MRI safety evaluation and labeling of passive implants:

Meeting the need with virtual and physical test capabilities

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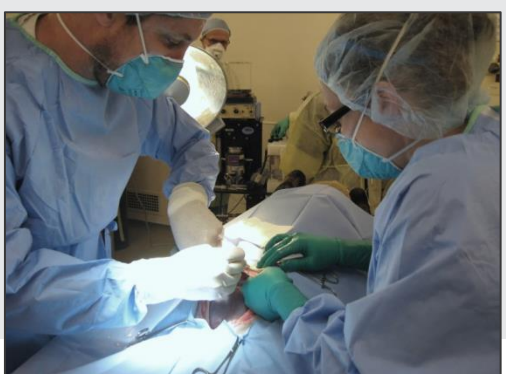
MED Institute, Inc.

Agenda

- Introduction to MED Institute
- Labeling passive devices for MR safety
  - **ASTM F2503**: Marking medical devices for MR safety
  - **ASTM F2052**: Magnetically induced displacement force
  - **ASTM F2119**: Image artifacts
  - **ASTM F2182**: RF induced heating
  - **ASTM F2213**: Magnetically induced torque
- MR safety evaluation case studies
  - Ferromagnetic devices
  - Devices with complicated geometry
  - Device length and orientation concerns

MED Institute has been involved with product design, engineering & bench testing of medical devices over the last 30 years

- Located in West Lafayette, Indiana
- Founded in 1983
  - Nonclinical testing services
  - Product design, engineering & simulation
  - Regulatory consulting
- ISO 17025 Accredited Laboratory (cert 2194-01)
- ISO 13485 and ISO 14155 Certified (BSI)
- Inspected to Good Laboratory Practices (GLP)
- We serve on 14 medical device standard committees



MED is active in many areas of research and criteria development and problem solving

MED Institute has entered into a Research Collaboration Agreement (RCA) with the FDA's CDRH

- Radiofrequency Safety Assessment of Generic Passive Implants
  - Three year research project
  - Assess RF induced heating of passive metallic medical devices during MR imaging
  - Information learned will guide engineers in designing appropriate MR safety testing strategies and understand thresholds for heating
  - Results will be shared via peer-reviewed manuscripts and written communications

Active in complex criteria and boundary condition development and specialize many other areas such as corrosion, fatigue, failure analysis

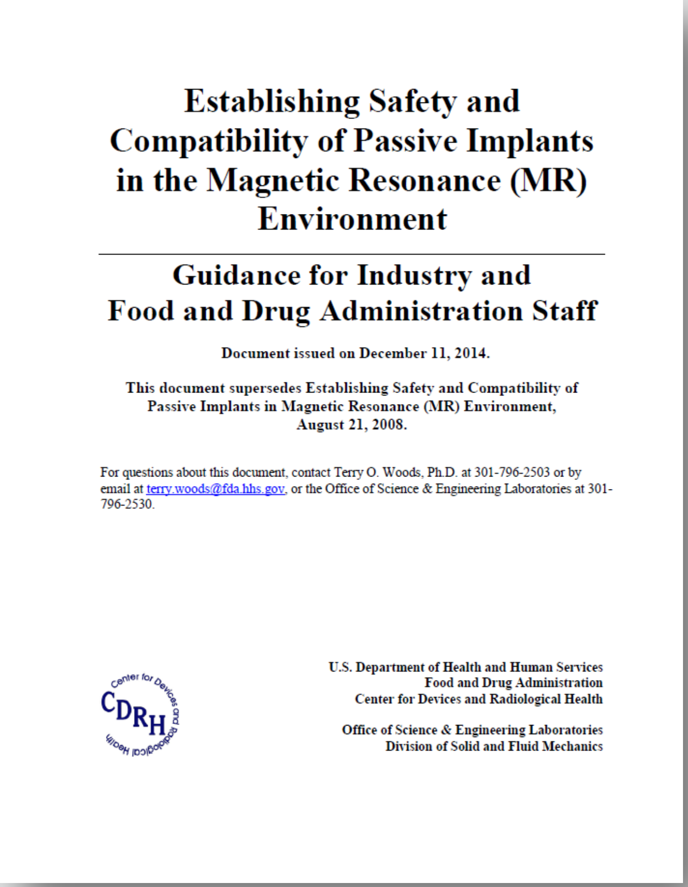
Tens of millions of MR scans are performed each year

- Advantages of MR over CT or X-ray
  - No ionizing radiation
  - Images acquired in multiple planes
  - Superior soft tissue contrast
  - Images obtained without use of contrast
- Disadvantages of MR
  - More expensive than CT and X-ray
  - Not safe for patients with some metal implants

http://science.howstuffworks.com/mri3.htm

Why label devices for MR Safety?

- Patient safety
  - Radiofrequency (RF) induced heating
  - Magnetically induced forces
  - Magnetically induced torques
- Expedite MR scanning
  - Clear, standardized information can help the MR technologist
  - Avoiding image artifact
- Regulatory compliance
  - Guidance has been given to publish MR labeling



Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment

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Guidance for Industry and Food and Drug Administration Staff

Document issued on December 11, 2014.

This document supersedes Establishing Safety and Compatibility of Passive Implants in Magnetic Resonance (MR) Environment, August 21, 2008.

For questions about this document, contact Terry O. Woods, Ph.D. at 301-796-2503 or by email at terry.woods@fda.hhs.gov, or the Office of Science & Engineering Laboratories at 301-796-2530.

Center for Devices and Radiological Health
CDRH

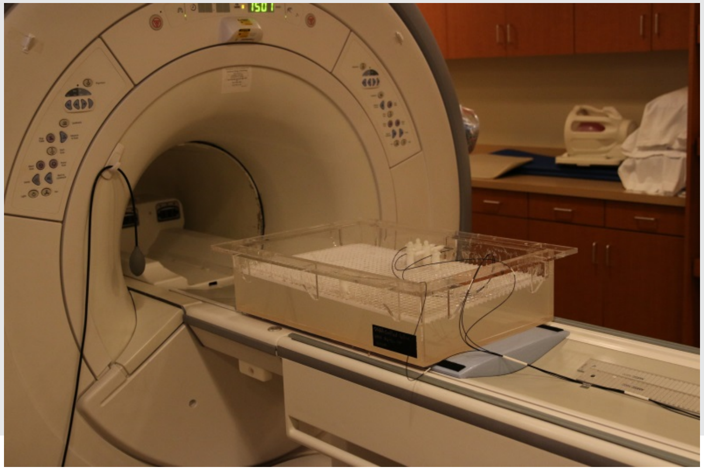
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Science & Engineering Laboratories
Division of Solid and Fluid Mechanics

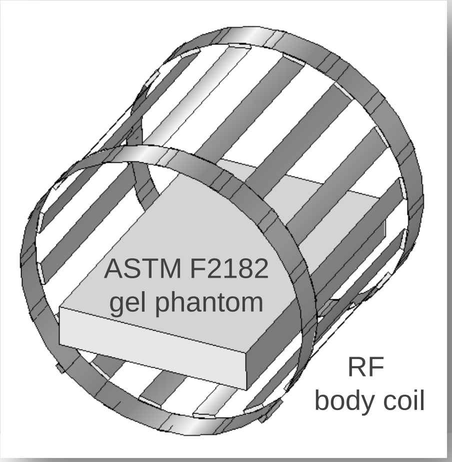
MED Institute has developed virtual and physical test capabilities for MR safety evaluation of passive devices

- **ASTM F2503**: Marking medical devices for MR safety
- **ASTM F2052**: Magnetically induced displacement force
- **ASTM F2119**: Image artifacts
- **ASTM F2182**: RF induced heating
- **ASTM F2213**: Magnetically induced torque

Physical test for ASTM F2182



Virtual test for ASTM F2182



MRI Device Classifications/Markings ASTM F2503

MED Institute can help navigate the spectrum of considerations for MR safety evaluation

- Acceptance criterion for RF induced heating
  - RF Heating
    - Clinically-relevant maximum temperature rise
    - Cumulative thermal damage (e.g. CEM43)
  - Magnetically induced force and torque
    - ASTM standard provided criteria
    - Clinically relevant criteria
- Method for measurement of magnetically induced displacement force
  - Deflection or force-gauge
- Identification of the worst-case implant configuration
  - Implant size and orientation
- Testing in a 1.5T or 3T MR scanner

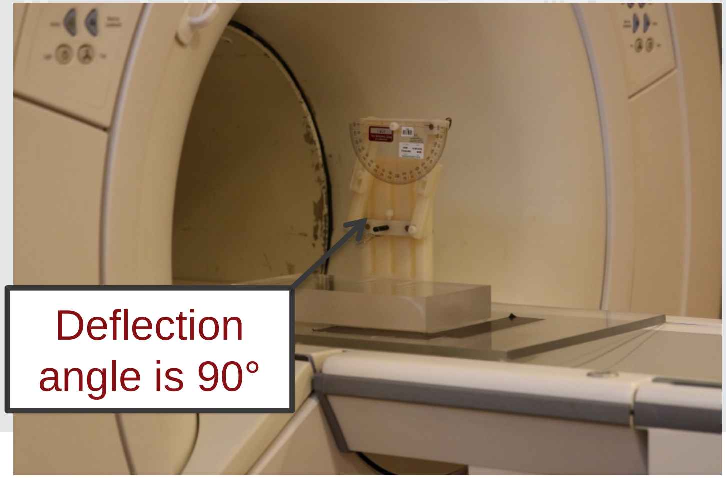
MR safety evaluation case studies

1. **What do you do when force and torque exceed ASTM reference points?**
2. Where should temperature measurements for RF induced heating be made on an implant?
3. Where should a hip implant be placed to measure maximum RF induced heating in ASTM F2182 test?

What do you do when force and torque exceed that of ASTM reference points?

- Product of static field and spatial gradient ($\boldsymbol{B_0} \cdot \nabla \boldsymbol{B_0}$) drives the magnetically induced force exerted on a magnetic material
- **ASTM F2052**
  - Hang device from string where deflection is greatest (where $\boldsymbol{B_0} \cdot \nabla \boldsymbol{B_0}$ is maximum)
  - Conservative reference point
    - Magnetic force is ≤ device weight if the deflection angle is ≤ 45°

Aortic endovascular graft with stainless steel Z-stents



If the deflection angle is ≥ 45° the test isn't necessarily over…

What do you do when force and torque exceed that of ASTM reference points?

Aortic endovascular graft with stainless steel Z-stents

- ASTM F2052 conservative reference point
  - Magnetic force is ≤ device weight if the deflection angle is ≤ 45°
  - Risk imposed is no greater than any risk imposed by normal daily activity in the Earth's gravitational field
- Measured force and torque and performed performance and safety assessment
  - Force and torque compared to physiologically relevant loads and acceptance criteria
  - Clinical data where patients with implants underwent MR imaging with no adverse clinical incidents
- Device has been labeled MR conditional

MR safety evaluation case studies

1. What do you do when force and torque exceed ASTM reference points?
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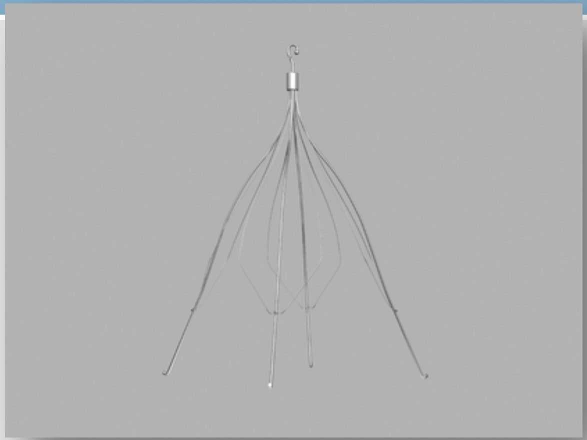
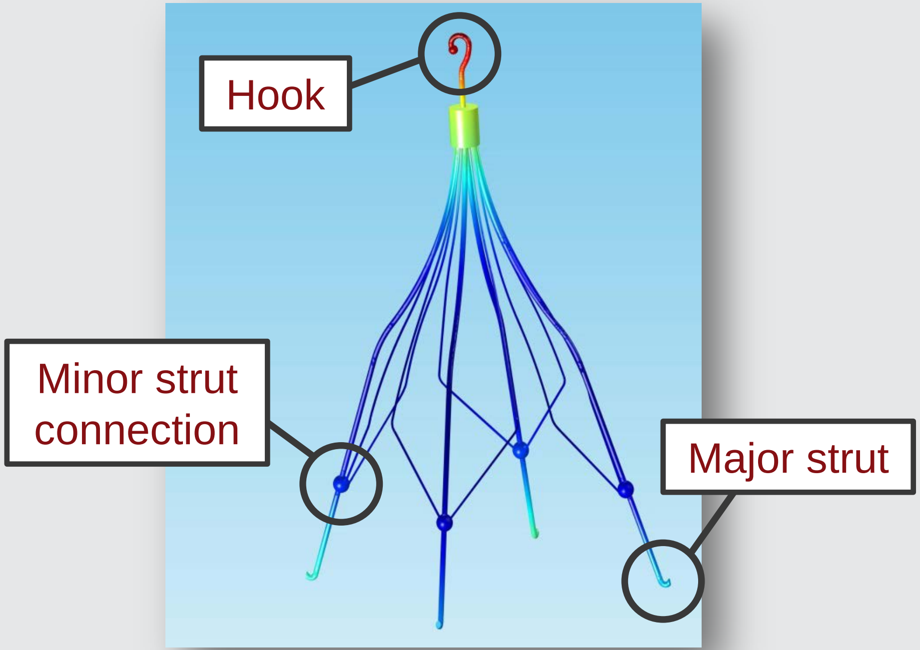
Where should temperature measurements be made for RF induced heating of a complicated structure?



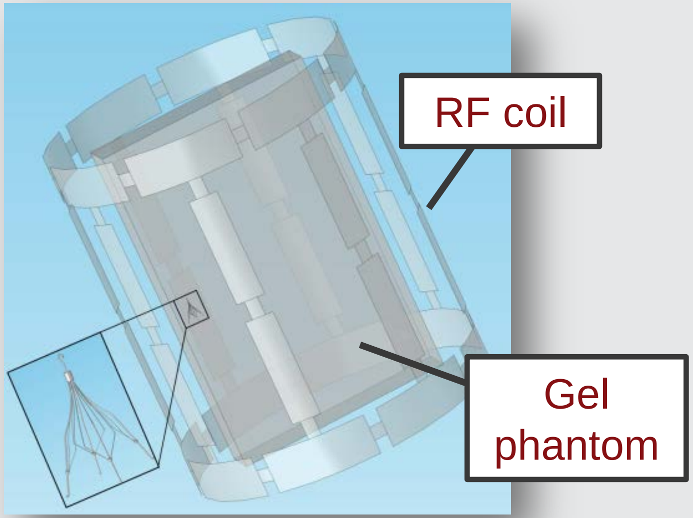
- **ASTM F2182**
  - Implant is tested in a phantom material that simulates the electrical and thermal properties of the human body
  - Temperature probes are placed at locations where the induced implant heating is expected to be the greatest
    - For an elongated implant, the greatest heating will likely occur near the ends of the implant
    - Maximum heating locations can be found by pilot experiments or predicted computationally

Where should temperature measurements be made for RF induced heating of a complicated structure?

- Finite element analysis performed in COMSOL Multiphysics®
- Hook expected to exhibit maximum temperature rise in the ASTM F2182 test

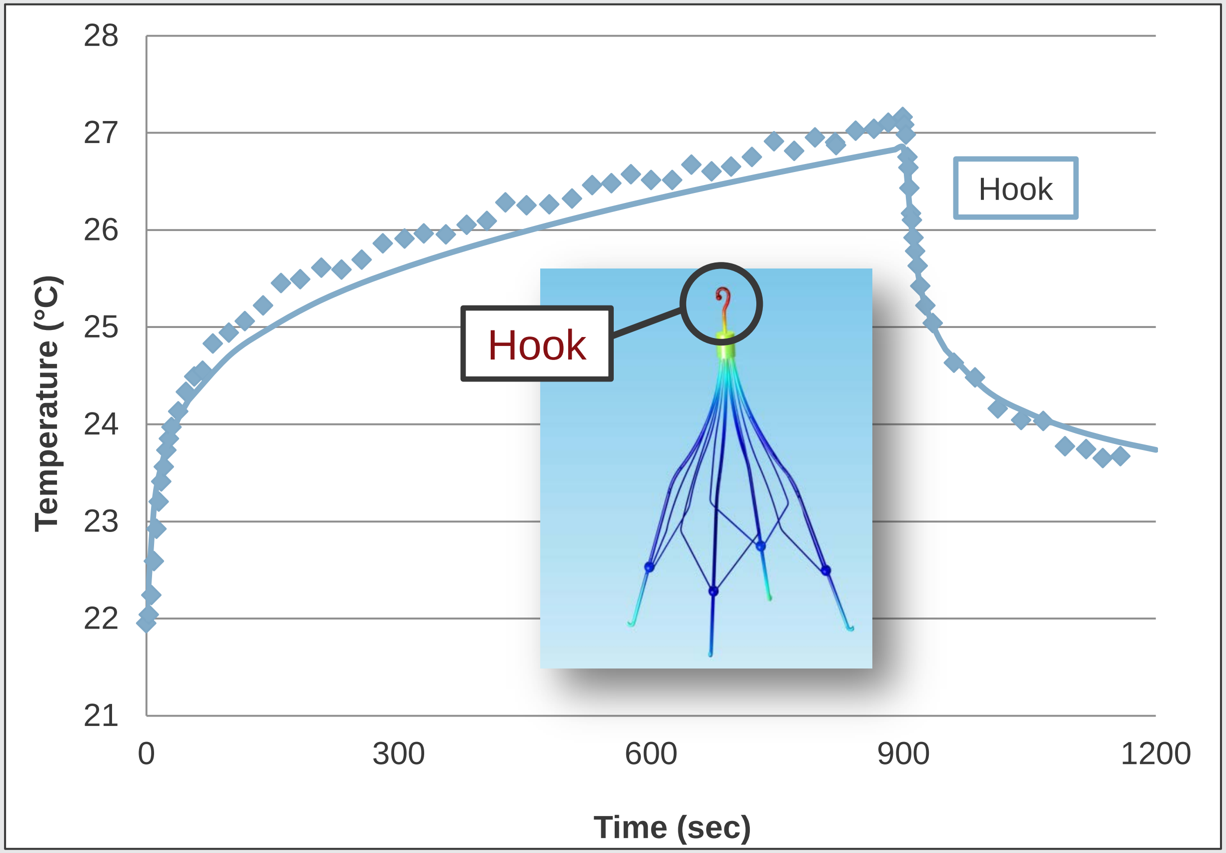


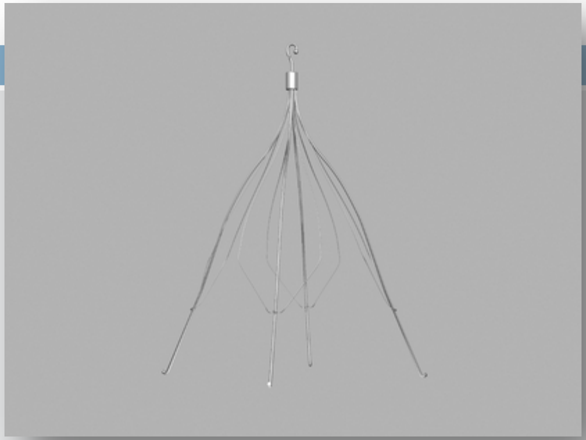
Predicted temperature rise following 15 minutes of RF application



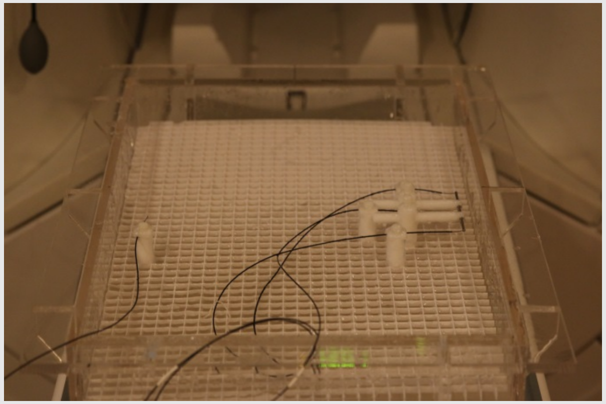
Simulation model

Strong correlation between RF heating simulation and test





Complicated structure



Test setup for RF heating test of structure in the ASTM gel phantom

Complete safety evaluation resulted in MR conditional label

MR

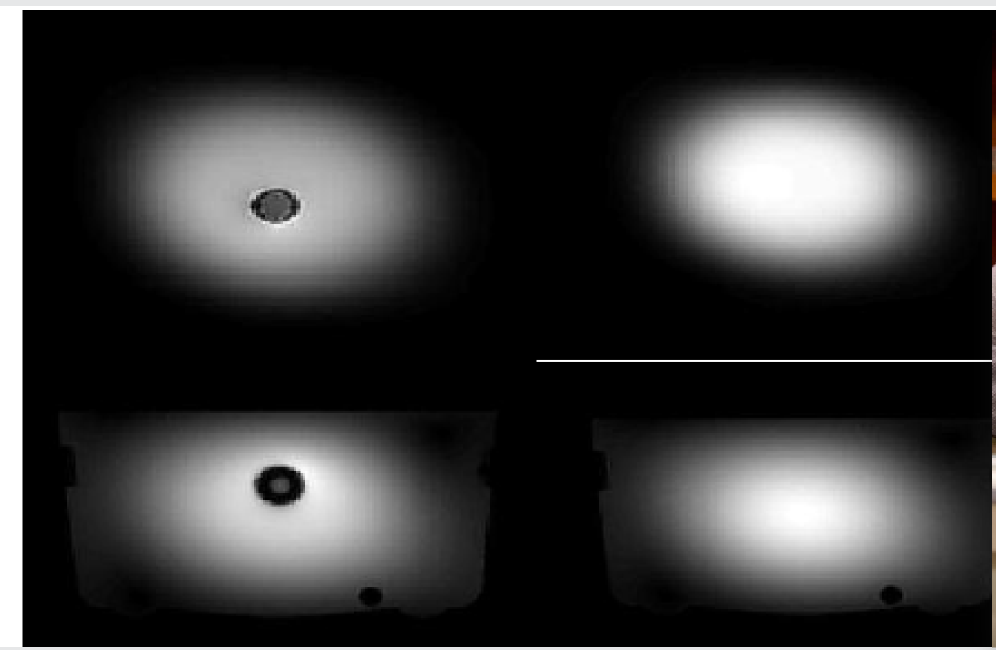


Image artifact

Magnetically induced torque

MR safety evaluation case studies

1. What do you do when force and torque exceed ASTM reference points?
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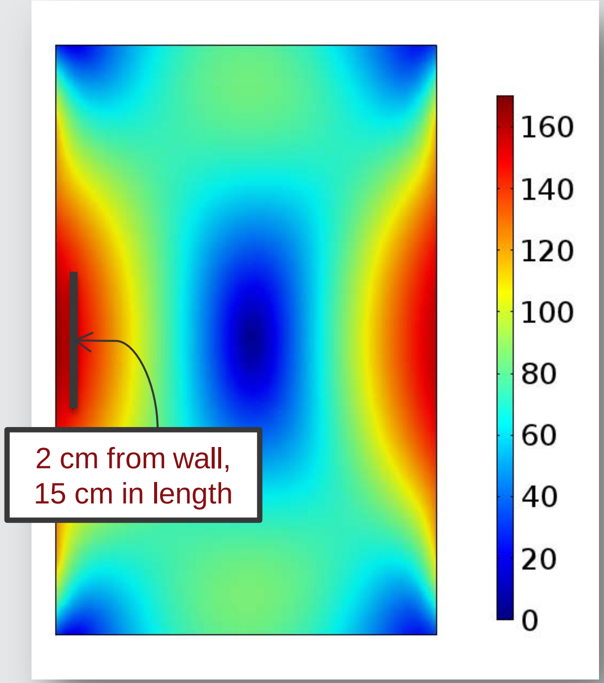
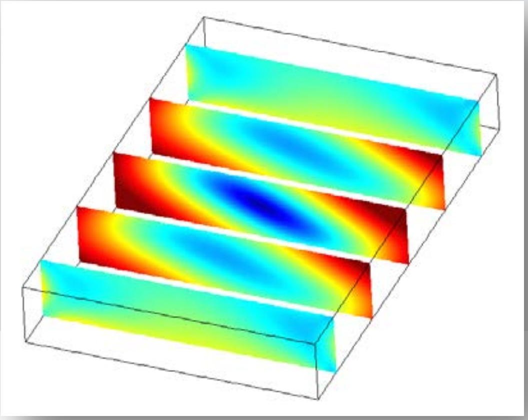
3. **Where should a hip implant be placed to measure maximum RF induced heating in ASTM F2182 test?**

Where should a hip implant be placed to measure maximum RF induced heating in ASTM F2182 test?

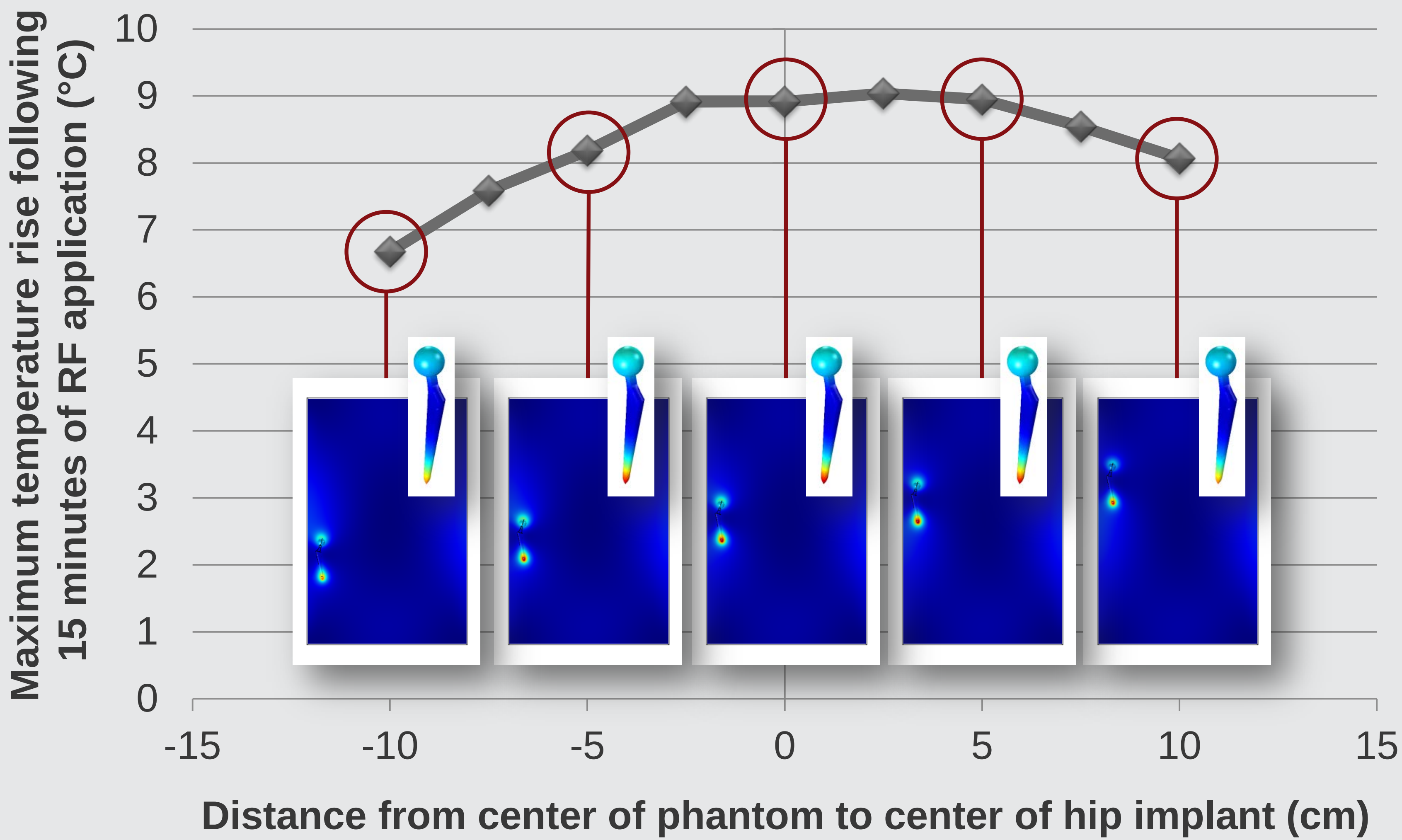
- **ASTM F2182**
  - Choose a volume…so the undisturbed E-field does not vary significantly…
  - **Note**: for the standard rectangular phantom geometry, with the phantom centered in the bore, and the lateral side of the implant placed 2 cm from the phantom wall, this location provides a high uniform tangential electric field over a length of approximately 15 cm.



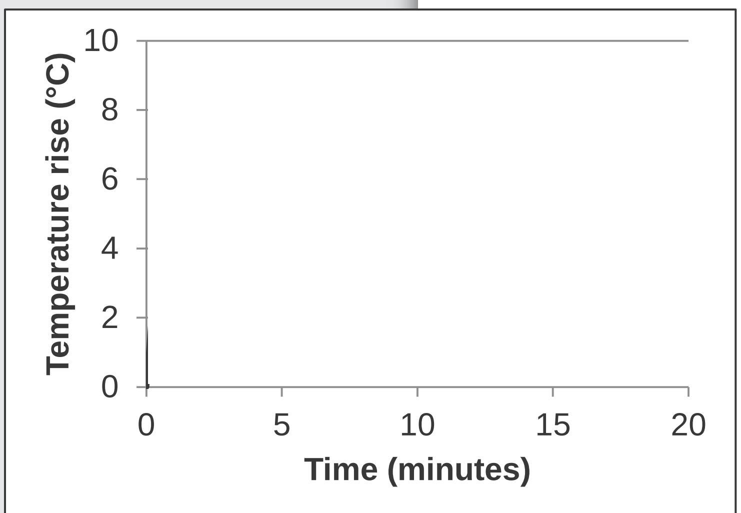


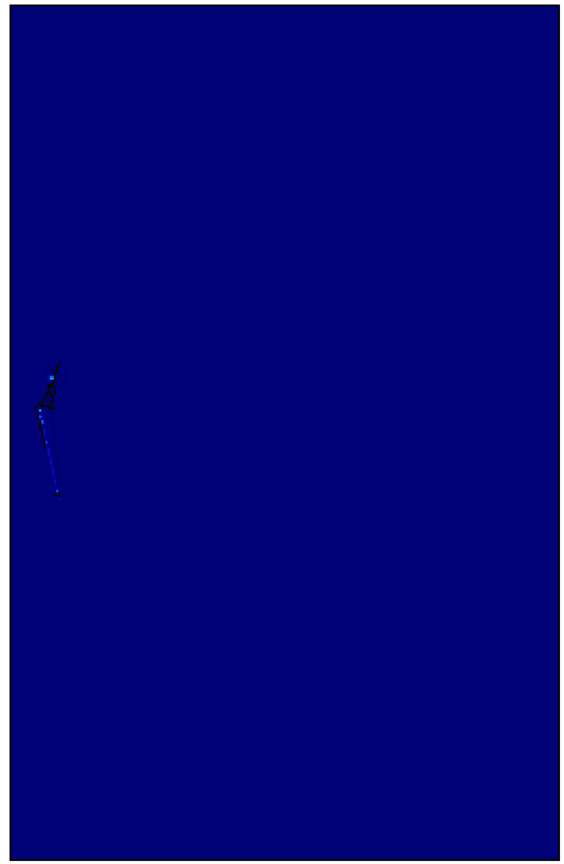
Electric field magnitude (V/m) within ASTM F2182 gel phantom

FEA predicted maximum temperature rise at stem tip; hip implant should be centered in the phantom



Temperature rise of hip implant for 15 minutes of RF application and 5 minutes cool-down





MED Institute has virtual and physical test capabilities to conduct MRI safety evaluations for passive implants

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