

CODMAN NEURO

 DePuySynthes

**CODMAN® HAKIM®
Programmable Valves**

EC REP

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ENGLISH

IMPORTANT INFORMATION

Please Read Before Use

CODMAN® HAKIM® Programmable Valves

STERILE | EO

 Only

Description

The CODMAN HAKIM Programmable Valve includes a valve mechanism (Figures 1 & 2) that incorporates a flat 316L stainless steel spring in which the calibration is accomplished by a combination between a pillar and a micro-adjustable telescoping fulcrum. The valve chassis is made of titanium. The ball and cone are manufactured from synthetic ruby. Intraventricular pressure is maintained at a constant level by the ball and cone valve seat design.

The pressure setting of the spring in the inlet valve unit is noninvasively adjusted by the use of an external programmer, which activates the stepper motor within the valve housing. The programmer transmits a codified magnetic signal to the motor allowing eighteen pressure settings, ranging from 30 mm to 200 mm H₂O (294 to 1960 Pa) in 10 mm (98 Pa) increments. These are operating pressures of the valve unit and have been determined with a flow rate of 15–25 mL H₂O per hour.

The valve is classified by its working pressure with a specified flow rate and not by the opening and closing pressures. The pressure that a valve sustains with a given flow is the parameter that reflects the working pressure of the valve once it is implanted. Before shipment, each valve is calibrated with special equipment. Duplication of these test procedures cannot be accomplished in the operating room.

The valve is marked with an x-ray detectable direction-of-flow indicator.

Indications

The CODMAN HAKIM Programmable Valves are implantable devices that provide constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

Contraindications

The CODMAN HAKIM Programmable Unitized Valve Systems are not recommended for atrial placement. Use the nonunitized versions for this procedure.

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.

WARNINGS

Subjecting the valve to strong magnetic fields may change the setting of the valve.

- The use of Magnetic Resonance (MR) systems up to 3 T will not damage the valve mechanism, but may change the setting of the valve. Confirm the valve setting after an MRI procedure. See *Programming the Programmable Valve*.
- Common magnets greater than 80 gauss, such as household magnets, loudspeaker magnets, and language lab headphone magnets, may affect the valve setting when placed close to the valve.
- Magnetic fields generated from microwaves, high-tension wires, electric motors, transformers, etc., do not affect the valve setting.

Read *MRI Information* before performing an MRI procedure on a patient implanted with the programmable valve.

The SIPHONGUARD® device is intended to reduce the rapid flow of CSF. It also reduces the ability to prime the shunt system during implantation to a rate of approximately 0.5 mL/minute.

MRI Information



Do not use the programmer in the MR suite.

The CODMAN HAKIM Programmable Valve is considered "MR Conditional" according to ASTM F 2503. The valve demonstrates no known hazards when an MRI is performed under the following conditions:

- MRI can be performed at any time after implantation
- Use an MR system with a static magnetic field of 3 T or less
- Use an MR system with a spatial gradient of 720 gauss/cm or less
- Limit the exposure to RF energy to a whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes
- Verify the valve setting after the MRI procedure (see *Programming the Programmable Valve*)

In non-clinical testing, the valve produced a temperature rise of 0.4°C at a maximum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3 T EXCITE® General Electric MR scanner.

MR image quality may be compromised if the area of interest is relatively close to the device. Distortion may be seen at the boundaries of the artifact. Therefore, optimization of the MR imaging parameters may be necessary.

The following chart provides a comparison between the signal void and imaging pulse sequence at 3 T:

Signal Void	Pulse Sequence
1590 mm ²	T1-SE
1022 mm ²	T1-SE
2439 mm ²	GRE
2404 mm ²	GRE

Precautions

The programmable valves are supplied without a specific programmed pressure and must be programmed prior to use.

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged,
- contents appear damaged, or
- the expiry date has passed.

This is an adjustable valve and the surgeon must take that into account when evaluating patients. It is important to verify the current pressure setting as part of any treatment plan.

Do not allow the programming unit or transmitter unit to remain in environmental extremes.

After exposure of the programming unit or the transmitter unit to environmental extremes, such as those found in transport or storage, allow the unit to come within operating range before operating.

Do not program the valve on a metal surface, such as a Mayo stand.

While becoming familiar with valve programming, it is recommended that the pressure setting of the implanted valve be changed in increments of no more than ±40 mm H₂O (392 Pa) in a 24-hour period. Patients whose pressure setting has been changed should be carefully monitored during the first 24 hours post programming. It is recommended that x-rays be taken to confirm the changes made to valve pressure setting.

Before use, check the programming unit and transmitter unit connections, settings, and function (see *Preimplantation Programming Familiarization Procedure*).

Use only Codman branded programmers to program the pressure of the CODMAN HAKIM Programmable Valve.

Unauthorized modifications to the programming unit or transmitter unit may cause a malfunction that could result in serious patient injury or death.

Electrical shock hazard: Do not open the programming unit or transmitter unit. Refer servicing to qualified service personnel.

Explosion hazard: Do not use the programming unit in the presence of flammable materials; i.e., anesthetics, solvents, cleaning agents, and endogenous gases.

Before turning on the 100/120, 220/240 VAC programming unit (catalog no. 82-3121 or 82-3190), verify that the supply voltage selector on the rear of the unit is set to the correct voltage for the electrical outlet.

Do not move the transmitter unit during programming.

Never immerse the programming unit or the transmitter unit in any liquid.

Do not sterilize the programming unit or the transmitter.

Use only with components compatible with the dimensions shown in the *Device Description* section.

Aseptic technique is necessary in all phases of the use of this product.

Silicone has a low cut and tear resistance; therefore, exercise care when placing ligatures so as not to tie them too tightly. The use of stainless steel ligatures on silicone rubber is not recommended.

Do not use sharp instruments when handling the silicone valve or catheter; use shod forceps. Cuts or abrasions from sharp instruments may rupture or tear the silicone components.

Do not fold or bend the valve during insertion. Incorrect insertion may cause rupture of the silicone housing.

To better stabilize the position of the valve underneath the scalp, proper valve placement is required. Place the flat underside of the valve against the bone, with the round top surface facing upward.

Verify proper placement and integrity of ligatures at all tubing junctions to prevent obstruction of the catheter lumen and tears or abrasions of the silicone tubing.

Do not fill, flush, or pump the valve with fluid in which cotton, gauze, or other lint-releasing material has been soaked.

Exercise extreme care to prevent the silicone components of the system from coming in contact with bare fingers, towels, drapes, talc, or any linty or granular surfaces. Silicone rubber is highly electrostatic and, as a result, attracts airborne particles and surface contaminants that could produce tissue reaction.

After implantation, avoid unnecessary pumping of the prechamber and pumping chamber to prevent rapid alteration of the intraventricular pressure.

Cylindrical Valves only: Before closing the scalp incision (or mastoidal incision, if a two-step passage technique is employed), confirm that the direction-of-flow arrow on the valve faces up.

Adverse Events

Devices for shunting CSF may have to be replaced at any time due to medical reasons or failure of the device.

Keep patients with implanted shunt systems under close observation for symptoms of shunt failure.

Complications of implanted shunt systems include mechanical failure, shunt pathway obstruction, infection, foreign body (allergic) reaction to implants, and CSF leakage along the implanted shunt pathway.

Clinical signs such as headache, irritability, vomiting, drowsiness, or mental deterioration may be signs of a nonfunctioning shunt. Low-grade colonization, usually with *Staph. epidermidis*, can cause, after an interval from a few days to several years, recurrent fevers, anemia, splenomegaly, and eventually, shunt nephritis or pulmonary hypertension. An infected shunt system may show redness, tenderness, or erosion along the shunt pathway.

Accumulation of biological matter (i.e. blood, protein accumulations, tissue fragments, etc.) in the programming mechanism can cause inability of the device to be reprogrammed.

Clogging of the programmable valve with biological matter can cause the valve to become unresponsive to attempts to change the pressure setting.

Do not use excessive force if attempting to remove the catheter(s). Excessive force can cause the catheter to break, leaving part of the catheter within the body.

Excessive CSF drainage can cause subdural hematomas, slit-like ventricles, and in infants, sunken fontanelles.

Particulate matter such as blood clots, brain fragments, or other tissue particles can obstruct the ventricular catheter. Also, the ventricular catheter can become obstructed by excessive reduction of ventricle size.

If not properly located in the lateral ventricle, the catheter can become embedded in the ventricular wall or choroid plexus.

Fibrous adhesions can bind the catheter to the adjacent choroids plexus or to the ventricular wall. Gentle rotation may free the catheter. DO NOT REMOVE THE CATHETER FORCEFULLY. If the catheter cannot be removed without force, it is recommended that it remain in place, rather than risk intraventricular hemorrhage.

The ventricular catheter can be withdrawn from, or lost in, the lateral ventricles of the brain if it becomes detached from the shunt system.

Blunt or sharp trauma to the head in the region of implant or repetitive manipulation of the valve during implant may compromise the shunt. Check valve position and integrity after occurrence.

Device Description

Programmable Valve Operating Pressure

30 to 200 mm H₂O (294 to 1960 Pa) programmable in steps of 10 mm H₂O (98 Pa)

Programmable Valve Configurations

- In-line with SIPHONGUARD Device
- In-line with SIPHONGUARD Device and Platform with Proximal Tube
- In-line
- Right Angle with SIPHONGUARD Device
- Right Angle
- Cylindrical with Prechamber
- Cylindrical with RICKHAM® Reservoir
- Cylindrical
- Micro with RICKHAM Reservoir
- Micro

CODMAN HAKIM In-line and Right Angle Valves include a programmable valve with a low profile and flat bottom, and an in-line or right angle integral reservoir with or without SIPHONGUARD.

CODMAN HAKIM Cylindrical Valves include a programmable valve, a pumping chamber, and an outlet valve available with a prechamber, without a prechamber, or with a RICKHAM reservoir.

CODMAN HAKIM Micro Valves include a programmable valve with or without an integral RICKHAM reservoir.

All programmable valve configurations are designed for use with components having the following dimensions:

Component	Inner Diameter	Outer Diameter
Ventricular Catheter	1.4 mm	2.7 mm
Drainage Catheter	1.0 mm	2.2 mm

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p02.17.3