Guideline
Use of MRI in patients with implants

This is the English translation of the Dutch guideline
'richtlijn Gebruik MRI bij patienten met implantaten'.
The Dutch version is officially approved by the Dutch Association of Medical Specialists (FMS)

INITIATIVE OF
Society for Medical Physics of the Netherlands (NVKF)

IN COLLABORATION WITH
Dutch Society for Medical Imaging and Radiotherapy(NVMBR)
Netherlands Society of Cardiology(NVvC)
Netherlands Society for Neurosurgery(NVvN)
Radiological Society of the Netherlands(NVvR)

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Knowledge Institute of the Medical Specialists

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Colophon

GUIDELINE USE OF MRI IN PATIENTS WITH IMPLANTS
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General introduction

Motivation for the guideline development

Every year more than 750,000 implants are placed in the Netherlands (van der Graaf, 2016). This number increases over time and more and more different types of implants are employed in an increasing number of pathologies. Many patients with implants will later on in life be referred for a diagnostic MRI examination, a technique that is increasingly used in clinical routine (RIVM, 2015). Based on current information on MRI contraindications of implants, an implant is either classified as 'MR safe' (MRI can be applied without risk) or 'MR conditional' (where MRI can take place safely under specific conditions), or into the category 'MR unsafe'. The additional risk of complications due to the presence of the implant is negligible for the categories 'MR safe' and 'MR conditional'. However, the classification of implants is performed by the implant manufacturer, who sometimes tests the implant in a limited setting and tends to define conservative conditions. In addition, the above classification assumes that one always knows all details of the implant, which is not always the case in clinical practice.

There is a lack of sufficient information in the clinic to properly determine whether the importance of an MRI examination for the patient with an implant that is not guaranteed to be MR safe or conditional outweighs the risk for that patient with respect to the loss of diagnostic information resulting from denying the MRI examination. This guideline provides an advice on how to deal with this trade-off for specific types of implants and, in some cases, to deviate from the conditions set for MRI by implant manufacturers.

Purpose of the guideline

The aim is to improve and guarantee the quality of the MR safety expert's advice to the medical proffesional, thus ensuring safety and access to MRI examinations for patients with implants. This guideline focuses on implants for which it is not entirely clear whether or not an MRI exam is safe, with the aim of making a risk assessment. In addition, the guideline aims to save time in practice as modules for certain implants provide recommendations for generic policies, eliminating the need to obtain further information about the specific implant model for each individual case.

With this guideline, therefore, a better estimation of the health risk of an MRI examination in a patient with an implant can be made and compared to the potential health benefit of the MRI exam for that patient.Currently different hospitals have varying policies in case of implant information lacking with respect to whether the patient can be scanned, and if this is the case, with respect to which (conservative) scan conditions should be applied. This guideline can therefore result in improved availability of MRI for certain patients and in certain hospitals, and in other cases or hospitals it could result in a better substantiated advice of possible limitations for the MRI exam.

Demarcation of the guideline

This guideline assumes that the hospital in which it is applied has a well-functioning MRI safety policy in place, based on good practices adopted worldwide to create a safe environment around MRI systems (Kanal, 2013; Cross, 2018; Sammet, 2016). Within the framework of such a policy, for example, each patient is screened for possible contraindications for undergoing the MRI scan prior to that examination.

This guideline is intended to be used when patients are referred for an examination on a whole body MRI scanner with horizontal closed bore superconducting magnet with a field

strength of 1.5 or 3 Tesla (T) and have an implant, according to the individual screening of the patient prior to the MRI examination. The systems chosen cover more than 95% of all diagnostic MRI systems in the Netherlands. Other types of MRI systems are not considered.

The first version of this guidelineline contains two modules:
Module "MRI in patients with a cerebral aneurysm clip"

- Some old types of cerebral aneurysm clips are an absolute contraindication for MRI, and can be fatal to the patient. Importantly, it is not always possible to determine exactly what type of clip was implanted in a patient, and therefore whether there is a risk. This module focuses specifically on the question of how to properly assess this risk in that case. Tthe module describes the MRI safety policy for patients with a cerebral aneurysm clip.

Module "MRI in patients with a prosthetic heart valve, annuloplasty ring or mitra clip"

- Many different types of prosthetic heart valves and annuloplasty rings exist, with a large number of those implants being 'MR conditional' with different conditions per type. The manufacturer of the implant has the freedom to specify the conditions, resulting in a wide variety of conditions. In addition, these conditions are often quite conservative, as a result of which some risks are overestimated. There are obvious differences in policy on how to scan patients with prosthetic valves between hospitals in the Netherlands. The aim of this guideline is to define a clear and unambigious guideline for MRI scans of patients with a prosthetic heart valve, annuloplasty ring or mitraclip.

Intended users of the guideline
The guideline is written for use by MR safety experts such as medical physics experts. In addition, the guideline may be informative to all professionals involved in planning MRI in patients with implants, i.e., radiologists, MR technologists and physicians referring for MRI.

Structure of the considerations in the modules
In addition to scientific literature, the information provided by manufacturers on the MR safety of their implants is of importance. This information is described in the MR safety databases of implants: partly in the freely accessible database of Prof. Frank Shellock www.MRIsafety.com, and partly in the commercial database of MagResource (MR:comp GmbH, Gelsenkirchen, Germany). A relevant summary for each module is included at the beginning of the considerations.

In addition, information from databases containing incident reports is important for this guideline. For each module relevant databases have been searched.

Finally, the considerations of each module have a fixed structure because the risks, when scanning patients with implants in the MRI scanner, can in general be classified as follows:

1. Risk of displacement and rotation of the implant due to the presence of the static magnetic field and the spatial gradient of this field.
2. Risk of implant heating due to interaction with the applied radio frequency (RF) field.
3. Risk of vibration or induction of currents by the oscillating magnetic field gradients applied for the spatial encoding of the MRI signal.
4. Artifact in the MRI image.
5. Risk of forces due to the Lenz effect during rapid movement of conductive implants in the static magnetic field of the MRI scanner.
6. Risk of interference with implant function.

Definitions and terms

For implants the general international terminology of (ASTM, 2013) is followed:

- MR safe: an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic.
- MR conditional: an item with proven safety in the MR environment within defined conditions. At a minimum, the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields should be addressed. Additional conditions, including specific configurations of the item, may be required.
- MR unsafe: an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

However, not all implants can be classified into these categories. For example, an implant that does contain metal and has not been proven to be safe, but that is known not to pose any unacceptable risk to the patient.

The 2013 ASTM definition was used while drafting this guideline. Notably older literature is based on an older definition for which reason one can encounter devices being declared 'MR safe' in that literature whereas - according to the newer ASTM definitions - they are now labeled 'MR conditional' (e.g. limited to 1.5 T). In the literature summaries in this guideline the above mentioned 2013 ASTM definition is used and the text from older publications has therefore been rephrased whenever appropriate.

MR allowed for 1.5 and 3 T

This guideline uses the additional term 'MR allowed for 1.5 and 3 T'. This is a form of MR conditional where the use of MRI in patients with these implants is allowed when using a whole body MRI system with a horizontal closed bore superconducting magnet with a field strength of 1.5 T or 3 T without further conditions.

MR safety expert

The MR safety expert (MRSE) is specified by the EFOMP (Hand, 2013) and recently ratified by a wider range of scientific associations including the ISMRM, ESR and ESMRMB (Calamante, 2016). In Dutch practice these are often medical physics experts with subspecialty Radiology and Nuclear Medicine and with sufficient knowledge of MRI, or physicists specialized in MRI.

MR safety officer

The MR safety officer (MRSO) as specified by the EFOMP (Hand, 2013) and recently ratified by a wider range of scientific associations including the ISMRM, ESR and ESMRMB (Calamante, 2016). In Dutch practice, for human MRI systems this is often a specialized MR technologist.

Classification of risk estimation

The severity of a risk is typically quantified by the probability of its occurrence on the one hand and the severity of the harm on the other hand.

For the severity of the injury, the classification is based on NEN-EN-ISO 14971 (NEN, 2012). This standard describes risk management for medical devices. However, the classification has been simplified into 2 categories with the definition of calamity as given in the NEN 8009 standard on safety management systems for hospitals (NEN, 2018), see table 1.

Table 1: qualitative description of severity of implant risk

Generic term	Description
Calamity	Fatal or permanent effects (other than scars)
Moderate	Restorable or minor injury or loss of function

For the probability that a complication will occur in an individual MRI examination, the following classification from the NEN-EN-ISO 14971 standard (NEN, 2012) has been used, see table 2. This has been further specified with a quantitative translation into the probability of occurrence, because clinical risks when withholding an MRI examination are sometimes (only) known in qualitative measures. This makes it possible to make a better assessment by comparing both probabilities.

Table 2: qualitative description and quantitative translation of probability

Qualitative description	Quantitative translation into chance
To be expected	0.1 to 1
Unusual	0.01 to 0.1
Rare	0.001 to 0.01
Unlikely	< 0.001

If multiple risks of complications are identified, it has added value to present the risks in a matrix, see table 3.

Table 3: example of a risk matrix in which two risks are presented

		Severity	
		Moderate	Calamity
Probability	To be expected	*R1*	
	Unusual		
	Rare		*R2*
	Unlikely		

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Accountability

Guide to the reader
The text below will be included in the Guidelines database (www.richtlijnendatabase.nl) after completion of the comment and authorisation phase. References to "related products" can be found in the current version of the guideline text as separate chapters (see table of contents of the guideline).

Only the Dutch version of this Guideline was used for authorization. The guideline was subsequently translated into English in order for the international community to take note of the content of the Guideline.

Methodology of the guideline development
Validity and maintenance
While drafting the guideline, the working group made an estimate of the period after which reassessment should take place and defined points of attention for a future revision (update). The validity of the guideline module lapses earlier if new developments give rise to start a revision process.

Module	Coordination[1]	Year of Authorization	Next assessment of validity module [2]	Frequency of review on validity[3]	Who supervises validity [4]	Relevant factors for changes in recommendation [5]
Prosthetic heart valve, annuloplasty ring or mitraclip	NVKF	2019	2024	Every five years	NVKF	New literature
Cerebral aneurysm clip	NVKF	2019	2024	Every five years	NVKF	New literature

The other scientific associations participating in this module or users of the guideline share the responsibility and inform the association taking the primary responsibility for the module of relevant developments within their field of expertise that might impact the validity of the module

Authorization
The guideline module is authorized by the Dutch Association of Medical Specialists (FMS), and more specifically by the *Society for Medical Physics of the Netherlands (NVKF); Dutch Society for Medical Imaging and Radiotherapy (NVMBR); Netherlands Society of Cardiology (NVvC); Netherlands Society for Neurosurgery (NVvN); Radiological Society of the Netherlands (NVvR).*

General data
The guideline development was supported by the Knowledge Institute of the Federation Medical Specialists (www.kennisinstituut.nl) and was financed by the Foundation Quality

[1] Coordinator of the module (this can differ per module and can also be shared)
[2] Maximum after five years
[3] (Semi-)yearly, once in two years, once in five years
[4] Directing association, shared directing associations, or (multidisciplinary) working group that is maintained
[5] Ongoing research, changes in compensation/organization, availability of new resources

Funds for Medical Specialists (Stichting Kwaliteitsgelden Medisch Specialisten: SKMS). The funder had no influence whatsoever on the content of the guideline.

Declarations of interest

The Royal Dutch Medical Association-code to prevent conflicts of interest has been followed. All working group members have provided written statements whether they have had direct financial interests (relations with commercial companies, personal financial interests, research financing) or indirect interests (personal relationships, reputation management, and interests related to knowledge valorisation) in the past three years. An overview of the statements by working group members about any potential conflicts of interest and the opinion on how to deal with possible interests can be found in the table below. The signed declarations of interest can be requested from the secretariat of the Knowledge Institute of the Federation Medical Specialists.

Working group member	Appointment	Additional appointments	Reported interests	Action taken
Götte	Cardiologist, Amsterdam UMC	Cardiologist, Cardiologie Centra Nederlands zero-hour appointment, paid	None	None
van der Graaf	Medical physics expert at RadboudUMC	None	None	None
Hofman	Medical physics expert, Amsterdam UMC	None	Involved in MRI research VUmc, basic reputation within the NVKF in the field of MRI	None
Kappert	System Specialist MRI, UMCG	Chairman Section MRI of NVMBR (unpaid) Until autumn 2018 member of the NVMBR Board of Governors (unpaid) Guest lecturer at Hanze University of Applied Sciences - MBRT (paid)	None	None
Kloeze	Medical physics expert Catharina Hospital	Member Mec-u (medical ethics committee) paid	None	None
Kuijer	Medical physics expert, Amsterdam UMC	None	Involved in scientific research projects using MRI. This does not concern research into the safety or function of implants. Reputation within the NVKF as medical physics expert with focus on MRI	None
Lavini	MRI physicist, Amsterdam UMC	None	None	None
Muller	Medical physics expert, Antoni van Leeuwenhoek Hospital	None	None	None

Nierop	Medical physics expert, UMC Utrecht	None	None	None
van Pul	Medical physics expert, Maxima Medical Center	Part-time appointment at TU Eindhoven - technical physics.	Participation in NWO-TTP-sponsored research into alarm reduction in neonatal intensive care. TU Eindhoven and Philips Research-Patient Monitoring Group are involved in this project. This project has NO relation with this guideline.	None
Stam	Medical physics expert in training, Amsterdam UMC	Unpaid: visitator for the College of Testing of the Dutch Medical Physicist Training Foundation (OKF).	None	None
Teeuwisse	MRI physicist, C.J. Gorter Center for High Field MRI, LUMC, Safety Expert MRI	None	None	None
Vonken	Radiologist, UMC Utrecht	None	None	None
van der Zwan	Neurosurgeon, UMC Utrecht	None	None	None

Input patient's perspective
No patient (representative) participated in the working group. The concept guideline has been submitted for feedback during the comment phase to the Patient Federation of the Netherlands.

Implementation
In the different stages of the development process, the implementation of the guideline and the practicability of the guideline were taken into account. The factors that could facilitate or hinder the introduction of the guideline in clinical practice have been explicitly considered. The implementation plan can be found with the Related Products.

Working method
AGREE
This guideline has been developed according to the requirements of the report Guidelines for Medical Specialists 2.0 by the advisory committee of the Quality Council. This report is based on the AGREE II instrument (Appraisal of Guidelines for Research & Evaluation II; Brouwers, 2010; www.agreetrust.org), a broadly accepted instrument in the international community, and on the national quality standards for guidelines: "Guideline for guidelines"(www.zorginstituutnederland.nl). For a step-by-step description of how an evidence-based module is created, we refer to the step-by-step plan Development of Medical Specialist Guidelines of the Knowledge Institute of the Federation Medical Specialists.

Identification of subject matter
Within the NVKF an analysis with a limited scope has led to the choice to develop these two modules.

Clinical questions and outcomes

The clinical questions were formulated by the chairman, working group members and the advisor. Subsequently, the working group inventoried which outcome measures are relevant for the patient, looking at both benificial and harmfull effects. The working group valued these outcomes according to their relative importance in the decision-making around recommendations, as critical (critical for decision-making), important (but not critical) and unimportant. The working group also defined, at least for the critical outcome measures, which differences they considered clinically relevant (to the patient).

Strategy for search and selection of literature

For the separate clinical questions, specific search criteria were formulated and published scientific articles were searched in (several) electronic databases. Furthermore, studies were scrutinized by cross-referencing for other included studies. The studies with potentially the highest quality of research were looked for first. The working group members selected literature in pairs (independently of each other) based on title and abstract. A second separation was performed based on full text. The databases, search terms and selection criteria are described in the modules containing the clinical questions. The search strategy can be retrieved from the Guidance database, see the tab 'Search accountability' for further details.

Quality assessment of individual studies

Individual studies were systematically assessed, based on methodological quality criteria that were determined prior to the search, so that risk of bias could be estimated. This is described in the "risk of bias" (RoB) tables. The RoB instruments used are validated instruments recommended by the Cochrane Collaboration:

- AMSTAR - for systematic reviews.
- Cochrane - for randomized controlled studies.

Summarizing of literature

The relevant research findings of all selected articles are shown in evidence tables. The most important findings from literature are described in summaries.

Grading quality of evidence and strength of recommendations

The strength of the conclusions of the scientific publications was determined using the GRADE-method: Grading Recommendations Assessment, Development and Evaluation (see http://www.gradeworkinggroup.org/) (Atkins, 2004).

GRADE defines four levels for the quality of scientific evidence: high, moderate, low or very low. These levels provide information about the certainty of the conclusions drawn in a study. (http://www.guidelinedevelopment.org/handbook/) (Schünemann, 2013).

GRADE	Definition
High	• We are very confident that the true effect lies close to that of the estimate of the effect. • It is highly unlikely that the conclusion changes when results of new large scale research is added to the literature analysis.
Moderate	• We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. • It is possible that the conclusion changes when results of new large scale research is added to the literature analysis.
Low	• Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect. • There is a resonable chance that the conclusion changes when results of new large scale research is added to the literature analysis.
Very low	• We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect. • The literature conclusions are unsure.

In the grading the quality of evidence of the scientific literature in the guideline according to the GRADE-method the borders of clinical desicions play an important role(Hultcrantz, 2017). Crossing these borders would lead to a change in the recommendations. To asses these borders of clinical descisons all relevant outcome measures and considerations should be taken into account. Therefore, these borders are not one to one comparable to the Minimal Clinically Important Difference (MCID). Especially, in situations in which an intervention has no important disadvantages and costs are relatively low, the border of clinical descisions in relation to the efficacy of the intervention will be at a lower value (closer to the zero-effect) than the MCID (Hultcrantz, 2017).

Drawing conclusions

For each relevant outcome measure, the scientific evidence was summarized in one or more conclusions based on literature where the level of evidence was determined according to the GRADE methodology. The working group weighed the beneficial and harmful effects of the intervention (overall conclusion). The overall evidential value was determined by the lowest evidential value found at one of the critical outcome measures. In complex decision-making processes in which many considerations also play a role in addition to the conclusions from the systematic literature analysis, an overall conclusion was omitted. In that case, the positive and negative effects of the interventions, together with all considerations, were weighed under the heading Considerations.

Considerations (from evidence to recommendation)

In order to propose a recommendation, in addition to (the quality of) the scientific evidence, other aspects were important as well and were taken into account, such as the expertise of the working group members, patient preferences, costs, availability of facilities and organisation of healthcare. These aspects were discussed in the paragraph Considerations.

Formulating recommendations

The recommendations answer the clinical question and are based on the available scientific evidence and the most important considerations, and a weighing of the beneficial and harmful effects of the relevant interventions. The strength of the scientific evidence and the weight given to the considerations by the working group together determine the strength of

the recommendation. In accordance with the GRADE methodology, a low probative value of conclusions in systematic literature analysis does not exclude a strong recommendation a priori, and weak recommendations are also possible with a high probative value. The strength of the recommendation is always determined by weighing all relevant arguments together.

Knowledge gaps

During the development of the guideline, a systematic literature search was performed. The results of which helped to answer the clinical questions. For each clinical question the working group determined if additional scientific research on this subject was desirable. An overview of recommendations for further research is available in the annex Knowledge Gaps.

Comment- and authorization phase

A draft version of the guideline has been commented on by the involved (scientific) associations, agencies and (patient) organizations. The comments were collected and discussed with the working group. The feedback was used to improve the guideline. Afterwards the working group made the guideline definitive. The final version of the guideline was shared with the involved scientific societies and was authorized by them. The full table with all commentaries (*in Dutch*) can be requested from the Knowledge Institute via secretariaat@kennisinstituut.nl.

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Module 1: MRI in patients with a prosthetic heart valve, annuloplasty ring or mitra clip

Clinical question

Can a patient with a prosthetic heart valve, annuloplasty ring or a mitra clip undergo an MRI examination?

Introduction

There is a wide variety of types of heart valve prostheses and annuloplasty rings. Most patients can undergo an MR scan while having this implant, however manufacturers define different specific conditions for performing this scan. Many of these manufacturer-set conditions are so conservative that they may impair patients diagnosis. There is a large variation between hospitals how this is handled. In addition, in some cases the type of prosthetic heart valve or the safety profile of the heart valve is unknown. Again, hospitals vary in their policies regarding screening and use of MRI for those patients. The compatibility of the heart valve with an MRI scanner is also important for examinations of other parts of the body than the heart.

In this module, both heart valve prostheses and annuloplasty rings are considered. In the text of this module, the term "prothetic heart valve " or "heart valve" also refers to annuloplasty rings. For the sake of completeness, the mitraclips are also included in the recommendations of this module. These have been left out of the systematic literature review, but came into focus later in the process. Considering the limited number of types of mitraclips on the market, it was still possible to include them in the recommendation.

Search and select

To answer the initial question, a systematic literature search was carried out with the search question:

> What is the likelihood of negative outcomes in patients with prosthetic heart valves or rings undergoing MRI testing?

P: patients with prosthetic heart valves or annuloplasty rings;
I: MRI examination;
C: No MRI examination;
O: negative outcomes:

a) Interactions between the prosthetic heart valve and the magnetic fields and radio frequency waves generated by the MRI scanner;
(b) effects on the patient as a result of the interactions described in (a).

Search and select (Method)

In the databases Medline (via OVID) and Embase (via Embase.com) relevant search criteria were used to search for studies on MRI research on heart valves. The literature search was performed on on March 07, 2018, and yielded 321 hits. In addition, on May 17, 2018, studies on MRI research in annuloplasty rings were searched in the same databases with relevant search criteria. The literature search yielded 41 hits. There was no limitation on type of study. The search accountability for both 'searches' is displayed under the Accountability tab.

Studies were selected based on the following selection criteria: studies of effects (interactions or clinical effects) of MRI studies in (patients with) prosthetic heart valves. Based on title and abstract, 46 studies were pre-selected in the first instance. After

consulting the full text, 31 studies were then excluded (see exclusion table under the Accountability tab) and 15 studies were finally selected.

Two of the selected studies deal with the Lenz effect (Robertson, 2000; Condon, 2000) and did not fit within the format of the evidence tables and summary of the literature. These studies are therefore further described under the considerations, and more literature is included on the Lenz effect following the commentary phase. Eleven *ex vivo* studies, one *in vivo* study and one combined *in vivo* and *ex vivo* study have been included in the literature analysis. The most important study characteristics and results are included in the evidence table. The assessment of the individual study design of the *in vivo* studies (risk or bias) is included in the risk or bias table.

Summary literature

Ex vivo research

Eleven studies examine *ex vivo* (outside the body) the interactions that occur between prosthetic heart valves and the magnetic fields and radio frequency waves of the MRI scanner, including one study that also examines *in vivo* effects (inside the body) (Edwards, 2000; Edwards, 2002; Edwards, 2005a; Pruefer, 2001; Randall, 1988; Saeedi, 2015; Shellock, 1988; Shellock, 1994; Shellock, 2001; Shellock, 2002; Soulen, 1985). In these studies, MRI equipment ranging from 0.35 to 4.7 Tesla is used. No interactions are detected that could be harmful to the patient.

Details of which prosthetic heart valve(s) were examined, with which equipment and which interactions were measured, are described in the evidence table.

In the study by Edwards (2005b), *ex vivo* research is performed on the effect of forces caused by the MRI-scanner on aged heart valve tissue. In this study, 18 tissue samples, cut out during routine heart valve replacement surgeries, were tested to determine the force required to tear the tissue and to loosen the suture from the heart valve tissue. Degenerative calcification and stiffness of the tissue significantly affected the maximum force required to tear the tissue. However, the forces required are greater than those caused by a 4.7T MRI scanner on the prosthesis. Therefore, patients with degenerative valve failure are unlikely to be at greater risk of valve loosening as a result of MRI.

In several studies *ex vivo* temperature measurements were carried out to measure RF induced heating (Soulen, 1985; Hassler, 1986, Randall, 1988; Shellock 94; Edwards, 2000; Shellock, 2001; Pruefer, 2001; Saeedi, 2015). Figure 1 summarizes these measurements. In most studies, in addition to measurements of the temperature increase at the implant, reference measurements were also taken in the phantom surrounding the implant at the same RF load, as described in the ASTM standard (ASTM, 2002). These reference measurements show MR temperature increases from 0.2°C to 0.5°C, except for the single measurement using the ASTM standard with a temperature increase of 0.8°C at the valve, with a reference measurement of 1.7°C (Saeedi, 2015).

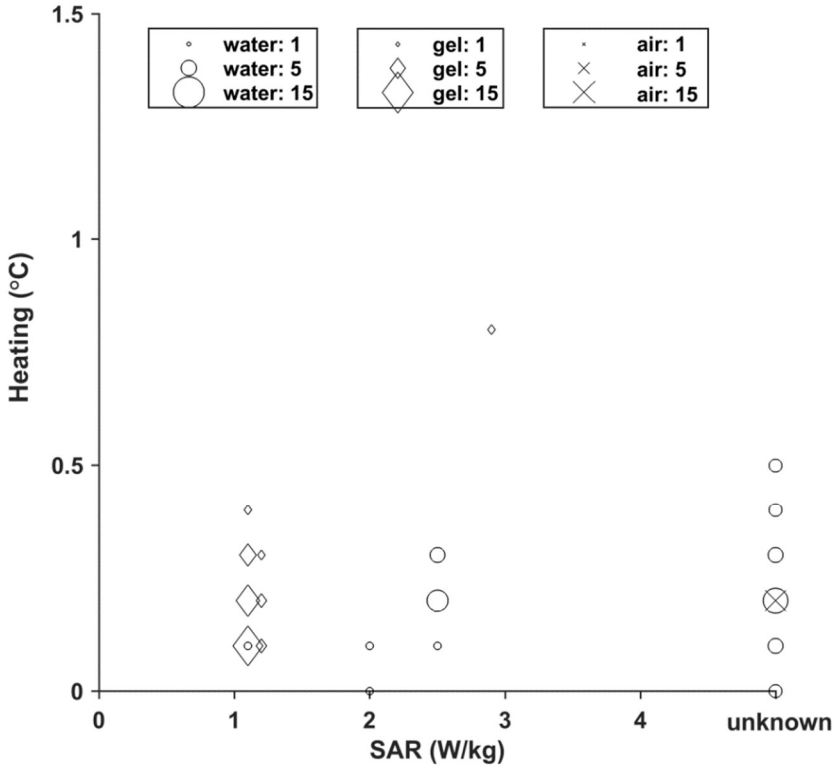

Figure 1: Measured heating of an implant in a phantom of gel (◇), water (O), or air (X) (Soulen, 1985; Hassler, 1986, Randall, 1988; Shellock 94; Edwards, 2000; Shellock, 2001; Pruefer, 2001; Saeedi, 2015). In a number of studies the SAR value used was not reported, these are shown on the right. The temperature increase compared to the reference measurement is shown, if no reference measurement was reported, the absolute temperature increase is shown. Most of the measurements were performed at 1.5 T (with a number of data points at 0.35 and 0.5T and one data point at 3 T). The size of the symbols is proportional to the number of values reported for different types of valves and/or rings.

In vivo research

Hartnell (1997) investigated the occurrence of arrhythmias visible on ECG or evidenced by clinical symptoms during MRI at 1 or 1.5 T in 25 patients who underwent heart valve replacement surgery. The type of heart valve was not indicated. No clinical signs of cardiac arrhythmia have been reported by patients. Neither changes in ECG rhythm were observed. In all cases, especially using gradient echo sequences, a signal loss in the images due to susceptibility effects was observed.

Randall (1988) investigated the occurrence of clinical symptoms and the occurrence of artifacts on MRI images in six cases with the following five types of heart valves:

- Lillehei-Kaster (Medical Incorporated), Pyrolite carbon disc.
- St. Jude Medical (St. Jude Medical), Bileaflet pyrolite disc impregnated with small amount of tungsten.
- Björk-Shiley spherical disc (Shiley), Pyrolite tilting carbon disc.
- Bioprosthetic Carpentier-Edwards (American Edwards), Porcine valve.
- Ionescu-Shiley (Shiley), Calf pericardium.

All cases underwent MRI at an 0.5T scanner. No arrhythmias or other clinical symptoms were observed and no patient discomfort was reported. The MRI images showed locally mild artifacts due to the metal and minor disturbances were seen outside the direct valve area.

Evidential power of the literature

The conclusions that follow from the *ex vivo* studies do not provide a measure of 'evidential value' because the GRADE methodology is currently not suitable for the assessment of this type of studies. The working group indicates that the interactions detected in *ex vivo* studies will be equal to or greater than those that will occur *in vivo*. The risks will therefore be overestimated rather than underestimated based on this type of study.

The evidential value of the conclusion for the outcome measure "effect on the patient", based on the *in vivo* studies, is rated as very low because of a high risk of bias, inaccuracy and indirectness. In fact, the two *in vivo* studies are non-comparative, have a very small study population and were partially performed with obsolete equipment (0.5 and 1T) compared to the equipment used nowadays (1.5 or 3 T). The conclusion should therefore be read with caution.

Conclusions

- **GRADE**	During MRI examinations at 3 T or below, no interactions between a prosthetic heart valve and the magnetic fields and radio frequency waves caused by the MRI scanner have been detected that could be harmful to the patient. *Sources (Edwards, 2000; Edwards, 2002; Edwards, 2005a; Pruefer, 2001; Randall, 1988; Saeedi, 2015; Shellock, 1988; Shellock, 1994; Shellock, 2001; Shellock, 2002; Soulen, 1985).*

- **GRADE**	Patients with degenerative valve disease are unlikely to have a greater risk of valve loosening as a result of MRI. *Sources (Edwards, 2005b)*

very low **GRADE**	Up to 1.5 T, there is some evidence, although limited, that MRI does not cause cardiac dysrhythmia in patients with a prosthetic heart valve. *Sources (Hartnell, 1997; Randall, 1988)*

Considerations

Summary information from implant manufacturers

The databases of MagResource (MR:comp GmbH, Gelsenkirchen, Germany) and MRISafety.com have been searched for information on heart valves and annuloplasty rings. The database of MagResource was searched on 6 April 2018 with the search term "heart valve" in the field "generic". 690 implants were found, sometimes displaying different (sub-) types and sizes separately and sometimes as a combination. After combining the main types, the search resulted in 288 implants. These were supplemented with 38 additional heart valves found in the database of MRISafety.com in the period May-June 2018. In total, the data from 326 main types of heart valves and annuloplasty rings were analyzed.

These main types of prosthetic heart valves and rings in the collected overview are MR safe or MR conditional:

- 43x MR safe according to ASTM-2013;
- 25x MR safe according to the old ASTM definition (also called MR compatible, often corresponding to MR conditional according to the current definition with limitation of field strength);

- 17x MR safe according to MRIsafety.com but conditional according to the manufacturer information in MagResource MR;
- 240x MR conditional.

The classification of only one type of these implants is unknown, as the manufacturer (for unclear reasons) is not in a position to advise on this. It concerns the annuloplasty ring of Carpentier-Edwards models 4400 and 4500, sold between 1980 and 1983, made of stainless steel (RVS). This type of ring is still being produced, but has been made of titanium since 1984. The version made of titanium is classified as MR conditional, with condition 3 T or lower.

For implants classified as MR conditional, limits are set by the manufacturer for the maximum gradient strength of the static magnetic field and at the maximum SAR level. The maximum gradient strength limits vary between 3.9 and 30 T/m (390 and 3000 Gauss/cm). Figure 2A shows how often a limit occurs for the heart valves and annuloplasty rings found in the MagResource database. The most common limit value is 7.2 T/m, the maximum gradient strength test value according to the 2013 ASTM standard. It is also noteworthy that manufacturers often recommend a higher maximum gradient strength. None of the manufacturers indicate that there is an attraction of the implant at the maximum gradient strength, this reported value is likely due to the maximum test condition under which the implant was tested.

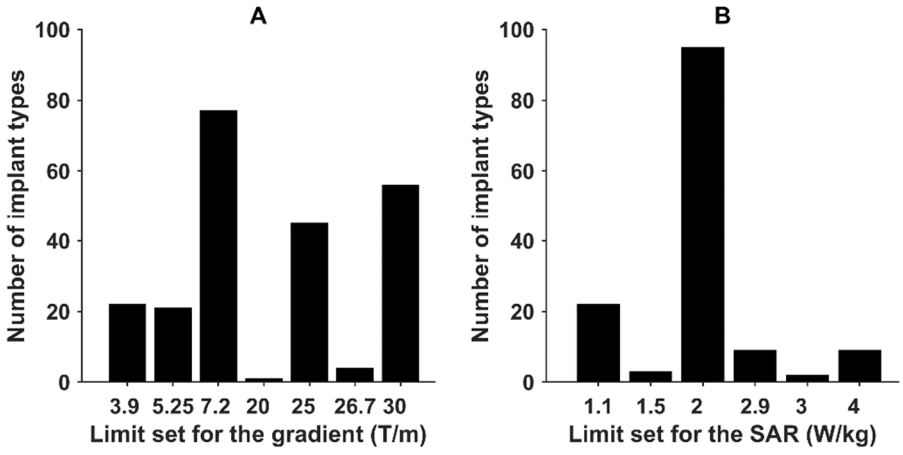

Figure 2: Number of implant types for which a certain gradient limit is set by the manufacturer (A) and number a certain SAR limit is set by the manufacturer (B), from MagResoure.

The maximum SAR levels indicated by manufacturers vary greatly (see Figure 2B). Again, it is notable that the condition specified in the ASTM standard (2 W/kg) is most commonly used by manufacturers.

Some manufacturers also report an expected or measured temperature increase at the set SAR condition shown in Figure 3A and Figure 3B. These measurements were determined *ex vivo* according to the ASTM standard where the heating was measured in a gel phantom into which the implant was inserted. This does not take into account the cooling caused by the blood circulation. For a number of implant types (n=75), manufacturers report temperature increases for both 1.5 and 3 T. There is no significant difference in heating between these two field strengths. From all of these measurements, the maximum measured temperature

increase is 3.5 °C at 2 W/kg, and the average measured temperature increase for a valve or ring is a factor 2 lower.

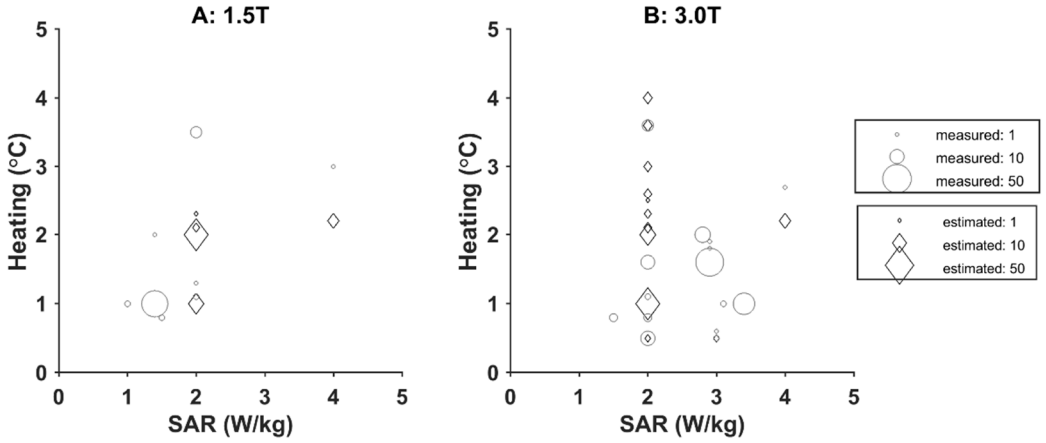

Figure 3: Manufacturer estimated (◇) and measured maximum (O) RF heating in an implanted gel phantom at 1.5 T (A) and 3.0 T (B). The size of the symbols is proportional to the number of values reported for different types of prosthetic heart valves and/or rings.

There is currently only one manufacturer marketing mitraclips: Abbott Vascular. These clips are classified by the manufacturer as MR conditional. The conditions are up to 3 T, maximum spatial gradient of 25 T/m, and whole body SAR of 3 W/kg for 15 minutes scanning. *In vitro* an increase in temperature of less than 1°C has been measured under these conditions. The artifact size was in the order of 6 to 7 cm at 3 T.

Summary of the information from implant incident databases.

For this module the following incident databases of implants have been searched:

- the recall database of the FDA;
- the database of the Health and Youth Care Inspectorate of the Netherlands (IGJ) with safety notifications as of December 15, 2015;
- The archive of the Health Care Inspectorate of the Netherlands (IGZ);
- the 'Implant' en 'Event' database of the International Consortium of Investigative Journalists (ICIJ).

The search accountability in these databases can be found in the table 'Search Databases of Recalls and Events'. In none of these databases reports were found that are relevant for this guideline module.

Classification of implant risks in main classes

In general, risks from metallic implants in the MRI can be classified in the following main classes:

1. Risk of displacement and rotation of the implant due to the presence of the static magnetic field and the spatial gradient of this field.
2. Risk of implant heating due to interaction with the applied radio frequency (RF) field.
3. Risk of vibration or induction of currents by the oscillating magnetic field gradients applied for the spatial encoding of the MRI signal.
4. Artifact in the MRI image.
5. Risk of forces due to the Lenz effect during rapid movement of conductive implants in the static magnetic field of the MRI scanner.
6. Risk of interference with implant function.

Several reviews and statements by different organizations or recognized researchers have indicated since 2004 that the risks of the MRI scan for the patient with a prosthetic heart valve or annuloplasty ring are negligible (Prasad, 2004; Shellock, 2004; Levine; 2007; Dill, 2008; Grainger, 2015). This is further substantiated by the absence of cases in which complications occurred during or after an MRI scan of patients with a heart valve prosthesis (Levine, 2007; also in the period 2007 to 2018 no cases were identified with the systematic literature search, and the incident database search).

Based on this information, many patients in the Netherlands with prosthetic heart valves and rings have undergone an MRI examination because the benefits of the scan (better diagnostics or even necessary MRI for diagnostics) are considered greater than the risk of undergoing the MRI scan for the patient. Although there is little documented on MRI safety of prosthetic heart valves, there is also no evidence of risk.

The expected effects depend on the materials used. Since 2000, manufacturers of heart valve prostheses have been paying attention to MRI compatibility and this has been taken into account in the choice of materials for new heart valves. Therefore, it is expected that no MR unsafe heart valves and annuloplasty rings will come on the market anymore, and that new models will probably be able to be scanned in an MRI of 1.5 T or 3 T. If other types of heart valves come on the market in the future, e.g. equiped with electronics or sensors, it goes without saying that the specific instructions of manufacturers with regard to MR safety must be followed for these types. Should these types of valves come on the market, it will have to be considered to adapt this guideline accordingly.

1. Risks due to displacement and rotation
Manufacturers regularly limit the maximum field gradient. Usually it is 7.2 T/m; the maximum gradient to which the prosthesis is exposed during the test situation. While this gradient has been proven safe, it doesn't imply that a stronger field gradient is unsafe. Based on the properties of current clinical MRI scanners, the working group determines that field gradient problems with horizontal closed bore superconducting MRI magnets up to 3 T are not to be expected, and therefore no conditions are included in the guideline.

Finally, there are two types of annuloplasty rings of which the MR classification has not been established; Carpentier-Edwards model 4400 and 4500, sold between 1980 and 1983. It is unknown whether this type of valve occurs in the Dutch patient population. These two models of the Carpentier-Edwards Classic Annuloplasty Ring are made of a slightly ferromagnetic stainless steel, as shown in experiments carried out by Shellock on model 4400 at 1.5 and 3 T (Shellock, 2001 and 2002). Therefore, the working group considers that these are MR conditional up to 3 T, and that the attraction forces by MRI are small compared *in vivo* forces in the working heart, the latter being in the order of 7.2 N (Soulen, 1985 and 1986). Finally, incidents of these two type of rings as a result of MRI have never been reported in the literature.

2. Risk of Implant Heating due to Interaction with RF Field
Many prosthetic heart valves and rings are classified MR conditional by the manufacturer, with a limitation of SAR level, typically a whole body SAR up to 2 W/kg, to limit tissue heating by the implant. This classification is based on *ex vivo* measurements according to the ASTM-F2182 standard (ASTM, 2002). This guideline states that the increase in temperature of an implant is measured by exposing it to RF radiation in the MRI scanner when implanted in a gel phantom. Manufacturers typically report the maximum measured temperature increase from this test, averaging approximately 1.5°C and up to 3.5°C (see Figure 3).

However, even without an implant, this test results in a significant temperature increase, which is not reported. The ASTM guideline states that in addition to a measurement near the implant, both a reference measurement in the phantom and a repeated measurement without an implant should be performed. In the scientific literature, this effect is better reported, see Figure 1. There it is visible that the additional heating due to the implant is limited to a maximum of 0.8°C. Also on theoretical grounds, given the wavelength of the RF and the physical size of the heart valves and rings, the working group expects that RF heating will be limited at 1.5 and 3 T.

The ASTM guideline allows for additional factors to be taken into account, such as increased heat transport by flowing blood, resulting in an reduced temperature rise *in vivo* compared to the measurements in a gel phantom. However, such a correction requires additional effort from a manufacturer and since there is limited impact on marketing, it is performed in practice. Heart valves are unambiguously implanted at a location (the heart) where heat transport by flowing blood - unlike the tests in a gel - is significant. This means that the actual maximum temperature increase of the prosthetic heart valve and surrounding tissue will be lower *in vivo* than in a gel phantom, in which only conduction heat transport is occurs. In scientific literature, little has been published on this subject. The working group asked a research group at the UMC Utrecht to carry out simulations to determine the expected heating of a valve or ring by RF in a gel phantom on the one hand, and to determine the effect of cooling by blood flow. Their results shows that RF in a gel phantom can cause heating in the order of a few degrees, but that the additional heating as a result of a valve or ring is much less. With cooling by bloodflow included in the simulation, the heating of the valve or ring at an RF load of 5 W/kg (the maximum level that is clinically used is 4 W/kg) less than 1 °C. Even in the case the valve or ring is made resonant by adding electrical capabilities in the simulation (which is certainly not the case in practice), the implants heating without perfusion is only 1.5 °C and with perfusion 0.7 °C, at an RF load of 5 W/kg (Stijnman, 2019).

In some hospitals in the Netherlands, patients with prosthetic heart valves without additional SAR restrictions (only limited by the IEC whole body SAR of 4 W/kg) have been scanned at 1.5 T and 3 T in recent years. As far as known, no complications have occurred.

These considerations together lead to the conclusion that SAR reduction other than the usual 4 W/kg ("IEC first level controlled SAR mode") is not required for field strengths up to 3 T. A SAR limitation to a lower level can adversely affect the quality of imaging and is therefore not recommended, even when a SAR limitation is set by the valve or ring manufacturer in their MR conditions.

3. Risk of vibration or current induction by the oscillating magnetic field gradient
The risk of vibration or current induction in the heart valve prosthesis due to the oscillating magnetic field gradient applied for spatial coding is negligible due to the small surface area of interaction with the gradient fields.

4. Artifact in the MRI image
The presence of a prosthetic heart valve has limited influence on image quality. This is described in detail by Suchá (2015). In summary, the signal loss is limited to the proximity (< 1 cm) of the heart valve or ring if it doesn't contain ferromagnetic materials. Evaluation of the heart function by means of cine imaging is possible. With prosthetic heart valves that do contain ferromagnetic materials, signal loss can occur over a significantly larger area when

using gradient echo techniques, but using spin echo techniques signal loss is also limited to the proximity of the heart valve.

5. Obstructed movement of valve blades

In the literature the Lenz effect is mentioned in relation to prostetic heart valves. This effect is induced by movement of an electrically conductive object through a (static) magnetic field. It results in a force counteracting the movement. In principle the movement of valve blades could be hindered by this.

Cordon (2000) described this effect as relevant to the functioning of heart valves. However, the relevance is doubted by a detailed model study by Robertson (2000), which reports that the force due to the Lenz effect at 1.5 T is less than 1% of the forces on the valve by blood flow, at 3 T less than 4%. Theoretically, the Lenz effect may be relevant to the mitral valve, which opens at relatively small pressure differences. A theoretical study by Golestanirad et al. (2012) determined that the effect at 1.5 T is negligible, but may have relevance at 3 T for a mitral valve with an all-metal blade. For valves with only a thin metal reinforcement, forces due to the Lenz effect appear to be negligible. The primary physiological effect would be a delayed atrial inflow over a mitral or tricupidal valve, due to the counteracting effect during valve movement.

Mitralis heart valves with all-metal valve blades belong (if made at all) to an older generation of heart valves. As far as a consulted cardiac surgeon was aware, there are no mitral valves with all-metal blades on the market today. Because of the diversity of valves on the market, it is difficult to rule out the possibility that they do exist, or will be reintroduced. The valve mentioned by Golestanirad et al. (2012) as an example is the Starr-Edwards 6500 valve. It was produced between 1968 and 1970 (Morse 2012) and has been implanted about 2500 times (Bonchek 1973). This valve indeed has a full metal blade, but this blade translates, and does not rotate. The flux changes in the blade are therefore negligible in a homogeneous magnetic field (inside the magnet bore) and at the magnet bore opening small compared to a rotation in the magnet isocenter.

On the orther hand, there are several valves with rotating blades on the market, made of pyrolitic carbon, which is also an electrically conductive material. Examples are the Tekna by Edwards and the Hall by Medtronic. However, the conductivity of pyrolitic carbon is more than a factor 10^6 lower than titanium (Graham 2010, website americanelements.com), with which Golestanirad et al. carried out their simulations. The force due to the Lenz effect scales with this conductivity. Therefore, the Lenz effect on pyrolitic carbon valves are considered negligible compared to titanium valves.

Golestanirad et al. further assumed a worst-case scenario that, in the opinion of the working group, is not realistic. Their calculation assumes an opening and closing time of the mitral valve of 10 ms. Opening times around 50 ms seem to be more realistic for both the aortic valve (Leyh 1999) and the mitral valve (Saito 2006, Lynch 1982, Yokote 2019). This would result to a five times lower force due to the Lenz effect. In addition, the orientation of the mitral valve is not perpendicular to the static magnetic field in an 1.5 T or 3 T scanner with a horizontal closed bore superconducting magnet, which is another assumption in Golestanirad's calculation. This will also result in a significant weaker force. *In vitro* measurements at 1.5 T by Edwards et al. (2015) showed that for some valves a small deviation in the movement of the valves in the magnetic field occured, the effect of this deviation on the cardiac output is limited. At the magnet bore opening it can be expected that the Lenz effect due to movement in the gradient of the static field is much smaller than the effects due to a 90 degree rotation in 10 ms at the magnet iso-center, as the speed of flux change is much lower.

In the literature and in incident databases there are no reports of patient cases of heart valve problems in MRI due to the Lenz effect. There are two possible explanations for this: the first

explanation is that, as far as the working group is aware, no mitral valves with full metal blades have been marketed, and the second explanation is that if mitral valves with full metal blades have been marketed, there is no noticeable effect on physiology.
In conclusion, the working group considers the likelihood of adverse effects on the patient due to the Lenz effect on the prosthetic heart valve negligible for 1.5 T and 3 T horizontal closed bore superconducting MRI systems.

6. Risk of Implant Disruption
The only potential risk here is the Lenz effect mentioned above.

Mitraclips
The mitraclips are also included in the recommendations of this guidlinemodule. These heart implants were not included in the systematic literature analysis because this type of implant was included later in the process for module for completeness. Considering the considerations for valves and rings as mentioned in this module, these mitraclips are also considered 'MR Allowed for 1.5 and 3 T', despite the MR conditions of the manufacturer.

Recommendation

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.

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Annex to module 1

Validity and Maintenance

Module [1]	Coordination [2]	Year of Authorization	Next assessment validty module [3]	Frequency of review on validaty [4]	Who supervises validity [5]	Relevant factors for changes in recommendation [6]
Prosthetic heart valve, annuloplasty ring or mitraclip	NVKF	2019	2024	Once every 5 years	NVKF	New types of heart valve, e.g. adjustable or equipped with sensors or electronics.

[1] Module name
[2] Coordination of the module (this can differ per module and can also be divided over several control holders)
[3] Maximum after five years
[4] (Semi-)yearly, once in two years, once in five years
[5] Directing association, shared directing associations, or (multidisciplinary) working group that is maintained
[6] Ongoing research, changes in compensation/organization, availability of new resources

Implementation plan

Recommendation	Timeline for implementation: <1 year, 1 to 3 years or >3 years	Expected effect on costs	Preconditions for implementation (within specified timeframe)	Possible barriers to implementation [1]	Actions to be taken for implementation [2]	Responsible for actions [3]	Other remarks
1[e]	<1 year	None	MRI Availability	None	Spreading the guideline		None

[1] Barriers can be at the level of the professional, the organization (the hospital) or at the system (outside the hospital). Think for example of disagreement regarding the recommendation, insufficient motivation or knowledge of the specialist, insufficient facilities or personnel, necessary concentration of care, costs, poor cooperation between disciplines, necessary reallocation of tasks, etcetera.
[2] Think of actions that are necessary for implementation, but also actions that are possible to promote implementation. Think for example of checking recommendation during quality audits, publication of the guideline, development of implementation tools, informing hospital administrators, arranging good compensation for a certain type of treatment, making collaboration agreements.
[3] Those responsible for implementing the recommendations will also depend on the level of barriers. Barriers at the professional level will often have to be solved by the professional association. Barriers at the organizational

level will often be the responsibility of the hospital administrators. In solving barriers at the level of the system, other parties, such as the NZA and health insurance companies are of importance.

Evidence tables

Evidence table for intervention studies (randomized controlled trials and non-randomized observational studies [cohort studies, case-control studies, case series])[1]

This table is also suitable for diagnostic studies (screening studies) that compare the effectiveness of two or more tests. This only applies if the test is included as part of a test-and-treat strategy - otherwise the evidence table for studies of diagnostic test accuracy should be used.

Research question: What is the risk of having a negative outcome when performing MRI in patients with prosthetic heart valves?

Study reference	Study characteristics	Patient characteristics [2]	Intervention(I)	Follow-up	Outcomes and effect size [4]	Comments
Saeedi, 2015	Type of study: *ex vivo* study Country: USA Source of funding: Unrestricted research grant provided by Vascular Innovations Company, Ltd, Thailand.	Inclusion criteria: Hydra Aortic Valve, Percutaneous Heart Valve Prosthesis, Vascular Innovations Company, Ltd, Thailand	3 Tesla MRI	Not applicable	Magnetic field **interactions** were negligible: - Deflection angle, 3 degrees - Torque, 0 MRI-related **heating** (at relative high specific absorption level, whole body average SAR, 2.9-W/kg) was minimal: - Max temp rise, 2.5°C - Background temp rise, 1.7°C MRI-related **heating** extrapolatedto a whole body averaged SAR of 4.0-W/kg (i.e., the upper allowable limit as specified by the U.S. Food and Drug Administration), the temperature rise would be 3.4 °C, which is still an acceptable level for a human subject. **Artifacts** (T1-weighted, spin echo, and gradient echo pulse sequences) were relatively small in relation to size and shape of implant	

					Conclusion: the TAVR bioprosthesis is "MR Conditional" (defined as an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use indicated) for patients at 3 Tesla or less.	
Edwards, 2005a	Type of study: *ex vivo* study Country: UK Source of funding: not reported	Inclusion criteria: 11 heart valve prosthesis and 12 annulosplasty rings: 1. Aspire, Porcine bioprosthesis, Mitral valve M55 2. Elan, Porcine bioprosthesis, Aortic valve AV33/P 3. Elan, Valve Graft Porcine bioprosthesis with valve graft, Aortic valve RE80/P 4. Carbon, Art Mechanical bileaflet valve graft, Aortic valve AVP27/30 5. Contegra, Pericardial bioprothesis, Pulmonary valve 200 6. Freedom, Pericardial bioprosthesis, Aortic valve PF 7. Freestyle, Porcine bioprosthesis, Aortic valve 995MS 8. MØre, Pericardial bioprosthesis, Aortic valve PN 9. Rain, Mechanical bileaflet, Aortic valve AGN-751	4.7 Tesla MRI 10 Carpentier Edwards (CE) Physio Rings were also evaluated for 1.5 Tesla MRI regarding their time-dependent ferromagnetic properties.	Not applicable	Magnetic field **interactions** (translational and rotational forces)**:** 0 for 17/23 prostheses, but not for: 9, 10, 13, 14, 15 16 (2 valves, 4 rings). Valves 9 and 10 demonstrated an interaction with the magnetic field deflecting by 2° and displaying a +2 measurement on our measurement scale for rotational force when oriented perpendicular to the magnetic field. All rings demonstrated translational forces (2°, ring 15 20° and ring 16 5°), rings 15 and 16 also rotational forces when oriented perpendicular to the magnetic field (torque +2). All prostheses attracted to the magnetic field were slightly paramagnetic/weakly ferromagnetic, and all demonstrated a magnetic acceleration less than that due to gravity. Further testing of different samples of the CE Physio Ring revealed that	This article refers to other studies which also detected effects of MRI at a field strength of 3 T on implants from Elgiloy. It concludes that further investigations are required to confirm the safety of Elgiloy.

		10. St Jude, Mechanical Valve Graft Mechanical bileaflet with root, Aortic valve CAVG 11. Toronto, Root Porcine bioprosthesis, Aortic valve Root 12. AnnuloFlex, Ring, Mitral Ring AF800 13. Carpentier Edwards Rigid/ Classic, Mitral ring 4425 14. Carpentier Edwards Rigid/ Classic, Tricuspid ring 4525S 15. Carpentier Edwards Physio, Mitral ring 4475 16. Colvin, Mitral ring 638B 17. Cosgrove, Atrioventricular ring 4625 18. Duran, Mitral ring H608 Duran, Tricuspid band H610 20. Mitral Repair System, Mitral ring MRS 21. Tailor, Mitral ring TARN 22. Seguin, Mitral ring SARP 23. Sovering, Mitral ring SB-M			without exception, all samples of the ring interacted with the magnetic field (Table 3). The five rings subjected to the 1.5 T MR system deflected by an angle of 2° with each exposure to the MR system and demonstrated a rotational force of 2 on the threepoint qualitative scale when oriented perpendicular to the magnetic field. The results of the remaining five rings tested at 4.7 T showed deflection angles of 17-20°, suggesting a threefold increase in magnetically induced forces compared to 1.5 T. Furthermore, the angles of deflection recorded at 4.7 T increased with increasing implant size **Conclusion:** all prostheses are considered safe* in static fields up to 4.7 Tesla, except for ring 15, made from Elgiloy, which may not be acceptable for patients in MR ≥4.7 Tesla.	
Edwards, 2005b	Type of study: *ex vivo* study Country: UK Source of funding: not reported	Inclusion criteria: - Eighteen tissue samples excised during routine heart valve replacement surgery	A pull-out test using a tensile materials testing machine. Five preconditioning cycles were applied before commencing the final destructive test. The test was complete when the sample ruptured and	Not applicable	Significant factors determining initial yield were - stenosed calcific tissue ($p < .01$) - calcific degeneration (single pathology) ($p < .04$) - tissue stiffness($p < .01$) Calcific degeneration ($p < .03$) and tissue stiffness ($p < .03$) were also significant in determining maximum	This article does not study the MR safety of specific types of heart valve implants. This article studies the forces required to cause partial or total detachment of a heart valve prosthesis in patients with age-related degenerative

			the suture was pulled completely free from the tissue. Results were compared with previously calculated magnetically induced forces at 4.7 Tesla MRI.		force required to cause total rupture. **Conclusion**. The required forces to pull a suture through valve annulus tissue are significantly greater than magnetically induced 4.7 Tesla. Therefore, patients with degenerative valvular diseases are unlikely to be at risk of valve dehiscence.	diseases exposed to MRI
Shellock, 2002	Type of study*: ex vivo* study Country: USA Source of funding: Contract grant sponsor: General Electric Medical Systems; Contract grant sponsor: Institute for Magnetic Resonance Safety, Education, and Research.	Inclusion criteria: 109 different implants and devices, of which 9 heart valve prostheses (2, 3, 5, 6 and 8-12) and 3 annuloplasty rings (1, 4 and 7). 1. AnnuloFlo Mitral Annuloplasty Device, Model AR-736 2. Carboseal Ascending Aortic Valve Conduit, Model AP-033 3. Carboseal Ascending Aortic Valve Conduit, Model AP-033 4. Carpentier-Edwards Classic Annuloplasty Ring, Mitral model 4400 5. Carpentier-Edwards Low Pressure Bioprosthesis, Porcine, mitral model 6625 6. Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis, Mitral model 6900	3.0 Tesla MRI	Not applicable	Magnetic field **interactions** (translational attraction and torque)**:** 0, except for ring nr 7 (deflection angle 4° and torque +1). **Conclusion:** Based on the ASTM criteria all cardiac implants (rings and valves) are considered safe* from a magnetic field interaction viewpoint (i.e., deflection angle less than 45°) at 3.0 Tesla.	

		7. Carpentier-Edwards Physio Annuloplasty Ring, Mitral model 4450 8. Edwards MIRA Mechanical Valve, Mitral, model 9600 9. Reduced Aortic CPHV Carbomedics Prosthetic Heart Valve, Model R5-029 10. Reduced Aortic CPHV Carbomedics Prosthetic Heart Valve, Model R5-029 11. Standard Mitral CPHV Carbomedics Prosthetic Heart Valve, Model R5-029 12. Standard Mitral CPHV Carbomedics Prosthetic Heart Valve, Model M7-033				
Edwards, 2002	Type of study: *ex vivo* study Country: UK Source of funding: not reported	Inclusion criteria: 60 heart valves For further details, see table 1 in article.	4.7 Tesla MRI	Not applicable	Magnetic field **interactions** (translational and rotational forces)**:** Translational forces were detected on 58 heart valves ranging from 0.5° to 7.5°. Seven valves exhibited paramagnetic/weakly ferromagnetic behaviour, and 51 valves exhibited diamagnetic behaviour. Rotational forces were observed for 46 valves (max +2). For further details, see table 2 in article. **Conclusion:** Criteria previously used for safety assessment of heart valve	

					prostheses and expressed in terms of magnetic forces suggest the forces observed in this study are compatible with the safe* use of these valves in magnetic resonance (MR) systems with static fields up to 4.7 Tesla.	
Shellock, 2001	Type of study*: ex vivo* study Country: USA Source of funding: Supported by an unrestricted research grant from Edwards Lifesciences, Irvine, California.	Inclusion criteria: 3 heart valve prostheses: 1. Carpentier-Edwards PERIMOUNT Pericardial Bioprosthesis (mitral, model 6900) 2. Carpentier-Edwards Low Pressure Bioprosthesis (porcine, mitral, model 6625-LP) 3. Edwards MIRA Mechanical Valve (mitral, model 9600) 2 annuloplasty rings 4. Carpentier-Edwards Physiol Annuloplasty Ring (mitral, model 4450) 5. Carpentier-Edwards Classic Annuloplasty Ring (mitral, model 4400)	1.5 Tesla MRI	Not applicable	Magnetic field **interactions**: Deflection angle1 . 2° 2. 0° 3. 2° 4. 6° 5. 0° Torque 1. +1 2. 0 3. +1 4. +1 5. 0 MRI-related **heating** (using high level of exposure to RF radiation): 1. + 0.5 2. + 0.7 3. + 0.5 4. + 0.6 5. + 0.6 **Artefacts** (T1-weighted, spin echo, and gradient echo pulse sequences) Artefacts appeared as localized signal voids, easily recognized on MR images. Artefact size was dependent on amount and type of	

					metal used for implant. GRE pulse sequence produced larger artefacts than T1-weoghted spin echo pulse sequence. **Conclusion**: MR procedures may be conducted safely* in patients with these implants using MR systems operating with 1.5 Tesla or less.	
Pruefer, 2001	Type of study: *ex vivo* study Country: Germany Source of funding: not reported	Inclusion criteria: 17 common heart valve prostheses (1-12 mechanical, 13-17 biological) 1. Baxter Mira 21 AF, Aortic 2. Baxter Mira 27M, Mitral 3. On-X 19 mm aortic valve prosthesis, Aortic 4. On-X 23 mm aortic valve prosthesis, Aortic 5. On-X 25 mm mitral valve prosthesis, Mitral 6. SJM 23 A 101, Aortic 7. SJM 25 MEC 102, Mitral 8. SJM (Silzone) 27MS-601, Mitral 9. Omniscience aortic valve, Aortic 10. Sorin Bicarbon 29 mm, Mitral 11. Ultracolor 27 mm, Mitral 12. Brörk-Shiley Monostrut, Mitral 13. Mitroflow 29 mm aortic valve, 11A29, Aortic 14. SJM Mitral 28 mm (Bioimplant), Mitral	1.5 Tesla MRI	Not applicable	Magnetic field **interactions** were negligible: - Deflection angles ranged from 0 - 5 degrees - The torque ranged from 0 - +2 - All type of materials used for the evaluated prostheses were either nonferromagnetic or only weakly ferromagnetic relative to the 1.5 Tesla MR environment. Highest temp changes in the assessment of RF MRI-related **heating,** ranged from 0.5 - 0.8°C. Highest reference temperature changes ranged from 0.4 - 0.5°C. **Artefacts** ranged from mild (+2) to severe (+4) and appeared as localized signal voids, easily recognizable on image. Gradient-echo pulse sequence produced larger artefact than T1-weighted pulse sequence. Artefacts were directly proportional to amount of metal present for a given prosthesis.	

		15. Baxter CE SAV® Mitral 33 mm, Mitral 16. Baxter CE Aortal 23 mm Perimount, Aortic 17. Baxter CE SAV aortic 31 mm, Aortic			**Conclusion**: MR procedures performed with 1.5 Tesla MR system can be applied safely* in patients with heart valve prostheses evaluated in this study.	
Edwards, 2000	Type of study: *ex vivo* study Country: USA/UK Source of funding: Not reported	Inclusion criteria: 31 heart valves. For further details, see table 1 in article.	1.5 Tesla MRI	Not applicable	Magnetic field **interactions** were negligible: - Deflection angle, 0-5 degrees - Torque, 0-2 MRI-related **heating** (at relative high specific absorption level, whole body average SAR, 1.1-W/kg) was minimal: - Max temp rise, up to 0.8°C - Background temp rise, 1.7°C **Artefacts** were mild (+2) to severe (+4) and appeared as localized signal voids, easily recognizable on the image. Gradient echo pulse sequence produced larger artefact than T1-weighted pulse sequence. For further details, see table 2 in article. **Conclusion**: the results indicate that MR procedures may be conducted safely* in individuals with the evaluated heart implants using MR systems with static magnetic fields of 1.5 Tesla or less.	
Hartnell, 1997	Type of study*: in vivo* prospective cohort study	Inclusion criteria: Patients who have undergone cardiac surgery and have retained	1- or 1.5- Tesla MRI	Length of follow-up: Until end of MR imaging	**Clinical signs:** None of the patients reported symptoms suggesting	

	Setting: university hospital Country: USA Source of funding: NR	metallic material, including valve replacements, and temporary epicardial pacing wires cut short at the skin. Presence of temporary epicardial pacing wires, prosthetic valves, and other metal materials was confirmed by chest radiography <7 dys of MRI. Exclusion criteria: patients without a contemporary chest radiograph or radiopaque material visible on chest radiograph. N total at baseline: 200 of whom 81 were examined with ECG monitoring. 52 coronary bypass surgery 25 valve replacement (With or without coronary bypass surgery) 51 temporary epicardial pacing wires 187 sternal wires 178 mediastinal surgical clips. All 25 patients with valve replacement were examined with ECG monitoring. Important prognostic factors2:		Loss-to-follow-up: 0 Incomplete outcome data: 3/200 2 patients were examined to elucidate the cause of recurrent but self-terminating ventricular arrhythmias that did not change in frequency from baseline. In both cases imaging was terminated because of poor image quality from gating irregularity during ventricular arrhythmias. 1 patient who received dipyridamole as part of a MR imaging stress perfusion protocol, requested early cessation of the examination because angina developed after injection of the dipyridamole. On reversal of the stress agent with aminophylline the symptoms subsided, and no evidence showed that this outcome was related to the MR imaging sequences.	arrhythmia or other cardiac dysfunction during MR imaging. **ECG rhythm:** No changes from baseline **Signal loss** because of susceptibility effects was seen with all valves and was more prominent with gradient-echo sequences. **Conclusion:** 1- or 1.5- Tesla MR can be performed safely* in patients who have undergone cardiac surgery and have retained metallic material, including valve replacements, and temporary epicardial pacing wires cut short at the skin.	

		No details of patient characteristics reported. Valve type unknown?				
Shellock, 1994	Type of study: *ex vivo* study Country: USA Source of funding: Not reported	Inclusion criteria: 13 heart valve prostheses For further details see table in article.	1.5 Tesla MRI	Not applicable	Magnetic field **interactions**: - No measurable deflections MRI-related **heating**: - Max temp rise immediately after 30 min MRI was +0.2°C for air experiment and +0.3°C for normal saline experiment. (For further details see table in article) **Artifacts** were minimal (all +) **Conclusion**: MR procedures performed with 1.5 Tesla (64-MHz) MR system may be performed safely in patients with heart valve prostheses evaluated in this study.	
Shellock, 1988	Type of study: *ex vivo* study Country: USA Source of funding: Supported by Public Health Service grant 1 AOl CA44014-01 from the National Cancer Institute and by a grant from the General Electric Co., Milwaukee, WI. I.	Inclusion criteria: 36 different metallic biomedical implants, of which 7 heart valve protheses: 1. Bjork-Shiley, convexo/concave (Shiley, Irvine CA) 2. Hall-Caster, Model A7700 (Medtronic, Minneapolis, MN) 3. Hancock I, porcine (Johnson & Johnson, Anaheim, CA) 4.Hancock II,porcine(Johnson & Johnson)	1.5 Tesla MRI (with high-field-strength)	Not applicable	Magnetic field **interactions**: - Deflection force (dynes): 1. 59 2. 91 3. 10 4. 8 5. 170 6. 152 7. 0 **Conclusion**: patients with heart valves evaluated in this study can be safely* imaged with high-field 1.5-T MR systems.	

		5. Lillehi-Kaster, model 3005 (Medical Inc., Inver Grove Heights, MN) 6. Starr-Edwards, model 2400 (American Edwards Laboratories, Santa Ana, CA) 7. St. Jude's (St. Jude Medical, St. Paul, MN				
Randall, 1988	Type of study: *ex vivo* and *in vivo* study Setting: University hospital Country: USA Source of funding: NR	Inclusion criteria: 5 heart valve prostheses: 1. Lillehei-Kaster (Medical Incorporated), Pyrolite carbon disc. 2. St. Jude Medical (St. Jude Medical), Bileaflet pyrolite disc impregnated with small amount of tungsten 3. Bjork-Shiley spherical disc (Shiley), Pyrolite tilting carbon disc. 4. Bioprosthetic Carpentier-Edwards (American Edwards), Porcine valve. 5. Ionescu-Shiley (Shiley), Calf pericardium. *In vivo* examinations were performed on patients who had same prosthetic valves and signed informed consent form. Exclusion criteria: patients with transvenous or epicardial pacing electrode or a pacemaker.	0,5 and 2 Tesla MR (*in vivo* all 0,5-T)	Not reported	*Ex vivo*: Magnetic field **interactions:** no evidence of valve deflection at the mouth of the 2-T magnet in the presence of a very large magnetic field gradient. MRI-related **heating:** No temp increase >0.2°C was observed. *In vivo*: Mild localized **artefacts** traceable to the metal components of the valve. There is little distortion of the image outside of the immediate valve area. **Clinical signs**: No arrhythmias were observed, no clinical signs or symptoms of discomfort were noted or volunteered. MRI demonstration of the valves *in vivo* gave little information as to their condition or function because valves appear as a signal void and valves caused minimal distortion or artefact formation in surrounding structures.	

		N total at baseline: 6. - Age 35 - 65 yrs - 2 women, 4 men - 5 aortic valves, 1 mitral valve			**Conclusion:** these studies can be performed safely* and reliably when problems in the vicinity of the valve require evaluation.	
Soulen, 1985	Type of study: ex vivo study Country: USA Source of funding: This work was performed by a contractor of the U.S. government and supported in part under U.S. Department of Energy contract DE-AC03-76SF00098.	Inclusion criteria: 9 different synthetic and tissue valves: 1. Carpentier-Edwards Bioprosthesis Model 6625 (Porcine valve) 2. Ionescu-Shiley Pericardial Xenograft (Bovine pericardial valve) 3. Björk-Shiley Unversal Spherical (Pyrolytic carbon disc) 4. Medtronic Hall (Pyrolytic carbon disc) 5. Beall (Surgitool) (Pyrolytic carbon disc) 6. Starr-Edwards Aortic Model 2320 (1970-1976) (Hollow stellite ball) 7. Starr-Edwards Aortic Model 1260 (1968 - present) (Silicone rubber ball with 2% BaSO4 by weight) 8. Smeloff-Cutter (Silicone elastomer ball) 9. Starr-Edwards Mitral Pre 6000 (1960 - 1964) (Silicone rubber ball)	0.35, 1.5 and 2.35 Tesla MRI	Not applicable	Magnetic field **interactions**: 0.35-T MR: No deflection 1.5-T MR: 1. 0° 2. 0° 3. 0.25° (2.6 x10-4N) 4. 0° 5. 0.75° (1.1 x10-3N) 6. 1.0° (1.1 x10-3N) 7. 0.33° (4.5 x10-4N) 8. 0.75° (1.6 x10-3N) 9. 3.0° (6.7 x10-3N) 2.35-T MR 1. 6.0° (5.3 x10-3N) 2. 0.5° (3.2 x10-4N) 3. 3.0° (3.1 x10-3N) 4. 1.5° (1.1 x10-3N) 5. 1.0° (1.5 x10-3N) 6. 8.7° (9.4 x10-3N) 7. 2.7° (3.7 x10-3N) 8. NA 9. 27.0° (6.5 x10-2N) Change in temp due to MRI-related **heating**:	

					No significant temperature rise followed exposure of valves in either cryomagnet (range -0.2 - + 0.4°C) **Artefacts**: image distortion varied from negligible to severe in both 0.35-T and 1.5-T images. Magnitude of distortion paralleled magnitude of prosthetic deflection, being most severe with valve 9. After removal of this valve, there was no alteration in adjacent images. **Conclusion**: Patients with present-day prosthetic heart valves can be safely* imaged in present-day MR imagers. Prosthesis-induced artefacts will not interfere with interpretation in most instances.	

* Tested implants are "MR Conditional" according to ASTM 2013, which is defined as an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use indicated

Research question: What is the risk of having a negative outcome when performing MRI in patients with prosthetic heart valves?

Study reference (first author, year of publication)	Bias due to a non-representative or ill-defined sample of patients? [1] (unlikely/likely/unclear)	Bias due to insufficiently long, or incomplete follow-up, or differences in follow-up between treatment groups? [2] (unlikely/likely/unclear)	Bias due to ill-defined or inadequately measured outcome ? [3] (unlikely/likely/unclear)	Bias due to inadequate adjustment for all important prognostic factors? [4] (unlikely/likely/unclear)
Hartnell, 1997	unlikely	likely	unlikely	likely
Randall, 1988	unlikely	likely	unlikely	likely

1. Failure to develop and apply appropriate eligibility criteria: a) case-control study: under- or over-matching in case-control studies; b) cohort study: selection of exposed and unexposed from different populations.
2. 2 Bias is likely if: the percentage of patients lost to follow-up is large; or differs between treatment groups; or the reasons for loss to follow-up differ between treatment groups; or length of follow-up differs between treatment groups or is too short. The risk of bias is unclear if: the number of patients lost to follow-up; or the reasons why, are not reported.
3. Flawed measurement, or differences in measurement of outcome in treatment and control group; bias may also result from a lack of blinding of those assessing outcomes (detection or information bias). If a study has hard (objective) outcomes, like death, blinding of outcome assessment is not necessary. If a study has "soft" (subjective) outcomes, like the assessment of an X-ray, blinding of outcome assessment is necessary.
4. Failure to adequately measure all known prognostic factors and/or failure to adequately adjust for these factors in multivariate statistical analysis.

Search Accountability

Annulopasty Rings

Database	Search criteria	Total
Medline (OVID) 1946 - May 2018	1 exp Magnetic Resonance Imaging/ or MRI*. ti. or magnetic resonance imaging.ti. or fMRI*. ti. or cardiovascular magnetic resonance.ti. or CMR.ti. (409699) 2 MITRAL VALVE ANNULOPLASTY/ or annuloplast*. ab,ti. or 'prostatic ring*'. ab,ti. (3923) 3 exp Safety/ or safet*. ab,ti. or exp Contraindications/ or contraindication*. ab,ti. or evaluation.ab,ti. or issue*. ab,ti. or adverse event*. ab,ti. or adverse effect*. ab,ti. or complication*. ab,ti. or deflection.ab,ti. (2717075) 4 1 and 2 and 3 (12) 5 limit 4 to english language (12) = 12 (12 unique)	41
Embase (Elsevier)	('nuclear magnetic resonance imaging'/exp OR mri*:ti OR 'magnetic resonance imaging':ti OR fmri*:ti OR 'cardiovascular magnetic resonance':ti OR cmr:ti) AND ('annuloplasty ring'/exp OR 'prostatic ring*':ab,ti OR annuloplast*:ab,ti) AND ('safety'/exp OR safet*:ab,ti OR 'contraindication'/exp OR contraindication*:ab,ti OR evaluation:ab,ti OR issue*:ab,ti OR 'adverse event*':ab,ti OR 'adverse effect*':ab,ti OR complication*:ab,ti OR deflection:ab,ti) AND [english]/lim NOT 'conference abstract':it = 36 (36 unique)	

Prostetic heart valves

Database	Search criteria	Total
Medline (OVID) 1946 - March 2018	1 exp *Magnetic Resonance Imaging/ or MRI*. ti. or magnetic resonance imaging.ti. or fMRI*. ti. or cardiovascular magnetic resonance.ti. or CMR.ti. (190114) 2 exp *Heart Valves/ or exp Heart Valve Prosthesis/ or heart valve*. ab,ti. or cardiac valve*. ab,ti. or aortic valve*. ab,ti. or TAVI.ab,ti. or AVI.ab,ti. or SAVR.ab,ti. or THV.ab,ti. or PAVR.ab,ti. or TAVR.ab,ti. or 'pulmonary valve*'. ti. or 'mitral valve*'. ti. or 'tricuspid valve*'. ti. (103619) 3 exp Safety/ or safet*. ab,ti. or exp Contraindications/ or contraindication*. ab,ti. or evaluation.ab,ti. or issue*. ab,ti. or adverse event*. ab,ti. or adverse effect*. ab,ti. or complication*. ab,ti. or deflection.ab,ti. (2663165) 4 1 and 2 and 3 (303) 5 limit 4 to english language (272) = 272	321
Embase (Elsevier)	('nuclear magnetic resonance imaging'/exp/mj OR mri*:ti OR 'magnetic resonance imaging':ti OR fmri*:ti OR 'cardiovascular magnetic resonance':ti OR cmr:ti) AND ('heart valve'/exp/mj OR 'heart valve prosthesis'/exp OR 'heart valve*':ti OR 'cardiac valve*':ti OR 'aortic valve*':ti OR tavi:ti OR avi:ti OR savr:ti OR thv:ti OR pavr:ti OR tavr:ti OR 'pulmonary valve*':ti OR 'mitral valve*':ti OR 'tricuspid valve*':ti) AND ('safety'/exp OR safet*:ab,ti OR 'contraindication'/exp OR contraindication*:ab,ti OR evaluation:ab,ti OR issue*:ab,ti OR 'adverse event*':ab,ti OR 'adverse effect*':ab,ti OR complication*:ab,ti OR deflection:ab,ti) AND [english]/lim NOT 'conference abstract':it = 197	

5

Search Databases of Recalls and Events

Database	Search criteria[1]	Total
FDA Recalls database[2] searched on 25-1-2019	1 'MR' OR 'magnetic' (329) 2 concerns implant and MRI (9) 3 concerns relevant implant for this module (0) = 0	0
IGJ database safety notifications[3] *notifications from 15-12-2015* searched on 29-1-2019	1a 'MR' (22) 1b 'MRI' (15) 1c 'magnetic' (11) 2 concerns implant and MRI (4) 3 concerns relevant implant for this module (0) = 0	
IGZ archive[4] searched on 17 and 29-1-2019	1a 'MR' (98) 1b 'MRI' (92) 1c 'magnetic' (27) 2 concerns implant and MRI (0) 3 concerns relevant implant for this module (0) = 0	
ICIJ database Implants[5] searched on 18-1-2019	1a 'Heart valve' (0) 1b 'cancellation charge' (0) 1c 'annuloplasty ring' (0) 1d 'prostatic ring' (0) 1e 'mitraclip' (0) = 0	
ICIJ database Implants[5] searched on 18-1-2019	1a 'MR' (38) 1b 'MRI' (17) 2 concerns implant and MRI (0) 3 concerns relevant implant for this module (0) = 0	
ICIJ database Events[5] searched on 25-1-2019	1a (Data_notes contains 'mitraclip' OR 'valve') AND (Reason contains 'mr' OR 'magnetic' (0)) 1b (Data_notes contains 'ring' OR 'annuloplasty') AND (Reason contains 'mr' OR 'magnetic' (0)) = 0	
ICIJ database Events[5] searched on 18 and 25-1-2019	1a 'MR' (603) 1b 'magnetic' (185) 2 Assess whether the hits are not from the FDA database (0) = 0 *This database has an overlap with the FDA database[2].*	

1 The databases have limited and different possibilities to search them. The search strategies chosen is via 'MRI'. Subsequently, all hits were read and assessed whether they concern an implant, and then whether the implant is relevant for this module. In addition, the databases have limitations, an example of this is an MRI related report of an implant from the IGZ database which isn't found in the FDA database because there the link to MRI had dissapeared.

2 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm.

3 https://www.igj.nl/onderwerpen/waarschuwingen-medische-hulpmiddelen/documenten.

4 https://igj.archiefweb.eu/?subsite=igz#archive.

5 https://medicaldevices.icij.org/.

Exclusion Table

after reading the full article

Author and year	Reasons of exclusion
Lee, 2017	other question
Suchá, 2015	non-systematic review
Ripley, 2016	non-systematic review
Karamitsos, 2017	opinion article, no primary research
Gulsin, 2017	non-systematic review
Salaun, 2016	other question
Musa, 2016	non-systematic review
Mangold, 2015	other question
Von Knobselsdorff-Brenkenhoff, 2014	non-systematic review
Saremi, 2014	other question
Ribeiro, 2014	other question
Merli, 2014	concerns a video, not an article
Lopez-Mattei, 2013	other question
Pham, 2012	non-systematic review
Myers, 2012	concerns a letter to the editor
Baikoussis, 2011	non-systematic review
Kahlert, 2010	other question
Hundley, 2010	expert opinion
Walsh, 2008	non-systematic review
Pamboucas, 2008	non-systematic review
Dill, 2008	non-systematic review
Martin, 2007	non-systematic review
D'Avenio, 2007	other question
Giroletti, 2005	seems systematic review, article not available
Shellock, 2004	non-systematic review
Prasad, 2004	editorial
Shellock, 2002b	non-systematic review
Ahmed, 2001	non-systematic review
Sawyer-Glover, 2000	non-systematic review
Shellock, 1991	non-systematic review
Shellock, 1988b	non-systematic review