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:	Thrombectomy suction catheter
Product Trade Name:	Penumbra System®
Products:	See Attachment(s)
Classification:	Reperfusion Catheter, Separator and 3D Revascularization Device: Class III based on Annex IX, Rule 6 of Directive 93/42/EEC, as amended Aspiration Tubing: Class IIa based on Annex IX, Rule 2 of Directive 93/42/EEC, as amended
GMDN Code:	Reperfusion Catheter, Separator and 3D Revascularization Device: 58173 - Thrombectomy suction catheter Aspiration Tubing: 41978 - Aspiration Tubing: Surgical irrigation/ aspiration system
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 (252.711, expiration date 20 September 2020), issued by NSAI (Dublin, Ireland, CE 0050).
- The Penumbra, Inc. EC Design Examination Certificate in accordance with Annex II.4 of the EC-Directive (252.711, expiration date 20 September 2020), issued by NSAI (Dublin, Ireland, CE 0050).

Signature: _____ Date: 12-Feb-2020

Name & Title: Teri Nguyen
Regulatory Affairs Specialist II

Digitally signed by Grabazei Alexandru
Date: 2022.10.08 21:07:00 EEST
Reason: MoldSign Signature
Location: Moldova

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Product List: "Penumbra System" (Class III, Rule 6)

Catalog Number	Description
PSC054	Reperfusion Catheter 054 straight, 132
PSC054L127	Reperfusion Catheter 054 straight, 127
PSC054L125	Reperfusion Catheter 054 straight, 125
PSC054MP127	Reperfusion Catheter 054 MP shape, 127
PSC054MP125	Reperfusion Catheter 054 MP shape, 125
PSC041	Reperfusion Catheter 041
PSC032	Reperfusion Catheter 032
PSC026	Reperfusion Catheter 026
4MAXC	Reperfusion Catheter 4MAX straight, 139
4MAXC130	Reperfusion Catheter 4MAX straight, 130
4MAXC125	Reperfusion Catheter 4MAX straight, 125
4MAXCMP	Reperfusion Catheter 4MAX MP shape, 139
4MAXCMP130	Reperfusion Catheter 4MAX MP shape, 130
4MAXCMP125	Reperfusion Catheter 4MAX MP shape, 125
3MAXC	Reperfusion Catheter 3MAX, 153
3MAXC	Reperfusion Catheter 3MAX, 160
PSC054	Reperfusion Catheter 5MAX, 132
PSC054L127	Reperfusion Catheter 5MAX, 127
PSC054L125	Reperfusion Catheter 5MAX, 125
PSC054L115	Reperfusion Catheter 5MAX, 115
5MAXACE132	Reperfusion Catheter 5MAX ACE / ACE 60, 132
5MAXACE127	Reperfusion Catheter 5MAX ACE / ACE 60, 127
5MAXACE125	Reperfusion Catheter 5MAX ACE / ACE 60, 125
5MAXACE115	Reperfusion Catheter 5MAX ACE / ACE 60, 115
5MAXACE064	Reperfusion Catheter ACE 64, 132
5MAXACE064L127	Reperfusion Catheter ACE 64, 127
5MAXACE064L125	Reperfusion Catheter ACE 64, 125
5MAXACE064L120	Reperfusion Catheter ACE 64, 120
5MAXACE064L115	Reperfusion Catheter ACE 64, 115
5MAXACE068	Reperfusion Catheter ACE 68, 132
5MAXACE068L127	Reperfusion Catheter ACE 68, 127
5MAXACE068L125	Reperfusion Catheter ACE 68, 125
5MAXACE068L120	Reperfusion Catheter ACE 68, 120
5MAXACE068L115	Reperfusion Catheter ACE 68, 115
5MAXJETDL139	Reperfusion Catheter JET D, 139
5MAXJETD	Reperfusion Catheter JET D, 138
5MAXJETDL137	Reperfusion Catheter JET D, 137
5MAXJETDL136	Reperfusion Catheter JET D, 136
5MAXJETDL135	Reperfusion Catheter JET D, 135
5MAXJET7	Reperfusion Catheter JET 7, 132
5MAXJET7L127	Reperfusion Catheter JET 7, 127
5MAXJET7L125	Reperfusion Catheter JET 7, 125
5MAXJET7L120	Reperfusion Catheter JET 7, 120
5MAXJET7L115	Reperfusion Catheter JET 7, 115
PSS054	Separator 054
PSS041	Separator 041
PSS032	Separator 032
PSS026	Separator 026

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Catalog Number	Description
PSF054	Separator Flex 054 / 5MAX
PSF041	Separator Flex 041 / 4MAX
PSF032	Separator Flex 032
PSF026	Separator Flex 026
3MAXS	Separator 3MAX
PSS3D	Separator 3D
PSC054KIT	Reperfusion Catheter 054 straight, 132 - KIT
PSC054L127KIT	Reperfusion Catheter 054 straight, 127 - KIT
PSC054L125KIT	Reperfusion Catheter 054 straight, 125 - KIT
PSC054MP127KIT	Reperfusion Catheter 054 MP shape, 127 - KIT
PSC054MP125KIT	Reperfusion Catheter 054 MP shape, 125 - KIT
PSC041KIT	Reperfusion Catheter 041 - KIT
PSC032KIT	Reperfusion Catheter 032 - KIT
PSC026KIT	Reperfusion Catheter 026 - KIT
4MAXCKIT	Reperfusion Catheter 4MAX straight, 139 - KIT
4MAXC130KIT	Reperfusion Catheter 4MAX straight, 130 - KIT
4MAXC125KIT	Reperfusion Catheter 4MAX straight, 125 - KIT
4MAXCMPKIT	Reperfusion Catheter 4MAX MP shape, 139 - KIT
4MAXCMP130KIT	Reperfusion Catheter 4MAX MP shape, 130 - KIT
4MAXCMP125KIT	Reperfusion Catheter 4MAX MP shape, 125 - KIT
3MAXCKIT	Reperfusion Catheter 3MAX, 153 - KIT
3MAXCKIT	Reperfusion Catheter 3MAX, 160 - KIT
PSC054KIT	Reperfusion Catheter 5MAX, 132 - KIT
PSC054L127KIT	Reperfusion Catheter 5MAX, 127 - KIT
PSC054L125KIT	Reperfusion Catheter 5MAX, 125 - KIT
PSC054L115KIT	Reperfusion Catheter 5MAX, 115 - KIT
5MAXACE132KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 132 - KIT
5MAXACE127KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 127 - KIT
5MAXACE125KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 125 - KIT
5MAXACE115KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 115 - KIT
5MAXACE064KIT	Reperfusion Catheter ACE 64, 132 - KIT
5MAXACE064L127KIT	Reperfusion Catheter ACE 64, 127 - KIT
5MAXACE064L125KIT	Reperfusion Catheter ACE 64, 125 - KIT
5MAXACE064L120KIT	Reperfusion Catheter ACE 64, 120 - KIT
5MAXACE064L115KIT	Reperfusion Catheter ACE 64, 115 - KIT
5MAXACE068KIT	Reperfusion Catheter ACE 68, 132 - KIT
5MAXACE068L127KIT	Reperfusion Catheter ACE 68, 127 - KIT
5MAXACE068L125KIT	Reperfusion Catheter ACE 68, 125 - KIT
5MAXACE068L120KIT	Reperfusion Catheter ACE 68, 120 - KIT
5MAXACE068L115KIT	Reperfusion Catheter ACE 68, 115 - KIT
5MAXJETDL139KIT	Reperfusion Catheter JET D, 139 – KIT
5MAXJETDKIT	Reperfusion Catheter JET D, 138 – KIT
5MAXJETDL137KIT	Reperfusion Catheter JET D, 137 – KIT
5MAXJETDL136KIT	Reperfusion Catheter JET D, 136 – KIT
5MAXJETDL135KIT	Reperfusion Catheter JET D, 135 – KIT
5MAXJET7KIT	Reperfusion Catheter JET 7, 132 – KIT
5MAXJET7L127KIT	Reperfusion Catheter JET 7, 127 – KIT
5MAXJET7L125KIT	Reperfusion Catheter JET 7, 125 – KIT
5MAXJET7L120KIT	Reperfusion Catheter JET 7, 120 – KIT
5MAXJET7L115KIT	Reperfusion Catheter JET 7, 115 – KIT

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Catalog Number	Description
PSR3D	3D Revascularization Device
	(Class IIa, Rule 2)
PST1	Aspiration Tubing
PST2	MAX Aspiration Tubing
PST3	Hi-Flow Aspiration Tubing

End of Product List

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

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

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

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

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

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

Verified by:
Operations Manager

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

Thrombectomy Suction Catheter [Penumbra System®]

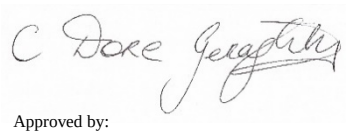
GMDN Code: 16779, 58173

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:	**252.711**
Original Approval:	**21 September 2006**
Last Amended on:	**05 August 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.

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

Thrombectomy Suction Catheter [Penumbra System®]

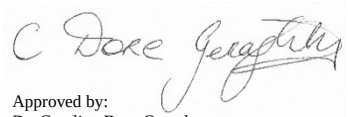
GMDN Code: 16779, 58173

CONCLUSION of EXAMINATION:

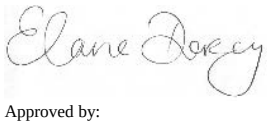
NSAI have performed an examination of the design dossier relating to the above named product family and conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)

Registration Number:	**252.711**
Original Approval:	**21 September 2006**
Last Amended on:	**5 August 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 252.711 dated 21 September 2006

This Certificate covers 102 model(s)

Model Reference	Detail
PSC054	Reperfusion Catheter 054 straight, 132 cm
PSC054L127	Reperfusion Catheter 054 straight, 127 cm
PSC054L125	Reperfusion Catheter 054 straight, 125 cm
PSC054MP127	Reperfusion Catheter 054 MP shape, 127 cm
PSC054MP125	Reperfusion Catheter 054 MP shape, 125 cm
PSC041	Reperfusion Catheter 041
PSC032	Reperfusion Catheter 032
PSC026	Reperfusion Catheter 026
4MAXC	Reperfusion Catheter 4MAX straight, 139 cm
4MAXC130	Reperfusion Catheter 4MAX straight, 130 cm
4MAXC125	Reperfusion Catheter 4MAX straight, 125 cm
4MAXCMP	Reperfusion Catheter 4MAX MP shape, 139 cm
4MAXCMP130	Reperfusion Catheter 4MAX MP shape, 130 cm
4MAXCMP125	Reperfusion Catheter 4MAX MP shape, 125 cm
3MAXC	Reperfusion Catheter 3MAX, 153 cm
3MAXC	Reperfusion Catheter 3MAX, 160 cm
PSC054	Reperfusion Catheter 5MAX, 132 cm
PSC054L127	Reperfusion Catheter 5MAX, 127 cm
PSC054L125	Reperfusion Catheter 5MAX, 125 cm
PSC054L115	Reperfusion Catheter 5MAX, 115 cm
5MAXACE132	Reperfusion Catheter 5MAX ACE / ACE 60, 132 cm
5MAXACE127	Reperfusion Catheter 5MAX ACE / ACE 60, 127 cm
5MAXACE125	Reperfusion Catheter 5MAX ACE / ACE 60, 125 cm
5MAXACE115	Reperfusion Catheter 5MAX ACE / ACE 60, 115 cm

Attachment to Certificate 252.711 dated 21 September 2006

This Certificate covers 102 model(s)

Model Reference	Detail
5MAXACE064L115	Reperfusion Catheter ACE 64, 115 cm
5MAXACE064L120	Reperfusion Catheter ACE 64, 120 cm
5MAXACE064L125	Reperfusion Catheter ACE 64, 125 cm
5MAXACE064L127	Reperfusion Catheter ACE 64, 127 cm
5MAXACE064	Reperfusion Catheter ACE 64, 132 cm
5MAXACE068L115	Reperfusion Catheter ACE 68, 115 cm
5MAXACE068L120	Reperfusion Catheter ACE 68, 120 cm
5MAXACE068L125	Reperfusion Catheter ACE 68, 125 cm
5MAXACE068L127	Reperfusion Catheter ACE 68, 127 cm
5MAXACE068	Reperfusion Catheter ACE 68, 132 cm
5MAXJETDL139	Reperfusion Catheter Penumbra JET D, 139 cm
5MAXJETD	Reperfusion Catheter Penumbra JET D, 138 cm
5MAXJETDL137	Reperfusion Catheter Penumbra JET D, 137 cm
5MAXJETDL136	Reperfusion Catheter Penumbra JET D, 136 cm
5MAXJETDL135	Reperfusion Catheter Penumbra JET D, 135 cm
5MAXJET7	Reperfusion Catheter Penumbra JET 7, 132 cm
5MAXJET7L127	Reperfusion Catheter Penumbra JET 7, 127 cm
5MAXJET7L125	Reperfusion Catheter Penumbra JET 7, 125 cm
5MAXJET7L120	Reperfusion Catheter Penumbra JET 7, 120 cm
5MAXJET7L115	Reperfusion Catheter Penumbra JET 7, 115 cm
PSS054	Separator 054
PSS041	Separator 041
PSS032	Separator 032
PSS026	Separator 026

Attachment to Certificate 252.711 dated 21 September 2006

This Certificate covers 102 model(s)

Model Reference	Detail
PSF054	Separator Flex 054 / 5MAX
PSF041	Separator Flex 041 / 4MAX
PSF032	Separator Flex 032
PSF026	Separator Flex 026
3MAXS	Separator 3MAX
PSS3D	Separator 3D
PSC054KIT	Reperfusion Catheter 054 straight, 132 cm - KIT
PSC054L127KIT	Reperfusion Catheter 054 straight, 127 cm - KIT
PSC054L125KIT	Reperfusion Catheter 054 straight, 125 cm - KIT
PSC054MP127KIT	Reperfusion Catheter 054 MP shape, 127 cm - KIT
PSC054MP125KIT	Reperfusion Catheter 054 MP shape, 125 cm - KIT
PSC041KIT	Reperfusion Catheter 041 - KIT
PSC032KIT	Reperfusion Catheter 032 - KIT
PSC026KIT	Reperfusion Catheter 026 - KIT
4MAXCKIT	Reperfusion Catheter 4MAX straight, 139 cm - KIT
4MAXC130KIT	Reperfusion Catheter 4MAX straight, 130 cm - KIT
4MAXC125KIT	Reperfusion Catheter 4MAX straight, 125 cm - KIT
4MAXCMPKIT	Reperfusion Catheter 4MAX MP shape, 139 cm - KIT
4MAXCMP130KIT	Reperfusion Catheter 4MAX MP shape, 130 cm - KIT
4MAXCMP125KIT	Reperfusion Catheter 4MAX MP shape, 125 cm - KIT
3MAXCKIT	Reperfusion Catheter 3MAX, 153 cm - KIT
3MAXCKIT	Reperfusion Catheter 3MAX, 160 cm - KIT
PSC054KIT	Reperfusion Catheter 5MAX, 132 cm - KIT
PSC054L127KIT	Reperfusion Catheter 5MAX, 127 cm - KIT

Attachment to Certificate 252.711 dated 21 September 2006

This Certificate covers 102 model(s)

Model Reference	Detail
PSC054L125KIT	Reperfusion Catheter 5MAX, 125 cm - KIT
PSC054L115KIT	Reperfusion Catheter 5MAX, 115 cm - KIT
5MAXACE132KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 132 cm - KIT
5MAXACE127KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 127 cm - KIT
5MAXACE125KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 125 cm - KIT
5MAXACE115KIT	Reperfusion Catheter 5MAX ACE / ACE 60, 115 cm - KIT
5MAXACE064KIT	Reperfusion Catheter ACE 64, 132 cm - KIT
5MAXACE064L127KIT	Reperfusion Catheter ACE 64, 127 cm - KIT
5MAXACE064L125KIT	Reperfusion Catheter ACE 64, 125 cm - KIT
5MAXACE064L120KIT	Reperfusion Catheter ACE 64, 120 cm - KIT
5MAXACE064L115KIT	Reperfusion Catheter ACE 64, 115 cm - KIT
5MAXACE068KIT	Reperfusion Catheter ACE 68, 132 cm - KIT
5MAXACE068L127KIT	Reperfusion Catheter ACE 68, 127 cm - KIT
5MAXACE068L125KIT	Reperfusion Catheter ACE 68, 125 cm - KIT
5MAXACE068L120KIT	Reperfusion Catheter ACE 68, 120 cm - KIT
5MAXACE068L115KIT	Reperfusion Catheter ACE 68, 115 cm - KIT
5MAXJETDL139KIT	Reperfusion Catheter Penumbra JET D, 139 cm - KIT
5MAXJETDKIT	Reperfusion Catheter Penumbra JET D, 138 cm - KIT
5MAXJETDL137KIT	Reperfusion Catheter Penumbra JET D, 137 cm - KIT
5MAXJETDL136KIT	Reperfusion Catheter Penumbra JET D, 136 cm - KIT
5MAXJETDL135KIT	Reperfusion Catheter Penumbra JET D, 135 cm - KIT
5MAXJET7KIT	Reperfusion Catheter Penumbra JET 7, 132 cm - KIT
5MAXJET7L127KIT	Reperfusion Catheter Penumbra JET 7, 127 cm - KIT
5MAXJET7L125KIT	Reperfusion Catheter Penumbra JET 7, 125 cm - KIT

Attachment to Certificate 252.711 dated 21 September 2006

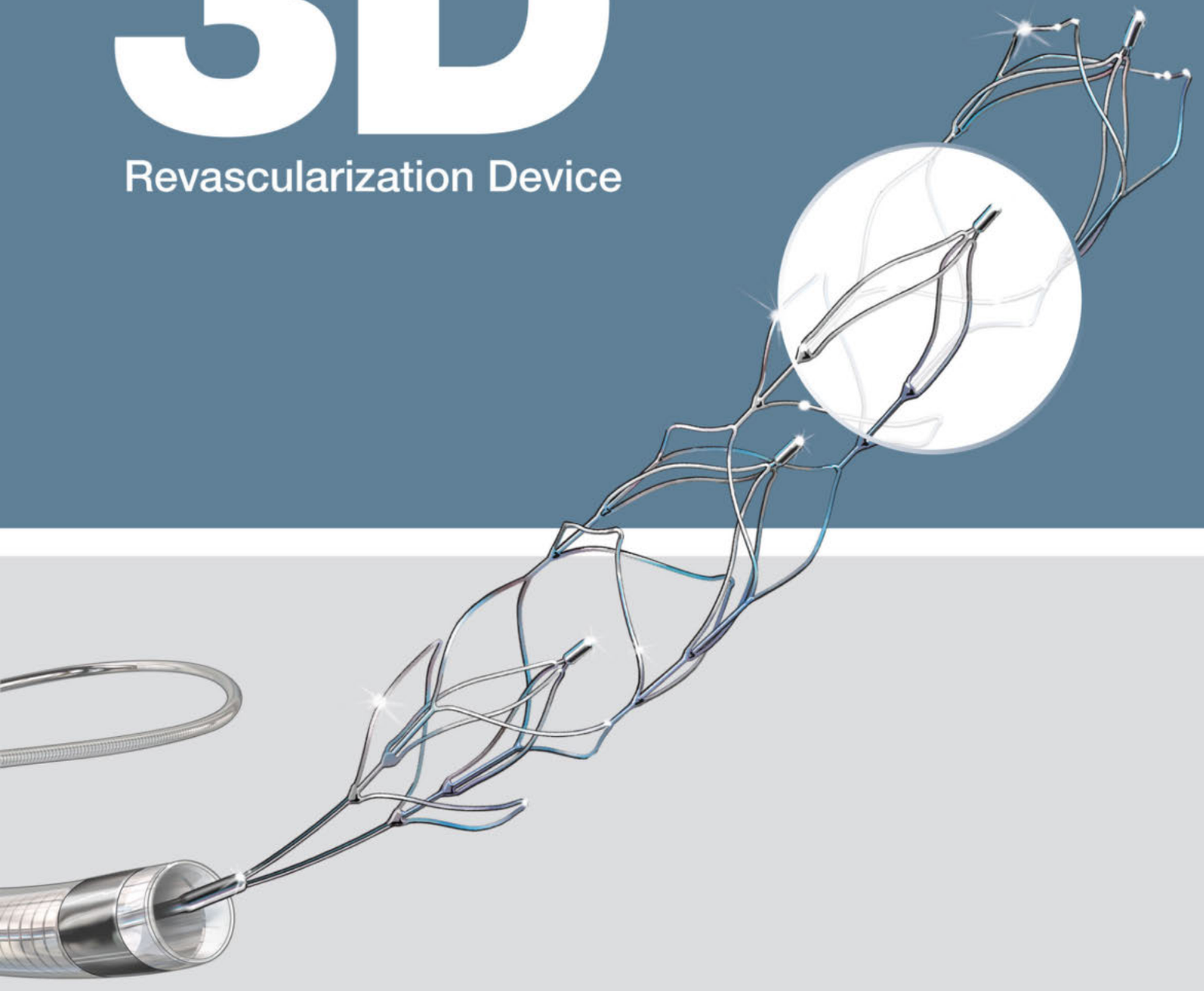
This Certificate covers 102 model(s)

Model Reference	Detail
5MAXJET7L120KIT	Reperfusion Catheter Penumbra JET 7, 120 cm - KIT
5MAXJET7L115KIT	Reperfusion Catheter Penumbra JET 7, 115 - KIT
PSR3D	3D Revascularization Device
	(Class IIa, Rule 2)
PST1	Aspiration Tubing
PST2	MAX Aspiration Tubing
PST3	Hi-Flow Aspiration Tubing

Penumbra System

3D

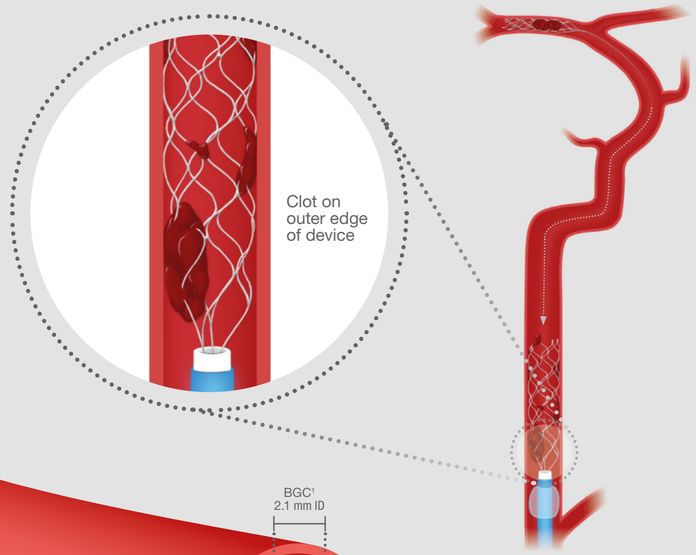
Revascularization Device

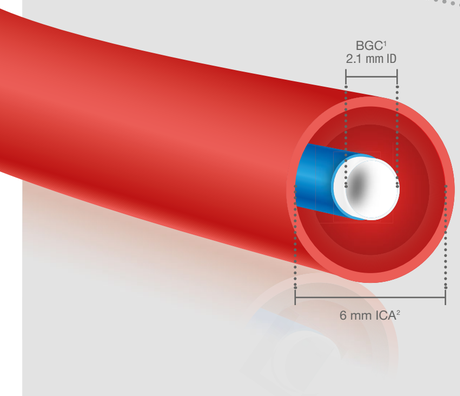


Penumbra

Hollow Tube Design Lacks Intraluminal Clot Capture

Hollow tube design
pushes clot to edge of device,
increasing potential to shear clot





8 F Balloon Guide Catheter[1]
mismatched for hollow tube retrieval
in proximal ICA

Renderings are for illustrative purposes only. Individual results may vary depending on a variety of patient-specific attributes.

1. 8 F Balloon Guide Catheter (BGC) measurement based on 8 F Stryker® FlowGate2®
2. Vessel diameters used are common clinical measurements.

Next Generation Technology Engineered to Retrieve Clot

Intraluminal chambers
lock clot centrally within device
for withdrawal into ACE Reperfusion Catheter

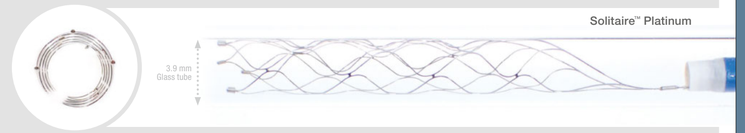
3D Revascularization Device

Lateral view[a] Down the barrel view[b]

First Generation Hollow Tube Design

Hollow tube design
expands and pushes clot against vessel wall,
increasing potential for downstream emboli

Solitaire™ Platinum



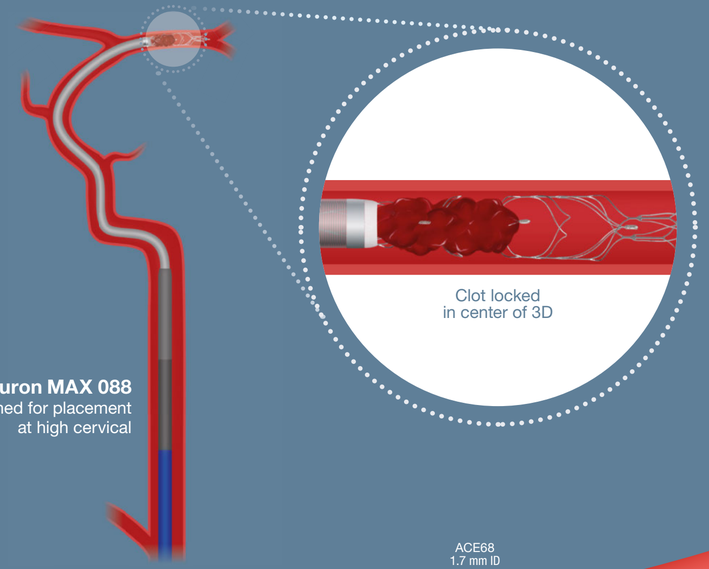
Down the barrel view[b] Lateral view[a]

Trevo® XP ProVue

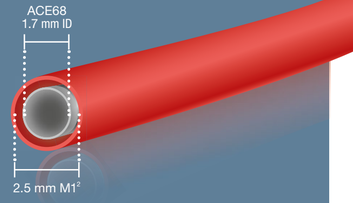
a. Photograph taken at same magnification with devices in 3.9 mm glass tube.
b. Photograph taken at same magnification with devices unconstrained in open air.
Photographs taken by and on file at Penumbra, Inc.

ACE68 + 3D System Optimised to Reduce Clot Shearing

Intraluminal chambers
designed to lock clot within center of device,
potentially reducing risk of clot shearing



Neuron MAX 088
designed for placement
at high cervical

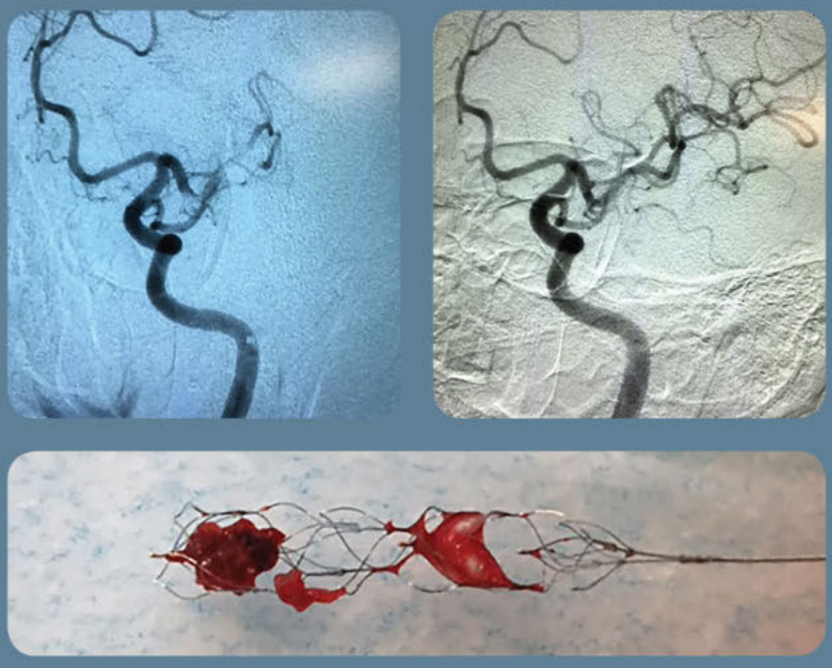


ACE68 Reperfusion Catheter
optimally sized to provide **2.8× more clot capture** in the M1 than 8 F BGC[1] in the ICA[3]

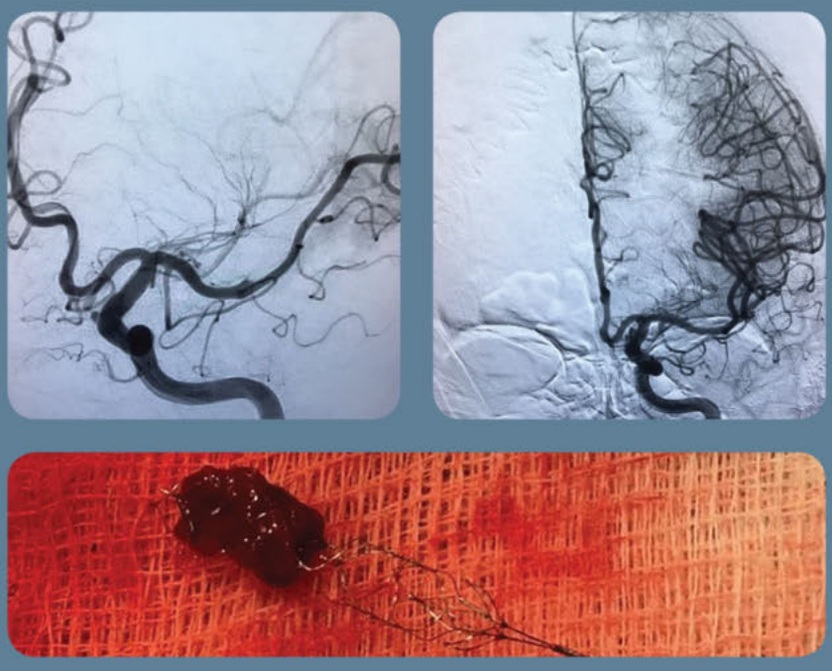
Renderings are for illustrative purposes only. Individual results may vary depending on a variety of patient-specific attributes.

1. 8 F Balloon Guide Catheter (BGC) measurement based on 8 F Stryker® FlowGate2®
2. Vessel diameters used are common clinical measurements.
3. Tests performed and data on file at Penumbra, Inc. Bench test results may not be indicative of clinical performance.

3D Revascularization Device Case Examples



Images courtesy of Dr. Zeguang Ren
Tampa General Hospital, FL, USA



Images courtesy of Dr. Raj Agrawal
Desert Radiology, Las Vegas, NV, USA

Images used with permission. Consents on file at Penumbra, Inc.

Ordering Information

Penumbra System

Catalog Number	Description	Proximal OD	Distal OD	Proximal ID	Distal ID	Working Length
Aspiration Kits						
5MAXACE068KIT	ACE68 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	6.0 F	.068"	.068"	132 cm
5MAXACE064KIT	ACE64 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	5.75 F	.068"	.064"	132 cm
5MAXACE132KIT	ACE60 Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	5.4 F	.068"	.060"	132 cm
PSC054KIT	5MAX Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	5.0 F	.064"	.054"	132 cm
4MAXCKIT	4MAX Reperfusion Catheter+Penumbra Hi-Flow Tubing	6.0 F (.080")	4.3 F	.064"	.041"	139 cm
3MAXCKIT	3MAX Reperfusion Catheter+Penumbra Hi-Flow Tubing	4.7 F (.062")	3.8 F	.043"	.035"	153 cm
Revascularisation Device		Diameter	Device Length	Working Length		
PSR3D	3D Revascularization Device	4.5 mm	26 mm	20 mm		
Delivery Microcatheter						
VEL160STR	Velocity Microcatheter					

Penumbra System with 3D Revascularization Device – Indication For Use
Penumbra System Reperfusion Catheters and Separators
As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Penumbra 3D Revascularization Device
As part of the Penumbra System, the Penumbra 3D Revascularization Device is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.
Penumbra Aspiration Tubing
As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Aspiration Pump.
Penumbra Aspiration Pump
The Penumbra Aspiration Pump is indicated as a vacuum source for Penumbra Aspiration Systems.
Contraindications
There are no known contraindications.
Warnings
- The Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- Do not advance, retract or use any component of the Penumbra System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter, revascularization device, or Separator against resistance may result in damage to the device or vessel.
- Do not use the Penumbra System with a pump other than the Penumbra Aspiration Pump.
- The Penumbra 3D Revascularization Device has not been evaluated in patients with angiographic evidence of pre-existing arterial injury.

Precautions
- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the "Use By" date.
- Use the Penumbra System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure that the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended.
- The Penumbra Separator is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such repositioning should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.[1] Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.
- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
- Limit the usage of Reperfusion Catheters to arteries larger than the catheter's outer diameter.

Potential Adverse Events
Possible complications include, but are not limited to, the following: allergic reaction and anaphylaxis from contrast media, acute occlusion, air embolism, arteriovenous fistula, death, device malfunction, distal embolization, emboli, false aneurysm formation, hematoma or hemorrhage at access site, inability to completely remove thrombus, infection, intracranial hemorrhage, ischemia, kidney damage from contrast media, neurological deficits including stroke, vessel spasm, thrombosis, dissection, or perforation.

Penumbra System – Indication For Use
Penumbra System Reperfusion Catheters and Separators – Indication For Use
As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.
Penumbra Aspiration Tubing – Indication For Use
As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX.
Contraindications
There are no known contraindications.
Warnings
- The Penumbra System should only be used by physicians who have received appropriate training in interventional neuro-endovascular techniques and treatment of acute ischemic stroke.
- Do not advance, retract or use any component of the Penumbra System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device or system as a unit. Unrestrained torquing or forced insertion of the catheter or separator against resistance may result in damage to the device or vessel.
- Do not use the Penumbra System with a pump other than the Penumbra Aspiration Pump.

Precautions
- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or Reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target neuro vasculature location.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all damaged devices and packaging to the manufacturer/distributor.
- Use prior to the "Use By" date.
- Use the Penumbra System in conjunction with fluoroscopic visualization.
- Maintain a constant infusion of appropriate flush solution.
- When performing aspiration, ensure the Penumbra Aspiration Tubing valve is open for only the minimum time needed to remove thrombus. Excessive aspiration or failure to close the Penumbra Aspiration Tubing valve when aspiration is complete is not recommended.
- The Penumbra Separator is not intended for use as a neurovascular guidewire. If repositioning of the Penumbra Reperfusion Catheter is necessary during the revascularization procedure, such reposition should be performed over an appropriate neurovascular guidewire using standard microcatheter and guidewire techniques.
- Do not use automated high-pressure contrast injection equipment with the Penumbra Reperfusion Catheter because it may damage the device.
- Administration of anticoagulants and antiplatelets should be suspended until 24 hours post-treatment. Medical management and acute post stroke care should follow the ASA guidelines.[1] Any neurological deterioration should be evaluated by urgent CT scan and other evaluations as indicated according to investigator/hospital best practice.
- The total time allowed to achieve patient revascularization is 120 minutes of using the Penumbra System.
- As in all surgical interventions, monitoring of intra-procedural blood loss is recommended so that appropriate management may be instituted.
- Limit the usage of Reperfusion Catheters in arteries larger than the catheter's outer diameter.

Potential Adverse Events
Possible complications include, but are not limited to, the following:
- allergic reaction and anaphylaxis from contrast media, acute occlusion, air embolism, arteriovenous fistula, death, device malfunction, distal embolization, emboli, false aneurysm formation, hematoma or hemorrhage at access site, inability to completely remove thrombus, infection, intracranial hemorrhage, ischemia, kidney damage from contrast media, neurological deficits including stroke, vessel spasm, thrombosis, dissection, or perforation

1. Adams et al., Guidelines for the Early Management of Adults with Ischemic Stroke: A Guideline from the AHA/ASA Stroke Council, Clinical Cardiology Council, Cardiovascular Radiology and Intervention Council, and the Atherosclerotic Peripheral Vascular Disease and Quality of Care Outcomes in Research Interdisciplinary Working Groups: The American Academy of Neurology affirms the value of this guideline as an educational tool for neurologists, Stroke May 2007; 38: 1655-1711.

Penumbra Pump MAX – Indication For Use
The Penumbra Pump MAX is indicated as a vacuum source for the Penumbra Aspiration Systems.
Contraindications
There are no contraindications.
Warnings/Precautions
- The canister/tubing is intended for single use only. Do not reuse. Reuse may result in canister cracking or tubing blockages, which may result in the inability to aspirate.
- Do not block bottom or back air vents. Unit may overheat and shut off or fail to restart if run for extended periods of time without airflow.
- To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Do not position the pump so that it is difficult to operate the power cord disconnection device.
- Remove and service the pump if liquids or solids have been drawn into the vacuum pump.
- Do not use in the presence of flammable anaesthetic mixture with air or nitrous oxide.
- Do not use in oxygen rich environment.
- To prevent fire or shock hazard, use replacement fuses of equal size and rating.
- To prevent fire or shock hazard, use a replacement power cord of equal rating.
- Do not re-infuse blood or fluid from the canister back into patient.
- Do not use petroleum base compounds, acids, caustics, or chlorinated solvents to clean or lubricate any parts. It will reduce service life of the pump. Use only water-base solvents for cleaning.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- No modification of this equipment is allowed.

Neuron MAX System – Indication For Use
The Neuron MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Contraindications
There are no known contraindications.
Warnings
- The Neuron MAX System should only be used by physicians who have received appropriate training in interventional techniques.

Precautions
- The device is intended for single use only. Do not resterilize or reuse. Resterilization and/or reuse may result in ineffective catheter coating lubrication, which may result in high friction and the inability to access the target vasculature location; and/or compromise the structural integrity of the device.
- Do not use kinked or damaged devices. Do not use open or damaged packages. Return all defective devices and packaging to the manufacturer/distributor.
- Use prior to the "Use By" date.
- Use the Neuron MAX System in conjunction with fluoroscopic visualization.
- Do not advance or withdraw the Neuron MAX System against resistance without careful assessment of the cause using fluoroscopy. If the cause cannot be determined, withdraw the device. Unrestrained moving or torquing the device against resistance may result in damage to the vessel or device.
- Maintain a constant infusion of appropriate flush solution.
- If flow through the device becomes restricted, do not attempt to clear the lumen by infusion. Remove and replace the device.

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

Product availability varies by country. Prior to use, please refer to the Instructions for Use for Penumbra System with 3D Revascularization Device, Penumbra System, Penumbra Pump MAX, Neuron MAX System, Penumbra Delivery Microcatheters for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use. Please contact your local Penumbra representative for more information.

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Содержит([Producatorul], 'Penumbr') И Содержит([Denumire], 'Revascular')