

20th May 2026

RE: FSN Namic Manifolds – Kimal Update

Dear Valued Customer,

We are writing to provide you with a further update regarding the ongoing Field Safety Notice (FSN) affecting Namic Manifolds, including Kimal procedure packs containing manifolds and the subsequent Device Safety Alert issued by the MHRA on 19th May 2026 – DSI/2026/002.

Kimal Procedure Packs – MHRA-Approved Warning Labelling

Kimal continues to work closely with the MHRA and Medline manufacturer of the Namic Manifolds. We are currently working through the labelling process and will be shipping your specific packs to you as swiftly as possible.

Update Option to Receive a Sterile Replacement Manifold

We understand that some customers may prefer not to use the manifold included within the pack even in emergency cases. Since we received notification of the FSN from Medline, Kimal has been working with both Medline and other manifold suppliers to be able to supply a separately packaged sterile manifold to accompany your procedure packs.

We anticipate this option will be available shortly. We are not in a position to confirm a date due to outstanding confirmation from Medline on product volumes and the requirement for other suppliers to secure UKRP status with MHRA. Please note we are prioritising all of these activities including expedited freight and customs clearance. We will communicate promptly as soon as we have sterile manifolds in stock with associated MHRA clearance for the alternative suppliers.

Stock codes on Manifolds

Part No	Part Description
42.05.50001	Manifold Set 3 Ports, Right, Off w/ Contrast Syringe 12ml
42.05.40003	3 Ports Manifold, Right, Off, 250 PSI, Rotating Lock
42.05.10003	2 Ports Manifold, Right, Off, 250 PSI, Rotating Lock
MMK-003	Manifold 3 port Right, Off, 500 PSI
MMK-001	Manifold kit 3 port Right, Off, 500 PSI
<u>70038307</u>	<u>Perceptor Manifold Pressure Transducer, 3 Ports, Right, Off, 200PSI</u>
70038200	Finger Grip Manifold, 2 Ports, Right, Off Handle 200PSI
70038301	Finger Grip Manifold, 3 Ports, Right, Off Handle 200PSI

Action Required

Given we anticipate the sterile manifolds will be available in short order then please advise your Kimal Sales Representative whether you do or do not wish to receive a separately packaged sterile manifolds alongside your procedure packs.

If you have any questions or require further information, please do not hesitate to contact your Kimal Sales Representative or our Customer Services team.

Kind Regards



Matthew Press
CEO
Kimal