

**FDA Webinar Testing and Labeling Medical Devices for  
Safety in the Magnetic Resonance (MR) Environment**

**Moderator: Irene Aihie**

**June 24, 2021**

**11:00 am ET**

Coordinator: Welcome and thank you for standing by. All parties' lines have been placed in listen-only mode until the question-and-answer session of today's conference. At that time if you'd like - wish to ask a question, please, press star 1. Today's conference is also being recorded. If anyone disagrees, you may disconnect at this time. It is now my pleasure to turn the call over to your host, Ms. Irene Aihie. Thank you. And you may begin.

Irene Aihie: Thank you. Hello and welcome to today's FDA webinar. I'm Irene Aihie, of CDRH's Office of Communication and Education. On May 19, 2021 the FDA issued the final guidance, testing and labeling medical devices for safety in the magnetic resonance environment. This guidance document provides the FDA's recommendations on testing to assess the safety and compatibility of medical devices in the MR environment, and the recommended format for magnetic resonance imaging safety information in medical device labeling.

Ensuring the safety of patients who use magnetic resonance imaging for disease diagnosis and health management, is vital. Today Sunder Rajan,

Research Chemist in the Office of Science and Engineering Laboratories here at CDRH, will share information about the final guidance. Following the presentation, we will open the line for your questions related to information provided during the presentation. Now I give you Sunder Rajan.

Sunder Rajan: Thank you, Irene. Good afternoon, everybody, and thanks for attending this webinar on the recent guidance document pertaining to the testing and labeling of medical devices for safety in the MR environment. My name is Sunder Rajan. I'm a scientist at the Office of Science and Engineering Labs, which is a part of CDRH.

So listed here is what we hope to cover today in today's session. First, a quick overview of the interactions of medical devices within the MR environment. Then we move on to an overview of the existing approaches for the safety testing. Then we will address the specific content of the new guidance document. And finally, we'll end up with trying to address the questions from the audience.

Okay. So this cartoon block here is a simplified depiction of the cylindrical (bore) MRI system. The blue, red, and green zones in the middle, represent regions inside the concentric cylindrical volumes that contain the superconducting magnet windings in blue, the gradient coil in red, and the radiofrequency coil, radiofrequency resonator in green. The brown figure just pertains to the MRI subject. The static field, static magnetic field, is typically 1.5 or (3T) inside the bore of the magnet. And the dropoff in the magnetic field away from the magnet, creates a spatial gradient of the static field.

These magnetic fields are responsible for attractive forces on magnetic materials present in devices. In some devices these forces can also result in a malfunction of the devices. Next, the gradient coil in red, they generate

timevarying magnetic fields. The amplitude of the magnetic fields generated very linearly with distance from the iso-center. That is the center of the magnet. These fields can induce device malfunction in active implants, tissue stimulation or implant device case heating due to the induced currents and associated voltages.

Next, the body coil, body size RF resonators show in the green box. These create an intense electromagnetic field during the pulse sequence when the transmission of the RF pulse occurs. These intense EM fields that interact with metallic medical devices, just like a TV antenna effect, with potential for thermal injury to nearby tissue. The intense RF fields can also cause device malfunction of active devices, active medical devices, and possibly tissue stimulation from direct rectified radiofrequency voltages.

So now I would like to provide a brief background of the regulatory landscape with regard to the MR safety testing for devices. For passive implants, we have had a suite of ASTM test standards for force and torque, image artifacts and RFheating. The most significant change in the recent ASTM standard for RF heating now requires the expression of temperature changes scaled to the local background SAR rather than the whole body average SAR)

Next, the last FDA guidance update on the subject was the one dedicated to the passive implant testing in December 2014. And with regard to the active devices, we have been informally aligned with the ongoing ISO/IEC 10974 technical specification, although not formally recognized. Hence, there is a need for a comprehensive guidance document that covers all devices in the MR environment.

So we issued this draft guidance in August of 2019 and it generated over 400 or 500 comments. We have tried to address these as best as we can and we have now issued a final guidance last month. And so this webinar is to summarize the final guidance document and also address questions from the MR community.

So - continuing on, here's a list of the consensus technical safety standards which are directly involved as I mentioned before. The ASTM tests 2052 F2119, 2182, 2213, and (2203) are primarily for passive implants, the ISOTS 10974 is primarily for active medical devices. And the IEC 60601-2-33 is the safety standard, for the essential performance of MRI equipment.

Here we define the scope of the final guidance. It applies to all medical devices that might be used in the MR environment. But it also excludes MR system components such as RF coils, special spacing pads that came with the MR system. The guidance document also provides recommendations for safety and compatibility assessments. There may be exceptions of - for novel device types, that may require nonstandard approaches. This guidance also provides recommendations for labeling information to be included in the premarket submissions, PMAs and 510(k)s.

I'm going to go through a few slides that list the terms used in the guidance in alphabetical order. These wording - the wording for this terminology is really being reproduced from the guidance document. And they are the same as what has been used historically in MR testing and they are some other standards as marked in italics. These are the active medical device, active implantable medical device, controlled access area.

Continuing further, passive implant, passive medical device, magnetic resonance environment, magnetic resonance system, and of course, the well-

known MR safe, MR conditional, and MR unsafe. These are unchanged from before.

And now we move onto addressing what are the hazards for medical devices in the MR environment. This slide lists all the possible hazards for medical devices. In contrast with the previous guidance that only addressed passive implants, we now also include the hazards that are relevant to the active medical devices. So the list now includes time varying gradient effects, , RF rectification effects, possible risk of tissue stimulation, potential device malfunction due to exposure of the EM fields.

Moving onto reporting the results from testing - we recommend that you provide test report summaries and if applicable, the complete test reports should include a list of the hazards addressed by the test, the test equipment used, and include the results and all report elements as defined in the consensus standards. For computational modeling reports, verification and validation are important. And please follow the guidance reporting of computational modeling studies and medical device submissions.

When the ASTM F2182 test method is used, translate the values of temperature increase degrees per volt per meter, degrees per volt per (KG), measured in the test, to an in vivo temperature increase. And scale for the exposure conditions, specified in the MR conditional labeling. Also we need a written narrative or testing summary including a discussion of the results and conclusion. I also wanted to call your attention in this regard, to the FDA guidance document, recommended content and format of nonclinical bench performance testing and pre-market submissions.

Here is an example of the test summary for a passive implant 40 mm in size provided in a tabular format. On the left a column for list for

hazards. Followed by the columns for the test method acceptance criteria, device configuration if applicable, summary of the tests, and where in the submission the test the reports are located.

Now we move onto the important area of MR safety labeling. And the labeling should include sufficient unambiguous information for the healthcare professional, to determine whether a device can safely enter the environment. A separate section of the device labeling should be provided. It's titled MR Safety Information. And it should be based on assessments for the previously defined labels MR Safe, MR Unsafe, and MR Conditional Labeling, along with appropriate symbols from ASTM 2503.

And it should also include a patient's medical device card with the appropriate MR safety information. We also ask that the same safety information be readily accessible on the manufacturer's Web site or by telephone. Here are the MR safety labels, which is the same as before - MR Safe, MR Conditional, and MR Unsafe as defined, and no change from the past on this.

So now we come to the meat of this, the MR conditional labeling for devices that are anticipated to enter the MR system bore. This section has the most significant changes relative to the legacy passive implant guidance. Although the changes that we have introduced here are evolutionary rather than something revolutionary, it's based on increasing complexity of devices and labeling, and MR technology.

So first, the MR conditional symbol or the term MR conditional is the same as the previous version of the guidance. MR medical device card is again the same as the past versions. Nominal values of permitted static magnetic fields strengths, same as the previous version. But bracketing of the field is okay

based on sound scientific rationale. And the following information should be included when needed for the specific medical device.

The nucleus being imaged. If no nucleus is listed it's presumed to be proton, which is also new for this guidance. And the scanner type is a cylindrical bore or not. The orientation of the magnetic field relative to the patient access. The spatial field gradient, I mean more than the previous ones, are new for this guidance. The spatial field gradient is the same as the previous version. And the maximum gradient slew rate for access is also new here, but is included in active medical implant labeling in the past.

Continuing further, about the RF, we need details on the RF field exposure, the RF excitation for example, is it restricted to CP or a multichannel too, coil type? The maximum permitted SAR), Specific absorption rate, SAR. Operating mode. And please note that for devices in - used in the, or implanted in the lower extremity or in the head, brain, SAR is controlled by partial body SAR and head SAR.

Next, the maximum B1 plus, B1 plus RMS value in Micro Tesla. The "mT" is a mistake, It should be a Micro Tesla, which can sometimes be specified as the primary option instead of SAR. If both are listed independently, implies both conditions are met simultaneously. Next is a scan duration and wait time, which is new to this guidance. The previous version of the guidance document had a reference to bench tests for 15 minutes, which caused challenges in the clinic because translating this information to the typical MR scans always was difficult and confusing. As more and more of the RF testing were derived from modeling and so on, it became difficult to use the 15 minute bench test data.

And then also include the MR exam exclusion zones, information on patient conditioning, landmarking . The diagram showing these exclusions can also be very helpful. Imaging information - the information about image artifact I should say, is also required, although the quantitative information is not always needed.

Continuing along with labeling, include the instructions to be followed before and after the MR exams, if any, including additional instructions or information for safe use that might be needed over and above what we have here. Include information for active medical devices about how to proceed if an alarm signal is present from a medical device. And then finally, please include a statement that says that if the information about a specific parameter is not included, there are no conditions associated with the parameter. And this is also for your information.

Here is something new coming from the requirement of needing scan duration in the labeling. This slide provides some further guidance on this. And it's especially useful for devices that were tested for 15 minutes of RF heating, and the possibility of extending the information to one hour scans. First of all, for devices that are less than 2 cm in all directions and sufficiently spread out more than 3 cm from other metallic devices, we don't require RF heating testing.

But we do require an MR conditional labeling that basically has a default label of SAR of 2 watts per kg in normal operating mode. Maximum scan time, one hour. Beyond that, you will need a cooling period.

For devices greater than 2 cm we have two cases. If the devices are adjacent to thermally sensitive tissue, examples are brain, eyes, neural tissue, then we have one limit which is - if the heating is less than or equal to 2 degrees in 15



minutes, in normal operating mode, then it can be labeled for an hour of continuous scanning without a break.

If the heating of the device is greater than 2 degrees in 15 minutes, the sponsor needs to provide the appropriate safe continuous scan time followed by a cooling period. And I have to point out that a 6 degree increase is considered okay. Anything beyond 6 degrees we recommend a cooling time, 6 degrees being the 43 degree limit where we start, irreversible cell injury.

For devices greater than 2 cm, larger than 2 cm, near terminally less sensitive, that means not as sensitive tissue like muscle, then we have a different set of limits but now the limit is 4 degrees. So heating less than or equal to 4 degrees in 15 minutes, in normal operating mode can be labeled for a whole hour of continuous scanning. Whereas if the heating is - higher than 4 degrees in 15 minutes, the sponsor needs to provide an appropriate scan time, with a cooling period based on a sound scientific rationale.

For devices anticipated to remain outside of the magnet bore, the key points are please include a MR conditional symbol directly on the medical device whenever possible. But why the positional conditions and the unambiguous positional conditions in terms of the maximum permissible static field, also known as the gaussline) restrictions, for example, 200 (gauss), include information directing the user on how to proceed when an alarm signal is present. If space permits, include the conditions of safe use on the medical device in a supplementary sign as defined by ASDM 2503.

And finally, there is the small section on safety and MRI not evaluated. This is a legacy designation. Only applies to a very limited number of medical devices that have historically, that don't historically have any information about MR safety for complicated reasons beyond the scope of this

guidance. This designation does not apply to a device that has either a known adverse event in the MR, or has typically been labeled as MR conditional, isMR unsafe, , if the new medical device type contains ferromagnetic material,. is an active medical device or is a partially implanted medical device.

And the labeling should include the following information - the device has not been evaluated for safety in the MR environment, has not been tested for heating or unmonitored movement. In the MR environment, the safety of the medical device in the MR environment is unknown, performing an MR exam on this person who has this device, may result in an injury or device malfunction.

Here is an example of a MR conditional device and, you know, the MR conditional symbol, the yellow triangle is important, on the left. The conditions for safe use are listed in the two column table with the name of the condition on the left, like static field strength. And the safe use value condition on the right, on the right column. Please note that unlike the previous versions of labeling there is no value of a temperature indicated, only the safe scan duration.

That kind of concludes what I have to say. This slide basically lists the URLs for the various resources, guidance documents, recognized consensus standards, guidance for multi-configurational devices, computational modeling studies, content and format of test reports and premarket notification for MR devices. And it's included in the guidance, so you should have it there. So that concludes what I have to say.

If you have questions that cannot be addressed today either because I don't know the answer or it's more complicated, feel free to send your questions to

OSEL\_CDRH. The underscore is difficult to see there, on the slide. But it's (OSOL\_CDRH@FDA.HHS.gov. Thank you very much. I'm happy to answer some questions. And I actually have, while we are waiting for the question and answer to get stacked up, I have maybe four questions that were already provided to me by my colleagues. And I think I can just address them. Is that okay, Irene?

Irene Aihie: Sure. I just want to let the operator make her announcements to get folks into the queue to ask questions.

Sunder Rajan: Okay.

Irene Aihie: And then give you a little time to take a quick breather and then you can start off with some questions. Thank you so much, Sunder.

Sunder Rajan: Okay.

Coordinator: Thank you. If you'd like to ask a question over the phone, please press star 1. Please ensure your phone is unmuted and record your name so you can be introduced. Again, that is star 1 to ask a question. If you need to withdraw your request, please press star 2. One moment while we wait for questions to come in.

Sunder Rajan: Okay. So I can probably address one or two easy questions that came to me, while we are waiting. Why is it important to specify nucleus being imaged in the MR conditional labeling? The answer is the nucleus, for imaging specifies the Larmor frequency which is the frequency of the RF used or close to the frequency of the RF used. Since RF heating effects are frequency dependent, the choice of nucleus can influence the extent of RF heating.

And let's see. I can - another one that came up was when both SAR and B1 are listed, is it satisfactory to scan if either one is satisfied? And the answer to this is no. All conditions for safe use in the MR conditional labeling have to be met simultaneously.

So please alter the pulse sequence parameters to bring both B1 plus and SAR within limits. I should point out that labeling - should typically be worked in a way to use B1+ limit primarily. And if - for systems that don't have B1 plus then use the conservatively prescribed SAR limit. I have one more. Should I go for one more? Okay.

In one of the labeling slides the time temperature is based on 15 minutes. Does that mean all labeling now needs to be derived for 15 minutes? No. The 15 minute example was to make the transition from the 15 minute bench testing that's used in ASFM F2182 to clinical setting. The choice of safe scan time and cooling time should be derived based on testing and sound scientific rationale.

Or last one, I have one last one. I think this might actually be an important one. For devices that demonstrate a high RF in use heating effect, can fractional whole body SAR be used in the labeling? We recommend actually, that you provide labeling for normal mode whenever possible, even if it means a shorter scan time, to compensate for it. This is because fractional SAR time as displayed on the MR systems may not be precise.

And although we recognize that in some instances we may not have any other viable option other than to use a fractional SAR, one option of course is that we might be able to, with more testing, come up with a B1 plus based labeling, which is more precise. Thank you.

Irene Aihie: Thank you so much, Sunder. It looks like we have some questions in the queue. Before our operator gets our participants into ask questions, Sunder can you go back to the final slide of the presentation so that folks can see the resources? Thank you so much. All right, (Sandy)...

Sunder Rajan: The resources? This one? You want this one?

Irene Aihie: Either that - we can go back to - yes, either that one or that last slide. Perfect.

Sunder Rajan: Okay. The last slide only has the email and the - okay, good. I'll leave it here.

Irene Aihie: Thank you. Okay, (Sandy). It's all yours.

Coordinator: All right. The first question (Carol Barons). You may go ahead.

(Carol Barons): Hi. Sunder, we have a question. We've been getting a lot of people with new orthopedic implants in the spine and a lot of the hardware is saying from the companies, system has not been evaluated for safety, treating migration, or compatibility in the MRI environment. And that it said, you know, you can cause heating too for the patient, may result in injury. So what do we do with something like that? We have a (three Tesla).

Sunder Rajan: Yes. You asked me the most difficult question I was anticipating. And that slide that I talked about the safety untested that I believe may end up, may be coming from some of those sources. I don't have a good solution except one.- Wwhen you see those, appeal to the sponsor and encourage them to come in for MR conditional labeling. And we will be happy to provide as much help if possible, to facilitate that. In the absence of that really I don't have a good answer for you.

(Carol Barons): Okay. All right.

((Crosstalk))

Woman: ...benefits?

Sunder Rajan: I'm sorry?

Woman: Scan the patient for the radiologist, is it risk versus benefit?

Sunder Rajan: Yes. it is absolutely - it is really then up to the radiologist to make the assessment based on risk/benefit. And I have to point out that there is ample evidence, ample clinical data and testing and knowledge in this area. So I would venture to guess that, you know, radiologists should be able to make an informed assessment of the risk to scan or not to scan.

For instance, we know now that, , small devices, linear dimension of around 4 or 5 cm don't heat significantly. So we can go back in the literature and look at some of this data. So there's a lot of information there for a physicist and radiologist to get some kind of an estimate. But it would be a - it's clearly an off label practice and it's something up to the radiologist and clinical practice to decide, rather than anything that I can offer at this time.

Woman: Okay. All right. Thank you. So encourage the company.

Coordinator: The next question comes from (Frank Sherlock). You may go ahead.

(Frank Sherlock): Hi. This is (Frank Sherlock). Sunder, on the examples that you showed for the MR labeling for the passive implant, I noticed that nowhere in that - on

that document that it even states MR conditional, only the icon was presented. So I suspect it was intended to have a MR conditional term added to it just as points of reference similar to what's been done previously. The other thing is it looks like there's no information for artifacts in a particular value. This just indicates that the artifacts are present and potentially may be necessary to adjust your pulse sequences if the implant is in the area of interest.

Can you comment on that? And then I have one other follow up question.

Sunder Rajan: Okay. So thanks (Frank). Thanks for your question and for pointing out this information - this request about - or the clarification needed for image artifact. We believe that for most of the devices where the image artifact is produced is - and it's not really that relevant to the particular MR exam because it's not in the plane or further away. It doesn't necessarily provide the technologist with a go/no go decision for starting the scan.

So we are paying less attention to the quantitative nature of the artifact and I still recommend that you do the ASTM tests and make a statement about it. But it's less important now as we have seen over the last few years that this is not used for MR imaging decisions.

However, in some cases it can be very important. In cases where you need to follow up with an MRI scan around an aneurysm coil and you could have a potential artifact that can cause a confound, then it becomes quite important. Or if there is a need, if the indication used for the device suggests the need for MR imaging information around the implant, then it has to be provided based on the type of imaging scans that are going to be used in the clinic.

(Frank Sherlock): Right.

Sunder Rajan: Does that clarify, (Frank)?

(Frank Sherlock): Yes. And then anyway, the other question that I had was can you explain briefly, RF rectification; how it's tested; and the relevance for the MRI labeling for an active implant?

Sunder Rajan: Okay. The - it goes a little bit beyond the scope of this - of what I had in mind today. But this is a test used for active medical implants.

(Frank Sherlock): Right.

Sunder Rajan: And when the pulse generator used in these active medical implants, have circuitry inside them, the voltage is generated from the long leads, assuming the device has leads. Just like the tips of the leads, the voltages can cause heating in the neighboring tissue, it can also generate voltages using the same principle into, inside the IPG.

And these voltages and the circuitry present in them can essentially act like a rectifier and cause a voltage that now doesn't oscillate at the radio frequency, but oscillates at a slower frequency. And these voltages can stimulate tissue, or have the potential to stimulate tissue.

And the ISO TS document that I talked about, has a detailed procedure and a network used to test for this. You can actually test for this using an oscilloscope and the appropriate testing network.

(Frank Sherlock): Thank you. And thanks for the webinar today.



Sunder Rajan: Thanks.

Coordinator: The next question comes from (Megan Sajab).

(Megan Sajab): Yes. Hello. I have a few questions around products that fall under the definition of MR safe. First question is that the guidance appears to recommend a patient medical device card for all implanted medical devices. However, the FDA guidance on medical device patient labeling only recommends patient implant cards for implants intended to be implanted for more than one year. Could FDA comment if implants that will not be implanted for longer than one year, are expected to have implant cards, and particularly for implanted devices that are MR safe and don't have any risk information to convey?

Sunder Rajan: So let me clarify. You would like to find out if MR safe devices implanted for less than one year, would still need an MR implant card?

(Megan Sajab): Yes.

Sunder Rajan: Am I correct? Okay.

(Megan Sajab): Yes.

Sunder Rajan: All right. I do not know the policy answer to this question. And I will note it down and see if I can - we can resolve this. Or if you can send me an email on the other - on the email link, I will try to respond to that. But my opinion is that it's probably not catastrophic for - from an MR perspective, but an implant card might be important for other reasons or - yes, besides the MR scan. So at any rate, I will wait to talk to my better informed colleagues about this, and get back to you.

(Megan Sajab): All right. Thank you. Another question I have is for non-electrically conductive devices that fall within the definition of MR safe based off their material composition, can you clarify if heating testing is expected?

Sunder Rajan: No. It's not - it's not necessary to do RF heating testing for devices that have conductivity similar to that of tissue, non-conductive or plastic.

(Megan Sajab): All right. Thank you. And then similarly, for image artifact testing, is that limited only to implants with metallic or magnetic material?

Sunder Rajan: I would say generally yes, but there could be material that's impregnated with iron oxide. A good example I can give you is if you take a piece of tape from an old cassette machine that looks like plastic, you know, audio cassette machines, that has iron oxide in it. And if you put it on top of the skin, you will see it effect the image under it. - You will get a dark artifact from it. So...

(Megan Sajab): Okay.

Sunder Rajan: ...so it - the answer is if you - based on your knowledge of the material you can provide a scientific rationale that there is going to be no artifact, then of course you don't need to worry about it.

(Megan Sajab): Okay. Thank you.

Coordinator: The next question comes from (Dasan Dalecia). You may go ahead. Ma'am, you may go ahead. Please check your mute button.

(Dasan Dalecia): Is this for (Dasan Dalecia)?

Coordinator: Yes.

(Dasan Dalecia): Okay. Thank you. I had two questions regarding medical device card that's recommended for medical devices in the guidance document. My first question is what is the expected implementation timing for the card requirement? And are there requirements on how it can deliver for example, electronically for hospitals and then they can print it? Or what is the matter of delivery if you can please comment on that, especially in regards to passive implant?

Sunder Rajan: We don't have a clear - I do not believe we have a clear requirement that it should be paper or electronic. In my opinion, as soon as the patient has an implant, they must have access to that information in a card and the card can be printable for all that I care new technology, might not have a card, but they might have an electronic version. But for now, let's just go with the card, with the paper card as prescribed.

(Dasan Dalecia): And does it matter if delivery doesn't need to be part of the packaging or it can be provided separately onto the patient?

Sunder Rajan: I'm sorry. I don't know the answer to that question, if it can be provided separately to the patient. Again, this is something I might have to get back to you on. So if you could just send an email to that address, I can check with the policy people and get back to you on that.

(Dasan Dalecia): Okay. Thank you. And my second question is how does CDRH intend to review information in premarket submissions? Will it be just the review of proposed content on the implant itself, or will there be some level of assessment like (field) assessment at some point, as well?

Sunder Rajan: Well we - typically, when we view the premarket submissions and the MR testing, we look at the testing and then we see how consistent it is for the labeling. And if everything works out fine then you go and check the implant card, what is provided in the documentation for the implant card, and see if the format is adequate, clear, and we go from there. So it's checked at that time.

(Dasan Dalecia): Okay. Thank you very much.

Sunder Rajan: Okay.

Coordinator: Before we go any further, please limit your questions to one per person. Thank you. One question per person. Mr. (Paul Lawson), you may go ahead.

(Paul Lawson): Hello. My question is we manufacture MR coils. So you said that excludes from the scope of this. My question is are you coming out with a similar guidance for accessories such as coils, in the future? Thank you.

Sunder Rajan: I don't believe so. There may already be some standards out there for coils and coil heating and so on. - I don't know of any plans to provide a guidance just for MR coils.

(Paul Lawson): Thank you.

Coordinator: Our next question comes from (Glen Sellner). Sir, you may go ahead.

(Glen Sellner): Hi. We have currently MR conditional labeling that's been approved by FDA in 2019. Our device is small. It's less than 2 cm and our current labeling includes largely everything that you provided in the example. My question is,

is since our labeling was approved in 2019 does it need to be updated based on new guidance, if that comes out? Or are we sort of grandfathered in?

Sunder Rajan: I believe it's grandfathered in. But if you come back with a device modification and it needs a new 510(k), there is a pretty good chance you would have to update your labeling.

(Glen Sellner): Thank you.

Coordinator: Our next question comes from Guy. You may go ahead.

(Guy): Hello. Thank you. Thank you for the review of the guidance. I wanted to ask if the labels suggested MRI for unsafe products must include a projectile hazard (text) or can it have only the Red Cross symbol as in the ASDM standard, assuming the product is not allowed - or the labeling to enter the MRI environment?

Sunder Rajan: I would strongly recommend a projectile symbol if you believe there is that risk. If you believe this device is going to be used around the MR environment and there is a potential for accidental use near a magnet, I would strongly recommend an MR unsafe symbol and a projectile symbol.

(Guy): Okay. Thank you very much.

Sunder Rajan: And if it is anywhere inside by some chance, where it can be quickly moved and I would strongly recommend it tethered so it's not something that can be walking around. Yes.

(Guy): Thank you.

Sunder Rajan: I mean this is again, from FDA's perspective, I know the labeling is important, but I may have overstepped a little bit the clinical practice. But that's the reason we asked this is we want to minimize the risk of it accidentally being used.

(Guy): Okay.

Coordinator: Our next question comes from (Amanda Penticost).

(Amanda Penticost): Hi. Thank you so much for your time.

Sunder Rajan: Hi.

(Amanda Penticost): I have a question regarding the like when labeling - when you're saying that you don't do - you haven't done the MR testing. So our company manufactures screws and plates, you know, very basic orthopedic implants. However, this isn't something that has been tested in the past but I know from experience and talking to others in the industry, that these are increasingly being tested whether that's a marketing decision or there's any regulatory pressure I'm not sure.

So I wanted to get your input on, you know, is the FDA going to require this type of testing to be done on those types of implants? Or is it (unintelligible)?

Sunder Rajan: Yes. Go ahead.

(Amanda Penticost): Oh, I just want to say or is it (unintelligible) discretion?

Sunder Rajan: I'm sorry. The last part, you faded a little bit. Could you repeat?

(Amanda Penticost): Oh. Or is it still up to the discretion of the company?

Sunder Rajan: Okay. So this comes back to the fact that - or reasons that I personally don't understand. It may have to do with deeper policy reasons that certain devices either because testing methods were not available, it was not least burdensome, were less about testing and ended up that untested labeling. But my understanding is going forward, it's going to be mandatory for all devices, all implants I should say, to have MR testing unless you can convince somebody that this patient is never going to have an MR scan.

(Amanda Penticost): Right. So I guess when submitting 510(k)s should we, you know, should we - do you think we should start doing this preemptively or, you know, would our reviewer, you know, give us information and say hey, we really think you should do this testing? Or will the guidance be updated to give, you know, a little bit more information for the types of devices, making it more clear...

Sunder Rajan: Okay.

(Amanda Penticost): ...that it's needed?

Sunder Rajan: Here's where I want to separate my opinion from what I, you know, I want to say that in my opinion, I think it's better to do it preemptively because it's good for the patient, it avoids the delay when the patient gets scanned. And you are positioned well in terms of the market, and you don't need to worry about the risk of things getting delayed. But the real questions within your organization, there is always the pre-submission process where you can approach the review division and pose this.

And my understanding is that MR conditional labeling is now required in all review divisions, all the review divisions at CDRH, unless there is a very clear signal that this is a let's say an investigational device, an IDE clinical trial and that there are some really very persuasive reasons why that cannot be done; MR can't be done.

(Amanda Penticost): Awesome. Thank you so much.

Sunder Rajan: Okay.

Coordinator: The next question comes from (Spencer Parent). You may go ahead.

(Spencer Parent): Hi. (Spencer Parent) from (Health Assure). My question is in regards to multi-configurational devices, specifically at the page 11 there's an update that says in some cases when a large number of variables are present a risk based assessment to determine the percentile for the heating comparison rather than a worst case approach, could be used. Will there be an update to the FDA guidance of RF testing of multi-configurational devices, specifically in regards to this worst case analysis?

Sunder Rajan: Okay. First off, we haven't actually started writing a guidance on that, although we have talked about it so my guess if anything, it's probably a few years away. I would strongly recommend that you reach out or send us an email and we'll be happy to engage with you one on one and give us our best thinking on that.

(Spencer Parent): Will do. Thank you very much.

Sunder Rajan: Okay.



Coordinator: The next question comes from (Alison Young). You may go ahead.

(Alison Young): Hi there. Can you hear me?

Sunder Rajan: Yes.

(Alison Young): I just wanted to clarify...

Sunder Rajan: Go ahead. I can hear you.

(Alison Young): ...for the patient (unintelligible). Can you clarify what content is required or not? Is it just the MR symbol or is there also a statement required or can that be provided electronically or within the IFU?

Sunder Rajan: Okay. That's a very good question because we have struggled with this because of the limited space available. And we've been more flexible in this. And essentially, trying to put in the most important information. It doesn't have to be a full reproduction of the whole MR conditional labeling page. It can be a subset that you think is the most important. And what was the second part of your question?

(Alison Young): Does that need to be provided on a physical patient implant card or would it be sufficient to provide the symbol on the patient implant card and provide the statement to the rest of the MR information within the (ISU) or in some electronic form?

Sunder Rajan: Yes. This was kind of related to before. I think we definitely need the symbol and we would probably need other summary information in the implant card as well. And the rest of it is of course, the IFU should be comprehensive anyway. So...

(Alison Young): Okay. Thank you.

Sunder Rajan: Okay.

Coordinator: The next question comes from (Tobias Gilk). You may go ahead.

(Tobias Gilk): Thank you very much. Thank you, Sunder for the presentation. I'm - my question is really asking for a clarification on what I heard as some conflicting information. So as I heard it in the body of your presentation, where you were talking about labeling and you talked about going back to the SAR versus B1 RMS question.

In the body of your presentation I thought I heard you say at one point, that if the label, if the MR conditional label says SAR) or B1 RMS you may use the less restrictive of the two even if the more restrictive one, if the value for a particular pulse sequence exceeds the limit, that would be considered on label because the labeling specifically defines or in the MR conditional label.

However, if the label doesn't specify or then it should be understood to be and because in your response at the end of your presentation where you have the pre-submitted questions, you made it sound like and is the operative condition.

And earlier you made it sound like if or is present in the label you can use or. And I'm hoping you can just clarify this because there are a number of existing MR conditional labels out in the world, some of which simply list both and some of which explicitly state or. Are those the same thing irrespective of the presence of the word or, or are they defining two distinct sets of conditions?

Sunder Rajan: Okay. Thanks, Toby) Thanks for clarifying and letting me know that I managed to confuse the situation a little bit. The first scenario is very clear, which is if there are listed in bullet point one after the other, or in the list of bullet points, without any further specification then they have to both be - it's very simple, very straightforward, all the conditions listed on the MR conditional labeling, listing one after the other had to be true. Okay? So there's no confusion about that.

The second scenario is if they have an or and then it really is the same bullet point except that it's one or the other, even though that's not my preferable format if it says that, you are okay with using one or the other. But I was also talking about the situation where typically you will have a preferred choice , which is B1 plus RMS.

And in those cases use B1 plus RMS unless B1 plus RMS is not available on your MRI system. It's on display on your MRI system, in which case you have no choice but to use the SAR value, SAR limit that's shown in the MR conditional labeling. Does that help?

(Tobias Gilk): Yes. I just - for the purpose of putting into practical application existing labeling, if a label just lists, you know, (SOR) of X, B1 plus (RMS) of Y, without an or operator in the labeling then the...

Sunder Rajan: Yes.

(Tobias Gilk): ...understanding is you have to comply with both criteria to...

Sunder Rajan: Right.

(Tobias Gilk): ...produce an on label scan.

Sunder Rajan: Correct.

(Tobias Gilk): But I want to make sure I completely understand the other option. And that is if the or operator is present...

Sunder Rajan: Yes.

(Tobias Gilk): ...complying with one even if the other one is exceeded for a specific pulse sequence, the FDA's interpretation is that would be an on label study.

Sunder Rajan: Yes. It's the or. Even though that - I have not seen that, if something like that happens, that's the way it will be - can be interpreted. And, you know, that's correct.

(Tobias Gilk): Thank you for the clarification. I appreciate it.

Coordinator: Our next question comes from (Ragu). You may go ahead.

(Ragu): Hi. Thank you for the presentation so far. My question is more on the science side. So when you mentioned about the rectification which I believe mostly is from a nonlinear element (unintelligible), is it safe to assume that having this component of (unintelligible) below or inside a titanium case, which is conductive even when non-magnetic, helps from (clarification) from the (unintelligible)?

Sunder Rajan: You're treading in territory that I don't know much about. I don't think it depends necessarily on the case. I think it's, as you mentioned, it's the circuitry and a physical connection of the rectified voltage wave forms, to be

back reflected via the wires. It doesn't necessarily depend on the case design. It really depends on the voltage incident and the port, and how that port voltage, what happens to the port voltage because of the components inside your device.

(Ragu): Okay. Thank you.

Sunder Rajan: Okay.

Coordinator: Our next question comes from (Suchan). You may go ahead.

(Suchan): Thank you. What if my device is a biodegradable implant device in the knee or the shoulder region? What kind of MR testing does this invoke?

Sunder Rajan: Well, I would say unless you are 100 % sure or can provide a good reason why a person with a biodegradable implant will not get an MRI scan, you would have to follow the same paradigm. Now, I know that an average metallic implant is not biodegradable to that extent, that it does disappear. So you're probably not talking about the conventional material. You're talking probably about something (special).

(Suchan): Correct.

Sunder Rajan: I have at this point, a priority, no idea what the conductivity is or the magnetic properties of such a device. So I would recommend that you go through this exercise of understanding the risks. And if you or the experts in your company are unsure please go through the pre-submission process or send an email to the email link there, and maybe we can try to figure out if the risks are so insignificant that we don't have to worry about MRI testing.

(Suchan): Okay. Sounds good. Thank you.

Sunder Rajan: Okay.

Coordinator: The next question comes from (Yashika). You may go ahead.

(Yashika): Thank you. Hi Sunder. Thank you for the wonderful webinar. My question is our company manufacturers things which are placed in the carotid artery. And I wanted to understand how important or how informative to define the cooling period in the scan duration.

Sunder Rajan: How - so you said your company makes a carotid stent or a carotid device...

(Yashika): Yes.

Sunder Rajan: ...that's placed in the carotid artery and you...

(Yashika): Yes.

Sunder Rajan: ...want to know what is the extent of the cooling period?

(Yashika): No. Should we define the cooling period or should we just follow it is less than 2 cm than we don't have to define it, you know, the - on the slide that you had shown?

Sunder Rajan: Yes. I mean I think if it's less than 2 cm does not require RF heating and you can use that canned MR conditional labeling that I showed in that slide or it's in the guidance document as well. And the idea is if you need - if you believe that the scan - if you want to get a labeling for a scan longer than an hour then you need to come up with a cooling item or cooling time. But if you - if the

one hour scan which is typically adequate for MR scans, then you're okay. You just need - if it's less than 2 cm you can use the canned language.

(Yashika): Thank you. Thank you.

Sunder Rajan: Okay.

Coordinator: The next question comes from (Chen Wee Lee). You may go ahead. Sir? Mr. (Lee)...

Sunder Rajan: Go ahead. I think he got the answer already.

Coordinator: I have. Just one moment. Let me bring up the next one. The next one is Ms. (just) (Lucy)? You may go ahead. Ma'am, you may go ahead. Let me bring up the next one. Just one moment. The next one is (Andrea Lara). You may go ahead.

(Andrea Lara): Hi. Can you hear me?

Sunder Rajan: Yes.

(Andrea Lara): Perfect. I had a follow up question regarding the patient implant card. So if we were to add the MR symbol and also the (CISU) symbol, would that be sufficient for us to just include the detailed information on the MR scan and the conditions within the IFU)?

Sunder Rajan: I - as I recommended previously, I think it is important to add a couple of key constraints, especially the SAR). If there is a SAR constraint, you know, the - what we used to have in the first three bullet points, know all of your bullets) from the past guidance. And so - we have some flexibility on what we're

going to add. But I leave it up to you to come up with the - your best shot on what you can put on a small card that provides the most information. Does that make sense?

(Andrea Lara): Yes.

Sunder Rajan: Okay.

Coordinator: And our next question comes from (Margaret Clippo). You may go ahead.

(Margaret Clippo): Hi. Yes. This is another follow up question regarding the patient implant card. Would it be sufficient to provide, similar to the last question, the MR conditional symbol plus a link to a Web site where the sole information would be provided, providing all of - that information would appear on the Web site? Because I believe providing the (SOR) information would make the card quite large and might require some additional testing in terms of, you know, redoing packaging validations and other things like that. So I'd just like some comment on that.

Sunder Rajan: My gut feeling is again to repeat we need to put in succinctly the key pieces of information. I - although I can again, if you left your email and the question specifically what you have in mind, I can check with some of my colleagues to see what they think is reasonable. But generally speaking, I'm not in favor of just having a symbol and nothing else in there.

(Margaret Clippo): Okay. Thank you. We'll likely follow up with an email as you recommended.

Sunder Rajan: Okay. Thank you. Yes.



Coordinator: At this time there are no additional questions in the queue. If you'd like to ask a question, please press star 1, unmute your phone and record your name. Once again, if you'd like to ask a question please hit star 1, unmute your phone and record your name. One moment while we wait for any additional questions.

Irene Aihie: Thank you so much, Operator. It looks like we have a question in the queue?

Coordinator: One moment while I get their name.

Irene Aihie: Thank you.

Coordinator: I'm sorry. I believe the name is (Paris). I'm not for sure. I can't hear it. Or (Parish)?

(Steve Parich): Yes. That's correct.

Coordinator: Can you speak up louder, sir?

(Steve Parich): Sure. The name is (Steve Parich).

Coordinator: You may go ahead.

Sunder Rajan: (Steve), go ahead. Ask your question.

Irene Aihie: (Steve), please go ahead with your question.

(Steve Parich): Well I had a question about the MR unsafe symbol. So on page 19 of the guidance it states that with non-implanted medical devices the MR unsafe label should appear directly on the medical device if possible.

So that should appear is obviously subject to interpretation, as well as the if possible. Is it following the typical FDA requirements that if there's room on the device then you should put it on the device?

Sunder Rajan: Yes. I think our thinking was if there is space on the device, please put a label on it.

(Steve Parich): Okay.

Sunder Rajan: Simple as that.

(Steve Parich): All right. Well, what if you only had it in your IFU and you didn't have it on the product label? We should eventually try to migrate to adding it to the product label, correct?

Sunder Rajan: Yes. Yes.

(Steve Parich): Okay. Okay. Very good. Thank you.

Coordinator: This one I also can barely hear. I believe it's Mr. (Lee). You may go ahead. Sir, you may go ahead. Hello? Please check your mute button. I'm sorry, we cannot hear you, sir.

Irene Aihie: Thank you, Operator. Do we have any further questions?

Coordinator: No. There are no additional questions.

Irene Aihie: Sunder, before I close would you - do you have any closing remarks?

Sunder Rajan: No. Thanks everybody, for coming to the webinar. And I know that it's a complicated topic with lots of moving parts. And if something was not clear feel free to reach out to me and I'll try to help as much as possible. Thank you.

Irene Aihie: Thank you, Sunder. Again, this is Irene Aihie. We appreciate your participation and thoughtful questions. Today's presentation and transcript will be made available on the CDRH Learn Web page at [www.FDA.gov/Training/CDRHLearn](http://www.FDA.gov/Training/CDRHLearn), by Friday, July 2nd. If you have additional questions about today's presentation please use the contact information provided at the end of the slide presentation.

As always, we appreciate your feedback. Following the conclusion of today's live webinar, please complete a short 13-question survey about your FDA CDRH webinar experience. The survey can be found at [www.FDA.gov/CDRHWebinar](http://www.FDA.gov/CDRHWebinar), immediately following the conclusion of today's live webinar. Again, thank you for participating and this concludes today's webinar.

Coordinator: Thank you for joining. You may now disconnect. And have a wonderful rest of your day. Speakers, please stand by.

END