# 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.

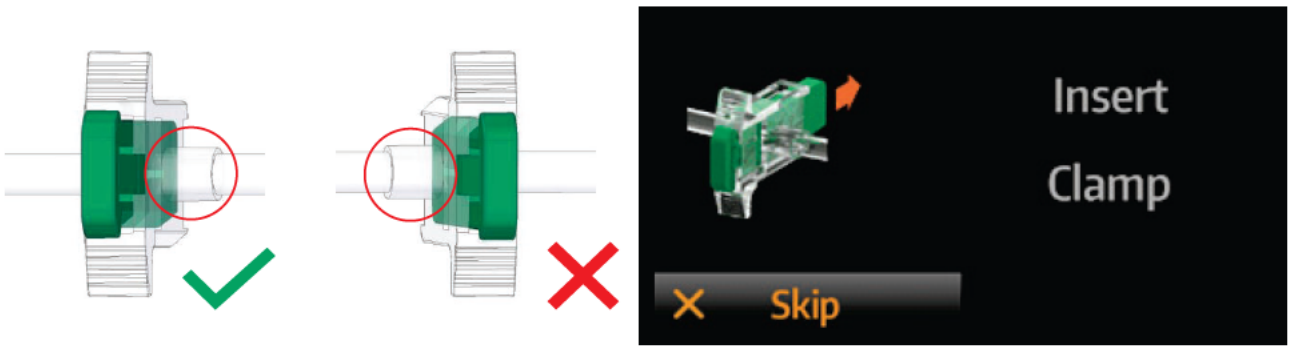
**Recommendations for users:**

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:

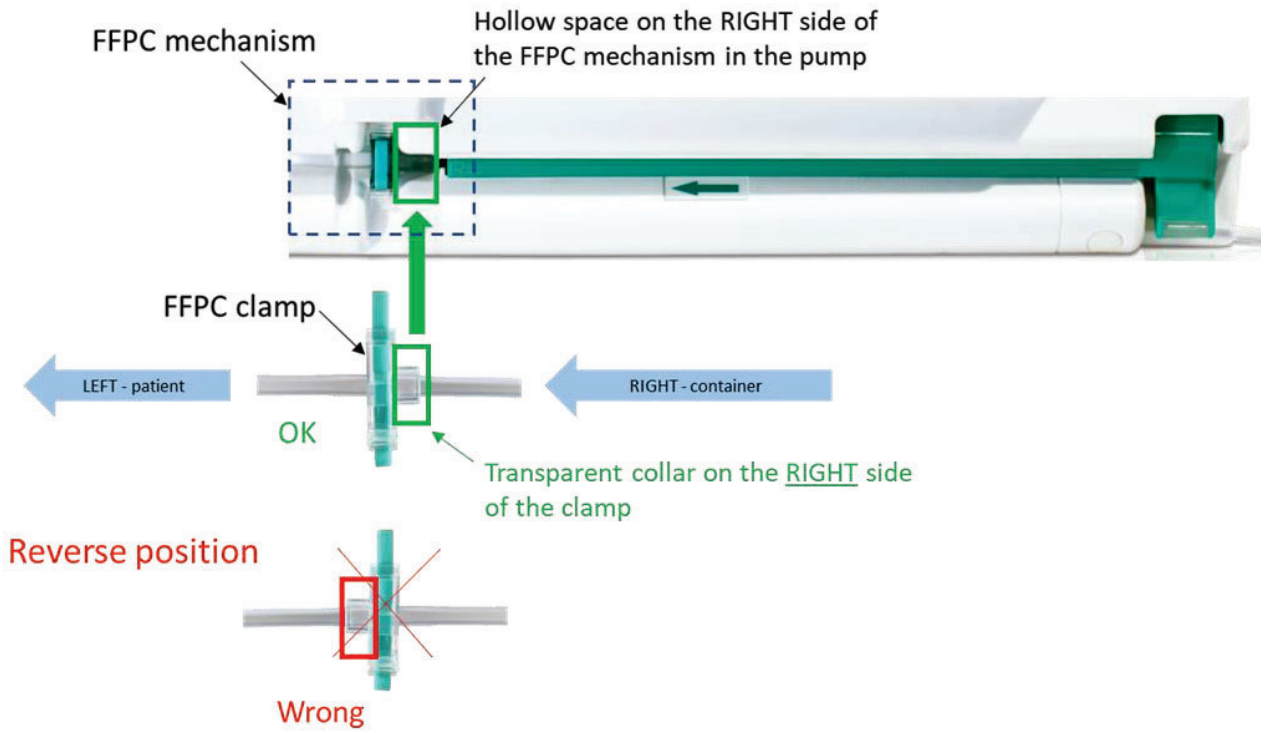
To ensure the correct installation of the FFPC, the spike should be on the right of the pump and the patient connector on the left of the pump.


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).<br>**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.**

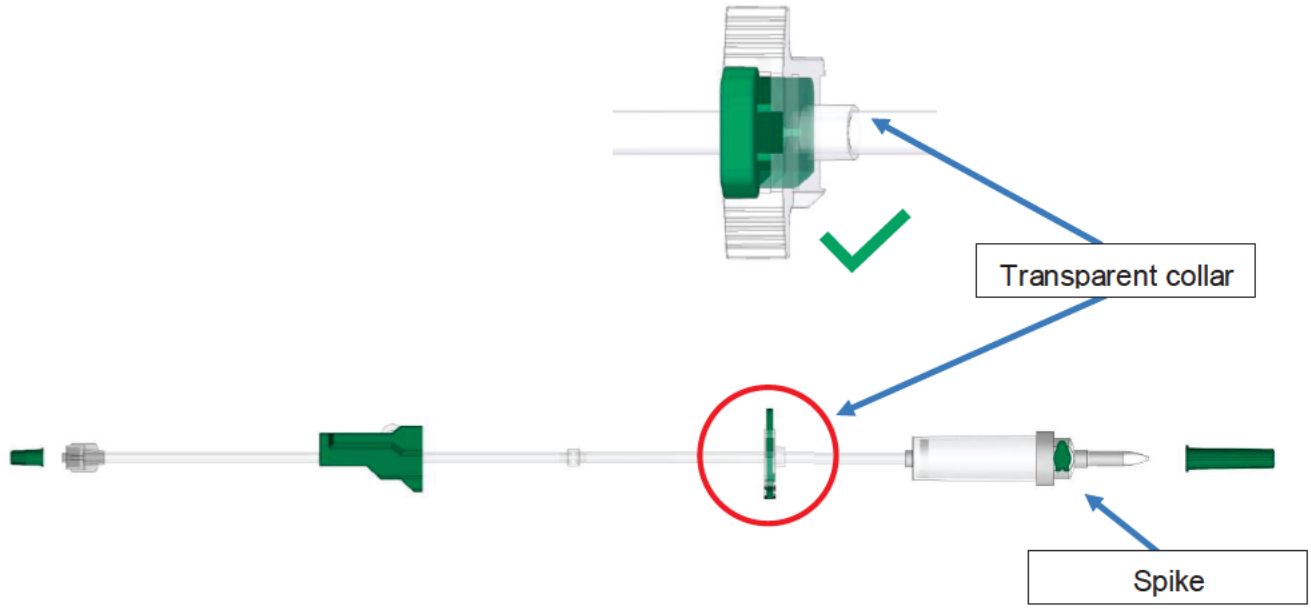
An investigation conducted by the supplier of Medima infusion sets determined that there is a potential for a manufacturing defect to be present in certain units of Medima sets containing the FFPC and distributed prior to June 2023.

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.

| 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,

**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 |

| 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 |

# URGENT FIELD SAFETY NOTICE: RESPONSE FORM

## Medima infusion Sets used with Large Volume Infusion Pumps

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)

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