



In the treatment of hydrocephalus

Safeguard Your Settings



Codman® CERTAS™ Plus Programmable Valve

Avoid unintentional changes in pressure settings, even from strong magnetic interference, up to and including a 3-T MRI.*

Codman
SPECIALTY SURGICAL

Codman®
CERTAS™ Plus
Programmable Valve

Codman® CERTAS™ Plus Programmable Valve

MRI resistant up to 3-T

CERTAS™ Plus Advantage

Designed to withstand unintended pressure-setting changes due to external magnetic influences, up to and including a 3-T MRI.*

Valve Performance Settings

- 7 settings ranging from 25 mmH2O to 215 mmH2O to optimize shunt performance
- Additional 8th setting, known as 'Virtual Off', with a minimum operating pressure greater than 400 mmH2O

SIPHONGUARD® Anti-Siphon Device (optional)

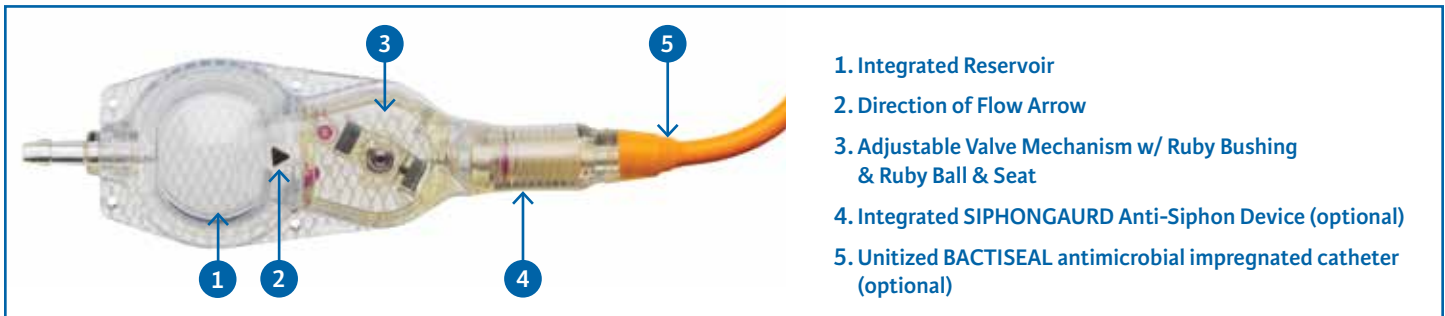
- SIPHONGUARD Anti-Siphon Device reduces the risk of overdrainage
- The SIPHONGUARD Anti-Siphon Device is position independent, allowing maximum treatment flexibility for the patient
- The SIPHONGUARD Anti-Siphon Device provides rigid housing which prevents increased resistance from sub-cutaneous pressure

BACTISEAL® Catheter

- Only programmable valve available with unitized antimicrobial impregnated catheter (optional)
- BACTISEAL catheters reduce gram positive bacterial colonization on the catheter surfaces up to 28 days
- The BACTISEAL Pledge: If you purchase a Codman valve with a BACTISEAL catheter and any part of the system requires a revision, for any reason, within one year of purchase, we will replace those components free of charge

CERTAS Tool Kit

- Allows for noninvasive reading, to assist in monitoring and adjusting the valve pressure
- Includes 2 locator tools for different tissue thicknesses



1. Integrated Reservoir
2. Direction of Flow Arrow
3. Adjustable Valve Mechanism w/ Ruby Bushing & Ruby Ball & Seat
4. Integrated SIPHONGUARD Anti-Siphon Device (optional)
5. Unitized BACTISEAL antimicrobial impregnated catheter (optional)

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 < 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.

T=tesla.

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

References

1. Hashimoto M, Mukai H, Tsukada T. Using the Codman® Hakim® programmable valve with SiphonGuard®. *Curr Pract Neurosurg.* 2004;14(9):923-926.
2. Bayston R, Ashraf W, Bhundia C. Mode of action of an antimicrobial biomaterial for use in hydrocephalus shunts. *J. Antimicrob Chemother.* 2004;53(5):778-782.

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