

Declaration of Conformity

Manufacturer: Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502, USA

Authorized EC Representative: Penumbra Europe GmbH
Am Borsigturm 44
13507 Berlin, Germany

Design / Manufacturing Facility: Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502, USA

Product Category: Vascular guide-catheter, single use
Product Trade Name: Neuron™ Intracranial Access System
Products: See Attachment(s)

Classification: Class III based on Annex IX, Rule 6 of Directive 93/42/EEC, as amended.

GMDN Code: Delivery Catheter:
17846 - Vascular guide-catheter, single use
Select Catheter:
10691 - Intravascular microflow catheter

Selected conformity assessment procedure: Annex II of Directive 93/42/EEC, as amended

I, the undersigned, hereby declare that the Medical Device(s) specified above meet the provisions of Directive 93/42/EEC (MDD), as amended, including 2007/47/EC which apply to them, as transposed into the national laws of the EU member states.

This declaration is supported by:

- The Penumbra, Inc. Quality System Certificate based on I.S. EN ISO 13485: 2016 (MD19.4277, expiration date 27 August 2021), issued by NSAI (Dublin, Ireland).
- The MDD Quality System Certificate, Annex II.3 of the EC Directive (252.761, expiration date 26 May 2024), issued by NSAI (Dublin, Ireland, CE 0050).
- The Penumbra, Inc. EC Design Examination Certificate in accordance with Annex II.4 of the EC-Directive (252.761, expiration date 26 May 2024), issued by NSAI (Dublin, Ireland, CE 0050).

Signature:  Date: 01 Apr 2020

Name & Title: Michaela Mahl
Senior Manager of Regulatory Affairs

ATTACHMENT TO THE DECLARATION OF CONFORMITY

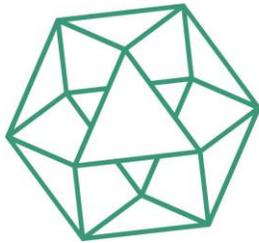
Product List: "Neuron™ Intracranial Access System" (Class III, Rule 6)

Catalog Number	Device Name
PND6F11512	Neuron Delivery Catheter (115cm/12cm)
PND6F11512M	Neuron Delivery Catheter (115cm/12cm - MP)
PND6F1156	Neuron Delivery Catheter (115cm/6cm)
PND6F1156M	Neuron Delivery Catheter (115cm/6cm - MP)
PND6F10512	Neuron Delivery Catheter (105cm/12cm)
PND6F10512M	Neuron Delivery Catheter (105cm/12cm - MP)
PND6F1056	Neuron Delivery Catheter (105cm/6cm)
PND6F1056M	Neuron Delivery Catheter (105cm/6cm - MP)
PND6F070956	Neuron Delivery Catheter (95cm/6cm)
PND6F070956M	Neuron Delivery Catheter (95cm/6cm - MP)
PND6F0701058	Neuron Delivery Catheter (105cm/8cm)
PND6F0701058M	Neuron Delivery Catheter (105cm/8cm - MP)
PNS5F130H1	Neuron Select Catheter 130 (H1)
PNS5F130SIM	Neuron Select Catheter 130 (Simmons)
PNS5F130BER	Neuron Select Catheter 130 (BER)
PNS5F120H1	Neuron Select Catheter 120 (H1)
PNS5F120SIM	Neuron Select Catheter 120 (Simmons)
PNS5F120BER	Neuron Select Catheter 120 (BER)
PNML6F088704M	6F 088 Neuron MAX Long Sheath 70/4 MP
PNML6F088704	6F 088 Neuron MAX Long Sheath 70/4 Straight
PNML6F088804M	6F 088 Neuron MAX Long Sheath 80/4 MP
PNML6F088804	6F 088 Neuron MAX Long Sheath 80/4 Straight
PNML6F088904M	6F 088 Neuron MAX Long Sheath 90/4 MP
PNML6F088904	6F 088 Neuron MAX Long Sheath 90/4 Straight
PNML6F0881004M	6F 088 Neuron MAX Long Sheath 100/4 MP
PNML6F0881004	6F 088 Neuron MAX Long Sheath 100/4 Straight
PNML6F088704MR	6F 088 Neuron MAX Long Sheath 70/4 MP RHV
PNML6F088704R	6F 088 Neuron MAX Long Sheath 70/4 Straight RHV
PNML6F088804MR	6F 088 Neuron MAX Long Sheath 80/4 MP RHV
PNML6F088804R	6F 088 Neuron MAX Long Sheath 80/4 Straight RHV
PNML6F088904MR	6F 088 Neuron MAX Long Sheath 90/4 MP RHV
PNML6F088904R	6F 088 Neuron MAX Long Sheath 90/4 Straight RHV
PNML6F0881004MR	6F 088 Neuron MAX Long Sheath 100/4 MP RHV
PNML6F0881004R	6F 088 Neuron MAX Long Sheath 100/4 Straight RHV
PNMD8F088704M	8F 088 Neuron MAX 088 Delivery Catheter 70/4 MP
PNMD8F088704	8F 088 Neuron MAX 088 Delivery Catheter 70/4 Straight
PNMD8F088804M	8F 088 Neuron MAX 088 Delivery Catheter 80/4 MP
PNMD8F088804	8F 088 Neuron MAX 088 Delivery Catheter 80/4 Straight
PNMD8F088904M	8F 088 Neuron MAX 088 Delivery Catheter 90/4 MP
PNMD8F088904	8F 088 Neuron MAX 088 Delivery Catheter 90/4 Straight

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Catalog Number	Device Name
PNMD8F0881004M	8F 088 Neuron MAX 088 Delivery Catheter 100/4 MP
PNMD8F0881004	8F 088 Neuron MAX 088 Delivery Catheter 100/4 Straight
PNS6F125SIM	6F Neuron Select Catheter 125 SIM
PNS6F125H1	6F Neuron Select Catheter 125 H1
PNS6F125BER	6F Neuron Select Catheter 125 BER
PNS6F125SIMV	6F Neuron Select Catheter 125 SIM-V
PNS6F105SIM	6F Neuron Select Catheter 105 SIM
PNS6F105H1	6F Neuron Select Catheter 105 H1
PNS6F105BER	6F Neuron Select Catheter 105 BER
PNS6F105SIMV	6F Neuron Select Catheter 105 SIM-V

End of Product List



NSAI

Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502
USA

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

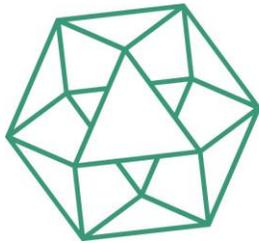
Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4277)

Approved by:
Geraldine Larkin
Chief Executive Officer

Approved by:
Caroline Dore Geraghty
Director of Medical Devices /
Head of Notified Body

Registration Number: MD19.4277
Certification Granted: August 21, 2007
Effective Date: August 28, 2021
Expiry Date: August 27, 2024





NSAI

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity

Location

Administration, Design,
Manufacturing, Distribution

Penumbra, Inc.
One Penumbra Place
Building 1351
Alameda, CA 94502
USA
File No.: MD19.4277

Administration, Design,
Manufacturing, Distribution

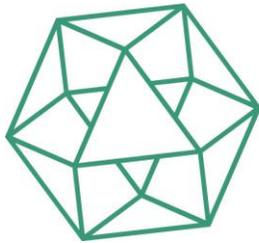
Penumbra, Inc.
One Penumbra Place
Building 1321
Alameda, CA 94502
USA
File No.: MD19.4277/A

Design

Penumbra, Inc.
One Penumbra Place
Building 1411
Alameda, CA 94502
USA
File No.: MD19.4277/B

Distribution

Penumbra Europe GmbH
Am Borsigturm 44
13507 Berlin
Germany
File No.: MD19.4277/C



NSAI

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity

Location

Distribution

Penumbra, Inc.
6336 Patterson Pass Rd
Suite D
Livermore, CA 94550
USA
File No.: MD19.4277/D

Manufacturing

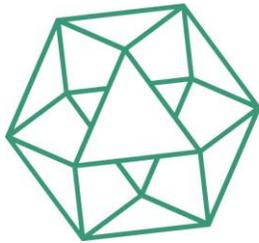
Penumbra, Inc.
One Penumbra Place
Building 1301
Alameda, CA 94502
USA
File No.: MD19.4277/E

Distribution

Penumbra, Inc.
6262 Patterson Pass Rd
Suite A
Livermore, CA 94550
USA
File No.: MD19.4277/F

Manufacturing

Penumbra, Inc.
One Penumbra Place
Building 1401
Alameda, CA 94502
USA
File No.: MD19.4277/G



NSAI

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity

Location

Distribution

Penumbra Neuro Australia Pty
Suite 3, Level 5, 1 Oxford St
Darlinghurst
Sydney NSW
Australia
File No.: MD19.4277/H

Distribution

Crossmed SpA,
Via Giuseppe di Vittorio 2/C
10098 Rivoli Torino
Italy
File No.: MD19.4277/I

Distribution

Crossmed SpA,
Via Primaticcio 184,
2017 Milano
Italy
File No.: MD19.4277/J

Distribution

Penumbra, Inc.
1070 South 3800 West
Suite 500
Salt Lake City, UT 84104
USA
File No.: MD19.4277/K



NSAI

Annex to Certificate Number: MD19.4277

Scope of Registration:

The Design, Manufacture and Distribution of Medical Devices for the Treatment of Neuro, Peripheral and Cardiovascular Disease Including: Delivery Catheters, Aspiration Catheters, Separators, Revascularization Devices, Embolization Implants, and Neurosurgical Aspiration Devices. The Design, Manufacture, Distribution, and Service of Active Aspiration Systems. The Distribution of Neurosurgical and Intravascular Access and Treatment Devices.

Activity

Manufacturing

Location

Penumbra, Inc.
630 Roseville Parkway
Roseville, CA 95747
USA
File No.: MD19.4277/L

**Verified by:
Operations Manager**



NSAI

Quality System Approval Certificate Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

APPROVES THE QUALITY SYSTEM APPLIED BY

Penumbra, Inc.

**One Penumbra Place
Alameda
CA 94502
USA**

to the Product Family

Vascular guide-catheter, single-use (Neuron Intracranial Access System)

GMDN Code: 17846 & 10691

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex
II, excluding (4)*

*The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of
Conformance for this product family is hereby authorised.*

Registration Number:	252.761
Original Approval:	20 September 2007
Last Amended on:	18 March 2020
Remains valid until:	26 May 2024

Signed:

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.



NSAI

EC Design Examination Certificate Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated
Notified Body, (identification number 0050), for the purposes of the European Communities
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

HAS EXAMINED THE DESIGN DOSSIER
Submitted by

Penumbra, Inc.

One Penumbra Place
Alameda
CA 94502
USA

For Product Family

**Vascular guide-catheter, single-use
(Neuron Intracranial Access System)**

GMDN Code: 17846 & 10691

CONCLUSION of EXAMINATION:

*NSAI have performed an examination of the design dossier relating to the above named product family and
conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)*

Registration Number:	252.761
Original Approval:	20 September 2007
Last Amended on:	18 March 2020
Remains valid until:	26 May 2024

Signed:

Approved by:
Dr. Caroline Dore Geraghty
Director, Medical Devices

Approved by:
Dr. Elaine Darcy
European Medical Device Operations Manager

CONDITIONS OF VALIDITY:

This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.

Approved model numbers are included in the associated attachment

Note: Not valid without a valid Annex II Section 3 Certificate.

Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the
product must receive further approval from NSAI.

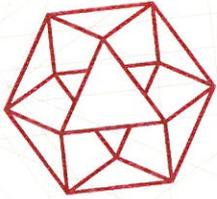
National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.



Attachment to Certificate 252.761 dated 20 September 2007

This Certificate covers 50 model(s)

Model Reference	Detail
PND6F11512	Neuron Delivery Catheter (115cm/12cm)
PND6F11512M	Neuron Delivery Catheter (115cm/12cm - MP)
PND6F1156	Neuron Delivery Catheter (115cm/6cm)
PND6F1156M	Neuron Delivery Catheter (115cm/6cm - MP)
PND6F10512	Neuron Delivery Catheter (105cm/12cm)
PND6F10512M	Neuron Delivery Catheter (105cm/12cm - MP)
PND6F1056	Neuron Delivery Catheter (105cm/6cm)
PND6F1056M	Neuron Delivery Catheter (105cm/6cm - MP)
PND6F070956	Neuron Delivery Catheter (95cm/6cm)
PND6F070956M	Neuron Delivery Catheter (95cm/6cm – MP)
PND6F0701058	Neuron Delivery Catheter (105cm/8cm)
PND6F0701058M	Neuron Delivery Catheter (105cm/8cm –MP)
PNS5F130SIM	Neuron Select Catheter 130 (Simmons)
PNS5F130H1	Neuron Select Catheter 130 (H1)
PNS5F130BER	Neuron Select Catheter 130 (BER)
PNS5F120SIM	Neuron Select Catheter 120 (Simmons)
PNS5F120H1	Neuron Select Catheter 120 (H1)
PNS5F120BER	Neuron Select Catheter 120 (Berenstein)
PNML6F088704M	6F 088 Neuron MAX Long Sheath 70/4 MP
PNML6F088704	6F 088 Neuron MAX Long Sheath 70/4 Straight
PNML6F088804M	6F 088 Neuron MAX Long Sheath 80/4 MP
PNML6F088804	6F 088 Neuron MAX Long Sheath 80/4 Straight
PNML6F088904M	6F 088 Neuron MAX Long Sheath 90/4 MP
PNML6F088904	6F 088 Neuron MAX Long Sheath 90/4 Straight
PNML6F0881004M	6F 088 Neuron MAX Long Sheath 100/4 MP
PNML6F0881004	6F 088 Neuron MAX Long Sheath 100/4 Straight
PNML6F088704MR	6F 088 Neuron MAX Long Sheath 70/4 MP RHV
PNML6F088704R	6F 088 Neuron MAX Long Sheath 70/4 Straight RHV
PNML6F088804MR	6F 088 Neuron MAX Long Sheath 80/4 MP RHV
PNML6F088804R	6F 088 Neuron MAX Long Sheath 80/4 Straight RHV



NSAI

Attachment to Certificate 252.761 dated 20 September 2007

This Certificate covers 50 model(s)

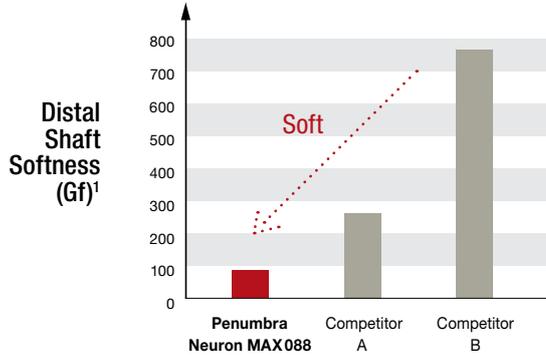
Model Reference	Detail
PNML6F088904MR	6F 088 Neuron MAX Long Sheath 90/4 MP RHV
PNML6F088904R	6F 088 Neuron MAX Long Sheath 90/4 Straight RHV
PNML6F0881004MR	6F 088 Neuron MAX Long Sheath 100/4 MP RHV
PNML6F0881004R	6F 088 Neuron MAX Long Sheath 100/4 Straight RHV
PNMD8F088704M	8F 088 Neuron MAX 088 Delivery Catheter 70/4 MP
PNMD8F088704	8F 088 Neuron MAX 088 Delivery Catheter 70/4 Straight
PNMD8F088804M	8F 088 Neuron MAX 088 Delivery Catheter 80/4 MP
PNMD8F088804	8F 088 Neuron MAX 088 Delivery Catheter 80/4 Straight
PNMD8F088904M	8F 088 Neuron MAX 088 Delivery Catheter 90/4 MP
PNMD8F088904	8F 088 Neuron MAX 088 Delivery Catheter 90/4 Straight
PNMD8F0881004M	8F 088 Neuron MAX 088 Delivery Catheter 100/4 MP
PNMD8F0881004	8F 088 Neuron MAX 088 Delivery Catheter 100/4 Straight
PNS6F125SIM	6F Neuron Select Catheter 125 SIM
PNS6F125H1	6F Neuron Select Catheter 125 H1
PNS6F125BER	6F Neuron Select Catheter 125 BER
PNS6F125SIMV	6F Neuron Select Catheter 125 SIM-V
PNS6F105SIM	6F Neuron Select Catheter 105 SIM
PNS6F105H1	6F Neuron Select Catheter 105 H1
PNS6F105BER	6F Neuron Select Catheter 105 BER
PNS6F105SIMV	6F Neuron Select Catheter 105 SIM-V

Neuron MAX 088

Soft Tip, 6F Long Sheath for Neurovascular Support

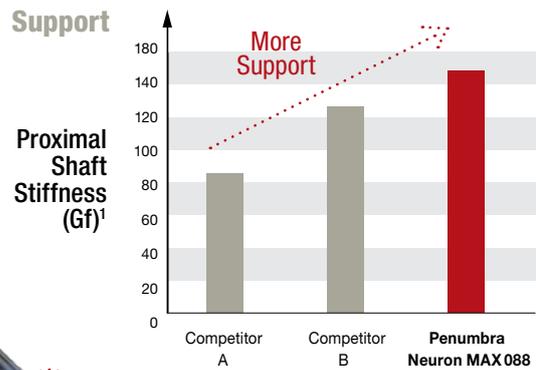
Distal flexibility – measuring tip softness

- 3x softer than Competitor A
- 9x softer than Competitor B



Optimal proximal support

- 75% more support than Competitor A



Largest lumen in class to deliver the widest range of devices

Penumbra Neuron MAX	Competitor A	Competitor B ²
.088"	.087"	.085"

Soft, beveled tip

PX SLIM

Compatible adjunctive device therapy

Penumbra Neuron MAX 088

- Prowler Select Plus
- XT-27
- Marksman
- Hyperform, Hyperglide, TransForm, Ascent, and Sceptre balloons

Penumbra

1. At 50 mm gauge length via 5 mm compression at 10 mm/min rate

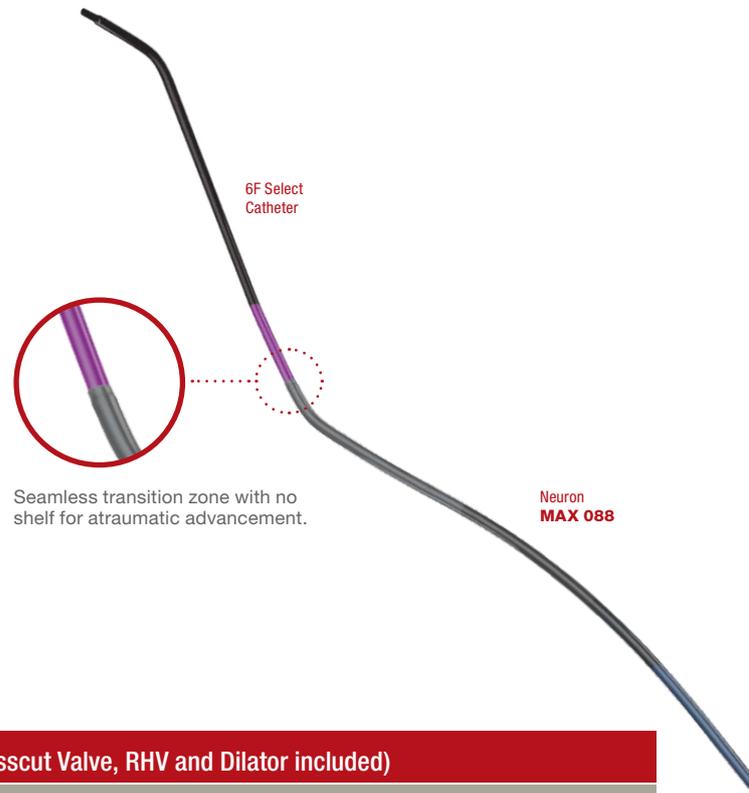
2. Based on measurements

Neuron **MAX 088** Soft Tip, 6F Long Sheath

- Full length stainless steel braid reinforced proximal support zone transitioning to 4 cm distal flexible zone with large .088" inner lumen
- Distal shaft has hydrophilic coating for optimal trackability
- Available in 80 cm and 90 cm lengths with Straight and Multipurpose (MP) tip shape

6F Select Catheter

1. Enables primary access and atraumatic placement into desired vessel without an over-the-wire exchange
2. Useful for diagnostic angiogram – .040" lumen
3. Stainless steel braided proximal shaft for support and torque response with a soft polymer distal shaft to enable atraumatic vessel selection



Ordering Information

Neuron **MAX 6F 088** Lumen Long Sheath (Crosscut Valve, RHV and Dilator included)

Catalog Number	Description	Tip Shape	Working Length	Distal Flexible Zone	Outer Diameter* Proximal / Distal	Inner Diameter	Wire Compatibility
PNML6F088804	6F 088 Neuron MAX Long Sheath, 80/4 Straight		80 cm	4 cm	8F / 8F	.088"	.035/.038"
PNML6F088804M	6F 088 Neuron MAX Long Sheath, 80/4 MP		80 cm	4 cm	8F / 8F	.088"	.035/.038"
PNML6F088904	6F 088 Neuron MAX Long Sheath, 90/4 Straight		90 cm	4 cm	8F / 8F	.088"	.035/.038"
PNML6F088904M	6F 088 Neuron MAX Long Sheath, 90/4 MP		90 cm	4 cm	8F / 8F	.088"	.035/.038"

6F Select Catheter

Catalog Number	Description	Tip Shape	Working Length	Distal Flexible Zone	Outer Diameter* Proximal / Distal	Inner Diameter	Wire Compatibility
PNS6F105BER	6F Select Catheter, 105 BER		105 cm	9 cm	5.6F / 6F / 5F	.040"	.035/.038"
PNS6F105H1	6F Select Catheter, 105 H1		105 cm	9 cm	5.6F / 6F / 5F	.040"	.035/.038"
PNS6F125BER	6F Select Catheter, 125 BER		125 cm	9 cm	5.6F / 6F / 5F	.040"	.035/.038"
PNS6F125SIM - NEW!	6F Select Catheter, 125 SIM	NEW!	125 cm	9 cm	5.6F / 6F / 5F	.040"	.035/.038"
PNS6F125H1	6F Select Catheter, 125 H1		125 cm	9 cm	5.6F / 6F / 5F	.040"	.035/.038"
PNS6F125SIMV	6F Select Catheter, 125 SIM-V		125 cm	9 cm	5.6F / 6F / 5F	.040"	.035/.038"

* A mid outer diameter is only listed if applicable to device.



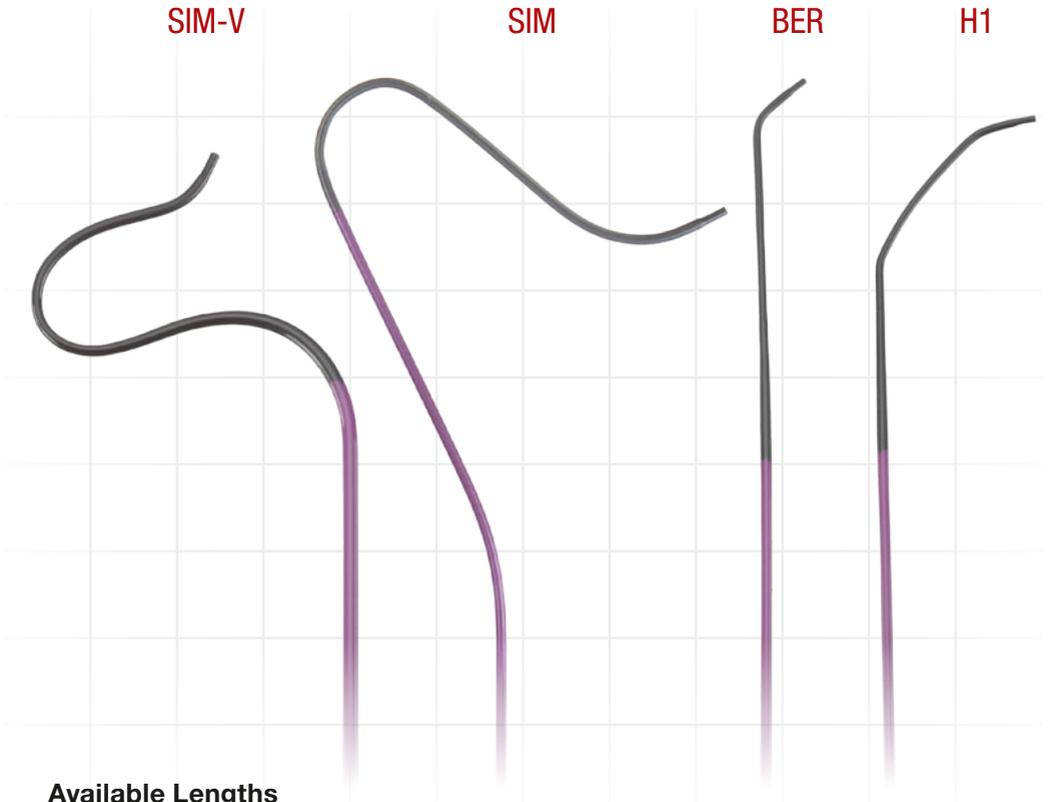
www.penumbrainc.com

Penumbra, Inc. USA
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F 1.510.748.3232
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info@penumbrainc.com

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F +49 30 2005 676-10
order@penumbrainc.de
info@penumbrainc.de

Penumbra Neuro Australia Pty Ltd
Suite 3, Level 5, 1 Oxford Street
Darlinghurst NSW 2010
Australia
T +61-1300 817 025
F +61-1300 817 026
order.anz@penumbrainc.com

Select Catheter Tip Shapes



Available Lengths

5 F	–	130 cm	120 cm 130 cm	120 cm 130 cm
6 F	125 cm	125 cm	105 cm 125 cm	105 cm 125 cm



6 F Select through
Neuron MAX



5 F Select through
BENCHMARK

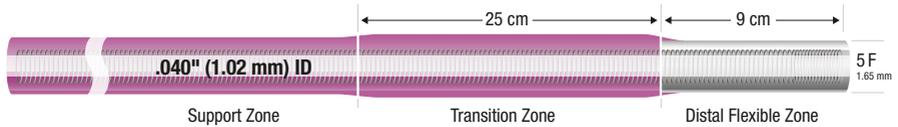
Seamless transition zone designed for atraumatic advancement

Select Catheter Construction

Penumbra Select Catheters

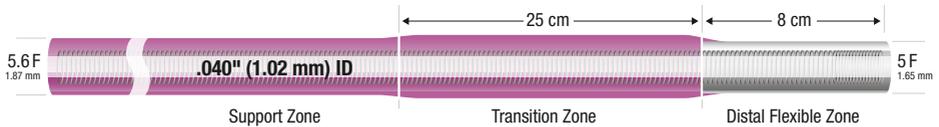
- Stainless braided shaft with radiopaque polymer steam-shaped tip
- Tapered profile of each Select Catheter optimised for seamless transition and torque response
- Penumbra Select Catheters do not have hydrophilic coating

5 F Select | 120/130 cm



- Designed to deliver soft-tipped BENCHMARK 071 and Neuron 070 Intracranial Access Catheters
- Not designed to deliver 6 F Long Sheath

6 F Select | 105/125 cm



- Designed to deliver Neuron MAX Long Sheath
- Not designed for use with smaller ID catheters

Prior to use, please refer to the Instructions for Use for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use.

NEURON Intracranial Access System – Intended Use
The NEURON Intracranial Access System is intended for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia;

neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

NEURON MAX System – Intended Use
The NEURON MAX System is intended for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

BENCHMARK Intracranial Access System – Intended Use
The BENCHMARK Intracranial Access System is intended for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Potential Adverse Events
Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.



Penumbra, Inc. USA
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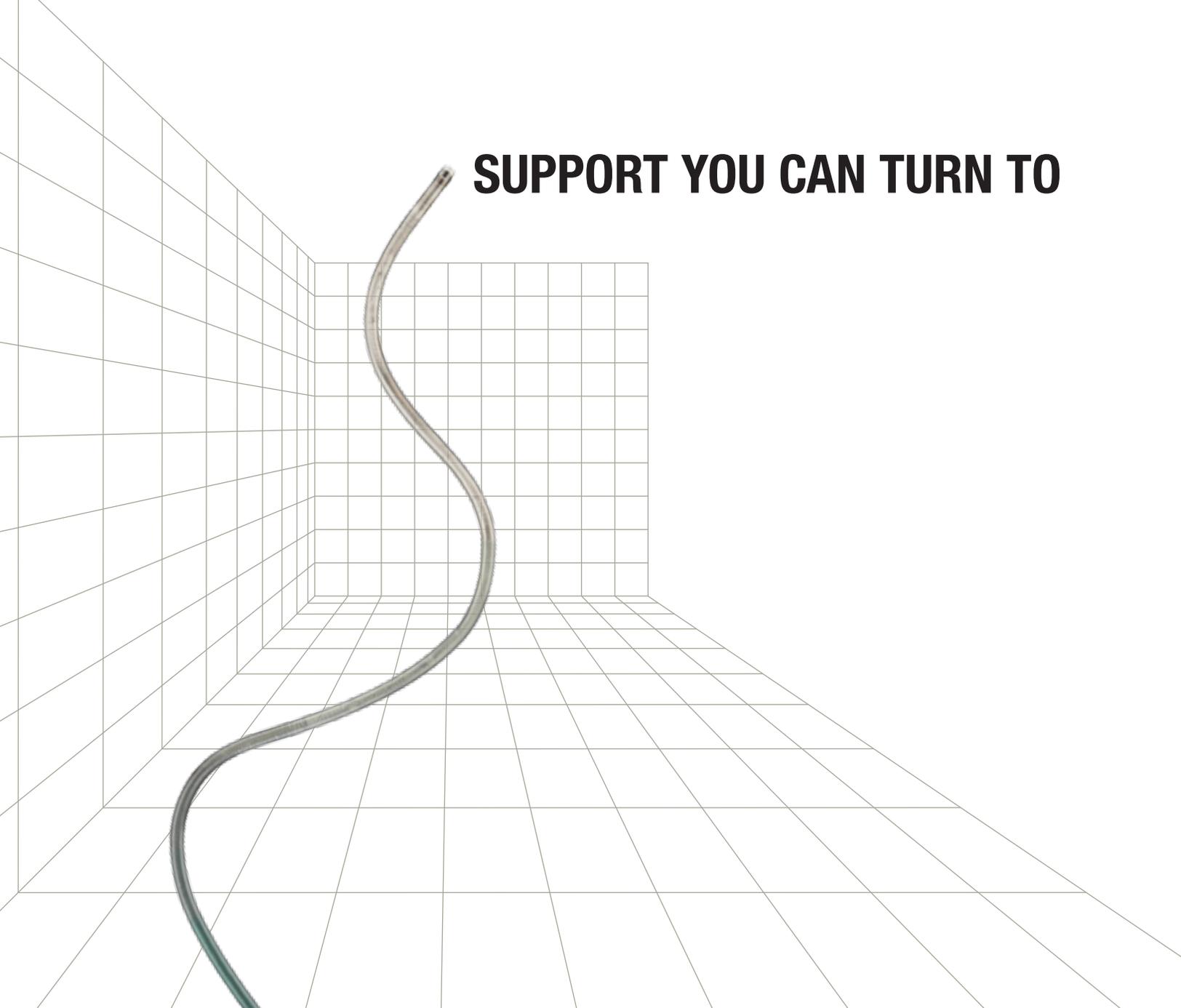
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Product availability varies by country. Please contact your local Penumbra representative for more information.

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SUPPORT YOU CAN TURN TO

**Neuron™ 6F
Intracranial Access System**

Now with a Larger 070 Therapy Delivery Lumen

Deliver all your therapies from simple to complex,
with improved support, closer to the treatment site

Penumbra 

Designed to Deliver Your Most Complex Multi-Device Therapies

Neuron 6F 070 Lumen Delivery Catheter

- Hybrid shaft design with multi-layer stainless steel braid re-enforced proximal support zone transitioning to a distal platinum coil flexible zone.
- Platinum reinforced distal shaft provides improved radiopacity for fluoroscopic visualization.
- Distal shaft has hydrophilic coating for optimal trackability.

Neuron 5F Select Catheter

- Stainless steel braided proximal shaft for support and torque response with a soft polymer distal shaft to enable atraumatic vessel selection.
- Full length radiopacity to help ease vessel selection.
- Lumen accommodates up to 038" wire.



Ordering Information

Catalog Number	Description	Working Length	Distal Flexible Zone	Outer Diameter Proximal/Distal	Inner Diameter	Wire Compatibility
Neuron 6F 070 Lumen Delivery Catheters						
PND6F070956	6F 070 Neuron Delivery Catheter, 95/6 Straight	95 cm	6 cm	6F / 6F	.070"	.035/.038"
PND6F070956M	6F 070 Neuron Delivery Catheter, 95/6 MP	95 cm	6 cm	6F / 6F	.070"	.035/.038"
PND6F0701058	6F 070 Neuron Delivery Catheter, 105/8 Straight	105 cm	8 cm	6F / 6F	.070"	.035/.038"
PND6F0701058M	6F 070 Neuron Delivery Catheter, 105/8, MP	105 cm	8 cm	6F / 6F	.070"	.035/.038"
Neuron 5F Select Catheters						
PNS5F120H1	5F Neuron Select Catheter, 120 H1	120 cm	9 cm	5F / 5F	.040"	.035/.038"
PNS5F120SIM	5F Neuron Select Catheter, 120 SIM	120 cm	9 cm	5F / 5F	.040"	.035/.038"
PNS5F120BER	5F Neuron Select Catheter, 120 Ber	120 cm	9 cm	5F / 5F	.040"	.035/.038"
PNS5F130H1	5F Neuron Select Catheter, 130 H1	130 cm	9 cm	5F / 5F	.040"	.035/.038"
PNS5F130SIM	5F Neuron Select Catheter, 130 SIM	130 cm	9 cm	5F / 5F	.040"	.035/.038"
PNS5F130BER	5F Neuron Select Catheter, 130 Ber	130 cm	9 cm	5F / 5F	.040"	.035/.038"
Neuron 6F 053 Lumen Delivery Catheters						
PND6F10512	6F Neuron Delivery Catheter, 105/12 Straight	105 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F10512M	6F Neuron Delivery Catheter, 105/12 MP	105 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F1056	6F Neuron Delivery Catheter, 105/6 Straight	105 cm	6 cm	6F / 5F	.053"	.035/.038"
PND6F1056M	6F Neuron Delivery Catheter, 105/6 MP	105 cm	6 cm	6F / 5F	.053"	.035/.038"
PND6F11512	6F Neuron Delivery Catheter, 115/12 Straight	115 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F11512M	6F Neuron Delivery Catheter, 115/12 MP	115 cm	12 cm	6F / 5F	.053"	.035/.038"
PND6F1156	6F Neuron Delivery Catheter, 115/6 Straight	115 cm	6 cm	6F / 5F	.053"	.035/.038"
PND6F1156M	6F Neuron Delivery Catheter, 115/6 MP	115 cm	6 cm	6F / 5F	.053"	.035/.038"



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REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE QSA 252.711
I.3. Certificatul CE	Certificat CE DE 252.962
I.3. Certificatul CE	Certificat CE QSA 252.761
I.3. Certificatul CE	Certificat CE QSA 252.934
I.3. Certificatul CE	Certificat CE QSA 252.885
I.3. Certificatul CE	Certificat CE TDA MDR 739880 R000
I.3. Certificatul CE	Certificat CE DE 252.969
I.3. Certificatul CE	Certificat CE QSA 252.807
I.3. Certificatul CE	Certificat CE QSA 252.949
I.3. Certificatul CE	Certificat CE QSA 252.901

Страница 1 из 3 (Всего элементов: 24) ⏪ 1 2 3 ⏩

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000359242	CATETER-GHID VASCULAR	NEURON™ INTRACRANIAL ACCESS SYSTEM	6F NEURON SELECT CATHETER 125 SIM	PNS6F125SIM	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359235	CATETER-GHID VASCULAR	NEURON™ INTRACRANIAL ACCESS SYSTEM	8F 088 NEURON MAX 088 DELIVERY CATHETER 70/4 STRAIGHT	PNMDSF088704	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359236	CATETER-GHID VASCULAR	NEURON™ INTRACRANIAL ACCESS SYSTEM	8F 088 NEURON MAX 088 DELIVERY CATHETER 80/4 MP	PNMDSF088804M	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	

Страница 11 из 11 (Всего элементов: 103) ⏪ 1 2 3 ... 5 6 7 8 9 10 11 ⏩

☑ Сележит(NameMake), Neuron



AGENTIA MEDICAMENTULUI
SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE QSA 252.711
I.3. Certificatul CE	Certificat CE DE 252.962
I.3. Certificatul CE	Certificat CE QSA 252.761
I.3. Certificatul CE	Certificat CE QSA 252.934
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I.3. Certificatul CE	Certificat CE QSA 252.949
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Страница 1 из 3 (Всего элементов: 24) ⏪ 1 2 3 ⏩

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod var
DM000226563	CATETER-GHID VASCULAR	Neuron™	6F 088 Neuron MAX LongSheath 80/4 Straight RHV	PNML6F088804R	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226562	CATETER-GHID VASCULAR	Neuron™	6F 088 Neuron MAX Long Sheath 80/4 MP RHV	PNML6F088804MR	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226554	CATETER-GHID VASCULAR	Neuron™	6F 088 Neuron MAX Long Sheath 80/4 MP	PNML6F088804M	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226555	CATETER-GHID VASCULAR	Neuron™	6F 088 Neuron MAX Long Sheath 80/4 Straight	PNML6F088804	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000359221	CATETER-GHID VASCULAR	NEURON™ INTRACRANIAL ACCESS SYSTEM	6F 088 NEURON MAX LONG SHEATH 80/4 STRAIGHT	PNML6F088804	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359228	CATETER-GHID VASCULAR	NEURON™ INTRACRANIAL ACCESS SYSTEM	6F 088 NEURON MAX LONG SHEATH 80/4 MP RHV	PNML6F088804MR	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359220	CATETER-GHID VASCULAR	NEURON™ INTRACRANIAL ACCESS SYSTEM	6F 088 NEURON MAX LONG SHEATH 80/4 MP	PNML6F088804M	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	
DM000359229	CATETER-GHID VASCULAR	NEURON™ INTRACRANIAL ACCESS SYSTEM	6F 088 NEURON MAX LONG SHEATH 80/4 STRAIGHT RHV	PNML6F088804R	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000155	30-06-2022	

✓ 🔍 Содержит(NameMake) „Neuron”) И Содержит(Nr. catalog) „PNML6F088804)