

Date: 1st May 2026

Kimal PLC: URGENT FIELD SAFETY NOTICE
(Updated FSN)

IMMEDIATE ACTION REQUIRED

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

MHRA Ref: 2026/004/017/601/048

Dear Customer,

The purpose of this letter is to advise you of an update to the previous urgent Field Safety Notice (24th April 2026) that Kimal PLC has issued for the RA syringe in procedure packs. This **updated FSN** needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

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 Risks

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.

Due to the risk of serious injury or death, customers are directed to remove and destroy all Namic RA Syringes. Over-labels will be provided for any affected procedure packs/medical devices on hand stating that the affected syringes must be removed and discarded from further use.

The only exception to this is in rare circumstances where angiography is urgently required, no alternative device is available, and postponing the procedure would place the patient at significant risk.

If the use is unavoidable because failure to proceed would result in patient harm, the Namic RA syringe must be used with extreme caution and vigilance, including manual stabilisation of syringe-to-manifold connections and continuous, 100% monitoring during setup and throughout the entire procedure. In such cases, strict adherence to all usage guidelines are also required including:

- Ensure that you are making secure connections when using this device to prevent the introduction of air into the system that could result in embolism and in rare instance death.
- All connections should be finger tightened. Over tightening can cause cracks and leaks to occur that could result in embolism and or exposure to biohazards.
- Verify that there is not leakage by aspirating and checking to see that air is not trapped in the systema to minimise the potential for embolism and in rare instances death.
- Examine product carefully for entrapped air and fully debubble prior to injection to minimise the potential for embolism and in rare cases death.

In addition, if the RA syringes unwind causing a loose connection or full disconnection **during procedural setup**, please take the following steps:

1. Remove and replace the RA syringes
2. Follow normal use guidelines and proceed with the procedural set up. Finger tightens the syringe and connection. Do not over tighten.
3. Verify the syringe connection remains secure
4. Ensure the manifold system is flushed and de-bubbled prior to use.
5. If the syringe replacement continues to shoe evidence of loosening or disconnecting from the manifold system DO NOT USE. Replace the manifold or entire manifold system.

If the RA syringes unwind causing a loose connection or full disconnection **during procedure**, please take the following steps:

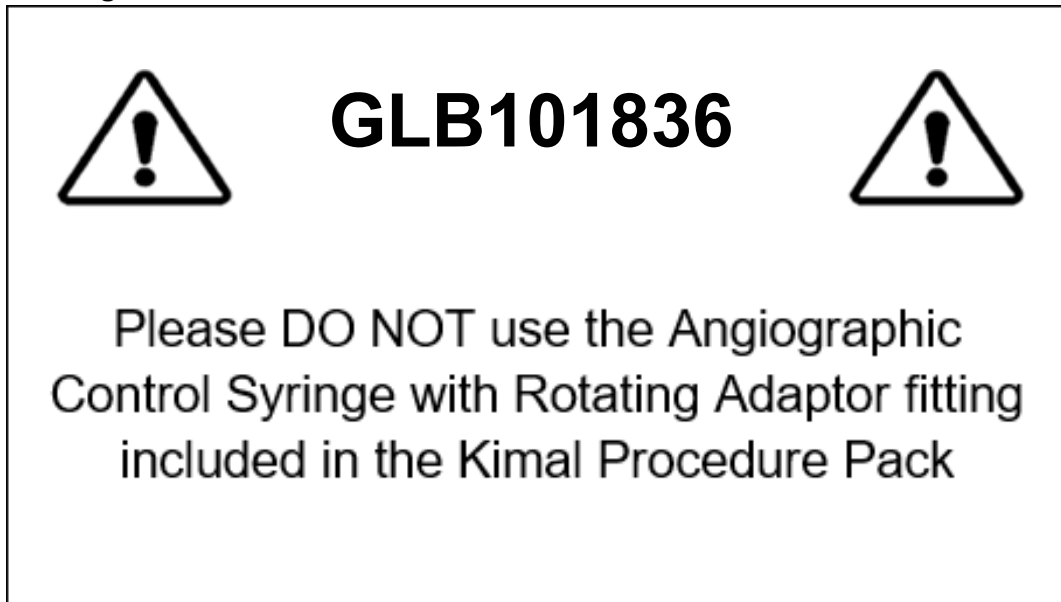
1. Disconnect the manifold system from the patient.
2. Once the manifold system is disconnected, remove and replace the control syringe.
3. Finger tightens the syringe and manifold connection. Do not overtighten.
4. Reprime the manifold system to ensure all air has been removed prior to use.
5. Verify RA syringe connection remains secure without evidence of loosening or disconnecting off the manifold during repriming of the manifold system.
6. Resume procedure with standard catheter connection protocol.
7. In the event that RA Syringe replacement continues to show evidence of loosening or backs off the manifold system DO NOT USE. Replace the entire manifold system.

Action Required:

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 updated Field Safety Notice (FSN) and inform all customers who have received the affected products.
2. Identify and quarantine the affected product codes and batches listed in Appendix 2 of this FSN. Quarantine all affected product.
3. Please complete the User form (Appendix 1) and indicate the number of units (Appendix 2) in your stock to receive the necessary quantity of "warning stickers". Return the completed Appendix 1 and Appendix 2 (if applicable) by e-mail to vigilance@kimal.com **as soon as possible**.
4. If you no longer have any of the impacted products in stock, please also complete the User form (Appendix 1) and return by e-mail to vigilance@kimal.com **as soon as possible**
5. Upon the receipt of your submitted response form, over-labels will be sent to you with instructions for your staff to place onto the procedure pack.

Warning Sticker:



If you have any questions or need support with finding alternative solutions, please contact your Kimal Sales Representative.

The UK national competent authority (MHRA) is aware of this action and has received a copy of this notice. The MHRA has been informed of this updated FSN.

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.

Time Period:

A response is required by MAY 22nd, 2026, to complete this FSN.

Yours Sincerely,



Signer ID: QACFKLPL8W...

Matthew Press

CEO

Appendix 1
Confirmation of Receipt of Field Safety Notice

Kimal plc: URGENT FIELD SAFETY NOTICE
GLB101836 (1st May 2026)
MHRA Ref: 2026/004/017/601/048

Please complete this form and return a copy by email by 22nd May 2026 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
- We have isolated stock that requires “warning stickers”

Appendix 2- Affected Product codes and Batches

Procedure Pack Code	Lot Numbers	Qty to return	Qty of "warning stickers" required
IE-K38863	23F0721 23E0834 23E0805 24K0854 24A0706 24G0191 24J0790 25A0820 25E0650 24L0576 24L0577 25C0558 25K0265 25D0693 26C0286 26D0478		