FSN Ref: 1035166-08/25/2024-001-R FSCA Ref: 1035166-08/25/2024-001-R

Date: 25 Aug 2024

# Urgent Field Safety Notice (FSN)
# Axillary Insertion Introducer and Introducer Kits - Risk of Infection

For Attention of*: All Axillary Insertion Introducer and Introducer Kit users involved in preparation and use of these devices

| Contact details of local representative (name, e-mail, telephone, address etc.) * |
| --- |
| **MDSS GmbH Schiffgraben 41, 30175 Hannover, Germany**<br>**Ph: (+49)-511-6262-8630**<br>**Email: info@mdss.com / DL-PHB-Regulatory@integer.net** |

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## Axillary Insertion Introducer and Introducer Kits - Risk of Infection

| | 1. Information on Affected Devices* |
|---|---|
| 1 | 1. Device Type(s)* |
| | Axillary Insertion Introducers and Introducer Kits |
| 1 | 2. Commercial name(s) |
| | Axillary Insertion Introducer |
| 1 | 3. Unique Device Identifier(s) (UDI-DI) |
| | Abiomed Axillary 23F S6CM SV PSET (Abiomed Model No.: 0052-0011-EU // Oscor Model No.: AB-81-006Z-B ) **GTIN:** 008856720097 |
| 1 | 4. Primary clinical purpose of device(s)* |
| | The Introducer Sheaths are intended for the introduction of pacing leads or catheters into the body. |
| 1 | 5. Device Model/Catalogue/part number(s)* |
| | **Abiomed Model No.: 0052-0011-EU // Oscor Model No.: AB-81-006Z-B** |
| 1 | 6. Software version |
| | N/A |
| 1 | 7. Affected serial or lot number range |
| | **1554119; 1588790; 1602807; 1605010; 1621646; 1638352; 1652405; 1668195; 1672375; 1680301; 1686703; 1702341; 1706967; 1713870; 1717202; 1729155; 1745030** |
| 1 | 8. Associated devices |
| | The Introducer Sheaths are intended for the introduction of pacing leads or catheters into the body. Abiomed sells the Introducer Sheaths both as stand-alone devices and in combination with Abiomed's Impella Pumps ("Impella Introducer Kits"). Per a dually signed and executed Supply Agreement between entities dated January 13, 2020, Oscor Inc. is the Legal Manufacturer of the Introducer Sheaths sold separately from the Abiomed Impella Introducer Kits.<br><br>Abiomed's affiliate, Abiomed Europe GmbH Neuenhofer Weg 3, 52074 Aachen ("Abiomed Europe"), is the acting Importer of the Oscor Inc. Introducer Sheaths sold separately from the Abiomed Impella Introducer Kits. |

| | 2 Reason for Field Safety Corrective Action (FSCA)* |
|---|---|
| 2 | 1. Description of the product problem* |
| | The outer pouch (breather bag) may have damage resulting in breach of the introducer sheath outer pouch. The outer pouch is the validated sterile barrier for the PETG tray and non-tray version of the introducer sheath product. |
| 2 | 2. Hazard giving rise to the FSCA* |
| | Sterility may be compromised on packaged Introducer Kits with identified breather bag defects; therefore, increasing patient risk of infection during the procedure. Per the Instructions for Use (IFU) packaged with each device: "Device is supplied sterile. Do not use if package has been previously opened or damaged." |
| 2 | 3. Probability of problem arising |
| | No change in rate of infection or signals have been identified, with a worldwide monthly infection complaint rate between 0% and 0.38%. The monthly complaint rate in the United States is between 0% and 0.17%. No field complaints have been received by Oscor Inc. in the last 3 years globally for similar defects or similar patient harms, including infection. It is unlikely that use of, or exposure to the product under review will cause adverse health |

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| | consequences as all Oscor Inc. Axillary Insertion Introducer Sheaths and Introducer Kit configurations are packaged in a double sterile barrier (i.e., sealed tray and breather bag) while the Axillary Insertion Introducer devices are packaged in an inner and outer Tyvek/Mylar pouch. All products are then sterilized. The probability of patient infection is unlikely: the devices would remain sterile within the inner sealed tray if the outer breather bag were breached or damaged. |
| 2 | 4. Predicted risk to patient/users |
| | The risk associated with this event is low as the probability of adverse health consequences is unlikely to cause any adverse event to the patient. Per the unambiguous Instructions for Use, a damaged package should not be used. The IFU states "Device is supplied sterile. Do not use if package has been previously opened or damaged." The risk of using a device from a damaged package could result in patient infection, which is medically reversible and/or classified as transient adverse health consequences. |
| 2 | 5. Further information to help characterise the problem |
| | There has been no recent observation of changes in trends or severity; rates remain stable over the past several years. |
| 2 | 6. Background on Issue |
| | During 100% inspection of the product, a breech to the integrity of the primary packaging level (i.e., outer breather bag) was identified. 295 units out of 54,332 inspected units had an identified packaging defect. Further investigation identified damaged sterilization baskets as the primary root cause of damage to the Introducer devices. The packaging damage was confirmed to be isolated to the outer pouch that both the trayed and non-trayed Introducers are sealed in. |
| 2 | 7. Other information relevant to FSCA |
| | N/A |

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| | **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<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br>☐ Other ☐ None<br>Provide further details of the action(s) identified. | |
| 3 | 2. By when should the action be completed? | Recall completion suggested four (4) months from initiation (est. 30 Dec 2024). In case you have units in stock, Abiomed Europe GmbH will contact you to coordinate replacement. Ensure contact information is provided in the Customer Reply Form below. |
| 3 | Is follow-up of patients or review of patients' previous results recommended?<br>No<br><br>The Oscor Inc. Introducer Sheaths are non-implantable devices. The Introducers are categorized according to ISO 10993-1:2018 as externally communicating devices with limited contact to circulating blood. The clinical use scenario for the | |

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| | devices indicates that an average length of contact is approximately eight (8) hours (i.e., cumulative use) with a worst-case scenario not exceeding 24 hours. | |
| 3 | 3. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |
| **3** | **4. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br><br>Oscor Inc. proposes four (4) months to achieve recall completion in accordance with the Introducer Sheath recall strategy. Status updates will be provided to Oscor Inc's contracted European Authorized Representative, Notified Body and corresponding Competent Authorities mid-way through the reconciliation activities and at recall closure. Interim status reports will also be made available upon request, as required. With patient safety as our main priority, Abiomed Europe will complete at least three (3) documented attempts though various communication mechanisms to contact consignees. The quantity of products returned by or destroyed at consignee locations will be accounted for and documented in the final report. Oscor Inc. intends to complete reconciliation activities with a percentage of 100% of the affected 165 consignees contacted in accordance with the recall strategy. | |
| 3 | 5. By when should the action be completed? | Recall completion suggested four (4) months from initiation (est. 30 Dec 2024). In case you have units in stock, Abiomed Europe GmbH will contact you to coordinate replacement. Ensure contact information is provided in the Customer Reply Form below. |
| 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? | |
| | No Not appended to this FSN | |

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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New |
| 4. | 2. For updated FSN, reference number and date of previous FSN | N/A |
| 4. | **3.** For Updated FSN, key new information as follows: | |
| | N/A | |
| 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: | |
| | N/A | |

| | | |
|---|---|---|
| 4 | 6. Anticipated timescale for follow-up FSN | N/A |
| 4. | 7. Manufacturer information: US-MF-000005944<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Only necessary if not evident on letter-head. |
| | b. Address | Only necessary if not evident on letter-head. |
| | c. Website address | Only necessary if not evident on letter-head. |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | If extensive consider providing web-link instead. |
| 4. | 10. Name/Signature | **Laura Medlin**<br>**Manager Regulatory 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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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.

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# Urgent Field Safety Notice (FSN)
# Axillary Insertion Introducer and Introducer Kits - Risk of Infection
# Customer Reply Form

| 1. Field Safety Notice (FSN) information | |
|---|---|
| FSN Reference number* | 1035166-08/25/2024-001-R |
| FSN Date* | 08/25/2024 |
| Product/ Device name* | Axillary Insertion Introducer and Introducer Kits |
| Product Code(s) | Abiomed Model No.: 0052-0011-EU<br>Oscor Model No.: AB-81-006Z-B |
| Lot# | **1554119; 1588790; 1602807; 1605010; 1621646; 1638352; 1652405; 1668195; 1672375; 1680301; 1686703; 1702341; 1706967; 1713870; 1717202; 1729155; 1745030** |

| 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. Customer action undertaken on behalf of Healthcare Organisation | | |
|---|---|---|
| ☐ | I confirm receipt of the Field Safety Notice and that I read and understood its content. * | Complete or enter N/A |
| ☐ | I confirm this is the number of units in our stock and will be returned as instructed* | Enter the number of units in your stock. State “0” or “NONE” if applicable. |
| ☐ | I performed all actions requested by the FSN. | Complete or enter N/A |
| ☐ | The information and required actions have been brought to the attention of all relevant users. | Complete or enter N/A |
| ☐ | I have a query please contact me | Enter contact details if different from above and brief description of query |
| Print Name* | | |
| Signature* | | |
| Date* | | |

| 4. Return acknowledgement to sender | |
|---|---|
| Email | EUFSCA@abiomed.com |
| Customer Helpline | +800 0 22 466 33 |
| Postal Address | Abiomed Europe GmbH<br>Karsten Wallbrück / Max Eisen / Mariano Santos<br>Neuenofer Weg 3<br>52074 Aachen<br>Germany |
| Web Portal | www.abiomed.eu; www.heartrecovery.eu |
| Deadline for returning the customer reply form* | **Please return within 7 working 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.

OSCOR INC. | AN INTEGER COMPANY
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