Rev 1: September 2018
FSCA Ref: SA-23-RAD-05

Date: 2023/08/16

Urgent Field Safety Notice
MEDRAD® Avanta Single Patient Administration Tubing (SPAT) used in conjunction with the MEDRAD® Avanta Injection System

For Attention of*: Identify either by name or role who needs to be aware of the hazard and/or take action. If this is multiple recipients then include full list.

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

Urgent Field Safety Notice (FSN)
MEDRAD® Avanta Single Patient Administration Tubing (SPAT) used in conjunction with the MEDRAD® Avanta Injection System
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	MEDRAD® Avanta Single Patient Administration Tubing (SPAT) used in conjunction with the MEDRAD® Avanta Injection System
1.	2. Commercial name(s)
	Avanta Single Patient Administration Tubing
1.	3. Unique Device Identifier(s) (UDI-DI)
	(01)00616258021485(11)230425(17)250425(10)231701 (01)00616258021454(11)230519(17)250519(10)232003
1.	4. Primary clinical purpose of device(s)*
	The MEDRAD Avanta Sterile Disposable Sets are specifically intended for use in the x-ray angiography environment. They are designed to administer intravascular radio-opaque contrast compounds, and common flushing agents at various volumes and flow rates into humans for use in diagnostic and interventional angiographic procedures performed in cardiology, radiology, and vascular surgery.
1.	5. Device Model/Catalogue/part number(s)*
	AVA 500 SPAT L – M/N 86566656 and AVA 500 SPAT ANGIO - M/N 86566745
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lots 231701 and 232003
1.	8. Associated devices
	Medrad® Avanta Injection System

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	The rotating luer which connects to the catheter has a manufacturing defect which may prevent the product from making an effective seal. This issue only impacts two (2) lots of AVA 500 SPAT (Lots 231701 and 232003) and has been distributed to a limited number of customers.
2.	2. Hazard giving rise to the FSCA*
	Administration Set Failure, Potential for arterial air injection to patient due to breach in disposables.
2.	3. Probability of problem arising
	The hazardous situation (air entering the fluid path) resulting from the identified problem above is associated with a probable frequency.
2.	4. Predicted risk to patient/users
	This issue has been identified to have a High level of risk and can lead to death or serious injury.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	Critical defect of the rotator identified in release testing
2.	7. Other information relevant to FSCA
	N/A

	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) ☐ Other ☐ None Quarantine immediately, return as soon as possible, but no later than 2023/09/30.	
3.	2. By when should the action be completed?	Quarantine immediately, return as soon as possible, but no later than 2023/09/30. See Appendix A for return details
3.	3. Particular considerations for: Diagnostic Imaging device Is follow-up of patients or review of patients' previous results recommended? No Administration set failure would not impact previous patient in contact with the device because the injury will occur immediately at the time of the injection/ use of the device.	
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 In collaboration with the Supplier, root cause analysis and corrective action including product recall of the impacted batches.	
3	6. By when should the action be completed?	2023/09/30
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	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
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:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	No
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Bayer Medical Care, Inc.
	b. Address	1 Bayer Drive, Indianola PA 15051 USA
	c. Website address	N/A
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * CA Notification will be completed by 2023/08/31.	
4.	9. List of attachments/appendices:	N/A
4.	10. Name/Signature	[redacted]

	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.

Bayer

APPENDIX A

RE: Avanta Single Patient Administration Tubing used with the Medrad® Avanta Injection System [Catalog Number AVA 500 SPAT]
Recall (Lots 231701 and 232003)
RECALL ID: SA-23-RAD-05 – Product Return Request

August 2023

[Local Country Address]
[Contact Details]
www.radiology.bayer.com

Dear Valued Customer,

Bayer is issuing a focused recall due to a quality issue for two (2) lots of MEDRAD® Avanta Single Patient Administration Tubing (SPAT) used in conjunction with the MEDRAD® Avanta Injection System.

Our records indicate that your facility received at least one box which may contain affected product subject to this recall.

Please immediately take the following steps:

1. Review your current inventory for affected product (Lots 231701 and 232003) and quarantine, as appropriate.
2. Complete the included response form and submit to *[Enter local customer support phone and/ or email address here]*. ***Please complete the Customer Reply Form regardless of whether you have affected product or not. This action will assist us in tracking all impacted product.***
3. You will receive a Return Goods Authorization (RGA) number to return any affected product remaining in your inventory.
4. Place the affected product in a box and label the outside of the container with the **RGA number provided and RECALL ID: SA-23-RAD-05** in large, bold writing. Use the shipping label provided via email when you receive your RGA number. Please return the affected product ***as soon as possible.***

Please distribute this letter to other appropriate departments and personnel within your facility who may need awareness of this recall.

We appreciate your cooperation and sincerely regret any inconvenience caused by this situation. We maintain high standards of quality control and are committed to providing effective products and service to support patient care.

Sincerely,

[Insert Country Head or other country rep name/signature here]

Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number*	SA-23-RAD-05
FSN Date*	2023/08/16
Product/ Device name*	MEDRAD® Avanta Single Patient Administration Tubing (SPAT) used in conjunction with the MEDRAD® Avanta Injection System
Product Code(s)	1 AVA 500 SPAT L 2 AVA 500 SPAT ANGIO
Batch/Serial Number (s)	1 M/N 86566656 Lot 231701 2 M/N 86566745 Lot 232003

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete. *See Appendix A for additional return details	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction	Customer to complete or enter N/A		

☐	Other Action (Define):	
☐	I do not have any affected devices.	Customer to complete or enter N/A
☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query
Print Name*		Customer print name here
Signature*		Customer sign here
Date*		

4. Return acknowledgement to sender	
Email	Pre-filled by manufacturer/sender/requester
Customer Helpline	Pre-filled by manufacturer/sender/requester
Postal Address	Pre-filled by manufacturer/sender/requester
Web Portal	Pre-filled by manufacturer/sender/requester
Fax	Pre-filled by manufacturer/sender/requester
Deadline for returning the customer reply form*	As soon as possible, but before 2023/09/30

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.