



Facility  
Service  
Address  
Address  
ZipCode City  
Country

## **URGENT: FIELD SAFETY NOTICE**

### **Medical Devices Recall**

Châteaubriant, 26/05/26

**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-26/04  
**ANSM Reference:** R2609971  
**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 \(pages 4-7\)](#)

Dear Customer,

#### **UPDATE 26<sup>th</sup> of May 2026**

This letter follows up on the Field Safety Notice regarding the Recall Namic Angiographic Control Syringe with Rotating Adaptor (RA) fitting (Namic RA syringes) issued on the 9<sup>th</sup> of April 2026. Medline allows the use of the Namic Angiographic Control Syringe in rare circumstances where angiography is urgently required, and no alternative device is available, and postponing the procedure would place the patient at significant risk. All impacted product codes for this product recall are listed in [Appendix \(pages 4-7\)](#) attached hereto.

#### **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.

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## 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 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 affected syringes, stating they 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.

In these emergency cases where patients must be treated immediately, 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.

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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 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 9<sup>th</sup> June 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 9<sup>th</sup> June 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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**FSN-26/04**



**Please DO NOT use the Angiographic Control Syringe with Rotating Adaptor fitting, except in life-threatening emergencies in accordance with FSN-26/04 safety instructions.**

If you have any questions or need support with finding alternative syringes, please contact your Medline Sales Representative or your Medline Local 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:  
**GMB-EU-FSN-FSCA-CHBT@medline.com**

**Medline Reference: FSN-26/04**

Please complete the Acknowledgement Receipt and Appendix 1, and send **both** back by email as soon as possible, **but no later than 9<sup>th</sup> June 2026**. The products impacted by this recall are listed in the **Appendix (pages 4-7)**.

**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-26/04 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](mailto: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	Lot	QTY on Stock
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	
65620979	0000069514, 0000072744, 0000073276, 0000073960, 0000075374	
70075027	77215, 79109, 82289, 84363, 90369, 107045, 114900, 120770, 122275, 125531, 125834, 132127, 132132, 135020, 135023, 137279, 141698, 141699, 144189, 147731, 149644, 151436, 156104, 156186, 156392, 156393, 158599, 159566, 161568, 165825, 167199, 176256, 176749, 187350	
70083007	77029, 81537, 84335, 87347, 89563, 113792, 115753, 122956, 127785, 131986, 158748, 175535, 187926	
70084007	78186, 81539, 84274, 86756, 89554, 94842, 96918, 105613, 109479, 111244, 114562, 115421, 117317, 118251, 120265, 120769, 121714, 123466, 124589, 131984, 131989, 138071, 140322, 142850, 147002, 152069, 162694, 173507, 174662, 174773, 176555, 178806, 189895	
70084017	84509, 86823, 95687, 165551, 165868, 166300	
70085007	74193, 77204, 77974, 79512, 83156, 85956, 86070, 86483, 90174, 90816, 90917, 92492, 94095, 96914, 98330, 99425, 100711, 100826, 101994, 113588, 116407, 116708, 117321, 119569, 120349, 121439, 121700, 123467, 124590, 126063, 127845, 132989, 134342, 134345, 134741, 136418, 138294, 141336, 147492, 149666, 150547, 152486, 152797, 155541, 156129, 156574, 158566, 164128, 166270, 167879, 167880, 168660, 170215, 170237, 171147, 172275, 173410, 187298, 187601, 187638	
70085107	75384, 96807, 133033, 147541, 154518, 167033, 179525	
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70087107	78897, 148131, 157141, 163681, 167174, 168020, 170851, 176075, 182252, 192254	
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70088007	77187, 86247, 90162, 95619, 104749, 109521, 119070, 122098, 125541, 135421, 138529, 141833, 156061, 157744, 161113, 163952, 168023, 172923, 178145, 186934	
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	<p>103555, 106721, 106964, 107510, 107536, 107959, 108049, 108050, 109430, 109592, 110369, 110800, 110820, 110918, 111345, 112227, 112968, 114117, 115122, 115130, 115133, 115715, 116669, 117287, 117333, 117592, 119131, 119132, 120359, 120378, 120379, 120477, 120926, 121795, 121799, 121856, 121863, 122659, 123853, 123896, 124655, 125050, 126181, 126182, 126183, 126184, 127096, 127134, 130082, 130189, 130543, 130888, 131003, 131298, 132780, 132835, 133210, 134869, 135426, 135751, 135757, 137216, 137259, 139521, 140407, 140436, 140460, 141378, 142312, 143949, 144525, 144816, 144858, 146335, 146688, 147279, 147758, 148526, 148881, 149157, 149356, 149534, 149591, 150043, 150047, 150277, 150927, 150974, 151304, 151311, 151562, 151735, 153278, 153284, 154621, 154788, 155411, 155753, 156008, 156801, 157245, 157352, 157358, 157585, 157587, 158717, 159713, 159723, 159984, 160326, 160371, 161181, 162113, 162661, 162717, 162771, 162801, 164285, 164301, 164302, 165507, 165537, 166941, 167627, 168370, 168574, 170238, 170490, 170657, 170658, 170774, 172184, 172253, 172513, 172514, 172515, 172517, 172518, 173418, 173434, 173451, 174052, 174053, 174725, 174726, 174727, 175214, 175215, 175384, 175424, 175529, 176612, 176730, 176735, 176752, 177132, 177400, 177401, 177413, 177961, 178119, 178736, 179115, 179339, 179394, 179845, 179890, 179892, 179934, 180103, 180117, 180167, 181513, 181515, 181778, 181916, 182018, 182891, 182911, 183051, 183052, 183327, 183346, 183527, 184160, 184623, 185644, 185648, 185650, 185749, 185759, 185769, 186949, 186950, 187389, 187394, 187519, 187575, 187576, 187577, 187578, 187579, 188490, 188841, 188887, 188910, 189111, 189112, 189155, 189196, 189197</p>	
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167971, 169151, 170064, 170157, 170159, 170191, 170618, 171787, 171814, 171818, 172763, 172766, 173231, 173232, 173233, 173234, 173247, 174297, 174299, 174312, 174326, 174327, 175651, 176231, 176507, 176617, 177589, 177957, 178097, 178099, 178800, 179118, 179119, 179357, 179358, 179359, 179906, 179922, 180197, 181163, 181815, 182069, 182717, 182776, 182777, 182835, 183531, 183532, 183591, 183662, 184146, 184178, 184332, 184352, 184776, 184777, 185117, 185118, 185660, 185661, 186183, 186212, 186254, 186265, 186566, 186876, 187378, 187393, 187532, 187533, 187581, 187583, 187602, 187628, 188843, 188844, 188889, 189198, 189242, 189684, 189685, 189686	
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80095007	105201, 106354, 112875, 114278, 123107, 125259, 143729, 145697, 157989, 161262, 162833, 162869, 164539, 172176, 172859, 176097, 178913, 181201, 181321, 185560	
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