

To the attention of Medical Device Vigilance
responsible / Central Pharmacy

Saint Priest, December 12, 2014

Subject: URGENT – RE-ISSUANCE OF FIELD SAFETY NOTICE.

Medical device: CEM™ Nosecones for use with CUSA® Excel/Excel+ Ultrasonic Aspirator

References: C6623, C6636

Legal Manufacturer:

Integra LifeSciences (Ireland) Limited - IDA Business and Technology Park - Sragh - Co. Offaly –
Tullamore – Ireland

Devices affected: all units.

Dear Customer,

This FSN is an update to Integra's last communication on 17 December 2013 to remind the end user of the purpose of this Field Safety Corrective action

The purpose of this Field Safety Notice is to provide you with additional important information when using a **CEM™ Nosecone (C6623 or C6636) with the CUSA® Excel/Excel+ Ultrasonic Aspirator.**

The CUSA® Excel/Excel+ series of Ultrasonic Surgical Aspirator systems are used in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable. The CUSA ElectroSurgical Module (CEM™) is intended for use with the CUSA® Excel/Excel+ Ultrasonic Surgical Aspirator System, CUSA® handpiece and the Covidien Force FX® ElectroSurgical Generator. It provides Desiccate Coagulation waveform electroSurgical capability to CUSA® Excel handpieces. The CUSA® handpiece with the CEM™ nosecone works in conjunction with the Force FX® Generator in surgical procedures where combined ultrasonic dissection and electroSurgical coagulation is desired, either simultaneously or independently.

Integra LifeSciences Corporation (Integra) has identified that there may be the possibility that the blue COAG button on the CUSA® Excel CEM™ nosecone could stick in the 'activated' position while using it with CUSA® Excel/Excel+ Ultrasonic Aspirator leading to a remaining activity. A small number of complaints where this has occurred have been reported and of those, a smaller number resulted in tissue burn.

This re-issuance of the FSN is to act as a reminder of the importance of the points 1-4 below and to give clarification on point 3 i.e. the 30 minutes is the total time that the CEM nosecone activation switch is activated during the surgery, not 30 minutes of continuous activation. The amount of time the activation switch of the CEM Nosecone should be activated at any one time during use is 10 seconds, followed by 30 seconds off.

Integra is undertaking corrective actions to limit the recurrence of the issue. In the interim our company is advising customers as follows:

- 1. If you observe the COAG button sticking at any time during the procedure, replace the CEM™ Nosecone with a new one and contact Integra customer service.**
- 2. Check the COAG button during setup and before patient use to verify that it is operating properly and that it does not stick. If sticking of the COAG button is observed, replace the CEM™ Nosecone and contact Integra customer service.**

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Integra LifeSciences Services (France)

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3. If the CEM™ Nosecone is to be used for more than approximately 30 minutes during a surgery, replace it with a new one after a total activation time of 30 minutes
4. Once the Cusa® CEM™ Nosecone is replaced, the surgical procedure can then be continued using the new CEM™ Nosecone.

Integra is notifying you of this Field Safety Notice as our records indicate that you have purchased the following products:

Description of affected product	References
CEM™ Nosecone for use with the CUSA® Excel/Excel+ Ultrasonic Aspirator	C6623 C6636

Please ensure that this Field Safety Notice and the “important information” are provided to every concerned user of CEM™ Nosecones for CUSA® Excel System with Catalog Numbers: C6623 and C6636

Please ensure to take account of the attached “important information”. This document is already present in the boxes of CEM™ Nosecones.

Additionally, please complete the attached Acknowledgement and Return Form and return it promptly as per the instructions on the form.

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

We also recommend that you keep a copy of this notification and a signed copy of the Acknowledgement and Return Form for your records.

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.

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

Integra are currently in the process of correcting the issue, the current expected timeline for completion of this correction is Q2 2015. Customers will then not be receiving the attached insert with shipments of the CUSA CEM Nosecone.

For any questions or concerns, please contact Angélique Aubert at the following e-mail address: angelique.aubert@integralife.com.

Sincerely,

Angélique AUBERT
Compliance Coordinator
Europe, Middle-East & Africa

Annexed: Important information

ACKNOWLEDGMENT AND RETURN FORM

Medical device: **CEM™ Nosecones for use with CUSA® Excel/Excel+ Ultrasonic Aspirator**

References: C6623, C6636

Legal Manufacturer:

Integra LifeSciences (Ireland) Limited - IDA Business and Technology Park - Sragh - Co. Offaly
- Tullamore - Ireland

Devices affected: all units.

Please Complete and Return Promptly

Please fill out this form and return by email or fax:

By fax/telecopy: **+33 (0)4 37 47 59 30**

or by e-mail: emea-fsca-neuro@integralife.com

With this form,

- I confirm that I have received, read and understood the information provided in the Integra Field Safety Notice regarding CEM™ Nosecones for use with CUSA® Excel/ CUSA® Excel+ Ultrasonic Surgical Aspirator System, CUSA® handpiece and the Covidien Force FX® Electrosurgical Generator and that I intend to fully comply with it;

- I confirm that this Field Safety Notice and the “important information” have been circulated to all affected users

Customer/Site Name	Customer Contact Name
Street Address	
City, Country, Postal Code	Telephone
Email	
Fax	Signature