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® 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

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 with known hypersensitivity to rifampin or rifampicin, as meningitis, ventriculitis, peritonitis, bacteremia, and septicemia are present.

BACTISEAL Catheters are contraindicated in patients with known hypersensitivity to rifampin or rifampicin.

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.
- 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.

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.

REFERENCES

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