Codman®

Codman® Hakim®

Programmable Valves

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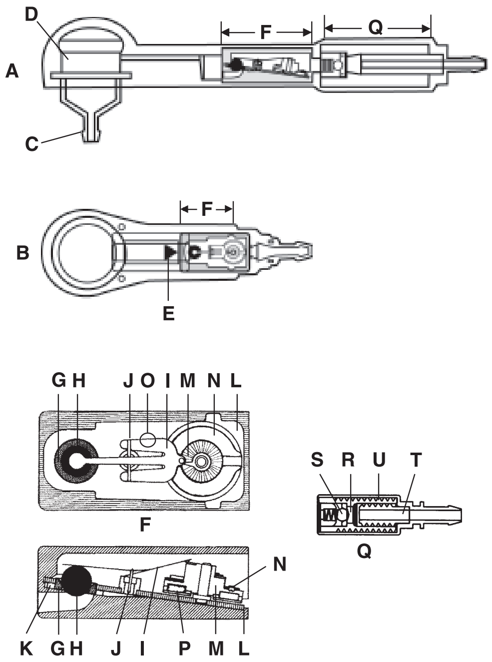

ENGLISH

Right angle design with SiphonGuard

A. Side view
B. Top view
C. Inlet connector
D. Reservoir
E. Direction-of-flow arrow
F. Inlet valve
G. Valve seat
H. Valve ball
I. Flat spring
J. Spring calibrating fulcrum
K. O-ring
L. Titanium base plate
M. Cam
N. X-ray cam position indicator (pressure)
O. Right-hand side x-ray indicator
P. Stepper motor
Q. Antisiphon device
R. Valve seat
S. Valve ball
T. Central passage
U. Spiral passage

FRANÇAIS

Modèle à angle droit avec dispositif SiphonGuard

A. Vue latérale
B. Vue supérieure
C. Raccord d'admission
D. Réservoir
E. Flèche de sens d'écoulement
F. Valve d'admission
G. Siège de la valve
H. Bille de la valve
I. Ressort plat
J. Pivot pour l'étalonnage du ressort
K. Joint torique
L. Plaque de support en titane
M. Came
N. Indicateur radiologique de position de la came (pression)
O. Indicateur radiologique latéral droit
P. Moteur pas à pas
Q. Dispositif anti-siphonnage
R. Siège de la valve
S. Bille de la valve
T. Passage central
U. Passage en spirale

DEUTSCH

Rechtwinklige Ausführung mit SiphonGuard

A. Seitenansicht
B. Draufsicht
C. Einlass-Anschluss
D. Reservoir
E. Flussrichtungspfeil
F. Einlassventil
G. Ventilsitz
H. Ventilkugel
I. Federscheibe
J. Verstellhebel
K. O-Ring
L. Titan-Basisplatte
M. Nocke
N. Röntgenindikator für Nockenposition (Druck)
O. Röntgenindikator für rechte Seite
P. Schrittmotor
Q. Antisiphon
R. Ventilsitz
S. Ventilkugel
T. Hauptkanal
U. Spiralkanal

NEDERLANDS

Haaks ontwerp met SiphonGuard

A. Zijaanzicht
B. Bovenaanzicht
C. Inlaatconnector
D. Reservoir
E. Pijl voor de stroomrichting
F. Inlaatklep
G. Klepzitting
H. Klepkogel
I. Platte veer
J. Kalibreringsdraaipunt voor veer
K. O-ring
L. Titanium bodemplaat
M. Camera
N. Röntgen-nokpositie-indicator (druk)
O. Rechter-röntgenindicator
P. Stappenmotor
Q. Antisifonregelaar
R. Klepzitting
S. Klepkogel
T. Centrale doorgang
U. Spiraalvormige doorgang

ITALIANO

Design ad angolo retto con SiphonGuard

A. Vista laterale
B. Vista dall'alto
C. Connettore di ingresso
D. Serbatoio
E. Freccia della direzione di flusso
F. Valvola di ingresso
G. Sede della valvola
H. Sfera della valvola
I. Molla piatta
J. Fulcro di calibrazione molla
K. O-ring
L. Piastra con base in titanio
M. Camma
N. Indicatore di posizione della camma a raggi x (pressione)
O. Indicatore per raggi x destro
P. Motore a passo
Q. Dispositivo antisifone
R. Sede della valvola
S. Sfera della valvola
T. Passaggio centrale
U. Passaggio a spirale

ESPAÑOL

Diseño de ángulo recto con SiphonGuard

A. Vista lateral
B. Vista superior
C. Conector de entrada
D. Reservorio
E. Flecha de dirección de flujo
F. Válvula de entrada
G. Asiento de la válvula
H. Esfera de la válvula
I. Resorte plano
J. Fulcro de calibración de resorte
K. Junta tórica
L. Placa de base de titanio
M. Leva
N. Indicador de posición de la leva de rayos X (presión)
O. Indicador de rayos X del lado derecho
P. Motor por pasos
Q. Dispositivo antisifón
R. Asiento de la válvula
S. Esfera de la válvula
T. Pasaje central
U. Pasaje en espiral

PORTUGUÊS

Conceção em ângulo reto com SiphonGuard

A. Vista lateral
B. Vista de cima
C. Conector de entrada
D. Reservatório
E. Seta de direção do fluxo
F. Válvula de entrada
G. Sede da válvula
H. Esfera da válvula
I. Mola plana
J. Fulcro de calibração de mola
K. Anel em "O"
L. Placa de base em titânio
M. Came
N. Indicador de posição do came para radiografia (pressão)
O. Indicador direito para radiografia
P. Motor escalonador
Q. Dispositivo antissifão
R. Sede da válvula
S. Esfera da válvula
T. Passagem central
U. Passagem em espiral

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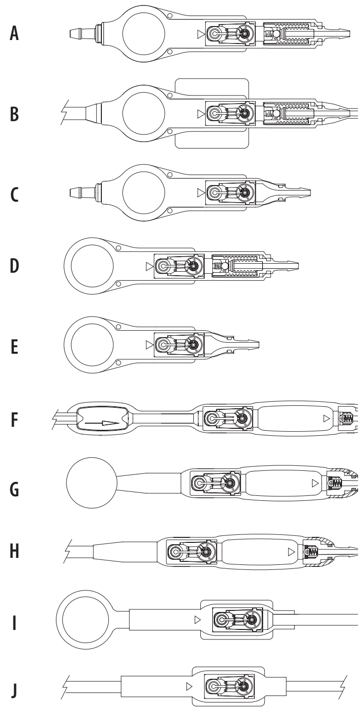

ENGLISH

Programmable valve configurations

A. In-line with SiphonGuard Device
B. In-line with SiphonGuard Device and Platform with Proximal Tube
C. In-line
D. Right angle with SiphonGuard Device
E. Right angle
F. Cylindrical with prechamber
G. Cylindrical with Rickham Reservoir
H. Cylindrical
I. Micro with Rickham reservoir
J. Micro

FRANÇAIS

Configurations de la valve programmable

A. En ligne avec dispositif SiphonGuard
B. En ligne avec le dispositif SiphonGuard avec tubulure proximale
C. En-ligne
D. À angle droit avec dispositif SiphonGuard
E. À angle droit
F. Cylindrique avec préchambre
G. Cylindrique avec réservoir Rickham
H. Cylindrique
I. Micro avec réservoir Rickham
J. Micro

DEUTSCH

Konfigurationen des programmierbaren Ventils

A. Inline mit SiphonGuard Durchflussregler
B. Inline mit SiphonGuard Durchflussregler und Plattform mit proximalem Schlauch
C. Inline
D. Rechtwinklig mit SiphonGuard Durchflussregler
E. Rechtwinklig
F. Zylindrisch mit Vorkammer
G. Zylindrisch mit Rickham-Reservoir
H. Zylindrisch
I. Mikro mit Rickham-Reservoir
J. Mikro

NEDERLANDS

Programmeerbare klepconfiguraties

A. Inline met SiphonGuard-regelaar
B. Inline met SiphonGuard-regelaar en platform met proximale buis
C. Inline
D. Haaks met SiphonGuard-regelaar
E. Haaks
F. Cilindervormig met voorkamer
G. Cilindrisch met Rickham-reservoir
H. Cilindrisch
I. Micro met Rickham-reservoir
J. Micro

ITALIANO

Configurazioni delle valvole programmabili

A. In linea con dispositivo SiphonGuard
B. In linea con dispositivo SiphonGuard e piattaforma con tubo prossimale
C. In linea
D. Ad angolo retto con dispositivo SiphonGuard
E. Ad angolo retto
F. Cilindrica con precamera
G. Cilindrica con serbatoio Rickham
H. Cilindrica
I. Micro con serbatoio Rickham
J. Micro

ESPAÑOL

Configuraciones de válvulas programables

A. En línea con dispositivo SiphonGuard
B. En línea con dispositivo SiphonGuard y plataforma con tubo proximal
C. En línea

D. Ángulo recto con el dispositivo SiphonGuard
E. Ángulo recto
F. Cilíndrica con antecámara
G. Cilíndrica con reservorio Rickham
H. Cilíndrica
I. Micro con reservorio Rickham
J. Micro

PORTUGUÊS
Configurações da válvula programável

A. Em linha com dispositivo SiphonGuard
B. Em linha com dispositivo SiphonGuard e plataforma com tubo proximal
C. Em linha
D. Ângulo reto com dispositivo SiphonGuard
E. Ângulo reto
F. Cilíndrica com antecâmara
G. Cilíndrica com reservatório Rickham
H. Cilíndrica
I. Microválvula com reservatório Rickham
J. Microválvula

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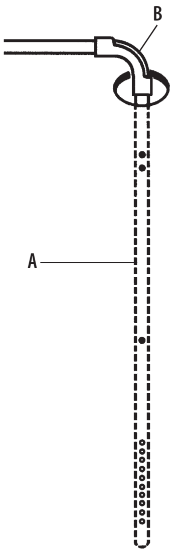

ENGLISH
A. Ventricular Catheter
B. Right Angle Adapter

FRANÇAIS
A. Cathéter ventriculaire
B. Adaptateur à angle droit

DEUTSCH
A. Ventrikelkatheter
B. Rechtwinkliger Adapter

NEDERLANDS
A. Ventriculaire katheter
B. Haakse adapter

ITALIANO
A. Catetere ventricolare
B. Adattatore ad angolo retto

ESPAÑOL
A. Catéter ventricular
B. Adaptador en ángulo recto

PORTUGUÊS
A. Cateter ventricular
B. Adaptador de ângulo recto

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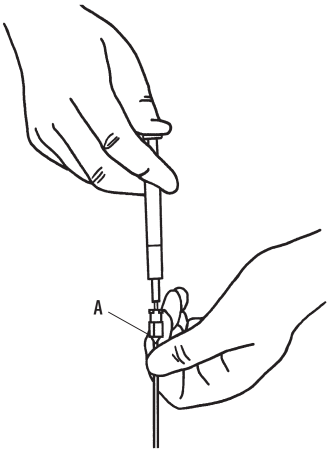

ENGLISH
A. Priming adapter

FRANÇAIS
A. Adaptateur d'irrigation

DEUTSCH
A. Starteradapter

NEDERLANDS
A. Irrigatieadapter

ITALIANO
A. Adattatore per irrigazione

ESPAÑOL
A. Adaptador de irrigación

PORTUGUÊS
A. Adapador de irrigação

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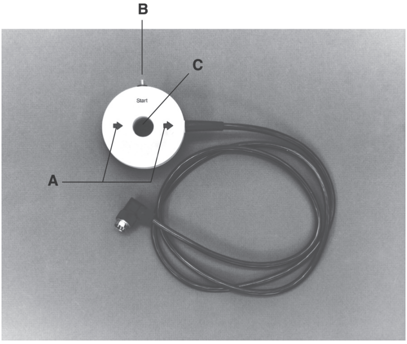

ENGLISH
A. Directional arrows
B. START button
C. Illuminated center hole

FRANÇAIS
A. Flèches directionnelles
B. Bouton START
C. Orifice central lumineux

DEUTSCH
A. Richtungspfeile
B. START-Taste
C. Beleuchtetes Mittelloch

NEDERLANDS
A. Richtingspijlen
B. Startknop
C. Verlichte centrale opening

ITALIANO
A. Frecce direzionali
B. Pulsante START
C. Foro centrale illuminato

ESPAÑOL
A. Flechas direccionales
B. Botón INICIAR
C. Orificio central iluminado

PORTUGUÊS
A. Setas direccionais
B. Botão START
C. Orifício central iluminado

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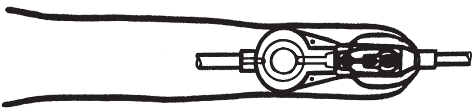

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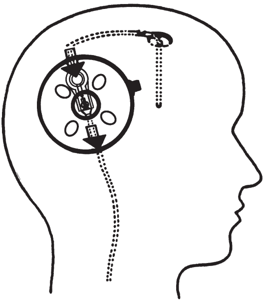

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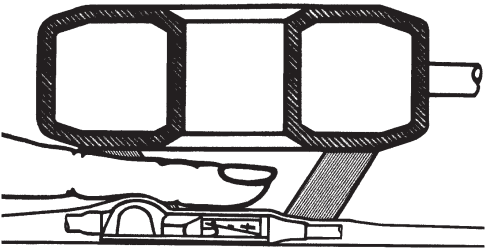

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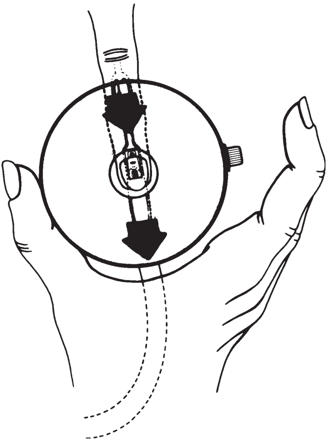

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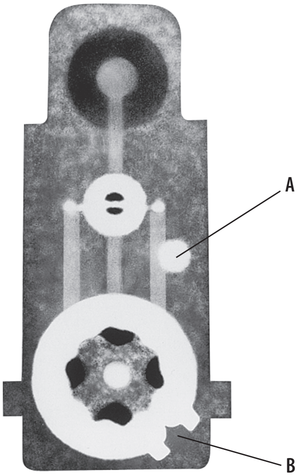

ENGLISH
A. White marker
B. Pressure indicator

FRANÇAIS
A. Repère blanc
B. Indicateur de pression

DEUTSCH
A. Weiße Markierung
B. Druckanzeiger

NEDERLANDS
A. Witte markering
B. Drukindicator

ITALIANO
A. Marcatore bianco
B. Indicatore di pressione

ESPAÑOL
A. Marcador blanco
B. Indicador de presión

PORTUGUÊS
A. Marcador branco
B. Indicador de pressão

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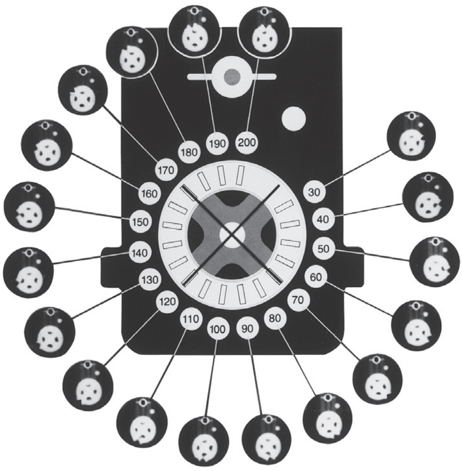

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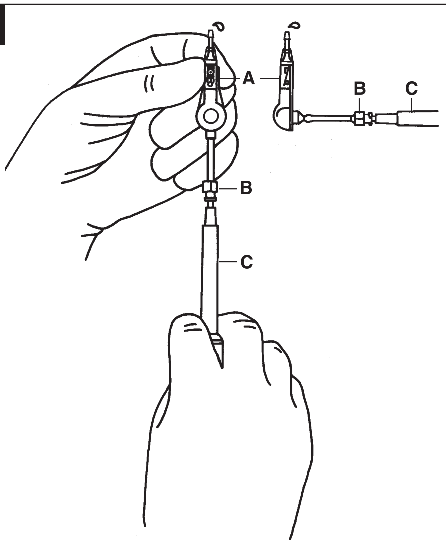

ENGLISH

A. Valve outlet
B. Priming adapter with tubing
C. Pyrogen-free sterile saline or antibiotic solution

FRANÇAIS

A. Évacuation de la valve
B. Adaptateur d'irrigation avec tubulure
C. Sérum physiologique stérile ou solution antibiotique apyrogène

DEUTSCH

A. Ventilauslass
B. Starteradapter mit Schlauch
C. Pyrogenfreie sterile Kochsalzlösung oder antibiotische Lösung

NEDERLANDS

A. Klepuitlaat
B. Irrigatieadapter met slang
C. Niet-pyrogene steriele zoutoplossing of antibioticumoplossing

ITALIANO

A. Uscita valvola
B. Adattatore per irrigazione con tubo
C. Soluzione salina sterile apirogena o soluzione antibiotica

ESPAÑOL

A. Salida de la válvula
B. Adaptador de irrigación con tubo
C. Solución salina estéril sin pirógenos o solución antibiótica

PORTUGUÊS

A. Saída da válvula
B. Adaptador de irrigação com tubo
C. Solução salina esterilizada apirogénica ou solução antibiótica

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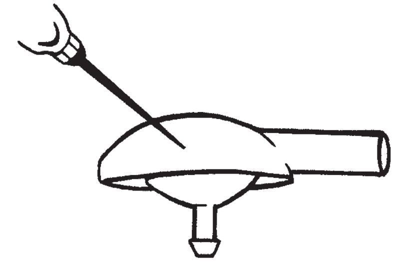

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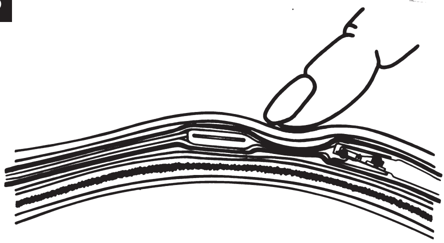

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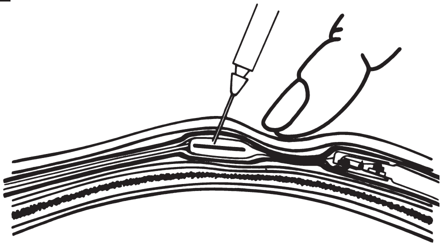

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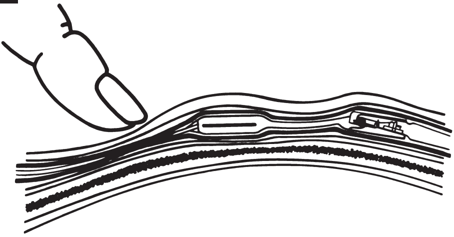

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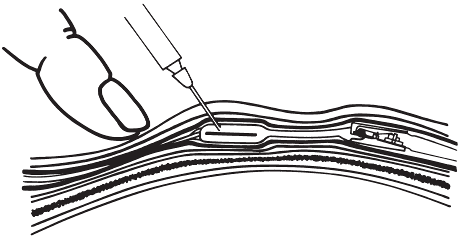


EN – ENGLISH

IMPORTANT INFORMATION

Please Read Before Use

Codman® Hakim® Programmable Valves

STERILE EO

Rx ONLY

Description

The Codman® Hakim® Programmable Valve is a single-use implantable device that provides constant intraventricular pressure and drainage of cerebrospinal fluid (CSF) for the management of hydrocephalus. It includes a valve mechanism (Figures 1 & 2) that incorporates a flat 316L stainless steel spring in which the calibration is accomplished by a combination between a pillar and a microadjustable telescoping fulcrum. The valve chassis is made of titanium and Vacoperm. Casing and connectors are made of polysulfone or nylon. The ball and cone are manufactured from synthetic ruby. Intraventricular pressure is maintained at a constant level by the ball and cone valve seat design. The valve mechanism is inserted into a silicone rubber housing. Tantalum markers are present for x-ray identification. Valve systems are supplied with barium impregnated silicone catheters and a polypropylene right angle adapter. The table below lists the range of materials used in all Codman Hakim Programmable Valves:

Material	Where used	Material Weight Range
Barium impregnated silicone	Catheter, tubing, reservoir	0.7 - 7.0 g
Epoxy adhesive	Valve mechanism	3 - 10 mg
Nylon	Connector, reservoir	0.12 g
Polypropylene	Right angle adapter	0.05 g
Polysulfone	Valve mechanism, SiphonGuard mechanism, Outlet valve mechanism, connector, Needle guard	0.1 - 0.6 g
Samarium Cobalt	Magnet	15 mg
Silicone rubber	Valve housing, splice, backing, reservoir	0.3 - 2.7 g
Stainless steel	Spring, stator, connector, reservoir	0.01 - 1.26 g
Synthetic ruby	Ball, ball seat, bearing	13 - 24 mg
Tantalum	Black dot, arrow, reference plate	0.01 g
Titanium	Valve mechanism, antechamber plate, connector	0.04 - 0.25 g

The performance setting of the valve can be set preoperatively and can also be noninvasively adjusted post-implantation by the use of an external programmer (sold separately) which activates the stepper motor, made of magnets encapsulated with epoxy, within the valve housing. The programmer transmits a codified magnetic signal to the motor allowing 18 pressure settings, ranging from 30 mm to 200 mm H_2O (294 to 1960 Pa) in 10 mm H_2O (98 Pa) increments. Each valve is calibrated at the mechanism level and tested at the time of manufacture.

Graph 1 describes the pressure-flow performance characteristics of the device as required by ISO 7197. Long-term stability performance of the device has been demonstrated through testing in accordance to this standard. The pressure shown in the table for each setting is an average, recorded with active flow through the valve alone at flow rates of 5, 20, and 50 mL/hr; the value at 20 mL/hr is shown. Note that testing of the device may give different results depending on the test conditions.

Graph 1. Average operating pressure (mm H_2O) for each pressure setting with active flow through the valve at flow rates of 5mL/hr, 20 mL/hr, and 50mL/hr.

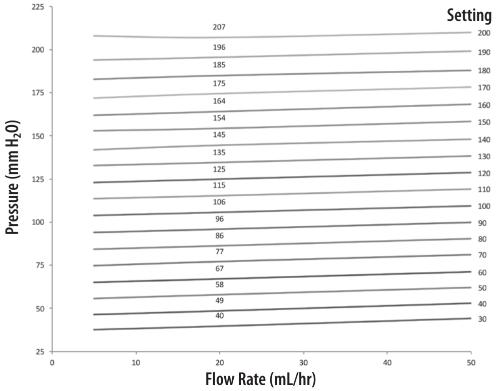


Table 1. The devices performed within a tolerance range of the average operating pressure (mm H_2O) at flow rates of 5mL/hr, 20mL/hr, and 50mL/hr as shown here regardless of gravitational orientation.

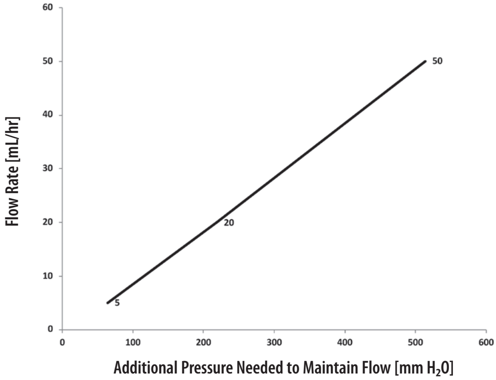
Settings 30 to 130	±12 mm H_2O
Settings 140 to 200	±15 mm H_2O

When adjusting the valve, the changes between each performance setting at flow rates of 5, 20, and 50 mL/hr are on average 10 mm H_2O.

When tested with a 120 cm long, 1 mm inner diameter peritoneal catheter, the average pressure increase is dependent on the flow rate as shown here:

5mL/hr	7 mm H_2O
20mL/hr	21 mm H_2O
50mL/hr	50 mm H_2O

Graph 2. Additional Pressure Needed to Maintain Flow for Integrated SiphonGuard Devices



The SiphonGuard® Device, included in some models of the valve, is designed with a dual pathway to prevent excessive drainage of CSF by the shunt system. Excessive draining can be induced by a rapid increase in hydrostatic pressure created by the elevation of the shunt ventricular catheter with respect to the shunt distal catheter (i.e. when a patient moves from a supine to an upright position). A sudden increase in CSF flow will close the ball and cone valve, and the entire volume of CSF will be forced through the longer secondary spiral passage, effectively slowing the rate at which CSF is shunted from the brain. Graph 2 describes the incremental pressure required for CSF to flow through the SiphonGuard secondary pathway.

Indications for Use

The Codman Hakim Programmable Valves are implantable devices that provide constant intraventricular pressure and drainage of CSF for the management of hydrocephalus.

Intended Clinical Benefits

The intended clinical benefits of the Codman Hakim Programmable Valves are to reduce cerebrospinal fluid (CSF) from the ventricles in the brain through drainage to the peritoneal cavity or other appropriate drainage site, such as the heart's right atrium, for the treatment of hydrocephalus.

Intended Users

The intended users of the Codman Hakim Programmable Valves are physicians or healthcare providers.

Intended Patient Population

The intended patient population of the Codman Hakim Programmable Valves are patients of any age, gender and ethnicity with hydrocephalus.

Contraindications

The Codman Hakim Programmable Unitized Valve Systems are not recommended for atrial placement. Use the nonunitized versions for this procedure.

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.

Adverse Events

Devices for shunting CSF may have to be replaced at any time due to medical reasons or failure of the device.

Keep patients with implanted shunt systems under close observation for symptoms of shunt failure.

Complications of implanted shunt systems include mechanical failure, shunt pathway obstruction, infection, foreign body (allergic) reaction to implants, and CSF leakage along the implanted shunt pathway.

Clinical signs such as headache, irritability, vomiting, drowsiness, or mental deterioration may be signs of a nonfunctioning shunt. Low-grade colonization, usually with *Staph. epidermidis,* can cause, after an interval from a few days to several years, recurrent fevers, anemia, splenomegaly, and eventually, shunt nephritis or pulmonary hypertension. An infected shunt system may show redness, tenderness, or erosion along the shunt pathway.

Accumulation of biological matter (i.e. blood, protein accumulations, tissue fragments, etc.) in the programming mechanism can cause inability of the device to be reprogrammed.

Clogging of the programmable valve with biological matter can cause the valve to become unresponsive to attempts to change the pressure setting.

Do not use excessive force if attempting to remove the catheter(s). Excessive force can cause the catheter to break, leaving part of the catheter within the body.

Excessive CSF drainage can cause subdural hematomas, slit-like ventricles, and in infants, sunken fontanelles.

Particulate matter such as blood clots, brain fragments, or other tissue particles can obstruct the ventricular catheter. Also, the ventricular catheter can become obstructed by excessive reduction of ventricle size.

If not properly located in the lateral ventricle, the catheter can become embedded in the ventricular wall or choroid plexus.

Fibrous adhesions can bind the catheter to the adjacent choroids plexus or to the ventricular wall. Gentle rotation may free the catheter. DO NOT REMOVE THE CATHETER FORCEFULLY. If the catheter cannot be removed without force, it is recommended that it remain in place, rather than risk intraventricular hemorrhage.

The ventricular catheter can be withdrawn from, or lost in, the lateral ventricles of the brain if it becomes detached from the shunt system.

Blunt or sharp trauma to the head in the region of implant or repetitive manipulation of the valve during implant may compromise the shunt. Check valve position and integrity after occurrence.

WARNINGS

Subjecting the valve to strong magnetic fields may change the setting of the valve.

- The use of Magnetic Resonance (MR) systems up to 3 T will not damage the valve mechanism, but may change the setting of the valve. Confirm the valve setting after an MRI procedure. See *Programming the Programmable Valve*.
- Common magnets greater than 80 gauss, such as household magnets, loudspeaker magnets, and language lab headphone magnets, may affect the valve setting when placed close to the valve.
- Magnetic fields generated from microwaves, high-tension wires, electric motors, transformers, etc., do not affect the valve setting.

Read *MRI Information* before performing an MRI procedure on a patient implanted with the programmable valve.

Any magnet may experience a degradation of magnetic field strength as a consequence of exposure to the significantly stronger magnet field induced in an MRI procedure.

- Based on the coercivity of the CHPV magnet material, the valve is resistant to magnetic degradation in a 1.5T MRI.
- Testing of the CHPV valve following exposure to 10 simulated MRI procedures at 3T indicates there may be demagnetization that, subsequently, could lead to a reduction in the ability to program the valve. Please refer to Troubleshooting section should any difficulty in programming occur.

The SiphonGuard Device is intended to reduce the rapid flow of CSF. It also reduces the ability to prime the shunt system during implantation to a rate of approximately 0.5 mL/minute.

Precautions

The programmable valves are supplied without a specific programmed pressure and must be programmed prior to use.

Inspect the sterile package carefully. Do not use if:

- the package or seal appears damaged,
- contents appear damaged, or
- the expiry date has passed.

This is an adjustable valve and the surgeon must take that into account when evaluating patients. It is important to verify the current pressure setting as part of any treatment plan.

Do not allow the programming unit or transmitter unit to remain in environmental extremes.

After exposure of the programming unit or the transmitter unit to environmental extremes, such as those found in transport or storage, allow the unit to come within operating range before operating.

Do not program the valve on a metal surface, such as a Mayo stand.

While becoming familiar with valve programming, it is recommended that the pressure setting of the implanted valve be changed in increments of no more than ±40 mm H_2O (392 Pa) in a 24-hour period. Patients whose pressure setting has been changed should be carefully monitored during the first 24 hours post programming. It is recommended that x-rays be taken to confirm the changes made to valve pressure setting.

Before use, check the programming unit and transmitter unit connections, settings, and function (see *Preimplantation Programming Familiarization Procedure*).

Use only Integra branded programmers to program the pressure of the Codman Hakim Programmable Valve.

Unauthorized modifications to the programming unit or transmitter unit may cause a malfunction that could result in serious patient injury or death.

Electrical shock hazard: Do not open the programming unit or transmitter unit. Refer servicing to qualified service personnel.

Explosion hazard: Do not use the programming unit in the presence of flammable materials; i.e., anesthetics, solvents, cleaning agents, and endogenous gases.

Before turning on the 100/120, 220/240 VAC programming unit (catalog no. 82-3121 or 82-3190), verify that the supply voltage selector on the rear of the unit is set to the correct voltage for the electrical outlet.

Do not move the transmitter unit during programming.

Never immerse the programming unit or the transmitter unit in any liquid.

Do not sterilize the programming unit or the transmitter.

Use only with components compatible with the dimensions shown in the *Device Description* section.

Aseptic technique is necessary in all phases of the use of this product.

Silicone has a low cut and tear resistance; therefore, exercise care when placing ligatures so as not to tie them too tightly. The use of stainless steel ligatures on silicone rubber is not recommended.

Do not use sharp instruments when handling the silicone valve or catheter; use shod forceps. Cuts or abrasions from sharp instruments may rupture or tear the silicone components.

Do not fold or bend the valve during insertion. Incorrect insertion may cause rupture of the silicone housing.

To better stabilize the position of the valve underneath the scalp, proper valve placement is required. Place the flat underside of the valve against the bone, with the round top surface facing upward.

Verify proper placement and integrity of ligatures at all tubing junctions to prevent obstruction of the catheter lumen and tears or abrasions of the silicone tubing.

Do not fill, flush, or pump the valve with fluid in which cotton, gauze, or other lint-releasing material has been soaked.

Exercise extreme care to prevent the silicone components of the system from coming in contact with bare fingers, towels, drapes, talc, or any linty or granular surfaces. Silicone rubber is highly electrostatic and, as a result, attracts airborne particles and surface contaminants that could produce tissue reaction.

After implantation, avoid unnecessary pumping of the prechamber and pumping chamber to prevent rapid alteration of the intraventricular pressure.

Cylindrical Valves only: Before closing the scalp incision (or mastoidal incision, if a two-step passage technique is employed), confirm that the direction-of-flow arrow on the valve faces up.

MR Conditional

MR

MRI Safety Information

Non-clinical testing has demonstrated that the Codman Hakim Programmable Valves are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 or 3 Tesla.
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg (First Level Controlled Operating Mode).

MRI Related Heating

Under the scan conditions defined above, the Codman Hakim Programmable Valve is expected to produce a maximum temperature rise of less than 4.0°C after 15 minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the device extends approximately 47 mm from the Codman Hakim Programmable Valve when imaged with a gradient echo pulse sequence and a 3-Tesla MRI system.

Device Description

Programmable Valve Operating Pressure

30 to 200 mm H_2O (294 to 1960 Pa) programmable in steps of 10 mm H_2O (98 Pa)

Programmable Valve Configurations

In-line with SiphonGuard Device
In-line with SiphonGuard Device and Platform with Proximal Tube
In-line
Right Angle with SiphonGuard Device
Right Angle
Cylindrical with Prechamber
Cylindrical with Rickham® Reservoir
Cylindrical
Micro with Rickham Reservoir
Micro

Codman Hakim In-line and Right Angle Valves include a programmable valve with a low profile and flat bottom, and an in-line or right angle integral reservoir with or without SiphonGuard.

Codman Hakim Cylindrical Valves include a programmable valve, a pumping chamber, and an outlet valve available with a prechamber, without a prechamber, or with a Rickham reservoir.

Codman Hakim Micro Valves include a programmable valve with or without an integral Rickham reservoir.

All programmable valve configurations are designed for use with components having the following dimensions:

Component	Inner Diameter	Outer Diameter
Ventricular Catheter	1.4 mm	2.7 mm
Drainage Catheter	1.0 mm	2.2 mm

SiphonGuard Device

CSF flows through the inlet valve and enters the SiphonGuard Device, where it flows into two internal passages. Under normal conditions, the majority of CSF flows through a central ruby ball and cone valve, and exits directly out of the distal port of the SiphonGuard Device. The ball is balanced between a spiral 316L stainless steel spring and a flat 316L stainless steel spring. The remaining CSF travels through a spiral passage that surrounds the central passage, and joins the fluid passing through the central passage, distal to the ball and cone valve.

A sudden increase in CSF flow will compress the spring to close the ball and cone valve, and the entire volume of CSF will be forced through the longer secondary passage, effectively slowing the rate at which CSF is shunted from the brain. Once the flow rate entering the SiphonGuard Device decreases, the flat spring will separate the ruby ball from the valve seat, opening the central passage. As long as CSF continues to be shunted from the ventricles, flow through the spiral passage of the SiphonGuard Device never stops, regardless of the patient's position.

Note: The SiphonGuard Device will not activate at low CSF flow rates.

The SiphonGuard Device has a rigid enclosing shell of polysulfone to prevent inadvertent closure (and subsequent reduction or blockage of CSF flow) caused by externally applied pressure.

How Supplied

The **Valve** includes a programmable valve, instructions for use, straight connector(s)*, introducer**, and priming adapter***.

The **Valve System** includes a programmable valve, 14 cm ventricular catheter, 120 cm peritoneal catheter, instructions for use, right angle adapter, and priming adapter***.

The **Valve System, Unitized**, includes a programmable valve, 14 cm ventricular catheter, 85 cm slit**** or 120 cm unitized peritoneal catheter, instructions for use, straight connector(s)*, introducer**, right angle adapter, and priming adapter***.

* Straight connectors provided with Cylindrical, Micro, and In-line with SiphonGuard and Platform with Proximal Tube versions only.

** Introducers provided with Cylindrical versions only.

*** Priming adapter provided with In-line, Right Angle, and Micro versions only.

**** 85 cm slit catheter packaged with 82-3853 only.

Components and Accessories

Valve Programmer

The valve programmer, available in 100/120 or 220/240 VAC, is supplied with a transmitter head, transmitter cord, and carrying case. The programmer is sold nonsterile and available separately. The programmer is required for changing the pressure setting of the valves.

Ventricular Catheter and Right Angle Adapter (Figure 3)

The ventricular catheter is a 14 cm straight ventricular catheter molded of radiopaque silicone elastomer with x-ray detectable dots and a preassembled stainless steel introducing stylet. The stylet provides structural support during insertion of the catheter into the brain ventricle. Once the desired depth is achieved, the stylet is to be removed from the catheter. A slight grip should be applied to the catheter to prevent undesired migration during removal of the stylet.

The right angle adapter, made of Prolene® Material, allows 90 degree bending of the ventricular catheter at the burr hole site.

Priming Adapter (Figure 4)

The priming adapter, provided with the In-line, Right Angle, and Micro Valves, facilitates preimplantation irrigation to the valve and catheters.

Straight Connector

The straight connector joins the proximal and distal catheters to the valve.

Valve Introducer

A disposable polyethylene valve introducer is supplied to aid in passing the valve and drainage catheter from the burr hole site to a mastoidal incision, when a two-step passage technique is used. Because of the malleability of this introducer, it can be preformed to a desired curvature prior to valve placement.

Sterility

This device is intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Integra will not be responsible for any product that is resterilized, nor accept for credit or exchange any product that has been opened but not used.

Integra single-use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminates such as Classic Creutzfeldt-Jakob Disease. Reuse can compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

As long as the individual package is not opened, damaged, or past its expiration, the product is sterile.

The following components have been tested and were determined to be nonpyrogenic:

Valve, In-line with SiphonGuard Device
Valve, In-line with SiphonGuard Device and Platform with Proximal Tube
Valve, In-line
Valve, Right Angle with SiphonGuard Device
Valve, Right Angle
Valve, Cylindrical with Prechamber
Valve, Cylindrical with Rickham Reservoir
Valve, Cylindrical
Valve, Micro with Rickham Reservoir
Valve, Micro
Peritoneal Catheter
Ventricular Catheter
Priming Adapter
Right Angle Adapter
Straight Connector

Preimplantation Performance Testing

Each Codman Hakim Programmable Valve is individually tested on a component level to ensure conformance to the advertised performance characteristics. Each valve is dynamically tested at six different settings for proper dynamic opening pressure over the entire performance range.

Performing a manometer test is not recommended, as it is susceptible to environmental factors. Manometer testing yields a result that is not physiologic in nature and for which manufacturers do not specify performance ranges. If the surgeon insists upon performing manometer testing for confirmation of Codman Hakim Valve closing pressures, it is possible, but is not recommended. When performed correctly, manometer testing generates valve closing pressures similar to the Codman Hakim Valve opening pressure setting. However, closing pressure results will typically vary noticeably from the opening pressure setting.

For those surgeons who wish to perform functional testing, please see *Preimplantation Performance Testing* in the Appendix.

Programming the Programmable Valve

Programmer Information

WARNING: The Codman Hakim Programmable Valves are supplied without a specific programmed pressure and must be programmed prior to implantation.

Programming must be performed prior to implantation through the nonsterile outer package. Perform programming postoperatively as needed.

The programmer consists of two parts, the programming unit and the transmitter unit. The programming unit control panel (Figure 5) features a power switch, programming instructions, and a representation of the programmable portion of the valve system as it appears when x-rayed. This representation also incorporates the 18 pressure selection buttons. Eighteen LEDs, corresponding to the position of the valve pressure indicator when viewed on x-ray, confirm the pressure setting chosen.

After depressing the desired pressure selector button, an LED lights in the programming unit. The lighted LED corresponds exactly with the position of the pressure indicator on the valve. When programming begins, the transmitter unit emits a sequentially coded electromagnetic signal. The stepper motor of the valve detects the signal and rotates the cam assembly, which, in turn adjusts the tension of the spring to the selected pressure setting.

Transmitter Information

Note: This Transmitter Information is for the Codman Hakim Programmers **ONLY**. When using another Integra programmer, please refer to the instructions for use packaged with your programmer.

The transmitter unit (Figure 6) incorporates an illuminated center hole and directional arrows to aid in proper positioning over the valve. It connects to the programming unit via a pronged plug and is activated by the START button.

Preimplantation Programming Familiarization Procedure

To become familiar with valve programming, perform the following preimplantation programming procedure while the valve remains in the blister package.

1. Insert the pronged plug from the transmitter unit into the receptacle at the back of the programming unit.
2. Plug the power cord from the programming unit into an appropriate power source.

   Note: The instructions contained in steps 3 through 6 are for the Codman Hakim Programmers **ONLY**. When using another Integra programmer, please refer to the instructions for use packaged with your programmer.
3. Press the programming unit's power button to the ON position. Both the ON button and Instruction 1 on the panel will illuminate. Press the desired pressure selection button; Instruction 2 illuminates.
4. Place the transmitter unit's four prongs in the four depressions in the blister around the inlet valve. Point the arrow on the transmitter unit in the same direction as the arrow on the blister (the direction of flow). Look through the illuminated center hole of the transmitter unit.

   CAUTION: Do not move the transmitter unit during programming.
5. Push the transmitter unit's START button. Instruction 3 on the control panel illuminates. During programming, the pressure selector buttons light sequentially until the selected pressure setting is attained.
6. When programming is completed (approximately five seconds), Instruction 4 on the panel illuminates momentarily and a buzzer sounds.

Postimplantation Programming Procedure

1. Insert the pronged plug from the transmitter unit into the receptacle at the back of the programming unit.
2. Plug the power cord from the programming unit into an appropriate power source.
3. Prior to programming, it is advisable to take an x-ray of the patient's head to verify the valve's pressure setting and position.

   Note: The instructions contained in steps 4 through 11 are for the Codman Hakim Programmers **ONLY**. When using another Integra programmer, please refer to the instructions for use packaged with your programmer.
4. Press the programming unit's power button ON. The ON button and Instruction 1 on the panel illuminate. Press the desired pressure selection button; Instruction 2 on the programmer panel and the center hole of the transmitter unit will illuminate.
5. **Note:** It is not necessary to shave the scalp for this procedure. Palpate the scalp to locate the implanted valve, specifically, the inlet valve, located distal of the reservoir. A fluoroscopic screen may assist in this process. Place the tip of the left forefinger precisely over the inlet valve, keeping the index finger parallel to the valve system and pointing in the direction of flow (Figure 7).
6. Place the transmitter unit's four prongs around the inlet valve so that the prongs are sitting on the scalp. The arrows on the transmitter unit should be parallel to the forefinger and pointing in the direction of flow (Figure 8).
7. Center the transmitter unit so that the illuminated opening is directly above the nail of the index finger (Figure 9).
8. Remove finger from the valve and push the transmitter unit's START button (Figure 10). Instruction 3 on the control panel illuminates, indicating that the valve is programming.

   CAUTION: Do not move the transmitter unit during programming.
9. During programming, the pressure selector buttons light sequentially until the selected pressure setting is attained.
10. When programming is completed (approximately five seconds), Instruction 4 on the panel illuminates momentarily and a buzzer sounds.
11. Verify the valve pressure setting with an x-ray.

X-Raying the Valve

Note: The instructions contained in *X-Raying the Valve* are for the Codman Hakim Programmers **ONLY**. When using another Integra programmer, please refer to the instructions for use packaged with your programmer.

It is advisable to x-ray the complete system immediately after implantation to have a permanent record of component placement and to verify valve pressure. It is also advisable to x-ray the valve whenever valve pressure is reprogrammed.

Use an x-ray with intensifying TV screen, or an x-ray plate to confirm proper valve pressure. When documenting the valve pressure with x-rays, take care when positioning so that:

- the nonimplanted side of the head rests on the plate (the implanted side is uppermost from the plate), and,
- the inlet valve is parallel to the x-ray plate.

Viewing the x-ray, the white marker on the valve indicates the right-hand side of the valve. The pressure indicator on the white ring indicates the chosen pressure setting (Figure 11).

There is a direct correlation between the position of the programming unit control panel pressure selector buttons and the position of the pressure indicator on the valve as seen when x-rayed. Note that when the valve is programmed to 70, 120, or 170, the pressure indicator aligns with the "X" in the center of the valve (Figure 12).

Programming Procedure in Case of an Inverted Valve

Note: The instructions contained in *Programming Procedure in Case of an Inverted Valve* are for the Codman Hakim Programmers **ONLY**. When using another Integra programmer, please refer to the instructions for use packaged with your programmer.

An inverted valve can be diagnosed on x-ray; the white marker will appear on the left side of the valve, instead of the right side. Programming the inverted valve requires a "double programming" to obtain the desired pressure setting.

1. Program the valve with the valve programmer at the 200 valve pressure setting.
2. Calculate the following: 210 (constant) minus the desired pressure setting equals the programming pressure setting. For example, where 70 is the desired pressure setting: 210 – 70 = 140.
3. Push the button for the programming pressure setting (in this example, 140) on the programmer; hold the transmitter in place for approximately 5 seconds until the confirmation tone is heard. If the surgeon is unsure whether the reprogramming took place, he or she must repeat the complete process, Steps 1 through 3, otherwise the programming will be incorrect.

   Note: When the valve is inverted, pressure settings of 190 and 200 are not possible to program.

Surgical Procedure

There are a variety of surgical techniques, which can be used to place the Codman Hakim Programmable Valves. The surgeon should choose in accordance with his or her own clinical experience and medical judgment.

Irrigation

Hold the valve vertically with the outlet end pointing upward. Using a syringe, or the action of the pumping chamber (if applicable), slowly and gently fill the entire valve system (Figure 13) with pyrogen-free, sterile saline solution or appropriate antibiotic solution. **Note:** A priming adapter with inlet tubing is provided with the In-line, Right Angle, and Micro versions to facilitate irrigation (Cylindrical Valves incorporate a pumping chamber for this purpose).

CAUTION: Do not fill, flush, or pump the valve with fluid in which cotton, gauze, or other lint-releasing material has been soaked.

Once fluid flows from the outlet end of the drainage catheter, occlude the inlet tubing of the valve system with shod forceps close to the ventricular end, and remove the syringe and priming adapter (if applicable).

CAUTION: Avoid any unnecessary pumping of the system to prevent overdrainage of the ventricles. Over irrigation of the valve system may damage the internal mechanism.

Please record the valve lot number on the patient's chart.

Reservoir Access

These instructions apply to the following valve configurations:

In-line with SiphonGuard Device
In-line with SiphonGuard Device and Platform with Proximal Tube
In-line
Right Angle with SiphonGuard Device
Right Angle
Cylindrical with Prechamber
Cylindrical with Rickham Reservoir
Micro with Rickham Reservoir

Pozicija Nr 35, 38

CAUTION: The valve reservoirs are made of silicone elastomer materials that typically exhibit low tear strength. Use care when inserting and removing the needle.

To inhibit coring of the reservoir cap, use a 25-gauge or smaller non-coring needle to penetrate the dome. Insert the needle at an oblique angle to achieve yield of CSF and to prevent the needle point from piercing the ventricular catheter. (Figure 14).

The reservoirs in the In-line and Right Angle valve configurations as well as the housing body of the Cylindrical valve and the pre-chamber (in valves so equipped) can be punctured up to 25 times with a 25-gauge or smaller, non-coring needle.

For multiple punctures of a Rickham reservoir, take care to insert the needle at various locations. Multiple punctures at a single location increase the risk of tearing.

Valve Flushing (Clearing Obstructions)

(Cylindrical with Prechamber Valves only)

To check the patency of the ventricular catheter, occlude the tubing between the prechamber and the valve unit with finger pressure (Figure 15). Press the prechamber. If the prechamber does not compress easily and does not return immediately to its original shape, or if the prechamber compresses easily but does not refill immediately, the ventricular catheter may be occluded. To correct this situation, first allow the prechamber to refill. Then, occlude the tubing between the prechamber and the valve unit with finger pressure and press the prechamber firmly. This forces fluid back through the ventricular catheter, helping to remove the obstruction. If necessary, repeat this procedure.

In some circumstances, the use of a syringe (with 25-gauge non-coring needle) is necessary to remove the obstruction. Occlude the tubing between the prechamber and the valve unit with finger pressure. Using light pressure, inject sterile, nonpyrogenic saline solution into the prechamber (Figure 16).

To test the patency of the tubing between the prechamber and the valve unit, occlude the tubing between the prechamber and the valve unit with pressure. Press and release the prechamber. If the prechamber immediately returns to its original shape after compression, remove finger from the tubing and press the pumping chamber. If the pumping chamber compresses readily but does not immediately return to its original shape, there may be an obstruction between the prechamber and valve unit. To remedy this situation, occlude the tubing between the prechamber and the ventricular catheter (Figure 17). Firmly press the prechamber with the adjoining finger to force fluid forward through the valve unit and drainage catheter. If necessary, repeat.

Occasionally, it may be necessary to use a syringe with 25-gauge non-coring needle to dislodge the obstruction. Occlude the tubing proximal to the prechamber. Using light pressure, inject sterile, nonpyrogenic saline solution into the prechamber (Figure 18).

To test the patency of the valve outlet or drainage catheter, press on the pumping chamber. If the pumping chamber resists compression, the valve outlet or drainage catheter may be obstructed. To dislodge the obstruction, press the valve unit forcefully, then release it to permit the prechamber to refill.

(Non-cylindrical valves without SiphonGuard)

CAUTION: Flushing is not recommended as a method for determining patency. Use clinical judgment and imaging studies or other techniques to confirm suspected cases of shunt malfunction.

To flush the ventricular (proximal) catheter, occlude the catheter distal to the reservoir with finger pressure, then depress the reservoir.

To flush the distal catheter, occlude the catheter proximal to the reservoir with finger pressure, then depress the reservoir.

In general, if one pushes on the reservoir and it does not spring back, then there might be an obstruction in the proximal catheter because the reservoir is not filling with CSF. On the other hand, if the reservoir feels rather stiff and more force is needed to depress it, then the valve and/or distal catheter may be clogged.

Note: While proximal pressure is maintained, reservoir will not refill with fluid.

Note: Flushing the distal catheter cannot be performed with the right-angle valve configuration.

Troubleshooting

If valve function is adversely affected by accumulations of biological matter, it may be possible to dislodge the material and restore proper function through one of the following methods:

- Flushing and/or pumping the valve (only for those valves without SiphonGuard)
- Multiple programming attempts

If these remedial steps fail to rectify the problem, replace the valve.

Disposal

After patient use, the system must be handled as biohazardous material and disposed of in accordance with applicable federal, state, local or international environmental requirements following facility protocols.

APPENDIX

Preimplantation Performance Testing

Although Integra does not recommend functional testing, some surgeons may choose to do so. Before testing, it is extremely important that a Codman Hakim Valve with or without SiphonGuard Device be flushed of all air bubbles. Air bubbles within the Codman Hakim Valve or SiphonGuard Device produce inaccurate manometer test results. The presence of air bubbles can reduce the cross-sectional area of the flow path, increase system resistance, and impede the flow of fluid through the system during testing.

SiphonGuard Device Functional Testing

Equipment Required (use all sterile equipment, perform testing under sterile conditions)
One manometer, wide-bore (e.g. 3.5 mm), graduated in mm (available in lengths from 38 to 60 cm)
One 4-way stopcock
One syringe, 5 mL
One syringe filter, 5 µm

Tubing adapters
Silicone tubing
One male luer connector with 1/16 in. barb
Saline solution

Flushing Procedure

Note: At a rate of 0.5 mL/minute, unitized versions require 2–3 minutes to complete flushing. This is the time required for fluid to fill the valve and exit the distal catheter. Allot additional time to ensure the system is free of air bubbles.

1. Assemble manometer, stopcock, syringe, and tubing (Figure A-1).

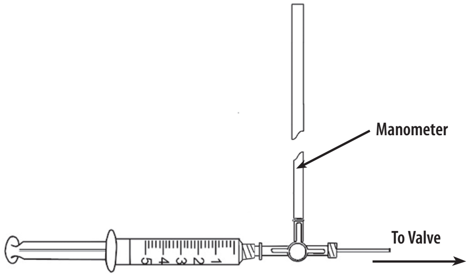


Figure A-1

2. Detach syringe from assembly and fill the syringe with sterile saline solution using the 5 µm filter in-line. Detach the filter after filling the syringe.
3. Set the valve opening pressure to 30 mm H_2O (294 Pa) while the valve remains in its sterile package.
4. Remove valve from the sterile package, and connect the valve to the manometer/syringe assembly.

   Note: Do not attach the distal catheter at this time.
5. Adjust the stopcock to connect the syringe to the valve assembly (Figure A-2).

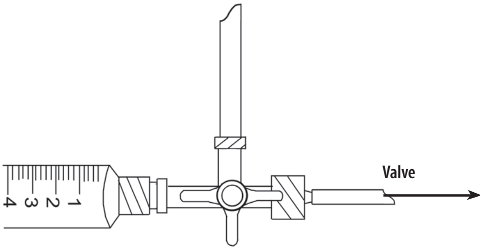


Figure A-2

6. Position the valve vertically to direct the flow of saline upward through the assembly. This orientation aids in flushing air from the system.
7. Using the syringe, gently flush saline through the system while gently depressing the prechamber to purge air bubbles from the valve assembly.
8. Attach the distal catheter and continue to flush the system using the syringe until saline solution exits the end of the distal catheter.

   Note: An excessive flow rate (>0.75 mL/min) activates the SiphonGuard Device and creates the impression that the valve is distally occluded. In reality, flow is being diverted to the high resistance secondary pathway.
9. The device is now ready for *SiphonGuard Device Functional Test* or *Manometer Testing*.

   Note: All valves are susceptible to damage due to excessive flow rate during testing. Take extreme care when flushing a valve as damage can occur when excessive flow rates are used. It is recommended to use a flow rate of no greater than 0.5 mL/min.

SiphonGuard Device Functional Test

Note: This procedure applies only to valves with an integrated SiphonGuard Device.

Note: Perform this procedure immediately after completing the flushing procedure. This procedure is designed to provide visual confirmation of proper functioning of the SiphonGuard Device.

1. Use a full syringe of saline solution attached to the 4-way stopcock to fill the manometer to the top.

2. Turn the stopcock to connect the manometer to the Codman Hakim Valve and SiphonGuard Device (Figure A-3).

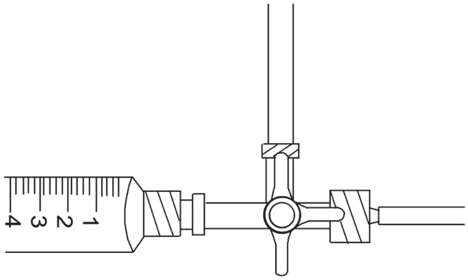


Figure A-3

Note: Attach the distal catheter at this time, flushed free of air bubbles.

3. Bring the end of the distal catheter level with the fluid level in the manometer (Figure A-4).

   Note: The Codman Hakim Valves with SiphonGuard Device must lie on a sterile surface and remain undisturbed for the duration of the test.

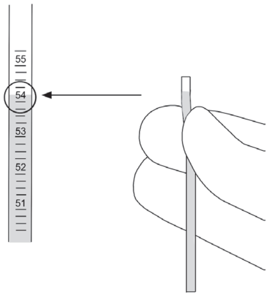


Figure A-4

4. Hold the catheter distal tip adjacent to the manometer and slowly lower the end of the distal catheter until the fluid level in the manometer begins to drop.
5. Continue to lower the catheter tip at a rate that exceeds the drop rate of the fluid level in the manometer. As you do so, you will note a corresponding increase in the rate of descent of the fluid level in the manometer.
6. A point will be reached where the rate of descent of the fluid level in the manometer dramatically decreases, but does NOT stop. This is the point at which the SiphonGuard Device primary pathway closes and flow diverts to the higher resistance secondary pathway. This confirms proper functioning of the SiphonGuard Device.
7. Repeat Steps 3 through 6 as necessary to reconfirm SiphonGuard Device function.
8. Remove distal catheter for manometer testing of valve.

Manometer Testing

Note: Performing a manometer test is not recommended as this test is susceptible to environmental factors and yields a result that is not physiologic in nature and for which manufacturers do not specify performance ranges.

Note: Perform this test only on devices that have been prepared according to Steps 1 through 8 in *Flushing Procedure*.

Equipment Required (use all sterile equipment, perform testing under sterile conditions)
One manometer, wide-bore (e.g. 3.5 mm), graduated in mm (available in lengths from 38 to 60 cm)
One 4-way stopcock
One syringe, 5 mL
One syringe filter, 5 µm
Tubing adapters
Silicone tubing
One male luer connector with 1/16 in. barb
Saline solution

Flushing Procedure

Prepare the valve following Steps 1 through 8 in *SiphonGuard Device Functional Testing, Flushing Procedure*.

Equipment Setup

1. Disconnect the valve from the tubing leading to the stopcock. Perform this step with the valve submerged in a water bath so as not to reintroduce air into the valve.

2. Place the end of the tubing leading from the stopcock into the water bath. Position the tubing so that the end does not come into contact with the sides of the bath.
3. Adjust the manometer height so that the zero level of the manometer and the fluid level in the water bath are at the same level (Figure A-5).

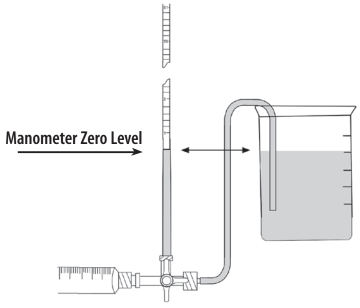


Figure A-5

4. Fill the syringe with saline solution using the syringe filter.
5. Disconnect the filter from the syringe and reconnect the syringe to the stopcock.
6. Turn the stopcock to isolate the valve from the manometer assembly, connecting the syringe to the manometer (Figure A-6).

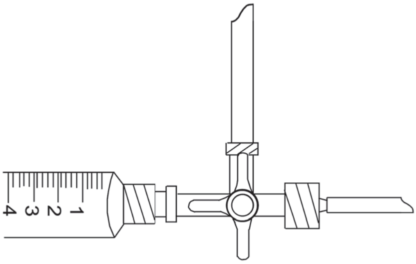


Figure A-6

7. Refill the manometer using the 5 mL syringe.

Zeroing the Manometer

1. After refilling the manometer, turn the stopcock to connect the manometer with the bath (Figure A-7).

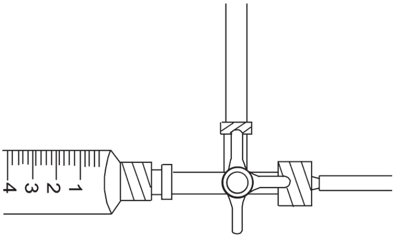


Figure A-7

2. Allow the water column in the manometer to fall. The water column should stop at the zero level of the manometer (Figure A-5).
3. If necessary, adjust the height of the manometer to bring the water level in the manometer to the same level as the fluid in the water bath.

Test Procedure

1. Set the opening pressure of the Codman Hakim Valve to 120 mm H_2O (1176 Pa). [Laboratory testing using ASTM test F647 has shown that the best correlation between manometer closing pressure and dynamic opening pressure is at a setting of 120 mm H_2O (1176 Pa)].
2. Reconnect the sterile valve to the sterile test apparatus. It is recommended that this step be performed under water in the water bath to prevent the reintroduction of air bubbles into the valve.
3. Remove the distal catheter at this time.

   Note: The attachment of a distal catheter can alter the test results as well as increase test time. This is not possible with unitized versions of the Codman Hakim Valve. Allot additional time for testing of unitized versions.

4. Submerge the valve completely in the water bath. For the unitized version, submerge the outlet of the distal catheter in the water bath to obtain accurate results. Confirm that there are no bubbles attached to the tip of the distal catheter and that the water bath does not obstruct the tip of the catheter.
5. Adjust the stopcock to connect the syringe to the manometer (Figure A-6 above) and refill the manometer to a height equal to the opening pressure setting of the Codman Hakim Valve plus 50 mm. If the Codman Hakim Valve is programmed to an opening pressure of 120 mm H_2O (1176 Pa), the height of the fluid in the manometer is 120 mm + 50 mm = 170 mm (17 cm) (1176 Pa + 490 Pa = 1666 Pa). This procedure minimizes the possibility of inadvertently activating the SiphonGuard Device during manometer testing.
6. Turn the stopcock to connect the manometer to the valve (Figure A-7 above).
7. The water column in the manometer will start to fall. Allow the water column to drop for 3–5 minutes or until a steady state is reached. *A steady state is defined as a change of less than 2 mm H_2O (20 Pa) in a 2-minute period*.
8. For valves with SiphonGuard Device, an extended test time is recommended in order to compensate for the possibility of a decreased flow rate due to SiphonGuard Device activation. Allow the water column to drop for 5–7 minutes or until a steady state is achieved.
9. Read the resultant pressure.

Variations between the manometer closing pressure test result and the Codman Hakim Valve setting of as much as ±25 mm H_2O (248 Pa) are possible based upon the test method utilized. Expect the same device to produce opening pressure results within ±10 mm H_2O (98 Pa) of the valve setting utilizing an industry standard test method such as ASTM F647 or ISO 7197.

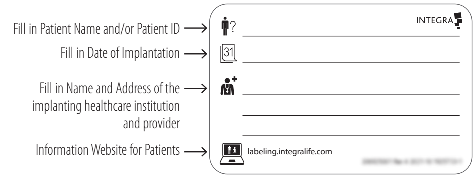
Any serious incident that has occurred in relation to the device for the user and/or the patient should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Summary of Safety and Clinical Performance (SSCP)

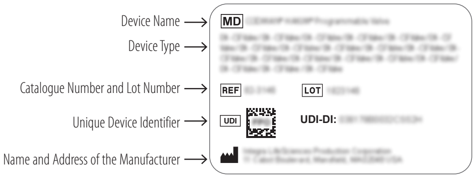
Summary of Safety and Clinical Performance (SSCP) is available upon request and on EUDAMED at https://ec.europa.eu/tools/eudamed.

This device is an implant and is delivered with a patient implant card. The purpose of a patient implant card is to ensure that the patient is aware of the details of the device that they have been implanted with and that you and other healthcare professionals involved in the care of the patient can identify the particular device. Additional information on this device can be found in the patient information leaflet, which can be accessed at www.labeling.integralife.com. Please fill in the information on the patient implant card per the instructions outlined below and provide the patient implant card to the patient or their legally designated representative after completion of the section to be filled by the healthcare professional. Please also direct the patient to the patient information leaflet with the additional information on this device at the website listed above, which is also listed on the patient implant card.

Fill in the front of the card using a ballpoint pen. Do not use pencil.



The back of the card is already pre-populated for your convenience with the following information:



The graphical display is for illustration purposes only and may not be to scale.

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