URGENT VOLUNTARY MEDICAL DEVICE RECALL NOTIFICATION

IMMEDIATE ACTION REQUIRED

THIS IS A RECALL ADVISORY PACKET.

You need to read this entire packet carefully and follow each step.

This packet contains the necessary items to successfully complete the urgent voluntary medical device recall for Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology (Penumbra reference: 3005168196-12/15/2020-015-R).

Product Name	Catalog Number (REF)	UDI	Lot Numbers
Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing	5MAXJET7KIT	00815948020962	ALL
Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing	5MAXJET7L138KIT	00815948021594	ALL
Penumbra JET 7 Reperfusion Catheter	5MAXJET7	00815948020955	ALL

Note: This notice does NOT apply to the Penumbra JET 7 Reperfusion Catheter with Standard Tip (REF: 5MAXJET7BKIT).

Please ensure that the attached Product Notification / Return Notification form is returned within 3 business days to acknowledge receipt within your Department/Facility. This may be a requirement within your healthcare organization.

If you have any questions regarding this recall, please contact Penumbra Customer Service at 1-888-272-4606, your Penumbra Sales Representative, or email us at notification@penumbrainc.com.

Penumbra, Inc.
One Penumbra Place
Alameda, CA 94502

T 1.510.748.3200
F 1.510.814.8303

www.penumbrainc.com

Penumbra

URGENT VOLUNTARY MEDICAL DEVICE RECALL NOTIFICATION

Product Name	Catalog Number (REF)	UDI	Lot Numbers
Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing	5MAXJET7KIT	00815948020962	ALL
Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing	5MAXJET7L138KIT	00815948021594	ALL
Penumbra JET 7 Reperfusion Catheter	5MAXJET7	00815948020955	ALL

Note: This notice does NOT apply to the Penumbra JET 7 Reperfusion Catheter with Standard Tip (REF: 5MAXJET7BKIT).

December 15, 2020

To the attention of: Recall Coordinator, Director of Purchasing, Risk Management, and Healthcare Providers

The purpose of this letter is to notify you that Penumbra is **voluntarily recalling all configurations of the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology (JET 7 Xtra Flex**). This notification follows the company's Notification to Healthcare Providers issued July 27, 2020.

Penumbra is recalling the JET 7 Xtra Flex because the catheter may become susceptible to distal tip damage during use. Distal tip damage in conjunction with pressurization or contrast injection may result in potential vessel damage, and subsequent patient injury or death.

Out of the more than 30,000 distributed units, Penumbra is aware of a total of 17 (0.056%) events involving patient injury and 14 (0.046%) events involving patient death related to distal tip damage, including damage related to expansion or rupture following contrast injection. These reports include one (1) event involving patient injury and one (1) event involving patient death for events that occurred after the July 27, 2020 Notification. Please note that these numbers reflect unique events, rather than total MDRs reflected in the MAUDE database as there can be duplicate reports submitted for individual events.

Excluding events related to distal tip damage, there have been a total of 11 events involving patient injury and zero (0) events involving patient death associated with JET 7 Xtra Flex. Overall, Penumbra has filed 239 reports for unique events associated with death, injury, malfunction or other events with JET 7 Xtra Flex.

Our records indicate that your facility was shipped one or more units of the affected products.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Share this recall notification with all users of the product within your facility to ensure that they are also aware of this recall.
2. Immediately review your inventory for the specific catalog numbers listed above.
3. Remove all units from inventory and place them in quarantine for return to Penumbra, Inc.
4. Complete and return the attached product identification / return form within 3 business days.

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5. Continue to report adverse events and quality problems experienced with the use of this product. Adverse events and quality problems may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax. For more information, please see https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

Actions to be taken by Penumbra:
Penumbra personnel will contact you directly to arrange return of affected units and replace/refund returned product.

Contact Information:
If you have any questions or concerns, please contact Penumbra Customer Service (order@penumbrainc.com or 1.888.272.4606), available Monday - Friday 7:30 AM to 4:00 PM PST, or your Penumbra Sales Representative.

Penumbra remains committed to consistently provide medical products that meet the requirements and expectations of our customers while maintaining compliance with all applicable regulations. We appreciate your prompt attention and cooperation in this matter.

Sincerely yours,

Kathleen Kidd
Vice President, Quality and Compliance

Mary Rose
Director, Regulatory Affairs

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Penumbra

URGENT VOLUNTARY MEDICAL DEVICE RECALL

Product Identification / Return Notification

Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology

Product Name	Catalog Number	UDI	Lot Numbers
Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing	5MAXJET7KIT	00815948020962	ALL
Penumbra JET 7 Reperfusion Catheter and Penumbra Hi-Flow Aspiration Tubing	5MAXJET7L138KIT	00815948021594	ALL
Penumbra JET 7 Reperfusion Catheter	5MAXJET7	00815948020955	ALL

Note: This notice does NOT apply to the Penumbra JET 7 Reperfusion Catheter with Standard Tip (REF: 5MAXJET7BKIT).

Submitting this form indicates you have received the medical device recall information and have quarantined all affected Penumbra JET 7 Reperfusion Catheters with Xtra Flex technology.

Notification Information	
Hospital/Facility	
Date Notice Received	

Units Identified and Quarantined for Return		
Catalog Number	**Lot Number**	**Quantity**

Printed Name: _____

Title: _____

Signature: _____ **Date:** _____

Please complete and return this form by email to Penumbra:
notification@penumbrainc.com

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