URGENT FIELD SAFETY NOTICE

Affected Devices: Rythmic Spike Set PN DEHP Free

Type of Action: Field safety corrective action – Recall

Ref.: FSN2017-01

Date:	21 March 2017
Attention:	Distributors, Biomedical Professionals, Homecare providers, Clinicians and other users of these devices
Details on affected devices:	Rythmic Spike Set PN DEHP Free Product Reference: KM1.EE.148.0 Lot Numbers: 10012465, 10012496, 10012517, 10012541

Dear Customer,

Micrel Medical Devices is issuing this field safety notice to notify its customers about a voluntary Field Safety Corrective Action for certain **Rythmic Spike Set PN DEHP Free** administration sets.

Micrel Medical Devices has become aware of a limited number of complaints for leakage from the filter that is integrated on the above-referenced administration sets. The leakage occurs from one of the air vents of the filter and can be observed during priming before the start of the infusion. If the leakage is noticed before the infusion or during the infusion, it could result in a delay of the therapy while the administration set is replaced. During the infusion with defective set/filter a small amount of under-delivery could occur.

Micrel Medical Devices has received no reports of serious injury or death related to this issue.

Only those Rythmic Spike Set PN DEHP Free administration sets with Product Reference and Lot Numbers listed above are affected by this Action.

Advise on action to be taken by the user:

Subject to this Urgent Field Safety Notice, Micrel Medical Devices is requiring its customers to return all unused administration sets with Product Reference and Lot number listed above.

1. Inspect your inventory for the administration sets listed above and isolate the affected sets

2. Complete and return the attached Confirmation Form by email to regulatory@micrelmed.com or Fax to +30 210 6032335 or within 15 days of receipt of this letter.
3. Upon receipt of the completed form, a customer service representative of Micrel will contact you for the replacement of the affected administration sets.

Actions taken by Micrel Medical Devices

Appropriate corrective and preventive actions have been initiated and successfully implemented by Micrel Medical Devices and the vendor of the filter.

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Contact reference

For additional information please contact Micrel Medical Devices through email: regulatory@micrelmed.com or fax: +30 210 6032335

The appropriate Regulatory Agency has been duly informed of this field safety notice.

We are fully committed to providing high quality products to our customers and we apologize for any inconvenience this situation may have caused.

Sincerely,

Sasa Karpeti
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URGENT FIELD SAFETY NOTICE ACKNOWLEDGMENT FORM

FSN2017-01

Please complete and return this Form by Fax to +30 210 6032335 or send an electronic copy via email to regulatory@micrelmed.com.

☐	**I do not have any unused inventory of the affected administration sets**
☐	**I have unused inventory of the affected administration sets, detailed in the table below**

Lot Number	**Quantity** (number of administration sets)

Name of facility:	
Facility address:	
Telephone number:	
Name:	
Signature:	
Date:	