

26-Nov-2019

Field Safety Notice - Voluntary Medical Device Recall

Details of potentially affected products: Invia Foam Dressing Kit with FitPad - X-Large

Sales Article Numbers: REF 087.6224 (3 pcs of 200.8908)

Dear Customer

This letter is to notify you that Medela is recalling certain lots (identified below) of the

**Invia Foam Dressing Kit with FitPad - X-Large
(Sales article number REF 087.6224 (3 pcs of 200.8908))**

Medela has determined that the sterility of products from certain production lots may be compromised by a potential breach of the sterile product packaging, even though the packaging may appear intact to the user. The affected production lots are listed below. Medela has implemented corrective actions to ensure the integrity of the sterile packaging of newly manufactured Invia Foam Dressing Kit with FitPad - X-Large.

Medela has not received any reports of serious injury associated with this issue and we expect the probability for serious injury associated with the use of products from the affected lots to be unlikely.

Medela takes its responsibilities to its customers and their patients very seriously and therefore requests, as a precaution, not to use products from the affected production lots.

The numbers of the affected lots can be found on the individual product package (box / piece) labelling and are as follows:

Lots:

17110012731,

17110022736,

17120012746,

18010012767,

18070012913,

18090012960,

18110013046

Medela requests that you take the following actions:

Customer Response Form - Part 1	<ol style="list-style-type: none"> 1. Immediately locate and remove all products from the affected lots from your inventory and place them in quarantine. The product code and lot number can be found on the individual product package (box / piece) labelling. 2. Complete and sign the attached Customer Response Form - Part 1 to confirm that you have received, read and understood this "Field Safety Notice - Voluntary Medical Device Recall" and return it back via email to vigilance@medela.ch or by Fax to +41 41 562 51 00 (to attn. Head of PMS & Complaint Handling).
Customer Response Form - Part 2	<ol style="list-style-type: none"> 3. Document the quantities of each lot number in the attached Customer Response Form - Part 2, even if you do not have any inventory. 4. If you have distributed this product to other facilities or departments within your organisation or outside of your organisation, please forward a copy of this Field Safety Notice with the Customer Response Form to them. 5. Please contact your Medela Sales Office to return all affected products. Alternatively, you may also choose to destroy all affected products terminally at your facility. In this case please confirm the destroyed quantity in the Customer Response Form - Part 2 6. Provide information on the distribution of products from the affected lots to other organizations and consolidate these quantities in your Customer Response Form - Part 2 (attachment, as appropriate) 7. Sign the Customer Response Form - Part 2 to confirm the quantity of product used, on stock and destroyed and send it via email to vigilance@medela.ch or by Fax to +41 41 562 51 00 (to attn. Head of PMS & Complaint Handling).

Thank you for your prompt attention. We apologize for any inconvenience this may cause. We are doing our utmost to ensure seamless continuation of your business. Should you have any questions or require any further assistance, please contact your Medela Sales Office.

Sincerely yours,



Dr. Erhard J Hüsler
 Director Quality Medela AG



Dr. Oliver A. Kohr
 Head of Post Market Surveillance
 & Complaint Handling

Customer Response Form

Part 1

Field Safety Notice - Voluntary Medical Device Recall Invia Foam Dressing Kit with FitPad - X-Large Sales Article Numbers: REF 087.6224 (3 pcs of 200.8908)

Products of potentially affected production lots and confirmation

You have received products of the potentially affected production lots of the Sales Article Number REF 087.6224. The lot numbers and quantities are identified below. Note: Each box (REF 087.6224) contains three pieces (200.8908).

Product Identification	Lot No.	Quantity Supplied (Qty boxes REF 087.6224, Qty pieces 200.8908)
REF 087.6224 Invia Foam Dressing Kit with FitPad X-Large (3 pcs of REF 200.8908)	17110012731	<i>This column is filled out by Medela</i>
	17110022736	<i>Example: boxes: 5 / pcs: 15</i>
	17120012746	
	18010012767	
	18070012913	
	18090012960	
	18110013046	
	Total Qty	

Acknowledgement			
By signing below, you acknowledge that			
<ul style="list-style-type: none"> You have received, read and understood the Field Safety Notice - Voluntary Medical Device Recall related to REF 087.6224, <i>Invia Foam Dressing Kit with FitPad X-Large</i> Any health care professional within your organization that needs to be aware of this Field Safety Notice has been informed. 			
Contact name		Organization	
Address		Phone	
		Email	
Date		Signature	

Please immediately complete, date and sign this page. Then submit it via email to vigilance@medela.ch or by Fax to +41 41 562 51 00 (to attn. Head of PMS & Complaint Handling)

Customer Response Form

Part 2

Field Safety Notice - Voluntary Medical Device Recall Invia Foam Dressing Kit with FitPad - X-Large Sales Article Numbers: REF 087.6224 (3 pcs of 200.8908)

Please complete the following table. Document the **quantity of boxes and pieces (pcs)**.
 Note: You may have open boxes with less than three pieces inside. Further, if you have no product in stock, please enter "0 / 0".

Column:		(A)	(B) = (A)-(C)-(D)- (E)	(C)	(D)	(E)	(F)
Product	Lot No.	Qty boxes / pcs supplied	Qty boxes / pcs in stock	Qty boxes / pcs consumed	Qty boxes / pcs distributed*	Qty boxes / pcs destroyed	Qty boxes / pcs to return
REF 087.6224 Invia Foam Dressing Kit with FitPad X-Large (3 pcs of REF 200.8908)	17110012731	<i>e.g. 5 / 15</i>					
	17110022736						
	17120012746						
	18010012767						
	18070012913						
	18090012960						
	18110013046						
	Total Qty						

*Complete attachment (provided on page 3) to account for the total quantity (boxes and pcs) distributed.

Acknowledgement			
By signing below, you acknowledge that			
<ul style="list-style-type: none"> All affected products have been removed from our inventory and put in quarantine (to be returned to Medela or have been destroyed terminally). Any other facility or organization that has received from you products of the affected production lots has been informed. 			
Contact name		Organization	
Address		Phone	
		Email	
Date		Signature	

Please immediately complete, date and sign this page. Then submit it via email to vigilance@medela.ch or by Fax to +41 41 562 51 00 (to attn. Head of PMS & Complaint Handling)



Medela AG

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**Customer Response Form
Part 2 - Attachment**

**Field Safety Notice - Voluntary Medical Device Recall
Invia Foam Dressing Kit with FitPad - X-Large
Sales Article Numbers: REF 087.6224 (3 pcs of REF 200.8908)**

The following organisations have been distributed product affected by this Voluntary Medical Device Recall:

Organization Name	Qty Boxes / Pcs Distributed	Lot Distributed	Address	Contact Name	Contact Email	Contact Phone No.	Date Recall Info sent out
TOTAL							
Make additional copies of this attachment as needed. Number of Copies:							

<input type="checkbox"/> Registered by Medela Date / Initials
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