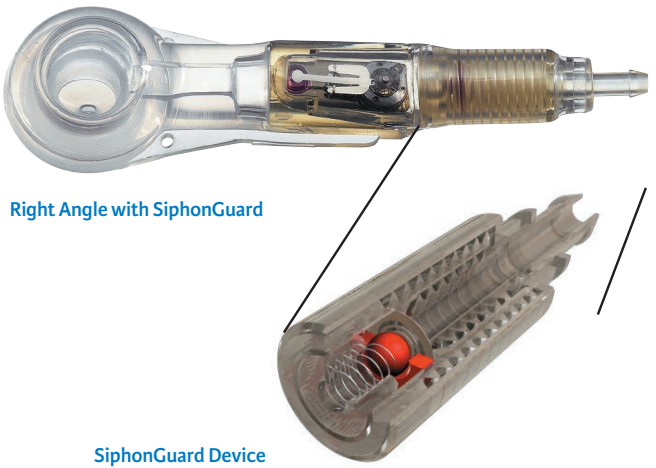


Codman® Hakim® Programmable Valve System for Hydrocephalus



# Codman® Hakim® Programmable Valve System for Hydrocephalus

SiphonGuard® Anti-Siphon Device is a uniquely new device for preventing excessive CSF flow during positional changes. The SiphonGuard Device can be placed anywhere distal to the valve and is unaffected by scar tissue encapsulation or external pressure. The mechanical design detects the difference between the normal and excessive flow and activates only when excessive flow occurs. Dual pathway design allows for slow release of CSF due to hydrostatic pressure.



The SiphonGuard Anti-Siphon Device never totally closes the shunt system but instead uses resistance to impede flow. SiphonGuard utilizes proven ball and cone technology, which is highly reliable.

# Codman® Hakim® Programmable Valve System for Hydrocephalus

## ADVANTAGE

The cranial cavity contains one of the most interesting hydrodynamic systems within the human body, one that has historically engaged the attention of both engineer and neurosurgeon in a search for a better method for treating hydrocephalus. Physicians have traditionally been limited when faced with choosing the right fixed pressure valve prior to implantation. Even if chosen correctly at the time of implantation, surgical revisions may be required as the patient's pathophysiology changes. Basically, the patient is forced to adapt to a fixed pressure valve.

With the advent of the CODMAN Hakim Programmable Valve System, neurosurgeons can pre-select one of 18 different pressure settings. After implantation, the valve can be adjusted non-invasively to adapt to changes in patient condition. That means surgeons are able to make precise pressure adjustments to help control intracranial pressure and ventricle size at any time. This opens up new specialized therapies and may eliminate the unknowns which historically complicated the treatment process.

## DESIGN

Unlike classic silicone shunt systems which only give surgeons three pressure ranges to choose from, the Codman Hakim Programmable Valve features 18 pressure ranges. These ranges provide the surgeon with the ability to make subtle alterations to the opening pressure. Each adjustment can be made quickly and easily through the programmer interface. Its precise mechanical design yields repeatable, linear pressure-flow responses. The micrometer scale (1/1000 mm) programming motions and tightly calibrated spring tensions which give the valve its accuracy are derived from the same microtechnology employed by the Swiss watch industry.

The same miniature manufacturing processes which make the valve accurate also make it reliable. Only superior materials that can stand up to the conditions evident in patients with hydrocephalus are chosen. The parts are also completely biocompatible, with the low profile of both the full housing and micro-housing resulting in an unobtrusive implant. Once assembled, the valves are tested five separate times prior to release to ensure they meet stringent performance standards.

## CONTACT

If you're interested in seeing a demonstration of the Codman Hakim Programmable Valve System, or would like further information, please contact your Integra Sales Representative or Customer Service.



## PROGRAMMING THE VALVE

- Turn on the programmer unit.
- Locate the programmable section of the valve.
- Press one of the raised buttons to choose the desired pressure.
- Place the programmer head over the valve so the feet straddle the mechanism and the arrows align with CSF flow direction.
- Press and release the start button on the programmer head.
- Hold in place until beeps indicate programming is complete.

Codman's VPV® programmer provides confirmation of the valve adjustment without the need for radiographic imaging when the "Adjustment Complete" message is displayed.

Magnets and an externally applied magnetic field generated by the programmer change the setting. The coded signal minimizes inadvertent programming by external fields. A marker within the valve lets you verify the setting by means of x-ray film or fluoroscopy.

Please refer to full product information provided with each product prior to use.



Codman Hakim Programmer



Codman Valve Position Verification (VPV) System



Non-invasive programming technique

# Codman Hakim Programmable Valve Product Codes

## Valves

Includes: Programmable Valve, Information Manual, Straight Connectors,\*\* Introducer\*\*\*\* and Priming Adapter.\*\*

- 82-3162 Codman Hakim Programmable Valve, Inline with SIPHONGUARD
- 82-3164 Codman Hakim Programmable Valve, Inline
- 82-3182 Codman Hakim Programmable Valve, Right Angle with SIPHONGUARD
- 82-3184 Codman Hakim Programmable Valve, Right Angle
- 82-3110 Codman Hakim Programmable Valve, Cylindrical with Prechamber
- 82-3115 Codman Hakim Programmable Valve, Cylindrical
- 82-3116 Codman Hakim Programmable Valve, Micro with RICKHAM Reservoir
- 82-3112 Codman Hakim Programmable Valve, Micro

## Valve Systems

Includes: Programmable Valve, 14cm Ventricular Catheter, 120cm Peritoneal Catheter,\* Information Manual, Right Angle Adapter and Priming Adapter.\*\*

- 82-3832 Codman Hakim Programmable Valve, Inline with SIPHONGUARD
- 82-3834 Codman Hakim Programmable Valve, Inline
- 82-3136 Codman Hakim Programmable Valve, Right Angle with SIPHONGUARD
- 82-3838 Codman Hakim Programmable Valve, Right Angle

## Valve Systems (Unitized)

Includes: Programmable Valve, 14cm Ventricular Catheter, 120cm Unitized Peritoneal Catheter,\* Information Manual, Straight Connectors,\*\* Introducer,\*\* Right Angle Adapter and Priming Adapter.\*\*

- 82-3842 Codman Hakim Programmable Valve, Inline with SIPHONGUARD, Unitized Distal Catheter
- 82-3844 Codman Hakim Programmable Valve, Inline, Unitized Distal Catheter
- 82-3146 Codman Hakim Programmable Valve, Right Angle with SIPHONGUARD, Unitized Distal Catheter
- 82-3148 Codman Hakim Programmable Valve, Right Angle, Unitized Distal Catheter
- 82-3111\* Codman Hakim Programmable Valve, Cylindrical with Prechamber, Unitized Distal Catheter
- 82-3113\* Codman Hakim Programmable Valve, Micro with RICKHAM Reservoir, Unitized Distal Catheter
- 82-3114\* Codman Hakim Programmable Valve, Micro Unitized Distal Catheter

## Programmer

- 82-3190 Codman Programmer
- 82-3192 Codman Valve Positioning Verification (VPV) System

Valves are customized to fit your special needs. Please contact your Codman Neurospecialist, or Codman Specials Department at (800) 843-0039 or [www.shuntworks.com](http://www.shuntworks.com).

## Accessories

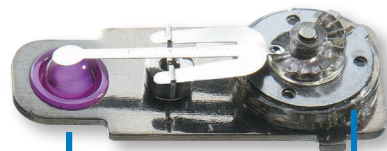
- 82-3041 Codman Ventricular Catheter, 14cm
- 82-3044 Codman Atrial Catheter, 46cm
- 82-3045 Codman Peritoneal Catheter, 120cm
- 82-3072 Codman BACTISEAL® Barium Silicone Catheter Kit
- 82-3073 Codman BACTISEAL Barium Silicone Ventricular Catheter
- 82-3074 Codman BACTISEAL Barium Silicone Peritoneal Catheter
- 82-1501 ACCU-FLO® Straight Metal Connector (11mm)
- 82-1504 ACCU-FLO Plastic Connector (17mm)
- 82-1507 Right Angle Connector, Plastic
- 82-1520 ACCU-FLO Three-way Plastic Connector

\* Includes: 85cm Unitized Peritoneal Catheter.

\*\* Provided with the Cylindrical and Micro versions.

\*\*\* Provided with Inline, Right Angle and Micro versions.

\*\*\*\* Provided with the Cylindrical versions only.



**Pumping reservoir** allows for patency checks and access port.

**Suture holes** for securing valve to the pericranium.

**Occluder** to provide directional pumping.

**Synthetic ruby ball** rotates freely to ease CSF flow through the valve, and is manufactured with a matching valve seat to ensure complete valve closure.

Specially designed non-distorted **stainless steel spring** ensures stability and repeatability of selected pressure.

**Wireless magnetic servo motor** rotates the spiral staircase cam via a coded magnetic signal.

Eighteen different settings on the **cam** give surgeons the ability to precisely optimize valve opening pressure.

**Integrated SiphonGuard® Device** to prevent overdrainage.



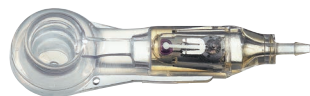
Inline with SiphonGuard



Inline



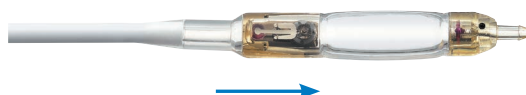
Right Angle with SiphonGuard



Right Angle



Cylindrical Valve with Prechamber



Cylindrical Valve



Micro Valve with Rickham® Reservoir



Micro Valve



Programmable Valve



Straight Connector



Priming Adapter



Introducer



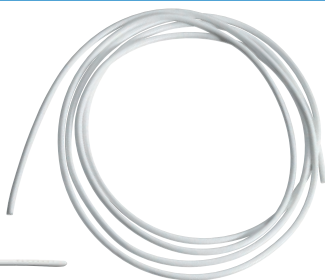
Programmable Valve



Priming Adapter



Ventricular Catheter



Peritoneal Catheter



Straight Connector



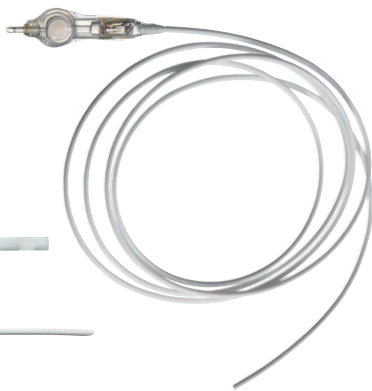
Priming Adapter



Introducer



Ventricular Catheter



Unitized Peritoneal Catheter

- 82-1521 ACCU-FLO Three-way Metal Connector
- 82-3048 Stainless Steel Straight Connector
- 82-1696 Type T Connector
- 82-3053 Codman Titanium Sterile Straight Connector (14mm)
- 82-3055 Plastic Introducer
- 82-3090 SiphonGuard, CSF Flow Control Device

## INDICATIONS

The Codman Valves are implantable devices that provide constant intraventricular pressure and drainage of CSF for the management of hydrocephalus and other conditions in which CSF flow and absorption are impaired.

## CONTRAINDICATIONS

These devices are contraindicated in patients receiving anticoagulants or known to have a bleeding diathesis. Shunt implantation should be avoided if infection is present within the body. Delay the shunt procedure when infections such as meningitis, ventriculitis, peritonitis, bacteremia and septicemia are present. Unitized valves are not designed for atrial drainage.

**See product insert for complete warnings, precautions, adverse events and warranties.**

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.

### Additional information for EMEA Customers only:

Products mentioned in this document are CE class I, IIa, IIb or III devices. Contact Integra should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as "NOT CE MARKED".

### Manufacturer:



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