Date : 08/01/2024

URGENT -BATCH RECALL – IMMRA01_2024

PHLEBOSET ® bloodleeting set - For home sampling

PHLEBOSET® H bloodletting set

Batch numbers: see table 1

For hospital pharmacies, wholesalers, dispensing pharmacies, home healthcare providers, and healthcare professionals performing bloodletting

This letter contains important information requiring your **immediate attention.**

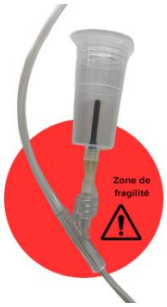
Dear customer,

IMM, the assembler of the PHLEBOSET® bloodletting set, has been notified of a quality issue with one of its components : the tubing with the integrated sampling device. IMM has decided voluntarily to recall some batches of the PHLEBOSET® bloodletting sets. Only the batches listed in Table 1 contain this tubing. ANSM has been informed of this recall.

PHLEBOSET ® bloodletting set For home sampling	Batch numbers : 704575, 704576, 704577, 704578, 704581, 704582, 704583, 704584, 704585, 704586, 704587, 704588, 704589, 704590, 704591, 704592, 704593, 704594, 704595, 704596, 704597, 704598, 704599, 704600, 704601, 704602, 704603
PHLEBOSET® Bloodletting Set For Hospital	705246, 705247, 705248, 705249, 705250

Table 1: Products involved

Description of defect : Despite quality control checks, defects in the tubing were noted during the use of the set. Cracks and/or breaks in the sampling device were identified.



International Medical Mediation 6,Fbg de Besançon 90000 BELFORT – Tél. 03 84 27 25 22 – Fax 03 84 27 25 23
E-mail : contact@immfrance.fr – www.immfrance.fr
SAS au capital de 100000 Euros – Siret 379 490 956 000 65 – APE 4646Z

Potential consequences: in few cases, it could lead to :

- ➢Air inlet, leading to progressive loss of suction.
- ➢Longer bloodletting times. Air bubbles in the tubing has also been reported.

Patient risk when using a set containing defective tubing : longer bloodletting time, or even the impossibility of bloodletting.

We ask you to apply the following measures:

➢ Inspect your inventory and isolate all products which correspond to the list of batches

➢ If you have redistributed this product, identify establishments concerned, inform them immediately of this recall and ask them to return devices.

➢ Complete and sign the customer response form on page 3 and return it by email to contact@immfrance.fr as soon as possible or by **February 15, 2024** at the latest, indicating the following :

- the quantities recovered **OR**
- that your facility no longer holds any of the products concerned in stock

Replacement sets will be sent to you to compensate for affected products. Dammage products will be collected before replacement by us. This form must be returned even if you no longer have the products concerned, for reconciliation purposes.

Special case of healthcare professionals residing in French overseas departments and territories: we will not collect the affected sets. Therefore, we ask you to destroy the quantity affected and provide a certificate of destruction for the equipment.

For further informations, please call +33 03.84.27.25.22 or e-mail contact@immfrance.fr.

For your information, sets currently distributed by IMM contain tubing that has been redesigned. The sampling device is now next to the tubing, rather than integrated into the tubing.

We apologize for any inconvenience caused.

Respectful greetings.

Romane LE PRIOL
General Manager

Marlène MARTINEZ
Quality / Regulatory Affairs Pharmacist

Customer reply form - LOT RECALL - IMMRA01_2024

PHLEBOSET® bloodletting set - For home bloodletting / PHLEBOSET ® bloodletting set H

This form must be returned to IMM at contact@immfrance.fr as soon as possible or at least on the **15th February 2024**.

We confirm that this notice has been read and understood and that all recommended measures have been put in place. Please tick the appropriate box below :

☐ We do not have any of the affected products.

☐ We have some of the affected devices listed in Table 1 and confirm that the devices in question have been isolated. (Please complete the table below with the batch number and quantity of devices isolated. Replacement devices will be sent to you).

Product reference	Batch number(s)	Quantity of sets isolated
PHLEBOSET® bloodletting set		

Name of company :	
Department (if applicable) :	
Address where sets are quarantined (for recovery organisation) :	
Postcode :	City
Name :	
Name of person to contact about the takeover (if different) :	
Function	
Phone number :	E-mail address :
Signature	Date :

Please do not return the products concerned and wait for our instructions.