Rev 1: September 2018

FSN Ref: FSN 01/2021 FSCA Ref: FSCA 01/2021

Rev: 01
Date: 26/04/2021

Urgent Field Safety Notice

Dear Customer / Distributor,

As Manufacturer of Medical Devices, Gruppo Bioimpianti Srl hereby notify about the issue of a Field Safety Corrective Action relating to the Medical Devices included in Annex 2.

Urgent Field Safety Notice (FSN)

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Orthopedics Implantable Medical Devices. See Annex 2 for the complete list of affected devices.
1.	2. Commercial name(s)
	See Annex 2 for the complete list of affected devices.
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not Applicable.
1.	4. Primary clinical purpose of device(s)*
	The device ref 110450142 is indicated to treat hip pathologies that require an arthroplasty to reduce or eliminate pain and / or improve joint function. All the other devices involved (see Annex 2 for the complete list) are intended to be used in a system (K-MOD or K-MOD REV) for total knee replacement. For specific indications, see specific Instruction For Use (IFU).
1.	5. Device Model/Catalogue/part number(s)*
	See Annex 2 for the complete list of affected devices.
1.	6. Software version
	Not Applicable.
1.	7. Affected serial or lot number range
	See Annex 2 for the complete list of affected devices.
1.	8. Associated devices
	Not Applicable.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Gruppo Bioimpianti Srl has used the Company Steril Milano Srl for the outsourcing of the Ethylene oxide sterilization process for medical devices made of Polyethylene. Following the communications received by Steril Milano Srl related to the falsification of the processing parameters of certain sterilization cycles used to sterilize medical devices manufactured by Gruppo Bioimpianti Srl, in order to assure the safety and conformity of the medical devices and patient health, some devices as samples of the involved sterilization batches and not were in advance submitted to sterility and EO residual analysis. On 16th March 2021 Gruppo Bioimpianti Srl received some test reports from the laboratory in charge of carrying out the analyzes including one characterized by a non-compliant result, i.e. not sterile device, related to the 20040711 sterilization batch. For this reason, a field safety corrective action was carried out with the issue of this FSN and recall of the devices involved to prevent their possible use, given the potential problem. Parallel to the recall action, Gruppo Bioimpianti has carried out further sterility tests on other devices belonging to the same sterilization batch and all the additional tests carried out up to now (10 in total) have shown compliant results, i.e. sterility of the analyzed devices.
2.	2. Hazard giving rise to the FSCA*
	Possible use of non sterile medical device.
	3. Probability of problem arising

2.	The affected sterilization batch dates back to April 2020 and no reports nor incident communications have been received by Gruppo Bioimpianti after 12 months of possible use of the devices sterilized with that specific sterilization batch. All the devices not yet used have been quarantined/recalled from the facilities and/or distributors to which they had been delivered, therefore the probability of using a new potentially non-sterile device belonging to this sterilization lot is zero. All the sterility analyses carried out subsequently on MD of the same sterilization batch reported compliant results, i.e. sterility of the medical devices tested, thus significantly reducing the probability of the problem occurring.
2.	4. Predicted risk to patient/users
	The use of a not sterile medical device can be the cause of infection.
2.	5. Further information to help characterise the problem
	Not Applicable.
2.	6. Background on Issue
	No additional information. See paragraph 2.1 for the description of the problem.
2.	7. Other information relevant to FSCA
	Not Applicable.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☒ Identify Device ☒ Quarantine Device ☒ Return Device to Gruppo Bioimpianti ☐ Destroy Device ☐ On-site device modification/inspection ☒ Follow patient management recommendations ☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None	
3.	2. By when should the action be completed?	Identification, quarantine and/or recall action already carried out worldwide.
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? Yes Post-operative monitoring of patients implanted with Medical Devices related to the involved lots is recommended. The protocol for this monitoring has to be evaluated and implemented by health professionals and health structures according to good clinical practice, evaluating if it is necessary to implement or not a more stringent monitoring schedule. The company remains available for discussion with healthcare professionals who may need it, thanks to the support of professionals specialized in the management of infections.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes (if the customer has not already answered)

3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
3	By when should the action be completed?	Quarantine and/or recall action already carried out worldwide.
3.	6. Is the FSN required to be communicated to the patient /lay user?	No
3	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item.	

	4. General Information*	
4.	1. FSN Type*	Update
4.	2. For updated FSN, reference number and date of previous FSN	FSN 01/2021 dated 18.03.2021 Reference number 306096
4.	**3.** For Updated FSN, key new information as follows:	
	Not Applicable.	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
4	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Gruppo Bioimpianti Srl**
	b. Address	**Via Liguria 28, 20068 Peschiera Borromeo, Milan (Italy)**
	c. Website address	**www.bioimpianti.it**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	**Annex 1 – Customer / Distributor Reply Form** **Annex 2 – List of affected products**
4.	10. Name/Signature	**Gruppo Bioimpianti Srl** **CEO** **Fabio Angelo Pietro Bedini**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

Annex 1 - Customer / Distributor Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 01/2021
FSN Date*	18/03/2021
Product/ Device name*	See Annex 2 for the complete list of affected devices.
Product Code(s)	See Annex 2 for the complete list of affected devices.
Batch/Serial Number (s)	See Annex 2 for the complete list of affected devices.

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

3. Distributor/Importer Details	
Company Name*	
Account Number	
Address*	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

4. Customer action undertaken on behalf of Healthcare Organisation				
☐	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:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		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 (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

5. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

6. Return acknowledgement to sender	
Email	qualita@bioimpianti.it
Customer Helpline	00390251650371
Postal Address	Via Liguria 28, 20068 Peschiera Borromeo, Milan - Italy
Web Portal	www.bioimpianti.it
Fax	00390251650393
Deadline for returning the customer reply form*	Within 10 days

Mandatory fields are marked with *

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

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

Annex 2 – List of affected products

Reference	Lot	Description	Expiration date
110450142	AF3854	Inserto Polietilene Int.28mm x Dm 42-44mm	03/04/2030
110450142	AF3854	Inserto Polietilene Int.28mm x Dm 42-44mm	02/04/2030
120700523	AG0054	K-MOD Inserto Mobile Ultra Congruente Tg.3 sp.10	02/04/2030
120700662	AG0472	K-MOD Inserto Fisso Ultra Congruente Tg.2 Sp.10	02/04/2030
120700674	AG0343	K-MOD Inserto Fisso Ultra Congruente Tg.4 Sp.12	02/04/2030
120700721	AG0344	K-MOD Inserto Fisso Dynamic Congruence Tg.1 Sp.12 Sx.	02/04/2030
120700725	AG0474	K-MOD Inserto Fisso Dynamic Congruence Tg.5 Sp.12 Sx.	02/04/2030
120700733	AG0345	K-MOD Inserto Fisso Dynamic Congruence Tg.3 Sp.14 Sx.	02/04/2030
120700742	AG0346	K-MOD Inserto Fisso Dynamic Congruence Tg.2 Sp.16 Sx.	02/04/2030
120700745	AG0475	K-MOD Inserto Fisso Dynamic Congruence Tg.5 Sp.16 Sx.	02/04/2030
120700763	AG0347	K-MOD Inserto Fisso Dynamic Congruence Tg.3 Sp.12 Dx.	02/04/2030
120700765	AG0348	K-MOD Inserto Fisso Dynamic Congruence Tg.5 Sp.12 Dx.	02/04/2030
120701815	AG0349	K-MOD Inserto Fisso PS 5x12	02/04/2030