Safety Communication رسالة سلامة

Potential to fracture or separate due to flexibility limits of device design

Device/ Product Description:	Pipeline™ Flex Embolization Device and Pipeline™ Flex with Shield Technology™
Affected product:	All Product Models
Manufacturer:	Medtronic
Problem:	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. 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.
Recommendation /Actions:	• Review this notice and ensure that affected personnel are aware of the contents. • Inspect the inventory to identify the affected products of the above-mentioned products. • If high forces or excessive friction is encountered during delivery (in patient), discontinue delivery of the device and identify the cause of the resistance, remove device and micro catheter simultaneously. • Contact the Authorized Representative for the required corrective action. For more information, please check the "FSCA" If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center

Devices/Products photo:		
Authorized Representative Details	AR name:	Medtronic Saudi Arabia
	Assigned Contact Person:	Faisal Matbuli
	Mobile/Phone:	0555066900
	Email:	faisal.matbuli@medtronic.com

SFDA