FCSA Ref: CO7044
FSN Ref CO7044-1

Gothenburg, April 11, 2022

URGENT - Field Safety Notice
XVIVO Organ Chamber™

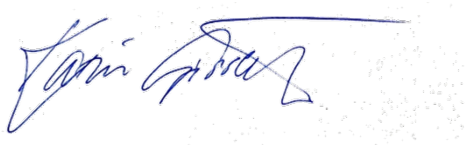
For attention of: Customers who have received XVIVO Organ Chamber™ (Catalogue No 19020) of the following batches:

13801
13802
13803
13804
13805
13806

Use by date 2024-09-30

Should you have any questions or require additional information, please contact customersupport@xvivogroup.com.

Sincerely,



Katrin Gisselfält
Global QA/RA Director

On behalf of XVIVO

XVIVO
Box 53015 | SE-400 Göteborg | Sweden
Visitors: Mässans gata 10 | 412 51 Göteborg | Sweden

info@xvivogroup.com
xvivogroup.com
Company No. 556561-0424

Gothenburg, April 11, 2022

URGENT - Field Safety Notice (FSN)
XVIVO Organ Chamber™

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Quality defect -Incomplete closure of the package

Dear valued customer,

A quality defect has been identified on the package for XVIVO Organ Chamber™ as described in this Field Safety Notice. Please adhere to the information as follows:

Information on Affected Devices:
Device Type: Organ Chamber (sterile, singe use)
Commercial name: XVIVO Organ Chamber™
Primary Clinical purpose of device: The XVIVO Organ Chamber™ is a sterile, single-use container intended to be used as a temporary receptacle for isolated donor lungs in preparation for eventual transplantation into a recipient.
Catalogue Number: 19020
Batches affected: LOT: 13801, UDI: (01)07350069520074(17)240930(10)13801 LOT: 13802, UDI: (01)07350069520074(17)240930(10)13802 LOT: 13803, UDI: (01)07350069520074(17)240930(10)13803 LOT: 13804, UDI: (01)07350069520074(17)240930(10)13804 LOT: 13805, UDI: (01)07350069520074(17)240930(10)13805 LOT: 13806, UDI: (01)07350069520074(17)240930(10)13806

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Reason for the Field Safety Corrective Action (FSCA):

It has been identified that the primary package for a number of batches of the XVIVO Organ Chamber™ may have notable defects in the weld of the bag. The notable defects are unsealed sections of the weld i.e. the bag is not completely closed. Unsealed sections in the weld may compromise the sterility of the product. It is therefore important to NOT use a product showing this defect.

We are currently investigating the root cause for this defect. XVIVO have not received any reports of serious injuries or death due to the issue.

In case new information of importance for you we will let you know.

Action to be taken by you as customer:

Identify whether you have XVIVO Organ Chamber(s) from the batches affected.

1. Carefully check the primary package for unsealed sections.
2. If unsealed sections can be noted the product shall not be used, please contact customersupport@xvivogroup.com for further action.
3. If no defects can be noted the product can be used as intended.

You do not need to confirm or reply to XVIVO in case no defects could be noted.

Transmission of this Field Safety Notice

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

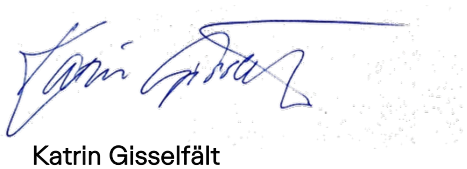
Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Regulatory Authority if appropriate, as this provides important feedback.

This is a NEW Field Safety Notice. In case new information of importance for you will be available we will let you know through an update.

As required the Regulatory Authority of your country has been informed about this notification.

Sincerely,



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