

## Risk Assessment Form

**ID: DR-GGC-RISK-212**

Use this form for any detailed risk assessment unless a specific form is provided. Refer to your Summary of Hazards/Risks and complete forms as required, including those that are adequately controlled but could be serious in the absence of active management. The Action Plan and reply section is to help you pursue those requiring action.

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| **Name of Initial Assessor/Reviewer:**  | Sarah Allwood-Spiers/ John McLean | **Post Held:** | Clinical Scientist/ MR Safety Expert |
| **Department:** | **Imaging** | **Date (Initial Review):** | **29/10/2023 (19/12/2018)** |
| Subject of Assessment: E.g.: hazard, task, equipment, location, people |
| Scanning patients in MRI with artificial intraocular lens (IOL) implants |
| Hazards (Describe the harmful agent(s) and the adverse consequences they could cause) |
| There are a range of hazards the MRI scanner presents. The static magnetic field may affect ferrous metallic objects. RF fields can lead to heating of metallic objects. If there are ferrous objects in the eye, there is a risk of serious eye injury due to translation or rotation of the object. |
| Description of RiskDescribe the work that causes exposure to the hazard, and the relevant circumstances. Who is at risk? Highlight significant factors: what makes the risk more or less serious – e.g.: the time taken, how often the work is done, who does it, the work environment, anything else relevant. |
| The magnetic field, RF power and imaging gradients can affect patients who have metallic implants while in the MRI environment. If a patient has ferromagnetic metallic objects in the eye, there is a risk of serious eye injury due to translation of the object. IOLs containing metals or dyes (containing iron oxide) are at risk of RF induced heating.The majority of eye lens implants are manufactured from non-metals including soft acrylics and plastic polymers, and therefore are considered MRI Safe. However, it is known that a select few, in circulation from the 1970s to early 1990s, incorporated metal in their design. Specifically, IOLs with platinum-iridium or titanium haptics and IOLs with steel-wire suturing material were used. Gwyneth A. van Rijn et al tested a range of IOLs (selection based on presence of dyes and metals and different geometric shapes) including a platinum design, at 7T. Keizer et al also tested IOLs with metallic loops (platinum and titanium) and those with steelwire suturing material at 1.0T. In both cases, the authors detected no significant displacement or RF-induced heating. The authors in [] also highlight that in the case of an IOL containing ferromagnetic material, given the lightweight of IOLs and taking into consideration in-vivo resistance provided by ocular tissue, the risk of displacement caused by magnetic forces is smaller than the risk imposed by normal daily activity in the Earth’s gravitational field. Furthermore, given the small size of IOLs (total length <2cm) [website reference], RF-induced heating is not considered a significant risk [ASTM ref] as made evident in the peer-reviewed literature. The MRI Conditional implantable miniature telescope IOL has a maximum allowable SAR of 3W/kg but is thought to be a reflection of the testing conditions rather than a true safety limit. To date there have been no reports of adverse events arising from the MRI scanning of eye lens implants. According to Shellock (2011 Reference Manual) no lens implant that has been tested has been shown to be unsafe.There is a risk that a patient will report that they have a lens implant when in fact they have contact lenses, or a retinal tack, or an eyelid spring. Some retinal tacks and eyelid springs are contraindicated for MRI. Coloured contact lenses may contain metal which may be ferrous and may cause image artefacts, so contact lenses must be removed prior to the patient entering the magnet room.A patient may give the wrong information when answering their MRI checklist. Given the multiple occasions that patients being referred for MRI (typically three) are asked about such implants, we feel the risk of this situation occurring is negligible. The radiographer goes through the checklist with the patient and confirms the details that the patient provides. |
| **Existing Precautions**  | **Describe how they might fail to prevent adverse outcomes.** |
| Patients are taken through an extensive MRI safety checklist to identify any implants that they may have. | **The patient may fail to declare an implant that they have.****The patient may confuse a lens implant with another type of ocular or maxillofacial implant.****In particular, some retinal tacks and eyelid springs are contraindicated for MRI.** |

**Level of Risk -** Is the control of this risk adequate?

Give more than one risk level if the assessment covers a range of circumstances. You can use the ‘matrix’ to show how ‘likelihood’ and ‘consequences’ combine to give a conclusion. Also, be critical of existing measures: if you can think how they might fail, or how they could be improved, these are indications of a red or orange risk.

**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** |

 **Very High**  **High** **Medium** **Low**

**Current risk level**

Given the current precautions, and how effective and reliable they are, what is the current level of risk? **Green** is the target – you have thought it through critically and you have no serious worries. Devise ways of making the risk green wherever you can. **Yellow** is acceptable but with some reservations. You can achieve these levels by reducing the inherent risk and or by effective and reliable precautions.

**High (Orange) or Very High (Red) risks are unacceptable and must be acted on: use the Action Plan section to summarise and communicate the problems and actions required.**

**Action Plan** (if risk level is **High (Orange) or Very High (Red)**

Use this part of the form for risks that require action. Use it to communicate, with your Line Manager or Risk Coordinator or others if required. If using a copy of this form to notify others, they should reply on the form and return to you. Check that you do receive replies.

Describe the measures required to make the work safe. Include hardware – engineering controls, and procedures. Say what you intend to change. If proposed actions are out with your remit, identify them on the plan below but do not say who or by when; leave this to the manager with the authority to decide this and allocate the resources required.

|  |  |  |  |
| --- | --- | --- | --- |
| **Proposed actions to control the problem**List the actions required. If action by others is required, you must send them a copy | **By Whom** | **Start date** | **Action due date** |
|  |  |  |  |

# Action by Others Required - Complete as appropriate: (please tick or enter YES, name and date where appropriate)

|  |  |
| --- | --- |
| **Report up management chain for action** |  |
| **Report to Estates for action** |  |
| **Contact advisers/specialists**  |  |
| **Alert your staff to problem, new working practice, interim solutions, etc** |  |

##### Reply

##### If you receive this form as a manager from someone in your department, you must decide how the risk is to be managed. Update the action plan and reply with a copy to others who need to know. If appropriate, you should note additions to the Directorate / Service Risk Register.

**If you receive this as an adviser or other specialist, reply to the sender and investigate further as required.**

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| **Date of last review:** | As per Q-Pulse | **Next review date:**  | As per Q-Pulse |