

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

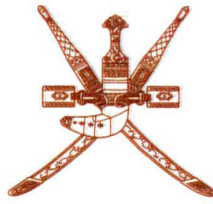
After Compliments,

Please find attached our Circular No 152 dated 18/7/23 Regarding NCMDR FSCA of Alcon Phaco Tips when used with included plastic wrench from (mfr:Alcon Laboratories Inc)).

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





Circular No. 152 / 2023

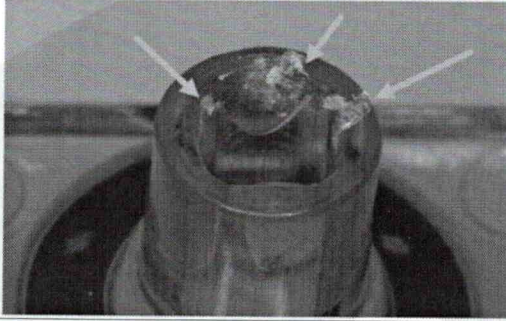
نقدم بثقة
Moving Forward
Confidence



30 -12-1444 H

18 -07-2023

Field Safety Corrective Action of Alcon Phaco Tips when used with included plastic wrench from Alcon Laboratories Inc

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19620
Product	Alcon Phaco Tips when used with included plastic wrench
Description	Surgical procedure kit, ophthalmic, non-medicated, single-use, Cataract extraction system handpiece tip, phacoemulsification, single-use.
Manufacturer	Alcon Laboratories Inc.
Local Agent	Muscat Pharmacy & Stores LLC.
The affected products	Catalog Numbers:8065752200, 8065741085, 8065750852, 8065750853, 8065750958, 8065752086, 8065752087, 8065752201, 8065752216, 8065752217 All Batches that were supplied.
Reason	The potential for the Phaco Tip wrench to generate plastic shaving particles if the Phaco Tip is over-tightened to the handpiece to the point where the wrench slips over the tip-to-wrench interface.
Action	1. In order to mitigate the occurrence of the above, customers are being advised to follow precautions in the attachment. 2. Contact the local agent for remedial action.
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 through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padc@moh.gov.om