Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical
Affairs and Drug Control
Muscat

سلطنة عُمان
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 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 250 **dated** 29/12/2022 **Regarding NCMDR Recall of NEO-fit Neonatal Endotracheal Tube Grip of MR systems from (mfr: Cooper Surgical 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**

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

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سلطنة عُمان
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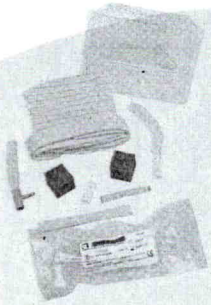
Circular No. 250/ 2022

05 -06-1444 H
29 -12-2022

Recall of NEO-fit Neonatal Endotracheal Tube Grip from Cooper Surgical Inc.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=18394
Product	NEO-fit Neonatal Endotracheal Tube Grip.
Description	Neonatal Endotracheal Tube Grip.
Manufacturer	Cooper Surgical Inc.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Part Number: 42-2540 Lots: Refer to "Appendix A" in the attached FSN.
Reason	Complaints relating to the metal clip becoming detached from the product strap and there is the risk that this clip may be ingested by the infant due to its proximity to the oral cavity.
Action	1. Return affected unexpired product. 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
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CooperSurgical®

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53175 Bonn
Germany
Phone: +49 (0)228-207-30
Email: poststelle@bfarm.de

10/18/2022

Medical Device Field Safety Corrective Action:
NEO-fit™ Neonatal Endotracheal Tube Grip
Part Number: 42-2540
Lots: Appendix A

Dear Sir/Madam

CooperSurgical will send a Field Safety Notice (FSN) notification to all affected customers. The products are being recalled due to receiving complaints relating to the metal clip becoming detached from the product strap and there is the risk that this clip may be ingested by the infant due to its proximity to the oral cavity.

CooperSurgical will notify affected consignees via certified mail with confirmed delivery receipt. The letter will identify the affected product and detail the necessary actions to be taken by customers who have received affected products. The letter will ask customers to contact CooperSurgical if they have any questions regarding the recall. At CooperSurgical's expense arrangements will be made to return affected unexpired product to CSI for credit.

There are up to 220,500 unexpired devices that are considered affected and distributed globally. CooperSurgical determined that the affected products were distributed to 2 consignees in Germany.

CooperSurgical has initiate CAPA 793 to determine root cause and implement a Corrective Action Plan (CAP) to address the root cause and prevent recurrence. Upon completion of all recall activities, CooperSurgical will formally submit a closure report. Copies of the Health Hazard Evaluation for risk analysis is enclosed.

Sincerely,

[redacted]
Manager of Risk Management

Appendix A – Lot Numbers of Potentially Affected Devices (Part Number: 42-2540)

Lot Number
247020
269476
269477
269478
269479
269480
269481
269482
269483
272992
274957
274958
274959
274960
274961
274962
274963
286859
286861
286862
286863
291949
291950
291951
291952
291953
292878
292879
292880
292881
292882
292883
292884
292885
292886
292887
292888
292889
292890
292891

Lot Number
292892
292893
292894
292895
292896
292897
292898
292899
292900
292901
292902
292903
292904
296234
296235
296236
296237
296238
296239
296240
296241
296890
296891
296892
296893
297033
297034
297035
297036
297037
298047
298048
298049
298051
298053
298054
298055
298056
298062
298063

Lot Number
298064
298065
301600
301601
301602
301603
301604
301605
301606
301607
302944
303769
303771
303772
303949
303950
304053
304363
304364
305016
305017
305018
305019
305020
305021
306282
306339
306340
306341
306342
306343
307080
307081
307616
307723
307724
307725
307726
307727
307728

Lot Number
307729
307730
308590
308591
309456
309544
309910
309912
309913
309914
311350
311465
311533
311690
312729
312730
312731
313142
313273
313274
314493
314675
314676
314969
315504
315505
315626
315810
316162
316866
316976
317032
318970
319205
319298
320400
321242