@4:38 10/10/18 Per Laura Class 1 - Consumer level to SDC

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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