Actual Size.
31.8 mm

CERTAS® PLUS SMALL FOR HYDROCEPHALUS MANAGEMENT

Think small. Live large.

Trust the small programmable valve that regulates CSF pressure.

Codman SPECIALTY SURGICAL

CERTAS® Plus Small
Programmable Valve
A Journey of Certainty

CERTAS® Plus Small

Programmable Valve

A Journey of Certainty

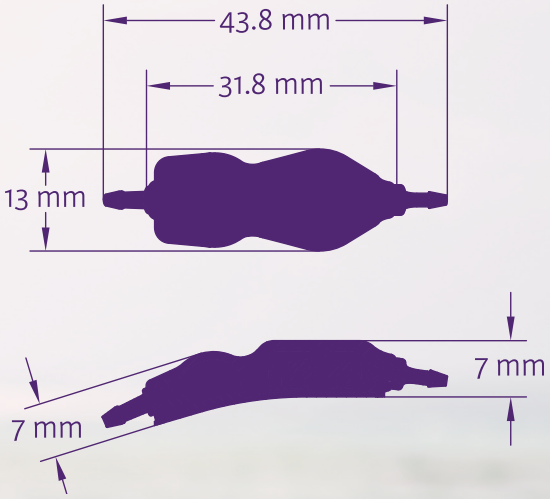
FOR THE MANAGEMENT OF HYDROCEPHALUS

CERTAS® Plus Small

Meeting your patients' needs through their life's journey

A small footprint and great flexibility

- Limiting uncertainty with a small programmable valve that regulates CSF pressure
- 7 settings including a "Virtual Off"
- Flexible, small footprint, curved valve shape, to fit a variety of patients (31.8 mm length, 13 mm width)



Reduce the risks of magnetic interference due to everyday magnets[1,2,*]

In bench studies, CODMAN® CERTAS® Plus Programmable Valves demonstrated resistance to unintended setting changes due to magnetic interference from:

- Common household magnets at close proximity (< 5 mm) better than Strata® II Programmable Valves.[1,†,‡]
- Magnetic fields created by 3T MRI scanners.[2,*]

11.26% of all Strata II valves tested were changed by **2** performance settings[1,2]

3.90% of all Strata II valves tested were changed by **3** performance settings[1,2]

Benchtop studies are not necessarily indicative of clinical performance.
T = Tesla.
*Clinician should confirm valve setting after an MRI procedure.
†Strata II Instructions for Use recommend products with magnets be kept at a minimum distance of 2 inches away from the site where the valve was implanted.
‡Testing included 6 samples of each valve, tested 162 times per product at a distance of 4.3 mm on average.

Codman SPECIALTY SURGICAL

A DIVISION OF INTEGRA LIFE SCIENCES

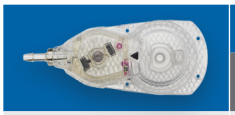
CERTAS® Plus Small is a **plus** in your surgical toolkit

- A small footprint
- Easy to program 7 settings with "Virtual Off"
- Resistance to common household magnets; MRI resistance

Ordering Information

SMALL		
	Without SIPHONGUARD	With SIPHONGUARD
Valve Only	82-8810PL	82-8814PL
Valve System	82-8811PL	82-8815PL
Valve System Unitized with BACTISEAL®	82-8813PL	82-8817PL

REGULAR		
	Without SIPHONGUARD®	With SIPHONGUARD
Valve Only	82-8800PL	82-8804PL
Valve System	82-8801PL	82-8805PL
Valve System Unitized	82-8802PL	82-8806PL
Valve System Unitized with BACTISEAL®	82-8803PL	82-8807PL



RIGHT ANGLE		
	Without SIPHONGUARD	With SIPHONGUARD
Valve Only	82-8820PL	82-8824PL
Valve System	82-8821PL	82-8825PL
Valve System Unitized with BACTISEAL®	82-8823PL	82-8827PL

Codman CERTAS Tool Kit	82-8851
Codman CERTAS Plus Electronic Tool Kit	82-8852

INDICATIONS
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.

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.
- 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.
- Read MRI Information before performing an MRI procedure on a patient implanted with the valve.
- Do not interchange the CODMAN CERTAS Tool Kit (82-8851) components with the CODMAN CERTAS Therapy Management System TMS (82-8850) components.
- 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.

PRECAUTIONS
- Use only the CODMAN CERTAS Tool Kit to adjust the setting of the CODMAN CERTAS and CODMAN CERTAS Plus Programmable Valves.
- Excessive swelling may make it difficult to determine and/or adjust the performance setting.
- See 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.
- 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.

INDICATIONS
The CERTAS Plus Electronic Tool Kit allows the noninvasive 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 value 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 mmH20.
- 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.

References:
1. Data on file. Jacobs Institute Engineering Solutions. Hydrocephalus Shunt Valve Assessment. February 5, 2019. Integra LifeSciences, Plainsboro, NJ, USA.
2. Data on file. Resistance of the CODMAN CERTAS® Plus Programmable Valve to Unintended Setting Changes When Exposed to a 3 Tesla MRI. February 2016. Integra LifeSciences. Plainsboro, NJ, USA.

Products tested in study: Dowling Magnets® DO-SS75 Magnet Mania Kit; Magformers® Classic (30 pieces) Set Magnetic Building Blocks, Educational Magnetic Tiles Kit, Magnetic Construction STEM Toy Set; Logitech® Slim Combo PN 820-008259; Mini Skater 24 Sets Magnetic Button Clasp Snaps—Purses, Bags, Clothes; iPhone® 6 Wallet Case, Crosspace iPhone® 6s Envelope Flip Handbag Shell Women Wallet PU Leather Magnetic Folio Cover Cases with Credit Card ID Holders Wrist Strap for Apple® iPhone® 6/6s 4.7-inch-Black; Cochlear™ Nucleus® CP810 Sound Processor Coil with 2M Coil Magnet installed; Uigos Digital Kitchen Timer II 2.0; Magz® 132 Piece Magnetic Building Set containing 84 Short Magnetic Rods and 48 Steel Balls; Apple® AirPod case; Apple® iPad Pro® 10.5-inch; Apple® iPhone® 5s; Apple EarPods® with 3.5 mm Headphone Plug.

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
USA 800-654-2873 ▪ 888-980-7742 fax
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