

Urgent Field Safety Notice

Pipeline™ Flex Embolization Device and Pipeline™ Flex with Shield Technology™ All Product Models Notification

September 2020

Dear Healthcare Professional:

Medtronic is providing this notice regarding a labeling update to ensure awareness among Pipeline™ Flex and Pipeline™ Flex with Shield Technology™ users, which describes the existing risks and potential patient harms associated with separation or fracture. This labeling change further clarifies certain conditions where the risk of separation may be increased, such as under conditions of increased vessel tortuosity and/or excessive resistance during advancement or retraction of the device.

Background:

Pipeline™ Flex embolization devices have the potential to fracture or separate at the distal section during advancement or retraction due to inherent flexibility limits of device design. The risk of fracture or separation is increased under certain anatomical use conditions, such as increased vessel tortuosity or high resistance. The overall complaint rate associated with fracture or unintended separation is 0.30%. This unintended separation may result in the distal portion of the device delivery system remaining in the patient. If this occurs, it could result in patient injury, including ischemic stroke, intracranial hemorrhage, neurological deficit, and/or death.

This is an intra-procedural risk. If a Pipeline™ Flex embolization device has already been implanted successfully, there is no risk for this fracture or separation. Therefore, patients should continue with their normal course of treatment.

What Is Changing?

The Instructions for Use (IFU) for the Pipeline™ Flex embolization device and Pipeline™ Flex with Shield Technology™ already contains cautions related to potential of fracture or separation. Medtronic will be supplementing the Instructions for Use with further updates to the Precaution and the Device Complications sections. (Updates are noted below in underlined text.)

- Update to Potential Complications Section: Breakage (including unintended device or component separation)
- Update to Caution statement as part of Directions for Use: If high forces or excessive friction is encountered during delivery, discontinue delivery of the device and identify the cause of the resistance, remove device and micro catheter simultaneously. Advancement or retraction of the Pipeline™ Flex embolization device against resistance may result in damage, including unintended device or component separation, fracture, or breakage of the delivery system due to inherent flexibility limits of device design. Device damage may result in patient injury or death.

Medtronic recommends that physician users be attentive to the updated information in the Instructions for Use and include this information in discussions with patients.

Transmission of This Communication:

Please share this communication within your organization, with other organizations where these devices have been transferred, and any other associated organizations that may be impacted by this action.

Please retain a copy of this letter for your records.

The Competent Authority of your country has been notified of this action.

Medtronic is committed to patient safety and appreciates your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative directly or via Tel. No: 01 511 1400.

Sincerely,



Keith Taverner

Regulatory Affairs Manager UK & Ireland