Vygon Nederland B.V.
Kerkhofstraat 21
5554 HG Valkenswaard

Valkenswaard, July 2018

URGENT: FSN-MEDICAL DEVICE RECALL

Lifecath midline

Dear customer,

VYGON GmbH & Co. KG has initiated a recall of the products listed in the table below. Please direct this notice to the appropriate personnel in the Quality/Regulatory Affairs, or to those responsible for inventory management of the affected product.

Scope of Recall:
The products being recalled are listed in the table below and no other products are affected.

Reason for Recall:
Following a routine inspection, an unacceptable level of bacterial endotoxin (Pyrogen) was measured. The products listed might contain unsafe levels of bacterial endotoxins (Pyrogens) that were introduced during a manufacturing step. Bacterial Endotoxins also called pyrogenic bacteria can activate the inflammatory process and produce fever, chills, and hypotension in a patient. A peelable sheath introducer was identified as root cause for this contamination.

Product Desicription	Code No.	Batch No.
Lifecath midline	1296.345	030518GK

We have identified the lots listed in the table above as the only affected products that were distributed to you. The problem has been investigated, and we have taken steps to assure this problem does not recur.

Please acknowledge receipt of this letter and complete and return the attached form by indicating the quantities withdrawn from your institution.
The Dutch health authority (IGZ) has been informed of this Field Safety Notice.
For further information, you can directly contact Mrs. N. van Veldhoven, quality contact, or sales administration phone number 040-2089380.

We apologize for any inconvenience this FSN-Recall may cause.

Vygon Nederland B.V.
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5554 HG Valkenswaard

ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM FEEDBACK FORM

For RECALL on Lifecath midline, code 1296.345, Batch No. 030518GK

Please fill in the form even if you have no products left in stock and sent it by e-mail to nvanveldhoven@vygon.com

Customer Name / Town: _____

Name/Function: _____

We acknowledge receipt of the above FSN and that the information contained in this field safety notice has been shared with all recipients/ end users of above products within your organization.

Product Desicription	Code No.	Batch No.	Quantity used	Quantity to be returned
lifecath midline	1296.345	030518GK		

Date/Signature: _____