

Urgent Field Safety Notice

Medtronic StrataMR™ Adjustable Valves & Shunts

Model numbers 42955, 42965, 45905, 46955, 46960, 46965, and 46970
Recall

March 2017

Medtronic reference: FA759

Dear Chief of Neurosurgery and/or Risk Manager:

The purpose of this letter is to advise you that Medtronic Neurosurgery (Brain Therapies) is initiating a voluntary recall of all unused units for the Medtronic StrataMR™ adjustable valves & shunts.

You are receiving this letter because you may have received one or more of the affected products. Medtronic is initiating this voluntary recall because the products identified above may experience a condition that may, in limited circumstances, affect the flow resistance in the valve and result in underdrainage of cerebrospinal fluid (CSF). The condition can occur when the valve mechanism is adjusted to a position that causes a higher than intended flow resistance. This higher than intended flow resistance is a result of the MRI Resistance Key on the bottom of the valve's rotor mechanism being placed on top of one of the MRI Resistance Walls, instead of in one of the pressure setting wells (see **Figures 1 & 2**). This condition only occurs during the valve adjustment process.

StrataMR™ Adjustable Valve

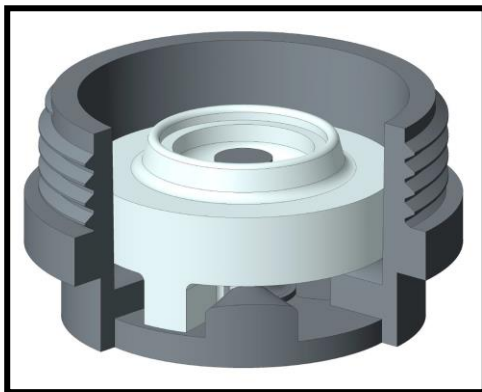
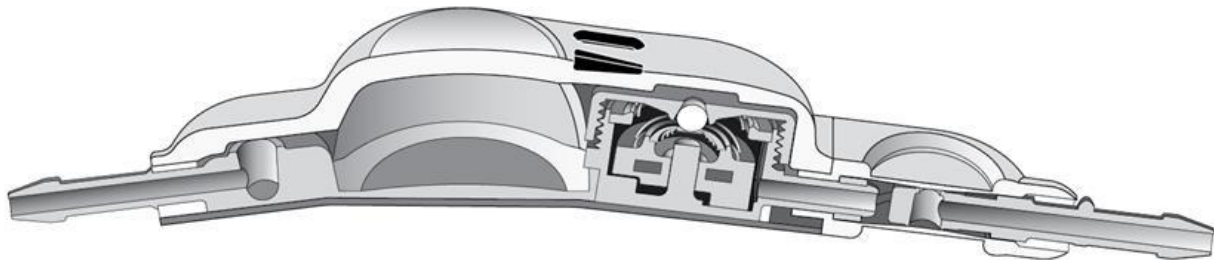


Figure 1
Example of a **Correct** rotor
orientation

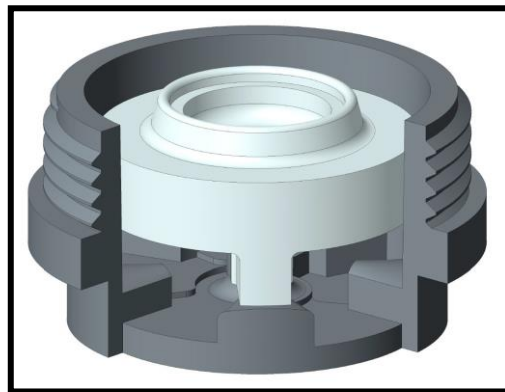


Figure 2
Example of an **Incorrect** rotor
orientation

When the StrataMR™ valve is set in an orientation as seen in Figure 2, pressure flow performance approximately twice the level above StrataMR's highest Performance Level setting of 2.5, can occur and lead to cerebrospinal fluid (CSF) underdrainage. This condition may result in the following adverse health consequences: headaches, nausea, vomiting and lethargy. If left untreated underdrainage has the potential to lead to coma and death.

Our investigation determined an increase in the occurrence rate of StrataMR™ complaints, related to incorrect flow or level change in the month of January 2017. Due to this increase, the complaint rate is 1.45% of total units distributed since November of 2015; 1.1% of total units distributed resulted in revision surgeries. There have been no reports of death.

The incorrect valve rotor orientation (Figure 2) can be caused by misalignment and/or off-center positioning of the StrataMR™ Locator Tool, relative to the valve mechanism.

The images that follow are examples that illustrate both correct and incorrect alignment and centering, and are intended to assist clinicians in their efforts to set the valve pressure level setting as intended.

Figure 3 provides an example of proper/correct technique. Figures 4, 5, & 6 provide examples of incorrect alignment and centering techniques that should be avoided.

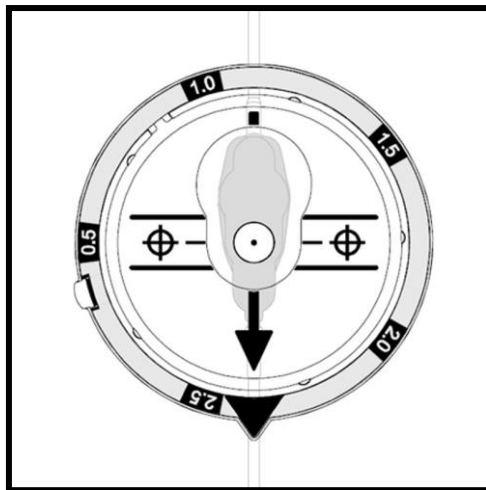


Figure 3
Correct
Good Alignment and Centering
of Locator Tool and Valve Mechanism

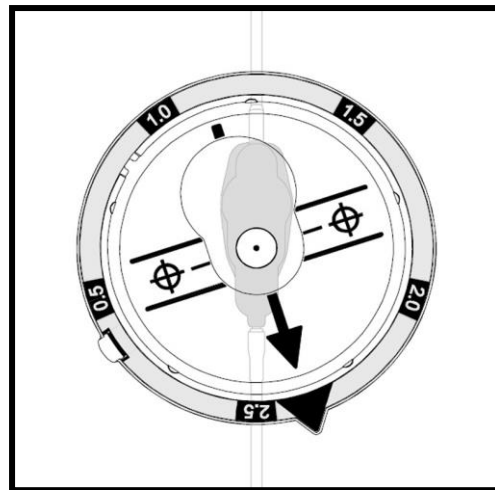


Figure 4
Incorrect
Poor Alignment, but good centering
of Locator Tool & Valve Mechanism

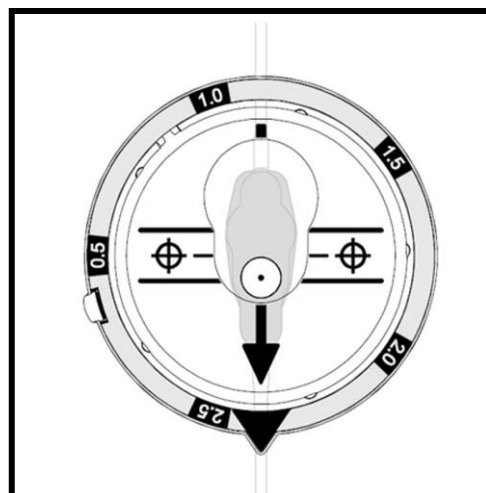


Figure 5
Incorrect
Good Alignment, but poor centering
of Locator Tool & Valve Mechanism

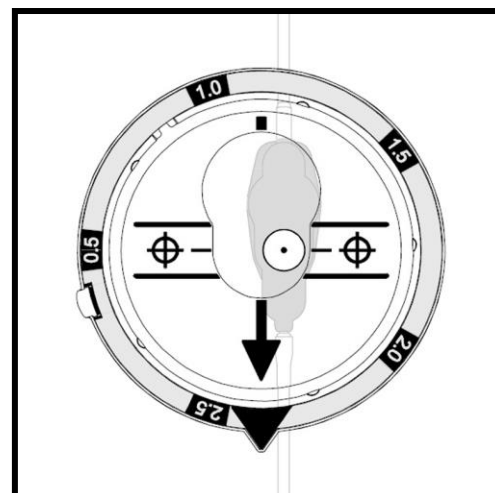


Figure 6
Incorrect
Good Alignment, but poor centering
of Locator Tool & Valve Mechanism



As part of the adjustment process of the StrataMR Adjustable Valve system, it is important to note that if the valve's pressure flow setting is accurately aligned and centered via proper technique as described in the IFU (also see Figure 3 and the instructions in Addendum A), the valve MRI Resistance Key will be set to the correct pressure setting well.

As a result, Medtronic is asking that you take the following actions:

1. Identify and quarantine unused affected devices that are in your inventory.
2. Return all affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.
3. If any of the indicated products have been implanted in patients, see the valve adjustment instructions in Addendum A for continued patient care.

The Competent Authority of your country has been notified of this action.

Please share this notification with others in your organization as appropriate or to any organization where the potentially affected product may have been transferred. In case of any questions related to this Urgent Field Safety Notice contact your Medtronic Representative at Baasiri, Tarek at +966550606933

We appreciate your cooperation and apologise for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern.

Sincerely,

Mohammed El Ansari

A handwritten signature in blue ink, appearing to read 'M. El Ansari', is positioned above the typed name.

Senior Business Manager- Brain and RTG
Kingdom of Saudi Arabia
Mohammed.ansari@medtronic.com

Addendum A: Extract From Instructions for Use

Addendum A

To ensure the valve is set at the desired setting, **it is critical to properly align and center the Locator Tool over the valve mechanism**. The following language is taken directly from the Instructions for Use (IFU) and will aid in proper technique to ensure the clinician can achieve the desired pressure level setting.

Warning: The StrataMR valve is designed with five wells separated by raised walls. The valve mechanism must be seated within the wells to achieve the intended pressure flow performance otherwise under drainage may occur and result in patient complications.

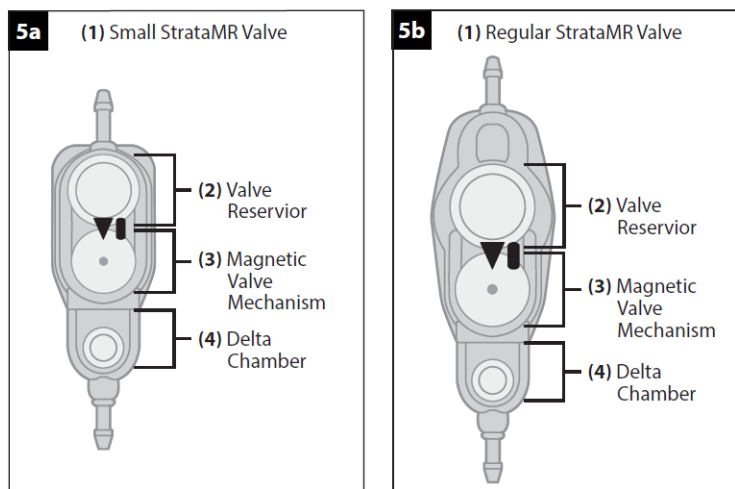
The StrataMR Adjustment Tools are for use by qualified personnel only; ensure users have adequate knowledge to prevent misuse.

The StrataMR valve is designed with five wells separated by raised walls. The valve mechanism must be seated within the wells to achieve the intended pressure flow performance otherwise under drainage may occur and result in patient complications. It is recommended that the initial performance level of the implanted StrataMR valve be changed no more than one performance level in any 24 hour period. Throughout this post adjustment period, the clinical condition of the patient should be carefully monitored.

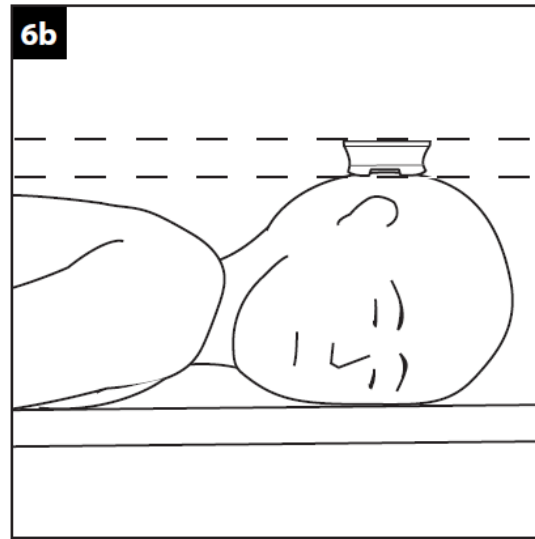
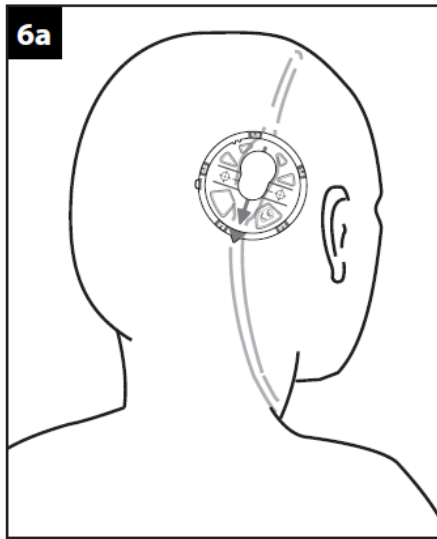
Positioning the Locator Tool after Implantation.

Warning: the Indicator Tool may give false performance level setting readings unless it is aligned with direction of CSF flow and centered over the magnetic valve mechanism.

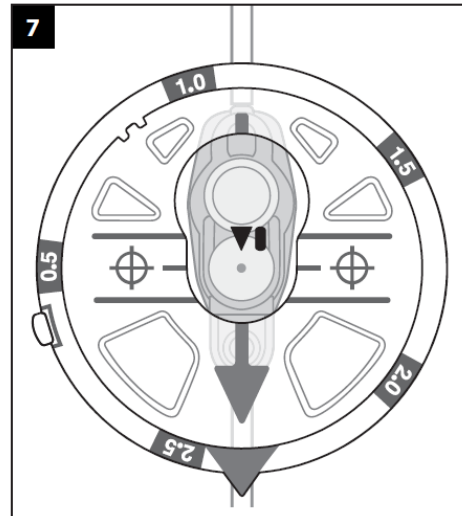
1. *Position the patient away from large metal objects, such that the implanted valve can be conveniently accessed. The patient may be upright or supine.*
2. *Palpate the valve implantation site to determine the location of the valve and valve reservoir. The magnetic valve mechanism is adjacent and downstream of the valve reservoir (figure 5a and 5b).*



3. *Position the Locator Tool above the valve so that the red flow direction arrow is aligned with the direction of CSF flow through the valve and is centered over the magnetic valve mechanism (figure 6a and 6b).*



4. Verify that the alignment zone of the Locator Tool is centered over the (hard plastic) valve mechanism, not the valve reservoir dome (figure 7).



It's important to note that the previously mentioned instructions are a subset of the entire IFU dedicated to the StrataMR™ adjustable valve system. Please reference the official IFU for complete instructions.