

URGENT MEDICAL DEVICE RECALL
RAPICIDE PA High-Level Disinfectant

September 8, 2026

ATTN: MATERIALS MANAGEMENT, SPD DIRECTOR, or QUALITY DIRECTOR

Dear Valued STERIS Customer:

STERIS is voluntarily implementing a recall for certain lots of RAPICIDE PA High-Level Disinfectant Part A ("RAPICIDE"). A small number of RAPICIDE bottles within these lots may begin to bulge or expand over time. Our records indicate that your facility purchased one or more of the affected lots. Please see Attachment A for the list of affected lots.

Description of the product – RAPICIDE PA High-Level Disinfectant is a two-part liquid disinfection system intended to be used with validated Automated Endoscope Reprocessing (AER) systems to provide high-level disinfection of non-critical and semi-critical precleaned, immersible, reusable heat sensitive devices including bronchoscopes and gastrointestinal endoscopes and their accessories.

Description of the issue – STERIS identified through Customer complaints that a small number of RAPICIDE PA Part A bottles within certain lots may begin to bulge or expand over time. Part A is the active component of chemistry that creates peracetic acid, which may off-gas during the shelf-life of the product. Under routine conditions, the Part A bottle cap includes a vent intended to allow gas to escape (off-gassing) and reduce the potential for gas accumulation. If the vented cap becomes blocked, gas may accumulate and the bottle may swell due to increased internal pressure. In some cases, excess vapor or liquid chemistry may escape from the bottle when the cap is twisted during opening, which could result in user exposure if required personal protective equipment (PPE) is not properly used. Such exposure may result in injury to the user or others in close proximity, including skin burns and irritation from vapor inhalation. For reference, pictures showing examples of a bulging bottle vs. a normal bottle are included in Attachment B to this letter.

Our investigation determined that a very small percentage of caps may have been manufactured with a fully or partially blocked vent, preventing proper off-gassing. **IMPORTANT NOTE:** This recall does not constitute a full removal. Our complaint rate to date indicates that more than 99.4% of the product is not affected and can and should be used normally. There is no impact to the efficacy of the RAPICIDE chemistry.

User Action – Users can continue using the RAPICIDE product through the remainder of its shelf life. Please immediately inspect your on-hand inventory for product affected by this recall. If bottle bulging is observed, follow the instructions below to release any accumulated pressure and dispose of the product:

1. **Users MUST wear personal protective equipment (PPE)** before handling the bottle, including:
 - a. Safety eyewear
 - b. Chemical-resistant gloves
 - c. A solvent-resistant apron
 - d. Protective footwear appropriate for chemical handling
2. Move the product to an appropriate, well-ventilated area. Respiratory protection is also recommended in accordance with the RAPICIDE PA Part A Safety Data Sheet (SDS). Refer to Attachment C to this letter for an excerpt of the SDS.
3. Carefully loosen the cap. Slowly begin untwisting the cap while keeping the threads engaged to allow any accumulated pressure to release gradually.
4. Allow the pressure to vent. Continue loosening the cap slowly over approximately 1 to 2 minutes until the pressure has been released and the cap can be fully removed.
5. Dispose of the bottle and contents through your facility's hazardous or special waste program in accordance with applicable local, regional, national, and/or international regulations. **Do not replace the cap on a bottle that has exhibited bulging.**
6. Please complete the Recall Response Form included with this letter, and return via email to Regulatory_Compliance@STERIS.com, or via fax to 440-392-8963. Replacement product will be provided for any product that had to be disposed.

Users are also reminded to report any adverse events via FDA's MedWatch Database or local competent authority should an event occur. 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 Account Manager.

Sincerely,





**MEDICAL DEVICE RECALL RESPONSE
ACKNOWLEDGEMENT RETURN FORM**

RESPONSE IS REQUIRED

Customer Name: _____

Street Address: _____

City, State, Postal Code: _____

RAPICIDE PA High-Level Disinfectant

If applicable, please identify the lot(s) and quantity (bottles) of affected products destroyed (example: 2 bottles of lot 689171).

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 440-392-8963**

Attachment A

SKU: ML020115

Affected Lot numbers outside of the US and Canada

Outer Case Lot Number	Part A Bottle Lot Number
687047	687046
688018	688017

SKU: ML020116

Affected Lot numbers in Canada

Outer Case Lot Number	Part A Bottle Lot Number
689172	689171
689982	689981
690994	690993
691740	691739
692571	692570
694358	694357

SKU: ML020117

Affected Lot numbers in the US

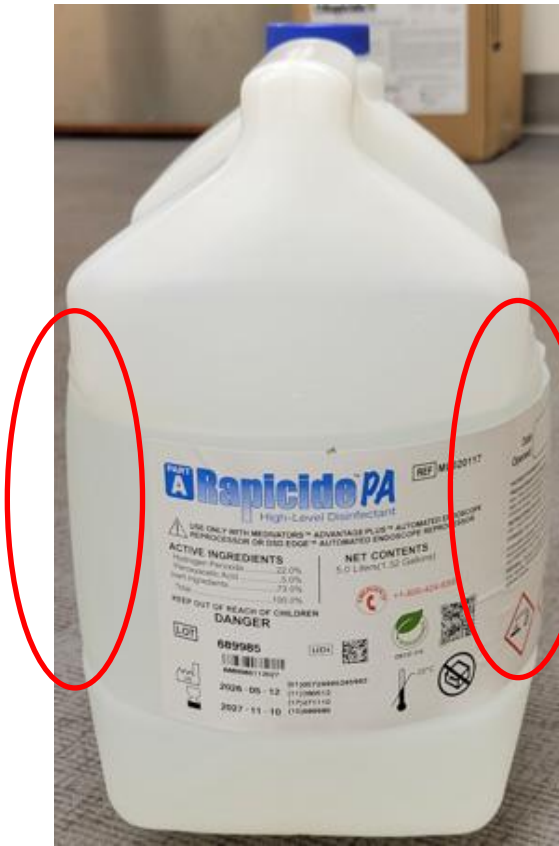
Outer Case Lot Number	Part A Bottle Lot Number
688020	688019
688022	688021
688024	688023
688026	688025
688577	688576
688581	688580
688583	688582
688585	688584
688587	688586
688589	688588
689174	689173
689176	689175
689178	689177
689180	689179
689984	689983
689986	689985
689988	689987
690300	690299
690302	690301
690996	690995
690998	690997

SKU: ML020117
Affected Lot numbers in the US (continued)

Outer Case Lot Number	Part A Bottle Lot Number
691000	690999
691002	691001
691744	691741
691746	691743
692204	691745
692207	692203
692209	692206
692212	692208
692214	692210
692216	692213
692218	692215
692537	692217
692573	692572
692575	692574
692577	692576
692579	692578
692581	692580
692583	692582
692731	692730
692733	692732
692735	692734
692737	692736
692739	692738
692741	692740
692743	692742
692745	692744
694360	694359
694362	694361
694364	694363

Attachment B

Bottle with bulging



The picture on the left shows a bottle exhibiting the bulging issue. The circles identify areas where the bottle sidewalls have expanded outward, resulting in a rounded or swollen appearance.

Bottle without bulging



The picture on the right shows a bottle without the bulging issue. The bottle retains its intended shape, with straight sidewalls and no visible outward expansion.

Attachment C – Excerpt from Safety Data Sheet

RAPICIDE™ PA Part A

Safety Data Sheet

according to the Hazard Communication Standard (CFR29 1910.1200) HazCom 2024.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Ensure good ventilation of the work station. Provide readily accessible eye wash stations and safety showers.

8.2.2. Personal protection equipment

8.2.2.1. Eye and face protection

Eye protection:

Safety eyewear complying with an approved standard such as the European Standard EN166 should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists or dusts.

8.2.2.2. Skin protection

Skin and body protection:

Wear solvent resistant apron and boots for spills.

Hand protection:

Wear suitable gloves resistant to chemical penetration. Consult glove manufacturer's product information on material suitability and material thickness.

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator. SDSs cannot provide detailed and complete respiratory protection guidelines. Selection of respiratory protection must be done by a qualified person who has assessed the work environment.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Handle in accordance with good industrial hygiene and safety procedures. Do not eat, drink or smoke when using this product.

For the full Safety Data Sheet, please visit: <https://www.steris.com/about/hse/safety-data-sheets>, and select “RAPICIDE PA High-Level Disinfectant & Test Strips” from the product picklist.