



Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of
Information Team
10 South Colonnade
Canary Wharf
London
E14 4PU

foi.request@mhra.gov.uk.

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00335 &
FOI2025/00336**

07 May 2025

Dear [REDACTED],

Thank you for your Freedom of Information (FoI) requests received on 4 April. You wrote:

I am drafting a hospital policy and require detailed information regarding any incidents involving patients, staff members, or members of the public who have a heart valve and have interacted with the MRI department. This includes any safety concerns, adverse events, or protocol deviations related to the presence of a cardiac stent in the MRI environment.

And:

I am drafting a hospital policy and require detailed information regarding any incidents involving patients, staff members, or members of the public who have a cardiac stent and have interacted with the MRI scanner. This includes any safety concerns, adverse events, or protocol deviations related to the presence of a cardiac stent in the MRI environment.

MHRA Response

Further to your request I can confirm the MHRA do hold this information.

As such please find data relating your query below:

We have conducted a search of our database for all the adverse incident reports concerning Magnetic Resonance Imaging (MRI) and/ or cardiac stents up to and including the 28th of April 2025. The search was conducted using the following Global Medical Device Nomenclature (GMDN) Collective Term (CT) code for heart valves:

- CT1169 (Heart valve prostheses)
- CT1178 (Heart valve bioprostheses)
- CT1457 (Vascular grafts and associated devices)
- CT1459 (Vascular grafts)
- CT2267 (Mechanical heart valve prostheses)
- CT2794 (Cardiovascular grafting/prosthetic implants)

Additionally, the GMDN CT codes used for cardiac stents were:

- CT1102 (Coronary artery stents)
- CT1812 (Drug-eluting coronary artery stents)
- CT2137 (Bioabsorbable vascular stents)

The search has been restricted to the specific devices mentioned in the request, and therefore other medical devices such as annuloplasty rings, aortic stents and heart valve clips have not been included.

Within the results from the data retrieved, we searched for the specific words "MRI" or "Magnetic Resonance Imaging" in the failure description of the report to conclude the request. It is important to note that the failure description field is a free-text field and therefore the information we receive is unstructured, as such the accuracy is dependent upon the reporter.

I can confirm that up to 28th April 2025, the MHRA has received 18 adverse incident reports relating to patients with a heart valve or cardiac stent, which refer to an MRI scanner or MRI department in the failure description field of the adverse incident report. In 11 of these reports, no adverse outcomes were reported. Of the remaining 7 reports, the adverse outcomes reported were: aneurysm, dyspnoea, paralysis, muscle weakness/atrophy, tics/tremor, endo leaks and stroke/CVA.

Another search was done in our database looking at the results we have for MRI scanners primarily. The below GMDN CT code for MRI scanners:

- CT105 (Magnetic resonance imaging (MRI) equipment)
- CT1779 (Breast MRI systems)
- CT1865 (Extremity MRI systems)
- CT1866 (Full-body MRI systems)

Further to the results we had, we did the same search using the words "heart", "valve", "cardiac" and "stent" in the failure description of the reports, however we did not identify any relevant reports.

When reviewing Adverse incident data please note:

- The majority of reports indicate an issue experienced by a single user. However, some cases may represent the same user experiencing further issues.
- Reports do not necessarily represent an individual patient. Individuals may report an incident at any time after the event and people can make multiple reports at any time on the same issue. Where possible, multiple reports for the same event are linked. However, as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate
- It should be noted that this information may include a range of recognised complications related to this type of procedure and does not necessarily indicate a fault with any particular device.
- The numbers may include reports where the incident has been taken from published literature.

- These numbers of reports are accurate at the time they are extracted from our database and minor changes in the numbers can occur if the reporter of the incident gives us more details later.
- The inclusion of a report on our adverse incident database does not necessarily mean the events described were caused by that device but could be due to unrelated patient/user factors. The data provided, therefore, is not a summary of known or proven adverse reactions to the device and must not be interpreted and used as such.

Please note that manufacturers are responsible for determining whether their device can be affected by MRI scanners and should provide appropriate guidance within their instructions for use (IFU). The [Coronary stents – NHS GGC MRI Physics](#) trust states the following: "Patients with single or multiple overlapping coronary stents, immediately following stent implantation, 1.5T or 3T MRI can safely proceed using the Normal Operating Mode of the scanner. Multiple pulse sequences per protocol are allowed but any single sequence must not exceed 15 mins in length." This information is based on a local trust only rather than a national guidance.

Healthcare professionals should refer to the Instructions for Use (IFUs) for cardiac stents to determine the MR status / MR compatibility of a device with MRI scanners. Please also refer to the [MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use](#) for more information (relevant sections include 2.2.6, 4.11 and 4.11.2.4).

I 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.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.

Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

Re-use of our information

The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL and these can be viewed here:

<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>