Medline International Germany GmbH – Medline Str. 1-3 – D-47533 Kleve

Company Name
Address
Address
ZIP City

Einschreiben-Rückschein

Kleve, 9. April 2026

URGENT: FIELD SAFETY NOTICE
Medical Devices Recall

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

Recall for Angiographic Control Syringe with Rotating Adaptor (RA) fitting

Medline Reference:	**FSN-26/05**
ANSM Reference:	**-**
Product description:	**Namic Angiographic Control Syringe with Rotating Adaptor (RA) fitting (Namic RA syringes)**
Legal Manufacturer SRN:	**US-MF-000009717**
Action type:	**Recall**
Product codes:	**See Appendix 1 *(pages 6-7)***

Dear Customer,

This letter is to advise you that Medline Industries, LP. has initiated a Recall regarding **Namic Angiographic Control Syringe with Rotating Adaptor (RA) fitting (Namic RA syringes)** which may be part of non-sterile Medline Fluid Management Kits. The impacted kits are listed in **Appendix *(pages 6-7).***

REASON FOR THE RECALL:

Medline has identified through post-market surveillance a potential risk of the syringe rotating adaptor unwinding during use, which may result in a loose connection and/or full disconnection between the syringe and manifold.

POTENTIAL RISKS:

Please find below potential risks announced by Medline Industries LP:

If unwinding occurs, there is potential for biohazard exposure, blood loss, and infection, as well as introduction of air into the line, which may result in air embolism – a condition that carries a risk of serious

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injury or death. All units have the potential to exhibit this failure mode.

Due to the risk of serious injury or death, customers are directed to remove and destroy all Namic RA Syringes. Over-labels will be provided for any affected kits on hand stating that the affected syringes must be removed and discarded from further use. The only exception is in rare circumstances where angiography is urgently required, no alternative device is available, and postponing the procedure would place the patient at significant risk.

If use is unavoidable because failure to proceed would result in patient harm, the Namic RA syringe must be used with extreme caution and vigilance, including manual stabilization of syringe-to-manifold connections and continuous, 100% monitoring during setup and throughout the entire procedure. In such cases, strict adherence to all usage guidelines and the Instructions for Use are also required, including:

- Ensure that you are making secure connections when using this device to prevent the introduction of air into the system that could result in embolism and in rare instances death.
- All connections should be finger tightened. Overtightening can cause cracks and leaks to occur that could result in embolism and or exposure to biohazards.
- Verify that there is not leakage by aspirating and checking to see that air is not trapped in the system to minimize the potential for embolism and in rare instances death.
- Examine product carefully for entrapped air and fully debubble prior to injection to minimize the potential for embolism and in rare instances death.

In addition to ensuring strict adherence to the IFU, if the Namic RA syringes unwind causing loose connection or full disconnection **during procedural set up**, please take the following steps:

1. Remove and replace the Namic RA syringes.
2. Follow normal use guidelines, in accordance with the Instructions for Use, and proceed with the procedural set up. Finger tighten the syringe and manifold connection. Do not overtighten.
3. Verify the syringe connection remains secure.
4. **Ensure manifold system is flushed and de-bubbled prior to use**.
5. If the syringe replacement continues to show evidence of loosening or disconnecting from the manifold system, **DO NOT USE.** Replace the manifold or entire manifold system.

If the Namic RA syringes unwind causing loose connection or full disconnection **during the procedure**, please take the following steps:

1. Disconnect the manifold system from the patient.
2. Once the manifold system is disconnected, remove and replace the control syringe.
3. Finger tighten the syringe and manifold connection. Do not overtighten.
4. Reprime the manifold system to ensure all air has been removed prior to use.

5. Verify Namic RA syringes connection remains secure without evidence of loosening or disconnecting off the manifold during repriming of the manifold system.
6. Resume procedure with standard catheter connection protocol.
7. In the event the Namic RA syringes replacement continues to show evidence of loosening or backs off the manifold system **DO NOT USE.** Replace the entire manifold system.

ACTIONS REQUIRED:

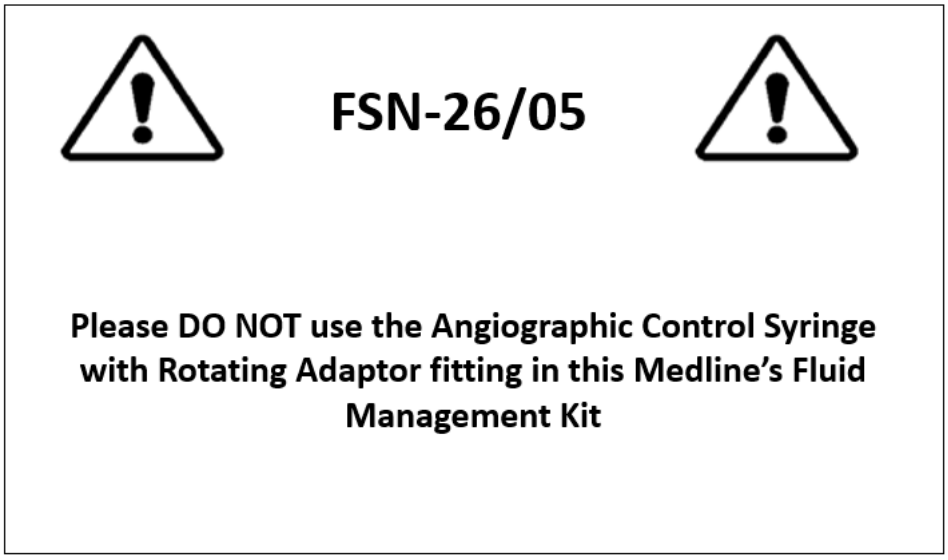
Step 1: Please take note of this recall and inform all customers.
Step 2: Immediately check your stock for the affected item number(s) and the affected lot number(s) listed on page 6-7. Quarantine all affected product.

Step 3: Please complete the Acknowledgment Receipt *(page 5)* and indicate the number of units *(pages 6-7)* in your stock to receive the necessary quantity of "warning stickers". Then, return pages 5-7 by email as soon as possible **but no later 20th April 2026**

Step 4: If you no longer have any of the impacted products in stock, please also complete the Acknowledgment Receipt *(page 5)* and return it by email as soon as possible **but no later than 20th April 2026**.

Step 5: Upon receipt of your submitted response form, your account will receive over-labels to place on affected inventory, with instructions to apply the warning sticker to the kits.

Warning Sticker:



If you have any questions or need support with finding alternative syringes, please contact your Medline Sales Representative or your local Medline Customer Service.

The relevant competent authorities have been informed of this recall.

Please proceed to the following pages to acknowledge receipt of this notice. Medline apologizes for the inconvenience caused by this recall and would like to thank you for your cooperation.

Yours sincerely,

Willem van Alst,
Sr. Manager Post Market Surveillance, Medline Europe

This urgent and important field safety notice is only addressed to facilities that have received the impacted products.

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

Medline Reference: FSN-26/05

Please complete the Acknowledgement Receipt and Appendix 1, and send **both** back by email as soon as possible, **but no later than 20th April 2026**. **The products impacted by this recall are listed in the Appendix *(pages 6-7).***

Quantity of warning labels needed: _____

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-26/05 by signing this document and returning it to Medline.

This notice needs to be passed on 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 impacted 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 GMB-EU-FSN-FSCA-KLEVE@medline.com.

Date: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

Appendix 1

Item Number	Lot Number	QTY on Stock
656000780	0000094444 0000096116 0000099440 0000116841 0000118601 0000119926 0000146198	
656000784	0000069279 0000072461 0000076540 0000082856 0000087380 0000088945 0000106748	
656001716	0000070836 0000073196 0000077580 0000078151 0000078320	
656209310	0000069359 0000073804 0000082854 0000091491	
656209312	0000069351 0000072054 0000073455 0000082473 0000099938 0000104329	
656209328	0000069754 0000071500 0000073278 0000077805 0000082861 0000083330 0000084066 0000086623 0000091882	
656608749	24JBN963 24JBA692 24IBA807 24GBT180 24FBD257 24EBO034 24EBH534 24CBT018 24CBM852 24CBI159 24BBK268 24ABI614 23FBE735 23DBM397	
6561062592	0000083925 0000087874	
65600171	0000069626 0000071501 0000072473 0000073218 0000075734 0000075952 0000076964	
65620932	0000069794 0000071505 0000079444 0000091246 0000095715 0000097798 0000100303 0000104694	
65620936	0000069797 0000071602 0000073217 0000073219 0000074930 0000077207 0000079407 0000081130 0000088947 0000100304 0000101271	
65620937	0000079402 0000083931 0000087404 0000089546 0000097082 0000103560 0000105533 0000106264 0000117538 0000122235 0000123018 0000132450 0000133131 0000137250 0000139598 0000145310 0000147764	
63620462A	0000069745 0000074242 0000075910 0000076960 0000083791 0000091846 0000094148 0000094162 0000097489 0000120370 0000121303 0000127737 0000145316 0000148393 0000157873 0000161101 0000165141 0000169771 0000171027 0000172536 0000176156 0000177497 0000178580 0000189278 0000069745 0000074242 0000075910 0000076960 0000083791 0000091846 0000094148 0000094162 0000097489 0000120370 0000121303 0000127737 0000145316 0000148393 0000157873 0000161101 0000165141 0000169771 0000171027 0000172536 0000176156 0000177497 0000178580 0000189278	
636209321	0000069963 0000071261 0000072039 0000075231 0000076152 0000103405 0000106329 0000109978 0000112451 0000116355 0000119184 0000124633 0000133186 0000140439 0000144466 0000157687 0000162636 0000167655 0000168367 0000177382	
63620681	0000089541 0000097900 0000101082 0000115136 0000124574 0000126517 0000192279	
63620973	0000071245 0000073283 0000106702 0000109852 0000112979 0000113203 0000117680 0000120249 0000125260 0000128575	

	0000132774 0000133026 0000137008 0000139703 0000142229 0000144064 0000154831 0000163322 0000163612 0000177185	
63148473813	0000072424 0000090766 0000103107 0000110843 0000112983 0000119548 0000121214 0000124632 0000127803 0000141810 0000145326 0000176791 0000177234 0000072424 0000090766 0000103107 0000110843 0000112983 0000119548 0000121214 0000124632 0000127803 0000141810 0000145326 0000176791 0000177234	
NAWK65004	293516 298404 45002237 45002240 45002242 45002244 45002250 45002251 45002252 45002253 45002255 45327249 45784608 49439101 50375090 50375092	
NAWK65006	293517 298009 45002330 45002336 45002339 45002342 45002348 45002353 45002361 45002365 45002372 45002378 45002387 45002391 45002395 45002402 45002406 45327228 45327230 45327232 45327234 45327236 45327238 51239745 51239746 51239747	
NAWK65007	293518 45002329 45002332 45002337 45002343 45002347 45002352 45002355 45002360 45002366 45002370 45002375 45002379 45002386 45002389 45002398 45002404 45327216 45327217 45327218 45327219 45327220	
NAWK65008	293327 45002509 45002511 45002512 45002513 45002514 45002515 45002516 45327246 46493790 50122020 50374994 50374996 51239792	
NAWK65009	293519 295839 45002383 45002393 45002399 45002409 50493479 50493483 50493486 50737672 50737675 50737676 50829953 51168371	
NAWK65011	45275858 45275859 50493529 50493531	
NAWK65012	51190459 53502695 53502700	
NAWK67005	55929324 56043783 56043785	
NAUK65021	45277135 45277136 45277137 45277138 45277139 45277140 47155191 47155192 50130012 50130013 50130014 50188956	
NANK65010	290384 296580 297045 45205236 45205239 45205241 46114401 46873807	
NANK65014	294008 45002258 54159173 55217250 55265723	
NANK65015	45275869 45275870 45275871 48513323 50553569 50685492	
NANK65026	54700141	