

OR Indwelling Neurosurgical Device Safety Compendium

Table of Contents

Terms

Baclofen Pump

Bovie

MRI

Deep Brain Stimulation

Bovie

MRI

Responsive Neurostimulation

Bovie

MRI

Shunt Valves

Programmable

Bovie

MRI

Nonprogrammable

Bovie

MRI

Spinal Cord Stimulation

Bovie

MRI

Vagus Nerve Stimulation

Bovie

MRI

References

Terms:

Monopolar Electrocautery: Commonly known in the OR as “Bovie”.

Diathermy: Diagnostic or Therapeutic ultrasonography (e.g lithotripsy); referring to ultrasonography causing heat. Usually not diagnostic ultrasonography.

Baclofen Pump

Monopolar (bovie) Synchronomed II

Monopolar (bovie) electrocautery is acceptable if there is a minimum of 15cm separation between the ultrasound and the implant.

Recommendation

Monopolar electrocautery can be used within 15cm or more from the pump and catheter.

MRI Synchronomed II

MRI may be utilized in patients with the Synchronomed II as it is MRI conditional. However, temporary motor stall and stall recovery may occur. Although the pump should technically resume normal operation upon MRI completion, it may take up to 2 to 24hrs for pump to return to appropriate infusion after MRI completion.

Recommendation

MRI is safe, but it suspends drug infusion, requiring the functionality to be checked afterwards.

Deep Brain Stimulation (DBS)

Electrocautery (bovie) Medtronic DBS

It is recommended that electrocautery be avoided at all times for patients with Medtronic DBS system as use of electrocautery can result in insulation damage around the lead or lead extension, component failure, or induced currents into the patient leading to tissue damage, patient stimulation or patient shock. Additionally, damage to the neurostimulator can lead to suppressed or increased stimulation. However, if electrocautery must be used, it should be used with the following precautions: the neurostimulator must be turned off prior to use and the cable connecting the lead or extension to a screener or external neurostimulator must be disconnected. Additionally, only bipolar cautery should be utilized but if unipolar cautery is necessary then only use the low-voltage mode at the lowest possible power setting with the current path or ground plate as far from the neurostimulator, extension, and lead as possible. The full-length operating room table grounding pad should not be used, and the electrocautery current flow

should be perpendicular to a line drawn between the neurostimulator case and lead electrodes. Neurostimulator function should be determined after using electrocautery.

Recommendation

Monopolar electrocautery is not safe but can be used if the device is off and current flow is perpendicular from a line demarcating leads from generator.

MRI for Medtronic DBS

Medtronic DBS system is considered MRI conditional as some models can lead to tissue heating, permanent injury, coma, paralysis, or death if Clinicians should refer to the Medtronic MRI manual to determine which systems are MRI compatible. For those found to be compatible, MRI's may be performed only with body or head transmit/receive RF coils.

Recommendation

MRI is safe if the device is turned off and the transmit/receive coil is used.

Responsive Neurostimulation (RNS)

RNS Neuropace Electrocautery (bovie)

Electrocautery is contraindicated in the RNS Neuropace system.

Recommendation

Monopolar electrocautery is a factory contraindication when a patient has an RNS.

RNS neuropace MRI

MRI is contraindicated in patients with the RNS Neuropace system and is classified as MRI Unsafe.

Recommendation

MRI is contraindicated as the system is MR Unsafe.

Shunt valves

Electrocautery (bovie) for nonprogrammable shunt valves

There is no advisory against or for use of electrocautery or diathermy for non-programmable shunt valves

Recommendation

Monopolar electrocautery can be used without restriction.

MRI for non-programmable shunt valves

MRI is safe for non-programmable shunt valves

Recommendation

MRI is safe and does not affect the shunt setting.

Electrocautery (bovie) for programmable shunt valves:

There is no advisory against or for use of electrocautery for programmable shunt valves.

Recommendation

Monopolar electrocautery can be used without restriction.

MRI for programmable shunt valves

Strata:

The strata II valve is classified as MRI conditional. Per Medtronic, the Strata valve mechanism will not be damaged in MRI systems up to 3 tesla. However, the performance level setting can change. Therefore, the shunt settings should always be checked before and after exposure to the MRI magnet.

Codman Certas:

The codman programmable valve (Certas) is classified as MRI conditional. MRI may be performed at anytime after implantation if the MRI systems has a static magnetic field of 3 tesla or less and a spatial gradient of 720Guass/cm or less. However, the shunt valve setting must be verified after exposure to the MRI magnet.

Recommendation

MRI is safe but it the setting needs to be checked afterwards.

Spinal Cord Stimulators

Electrocautery (bovie) Medtronic Intellis Spinal Cord Stimulator and Intact Electrodes

Electrocautery may transmit electromagnetic interference which may lead to patient injury or death, damage to the neurostimulation system and damage to the surrounding tissue. Although the neurostimulator contains features that protect from electromagnetic interference this is not a guarantee.

Recommendation

There is no guarantee that monopolar electrocautery is safe even if used with restrictions.

MRI Medtronic Intellis Spinal Cord Stimulator and Intact Electrodes

Medtronic Intellis Spinal Cord Stimulator and electrodes are considered MRI conditional. An MRI scan should never be done unless the implanted model is known and determined to be safe as only certain models can undergo MRI scanning.

Recommendation

MRI safe only if specified by the Medtronic Intellis MRI eligibility check-list and device is in MRI mode.

Vagus Nerve Stimulation (VNS)

Monopolar (Bovie) Cyberonics VNS

Caution must be taken with use of electrocautery in patients with cyberonics VNS leads and generators. When implanting Cyberonics VNS, electrocautery should not be utilized after the generator is placed in the sterile field. Electrocautery may be used in a patient who already has an implanted Cyberonics VNS generator, but care should be taken to minimize the current flowing through the generator and lead system. Cyberonics suggests positioning the electrosurgical electrodes as far as possible from the generator and lead, avoiding electrode placement in direct path of current flow to the lead or generator or in the same body cavity as the generator, and confirming the generator is functioning as programmed after electrosurgery

Recommendation

Monopolar (Bovie) is safe if the output current parameters are set to zero, current flow through the generator and leads must be minimized, and the device functionality checked following surgery.

MRI Cyberonics VNS intact Electrodes

Cyberonics VNS with intact electrodes are considered MRI conditional if cyberonic guidelines are followed. If cyberonic guidelines are not adhered to including exclusion of the area of the implant from the radiofrequency field, there is a risk for heating of the lead electrodes which can result in temporary injury, necrosis, or permanent tissue damage including damage to the vagus nerve and structures of the carotid sheath.

Recommendation

MRI is safe if the area of the implant (C7-T8) is excluded from the radiofrequency field.

MRI Cyberonics VNS broken electrodes

Care should be taken with MRI's on patients with suspected or known broken leads as the exposed lead wire is a point at risk for heating of the electrode leading to damage above. These are still MRI conditional in 1.5 and 3 tesla MRI's but only if the VNS current parameters are set to zero and the transmit/receive head or extremity coils as far as the > 2cm of the lead is still implanted and <2cm is exposed. The transmit/receive bodycoil must never be used in these patients. If a transmit RF body coil is needed then surgery must be undertaken to remove the VNS system prior to imaging.

Recommendation

MRI is safe in 1.5 and 3T strength, but the transmit/receive head or extremity coils must be used.

References

- “Cyberonics Announces 100,000th Patient Implant of VNS Therapy®.” *PR Newswire: News Distribution, Targeting and Monitoring*, PRNewswire, 20 Dec. 2012, www.prnewswire.com/news-releases/cyberonics-announces-100000th-patient-implant-of-vns-therapy-184314661.html.
- Chi JH, Fullerton HJ, Gupta N: Time trends and demographics of deaths from congenital hydrocephalus in the United States: National Center for Health Statistics data, 1979 to 1998. *J Neurosurg* 103:113-118, 2005
- Simon, Tamara D., et al. “Hospital Care for Children with Hydrocephalus in the United States: Utilization, Charges, Comorbidities, and Deaths.” *Journal of Neurosurgery: Pediatrics*, vol. 1, no. 2, 2008, pp. 131–137., doi:10.3171/ped/2008/1/2/131.
- Codman Hakim Programmable Valve System for Hydrocephalus: Procedure Guide. 2006
- Codman Certas Plus Programmable Valve. Codman Neuro. Depuy Synthes. 2015
- MRI Guidelines for Medtronic Deep Brain Stimulation Systems: Instructions for Use. 2015.
- Medtronic DBS Therapy Implanted Neurostimulators: Information for Prescribers. 2017.
- Medtronic Pain Therapy Using Intellis Neurostimulation System for Chronic Pain. Information for Prescribers. 2017
- Medtronic Strata II Valve: Instructions for Use.
- Medtronic SynchroMed IsoMed 8626, 8627, 8637, 8472 Implantable Infusion Systems: Information for Prescribers (Includes MRI Eligibility Information). 2017
- MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain: Instructions for Use. 2017.
- MRI With The VNS Therapy System. 2017
- VNS Therapy System Physicians Manual. 2018.