

November 18th , 2025

Ref#: FA-2025-028

## URGENT: MEDICAL DEVICE RECALL

**RE: MedNet GmbH Urgent Medical Device Recall – Colour Coded Syringes**

Dear Valued Customer,

This letter is to inform you of a voluntary medical device recall initiated by **MedNet GmbH** to notify you that contamination with particles was identified in some syringes. Please refer to the enclosed **MedNet GmbH** notification for more details.

**EVENT DETAILS:**

MedNet GmbH is issuing this urgent field safety notice after contamination with particles was identified in some syringes. Particles may not be detectable before use due to the potential for the particle to adhere to the syringe seal; therefore, in the worst-case scenario, their use on patients could lead to an embolism. Investigations in the production environment have revealed that 90% of the specified batches are not affected. For the remaining 10%, contamination cannot be definitively ruled out. Therefore, the batches detailed in Table 1 are being recalled in their entirety.

The following medical device procedure kits/trays, including the MedNet GmbH syringes within, manufactured by ArcRoyal are impacted by this recall and are listed below in Table 1. The affected kits/trays were manufactured between 03 Apr 2024 and 02 May 2025.

**Table 1: Affected product**

ArcRoyal Syringe Code	MedNet Syringe Code	MedNet GmbH Lot	Description	Pack Code	Work Order/Lot
10-009155	10301400	P2416002	Colour Coded Syringe, 10ml, LL, Polycarbonate, blue	Q06523	821804, 823208, 825543, 826630, 827992, 833136
10-009168	10301200	P2342004	Colour Coded Syringe, 10ml, LL, Polycarbonate, red	60-044926	800370, 800981, 803336, 806510, 807063, 808633, 809043, 811416, 812016, 814529, 815514, 818427, 819071, 819690, 820180, 820801, 823217, 823911, 824415, 824929, 824930, 826128, 826778

				60-104347	800299, 805841, 807096, 807585, 809044, 810705, 812962, 814010, 815410, 816306, 817726, 818502, 819717, 821445, 821970, 822470, 823262, 823263, 824426
				89-107324	817860
				89-111263	817852, 823475
				Q07340	814152
				Q07356	814155
				Q07129	804134, 807010, 808115, 809038, 809624, 815272, 816832
				NV2026	805542, 818801, 821626, 825311

**ACTIONS TO TAKE:**

**If you received any of the work orders/lots identified above, please review your inventory, and segregate and quarantine all affected product.**

- **Customers (end-users):**
- Ensure the contents of this Field Safety Notice are read and understood by those within your organisation who may use packs with syringes listed in the above Table 1.
- Inspect your inventory, locate and identify any units of the impacted lot numbers as per those detailed in Table 1.
- If you have further distributed the product, identify those facilities, notify them at once of this product removal and have them remove and destroy the affected product.
- Complete and return the Field Safety Response Form, to ArcRoyal ([ArcRoyal.QARAQueries@owens-minor.com](mailto:ArcRoyal.QARAQueries@owens-minor.com)) confirming receipt of this notification and agreement to remove and destroy the syringes upon use of the pack.
- On use of pack codes listed, ArcRoyal Code 10-009168 Colour Coded Syringe, 10ml, LL, Polycarbonate, blue and 10-009155 Colour Coded Syringe, 10ml, LL, Polycarbonate, red are to be removed and destroyed. The affected Syringe shall be disposed of at the end users facility in accordance with local requirements. The remainder of the CPT remains safe for use.
- Retain/Attach a copy of this notification with each affected pack in inventory until use.

**Complete the attached Recall Response Form and return as soon as possible.**

**ADDITIONAL INFORMATION:**

We confirm that the appropriate regulatory agencies have been informed of these actions.

Report any quality problems or adverse events associated with the products listed in this notification [arcroyal.qaraqueries@owens-minor.com](mailto:arcroyal.qaraqueries@owens-minor.com). Your assistance is appreciated and necessary to prevent any risk to patient health as a result of not following the recall instructions.

Thank you,



ArcRoyal

**Enclosures:** Recall Response Form, Original Supplier Recall Notice.

