URGENT - URGENT SAFETY NOTICE (FSN)

PRODUCT RECALL

PSO VT and PSO VTT

Date : Apr 9, 2024

Safety advisory no.: FSCA2024-01

Product number : PSO-VT and PSO-VTT
Product description: Pressio® ventricular tunnelling catheter kit for the monitoring of ICP (Intra-Cranial Pressure) alone or ICP and TIC (Intra-Cranial Temperature)
Subject: Risk of catheter leakage

Dear partner,

Sophysa is voluntarily withdrawing certain serial numbers of Pressio® ventricular tunnellable catheter kit for monitoring ICP (Intra-Cranial Pressure) alone or ICP and TIC (Intra-Cranial Temperature) (ref: PSO-VT and PSO-VTT) due to an increase in claims related to leakage of cerebrospinal fluid (CSF) from the proximal part of the catheter.

The reported CSF leaks were all detected during implantation, and the catheters concerned were immediately replaced. The complaints received do not therefore indicate any harm to patients. However, in the event of a leak going undetected during implantation, it could pose an infectious risk to the patient.

Our analyses have enabled us to determine that this risk of leakage is linked to a manufacturing operation involving the setting up of the stylet used to insert the catheter. According to our information, your establishment has received products concerned by this notification.

Attached to this letter is a complete list of all products sent to you, with product description, UDI-DI, batch numbers and expiry date. Please note that only the products listed in the table below are affected. No other Sophysa products are affected by this

safety notification. Any distribution or use of a product affected by this communication must cease immediately.

INSTRUCTIONS:

1- Please stop using the listed products immediately and remove all affected units from your inventory,
2- Thank you for informing healthcare professionals who use these products,
3- Isolate the units concerned in a safe place for return to Sophysa
4- Please complete the list and identify which units have to be returned and send it back to us by email with the acknowledgement form signed, no later than April 10, 2024.
5- If you have products to return, please pack them in an appropriate shipping box. Upon receipt of the verification form, Sophysa will contact you to arrange the return of the products.

The competent authority in your country has been informed of this safety information notification.
We regret the inconvenience caused by this measure, which is designed to ensure patient safety and customer satisfaction.

Julie Lopez
Regulatory affairs director
Sophysa SA

Attachment:

- list of products concerned
- acknowledgement form