Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمـان وزارة الصحـة مركز سلامة الـدواء 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 53 dated 24 4 24 Regarding NCMDR Recall of Tri-Staple<sup>TM</sup> 2.0 Black Reinforced Intelligent Reload from (mfr: Covidien LLC).

## Copy to:

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





## Sultanate of Oman Ministry of Health Drug Safety Center Muscat



سلطنة عُمان وزارة الصحة مركز سلامة الدواء مسقط

Circular No. 53 / 2024

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## Recall of Tri-Staple<sup>TM</sup> 2.0 Black Reinforced Intelligent Reload from Covidien LLC.

Source	NCMDR - National Center Medical Device Reporting- SFDA. <a href="https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=20999">https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&amp;rid=20999</a>
Product	Tri-Staple™ 2.0 Black Reinforced Intelligent Reload.
Description	Non-Biodegradable Surgical Stapler.
Manufacturer	Covidien LLC.
Local agent	Al Zahrawi Medical Supplies.
The affected products	Model: SIGTRSB60AXT Lot Number: N3G1372Y GTIN Numbers: 10884521717633,20884521717630
Reason	The affected product has the potential for a damaged cartridge.
Action	<ol> <li>Immediately identify and quarantine all unused of the affected product from the specified lot mentioned above.</li> <li>Return all unused product in your inventory, corresponding to the specified lot mentioned above to Medtronic.</li> <li>Contact the local agent for remedial action.</li> </ol>
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 through the E-mail: <a href="Med-device@moh.gov.om">Med-device@moh.gov.om</a>

Dr. Mohammed Hamdan Al Rubaie Director General





