

MAGNETIC FIELD INFLUENCES AND YOUR STRATA™ VALVE

Strata™ II Valves



Medtronic



Magnetic field influences on your Strata™ valve

You have a Medtronic adjustable valve to treat your hydrocephalus or other CSF disorder. Adjustable valves contain a magnet, which allows your neurosurgeon to change the performance level setting in his or her office.

If the performance level of your Strata™ valve needs to be changed, you will not need another surgical procedure. Your neurosurgeon will change the valve setting using a set of simple hand tools that rely on magnetic coupling with the valve through your skin. The same hand tools are used to verify that the change has been made correctly. Since your adjustable valve contains a magnet, you should observe certain precautions.

Check with your healthcare team about specific neuroimaging procedures related to your ongoing treatment.



Magnetic resonance imaging (MRI)

We conducted extensive testing of the Strata™ valves using MRI with a static magnetic field capacity of 3.0 tesla. The test results indicate that our adjustable valves are MR Conditional. That is, exposure of the Strata™ valve of up to 3.0 tesla MRI will not damage your valve*, but may change the valve's performance level setting. Therefore, before and after MRI exposure, your neurosurgeon or attending physician will need to check the valve's setting.



Other magnets

Magnets are common in many products used in everyday life. They are found in refrigerator door seals, computer tablets, such as the iPad®, headphones, earbuds, and in some children's toys.

Your Strata™ valve also contains an internal magnet that can be adjusted using a strong external magnetic tool. In order to adjust the valve setting, a minimum of 90 gauss¹⁻³ directly adjacent to the valve is required. "Gauss" is a measure of magnetic field strength. The external Strata™ adjustment tool is a very strong magnet (over 3000 gauss) to ensure reliable valve adjustment through a patient's scalp and hair.

Because magnets are used to adjust your valve setting, you may be concerned about the potential effect other magnets may have on your valve's setting. It is important to know that the strength of a magnet weakens significantly with distance.



Medtronic tested a number of representative products to demonstrate that magnets pose a very minimal risk to patients with an adjustable valve. The table here highlights examples of how magnetic strength weakens with distance.

| Product Tested | Typical Magnetic Strength at Source (Gauss) | Typical Magnetic Strength at 2" (5 cm Distance) (Gauss) |
|--------------------------------|--|--|
| iPad® Smart Cover | 2060 | 1.3 |
| Cellphone – Clam Shell Type | 525 | 1.5 |
| Headphones (Earbud Type) | 350 | 0.0 |
| Refrigerator Door Seal | 340 | 0.2 |
| Decorative Refrigerator Magnet | 305 | 0.0 |
| Noise-Canceling Headphones | 115 | 1.1 |
| Walk-Through Metal Detectors | 1.5 | 0.0 |
| Handheld Security Wand | 1.0 | 0.0 |



Specific recommendations

While it is impossible to test all of the various magnets in our day-to-day lives, the vast majority will not impact your Strata™ valve. We realize, however, that there may be unique situations that can impact the valve setting, so we recommend that you keep all products with magnets a minimum of 2" (5 cm) away from the site where your valve was implanted.

For this reason, you should never use magnetic therapy pads and pillows.



We encourage you to always carry your shunt identification card. The information is helpful to your healthcare providers.

Walk-through security detectors in stores and airports, as well as hand-held security wands, do not have enough magnetic strength to change the setting of your adjustable valve. The newer full body imaging systems used at some airports are x-ray-based systems and will not interfere with the Strata™ valve setting. Therefore you should not be concerned with airport travel or entering stores with security systems.

Most headphone speaker magnets are too weak to interfere with the valve setting. However, you should use caution around professional-type audio headphones.

For devices like cell phones that must be used close to your head, we recommend that you use them on the side of your head opposite from your valve implant.

Many patients depend on devices such as pacemakers, deep brain stimulators (DBS), insulin pumps, cochlear implants, hearing aids, and vagal nerve stimulators. These devices will not affect your adjustable valve setting, but we encourage you to talk with your physician if you have specific concerns.

Electromagnetic fields such as those generated by high voltage wires, computers, and microwaves will not have any influence on the adjustable valve pressure setting.

* Biological debris inside the valve may impact adjustability and may lead to adjustment mechanism damage if exposed to 3.0 tesla MRI. If difficulty is experienced adjusting or reading the valve setting, radiographic setting confirmation should be considered. The reading from the Strata II indicator tool or StrataVarius may be reversed (180 degrees opposite) from the radiographic image. In this situation, radiographic imaging should be used to determine the setting of the valve.

1. MNS Report RD9310-04, "Kronos" Valve Resistance to Spontaneous PL Setting changes"; Dec 15, 1998.
2. MNS Technical Document TD-02843, "Strata II Valve Design Verification Report: Resistance to Inadvertent Switching"; Sept 3, 2004.
3. MNS Technical Document TD-02864, "Magnetic Inadvertent Switching: Non-homogeneous Dynamic Magnetic Influence Characterization of the Strata NSC Valve and Codman Hakim Programmable Valve"; Nov 15, 2004.

Caution: Federal Law (USA) restricts these devices for sale by or on the order of a physician. Refer to product instruction manual/package insert for instructions, warnings, precautions and contraindications. Healthcare professionals must review the product technical manual prior to use for detailed disclosure. For information on Indications, Safety, and Warnings, call Medtronic at (800)328-0810. For further information, please contact Medtronic Neurosurgery at (877) 242-9504, and/or consult Medtronic's website at www.medtronic.com.

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