Title: MRI safety of heart valves and annuloplasty rings, including their use in combination with stenting systems (i.e. for TAVI, TAVR and PAVR procedures)

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V1.0	02/2022	
V1.2	05/2024	No limit on spatial gradient included. Implant manufacturer and databases sections updated.

About this document

1. This template follows the guidance document "A framework for developing Generic Implant Safety Procedures (GISPs) for scanning medical implants and devices in MRI". Further details on developing a GISP can be found here.
2. The procedure statement provides a simple overview of the practical implementation of the GISP (typically completed last).
3. The Evidence review contains all the evidence which backs up the risk assessment and procedure statement (typically completed first).
4. The risk assessment provides an overview of the risk associated with the GISP
5. **Roll over each section title for information on how to complete the section**
6. Each section title links through to relevant online material – mostly this is the joint society published guidance for developing GISPS (still to be published – so currently the links send you nowhere).

1 Table of Contents

2 Procedure Statement

Disclaimer

Compiled here are Generic Implant Safety Policies (GISP's) for MRI. While steps have been taken to minimise the risk of adoption of these policies, it should be noted that these are not completely without risk. Health boards, integrated care systems, trusts or private medical organisations should consider carefully whether they wish to adopt these procedures. They should do so via their own governance process and the procedures should be reviewed prior to use. Any institutions use of this policy shall be done so at their own risk. If you are a patient reading this, then we strongly advise you to contact your healthcare provider directly with any concerns prior to attending for your scan, as approaches may vary. It remains the responsibility of the individual registered radiographer to apply their MRI knowledge and professional judgment to the situation under consideration. If there is any doubt regarding the safety of the patient then additional advice should be sought from e.g. the MR Responsible person, MRSE and MR Clinician.

Brief description:

- Used to repair or replace heart valves. Can be used in combination with a stent system (procedure known as TAVR, PAVR or TAVI).
- Constructed from bio-materials (e.g. porcine or bovine tissue), polyesters or metals (common metals include titanium, nitinol or pyrolytic carbon).

What the procedure covers:

- All commercial artificial heart valves and annuloplasty rings, including those where the specific make and model of the implant is not available.
- Valid for scanning at 1.5 and 3T (all vendors) in the normal mode of operation.
- Valid for all implants where the implant is inserted correctly.
- Valid for situations where a stent system is also incorporated (e.g. TAVR, PAVR, TAVI).
- Valid for MR scanning activity immediately post-implantation.
- Valid for all implants irrespective of year of implantation or implantation centre location.

What the procedure does not cover, including notable exceptions:

- Not valid for scanning outside the normal mode of operation.
- Not valid for implants that are not inserted correctly.
- Not valid for implants other than heart valves and annuloplasty rings.

Advice summary:

All heart valves and annuloplasty rings can be undergo an MRI scan under the following conditions:

- Field strength of 1.5 or 3 Tesla, regardless of the value of the spatial gradient magnetic field.
- Maximum whole-body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system.
- Typical imaging gradient slew rates for 1.5T and 3T clinical systems (All NHS Scotland scanners comply).

3 Evidence Review

3.1 Introduction

Implementing a GISP within an MRI department has a number of advantages for the department and the patient. These are outlined below:

- Facilitates scanning when implant information is not available and avoids the need for multidisciplinary team review of the specific patient case
- Facilitates immediate scanning when implant information takes some time to obtain, removing delays to patient care.
- Immediate scanning avoids wasted scan slots leading to an improved and more cost-effective MR utilization.
- Reduces the need for staff resources to obtain and evaluate specific implant information.
- Provides an evidence-based methodology for managing patients with implants where there appears to be overly conservative MR conditions.
- Allows greater emphasis to consider implants not covered by the GISP and ensures the safety focus is on these implants which are typically higher risk.
- Evidence based and therefore a more proportionate attitude towards risk

There are also a number of risks of implementing GISPS as outlined below:

- Newly developed or previously unrecognized unsafe implant (or MR Conditional where the GISP does not follow the conditions)
- Updated MR safety information that changes the safety status of an implant such that it is no longer safely scanned under a GISP
- When following a GISP, implants not disclosed by the patient at screening might not be discovered, whereas identifying implant specifics in patient notes can highlight inaccuracies in the patients account of their own medical history.
- Confusion regarding exactly what implants or patient groups a GISP covers. When make and model are identified this ambiguity is removed (e.g. an active orthopaedic implant mistakenly categorised as a passive orthopaedic implant).

Clinical context

Heart valve replacement is a procedure to replace leaking, narrowed or infected valves. Damaged or faulty heart valves can affect how efficiently the heart pumps blood around the body. The opening and closing mechanism of the valve leaflets enables the healthy valve to regulate the flow of blood into or out of the heart. Failure of this mechanism (e.g. through calcification) can result in poor circulatory efficiency alongside other more complicated pathologies such as ‘reverse flow’. If a damaged heart valve cannot be repaired then it can be replaced with a prosthetic heart valve.

There are two main types of prosthetic heart valve: mechanical valves and bioprosthetic valves.

Mechanical heart valves are made from materials such as titanium and carbon. They typically consist of two or three leaflets and a metal ring surrounded by a ring of knitted fabric which is sewn into the heart in place of the original valve. The main advantage of a mechanical heart valve is the durability with a lifespan of 20-30 years, making them favourable for younger patients . However, these valves

provide a surface for blood clots to form meaning the patient has to be on blood thinning medication, such as warfarin. For this reason, mechanical valves are not used in women of child-bearing age as warfarin is not used in pregnancy due to the higher risk of bleeding.

Bioprosthetic heart valves are made from human or animal (bovine (cow), equine (horse) or porcine (pig)) tissue treated with a preserving solution that is mounted on to a flexible frame to assist in deployment during surgery. Bioprosthetic valves do not require the patient to be on blood-thinning medication. However, bioprosthetic valves are less durable than mechanical valves and require replacement every 10-15 years (1).

Image credit: Heart Valve Surgery - Mechanical Vs. Bioprosthetic – Which Is Better? • MyHeart

The procedure for replacing heart valves is usually performed by open heart surgery. This involves an incision into the chest to access the heart. The heart is stopped and a heart-lung machine is used to maintain cardiac function during the operation. The damaged or faulty valve is removed and replaced with the new prosthetic one. The heart is then restarted and the opening in the chest is closed. Alternative procedures are available if open heart surgery is deemed too risky, such as a transcatheter aortic valve implementation (TAVI) where the replacement valve is guided into place through the blood vessels, rather than through a large incision in the chest.

An annuloplasty is a procedure to tighten or reinforce the ring around a valve in the heart. The ring around a valve can widen and change from its normal shape which may occur if the heart is enlarged. Widening of the ring can cause the valve leaflets to not close properly which can cause blood to leak backwards through the valve. To perform an annuloplasty doctors sew a ring to the existing ring around the valve which may be rigid or flexible.

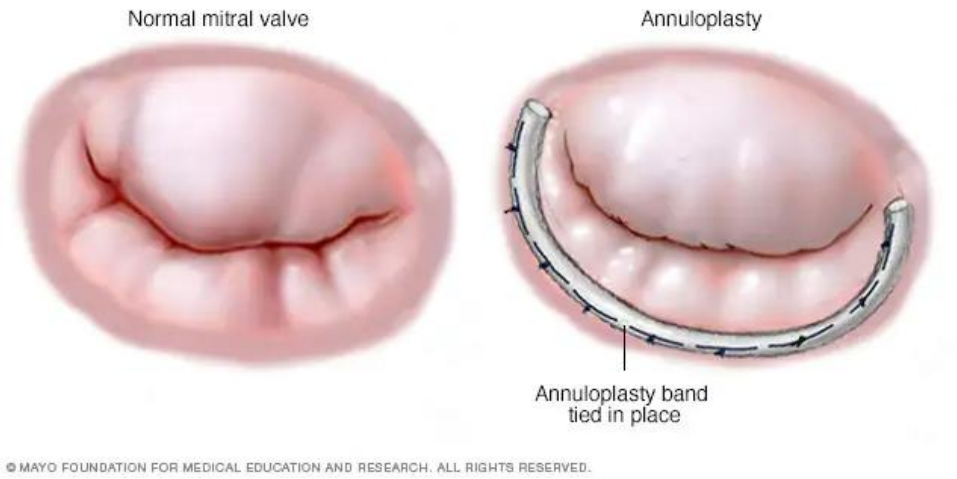

Image credit: Annuloplasty: Surgery to repair a leaky heart valve - Type - Mayo Clinic

Results

Online MRI implant safety databases (Date queried: DD/MM/YY)

Source: www.mrisafety.com

Date of query: 25/03/2024

Comments: Search on www.mrisafety.com using search terms 'heart valve' and 'annuloplasty rings'. Object category: Heart Valves and Annuloplasty Rings.

Results: The search returned 343 implants, all either defined as MR Safe or MR Conditional. These items are also included in Section 3.3.3.

Frank Shellock also has his own guidelines titled: Guidelines for the Management of Patients with Heart Valve Prostheses and Annuloplasty Rings Referred for MRI Examinations. This contains a comprehensive literature review on guidelines for the management of patients with heart valve prostheses and annuloplasty rings referred for MRI procedures. The guidelines covers heart valve prostheses, including transcatheter aortic valve replacements (TAVR), transcatheter aortic valve implantation (TAVI) devices, percutaneous aortic valve replacement (PAVR) implants, transcatheter heart valves (THV), as well as other similar valve implants used in association with minimally invasive procedures and annuloplasty rings.

The review concluded that a patient with a heart valve prosthesis or an annuloplasty ring may undergo MRI using the following guidelines:

- 3 Tesla or less
- No restriction for the spatial gradient magnetic field
- Whole body averaged specific absorption rate (SAR) of 2 W/kg (i.e. operating in the Normal Operating Mode for the MR system)
- Maximum imaging time, 15 minutes per pulse sequence (multiple pulse sequences per patient are allowed)

Any deviation from the above MRI conditions requires approval by a radiologist.

Locally implanting Teams

An MRI safety review for NHS Tayside (NHST) has been performed twice (in 2016 and 2018) for scanning heart valves and annuloplasty rings. Information was sourced from previous safety investigations within NHST, local discussions, manufacturer guidelines, relevant literature and Frank Shellock's website. Table 2 summarises the results from these audits. The MRI Conditional devices were scanned at 1.5 T in normal mode.

2016 Review	**Total: 136**	
Manufacturer	**Number of Products Reviewed**	**Safety Status**
AorTech	2	MR Conditional
ATS Medical	11	MR Conditional
Pfizer Inc.	8	MR Safe
Edwards Lifesciences	21	MR Safe
	29	MR Conditional
Johnson & Johnson	1	MR Safe
	3	MR Conditional
Medtronic	18	MR Safe
	2	MR Conditional
LivaNova (Includes Sorin and Carbomedics)	2	MR Safe
	16	MR Conditional
St Jude	23	MR Conditional
2018 Review		**Total: 53**
Edwards Lifesciences	1	MR Safe
	15	MR Conditional
St Jude	9	MR Conditional
Medtronik	8	MR Conditional
LivaNova (Includes Sorin and Carbomedics)	6	MR Conditional

Unrecorded	2	MR Safe
	12	MR Conditional

The result of both MR safety audits supports the literature that all devices are safe to scan within the conditions stated in the section 'Review of MRI implant safety Databases'. Something to note from the 2018 audit is that 14 of the safety requests did not reference the device manufacturer. However, they were still recommended as safe to scan provided the above guidelines were adhered to. Additionally, NHST does not perform implantation of prosthetic heart valves or annuloplasty rings. These patients usually come from other centres in Scotland and so the manufacturers represented in the NHST audit results should provide a good overview of typical implants used in Scotland.

At the Institute for Neurosciences in NHS Greater Glasgow and Clyde they have been scanning patients with heart valves at 3T for more than 15 years without any incidents.

This GISP has been implemented throughout Scotland since 2020 with no incidents having been reported.

Implant manufacturers

A comprehensive search of all the manufacturers listed on www.mrisafety.com was performed covering 234 heart valves and 60 annuloplasty rings. None of these implants were listed as MR Unsafe.

The MR safety advice from the main heart valve manufacturers was reviewed, including Carbomedics, Edwards Lifesciences, St Jude Medical (now Abbott) and Medtronic. Any heart valves or annuloplasty rings that had MRI scanning conditions more restrictive than being MR Conditional at 3T when scanning in Normal mode are displayed in Table 1.

Manufacturer	**Document**	**Comments**	**Date Accessed**
Carbomedics	MRI Information for Corcym Heart Valve Prostheses and Annuloplasty devices Microsoft Word - CC-MK-00000_B - MRI for OUS.docx (corcym.s3.eu-central-1.amazonaws.com)	All Corcym heart valves and annuloplasty rings manufactured are MR Safe or MR Conditional up to 3T. The most restrictive condition is for the Biological Valves Model 12 and Model LX which are MR Conditional under the following conditions: • 3T or less • Spatial gradient field of 525 G/cm or less • Maximum whole-body averaged SAR of 1.5 W/kg for 20 minutes of scanning.	17/04/2024

Carpentier-Edwards	MRI Information OUS MRI Letter.pdf (kc-usercontent.com)	All Carpentier-Edwards heart valves and annuloplasty rings manufactured are MR Safe or MR Conditional up to 3T with the following exceptions: 1. **Starr-Edwards aortic and mitral prosthesis, Models 1000, 1200, 2300, 2310, 2400, 6000, 6120, 6300, 6310, 6320, 6400. "**Testing of these devices in a static magnetic field up to 1.5 tesla show that they are safe during MR procedures performed at 1.5 tesla or less though they are weakly ferromagnetic." 2. **Starr-Edwards aortic and mitral prosthesis, Models: Pre-1000, Pre-6000, 1260, 2320, 6520 (plastic disk)**. "Testing of these devices in a static magnetic field up to 2.35 tesla show that they are safe during MR procedures performed at 2.35 tesla or less though they are weakly ferromagnetic." 3. **Annuloplasty rings, Models 4400 and 4500, marketed from 1980 to 1983**, were made of stainless steel. "Therefore we are unable to advise on the safety of MR procedures for patients with these particular annuloplasty rings." 4. **Classic annuloplasty mitral and tricuspid rings + those with Duraflo treatment, Models 4400, 4500, 4425, 4525, Edwards MC3 Tricuspid annuloplasty ring Model 4900.** "Testing of these devices in a magnetic field of 1.5 tesla has shown that these devices are safe and compatible during MRI (magnetic resonance imaging) procedures. Rings have titanium alloy cores."	17/04/2024

		5. **Edwards-Duromedics bileaflet aortic and mitral prostheses, Models 3160, 3160R, 9120, 9120R, Edwards TEKNA bileaflet aortic and mitral valves, Models 3200, 9200.** "Testing of these devices in a static magnetic field up to 1.5 tesla show that they are safe during MR procedures performed at 1.5 tesla or less. Valve housings are composed of solid pyrolytic carbon and the leaflets are graphite substrate coated with pyrolytic carbon. The retainer rings in the sewing ring are commercially pure titanium grade II. The stiffener rings are Stellite 25." 6. **Edwards MIRA mechanical aortic and mitral valves, Models 3600, 3600f, 3600u, 9600**. "Testing of these devices in a magnetic field of 1.5 tesla has shown that these devices are safe and compatible during MRI (magnetic resonance imaging) procedures. Valve housing is composed of ASTM B348 Grade 5 Ti6Al-4V titanium alloy coated with turbostatic carbon. Leaflets are composed of graphite substrate coated with pyrolytic carbon"	

The specific wording in the Carbomedics Corcym MRI information is that the devices "have been demonstrated to pose no known hazard in a specified MR environment with specified conditions of use". Similarly, the wording for the devices in Table 1 in the Carpentier-Edwards devices are that "testing of these devices in a magnetic field of 1.5 Tesla has shown...". This implies these conditions are only listed as that is what they have been tested to, not that this is a limit above which there is a risk to the patient. Additionally, all of the valves in Table 1 are made from similar materials to other heart valves and annuloplasty rings that do not have these restrictive values. Therefore, there appears no substantive evidence to exclude these devices from being scanned at 3T in Normal Mode. Similarly, although there are annuloplasty rings Model 4400 and 4500, made of stainless

steel, there have been no MR incidents reported for these devices and there is no evidence as to why they should be excluded from this policy.

A number of heart valves or annuloplasty rings listed on www.mrisafety.com stated that the device were MR Safe or MR Conditional up to 1.5T only. Table 2 outlines these implants and the materials used where available. For those implants where the material is not available there have been no MR incidents reported involving these devices. The materials that are listed are all non-ferromagnetic (silicone, other polymers, titanium, non-ferromagnetic grades of stainless steels, and barium sulphate). In contrast with these, some of the products designated MR Conditional also contain stainless steel (unspecified grades) or cobalt-chromium. A full list of materials is given in the table below. The hazards associated with scanning patients with heart valves or annuloplasty can be divided into displacement and heating:

- Displacement: The implants in Table 2 do not contain ferromagnetic components and will therefore not be subject to forces/torques that would cause displacement. Conversely, ferromagnetic materials, such as some stainless steels, will experience a force/torque in a magnetic field. There is therefore no scientific justification for imposing more stringent restrictions on magnetic field strength or spatial field gradient for the heart valves or annuloplasty rings labelled only at 1.5T than for the devices where conditions up to 3T are given.

- Heating: The presence of metal components (mainly in the valve leaflets if mechanical and supporting ring) results in the possibility of RF-induced heating. The metal components in the heart valves and annuloplasty rings are small, and the devices labelled to 1.5T are not expected to be markedly different in size, shape, or location to the devices where conditions up to 3T are given and will therefore be expected to give rise to similar levels of heating. There is therefore no scientific justification for imposing more stringent restrictions on SAR for these devices than for the heart valves and/or annuloplasty rings where conditions up to 3T are given.

Manufacturer	**Model**	**Mrisafety.com label**	**Material**	**Source**	**Date accessed**
Aortech Ltd. Strathclyde	3800, 4800	1.5T MR Conditional	Model 388 pyrolitic carbon, Frade A070 titanium with knitted teflon	www.mrisafety.com	18/04/2024

ATS Medical	ATS Medical Open Pivot, all models	Shown to be MRI safe when tested at field strengths of 1.5T or less	Pyroltic carbon with titanium band	P990046c.pdf (fda.gov)	16/04/2024
Autogenics Europe Ltd	Model APHV, ATCV	1.5T MR Safe	Eligoy	www.mrisafety.com	24/04/2024
Coratomic Inc.	Beall mitral heart Valve Model 103, 104	Unknown	Teflon-coated titanium struts, and a teflon disc	Beware of the B(e)all Valve - PMC (nih.gov)	24/04/2024 Discontinued in mid-1970s
	Beall mitral valve model 105, 106	1.5T MR Conditional	Pyrolitic carbon	www.mrisafety.com	24/04/2024 Discontinued in mid-1970s
Medtronic	Bileaflet Model A7760	1.5T MR Safe	N/A	www.mrisafety.com	24/04/2024
Pfizer, Inc.	Bjork Shiley Monostrut Model ABMS, MBRMS, MBUP	1.5T MR Safe	Chromium cobalt alloy	www.mrisafety.com	24/04/2024
Pfizer, Inc.	Bjork Shiley Monostrut Model MBUM, MBRP	1.5T MR Conditional	Chromium cobalt allot	www.mrisafety.com	24/04/2024
Shiley, Inc.	Bjork-Shiley convexo/concave	1.5T MR Safe	Haynes 25 alloy	Pfizer completes sale of Shiley product lines - UPI Archives 17/04/2024	Withdrawn from market in 1986, implanted in ~86000 patients
Shiley, Inc.	Bjork-Shiley (universal/spherical), Model 22 MBRC 11030, MBC	1.5T MR Conditional	N/A	www.mrisafety.com	24/04/2024
Carbomedics	Heart valve Model R500, size 19, 21,23, 25, 27, 29, 31, 16, mitral	1.5T MR Safe	N/A	www.mrisafety.com	24/04/2024

	standard Model 700, size 23, 25, 27, 29, 31, 33, Mitral valve size 33				
Sorin group	Freedom Solo biological valve	1.5T MR Safe	N/A	P130011c.pdf (fda.gov)	18/04/2024
Medtronic	Hall-Kaster Model A7700	1.5T MR Conditional	Graphite substrate, tantalum, pyrolytic carbon, titanium ,teflon	| National Museum of American History (si.edu) www.mrisafety.com	Manufactured in 1977, discontinued in 2009
Medtronic	Hancock Pericardial Mitral Model T410	1.5T MR Safe	Haynes alloy	www.mrisafety.com	18/04/2024
Johnson & Johnson	Hancock Vascor, Model 505	1.5T MR Safe	N/A	www.mrisafety.com	18/04/2024
Inonescu-Shiley	Universal ISM Heart valve	1.5T MR Conditional	N/A	www.mrisafety.com	18/04/2024
Inonescu-Shiley	Peicardial xenograft		Bovine valve onto a dacron-covered	Ionescu-Shiley: the forgotten biological valve prosthesis | European Journal of Cardio-Thoracic Surgery | Oxford Academic (oup.com)	24/04/2024 Withdrawn from use in 1987
Medtronic	Intact Aortic, Model A805, M 705	1.5T MR Safe	A805 – porcine tissue with dacron polyester fabric	www.mrisafety.com	24/04/2024
Axion Medical	Jyros Mitral, Model J1M, J1A	1.5T MR Safe	J1M – pyrolitic carbon, J1A –	Prosthetic heart valves: Evaluation of magnetic field	24/04/2024

			impregnated with boron carbide	interactions, heating, and artifacts at 1.5 T (mriquestions.com)	
Medical Inc. Inver grove heights	Lillehi-Kaster Model 300S, Model 5009	1.5T MR Conditional	Pyrolitic disc suspended in a weldless titanium housing encirlced in a teflon fabric ring	Clinical experience with the Lillehei-Kaster cardiac valve prosthesis (jtcvs.org) www.mrisafety.com	24/04/2024
TRI Technologies	Mitral prosthetic heart valve Model 2100	1.5T MR Safe	N/A	www.mrisafety.com	24/04/2024
Sulzer-Medica and Mitroflow international	Mitroflow pericardial heart valve Model 12	1.5T MR Safe	Dacron	Hydrodynamic function of the second-generation mitroflow pericardial bioprosthesis - ScienceDirect	Model 12 developed in 1991. 24/04/2024
Mitroflow Sulzer Carbomedics	Mitroflow aortic, Model 11A, 14A, 11M	1.5T MR Safe	Dacron	Hydrodynamic function of the second-generation mitroflow pericardial bioprosthesis - ScienceDirect	Model 11 developed in 1982. 24/04/2024
Medical Inc. Inver grove heights	Omnicarbon Model 35231029, 6522	1.5T MR Conditional	Pyrolite carbon disc, nickel-free titanium housing with PTFE ring	Mechanical heart valve prostheses:: identification and evaluation (erratum) - ScienceDirect www.mrisafety.com	24/04/2024

				www.mrisafety.com	
Sorin Group	Pericarbon Freedom stentless biological valve	1.5T MR Safe	N/A	www.mrisafety.com	18/04/2024
Medtronic	Sculptor Annuloplasty ring Model 605M	1.5T MR Safe	N/A	www.mrisafety.com	18/04/2024
Sorin Biomedica	Smelloff Cutter Aortic, Sorin Allcarbon AS Model MTR-29AS, stented mitral pyrolytic carbon, sorin N20	1.5T MR Conditional	Titanium, pyrolytic carbon	www.mrisafety.com	22/04/2024
Sorin	Allcarbon, Monocast and Carbocast tilting disc		Pyrolytic carbon over a graphite substrate, haynes HS25 cage material with a teflon ring	Mechanical heart valve prostheses:: identification and evaluation (erratum) - ScienceDirect	24/04/2024
St Jude Medical (now Abbott)	Model A100	1.5T MR Conditional	N/A	www.mrisafety.com	24/04/2024
Baxter Healthcare Corporation	Model 2400	1.5T MR Safe	N/A	www.mrisafety.com	18/04/2024
Sulzer-Medica and Mitroflow International	Sulzer/carbomedics synergy PC pericardial heart valve	1.5T MR Safe	Porcine valve with an acetal copolymer stent	An echocardiographic description of the Sulzer Carbomedics Synergy ST (Labcor) porcine valve in the aortic position | The Journal Of Heart	24/04/2024

				Valve Disease (icr-heart.com) www.mrisafety.com	
Medtronic	Tascon Aortic	1.5T MR Safe	Porcine aortic valve, mounted on a dacron-covered stent of flexible elgiloy	A new bioprosthesis for aortic and mitral valve replacement: preliminary evaluation of the Tascon valve. - Abstract - Europe PMC www.mrisafety.com	18/04/2024
Sorin Biomedica	Wessex aortic Model WAV10, WMV20	1.5T MR Safe	Porcine tissue with acetal polymer with cloth reinforced with silicone rubber	Prosthetic heart valves: Evaluation of magnetic field interactions, heating, and artifacts at 1.5 T - Edwards - 2000 - Journal of Magnetic Resonance Imaging - Wiley Online Library www.mrisafety.com	24/04/2024
Xenofix	aortic Model AP80	1.5T MR Safe	Bovine tissue, teflon with stainless steel marker	Prosthetic heart valves: Evaluation of magnetic field interactions, heating, and artifacts at 1.5 T - Edwards - 2000 - Journal of Magnetic Resonance	24/04/2024

				Imaging - Wiley Online Library www.mrisfaty.com	

Review of the peer reviewed literature

If placed in an MRI unit these implants may be subject to the following hazards:

1. In the presence of the static magnetic field ferromagnetic materials will experience a force that may cause a device to be moved, rotated, dislodged or accelerated towards the magnet.
2. Currents within electrically conductive devices may be induced by time-varying magnetic fields which may impact device function.
3. Device heating may occur through the absorption of RF energy if the device is metallic.

Theodoros D. Karamitsos et al. performed an MRI literature review of heart valves and annuloplasty rings. They concluded there is no evidence to date of why a patient with one of these devices should be excluded from MRI, including imaging of the heart itself. Although not a direct safety concern, the image quality may be affected if the implant is in the scanning field of view; however this depends on the type of device and they state that the images may remain diagnostic in most centres with relevant experience (2). The authors also confirmed that the Pre-6000 Starr-Edwards caged-ball prosthesis (available from 1960 to 1964) is MRI safe at 1.5T, including when imaging the heart itself.

The heart valve and annuloplasty ring safety information article on Frank Shellock's website performed testing on many of these devices up to 4.7 T and states that an MR procedure is not considered hazardous for a patient that has any heart valve prosthesis or annuloplasty ring (6). This recommendation includes the Starr-Edwards model Pre-6000 heart valve prostheses previously suggested to be a potential risk for a patient undergoing an MR examination.

Frank Shellock et al. considered imaging patients where the labelling information of the manufacturer and model of heart valves or annuloplasty rings are unknown (7). After considering peer-reviewed literature and other related documents he suggested conservative guidelines for scanning of these patients:

"· Patients with all commercially available heart valve prostheses and annuloplasty rings can be scanned at 1.5T/64MHz or 3T/128MHz, regardless of the value of the spatial gradient magnetic field.

· Patients with all commercially available heart valve prostheses and annuloplasty rings can undergo MRI immediately after placement of these implants.

· The MRI examination must be performed using the following parameters:

- 1.5-Tesla or 3-Tesla only.
- Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system.

- Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed).

Any deviation from the above MRI conditions requires prior approval by a radiologist or supervising physician."

Projectile Risk

Heart valves are not constructed from ferromagnetic materials and are therefore not a projectile risk. The force exerted on the valve from an MRI is reported to be less than either (i) the force experienced through gravity or (ii) the beating heart and resultant pulsatile flow (2).

Lenz Effect

A number of studies have considered the Lenz effect on heart valve prosthesis in the presence of the B0 field. Edwards et al. considered the Lenz Effect on heart valves at 1.5T. They assessed the Lenz forces on 9 heart valve prostheses and assessed the risk of impedance of valve function. Irregularities were observed on the pressure profiles of 4 prostheses providing evidence that the Lenz effect due to exposure to the MR B0 field causes functional valve impedance. While this study hints at a possible mechanism for an interaction between the MRI and heart valves, this hasn't been replicated.

Furthermore, empirically there have been no reported issues as a result of the lenz effects in patients with heart valves at 1.5 and 3T.

Robertson et al. evaluated the Lenz effect on mathematical models of two common forms of single-leaflet valves and the magnitude of the torque which opposes the motion of the valve leaflet. They reported that at 1.5T the magnetic effect is ≤ 1 % of the pressure effect for both mitral and aortic valves based on the differences between normal and delayed opening times of the valve in a given magnetic field. However, the authors calculated that these magnetic effects increase to nearly 10 % for native mitral (9.95%) and aortic (9.91%) valves at field strengths between 3T and 4.7T, suggesting there is a significant increase in the risk of valve impedance with increasing field strength (4).

The Lenz effect is discussed in the safety article "Heart Valves and Annuloplasty Rings" on Frank Shellocks website (www.mrisafety.com). It is discussed that there is a theoretical change of forces being stimulated in a heart valve prostheses that have metallic disks or leaflets with the potential to inhibit both the opening and closing aspects of the valve. Edwards et al. conducted an in vitro study on the occurrence of Lenz-related forces on various heart valve prostheses at 1.5T and assessed the risk of the impedance of valve function. Their findings provided further evidence of the Lenz effect on certain cardiac valve prosthesis exposed to the static magnetic field (3).

Whilst there is a body of evidence that the Lenz forces do act upon heart valve prosthesis, at 1.5T there have been no known incidents relating to patient's being scanned with prosthetic heart valves. At this field strength the forces exerted on the prosthesis due to the Lenz effect are minimal compared to the forces exerted onto the prosthesis from the beating heart. It has been mentioned in all papers analysed that the Lenz forces are proportional to the magnetic field strength and that at higher field strengths (≥ 3T) the risk of valve impedence due to the Lenz force may become significant. Effects at higher field strengths have been considered theoretically with mathematical models, however no studies have been found testing at higher fields.

Due to the lack of evidence at higher field strengths of the impact of Lenz forces on heart valve prostheses advice in this policy should only apply to 1.5 and 3T field strengths where it is known the forces acting on the valve are minimal compared to the forces from the beating heart.

Device Heating

Testing has shown the temperature changes due to RF pulses in these implants to be minimal (2). Maria-Benedicta Edwards et al. assessed the heating effects from MRI in 13 heart valves at 1.5T. The valves were scanned for 15 minutes at a SAR of 1.1 W/kg with heating reported as ≤ 0.8 ºC (1). Similarly, Frank Shellock assessed the heating of 5 heart valves at 1.5T where the valves were imaged for 15 minutes at a SAR of 1.2 W/kg. The heating effect was reported as ≤ 0.7 ºC (2). Mahrad Saeedi et al. evaluated the Hydra Aortic valve at 3T. The valve was imaged for 15 minutes at a SAR of 2.9 W/kg with a maximum temperature rise of 2.5 ºC (3). It should be noted that in all of the above studies the valves were placed in gel-filled phantoms and temperature measurements were performed by fluoroptic thermometry. During the intended *in-situ* use of a heart valve or annuloplasty ring the considerable blood flow that occurs through the valve/annuloplasty rings may mitigate any temperature increase during MRI. Therefore, the inclusion of a 15 minute per pulse sequence limit as included above in Frank Shellocks recommended guidelines is not deemed necessary.

Internet search (non peer reviewed literature)

Source: Google

Date of Query: 08/04/2024

Comments: A search of "heart valve MRI incidents" and "annuloplasty ring MRI incidents" was conducted.

Results: The search did not reveal any incidents related to heart valves or annuloplasty rings and MRI.

Source: Facebook MRI Safety Group

Date of Query: 27/06/2023

Comments: A search of "heart valves" and "annuloplasty rings" was conducted.

Results: The search revealed numerous posts asking questions relating to heart valves and/or annuloplasty rings and MRI safety. A selection of these is summarised in the following Table. The remainder of the questions were along similar lines to the ones listed. There were no reports of any incidents.

Date of Question	Question	Comments
23/06/2021	Mechanical heart valve, 20+ years ago, no info...safe in a 1.5T? Possible abscess	Frank Shellock: Safety Topic/Article: (mrisafety.com). This applies, even for a 20 year old heart valve prosthesis (FYI, we started testing heart valves in 1986).
29/01/2021	Has anyone scanned a TAVR heart valve replacement?	Frank Shellock: Safety Topic/Article: (mrisafety.com) "including transcatheter aortic valve replacements (TAVR), transcatheter aortic

		valve implantation (TAVI) devices, percutaneous aortic valve replacement (PAVR) implants, transcatheter heart valves (THV), as well as other similar valve implants used in association with minimally invasive procedures]".
20/08/2021	If a patient has a heart valve implant card that says 720 g/cm and the machine I'm scanning on is 1500 g/cm, can I safely scan the patient?	Frank Shellock: As I've stated before, I don't think that the spatial gradient magnetic field info indicated in the labelling for implants is important at all. I know of no implant that has been tested at 1.5 and/or 3T that, if you did not follow the value for the spatial gradient magnetic field, the result would be a patient injury. Notably, the 45 degree deflection angle is based on testing an implant that is able to "freely" move in space. Virtually all implants have counter-forces present that help to retain them in situ.

Regulatory Medical Device Databases

Source: MAUDE (Manufacturer & User Facility Device Experience) Database

Date of Query: 25/03/2024

Comments: The MAUDE database was searched using key words "heart valve", "annuloplasty ring" AND MRI.

Results: The search returned 500 results, not all were viewed however those that were involved post-surgery complications where MRI was part of the investigation.

Source: MDR Database

Date of query: 25/03/2024

Comments: The database was searched using key words "heart valve" which returned 500 records and "annuloplasty rings" which returned 480 records.

Results: All of the reports were dated pre-2000; the most recent 10 reports for each category were reviewed and none of them involved MRI.

Source: Clinical Trials Database (www.clinicaltrials.gov)

Date of query: 25/03/2024

Comments: A search of www.clinicaltrials.gov using key words "heart valve" and "MRI" revealed 26 entries. All of these trials involved existing devices.

Regulatory Professional and Standards bodies

A search of the MHRA database was not requested as it was felt there was enough existing evidence for the policy.

Anecdotal evidence

Discussion (optional)

This document has considered the MRI safety status of heart valve prosthesis and annuloplasty rings. A review of the manufacturers on www.mrisafety.com which considered 27 manufacturers and 231 implants demonstrated there are no devices that are considered MRI unsafe. Of the implants considered all were MRI conditional at 1.5T. Only certain devices were MRI conditional at 3T, upon closer investigation these devices are likely to be bioprosthetic valves, which contain less metal than mechanical valves. Therefore, advice applicable to all valves should be applied at 1.5T field strength.

Some valves are implanted through open chest surgery. These patients will have additional sternal wires from this surgery. Extra care for these patients should be taken to ensure there is no direct contact with the scanner and that there are no current loops. Scanning should be performed in normal mode to minimise power deposition.

The artefacts generated by these devices are proportional to the amount of metal present. This will be higher for mechanical valves than bioprosthetic valves. Although this is not a direct safety issue it may be of interest to healthcare workers.

The Lenz effect has been considered at 1.5T and deemed insignificant compared to the forces of the beating heart at this field strength or less. There is opportunity to evaluate at higher field strengths to confirm whether the Lenz forces become a safety concern.

In summary the evidence collected in this document confirms that patients with heart valves or annuloplasty rings can safely be scanned provided the following conditions are adhered to:

- Field strength of 1.5 or 3 Tesla, regardless of the value of the spatial gradient magnetic field.
- Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system.
- Typical imaging gradient slew rates for 1.5T and 3T clinical systems (All NHS Scotland scanners comply).

4 Bibliography

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5 Risk Assessment

5.1 Hazards

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.

5.2 Description of Risk

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.

5.3 Existing precautions

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.

5.4 Level of Risk

Risk Description	Likelihood	Consequence	Risk
A new heart valve or annuloplasty ring is brought to the market that is MR Unsafe	Rare	Minor	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

Medium (Yellow) High (Orange) or Very High (Red) risks are unacceptable. A GISP should only be created where the risk is low.