Date: **20 Mar 2024**
FSN Ref: **FSN24-03-001 V.01**
FSCA Ref: **FSA24-03-001 V.01**

Urgent Field Safety Notice (FSN)

Bipolar Pacing Catheter Spike Flow
Batch: H230400158

For Attention to:

FIAB SpA – Distributor (c/o Francesco Batistini – QA Manager)

Medical Practitioners (c/o Field Hospital Administrators)

EX-Directorate General of Medical Devices and Pharmaceutical Service (c/o Dr. Laura Serino)

DEKRA Certification B.V. (c/o A.J. Knipmeijer)

Shanghai International Holding Corp. GmbH (Europe) - EC-REP (c/o Jin Liang)

Contact details of local representative (name, e-mail, telephone, address etc.) *
FIAB SpA Francesco Batistini Via Passerini 2-4-6 50039 Vicchio (FI) ITALY Phone: (0039) 055 8497943 Fax: (0039) 055 8497987 Email: quality@fiab.it

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Risk addressed by FSN:

Non-stimulation / non-pacing of the device while inside the patient's heart caused by a short circuit.

1. Information on Affected Devices *	
1.1	Device Type(s) *
	Brand: Bipolar Pacing Catheter Spike Flow **Device Name:** Bipolar Pacing Catheter **Common Name:** Temporary Pacing Catheter, Temporary Pacing Leads **Condition:** Supplied sterile (EO Sterilization)
1.2	Commercial name(s) *
	Bipolar Pacing Catheter Spike Flow
1.3	Unique Device Identifier(s) (Basic UDI-DI)
	888648350907SB
1.4	Primary clinical purpose of device(s) *
	Intended for temporary transvenous cardiac pacing by transmitting a pacing electrical stimulus from a pulse generator to the patient heart. It can also be used for transmitting electrical signal of the patient heart to a recording device.
1.5	Device Model/Catalogue/part number(s) *
	Model ID (REF): BP-2502-10 P/N: BP-0002-011 Catalogue Number: 12165
1.6	Software version
	Not applicable.
1.7	Affected serial or lot number range *
	LOT nr. H230400158
1.8	Associated devices
	No associated device or accessories.

2. Reason for Field Safety Corrective Action (FSCA) *	
2.1	Description of the product problem *
	Non-stimulation / non-pacing of the device while inside the patient's heart caused by a short circuit.
2.2	Hazard giving rise to the FSCA *
	No pacing / no stimulation has the potential to lead to (might lead to) a serious incident (if severe: Heart attack or myocardial infarction) due to untimely delays in medical procedure or untimely medical intervention is initiated.
2.3	Probability of problem arising
	The occurrence level of pacing malfunction is O-1 [p < (1 in 100,000), p < 0.0010%] which is extremely or highly unlikely the condition will occur.
2.4	Predicted risk to patient/users
	The risk of pacing malfunction and its potential effects is in the Low Level (RPN: 5, S-5, O-1). The most common effects to patient are: Arrythmia, bradycardia, tachycardia, heart block. Potential severe effect is: Heart attack or myocardial infarction due to untimely delays in medical procedure or untimely medical intervention is initiated.
2.5	Further information to help characterise the problem
	No stimulation / no pacing could have several causes. Although this risk is not uncommon to this type of device in general, no stimulation / no pacing due to a short circuit is rare as manufacturers have quality control in place during manufacturing to check for electrical continuity and insulation.
2.6	Background on Issue
	The manufacturer received a report from a user healthcare facility in Italy that the product Bipolar Pacing Catheter Spike Flow (Lot #: H230400158) did not stimulate while inside the patient heart. The connection cables and the cardiac stimulator were changed, without solving the problem. The procedure was then completed with success by replacing the Spike flow with another product of a different brand, inserted in the same position. It was further reported that there was no patient consequences or injury observed and reported after the incident. After the manufacturer's investigation, it was found out that the device unit used by the hospital had a short circuit. The short circuit was caused by a protrusion in the wire connection that punctures the black heat shrinkable tube (electrical insulator) in the catheter hub bringing the distal and proximal wires in contact. Only 1 unit out of 1,500 unit sold for this particular lot was reported to have short circuit and was evaluated to be an isolated incident.
2.7	Other information relevant to FSCA
	This batch (H230400158) bearing the customer brand Bipolar Pacing Catheter Spike Flow, model BP-2502-10 (cat# 12165), totalling 1,500 units, was only shipped to Italy distributor FIAB SpA. The manufacturer has not shipped this brand and batch to another distributor. This is an isolated case and a localized event.

3. Type of Action to mitigate the risk *

3.1 Action To Be Taken by the User *

☒ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device

☐ On-site device modification/inspection.

☐ Follow patient management recommendations.

☐ Take note of amendment/reinforcement of Instructions for Use (IFU).

☐ Other ☐ None

Provide further details of the action(s) identified:
The hospital administrator should check and identify if there are still units of lot H230400158 left in their inventories. If there is, quarantine the remaining units and return to the distributor FIAB SpA for subsequent disposal by the manufacturer in Singapore.

3.2	By when should the action be completed?	As soon as the user (hospital administrator) becomes aware of this FSN.

3.3 Particular considerations for:

Is follow-up of patients or review of patients' previous results recommended?
No. Bipolar Pacing Catheter Spike Flow is a single-use, disposable medical device with recommended indwelling of not more than three (3) days from the patient's heart. No pacing / no stimulation is detectable during device precheck or during medical procedure. If such event occurs, effect/s to patient is evident during medical procedure and not during patient recovery.

3.4	Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes. Refer to: - FSN Distributor/Importer Reply Form (BPI-WI-001-04) - FSN Customer Reply Form (BPI-WI-001-05)

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:
The manufacturer has advised the Italian distributor to collect the remaining units from the consigned hospital/s and return back to the manufacturer the units together with the remaining units left in the distributor's warehouse.

3.6	By when should the action be completed?	Estimated: 06/2024 (to be updated with follow-up based on the FSCA)
3.7	Is the FSN required to be communicated to the patient /lay user?	No. The intended users of this device are medical practitioners and not the patient itself or lay person.
3.8	If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Not applicable. Users of this device are medical practitioners only.	

4. General Information *		
4.1	FSN Type *	Removal of a device from the market.
4.2	For updated FSN, reference number and date of previous FSN	Not applicable.
4.3	For Updated FSN, key new information as follows:	
	Not applicable.	
4.4	Further advice or information already expected in follow-up FSN? *	Yes.
4.5	If follow-up FSN expected, what is the further advice expected to relate to:	
	Disposal updates of the returned units at the manufacturing facility.	
4.6	Anticipated timescale for follow-up FSN	06/2024 (to be updated based on the FSCA)
4.7	**Manufacturer information** (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Bioptimal International Pte. Ltd.
	b. Address	36 Jalan Tukang, SINGAPORE 619266
	c. Website address	www.bioptimalg.com
4.8	Is the Competent (Regulatory) Authority of the country where this FSN is applied has been informed about this communication to customers? *	To inform using this FSN (FSN24-03-001) and FSCA (FSA24-03-001).
4.9	List of attachments/appendices:	FSCA (FSA24-03-001) FSN Distributor/Importer Reply Form (BPI-WI-001-04) FSN Customer Reply Form (BPI-WI-001-05)
4.10	Name/Signature	 Francis Joey Eduave QARA Manager / QMR / PRRC

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.