

Date: 1st May 2026

Kimal PLC: URGENT FIELD SAFETY NOTICE

(Updated FSN)

IMMEDIATE ACTION REQUIRED

Recall of packs containing Namic White Star Handle Manifolds included in Medline's Namic Systems

MHRA Ref: 2026/004/017/601/053

Dear Customer,

The purpose of this letter is to advise you of an update to the previous urgent Field Safety Notice (dated 24th April 2026) that Kimal PLC has issued for the Namic White Star Handle Manifolds 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 recall of specific batches of product, which they have through Post Market surveillance, identified a potential risk of foreign particulate within the fluid pathway of Namic White Star Manifolds.

Potential Risk

The potential presence of foreign particulates within the fluid pathway of the Namic White Star Handle Manifolds, under certain conditions, result in: -

- Delay in patient care,
- Embolisms,
- In rare instances, death

Based on the review of currently available post market surveillance data, there have been no reported events resulting in embolism or death.

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

In exceptional circumstances where an emergency procedure must be performed, no alternative device is available, and postponing the procedure would place the patient at significant risk, the use of the originally supplied Namic White Star Handle Manifold may be considered as a last resort. In such cases, the user must perform a full and careful flush of the Namic White Star Handle Manifold and associated tubing with saline, thoroughly inspect the manifold and lines for any particulate matter, and must not use the device if any particulate is observed.

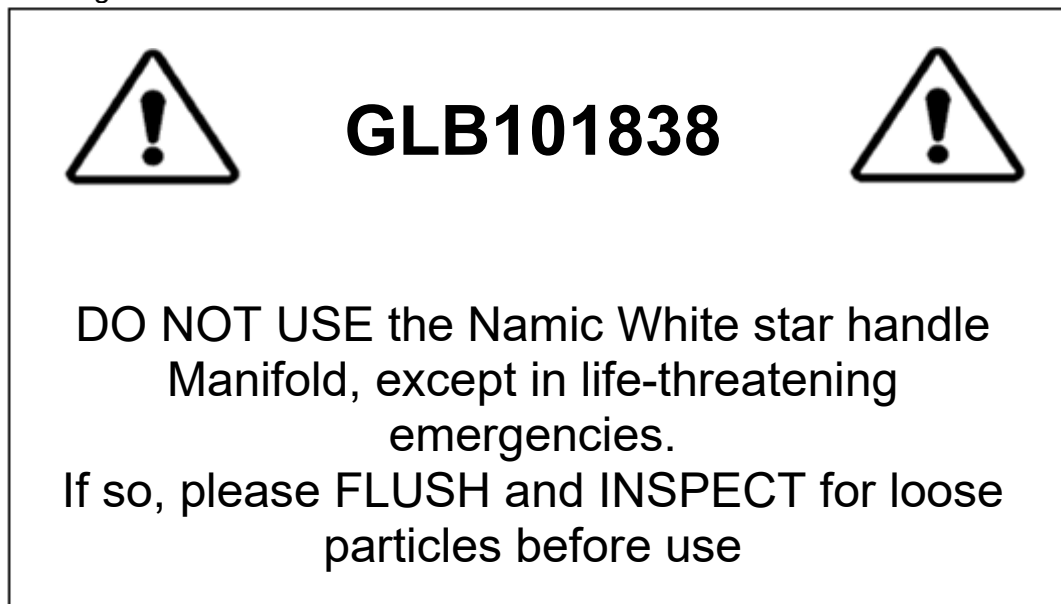
As these products are within Kimal procedure packs, we have identified affected pack codes and lot codes as listed in Appendix 2.

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. Should you not have those contact details then please contact Kimal Customer Services on +44 (0)845 437 9542.

The UK national 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.

Time Period:

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

Yours Sincerely,

A handwritten signature in blue ink, appearing to read 'M Press', is positioned below the closing text.

Matthew Press

CEO

Appendix 1

Confirmation of Receipt of Field Safety Notice

Kimal plc: URGENT FIELD SAFETY NOTICE

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 "warning stickers"

Appendix 2- Affected Product codes and Batches

Procedure Pack Code	Lot Numbers	Qty to return	Qty of “warning stickers” required
K20108	23C0208 23H0227 25A0384 24F0316 24A0964 25G0114 25H0787 25K0482 26D0061		
K56729	23E0321 23C0663 23K0397 23F0730 23G0768 25A0680 24F0181 24L0155 23M0035 24C1016 25E0050 25G0578 26A0310 25K0631 26D0531		
K38575	23F0575 23H0478 23L0584 23D0068 23F0301 25D0500 24L0606 25A0159 24E0259 24G0340 23M0138 23M0592 25G0130 25E0672 25G0770 25M0247 26C0164 26D0517		
K26291	23K0365 23E0086 23H0979 23G0143 23D0163 24M0088 25D0641 24B0464 24E0805 23M0585 25B0229 24J0705 24H0183 24D0269 25H0325 25F0532 25M0243 26B0107 25K0133 26D0072		
SPIRE50760	23G0697 23D0187 25A0966 24J0743 23A0435 23L0651 24A0453 25E0901 25K0192 26C0720		
K37267	23C0698 23E0348 23B0773 23H0760 24A0866 25B0673 24G0530 24L0602 24B0657 25E0944 26A0298 26D0514		
IE-K38863	23F0721 23E0834 23E0805 24K0854 24A0706 24G0191 24J0790 25A0820 25E0650 24L0576 24L0577 25C0558 25K0265 25D0693 26C0286 26D0478		
K46990	23C0363 23J0851 23F0583 23B0183 23H0606 23D0625 24J0855 25C0320 24F0425 24L0621 25A0664 24C0643 24F0409 23L0296 24D0289 24B0544 23M0556 24E0082 25D0729 25J0330 25K0156 25G0148 25F0128 25M0493 26B0298 26D0521		
K26312	23H0747 23F0223 23L0083 23D0253 24H0230 24K0921 25B0654 24E0807 24C0173 23J0279 25E0939 25H0176 26A0518 26C0658		
K26317	23G0909 23J0721 23G0096 23E0547 23D0056 24K0205 24L0824 24H0704 25A0151 25B0551 24C0620 24D0127 24B0688 24E0864 23L0462 24A0318 24A0458 24G0335 25G0812 25H0177 25E0880 25D0018 25E0198 25M0457 25K0721 26A0690 26D0502 26D0073		
K32169	23F0227 25B0662 24J0214 24C0319 25E0664 25H0180 26D0506		
K50518A	23G0774 23B0685 23D0499 25B0597 24K0502 25A0169 24H0136 24A1037		

Appendix 2- Affected Product codes and Batches

	23K0523 23M0363 24E0513 24C0384 24F0172 26A0365 25G0328 25E0044 26D0523 26D0308		
K26263	24C0756 25D0322 24K0316 24F0487 24A0163 25F0788 25K0719		
K26275	23K0138 23B0655 23F0416 23D0252 23H0215 24J0202 24G0810 24L0588 25B0401 24K0682 23A0254 24D0124 24B0685 23L0570 24A0367 24F0159 25F0790 25D0061 25H0693 25K0271 25E0606 26B0638 25M0590		
K51106/P1	23J0675 23G0773 23D0264 23E0676 24K0329 25C0324 24M0075 23B0722 24G0829 24E0189 24A0522 23M0147 25L0023 25G0650 25E0912 26A0532 25L0412		
K74893	26A0282 26B0324 25J0817 26D0552		