

Notification to Healthcare Providers

July 27, 2020

Dear Healthcare Provider:

Penumbra has received reports of Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology (JET 7 Xtra Flex) distal tip expansion or rupture when used during injection of contrast media. JET 7 Xtra Flex may become susceptible to expansion or rupture during contrast injection due to distal tip weakening from manipulation against resistance or use with other manufacturers' revascularization devices. Distal tip expansion or rupture may cause vessel damage and subsequent patient injury or death.

Performing contrast injections through JET 7 Xtra Flex is not consistent with the intended use of the product or the Instructions for Use, which instructs the user to perform contrast injections through the guide catheter. The use of JET 7 Xtra Flex with other manufacturers' revascularization devices is not an authorized use per the Instructions for Use. JET 7 Xtra Flex has not been tested for compatibility with other manufacturers' revascularization devices.

In response to these reports, Penumbra is notifying healthcare providers of a labeling update to include the following WARNING, PRECAUTIONS and REVISIONS in the Instructions for Use:

Warning: Do not inject contrast media through the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology using a syringe or automated high-pressure contrast injection equipment. Injecting contrast media through the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology may cause the distal tip of the catheter to expand or rupture, resulting in potential vessel damage and subsequent patient injury or death. When injecting contrast media for angiography, always inject through the guide catheter.

Precaution: The Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology has not been tested for compatibility with other manufacturers' revascularization devices. The safety and effectiveness of combined use is unknown and could result in damage to the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology.

Precaution: Use caution and slowly flush heparinized saline. If you see expansion of the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology, immediately discontinue use of the catheter.

Revision: Obtain a post-treatment angiogram by injecting contrast media through the guide catheter. Remove the Reperfusion Catheter from the guide catheter if necessary for adequate visualization.



Penumbra has not received any reports resulting in patient injury or death for the Penumbra JET 7 Reperfusion Catheter (without the Xtra Flex technology) or the ACE 68 Reperfusion Catheter in 2019 or 2020. Through bench testing, based on the device design, the JET 7 Xtra Flex may not be able to withstand the same burst pressures in comparison to the JET 7 Reperfusion Catheter or the ACE 68 Reperfusion Catheter. Penumbra recommends that you consider the risks described in this safety notification when deciding to use JET 7 Xtra Flex, Penumbra JET 7 Reperfusion Catheter, or ACE 68 Reperfusion Catheter.

At Penumbra, we are committed to product safety and performance, and we value the opportunity to support you and your patients. Penumbra is continuing to monitor and investigate these adverse event reports.

WE ASK THAT YOU TAKE THE FOLLOWING ACTIONS:

1. Distribute this notification to all healthcare providers that utilize the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology within your facility.
2. Complete the Notification Acknowledgment form and email it to notifications@penumbrainc.com. Return of this form will acknowledge your receipt and understanding of this notification.

If you have any questions or concerns regarding this labeling update, please contact Penumbra Customer Service (order@penumbrainc.com or 1.888.272.4606) or your Penumbra Sales Representative.

Report JET7 Xtra Flex distal tip expansion or rupture adverse events to the FDA using the MedWatch Online Voluntary Reporting Form (FDA Safety Information and Adverse Event Reporting program) and to Penumbra. Per FDA requirements, user facilities must comply with Medical Device Reporting (MDR) regulations. Healthcare personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities. Prompt reporting of adverse events can help the FDA and Penumbra identify and better understand the risks associated with the specified medical devices.

Sincerely,

A handwritten signature in black ink that reads "Mary Rose".

Mary Rose
Director of Regulatory Affairs

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Acknowledgment Form
Notification to Healthcare Providers:
Penumbra JET 7 Reperfusion Catheter with Xtra Flex Technology

**PLEASE RETURN THIS FORM TO ACKNOWLEDGE YOUR RECEIPT AND
UNDERSTANDING OF THIS NOTIFICATION**

I have read and understood the attached notice.

Name (print): _____

Title (print): _____

Signature: _____

Date: _____

Facility Name: _____

Facility Address: _____

Phone Number: _____

Email Address: _____

Please email this completed form to notifications@penumbrainc.com
If you have any questions, please contact Penumbra Customer Service at 1.888.272.4606.

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