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

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

accelerated battery depletion cause elevated likelihood for early replacement

Device/ Product Description:	Subcutaneous Implantable Cardioverter Defibrillators
Brand Name:	EMBLEM MRI S-ICDs
Lot numbers/Serials:	213750, 213773, 213831, 213852, 213925, 213954, 213960, 213971, 214034, 214037, 214051, 214072
Manufacturer:	Boston Scientific
Problem:	performance of EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) may result in a need for device replacement (ERI/EOL) earlier than expected due to compromised performance of an electrical component causing accelerated battery depletion.
Recommendation/Actions:	- monitor patients via LATITUDE to facilitate prompt detection of ERI/EOL - Perform a device follow-up every 3 months via remote or in-office interrogation. - Promptly investigate any suspected indication of accelerated depletion - Evaluate Risk for patients : • with a history of life-threatening ventricular arrhythmias such as a secondary prevention • indication or previous appropriate shock for VT/VF2 . • who are unable to be reliably followed every 3 months (via LATITUDE and/or in-clinic • interrogation). • who are not monitored via LATITUDE and are unable to hear beeping tones. - Replace As Needed You can find more information and recommendations from (HERE).

Devices/Products photo:	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product 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.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2995, 2952
Fax: +966 (11) 2757245
Or
Saudi Vigilance

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Sincerely,
NCMDR Team