

Date: 17th April 2026

Kimal PLC: URGENT FIELD SAFETY NOTICE

IMMEDIATE ACTION REQUIRED

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

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 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

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

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 collection/ credit.

Appendix 2- Affected Product codes and Batches

Procedure Pack Code	Lot Numbers	Qty to return
DE-K34900	23H0072, 23K0231, 23L0438, 23M0496, 24D0067, 24D0607, 24F0288, 24K0888	
FI-K66649	23H0085, 25H0555, 25K0685	
IE-K26301	23K0358, 23L0821, 23M0019, 23M0408, 24C0007, 24E0458, 24E0853, 24J0695, 24K0853, 24M0357, 25A0819, 25B0392, 25D0122, 25E0525, 25G1050, 25K0074, 25L0119, 26B0367	
IE-K38863	24G0191, 24J0790, 24K0854, 24L0576, 24L0577, 25A0820, 25C0558, 25D0693, 25E0650, 25K0265	
IE-K70443	23M0214	
IE-K71828	25E0562, 25E0915, 25E0932, 25K0359	
K20108	24A0964, 25A0384, 25G0114, 25H0787, 25K0482	
K211/4001/10	25E0656	
K26263	23H0330, 24A0163, 24C0756, 24F0487, 24K0316, 25D0322, 25F0788	
K26287/P1	24H0182, 24L0402, 25A0837, 25E0197, 25G0986	
K26317	24A0458, 24C0620, 24H0704, 24K0205, 24L0824, 25A0151, 25B0551, 25D0018, 25E0198, 25E0880, 25G0812, 25H0177, 25K0721, 25M0457	
K26330/P1	24K0862	
K3216	24C0319, 25B0662, 25E0664, 25H0180	
K37267	24B0657, 24G0530, 24L0602, 25B0673, 25E0944, 26A0298	
K38575	23M0592, 24E0259, 24G0340, 24L0606, 25A0159, 25D0500, 25E0672, 25G0130, 25G0770, 25M0247, 26C0164	
K46990	23M0556, 24B0544, 24C0643, 24D0289, 24E0082, 24F0409, 24F0425, 24J0855, 24L0621, 25A0664, 25C0320, 25D0729, 25F0128, 25G0148, 25J0330, 25K0156, 25M0493, 26B0298	

K50518A	24A1037, 24C0384, 24E0513, 24F0172, 24H0136, 24K0502, 25A0169, 25B0597, 25E0044, 25G0328, 26A0365	
K56729	24L0155, 25A0680, 25E0050, 25G0578, 25K0631, 26A0310	
K67427/P1	23K0225, 24G0376	
K73353	24L0421	
K74893	26A0282, 26B0324	
LB-K20500	24B0087, 24H0263, 25F0614	
MA-K61985	24C0460, 24C0803, 24K0534, 25M0298	
OM-K73658	25G0774	
QA-K70928	24B0728, 24B0242, 25M0348	
RO-K37082	23J0387, 24D0327, 24G0400, 24L0362, 25E0490, 26A0562	
SA-K41949	25C0689	
SI-K33607	23K0298, 24A0926, 24E0421	
ZA-K42618	23M0036, 24A0929, 25A0714, 25E0505	