Title: Intrauterine Devices

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1.0	06/07/2023	Initial Version

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 Procedures (GISP's) for MRI. While steps have been taken to minimise the risk of adoption of these procedures, 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 the lead clinician for MR safety

Brief description:

IUDs are typically t-shaped implants designed to be used as a long-term contraception. They come in variety of forms containing both metallic and plastic components.

What the procedure covers:

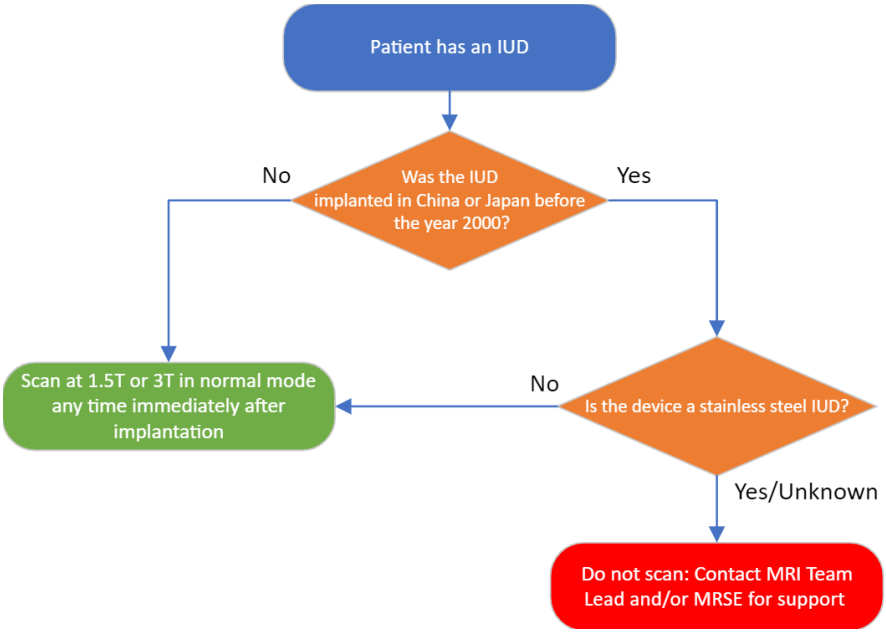
This policy considers IUDs used for the purpose of contraception.

What the procedure does not cover, including notable exceptions:

Other intrauterine devices which are used for some other purpose than contraception. IUDs implanted in China and Japan prior to 2000. Contraceptives which are not specifically IUDs are also not covered.

Advice summary:

Modern IUDs are typically MR Safe/Conditional and can be safely scanned. In the past in China and Japan there has been instances of MR Unsafe devices which should not be scanned.



3 Evidence Review

3.1 Clinical context

Intrauterine devices (IUD) are t-shaped implants inserted into the womb, used as a long-term form of contraception. Typically, IUDs come in two varieties, hormonal and non-hormonal. The hormonal variant, also known as intrauterine systems (IUS) are usually constructed of plastic. They release progestogen causing the cervical mucus to thicken, hence preventing sperm reaching the fallopian tubes. The non-hormonal variant is not completely plastic but instead contains copper. These copper ions are toxic to sperm, hence acting as a contraceptive device.

3.2 Results

3.2.1 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, n.d.). 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 mode. The MR Unsafe implant was the Chinese Ring IUD (discussed in more detail in later sections).

As well as the above, a summary for this implant category is also provided. The main message from this is that stainless steel IUDs exist (i.e. the Chinese/Japanese 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 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 copper nature 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.

3.2.2 Locally implanting Teams (Date queried: 10/07/23)

The local sexual health clinic was contacted to determine what IUDs are implanted. They use several IUDs but none of them contain ferromagnetic components. Within the Highland health board, the following IUDs are implanted.

IUD Type	Model Name
Copper Containing IUDs	TT380 T-safe 380A QL Nova T 380
Hormonal IUDs with no metal	Mirena Levosert
Non-Hormonal IUDs with a silver ring	Kyleena Jaydess

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 from personal experience and may not be correct.

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

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

3.2.4 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 it reacts 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. In all 18 patients none reported any discomfort, heating, or pain in the pelvic region during the MRI. Out of these patients one was referred to a gynaecologist. It was determined that the IUD (Nova T370) had dislocated. The authors discuss that this patient had further MRIs at 6 and 12 months after the initial scan. In both 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. Regardless this possibility cannot be fully ruled out. 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, owing to the high magnetic susceptibility of steel. 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. However, the Chinese ring is to be considered as MR Unsafe, the significant deflection and torque may result in potential 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. The recommended that hormone (plastic) based IUDs are MR Safe, metallic IUDs are 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 0.35 and 1.5T (Mark & Hricak). The Lippes Loop and Cu-7 was 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 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 all metallic are tested in a 1.5T and 3T MRI scanners. No significant temperature increase, deflection or torque was measured for any of the ICUs. The artefact was strongly limited 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 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 has been 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 conclude 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.

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

Mriquestions.com (Allen D Elster, n.d.) contains an article on IUDs. The page highlights that a large number of both 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 his known to be MR Unsafe is the stainless-steel ring, distributed exclusively in China between 1988 and 2000. A search on "www.google.com" for "stainless steel IUD" and "stainless steel intrauterine device" yielded no results of stainless-steel IUD being used out with China and Japan. No results highlighted any evidence of MR Unsafe IUDs being used after the year 2000.

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

No Relevant devices were found on the MHRA Public Access Registration Database (Medicines and Healthcare products Regulatory Age, Public Access Registration Database (PARD), n.d.), European Database (European Commission, n.d.) or Medical Device and Global Unique Device Identification Database (Food and Drug Administration, n.d.).

3.2.7 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, n.d.) yielded no finding for search terms of "IUD" and "intrauterine devices". A search of the MAUDE (U.S. Food & Drug Administration, n.d.) 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 MRI 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) that copper IUDs are safe at 1.5T and 3T.

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

From the MR Safety Facebook page (MRI Saftey Facebook Page, n.d.) there is some discussion regarding MRI safety and IUDs. There were no reports of adverse incidents, with majority of conversations concluding that IUDs are safe up to 3T, although MR Unsafe IUDs do exist. One post by Frank Shellok (A well respected figure in MRI safety) highlighted that at least 4 stainless steel IUD exists: The Chinese Ring, Chinese Double Ring, Ota Ring and Chongqing Uterine-shaped IUD. From these four IUDs, three are from China (Cheung, 2010). The exception being the Ota Ring originating from Japan (Allen Memorial Medical Library, n.d.). From discussions with Frank Shellock, it was highlighted these devices were in use within Asia/China. Please note, these 4 IUDs highlighted here appear not to include all stainless-steel IUDs (with (Cheung, 2010) highlighting the Gamma Cu 380 IUD, which was not mentioned in the Facebook post). This IUD was produced in Shanghai contains stainless steel, hence continues the narrative of such devices originating from Asia/China.

From a search of the Scottish MRI mail base (MRI Physics Scotland Mail base, n.d.), MRI Physics mail base (MRI Physics Mail base, n.d.) and the Medical Physics Mail Base (Medical Physics Mailbase, n.d.) of "IUD" and "Intrauterine Device". One poster highlighted that they were previously unaware of the MR Unsafe Chinese ring device. The poster was also not aware of any adverse incidents or near misses regarding this device. One replier to this thread also repeats that they have never encountered any adverse incidents regarding this implant or even any policies that consider it. Another post was questioning if it is worth highlighting in the safety form if an IUD is present. The poster also comments that they are aware of other centres which have fully removed this question from the safety form, despite being aware of the rare instances of a Chinese ring IUD.

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

None available.

4 Risk Assessment

4.1 Hazards

- A previously unknown device which is unsafe in MRI.
- A newly developed device not captured in this GISP which is unsafe in MRI
- Heating of a device during scanning.
- The known device which poses a risk in MRI (the "Chinese ring") being scanned

4.2 Description of Risk

From the evidence base discussed previously, 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. Furthermore, the artefact associated with the copper IUD is very constrained and is not expected to cause any significant degradation in image quality. From the manufacturers literature it can be concluded that copper and plastic IUDs as a whole are MR Conditional with the following conditions.

- 1.5T or 3T static field
- 7.2T/m
- Scan in normal mode (2W/kg whole body SAR)

Although rare, MR Unsafe IUDs have existed in the past although have been limited to the Japanese/Chinese market. Only one study (Bussmann, et al., 2018) carried out in vivo testing of a MR Unsafe IUDs (Chinese Ring). The authors highlighted it demonstrates significant torque and deflection; hence the risk of uterine perforation is present. From the only study of the Chinese Ring (Bussmann, et al., 2018) no increase in heating at 1.5T or 3T was determined over the copper IUDs also tested. Therefore, a low risk of burns is expected with the Chinese ring IUD (at 1.5 or 3T).

One study (Thomas & Hindman, 2022) does highlight that out of the eight patients scanned with this implant, there were no reported adverse reactions. Suggesting the risk may be overestimated 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.

The prevalence of the Chinese ring IUD in the UK is expected to be quite low. From discussions with the local consultant, she only encountered the Chinese Ring once 10 years ago. When considering the fact this consultant has been inserting IUDs since 1994, this further solidifies the low prevalence of stainless-steel IUDs in the UK. It is worth highlighting that although no evidence of stainless-steel IUDs was found outside of Japan or China (in the English written literature), there is a theoretical risk that such IUDs may be implanted in the surrounding geographical area.

4.3 Existing precautions

The stainless-steel IUD appears to be localised to the Chinese/Japanese market. Hence a sensible precaution is if a patient has had an IUD implanted in China or Japan prior to 2000 then this should be further investigated prior to the scan. This can be identified during the standard pre-MRI screening questionnaire. An example of radiographic imaging of the Chinese ring can be found at Thomas & Hindman, 2022)

4.4 Level of Risk

Risk Description	Likelihood	Consequence	Risk
A previously unknown device which is unsafe in MRI.	Rare	Minor	Low
A newly developed device not captured in this GISP which is unsafe in MRI	Rare	Negligible	Low
Heating of a device during scanning.	Unlikely	Negligible	Low
The known device which poses a risk in MRI (the "Chinese ring") being scanned	Rare	Minor	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

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