

**URGENT MEDICAL DEVICE RECALL (REMOVAL)**

**Products Impacted:**

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

**Axillary Introducer Kits**

Dear Valued Customer,

At Abiomed, Inc. (“Abiomed”), our first priority is to our patients, including the safe and effective use of our products.

Abiomed has initiated a voluntary medical device recall (removal) of specific distributed lots of Introducer Kits that are used with the Impella. During inspection of incoming product, we found a hole(s) to the outer pouch of the Introducer Kits (both trayed and non-trayed) in <0.6% of all that was received. This type of packaging damage may compromise the sterile barrier of the Introducer Kits. There have been no reported complaints for this type of packaging damage related to this issue. This type of packaging damage found is isolated to the outer pouch which is the sterile barrier for the Introducer Kit. The identified defect does not affect any other packaged products within the pump set.

**INTENDED USE**

Introducer Kits are intended for the introduction of the Impella Catheter into the body.

**REASON FOR MEDICAL DEVICE RECALL (REMOVAL)**

Sterility cannot be confirmed on packaged Introducer Kits with this type of packaging damage.

**POTENTIAL PATIENT IMPACT:**

Non-sterile product exposes patients to the possibility of the introduction of micro-organisms into the vasculature and/or access site, leading to an infectious process, bacteremia or sepsis.

**ACTIONS RELATED TO THIS RECALL (REMOVAL)**

**EFFECTIVE IMMEDIATELY – QUARANTINE PRODUCT ASSOCIATED WITH THE BATCH / LOT NUMBERS IN SCOPE.**

**DO NOT USE THE FOLLOWING PRODUCT CODES WITHOUT REFERING TO IMPORTANT INFORMATION AND ACTIONS REQUIRED.**

Introducer Part Number(s)	Part Description(s)	GTIN / UDI-DI	Contained in Pump Set	Batch Numbers In-Scope
0052-3046	Kit, 14Fr Introducer, 13cm&25cm, Sterile	N/A	Impella CP with SmartAssist	Pump Set Batch Numbers ≤ 2024391158  (2024391159 and above are NOT in scope)
0052-3025	Oscor Intro Kit, 14Fr x 13 and 25 cm	N/A	Impella CP with SmartAssist	
0052-3025	Oscor Introducer Kit, 14Fr x 13cm	N/A	Impella CP	
2000342	Kit, 23Fr Introducer, 11cm, Sterile	N/A	Impella RP Flex with SmartAssist	
0052-3006	Axillary Insertion Introducer	00885672009755	Impella 5.0 Impella 5.5 with SmartAssist Impella BTR	
0052-3021	Introducer Kit, 23 Fr, w/Hlx Vlv Sterile	00885672009786	Impella RP Impella RP with SmartAssist	
Introducer Part Number(s)	Part Description(s)	GTIN / UDI-DI	Single Sale Part Numbers	Lot Numbers In-Scope
0052-3014	Oscor Introducer Kit, 14Fr x Short	N/A	0052-0001, 0052-0016	Individual Package Lot Numbers ≤1764215  (1764216 and above are NOT in scope)
0052-3015	Oscor Introducer Kit, 14Fr x Long	N/A	0052-0017	
0052-3052	Kit, 14Fr Introducer, 13cm, Long Taper	N/A	0052-0038	
0052-3053	Kit, 14Fr Introducer, 25cm, Long Taper	N/A	0052-0039	
0052-3006	Axillary Insertion Introducer	00885672009755	0052-0011	
0052-3021	Introducer Kit, 23 Fr, w/Hlx Vlv Sterile	00885672009786	0052-0002	
0052-3057	KIT, 14Fr Introducer, 13 cm, ABMD	N/A	0052-0038	
NOTE: For axillary kits (part number 0052-3009), which contain an axillary introducer (part number 0052-3006), please note that <b>only</b> part number 0052-3006 is in scope for this recall.				

**Abiomed requests that customers perform an immediate quarantine and inspection of the Introducer Kits on the shelf at your institution, per the guidance in Attachment 2.**

Abiomed will replace all affected Introducer Kits, sold both as part of a pump set and as a single sale item. The rate of this type of packaging damage is <0.6%. In case a pump set needs to be used, the operator may use the pump set after a detailed examination of the Introducer Kit packaging is performed. In these cases, it is essential to refer to the specific recommendations provided below.

**ACTIONS TO BE TAKEN BY THE CUSTOMER/USER:**

1. Examine your inventory **immediately and check the batch / lot number** to determine if you have product subject to this recall (removal) and for any holes in the outer pouch. For Introducers in Pump Sets, keep the Introducer Kit in the Impella Pump Set box after inspection. Refer to Attachment 1 for the Product Identification Tool to identify products that are subject to this recall (removal) by using package labels. **QUARANTINE AND DO NOT USE THE SUSPECTED PRODUCTS UNLESS CLINICALLY NEEDED.**  
**IF AN IMPELLA PUMP IS CLINICALLY NEEDED,** review the IMPORTANT INFORMATION section below for best practices in the event you must use these devices while you wait for a replacement.

2. Your Abiomed Representatives have been provided instructions to support facilitation of locating, separating, and returning affected product for replacement, and will provide the Business Response Form (BRF) to be completed. Work with your Abiomed Representative to review, complete **all** fields, and sign the BRF. **IMPORTANT: The Business Response Form must be completed even if you have used any units of the subject product on hand.**
3. Your Abiomed Representatives will support the identification and return of the affected product to Sedgwick with the completed BRF and support the initiation of replacement Introducer Kits to your facility. Contact Sedgwick at (877) 497-2489 (email [abiomed8298@sedgwick.com](mailto:abiomed8298@sedgwick.com), fax (866) 606-8265) or Abiomed Customer Service, 1-800-422-8666, option 2 (email [fieldaction@abiomed.com](mailto:fieldaction@abiomed.com)) with any questions during the product return and replacement process.
4. Forward this notice to any personnel in your facility who need to be informed.
5. If any of the product subject to this recall (removal) has been forwarded to another facility, contact that facility and provide a copy of this notice to the relevant personnel.
6. Post a copy of this notice in a visible area for awareness of this field safety notice.
7. 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 using the link below: <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>.

## **IMPORTANT INFORMATION**

### **IF AN IMPELLA PUMP IS CLINICALLY NEEDED, ACTIONS TO BE TAKEN BY THE USER:**

1. Prior to usage, carefully examine the outer pouch of the Introducer Kit for holes following the provided instructions in Attachment 2.
2. If used, document the use on the Business Request Form provided by your Abiomed Field Representative.

Please contact Abiomed Customer Service, 1-800-422-8666, option 2 (email [fieldaction@abiomed.com](mailto:fieldaction@abiomed.com)) if you need any support troubleshooting or if you have any further questions.

Thank you for your cooperation.

Abiomed Inc.  
22 Cherry Hill Drive  
Danvers, MA 01923  
[fieldaction@abiomed.com](mailto:fieldaction@abiomed.com)

### **Attachments:**

Attachment 1 - Instructions to Locate Introducer (within Single Sale Kit or Pump Set)  
Attachment 2 – Packaging Inspection Details

**URGENT MEDICAL DEVICE RECALL (REMOVAL)**  
**Impella Combo Introducer Kits (sold within Impella Pump sets and Single Sale)**  
**Axillary Introducer Kits**

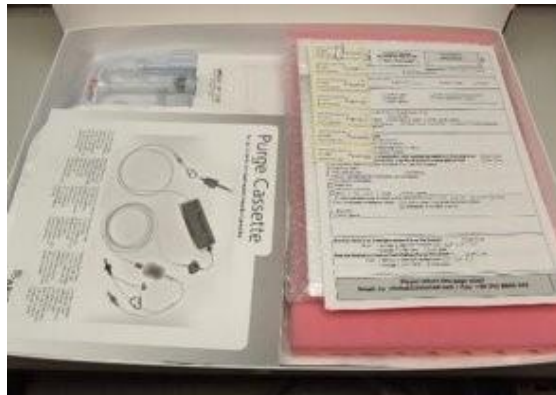
**ATTACHMENT 1 – Instructions to Locate Introducer (within Single Sale Kit or Pump Set)**

**Instructions to locate your Introducer Kit within an Impella Pump Set:**

First, locate the batch number on the label of your Impella Pump Set to identify if you have a batch number in scope of the recall.



The Impella pump set contains a sterile pump, sterile introducer kit, a purge cassette, and a guidewire in addition to packaging foam and a tracking sheet. This is all contained in the Impella Pump Set box which is labeled and sealed. This recall affects all subject Introducer Kits within the Impella Pump Sets (5.5, RP and CP).



This type of damaged packaging (holes) is for the Impella Introducer Kits, which are provided within each Impella Pump Set box. The Introducer Kit should be located on top of the Impella Pump and underneath the packing foam included in the box.

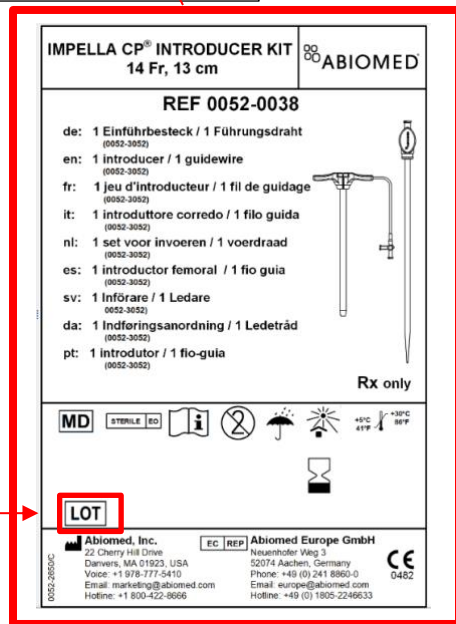
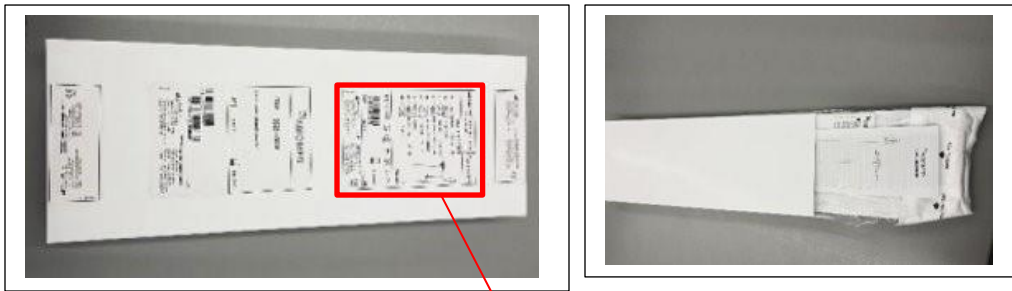


Note: For Introducers in Pump Sets, keep the Introducer Kit in the Impella Pump Set box after inspection.

**Instructions to locate your Introducer Kit within a Single Sale Introducer Kit:**

First, locate the lot number on the label of your Single Sale Introducer kit to identify if you have a lot number in scope of the recall.

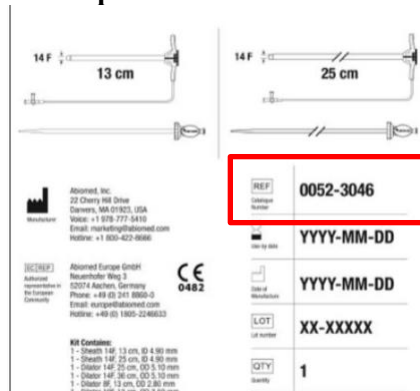
Single Sale Introducer Kits may be provided with the Impella Pump Sets, but are separated into a separate box as noted below.



Lot Number

To locate your Introducer Kit Part Number, first locate your Introducer Kit package (it will be facing label-down in the pump set box). The affected introducer kits will have a label that resembles the below image, part number and exact label configuration may vary.

**Example Introducer Kit Label:**



Part Number

Once above steps are complete, keep the Impella Pump Sets and Introducer Kits quarantined and segregated until a replacement introducer is obtained.

If you have questions or concerns, please contact Abiomed customer service at (800) 422-8666 option 2 (email [fieldaction@abiomed.com](mailto:fieldaction@abiomed.com)) and/or your local clinical field staff.

**URGENT MEDICAL DEVICE RECALL (REMOVAL)**  
**Impella Combo Introducer Kits (sold within Impella Pump sets and Single Sale)**  
**Trayed Introducer Kits**

**ATTACHMENT 2 – Packaging Inspection Details**

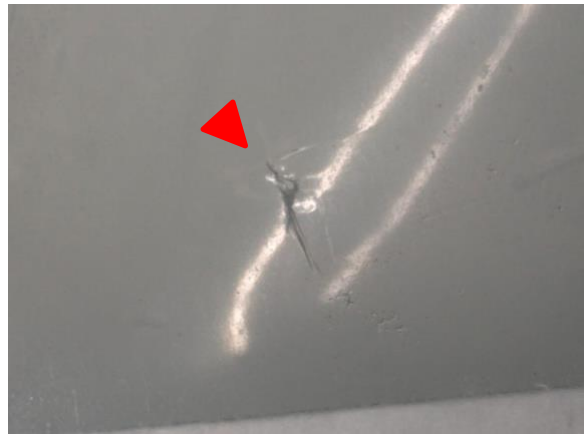
**Impella CP® and RP® Introducer Kit – Introducer Kits with Tray Inside Outer Pouch**

- Inspect both sides of the outer pouch (transparent side and labeled side) for holes.

Visual of Trayed Introducer:



Examples of Potential Outer Pouch Holes:



**URGENT MEDICAL DEVICE RECALL (REMOVAL)**  
**Impella Combo Introducer Kits (sold within Impella Pump sets and Single Sale)**  
**Axillary Introducer Kits**

**ATTACHMENT 2 – Packaging Inspection Details (Continued)**

**Impella 5.5® Introducer Kit – Introducer Kits with no Tray**

- Inspect transparent film side of packaging for holes.

Visual of Non-Trayed Introducer:



Examples of Potential Packaging Holes:

