CHANNEL MEDSYSTEMS®

URGENT FIELD SAFETY NOTICE

Updated Troubleshooting Instructions in Cerene Cryotherapy Device Instructions for Use (IFU)

Date:	May 3rd, 2024
Reference:	3012018285/04242024/C/00001
Products Affected:	FGS-7000, UDI-DI: 00850008595035 Lot Numbers: 101635693, 101635694, 101635695, 101635696, 102211255, 102211256, 102211257, 102211258, 102887363, 102887364, 103151029, 103151030, 103151031, 103151032, 103489753, 103489754, 103489755, 103489756, 103489757, 103925402, 104008714, 104008715, 104521903, 104521904, 104521905, 104521906, 104521907, 104808352, 104808353, 105418198, 105733204, 105733205
Population Affected:	Patients treated with a Cerene Cryotherapy Device that displays a reset error code 003 on the device LCD screen during or after complete cryoablation treatment.

General Product Description

The Cerene Cryotherapy Device (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. The device is intended for use by healthcare professionals who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with endometrial ablation. The Cerene Device is single use, disposable, and provided sterile. The average procedure time is 7 minutes, with 2.5 minutes of active cryoablation.

Ablation is achieved throughout the uterine cavity through the use of cryothermic energy. The cryothermic energy is provided by a liquid-to-gas phase change of N_2O. During the 2.5-minute treatment cycle, liquid N_2O (originating from a small Cylinder located in the device handle) flows through a delivery line and into an inflow line with multiple jets. This liquid N_2O is infused into an ultra-thin polyurethane Liner, where it converts into gas. The gaseous N_2O is exhausted through the Exhaust Hose exiting the bottom of the handle.

Description of Change

Channel Medsystems is updating its troubleshooting instructions to further inform healthcare professionals on the safe use and troubleshooting of the Cerene Device. This is in response to new information gathered through post-market surveillance, as well as industry practices related to possible off-label repeat treatment immediately after a partial endometrial ablation treatment and the serious risks to health that it can pose.

<u>Update to Troubleshooting:</u>

Error Code 003 is an error code displayed when there has been a device reset of the software. If "Error 003" is displayed, the device will also instruct the user to remove the device from the patient and vent the device. Once “Error 003” is triggered, the device is essentially rendered disabled and cannot be used again.

During the review, evaluation, and investigation of eight (8) device reset malfunction complaints, it was specifically noted that a device reset error code 003 can be triggered any time during the use of

the Cerene Device and is not only limited to display only prior to initiation of cryoablation as per the IFU. Four (4) of these malfunctions occurred prior to cryoablation treatment as per the IFU; the other four malfunctions were reported as occurring during cryoablation treatment (two reports) and after completed treatment (two reports).

Subsequently, the IFU has been updated to clarify that error code 003 can occur at any time (not only before, but also during, or after cryoablation treatment) and to instruct the user to continue to follow the correctly displayed Cerene Device LCD message and corresponding IFU troubleshooting instructions – specifically, **"Uterus Partially Treated, End procedure, Do NOT re-treat"** or **"Uterus Treated End procedure Do NOT re-treat"** as the "Treatment Status & Next Steps" matching the corresponding displayed Cerene Device LCD screen message/error code 003.

There have been no associated adverse events, device-related or otherwise, reported during the four incidents where the error code 003 displayed either during or after treatment was completed.

Refer to **Appendix I - IFU Troubleshooting Information Update**, for the applicable updated Table 22. Summary of LCD Messages and Error Codes.

Potential Risks

If a user experiences confusion when referring to the troubleshooting instructions in the previous IFU after an Error Code 003 is displayed during or after treatment, that confusion could potentially lead to the risk of a user performing a repeat endometrial ablation.

Products Affected

Affected Cerene Cryotherapy Device (FGS-7000) lots without the error code 003 troubleshooting update include: 101635693, 101635694, 101635695, 101635696, 102211255, 102211256, 102211257, 102211258, 102887363, 102887364, 103151029, 103151030, 103151031, 103151032, 103489753, 103489754, 103489755, 103489756, 103489757, 103925402, 104008714, 104008715, 104521903, 104521904, 104521905, 104521906, 104521907, 104808352, 104808353, 105418198, 105733204, 105733205

Actions by Channel Medsystems

Channel Medsystems has updated the troubleshooting section of the IFU and has made it available at https://cerene.com/wp-content/uploads/2024/03/IFU-3757-Rev-C-Cerene-Cryotherapy-Device-Global-IFU.pdf.

Actions to be taken by Customers/Healthcare Providers

1. Follow your facility's established procedures for handling updated labeling/documents, such as immediately providing a copy of this notice to relevant healthcare professionals and notifying them of the updated IFU (Troubleshooting) and its online availability.
2. No product is being recalled and you are not required to return devices or IFUs to Channel Medsystems.
3. Complete and return the acknowledgment form at the end of this urgent field safety notice within one month of receipt.

Channel Medsystems Contact Information

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

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.

We appreciate your attention to this urgent field safety notification regarding the updated troubleshooting information to enhance the safe use of the Cerene Cryotherapy Device, and timely receipt of the customer acknowledgement form.

For any questions regarding this field safety notice, please contact your local Channel Medsystems sales representative or visit www.cerene.com.

Sincerely,

Edward Yu
EVP, Regulatory and Clinical Affairs

CUSTOMER ACKNOWLEDGMENT FORM

Reply form to Urgent Field Safety Notice – Updated Troubleshooting Instructions in Cerene Cryotherapy Device Instructions for Use (IFU)

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

I confirm receipt of this field safety notice and I confirm that I have read and understood its content.

I will forward this information as instructed and appropriate.

Channel Medsystems Reference	3012018285/04242024/C/00001
Name of Customer/Healthcare Provider	
Address of Customer/Healthcare Provider	

Name	
Title	
Email address	
Phone number	
Fax number	
Signature	
Date	

APPENDIX I – IFU TROUBLESHOOTING INFORMATION UPDATE

Table 22. Summary of LCD Messages and Error Codes (page 16)

Table 22. Summary of LCD Messages and Error Codes (continued)

Error Code	LCD Message	Instructions	Treatment Status & Next Steps
001-179	Error _ _ _ ***alternating with*** Unlock and Rotate Ring to Vent	When prompted, unlock the *Vent Lock* and slide the *Vent Tab* to vent the *Cerene Device*.[1] Wait for the *LCD Screen* to display "Safe for Disposal." Empty the *Exhaust Collection Bag* per local practice.	**Uterus Not Treated**[2] **Treat with NEW *Cerene Device***
201-291	Error _ _ _ ***alternating with*** Wait _	Wait until prompted, then gently remove the *Cerene Device* and press the *Button*. When prompted, unlock the *Vent Lock* and slide the *Vent Tab* to vent the *Cerene Device*.[1] Wait for the *LCD Screen* to display "Safe for Disposal." Empty the *Exhaust Collection Bag* per local practice.	
300 003[3]	Possible Perforation Abort Procedure	Wait until prompted, then gently remove the *Cerene Device* and press the *Button*. When prompted, unlock the *Vent Lock* and slide the *Vent Tab* to vent the *Cerene Device*. Wait for the *LCD Screen* to display "Safe for Disposal." Empty *the Exhaust Collection Bag* per local practice.	**Uterus Not Treated** **Treat with NEW *Cerene Device* if no perforation identified**
301-391	Error _ _ _ Treated _ _ _ Sec ***alternating with*** Time Until Removal _ _ sec	Wait until prompted, then gently remove the *Cerene Device* and press the *Button*. When prompted, unlock the *Vent Lock* and slide the *Vent Tab* to vent the *Cerene Device*.[1] Wait for the *LCD Screen* to display "Safe for Disposal." Empty the *Exhaust Collection Bag* per local practice.	**Uterus Partially Treated** **End procedure Do NOT re-treat**
404-468	Error _ _ _ ***alternating with*** Time Until Removal _ _ sec	Wait until prompted, then gently remove the *Cerene Device* and press the *Button*. Wait for the *LCD Screen* to display "Safe for Disposal." Empty the *Exhaust Collection Bag* per local practice.	**Uterus Treated** **End procedure** **Do NOT re-treat**
504-589	Error _ _ _ Venting _ _ min	Wait for the *LCD Screen* to display "Safe for Disposal." Empty the *Exhaust Collection Bag* per local practice.	
For the following errors, Call Channel Medsystems.			
none	UNSAFE TO DISPOSE Contact Channel Med	Call Channel Medsystems (+1-510-338-9301) for additional instructions. Do NOT dispose of the *Cerene Device*.	**Uterus Treated** **Do NOT re-treat**
001-589	UNSAFE TO DISPOSE Contact Channel Med ***alternating with*** UNSAFE TO DISPOSE Error _ _ _ ***May alternate with*** UNSAFE TO DISPOSE Treated _ _ _ sec	Call Channel Medsystems (+1-510-338-9301) for additional instructions. Do NOT dispose of the *Cerene Device*.	**Refer to specific error code above**

[1] For Error Codes 001, 101, 201, and 301, the LCD will not prompt the operator to unlock the *Vent Lock* and slide the *Vent Tab*. The error is due to the *Vent Tab* having been positioned prematurely to vent the *Cerene Device*.
[2] Ablation does not start until nitrous oxide has flowed for > 5 seconds.
[3] Error Code 003 can occur prior to, during, or after treatment. Follow instructions on LCD and refer to "Treatment Status & Next Steps" in Table 22 that corresponds to the LCD message shown.