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ORDIN DE PLATA NR.: 54                                TIP.DOC. 1 :
                                DATA EMITERII:8 iulie 2021 :
=====:
PLATITI: 4000-00                                LEI: Patru Mii lei 00 bani :
:
:
=====:
PLATITOR: (R) S.C. "OXIVI          CONTUL DE PLATI/CODUL IBAN :
T-MED" S.R.L.                                MD44ML000000002251729503 :
                                CODUL FISCAL :1007600044280 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. fil."Invest" Chisinau        :MOLDMD2X329:
=====:
BENEFICIAR (R)IMSP Spitalu          CONTUL DE PLATI/CODUL IBAN :
l Clinic Republican "Timofei        MD32ML000000002251502448 :
Mosnea                                CODUL FISCAL :1003600150783 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"Moldindconbank"S.A.                                :MOLDMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru:          TIPUL TRANSFERULUI :
oferta la procedura de achizitie public:            NORMAL/URGENT :N:
a nr. ocds-b3wdpl-MD-1623927917875 din :           :
09.07.2021 :                                       :
:                                       :
:                                       :
:                                       L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
                                DATA PRIMIRII:08/07/2021 : SEMNATURILE :
                                DATA EXECUTARII: : EMITENTULUI :
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CONducATOR:Web Kojevnikov Dmitrii
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CONTABIL-SEF:Web Kojevnikov Dmitrii :
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:
L.S.                                (semnatura electronica) :
CONducATOR:                                (semnatura manuala) :
:
CONTABIL-SEF:                                (semnatura manuala) :
SEMnATURA PRESTATORUL                                L.S. :
:
MOTIVUL REFUZULUI                                : L.S. :
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Nr. 12101-504

18.03.2016

**CERTIFICAT  
PRIVIND EXISTENTA CONTURILOR CURENTE**

Prin prezentul, **BC „Mobiabancă – Groupe Societe Generale” S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **OXIVIT-MED SRL**, cod fiscal (IDNO) **1007600044280**, deține următoarele conturi curente la BC "Mobiabancă-Groupe Societe Generale" S.A., Filiala, 1 Stejaur :

1. **MDL - 2224710SV23488147100; IBAN- MD09MO2224ASV23488147100**
2. **EUR - 2224710SV22227957100; IBAN- MD17MO2224ASV22227957100**
3. **USD - 2224710SV22214937100; IBAN- MD86MO2224ASV22214937100**

Certificatul este emis în baza cererii întreprinderii: Oxivit-Med SRL.



Dumitru Popa  
Director filială „Stejaur”



Executor : Mariana Guzun  
Tel: 022 812 614

Filiala Nr. 1 „Stejaur”  
Bd. Ștefan cel Mare și Sfânt 196  
MD-2004, Chișinău, Moldova  
Cod MOBBMD22  
Cont de corespondență 35213892  
la Centrul de Decontări al BNM

Tel. +373 22 81 26 15  
Fax. +373 22 81 26 15  
www.mobiasbanca.md

BC „Mobiabancă – Groupe Société Générale” SA  
Capital Social: 100 000 000 MDL  
Număr de înregistrare de stat - 1002600006089  
Sediul Central:  
bd. Ștefan cel Mare și Sfânt 81a  
MD-2012, Chișinău, Moldova

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

**Societatea Comercială "OXIVIT-MED" S.R.L.**  
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

*Numărul de identificare de stat - codul fiscal*  
**1007600044280**

*Data înregistrării*

**30.07.2007**

*Data eliberării*

**30.07.2007**

**Bordeianu Tatiana, registrator de stat**

*Funcția, numele, prenumele persoanei  
care a eliberat certificatul*

*semnătura*

MD 0067985





**I.P. "AGENȚIA SERVICII PUBLICE"**

Departamentul înregistrare și licențiere a unităților de drept

**EXTRAS**  
**din Registrul de stat al persoanelor juridice**

nr. 8871 din 05.05.2021

Denumirea completă: **Societatea Comercială «OXIVIT-MED» S.R.L.**

Denumirea prescurtată: **S.C. «OXIVIT-MED» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1007600044280.**

Data înregistrării de stat: **30.07.2007.**

Sediul: **MD-2032, bd. Decebal, 82, ap.(of.) 90, mun. Chișinău, Republica Moldova.**

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 2 Comerțul cu ridicata al parfumurilor și produselor cosmetice;**
- 3 Comerțul cu amănuntul al produselor cosmetice și de parfumerie, articolelor de toaletă;**
- 4 Intermedieri pentru vânzarea unui asortiment larg de mărfuri;**
- 5 Alte tipuri de comerț cu amănuntul în magazine nespecializate;**
- 6 Alte tipuri de comerț cu ridicata;**
- 7 Închirierea altor mașini și echipamente.**

Capitalul social: **5400 lei.**

**Administrator: KOJEVNIKOV DMITRII, IDNP 0972305012362,**

Asociați:

**1. KOJEVNIKOV DMITRII , IDNP 0972305012362**

**cota 5400.00 lei, ce constituie 100 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 05.05.2021.

Specialist coordonator  
tel. 022-207-840



Lazari Aliona



EEI 0354094

# OXIVIT MED

c/f: 1007600044280; adresa: str. Decebal 82-90, or. Chişinău, Republica Moldova

telefon: + 373 22 808002; fax: + 373 22 808003

web: [www.oxivit-med.com](http://www.oxivit-med.com); e-mail: [info@oxivit-med.com](mailto:info@oxivit-med.com)

## **Lista fondatorilor companiei SRL „Oxivit-Med”**

Nr.	Numele, Prenumele	Codul Personal
1	Kojevnikov Dmitrii	0972305012362

# CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands

including the implementation meets the requirements of the standard:

# EN ISO 13485:2016 ISO 9001:2015

### Scope:

Sales, order management, warehousing and distribution of medical devices.  
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021  
Certificate effective date: 1 July 2018  
Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Certified organization(s) and/or locations:

	Different scope
Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices including technical service and customer education.  Warehousing and distribution of medical devices, including spine loaner operations
Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy	Sales, order management and distribution of medical devices. Including technical service and customer education. Promotion, invoice and order management of medicinal products.
Medtronic Danmark A/S. Arne Jacobsens Allé 17 2300 Kopenhagen Denmark	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic Medikal Teknoloji Ticaret Ltd Sti Saray Mah. Esnaf Sk. Akkom Ofis Park Laodik Plaza Sitesi B Blok Apt: 2/8 00000 Umraniye - Istanbul Turkey	Sales, order management and distribution of medical devices. Including technical service and customer education

# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.  
Waterfall Distribution Campus  
CNR K101 and Bridal Veil Road  
Waterfall Midrand  
1685 Gauteng  
South Africa

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Ibérica S.A.  
Calle de María de Portugal, 11  
28050 Madrid  
Spain

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Romania SRL  
Ploiesti 42-44, Building B, B2  
Wing, 2nd floor, district 1  
Baneasa Business & Technology Park  
013696 Bucharest  
Romania

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Norge AS  
Martin Linges vei 25  
1364 Fornebu  
Norway

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Portugal, LDA-  
Avenida Gomes Pereira 61B  
Benfica  
1600 Lisboa  
Portugal

Sales, Order Management and distribution of medical devices Including technical service and customer education.

Warehousing and distribution of medical devices, including spine loaner operations.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Service & Repair CoE  
C-Mill gebouw K  
Jan Campertstraat 21-A  
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.  
Polígono Industrial La Garena  
Calle Francisco Rabal 7  
28806 Alcalá De Heneras, Madrid  
Spain

Spine loaner operations.

Medtronic Ibérica S.A.  
WTC Almeda Park  
Placa de la Pau, s/n. Edificio 7, 3 piso  
08940 Cornellà de Llobregat, Barcelona  
Spain

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS  
27/33 Quai Alphonse Le Gallo  
92513 Boulogne-Billancourt  
France

Sales, order management and distribution of medical devices. Including technical Service and customer education

Medtronic Trading NL B.V.  
Larixplein 4  
5616 VB Eindhoven

Sales, order management and distribution of medical devices. Including technical service and customer education

Medtronic GmbH  
Earl-Bakken-Platz 1  
40670 Meerbusch  
Germany

Distribution of medical Devices, medical equipment and related services.

# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Osterreich GmbH  
Millennium Tower, 20th floor  
Handelskai 94-96  
1200 Wien  
Austria

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic (Schweiz) AG  
Talstrasse 9  
3053 Munchenbuchsee  
Switzerland

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic Hellas S.A.  
Avenue Kifisias 24 Building B  
151 25 Marousi Pref. Attica  
Greece

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Serbia Ltd.  
Bulevar Zorana Djindjica, 64a  
11070 Belgrade  
Serbia

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.  
Bocskai út 134-146  
Cépulet 3. emelet  
1113 Budapest  
Hungary

Sales, order management and distribution of medical devices. Including customer education.

Medtronic CCO SSC Warsaw  
Polna 11  
00-633 Warszawa  
Poland

Order management of medical devices.

# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Finland Oy  
Lentäjätie 3  
01530 Vantaa  
Finland

Sales, order management and distribution of medical devices.  
Including technical service and customer education.

Medtronic AB  
P.O. Box 1034  
164 21 Kista  
Sweden

Sales, order management and distribution of medical devices.  
Including technical service and customer education

Medtronic Trading Ltd.  
10 Hamada Street  
4673344 Herzlyia  
Israel

Import, sales, order management and distribution of medical  
devices. Including technical service and customer education

Addendum expiry date: 1 July 2021  
Addendum effective date: 1 July 2018

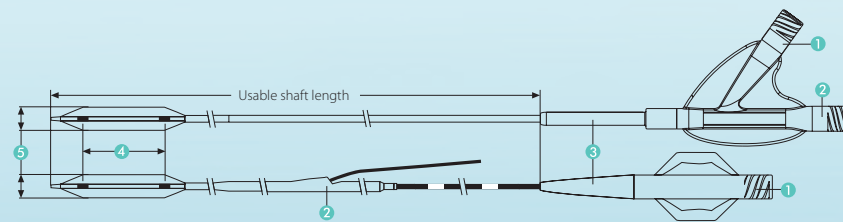
# Amphirion Deep

## Technical Specifications

Catheter design	Over the Wire (OTW)	Rapid Exchange (RX)
Balloon material	FLEXITEC™ Ultra	FLEXITEC™ Ultra
Balloon coating	Balloon and distal shaft LFC hydrophilic	Balloon and distal shaft LFC hydrophilic
Shaft diameter	proximal 3.9F middle 3.3F distal 2.8F	proximal 2.0F distal 3.3F
Max. recommended guidewire	0.014"	0.014"
Introducer sheath compatibility	4F	4F
Guiding catheter compatibility	–	5F (I.D. >0.056")
NBP	7 bar	7 bar

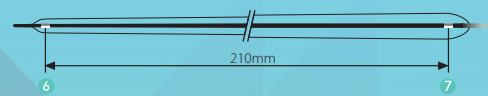
## Order Information

OTW - Ref. N° 120 cm shaft length	OTW - Ref. N° 150 cm shaft length	RX - Ref. N° 150 cm shaft length	Balloon Ø (mm)	Balloon length (mm)	Markers	RBP (bar)
AMD 015 020 001	AMD 015 020 151	–	1.50	20	1	14
AMD 015 020 002	AMD 015 020 152	–	1.50	20	2	14
AMD 020 040 002	AMD 020 040 152	AMD 020 040 RX2	2.00	40	2	15
AMD 020 080 002	AMD 020 080 152	AMD 020 080 RX2	2.00	80	2	14
AMD 020 120 002	AMD 020 120 152	AMD 020 120 RX2	2.00	120	2	14
AMD 020 150 002	AMD 020 150 152	AMD 020 150 RX2	2.00	150	2	14
AMD 025 040 002	AMD 025 040 152	AMD 025 040 RX2	2.50	40	2	16
AMD 025 080 002	AMD 025 080 152	AMD 025 080 RX2	2.50	80	2	15
AMD 025 120 002	AMD 025 120 152	AMD 025 120 RX2	2.50	120	2	14
AMD 025 150 002	AMD 025 150 152	AMD 025 150 RX2	2.50	150	2	14
AMD 030 040 002	AMD 030 040 152	AMD 030 040 RX2	3.00	40	2	16
AMD 030 080 002	AMD 030 080 152	AMD 030 080 RX2	3.00	80	2	15
AMD 030 120 002	AMD 030 120 152	AMD 030 120 RX2	3.00	120	2	14
AMD 030 150 002	AMD 030 150 152	AMD 030 150 RX2	3.00	150	2	14
AMD 035 040 002	AMD 035 040 152	AMD 035 040 RX2	3.50	40	2	16
AMD 035 080 002	AMD 035 080 152	AMD 035 080 RX2	3.50	80	2	15
AMD 035 120 002	AMD 035 120 152	AMD 035 120 RX2	3.50	120	2	14
AMD 035 150 002	AMD 035 150 152	AMD 035 150 RX2	3.50	150	2	14
AMD 040 040 002	AMD 040 040 152	AMD 040 040 RX2	4.00	40	2	16
AMD 040 080 002	AMD 040 080 152	AMD 040 080 RX2	4.00	80	2	15
AMD 040 120 002	AMD 040 120 152	AMD 040 120 RX2	4.00	120	2	14
AMD 040 150 002	AMD 040 150 152	AMD 040 150 RX2	4.00	150	2	14



### Amphirion Deep tapered balloon

OTW - Ref. N° 120 cm shaft length	OTW - Ref. N° 150 cm shaft length	RX - Ref. N° 150 cm shaft length	Balloon Ø (mm)	Balloon length (mm)	Markers	RBP (bar)
AMD 225 210 002	AMD 225 210 152	AMD 225 210 RX2	2.00/2.50	210	2	14
AMD 253 210 002	AMD 253 210 152	AMD 253 210 RX2	2.50/3.00	210	2	14
AMD 335 210 002	AMD 335 210 152	AMD 335 210 RX2	3.00/3.50	210	2	14
AMD 354 210 002	AMD 354 210 152	AMD 354 210 RX2	3.50/4.00	210	2	14



- 1 Balloon inflation port
- 2 Guidewire port
- 3 Kink protection
- 4 Balloon length
- 5 Balloon diameter
- 6 Distal balloon diameter
- 7 Proximal balloon diameter



# Amphirion Deep

INFRAPOPLITEAL OTW + RX PTA BALLOON CATHETER 0.014"

## Flexibility and Conformability

WELCOME TO  
**PERIPHERAL  
POWER.**

TO INNOVATE

TO COLLABORATE

TO TREAT

Innovating for life.

[www.medtronic.com](http://www.medtronic.com)  
[www.invatec.com](http://www.invatec.com)

Via Martiri della Libertà 7  
25030 Roncadelle (BS) – Italy  
Phone: + 39 030 2589311

**Global Headquarters**  
Hungerbühlstrasse 12  
8500 Frauenfeld – Switzerland

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# Amphirion Deep

INFRAPOPLITEAL OTW + RX PTA BALLOON CATHETER 0.014"

## Easy access to the extremities

- Tip profile (0.017")
- LFC Hydrophilic Coating
- Three-step shaft design to optimize tracking through distal vessels
- Reinforced proximal shaft design for strong pushability
- 4F compatible in all sizes

## Balloon sizes to accommodate your needs

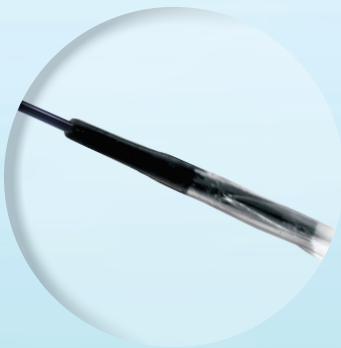
- Size range 1.5–4.0mm in diameter and 20–210mm in length
- Long balloons (up to 210mm) are suited for treatment of extremely diffuse lesions

## Conformable balloon material

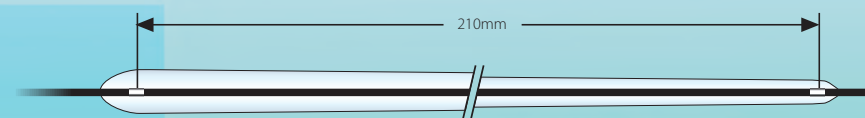
- Proprietary Polymer blend provides wonderful conformability

## Tapered balloon

- The 210mm balloon tapers by 0.5mm to respect the arterial anatomy



Balloon tip design



Tapered balloon

**All in One:  
Flexibility, Trackability  
and Conformability**



courtesy of Dr. Graziani, Brescia

# AORTIC PERIPHERAL AND VENOUS PRODUCT CATALOGUE

AORTIC



PERIPHERAL

VENOUS

**Medtronic**  
Further, Together

# EverFlex™ with Entrust™ Delivery System

## Self-Expanding Stent System

AORTIC

PERIPHERAL



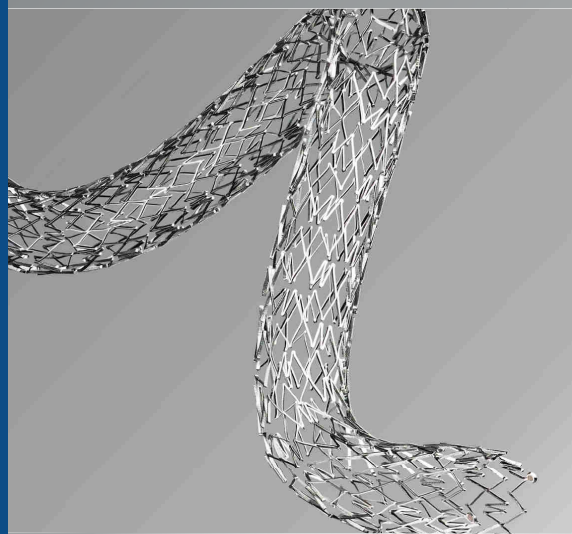
The Entrust™ delivery system is a one-handed, triaxial stent delivery system with a low 5 F profile.

This low profile was achieved without compromising the design of the EverFlex™ stent or the 0.035" guidewire compatibility.

The device was engineered specifically for control and accuracy based on physician feedback provided during extensive interviews and procedural observations.

EverFlex™ stent: The DURABILITY II study proves strong stent performance with a 60% primary patency at 3 years.

EverFlex™ Entrust™ catheter lengths: 80 cm, 120 cm, 150 cm.



VENOUS

# EverFlex™ with Entrust™ Delivery System

## Self-Expanding Stent System

### ORDER INFORMATION

Product Catalogue Number			Stent Dimensions (Unconstrained)		Size Compatibility		Guidewire Acceptance (inch)
Catheter Length 80 cm	Catheter Length 120 cm	Catheter Length 150 cm	Diameter (mm)	Length (mm)	Vessel Size (mm)	Sheath / Guide (F)	
EVX35-05-020-080	EVX35-05-020-120	EVX35-05-020-150	5	20	3.5 - 4.5	5	0.035
EVX35-05-040-080	EVX35-05-040-120	EVX35-05-040-150	5	40	3.5 - 4.5	5	0.035
EVX35-05-060-080	EVX35-05-060-120	EVX35-05-060-150	5	60	3.5 - 4.5	5	0.035
EVX35-05-080-080	EVX35-05-080-120	EVX35-05-080-150	5	80	3.5 - 4.5	5	0.035
EVX35-05-100-080	EVX35-05-100-120	EVX35-05-100-150	5	100	3.5 - 4.5	5	0.035
EVX35-05-120-080	EVX35-05-120-120	EVX35-05-120-150	5	120	3.5 - 4.5	5	0.035
EVX35-05-150-080	EVX35-05-150-120	EVX35-05-150-150	5	150	3.5 - 4.5	5	0.035
EVX35-06-020-080	EVX35-06-020-120	EVX35-06-020-150	6	20	4.5 - 5.5	5	0.035
EVX35-06-040-080	EVX35-06-040-120	EVX35-06-040-150	6	40	4.5 - 5.5	5	0.035
EVX35-06-060-080	EVX35-06-060-120	EVX35-06-060-150	6	60	4.5 - 5.5	5	0.035
EVX35-06-080-080	EVX35-06-080-120	EVX35-06-080-150	6	80	4.5 - 5.5	5	0.035
EVX35-06-100-080	EVX35-06-100-120	EVX35-06-100-150	6	100	4.5 - 5.5	5	0.035
EVX35-06-120-080	EVX35-06-120-120	EVX35-06-120-150	6	120	4.5 - 5.5	5	0.035
EVX35-06-150-080	EVX35-06-150-120	EVX35-06-150-150	6	150	4.5 - 5.5	5	0.035
EVX35-07-020-080	EVX35-07-020-120	EVX35-07-020-150	7	20	5.5 - 6.5	5	0.035
EVX35-07-040-080	EVX35-07-040-120	EVX35-07-040-150	7	40	5.5 - 6.5	5	0.035
EVX35-07-060-080	EVX35-07-060-120	EVX35-07-060-150	7	60	5.5 - 6.5	5	0.035
EVX35-07-080-080	EVX35-07-080-120	EVX35-07-080-150	7	80	5.5 - 6.5	5	0.035
EVX35-07-100-080	EVX35-07-100-120	EVX35-07-100-150	7	100	5.5 - 6.5	5	0.035
EVX35-07-120-080	EVX35-07-120-120	EVX35-07-120-150	7	120	5.5 - 6.5	5	0.035
EVX35-07-150-080	EVX35-07-150-120	EVX35-07-150-150	7	150	5.5 - 6.5	5	0.035
EVX35-08-020-080	EVX35-08-020-120	EVX35-08-020-150	8	20	6.5 - 7.5	5	0.035
EVX35-08-040-080	EVX35-08-040-120	EVX35-08-040-150	8	40	6.5 - 7.5	5	0.035
EVX35-08-060-080	EVX35-08-060-120	EVX35-08-060-150	8	60	6.5 - 7.5	5	0.035
EVX35-08-080-080	EVX35-08-080-120	EVX35-08-080-150	8	80	6.5 - 7.5	5	0.035
EVX35-08-100-080	EVX35-08-100-120	EVX35-08-100-150	8	100	6.5 - 7.5	5	0.035
EVX35-08-120-080	EVX35-08-120-120	EVX35-08-120-150	8	120	6.5 - 7.5	5	0.035
EVX35-08-150-080	EVX35-08-150-120	EVX35-08-150-150	8	150	6.5 - 7.5	5	0.035

INDICATIONS: The stent is indicated for use in occlusions, lesions at high risk for abrupt closure or threatened closure following percutaneous transluminal angioplasty (PTA); or lesions believed to be at high risk for restenosis following PTA in the common iliac, external iliac, superficial femoral, proximal popliteal, or subclavian arteries. Stenting is intended to improve and maintain artery luminal diameter.



# Amphirion™ Deep

## Infrapopliteal PTA Balloon Catheter OTW 0.014"

### Easy access to the extremities\*

- Tip profile (0.017")
- LFC hydrophilic coating
- Three-step shaft design to optimize tracking through distal vessels
- Reinforced proximal shaft design for strong pushability
- 4 F compatible in all sizes

### Balloon sizes to accommodate your needs\*

- Size range 1.5–4.0 mm in diameter and 20–210 mm in length
- Long balloons (up to 210 mm) are suited for treatment of extremely diffuse lesions

### Conformable balloon material\*

- Proprietary polymer blend provides wonderful conformability

### Tapered balloon\*

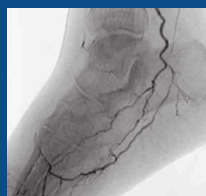
- The 210 mm balloon tapers by 0.5 mm to respect the arterial anatomy

### TECHNICAL SPECIFICATIONS

Catheter design	Over-the-wire
Balloon marker	1/2 swaged, Platinum Iridium
Shaft diameter	Proximal 3.9 F Middle 3.3 F Distal 2.8 F
Introducer sheath compatibility	4 F
Guidewire compatibility	0.014"
Nominal pressure	7 atm



Image courtesy of Dr. Marco Manzi, Italy.



Below the ankle



\* Bench Test Data on file with Medtronic, Inc.  
Test data not indicative of clinical performance

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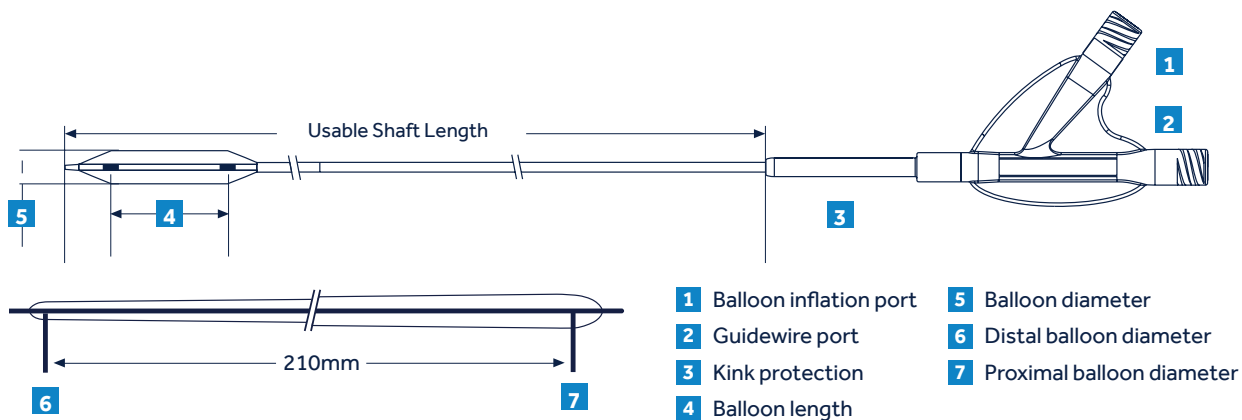
VENOUS

# Amphirion™ Deep

## Infrapopliteal PTA Balloon Catheter OTW 0.014"

### ORDER INFORMATION

Product Catalogue Number		Balloon Diameter (mm)	Balloon Length (mm)	Recommended Introducer Sheath (F)	Nominal Pressure (BAR)	RBP (BAR)
OTW Usable Length 120 cm	OTW Usable Length 150 cm					
AMD 015 020 001	AMD 015 020 151	1.5	20	4	7	14
AMD 015 020 002	AMD 015 020 152	1.5	20	4	7	14
AMD 020 040 002	AMD 020 040 152	2.0	40	4	7	15
AMD 020 080 002	AMD 020 080 152	2.0	80	4	7	14
AMD 020 120 002	AMD 020 120 152	2.0	120	4	7	14
AMD 020 150 002	AMD 020 150 152	2.0	150	4	7	14
AMD 025 040 002	AMD 025 040 152	2.5	40	4	7	16
AMD 025 080 002	AMD 025 080 152	2.5	80	4	7	15
AMD 025 120 002	AMD 025 120 152	2.5	120	4	7	14
AMD 025 150 002	AMD 025 150 152	2.5	150	4	7	14
AMD 030 040 002	AMD 030 040 152	3.0	40	4	7	16
AMD 030 080 002	AMD 030 080 152	3.0	80	4	7	15
AMD 030 120 002	AMD 030 120 152	3.0	120	4	7	14
AMD 030 150 002	AMD 030 150 152	3.0	150	4	7	14
AMD 035 040 002	AMD 035 040 152	3.5	40	4	7	16
AMD 035 080 002	AMD 035 080 152	3.5	80	4	7	15
AMD 035 120 002	AMD 035 120 152	3.5	120	4	7	14
AMD 035 150 002	AMD 035 150 152	3.5	150	4	7	14
AMD 040 040 002	AMD 040 040 152	4.0	40	4	7	16
AMD 040 080 002	AMD 040 080 152	4.0	80	4	7	15
AMD 040 120 002	AMD 040 120 152	4.0	120	4	7	14
AMD 040 150 002	AMD 040 150 152	4.0	150	4	7	14
AMD 225 210 002	AMD 225 210 152	2.0/2.5	210	4	7	14
AMD 253 210 002	AMD 253 210 152	2.5/3.0	210	4	7	14
AMD 335 210 002	AMD 335 210 152	3.0/3.5	210	4	7	14
AMD 354 210 002	AMD 354 210 152	3.5/4.0	210	4	7	14



# SpiderFX™

## Embolic Protection System

The SpiderFX™ System is the only embolic protection device that works with any 0.014" or 0.018" guidewire of choice to cross the most challenging lesions.

The device offers enhanced visibility due to the nitinol frame with gold / tungsten marker. The extensive product portfolio permits treatment within a range of vessel sizes from 2 mm to 7 mm. The SpiderFX™ System is compatible with a guide catheter / sheath minimum ID of 0.066" ( typically a 6 F guide catheter or 5 F access / long sheath ). Check catheter manufacturer information for size compatibility.

The use of the SpiderFX™ device is strongly associated with:

- Lower costs
- Shorter inpatient hospital stays
- Lower ICU utilization rate
- Shorter OR times

### Basket design

- The unique braided nitinol filter conforms to the vessel wall and maintains full-wall apposition during the intervention. Flow is directed into the filter's conical design, effectively capturing debris while maintaining blood flow

### Visible markers

- A gold tungsten loop around the mouth of the filter, along with radiopaque markers, allows for precise positioning and verification of apposition before proceeding with the intervention

### Wire movement

- The capture wire (available in 190 cm and 320 cm lengths) rotates and moves longitudinally, independent of the filter, for enhanced stability during the procedure
- The SpiderFX™ device is available in a variety of sizes (3 – 7 mm) for optimal fit and apposition in a range of vessels



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VENOUS

### ORDER INFORMATION

Product Catalogue Number (1/Box)	Capture Wire				Delivery Catheter Cross Profile (F)	Recovery Catheter Diameter (F)	Guide Catheter Sheath Minimum ID (inch)
	Filter Size (mm)	Target Vessel Size (mm)	Wire Length OTW/RX (cm)	Wire Diameter (inch / mm)			
SPD2-030-190	3.0	2.0–3.0	190	0.014 / 0.36	3.2	4.2	0.066
SPD2-030-320	3.0	2.0–3.0	320 / 190	0.014 / 0.36	3.2	4.2	0.066
SPD2-040-190	4.0	3.1–4.0	190	0.014 / 0.36	3.2	4.2	0.066
SPD2-040-320	4.0	3.1–4.0	320 / 190	0.014 / 0.36	3.2	4.2	0.066
SPD2-050-190	5.0	4.1–5.0	190	0.014 / 0.36	3.2	4.2	0.066
SPD2-050-320	5.0	4.1–5.0	320 / 190	0.014 / 0.36	3.2	4.2	0.066
SPD2-060-190	6.0	4.5–6.0	190	0.014 / 0.36	3.2	4.2	0.066
SPD2-060-320	6.0	4.5–6.0	320 / 190	0.014 / 0.36	3.2	4.2	0.066
SPD2-070-190	7.0	5.5–7.0	190	0.014 / 0.36	3.2	4.2	0.066
SPD2-070-320	7.0	5.5–7.0	320 / 190	0.014 / 0.36	3.2	4.2	0.066

#### INDICATIONS:

The SpiderFX™ Embolic Protection System provides distal embolization protection during general vascular use, including peripheral, coronary, and carotid interventions.

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# SGS

Certificate US97/10052

The management system of

## NuMED Canada, Inc.

45 Second Street West,  
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has been assessed and certified as meeting the requirements of

# ISO 13485:2016 EN ISO 13485:2016



For the following activities

**Design, manufacture and contract manufacture of non-sterile and sterile sizing catheters, sterile stent placement, dialysis, dilatation, electrode catheters and sterile angiographic catheters and sterile cardiovascular stents, and sterile introducers.**

This certificate is valid from 02 May 2019 until 02 May 2022 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 13 July 2021  
Issue 17. Certified since 09 June 1997

*Expiry date of last certificate: 31 March 2019  
End date of last recertification audit: 13 July 2018*

Authorised by

A stylized handwritten signature in black ink.



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## Atrioseptostomy

### Z-5™

The Z-5™ Atrioseptostomy catheter was developed in collaboration with **Dr Ziyad Hijazi** and was first approved and introduced in 1996. With over 25 years of proven safety and clinical experience, the Z-5™ is trusted by interventional pediatric cardiologists throughout the world. The dual lumen shaft design provides pushability, coupled with exceptional pull strength. The Z-5™ is available in 9.5mm and 13.5mm diameters.

## Unique Benefits

The Z-5™ features a micro-thin non-compliant balloon for a low deflated profile that maintains its flexibility. The balloon inflation is controlled by volume. The tip of the catheter is angled at 35 degrees to facilitate passage into the left atrium. The Z-5™ catheter has a dual lumen, with an end hole that can accommodate a guidewire. The catheter body is radiopaque to facilitate reliable positioning of the catheter. The reduced 9.5mm inflated balloon size makes atrioseptostomy easier to perform on neonates with a small left atrium.

The catheter body is Polymeric, DEHP-free, and not made with natural rubber latex. The balloon is a thermoplastic elastomer (non-compliant), DEHP-free, and not made with natural rubber latex.

## Z-5™ Atrioseptostomy Balloon Catheter

Balloon Diameter (mm)	Balloon Length (cm)	Introducer (FR)	Shaft Size (FR)
9.5	0.95	5	4.0
13.5	1.35	6	5.0

### Disclaimer

*All products are subject to individual country regulations in regards to the importation and/or sale of these products. Refer to Instructions for Use for a complete listing of indications, contraindications, warnings, and precautions.*



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