



Medline International Germany GmbH [Redacted]

Company Name
Address
Address
ZIP City

Kleve, 19. Mai 2026

URGENT: FIELD SAFETY NOTICE

Medical Devices Emergency Treatment

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 Rev04
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 18th MAY 2026

This letter follows up on the Field Safety Notice – Emergency Treatment regarding the Recall of Namic White Star Handle Manifolds issued on 1st May 2026. We need to inform you that additional information has been added in the FSN letter to ensure customers can make a well informed decision on the need for emergency use of impacted Namic White Star Handle Manifolds. All impacted product codes for this FSN are listed in Appendix 1 (page 6-7) attached hereto.

1 Medline International Germany GmbH

Regulatory Affairs

[Redacted contact information]





Medline hereby informs all customers 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 particle is observed.

A specific recommended flushing procedure has not been validated by Medline. The above-mentioned flushing recommendation is intended as a risk mitigation step and may not fully eliminate the risk of potential foreign particle within the device.

REASON FOR THE FIELD SAFETY NOTICE:

Medline has received information through post-market surveillance regarding the potential risk of foreign particle within the fluid pathway of Namic Compensator Manifolds. Customers reported observing particle within the fluid path of manifold assemblies during routine visual inspection prior to use. Medline has not received any complaints where particle was observed during use. The total quantity of product that is expected to be impacted by foreign particle is 1,133 out of 1,953,521 manufactured manifolds.

The cause of the defect was confirmed to be the localized plastic flash on the Star Off Handle at a specific location, which can be sheared off during the assembly into the manifolds, potentially introducing loose particle in the fluid path (Fig 1-3). The area of the particle measured from samples is in the range of 0.19 mm²- 0.25 mm².



Fig 1-3





The purpose of this communication is to ensure transparency and to support customers who have been disproportionately impacted by the limited availability of Namic White Star Handle Manifolds following previous corrective actions. Medline covers a significant part of the market in certain European countries, with no immediate alternative product available. Medline's production of conforming products has resumed, but no indication can be provided when stock levels will have recovered sufficiently to serve all customers.

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. Medline makes available single sterile manifolds to replace the defective Namic White Star Handle Manifolds included in the NAMIC Systems, if so requested by customers, subject to availability of quantities. If you have any questions or need support, please contact your Medline Sales Representative or your local Medline Customer Service.

POTENTIAL RISKS:

The potential presence of foreign particles 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 5*). Then, return page 5 by email as soon as possible **but no later than 8th June 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:

	FSN-26/06	
<p>DON'T USE the Namic White Star Handle Manifold included in Medline's Namic Systems, except in life-threatening emergencies.</p> <p>If so, please FLUSH and INSPECT for loose particles before use</p>		

Yours sincerely,

This urgent and important field safety notice is only addressed to 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 8th of June 2026. The referenced products are listed in the Appendix (page 6-7).

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

REFERENCE				
6014847381	606003415	63148473814	656608749	NANK65009
60148473821	606003419	63148473816	656608753	NANK65010
60148473828	60610625918	63620462A	656608755	NANK65013
60148473831	60614847381	63620681	65750039	NANK65014
60148473832	60620881	636209321	84038200	NANK65015
6018491711	60620896	63620973	84038301	NANK65026
603116671	606209123	64038200	BGCAN007	NASK60003
6060007100	606209316A	64038301	BGCAN007A	NAUK60001
6060007101	606209318	656000780	FGRAN014	NAUK60002
6060007108	606209319	656000784	FPRAN014B	NAUK60003
6060007112	60620932	65600086	FPRAN014C	NAUK60005
6060007118A	606209330	6561062592	HGGAN115C	NAUK60006
6060007119	606209331	656206837	HGGAN166A	NAUK60007
6060007120	606209332	656209310	HGGAN273A	NAUK65001
6060007124	606209333	656209312	HGGAN336	NAUK65002
6060007126	60620937	656209317	HGGAN423	NAUK65002A
6060007128A	60620938	65620932	HGGAN423A	NAUK65003
6060007128B	60620973	656209328	NABK60008	NAUK65004
6060007129	606604044	65620934	NADK60001	NAUK65005
606000750	606608233	65620936	NADK60002	NAUK65007
606000764	60660829	65620937	NADK60005	NAUK65008
606000775	606608710	65660872	NAEK60001	NAUK65010
606000776	606608715	656608724	NANK60002	NAUK65014
606000790	606608719	656608737	NANK60004	NAUK65016
60600081	60750033A	656608739	NANK60006	NAUK65017
606001719	60750034	656608745	NANK60013	NAUK65019





NAUK65020	NAWK60012	NAWK60023	NAWK65003	NAWK65012
NAUK65021	NAWK60016	NAWK60025	NAWK65004	NAZK60002
NAWK60001	NAWK60018	NAWK60027	NAWK65005	WGHAN139
NAWK60002	NAWK60019	NAWK60028	NAWK65006	
NAWK60004	NAWK60020	NAWK60029	NAWK65007	
NAWK60006	NAWK60021	NAWK65001	NAWK65008	
NAWK60008	NAWK60022	NAWK65002	NAWK65009	

