

CERTAS™ Plus Programmable Valves







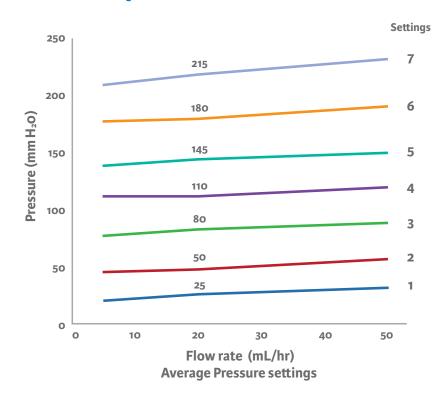
CERTAS™ Plus Programmable Valves

The CERTASTM 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 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. Testing shows that the valve mechanism is resistant to unintended changes in the setting in a 3 Tesla MRI.

The setting of the CERTAS Plus Programmable Valve is changed through the use of an externally applied magnetic field. Applying a specific magnetic field 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 CERTAS Plus Programmable Valve is available in eight basic configurations in three different housing options (regular, small, and right angle). Configuration options include CERTAS Plus with SiphonGuard® anti-siphon device and unitized BACTISEAL® an antimicrobial catheter impregnated with clindamycin and rifampin.



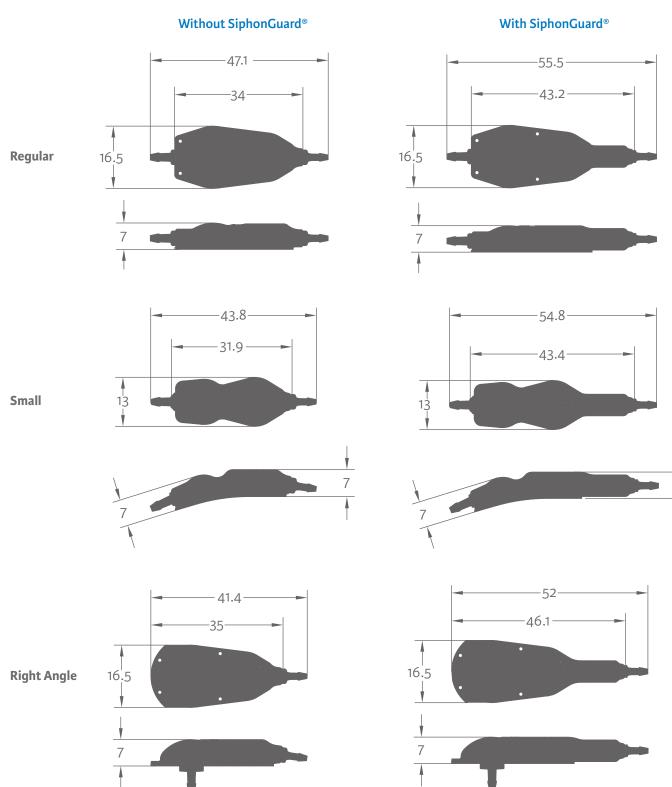
Performance Setting Guide



The valves perform within a tolerance range of the average pressure as shown here, regardless of gravitational orientation:

| Settings 1, 2, 3 | ±20 mm H ₂ O |
|---|--|
| Setting 4 | ±25 mm H ₂ O |
| Settings 5, 6, 7 | ±35 mm H ₂ O |
| Setting 8 | is intended to limit flow through the valve and has a minimum pressure of 400 mm H ₂ O. |
| CERTAS Plus Programmable Valves were made available <u>after</u> March 2015 | |

Shape and Dimensions (Scale: 100% / Measurements in Millimeters)





Codman CERTAS Tool Kit

Allows for non-invasive monitoring and adjusting of the valve pressure setting



828851 CERTAS Tool Kit

Includes:

- Indicator Tool
- Adjustment Tool
- Adjustable Height Locator Tool
- Low Profile Locator Tool
- X Ray Overlay Tool
- Instructions for Use

Codman CERTAS Plus Electronic Tool Kit

A digital tool kit that reduces post-operative reprogramming time



828852 CERTAS Plus Electronic Tool Kit

Includes:

- Locator Tool
- Adjustment Tool
- Quick Reference Card
- Instructions for Use
- X Ray Overlay Tool
- Spare Batteries (CR123A)
- Screw Driver



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.



Adjustment Too

Changes the valve's performance setting. It provides an audible click and tactile response as you turn to each setting. Features a safety stop between settings 1 and 8.



Adjustable Height Locator Tool

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.



Low Profile Locator Tool

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



X-Ray Overlay Tool

Use this tool when viewing the x-ray film or screen to confirm the valve setting.



Please refer to the Instructions for Use (in pocket of carrying case) for step-by-step instructions of pre- and post-implantation procedures for indicating and programming the CERTAS Plus Programmable Valve.

Simple Steps with Visual Guidance

- Provides clear and easy-to-follow visual guidance to locate the valve.
- Locating dot provides instant feedback and shortens procedure time.

Accurate and Reliable Setting Change

- Offers tactile feedback during adjustment for more confidence in setting changes.
- Number and checkmark indicator gives assurance of proper setting.
- Features a safety stop between settings 1 and 8.

Ergonomic Design

 The soft concave section of the locator tool reduces patient discomfort. The handle design improves ease and comfort of handling the Tool Kit.









Adjust

Confirm



Without

82-8810PL

82-8811PL

SiphonGuard Anti-Siphon Device Regular Small

A DIVISION OF INTEGRA LIFESCIENCES

82-8800PL

82-8801PL

82-8803PL

82-8802PL







82-8820PL





VALVE SYSTEM

VALVE ONLY

- Priming adaptor, plastic

- Valve with integrated plastic connectors

INCLUDES:

- Valve with integrated plastic connectors

- 14 cm ventricular catheter (ref. 82-3041)
- Stainless Steel Stylet
- 120 cm distal catheter (ref. 82-3045)



82-8813PL

Configuration not available

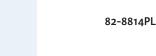


82-8821PL



82-8804PL

82-8805PL



With

SiphonGuard®Anti-Siphon Device

82-8815PL



Right Angle

82-8824PL

82-8825PL

82-8827PL



and SiphonGuard Device

INCLUDES:

- Priming adaptor, plastic

VALVE SYSTEM

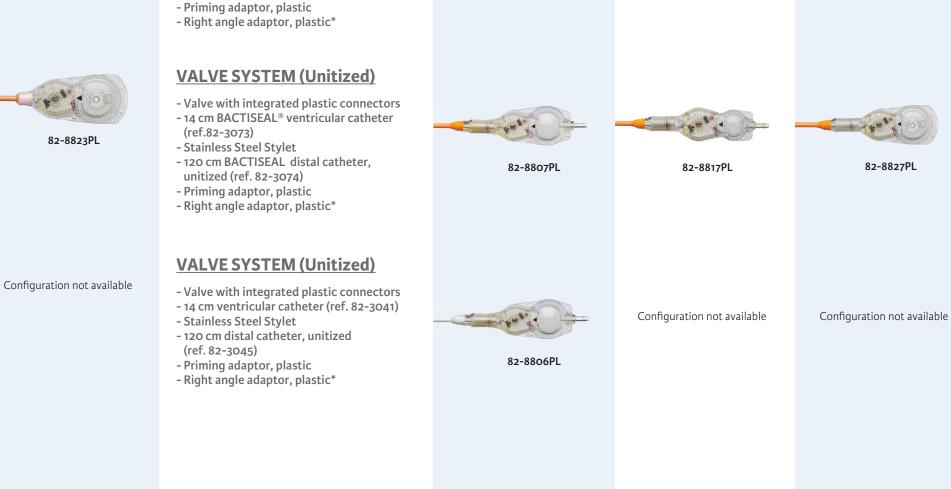
- Valve with integrated plastic connectors and SiphonGuard Device
- 14 cm ventricular catheter (ref. 82-3041)
- Stainless Steel Stylet
- 120 cm distal catheter (ref. 82-3045)
- Priming adaptor, plastic
- Right angle adaptor, plastic*

VALVE SYSTEM (Unitized)

- Valve with integrated plastic connectors and SiphonGuard Device
- 14 cm BACTISEAL ventricular catheter (ref. 82-3073)
- Stainless Steel Stylet
- 120 cm BACTISEAL distal catheter, unitized (ref. 82-3074)
- Priming adaptor, plastic
- Right angle adaptor, plastic*

VALVE SYSTEM (Unitized)

- Valve with integrated plastic connectors and SiphonGuard Device
- 14 cm ventricular catheter (ref. 82-3041)
- Stainless Steel Stylet
- 120 cm distal catheter, unitized (ref. 82-3045)
- Priming adaptor, plastic
- Right angle adaptor, plastic*



^{*} Not included with the right angle housing option

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Hydrocephalus Catalog ■ CERTAS™ Plus Programmable Valves

Availability of these 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.

For more information or to place an order, please contact:

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