

FIELD SAFETY NOTICE

LCRD2 filter: Increased rate of breakages of filter internal welding
during centrifugation

Macopharma reference: DEV-2022-00209

ANSM reference: R2212724

Tourcoing, 25th of April 2022

Dear Sir or Madam,

We would like to inform you that Macopharma has decided to implement a field safety notice for the use of devices containing LCRD2 filters.

Context:

Since the beginning of 2022, we noticed an increasing rate of failed leucodepletion results for the use of LCRD2-equipped devices linked to breakages within the internal welding of the filtering mattress after the centrifugation step within a small number of sites.

We know this type of defect may occur sporadically during the customer processing following an unfavourable positioning of the filter inside the centrifugation bucket, our trend monitoring shows a significant increase of reported defects at some customer sites.

Due to this trend, an internal working group has been launched to study all the possible additional root causes.

Frequency:

Overall, the frequency is currently of 1 defect per million (1 DPM). Nevertheless, depending on the customer, it can reach 800 DPM (0,08%).

Detectability:

The breakage of the internal welding of the filter is easily detectable during the filtration step :

- Unusually fast priming of filtration with direct flowing of the blood through the filter to the outlet compartment of the filter (around the internal welding)
- Large presence of air inside the post-filtration line. A preferential path between both compartments of the filter can allow the post filtration line to completely or partially drain.

We recommend, as mentioned in our training modules, to control the leucodepletion results of any filtration presenting an unusually fast priming or with a large presence of air observed in the post filtration line.

Severity:

Two major risks have been identified for case of transfusion of blood products that have not been leucoreduced to patients who are immunocompromised: Graft Versus Host Disease and Cytomegalovirus (CMV) transmission. In the first case, standard procedure consists in transfusing blood products that have previously been irradiated to inactivate Tumor-Infiltrating Lymphocytes to patients identified as "at risk". Regarding CMV transmission, it is recommended for high-risk patients (pregnant women, in utero transfusion, infants, and severely immunocompromised patients) only to receive "CMV-negative" red cell concentrates.

Please note that no patient incident has ever been reported to this day due to a similar issue and that the compliance criteria regarding the performance of batches in terms of residual white blood cells are still respected (95-97% of Quality Level at 95% of confidence depending on the country).

Recommendations:

We would like to remind you of the importance of our recommendations of use for the LCRD2 equipped devices:

According to our IFU and training modules, we remind you that it is essential to respect our device packing recommendations for the centrifugation step and to:

- Respect the LCRD2 filter orientation: 45° orientation (angle between vertical axis and the axis going through the inlet and outlet tubes of the filter)
- Never bend or put pressure on the LCRD2 filter
- Make sure that there is no contact with rigid parts (rigid bag tubes, tubing, etc...)

Moreover, we remind you that it is important to check the leucodepletion results of devices presenting an excessive amount of air in the post filtration line at the end of filtration. Indeed, the excessive presence of air is a good indicator of a potential preferential passage within the filter which generates out of specification filtrations.

Re-trainings and awareness campaigns have been carried out or are being planned at our customers' sites where appropriate.

The ANSM (French National Competent Authorities) has been informed of this Field Safety Notice.

Please fill out the attached form, indicating that you have received this FSN and that it's been forwarded to our services.

Thank you in advance for your support and cooperation.

We remain available for any question you might have,

Best regards,



Béatrice CARVALHO
Complaints & Vigilance MD Manager

List of LCRD2-equipped references by country:

Country	References
France	NPT6280LA NPT610A
EBA (UK, Belgium, Australia, New Zealand, Ireland)	LQT614B NQT614B
Denmark	LQT6283LE LQT6284LE
Sweden	LQT6283LE LQT6284LE NPT610E NPT6280LE
Norway	LQT6284LE
Germany	LQT7242FC LQT7244LC LQT7247LC LQT7248LC LQT7296LC LQT747C LQT748C
Switzerland	LQT610U NPT611W NPT6281LW
Austria	LQT610U
Greece	LQT610U



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