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

December 1, 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,

Michelle LaVan

Michelle LaVan
Lead Quality & Regulatory Compliance Specialist
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.