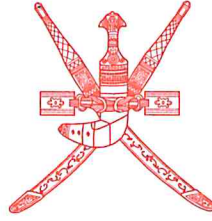


# Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs  
and Drug Control  
MUSCAT



سلطنة عمان  
وزارة الصحة  
المديرية العامة للصيدل  
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. 2/2020 dated 1/1/2020 regarding TGA recall of Textured Nagor GFX, CoGel and Impleo Mammary breast Implants (Mfr: Nagor Limited)

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

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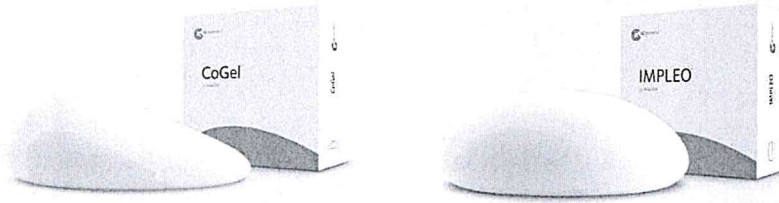
سلطنة عمان  
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مسقط

Circular No. 02 / 2020

05-05-1441 H

01-01-2020

## Recall of Textured GFX, CoGel and Impleo Mammary Implants from Nagro

Source of Recall	TGA Recall
Product	Textured Nagor GFX, CoGel and Impleo Mammary breast Implants
Manufacturer	Nagor Limited
The affected products	Nagor Mammary Implants Gel-filled- textured ; 9-cell CoGel gel-filled Nagor mammary implant range - textured; Impleo gel-filled Nagor mammary implant range - textured
Reason for Recall	Degree of risk of BIA-ALCL has been linked to this range of devices.
Action	1. Kindly check your stock, contact your local agent for remedial action 2. Implanting surgeons are requested to review the relevant literature in the context of their particular patients on a case-by-case basis. 3. The TGA has been advised that removal or replacement of macro-textured breast implants or tissue expanders in asymptomatic patients is not recommended..
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 Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control  
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie  
DIRECTOR GENERAL

