

A Case Based Review of Implant Safety in Pediatric MRI

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Case 1: 13 Year Old Female, Scoliosis MRI

- Clinical HX/Reason for the exam:

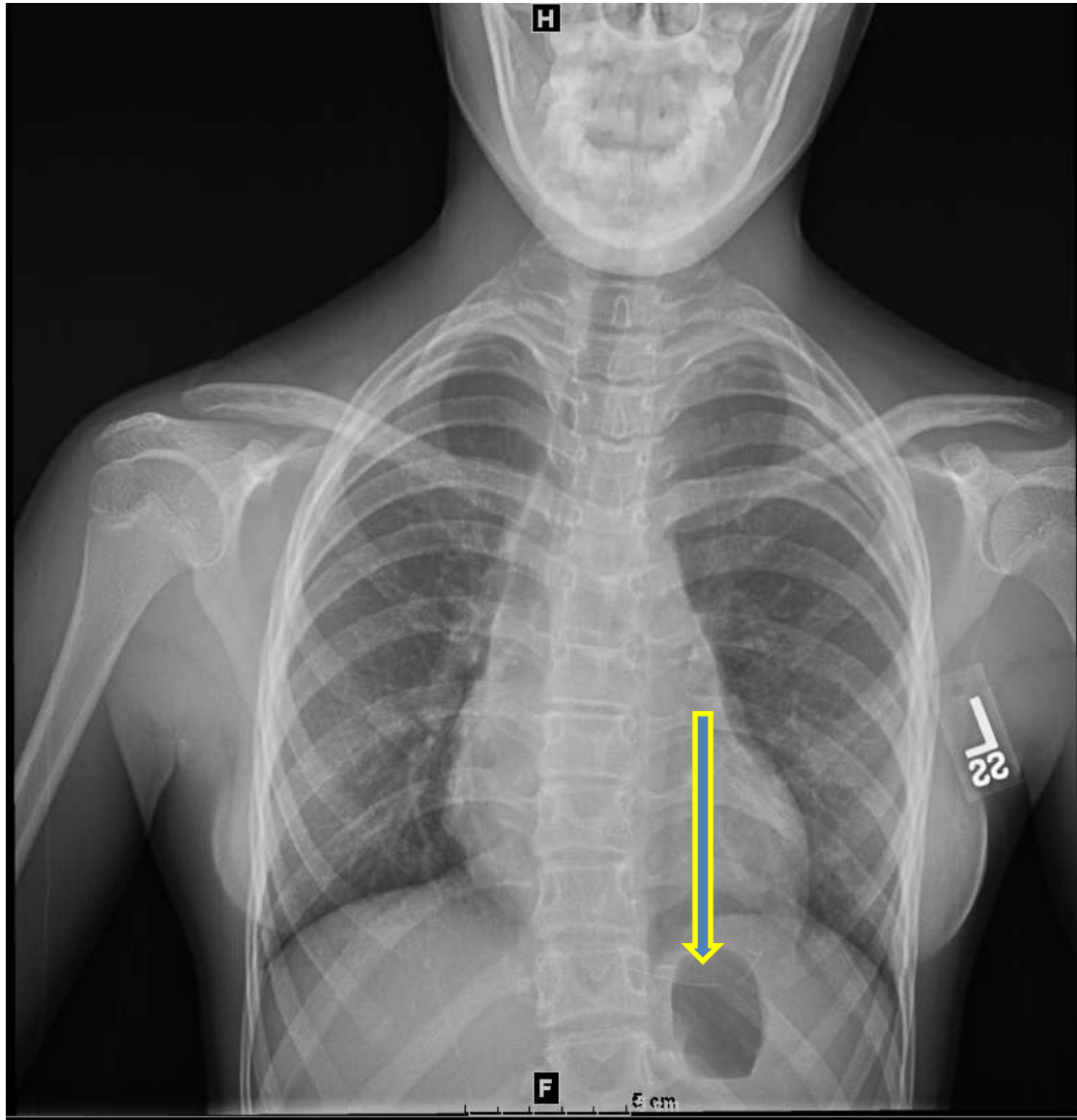
“Scoliosis Unspecified: MR entire spine to assess for congenital vertebral anomalies and assess for intrathecal abnormalities – HX of congenital heart defect s/p surgery”



CASE 1: 13 Year Old Female, Scoliosis MRI

- Family completed screening form - no history of implanted devices / pacemaker.
- The patient had a history of cardiac surgery for Taussig-Bing cardiac malformation.
- Per current protocol for 1st MR exam at our institution in patients w/ history of cardiac surgery - a chest x-ray is obtained.

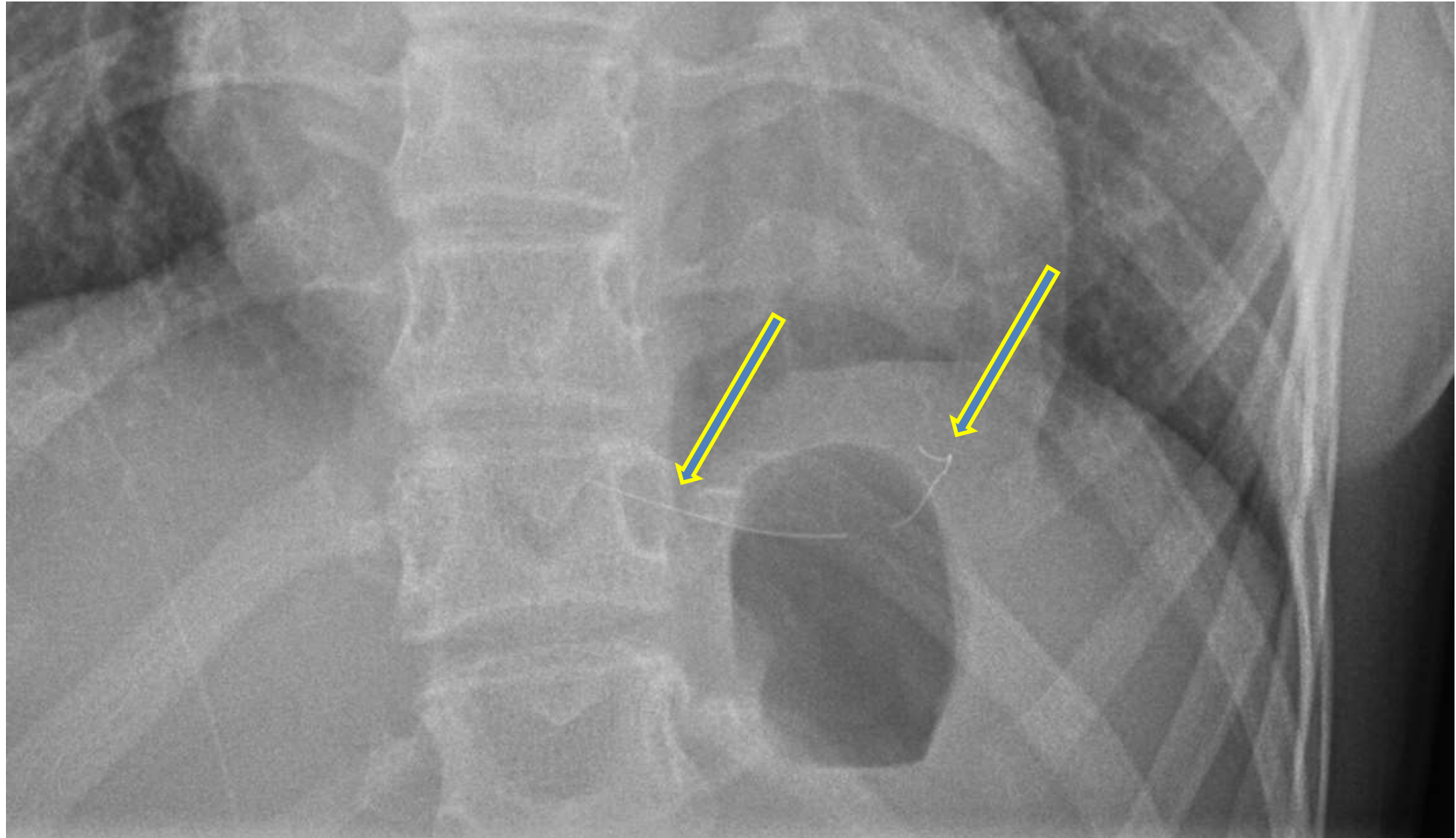
2 View Chest X-ray



Conclusion: Remnant/Orphaned Pacer Wire

- The attending radiologist informed us that the wire is a remnant/orphaned pacer wire.
- Temporary pacer wires are sometimes placed during cardiac surgery in order to prevent the need for a second open heart surgery if the patient develops the need for a pacemaker.
- If the patient's heart rate is steady after surgery, the pacer wires are mechanically removed.
- During the removal process, it is possible that a piece of the pacer wire can break off and remain as an orphaned/remnant wire.

Remnant/Orphaned Pacer Wire



Conclusion: Remnant/Orphaned Pacer Wire

- Remnant/Orphaned pacer wires are MR Unsafe.
- The MR examination was cancelled as the wires are in close proximity to the heart and within superficial soft tissues so there was a risk of local soft tissue & myocardial/pericardial heating and patient discomfort.
- The attending radiologist decided to cancel the MRI exam and ordered a CT exam to assess the scoliosis.
- The family was made aware of the orphaned pacer wires for future MR examinations.

Case 2: 11 Year Old Female, Tuberous Sclerosis

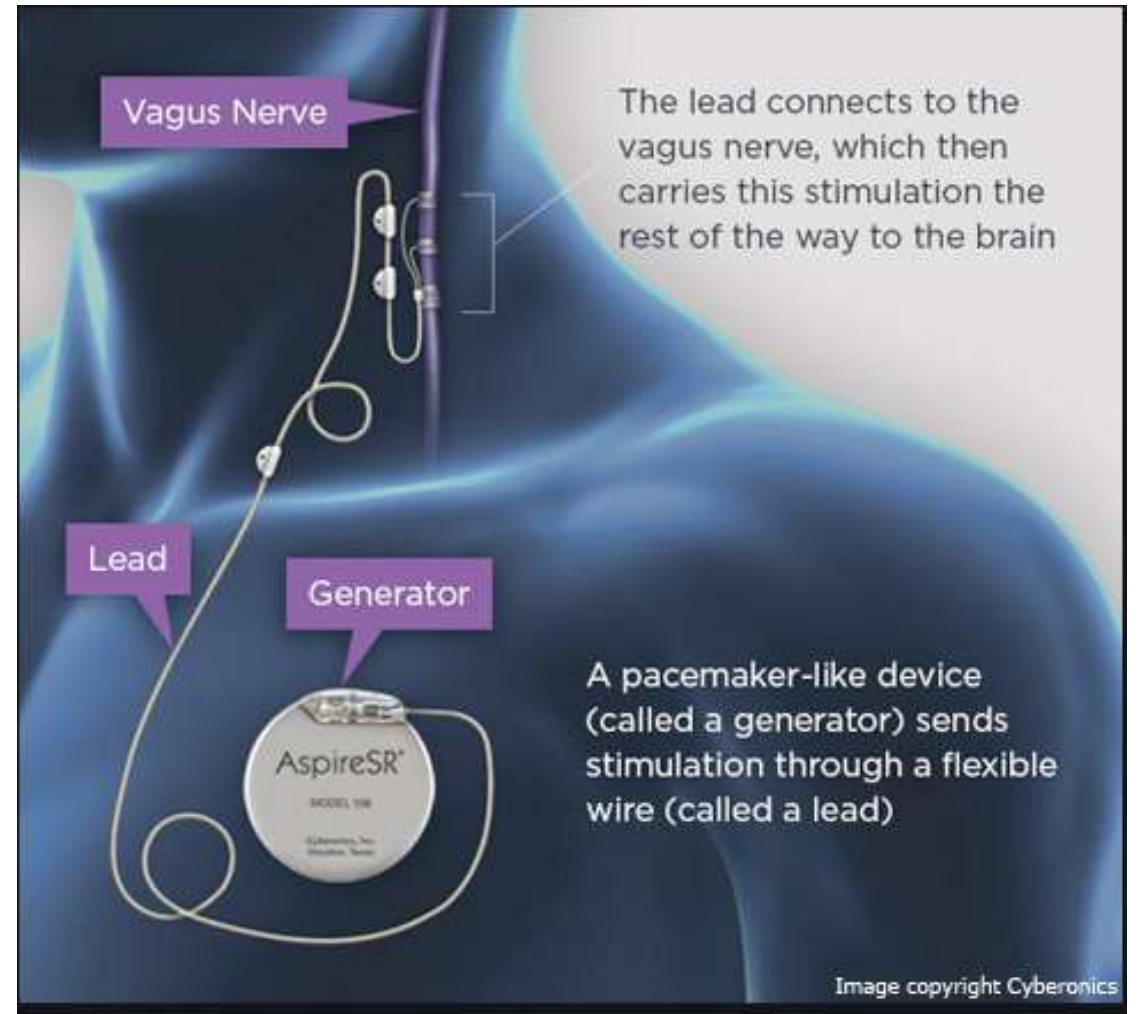
- Clinical HX/Reason for the exam:

“MR Abdomen to evaluate Tuberous Sclerosis. HX: patient has a history of a vagal nerve stimulator.”



VNS Therapy Systems

- Our first step with VNS is to call the manufacturer Cyberonics/Livanova.
- Cyberonics/LivaNova can find any patient usually just with their name and birth date as there are so few of these implants.
- Cyberonics/LivaNova can provide or confirm the model number of the VNS. In this case the patient had Model 1000.
- Once the model number is known, the most recent guidelines can be found at: <http://vnstherapy.info>



MRI with the VNS Therapy® System



October 2019

RxOnly



The year of authorization to affix the CE mark:

102/102R - 2003
103/104 - 2005
105 - 2011
106 - 2014
1000 - 2017
8103 - 2019
302 - 2003
303 - 2008
304 - 2009

The information contained in this document is one part of the full labeling for the implanted portions of the VNS Therapy System. It is not intended to serve as a substitute for a complete and thorough understanding of the material presented in all VNS Therapy physician manuals, nor does this represent full disclosure of all pertinent information concerning use of this product, potential safety complications, or efficacy outcomes.

Example of Generator Placement at “Upper left chest at or Above Armpit”

- This patient had Model 1000.
- We then typically would need to determine the location of the generator.



MRI Guidance Applicability Flowchart

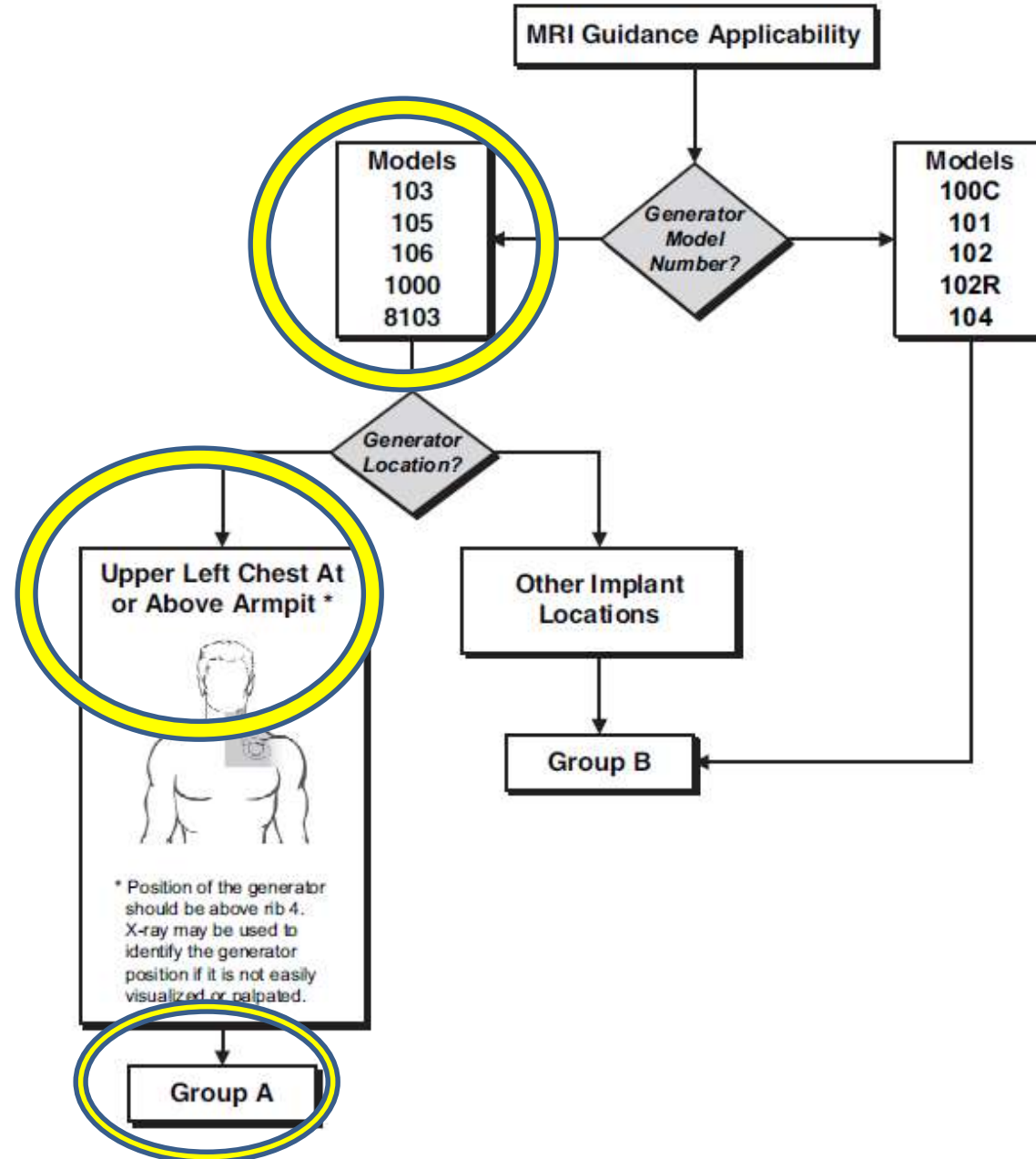








Table 2. Summary of Conditional MR Use

VNS Device		Group A	Group B
Scanner Type		Horizontal field, cylindrical closed-bore, clinical system for hydrogen proton imaging	
Scanner Characteristics	Static magnetic field strength	1.5 or 3 T	
	Spatial field gradient	Models 100C and 101: ≤ 720 Gauss/cm Models 102 through 1000 and 8103: ≤ 3000 Gauss/cm	
	Maximum slew rate	200 T/m/s	
Scanner Operation	Operating mode	Normal Operating Mode	
	Transmit RF coil	Head or extremity coils: Scan (placement of entire coil) must be outside of C7 - T8 Body coil: Iso-center of scan (center of the MRI bore) must be outside of C7 - L3. This may be accomplished by landmarking above C7 or below L3.	Transmit/receive head or extremity coils only: Scan (placement of entire coil) must be outside of C7 - T8
	Maximum Specific Absorption Rate (SAR)	Transmit head coil: 3.2 W/kg Transmit body coil: 2.0 W/kg	Transmit/receive head coil: 3.2 W/kg
	Exposure time	Transmit head or extremity coil: No restriction Transmit body coil: ≤ 15 minutes of active scan time within a 30 minute window	Transmit/receive head or extremity coil: No restriction
	Additional Restriction(s)	Transmit head or extremity coil: None Transmit body coil: Circularly Polarized (CP) mode only (i.e., no shimming)	none

VNS Therapy Systems

- It turned out that our patient had the VNS system explanted.
- However, the explantation of the system left a remnant/orphaned wire on the vagal nerve.
- Based on our experience with remnant orphaned cardiac pacer wires, we suspected that there was no labeling for this remnant.
- To our surprise, the manufacturer actually has a label for partially explanted VNS Therapy Systems.

Table 3. Scan Conditions for Partially Explanted VNS Therapy Systems or Damaged Leads

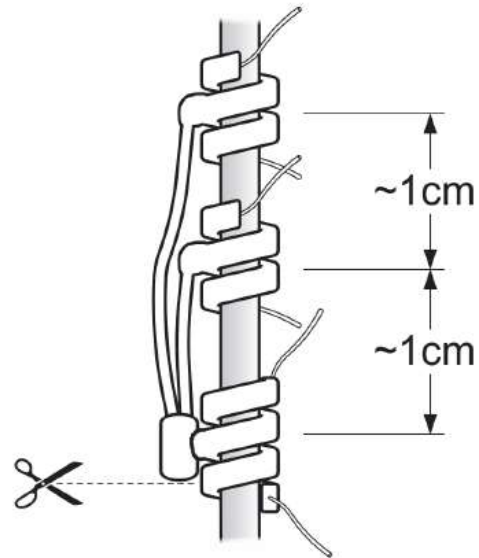
Implant Configuration	Scan Conditions	
	1.5T or 3T with transmit/receive Head Coil or transmit/receive Extremity Coil	1.5T or 3T with transmission of RF with the Body Coil
VNS Therapy System with a suspected lead break (IPG is still connected)	 C7-T8 exclusion zone (i.e., Group B Scan Conditions)	
Lead length > 2 cm remains (No IPG)	 C7-T8 exclusion zone (i.e., Group B Scan Conditions)	
≤ 2 cm of lead remains (i.e. electrodes remain implanted and no IPG)	 no exclusion zones	 any landmark, no exclusion zones



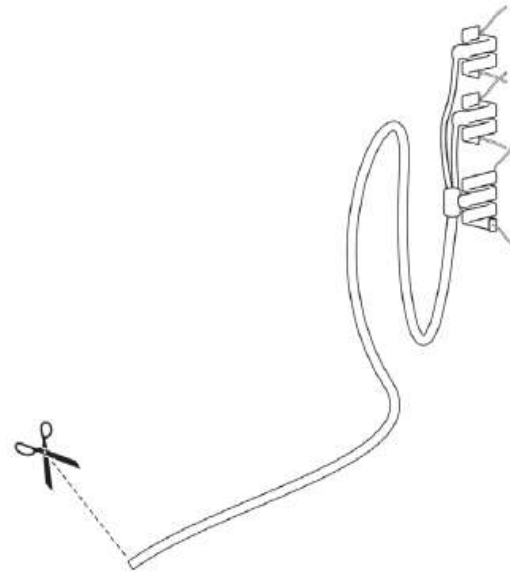
Note: See “MRI Conditions for Use” for further guidelines.

Evaluating Remnant Lead Length

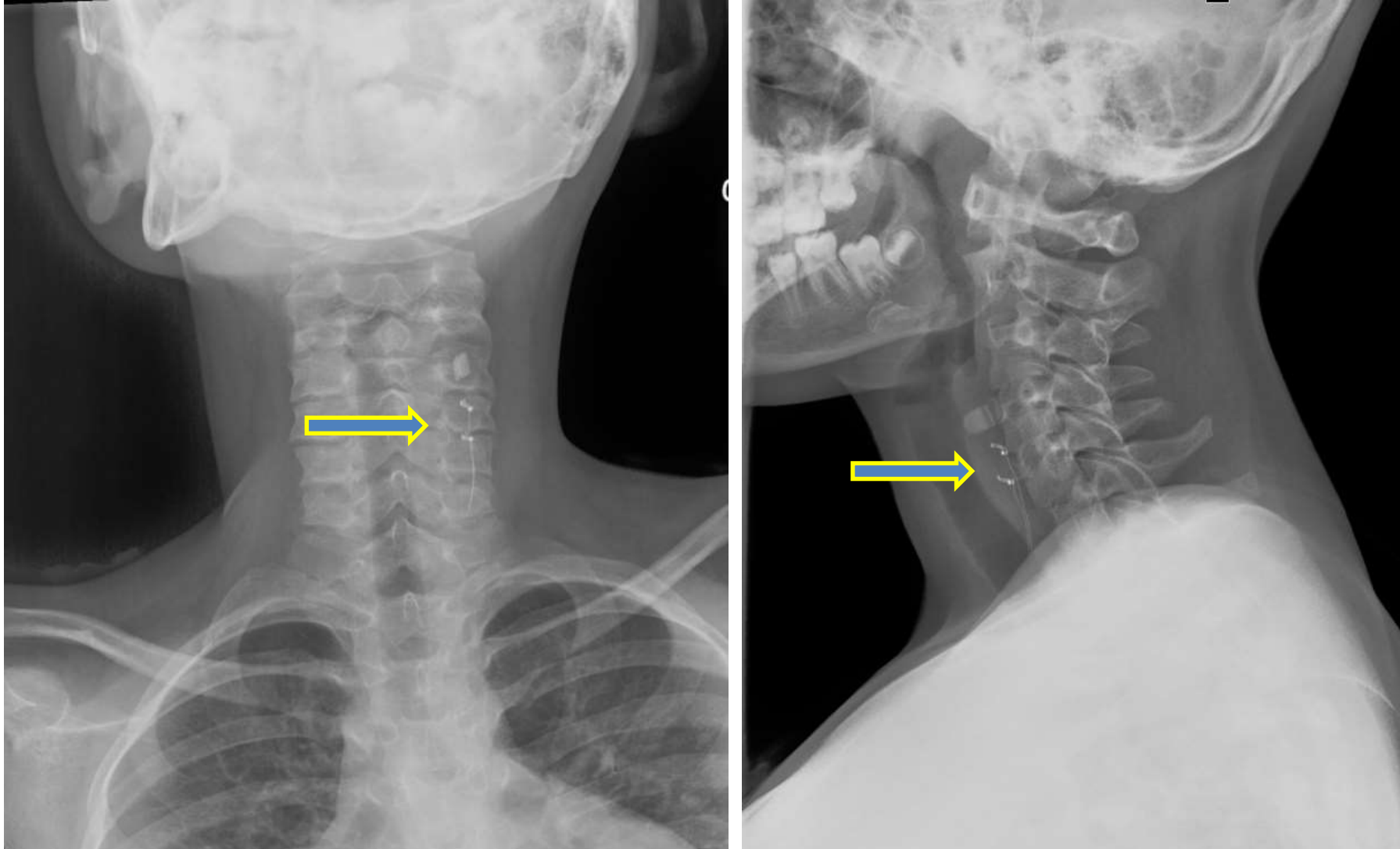
Transected Lead (≤ 2 cm)



Transected Lead (> 2 cm)



2 View Cervical X-ray to Assess Lead Length



Conclusion: Partially Explanted VNS System

- The remnant lead length measured on the x-ray was approximately 2 cm making the decision somewhat subjective.
- We decided to cancel the MRI due to the because of the risk of potential heating and because patient was delayed/non-verbal and required general anesthesia (and therefore could not communicate discomfort).
- A CT abdomen with contrast was ordered as an alternative to the MR abdomen.

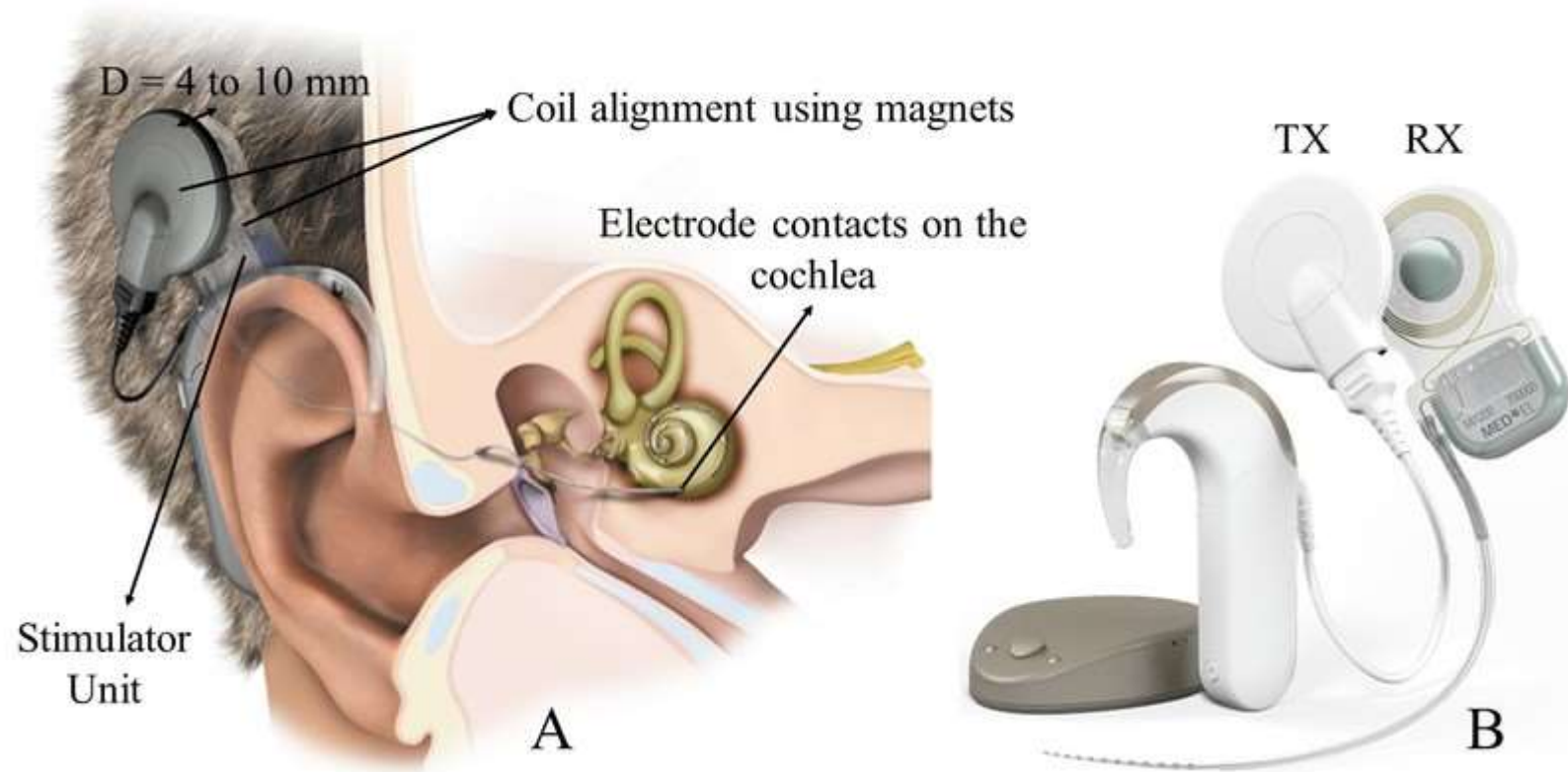


Case 3: 1 Year Old Male, Cochlear Implant

- Clinical HX/Reason for the exam(s):
- “Severe, profound sensorineural bilateral hearing loss. Left ear cochlear implant implanted at 1 year old. Right ear cochlear implant implanted at 4 years old. History of choroid fissure cyst.”

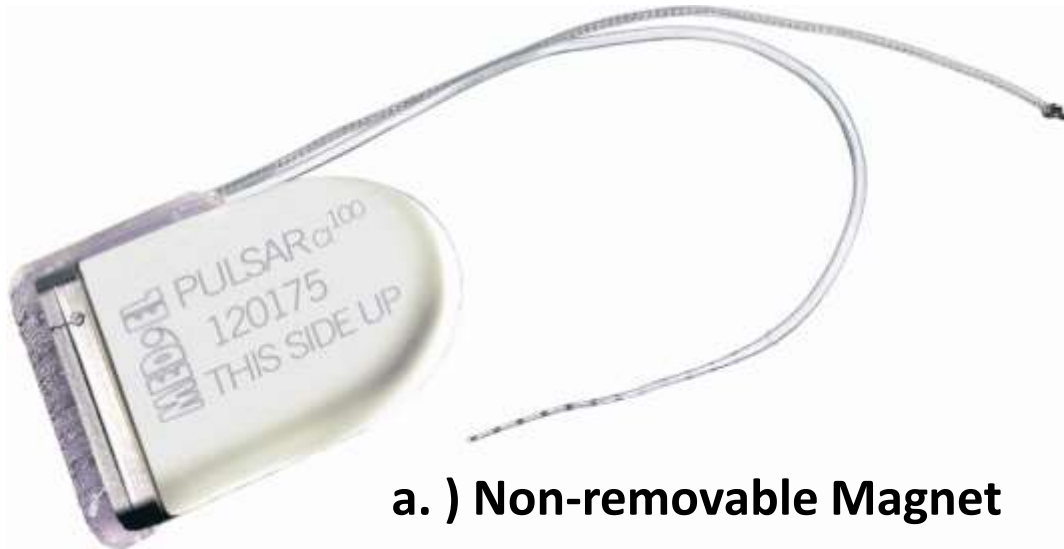


Cochlear Implant Design



Reference: https://www.researchgate.net/figure/A-Implant-RX-coil-positioned-beneath-the-skull-behind-the-ear-in-cochlear-implant-being_fig15_315321686 [accessed 30 Apr, 2019]

Cochlear Implant Design (3 principle types)



a.) Non-removable Magnet



b.) Removable Diametric Magnet

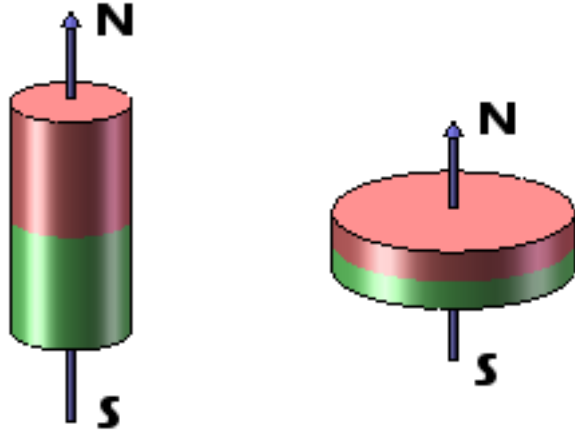
c.) Removable Axial Magnet



Picture References: a. <http://isobelsears.blogspot.com/2012/08/isobels-cochlear-implant.html>;

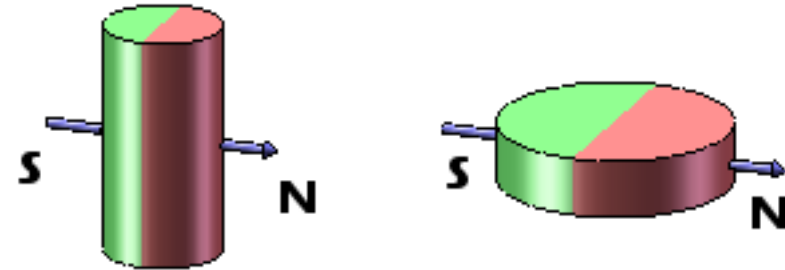
b. <https://advancedbionics.com/us/en/home/professionals/hires-ultra-3d-cochlear-implant.html> c. <https://cochlearimplanthelp.com/tag/recall/>

Cochlear Implant Design



Axial Magnet Pole Orientation

If the north and south pole of the magnet is oriented along the cylinder axis, it is more likely to torque when the patient is put in or out of the MRI. Therefore, these designs require head wraps to restrict them from moving.



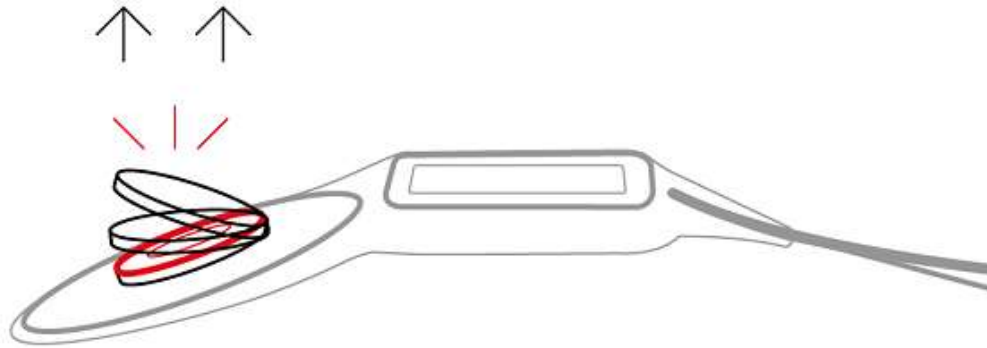
Diametric Magnet Pole Orientation

If the north and south pole of the magnet is oriented along the cylinder diameter, it is more likely to rotate along its axis when it is placed in the MRI and not transfer pressure to the patient. Therefore, these designs do not require head wraps.

Cochlear Implant Design

Magnet Dislocation

Non-secure axial magnet in soft silicone pocket



Axial Magnets Torque in MRI field

Diametric Magnet "Spin" in MRI field

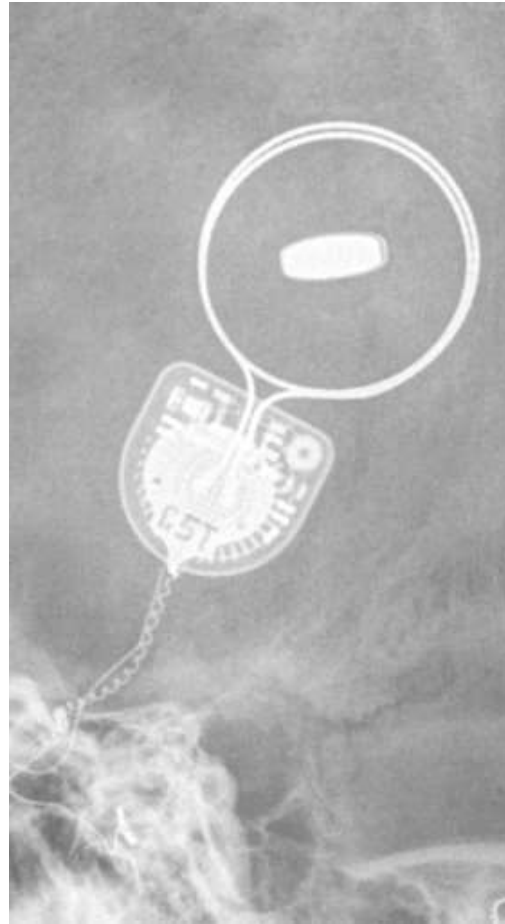


Picture Reference: <http://blog.myesr.org/cochlear-implants-mri-safety/>

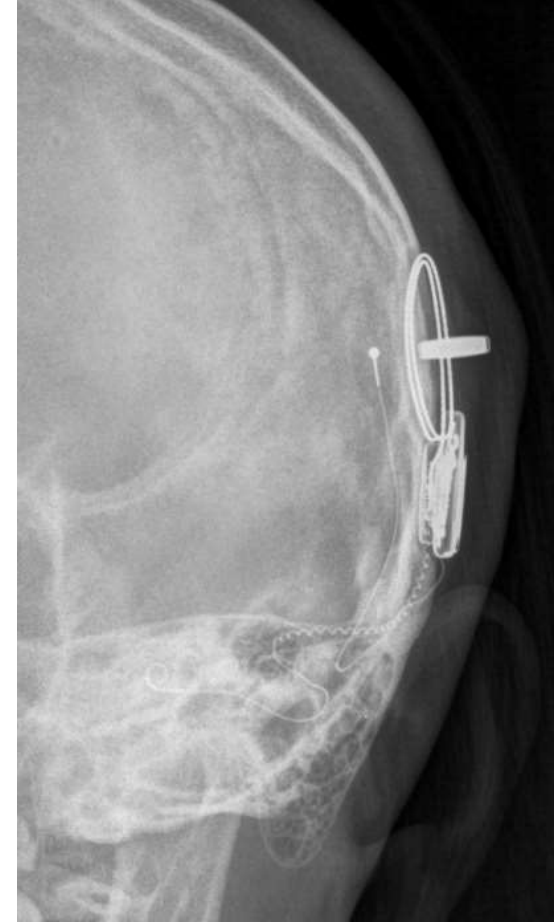
Example of Cochlear Implant Magnet Displacement after MRI



Normal Orientation



Displaced Orientation



Workflow for scanning a patient with a Cochlear Implant

- **Determine appropriateness**
- **Determine if the exam requires consent (off label vs. on label)**
- **Determine if the patient needs GA/sedation or head wrap**

The Decision of Whether or Not to Remove the CI Magnet

- If the care team wants to stay strictly on label it may be necessary to remove the magnet for some models of cochlear implants.
- At Lurie Children's, we chose to perform imaging with the magnet in place unless the susceptibility artifact caused by the implant would make the images non-diagnostic.
- We would rather scan off label and risk the possibility of a minor surgical revision after the MRI than expose every cochlear implant patient to two surgeries (one to remove the magnet, and one to replace it) and the duration of hearing loss between surgeries.
- Most cochlear implants have a finite number of times the magnet can be removed and replaced as the process can damage the sleeve.

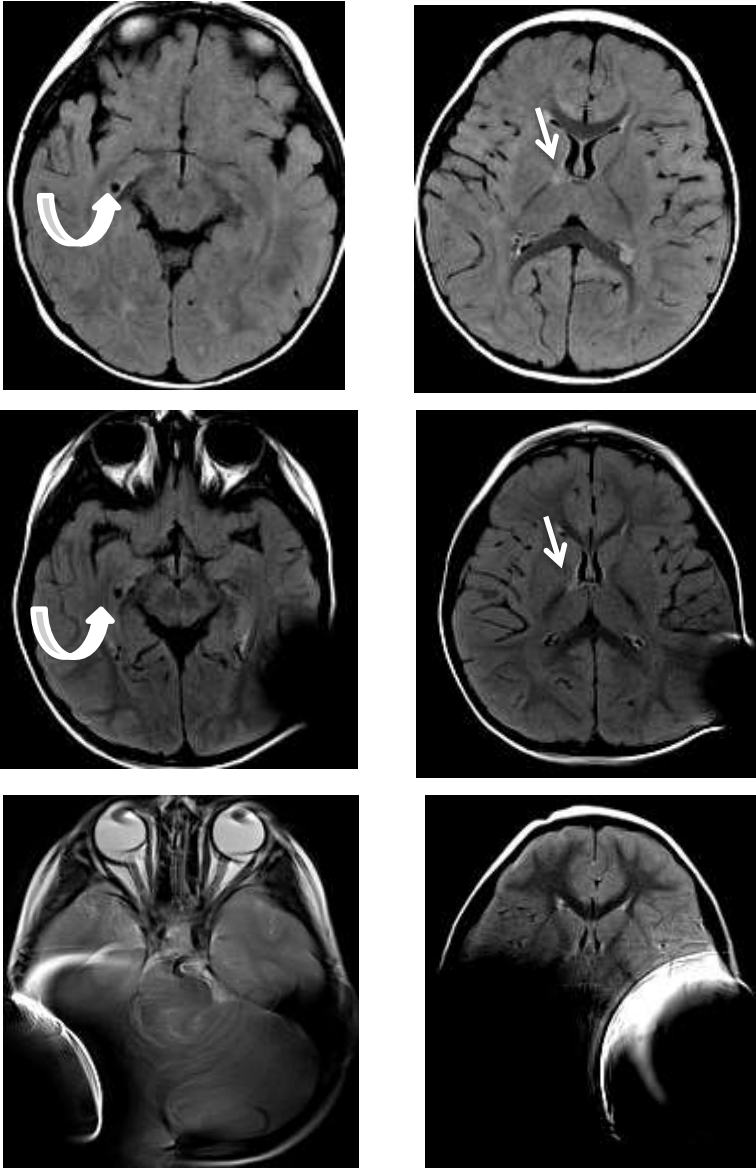
Lurie Children's Workflow, Cochlear Magnet In Place

Manufacturer	Model	Magnet Type	Casing Material	MR Safety Label (with magnet in place)	Head wrap required?	Obtain Consent (Lurie Children's)?	GA/Sed Required?
MR Unsafe (if magnet in place)							
Advanced Bionics	C1	Non-removable, axial	Ceramic	MR Unsafe	Yes	Yes (off label)	Yes
Advanced Bionics	C1.2	Non-removable, axial	Ceramic	MR Unsafe	Yes	Yes (off label)	Yes
Advanced Bionics	CI Bionic Ear™	Non-removable, axial	Ceramic	MR Unsafe	Yes	Yes (off label)	Yes
Advanced Bionics	HiRes™ 90K	Removable, axial	Titanium & Silicone	MR Unsafe	Yes	Yes (off label)	Yes
Advanced Bionics	HiRes™ 90K Advantage	Removable, axial	Titanium & Silicone	MR Unsafe	Yes	Yes (off label)	Yes
Cochlear Americas	22 CI22M (1985-1995)	Non-removable, axial	Silicone	MR Unsafe	Yes	Yes (off label)	Yes
Cochlear Americas	22 CI22M (after 1996)	Removable, axial	Silicone	MR Unsafe	Yes	Yes (off label)	Yes
Cochlear Americas	24 CI24M	Removable, axial	Silicone	MR Unsafe	Yes	Yes (off label)	Yes
Cochlear Americas	24 CI24R (CA), (CS), and	Removable, axial	Silicone	MR Unsafe	Yes	Yes (off label)	Yes
MR Conditional and Head Wrap Required (if magnet in place)							
Advanced Bionics	HiRes™ Ultra	Removable, axial	Titanium & Silicone	MR Conditional up to 1.5T	Yes	No (on label)	Yes
Cochlear Americas	CI24RE, CI24REH, RE(CA),	Removable, axial	Silicone	MR Conditional up to 1.5T	Yes	No (on label)	Yes
Cochlear Americas	CI512	Removable, axial	Silicone	MR Conditional up to 1.5T	Yes	No (on label)	Yes
Cochlear Americas	CI422	Removable, axial	Silicone	MR Conditional up to 1.5T	Yes	No (on label)	Yes
Cochlear Americas	CI522	Removable, axial	Silicone	MR Conditional up to 1.5T	Yes	No (on label)	Yes
Cochlear Americas	CI532	Removable, axial	Silicone	MR Conditional up to 3.0T	Yes	No (on label)	Yes
MED ^o EL	Combi 40+	Non-removable, axial	Ceramic	MR Conditional up to 1.5T	Yes	No (on label)	Yes
MED ^o EL	Pulsar	Non-removable, axial	Ceramic	MR Conditional up to 1.5T	Yes	No (on label)	Yes
MED ^o EL	Sonata	Non-removable, axial	Silicone & Titanium	MR Conditional up to 1.5T	Yes	No (on label)	Yes
MED ^o EL	Concert	Non-removable, axial	Silicone & Titanium	MR Conditional up to 1.5T	Yes	No (on label)	Yes
MR Conditional and Head Wrap not Required (if magnet in place)							
Advanced Bionics	HiRes™ Ultra 3D	Removable, diametric	Titanium & Silicone	MR Conditional up to 3.0T	No	No (on label)	No
MED ^o EL	Synchrony #	Removable, diametric	Silicone & Titanium	MR Conditional up to 3.0T	No	No (on label)	No

Cochlear Implant Work Flow

- The patient has bilateral cochlear implants from Cochlear Americas Model CI24RE.
- This model has a removable axial magnet but we choose not remove the magnet unless we find that image quality is non-diagnostic.
- With the magnet in place, this cochlear implant has MR conditional labeling for field strengths up to 3T with a head wrap required.
- Because we are following the manufacturer's label (allowing us to leave the magnet in and wrap the head), the study does not require additional consent.
- Due to the discomfort of the procedure, we chose to use general anesthesia.

Cochlear Implant Effect on MRI Image Quality



T2 FLAIR IMAGES

Pre-implantation MRI: small choroid fissure cyst (curved arrow) and presumed gliosis in the basal ganglia (straight arrow)

MRI after implantation of the left cochlear implant contralateral to the region of interest – The pre-implantation findings are still identifiable.

MRI after implantation of bilateral cochlear implants which produces non-diagnostic images for the purposes of evaluating the previous findings. Consideration is then made whether to remove the magnets and repeat MRI imaging.

Thank you!

Questions?

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