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ZipCode City
Country

URGENT: FIELD SAFETY NOTICE

Medical Devices Recall

Châteaubriant, Date

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-26/03
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 \(pages 6-16\)](#)

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 Medline Fluid Management Kits or Medline procedure Packs. The impacted kits are listed in [Appendix \(pages 6-16\)](#).

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.

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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 users in your facility.

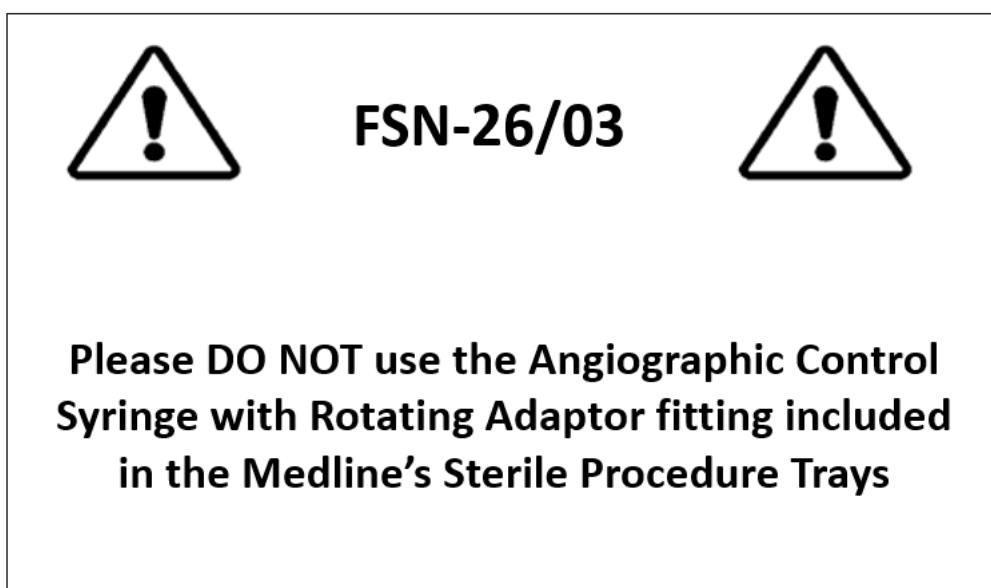
Step 2: Immediately check your stock for the affected item number(s) and the affected lot number(s) listed on page 6-15. Quarantine all affected product.

Step 3: Please complete the Acknowledgment Receipt (*page 5*) and indicate the number of units (*pages 6-16*) in your stock to receive the necessary quantity of “warning stickers”. Then, return pages 5-16 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 3*) 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 for your staff to remove and discard the affected component prior to using the kit.

Warning Sticker:



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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.

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Please email the Acknowledgement Receipt to the following email address:
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Medline Reference: FSN-26/03

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 6-16)**.

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-26/03 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-CHBT@medline.com.

Date: _____

Name: _____

Position: _____

Facility or Business Entity: _____

Address: _____

City: _____

Medline Account Number: _____

Telephone: _____

Email address: _____

Signature: _____

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Appendix 1

Item Number	Lot Number	QTY on Stock
BGCAN007	49870189 49870190 49870191 49870192 49870193	
BGCAN007A	52579564 52588666 52588667 52588668 52588671 52588672 52588674	
BGCAN007B	57255256	
DGFAN837	50169459 50169461 50169462 50169463 50169464	
DGFAN837A	55398582 55398584	
EGDAN001A	48648779 48648780 48648781 48648782 48648783 48648784 48648785 48648786 48648787 48648789 49375643 51582639 51582640	
HGGAN115A	296139 297467 45001763 45001767 45001768 45001769 47731338 47731339 47731340 47731341 47731342 47731345 47731346 47731348 47731349 47731351 47731353	
HGGAN116A	296177 45001792 45001795 45001798 45001802 45001805 45001809 45001810 52937570	
HGGAN130	284604 290601 297580 45001989 45001993 45001996 45001999 45002001 45002002 45002004 45002006 45002008 45002010 45002011 45002013 45002014 45327182 45837369 46493748 47107748 48372107	
HGGAN131	286529 293975 299865 45016378 45016380 45016387 45016389 45016390 45016391 45016392 45016395 47490063 48374066	
HGGAN154	294225	
HGGAN154A	45157827 45157828 45157831 45157834 45157837 53785570 54030243 54030245 54030246	
HGGAN188	286142 290467 291653 47992564 47992567 47992568 47992569 50123834 50123835 50187050	
HGGAN248	293910 295792	
HGGAN264	45157900 46461433 51242263 51242264 51242265 51242268 54161712 54161714	
HGGAN265	45157985 45157987 45157989 45157990 45157993 45157994 47014119 47490131 47490133 47749120 49700228 49700230 56354873 56354874	
HGGAN325	46913829 46913830 57219452 57219453	

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HGGCV194A	45021903 46496443 46874936 47532506 47629632 47993068 47993069 51169410 51169411	
HGGCV195	45021631 45021632 45021633 46790038 47013973 47826025 47993052 48374833 49029846 49208091 49389746 49621858 50311725 50494498 50494499 50494500	
HGGCV204	266132	
HGGNE240	55817812 55817814 55817816	
LGTCV041B	45041673 45041676 45041678	
LGTCV041C	51891550	
NABK60004	50255998 51000498 51000499 51000500 51000501 53511207 53511208 53511209 53511210 53511212	
NABK60006	51803922 51803923 51803924 51803925	
NAIK67001	55098610 55532191	
NALK60001	51404872 51404873 51404877	
NANK60010	51799220 54504579 55771634 56312025 56382599 56433848 56456440	
NANK60011	51799249 52617013 52665482 53000909 53502813 53502821 53502831 53502835 53502837 53502841 53502843 53502850 55507161	
NANK60013	53914165 53914167 53914172 53914173 53914176 54829542	
NANK60018	52980424 52980425	
NANK60020	51803965 51803966	
NANK60022	54506928 54506929	
NANK60024	54506951	
NASK60002	45334641 45419870 45419871 45419872 45419873 50496243 50496244 50496245 50746459	
NASK60005	52590577 52590579	
NASK60006	52587845 52587848 52587851	
NASK60012	57051044	
NAUK60002	24071150 24081352 24100252 24102150 289658 293418 297190 47009139 47009141 47009142 47009144 47009148 47009150 47009154 47009157 47009159 47116941 47301235 47301239 47637916 47637917 48302743 48303136 48303137 48307730 48572822 48795002 49139072 49642085 49642087 49642089	

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	49642092 49938441 50122034 50122035 50252097 50252101 50737667 50737668 50737670 50737673 50786551	
NAUK60003	45046105 45046116 45359587 45359588 45359611 45816376 45816450 45844244 46029188 46075808 46077795 46155545 46162658 46234205 46692019 47116940 47116949 47637221 48278206 48302742 48303118 48518422 48518426 48518429 48859705 49033062 49033065 49666525 49666528 49666529 50529926 51192401 51454938 51760960 51840059 52283474 52944513 52944519 52944522 53154438 53511385 53739854	
NAUK60007	49651962 49722936 49722938 49722942 49722947 49722950 50188944 50496201 50530459 50530460	
NAWK60001	291200 295011 297833 45002260 45002262 45002265 45002271 45002273 45002277 45002280 45002283 45327260 47008884 50035500 50035503 53465585 53465587 53502595 54122814	
NAWK60002	287873 288725 45002176 45002179 45002183 45002185 45002187 45002189 45002191 45002194 45002195 45002197 45327221 46493738 47965219 47991080 48085537	
NAWK60004	46463593 46463594 46463596 50495435 50495441 50495442 50495445 50495446 50495447 51246323	
NAWK60006	45002137 45002142 45002145 45002147 45327226 45459987 47008938	
NAWK60008	283866 292979 45002263 45002268 45002269 45002272	
NAWK60012	45002209 45002212 45002213 45002217 45002218 45002220 45275854 45275855 47488379 48582635	
NAWK60013	293441 298407 45045776 45045799 45045815 45045829 45045834 45045844 45045846 45045847 45045849 45045852 45045856 45045858 45045860 45045862 45045865 45045867 45045869 45352193 45844297 45844299 45844301 47018191 47018192 47018193 47494545 48518595	
NAWK60015	48410491	
NAWK60016	45265432 45265445 50493367 50493369 50493370 54632460 54765701 54765703 56312168	
NAWK60017	45265434 45707338	
NAWK60018	45265434 45707338	
NAWK60020	45265429 45265444 50493389 50493394 50493398	
NAWK60021	45265465 45265484 50493437 50493439 50493441 50493443 50493446 50493447 50493450	

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NAWK60022	45265482 45265491 45265496 45265517 50493484 50493488 50493490 50493492 50493494 50493495 50493497 50493498 50493500 50493502 50493504 50493506 50493507 50997835	
NAWK60023	45265481 45265518 50493381 50493384 50493388 50493392 50493395 50493397	
NAWK60026	55450441	
NAWK60033	54504782	
NAWK60034	54504833 54504837	
NAWK60035	54504719 54504723	
NAWK60037	54504813 56440287	
NAWK60038	54504888	
NAWK60040	54504662	
NAWK60042	54504747	
NAWK60048	56458503	
NAZK60006	54523999	
PGSAN038A	42155778 42155780 42155781 42594635 43704582 44445665 47503662 48088153 49043806 49043807 50138406 50755290 50856246	
PGSAN109B	42161951 42161956 42594893 43585087 44338982 49371921 49473652	
ST01-EGDAN003	57818680	
ST01-FGRAN027	57701030	
ST01-HGGAN130A	55308237	
ST01-HGGAN131A	55308236	
ST01-NAFK60003	52735078	
ST01-NAFK60004	52735079	
ST01-NAFK60013	53160610	
ST01-NALK60002	52112228	
ST02-HGGAN204	46395073	
WGHAN138	46167260 46463530 46463531 46463532 46463533 46463534 46980218 47154130 47154132 47270490 47270494	

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WGHAN138A	49312429 49565974 49565977 51328631	
6060007112	0000073830 0000077217 0000083090 0000086091 0000087465 0000087643 0000088946	
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60610625918	0000069788 0000073216 0000073956 0000074893 0000075679 0000077146 0000079462 0000080514 0000080715 0000104586 0000106277 0000109019 0000108707 0000113760 0000115833 0000119164 0000119163 0000122981 0000127974 0000132827 0000137880 0000141867 0000145527 0000147280 0000150938 0000150944 0000155669 0000156914 0000166319 0000167193 0000167228 0000168335 0000172076 0000174929 0000175933 0000178768 0000178807 0000184675	
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HGGAN113	298349 299086 45001781 45001784 45001786 45001791 45001799 45837407 45915754 46493522	
FPRAN014C	53383802 53383803 53383804 53383805 53383806 53383807 53383808 53383809 53691776 53691778 53691780 53691784 53691787	
FPRAN014B	48947200 48947220 48947237 48968647 49006451 49006453 49006454 49006456 49006458 49006460 49006462 49006468 49006470 49006472 49006478 49006480 49006482 49006483 49006484 49006485 49006486 49006487 49006489 49006490	

	49006493 49006495 49006497 49006498 49006499 49006502 49006504 49006505 49006506 49006507 49055448	
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WGHAN139	56043153 56043154 56043151 56043152	
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606209331	0000073649 0000082977 0000087859 0000091850 0000096446 0000099413 0000104581 0000109925 0000111994	
606209330	0000069313 0000077147 0000079106 0000079486 0000085369 0000111989 0000115046 0000122117 0000128800 0000130135 0000133034 0000140444 0000142818 0000149345 0000150943 0000152158 0000152845 0000172127 0000172899 0000174807 0000176122 0000177463 0000178573 0000181777 0000186526 0000187990 0000189309	
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606209317	0000070472 0000072526 0000074457 0000079765	
606209316	0000075874 0000077161 0000083889	



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