

CODMAN NEURO



DePuy Synthes

COMPANIES OF *Johnson & Johnson*

CODMAN CERTAS® Plus Programmable Valve and CODMAN CERTAS® Tool Kit

Provides the flexibility, versatility and confidence to
manage the needs of the hydrocephalus patient.



Codman
CERTAS[®] **PLUS**
Programmable Valve

Providing Choice

Hydrocephalus is one of the most complex and debilitating disorders that neurosurgeons treat. That is why *Codman Neuro* has added yet another solution to the surgical management of hydrocephalus. With a rich clinical and technological heritage, CODMAN CERTAS Plus Programmable Valve provides a range of 8 settings that delivers an answer for the majority of patients.

CODMAN CERTAS® Plus Programmable Valve

Flexibility

CODMAN CERTAS® Tool Kit

Versatility

SIPHONGUARD® Anti-Siphon Device

Control

BACTISEAL® Antimicrobial Catheters

Usability



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

- 2 Locator Tool options to choose from for optimal alignment with the valve
- Indicator Tool provides rapid reading of valve setting
- Lightweight design and portable carrying case



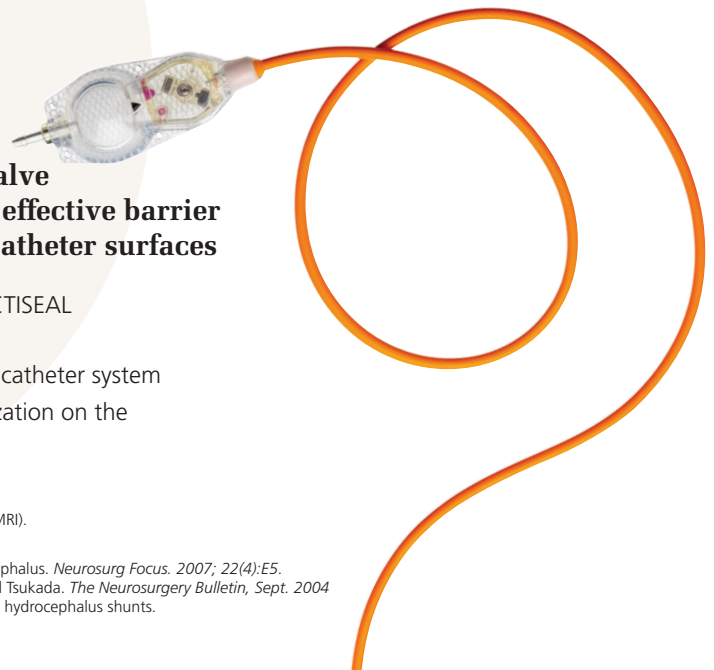
The CODMAN CERTAS Plus Programmable Valve integrated with the SIPHONGUARD Anti-Siphon Device reduces the risk of overdrainage

- Consistency and durability with a clinically proven mechanical design¹
- The SIPHONGUARD Anti-Siphon Device is position independent, allowing maximum treatment flexibility of the patient²
- 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 days³


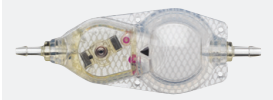



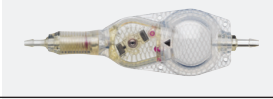
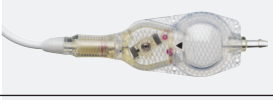




*Clinician should confirm the valve setting after a magnetic resonance imaging procedure (MRI).

REFERENCES

1. IKurton 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.

ORDERING INFORMATION

Product Configurations – Valves		
828800PL		CODMAN CERTAS® Plus In-Line Valve only
828801PL		CODMAN CERTAS® Plus In-Line Valve with catheters & accessories
828802PL		CODMAN CERTAS® Plus In-Line Valve with unitized catheter & accessories
828803PL		CODMAN CERTAS® Plus In-Line Valve with unitized BACTISEAL® Antimicrobial Catheter & accessories
828804PL		CODMAN CERTAS® Plus In-Line Valve-only with SIPHONGUARD® Anti-Siphon Device
828805PL		CODMAN CERTAS® Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device catheters & accessories
828806PL		CODMAN CERTAS® Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device, unitized catheter & accessories
828807PL		CODMAN CERTAS® Plus In-Line Valve with SIPHONGUARD® Anti-Siphon Device, unitized BACTISEAL® Antimicrobial Catheter & accessories
828851		CODMAN CERTAS® Tool Kit



CODMAN NEURO



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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 CODMAN CERTAS® Plus Programmable Valve is contraindicated for drainage to the atrium.

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 < 10mm). 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 >10mm above the valve. In these instances, verify the valve setting with x-ray or fluoroscopy.

Please consult the Instructions for Use for more detailed information about Warnings, Precautions and appropriate use of the devices.