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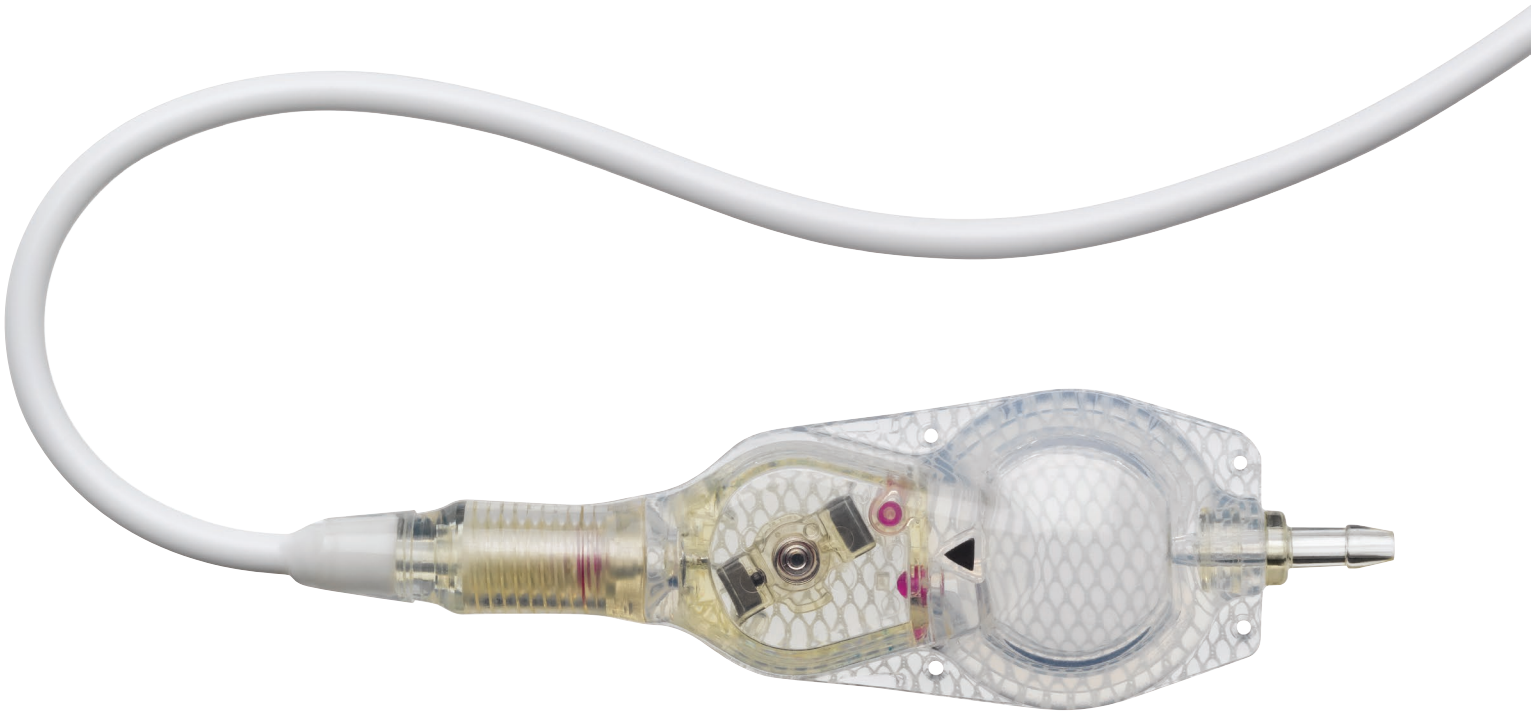
Codman®
SPECIALTY SURGICAL

Value Analysis Committee Information Package

Codman® CERTAS™ Plus

Programmable Valve



Revision Date – December 20, 2018

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Codman® CERTAS™ Plus Programmable Valve

Product Information

Codman® CERTAS™ Plus Programmable Valve and Codman® CERTAS™ Tool Kit provides the flexibility, versatility and confidence to manage the needs of the hydrocephalus patient.

Broad range of settings to meet the needs of most patients

- 8 discrete settings including a 'Virtual Off' setting
- MRI resistant up to 3 Tesla*

Allows for a non-invasive reading to assist in monitoring and adjusting valve pressure

- Hand held CERTAS Tool Kit contains 2 Locator Tool options to choose from for optimal alignment with the valve.
- Electronic Tool Kit provides clear and easy-to follow visual guidance to locate the valve and allows for faster post-operative adjustment.

The Codman CERTAS Plus Programmable Valve integrated with the SIPHONGUARD® Anti-Siphon Device reduces the risk of overdrainage

- Consistency and durability with a clinically proven mechanical design[1]
- The SIPHONGUARD Anti-Siphon Device is position independent, allowing maximum treatment flexibility of the patient[2]
- Available in an integrated or stand-alone configuration

The Codman CERTAS Plus Programmable Valve unitized with BACTISEAL® Catheter creates an effective barrier in reducing gram positive colonization on all catheter surfaces

- First programmable valve that is available unitized with Bactiseal Antimicrobial Catheter
- Bactiseal Catheter is an impregnated antimicrobial shunt catheter system
- Bactiseal Catheters reduce gram positive bacterial colonization on the catheter surfaces for up to 28 days[3]

*Clinician should confirm the valve setting after a magnetic resonance imaging procedure (MRI)

REFERENCES

1. IKurtom K, Magram G. Siphon Regulatory Devices: Their Role in the Treatment of Hydrocephalus. *Neurosurg Focus. 2007; 22(4):E5*.
2. Using the Codman HAKIM Programmable Valve with SiphonGuard Hashimoto, Mukai and Tsukada. *The Neurosurgery Bulletin, Sept. 2004*
3. Bayston R, Ashraf W, Bhundia C. Mode of action of an antimicrobial biomaterial for use in hydrocephalus shunts. *J. Antimicrobial Chemotherapy. 2004; 53:778-782.*

Product Description

Product Code	Product Description	UOM	UOM Quantity
828800PL	Codman® CERTAS™ Plus In-Line Valve only	EA	1
828801PL	Codman® CERTAS™ Plus In-Line Valve with catheters & accessories	EA	1
828802PL	Codman® CERTAS™ Plus In-Line Valve with unitized catheter & accessories	EA	1
828803PL	Codman® CERTAS™ Plus In-Line Valve with unitized BACTISEAL® Antimicrobial Catheter & accessories	EA	1
828804PL	Codman® CERTAS™ Plus In-Line Valve-only with SIPHONGUARD® Anti-Siphon Device	EA	1
828805PL	Codman® CERTAS™ Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device catheters & accessories	EA	1
828806PL	Codman® CERTAS™ Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device, unitized catheter & accessories	EA	1
828807PL	Codman® CERTAS™ Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device, unitized BACTISEAL® Antimicrobial Catheter & accessories	EA	1
828810PL	Codman® CERTAS™ Plus In-Line Small Valve only	EA	1
828811PL	Codman® CERTAS™ Plus In-Line Small Valve with catheters & accessories	EA	1
828813PL	Codman® CERTAS™ Plus In-Line Small Valve with unitized BACTISEAL® Antimicrobial Catheter & accessories	EA	1
828814PL	Codman® CERTAS™ Plus In-Line Small Valve-only with SIPHONGUARD® Anti-Siphon Device	EA	1
828815PL	Codman® CERTAS™ Plus In-Line Small Valve with SIPHONGUARD® Anti-Siphon Device catheters & accessories	EA	1
828817PL	Codman® CERTAS™ Plus In-Line Small Valve with SIPHONGUARD® Anti-Siphon Device, unitized BACTISEAL® Antimicrobial Catheter & accessories	EA	1
828820PL	Codman® CERTAS™ Plus Right Angle Valve only	EA	1
828821PL	Codman® CERTAS™ Plus Right Angle Valve with catheters & accessories	EA	1
828823PL	Codman® CERTAS™ Plus Right Angle Valve with unitized BACTISEAL® Antimicrobial Catheter & accessories	EA	1
828824PL	Codman® CERTAS™ Plus Right Angle Valve-only with SIPHONGUARD® Anti-Siphon Device	EA	1
828825PL	Codman® CERTAS™ Plus Right Angle Valve with SIPHONGUARD® Anti-Siphon Device catheters & accessories	EA	1
828827PL	Codman® CERTAS™ Plus Right Angle Valve with SIPHONGUARD® Anti-Siphon Device, unitized BACTISEAL® Antimicrobial Catheter & accessories	EA	1
828851	Codman® CERTAS™Tool Kit	EA	1
828852	Codman® CERTAS™ Electronic Tool Kit	EA	1
828859	X-Ray Overlay Tool (10 pack) *one unit included in 828851	EA	1

CERTAS™ Plus

Programmable Valves

Codman® SPECIALTY SURGICAL

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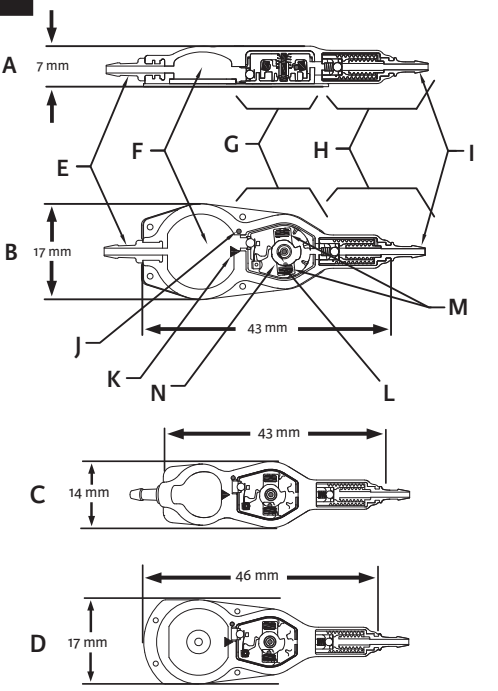
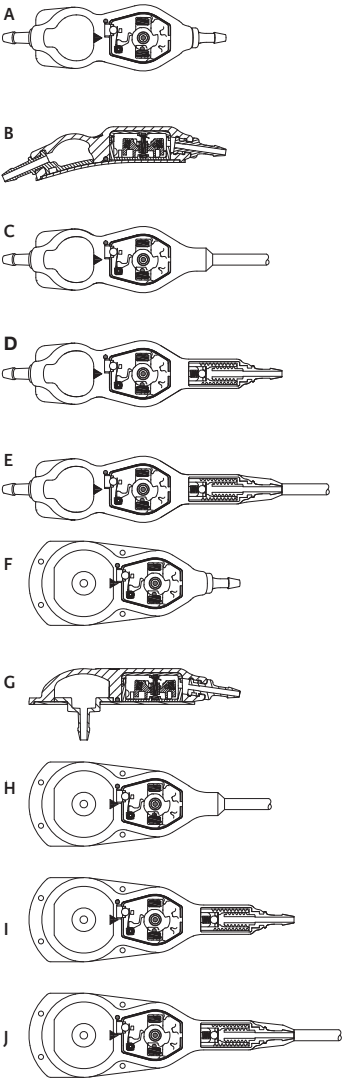
1



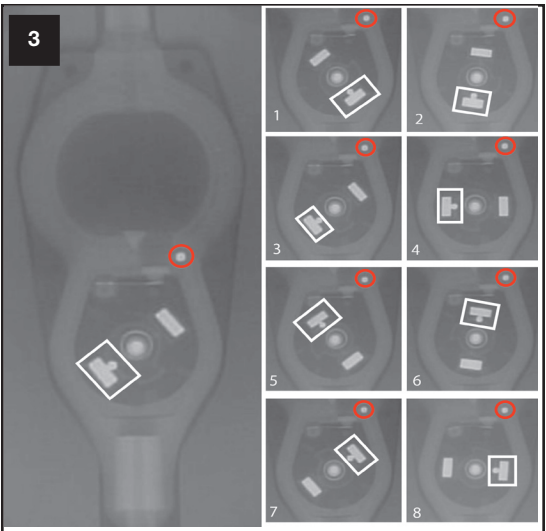
A. Regular valve side view
B. Regular valve top view
C. Small valve top view
D. Right angle valve top view
E. Proximal inlet connector barb
F. Reservoir
G. Hard valve mechanism
H. Optional SIPHONGUARD®
I. Distal outlet connector barb
J. Right-hand side (RHS) X-Ray marker
K. Direction-of-flow arrow
L.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

2



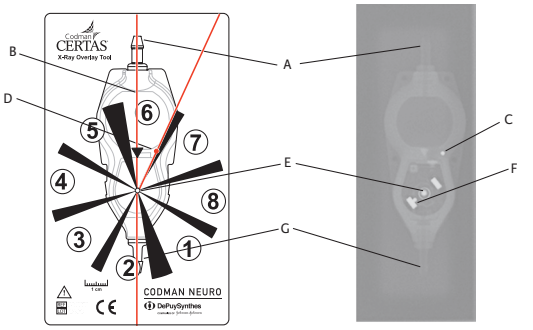
CERTAS™ Plus
Programmable Valve
Configuration

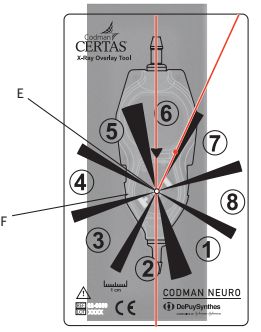
A. Inline Small
B. Inline Small side view
C. Inline Small unitized with distal catheter
D. Inline Small with SIPHONGUARD
E. Inline Small with SIPHONGUARD unitized with distal catheter
F. Right Angle top view
G. Right Angle side view
H. Right angle unitized with distal catheter
I. Right Angle with SIPHONGUARD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



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.

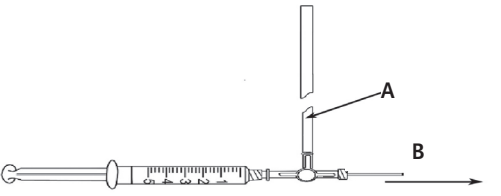
4





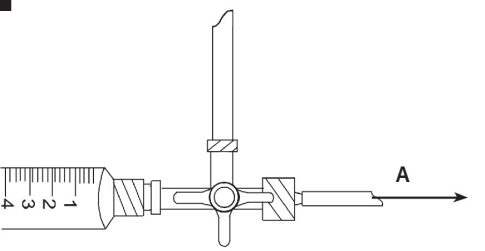
A. Proximal connector
B. RED Centerline of valve
C. Right hand side (RHS) marker
D. RHS marker red line (contains RHS dot)
E. Rotating construct (RC)
F. Magnet with tantalum ball (setting indicator)
G. Distal connector

A-1



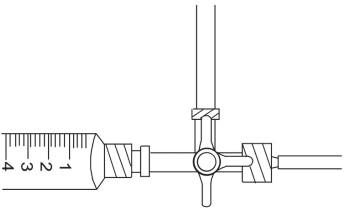
Manometer To Valve
A. Manometer
B. To Valve

A-2



Valve
A. Valve

A-3



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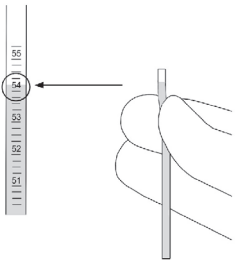

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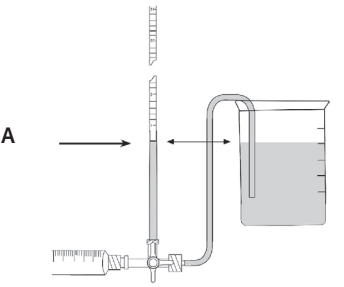
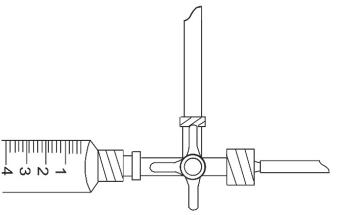


Manometer Zero Level
A. Manometer Zero Level

A-6



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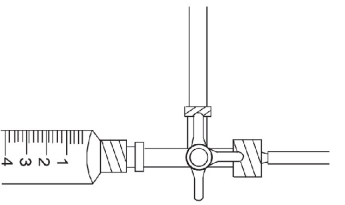

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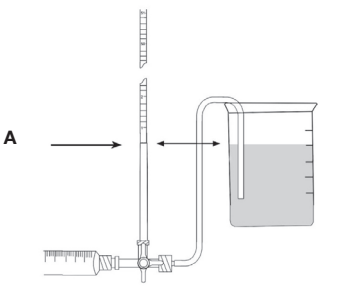


Manometer Zero Level
A. Manometer Zero Level

CERTAS™ Plus

Programmable Valves

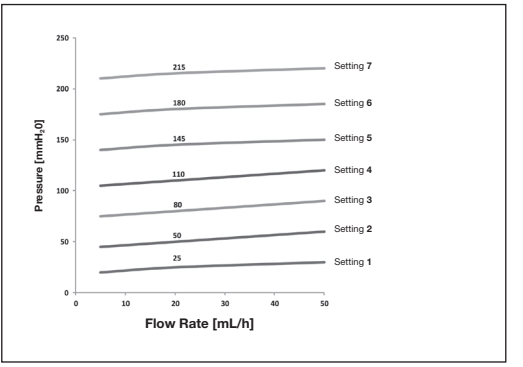
IMPORTANT INFORMATION

Please read before use

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 7197:2009. In addition, long-term stability performance of the device has been demonstrated through testing in accordance to this standard. The pressure shown in the 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

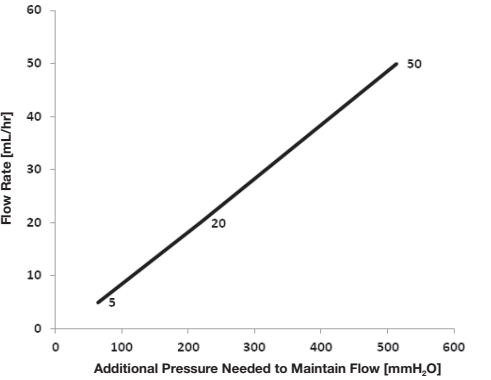
Setting 8 is intended to limit flow through the valve and has an average pressure greater than 400 mmH_2O.

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. The ball is manufactured of synthetic ruby, as is the matching cone. Together these components provide a precise fit for regulating the flow of CSF through the valve.

SIPHONGUARD®, included in some models of the valve, is designed 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). Graph 2 describes the pressure-flow performance characteristics of the valve with SIPHONGUARD.



Graph 2

The BACTISEAL® Catheters, included in some models of the valve, are subjected to a treatment process by which the silicone is impregnated with rifampin and clindamycin hydrochloride. The BACTISEAL Silicone Catheters have been shown to reduce the colonization of gram positive bacteria on the tubing surface.

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.

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

Warnings

- Choose an implantation site for the valve where the tissue over the valve is not too thick (i.e. tissue thickness <10 mm). Otherwise locating, reading, and adjusting the valve with the tool kit may be difficult (i.e.; multiple attempts may be required) or impossible. If unable to adjust the valve, the valve will maintain a constant operating pressure and the patient should be informed of this risk (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
- The safety and effectiveness of Bactiseal catheters for VA shunting has not been established.
- 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 CODMAN 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 or BACTISEAL® 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 valve and enters SIPHONGUARD, where it flows into two internal passages. Under normal conditions, most of the CSF flows through a central ruby ball and cone valve, and exits directly out of the distal port of SIPHONGUARD. 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 from the brain. Once the flow rate entering SIPHONGUARD 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 SIPHONGUARD never stops, regardless of the patient's position. See Graphs 1 and 2 for pressure flow characteristics.

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

SIPHONGUARD has a rigid enclosing shell of polyethersulfone 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 silicone elastomer with x-ray detectable 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.

The BACTISEAL Catheters that are supplied with some models of the valve are made of radiopaque barium-impregnated silicone tubing that is subjected to a process by which the silicone is impregnated with rifampin and clindamycin hydrochloride.

The quantities of rifampin and clindamycin hydrochloride used to impregnate the catheters are only a small fraction of a therapeutic dose of these two antibiotics, and have no potential for systemic therapeutic effect.

BACTISEAL Catheters are also available separately.

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

The valve and its accessories are for **SINGLE USE ONLY; DO NOT RESTERILIZE.** 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 Creutzfeldt-Jakob Disease. Reuse might also 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.

Integra will not be responsible for product that is re-sterilized, nor accept for credit or exchange product that has been opened but not used.

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

Testing has shown that the following components are nonpyrogenic:

- Valve and Valve with SIPHONGUARD
- Ventricular catheter (both BACTISEAL Catheters and non-treated catheters)
- Distal catheter (both BACTISEAL Catheters and non-treated catheters)
- Right angle adapter
- Priming adapter

Storage – BACTISEAL Catheters
Store any valve kits that contain BACTISEAL Catheters at temperatures between 2°C (36°F) and 27°C (81°F), away from direct light. Do not remove the product from the packaging until it will be used. The shelf life of products containing BACTISEAL Catheters is one year from the date of sterilization. The “Use By” date is indicated on the labeling; the product can be used through the last day of the month shown.

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:
- The concentration of antibiotics in the BACTISEAL Catheters can be reduced by the testing.
- 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.
- Do not immerse the BACTISEAL Catheter in antibiotic solutions. Only use sterile water or normal saline to immerse the BACTISEAL catheter as other solutions are not recommended and may cause precipitation and consequent adverse effects (e.g., catheter occlusion, hydrocephalus). Keep the time the BACTISEAL catheter is immersed in sterile water or normal saline to a minimum (i.e., seconds) to reduce the risk of introducing infectious agents. A pale orange color might be imparted to the immersion solution. Manometer testing of the valve with BACTISEAL Catheter is not advised.

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, for catheters other than BACTISEAL Catheters, 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.

It is recommended to record the setting of the valve in the patient records and on the patient I.D. wallet card. Labels are provided with each valve to record the product lot number information in the patient records. I.D. wallet cards are available from the local Integra sales representative.

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

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 HUBER® type needle into the reservoir only. The reservoir can be punctured up to 25 times with a 25-gauge or smaller non-coring HUBER 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: 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 the ventricular (proximal) catheter:

- Occlude the catheter distal to the reservoir with finger pressure, then depress the reservoir.
- Failure of the reservoir to refill might indicate proximal catheter blockage.

To flush the distal catheter:

- Occlude the catheter proximal to the reservoir with finger pressure, then depress the reservoir.
- Failure of the reservoir to depress easily might indicate distal catheter blockage.

  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.

Warranty

Integra LifeSciences, Inc. warrants that this medical device is free from defects in both materials and workmanship. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.

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

QTY	Quantity
	Use by (YYYY-MM-DD)
LOT	Batch Code
STERILE	Sterilized using steam
	Do not reuse
81°F 27°F 36°F 2°F	Temperature Limitations
	Caution
	Consult instructions for use
STERILIZE	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 licensed healthcare practitioner.
	Manufacturer
MADE IN	Made in
	Nonpyrogenic, see instructions for use
MR	MR Conditional
REF	Catalogue Number

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CODMAN CERTAS®
Tool Kit (REF 82-8851)

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IMPORTANT INFORMATION
Please read before use

CODMAN CERTAS® Tool Kit (REF 82-8851)

℞ Only

Description
The CODMAN CERTAS Tool Kit is used to adjust and confirm the performance setting of a CODMAN CERTAS or CODMAN CERTAS Plus Programmable Valve. The actions are performed both preoperatively (with the valve still in the sterile package) and postoperatively (on the implanted valve) through noninvasive means. The CODMAN CERTAS Tool Kit employs magnetic force to change the performance setting. Please see Figure 1A for images of the CODMAN CERTAS Tool Kit components.

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

Warnings

- The **Indicator Tool** has a precise operating mechanism and is vulnerable to damage if mishandled. Store and carry all components of the Tool Kit in the storage case when not in use to prevent damage. Replace the Indicator Tool immediately if dropped (or suspected of being dropped) to ensure accurate performance. Replacement **Indicator Tools** are available from your local Codman representative.
- **Do not interchange** the CODMAN CERTAS Tool Kit (82-8551) components with the components of the CODMAN CERTAS Therapy Management System TMS (82-8850).

Precautions

- **Do not use** any of the CODMAN CERTAS Tool Kit components on a metal surface, such as a Mayo stand as this could interfere with the Indicator Tool magnets.
  Note: the **Adjustment Tool** contains powerful magnets.
- **Inspect** the CODMAN CERTAS Tool Kit components before each use. Check for damage, such as cracks. Do not use the Tool Kit if damage is present. Contact your local Codman sales representative for a replacement kit.
- **Carefully monitor** the patient during the first 24 hours after adjusting the performance setting of the valve. 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.
- **Confirm** the valve performance setting after an MR procedure.
- **Excessive swelling** may make it difficult to determine and/or adjust the performance setting.
  - See Step 4 in *SECTION B: Post-Implantation Adjustment Procedure* for instructions for using the **Low Profile Locator Tool in these instances.**
  - If difficulty correctly positioning both **Locator Tools** persists, wait until the swelling is reduced or confirm the valve setting with x-ray. See *SECTION D: Confirming the Current Valve Setting* for more information.
- **Failure to accurately position** the **Locator tool** could result in an inaccurate indication of the performance setting, potentially leading to a false reading (i.e. an incorrect number may appear in the window of the Indicator Tool). The Locator Tool must be precisely aligned with both the valve's direction of flow and the center of the hard valve mechanism for an accurate indication reading. Alignment can be more challenging if tissue thickness is >10 mm

above the valve. In these instances, verify the valve setting with x-ray or fluoroscopy. See *SECTION C: Troubleshooting* and *SECTION D: Confirming the Current Valve Setting.*

Adverse Events

Accumulation of biological matter within the valve can:

- cause difficulties adjusting the valve setting with the Tool Kit
- impair the antireflux 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.

MRI (Magnetic Resonance Imaging) Safety Information

The CODMAN CERTAS Tool Kit is considered "MR Unsafe" in accordance with the American Society for Testing and Materials (ASTM) Standard F2503-13.

CAUTION: Do not use the CODMAN CERTAS Tool Kit in the MR suite.

Detailed Product Description

The CODMAN CERTAS Tool Kit (see Figure 1A) consists of five components:

- Adjustable Height Locator Tool
- Low Profile Locator Tool
- Indicator Tool
- Adjustment Tool
- X-Ray Overlay Tool

These components are packaged within a case (see Figure 1B) that, when closed, will help minimize the effect of the CODMAN CERTAS Tool Kit magnets on other items.

The CODMAN CERTAS Tool Kit is provided as a non-sterile product.

CAUTION: Do not sterilize the CODMAN CERTAS Tool Kit.

Disinfecting the CODMAN CERTAS Tool Kit

After use, wipe the areas of the tools that contact the patient with a combination wipe (Quaternary Ammonium/Isopropyl Alcohol). Follow Steps 1 through 4 below.

1. Thoroughly wet the surfaces with a wipe.

2. Keep the surfaces wet for 2 minutes. Use as many wipes as needed to keep the surfaces wet for the entire 2 minutes.

3. Allow the wetted surfaces to air dry.

4. Inspect the components to ensure that all soil, blood, or debris has been removed. If needed, repeat Steps 1 through 3 and inspect again.

Visually inspect all parts after disinfection to ensure markings remain. Do not use the Tool Kit components if markings are compromised. Contact your local Codman sales representative for a replacement kit.

Instructions for Use

Note: Additional training materials are available from your local Codman sales representative.

SECTION A: Pre-implantation Adjustment Procedure

Adjust the performance setting before implanting the CERTAS Plus Programmable Valve. This step is performed before the sterile inner package of the valve is opened.

1. Place the valve sterile package on a non-metallic surface so the clear portion of the package faces up. Place the **Adjustable Height Locator Tool** in the circular grooves

of the package so that the arrow on the tool points in the same direction as the arrows molded into the plastic package (See Figure 2). Ensure that the **Adjustable Height Locator Tool** is fully seated in the grooves. If necessary, maintain hold of the **Adjustable Height Locator Tool** throughout the procedure to keep it firmly in the grooves of the package.

CAUTION: Failure to maintain a fully-seated Locator Tool above the valve mechanism could result in an inaccurate indication of the performance setting.

Note: Do not use the **Low Profile Locator Tool** for programming the valve in the package, as it does not contain a base that will fit into the circular grooves of the packaging.

2. Fully seat the **Indicator Tool** into the **Adjustable Height Locator Tool** so that the red markings are aligned (Figure 3). You may hear a click when the tool seats; the **Indicator Tool** will not rotate within the **Locator Tool** when properly seated.

   CAUTION: When reading the performance setting with the Indicator Tool, make sure that the Adjustment Tool and any other magnetic devices are at least 36 cm (14 in.) away from the Indicator Tool. Failure to do so can result in an inaccurate indication of the performance setting.

3. When the number dial on the **Indicator Tool** stops moving, observe the number and its position within the window to determine the performance setting. A single number within the window, with full purple background and both gray side lines visible (Figure 12), indicates the performance setting of the valve when the tools are properly aligned. Once the valve performance setting has been read, remove the **Indicator Tool.**

4. Insert the **Adjustment Tool** into the **Adjustable Height Locator Tool** so that the arrow is pointing to the current performance setting. With one hand holding the "petals" of the **Adjustable Height Locator Tool**, turn the **Adjustment Tool** with the other hand until the arrow points to the desired performance setting (Figure 4). The **Adjustment Tool** will provide an audible click and a tactile response as you turn to each setting.

   Note: The **Adjustment Tool** is equipped with a mechanical stop between Settings 1 and 8. This is to prevent inadvertent adjustment between the extremes of the available settings.

   Note: Successful adjustment is accomplished by starting at the valve's current setting and moving directly to the desired setting.

5. Remove the **Adjustment Tool** from the **Adjustable Height Locator Tool** by lifting it straight upwards a minimum of 3 cm (1.25 in.) before moving it horizontally away from the **Adjustable Height Locator Tool** in order to avoid inadvertently changing the valve setting.

6. **Repeat Steps 2 and 3 to confirm successful adjustment of the performance setting.** Always confirm the desired performance setting of the valve.

7. If the desired performance setting is not achieved, repeat Steps 4 through 6.

8. It is recommended to record the valve setting in the patient's record and I.D. wallet card (available from local Codman sales representative).

9. Return all tools to their proper locations in the storage case to prevent damage.

   Note: fully collapse the **Adjustable Height Locator Tool** (see figure 1B).

SECTION B: Post-Implantation Adjustment Procedure

Adjust the valve at any time after the implantation surgery. If needed, apply a sterile drape over the incision site. The drape will not interfere with the magnetic coupling of the adjustment procedure.

CAUTION: Excessive swelling or thick tissue may make it difficult to determine and/or adjust the performance setting. See Step 4 in this section for instructions for using the Low Profile Locator Tool in these instances. If difficulty correctly positioning both Locator Tools persists, wait until the swelling is reduced or confirm the valve setting with x-ray. See *SECTION C: Troubleshooting* and *SECTION D: Confirming the Current Valve Setting* for more information.

1. Position the patient so that the implanted valve and tools are horizontal, to optimize Indicator Tool performance (see Figure 5).

   CAUTION: If Indicator Tool is not horizontal, an inaccurate reading might result.

2. Locate the valve by palpation. Palpate and mark the center of the valve mechanism i.e., the hard portion of the valve distal to the reservoir. Palpate and mark the position of the inlet and outlet connector barbs/catheters. (See Figure 6)

3. Select the appropriate **Locator Tool (Adjustable Height Locator Tool or Low Profile Locator Tool).** If the tissue in the area of the valve is thick tissue or if edema is present (>10 mm above the valve), use the **Low Profile Locator Tool** (Figure 7). Otherwise, use the **Adjustable Height Locator Tool**. Optimal placement is achieved when the selected **Locator Tool** is stable on the patient's head and the tissue that covers the valve mechanism is just below the cut-out in the **Locator Tool** (Figures 8A & 8C).

4. Place the appropriate **Locator Tool** atop the implanted valve so that the black lines are aligned with the marked center of the hard valve mechanism and the direction of flow arrow aligns with the catheter barb marks (Figure 9).

   Note: If using the **Adjustable Height Locator Tool,** rotate the white outer ring to adjust the height until the tissue that covers the valve mechanism is just below the cut-out in the **Locator Tool** to optimize the tool performance (Figure 8C).

   Note: If using the **Low Profile Locator Tool**, ensure that the tissue that covers the valve mechanism does not protrude through the cut-out in the **Locator Tool**. If tissue is protruding through the opening, **gently** hold the tool against the head to see if the tissue stays below the cut-out. If there is too much tissue protrusion, use the **Adjustable Height Locator Tool** instead.

   CAUTION: Failure to accurately position the Locator Tool could result in an inaccurate indication of the performance setting, potentially leading to a false reading (i.e. an incorrect number may appear in the window of the Indicator Tool). The Locator Tool must be precisely aligned with both the valve's direction of flow and the center of the hard valve mechanism for an accurate indication reading. Alignment can be more challenging if tissue thickness is >10 mm above the valve. In these instances, verify the valve setting with x-ray or fluoroscopy. Refer to *SECTION C: Troubleshooting* and *SECTION D: Confirming the Current Valve Setting.*

5. Fully seat the **Indicator Tool** into the **Locator Tool** so that the red markings are aligned (Figure 10). You may hear a click when the tool seats. The indicator tool will not rotate within the locator tool when properly seated.

CAUTION: When reading the performance setting with the Indicator Tool, make sure that the Adjustment Tool and any other magnetic devices are at least 36 cm (14 in.) away from the Indicator Tool. Failure to do so can result in an inaccurate indication of the performance setting.

6. When the number dial on the **Indicator Tool** stops moving, observe the number and its position within the window to determine the performance setting. A single number within the window that has the full purple background and both gray side lines visible (Figure 12) indicates the performance setting of the valve when the tools are properly aligned. Once the valve performance setting has been read, remove the **Indicator Tool.**

   Note: If a single number with the purple background and both gray side lines are not fully visible, then the **Locator Tool** is not accurately aligned with the valve. Remove the **Indicator Tool** and reposition the **Locator Tool**, ensuring the black center lines are centered with the valve mechanism (Figure 9). Repeat Steps 1 through 6.

   CAUTION: Do not move the Locator and Indicator Tools together to obtain or center a number in the window as this could result in an inaccurate indication of the performance setting.

7. Insert the **Adjustment Tool** into the **Locator Tool** so that the arrow is pointing to the current performance setting. With one hand holding the “petals” of the **Locator Tool**, turn the **Adjustment Tool** with the other hand until the arrow points to the desired performance setting (Figure 11). The **Adjustment Tool** will provide an audible click and a tactile response as you turn to each setting.

CAUTION: Failure to accurately position the Locator Tool could result in an inability to adjust the performance setting. The Locator Tool must be precisely aligned with both the valve's direction of flow and the center of the hard valve mechanism for an accurate adjustment. Alignment can be more challenging if tissue thickness is >10 mm above the valve. In these instances, verify the valve position and orientation with x-ray or fluoroscopy. Refer to *SECTION C: Troubleshooting* and *SECTION D: Confirming the Current Valve Setting.*

Note: The **Adjustment Tool** is equipped with a mechanical stop between Settings 1 and 8. This is to prevent inadvertent adjustment between the extremes of the available settings.

Note: Successful adjustment is accomplished by starting at the valve's current setting and moving directly to the desired setting.

8. Remove the **Adjustment Tool** from the **Locator Tool** by lifting it straight upwards a minimum of 3 cm (1.25 in.) before moving it horizontally away from the **Locator Tool** in order to avoid inadvertently changing the valve setting.

9. **Repeat Steps 7 and 8 to confirm successful adjustment of the performance setting.** Always confirm the desired performance setting of the valve.

10. If the desired performance setting is not achieved, repeat Steps 7 through 9.

11. It is recommended to record the valve setting in the patient's record and I.D. wallet card (available from local Codman sales representative).

12. Disinfect the tool kit components (see *Disinfecting the CODMAN CERTAS Tool Kit*).

13. Return all tools to their proper locations in the storage case to prevent damage.

Note: place the **Low Profile Locator Tool** under the elastic webbing in the bottom of the storage case and fully collapse the Adjustable Height Locator Tool (see Figure 1B).

SECTION C: Troubleshooting

If there is difficulty in indicating and/or adjusting the valve setting:

- To optimize **Indicator Tool** performance, ensure that the patient is positioned so that the valve is horizontal and the tool components are used horizontally. See Figure 5.
- Use fluoroscopy or x-ray to locate the position and orientation of the valve mechanism for adjustment and/or to determine the performance setting of the valve. A fiducial mark may be helpful for this technique.

It may be challenging to get the correct position of the Locator Tool above the implanted valve. Consider using the **Low Profile Locator Tool.**

- Palpate to feel for the hard valve mechanism and make sure the black lines on the **Low Profile Locator Tool** are aligned with the center of the valve mechanism.
- Mark the patient's skin in the center of the valve mechanism between the two black lines. Also mark the location of the valve barbs/ catheters on the proximal and distal ends. See Figure 6. This will facilitate the proper position and orientation of either **Locator Tool** above the implanted valve.
- Make sure the black lines on the **Locator Tool** line up with the mark for the center of the valve mechanism and that the direction of flow arrow is aligned with the marks for the proximal and distal barbs/catheters.

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

SECTION D: Confirming the Current Valve Setting

The setting of an implanted valve can be determined by using the CODMAN CERTAS Tool Kit, and following *SECTION B: Post Implantation Adjustment Procedure,* Steps 1 through 6.

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 13 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 (See *SECTION E: Reading the Valve Setting with the X-Ray Overlay Tool*, Steps 1–5).

SECTION E: Reading the Valve Setting with the X-Ray Overlay Tool

See Figure 14.

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.

CODMAN CERTAS Tool Kit Replacement

The CODMAN CERTAS Tool Kit cannot be repaired. Contact your local Codman representative for replacement of the CODMAN CERTAS Tool Kit.

Warranty

Codman Neuro warrants that this medical device is free from defects in both materials and workmanship. **Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.**

DO NOT STERILIZE **Do not sterilize**
Ne pas stériliser
Nicht sterilisieren
Niet steriliseren
Non sterilizzare
No esterilizar
Não esterilizar

 **See instructions for use**
Voir le mode d'emploi
Siehe Gebrauchsanweisung
Zie de gebruiksaanwijzing
Vedere le istruzioni per l'uso
Vea las instrucciones de uso
Leia as instruções de utilização

REF **Catalog number**
Numéro de catalogue
Katalognummer
Catalogusnummer
Codice
Código
N. ° de catálogo

 **Caution**
Attention
Achtung
Voorzichtig
Attenzione
Atención
Cuidado

 **Fragile**
Fragile
Zerbrechlich
Breekbaar
Fragile
Frágil
Frágil

MADE IN **Made in**
Fabriqué en
Hergestellt in
Geproduceerd in
Prodotto in
Hecho en
Produzido em

MR Unsafe
Dangereux avec la RM
MR-ungeeignet
MR Unsafe (MRI-onveilig)
Non sicuro per la RM
RM no seguro
Não é seguro em ressonância magnética

QTY **Quantity**
Quantité
Menge
Aantal
Quantità
Cantidad
Quantidade

LOT **Batch Code**
Code de lot
Chargencode
Partijnummer
Codice lotto
Número de lote
Número de lote

US REP US Representative
Représentant américain
US-Vertretung
Vertegenwoordiger voor de VS
Rappresentante USA
Representante en los EE.UU.
Representante nos EUA

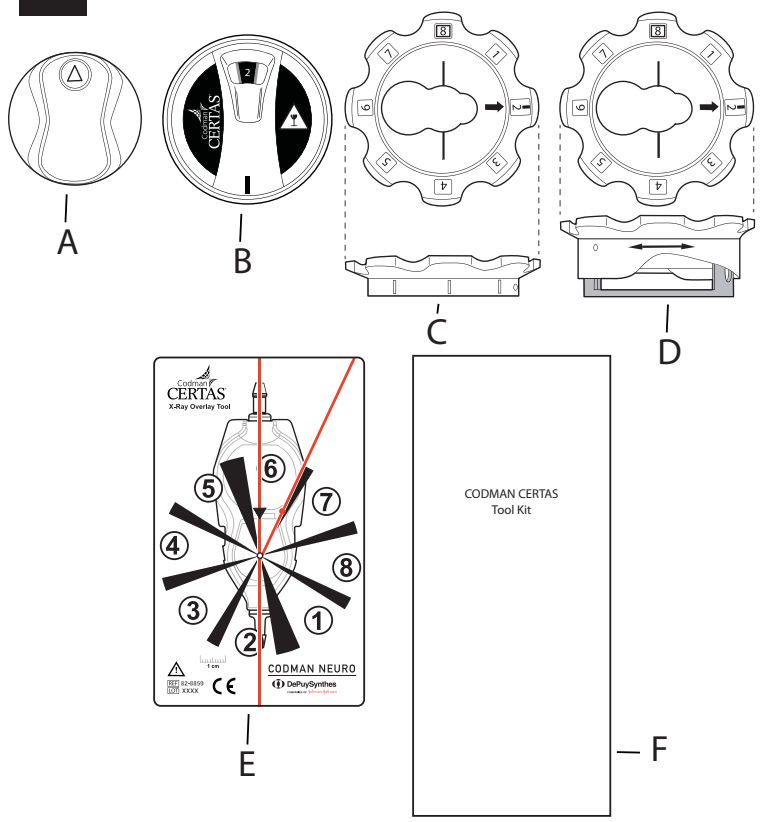
NONSTERILE Nonsterile
Non stérile
Unsteril
Niet-steriel
Non sterile
No estéril
Não esterilizado

℞ Only Prescription device only (USA)
Disponible uniquement sur ordonnance (États-Unis)
Verschreibungspflichtiges Produkt (USA)
Alleen op medisch voorschrift (VS)
Dispositivo solo su prescrizione (USA)
Dispositivo para uso bajo prescripción solamente (EE.UU.)
Dispositivo vendido unicamente mediante receita médica (EUA)

Manufacturer
Fabricant
Hersteller
Fabrikant
Produttore
Fabricante
Fabricante

CODMAN CERTAS
Tool Kit (REF 82-8851) **208079-001/A**

1A



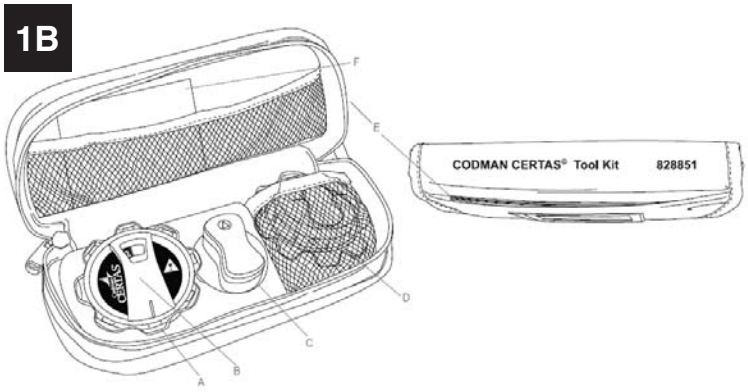
ENGLISH

A. Adjustment Tool
B. Indicator Tool
C. Low Profile Locator Tool
D. Adjustable Height Locator Tool
E. X-Ray Overlay Tool
F. Instructions for Use Booklet (in outer back pocket of case)

FRANÇAIS

A. Outil de réglage
B. Outil d'indication
C. Outil de localisation à profil bas
D. Outil de localisation à hauteur réglable
E. Outil de superposition d'images radiologiques
F. Mode d'emploi (dans la poche arrière extérieure du boîtier)

1B



ENGLISH

A. Adjustable Height Locator Tool
B. Indicator Tool
C. Adjustment Tool
D. Low Profile Locator Tool
E. Instructions for Use Booklet (in outer back pocket of case)
F. X-Ray Overlay Tool

FRANÇAIS

A. Outil de localisation à hauteur réglable
B. Outil d'indication
C. Outil de réglage
D. Outil de localisation à profil bas
E. Mode d'emploi (dans la poche arrière extérieure du boîtier)
F. Outil de superposition d'images radiologiques

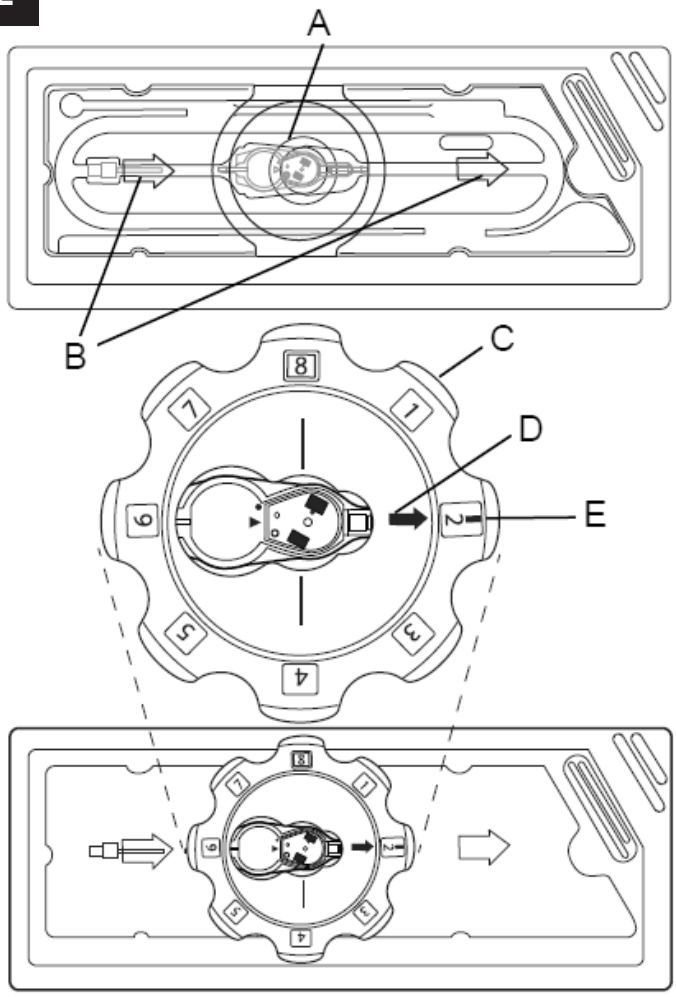
DEUTSCH

A. Lokalisierer mit einstellbarer Höhe
B. Indikator
C. Verstellkomponente
D. Lokalisierer mit flachem Profil
E. Broschüre mit der Gebrauchsanleitung (in der Außentasche auf der Rückseite des Behälters)
F. Röntgen-Overlay

NEDERLANDS

A. Positioneringstool met instelbare hoogte
B. Indicatortool
C. Bijstellingstool
D. Positioneringstool met laag profiel
E. Gebruiksaanwijzing (in het vak aan de achterkant van de doos)
F. Röntgen-overlaytool

2



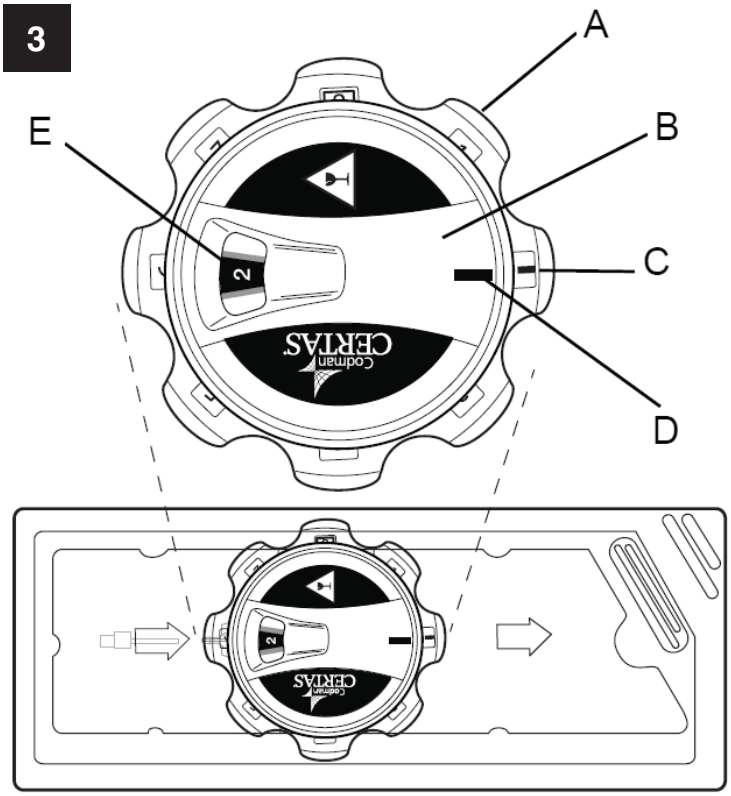
ENGLISH

A. Valve (inside sterile package)
B. Arrows molded into Plastic Package
C. Adjustable Height Locator Tool
D. Direction of Flow Arrow
E. Red Alignment Marker on Locator Tool

FRANÇAIS

A. Valve (à l'intérieur de l'emballage stérile)
B. Flèches moulées dans l'emballage en plastique
C. Outil de localisation à hauteur réglable
D. Flèche du sens de débit
E. Repère d'alignement rouge sur l'outil de localisation

3



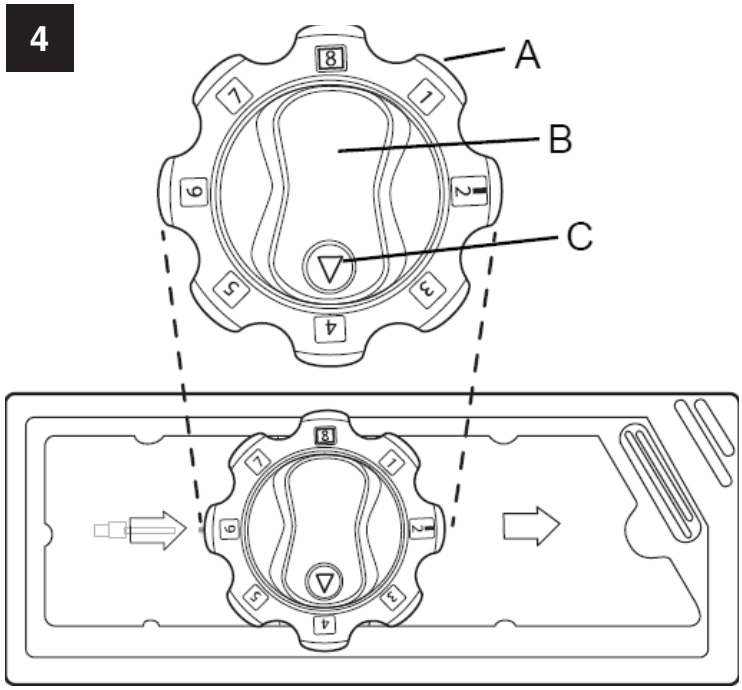
ENGLISH

A. Adjustable Height Locator Tool
B. Indicator Tool
C. Red Alignment Marker on Locator Tool
D. Red Alignment Marker on Indicator Tool
E. Indicator Tool Window

FRANÇAIS

A. Outil de localisation à hauteur réglable
B. Outil d'indication
C. Repère d'alignement rouge sur l'outil de localisation
D. Repère d'alignement rouge sur l'outil d'indication
E. Fenêtre de l'outil d'indication

4



ENGLISH
A. Adjustable Height Locator Tool
B. Adjustment Tool
C. Arrow on Adjustment Tool

FRANÇAIS
A. Outil de localisation à hauteur réglable
B. Outil de réglage
C. Flèche sur l'outil de réglage

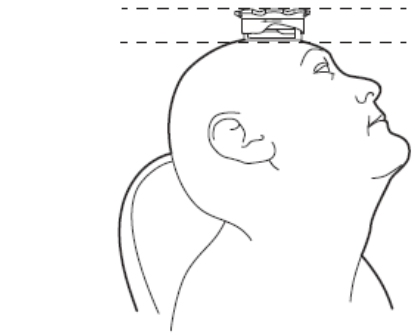
DEUTSCH
A. Lokalisierer mit einstellbarer Höhe
B. Verstellkomponente
C. Pfeil an der Verstell-komponente

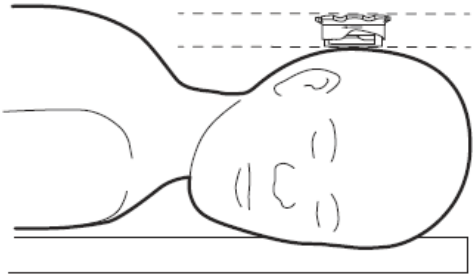
NEDERLANDS
A. Positioneringstool
B. Bijstellingstool
C. Pijl op bijstellingstool

ITALIANO
A. Strumento di individuazione ad altezza regolabile
B. Strumento di regolazione
C. Freccia sullo strumento di regolazione

ESPAÑOL
A. Herramienta localizadora de altura ajustable
B. Herramienta de ajuste
C. Flecha de la herramienta de ajuste

5





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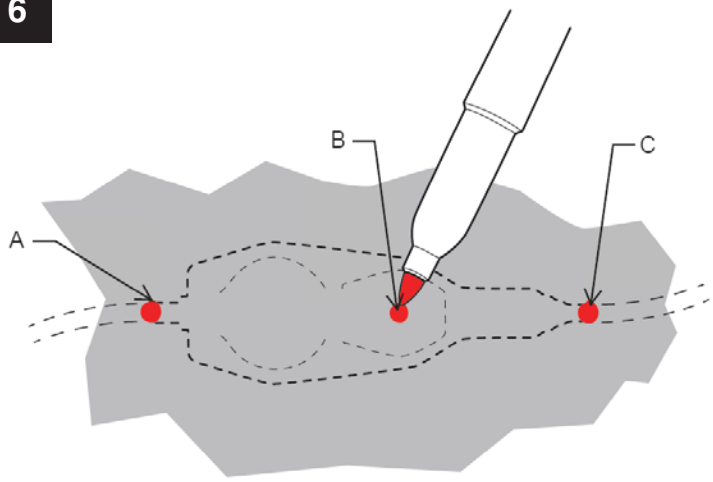


ENGLISH
Implanted Valve with SIPHONGUARD

A. Proximal Inlet Connector Barb/Catheter
B. Center of Hard Valve Mechanism
C. Distal Outlet Connector Barb/Catheter

FRANÇAIS
Valve implantée avec dispositif SIPHONGUARD

A. Cathéter/barbillon du raccord d'entrée proximal
B. Centre du mécanisme dur de la valve
C. Cathéter/barbillon du raccord de sortie distal

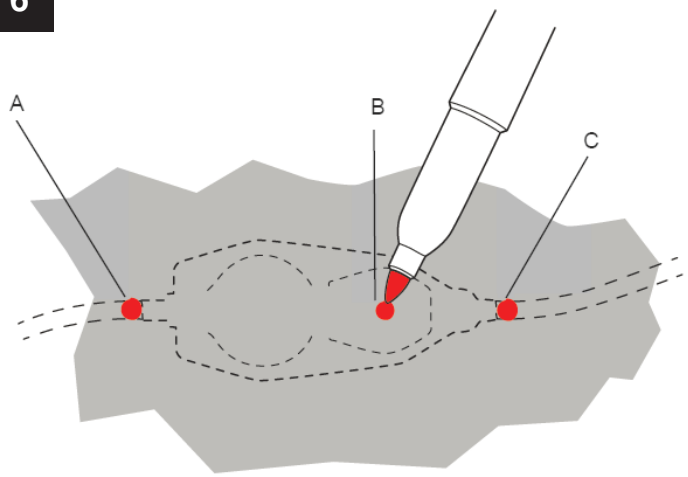
DEUTSCH
Implantiertes Ventil mit SIPHONGUARD

A. Proximaler Einlass-Anschlussstutzen/Katheter
B. Mitte des harten Ventilmechanismus
C. Distaler Auslass-Anschlussstutzen/Katheter

NEDERLANDS
Geïmplanteerde klep met SIPHONGUARD

A. Proximaal inlaatfixatiehaakje/katheter
B. Kern van het harde-klepmechanisme
C. Distaal uitlaatfixatiehaakje/katheter

6



ENGLISH

Implanted Valve without SIPHONGUARD

A. Proximal Inlet Connector Barb/Catheter
B. Center of Hard Valve Mechanism
C. Distal Outlet Connector Barb/Catheter

FRANÇAIS

Valve implantée sans dispositif SIPHONGUARD

A. Cathéter/barbillon du raccord d'entrée proximal
B. Centre du mécanisme dur de la valve
C. Cathéter/barbillon du raccord de sortie distal

DEUTSCH

Implantiertes Ventil ohne SIPHONGUARD

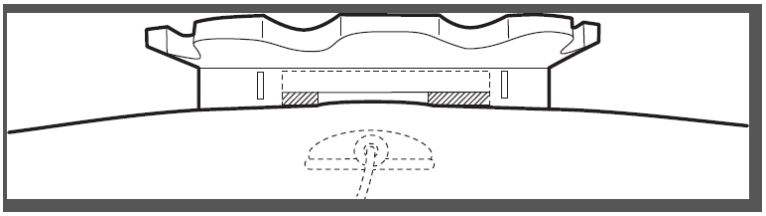
A. Proximaler Einlass-Anschlussstutzen/ Katheter
B. Mitte des harten Ventilmechanismus
C. Distaler Auslass-Anschlussstutzen/ Katheter

NEDERLANDS

Geïmplanteerde klep zonder SIPHONGUARD

A. Proximaal inlaatfixatiehaakje/ katheter
B. Kern van het harde-klepmechanisme
C. Distaal uitlaatfixatiehaakje/ katheter

7



ENGLISH
Low Profile Locator Tool

FRANÇAIS
Outil de localisation à profil bas

DEUTSCH
Lokalisierer mit flachem Profil

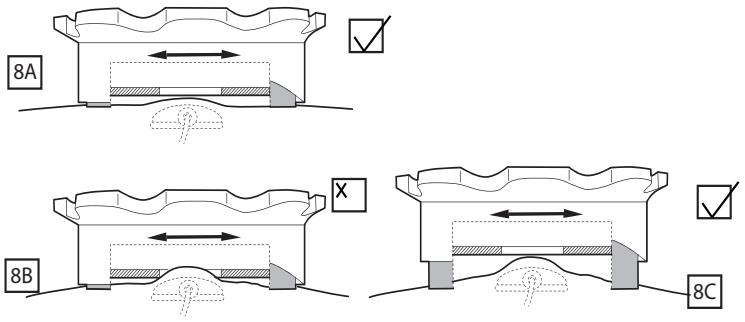
NEDERLANDS
Positioneringstool met laag profiel

ITALIANO
Strumento di individuazione a basso profilo

ESPAÑOL
Herramienta localizadora de perfil bajo

PORTUGUÊS
Ferramenta Localizadora de Baixo Perfil

8



ENGLISH
Adjustable Height Locator Tool

FRANÇAIS
Outil de localisation à hauteur réglable

DEUTSCH
Lokalisierer mit einstellbarer Höhe

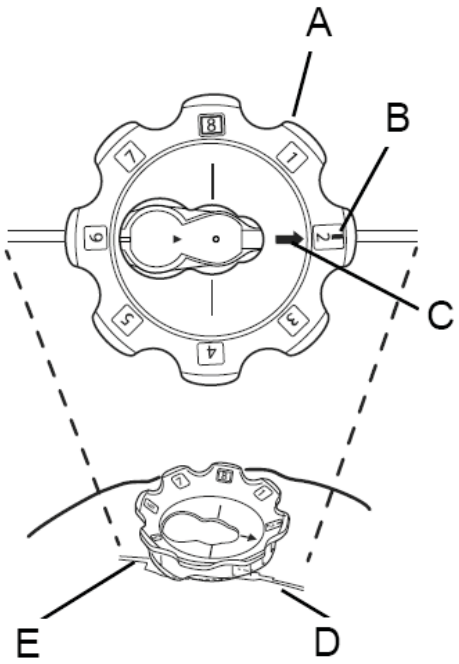
NEDERLANDS
Positioneringstool met instelbare hoogte

ITALIANO
Strumento di individuazione ad altezza regolabile

ESPAÑOL
Herramienta localizadora de altura ajustable

PORTUGUÊS
Ferramenta Localizadora de Altura Ajustável

9



ENGLISH

A. Locator Tool
B. Red Alignment Marker
C. Direction of Flow Arrow
D. Distal Catheter (implanted)
E. Proximal Catheter (implanted)

DEUTSCH

A. Lokalisierer
B. Roter Ausrichtungsmarker
C. Flussrichtungspfeil
D. Distaler Katheter (implantiert)
E. Proximaler Katheter (implantiert)

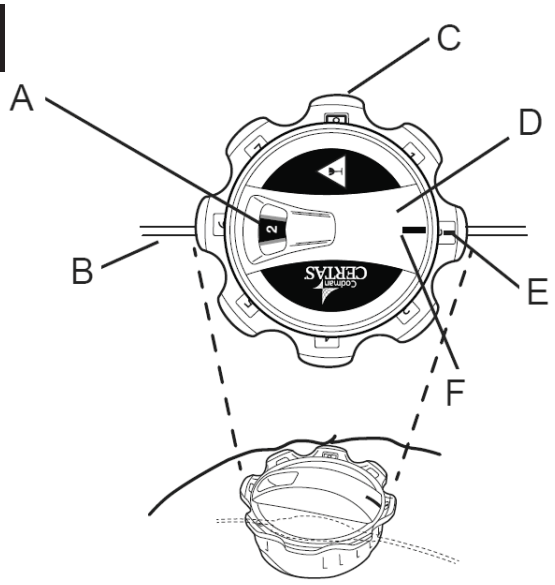
FRANÇAIS

A. Outil de localisation
B. Repère d'alignement rouge
C. Flèche de sens d'écoulement
D. Cathéter distal (implanté)
E. Cathéter proximal (implanté)

NEDERLANDS

A. Positioneringstool
B. Rode uitlijnmarkering
C. Pijl voor de stroomrichting
D. Distale katheter (geïmplanteerd)
E. Proximale katheter (geïmplanteerd)

10



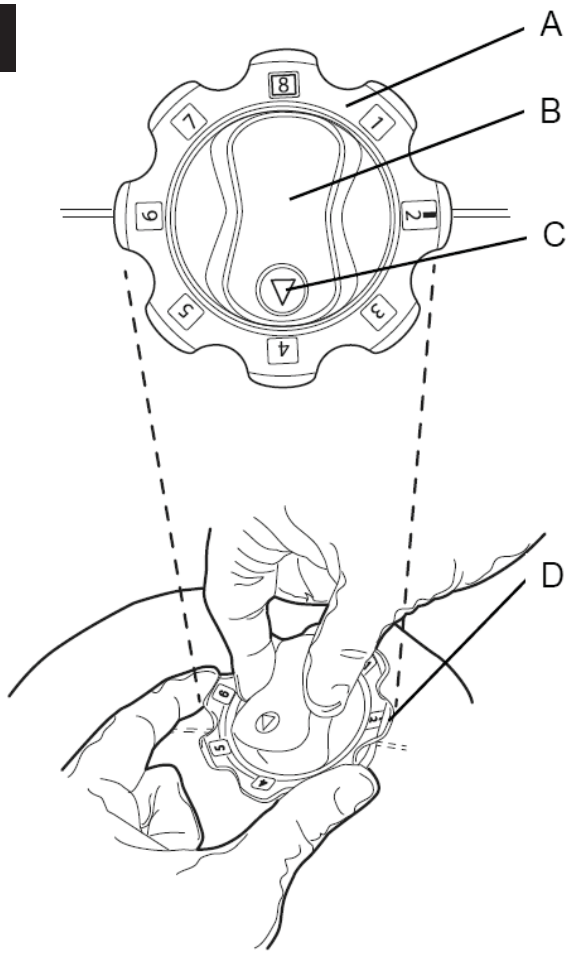
ENGLISH

A. Indicator Tool Window
B. Proximal Catheter (implanted)
C. Locator Tool
D. Indicator Tool
E. Red Alignment Marker on Locator Tool
F. Red Alignment Marker on Indicator Tool

FRANÇAIS

A. Fenêtre de l'outil d'indication
B. Cathéter proximal (implanté)
C. Outil de localisation
D. Outil d'indication
E. Repère d'alignement rouge sur l'outil de localisation
F. Repère d'alignement rouge sur l'outil d'indication

11



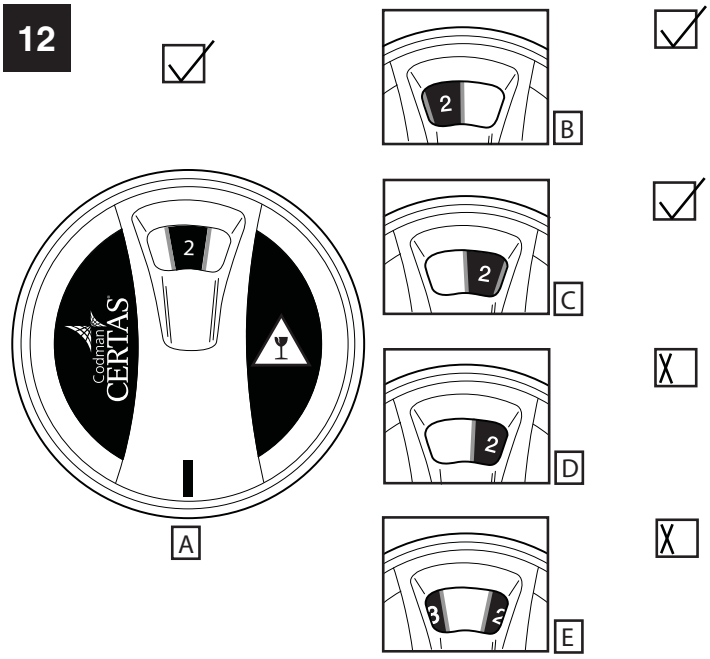
ENGLISH
A. Locator Tool
B. Adjustment Tool
C. Arrow
D. Petals of Locator Tool

FRANÇAIS
A. Outil de localisation
B. Outil de réglage
C. Flèche
D. Pétales de l'outil de localisation

DEUTSCH
A. Lokalisierer
B. Verstellkomponente
C. Pfeil
D. Einstellungsring des Lokalisierers

NEDERLANDS
A. Positioneringstool
B. Bijstellingstool
C. Pijl
D. Bloemblaadjes van positioneringstool

12



ENGLISH

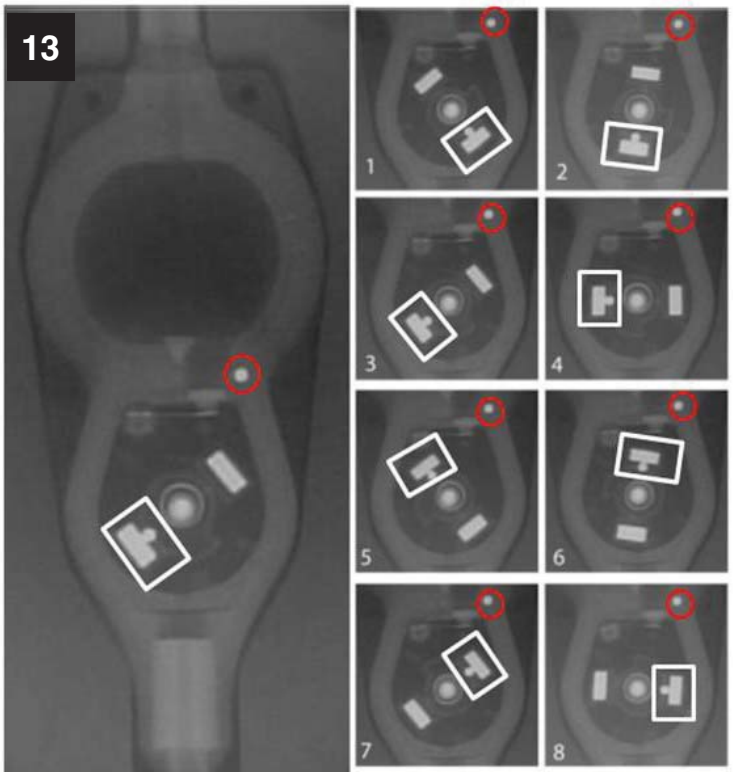
Indicator Tool Performance Setting Readings

Views A, B & C	Correct Readings A single number and both gray side lines are visible
View D	Incorrect Reading: only 1 gray line is visible
View E	Incorrect Reading: 2 numbers are visible

FRANÇAIS

Lectures du réglage de la performance de l'outil d'indication

Vues A, B & C	Lecture correcte : un seul numéro et les deux lignes grises secondaires visibles
Vue D	Lecture incorrecte : seule une ligne grise est visible
Vue E	Lecture incorrecte : 2 numéros sont visibles



ENGLISH

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.

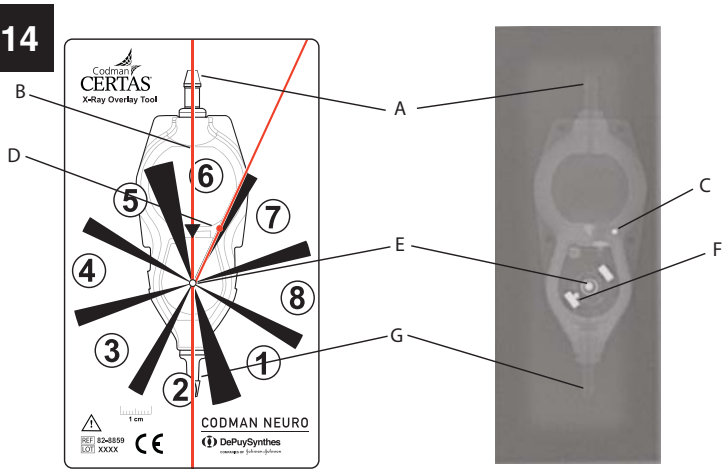
FRANÇAIS

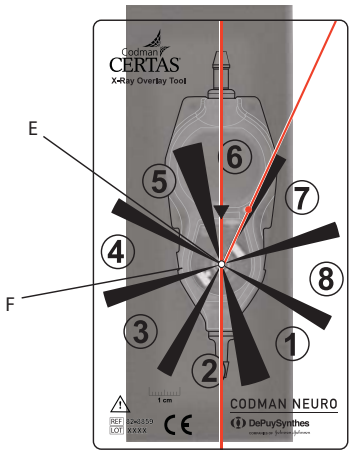
Le chiffre dans le coin inférieur gauche de chaque vue indique le numéro de réglage qui s'affiche.
La case blanche indique l'indicateur de réglage.
Le cercle rouge indique le repère de droite (RHS).

DEUTSCH

Die Zahl in der linken unteren Ecke einer jeden Ansicht gibt die angezeigte Leistungseinstellung an.
Das weiße Kästchen kennzeichnet die Einstellungsanzeige.
Der rote Kreis kennzeichnet den rechtseitigen (RHS) Marker.

14





ENGLISH

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

FRANÇAIS

A. Connecteur proximal
B. Ligne central ROUGE de la valve
C. Repère côté droit (RHS)
D. Ligne rouge de repère côté droit (contient un point du côté droit [RHS])
E. Élément de rotation (RC)
F. Aimant avec bille en tantale
G. Connecteur distal

REF 82-8852

CERTAS™ Plus

Electronic Tool Kit

EN – ENGLISH

Codman SPECIALTY SURGICAL

INTEGRA

A DIVISION OF INTEGRA LIFESCIENCES

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CERTAS™ Plus

Electronic Tool Kit

IMPORTANT INFORMATION
Please Read Before Use

Rx ONLY

Tool Kit Description

The CERTAS™ Plus Electronic Tool Kit (Tool Kit) is a battery-powered, handheld device used to locate, indicate, adjust and confirm the performance setting of all implantable CERTAS and CERTAS Plus Programmable Valves in the treatment of hydrocephalus.

The Tool Kit contains (see Figure 1 for images of the CERTAS Plus Electronic Tool Kit components):

A. Locator device including batteries
B. Adjustment tool
C. Screwdriver
D. Spare (123A) batteries
E. X-Ray Overlay Tool
F. Instructions for Use
G. Quick Reference Card

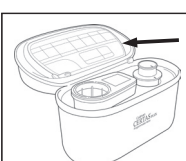
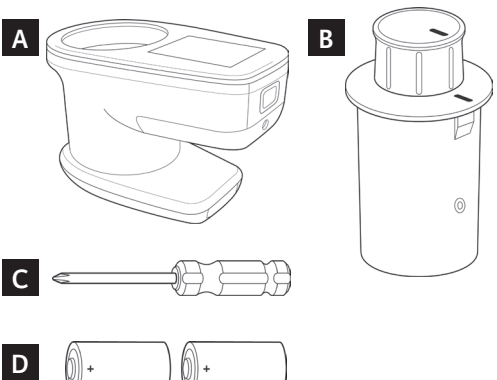
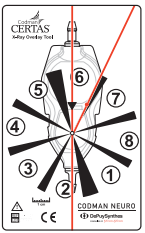


Figure 1

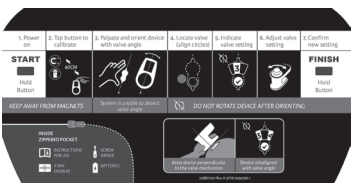


E



F

G



Valve Description

The CERTAS Plus Programmable Valve is a single-use implantable valve that can be set to eight different performance settings for intraventricular pressure and drainage of CSF. The Tool Kit is designed to indicate and adjust all CERTAS and CERTAS Plus Programmable Valves.

Indications for Use

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

Precautions

- The device should be used only in professional healthcare facility environments.
- The device should not be used near high frequency surgical equipment, in proximity to an MRI, or anywhere the intensity of electromagnetic disturbances is high. If used in an environment other than specified, degradation of the performance of this equipment could result, meaning the device may not provide a stable indication or screen flickers may be seen.
- Do not use any of the Tool Kit components on a metal surface, as this could interfere with the use of the device.
- The Adjustment Tool contains powerful magnets and should be kept away from magnetic materials.
- Store and carry all components of the Tool Kit in the storage case when not in use to prevent damage.
- Inspect the Tool Kit components before each use. Check for damage, such as cracks. Do not use the Tool Kit if damage is present. Contact your local sales representative for a replacement kit.

- Carefully monitor the patient during the first 24 hours after adjusting the 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.
- Excessive swelling may make it difficult to determine and/or adjust the setting. If difficulty correctly positioning the Locator persists, wait until the swelling is reduced. X-ray may be used to confirm the valve setting.
- Failure to accurately position the Locator could result in an inaccurate indication of the performance setting, potentially leading to a false reading (i.e., an incorrect number may appear in the window of the Locator). Alignment can be more challenging if tissue thickness is >10 mm above the valve. In these instances, verify the valve setting with x-ray or fluoroscopy.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 class A).

Adverse Events

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

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

Magnetic Resonance Imaging (MRI) Safety Information

MR Unsafe

The Tool Kit is considered "MR Unsafe" in accordance with the American Society for Testing and Materials (ASTM) Standard F2503-13.

CAUTION: Do not use the CERTAS Plus Electronic Tool Kit in the MR suite.

Disinfecting the CERTAS Plus Electronic Tool Kit

The CERTAS Plus Electronic Tool Kit is provided as a non-sterile product.

After use, wipe the surfaces of the Tool Kit components that touch the patient with a 70% Isopropyl wipe. Follow Steps 1 through 4 below.

1. Thoroughly wet the surfaces with a wipe.
2. Keep the surfaces wet for 2 minutes. Use as many wipes as needed to keep the surfaces wet for the entire 2 minutes.
3. Allow the wetted surfaces to air dry.
4. Inspect the components to ensure that all soil, blood, or debris has been removed. If needed, repeat Steps 1 through 3 and inspect again.

CAUTION: Do not sterilize the Tool Kit.

Instructions for Use

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

SECTION A: Preparation and Set-Up

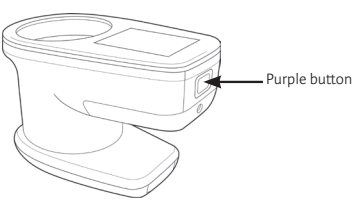
Pre-implantation: Confirm and/or adjust the performance setting before implanting the CERTAS Plus Programmable Valve. This procedure is performed before the sterile inner package is opened. Place the valve's sterile package on a non-metallic surface so the clear portion of the package faces up. Complete the procedure as described in SECTION B.

Post-implantation: The valve may be adjusted any time after the implantation surgery. If needed, apply a sterile drape over the incision site. The drape will not interfere with the magnetic coupling of the adjustment procedure. Position the patient for the indication and/or adjustment procedure prior to turning on the device. Complete the procedure as described in SECTION B.

CAUTION: Excessive swelling or thick tissue may make it difficult to determine and/or adjust the performance setting. If difficulty correctly positioning the Locator persists, wait until the swelling is reduced. X-ray may be used to confirm the valve setting.

SECTION B: System Start-up

1. Power on the Locator by pressing and holding the purple button on the front of the device until the screen turns on. The CERTAS Plus logo will appear followed by a calibration screen. Make sure the Adjustment tool is at least 60 cm (24 in.) from the Locator to avoid influencing the calibration.



Calibration Screen

Note: If the Adjustment Tool is within the Adjustment Tool Cavity of the Locator, the screen will alert the user to remove the Adjustment Tool. Calibration cannot be completed until the Adjustment Tool is removed from the device.

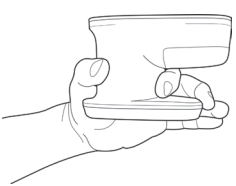
2. Press and release the purple button on the front of the device again to complete calibration. After calibrating, the device is ready for use and the system-ready screen will be shown.

System-ready screen

SECTION C: Indication / Adjustment Procedure

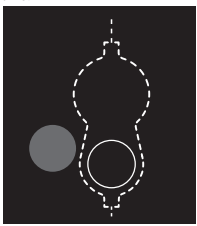
1. Locate the valve and determine the general direction of flow.
   Pre-Implantation: If in the package, ensure the direction of flow arrow on the package and Locator are aligned (Figure 2).
   Post-Implantation: For a valve implanted in a patient, locate and determine the direction of flow of the valve by palpation, focusing on the hard valve mechanism and inlet and/or outlet connections (barbs/catheters).

2. Place the Locator on top of the blister or in contact with the patient, oriented with the valve's direction of flow. A valve illustration is inside the Adjustment Tool cavity to serve as a reference for the valve. (Figure 2)

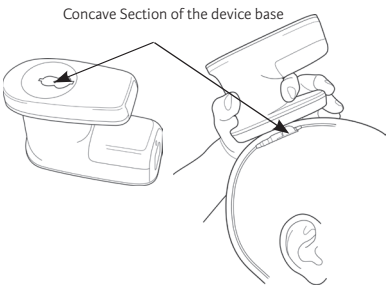


Note: During post-implantation, for best procedural results and increased stability, grip the device around its base and place the concave portion of the Locator perpendicular to the valve, maximizing contact between hand and patient. This will help to maintain the appropriate position above the valve mechanism.

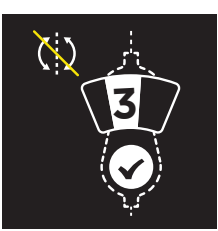
3. When in proximity of the valve (within 2 cm or 0.8 in), the device will display a locating dot. To center the device over the valve mechanism, move the device to align the locating dot into the circle within the valve. Move the device in a linear direction parallel to the valve, with the **concave section of the device base in contact with the patient.** It is important to maintain proper orientation with direction of flow.
Note: Tilting the Locator may result in challenges locating, indicating, and adjusting the valve.

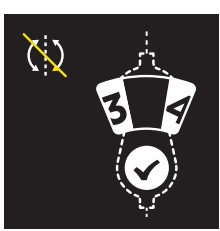


CAUTION: Failure to accurately orient the device with the valve direction of flow could result in an inaccurate indication of the valve setting.



4. Once the device is centered, the locating dot will illuminate white with a checkmark and an indication dial window will appear. A single fully visible number within the window indicates the current setting of the valve.





Note: If a single number is not fully visible, then the Locator is not accurately oriented with the valve. Remove the Locator and re-determine the valve's direction of flow before attempting to indicate again.

CAUTION: Do not rotate the Locator to obtain or center a number in the window as this can result in an inaccurate indication of the performance setting.

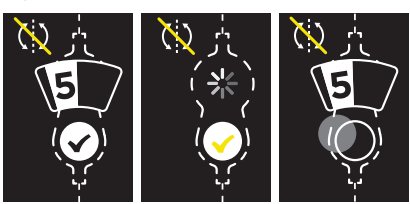
Do not rotate icon

5. Insert the Adjustment Tool into the Locator so that the line on the Adjustment Tool is pointing towards the current setting. When the Adjustment Tool is placed in the Locator, the device will not display Location or Indication information.
   Note: Failure to maintain accurate position (i.e., location and orientation) could result in an inability to correctly adjust the setting.

6. Stabilize the Locator on the patient and turn the Adjustment Tool directly to the desired performance setting. The Adjustment Tool will provide an audible click and a tactile response as you turn to each setting.
   Note: The Adjustment Tool is equipped with a mechanical stop between settings 1 and 8 to prevent inadvertent adjustment between the extremes of available settings.

7. Maintain stability of the Locator on the patient and withdraw the Adjustment Tool in a straight, upward motion. Keep the Adjustment Tool a minimum distance of 60 cm (24 in.) from the Locator.

8. The Locator will begin to indicate the new valve setting once the Adjustment Tool is removed. Always confirm the desired setting has been achieved after adjustment.
   - If the device does not provide an indication (or processing icon persists), repeat steps 2 and 4 to confirm successful adjustment of the performance setting.
   - If the desired setting of the valve is not achieved, repeat the full procedure.



Note: Check mark is not required to indicate. The performance setting may still be indicated as long as the device is in proximity of the valve and accurately oriented with the valve's direction of flow.

CAUTION: Failure to move the Adjustment Tool at least 60 cm (24 in) away from the Locator can result in challenges locating, indicating, and adjusting the valve.

9. Once the desired performance setting has been achieved, power down the Locator by pressing and holding the purple button on the front of the device until the screen turns off.

Disinfect the tool kit components (see Disinfecting the *CERTAS Plus Electronic Tool Kit* section).

It is recommended to record the valve setting in the patient's record and Patient I.D. Card (available from your local sales representative).

Return both tools to their proper locations in the storage case.

Troubleshooting

If there is difficulty in indicating and/or adjusting the valve setting:

- If the display shows an indication between two settings and the Locator is centered and oriented, remove the device from the patient and repeat steps 1 and 2 of Section B. If the indication between settings persists and the Locator is centered and oriented, insert the Adjustment Tool at the desired setting and remove without rotating to a new setting.

- If there is difficulty receiving a valve indication, repeat calibration with the Locator a minimum of 10 cm (4 in) above the valve while keeping it aligned and parallel to the valve.
    - Confirm that the Adjustment Tool is a minimum distance of 60 cm (24 in.) away from the Locator.
    - Confirm that the Locator is not tilted forward by ensuring that the concave section of the device base is fully in contact with the patient.
- If difficulties persist, use fluoroscopy or x-ray to determine orientation of the valve for adjustment and/or to determine the performance setting of the valve. A fiducial mark may be helpful for this technique. It may be challenging to get the correct position of the Locator above the implanted valve. Palpate to feel for the hard valve mechanism and make sure the Locator is aligned with the valve's direction of flow.

If the display shows >10 mm, it means the bottom of the device is >10 mm away from the valve but it can provide valve location If the device is not providing indication after multiple attempts, take fluoroscopy or x-ray.

Additional Locator Icons

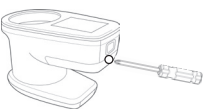
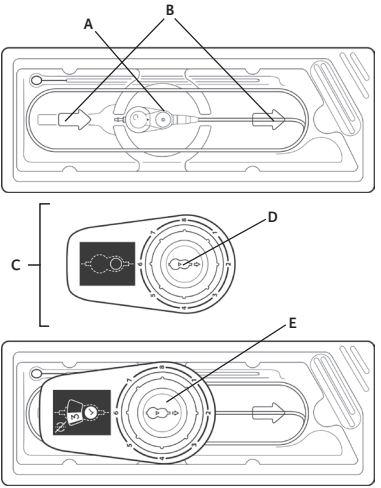
	If the display shows low battery reminder icon, the system has less than 4 minutes of power remaining before batteries need to be replaced. Replace the batteries using the screwdriver stored inside of the zipped packet of the tool kit.	Batteries and a screwdriver are stored in the case pocket. 
	If the display shows battery alert icon, the batteries must be replaced using the screwdriver stored inside of the zipped pocket of the tool kit.	Batteries can be replaced by using the screw placed under the purple button. Only replace with 123A batteries. 
	If the display shows system error icon, contact your local sales representative.	
 	When left idle for a prolonged period, the system will show an auto shutdown alert and countdown timer. The system will automatically shut down unless the front button is pressed before the timer counts down to :00 seconds.	

Figure 2



A. Valve (inside sterile package)
B. Arrows molded into plastic package
C. Locator (top view)
D. Valve Image with direction of the flow
E. Locator's Valve Image on valve in the package

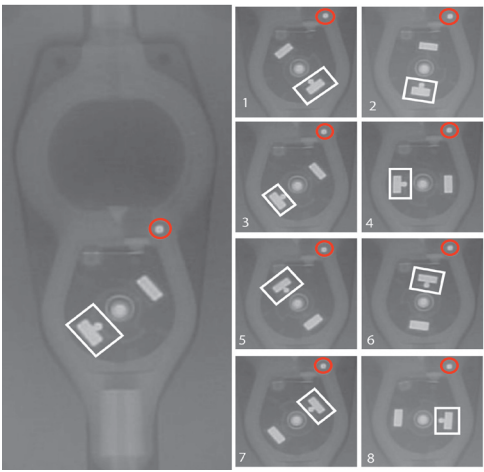
Confirming the Current Valve Setting

The setting of an implanted valve can be determined by using the Tool Kit, and following SECTIONS A & B, followed by either SECTION C or D.

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 below 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.

Figure 3



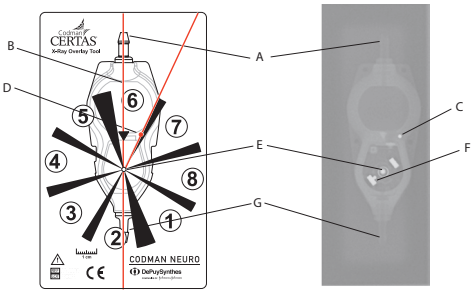
The number in the lower left corner of each view indicates which Performance Setting is shown. White box indicates the setting indicator. Red circle indicates the right hand side (RHS) marker.

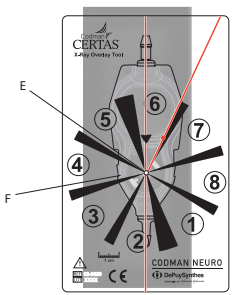
Reading the Valve Setting with the X-Ray Overlay Tool

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

1. Align **RED** center line of valve on overlay with the center line of the valve x-ray under review. This can be accomplished by aligning the proximal and/or 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** center line. 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.

Figure 4





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

Environmental Specifications

Operating Temperature Range	+10 °C to +30 °C
Operating Humidity Range	30% to 80% relative humidity, non-condensing
Operating Pressure Range	70 kPa to 101.3 kPa
Transport & Storage Temperature Range	–30 °C to +60 °C
Transport & Storage Humidity Range	15% to 85% relative humidity, non-condensing
Transport & Storage Pressure Range	60 kPa to 101.3 kPa

Electromagnetic Compatibility

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document.

The essential performance of the electronic Locator device is to locate the CERTAS Plus programmable valve mechanism and display an indication dial for the determination of valve performance setting.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the locator device. Otherwise, degradation of the essential performance of this equipment could result, meaning the device may not provide a stable indication or screen flickers may be seen.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.

Table 1
Guidance and manufacturer's declaration - electromagnetic emissions

The CERTAS Plus Electronic Tool Kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Tool Kit should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Locator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Locator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Table 2
Guidance and manufacturer's declaration – electromagnetic immunity

The CERTAS Plus Electronic Tool Kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Tool Kit should ensure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromanetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable	Not applicable
Surge IEC 61000-4-5	Not applicable	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3
Guidance and manufacturer's declaration – electromagnetic immunity

The CERTAS Plus Electronic Tool Kit is intended for use in the electromagnetic environment specified below. The customer or the user of the Tool Kit should ensure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromanetic environment – guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Tool Kit than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Locator device is used exceeds the applicable RF compliance level above, the Locator devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Tool Kit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4
Recommended separation distances between portable and mobile RF communications equipment and the Tool Kit

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Replacement
The CERTAS Plus Electronic Tool Kit cannot be repaired. Contact your local sales representative for replacement.

Product End of Life
The CERTAS Plus Electronic Tool Kit has an expected use life of five years. The Tool Kit contains electrical components and should be disposed of in accordance with local ordinances at end of life.

Warranty
Integra LifeSciences, Inc. warrants that this medical device is free from defects in both materials and workmanship. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.

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CE

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INTEGRA

A DIVISION OF INTEGRA LIFESCIENCES

LCN 208875-001 Rev. A 10/18 1032232-2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 27, 2015

Medos International Sarl
Ms. Jocelyn Raposo
Project Manager, Regulatory Affairs
Chemin-Blanc 38
Le Locle, Switzerland CH-2400

Re: K152152
Trade/Device Name: Codman Certas Plus Programmable Valve
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: July 31, 2015
Received: August 3, 2015

Dear Ms. Jocelyn Raposo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152152

Device Name

Codman Certas Plus Programmable Valve

Indications for Use *(Describe)*

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 19, 2015

Medos International Sarl
% Michelle Godin
Project Manager, Regulatory Affairs
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K143111
Trade/Device Name: Codman Certas Plus Programmable Valve; Codman Certas Tool Kit
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt And Components
Regulatory Class: Class II
Product Code: JXG
Dated: October 28, 2014
Received: October 29, 2014

Dear Ms. Godin,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143111

Device Name
Codman Certas Plus Programmable Valve; Codman Certas Tool Kit

Indications for Use *(Describe)*
The Codman Certas Plus Programmable Valve is an implantable device that provides constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

6. 510(k) Summary

I. Submitter

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

On behalf of:
Medos International SARL
Chemin-Blanc 38
CH 2400 LeLocle, Switzerland

Phone: 508-828-3312
Fax: 508-977-6979

Contact Person: Michelle Godin
Date of Submission**:** October 28, 2014

II. Device

Name of Device	Codman Certas Plus Programmable Valve Codman Certas Tool Kit
Common Name	Hydrocephalus Shunt
Classification Name	Central Nervous System Fluid Shunt and Components (21 CFR 882.5550)
Regulatory Class	II
Product Code	JXG

III. Predicate Device

Codman Certas Programmable Valve System and Codman Certas Therapy Management System (K112156)

IV. Device Description

The Codman Certas Plus Programmable Valve is a sterile, single use, implantable device designed for shunting cerebrospinal fluid (CSF) for the treatment of hydrocephalus.

The Codman Certas Plus Programmable Valves are pressure-regulating valves utilizing the ruby ball-in-cone principle with a pressure inducing spring design. Intraventricular pressure is maintained by the ball and cone valve seat design. As the differential pressure across the shunt increases, the ball further displaces from the cone, through which CSF flows, thereby increasing flow and re-establishing the selected pressure. The ball is manufactured of synthetic ruby, as is the matching cone. Together these components provide a precise fit for regulating the flow of CSF through the valve.

510(k) Summary (Cont)

IV. Device Description (Cont.)

The valve is available with 8 different performance settings for constant intraventricular pressure and drainage of CSF. Seven (7) of the settings provide for a change in operating pressure, with a range of 25 to 215 mmH_2O. The eighth setting provides a minimum opening pressure of '400' mmH_20, thus allowing a physician to turn the valve "virtually off" without the need to surgically remove the valve to limit flow. The pressure of the valve is set preoperatively and can be noninvasively changed post-implantation by using the Codman Certas Tool Kit, which employs magnetic force to select one of the 8 settings.

V. Indications for Use

The Indications for Use statements are identical to the predicate device.

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

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

VI. Comparison to Predicate Device

Compared to the predicate device, the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit include the modifications listed in **Table 1**

Table 1. Modifications Proposed for the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit

Component	Modification	Rationale
Codman Certas Plus Programmable Valve	Changes to components contained in the Adjustable Mechanism of the programmable valve • Minor dimensional changes to the profile of the Cam of the Rotating Construct and dimensional changes to the Cam/Ball Arm Assembly • Addition of Ruby Bearing (same ruby material currently used in the predicate device, K112156) to through-hole of the Rotating Construct	Minor modifications improve the overall performance of the programmable valve without changing the fundamental scientific technology or intended use of the predicate device.

510(k) Summary (Cont)

Table 1. Modifications Proposed for the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit		
Component	**Modification**	**Rationale**
Codman Certas Tool Kit	**Locator Tool**: Includes 2 Locator Tools: The Low Profile Locator Tool which allows the clinician to get as close to the valve as possible in cases of edema and an Adjustable Height Locator Tool which allows the clinician to rotate the center ring to change the height of the locator when valve protrusion exists in a patient. In addition, the petals will be slightly wider for better grip on both tools. Minor enhancements to the tools include machined black centering lines versus pad printed black lines to improve precision for location and the addition of a v-groove to contain the 360° stop alignment pin for increased pin retention strength. **Indicator Tool**: Removed the black button and improved the pivot-bearing design to reduce toggle time to indicating a valve setting. Modified background of setting number and added a contoured handle. **Carrying Case**: Increased in size to accommodate 4 tools rather than 3 tools and added a bump feature for easier removal of the Adjustment Tool. **Accessory Tool**: X-ray Overlay Tool added to verify the valve setting on x-ray.	Modification of ergonomic and user interface; no change to fundamental scientific technology or intended use of predicate device.
Labeling	Updated IFU and product labeling for name change, clarification, and/or additional steps.	Labeling update to ensure proper use of device, no change to indications for use or intended use.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Bench testing on the proposed device, Codman Certas Plus Programmable Valve and Certas Tool Kit, included the following:

- Structural testing
- Pressure flow testing in accordance with ISO 7197:2009 *Neurosurgical Implants – Sterile, Single-Use Hydrocephalus Shunts and Components* and ASTM F647:1994 (R2006) *Standard Practice*

for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application

- MRI testing
- Indication and Adjustment testing
- Shelf Life testing including structural testing, pressure flow testing, and MRI testing.

Validation testing included:

- Pre-implantation Use - in-package indication and programming
- Post-implantation Use – indication and adjustments post-implantation using simulated skin thicknesses
- Valve patency
- Tool Kit validation
- Identifying the valve setting on x-ray with and without using the X-Ray Overlay Tool
- Manometer IFU language

Test results demonstrated that the acceptance criteria were met, therefore, the Codman Certas Plus Programmable Valve and the Codman Certas Tool Kit conform to expected device performance and intended use. Results of verification and validation testing have demonstrated that the proposed Codman Certas Plus Programmable Valve and the Codman Certas Tool Kit are substantially equivalent to the predicate Codman Certas Programmable Valve and Codman Therapy Management System, and that the modifications do not impact the safety or effectiveness of the proposed device.

Magnetic Resonance (MR) Testing

The safety test requirements of the ASTM MR standards for the proposed Certas Plus Programmable Valve have been met through testing (ASTM F2052-14 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment;* ASTM F2182-11a *Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging;* ASTM F2119-07 (R2013) *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants;* ASTM F2213-06 (R2011) *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*).

The Codman Certas Plus Programmable Valve is MR-Conditional at 3.0 Tesla per the ASTM standards.

Biocompatibility Testing

The biocompatibility evaluations for the Codman Certas Plus Programmable Valve and the Codman Certas Tool Kit were conducted in accordance with the FDA Blue Book Memorandum #G95-1 *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and*

Testing May 1, 1995, and International Standard ISO 10993-1 *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process* as recognized by FDA.

Codman Certas Plus Programmable Valve

The Codman Certas Plus Programmable Valve is considered a permanent contact implant device. The only new component in the proposed device is the inclusion of a ruby bearing. Since the same ruby material is already included in the predicate Codman Certas Programmable Valve, additional biocompatibility testing was not required. However, as part of a cleaning validation for this component, cytotoxicity testing was completed with passing results.

Codman Certas Tool Kit

The Codman Certas Tool Kit is considered a surface device with limited contact (≤24 hours) with breached or compromised surfaces. Biocompatibility testing was completed with passing results. The following tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- USP Limits Testing for USP <661> for Plastics, Physiochemical Testing

Animal Studies

No animal studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Clinical Studies

No clinical studies were required as appropriate verification and validation of the design modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

VIII. Conclusion

Based upon the intended use, design, materials, function, comparison to currently marketed devices, and testing performed by Codman & Shurtleff, Inc., it is concluded that the Codman Certas Plus Programmable Valve and Codman Certas Tool Kit was found to have a safety and effectiveness profile that is similar to the predicate device.

November 20, 2018

Integra LifeSciences Corporation
Nancy MacDonald
Regulatory Affairs Manager
11 Cabot Boulevard
Mansfield, Massachusetts 02048

Re: K182265
Trade/Device Name: Codman Certas Plus Programmable Valve (Certas Plus Inline Small and Certas Plus Right Angle)
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: August 21, 2018
Received: August 22, 2018

Dear Nancy MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

October 25, 2018

Integra LifeSciences Corp.
Nancy MacDonald
Regulatory Affairs Manager
11 Cabot Blvd.
Mansfield, Massachusetts 02048

Re: K181902
Trade/Device Name: Codman Certas Plus Electronic Tool Kit
Regulation Number: 21 CFR 882.5550
Regulation Name: Central Nervous System Fluid Shunt and Components
Regulatory Class: Class II
Product Code: JXG
Dated: September 25, 2018
Received: September 26, 2018

Dear Nancy MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Shunt Reimbursement Guide - 2018

Effective October 1, 2015, the Centers for Medicare & Medicaid Services (CMS) is implementing International Classification of Diseases, 10th Revision (ICD-10) Procedure Coding System (PCS) in place of the 9th Revision (ICD-9) procedure codes. CMS has provided a General Equivalence Mappings (GEMS) that crosswalk ICD-9 procedure codes to ICD-10 PCS (available at https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html). Below, Integra LifeSciences Corporation provides the mappings for select ICD-9 procedure codes. While Integra LifeSciences Corporation has used reasonable efforts to provide accurate coding information, this information should not be construed as providing clinical advice, dictating reimbursement policy, or substituting for the judgment of a practitioner. **It is always the Provider's responsibility to determine and submit appropriate codes, charges, and modifiers for services that are rendered.** Integra LifeSciences Corporation assumes no responsibilities or liabilities for the timeliness, accuracy, and completeness of the information contained herein. Since reimbursement laws, regulations, and payor policies change frequently, it is recommended that providers consult with their payors, coding specialists, and/or legal counsel regarding coverage, coding and payment issues.

Inpatient Reimbursement

ICD-9 Procedure Codes	ICD-10 PCS Code	Code Description	Potential MS - DRG Assignment
02.32		Ventricular Shunt to Circulatory System	
	00160J2	Bypass Cerebral Ventricle to Atrium with Synthetic Substitute, Open Approach	031 – 033 820 – 822 826 – 830 907 – 909 957 – 959
	00160J3	Bypass Cerebral Ventricle to Blood Vessel with Synthetic Substitute, Open Approach	
	00163J2	Bypass Cerebral Ventricle to Atrium with Synthetic Substitute, Percutaneous Approach	
	00163J3	Bypass Cerebral Ventricle to Blood Vessel with Synthetic Substitute, Percutaneous Approach	
02.33		Ventricular Shunt to Thoracic Cavity	
	00160J4	Bypass Cerebral Ventricle to Pleural Cavity with Synthetic Substitute, Open Approach	031 – 033 820 – 822 826 – 830 907 – 909 957 – 959
	00163J4	Bypass Cerebral Ventricle to Pleural Cavity with Synthetic Substitute, Percutaneous Approach	
	0W110J9	Bypass Cranial Cavity to Right Pleural Cavity with Synthetic Substitute, Open Approach	
	0W110JB	Bypass Cranial Cavity to Left Pleural Cavity with Synthetic Substitute, Open Approach	

ICD-9 Procedure Codes	ICD-10 PCS Code	Code Description	Potential MS - DRG Assignment
02.34		Ventricular Shunt to Abdominal Cavity and Organs	
	00160J5	Bypass Cerebral Ventricle to Intestine with Synthetic Substitute, Open Approach	031 – 033 820 – 822 826 – 830 907 – 909 957 – 959
	00160J6	Bypass Cerebral Ventricle to Peritoneal Cavity with Synthetic Substitute, Open Approach	
	00163J5	Bypass Cerebral Ventricle to Intestine with Synthetic Substitute, Percutaneous Approach	
	00163J6	Bypass Cerebral Ventricle to Peritoneal Cavity with Synthetic Substitute, Percutaneous Approach	
	0W110JG	Bypass Cranial Cavity to Peritoneal Cavity with Synthetic Substitute, Open Approach	031 – 033 820 – 822 826 – 830 907 – 909 957 – 959
	0W110JJ	Bypass Cranial Cavity to Pelvic Cavity with Synthetic Substitute, Open Approach	
03.71		Spinal Subarachnoid-Peritoneal Shunt	
	001U0J6	Bypass Spinal Canal to Peritoneal Cavity with Synthetic Substitute, Open Approach	028 - 030 820 - 822 826 - 830
	001U3J6	Bypass Spinal Canal to Peritoneal Cavity with Synthetic Substitute, Percutaneous Approach	

Possible MS-DRG Assignments Where Shunting May Be Used**

MS-DRG	MS-DRG Description	Medicare National Average Payment
028	Spinal Procedures with MCC	$33,507.08
029	Spinal Procedures with CC or Spinal Neurostimulator	$19,734.73
030	Spinal Procedures without CC/MCC	$12,859.10
031	Ventricular Shunt Procedures with MCC	$24,548.15
032	Ventricular Shunt Procedures with CC	$12,825.34
033	Ventricular Shunt Procedures without CC/MCC	$10,253.92
820	Lymphoma and Leukemia with Major O.R. Procedures with MCC	$32,644.46
821	Lymphoma and Leukemia with Major O.R. Procedures with CC	$14,062.91
822	Lymphoma and Leukemia with Major O.R. Procedures without CC/MCC	$7,464.57
826	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC	$31,394.84
827	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with CC	$14,255.20
828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure without CC/MCC	$9,759.46
829	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other O.R. Procedure with CC/MCC	$18,861.26
830	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other O.R. Procedure without CC/MCC	$7,704.49
907	Other O.R. Procedures for Injuries with MCC	$25,146.14
908	Other O.R. Procedures for Injuries with CC	$12,205.66
909	Other O.R. Procedures for Injuries without CC/MCC	$8,479.10
957	Other O.R. Procedures for Multiple Significant Trauma with MCC	$44,026.08
958	Other O.R. Procedures for Multiple Significant Trauma with CC	$25,669.37
959	Other O.R. Procedures for Multiple Significant Trauma without MCC	$16,241.46

*Hospital's Accounting department can provide specific rates for their own particular hospital

Hospital Outpatient Department (HOPD)/Ambulatory Surgical Center (ASC) Reimbursement (for Medicare) - Reservoir Insertion**

CPT Code	Code Description	APC	Relative Weight	2018 Medicare Base Payment Rate – Hospital Outpatient	2018 Medicare Payment Rate – Ambulatory Surgical Center
61215	Insertion of subcutaneous reservoir, pump or continuous infusion system for connection to ventricular catheter (for chemotherapy, use 96450)	5432	58.8442	$4,627.27	$2,033.36

Physician Reimbursement - Reservoir Insertion

CPT Code	Code Description	Work Relative Value Unit	2018 National Medicare Reimbursement Rate - Facility
61215	Insertion of subcutaneous reservoir, pump or continuous infusion system for connection to ventricular catheter (for chemotherapy, use 96450)	5.85	$532.43

Physician Reimbursement - Ventricular Shunt Insertion (not allowable in HOPD or ASC for Medicare)

CPT Code	Code Description	Work Relative Value Unit	2018 National Medicare Reimbursement Rate - Facility
62180	Ventriculocisternostomy (Torkildsen type operation)	22.58	$1,690.54
62190	Creation of shunt; subarachnoid/subdural-atrial, -jugular, -auricular	12.17	$974.15
62192	Creation of shunt; subarachnoid/subdural-peritoneal, -pleural, other terminus	13.35	$1,027.43
62200	Ventriculocisternostomy, third ventricle;	19.29	$1,454.02
62201	Ventriculocisternostomy, third ventricle; stereotactic, neuroendoscopic method	16.04	$1,267.19
62220	Creation of a shunt; ventriculo-atrial, -jugular, -auricular	14.10	$1,062.35
62223	Creation of shunt; ventriculo-peritoneal, -pleural, other terminus	14.05	$1,094.03
62258	Removal of complete cerebrospinal fluid shunt system; with replacement by similar or other shunt at same operation	15.64	$1,171.79

HOPD Reimbursement– Lumbar Shunt Creation (not allowable in ASC for Medicare)**

CPT Code	Code Description	APC	Relative Weight	2018 National Medicare Reimbursement Rate
63740	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; including laminectomy	N/A	N/A	N/A (Not allowable in HOPD)
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneaous, not requiring laminectomy	5432	58.8442	$4,627.27

Physician Reimbursement - Lumbar Shunt Creation

CPT Code	Code Description	Work Relative Value Unit	2018 National Medicare Reimbursement Rate - Facility
63740	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; including laminectomy	12.63	$1,024.91
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneaous, not requiring laminectomy	9.12	$710.63

Hospital Outpatient Department (HOPD) /Ambulatory Surgical Center (ASC) Reimbursement (for Medicare) – Spinal Puncture**

CPT Code	Code Description	APC	Relative Weight	2018 National Medicare Reimbursement Rate	2018 Medicare Payment Rate – Ambulatory Surgical Center
62270	Spinal puncture, lumbar, diagnostic	5442	6.9096	$543.34	$283.10
62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)				

Physician Reimbursement – Spinal Puncture

CPT Code	Code Description	Work Relative Value Unit	2018 National Medicare Reimbursement Rate - Facility	2018 National Medicare Reimbursement Rate – Non-Facility
62270	Spinal puncture, lumbar, diagnostic	1.37	$81.00	$162.36
62272	Spinal puncture, therapeutic, for drainage of cerebrospinal fluid (by needle or catheter)	1.35	$86.76	$208.08

Physician Reimbursement – Neuroendoscopy (not allowable in HOPD or ASC for Medicare)

CPT Code	Code Description	Work Relative Value Unit	2018 National Medicare Reimbursement Rate - Facility
+62160*	Neuroendoscopy, intracranial, for placement or replacement of ventricular catheter and attachment to shunt system or external drainage (List separately in addition to code for primary procedure)	3.00	$201.96
62161	Neuroendoscopy, intracranial; with dissection of adhesions, fenestration of septum pellucidum or intraventricular cysts (including placement, replacement, or removal of ventricular catheter)	21.23	$1,600.54
*Use 62160 only in conjunction with 61107, 61210, 62220-62230, 62258			

****FYI – There are no HCPCS codes associated with the use of shunts, meaning there is no separate product payment. Reimbursement for the device is bundled/packaged with the DRG payment or the HOPD/ASC payment for Medicare**.

For assistance with coding and reimbursement, please contact our Integra Reimbursement Hotline at 1-877-444-1122, option 3, option 2, Monday to Friday, 8 am to 6 pm, or via email at reimbursement@integralife.com

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

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

For more information or to place an order, please contact:

United States, Canada, Asia, Pacific, Latin America

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