STERIS

URGENT FIELD SAFETY NOTICE
NEUTRA-FLUSH + Endoscope Channel Cleanser

May 19, 2026

ATTN: GI DIRECTOR OR STERILE PROCESSING DEPARTMENT

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a Field Safety Corrective Action (FSCA) for four (4) lots of NEUTRA-FLUSH + Endoscope Channel Cleanser (UDI: 80115117TDF00024ZS) distributed between November 17 – December 18, 2025. Our records indicate that your facility purchased one or more of the lots impacted by this FSCA.

Lot	SKU(s)
160625	100848K, 100849K
170625	100848K, 100850K, 100851K
180625	100848K, 100849K, 100850K
190625	100849K

Description of the product – NEUTRA-FLUSH + is a convenient, space saving, pre-cleaning kit containing a neutral, low foaming cleanser intended for the post procedural initial flush and wipe of an endoscope at the bedside. NEUTRA-FLUSH + is indicated for use immediately after endoscopy procedures to prevent drying of organic debris on an endoscope.

Description of the problem – STERIS has received Customer complaints reporting an unusual, sulfur-like odor from four lots of NEUTRA-FLUSH +. In one instance, the user facility reported that the "smell was very bad making staff and patients feel physically sick." A thorough investigation was performed by both STERIS and our supplier, including full review of the manufacturing line where the sachets are filled. Laboratory testing was performed of both the affected product and the filling line. The culture showed no detectable microbiological contamination. No sources of potential contamination were identified, and all measured values were within specification. Therefore, the only known risk of the affected product is from the atypical odor itself.

STERIS Action – STERIS will provide replacement product at no cost to Customers who have product remaining in stock. The competent (regulatory) authority of your country has been informed of this notice.

User Action – Please ensure the following steps are completed:

1. Please inspect your on-hand inventory for product affected by this FSCA.
2. Please complete the Response Form included with this letter and destroy any remaining affected inventory in your possession.
3. Return the completed Response Form via email to: Regulatory_Compliance@STERIS.com or via fax to +1 440-392-8963. **NOTE**: No replacement product will be provided until a completed Response Form is received.

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 your local STERIS Representative.

Sincerely,

Michelle LaVan

Michelle LaVan
Quality & Regulatory Compliance, Manager
STERIS

MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION RESPONSE FORM

RESPONSE IS REQUIRED

Customer Name:_____

Street Address:_____

City / Country / Postal Code:_____

NEUTRA-FLUSH + Endoscope Channel Cleanser

Affected Lot Numbers:

160625, 170625, 180625, and 190625

1. A review of on-hand inventory identified unused product affected by this FSCA.

   ☐ Yes ☐ No

2. If answered "Yes" to Question 1, was all affected product destroyed upon receipt of the Notification Letter?

   ☐ Yes

3. Please list the SKU(s) and quantity (boxes) of affected product destroyed (example: 2 boxes of 160625).

   _____

_____

Printed Name and Title

_____

Signature and Date

Please fill out in entirety, scan, and return via email to Regulatory_Compliance@STERIS.com or via fax to +1 440-392-8963