

Joure Netherlands 20-07-2021

Urgent: Field Safety Notice – COM21KLA.008
Batch KIT IRIS
Type of Action: Advisory

Dear customer,

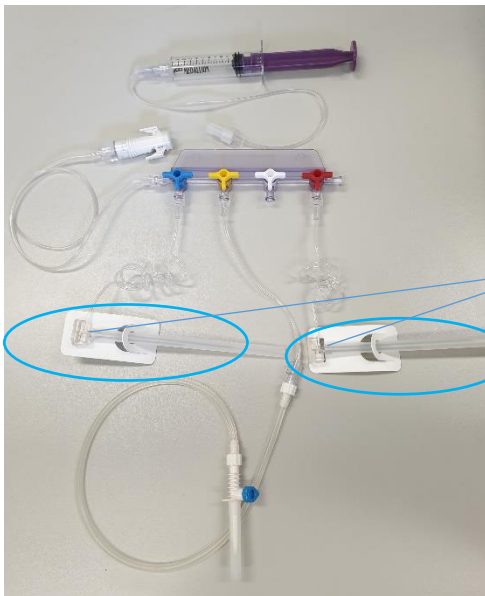
It has come to our attention that in Batch KIT IRIS a problem has been recognized. The problem concerns the missing of a Filter in the base of the needle for the Bulk vial and/or the waste vial.

It concerns:	
Name:	Batch KIT IRIS
Part-number:	0246050022
Batch number:	Unknown at the time of writing this notification

Due to the missing filter the sterility of the Radiopharmaceutical in the bulk vial can be compromised.

We are working with our supply chain to have sufficient stock to replace all stock in the market, however, till then we advise you to check the presence of the filter before the use of the kit in 100% of the cases. To prevent unintended use of needles without the filter we sent you this notification with the request to check the 2 needle sets before using them in the IRIS. For selection you can use the below photos as reference:

Batch KIT IRIS content:



Suspected Needle assemblies

In these needle assemblies we can see a white filter as below:

NOT GOOD and **GOOD** situation.

NOT GOOD



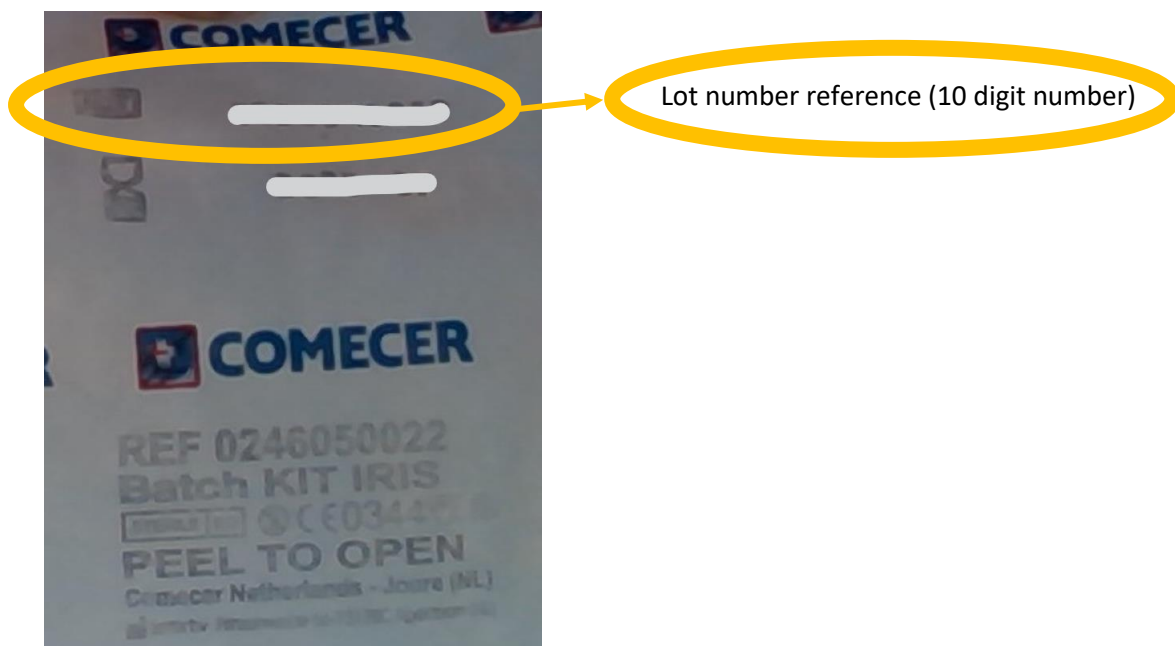
GOOD



If you find any anomalies in your product, do not use that specific needle/kit.

As our needle supplier cannot say a definite failure ratio (although expected below 1%) we would like to hear from you as soon as possible any found rejected part (without the filters) to determine the impact and involved batches.

For this we kindly ask you to let us know the batch information as printed on the sterile packaging of the main kit. It concerns batches that were produced up to and including week 27-2021, which can be recognized by the first 4 digits of the batch number, for example 2721XXXXXX.



To have sufficient stock to replace the kits in the market we need to inventory all stock levels. To understand the stock situations at your facility, we kindly ask for your current stock level and expected/planned use in the coming months. Please fill in the Customer Acknowledgement Form and send the completed form as soon as possible to infoln@comecer.com no later than 2 August 2021.

Should you have any questions or experience any issues associated with this product or issue described in this Field Safety Notice, please contact your local Comecer representative. The manufacturer of this product, Lettix BV in the Netherlands, has in collaboration with Comecer notified the appropriate regulatory agencies of these actions.

Comecer and Lettix BV are committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thanks for your co-operation and understanding.

Yours sincerely,

D. Sainato



Managing Director
Comecer Netherlands B.V.

T.J. Dam



Quality Assurance manager
Comecer Netherlands B.V.

Customer Acknowledgement Form – COM21KLA.008

Please read in conjunction with Field Safety Notice and return the completed and signed form as soon as possible or no later than 2 August 2021 to infol@comecer.com.

By completing the information below you confirm you have read, understood and distributed the contents of this Field Safety Notice accordingly.

Name of Facility	
Current available stock and corresponding batch number(s)	
If applicable: Number of sets found without filter with corresponding batch number(s)	
Telephone number	
Name and function of the contact person	
E-mail Address of contact person	
Signature	
Date	