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To the attention of Medical Device Vigilance responsible / Central Pharmacy

Saint Priest, 04/03/2016

Subject: **URGENT - FIELD SAFETY NOTICE**

Medical devices:
Integra® MicroFrance® Monopolar Instruments
Integra® MicroFrance® Bipolar Instrument Handle CEV669E
References:
See Attachment 1
Legal Manufacturer:
Integra MicroFrance SAS, Le Pavillon, 03160 Saint Aubin le Monial
Concerned batches:
All batches

Dear Valued Customer,

Integra MicroFrance SAS, a company within Integra Lifesciences Group, is issuing this Field Safety Notice **to reinforce the importance of following the instructions for use of the Integra® MicroFrance® Monopolar Instruments and Integra® MicroFrance® Bipolar Instrument Handle, CEV669E** as stated in the following Integra® MicroFrance® Instructions for Use (IFU).

- IFU No. NT111A-2015/09 - Integra® MicroFrance® Monopolar Electrosurgical (Metallic Tube) Instruments
- IFU No. NT060H-2015/09 - Integra® MicroFrance® Monopolar Electrosurgical, Lap Instruments
- IFU No. NT058I-2015/09 - Integra® MicroFrance® Bipolar Electrosurgical Instruments
- IFU No. NT061H-2015/09 - Integra® MicroFrance® Monopolar Electrosurgical Instruments (Not Laparoscopic Use)

Integra MicroFrance SAS has received a very low level of complaint reports related to unintended patient or operator burns or operator electric shock for some of the electrosurgical instruments that are in Attachment 1.

Therefore, out of an abundance of caution and to ensure safety and service, Integra MicroFrance SAS is providing the attached Addendum to reinforce and remind you of the appropriate Warnings, Precautions, and Adverse Events that are in the IFU for these devices that could relate to the complaints.

We are notifying you of the Field Safety Notice as our records indicate that you have been supplied with Integra® MicroFrance® Monopolar Instruments and/or Integra® MicroFrance® Bipolar Instrument Handle CEV669E

Description of affected product	Reference	Affected Lot Number
Integra® MicroFrance® Monopolar Instruments Integra® MicroFrance® Bipolar Instrument Handle CEV669E	See Attachment 1	All batches

Please ensure that this Field Safety Notice and the Addendum are provided to every concerned user of Integra® MicroFrance® Monopolar Instruments and/or Integra® MicroFrance® Bipolar Instrument Handle CEV669E (References / see Attachment 1).

Additionally, please sign and return the "Recall acknowledgment and Return Form" enclosed, by which you confirm that you have received this Field Safety Notice and you intend to fully comply with. You also confirm that this notification has been forwarded to every concerned users.

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

Integra LifeSciences Services (France)
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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. Your cooperation is appreciated, and we thank you for your continued collaboration.

Yours Sincerely,

Jeremie Nadam
Senior Regulatory Affairs Manager
Europe - Middle East – Africa

Enclosed: Recall Acknowledgment and Return Form (Page 3)
Attachment 1 List of References (Page 4)
ADDENDUM Integra® MicroFrance® Monopolar Instruments and Integra® MicroFrance® Bipolar Instrument Handle CEV669E (Page 5)

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FIELD SAFETY NOTICE ACKNOWLEDGMENT AND RETURN FORM

Medical devices:
Integra® MicroFrance® Monopolar Instruments
Integra® MicroFrance® Bipolar Instrument Handle CEV669E

Legal manufacturer:
Integra MicroFrance SAS, Le Pavillon, 03160 Saint Aubin le Monial

Concerned batches:
All Batches

February 2016

Please send the form back to :

By fax/telecopy: +33 (0)4 37 47 59 30
Or by e-mail: EMEAFSCASSSINST@integralife.com

With this form,

I have received, read and understood the information provided in the Integra *Field Safety Notice* notification regarding Integra® MicroFrance® Monopolar Instruments and Integra® MicroFrance® Bipolar Instrument Handle CEV669E.

I confirm that this Field Safety Notice and the Addendum have been circulated to all affected users.

Healthcare facility name

Contact Name

Street Address

City, Country, Postal Code

Telephone

Email

Signature

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ATTACHMENT 1

Product Description	Catalogue No.'s	
Integra® MicroFrance® Monopolar Electrosurgical, Lap Instruments *Metallic Tubes* IFU No. NT111A-2015/09	*CEV649B5* *CEV649BGP* *CEV649GP* *CEV8649B5* *CEV8649BGP*	*CEV8649GP* *CEV9649B5* *CEV9649BGP* *CEV9649GP*
Integra® MicroFrance® Monopolar Electrosurgical, Lap Instruments *Insulated Tubes* IFU No. NT060H-2015/09	*CEV646B5* *CEV647B5* *CEV648B5* *CEV649-5B* *CEV649-5N* *CEV8646B5* *CEV8647B5* *CEV8648B5*	*CEV8649-5-B* *CEV8649-5N* *CEV9646B5* *CEV9647B5* *CEV9648B5* *CEV9649-5-B* *CEV9649-5N*
Integra® MicroFrance® Monopolar Electrosurgical, Lap Instruments *Handles* IFU No. NT060H-2015/09	*CEV1019-5B* *CEV10195C* *CEV10195D* *CEV1019-5N* *CEV10195NA* *CEV10195R* *CEV1039-5-B* *CEV10395D* *CEV1039-5N*	*CEV10395R* *CEV1039G5* *CEV618-5N* *CEV6185R* *CEV638-5N* *CEV6385R* *CEV720BR* *CEV720R* *CEV7285R*
Integra® MicroFrance® Monopolar Electrosurgical, Lap Instruments *Semi-Modular Instruments* IFU No. NT060H-2015/09	*CEV391I* *CEV393I* *CEV394I* *CEV395I* *CEV396I* *CEV398I* *CEV399I* *CEV899I*	*CEV605-5* *CEV891I* *CEV893I* *CEV894I* *CEV895I* *CEV896I* *CEV898I*
Integra® MicroFrance® Monopolar Electrosurgical, Lap Instruments *Non dismountable forceps* IFU No. NT060H-2015/09	*CEV104M* *CEV114M* *CEV211* *CEV220* *CEV391B* *CEV394B* *CEV395B* *CEV399B* *CEV899* *CEV405* *CEV406* *CEV407* *CEV460* *CEV470* *CEV470-1* *CEV511M* *CEV514M* *CEV515M*	*CEV520M* *CEV525M* *CEV531-3* *CEV815M* *CEV891M* *CEV894M* *CEV895M* *CEV995M* *CEV996M* *CEV997M* *CEV998M* *CM107* *CM110* *CM111* *CM111R* *CM112* *CM113* *CM115* *CM120*
Integra® MicroFrance® Monopolar Electrosurgical, not Lap Instruments *Non dismountable forceps* IFU No. NT061H-2015/09	*MCLP20* *MCLP25* *MCLP30* *MCLP40*	
Integra® MicroFrance® Bipolar Electrosurgical, Lap Instrument *Handle* IFU No. NT058I-2015/09	CEV669E	

FSN-HHE-609-220216

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ADDENDUM
Integra® MicroFrance® Monopolar Instruments
Integra® MicroFrance® Bipolar Instrument Handle, CEV669E

The following information reinforces the Integra® MicroFrance® Monopolar Instruments and the Integra® MicroFrance® Bipolar Instrument Handle, CEV669E Instructions for Use and is intended to emphasize the current WARNINGS, PRECAUTIONS and ADVERSE EVENTS associated with electrical safety of the Integra® Micro France® Monopolar Instruments and the Integra® MicroFrance® Bipolar Instrument Handle, CEV669E

WARNINGS – Monopolar and Bipolar Instrumentation

- ⚠ **For devices that incorporate suction, do not extend suction tube while energy is applied to avoid accidental burns.**
- ⚠ **Do not place the instrument on the patient when not in use. Place the instrument in an insulated support or on a clean, dry surface, very visible and non-conductive, so as to avoid accidental electrical injuries.**
- ⚠ **Do not try to modify the instrument. Do not try to repair the electrical insulation.**
- ⚠ **Do not "buzz" the instrument during the surgical procedure to reduce the risk of burning the patient or the physician.**
- ⚠ **The pathways of the current through conductive elements like metal instruments and endoscopes can cause local burns to the patient, the physician or another member of the care team. Contacting conductive elements with the active cautery area may cause undesired tissue heating and burns.**
- ⚠ **The temperature of the instrument in the active cautery area can remain high enough after use that it burns the patient, the physician or another person, even when the electrical current is turned off.**
- ⚠ **To avoid alternate site burns, ensure hinges, handles and proximal un-insulated portions of the electrosurgical instruments do not inadvertently contact patient.**
- ⚠ **Extreme care should be taken when handling instruments with a dielectric coating. Damage to the dielectric coating may result in patient/user injury**
- ⚠ **Begin procedure at the lowest possible electrosurgical power setting to reduce the risk of patient burns at high voltages.**

ADDITIONAL WARNINGS – Monopolar Instrumentation

- ⚠ **Apply the patient return electrode according to the recommendations of the generator manufacturer.**
- ⚠ **The entire surface of the neutral electrode should be securely connected to the patient's body and as close as possible to the surgical field.**
- ⚠ **The patient should not be in contact with grounded metal parts or parts having an appreciable capacity with respect to the ground (for example operating table, supports, etc.). Antistatic wrapping is recommended in this case.**
- ⚠ **Skin to skin contact (for example between the patient's arms and body) must be avoided, for example by separation with dry gauze.**

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ADDITIONAL WARNINGS – Bipolar Instrumentation

⚠ **Do not place a patient return electrode for bipolar procedures.**

PRECAUTIONS– Monopolar and Bipolar Instrumentation

⚠ **Make a visual inspection of the instrument and the cable to ensure that the electrical insulation is in good condition.**

⚠ **The use of trocars made entirely of plastic or metal is recommended with electrosurgical devices in order to avoid thermal injuries in the surgical access zones.**

ADVERSE EVENTS - Monopolar Instrumentation

⚠ **Localized burns to the patient or physician may result from electrical current carried through conductive objects (such as trocar cannulas). Electrical current may be generated in conductive objects by direct contact with the active electrode, or by the active accessory (electrode or cable) being in close proximity to the conductive object.**

ADVERSE EVENTS - Bipolar Instrumentation

⚠ **Adverse events reported while using bipolar electrosurgical devices include inadvertent activation with resultant tissue damage at the wrong site and/or equipment damage. Fires involving surgical drapes and other combustible materials have been reported. Alternate pathways resulting in burns where the patient or physician or assistant is in contact with exposed metal.**

Please refer to the Integra LifeSciences website, http://integralife.com/MicroFrance/microfrance-instructions.aspx for the complete Instructions for Use for Integra® MicroFrance® Monopolar Instruments (IFUs NT 111 A - 2015/09; NT 060 H – 2015/09; NT061H-2015/09) and Integra® MicroFrance® Bipolar Instrument Handle; (NT 058 I – 2015/09) including indications for use, and comprehensive handling and reprocessing information.

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