



RAFFIN MEDICAL
746, route de Sarcey
69490 Saint Roman de Popey - France
Phone : +33 (0) 4 37 58 10 10
Fax : +33 (0) 4 74 26 83 60
www.raffin-medical.com

FSN 2022-02/ CAPA202205-02 Quarantine – Page 1 on 3

For the attention of the Pharmacist in charge of medical devices,
The Vigilance Correspondent,
The Biomedical Engineer

Saint Romain de Popey, 15 June 2022

URGENT – SAFETY INFORMATION REGARDING RAFFIN SET REFERENCES LISTED BELOW

Type of action	Quarantine	
FSN internal ID	2022-02/ CAPA202205-02	
Identification of the product concerned		
Raffin Item Code	Designation	Batch number
400213	Catheter connection and disconnection kit N°29	202101
401085-2	Chemotherapy set	
400219-1	Fistula connection and disconnection kit No.48	
400014	Kit:On/Off Central Line Kit No.3	
400035	Kit:On Central Line Kit No.2	
400036-1	Kit:Off Central Line Kit No.2	

Dear Customer,

As part of the management of its medical devices vigilance, Raffin Medical has decided to quarantine the products listed in the table above.

Reason for quarantine request:

Following an annual review involving the welder used to seal the products listed in the table above, it is impossible for us to guarantee the sealing parameters over the corresponding production period. Even though no complaint has been reported to us to date, signalling a non-compliance on these references/batches and calling into question the integrity of the primary packaging of the products, verification by sampling is necessary for this validated process.

Aware of the inconvenience caused, we would like to apologise in advance. Committed to patient safety and product quality, we would be grateful for your immediate attention to this notification.



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Actions required:

(a) This urgent safety information must be transmitted to all persons in your organisation who need to be informed and to all annexed departments that have received the relevant devices. Please forward this urgent safety information to end users, physicians, risk managers, logistics/distribution centres, etc.

Please disseminate this urgent safety information until all required measures have been taken within your organisation.

(b) The devices must be identified and quarantined where they are still held in your inventory.

(c) We kindly ask you to return the acknowledgement form, duly completed, by email **no later than 30 June 2022** to the following address:

product.complaint@raffin-medical.com, **indicating in the subject FSN 2022-02/CAPA 202205-02**

Recommendations for distributors of the products concerned

If you are a distributor, please pass on this safety information to all your customers who have received affected products.

The Competent Authority in your country has been informed of this communication to customers.

A handwritten signature in blue ink, appearing to read "DLO." followed by a stylized signature.

Delphine LOKOSSI

Vigilance Correspondent.



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ACKNOWLEDGEMENT OF RECEIPT OF URGENT SAFETY INFORMATION –

I certify that I have read and understood the terms and conditions of this safety information referenced **FSN 2022-02 / CAPA202205-02** by returning this acknowledgment of receipt duly completed.

Our stock, as well as that of our end users, has been verified and the results are as follows:

- We have no affected products in stock
- We have in stock the references of the sets concerned in the quantities indicated below and we undertake to quarantine them.

Raffin reference	Raffin designation	Batch	Quantity of products in your stock
400213	Catheter connection and disconnection kit N°29	202101	
401085-2	Chemotherapy set		
400219-1	Fistula connection and disconnection kit No.48		
400014	Kit:On/Off Central Line Kit No.3		
400035	Kit:On Central Line Kit No.2		
400036-1	Kit:Off Central Line Kit No.2		

Contact's surname/first name:

Position:

Email:

Date / signature stamp of the home institution:

Health institution(s) concerned: