

Laboratoire CCD – FSN 2021-08-001

Laboratoire CCD  
48 rue des Petites Ecuries  
75010 Paris  
Tel 01 44 95 14 95  
[customer-service@ccdlab.com](mailto:customer-service@ccdlab.com)

**URGENT: FIELD SAFETY NOTICE**  
CCD Number: **FSN 2021-08-001**  
**Warning – Medical Device Safety**  
1ml IVF and AI Syringes- REF 1323101

17<sup>th</sup> July 2021

**To:**

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

**PRODUCT :**

**1ml IVF and AI Syringes** : reference 1323101

**Product Indication:** embryo transfers and artificial insemination (IA)

**Description of the issue:**

Some users have detected an issue while handling the plunger with IVF and AI Syringes indicated for “embryo transfers”.

All products are compliant with the current regulation and standards. The Laboratoire CCD determined that the events are random in nature and is possibly in connection with the user’s gesture.

**Accordingly**, LABORATOIRE CCD reminds users to verify that the plunger moves smoothly before using the syringes and to perform an initial rinse prior to transfer procedure.

**Potential risk to patients:**

A possible effect on the embryo transfer and on the chances of a successful pregnancy at 15 days is to be considered if the fluidity of the plunger is not maintained.

No patients endangerment has been observed in the claims received by LABORATOIRE CCD to date.

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

An Instruction for Use (IFU) will be available for this product with the protocol identified in Annex 1. Please read carefully this protocol before each use.

Laboratoire CCD – FSN 2021-08-001

**Communication of this information:**

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

For any question, please contact our customer service to the following address: [customer-service@ccdlab.com](mailto:customer-service@ccdlab.com).

Rest assured that the Laboratoire CCD considers the safety and satisfaction of its customers and users to be paramount and we apologize for any inconvenience caused.

The French Health authority (ANSM) has been informed concerning this Field Safety Notice.

Please complete the acknowledgment in Annex 2 and send it by email to the following address: [customer-service@ccdlab.com](mailto:customer-service@ccdlab.com).

Best Regards,

**Dominique Bonnet**

Correspondent for Medical Device Vigilance  
Regulatory affairs and quality Director for medical devices  
LABORATOIRE CCD

17-Aug-21 | 17:14 CEST

DocuSigned by:  
**Dominique BONNET**  
45DCAB5E51934B4...

Laboratoire CCD – FSN 2021-08-001

## ANNEXE 1: Instruction

### Recommendations for rinsing:

- 1- Before use, push the plunger of the syringe to the maximum.
- 2-Pull to the maximum and push the plunger of the syringe to the maximum again(vacuum).
- 3-Attach syringe to Luer-style fitting of the transfer catheter.
- 4-Flush the catheter through with medium and expel medium.
- 5- Follow laboratory procedure for loading embryos into catheter.

## ANNEX 2: ACKNOWLEDGMENT

### Information (mandatory):

\_\_\_\_\_  
Institution Name

\_\_\_\_\_  
Telephone Number

\_\_\_\_\_  
Address/City/Postcode

I certify having received, written and understood this Field Safety Notice.

I hereby agree to communicate this Field Safety Notice and this additional instruction to all concerned users.

\_\_\_\_\_  
Completed by (Name/Signature) Date: \_\_\_\_