Right angle design with SIPHONGUARD

A. Side view
B. Top view
C. Inlet connector
D. Reservoir
E. Direction of flow
F. Inlet valve
G. Valve seat
H. Valve ball
I. Spring calibrating fulcrum
J. Flat spring
K. Spring pillar
L. Titanium base plate
M. O-ring
N. Antisiphon device
O. Valve seat
P. Valve ball
Q. Central passage
R. Spiral passage
A. In-line with SIPHONGUARD device
B. In-line
C. Right angle with SIPHONGUARD device
D. Right angle
E. Cylindrical with prechamber
F. Cylindrical
G. Micro with RICKHAM reservoir
H. Micro
3

4

Priming adapter
A. Valve outlet
B. Priming adapter with tubing
C. Nonpyrogenic sterile saline or antibiotic solution
IMPORTANT INFORMATION
Please Read Before Use

CODMAN® HAKIM® Precision Fixed Pressure Valves With BACTISEAL® Catheters

Description
The CODMAN HAKIM Precision Fixed Pressure Valves with BACTISEAL Catheters include a valve mechanism (Figures 1 and 2) that incorporates a flat 316L stainless steel spring in which the calibration is accomplished by a combination between a pillar and a micro-adjustable telescoping fulcrum. The valve chassis is made of titanium. 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 operating pressures of the valve unit have been determined with a flow rate of 10–25 ml H₂O per hour. The valve is classified by its operating pressure with a specified flow rate and not by its opening and closing pressures. The pressure that a valve sustains with a given flow is the parameter that reflects the operating pressure of the valve once it is implanted. Before shipment, each valve is calibrated with special equipment: duplication of these test procedures cannot be accomplished in the operating room.

Several models of the valve have been marked with an x-ray detectable direction-of-flow indicator.

The CODMAN BACTISEAL Catheters are made of radiopaque (barium-impregnated) silicone tubing and are supplied sterile. The catheters are subjected to a treatment process by which the silicone tubing is impregnated with rifampin and clindamycin hydrochloride.

Laboratory studies have shown that BACTISEAL Silicone Catheters reduce the colonization of gram positive bacteria on the tubing surface.

The quantities of rifampin and clindamycin hydrochloride used to impregnate the catheters are only a small fraction of a therapeutic dose of these two antibiotics, and have no potential for systemic therapeutic effect.

Indications
The CODMAN HAKIM Precision Fixed Pressure Valves with BACTISEAL Catheters are implantable devices that provide constant intraventricular pressure and drainage of CSF (cerebrospinal fluid) for the management of hydrocephalus.

Contraindications
This device is not designed, sold, or intended for use except as indicated.

The CODMAN HAKIM Precision Fixed Pressure Valves with BACTISEAL Catheters are not recommended for atrial placement. Use the non-unitized versions for this procedure.
Do not implant this device in patients with active infections, such as ventriculitis, peritonitis, meningitis, or skin infections at or near the implantation site. Treat the infection before implanting this device.

Do not implant this device in patients with known hypersensitivity to rifampin or clindamycin hydrochloride.

Use of this device is contraindicated in patients receiving anticoagulants or known to have a bleeding diathesis.

**WARNINGS**

As with any shunting system, complications such as infection, ventricular and peritoneal obstruction, and damage to the intracranial or intra-abdominal structures may occur in patients in whom this shunt component has been placed.

The valve unit contains components made from titanium and 316L stainless steel. When tested with MRI magnets of up to 1.5 Tesla, the valve produced an insignificant amount of force and torque. This shunt system, as with other implants containing metallic components, may produce an artifact during MRI. The requesting physician must determine whether the location of the artifact will affect the area of interest.

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 cc/minute.

The decision to use the peritoneal catheter in the treatment of a patient who has a history of peritonitis must be made by the physician on a case-by-case basis.

**Precautions**

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

Do not immerse the BACTISEAL Catheter in antibiotic solutions. Only use sterile water or normal saline to immerse the BACTISEAL catheter as other solutions are not recommended and may cause precipitation and consequent adverse effects (e.g., catheter occlusion, hydrocephalus). Keep the time the BACTISEAL catheter is immersed in sterile water or normal saline to a minimum (i.e., seconds) to reduce the risk of introducing infectious agents. A pale orange color may be imparted to the immersion solution. Manometer testing on the CODMAN HAKIM Precision Fixed Pressure Valves with BACTISEAL Catheters is not advised.

This is a fixed pressure valve. It functions on a fixed pressure system within the indicated range.

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 rupture 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 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 black dot on the outlet valve faces up and that the reservoir is placed just distal to the ventricular catheter.

### 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.

Accumulated biological matter (i.e. blood, protein accumulations, tissue fragments, etc.) in the ball/seat interface can interfere with the pressure regulation of the device.

Biological matter can obstruct the ventricular catheter. Also, the ventricular catheter can become obstructed by excessive reduction of ventricle size.

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.

If not properly located in the lateral ventricle, the catheter can become embedded in the ventricular wall or choroid plexus.
Fibrous adhesions may bind the catheter to the adjacent choroid 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.

Bowel perforation, abdominal cysts and pseudocysts, umbilical fistula, simulated acute appendicitis, infection, and ascites have been cited as complications of ventriculoperitoneal shunting in general. In addition, shunt revisions have been necessitated by the following complications associated with peritoneal catheters: subcutaneous kinking, fracture, obstruction of the distal end, and retraction of the distal end from the peritoneal cavity.

**Device Description**

**Precision Fixed Pressure Valve**

Precision Fixed Pressure Valves have a preset pressure, available in five ranges. The valve pressure range is identified by an x-ray detectable dot code applied to the valve. These codes are as follows:

<table>
<thead>
<tr>
<th>Operating Pressures</th>
<th>Dot Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mm H₂O (98 Pa) – Very Low Range</td>
<td>•</td>
</tr>
<tr>
<td>40 mm H₂O (392 Pa) – Low Range</td>
<td>••</td>
</tr>
<tr>
<td>70 mm H₂O (686 Pa) – Medium Low Range</td>
<td>•••</td>
</tr>
<tr>
<td>100 mm H₂O (980 Pa) – Medium High Range</td>
<td>••••</td>
</tr>
<tr>
<td>130 mm H₂O (1274 Pa) – High Range</td>
<td>•••••</td>
</tr>
</tbody>
</table>

**Precision Fixed Pressure Valve Configurations**

- In-line with SIPHONGUARD Device
- In-line
- Right Angle with SIPHONGUARD Device
- Right Angle
- Cylindrical with Prechamber
- Cylindrical Micro with RICKHAM® Reservoir
- Micro

**CODMAN HAKIM In-line and Right Angle Valves** include a precision fixed pressure valve with a low profile and flat bottom, and an in-line or right angle integral reservoir, with or without SIPHONGUARD Device.

**CODMAN HAKIM Cylindrical Valves** include a precision fixed pressure valve, a pumping chamber, and an outlet valve with or without a pre chamber.

**CODMAN HAKIM Micro Valves** include a precision fixed pressure valve with or without a RICKHAM Reservoir.
All precision fixed pressure valve configurations are designed for use with components having the following dimensions:

<table>
<thead>
<tr>
<th>Component</th>
<th>Inner Diameter</th>
<th>Outer Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventricular Catheter:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barium</td>
<td>1.4 mm</td>
<td>2.7 mm</td>
</tr>
<tr>
<td>Clear with Barium Stripe</td>
<td>1.2 mm</td>
<td>2.5 mm</td>
</tr>
<tr>
<td>Peritoneal Catheter:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barium</td>
<td>1.0 mm</td>
<td>2.2 mm</td>
</tr>
<tr>
<td>Clear with Barium Stripe</td>
<td>1.2 mm</td>
<td>2.5 mm</td>
</tr>
</tbody>
</table>

How Supplied
The CODMAN HAKIM Precision Fixed Pressure Valves with BACTISEAL Catheters include a precision fixed pressure valve, 14 cm ventricular catheter with stylet, 120 cm unitized peritoneal catheter, instructions for use, straight connectors*, right angle adapter**, and priming adapter***.

* Straight connectors provided with Cylindrical and Micro versions only
** Right Angle adapter provided with Cylindrical, In-line, and Micro w/o RICKHAM Reservoir versions only
*** Priming adapter provided with In-line, Right Angle, and Micro versions only

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 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 close the ball and cone valve and the entire volume of CSF will be forced through the longer spiral passage, effectively slowing the rate at which CSF is shunted from the brain. Once the flow rate entering the SIPHONGUARD Device decreases, the ruby ball separates 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 polyethersulfone to prevent inadvertent closure (and subsequent reduction or blockage of CSF flow) caused by externally applied pressure.

Components and Accessories
Ventricular Catheter
The ventricular catheter supplied with your precision fixed pressure valve is either barium or clear with a barium stripe. The barium catheter is 14 cm long and has 24 inlet holes (3 rows of 8 holes) at the proximal end. The clear catheter with a barium stripe is 14 cm long and has 40 inlet holes (4 rows of 10 holes) at the proximal end. Depth marks have been added to the
catheter (one dot at 5 cm and two dots at 10 cm).

Peritoneal Catheter
The peritoneal catheter is 120 cm long. It may be trimmed to the proper length.

Right Angle Adapter (Figure 3)
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. trimmed to the proper length.

Straight Connector
The straight connector joins the proximal and distal catheters to the Cylindrical and Micro Valves.

CODMAN Catheter Passer
Catheter passers [catalog no. 82-1515, 82-1516, and 82-1517] are available separately. They are recommended for passing the catheter from the abdominal incision to the scalp incision.

Sterility
The CODMAN HAKIM Precision Fixed Pressure Valves with BACTISEAL Catheters are intended for SINGLE USE ONLY; DO NOT RESTERILIZE. Use aseptic technique in all phases of handling. Codman & Shurtleff 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.

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

The following components have been tested and were determined to be nonpyrogenic:
- Valve, Cylindrical
- Valve, Cylindrical with Prechamber
- Valve, Micro
- Valve, Micro with RICKHAM Reservoir
- Valve, In-line
- Valve, In-line with Unitized Distal Catheter
- Valve, In-line with SIPHONGUARD Device
- Valve, Right Angle
- Valve, Right Angle with Unitized Distal Catheter
- Valve, Right Angle with SIPHONGUARD Device
- Priming Adapter
- Right Angle Adapter
- 120 cm Unitized BACTISEAL Peritoneal Catheter
- Ventricular Catheter
- Straight Connector

Storage
Store this product between 2°C (36°F) and 27°C (81°F), away from direct light. Do not remove the product from the packaging until it will be used.

The shelf life of this product is one year from the date of sterilization. The “Use By” date is indicated on the labeling.

Preimplantation Performance Testing
The CODMAN HAKIM Precision Fixed Pressure Valves
with BACTISEAL Catheters are individually tested on a component level to ensure conformance to the advertised performance characteristics. Each valve is calibrated at its prescribed opening pressure during manufacture.

**Surgical Procedure**

There are a variety of surgical techniques that can be used to place CODMAN HAKIM Precision Fixed Pressure Valves with BACTISEAL Catheters. The surgeon must choose a technique 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 5) with nonpyrogenic, sterile saline solution. Note: A priming adapter is provided with the In-line, Right Angle, and Micro Valve 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.

**WARNING:** 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 cc/minute.

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 unnecessary pumping of the system to prevent over drainage of the ventricles. Over-irrigation of the valve system may damage the internal mechanism.

Record the valve serial number on the patient’s chart.

**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 6). 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 HUBER® Point 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 7).

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 8). 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 HUBER Point Needle to dislodge the obstruction. Occlude the tubing proximal to the prechamber. Using light pressure, inject sterile, nonpyrogenic saline solution into the prechamber (Figure 9).

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.

**Reservoir Injection** *(Cylindrical with prechamber Valves)*

To inhibit coring of the reservoir cap, use a HUBER Point Needle (24-or 26-gauge) to penetrate the dome. Insert the needle at an oblique angle to achieve the greatest yield of CSF and to prevent the needle point from piercing the ventricular catheter (Figure 10).

**Troubleshooting**

If valve function is adversely affected by accumulations of biological matter, it may be possible to dislodge the material and restore proper function on a valve without SIPHONGUARD Device by flushing and/or pumping the valve. If this remedial step fails to rectify the problem, replace the valve.

**Warranty**

Integra LifeSciences, warrants that this medical device is free from defects in both materials and workmanship. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Suitability for use of this medical device for any particular surgical procedure should be determined by the user in conformance with the manufacturer's instructions for use. There are no warranties that extend beyond the description on the face hereof.

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Do not resterilize
Do not use if package is damaged
Prescription device only (USA)
Manufacturer

Made in
Nonpyrogenic, see instructions for use
Temperature Limit
Quantity
Sterilized using steam

Do not reuse
Caution
Consult instructions for use