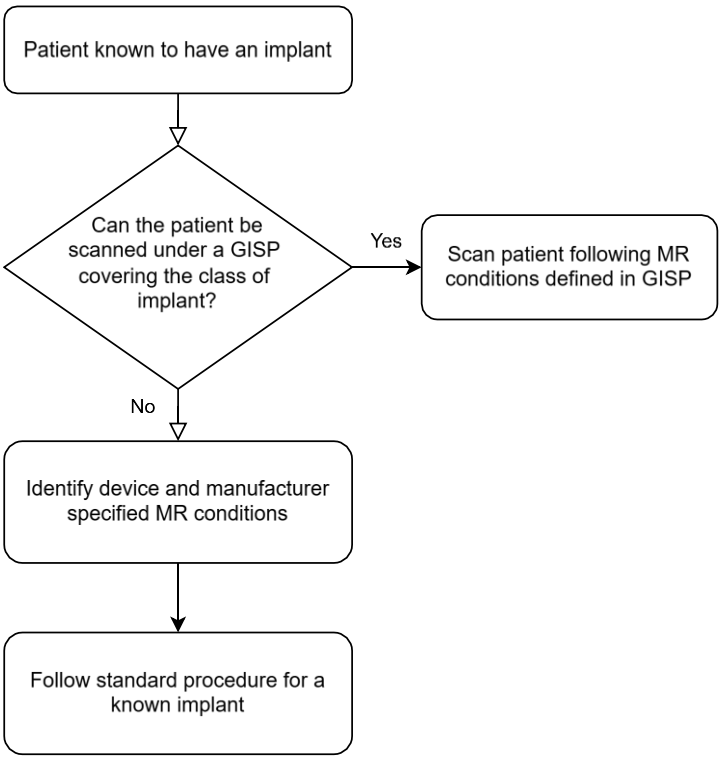
Generic Implant Safety Procedures

MHRA guidelines recommend that MRI departments should have a procedure for identification, documentation, imaging and aftercare for patients with implantable medical devices who undergo MRI. The guidance states that users should refer to the implant manufacturers for advice. Similar guidance exists in multiple other countries.

Identification of devices and their manufacturer's instructions can be difficult. There is compelling evidence that the risk posed by certain categories of device is very low. In these categories, it may be appropriate to use a standardised "generic" workflow without the need for explicit identification.

Generic implant safety procedures (GISPs) are locally developed procedures, incorporating an evidence-based risk-benefit decision to scan certain groups of patients and implants under specific conditions without exact identification of the implant or without the assurance of MR safety by the manufacturer.



The GISP process occurs before the normal procedure of rigorous device identification and determination of manufacturer provided MR conditions.

Guidance on the development of GISPs [1] has recently been produced by a multi-professional group. This guidance provides a detailed framework on the development process, from evidence review and risk assessment, through to dissemination, governance procedures, and subsequent audit and updates.

Potential risks of GISPs include outdated procedures which don't incorporate new or changed devices; scanning against labelled MR conditions (off-label) ; and confusion about applicability. For this reason, GISPs need to be implemented within an appropriate governance framework.

1. Ashmore et al. Br J Radiol (2025) Mar 1;98(1167):336-344 2025 https://pubmed.ncbi.nlm.nih.gov/39535863/

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