

## TECHNICAL NOTE

# Development of a Searchable System to Confirm MR Imaging Safety Information for Implantable Medical Devices

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The purpose of this study was to develop a searchable system to confirm magnetic resonance (MR) safety information of implantable medical devices (IMDs) to safely perform magnetic resonance imaging examinations. We labeled MR safety information for IMDs based on package insert descriptions and then categorized allowed MR conditions for IMDs. Finally, a searchable system was developed to use the database via the internet. This system enables efficient and accurate confirmation of MR safety information for IMDs.

**Keywords:** *implantable medical device, magnetic resonance imaging, magnetic resonance safety information, safety management*

## Introduction

Magnetic resonance imaging (MRI) is a non-invasive imaging technique to obtain valuable anatomical information, which plays a significant role in medical diagnosis. The number of patients that require MRI examinations for diagnosis has increased annually.<sup>1</sup> Concurrently, various newly developed implantable medical devices (IMDs), which can be implanted in the body, have become widespread as a result of medical technological advances. Therefore, situations that require MRI examination of patients who have IMDs have been increasing.<sup>2,3</sup>

There are safety risks for patients with IMDs during MRI examinations, such as displacement force, torque, and heating by interaction with the magnetic environment.<sup>3</sup> To reduce the risks related to these interactions, when conducting MRI examinations on patients with IMDs, it is necessary to confirm the safety of the IMD under the MR environment (MR safety information) in advance; then, the examination must be performed under an allowed usage condition.<sup>3,4</sup> In recent years, in addition to passive IMDs without power supplies, such as intravascular stent and cerebral aneurysm clips, active IMDs with power supplies, such as MR conditional cardiac pacemaker, have been approved. Thus, the importance of confirmation and the responsibility

of medical personnel has increased. Many IMDs that can undergo MR examination are allowed in specific MR conditions, such as a static magnetic field, maximum MR system reported averaged whole-body specific absorption rate (SAR), and  $dB/dt$ . Therefore, it is necessary to confirm these conditions for each IMD. However, there is no established method for confirming the MR safety information of various IMDs in Japan. Therefore, the confirmation method has varied depending on the facility<sup>5</sup>; moreover, this process requires additional time to verify. These aspects not only increase the burden on medical personnel, but may also lower the accuracy of confirmation for IMD.

The websites of “MRIsafety.com” and “MagResource” have provided MR safety information regarding IMDs to medical personnel worldwide.<sup>6,7</sup> These sites are internationally known and extremely useful because they provide reliable information. The website of “MRIsafety.com” provides MR safety information based on its own investigation; its categories for MR safety information are different with those of the standard of ASTM International.<sup>8</sup> In addition, the description of the allowed usage MR conditions is unified for each classification of MR safety information. “MagResource” provides MR safety information based on that published by manufacturers and is consistent with the standard of ASTM International. Although the allowed usage MR conditions have been provided, they have not been classified for all MR conditions. In both websites, the product name may differ from the name mentioned on the package insert in Japan. Therefore, when using these services in Japan, it may not be possible to identify the product. Moreover, because information sources of these websites are not the package inserts provided in Japan, the information provided by these websites may differ from that provided by such package inserts. Therefore, it is difficult to use this information as a standard method to confirm the MR

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safety information of IMDs. To confirm the MR safety information of IMDs implanted in Japan, it is necessary to use information based on the description in the package insert in Japan. However, because the description within the package insert is not focused specifically on MR safety information, it is necessary to choose only the information necessary for MRI examination and to classify each item with appropriate information.

To resolve this problem, we previously reported that a prototype system was constructed to confirm MR safety information for IMDs.<sup>5</sup> Although the system enabled easy, rapid access to MR safety information, the number of IMDs in the database was limited, and classification for the labeling of MR safety information was insufficient. To provide this system with a measure of clinical usefulness, it was necessary to investigate the MR safety information of many categories of IMDs and aggregate them based on the objective data.

The purpose of this study was to develop a searchable system to confirm MR safety information for various IMDs and was to evaluate its usefulness in clinical applications.

## Materials and Methods

### Selection of IMD to be investigated

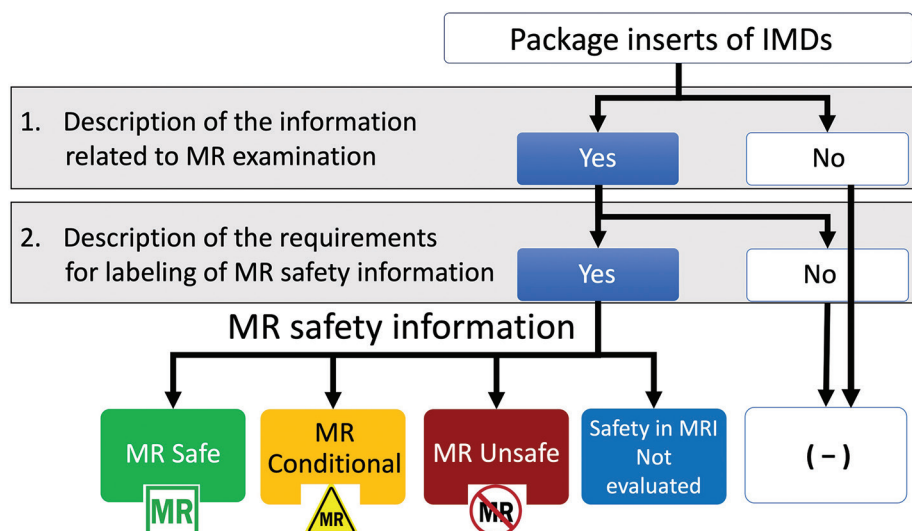
To create a database of MR safety information of IMD, IMDs to be investigated were selected from among common products sold in Japan. The IMDs were chosen from package inserts posted on the website of the Pharmaceutical and Medical Device Agency (PMDA) using Japan Medical Device Nomenclature (JMDN) classification. In Japan, there were a total of 4320 JMDN classifications of medical devices as of March 30, 2018. From among these classifications, we selected 394 JMDN classifications that we considered to include IMDs. A total of 5051 IMDs corresponding to those classifications were investigated.

### Labeling for MR safety information of IMD

The MR safety information of each IMD was labeled based on the description of package inserts. The MR safety information was classified into four categories, on the basis of ASTM International and Food and Drug Administration (FDA) guidance, as follows: “MR safe,” “MR conditional,” “MR unsafe,” “Safety in MRI not evaluated”.<sup>8,9</sup> Figure 1 shows the flow-chart for the labeling of MR safety information. The format for description related to MR safety information in the package insert was not uniform, and the description method of MR safety information was different for each IMD or manufacturer. Therefore, we defined seven requirements to objectively label MR safety information (Table 1). As on the flow-chart, if there was a description related to MRI examination and there were the requirements for the labeling of MR safety information, as listed in Table 1, then the IMD was labeled. When the description of the package insert did not meet the requirements, it was not labeled and was marked as “-”.

### Investigation of usage MR conditions for IMD

All MR safety information of each IMD was investigated and labeled based on descriptions within the package inserts that were obtained via the PMDA website.<sup>10</sup> Moreover, we collected package inserts for IMDs and gathered information related to the allowed usage MR conditions. The investigated usage MR conditions were as follows: static magnetic field, maximum allowed spatial field gradient, maximum MR system reported whole-body averaged SAR, MR system reported  $B_{1+RMS}$ , the slew rate of the gradient field,  $dB/dt$ , maximum allowed scan time per series, and other conditions or individual comments for the usage MR conditions. We also investigated the results of non-clinical tests of IMD based on the international standards of ASTM International and the International Electrotechnical Commission<sup>11</sup> in the descriptions of package inserts for IMDs. The investigation



**Fig. 1** Flow-chart for labeling of MR safety information for IMD. We investigated the package inserts of IMDs. When there was a description of both information related to MR examination and the requirements listed in Table 1 for labeling of MR safety information, we labeled MR safety information as one of four categories. IMD, implantable medical devices.

**Table 1** Requirements for labeling of MR safety information

Requirements
1. Non-clinical tests based on the ASTM or IEC
2. Non-clinical tests based on an unknown standard
3. Evidence based on the properties of materials
4. Not evaluated for MRI safety
5. Electrically active IMD
6. Scholarly resource
7. Other evidence

IEC, International Electrotechnical Commission; IMD, implantable medical device.

items were as follows: scanning time, scanning sequence, increase in temperature, size of artifacts, and the name of MRI equipment vendor used in non-clinical tests.

### *Development of the searchable system*

We collected the above information and created the MR safety information database using these data. The database was connected to a web server using a method similar to that of our previous report.<sup>5</sup> Finally, a web-based searchable system was developed to confirm the MR safety information of IMD, which was accessible to medical personnel via the internet using a personal computer (PC), tablet PC, or smartphone.

### *Clinical evaluation*

The study protocol was approved by the Institutional Review Board of Kumamoto University. We recruited evaluators by sending letters and e-mails to 1874 medical personnel registered in this system through March 31, 2018. After informed consent was obtained from the participants, a questionnaire to evaluate the usefulness of the system was provided on the website via the internet. Table 2 shows the list of questions presented to evaluators. In questionnaires 4–9, four answers (a–d) were divided into two groups: a, b and c, d. Then, a Chi-squared test was performed to compare the two groups using Prism 6.0 (GraphPad Software Inc., San Diego, CA, USA). We considered a *P*-value of <0.05 to indicate a significant difference.

## **Results**

### *Construction of an MR safety information database and web-based searchable system*

As a result of investigating 5051 IMDs, we labeled the MR safety information of 1205 IMDs. The MR safety information of these IMDs was 9 (0.17%) for MR safe, 560 (11.08%) for MR conditional, 280 (5.54%) for MR unsafe, and 356 (for 7.04%) for safety in MRI not evaluated. The remaining 3846 IMDs (76.14%) were not labeled because the descriptions within package inserts for these IMDs did not meet the requirements for labeling suitability.

Figure 2 shows the settings screen of the search criteria in this system. The user can set the search criteria as necessary, such as brand name, marketing authorization holder, or generic name of JMDN. If the user pushes the search button, the search can begin for the match with these criteria.

The screen for providing detailed information regarding the IMD search results is shown in Fig. 3. The detailed information of the IMD was separated into five categories. The first category showed basic device information, such as brand name and marketing authorization holder. The second category showed the safety information for MRI examination, such as body parts where the device can be implanted, materials, labeling for MR safety information, and individual comments for safety in clinical examination. The third category showed information for allowed usage MR conditions for MRI examination, which contained various conditions, such as a static magnetic field, maximum allowed spatial field gradient, and maximum MR system reported whole-body averaged SAR. The fourth category shows the indications of safety and effectiveness for safety MRI examination, which contained the results of non-clinical tests, such as the increase in temperature and size of the artifacts. The last category shows the information of the package insert used in the survey. At the bottom of the detailed information for IMD, the link to access the package insert information was shown. When the user needed to confirm information from package inserts directly, if the user pushed this button, the package insert of the IMD would be opened.

### *Clinical evaluation of the system*

A total of 510 medical personnel participated in the assessment among 1874 registrants who used this system. The effective response rate was 27%. The jobs of participants in this study were 93% radiological technologist, 5% doctor, 1% clinical laboratory technologist, and 1% nurse.

Figure 4 shows the results of the survey of the adequacy of each item screen as follows: critical search settings, basic IMD information, safety information for MRI examination, allowed usage MR conditions, indications of safety and effectiveness information, and package insert information. In all the questionnaires regarding information displayed to the screen, more than 80% of the evaluators selected or probably appropriate.

Figure 5 shows the results of the survey for the accuracy and efficiency of the confirmation of MR safety information for IMD in this system. It is notable that 96.5% of medical personnel answered that the accuracy and efficiency of this system to confirm the IMD was improved or probably improved compared with currently available confirmation methods; these differences were statistically significant ( $P < 0.01$  in both). As a result of questioning whether this system could be a standard method to confirm the MR safety information of IMD at your hospital, the answer was as follows: 46.1% for available, 47.3% for probably available, 4.7% for not probably not available, and 2.0% for not available.

**Table 2** Questionnaires presented to medical personnel

Question	Choice
1. What is your job?	a) Radiological technologist, b) Medical doctor, c) Nurse, d) Other
2. In the search settings condition, is the displayed information appropriate?	a) Appropriate, b) Probably appropriate, c) Probably inappropriate, d) Inappropriate
3. Is the item displayed in the basic IMD information appropriate for the search performed?	a) Appropriate, b) Probably appropriate, c) Probably inappropriate, d) Inappropriate
4. Is the item displayed in the safety information about MRI examination appropriate for the search performed?	a) Appropriate, b) Probably appropriate, c) Probably inappropriate, d) Inappropriate
5. Is the item displayed in the acceptable usage condition for MRI examination appropriate for the search performed?	a) Appropriate, b) Probably appropriate, c) Probably inappropriate, d) Inappropriate
6. Is the item displayed in the indications of safety and effectiveness information appropriate for the search performed?	a) Appropriate, b) Probably appropriate, c) Probably inappropriate, d) Inappropriate
7. Is the item displayed in the package insert information appropriate for the search performed?	a) Appropriate, b) Probably appropriate, c) Probably inappropriate, d) Inappropriate
8. In comparison with current confirmation methods, when this system is used, do you think that the efficiency of confirmation will change based on this system?	a) Improve, b) Probably improve, c) Probably reduce, d) Reduce
9. In comparison with current confirmation methods, when this system used, do you think that the accuracy of confirmation will change based on this system?	a) Improve, b) Probably improve, c) Probably reduce, d) Reduce
10. Can this system be a standard method to confirm MR safety information of IMDs in your hospital?	a) Usable, b) Probably usable, c) Probable not available, d) Not available

IMD, implantable medical devices.

### Search settings conditions

**Brand name**

**Company name**

**JMDN code/Generic Name**

**Implanting in body parts**

**Labeling for MR safety information**

**Safety comments in clinical practice**

**Static magnetic field [T]**

**Approval number**

**Management number of package insert**

**Fig. 2** Settings of the search criteria for the system. JMDN, Japan Medical Device Nomenclature.

### Basic IMD information

Brand name	[REDACTED]
Company name	[REDACTED]
JMDN code/Generic name	44279000 Iliac artery stent

### Safety information for MRI examination

Implanted in specific body parts	Abdomen (including pelvis)
Materials	Titan, titanium alloy Nickel, titanium, platinum alloy polyamide
Descriptions of the safety information	Yes
Descriptions of the requirements	Yes
Requirement of MR safety information	Non-clinical tests based on an unknown standard
Labeling of MR safety information	MR Conditional
Safety comments in clinical practice	

### Acceptable usage condition for MRI examination

Details of usage condition		
Static magnetic field [T]	1.5, 3.0	
	1.5T	3.0T
Allowed spatial field gradient [T/m]	25	25
MR system reported, maximum whole-body averaged SAR [W/kg]	2.0	2.0
MR system reported, B1+rms [μT]		
Slew rate of the gradient field [T/m/s]		
Max dB/dt [T/s]		
Scanning time for non-clinical tests [min]		
Maximum allowed scan time per series [min]	15	15
Other conditions		
Special comments for condition		

### Indications of safety and effectiveness information

	1.5T	3.0T
Increase in temperature [degrees]		
Size of artifact [mm]		
Other comments		

### Package insert information

Final revision date of package insert	2014.2.6
Final edition of package insert	1 <sup>st</sup> edition
Approval number	226008ZX00035000
Certification number	
Report number	
Management number (PMDA)	226008ZX00035000_A_01_01
Management number (Company)	APL2098103-1
Published on website of PMDA	Yes

Remarks

[\[PDF\] View package insert](#)

Fig. 3 An example display of the search results. The results were separated into five categories as follows: basic implantable medical device information, safety information for MRI examination, allowed usage condition for MRI examination, indications of safety and effectiveness information, and package insert information. IMD, implantable medical devices.

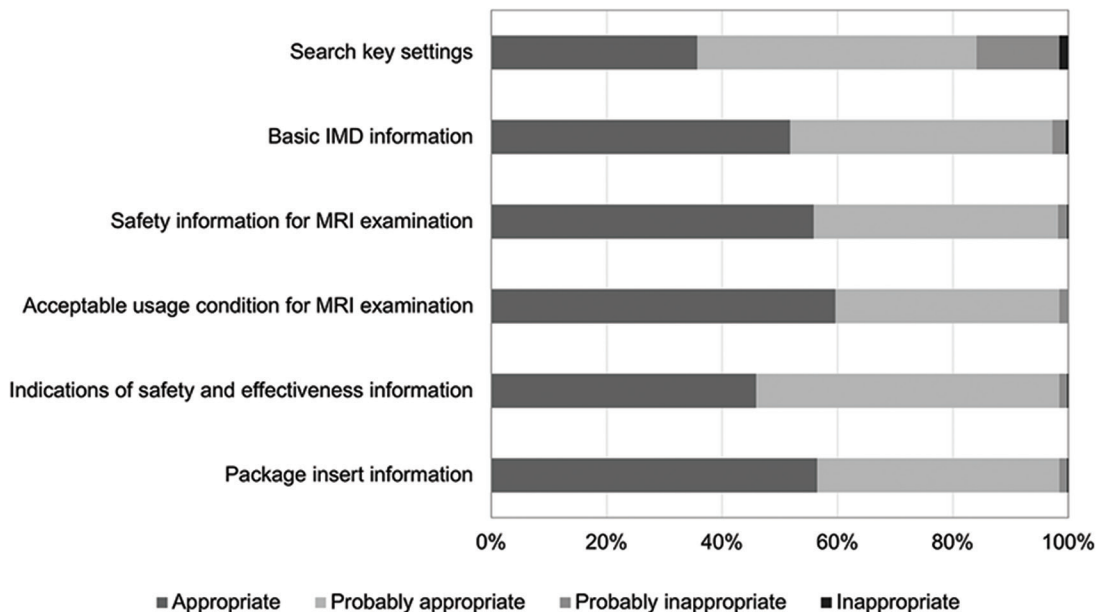
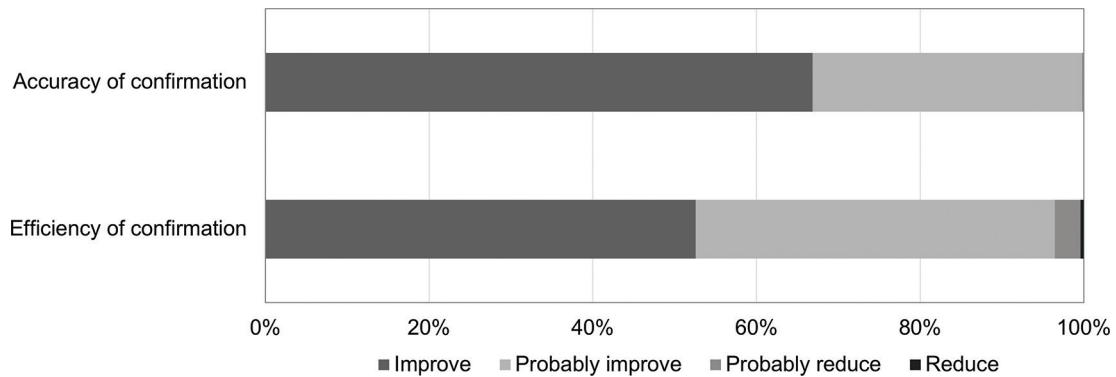


Fig. 4 Questionnaire results regarding the perception of the system by medical personnel. IMD, implantable medical devices.



**Fig. 5** Questionnaire results regarding the efficiency and accuracy of the system to confirm MR safety information of implantable medical devices, as rated by medical personnel.

## Discussion

In order to safely perform MRI examination of patients with IMDs, it is necessary to provide aggregated MR safety information of IMDs to medical personnel. In this study, we developed a searchable system to confirm MR safety information of IMDs and demonstrated its usefulness.

The use of a medical device must follow the description in the package inserts. Therefore, we investigated the contents of the package inserts of IMDs and objectively classified them by labeling MR safety information according to international standards, such as ASTM International and FDA guidance.<sup>8,9</sup> As a result, the number of investigated IMD was over 5000 and the safety information of these IMDs for MRI examination was registered in the database. This database covered a large number of IMDs available in Japan. To our knowledge, this is the first report regarding the creation of a large-scale MR safety information database based on package inserts of IMDs in Japan.

Some IMDs for investigation could not be labeled because the description contents of the package insert were unclear. However, all information regarding MRI examination described in package inserts was recorded in the database and presented as MR safety comments in the search results. Therefore, these comments may be useful for judging whether to perform an MRI examination.

To accurately label all IMDs, it is necessary to perform non-clinical tests based on international standards and standardized descriptions in the package inserts. Furthermore, if manufacturers did not perform non-clinical tests of IMD, it is necessary to describe that fact in the package inserts. Kuroda proposed a standardized format to present MR safety information based on non-clinical tests in package inserts, with reference to FDA guidance in Japan.<sup>9,12</sup> In future, if this system is used as a standard tool to confirm MR safety information, it may provide an opportunity to promote the standardization of the description in the package inserts.

For IMDs with MR conditional, we not only labeled the IMDs but also investigated the usage MR condition IMDs,

categorized each item, and showed them as results. Therefore, medical personnel can easily understand these allowed usage conditions or limits for safe MR examinations of patients with IMDs by confirming the search results of the IMD. However, we did not summarize the usage MR conditions for arrhythmia devices in the database because these devices have strict requirements; the requirements for acceptable use conditions are complicated, and inspections must meet facility standards. In the search results of these IMDs, to avoid incorrect recognition by medical personnel and to avoid incomplete information, comments were shown to encourage medical personnel to refer to the package inserts directly. In addition, we posted the links to the websites of MR safety information that manufacturers themselves provide. The user can obtain MR safety information by directly checking the websites provided by the manufacturers selling the IMDs.

This system allows MR safety information confirmation to be performed via the internet from any location using a personal computer, tablet computer, or smartphone. Therefore, MR safety information from IMDs is easily accessible by medical personnel. The information sources for this system are based on the descriptions within package inserts in Japan, which differ from those of the “MRIsafety.com” or “MagResource” websites. In addition, this system can provide MR safety information with a detailed classification method that differs from those of the above services. Therefore, our proposed system may be more useful to medical institutions in Japan.

As a result of the questionnaire, the method of providing information regarding MR safety information of IMD was suggested to be appropriate for medical personnel. By classifying and displaying the usage conditions of MR safety information in detail, it is considered that medical personnel could more easily understand this information, compared with reading the contents of the package inserts.

In addition, a significant proportion of medical personnel answered that the accuracy of confirmation was improved compared with the conventional method. This indicates that medical personnel recognize that the information to be provided

is highly reliable. Therefore, our proposed system enables provision of highly accurate and organized information related to MR safety information. These facts are extremely useful for improving the safety of MRI examination. As another factor for confirming MR safety information, a significant proportion of medical personnel answered that the efficiency of confirmation was improved compared with the conventional method. This indicates that medical personnel recognize that the information is easily obtained. Therefore, it may reduce the burden of confirmation on medical personnel. Furthermore, new IMDs may be sold, or the package inserts of previous products may be updated. To provide up-to-date MR safety information to medical personnel, we must continuously monitor new information and frequently update the database.

There were several limitations to this study. The number of the evaluator for this system was relatively small and limited in the number of registrants. Moreover, our system did not directly compare with the previously proposed systems, such as “MRISafety.com” or “MagResource”. Thus far, medical personnel have confirmed MR safety information by various means; therefore, we compared with methods conducted at the facilities of each evaluator.

## Conclusion

We have developed a searchable system to confirm the MR safety information of IMDs before MRI examinations. This system makes it possible to obtain MR safety information for IMDs more efficiently and accurately, and to improve safety management for patients.

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## Conflicts of Interest

Authors Hitoshi Fujioka, Maiko Sekiguchi, Haruna Tanaka, and Tomoko Watanabe are employees of Medie Corporation Ltd, Tokyo, Japan. All other authors declare that they have no conflicts of interest.

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