Safety Concerns with Implantable Infusion Pumps in the Magnetic Resonance (MR) Environment: FDA Safety Communication

Date Issued:

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Audience:

- **Patients who have an implantable infusion pump**
- **Caregivers of patients with an implantable infusion pump**
- **Health care providers who treat or manage the care of patients with implantable infusion pumps**
- **Health care providers and MR technologists involved in the magnetic resonance imaging of patients with implantable infusion pumps**

Specialties:

Cardiology, Emergency Medicine, General Surgeons, Magnetic Resonance Technologists, Neurosurgeons, Neurologists, Nurses and Nurse Practitioners, Orthopedic Surgeons, Physician Assistants, Primary Care Physicians, Radiologists

Devices:

Implantable infusion pumps are devices that are surgically implanted under the skin, typically in the abdominal region. They are connected to an implanted catheter and are used to deliver medications and fluids within the body. Implantable infusion pumps are periodically refilled with medications or fluids by a health care provider. Implantable infusion pumps may be used to treat chronic pain, muscle spasticity, and many other diseases or conditions.

Magnetic Resonance Imaging (https://wayback.archive-it.org/7993/20190424073220/http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/default.htm) (MRI) is a medical diagnostic exam that creates images of the internal structures of the body by using strong magnetic fields and radio waves (radiofrequency energy). These images provide information to physicians and can be useful in diagnosing a wide variety of diseases and conditions. Some medical devices, including some implantable infusion pumps, can be affected by the strong magnetic fields associated with MRI.

Purpose:

The FDA is informing patients, caregivers, MR technologists, and health care providers of important safety precautions to help patients with implantable infusion pumps safely have an MRI exam.

Summary of Problem and Scope:

The FDA has received reports of serious adverse events, including patient injury and death, associated with the use of implantable infusion pumps in the MR environment. These reports describe medication dosing inaccuracies (e.g., over-infusion or under-infusion, unintended bolus) and other mechanical problems with the pump (e.g., motor stall, pump not restarting after an MRI exam).

MRI systems provide images of the internal structures of the body that can be useful in diagnosing a wide variety of diseases and conditions. However, the MR environment presents safety hazards for patients with implantable infusion pumps. Only implantable infusion pumps labeled as MR Conditional may be used safely within an MR environment, and only under the specified conditions of safe use. The specific conditions that health care practitioners and patients should follow before, during, and after the MRI exam vary by the make and model of the implantable infusion pump system. Importantly, each implantable pump model may have unique conditions that must be followed in order for a patient to safely undergo an MRI exam. Failure to adhere to these conditions can result in serious injury or death.

The benefits and risks of an MRI exam must be considered for each patient. The value of the information to be gained from the MRI exam should be weighed against the risks of the exam. All medical devices present in the MR environment during the exam (including implants, external devices and accessory devices) should be considered.

Recommendations:

To help reduce the likelihood of serious adverse events, FDA recommends the following before, during, and after a patient with an implantable infusion pump has an MRI exam:

Patients with implantable infusion pumps and their caregivers:

- Be aware that specific instructions must be followed by your health care providers and MR technologist before, during, and after an MRI exam. These instructions may differ by manufacturer and model of the pump.
- If you are scheduled for an MRI, make sure your physicians and the MR technologist know that you have an implantable infusion pump.
- Be able to identify the make and model of your implantable infusion pump. Most patients are provided with an "implant card" that lists this information.
- Bring the implant card for your implantable infusion pump with you when you go for your MRI exam. Before you can safely have an MRI exam, your health care team will need to identify your specific pump model to locate the specific MRI safety information for your pump. If there are any questions about the make and model of implantable infusion pump you have, contact the physician who manages your pump and do not have the MRI exam until the specific implantable pump model is identified.
- Consider obtaining a medical alert bracelet or necklace in case of an emergency situation. Include information to notify medical professionals that you have an implantable pump and that MRI precautions need to be followed.
- Be aware that MRI exams may affect the function or programming of your infusion pump, even when the specified conditions of MR Conditional use have been followed. For example, your implantable pump may need to be checked and/or reprogrammed by your physician before and after your MRI.
- Only implantable infusion pumps labeled as MR Conditional may be safely scanned, and only under the specific conditions of safe use. Consult with your physician and the MR technologist to determine whether it is safe for you to have an MRI.

MRI Technologists:

- Be aware of and follow the policies and procedures at your site for patient screening prior to MRI exposure. Be sure all patients are screened for implantable devices such as implantable infusion pumps.
- Do NOT scan the patient until the pump model has been positively identified and instructions for safe MRI exposure are understood. Before scanning a patient with an implantable infusion pump, ask the patient for their implant card to confirm the pump model. If there are any questions about the specific pump model a patient has, contact the health care provider managing the pump.
- Only implantable infusion pumps labeled as MR Conditional may be safely scanned, and only under the specific conditions of safe use. Contact the implantable infusion pump manufacturer if there are any questions about the MRI safety status of the implantable pump system.
- Be aware that the steps that must be followed before, during, and after an MRI exam may be different for each manufacturer and model of pump. Be sure to verify that the conditions of safe MRI use can be followed prior to scanning the patient.
- Ensure that the MRI system at your site meets all conditions provided in the MR Conditional labeling of the implantable pump. For example, some implantable pump models can be safely imaged only at 1.5 tesla (T), but not 3T. (Tesla or "T" is a measure of magnetic field strength.)

Radiologists:

- Consider the benefits and risks of an MRI exam for each patient and weigh the value of the information gained from the magnetic resonance images against the risks of the exam for the patient. All medical devices present in the MR environment during the exam (including implants, external devices and accessory devices) should be included in the risk assessment.

- Only implantable infusion pumps labeled MR Conditional may be safely scanned, and only under the specified conditions of safe use. Contact the implantable infusion pump manufacturer if there are any questions about the MRI safety status of the implantable pump system.

Health Care Providers who implant infusion pumps:

- When selecting the appropriate pump for each patient, please be aware that only patients implanted with MR Conditional pumps can safely undergo MRI exams, and only under very specific conditions of safe use. The conditions of safe MRI use may differ by manufacturer and model of the pump. This information should be discussed with the patient before and after the pump is implanted.
- Ensure that your patients receive and understand information about their implantable infusion pump, including how to use their patient implant card.
- Document the implantable device identification information in the patient's medical record.

Health Care Providers who manage implantable infusion pumps:

- Be aware that only patients implanted with MR Conditional pumps can safely undergo MRI exams, and only under the specified conditions of safe use. The conditions of safe use may differ by manufacturer and model of the pump.
- Before ordering an MRI scan for a patient with an implantable infusion pump, determine the make and model of the implantable infusion pump and ask the patient for their implant card to confirm the pump model.
- Only implantable infusion pumps labeled as MR Conditional may be safely scanned, and only under the specific conditions of safe use. Contact the implantable infusion pump manufacturer if there are any questions about the MRI safety status of the implantable pump system.
- Be aware that specific instructions must be followed before, during, and after MRI exams of patients with implanted infusion pumps, and that these instructions may differ by manufacturer and model of the pump.
- Inform your patients that they should notify you **before** having an MRI exam that another health care provider orders. MRI exams may affect the function or programming of the implantable infusion pump. For example:
  - Some pump models may automatically stop delivering medication during the MRI exam, and some may need to be reprogrammed before and/or after the exam. Depending on the medication delivered by the implantable pump, alternative drug therapy may need to be considered to prevent drug withdrawal.
  - Some pump models may need to be completely emptied of drug prior to the MRI exam to prevent unintended over delivery of medication and drug overdose.
- Ensure that your patients have received their implant card, and are aware of the MRI safety information specific to their pump.
- Ensure that care for your patient is coordinated between you, the physician who ordered the MRI exam, and the facility that will perform the MRI exam.

Health Care Providers that prescribe MRI Exams:

- Be aware that only patients implanted with MR Conditional pumps can safely undergo MRI exams, and only under specified conditions of safe use. The conditions may differ by manufacturer and model of the pump.
- You should ask all of your patients if they have any implantable pumps or other implants when determining whether an MRI exam is safe for them.
- Before ordering an MRI scan for a patient with an implantable infusion pump, determine the make and model of the implantable infusion pump and ask the patient for their implant card to confirm the pump model. If there are any questions about the specific pump make and model a patient has, contact the health care provider managing the pump.
- Only implantable infusion pumps labeled as MR Conditional may be safely scanned, and only under the specific conditions of safe use. Contact the implantable infusion pump manufacturer if there are any questions about for the MRI safety status of the implantable pump system.
- Consider the benefits and risks of an MRI exam and weigh the value of the information to be gained from the MRI exam against the risks of the exam for the patient. All medical devices present in the MR environment during the exam (including implants, external devices and accessory devices) should be included in the risk assessment.
- If needed, consult with a radiologist to determine if the MRI exam will deliver the expected benefits. For example, under some circumstances, artifacts from the pump may compromise the quality of acquired images.
- Ensure that care for your patient is coordinated between you, the physician who manages the implantable pump, and the facility that will perform the MRI exam.

FDA Activities:

Before an implantable infusion pump is introduced into clinical use, the FDA reviews evidence supporting the safe and effective use of that pump. This review may include evidence supporting the MR Conditional labeling. After an implantable infusion pump is approved for clinical use, the FDA monitors adverse events related to the pump.

An analysis of adverse event information and manufacturer labeling alerted the FDA to a potential safety problem with the use of implantable infusion pumps in the MR environment. The FDA is working with the applicable manufacturers to update MRI safety information in their labeling to ensure that instructions for the safe use of these devices are clear and up-to-date with current terminology and definitions.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect an implantable pump of having problems during an MRI exam, we encourage you to file a voluntary report through **MedWatch (https://wayback.archive-it.org/7993/20190424073220/http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm)**, the FDA Safety Information and Adverse Event Reporting program.

Device manufacturers and user facilities must comply with the applicable **Medical Device Reporting (MDR) regulations. (https://wayback.archive-it.org/7993/20190424073220/http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)**

Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements (https://wayback.archive-it.org/7993/20190424073220/http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** should follow the reporting procedures established by their facilities.

Other Resources:

- FDA's **Manufacturer and User Facility Device Experience (MAUDE) database (https://wayback.archive-it.org/7993/20190424073220/http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM)** – search under the Product Code "LKK" for MDRs related to implantable infusion pumps and MRIs
- FDA's **MRI (Magnetic Resonance Imaging) (https://wayback.archive-it.org/7993/20190424073220/http://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/default.htm)** website
- **FDA/Society for Magnetic Resonance Technologists (SMRT), MRI Safety Posters (/7993/20190424073220/https://www.fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/ucm482788.htm)**, **Magnetic Resonance Imaging - Tips for Scanning Patients with Implants (/7993/20190424073220/https://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MRI/UCM528077.pdf)**

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041 or 301-796-7100.