B. Braun Medical Inc.
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Allentown, PA 18109
Telephone: (844) 903-6417
Fax: (610) 849-1197
E-mail: recalls@bbraunusa.com

02JUL2025

URGENT MEDICAL DEVICE RECALL NOTIFICATION
Microbore Extension Set, V6215

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 lots of product V6215, Microbore Extension Set, due to the product being labeled as containing an air eliminating filter, when in fact, the filter is not air eliminating.

Affected Product and Distribution Information:

Product Catalog Number	Product Description	Primary DI Number	Unit of Use DI	Distribution Range	Region Distributed	Lot Number	Expiration Date
V6215	Microbore Extension Set	04046964189173	04046964189166	30NOV2020 – 09JUN2025	US & Canada	0061742452	30JUN2025
						0061747379	31AUG2025
						0061767411	31JAN2026
						0061780914	30APR2026
						0061803499	30SEP2026
						0061806173	30NOV2026
						0061822333	30APR2027
						0061836578	30APR2027
						0061849109	31JUL2027
						0061850836	31AUG2027
						0061899902	30SEP2028
						0061936368	31MAR2029
						0061936119	31MAR2029
						0061936369	31MAR2029
						0061940584	30APR2029

The depth of this voluntary recall is to the hospital/healthcare facility level. This recall is being conducted with the knowledge of the United States Food & Drug Administration and Health Canada.

Reason for the recall:

The product is not labeled properly. Specifically, the product label indicates that the device contains an air eliminating filter. However, the filter utilized on this extension set is not indicated for removal of air and does not feature an air vent, which is common to air eliminating filters.

Risk to Health:

To date there have been no reports of serious injury or death associated with this issue. If the product is used and there is air within the line or filter itself, the air can occlude the filter. This could lead to a significant delay in therapy with significant impact on patient status (e.g. with life sustaining drugs). Because the filter is not indicated to remove air, there is potential for air to escape the filter and enter the patient where embolization could occur. This could lead to patient harm up to and including permanent organ damage or death.

Actions Required by B. Braun Medical Inc. (BBMI) Customer/User:

1. Review the Urgent Medical Device Recall Notification in its entirety and ensure that all users in your organization of the above-mentioned product, and other concerned persons 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 hospital/healthcare facility level.
2. Determine your current inventory of the affected items within inventory of your facility, cease use and quarantine product subject to recall. Do not destroy any affected product.
3. Utilizing the attached "Urgent Medical Device 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 "Urgent Medical Device Recall Acknowledgement Form" to the B. Braun Medical Inc. Postmarket Surveillance department by faxing the form to (610) 849-1197 or e-mail to recalls@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.

Recommended Alternatives for B. Braun Medical Inc. (BBMI) Customer/User:

If you require a Microbore Extension set that is PE lined and an air eliminating filter, you will need to order them separately. The following items are available:

a. Microbore Extension Sets

Product Catalog Number	Product Description	Additional Set Information
V6203	Microbore Extension Set with Female Luer Lock Connector, Spin-Lock® Connector, and PE Fluid Path Tubing	Extension Set Priming Volume: 0.6 mL, Length: 36 in. (91 cm)
V6220	Microbore Extension Set with Female Luer Lock Connector, Spin-Lock® Connector, and PE Fluid Path Tubing	Extension Set Priming Volume: 0.3 mL, Length: 36 in. (91 cm)

b. Air Eliminating Filter

Product Catalog Number	Product Description	Additional Filter Information
473036	PFE2000 LOW VOL IN-LINE FILTER	Priming Volume: 0.8 mL

Adverse reactions or quality problems experienced with this product may be reported to BBMI's Postmarket Surveillance Department by calling 1-833-425-1464.

In the United States:

Adverse Reactions or quality problems in the United States 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[1]

- Regular Mail or Fax: Download form[2] 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

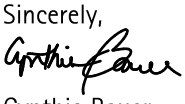
In Canada:

Adverse Reactions or quality problems in Canada may also be reported to Health Canada online, via URL: *https://health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/medical-device-consumer.html* (English) or *https://canada.ca/fr/sante-canada/services/medicaments-produits-sante/conformite-application-loi/rapport-incident/instruments-medicaux-consommateurs.html* (French)

For questions about this recall please contact our BBMI's Recalls Department at 844-903-6417.

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

Sincerely,



Electronically signed by: Cynthia Bauer
Reason: For the reason(s) specified in the document.
Date: Jul 2, 2025 09:22 EDT

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

Enclosures:
Urgent Medical Device Recall Acknowledgment 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
2. URL for Downloadable Form: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting