Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة
والرقابة الدوائية
مسقط

To:
THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.98**..... dated** 2e/e5/12 **Regarding** IMAGER II 5F Angiographic Catheters **recall of (Mfr:** Boston Scientific)

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص . ب:
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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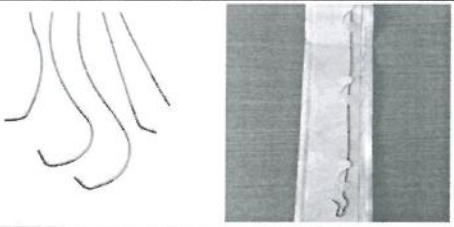
Circular No. 98 **/ 2020**

26 -Ramadhan-1441 H

20 -May-2020

Field Safety Corrective Actions (FSCA) **of** IMAGER II 5F Angiographic Catheters **from:** Boston Scientific

Source	US FDA https://www.fda.gov./medical-devices/medical-device-recalls/boston- scientific-corporation-recall-imager-ii-angiographic-catheters
Product	IMAGER II 5F Angiographic Catheters
Manufacturer	Boston Scientific
Local Agent	Global Source
The affected products	Multiple lot numbers as attached.
Reason	Because there is a potential for the catheter tip to become detached during a patient procedure or during procedure preparation. Use of the affected product may lead to additional surgical intervention to remove the catheter tip in the patient's blood vessel and increased time in the hospital. There is also the potential for serious adverse events including obstruction of blood flow (embolism), stroke or death.
Action	- Remove any affected lots in the hospital inventory. - Stop using any product with the affeected lot number. - Return the affected lot to the local agent.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Department of Medical Device Control contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

ص . ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

On February 11, 2020, Boston Scientific Corporation sent a letter to customers informing them of the affected lot numbers and provided the following instructions:

- Remove any affected lots in the hospital inventory
- Stop using any product with the affected lot number
- Complete the Verification Form and include the quantity of units from each affected lot
- Return the affected lots to Boston Scientific Corporation

Contact Information

Customers who have questions about the notification should contact their local sales representative or BSCFieldActionCenter@bsci.com (mailto:BSCFieldActionCenter@bsci.com).

Full List of Affected Devices

Product Description	Outer Package UPN #	Inner Package UPN #	GTIN	Lot/Batch #	Expiration Date
Imager™ II Angiographic Catheter	M001314051	M001314050	08714729354871	134092	23-Aug-2020
	M001314051	M001314050	08714729354871	134600	12-Sep-2020
	M001314061	M001314060	08714729354888	134011	20-Aug-2020
	M001314141	M001314140	08714729354963	133737	10-Aug-2020
	M001314341	M001314340	08714729355168	139512	12-Mar-2021
	M001314581	M001314580	08714729355403	134631	13-Sep-2020
	M001314591	M001314590	08714729355410	132447	13-Jun-2020
	M001314661	M001314660	08714729355489	132355	8-Jun-2020
	M001315151	M001315150	08714729355892	132823	26-Jun-2020
	M001315151	M001315150	08714729355892	133447	13-Jul-2020
	M001315151	M001315150	08714729355892	133448	16-Jul-2020
	M001315151	M001315150	08714729355892	134946	25-Sep-2020

Additional Resources:

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=179611)