

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سِلاطَنَةُ عُومَانِ
وَزَارَةُ الصِّحَّةِ
وَالرِّقَابَةِ الدَّوَلِيَّةِ
مَسْقَط

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. 27..... dated 09/02/2020 Regarding Safety Alerts of Sterilizable handle hub (Mfr: MAQUET)

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

Sultanate of Oman

Ministry of Health

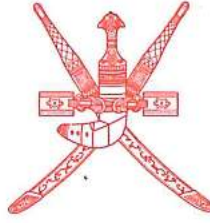
Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT

Circular No. 27 / 2020

15-06-1441 H


09-02-2020



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدل
والرقابة الدوائية
مسقط

Ref: 19/2020

Safety Alerts of Sterilizable handle hub from MAQUET

Source of Recall	Gulf Health Council file:///C:/Users/moh76697/Downloads/Hanaulux%20%20(3).pdf
Product	Sterilizable handle hub for surgical light (Hanaulux)
Manufacturer	MAQUET
Local Agent	Waleed Pharmacy
The affected products	Please Refer to attachment
Reason for Recall	Manufacturer has identified that the circlip, which is part of the locking system, may break. As a result, when the user unlocks the sterilizable handle the locking mechanism may fall. If during surgery the handle is removed for potential aseptic reasons, the circlip or other components may fall on the surgical field. The manufacturer conducted investigations, which established that some cleaning products and cleaning protocols more aggressive than those mentioned in the product labelling might be used. This results in altering the circlip, notably causing its oxidation resulting in a breakage. This issue may result in preventing the usage of the device causing delays in planned surgery. It may also create a contamination issue if the circlip falls on the surgical field
Action	<ol style="list-style-type: none">1. Kindly check your stock, contact your local agent for remedial action2. Review this notice and ensure that affected personnel aware of the contents.3. Verify that the locking mechanism works correctly before use.4. If you have affected product at your facility, or if the mechanism does not work or lock correctly, contact the authorized representative to arrange for the correction of your device.5. Only use the recommended cleaning materials and cleaning protocols
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



25/5/1441 :
20/01/2020 :
:
20-01-20/0101 :

التاريخ الهجري
التاريخ الميلادي
المرفات
رقم

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council



تقارير السلامة للأجهزة والمستلزمات الطبية
Safety Alerts of Medical Device Products

To: HE / Members of the Executive Committee of the Cooperation Council States Members	إلى: سعادة/ أعضاء الهيئة التنفيذية بدول مجلس التعاون.	
Subject:	تحذير سلامة لمنتج طبي	الموضوع:
Product Name:	Sterilizable handle hub (Hanaulux)	اسم المنتج:
Company Name:	MAQUET Inc.	اسم الشركة:
Product Photo:	None	صورة المنتج:
Affected Devices:	Please Refer to attachment	الأجهزة المتضررة:
Product Reg. Status in GHC:	None	وضع المنتج في مجلس الصحة:
Source of Warning:	الشركة المصنعة (MAQUET Inc.) و SFDA	مصدر التحذير:
Reason for Warning:	<p>Under certain conditions, the manufacturer has identified that the circlip, which is part of the locking system, may break. As a result, when the user unlocks the sterilizable handle, the circlip or other components of the locking mechanism may fall. If during surgery the handle is removed for potential aseptic reasons, the circlip or other components may fall on the surgical field.</p> <p>The manufacturer conducted investigations, which established that some cleaning products and cleaning protocols more aggressive than those mentioned in the product labeling might be used. This results in altering the circlip, notably causing its oxidation resulting in a breakage. This issue may result in preventing the usage of the device causing delays in planned surgery. It may also create a contamination issue if the circlip falls on the surgical field.</p>	سبب التحذير:

25/5/1441 هـ
20/01/2020 م
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20-01-20/0101 : رقم

التاريخ الهجري
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تقارير السلامة للأجهزة والمستلزمات الطبية
Safety Alerts of Medical Device Products

Recommendation:	<ol style="list-style-type: none">1. Review this notice and ensure that affected personnel are aware of the contents.2. Verify that the locking mechanism works correctly before use.3. If you have affected product at your facility, or if the mechanism does not work or lock correctly, contact the authorized representative to arrange for the correction of your device.4. Only use the recommended cleaning materials and cleaning protocols	التوصيات:								
Authorized Representative Details:	<table border="1"><tr><td>AR name:</td><td>Gulf Medical Co.</td></tr><tr><td>Assigned Contact Person:</td><td>Mohammed Al Ghamdi</td></tr><tr><td>Mobile/Phone:</td><td>0551417735</td></tr><tr><td>Email:</td><td>regulatory@gulfmedical.com</td></tr></table>	AR name:	Gulf Medical Co.	Assigned Contact Person:	Mohammed Al Ghamdi	Mobile/Phone:	0551417735	Email:	regulatory@gulfmedical.com	بيانات التواصل مع ممثل الشركة بالسعودية
AR name:	Gulf Medical Co.									
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Email:	regulatory@gulfmedical.com									
Link of Circular	رابط الخبر هنا	رابط التعميم:								
Any Comment & Report Adverse Reaction:	pms@ghc.sa	للاستفسارات والإبلاغ عن الآثار الجانبية للدواء:								