# FDA Slaps Highest Risk Label on St. Jude Medical's Amplatzer TorqVue FX Recall

Mass Device

**St. Jude Medical recalls its Amplatzer TorqVue FX delivery system over concerns about fractures in the core wire.**

The FDA issued the highest-risk label on St. Jude Medical's [1] (NYSE:STJ [2]) recall of its Amplatzer TorqVue FX delivery system.

St. Jude recalled a component of its Amplatzer Occluder over concerns that part of the delivery system may fracture, potentially causing adverse consequences or even death, according to the FDA report.

The Amplatzer device was designed to treat a condition called *patent foramen ovale*, in which a naturally occurring hole in the heart fails to close after birth, potentially allowing blood clots to travel from 1 side of the hart to the other and then to the brain, causing a stroke.



**Links:**
[1] http://www.massdevice.com/company/st-jude-medical
[2] http://www.google.com/finance?q=stj