

To the attention

Pharmacist responsible for sterile and  
of the Local Materiovigilance Correspondent

Lissieu, 09/03/2023

N/Ref: BW/ FSN-PN-MDX3515M/ R2303496

Subject: PN-MDX3515M Safety Information

**URGENT SAFETY NOTIFICATION**

Dear Madam, Dear Sir,

As part of our material vigilance management, Cair LGL has decided to provide security information regarding the following product:

**Reference: PN-MDX3515M – Guerbet Part Number: 240004**  
**Description: 150CM EXT/INJ LINE STRAIGHT CT/MR**  
**Lot Number: cf annex**



*Figure 1: product image*

**Service Commercial**

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commercial@cairgl.fr

**Service Commandes**

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Fax +33 (0) 4 78 43 77 09  
commande@cairgl.fr

**Service Export**

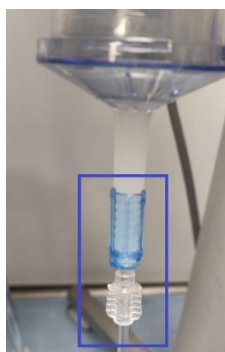
Tél. +33 (0) 4 78 43 77 44  
Fax +33 (0) 4 78 43 77 09  
export@cairgl.fr

Following the market feedback of several customers, we were able to notice the probability of crack of the luer lock female linden compatible of PN-MDX3515M extenders. This crack may result in the leakage of contrast fluid and, in more unlikely cases, the entry of air into the device.

The leakage of contrast medium could lead to having a patient receiving a lower dose than the prescribed dose for a specific indication. A second scan with a second contrast medium injection may be required to establish a good diagnosis. There is a risk of injury induced by exposure of the user or the patient to the contrast medium that may induce some signs of allergic reaction or irritation on the skin or in the eyes.

The entry of air into the device could potentially lead to an embolism with potential health consequences depending on the volume of injected air. Large-volume venous air embolism (> 100 mL) is potentially fatal. Vascular air embolism resulting from the injection of a few milliliters of air during intravenous administration of contrast medium may remain asymptomatic. For information, the total volume of the tubulure is not higher than 4.88mL. The entry of air might also lead to contamination of the solution with microbial germs. The patients may develop general symptoms characteristic of an infection disorder.

Users are advised to be careful when connecting the device with the injection syringe and to not apply excessive screwing on the device. This potential failure is detectable when the device is connected to and purged from the injection syringe. If the crack or leak is found during the line purge, please put the device aside and follow instruction that will be provided by Guerbet upon complaint filling. You can replace this device with one of the same batch number because this problem is random and with very low probability.



*Figure 2: Illustration of the syringe/extender connection point*

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*Au commencement, il y avait un patient...*

In parallel with this safety information, we are working on a solution to correct this potential defect.

As Guerbet is our customer and exclusive distributor for this medical device, we kindly ask you to confirm the receipt of this information by returning the following form to the following address:

Return of the form to:

Entity Name: \_\_\_\_\_

Contact Name: \_\_\_\_\_

Email address: \_\_\_\_\_

Fax: \_\_\_\_\_

Please contact our complaint department to report any event described as above by completing the "**Customer & Product Information Feedback Form**" **F012149-06** (provided separately) and return it to the email: [lf.pmquality@guerbet.com](mailto:lf.pmquality@guerbet.com). Our department will also be at your disposal at the phone number or at the email address below:

Tel: \_\_\_\_\_

Email: \_\_\_\_\_

As this security information follows a due diligence procedure, the competent authorities concerned are informed of this decision and we will keep them informed of the progress of the operation.

We would like to thank you for your cooperation and apologize for the inconvenience. With this information, CAIR LGL is renewing its commitment to provide you with secure and efficient products.

We remain at your disposal for any further information.

Best Regards

\_\_\_\_\_  
Vigilance correspondant

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RETURN AND ACKNOWLEDGEMENT FORM  
Safety information ref: BW/ FSN PN-MDX3515M/ R2303496  
**REF : PN-MDX3515M / Guerbet Part number : 240004**

**To be completed and returned upon receipt:**

Email: \_\_\_\_\_

Fax: \_\_\_\_\_

Stamp of the Institution:

We hereby certify the receipt of the Field Safety Notification sent by CAIR LGL via the intermediary of Guerbet and/or its distributors and the transmission to all persons needing to be informed in our organisation

Field Safety Notification was read and understood.

Name/ Quality of the person who completed the form:

Response Date: \_\_\_\_\_

Signature: \_\_\_\_\_

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## Annex

**Reference: PN-MDX3515M – Guerbet Part Number: 240004**

**Description: 150CM EXT/INJ LINE STRAIGHT CT/MR**

### Lot numbers

Lot numbers
21H09-T
21H10-T
21H16-T
21H17-T
21H23-TW
21K25-T
21L02-T
21L08-TW
21L09-TW
22A06-TW
22A10-T
22A19-T
22A27-T
22B02-T
22B10-T
22B23-T
22B24-T
22C08-T
22C09-T
22C10-T
22C23-TW
22C31-TW
22D04-TW
22D12-TW
22D19-TW
22D23-TW
22D27-TW
22D28-TW

Lot numbers
22E04-TW
22E05-TW
22E09-TW
22E10-TW
22E17-TW
22E23-TW
22F08-TW
22G07-T
22G12-T
22G18-T
22G28-T
22H11-TNV
22H12-T
22H13-T
22H15-T
22H25-T
22H26-T
22H31-T
22I08-T
22J13-T
22J17-T
22J31-T
22K09-T
22K16-T
22K21-T
22K30-T

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