

Date: 2024/02/15

**Field Safety Notice**  
**CUSTOM PACKS**  
**800462AAGSCHC and 804115AAGSCHC**  
**RECALL**

Dear Customer

This notice communicates that Mediberg Srl Unipersonale started a recall of all lots of Custom Packs listed in the table due to a potential safety issue.

Our records indicate that you received the affected products.

REF	batch	Description
800462AAGSCHC	<b>235990</b>	UNIVERSAL CUSTOM PACK LAPAROTOMIE
804115AAGSCHC	<b>236218</b>	CUSTOM PACK OBSTETRICS CAESAREAN

**ISSUE**

The above listed medical devices included as component different codes of Yankauer Cannula.

There was an isolated case in which a metal fragment released from the Yankauer Cannula leaked from it during use of one Mediberg Srl Unipersonale custom pack.

Mediberg Srl Unipersonale cannot exclude that Yankauer Cannulas provided inside Custom Packs on the markets are not affected.

**REQUIRED ACTIONS**

Mediberg Srl Unipersonale requires you to do the following:

1. Immediately identify and quarantine all affected products still in your stock. Affected products should not be used.
2. If distributor, identify all customers involved in the recall and forward to them the Safety Notice complete with form. This notice needs to be passed on all those who need to be aware within your organization where the potentially affected devices have been transferred
3. Filled Customer Response Forms are to be sent to the distributor.
4. Distributor has to send all Customer Response Forms from customers and the Distributor Response Form to Mediberg Srl Unipersonale.
5. Distributor has to withdraw the affected products from each customer and then arrange the return of all affected products to Mediberg Srl Unipersonale.

Please be aware that new lots of the impacted codes, will be manufactured by Mediberg Srl Unipersonale without Yankauer cannulas.

Mediberg Srl Unipersonale confirms that this notice has been notified to the appropriate Competent Authority.

Please be assured that Mediberg Srl Unipersonale consider safety and quality its highest priority. We apologies for the inconvenience this situation may cause you and thank you in advance for helping to close the requested actions as quickly as possible.

Sincerely,

Quality Assurance Manager

---

Giulia Spagnolini

## Customer Reply Form

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number	RAC2024-0131a
FSN Date	15 February 2024
Product/ Device name	Custom Pack
Product Codes and lots	800462AAGSCHC batch <b>235990</b> 804115AAGSCHC batch <b>236218</b>

<b>2. Healthcare facility</b>	
Healthcare Organisation Name	
Organisation Address	
Address	
Contact Name	
Title or Function	
Telephone number	
Email	

<b>3. Return acknowledgement to Sender</b>	
Distributor/Importer	artur.cota@vicart.ch
Deadline for returning the reply form	22 February 2024

<b>4. Actions (Tick all that apply)</b>		
<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	
<input type="checkbox"/>	I have checked my stock and quarantined inventory	<i>Add quantity for each lot</i>
<input type="checkbox"/>	I will return the devices following distributor and manufacturer instruction	
<input type="checkbox"/>	I do not have any affected devices.	
Print Name		
Signature		
Date		