Title: Embolisation/aneurysm coils

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Version History		
Version	Date	Description
V1	24/05/21	Initial review
V2	05/05/23	Review and extension to flow-diverting stents, removal of year and geographic restrictions, embolisation devices merged with respective embolisation coil policies

About this document

1. This template follows the guidance document "A framework for developing Generic Implant Safety Procedures (GISPs) for scanning medical implants and devices in MRI". Further details on developing a GISP can be found here.
2. The procedure statement provides a simple overview of the practical implementation of the GISP (typically completed last).
3. The Evidence review contains all the evidence which backs up the risk assessment and procedure statement (typically completed first).
4. The risk assessment provides an overview of the risk associated with the GISP
5. **Roll over each section title for information on how to complete the section**
6. Each section title links through to relevant online material – mostly this is the joint society published guidance for developing GISPS (still to be published – so currently the links send you nowhere).

1 Table of Contents

2 Procedure Statement

Disclaimer

Compiled here are Generic Implant Safety Policies (GISP's) for MRI. While steps have been taken to minimise the risk of adoption of these policies, it should be noted that these are not completely without risk. Health boards, integrated care systems, trusts or private medical organisations should consider carefully whether they wish to adopt these procedures. They should do so via their own governance process and the procedures should be reviewed prior to use. Any institutions use of this policy shall be done so at their own risk. If you are a patient reading this, then we strongly advise you to contact your healthcare provider directly with any concerns prior to attending for your scan, as approaches may vary. It remains the responsibility of the individual registered radiographer to apply their MRI knowledge and professional judgment to the situation under consideration. If there is any doubt regarding the safety of the patient then additional advice should be sought from e.g. the MR Responsible person, MRSE and MR Clinician

Brief description:

Embolisation/aneurysm coils and devices are used to provide vascular occlusion, including the treatment for aneurysms. The device is inserted into the aneurysm or vessel, reducing blood flow and promoting clotting. 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.

Liquid embolic agents are rapidly solidifying agents that are also used to provide vascular occlusion, including into an aneurysm or AVM lumen.

Radioembolisation microspheres are glass or resin spheres containing Yttrium-90 that can be used to embolise unresectable tumours.

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".

WEB aneurysm embolisation devices 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.

The evidence review produced 2 separate GISPs:

1. Cerebral vascular embolisation/aneurysm coils and embolisation devices
2. Non-cerebral vascular embolisation coils and embolisation devices

Policy 1: Cerebral vascular embolisation/aneurysm coils and embolisation devices

What the procedure covers:

This policy covers 1.5 and 3T MRI scanning of patients with cerebral vascular embolisation coils, WEB aneurysm embolisation devices, flow-diverting stents, liquid embolic devices and radioembolisation microspheres.

What the procedure does not cover, including notable exceptions:

This GISP does not cover any devices implanted outside the cerebral vascular area.

This GISP does not cover aneurysm clips, nor situations where any non-embolisation implants are placed in close proximity to embolisation implants. Situations where the catheter is broken and retained are also excluded from this GISP and must be investigated on a case-by-case basis.

If a patient reports that their coil was inserted as part of a clinical trial or research study, these must be investigated on a case-by-case basis.

Embolisation coiling can be very inconsistent in the approaches used, if there are any unusual circumstances these should be considered outside this GISP. These circumstances can be identified at the time of screening or from previous imaging and may include a large number of coils (30+) in close proximity. It is at the radiographer's professional discretion what is deemed an "unusual circumstance".

Advice summary:

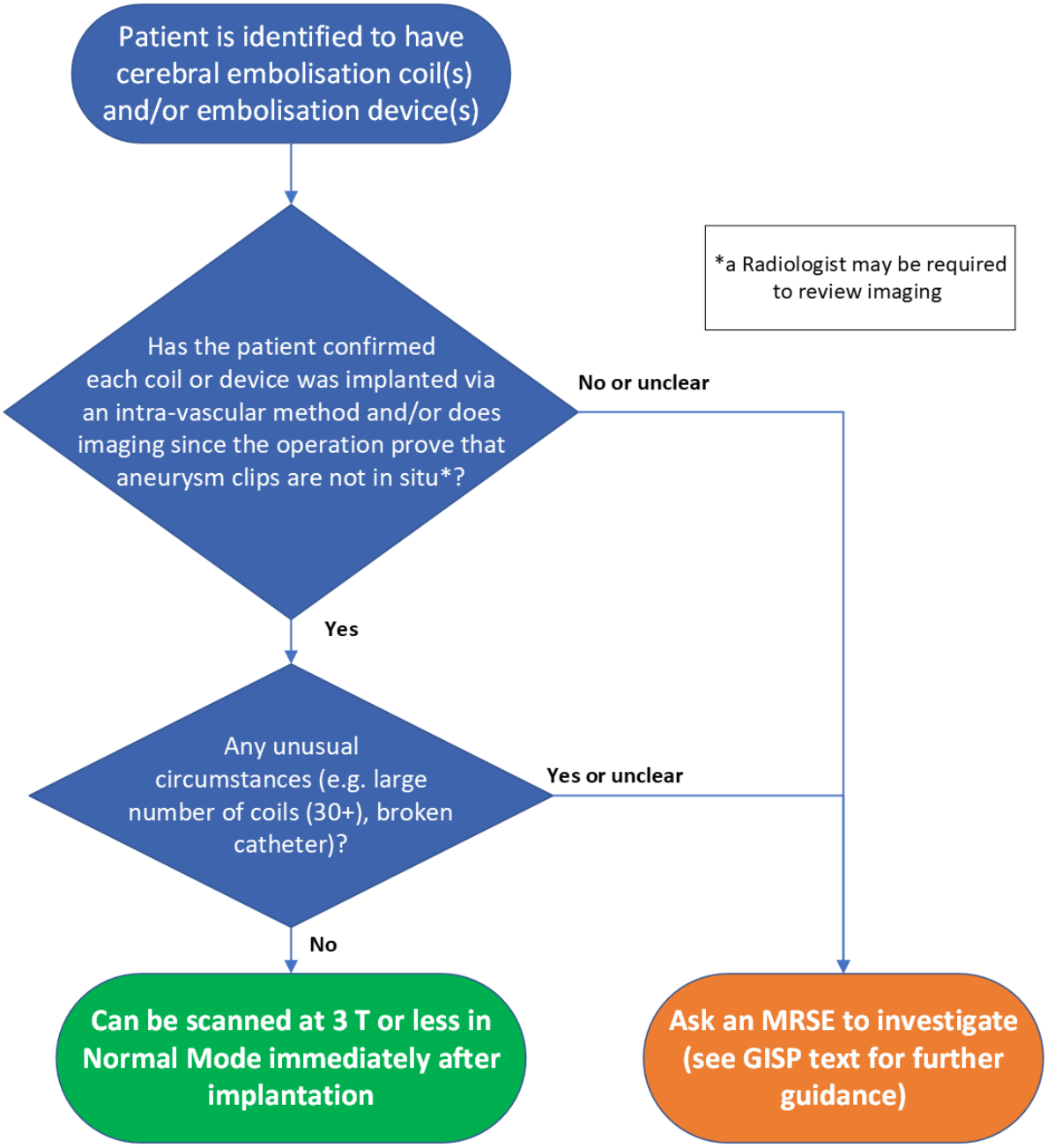

Figure: Summary of the cerebral vascular embolisation implant policy – see below for further detail

Particular care must be taken to confirm cerebral aneurysm embolisation coils and other embolisation implants are not confused with aneurysm clips. If a referrer or patient reports that a patient has cerebral aneurysm coils or other embolisation implants, the patient must be asked how the procedure or operation was performed (e.g. identify if it was via an intra-vascular procedure or craniotomy). If there is any doubt, a review of prior imaging or clinical notes is recommended to exclude the presence of an aneurysm clip. If an aneurysm clip cannot be ruled out, the make and model of each implant must be identified or a screening x-ray may be required as part of a risk-benefit analysis.

If the implant(s) fall within the remit of the GISP as outlined above, they can undergo an MR examination at 3T or less, in Normal Operating Mode, at any time after coil implantation. This advice is regardless of the value of the spatial gradient of the MRI scanner. Note that this information applies to cases in which the coils are in the area of the transmitted RF. If no clinical need to scan at 3T and 1.5T is available, scan at 1.5T.

For stent-assisted coiling, please also follow the non-coronary vascular stent policy.

Additional background information and discussion:

There will be significant susceptibility artefact from stainless steel embolisation coils that may limit the usefulness of the MR examination if the coils are near the area of interest. For platinum coils that are used more frequently, the susceptibility artefact is greatly reduced.

The following images are provided as an example of how an aneurysm clip and embolisation coils may appear in prior imaging. If in any doubt, images should be reviewed by a Consultant Radiologist and further advice can be provided from MR Physics.

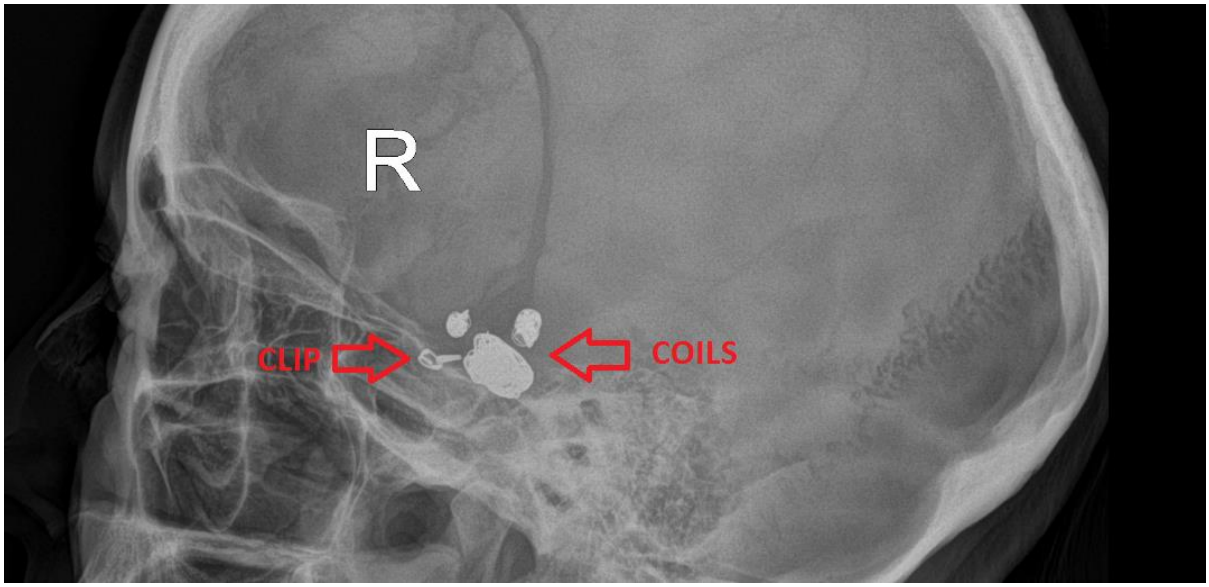

Figure: X-ray of patient with an aneurysm clip and 3 embolisation coils

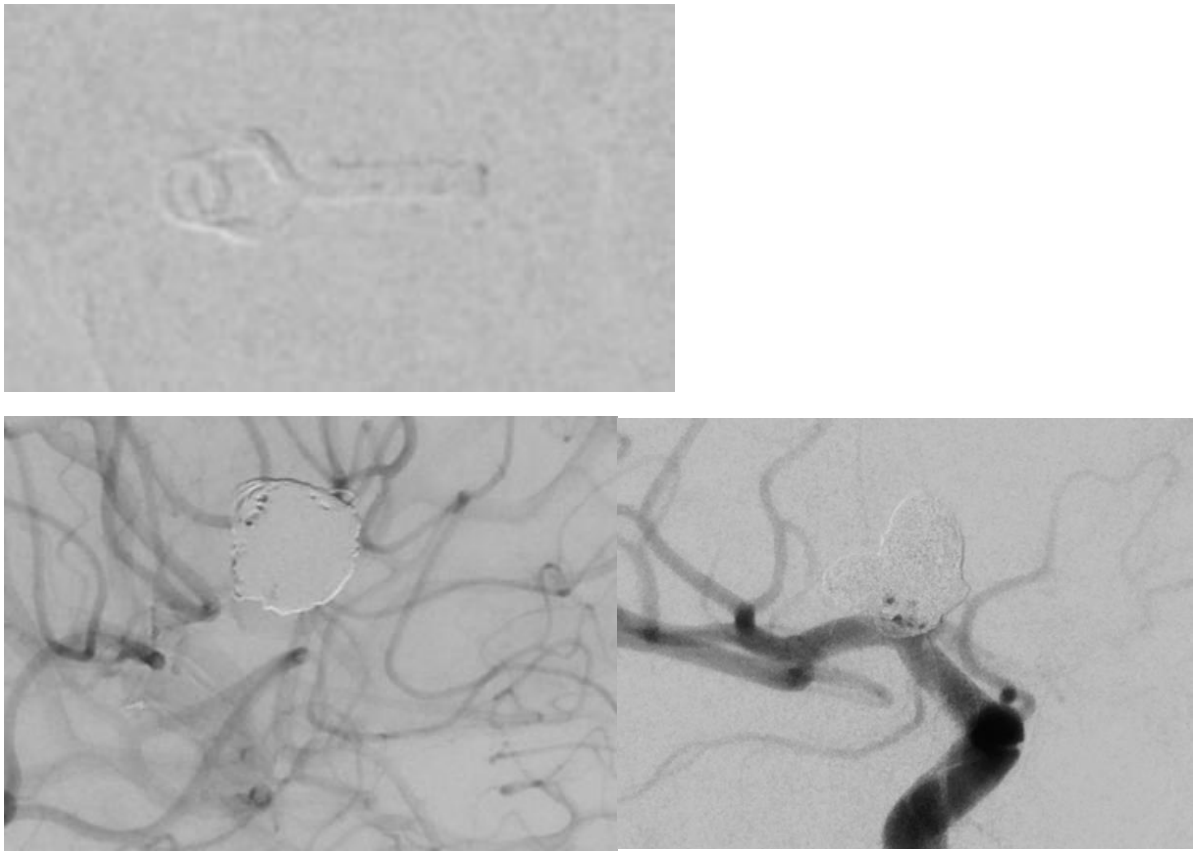

Figure: Aneurysm clips (top) and embolisation coils (bottom) may also be spotted on angiography imaging

There will likely be significant signal loss within a WEB device such that MRI cannot be used to confirm complete thrombus formation within the implant.

Policy 2: Non-cerebral vascular embolisation coils and embolisation devices

What the procedure covers:

This policy covers 1.5 and 3T MRI scanning of patients with non-cerebral vascular embolisation coils, liquid embolic devices and radioembolisation microspheres.

What the procedure does not cover, including notable exceptions:

This GISP does not cover cerebral embolisation/aneurysm implants.

This GISP does not cover aneurysm clips, lung volume reduction coils nor situations where any implants other than stents are placed in close proximity to embolisation implants. Situations where

the catheter is broken and retained are also excluded from this GISP and must be investigated on a case-by-case basis.

If a patient reports that their implant was inserted as part of a clinical trial or research study, these must be investigated on a case-by-case basis.

Embolisation coiling can be very inconsistent in the approaches used, if there are any unusual circumstances these should be considered outwith this GISP. These circumstances can be identified at the time of screening or from previous imaging and may include a large number of coils (30+) in close proximity. It is at the radiographer's professional discretion what is deemed an "unusual circumstance".

Advice summary:

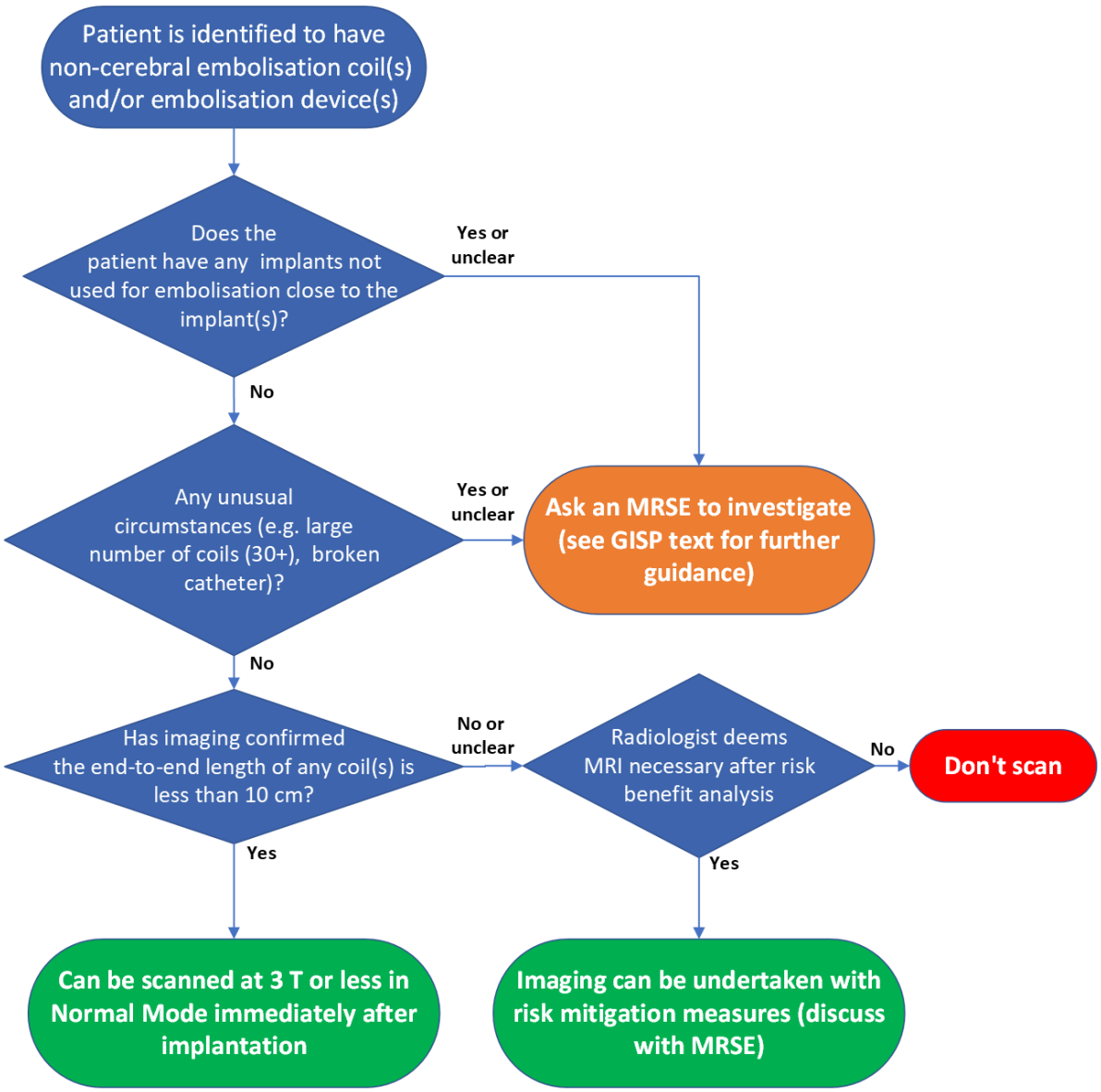

Figure: Summary of the non-cerebral vascular embolisation implant policy – see below for further detail

If available, prior imaging must be reviewed for all body embolisation to check whether a coil has been coiled and to ascertain the total length of all implants in close proximity.

If the implant(s) are confirmed to have an end-to-end length less than 10 cm (for 1.5 or 3T examinations), and the implants fall within the remit of the GISP as outlined above, the patient can undergo MR examination at 3T or less, in Normal Operating Mode, at any time after implantation. This advice is regardless of the value of the spatial gradient of the MRI scanner. Note that this information applies to cases in which the implants are in the area of the transmitted RF. If no clinical need to scan at 3T and 1.5T is available, scan at 1.5T.

If the end-to-end length of a coil or combination of coils exceeds 10 cm (for 1.5 or 3T examinations) or there is no prior imaging available then a risk-benefit analysis will be required. Guidance on the risk component is contained in the additional background information and discussion section of this policy. Risk mitigation approaches can be considered 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). If no prior imaging, x-ray screening may be considered to determine the end-to-end length of the coil(s), particularly for patients with varicocele or ovarian coiling, to inform the risk component of the risk-benefit analysis.

For stent-assisted coiling, please also follow the non-coronary vascular stent policy.

Additional background information and discussion:

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). It is not well known what the risk of heating above these lengths are as no reports of MRI safety testing from manufacturers, the literature or any case studies or systematic reviews could be found. The theoretical risk of heating is present but given the lack of reported incidents, it should be deemed low risk such that if the referral is valid then the benefit will likely outweigh the risk.

The end-to-end length of a coil can be measured on PACS. To do this, identify the image orientation that best displays the full length of the elongated coil and use the PACS measurement tool to draw a straight line from one end of the coil to the other, as demonstrated by the red line in the image below. If in any doubt, images should be reviewed by a Consultant Radiologist and further advice can be provided from MR Physics.

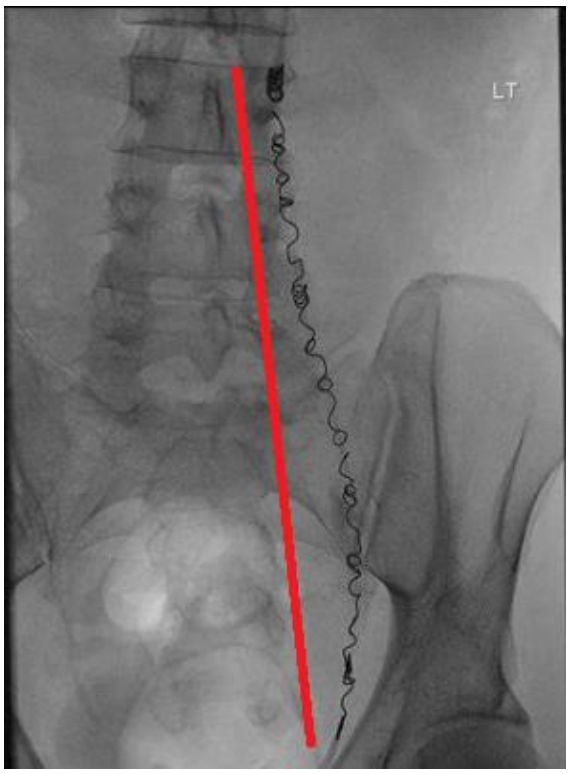

Figure: Illustration of the end-to-end (red line) length of an embolisation coil.

There will be significant susceptibility artefact from stainless steel embolisation coils that may limit the usefulness of the MR examination if the coils are near the area of interest. For platinum coils that are used more frequently, the susceptibility artefact is greatly reduced.

3 Evidence Review

3.1 Introduction

Implementing a GISP within an MRI department has a number of advantages for the department and the patient. These are outlined below:

- Facilitates scanning when implant information is not available and avoids the need for multidisciplinary team review of the specific patient case
- Facilitates immediate scanning when implant information takes some time to obtain, removing delays to patient care.
- Immediate scanning avoids wasted scan slots leading to an improved and more cost-effective MR utilization.
- Reduces the need for staff resources to obtain and evaluate specific implant information.
- Provides an evidence-based methodology for managing patients with implants where there appears to be overly conservative MR conditions.
- Allows greater emphasis to consider implants not covered by the GISP and ensures the safety focus is on these implants which are typically higher risk.
- Evidence based and therefore a more proportionate attitude towards risk

There are also a number of risks of implementing GISPS as outlined below:

- Newly developed or previously unrecognized unsafe implant (or MR Conditional where the GISP does not follow the conditions)
- Updated MR safety information that changes the safety status of an implant such that it is no longer safely scanned under a GISP
- 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.
- 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).

3.2 Clinical context

Aneurysm/embolisation coils and other embolic devices are used to provide vascular occlusion, including the treatment for intracranial aneurysms. The device is inserted into the aneurysm or vessel, reducing blood flow and promoting clotting. Coils are typically used for aneurysms and large vessel occlusion but may be used in tumour embolisation and in emergency cases. A range of metals have been used in embolisation coils including Nitinol, platinum, stainless steel, Inconel, tungsten and iridium. Liquid embolic agents typically contain a metallic powder such as gold or tantalum. Radioembolisation microspheres do not typically contain metal. Woven EndoBridge (WEB) devices are made from nitinol and platinum.

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

There is also the risk that aneurysm coils may be confused with aneurysm clips.

Migration of embolisation coils are a potential concern in ferromagnetic coils that have been implanted less than 6 weeks ago, however coils implanted nowadays are generally non-ferromagnetic. The number and length of coils may also be a safety consideration with regards to heating.

3.3 Results

3.3.1 Online MRI implant safety databases (Last updated: 05/05/23)

Review of MRI implant safety databases (performed 22/11/19, secondary search performed 25/3/20, third search performed 29/10/20, fourth 05/05/23)

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 5 (meaning check the manufacturer's website for MRI Conditions), MRI Conditional 6, MRI Conditional 8 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 implants from Shape Memory Medical were identified using the search term "embolic". The subject category "Coils, Stents, Filters and Grafts" 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 mechanims 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."*

3.3.2 Locally implanting Teams (Last updated: 11/08/23)

No local information provided at this time.

3.3.3 **Implant manufacturers** (Last updated: 05/05/23)

116 different models of embolisation coils, WEB aneurysm embolisation devices, liquid embolic devices and radioembolisation 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.

Where either a statement from the manufacturer that the product is MR Safe or MRI Conditions could be identified (90/116 implants investigated), all were safe at 3T or less in Normal Operating Mode, with a maximum spatial gradient of 7.2 T/m, with the exception of a stainless steel coil from Braile Biomedica and the Codman Trufill DCS. The IFU of the Braile Biomedica 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. The Codman Trufill DCS is listed as an 'MR Safe' Cordis product on mrisafety.com but when looking for the IFU, it was discovered that the coil was a Codman (now Cerenovus) MR Conditional coil with a maximum spatial gradient limit of 3.25 T/m. The Codman Trufill coils are discussed in more detail in the following paragraph. Another manufacturer, Kaneka, reported ASTM testing had been performed for their ED coil but did not provide a condition for the maximum spatial gradient.

Two devices were classed as MR Safe and a further nine were presumed to be MR Safe as they are non-metallic (5, e.g. PVA particles, glass and resin). A further five (excluding the Trufill DCS as conditions were provided from the manufacturer) were listed as MR Safe on mrisafety.com, despite containing metallic components. 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. No embolisation coils were listed as MR Unsafe on mrisafety.com but there were 12 devices that were listed as either MRI Conditional 5 (meaning check the MR Conditions with the manufacturer, 5 devices) or no MRI safety information found (7). Some of these implants where MR Conditions could not be found appear to be renamed or bought by another company. The main risk is around the seven coils without manufacturer information or listed on MRIsafety.com. Four of these are reported to be made from platinum or hydrogel (which may or may not contain platinum) and three are reported to be made from a platinum-tungsten alloy and are thus likely to be MR Conditional.

All manufacturers of coils listed as MR Safe on MRIsafety.com with known metallic components were contacted to request the IFU. The Trufill pushable coil and Trufill DCS coil, were reported to be platinum coils. For this reason, the company listed on MRIsafety.com, Cordis, was contacted to request their IFUs. It was discovered that Cordis never made Trufill coils and that it was actually a Codman product. They were both once part of the Johnson & Johnson company so it must have been reported incorrectly at that time. A Codman representative then reported that the Trufill DCS is MR Conditional and the Trufill pushable coil has never been tested in MRI. The statement regarding the Trufill pushable coil was retracted upon further questioning as the IFU related to the coil delivery system rather than the coil itself. However, once the correct IFU for the coils was received it contained a similar 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."

This was forwarded to Dr Shellock and he commented that this information "does not constitute proper MRI labelling" and that the MR Safe status was given prior to the change in terminology in 2005. I responded asking if he would change the status to MR Conditional now and what his recommended conditions would be for these devices. At the time of writing, we are still awaiting a response.

Even with the MR Conditional Trufill DCS, the spatial gradient conditions are quite restrictive (3.25 T/m), especially given it is listed as MR Safe on mrisafety.com. Dr Shellock was asked to look into this and provide the results of the tests performed on these coils to clarify. Again, at the time of writing, we are still awaiting a response. It is worth noting that the Trufill coils are platinum and as such are non-ferrous. Hence 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.

<u>Update 05/05/23:</u>

Additional implants were identified that fit within the scope of this GISP, with a focus on expanding the scope to include flow diverting stents and other embolisation devices:

- Microvention PHIL (Precipitating Hydrophobic Injectable liquid) – MR Safe

- Microvention FRED and FRED Jr and FRED X – MR Conditional and conditions are covered by GISP
- Acandis Derivo embolization devices – MR Conditional and stated conditions are covered by GISP
- Medtronic Pipeline Flex and Pipeline Shield embolization devices – MR Conditional and conditions are covered by GISP
- Stryker Surpass Evolve Flow Diverter System – MR Conditional and conditions are covered by GISP
- Phenox p64 MW, p48 MW, p64 flow modulation devices – MR Conditional and stated conditions are covered by GISP
- Phenox pEGASUS flow diverting stent – MR Conditional and stated conditions are covered by GISP
- Phenox pCONUS 1 and pCONUS 2 bifurcation aneurysm implant – MR Conditional and stated conditions are covered by GISP
- Phenox pCANVAS Bifurcation Aneurysm Flow Modulating Implant – MR Conditional and stated conditions are covered by GISP
- Phenox Avenir Coil – this is manufactured by Wallaby Medical so was previously identified.
- Medtronic Solitaire AB – contacted Medtronic for more information 25/5/23 but no reply. The product does not appear to be available. The Medtronic Solitaire X is outwith the scope of this GISP.
- Codman BRAVO flow diverter – MR Conditional and conditions are covered by GISP
- TaeWoong Flowise Cerebral Flow Diverter Stent – listed as MR Conditional 5 on mrisafety.com so contacted TaeWoong for more information and they stated it is not currently available anywhere in the world (30/5/23)
- Balt Extrusion SILK Vista – MR Conditional and stated conditions are covered by GISP but contacted Balt 30/5/23 to check if older models have the same conditions but no reply
- Balt Extrusion SQUID and SQUID Peri Liquid Embolic – assumed to be MR Conditional as it is an “EVOH co-polymer with micronized grain size of Tantalum powder”
- Balt Extrusion Magic Glue – assumed to be MR Safe but contacted Balt for more confirmation 30/5/23 but no reply
- Balt Extrusion Prestige Plus peripheral coil – stated to be MR Conditional on mrisafety.com and identified MR Conditions through Facebook. Contacted Balt for confirmation 30/5/23 but no reply
- Microport Tubridge – at the time of review, this device is still going through the final CE approval process but Microport shared the MR Conditions and they are covered by the GISP
- Cerenovus PulseRider – MR Conditional and stated conditions are covered by GISP
- Cerenovus Enterprise Aneurysm Stent – MR Conditional and conditions are covered by GISP

- Cerenovus CEREPAK detachable coils – MR Conditional and conditions are covered by GISP

The majority of these devices are either liquid embolic agents or embolisation devices so fit best in the previously titled "WEB embolisation devices, liquid embolic agents and radioembolisation microspheres" part of the policy, which we propose updating to "WEB embolisation devices, flow-diverting stents, liquid embolic agents and radioembolisation microspheres".

All can be scanned at 1.5T or 3T in Normal Operating Mode. The Acandis Derivo and Phenox devices do not have any static field gradient or SAR limitations stated in their IFU. I contacted these companies requesting further details. Acandis replied with "The maximum of the whole body averaged SAR were 2,7 W/kg with 1,5 T and 2,1 W/kg with 3,0 T". Phenox provided further information on the MRI safety testing of the Phenox p64, p48MW, p64MW, pEGASUS, pCANVAS and pCONUS implants. In this, the implants were shown to be within the GISP restrictions of 1.5T or 3T and Normal Operating Mode but it is worth noting that the p48MW and p64MW implants have only been tested up to a spatial field gradient of 4.5 T/m. Given these implants are made from platinum and nitinol, the risk of these implants in a higher spatial field gradient is negligible. Similarly, the Numen Coil Embolisation System from Microport has a maximum spatial field gradient of 4.5 T/m in their MR Conditions but it is made from a platinum-tungsten alloy so would not present an MRI safety concern at higher spatial field gradients. The issue of a low spatial field gradient was discussed earlier in relation to the Trufill DCS coils in the first draft of this GISP and the rationale was approved by MRSEs and an MRRP so this is not expected to present an issue.

The Cerenovus PulseRider is reported as a self-expanding stent to assist embolisation coiling. This was previously noted as an exception in this GISP but with the addition of flow diverting stents, this exclusion has now been removed. By following this GISP, the MR Conditions for this device would be followed.

3.3.4 Review of the peer reviewed literature (Last updated: 05/05/23)

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

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 literature review highlighted that most embolization coils are predominantly made from stainless steel or platinum (including some hydrogel coils which are platinum coated with a polymer), with platinum becoming the only primary material in clinical use (Hui et al., 2014). 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, 2013) and tantalum powder (Ne, 2018 and Park 2019). These are useful for vessels too small even for microcoils (Park, 2019). All three papers mention an MRI scan was performed after the liquid embolisation (Audet-Griffin, 2013, Ne, 2018 and Park 2019), despite tantalum being paramagnetic. Another article highlighted the possibility of radioembolization using Yttrium-90 microspheres (Riaz, 2009). Both liquid embolic devices and radioembolic devices have been included in the GISP.

Similarly, the Woven EndoBridge (WEB) 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. Whilst it is not an embolisation coil, the WEB device has been included in the GISP.

Stent-assisted coiling is another topic that was identified through the literature review (Li 2010, Mohlenbruch 2014, Ryu 2019). Whilst, the stent component of stent-assisted coiling is not included in this GISP, it is worth noting that we identified no MR Unsafe stents during this review. The reason for this exclusion was purely to limit the scope of the review. Stents are currently being reviewed in a separate GISP.

Finally, Woods (2007) wrote in a review of 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 the GSST GISP discussion within the Internet Search section.

Update 05/05/23:

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".

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.

3.3.5 Internet search (non peer reviewed literature) (Last updated: 05/05/23)

Review of the SMRT MR Technologist mail base (initial search completed 12/3/20, second search completed 25/3/20)

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 neurostimulation 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. Furthermore, there were suggestions on the mailbase that there are strongly ferromagnetic aneurysm coils – a potentially high risk situation. The potential for tissues adjacent to coils to be inadvertently stimulated by the gradients was also highlighted as a theoretical possibility by Dr Kanal 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.

Update 05/05/23: No further relevant posts identified

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.

Update 05/05/23: No further relevant posts identified

Internet Search (last updated 30/05/20)

GISPs from other sites were reviewed in this section:

Kings College Hospital (KCH) – 17/05/2016

Outcome (clinical scanning) – "Embolization coils for aneurysm can be scanned immediately at 1.5T and 3T for all patients and for all clinical indications, provided implanted at KCH. If implanted elsewhere embolization coils for aneurysm can be scanned immediately for the clinical indication of embolization follow up at 1.5T and 3T. If not implanted at KCH and not scanning for the clinical indication of aneurysm follow up then the make and model should be positively identified or a risk benefit analysis should be undertaken."

Generic conditions included:

- 3T or less

- Max spatial gradient of 3.3 T/m (advice to position patient centrally and avoid area near covers at entrance)
- Can be scanned immediately
- Normal Operating Mode (if including devices implanted elsewhere)
- Max dB/dt First Level

There are no contradictions with the information identified during this GISP but the site is more restrictive with coils implanted from external sites and with the maximum spatial gradient restriction. The SMRT mailbase review from this GISP is incorporated in the SMRT section above.

Guy's and St Thomas' – 30/5/2018

Only applies to cerebral aneurysm embolization coils. Suggest identification of the method of surgery suitable to rule out aneurysm clips (intra-vascular procedure vs. craniotomy). Only coils implanted in Europe or North America after 2000 are covered in the GISP – others require make/model or off-label scanning. Similarly, this GISP requires a 6 week wait. Conditions if these are met include:

- 3T or less
- Max spatial gradient of 7.2 T/m (advice to position patient centrally and avoid area near covers at entrance)
- 6 weeks after implantation
- Normal Operating Mode
- No limit on gradient switching mode

No coils labelled MR Unsafe were identified although some MRI safety information could not be found and so may be presumed MR Unsafe. It is noted that the maximum spatial gradient of 7.2 T/m is known to represent the conditions used in testing rather than a demonstrated hazard at higher spatial gradients. The six week wait was "to reduce the risk associated with previously unrecognised stainless steel (ferromagnetic) embolization coils". The GSST GISP reported that searches of the MHRA, MAUDE and MDR databases revealed no MRI safety incidents. The GSST GISP states 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. Whilst the GSST GISP mentions safety information is not available for some coils used in the 1970s and 1980s, the converse argument can be made that no evidence has been found that any are MR

Unsafe. Nonetheless, it was decided that it would be prudent within this review to treat implants prior to 2000 on a case-by-case basis to investigate and check if the benefit outweighs the risk.

At the time of this review, GSST were also updating their GISP with the aim of extending it to non-cerebral embolisation coils. A summary of this has not been included as it is still being drafted but information was shared between sites which aided the identification of coil manufacturers and relevant literature. A section from the GSST literature review sought to identify typical and maximum sizes of various aneurysms and other conditions requiring embolisation is copied below with permission from the lead reviewer for GSST.

"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 nothing after reviewing the information above:

- Splenic artery aneurysms over 10 cm have been reported (Yadav 2012, Kehagias 1998).
- Whilst the pulmonary AVM measured 6cm in Jimyung Park et al. (2015), 37 coils were used in total with diameters ranging from 3-14mm.
- 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.

<u>Sheffield – 17/7/2017</u>

This GISP contained a simple flow diagram detailing that all aneurysm coils, WEB devices or flow diverter (Pipeline) stents delivered via an intra-vascular procedure can be scanned in Normal Operating Mode at 3T or less – anything outwith this must be escalated to MR Physics or sent back to the referrer for more information. No further information was available.

A general internet search identified the following text from the Shellock book 'Magnetic Resonance Procedures: Health Effects and Safety': "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: An FDA recall on 22/9/2021 for Medtronic's Pipeline Flex Embolization Devices was identified for "Risk of Delivery System Fractures During Placement, Retrieval, or Movement of Device" (FDA, 2021). The recall includes 8,825 Pipeline Flex Embolisation Devices in the US that were distributed between 18/04/2019 to 13/08/2020 but it is unclear how many were distributed outside the US. The reason for the recall is the "risk of the delivery system's wire and tubes fracturing and breaking off when the system is being used to place, retrieve, or move the stent inside a patient". The recall goes on to state:

"Fractured pieces could be left inside the patient's brain bloodstream. It is also possible that attempts to retrieve the fractured pieces may make the patient's condition worse. The fragments can also cause other serious adverse health consequences such as continued blockage of blood vessels, stroke, and death.

There have been 59 reported device malfunctions, 10 serious injuries, and two deaths related to this recall."

The recall does not mention MRI safety.

3.3.6 Regulatory Medical Device Databases (Last updated: 11/08/23)

A search for devices containing the word "embolization" with an MR Safety Status on "MR Unsafe" produced 45 results, all of which related to detachment systems, catheters or cannulas rather than any implant.

3.3.7 Regulatory Professional and Standards bodies (Last updated: 11/08/23)

Nothing to report

3.3.8 Anecdotal evidence (Last updated: 05/05/23)

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 (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”.

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 05/05/23: No further relevant posts identified

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 useful 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 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. However, it is worth noting that Dr Shellock commented that there are embolisation coils that have not been tested for MRI.

It became apparent during the review that the topic of generic policies for embolisation coils is something that would be concerning to many 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 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, with one commenter using the analogy "I have never been hit by a car but I still look both ways before crossing the street. It is the process that keeps us safe." 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 not coiled, giving an increased heating risk. One example given where a coil is sometimes not coiled is varicocele 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 stated 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. Interestingly, one post mentioned that Stryker coils are tested using a bundle of 30 coils.

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.

Given the reports of ferrous coils and the discussion of heating risk on both the SMRT mailbase and Facebook MRI Safety group, Dr Kanal was emailed to ask to clarify whether the coils he reported to have very high deflection angles were the stainless steel Cook coils that were previously labelled MR Unsafe or if there are other ferromagnetic coils. The email also asked if he had any cause for concern in a GISP being implemented for embolisation coils and whether there was a greater risk of heating in non-cerebral embolisation coils compared with cerebral embolisation coils. His response was received on the 20th of May 2020 and is copied in full below:

"*BS"D*

Good morning Blair. There are coils that are ferromagnetic and others that are only weakly ferromagnetic and others that do not exhibit significant ferromagnetic properties. I do not any longer maintain my own database of implant MR safety labeling or test results, since I advise our own institution (as well as everyone else) that the only party that has legal responsibility for the accurate labeling of the device is the device manufacturer. Further, labeling can change over time, as your own example below demonstrates.

I do not concur with the risk of heating that so many like to quote. I feel that often we hear arguments that play both sides of the fence. They claim that there is no flow and therefore it is not necessarily catastrophic if substantial heart is inadvertently generated. Paradoxically, there are also claims of significantly reduced heating that is not entered into our calculations due to underestimating the amount of energy/heat dissipation accomplished by adjacent blood flow.

In reality in the vast majority of case where occluding coils are used occlusion is indeed accomplished, and I do not believe that one should count on or expect significant energy/heat dissipation from adjacent blood flow. I therefore DO feel that substantial MR-related heating of occluding coils IS indeed a potential source of significant patient injury since it might result in a local destructive and/or inflammatory process that might threaten the integrity of the entire vessel in which it is contained, even proximal to an adjacent occlusion if there is a vascular bifurcation proximal to and near the occluding coils.

Occluding coils can be used for aneurysms and/or for vascular structures (e.g., to intentionally occlude an internal carotid artery). The potential thermal related concerns, in my opinion, are not equivalent in these cases, but there is also overlap in the even in aneurysm occlusions one may find somewhat linear configurations (albeit far shorter in geometric (not electrical) length. When occluding larger structures, be they vascular or aneurysmal in nature, more - or even many more (as in dozens at times - literally) are often used.

For such reasons I do not personally accept ANY such generalizations as, "All occluding coils are safe in MRI" or anything of that nature, as I believe them to be unfounded and not consistent with known potential risks or clinical realities as to how these devices are used.

Does this address your questions, Blair? If I misunderstood my apologies - please clarify and I would be glad to try to address what I may have missed.

If you feel that a real time video or phone chat might be preferable, just let me know and I am sure we can arrange that as well. All the best -

manny - Wednesday, May 20, 2020; 10:50 am

Emanuel Kanal, MD, FACR, FISMRM, MRMD, MRSE, AANG
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Whilst we acknowledge the theoretical concerns raised by Dr Kanal in this response, he has not supplied any evidence to suggest a GISP cannot be safely implemented. We agree that a generic policy stating "All occluding coils are safe in MRI" would be unwise and have therefore sought to introduce strict criteria and exceptions within our generic policy. No evidence has been identified in this detailed review to suggest a carefully worded GISP would be unsafe. Nonetheless, the risk of

heating is accepted as the main risk factor in this GISP and measures have been taken to minimise this risk.

Heating risk and testing of embolisation coils in MRI:

In order to investigate the risk of heating further, Dr Shellock was contacted to explain how embolisation coils would typically be tested through his company. His initial response included the following quote: "I'm not sure that you can come up with a general policy for coils based on my experience". However, he was willing to review the policy once it was explained that it would involve a number of checks and exclusions. In response to the original query, he stated on 1/6/20:

"*To my knowledge and based on my experience testing coils for various manufacturers, typically only a single coil was tested or, in some cases, less than five were used with the configuration being a sphere shape*
The shape represented a cerebral aneurysm
The coils were never elongated or uncoiled
Thus possible heating issues for those scenarios is unknown

Frank G. Shellock, Ph.D., FACC, FACR, FISMRM"

One company, Stryker Neurovascular, provides a little detail on the MRI safety testing performed within their MRI safety statement on their website and divides their MRI safety statements into Neurovascular Use and Peripheral Use. For example, the MRI safety statement for Stryker GDC Detachable Coils, GDC 360 Detachable Coils, and Matrix2 Detachable Coils states the following for Neurovascular Use (10/06/20):

"*Non-clinical testing and analysis have demonstrated that when used in the neurovasculture, Stryker Detachable Coils are MR Conditional. A patient with Stryker Detachable Coils can be safely scanned immediately after placement of the coils, under the following conditions:*

- *Static magnetic field of 1.5 or 3.0 Tesla*
- *Spatial gradient field up to 2500 Gauss/cm (25 Tesla/m)*
- *Normal operational mode for gradients and SAR (maximum whole body averaged specific absorption rate (SAR) of lower than 2.0 W/kg and maximum head SAR of lower than 3.2 W/kg) for a total active MR scan time (with RF exposure) of 15 minutes or less per scan sequence.*

In an analysis based on the temperature rises in non-clinical testing of spherical aneurysm models, the Detachable Coils were determined to produce an in-vivo temperature rise of 4°C or less for 15 minutes of MR scanning in normal mode operation in 1.5 T and 3 T MR systems. The Detachable Coils should not migrate in this MRI environment.

Temperature testing was not conducted in arteriovenous malformations or fistulae models. MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR [imaging] parameters for the presence of this implant."

The MRI safety for the same coils but for Peripheral Use states:

"*Non-clinical testing and analysis have demonstrated that when used in peripheral vasculature Stryker Detachable Coils are MR Conditional. A patient can be safely scanned immediately after placement of the coils, under the following conditions:*

- *Static magnetic field of 1.5 and 3.0 Tesla*
- *Spatial gradient field up to 2500 Gauss/cm (25 Tesla/m)*
- *Normal operational mode for gradients and SAR (maximum whole body averaged specific absorption rate (SAR) of lower than 2.0 W/kg and maximum head SAR of lower than 3.2 W/kg) for a total of active MR scan time (with RF exposure) of 15 minutes or less per scan sequence.*

In an analysis based on the temperature rises in non-clinical testing of a bundle of 30 test coils with a length of 109mm and the calculated SAR in the patient during MR scan, 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. The Detachable Coils should not migrate in this MRI environment. The SAR limit of 2 W/kg applies only for coil placement in the torso. A reduction of SAR limits may be appropriate for coil placement in the legs or arms.

MR image quality may be compromised if the area if interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant."

Whilst the listed conditions are the same, the description of the tests performed differ. 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. Unfortunately, this statement makes no distinction between coiled and uncoiled applications nor was it clear if they had tested the coils in their elongated or uncoiled application.

Interestingly, Stryker also suggest that lower SAR limits might be appropriate for coils implanted in the limbs but do not suggest what this lower limit should be or provide a justification for this suggestion. No other manufacturer makes a distinction in the MRI safety information with regards to the location or usage of an embolisation coil.

The correspondence with Dr Shellock and related discussion regarding Stryker coils 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. This suggests checking coil positioning would be prudent prior to an MRI scan. 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.

Australian implants

With the aim of expanding the geographical locations included in the GISP, Greg Brown, a diagnostic radiographer with extensive MRI safety experience in Australia, was contacted to try to ascertain whether implant MRI labelling was adopted directly from European or North American sources and could, therefore, be included in the remit of the GISP. Through personal communications, I received a copy of his chapter "MRI Safety Standards and Guidelines in Australia" from the (in press) second edition of MRI Bioeffects, Safety, and Patient Management. Within it, the following text was included:

"*The ARTG system also approves all implanted medical devices used in Australia. The registration process assesses information provided by a device sponsor against a set of defined "essential principles". The essential principles require that use of the sponsored device does not compromise health and safety, that it has been designed and constructed to comply with safety principles, that the device remains safe throughout its useful life, and that the benefits of the device outweigh any undesirable effects. There are also additional "essential principles" regarding design and construction that include specific information to be supplied by the manufacturer. These requirements define the content of Australian Information for Use, (IFU) documents for implants and medical devices, requiring them to include "Any warnings, restrictions on use, or precautions that should be taken in*

relation to the device." The TGA regulations are similar to those of the European Union (EU). The TGA will accept conformity assessments issued by specific EU Notified Bodies or other evidence of compliance with Australian or international standards, as evidence of compliance with many of the essential principles. The ARTG requirements to provide warnings, restrictions on use, and precautions, includes exposure to MR systems, but the TGA does not prescribe a format for information regarding MRI and device interactions in the way that the U.S. Food and Drug Administration (FDA) has done since 2005. As a result, the information concerning interactions between devices and MR systems is variable but most "Instructions for Use" for an implant include FDA-style statements of the MRI conditions for safe scanning, and use the American Society for Testing and Materials International (ASTM)/IEC symbols for MR Safe, MR Conditional and MR Unsafe.

The TGA relies upon the Advisory Committee on Medical Devices (ACMD) to consider the information for an implant or device. Most of the 15 members of the advisory committee are surgeons, with one eminent biomedical engineer, but no medical physicists or members familiar with MRI safety. In 2017, the ACMD assumed the responsibilities of the Advisory Committee on the Safety of Medical Devices during a re-organization. The ACMD is reactive, collaborating closely with industry on problems that have been identified through complaints and incidents. Notably, a review of the guidelines commenced in 2016 but has not been completed at the time of writing. Several submissions regarding standardizing information for MRI-related interactions were received. Early reports suggest that the scope of the MRI section will be reduced in length (16). In the initial responses to professional (17) and industry submissions (17, 18) contained some worrying signs. The ACMD decided to disregard the International Organization for Standardization Technical Standard (ISO TS) 10974, and to remove requirements for MR specific labeling as well as patient identification cards for implants, although they recognize that such information will be helpful to the TGA to grant device approval (16). New guidelines will need close review to determine if they decrease rather than increase the information provided about devices in the MRI environment."

This suggests that the majority of Australian implants will follow EU MRI labelling. Whilst we acknowledge the risk of including embolic devices implanted in Australia is low, we have excluded them from the remit of the GISP due to the potential for the ACMD, a panel with no expertise in MR safety, to accept an implant from outwith the EU.

<u>Update 11/08/23</u>:

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 poster from NHS Lothian highlighted this 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 dept 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") but didn't provide any evidence that they knew of any MR Unsafe aneurysm coils.

Finally, Frank Shellock shared his latest ‘Guidelines for Patients with Embolization Coils Used for Cerebral Aneurysms’ in June 2023 (see Figure below). These guidelines are in general agreement with our current cerebral embolisation coil policy but it is noted there is no time or geographic restrictions included in Shellock’s policy. We propose to remove these time and geographic restrictions following this review.

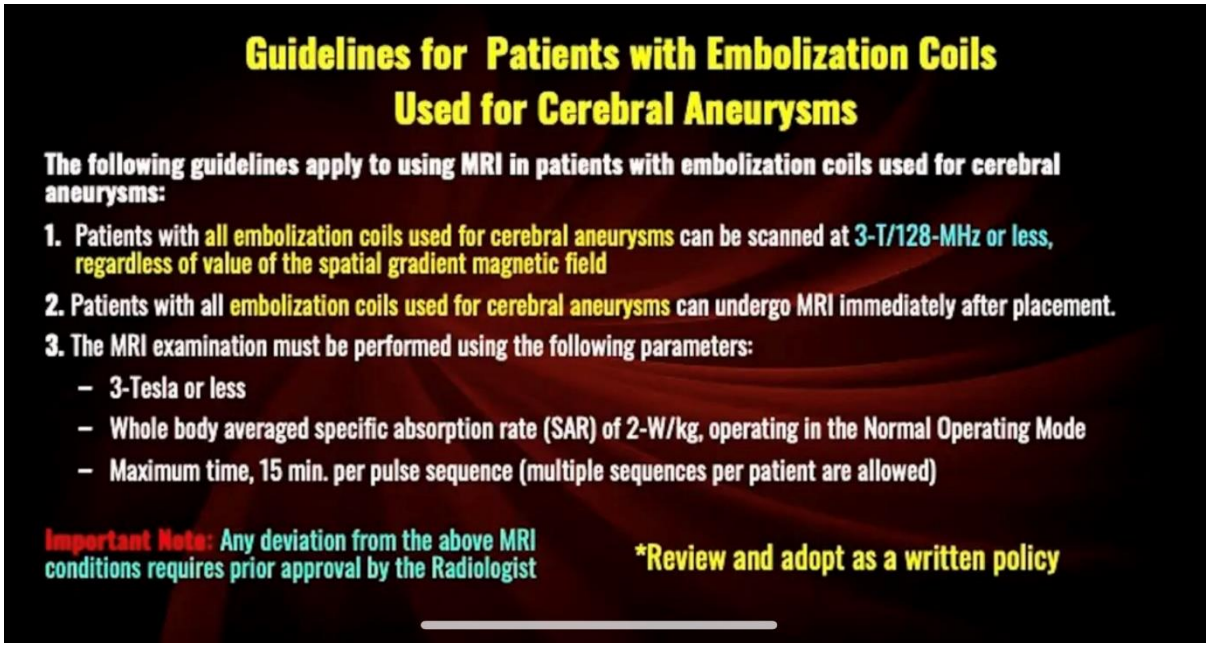

Figure: Frank Shellock’s new guidance on cerebral embolisation coils, June 2023.

3.3.9 Local MR safety databases and empirical evidence (Last updated: 05/05/23)

A search of the implant safety queries received by the NHS Greater Glasgow and Clyde MRI Physics group since the introduction of a generic shared email (~November 2017-March 2020) highlighted

21 cases involving embolisation coils. Over this period, 16 of these cases were recommended to scan (including at least 5 with no make/model information), 4 were advised to consider alternative imaging methods and perform a risk/benefit analysis if an MRI scan was deemed necessary (with at least one of these going on to be scanned) and 1 is unclear how it was resolved.

We are only aware of a patient reporting discomfort from one of these safety queries and this was unlikely to be due to the embolisation coil due to the nature of the complaint and the other implanted devices in situ.

3.4 Discussion (optional)

Summary of risks from implant associated with static field, RF and imaging gradients (last updated 30/05/20)

Risk of migration or dislodgement from the static field

Most embolisation coils are MR Conditional at 3T or less. No evidence has been identified for higher field strengths but if the make and model can be found, it may be possible assess the risk for higher field strengths in coils with no ferromagnetic components. The reports of strongly ferromagnetic embolisation coils increase the risk in cases where the make or model is not identified. However, 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 and even in these cases 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. Furthermore, the literature from Levine et al. (2007), Slesnick et al. (2016) and Alsafi et al. (2019) suggest 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.

Risk of heating, particularly at 7T or higher

Again, there is no evidence of embolisation coils being tested at 7T 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 but we acknowledge there may be cases where the risk is higher and thus require a review of previous imaging for all non-cerebral coiling. 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 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 was mentioned as a theoretical possibility by Dr Kanal on the SMRT mailbase but not mentioned or reported anywhere else, and is thus considered low risk.

Consideration of risks, specific to this implant category

There is a significant 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 known to be 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.

Discussion

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 coils/devices and non-cerebral vascular embolisation coils/devices. Embolisation devices encompass all liquid, particulate, flow-diverting stent and WEB embolisation devices. The risk assessment covers both categories but they have individual policy statements.

3.5 References

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4 Risk Assessment (DR-GGC-RISK-083)

4.1 Hazards

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.

4.2 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 coils 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 coils 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.

Similarly, 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. For non-cerebral coils with an end-to-end length greater than 10 cm or of unknown length, a risk-benefit analysis must be performed. To aid this, a risk-assessment has been performed and included as a Supplementary Risk Assessment at the end of this document. However, to quote mrisafety.com, “To date, there has been no reported case of excessive heating in association with MRI and these types of implants.”

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 reliable evidence has been found to this effect during a detailed review. Therefore the risk from the static magnetic field is considered low.

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

4.3 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 we will instruct the radiographer to enquire about the method of surgery (i.e. identify if it was via an intra-vascular procedure (coil/embolisation device) or craniotomy (clip)).

The presence of coils/embolisation devices (or absence of aneurysm clips or other implants) can also be verified through a review of the images on the PACS system, which is generally advisable for all embolisation implants given the varied applications of embolisation coils and devices.

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.

4.4 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.

4.5 Level of Risk

Risk Description	Likelihood	Consequence	Risk
Scanning patients in MRI under a vascular embolisation coils and devices GISP	Rare	Moderate	Low

Risk Matrix

Likelihood	Impact/Consequences				
	Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	Low	**Low**	Medium	Medium

Medium (Yellow) High (Orange) or Very High (Red) risks are unacceptable. A GISP should not be created where the risk is low

5 Supplementary Risk Assessment (DR-GGC-RISK-085)

5.1 Subject of Assessment

Scanning patients in MRI with vascular embolisation coils where the end-to-end length is greater than 10 cm

5.2 Hazards

The main hazard presented to patients with vascular embolisation coils from the MRI scanner is RF heating. There are circumstances where a large number of coils need to be implanted or where coils are implanted elongated or uncoiled, which could increase the risk of heating.

5.3 Description of Risk

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. The longest known individual embolisation coil is 60 cm (Endovascular Today).

The risk here relates to embolisation coils that have an end-to-end length greater than 10 cm. 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. During the detailed review for the embolisation coil GISP (generic implant safety policy), a prominent figure in MRI safety, Frank Shellock, stated:

“To my knowledge and based on my experience testing coils for various manufacturers, typically only a single coil was tested or, in some cases, less than five were used with the configuration being a sphere shape

The shape represented a cerebral aneurysm

The coils were never elongated or uncoiled

Thus possible heating issues for those scenarios is unknown”

Therefore we cannot make any assertions as to the safety in the uncoiled configuration.

The detailed review included a review of the literature, online MRI safety resources such as mrisafety.com, MRI safety mailbases and MRI safety groups on social media, GISPs from other centres - including previous reviews of the MHRA, MAUDE and MDR incident databases, and direct communication with prominent MRI safety figures – no previous incidents related to embolisation coils were identified. A review of previous incidents in NHS Greater Glasgow and Clyde identified one

patient with three cerebral Axium embolisation coils who reported some sensation/discomfort in synchronisation with certain cardiac 3T sequences but this has, to our knowledge, never been replicated and is likely to be unrelated to RF heating. The theoretical risk of heating is present but given the lack of reported incidents, if the referral is valid then the benefit will likely outweigh the risk, particularly if risk mitigation methods are utilised.

Woods (2007) wrote in a review of an 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."

An abstract for ISMRM 2019 reported 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 (7.9°C) and 13 cm (15.3°C) respectively).

Whilst this risk assessment is focused on the increased risk of RF heating due to an end-to-end length greater than 10 cm, please also consider the risks of embolisation coils generally, which is detailed in a separate risk assessment.

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5.4 Existing precautions

The presence of coils (or absence of aneurysm clips or other implants) and the end-to-end length can be verified through a review of the images on the PACS system, which is generally advisable for all embolisation coils given the varied applications of embolisation coils.

If no prior imaging, x-ray screening may be considered to determine the end-to-end length of the coil(s), particularly for patients with varicocele or ovarian coiling, to inform the risk component of the risk-benefit analysis.

For coils with an end-to-end length greater than 10 cm or of unknown length, a risk-benefit analysis must be performed. However, 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 mitigation approaches can be considered 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).

5.5 Describe how existing precautions might fail to prevent adverse outcomes

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.

5.6 Level of Risk

Risk Description	Likelihood	Consequence	Risk
Scanning patients in MRI with vascular embolisation coils where the end-to-end length is greater than 10 cm	Unlikely	Moderate	Medium

Risk Matrix

Likelihood	Impact/Consequences				
	Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	**Medium**	Medium	High
Rare	Low	Low	Low	Medium	Medium

Medium (Yellow) High (Orange) or Very High (Red) risks are unacceptable. A GISP should not be created where the risk is low