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

Saint Priest, May 24th, 2024

Subject: URGENT - FIELD SAFETY NOTICE – INTEGRA – CUSA® Excel 23KHz Straight Handpiece – Reference: C2600 – FIELD SAFETY ACTION

Legal manufacturer: Integra Lifesciences, IDA Business and Technology Park, Sragh Ave, Tullamore, Co. Offaly – IRELAND. IE-MF-000003849

Medical device:
The CUSA® Handpiece is intended for use with the CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System and accessories. The CUSA® Excel/ CUSA® Excel+ Ultrasonic Surgical Aspirator System is an ultrasonic tissue ablation system that allows a surgeon to remove tissue selectively. It performs three functions:

1. Fragmentation: when the vibrating tip of the handpiece comes into contact with tissue, the cells of the tissue break apart or "fragment".
2. Irrigation: irrigation fluid from a user-supplied saline bag or Lactated Ringer's solution is transferred to the distal tip of the handpiece.
3. 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:
The CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable:

- Neurosurgery
- Gastrointestinal and affiliated organ surgery
- Urological surgery
- General surgery
- Orthopedic surgery
- Gynecological surgery
- Laparoscopic surgery

Concerned reference:
C2600
Serial Numbers:
All serial numbers distributed from 1st of January 2017 to 14th of December *2023 (refer to paragraph B. How to confirm the serial number)*

Dear Valued Integra Distributor,

The purpose of this letter is to notify you that Integra LifeSciences is issuing a voluntary medical device correction for any serial numbers of the CUSA Excel Handpiece manufactured prior to November 2023.

The decision to conduct a voluntary correction of the product was based on the following: through an internal investigation of customer complaints, it was identified that there is a potential for the CUSA Excel 23KHz Handpiece housing to crack. In order to mitigate this issue, the devices will be reworked through our service and repair process for the units manufactured prior to November 2023.

***Note:** A replacement housing was introduced in November 2023 to fix the crack housing, as such any new parts manufactured after November 2023 do not have the potential of cracked housing issue. These devices started getting distributed on December 12th, 2023.*

Table 1: Impacted Product Information

Manufacturer's Product Number (Catalog Number)	Product Name (Description)	UDI Number	Serial Number	Expiration Date	Distribution Dates (DD/M//YYYY)
C2600*	CUSA® Excel C2600 23KHz Handpiece	10381780039419	All Serial Numbers Distributed before 14/12/2023	N/A	Before 14/12/2023

*Note: you may see C2600P or C2600SRL on labeling. This notice is applicable for those SKUs as well.

This voluntary correction is limited to the reference and specific serial numbers outlined in Table 1.

Risk to Health

Based on the health hazard evaluation conducted for this issue, the potential harms are listed in the following table:

Hazardous Situation	Harm
System does not function during use	Inconvenience to User (no or minor delay in patient treatment)
System does not function prior to use	Inconvenience to User
System does not function as intended during use	Delay in patient treatment within the standard of care (e.g. leading to increased time under anesthesia, less than 30 minutes) may result in transient post-operative confusion)
	Clinically relevant delay in treatment beyond the standard of care (e.g. greater than 30 minutes); older individuals may be at increased risk of postoperative fever

Note: Prolonged anesthesia time risks may vary among different patient populations i.e., age, underlying health conditions, type of surgery, and individual responses to anesthesia. However, elderly are more susceptible to risks of postoperative confusion and fever.

There have been a total of 238 complaints reported worldwide as of April 15, 2024, due to this issue. Out of the 238 worldwide complaints, 6 serious incidents with clinically relevant delay in treatment beyond the standard of care (e.g. greater than 30 minutes); have been reported for Europe.

Actions to be Taken by Distributor:

1. Please **review and understand** the information provided in this letter.
2. Review your inventory and determine if you have any of the serial numbers that are impacted. All serial numbers for the CUSA Excel 23KHz straight handpiece start with
   i. HA – indicating the product family followed by
   ii. Letter – indicating the month of manufacture where A = January; B = February; C = March etc noting that the letter I is not used.
   iii. Two digits e.g 24 indicating the year of manufacture with 24 representing 2024.
   iv. The next set of 3 digits are random serial numbers unique to each handpiece.
   v. The last 2 digits represent the model number.
   vi. IE indicates the location of manufacture.

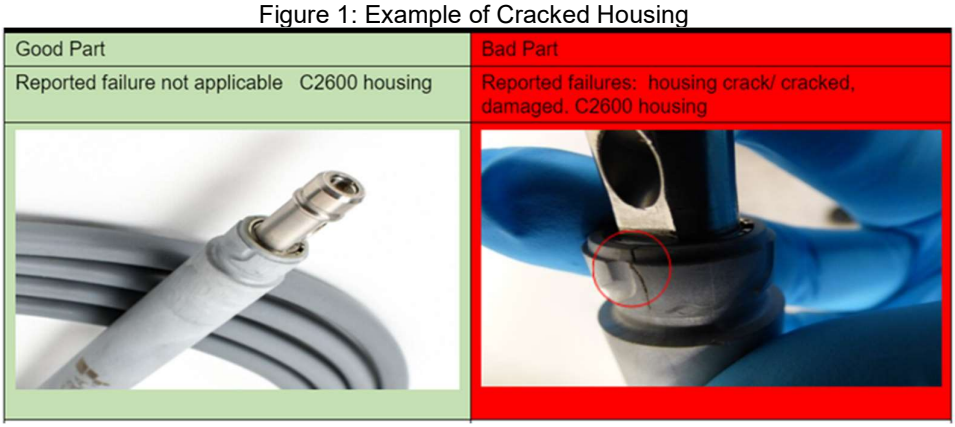
   Example: Serial number HAL2300103IE represents a product that is manufactured in November 2023 and is acceptable for continued use.

3. If your handpiece was manufactured prior to HAL23XXXXXXIE (affected products) and you have it in your warehouse, you should take the following actions:
   a. Follow "actions to be taken by customers" (below)
   b. Check the box "I do have affected product" in the enclosed reply form.
   c. Record on the reply form the total quantity of affected products and serial numbers that you have.
4. If **you do not have** affected products in your warehouse**,** check the box, "I do not have affected products".
5. Please check **your customer traceability records** for shipments of affected products.
6. **Forward a copy of the enclosed Field Safety Notice** to any of your customers that have purchased the affected products and ask them to follow the instructions under "Actions to be Taken by Customer" below.
7. The handpiece(s) should be returned to Integra S&R for service, email: TCS.Distributors@integralife.com, and there will be free replacement of the handpiece housing.

Actions to be Taken by your Customers:

1. Inspect the housing for the presence of a crack – see image below.

Figure 1: Example of Cracked Housing



2. The Handpiece cracked housing may be visually detected by clinical staff during inspections prior to or post-surgery. If a crack is noted, please remove the handpiece and return it for a free housing replacement.

3. If a crack is not noted,
Regardless of the service contract status, the housing will be replaced free of charge during your next service.

Please note that as per our standard IFU the recommended service frequency, should be performed every 50 hours of use or 100 procedures whichever comes first.

8. Please return the completed Reply form by email to emea-fsca-neuro@integralife.com, or Fax to +33 (0)4.37.47. 59.30. By filling in this form, you confirm that you have received this Safety Notice and you intend to fully comply with this notification. **We expect a response within 3 weeks.** You also confirm that this notification has been forwarded to every concerned person in your organization.
9. We recommend that you retain a copy of the form for your records.

The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information.

National Competent Authorities may perform audits of field actions of this nature to verify that our customers have been notified and understand the nature of the field action being taken.

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

Thank you for your cooperation with this Field Safety Corrective Action and for returning the attached Reply Form.

Please feel free to contact our Post Market Surveillance Department at emea-fsca-neuro@integralife.com for any additional questions. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Post Marketing Surveillance Department

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

DISTRIBUTOR REPLY FORM

1. Field Safety Notice (FSN) information	
FSN Reference number	**FSN-2024-HHE-006**
FSN Date	**24/05/2024**
Device name	**CUSA® Excel 23KHz Straight Handpiece**
Product Code	**C2600**
Serial Numbers	**All serial numbers prior to HAL23XXXXXXIE (distributed before 14/12/2023)**

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

3. Distributors/Importers (Tick all that apply)		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content. *	
☐	I have checked my inventory and I do have affected products.	**Quantity:** **Serial numbers:**
☐	I have checked my inventory and I do not have affected products	
☐	I have identified customers that received affected products and informed them of this Field Safety Notice *	**Date of communication:**
☐	I have received confirmation of reply for all identified customers	
☐	My customers have affected products	**Quantity:** **Serial numbers:**
☐	My customers have not received any affected products, or all of the received affected products are not used anymore	
Print Name*		*Distributor print name here*
Signature*		*Distributor sign Here*
Date *		

4. Return acknowledgement to Sender	
Email	emea-fsca-neuro@integralife.com
Distributor Helpline	+33 (0) 6 30 20 69 66
Postal Address	Post Market Surveillance Department Integra Immeuble Séquoia 2, 97 allée Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	https://integralife.eu/
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	14/06/2024

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.