UNDERSTANDING HYDROCEPHALUS

Offering solutions for patients.

Codman®
SPECIALTY SURGICAL

A DIVISION OF INTEGRA LIFESCIENCES

Dear Reader:

Your doctor has either recommended the Codman® Hakim® Precision Fixed Pressure Valve, the Codman® Hakim® Programmable Valve (CHPV), the Codman® CERTAS™ Plus Programmable Valve, or the OSV® II or Integra Low-Flow Flow Regulating Valves for use in treating hydrocephalus. This handbook is designed to provide basic information regarding the use of Codman hydrocephalus valves. It is not a substitute for a thorough discussion with your doctor regarding the use of a particular Codman valve for treating your specific medical condition. If you have any questions concerning any of the Codman valves, contact your doctor.

All Codman valves are used for the treatment of hydrocephalus. The Codman CERTAS Plus Programmable Valve and CHPV are designed with a programmable feature that allows the doctor to adjust the setting of the valve if needed. The Codman Hakim Precision Fixed Pressure Valves are not adjustable, but are available at five different fixed pressure settings. The Flow Regulating Valves have a self-adjusting feature to adapt to the patient's cerebrospinal fluid (CSF) needs.

As with all types of hydrocephalus shunts, both adjustable and nonadjustable, it is important for you to be aware of information that is critical to successful management of your condition.

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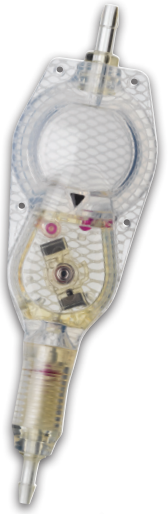
Codman® CERTAS™ Plus Programmable Valve



Codman® Hakim® Programmable Valve

OSV II® Hydrocephalu

Codman® Hakim® Precision Valve

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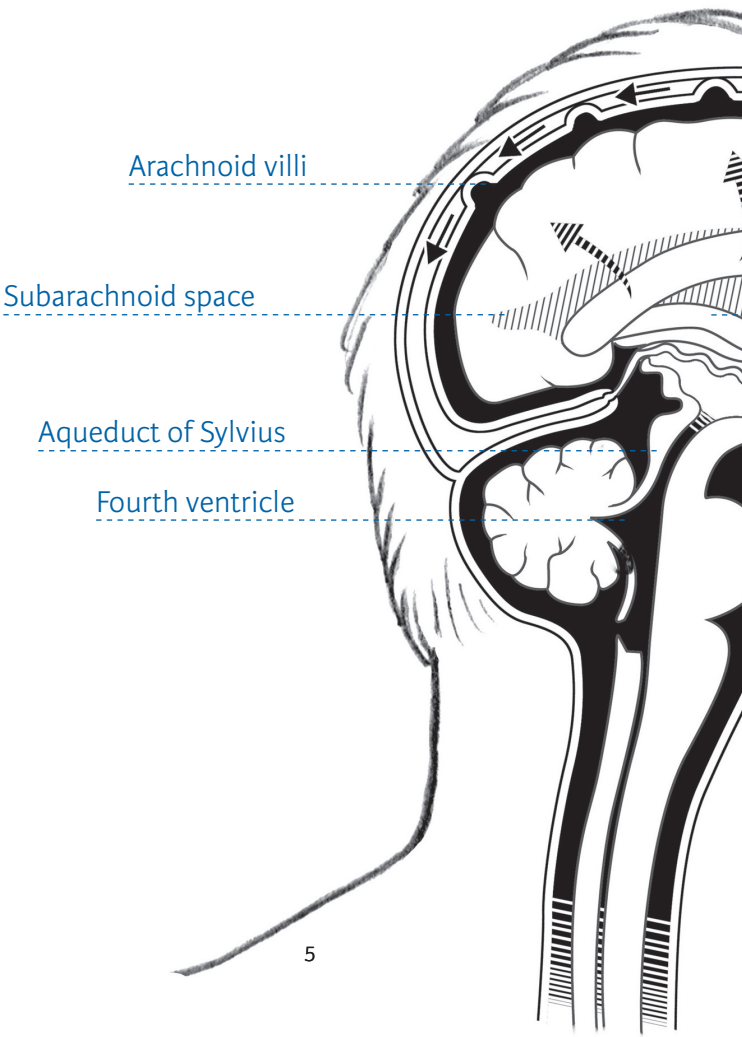
What is hydrocephalus?

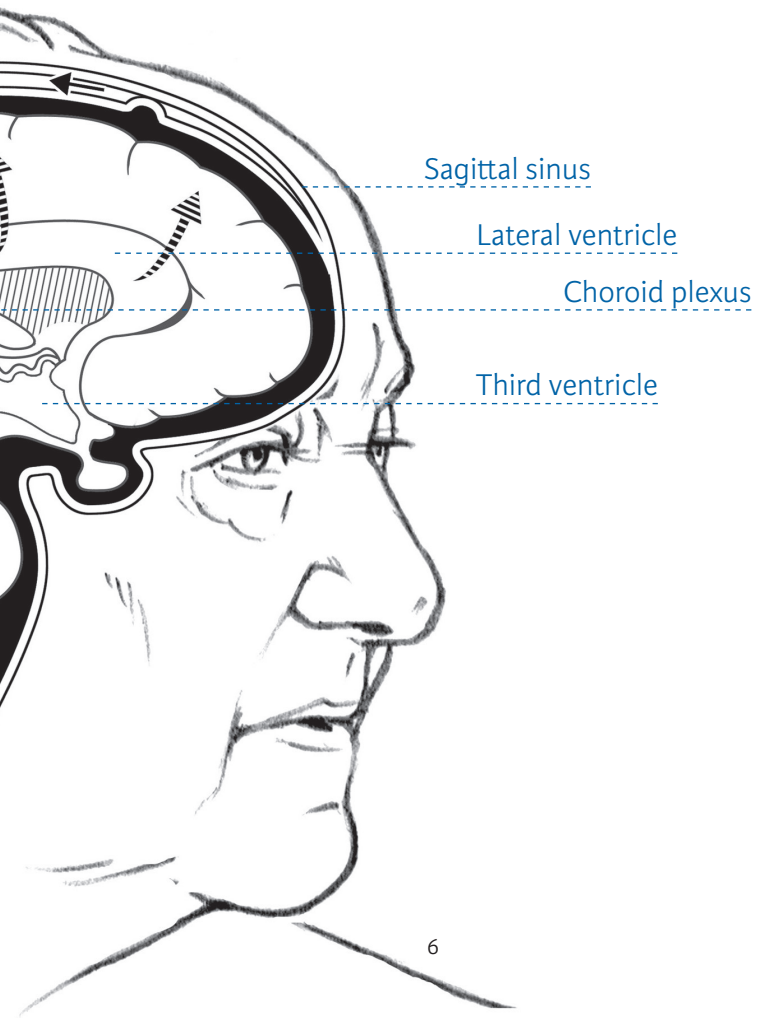
Hydrocephalus is an abnormal (excessive) accumulation of CSF in the head. The CSF is located and produced within cavities of the brain called ventricles.

The function of CSF is to cushion the delicate brain and spinal cord tissue from injuries and maintain proper balance of nutrients around the central nervous system.



Understanding hydrocephalus

Normally, most of the CSF produced on a daily basis is absorbed by the bloodstream. Every day your brain produces a certain amount of CSF, and that same amount of CSF is absorbed in the brain. When an imbalance occurs, an excess of CSF fluid builds up, resulting in the condition known as hydrocephalus. Left untreated, hydrocephalus will create increased pressure in the head and may result in brain damage or even death.



What are the causes and types?

In general, hydrocephalus can be caused by one or more of the following:

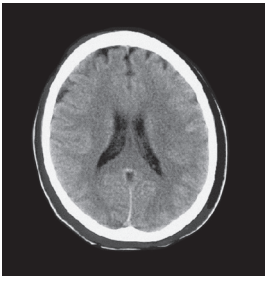
- **Interference** with normal CSF flow, due to an obstruction or blockage in the CSF fluid pathway
- **Overproduction** of CSF
- **Underabsorption** of CSF into the blood stream

There are two types of hydrocephalus:

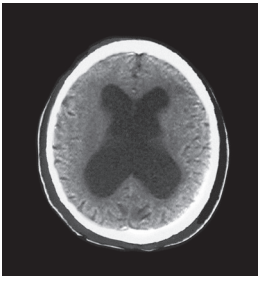
- **Communicating hydrocephalus**, caused by the overproduction or underabsorption of CSF
- **Noncommunicating or obstructive hydrocephalus,** caused by a blockage of the CSF pathways

Understanding hydrocephalus

Normal pressure hydrocephalus (NPH) is an accumulation of cerebrospinal fluid that causes the ventricles in the brain to become enlarged, sometimes with little or no increase in intracranial pressure (ICP). It is most commonly seen in older adults and is accompanied by some or all of the following triad of symptoms: gait disturbance (changes in the way you walk), mild dementia, and impaired bladder control. In most cases of NPH, it is not clear what causes the CSF absorptive pathways to become blocked.*



Normal Brain



Hydrocephalus

Hydrocephalus is termed congenital if present before or since birth, or acquired if developing after birth. A variety of causes can contribute to acquired hydrocephalus. Some are head injury, tumors, or meningitis. In most cases the circumstances contributing to hydrocephalus are beyond a person's control.

*Courtesy of the Hydrocephalus Association.

What are some symptoms of uncontrolled hydrocephalus?

When too much CSF exists within the brain, the pressure within the skull may increase (except in the case of Normal Pressure Hydrocephalus), causing symptoms such as headaches, nausea, vomiting, sleepiness, failing mental function, blurred vision, and loss of coordination. In infants, the skull bones are not completely formed and joints between the bones of the skull are not closed, so the increased amount of fluid may cause the skull to increase in size. This is a visual sign of hydrocephalus, but is only noticeable in infants and newborns.

Usually, hydrocephalus causes the ventricles of the brain to enlarge due to increased CSF within the skull. If a person exhibits symptoms of hydrocephalus, a doctor may perform several tests to confirm if hydrocephalus exists.

What are some of the diagnostic tools?

- **Ultrasound:** a device that uses sound to outline the structures within the skull. This is similar to scans that pregnant women have to check that their babies are healthy.

- **CT Scan (Computerized Tomography):** a technique that uses x-rays to image and outline the size of the ventricles.

- **MRI (Magnetic Resonance Imaging):** a technique that uses radio signals and a magnet to form images of the brain so that the size and shape of the ventricles can be determined.

- **CSF Flow Studies:** using dyes or other materials to trace the flow patterns of CSF.

- **Neuropsychological Test**: a series of questions and answers used to determine if there is a loss of brain function due to hydrocephalus.

- **CSF tests to predict shunt responsiveness and/or determine shunt pressure include:** lumbar puncture, external lumbar drainage, measurement of CSF outflow resistance, intracranial pressure (ICP) monitoring and isotopic cisternography. Though there is no way to accurately predict a patient's responsiveness to any particular shunt, many doctors find that these tests are helpful in determining the likelihood of a positive response to shunting. People who have abnormal bleeding tendencies or take medications that affect bleeding should talk with their medical team about any special precautions before invasive procedures.*

*Courtesy of the Hydrocephalus Association.

How is hydrocephalus managed?

A surgical procedure may be performed to divert the CSF from the ventricles to either the abdominal cavity or to a chamber in the heart known as the right atrium. Another technique exists to channel the CSF from the lumbar into the peritoneal cavity. By removing the CSF, the pressure in the skull may return to normal. To remove the CSF, the surgeon implants a flexible tube with a valve mechanism called a shunt system. A shunt may help to control the hydrocephalus, but is not a cure.

What shunt systems are available?

Shunt systems come in a variety of models, but always have two similar parts: catheters or tubing, which transport and divert the CSF from the ventricles to either the abdominal cavity or right atrium of the heart; and a valve that regulates the flow of CSF from the ventricles. Adjustable valves allow the surgeon to choose a pressure setting for the valve based on the needs of the patient.

Many shunt systems also have a flexible flushing chamber called a reservoir. The reservoir serves several important functions. It allows the doctor to remove samples of CSF for testing using a needle and syringe. The doctor also may inject fluid into the shunt system to test for flow, to be sure the system is working properly.

The parts of a shunt are named according to where they are implanted (placed) in the body. For example, the portion of the tube that is inserted into the ventricles is called the ventricular catheter: the peritoneal catheter is the portion of the tube that drains CSF into the abdominal or peritoneal cavity: if a drainage tube is placed into the right atrium of the heart, it is called the atrial catheter.

To get a better understanding of what a shunt system looks like, ask your doctor or nurse to show you samples of the shunts they use.

All of the components of a shunt system are made from materials that are well-known to be tolerated by the body. For this reason, the entire shunt system is implanted under the skin. There are no external parts.

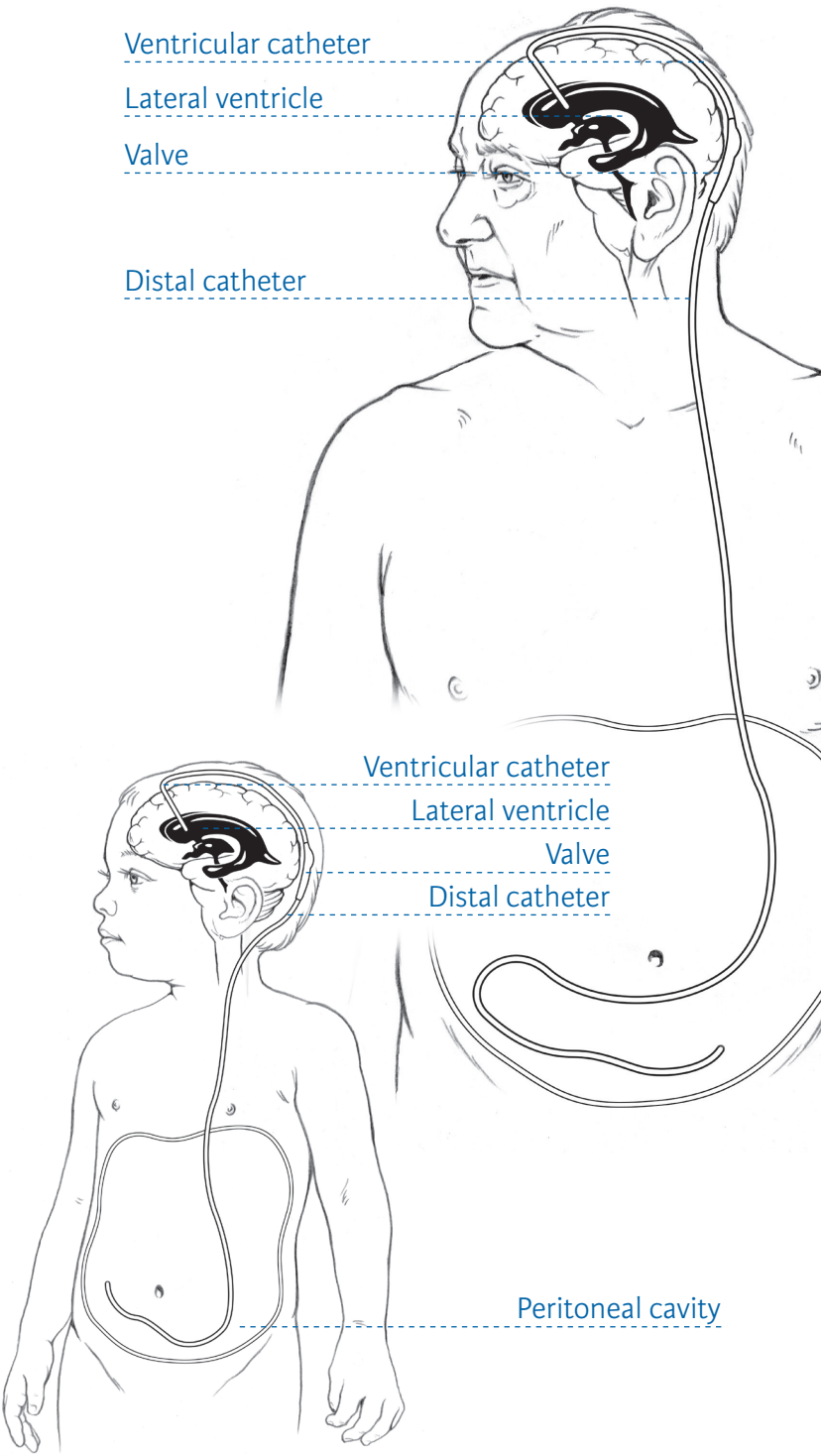
How is the shunt surgically implanted?

The shunt is implanted surgically and the procedure is relatively short. Surgery to implant a shunt is performed in the operating room under sterile conditions, using general anesthesia. A neurosurgeon, a doctor specially trained to operate on the brain, performs the operation.

An incision is made on the scalp, and a small hole is made in the skull to allow placement of the ventricular catheter. This allows the CSF to drain away from the brain. Another incision is made in the abdomen, and the valve unit and associated tubing is passed under the skin between the scalp and the abdominal incision. The surgeon connects the valve unit to the ventricular catheter and then inserts the end of the tube or peritoneal catheter into the peritoneal cavity of the abdomen.

Alternatively, if the drainage catheter is to be placed in the heart, the surgeon will introduce the catheter through an incision in the neck and pass the tube through various blood vessels until the catheter is positioned in the right atrium of the heart.

Once the shunt system is in place, the one-way valve will automatically open to drain excess CSF whenever the pressure in the skull exceeds the valve setting.


Ventricular catheter
Lateral ventricle
Valve
Distal catheter
Ventricular catheter
Lateral ventricle
Valve
Distal catheter
Peritoneal cavity

What are the potential complications?

Patients and/or their carergivers also must be alert for the signs and symptoms of potential shunt complications. The major complications of shunting are obstruction, infection, and overdrainage.

Obstruction

When a shunt malfunction occurs, it is usually due to a partial or complete blockage of the system. The blockage can occur anywhere in the tubing or the valve and prevent the CSF from draining properly. If not corrected, this will cause the original hydrocephalus symptoms to return.

Infection

A shunt infection usually is caused by the patient's own bacterial organisms, and is not acquired from exposure to other people. Infection should be suspected if there is any unusual redness or swelling of the wounds or along the shunt system.

Overdrainage

This is caused by too much CSF being removed from the ventricles. This will cause the ventricles to decrease in size to a point where the brain may pull away from the skull. This may cause bleeding and require further surgery.

Other complications which can lead to the return of the hydrocephalus symptoms include underdrainage, disconnection of the tubing, and mechanical failure of the valve. If any symptoms occur or you suspect any complications, contact your doctor immediately.

What kind of follow-up is required?

Generally, patients with an implanted shunt system are not restricted in their daily activities, except those involving great physical exertion. Your doctor will discuss with you any restrictions that may be advisable.

Because hydrocephalus is an ongoing condition, patients do require long-term follow-up care by a doctor. Having regular medical checkups at intervals recommended by the neurosurgeon is advisable. Occasionally, patients with shunt systems require revisions. A revision is a surgical procedure to modify, repair, or replace a shunt system due to a complication or change in patient conditions.

Regular follow-up visits will help the neurosurgeon to identify any subtle changes that may be indicative of a shunt problem. Patients and their carergivers should become familiar with the signs and symptoms of shunt complications as described on page 15 and of shunt malfunction as described on page 17. Occasionally, the doctor can adjust the settings to treat these symptoms.

Some symptoms* of shunt malfunction

Infants

- Enlargement of the baby's head
- Fontanel is full and tense when the infant is upright and quiet
- Swelling or redness along the shunt track
- Fever
- Unexplained irritability
- Increasing muscle stiffness
- Difficulty reaching developmental milestones
- Vomiting
- Sleepiness
- Eyes pushed downwards
- Seizures

Toddlers/Children

- Head enlargement
- Fever
- Vomiting
- Headache
- Irritability and/or sleepiness
- Swelling or redness along the shunt track
- A loss of previous abilities (sensory motor function)
- Seizures (very rare)
- Increasing muscle stiffness
- Difficulty reaching developmental milestones
- Personality changes
- Worsening of school/academic performance

Adults

- Incontinence
- Dementia
- Headache
- Vision Problems
- Irritability and/or tiredness
- Personality change
- Loss of coordination or balance and/or difficulty walking
- Seizures (very rare)
- Difficulty in waking up or staying awake
- Swelling or redness along the shunt track (infrequent)

This list of symptoms is for your reference only, and is not a diagnostic aid. If you are in doubt about your child's or your own medical condition, consult your doctor immediately.

*List of symptoms was adapted from www.hydroassoc.org

What is the difference between fixed and programmable valves?

Fixed Pressure Valves

Hydrocephalus valves typically open at a specific pressure setting, expressed in terms of millimeters of water (mmH_2O). The pressure setting defines a specified range. For example: a medium pressure valve may have an opening pressure of 70 mmH_2O +/- 10, meaning the valve is manufactured to open at one point between 60 and 80. Valves open when pressure from the CSF is greater than the pressure exerted by the valve mechanism. The valve's function is to open to allow CSF to drain and to close when the pressure in the skull is less than the valve setting.

Surgeons choose to use valves of a particular design and pressure setting based on experience and the patient's condition. Nevertheless, after surgery the patient may experience symptoms or complications such as over-drainage or under-drainage of CSF. In such cases, the surgeon may perform a shunt revision, which would require surgery in order to replace the valve for one with a different pressure range.

The Codman Hakim Precision Fixed Pressure Valve is an example of a nonprogrammable valve. It is available in five different fixed pressure settings.

Flow Regulating Valves

Unlike valves that open with changes in differential pressure, flow regulating valves maintain a constant flow of CSF throughout a wide range of pressures. The normal CSF production and reabsorption rate is considered to be 18 ml-30 ml/hr; most flow regulating valves maintain this flow rate the majority of time. When the pressure range is low, the shunt will allow a low flow rate. When pressure increases, the shunt will increase the flow rate of CSF, but still within the brain's normal CSF production rate. If pressure in the ventricles increases drastically to abnormal values, the rapid flow rate mode engages to facilitate pressure normalization. Once pressure is normalized, the shunt returns to a normal or low-flow regulation.

Integra OSV II Valves are designed to regulate flow at a normal CSF production rate. Integra Low Flow Valves are designed for patients who require a reduced drainage rate; for example elderly patients with normal pressure.

How does a programmable valve work?

A programmable valve is one that has a range of pressure settings that the surgeon can choose from based on the patient's condition. It is the same size as traditional fixed pressure shunts and is implanted in exactly the same way. Using an external programming device, the surgeon selects the initial pressure setting prior to the procedure, and can then easily adjust the setting at any time and as many times as necessary without further surgery. The large range of pressure settings allows the surgeon to make pressure adjustments in order to improve symptoms after the shunt is implanted, without needing to perform more operations. The non-invasive adjustments take only seconds and can be done right in the office with little or no patient discomfort. Aside from the programming feature, the valves operate the same way as any fixed pressure or nonprogrammable valve.

The Codman CERTAS Plus Programmable Valve is an example of a programmable valve. It has 8 operating pressure settings that a surgeon can adjust noninvasively to optimize the operating pressure settings. The CHPV is another programmable valve, but with 18 different pressure settings. Both valves have programmers that allow the surgeon to set the pressure settings before surgery and to easily change them afterwards based on the patient's needs.

Adjustment Tool

Locator Tool

How is the valve programmed?

The Codman CERTAS Plus Programmable Valve has been designed so a doctor can easily read and adjust the pressure settings noninvasively, in order to meet the patient's needs. To make these adjustments, the doctor will use the Codman CERTAS Tool Kit or the Codman CERTAS Plus Electronic Tool Kit. Changing the setting with either of these devices requires the doctor to palpate or fee the patients head for the placement of the valve, placing the locator tool on the skin over the valve and using the adjustment tool (magnet) to change the setting. By simply turning the adjustment tool, the doctor can adjust the pressure settings to the desired performance level of the valve.

The Codman Hakim Programmable Valve can be used with the Codman Hakim Programmer specifically designed for it. The system is a small electrical box connected to a transmitter. In order to program the valve, the transmitter is placed over the valve so that the valve is centered under the transmitter. While holding the transmitter steady, the valve is programmed to the desired setting. If the CHPV is already implanted, the doctor holds the transmitter on the skin over the valve body, and selects the desired setting. It is important that the patient remains completely still for 5 to 10 seconds during reprogramming while the doctor is holding the transmitter over the valve. Once the doctor has reprogrammed the valve, an x-ray (or fluoroscopy) must be taken to verify that the desired pressure setting is achieved. The doctor can change the pressure setting of the valve in the office. Changing the pressure does not require a revision or surgical procedure.

How does the programming change the pressure setting?

The Codman CERTAS Plus Programmable Valve and the Codman Hakim Programmable Valve both use a unique spring, ball, and cone mechanism to establish the pressure setting. To change the opening pressure of the valve, the tension is adjusted on the spring. A small magnetic device is activated by the programmer and rotates a cam or stepped mechanism, which turns to a new position and creates more or less tension on the spring. More tension on the spring increases the opening pressure, less tension on the spring lowers the opening pressure.

The Codman CERTAS Plus Programmable Valve can only be programmed with the Codman CERTAS Tool Kit or the Codman CERTAS Plus Electronic Tool Kit.

Shunting is only a method for treating hydrocephalus, and is not a cure. Therefore, regular visits to your doctor are necessary for the continuing care of this condition. Since the Codman CERTAS Plus Programmable Valve and the Codman Hakim Programmable Valve are both adjustable, your doctor can adjust the pressure setting of the valve and check the current pressure setting as part of your treatment plan.

If you have any questions concerning the Codman CERTAS Plus Programmable Valve or the Codman Hakim Programmable Valve contact your doctor.

Codman CERTAS Plus

INDICATIONS

The Codman CERTAS Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

The Codman CERTAS Tool Kit allows the noninvasive reading or adjustment of the valve setting.

CONTRAINDICATIONS

These devices are contraindicated in patients receiving anticoagulants or known to have a bleeding diathesis. Avoid shunt implantation if infection is present within the body. Delay the shunt procedure when infections such as meningitis, ventriculitis, peritonitis, bacteremia, and septicemia are present.

The BACTISEAL Catheters are contraindicated in patients with known hypersensitivity to rifampin or clindamycin hydrochloride.

WARNINGS

- Choose an implantation site for the valve where the tissue over the valve is not too thick (i.e. tissue thickness <10 mm). Otherwise locating, reading, and adjusting the valve with the tool kit may be difficult (i.e.; multiple attempts may be required) or impossible. If unable to adjust the valve, the valve will maintain a constant operating pressure and the patient should be informed of this risk.
- Testing shows that the valve mechanism is resistant to unintended changes in the setting in a 3 Tesla MRI. However, the clinician should confirm the valve setting after a magnetic resonance imaging (MRI) procedure.
- Read MRI Information before performing an MRI procedure on a patient implanted with the valve.
- Do not interchange the Codman CERTAS Tool Kit (82-8851) components with the Codman CERTAS Therapy Management System TMS (82-8850) components.
- The Indicator Tool has a precise operating mechanism and is vulnerable to damage if mishandled. Store and carry all components of the Tool Kit in the storage case when not in use to prevent damage. Replace the Indicator Tool immediately if dropped (or suspected of being dropped) to ensure accurate performance. Replacement Indicator Tools are available from your local Codman representative.

PRECAUTIONS

- Use only the Codman CERTAS Tool Kit to adjust the setting of the Codman CERTAS and Codman CERTAS Plus Programmable Valves.
- Excessive swelling may make it difficult to determine and/or adjust the performance setting.
  - See instructions for using the Low Profile Locator Tool in these instances.
  - If difficulty correctly positioning both Locator Tools persists, wait until the swelling is reduced or confirm the valve setting with x-ray.
- Failure to accurately position the Locator tool could result in an inaccurate indication of the performance setting, potentially leading to a false reading (i.e. an incorrect number may appear in the window of the Indicator Tool). The Locator Tool must be precisely aligned with both the valve's direction of flow and the center of the hard valve mechanism for an accurate indication reading. Alignment can be more challenging if tissue thickness is >10 mm above the valve. In these instances, verify the valve setting with x-ray or fluoroscopy.

CERTAS Plus Electronic Tool Kit

INDICATIONS

The CERTAS Plus Electronic Tool Kit allows the noninvasive reading or adjustment of the valve setting for the CERTAS and CERTAS Plus Programmable Valves.

PRECAUTIONS

- The device should be used only in professional healthcare facility environments.
- The device should not be used near high frequency surgical equipment, in proximity to an MRI, or anywhere the intensity of electromagnetic disturbances is high. If used in an environment other than specified, degradation of the performance of this equipment could result, meaning the device may not provide a stable indication or screen flickers may be seen.
- Do not use any of the Tool Kit components on a metal surface, as this could interfere with the use of the device.
- The Adjustment Tool contains powerful magnets and should be kept away from magnetic materials.
- Store and carry all components of the Tool Kit in the storage case when not in use to prevent damage.
- Inspect the Tool Kit components before each use. Check for damage, such as cracks. Do not use the Tool Kit if damage is present. Contact your local sales representative for a replacement kit.
- Carefully monitor the patient during the first 24 hours after adjusting the value setting. It is recommended that each adjustment be limited to an increase or a decrease of one setting, since setting changes can range between 15 and 50 mmH_2O.
- The valve setting should be confirmed after an MR procedure.
- Excessive swelling may make it difficult to determine and/or adjust the setting. If difficulty correctly positioning the Locator persists, wait until the swelling is reduced. X-ray may be used to confirm the valve setting.
- Failure to accurately position the Locator could result in an inaccurate indication of the performance setting, potentially leading to a false reading (i.e., an incorrect number may appear in the window of the Locator). Alignment can be more challenging if tissue thickness is >10 mm above the valve. In these instances, verify the valve setting with x-ray or fluoroscopy.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 class A).

ADVERSE EVENTS

Accumulation of biological matter within the valve can cause difficulties adjusting the valve setting and impair the anti-reflux function.

Adjusting the valve to a performance setting that is lower than necessary can lead to excessive CSF drainage, which can cause subdural hematomas and slit-like ventricles.

Glossary

- **Acquired Hydrocephalus:** hydrocephalus occurring after birth
- **Atrium:** one of the two upper chambers of the heart
- **Catheter:** a silicone tube used to divert and drain CSF
- **Cerebrospinal Fluid (CSF):** the watery fluid bathing the brain and the spinal cord
- **Communicating Hydrocephalus:** hydrocephalus caused by an overproduction and/or reduced absorption of CSF in the presence of unobstructed ventricular pathways
- **Congenital Hydrocephalus:** hydrocephalus caused by conditions existing at birth
- **Hydrocephalus:** a condition in which an increased amount of CSF exists in the ventricles and along the CSF pathways. This condition may occur when the rate of CSF production exceeds the rate of absorption, or when pathways of CSF flow are blocked. The result is excess fluid and pressure in the skull
- **Intracranial Pressure:** pressure within the skull
- **Meningitis:** an infection of the protective membranes covering the spinal cord and brain

- **Normal Pressure Hydrocephalus (NPH):** an accumulation of cerebrospinal fluid that causes the ventricles in the brain to become enlarged, sometimes with little or no increase in intracranial pressure (ICP).

  It is most commonly seen in older adults and is accompanied by some or all of the following triad of symptoms: gait disturbance (changes in the way you walk), mild dementia and impaired bladder control. In most cases of NPH, it is not clear what causes the CSF absorptive pathways to become blocked

- **Noncommunicating Hydrocephalus:** hydrocephalus caused by an obstruction in the ventricles or along the CSF pathway, causing a backup of fluid into the brain

- **Peritoneal Cavity:** the cavity containing the abdominal organs; the belly

- **Shunt (n):** an implanted system used to direct fluid from one part of the body to another. A shunt usually contains: catheters, valve, and a reservoir

- **Shunt (v):** to divert fluid from one part of the body to another

- **Skull:** the bony structure surrounding the brain

- **Valve:** a one-way, pressure or flow resistance device used to control the drainage of excess fluid from the brain

- **Ventricle:** one of four cavities found within the brain where CSF can be accessed

Important information

Magnetic fields generated from microwaves, wireless telephones, high-tension wires, electric motors, and transformers do not affect the valve setting.
If you sustain excessive force resulting in pain or direct trauma of the area over the valve, see your doctor to make sure there is no damage to the valve.
See your doctor for increasing headaches, blurred vision, nausea, vomiting or lethargy, as these may be a sign of valve dysfunction.

CERTAS Plus Programmable Valves

Result of Testing indicated that user of 3.0 Tesla MRI does not affect this valve's setting. However, the clinician will confirm the valve setting after an MRI scan. Magnets are commonly used in many products in our everyday life. Most valves are subject to unintended setting changes due to the strength, proximity, and hidden nature of everyday magnets.

However, CERTAS Plus programmable Valve is designed to minimize unintended setting changes from magnetic interference, protecting the valve from unintended setting changes due to everyday magnets and 3.0 Tesla MRI machines

CHPV

The use of MRI systems (up to 3 tesla) will not damage the valve mechanism, but may change the operating pressure of the valve. Following any MRI procedure, be sure to confirm the valve pressure setting and reprogram the valve if necessary. High-powered magnets may affect the valve adjustment when placed close to the valve. Please contact your doctor if you suspect close exposure to strong magnets.

Fixed Pressure and Flow Regulating Valves

All Integra/Codman Flow Regulating Valves and Fixed Pressure Valves are MRI Conditional.

Only your doctor should adjust the pressure setting on programmable valves.

This booklet provides a summary of the information regarding the appropriate use of the Codman Hakim Precision Fixed Pressure Valve, the Codman CERTAS Plus Programmable Valve, the Codman Hakim Programmable Valve, the Integra OSV II and Low-Flow Flow Regulating Valves. It is not a substitute for a thorough discussion with your doctor regarding the use of any Codman valve for your specific medical condition. If you have any questions or want more information, be sure to discuss your questions with your doctor.

References: 1. Data on file. Jacobs Institute Engineering Solutions. Hydrocephalus Shunt Valve Assessment. February 5, 2019. Integra LifeSciences, Plainsboro, NJ, USA. 2. Data on file. Resistance of the Codman CERTAS® Plus Programmable Valve to Unintended Setting Changes When Exposed to a 3 Tesla MRI. February 2016. Integra LifeSciences. Plainsboro, NJ, USA.

Resources

Hydrocephalus Association, San Francisco
Email: Info@Hydroassoc.org
www.LifeNPH.com
www.hydro-kids.com
www.hydroassoc.org

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

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