Medline International France
Quality & Regulatory Affairs Dept.
[redacted]

Facility
Service
Address
Address
ZipCode City
Country

URGENT: FIELD SAFETY NOTICE
Medical Devices Emergency Treatment

[redacted] 24/04/2026

ATTENTION: Pharmacist/Risk Manager responsible for medical device vigilance and the Biomedical/Engineering Department

Field Safety Notice regarding the Emergency Treatment of Namic White Star Handle Manifolds included in Medline's Namic Systems

Medline Reference:	**FSN-26/06**
MoH Reference:	**N/A**
Product description:	**Namic Systems with Namic White Star Handle Manifolds included**
Legal Manufacturer SRN:	**FR-PR-000003713**
Action type:	**Field Safety Notice – Emergency Treatment**
Product codes:	**See Appendix 1**

Dear Customer,

UPDATE 24th APRIL 2026

This letter follows up on the Field Safety Notice – Emergency Treatment regarding the Recall of Namic White Star Handle Manifolds issued on 21st April 2026. We need to inform you that additional product codes fall under the scope of the Field Safety Notice (FSN) of Namic White Star Handle Manifolds. All impacted product codes for this FSN are listed in Appendix 1 (page 5) attached hereto.

An additional required action has been added to this FSN to ensure continuity of use. Customers are now instructed to order a replacement single sterile manifold to replace the defective manifold included in the NAMIC Kit.

Medline hereby informs all customers in the Netherlands that single sterile replacement manifolds are available upon request to replace the defective Namic White Star Handle Manifolds included in NAMIC Systems.

To ensure continuity of interventional cardiology procedures, customers are instructed to order a replacement single sterile manifold to replace the defective manifold supplied within the NAMIC Kit.

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.

REASON FOR THE FIELD SAFETY NOTICE:

Customers in the Netherlands have been disproportionately impacted by the limited availability of Namic White Star Handle Manifolds following previous corrective actions.

This Field Safety Notice is issued to inform customers that single sterile replacement manifolds are available upon request to replace the defective manifolds supplied within NAMIC Systems, and to define controlled measures to ensure that patients at immediate and significant clinical risk may continue to receive emergency interventional cardiology treatment.

POTENTIAL RISKS:

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

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

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

ACTIONS REQUIRED:

Step 1: Please take note of this FSN and inform all users in your facility.

Step 2: Please complete the Acknowledgment Receipt (*page 4*). Then, return page 4 by email as soon as possible **but no later than 15th May 2026.**

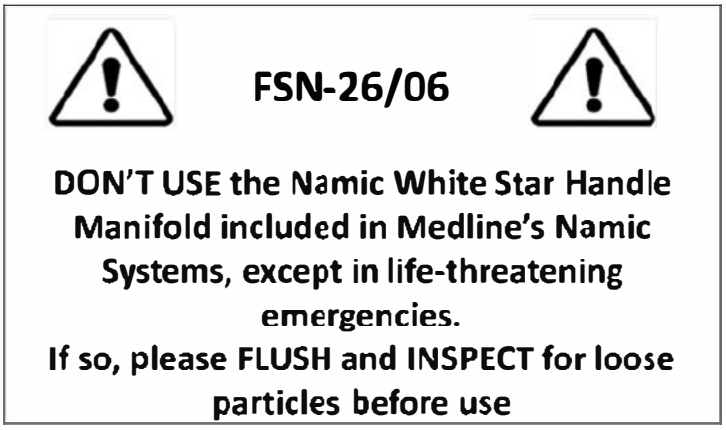
Step 3: To obtain a single sterile manifold as a replacement for the defective component identified in your NAMIC Kit, please contact your Medline Sales Representative to place an order.

Step 4: If you have any questions or need support, please contact your Medline Sales Representative or your local Medline Customer Service.

The relevant competent authorities have been informed of this FSN.

Please proceed with the following pages to acknowledge receipt of this FSN. Medline would like to thank you for your cooperation.

WARNING LABEL:



Yours sincerely,

[redacted]

This urgent and important field safety notice is only addressed to Dutch facilities that may receive the referenced products.

Medline International France SAS
[redacted]

Quality & Regulatory Affairs Dept.
[redacted]

Please email the Acknowledgement Receipt to the following email address: GMB-EU-FSN-FSCA-KLEVE@medline.com

Medline Reference: FSN-26/06

Please complete the Acknowledgement Receipt, and send back by email as soon as possible, but no later than 15th of May 2026. The referenced products are listed in the Appendix *(page 5)*.

By completing and signing this acknowledgement receipt, I confirm that I have read and I understood the instructions provided. I acknowledge receipt of the FSN-26/06 by signing this document and returning it to Medline.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations on which this action has an impact. (As appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

If you are a dealer, wholesaler, distributor/reseller, that distributed any referenced products to other facilities: per Medical Device Regulation 2017/745, Article 14, part 4, please distribute this notification to your customers and provide confirmation to Medline that your customers have been notified by completing the information below and returning it to Medline per email to [redacted].

Date: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

Appendix 1

Item number
606000776
606209316A
60610625918
60148473821
606209331
6060007128B
606209318
NABK60008
NADK60002
NANK60013
NASK60002
NASK60003
NAUK60003
NAUK60006A
NAWK60001
NAWK60002

Item number
NAWK60004
NAWK60006
NAWK60008
NAWK60012
NAWK60016
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