Date: **10 Feb 2025**
FSN Ref: **FSN25-02-001 V01A**
FSCA Ref: **FSA25-02-001 V01**

Urgent Field Safety Notice (FSN)

Bioptimal Vascular Introducer Kit

Batch: H230200020

For Attention to:

Dr. Karmela Kopčić, DMD
Principal Coordinator for Medical Device Vigilance
Agency for Medicinal Products and Medical Devices (HALMED)
Ksaverska cesta 4, 10 000 Zagreb, CROATIA

Risk addressed by FSN:

Ruptured introducer sheath that was left inside the patient during device removal.

1. Information on Affected Devices*
1. Device Type(s)*
Brand: Bioptimal Vascular Introducer Kit **Device Name:** Introducer Kit **Common Name:** Introducer Sheath **Condition:** Supplied sterile (EO Sterilization)
2. Commercial name(s)
Bioptimal Vascular Introducer Kit
3. Unique Device Identifier(s) (UDI-DI)
08886483504738
4. Primary clinical purpose of device(s)*
Intended to assist in the introduction of temporary pacing leads, balloon catheters, closed end catheter or angiographic catheters into the vasculature.
5. Device Model/Catalogue/part number(s)*
Model ID: **CPIK 8.5F - EUROPE**
6. Software version
Not applicable.

7. Affected serial or lot number range
H230200020
8. Associated devices
No associated device or accessories supplied.

2. Reason for Field Safety Corrective Action (FSCA)*

1. Description of the product problem*
Part of the ruptured introducer sheath remained in the patient after device removal. The broken part of the introducer sheath left in the patient was surgically removed by the medical doctor.
2. Hazard giving rise to the FSCA*
Broken part of the introducer sheath that was left in the patient after catheter removal has the potential to lead to a serious incident (if severe: vessel damage, embolization, arrhythmias, tricuspid valve injury, pneumothorax, cardiac perforation) if untimely medical intervention is initiated to remove the broken part. Minor complications may include haemoptysis, hematomas, and hypertensive episodes.
3. Probability of problem arising
The occurrence level of broken/ruptured introducer sheath is O-1 [p < (1 in 100,000), p < 0.0010%] which is extremely or highly unlikely the condition will occur.
4. Predicted risk to patient/users
The risk of broken/ruptured introducer sheath left in the patient after catheter removal and its potential effects is in the Low Level (RPN: 4 = Severity: S-4 / Occurrence: O-1). The most common effects to patient are haemoptysis, hematomas, or hypertensive episodes. Potential severe effects are vessel damage, embolization, arrhythmias, tricuspid valve injury, pneumothorax, cardiac perforation, if untimely medical intervention is initiated.
5. Further information to help characterize the problem
Broken, ruptured or fractured introducer sheaths could have several causes. The most common is the application of excessive force during maneuvering or removal of the sheath in/from the patient. On some occasions when the integrity of the introducer sheath is compromised, bending or torsional force may cause it to break, rapture or fracture. This condition is exacerbated when the introducer sheath is unintentionally cut or punctured by a sharp object during the clinical procedure. As such, care should be exercised during insertion, manipulation and withdrawal of the device.
6. Background on Issue
The manufacturer received a report from our Croatian distributor of a hospital case of ruptured introducer sheath that was left inside the patient's vasculature that was subsequently surgically removed by the medical doctors. The case is reported as follows: "A Bioptimal introducer - CPIK 8.5F ruptured during placement of a catheter for hemodynamic parameter measurements – the Bioptimal TD2755ND thermodilution catheter. The ruptured part of the introducer remained in the patient (around 8 cm in length), and she was immediately moved to the operating room to have the ruptured part removal. The patient is currently in good health, but we do not yet know whether there will be any permanent health consequences." After the manufacturer's investigation, the manufacturer could not find any evidence that the ruptured introducer sheath is caused by device deficiency or abnormality on its manufacturing processes and records. Based on the results of the investigations, the manufacturer could not fully determine the actual root cause of the ruptured introducer sheath. It is suspected that the ruptured introducer sheath could have been caused by an unintentional cut or puncture by a sharp object or any other factor related to the actual clinical use. This case is considered an isolated incident by the manufacturer.

7. Other information relevant to FSCA

Based on historical data of this batch and of its base model (CPIK 8.5F or Introducer Kit 8.5F) from other lots, **there is no similar case (broken/ruptured introducer sheath during vasculature removal) that occurred from the period: Jan 2023 - Dec 2024**. It is noted that Introducer Kit batch H230200020 was manufactured in Feb 2023. The selected period of review started from 2023 to capture the market distribution of the affected lot (H230200020), to determine if after the market distribution, any similar cases occurred previously.

This is an isolated case and a localized event.

3. Type of Action to mitigate the risk*

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 Introducer Kit (Lot: H230200020) left in their inventories. If there is, quarantine the remaining units, feedback the remaining quantities to the distributor and dispose according to the hospital disposal protocol of hazardous waste. If in-house hospital disposal is not feasible, return to distributor for subsequent disposal.

2. By when should the action be completed?

As soon as the user (hospital administrator) becomes aware of this FSN.

3. Particular considerations for:

Is follow-up of patients or review of patients' previous results recommended?

Bioptimal Vascular Introducer Kit is a single-use, disposable medical device and is not intended to be re-used or re-sterilized. Broken or ruptured part of the introducer sheath is detectable during device prechecks, pre-operative, during medical procedure or during device removal from the patient. If such event occurs that the broken or ruptured part of the introducer sheath is left in the patient's vasculature, the medical practitioner should initiate timely medical intervention and monitor patient health post-operative. If any adverse event or serious adverse event occurred post-operative, please report to the distributor or to the manufacturer at ra-bpi@bioptimalg.com.

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)

5. **Action Being Taken by the Manufacturer**

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

The manufacturer advised the distributors to inform respective hospitals where the Introducer Kit with Lot: H230200020 was distributed, to dispose this lot within the hospital facilities in accordance with the hospital disposal protocols.
6. By when should the action be completed? Estimated: 30 May 2025 (1st disposal)
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 a lay person.
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*	
1. FSN Type*	Disposal of a device from the market
2. For updated FSN, reference number and date of previous FSN	Not applicable.
3. For Updated FSN, key new information as follows: Not applicable.	
4. Further advice or information already expected in follow-up FSN? *	Yes.
5. If follow-up FSN expected, what is the further advice expected to relate to: Disposal updates of the hospitals (or the distributor) on the affected lot, if any inventories left.	
6. Anticipated timescale for follow-up FSN	06 Jun 2025
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
8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * To inform using this FSN (FSN25-02-001) and FSCA (FSA25-02-001).	
9. List of attachments/ appendices:	FSCA (FSA25-02-001) FSN Distributor/Importer Reply Form (BPI-WI-001-04) FSN Customer Reply Form (BPI-WI-001-05)
10. Name/Signature	Sign here.  Dr. Wu Di, MD, PhD Medical Affairs

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.