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

Saint Priest, 14/10/2019

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 notify you that the legal manufacturer Integra LifeSciences, is voluntarily issuing a Field Safety Notice for the CUSA® Clarity console C7000 Operator's Manual.

Integra LifeSciences has recently identified through an internal review that the Operator's Manual need to be revised in order to reflect the most accurate sterilization parameters and hence the dry time parameters have been changed from 30 minutes to 40 minutes for the CUSA Clarity 36kHz handpiece and components consistent with the CUSA Clarity 23kHz handpiece and components.

The assessment completed by the legal manufacturer Integra LifeSciences, concluded that 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.

It is highly unlikely that a shortened dry time will result in a non-sterile product given that the drying occurs after the steam application, however 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 Safery 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**.

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 Customer/Distributor Reply Form (2 pages), Appendix 1, Appendix 2

Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-HHE-342A-250919
FSN Date*	15 of October 2019
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/Importer 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*	25th of November 2019

4. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	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	

☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	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

Sterilization Parameters:

All handpieces and components require a 40-minute dry cycle for the overall sterilization process.
Replace the "Sterilization parameters" in Section 11 of the Operator's Manual with the following information:

Sterilization Tray Packaging

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

- Wrapped – Sterilization tray double wrapped in hospital CRS material
- Flash (Unwrapped) – Sterilization tray unwrapped

The cycles below are acceptable for sterilizing the CUSA Clarity handpiece components.

Packaging	Temp	Type	Time	Dry Cycle
Wrapped	132 ºC (269.6 ºF) to 134 ºC (273.2 ºF)	Prevac	4 min – 18 min	**40 min**
	134 ºC (273.2 ºF)	Prevac	3 min – 18 min	**40 min**
	134 ºC (273.2 ºF) to 137 ºC (278.6 ºF)	Prevac	3 – 3.5 min	**40 min**
Flash (Unwrapped)	132 ºC (269.6 ºF)	Prevac	4 min	None

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

To the attention of Medical Device Vigilance Manager / Central Pharmacy

Saint Priest, 14/10/2019

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Customer Reply Form

1. Field Safety Notice (FSN) information	
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FSN Date	15 of October 2019
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. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here

Signature*	Customer sign here
Date*	

4. Return acknowledgement to sender	
Email	emea-fsca-neuro@integralife.com
Customer 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
Fax	+33 (0) 4 37 47 59 30
Deadline for returning the customer reply form*	25th of November 2019

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