Rev 1: September 2018

FSN Ref: 3005053560-03/01/2023-001-FSN FSCA Ref: 3005053560-03/01/2023-001-C

Date 24 February,2023:

Urgent Field Safety Notice
MRidium 1057 MRI Syringe Adapter Set

For Attention of*:Risk Manager, FSCA Coordinator,

Contact details of local representative (name, e-mail, telephone, address etc.)*
This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages

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Urgent Field Safety Notice (FSN)
MRidium 1057 MRI Syringe Adapter Set
Unexpected Inlet Occlusion Alarm, possible delay in infusion

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Single use, sterile, infusion set for use with a syringe
1.	2. Commercial name(s)
	MRidium 1057 MRI Syringe Adapter Set
1.	3. Unique Device Identifier(s) (UDI-DI)
1.	4. Primary clinical purpose of device(s)*
	Device is used for administration of medication during a MRI exam
1.	5. Device Model/Catalogue/part number(s)*
	1057-50 for a box of 50 sets
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range
	21K50N, 22A03N, 22A59N, 22B54N, 22D15N, 22D28N, 22D58N, 22I17N, 031851, 22J46N, 032198, 22L02N, 032822
1.	8. Associated devices
	Utilized with Iradimed MRidium 3860+ and 3861.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Iradimed has received reports of 1057 Syringe Adapter Sets not properly venting air into the attached syringe during use, which can reduce flow with the MRidium infusion pump and result in an occlusion with an associated Inlet Occlusion alarm. No patient injuries have been reported.
2.	2. Hazard giving rise to the FSCA*
	Delays in therapy may occur as a result of an occlusion caused by improper venting of the 1057 Syringe Adapter Set, leading to a need for intervention in patient care and replacement of the occluded 1057 syringe set. Depending on the duration of the intervention, underdosing could occur until the inlet occlusion is resolved by replacement of the occluded infusion set. During the time of the intervention, serious adverse health events could occur.
2.	3. Probability of problem arising
	A defect in an injection molded part within the set is 0.4%
2.	4. Predicted risk to patient/users
	Health Hazard Evaluation determined the worst-case severity is Catastrophic and the probability is Remote.
2.	5. Further information to help characterise the problem
	For patient harm to occur, the follow sequence of events must occur. Patient stability is dependent on the continuous IV delivery of a drug. Patient is connected to defective 1057 syringe set. Pressure in syringe reaches a pressure level to create an inlet occlusion, which stops therapy and causes device to alarm. Infusion is not resumed before harm happens.

2.	6. Background on Issue
	Iradimed has investigated the issue and determined that the problem is due to a defective injection molded part that can limit the effectiveness of the syringe vent and result in inlet occlusion and resulting alarm condition in an estimated 0.4% of the below listed lots of 1057 Syringe Adapter IV Sets manufactured in 2021, 2022 and 2023.
2.	7. Other information relevant to FSCA
	To date, Iradimed has received 5 customer complaints of an unexpected inlet occlusion alarm and subsequent stopped infusion due to lack of air venting into the syringe, necessitating the replacement of the infusion set and restarting of the infusion.

	3. Type of Action to mitigate the risk*	
3.	**1. Action To Be Taken by the User*** ☐ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device ☒ On-site device modification/inspection ☐ Follow patient management recommendations ☒ Take note of amendment/reinforcement of Instructions For Use (IFU) Confirm new labelling is received and understood. ☐ Other ☐ None Inspection steps are listed below to ensure the syringe vent is functioning as intended as part of priming the infusion set. If a defective set is identified in step 5, the defective set should be destroyed, and the process restarted with a new 1057 set as indicated in that step. 1. Remove protective Clear Cap. Attach syringe with fluid to vented Syringe Adapter Fitting. Ensure Tube Slide Clamp and FLOW-PREVENTER are open. 2. Prime IV Set removing all air bubbles. 3. Open Air Vent Cap on Syringe Adapter Fitting. 4. Close Tube Slide Clamp and FLOW-PREVENTER (pull BLACK slide clamp out). 5. With the syringe plunger facing up, gently pull the syringe plunger out approximately 1mL and verify air bubbles are seen rising in the syringe. If no bubbles are seen, restart from Step 1 with a new 1057 set. 6. Grasp FLOW-PREVENTER slide clamp and load pump segment into pump. 7. Close Pump Door. Ensure syringe with fluid is mounted vertically after set is loaded and Door is closed. 8. Attach distal luer-outlet (Blue cap) to the port nearest the patient's vascular access device. 9. Open set slide clamp and begin infusion.	
3.	2. By when should the action be completed?	While using affected product Lot #'s.

3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Checking for the appearance of bubbles is part of ensuring the vent operation is working and that the vent cap was not unintentionally left in the closed position. It also will ensure that the complete venting pathway of the 1057 Infusion Set vent is operational. No patient follow-up required.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☒ IFU or labelling change ☐ Other ☐ None 1057 package label will be updated with additional instructions. 3860+ Operation Manual REF 1038 will also be updated when describing priming a 1057 set.	
3	6. By when should the action be completed?	While using affected product Lot #'s.
3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Not appended to this FSN	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	Not Applicable – no previous FSN
4.	**3.** For Updated FSN, key new information as follows:	
	Not Applicable – no previous FSN	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	None	
4	6. Anticipated timescale for follow-up FSN	Not Applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Iradimed Corporation**
	b. Address	**1025 Willa Springs Drive, Winter Springs, FL USA**
	c. Website address	**www.iradimed.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Yes	
4.	9. List of attachments/appendices:	**Customer Response**
4.	10. Name/Signature	**Steven J Kachelmeyer** **Vice President Regulatory Affairs and Quality Assurance**

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) 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 Competent Authority if appropriate, as this provides important feedback..*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.