P M H
PRODUTOS MÉDICO HOSPITALARES
Sociedade Anónima
Capital Social: €6.924.000,00
NIPC: PT 502PMH, Produtos Médico Hoispitalares 376 899
Reg. na C.R.C de Benavente nº 502 376 899

FSN Ref: 02/2023
FSCA Ref: FSCA02/2023
Date: 2023/10/11

Urgent Field Safety Notice

PMH Infusion set
Ref.as AMT 003; AMT 0031; AMT 0090; AMT 0217; AMT0337

For Attention of: **all costumers**

Dear Costumers

PMH as decide to recall the define article/ lot PMH Infusion set - ref. AMT 003; AMT 0031; AMT 0090; AMT 0217; AMT0337, in the course of a field corrective action from the market for the following lots:

Device Type(s)*	IV administration system with hydrophilic filter, non-return valve, 4 ¾-way stopcocks and luer lock
Commercial name(s)*	PMH Infusion set - Sicherheitsinbfusionsgeraet
Primary clinical purpose of device(s)	These devices are intended for channelling liquids/or cytostatic for the purpose of infusion or administration into the body.
Device part number(s)* / Batch:	**AMT0003 - Lot 31 23 07H** **AMT0031 - Lot: 31 23 07C** **AMT0090 - Lot 31 23 07G** **AMT0217 – Lots 31 23 07 H , 31 23 07T, 31 23 07U, 31 23 08B and 31 23 08C** **AMT0337 - Lot 31 23 07B**

Reason for Field Safety Corrective Action (FSCA):

Description of the product problem*
Potential Stopcock leakage due to a hole inside the stopcock
Hazard giving rise to the FSCA
Potential leakage could lead to loss of medication.
Probability of problem arising
No serious incidents have been reported as this problem can be detected during purge. However, as the product is intended for the administration of medication, and given the risk of the leak occurring during the administration of the chemical/drug, there is a high probability that the medication will not be administered with consequences for the patient.

Zona Industrial da Murteira
Rua Guiné Bissau, Lt. 9
2135-327 Samora Correia
Tel. +351 263 650 680
Fax. +351 263 650 695
Zona Industrial 1
4560-164 Guilhufe - Penafiel
Tel. +351 255 72 140
Fax. +351 255 724 810
PORTUGAL
www.pmh.pt

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Background on Issue
No serious incidents have been reported. The problem was detected by one customer during the system purging process and the device was discarded. There was no serious incident involving risk to patient or health care professional as the problem was detected before the drug was administered.

Type of Action to mitigate the risk and to be taken by the user

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organization and other concerned persons are informed about this Field Safety Notice.
- Identify, quarantine, and return affected articles.
- not use affected devices anymore.
- Confirm receipt of this information by completing the attached form and return to PMH, SA
- As distributor, please forward this correction notification to your customers, and collect the batch from customers
- Return the devices collected from the batch to PMH

Contact details of local representative
AMT Medica GmbH **Robert-Bosch-Str. 3** **71088 Holzgerlingen** **Germany** **Email: rajkumar.daniel@amt-medica.de** **Tel. +49 7031 209 412 27**

[redacted]
Quality Director

Enclosure: Costumer response form

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Rua Guiné Bissau, Lt. 9
2135-327 Samora Correia
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Field Safety Notice distributer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 03/2023
FSN Date*	23/10/2023
Product/ Device name*	Infusion Set
Product Code(s)	AMT 003; AMT 0031; AMT 0090; AMT 0217; AMT0337
Batch/Serial Number (s)	AMT0003 - Lot 31 23 07H AMT0031 - Lot: 31 23 07C AMT0090 - Lot 31 23 07G AMT0217 – Lots 31 23 07 H , 31 23 07T, 31 23 07U, 31 23 08B and 31 23 08C AMT0337 - Lot 31 23 07B

2. Distributor/Importer Details	
Company Name*	**AMT Medica GmbH**
Address*	Robert-Bosch-Str. 3 71088 Holzgerlingen Germany
Shipping address	Robert-Bosch-Str. 3 71088 Holzgerlingen Germany
Contact Name*	Rajkumar.Daniel
Title or Function	Quality Control In-Charge
Telephone number*	rajkumar.daniel@amt-medica.de
Email*	Tel. +49 7031 209 412 27

3. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form

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☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

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FSN Ref: 02/2023
FSCA Ref: FSCA02/2023
Date: 2023/10/11

Urgent Field Safety Notice

PMH Infusion set - ref. AMT0158

For Attention of: **all costumers**

Dear Costumers

PMH as decide to recall the define article/ lot PMH Infusion set - ref. AMT0158, lot 31 23 07H in the course of a field corrective action from the market:

Device Type(s)*	IV administration system with hydrophilic filter, non-return valve, 4 ¾-way stopcocks and luer lock
Commercial name(s)*	PMH Infusion set - ref. AMT0158 Sicherheitsinbfusionsgeraet
Primary clinical purpose of device(s)	These devices are intended for channelling liquids/or cytostatic for the purpose of infusion or administration into the body.
Device part number(s)*	**AMT 0158**
Batch:	**31 23 07H**

Reason for Field Safety Corrective Action (FSCA):

Description of the product problem*
Potential Stopcock leakage due to a hole inside the stopcock
Hazard giving rise to the FSCA
Potential leakage could lead to loss of medication.
Probability of problem arising
No serious incidents have been reported as this problem can be detected during purge. However, as the product is intended for the administration of medication, and given the risk of the leak occurring during the administration of the chemical/drug, there is a high probability that the medication will not be administered with consequences for the patient.

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Background on Issue
No serious incidents have been reported. The problem was detected by the customer during the system purging process and the device was discarded. There was no serious incident involving risk to patient or health care professional as the problem was detected before the drug was administered.

Type of Action to mitigate the risk and to be taken by the user

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organization and other concerned persons are informed about this Field Safety Notice.
- Identify, quarantine, and return affected articles.
- not use affected devices anymore.
- Confirm receipt of this information by completing the attached form and return to PMH, SA
- As distributor, please forward this correction notification to your customers, and collect the batch from customers
- Return the devices collected from the batch to PMH

Contact details of local representative
AMT Medica GmbH **Robert-Bosch-Str. 3** **71088 Holzgerlingen** **Germany** **Email: rajkumar.daniel@amt-medica.de** **Tel. +49 7031 209 412 27**

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Quality Director

Enclosure: Costumer response form

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Field Safety Notice distributer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	FSN 02/2023
FSN Date*	11/10/2023
Product/ Device name*	Infusion Set
Product Code(s)	AMT0158
Batch/Serial Number (s)	31 23 07H

2. Distributor/Importer Details	
Company Name*	**AMT Medica GmbH**
Address*	Robert-Bosch-Str. 3 71088 Holzgerlingen Germany
Shipping address	Robert-Bosch-Str. 3 71088 Holzgerlingen Germany
Contact Name*	Rajkumar.Daniel
Title or Function	Quality Control In-Charge
Telephone number*	rajkumar.daniel@amt-medica.de
Email*	Tel. +49 7031 209 412 27

3. Distributors/Importers (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
☐	I have identified customers that received or may have received this device	
☐	I have attached customer list	
☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
☐	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		