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Guidance

Using parenteral and enteral nutrition bags manufactured by Diffuplast: guidance for patients

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Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) has been notified of a potential issue related to sterilisation of empty parenteral and enteral nutrition bags manufactured by Diffuplast.

The information available indicates that the risk of infection is very low. Please continue to use these bags as normal. If you are concerned that you may have been affected by this issue, please contact your healthcare professional.

Background

The manufacturer (Diffuplast) has identified an issue with their third-party sterilisation provider and it is likely that some devices have not been sterilised to the usual standard.

Established quality checks will ensure that if there are any concerns around the safety of products they will not be used.

The available information indicates that the patient safety risk is very low. Public Health England (PHE) has confirmed that there is no evidence to suggest that this issue has caused any increase in infections. However, any potential infection risk (which is deemed low risk) is from contamination of the infusate (the fluid which is placed into the bag) leading very uncommonly to a line infection.

No safety signals related to reports of infections associated with parenteral or enteral bags have been identified by the MHRA. The manufacturer has also not had any reports of infections related to these devices.

MHRA, PHE and the NHS are working closely with the manufacturer to ensure that appropriate actions are taken if additional evidence is identified which changes the level of risk, or if any further problems with sterility are identified.

The manufacturer has issued a field safety notice (<https://mhra.gov.filecamp.com/s/BtzOcP9mXZhQEdSn/d>) (FSN). This information is intended for healthcare professionals to help them identify potential batches impacted. Note that any products where the risks outweigh the benefits will result in a recall. The FSN covers the whole of the UK and the same approach is being taken across the UK.

Actions

You do not need to take any action at the current time. Please continue to use the parenteral and enteral nutrition bags that you are provided with. You will be contacted by the NHS, or your healthcare professional, if the situation changes

If you have any concerns, please contact your healthcare professional.

Further information

- Total parenteral (TPN) and enteral nutrition bags manufactured by Diffuplast: Sterilisation issue (<https://www.gov.uk/drug-device-alerts/total-parenteral-tpn-and-ental-nutrition-bags-manufactured-by-diffuplast-sterilisation-issue>) (MHRA guidance)

- [MHRA alerts and recalls for drugs and medical devices \(https://www.gov.uk/drug-device-alerts?alert_type%5B%5D=national-patient-safety\)](https://www.gov.uk/drug-device-alerts?alert_type%5B%5D=national-patient-safety)

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