Strata Adjustable Pressure Valve

https://www.medtronic.com/us-en/healthcare-professionals/products/neurological/shunts/strata-adjustable-pressure-valve.html

The Strata® Valve from Medtronic is part of a Ventricular shunt system used to treat the symptoms of hydrocephalus.

It is an Adjustable differential pressure valve.

Settings

The Strata valve has 5 settings or P/L, ranging from 0.5 to 2.5.

0,5 provides max CSF outflow.

Each performance level corresponds to a range of opening pressures and flow rates; generally, a lower performance level corresponds to a lower opening pressure. The range of opening pressures is between 15 and 170 mm H2O. Multiple models of the Strata valve have been introduced, including the Strata II valve and the Strata small valve.

All make use of the same radiographic scheme for setting assessment; the position of a notched disk relative to 2 small dots defines the P/L setting. Current product literature states that patients with Strata valves may undergo MR imaging by using a static field of ≤3T but that inadvertent changes of the setting are possible. It advises that the setting be checked after MR imaging to ensure that this has not occurred [1)].

Pre and post operative adjustment of Strata valves

<html><iframe width="560" height="315" src="https://www.youtube.com/embed/qydh-bZHQbQ" frameborder="0" allowfullscreen></iframe></html>

Indications

The Strata II valve is a shunt component designed to provide continued cerebrospinal fluid flow from the ventricles of the brain into the right atrium of the heart or the peritoneal cavity. The Strata II valve allows the physician to non-invasively adjust the pressure/flow performance level pre- and post-implantation without the need for radiographic confirmation in order to address changing patient needs. Additionally, the Strata II valve minimizes the excessive reduction of intraventricular pressure and volume due to excessive drainage of CSF, which may be caused by the siphon effect of hydrostatic pressure of the distal catheter.

Contraindications

Shunting of CSF into the peritoneal cavity or other areas of the body should not be carried out if there

is infection in any areas in which the various components of the shunt system will be implanted. These include infections of the scalp and other skin area through which the shunt system will traverse, the meninges and cerebral ventricles, peritoneum and intraperitoneal and retroperitoneal organs, pleura and blood stream. CSF shunting is contraindicated if there is infection present in any area of the body. Additionally, shunting into the atrium of patients with congenital heart disease or other serious cardiopulmonary abnormalities is contraindicated.

Warnings and Precautions

Magnetic Fields

The Strata valves were reprogrammed by direct contact (distance 0 mm) with the Bose headphones. When a rotation component was added, all 3 headphones reprogrammed the Strata valves at 0 mm. At all distances above 0 mm, the headphones did not affect the shunts. The proGAV valve was not affected by headphones at any distance.

Although all the headphones studied generated significant gauss fields at distances less than 5 mm, the programmable valve settings only changed at a distance of 0 mm (i.e., with direct contact). Given the subcutaneous location of the valve, the authors conclude that is highly unlikely that commercially available or customary headphones can contribute to the reprogramming of shunts [2)].

The valve pressure level setting should always be verified following patient exposure to high magnetic fields.

Devices known to contain magnets should be kept away from the immediate valve implant location, as they may have an effect on the performance level setting of the Strata-type valve. All magnets have an exponentially decreasing effect on the valve the further away they are located. Common environmental levels of electromagnetic (radio frequency) radiation generated by security scanners, metal detectors, microwave ovens, mobile telephones, high voltage lines, and transformers should not affect the performance level settings.

Valve function and performance level setting should be checked in the event that the valve is subjected to significant mechanical shock or trauma.

Use Medtronic Neurosurgery PS Medical Adjustment Kit REF 45805 to change Performance Level in the Strata II valve.

The Adjustment Tool contains strong magnets. Care should be taken when using the tool near magnetically sensitive medical implants (e.g. pacemakers and vagal nerve stimulators), electronic equipment, data storage devices such as computer diskettes or credit cards.

The Locator Tool, Indicator Tool, and Adjustment Tool should NOT be sterilized.

Ferromagnetic substances may impede the ability of the adjustment tools to change and confirm the Performance Level setting.

Refer to Adjustment Kit insert for instructions, warnings, precautions and complications.

The appropriate product and size must be chosen for the specific patient's needs, based on diagnostic tests and physician experience. Product labeling specifies applicable product performance levels or

ranges.

Lint, fingerprints, talc, other surface contaminants, or residues from latex gloves can cause foreign body or allergic reactions.

Improper use of instruments in the handling or implantation of shunt products may result in the cutting, slitting or crushing of components. Such damage may lead to loss of shunt integrity, and necessitate premature surgical revision of the shunt system.

Care must be taken to ensure that particulate contaminants are not introduced into shunt components during preimplantation testing or handling. Introduction of contaminants could result in improper performance of the shunt system. Particulate matter that enters the shunt system may result in shunt occlusion, or may also hold pressure/flow controlling mechanisms open, resulting in overdrainage.

In securing catheters to connectors, the encircling ligatures should be securely, but not too tightly, fastened, lest they eventually cut through the silicone tubing.

Care must be taken in the routing of catheters to prevent kinking and needless abrasion along their course. Abrasion can result in premature catheter failure (fracture). The rim of the twist drill or burr hole may be trimmed to provide a beveled notch where the ventricular catheter emerges and is curved to lie adjacent to the skull.

“Small” size catheters have thinner walls and lower overall strength as compared with “Standard” size catheters. These characteristics result in a comparatively greater potential failure (fracture) rate and, therefore, shorter life expectancy for “Small” size catheters. Physicians who implant “Small” size catheters for cosmetic reasons must acknowledge the potentially higher rate of catheter revision and weight this against the cosmetic benefit.

Patients with hydrocephalus shunt systems must be kept under close observation in the postoperative period for signs and symptoms that suggest shunt malfunction. The clinical findings may indicate shunt malfunction. The clinical findings may indicate shunt obstruction or overdrainage of CSF.

Shunt obstruction may occur in any of the components of the shunt system. The system may become occluded internally due to tissue fragments, blood clots, tumor cell aggregates, bacterial colonization or other debris. Catheters which contact internal body structures can become kinked or blocked at their tips (e.g., investment of a ventricular catheter tip into the choroid plexus or of the distal catheter tip into the greater omentum or loops of the bowel). Finally, shunt obstruction may occur due to growth of an infant or child, or physical activities which result in disconnection of the shunt components or withdrawal of a distal catheter from its intended drainage site.

Shunt obstruction may occur in any of the components of the shunt system. The ventricular catheter may become occluded by particulate matter such as blood clots or brain fragments, by investment of the catheter tip in choroid plexus, by embedding of the catheter in brain tissue, or by coaptation of the ventricular walls in the presence of overdrainage (“slit ventricle”).

Disconnected shunt components may further migrate.

Shunt systems may fail due to mechanical malfunction, leading to under- or overdrainage.

Malfunction or obstruction of the shunt system may lead to signs and symptoms of increased intracranial pressure if the hydrocephalus is not compensated. In the infant, the common symptoms are increased tension of the anterior fontanelle, congestion of scalp veins, listlessness, drowsiness

and irritability, vomiting and nuchal rigidity. In older children and adults, the common symptoms are headaches, vomiting, blurring of vision, nuchal rigidity, deterioration of consciousness, and various abnormal neurological findings.

Overdrainage of CSF may predispose development of a subdural hematoma or hydroma or collapse of the lateral ventricular walls leading to obstruction of the ventricular catheter.

If the ventricular catheter becomes bound to the choroid plexus or adjacent brain tissue by fibrous tissue adhesions, it is suggested that it should not be forcibly removed. It is suggested that gentle rotation of the catheter may help to free it. It is advised that the catheter be left in place rather than risk intraventricular hemorrhage which may be caused by forcible removal.

Subcutaneous catheter passers can break at welds or component assembly points, or due to extreme deformation of the malleable shaft. Sudden breakage can lead to trauma of tissues or organs, and damage to the shunt system. Instruments must be inspected prior to use to ensure continued integrity and functionality. Disposable instruments must never be reused, or injury to the patient and physician is possible.

MRI Information Valves The Strata® II valve is considered Magnetic Resonance Conditional in accordance with ASTM F2503.

MRI systems of up to 3.0 Tesla may be used any time after implantation and will not damage the Strata® II valve mechanism, but can change the performance level setting. The performance level setting should always be checked before and after MRI exposure.

The results of the tests performed to assess magnetic field interactions, artifacts, and heating, indicated the presence of the valves evaluated should present no substantial risk to a patient undergoing an MRI procedure using the following conditions:

Static magnetic field of 3.0 Tesla or less

Spatial Gradient of 720 G/cm or less

Radio Frequency (RF) Fields with an average Specific Absorption Rate (SAR) of 3 W/kg for 15 minutes. Using the GE 3.0T Excite® HD Magnetic Resonance Imaging System, the valve experienced a maximum temperature change of 0.4°C over a 15-minute exposure period. The table provides maximum signal voids (artifact sizes) for standard imaging pulse sequences at 3.0 Tesla per ASTM F2119.

Valve Pulse Sequence Plane Imagine Max. Signal Void (Artifact), cm2 Strata II T1-SE Parallel 35.16 T1-SE Perpendicular 33.03 GRE Parallel 73.91 GRE Perpendicular 66.55 Adjustment Kits Do NOT take the Adjustment Tool into an MRI facility as these magnets could potentially be a safety hazard to the patient and/or user.

Proximity to MRI suite may impede the mechanism in the Indicator Tool due to the field strength of an MRI magnet. Move out of the vicinity prior to attempting to verify a valve setting.

Complications

Complications associated with ventriculoperitoneal CSF shunting systems may be similar to those experienced in any surgical procedure carried out under local and/or general anesthesia. These

include reactions to drugs and anesthetic agents, electrolyte imbalance and excessive blood loss, particularly in infants. A patient may rarely exhibit a reaction due to sensitivity to the implant.

In CSF shunting procedures, the most common complications are due to obstruction of the system as described under “Warnings.” Obstruction may occur in any component of the system due to plugging by brain fragments, blood clots, and/or tumor cell aggregates at some point along its course. Obstruction may also occur because of separation of the system components or kinking and/or coiling of the catheter. This may predispose migration of the ventricular catheter into the lateral ventricle and the distal catheter into the peritoneum, or other structure in which the catheter is implanted. As noted previously, growth of the infant or child may cause the distal catheter to be withdrawn from the atrium into the internal jugular vein or from the peritoneum into tissue planes where the fluid cannot be absorbed.

There are other potentially serious complications. Local and systemic infections are not uncommon with shunting procedures. Usually, they are due to organisms inhabiting the skin, particularly Staphylococcus epidermidis. Other pathogens circulating in the blood stream may colonize the shunt and, in the majority of patients, require its removal.

In 1973, Robertson et al. summarized the incidence of infection in ventriculoperitoneal shunts reported up to that time. Infection in ventriculoperitoneal shunting occurred in 5 to 10% of the patients in most of the reports.

In 1993, Kestle et al. reported significant reductions in infection (less than 4%) with the use of antibiotics, short duration of surgery (surgical experience) and control of the operating room environment (e.g., designated operating room, limited personnel and traffic, covered skin surfaces). The article states that results can also be obtained without the use of antibiotics, but with rigorous perioperative control of the environment.

Using prophylactic antibiotics in shunted patients is somewhat controversial as their use may predispose infection by more resistant organisms. Therefore, the decision to use antibiotics prophylactically rests with the attending physician and/or surgeon. Shunting into the peritoneum may fail because of investments of the catheter in loops of bowel or in the greater omentum. Perforation of the bowel by the peritoneal catheter with subsequent development of peritonitis has been described.

CSF overdrainage may result in excessive reduction of CSF pressure and predispose the development of a subdural hematoma or hygroma, and excessive reduction of ventricular size leading to obstruction because of impingement of the ventricular walls on the inlet holes in the catheter. In the infant, this excessive pressure reduction will cause marked depression of the anterior fontanelle, overriding of cranial bones and may convert communicating into obstructive hydrocephalus.

The incidence of epilepsy after ventricular shunting procedures has been reported. This study also indicated that the incidence of seizures increased with multiple catheter revisions.

StrataVarius Adjustment System Indications

StrataVarius is intended for use by physicians, to non-invasively identify the Strata-type valve Performance Level (PL) setting and display that information numerically in terms of PL level and the equivalent pressure reading in millimeters of water (mm H2O).

The StrataVarius allows the user to change the pressure setting of the valve non-invasively without the need for radiographic confirmation.

Contraindications

The Medtronic Neurosurgery StrataVarius system should not be used as a diagnostic tool, but rather only for confirmation of, or to change a pressure level in, a Strata-type valve.

StrataVarius should not be used on any fixed pressure valve. Use only on PS Medical Strata-type adjustable valves. StrataVarius should not be used in a sterile environment.

Warnings and Precautions

The StrataVarius is for use by qualified personnel only, ensure users have adequate knowledge prior to use. An incorrect PL setting may lead to over or under drainage of CSF which may give rise to patient complications. Radiographic confirmation of the pressure setting is recommended as an alternate method to determine the Strata valve PL setting. Risks associated with radiographic imaging include exposure to low levels of radiation, radiation-induced injuries to the skin and underlying tissue, or the possibility of developing a radiation-induced cancer. Care should be taken to use the least amount of radiation exposure needed to produce the image. Do not use the StrataVarius to detect or adjust any valve other than PS Medical Strata-type valves. Check StrataVarius system for damage prior to use. Allow StrataVarius to come to operating temperature prior to use (see Operating/Storage Temperatures). Always be sure to verify that the correct Smart Card has been inserted. Use only specified 1.5 volt (AA) alkaline batteries in the StrataVarius. Check battery charge status on LCD during use. A blinking battery icon indicates low battery power (voltage); REPLACE BATTERIES. If StrataVarius will be out of use for 6 months or more, remove the batteries before storing. The batteries used in the StrataVarius may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 100 degrees C, or incinerate. Use of another battery type may present a risk of fire or explosion. Dispose of batteries promptly and properly. Keep away from children. Dispose of batteries or other StrataVarius system components according to local environmental regulations. Do not touch the battery terminals of StrataVarius. Do not use acetone as a cleaning agent as damage to the product may occur. Do not immerse any part of the StrataVarius system. Do not drop the StrataVarius or components onto hard surfaces as internal device damage could occur. To minimize the possibility of infection, clean the StrataVarius and Adjustment Tool between patients. The Adjustment Tool contains strong magnets and may cause damage to credit cards. Keep away from all magnetic cards and materials, as well as computer hard drives and other magnetic data storage media. Do not take into or use the StrataVarius or Adjustment Tool within a room housing an MRI device. There are no user-serviceable components in the StrataVarius system. Should the system require repairs, contact your local Medtronic Neurologic Technologies Sales Representative or call Customer Service at 1-800-468-9710 for instructions. International customers should contact their local Medtronic Neurologic Technologies Sales Representative. StrataVarius provides a means of checking the valve noninvasively; however, the valve setting can also be determined by x-ray image. This equipment has been tested and found to comply with the EN limits of the international standard EN/ IEC 60601-1, ANSI/AAMI ES 60601-1, and CAN/CSSA C22.2 No. 60601-1-08. These limits are designed to provide reasonable protection against interference in a typical medical environment. However, there is no guarantee that interference will not occur with other devices in any particular installation or use. If this equipment causes interference with other devices, which can be determined by turning the instrument on and off, the user is encouraged to try to correct the interference by one or more of the following measures: Reorient or relocate the device Increase the separation between the equipment The StrataVarius System does not contain any latex materials. WARNING: NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

Trials

A multicentre prospective randomised trial was performed on a total of 58 patients suspected of INPH.

Thirty patients were assigned to (control) group 1 and received a Strata shunt (Medtronic, Goleta, USA) with the valve preset at a performance level (PL) of 1.0, while 28 patients were assigned to group 2 and received a Strata shunt with the valve preset at PL 2.5. In this group the PL was allowed to be lowered until improvement or radiological signs of overdrainage were met. RESULTS:

Significantly more subdural effusions were observed in the improved patients of group 1. There was no statistically significant difference in improvement between both groups overall.

On the basis of this multicentre prospective randomised trial it is to be recommended to treat patients with INPH with a shunt with an adjustable valve, preset at the highest opening pressure and lowered until clinical improvement or radiological signs of overdrainage occur although slower improvement and more shunt adjustments might be the consequence [3)].

Case series

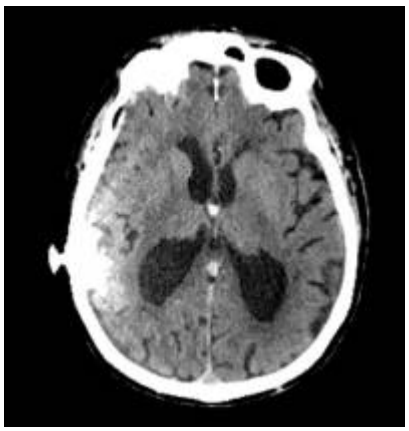
In the study, we reported the experience of shunting 24 patients with iNPH using Strata® (Medtronic) valve, following a protocol based on a positive Tap Test.

We observed clinical improvement in 20 patients and stability/worsening in 4 patients. Complications occurred in five patients, including one death. The results display improvement, and complications occurred at a lower rate than reported in other studies.

The Strata® valve used in the proposed protocol represents an efficient and safe tool in the treatment of iNPH [4)].

Strata Adjustable Pressure Valve General University Hospital of Alicante Cases

82-year-old male with Ventriculoperitoneal shunt placement 3 years ago, fell 3 weeks ago, hitting herself with an iron table on the right side. Since then, he reported a continuous headache that worsens in the afternoons. He refers to instability that has increased since the blow.



CT artifact

1)

Medtronic. MRI information. http://www.medtronic.com/neurosurgery/mri.html. Accessed May 22, 2009

2)
Spader HS, Ratanaprasatporn L, Morrison JF, Grossberg JA, Cosgrove GR. Programmable shunts and headphones: Are they safe together? J Neurosurg Pediatr. 2015 Jul 7:1-4. [Epub ahead of print] PubMed PMID: 26149436.
3)
Delwel EJ, de Jong DA, Dammers R, Kurt E, van den Brink W, Dirven CM. A randomised trial of high and low pressure level settings on an adjustable ventriculoperitoneal shunt valve for idiopathic normal pressure hydrocephalus: results of the Dutch evaluation programme Strata shunt (DEPSS) trial. J Neurol Neurosurg Psychiatry. 2013 Jul;84(7):813-7. doi: 10.1136/jnnp-2012-302935. Epub 2013 Feb 13. PubMed PMID: 23408069.
4)
Oliveira MF, Saad F, Reis RC, Rotta JM, Pinto FC. Programmable valve represents an efficient and safe tool in the treatment of idiopathic normal-pressure hydrocephalus patients. Arq Neuropsiquiatr. 2013 Apr;71(4):229-36. PubMed PMID: 23588284.