http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107705.htm#4

www.mrisafety.com

Implants Interactions in MR

vkimbrell

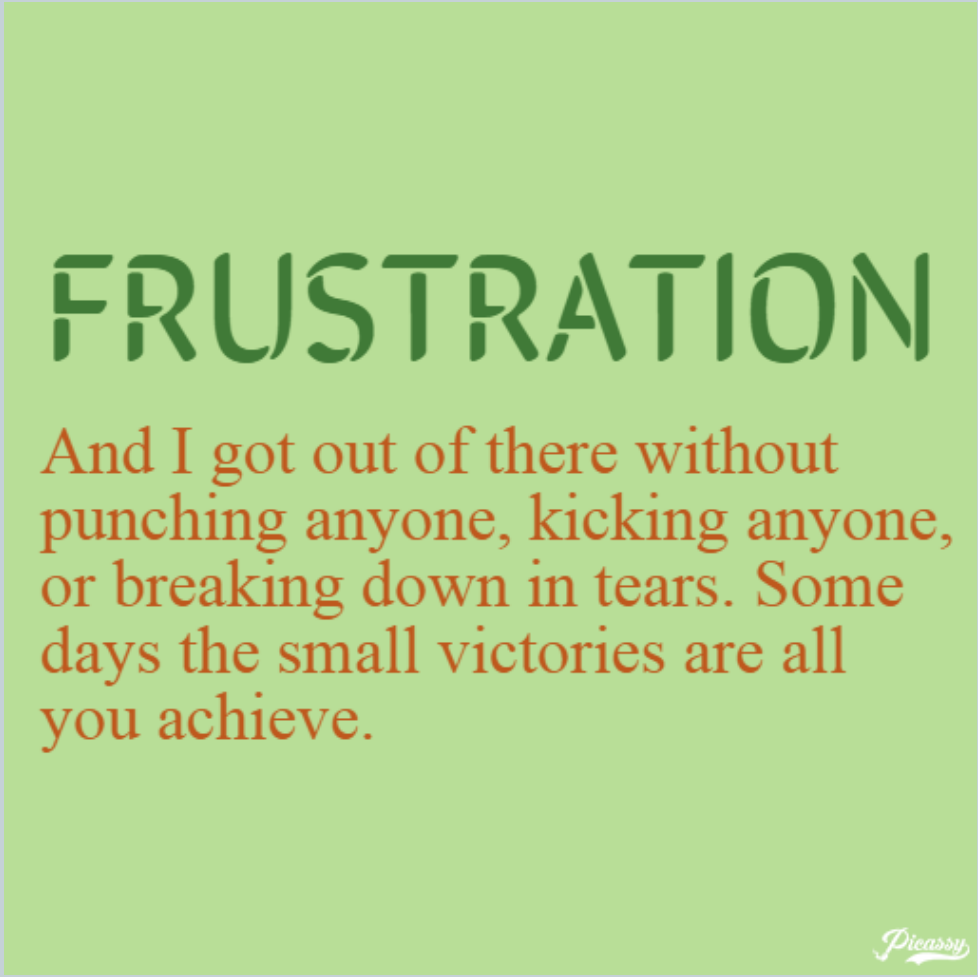
http://www.mhra.gov.uk/home/groups/dts-iac/documents/publication/con2033065.pdf

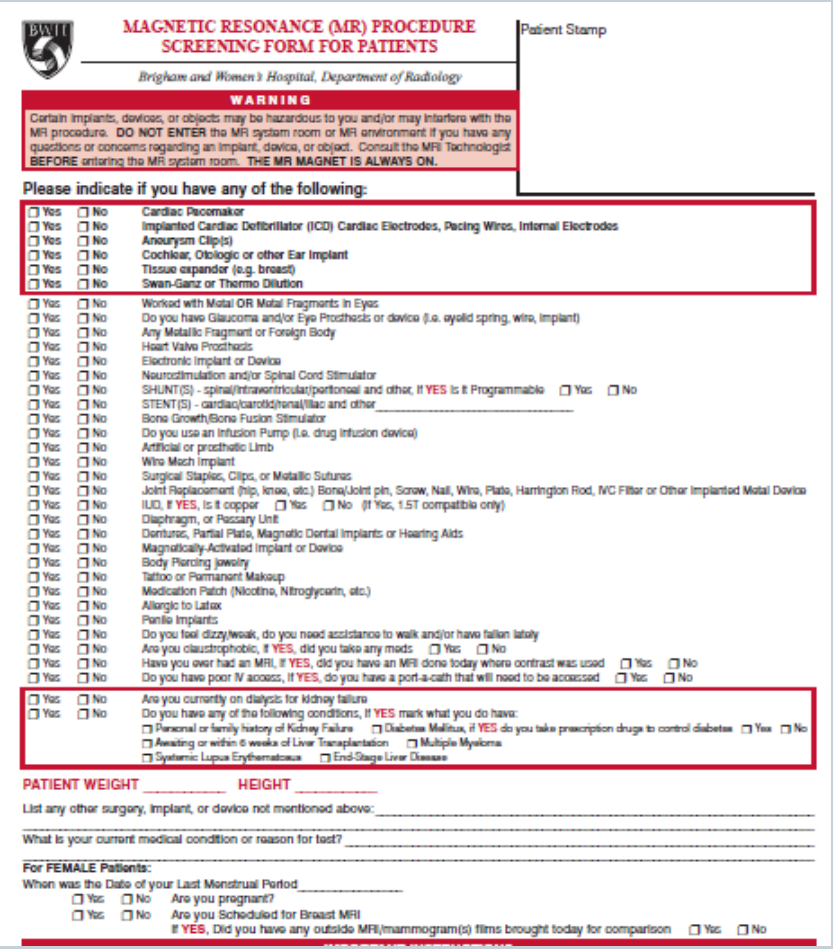
Challenges

- Screening to Identify Implants
- Researching implants
- Risk versus Benefit Decision
- Scanning Safely under the Conditions of a Device

Screening

- Patient Condition and Compliance
  - Language Barriers
  - Lack of overall understanding and memory of medical history
  - Blatant Disregard for potential dangers or misunderstanding the impact of incorrect answers





MAGNETIC RESONANCE (MR) PROCEDURE SCREENING FORM FOR PATIENTS

Brigham and Women's Hospital, Department of Radiology

Patient Stamp

WARNING

Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure. **DO NOT ENTER** the MR system room or MR environment if you have any questions or concerns regarding an implant, device, or object. Consult the MR Technologist **BEFORE** entering the MR system room. **THE MR MAGNET IS ALWAYS ON.**

Please indicate if you have any of the following:

☐ Yes	☐ No	**Cardiac Pacemaker**
☐ Yes	☐ No	**Implanted Cardiac Defibrillator (ICD) Cardiac Electrodes, Pacing Wires, Internal Electrodes**
☐ Yes	☐ No	**Aneurysm Clip(s)**
☐ Yes	☐ No	**Cochlear, Otologic or other Ear Implant**
☐ Yes	☐ No	**Tissue expander (e.g. breast)**
☐ Yes	☐ No	**Swan-Ganz or Thermo Dilution**
☐ Yes	☐ No	Worked with Metal OR Metal Fragments in Eyes
☐ Yes	☐ No	Do you have Glaucoma and/or Eye Prosthesis or device (i.e. eyelid spring, wire, implant)
☐ Yes	☐ No	Any Metallic Fragment or Foreign Body
☐ Yes	☐ No	Heart Valve Prosthesis
☐ Yes	☐ No	Electronic Implant or Device
☐ Yes	☐ No	Neurostimulation and/or Spinal Cord Stimulator
☐ Yes	☐ No	SHUNT(S) - spinal/intraventricular/peritoneal and other, If YES Is it Programmable ☐ Yes ☐ No
☐ Yes	☐ No	STENT(S) - cardiac/carotid/renal/iliac and other _____
☐ Yes	☐ No	Bone Growth/Bone Fusion Stimulator
☐ Yes	☐ No	Do you use an Infusion Pump (i.e. drug infusion device)
☐ Yes	☐ No	Artificial or prosthetic Limb
☐ Yes	☐ No	Wire Mesh Implant
☐ Yes	☐ No	Surgical Staples, Clips, or Metallic Sutures
☐ Yes	☐ No	Joint Replacement (hip, knee, etc.) Bone/Joint pin, Screw, Nail, Wire, Plate, Harrington Rod, IVC Filter or Other Implanted Metal Device
☐ Yes	☐ No	IUD, If YES, Is it copper ☐ Yes ☐ No (If Yes, 1.5T compatible only)
☐ Yes	☐ No	Diaphragm, or Pessary Unit
☐ Yes	☐ No	Dentures, Partial Plate, Magnetic Dental Implants or Hearing Aids
☐ Yes	☐ No	Magnetically-Activated Implant or Device
☐ Yes	☐ No	Body Piercing Jewelry
☐ Yes	☐ No	Tattoo or Permanent Makeup
☐ Yes	☐ No	Medication Patch (Nicotine, Nitroglycerin, etc.)
☐ Yes	☐ No	Allergic to Latex
☐ Yes	☐ No	Penile Implants
☐ Yes	☐ No	Do you feel dizzy/weak, do you need assistance to walk and/or have fallen lately
☐ Yes	☐ No	Are you claustrophobic, If YES, did you take any meds ☐ Yes ☐ No
☐ Yes	☐ No	Have you ever had an MRI, If YES, did you have an MRI done today where contrast was used ☐ Yes ☐ No
☐ Yes	☐ No	Do you have poor IV access, If YES, do you have a port-a-cath that will need to be accessed ☐ Yes ☐ No
☐ Yes	☐ No	Are you currently on dialysis for kidney failure
☐ Yes	☐ No	Do you have any of the following conditions, If YES mark what you do have:

☐ Personal or family history of Kidney Failure ☐ Diabetes Mellitus, if YES do you take prescription drugs to control diabetes ☐ Yes ☐ No
☐ Awaiting or within 6 weeks of Liver Transplantation ☐ Multiple Myeloma
☐ Systemic Lupus Erythematosus ☐ End-Stage Liver Disease

PATIENT WEIGHT _____ **HEIGHT** _____

List any other surgery, implant, or device not mentioned above: _____

What is your current medical condition or reason for test? _____

For FEMALE Patients:

When was the Date of your Last Menstrual Period _____

☐ Yes ☐ No Are you pregnant?

☐ Yes ☐ No Are you Scheduled for Breast MRI

If YES, Did you have any outside MRI/mammogram(s) films brought today for comparison ☐ Yes ☐ No

MR SAFETY IMPLANT WORKSHEET

Patient Name: **Patient MRN:**

Exam:

Scheduled time: 13:04:51 2014-09-11 **Scanner:** Select...

Referring MD:

Implant or device:

Make and Model

FOR AIMD WE ALSO NEED LEAD INFORMATION:

Location of the lead

Model # of the lead

- Device type and Group (1-5): Group 1 (See Worksheet 1)

  Check all that apply and attach information:

  - ☐ Manufacturer's recommendations
    - ☐ Safe
    - ☐ Conditional
    - ☐ Unsafe
    - ☐ Unclear or Does Not State
    - ☐ Cannot be located
  - ☐ Copy of Implant card
  - ☐ MRsafety.com references
  - ☐ Pertinent Literature (articles or documentation)
- All Group 2-5 devices need RBA by a Level 2 Certified MR Radiologist

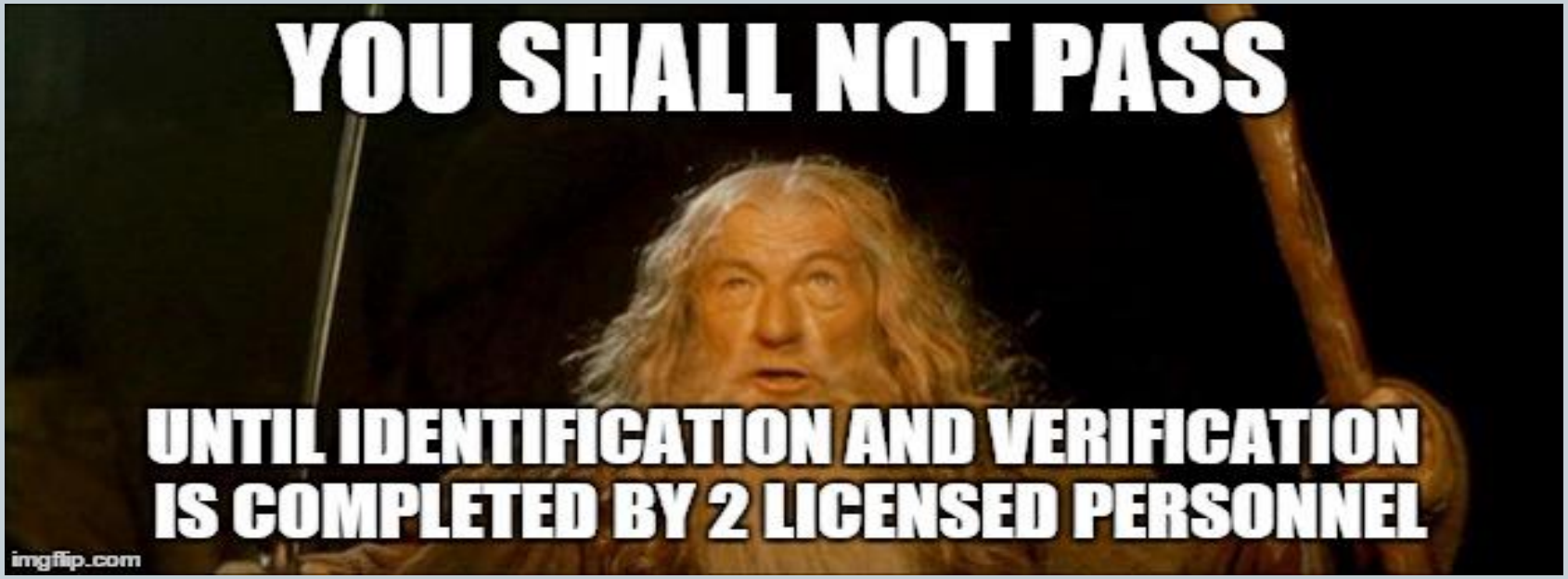
  Attached by technologist (check all that apply):

  ☐ Operative notes -- Filename: Browse... No file selected.

  (Download Click here)

Positive Identification of a Device

- At this date in time:
  - No standard exists for surgical notes or how implants are documented into medical records
  - There are guidelines but no laws for how companies making medical devices test implants and devices
  - The means of indentifying a device is not standard and no easy solution exists
    - RFID
    - X-ray
    - Implant cards, medical records, patient recollection



Researching Devices

- Correct information about the actual device
  - Implant cards
  - Surgery notes
  - Patient or family knowledge
  - Finding the actual company or manufacturer of the device
  - Obtaining information on MR testing and conditions for scanning

Risk versus Benefit Decisions

- Composite of all known information about the device
- Review of the patients history and medical need for the scan
- Decision to weigh this information and make a decision to scan or not to scan

Conditions for scanning

- Manufacturer of the Device has set up guidelines for scanning
- MR scanner and Zone 4 room has known design layout and properties
- MR Technologist must understand conditions and match those against the scanner capabilities and limits

Why is that so hard?

- Patient cooperation is not always good for many reasons
- Implant testing is not uniformly followed despite FDA guidelines
- Information on implants is not always easy to find
- Once found following the conditions and matching them to the scanner capabilities can be difficult

Physicist's role

- Large teaching hospitals typically have a team of highly trained PhDs available
  - Help build protocols, policy and procedure
  - Review data for devices as they come thru
  - Develop material for each scanner to help techs understand system specifications
  - Teach, train and participate in MR safety committees and informal groups
- Some sites are at a disadvantage and may need outside resources to accomplish work clearing implants

Physician/Radiologist's Role

- Knowledge and understanding of MR Safety
- Direct the process for screening and clearing devices
- Guide risk/benefit decisions
- Respond to concerns and support MR safety policies

Technologist Role

- Screen
- Research
- Provide the Radiologist(s) with latest and most complete MR safety information
- Remain educated and up to date on all MR Safety information and news
- Counsel patients about MR safety as it relates to screening, changing and potential safety concerns

Safety Issues

- Attraction by the B0 field
- Torque from moving thru B0 field
- Heating from the RF (B1)
- Current induction from the Gradient Field
  - Peripheral Nerve Stimulation
- Noise from the Gradients
- Artifacts
  - Metal
  - RF
  - Electrical currents

Screening and Changing Pts

- To ensure all pts are as safe as possible in our magnets please review the your safety policy and adhere to the following guidelines:
  - All pts must change into MR safe clothing prior to exam
  - All pts (or a proxy) must complete a MR screening form
  - All pts must have hearing protection
  - All implants and devices will be identified and researched as needed
  - Every patient will have a “communication tool” such as buzzer or squeeze ball in case of emergency
  - No patient will be left unattended during an exam
  - All Conditions and guidelines for safety will be followed

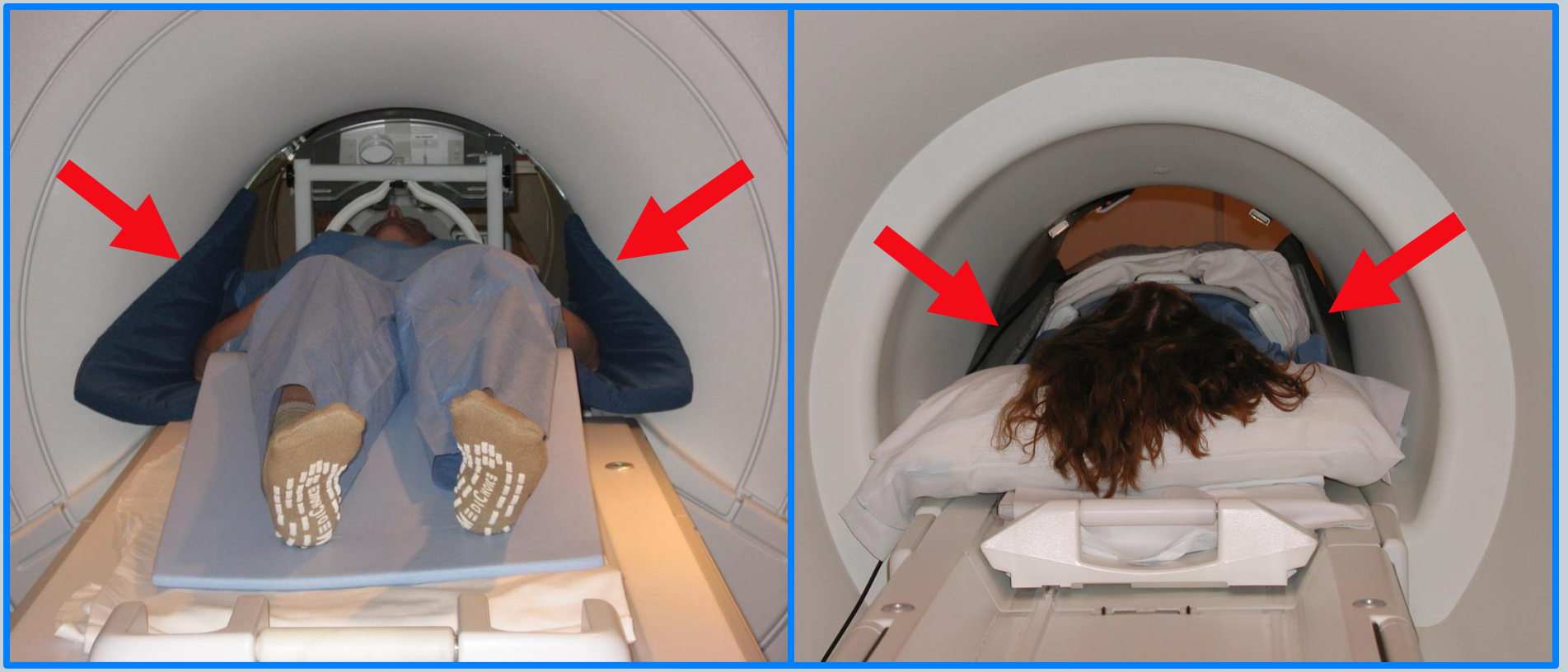
Scan room checks

- Infection control
  - Linen, coils, pads, etc. disinfected prior to placing pt on the table
  - RFID chips-New way to prevent theft—some artifacts
  - Review all equipment to ensure it is in good working order, is clean and properly housed in safe location
    - MR conditional equipment is at proper location
    - No loose wires, damaged or frayed connectors
    - All padding and linen is clean and in good condition
  - Review with pt and all who must enter the scan room to ensure they are MR safe

Positioning on table

- Tips for keeping pts safe in the RF (B1) field
  - Don’t bundle too much-remember we will heat them about 1’C
  - Room temp a little on the cool side-Vendor typically recommends 68’
  - Pad between the pt and all coils, wires, devices. Do not allow any loops that could conduct RF
    - Loops with wires
    - Loops by touching tissues
    - Loops when the body touches the RF coil (s)

RF Electromagnetic Fields (B_1)



Sponge pads are required between arms & magnet bore walls.

Courtesy of Anne Sawyer
Stanford University

B0 or the main magnetic field

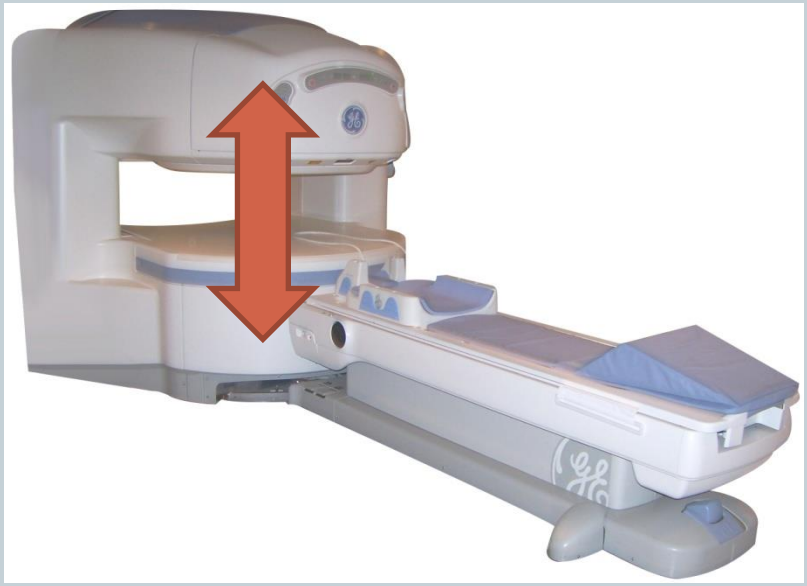
- Attraction when the metal is ferrous
  - FDA limits are 3T for clinical and 8T for all human research
  - Most implants are rated to 1.5T but most can be interpolated to higher field
- Torque as we move thru the field
  - Spatial field gradients
    - SFG(spatial field gradients) or MFG(magnetic field gradients)
    - g/cm or T/M

Types of Magnets

- *Horizontal Field*-This is all our magnets. It means the magnet field runs horizontally thru the magnet (s/i) or parallel to the bore
- *Vertical Field* is usually a permanent magnet and the magnetic field runs perpendicular to the bore/opening
- *Open vs. closed-This* term indicates that our “cylindrical” magnets are “closed”. The permanent C-shaped and clam shell design would be “open”

- Closed Bore-Horizontal field

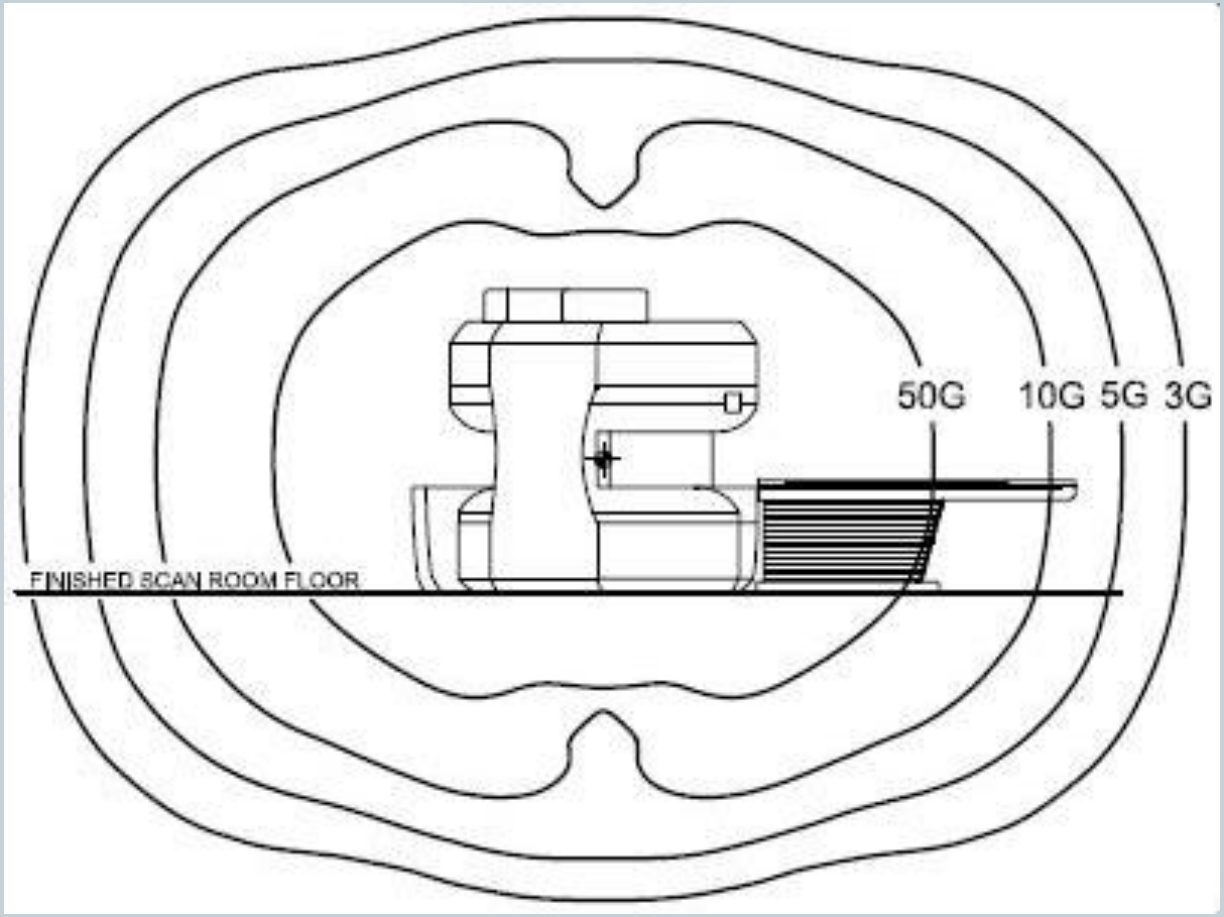
- Open Bore-Vertical field



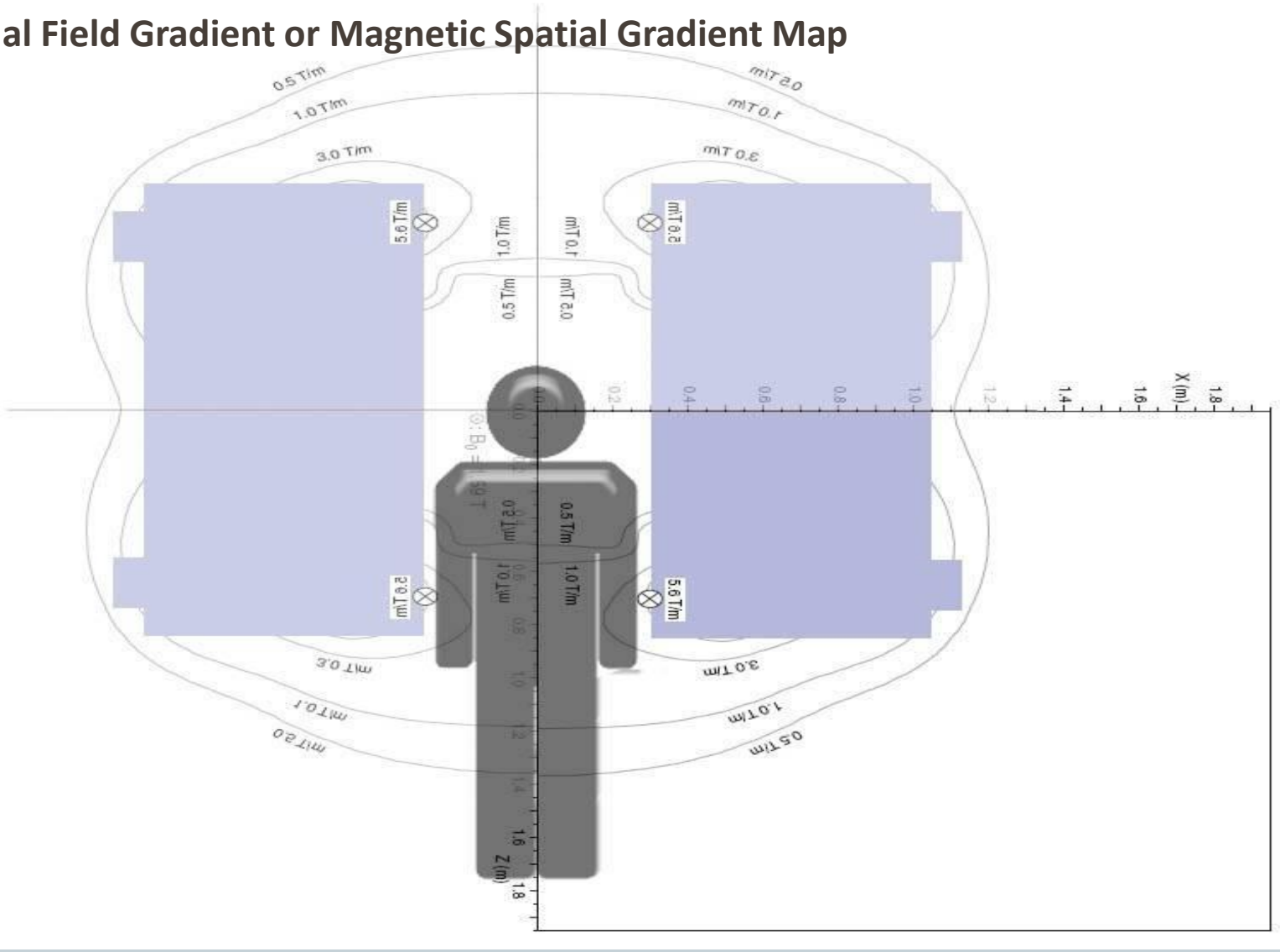
Spatial Field of B0

- Implants that have weak magnetic fields could experience “torque” as they move thru the field from high to low or vice versa
  - This could cause damage to the tissue surrounding the implant and is a risk for unknown stents, clips, coils, etc
- Fringe field is measured in gauss and the movement is g/cm or T/m
- Individual magnets SFG are written as a calculation of Field strength and shielding
- Typical #s- 550G/cm(5.5T/m) up to 1500G/cm (15T/m)
  - **To convert T/m to G/cm, multiply by 100*

Fringe Field of the Magnet



Spatial Field Gradient or Magnetic Spatial Gradient Map

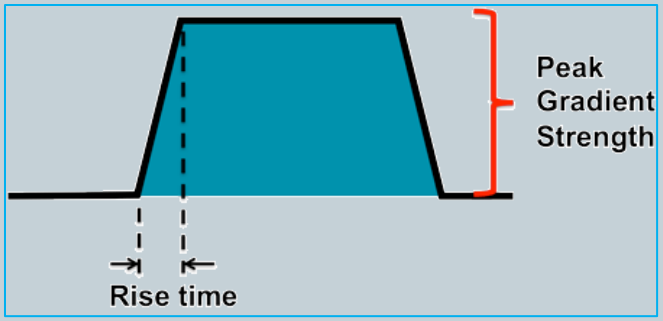


Spatial Gradient Field

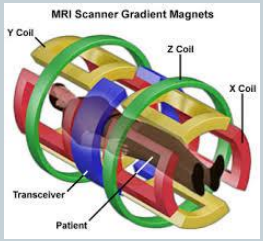
- As you walk either towards or away from the middle of the magnet you will experience a changing magnetic field. This is the Spatial Gradient or Magnetic Spatial Gradient Field
- Measured in Gauss per cm (strength over distance) or mTesla per meter (i.e..... 11T/m = 1100 G/cm)
- SGF is strongest at the front and back of the magnet on both sides

Gradient Slew Rate

- This relates to the strength and speed of the gradients (those that make the loud noise). Slew rate is a product of how fast and at what power the gradients are working.
- A typical high end new system is 200 T/m/s
- Gradient modes vary
  - SLOW (quietest and weakest)
  - NORMAL
  - FAST (loudest and strongest)



http://mri-q.com/gradient-specifications.html

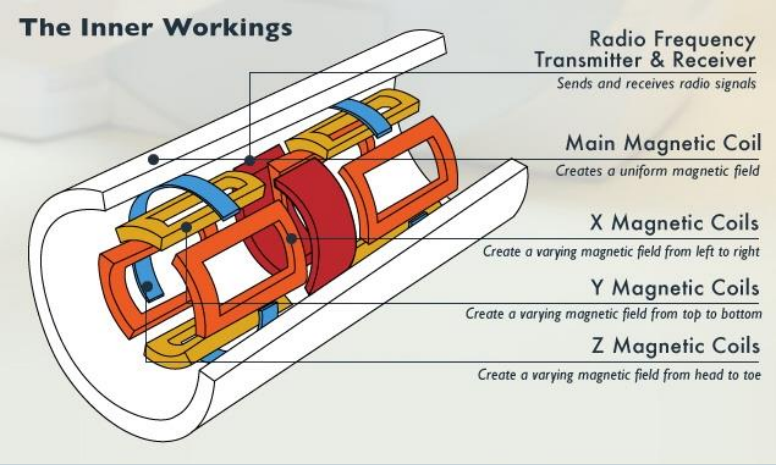


Radio Frequency

- Sometimes referred to as B1
- Transmit coil
  - Is actually creating a weak magnetic field
  - Uses power to send RF into the pt based on pulse sequence and pts weight and distribution
  - Typically the body or internal coil but in the case of some T/R coils (head and ext usually) one local coil may do both
- Receive coil
  - Is only the antenna and not a power source
  - Remember the RF transmission does generate a current. Any current can have consequences

https://nationalmaglab.org/education/magnet-academy/learn-the-basics/stories/mri-a-guided-tour

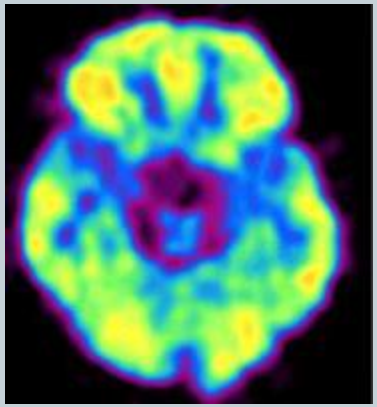
Transmit RF



https://nationalmaglab.org/education/magnet-academy/learn-the-basics/stories/mri-a-guided-tour

- **SAR** (Specific Absorption Rate) is a calculation of pulse sequence needs and the patients weight/tissue makeup
  - Prescan does this job. During this step the RF power is calculated (slightly differently for different scanners/vendors)
- **B1 rms** (root mean square) is calculated from RF power the scanner will output for the sequence you want to run
  - Measured in microTesla(μT)(1,000,000 μT = 1 T)
  - The same parameters that reduce SAR also reduce B1rms

Heating measurements



- Specific Absorption Rate limits
  - Low SAR (most conservative level) 1.2 w/kg
  - Normal -2w/kg *most implants want this*
  - 1st level (highest clinical level) 4 w/kg
  - 2nd or Research level (need research key)
- These are buttons on your machine and can be set during the scan. You also can view the “SAR monitor” to see how close you are to your limits
- Newer cards may read B1rms (that is the total power output of the RF) Measured in microtesla the number is specific to the protocol and not the pt.

http://www.eeweb.com/electronics-quiz/what-is-the-maximum-specific-absorption-rate-sar-allowed-in-the-us-for-cell

What impacts Heating?

- All Parameters that affect RF
  - TR
    - Because if you deliver a RF pulse then wait (time of repetition) we give the tissue coiling time
  - Echo Trains/Turbo Factor
    - Each of these are RF pulses more ETL or TF is more RF
    - Flip angle of the ETL/TF (higher flips are more RF power)
  - SAT Bands-
    - This are RF pulses therefore more SAR
  - More Slices=more RF transmission

What impacts PNS?

- Type and Slew rate of the Magnet
- Type of Pulse sequence
- Gradient mode
- Patient positioning
- Equipment/leads?

What impacts Noise?

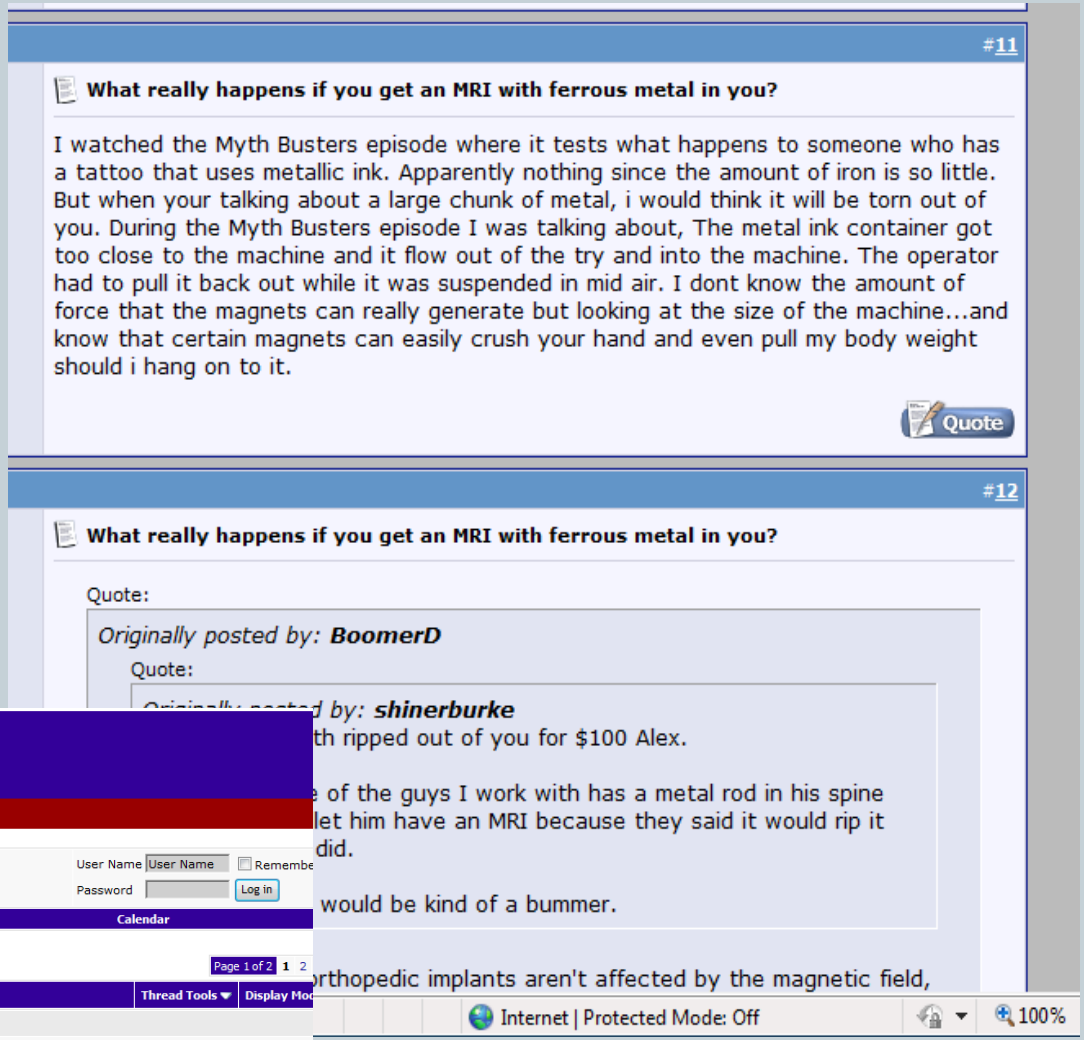
- Type and Slew rate of the Magnet
- Type of Pulse sequence
- Gradient mode
- Type and function of Hearing protection
- Patient to some degree

Let's now look at some implants and talk about if & how to scan patients who have them-

- **Decision: "a conclusion or resolution reached after consideration."**
- **Risk: :An unknown with measurable probability"**

Disclaimer*******The second I drafted this it became out-dated. Every implant should be researched prior to scan for the most updated information. This is meant only as a guideline and educational tool. Refer to LMR instructions to direct you to look up devices.

Because everything you read on the internet is true….



#11

What really happens if you get an MRI with ferrous metal in you?

I watched the Myth Busters episode where it tests what happens to someone who has a tattoo that uses metallic ink. Apparently nothing since the amount of iron is so little. But when your talking about a large chunk of metal, i would think it will be torn out of you. During the Myth Busters episode I was talking about, The metal ink container got too close to the machine and it flow out of the try and into the machine. The operator had to pull it back out while it was suspended in mid air. I dont know the amount of force that the magnets can really generate but looking at the size of the machine...and know that certain magnets can easily crush your hand and even pull my body weight should i hang on to it.

Quote

#12

What really happens if you get an MRI with ferrous metal in you?

Quote:

Originally posted by: ***BoomerD***

Quote:

Originally posted by: ***shinerburke***

th ripped out of you for $100 Alex.

of the guys I work with has a metal rod in his spine let him have an MRI because they said it would rip it did.

would be kind of a bummer.

orthopedic implants aren't affected by the magnetic field,

Internet | Protected Mode: Off

100%

THE STRAIGHT DOPE

FIGHTING IGNORANCE SINCE 1973

(IT'S TAKING LONGER THAN WE THOUGHT)

Straight Dope Message Board > Main > General Questions

Can an MRI really rip metal through flesh?

User Name | Password | Log in

Register | FAQ | Calendar

Post Reply

Page 1 of 2 1 2

Thread Tools | Display Mo

04-25-2010, 12:29 AM

Stoid

Charter Member

Join Date: Jun 199
Location: City of A
Posts: 14,301

Can an MRI really rip metal through flesh?

Magnetic Resonance Imaging or "MRI" uses a super-powerful magnet. So they always tell you to remove all metal, and apparently cannot be used on anyone who has metal inside his or her body.

I've heard joking remarks on TV about MRIs ripping people open if used on someone with metal in their body. Would that really happen?

I was watching 20/20 about a woman who has shotgun pellets in her brain and I thought - man, an MRI would scramble her brains!

So what's the truth? I'm sure shotgun pellets probably could be pulled through brain tissue, which is notoriously soft, and the pellets are unanchored. But what about and plates bound in bones?

Reading conditional labeling

conditions:

- Horizontal closed bore clinical scanner working in the Normal Operating Mode or First Level Controlled Operating Mode, whole body specific absorption rate (SAR) ≤4.0 W/kg and head SAR ≤3.2 W/kg.
- Static magnetic field strength of 1.5 Tesla (T) only
- Maximum gradient slew rate of 200 T/m/s per axis.

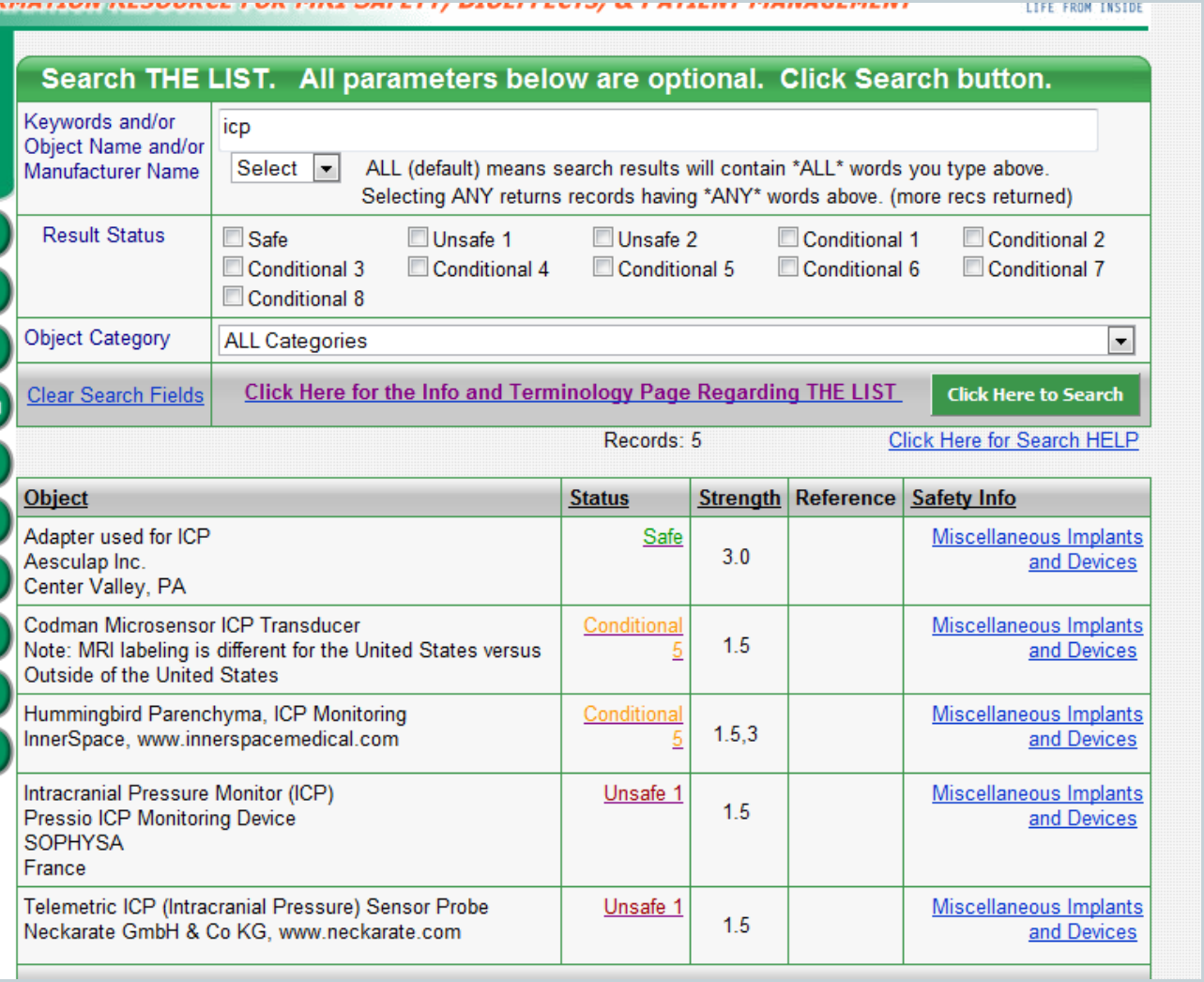
MR Conditional Contraindications

- Patients who do not have a complete St. Jude Medical® MR Conditional pacing system, which includes a St. Jude Medical MR Conditional pulse generator and St. Jude Medical MR Conditional leads, are contraindicated for an MRI scan.
- Patients with broken or intermittent St. Jude Medical MR Conditional leads, or lead impedance measurements not within the programmed lead impedance limits are contraindicated for an MRI scan.
- Patients with abandoned cardiac hardware including leads, lead extenders, or lead adaptors are contraindicated for an MRI scan.
- Use of local transmit-only coils or local transmit and receive coils placed directly over the pacing system has not been studied and such use is contraindicated.
- All spectroscopy and imaging for atoms other than hydrogen are contraindicated.

Aneurysm Clips

- ***Aesculap does not recommend the use of MRI on a patient implanted with a YASARGIL aneurysm clip identified with the letters "FD".***
- **Op notes are needed to Positively Indentify the Device.**
- **Must know the Make/Model and be able to look them up. www.mrisafety.com is a pretty good place to start.**
  - **Yes I know they are mostly ok…however the consequence of getting this wrong could be fatal to your pt.**

Intracranial Pressure Monitors (ICP)



Search THE LIST. All parameters below are optional. Click Search button.

Keywords and/or Object Name and/or Manufacturer Name: icp

Select — ALL (default) means search results will contain *ALL* words you type above. Selecting ANY returns records having *ANY* words above. (more recs returned)

Result Status: Safe, Unsafe 1, Unsafe 2, Conditional 1, Conditional 2, Conditional 3, Conditional 4, Conditional 5, Conditional 6, Conditional 7, Conditional 8

Object Category: ALL Categories

Clear Search Fields | Click Here for the Info and Terminology Page Regarding THE LIST | Click Here to Search

Records: 5 | Click Here for Search HELP

Object	Status	Strength	Reference	Safety Info
Adapter used for ICP Aesculap Inc. Center Valley, PA	Safe	3.0		Miscellaneous Implants and Devices
Codman Microsensor ICP Transducer Note: MRI labeling is different for the United States versus Outside of the United States	Conditional 5	1.5		Miscellaneous Implants and Devices
Hummingbird Parenchyma, ICP Monitoring InnerSpace, www.innerspacemedical.com	Conditional 5	1.5,3		Miscellaneous Implants and Devices
Intracranial Pressure Monitor (ICP) Pressio ICP Monitoring Device SOPHYSA France	Unsafe 1	1.5		Miscellaneous Implants and Devices
Telemetric ICP (Intracranial Pressure) Sensor Probe Neckarate GmbH & Co KG, www.neckarate.com	Unsafe 1	1.5		Miscellaneous Implants and Devices

- The Camino 110-4B, Camino 110-4BT, Camino 110-4G, and the Camino 110-4L are MR Unsafe.

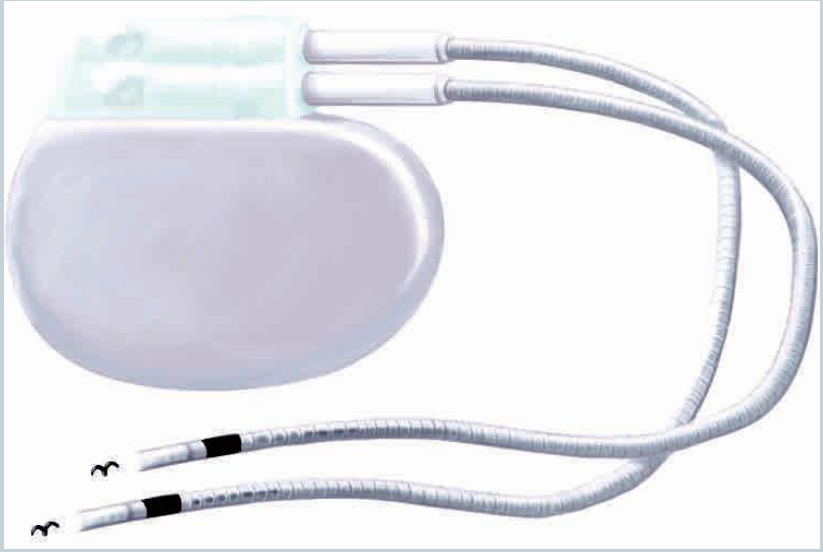
Mrisafety.com

Pacemaker

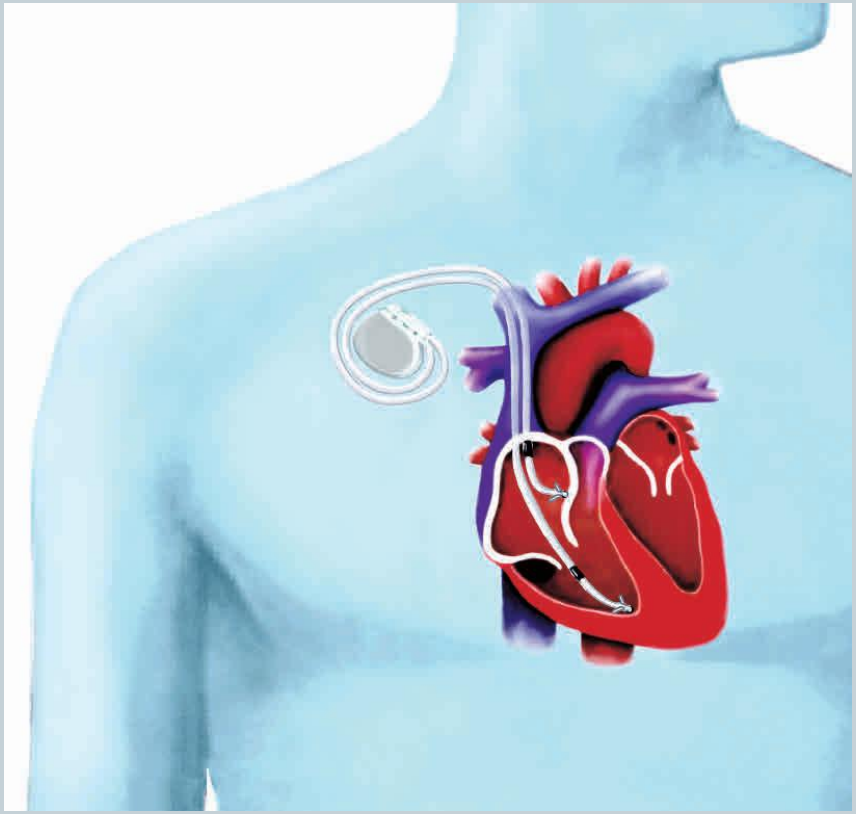
- Patients with bradycardia may be eligible for a

  pacemaker that will monitor their heart. If the pacemaker detects an irregular or slow heart rate it will send out electrical signals to correct it.

Some but not all are MR Conditional



Revo/Advisa Medtronics system



- The SureScan® pacing system is MR Conditional designed to allow patients to undergo MRI under the specified conditions for use. A complete system, consisting of a Medtronic MRI SureScan IPG implanted with two CapSureFix MRI® SureScan leads, is required for use in the MRI environment.

Revo/Advisa Conditions:

Pt must have Cardiology appt 1st to put the device into Safe mode

- Horizontal cylindrical bore magnet static magnetic field of 1.5 Tesla (T)
- Maximum gradient slew rate performance per axis of ≤ 200 Tesla per meter per second(T/m/s) must be used.
- The scanner must be operated in Normal Operating Mode
- Proper patient monitoring must be provided during the MRI scan. This includes visual and verbal contact with the patient, and monitoring heart rate using instrumentation

Implanted Cardiac Defibulator

- ICD-conditions are similar to Pacemaker
- Medtronics has a Evera Surescan that has the exact same conditions as the Revo and Advisa pacer

Cardiac Monitoring

- Reveal® XT Insertable Cardiac Monitor (ICM) captures the ECG you need to make informed decisions about your syncope patients and those who experience transient symptoms that may suggest a cardiac arrhythmia.
- **Reveal XT ICM Provides**
- 3-year longevity for long-term monitoring[1]
- MR conditional labeling for safe patient management‡
- Medtronic CareLink® Network compatibility for remote monitoring

MR Conditions Medtronics Reveal and Linq

A patient with a Reveal LINQ device can be safely scanned in an MR system that meets the following conditions. Failure to follow these conditions for use may result in a hazard to the patient during an MRI scan:

- Cardiology must first download all data as the MR may erase information
- Horizontal cylindrical bore magnet, clinical MRI systems with a static magnetic field of 1.5 Tesla (T) or 3.0T
- Maximum spatial gradient of the static magnetic field specification must be ≤25 T/m (2500 gauss/ cm).
- Whole body gradient systems with gradient slew rate specification must be ≤200 T/m/s per axis.
- The Whole Body Specific Absorption Rate (WB-SAR) as reported by the MRI equipment must be ≤4.0 W/kg; the head SAR as reported by the MRI equipment must be ≤3.2 W/kg.
- Do not use local transmit coils on the chest, trunk, or shoulder region.
- There are no restrictions on the placement of receive-only coils, and there are no restrictions on the use of local transmit or receive coils for imaging of the head or extremities

Vagus Nerve Stimulator

Cybertronics

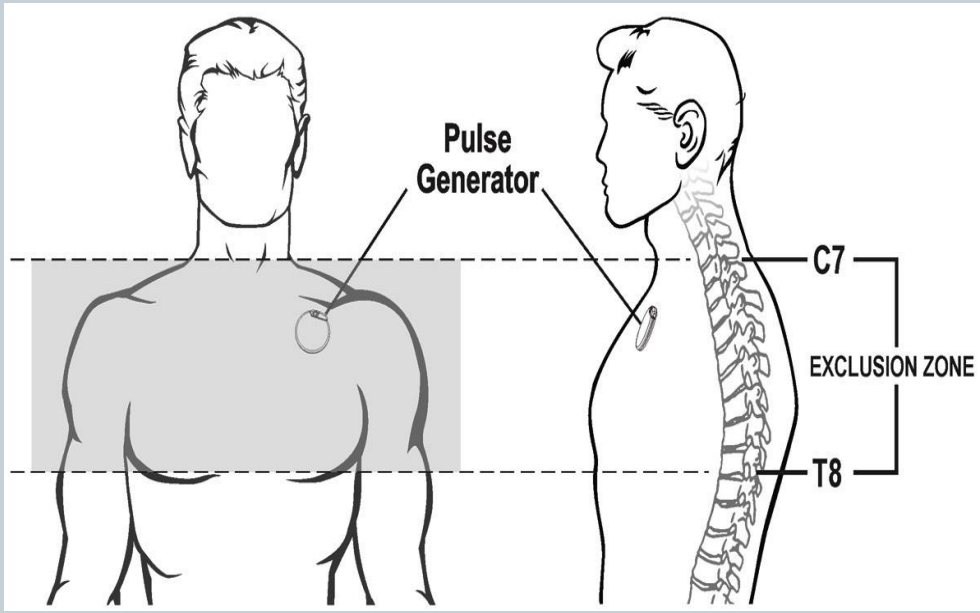
Generator Model	102	102R	103	104	105
Lead Compatibility	Single Pin	Dual Pin	Single Pin	Dual Pin	Single Pin
Available Since	2002	2003	2007	2007	2011
Thickness*	7 mm	7 mm	7 mm	7 mm	7 mm
Volume*	14 cc	16 cc	8 cc	10 cc	14 cc
Weight*	25 g	27 g	16 g	18 g	25 g

VNS MR Conditional

MR Conditions

- Patient appt before and after with Neurology
- 1.5 or 3T
- Transmit and Receive coil
- SGF-720 g/cm
- Normal operating mode

Exclusion Zone

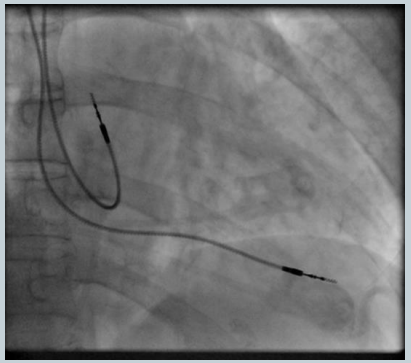


Medtronics MRI Device Types

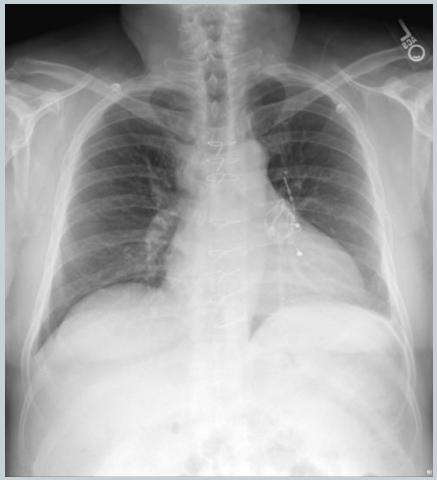
********Always review the most current labeling prior to performing an MRI scan.

Deep Brain Neurostimulators
Gastric Electrical Neurostimulators
Intrathecal Drug Infusion Systems
Sacral Nerve Neurostimulators
Spinal Cord Neurostimulators
Other Medtronic products

Retained Leads



- **Pericardial Leads**
  - Patients with retained temporary *epicardial* pacing wires are believed to be able to safely undergo MRI procedures. Importantly, these patients do not need to be routinely screened for the presence of such wires before scanning. Because of the possible risks involved with temporary-pacemaker external pulse generators, such pulse generators should not be allowed in the MRI environment.



- **Intracardial leads**
  - scanning patients with temporary *intracardiac* pacing leads (without the pulse generator) is not recommended, although lead heating might be minimized or avoided by scanning anatomic regions above (e.g., head/brain) or below (e.g., lower extremities) the cardiac pacing leads. Furthermore, because the harsh electromagnetic environment associated with the MR system can alter the operation of an external pulse generator or damage it, it may not be possible to reliably pace the patient during the MRI examination, which makes the issue of scanning a patient with a temporary intracardiac, transvenous lead irrelevant in most cases.

http://www.mrisafety.com/SafetyInfov.asp?SafetyInfoID=286

Medtronics Interstim Bladder stimulator

- The implantable InterStim neurostimulator produces mild electrical pulses that are delivered via the lead to an area near the sacral nerve to help normalize neural activity from the bladder or bowel to the brain. Control of symptoms is achieved through direct modulation of the nerve activity that influences the behavior of the pelvic floor, lower urinary tract, urinary and anal sphincters, and colon.*

Interstim Bladder Stimulator

- 1.5-Tesla (T) horizontal closed bore
- Maximum spatial gradient of 19 T/m (1900 gauss/cm)
- RF transmit/receive head coil only (no RF transmit body coil)
  - Usually only head and ext coils (BWH-Pike, L1-Aera)
- Gradient slew rate limited to 200 T/m/s
- Normal operating mode
- If possible, do not sedate the patient

- Pt will need potentially an appt with Urology pre and post
  - **Model 3058 and eligible Model 3023 Neurostimulators: Turn the neurostimulator off**
  - **Eligible Model 3023 Neurostimulators only: Disable the magnet switch**

Deep Brain Stimulator

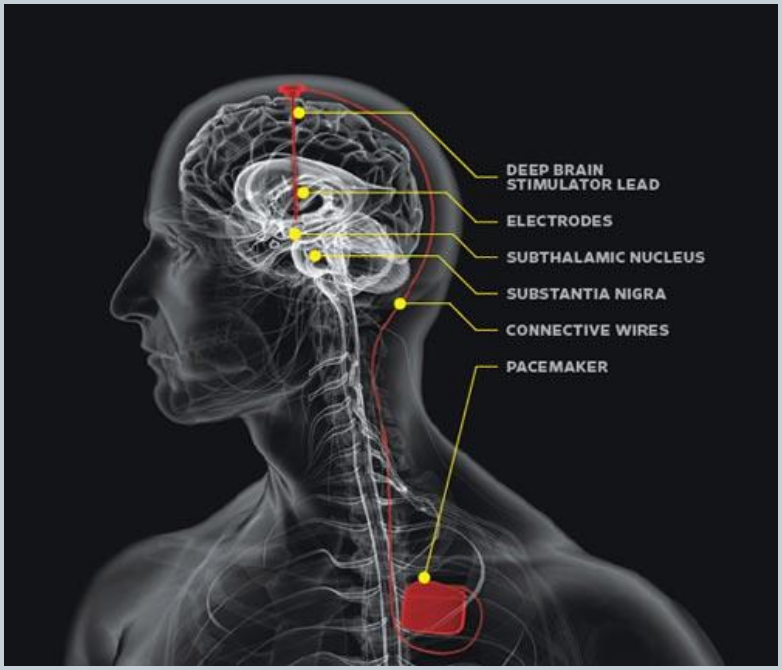
Models that are MR conditional

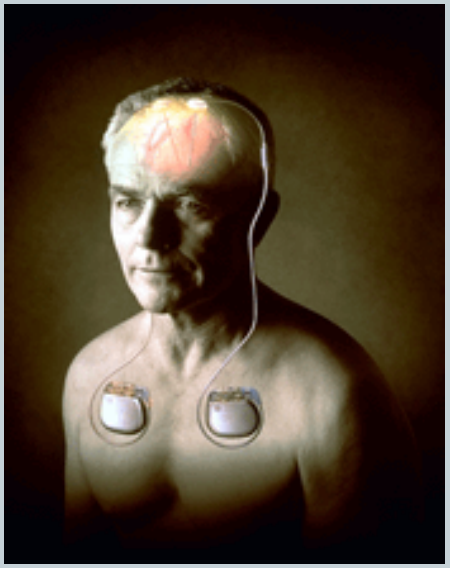
- Itrel II Model 7424
- Soletra Model 7426
- Kinetra Model 7428
- Activa PC Model 37601
- Activa RC Model 37612
- Activa SC Model 37602
- Activa SC Model 37603

Recommended neurostimulator settings (for all programs) for MRI Parameters Settings

Stimulation output :

- Turn neurostimulator off for: Itrel II, Soletra,Kinetra, Activa PC, Activa RC, and ActivaSC
- Stimulation mode-Bipolar (Soletra and Itrel II only)
  - Amplitude 0 volts (Soletra and Itrel II only)
  - Magnetic (reed) switch Disabled (Kinetra only)
  - Day cycling Disabled (Kinetra only)
  - Other parameters Do not change





DEEP BRAIN STIMULATOR

Similar to a pacemaker, the device contains a battery and microelectric circuitry that provides a controlled electrical pulse. It is implanted under the skin near the clavicle. The electrical signals generated are delivered to the desired region of the brain via an extension and lead. Also called a pulse generator.

Medtronics DBS-MR Conditions

- Pt must have appt with Neurology to evaluate the device and program to correct mode
- Average head SAR to 1/10(0.1)W/kg or less for all RF pulse sequences unless the applied SAR is known
- 1.5-Tesla horizontal bore MRI
- Use only a transmit-receive head coil
- Gradient dB/dt field to 20 Tesla per second or less
  - Normal Gradient mode
- Monitor the patient both visually and audibly
- Verify that the stimulator is functional.
- Reprogram the stimulator to pre-MRI settings.

New labeling 2017

MRI and Medtronic DBS Therapy

MR Conditional – Non-clinical testing has demonstrated that Medtronic DBS Systems have been found to be MR Conditional. If this patient is implanted with a Medtronic DBS System, MRI examinations of the head or the entire body may be safely performed depending on the DBS syste components implanted.

Medtronic DBS Systems that are eligible for MRI scans of the entire bod full-body eligible) must be scanned under the following conditions:

- 1.5-tesla (T) horizontal closed bore
- Maximum spatial gradient of 19 T/m (1900 gauss/cm)
- RF transmit/receive body coil (built-in) or RF transmit/receive head
- Maximum RF power of 2.0 µT B1+rms (B1+ root mean squared)
- If B1+rms is not available, a maximum RF power of 0.1 W/kg (0.05 whole body and head SAR (specific absorption rate). Using a SAR setting may result in a more restrictive MRI scan.
- Gradient slew rate limited to 200 T/m/s

Medtronic DBS Systems that are eligible for MRI scans of the head only must be scanned under the following conditions:

- 1.5-tesla (T) horizontal closed bore
- RF transmit/receive head coil only
- Maximum RF power of 0.1 W/kg (0.05 W/lb) head SAR
- Gradient slew rate limited to 200 T/m/s

Programmable Shunts

- Static magnetic field of 3.0 Tesla or less
- Spatial Gradient of 720 G/cm or less
- Radio Frequency (RF) Fields with an average Specific Absorption Rate (SAR) of 3 W/kg for 15 minutes.
- Performance level setting should always be checked before and after MRI exposure.

********Subjecting the programmable valve placed in various orientations to multiple exposures to the 3-T static magnetic field and MRI performed using eight different pulse sequences altered the valve setting for 56% to 67% of the devices

Strata NSC Lumboperitoneal Adjustable Pressure Shunts

- Strata® NSC LP adjustable pressure shunts provide treatment for communicating hydrocephalus and idiopathic intracranial hypertension (pseudotumor cerebri).

- The PS Medical Strata NSC lumboperitoneal valve is considered Magnetic Resonance Conditional
- MRI systems of up to 3.0 Tesla may be used any time after implantation and will not damage the Strata® II valve mechanism, but can change the performance level setting. The performance level setting should always be checked before and after MRI exposure.
- Static magnetic field of 3.0 Tesla or less
- Spatial Gradient of 720 G/cm or less
- Radio Frequency (RF) Fields with an average Specific Absorption Rate (SAR) of 3 W/kg for 15 minutes.
- Using the GE 3.0T Excite® HD Magnetic Resonance Imaging System, the valve experienced a maximum temperature change of 0.4°C over a 15-minute exposure period.

Boston Scientific Precision Stimulators for Pain

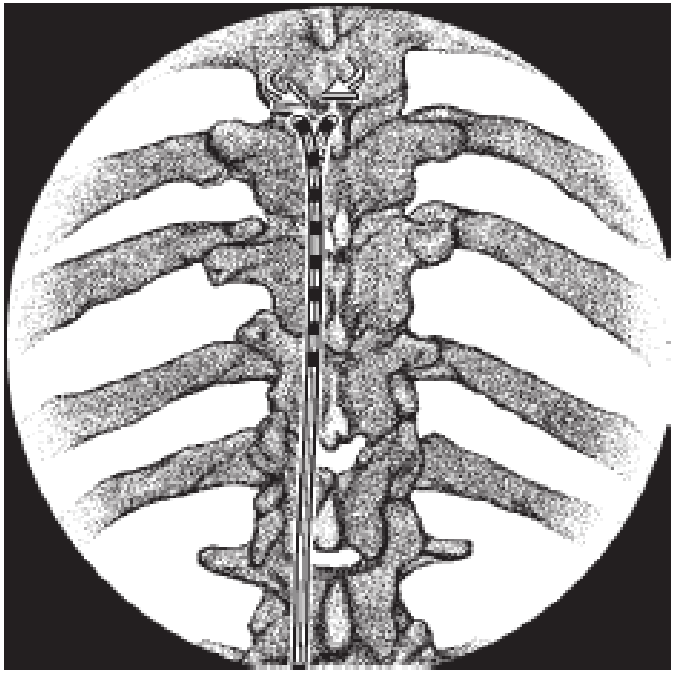
- Pt to have Neuro visit pre/post exam
  - 1.5 T Horizontal closed bore
  - 4000g/cm spatial gradient
  - Transmit/Receive Head coil
  - Gradient strength-200 T/m/s
  - No RF within 10cm of components
  - Normal operating mode
  - Monitor pt visually and verbal communication

Medtronics Spinal Stimulator

- A Medtronic implantable neurostimulation system is indicated for spinal cord stimulation (SCS) system as an aid in the management of chronic, intractable pain of the trunk and/or limbs-including unilateral or bilateral pain

- **Applicable Systems:**
- RestoreSensor® SureScan® MRI Model 97714
  RestoreSensor® Model 37714
  RestoreUltra® SureScan® MRI Model 97712
  RestoreUltra® Model 37712
  RestoreAdvanced® SureScan® MRI Model 97713
  RestoreAdvanced® Model 37713
  Restore® Model 37711
  RestorePrime® Model 37701
  PrimeAdvanced® SureScan® MRI Model 97702
  PrimeAdvanced® Model 37702
  SynergyPlus® Model 7479
  SynergyCompact® Model 7479B
  Synergy® Model 7427
  Synergy Versitrel® Model 7427V
  Itrel® 3 Model 7425

Medtronic Spinal Stimulator



NOTE:
Ensure that the pocket is created so the neurostimulator will be placed parallel to the skin and at a depth that allows for efficient and successful telemetry and recharging (if applicable):

For rechargeable neurostimulators:
Implant no deeper than 1 cm below the skin.

For non-rechargeable neurostimulators:
Implant no deeper than 4 cm below the skin.

4 Making sure not to allow fluid into the connector block, verify the pocket size (FIGURE 46).

ılator

MR Conditions for Medtronic's Spinal Stimulator

- **Caution: Before conducting the MRI scan, confirm that the patient's implanted neurostimulation system is off ******Pt. needs appt with Neurosurg pre and post**
- 1.5-T horizontal closed bore with maximum
- Spatial gradient of 19 T/m (1900 gauss/cm)
- Transmit coil:
  - body transmit/receive (built-in), quadrature only.
  - head transmit/receive, quadrature only.

Pain Pumps

- The SynchroMed II (Baclofen)Infusion System is indicated when patient therapy requires the long-term infusion of drugs or fluids.

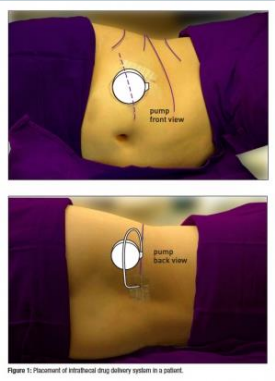
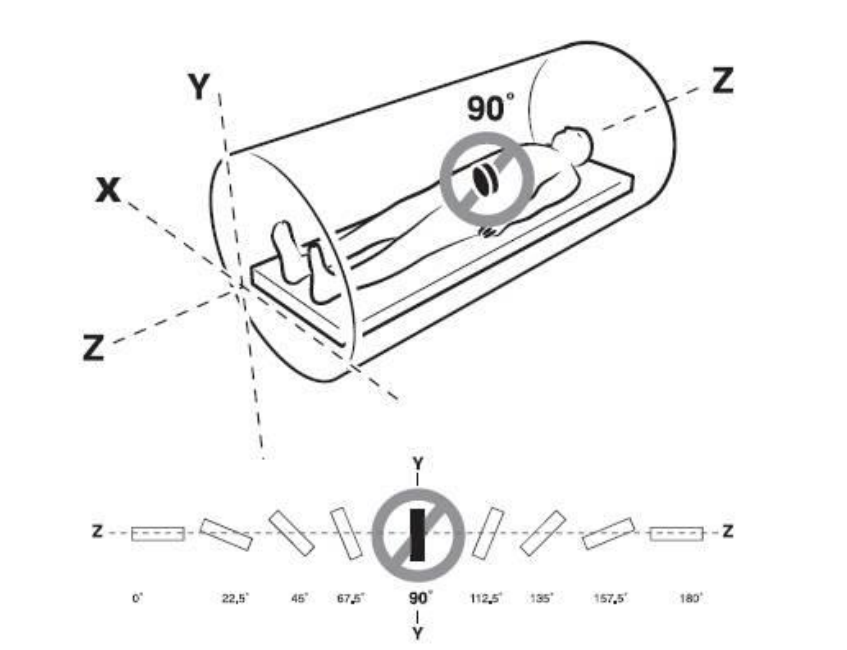


Figure 2: Medtronic Synchromed II Intrathecal Pump, the health care provider programmer, and the patient therapy manager.
Images courtesy of Medtronic, Inc.

Conditions of Synchromed Pain Pumps

Not safe when device is Perpendicular or 90’ to Z axis



- 3T
- Normal Mode
- 20 T/s db/dt
- Device must be parallel with the Z axis. **Not** perpendicular (90’)
- Image artifacts may occur if scanning area where of pump
- Device must be interrogated post MR to insure it is working correctly

General Guidelines for Otologic devices

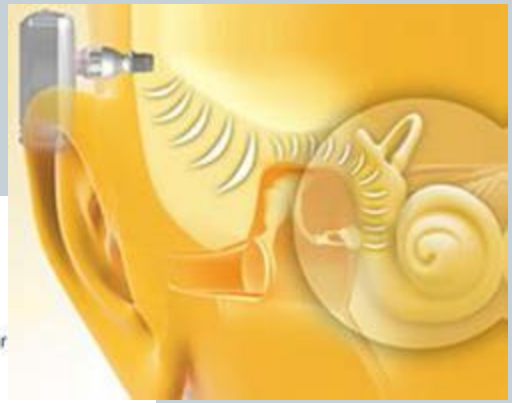
Stapes Prosthesis and Metallic Middle Ear Ossicular Chain Reconstruction Implants: All devices are safe for use in a 1.5T magnetic field or less with the exception of the 1987 McGee stainless steel prosthesis.

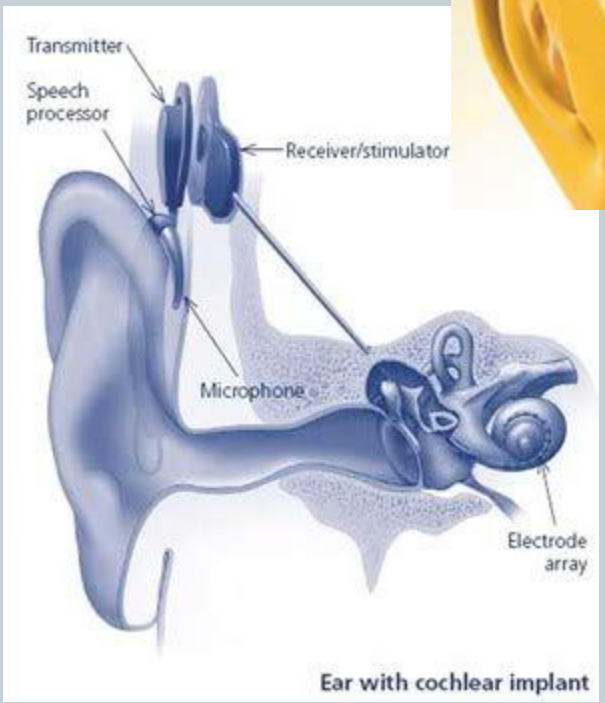
Osseointegrated Cochlear Stimulator: The BAHA and Ponto System by Oticon Medical's abutment and fixture are MRI safe. The Sophono Alpha 1 is contraindicated for MRI use as it involves an implanted magnet which ultimately osseointegrates into the skull.

Middle Ear Implantable Hearing Devices: These devices are contraindicated for MRI use. There are several studies in the literature looking at the effect of MRI on patients with Vibrant Soundbridge implants. There are reports of disturbing noise perception, pain, pressure at the receiver bed, subcutaneous movement of the implant
receiver, and the need for repositioning of the FMT portion of the VSB in these patients.

Cochlear Implants: Overall these Implants are contraindicated for MRI use in the United States with some exceptions. Implants with removable magnets can be safely used when the magnet is removed. The newer MEDEL implants are approved in magnetic strengths up to 0.2T.

Cochlear Implants





Current Cochlear Implant Systems

- The Nucleus Cochlear Implant Systems
- The Clarion Cochlear Implant Systems
  - Removable magnet for MRI compatibility. MRI safe for scans at 0.3T and and 1.5T with the magnet removed
- The MED-EL Cochlear Implant
  - This is the one that says you can put elastic around the head. .2 and 1.5T safe

Nucleus Bone conductors (BaHa)

- **The Cochlear™ Nucleus® 5 (CI500 series) Cochlear Implant, Cochlear Nucleus Freedom™ cochlear implant, Nucleus 24 cochlear implant, and some Nucleus 22 cochlear implants have a removable magnet and specific design characteristics to enable them to withstand MRI up to 1.5 tesla with the magnet removed, but not higher. Those with a magnet in place must not enter Zone 4.**

Baha Cochlear Implants

- *The Baha sound processor and SP Magnet* ***must be removed before entering a room where an MRI***
- *scanner is located.*
- Non-clinical testing has demonstrated that the BIM400 Implant Magnet, in combination with BI300 Implant,
- is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following
- conditions. Scanning under other conditions may result in severe patient injury or device malfunction.
  - • Static magnetic field of 1.5 Tesla only
  - • Maximum spatial gradient field of 26600 Gauss/cm (266 T/m)
  - • Maximum switched gradient slew rate per axis of 200 mT/m/ms
  - • Maximum switched gradient amplitude per axis of 45 mT/m
  - • Maximum MR System reported whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode)
  - • Baha sound processor and SP Magnet must be removed before patient enters a room containing an MR scanner
  - Additional instructions essential to safe use in the MR environment:

    • Under the scan conditions defined above, the BIM400 Implant Magnet is expected to produce a maximum temperature rise of 4.5°C after 30 minutes of continuous scanning.
  - • In non-clinical testing with the implant magnet in place, the image artifact caused by the device extends approximately 11.5 cm (4.5 in.) from the BIM400 Implant Magnet when imaged with a gradient echopulse sequence and a 1.5 Tesla MRI system.

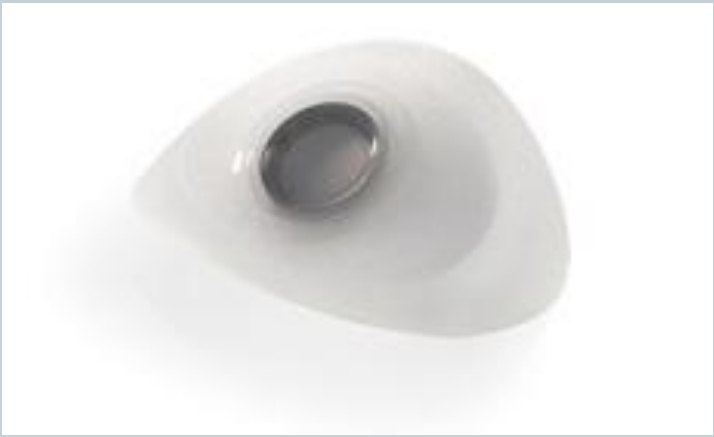
Animas Insulin pump

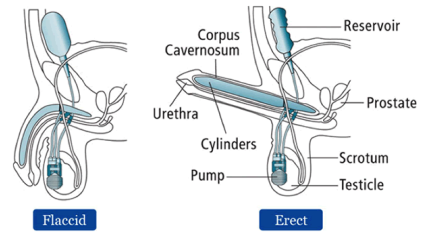
- Insulin pump should not be exposed to very strong electromagnetic fields, such as MRIs, RF welders, or magnets used to pick up automobiles. Very strong magnetic fields, such as that associated with MRI, can “magnetize” the portion of the insulin pump’s motor that regulates insulin delivery and, thus, damage the device.
- Mrisafey.com

Animas.com

Breast Tissue Expanders

- Adjustable breast tissue expanders are utilized for breast reconstruction following mastectomy for the correction of breast.
- MR procedures are deemed unsafe for patients with these specific breast tissue expanders.





Penile Implants

- Some penile implants evaluated for ferromagnetic qualities had substantial deflection forces measured when exposed to a 1.5 Tesla magnetic field. Although it is unlikely that a penile implant would severely injure a patient undergoing an MR procedure because of the manner in which it is used, it would undoubtedly be uncomfortable. For this reason, subjecting a patient with one of these implants to an MR procedure is inadvisable
- The Titan OTR is MRI conditional 6

  -Static magnetic field of 3-Tesla or less
  - Maximum spatial gradient magnetic field of 720-Gauss/cm
  - Maximum MR system reported whole-body-averaged specific absorption rate (SAR) of 3-W/kg for 15 minutes of scanning (per pulse sequence)

Penile implant, Duraphase Unsafe 1 1.5

It may be uncomfortable for a patient with a Duraphase or Omniphase penile implant to undergo an MR examination. For this reason, an MR procedure is not advisable.

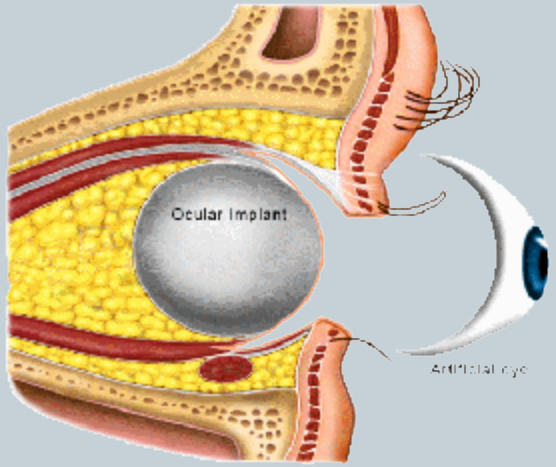
Opthalmic Implants

courtesy of mrisafety.com

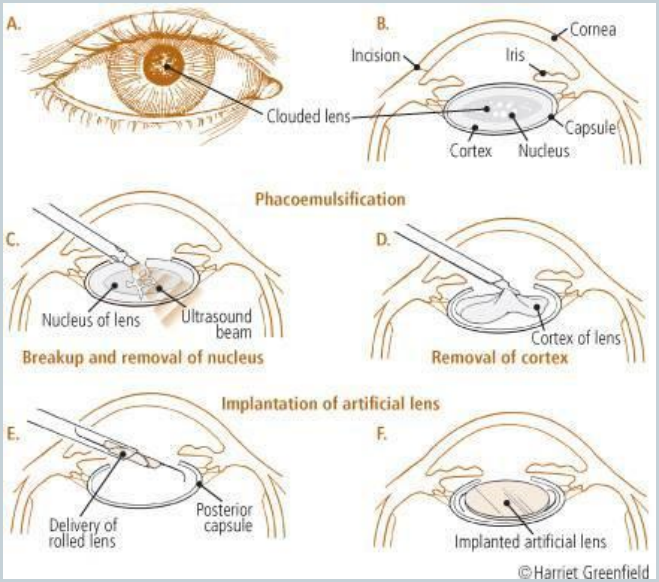
Posterior Chamber Intraocular Lens STAAR Surgical Company, Staar www.staar.com		1.5		Implants, and Devices
STAAR Surgical Elastimide Posterior Chamber Intraocular Lens STAAR Surgical Company, Staar www.staar.com	Safe	1.5		Ocular Implants, Lens Implants, and Devices
STAAR Surgical Elastimide Posterior Chamber Intraocular Lenses STAAR Surgical Company, Staar www.staar.com	Safe	1.5		Ocular Implants, Lens Implants, and Devices
Morcher Capsular Tension Ring Morcher Implants, http://www.morcher.com/	Safe	1.5		Ocular Implants, Lens Implants, and Devices
Afinity Collamer Aspheric IOL (Intraocular Lens) STAAR Surgical Company, Staar www.staar.com	Safe	1.5		Ocular Implants, Lens Implants, and Devices
AquaFlow Collagen Drainage Device Glaucoma Drainage STAAR Surgical Company, Staar www.staar.com	Safe	1.5		Ocular Implants, Lens Implants, and Devices
ARGOS-IO, Eye Implant, Ocular Implant Implandata Ophthalmic Products GmbH, www.implandata.com	Conditional 6	3		Ocular Implants, Lens Implants, and Devices
Hydrus Aqueous Implant, Ocular Implant Ivantis, Inc. www.ivantisinc.com	Conditional 6	3		Ocular Implants, Lens Implants, and Devices
Intraocular Lens, Models 12A, 12P, 12S, 24P, 31P, 42P, 61P, 71, 71B, 71M, 71P, 71PC, 71R, 75M, 75P, EXP D Bausch & Lomb, www.bausch.com	Unsafe 1	1.5		Ocular Implants, Lens Implants, and Devices
Precision Cosmet Lens, Models 3110, 3120, 5110, 5120 Bausch & Lomb, www.bausch.com	Unsafe 1	1.5		Ocular Implants, Lens Implants, and Devices
Implantable Miniature Telescope VisionCare Ophthalmic Technologies, Inc. www.visioncareinc.net	Conditional 6	3		Ocular Implants, Lens Implants, and Devices
OZURDEX Implant (dexamethasone intravitreal implant) Allergan, Inc. www.allergan.com	Safe	1.5		Ocular Implants, Lens Implants, and Devices
Wide Angle Implantable Miniature Telescope VisionCare Ophthalmic Technologies Inc Saratoga, CA	Conditional 6	3		Ocular Implants, Lens Implants, and Devices

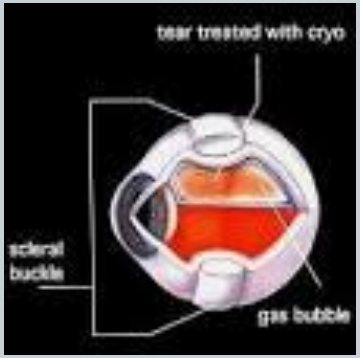
Internet | Protected Mode: Off

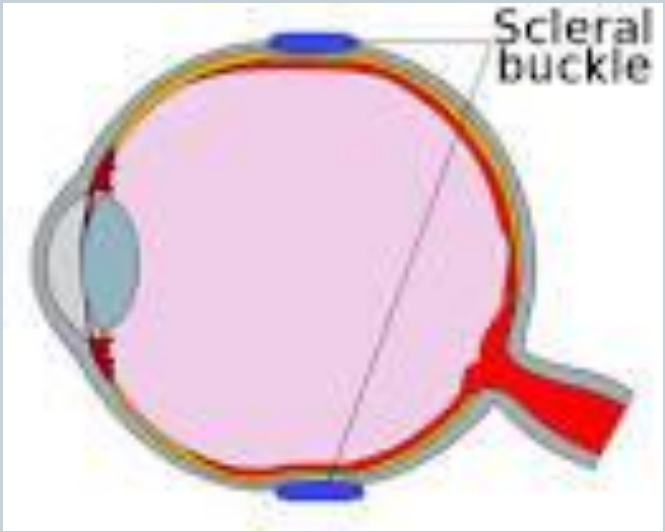
Implants…must be checked



Scleral Buckles- Are ok







From Dr. Shellock on ocular implants

- Of the different ocular implants, lens implants, and devices tested in the MR environment, the Fatio eyelid spring, the retinal tack made from ferromagnetic stainless steel, the Troutman magnetic ocular implant, and the Unitek round wire eyelid spring demonstrated positive magnetic field interactions in association with exposure to 1.5-Tesla MR systems. By comparison, many of the lens implants pose no hazard to the patient during an MRI procedure since they do not contain metallic materials
  A patient with a Fatio eyelid spring or round wire eyelid spring may experience discomfort but would probably not be injured as a result of exposure to an MR system. In fact, patients have undergone MR procedures with eyelid wires after having a protective plastic covering placed around the globe along with a firmly applied eye patch as a precaution.
  The retinal tack made from martensitic stainless steel and Troutman magnetic ocular implant may injure a patient undergoing an MR procedure, although no such case has ever been reported.
- Interestingly, Tokue, et al. (2013) reported that certain color contact lenses, which are a type of cosmetic contact lens, may contain iron oxide or other metals, which means that their presence during MRI may be problematic due to the associated imaging artifacts.
- Tantalum clips were found to be less bulky than sutures, allowing the surgeon to adjust the tension of the circling band for the **scleral buckle**. Tantalum clips did not cause tissue reaction and did not harbor infection. Because tantalum is a non-ferrous metal (non-magnetic), these clips are considered to be acceptable for patients undergoing MRI procedures

Endoscopy clips

Endoscopy Clips that are issues

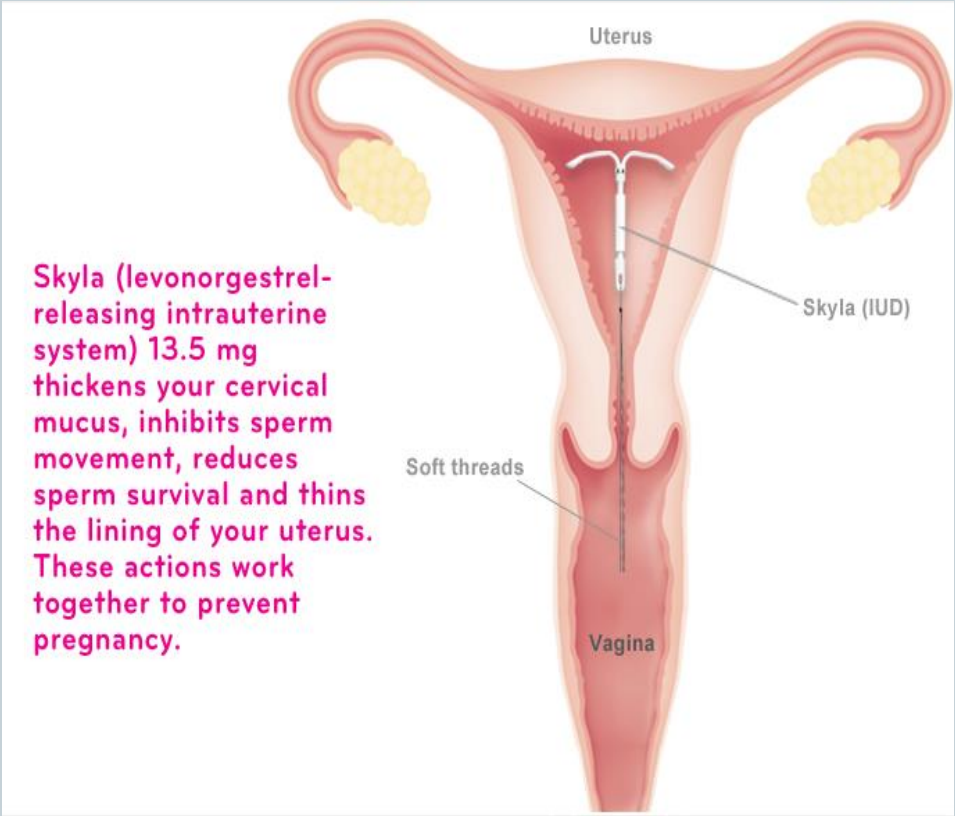
- Long Clip, HX-600-090L
- QuickClip2, HX-201LR-135 & HX-201UR-135. The QuickClip2, HX-201LR-135 & HX-201UR-135 (Olympus Medical Systems Corporation)
- TriClip Endoscopic Clipping Device
  - All of these have a warning: “Do not perform MRI procedures on patients who have clips placed within their gastrointestinal tracts. This could be harmful to the patient.”

Endo Capsules

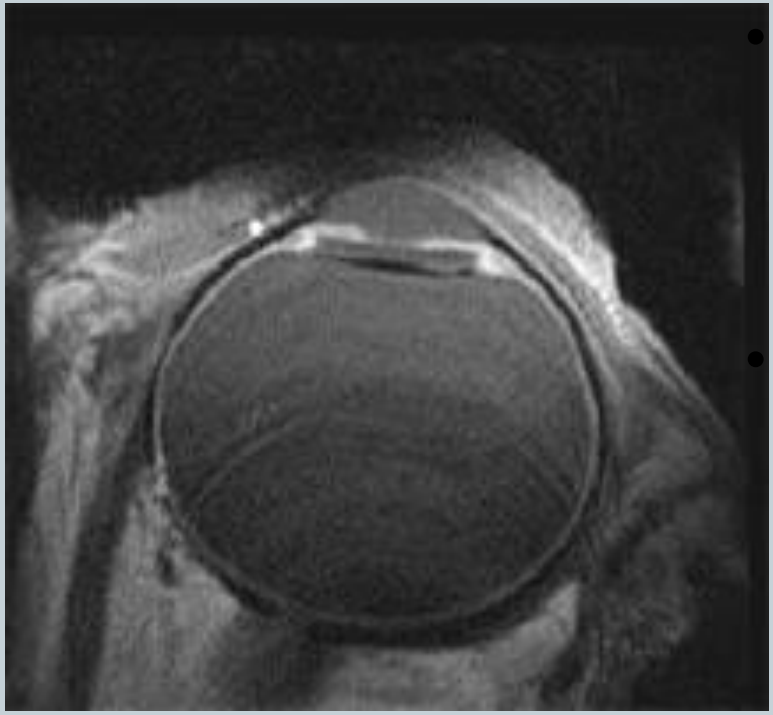
- **Is there anything special I should do during the procedure?**
  - While the capsule is in your body, you should not have an MRI exam or be near an MRI machine.

Skyla IUD

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 36,000 Gauss/cm (T/m) or less
- Maximum whole body averaged specific absorption rate (SAR) of 4W/kg in the First Level Controlled mode for 15 minutes of continuous scanning
- In non-clinical testing, the Skyla produced a temperature rise of less than 1.8°C at a maximum whole body averaged specific absorption rate (SAR) of 2.9 W/kg, for 15 minutes of MR scanning at 3T using a transit/receive body coil.
- MR Image quality may be compromised (that is, a small amount of artifact may occur) if the area of interest is in the exact same area or relatively close to the position of Skyla. Image artifact extended up to 5 mm from Skyla in a Gradient Echo



Lens Implants



- Many of the lens implants pose no hazard to the patient during an MRI procedure since they do not contain metallic materials (see **The List**).
- There were some Lens implants pre 1980 which were not tested. These are probably ok but not testing data exists
- Interestingly, Tokue, et al. (2013) reported that certain color contact lenses, which are a type of cosmetic contact lens, may contain iron oxide or other metals, which means that their presence during MRI may be problematic due to the associated imaging artifacts.

Things we don't worry much about (today) but still have to know for sure

- Cardiac Stents
  - Per Shellock and others Cardiac stents currently ok
  - Tattoos
    - We know there is potential for heating but the incidence is very low
    - Burns have occurred and pts must be made aware
- Non-programmable shunts
  - Some artifact but they are thought to be safe
- IUDs
  - Must be vetted but currently most are safe
- Hemostatic Clips, Fasteners, and Staples
  - Able to scan with no waiting time
- Things that are stationary, not electronic, non-ferrous and scarred into tissue.
  - Not on/around vital organs like major blood vessels, brain, nerves

The Final Word

- For all Category 3 and above devices an implant form must be completed. This form has 2 components:
  - Tech
    - Research and patient information
  - Radiologist
    - Risk vs. Benefit assessment and communication to techs/referring and patient when necessary
- When in doubt ask your chief technologist, Radiologist or safety officer for help or clarification