

Medos Medizintechnik AG . Obere Steinfurt 8 - 10 . 52222 Stolberg, Germany

Contact person:

To whom it concerns

Fax: +49 7131 2706-299
E-Mail: FSN@xenios-ag.com

Heilbronn, 21. Mai 2021

Important safety note

FSN21-02: Due to the increased complaints rate (trend) of pump head recently, Medos Medizintechnik AG recognized a potential risk of the product and thus decided to recall following products from the market.

Affected Products:	Tubing set for the organ perfusion	
Brand names	Liver Assist-Set, Model Organ Assist	Organ Perfusionset, Kidney net, Model Organ Assist
Reference number	MEH133411	MEH132909
Affected batch number	190220M146	190403M954

Date: 21. May 2021

Reference number: FSN 21-02

Addressee: Organ Assist Products B.V.

Reason: This letter means to inform you about the deficiency of the products. The products with above mentioned batch number include defective pump head and this could cause malfunction of the tubing set.

Dear valued customer,

Due to the increased complaints regarding pump head DP2, the company Xenios recognize a potential risk of the product. The results of the complaints investigation shows the pump head was glued together and thus a non-rotating pump head.

Description of the product deficiency

The described pump head problem is caused by deficiencies during the production phase.

Measures of recall on affected products

- Please assure to return the products immediately.
- Please check your stock for the appropriate products or batches.
- Complete the enclosed feedback form and send it either by fax to:+49 7131 2706-299, in electronic form by e-mail to fsn@xenios-ag.com or by mail to Medos Medizintechnik AG, Safety Officer, Subject: FSN 21-02, Im Zukunftspark 1, 74076 Heilbronn, Germany.
- Return all remaining stocks of this product immediately.

Passing on this safety notice:

This notice and the resulting actions must be followed for an appropriate period of time to ensure the success of the actions.

Contact:

For questions regarding the attached feedback form, please contact us by e-mail at fsn@xenios-ag.com.

A copy of this urgent safety notice has been sent to the Federal Institute for Drugs and Medical Devices, as the coordinating authority, to inform them of the proposed action.

We hereby expressly apologize for any inconvenience caused and thank you for your cooperation!

Heilbronn, 21. Mai 2021

Name
Position	Safety Officer (MPG) Medos Medizintechnik AG	Technical Product Manager Medos Medizintechnik AG

Urgent Safety Notice Feedback Form

FSN21-02: Due to the increased complaints rate (trend) of pump head recently, Medos Medizintechnik AG recognized a potential risk of the product and thus decided to recall following products from the market.

Medos Medizintechnik AG
 - Safety Officer
 Im Zukunftspark 1
 74076 Heilbronn
 Deutschland
 Fax : +49 7131 2706-299
 Email: fsn@Xenios-ag.com

Customer Data

Kunden Details	
Name of the healthcare facility *	
Address*	
Department	
Shipmentaddress, if different	
Contact Name*	
Title or Function	
Phonenummer*	
Email*	

*Must fields

Affected products Liver Assist-Set, Model Organ Assist

Product Name	Reference number
Liver Assist-Set, Model Organ Assist	MEH133411

Affected Lots

Lot-Number	Quantity of available products	Quantity of used products	Quantity of returned products	Quantity of disposed products
190220M146				

Affected products Organ Perfusionset, Kidney net, Model Organ Assist

Product Name	Reference number
Organ Perfusionset, Kidney net, Model Organ Assist	MEH132909

Affected Lots

Lot-Number	Quantity of available products	Quantity of used products	Quantity of returned products	Quantity of disposed products
190403M954				

Actions performed within the healthcare facility	
<input type="checkbox"/>	I acknowledge receipt of the urgent safety notice and that I have read and understood its contents.
<input type="checkbox"/>	I have carried out all the actions required by the safety notice.
<input type="checkbox"/>	The information and required actions were brought to the attention of all relevant users and executed.
<input type="checkbox"/>	There are no affected devices available for return/destruction / Our healthcare facility is not affected
<input type="checkbox"/>	I have performed other actions (please describe them).
Name*:	
Signature*:	
Date*:	