ID:

Risk Assessment Form

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.

Name of Assessor:	Jennifer Summersgill	**Post Held:**	Medical Physicist
Department:	MRI	**Date:**	06/05/2020

Subject of Assessment: E.g.: hazard, task, equipment, location, people

Scanning patients in MRI who have *heart valves and/or annuloplasty rings, including use of these devices in combination with stenting systems (i.e. for TAVI, TAVR and PAVR procedures)*

Hazards (Describe the harmful agent(s) and the adverse consequences they could cause)

Heart valve and annuloplasty rings come in both biological (porcine, bovine) and mechanical constructions.

The biological implants do not contain any metal and do therefore not pose an MRI safety risk.

The mechanical valves contain metal components, the safety concerns relating to these implants include:

- Projectile force or torque arising from the interaction of the static magnetic field with the implant may cause displacement or rotation of the device.
- Time varying magnetic field gradients may induce currents within conductive materials which may impact the device function.
- RF fields can lead to heating of metallic components.

Description of Risk

Describe 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 theoretical risks described above of the interactions between the MRI environment and mechanical valves have not been borne out in practice and there have been no published cases of patients with heart valves or annuloplasty rings having any adverse outcome or injury as a result of being scanned in MRI. Mechanical valves are typically made from titanium which is non-ferromagnetic, thus will not be a projectile risk. Studies have shown the force exerted onto the valve from being exposed to the static magnetic field is negligible when compared to the force exerted on the implant by the heart itself.

Upon referring a patient for an MRI scan the referrer is required to complete a safety checklist where they should declare any patient implants. The patient is also taken through an MRI safety checklist upon arrival to the MRI department. Due to the format of the safety questionnaires used, patients are typically asked about implants three times in different ways, therefore the risk of misidentification is negligible.

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.

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.

The literature and departmental experience has demonstrated there are no known risk of a heart valve or annuloplasty ring being exposed to an MRI environment. Therefore, if a patient with an undeclared heart valve or annuloplasty ring is exposed to an MRI environment the risk is negligible.

The MRI safety questionnaire required to be performed by both the referrer and the patient makes the likelihood of a heart valve or annuloplasty ring being undeclared rare. This gives the current level of risk as 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

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.

Assessment completed - date: 2/6/2021	**Review date: as per qpulse record**