

Friday, March 8, 2024

Urgent safety information

Object: CBS™ High Security Vitrification straw green catalog number 025251, recall of batches CBS021052 and CBS021054

Our reference: rappel CBS-2024-03-07

Dear Madam, Dear Sir,

A manufacturing defect may affect some of the gutters included in the **High Security Vitrification Straw Green kits reference 025251** of lots **CBS021054** and **CBS021052**.

Due to this defect, the gutter may jam when inserted into the straw.



Defective gutter

Conforming gutter

When this happens, the vitrification procedure may be delayed or stopped, preventing the embryo or oocyte from being vitrified with the same straw.

CBS has registered two complaints for the same reason with straws reference 025251 also from batch CBS021054 (complaints registered in our files under numbers REC 02-2024-008 and REC 02-2024-025). In both cases, the problem was highlighted during a blank test by the users, before placing the biological sample on the defective gutter, thus without any impact on the biological samples.

CBS is also aware of one case of blockage resulting in embryo loss, the procedure had to be stopped at the time of vitrification. This incident was reported to the French competent authority ANSM on February 07, 2024.

The problem arises when the gutter included in the kit is so thick that the diameter of the gutter is no longer compatible with the diameter of the straw into which it is to be inserted.

Blocking is not systematic and only occurs in the unfavorable case where the gutter has an injection defect, and the internal diameter of the straw is within the low tolerance. Our tests suggest that this unfavorable combination accounts for between 25 and 35% of vitrification straws.

Identification of the root cause of the problem enabled us to confine the problem to a single batch of gutters (batch 28170), which was then used in the production of 5 batches of vitrification straws.

Of these 5 batches, 3 were still in stock at CBS and were immediately quarantined. Two batches were delivered to customers, either partially or in full, batches CBS021054 and CBS021052.

We have identified you as the recipient of vitrification straws from these batches.

As part of the safety corrective action aimed at withdrawing specific batches, we would be grateful if you could immediately implement the following measures on receipt of this letter:

- Stop distributing affected products;
- Recall products delivered to your customers according to your recall procedure;
- Collect returned products and maintain a tally of products received;
- Isolate them for return to CBS or destruction by your own;
- In the event of destruction, please complete the attached certificate of destruction and send it by e-mail to the following address qualite@imv-technologies.com ;
- Complete and return the attached acknowledgement of receipt by March 15, 2024, by e-mail to qualite@imv-technologies.com, even if you no longer have stock in your establishment. ;
- Distribute this notice to all persons who need to be informed within your establishment or to any organization where potentially affected products have been transferred..

If you have any questions or difficulties in applying these measures, please contact your usual sales representative who has been informed of this corrective action.

If you have any problems with our products, please send us a complaint in the usual way.

We regret and apologize for this inconvenience and assure you that maintaining high quality standards continues to be our highest priority. As such, we have put in place the necessary controls during the production and release stages of this product to avoid any recurrence of this problem.

Best regards,

A handwritten signature in black ink, appearing to read 'Romain Lelievre', with a long horizontal line extending to the right.

Romain LELIEVRE
Director Quality and Regulatory Affairs

Acknowledgement of receipt

Rappel CBS-2024-03-07

To be scanned and sent by email to qualite@imv-technologies.com with the following subject line : « rappel CBS-2024-03-07 »

Organisation :

Name : _____

Address : _____

Contact :

Name : _____

Function : _____

Email : _____

	Lot CBS021052	Lot CBS021054
Quantity received		
Quantity available		
Quantity used		
Quantity destroyed (if destroyed, attach certificate of destruction as per attached model)		

Certificate of destruction

Rappel CBS-2024-03-07

To be scanned and sent by email to qualite@imv-technologies.com with the following subject line : « rappel CBS-2024-03-07 »

Organisation:

Name :

Address :

Lot	Quantity destroyed	Date of destruction
CBS021052		
CBS021054		

I certify that the products identified in the table above have been destroyed.

Name :

Function :

Email :

Date :

Signature :
