

# Harvard Heart Letter

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## Clash of the titans

*The pacemaker and the MRI can't work together—at least not yet.*

**H**ere's a cruel irony: If you have a pacemaker or implantable cardioverter/defibrillator (ICD), you can't take advantage of another of the 20<sup>th</sup> century's life-saving devices, the MRI. Energy from an MRI scan can change how these devices control the heart, damage the devices, or harm the heart tissue around them.

This incompatibility is serious business, because MRIs are increasingly important in diagnosing everything from stroke and cancer to problems with the brain and spinal cord. Someday soon they may even rival the angiogram for spotting narrowed or blocked coronary arteries. By one estimate, at least half of all people with pacemakers or ICDs will need an MRI at some point.

No pacemakers or ICDs currently on the market have been designed and built from the get-go to be completely MRI safe, and no MRI-safe devices have been approved by the FDA. That will change, though whether it's sooner rather than later is hard to predict.

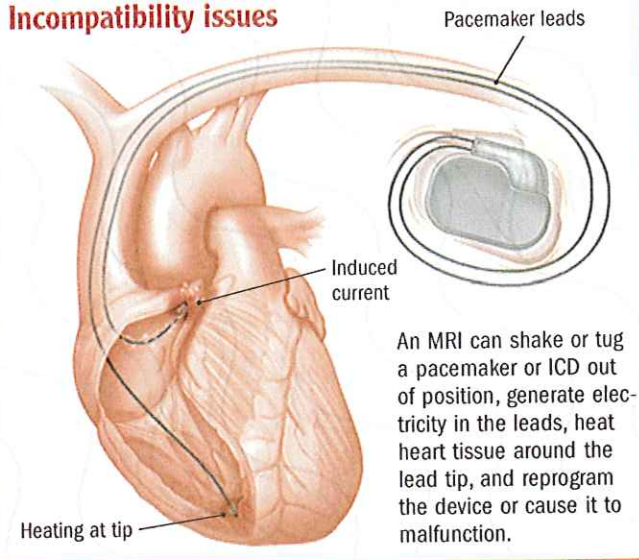
### Technology at odds

Each year, about one-third of a million Americans get an implanted device. Pacemakers help the heart maintain a steady, rhythmic beat. ICDs monitor the heart's rhythm for signs of a potentially deadly pattern and, if one appears, deliver a jolt of electricity that stops the pattern and restores a normal heartbeat. Some devices do both.

MRI scanners use a strong magnetic field and pulses of radio waves to see inside the body. Both energy sources can interfere with pacemakers and ICDs:

- The magnetic field can shake or tug a device, especially an older one, out of position.
- The field can generate a flow of energy through the "leads," the wires that connect the device with the heart muscle. This rogue energy can emerge as heat around the tip of a lead. If it causes a scar, signals from the pacemaker or ICD may have trouble getting through to the heart.

### Incompatibility issues



- Pulsing radio waves create electrical currents inside leads that may be powerful enough to make the heart contract hundreds of times a minute at a rate that may be far too fast for life-sustaining circulation.
- MRIs can reprogram pacemakers or ICDs, foul their batteries, and cause the devices to malfunction.

These problems aren't theoretical. At least 10 deaths have been attributed to MRIs done inadvertently on people with pacemakers. At the same time, sev-

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### New from Harvard Medical School

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## Pacemakers and MRI *continued*

eral hundred people have been safely scanned with pacemakers in place. No one knows the full extent of the hazard.

### Can they work together?

Most doctors tell their patients with pacemakers or ICDs that they can't have MRIs. This is in keeping with recommendations from the American College of Radiology and the Heart Rhythm Society.

Yet a handful of studies published in the last five years indicate that some people, with certain models of pacemakers or ICDs, under the right conditions, can safely have an MRI. But there are far too many variables to make a blanket statement about the safety of doing this.

A better approach would be to build pacemakers and ICDs that aren't affected by MRIs. One company that has been public about its work in this area is Biophan Technology, a start-up based in West Henrietta, New York. Cofounded with Wilson Greatbatch, the inventor of the first successful pacemaker, Biophan has designed leads that filter out MRI radio waves and has devised a new way to make and implant leads. Together, these changes prevent stray voltages and heating at the tip, says Biophan CEO Michael Weiner.

Companies that make pacemakers and ICDs are looking for their own solutions. But they are reluctant to offer specifics, and they aren't saying when, or if, they are coming out with MRI-safe devices. Their foot-dragging stems partly from the challenges of redesigning their products and partly from the long, potentially costly process of getting the FDA to approve new or redesigned leads. Several crowbars could force the industry to make MRI-safe devices. These include lawsuits against one or more companies for MRI-induced death or damage, regulations from the FDA mandating compatibility, or

the emergence of an MRI-safe pacemaker or ICD that sells well.

The Pacemaker Club, an online support group, hopes that grassroots action might move things forward. The club started a letter-writing campaign to urge device makers to roll out MRI-safe pacemakers and ICDs. You can find a link to the effort at [health.harvard.edu/heartextra](http://health.harvard.edu/heartextra) under the April 2006 heading.

### In the meantime

If you have a pacemaker or ICD and need an MRI, you might be able to get one if you are willing to take a chance and you find a radiologist and a cardiologist who will work together throughout the scan. Here are the essentials:

- A radiologist well-versed in the safety issues must design and monitor the MRI.
- A cardiologist who specializes in arrhythmias must be in the MRI suite during the entire scan.
- The cardiologist should check your implanted device before the scan, and reprogram it if necessary.
- During the scan your heart rhythm, pulse, and blood oxygen level must be continuously monitored.
- Equipment to revive you and sustain your heartbeat must be on hand, just in case there's a problem.
- After the scan, your cardiologist should check your pacemaker or ICD to make sure it is working okay. You also need to visit your cardiologist several times in the months following the scan.

The policy of forbidding anyone with a pacemaker or ICD from having a potentially life-saving MRI may be on its way out. It's too bad that the day hasn't yet arrived when everyone with a pacemaker or ICD can safely have an MRI. ♥