

Wellington House  
133 – 155 Waterloo Road  
London  
SE1 8UG

23 May 2026

- To:
- NHS Trust:
    - chief operating officers
    - medical directors
    - heads of procurement
    - heads of emergency preparedness, resilience and response (EPRR)
    - nursing directors
    - directors of communication
    - materials management teams
  - Independent sector partners if relevant (via Trusts)
- cc.
- Regional
    - chief operating officers
    - directors of communication
    - deputy directors of EPRR
    - medical directors
    - directors of nursing
  - Integrated care board (ICB):
    - EPRR leads
    - medical directors
    - procurement leads
    - directors of nursing
    - communication leads

Dear colleagues,

## **Kimal – disruption to the supply of medical equipment and consumables**

We are writing to update you on a disruption to the supply of procedure packs used in cardiology, following the identification of defects in manifolds and syringes. These products are manufactured by Medline, and then included in procedure packs sold by Kimal in the UK.

### **Clinical risks and field safety notices**

The following Field Safety Notices have been sent to customers

- **Recall of packs containing Namic White Star Handle Manifolds included in Medline’s Namic Systems**– noting a risk of foreign particulate within the fluid pathway of Namic White Star Manifolds, which could under certain conditions result in

embolism or major harm. *Kimal FSN [MHRA ref: 2026/004/017/601/053](#), Medline [MHRA ref: 39595226 2026/005/019/601/092](#)*

- **Angiograph Control Syringe with Rotating Adaptor (RA) fitting in Kimal Procedure Pack** – noting a risk of the syringe rotating adaptor unwinding during use, which may result in a loose connection and / or full disconnection between syringe and manifold, with associated risk of introduction of air into the line and potential air embolism, as well as possible biohazard exposure, blood loss, and infection. *Kimal FSN [MHRA ref: 2026/004/017/601/048](#), Medline FSN [MHRA ref: 39595226 2026/005/019/601/092](#)*

Kimal have now re-started the supply of *affected* procedure packs with stickers warning that they should only be used in life-threatening emergency situations.

As of 22 May 2026, the Medicines Health Regulations Authority (MHRA) has issued an updated [Device safety information note: DSI/2026/002](#) which provides more detailed information on the above definition.

The updated device safety information (DSI) changes the wording from 'emergency situations' to 'urgent procedures'. This reflects how procedures are classified in the clinical settings where these devices are used, and enables clinicians to take a risk-based approach when deciding whether to use the affected manifolds. MHRA continue to investigate and liaise with Kimal.

### **Implications for care**

If healthcare professionals judge that continued use of the impacted products in Kimal procedure packs is necessary, they should carefully assess the case for use and overall risk of not proceeding if no alternatives are available and implement risk mitigation measures when using the impacted products.

Further advice and context are available in the [MHRA DSI](#) and the communication of 22 May 2026 from the British Cardiology Intervention Society which is also enclosed with this cascade.

Local clinician-led risk assessment and informed patient consent will be key.

Where unaffected stock is available, it should be used first – irrespective of the type of procedure. Any remaining locally held affected stock should be retained for use in the event that the supply of unaffected stock is interrupted.

### **Current supply and availability**

We understand that Kimal hold approximately one month's supply of **affected** procedure packs (at normal ordering volumes) and this is already in the UK. However, this may include different configurations of procedure packs that your trust and clinicians are not familiar with.

Kimal also currently hold a very limited amount of previous **unaffected** procedure packs in the UK; however, they are prioritising these for emergency orders only.

Further supplies of **unaffected** manifolds have arrived in the UK this week and will be distributed by Kimal as soon as possible, beginning today (22 May 2026), providing unaffected stock to use over the coming bank holiday weekend and into next week. These should be used in conjunction with the other contents of the procedure packs.

There is currently no replacement stock available for the syringes, but work continues with Kimal and Medline to support this and alternatives are available.

Given the disruption to the manufacture of these products by Medline as well as the distribution of stock by Kimal, there may be an extended period of pressure on supply.

For day-to-day updates on supply and ordering, please refer to NHS Supply Chain's 'Important Customer Notice' (ICN): [Field Safety Notice Kimal Namic White Star Handle Manifolds and Namic Rotating Adaptor Syringes \(ICN 3326\)](#). This will be kept updated.

## **Next steps and contact details for queries**

### Patient safety and clinical concerns

If trusts have any **concerns about persistent particulate matter or patient harm following use of the flushing process**, please escalate to the National Operations Centre immediately at [england.nationaloperationscentre@nhs.net](mailto:england.nationaloperationscentre@nhs.net) as well as undertaking usual local safety processes.

Should colleagues observe syringes unscrewing or particulates present in manifolds, they should complete a Yellow Card report to support MHRA's on-going monitoring:

<https://yellowcard.mhra.gov.uk>.

### Supply issues and escalation

Department of Health and Social Care (DHSC), NHS England and NHS Supply Chain will continue to work with Kimal and alternative suppliers to minimise the length of disruption and maximise the availability of clinically acceptable alternatives. We will continue to review how stock is allocated as equitably as possible across trusts, based on need and your feedback.

If trusts have concerns regarding supply, they should follow the [process for reporting potential supply disruptions of medical equipment and consumables](#).

Please contact Kimal in the first instance and ensure your NHS Supply Chain Customer Services Advisor and ICS Manager are aware (if you purchase via this route).

Should there remain supply concerns and if you require urgent support, DHSC's National Supply Disruption Response (NSDR) service should be informed at: [nsdr@dhsc.gov.uk](mailto:nsdr@dhsc.gov.uk)

Ongoing updates

Updates will be provided in due course via the [Important Customer Notice](#) webpage, British Cardiovascular Intervention Society (BCIS), and through existing meetings and networks.

Your co-operation and proactive engagement are vital to the success of this strategy, ensuring we continue to provide safe and effective care across all settings.

Yours sincerely,

**Prof Simon Ray**

National Clinical Director for Heart  
Disease  
NHS England

**Dr Dawn Adamson**

National Speciality Advisor for Heart  
Disease  
Chair of Heart Attack and OOHCA Expert  
Advisory Groups, NHS England



Dear BCIS Member,

Problems persist with the supply of manifolds from Kimal. Kimal have communicated to NHS England that unaffected stock will be delivered to hospitals across the NHS today, but we expect supply to remain unpredictable for some time.

The MHRA have issued guidance that affected stock- that in which there is the potential for particulate matter to be found within the manifolds - can continue to be used, but only in urgent and emergency cases. We would consider this to refer to all patients requiring in-patient procedures. Affected stock should not be used for elective activity.

Specific measures should be applied when affected stock is used, as described in our previous communication, and repeated below for clarity.

We would advise members against the use of 'home-made' manifolds, which we are aware has been considered in some units.

We will continue to update BCIS members as this situation evolves.

**Dan Blackman, President**

**Helen Routledge, Honorary Secretary**

**Tom Johnson, Clinical Standards Lead**

Protocol for use of Kimal Manifolds affected by potential particulate matter

Prior to use, completely disconnect the manifold from all tubing, lines, and accessories so it is fully separated.

- Flush sterile saline through each port and stopcock of the manifold, one at a time, allowing the fluid to drain into a separate sterile container.
- Dispose of all flushed fluid and the container as clinical waste.
- Once completed, proceed with full procedural set-up in accordance with standard practice.