
Urgent Field Safety Notice (FSN)

Commercial name of the affected device products:

LoFric Origo - 40 cm, single use, intermittent urinary catheters

FSCA-identifier: CR-U-202000574

Type of action: RECALL

Date: 16 June 2020

To: Users, caregivers, distributors, importers of LoFric Origo 40cm catheters

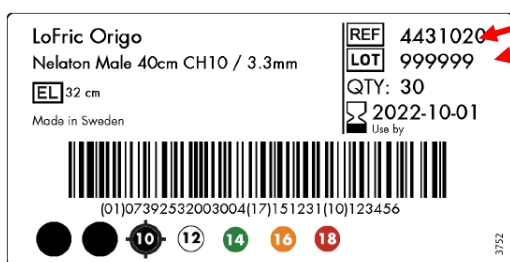
Details on affected products that are recalled:

The LoFric Origo products are sterile single use catheters intended for intermittent urinary catheterization.

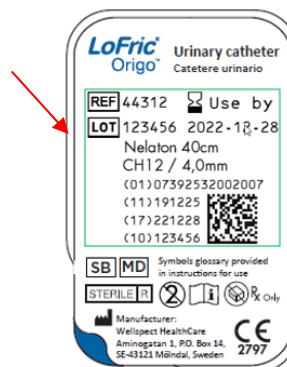
A potential defect, a non-conformity, has been identified on a few **LoFric Origo 40 cm** products, intended for adult use. The defect may be present for distributed **LoFric Origo 40 cm** catheters with either **Nelaton (straight, round) tip or Tiemann (curved, coudé) tip**, in **sizes CH10, CH12, CH14 and CH16**. The recalled catheters have been supplied in customer boxes with 30 pcs, the most common package, and some in boxes with only 5 pcs.

The table on next page shows which specific products that may have a defect, including their article number (REF) and their production identity number (LOT) where this could have occurred. The picture below shows **example of labels and where / how to locate the information** on each customer product box to help you identify if your device must be returned. Please note that the numbers or text on example labels may be different than on your product.

30 pack Customer box label



single pack label



5 pack Customer box label

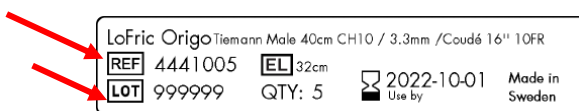


Table: Recalled Products – total list [this table shows all REFs and LOTs included in recall in all countries. The table will look differently in each country's FSN, where it will only include the REFs and LOTs that have been distributed locally. Also the REF-XX suffix number varies per country]

CUSTOMER BOX REF	PRODUCT NAME, DESCRIPTION	LOT (ALL)
44310XX	LoFric Origo, Nelaton 40cm, CH10/ 3.3 mm	446876, 447123, 447124, 447173, 447624, 447669, 447670, 448046, 448047, 448404, 448405, 448467, 448754, 449666, 449667, 449668, 450110, 450199, 450544, 451054, 451363
44312XX	LoFric Origo, Nelaton 40cm CH12/4.0 mm	451683, 451712
44316XX	LoFric Origo, Nelaton 40cm CH16/5.3 mm	446929, 447564
44410XX	LoFric Origo, Tiemann 40cm CH10/3.3 mm	450273
44412XX	LoFric Origo, Tiemann 40cm CH12/4.0 mm	450422
44414XX	LoFric Origo, Tiemann 40cm CH14/4.7 mm	446075, 447036, 447121, 447260, 448251, 448546, 448760, 449679, 449680, 450112, 450503, 450978, 451696
44416XX	LoFric Origo, Tiemann 40cm CH16/5.3 mm	447176

Note: NONE of the LoFric Origo 30cm Nelaton catheters, for use by children, are affected
Customer boxes with other LOTs than those listed should not be returned.

Reason for recall and description of the problem:

This recall is performed as a precaution since the manufacturer has discovered, during routine sampling, that a few LoFric Origo 40 cm catheters, have had tips being damaged and stuck into the package's seal.

Faulty catheters may have a deformed, sharp tip and/or be non-sterile. This may not be easily noticed before use. A sharp catheter tip can cause pain and severe bleeding from the urethra during insertion. Since also the single catheter package may have been broken, the sterility of the products cannot be guaranteed.

Users who experience a severe bleeding or are using a non-sterile catheter may have to seek medical care. Due to the risk of developing a urinary tract infection, treatment with antibiotic medicine may also be required.

There are to-date, no customer or user complaint reported to the Manufacturer, which has involved any injuries or harm when catheter from the affected production LOTs have been used. However, the manufacturer does not exclude it can happen why this recall is taken as a precaution.

Advise on action to be taken by the customer/user:

1. Urgently identify and check the REF and LOT numbers on your LoFric Origo 40 cm product(s) customer box label and compare with the Table above. If you no longer have your customer box, for storing unused products, check the REF and LOT on the individual catheters you have left. If the 5 digit of the REF and LOT number in single package match those in the table above, the catheter shall be returned.
2. Should both REF and LOT numbers match those listed in the Table above, return the boxes with remaining catheters, without delay to the following address and make sure to include a note of name and address of sender so we know from **where it is coming:** [in certain countries, the address may instead be a named local 'hub' destination, from where shipments will be made to WHC Sweden]

“Recall 202000574”
Wellspect HealthCare
Aminogatan 1
P.O. Box 14
SE-431 53 Mölndal.
Sweden

3. Please **confirm receipt of this Filed Safety Notice** by **immediate response** to the sender of this message

NOTE: Any adverse events experienced and suspected related to the use of the affected LoFric Origo 40 cm catheters should be promptly reported to your local Wellspect HealthCare contact. Please see the Instructions For Use leaflet, provided inside the box, for contact details. Local contact information is also found via www.wellspect.com, by selecting your country.

For replacement:

If you are a patient, please contact your health care provider.

If you are a health care provider or distributor, importer please place a new order.

Returned product will be reimbursed.

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 LoFric Origo catheters have been transferred.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person

If you have any questions, you can contact us directly. We will help to answer your questions.

Contact information:

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The undersigned confirms that this notice has been notified to the appropriate Regulatory Authority.

Herman Fahlström

Vice President Quality Assurance & Regulatory Affairs