To the attention of Quality Assurance Dpt or Regulatory Affairs Dpt or Management

Saint Priest, 17/02/2020

Subject: **URGENT - FIELD SAFETY NOTICE** – CUSA® Clarity Console C7000 Operator's Manual- CUSA Clarity Console
Legal manufacturer:
Integra LifeSciences (Ireland) Limited - IDA Business and Technology Park Sragh - Tullamore, County Offaly, Ireland
EC Rep :
INTEGRA LIFESCIENCES (France) SAS – Immeuble Séquoïa 2 – 97 Allée Alexandre Borodine – 69800 SAINT PRIEST

Medical devices:
The CUSA Clarity system is an ultrasonic surgical aspirator system that allows a surgeon to remove tissue efficiently and selectively. It performs three functions:
*• **Fragmentation:** When the vibrating tip of the handpiece comes into contact with the tissue, the cells of the tissue break apart or "fragment".*
*• **Irrigation:** Irrigation fluid from a user-supplied saline bag or Lactated Ringer's solution is transferred to the distal tip of the handpiece.*
*• **Aspiration (Suction):** Draws or "aspirates" irrigation fluid, fragmented tissue, and other material through the distal end of the surgical tip to the user-supplied canister.*

Primary clinical purpose of device(s):
The CUSA® Clarity Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable. The CUSA Clarity Ultrasonic Surgical Aspirator is indicated for use in:
Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, General surgery, Orthopedic surgery, Gynecological surgery, Laparoscopic surgery.

Concerned references and batches:
All lots sold between 2017 - today

Dear Valued Customer,

The purpose of this letter is to advise you that Integra LifeSciences is updating the previous Field Safety Notice regarding the Operator's Manuals associated with C7000 – CUSA® Clarity Console.

Integra LifeSciences notified you in early November 2019, that when following the steps described in the current Operator's Manual, the dry time parameter must be increased from 30 minutes to 40 minutes for the CUSA Clarity 36kHz handpieces and components consistent with the CUSA Clarity 23kHz handpiece and components.

In parallel with the initial notification, Integra investigated the issue further and recently validated a 30-minute dry time that can be used if you choose, but only if using appropriately sized Central Supply Room (CSR) wraps for the specific load and allowing the tray to cool an additional 30 minutes after it is removed from the sterilizer.

We are updating the field safety notice to alert you of this new information and of the information noted above associated with 30 min dry time.

There is an **improbable** likelihood that serious injuries could occur due to the corrections identified within this field action. The internal review confirms that there have been no adverse events or complaints that Integra LifeSciences is aware of associated with the dry cycle time noted in the current Operator's Manuals, nor have there been any reports of serious injuries or deaths related to this issue.

While it is highly unlikely that a shortened dry time of 30 minutes without using the appropriate wrap and 30 min cool time will result in a non-sterile product given that the drying occurs after the steam application, it may result in visible moisture (most likely on the outer wrap). Sterilization Dry Time moisture may be detected by inspection of components and the outer wrap for visible moisture or water. Where visible moisture is noted the product should be re-wrapped and re-sterilized.

The risks mentioned above have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

We are notifying you of the Field Safety Corrective Action as our records indicate that you have been supplied with:

Description of Concerned product	Reference
CUSA Clarity Console	**C7000**

To mitigate the risk, we kindly ask you to:

- ***Identify Device***
- ***Review and understand the information provided in Appendix 1***
- ***Review "The Sterilization Parameters" in Section 11 of your Operator's Manual***
- ***Replace the information in Section 11 of your Operator's Manual with the information provided in Appendix 1, as appropriate***

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially concerned devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

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 reply is required. A form is attached to this Field Safety Notice. The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. We expect a response **within 3 weeks**.

This Field Safety Notice is an update of a precedent FSN-HHE-342A-250919 sent on the 4th of November 2019.

We also recommend that you keep a copy of this notification and a signed copy of the acknowledgement form for your records.

The National Competent Authority of your country has been alerted of this Field Safety Corrective Action.

Please feel free to contact me at angelique.aubert@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Angelique AUBERT
EMEA Compliance Coordinator

Enclosed: Field Safety Notice Distributor Reply Form (2 pages), Appendix 1, Appendix 2

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-HHE-342A-191219
FSN Date*	17th of February 2020
Product/ Device name*	CUSA® Clarity Console C7000 Operator's Manual
Product Code(s)	Listed in Appendix 2
Batch/Serial Number (s)	All lots sold between 2017 - today

2. Distributor Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	emea-fsca-neuro@integralife.com
Distributor Helpline	+33 (0) 4 37 47 59 16
Postal Address	Integra Regulatory Affairs • Immeuble Séquoia 2, 97 allées Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	www.integralife.com
Deadline for returning the Distributor reply form*	16th of March 2020

4. Distributors		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor to complete or enter N/A
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor print name here
Signature*		Distributor sign Here
Date*		

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

APPENDIX 1

Using the following instructions either a 30-minute or 40-minute dry time can be employed to achieve the desired requirements.

Sterilization

Steam (moist heat) sterilization shall be performed in a locally approved, pre-vacuum (forced air removal) cycle. The steam sterilizer should be validated to the requirements of any local standard and guidance such as EN 285 or ANSI/AAMI ST8. The steam sterilizer should be installed and maintained in compliance with manufacturer's instructions and local requirements. Ensure that the steam sterilizer cycle chosen is designed to remove air from porous or lumened device loads in accordance to manufacturer's instructions; and the maximum sterilizer load is not exceeded as defined by the sterilizer manufacturer or reprocessor's validation.

Sterilization Tray Packaging

The handpiece and components can be packaged in the sterilization tray either:

- Wrapped – Select the appropriate Central Supply Room (CSR) wrap according to the size, shape, and weight of the tray using the wrap's manufacturer's instructions
- Immediate-Use Steam Sterilization / Flash (Unwrapped) – Sterilization tray unwrapped

The cycles below were validated for sterilizing the CUSA Clarity handpiece and components

Sterilization Cycles for the 23 kHz and 36 kHz Handpiece and Components

30 Minute Dry Time Cycle

Packaging	Temp	Type	Time	Dry Cycle*
Wrapped	132 ºC (269.6 ºF) to 134 ºC (273.2 ºF)	Prevac	4 – 18 min	**30 min**
	134 ºC (273.2 ºF)	Prevac	3 – 18 min	**30 min**
	134 ºC (273.2 ºF) to 137 ºC (278.6 ºF)	Prevac	3 – 3.5 min	**30 min**
Immediate-Use Steam Sterilization / Flash (Unwrapped)	132 ºC (269.6 ºF)	Prevac	4 min	None

Sterilization Cycles for the 23kHz and 36 kHz Handpiece and Components

40 Minute Dry Time Cycle

Packaging	Temp	Type	Time	Dry Cycle*
Wrapped	132 ºC (269.6 ºF) to 134°C (273.2°F)	Prevac	4 – 18 min	**40 min**
	134 ºC (273.2 ºF)	Prevac	3 – 18 min	**40 min**
	134 ºC (273.2 ºF) to 137 ºC (278.6 ºF)	Prevac	3 – 3.5 min	**40 min**
Immediate-Use Steam Sterilization / Flash (Unwrapped)	132 ºC (269.6 ºF)	Prevac	4 min	None

***Terminally sterilized items should be allowed to cool to room temperature before handling.
After completion of the dry cycle, allow the tray to cool to ambient temperature for a minimum of 30 minutes before use.

The efficiency of steam sterilizer drying can range considerably depending on the sterilizer design, loading, wrapping, ambient conditions, and steam supply during the sterilization process. In accordance with ANSI/AAMI ST79 and EN 285 standards, the user should employ verifiable methods (e.g. visual inspections) to confirm adequate drying.

These instructions for use have been validated in accordance with ISO 17664 and ANSI/AAMI ST79. It remains the responsibility of the facility to ensure that processing is performed using equipment, materials and personnel at a designated area, and achieves the desired requirements. This includes validation and routine monitoring of the process. Likewise, any deviation by the processor from these recommendations should be evaluated for effectiveness and any potential adverse consequences.

APPENDIX 2

Description	Part/Number		Description	Part/Number
US Operator's Manual	60905769		US Operator's Manual	60905197
OUS Operator's Manual	60905789		OUS Operator's Manual	60905217
French Operator's Manual	60905770		French Operator's Manual	60905198
Spanish Operator's Manual	60905771		Spanish Operator's Manual	60905199
German Operator's Manual	60905772		German Operator's Manual	60905200
Italian Operator's Manual	60905773		Italian Operator's Manual	60905201
Swedish Operator's Manual	60905774		Swedish Operator's Manual	60905202
Russian Operator's Manual	60905775		Russian Operator's Manual	60905203
Japanese Operator's Manual	60905776		Japanese Operator's Manual	60905204
Chinese-Traditional Operator's Manual	60905777		Chinese-Traditional Operator's Manual	60905205
Chinese-Simplified Operator's Manual	60905778		Chinese-Simplified Operator's Manual	60905206
Portuguese Operator's Manual	60905779		Portuguese Operator's Manual	60905207
Brazilian Operator's Manual	60905780		Brazilian Operator's Manual	60905208
Danish Operator's Manual	60905781		Danish Operator's Manual	60905209
Finnish Operator's Manual	60905782		Finnish Operator's Manual	60905210
Dutch Operator's Manual	60905783		Dutch Operator's Manual	60905211
Korean Operator's Manual	60905784		Korean Operator's Manual	60905212
Polish Operator's Manual	60905785		Polish Operator's Manual	60905213
Croatian Operator's Manual	60905786		Croatian Operator's Manual	60905214
Czech Operator's Manual	60905787		Czech Operator's Manual	60905215
Norwegian Operator's Manual	60905788		Norwegian Operator's Manual	60905216