FSN Ref: Manufacturer's ref number FSCA Ref: SA-2026-RAD-03

01-May-2026

# Urgent Field Safety Notice
# Avanta Multi-Patient Administration Tube sets
# (AVA 500 MPAT Part 2 of 2)

For Attention of*: Interventional Radiologists, Cardiologists, Technologists

| Contact details of local representative: |
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| Melanie Donguy, Bayer Medical Care, email: melanie.donguy@bayer.com |

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# Urgent Field Safety Notice (FSN)
# Avanta Multi-Patient Administration Tube sets
# (AVA 500 MPAT Part 2 of 2)
# CFCV to Stopcock Fitment Issues

| 1. Information on Affected Devices* | |
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| 1. | 1. Device Type(s)* |
| | Multi-Patient Disposable Set (Part 2 of 2) used in conjunction with MEDRAD® Avanta Fluid Management Injection System |
| 1. | 2. Commercial name(s) |
| | Multi-Patient Disposable Set (Part 2 of 2) / AVA 500 MPAT (Part 2 of 2) |
| 1. | 3. Unique Device Identifier(s) (UDI-DI)* |
| | (01)00616258024004(11)250616(17)270616(10)252502,<br>(01)00616258024004(11)251127(17)271127(10)254802,<br>(01)00616258024004(11)250602(17)270602(10)252302,<br>(01)00616258024004(11)250625(17)270625(10)252602,<br>(01)00616258021461(11)251014(17)271014(10)254202,<br>(01)00616258024004(11)250815(17)270815(10)253304,<br>(01)00616258024004(11)250422(17)270422(10)251702,<br>(01)00616258024004(11)250708(17)270708(10)252802,<br>(01)00616258007717(11)250702(17)270702(10)252702,<br>(01)00616258024004(11)250908(17)270908(10)253702,<br>(01)00616258024004(11)250912(17)270912(10)253704,<br>(01)00616258024004(11)251122(17)271122(10)254704,<br>(01)00616258024004(11)250920(17)270920(10)253804,<br>(01)00616258024004(11)251025(17)271025(10)254304 |
| 1. | 4. Primary clinical purpose of device(s)* |
| | 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 MPAT (Part 2 of 2)/ 87629007, 60729458, 86566648 |
| 1. | 6. Software version |
| | N/A |
| 1. | 7. Affected serial or lot number range |
| | 251702, 252302, 252502, 252602, 252702, 252802, 253304, 253702, 253704, 253804, 254202, 254304, 254704, 254802 |
| 1. | 8. Associated devices |
| | Used in conjunction with MEDRAD® Avanta Fluid Management Injection System |

| 2 Reason for Field Safety Corrective Action (FSCA)* | |
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| 2. | 1. Description of the product problem* |
| | A recent change to a component of the MPAT Tubing stopcock resulted in a failure of the product to consistently and reliably engage with the Contrast Flow Control Valve (CFCV) snap interface on the Avanta Injection System. |
| 2. | 2. Hazard giving rise to the FSCA* |
| | The Injector Not Available hazard, associated with critical severity harms of Interrupted Procedure and Delay in Procedure for the patient, is indicated for the impacted product. |

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| 2. | 3. Probability of problem arising |
| | Based on the technical evaluation that all product manufactured after April 2025 will lead to the Injector Not Available hazard, the probability of the problem arising is Frequent. |
| 2. | 4. Predicted risk to patient/users |
| | The Health Risk Assessment has indicated that the safety risk associated with the Injector Not Available hazard at a Critical severity fell within the Medium risk level of the Risk Evaluation Matrix established in the Avanta Safety Risk Management Plan. |
| 2. | 5. Further information to help characterise the problem |
| | N/A |
| 2. | 6. Background on Issue |
| | A recent change to a component of the MPAT stopcock has resulted in a failure of the product to consistently and reliably engage with the Contrast Flow Control Valve (CFCV) snap interface on the Avanta Injection System. Bayer is issuing a focused recall due to this quality issue for these specific fourteen (14) lots of MEDRAD® Avanta Multi Patient Administration Tubing (MPAT) used in conjunction with the MEDRAD® Avanta Injection System. |
| 2. | 7. Other information relevant to FSCA |
| | Given the impact of the recall and time needed for replenishment, we anticipate an approximately 12-week delay in order shipment, effective immediately. |

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| | **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<br>☐ On-site device modification/inspection<br>☐ Follow patient management recommendations<br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br>☐ Other ☐ None<br>N/A | |
| 3. | 2. By when should the action be completed? | 30-June-2026 or earlier |
| 3. | 3. Particular considerations for: Diagnostic Imaging device<br>Is follow-up of patients or review of patients' previous results recommended?<br>Choose an item.<br>No patient follow-up/review of results recommended for this product; product recall of specific lots is only due to a fitting issues of a component with the Avanta Injector System. | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |

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| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☐ Other ☐ None<br><br>Bayer will notify all impacted customers to ensure that affected lots are returned to the manufacturer. | |
| 3 | 6. By when should the action be completed? | 30-Jun-2026 |
| 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 | |

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| | **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 | N/A |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | Bayer HealthCare |
| | b. Address | 1 Bayer Drive, Indianola PA 15051 |
| | c. Website address | www.radiology.bayer.com |
| 4. | 8. The Regulatory Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | Customer Reply Form, Customer Letter |
| 4. | 10. Name/Signature | **Louise Dryden**<br>  |

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| | **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)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>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.