




From: Michael Reardon, MD 
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Subject: Patients Implanted with Titan Spinal Fusion System Undergoing MR exams

TRA recently became aware that Titan interbody fusion products have not undergone any MR safety related testing. Although Medtronic has acquired Titan and is in the process of testing these devices for the MR environment, the most concerning part for us is the current statement from the product literature (available at <https://www.medtronic.com/us-en/healthcare-professionals/therapies-procedures/spinal-orthopaedic/interbody-science/indications-safety-warnings/titan-endoskeleton-posterior-lumbar-products.html>):

“The Titan Spine Endoskeleton TT Interbody Fusion Device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Endoskeleton TT Interbody Fusion Device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.”

We have likely scanned these patients many times in the past and the risk is likely negligible. However the above statement is alarming. Accordingly, until Medtronic changes the wording in the product literature or completes the appropriate MR safety testing, all patients implanted with this particular hardware should read the product information prior to undergoing an MR study.

Effective immediately, please provide these patients the attached Patient Information sheet before their exam. In addition, please complete the *TRA MR Technologist Worksheet for Magnetic, Conducting, and/or Metallic Implant* (available at the TRA website or in the TRA MR Safety Manual). On the form, please write “TITAN INFORMATION PROVIDED.” Please scan into the Study Notes the completed Technologist Worksheet.

These patients should only be scanned Monday through Friday during normal business hours. If the patients have questions, they may speak with an MR radiologist in person or by telephone. If the patient chooses not to proceed with the MR scan, the ordering physician should be notified and, if appropriate, decide on an alternative study.

Thank you for your assistance. If you have any questions, please contact me at mreardon@triadradiology.com.

Attachments

1. TRA Patient Information about MRI and Titan Fusion Products
2. TRA MR Technologist Worksheet for Magnetic, Conducting, and/or Metallic Implant
3. SAMPLE TRA MR Technologist Worksheet for Magnetic, Conducting, and/or Metallic Implant