IPEM MR-SIG Generic Implant Safety Procedure (GISP) Task and Finish Group Report:

Recommendations for MRI scanning of patients with embolisation devices

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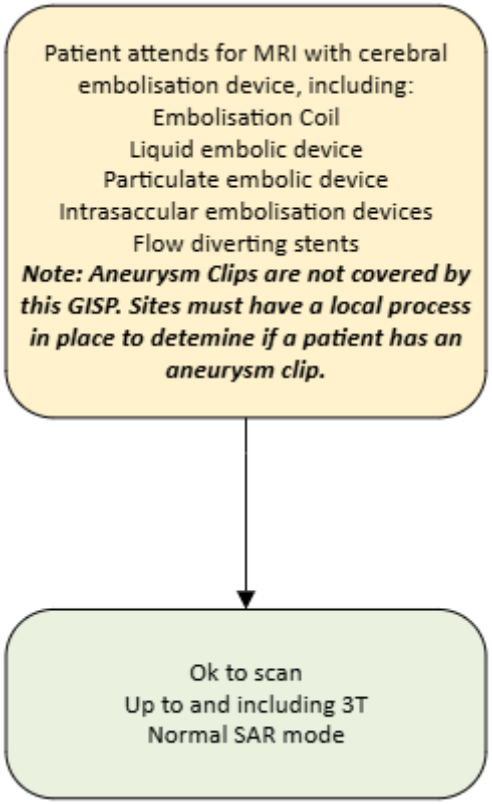
Scope

The safety of patients with embolisation devices undergoing MRI has been considered. This includes embolisation coils (cerebral and non-cerebral), liquid embolic devices (cerebral and non-cerebral), particulate embolic devices (e.g. microspheres, cerebral and non-cerebral), intrasaccular embolisation devices (cerebral), flow-diverting stents (cerebral) and vascular plugs (non-cerebral). The GISP has been separated into cerebral embolisation devices and non-cerebral embolisation devices. Artefacts arising from these devices have not been considered as part of this process, but have been mentioned in the evidence review, where relevant.

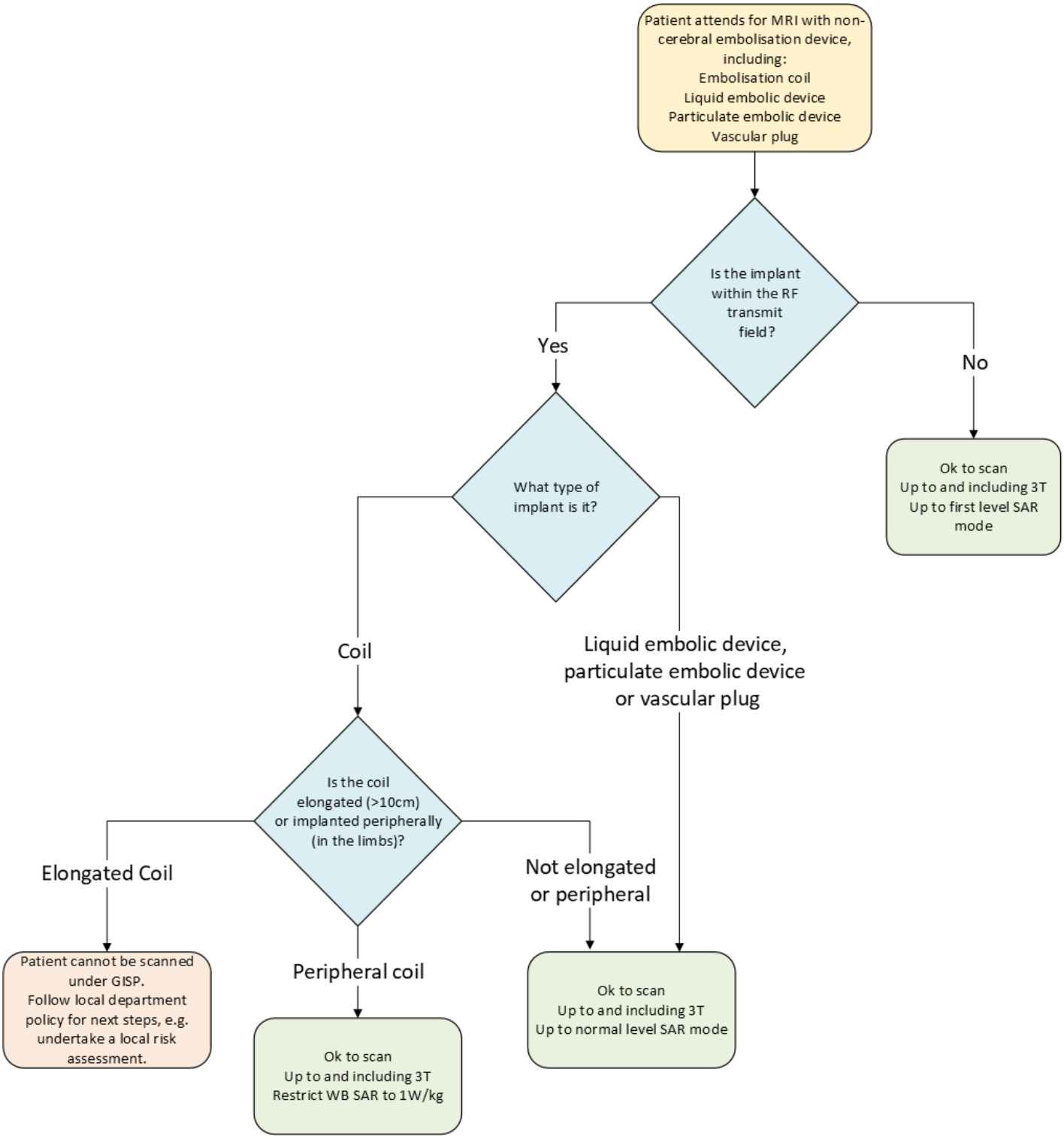
Suggested flowcharts

Example flowcharts are shown below, although departments may wish to adapt to meet their local needs.

Cerebral embolisation devices



Non-cerebral embolisation devices



Supporting Evidence

A full evidence review is given in Appendix 1 and a risk assessment is given in Appendix 2, and sites are advised to read these before implementing this policy locally.

Summary of Consensus – Cerebral Embolisation Devices

The following is the consensus of the MRSE group, with the final meeting held on the 8th of July 2026.

Scan condition (Adapted from Table X1.2 of ASTM standard F2503-23)	**Recommendation (% consensus)** The suggested workflow for the GISP includes conditions where the consensus was greater than 90%.	**Summary of justification**
Geographical implantation location	No restrictions (100%)	Comprehensive (English language) literature and manufacturer review, new products all tending to use the same materials, no geographical restrictions on similar GISPs from prominent figures.
Implantation date	No restrictions (100%)	No MR Unsafe embolisation device identified. Stainless steel coils now labelled MR Conditional.
Time since implantation	No restrictions (100%)	No MR Unsafe embolisation device identified. Stainless steel coils now labelled MR Conditional with no time since implantation restriction and most would have been implanted for a long time now too.
Static Magnetic Field Strength (B_0)	Any field strength up to and including 3T (100%)	In line with manufacturer's conditions or justified based on materials used.
Maximum Spatial Field Gradient (SFG)	Any clinically approved SFG (100%)	In line with manufacturer's conditions or justified based on materials used.
Maximum Gradient Slew Rate per axis	Any clinically approved slew rates (100%)	In line with manufacturer's conditions.
RF Polarisation	Any clinically approved RF polarisation (100%)	Few implants in this category stipulate CP mode but the majority do not include an RF polarisation condition. The group of experts reported that multi-transmit mode often reduces hotspots rather than increases them and so the group agreed that restricting this is unnecessary.
RF Transmit Coil	Any clinically approved RF transmit coil (100%)	In line with manufacturer's conditions.
RF Receive Coil	Any clinically approved RF receive coil (100%)	In line with manufacturer's conditions.

MR System (RF) Operating Modes or Constraints	Normal Operating Mode (100%) First Level Controlled Operating Mode did not reach consensus (82%)	In line with manufacturer's conditions. Whilst the implant conditions generally state Normal Operating Mode, a group of MRSEs, but not enough to reach consensus, would have been happy to proceed in First Level Controlled Operating Mode due to the size of the implants and the fact the SAR conditions for the head are the same for Normal and First Level Operating Mode.
Anatomy at Isocentre i.e. any anatomical restrictions.	No restrictions (100%)	In line with manufacturer's conditions.
Patient Characteristics e.g. patient height or pregnancy	No restrictions (100%)	In line with manufacturer's conditions.
Patient Position in Scanner e.g. supine, prone	No restrictions (100%)	In line with manufacturer's conditions.
Implant Configuration	No restrictions (100%)	In line with manufacturer's conditions.
Scan Duration and Wait Time between sequences	No restrictions (100%)	In line with manufacturer's conditions.

A full breakdown of the results from the consensus process are shown in Appendix 3.

Summary of Consensus – Non-cerebral Embolisation Devices

The following is the consensus of the group on the 8th of July 2026.

Scan condition (Adapted from Table X1.2 of ASTM standard F2503-23)	**Recommendation (% consensus)** The suggested workflow for the GISP includes conditions where the consensus was greater than 90%.	**Summary of justification**
Geographical implantation location	No restrictions (95%)	Comprehensive (English language) literature and manufacturer review, new products all tending to use the same materials, no geographical restrictions on similar GISPs from prominent figures.
Implantation date	No restrictions (95%)	No MR Unsafe embolisation device identified. Stainless steel coils now labelled MR Conditional.
Time since implantation	No restrictions (100%)	No MR Unsafe embolisation device identified. Stainless steel coils now labelled MR Conditional with no time since implantation restriction, and most would have been implanted for a long time now too.
Static Magnetic Field Strength (B_0)	Any field strength up to and including 3T (100%)	In line with manufacturer's conditions or justified based on materials used.
Maximum Spatial Field Gradient (SFG)	Any clinically approved SFG (100%)	In line with manufacturer's conditions or justified based on materials used.
Maximum Gradient Slew Rate per axis	Any clinically approved slew rates (100%)	In line with manufacturer's conditions.
RF Polarisation	Any clinically approved RF polarisation (100%)	Few implants in this category stipulate CP mode but the majority do not include an RF polarisation condition. The group of experts reported that multi-transmit mode often reduces hotspots rather than increases them and so the group agreed that restricting this is unnecessary.
RF Transmit Coil	Any clinically approved RF transmit coil (100%)	In line with manufacturer's conditions.
RF Receive Coil	Any clinically approved RF receive coil (100%)	In line with manufacturer's conditions.
MR System (RF) Operating Modes or Constraints	If outside RF field: First Level Controlled Operating Mode (95%) If within RF field & non-peripheral coil (not implanted in the limbs):	The group of experts concluded that there was no risk of RF heating to the implant if the implant is outside the RF field during the scan. Scanning in Normal Operating Mode is in line with all but one of the manufacturer's conditions. The exception is a peripheral vascular coil which has a condition to limit whole body SAR to less than 1 W/kg,

	Normal Operating Mode (100%) If within RF field & peripheral coil (implanted in the limbs): Limit Whole body SAR < 1 W/kg (100%) Normal Operating Mode did not reach consensus (77%)	hence the exception in the GISP. The majority of MRSEs, but not enough to form a consensus, would have been willing to perform the MRI in Normal Operating Mode for peripheral vascular coils due to the similar properties to other peripheral vascular coils that allow scanning in Normal Operating Mode.
Anatomy at Isocentre i.e. any anatomical restrictions.	No restrictions (100%)	In line with manufacturer's conditions.
Patient Characteristics e.g. patient height or pregnancy	No restrictions (100%)	In line with manufacturer's conditions.
Patient Position in Scanner e.g. supine, prone	No restrictions (100%)	In line with manufacturer's conditions.
Implant Configuration	Elongated coils (>10cm) within RF transmit field excluded from GISP (no consensus to include, even with reduced SAR constraints)	The evidence review highlighted a gap in the MR Safety testing performed by manufacturers as manufacturers only perform testing of bundled coils but there is a theoretical risk of heating for implants with elongated non-cerebral embolisation coils. Whilst the manufacturer's MR Conditions include elongated embolisation coils, the expert group determined that patients with elongated coils should be reviewed on a case-by-case basis.
Scan Duration and Wait Time between sequences	No restrictions (100%)	In line with manufacturer's conditions.

A full breakdown of the results from the consensus process are shown in Appendix 4.

List of contributors

We greatly appreciate the time and expertise the following people have contributed to the development of this procedure.

Name	Role
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Appendix 1: Evidence Review

1. Clinical context

Embolisation devices are used to provide vascular occlusion, most commonly in the treatment of intracranial aneurysms. The device is typically inserted in or adjacent to the aneurysm or vessel, reducing blood flow and promoting clotting. This GISP covers a range of embolisation devices: embolisation coils (cerebral and non-cerebral), liquid embolic devices (cerebral and non-cerebral), particulate embolic devices (e.g. microspheres, cerebral and non-cerebral), intrasaccular embolisation devices (cerebral), flow-diverting stents (cerebral) and vascular plugs (non-cerebral).

Embolisation coils are typically used for aneurysms and large vessel occlusion but may be used in tumour embolisation and to stop internal bleeding. A range of metals have been used in embolisation coils including Nitinol, platinum, stainless steel, Inconel, tungsten and iridium. Multiple coils are typically used for aneurysms and large vessel occlusion but have a range of uses including applications where the coil may be uncoiled or elongated.

Migration of embolisation coils are highlighted as a potential concern in ferromagnetic coils that have been implanted less than 6 weeks ago. However, aside from the Braille Biomedica coil implanted in Brazil, all embolisation coils currently on the market are made from non-ferromagnetic materials. It is considered unlikely that a patient will undergo an MRI in the UK with a ferromagnetic embolisation coil implanted less than 6 weeks ago. The number and length of coils may also be a safety consideration with regards to heating.

Liquid embolic agents are rapidly solidifying agents that are also used to provide vascular occlusion, including into an aneurysm or AVM lumen. Liquid embolic agents may contain a metallic powder such as gold or tantalum.

Particulate embolic agents such as microspheres come in different sizes and materials to suit the embolisation target and do not typically contain metal. A subset of these, radioembolisation microspheres, are glass, resin, polymer carriers containing a radionucleotide that can be used to embolise unresectable tumours.

Intrasaccular embolisation devices (e.g. Woven EndoBridge (WEB)) are used to provide vascular occlusion, including the treatment for aneurysms and other neurovascular abnormalities such as arteriovenous fistulae (AVF). The device is inserted into the aneurysm or vessel, reducing blood flow and promoting clotting. They are generally made from nitinol and platinum.

Flow-diverting stents are used to divert the flow of blood away from the aneurysm. They are often used in combination with embolisation coils and the procedure is often referred to as “stent-assisted coiling”.

Vascular plugs are used for embolisation i.e. to reduce or obstruct blood flow in peripheral vasculature. Examples where vascular plugs may be used are for internal iliac aneurysms, splenic artery embolisation and portal vein embolisation. Vascular plugs are generally made from nitinol.

The make and model of embolisation devices are often not well documented during implantation. Furthermore, patients often require multiple embolisation devices or multiple attempts and thus may have many different types of devices, all in close proximity to one another.

There is a risk that embolisation devices such as aneurysm coils may be confused with aneurysm clips.

2. Results

2.1 Online MRI implant safety databases (Last updated: 11/05/26)

Review of MRI implant safety databases (performed 22/11/19, 25/3/20, 29/10/20, 05/05/23 and 03/07/25, 11/05/26)

A search of MRIsafety.com revealed that all implants under the search terms “aneurysm” (with a filter that the subject contains “coil”) or “embolization” are listed as MRI Conditional or MRI Safe. A second search was performed (with a filter that the subject contains “coil”) using the search terms “AVM”, “PDA”, “aortic” or “varicocele” but no results were found. When the searches were performed with the filter removed no further embolisation coils were identified. Three further MR Conditional implants from Shape Memory Medical were identified using the search term “embolic”. Searching “liquid embolic”, “radioembolisation”, “radioembolization”, “microspheres”, “intrasaccular”, “flow-diverting”, and “vascular plug” only identified devices with MR Conditional labelling.

MRIsafety.com contains the safety topic “Coils, Stents, Filters and Grafts” which states the following:

“Coils, stents, filters and vascular grafts have been evaluated relative to the use of MR systems. Several of these demonstrated magnetic field interactions. Fortunately, the devices that exhibited positive magnetic field interactions typically become incorporated securely in tissue within six weeks after implantation due to ingrowth and other mechanisms. Therefore, for most coils, filters, stents and grafts that have been tested, it is unlikely that these implants would become moved or dislodged as a result of exposure to MR systems operating at 1.5-Tesla or less. Additionally, many of these items have been evaluated at 3-Tesla (see below). MRI-related heating may also be of concern for certain configurations or shapes for coils, stents, filters, and vascular grafts. To date, there has been no reported case of excessive heating in association with MRI and these types of implants.

Many coils, filters, stents and grafts are made from nonferromagnetic materials, such as the LGM IVC filter (Vena Tech) used for caval interruption and the Wallstent biliary endoprosthesis (Schneider, Inc.) used for treatment of biliary obstruction. As such, these implants are acceptable for patients undergoing MR procedures relative to the use of the particular field strength utilized in the ex vivo testing (for specific information, see **The List**). Notably, it is unnecessary to wait after surgery to perform an MR procedure in a patient with a “passive” metallic implant that is made from a nonmagnetic material (see **Guidelines for the Management of the Post-Operative Patient Referred for a Magnetic Resonance Procedure**). In fact, there are reports in the peer-reviewed literature that describe placement of vascular stents or other similar devices using MR-guidance at 1.5-Tesla and 3-Tesla. Interestingly, some of these vascular implants (e.g., vascular stent grafts and stainless steel embolization coils) display high magnetic field interactions in association with 1.5- and 3-Tesla MR systems, yet have MR Conditional labeling approved by the Food and Drug Administration.

Patients with the specific coils, stents, filters and vascular grafts indicated in **The List** have had procedures using MR systems operating at static magnetic field strengths of 3-Tesla or less without reported injuries or other problems.

A study by Taal, et al. (1997) supports the fact that not all stents are safe for patients undergoing MR procedures. This investigation was performed to evaluate potential problems for four different types of stents: the Ultraflex (titanium alloy), the covered Wallstent (Nitinol), the Gianturco stent (Cook), and the modified Gianturco stent (Song) - the last two are made from stainless steel. Taal, et al. reported “an appreciable attraction force and torque” found for both types of Gianturco stents. Taal,

et al. stated, “the Gianturco (Cook) stent pulled toward the head with a force of 7 g…however, it is uncertain whether this is a potential risk for dislodgment.” In consideration of these results, the investigators advised, “…specific information on the type of stent is necessary before a magnetic resonance imaging examination is planned.”

MRI at 3-Tesla and Coils, Stents, Filters and Vascular Grafts. Different coils, stents, filters and vascular grafts have been evaluated at 3-Tesla. Of these implants, two displayed magnetic field interactions that exceeded the American Society for Testing and Materials (ASTM) International guideline for safety (i.e. the deflection angles were greater than 45 degrees). However, similar to other comparable implants, tissue ingrowth and other mechanisms are sufficient to prevent them from posing a substantial risk to a patient or individual in the 3-Tesla MR environment. Please refer to The List for specific information related to coils, stents, filters and vascular grafts.”

It was not specified which implant category the devices that exceed 45 degree deflection angle belong to. It is worth noting that two implants within the category “Coils, Stents, Filters and Grafts” are labelled as MR Unsafe and these are both stents. The Cook stainless steel embolisation coils have been previously reported to demonstrate marked deflection angles but are labelled MR Conditional, covered in more detail later (Teitelbaum et al., 1988).

The subject category “Guidelines for the Management of Patients with Embolization Coils Used for Cerebral Aneurysms or Arteriovenous Malformations Referred for MRI Examinations*” states the following:

“In the clinical magnetic resonance imaging (MRI) setting, it is often necessary to manage patients with embolization coils used for cerebral aneurysms or arteriovenous malformations (AVMs)(1-6). MRI labeling information exists for numerous embolization coils used for those applications. By following the MRI labeling information (i.e., presented in the Instructions for Use, Product Manual, Patient Identification Card, etc.), patients with embolization coils used for cerebral aneurysms or AVMs have safely undergone MRI examinations, including those performed using MR systems operating at 3-Tesla. Notably, there has never been an adverse event reported in association with performing MRI exams in patients with these implants.

The standard policy that MRI labeling information is required before allowing the use of MRI in patients with embolization coils used for cerebral aneurysms or AVMs limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. Taking into account the peer-reviewed literature and other related information (1-7), it is acceptable to perform MRI examinations in patients with all embolization coils used for cerebral aneurysms or AVMs by following specific guidelines developed by considering the primary safety concerns (i.e., magnetic field-related force, torque, RF-induced heating) for these implants.

Guidelines: A patient with embolization coils used for cerebral aneurysms or AVMs may undergo MRI using the following guidelines:

- 3-Tesla or less
- No restriction on the direction of the static magnetic field
- No restriction on the value of the spatial gradient magnetic field
- For embolization coils located inside of the area of the transmitted RF energy, use a whole-body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating the MR system in the Normal Operating Mode)

- For embolization coils located entirely outside of the area of the transmitted RF energy, a whole-body averaged specific absorption rate (SAR) of 4-W/kg (i.e., operating the MR system in the First Level Controlled Operating Mode) may be used
- Maximum imaging time, 15 minutes per pulse sequence, multiple pulse sequences are allowed

***Important Note:** The "Guidelines for the Management of Patients with Embolization Coils Used for Cerebral Aneurysms or Arteriovenous Malformations Referred for MRI Examinations" should only be implemented for use after the careful review by the supervising radiologist or other physician responsible for the MRI facility and with the adoption of the information as a written policy.

Important Note: Any deviation from the above MRI conditions requires prior approval by the supervising physician.

Important Note: These guidelines must be reviewed on an annual basis to confirm that no embolization coil used for the treatment of a cerebral aneurysm or an AVM has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe."

2.2 Implant manufacturers (Last updated: 12/05/26, previous review additions merged into main text)

191 different models of embolisation coils, intrasaccular (e.g. WEB) embolisation devices, flow diverting stents, vascular plugs, liquid embolic devices and microspheres were identified and investigated. Where MRI safety information was not provided by the manufacturer or reported in GISPs from other sites, the information was reported from MRIsafety.com, if available. All manufacturers were contacted to provide the latest MRI safety information if this information was not readily available on their website or MR Conditional with stated conditions on MRIsafety.com.

39 products were identified as MR Safe, assumed to be MR Safe (i.e. appear to contain no metallic components) or are considered effectively MR Safe (only tantalum powder present). Of the remaining 152 devices where a statement from the manufacturer containing MRI Conditions could be identified (130/152 implants investigated), all were safe at 3T or less in Normal Operating Mode, with a maximum spatial gradient of 7.2 T/m, with a few exceptions detailed below.

Of the 22 metallic implants where MR Conditions could not be found, 5 were listed as MR Safe on mrisafety.com. These are likely to have been tested prior to the change in MR safety terminology in 2005 that precludes metallic items from being labelled MR Safe but it does suggest they would be MR Conditional using updated terminology. No embolisation coils were listed as MR Unsafe on mrisafety.com but there were 5 devices that were listed as MRI Conditional 5 (meaning check the MR Conditions with the manufacturer). MR Conditions could not be found for some of the embolisation implants identified, typically in the cases where the implant appears to have been renamed or bought by another company. However, for each of these, the materials used in the implant were discovered to be non-ferromagnetic (e.g. platinum, nitinol or platinum-tungsten alloy) and are thus likely to be deemed MR Conditional. Some of those where MR Conditions could not be found were listed as MR Conditional on the Global Unique Device Identification Database (GUDID).

The IFU of the Braile Biomedica stainless steel coil stated it was "safe against a magnetic field of 1.5 tesla intensity". However, the coil did not appear to have undergone ASTM testing given the lack of conditions relating to SAR or maximum spatial gradient. Likewise, the Flower microcoil (Target

Therapeutics) is reported to be a platinum coil that does not move or deflect in a 1.5T field by Shellock and colleagues (1993) but no further information or MR Conditions could be found. The C-Stopper coil (Solution, Yokohama, Japan) was also identified in this review (Leyon et al., 2014) which is described as a bare platinum coil but no MRI safety information could be found for this device and the company could not be found online (Irie, 2006 & Hayashi et al., 2014). The Trufill pushable platinum coil IFU contained the statement: “To date, there have been no reports of adverse events associated with Magnetic Resonance Imaging (MRI) procedures conducted on patients with platinum pushable coils in their neuro and peripheral vasculature. However, compatibility with MRI has not been established, and the degree of imaging distortion resulting from the pushable coil has not been measured.” The Nitinol Enhanced Device (NED) coil from Embolization Inc. is labelled MR Conditional for 3T only. The manufacturer representative confirmed that this was because the device has only been tested at this magnetic field strength. Whilst technically untested at lower magnetic field strengths, it is unlikely to present an additional risk. Despite the lack of sufficient MR safety information from the manufacturer in each of these cases, all coils highlighted in this paragraph are not expected to present any greater MRI safety risk than any of the other embolisation coils investigated due to the similar designs and the metals used in the implants.

Some MR Conditions listed maximum spatial gradients lower than 7.2 T/m (Codman Trufill DCS: 3.25 T/m, Phenox p48MW & p64MW: 4.5 T/m, Microport Numen Coil Embolisation System: 4.5 T/m). Another manufacturer, Kaneka, reported ASTM testing had been performed for their ED coil but did not provide a condition for the maximum spatial gradient. Given these implants are made from non-ferromagnetic materials (e.g. platinum, nitinol and platinum-tungstem alloy), the risk of these implants in a higher spatial field gradient is negligible. It is likely that the low spatial gradient limit is due to the equipment used during testing rather than a demonstrated hazard at higher spatial gradients.

Stryker Neurovascular provides some detail on the MRI safety testing performed within their MRI safety statement on their website. Their MR safety information is divided into coils used for Neurovascular Use and Peripheral Use. No other manufacturer makes a distinction in the MRI safety information with regards to the location or usage of an embolisation coil and, interestingly, the description of the tests performed differ. Unfortunately, the statement makes no distinction between coiled and uncoiled applications nor was it clear if they had tested the coils in their elongated/uncoiled application. For Stryker GDC Detachable Coils, GDC 360 Detachable Coils, and Matrix2 Detachable Coils, the MR Conditions are the same for Neurovascular Use or Peripheral Use. The Neurovascular Use assumes a spherical aneurysm whereas the Peripheral Use tests a bundle of 30 coils with a length of 10.9 cm. The temperature rise quoted is therefore higher in the Peripheral Use statement. The Peripheral Use MR safety information also suggests that lower SAR limits might be appropriate for coils implanted in the limbs but do not suggest what this lower limit should be. For Stryker Target Detachable coils, the MR Conditions vary depending on whether they are for Neurovascular Use or Peripheral Use. If for Neurovascular Use, they can be scanned in Normal Operating Mode, but if for Peripheral Use, the whole body averaged SAR must be restricted to less than 1 W/kg. After communication with Stryker, it is understood that this whole body SAR condition has been set to limit the local SAR in the extremities. If an embolisation coil has been deployed successfully, then there will be limited heat dissipation from blood flow which may increase the risk from implant heating. An experienced Interventional Radiologist stated in June 2025 that it is very rare for embolisation coils to be used in the limbs so this is not expected to come up often. This was verified by a representative of BSIR in the consensus meetings.

All of the liquid embolic devices, microspheres, intrasaccular embolisation devices, flow-diverting stents and vascular plugs identified in this review have either been confirmed to be MR Conditional with standard conditions (i.e. up to 3T, Normal Operating Mode) or are deemed similar to other devices with these conditions. Notably, the Sirtex LAVA liquid embolic system has been labelled as MR Conditional up to 7T.

Two embolisation coils, Cerenovus Cerepak Detachable coil and Boston Scientific Embold coil, one neurovascular stent, Medtronic Solitaire AB, and one vascular plug, Abbott Amplatzer Vascular Plug devices, included Circularly Polarised (CP) mode within their MR Conditions.

2.3 Review of the peer reviewed literature (Last updated: 13/05/26)

Review of the peer reviewed literature (the majority of the literature searches were performed on 22/11/19).

For the initial searches, various combinations of search terms were used in Google Scholar including: “aneurysm coil”, “embolisation coil”, “embolization coil”, “coil embolisation”, “coil embolization”, “PDA coil”, “varicocele”, “AVM”, “aortic coil”, “MRI safety”, “magnetic resonance”, “safety”, “MR Unsafe”, “MRI Unsafe” and “heating”. 83 articles were investigated. Of those, 34 mentioned MRI safety testing or performing an MRI scan post-implantation (9 of which included embolic devices scanned at 3T) and 11 discussed MRI safety of embolisation devices.

None of the articles mention any adverse events from MRI scanning but one patient may have been excluded from MR imaging due to “pacemakers and metallic devices” being part of their exclusion criteria, however it is unclear if they included the PDA coil among this exclusion criteria (Elzayat et al., 2018). Two papers by Tomita and colleagues (2006 and 2009) mentioned there are “MRI incompatible” stainless steel coils. However, Slesnick et al. (2016) reported that the standard Cook embolization coil, made from stainless steel and discontinued in 2012, was originally deemed MR Unsafe but was changed to MR Conditional in 2012. The maximum number of coils reported in the literature for a single patient that went on to undergo an MRI scan is 55 (which included stainless steel coils) (Slesnick et al., 2016).

A number of papers have aimed to make generic statements regarding the MRI safety of embolisation coils. The three most notable and comprehensive are summarised below.

Slesnick et al. (2016) reviewed the MRI safety of stainless-steel coils for over 500 MRI examinations and determined that “patients with previously implanted SSEC [stainless steel embolization coils] should be considered to have a very low safety risk of MRI examinations on 1.5-T scanners.”

Alsafi et al. (2019) reviewed the safety of embolization coils used for pulmonary arteriovenous malformations (PAVM) implanted at Hammersmith Hospital, London between 1984 and 2017. Slesnick and colleagues (2016) did not include PAVM embolization in their study and as PAVM embolization coils are at a greater risk of migration due to the anatomy of the lungs, Alsafi and colleagues (2019) performed a retrospective review on both stainless-steel and platinum PAVM embolization devices (including stainless steel coils and Amplatzer vascular plugs) and found that they can “safely undergo 1.5 T MRI which should not be delayed in emergency situations”.

Levine et al. (2007) reviewed the MRI safety of a range of cardiovascular devices, including stainless steel, platinum, nitinol and platinum and iridium embolization coils. In this article they make the following recommendation: “Patients who have been treated with nonferromagnetic embolization

coils can undergo MR examination any time after coil implantation. The timing of MR examination at 3 T or less in patients with embolization coils that are weakly ferromagnetic should be weighed on a case-by-case basis. For cases in which there is a clear potential clinical benefit of scanning in the days to weeks after implantation, the benefits of the MR examination will likely outweigh the risks of the examination, and MR examination should generally be performed. In patients with chronic conditions in which it makes little difference whether the scan is performed at a given time or weeks later, it may be prudent to defer MR examination until 6 weeks after device implantation. Patients with tested coils may undergo MR examination at up to 3T, according to the conditions under which they were tested."

The first reported technique using an embolisation coil was performed in 1974 using copper coils (Xiao and Lewandowski, 2022). The literature review highlighted that most embolization coils are predominantly made from stainless steel or platinum, with platinum becoming the main primary material in clinical use (Hui et al., 2014, Xiao and Lewandowski, 2022). However, other materials used in coils include: tungsten (Bachthaler, 2004, Shellock 2005), Inconel, a nickel-based alloy (Grifka, 2008, Kische, 2010), a platinum-tungsten alloy (Elsayed, 2019), Nitinol (Levine, 2007, Khan, 2013) and iridium (Levine, 2007). Notably, Bachthaler and colleagues (2004) advised against the use of tungsten embolization coils, but due to corrosion rather than any MRI safety issue.

The review also identified liquid embolic devices that contain metals such as gold (Audet-Griffin, 2014), tungsten (Pal, 2023) and tantalum powder (Ne, 2018, Pal, 2023 and Park 2019). These are useful for vessels too small even for microcoils (Park, 2019). Three of these papers mention an MRI scan was performed after the liquid embolisation (Audet-Griffin, 2014, Ne, 2018 and Park 2019), despite tantalum being paramagnetic, and Audet-Griffin and colleagues performed MR safety testing.

Particulate embolic agents were reviewed by Lee and colleagues (2023) and, with the exception of Merit Medical's EmboGold microspheres, no metallic particles were mentioned in the review. Merit Medical describe the EmboGold microspheres as MR "compatible". Other articles highlighted the possibility of radioembolization microspheres consisting of glass, resin, polymer carriers containing a radionucleotide (Riaz, 2009, Alrfooh, 2021, Serhal, 2023). Drug eluting beads (DEBs) have also been developed that can deliver therapeutics locally such as chemotherapeutic agents (Lee, 2023 and Wang, 2020). It is often desirable to have microspheres that are visible on imaging so some products on the market or in development contain tantalum, iron-cobalt nanoparticles or ultra-small paramagnetic iron oxide (Wang, 2020). One device reported to be in development in animal models is a thermal-responsive magnetic hydrogel which is designed to heat the hydrogel using an alternating magnetic field (Yan, 2022). The mechanism for heating operates at low frequency (around 300kHz) whereas the static field in MR is constant, the RF works at a much higher frequency (64 to 128 MHz) and the gradient switching rates tend to be much lower 0-3kHz. Furthermore, the presence of the static magnetic field magnetically saturates the microspheres so they cannot rotate or flip rapidly, preventing the mechanism for heat generation. These particles are not continuous electrical conductors so cannot generate eddy currents, removing the common cause of heating in MRI. An example of magnetic microspheres are ultra-small superparamagnetic iron oxide particles (USPIOs) which are used as contrast agents in MRI so they would not be expected to significantly heat in a clinical MRI scanner (Ghazi et al., 2025).

The Woven EndoBridge (WEB) device, an example of an intrasaccular embolisation device, was identified (Arthur et al., 2019). This is a Sequent Medical (parent company Microvention/Terumo) product developed to treat wide-necked bifurcation aneurysms and consists of a self-expanding spherical or cylindrical shape with single layers of braided nitinol/platinum wires. A study by Nawka

and colleagues (2018) reported a significant signal dropout within a WEB device during MRI, possibly due to the Faraday cage effect, such that MRI cannot be used to confirm complete thrombus formation within the WEB. Other manufacturers have since released products similar to the WEB device, all of which are MR Conditional (1 device is labelled MR Conditional on the Global Unique Device Identification Database (GUDID) but manufacturer labelling could not be found).

Stent-assisted coiling is another topic that was identified through the literature review (Li 2010, Mohlenbruch 2014, Ryu 2019). No MR Unsafe stents used for stent-assisted coiling were identified during this review.

Belanger and colleagues (2022) reported results from using a pre-clinical Resolv stent in an idealized bifurcation aneurysm model. The Resolv stent is stated to be a unique hybrid metal/polymer stent but no manufacturer information was identified in the publications related to this stent. No more recent information could be found on this Resolv stent and it produced no relevant results when searched on the AccessGUDID or mrisafety.com websites.

Vascular plugs were reviewed by Ghosh and colleagues (2022). This highlighted that the first vascular plug on the market was the Amplatzer Vascular Plug in 2004 and plugs generally are made from non-ferromagnetic materials such as nitinol and platinum.

Woods (2007) wrote in a review of the ASTM standard for medical devices in MRI: “The potential for heating is maximized for devices with a length in the range of an odd number of half wavelengths of the MR RF field. For 1.5 T and 3.0 T scanners (with Larmour frequencies approximately 63.8 MHz and 127.7 MHz, respectively), critical lengths can occur for lengths greater than approximately 6 cm. The critical length for a specific device during a particular MR scan can not be calculated precisely, so it is necessary to evaluate a range of lengths and conditions to determine the worst case conditions for RF induced heating.” A review of the typical and maximum sizes of various aneurysms and other conditions requiring embolisation is included within the discussion of GISPs from around the UK within the Internet Search section.

A review of the FDA adverse event reports over a 10 year period by Defino and colleagues (Defino 2019) reported an FDA “warning to healthcare providers that images from magnetic resonance angiography performed on patients with neurovascular embolization coils containing 304 V stainless steel may contain larger than expected MR artifacts and result in inaccurate diagnosis of occlusion status”.

A review of embolisation agents by Leyon and colleagues (2014) was identified and reviewed. The C-Stopper embolisation coil was identified and investigated as highlighted earlier in the detailed review. The review highlighted the use of balloons for large vessel embolisation. These are less commonly used now and typically only for temporary occlusion devices. Other than the risk of a potential catheter break which could occur for any embolisation technique, no MR safety issues were identified relating to the use of balloons. This review provides a good summary of the embolisation products available in 2014 and provided assurance that all embolisation products can be covered under a single GISP.

2.4 Internet search (non peer reviewed literature) (Last updated: 20/01/26)

Review of the SMRT MR Technologist mail base (initial search completed 12/3/20 with a further search in 2023)

10 discussions were found on the SMRT mailbase that mentioned “aneurysm coil”, “embolisation coil”, “embolization coil”, “embolisation”, or “embolization”. No evidence of any incidents or injuries as a result of scanning embolisation coils were identified. Safety considerations such as heating and inadvertent stimulation of adjacent tissue were mentioned but nothing that contradicts any evidence found in this GISP thus far.

The earliest record found on the SMRT mailbase was 4/8/2016. However, the information contained in GISPs from other sites where the SMRT mailbase was summarised and relevant sections copied into an appendix has also been reviewed. The King’s College Hospital review of the SMRT mailbase goes back further than my search was able to but it yielded similar information to the results of the literature search. There is a suggestion that “when the make and model of an embolisation coil cannot be identified a risk/benefit analysis is necessary due to the potential (albeit rare) [possibility] that a strongly ferromagnetic coil was implanted”. This will be considered in the risk assessment (Appendix 2). Furthermore, there were suggestions on the mailbase that there are strongly ferromagnetic aneurysm coils – a potentially higher risk situation. No evidence has been found in this detailed review to suggest that strongly ferromagnetic coils have ever been used. The potential for tissues adjacent to coils to be inadvertently stimulated by the gradients was also highlighted as a theoretical possibility but has not been reported in any cases or literature identified in this review, and is thus considered low risk.

A second search was performed using the search terms “AVM”, “PDA coil”, “aortic coil” or “varicocele”. No results were found but I do not have access to records prior to 2016. When searching “PDA” rather than “PDA coil”, three discussions were identified relating to PDA clips. In one of these threads Dr Shellock states “Not all PDA implants have undergone testing and, thus, some may be MR Unsafe”. This is in response to a query about PDA clips but given the wording this has been taken into consideration in this review.

Review of the UK MRI mail base

Searches were performed on 30/1/20. Search terms including “aneurysm coil”, “embolisation coil”, “embolization coil”, “embolisation”, and “embolization” yielded no results.

Additional searches were performed on 25/3/20. Search terms including “AVM”, “PDA coil”, “aortic coil” and “varicocele” yielded no results. Searching “PDA” rather than “PDA coil” yielded only a discussion about a magnetometer.

When searching for terms related to vascular plugs on 12/5/26, one query related to the Amplatzer device and satisfying maximum spatial gradient considerations. The two responses suggested to consider a risk/benefit approach.

Update 03/07/25:

In May 2022, the MHRA released a Field Safety Notice (MHRA Field Safety Notices: 16 to 20 May 2022 - GOV.UK) relating to Cook Medical embolisation coils. As detailed in the report, certain embolisation coils were found to contain a small, unintended stainless steel cannula inside. These embolisation coils are intended for use in the peripheral vasculature (Hilal Embolisation Microcoils, Nester® Embolisation Microcoils, and Tornado® Embolisation Microcoils). The risk of a “*burn (from*

magnetic resonance imaging if unintended cannula is unnoticed)" was included among the hazards in the Cook Medical Field Safety Notice. In later communication they outlined that the recall was initiated due to non-MRI related potentially life threatening events but included the warning of "*imaging effects and the possibility of MRI relating heating and/or burn*" as other potential side effects.

Cook were contacted when this Field Safety Notice came out to investigate the risk further and the risk was deemed low for the following reasons:

- These stainless steel cannulas were made from 304 stainless steel which is weakly ferromagnetic and is the same material used in Cook's MR Conditional stainless steel embolisation coils. We therefore determine the risk due to introducing these into the static magnetic field is low.
- The size of the stainless steel cannula and the dimensions were given as: *OD: 0.022 – 0.025, ID: 0.0145"+/-0.0005", Length: 0.325"+/-0.015"*. Given these dimensions, this stainless steel component would not be expected to produce any significant heating.
- Cook informed us that the affected lots were manufactured between September 2021 and March 2022 and whilst they were unable to estimate the percentage of affected products that were distributed, they found the issue in 7 cannula out of the 11000 that were tested. It is likely that there would be significant resistance felt by the user in these affected products when trying to introduce the coil into the catheter and when trying to advance the coil down the catheter. Cook estimate that the resistance felt is high enough that they expect a user would remove the coil and use a new one. Cook advise that "If there were no complaints or adverse events at the time of the procedure, no additional actions or notifications are recommended by Cook at this time."
- If the cannula did end up in the body it is difficult to predict where in the body it would end up as it depends on the target embolisation site. If it was irretrievable, it would "likely be embolized into the vasculature distal to the site of the expected therapeutic embolisation with the coil". The cannula cannot be identified reliably via x-ray.
- Please note that there may be additional artefact in MRI if this cannula is present.

Internet Search (last updated 29/01/26)

Relevant GISPs from other sites were reviewed in this section. Eight health boards/trusts shared their current embolisation coils and/or devices GISPs in January 2026 and two further GISPs produced in 2016 and 2018 were available from previous reviews.

- The scope of these GISPs varied as some were covering cerebral embolisation coils only whereas others included non-cerebral embolisation coils and embolisation devices.
- All GISPs include up to 3T but some included a suggestion to scan at 1.5T if practical to do so.
- None of the recent GISPs contained a restriction on the spatial gradients the implants could be exposed to.
- All GISPs recommended scanning in Normal Operating Mode for SAR limits
- All GISPs recommended scanning up to First Level Controlled Mode for dB/dt limits
- All of the recent GISPs recommended that an MRI can be performed immediately post-implantation
- There was variation among the recent GISPs whether any geographic restrictions should apply. Five GISPs had no geographic restrictions, one limited it to implants from the UK, EU, US, Canada, Australia, Japan or in Middle East at a JCI-accredited organisation, one limited it to Europe or North America, one limited it to the UK only

- Similarly, most recent GISPs had no time restriction (6) but two only covered implants from the year 2000 onwards.
- All GISPs recommended ensuring that aneurysm coils were not confused with aneurysm clips.
- Of the recent GISPs covering non-cerebral embolisation coils (6), 3 did not require any additional checks for elongated embolisation coils whereas 3 recommended checking the length of the coil is less than 10cm. For the latter, it is assumed that this condition only applies if the coil will be in the RF field but only explicitly stated in one of these GISPs. Furthermore, one of the GISPs that recommends checking the length of the coil is less than 10cm only recommends this for scans taking place at 3T but not 1.5T and is one of the GISPs which recommends scanning at 1.5T rather than 3T if practical to do so.
- GISPs reported that no MRI safety incidents have been reported for this implant category, either in the literature or in the MHRA, MAUDE and MDR databases

One of the GISPs included a review of the SMRT mailbase which has been incorporated within the SMRT mailbase section in this evidence review.

No coils labelled MR Unsafe were identified although some MRI safety information could not be found and so may be considered MR Unlabelled.

Some GISPs stated safety information is not available for some models of stainless steel embolization coils manufactured in the 1970s and 1980s and at least one other stainless steel embolisation coil that was still being sold in 2018 from a manufacturer outwith Europe and North America, Braile Biomedica – hence the exclusions detailed. After numerous requests for MRI safety information were sent to Braile Biomedica, I finally received their instructions for use. As mentioned in the review of manufacturer implant information, the IFU contained the MR Conditions but the wording suggested they had not undergone ASTM testing. For coils used in the 1970s and 1980s, no evidence has been found that any are MR Unsafe and Cook stainless steel coils are labelled MR Conditional.

A GISP specifically for (non-cerebral) vascular plugs concluded that it is safe to scan vascular plugs implanted in the UK on 3T or lower field scanners in Normal Operating Mode. It was noted that where possible, imaging should be viewed to verify the length of the implanted area. It was also noted that these are often implanted in conjunction with non-cerebral embolisation coils, in which case, their local non-cerebral vascular embolisation coils policy must be followed.

A section from one literature review sought to identify typical and maximum sizes of various aneurysms and other conditions requiring embolisation. The text is copied below with permission from the lead reviewer for this GISP.

“Whilst cerebral aneurysms are normally less than 1 cm they can rarely can reach 2.5 cm [Young-Gyun Jeong 2009]. A study of ruptured internal iliac artery aneurysms showed a mean maximal ruptured artery diameter of 6.84 cm with range, 2.5-11.6 cm [Laine 2017]. Splenic artery aneurysms are normally less than 3 cm in diameter but can be up to 10 cm in a very few cases [Yadav 2012]. Aortic aneurysms are generally recommended for treatment when >5.5 cm with a maximum reported case at 9.1 cm [Saade 2015]. Pulmonary arteriovenous malformation might require overall coiling volumes up to 6 cm [Jimyung Park 2015]. Liver portal vein diameters may measure up to 1.6 cm [Stamm 2016].”

There are a few additional details worth noting after reviewing the information above:

- Splenic artery aneurysms over 10 cm have been reported (Yadav 2012, Kehagias 1998).
- Whilst the average liver portal vein diameter was measured to be 1.6 cm in healthy volunteers, the maximum was reported to be 2.3 cm (Stamm 2016).

In addition, a list from Endovascular today was shared detailing a range of information about different embolisation coils including the material, maximum coil length and US FDA Indicated Use. Of note, the joint longest coil lengths were 60 cm from the Boston Scientific Interlock-18 Fibered IDC Occlusion System, Penumbra coils (Packing Coil, POD and Ruby Coil) and Wallaby Medical Avenir.

A general internet search identified the following text from the book 'Magnetic Resonance Procedures: Health Effects and Safety' (Shellock): "more than 100 patients with GDCs have undergone MRI without incident. Similarly, other embolization coils made from nitinol, platinum, or platinum and iridium have been evaluated and found to be safe for patients undergoing MR procedures." In addition, an Evidence-Based Analysis for Coil Embolization for Intracranial Aneurysms by the Ontario Health Technology Assessment Series from January 2006 was reviewed. No MRI safety concerns were highlighted but it contained Appendices that aided the manufacturer search. Similarly, a table listed in Endovascular Today revealed an embolisation coil that had not been identified previously.

An abstract for ISMRM 2019 was found detailing RF heating testing of titanium rods at 1.5T and 3T (Martinez et al., 2018). They report that the temperature rise was greatest at the half-wavelength length rod for both 1.5T and 3T (26 cm and 13 cm respectively).

Update 05/05/23: In July 2021 Medtronic's Pipeline Flex Embolization Devices was recalled after "reports of serious injuries and deaths in connection with delivery pushwire fracture at the distal section of the Pipeline Flex™ delivery system during use" (MHRA, 2021). The Field Safety Notice stated:

"As of July 2, 2021, Medtronic has received reports of 71 confirmed and unconfirmed fractures. These events include reports of ten (10) serious injuries and two (2) deaths. One (1) additional serious injury originated from Europe (Finland), however all the other serious injuries and 2 deaths occurred outside Europe, Middle East and Africa."

The recall includes Pipeline Flex Embolisation Devices distributed between April 2019 to October 2019.

The recall does not mention MRI safety.

2.5 Regulatory Medical Device Databases (Last updated: 11/09/26)

An AccessGUDID search for devices containing the word "embolization" with a filter for implantable devices and an MR Safety Status of "MR Unsafe" produced 2 results, both of which related to coil detachment handles rather than an implant. A further 661 devices listed stated "Labeling does not contain MRI Safety Information", these included embolization liquids, particles, microspheres and coils, all of which are known to be MR Safe or Conditional. The remaining devices with this labelling are assist devices that would not be implanted.

2.6 Regulatory Professional and Standards bodies (Last updated: 11/09/26)

Nothing to report

2.7 Anecdotal evidence (Last updated: 13/05/26)

In NHS Greater Glasgow and Clyde in 2016, a patient with three cerebral aneurysm coils reported some sensation/discomfort in synchronisation with certain sequences during a cardiac study on a 3T MRI scanner. The patient pressed the buzzer, explained what was happening and the decision was taken to abort the scan. The coils were later found to be Axium coils which are MR Conditional.

Review of Facebook MRI safety groups (initial searches performed 25/3/20 (1/6/20 for MRI World review)):

UK MRI Safety Group:

Search terms included “aneurysm coil”, “embolisation coil”, “embolization coil”, “embolisation”, “embolization”, “AVM”, “PDA coil”, “aortic coil” and “varicocele”. Three posts were identified but none revealed any pertinent MRI safety information.

Update 05/05/23: There was a post asking if anyone has a policy with a limit on the amount of “MRI compatible coils”. There was no real answer to this question in the responses due to some confusion over stents and embolisation coils and the use of the term “compatible”.

Update 03/07/25: No further relevant posts identified

Update 13/05/26: No posts identified relating to vascular plugs

MRI World:

Search terms included “aneurysm coil”, “embolisation”, “embolization”, “AVM”, “PDA coil” and “varicocele”. A number of posts were identified but the only one relevant to this GISP highlighted a case of a patient with a reported plastic urinary stent that appeared to be an elongated (uncoiled) metallic embolisation coil. This was initially thought to be a varicocele embolisation but was corrected to an ovarian vein embolisation when the gender was known.

Update 03/07/25: No further relevant posts identified

Update 13/05/26: No posts identified relating to vascular plugs

MRI Safety Group:

Search terms included “aneurysm coil”, “embolisation”, “embolization”, “AVM”, “PDA coil”, “aortic coil” and “varicocele”. One hundred and twenty posts were identified, twenty-eight of which contained information or discussion relevant to this GISP.

The main concern is a discussion from 2017 where a Cook stainless steel PDA coil from 2003 was deemed MR Unsafe. In response, both Cook and the original poster were contacted to follow up. Cook responded on 3/6/20 to confirm that “The MRI information we have covers all of our coils including historically manufactured stainless steel ones. Cook revalidated all of the MRI conditionality in 2015 which demonstrated the stainless steel coils were safe to scan under the conditions specified” in an attached letter. This was the only device that was reported to be MR Unsafe, although on one comment a poster described Gianturco bird’s nest coils as “very

dangerous", it is unclear if they mean a Gianturco bird's nest filter or a Gianturco embolization coil. If the poster was referring to the embolisation coil, whilst it is weakly ferromagnetic (Teitelbaum et al., 1988, Shellock, 1988) it is classed as MR Conditional under the Cook Medical MR Conditions for stainless steel coils reported above.

It became apparent during the review that the topic of generic policies for embolisation coils is something that would be concerning to some of the radiographers that comment on that site. However, there was no evidence to explain why a generic policy could not be written other than possible confusion with aneurysm clips, some coils may have not been MRI safety tested or coils manufactured outside the US may not be made with materials to ensure no MRI issues. Most radiographers agreed that documentation or a knowledgeable radiologist was required to allow an MRI scan to proceed. Whilst some conceded that they have never come across a coil that is MR Unsafe, they still considered that obtaining the make and model was best practice. However, there is evidence that other sites are using GISPs with sites such as the Mayo clinic having a policy that all aneurysm coils are safe at 3T or less and another stating all coils implanted in the US or UK since 2000 are MR Conditional.

Heating was the most common concern highlighted, particularly in previous examples where a coil was elongated (i.e. not coiled), giving an increased heating risk. Examples given where a coil is sometimes not coiled are varicocele or ovarian embolisation. The acceptable total length of the coil or coils was a topic for discussion in many posts but the numbers given were inconsistent. One post claimed a patient contained 19.2 feet (~585 cm) of an unknown coil. The consensus was to check if it was indeed coiled, and, if so, heating was not a major concern. Similarly, it was stated that the number of coils should not be a limiting factor but rather the resonant circuit length.

There was a discussion over whether there is any need to wait 6 weeks after implantation of a coil. The general consensus was that this is not necessary unless the conditions state it explicitly.

One post mentioned that a Boston Interlock coil has a condition that it requires a Transmit-Receive head coil, however another thread posted conditions which stated a Transmit-Receive head coil and/or whole body transmit coil could be used for a Boston Scientific Interlock Fibered IDC coil. The Interlock coil is listed as "Conditional 8" on mrisafety.com which further supports the latter statement. I have found no evidence support the condition for a Transmit-Receive head coil only but have emailed Boston Scientific to seek further reassurance, at the time of writing I am still awaiting a response.

Another post highlighted the possibility of an MR Unsafe microcatheter breaking during insertion of an embolisation coil and remaining in situ. This will be added to the notable exclusions within the GISP.

Update 11/08/23:

One poster asked if there were any MR Unsafe embolization coils. None were mentioned in the responses and no objections were raised with proceeding to scan a 1997 embolisation coil if a Radiologist decides the benefit outweighs the risk.

Another post asked about Onyx embolisation. The responses highlighted that this is MR Conditional and a non-ferrous glue-like substance. One of the responses reported a case where the catheter used to inject the Onyx solution became stuck and had to be left in situ and, after a radiologist assessed the risk and deemed heating was limited due to the catheter being in flowing blood, the scan of the head went ahead with no incident.

A poll was performed in September 2020 asking “What is your site doing for patients with brain embolization coils?” 143 votes were cast and 90% stated they “Research all”, 6% state they “Approve all”, and 4% state they “Approve all implanted at my hospital site”.

A poster reported that a patient who had undergone multiple MRI scans previously felt a slight tug at his head during one of their previous MRI scans. The patient had an AVM repair about 40 years ago but no documentation could be found.

In May 2023, a poster asked for the MR Conditions of a Micrus Helical Coil. Shellock stated “Maybe we need general MRI guidelines for embolization coils used for neuro applications?” A contributor highlighted the NHS Scotland GISP. Shellock commented that there is no reference to the value of the spatial gradient magnetic field and questioned: “Does that mean that it does not matter?” The poster replied that whilst they can’t comment on behalf of the authors but from the many MRI conditions they see for neuro coils in the neuro department they have never seen any spatial gradient conditions that would have prevented scanning on the clinical scanners they have used.

In another post from May 2023, a poster asked if people would scan without knowing the make and model of an aneurysm coil (provided it was definitely a coil and not a clip). Shellock stated "I know of no MR Unsafe embolization coil used for a cerebral aneurysm". Kanal advised against using absolutes (e.g. the word "never").

Finally, Frank Shellock shared his latest ‘Guidelines for Patients with Embolization Coils Used for Cerebral Aneurysms’ in June 2023 (see Figure below). It is worth noting that these guidelines do not include any spatial gradient, implant date or geographic restrictions.

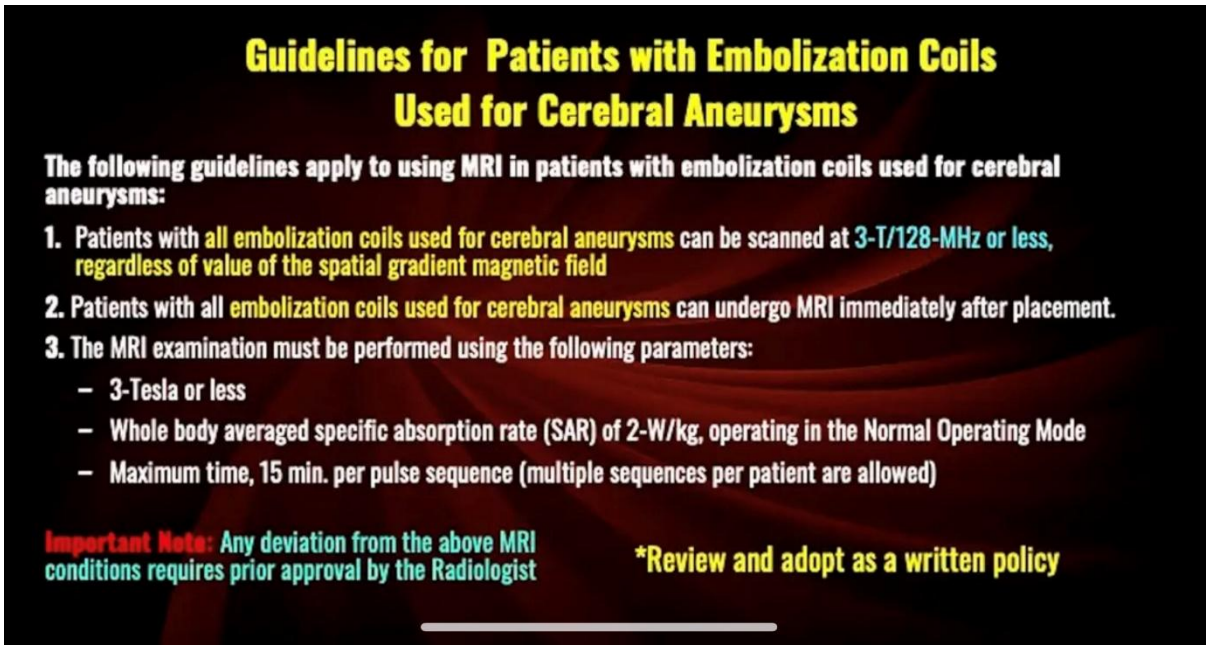


Figure: Frank Shellock’s guidance on cerebral embolisation coils, June 2023.

Update 03/07/25:

Shellock posted the MR Conditions for the SEAL (Saccular Endovascular Aneurysm Lattice) device by Galaxy Therapeutics to the MR Safety Facebook page 26/04/25. The MR Conditions are not restrictive (3T or less, Normal Operating Mode).

Update 13/05/26: Shellock stated in 2023 that he knows of no vascular plug that is unsafe for a patient undergoing an MRI exam.

Further investigation into heating risk and testing of embolisation coils in MRI:

Embolisation coils will not dissipate heat through blood flow if the vessel is occluded and therefore MR-related heating of occluding coils is considered the main risk factor in this GISP. Following discussions with prominent MR safety figures and the related discussion regarding Stryker coils (in Section 2.2), it is understood that MR safety testing on embolisation coils, typically only includes a single coil but occasionally testing is performed on a small number of bundled coils. However, no MR safety testing has been reported on embolisation coils when they are elongated or uncoiled. This calls into question the validity of MRI safety testing on embolisation coils and the MR Conditions provided if they are not being tested in their worst-case, yet on-label, application. To investigate this further, several other manufacturers (Cook, Boston, Terumo and Cerenovus (formerly Codman)) were asked the following questions:

1. Does your labelling for use for the coils include a varicocele procedure or other techniques where the coil would be implanted uncoiled (i.e. not the spherical shape used in aneurysms)? This isn't asking about MRI, just trying to determine if clinicians are implanting coils off-label.

2. What configuration are your embolisation coils placed in for MRI safety testing? I'm particularly interested if they are tested in the "uncoiled" or elongated configurations typically used for varicocele embolisation.

3. If it is on label, do the MR Conditions provided in the IFU apply for all configurations of coils?

At the time of writing, only Cerenovus and Terumo replied to this request. On 9/6/20 a Cerenovus representative stated:

"All CERENOVUS coils with the exception of GALAXY G3 XSFT are indicated for arterial and venous embolizations in the peripheral vasculature. My comments to the specific questions are below:

1. Yes, it is common for coils to not fulfill their D_3 Tertiary Shape. Vessel take-downs are very common coiling procedures and a very similar to the varicocele embolization

2. We are still waiting for feedback

3. Yes, there is only one set of MRI Conditions and these would apply to all on label indications."

(Original questions as listed above, removed from quotation).

On 29/6/20, a representative from Terumo commented that these questions had never been asked previously and they were unable to specifically answer my questions. They included the IFUs for their coiling products (which contained no details on MRI safety testing) and reasserted that the coils are MR Conditional and that the "IFU's do not specify the configuration of the coils when they are deployed, as that completely depends upon physician technique and patient anatomy".

At the time of writing, Cook and Boston had not responded.

3. Discussion

Summary of risks from implant associated with static field, RF and imaging gradients (last updated 23/07/26)

Risk of migration or dislodgement from the static field

Most embolisation devices are MR Conditional at 3T or less. The exceptions to this are outlined in the evidence review alongside a justification of why this is not considered a risk to the GISP. With the exception of the Sirtex LAVA liquid embolic system which is MR Conditional up to 7T, no evidence has been identified for field strengths higher than 3T.

The summary provided by Dr Shellock in the Coils, Stents, Filters and Vascular Grafts review on mrisafety.com is that only two implants from this category exceeded 45 degrees during deflection testing but these are thought to be stents rather than embolisation devices. Even if a stainless steel embolisation coil is identified, the tissue ingrowth and other mechanisms are sufficient to prevent them from posing a substantial risk to a patient or individual in the 3T environment. The literature from Levine et al. (2007), Slesnick et al. (2016) and Alsafi et al. (2019) report that the risk of migration from stainless steel embolisation coils is low in 1.5T scanners, even when implanted in anatomy where they would not be as strongly fixed.

New devices tend to be similar in design and use similar materials to MR Conditional devices. A thorough literature review and internet search revealed devices originating from around the world and they all used a similar design.

Whilst manufacturers provide limits on the maximum spatial field gradient, it is understood that these are often based on the spatial field gradient of the MRI scanner used for testing rather than an absolute limit. It was considered reasonable to restrict the spatial field gradient to include all clinically approved spatial field gradients.

Risk of heating

Again, there is no evidence of embolisation devices being tested on field strengths above 3T and this would perhaps be of larger concern than the static field due to the typical lengths and numbers of coils used. The risk of heating in 3T systems and lower field strength systems is considered low for the typical length and number of coils used. Some patients may have a large number of coils in situ, the most found during the literature review that went on to have an MRI scan was 55 coils. In addition, as stated in Levine et al. (2007), “because of the shape of certain coils, the theoretical potential of coil heating during an MR examination exists“. In particular, if a large length of coil (greater than 10 cm) were to be left uncoiled within the vasculature then there is a potential for heating. Despite these theoretical risks, all embolisation coils where the manufacturer’s MR Conditions could be identified were able to be scanned in Normal Operating Mode (excluding coils implanted in the limbs) with no conditions relating to the placement or application of the coil. To quote mrisafety.com, “To date, there has been no reported case of excessive heating in association with MRI and these types of implants.”

Risk of neurostimulation of adjacent tissue

This has been raised as a theoretical possibility but has not been reported in practice and is thus considered low risk.

Consideration of risks, specific to this implant category

There is a risk that an aneurysm clip may be accidentally reported as an aneurysm coil.

There is a possibility that lung volume reduction coils (LVRC, such as the ELEVAIR and RePneu coils) are mistaken for embolisation coils. LVRC treatment is a minimally invasive treatment option for emphysema patients who suffer from severe hyperinflation. The treatment is aimed at patients where lung volume reduction surgery and bronchoscopic lung volume reduction using endobronchial valves are not an option, or alternatively, can be offered as a bridge to lung transplantation. The coils are made from nitinol, with a distinctive shape and multiple coils are implanted during the procedure. The ELEVAIR and RePneu coils are MR Conditional but an extensive review has not taken place so there may be alternative products. These coils can be distinguished from embolisation coils by asking about the method of delivery (bronchoscopic rather than intra-vascular), or by reviewing patient notes or prior imaging.

During this investigation it became clear that there is a possibility for a microcatheter to break during the insertion of an embolisation coil and remain implanted. These are not covered in this policy as some are labelled as MR Unsafe.

The use of clinical notes to determine the length of coiling may be unreliable. An example of this risk came from a recent MHRA field safety notice, detailing that a batch of Balt Extrusion SPIF coil implant traceability labels were mixed up between the 5 cm coils and the 20 cm coils (MHRA Field Safety Notices – 18 to 22 May 2020 updated). Clearly, the difference between coils with lengths 5 and 20 cm is quite significant from an MRI safety perspective. Furthermore, Balt is one of the companies that have not supplied MRI safety information. This product has been recalled but some from that batch may have already been implanted. Similarly, there may have been other embolisation coils that have been incorrectly labelled.

The identification of historic devices that are no longer on the market or new devices that are not yet on the open market has been problematic during this review.

Furthermore, the different names given to embolisation/embolization/aneurysm coils or coiling may mean that material may have been missed during this review.

Finally, the use of coils to describe MRI equipment further complicated the search and may have led to some content being missed where the author has simply stated “coils” or a specific type, application or manufacturer of a coil not included in the search terms.

Conclusion

This detailed review concludes that there should be 2 separate policies from this review: cerebral vascular embolisation devices and non-cerebral vascular embolisation devices. The risk assessment (Appendix 2) covers both categories but they have individual policy statements.

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Appendix 2: Risk Assessment

1. Hazards

1.1 Hazards Shared by all GISPs

- Unknowingly scanning an implant that is unsafe for MRI, for example an implant previously unrecognized.
- Unknowingly scanning an implant where the MRI safety information has changed such that it is no longer safely scanned under a GISP.
- Knowingly scanning an MR Conditional device under a GISP outside its MRI conditions (also termed “off-label”) with the associated institutional liability.
- Unknowingly scanning undisclosed implants. When following a GISP, implants not disclosed by the patient at screening might not be discovered, whereas identifying implant specifics in patient notes can highlight inaccuracies in the patients account of their own medical history.
- Unknowingly scanning a different implant than the one intended. Confusion regarding exactly what implants or patient groups a GISP covers. When make and model are identified this ambiguity is removed (e.g. an active orthopaedic implant mistakenly categorised as a passive orthopaedic implant).

1.2 Hazards Specific to this GISP

The main hazard presented to patients with vascular embolisation coils and embolisation devices from the MRI scanner is RF heating. Whilst the static magnetic field is not a major hazard for the majority of patients with embolisation coils and devices, there are some stainless steel coils that are reportedly untested in the MR Environment.

2. Description of Risk

Historically there has been some concern about components of the magnetic field, RF power and imaging gradients affecting patients with vascular embolisation devices while in the MR Environment. However, this has not been borne out in practice and there have been no published cases of patients with any number of embolisation devices having any adverse outcome or injury as a result of been scanned in MRI. That being said, there are practical and theoretical considerations that need to be reviewed prior to scanning.

Many in the MRI community are wary of blanket statements of MRI safety for implants. One reason for this is a patient may give the wrong information when answering their MRI checklist. For example, a patient may report that they have an aneurysm coil when in fact they have an aneurysm clip. However, this risk assessment must assume that a process is in place to rule out the presence of aneurysm clips.

Embolisation coils come in many lengths, are deployed using a range of techniques and are often implanted in close proximity to other coils or implants. There are circumstances where a large number of coils need to be implanted or where coils would be implanted elongated or uncoiled, which could increase the risk of heating. The longest known individual embolisation coil is 60 cm. Non-cerebral coils with an end-to-end length greater than 10 cm are excluded from this GISP and require a local process to determine if safe to proceed with the MRI. The threshold of 10 cm is set because this is the longest length of any coil or bundle of coils reported during MRI safety testing (reported by Stryker as 10.9 cm). “The test coils were determined to produce an in-vivo temperature rise of 7.4°C or lower for 15 minutes of MR scanning in normal operational mode in 1.5 T and 3 T MR

systems" (Stryker Neurovascular). No reports of MRI safety testing from manufacturers, the literature or any case studies or systematic reviews could be found above this length. However, it is worth noting that proceeding to scan would be within the manufacturer's MR Conditions (i.e. on-label) and there have been no reported cases of excessive heating in association with MRI and these types of implants.

Older models of embolisation coils were made from stainless steel and were previously considered MR Unsafe but this labelling was subsequently updated to MR Conditional. A current model of embolisation coil made from stainless steel was identified but is not considered any greater risk than the older stainless steel embolisation coils. Whilst anecdotal evidence has suggested there exists a patent ductus arteriosus (PDA) coil that is MR Unsafe and stainless steel embolisation coils that are untested in the MR Environment, no conclusive evidence has been found to this effect during a detailed review. The majority of the embolisation devices implanted are made from non-ferromagnetic materials. The risk from the static magnetic field is considered low.

The risk of stimulation of adjacent tissue has been previously mooted as a theoretical possibility but has never been reported in practice and is rarely discussed.

3. Existing precautions

Clinicians referring patients for an MRI scan must state whether or not the patient has had an aneurysm clipped or treated. This will flag most aneurysm clips to avoid confusion.

On attending their MRI examination, patients are taken through an extensive MRI safety checklist to identify any implants that they may have. During this checklist, if patient's report any vascular aneurysm coil(s) or embolisation devices it is recommended to follow the local procedure for confirming whether an aneurysm clip is present. This may be through enquiring about the method of surgery (i.e. identify if it was via an intra-vascular procedure (coil/embolisation device) or craniotomy (clip)), reviewing prior imaging, or checking medical records.

Similarly, a local process may be required to determine if an embolisation coil is elongated with an end-to-end length greater than 10cm. This is more likely for patients with varicocele or ovarian coiling. Identification of these patients is at the discretion of local sites. Alternatively, sites may choose to scan these patients in Normal Operating Mode (as per the manufacturer's MR Conditions), or apply risk mitigation approaches such as scanning on a lower field strength scanner, low SAR sequences, interleaving of low SAR and high SAR sequences or use of a transmit-receive RF coil (provided no part of the embolisation coil(s) are within the RF field).

Due to one embolisation coil model requiring low SAR if deployed for peripheral use, the GISP recommends that embolisation coils or devices in the limbs are scanned with the whole body SAR limit < 1 W/kg, unless the implant is identified and the MR Conditions state otherwise. This is not expected to affect many patients.

We emphasise in this GISP that the presence of a GISP is no reason to ignore their MRI safety mindset and instincts. If something is unusual about a case, it can be reviewed individually.

4. Describe how existing precautions might fail to prevent adverse outcomes

The patient may fail to declare an implant that they have or inaccurately report implants. However, given the multiple instances on which patients will be asked about their medical history and the opportunity to review previous imaging, the likelihood of not detecting the presence of an aneurysm

clip or another implant as a result is low. It is the site's responsibility to exclude the presence of an aneurysm clip.

The theoretical risk of heating for implants with an end-to-end length greater than 10.9 cm has not yet been disproved and the manufacturers do not test implants in this “worst-case scenario” for RF heating. However, the absence of reported incidents suggests this theoretical risk is not borne out in practice.

5. Level of Risk

The severity of consequences was judged based off the most probable reasonably foreseeable outcomes to avoid inflating the severity with extreme edge cases.

Assessing the hazards identified and the precautions recommended, the most probable residual risk of adopting this GISP is that a patient may feel some heating or discomfort during their scan which will subside quickly once the scan is stopped and they leave the MR Environment.

Risk Description	Likelihood	Most Likely Consequence	Risk
Scanning patients in MRI under a vascular embolisation devices GISP (after confirming no aneurysm clip present)	Remote	Minor	Low

There are other potential risks associated with use of this GISP if, for example, unknowingly scanning a strongly ferromagnetic MR Unsafe embolisation device. However, based on the evidence presented in this GISP, these worse case scenarios were considered to be extremely unlikely by the panel so the overall risk of this GISP remains low.

Risk Matrix

	(1) Negligible **Minimal injury requiring no / minimal intervention or treatment.**	**(2) Minor** **Minor injury or illness, requiring minor intervention**	**(3) Serious** **Moderate injury requiring professional intervention**	**(4) Critical** **Major injury leading to long term incapacity / disability**	**(5) Catastrophic** **Incident leading to death**
(5) Frequent (≥10-3)	Medium	High	High	V High	V High
(4) Probable (<10-3 and ≥10-4)	Medium	Medium	High	High	V High
(3) Occasional (<10-4 and ≥10-5)	Low	Medium	Medium	High	High
(2) Remote (<10-5 and ≥10-6)	Low	Medium	Medium	Medium	High
(1) Improbable (<10-6)	Low	**Low**	Low	Medium	Medium

This risk matrix has been adapted from ISO 14971:2019 – Medical Devices – Application of Risk management to medical devices.

Appendix 3: Detailed Consensus – Cerebral Embolisation Devices

Consensus was defined as >90% agreement. Modifications were made to the questions during the process for clarity.

Survey 1 (25 responses)	**Agreement**	**Consensus reached**
Implantation date condition: No exclusions	92%	Yes
Time since implantation date condition: No exclusions	92%	Yes
Geographical Location Condition: No exclusions.	88%	No
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
WB SAR or B1+rms condition: First level SAR mode	32%	No
Anatomy at isocentre and patient position in scanner condition: No exclusions	92%	Yes
Static magnetic field strength condition: Up to and including 3T	100%	Yes
Spatial field gradient conditions: No exclusions for clinical MRI scanners	96%	Yes
Gradient Slew Rate condition: No exclusions for clinical MRI scanners	96%	Yes
RF polarisation condition: Circularly polarised only	100%	Yes
RF polarisation condition: No exclusions	100%	Yes
RF transmit coil condition: No exclusions	100%	Yes
RF receive coil condition: No exclusions	100%	Yes
Patient characteristics condition: No exclusions	100%	Yes
Scan duration and wait time condition: No exclusions	100%	Yes
Implant configuration condition: No exclusions	96%	Yes

Survey 2 (22 responses)	Agreement	Consensus reached
Implantation date condition: No exclusions	100%	Yes
Time since implantation date condition: No exclusions	100%	Yes
Geographical Location Condition: No exclusions.	95%	Yes
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
WB SAR or B1+rms condition: First level SAR mode	41%	No
Anatomy at isocentre and patient position in scanner condition: No exclusions	100%	Yes
Static magnetic field strength condition: Up to and including 3T	100%	Yes
Spatial field gradient conditions: No exclusions for clinical MRI scanners	100%	Yes
Gradient Slew Rate condition: No exclusions for clinical MRI scanners	100%	Yes
RF polarisation condition: Circularly polarised only	100%	Yes
RF polarisation condition: No exclusions	86%	No
RF transmit coil condition: No exclusions	100%	Yes
RF receive coil condition: No exclusions	100%	Yes
Patient characteristics condition: No exclusions	100%	Yes
Scan duration and wait time condition: No exclusions	100%	Yes
Implant configuration condition: No exclusions	100%	Yes

Survey 3 (23 responses)	Agreement	Consensus reached
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
WB SAR or B1+rms condition: First level SAR mode	83%	No
RF polarisation condition: Circularly polarised only	100%	Yes
RF polarisation condition: No exclusions	100%	Yes

Survey 4 (22 responses)	Agreement	Consensus reached
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
WB SAR or B1+rms condition: First level SAR mode	82%	No

Appendix 4: Detailed Consensus – Non-cerebral Embolisation Devices

Consensus was defined as >90% agreement. Modifications were made to the questions during the process for clarity.

Survey 1 (26 responses)	Agreement	Consensus reached
Implantation date condition: No exclusions	92%	Yes
Time since implantation date condition: No exclusions	92%	Yes
Geographical Location Condition: No exclusions.	92%	Yes
WB SAR or B1+rms condition: Normal SAR mode for all non-cerebral embolisation devices	73%	No
WB SAR or B1+rms condition: Low SAR (1 W/kg) for peripheral coils (implanted in the limbs) but Normal SAR Mode for all other non-cerebral embolisation devices	96%	Yes
Anatomy at isocentre and patient position in scanner condition: No exclusions	92%	Yes
Static magnetic field strength condition: Up to and including 1.5T	100%	Yes
Static magnetic field strength condition: Up to and including 3T	92%	Yes
Spatial field gradient conditions: No exclusions for clinical MRI scanners	100%	Yes
Gradient Slew Rate condition: No exclusions for clinical MRI scanners	96%	Yes
RF polarisation condition: Circularly polarised only	100%	Yes
RF polarisation condition: No exclusions	88%	No
RF transmit coil condition: No exclusions	92%	Yes
RF receive coil condition: No exclusions	100%	Yes
Patient characteristics condition: No exclusions	96%	Yes
Scan duration and wait time condition: No exclusions	96%	Yes
Implant configuration condition: No exclusions	58%	No
Implant configuration condition: Exclude coils that are elongated and have an end-to-end length greater than 10cm	100%	Yes

Survey 2 (20 responses)	**Agreement**	**Consensus reached**
Answers below for all non-cerebral coils excluding elongated (>10cm) and peripheral (implanted in the limbs)		
Implantation date condition: No exclusions	95%	Yes
Time since implantation date condition: No exclusions	100%	Yes
Geographical Location Condition: No exclusions.	95%	Yes
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
Anatomy at isocentre and patient position in scanner condition: No exclusions	100%	Yes
Static magnetic field strength condition: Up to and including 3T	100%	Yes
Spatial field gradient conditions: No exclusions for clinical MRI scanners	100%	Yes
Gradient Slew Rate condition: No exclusions for clinical MRI scanners	100%	Yes
RF polarisation condition: Circularly polarised only	100%	Yes
RF polarisation condition: No exclusions	90%	Yes
RF transmit coil condition: No exclusions	100%	Yes
RF receive coil condition: No exclusions	100%	Yes
Patient characteristics condition: No exclusions	100%	Yes
Scan duration and wait time condition: No exclusions	100%	Yes
Answers below for all elongated coils (>10cm)		
Include these devices in the GISP, using the same conditions as other non-cerebral coils	53%	No
Include with additional conditions	32%	No
Exclude from GISP	16%	No
Answers below for all peripheral coils (implanted in limbs)		
Include these devices in the GISP, using the same conditions as other non-cerebral coils	53%	No
Include with additional conditions	37%	No
Exclude from GISP	11%	No

Survey 3 (21 responses)	**Agreement**	**Consensus reached**
Answers below for all non-cerebral coils excluding elongated (>10cm) and peripheral (implanted in the limbs)		
WB SAR or B1+rms condition: First Level SAR mode.	43%	No
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
RF polarisation condition: No exclusions	100%	Yes
Answers below for all elongated coils (>10cm)		
If outside RF field, include in GISP using the same conditions	100%	Yes
If within RF field and at 1.5T: Normal SAR mode	71%	No
If within RF field and at 1.5T: Exclude from GISP	29%	No
If within RF field and at 3T: Normal SAR mode	60%	No
If within RF field and at 3T: Exclude from GISP	40%	No
Answers below for all peripheral coils (implanted in limbs)		
If outside RF field, include in GISP using the same conditions	100%	Yes
If within RF field and at 1.5T: First Level SAR mode	10%	No
If within RF field and at 1.5T: Normal SAR mode	71%	No
If within RF field and at 1.5T: WB SAR up to 1W/kg	95%	Yes
If within RF field and at 1.5T: Exclude from GISP	5%	No
If within RF field and at 3T: First Level SAR mode	10%	No
If within RF field and at 3T: Normal SAR mode	65%	No
If within RF field and at 3T: WB SAR up to 1W/kg	90%	Yes
If within RF field and at 3T: Exclude from GISP	10%	No

Survey 4 (22 responses)	**Agreement**	**Consensus reached**
Answers below for all non-cerebral coils excluding elongated (>10cm) and peripheral (implanted in the limbs)		
If the implant is outside of the RF transmit field: Ok to scan up to and including 3T, up to first level SAR mode	95%	Yes
If within RF field, WB SAR or B1+rms condition: First Level SAR mode.	36%	No
If within RF field, WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
Answers below for all elongated coils (>10cm)		
If within RF field and at 1.5T: First Level SAR mode	5%	No
If within RF field and at 1.5T: Normal SAR mode	77%	No
If within RF field and at 1.5T: WB SAR up to 1W/kg	82%	No
If within RF field and at 1.5T: Exclude from GISP	18%	No
If within RF field and at 3T: Normal SAR mode	68%	No
If within RF field and at 3T: WB SAR up to 1W/kg	73%	No
If within RF field and at 3T: Exclude from GISP	27%	No
Answers below for all peripheral coils (implanted in limbs)		
If within RF field and at 1.5T: First Level SAR mode	5%	No
If within RF field and at 1.5T: Normal SAR mode	77%	No
If within RF field and at 1.5T: WB SAR up to 1W/kg	100%	Yes
If within RF field and at 3T: Normal SAR mode	77%	No
If within RF field and at 3T: WB SAR up to 1W/kg	100%	No