW	L 3.5-100 OTW
120	L 2.0-120 OTW	L 2.5-120 OTW	L 3.0-120 OTW	L 3.5-120 OTW
150	L 2.0-150 OTW	L 2.5-150 OTW	L 3.0-150 OTW	L 3.5-150 OTW
200	L 2.0-200 OTW	L 2.5-200 OTW	L 3.0-200 OTW	L 3.5-200 OTW

CE 1434

Issued under the Contract No. MD-170/2019
Application No: 260/2019
Certificate bears the qualified person signature.
Warsaw, 19/05/2020

mgr Anna Wyroba
Vice-President

APPLICABLE STANDARDS

Standard:	Title:
EN 556-1:2001/AC:2006	Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 1: Requirements for terminally sterilized medical devices
EN 868-2:2017	Packaging for terminally sterilized medical devices. Sterilization wrap. Requirements and test methods.
EN 1041:2013	Information supplied by the manufacturer of medical devices
EN 1422:2014	Sterilizers for medical purposes — Ethylene oxide sterilizers — Requirements and test methods
EN ISO 10555-1:2013/ Amd 1:2017	Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
EN ISO 10555-4:2013	Intravascular catheters - Sterile and single-use catheters Part 4: Balloon dilatation catheters
EN ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation
EN ISO 10993-7:2008/ Amd 1:2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2013	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2017	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices — Part 12: Sample preparation and reference Materials
EN ISO 10993-18:2020	Biological evaluation of medical devices — Part 18: Chemical characterization of materials
EN ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements
EN ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes
EN ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018	Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 12417-1:2015	Cardiovascular extracorporeal systems – Vascular device-drug combination products – Part 1: General requirements
EN ISO 13408-1:2018/ Amd 1:2013	Aseptic processing of health care products — Part 1: General requirements

Standard:	Title:
PN EN ISO 13485:2016	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice
EN ISO 14630:2012	Non-active surgical implants — General requirements
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration
EN ISO 14644-2:2015	Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
EN ISO 14644-3:2019	Cleanrooms and associated controlled environments — Part 3: Test methods
EN ISO 14698-1:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 1: General principles and methods
EN ISO 14698-2:2003	Cleanrooms and associated controlled environments -Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
EN ISO 14971:2019	Medical devices -- Application of risk management to medical devices
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
EN ISO/IEC 17050-1:2010	Conformity assessment -- Supplier's declaration of conformity -- Part 1: General requirements
EN 20594-1:1993/AC:1996	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements
Ph.Eur. current edition,<1794>	Paclitaxel
Ph.Eur. current edition,<1149>	Shellac
Ph.Eur. current edition, <General Methods, 2.6.1>	Sterility
Ph.Eur. current edition, <General Methods, 2.6.14>	Bacterial Endotoxins (LAL)
ISTA 2A	Packaged-Products weighing 150 lb (68 kg) or Less
ASTM F1980-07	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F1886/ F1886M - 09	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F88 / F88M - 09	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1929 – 15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F2096 – 11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

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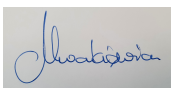
1434



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Date: 2022.07.25 14:30:47 +02'00'

Bonn, date next to signature **by: Monika MROCZKIEWICZ, Quality & Regulatory Affairs Director**

Document bears qualified signature

CERTIFICATE

No. M - 62/2/2021

This is to certify that:

CARDIONOVUM GmbH
Am Bonner Bogen 2, 53227 Bonn, Germany

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control, sales and distribution of sterile, non-active endovascular and cardiovascular medical devices for interventional applications, coated with medicinal substances and uncoated

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from 11.12.2021 to 10.12.2024

Issued under the Contract No. 3660/M/1/2021
Date of certification decision: 24.05.2021
Certificate bears a qualified signature.
Warsaw, 28.10.2021

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji – Certyfikacja Systemów Zarządzania
AC 019

IAF Member of Multilateral Recognition Arrangement

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.10.28 14:46:37 +02'00'

Member of the Board

CARDIONOVUM
Life deserves the best

Declaration of Conformity

Declaration No. 22/LOTW/01

We

Manufacturer's name **CARDIONOVUM GmbH**

address: Am Bonner Bogen 2
53227 Bonn, Germany
SRN DE-MF-000005316

hereby declare on our sole responsibility that the below mentioned medical device:

Device Name: **LEGFLOW OTW**

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter

Class; Rule: III; Rule 13

EMDN code C01040299

GMDN Code: 62551

UMDNS code 10727

Basic UDI 590619015LEGFLOWOTWA2

Types/ Sizes:

Balloon length (mm)	OTW 0.035" Catheter length 800 mm (LS) or 1350 mm (L)						
	Balloon diameter (mm)						
	4.00 mm	5.00 mm	6.00 mm	7.00 mm	8.00 mm	9.00 mm	10.00 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	L 9.0-80 OTW LS 9.0-80 OTW	L 10.0-80 OTW LS 10.0-80 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	L 9.0-100 OTW LS 9.0-100 OTW	L 10.0-100 OTW LS 10.0-100 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	L 9.0-120 OTW LS 9.0-120 OTW	L 10.0-120 OTW LS 10.0-120 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	-	-

Balloon length (mm)	OTW 0.018" Catheter length 1200 (LS) or 1500 mm (L)					
	Balloon diameter (mm)					
	2.00 mm	3.00 mm	4.00 mm	5.00 mm	6.00 mm	7.00 mm
40 mm	L 18 2.0-40 LS 18 2.0-40	L 18 3.0-40 LS 18 3.0-40	L 18 4.0-40 LS 18 4.0-40	L 18 5.0-40 LS 18 5.0-40	L 18 6.0-40 LS 18 6.0-40	L 18 7.0-40 LS 18 7.0-40
60 mm	L 18 2.0-60 LS 18 2.0-60	L 18 3.0-60 LS 18 3.0-60	L 18 4.0-60 LS 18 4.0-60	L 18 5.0-60 LS 18 5.0-60	L 18 6.0-60 LS 18 6.0-60	L 18 7.0-60 LS 18 7.0-60
80 mm	L 18 2.0-80 LS 18 2.0-80	L 18 3.0-80 LS 18 3.0-80	L 18 4.0-80 LS 18 4.0-80	L 18 5.0-80 LS 18 5.0-80	L 18 6.0-80 LS 18 6.0-80	L 18 7.0-80 LS 18 7.0-80
100 mm	L 18 2.0-100 LS 18 2.0-100	L 18 3.0-100 LS 18 3.0-100	L 18 4.0-100 LS 18 4.0-100	L 18 5.0-100 LS 18 5.0-100	L 18 6.0-100 LS 18 6.0-100	L 18 7.0-100 LS 18 7.0-100
120 mm	L 18 2.0-120 LS 18 2.0-120	L 18 3.0-120 LS 18 3.0-120	L 18 4.0-120 LS 18 4.0-120	L 18 5.0-120 LS 18 5.0-120	L 18 6.0-120 LS 18 6.0-120	L 18 7.0-120 LS 18 7.0-120
150 mm	L 18 2.0-150 LS 18 2.0-150	L 18 3.0-150 LS 18 3.0-150	L 18 4.0-150 LS 18 4.0-150	L 18 5.0-150 LS 18 5.0-150	L 18 6.0-150 LS 18 6.0-150	L 18 7.0-150 LS 18 7.0-150

Balloon length (mm)	OTW 0.014" Catheter length 1500mm			
	Balloon diameter (mm)			
	2.00 mm	2.50 mm	3.00 mm	3.50 mm
8 mm	L 2.0-8 OTW	L 2.5-8 OTW	L 3.0-8 OTW	L 3.5-8 OTW
10 mm	L 2.0-10 OTW	L 2.5-10 OTW	L 3.0-10 OTW	L 3.5-10 OTW
20 mm	L 2.0-20 OTW	L 2.5-20 OTW	L 3.0-20 OTW	L 3.5-20 OTW
30 mm	L 2.0-30 OTW	L 2.5-30 OTW	L 3.0-30 OTW	L 3.5-30 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	L 2.0-60 OTW	L 2.5-60 OTW	L 3.0-60 OTW	L 3.5-60 OTW
80 mm	L 2.0-80 OTW	L 2.5-80 OTW	L 3.0-80 OTW	L 3.5-80 OTW
100 mm	L 2.0-100 OTW	L 2.5-100 OTW	L 3.0-100 OTW	L 3.5-100 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
200 mm	L 2.0-200 OTW	L 2.5-200 OTW	-	-

complies with the requirements of the:

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993concerning medical devices, Annex II including section 4;
- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

Supplementary information

Notified body involved in assessment procedure	Polish Centre for Testing and Certification S.A.	**NB Identification number**	1434
Address:	Pulawska 469 St., 02-844 Warsaw; Poland		
Conformity assessment procedure:	Annex II including section 4		
EC Certificate:	1434-MDD-218/2020	EC-Design Examination	
EC Certificate	1434-MDD-219/2020	Full Quality Assurance System	

Manufacturer established Quality Management System and obtain Certificate of Management System according to the EN ISO 13485:2016 standard, reference number M-62/2/2021 valid from 11.12.2021 issued by PCBC S.A., Pulawska 469 St., PL 02-844 Warsaw; Poland, Certification Body

Additionally, the aforementioned device meets provisions of the standards incl. harmonised standards set in **Annex I** to this Declaration.

For regulatory topics only, contact:

CARDIONOVUM GmbH
Am Bonner Bogen 2
53227 Bonn, Germany
Monika Mroczkiewicz, Quality & Regulatory Affairs Director
info@cardionovum.com
Phone: +49 228 90 90 59-0
Fax: +49 228 90 90 59-20

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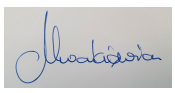
1434

Bonn, date next to signature



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Date: 2022.07.25 14:36:02 +02'00'

Declaration bears as qualified signature **by: Monika MROCZKIEWICZ, Quality & Regulatory Affairs Director**

LEGFLOW® RX/OTW

Paclitaxel Releasing Peripheral Balloon Dilatation Catheter

Powered by SAFEPAX® Technology:

The 3rd generation, unique paclitaxel matrix system with the 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

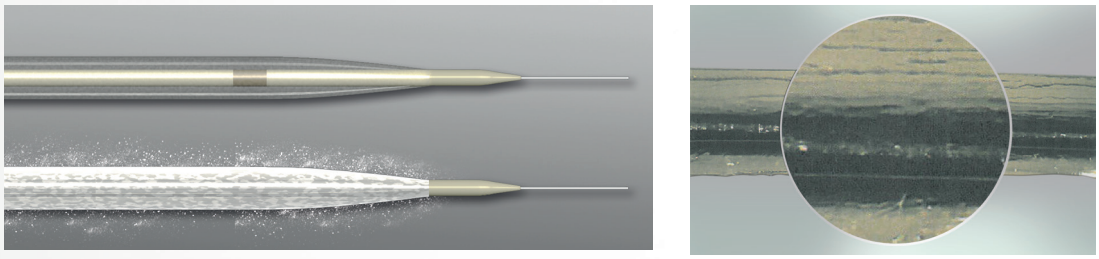
With SAFEPAX® CARDIONOVUM is leading the way in matrix technology. SAFEPAX® is a third-generation paclitaxel balloon matrix coating, developed exclusively for the CARDIONOVUM family of DCBs for maximal safety and optimised drug delivery.

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

Virtually loss-less matrix for improved homogeneity of drug transfer

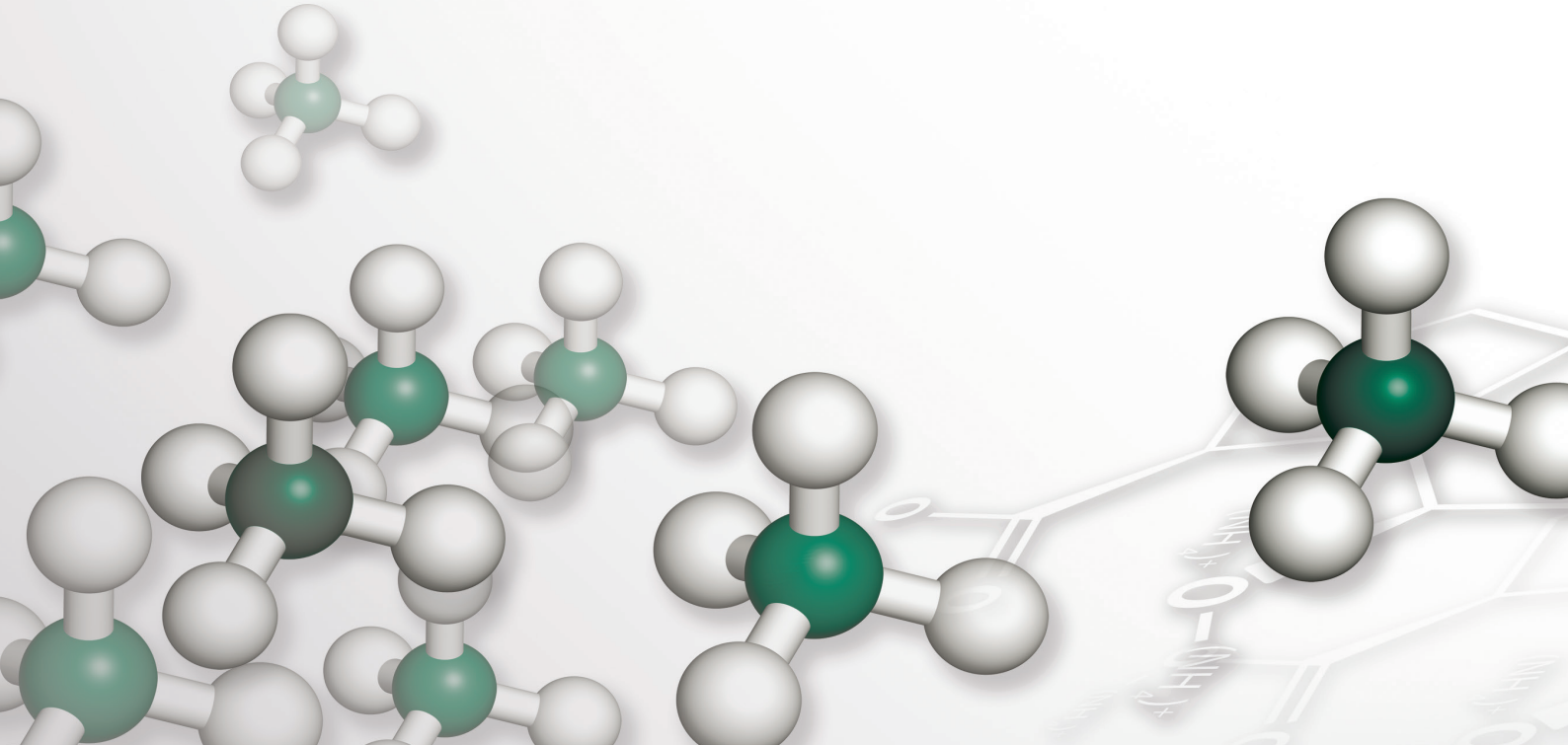
Proprietary ammonium salt solution excipient

- **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*

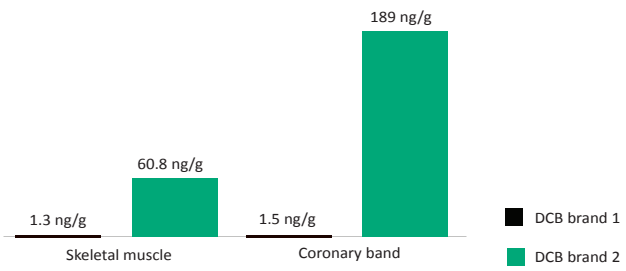
There have been no safety issues in LEGFLOW® clinical trials and registries to date (2018).

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]

Downstream paclitaxel levels in downstream tissues# in pigs, 28 days after DCB treatment[2]



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.

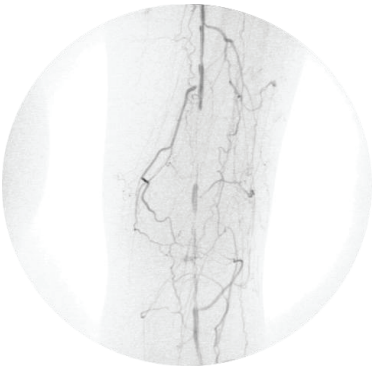
Guidewire friction is further reduced by an extruded guidewire lumen and an atraumatic tip.

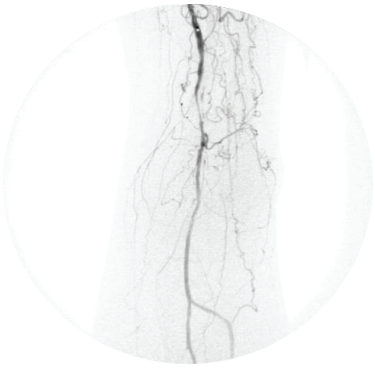
The PTA balloon was specifically designed for maximal synergy with the unique SAFEPAX® matrix.

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

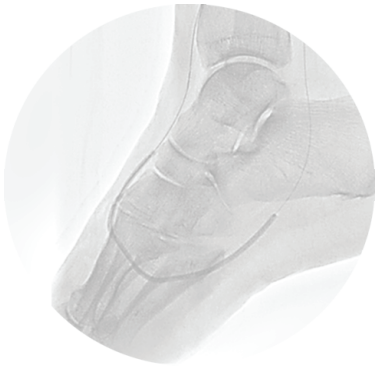
CARDIONOVUM offers an unsurpassed range of DCBs for the widest application:

- 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)

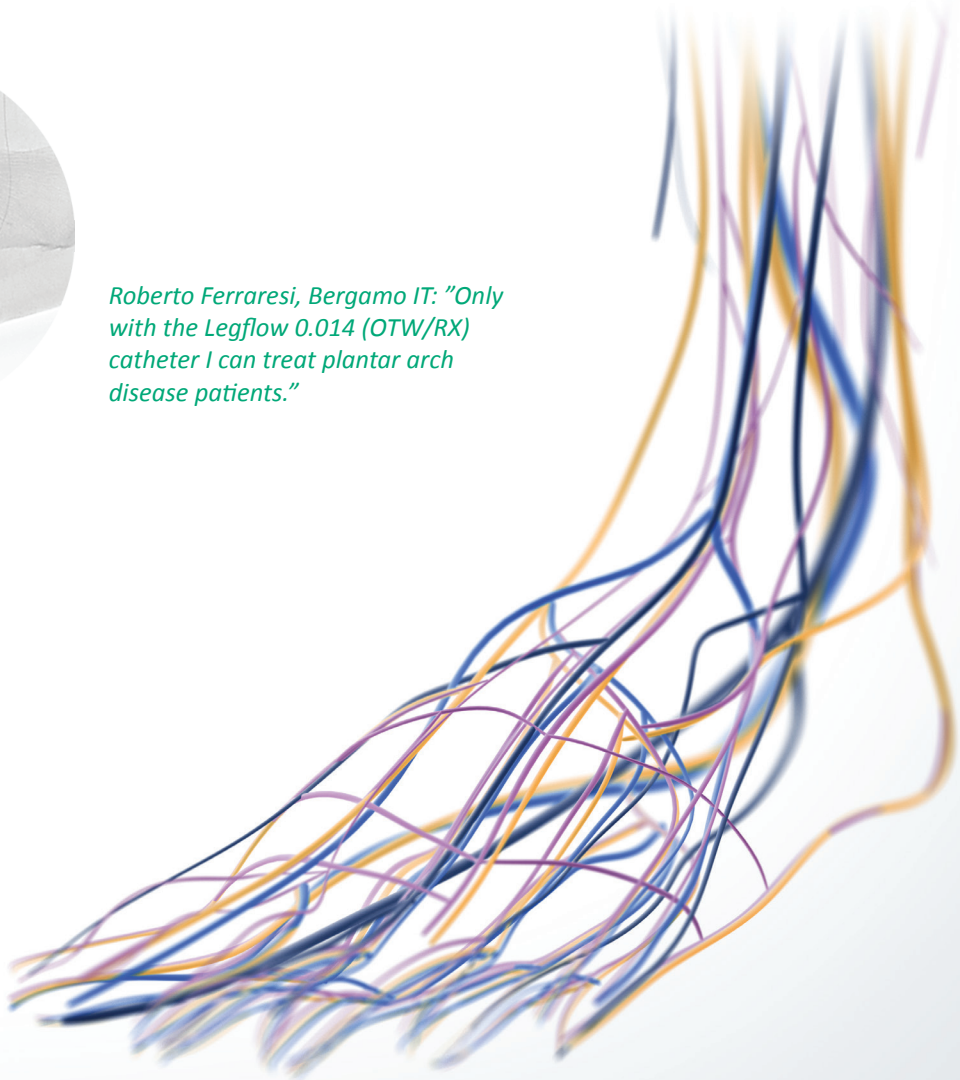
The range guarantees physicians the widest choice to ensure that patients benefit from **SAFEPAX®** technology **without compromise.**

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.”

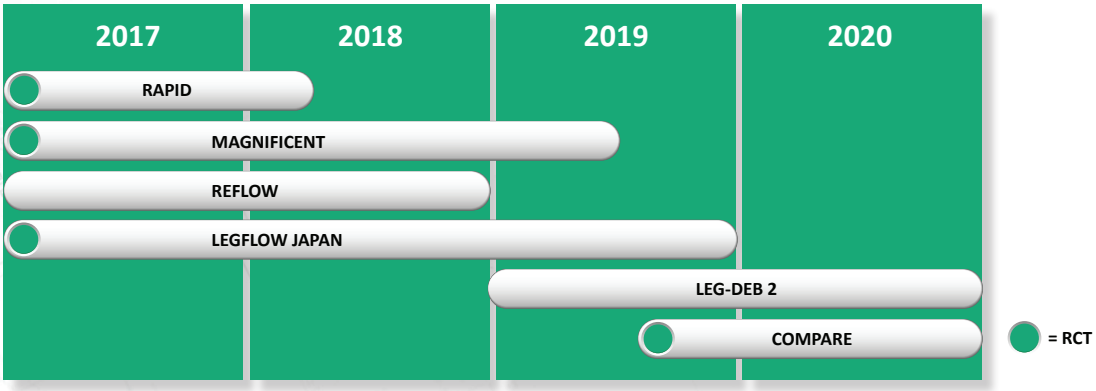


Clinical Program

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

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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).
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4. S. D. Thomas, R. R. A. McDonald, R. L. Varcoe, J. Vasc. Surg. 59, 520–523 (2014).

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