POST-OPERATIVE PROGRAMMING AND X-RAY PROCEDURE GUIDE

Programmable Valve System for Hydrocephalus

Utilizing the CODMAN CERTAS® Tool Kit
The CODMAN CERTAS® Plus Programmable Valve offers the ability to optimize the opening pressure of a shunt system before and after implantation. A shunted patient’s condition will often change over the course of their treatment making pressure changes necessary. The CODMAN CERTAS Plus Programmable Valve allows a surgeon to non-invasively change the opening pressure to one of eight Performance Settings, which range from 1 (low pressure) to 7 (high pressure), plus Performance Setting 8, which is a ‘Virtual Off’. This programmability may negate the need for revision surgery to alter the valve pressure.

The setting of the CODMAN CERTAS Plus Programmable Valve is changed through the use of an externally applied magnetic field. Applying a specific magnetic adjustment tool to the adjustable valve mechanism will permit the cam to turn slightly, increasing or decreasing the tension on the spring, and changing the setting of the valve. The CODMAN CERTAS Plus Programmable Valve is available in eight configurations.
VALVE IMPLANTATION

It is acceptable to use a syringe to slowly and gently fill the entire valve system with pyrogen-free, sterile saline solution or, for catheters other than BACTISEAL® Antimicrobial Catheters, an appropriate antibiotic solution. If the valve housing includes the SIPHONGUARD® Anti-Siphon Device, it reduces the ability to prime the shunt system during implantation to a rate of approximately 0.5 ml/minute.

The valve must be oriented such that the direction of flow arrow faces up towards the scalp and points in the direction of flow of CSF.

Placement of the valve can impact the performance of the tool kit and should be taken into account for proper patient therapy. Select a location where the implanted valve can be positioned horizontally for use with the tool kit. Avoid placement too close to structures, such as the ear. It is also important to choose an implantation site where the tissue over the valve is not too thick (>10 mm) otherwise locating, reading and adjusting with the CODMAN CERTAS Tool Kit may not be possible.
POST-OPERATIVE PROGRAMMING USING THE CODMAN CERTAS TOOL KIT

2 Locator Tools

The **Adjustable Height Locator Tool** provides freedom to select the optimal height so that the skin is just below the valve cut-out. This allows the Indicator and Adjustment Tools to sit as closely to the valve mechanism as possible without touching the skin, facilitating correct indication and adjustment. This Locator Tool is also used to program the valve in the package.

- **Petals provide easy grip**
- **Collapses down to fit into carrying case**
- **White ring rotates to adjust height of tool**
- **Smooth contoured edges on base for patient comfort**

The **Low Profile Locator Tool** is for use when tissue thickness above the valve is greater than 10mm or when edema is present. This tool has a flat bottom so it can sit flush against the skin.

- **Black center lines**
- **Direction of flow arrow**

**Indicator Tool**

Provides rapid reading of the valve’s performance setting. The position of the number in the window helps confirm that the tools are properly aligned with the valve.

- **Wide window with colored number graphics**
- **Alignment marker**

**Adjustment Tool**

Changes the valve’s performance setting. It provides an audible click and tactile response as you turn to each setting. It also features a safety stop between settings 1 and 8.
1. Position the patient so that the implanted valve is horizontal.
2. Locate the valve by palpation. Mark the center of the valve mechanism and the inlet and outlet connector barbs.

Select the appropriate **Locator Tool** (based on tissue thickness). It should be stable and with the tissue just below the valve cut-out.

- **Low Profile Locator Tool**
  - if thick tissue or edema is present (>10 mm above the valve).

- **Adjustable Height Locator Tool**
  - Tissue should not protrude through valve cut-out.

3. Place **Locator Tool** atop the implanted valve:
   - black lines are aligned with the marked center of the hard valve mechanism
   - direction of flow arrow aligned with the catheter barb marks

4. Insert the **Adjustment Tool** into the **Locator Tool** with the arrow pointing to the current performance setting. Holding the "petals" of the **Locator Tool**, turn the **Adjustment Tool** until the arrow points to the desired performance setting.

5. Lift the **Adjustment Tool** from the **Locator Tool** straight upwards a minimum of 3 cm (1.25 in.) then move it horizontally away to avoid inadvertently changing the valve setting.

6. To determine the current valve setting, fully seat the **Indicator Tool** into the **Locator Tool** with red markings aligned. Remove the **Indicator Tool**.

7. Repeat Steps 4 and 5 to confirm successful adjustment of the performance setting. Always confirm the desired performance setting of the valve.

8. If the desired performance setting is not achieved, repeat Steps 6 through 8.

9. It is recommended to record the valve setting in the patient's record and I.D. wallet card.

10. Disinfect the tool kit components.

11. Return all tools to their proper locations in the storage case to prevent damage. Note: place the **Low Profile Locator Tool** under the elastic webbing in the bottom of the storage case and fully collapse the **Adjustable Height Locator Tool**.

12. Please consult the Instructions for Use for more detailed information and appropriate use of the devices.
PERFORMANCE SETTING VERIFICATION UTILIZING X-RAY

X-Ray Technique:

A proper radiograph will be generated when the film is shot perpendicular to the plane of the valve with the non-implanted side of the patient’s head resting on the plate. The film must be taken in relation to the valve and not the patient’s anatomy.

Reading the valve setting:

The valve setting is determined by the Setting Indicator, relative to the Right Hand Side X-ray Marker.
Reading the Valve Setting with the X-Ray Overlay Tool

Note: Position the X-Ray Overlay Tool flush against the x-ray image.

1. Align **RED** centerline of valve on overlay with the centerline of the valve x-ray under review. This can be accomplished by aligning the proximal and distal connectors of the x-ray image with those on the overlay.

2. Ensure that the numbers on the overlay that depict the performance settings are properly oriented for viewing. In this orientation the right hand side (RHS) marker red line extends to the right of the **RED** centerline. This ensures proper overlay orientation.

3. Align rotating construct (RC) center dot on overlay with the center of the RC of the x-ray image.

4. Ensure RHS marker red line containing red dot is aligned with the RHS marker of the x-ray image (if present).

5. The valve setting is determined by identifying the region of the overlay that contains the majority of the image of the magnet that has the tantalum ball adjacent to it.

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**Legend:**

- A. Proximal connector
- B. **RED** Centerline of valve
- C. Right hand side (RHS) marker
- D. RHS marker red line (contains RHS dot)
- E. Rotating construct (RC)
- F. Magnet with tantalum ball (setting indicator)
- G. Distal connector
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, pancytosis, bacteremia, and sepsisemia 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.