Codman®

CERTAS® Plus

Programmable Valves

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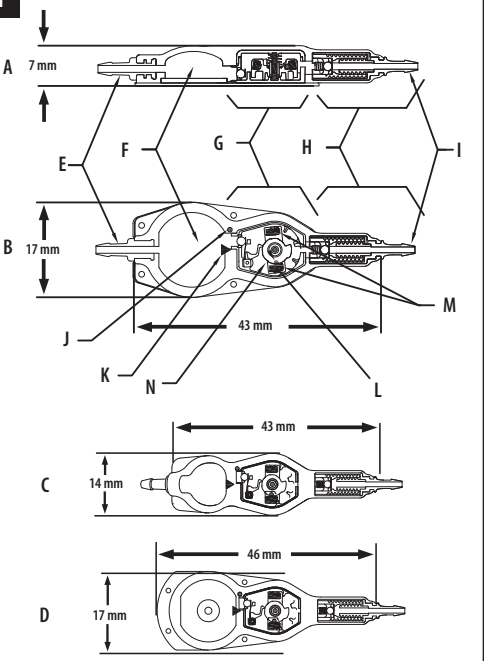
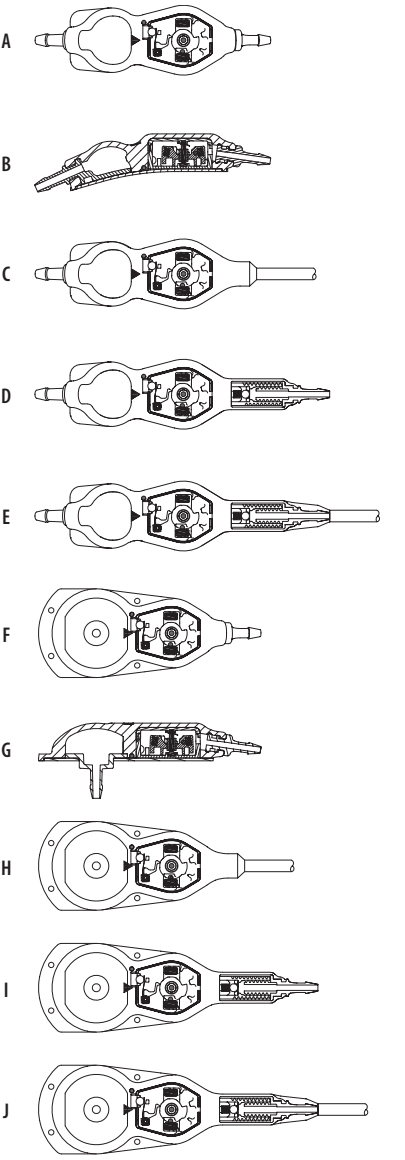
1



A. Regular valve side view
B. Regular valve top view
C. Small valve top view
D. Right angle valve top view
E. Proximal inlet connector barb
F. Reservoir
G. Hard valve mechanism
H. Optional SIPHONGUARD®
I. Distal outlet connector barb
J. Right-hand side (RHS) X-Ray marker
K. Direction-of-flow arrow
L. Setting indicator with tantalum ball
M. Magnets (2)
N. Rotating construct (RC)

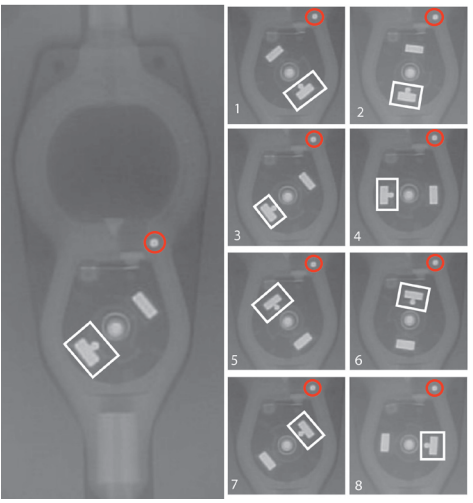
2



CERTAS® Plus Programmable Valve Configuration

A. Inline Small
B. Inline Small side view
C. Inline Small unitized with distal catheter
D. Inline Small with SIPHONGUARD
E. Inline Small with SIPHONGUARD unitized with distal catheter
F. Right Angle top view
G. Right Angle side view
H. Right angle unitized with distal catheter
I. Right Angle with SIPHONGUARD
J. Right Angle with SIPHONGUARD unitized with distal catheter

3

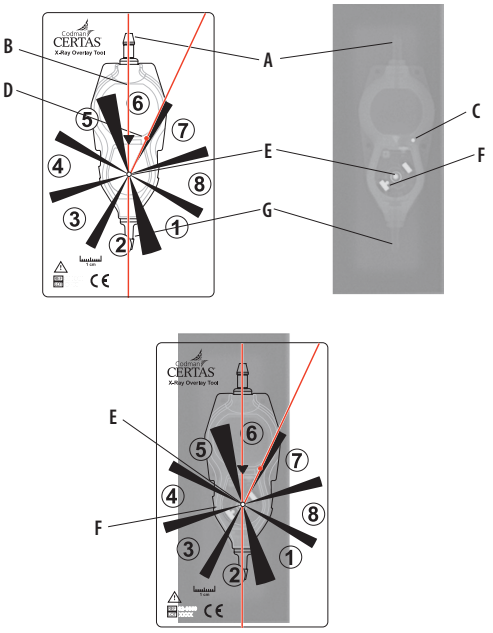


The number in the lower left corner of each view indicates which Performance Setting is shown.

White box indicates the setting indicator.

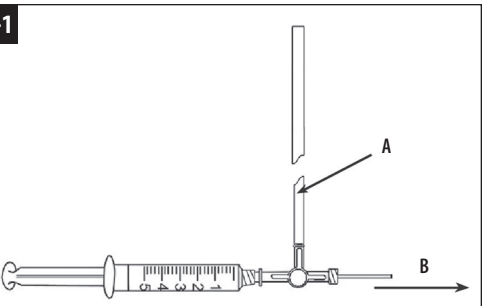
Red circle indicates the right hand side (RHS) marker.

4



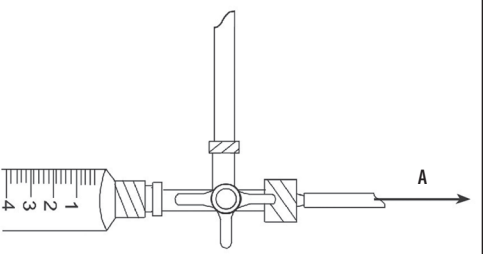
A. Proximal connector
B. RED Centerline of valve
C. Right hand side (RHS) marker
D. RHS marker red line (contains RHS dot)
E. Rotating construct (RC)
F. Magnet with tantalum ball (setting indicator)
G. Distal connector

A-1



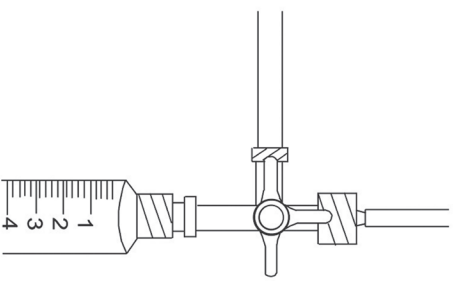
Manometer To Valve
A. Manometer
B. To Valve

A-2



Valve
A. Valve

A-3



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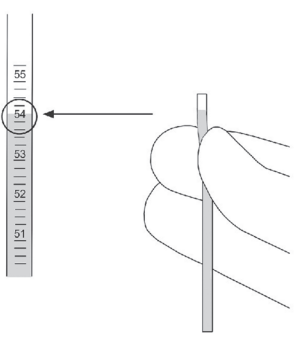
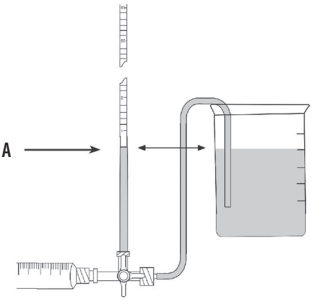
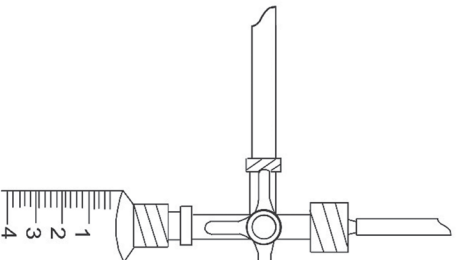


A-5

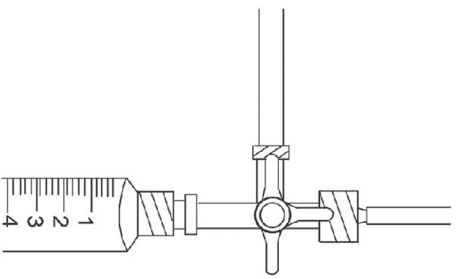


Manometer Zero Level
A. Manometer Zero Level

A-6



A-7



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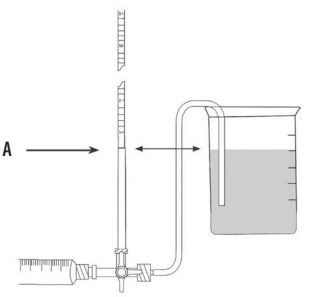


Manometer Zero Level
A. Manometer Zero Level

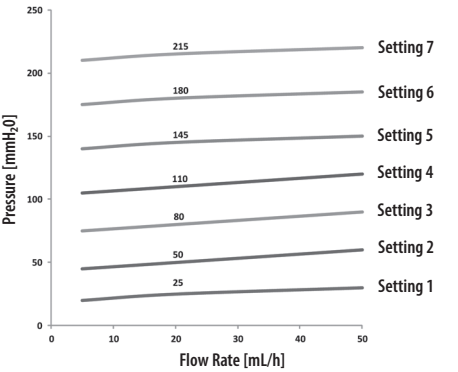
EN – ENGLISH

IMPORTANT INFORMATION
Please Read Before Use

CERTAS® Plus Programmable Valves

Rx ONLY

Description
The CERTAS® Plus Programmable Valves are single-use implantable devices that can be set to eight different performance settings for intraventricular pressure and drainage of CSF. The performance settings of the valves can be set preoperatively and can also be noninvasively changed post-implantation by using the CERTAS® Tool Kits. The CERTAS Tool Kits employ magnetic force to select one of eight settings. Please see Figure 1 for diagrams of the valves.



Graph 1

Each CERTAS Plus Valve is calibrated and tested at the time of manufacture. Graph 1 describes the pressure-flow performance characteristics of the device as required by ISO 7197. In addition, long-term stability performance of the device has been demonstrated through testing in accordance to this standard. The pressure shown in the graph for each setting is an average recorded with active flow through the valve alone at flow rates of 5, 20 and 50 mL/h; the value at 20 mL/h is shown. Note that testing of the device may give different results depending on the test conditions.

The devices performed within a tolerance range of the average pressure as shown here regardless of gravitational orientation:

Settings 1, 2, 3	± 20 mmH_2O
Setting 4	± 25 mmH_2O
Settings 5, 6, 7	± 35 mmH_2O

When adjusting the valve, the changes between each performance setting at flow rates of 5, 20, and 50 mL/h are:

Incremental steps between settings 1,2,3,4	15 – 40 mmH_2O
Incremental steps between settings 4,5,6,7	20 – 50 mmH_2O

Setting 8 is intended to limit flow through the valve and has an average pressure greater than 400 mm H_2O.

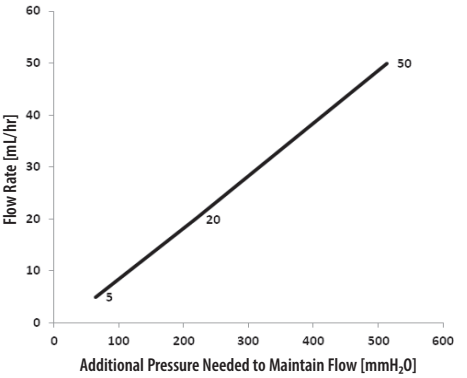
When tested with a 120 cm long, 1 mm ID Distal Catheter the average pressure increase is dependent on flow rate as shown here:

5 mL/h	6 mmH_2O
20 mL/h	21 mmH_2O
50 mL/h	50 mmH_2O

Intraventricular pressure is maintained at a constant level by the ball and cone valve seat design. It includes a valve mechanism that incorporates a flat 316L stainless steel spring. Spring compression at each operating pressure is generated by a finger pushing on a rotative cam that is located by a titanium shaft. Magnets encapsulated with epoxy couple the rotative cam with programming tool. The valve mechanism and connectors are made of polysulfone. The ball, cone and bearings are manufactured from synthetic ruby. Valve mechanism is inserted in a silicone rubber housing. Tantalum markers are present for X-ray identification. Together these components provide a precise fit for regulating the flow of CSF through the valve.

The SIPHONGUARD® device, included in some models of the valve, is designed with a dual pathway to prevent excessive drainage of CSF by the shunt system. Excessive draining can be induced by a rapid increase in hydrostatic pressure created by the elevation of the shunt ventricular catheter with respect to the shunt distal catheter (i.e., when patient moves from a supine to an upright position). 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 secondary spiral passage, effectively slowing the rate at which CSF is shunted from the brain. Graph 2 describes the incremental pressure required for CSF to flow through the SIPHONGUARD secondary pathway.



Graph 2

A CERTAS Tool Kit must be used to adjust the valve setting. It can also be used to confirm the setting. CERTAS Tool Kits are available separately (see Tool Kit Instructions for Use for more information).

Indications

The CERTAS Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of 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.

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 (see Tool Kit Instructions for Use for more information).
- As with all programmable valves, the magnets within the CERTAS Plus valve will cause an image artifact on CT and MRI imaging. As a result, the implantation site should be chosen so that the artifact will be minimized in areas of significant clinical interest, such as a tumor, that may require repeated future imaging assessment.
- 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.
- The valve setting is adjusted with the application and manipulation of strong magnets. A change to the valve setting is unlikely to occur under normal circumstances. However, magnetic fields should not be placed near the valve due to the possibility of an unintentional setting change.
- Read MRI Information before performing an MRI procedure on a patient implanted with the 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 CERTAS Plus magnet material, the valve is resistant to magnetic degradation in a 1.5T MRI.
- Testing of the CERTAS Plus valve following exposure to 10 simulated MRI procedures at 3T indicates there is no substantial demagnetization or significant reduction in programmability. Please refer to the Tool Kit IFU if any difficulty in programming occurs.

Precautions

- Inspect the sterile package carefully. Do not use if:
  - the package or seal appears damaged,
  - contents appear damaged, or
  - the expiry date has passed.
- Use sterile technique in all phases of handling the valves and accessories.
- Use only with catheters that are compatible with the dimensions shown in the Detailed Product Description section.
- Ventriculoatrial (VA) shunting could be considered in patients when:
  - peritoneal CSF absorption is impeded and alternative sites for shunting are necessary
  - the patient presents with peritoneal adhesions, pseudocysts or dialysis catheters
- Surgeons should consider the additional risks and benefits prior to considering a VA shunt:

- in patients with cardiopathies or other malformations of the cardio-pulmonary system
- in children, VA distal catheter location is more crucial for proper function, since rapid growth may cause cephalad migration of the tip over time

- Carefully monitor the patient during the first 24 hours after adjusting the valve 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.
- Use only a CERTAS Tool Kit to adjust the setting of the CERTAS and CERTAS Plus Programmable Valves.
- Excessive swelling may make it difficult to determine and/or adjust the performance setting.
  - If difficulty correctly positioning the Tool persists, see the Tool Kit IFU.
- Integra has not evaluated the effect of having other medical devices implanted in close proximity to the CERTAS Plus Valve.

Adverse Events

Devices for shunting CSF might need 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 might 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 might show redness, tenderness, or erosion along the shunt pathway.

Accumulation of biological matter within the valve can:

- cause difficulties adjusting the valve setting with the Tool Kit
- 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, slit-like ventricles, and in infants, sunken fontanels.

The ventricular catheter can become obstructed by:

- Biological matter
- Excessive reduction of ventricle size
- Choroid plexus or ventricular wall
- Fibrous adhesions, which can bind the catheter to the choroid plexus or ventricular wall

If fibrous adhesions cause the catheter to become obstructed, use gentle rotation to free the catheter. Do not remove the catheter with force. 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 implanted valve might compromise the shunt. Check valve position and integrity if this occurs.

Magnetic Resonance Imaging (MRI) Safety Information

MR Conditional

Non-clinical testing demonstrated that the CERTAS Plus Programmable Valve is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- A horizontal cylindrical-bore MRI scanner
- Static magnetic field of 1.5 and 3 T
- Maximum spatial field gradient of 2,000 Gauss/cm (20 T/m).
- Maximum console reported SAR corresponding to first level controlled operating mode (WB SAR of 4 W/kg, Head SAR of 3.2 W/kg and partial body SAR of 4-10 W/kg)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg in the First Level Controlled Operating Mode of operation for the MR system.

WARNING: Do not use Transmit/Receive RF Head coils. Only use Transmit/Receive RF Body coil or Transmit RF Body coil/Receive-only RF Head coil.

WARNING: Do not use Transmit/Receive local coils that are placed directly over the location of valve.

In non-clinical testing, under the scan conditions defined above, the CERTAS Plus Programmable Valve is expected to produce a maximum Temperature rise of 3.4°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 25 mm from the CERTAS Plus Valve when imaged with a gradient echo pulse sequence and a 3T MRI System.

MRI Additional Information

- The highest magnetic field spatial gradient is commonly located off-axis, at a side wall, and near the opening of the bore of the scanner. Please refer to MRI manufacturer's published value and location of the peak magnetic field spatial gradient that is accessible to the patient.

Specific Guidelines

The valve setting should be verified after the MRI procedure.

Detailed Product Description CERTAS Plus Programmable Valve

The valve features an adjustable mechanism and a reservoir. All valves are marked with a radiopaque direction-of-flow arrow and a right-hand side (RHS) marker. A priming adapter is included with all valves. Valves are available with or without SIPHONGUARD. Valves are also available with or without accessories, including silicone catheters (see Figure 1).

Programmable Valve Configurations

Inline with SIPHONGUARD
Inline
Inline Small with SIPHONGUARD
Inline Small
Right Angle with SIPHONGUARD
Right Angle
The valves are designed for use with catheters having the following dimensions:

Component	Inner Diameter	Outer Diameter
Ventricular catheter	1.4 mm	2.7 mm
Distal catheter	1.0 mm	2.2 mm

SIPHONGUARD

SIPHONGUARD is supplied with some models of the valve. 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 ball is balanced between a spiral 316L stainless steel spring and a flat 316L stainless steel spring. 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 compress the spring to close the ball and cone valve, and the entire volume of CSF will be forced through the longer secondary passage, effectively slowing the rate at which CSF is shunted from the brain. Once the flow rate entering the SIPHONGUARD Device decreases, the flat spring will separate 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. See Graphs 1 and 2 for pressure flow characteristics.

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

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

Accessories

Accessory components supplied with some models of the valve include:
Ventricular catheter
Distal catheter (unitized or separate)
Right angle adapter
Priming adapter

Catheters

The ventricular catheter is a 14 cm straight ventricular catheter molded of radiopaque barium-impregnated silicone elastomer with X-ray detectable tantalum dots and a preassembled stainless steel introducing stylet. The distal catheter is 120 cm long, molded of radiopaque silicone elastomer with X-ray detectable dots.

Right Angle Adapter

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

Priming Adapter

The priming adapter with inlet tubing facilitates pre-implantation irrigation of the valve and catheters.

How Supplied

This device is 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 contaminates, such as Classic Creutzfeldt-Jakob Disease. Reuse can compromise device performance and any usage beyond the design intent of this single use device might result in unpredictable use hazards or loss of functionality.

As long as the inner unit of the valve package is not opened, damaged or past its expiration date, the product is sterile.

Testing has shown that the following components are nonpyrogenic:

- Valve and Valve with SIPHONGUARD
- Ventricular catheter
- Distal catheter
- Right angle adapter
- Priming adapter

Pre-implantation Performance Testing

Every CERTAS Plus Programmable Valve is calibrated during manufacture and is tested for proper performance.

Performing manometer testing is not recommended for the following reasons:

- Customer-performed testing is susceptible to environmental factors.
- The results yielded are not physiologic in nature.
- If the surgeon insists upon performing manometer testing for confirmation of valve closing pressures, please see Optional Manometer Testing in Appendix A.

Instructions for Use

NOTE: Additional training materials are available from your local Integra sales representative.

Surgical Procedure Precautions

- 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 might rupture or tear the silicone components.
- Do not fold or bend the valve during insertion. Folding or bending might cause rupture of the silicone housing, needle guard dislodgement, or occlusion of the fluid pathway.
- 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.
- 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.

Irrigation

It is required that the valve be irrigated before implantation to help ensure proper performance.

1. Hold the valve vertically with the **distal connector barb pointing downward.**
2. Using a syringe, slowly and gently fill the entire valve system with pyrogen-free, sterile saline solution or an appropriate antibiotic solution. Once fluid begins flowing through the valve mechanism, the distal connector barb of the valve can be pointed upward to assist in evacuating air from the system.

   NOTE: A priming adapter with inlet tubing is provided to facilitate irrigation.

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

   NOTE: More pressure might be required on the syringe before fluid starts flowing through the valve mechanism. This is normal and will only occur during initial irrigation of the valve. A popping sound may occur.

   NOTE: SIPHONGUARD 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.

3. Once fluid flows from the distal connector barb of the valve (or the distal catheter, on unitized models), and air has been evacuated from the valve, remove the syringe and the priming adapter (if used).

Surgical Technique

There are a variety of surgical techniques that can be used to place the valves. The surgeon should choose in accordance with his or her own clinical experience and medical judgment. It is required that the valve be irrigated as outlined in Irrigation, to help ensure proper performance.

CAUTION: Placement of the valve can impact the performance of the tool kit and should be taken into account for proper patient therapy. Select a location where the implanted valve can be positioned for use with the tool kit. Avoid placement too close to structures, such as the ear. It is also important to choose an implantation site where the tissue over the valve is not too thick (>10 mm) otherwise locating, reading and adjusting with the CERTAS Tool Kit may not be possible.

Troubleshooting

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

- flushing and/or pressing the valve (only for those valves without the SIPHONGUARD feature)
- multiple attempts to adjust the setting

Disposal

After patient use, the system must be handled as biohazardous material and disposed of in accordance with applicable federal, state, local or international environmental requirements following facility protocols.

Confirming the Current Valve Setting

The setting of an implanted valve can be determined by using the CERTAS Tool Kit, (refer to the Tool Kit IFU for more information).

An alternate method is to x-ray the valve. A proper X-ray is generated when the film is shot perpendicular to the plane of the valve with the non-implanted side of the patient's head resting on the plate. The film must be taken in relation to the valve and not the patient's anatomy. See Figure 3 for X-ray views of the valve at each setting.

When viewing the X-ray film or screen to confirm the valve setting, use the X-Ray Overlay Tool (refer to the Tool Kit IFU for more information).

Reading the Valve Setting with the X-Ray Overlay Tool

See Figure 4.

NOTE: Position the **X-Ray Overlay Tool** flush against the X-ray image.

1. Align **RED** centerline of valve on overlay with the centerline of the valve X-ray under review. This can be accomplished by aligning the proximal and distal connectors of the X-ray image with those on the overlay.
2. Ensure that the numbers on the overlay that depict the performance settings are properly oriented for viewing. In this orientation the right-hand side (RHS) marker red line extends to the right of the **RED** centerline. **This ensures proper overlay orientation.**
3. Align rotating construct (RC) center dot on overlay with the center of the RC of the X-ray image.
4. Ensure RHS marker red line containing red dot is aligned with the RHS marker of the X-ray image (if present).
5. The valve setting is determined by identifying the region of the overlay that contains the majority of the image of the magnet that has the tantalum ball adjacent to it.

Injection

If hypodermic injection is required, inject with a 25-gauge or smaller non-coring type needle into the reservoir only. The reservoir can be punctured up to 25 times with a 25-gauge or smaller non-coring type needle.

CAUTION: A needle guard has been included in the valve housing to provide tactile feedback during needle insertion but is not intended to prevent puncturing through the back of the valve under forceful pressure.

Valve Flushing

(Valves without SIPHONGUARD only)

CAUTION: Flushing is not recommended as a method for determining patency. Use clinical judgment and imaging studies or other techniques to confirm suspected cases of shunt malfunction.

To flush the ventricular (proximal) catheter, occlude the catheter distal to the reservoir with finger pressure, then depress the reservoir.

To flush the distal catheter, occlude the catheter proximal to the reservoir with finger pressure, then depress the reservoir.

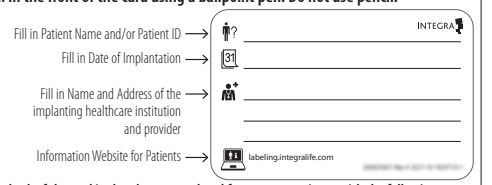
In general, if one pushes on the reservoir and it does not spring back, then there might be an obstruction in the proximal catheter because the reservoir is not filling with CSF. On the other hand, if the reservoir feels rather stiff and more force is needed to depress it, then the valve and/or distal catheter may be clogged.

NOTE: While proximal pressure is maintained, reservoir will not refill with fluid.

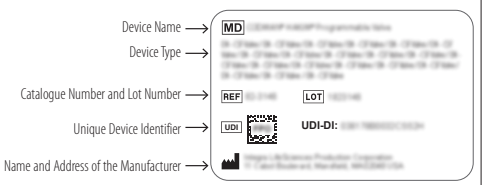
NOTE: Flushing the distal catheter cannot be performed with the right-angle valve configuration.

This device is an implant and is delivered with a patient implant card. The purpose of a patient implant card is to ensure that the patient is aware of the details of the device that they have been implanted with and that you and other healthcare professionals involved in the care of the patient can identify the particular device. Additional information on this device can be found in the patient information leaflet, which can be accessed at www.labeling.integralife.com. Please fill in the information on the patient implant card per the instructions outlined below and provide the patient implant card to the patient or their legally designated representative after completion of the section to be filled by the healthcare professional. Please also direct the patient to the patient information leaflet with the additional information on this device at the website listed above, which is also listed on the patient implant card.

Fill in the front of the card using a ballpoint pen. Do not use pencil.



The back of the card is already pre-populated for your convenience with the following information:



The graphical display is for illustration purposes only and may not be to scale.

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Appendix A

Optional Manometer Testing

Although Integra does not recommend functional testing, some surgeons might choose to do so. Before testing, it is extremely important that a CERTAS Programmable Valve with or without SIPHONGUARD be flushed of all air bubbles. Air bubbles within the valve or SIPHONGUARD will 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.

SIPHONGUARD Functional Testing

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, 10mL minimum is recommended
One sterile syringe filter, 5 µm
Sterile tubing adapters
Sterile silicone tubing
One sterile male luer connector with 1/16 in. (1.6 mm) barb
Sterile saline solution

Flushing Procedure

NOTE: At a rate of 0.5 mL/minute, unitized versions require 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 not 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).
3. Adjust the valve setting to 1 while the valve remains in its sterile package.
4. Remove valve from the sterile package, and connect the valve to the manometer/syringe assembly.
5. Adjust the stopcock to connect the syringe to the valve assembly (Figure A-2).
6. Position the valve vertically with the outlet pointed downward.
7. Using the syringe, gently flush saline through the system while gently pressing the reservoir to purge air bubbles from the valve assembly. Once fluid begins flowing through the valve mechanism, the outlet of the valve can be pointed upward to further assist in evacuating air from the system.

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

8. Attach a distal catheter to the valve and gently flush saline through the system to ensure that the catheter is purged of air.
9. The device is now ready for SIPHONGUARD Test Procedure or 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.

SIPHONGUARD Test Procedure

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

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

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

   NOTE: The device must lie on a sterile surface and remain undisturbed for the duration of the test.
4. Hold the distal end of the catheter adjacent to the manometer and slowly lower the end of the catheter until the fluid level in the manometer begins to drop.
5. Continue to lower the end of the catheter 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 SIPHONGUARD's primary pathway closes and flow diverts to the higher resistance secondary pathway. This confirms proper functioning of SIPHONGUARD.
7. Repeat Steps 3 through 6 as necessary to reconfirm SIPHONGUARD function.

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, 10mL minimum is recommended
One sterile syringe filter, 5 µm
Sterile tubing adapters
Sterile silicone tubing
One sterile male luer connector with 1/16 in. (1.6 mm) barb
Sterile saline solution
Sterile fluid reservoir or water bath

Equipment Setup

1. Fill syringe with sterile saline using the 5 µm syringe filter. The syringe filter should not 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).
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).
5. Adjust the stopcock to connect the syringe to the tubing in the water bath (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).
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).
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).
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.

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. Adjust the stopcock to connect the syringe to the valve assembly (see Figure A-2).

4. Position the valve vertically with the outlet pointed downward.
5. Using the syringe, gently flush saline through the system while gently pressing the reservoir to purge air bubbles from the valve assembly. Once fluid begins flowing through the valve mechanism, the outlet of the valve can be pointed upward to further assist in evacuating air from the system.

   NOTE: An excessive flow rate (>0.75 mL/min) activates SIPHONGUARD and creates the impression that the valve is distally occluded. In reality, flow is being diverted to the high resistance secondary pathway.
6. Once all air has been removed from the valve, submerge the valve completely in the water bath. For valves with a distal catheter, submerge the end of the 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.
7. Adjust the stopcock to connect the syringe to the manometer (see Figure A-6) and refill the manometer to a height equal to the operating pressure of the next highest setting above the valve setting being tested, or to 60 cmH_2O if one is testing Setting 8. Refer to Table 1 for operating pressure specifications.
8. Turn the stopcock to connect the manometer to the valve (see Figure A-7).
9. The water column in the manometer will start to fall. Allow the water column to drop for 2 minutes and then read the resultant pressure.

   NOTE: For valves with distal catheter and/or SIPHONGUARD, an extended test time is recommended in order to compensate for the possibility of a decreased flow rate due to the additional catheter resistance and/or SIPHONGUARD activation. Allow the water column to drop for 4 minutes and then read the resultant pressure.

Test Results

The resultant closing pressure may be compared to the table below.

NOTE: Variations in the manometer closing pressure test result are possible based upon the test conditions and the test method utilized.

Valve Setting	Minimum Closing Pressure (mmH_2O)
1	0 mmH_2O
2	0 mmH_2O
3	30 mmH_2O
4	55 mmH_2O
5	80 mmH_2O
6	105 mmH_2O
7	140 mmH_2O
8	300 mmH_2O

.

Symbols Used on Labeling

QTY	Quantity
	Use-by date (YYYY-MM-DD)
	Date of manufacture (YYYY-MM-DD)
LOT	Batch code
STERILE	Sterilized using steam or dry heat
	Do not re-use
	Temperature limit
	Caution
	Consult instructions for use or electronic instructions for use
	Do not resterilize
	Do not use if package is damaged and consult instructions for use
Rx ONLY	Prescription Use Only
	Manufacturer
MADE IN	Made in
	Non-Pyrogenic
	Magnetic Resonance (MR) conditional
REF	Catalogue number
	Patient identification
	Date
	Health care center or doctor
	Patient information website
MD	Medical device
UDI	Unique Device Identifier

The symbols glossary is provided electronically at www.integralife.com/symbols

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