

Date: 17th April 2026

Kimal PLC: URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

Angiograph Control Syringe with Rotating Adaptor (RA) fitting in Kimal Procedure Pack

Dear Customer,

The purpose of this letter is to advise you that Kimal PLC is initiating a recall for specific batches of product. This recall is to prevent potential patient harm.

Description of issue:

Kimal PLC has received a notification from our supplier for specific batches of product which through Post Market surveillance they have identified a potential risk of the syringe rotating adaptor unwinding during use, which may result in a loose connection and/ or full disconnection between syringe and manifold.

Potential Risk

If unwinding occurs, there is potential for biohazard exposure, blood loss, and infection, as well as introduction of air into the line, which may result in air embolism. – a condition that carries a risk of serious injury or death. All units have the potential to exhibit this failure mode.

As these products are within Kimal procedure packs, we have identified affected pack codes and lot codes for immediate recall.

Time Period:

Kimal plc have assigned a period of 30 days from date of issue, to complete this FSN.

Action to be taken by User/ Hospital

Our records indicate that Kimal plc has shipped Packs that contain the affected product to your facility; therefore, we draw your attention to the following:

1. Please review the content of this Field Safety Notice.
2. Identify and quarantine the affected product codes and batches listed in Appendix 2 of this FSN. Do not use these devices.
3. Please complete the user form included in Appendix 1 to indicate completion, sign, and return to vigilance@kimal.com
4. If you signify you still have affected stock, please list the quantity by lot code and we will then advise on disposal or return.

The co-ordinating competent authority (MHRA) is aware of this action and has received a copy of this notice.

We regret any inconvenience this action may have caused and appreciate your understanding, as we have taken this action in the interest of patient safety.

Yours Sincerely,



Amanda Makemson

Group Quality & Regulatory Director

Appendix 1

Confirmation of Receipt of Field Safety Notice

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Please complete this form and return a copy by email to confirm that you have received this confirmation and acted on the options below.

Email: vigilance@kimal.com

Customer Name and Address:	
Reply confirmation completed by:	
Title:	
Telephone Number:	
Email:	
Signature:	

We confirm:

- We have read and understood the Field Safety Notice.
- We have communicated the information to staff and other services / departments / units / facilities who need to know.
- We do not have any stock of this lot code
- We have isolated stock that requires collection/ credit.

Appendix 2- Affected Product codes and Batches

Procedure Pack Code	Lot Numbers	Qty to return
AT-K52012	23M0211, 24C0260, 24F0789, 24K0833, 25B0506, 25F0039, 25F0573, 25J0128	
DE-K33191	23J0354, 23M0083, 24B0169, 24M0432, 25D0266, 25K0378	
DE-K63141	24C0091, 24K0055, 25F0831, 25K0102, 26A0114	
DE-K73099	25A0023, 25C0195, 25F0261, 25H0357, 25J0165, 25K0475, 25L0691	
GR-K70312	24E0464, 24E0590, 24L0519, 24L0780, 25B0381, 25B0562, 25C0709, 25H0753	
HU-K65391	23L0679	
IE-K26301	23L0821, 23M0019, 23M0408, 24C0007, 24E0458, 24E0853, 24H0259, 24K0853, 24M0357, 25B0392, 25D0122, 25E0525, 25G1050, 25K0074, 25L0119, 26B0367	
IE-K38863	23E0805, 23E0834, 24A0706, 24G0191, 24J0790, 24K0854, 24L0576, 24L0577, 25A0820, 25C0558, 25D0693, 25E0650, 25K0265	
IE-K65915	24B0142, 24D0446, 24F0623, 24H0293, 24L0578, 25B0222, 25B0394, 25M0321	
IE-K7247	25A0823, 25D0053, 25E0651, 25H0164, 25J0726, 25K0285, 25M0103	
JO-K72888	24L0802	
K73353	24L0421	
K90/30	26A0568, 24D0219	
KE-K55741	23K0554, 24C0338, 24F0556, 24H0618, 24K0165, 25L0189	
LB-K20500	23E0116, 24B0087, 24H0263, 25F0614	
MA-K20156	24D0338, 24F0560	
NO-K70566	23J0419, 23M0480	

OM-K57675	23E0117, 23K0286, 24B0377, 24G0205, 24J0551, 25B0459, 25M0644	
OM-K73658	25G0774	
QA-K20504	25J0652	
QA-K70928	24B0242, 24B0728, 25M0348	
RO-K37082	23H0965, 23J0387, 24D0327, 24F0791, 24G0400, 24J0389, 24L0362, 25E0490, 26A0562	
RO-K39404	24D0329, 24F0793, 24G0401, 24J0391, 24L0215, 25A0454, 25E0079, 26A0563	
RW-K67119	23H0105, 23L0038	
SA-K2351	24B0729, 25B0770, 25H0171, 26B0542	
SA-K52811	23D0117, 23J0941, 23M0099, 24A0202, 24A0693, 24B0754, 25F0176	
SPR/10002/72261	25D0836, 25G0792	
SPR/20567/73965	24M0226	
SPR/2093/70312	23L0104	
SPR/2093/71606	24A0277	
SPR/9911/73656	24K0549	
SPR/99300/72261	24E0591	
SPR/99456/71756	24A0796	
SPR/99795/68465	24D0688	
SPR/99795/69433	25C0375	