

Strata® Valves and Magnetic Fields

The Medtronic Strata® products are a valve technology used in the treatment of hydrocephalus. Strata valve products contain a magnet inside the valve mechanism that allows the neurosurgeon to change the pressure setting of the valve in his office. Changing the pressure setting of the valve does not require a revision or surgical procedure. The change is made using a set of simple hand tools that rely on magnetic coupling with the valve through the skin. The same hand tools are used to verify that the change has been made correctly, without the need for x-ray confirmation.

Since the Strata valves contain a magnet, the patient should observe certain precautions.

Magnetic Resonance Imaging (MRI)

Extensive testing of the Strata valve was conducted using MRI with a static magnetic field capacity of 3.0 Tesla. Results of the testing indicate that the valve is "MRI Safe". That is, exposure of the valve to MRI will not damage the valve, but may change the valve pressure setting. **Therefore, immediately after MRI exposure, the valve pressure setting needs to be checked by your neurosurgeon or attending physician.**

Other Magnets

Magnets are common in many products in our everyday life. Magnets are found in electronic equipment, refrigerator door seals, some computer tablets such as the iPad®, audio speakers and in some children's toys. The magnets in these devices can vary in strength and are so common we may not even know they are present.

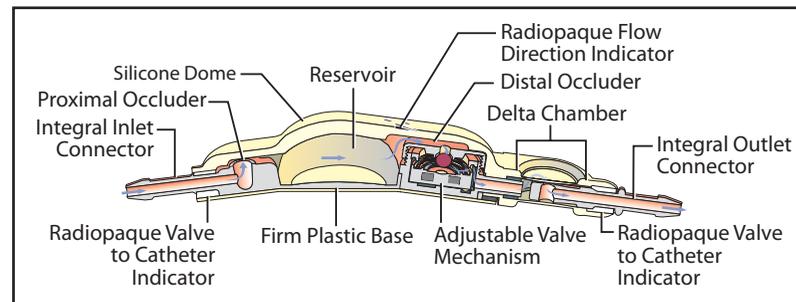
The Strata valve also contains an internal magnet which is designed to be adjusted using a strong external magnetic tool. In order to adjust the valve setting, a minimum of 90 gauss¹⁻³ directly adjacent to the valve is required. "Gauss" is a measure of magnetic field strength. The external Strata adjustment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

Check with your health care team about specific neuro-imaging procedures related to your ongoing treatment.

Because magnets are used to adjust the valve setting, it is reasonable for a person to be concerned about the potential effects other magnets may have on their Strata valve setting. It is very important to know that the strength of a magnet weakens dramatically with distance. Medtronic has tested a number of representative products to demonstrate that the risk to a Strata patient is very minimal. The following table highlights examples of how magnetic strength weakens with distance.

Product Tested ⁴	Typical Magnetic Strength at Source (Gauss)	Typical Magnetic Strength at 2" (5 cm) Distance (Gauss)
iPad® 2 & Smart Cover	2060	1.3
Cellphone – Clam Shell Type	525	1.5
Headphones (Earbud-Type)	350	0.0
Refrigerator Door Seal	340	0.2
Flexible Decorative Refrigerator Magnet	305	0.0
Noise-Canceling Headphones	115	1.1
Walk-Thru Metal Detectors	1.5	0.0
Handheld Security Wand	1.0	0.0

Medtronic realizes that there may be unique situations that can impact the Strata valve setting, so it recommends that all products with magnets be kept at a minimum of 2" (5 cm)* from the Strata valve implant site. Magnetic therapy pads and pillows should not be used at all. For devices that must be used close to the head (e.g., cell phone, cochlear implant, etc.) it is recommended that they be used on the side of the head opposite the valve implant. Most headphone speaker



Cutaway Illustration of a Strata® Valve



Adjustable Strata® Valves and Adjustment Tools

magnets are too weak to interfere with the valve setting. Caution should be used around professional-type audio headphones.

Walk-thru security detectors in stores and airports, and hand-held security wands, do not have enough magnetic strength to change the pressure setting of the 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. There should be no concern with airport travel, or entering stores with security systems.

Electromagnetic fields such as those caused by a high voltage wire will not have any influence on the valve pressure setting.

While it is impossible to quantify all the various magnets in our day-to-day lives, the vast majority will not impact the Strata valve as long as the recommended distance from the valve implant site of 2" or more is maintained.

* Some unusual industrial work environments may require a further separation than 2 inches (5 cm).

iPad® is a registered trademark of Apple, Inc.

For more information:
www.medtronic.com

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.
4. Data available upon request.

For more information, please contact us at **800-510-6735**,
or refer to www.medtronic.com

This therapy is not for everyone. Please consult your physician. A prescription is required. Caution: Federal (USA) law restricts these devices to sale by or on the order of a physician. Refer to product package insert for instructions, warnings, precautions and complications.

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Strata® Valves

MAGNETIC FIELD INFLUENCES

