B. Braun Medical Inc.
2525 McGaw Avenue
Irvine, CA 92614-5895
PH: 1-800-227-2862

URGENT RECALL NOTICE

13 Jun 2019

Dear Valued Customer

The purpose of this letter is to advise you that B. Braun Medical Inc. (BBMI) is voluntarily recalling one (1) batch of product due to a failure in ongoing stability data.

Affected Product and Distribution Information:

This voluntary product recall is being initiated for the following product catalog number and affected batch number:

Product Catalog Number	Product Description	Batch Number	Distribution Date Range	Expiration Date
P5872 (NDC: 0264-9587-20)	Heparin Sodium 25,000 USP units per 250 mL (100 USP units per mL) in 5% Dextrose Injection in Excel® IV Container	J7B259	27 Mar 2017 – 27 Apr 2017	31 Aug 2019

Reason for Recall:

During stability testing of Batch J7B259, an out-of-specification result was identified at the 104 week stability interval for the drug anti-factor IIa potency.

Risk to Health:

To date there have been no reports of adverse events or injury associated with this issue. Low potency of Heparin may result in reduced anti-coagulation effects. This may range in impacts from the need for additional doses or titrations to the patient. Depending on the patient's condition and treatment requirements, the reduced potency may range in outcomes from mild to moderate impact up to life-threatening circumstances in cases where thromboembolism is not adequately prevented.

Actions to be taken by the Customer/User:

1. Review the Product Recall Notification in its entirety and ensure that all users in your organization and other concerned persons are informed about this voluntary recall and the affected product(s).
2. If you are a distributor, please forward this recall notification to your customers. Under the FDA recall enforcement policy, you are legally obligated to notify your customers of drug recalls such as this one. It is highly recommended that you determine your customers' inventory levels and request the return of these lots to you. Please combine your customers' inventory with your own inventory and return all affected product to B. Braun Medical Inc. at one time.
3. Determine your current inventory of the affected lot(s) within your facility. Do not destroy any affected product.
4. Utilizing the attached "Product Recall Acknowledgement" form, record the total number of individual units (within partial cases) and the number of full unopened cases. If you have no inventory remaining, please enter zero (0) on the form.
5. Return the completed "Product Recall Acknowledgement" form to B. Braun Medical Inc. Quality Assurance department by utilizing the enclosed self-addressed envelope or via fax to (610) 849-5430 within two (2)

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weeks of receipt, even if the total inventory in your possession is zero (0). It is important this form is returned so B. Braun Medical Inc. can meet regulatory requirements of the United States Food and Drug Administration.

6. If you have any full cases, partial cases or unused individual units of the affected product, please call B. Braun Medical Inc. Customer Support Department at 1-800-227-2862 to arrange for return and replacement product. A Customer Support Representative will provide you with instructions for handling affected product. We will arrange for all affected product to be returned to B. Braun Medical Inc. for proper disposition.

Should you experience any adverse reactions or quality problems with the product, please report the event promptly to BBMI by contacting our Medical Affairs Department at 1-800-854-6851. Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Additionally, adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- 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

This product recall is being performed with the knowledge of the United States Food and Drug Administration.

We apologize for the inconvenience that this issue may have caused you and your facility, but we appreciate your understanding of our commitment to assuring our products are safe and effective for both health care professionals and patients.

Sincerely,

Jonathan Severino

Director, Product Quality Excellence

Enclosures

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PRODUCT RECALL ACKNOWLEDGEMENT

Heparin Sodium 25,000 USP units per 250 mL (100 USP units per mL) in 5% Dextrose Injection, Batch: J7B259

Customer Name	
Street Address	
City, State Zip	

Please complete the information below and return to B. Braun by mail using the enclosed envelope or by fax to (610) 849-5430 within 2 weeks of receipt even if the inventory in your possession is zero. It is important that B. Braun receives the necessary information on the amount of affected products in your possession.

For product return, shipping instructions, or additional information, please contact the B. Braun Medical Inc. Customer Support Department at 800-227-2862 Monday through Friday, 8 a.m. – 6 p.m. EST.

Please check ALL appropriate Boxes

☐ Checking this box indicates you have read and understand the recall instructions provided in the Recall Notification Letter.

☐ I have checked my stock and have placed affected material into quarantine.

If this box is checked, please complete the following table.

INVENTORY OF RECALLED PRODUCT						
Product Catalog No.	**NDC Number**	**Product Description**	**Batch**	**No. of UNITS (out of case) on Hand**	**No. of CASES (unopened cases) on HAND**	**Total Units to Return**
P5872	0264-9587-20	Heparin Sodium 25,000 USP units per 250 mL (100 USP units per mL) in 5% Dextrose Injection	J7B259			

☐ Checking this box indicates you have zero inventory of affected items and no product to be returned.

☐ *DISTRIBUTORS ONLY* - Checking this box indicates that you have identified and notified all of your customers that were shipped or may have been shipped this product by (specify date and method of notification:_____

Name of Person Responding	**Title**	**Signature**	**Date**
Contact Number		**Contact E-mail:**	