

MHRA Device Safety Information

Reference

MDSI2110

Issued

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Baihe Rheovalves disposable needle-free valves: stop using specific lots due to risk of breakage in patient

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 20 December 2021. The original webpage can be accessed [here](#).

Summary

Baihe Medical have identified an increase in complaints from specific lots for Rheovalves disposable needle-free valves product code RVNF1. The device may break in use.

Action

Actions for health care professionals – heads of renal units, renal nursing and IV nurse practitioners

1. Identify whether you have any Rheovalve needle-free connectors of lot numbers OHH-T200316 & OHH-T210710, particularly in renal departments.
2. Quarantine all unused stocks and contact your distributor or the manufacturer to confirm whether devices should be thrown away or returned.
3. Identify patients who currently have the connectors used on their HD or other IV central lines. As clinically appropriate, undertake extra vigilance when removing the connector in line with established local protocols, as the device has the potential to break off in the catheter.
4. Report any suspected or actual adverse incidents involving these devices through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: [England](#), [Scotland](#), [Northern Ireland](#), [Wales](#).

Information for patients

No action is required by patients. This information is targeted at Healthcare Professionals who will identify if you are affected by this safety issue as part of your ongoing clinical care and take appropriate action at your next appointment.

Actions for manufacturers

The manufacturer Baihe Medical will provide a further update to the MHRA once they have completed their investigation

Equipment Details

Rheovalves disposable needle-free valves

Product code: RVNF1

Affected lot numbers: 0HH-T200316 & 0HH-T210710.

Manufactured by Guangdong Baihe Medical Technology (Baihe Medical) or branded as Linc Medical devices

Background

Baihe Medical have identified an increase in complaints from specific lots for Rheovalves disposable needle-free valves product code RVNF1. The device may break in use.

You should stop using the affected lots of devices whilst the manufacturer investigates and informs the MHRA of the outcome.

The manufacturer has previously issued a [Field Safety Notice](#), but this is no longer valid as more information is now available.

Risk involved with using affected product

There is a risk of the product breaking whilst being removed from the access catheter, leading to the risk of infection for the patient.

Reported issues to date include:

- increased risk of infection – sepsis / bacteraemia
- delay in dialysis treatment
- fragments of connector remaining within the dialysis catheter

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)

NHS National Services Scotland

Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Tel: 0131 275 7575 Email: nss.irc@nhs.scot

For information on how to report an incident: [How to report an Adverse Incident](#)

General information about adverse incidents and safety alerts can be found in [CEL 43 \(2009\)](#) or by contacting IRIC at the above address.

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service.

<https://www.nss.nhs.scot/>

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