To the attention of Medical Device Vigilance Manager / Central Pharmacy

Saint Priest, 17/06/2020

Subject: **URGENT - FIELD SAFETY NOTICE** – INTEGRA® MICROFRANCE® BIPOLAR ELECTROSURGICAL LAP AND NON-LAP INSTRUMENTS. – Disassembly issues - Product Removal

Legal manufacturer :
INTEGRA MICROFRANCE SAS, Le Pavillon, 03160 Saint Aubin Le Monial, FRANCE

Medical devices:
The bipolar electrosurgical instruments consist of scissors, forceps, and probes, available in different configurations for laparoscopic or endoscopic access and open field surgery. Electrical insulation is applied to selected portions of the instrument and a connector is provided to attach the instrument to a variety of currently available bipolar electrosurgical generators. These devices are intended to be used by qualified physicians and operating room personnel familiar with high frequency current who have been properly and correctly trained in the surgical techniques that must be used. Physicians should seek relevant pre-clinical education before attempting new surgical procedures, especially those in insufflated cavities.

Primary clinical purpose of device(s):
The bipolar electrosurgical instruments are indicated for general surgery or specialized surgeries including open and laparoscopic/endoscopic surgery where the physician determines that high-frequency electrical current is appropriate to remove tissue and/or control of bleeding.

Concerned reference(s) and batches:
CEV130; CEV133; CEV134; CEV134BG; CEV136; MCL34; MCL340

batches listed in the appendix 1

Dear Valued Customer,

The purpose of this letter is to notify you that the legal manufacturer Integra LifeSciences, is voluntarily issuing a Field Safety Notice for the INTEGRA® MICROFRANCE® BIPOLAR ELECTROSURGICAL LAP AND NON-LAP INSTRUMENTS for the part numbers and lots listed below.

Integra LifeSciences received customer complaints noting disassembly or breakage issues. The failures observed are due to modifications implemented in production since February 2020 where the plastic connector material was changed in order to comply with 60601-1 Electrical Safety Testing.
As the forceps are currently assembled, the set screw is screwed in the Plastic part, going through the metal connector and pressing on the electrode wire to keep it in place. During the autoclave process, the instruments withstand a 134°C heat, which causes all material to expand at different rates, depending on their thermal properties.
A root cause investigation has determined that the thermal expansion of the plastic component is greater than initially relative to the set screw, causing the set screw to loosen. As this is happening the electrodes are no longer held in place and would therefore potentially disassemble.

Consequently, Integra LifeSciences has decided to voluntarily recall the impacted products due to the potential of disassembly concerns.

The assessment completed by the legal manufacturer Integra LifeSciences, concluded that the severity of harm has been assessed to be negligible. The disassembly issue will cause inconvenience to user and minor prolongation of procedure. The risks mentioned above have been assessed based on standard ISO 14971 and other applicable regulations listed in our internal procedures.

We are notifying you of the Field Safety Corrective Action as our records indicate that you have been supplied with INTEGRA® MICROFRANCE® BIPOLAR ELECTROSURGICAL LAP AND NON-LAP INSTRUMENTS listed in the appendix 1.

To mitigate the risk, we kindly ask you to:

☑ Identify Device ☑ Quarantine Device ☑ Return Device

Integra Customer Service will contact you upon receipt of this notice to organize the return and of the concerned products (Return Merchandise Authorization number assignment). Depending on the manufacturer site assessment, the product could be either repaired or replaced.

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially concerned devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer reply is required. A form is attached to this Field Safety Notice. The receipt of this form ensures that Integra has achieved a level of effectiveness in communicating this information. **We expect a response within 3 weeks.**

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

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

Yours Sincerely,

Angelique AUBERT
EMEA Compliance Coordinator

Enclosed: Field Safety Notice Customer Form (2 pages), Appendix 1

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN-HHE-006-120520
FSN Date*	17 of June 2020
Product/ Device name*	INTEGRA® MICROFRANCE® BIPOLAR ELECTROSURGICAL LAP AND NON-LAP INSTRUMENTS
Product Code(s)	CEV130 ; CEV133 ; CEV134; CEV134BG; CEV136; MCL34; MCL340
Batch/Serial Number (s)	Listed in Appendix 1

2. Customer Details	
Account Number	
Healthcare Organization Name*	
Organization Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organization				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		
☐	Other Action (Define):			
☐	I do not have any affected devices.	Customer to complete or enter N/A		
☐	I have a query please contact me	Customer to enter contact details if different from above and brief description of query		

	(e.g. need for replacement of the product).	
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	emea-fsca-neuro@integralife.com
Customer Helpline	+33 (0) 4 37 47 59 16
Postal Address	Regulatory Affairs Integra Immeuble Séquoia 2, 97 allées Alexandre Borodine Parc technologique de la Porte des Alpes 69800 Saint Priest, France
Web Portal	www.integralife.eu
Fax	+33 (0)4 37 47 59 30
Deadline for returning the customer reply form*	13 of July 2020

Mandatory fields are marked with *

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.

APPENDIX 1

Description of Concerned product	Reference	Concerned Lot Number
Manhès bipolar forceps, 3mm jaws, 5mm diam, 360mm length	CEV130	4472984 ; 4472082 ; 4472984 - 6
Botella bipolar forceps, 5mm diam., 360mm length, triangular jaws	CEV133	4458141 ; 4459360 ; 4449381 ; 4472990 ; 4472081 ; 4449379 ; 4458141 - 2, 4472081 – 8 ; 4472990 - 3 ; 4458141 – 3 ; 4449381 – 3 ; 4472990 - 1
Mouiel bipolar forceps with fenestrated jaws, 5mm diam, 360mm length	CEV134	4482103 ; 4517600 ; 4517601
Gayet bipolar forceps, fenestrated jaws, 5mm diam, 360mm length, graduated tube 100mm, ergonomic handle	CEV134BG	4522657 ; 4525209 ; 4449383, 4449384 ; 4522657 – 6 ; 4525209 - 8
Gayet bipolar forceps with long fenestrated jaws,5mm diam., 365mm length	CEV136	4455141 ; 4455142 ; 4455142 – 8 ; 4455141 - 8
Bipolar forceps with box and tray, 290mm	MCL34	4449386 ; 4449387 ; 4449387- 2 ; 4449386- 1
Micro bipolar forceps 45deg jaws WL 210mm	MCL340	4455134