

**RESPONSE TO A REPORT TO PREVENT FUTURE DEATHS  
REGULATION 29 OF THE CORONERS (INVESTIGATIONS) REGULATIONS  
2013**

Please do not include any living persons' names in this document, in accordance with the Chief Coroner's [PFD Publication Policy \(2026\)](#).

THIS RESPONSE IS BEING SENT TO:

**The Senior Coroner, Paul D Smith for the Coroner Area of Greater Lincolnshire** in response to a '**REPORT TO PREVENT FUTURE DEATH REGULATION 28**' following an inquest into the death of **Mr Benjamin Daniel Rowley** that has not yet been heard, where the investigation was initiated on **20 November 2025**.

1.	<p><b>RESPONDENT</b></p> <p>In line with our duty under Regulation 29 of the Coroners (Investigations) Regulations 2013, <b>Medicines and Healthcare products Regulatory Agency</b> provides this response within 56 days (plus any extension granted) of the date of the Report to Prevent Future Deaths.</p>
2.	<p><b>DATE OF RESPONSE</b></p> <p>25 May 2026</p>
3.	<p><b>CONFIRMATION OF CORONER'S MATTERS OF CONCERN</b></p> <p>The <b>MATTERS OF CONCERN</b> were identified in the report are as follows:</p> <p>Following investigation and independent examination of the CVCs used in the two patients, the root cause of the detachment has been attributed to the failure of the bond between the venous port of the CVC and the tubing.</p> <p>Concerns were endorsed by the coroner that these events could represent a more widespread vulnerability of this brand or batch of dialysis lines and it was recommended that these events are reported to the Medicines and Healthcare products Regulatory Agency (MHRA).</p>

3. **DETAILS OF ACTION TAKEN**, how has the concern been addressed.  
[If no action is proposed please explain why here].

Thank you for your Regulation 28 report dated 1<sup>st</sup> May 2026 in which you asked the Medicines and Healthcare products Regulatory Agency (MHRA) to provide a response following the ongoing investigation and inquest into the death of Mr Rowley. We are saddened to hear of the death of Mr Rowley and offer our sincere condolences to his family.

I am writing in relation to the concerns raised in your report where you considered that the MHRA should take action to prevent similar events of this kind occurring in the future.

To provide relevant background, the MHRA is an executive agency of the Department of Health and Social care with responsibility for delivering the regulation of medicines and medical devices with the objective that they meet appropriate standards of quality, efficacy and safety. The Human Medicines Regulations 2012 (HMRs) lays out the conditions of the licencing and marketing of a medicine, and the Medical Devices Regulations 2002 underpins the requirements legal manufacturers of medical devices must meet to legally place a device on the market. This has recently been updated with the Medicines and Medical Devices Act 2021, which provides the legal framework to update regulations on medical devices, aiming to improve patient safety, increase transparency, and align with international standards. We take all reasonable steps to protect public health and safeguard patients, the public and users.

The MHRA has reviewed the details outlined in the Regulation 28 report to prevent future deaths and below addresses those which fall within the remit of the MHRA.

The matters of concern raised in the report are as follows:

1. Two separate incidents concerning Covidien Palindrome Chronic Dual Lumen Catheters, of different batches, relating to the detachment of the venous port of the central venous catheter (CVC) from the silicone tubing attributed to the mechanical failure of the bond between these components.
2. Concern that this may represent a more widespread vulnerability of this brand or batch of dialysis lines and these events should be reported to the MHRA.

The MHRA can confirm that we are in receipt of both incident reports from the University Hospitals of Leicester NHS Trust discussed within this Regulation 28 report, both from the original healthcare professional reporter, as well as the corresponding vigilance report from the legal manufacturer, Mozarc Medical. It is important to note that Mozarc Medical is an [independent company supported by investment between Medtronic, Inc. and DaVita Inc](#), focussing on kidney-related health technologies.

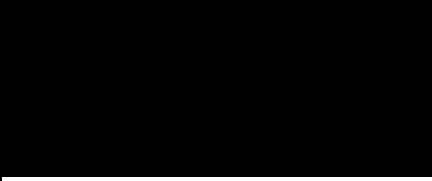
As part of our regulatory responsibility, the MHRA has followed up with Mozarc Medical after receiving these incident reports. The MHRA requested the number of global and UK reports relating to detachment events in the past 5 years, if a root cause for this detachment has been identified or otherwise investigated, as well as for copies of the associated risk evaluation documents associated with these types of events.

At this time, no batch-specific or manufacturing issues have been able to be identified, and a root cause for this mechanical failure has not otherwise been determined or communicated to the MHRA. In the second serious case which resulted in blood loss inappropriate catheter repair was reported; the manufacturer has stated to the MHRA that they have worked with the reporting site regarding appropriate repair techniques.

Review of the available UK data within the MHRA's safety database did not identify additional reports that would indicate a wider potential safety concern. This is reflected in the legal manufacturer's data, particularly when accounting for global use and sales. The MHRA has also reviewed the accompanying Instructions For Use (IFU) and determined that whilst the documents are in line with the legal requirements, improvements can be made to provide users with guidance on catheter line durability, maintenance and repair. The MHRA is working with the manufacturer in addressing this.

#### Actions taken by MHRA in response to this Regulation 28 report

- The MHRA has reviewed the investigation undertaken by Mozarc Medical in response to these two events of venous port detachment. Based on the limited number of UK and global reports, there does not appear to be a batch or device trend indicating a wider issue with a failure in bonding of components of this catheter type observed at this time. No root cause has been identified by the company based on their product and manufacturing analysis. The MHRA has asked Mozarc Medical to provide routine updates on the number of UK and global reports concerning venous port detachment and mechanical bond failure, whilst this investigation is ongoing. This is in addition to their routine post-marketing surveillance requirements.
- The MHRA has put in place measures to increase monitoring of events related to Covidien Palindrome Chronic Dual Lumen Catheters and will continue to review these as part of our vigilance activities. Any further regulatory actions required following this will be communicated via the usual routes.

4.	<p><b>DETAILS OF FURTHER ACTION PROPOSED</b></p> <p><i>Please note that any links to webpages included in the response will not be checked for sensitive information prior to publication, as the information is already online.</i></p> <p>The MHRA is working with the manufacturer to ensure improvements to the product literature are addressed accordingly.</p>
	 <p><b>21 May 2026</b></p>