

Codman[®]

CODMAN[®] HAKIM[®] Programmable Valves



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ENGLISH

IMPORTANT INFORMATION

Please Read Before Use

CODMAN® HAKIM® Programmable Valves

STERILE EO

R_x 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.

Any magnet may experience a degradation of magnetic field strength as a consequence of exposure to the significantly stronger magnet field induced in an MRI procedure.

- Based on the coercivity of the CHPV magnet material, the valve is resistant to magnetic degradation in a 1.5T MRI.
- Testing of the CHPV valve following exposure to 10 simulated MRI procedures at 3T indicates there may be demagnetization that, subsequently, could lead to a reduction in the ability to program the valve. Please refer to Troubleshooting section should any difficulty in programming occur.

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.

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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 Integra 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

SIPHONGUARD Device

CSF flows through the inlet valve and enters the SIPHONGUARD Device, where it flows into two internal passages. Under normal conditions, the majority of CSF flows through a central ruby ball and cone valve, and exits directly out of the distal port of the SIPHONGUARD Device. The remaining CSF travels through a spiral passage that surrounds the central passage, and joins the fluid passing through the central passage, distal to the ball and cone valve.

A sudden increase in CSF flow will close the ball and cone valve and the entire volume of CSF will be forced through the longer spiral passage, effectively slowing the rate at which CSF is shunted from the brain. Once the flow rate entering the SIPHONGUARD Device decreases, the ruby ball separates from the valve seat, opening the central passage. As long as CSF continues to be shunted from the ventricles, flow through the spiral passage of the SIPHONGUARD Device never stops, regardless of the patient's position.

Note: The SIPHONGUARD Device will not activate at low CSF flow rates.

The SIPHONGUARD Device has a rigid enclosing shell of polyethersulfone to prevent inadvertent closure (and subsequent reduction or blockage of CSF flow) caused by externally applied pressure.

How Supplied

The **Valve** includes a programmable valve, instructions for use, straight connector(s)^{*}, introducer^{**}, and priming adapter^{***}.

The **Valve System** includes a programmable valve, 14 cm ventricular catheter, 120 cm peritoneal catheter, instructions for use, right angle adapter, and priming adapter^{***}.

The **Valve System, Unitized**, includes a programmable valve, 14 cm ventricular catheter, 85 cm slit^{****} or 120 cm unitized peritoneal catheter, instructions for use, straight connector(s)^{*}, introducer^{**}, right angle adapter, and priming adapter^{***}.

^{*}Straight connectors provided with Cylindrical, Micro, and In-line with SIPHONGUARD and Platform with Proximal Tube versions only.

^{**}Introducers provided with Cylindrical versions only.

^{***}Priming adapter provided with In-line, Right Angle, and Micro versions only.

^{****}85 cm slit catheter packaged with 82-3853 only.

Components and Accessories

Valve Programmer

The valve programmer, available in 100/120 or 220/240 VAC, is supplied with a transmitter head, transmitter cord, and carrying case. The programmer is sold nonsterile and available separately. The programmer is required for changing the pressure setting of the valves.

Ventricular Catheter and Right Angle Adapter (Figure 3)

The ventricular catheter is a 14 cm straight ventricular catheter molded of radiopaque silicone elastomer with x-ray detectable dots and a preassembled stainless steel introducing stylet.

The right angle adapter, made of PROLENE[®] Material, allows 90 degree bending of the ventricular catheter at the burr hole site.

Priming Adapter (Figure 4)

The priming adapter, provided with the In-line, Right Angle, and Micro Valves, facilitates preimplantation irrigation to the valve and catheters.

Straight Connector

The straight connector joins the proximal and distal catheters to the valve.

Valve Introducer

A disposable polyethylene valve introducer is supplied to aid in passing the valve and drainage catheter from the burr hole site to a mastoidal incision, when a two-step passage technique is used. Because of the malleability of this introducer, it can be preformed to a desired curvature prior to valve placement.

Sterility



The CODMAN HAKIM Programmable Valve Systems are intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Integra will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

Integra single-use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality. (THIS STATEMENT APPLIES TO NON-IMPLANTABLE COMPONENTS ONLY.)

As long as the individual package is not opened or damaged, the product is sterile.

The following components have been tested and were determined to be nonpyrogenic:

Valve, In-line with SIPHONGUARD Device
Valve, In-line with SIPHONGUARD Device and Platform with Proximal Tube
Valve, In-line
Valve, Right Angle with SIPHONGUARD Device
Valve, Right Angle
Valve, Cylindrical with Prechamber
Valve, Cylindrical with RICKHAM Reservoir
Valve, Cylindrical
Valve, Micro with RICKHAM Reservoir
Valve, Micro
Peritoneal Catheter
Ventricular Catheter
Priming Adapter
Right Angle Adapter
Straight Connector

Preimplantation Performance Testing

Each CODMAN HAKIM Programmable Valve is individually tested on a component level to ensure conformance to the advertised performance characteristics. Each valve is dynamically tested at six different settings for proper dynamic opening pressure over the entire performance range.

Performing a manometer test is not recommended, as it is susceptible to environmental factors. Manometer testing yields a result that is not physiologic in nature and for which manufacturers do not specify performance ranges. If the surgeon insists upon performing manometer testing for confirmation of CODMAN HAKIM Valve closing pressures, it is possible, but is not recommended. When performed correctly, manometer testing generates valve closing pressures similar to the CODMAN HAKIM Valve opening pressure setting. However, closing pressure results will typically vary noticeably from the opening pressure setting.

For those surgeons who wish to perform functional testing, please see *Preimplantation Performance Testing* in the Appendix.

Programming the Programmable Valve

Programmer Information

WARNING: The CODMAN HAKIM Programmable Valves are supplied without a specific programmed pressure and must be programmed prior to implantation.

Programming must be performed prior to implantation through the nonsterile outer package. Perform programming postoperatively as needed.

The programmer consists of two parts, the programming unit and the transmitter unit. The programming unit control panel (Figure 5) features a power switch, programming instructions, and a representation of the programmable portion of the valve system as it appears when x-rayed. This representation also incorporates the 18 pressure selection buttons. Eighteen LEDs, corresponding to the position of the valve pressure indicator when viewed on x-ray, confirm the pressure setting chosen.

After depressing the desired pressure selector button, an LED lights in the programming unit. The lighted LED corresponds exactly with the position of the pressure indicator on the valve. When programming begins, the transmitter unit emits a sequentially coded electromagnetic signal. The stepper motor of the valve detects the signal and rotates the cam assembly, which, in turn adjusts the tension of the spring to the selected pressure setting.

Transmitter Information

Note: This Transmitter Information is for the CODMAN HAKIM Programmers **ONLY**. When using another Integra programmer, please refer to the instructions for use packaged with your programmer.

The transmitter unit (Figure 6) incorporates an illuminated center hole and directional arrows to aid in proper positioning over the valve. It connects to the programming unit via a pronged plug and is activated by the START button.

Preimplantation Programming Familiarization Procedure

To become familiar with valve programming, perform the following preimplantation programming procedure while the valve remains in the blister package.

1. Insert the pronged plug from the transmitter unit into the receptacle at the back of the programming unit.
2. Plug the power cord from the programming unit into an appropriate power source.

Note: The instructions contained in steps 3 through 6 are for the CODMAN HAKIM Programmers **ONLY**. When using another Integra programmer, please refer to the instructions for use packaged with your programmer.

3. Press the programming unit's power button to the ON position. Both the ON button and Instruction 1 on the panel will illuminate. Press the desired pressure selection button; Instruction 2 illuminates.
4. Place the transmitter unit's four prongs in the four depressions in the blister around the inlet valve. Point the arrow on the transmitter unit in the same direction as the arrow on the blister (the direction of flow). Look through the illuminated center hole of the transmitter unit.

CAUTION: Do not move the transmitter unit during programming.