

URGENT MEDICAL DEVICE RECALL (REMOVAL)

Product Code	Product Description
1000434	14 Fr x 13 cm Low Profile Introducer Kit for Impella CP
1000435	14 Fr x 25 cm Low Profile Introducer Kit for Impella CP
1000413	Impella CP Set with SmartAssist (10 th Generation)

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 14Fr Low Profile Introducer Kits due to complaints related to thrombus formation during prolonged use of the introducer. These complaints were identified as part of Abiomed's post market surveillance process.

This recall impacts six (6) customers within the United States for the product codes listed above.

Our records show that your facility received one or more units 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 a higher rate of complaints than expected related to thrombus formation on the 14Fr Low Profile Introducer Kit during prolonged use of the introducer. The 14Fr Low Profile Introducer Kit (Product codes 1000434 & 1000435) is only compatible with Impella CP 10th generation (Product code 1000413) and therefore the pump set is included in the removal. This recall does not involve any other generation of Impella CP that is commercially available.

POTENTIAL PATIENT IMPACT:

If thrombus formation were to occur, the user may encounter difficulty aspirating the sheath sidearm or valve and may observe thrombus in the syringe or sidearm post aspiration or around the valve post CP pump removal.

Thrombus formation within the indwelling sheath lumen and / or the annular gap between the sheath inner diameter and the catheter outer diameter during prolonged support may result in disruption of blood flow near the access site. If thrombus is dislodged during ongoing support, manipulation, or removal, this may result in peripheral vessel obstruction with ischemia requiring prompt clinical assessment and intervention to restore perfusion. Under less common circumstances, exposure could progress to irreversible vascular occlusion with potential for permanent impairment if not corrected.

A review of global complaints from December 1, 2025, to May 1, 2026, identified thrombus-related or potentially thrombus-related complaints in 12.6% of cases that used the 14Fr Low Profile Introducer Kit (15 complaints reported). The complaints review determined there have been no patient deaths directly caused by thrombus. However, there have been three (3) cases of serious injury possibly related to thrombus.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

**This recall impacts six (6) customers within the
United States for the product codes listed within Attachment 1.**

- Review your inventory for the 14Fr Low Profile Introducer Kit as directed per Attachment 1 – Product Identification Tool. If impacted product is identified, please set aside and quarantine for return.
- 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 (877) 643-8438.
- Review, complete all fields, sign, and return the attached business response form (BRF) (refer to Attachment 1) to Abiomed2981@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.

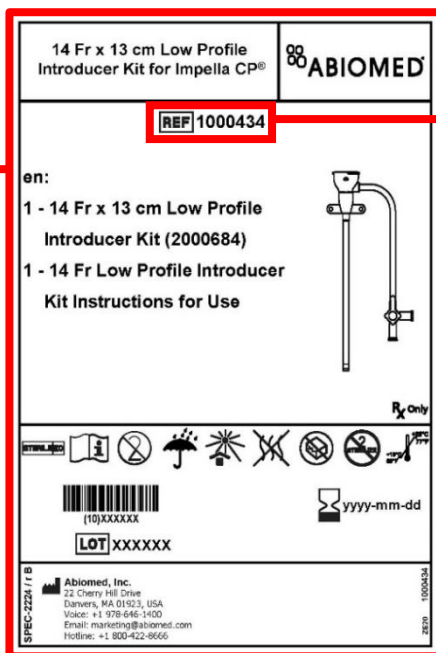
Attachments:

Attachment 1 – Product Identification Tool

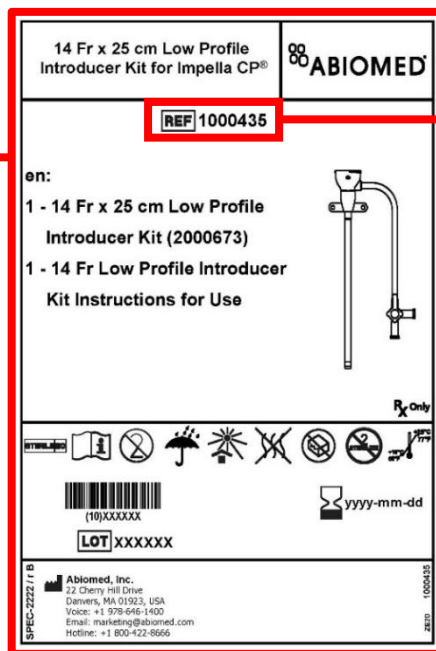
Attachment 1 – Product Identification Tool

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 product code (REF) on the label (red box) and check if the REF number matches the product code(s) listed below.

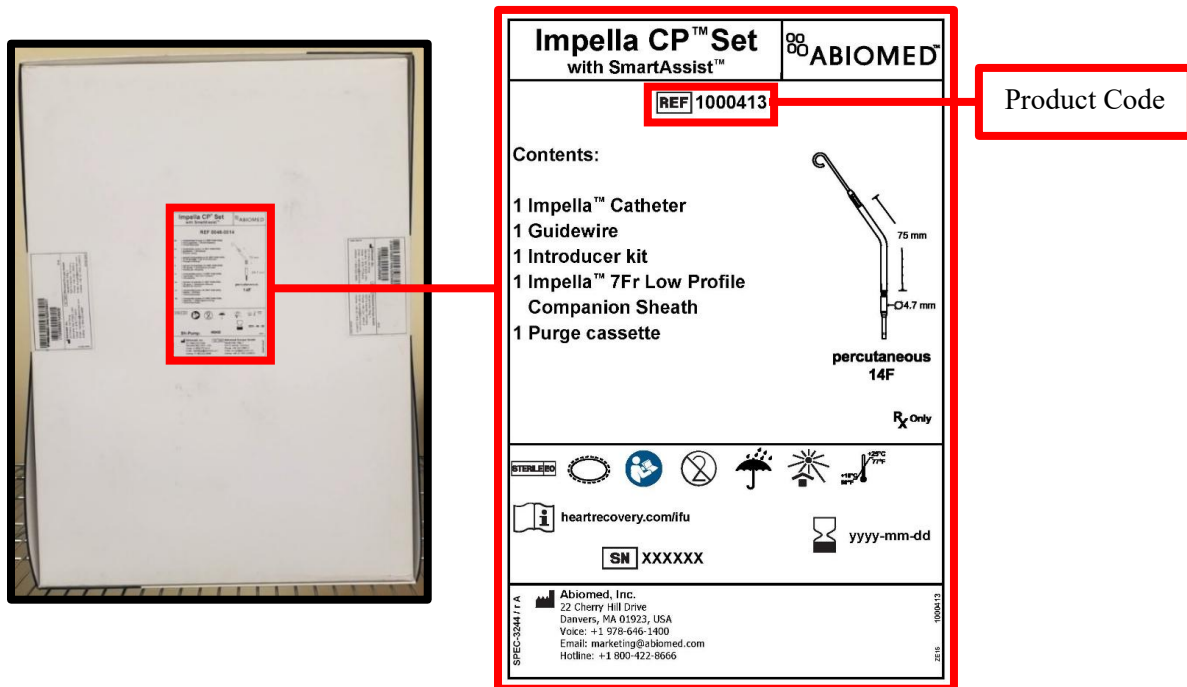
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Product Code



Product Code



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