المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Recall of FlexCath Advance Steerable Sheath manufactured by Medtronic

Device/ Product Name:	FlexCath Advance Steerable Sheath
Lot numbers/Serials:	Model 4FC12
Manufacturer:	Medtronic Inc
Problem:	Air embolism is a known risk for patients undergoing percutaneous interventions requiring access to the left atrium, such as ablation procedures. According to the 2017 HRS/EHRA/ECAS/APHRS/ SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation, "the most common cause of air embolism is introduction of air via the transseptal sheath."1 Medtronic has supplemented the FlexCath Advance Steerable Sheath IFU to highlight the known risk of air embolism more prominently. These updates do not impact current clinical practice as this information is consistent with current training and education materials, and with recommendations from HRS, JHRS, and EHRA. This letter contains a summary of the IFU updates.
Recommendation/Actions:	• Review the IFU Update Summary regarding air ingress and air embolism as provided in this letter. • Please share this information with clinicians in your hospital that use the FlexCath Advance Steerable Sheath. Also share this information with any other organization where these devices may have been transferred. • Please maintain a copy of this notice in your records.

Devices/Products photo:	

Authorized Representative Details	**Company name:**	**Medtronic Saudi Arabia Co.**
	Contact Person:	**Quality and Regulatory Affairs dep.**
	Phone:	**+966 114048884**
	Email:	**ksa.ra@medtronic.com**

For further information, please see the attached letter from the manufacturer. (Click Here)

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting (NCMDR Website).
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

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Sincerely,
NCMDR Team