No. 5/2024
Zagreb, 6.2.2024.

URGENT FIELD SAFETY NOTICE

HYDROPHILIC URINARY CATHETER LENTY™

REF: See Table 1, Lot Numbers: See Table 1

Type of Action: Product Recall

Attention: Patients, Clinical & Medical staff, Risk Managers, Distributor, CPSU, Medicines Authority, Malta

This letter contains important information which requires your **immediate** attention.

Dear Customer,

Lentismed is conducting a Field Safety Corrective Action to remove specific lots of certain Hydrophilic Urinary Catheter Lenty™ and our distribution records indicate your organization may have received the impacted products. Products were distributed during 2023. only on Malta market.

PRODUCT CODE (REF)	PRODUCT NAME	LOT NUMBER (Shelf life)	UDI NUMBER (on the box)	UDI NUMBER (on the transport carton)
101300	Lenty Ch08 M hid.cath.ur. 40cm ST	230306T (31.03.2026)	(01)03858892210000 (17)260331(10)230306T	(01)03858892210062 (17)260331(10)230306T
101301	Lenty Ch10 M hid.cath.ur. 40cm ST	230510T (31.05.2026)	(01)03858892210017 (17)260531(10) 230510T	(01)03858892210079 (17)260531(10) 230510T
101301	Lenty Ch10 M hid.cath.ur. 40cm ST	230803T (31.08.2026)	(01)03858892210017 (17)260831(10) 230803T	(01)03858892210079 (17)260831(10) 230803T
101302	Lenty Ch12 M hid.cath.ur 40cm ST	220353T (28.02.2025)	(01)03858892210024 (17)250228(10) 220353T	(01)03858892210086 (17)250228(10) 220353T
101302	Lenty Ch12 M hid.cath.ur 40cm ST	230810T (30.09.2026)	(01)03858892210024 (17)260930(10) 230810T	(01)03858892210086 (17)260930(10) 230810T
101303	Lenty Ch14 M hid.cath.ur. 40cm ST	220415T (31.03.2025.)	(01)03858892210031 (17)250331(10) 220415T	(01)03858892210093 (17)250331(10) 220415T
101303	Lenty Ch14 M hid.cath.ur. 40cm ST	230501T (31.05.2026)	(01)03858892210031 (17)260531(10) 230501T	(01)03858892210093 (17)260531(10) 230501T
101303	Lenty Ch14 M hid.cath.ur. 40cm ST	230518T (30.06.2026)	(01)03858892210031 (17)260630(10) 230518T	(01)03858892210093 (17)260630(10) 230518T

PRODUCT CODE (REF)	PRODUCT NAME	LOT NUMBER (Shelf life)	UDI NUMBER (on the box)	UDI NUMBER (on the transport carton)
101304	Lenty Ch16 M hid.cath.ur. 40cm ST	220414T (31.03.2025.)	(01)03858892210048 (17)250331(10) 220414T	(01)03858892210109 (17)250331(10) 220414T
101304	Lenty Ch16 M hid.cath.ur. 40cm ST	230307T (31.03.2026)	(01)03858892210048 (17)260331(10) 230307T	(01)03858892210109 (17)260331(10) 230307T
101305	Lenty Ch18 M hid.cath.ur. 40cm ST	230308T (31.03.2026)	(01)03858892210055 (17)260331(10) 230308T	(01)03858892210116 (17)260331(10) 230308T
101327	Lenty Ch22 M hid.cath.ur. 40cm ST	230811T (31.08.2026)	(01)03858892210437 (17)260831(10)230811T	(01)03858892210482 (17)260831(10)230811T

Table 1: Impacted products

Manufacturer SRN: HR-MF-000018298

This product recall is limited to the product codes / lot numbers listed in Table 1. No other product codes or lot numbers are affected.

Description of the problem

Incident reports were recorded by Malta Medicines Authority for hydrophilic catheters Lenty™ from four different patients. Patients claimed that the catheters are rigid and have a yellowish color, that there is a visual difference between this batch and the previous batch dispensed to the patient, that catheters caused significant discomfort and bleeding after inserting of the device, and that they caused trauma leading to inability to catheterize.

Causes

Yellowish color of the catheter is a result of sterilization process but it doesn't change the physical properties of the catheter nor can influence its performance. Bleeding is an expected side-effect of catheterization that is described in instructions for use and literature shows many examples and medical conditions that can be the cause of bleeding. The possible cause has been traced back to a raw material. Change of the raw material combined with sterilization made catheters less flexible and more rigid. We cannot be sure what caused the bleeding in these cases but there is a possibility that using these catheters combined with potential medical conditions of the patients might have led to temporary deterioration of patients state of health.

Risks

A risk assessment has been carried out and has determined that there is a risk of discomfort and bleeding as expected side-effect of the catheterization.

Actions taken by Lentismed

Conduct product recall of the products listed in the Table 1. Provide alternative products for the patients on Malta market.

Immediate action taken by the user/customer:

Immediately stop using the product Lenty™ hydrophilic urinary catheter listed in table 1.
Return affected products to the distributor Krypton Chemists Ltd.

Action to be taken by distributor Krypton Chemists Ltd:

We ask that you locate and cease to use all products covered with this Filed Safety Notice.
Please proceed as follows:

1. Cease the distribution of any product identified in this notification.
2. Perform an inventory of your stocks, identify all affected products, and place them in distributor quarantine.
3. Identify all customers who have received affected products.
4. Circulate this information to all customers who use or order these products.
5. Ask customers to identify affected products in their stocks and place them in quarantine.
6. Collect products that customers have placed in quarantine and place them in distributor quarantine.
7. Fill in the enclosed acknowledgement of receipt form and email it to lentismed@lentismed.com , even if you have no products in stock.
8. Upon receipt, our operations department will contact you to organize the return of the products as soon as possible.

Disclosure of the information described herein:
Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are made aware of this Field Safety Notice. If you have given the products to third parties, please forward a copy of this information.

Please keep this information at least until the action has been completed.

Malta Medicines Authority has received a copy of this Field Safety Notice.

We apologize for any inconvenience this may cause you. Please be assured that maintaining a high level of safety and quality is our highest priority. If you have any questions or concerns about this notification, please contact us on lentismed@lentismed.com or +385 1 558 4259.

Sincerely,

Managing director
Zlatan Žmirak

ACKNOWLEDGEMENT OF RECEIPT

DISTRIBUTOR RESPONSE FORM

Please fill in this form within 7 days and send it back to us by email to lentismed@lentismed.com

I attest that:

- I have received Lentismed Field Safety Notice concerning the recall of Hydrophilic urinary catheter Lenty™ listed in the Table 1. Of Field Safety Notice (No. 5/2024),
- I have checked my stocks for the products concerned by this notification, and I have implemented the immediate steps as requested,
- I have identified and informed the customers that had received the products concerned by this notification,
- I have received confirmation of receipt of this notification from these customers,
- I have submitted this declaration to the competent authority in my country, in application of current regulations.

Check the appropriate response(s) and indicate the number of devices identified:

- We have identified the customers that had received the products concerned and we have informed them:

Customer name	Date of customer notification by the distributor

- Further to placing the products in our stocks in quarantine and the recall of the products in our customers' stocks, we wish to return the following products

PRODUCT CODE (REF)	PRODUCT NAME	LOT NUMBER (Shelf life)	QUANTITY (pieces)
101300	Lenty Ch08 M hid.cath.ur. 40cm ST	230306T (31.03.2026)	
101301	Lenty Ch10 M hid.cath.ur. 40cm ST	230510T (31.05.2026)	
101301	Lenty Ch10 M hid.cath.ur. 40cm ST	230803T (31.08.2026)	
101302	Lenty Ch12 M hid.cath.ur 40cm ST	220353T (28.02.2025)	
101302	Lenty Ch12 M hid.cath.ur 40cm ST	230810T (30.09.2026)	
101303	Lenty Ch14 M hid.cath.ur. 40cm ST	220415T (31.03.2025.)	
101303	Lenty Ch14 M hid.cath.ur. 40cm ST	230501T (31.05.2026)	
101303	Lenty Ch14 M hid.cath.ur. 40cm ST	230518T (30.06.2026)	
101304	Lenty Ch16 M hid.cath.ur. 40cm ST	220414T (31.03.2025.)	
101304	Lenty Ch16 M hid.cath.ur. 40cm ST	230307T (31.03.2026)	
101305	Lenty Ch18 M hid.cath.ur. 40cm ST	230308T (31.03.2026)	
101327	Lenty Ch22 M hid.cath.ur. 40cm ST	230811T (31.08.2026)	

- We have checked all of our storage areas and those of our customers and we do not have or no longer have products from these lots in stock.

Distributor: Date:

Name and position of the signer: Signature:

Upon receipt of this form, our operations department will contact you to organize the return of the products and their replacement as soon as possible.