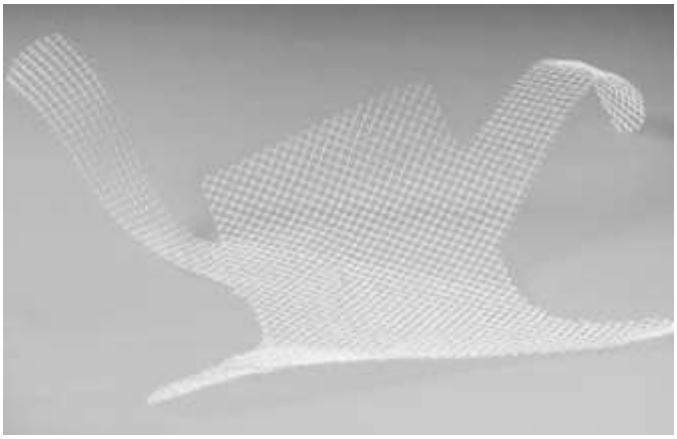
Urgent Safety Communication

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

Device/ Product Name:	Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling (Mesh, polymeric, non-biodegradable)
Lot numbers/Serials:	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
Manufacturer:	Coloplast
Problem:	Saudi FDA would like to bring to your attention that the Therapeutics Goods Administration (TGA) decided to remove the above mentioned products from the Australian Register of Therapeutic Goods (ARTG). The TGA believes there is currently a lack of adequate scientific evidence for it to be satisfied that the risks to patients are outweighed by the benefits of these devices. As a result Coloplast is recalling all Restorelle DirectFix Anterior, Restorelle DirectFix Posterior, and Altis Single Incision Sling products from the Australian market.

Recommendation/Actions:	• Quarantine any affected product for return to Coloplast.
Devices/Products photo:	

Authorized Representative Details	**Company name:**	**Janat Al Arab Trading**
	Contact Person:	**Ahmed El-Kafrawy**
	Phone:	**+966 559995320**
	Email:	aelkafrawy@janatalarab.com

For further information, please **see the recall by 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.
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

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team