Rev 4: 20 May 2024
FSN Ref: CC-24-0202 Rev A FSCA Ref: 3012018285/04242024/C/00001

Date: 20 MAY 2024

Urgent Field Safety Notice
Cerene Cryotherapy Device

For Attention of: Dr. Fleur Bergwerff and associates

Contact details of local representative (name, e-mail, telephone, address etc.)*
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Channel Medsystems, Inc.
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Urgent Field Safety Notice (FSN)

Cerene Cryotherapy Device

Updated Troubleshooting Instructions in Instructions for Use (IFU)

1. Information on Affected Devices	
1.	1. Device Type(s)
	The Cerene Device uses nitrous oxide 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.
1.	2. Commercial name(s)
	Cerene Cryotherapy Device
1.	3. Unique Device Identifier(s) (UDI-DI)
	00850008595035
1.	4. Primary clinical purpose of device(s)
	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
1.	5. Device Model/Catalogue/part number(s)
	FGS-7000
1.	6. Affected serial or lot number range
	Lot Numbers: All non-expired lots manufactured through February 2024 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

2 Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Error code 003 was not listed in certain rows of the Cerene Cryotherapy Device Instructions for Use “Troubleshooting” section (i.e., Table 22. Summary of LCD Messages and Error Codes).
2.	2. Hazard giving rise to the FSCA
	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. The update to the IFU is intended to mitigate that risk and eliminate any confusion for the user in interpreting the troubleshooting instructions in the IFU.

2.	3. Probability of problem arising
	The error in the IFU (error code 003 not listed in certain rows) is present in the IFUs packaged with all unexpired devices in distribution, pending distribution, or in inventory. To-date there have been two (2) Error Code 003 during treatment (0.07% of all devices sold).
2.	4. Predicted risk to patient/users
	Repeat endometrial ablation can pose a serious risk to health, but a user electing to perform a repeat ablation in the event that the Cerene Device LCD message displays an error code 003 is believed to be unlikely. Further, when the Cerene Device displays any error code the device cannot be used again, and a user would need to intentionally use a new device to proceed with a repeat treatment. Also, the IFU (previous version and updated version) states that repeat treatment is contraindicated and may result in serious patient injury; lastly, repeat ablation is a contraindication common to all marketed endometrial ablation devices and is noted in the professional training and as well as understood within the general experience of gynecologists that are familiar with the principles, clinical applications, complications, side effects, and hazards commonly associated with the performance of any endometrial ablation.
2.	5. Background on Issue
	It was noted during the review and investigation of reported complaints that Error Code 003 can be displayed at any time during the use of the Cerene Device if a device reset is triggered and is not limited to display only prior to initiation of cryoablation, as was contemplated during device development and in the previous IFU.

	3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Take note of amendment/reinforcement of Instructions For Use (IFU)		
3.	2. By when should the action be completed?	Immediately	
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)		Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ IFU or labelling change		
3	5. By when should the action be completed?	The updated IFU has been posted on the manufacturer's website and the printed IFU is anticipated to be in shipped inventory by September 2024.	
3.	6. Is the FSN required to be communicated to the patient /lay user?		No

	4. General Information	
4.	1. FSN Type	New
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Channel Medsystems**
	b. Address	**2919 7th Street, Berkeley, CA 94710 USA**
	c. Website address	**www.cerene.com**
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	**1. Customer Acknowledgement Form** **2. IFU Troubleshooting Information Update**
4.	6. Name/Signature	**Edward Yu, EVP Clinical and Regulatory Affairs**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

CUSTOMER ACKNOWLEDGMENT FORM

Please complete this form in full and send it back by email or fax as soon as possible (within 30 days maximum) to safetynotice@cerene.com or +1-510-338-9303.

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 2 – 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.

16 Customer Support: +1-510-338-9301 | support@cerene.com