

Think Certas. Be Certain.

1 Prepare



Press and hold the purple button on the Locator Tool until the screen turns on. Tap purple button to calibrate the device.

*Keep the Adjustment Tool a minimum distance of 60 cm (24 in) from the Locator Tool.**

2 Locate



Palpate the valve and determine the direction of flow, then place the concave section of the Locator Tool's base on the patient's head directly over the implanted valve. Move the device in a linear direction parallel to the valve until the locating dot aligns in the circle.

You will see a check mark and the valve's current setting when the device is oriented to the direction of flow and centered on the valve.

3 Adjust



Insert the Adjustment Tool into the Locator Tool directly from above with the purple line pointing towards the current setting. Turn the Adjustment Tool so that the purple line is pointing to the desired setting.

4 Confirm



Remove the Adjustment Tool in a straight, upward motion, ensuring it is 24 in from the Locator Tool. Confirm your new, desired setting on the screen.

Don't forget to switch off your tool by holding the purple button until the screen turns off. Disinfect the tools after each use.

Refer to the IFU for more detailed information.

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

Codman
SPECIALTY SURGICAL

A DIVISION OF INTEGRA LIFESCIENCES

CERTAS® Plus
Programmable Valve
Be Certain

certasplus.com

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 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 mmH₂O.
- 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.

Products tested in study: Apple® AirPods® case; Apple® iPad Pro® 10.5-inch; Apple® iPhone® 5s; Apple® EarPods® with 3.5 mm Headphone Plug; Apple® iPhone® 12 Mobile Digital Devices; Apple® MagSafe® Wireless Chargers; Mini Skater 24 Sets Magnetic Button Clasp Snaps—Purses, Bags, Clothes; iPhone® 6 Wallet Case, Crossspace 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; Dowling Magnets® DO-SS75 Magnet Mania Kit; Magformers® Classic (30 pieces) Set Magnetic Building Blocks, Educational Magnetic Tiles Kit, Magnetic Construction STEM Toy Set; Progressive Trading Magz® 132 Piece Magnetic Building Set containing 84 Short Magnetic Rods and 48 Steel Balls; Logitech® Slim Combo PN 820-008259; Cochlear™ Nucleus® CP810 Sound Processor Coil with 2M Coil Magnet installed; Uigoo Digital Kitchen Timer II 2.0.

Availability of the CERTAS Plus 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.

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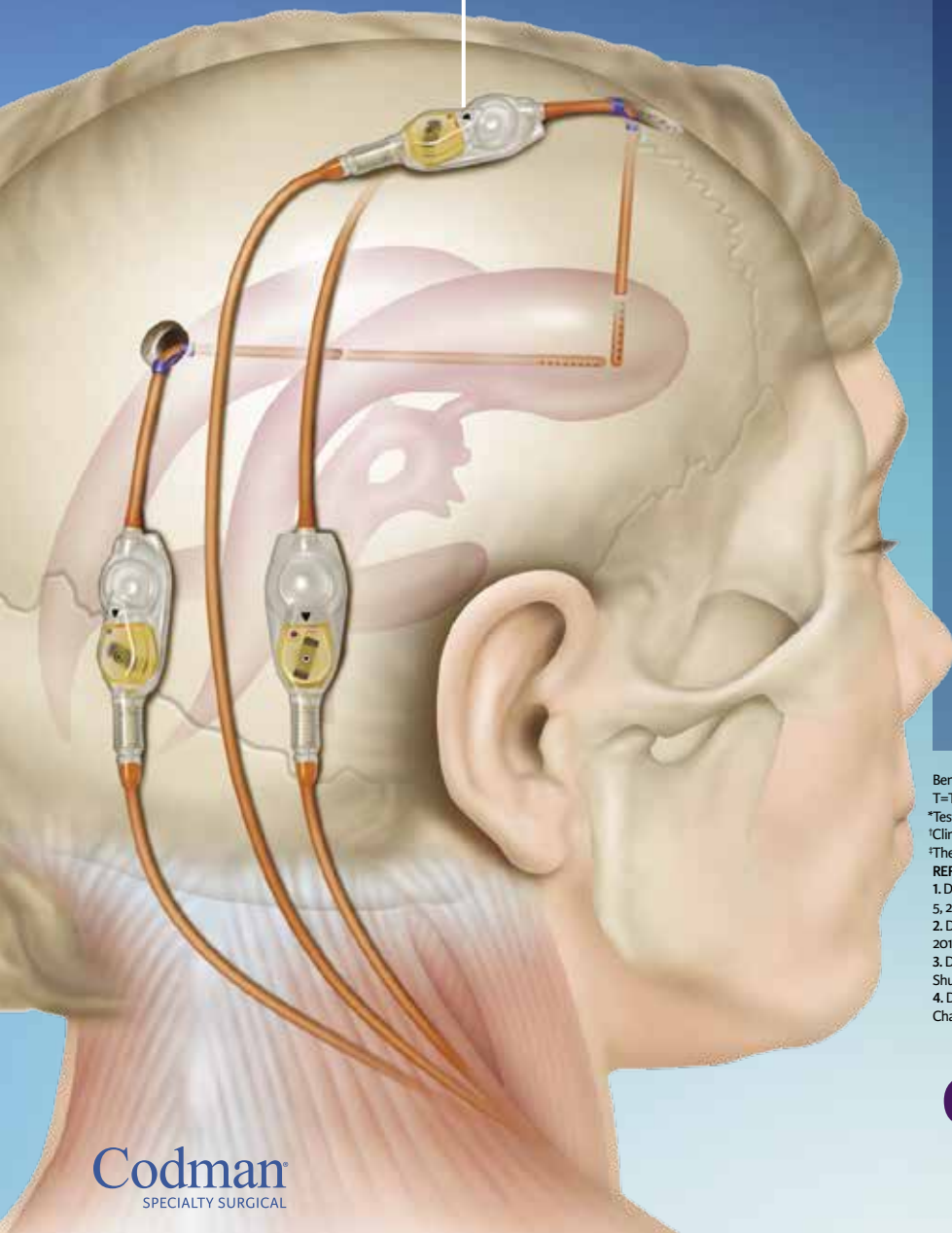
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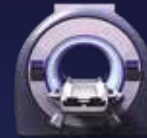
CERTAS® PLUS SMALL FOR THE TREATMENT OF HYDROCEPHALUS

One Less Worry, More Certainty



CERTAS® Plus Programmable Valves demonstrate resistance to unintended setting changes due to magnetic interference from:

- Common household magnets at close proximity (<5 mm) in laboratory testing^{1,2,3,*}
- Magnetic fields created by 3T MRI Scanners^{4,†}



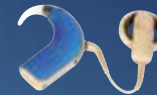
3T MRI Scanners



Apple® iPhone® Mobile Digital Devices[‡]



Magnetic Toys



Cochlear implants



Magnetic Purse Clasps



Apple® MagSafe® Wireless Charger, Headphones, and Earbuds



Magnetic Phone and Tablet Cases

Benchmark studies are not necessarily indicative of clinical performance.
T=Tesla.

*Testing included 6 samples of each valve, tested 162 times per product at a distance of 4.3 mm on average.

†Clinician should confirm valve setting after an MRI procedure.

‡The content of this document is not supplied or approved by Apple, Inc.

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. Jacobs Institute Engineering Solutions. Hydrocephalus Shunt Valve Assessment. Oct. 16, 2019. Integra LifeSciences, Plainsboro, NJ, USA.

3. Data on file. Jacobs Institute Engineering Solutions. Magnetic Influence of CHPV, CERTAS, and Strata II Shunt Valves. September 16, 2021. Integra LifeSciences, Plainsboro, NJ, USA.

4. 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.

CERTAS® Plus Small
Programmable Valve
A Journey of Certainty

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