Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

10th May 2024

Dear [redacted]

FOI 24/352

Thank you for your FOI request dated 12th April 2024, where you requested the following information:

> *I am an MRI Physics at Guy's and St Thomas' Hospital conducting a review of our policy on the safety of scanning patients with embolization coils and vascular plugs.*
>
> *Please could I enquire if there have been any reported MRI related incidents involving these devices.*

Please see Table 1 below with the corrected data for this request.

Table 1: The number of adverse incident reports for the device types listed above and MRI systems up to and including 7th May 2024.

Device type	GMDN CT Codes	Number of incidents on the MHRA database
1. Embolization coils AND magnetic resonance imaging (MRI) systems	CT2480	1
2. Embolization plugs AND magnetic resonance imaging (MRI) systems	CT2479	None reported.

I would like to take this opportunity to reiterate the importance of considering the below factors in relation to the data provided in the table above:

- This information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- The database search encompassed the querying of the failure description, a mandatory free-text field that may not always be fully completed. Therefore, the outcome may vary depending on the availability, and accuracy of the entered text.
- The number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.
- The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.
- These figures need to be interpreted with caution as they are not the same as complication rates.

As with all medical devices, MHRA continues to monitor their safety and performance and encourages reporting of any adverse incidents through its Yellow Card scheme on https://yellowcard.mhra.gov.uk/. Any emerging evidence relating to possible risks associated with these devices will be carefully reviewed and, if appropriate, regulatory action will be taken if any serious risks are confirmed.

We hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Safety and Surveillance

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SK9 5AF

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