Saint Priest, 25/09/17

Subject: **URGENT - FIELD SAFETY NOTICE RECALL - NOTIFICATION LETTER**
Medical devices:
Integra® CUSA® Clarity Footswitch packaged with CUSA® Clarity Console (Ref C7000)

Reference:
C7002

Legal manufacturer:
Integra LifeSciences (Ireland) ltd. - IDA Business & Technology Park, - Sragh, Tullamore, County of Offaly, Ireland

Concerned lots:
1923802; 1985221; 2057996; 2109587; 2118507

Dear Valued Customer,

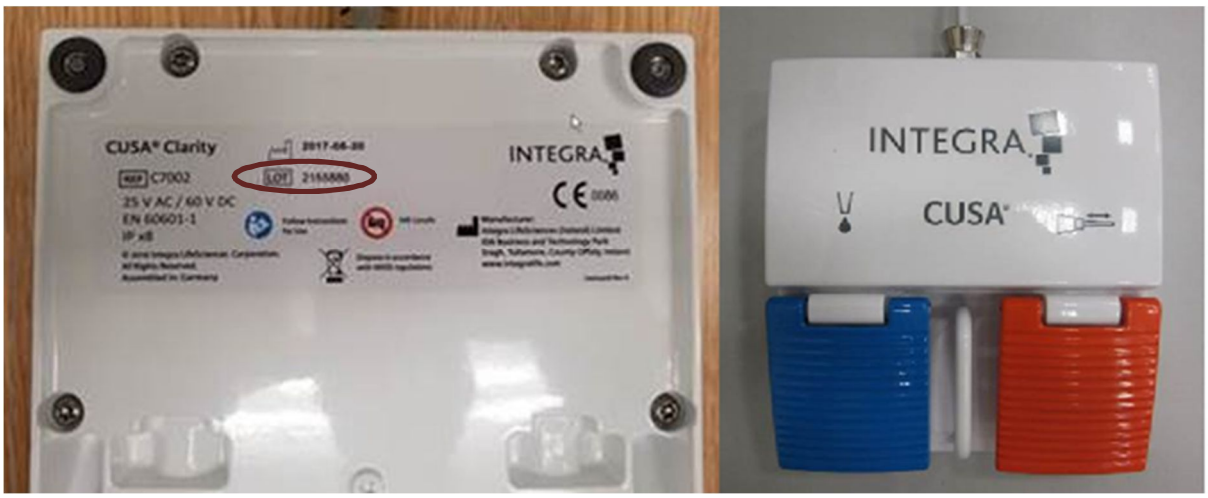
Integra LifeSciences (Ireland) has recently identified a supplier manufacturing issue, through a complaint investigation, involving certain lots of footswitch that is packaged with the CUSA® Clarity console (Ref C7000).

The faulty footswitch may result in unintended ultrasonic fragmentation activation. There are two scenarios during which the failure mode may occur:

- Ultrasonic fragmentation may be activated after set-up is complete and the user goes to the Main Screen (without the footswitch pressed).
- Ultrasonic fragmentation may remain activated during surgical use once the footswitch Amplitude pedal is disengaged

Consequently, out of abundance of caution the legal manufacturer Integra LifeSciences (Ireland), has made the decision to conduct a voluntary recall of the lots.

The Lot Number can be located on the label under the footswitch or on the individual box label.



Integra LifeSciences Services (France)
Siège Social : Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine ▪ Parc Technologique de la Porte des Alpes ▪
69800 Saint Priest ▪ France
33 (0)4 37 47 59 00 office ▪ 33 (0)4 37 47 59 99 fax ▪ integralife.com
Société par Actions Simplifiée au capital de 37.000 € ▪ NAF 4646Z ▪ 492 534 466 RCS Lyon
Deutsche Bank AG Paris FR76 1778 9000 0110 5107 2400 081 DEUTFRPP ▪ No TVA Intracommunautaire / I.V.A.T. : FR 82 492 534 466

We are notifying you of the recall as our records indicate that you have been supplied with some Integra® CUSA® Clarity footswitch reference C7002 lot 1923802; 1985221; 2057996; 2109587; 2118507.

Description of affected product	Reference	Affected Lot Number
Integra® CUSA® Clarity Footswitch	C7002	1923802; 1985221; 2057996; 2109587; 2118507

We kindly ask you to examine your inventory to determine if you have an Integra® CUSA® Clarity Footswitch reference C7002 lot 1923802; 1985221; 2057996; 2109587; 2118507, if you do have an affected lot number, please quarantine them and contact your sales representative who will proceed to the replacement.

Once the audit of your inventory achieved, please sign and return the "Recall acknowledgment and Return Form" enclosed, by which you confirm that you have received this Recall notification and you intend to fully comply with this Recall notification.

With this form, you will ensure that all the Integra® CUSA® Clarity Footswitch reference C7002 lot 1923802; 1985221; 2057996; 2109587; 2118507 affected will be quarantined. You also confirm that this notification has been forwarded to every concerned users.

An Integra representative will contact you in order to perform the replacement of the footswitch in your facility.

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 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.

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

Please feel free to contact me for any additional questions. We apologize for the inconvenience and thank you for your cooperation and support.

Yours Sincerely,

[redacted]

Enclosed: Acknowledgment and Return Form (1 page)

Integra LifeSciences Services (France)
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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical devices:
Integra® CUSA® Clarity Footswitch included in CUSA® Clarity Console (Ref C7000)

Reference:
C7002

Legal manufacturer:
Integra LifeSciences (Ireland) ltd. - IDA Business & Technology Park, - Sragh, Tullamore, County of Offaly, Ireland

Concerned lots:
1923802; 1985221; 2057996; 2109587; 2118507

September 2017

Please send the form back to :

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 Recall notification regarding Integra® CUSA® Clarity Footswitch reference C7002 lot 1923802; 1985221; 2057996; 2109587; 2118507.

I ensure that all the affected products are being quarantined waiting for the replacement by the Integra representative.

My inventory has been reviewed and the results are as follow (*please tick the appropriate answer*):

☐ **Yes**, I do have affected product(s) in my inventory. These affected product(s) have been isolated.

Please indicate quantity in the table below:

Description of affected product	Reference	Affected Lot Number	Quantity
Integra® CUSA® Clarity Footswitch	C7002		

☐ **No**, I do not have the affected product in my inventory.

Healthcare name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature

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