URGENT MEDICAL DEVICE CORRECTION
Cerene Cryotherapy Device

March 20th, 2025

Dear Doctor,

The purpose of this letter is to notify you of a voluntary medical device correction conducted by Channel Medsystems, Inc. for certain lots of the Cerene Cryotherapy Device (Cerene Device).

Date:	March 20th, 2025
Reference:	3012018285/03102025/C/00002
Products Affected in Distribution:	Model Number: FGS-7000, UDI: 00850008595035 Lot Numbers: 108638953, 108645585, 108645586, and 108645587

Product Description:

The Cerene Device is indicated for endometrial cryoablation in premenopausal women with heavy menstrual bleeding due to benign causes for whom child bearing is complete. The Cerene Device uses nitrous oxide (N_2O) to freeze and ablate the endometrium to reduce future menstrual bleeding.

Reason for the Voluntary Correction:

The reason for this correction is that the evaporator gasket inside the handle of the device may not seal properly, which can cause liquid nitrous oxide to drip/leak from the bottom of the device handle during treatment or after treatment during venting of the device. At this time, we are aware of 4 complaints associated with this problem, which we estimate is about 3% of affected devices. In one of these cases, a physician received a minor thermal injury (burn) on his leg that did not require treatment or intervention and is expected to resolve.

Risk to Health:

Liquid nitrous oxide that drips onto the physician may cause a minor thermal injury. Liquid nitrous oxide dripping from the device will evaporate into gaseous nitrous oxide, which could potentially have transient euphoric and anesthetic effects on the physician user, patient, and/or personnel. This drip from the handle has no impact on the patient's treatment, as it is excess liquid nitrous oxide being exhausted from the device.

How to recognize that the device may fail: if liquid nitrous oxide is seen dripping from the bottom of the device handle, that is an indication that the evaporator is not sealed properly.

Actions to be taken by the Customer/User:

Our records indicate that you have received at least one of the affected devices and you are therefore affected by this action. We request that you read this notice carefully and complete the following actions:

1. Check your internal inventory to determine if you have any affected devices.
2. Stop use of affected devices.
3. Vent the affected devices by following the attached instructions and then discard the devices according to your facility's procedures.
4. Complete and return the customer acknowledgement form. It may be that you no longer have any physical inventory on site. Completing this form will allow us to update our records and will also negate the need for us to send any further unnecessary communications on this matter. Therefore, please complete the form even if you no longer have any of the affected devices in your physical inventory.
5. Circulate this letter to all other relevant parties, as needed.

Type of Action by the Company:

Once the acknowledgement form is received, replacement devices will be issued. This problem has already been corrected in subsequent lots of devices.

Reporting an Adverse Event

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

Channel Medsystems Contact Information

Channel Medsystems, Inc.
2919 7th Street
Berkeley, California 94710
(510) 338-9301
safetynotice@cerene.com
Office Hours: Monday through Friday, 8:00 AM to 5:00 PM, Pacific Time

We appreciate your attention to this letter regarding the correction of the Cerene Cryotherapy Device, and timely receipt of the customer acknowledgement form.

For any additional questions regarding this letter, please contact Channel Medsystems at safetynotice@cerene.com.

Sincerely,

Edward Yu
EVP, Regulatory and Clinical Affairs

URGENT MEDICAL DEVICE CORRECTION
Customer Acknowledgement Form
Cerene Cryotherapy Device

Reference Number: 3012018285/03102025/C/00002

Lot numbers: 108638953, 108645585, 108645586, 108645587

I confirm that I have read and understand the instructions provided in the March 20th, 2025 letter and will forward this information as instructed and appropriate.

Please complete the Affected Product Information table below, or if you no longer have any of these devices in inventory, please check the box noting as such.

Affected Product Information Table			
Product Brand Name	Catalog Number	Lot Number	Quantity disposed
Cerene Cryotherapy Device	FGS-7000	108638953	
Cerene Cryotherapy Device	FGS-7000	108645585	
Cerene Cryotherapy Device	FGS-7000	108645586	
Cerene Cryotherapy Device	FGS-7000	108645587	

☐ I no longer have any Cerene Cryotherapy Devices with lot numbers above in inventory.

Name/Title	
Telephone	
Email address	
Signature	
Date	

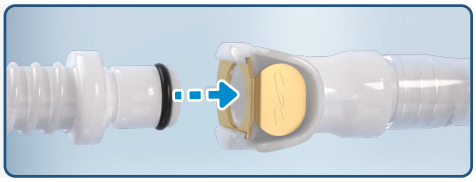
To enable compliance to traceability requirements, please complete this form as soon as possible and send it back by email to safetynotice@cerene.com or fax to 510-338-9303.

Customer Disposal Instructions

cerene® Cryotherapy Device

This document applies to **unused** Cerene Cryotherapy Devices, **meaning product that has not been opened and removed from packaging,** that contains nitrous oxide and needs to be disposed of.

1. Connect the Exhaust Collection Bag to the Cerene Device. Make sure the Exhaust Hose and the Exhaust Collection Bag are not tangled.

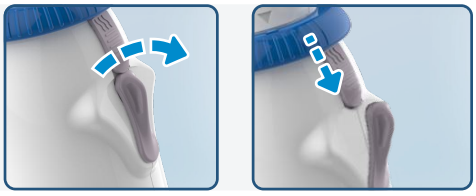


2. Remove Battery Tab & rotate the blue Twist Ring until the arrows line up to power on.

3. Wait for the first instructions to pop up on screen. Instructions should be 'Confirm Collection Bag Attached'.

   NOTE: If an error code pops up, STOP following these instructions. From this point on, follow the instructions on the screen and set device back in the tray once completed. Contact Channel Medsystems to report the error code: +1 510-338-9301, support@cerene.com

4. Rotate the Vent Lock & pull down the Vent Tab.



5. After activating venting, the device should display a x01 or 100 series error code. A countdown timer for venting will start. Let the device vent until it says, 'Safe to Dispose'. This will take about 25 minutes.

6. Once 'Safe to Dispose' message is displayed on the LCD screen, you may disconnect the Exhaust Collection Bag and dispose of the device and bag as your facility normally would.

7. Fill out the Customer Disposal Confirmation Form (found on page 1) and email to customerservice@cerene.com.

! If the device says, 'Unsafe to Dispose', place device back in tray and contact Channel Medsystems for further instructions (+1 510-338-9301, support@cerene.com). DO NOT dispose of the device.

Important Safety Information

Cerene® Cryotherapy Device is indicated to ablate the endometrial lining of the uterus in premenopausal women with heavy menstrual bleeding due to benign causes for whom childbearing is complete. Pregnancy following the Cerene procedure can be dangerous; therefore, contraception must be used until menopause. The Cerene procedure is not for those who have or suspect uterine cancer; have an active genital, urinary or pelvic infection; or an IUD. There are risks and considerations associated with the use of the Cerene Cryotherapy Device. Temporary side effects may include uterine cramping, vaginal infection, and lightheadedness. For detailed benefit and risk information, consult the Cerene Instructions for Use (IFU) or your healthcare professional.

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