05 JUN 2023

**URGENT MEDICAL DEVICE RECALL**

**KITS CONTAIN INCORRECT FILTER STRAW**

Dear Valued Customer:

The purpose of this letter is to inform you that B. Braun Medical Inc. (BBMI) is issuing a voluntary medical device recall for specific batches of Epidural Kits that were inadvertently assembled with the incorrect Filter Straw. The kits should contain Filter Straws with Standard Luer Connections however the kits contain Filter Straws with Neuraxial connectors preventing interface with the other components of the kit.

**Affected Product and Distribution Information:**

<table>
<thead>
<tr>
<th>Article Number</th>
<th>Lot Number:</th>
<th>GTIN</th>
<th>Description</th>
<th>Distribution Date Range</th>
<th>Region Distributed</th>
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<tbody>
<tr>
<td>332217</td>
<td>0061850767</td>
<td>04046964178283</td>
<td>CE18TKCD10L 18GA TUOHY/10CC GLAS</td>
<td>09.NOV.2022 – 13.DEC.2022</td>
<td>United States</td>
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<tr>
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<td>04046964177361</td>
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<td>10.NOV.2022 – 23.NOV.2022</td>
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</table>

The depth of this voluntary recall is to the user/consumer level. This removal is being conducted with the knowledge of the United States Food & Drug Administration.

**Reason for the recall:**

The kits should contain Filter Straws with Standard Luer Connectors however the kits contain Filter Straws with Neuraxial Connectors preventing interface with the other components of the kit.
Risk to Health:
To date, there have been zero reports of serious injury associated with this issue. BBMI has received customer complaints reporting the inability to attach the filter straw to the epidural dose syringe. The inability to connect the filter straw may result in procedural delays while a compatible component is sought.

Actions Required by B. Braun Medical Inc. (BBMI) Customer/User:
1. Review the Device Recall Notification in its entirety and ensure that all users in your organization of the above-mentioned product, and other concerned personnel are informed about this voluntary recall. If you are a distributor and have further distributed the product, please forward this notice to your consignees. The recall is to be extended to the consumer level.
2. Determine your current inventory of the affected batches within inventory of your facility, cease use and quarantine product subject to recall. Do not destroy any affected product.
3. Utilizing the attached “Product Recall Acknowledgement Form”, record the total number of individual impacted units. If you have no inventory remaining, please enter zero (0) on the form.
4. Return the completed “Product Recall Acknowledgement Form” to B. Braun Medical Inc. Quality Assurance department by faxing the form to (610) 849-1197 or e-mail to PA_QualityAssurance.BBMUS_Service@bbraunusa.com within two (2) weeks of receipt, even if the total inventory in your possession is zero (0).
5. Once we receive your acknowledgement form a B. Braun Customer Support representative will contact you with instructions on how to return any impacted cases, including partial cases, in your possession and provide credit and/or replacement of the product based on your individual needs.

Adverse reactions or quality problems experienced with this product, or questions about this recall may be reported to BBMI’s Postmarket Surveillance Department by calling 1-833-425-1464. They may also 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.
   - Regular Mail or Fax: Download form 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

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,

Cynthia Bauer
Manager II, Customer Complaint Advocacy & Recalls
Postmarket Surveillance
B. Braun Medical Inc.

Enclosures:
Medical Device Product Recall Acknowledgement Form

Notes:
1. URL for reporting online: https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda
Attachment 1
Product Recall Acknowledgment Form
KITS CONTAIN INCORRECT FILTER STRAW

Please complete and return this form by one of the below options:
Fax: (610) 849-1197 or Email PA_QualityAssurance.BBMUS_Service@bbraunusa.com

Name of Customer:
Street Address
City, State, Zip Code

- Checking this box indicates you have read and understand the recall instructions provided.
- Checking this box indicates you have zero (0) inventories of affected items.
- *DISTRIBUTORS ONLY* - checking this box indicates you have contacted all affected customers, if applicable.

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<th>Article Number</th>
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Name of Person Completing Notice

__________________________________________
Signature

__________________________________________
Contact Number

__________________________________________
Title

__________________________________________
Fax Number

__________________________________________
Date

__________________________________________
Email Address

__________________________________________
Account #: __________