

**URGENT: MEDICAL DEVICE RECALL
 INITIAL NOTIFICATION LETTER**

EXOGEN Ultrasound Gel
 Potential Contamination

**Device Recall Notice:
 3010203571-12/14/20-001-R**

December 14, 2020

Dear Valued Customer,

We have learned that certain lots of EXOGEN Ultrasound Gel Pump bottles used with the EXOGEN device may have microbial contamination. We have identified the affected lots and are requesting that patients discard gel bottles from those lots. To date, Bioventus has not received any reports of adverse events related to this recall. This letter will tell you how to determine if you have recalled bottles of gel and what actions to take.

Recalled Lot Numbers

This recall applies to all the lot numbers in this table.

Product name	EXOGEN Ultrasound Gel Pump
Lot #s	190204, 190211, 190213, 190215, 190226, 190228, 190230, 190235, 190235T, 190250, 190251, 190252, 190263 200201, 200203, 200207, 200212, 200212T, 200215, 200215T, 200218, 200227, 200228, 200228T, 200229, 200240, 200240T

Please check all of your gel bottles. Your lot # is listed on the bottom edge of the gel pump as shown here. If any of your lot #s match any of the numbers listed above, please follow the requested actions on the next page.



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Requested Actions

1. Keep track of the lot number for each bottle. Throw away any gel bottle that has a recalled lot number from the table above.
2. Complete the Disposal Certification form below.
3. Return the completed form to Bioventus by **choosing one of the options below**:
 - a. Complete and mail the pre-addressed and postage paid response card provided with this notification.
 - b. Scan and email a copy to exogensystem@stericycle.com.
 - c. Using a smartphone, take a photo of the completed Disposal Certification and email to exogensystem@stericycle.com.
4. If you are still utilizing EXOGEN and need replacement gel to continue therapy, please call 00800-02-04-06-08 and we will quickly send replacement gel.
5. If you have additional questions, please call 00800-02-04-06-08.
6. Important: If you have distributed affected product further, please provide a copy of this notification to these patients.

DISPOSAL CERTIFICATION

1. Do you have any of the impacted gel pumps on hand?
YES___ NO___
2. If the answer to the question above is YES, please complete the table below and dispose of the gel pump.

Record the lot # and quantity of the impacted product in your possession

Lot Number	Quantity Disposed

I affirm that I have discarded the recalled gel bottles in my possession.

Customer Name: _____

Signature: _____

Email: _____

Telephone: () _____ - _____

Date: ____/____/____