

FIELD SAFETY NOTICE

Re. Recall of LoFric Sense Urinary Catheters

The quality system of Wellspect HealthCare is in place to secure that we constantly deliver products with the highest quality possible to our customers.

This action is initiated as a precautionary measure following an internal quality review in which a small number of LoFric Sense packages potentially being compromised have been identified.

The batches of LoFric Sense mentioned below are hereby recalled and based on our traceability records you have received products from one or more of the batches involved.

Ref No	Batch No
4161220	136085
4161420	136086
4161220	136274

Description

LoFric Sense is a hydrophilic catheter for intermittent catheterization. The packaging of Lofric Sense may be compromised and therefore a small proportion may not maintain sterility throughout shelf life. Within the batches being recalled it is estimated that about 2,6% of the products could potentially be affected.

If a nonsterile product is inserted into the urethra there is a possible risk of urinary tract infection, however, the chances of this occurring are remote.

Wellspect HealthCare has not received any adverse event reports or complaints related to this issue.

The reference numbers are country specific and this notice is only valid for products distributed to the Nordic countries, excluding Iceland.

Instructions

Please identify and quarantine any unused products of the concerned batches.

Any adverse events related to the use of the affected LoFric Sense products should be reported to Wellspect HealthCare.

Transmission of this Field Safety Notice

Please forward this message to relevant persons in your organization. If you have further distributed items of the actual product please notify the consignees at once of this recall.

Please transmit a copy of the attached user letter to each of your customers to request they cease use of the affected lots.

Disposition of products

Affected products to be returned to Wellspect HealthCare as soon as possible labeled "recall 201307". Please see address below:

Wellspect HealthCare
Dentsply IH AB
Aminogatan 1
SE-431 21 Mölndal

For fast replacement products, please place a new order.

If you have any questions with regards to this recall please contact Håkan Strandberg, phone +46 31 3763060, mobile +46 702230308, hakan.strandberg@wellspect-healthcare.com, or Petra Grapengiesser, phone +46 31 776 32 04, mobile +46 703410335, petra.grapengiesser@wellspect-healthcare.com.

Wellspect HealthCare



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