Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL08-11 March 12, 2008

Item: STERIS C1160 Universal Flexible Processing Trays used with the STERIS System 1 Sterile Processing Systems

Specific Incident: STERIS Corporation issued an Urgent Recall Notice about the design/operation of the C1160 universal flexible processing tray that may compromise the ability of the STERIS System 1 Sterile Processor to provide an effective sterilization cycle when the C1160 tray is used.

STERIS identified this issue internally during quality control procedures; STERIS indicated there have been no adverse incidents reported from facilities regarding this issue. It is possible, however, that devices (e.g., endoscopes, esophageal dilators) sterilized in the STERIS System 1 with C1160 trays may not have been adequately sterilized. Additional diagnostic cycles recommended by STERIS will ensure the processor is operating within acceptable limits.

NOTE: This Patient Safety Alert applies to all STERIS System 1 models and all serial numbers of C1160 trays. This Patient Safety Alert does not apply to C1200, C1220, or C1140 trays.

General Information: Prior to STERIS' Urgent Recall Notice, STERIS' operating instructions indicated that a diagnostic cycle is only required to be run once every 24 hours. Since the discovery that the C1160 tray may compromise the ability of the STERIS System 1 to provide an effective sterilization cycle when the C1160 tray is used, STERIS is now indicating that, in addition, diagnostic cycles be run after each C1160 tray is processed in the STERIS System 1.

Actions: Chief of SPD (or designee) will ensure the following actions are carried out by close of business Friday, March 14, 2008:

1. Reprocessing personnel who utilize the STERIS System 1 must read this Patient Safety Alert and the attachments.
   NOTE: Be sure to identify all areas in your facility that have STERIS System 1 Processing Systems that may include, but are not limited to the following: Ambulatory Surgery, Endoscopy, GI, GU, OR, Respiratory, SPD, and Urology.
2. If possible, discontinue the use of STERIS C1160 trays with the STERIS System 1 until STERIS is able to correct the problem at your facility. (STERIS began field correction on March 7, 2008.) Use alternative trays in the meantime to sterilize your devices.
   NOTE: The alternative trays must be suitable for use with the particular device(s) to be reprocessed and with the STERIS System 1 (i.e., obtain written confirmation of suitability from the device manufacturer or STERIS on the proper tray to be used with each device).

3. If you must utilize the C1160 trays to sterilize devices in the STERIS System 1, until STERIS performs a field correction to fix the problem at your facility, reprocessing personnel must run a diagnostic cycle at the beginning of each day and after every sterile processing cycle with the C1160 tray. The device reprocessed in the C1160 tray must be held until its diagnostic cycle has been completed and passed. If the device's diagnostic test did not pass, the problem must be corrected and the device reprocessed.

Add'l Information: Guidance regarding notification of patients that may have been exposed to pathogens as a result of possible improper reprocessing is not addressed in this Patient Safety Alert. Such guidance could potentially be provided in a separate communication.

Source: Manufacturer, VA medical facility

Contacts: Bob Osburn, National SPD at (214) 857-4190, or
Holly Wright Lee, STERIS Corporation at (800) 548-4873 or (440) 392-7019.

Attachments: 1.) Urgent Recall Notice from STERIS Corporation, dated February 19, 2008
A.) Figure of C1160 Universal Flexible Processing Tray
B.) Illustration of diagnostic cycle failure messages

Attachment 1

Urgent Recall Notice from STERIS Corporation, dated February 19, 2008.

STERIS

URGENT RECALL NOTICE
C1160 Universal Flexible Processing Tray
Used with the
STERIS SYSTEM 1 Processor

February 19, 2008

ATTN: HOSPITAL ADMINISTRATOR, MATERIALS MANAGER, PURCHASING MANAGER, OR MANAGER, CSSD/GI MANAGER AND RISK MANAGER, AND BIOMEDICAL ENGINEER

RE: ALERT — CHANGE IN DEVICE OPERATION – C1160 Universal Flexible Processing Tray

SYSTEM 1 model numbers: All
Tray C1160 serial numbers: All

Dear Valued Customer:

STERIS is issuing this notification to inform you of a problem that necessitates a change in the way the C1160 Tray accessory is used with the SYSTEM 1 Sterile Processing System.

Description of the problem – STERIS has become aware that under certain conditions the design/operation of the C1160 Tray may compromise the ability of the SYSTEM 1 processor to provide an effective sterilization cycle when a C1160 Tray is used (see Attachment A). The device sterilized in the C1160 tray should **not** be used clinically prior to completion of a successful diagnostic cycle. This alert applies *only* to the C1160 Tray, and *does not apply* to the C1200, C1220, or C1140 Trays.

UNTIL FURTHER NOTICE, you must run a diagnostic cycle **after each sterile cycle** involving a C1160 Tray or alternately you must discontinue use of these trays. The diagnostic cycle will ensure that the processor is operating within acceptable limits.

User Action Requested – Until STERIS informs you otherwise, we require that when using the C1160 Tray in the SYSTEM 1, you must run a diagnostic cycle at the beginning of each day, and after EACH sterile processing cycle with the C1160 tray. STERIS cannot guarantee the sterility of devices processed in the C1160 Tray in the SYSTEM 1 processor if this procedure is not followed. Prior to this notification, STERIS operating instructions specified that you run a diagnostic cycle once every 24 hours when using the STERIS SYSTEM 1 Processor. If you experience a diagnostic cycle failure, the SYSTEM 1 Processor will stop working, and you should immediately contact your STERIS Service Technician.

C1160 Trays have been in use since 1999. The affected trays include all C1160 trays processed between the last successful diagnostic cycle and the time of the cycle failure. The condition described in this letter would appear as a high pressure pump fault reading on the printout from the diagnostic cycle of the SYSTEM 1 Processor. If any printout from the diagnostic cycle of your SYTEM 1 processor shows the following reading –

Attachment 1 - continued

"HP PUMP FAULT xx.xx" [any number >5]
or
"HP PUMP FAULT - PUMP ON"

(*see* Attachment B for an illustration), then you may have experienced the condition described in this letter. In that case, we recommend that you notify the physicians of patients who had procedures performed with devices processed in the affected C1160 Trays of the possible sterilization failure and ask them to assess the risk to their patients and consider the degree of follow-up needed for those at risk. In determining the degree of patient follow-up, we recommend that physicians consider the time elapsed since a patient's procedure. Also, please notify STERIS if you discover the fault condition on the printout tape described above.

Description of resolution – STERIS will contact you when we have completed development of the field corrective action required to resolve this malfunction with the tray. STERIS expects to commence a field corrective action approximately March 7, 2008, and we will visit your facility to implement it. This corrective action, once implemented, will eliminate the need to run a diagnostic cycle in conjunction with each sterile cycle on the C1160 Tray.

STERIS Corporation is dedicated to supporting our products and valued customers. If you have questions regarding this matter, please call Tamara Struk, Product Manager at 440-392-7437or 1-800-548-4873 between 8 a.m. and 5 p.m. EST, Monday - Friday.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid FDA form 3500 available at:
  www.fda.gov/MedWatch/getforms.htm.
  Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- **Fax**: 1-800-FDA-0178

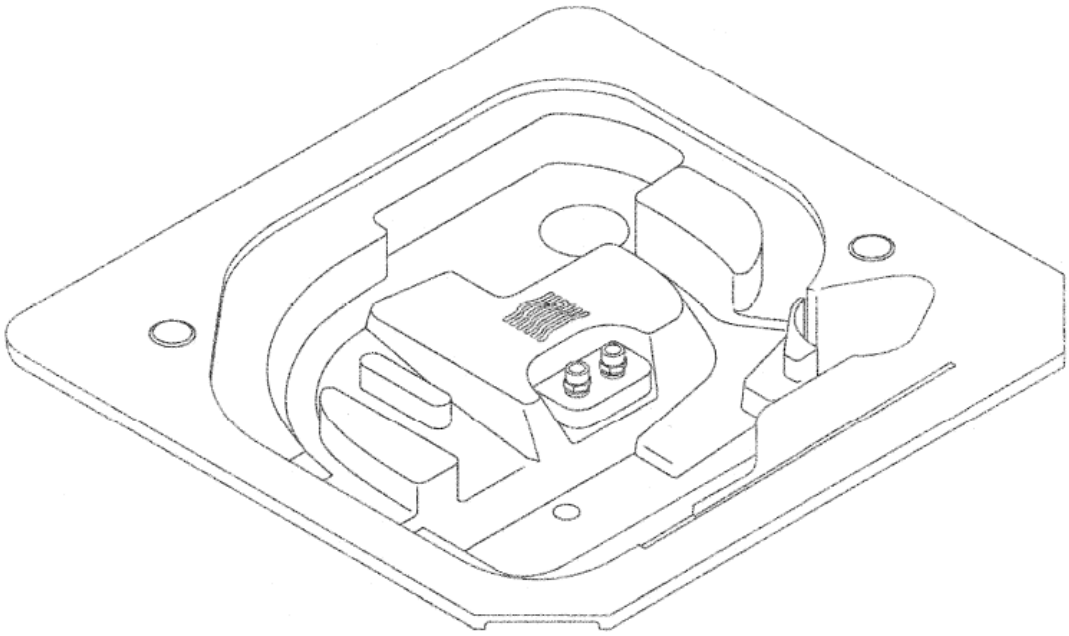
CAUTION: DO NOT RUN SYSTEM 1 WITH A C1160 TRAY UNLESS YOU RUN A DIAGNOSTIC CYCLE AT THE BEGINNING OF EACH DAY AND AFTER EVERY STERILE PROCESSING CYCLE. THE DIAGNOSTIC CYCLE MUST RESULT IN AN ACCEPTABLE DIAGNOSTIC PRINT OUT BEFORE ANY DEVICES PROCESSED ARE USED.

Sincerely,

Robert F. Sullivan
Senior Director of FDA Regulatory Affairs
STERIS Corporation
5960 Heisley Road, Mentor, Ohio 44060-1834

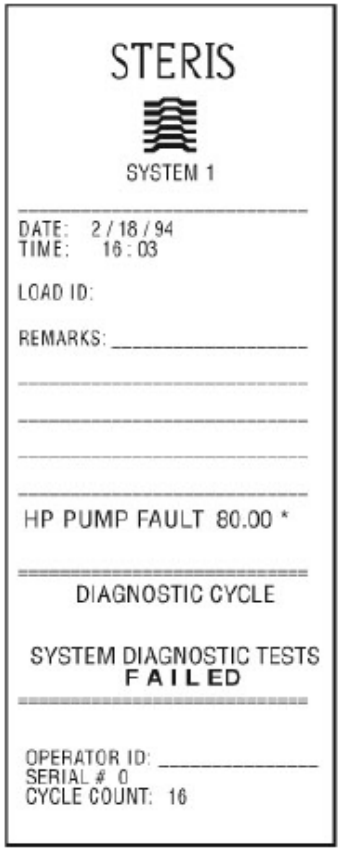
Attachment A

C1160 Universal Flexible Processing Tray



Attachment B

Illustrations of diagnostic cycle failure messages



* NUMBER INDICATED MUST BE >5.