rates as other commercially available catheters with no safety concerns. More prospective clinical data is needed to fully assess the Q Aspiration Catheter.

**Abbreviations** AIS (acute ischemic stroke), MT (mechanical thrombectomy), ASPECTs (Alberta Stroke Program Early CT Score), mTICI (modified TICI score), NIHSS (National Institute of Health Stroke Scale), mRS (modified Rankin Scale), ENT (embolization to a new territory), sICH (symptomatic intracranial hemorrhage)


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**P-014 REPERFUSION CATHETER MALFUNCTION DURING STROKE INTERVENTION: AN ANALYTICAL REVIEW OF THE FDA’S MAUDE DATABASE**

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**Background** In December 2020, the JET7 Xtra Flex reperfusion catheter was voluntarily recalled after reports of injury and death associated with device malfunction. The FDA’s MAUDE (Manufacturer and User Facility Device Experience) database aggregates reports of adverse events and product problems involving medical devices. We present the first analytical review of all MAUDE reports involving FDA cleared reperfusion catheters in order to summarize safety events to date and characterize unique modes of device failure.

**Methods** All publicly available MAUDE datasets were downloaded and linked, and all events associated with catheters carrying product code ‘NYR’ were extracted. Product code ‘NYR’ encompasses all devices intended to restore blood flow by removing thrombus/clots in patients experiencing ischemic stroke. Note that this review does not include catheters used off-label for aspiration thrombectomy.

Event characteristics including device type, malfunction and adverse events were collected directly as reported on MedWatch Form 3500. In order to characterize procedure-specific details, narrative information submitted in MedWatch Form 3500 Sections B and H was coded by 2 independent raters.

**Results** Between 1/1/2003 and 8/31/2020, there were 1,808 reperfusion catheter defects and/or malfunctions reported in the MAUDE database. Of these, 93.4% did not result in any adverse event on patients. There were 112 malfunctions associated with an adverse event, of which 98 (87.5%) resulted in injury, and 12 (12.5%) resulted in death. A summary of malfunctions is available in Table 1. When interpreting these findings, it is important to note that FDA surveillance of these devices does not include data on the number of units sold, thus event rates cannot be determined or compared across devices.

Of 14 reported deaths, 13 involved malfunctions of the Jet 7 Xtra Flex catheter. All of these cases reported mechanical failure at the tip of the catheter, 10 of which involved tip rupture or ballooning following contrast injection. Ballooning was unique to the Jet 7 Xtra Flex, and was also responsible for 3 patient injuries and 37 cases of malfunction that did not result in adverse outcomes.

One death and 45 injuries involved the 3 MAX Reperfusion catheter. All of these events were caused by catheter fracture leading to fragment embolization or vessel injury. This mechanism of failure was not unique to the 3 MAX, and was present in 61.2% of all malfunctions resulting in injury.

Among malfunctions that did not result in adverse events, the majority (59.1%) were attributable to damage that