

Laboratoire CCD
48 rue des Petites Ecuries
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customer-service@ccdlab.com

URGENT: FIELD SAFETY NOTICE
Warning – Medical Device Safety
Batch Recall
1ml IVF and AI Syringes
Item no. 1323101/7002655

18 October 2019

To:

Procurement Departments, Head Pharmacists, Medical Device Safety Officers, Internal Pharmacies, Assisted Reproduction Centres

Description of the issue:

Some users have detected an issue with using 1ml IVF and AI Syringes, item no. 1323101/7002655. LABORATOIRE CCD is initiating a recall of the following batches:

- 50036061
- 50036279
- 50036442
- 50036968
- 50037764

As a precautionary measure, we recommend that users stop using the batches above in embryo transfers.

For other batches not affected by the recall, LABORATOIRE CCD recommends that users check that the plunger moves smoothly before using the syringes, when unsticking or loosening it, and during the initial rinse prior to transfer procedures.

Potential risk to patients:

No patients have been endangered in any of the claims received by LABORATOIRE CCD to date.

A possible effect on the embryo transfer and on the chances of a successful pregnancy at 15 days is to be considered.

No risks have been identified in using the syringes for artificial insemination.

Actions:

1. Check your stocks for the item number affected (1323101/7002655) and for the batches listed above, and remove any recalled products from circulation.
2. Complete the Destruction Form and email it to customer-service@ccdlab.com with the subject line "Batch Recall – LABORATOIRE CCD 1ml syringes".

Once we have received the Destruction Form, LABORATOIRE CCD will contact you to arrange to replace the products at no charge.

Note: if you do not have any of the recalled products in stock, or if you do not use them for embryo transfers, please complete the form and indicate that you are disposing of zero products or are using them for artificial insemination. Return the completed form to LABORATOIRE CCD at customer-service@ccdlab.com with the subject line “Batch Recall – 1ml IVF and AI syringes, item no. 1323101/7002655”.

Forward this information:

Please forward this information to all users of 1ml IVF and AI Syringes, item no. 1323101/7002655.

If you have any questions, contact our customer service department at customer-service@ccdlab.com.

The appropriate regulatory agencies have been informed of the measures proposed in this letter.

The safety and wellbeing of patients and health professionals is LABORATOIRE CCD’s number one priority and we want to ensure only the best products for our customers.

We apologise for any inconvenience. Thank you for your cooperation and for helping us resolve this issue as quickly and efficiently as possible.

Sincerely,

Geraldine Douglas
Head Pharmacist
LABORATOIRE CCD

Destruction Form

1ml IVF and AI Syringes, item no. 1323101/7002655

Check your stocks and complete the form below, even if you do not have any of the items in stock.

Any error in completing the form may cause delays in replacing your products.

Scan and email the completed form to customer-service@ccdlab.com with the subject line “Batch Recall – 1ml IVF and AI syringes, item no. 1323101/7002655”.

Once we have received the form, LABORATOIRE CCD will contact you to arrange to replace the products at no charge.

Please double check the contact information below.

You will receive replacements only for the items that have been recalled.

Information (mandatory):

Institution Name

Telephone Number

Address/City/Postcode

Batch Numbers and Quantity Destroyed (units)

Completed by (Name/Signature/Date)

For LABORATOIRE CCD use only

Batch Numbers and Quantity Replaced (units):

This form must be returned to LABORATOIRE CCD before this action is considered complete for your institution.