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

URGENT: FIELD SAFETY NOTICE
Medical Devices Emergency Treatment

[redacted] 21/04/2026

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,

This letter is to advise you that Medline has initiated a Field Safety Notice (FSN) regarding Namic White Star Handle Manifolds, which are included in -Medline's Namic Systems listed in the table in Appendix 1 (page 5).

Medline has decided to notify all customers in the Netherlands that Namic Systems with Namic White Star Handle Manifolds included that were previously recalled under FSN-26/02 will exceptionally be distributed again for the sole purpose of ensuring continued intervention cardiology procedures in true emergency instances (emergency treatment).

A warning label will be applied to the packaging by Medline, stating that the Namic White Star Handle Manifold must be removed and discarded from further use, with the only exception being in rare circumstances where a

manifold is urgently required, no alternative device is available, and postponing the procedure would place the patient at significant risk.

In such cases, the user should perform a **full and careful flush** of the Namic White Star Handle Manifold and associated tubing with saline, carefully examine the Namic White Star Handle Manifold and lines for any particulate, and not use the Namic White Star Handle Manifold and lines if any particulate is observed.

REASON FOR THE FIELD SAFETY NOTICE:

As Dutch customers have been disproportionately impacted by the earlier Recall FSN-26/02 of Namic White Star Handle Manifold, Medline issues this FSN.

Through this FSN Medline aims to ensure that patients at immediate and significant risk can continue to receive emergency treatment in the Dutch market.

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.

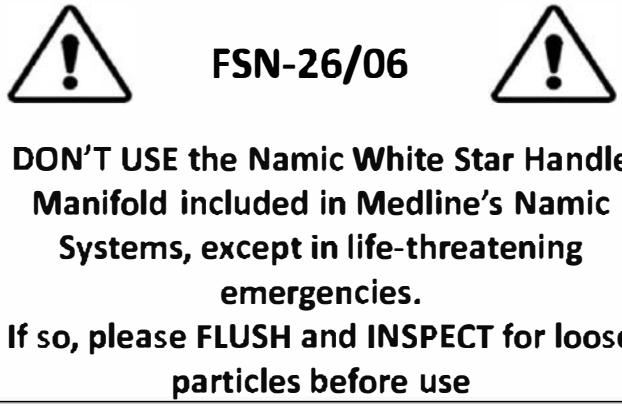
Step 2: Please complete the Acknowledgment Receipt (*page 4*). Then, return page 4 by email as soon as possible **but no later than 30th April 2026.**

Step 3: 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 to 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.

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 30th April 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: _____

Medline International France SAS
[redacted]

Quality & Regulatory Affairs Dept.
[redacted]

Appendix 1

Item number
NABK60007
NABK60008
NADK60002
NANK60013
NASK60002
NASK60003
NAUK60003
NAUK60006A
NAWK60001
NAWK60002
NAWK60006

Item number
NAWK60012
NAWK60016
NAWK60019
NAWK60020
NAWK60021
NAWK60022
NAWK60025
NAWK60027
NAWK60028
NAWK60036
NAWK60041