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

Saint Priest, June 13th, 2014

Subject: **URGENT – VOLUNTARY RECALL NOTIFICATION LETTER**
Medical device: **Integra® LED Battery Charger, Single Bay**
Reference: 90523
Legal Manufacturer: Integra, 589 Davies Drive, York, PA 17402
Affected lot numbers: please refer to table herein below.

Dear Customer,

Integra LifeSciences (Integra) has identified through an investigation of complaints that some lot numbers of the Integra® LED Battery Charger, Single Bay may prematurely fail and will not charge the Integra® LED Battery as intended.

Integra® LED Battery Charger, Single Bay (reference: 90523) is an accessory that can be used with the Integra®LED Headlight Systems that can either be operated with Alternating Current (AC) and Direct Current (DC) power.
The intended use of the Integra® LED Headlight System is to provide visible illumination of the surgical field or the patient.

In light of the above information, we are voluntarily recalling any Integra® LED Single Bay Battery Chargers from the affected Lot Numbers. You may have received an affected product directly, or had it provided with one of the LED Headlight Systems or Battery Kits below:

Products	References
Integra® LED Headlight Systems	90520US; 90520EU ; 90520UK ; 90520AU
Integra® Battery Kits	90530US ; 90530EU ; 90530UK ; 90530AU
Integra® LED Battery Charger, Single Bay	90523

There have been no reports of patient injury or adverse health consequences associated with the above. Out of an abundance of caution, Integra is voluntarily recalling specific lot numbers and notifying you of this recall.

You are notified of this recall as our records indicate that you have purchased an **Integra® LED Battery Charger, Single Bay; Integra® LED Headlight Systems** and/or **Integra® Battery** Kits with an affected lot number below.

Description of affected product	Reference	Affected Lot Numbers
Integra® LED Battery Charger, Single Bay	90523	IE123610, IE123710, IE123810, IE123910, IE124010, IE124110, IE124210, IE124310, IE124410, IE124510, IE124610, IE124710, IE124810, IE124910, IE125010, IE125110, IE125210, IE130110, IE130210, IE130310, IE130410, IE130510, IE130610, IE130710, IE130810, IE130910, IE131010.

Integra is kindly asking you to do the following:

1. We kindly ask you to examine your inventory and to request to your final customers to examine their inventories to determine if you have or if they have Integra® LED Battery Charger, Single Bay (reference: 90523) with an affected lot number listed hereinbefore and on the Recall acknowledgment and return form (please see picture on the next page for location of Lot Number on the bottom of the charger).

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

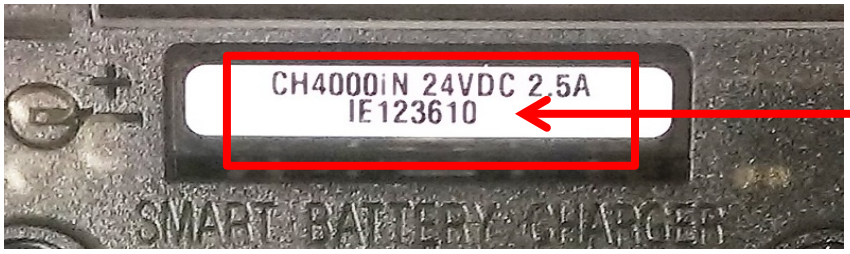

Image 1: Lot number location on Integra® LED Battery Charger

If you or your final customers have also Integra® LED Headlight Systems and/or Integra® Battery Kits, please check your inventory and please ask to your final customers to check their inventories.

2. Once the audit of you and your final customers' inventories achieved, please complete the attached recall acknowledgement & return form:

- If you or your final customers do **NOT** have an affected lot number on the list, **you can continue to ship them these products and your final customers can continue to use their Integra® LED Battery Charger, Single Bay.**
  Tick the box: **I do not have the affected product with affected Lot Numbers in my inventory and/or my final customers' inventories.**
- If you or your final customers do have product(s) on the affected lot number list**, you must stop shipping them and ask to your final customers to remove them from use and put them in quarantine.**
  Tick the box: **I do have affected product(s) in my inventory and/or my final customers' inventories.**
  Please record the total quantity corresponding to the lot number(s) you and/or your final customers have.

3. Complete the other information on the recall acknowledgement & return form and return the form promptly as indicated on the form.

When your form is received, and if you have noted you and/or or your final customers have affected product(s), our Customer Service will send you replacements for the quantity you have reported and provide an RMA number and directions to return your recalled products.

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.

Please note that your National Competent Authority has been alerted of this recall.

Thank you for your cooperation with this Recall and for returning the attached Recall Acknowledgement and Return Form.

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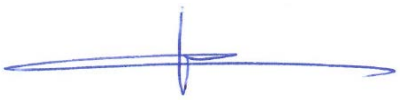
For any questions or concerns, please contact Jean-Charles Moncenis at the following e-mail address: jean-charles.moncenis@integralife.com.

Sincerely,



Jean-Charles MONCENIS
Senior Project Manager - Regulatory Affairs
Neurosurgery Products Division
Europe, Middle-East & Africa

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RECALL ACKNOWLEDGMENT AND RETURN FORM

Medical device: **Integra® LED Battery Charger, Single Bay**
Reference: 90523
Legal Manufacturer: Integra, 589 Davies Drive, York, PA 17402
Affected lot numbers: please refer to table herein below.

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

I have received, read and understood the information provided in the Integra Recall notification regarding **Integra® LED Battery Charger, Single Bay.**

My inventory and my final customer's inventory have been reviewed, including additional products mentioned in the Integra Recall notification and the results are as follow (please tick the appropriate answer):

☐ **Yes**, I do have affected product(s) in my inventory and/or my final customers' inventories.
Please circle affected lot(s) and indicate quantity in the table below:

Description of affected product	Reference	Affected Lot Numbers	Quantity
Integra® LED Battery Charger, Single Bay	90523	IE123610, IE123710, IE123810, IE123910, IE124010, IE124110, IE124210, IE124310, IE124410, IE124510, IE124610, IE124710, IE124810, IE124910, IE125010, IE125110, IE125210, IE130110, IE130210, IE130310, IE130410, IE130510, IE130610, IE130710, IE130810, IE130910, IE131010.	

☐ **No**, I do not have the affected product with affected Lot Number in my inventory and/or my customers' inventories.

With this form,
- I confirm that I have received this Recall notification and that I intend to fully comply with it;
- I confirm that this recall notification has been circulated to all affected users/customers. They have been asked to check their inventory and to immediately stop using the affected products and to remove them from service;
- I ensure that all the affected products, including those I had already sent to my customers, are being quarantined and will be shipped back to Integra.

Please complete contact point details on next page.

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Contact point details

Customer/Site Name

Customer Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Fax

Signature

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