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 Initial Assessor /Reviewer:	Blair Johnston	**Post Held:**	Clinical Scientist
Department:	**Imaging**	**Date (Initial Review):**	**28/10/2020 (updated 21/10/22)**

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

Scanning patients in MRI with sternal wires or sternal fixation devices

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

The main hazard presented to patients with sternal wires or sternal fixation devices from the MRI scanner is RF heating.

Patients with sternal wires or fixation devices are more likely to have other implanted devices, which must be checked separately for MRI safety.

Sternal wires and fixation devices may also affect image quality if in the imaging field of view and in proximity to any underlying pathology.

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.

Historically, patients with sternal wires have been scanned routinely and there have been very few anecdotal reports of adverse events – all of which were relatively minor and subsided once MRI scanning was stopped. There is also uncertainty over whether the adverse events were due to heating, vibration or another factor. Whilst more complex configurations of sternal wires and newer sternal fixation devices such as the MR Unlabelled sternal talon present an increased theoretical risk of localised heating, this has not been observed in practice. The make and model of any sternal fixation is not investigated in standard MRI safety practice and thus it is likely these newer wire configurations and fixation devices have been scanned without incident.

Two sternal fixation device manufacturers have labelled some of their devices as MR Unsafe in the FDA's AccessGUDID database. More detail on the investigation into devices is included in the detailed review but it is unclear whether they have undergone any formal MR safety testing. There are also other sternal fixation device manufacturers that have stated they have not performed any MR safety testing or provided no MR safety statement. This is a common situation in fixed, passive, internal orthopaedic implants but these are routinely scanned around the world despite many being MR Unlabelled or MR Unsafe. Whilst not screwed into the bone, sternal fixation devices are effectively fixed, passive, internal orthopaedic implants and all are made from non-ferromagnetic metals or weakly ferromagnetic stainless steel, suggesting the risk from the static field is negligible.

Typically, when sternal closure is required, the patient has undergone major surgery. It is important to check whether there are any other implants added during this surgery so that the MRI safety of these implants can be determined.

Many MR Conditions state that the conditions only apply when the needle has been removed from the sternal wire. As this is common practice, this is not expected to present a problem but it has been included as an exception to the policy in the unlikely event that a needle was retained.

There is a small risk that pectus (Nuss) bars and pectus excavatum devices are assumed to be included in this GISP. These are rare and sufficiently different from standard sternal fixation that they would be expected to be identified during the referral or screening process.

Existing Precautions	Describe how they might fail to prevent adverse outcomes.
On attending their MRI examination, patients are taken through an extensive MRI safety checklist to identify any implants that they may have. If a patient is identified as having a sternal wire or fixation device, they must be warned about the risk of heating and told to press the patient call button should they feel any heating or unusual sensations. When the sternum is in the imaging field of view, look to keep the SAR as low as reasonably practical, particularly if the implant is known to be a sternal fixation device such as the sternal talon. This can be done by only running sequences that are required and interleaving low SAR sequences with any high SAR sequences that are required or through the use of a local transmit/receive coil. If a patient reports any heating or unusual sensation the scan must be stopped and the incident reported to MRI Physics and on the incident management system. We emphasise that the presence of a GISP is no reason for anyone to ignore their MRI safety mindset and instincts. If something is unusual about a case, it can be reviewed individually.	There remains a small risk that patients with sternal wires or fixation devices could experience heating or vibration. However, this is likely to resolve immediately after the MRI scan is stopped.

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.

Date of last review:	As per QPulse record	**Next review date:**	As per QPulse record