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

سلطنة عمان
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. 24/2 **dated** 27/12/2 **Regarding NCMDR Recall of Medisafe Distal Duck Kit and Duck Bag (Humidity Pack) from (STERIS Corporation).**

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**

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

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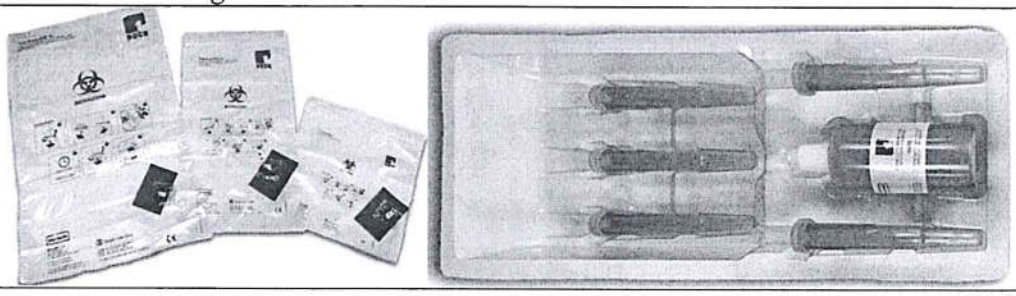
Circular No. 242/ 2020

12 -05 -1442 H

27 -12-2020

Recall of Medisafe Distal Duck Kit and Duck Bag (Humidity Pack) from STERIS Corporation.

Source	NCMDR- National Centre Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=15461
Product	Medisafe Distal Duck Kit and Duck Bag (Humidity Pack).
Description	General equipment for medical treatment - cleaning / disinfection / sterilisation.
Manufacturer	STERIS Corporation.
The affected products	Medisafe Distal Duck Kits (M20400) and Duck Bag Humidity Packs (M20350, M20358, M20359) distributed from November 28. 2018 to September 9. 2020.
Reason	Certain lots of diluted 4-Zyme may contain bacteria, specifically Pseudomonas fluorescens.
Action	1. Please immediately inspect on-hand inventory for Medisafe Distal Duck Kits and Duck Bag Humidity Packs. For the full list of affected product and associated lots, please reference Attachment A to this letter. 2. If you have product remaining in inventory from any of the affected lot numbers listed in Attachment A, please complete the Medical Device Recall Response Form included with this Customer Notification Letter and destroy any remaining product in inventory. STERIS will coordinate shipment of replacement product upon receipt of the completed Recall Response Form. 3. 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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني : dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

STERIS

URGENT MEDICAL DEVICE RECALL
Medisafe Distal Duck Kit and Duck Bag (Humidity Pack)

November XX, 2020

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a recall for certain lots of Medisafe Distal Duck Kits (M20400) and Duck Bag Humidity Packs (M20350, M20358, M20359) distributed from November 28, 2018 to September 9, 2020. Our records indicate that you have received product affected by this recall.

Description of the product – The Medisafe Distal Duck range of products are intended to keep instruments moist during transportation between point of use and cleaning as an initial step of reprocessing.

The Distal Duck Kit comprises of 5 tip soakers filled with enzymatic detergent (4-Zyme) and a 100 mL bottle of diluted 4-Zyme. The Duck Bag Humidity Pack contains a sachet of diluted 4-Zyme.

Description of the problem – STERIS has identified that certain lots of diluted 4-Zyme may contain bacteria, specifically *Pseudomonas fluorescens*. The presence of this bacteria can cause the color of the detergent to darken over time. There is an improbable risk to users of the product from exposure to this bacteria, and no risk to patients.

User Action Required – Please ensure the following steps are completed:

1. Please immediately inspect on-hand inventory for Medisafe Distal Duck Kits and Duck Bag Humidity Packs. For the full list of affected product and associated lots, please reference Attachment A to this letter.

2. If you have product remaining in inventory from any of the affected lot numbers listed in Attachment A, please complete the Medical Device Recall Response Form included with this Customer Notification Letter and destroy any remaining product in inventory. STERIS will coordinate shipment of replacement product upon receipt of the completed Recall Response Form. Your STERIS Sales Representative can assist you should you have any questions while completing the form.

3. Return the completed Recall Response Form via email to Regulatory_Compliance@STERIS.com or via fax to (440) 392-8963. This form must be completed and returned if you identify affected product in inventory and wish to receive replacement product.

We apologize for any inconvenience this matter may cause, and as always, STERIS is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact Emma Barrett, Senior Marketing Manager at Emma_Barrett@STERIS.com, your local STERIS Representative, or STERIS Customer Operations teams as follows:

- UK / Ireland, please call +44 116 2740600;
- Europe / Middle East / Africa, please call +33 (0)5 56 939560; or
- Latin America / Asia, please call 1-800-884-9550.

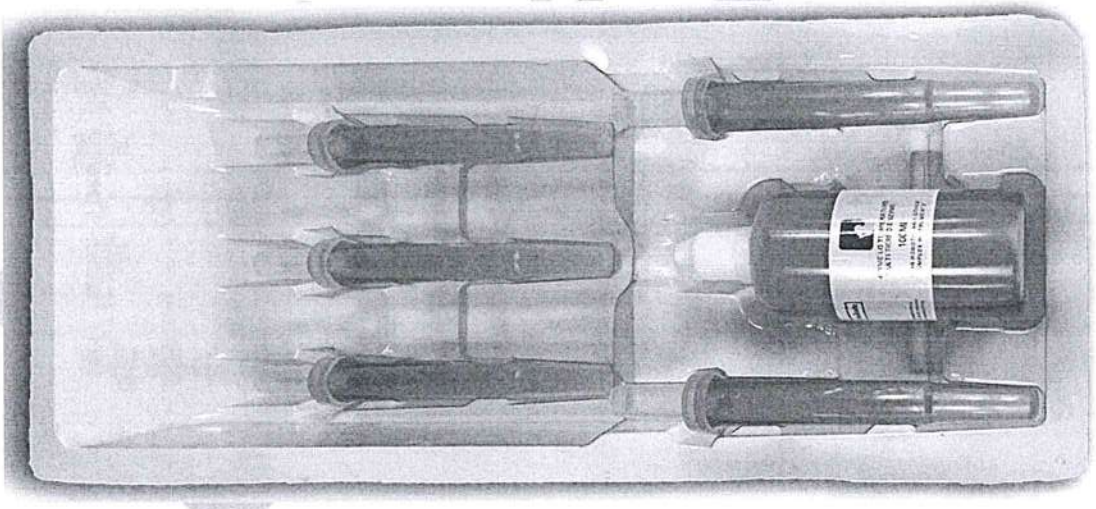
Sincerely,

[redacted]

STERIS

Attachment A – List of affected product

Product Number	Product Description	Affected Lot Numbers
M20350	1/2 Half Size Duck Bag (Box of 50)	1811273, 1811277, 1906484, 1908593, 1909635, 1910651, 1911658, 2001730, 2004770
M20358	Duck Bag Full Din (Box of 50)	1903408, 1906508, 1907556, 1909644, 2001718, 2004772
M20359	Duck Bag Super Size (Box of 50)	1811278, 1906499, 1910649, 1911680, 1911691, 1912708, 2001719, 2004768



Product Number	Product Description	Affected Lot Numbers
M20400	Duck Kit (Single Kit)	1901340, 1901349, 1902374, 1904448, 1904464, 1905505, 1906529, 1907571, 1908595, 1909624, 1910653, 1912700, 2001717, 2004766, 2004774, 2006797

STERIS

MEDICAL DEVICE RECALL RESPONSE ACKNOWLEDGEMENT RETURN FORM

RESPONSE IS REQUIRED

Facility Name: _____

Street Address: _____

City, State, Country, Zip/Post Code: _____

Medisafe Distal Duck Kit and Duck Bag (Humidity Pack)

Affected Lot Numbers:

1811273, 1811277, 1811278, 1901340, 1901349, 1902374, 1903408, 1904448, 1904464, 1905505, 1906484, 1906499, 1906508, 1906529, 1907556, 1907571, 1908593, 1908595, 1909624, 1909635, 1909644, 1910649, 1910651, 1910653, 1911658, 1911680, 1911691, 1912700, 1912708, 2001717, 2001718, 2001719, 2001730, 2004766, 2004768, 2004770, 2004772, 2004774, 2006797

1. A review of on-hand inventory identified remaining Distal Duck Kit(s) and/or Duck Bag(s).
   ☐ Yes ☐ No
2. If answered "Yes" to Question 1, were all remaining products destroyed upon receipt of the Recall Notification Letter?
   ☐ Yes ☐ No ☐ N/A
3. Please identify the lot(s) and quantity of affected product destroyed (example: 2 boxes of lot 1811277 and 1 kit of lot 2004766):

   _____

   _____

   _____

_____
Printed Name and Title of Person Completing this Form

_____
Signature Date

Please complete this form in its entirety, scan and return via email to Regulatory_Compliance@STERIS.com or via fax to (440) 392-8963.