Gemert, November 22, 2022

URGENT - Field Safety Notice

Liver Assist Dual Set

For attention of: Customers who have received Liver Assist Dual Set (NL 40046511 / 11.451) of the following batches:

70220013
70220016
70220019
70220025
70220088
70220146
70220239
70220240
70220551
70220553

Please confirm the acknowledgement of this information by email to customersupport@xvivogroup.com . Should you have any questions or require additional information you may contact our customer support as well.

Sincerely,

Maarten Kanters
QARA Manager
ECM Europe BV

Gemert, November 22, 2022

URGENT - Field Safety Notice (FSN)

Liver Assist Dual Set

Quality defect – potential leakage of set

Dear valued customer,

ECM Europe BV is the manufacturer of these Liver Assist Dual Sets, the distribution of these sets is handled by XVIVO. We ask that all communication be done via XVIVO.

A quality defect has been identified for the Liver Assist Dual Set as described in this Field Safety Notice. Please adhere to the information as follows:

Information on Affected Devices:
Device Type: Perfusion set (sterile, single use)
Commercial name: Liver Assist Dual Set Ref NL 40046511 / 11.451
Primary Clinical purpose of device: The Liver Assist Dual Set is intended to be used for ex-vivo hypothermic and normothermic oxygenated machine perfusion to preserve and evaluate donor livers prior to transplantation.
Batches affected: Liver Assist Dual Set - Manufacturer ECM Europe BV, distributed by XVIVO BV LOT: 70220013, UDI: (01)08720598095531(10)70220013(17)250328 LOT: 70220016, UDI: (01)08720598095531(10)70220016(17)250408 LOT: 70220019, UDI: (01)08720598095531(10)70220019(17)250503 LOT: 70220025, UDI: (01)08720598095531(10)70220025(17)250523 LOT: 70220088, UDI: (01)08720598095531(10)70220088(17)250125 LOT: 70220146, UDI: (01)08720598095531(10)70220146(17)250221 LOT: 70220239, UDI: (01)08720598095531(10)70220239(17)250622 LOT: 70220240, UDI: (01)08720598095531(10)70220240(17)250725 LOT: 70220551, UDI: (01)08720598095531(10)70220551(17)250712 LOT: 70220553, UDI: (01)08720598095531(10)70220553(17)250809

Reason for the Field Safety Corrective Action (FSCA):

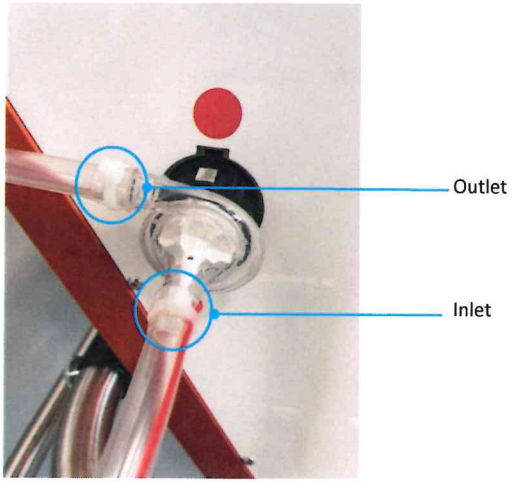

Figure 1: connections of the pump head

In rare cases, leakage could occur at the tubing connections of the pump head. Each perfusion set contains two pump heads with both an inlet and an outlet. The potential leakage can be determined already during priming when high pressures are applied. The leakage can be noticed by drop formation or persistent air bubbles at the tubing connections of the pump head

We are currently investigating the root cause for this defect. ECM Europe or 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:

1. During priming, carefully check the connections at each pump head (4 in total). Check the inlet side for potential air bubbles in the solution or leakage. Also check the outlet side for potential leakage of solution. When handling the pump head do not extensively pull the tubing or connections.
2. If above issues are observed during priming, you can choose to replace the cable tie of the affected pump head or replace the full set.
3. If replacing the full set, save the affected set as it needs to be returned for investigation and refund.
4. If no leakages or persistent air bubbles are observed the perfusion set can be used as intended.

Instructions replacing cable ties

For an experienced user, the affected connection at the pump head can be improved by replacing the cable tie. This should take place before placing an organ on the device. Take notice that the recommended size of the new cable tie is smaller (3,5 mm instead of the current 4,6 mm).

In case of urgent questions please contact the XVIVO helpdesk: +31 50 364 01 16.

Transmission of this Field Safety Notice

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

Please transfer this notice to other organizations 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,

Maarten Kanters
QARA Manager
ECM Europe BV