Johnson&Johnson MedTech

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URGENT MEDICAL DEVICE RECALL (CORRECTION)

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

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

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, US	All current unexpired Pump Set batches in field
0052-3021	Introducer Kit, 23Fr	**0046-0035**	00813502011869	Impella RP Set with SmartAssist, US	
0052-3006	Axillary Insertion Introducer	**1000100**	00813502012828	Impella 5.5 Set with SmartAssist, US	
0052-3046	Kit, 14Fr Introducer, 13cm&25cm, Sterile	**0048-0003**	00813502012279 00813502011876	Impella CP Set, US	
0052-3046	Kit, 14Fr Introducer, 13cm&25cm, Sterile	**0048-0014**	04260113630280 00813502012873 00813502013344 00813502013368	Impella CPSA Set	
0052-3025	Oscor Intro Kit, 14Fr x 13 and 25 cm	**0048-0014**	00813502011944	Impella CPSA Set, EU	
0052-3046	Kit, 14Fr Introducer, 13cm&25cm, Sterile	**0048-0044**	00813502012200	Impella CPSA Set, CA	
0052-3025-JP	Oscor Intro Kit, 14Fr x 13 and 25 cm-JP	**0048-0024-JP**	00813502011609	Impella CPSA Set, JP	
0052-3006-JP	Introducer Kit, 23Fr Short, Sterile, JP	**1000459**	00813502013054	Impella 5.5 SA S2 Set, JP	
0052-3006	Axillary Insertion Introducer	**1000482**	00813502013276 00813502013351	Impella 5.5 SA S2 Set	
0052-3021	Introducer Kit, 23 Fr, w/Hlx Vlv Sterile	**0046-0011**	04260113630273	Impella RP Pump Set, EU	
0052-3006	Axillary Insertion Introducer	**1000551**	00813502013375	Impella 5.5 SA S2 Set, CA	
0052-3006	Axillary Insertion Introducer	**2000193**	00813502013757	Impella 5.5 SA S2 Set, TW	
0052-3006	Axillary Insertion Introducer	**0550-0004**	00813502010466	Impella 5.5 SA Set, CA	
0052-3006	Axillary Insertion Introducer	**0550-0002**	00813502011630	Impella 5.5 SA Set, EU	
0052-3006-JP	00813502011326	**1000211**	00813502012453	Impella 5.5 SA Set, JP	

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0052-3006	Axillary Insertion Introducer	**005060**	04260113630174	Impella 5.0 IMC Pump Set EU	
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 unexpired 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**	00813502012729 00813502011708	Impella CP Introducer Kit 14 Fr, 13 cm	
0052-3053	Kit, 14Fr Introducer, 25cm, Long Taper	**0052-0039**	00813502012736 00813502011715	Impella CP Introducer Kit 14 Fr, 25 cm	
0052-3025-JP	Oscor Intro Kit, 14Fr x 13 and 25 cm-JP	**0052-0023-JP**	00813502011449	Intro Kit, 14Fr x 13 and 25 cm, PKGD, JP	
0052-3021	Introducer Kit, 23F, Pkgd, EU	**0052-0002-EU**	00813502010572	Introducer Kit, 23F, Pkgd, EU	
0052-3006	Axillary Insertion Introducer	**0052-0011-EU**	00813502010565	Axillary Insertion Kit, PKGD, EU	
0052-3006-JP	Introducer Kit, 23Fr Short, Sterile, JP	**0052-0011-JP**	00813502011340	Insertion Kit, Pkgd, Jp	
0052-3006	Axillary Insertion Introducer	**0052-0011-CA**	00813502010602	Axillary Insertion Kit, Pkgd, CA	
0052-3006	Axillary Insertion Introducer	**1000362**	00813502012934	5.5 Accessories AU	

June 11, 2026

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.**

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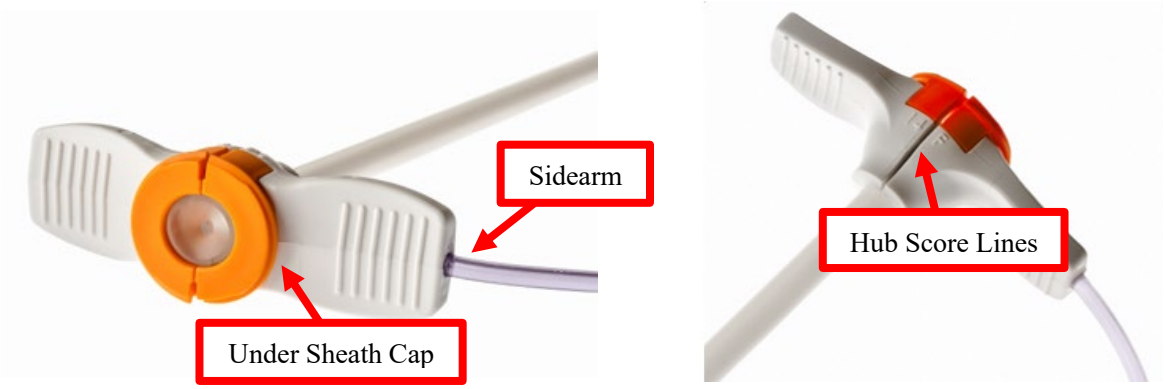
REASON FOR NOTIFICATION:

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:

Patients without alternate mechanical support in place could be at increased risk for serious injury or 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

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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, complete all fields, sign, and return the attached business response form (BRF) (refer to Attachment 1) to your local Abiomed representative.
- 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 according to your procedures and applicable regulatory requirements.

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 your local clinical field staff. Thank you for your cooperation.

Attachments:
Attachment 1 – Business Reply Form

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Attachment 1 – Business Reply Form (BRF)

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0052-3006-JP	00813502011326	**1000211**	00813502012453	Impella 5.5 SA Set, JP	
0052-3006	Axillary Insertion Introducer	**005060**	04260113630174	Impella 5.0 IMC Pump Set EU	

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0052-3006	Axillary Insertion Introducer	**1000362**	00813502012934	5.5 Accessories AU	

Please complete this Business Reply Form **within 3 business days upon receipt of the notification** and return this form to your local Abiomed representative.

By signing this form, I am confirming that I have read and understand the information provided in this letter and actions were taken appropriately.

Acknowledgement Signature		**Date**	
Print Name		**Telephone**	
Account Name & Address			
Email			
Comments:			