

Urgent – Medical Device Recall **Medtronic StrataMR™ Adjustable Valves & Shunts**

Catalog Number 42955, STRATAMR VALVE, SMALL

E11656, E12556, E12753, E13482, E13483, E13484, E13641, E14518, E14519, E18555, E18556, E18557, E18558, E19670, E19866

Catalog Number 42965, STRATAMR VALVE, REGULAR

E11655, E12041, E12265, E12266, E12950, E12951, E12952, E12953, E13485, E13698, E18559, E18560, E19084, E19540, E19671, E19867, E22208, E22242

Catalog Number 46955, STRATAMR SHUNT ASSEMBLY, SMALL

E12752, E12932, E16247

Catalog Number 46960, STRATAMR SNAP SHUNT, SMALL

E12780, E12934, E14748

Catalog Number 46965, STRATAMR SHUNT ASSEMBLY REGULAR

E12779, E12933, E14270

Catalog Number 46970 STRATAMR SNAP SHUNT, REGULAR

E12272, E12620, E12935

Date: 06 March 2017

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 product(s). 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

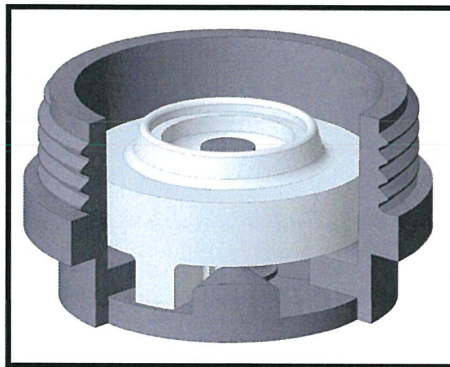
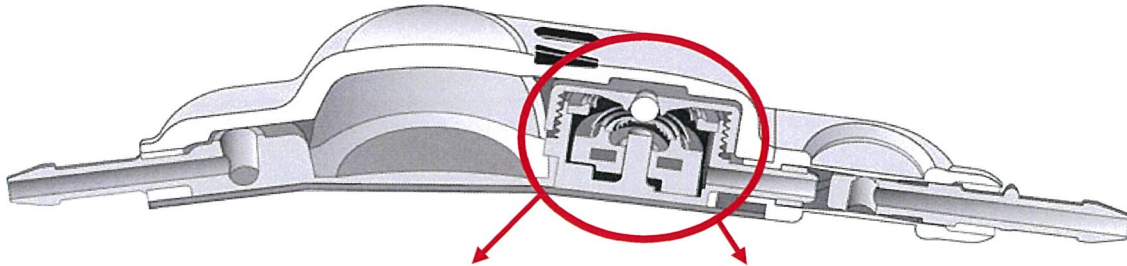


Figure 1
Example of an **Correct** rotor
orientation

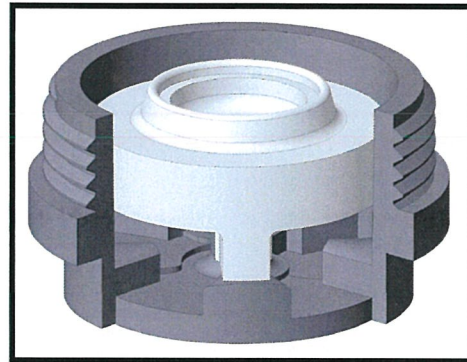


Figure 2
Example of an **Incorrect** rotor
orientation

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.

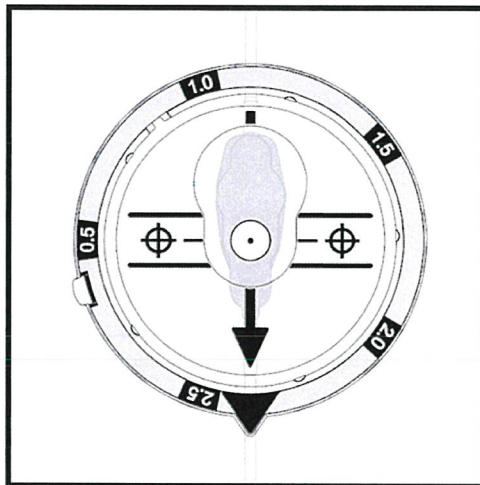


Figure 3
Correct

Good Alignment and Centering
of Locator Tool and Valve Mechanism

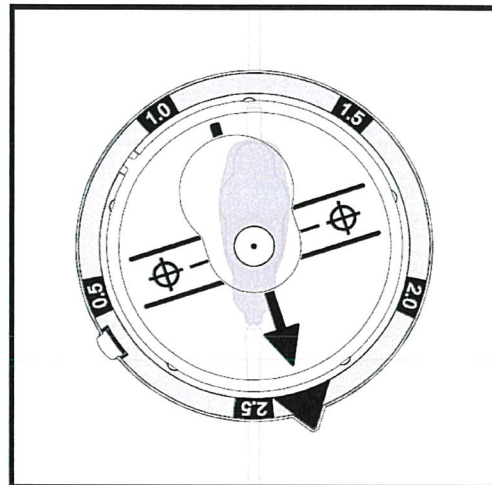


Figure 4
Incorrect

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

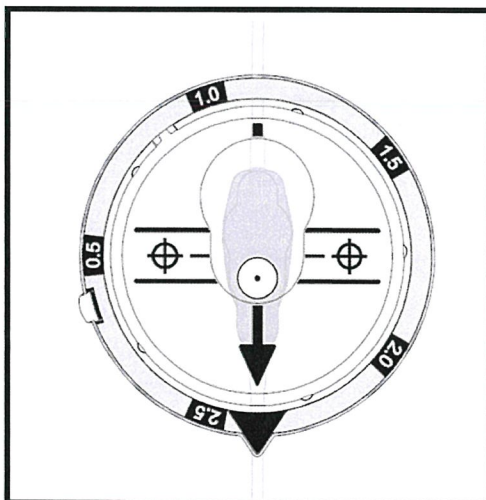


Figure 5
Incorrect

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

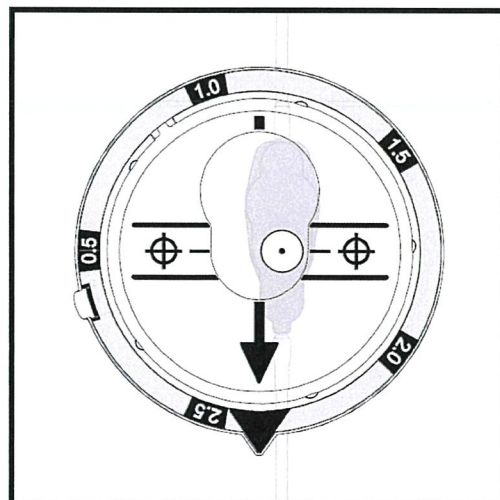


Figure 6
Incorrect

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 instructions in Attachment A), the valve MRI Resistance Key will be set to the correct pressure setting well.

We ask that the following actions be initiated immediately:

- 1. Cease use of the listed product.**
- 2. If any of the indicated products have been implanted in patients, see the valve adjustment instructions in Attachment A for continued patient care.**
- 3. Account for number of product units implanted or discarded and return any unused units by completing the attached individualized customer product accountability form provided in Attachment B. Please follow the instructions described in Attachment B.**

This letter is intended to document this event for your files. We request this letter be provided to all those who need to be aware of this matter within your organization or to any organization where the potentially affected product may have been transferred.

We sincerely regret any inconvenience this situation may have caused. Please feel free to contact me should you have any questions or concerns.

Fax your "Customer Acknowledgement Response Form" to Medtronic Neurosurgery at +65 6776 6355.

Yours Sincerely,



Shirley Loh
Marketing Director

Enclosed:

Attachment A: Instructions for implanting surgeons

Attachment B: Recall re-conciliation form

Attachment C: Physician Acknowledgement Form

ATTACHMENT A

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. The images that follow are meant to communicate examples of both correct and incorrect alignment and centering 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.

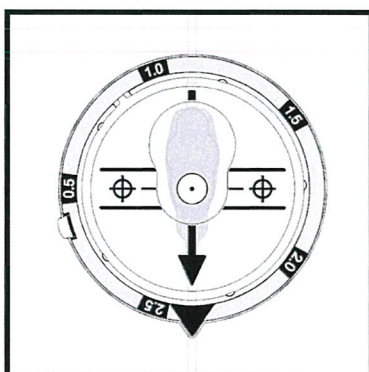


Figure 3
Correct

Good Alignment and Centering
of Valve Mechanism and Locator Tool

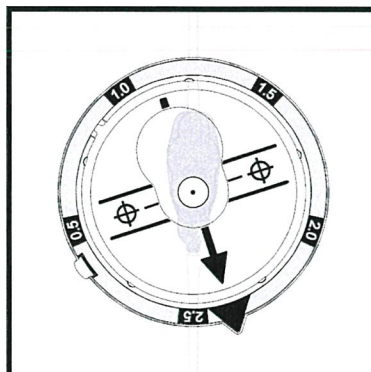


Figure 4
Incorrect

Poor Alignment, but good centering of
Locator Tool and Valve Mechanism

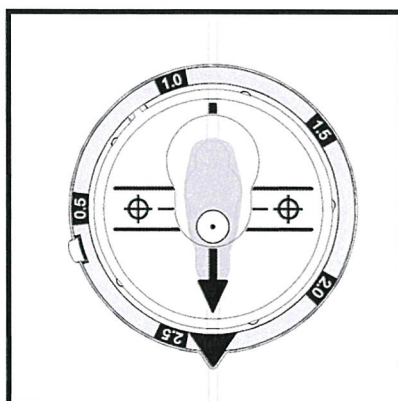


Figure 5
Incorrect

Good Alignment, but poor centering of
Locator Tool and Valve Mechanism

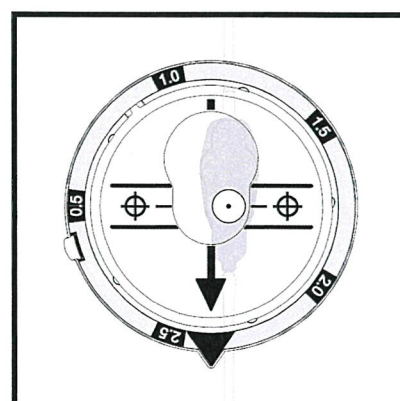


Figure 6
Incorrect

Good Alignment, but poor centering of
Locator Tool and Valve Mechanism

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

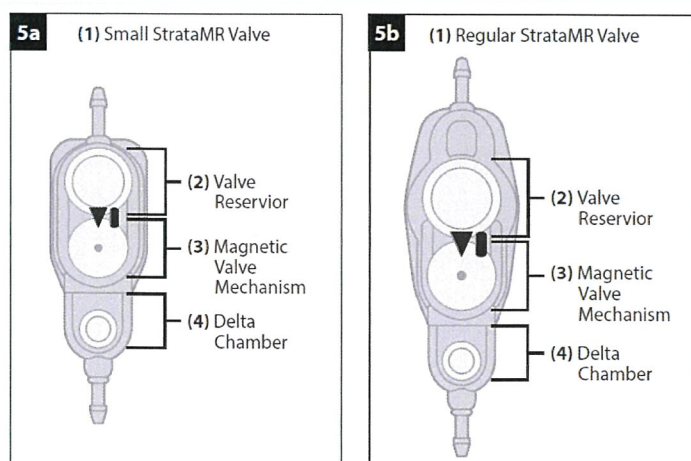
The StrataMR Adjustment Tools are for use by qualified personnel only; ensure users have adequate knowledge to prevent misuse

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.

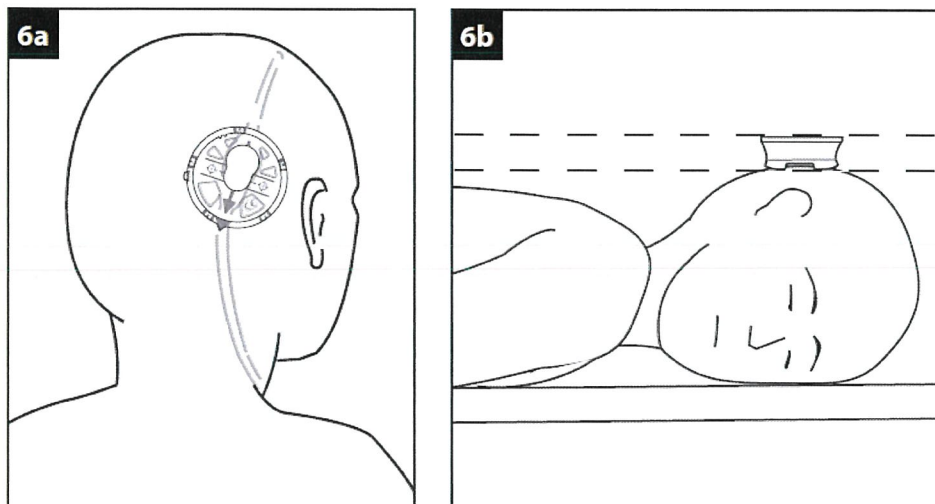
Positioning the Locator Tool after Implantation

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.

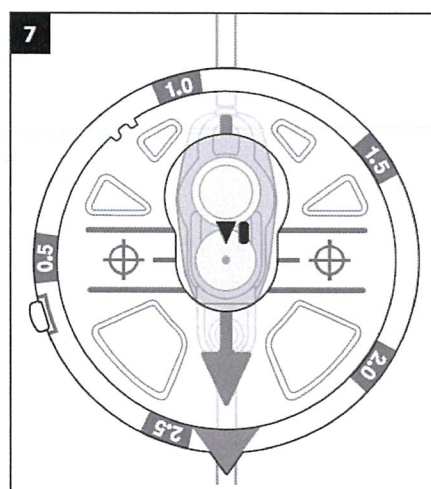
1. Position the patient away from large metal objects, such that the implanted valve can be conveniently accessed. The patient may be upright or supine.
2. Palpate the valve implantation site to determine the location of the valve and valve reservoir. The magnetic valve mechanism is adjacent and downstream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

ATTACHMENT B

Urgent – Medical Device Recall Medtronic StrataMR™ Adjustable Valves & Shunts

06 March 2017

Dear Customer Representative,

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. The following products are affected:

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E12779, E12933, E14270

Catalog Number 46970 STRATAMR SNAP SHUNT, REGULAR

E12272, E12620, E12935

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).

Our records indicate that you have received affected product (as shown below).

Customer Information	Catalog Number	Lot Number	Quantity Shipped	Purchase Order Number

Please determine the status of the above listed product and complete the table below. The status of all listed product must be provided. If product has been used or discarded, please note the quantities below.

Catalog Number	Lot Number	Quantity Shipped	# of Product Available to be Returned	# of Product Used and/or Discarded

Hospital Representative Signature: _____ Date: _____

Hospital Representative Name (print): _____

Hospital Representative Telephone#: _____

ATTACHMENT C

CUSTOMER ACKNOWLEDGMENT RESPONSE FORM

Medtronic Neurosurgery
Medtronic StrataMR™ Adjustable Valves & Shunts

I have received, read and notified all appropriate personnel of the information provided for Medtronic Neurosurgery's voluntary recall of all unused units for the Medtronic StrataMR™ adjustable valves & shunts.

Recipient Name (printed): _____

Recipient Signature: _____ **Date:** _____

Recipient Stamp: _____

Recipient Title: _____

Return this form (keep a copy for your records) to:

POSTAL MAIL:

Medtronic International Ltd., 49 Changi South Avenue 2, Singapore 486056

FAX:

+65 6776 6355

Comments/notes: _____