# OSMA Update: Regulatory Initiatives in the US and EU

Ryan Belaney, MS

Vice President: OSMA Board of Directors

Vice President: Clinical & Regulatory Affairs, Active Implants

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# Agenda

- Introduction to OSMA
- Recent US Initiatives:
  - April 2023 MR Testing & Labeling Panel
  - April 2023 Biocompatibility Panel
- EU Initiatives: January 2023 MDR Panel
- Summary

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# Introduction to OSMA

- Orthopedic Surgical Manufacturers Association (OSMA) is a nonprofit organization formed in 1954.
- OSMA is one of the oldest trade associations dedicated to the manufacturing of orthopedic surgical devices.
- Represents the orthopedic medical device community, including spine, large joint, extremities, trauma, and orthobiologics.
- Membership consists of manufacturers of orthopedic surgical implants, instruments, and equipment.
- Advocates for clear, consistent, and efficient implementation of government regulations and industry standards.

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# OSMA's Mission and History

- OSMA's mission is to facilitate the timely availability of quality orthopedic technologies.
- The association encourages the development of national and international performance standards for biomaterials and medical devices.
- Has played a key role in regulatory guideline development and regulatory education.
- Participated in significant events in the orthopedic device industry, such as the formation of the ASTM F-4 Committee and the FDA advisory panel for orthopedic devices.

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1995 - AAOS Orthopaedic Device Forum Formed

# The road we've traveled…

1. OSMA formed in 1954
2. ASTM F-04 Committee formed in 1962
3. Early 1970s - Focus on development of orthopedic standards
4. 1970s - Screw head slots/ screw driver incompatibility issue
5. 1970s - Total hip replacement gains in popularity in the US
6. 1970s - FDA orthopedic advisory panel formed to classify devices
7. 1970s - GMPs drafted for orthopedic devices
8. May 28, 1976 - Medical device amendments to FDA FD&C Act
9. …early beginnings…

# OSMA Quarterly Meetings

- Quarterly, 2-day meetings focus on current topics in the industry
  - Spring/Fall – US and FDA focused
  - Summer/Winter – EU and international
- Meeting initiatives to drive change
  - Networking/mentorship opportunities
  - Guest speakers including FDA, Notified Bodies, industry, and consultants
  - Panel sessions to answer member-specific questions
  - Workgroups:
    - Orthopedic Alliance Roundtable
    - Real-world Evidence
    - Anti-Infective Devices
  - Industry performance surveys

# Recent US Initiatives

- MR Labeling and Testing Panel
- Biocompatibility Panel

# MR Labeling and Testing Panel Members

- Diverse panel including FDA, Notified Body, ASTM, Industry, Test Facility, and Consultant perspectives
- Topics included:
  - Overview of MRI Safety Evaluations
  - Labeling for Devices and Items for the MR Environment
  - Common Deficiencies and Trends
  - MDR/FDA Comparison
  - Industry Perspective of MR Submission Requirements
  - MR Questions you should be asking

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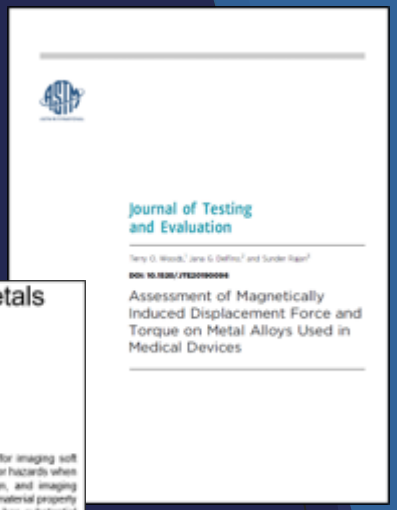
# MR Labeling and Testing

- Clinical motivation for evaluating MRI safety
  - >90 Million MRI scans per year
  - Millions of patients with implanted medical devices
- Injuries to patients during MRI:
  - In 1992, a patient with a cerebral aneurysm clip was fatally injured during MRI.
  - In 2001, an oxygen tank was pulled toward the MRI and fatally crushed a 6-year-old.
  - In 2004, a patient with DBS electrodes was paralyzed due to RF-induced heating.

# MR Testing

- Physical testing
  - Force
  - Torque
  - Image artifact
  - RF-induced heating
- Computational Testing
  - Image artifact
  - RF-induced heating

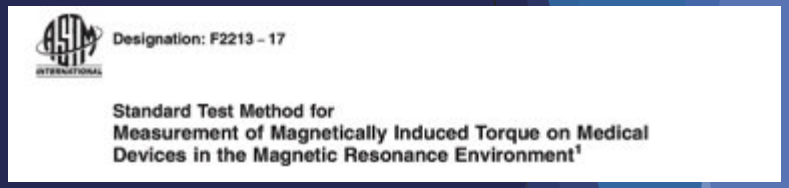

Journal of Testing and Evaluation

Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices


Magnetic Susceptibility of Common Metals and Alloys Used in Medical Devices

Abstract

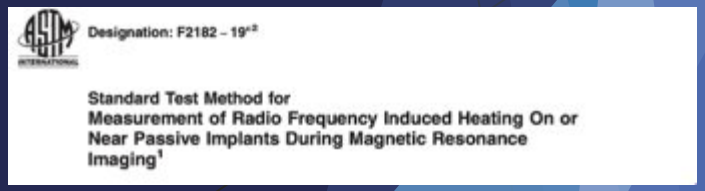
Magnetic resonance imaging (MRI) is a widely used imaging modality that is ideally suited for imaging soft tissues. The use of strong magnetic and electric fields employed in MRI creates the potential for hazards when imaging patients with metallic implants. With the proper material selection, implant design, and imaging procedure, many of these hazards can be adequately managed. Magnetic susceptibility (χ) is a material property indicating a material's tendency to interact with and distort an applied magnetic field, and it has substantial influence on both the force and torque experienced by an implant in a magnetic field, as well as the size of the image artifact. In this study, the magnetic susceptibility of 45 different medically relevant alloys and alloy composites is determined and reported. This data will aid in material selection for medical devices intended to be labeled as MR Conditional.


Designation: F2213 – 17

Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment[1]


Designation: F2119 – 07 (Reapproved 2013)

Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants[1]


Designation: F2182 – 19[e2]

Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging[1]

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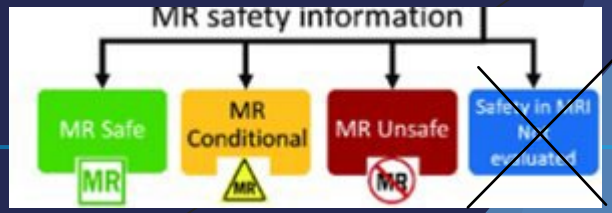
# MR Labeling




- MR Safe
- MR Conditional
- MR Unsafe

- Contradictory to FDA 2021 Testing and Labeling Medical Devices for **Safety in MRI, *Not Evaluated*** is not an option.
- Definition of MR Unsafe: an item that poses unacceptable risks to the patient, medical staff, or other persons within the MR environment
- If an item is **not evaluated** it poses an unacceptable risk, thus it should be considered **MR unsafe**

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# MR Example Label


## MRI Safety Information

A person with the Star implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

| | |
|---|---|
| Device Name | Star implant |
| Static Magnetic Field Strength ($B_0$) | 1.5T or 3.0T |
| Maximum Spatial Field Gradient | 30 T/m (3,000 gauss/cm) |
| RF Excitation | Circularly Polarized (CP) |
| RF Transmit Coil Type | There are no Transmit Coil restrictions |
| Operating Mode | Normal Operating Mode |
| Maximum Whole-Body SAR | 2 W/kg (Normal Operating Mode) |
| Maximum Head SAR | 3.2 W/kg (Normal Operating Mode) |
| Scan Duration | 2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks) |
| MR Image Artifact | The presence of this implant may produce an image artifact. |

# MR Labeling and Testing: Panel Q&A Highlights

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# MR Labeling and Testing: Key Considerations

- Testing Strategy
  - Systems approach, including compatible components that drive worst-case assessment
- Knowledge of Standards and Guidance Document
  - Internal subject matter expert
  - Consultant with expertise in MRI testing/analysis
- Labeling Requirements
  - IFU and PIC
- Unique Device? Partner with FDA
  - Q-submissions or interactively during review

# Biocompatibility Panel Members

- Panel Members included FDA, Test Facility, Industry, and Industry Consultant Perspectives
- Topics include:
  - Common Deficiencies and Trends
  - Chemical Characterization & Toxicological Risk Assessment
  - Extraction & Leachable Studies

# Biocompatibility: Common Review Concerns

- Biocompatibility Risk Assessment Rationales
- Biological Testing
- Analytical Testing Concerns
- Submission/Administrative Concerns

# Biocompatibility Panel: Rationale Summary

- Lack of adequate assessment of manufacturing materials/processes
- No biocompatibility on device packaging in close contact with the device
- Unclear language: “similar”/“equivalent” to predicate
- History of use OUS as a rationale

# Biocompatibility Panel: Biological Testing

- Test article issues: final finished, post sterilization
- Test extract observations: color change, cloudiness
- Test extraction methods: worst-case extraction not considered. Temperature and extraction vehicle.
- Testing dosage: Leveraging an implantation study for systemic toxicity needs to consider worst-case dosing. Does the animal test article represent the human dose?

# Biocompatibility Panel: Analytical Testing

- Test methods
  - Not worst-case clinical exposure
  - Incorrect extraction solvents
- Sensitivity/Reporting Limits: Analytical Evaluation Threshold doesn't account for instrument variability
- Method Validation: Standard selection and concentration ranges
- Identification
  - "unknown" compounds due to library matched
  - Unidentified compounds

# Biocompatibility Panel: Administrative Concerns

- Incomplete biocompatibility assessment
- Changes to 510(k) cleared devices have unintended consequences: vendor changes
- Lack of clarity on the reason for inclusion of test reports
- Organizing the test reports

# Biocompatibility Panel Q&A

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# MDR Panel Experts

- Entire day focused on MDR Q&A directly to notified bodies at DEKRA, TUV SUD, GMED, BSI, AKRA TEAM (Industry Consulting Group)
- Presentations on the following topics:
  - MDR Review Process
  - Clinical Focus
  - General Session
  - Audit Approach
  - Recommendations to implement EU MDR

# MDR Insights

- Lessons Learned from a NB Perspective
- MDR Best Practices
  - Communicate with the NB
  - Refer to recent Team NB Best Practice Guidance on MDR Technical Documentation Submissions
  - NB internal completeness checks performed prior to review commencements

# MDR Insights

- Extension of Transition Provisions
- Applies only to devices:
  - That do not present unacceptable risk to health and safety;
  - that have not undergone significant changes in design or intended purpose; and
  - for which manufacturers have already undertaken necessary steps to launch the certification process under the MDR
    - Adaption of QMS to MDR
    - Application for conformity assessment by an NB before a certain deadline
- 2027 for class III and IIb
- 2028 for class IIa and class I devices

# MDR Panel Q&A

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# OSMA MDR Next Steps

- OSMA-wide performance survey
  - Timing of reviews
  - Cost
  - Challenges
- Anonymous member review concerns
  - Example: MDR deficiency question

# OSMA's Benefits to Members

- OSMA provides a forum to collaborate and communicate, facilitating the sharing of knowledge and strategies.
- Members have access to regular meetings for education and business discussions, keeping them abreast of regulatory issues.
- Educational programs provide unique opportunities for member interaction with regulatory and industry representatives from across the globe.
- Task forces have been established to address relevant topics impacting the orthopedic device industry, such as Advanced Manufacturing, Class I Accessories, and Endotoxin Testing.

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# Becoming a Member

- Membership is open to any business entity that is a manufacturer of finished surgical appliances, devices, biological products, instruments, equipment, or technology used in orthopedic indications.
- OSMA offers an engaging platform where members can stay informed, share ideas, and collaborate to enhance the orthopedic medical device industry

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# Collaboration Opportunities


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# Conclusions

- OSMA: A powerful advocate for the orthopedic medical device industry, including spine, large joint, extremities, and trauma devices.
- Through its education programs and regular meetings, OSMA keeps members informed about current regulatory issues and industry trends.
- OSMA has proven its impact by facilitating discussions that help to refine and harmonize regulatory responses, as demonstrated by its role in addressing challenges presented by EU MDR.
- Encourage eligible companies to consider OSMA membership to reap these benefits and contribute to the collective advancement of the industry.

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# Resources:

- Guidance Documents (Medical Devices and Radiation-Emitting Products) https://www.fda.gov/medical-devices/device-advice- comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products
- FDA Recognized Consensus Standards https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- The Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessment-radiofrequency- induced-heating-magnetic-resonance-mr-environment-multi-configuration
- Reporting of Computational Modeling Studies in Medical Device Submissions https://www.fda.gov/regulatory-information/search- fda-guidance-documents/reporting-computational-modeling-studies-medical-device-submissions
- Requests for Feedback and Meetings for Medical Device Submissions: The QSubmission Program https://www.fda.gov/regulatory- information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
- Recommended Content and Format of Complete Test Reports for Non-Clinical Bench Performance Testing in Premarket Submissions https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non- clinical-bench-performance-testing-information-premarket
- Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices https://www.fda.gov/regulatory- information/search-fda-guidance-documents/submission-premarket-notifications-magnetic-resonance-diagnostic-devices

# Be part of our journey…

https://osma.net/membership

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