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Ihre Zeichen, Ihre Nachricht vom	Unser Zeichen, unsere Nachricht vom	Durchwahl, Name	Datum
	DD	-21/Daniela Dahlhauser	28.01.2014

Product recall

regarding occasional quality defects when using the products ELS 200 ml syringe and syringe sets (ELS) of MEDTRON AG

Article numbers concerned: REF 316025,
REF 316026,
REF 317616,
REF 317624,
REF 317625,
REF 317627,
REF 317628.

Dear Sir or Madam,

We have been informed by our supplier of the above-mentioned ELS syringes and syringe sets that the mentioned batches may possibly contain particles.
In the investigations carried out together with our supplier we found out that blue particles of the protective caps have occasionally peeled off and got inside the syringe.

In order to avoid any danger for patients, we recall the batches concerned.

To this day, MEDTRON AG has not been informed about any notifiable incidents. If you know about such incidents on patients, please report them to us immediately.

After having consulted the supplier, we can definitely limit the potential defect to the mentioned batches.

According to the supplier, the defect has in the meantime been eliminated in the production. Moreover, our supplier assures that no batches other than the above-mentioned ones are concerned.

Identification of the medical devices concerned:

Ref. Nr.	Batch Nr.	Ref. Nr.	Batch Nr.	Ref. Nr.	Batch Nr.
316025	13031337	**316026**	13031125	**317616**	13041605
	13031360		13031542		13051179
	13031455		13041179	**317616**	13041605
	13031543		13041386		13051179
	13031547		13041606	**317624**	13051382
	13031548		13041607	**317625**	13031077
	13031549		13061118		13031261
	13041185		13061121		13041383
	13061119		13061467		13051378
	13061120		13061488		13101137
	13061466		13061706	**317627**	13031127
	13061489		13071612		13031260
	13071236		13081216		13041382
	13071292		13081230		13041616
	13071293		13081231		13041617
	13071386		13081357		13051377
	13071387		13091113		13101136
	13071510		13091191	**317628**	13051226
	13071557		13091342		13051249
	13071613		13101016		13051379
	13071714				13051380
	13081356				13071332
	13081358				13071333
	13081362				13091134
	13091114				13091136
	13091192				13091435
	13091531				13091464
	13101107				
	13101520				
	13101521				

Description of the problem including the identified cause:

In the case of the batches concerned, there is a material abrasion when the protective cap is screwed on during the production process of the syringe. In the worst-case scenario the abraded material will get inside the syringe.

The cause for this was a tool modification by the syringe manufacturer.

Measures to be taken by the user:

We have to point out to you that the batches concerned must not be used any more. Please return the enclosed "*Acknowledgement of receipt of product recall R-2014-001*" to the specified fax number until **February 4th 2014**.
If you still have any unused products of the batches concerned, please return them to your distributor or to MEDTRON AG so that we can replace the products or credit the purchase price to your account.

Forwarding the information described in this letter:

Please make sure that all users of the above-mentioned products in your company and other persons to be informed take note of this **"Urgent Safety Information"**. If you have passed the products to third parties, please forward a copy of this information or inform the contact person mentioned below.

Please keep this information at least until the measure has been completed, i.e. until the products of the mentioned batches are no longer in use.

The "Bundesinstitut für Arnzeimittel und Medizinprodukte" (German Federal Institute for Drugs and Medical Devices) has received a copy of this "Urgent Safety Information".

Contact person:

Dr. Daniela Dahlhauser
Safety Officer acc. to art. 30 Medical Devices Act

Telephone: +49 681 97017 21
Telefax: +49 681 97017 20
E-mail: d.dahlhauser@medtron.com

We apologise for the defects that have occurred and hope that we can reliably prevent such mistakes in future.

If you have any further questions, please do not hesitate to contact us.

Yours faithfully,
MEDTRON AG

Dr. Daniela Dahlhauser
Head of Quality Management

Acknowledgement of receipt of product recall R-2014-001

Please fill in this form and return it immediately by fax to

++49 681 / 97017-20

☐ We hereby confirm that we have been informed about the product recall of 2014-01-28 regarding the above-mentioned article and batch numbers. The product recall has been communicated within our organisation.

References concerned	**Batch number**	**Quantity delivered**	**Quantity identified in stock and put in quarantine**	**Quantity distributed/ Sold** ***(only for distributors)***	**Quantity recovered from your customers** ***(only for distributors)***	**Quantity used by your customers**
			(to be returned to MEDTRON)		***(to be returned to MEDTRON)***	

Name: _____

Telephone/fax number: _____

Date/signature: _____

Stamp: