2025-02-27 Ref 25-031

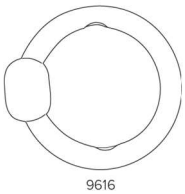
Urgent Field Safety Notice

Regarding: Appendix to Instructions for Use (IFU) regarding the metal core in CETRO® Prolapse Incontinence.

Dear Customer,

Cetro Medical AB is writing to you to inform you about corrective actions for the following products;

9616 CETRO® Prolapse Incontinence



This notice applies for the following REF-numbers:

REF-nr	*Commercial name*	*LOT-no*	*UDI-DI*
9616-2	CETRO® Prolapse Incontinence 57 mm	100057 3350 3892 9382	07340194306568
9616-3	CETRO® Prolapse Incontinence 64 mm	100058 101413 3137 3641 4035 9383	07340194306575
9616-4	CETRO® Prolapse Incontinence 70 mm	101419 3138 3639 4281 9384 9800	07340194306582
9616-5	CETRO® Prolapse Incontinence 76 mm	100090 101420 9385 9801	07340194306599

Post address: Cetro Medical AB, Nitgatan 11, SE-333 33 Smålandsstenar, Sweden Telephone: +46 371 330 30
Visiting address: Nitgatan 11, SE-333 33 Smålandsstenar, Sweden e-mail: info@cetromedical.se

The products have been delivered from Cetro Medical AB between 2020-01-01 —2025-01-22.

The product is a sterile, single use, invasive device intended for treatment of uterus prolapse grade I and II, or for treatment of incontinence due to a prolapsed pelvic floor. The product is intended to be inserted into the vagina and gives mechanical support to surrounding tissue.

Reason for Field Safety Corrective Action (FSCA)

Cetro Medical AB has noted that the text in the Instructions for Use (IFU) regarding the metal core inside the 9616 CETRO® Prolapse Incontinence has been missing.

The purpose of this Field Safety Notice is to provide an Appendix to be used in conjunction with the existing IFU and to ensure that affected patients receive correct information. The clarification is that patients using the product should remove the product before entering any MRI examination.

Probability of problem arising

Cetro Medical AB assesses that the probability of any problem occurring is low. No reported incidents have come to Cetro Medical AB acknowledge. In total, over the years, approximately 2550 products have been delivered to the market over the years.

Soft tissue injuries could occur if the patient undergoes an MRI examination with the product sitting inside the body.

Actions to be taken

Read this URGENT Field Safety Notice and inform the end user of the product.

1. Please Confirm that your organization has received this URGRNT Field Safety Notice and its Appendix and has forwarded this information to all relevant parties within your organization and affected patients by completing the “CONFIRMATION RECEIPT” and returning it via email in accordance with the instructions provided. We need to receive the receipt by **March 12, 2025** at the latest.

2. If you are a reseller or a distributor which has supplied any of the affected products to other healthcare facilities in accordance with regulation (EU) 2017/745 regarding medical devices, Article 14, section 4, please distribute this Field Safety Notice to your customers and inform Cetro Medical AB that your customer has been informed by filling in the “CONFIRMATION RECEIPT”. We need to receive the receipt by **March 12, 2025** at the latest.

This URGENT Field Safety Notice shall be forwarded to anyone within your organization who needs to know, as well as to other organizations to whom potentially affected products have been delivered.

Forward this URGENT Field Safety Notice to other organizations affected by this action.

Cetro Medical AB thanks you for your participation and apologizes for any inconvenience this may have caused.

Relevant competent authorities have been informed of this URGENT Field Safety Notice.

Use the forms on the following pages for the confirmation receipts.

Please contact us at the following e-mail address for any questions: elisabeth@cetromedical.se

Best regards

Anna Arlbrandt

Quality Manager Cetro Medical AB

Attached Appendices

• 40-960S-241011 Appendix 2025-02-25

URGENT Field Safety Notice – CONFIRMATION RECEIPT

Reference: Ref 25-031

Appendix to IFU regarding metal core in CETRO® Prolapse Incontinence

Instructions: Complete and return this form to Cetro Medical AB as soon as possible and no later than **March 12, 2025**. By completing this form, you confirm that you have received the URGENT Field Safety Notice, that you understand the issue, and that you are aware of the actions that must be taken.

• Inform everyone within your organization who needs to know about this URGENT Field Safety Notice, as well as other organizations to which potentially affected products have been delivered.

• Informer affected patients.

We confirm that we have received and understood the accompanying URGENT Filed Safety Notice to the market. We confirm that the information contained in this letter has been correctly distributed to all users handling the affected products.

Name of the person filling out the form:

Signature: _____

Name clarification: _____

Titel: _____

Phone number: _____

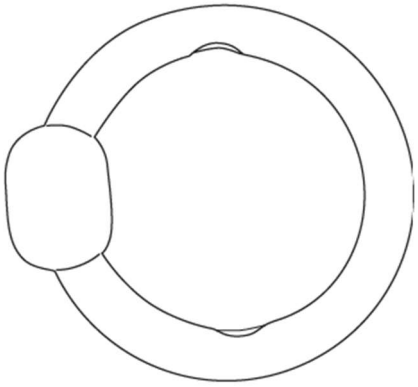
E-mail: _____

Date (DD/MMM/ÅÅÅÅ): _____

It is important that your organization acknowledges receipt of this letter. Your organization's response is the evidence required for us to follow the progress of the URGENT Field Safety Notice to the market. Mail this completed form to Cetro Medical AB to elisabeth@cetromedical.se

40-960S-241011 Appendix 2025-02-25

Additional information:
9616 CETRO® Prolapse Incontinence



9616

Applies to following article numbers:

9616-2	9616-3	9616-4	9616-5

Caution: **The ring contains metal. Remove before MR examination.**

Cetro Medical AB, Nitgatan 11, SE-333 33 Smålandsstenar, Sweden, +46 371 330 30, info@cetromedical.se