

URGENT MEDICAL DEVICE RECALL (REMOVAL)

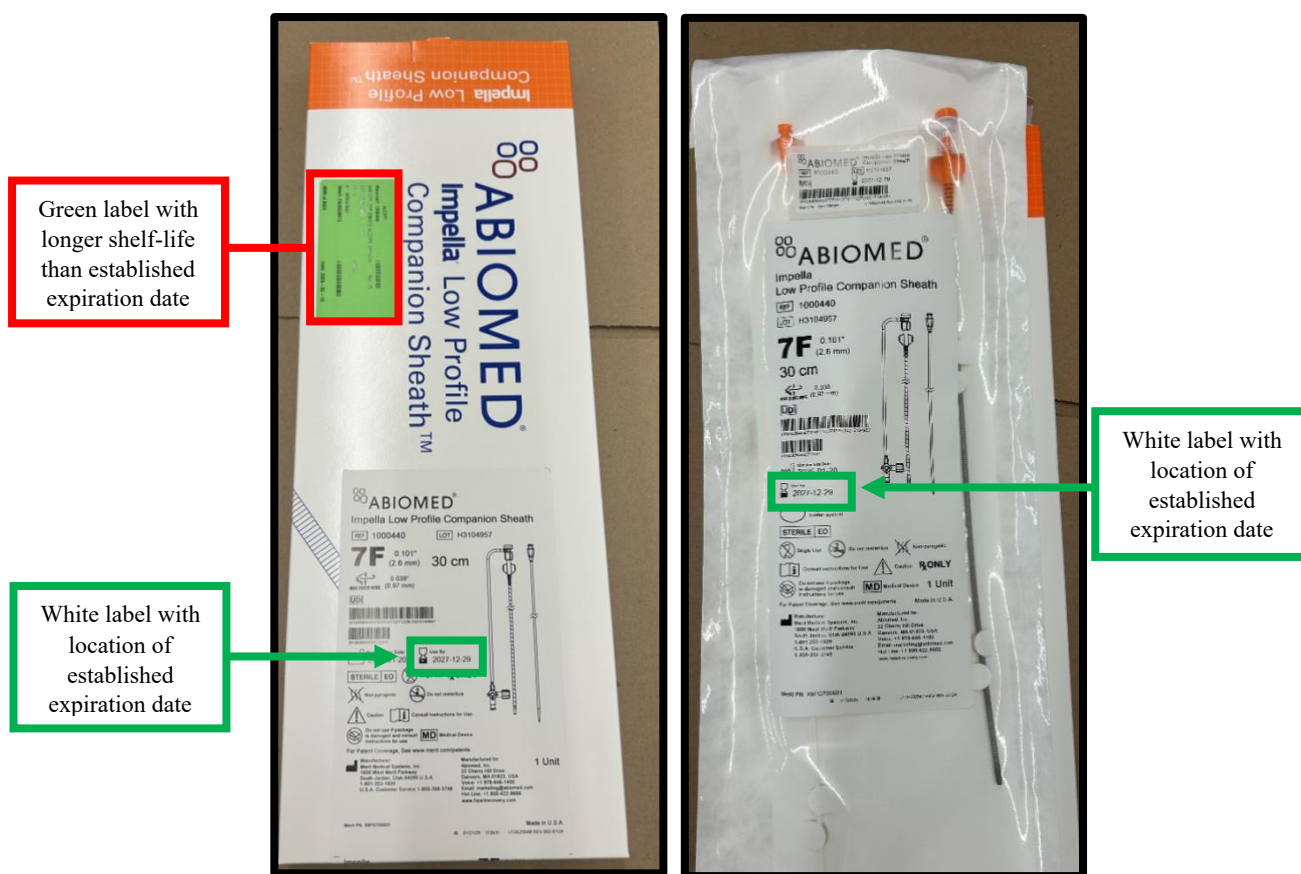
Product Code	Product Description	UDI-DI	Impacted Lot Numbers	Expiration Date
1000440	7Fr Impella Low Profile Companion Sheath	00884450732311	H2981605S1	2026-10-31
			H3077100	2027-11-11

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 two specific lots of the 7Fr Impella Low Profile Companion Sheath due to a shelf-life discrepancy on the exterior box labeling. The green label applied to the product carton indicates a longer shelf-life than the established expiration date. The established expiration date is included on the white information label on the product pouch inside the carton (shown below).

Examples of 7Fr Impella Low Profile Companion Sheath labeling with Shelf-Life Location Indicated:



REASON FOR REMOVAL:

Abiomed has identified the expiration date shown on the green Abiomed carton label indicates a longer shelf-life than the established expiration date identified on the white information label and on the product pouch label.

POTENTIAL PATIENT IMPACT:

As of this recall letter, the affected lots, (H2981605S1 & H3077100) are currently within their established expiration dates (October 31, 2026 & November 11, 2027 respectively). Abiomed is proactively removing these lots of companion sheaths to prevent them from being used after their established expiration date. To date, we have not received any reports of complaints related to this matter.

ACTIONS TO BE TAKEN BY CUSTOMER/USER:

- Review all 7Fr Impella Low Profile Companion Sheaths within inventory and if your 7Fr Impella Low Profile Companion Sheath is identified as impacted per Attachment 1 – Product Identification Tool, please set aside and quarantine.
- A return shipment label has been provided to impacted customers 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) 843-0254.
- Review, complete all fields, sign, and return the business response form (BRF) that was provided to impacted customers.
- 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:

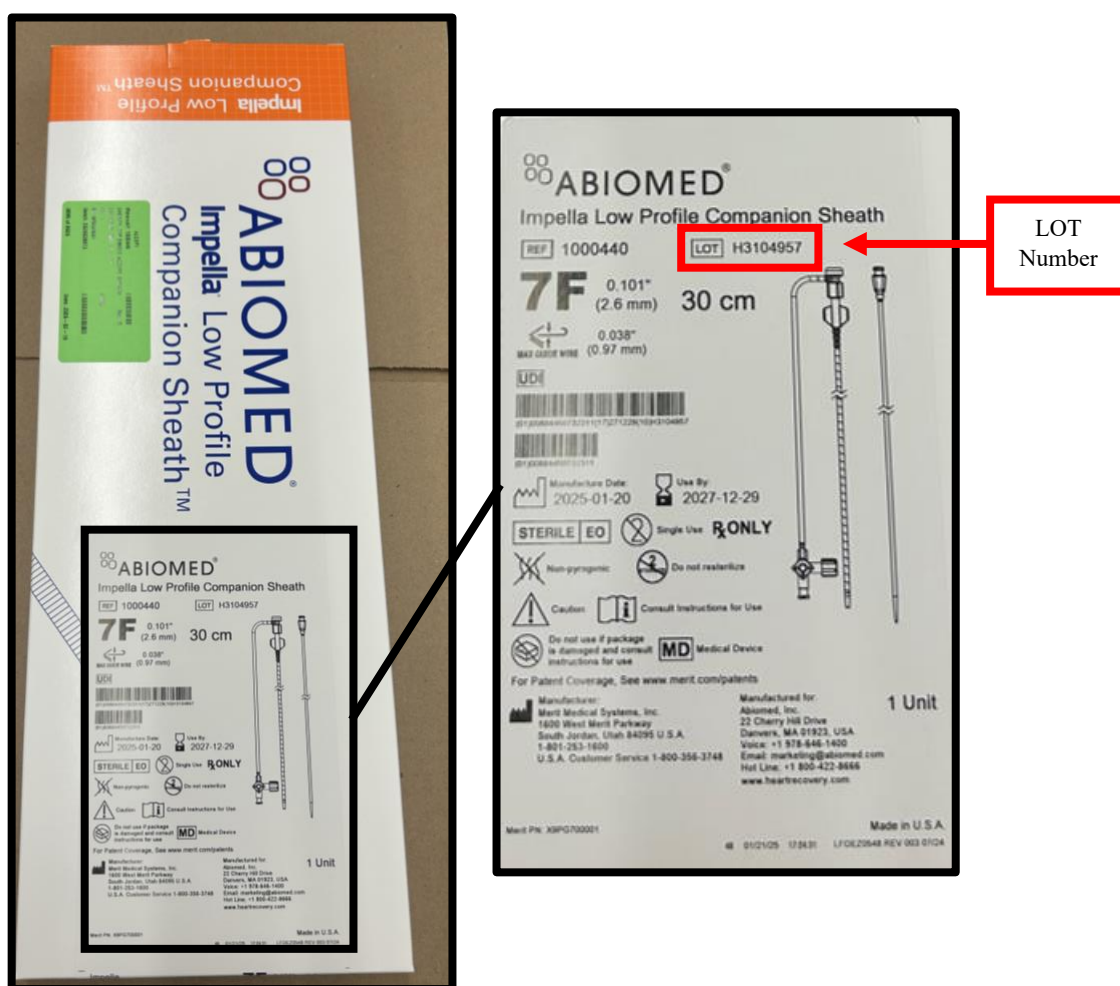
Attachment 1 – Product Identification Tool

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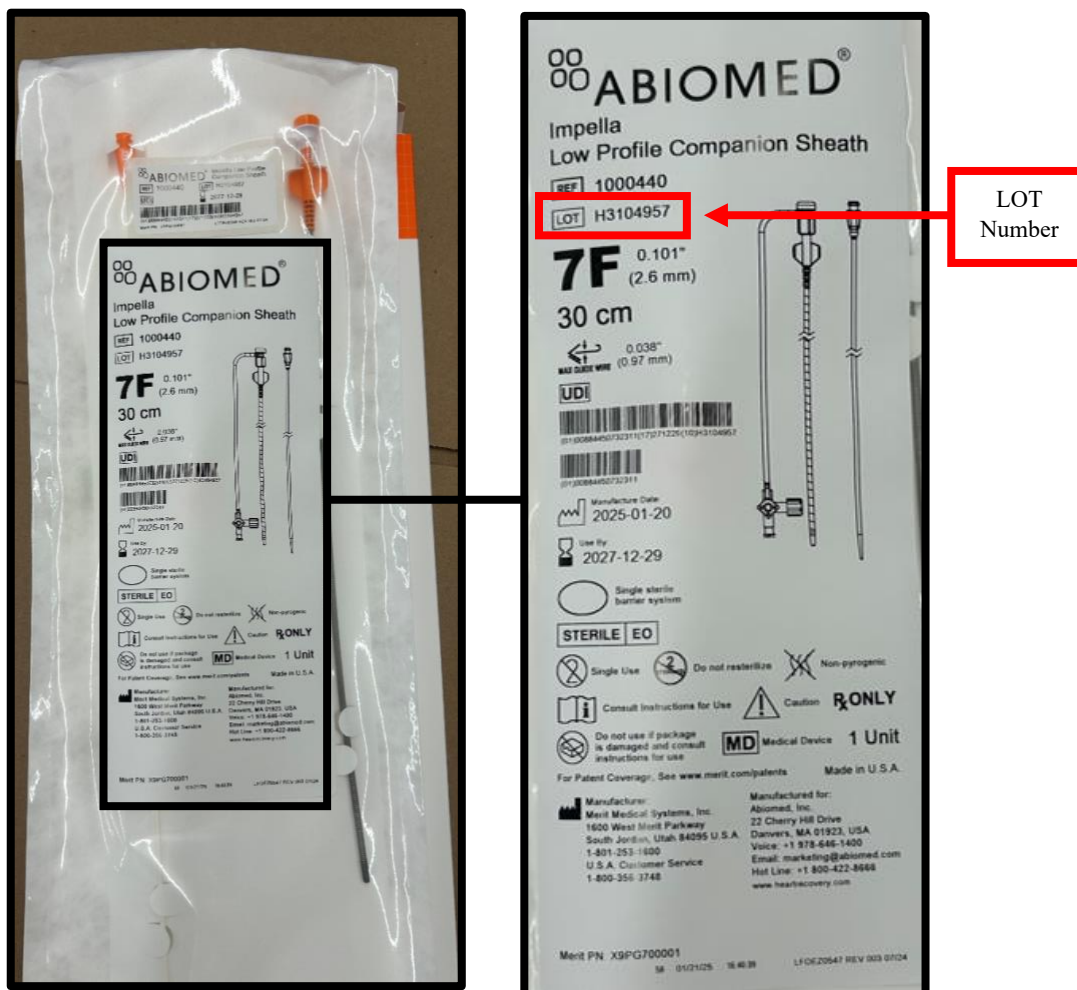
The subject devices have a label on the carton as seen below. To identify if your units are affected by this field action, refer to the lot number (LOT) on the label (red box) and check if the lot number matches the lot number(s) listed below.

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Example Labels to Locate Impacted LOT Number



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