



URGENT: MEDICAL DEVICE RECALL

June 6, 2018

B. Braun Singapore Pte Ltd
Hui Min, Teng
600 North Bridge Road
#15-05 Parkview Square
Singapore 188778

Dear Ms. Teng:

This letter is to inform you of a voluntary recall of certain lots of **NeoMed Enteral Feeding Tubes with Enteral Only Connectors**. The affected products shipped to you are identified in the table below:

Model Number	Lot Number	QTY
FTS6.5P-EO	20171214	1
FTM6.5P-EO	20171219	10
FTM8.0P-EO	20171222	1

This recall was initiated due to the potential for the tethered plug on the hub inadvertently opening after closure. The photograph below depicts the hub with tethered plug in the open position. This problem affects only certain production LOTs. As described in the Instructions for Use provided with the product, when the tube is flushed with sterile water before and after use, NeoMed has determined that the patient risk resulting from an open hub is extremely low. No adverse events related to this issue have been reported to NeoMed.



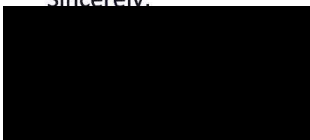
Please examine your inventory for product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them of this product recall. You may include a copy of this letter in any notification you provide your customers.

Please contact NeoMed Quality Assurance at recall@neomedinc.com to confirm receipt of this letter and obtain a Return Materials Authorization for any units identified above that remain in your inventory. You may instruct your customers to contact NeoMed directly or you may arrange the return of any product remaining in their inventory to NeoMed. You may also contact NeoMed at +1 770-516-2225.

Please notify us if you require any information for your reporting obligations to the Singapore Health Sciences Authority. We are reporting this field action to the United States Food and Drug Administration.

NeoMed appreciates your support and remains committed to meet your product needs.

Sincerely,



NeoMed Inc., 100 Londonderry Ct #112, Woodstock, GA 30188, United States



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Regulatory and Quality Consultant for NeoMed