ID: DR-GGC-RISK-026



### **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:	John McLean	Post Held:	MR Safety Expert
Department:	Imaging	Date (Initial Review):	11/8/20 (19/3/2015)

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

MRI Scanning of patients who have gastric bands.

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. Some gastric bands contain metallic components typically at an injection port site.

#### **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.

Patients attending for MRI scans who have gastric bands. While the majority of gastric bands are MR conditional devices, there are a small number of devices (e.g. Allegan's Easyband device and Cavu Medical's Attune device) with particularly restrictive MR conditional criteria or no statement on their MRI safety status.

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.
Location and date of implantation are determined.  If necessary, the make and model of the gastric band will be determined such that the MR safety status of the device can be determined to inform a decision in regard to patient suitability for their MRI scan.	An older device or legacy device (e.g. a device that was in clinical trials but never got to market) has not been identified.  A new gastric band with unsafe components could be brought on the market. However, the likelihood of this happening and MRI Safety experts not being aware of the device is very low. Moreover, the fact that any new device is highly unlikely to be MRI unsafe means this scenario can be considered to pose a negligible risk.

**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	<u>Medium</u>	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

Very High	High	Medium	Low
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### **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