



Effects of Magnetic Resonance Imaging (MRI) on St. Jude Medical Implantable Cardiac Rhythm Devices

This letter is being provided in response to your request for information about MRI and St. Jude Medical implantable cardiac rhythm devices.

Background

Magnetic Resonance Imaging (MRI) is contraindicated by MRI manufacturers for patients with implanted cardiac rhythm management devices, including both pacemakers and implantable cardioverter defibrillators (ICDs). Clinicians should carefully weigh the decision to use MRI with ICD or pacemaker patients. MRI may cause device malfunction or injury to the patient. The powerful magnetic and radiofrequency fields generated by MRI systems may cause inappropriate operation or permanent damage to implanted pacemakers or ICDs.

Potential Effects

Potential effects of MRI exposure range from single-beat inhibition of pacing to component damage leading to inappropriate operation or device failure.

- Magnetic and RF fields produced by MRI may increase pacing rate, inhibit pacing, cause asynchronous pacing or result in pacing at random rates.
- MRI may result in changes in capture thresholds due to heating of pacing leads in any patient.
- MRI may irreversibly damage the pulse generator.

A summary of potential effects is provided in the table below and is based on device testing at St. Jude Medical, clinical experience and a review of the scientific literature.

Potential Effect	Estimated Frequency	
	Pacemakers	ICDs
Reversion to magnet mode	Common	Common
Asynchronous pacing/noise reversion	Common	Common
Single-beat inhibition	Common	Common
Lead dislodgement on acute leads	Uncommon	Uncommon
Device movement in the pocket	Uncommon	Uncommon
High rate pacing	Rare	Rare
Lead heating, possibly leading to tissue damage and pacing threshold changes	Rare	Rare
Component damage	Rare	Rare
Inappropriate therapy delivery	Not applicable	Rare
Failure to deliver needed therapy	Not applicable	Rare
Reset mode	Not applicable	Rare



Recommendations

Clinicians should carefully weigh the decision to use MRI with pacemaker or ICD patients. If MRI must be performed, the following should be considered:

- As clinically appropriate, program the device to an asynchronous pacing mode such as DOO or VOO. ODO may also be considered for non-pacemaker dependent patients if pacing is not desired.
- Patients should be closely monitored during the MRI.
- Device operation should be assessed after exposure to MRI and may be compared to previous device assessments if necessary.

If you have any questions on this topic, please contact St. Jude Medical Technical Services at 800-722-3774.