

## **Penumbra's Response to FFJ Questions**

**August 31, 2020**

Since the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology received 510(k) clearance in June 2019 (K190010), physicians have used the catheter successfully in tens of thousands of ischemic stroke patients with large vessel occlusions. For many neurointerventional procedures, microcatheters, delivery catheters, intermediate catheters and guide catheters are used routinely for contrast injection. On the other hand, reperfusion catheters are designed for the removal of stroke-causing clots by aspirating or suctioning the clot out of the arteries in the brain, and not for contrast injection, as any injection pushed through the catheter may re-introduce clot to the brain arteries which may result in another stroke. The Penumbra System labeling for reperfusion catheters has always stated contrast injections should be made through a guide catheter used to access the brain arteries, as does the labeling for other manufacturers' catheters. Penumbra actively discussed the reported adverse events and deaths with the FDA and published a voluntary Notification to Healthcare Providers with FDA's support to notify physicians of labeling changes, intended to further remind physicians about the use of the catheter and contrast injection. In the U.S., the printed Notification was sent to the attention of the risk management department at hospitals that had purchased the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology, and the Notification was posted on the Penumbra website. Notifications were also delivered to customers in other countries where the catheter is available through Penumbra or our distribution partners. Courtesy notices were shared with professional societies to ensure the communication

was widely received. Since the Notification was shared, Penumbra continues to see strong demand for the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology and is not aware of any new reports of events that were the subject of the Notification.

Here are the answers to your specific questions:

1. FDA Maude data through 6/30 lists 11 deaths related to the Jet 7 Xtra Flex Catheter. **Does Penumbra management acknowledge this? Is there a comment on this?**

Yes, Penumbra filed medical device reports for all adverse events with the FDA which are reflected in the MAUDE database, including for those deaths, in accordance with medical device reporting regulations, 21 CFR Part 803.

As a company dedicated to developing devices that can help patients facing life-threatening conditions, we take adverse events seriously. Following our investigation into the reports, we worked diligently to communicate with physicians using the Penumbra Jet 7 Reperfusion Catheter with Xtra Flex technology.

2. **Given the subject of the 7/27 letter is the Jet 7 Xtra Flex Catheter, why does management refer to an absence of deaths from a previous, different model? Who approved this deeply misleading statement? (Attached find a screen cap of the paragraph in question.)**

The statement is factual and not misleading. Penumbra prepared the voluntary Notification to Healthcare Providers through active