StrataMR™ Quick Start Adjustment Guide

Refer to the Instructions For Use, which accompany the StrataMR™ Adjustment Tools, for complete instructions, warnings, and precautions.
Position the Locator Tool above the valve in the sterile package so that the red flow direction arrow is aligned and centered with the direction of CSF flow through the valve, as indicated by the valve radiopaque marker.

Set the Indicator Tool into the Locator Tool while aligning the red flow directional arrows on the tools. The Indicator Tool pointer will now point to the valve’s current performance level setting.

Carefully keeping the Locator Tool in position, remove the Indicator Tool. Place the Adjustment Tool 15 cm (6 in) above the Locator Tool. Align the triangular mark on the Adjustment Tool with the current performance level setting. Lower the Adjustment Tool straight into the Locator Tool until it sits flush.

Always ensure that the Adjustment Tool is at least 76 cm (30 in) away from the valve to avoid influencing the readings.

Hold the Locator Tool and rotate the Adjustment Tool until the triangular mark points to the desired performance level setting.

Withdraw the Adjustment Tool straight up while keeping the Locator Tool in position over the valve. Immediately return the Adjustment Tool to the magnetically shielded storage case. Avoid metallic components such as hinges and latch.

Place the Indicator Tool into the Locator Tool. The Indicator Tool pointer will now point to the valve’s performance level setting.

Record the performance level setting on the patient card.

Performance Level
The physician must determine the proper initial performance level setting for each patient and adjust the valve accordingly before implantation.
Postoperative

1. Position the patient away from large metal objects. The patient may be upright or supine. Palpate the valve implantation site to determine the location of the valve and valve reservoir.

2. 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. Verify that the alignment zone marker of the Locator Tool is centered over the valve mechanism, not the reservoir dome.

3. Set the Indicator Tool into the Locator Tool while aligning the red flow directional arrows on the tools. The Indicator Tool pointer will now point to the valve’s current performance level setting.

4. Carefully keeping the Locator Tool in position, remove the Indicator Tool. Place the Adjustment Tool 15 cm above the Locator Tool. Align the triangular mark on the Adjustment Tool with the current performance level setting. Lower the Adjustment Tool straight into the Locator Tool until it sits flush.

5. Hold the Locator Tool and rotate the Adjustment Tool until the triangular mark points to the desired performance level setting.

6. Withdraw the Adjustment Tool straight up while keeping the Locator Tool in position over the valve. Return Adjustment Tool to the magnetically shielded storage case. Avoid metallic components such as hinges and latch.

Caution: Maintain alignment of the Adjustment Tool with the valve setting when the distance between the tool and the valve is less than 15 cm (6 in). Otherwise, an inadvertent change in valve performance level setting may occur.

7. Verify that the Locator Tool is still aligned with the direction of CSF flow and centered over the magnetic valve mechanism. The Indicator Tool pointer will now point to the valve’s performance level setting.

8. If the targeted setting was not achieved, rotate the Adjustment Tool through all available settings and then adjust the valve to the desired performance level setting and repeat step 7.

Record the performance level setting on the patient card.

Ensure that the Adjustment Tool is at least 76 cm (30 in) away from the valve to avoid influencing the readings.

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. Verify that the alignment zone marker of the Locator Tool is centered over the valve mechanism, not the reservoir dome.

Set the Indicator Tool into the Locator Tool while aligning the red flow directional arrows on the tools. The Indicator Tool pointer will now point to the valve’s current performance level setting.

Carefully keeping the Locator Tool in position, remove the Indicator Tool. Place the Adjustment Tool 15 cm above the Locator Tool. Align the triangular mark on the Adjustment Tool with the current performance level setting. Lower the Adjustment Tool straight into the Locator Tool until it sits flush.

Hold the Locator Tool and rotate the Adjustment Tool until the triangular mark points to the desired performance level setting.

Withdraw the Adjustment Tool straight up while keeping the Locator Tool in position over the valve. Return Adjustment Tool to the magnetically shielded storage case. Avoid metallic components such as hinges and latch.

Caution: Maintain alignment of the Adjustment Tool with the valve setting when the distance between the tool and the valve is less than 15 cm (6 in). Otherwise, an inadvertent change in valve performance level setting may occur.

Verify that the Locator Tool is still aligned with the direction of CSF flow and centered over the magnetic valve mechanism. The Indicator Tool pointer will now point to the valve’s performance level setting.

If the targeted setting was not achieved, rotate the Adjustment Tool through all available settings and then adjust the valve to the desired performance level setting and repeat step 7.

Record the performance level setting on the patient card.
Warnings and Precautions

To avoid injury or damage, the Adjustment Tool should be stored in the magnetically shielded case before and immediately after use. The Adjustment Tool contains strong magnets. Care should be taken when using the tool near magnetically sensitive medical implants (for example, pacemakers and vagal nerve stimulators), electronic equipment, and data storage devices such as computer diskettes or credit cards.

Do NOT take the Adjustment Tools or the case into an MRI facility as these magnets could potentially be a safety hazard to the patient and/or user. Excessive swelling or bandages may make it difficult to determine a valve setting. Wait until swelling is reduced, or confirm with radiographic imaging. In addition, scalp and overlying tissue thickness can make it difficult to determine the valve setting. If this is the case, confirm the valve setting with radiographic imaging.