ID: DR-GGC-RISK-075



### **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	Pauline Hall Barrientos	Post Held:	Clinical Scientist
Department:	Imaging	Date (Initial review):	26/02/2020

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

MRI scanning of patients with biliary stents inserted within Greater Glasgow and Clyde (GGC) and Ayrshire and Arran (A&A) NHS sites.

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

There are several types of hazards the MRI scanner presents. The two main hazards are

- The magnetic static field causing ferrous metals to be pulled or rotated.
- RF fields can cause heating of metallic objects.

The majority of biliary stents are made from non-ferromagnetic metallic materials. Therefore, there has been some concern that RF heating could affect patients with a biliary stent during MRI scans.

### **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.

We check the make and model of all non-vascular stents prior to a patient being scanned. However, the full name of the biliary stent is not noted in the operation notes making it difficult to determine the MR safety status and/or the MR scanning conditions. If the MR safety status/MR conditions are not met this could lead to displacement/overheating of the biliary stent.

## **Existing Precautions**

Patients are taken through an extensive MRI safety checklist to identify any implants they may have.

If the biliary stent has been inserted at a GGC or A&A site, the patient may undergo an MRI scan without checking the make and model of the stent. These biliary stents are MR conditional, and MR imaging can be performed immediately post-insertion.

The biliary stents used are WallFlex Biliary RX stents, manufactured by Boston Scientific. This has been confirmed by the surgical teams from both health boards.

Describe how they might fail to prevent adverse outcomes.

A new biliary stent may come into use in GGC or A&A departments of which we are unaware. Consequently, we may be unable to determine the scanning conditions for the device. However, these types of stents are typically made from non-ferromagnetic or plastic materials, so the risk of heating or displacement is generally low.

Additionally, devices typically must pass clinical trials before being introduced to markets. Therefore, patients with these new devices will inevitably undergo MRI scans. We actively monitor international forums on MRI safety, making it highly unlikely that a new, unsafe device would be made available to our patients without our awareness.

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	<u>Low</u>	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.

As per QPulse record

As per QPulse record

Next review date:

Date of last review: