

**URGENT – Voluntary Recall**  
**Lovo Cell Processing System Primary Kits**

October 23, 2024

**Subject:** Voluntary recall of Lovo Cell Processing System Primary Kits

**Affected Products:**

- X6R4906A Lovo Cell Processing Disposable Kit (A)
- X6R4909A Lovo Cell Processing Disposable Kit with Bag Access (A)

Dear Valued Customer,

Fresenius Kabi is initiating a voluntary recall of specific lots of Lovo Cell Processing System primary kits (product codes X6R4906A and X6R4909A) per the list below. Some kits may contain a defect that can result in cell loss to the waste container. This letter details the issue and the required steps for you to perform.

**Issue and Potential Risk**

Fresenius Kabi has identified, as part of post market surveillance activities, that specific lots of Lovo Cell Processing System primary kits may contain a defective spinner membrane, which detaches from the spinner's rotor during cell processing, thereby allowing target cells (>4µm in diameter) to enter the waste (filtrate) container. This results in low target cell recovery in the final product (retentate) container. In complaints submitted to Fresenius Kabi, the defect was variously described as low cell recovery in the final product container, cells went into the filtrate container, and/or the spinning membrane is not concentrating cells.

When functioning as intended, the membrane remains bonded to the spinner's rotor throughout cell processing, thereby excluding target cells from entering the waste container and resulting in the collection of target cells only in the final product container.

NOTE: If a Lovo primary kit from an affected lot was previously used for cell processing and target cell recovery in the final product container was acceptable, the individual kit performed as intended. When the membrane remains intact, the cells are directed to the retentate bag during the final cycle, rather than the filtrate (waste) bag, as occurs with a defective membrane. Therefore, there is no evidence to suggest that the kit's safety or performance are otherwise impacted if the membrane stays properly connected to the spinner's rotor.

Fresenius Kabi is initiating this recall to reduce the risk of processing cells using a kit with a defective membrane, which may cause a Lovo procedure to result in target cell loss to the waste (filtrate) container.

**Affected Product and Relevant Lot Numbers**

Our records indicate that you may have received product from one of the following impacted lots as of this communication.

<b>Product Code</b>	<b>Description</b>	<b>Lot Numbers</b>
X6R4906A	Lovo Cell Processing Disposable Kit (A)	FA24C04206, FA24C22133
X6R4909A	Lovo Cell Processing Disposable Kit with Bag Access (A)	FA23J31016, FA23K16049, FA23K21114 FA23K30057, FA23L04076, FA23L05065 FA23L07061, FA24A08060, FA24A09209 FA24A09217, FA24A22244, FA24A23234 FA24A24273, FA24A25197, FA24A26187 FA24B01188, FA24B02186, FA24B23232 FA24C04198, FA24C05229, FA24C06227 FA24C25193, FA24C26167, FA24C27173 FA24D10144, FA24D22131, FA24E09150 FA24F17219

**Required Actions for Users**

The following is a list of required actions your institution should take:

- 1) Check inventory for these lots and inform potential users of these products in your organization of this notification. If your facility further distributes or transfers products to satellite sites or other locations, please inform them or ask these locations to contact Fresenius Kabi so we can send notice to those entities directly.
- 2) Complete the attached Customer Reply Form based on either Option A or B and return it via the fax number or email address provided on the response form.
  - a. Option A: If you have no remaining inventory of the affected product, please complete the response form, and return it to Fresenius Kabi.
  - b. Option B: If you have affected product in inventory, please destroy or return the product and request replacement inventory.
- 3) Please contact Fresenius Kabi Customer Service at 800-333-6925, Prompt 1, if you intend to destroy or return recalled product. If you intend to destroy recalled product, Fresenius Kabi will provide a certificate of destruction for completion. Once completed, the certificate should be returned to Fresenius Kabi.

**Required Actions by Fresenius Kabi for Replacement Inventory**

Fresenius Kabi is working on control measures and corrective actions to assure supply continuation of the Lovo Cell Processing System Primary Kits. Fresenius Kabi will work with customers regarding product replacement options.

For further inquiries, including product replacement options, please contact Fresenius Kabi Customer Service at 800-333-6925, Prompt 1.

Thank you for your support and cooperation on this important matter. Fresenius Kabi is committed to providing you with the highest level of service, product quality, safety, and reliability.

Sincerely,

*Rebecca McCandless 23 Oct 2024*

Rebecca McCandless

Sr Director, Quality Assurance & US National Safety Officer  
Fresenius Kabi MedTech

Enclosure:

Customer Reply Form