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 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

After Compliments,

Please find attached our Circular No.....15..... dated 28/02/18 regarding the Recall of (Mesh Products) Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling manufactured by Coloplast.

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

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٤٦٠١٠٤٤ /٢٤٦٠٢١٧٧ - فاكس: ٢٤٦٠٢٢٨٧ - البريد الالكتروني : mohphar@omantel.net.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 24601044 / 24602177 - Fax: 24602287 - E-mail : mohphar@omantel.net.om

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Circular No. 15 / 2018

12 -06-1439 H
28 -02-2018

Urgent Recall of (Mesh Products) Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling Manufactured by Coloplast

The Saudi Food & Drug Authority has recently issued an Urgent Safety Communication stating that the Therapeutics Goods Administration (TGA) decided to remove the following product from the Australian Register of Therapeutic Goods (ARTG) due to lack of adequate scientific evidence which confirm its benefits outweigh the risks to patients.

Restorelle DirectFix Anterior
Model/Catalogue Number: 501450
SKU Number: 5014501022

Restorelle DirectFix Posterior
Model/Catalogue Number: 501460
SKU Number: 5014601022

Altis Single Incision Sling System
Model/Catalogue Number: 519650
SKU Number: 5195601022

The manufacturer, M/s. Coloplast, is recalling all Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling producted from the Australian market. In case this product is available with you, please return to the supplier immediately.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above device or any other medical device to

Director of Medical Device Control
Directorate General of Pharmaceutical Affairs & Drug Control
Ministry of Health, PO Box 393, Muscat, PC-100
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٤٦٠١٠٤٤ /٢٤٦٠٢١٧٧ - فاكس: ٢٤٦٠٢٢٨٧ - البريد الالكتروني : mohphar@omantel.net.om
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