Implanted Devices Evaluation
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No Conflict of Interest to Declare
List of Active and Passive Devices

- **Active Implanted Medical Devices**
  - Cardiac (pacemakers, ICD, CRT-D, loop recorders)
  - Stimulation (deep brain, vagal nerve, spinal, bone and bladder)
  - Programmable Shunts and Pumps (pump, drug, insulin)
  - Cochlear Implants

- **Passive Implanted Devices & Retained Foreign Objects**
  - Neurological (aneurysm clips, coils, shunts)
  - Orthopedic and dental (prosthetics, rods, screws, braces)
  - Gastrointestinal (cap, Balloon, Pill, Cam, magnetic sphincter)
  - Foreign objects (metal in orbits, BBs, bullet fragments)

- **External Objects and Devices**
  - Medication patches, Glucose Monitor, Hearing aids
  - Permanent makeup, tattoos, piercings
  - Immobilization, temporary fixation, patient comfort (blankets)

- **Implanted Devices MR Safety Labeling**
  - MRI Safe: The item is safe for use in MRI under all conditions.
  - MRI Unsafe: The item is not safe for use in MRI under any conditions.
  - MRI Conditional: The item is safe for use in MRI only under certain conditions.
  - NO Label: The item has not been evaluated for MR safety.

- **Absolute Contraindication Implants for MRI?**
  - 10 years ago – most active implanted device and many passive
    - Cardiac (pacemakers, ICD, CRT-D, loop recorders)
    - Stimulators (deep brain, vagal nerve, spinal, bone and bladder)
    - Pain Pumps
    - Cochlear implants
  - 5 years ago – majority active implanted devices
    - Stimulators (deep brain)
    - Pain Pumps
    - Cochlear implants
  - Today
    - ?
Typical Implanted Device Evaluation Call

- Patient is in the waiting room
- Does not have any information on implanted device
- Claims had MRI at another site (most likely it was CT)
- There is no prior history or images in PACS
- Can we safely scan this patient?
  - Also can you please give me an YES and NO answer in 5 mins, we are running 30 minutes behind schedule
- Hmm…it Depends!

Implants in MRI: Challenges

- Rapid growth of patients with implants
  - Increased number of MRI conditional implants
  - Multiple implants and retained implants
  - Poor documentation in patient EMR
  - Direct vendor patient marketing as “MRI conditional”
  - Evolving and retroactive MRI conditional labeling
- Rapid growth of MRI systems
  - High field (7T) and Low Field (<1T MR-Linac)
  - Hybrid Systems (PET-MR, Hybrid MR-OR)
  - Advanced procedures with high end hardware (fast gradients, multichannel transmit, scan parameter complexity)

Complexity vs Clarity

- Opportunity for physicists to step in and assert our role in clinical practice as MRSE
- Radiation safety framework
  - Leverage Radiation Safety model as an analogy
  - Radiation Safety Committee
- We are all in the same boat – lean on each other
  - Interpersonal – Call a friend
  - Departmental – MR Safety Task Force
  - Institutional/Enterprise – MR Safety Committee
  - Professional Communities – AAPM and ISMRM Safety Committees
Objectives

• How to operationalize implanted device evaluation and expand scope of our practice as MR Safety Experts
  1. Operational framework for device evaluation (evolving)
  2. Review relevant resources and guidelines (evolving)
  3. MRSE device evaluator starter guide (evolving)

Safety Concerns – MR Conditional Devices

• Static Field (B0)
• Radio Frequency Field
  - SAR
  - B1+ rms
  - Duration of single series or entire scanning session
• Type of coil
• Spatial Gradient
• Identify
• Find vendor guidance
• Time-Varying Gradient Slew Rate
• Acoustic Noise
• Positioning/Landmarking/Centering
• Patient height, weight
• Location of device implantation
• Immobilization: external, comfort
• Patient monitoring
• Additional implants
• Artifacts

Operationalize Implanted Devices Evaluation

Evaluation Checks Pre/During

- Verbal, visual, physical screening
- Evaluation; interpretation and communication plan
- Escalation process, MRSE, MRMD
- Scan coordination
- Inter/intra departmental communication
- Vendors
- Safe execution
  - Positioning; coils selection; monitoring;
  - Pulse sequences and parameters (Ultra low SAR protocols)

Evaluation Checks Before

- Institutional framework
  - Patient EMR
- Departmental Framework
  - Schedulers MRSE, MRMD
- Guidelines and Policies
- Patient framework
- Screening Form

Post Scan

- Reporting
  - Internal and external (FDA/MAUDE)
- Education and Training
- Safety committee review
- Guidelines and policy update
Operationalize Implanted Devices Evaluation

Evaluation Checks Before
- Institutional Framework
  - Patient EMR
- Departmental Framework
  - Schedulers MRSO
  - Guidelines and Policies
- Patient Framework
  - Screening Process

Institutional Framework – Patient EMR

Departmental Framework – Schedulers, MRSOs

https://www.nwforums.com/appsupport/
Blanket Policies - “All Stents are Safe”

- Use caution when using blanket safety statements in guideline

Multiple overlapping stents represent a potential thermal risk at higher fields due to shorter wavelength.

Patient Framework – Screening Form

- Screen patients for MR conditional and MR unsafe stents.
- Future plans could include integrating screening forms into the patient's medical record.
Operationalize Implanted Devices Evaluation

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Screening: Verbal, Visual, Physical

Escalation Process: MRSO → MRSE → MRMD

MRI Safety Assessment Strategy

Assess risk and benefit with radiologist
- Search for device safety information
- Use internet search:
  - Medline
  - PubMED
  - wire/note
  - internet, hospital
- Information from the manufacturer
  - Device search device name
  - "safe device"

MRSE clearly communicate technical nuance on risks in MRI environment to aid in making effective patient management decisions
- Low SAR scanning protocols; off label scanning; positioning; monitoring; coils; pulse sequences and parameters
- Does not make medical decisions
- Does advise on technical conditions for scanning on label
- May be asked to advise on approaches to scanning off label and associated risks
<table>
<thead>
<tr>
<th>Safety Concerns - Evaluation</th>
<th>Device</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lead Heating</strong></td>
<td></td>
<td></td>
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<tr>
<td>Conductive lead acts as an antenna, picking up RF energy. A portion of this energy is dissipated as heat in cardiac tissue near tip of the electrode.</td>
<td>Heat and electroshock by concentrating RF energy; myocardial stimulation; tissue damage may affect therapy.</td>
<td></td>
</tr>
<tr>
<td><strong>Unintended Stimulation/Heating</strong></td>
<td></td>
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<tr>
<td>Gradient and RF fields induce voltages in leads that will be applied to the lead electrodes. Large voltage pulses may directly stimulate the heart. Electrical currents may be induced on the conductive surface of the case.</td>
<td>May lead to a single or intermittent stimulation from oversensing or undersensing; sustained tachyarrhythmia; thermal tissue damage near the case.</td>
<td></td>
</tr>
<tr>
<td><strong>Device Interactions/Vibration</strong></td>
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</tr>
<tr>
<td>Static field will act on ferromagnetic material producing a translation or rotation of the device or lead. Gradient and RF fields can induce electrical currents on conductive surfaces of device components. Interaction with static field may result in components to vibrate.</td>
<td>Pacemaker or defibrillator movement, patient discomfort, malfunction or failure (asynchronous pacing)</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from: [http://www.medtronic.com/](http://www.medtronic.com/)
Operationalize Implanted Devices Evaluation

Post Scan
- Reporting
  - Internal and external (FDA MAUDE)
- Education and Training
- Safety committee review
  - Guidelines and policy update
**Reporting – Internal**

### Event Information
- **Event Type & Date**: ACCIDENTAL INJURY & EYETHANK, 7:30 AM
- **Event Location**: INTERNAL NEWS & HEADQUARTERS
- **Severity & Stage**: NO & NO
- **Event Document**: MEDICINE & MD'S

### Observation
- **Observation**: 1ST DEGREE BURN POST OPER: PATIENT HAS A 1ST DEGREE BURN WITHOUT ACID BURN. THE NEXT MORNING, SHE CALLED THE REDNESS HAS GONE AWAY. SHE THOUGHT IT MIGHT BE RELATED TO HER UNDERSOIL. THE LABEL STATED 98% POLYESTER, 2% SPANDEXY, 1% OTHER FIBER. SHE WILL FOLLOW UP LATER WITH OUR MD'S AND ENGINEERS.

### Injury & Description
- **Injury & Description**: NO SEVERAL ORGANIZATIONS, 1 ROOM DOWANIZED FOR A STRIKE LIKE AREA.

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**Reporting – External FDA MAUDE**

**Medical Device Reporting (MDR): How to Report Medical Device Problems**

**FDA MAUDE Database Search**

- Product Codes LNH (Nuclear Magnetic Resonance systems, 892.1000)
- MOS (coil Magnetic Resonance, 892.1000).

**FDA MAUDE Database Search**

- [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search_CFM](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search_CFM)
Closing the Loop: MR Safety Committee

- Radiologist (MRMD)
- Technologist (MRSO)
- Physicist (MRSE)
- Administrators (Supervisors and Managers)

1. Training and Education
2. Guideline and Policy Updates
Policy and Guideline Updates

- VNS – Brain w/wo
  - Pt scanned at 1:00 pm
    - VNS identified (pt disclosed) and noted in the screening form; VNS turned OFF, set to 0 mA.
    - Non-TR coil used; TR coil was not identified correctly
  - Pt rescanned at 3:00 pm
    - VNS missed (pt did not disclose)
    - TR coil not used
- Patient screening form must be reviewed and signed each and every time any patient presents for an exam
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Tools of Trade – Start as MRSE Device Evaluator

Sample of MR implant safety standards & guidance

- Guidance Document on MRI Safe Patient
- Dr. Jason Stafford
Where to Start?


