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

Recommendations for MRI scanning of patients with intrauterine devices (IUDs)

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Version Number: **1.2**

Date of issue: **01/05/2025**

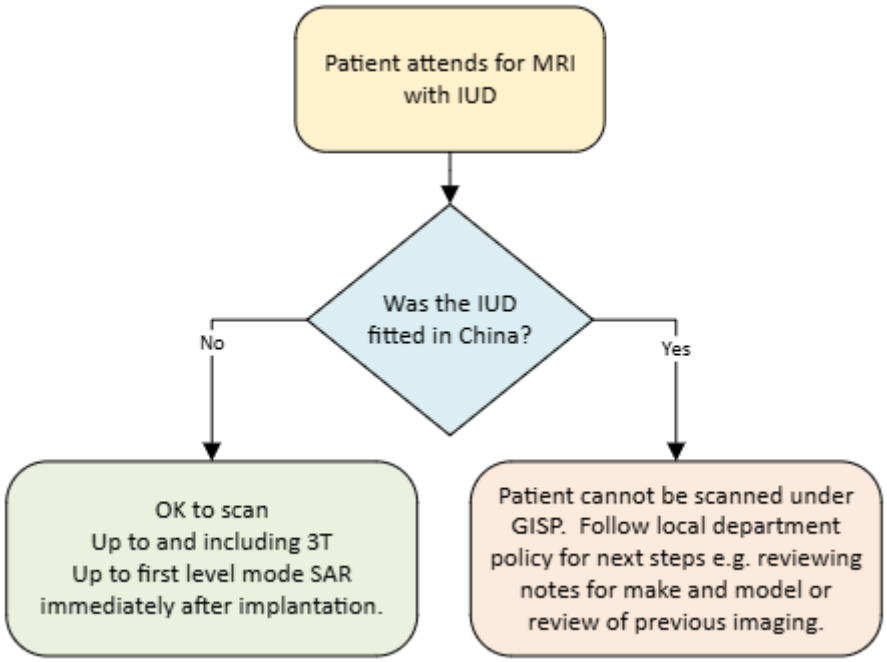
Date of last update: **26/06/2025**

Scope

The safety of patients with passive IUD implants undergoing MRI has been considered. Artefacts arising from the IUD have not been considered as part of this process.

Suggested flowchart

An example flowchart is shown below, although departments may wish to adapt to meet their local needs, e.g. they may wish to add in a question specifically about pregnancy, as consensus was not reached on this topic.



Supporting Evidence

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

Summary of Consensus

The following is the consensus of the group on 26th September 2024.

Scan condition	Recommendation (% consensus)
Implantation location	Devices fitted outside of China can be scanned without further investigation (92%)
Implantation date	No restrictions (100%)
Static Magnetic Field Strength (B_0)	Any field strength up to and including 3T (100%)
Maximum Spatial Field Gradient (SFG)	Any clinically approved SFG (100%)
Maximum Gradient Slew Rate per axis	Any clinically approved slew rate (100%)
RF Polarisation	Any clinically approved RF polarisation (100%)
RF Transmit Coil	Any clinically approved RF transmit coil (100%)
RF Receive Coil	Any clinically approved RF receive coil (100%)
MR System (RF) Operating Modes or Constraints	First Level Controlled Operating Mode permitted (92%)
Anatomy at Isocenter	No restrictions (100%)
Patient Characteristics, e.g. pregnancy	The risk of scanning a pregnant patient with a retained IUD is thought to be low. Consensus was not reached on whether the risk was low enough to include patients in GISP (46%) or require a further discussion locally (54%).
Patient Position in Scanner	No restrictions (100%)
Item Configuration	No restrictions (100%)
Scan Duration and Wait Time between sequences	No restrictions (100%)
Requirement to review previous imaging	No routine requirement to review previous imaging, however imaging may be helpful for device identification (100%)

A full breakdown of the results from the consensus process are shown in Appendix 2.

List of contributors

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

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Appendix 1: Evidence Review

1. Clinical context

Intrauterine devices (IUD) are implants inserted into the womb, most commonly T-shaped, used as a long-term form of contraception. IUDs can also be used for other purposes such as controlling bleeding or hormone replacement therapy. Typically, IUDs come in two varieties, hormonal and non-hormonal, the hormonal variants are usually constructed of plastic.

2. Results

2.1 Online MRI implant safety databases (Date queried: 06/07/23)

A search for "IUD" and "intrauterine device" was conducted in MRIsafety.com (Frank G. Shellock, 2023). From the search, a total of 15 devices were returned. From this 4 are considered MR Safe, 10 MR Conditional and 1 MR Unsafe. From the 10 MR Conditional devices, the most conservative condition is a main magnet strength of 1.5T or 3T, spatial gradient strength of 7.2T/m and scanning in normal SAR mode. The MR Unsafe implant was the Chinese Ring IUD (discussed in more detail in later sections).

As well as the above, mrisafety.com also provides a summary for this implant category. The main message from this is that stainless steel IUDs exist (i.e. the Chinese ring) and as of the time this summary was written, were untested. It also comments that the "Copper T", "Copper 7", "Multiload Cu375", "Nova T" and "Gyne T" have only been tested at 1.5T. Please note "the list" (a database of devices and their MR safety status on MRIsafety.com) contradicts this statement in the summary. "The list" states that "Copper 7", "Multiload Cu375", "Nova T" are safe at 3T as well as 1.5T. The summary also highlights that due to the material of these devices, a metal artefact is expected but should be relatively minor. Finally, the summary discusses that non-metallic IUDs exist ("Mirena" and "Implanon") and due to the lack of metallic components are considered MR Safe. It should be noted that although the Implanon device is in "the list" as an IUD, it is in fact not an IUD.

2.2 Implant manufacturers (Date queried: 19/07/23)

To better understand the general MR safety status of the device, a non-exhaustive list of implants encountered during the construction of this document. For each implant the manufacturer's advice is displayed below.

IUD Type	Manufacturer	MR Safety status	Static Condition	Maximum Spatial Gradient	SAR Condition (Whole Body)
T-safe 380A QL	Eurim Pharm	MR Conditional	Up to 3T	None Given	None Given
T-safe 380	Eurim Pharm	MR Conditional	Up to 3T	None Given	None Given
Nova T 380	Bayer	MR Conditional	Up to 3T	None Given	None Given
Mirena	Bayer	MR Unlabelled (Plastic)	N/A	N/A	N/A
Levosert	Gedeon Richter	MR Unlabelled (Plastic)	N/A	N/A	N/A
Kyleena	Bayer	MR Conditional	Up to 3T	360T/m	4W/Kg

Jaydess	Bayer	MR Conditional	Up to 3T	7.2T/m	None Given
Skyla	Bayer	MR Conditional	Up to 3T	360T/m	4W/Kg
Liletta	Odyssea Pharma	MR Safe	N/A	N/A	N/A
ParaGard	CooperSurgical	MR Conditional	1.5T or 3T	40T/m	2W/Kg
Gynefix	Soyin	MR Conditional	1.5T or 3T	129T/m	2W/kg
Flexi-T 300	Trimedica	MR Conditional	Up to 3T	None Given	None Given
Flex-T +300	Trimedica	MR Conditional	Up to 3T	None Given	None Given
Flexi-T +380	Trimedica	MR Conditional	Up to 3T	None Given	None Given
Mona Lisa (All Models)	Mona Lisa	MR Conditional	1.5T or 3T	127T/m	2W/kg
IUB Ballerine MIDI	OCON Medical Ltd.	MR Conditional	1.5T or 3T	30T/m	2W/kg
Multi-Safe 375	Eurim Pharm	MR Conditional	Up to 3T	None Given	None Given
Neo-Safe T380	Eurim Pharm	MR Conditional	Up to 3T	None Given	None Given

2.3 Review of the peer reviewed literature (Date queried: 06/07/23)

A study conducted in 1996 (Hess, Stepanow, & Knopp, 1996), discusses 3 implants (Multiload Cu375, Nova T and Gyne T, all which contain metal) and how they react in a 1.5T MRI. None of these implants showed any deflection when exposed to a 1.5T field, additionally no significant changes in temperature of the implant were measured. Another study (Berger-Kulemann, et al., 2013) conducted a survey of patients following a 3T MRI with IUDs present. Out of the 18 patients surveyed, none reported any discomfort, heating, or pain in the pelvic region during the MRI. Half of those surveyed consulted a gynaecologist after the scan, and it was determined that the IUD (Nova T370) had dislocated for one patient. The authors discuss that this patient had further MRIs at 6 and 12 months after the initial scan. In both of these scans no further complications were reported. The authors then conclude that due to this and the available literature, they believe the adverse event was unlikely to be caused by the scan. Another caveat with this study is that only half of the 18 patients consulted a gynaecologist, hence the dislocation rate may be higher than reported. Regardless, none of the 18 patients reported any adverse effects following the scan, hence there is no presented evidence to suggest that dislocation is higher than the reported amount. Finally, this study also considered the artefact caused by such implants. Out of the 9 pelvic exams conducted, no susceptibility artefact was noted by two experienced radiologists. It is also worth highlighting that one limitation of this study is the status of the IUD was not confirmed immediately prior to the exam.

A further work (Bussmann, et al., 2018) also examines the impact of a 1.5T and 3T MRI on 4 IUDs. Namely Nova T 380, Mona Lisa Cu375m, Gold Luna and the Chinese Ring. The 3T field deflection measured from Nova T 380, Mona Lisa Cu375m and Gold Luna was negligible, but the Chinese ring exhibited a high degree of deflection even at much lower spatial gradients. The torque at 3T was also rated on a scaled of 0-6 in a subjective manner. For the Nova T 380, Mona Lisa Cu375m and Gold Luna, no torque was reported (rated as 0) whereas the Chinese ring was rated as 6 (strong torque). No significant heating was

measured for any of the tested IUDs at 3T or 1.5T. Finally, the Nova T 380, Mona Lisa Cu375m and Gold Luna, exhibited a low degree of artefact in the image whereas the Chinese ring showed a much larger artefact presumably owing to the type of steel it is constructed from. The article concluded that Nova T 380, Mona Lisa Cu375m and Gold Luna can be considered MR Conditional at 1.5T and 3T, up to a SAR of 4W/kg and spatial gradient of 40T/m. The Chinese ring, however, is to be considered as MR Unsafe, due to the significant deflection and torque, which may result in injury of the patient.

A general review of MR Safety issues which are particular to female patients (Ciet & Litmanovich, 2015), briefly discusses IUDs. It discusses that a selection of both non-metallic IUDs (Mirena, Lippey loop and LCS Ultra Low Dose Levonorgestrel Contraceptive System) as well as the metallic (Multiload Cu-375, Nova T, Copper T and Copper T 380A) counterparts are MR Safe or MR Conditional for MRI up to 3T. The article makes no comment on SAR limits.

A review study considering gynaecological devices (Correia, Ramos, MacHado, Rosa, & Marques, 2012) in relation to MRI, discusses IUDs. The article considers four studies and concludes that non-metallic IUDs can be considered MR Safe, and Copper IUDs considered MR Conditional up to 3T. The article highlights that no clinically significant heating was reported in the studies nor was any significant artefact present.

A group of 10 radiologists came to a consensus regarding various MRI safety issues (MRI Safety and Devices: An Update and Expert Consensus, 2020), IUDs being one of them. They recommended that hormone (plastic) based IUDs are MR Safe, metallic IUDs are MR Conditional up to 3T, and that the Chinese Ring IUD is MR Unsafe.

In (Zieman & Kanal, 2007) the Copper T 380A IUD was tested for deflection, torque, heating and artefact influence in a 3T system. The authors found no significant, deflection, torque or heating and the artefact introduced into the image was small.

An article considering MRI safety for pregnant patients (Little & Bookwalter, 2020), highlights some potential complications with IUDs. They highlight that an intrauterine pregnancy may rarely occur due to a retained but displaced IUD. They highlight that hormonal (plastic) IUDs should pose no heating risk and that metallic IUDs are typically MR Conditional. As with previous studies, they highlight that the MR Unsafe Chinese ring does exist, which may harm the foetus.

A study carried out in 1987 considered the effect of MRI imaging on plastic and metallic IUDs in 0.35T and 1.5T (Mark & Hricak, 1987). The Lippes Loop and Cu-7 were tested; no rotation, deflection, and no statistically significant heating (between the vials containing the IUD and the control vials) was reported. Furthermore, no imaging artefacts arose due to the plastic or metallic IUD. They conclude that the study shows the Cu-7 and Lippes Loops can be safely imaged with MRI.

A review article regarding developments of IUDs in the United States (Nelson & Massoudi, 2016) briefly mentions that Skyla, Jaydess and CuT-380A IUD are MR Conditional up to 3T and 15 minutes of exposure. In (Neumann, et al., 2019), seven IUDs (Cu380, Cu375, CuT-380A-QL, GoldLuna, Gynefix with visualisation element and without and an IntraUterine Ball), which are all metallic were tested in a 1.5T and 3T MRI scanner. No significant temperature increase, deflection or torque was measured for any of the IUDs. It was found that the image artefact was limited to the region directly adjacent to the IUD. Although in the case of the GyneFix, the visualisation element (which is constructed of steel) produced a noticeable spherical artefact surrounding the element. Additionally, the IntraUterine Ball is a set of copper beads connected by a nitinol wire. It was also highlighted that a signal void artefact surrounding the nitinol wire is also present.

A study conducted in 1997 (Pasquale, Russer, Foldesy, & Mezricht, 1997) considered how the CuT380A IUD interacts with a 1.5T MRI scanner. This study was conducted in response to 3 reports to the

manufacturer of pelvic pain or heating during an MRI with the ParaGard-T380A IUD. In a 1.5T scanner, no deflection, torque, or any significant heating was observed. The authors then concluded the cases which prompted this study were unlikely to be caused by the MRI.

A large centre with significant Chinese immigrants, carried out MRI studies imaging the head of eight patients with the Chinese ring implanted (Thomas & Hindman, 2022). The centre was aware of the MR Unsafe nature of the device but following a risk-benefit analysis it was decided that the scan should go ahead. The study reports that from these 8 patients no adverse incidents were reported. Five of these patients have follow up (non-MR) imaging which confirmed the stable appearance of the IUD. The authors concluded that the displacement force and torque is not significant enough to dislodge the device and perhaps the MR Unsafe labelling should be revisited at 1.5T.

In (Bussmann, et al., 2018) at a worst case extrapolated spatial field gradient of 40T/m, the magnetic acceleration forces were shown to be 10-fold smaller than gravitational forces (for the Mona Lisa, Gold Luna and Nobo T IUD).

In (Bussmann, et al., 2018) and (Neumann, et al., 2019) the temperature rise of the Mona Lisa, Gold Luna, Nobo T IUD, Cu380. Cu375, CuT-380A-QL, Gynefix 200 and IntraUterine Ball were examined. They highlighted a max rise of 4.8°c when scanning in first level mode.

Although majority of the previous discussion revolves around China, there is evidence of stainless-steel IUDs historically used in other countries (Shubeck, 1971). There is also discussion of fragments of the Chinese ring remaining even after removal, as highlighted in (Cheung, A 10-year experience in removing Chinese intrauterine devices, 2010) and (Cheung, Embedded stainless steel ring intrauterine device, 2013). It is worth highlighting that although there is some evidence that production ceased of the stainless-steel Chinese ring by 2000, there is also evidence that it was still in use after this date. A case-study in promotion and improvement of family planning (Pillsbury & Winfrey, 2008) discusses that from an assessment carried out in 2002, expired IUDs were often found in implanting centres.

There is small probability (between 1 and 3% (Thonneau, 2001)) that a patient with an IUD may become pregnant, potentially posing a heating risk. The manufacturer of the Mona Lisa IUD was contacted and provided the following statement:

While our device has been demonstrated to be MR conditional and generally safe for use under these specified conditions, the presence of a retained IUD during pregnancy introduces additional considerations. The primary safety concerns during pregnancy pertain to the general safety of MRI procedures, rather than the IUD itself. Therefore, it's crucial to consult with a healthcare provider to assess the risks and benefits of conducting an MRI during pregnancy on a case-by-case basis.

In the case of pregnancy with a retained IUD it is expected that the implant would be removed (Kim, 2009).

2.4 Internet search (non peer reviewed literature) (Date queried: 05/07/23)

Mriquestions.com (Allen D Elster, 2023) contains an article on IUDs. The page highlights that many plastic and copper containing IUDs have been tested and appear to offer no issues up to 3T. It then goes on to discuss that the only IUD which is known to be MR Unsafe is the stainless-steel ring, distributed exclusively in China between 1988 and 2000.

2.5 Regulatory Medical Device Databases (Date queried: 26/07/23)

A search for “intrauterine device” and “IUD” was made on the GUDID database (Food and Drug Administration, 2023) which yielded no devices which are MR Conditional or MR Unsafe.

2.6 Regulatory Professional and Standards bodies (Date queried: 26/07/23)

A search of the MHRA field safety notices (Medicines and Healthcare products Regulatory Age, Alerts, recalls and safety information: drugs and medical devices, 2023) yielded no finding for search terms of "IUD" and "intrauterine devices". A search of the MAUDE (U.S. Food & Drug Administration, 2023) database for "intrauterine device MRI", "intrauterine device magnetic resonance imaging", "IUD MRI" and "IUD magnetic resonance imaging" was carried out and yielded no relevant incidents. The Faculty of Sexual & Reproductive Healthcare (Faculty of Sexual & Reproductive Healthcare, 2023) has published guidelines regarding the use of IUDs and has a section discussing MRI. Within it mentions that Mirena, levosert and Benilexa IUDs contain no metal, hence are MR Safe. It goes on to discuss some IUDs contain metallic components, it then mentions from the limited evidence, copper IUDs, Kyleena and Jaydess are safe at a field strength of 1.5 or 3T. The advice concludes by mentioning that IUDs inserted outside the UK may contain metals which are ferromagnetic, the example given being the Chinese ring. The guidance highlights IUDs currently used within the UK are not made from alternative metals such as stainless steel. It is highlighted that Kyleena and Jaydess IUDs have a silver ring on their stem but is safe to scan with a field strength of less than 3T and a gradient strength of less than 7.2T/m. The MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (MHRA, 2021) states that copper IUDs are safe at 1.5T and 3T.

2.7 Anecdotal evidence (Date queried: 26/07/23)

From the MR Safety Facebook page (MRI Safety Facebook Page, 2023) there is some discussion regarding MRI safety and IUDs. There were no reports of adverse incidents, with majority of conversations concluded that IUDs are safe up to 3T, although some posts did suggest that MR Unsafe IUDs do exist. One poster highlighted that at least 4 stainless steel IUD exists: The Chinese Ring, Chinese Double Ring, Ota Ring and Chongqing Uterine-shaped IUD. All four IUDs, are from China (Cheung, Sonographic Appearances of Chinese Intrauterine Devices, 2010) although evidence from (College of Arts and Science Case Western Reserve Univeristy, 2023) and (Museum of Contraception and Abortion, 2023) suggest the Ota Ring is not made of stainless steel but may contain a gold plated silver wire. Subsequent discussions from this post highlighted these devices were in use within Asia/China. It was worth noting that there are additional stainless-steel IUDs beyond the four highlighted above, in particular the Gamma Cu 380 IUD which was reported by Cheung (Cheung, Sonographic Appearances of Chinese Intrauterine Devices, 2010)). This IUD was produced in Shanghai containing stainless steel, hence continues the narrative of such devices originating from Asia/China.

The sexual health clinic at Raigmore Hospital was contacted to determine what IUDs are implanted. They use several IUDs but none of them contain ferromagnetic components. After discussions with the local sexual health consultant, she informed us that since 1994, she has only ever encountered one Chinese ring IUD, 10 years ago. As far as the consultant is aware, no other country used MR Unsafe IUDs other than China, but she qualified this by highlighting that this is only from their personal experience.

2.8 Local MR safety databases and empirical evidence (Date queried: 10/08/23)

None available, although the authors and reviewers are not aware of any incidents as a result of IUDs at their respective sites.

3. Risk Assessment

3.1 Hazards

Hazards Specific to GISPs

- Unknowingly scanning an MRI Unsafe implant, e.g. 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.
- 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 the GISP covers. When make and model are identified this ambiguity is removed.

Hazards specific to scanning IUDs.

- The stainless steel "Chinese ring" device excluded from the GISP unknowingly being scanned.
- Displacement of an IUD by the MRI static magnetic field, potentially causing dislodgement and malfunction.
- Heating of an IUD during scanning, potentially causing local tissue damage/burns.
- Scanning a pregnant patient with a retained IUD, potentially causing foetal heating.

3.2 Description of Risk

From the evidence review, there is no risk of migration of copper and plastic IUDs in static field strengths up to 3T. Several studies have determined that the deflection and torque was negligible in a range of IUDs (both copper and plastic). Throughout the literature there is no evidence found to suggest any significant heating of the implant will occur. From the literature review all IUDs (except the Chinese ring) exhibited very little magnetic response, hence displacement of the device is unlikely. The literature highlights a maximum temperature rise of 4.8°C in first level mode, therefore harmful amount of heating is unexpected.

It was found that none of the manufacturers guidance provided advice for RF polarisation or slew rate conditions. Given the lack of reported incidents and limited theoretical concern all clinically relevant slew rates and RF polarisation would be considered low risk. From the evidence review it can be concluded that all IUDs excluding the stainless steel Chinese ring can be safely scanned with the following conditions.

- All static fields up to 3T.
- All spatial gradients on clinically approved MR systems up to 3T. Acceptable to scan up to first level mode.
- All clinically approved slew rates.
- No restriction on clinically approved RF transmit or RF receive coils.
- No restriction on RF polarisation.
- No restriction on iso centre, patient position or implant location.
- No restriction on scan time.
- Can be scanned immediately after implantation

Although rare, ferromagnetic stainless-steel IUDs have existed in the past. Only one study (Bussmann, et al., 2018) carried out in vitro testing of a stainless-steel Chinese Ring IUD. and this demonstrated significant torque and deflection; hence the risk of uterine perforation is present. This study also showed no difference in heating at 1.5T or 3T for the stainless-steel ring compared to copper IUDs also tested, suggesting a low risk of thermal injury. As discussed previously, there is a risk of fragments remaining after a stainless-steel IUD is removed, hence caution is advised if this situation arises.

One study (Thomas & Hindman, 2022) does highlight that out of the eight patients scanned with the stainless-steel Chinese ring there were no reported adverse reactions. Suggesting the risk may be overestimated (and MR Unsafe labelling unjustified) but it is difficult to conclude this based on only one limited study. There are limited studies which test the Chinese Ring IUD safety status, but many mentions of it as an MR Unsafe device due to its ferromagnetic nature.

There is evidence that some stainless steel rings were implanted in the USA (Shubeck 1971, Thomsen 1984). One device (Comet) was "now of limited availability" in 1971. The Ihiband was discontinued in 1973, after about 100,000 were sold. There was also a predecessor to the Ihiband called the Hall-Stone ring. Given the length of time since their availability and the limited numbers produced, the likelihood of encountering these devices is very low.

In addition to the ring devices, there were at least three IUDs made in the US from stainless steel wire. The Majzlin spring, produced 1967 – 1973 from an unspecified non-magnetic stainless steel, c.100,000 devices, was withdrawn due to serious complications and is unlikely to have been retained by women long term (Shubeck 1971, Thomsen 1984). The M-213 (patented 1968) was made from 316 stainless steel, while the similar 'Web' IUDs were made from an unspecified stainless steel wire (Shubeck 1971). It appears that the Web IUDs were not commercially manufactured or distributed but were developed by an individual clinician (Shubeck, 1971). Unlike the ring devices, the wire designs are unlikely to be suited to long term retention without complications.

With the exception of the early US models, there appears to be no evidence of stainless-steel IUDs being implanted outside China (in the English written literature), however there remains a theoretical risk that such IUDs may be implanted in the surrounding geographical area. As highlighted in the literature review, stainless steel implants are potentially still in use after the year 2000. Hence despite some discussion to include the year 2000 as a threshold, it is recommended that no such date be applied.

In the instances of a retained IUD during pregnancy, there is a theoretical risk of foetal heating. During the Delphie process, consensus was not reached if this risk is low enough to be included in this procedure. The manufacturer of the Mona Lisa IUD was contacted and appears to not have any concerns over a retained IUD in a pregnant patient other than the additional concerns that would already be present with such a patient. Since it is expected that a retained IUD would most likely be removed in the case of pregnancy. Pregnant patients with retained IUD are not covered by the procedure.

3.3 Existing Precautions

The stainless-steel IUD appears to be localised to the Chinese market. Hence a sensible precaution would be to exclude patients with IUD's implanted in China from this GISP. If a patient can confirm they did not have a stainless-steel IUD implanted (to the satisfaction of the local institutions patient screening policy) or if the stainless steel IUD can be excluded through alternative imaging then the MRI can safely be undertaken following this GISP. An example of radiographic imaging of the Chinese ring can be found at Thomas & Hindman, 2022 with other examples of IUDs found in (Peri, Graham, & Levine, 2007).

3.4 Level of Risk

Risk Description	Likelihood	Consequence	Risk
Overall Risk	Rare	Minor	Low

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

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Appendix 2: Detailed Consensus (IUDs)

This was the first run through of the delphi process [1], and therefore there was a number of modifications to the questions asked to make these as clear as possible. Consensus was defined as >90% agreement

Survey 1 (25 responses)	Agreement	Consensus reached
Do you agree that a GISP is appropriate for this implant category?	100%	Yes
Do you agree with the Implantation Date Conditions: Exclude devices prior to year 2000 (China and Japan stainless steel IUD only).	64%	No
Do you agree with the Geographical Location Conditions: Exclude devices implanted in China and Japan (for pre 2000 stainless steel IUD devices only).	76%	No
Do you agree with the Static Magnetic Field Strength (B0) Condition: All Static Magnetic Field Strengths up to 3T.	96%	Yes
Do you agree with the Maximum Spatial Field Gradient (SFG) Condition: All Spatial Gradients on clinically approved MR systems up to 3T.	92%	Yes
Do you agree with the Maximum Gradient Slew Rate per axis Conditional: All Gradient Slew Rates on clinically approved MR systems up to 3T.	96%	Yes
Do you agree with the RF Polarization Condition: CP Polarised Only.	72%	No
Do you agree with the RF Transmit Coil Condition: Any Clinically Approved Transmit RF Coil may be used.	96%	Yes
Do you agree with the RF Receive Coil Condition: Any Clinically Approved Receive RF Coil may be used.	96%	Yes
Do you agree with the SAR or B1+RMS Condition: Normal Operating Mode SAR.	96%	Yes
Do you agree with the Anatomy at Isocentre Condition: Any anatomic location at isocenter is acceptable.	96%	Yes
Do you agree with the Patient Characteristics Condition (e.g. other implants nearby, patient height, patient able to communicate): No restrictions, all patients can be scanned.	88%	No
Do you agree with the Patient Position in Scanner Condition: No restrictions, patient's can be scanned in any position.	88%	No
Do you agree with the Item Configuration Condition: No restrictions, the patient can be scanned regardless of item configuration.	88%	No
Do you agree with the Scan Duration and Wait Time Condition: There is no limit on MR scan duration.	96%	Yes
Do you agree with the conditions for reviewing previous imaging: No requirement to review previous imaging.	76%	No
Do you agree with the following condition which is specific to this implant category: Patients who confirm they do not have a stainless steel ring can have an MRI regardless of which country it was implanted in, or when it was implanted.	72%	No

Survey 2 (24 responses)	Agreement	Consensus reached
Do you agree that a GISP is appropriate for this implant category?	100%	Yes
Do you agree with the Implantation Date Conditions: Exclude devices fitted in excluded geographical areas, only prior to year 2000.	25%	No
Do you agree with the Implantation Date Conditions: No date condition should be applied.	79%	No
Do you agree with the Geographical Location Conditions: Exclude devices implanted in China only.	38%	No
Do you agree with the Geographical Location Conditions: Exclude devices implanted in China and Japan.	42%	No
Do you agree with the Geographical Location Conditions: Exclude devices implanted in East Asia.	29%	No
Do you agree with the Static Magnetic Field Strength (B0) Condition: All Static Magnetic Field Strengths up to 3T.	96%	Yes
Do you agree with the Maximum Spatial Field Gradient (SFG) Condition: All Spatial Gradients on clinically approved MR systems up to 3T.	100%	Yes
Do you agree with the Maximum Gradient Slew Rate per axis Conditional: All Gradient Slew Rates on clinically approved MR systems up to 3T.	100%	Yes
Do you agree with the RF Polarisation Condition: CP Polarised Only.	25%	No
Do you agree with the RF Polarisation Condition: No restrictions on RF polarisation.	92%	Yes
Do you agree with the RF Transmit Coil Condition: Any Clinically Approved Transmit RF Coil may be used.	100%	Yes
Do you agree with the RF Receive Coil Condition: Any Clinically Approved Receive RF Coil may be used.	100%	Yes
Do you agree with the SAR or B1+RMS Condition: Normal Operating Mode SAR only.	71%	No
Do you agree with the SAR or B1+RMS Condition: First Level Operating Mode SAR .	54%	No
Do you agree with the Anatomy at Isocentre Condition: Any anatomic location at isocenter is acceptable.	100%	Yes
Do you agree with the Patient Characteristics Condition (e.g. other implants nearby, patient height, patient able to communicate, patient pregnant): No restrictions, all patients can be scanned.	58%	No
Do you agree with the Patient Characteristics Condition (e.g. other implants nearby, patient height, patient able to communicate, patient pregnant): Exclude pregnant patients from GISP, all other patients can be scanned.	63%	No
Do you agree with the Patient Position in Scanner Condition (e.g. supine, prone): No restrictions, patients can be scanned in any position.	100%	Yes
Do you agree with the Item Configuration Condition: No restrictions, the patient can be scanned regardless of IUD orientation/position.	100%	Yes
Do you agree with the Scan Duration and Wait Time Condition: There is no limit on MR scan duration or requirement for wait time between scans.	100%	Yes
Do you agree with the conditions for reviewing previous imaging: No routine requirement to review previous imaging, however previous imaging may be useful for identification where there is uncertainty over implant type.	100%	Yes
Do you agree with the following condition which is specific to this implant category: Patients who confirm they do not have a stainless steel/ring IUD can have an MRI regardless of which country it was implanted in, or when it was implanted, if the radiographer deems the patient a good historian.	92%	Yes

Survey 3 (24 responses)	Agreement	Consensus reached
Implantation Date Conditions: Devices fitted in agreed geographical areas, only prior to year 2000 should be investigated further.	25%	No
Implantation Date Condition: No date condition. Devices fitted in the agreed geographical area, no matter the date of implantation should be investigated further.	92%	Yes
Geographical Location Condition: Devices implanted in China (for agreed implantation date) should be investigated further.	83%	No
Geographical Location Condition: Devices implanted in China and Japan (for agreed implantation date) should be investigated further.	67%	No
Geographical Location Condition: Devices implanted in East Asia (for agreed implantation date) should be investigated further.	71%	No
Static Magnetic Field Strength (B0) Condition: All Static Magnetic Field Strengths up to 3T.	100%	Yes
RF Polarisation Condition: CP Polarised.	67%	No
RF Polarisation Condition: No restrictions on RF polarisation.	96%	Yes
SAR or B1+RMS Condition: Normal Operating Mode SAR.	100%	Yes
SAR or B1+RMS Condition: First Level Operating Mode SAR.	75%	No
Patient Characteristics Condition (e.g. other implants nearby, patient height, patient able to communicate, patient pregnant): No restrictions, all patients can be scanned.	63%	No
Patient Characteristics Condition (e.g. other implants nearby, patient height, patient able to communicate, patient pregnant): Exclude pregnant patients from GISP, all other patients can be scanned.	79%	No
Patients who confirm they do not have a stainless steel/ring IUD can have an MRI regardless of which country it was implanted in, or when it was implanted, if the patient is deemed to be a good historian.	88%	No

Survey 4 (26 responses)	Agreement	Consensus reached
Geographical Location Condition: Devices fitted outside China can be scanned and do not require further investigation.	92%	Yes
Geographical Location Condition: Devices fitted outside China and Japan can be scanned and do not require further investigation.	88%	No
Geographical Location Condition: Devices fitted outside East Asia can be scanned and do not require further investigation.	92%	Yes
RF Polarisation Condition: CP Polarised.	96%	Yes
RF Polarisation Condition: No restrictions on RF polarisation.	100%	Yes
SAR or B1+RMS Condition: Normal Operating Mode SAR.	100%	Yes
SAR or B1+RMS Condition: First Level Operating Mode SAR.	92%	Yes
Pregnant patients with an IUD are at increased risk from their device undergoing MRI.	54%	No