FSN Ref: FSN-2023-001 FSCA Ref: FSCA-A1390-001

Date: 2023-09-29

Field Safety Notice
Hegenberger Retractor – A1390
Missing Instructions for Use

Dear Customer,

We have been made aware that some boxes of the Hegenberger Retractor (A1390) have been shipped without Instructions for Use (IFU).

Our investigation suggests that this issue is limited to Lot Number 4227 however we are continuing to investigate in order to determine if any other lots have been affected.

The purpose of this Field Safety Notice (FSN) is to provide the IFU to you so that you can provide them to the affected users.

Please refer to the following pages, which provide further information and actions for you to take. Please follow the “Action to be taken by Customer/User” section of this notice as soon as possible.

This issue has been reported to the appropriate regulatory agencies.

I sincerely regret the inconvenience that this may cause you. Your satisfaction with Cetro Medical’s products and with our response to this issue is very important to us.

Please contact your local Hegenberger Retractor representative if you have any questions or concerns about this Field Safety Notice and/or the actions we are asking you to follow.

Sincerely,

Lena Nurbo
Head of Quality Assurance & Regulatory Affairs

Nitgatan 11, SE- 333 33 Smålandsstenar
Tel: +46 371 330 30
Web: www.cetromedical.se

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Missing Instructions for Use

1. Information on Affected Devices	
1.	1. Device Type(s)
	Postpartum vaginal retractor
1.	2. Commercial name(s)*
	Hegenberger Retractor
1.	3. Unique Device Identifier(s) (Basic UDI-DI)
	73401943139SCN
1.	4. Primary clinical purpose of device(s)
	The product is sterile, single use and intended to allow healthcare professionals access to postpartum inner lesions by mechanical separation of vaginal walls.
1.	5. Device Model/Catalogue/part number(s)
	A1390
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	Lot No. 4227
1.	8. Associated devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	We have received reports that at least some of the products in lot number 4227 were shipped without instructions for use (IFU).
2.	2. Hazard giving rise to the FSCA
	We assess the risk as low because the Hegenberger Retractor is easy to use and customer training is provided to new users, however the lack of printed IFU can potentially lead to improper use of the device, which can cause minor injury to patients.
2.	3. Probability of problem arising
	IFUs are provided on the basis of one printed IFU per 10 Hegenberger Retractors. Therefore, it is not expected that a copy of the IFU must be consulted each time the device is used. As such, we assess the probability of minor injury to patients as low, where the IFU is not available to the clinician when using the device.
2.	4. Predicted risk to patient/users
	The risk of harm to patients/users is low, as outlined in 2.3 above.
2.	5. Further information to help characterise the problem
	N/A – IFU was not shipped with product.
2.	6. Background on Issue
	We received a report from a Distributor in Ireland who indicated they could not find the IFU with 25 boxes of product in their inventory. When investigating the production of lot 4227, a discrepancy was noted between the number of products produced and the

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	number of IFU allocated, according to the enterprise resource planning (ERP) system. The discrepancy suggests that the parts – including the IFU – were allocated within the system at a diffent point in time compared to when the devices were produced. According to the ERP system, a maximum of 10,560 products may be affected, but we have so far confirmed that the IFU is missing for 25 boxes. It is not possible to tell exactly when this error occurred. It is likely due to an error by Packaging Operators outside the clean room who failed to include the IFU, which in turn was missed upon final product release.
2.	7. Other information relevant to FSCA
	A copy of the IFU is being provided with this FSN. This is considered to be a Field Correction. Please note that Wing Plast AB have undergone a name change to Cetro Medical in January 2023.

3. Type of Action to mitigate the risk		
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On-site device modification / inspection ☐ Follow patient management recommendations ☒ Take note of amendment / reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Please ensure all affected users receive a copy of the IFU, attached.	
3.	2. By when should the action be completed?	As soon as possible, and no later than 6th October 2023
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None IFU is being provided with this FSN. Please provide to all affected users.	
3.	5. By when should the action be completed?	29th September 2023
3.	6. Is the FSN required to be communicated to the patient /lay user?	No
3.	7. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No	Not appended to this FSN

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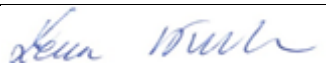
4. General Information		
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	3. For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN?	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	No follow-up FSN expected.	
4.	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Cetro Medical AB
	b. Address	Nitgatan 11 , SE- 333 33 Smålandsstenar, Sweden
	c. Website address	https://cetromedical.se/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	Hegenberger Retractor Instructions for Use
4.	10. Name/Signature	Lena Nurbo Head of Quality Assurance & Regulatory Affairs 

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