URGENT MEDICAL DEVICE RECALL

12 December 2018

Dear Valued VeriCor Customer,

B. Braun Medical, Inc. (BBMI) has notified VeriCor, LLC, of an Urgent Medical Device Recall regarding specific lots of their Rate Flow Regulator Administration Sets manufactured by Leventon S.A.U. This notice has been issued due to reported deficiencies in the manufacturer's quality systems at its manufacturing facility. Affected product first shipped November 5, 2015.

For clinical inquiries, please contact B. Braun Medical Affairs at (800) 854-6851.

Through our SmartBook™ tracking we have verified that we shipped you product affected by this notice. Carefully review the information in this letter and follow the instructions provided below.

Refer to Attachment 1 for a list of affected lot numbers and how to locate the specific product.

VeriCor Customer Instructions:

1) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed on Attachment 1.
    a. A copy of the Urgent Medical Device Recall from B. Braun Medical, Inc. has been included for reference (see page 2, REF/Product Code V5200).

2) Fill out the VeriCor Reply Form and return it to the Customer Service Center via fax to (608) 399-1740. To ensure timely processing for your replacement product and support, the completion of this notice is required. Please respond within 30 days.

Please note: Any product returned in addition to, or in lieu of, affected product will be destroyed without issuance of replacement. The affected product lot numbers are listed on Attachment 1. Once the product is returned, replacement product will be sent to you at no cost.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about the information provided in this communication, please contact the Customer Service Center at recalls@vericormed.com or call 866-469-6019 ext. 304.

Thank you for your prompt attention,

Customer Service Center
Toll Free: 866-469-6019 x 304
Email: recalls@vericormed.com
www.VeriCorMed.com

ATTACHMENT 1

VeriCor #	MFG Catalog #	Description	Affected Lot(s)
233739	V5200	Tubing, IV Extension, Flow Rate Regulator, EA	151413L; 151684L; 151685L; 151686L; 151855L; 160095L; 160096L; 160386L; 160511L; 160512L; 160513L; 160767L; 160768L; 160940L; 160941L; 160942L; 161188L; 161335L; 161336L; 161337L; 161927L; 161928L; 161930L; 170531L; 170532L; 170533L; 171613L; 171614L; 171929L; 171930L; 171931L; 172162L; 180214L; 180215L; 180252L; 180536L; 180537L

HOW TO LOCATE THE PRODUCT WITH YOUR SMARTBOOK™

Method 1: Using the Digital File
Open the file on the SmartBook™ CD named "INVENTORY…" (*contains a complete listing of all products in the system). Sort the file by "Description" or use the find option to locate the item listed above. Then check the lot numbers to find the affected product.

Method 2: Using the Printed Version
Find the section "Complete Inventory Sorted by Item Description" and use it as a reference to find the physical location(s) of the item listed above. Then physically locate the item to check the lot number(s) to find the affected product.

VeriCor, LLC
B. Braun Rate Flow Regulator Admin Sets
Recall Reply Form: VRC-2018-1002

Fill out this Recall Reply Form and fax it to Customer Service Center at 608-399-1740. **Do not mail!**

_____ I acknowledge that VeriCor, LLC has notified me of this recall. I DO have affected product but DO NOT wish to exchange for replacement. I am responsible for disposal and replacement. *Please enter "0"in the "Quantity" field below if you do not plan to return the affected product(s) on hand.*

_____ I acknowledge that I DO HAVE affected product as indicated below and wish to return product for replacement.

Signature _____ Organization _____

Title _____ Email _____

VeriCor #	Quantity	Unit of Measure	MFG Catalog #	Description
233739		EA	V5200	Tubing, IV Extension, Flow Rate Regulator, EA

**** Please Note: Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of replacement. The affected lot numbers are listed on Attachment 1. Once the product is returned, replacement product will be sent to you at no cost. ****

Instructions to Return for Exchange

1. Fill out the shipping information below.
2. Provide a copy of this form in the box of products being returned.
3. Return affected product via the carrier of your choice, at your expense, to:
   VeriCor, LLC, Recall VRC-2018-1002, 703 Western Ave, Holmen, WI 54636
4. Upon receipt of merchandise, replacement product will be sent back to you at no additional cost.

Shipping Details for Replacement Product

Agency: _____

Attention: _____

Address: _____

City :_____ State: _____ Zip: _____

If you have any questions about information provided in this communication, please contact the Customer Service Center at 866-469-6019 x 304.

B. Braun Medical Inc.
901 Marcon Blvd.
Allentown, PA 18109
Telephone: (610)-266-0500
Fax: (610)-849-1197
Email: PA_QualityAssurance.BBMUS_Service@bbraunusa.com

October 2, 2018

URGENT MEDICAL DEVICE – RECALL NOTIFICATION

Dear Valued Customer:

This is to inform you that B. Braun Medical Inc. (BBMI) is issuing a voluntary medical device recall of Rate Flow® Regulator Administration sets due to reported deficiencies in the manufacturer's quality systems at its manufacturing facility. Rate Flow Regulator Administration sets are manufactured by Leventon S.A.U. and purchased as a finished product by BBMI. The specific products impacted by this recall are identified below.

REF/ Product Code	Item Description	Lot Numbers	Distribution Dates
375152 / US5322	Rate Flow® Regulator IV Set; 84 in.; 20 Drops/mL	151799L; 151837L; 160035L; 160483L; 160686L; 161201L; 161211L; 161519L; 161909L; 170197L; 170572L; 171537L; 172225L; 180189L; 180264L; 180574L	02 Feb 2016 – 14 Sep 2018
375153 / US5932	Rate Flow® Regulator IV Set; 90 in.; 20 Drops/mL	151489L; 151648L; 152003L; 160036L; 160429L; 160430L; 160486L; 160637L; 160687L; 160849L; 160988L; 161210L; 161518L; 161520L; 161521L; 161908L; 161998L; 170060L; 170219L; 170573L; 170796L; 170801L; 171125L; 171190L; 171538L; 180190L; 180267L; 180442L; 180888L; 180934L; 181253L	14 Dec 2015 – 14 Sep 2018
375173 / USNF5932	Rate Flow® Regulator IV Set; 89 in.; 20 Drops/mL	170735L; 171238L; 171624L; 172218L; 180440L; 180862L; 180951L; 181200L	12 Jul 2017 – 11 Sep 2018
NF5300	Rate Flow® Regulator Extension Set; 19 in.	151581L; 151716L; 161667L; 161899L; 170133L; 170363L; 170988L; 171203L; 171935L; 172217L; 172467L; 180224L; 180441L; 180606L; 180781L; 180942L; 181317L	15 Mar 2016 – 14 Sep 2018
NF5932	Rate Flow® Regulator ADDitIV IV Set; 90 in.; 20 Drops/mL	151557L; 151797L; 151832L; 160485L; 160685L; 160708L; 160735L; 160843L; 161379L; 161517L; 170374L	22 Dec 2015 – 06 Sep 2018
US5300	Rate Flow® Regulator Extension Set; 18 in. (priming volume 2.8mL)	151409L; 151410L; 151687L; 151688L; 151689L; 151690L; 151691L; 151858L; 151909L; 160098L; 160099L; 160100L; 160101L; 160514L; 160515L; 160516L; 160517L; 160518L; 160519L; 160520L; 160769L; 160770L; 160936L; 160937L; 160938L; 160939L; 160998L; 161331L; 161332L; 161333L; 161334L; 161391L; 161923L; 161924L; 161925L; 161926L; 161982L; 161983L; 161984L; 170525L; 170526L; 170527L; 170528L; 170529L; 170530L; 171178L; 171179L; 171180L; 171181L; 171609L; 171612L; 171619L; 171925L; 171926L; 171927L; 171928L; 172158L; 172159L; 172160L; 172161L; 180216L; 180217L; 180218L; 180219L; 180253L; 180504L; 180505L; 180534L; 180535L; 180943L; 180944L; 180945L; 180946L; 180947L; 181164L; 181165L	01 Dec 2015 – 14 Sep 2018

REF/ Product Code	Item Description	Lot Numbers	Distribution Dates
V5200	Rate Flow® Regulator Extension Set; 18 in. (priming volume 2.6mL)	151413L; 151684L; 151685L; 151686L; 151855L; 160095L; 160096L; 160386L; 160511L; 160512L; 160513L; 160767L; 160768L; 160940L; 160941L; 160942L; 161188L; 161335L; 161336L; 161337L; 161927L; 161928L; 161930L; 170531L; 170532L; 170533L; 171613L; 171614L; 171929L; 171930L; 171931L; 172162L; 180214L; 180215L; 180252L; 180536L; 180537L	23 Nov 2015 – 14 Sep 2018
V5922	Rate Flow® Regulator IV Set; 83 in.; 20 Drops/mL	151472L; 151492L; 151493L; 151495L; 151496L; 151497L; 151498L; 151499L; 151500L; 151501L; 151649L; 151651L; 151652L; 151653L; 151654L; 151655L; 151656L; 151657L; 151658L; 151790L; 151798L; 151800L; 151801L; 151802L; 151803L; 151804L; 151805L; 151834L; 151835L; 151836L; 151838L; 151839L; 151840L; 151841L; 151844L; 151949L; 152140L; 160023L; 160024L; 160025L; 160026L; 160027L; 160028L; 160029L; 160030L; 160031L; 160075L; 160076L; 160077L; 160078L; 160079L; 160080L; 160115L; 160116L; 160117L; 160118L; 160119L; 160120L; 160121L; 160122L; 160123L; 160157L; 160200L; 160206L; 160207L; 160208L; 160209L; 160255L; 160256L; 160257L; 160487L; 160489L; 160491L; 160557L; 160564L; 160565L; 160676L; 160678L; 160679L; 160683L; 160688L; 160689L; 160690L; 160709L; 160710L; 160850L; 160852L; 160978L; 160990L; 161057L; 161109L; 161110L; 161127L; 161128L; 161135L; 161136L; 161137L; 161198L; 161200L; 161202L; 161203L; 161204L; 161206L; 161207L; 161208L; 161326L; 161327L; 161328L; 161342L; 161380L; 161381L; 161382L; 161383L; 161384L; 161385L; 161386L; 161523L; 161524L; 161525L; 161526L; 161527L; 161528L; 161529L; 161530L; 161531L; 161532L; 161533L; 161534L; 161535L; 161904L; 161905L; 161906L; 161907L; 161910L; 161911L; 161912L; 161913L; 161914L; 161915L; 161916L; 161917L; 161999L; 162000L; 162003L; 162004L; 162005L; 162128L; 170061L; 170064L; 170065L; 170066L; 170070L; 170071L; 170072L; 170073L; 170193L; 170194L; 170195L; 170196L; 170314L; 170315L; 170316L; 170317L; 170318L; 170321L; 170375L; 170376L; 170558L; 170559L; 170560L; 170562L; 170574L; 170575L; 170576L; 170644L; 170645L; 170650L; 170651L; 170652L; 170653L; 170764L; 170765L; 170797L; 170931L; 170932L; 170933L; 170934L; 171004L; 171005L; 171006L; 171010L; 171011L; 171124L; 171169L; 171171L; 171173L; 171391L; 171464L; 171540L; 171542L; 171543L; 171544L; 171545L; 171546L; 171547L; 171548L; 171549L; 171697L; 171748L; 171749L; 171750L; 171751L; 171752L; 171874L; 171875L; 171877L; 172020L; 172021L; 172022L; 172023L; 172024L; 172226L; 172227L; 172228L; 172271L; 172272L; 172280L; 172282L; 172283L; 172284L; 172285L; 172471L; 172472L; 172473L; 172475L; 172476L; 172477L; 172478L; 172494L; 172495L; 172496L; 172497L; 172498L; 172499L; 172502L; 172503L; 172504L; 172505L; 172506L; 180262L; 180265L; 180268L; 180269L; 180270L; 180271L; 180272L; 180273L; 180274L; 180275L; 180276L; 180277L; 180279L; 180422L; 180575L;	05 Nov 2015 – 13 Sept 2018

REF/ Product Code	Item Description	Lot Numbers	Distribution Dates
		180576L; 180577L; 180578L; 180579L; 180580L; 180581L; 180582L; 180809L; 180810L; 180811L; 180814L; 180819L; 180821L; 180826L; 180827L; 180954L; 180955L; 180958L	
V5926	Rate Flow® Regulator IV Set; 83 in.; 60 Drops/mL	151831L; 160484L; 160707L; 160734L; 160740L; 161205L; 161359L; 162001L; 170571L; 170927L; 171392L; 171539L	09 Mar 2016 – 12 Sep 2018
V5932	Rate Flow® Regulator ADDitIV IV Set; 89 in.; 20 Drops/mL	160842L; 160890L; 160911L; 161209L; 180188L	04 Aug 2016 – 13 Sep 2018

Reason for the recall:

BBMI has reviewed recently reported deficiencies related to validation and process control of the manufacturing facility of the Rate Flow Regulator Administration Sets and, out of an abundance of caution, BBMI has elected to remove this product from the market.

Risk to Health:

To date there have been no reports of serious injury or death associated with the Rate Flow Regulator Administration Sets nor have there been any adverse trends in post-market data which would be indicative of a significant risk to health.

Actions Required By 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 persons, are informed about this voluntary product recall. If you are a distributor, please forward this recall notification to your customers.
2. Determine your current inventory of the affected lots within your facility. Do not destroy any affected product.
3. ~~Utilizing the attached "Product Removal 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.~~
4. ~~Return the completed "Product Removal 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. ~~If you have any full cases, partial cases, or unused individual pieces of these affected products as identified in the "Product Removal Acknowledgement" form that was submitted to BBMI Quality Assurance Department, a BBMI Customer Support Representative will contact you to provide instructions for handling the affected product and arrange for return to BBMI.~~

Should you have any concerns with the products impacted by the scope of this recall, please contact Medical Affairs Department at 1-800-854-6851. Additionally, any adverse reactions or quality problems experienced during the use of this product 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**: 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

For Canadian customers, any adverse reactions experienced with the use of this product may also be reported to the Health Products and Food Branch Inspectorate at: http://health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/health-product-complaint-form-0317.html

We apologize for the inconvenience this recall may cause 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,

Laura Elmo
Director, Quality – Purchased Finished Goods
B. Braun Medical Inc.

Enclosures: Medical Device Recall Acknowledgement