Johnson&Johnson MedTech

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URGENT MEDICAL DEVICE RECALL (REMOVAL)

Product Code	Product Description	Impacted Serial Numbers
0048-0003	Impella CP Set with SmartAssist	613525, 644314, 645428, 644591, 672986, 673252, 677223

PLEASE DISTRIBUTE THIS INFORMATION TO APPROPRIATE PERSONNEL AT YOUR FACILITY WHO MAY USE THE PRODUCT THAT IS THE SUBJECT OF THIS NOTICE

Dear Valued Customer,

Abiomed, Inc. has issued a voluntary device recall (removal) of specific distributed units of Impella CP with SmartAssist (Product Code: 0048-0003).

Our records show that your facility received one of the devices subject to this recall. Please carefully review this notice for the steps that you should take to respond to this medical device recall (removal).

REASON FOR NOTIFICATION:

Abiomed has identified seven (7) specific distributed units of Impella CP with SmartAssist that do not meet design specifications. This out-of-specification may result in low purge pressure events from the onset of the case.

POTENTIAL PATIENT IMPACT:

Exposure to the low purge pressure occurrence may result in persistent low purge pressure alarms and, in some cases, interruption or loss of mechanical circulatory support. Loss of support may lead to an acute change in care when the pump is exchanged, hypotension, end-organ hypoperfusion, and risk of death if not promptly corrected.

A review of global complaints from January 1, 2024 to April 12, 2026 identified the issue in 0.01% of cases (12 complaints reported out of 107,277 cases). The complaints review determined that there has been one (1) patient death where the association of the above-described issue could not be excluded due to pump exchange. There have been an additional three (3) cases where the failure resulted in the user choosing to exchange the pump, which is considered a medical intervention.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Review all Impella CP Sets within inventory and if your Impella CP Set is identified as impacted per Attachment 1 – Product Identification Tool, please set aside and quarantine.
- A return shipment label has been provided by Sedgwick along with this letter. If impacted product is identified, utilize the return shipment label to initiate the return. If there are any questions on the return process and / or the need for a new label, reach out to Sedgwick at (888) 759-6907.
- Review, complete all fields, sign, and return the business reply form (BRF) provided to impacted customers and send it to Abiomed4495@sedgwick.com.
- Upon receipt of returned product and completed BRF, Abiomed will provide a copy of a credit memo for the amount returned.
- Forward this notice to anyone in your facility that needs to be informed (i.e., those who manage, transport, store, stock, or use the subject products).

- If any of the subject products have been forwarded to another facility, contact that facility and provide them with this notice.
- Post a copy of this notice in a visible area for awareness.
- As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported to the FDA's MedWatch Adverse Event Reporting Program as per below instructions:
    - Complete and submit the report online: www.fda.gov/medwatch/report.htm or
    - Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

At Abiomed, our priority is to our customers and their patients, and that includes the safe and effective use of our products. If you have questions or concerns regarding this notice, please contact OneMD-Field-Actions@its.jnj.com or your local clinical field staff. Thank you for your cooperation.

Attachments:
Attachment 1 – Product Identification Tool

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Attachment 1 – Product Identification Tool

The subject devices have a label on the outer box as seen below. To identify if your units are affected by this field action, refer to the serial number (SN) on the label (red box) and check if the serial number matches the serial number(s) listed below.

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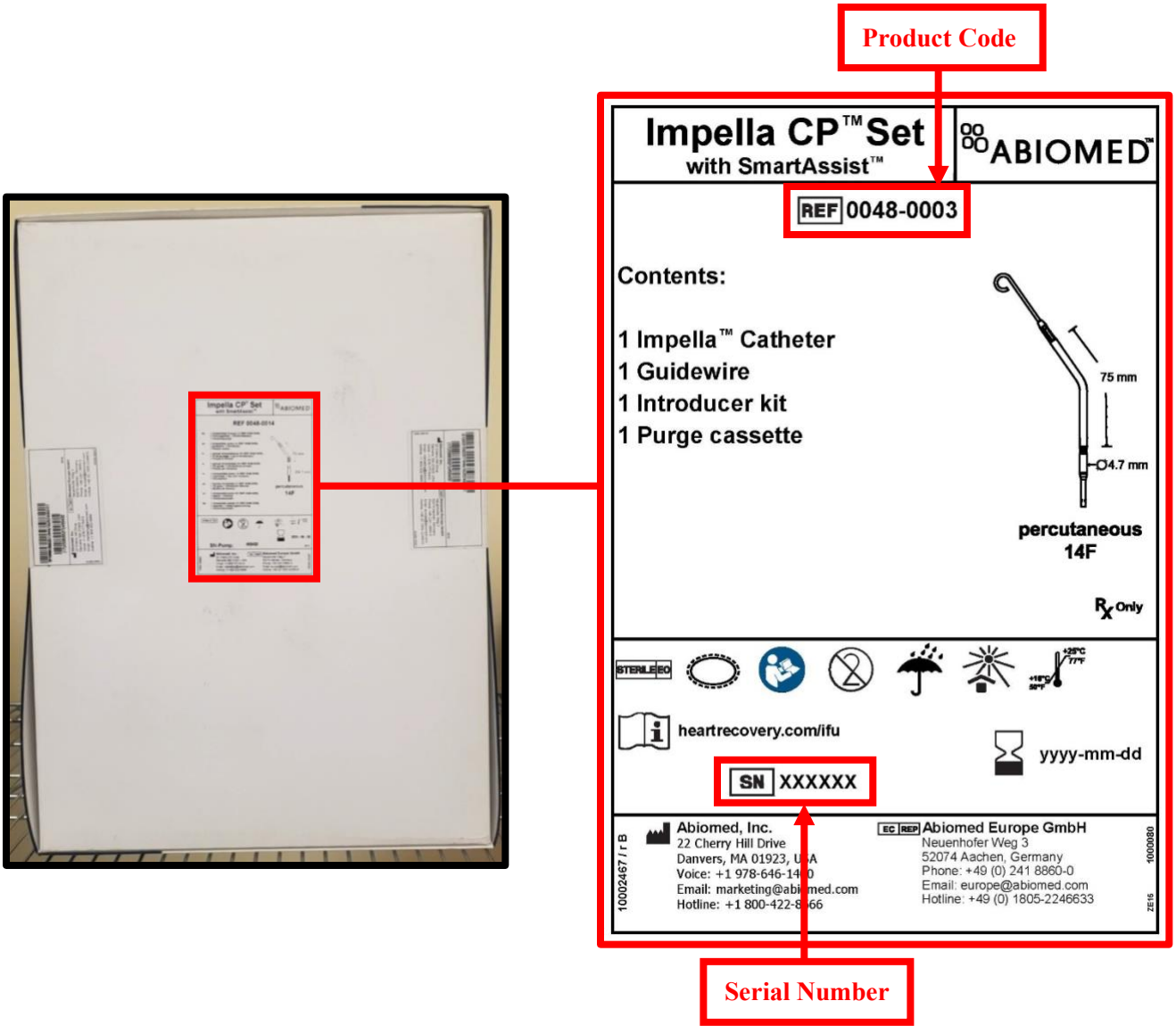

If your product is identified to be affected product, please quarantine and segregate the product for return.