

IPEM MR-SIG Generic Implant Safety Procedure (GISP) Task and Finish Group Report:

Recommendations for MRI scanning of patients with Heart Valves, Annuloplasty Rings and Transcatheter Edge-to-Edge Repair (TEER) Clips.

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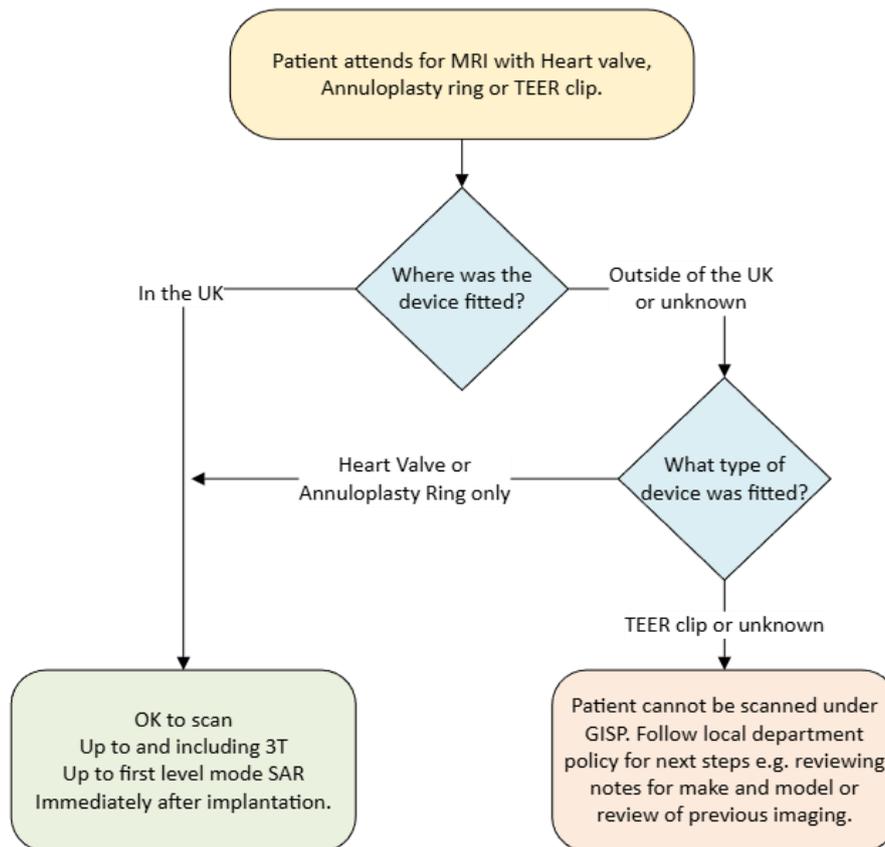
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Scope

The safety of patients with heart valves, annuloplasty rings and TEER clips undergoing MRI has been considered. Artefacts arising from these devices have not been considered as part of this process.

Suggested flowchart

An example flowchart is shown below, although departments may wish to adapt to meet their local needs.



Supporting Evidence

A full evidence review is given in Appendix 1 and sites are advised to read this before implementing this policy locally.

Summary of Consensus

The following is the consensus of the MRSE group when they met in September and October 2025.

Scan condition (Adapted from Table X1.2 of ASTM standard F2503-23 [1])	Recommendation (% consensus)
Implantation location i.e. country in which it was implanted.	The suggested workflow for the GISP includes conditions where the consensus was greater than 90%. No restrictions on heart valves and annuloplasty rings. Include TEER clips fitted in: Europe (83%) Japan (67%) Australia (83%) Canada (75%) UK (100%) USA: (83%) Rest of the world: (54%)
Implantation date	No restrictions (100%)
Static Magnetic Field Strength (B_0)	Any field strength up to and including 3T (100%)
Maximum Spatial Field Gradient (SFG)	Any clinically approved SFG (100%)
Maximum Gradient Slew Rate per axis	Any clinically approved slew rate (96%)
RF Polarisation	Any clinically approved RF polarisation (100%)
RF Transmit Coil	Any clinically approved RF transmit coil (100%)
RF Receive Coil	Any clinically approved RF receive coil (100%)
MR System (RF) Operating Modes or Constraints	First Level Controlled Operating Mode permitted (92%) Normal Level Operating Mode (100%)
Anatomy at Isocenter i.e. any anatomical restrictions.	No restrictions (100%)
Patient Characteristics e.g. patient height	No exclusions (100%)
Patient Position in Scanner e.g. supine, prone	No restrictions (100%)
Implant Configuration e.g. any constraints on device orientation, or combination of components.	No restrictions (96%)
Scan Duration and Wait Time between sequences	No restrictions (100%)
Requirement to review previous imaging	No requirement (96%)

A full breakdown of the results from the consensus process is provided in Appendix 2.

List of contributors

We greatly appreciate the time and expertise the following people have contributed to the development of this procedure.

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Appendix 1: Evidence Review

1 Procedure Statement

1.1 Brief description:

This procedure covers the MR safety of implants used for heart valve replacement or repair.

Prosthetic heart valves are used for heart valve replacement. They may be mechanical or bioprostheses [2]:

- Mechanical heart valves usually feature a tilting disc, bileaflet or caged-ball design. All contain metal. Some may contain stainless steel.
- Bioprosthetic heart valves may be autograft, allograft or xenograft. They may be stent-less or stented. Stented heart valves may contain metal.

Annuloplasty rings are used for heart valve repair. They reinforce the ring of tissue around the heart valve to tighten leaky heart valves [3]. They may be partial (C-shaped) or complete (O-shaped) [4], and may be rigid, semi-rigid or flexible. Many contain metal e.g. titanium or Elgiloy. Some contain stainless steel. Some are biodegradable.

Transcatheter edge-to-edge repair (TEER) clips are used for heart valve repair. They hold together multiple leaflets of a heart valve [3][5].

1.2 What the procedure covers:

- **Prosthetic heart valves**, including mechanical heart valves and bioprostheses, implanted surgically or transcatheter (e.g. TAVI, TAVR).
- **Annuloplasty rings**
- **Transcatheter edge-to-edge repair (TEER) clips** - e.g. transcatheter mitral valve repair (TMVr) clips.

1.3 What the procedure does not cover, including notable exceptions:

- **Cardiac implantable electronic devices (CIEDs)** - Including permanent pacemakers (PPM), implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy (CRT) devices, temporary epicardial pacing leads, abandoned cardiac leads, and loop recorders.
- **Cardiac occluders/closure devices** - For pathologies such as: patent ductus arteriosus (PDA), atrial septal defect (ASD), ventricular septal defect (VSD), or patent foramen ovale (PFO)
- **Coronary artery stents** - i.e. percutaneous coronary intervention (PCI) / coronary angioplasty.
- **Coronary artery bypass graft (CABG) clips**
- **Other cardiac surgeries** - e.g. balloon valvuloplasty, cardiac ablation, heart transplant

2 Clinical Context

The first heart valve repair surgery was performed in 1923. The first prosthetic heart valve implantation was in 1952 [6].

Prosthetic heart valves may be implanted surgically (e.g. surgical aortic valve replacement (SAVR)) or percutaneously (e.g. transcatheter aortic valve implantation/replacement (TAVI/TAVR)) [7]. They may be positioned intra-annularly or supra-annularly.

Annuloplasty rings may be implanted surgically or percutaneously. The annuloplasty ring was developed in the late 1960s [8].

TEER clips are implanted percutaneously. Several TEER clips may be implanted in close proximity [5]. The first TEER clip implantation was in 2003 [9]. TEER clips are a relatively new and the number implanted has been increasing over time. In 2019, 100 TEER procedures were performed in the UK (1.5 per million population) [10].

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3 Evidence Review

3.1 Regulatory Professional and Standards Bodies (Queried 02/05/2025)

3.1.1 Medicines and Healthcare Products Regulatory Agency (MHRA) [11]

In 2021, the MHRA recommended:

“Many patients and volunteers with prosthetic cardiac valves have been safely scanned without the danger of valve displacement. Under testing, the measured attraction to the static magnetic field is often minimal compared to the force exerted by the beating of the heart. The manufacturer should be asked to confirm MR safety of the device”

3.1.2 Society for Medical Physics of the Netherlands (NVKF) [12]

In 2019, the NVKF recommend:

“Scan the patient with a prosthetic heart valve, annuloplasty ring or mitra clip with an 1.5 T or 3 T whole body MRI system with a horizontal closed bore superconducting magnet; without further restrictions”

3.1.3 American College of Cardiology Foundation (ACCF), American College of Radiology (ACR), American Heart Association (AHA), North American Society for Cardiovascular Imaging (NASCI), and Society for Cardiovascular Magnetic Resonance (SCMR) [13]

IN 2010, these groups came to the expert consensus that:

“The majority of prosthetic heart valves and annuloplasty rings that have been tested have been labeled as MR safe, with a lesser number labeled as MR conditional. In general, the presence of a prosthetic heart valve or annuloplasty ring is not considered a contraindication to CMR examination up to 3.0-T at any time after implantation. The forces exerted on valve prosthesis are substantially less than those exerted by the beating heart and pulsatile flow. The forces required to pull a suture through the valve annulus tissue have been shown to be greater than magnetically induced forces up to a field strength of 4.7-T. Thus, patients with valve prosthesis are unlikely to be at risk for valve dehiscence during clinical CMR examinations. Associated CMR-related heating has been determined to be less than 1°C in ex vivo studies; this is likely to be less due to the heat-sink effect of flowing blood. Valve dysfunction due to interaction with the magnetic field has not been reported.”

3.1.4 American Heart Association [14]

In 2007, the AHA recommend:

“The majority of prosthetic heart valves and annuloplasty rings that have been tested have been labeled as ‘MR safe’; the remainder of heart valves and rings that have been tested have been labeled as ‘MR conditional.’ On the basis of the above studies and findings, the presence of a prosthetic heart valve or annuloplasty ring that has been formally evaluated for MR safety should not be considered a contraindication to an MR examination at 3 T or less (and possibly even 4.7 T in some cases) any time after implantation.”

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3.2 Review of the Peer Reviewed Literature (Queried 02/05/2025)

3.2.1 Prosthetic Heart Valve

3.2.1.1 Deflection, Torque & Heating

A range of ex vivo studies have looked at the deflection, torque and heating of prosthetic heart valves.

Their results are summarised in Table 1, Table 2 and Table 3.

Authors	Ref	#Heart Valves	Max G/cm	Scanner Field Strength (T)							Max Deflection (°)
				0.35	0.5	1.5	2	2.35	3	4.7	
Soulen et al	[15]	9	63	✓	-	✓	-	✓	-	-	27
Randall et al	[16]	5	450	-	✓	-	✓	-	-	-	0
Shellock & Crues	[17]	7	-	-	-	✓	-	-	-	-	1.7*
Frank et al	[18]	7	-	-	-	✓	-	-	-	-	1
Shellock & Morisoli	[19]	13	-	-	-	✓	-	-	-	-	0
Edwards et al	[20]	32	450	-	-	✓	-	-	-	-	5
Shellock	[21]	3	450	-	-	✓	-	-	-	-	2
Edwards et al	[22]	60	500	-	-	-	-	-	-	✓	7.5
Shellock	[23]	9	325	-	-	-	-	-	✓	-	0
Edwards et al	[24]	11	-	-	-	-	-	-	-	✓	2
Saeedi et al	[25]	1	720	-	-	-	-	-	✓	-	3**
Hatamifar et al	[26]	1	466	-	-	-	-	-	✓	-	9

Table 1: Deflection of prosthetic heart valves. * $\times 10^{-3}N$, ** Mean

Authors	Ref	#Heart Valves	Scanner Field Strength (T)					Max Torque (0-4)
			0.5	1.5	2	3	4.7	
Randall et al	[16]	5	✓	-	✓	-	-	+1
Shellock	[21]	3	-	✓	-	-	-	+1
Edwards et al	[22]	60	-	-	-	-	✓	+2*
Shellock	[23]	9	-	-	-	✓	-	0
Edwards et al	[24]	11	-	-	-	-	✓	+2*
Saeedi et al	[25]	1	-	-	-	✓	-	0***
Hatamifar et al	[26]	1	-	-	-	✓	-	0
D'Avenio et al	[27]	3	-	-	-	-	✓	2.3**

Table 2: Torque of prosthetic heart valves. 0 = No torque, +1 = Mild torque, +2 = Moderate torque, +3 = Strong torque, +4 = Very strong torque. *For this value +2 = $>45^\circ$ to 90° , ** $\times 10^{-5}Nm$, *** Mean.

Authors	Ref	#Heart Valves	wbSAR (W/kg)					Time (min)	Max Heating (°C)
			0.35T	0.5T	1.5T	2T	3T		
Soulen et al	[15]	9	✓	-	✓	-	-	8 (0.35T), 256s per pulse sequence (1.5T)	0.4
Randall et al	[16]	5	-	✓	-	✓	-	7.4 to 10.5	≤ 0.2
Frank et al	[18]	7	-	-	✓	--	-	6	0.6
Shellock & Morisoli	[19]	13	-	-	2.5	-	-	60	0.3
Edwards et al	[20]	32	-	-	1.1	-	-	15	0.8
Shellock	[21]	3	-	-	1.2	-	-	15	0.7
Saeedi et al	[25]	1	-	-	-	-	2.9	15	2.5
Hatamifar et al	[26]	1	-	-	2.7	-	2.9	15	2.7

Table 3: Heating of prosthetic heart valves

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3.2.1.2 Lenz Effect

Several computational models have been made to examine the impact of the Lenz effect.

Condon & Hadley [28] used a model of a non-metallic tilting disc with diameter of 39mm, supported by a fixed ring strengthener made from 1mm thick titanium or Stellite no. 21 (Haynes) alloy. The valve opened 75° in 10-50ms, within a 1.5T field.

In the worst case, a titanium ring strengthener opening in 10ms at 1.5T, the resistive force was 18% of the 7.2N force of a beating heart. The authors warned that this would increase linearly with field strength.

The authors also suggested that caged-ball valves would not experience a resistive force due to the Lenz effect, as the net flux through them remains constant during opening and closing.

Robertson et al [29] looked at models of a of a metallic tilting disc with diameter of 39mm, and a non-metallic tilting disc supported by a metallic ring strengthener. The metals used were titanium or Stellite. The valves opened 85° in 10-50ms. The field strength varied from 1-10T.

At 1.5T, the worst-case resistive force was 0.81% of the mitral pressure and 0.88% of the aortic pressure. At 3T, the worst-case resistive pressure was 3.48% of the mitral pressure and 3.68% of the aortic pressure.

The authors summarised this as:

“The Lenz effect is significant but not seriously so for the field strengths which commercial MRI systems currently employ. The most common field strength is 1 to 1.5 T for which the magnetic effect is less than 1% of the pressure effect for mitral and aortic valves). However, 3 to 5 T systems are becoming more prevalent and for such field strengths the percentage effect is 9.95% for a valve in the mitral position and 9.91% for a valve in the aortic position. Beyond this static magnetic field strength, experiment and medical advice would be required in order to pronounce judgment on further safety aspects.

Should the torque be significant, and it should be stressed that it could be significant in only a small subset of patients with mechanical heart valves which have moving metal components, it would be recognized by symptoms such as breathlessness in the patient and reduced cardiac output. That is, the Lenz effect could make the heart behave as though it were diseased with the resulting symptoms and difficulties.”

Golestanirad et al [30] looked at models of a solid disc, a ring with an inner diameter of half the outer diameter, and a wire-like ring. All models used an outer diameter of 40mm and were made from 2mm thick titanium. The valves opened 90° in 10ms. The field strength varied from ~0.5-10T. The skin effect was accounted for when calculating eddy currents.

The authors criticised Condon & Hadley [28] for not accounting for the skin effect.

The results are summarised in Figure 1.

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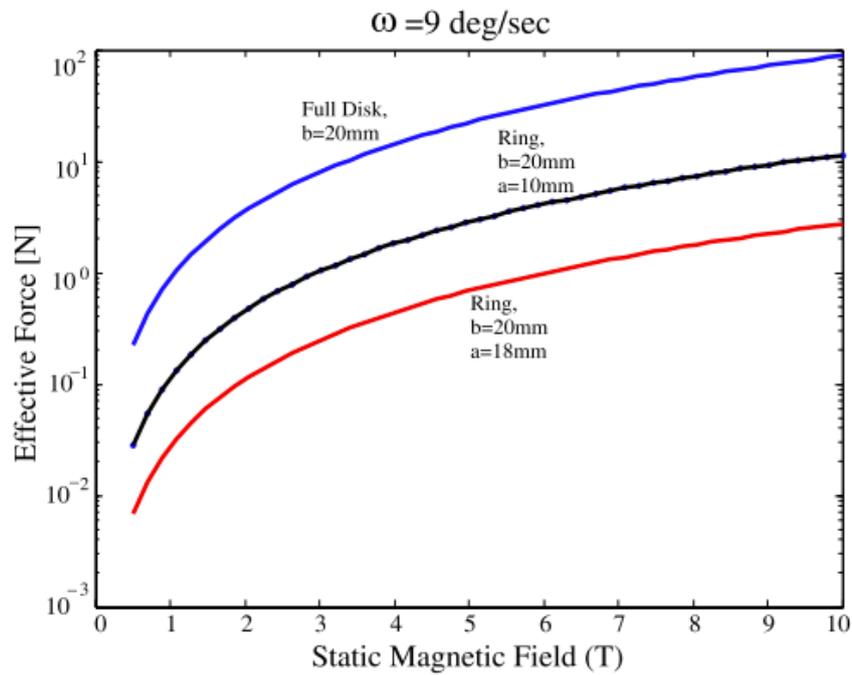


Figure 1: Worst-case effective resistive force for each valve. a) is the inner diameter of the ring. b) is the outer diameter.[30]

For the wire-like ring, the resistive force remained below 2N at all tested field strengths.

The authors also calculated that the inhomogeneity due to spatial gradients was negligible compared to the rate of change of magnetic field due to the disc’s rotational motion.

The authors concluded:

“In summary, the result of this study shows that mechanical heart valves with strengthening rings may be considered safe even under ultra-high imaging conditions with field intensities as high as 10 T. This conclusion is based on the fact that the magnitude of Lenz forces due to the valve rotational motion in this case is less than typical forces of a beating heart which is 7.2 N. However, heart valves such as Starr-Edwards 6500 which have solid metallic disk are subject to high adverse forces during MRI even at typical clinical field intensities. For example, the resistive force applied over the surface of a valve with titanium metallic disk at 4T is approximately 14 N. Considering the surface of the valve, which is 12.6 cm², this force is applying a pressure of 83mmHg over the valves disk. If the valve is located in mitral position, it should open and close under a pressure difference of only a few mmHg (less than 4mmHg) between the relaxing left ventricle and the left atrium. High resistive pressures as the one computed here, could severely hinder the normal operation of the heart valve and thus, heart valves with full conducting disks should be considered as contraindication to MR imaging.”

The Society for Medical Physics of the Netherlands (NVKF) [12] has raised several criticisms of Golestanirad et al:

- Rotating all-metal blade models are not representative of the modern market and potentially non-existent, as even the Starr-Edwards 6500’s all-metal valve blade translates instead of rotating.
- Rotating blade models are commonly made from pyrolytic carbon, which is factor of 10⁶ less conductive than titanium.
- Opening times of 50ms are more realistic than 10ms.

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Edwards et al [31] performed an in vitro study of the Lenz effect. 9 models of prosthetic heart valves were tested, 6 mechanical and 3 bioprostheses. 2 of the mechanical were caged-ball designs, 1 caged disc, 2 were tilting disc, and 1 was bileaflet. The tilting discs were made from pyrolytic carbon with chromium cobalt alloy or titanium. They placed in a hydraulic system controlled by a piston pump was used to simulate cardiac blood flow, with an impulse rate of 75rpm and an output of 5L/min. A strain gauge was used to monitor pressure. The system was placed on a 1.5T scanner and moved from the 5 Gauss line to isocentre and back.

4 of the 9 valves showed irregularities which are atypical for those valves:

- Bjork Shiley tilting disc valve
- Edwards Tekna bileaflet
- Hancock Modified Orifice II bioprosthesis
- Starr Edwards caged ball valve

The authors explicitly could not explain why a bioprosthesis was affected. They also offered no explanation why a caged ball valve was affected, in contradiction of Condon & Hadley's [28] analysis.

The impedance seen was more pronounced post-exit from the magnet bore than on entrance, suggesting the prostheses become magnetised. The authors stated that this contradicts Golestanirad et al's suggestion that any movement due to Lenz forces would be unaffected by the changes inhomogeneity of the field.

The authors concluded:

"In conclusion, this investigation provides empirical evidence to support the theory, movement of a prosthetic heart valve through the B0 field associated with MRI generates resistive forces around the valve's leaflet(s)/occluder, which in turn can impede the opening and closing of the valve, resulting in retardation of fluid output. Moreover, greater pressure drops across the valve than those previously calculated were recorded, suggesting certain patients may be at increased risk of regurgitation and complications associated with this."

3.2.1.3 In Vivo

Two studies have looked at the in vivo impact of MRI on prosthetic heart valves.

Randall et al [16] had 6 patients with prosthetic heart valves undergo MRI at 0.5T while being monitored by ECG. The implantations were performed 4 months to 4 years before the MRI study. No arrhythmias were observed during the study. Heart rates did slow once the patient settled into the scanner, but the authors attributed this to the patients relaxing over time. No clinical signs or symptoms of discomfort were observed or reported by the patients. The authors concluded that studies can be safely and reliably performed in the vicinity of the tested valves.

Hartnell et al [32] had 25 patients with prosthetic heart valves undergo cardiac or aortic MRI at 1.0 or 1.5T while being monitored by ECG. Images of diagnostic quality were obtained for all but 2 patients, who had pre-existing ventricular arrhythmias. Some patients reported feelings of claustrophobia, but not symptoms of worsening cardiac function, new arrhythmia, or other adverse events were reported. The authors concluded:

"The presence of prosthetic valves did not appear to pose a risk, confirming the findings of Randall et al. and our clinical experience."

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3.2.2 Annuloplasty Rings

A range of ex vivo studies have looked at the deflection, torque and heating of annuloplasty rings. Their results are summarised in Table 4, Table 5 & Table 6.

Authors	Ref	#Annuloplasty Rings	Max G/cm	Scanner Field Strength (T)	Max Deflection (°)
Edwards et al	[24]	12	-	4.7	20
Shellock	[21]	2	450	1.5	6
Shellock	[23]	3	325	3.0	4

Table 4: Deflection of annuloplasty rings

Authors	Ref	#Annuloplasty Rings	Scanner Field Strength (T)	Max Torque (0-4)
Edwards et al	[24]	12	4.7	+2*
Shellock	[21]	2	1.5	+1
Shellock	[23]	3	3.0	+1

*Table 5: Torque of annuloplasty rings. 0 = No torque, +1 = Mild torque, +2 = Moderate torque, +3 = Strong torque, +4 = Very strong torque, *For this value +2 = >45° to 90°*

Authors	Ref	#Annuloplasty Rings	Scanner Field Strength (T)	wbSAR (W/kg)	Time (min)	Max Heating (°C)
Shellock	[21]	2	1.5	1.2	15	0.6

Table 6: Heating of annuloplasty rings

Edwards et al [24] also demonstrated increased magnetisation for an Elgiloy annuloplasty ring that re-entered the MR system.

3.2.3 TEER Clip

A variety of novel TEER clips are produced in China, including:

- Valgen Medtech’s DragonFly [33]
- Peijia Medical’s GeminiOne [34]
- Shenqi Medical’s Kyrin Tricuspid [35]
- Shenqi Medical’s SQ-Kyrin-M [36]
- Dawneo Medical Technology’s Neoblazar [37]
- Hanyu Medical Technology’s ValveClamp [38]
- Jens Medical’s JensClip [39]
- Enlight Medical Technologies’ NovoClasp [40]

The DragonFly is a made from nickel-titanium alloy, stainless steel, cobalt-chromium alloy, polyethylene terephthalate, and nitinol [33].

3.2.4 Cardiac Tissue Strength

Edwards et al [41] looked at the strength of annular ring tissue samples, consensually taken from 18 patients during first-time elective aortic or mitral heart valve replacement surgery to treat aortic stenosis, mixed valve disease, calcific degeneration or infective endocarditis. A modified suture pull-out strength test was performed. The tissues were pre-conditioned with loads to reach a stable reference state, then destructively tested.

All samples followed the failure pattern:

1. An initial toe region until the suture is fully tensioned
2. A linear, elastic region until a yield force where initial tearing begins
3. A failure region when a maximum force is reached

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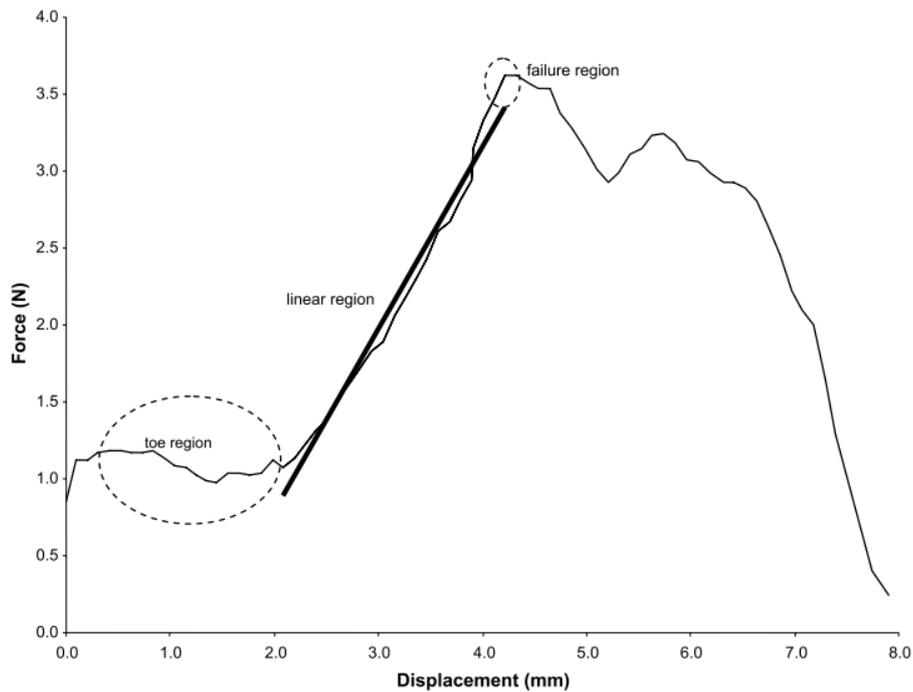


Figure 2: An example of the failure pattern of human cardiac tissue

The mean force at which the tissue yielded was $4.0 \text{ N} \pm 3.3 \text{ N}$ (mode 3.1 N , range $0.2\text{--}14.0 \text{ N}$) and the mean maximum force was $4.9 \text{ N} \pm 3.6 \text{ N}$ (mode 3.4 N , range $1.4\text{--}14.0 \text{ N}$).

The authors stated that the results showed that the force needed to pull out a single suture is roughly equivalent to the mechanical forces of a beating heart. However, they also claimed that cardiac prosthetics customarily use at least 14 sutures. The authors referenced Edwards et al [22] to say that the forces on cardiac implants at 4.7T are at least 1000x smaller than the mechanical forces of a naturally beating heart.

The authors summarised the above as:

“[...] forces required to cause total detachment from the surrounding tissue will be significantly smaller than magnetic field induced forces observed at 4.7 T”.

However, given their argument that cardiac prostheses have a greater pull-out force than the forces of a naturally beating heart, and that a beating heart applies more than 1000x the force from a magnet at $\leq 4.7\text{T}$, this was presumably intended to say the pull-out force is significantly larger than the magnetic force, not smaller.

The authors concluded:

“Over time, tissue becomes more rigid and stiffer and requires increasing forces to achieve total suture/tissue destruction. Thus, patients suffering from age-related stenosis and/or calcification of the valve annulus would be unlikely to be at risk of partial or total valve dehiscence whilst undergoing MRI $\leq 4.7 \text{ T}$. Similarly, tissue scarred by previous surgery also becomes more rigid and stiffer and would therefore be unlikely to pose a risk to patients exposed to MRI $\leq 4.7 \text{ T}$. Although the endocarditic tissue sample failed at a significantly lower force than tissue with other valve pathologies, it is impossible, at this stage, to make any definitive conclusions whether this pathology is more likely to cause partial or total valve dehiscence during MRI.”

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3.3 Internet Search (Non Peer Reviewed Literature) (Queried 02/05/2025)

3.3.1 mrisafety.com [42]

mrisafety.com provides a summary for topic 179, Heart Valves and Annuloplasty Rings:

“Many heart valve prostheses and annuloplasty rings have been evaluated for MR issues, especially with regard to the presence of magnetic field interactions associated with exposure to MR systems operating at field strengths of as high as 4.7-Tesla. Of these, the majority displayed measurable yet relatively minor magnetic field interactions. That is, because the actual attractive forces exerted on the heart valve prostheses and annuloplasty rings were minimal compared to the force exerted by the beating heart (i.e., approximately 7.2-N), an MR procedure is not considered to be hazardous for a patient that has any heart valve prosthesis or annuloplasty ring tested relative to the field strength of the magnet (i.e., MR system) used for the evaluation.

Importantly, this recommendation includes the Starr-Edwards Model Pre-6000 heart valve prosthesis previously suggested to be a potential risk for a patient undergoing an MR examination.

With respect to clinical MR procedures, there has been no report of a patient incident or injury related to the presence of a heart valve prosthesis or annuloplasty ring.”

“While further evaluation of this phenomenon may be warranted, to date, the Lenz Effect has not been observed in association with clinical MR examinations nor has it posed additional risks for patients with certain heart valve prostheses (i.e., those with metallic leaflets or disks) undergoing MRI.”

“Findings obtained at 3-Tesla for various heart valve prostheses and annuloplasty rings that underwent testing indicated that certain implants exhibit relatively minor magnetic field interactions. Similar to heart valve prostheses and annuloplasty rings tested at 1.5-Tesla, because the actual attractive forces exerted on these implants are deemed minimal compared to the force exerted by the beating heart, MR procedures at 3-Tesla are not considered to be hazardous for patients or individuals that have these devices. To date, for the heart valves that have been tested, MRI-related heating has not been shown to reach substantial levels.”

3.3.2 mriquestions.com [43]

mriquestions.com provides a summary for this implant category:

“Artificial cardiac valves may be implanted by either an open surgical or transcatheter approach. They are classified as either bioprosthetic or mechanical.

Bioprosthetic valves are either homografts (made from human tissue) or xenografts (porcine, bovine, equine). Some have no metallic components and are MR Safe at all field strengths. (Their visibility on x-ray is due to admixture of a small amount of barium sulfate to the silicone structure). Others, especially transcatheter ones, have support rings or stents containing titanium, tungsten, or non-ferromagnetic alloys, making them MR Conditional. Because the lifespan of bioprosthetic valves is only 10 to 20 years, they are typically implanted in older patients.

Mechanical valves all contain metal (titanium or an alloy) at least in their support structure. Currently available valves have either one or two tilting disks. Older mechanical valves (such as Björk-Shiley or caged-ball models, including some made of stainless steel) may rarely be encountered, but like their modern counterparts are considered MR Conditional.

Annuloplasty is a procedure to tighten, reshape, or reinforce the ring (annulus) around a heart valve. It is most frequently performed for degenerative mitral regurgitation. Both open surgical and transcatheter techniques/devices are available.

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Most common surgically implanted annuloplasty devices have no metallic components and are MR Safe at all field strengths. However, the popular Carpentier-Edwards (Edwards LifeSciences) series and several others are composed of titanium alloys and are MR Conditional.

At least two MR Conditional transcatheter annuloplasty systems are now commercially available:

- *Carillon Mitral Contour System® (Cardiac Dimensions) is a flexible wire titanium-alloy device that is placed in the coronary sinus to wrap around and reshape the mitral valve indirectly.*
- *Cardioband® (Edwards LifeSciences) is a direct annuloplasty method wherein an adjustable C-shaped Dacron band is deployed via a transseptal approach and anchored to the left atrial side of the mitral annulus.*

*Two very similar **MR Conditional** transcatheter mitral valve repair systems are also commercially available, indicated for high risk patients who cannot tolerate an open surgical procedure - the **MitraClip®** (Abbott) and the **PASCAL® Repair System** (Edwards LifeSciences). The clips are made of Nitinol®.*

After entering the right heart by a venous approach, the intra-atrial septum is penetrated by the guide catheter and advanced so its tip lies in the left ventricle just below the margins of the mitral valves. A small clip then captures each valve leaflet pulling them together, in theory thus reducing mitral regurgitation.

The results of numerous investigations have demonstrated that metal-containing valves do undergo magnetically induced torques, but the magnitude of this effect is much less than the force exerted by the beating heart itself. This is in part because the metals used in modern mechanical valves (titanium, Elgiloy®) are not ferromagnetic. Even very old stainless steel valves are likewise considered of no danger in MRI. Thus at present, most centers consider all implanted heart valves and annuloplasty rings conditionally safe for MR imaging up to 3.0T, and do not require any waiting period after surgery before they can be scanned.

Pre-6000 series Starr-Edwards valves were once considered contraindicated for MR imaging, but this prohibition has now been removed. In any case, because most of these valves were implanted over 40 years ago, few, if any, patients are still alive who received them.

At one time worries existed that an electromagnetic phenomenon known as the ‘Lenz effect’ could inhibit the opening and closing of valves (such as the Björk-Shiley) made of metal disks or leaflets. This theoretical concern was not born out experimentally, so all-metal valves remain safe to scan at fields at least up to 3T.

Carpentier-Edwards annuloplasty rings, Models 4400 and 4500, marketed from 1980 to 1983, were made of stainless steel. The manufacturer is unwilling to provide an MR safety statement, so these must be considered ‘MR Unsafe.’ It is highly unlikely, however, that anyone with mitral valve disease requiring angioplasty 40 years ago is still alive to be scanned, so I do not worry about the possibility of such a ‘black swan’ event.”

3.4 Regulatory Medical Device Databases

3.4.1 Public Access Registration Database (PARD) (Queried 25/03/2025) [44]

Medical devices must be registered with the MHRA before they can be placed on the Great Britain market [45]. Medical device sales on the Northern Irish market generally requires MHRA registration, but there are exceptions for custom-made or Class I devices under certain conditions. Heart valves are usually Class III devices. Once registered, the company name and registered medical device types are added to PARD.

IPEM MR-SIG – MRI of Prosthetic Heart Valves, Annuloplasty Rings & TEER Clips – Evidence Review

Searches for the Global Medical Device Nomenclature (GMDN) terms listed in Appendix B were made on the PARD to identify the corresponding manufacturers.

3.4.1.1 Prosthetic Heart Valves

- Abbott Medical
- Boston Scientific Corporation
- Corcym Canada Corp.
- Corcym S.R.L.
- Edwards Lifesciences LLC
- JenaValve Technology Inc.
- Medtronic B.V.
- Medtronic CoreValve LLC
- Medtronic, Inc.
- Meril Life Sciences Pvt. Ltd.
- NVT GmbH
- On-X Life Technologies, Inc.
- St. Jude Medical
- Vascular Innovations Co. Ltd
- Venus Medtech (Hangzhou) Inc.

3.4.1.2 Annuloplasty Rings

- Abbott Medical
- Corcym Inc.
- Corcym S.R.L.
- Edwards Lifesciences LLC
- Medtronic Inc.
- St. Jude Medical

3.4.1.3 TEER Clips

- Abbott Medical
- Abbott Vascular
- Edwards Lifesciences LLC

3.4.2 Global Unique Device Identification Database (GUDID) (Queried 28/03/2025) [46]

GUDID provides details on implants that are approved by the FDA. Searches for the GMDN terms listed in Appendix B were made on the GUDID by importing the .csv from gudid_full_release_20250304 into SQL. The number of unique model brand names were identified for each manufacturer, and the number of total models were identified for each MR safety status. Model brand names were often shared between multiple sub-models.

3.4.2.1 Prosthetic Heart Valves

Manufacturer	Number of Unique Brand Names
Artivion, Inc.	3
Corcym Canada Corp	8
Corcym S.R.L.	7
Edwards Lifesciences LLC	40
LifeNet Health	2
Medtronic 3F Therapeutics, Inc	1
Medtronic, Inc.	17
On-X Life Technologies, Inc.	9
St. Jude Medical, Inc.	15

Table 7: Summary of the prosthetic heart valve manufacturers of GUDID

MR Safety Status	Total Number of Models
MR Unsafe	0
Unknown	536
MR Conditional	972
MR Safe	121

Table 8: Summary of GUDID's heart valve MRI safety status information

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3.4.2.2 Annuloplasty Rings

Manufacturer	Number of Unique Brand Names
Corcym Inc.	1
Corcym S.R.L.	3
Edwards Lifesciences LLC	6
Genesee BioMedical, Inc.	6
Medtronic, Inc.	17
St. Jude Medical, Inc.	5

Table 9: Summary of the prosthetic annuloplasty ring manufacturers of GUDID

MR Safety Status	Total Number of Models
MR Unsafe	0
Unknown	44
MR Conditional	227
MR Safe	134

Table 10: Summary of GUDID's annuloplasty ring MRI safety status information

3.4.2.3 TEER Clips

Manufacturer	Number of Unique Brand Names
Abbott Vascular, Inc.	1
Edwards Lifesciences LLC	2
St. Jude Medical, Inc.	2

Table 11: Summary of the prosthetic heart valve clip manufacturers of GUDID

The GUDID has the MitraClip registered under both Abbott Vascular and St. Jude Medical.

MR Safety Status	Total Number of Models
MR Unsafe	0
Unknown	1
MR Conditional	17
MR Safe	0

Table 12: Summary of GUDID's heart valve clip MRI safety status information

3.4.3 Australian Register of Therapeutic Goods (ARTG) (Queried 24/06/2025) [47]
ARTG provides a list of therapeutic goods that can be legally supplied in Australia. Searches for the GMDN terms listed in Appendix B were made on the ARTG search visualisation tool.

3.4.3.1 Prosthetic Heart Valves

Manufacturer	Number of Unique Brand Names
Abbott Medical	13
Boston Scientific Corporation	2
Corcym Canada Corp	1
Corcym Srl	1
Edwards Lifesciences LLC	14
Medtronic Inc	14
Medtronic Corevalve LLC	3
St. Jude Medical	6
Venus Medtech	1

Table 13: Summary of the prosthetic heart valve manufacturers of ARTG

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3.4.3.2 Annuloplasty Rings

Manufacturer	Number of Unique Brand Names
Coroneo Inc	1
Edwards Lifesciences LLC	4
Corcym Srl	2
Medtronic Inc	12
Abbott Medical	2

Table 14: Summary of the prosthetic annuloplasty ring manufacturers of ARTG

3.4.3.3 TEER Clips

Manufacturer	Number of Unique Brand Names
Abbott Medical	2
Abbott Vascular	5
Edwards Lifesciences LLC	6

Table 15: Summary of the TEER clip manufacturers of ARTG

3.4.4 European Database on Medical Devices (EUDAMED) (Queried 18/06/2025) [48]
 EUDAMED provides details on implants that are or have been available on the European Union’s market. EUDAMED registration is voluntary as it is still being rolled out. A search of devices under European Medical Device Nomenclature (EMDN) code P0703: Cardiac Valves, including historical records, found 44 results. After filtering out tools, the results were:

Manufacturer	Number of Unique Trade Names
Boston Scientific Corporation	1
Coroneo Inc.	1
JenaValve Technology, Inc.	1
Meril Life Sciences Pvt. Ltd.	3
TTK Healthcare Limited Heart Valve Division	1
Vascular Innovations Co. Ltd.	1

Table 16: Summary the prosthetic heart valve implant manufacturers on EUDAMED

3.5 Implant Safety Databases

3.5.1 MHRA Alerts, Recalls and Safety Information: Medicines and Medical Devices (Queried 25/06/2025) [49]

A search was performed for Device Safety Information under Vascular and Cardiac Surgery for “heart valve”, “annulo”, “TEER, or “edge-to-edge”. No MR-related results were found.

3.5.2 Northern Ireland Adverse Incident Centre (NIAIC) (Queried 25/06/2025) [50]

NIAIC was searched for “heart valve”, “annulo”, “TEER, or “edge-to-edge” under current and historical alerts. No MR-related results were found.

3.5.3 Manufacturer and User Facility Device Experience (MAUDE) Database (Queried 28/06/2025) [51]

3.5.3.1 Heart Valves

Searches of MAUDE were performed for the FDA product codes for heart valves (shown in Appendix C) and “MRI”. The Event Text checked to see if the results were MR-related.

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The searches for “NPT MRI” and “LWQ MRI” hit the maximum number of results limit.

The search for “DYE MRI” also hit the maximum number of results limit but included many devices of other types. The results were filtered for Product Code “DYE”. An advanced search for Product Code “DYE” was also performed (again reaching the limit), and the results filtered for Event Text containing “MRI”.

The results were:

MW5074530 – *“event description: a radiology pt was having an MRI of the left knee. Pt stated she has pulmonary atresia. She stated she has a (b)(4) transcatheter heart valve (MRI conditional 8). Pt did not bring her implant MRI card to have the MRI. MRI technologist called the physician, which stated that it was okay for the pt to be put in the MRI machine. Once scan started the pt stated had immediate chest pain. Immediately took pt out of scan room, took her vitals in the arthrogram room. HR (b)(6)-BP (b)(6)-02:100 at 1745. Charge tech immediately went to operating room for nurse. The nurse checked pt still having some pain. The charge went to get physician. Pt was assessed HR (b)(6)-BP (b)(6)- 02:100. At 1800, pt was brought to the injury clinic for monitoring. Pt stated she was feeling fine. Dr talk to pt and grandmother that if she starts having any kind of pain to go immediately to the ER. Pt was in good spirits when she left. Pt also has sternal wires from open heart surgery. Chest pain was of unclear origin.”*

MW5062690 - *“Event description: this pt had an outpatient MRI with contrast. The pt has a pacemaker and an aortic heart valve. Before the exam, a St. Jude pacemaker rep set the pacemaker to MRI mode (asynchronous pulsing) pt was placed on MR safe vitals monitor. IV contrast was administered roughly 30 minutes into the exam. Pt did not express distress throughout the exam. Upon removing the pt from the scanner, she appeared diaphoretic. The pt sat up, complained of shortness of breath, and presented audible wheezing. Pt was transferred to a stretcher where she deteriorated rapidly, and a code team was called. The code team arrived quickly and began to work the code. Pt was intubated, and stabilized. The St. Jude rep interrogated the pacer and placed it back in normal mode. She was rushed to the emergency room, for further care. This is in conjunction with another voluntary report on a St. Jude pacemaker.”*

3.5.3.2 Annuloplasty Rings

Searches of MAUDE were performed for the FDA product code for annuloplasty rings (KRH) and “MRI” and the Event Text checked to see if the results were MR-related. The No MR-related incidents were found.

3.5.3.3 TEER Clips

Searches of MAUDE were performed for the FDA product code for mitral valve repair devices (NKM) and “MRI” and the Event Text checked to see if the results were MR-related. The No MR-related incidents were found.

3.5.4 International Medical Devices Database (Queried 06/05/2025) [52]

Searches of the International Medical Devices Database’s cardiovascular devices for “MRI” or “magnetic resonance” found 16 and 7 events respectively, none of which were relevant.

3.6 Clinical Trials (Queried 19/06/2025)

A search of clinicaltrials.gov [53] for “transcatheter edge-to-edge repair” was performed and the summaries read to identify novel TEER clips. The results were:

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Trial ID	Model	Locations	Time Period	Number Enrolled
NCT04921605	DragonFly	China	2020-2023	10
NCT04734756	DragonFly	China	2021-2027	120
NCT04733404	DragonFly	China	2023-2027	120
NCT05927441	DragonFly	Unknown, likely China	2023-2029	168
NCT05671640	DragonFly-T	China	2022-2024	10
NCT05556460	DragonFly-T	China	2024-2027	236
NCT05655897	GeminiOne	China	2022-2029	120
NCT05417945	JensClip	Unknown, likely China	2022-2024	124
NCT05497141	Neoblazar	China	2022-2023	98
NCT06021509	NovoClasp	China	2022-2028	102
NCT05040074	SQ-Kyrin	China	2021-2026	20
NCT06467110	SQ-Kyrin	China	2021-2028	118
NCT06605313	SQ-Kyrin	China	2022-2027	12
NCT05988450	SQ-Kyrin	China	2022-2027	125
NCT06823700	SQ-Kyrin	Spain	2024-2026	34
NCT03869164	ValveClamp	China	2019-2025	110

Table 17: Summary of the TEER clips clinical trials

Additionally, the CardioClip study (NCT06241430) implanted a CardioMEMS pulmonary artery pressure monitoring device alongside MitraClip TEER clips.

3.7 Online MRI Implant Safety Databases (Queried 25/03/2025)

3.7.1 Prosthetic Heart Valves and Annuloplasty Rings [54]

A search of safety topic 179 “Heart Valves and Annuloplasty Rings” was conducted on [mrisafety.com](https://www.mrisafety.com). The results are summarised in Table 18.

MR Safety Status	Field Strength (T)			Total
	1.5	3	1.5 or 3	
Unsafe	0	0	0	0
Conditional 5	49	42	20	111
Conditional 6	0	54	1	55
Conditional 8	0	0	21	21
Safe	75	57	24	156
Total	124	153	66	343

Table 18: Summary of safety topic 179 on [mrisafety.com](https://www.mrisafety.com)

Conditional 5 requires that the manufacturer’s MR Conditions be found and followed.

Conditional 6 and Conditional 8 allow scanning with:

- Static magnetic field of 3-Tesla or less (for Conditional 6) or 1.5-Tesla and 3-Tesla only (for Conditional 8)
- Maximum spatial gradient magnetic field of 720-gauss/cm
- Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 2-W/kg (i.e., the Normal Operating Mode) for 15 minutes of scanning (per pulse sequence).

The Safe status does not follow the current definition of MR Safe. Instead, it means the object is considered to be safe for individuals in the MR environment, with special reference to the highest static magnetic field strength that was used for the MR safety test.

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The manufacturers include:

- Aortech
- Arbor Surgical Technologies
- ATS Medical
- Autogenics Europe
- Axion Medical
- Baxter Healthcare
- BioStable Science & Engineering, Inc.
- Boston Scientific
- Cardiac Dimensions, Inc.
- CardiAQ Valve Technologies
- Cardiosolutions, Inc.
- Coratomic
- Corlife
- Cutter Laboratories
- Direct Flow Medical, Inc.
- Durafic
- Edwards Lifesciences
- Genesee BioMedical, Inc.
- Heart Leaflet Technologies
- Highlife Medical, Inc.
- Inonescu-Shiley, Universal ISM
- JenaValve Technologies
- Johnson & Johnson
- Labcor Laboratorios
- LivaNova
- Marvel Medical Technologies
- Medical Inc, Ltd.
- Medtronic
- MiCardia
- MitralTech Ltd.
- MitraSpan, Inc.
- Navigate Cardiac Structures, Inc.
- Neovasc
- On-X Life Technologies
- Percutaneous Valve Technologies
- Shiley
- Sorin Biomedica
- St. Jude Medical
- Sulzer-Medica & Mitroflow International
- Symetis
- TRI Technologies
- TTK Healthcare Limited
- Valcare Medical Ltd.
- ValTech
- Valve Medical Ltd
- Vascular Innovations Co. Ltd
- Venus Medtech (Hangzhou) Inc.
- Xenofic

3.7.2 TEER Clips [55]

A search of safety topic 180 “Hemostatic Clips, Other Clips, Fasteners, and Staples” was conducted on mrisafety.com. The results are summarised in Table 19:

	1.5	3	1.5 or 3	Total
Unsafe	0	0	1*	1
Conditional 5	0	26	5	31
Conditional 6	0	28	1	29
Conditional 8	0	0	12	12
Safe	26	14	2	42
Total	26	68	21	115

Table 19: Summary of safety topic 180 on mrisafety.com

The MR Unsafe model was Cook Medical’s TriClip, an endoscopic haemoclip.

Filtering for “heart”, “cardiac”, “valve”, “edge” or “TEER” found 2 results:

Manufacturer	Model	Field Strength (T)	MR Safety Status
Medtronic Cardiac Surgery	U-CLIP	3	Conditional 6
Evalve, Inc.	EVALVE clip	3	Safe

Table 20: Summary of the filtered safety topic 180 on mrisafety.com

U-Clips are a CABG clip model [56].

Evalve, Inc was acquired by Abbott in 2009, and their clip became the MitraClip, a TEER clip [57].

3.8 Implant Manufacturers (Queried 05/09/2025)

3.8.1 Corcym

In 2021, Corcym published a statement about the MR safety status of their prosthetic heart valves and annuloplasty rings for the non-USA market [58]. All listed devices were MR Safe or MR Conditional.

For heart valves, the combined most restrictive conditions were:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient magnetic field of 525 Gauss/cm or less
- Whole-body averaged specific absorption rate (WB-SAR) of 1.5 W/kg in the Normal Operating Mode for 15 minutes (i.e., per pulse sequence)

The highest temperature change for heart valves was $<+3^{\circ}\text{C}$ with a highest specified value of $+2.7^{\circ}\text{C}$.

The WB-SAR 1.5W/kg limit came with the following statement:

“In non-clinical testing, the Mitroflow valve produced a temperature rise of less than 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5 Tesla, Model Signa MR, GE Medical System, Milwaukee, WI, MR scanner.”

For annuloplasty rings, the combined most restrictive conditions were:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- Whole-body averaged specific absorption rate (WB-SAR) of 2 W/kg in the Normal Operating Mode for 15 minutes (i.e., per pulse sequence)
- Transmit quadrature-driven coil (circularly polarized)

The highest temperature change for annuloplasty rings was $+2.4^{\circ}\text{C}$.

3.8.2 Edwards Lifesciences

Edwards Lifesciences have published a letter about the MR safety status of their prosthetic heart valves and annuloplasty rings for the non-USA market [59]. All listed prosthetic heart valves were MR Safe or MR Conditional.

For prosthetic heart valves, the combined most restrictive conditions were:

- Static magnetic field of 1.5 Tesla
- Maximum spatial gradient magnetic field of 720 Gauss/cm
- WB-SAR of 1.5 W/kg in the Normal Operating Mode for 15 minutes (i.e., per pulse sequence)

The highest temperature change for heart valves was $+4^{\circ}\text{C}$.

For annuloplasty rings, the combined most restrictive conditions were:

- Static magnetic field of 1.5 Tesla
- Maximum spatial gradient magnetic field of 720 Gauss/cm
- WB-SAR of 1.2 W/kg in the Normal Operating Mode for 15 minutes (i.e., per pulse sequence)

The highest temperature change for annuloplasty rings was $\leq+1.8^{\circ}\text{C}$.

The letter also contained the following statement:

“Carpentier-Edwards 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. These older rings were labeled with lot numbers (not serial numbers) that had the following format: 1C005 (i.e., where the first character was numeric, the second character was a letter from A to L and the last three or four characters were numeric)."

The eIFU for the PASCAL and PASCAL ACE TEER clips [60] confirms them to be MR Conditional with the statement:

"Non-clinical testing has demonstrated that the PASCAL and PASCAL Ace implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- *Static magnetic fields of 1.5 T and 3.0 T*
- *Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)*
- *Maximum MR system-reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode).*

Under the scan conditions defined above, the implant is expected to produce a maximum temperature rise of less than 4 °C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by the device in a worst case multiple implant configuration extends up to 15 mm from the implant when imaged in the worst case gradient echo pulse sequence in a 3.0 T MRI system."

3.8.3 Abbott

Abbott has eIFUs which give MR Conditions for the MitraClip NTR/XTR, MitraClip G4, MitraClip G5, TriClip G4 and TriClip G5 TEER clips [61]. MR Conditions for the MitraClip NT are available via the FDA [62]. GUDID states the original MitraClip is MR Conditional [63], but the conditions could not be found.

"Non-clinical testing has demonstrated that the MitraClip™ NT is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- *Static magnetic field of 1.5 or 3 Tesla*
- *Maximum spatial field gradient of 2500 Gauss / cm*
- *Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W / kg (First Level Controlled Operating Mode).*

Under the scan conditions defined above, MitraClip™ NT is expected to produce a maximum temperature rise of less than 3°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by a pair of devices extends approximately 30 mm beyond MitraClip™ NT when imaged with a spin echo or gradient echo pulse sequence and a 3 T magnetic resonance system. It may be necessary to optimize the magnetic resonance imaging parameters due to the presence of the implant"

"Non-clinical testing has demonstrated that the MitraClip [NTR/XTR] Implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- *Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3.0 T)*
- *Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)*
- *Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).*

Under the scan conditions defined above, MitraClip Implants are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by a pair of MitraClip Implants extends approximately 40 mm beyond the MitraClip Implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system"

“A patient with a MitraClip™ G4 Implant can be safely scanned in an MR system following these parameters:

- *Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3.0 T)*
- *Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)*
- *Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).*

Under the scan conditions defined above, the Clips are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by a pair of Clips extends approximately 40 mm beyond the Clips when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient’s valve may increase the image artifact size when imaged in an MRI system”

The MitraClip G5 MR Conditions are:

	A patient with the MitraClip™ G5 Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient or device malfunction.
Name/Identification of the Device	MitraClip™ G5 Implant
Nominal Value(s) of Static Magnetic Field [T]	1.5T or 3.0T
Maximum Spatial Field Gradient [T/m and gauss/cm]	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2W/kg
Limits on Scan Duration	2 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) (Under these scan conditions, the implants are expected to produce a maximum temperature rise of less than or equal to 2.7°C after 15 minutes of continuous scanning.)
MR Image Artifact	In non-clinical testing, the image artifact caused by a pair of implants extends approximately 40 mm beyond the implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system.
If information about a specific parameter is not included, there are no conditions associated with the parameter.	

Figure 3: MitraClip G5 MR Conditions [61]

“A patient with a TriClip™ G4 Implant can be safely scanned in an MR system following these parameters:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3.0 T)
- Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Clips are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning. In non-clinical testing, the image artifact caused by a pair of Clips extends approximately 40 mm beyond the Clips when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system”

The TriClip G5 MR Conditions are:

	A patient with the TriClip™ G5 Implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient or device malfunction.
Name/Identification of the Device	TriClip™ G5 Implant
Nominal Value(s) of Static Magnetic Field [T]	1.5T or 3.0T
Maximum Spatial Field Gradient [T/m and gauss/cm]	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [W/kg]	2W/kg
Limits on Scan Duration	2 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks) (Under these scan conditions, the implants are expected to produce a maximum temperature rise of less than or equal to 2.7°C after 15 minutes of continuous scanning.)
MR Image Artifact	In non-clinical testing, the image artifact caused by a pair of implants extends approximately 40 mm beyond the implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient's valve may increase the image artifact size when imaged in an MRI system.
If information about a specific parameter is not included, there are no conditions associated with the parameter.	

Figure 4: TriClip G5 MR Conditions [61]

3.8.4 Meril Life Sciences

Meril's MyClip TEER clip has an eIFU [64] which provides the following information:

- *“MyClip is MRI conditional.*
- *Device Composition: Made of materials (cobalt-chromium and polyester) shown to be non-ferromagnetic and MRI-safe under conditional parameters.*
- *Patients with an implanted MyClip may safely undergo an MRI under the following conditions :*
 - *Static magnetic field strength: 1.5 to 3.0 Tesla*
 - *Bandwidth: 32kHz (required)*
 - *Maximum spatial gradient magnetic field: ≤ 2,500 Gauss/cm.*
 - *Specific Absorption Rate (SAR): Whole-body SAR should not exceed 4.0 W/kg for 15 minutes of scanning (normal operating mode).*
- *Time after implantation: MRI may be performed immediately post-implantation.”*

3.8.5 Artivion

Artivion has published a statement about the MR safety status of their human allograft prosthetic heart valves for the USA market [65]. They stated:

“No ferromagnetic or metallic materials are applied to the tissue. To the best of our knowledge, there have been no adverse events related to allograft structure or function in patients undergoing MRI procedures.”

3.9 Local Policies (Queried 23/05/2025)

A 2022 survey of MRI superintendent/lead radiographers and clinical scientists across the UK [66] with 86 responses found that 33% of sites have a heart valve GISP.

NHS Wales has a GISP for MRI scans of a prosthetic heart valves, annuloplasty rings, mitral or tricuspid TEER systems, and cardiac occlusion or closure devices. This allows scanning at 1.5 or 3T, with 1.5T preferred. No limits are placed on spatial gradients or SAR, but patients should be positioned centrally, avoiding areas next to the covers at the bore entrance. No post-implantation waiting period is required for prosthetic heart valves, annuloplasty rings, or mitral or tricuspid TEER systems.

NHS Greater Glasgow and Clyde (GGC) has a GISP for MRI scans of a prosthetic heart valves and annuloplasty rings [67]. The implants must be commercial and inserted correctly. The policy allows scanning at 1.5 or 3T in Normal Operating Mode, with a maximum scanning time of 15 minutes per pulse sequence (multiple sequences per patient are allowed). No post-implantation waiting period is required. Spatial gradient is not restricted. The implantation date or implantation centre’s geographic location do not affect the policy. Any stenting does not affect the policy. NHS GGC has performed an evidence review to support this policy [68].

NHS University Hospitals of North Midlands (UHNM) has a GISP for the scanning of heart valves or annuloplasty rings. The implants must not be implanted as part of a research trial. The implant must be implanted in Europe or the United States of America. These implants may be scanned at 1.5 or 3T in Normal Operating Mode.

NHS The Christie has a policy that all heart valves or annuloplasty rings can be freely scanned at 1.5T or 3T without further screening immediately after insertion.

NHS Clatterbridge Cancer Centre (CCC) has a policy that MRI scans of heart valves and annuloplasty rings may be performed at 1.5T in Normal Operating Mode. The implants must not be implanted as part of research trial, damaged or incorrectly positioned, or close to an abnormal number of other implants. They must be implanted in the United Kingdom (UK) or the European Union (EU). These restrictions are the loosest allowed for any GISP at CCC.

In 2024, Frank Shellock [69] recommended:

“A patient with a heart valve prosthesis or an annuloplasty ring may undergo MRI using the following guidelines:

- *3-Tesla or less*
- *No restriction on the direction of the static magnetic field*
- *No restriction on the value of 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)”*

3.10 Anecdotal Evidence

3.10.1 MRIPHYSICS@JISCMail.AC.UK (Queried 26/03/2025) [70]

A search of the MRIPHYSICS JISCMail mailing list for “heart valve” or “annulo” found the following relevant results:

- Two conversations about new guidance (NVKF and Frank Sherlock’s).
- A query about scanning a pacemaker with an annuloplasty ring in place. An MR physicist from UHNM responded saying they had scanned 8 such cases by following the combined MR Conditions.
- A query about a heart valve reportedly implanted in 1947. The only response suggested asking the British Heart Valve Society. This predate the first heart valve replacement by 5 years [6], it is likely either a mistake or a heart valve repair surgery.

A search for “clip” found no relevant results.

3.10.2 MEDICAL-PHYSICS-ENGINEERING@JISCMail.AC.UK (Queried 20/06/2025) [71]

A search of the MEDICAL-PHYSICS-ENGINEERING JISCMail mailing list for “heart valve”, “annulo” or “clip” found one relevant query about scanning heart valves with a maximum spatial gradient greater than the one in the MR Conditions. The only response recommended using field plots to make an informed decision.

3.10.3 NHS-SCOTLAND-MRI-PHYSICS@JISCMail.AC.UK (Queried 26/03/2025) [72]

A search of the NHS-SCOTLAND-MRI-PHYSICS JISCMail mailing list for “heart valve” or “annulo” found:

- A conversation about reworking the NHS GGC GISPs.
- A conversation about what other types of implants should be included in a heart valve policy.
- A conversation saying that heart valves should not be included in MRI referral questions as they can be covered by a GISP so knowledge of them is not required before the day of the scan.

A search for “clip” found a conversation on whether clip policies should be divided into categories, but no mentions of TEER clips.

3.10.4 Guideline Use of MRI in patients with implants [12]

The NVKF guidelines include an evidence review. They searched mrisafety.com and MagResource for MRI safety statuses of heart valves and annuloplasty rings. The results are shown in Table 21.

MR Safety Status	# Heart Valves or Annuloplasty Rings
ASTM 2013 MR Safe	43
Old ASTM MR Safe	25
MR Safe on mrisafety.com but MR Conditional on MagResource	17
MR Conditional	240
Total	326

Table 21: NVKF’s results for MRI safety status

Using MagResource, they found the following manufacturer MR Conditions:

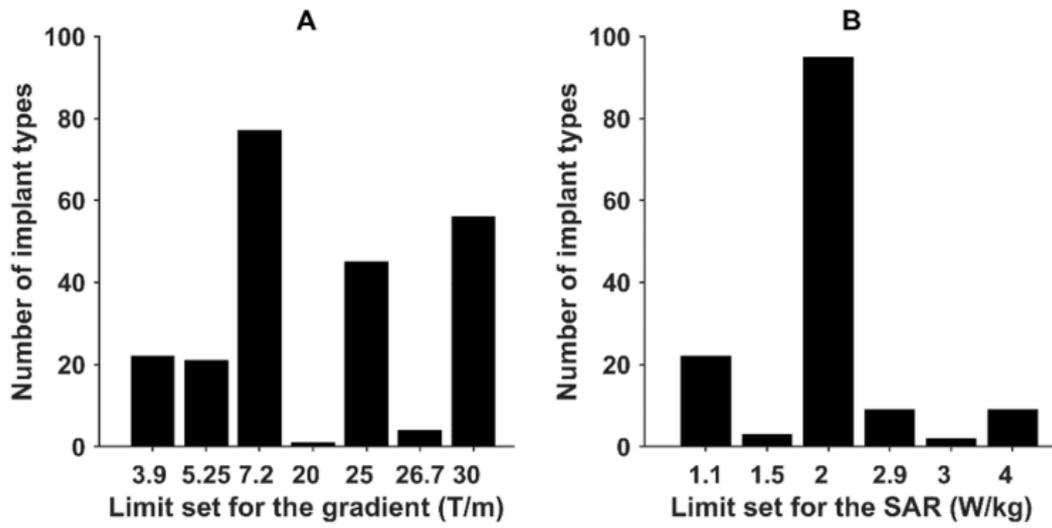


Figure 5: NVKF's results for MR Conditions for heart valves and annuloplasty rings [12]

3.11 Evidence Summary

The equation for CEM43°C is:

$$CEM43^{\circ}C = \sum_{i=1}^n t_i \cdot R^{(43-T_i)}$$

Equation 1 [73]

$CEM43^{\circ}C$ = Cumulative number of equivalent minutes at 43 °C

n = Number of time intervals

t_i = i^{th} time interval (minutes)

T_i = average temperature during time interval t_i (°C)

R is related to the temperature dependence of the rate of cell death. If $T < 43^{\circ}C$, $R = \frac{1}{4}$. If $T > 43^{\circ}C$, $R = \frac{1}{2}$.

For a worst-case scenario of $n = 1$, this gives:

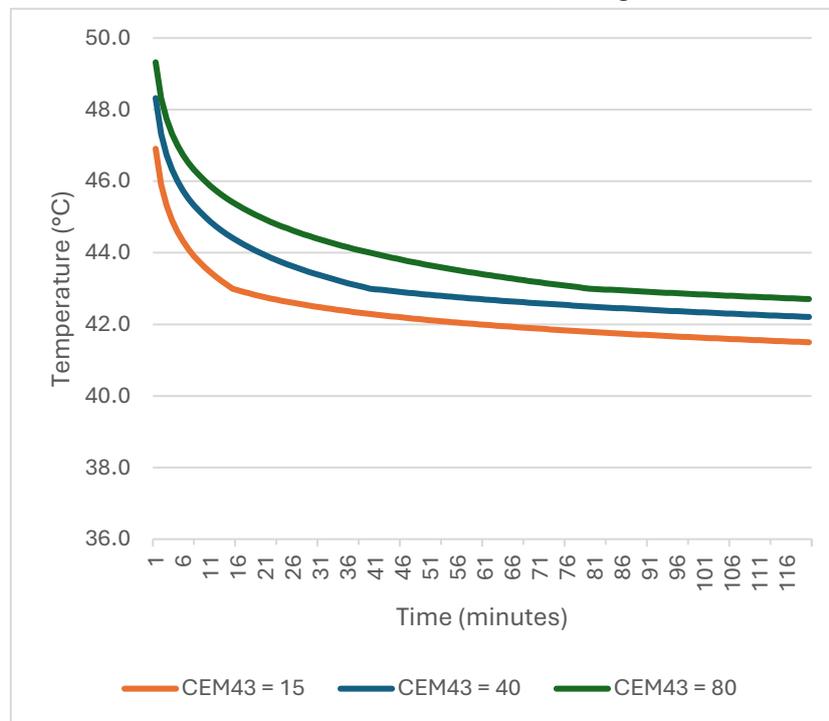


Figure 6: Plot of temperature against time for different CEM43 values

The CEM43°C range for reversible effects to human muscle is >40 and ≤ 80 [73]. For a two-hour scan, a CEM43°C of 40 would be reached with a temperature of 42.2°C. Assuming a human body temperature of 37.5°C, this would require heating of 4.7°C. A significant cooling effect may also be expected in vivo due to blood flow [74][25].

3.11.1 Heart Valves

3.11.1.1 Hazards

- **Deflection** – The maximum ex vivo deflection was 27° for the Starr-Edwards Pre 6000 [15]. This is less than the force due to gravity and much less than the mechanical force of a beating heart [75], however, this implant was only tested up to 2.35T. All other models tested deflected $\leq 9^\circ$ [15-26]. The mechanical forces within a beating heart far exceed the force on a prosthetic heart valve due to a magnetic field of $\leq 4.7\text{T}$ [22].
- **Torque** – At up to 3T, the maximum ex vivo torque was +2 (moderate) [16, 21-27]. At 4.7T, the maximum ex vivo torque was $>45^\circ$ to 90° [22, 24].
- **Heating** – The maximum ex vivo heating in the peer reviewed literature was +2.7°C at 1.5T and whole-body average SAR of 2.7W/kg for the Medical Technologies AltaValve [15-16, 18-21, 25-26]. The authors of the paper that found this heating stated it was “*relatively minor and therefore physiologically acceptable for a human subject*”. The maximum ex vivo heating tested by manufacturers was +4°C at 3T and whole-body average SAR of 2W/kg [59].
- **Lenz Effect** – Several attempts at computationally modelling the impact of the Lenz effect have produced conflicting results [28-30]. The most realistic model was the wire-like ring by Golestanirad et al [30]. This demonstrated a force $<2\text{N}$ up to 10T and less than 1N up to 3T. This model is a worst-case scenario due to using an opening time of 10ms when 50ms is more realistic. Edwards et al [31] found several valves were affected in vitro at 1.5T. No in vivo effects were found when scanning up to 1.5T [16][32].

3.11.1.2 Safety incidents

Two safety incidents relating to the MRI scanning of this implant were found [51]. One where pain was caused in a patient with a prosthetic heart valve and sternal wires. The other where shortness of breath was caused in a patient with a prosthetic heart valve and a pacemaker. Neither case attributed the prosthetic heart valve as the cause.

3.11.1.3 MR Unsafe or Unlabelled Models

No MR Unsafe or Unlabelled models were identified. However, MR safety status was not found for all models.

3.11.1.4 Conditions

- **Geographical Location** – NHC CCC’s GISP restricts the implantation location to the UK or EU. NHS UHNM’s GISP restricts the implantation location to Europe or the USA. However, these restrictions apply to all GISPs at those trusts.
- **Implantation Date** – The Starr-Edwards Pre 6000 deflected much more than any other model tested [15]. This model was available during the early 1960s [15]. However, even this model would likely have deflection forces far less than the mechanical forces of a beating heart [22]. Additionally, it is 60 years since this model was last implanted, so it unlikely they will be encountered.
- **Time since Implantation** - All intra-cardiac implants must be able secure enough to resist the mechanical forces within a beating heart immediately after implantation. None of the available guidance recommends a post-implantation waiting period [11-14]. Several specify that no waiting period is necessary [12] [14].
- **Patient Characteristics** – No evidence was found which suggested restrictions on patient characteristics were required.
- **Implantation Configuration** - When location is specified, the evidence generally relates to aortic or mitral valves, not pulmonary or tricuspid valves. This is likely due to relative prevalence; pulmonary and tricuspid valves represent a minority of heart valves [2].
- **Requirement for Previous Imaging** – Several local GISPs required the device to be implanted correctly or undamaged. It is unclear whether they simply prevent the scanning of devices that are

known to be incorrectly implanted or damaged, or if this information should be confirmed. If it must be confirmed, a review of previous imaging may be useful.

- **Static Field Strength** – Several guidance documents recommend that scanning may be safely performed at 1.5 or 3T [11-14]. Several local GISPs also have this restriction. Edwards Lifesciences' most restrictive MR Conditions limit static field strength to 1.5T [59].
- **Anatomy at Isocentre** - No evidence was found which suggested restrictions on the anatomy at isocentre were required.
- **Spatial Gradients** - Corcym's most restrictive MR Conditions require a spatial gradient of ≤ 525 Gauss/cm [58]. Edwards Lifesciences most restrictive MR Conditions a spatial gradient of ≤ 720 Gauss/cm [59]. NVKF found MR Conditions with spatial gradient limits as low as 390 Gauss/cm [12].
- **Gradient Limits** – Neither NVKF nor Frank Shellock recommend gradient limits [12][69]. NHS CCC and UHNM have GISPs that require remaining in Normal Operating Mode. Corcym and Edward's Lifesciences most restrictive MR Conditions require Normal Operating Mode [58][59].
- **SAR or B1+Rms** – Ex vivo evidence of heating up to $+2.7^{\circ}\text{C}$ has been found [26]. Frank Shellock recommends restricting whole-body averaged SAR to $\leq 2\text{W/kg}$ [69]. NHS CCC and UHNM have GISPs that require remaining in Normal Operating Mode. Corcym and Edward's Lifesciences most restrictive MR Conditions require whole-body averaged SAR of 1.5 W/kg [58][59]. NVKF found the most restrictive MR Conditions require whole-body averaged SAR of 1.1 W/kg [12].
- **RF Polarisation** – No evidence was found which suggested RF polarisation restrictions were required.
- **RF Transmit Coil** - No evidence was found which suggested RF transmit coil restrictions were required.
- **RF Receive Coil** - No evidence was found which suggested RF receive coil restrictions were required.
- **Scan Duration and Cool-Down Time** - Frank Shellock recommends restricting the scan time per pulse sequence to ≤ 15 minutes [69]. NHS GGC also have this restriction in their GISP [67]. Corcym and Edward's Lifesciences most restrictive MR Conditions require ≤ 15 minutes per pulse sequence [58][59].
- **Any Other Conditions** – MHRA recommends confirming the implants MR safety with its manufacturer [11]. Several local GISPs only apply to commercial implants or those not implanted as part of a research trial. Several also require the implant is properly implanted. NHC CCC requires the implant is not damaged, or close to an abnormal number of other implants.

3.11.2 Annuloplasty Rings

3.11.2.1 Hazards

- **Deflection** – The maximum ex vivo deflection was 20° for the Carpentier Edwards Physio 4450, tested at 4.7T [21][23][24]. There is some evidence of annuloplasty rings becoming magnetised from repeat exposure [24].
- **Torque** – At up to 3T, the maximum ex vivo torque was +2 (moderate) [21][23]. At 4.7T, the maximum ex vivo torque was >45° to 90° [24].
- **Heating** - The maximum ex vivo heating in the peer reviewed literature was +0.6°C [21]. This is based on only a small range of models. The maximum ex vivo heating tested by manufacturers was +2.4°C [58].

3.11.2.2 Safety incidents

No safety incidents relating to the MRI scanning of this implant were found.

3.11.2.3 MR Unsafe or Unlabelled Models

No MR Unsafe models were identified. Carpentier-Edwards Models 4400 and 4500, marketed from 1980 to 1983, were made of stainless steel, and are MR Unlabelled [59]. MR safety status was not found for all models.

3.11.2.4 Conditions

- **Geographical Location** - NHC CCC's GISP restricts the implantation location to the UK or EU. NHS UHNM's GISP restricts the implantation location to Europe or the USA. However, these restrictions apply to all GISPs at those trusts.
- **Implantation Date** - Carpentier-Edwards Models 4400 and 4500, marketed from 1980 to 1983, were made of stainless steel, and are MR Unlabelled [59].
- **Time since Implantation** - All intra-cardiac implants must be able secure enough to resist the mechanical forces within a beating heart immediately after implantation. None of the available guidance recommends a post-implantation waiting period [11-14]. Several specify that no waiting period is necessary [12][14].
- **Patient Characteristics** – No evidence was found which suggested restrictions on patient characteristics were required.
- **Implantation Configuration** - When location is specified, the evidence generally relates to mitral or tricuspid valves, not pulmonary or aortic valves [21][23][24].
- **Requirement for Previous Imaging** – Several local GISPs required the device to be implanted correctly or undamaged. It is unclear whether these simply prevent the scanning of devices known to be incorrectly implanted or damaged, or if this information should be confirmed. If it must be confirmed, a review of previous imaging may be useful.
- **Static Field Strength** – Several guidance documents recommend that scanning may be safely performed at 1.5 or 3T [12-14]. Several local GISPs also have this restriction. Edwards Lifesciences' most restrictive MR Conditions limit static field strength to 1.5T [59].
- **Anatomy at Isocentre** - No evidence was found which suggested restrictions on the anatomy at isocentre were required.
- **Spatial Gradients** - Edwards Lifesciences most restrictive MR Conditions a spatial gradient of ≤720 Gauss/cm [59]. NVKF found MR Conditions with spatial gradient limits as low as 390 Gauss/cm [12].
- **Gradient Limits** - Neither NVKF nor Frank Shellock recommend gradient limits [12][69]. NHS CCC and UHNM have GISPs that require remaining in Normal Operating Mode.
- **SAR or B1+Rms** – Ex vivo evidence of heating up to +0.6°C [21]. Frank Shellock recommends restricting whole-body averaged SAR to ≤2W/kg [69]. NHS CCC and UHNM have GISPs that require remaining in Normal Operating Mode. Edwards Lifesciences most restrictive MR Conditions require whole-body averaged SAR of 1.2 W/kg [59]. NVKF found the most restrictive MR Conditions require whole-body averaged SAR of 1.1 W/kg [12].

- **RF Polarisation** - Corcym's most restrictive MR Conditions require circularly polarisation [58].
- **RF Transmit Coil** - No evidence was found which suggested RF transmit coil restrictions were required.
- **RF Receive Coil** - No evidence was found which suggested RF receive coil restrictions were required.
- **Scan Duration and Cool-Down Time** - Frank Shellock recommends restricting the scan time per pulse sequence to 15 minutes [69]. NHS GGC also have this restriction in their GISP [67].
- **Any Other Conditions** – Several local GISPs only apply to commercial implants or those not implanted as part of a research trial. Several also require the implant is properly implanted. NHC CCC requires the implant is not damaged, or close to an abnormal number of other implants.

3.11.3 TEER Clips

Table 22 shows the TEER clip models identified in this review, and their MR safety statuses.

Make	Model	Model No.	MR Safety Status
Edwards Lifesciences	PASCAL	20000IS	MR Conditional
Edwards Lifesciences	PASCAL Ace	20000ISM	MR Conditional
Abbott	MitraClip	CDS0201	MR Conditional
Abbott	MitraClip NT	CDS0501	MR Conditional
Abbott	MitraClip NTR/XTR	CDS0601-NTR, CDS0601-XTR	MR Conditional
Abbott	MitraClip G4	CDS0701-NT, CDS0701-NTW, CDS0701-XT, CDS0701-XTW	MR Conditional
Abbott	MitraClip G5	TCDS0802-NT, TCDS0802-NTW, TCDS0802-XT, TCDS0802-XTW	MR Conditional
Abbott	TriClip G4	TCDS0302-NT, TCDS0302-NTW, TCDS0302- XT, TCDS0302-XTW	MR Conditional
Abbott	TriClip G5	TCDS0802-NT, TCDS0802-NTW, TCDS0802- XT, TCDS0802-XTW	MR Conditional
Meril Life Sciences	MyClip	Unknown	MR Conditional
Valgen Medtech	DragonFly	SN0409, XN0412, SW0609, XW0612	Unknown
Valgen Medtech	DragonFly-T	Unknown	Unknown
Peijia Medical	GeminiOne	Unknown	Unknown
Shenqi Medical	SQ-Kyrin-T	Unknown	Unknown
Shenqi Medical	SQ-Kyrin-M	Unknown	Unknown
Dawneo Medical Technology	Neoblazar	Unknown	Unknown
Hanyu Medical Technology	ValveClamp	Unknown	Unknown
Jens Medical	JensClip	Unknown	Unknown
Enlight Medical Technologies	NovoClasp	Unknown	Unknown

Table 22: MR safety status of TEER clips

All known TEER clips approved for use in the UK, USA or Australia are MR Conditional; all their conditions are listed in Table 23. A range of TEER clips are produced in China that have no known MR safety labelling. No safety incidents relating to the MRI scanning of TEER clips were found.

The MyClip requires a bandwidth of 32kHz and has the condition “Whole-body SAR should not exceed 4.0 W/kg for 15 minutes of scanning (normal operating mode).” [64]

Make	Model	Static Magnetic Field (T)	Spatial Gradient (G/cm)	Operating Mode	WB-SAR (W/kg)	Temperature Rise (°C)*
Edwards Lifesciences	PASCAL	1.5 or 3.0	≤3,000	First Level Controlled	≤4	≤4
Edwards Lifesciences	PASCAL Ace	1.5 or 3.0	≤3,000	First Level Controlled	≤4	≤4
Abbott	MitraClip	Unknown	Unknown	Unknown	Unknown	Unknown
Abbott	MitraClip NT	1.5 or 3.0	≤2,500	First Level Controlled	≤4	≤3
Abbott	MitraClip NTR/XTR	1.5 or 3.0	≤4,000	Normal	≤2	≤3.1
Abbott	MitraClip G4	1.5 or 3.0	≤4,000	Normal	≤2	≤3.1
Abbott	MitraClip G5**	1.5 or 3.0	≤4,000	Normal	≤2	≤2.7
Abbott	TriClip G4	1.5 or 3.0	≤4,000	Normal	≤2	≤3.1
Abbott	TriClip G5**	1.5 or 3.0	≤4,000	Normal	≤2	≤2.7
Most Restrictive Known Conditions		1.5 or 3.0	≤2,500	Normal	≤2	≤4

Table 23: MR Conditions for TEER clips available in the UK, USA or Australia

*Maximum temperature rise was determined for 15 minutes of continuous scanning. A significant cooling effect may also be expected in vivo due to blood flow [74][25].

**Requires circular polarisation and a maximum continuous RF time of 60 minutes.

4 Discussions

The IPEM MR-SIG GISP Task & Finish Group discussed the following topics:

- **Geographical Location** – Concerns were raised about the lack of information on Chinese models of TEER clips. Since these may be implanted in countries other than China, it was determined that countries should be whitelisted. While the UK, USA, Europe, Australia, Canada, & Japan were all considered for whitelisting, consensus was only reached for the UK.
- **Implantation Date** – The group discussed limiting the implantation date of annuloplasty rings to exclude the MR Unlabelled stainless steel Carpentier-Edwards Models 4400 and 4500. These implants may be untested as, of the two papers that test these models [21][23], one used a titanium version and the other was unclear. Consensus was reached that no limitation was necessary as they would now be extremely rare and would likely be firmly fixated in place.
- **Time since Implantation** – The group agreed that if the implants could stay in place under the forces of the heart, no additional time was needed for them to get more firmly fixated.
- **Patient Characteristics** – It was noted that thermoregulatory compromised patients may require reduced RF heating, but this was considered beyond the scope of a GISP.
- **Implantation Configuration** – There was some discussion on whether valves used in combination with stents should be included, but it was agreed to be beyond the scope of a GISP.
- **Requirement for Previous Imaging** – It was considered whether imaging could be used to determine if there are any other nearby implants that could increase heating, or if the implants are implanted correctly and undamaged. However, these facts were determined to be beyond the scope of a GISP.
- **Static Field Strength** – The group immediately reached consensus that scanning was okay up to and including 3T.
- **Anatomy at Isocentre** – The group immediately reached consensus that no limitations were necessary.
- **Spatial Gradients** – The group immediately reached consensus that no limitations were necessary.
- **Gradient Limits** – The group immediately reached consensus that no limitations were necessary.
- **SAR or B1+Rms** – There was a disagreement about whether First Level Operating Mode was safe, if it should be restricted to outside the thorax or outside the transmit coil, or if it was suitable for a GISP to allow it at all. Consensus was reached that it was acceptable for First Level Operating Mode to be used without restricting body region after a discussion of blood flow cooling and the likelihood of scenarios needed to reach dangerous levels of heating. The group determined that a GISP not excluding First Level Operating Mode was not a recommendation to use it, as that should be a local, patient-specific decision.
- **RF Polarisation** – The group discussed the fact several sets of MR conditions limited scans to circular polarisation. Consensus was reached that no limitation was necessary. The point was raised without dissent that it would be redundant when SAR is limited.
- **RF Transmit Coil** - The group immediately reached consensus that no limitations were necessary.
- **RF Receive Coil** - The group immediately reached consensus that no limitations were necessary.
- **Scan Duration and Cool-Down Time** - The group immediately reached consensus that no limitations were necessary.
- **Any Other Conditions** - While not put forwards for formal consensus, the following arguments were raised without dissent:
 - MyClip’s MR condition of “Bandwidth: 32kHz (required)” has no basis in MR safety.
 - The simulation and in vitro papers covering the Lenz effect are flawed. Given the findings of the in vivo papers and lack of clinical incidents, the Lenz effect is not a significant concern at up to or including 3T.

5 Risk Assessment

5.1 Hazards

5.1.1 Hazards Shared by all GISPs [76]

- Unknowingly scanning an implant that is unsafe for MRI, for example an implant previously unrecognized.
- Unknowingly scanning an implant where the MRI safety information has changed such that it is no longer safely scanned under a GISP.
- Knowingly scanning an MR Conditional device under a GISP outside its MRI conditions (also termed “off-label”) with the associated institutional liability.
- Unknowingly scanning undisclosed implants. 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.
- Unknowingly scanning a different implant than the one intended. 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).

5.1.2 Hazards Specific to this GISP

- Displacement or torque due to the static magnetic field
- Heating due to radiofrequency waves and gradient fields
- Lenz effect due to movement of prosthetic heart valves through the static magnetic field
- Unknowingly scanning an MR Unlabelled TEER clip, produced in China but implanted outside of China. There is little information available on the TEER clips produced in China. It is possible they may not be safe for MRI. These clips may be implanted outside of China.

5.2 Precautions

- Static field is limited to $\leq 3T$.
- SAR is limited to Normal or First Level Controlled Operating Mode.
- TEER clips implanted outside of the UK are excluded from the GISP.

5.3 Residual Risk

The severity of consequences was judged based off the most probable reasonably foreseeable outcomes to avoid inflating the severity with extreme edge cases.

Assessing the hazards identified and the precautions recommended, the most probable residual risk of adopting this GISP is that a patient may feel some discomfort during their scan which will subside quickly once the scan is stopped and they leave the MR Environment. This may require further investigation by the cardiology team.

Likelihood	Most Likely Consequence	Risk
1	2	2

Table 24: Most probably residual risk with the precautions in place

There are other potential risks associated with use of this GISP if, for example, unknowingly scanning a strongly ferromagnetic MR Unsafe heart valve. However, based on the evidence presented in this GISP, these worse case scenarios were considered to be extremely unlikely by the panel so the overall risk of this GISP remains low.

5.3.1 Risk Matrix

	(1) Negligible Minimal injury requiring no / minimal intervention or treatment.	(2) Minor Minor injury or illness, requiring minor intervention	(3) Serious Moderate injury requiring professional intervention	(4) Critical Major injury leading to long term incapacity / disability	(5) Catastrophic Incident leading to death
(5) Frequent ($\geq 10^{-3}$)	Medium	High	High	V High	V High
(4) Probable ($< 10^{-3}$ and $\geq 10^{-4}$)	Medium	Medium	High	High	V High
(3) Occasional ($< 10^{-4}$ and $\geq 10^{-5}$)	Low	Medium	Medium	High	High
(2) Remote ($< 10^{-5}$ and $\geq 10^{-6}$)	Low	Medium	Medium	Medium	High
(1) Improbable ($< 10^{-6}$)	Low	Low	Low	Medium	Medium

This risk matrix has been adapted from ISO 14971:2019 – Medical Devices – Application of Risk management to medical devices [77].

6 References

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Appendix A. Excluded Literature

Author	Reference	Reason for Exclusion
Prasad & Pennell	[78]	Editorial
Baretta et al	[79]	Full Text Unavailable
Giroletti & Corbucci	[80]	Full Text Unavailable
Pruefer et al	[81]	Full Text Unavailable
Shellock & Shellock	[82]	Full Text Unavailable
Stijnman et al	[83]	Full Text Unavailable
Myers et al	[84]	Letter to Editor
Bachmann et al	[85]	Non-English
Baretti et al	[86]	Non-English
Boztosun et al	[87]	Non-English
Hassler et al	[88]	Non-English
Kalden et al	[89]	Non-English
von Knobelsdorff et al	[90]	Non-English
Koito et al	[91]	Non-English
Müllerleile et al	[92]	Non-English
Ahmed & Shellock	[93]	Non-Systematic Review
Baikoussis et al	[94]	Non-Systematic Review
Dill	[95]	Non-Systematic Review
Gulsin et al	[96]	Non-Systematic Review
Lebel et al	[97]	Non-Systematic Review
Leiner et al	[98]	Non-Systematic Review
Martin & Sandler	[99]	Non-Systematic Review
Onciul et al	[100]	Non-Systematic Review
Pamboukas & Rokas	[101]	Non-Systematic Review
Pham et al	[102]	Non-Systematic Review
Ripley et al	[103]	Non-Systematic Review
Sawyer-Glover & Shellock	[104]	Non-Systematic Review
Shellock	[105]	Non-Systematic Review
Shellock	[106]	Non-Systematic Review
Shellock & Crues	[107]	Non-Systematic Review
Walsh et al	[108]	Non-Systematic Review
Karamitsos & Karvounis	[109]	Opinion Paper
Shaffer et al	[110]	Systematic Review

Table 25: Excluded papers

Appendix B. GMDN Search Terms

GMDN Code	GMDN Term
60240	Aortic bi-leaflet mechanical heart valve prosthesis
60423	Aortic bi-leaflet mechanical heart valve prosthesis/biologic-polymer aorta graft
60241	Mitral bi-leaflet mechanical heart valve prosthesis
60242	Aortic heart valve bioprosthesis
60244	Mitral heart valve bioprosthesis
60245	Aortic transcatheter heart valve bioprosthesis, stent-like framework
60350	Aortic heart valve bioprosthesis/synthetic polymer aorta graft
60246	Mitral transcatheter heart valve bioprosthesis
60247	Pulmonary transcatheter heart valve bioprosthesis
60337	Pulmonary heart valve bioprosthesis
65121	Tricuspid transcatheter heart valve bioprosthesis
61625	Cadaveric pulmonary artery bioprosthesis

Table 26: Summary of GMDN terms for prosthetic heart valves

GMDN Code	GMDN Term
47931	Aortic annuloplasty ring
45577	Mitral annuloplasty ring
45578	Mitral/tricuspid annuloplasty ring
66338	Mitral/tricuspid annuloplasty ring, open-surgery

Table 27: Summary of GMDN terms for annuloplasty rings

GMDN Code	GMDN Term
57790	Heart valve clip

Table 28: Summary of GMDN terms for TEER clips

Appendix C. FDA Product Code Search Terms

FDA Product Code	Product Code Name
OHA	Heart-valve, more than minimally manipulated allograft
LWR	Heart-valve, non-allograft tissue
NPU	Prosthesis, mitral valve, percutaneously delivered
NPT	Aortic Valve, Prosthesis, Percutaneously Delivered
NPW	Percutaneously Delivered Prostheses And Tricuspid Valves
NPV	Pulmonary Valve Prosthesis Percutaneously Delivered
LWQ	Heart-valve, mechanical
DYE	Replacement heart valve

Table 29: Summary of FDA terms for prosthetic heart valves

FDA Product Code	Product Code Name
KRH	Ring, annuloplasty

Table 30: Summary of FDA terms for annuloplasty rings

FDA Product Code	Product Code Name
NKM	Mitral valve repair devices

Table 31: Summary of FDA terms for TEER clips

Appendix 2: Detailed Consensus

Consensus was defined as >90% agreement. Modifications were made to the questions during the process for clarity.

Survey 1 (27 responses)	Agreement	Consensus reached
Do you agree that including the following condition in a GISP would result in an acceptable level of risk:		
Implantation date condition: No exclusions.	78%	No
Implantation date condition: Exclude annuloplasty rings fitted before 1986.	70%	No
Time since implantation date condition: No exclusions.	100%	Yes
Geographical Location Condition: Exclude TEER clips fitted in China.	67%	No
Geographical Location Condition: No exclusions.	59%	No
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
WB SAR or B1+rms condition: First level SAR mode	33%	No
Anatomy at isocentre and patient position in scanner condition: No exclusions	100%	Yes
Static magnetic field strength condition: Up to and including 3T	93%	Yes
Static magnetic field strength condition: Up to and including 1.5T	70%	No
Spatial field gradient conditions: No exclusions	96%	Yes
Requirement to review previous imaging: No requirement	89%	No
Gradient Slew Rate condition: No exclusions	96%	Yes
RF polarisation condition: Circularly polarised only	70%	No
RF polarisation condition: No exclusions	85%	No
RF transmit coil condition: No exclusions	96%	Yes
RF receive coil condition: No exclusions	100%	Yes
Patient characteristics condition: No exclusions	93%	Yes
Scan duration and wait time condition: No exclusions	96%	Yes
Implant configuration condition: No exclusions	93%	Yes

Survey 2 (27 responses)	Agreement	Consensus reached
Do you agree that including the following condition in a GISP would result in an acceptable level of risk:		
Implantation date condition: No exclusions.	100%	No
Time since implantation date condition: No exclusions.	96%	Yes
Geographical Location Condition: No exclusions.	78%	No
Geographical Location Condition: Exclude TEER clips fitted in China	81%	No
Geographical Location Condition: Exclude TEER clips outside UK and US	96%	Yes
WB SAR or B1+rms condition: Normal SAR mode	100%	Yes
WB SAR or B1+rms condition: First level SAR mode	48%	No
Anatomy at isocentre and patient position in scanner condition: No exclusions	100%	Yes
Static magnetic field strength condition: Up to and including 3T	100%	Yes
Spatial field gradient conditions: No exclusions	100%	Yes
Requirement to review previous imaging: No requirement	96%	Yes
RF polarisation condition: No exclusions	100%	Yes
RF transmit coil condition: No exclusions	100%	Yes
RF receive coil condition: No exclusions	100%	Yes
Patient characteristics condition: No exclusions	100%	Yes
Scan duration and wait time condition: No exclusions	96%	Yes
Implant configuration condition: No exclusions	96%	Yes

Survey 3 (28 responses)	Agreement	Consensus reached
TEER clips with unknown safety status:		
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings	75%	No
Approve for MR scanning under GISP with different locally-defined MR conditions to heart valves and annuloplasty rings.	18%	No
Do not approve for MR scanning under GISP	7%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Europe	86%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Japan	79%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Australia	89%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Canada	82%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): UK	96%	Yes
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): USA	89%	No
For all implants covered by GISP		
Do you agree that including the following condition in a GISP would result in an acceptable level of risk: First Level SAR mode	68%	No
Do you agree that including the following condition in a GISP would result in an acceptable level of risk: First Level SAR mode if implant outside of transmit coil, Normal Level SAR if implant within the transmit coil	82%	No
Do you agree that including the following condition in a GISP would result in an acceptable level of risk: Normal Level SAR	100%	Yes
Do you agree that including the following condition in a GISP would result in an acceptable level of risk: Gradient Slew Rate: No exclusions	96%	Yes

Survey 4 (24 responses)	Agreement	Consensus reached
TEER clips with unknown safety status:		
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Europe	83%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Japan	67%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Australia	83%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): Canada	75%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): UK	100%	Yes
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): USA	83%	No
Approve for MR scanning under GISP with the same locally-defined MR conditions as heart valves and annuloplasty rings, if fitted in the following location (tick all that you agree with): USA	54%	No
For all implants covered by GISP:		
Do you agree that including the following condition in a GISP would result in an acceptable level of risk: First Level SAR mode	92%	No