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URGENT MEDICAL DEVICE RECALL (CORRECTION)

Introducer for Impella (*sold within Impella Pump Sets and Individually Packaged*)

Table for Impacted US Products

Information for Impacted Introducers in Pump Sets					
Introducer Product Code	Introducer Product Description	Pump Set Product Code	Pump Set GTIN	Pump Set Description	Batch Numbers in Scope
2000342	Kit, 23Fr Introducer, 11cm, Sterile	1000323	00813502012811	Impella RP Flex with SmartAssist Set	All current Pump Set batches in field
0052-3021	Introducer Kit, 23Fr	0046-0035	00813502011869	Impella RP Set with SmartAssist	
0052-3006	Axillary Insertion Introducer	1000100	00813502012828	Impella 5.5 Set with SmartAssist	
0052-3046	Kit, 14Fr Introducer, 13cm&25cm, Sterile	0048-0003	00813502012279 00813502011876	Impella CP Set	
Information for Impacted Introducers in Single Sale Kits					
Introducer Product Code	Introducer Product Description	Single Sale Product Code	Single Sale GTIN	Single Sale Kit Description	Batch Numbers in Scope
2000342	Kit, 23Fr Introducer, 11cm, Sterile	1000441	00813502012910	Introducer Kit 23 Fr, 11 cm	All current Single Sale batches in field
0052-3021	Introducer Kit, 23Fr	0052-0002	00813502011319	Introducer Kit 23 Fr for Impella RP	
0052-3006	Axillary Insertion Introducer	0052-0011	00813502010015	Axillary Insertion Kit	
0052-3046	Kit, 14Fr Introducer, 13cm&25cm, Sterile	1000550	00813502013474	Impella CP Introducer Kit 14 Fr, 13 and 25 cm	
0052-3052	Kit, 14Fr Introducer, 13cm, Long Taper	0052-0038	00813502011708 00813502012729	Impella CP Introducer Kit 14 Fr, 13 cm	
0052-3053	Kit, 14Fr Introducer, 25cm, Long Taper	0052-0039	00813502011715 00813502012736	Impella CP Introducer Kit 14 Fr, 25 cm	

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. and its manufacturing partner, Oscor (an Integer owned company), have initiated a voluntary device recall (correction) for all currently distributed Introducer Kits that are used with Impella heart pumps to notify customers of a potential for unexpected introducer sheath leakage from the sidearm and under the sheath cap and along the hub score lines in the hub region. Introducer leakage may impair hemostasis and increase the risk of access-site bleeding, particularly in anticoagulated patients. This information is provided to support appropriate clinical awareness, monitoring, and patient support as needed. The identified defect does not affect any other packaged products within the pump set. **Product removal is not required, and hospitals may continue to use existing inventory**.

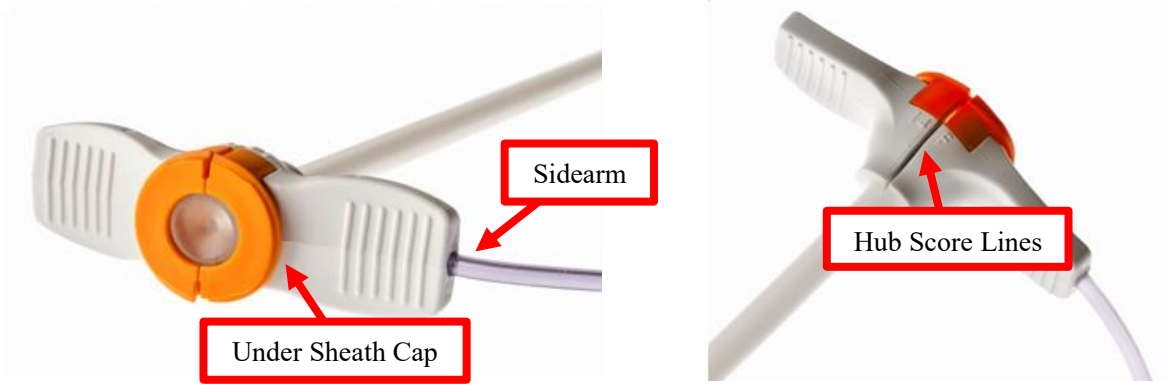
REASON FOR MEDICAL DEVICE RECALL (CORRECTION):

Abiomed has identified a potential for introducer sheath leakage from the sidearm and under the sheath cap and along the hub score lines in the hub region, identified in 14Fr and 23Fr Introducers. The unexpected leakage in these specified locations is due to certain manufacturing related issues, which increase the risk of access-site bleeding. Abiomed, in collaboration with its contract

manufacturer (Oscor), has initiated containment, correction, and corrective/preventative action activities to address the issue.

If this issue were to occur, the user would see blood loss at the sidearm and hub of the introducer sheath as shown below on the 14Fr introducers. Leak locations are the same for both 14Fr and 23Fr introducers.

Areas where users may see blood loss from the sidearm and hub region:



Abiomed, in collaboration with its manufacturing partner (Oscor), has implemented additional manufacturing controls and inspection measures to mitigate the identified leakage condition for future lots that are distributed. These additional controls and inspection measures do not apply to current lots in the field. In parallel, a comprehensive investigation is underway to determine root cause and to evaluate additional potential longer-term improvements to manufacturing processes and product design.

POTENTIAL PATIENT IMPACT:

Introducer leakage may reasonably be expected to result in access-site bleeding at the time of sheath insertion or early device manipulation. In certain instances, this would be expected to cause blood loss requiring medical intervention, such as device exchange or removal, manual compression, and, in some cases, blood transfusion.

In unusual circumstances, particularly patients undergoing large bore vascular access with systemic anticoagulation or limited physiologic reserve (with a bleed that went undetected), exposure to this hazard may result in life-threatening hemorrhage and hemodynamic instability which may lead to an outcome of death.

A review of global Abiomed complaints from February 1, 2023 to April 22, 2026 found Introducer leaking in 0.05% of cases (76 complaints reported).

The complaints review determined that no patient deaths are attributable to the issue under investigation. However, three complaints have corresponding MDRs reporting patient deaths. Abiomed has received eight reports of major bleeding which is a serious injury and have been reported as such.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Product removal is not required, and hospitals may continue to use existing inventory. Physicians should continue to use appropriate clinical awareness, monitoring, and patient support as needed. Consider a device exchange or using the repositioning sheath to minimize blood loss if potential leakage from the sidearm and under the sheath cap and along the hub score lines in the hub region is observed.

- Review the information within this letter and 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.