MEDIMA Sp. z o.o. ICU Medical Group
Al. Jerozolimskie 200,
02-486 Warszawa,
Poland
www.medima.pl

URGENT: FIELD SAFETY NOTICE

Medima infusion Sets used with Large Volume Infusion Pumps

2 August 2023

Dear Valued Medima Infusion System Customers:
Director of Biomedical Engineering
Director of Nursing
Director of Risk Management

Medima Sp. z o. o. is issuing this letter to notify you of two potential issues related to Medima infusion sets containing a Free Flow Protection Clamp (FFPC):

Issue 1: Potential for reverse installation of infusion sets into Medima Volumetric infusion pumps

Issue 2: Potential for a manufacturing defect leading to an incorrect assembly of the Free Flow Protection Clamp (FFPC) on Medima infusion sets

Potential Risk:

If the FFPC of the Medima set is installed in the wrong direction into the Medima Volumetric infusion pump; the following potential risks may occur:

1. A delay in the delivery of the infusion solution
2. A potential backflow of the medication and/or patient's blood into the Medima infusion line.

To date, Medima has not received any report of a serious adverse event that may have been related to these issues.

The following information details the issues and the required steps for you to perform.

ISSUE 1: Potential for reverse installation of infusion sets into Medima Volumetric infusion pumps

Medima received customer reports of users installing the FFPC of Medima infusion sets in a reverse direction into the Medima volumetric infusion pump.

Recommendations for users:

Medima would like to remind users to install the FFPC following the instructions outlined in the Medima Volumetric infusion pump user manual as summarized below:

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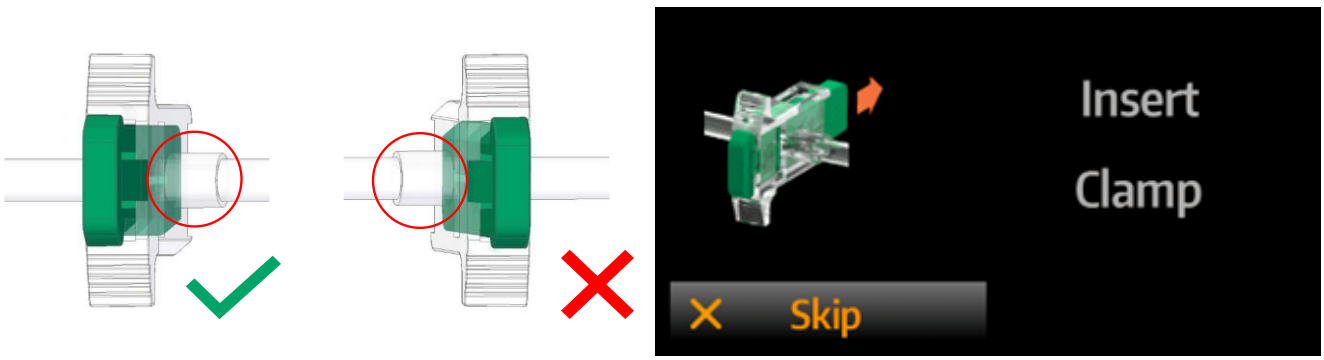
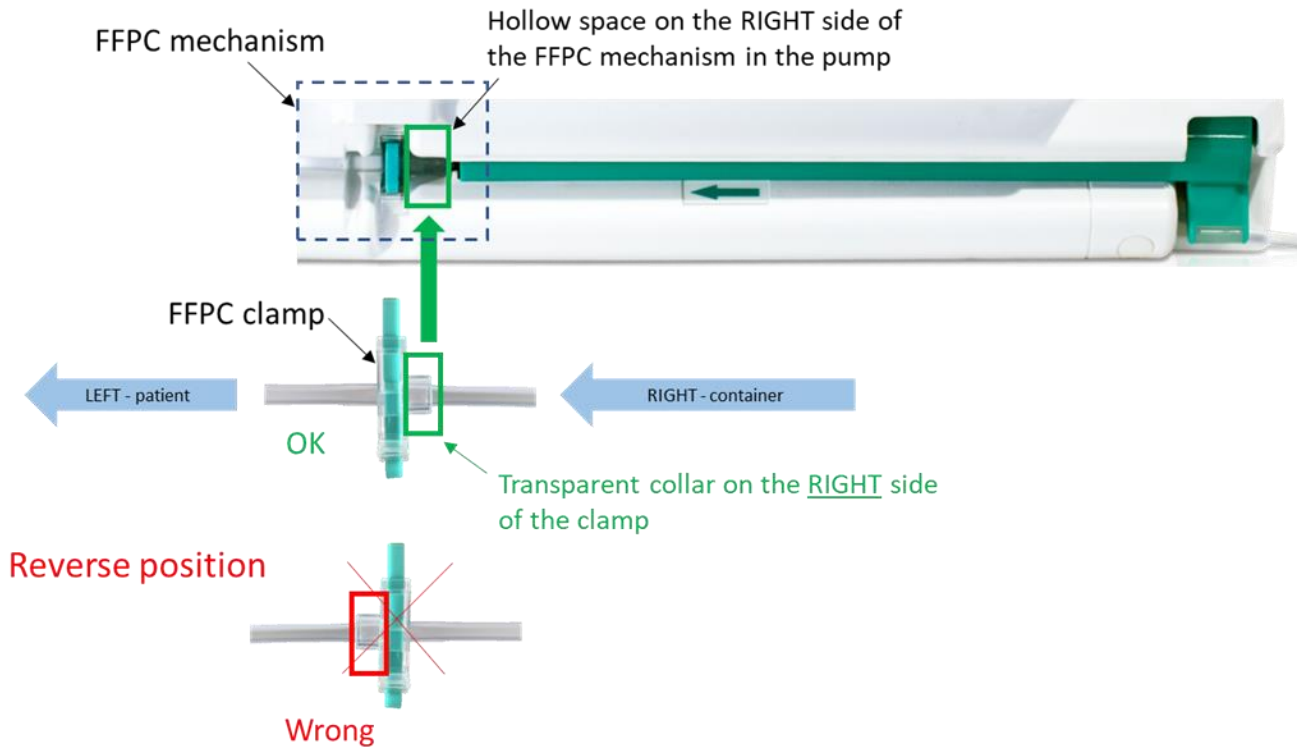
To ensure the correct installation of the FFPC, the spike should be on the right of the pump and the patient connector on the left of the pump.

NOTE: The direction of fluid flow is indicated by an arrow just below the pump mechanism as shown below and on the instructions on the pump screen.

When inserting the set in the pumping mechanism of the pump, the transparent collar on the FFPC should be on the right and inserted as shown below:



Attention!	Shortly before placing the FFPC clamp in the FFPC mechanism of the pump, pay attention to install the clamp correctly. Transparent collar presented on the drawing below, must be on the right side of the FFPC clamp. It allows to provide the correct flow of the fluid from the container (right) to the patient (left). **Do not install the FFPC clamp in reverse position!**



Medima Actions:

Medima has initiated an update to the user manual to include further clarification to the users regarding the correct installation of FFPC and to explicitly caution against incorrect installation of the FFPC. (Refer to the enclosed user manual PDF document attached).

ISSUE 2: Potential for a manufacturing defect leading to an incorrect assembly of the Free Flow Protection Clamp (FFPC) on Medima infusion sets.

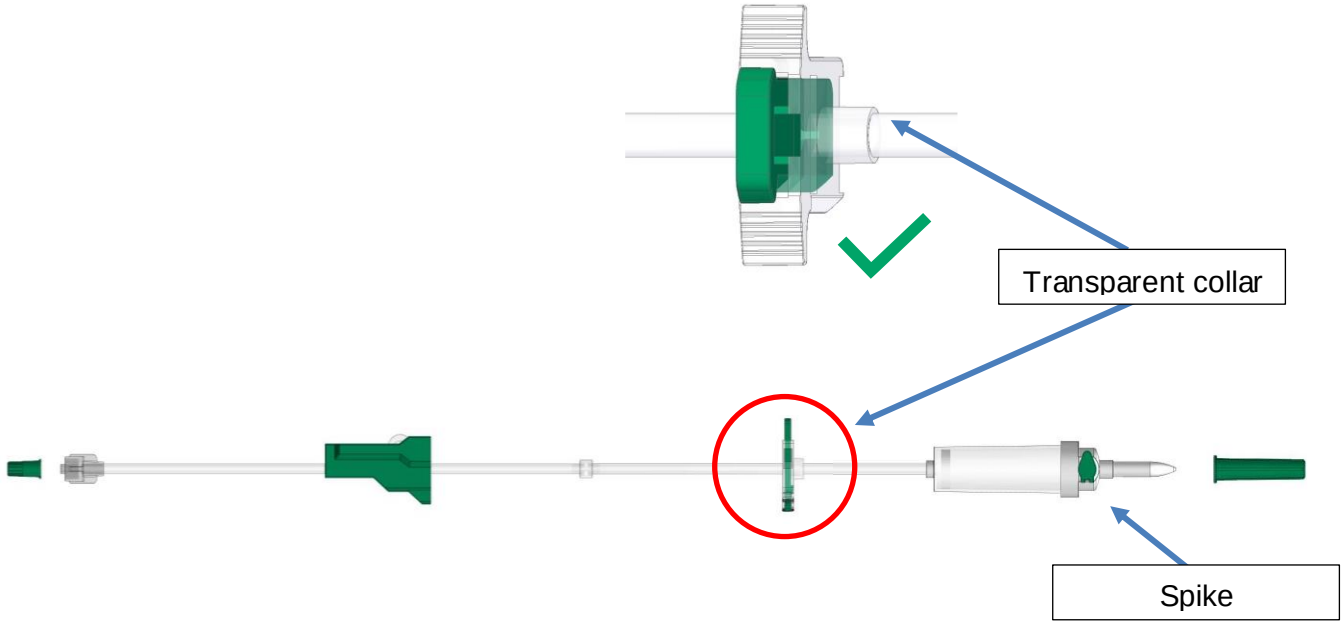
An investigation conducted by the supplier of Medima infusion sets determined that there is a potential for a manufacturing defect to be present in certain units of Medima sets containing the FFPC and distributed prior to June 2023.

This potential defect is resulting in an incorrect assembly (wrong direction) of the FFPC on Medima sets that include an FFPC as part of the set configuration. See Table 1 below for the complete list of affected items.

Recommendations for users:

Prior to the use of any Medima infusion set with an FFPC, please check every set to ensure that the transparent collar is on the right side of the FFPC (as shown below) and on the same side as the spike. If this is not the case, please discard the infusion set as the FFPC may have been mounted incorrectly and repeat the above steps with a new infusion set.

Correct assembly of a pumping segment with FFPC clamp is shown on the picture below:



Medima Actions:
As of May 2023, Medima has implemented corrective actions as part of the manufacturing process to prevent this defect.

Required Actions for Users:

There is no need to return or discontinue using your Medima Volumetric infusion pump and/or Medima infusion sets.

Please inform all Health professionals in your facility of this field notification

1. Ensure that all users or potential users are immediately made aware of this notification and request that users:

   (a) follow the installation instructions according to the User Manual when installing the Medima infusion set with Medima Volumetric Infusion Pumps.
   (b) inspect the Medima infusion sets with FFPC (refer to the below table 1 for lots impacted) to ensure that the FFPC was adequately assembled prior to use on patient

2. Complete and return the attached Response Form to EMEA-Quality@icumed.com within ten days of receipt to acknowledge your understanding of this notification.
3. **DISTRIBUTORS**: If you have distributed potentially affected products to your customers, please immediately forward this notice to them and ask them to return completed response forms to you. When you have received all completed response forms from your customers, please complete a SINGLE COMPLETED form with the required details and return to EMEA-Quality@icumed.com

For further inquiries, please contact Medima Sp. z o. o using the information provided below.

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Medima Contact	Contact Information	Areas of Support
Complaint Management	complaints@medima.pl	To report adverse events or product complaints
Technical Assistance	dreny@medima.com.pl	Additional information or assistance

Your country regulatory agency has been notified of this action.

Medima Sp. z o. o. is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Aleksandra Styczek-Grabowska
Senior Manager, Quality and Regulatory Affairs

See attachment below: *Customer Response Form*

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Table 1: Affected Items for Issue 2 – potential for a manufacturing defect leading to an incorrect assembly of the Free Flow Protection Clamp (FFPC) on Medima infusion sets.

Type	LOT
Medima Line BL10	BQ200755604
	BQ210882604
	BQ220212102
	BQ220872902
	BQ230132503
	BQ230132602
	BQ230540002
Medima Line BL11	BQ200755605
	BQ220995602
	BQ230132606
Medima Line BL12	BQ200755609
	BQ220159903
	BQ220212104
	BQ220872913
	BQ220912104
	BQ230132506
Medima Line NE52	BQ210129201
	BQ210882603
	BQ230547103
Medima Line NE62	BQ210433901
	BQ211010001
	BQ220159905
	BQ230132604
	BQ230546320
Medima Line NP10F12	BQ211128701
Medima Line NP10F12L	BQ220872907
	BQ230132501
	BQ230540008
Medima Line NP12F12	BQ210541205
Medima Line NP12F12L	BQ210747711
Medima Line ON12F02	BQ210541201
Medima Line ON12F02L	BQ210747706
	BQ230540005
Medima Line ON23	BQ200755607
	BQ220159902
Medima Line ON23L	BQ210747707
Medima Line ON24	BQ220112105
	BQ220212105

Type	LOT
Medima Line ON24L	BQ202212001
	BQ210747708
	BQ220212001
	BQ230540007
	BQ230547102
Medima Line ON25	BQ200755601
	BQ210781801
	BQ211012001
Medima Line ON25L	BQ210747709
Medima Line ON26	BQ210781802
	BQ211012002
	BQ220159904
Medima Line ON26L	BQ210553002
	BQ210747701
	BQ230540004
Medima Line PD51	BQ230547104
Medima Line PD52	BQ200755608
	BQ220872904
	BQ230546319
Medima Line ST10	BQ200755603
	BQ210324702
	BQ210882602
	BQ220159901
	BQ220212101
	BQ220872901
	BQ220872910
	BQ230132502
	BQ230132601
	BQ230540001
	BQ230546101
	BQ230546201
	BQ230546317
	BQ230646001
Medima Line ST10L	BQ210747703
	BQ210781803
	BQ210882606
	BQ220872905
	BQ230132507
	BQ230540003

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Type	LOT
Medima Line ST11	BQ200755602
	BQ210324401
	BQ210882601
Medima Line ST11L	BQ210747704
	BQ210781804
	BQ210882801
	BQ230132607
Medima Line ST12	BQ200755606
	BQ220212103
	BQ220872903
	BQ220872912
	BQ230132505
	BQ230132603
Medima Line ST12L	BQ210747705
	BQ210781805
	BQ220159910
	BQ220212106
	BQ220872906
	BQ220872914
	BQ230540006
Medima Line ST14	BQ210541206
	BQ230547101

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URGENT FIELD SAFETY NOTICE: RESPONSE FORM

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2 August 2023

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and return it to EMEA-Quality@icumed.com via email. If you have questions about this form please contact EMEA-Quality@icumed.com, or your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

I have affected product:

☐ **YES** ☐ **NO**

I acknowledge receipt of this communication and confirm that I have notified users at my facility of this Field communication:

☐ **YES** ☐ **NO**

I have received the most up to date version of the Medima Infusion pump user manual and will be sharing it with users in my facility:

☐ **YES** ☐ **NO**

- Have you distributed the product further to the retail level? ☐ **YES** ☐ **NO**
- If yes, have you notified your retail customers and asked them to contact EMEA-Quality@icumed.com to obtain a response form? ☐ **YES** ☐ **NO** (if no, explain below)

Adverse events and complaints associated with the use of these products should be reported and emailed to complaints@medima.pl