Codman®

HAKIM®

Programmable Valve Lumbo-Peritoneal (L-P)

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HAKIM®

Programmable Valve Lumbo-Peritoneal (L-P)

IMPORTANT INFORMATION

Please Read Before Use

Rx ONLY

Description

The Codman® HAKIM® Programmable Valve Lumbo-Peritoneal (L-P) is a single-use implantable device that provides constant intraventricular pressure and drainage of cerebrospinal fluid (CSF) for the management of hydrocephalus.

It 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 performance setting of the valve can be set preoperatively and can also be noninvasively adjusted post-implementation by the use of an external programmer (sold separately), which activates the stepper motor within the valve housing. The programmer transmits a codified magnetic signal to the motor allowing for adjustment between the 18 pressure settings, ranging from 30 mm to 200 mmH_2O (294 to 1960 Pa) in 10 mmH_2O (98 Pa) increments.

Each valve is calibrated at the mechanism level and tested at the time of manufacture. The graph and tables below describe the pressure-flow performance characteristics of the device as required by EN ISO 7197:2009. In addition, long-term stability performance of the device has been demonstrated through testing in accordance to this standard. The pressure shown in the table for each setting is an average, recorded with active flow through the valve at flow rates of 5 mL/hr, 20 mL/hr, and 50 mL/hr; the value at 20 mL/hr is shown. Note that testing of the device may give different results depending on the test conditions.

Graph 1. Average operating pressure (mmH_2O) for each pressure setting with active flow through the valve unitized with a 120 cm peritoneal catheter at flow rates of 5mL/hr, 20mL/hr, and 50mL/hr.

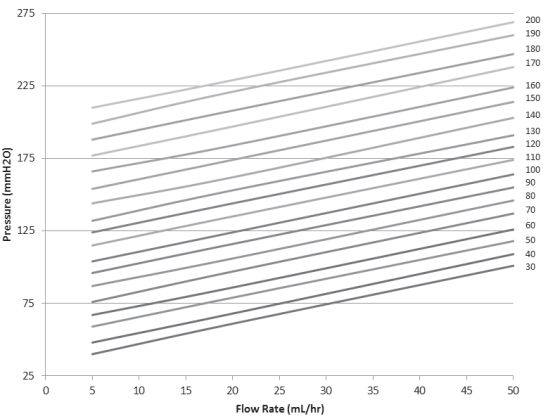


Table 1. Average operating pressure (mmH_2O) for each pressure setting with active flow through the valve unitized with a 120 cm peritoneal catheter at a flow rate of 20mL/hr.

Setting	30	40	50	60	70	80	90	100	110
Operating Pressure	61	68	79	86	97	106	116	124	135

Setting	120	130	140	150	160	170	180	190	200
Operating Pressure	144	153	162	174	184	197	208	221	229

Table 2. The devices performed within a tolerance range of the average operating pressure (mmH_2O) at flow rates of 5mL/hr, 20mL/hr, and 50mL/hr as shown here regardless of gravitational orientation (valve unitized with a 120 cm peritoneal catheter).

Settings 30 to 120	±14 mmH_2O
Settings 130 to 200	±19 mmH_2O

When adjusting the valve, the changes between each performance setting at flow rates of 5, 20, and 50 mL/h are on average 10 mmH_2O.

All programmable valve L-P configurations are designed for use with a lumbar catheter with an inner diameter of 0.76mm and an outer diameter of 1.65mm.

When tested with an 80 cm long, 0.76 mm inner diameter lumbar catheter, the average pressure increase is dependent on flow rate as shown here:

5 mL/hr	7 mmH_2O
20 mL/hr	30 mmH_2O
50 mL/hr	80 mmH_2O

The valves are available in the configurations listed (Figures 1a and 1b):

- In-line valve
- In-line valve with a SIPHONGUARD® Anti-Siphon Device
- In-line valve with a SIPHONGUARD Device and a post-chamber

The valve includes a valve mechanism (see Figure 2) that incorporates a flat 316L stainless steel spring and the valve chassis 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 SIPHONGUARD Device, included in some models of the valve, is designed to prevent excessive drainage of CSF by the shunt system. It provides a dual pathway and implantation in any orientation and body location distal to the valve mechanism is allowed. During normal flow of CSF, both the primary and secondary pathways are open. When excessive flow is induced by a rapid increase in hydrostatic pressure, the primary pathway closes but the secondary pathway remains open. The resistance of the secondary pathway is 1 cmH_2O/mL/hour.

Indications

The Codman HAKIM Programmable Valve Lumbo-Peritoneal (L-P) is a single-use implantable device that provides constant intraventricular pressure and drainage of cerebrospinal fluid (CSF) for the management of hydrocephalus.

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.

Lumbo-peritoneal shunting is contraindicated in the presence of spinal canal stenosis or in the presence of obstructive or non-communicating hydrocephalus unless a pathway has been created by prior surgery.

Catheter placement cannot be performed in the presence of cerebrospinal fluid containing debris and blood particles, as these can obstruct the narrow lumen of the catheter.

WARNINGS

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

- The use of Magnetic Resonance (MR) systems up to 3T 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 L-P*.
- 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.

To avoid damage to the catheter, care must be taken not to withdraw the catheter from the needle in order to reposition it in the subarachnoid space. If the catheter must be removed, withdraw the needle and catheter simultaneously.

Implant the valve so not more than **1 cm** of tissue thickness lies over the valve mechanism. This will facilitate the ability to locate and change the pressure setting of the valve. The programmer is capable of adjusting the valve to the desired setting up to an average depth of 2 cm.

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.

Precautions

The programmable valves L-P 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,
- the contents appear damaged, or
- the expiry date has passed.

Use only the Codman HAKIM Programmer or the Codman® VPV® System, Valve Position Verification Programmer to program the pressure of the Codman HAKIM Programmable Valve L-P. Refer to the manuals that accompany the Codman programmers for specific information.

NOTE: The acoustic feature in the Codman VPV System has not been specifically tested for efficacy with Codman HAKIM Programmable Valve (L-P) in an L-P placement. Therefore, it is recommended that the HAKIM programmer or the "Packaged Valve Mode" of the VPV System be used to adjust the setting of the valve. See the instruction manual of the VPV System for details.

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 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 mmH_2O (392 Pa) in a 24-hour period. Patients whose pressure settings have 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.

Do not use the programmer in the MR suite. The programmer is "MR Unsafe." 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 skin, proper valve placement is required. Place the flat underside of the valve down, 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 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.

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.

Headache, irritability, vomiting, drowsiness, or mental deterioration may be clinical signs of a nonfunctioning shunt. Low-grade colonization, usually with *Staph. epidermidis*, can cause recurrent fevers, anemia, splenomegaly, and eventually, shunt nephritis, scoliosis, tonsillar herniation, adhesive arachnoiditis or pulmonary hypertension after an interval of a few days to several years. An infected shunt system may show redness, tenderness, or erosion along the shunt pathway. Patients with L-P shunts may present with signs of meningitis (high fever, stiff neck, seizures or altered mental status) that are not typically seen with V-P shunts.

Accumulation of biological matter (e.g., 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. Clinical symptoms that may indicate CSF over-drainage include postural headache that is relieved in the supine position.

Particulate matter such as blood clots or other tissue particles can obstruct the lumbar catheter.

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

MRI Safety Information

Non-clinical testing has demonstrated that the Codman HAKIM Programmable Valve L-P is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 3 Tesla or less
- Maximum spatial field gradient of 5,800 G/cm (58 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode)

MRI-Related Heating

Under the scan conditions defined above, the Codman HAKIM Programmable Valve L-P is expected to produce a maximum temperature rise of less than 2.8°C after 15 minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the device extends approximately 40mm from the Codman HAKIM Programmable Valve L-P Valve when imaged with a gradient echo pulse sequence and a 3T MRI system.

Product Description

Codman HAKIM Programmable Valve L-P

The Codman HAKIM Programmable Valve Lumbo-Peritoneal (L-P) (see Figures 1a and 1b) includes a programmable Valve L-P with a 120 cm unitized peritoneal catheter. The silicone tubing at the proximal end of the valve includes a titanium connector for joining with a lumbar catheter. A priming adapter is also included to facilitate pre-implantation irrigation of the valve and peritoneal catheter.

The valve L-P is designed with an in-line integral reservoir and a wide flat bottom to help maintain correct (upward-facing) position. The valve L-P is marked with an x-ray detectable direction-of-flow indicator. The reservoir is backed with a nylon needle guard.

The use of a non-invasive programmer is required to change the pressure setting of the valve. The Codman HAKIM Valve Programmer or the Codman VPV System, Valve Position Verification Programmer may be used and are available separately. Refer to the manuals that accompany the Codman programmers for specific information.

NOTE: The acoustic feature in the Codman VPV System has not been specifically tested for efficacy with Codman HAKIM Programmable Valve (L-P) in an L-P placement. Therefore, it is recommended that the HAKIM programmer or the "Packaged Valve Mode" of the VPV System be used to adjust the setting of the valve. See the instruction manual of the VPV System for details.

SIPHONGUARD Device

The SIPHONGUARD Device, included in some models of the valve, is designed to prevent excessive drainage of CSF by the shunt system. 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 (see Figure 1b). The remaining CSF travels through a spiral passage that surrounds 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. 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, 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 to prevent inadvertent closure (and subsequent reduction or blockage of CSF flow) caused by externally applied pressure.

Post-chamber

The post-chamber, included in some models of the valve, has been provided to facilitate injection for the purpose of evaluating peritoneal catheter patency. The post-chamber contains a titanium needle guard to provide tactile feedback during needle insertion.

L-P Shunt Accessory Kit:

See Figure 3 for an illustration of the kit contents.

Lumbar Catheter

The lumbar catheter is 80 cm long with an inner diameter of 0.76mm and an outer diameter of 1.65mm.

The proximal end of the catheter is fenestrated with 16 holes (4 rows of 4 holes each). The catheter is marked with numerals at 5, 10, 15, 20, and 25 cm from the proximal end, as well as a mark for each centimeter between the numerals. There is an additional distinct band marking at the 12 cm point.

Priming Adapter

The priming adapters facilitate pre-implantation irrigation of the valve and catheters.

Fixation Tabs

Three silicone fixation tabs are included in the kit:

- The peritoneal fixation tab has two suture holes
- The two lumbar fixation tabs have a single suture hole

Required Equipment

Codman HAKIM Programmer or Codman VPV System, Valve Position Verification Programmer

The programmers are sold non-sterile and are available separately. The programmers are required for changing the pressure setting of the valves. Refer to the manuals that accompany the Codman programmers for specific information.

NOTE: The acoustic feature in the Codman VPV System has not been specifically tested for efficacy with Codman HAKIM Programmable Valve (L-P) in an L-P placement. Therefore, it is recommended that the HAKIM programmer or the "Packaged Valve Mode" of the VPV System be used to adjust the setting of the valve. See the instruction manual of the VPV System for details.

How Supplied

The Codman HAKIM Programmable Valves (L-P) and the L-P Accessory Kits are intended for **SINGLE USE ONLY; DO NOT RESTERILIZE**. Use aseptic technique in all phases of handling. Integra LifeSciences will not be responsible for any product that is re-sterilized, nor accept for credit or exchange any product that has been opened but not used.

Codman 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 contaminates 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 peritoneal catheter
- Valve, In-line with SIPHONGUARD Device and peritoneal catheter
- Valve, In-line with SIPHONGUARD Device, post-chamber and peritoneal catheter
- Lumbar catheter
- Priming adapters and tubing

Pre-implantation Valve Performance Testing

Each Codman Programmable Valve L-P 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 operating 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 Valve L-P closing pressures, it is possible, but is not recommended. Manometer testing will generate valve closing pressures that may vary from the operating pressure setting.

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

Pre-implantation Valve Programming Procedure

Precaution: The Codman HAKIM Programmable Valves (L-P) are supplied without a specific programmed pressure and must be programmed prior to implantation.

Programming must be performed prior to implantation through the outer blister package.

Refer to the manuals that accompany the Codman programmers for specific instructions for use.

Pre-implantation Irrigation

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

Prime the valve prior to implantation. Insert the inlet connector of the valve into the tubing of the priming adapter. Hold the valve vertically with the peritoneal catheter side pointing upward. Using a syringe inserted in the priming adapter, slowly and gently fill the entire valve system (Figure 4) with pyrogen-free, sterile saline solution.

CAUTION: Avoid any unnecessary pumping of the system. Over-irrigation of the valve system may damage the internal mechanism.

Use the priming adapter provided in the L-P Shunt Accessory Kit to prime the lumbar catheter. Use a syringe to slowly and gently fill the entire catheter with pyrogen-free, sterile saline solution.

Surgical Procedure

There are a variety of surgical techniques, which can be used to implant the Codman HAKIM Programmable Valve L-P. The surgeon should select the technique based upon clinical experience and medical judgment.

The following steps relate to the implant of the Codman HAKIM Programmable Valve (L-P) and the L-P Shunt Accessory Kit components.

1. At the chosen lumbar interspinous space, make a puncture using a Tuohy needle (14 gauge or larger) with the bevel of the Tuohy needle oriented parallel to the spine (median or paramedian approach). Rotate the needle 90° cephalad so that the bevel of the needle (and corresponding bevel-locating tab on the stylet) points to the cranial direction. Remove the stylet from the needle and confirm CSF flow.
2. Slowly insert the lumbar catheter to the desired depth and confirm CSF flow.

   CAUTION: To avoid damage to the catheter, care must be taken not to withdraw the catheter from the needle in order to reposition it. If the catheter must be removed, withdraw the needle and catheter simultaneously.
3. With the Tuohy needle remaining in place, make a skin incision to enable easy insertion of the valve.
4. Remove the Tuohy needle while stabilizing the position of the catheter. Clamp the catheter with shod forceps, or substantially similar instrument, to prevent over-drainage.
5. Use a shunt passer to create a shallow, subcutaneous tunnel (not more than 1 cm deep) from the lumbar incision and traverse the catheter through the tunnel per passer instructions. The programmer can adjust the valve to the desired setting up to an average depth of 2 cm; however, excessive tissue may complicate the ability to locate the valve and change the pressure setting post-operatively.
6. Using blunt dissection, create a small pocket, near the lumbar incision, under the skin to avoid unnecessary pull strength on the drainage catheter when positioning the shunt.
7. Once the peritoneal catheter has been passed through the subcutaneous tunnel, gently pull the peritoneal catheter while pushing the valve until the valve sits in the valve pocket. If excessive resistance is felt, remove the valve from the pocket and enlarge the pocket.
8. Confirm that the valve is not inverted. It is recommended to suture the valve to the surrounding tissue using non-absorbable suture to prevent future inversion.
9. Trim the lumbar catheter as needed. Ensure sufficient catheter length to allow for patient movement and to avoid catheter tension.
10. Verify that the CSF is clear (free of blood and debris) and connect the lumbar catheter to the connector attached to the inlet of the valve. Tie a ligature of non-absorbable suture material to secure the catheter over the connector. **NOTE**: The proximal catheter with connector is unitized to the valve, but for a more secure connection, an additional ligature may be placed over the connection (see Figure 5).
11. Trim the distal catheter to the appropriate length. If desired, place a peritoneal catheter fixation tab near the peritoneal incision. **NOTE:** The peritoneal fixation tab has two suture holes.
12. If desired, secure a lumbar catheter fixation tab to the catheter and the surrounding tissue at the spinal insertion point. **NOTE:** Two lumbar fixation tabs are provided; they each have a single suture hole.
13. Confirm the patency of the shunt system by observing CSF flow from the end of the catheter. Insert the end of the catheter into the peritoneal incision using standard surgical practice. Close the incisions.
14. Record the valve lot number and setting on the patient's chart.

Post-Implantation Programming Procedure

Perform programming post-operatively as needed.

The programmers are required for changing the pressure setting of the valves. The programmers are sold non-sterile and are available separately. Use either the Codman

HAKIM Valve Programmer or the Codman VPV System, Valve Position Verification Programmer.

Refer to the manuals that accompany the Codman programmers for specific information.

NOTE: The acoustic feature in the Codman VPV System has not been specifically tested for efficacy with Codman HAKIM Programmable Valve (L-P) in an L-P placement. Therefore it is recommended that the HAKIM programmer or the "Packaged Valve Mode" of the VPV System be used to adjust the setting of the valve. See the instruction manual of the VPV System for details.

Programming Procedure in Case of an Inverted Valve

Refer to the manuals that accompany the Codman programmers for specific information on this procedure.

X-Raying the Valve

It is advisable to x-ray the complete system immediately after implantation to have a permanent record of component placement and to verify valve pressure. It is also advisable to x-ray the valve whenever valve pressure is reprogrammed.

Use an x-ray with intensifying TV screen, or an x-ray plate to confirm proper valve pressure. A proper radiograph will be generated when the film is shot perpendicular to the plane of the valve with the non-implanted side of the patient's body resting on the plate. The film must be taken in relation to the valve not the patient's anatomy.

Viewing the x-ray, the white marker on the valve indicates the right-hand side of the valve. The pressure indicator on the white ring indicates the chosen pressure setting (see Figure 6).

Refer to Figure 7 for correlation between pressure setting and position of the pressure indicator as seen when x-rayed. Note that when the valve is programmed to 70, 120, or 170, the pressure indicator aligns with the "X" in the center of the valve.

NOTE: The use of fluoroscopy is recommended to assist in locating the post-chamber.

Injection

CAUTION: A needle guard has been included in the reservoir and post-chamber to provide tactile feedback during needle insertion but is not intended to prevent puncturing through the back of the valve under forceful pressure. If hypodermic injection is required, inject with a 25-gauge or smaller non-coring Huber-type needle into the reservoir or post-chamber (see Figures 8 & 9). Both locations can be punctured up to 25 times with a 25-gauge or smaller non-coring Huber-type needle.

Valve Flushing (Detecting Obstructions)

CAUTION: Shunt obstruction may occur in any component of a shunt system and should be diagnosed by clinical findings and diagnostic testing. Valve flushing characteristics may not be adequate to diagnose occlusion of catheters.

CAUTION: While flushing may be used as a method for determining patency, it is not recommended. Use clinical judgment and imaging studies or other techniques to confirm suspected cases of shunt malfunction.

To flush or check the patency of the lumbar catheter, press the reservoir. Failure of the reservoir to refill might indicate lumbar catheter blockage.

For valves including a post-chamber, inject saline or contrast into the post-chamber to flush or check the patency of the peritoneal catheter. If resistance is felt, there is a possibility of distal occlusion.

NOTE: The use of fluoroscopy is recommended to assist in locating the post-chamber.

Troubleshooting

If valve function is adversely affected by accumulations of biological matter, it may be possible to dislodge the material and restore proper function through one of the following methods:

- Flushing and/or pumping the valve (only for those valves without the SIPHONGUARD Device)
- Multiple programming attempts

Multiple programming attempts using a current Codman programmer (catalog no. 82-3190, 82-3190R, 82-3192 or 82-3192R) should be attempted if there is difficulty in programming or changing the setting of the valve. For additional information related to programming the valve, please refer to the manual packaged with your Codman Programmer.

If these remedial steps fail to rectify the problem, replace the valve.

For Troubleshooting information related to programming the valve, please refer to the manual packaged with your Codman Programmer.

APPENDIX

Pre-implantation Performance Testing

Although Codman does not recommend functional testing, some surgeons may choose to do so. Before testing, it is extremely important that a Codman Valve L-P with or without SIPHONGUARD Device be flushed of all air bubbles. Air bubbles within the Codman Valve L-P or SIPHONGUARD Device produce inaccurate manometer test results. The presence of air bubbles can reduce the cross-sectional area of the flow path, increase system resistance, and impede the flow of fluid through the system during testing.

A. Pre-Test Flushing Procedure

Equipment Required: Use all sterile equipment; perform testing under sterile conditions

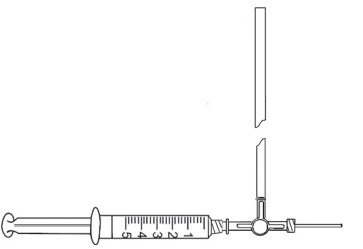
- One sterile manometer, wide-bore (e.g., 3.5 mm), graduated in mm (available in lengths from 38 to 60 cm)
- One sterile 4-way stopcock
- One sterile syringe, 10 mL minimum is recommended
- One sterile syringe filter, 5 µm
- Sterile priming adapter
- Sterile silicone tubing
- Sterile saline solution

Flushing Procedure

NOTE: At a rate of 0.5 mL/min, the valve L-P requires 2–3 minutes to complete flushing. This is the time required for fluid to fill the valve and exit the distal catheter. Allot additional time to ensure the system is free of air bubbles.

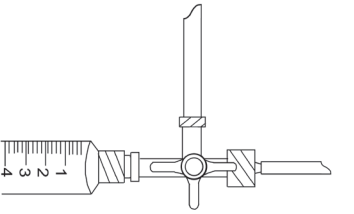
1. Fill syringe with sterile saline using the 5 µm syringe filter. The syringe filter should be reused in any subsequent refilling of the syringe. Once the syringe has been filled, remove the filter from the syringe.
2. Assemble manometer, stopcock, syringe, and tubing (Figure A-1).

Figure A-1



3. Set the valve operating pressure to 30 mmH_2O (294 Pa) while the valve remains in its sterile package.
4. Remove valve from the sterile package, and connect the valve inlet to the manometer/syringe assembly.
5. Adjust the stopcock to connect the syringe to the valve assembly (Figure A-2).

Figure A-2



6. Position the valve vertically to direct the flow of saline upward through the assembly. This orientation aids in flushing air from the system.
7. Using the syringe, gently flush saline through the system while gently depressing the pre-chamber to purge air bubbles from the valve assembly. Continue to flush the system using the syringe until saline solution exits the end of the distal catheter.

   NOTE: An excessive flow rate (>0.75 mL/min) activates the SIPHONGUARD Device and creates the impression that the valve is distally occluded. In reality, flow is being diverted to the high resistance secondary pathway.
8. The device is now ready for *B. SIPHONGUARD Device Functional Testing* or *C. Manometer Testing.*

   NOTE: All valves are susceptible to damage due to excessive flow rate during testing. Take extreme care when flushing a valve as damage can occur when excessive flow rates are used. It is recommended to use a flow rate of no greater than 0.5 mL/min.

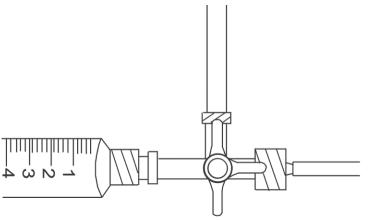
B. SIPHONGUARD Device Functional Testing

NOTE: This procedure applies only to valves with an integrated SIPHONGUARD Device.

NOTE: Perform this procedure immediately after completing the flushing procedure. This procedure is designed to provide visual confirmation of proper functioning of the SIPHONGUARD Device.

1. Use a full syringe of saline solution attached to the 4-way stopcock to fill the manometer to the top.
2. Turn the stopcock to connect the manometer to the valve (Figure A-3).

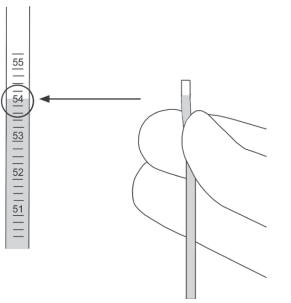
Figure A-3



3. Bring the end of the distal catheter level with the fluid level in the manometer (Figure A-4).

   NOTE: The valve must lie on a sterile surface and remain undisturbed for the duration of the test.

Figure A-4



4. Hold the end of the distal catheter adjacent to the manometer and slowly lower the catheter end until the fluid level in the manometer begins to drop.
5. Continue to lower the catheter end at a rate that exceeds the drop rate of the fluid level in the manometer. As you do so, you will note a corresponding increase in the rate of descent of the fluid level in the manometer.
6. A point will be reached where the rate of descent of the fluid level in the manometer dramatically decreases, but does NOT stop. This is the point at which the SIPHONGUARD Device primary pathway closes and flow diverts to the higher resistance secondary pathway. This confirms proper functioning of the SIPHONGUARD Device.
7. Repeat Steps 3 through 6 as necessary to reconfirm SIPHONGUARD Device function.

C. Manometer Testing

NOTE: Performing a manometer test is not recommended as this test is susceptible to environmental factors and yields a result that is not physiologic in nature and for which manufacturers do not specify performance ranges.

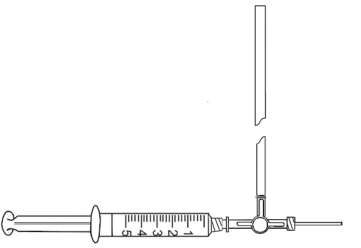
Equipment Required: Use all sterile equipment; perform testing under sterile conditions.

- One sterile manometer, wide-bore (e.g., 3.5 mm), graduated in mm (available in lengths from 38 to 60 cm)
- One sterile 4-way stopcock
- One sterile syringe, 10 mL minimum is recommended
- One sterile syringe filter, 5 µm
- Sterile priming adapter
- Sterile silicone tubing
- Sterile saline solution

Equipment Setup

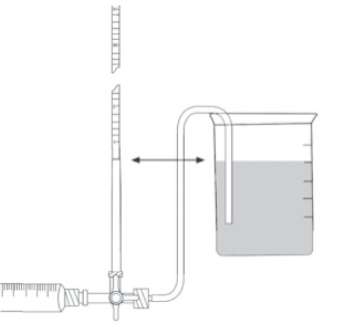
1. Fill syringe with sterile saline using the 5 µm syringe filter. The syringe filter should be reused in any subsequent refilling of the syringe. Once the syringe has been filled, remove the filter from the syringe.
2. Assemble manometer, stopcock, syringe, and tubing (Figure A-1).

Figure A-1



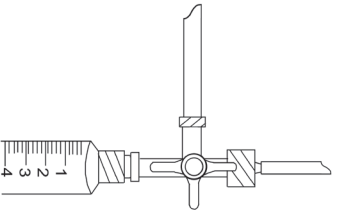
3. Place the end of the tubing leading from the stopcock into the water bath. Position the tubing so that the end does not come into contact with the sides of the bath.
4. Adjust the manometer height so that the zero level of the manometer and the fluid level in the water bath are at the same level (Figure A-5).

Figure A-5



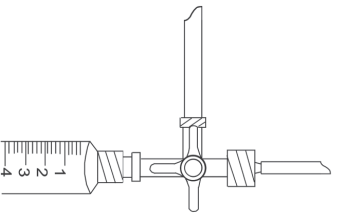
5. Adjust the stopcock to connect the syringe to the tubing in the water bath (Figure A-2).

Figure A-2



6. Using the syringe, flush the stopcock and tubing with sterile fluid to purge the system of air.
7. Turn the stopcock to connect the fluid pathway from the syringe to the manometer (Figure A-6).

Figure A-6

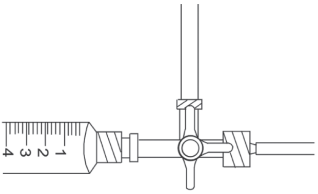


8. Using the syringe, fill the manometer to a minimum of 10 cmH_2O.

Zeroing the Manometer

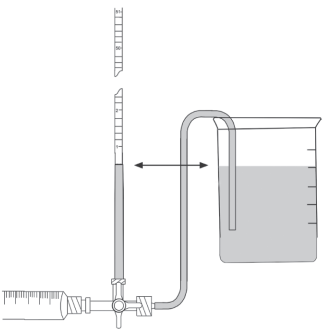
1. After filling the manometer, turn the stopcock to connect the manometer with the bath (Figure A-7).

Figure A-7



2. Allow the water column in the manometer to fall. The water column should stop at the zero level of the manometer (Figure A-8).

Figure A-8



3. If necessary, adjust the height of the manometer to bring the water level in the manometer to the same level as the fluid in the water bath.

Manometer Test Procedure

1. Adjust the valve to desired setting while the valve remains in its sterile package.

2. Remove valve from the sterile package, and connect the valve to the manometer/syringe assembly using the tubing placed in the water bath.

3. Position the valve vertically to direct the flow of saline upward through the assembly. This orientation aids in flushing air from the system.

4. Using the syringe, gently flush saline through the system while gently depressing the pre-chamber to purge air bubbles from the valve assembly. Continue to flush the system using the syringe until saline solution exits the end of the distal catheter.

NOTE: An excessive flow rate (>0.75 mL/min) activates the SIPHONGUARD Device and creates the impression that the valve is distally occluded. In reality, flow is being diverted to the high resistance secondary pathway.

5. Submerge the end of the distal catheter in the water bath to obtain accurate results. Confirm that there are no bubbles attached to the end of the distal catheter and that the water bath does not obstruct the end of the catheter.

6. Adjust the stopcock to connect the syringe to the manometer (Figure A-6 above) and refill the manometer to a height equal to the operating pressure setting of the valve plus 50 mm. If the valve is programmed to an operating pressure of 120 mmH_2O (1176 Pa), the height of the fluid in the manometer is 120 mm + 50 mm = 170 mm (17 cm) (1176 Pa + 490 Pa = 1666 Pa). This procedure minimizes the possibility of inadvertently activating the SIPHONGUARD Device during manometer testing.

7. Turn the stopcock to connect the manometer to the valve (Figure A-7 above).

8. The water column in the manometer will start to fall. Allow the water column to drop for 2 minutes or until a steady state is reached. *A steady state is defined as a change of less than 2 mmH_2O (20 Pa) in a 2-minute period.*

9. For valves with SIPHONGUARD Device, an extended test time is recommended in order to compensate for the possibility of a decreased flow rate due to SIPHONGUARD Device activation. Allow the water column to drop for 5–7 minutes or until a steady state is achieved.

10. Read the resultant pressure.

Variations between the manometer closing pressure test result and the Codman Valve L-P setting are possible based upon the test method utilized. Expect the same device to produce operating pressure variance from the valve setting utilizing an industry standard test method such as ASTM F647 or ISO 7197.

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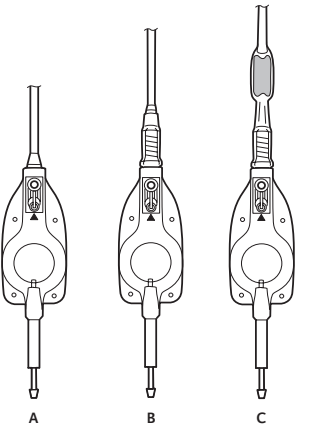
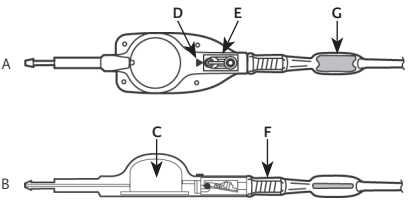
1a



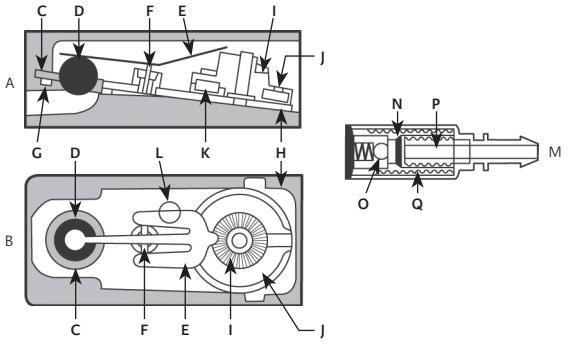
A. In-line valve
B. In-line valve with a SIPHONGUARD® Anti-Siphon Device
C. In-line valve with a SIPHONGUARD Device and a post-chamber

1b



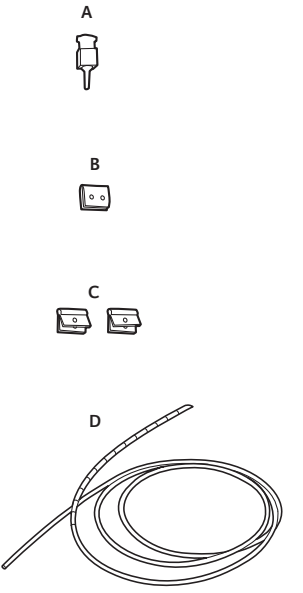
A. Top view
B. Side view
C. Reservoir
D. Direction of flow arrow
E. Codman HAKIM Programmable Valve Mechanism
F. SIPHONGUARD Anti-Siphon Device
G. Post-chamber

2



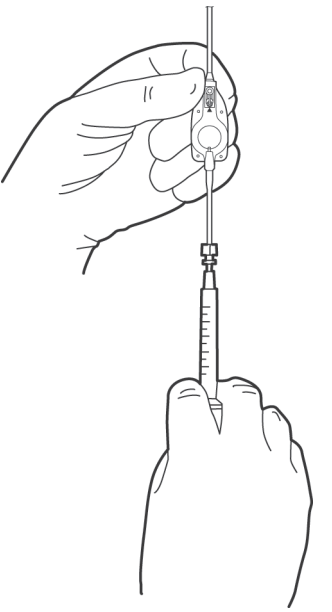
A. Valve mechanism side view
B. Valve mechanism top view
C. Valve seat
D. Valve ball
E. Flat spring
F. Spring calibrating fulcrum
G. O-ring
H. Titanium base plate
I. Cam
J. X-ray cam position indicator (pressure)
K. Stepper motor
L. Right-hand side x-ray indicator
M. SIPHONGUARD Device
N. Valve seat
O. Valve ball
P. Central passage (primary pathway)
Q. Spiral passage (secondary pathway)

3



A. Priming adapter (for irrigation of the lumbar catheter)
B. Fixation tab for peritoneal catheter (1)
C. Fixation tabs for lumbar catheter(2)
D. Lumbar catheter

4



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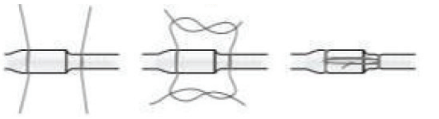
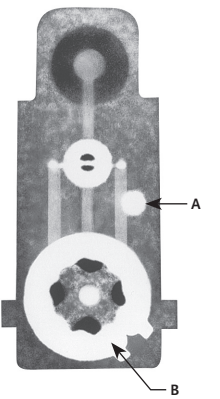


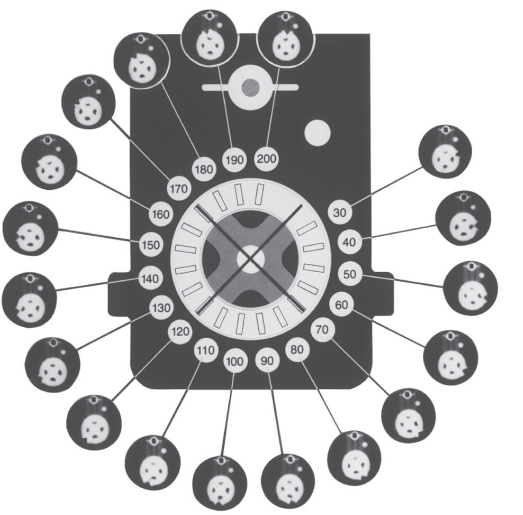
Devised method of connection/double string suture

6



A. White marker
B. Pressure indicator

7



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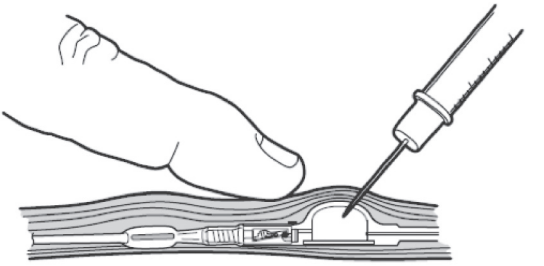

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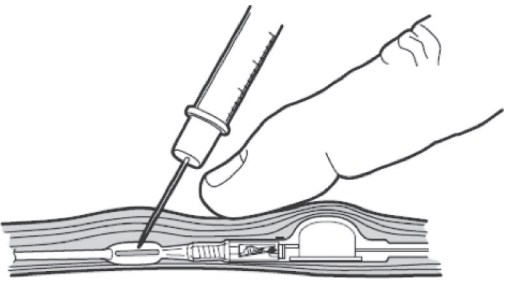

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Do not resterilize

Do not use if package is damaged

Rx ONLY

Caution: Federal (US) law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

Manufacturer

Made in

Nonpyrogenic, see instructions for use

Magnetic Resonance (MR) Conditional

Quantity

Do not reuse

Caution

Consult instructions for use

Catalogue number

Sterilized using ethylene oxide

Batch code

Use-by date (YYYY-MM-DD)

Date of manufacture (YYYY-MM-DD)

Integra LifeSciences Switzerland Sarl
Rue Girardet 29 (2nd Floor)
Le Locle Neuchatel CH-2400, Switzerland

Codman® SPECIALTY SURGICAL

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