INTEGRA
LIMIT UNCERTAINTY

To the attention of Medical Device Safety Officer / Central Pharmacy

Saint Priest,15/07/19

Subject: **URGENT - FIELD SAFETY NOTICE - SAFETY INFORMATION**

Medical devices: ISOCOOL®Bipolar Forceps Tips Model: 8145100S

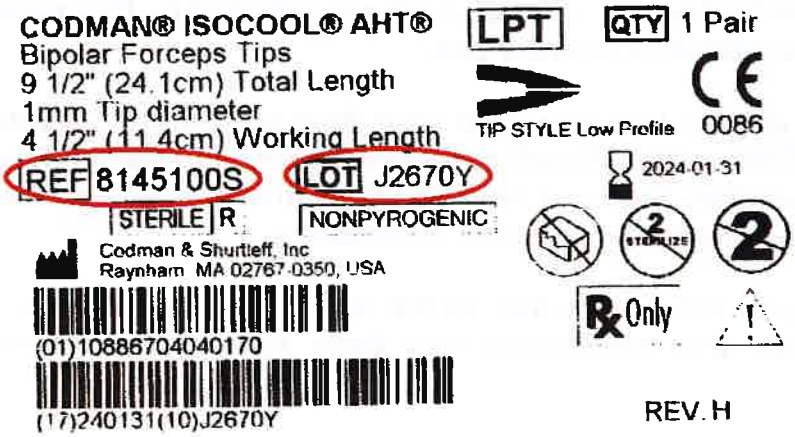
Legal manufacturer: Codman & Shurtleff, Inc, 325 Paramount Drive, Raynham, MA 02767-0350

EC Rep: Codman A division of Johnson & Johnson Medical Ltd, Pinewood Campus, Nine Mile Ride, RG40 3 EW, United Kingdom

Concerned batches: Lot J2670Y sold between March 2017 and present

Dear Customer,

Integra Lifesciences has recently identified during an internal routine product inspection, a defective insulation coating of Codman ISOCOOL®Bipolar Forceps Tips Model: 8145100S lot J2670Y product.



During the use, an inadequate product insulation coating may lead to a bad coagulation. There have been no reported complaints or patient injuries as result of this defect.
The non-conformance was determined during an investigation, and corrective/preventive actions will be implemented to eliminate the root cause. Only this

Integra LifeSciences Services (France)
Siège Social : Immeuble Séquoia 2 ▪ 97 allée Alexandre Borodine ▪ Parc Technologique de la Porte des Alpes ▪ 69800 Saint Priest ▪ France
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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

lot product does not meet our specification. This defect does not apply to other lots distributed in the field.
If the user experiences insufficient power from the Electrosurgical Generator and/or the expected coagulation is not observed from the forceps, this could indicate the tips are faulty.

The Isocool Bipolar Forceps (handles and tips), when used as part of a system including a bipolar electrosurgical generator are indicated for cauterizing, coagulating, grasping, and manipulating tissue during general surgery, neurosurgery, ENT surgery, OB/GYN surgery, and maxillofacial / plastic surgery procedures. The Isocool Forceps are also indicated for cauterizing, coagulating, grasping, and manipulating soft tissue during spine surgery and orthopedic surgery. Indications for use in OB/GYN surgery exclude contraceptive coagulation of fallopian tube tissue.

We are notifying you of this Field Safety Notice as our records indicate that you have been supplied with devices listed **below**.

Model:	Impacted product description	Reference
8145100S	**ISOCOOL Bipolar Forceps**	**J2670Y**

We kindly ask you to examine your inventory to determine if you have the devices affected lot.

If you have identified one or several products affected by this recall, quarantine them until the reception of the new one.

Once the audit of your inventory and your final customers' 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 devices affected will be returned. You also confirm that this notification has been forwarded to every concerned customer.

Integra Customer Service will contact you upon receipt of this information to organize the replacement of the concerned products (Return Merchandise Authorization number assignment).

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

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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.

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

For any questions or concerns, please contact us at the following e-mail address: emea-fsca-recon@integralife.com

Sincerely,

Angélique Aubert
Compliance coordinator
Europe, Middle-East & Africa

Appendix: Recall Acknowledgement and return form (1 page)

Integra LifeSciences Services (France)
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RECALL ACKNOWLEDGMENT AND RETURN FORM

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EC Rep: Codman A division of Johnson & Johnson Medical Ltd, Pinewood Campus, Nine Mile Ride, RG40 3 EW, United Kingdom

Concerned batches: Lot J2670Y sold between March 2017 and present

July 2019

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 ISOCOOL®Bipolar Forceps Tips Model: 8145100S lot J2670Y.

I ensure that all the affected products, including those I had already sent to my customers are being quarantined **until the reception of the new product.**

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 and will be sent back.
Please indicate quantity in the table below.

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

Model:	Impacted product description	Reference	Quantity
8145100S	**ISOCOOL Bipolar Forceps**	**J2670Y**	

Distributor / Healthcare facility name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature

FSN-N-HHE-343-15072019

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