



Greater Lincolnshire Coroners

Paul D Smith

HM Senior Coroner for Greater Lincolnshire



Re: Regulation 28 Report to Prevent Future Deaths dated 1 April 2026

Dear Mr. Smith,

We acknowledge receipt of your Regulation 28 Report to Prevent Future Deaths dated 1 April 2026, and we thank you for bringing these important matters to our attention. Mozarc Medical was informed of this matter by Medtronic Limited and is responding in relation to the product referenced in your report.

We extend our sincere condolences to Mr. Rowley's family. We recognize the seriousness of the circumstances described in your report and share your commitment to patient safety. We are treating the matters referred to in your report with the utmost seriousness.

In line with our established post market surveillance process, we have logged both incidents in our quality system as the initial step in our evaluation process. As part of the process, we have undertaken a review of the available complaint data. We will continue to actively monitor incoming data as part of our ongoing vigilance activities.

We have engaged with the reporting clinic identified in your report, University Hospitals of Leicester, through appropriate channels, to support information gathering and to better understand the circumstances surrounding the events described. We appreciate the cooperation that has been provided to date.

Additionally, Mozarc Medical is in active communication with the Medicines and Healthcare products Regulatory Agency (MHRA) regarding these matters, including a recent meeting held on 11 May 2026. We will continue to work constructively with the MHRA as our review progresses.

We have initiated a detailed internal investigation, to better understand the factors that may have contributed to the incidents described. This work remains ongoing, and we have not reached any final conclusions at this stage. To support a thorough evaluation, it would be of

significant benefit to examine the devices referenced in your report. We fully recognize that these items may form part of the coroner's investigation; however, should it be possible to facilitate return of the devices for controlled analysis, or alternatively to arrange examination in situ or obtain additional detailed imagery or documentation, we would welcome the opportunity to coordinate such efforts in a manner that supports your process. Could you please let us know if you would be willing to send the devices to us or enable our in situ examination?

Our priority at this stage is to continue gathering and assessing all available information to better understand the condition and performance of the catheters referenced, and to determine whether any further actions may be warranted.

We remain committed to supporting the investigation and to taking any appropriate actions necessary to protect patient safety. We appreciate the matters of concern you have raised and the opportunity to respond. We will wait to hear from you regarding the possibility of us examining the devices and we look forward to continuing engagement as additional information becomes available.

Yours sincerely,



Sr Director, Global Quality
Mozarc Medical