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March 26, 2025

URGENT: MEDICAL DEVICE RECALL
ON-X INSTRUMENT KIT

Hospital Serdang
(Hospital Sultan Idris Shah)
Jalan Puchong,
43000 Kajang, Selangor

Dear Customer,

The purpose of this letter is to advise you that Artivion, Inc. is voluntarily recalling the On-X Instrument Kit. The On-X Instrument Kit is intended to be used to facilitate the implantation of On-X Prosthetic Heart Valves and On-X Ascending Aortic Prostheses only.

Note: Patient injury is unlikely as the device failure is not expected.

The Artivion Quality Department recently became aware of the fact that the On-X Instrument Kit includes two 25mm sizers and does not contain a 21mm sizer.

- Artivion, Inc. is not aware of any product failures.
- No adverse incidents have been reported to date.

Patient injury is unlikely as device failure is not expected. The sizer must be removed from the mislabeled bag prior to sterilization, and the mislabeled bag would not be present at the time of a procedure. For this specific issue, there is minimal risk to the patient as the Design History File review documents that the sizers met all other release specifications. However, there may be a slight delay in the surgery during which the surgeon may potentially need a different modality to estimate the correct valve size. This delay would be negligible and would not likely have a significant clinical impact to the patient.

No new health risks have been identified as a result of this event and the resultant failure modes. Controls are in place to ensure these risks are reduced as far as possible and to acceptable levels; the applicable failure modes have risk ranking calculations defined as “Low.”

It is essential that Artivion, Inc. confirms your receipt of this notification. **Please complete and return the third page of this letter, Medical Device Recall Response, affirming that you have (1) received this notification and (2) completed the instructions to correct the situation.**

Product and Distribution Information Table					
Product Name	Manufacturer’s Product Number	Lot Number	Manufacturing/Distribution Dates	Expiration Date	Quantity
On-X Instrument Kit	ONXI3-CK	57-00-A11993	Date of Manufacture: February 17, 2025 Distribution Date: February 27, 2025	N/A	1

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Artivion, Inc. will provide the 21mm sizer for inclusion into the On-X Instrument Kit.

We appreciate your assistance and prompt attention to this matter. If you have any questions or require clarification, please contact Rochelle Maney, Vice President, Quality, at 678-290-4531.

Sincerely,

Jennifer L. Woods, RN

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MEDICAL DEVICE RECALL RETURN RESPONSE
Acknowledgement and Receipt Form
Response is required

Hospital Sultan Idris Shah Serdang
Jalan Puchong,
43000 Kajang, Selangor

On-X Instrument Kit

Please distribute this information to the appropriate personnel at your facility including surgeons who may have received the product which is the subject of this recall notice.

Lot number: 57-00-A11993

I have read and understand the recall instructions provided in the letter.
Yes _ No _

Please return the instrument kit to the distributor, Medi-life. A 21mm sizer has been provided to the distributor and will be placed in the On-X Instrument Kit prior to use.

Affected product information:

Product Name, UDI	Manufacturer's Product Number	Lot Number shipped to distributor	Quantity in inventory
On-X Instrument Kit, 00851788001730	ONXI3-CK	57-00-A11993	1

Return Response Box:

Please provide any additional information, if applicable.

PLEASE RETURN COMPLETED RESPONSE FORM TO:

FieldAssurance@artivion.com