

**Field Safety Notice –
 Extension of the Recall**

08.07.16
 Fax: 01283 576 808

Activa Healthcare Ltd
 1 Lancaster Park
 Newborough Road
 Needwood
 Burton on Trent
 Staffordshire
 DE13 9PD

Urgent Field Safety Notice

**Extension of the Product Recall due to possible contamination with
 metal needles in Metalline products**

Known:

REF	Product	Lot
23080	Metalline Wound dressing 5/10 1Stk gero	605212315
23082	Metalline wound dressing 10x12 50ste	550512208
23084	Metalline wound dressing 10x12 10ste	550512208
23088	Metalline Drain-K Kruetten 6x7 8000Stk	551412208
23093	Metalline Drain 6x7 50ste	603212208
23093	Metalline Drain 6x7 50ste	606412208
23093	Metalline Drain 6x7 50ste	609212208
23093	Metalline Drain 6x7 50ste	614312208
23094	Metalline Tracheo 8x9 50ste	606512208
23094	Metalline Tracheo 8x9 50ste	609412208
23094	Metalline Tracheo 8x9 50ste	614512208

New:

REF	Produkt	Charge
23080	Metalline wound dressing 5/10 1Stk gero	544212315 623412315
23081	Metalline wound dressing 8x10 50ste	551112208 551212208
23083	Metalline wound dressing 8x10 10ste	551212208 554512208
23093	Metalline Drain 6x7 50ste	549112208 551312208 546112208 545512208 541512208 538412208
23094	Metalline Tracheo 8x9 50ste	602512208 601112208 546312208 544512208

		543312208
		542212208

Dear Sir or Madam,

Today, in terms of patient safety, we would like to inform you about the **extension** of our precautionary product recall of the above mentioned products.

During the further quality control of the production process two additional raw material batches of the backfacing nonwoven were identified as affected. Therefore we have to extent our current recall and to inform you.

Event and further procedure

During the quality control process parts of needles or whole needles were detected on or in the backfacing nonwoven of some final products. The needles are from the needling process during manufacturing of the backfacing nonwoven, which are usually detected by a metal detector and separated.



The probably affected products were immediately separated and the affected batches were blocked in the warehouse.

However, as we can not completely exclude that products with metal needles have already been delivered to customers, we decided to perform a precautionary recall of the products in terms of patient safety.

Until today we have not received any complaints from the market. Theoretically, the parts of the needles could cause puncture wounds, inflammation or foreign body reaction.

Please send the affected batches of the products (see list in enclosure) with the enclosed form back to us (small amounts can be destroyed locally). You will receive a credit note for the returned/destroyed products in short term.

Please ensure within your organization that all users of the above mentioned products and other relevant persons are aware of this **Urgent Field Safety Notice** and send the enclosed confirmation back to us.

If you have delivered the product to third parties, please forward a copy of that information to them.

We thank you in advance for your cooperation and apologize for any inconvenience.

Yours faithfully

Lohmann & Rauscher GmbH & Co KG
On behalf of

Regional Vigilance Office: Pierina Anderson



an  Company

Attachment:

Urgent Field Safety Notice, Product Recall due to possible contamination with metal needles in Metalline products

List of affected articles and batches

Urgent Field Safety Notice!

08.07.16

Extension of the Product Recall due to possible contamination with metal needles in Metalline products

Sender: Activa Healthcare Ltd
1 Lancaster Park
Neworough Road
Needwood
Burton on Trent
Staffordshire
DE13 9PD

Addressee: & all users who use the below mentioned products.

Description: Recall of the following products due to possible contamination with metal needles in Metalline products

- **Metalline products affected**
Article numbers and batches see enclosure

Corrective Actions:

We ask you not to use the above mentioned products anymore and to send them back to us!

To ensure a free return to us, please contact our Activa returns department:

Fax: 01283 576 808

Tel: 01283 576 800

Contact Person for Activa Healthcare within your facility:

Name	Graeme Smith	Function
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Telephone number 01283 576 800	Email Graemesmith@activahealthcare.co.uk
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Please inform your employees who use the products of this Field Safety Notice and confirm to us that the products are not used anymore and the products have been returned to us or have been destroyed locally.

The undersigned confirms (please tick):

- that he does not possess the above mentioned products anymore,
- that he has not given the above mentioned products to third parties,
- that if he has given the above mentioned products to employees or third parties, he has informed the employees and third parties about the recall,



an  Company

- that he will return the above mentioned products, which have been delivered to him and are still in his possession or in the possession of third parties, to Activa Healthcare Ltd
- that he destroyed a small amount locally (maximum: 2 packages).

The batches and amounts are listed in the table below.

Please enter the returned products with quantity in the following table:

REF	Product	Lot	Quantity of returned products	Destroyed
N.N.	Metalline N.N.	N.N.		

Date / Signature : _____

Printed Name: _____

Position: _____

Department / Institution: _____

Phone and Email: _____