FIELD SAFETY NOTICE (FSN)

Subject: Withdrawal of products from the market / from use

1. Identification of devices:

REF	Name
11-5133	**Complete suction circuit Victoria Lipos, Versa - PVC**

Affected batches (LOT): CH211208-CH260218
Field safety notice reference number: ON260014
Release date: 16.11.2026

2. Description of the problem

The reason for this field safety notice and corrective action is the issuance of a decision by the State Institute for Drug Control (SÚKL) regarding the classification and qualification of the affected devices.

3. Information on measures to be taken by the user

In connection with the above issue, we request all affected users and distributors to immediately implement the following measures:

1. Checking inventory and identifying affected devices

Immediately check your inventory and identify all devices listed in this field safety notice. Report the total number of affected devices identified to CHEIRÓN a.s.

2. Immediate withdrawal from use and distribution

Immediately remove all identified devices from use and ensure they are not used or distributed further.

3. Return of the devices concerned

Please immediately return all affected devices to the following address:

CHEIRÓN a.s.
Republikánská 1102,

312 00 Plzeň 4, Česká republika

For each affected device returned, CHEIRÓN a.s. will provide, free of charge, one new replacement unit of the corresponding product that complies with all applicable legal and regulatory requirements, including Regulation (EU) 2017/745 (MDR).

4. Confirmation of implementation of measures

Please complete the attached confirmation form (Appendix 1, page 4) and return it to CHEIRÓN a.s. by **28 February 2027** to the following email address: vigilance@cheiron.eu or mduffkova@cheiron.eu

Please return the confirmation form even if you no longer have any affected devices, for example, because they have already been used, taken out of service, or disposed of. In such cases, please indicate this in the confirmation form.

Replacement devices will only be provided for units actually returned..

4. Transmission of information about FSN

This information must be provided to all persons within your organization who need to be aware of it, as well as to all organizations or persons to whom the affected devices have been transferred, provided, loaned, sold or otherwise made available.

Please forward this safety notice to all other organizations affected by this measure.

Ensure that information about this field safety notice and the actions remain available and is retained for the period necessary to ensure effective implementation of the corrective action.

CHEIRÓN a.s. issues this field safety notice to ensure the safety and protection of patients and users of the devices, to meet the relevant requirements of applicable legislation, and to prevent possible complications that could arise during the clinical use of the affected devices.

Thank you for your cooperation and for the immediate implementation of the above measures.

5. Contact person

CHEIRÓN a.s., Monika Duffková, Republikánská 45, 312 00 Plzeň

e-mail: vigilance@cheiron.eu or mduffkova@cheiron.eu

CONFIRMATION FORM

Confirmation of receipt and implementation of measures according to the FSN

Please complete the following form (see page 4 of the document). Send the **completed and signed form back to CHEIRÓN a.s. by February 28, 2027, to the following email address**: **vigilance@cheiron.eu or mduffkova@cheiron.eu.**

Confirmation of the responsible person

By completing and signing this confirmation form, you confirm that:

1. You have received and read the information contained in the field safety notice.
2. You have forwarded the information about the field safety notice to all relevant persons within our organization who are affected by this notice, as well as to all persons and organizations to whom you have supplied devices.
3. You have read and understood the information provided in the field safety notice.
4. Appropriate precautions described in the field safety notice have been taken.

ANNEX 1 – CONFIRMATION FORM

Organization name:		
Organization address:		
Responsible person:		
E-mail:		
Phone:		
Function:		
Do you own or have access to the device Complete suction circuit, Victoria Lipos, Versa - PVC (REF:11-5133)?	YES / NO	If YES, state the number of devices and their LOT:
Have you distributed the above funds to other organizations?	YES / NO	If YES, identify the organizations and add addresses and contact details:
Date of receipt of information:		
Signature of the responsible person:		

Please send the completed and signed form back to CHEIRÓN a.s. by 28 February 2027 to the following email address: vigilance@cheiron.eu or mduffkova@cheiron.eu.

We apologize for the complications. Thank you for your cooperation.

Lenka Procházková
CHEIRÓN a.s., Head of Quality Management Department
Person Responsible for Regulatory Complianc

Lenka Procházková
Digitálně podepsal Lenka Procházková
Datum: 2026.11.20 11:10:40 +01'00'