INTEGRA NEUROSCIENCES™

Instructions for Use - Mode d'emploi - Gebrauchsanleitung
Istruzioni per l'uso - Instrucciones de uso - Instruções de utilização

HYDROCEPHALUS PRESSURE CONTROL VALVE SYSTEMS - HAKIM VALVE SYSTEMS[1] - OMNISHUNT® VALVE SYSTEMS[1,2]

Systèmes de valve à pression régulée pour l'hydrocéphalie - Valves Hakim[1] - Valves Omnishunt[1,2] ; Hydrozephalus-DruckKontrol-Ventilsysteme, Hakim-VentilSysteme[1] , Omnishunt VentilSysteme[1,2] ; Sistemi a valvola per il controllo della pressione nell'idrocefalo - Sistemi a valvola Hakim[1] - Sistemi a valvola Omnishunt[1,2] ; Sistemas de Válvula por control de presión para Hidrocefalia - Sistemas de válvula Hakim[1] - Sistemas de válvula Omnishunt[1,2] ; Sistemas de válvula para controle da pressão hidrocefálica- Sistemas de válvula Hakim[1]- Sistemas de válvula Omnishunt[1,2]

1. Incorporating the original Hakim valve mechanism - Incorporant le mécanisme original Hakim - Mit Standard-Hakim Ventilmechanismus - Incorpora la valvola originale Hakim - Incluyendo el mecanismo original de válvula Hakim - Inclui o mecanismo de válvula original de Hakim
2. Developed in conjunction with Marion L.Walker, M.D., Primary Children's Hospital, Salt Lake City, Utah.

MADE BY / Fabriqué par / Hergestellt von /
Prodotto da / Manufacturado por / Fabricado por
Integra NeuroSciences Implants S.A.
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06921 Sophia Antipolis Cedex, **FRANCE**

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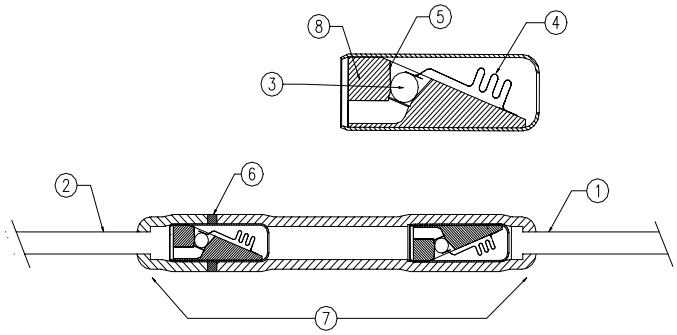
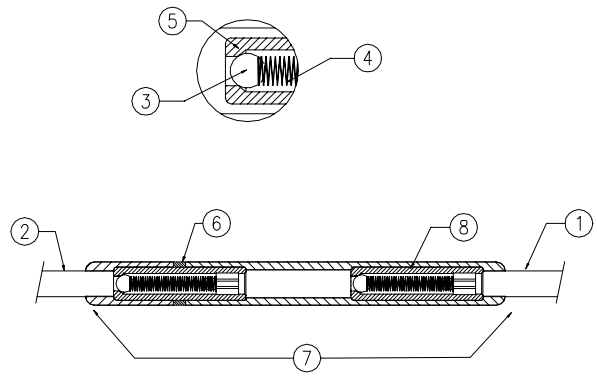
Figure 1. Valve components - Composants de la valve - Komponenten des Ventils
Componenti della valvola - Componentes de la válvula - Componentes da válvula



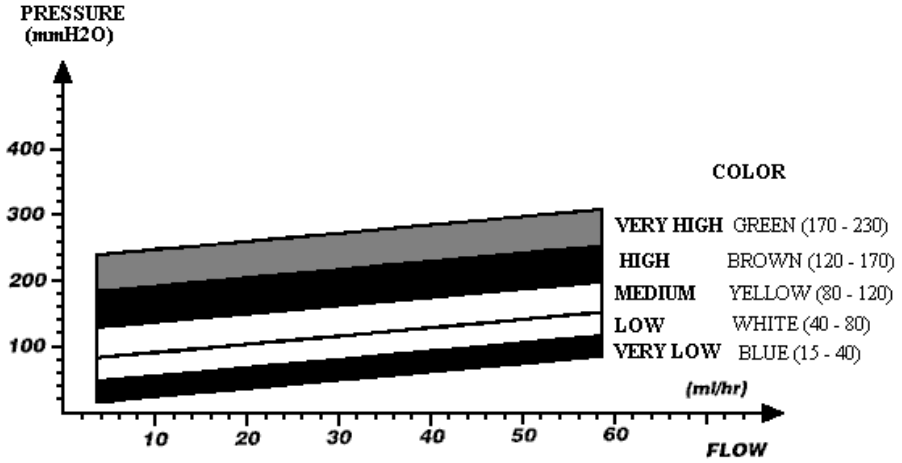
Standard Configuration - Configuration standard - Standard-Konfiguration - Configurazione standard –Configuración estándar - sistema de válvula padrão.



Pediatric Configuration - Configuration pédiatrique - Pädiatrische Konfiguration - Configurazione pediatrica - Configuración pediátrica - sistema de válvula pediátrica.

- Radiopaque open-ended drainage catheter with slits - Cathéter péritonéal radiopaque à extrémité distale ouverte et à fentes distales multiples - Röntgensichtbarer Drainagekatheter mit offenem Ende und Schlitzen - Catetere di drenaggio radiopaco a punta aperta con fessure - Catéter de drenaje radioopaco de extremo abierto con ranuras - Cateter de drenagem radiopaco de extremidade aberta com ranhuras
- Inlet tubing - Tubulure d'entrée - Ventileinlaß - Tubicino di ingresso - Tubos de entrada - Tubagem de entrada
- Ruby ball - Bille en rubis - Kugel aus synthetischem Rubin - Pallina di rubino - Bola de rubí - Esfera de rubi
- Spring - Ressort - Federmechanismus - Molla - Resorte - Mola
- Cone-shaped seat - Siège conique - Konusförmiger Kugelsitz - Alloggiamento a cono - Asiento en forma de cono - Assento em forma de cone
- Color-coded band - Anneau de couleur - Farbcodierung - Banda colorata - Banda código de colores - Código de cores
- Valve unit - Valve - Ventileinheit - Unità valvolare - Válvula - Válvula
- Valve housing - Corps de la valve - Zylinder mit Ventilmechanismus - Alloggiamento della valvola - Cubierta de la válvula - Invólucro da válvula

Figure 2. Pressure/Flow Characteristics- Caractéristiques de pression/débit - Druck-/Flußeigenschaften
Caratteristiche flusso/pressione - Caracteristicas de Presión/Flujo - Características de pressão/fluxo



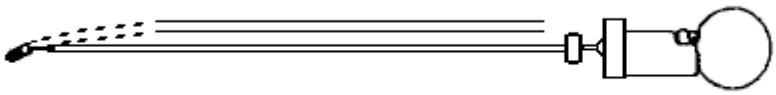


Figure 3. Ventricular Catheter Introducer - Introducteur de cathéter ventriculaire – Einführhrstab eines Ventrikelkatheters - Introduttore del catetere ventricolare - Introductor del Catéter Ventricular - Introdutor de cateter ventricular.

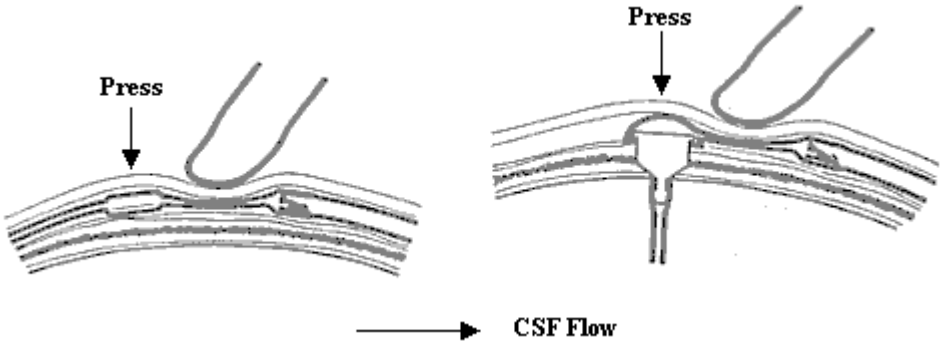


Figure 4. Pumping method of unclogging the ventricular catheter - Méthode de pompage pour déboucher le cathéter ventriculaire - Pumpüberprüfung des Katheterschenkels zwischen Ventrikel und Ventrileinlaß - Metodo di pompaggio per la disostruzione del catetere ventricolare - Sistema de bombeo para desobstruir el Catéter Ventricular.

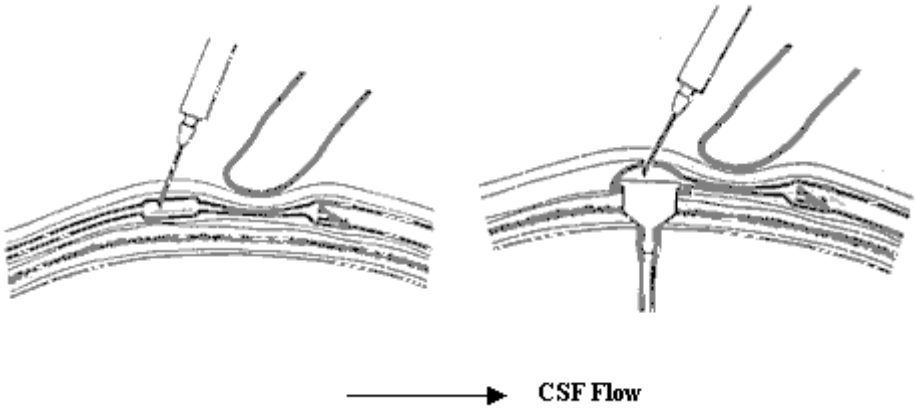


Figure 5. Syringe method of unclogging the ventricular catheter - Méthode d'injection pour déboucher le cathéter ventriculaire - Möglichkeit der Beseitigung von Okklusionen Im Ventrikelkatheterbereich mit Hilfe einer Spritze - Uso della siringa per la disostruzione del catetere ventricolare – Metodo de Jeringa para desobstruir el catéter ventricular.

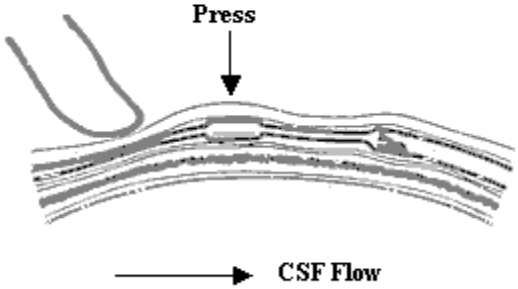


Figure 6. Forcing fluid toward valve unit and drainage catheter - Méthode pour forcer le LCR à travers la valve et le cathéter distal - Pumpen von CSF durch die Ventileinheit und den Drainagekatheter - Spinta del liquido verso l'unità valvolare e il catetere di drenaggio - Forzando el liquido hacia la válvula y el catéter de drenaje.

Sterile - Sterilized with ethylene oxide gas. Non pyrogenic. For single use only. Do not use open or damaged packages. Do not resterilize. Rx only.

WARRANTY DISCLAIMER AND LIMITATION OF REMEDY

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Descriptions and specifications appearing in Integra NeuroSciences printed matter, including this publication, are meant solely to generally describe the product at the time of manufacture and do not constitute any express warranties. Integra NeuroSciences hydrocephalus valve systems, components and accessories are designed to perform reliably over an extended period of time. However, any implanted component may have to be replaced at any time because of failure or for medical reasons, and the patient and/or the patient's family should be made aware of this possibility.

Note: After implantation, complete the patient identification card for the patient or family.

Product returns to Integra NeuroSciences: Contact your local Representative for instructions on return of products.

INDICATIONS

Integra NeuroSciences valve systems are implantable devices which serve as a parallel flow pathway to divert cerebrospinal fluid (CSF) from the cerebral ventricles to an appropriate drainage site. They provide controlled intraventricular pressure and CSF drainage in patients with hydrocephalus or other conditions in which CSF flow and/or absorption is impaired. The very low pressure valve (blue band) is used for postoperative drainage of hygromas and other extraventricular conditions.

CONTRAINDICATIONS

Integra NeuroSciences hydrocephalus valve systems and components should not be used when an infection exists along the shunt pathway (meningitis, ventriculitis, peritonitis, septicemia and/or bacteremia). Postponement of shunt or component implantation is advisable if infection is present anywhere in the body. The use of the ventriculoatrial approach is contraindicated in patients with serious heart or cardiopulmonary disease.

SIDE EFFECTS

- In addition to the risks associated with shunt system or component implantation, major complications include mechanical failure, such as tubing fracture, material deterioration with time, or shunt pathway obstruction, infection, reaction to materials, and CSF leakage along the shunt pathway. System disconnection can lead to catheter migration into the atrium, peritoneum or lateral ventricles.
- Ventricular shunting has been associated with epilepsy, and shunt dependency. Intracranial hypertension syndrome is a specific result of obstruction. Overdrainage may result in subdural hematomas, craniostenosis, intracranial hypotension syndrome or sunken fontanelles (in infants).
- Shunt system failure should be suspected if any of these is noted: Continuing symptoms of hydrocephalus; CSF leakage; redness, tenderness or erosion of the skin along the shunt pathway. These complications require prompt replacement of the shunt system or affected component(s).
- Low-grade bacterial colonization may cause recurrent fevers, anemias, splenomegaly, shunt nephritis or pulmonary hypertension.
- With atrial catheterization, the possibility of clot formation around the atrial catheter tip could lead to pulmonary tree embolization.
- Perforation of an abdominal viscus is a rare complication of ventriculoperitoneal shunts.

PRECAUTIONS

This product is recommended for single use only. Do not implant explanted systems or components in another patient. *This product is sterilized with ethylene oxide. Do not use if the package is open or damaged. Use the device prior to the "Use Before" date on the package label.* **Caution - Do not resterilize. Integra NeuroSciences will not be liable for any direct, indirect, incidental or consequential damages resulting from or related to resterilization.**

- Closely observe patients with an implanted valve system for shunt failure symptoms (see "Side Effects").

- Have duplicates of each component available during implantation.
- Avoid nicking the tubing. Cover forceps and clamp jaws with silicone elastomer tubing.
- Do not lubricate valves. They will be lubricated adequately by the CSF.
- Do not pump the valve unit, antechamber or Burr hole reservoir unnecessarily.
- Avoid contaminants such as glove talc and contact with skin oils when handling tubing.
- Any modification or manipulation of the device, other than trimming catheters or valve tubing, may result in the failure of the device to function as originally intended.

SYSTEMS DESCRIPTION

Hydrocephalus pressure control valve systems provide differential pressure control by draining CSF from the cerebral ventricles to the peritoneal cavity (or another appropriate drainage site). A variety of system configurations are available (Standard Valve Systems, Pediatric Valve Systems, Integral Shunt Systems, Valve Unit only, Omnishunt Valve Systems). Each valve system includes all the necessary radiopaque components required for an implantation procedure (see on label). Marked ventricular catheters feature radiopaque length markings at 2 cm intervals from the tip. Several color-coded pressure ranges are offered (see figure 2, page 2).

Valve Operation (see figure 1, page 2)

The valve unit consists of the original Hakim valve mechanism(s) (one or two) in a silicone elastomer chamber. In each mechanism, a ruby ball is held against a cone-shaped seat by a spring, calibrated to determine the operating pressure range. Each valve unit is color-coded according to its measured average pressure value (see "Pressure Ranges"). **Note**: the Omnishunt System contains only one original Hakim Valve mechanism.

Implanted materials : The product may contain one or more of the following : silicone elastomer with or without barium sulfate, tantalum, stainless steel, polypropylene and ruby.

Compatibility with Magnetic Resonance Imaging (MRI)

Integra NeuroSciences tests indicate that MRI exposure does not affect the Integra NeuroSciences standard or pediatric valve pressure settings. No significant forces were apparently exerted on the valve unit or on the straight connector during MRI exposure.

PRESSURE RANGES (see figure 2 - page 2)

Each valve is tested for operating pressure (using an air flow rate equivalent to a water flow rate of 5 cc/hr) and is color-coded based on its average pressure measured at the time of manufacture. This measurement reflects the valve's average pressure prior to packaging and sterilization. This value (identified at the time of manufacture) may not be repeatable during subsequent testing due to several factors including: the inherent properties of the valve; differences in valve testing conditions and the modifications regularly implemented by physicians on valve systems prior to implantation. The color bands are used to designate different pressure groups and are intended solely to facilitate ordering of the valves. Due to variations inherent in the test method and valve design, the operating pressure may vary ± 30 mmH_20 in Standard valves from the labeled value; in Pediatric valves the potential variation is ± 20 mmH_20. The average value shown on the label is determined at the time of manufacture and is provided as a convenience to the user.

Color code	**Operating pressure*** **(mm H_2O)**	**Indications**
Blue (very low)	15-40	Postoperative drainage of extraventricular structures
White (low)	40-80	Hydrocephalus with large ventricles
Yellow (medium)	80-120	Hydrocephalus / normal pressure hydrocephalus
Brown (high)	120-170	Hydrocephalus with small ventricles; inoperable midline brain tumors treated with X-ray therapy
Green (very high)	170-230	Hydrocephalus with ventricular normalization or when further reduction is not desired

* Measured at an air flow rate equivalent to a water flow rate of 5 cc/hr.

Each valve mechanism is reflux tested at a back pressure of 200 mm H_2O to ensure that reflux does not exceed a rate of 1.5 cc/hr. This verification is applicable only to the in-vitro conditions present during the manufacturing test.

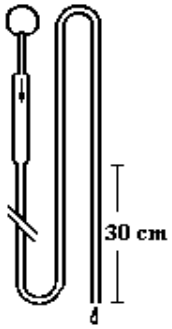
RECOMMENDED IMPLANTATION PROCEDURE

Before implantation, the valve serial number should be recorded in the patient's file.

Clinical Judgment

Incision size, size and type of nonabsorbable suture material, etc, should be selected according to the surgeon's experience and preference. All references to solution, unless otherwise noted, refer to sterile, pyrogen-free saline or antibiotic solution. Procedure may be varied in accordance with the surgeon's clinical judgment.

Intraoperative Testing - Patency



Before implantation, Integra NeuroSciences recommends testing of valve patency only.

1. Place inlet tubing in solution.

2. Attach Luer lock connector and syringe to distal tubing. Draw solution through mechanism.

3. Disconnect Luer lock connector. Hold proximal tubing end, allowing distal end to hang freely. Patency is confirmed if solution drips from distal end.

Ventriculoperitoneal Approach

Checking valve Patency

The described procedure is based on the use of a separate ventricular catheter. If a valve with an integral catheter is used, follow the procedure "Introduction of Integral Ventricular Catheter".

1. Administer anesthesia. Place the patient in the supine position. Padding may be placed under the neck. To facilitate tunneling, the head is turned to the contralateral side, placing the abdomen, thorax, neck and skull of the occipital region on a straight line.
Note - The skull incision location depends on the ventricular approach (frontal, temporal or occipital).

2. The skin, periosteum, skull and dura are opened by a technique consistent with the surgeon's experience. Expose the skull by making a 25mm linear incision. Using a perforator, make a Burr hole 3.0 mm or larger. Using an electrocoagulator, make an opening in the dura just large enough for ventricular catheter passage.

3. Make an abdominal incision. Pass the Integra NeuroSciences Disposable Malleable Tunneler from the head to abdominal incisions, directing the tunneler tip by trapping it between the thumb and the index finger. The tunneler may be formed to follow body contours. Remove the handle. Using the internal wire, with the drainage catheter attached to the catheter connector, pass the drainage catheter from the head to the abdominal incisions, and position the valve system under the skin. Remove the metal outer shaft.
Note - An alternate method may be necessary when the tunneler is not long enough or when patient positioning precludes a single pass without an interim incision.

4. Place the introducing rod into the ventricular catheter. If the Right Angle Guide (RAG) is used, introduce the ventricular catheter into the center of the RAG and insert the catheter into the ventricle. Holding the catheter with covered forceps, remove the introducing rod. Verify adequate CSF flow. Connect a syringe with a Luer connector to the ventricular catheter and aspirate 2 to 3 ml of CSF to eliminate possible debris.
Note - Sample CSF for analysis or inject antibiotics at this time, if desired.

5. Place the RAG into the Burr hole. The channel should point in the direction of the anticipated valve placement. Bend the exposed catheter into the channel of the guide until the catheter snaps in place.
Note - The use of the RAG in premature infants or neonates is at the discretion of the surgeon. If the RAG is not used, the surgeon should trim the rim of the Burr hole where the catheter emerges to provide a smooth angular transition for the catheter. Trim the ventricular catheter to length (approximately 2 cm from the Burr hole).

6. Carefully insert the integral inlet straight connector of the valve into the ventricular catheter. Do not dislodge the catheter. Tie the catheter using appropriate sutures.

7. As desired, trim the drainage catheter at the proximal end only, as there are slits at the distal end.

8. Open the peritoneum using any technique consistent with the surgeon's experience.

9. Prior to the introduction of the drainage catheter into the abdominal cavity, it is advisable to confirm the patency of the system by observing the formation of CSF droplets at the end of the distal catheter.
   Note : Insert sufficient drainage catheter length into the abdominal cavity to allow for patient growth.

Introduction of Integral Ventricular Catheter of One-Piece Valve Systems

If the RAG is used, slide the catheter through the center hole of the RAG. Position the RAG as far along the catheter as possible. Lock the stylet of the ventricular catheter introducer into its cannula as shown in Figure 3 - page 3. Insert the tip of the introducer into the second hole from the tip of the ventricular catheter. Align the catheter with the introducer cannula and snap it into the adjustable plastic collar.

Caution: To avoid improper placement, do not overstretch the ventricular catheter when positioning it on the introducer. Puncture the ventricle with this assembly. Carefully withdraw the stylet from the introducer cannula, causing the ventricular catheter to disengage from the stylet.

Note: Sample CSF at this time if desired by withdrawing fluid from the distal catheter. If injection of antibiotics is required, carefully occlude the tubing between the antechamber and the valve unit and slowly inject antibiotics into the antechamber. Release the tubing between the antechamber and the valve unit once the injection is complete.

Disengage the catheter from the collar on the cannula, ensuring that the catheter's position is maintained. Remove the introducer cannula from the Burr hole. For instructions on the use of the right angle guide, refer to step 5 of the "Ventriculoperitoneal Approach" procedure.

Ventriculoatrial Approach

CAUTION : trim the distal end of the drainage catheter in order to remove slits (6 cm).
Attention: The procedure is based on the use of a separate Ventricular Catheter. If a valve with integral Ventricular Catheter is used, follow the procedure "Introduction of Integral Ventricular Catheter".

1. Position the patient as described in step 1 and 2 of the "Ventriculoperitoneal Approach" procedure.

2. Make a neck incision over the point where the angle of the mandible crosses the anterior edge of the sternocleidomastoid muscle. If the internal jugular vein is used, facilitate entry by mobilizing the common facial vein to its junction with the internal jugular vein.

3. Tunnel the drainage catheter toward the neck incision. Position the valve assembly and connect it to the ventricular catheter (follow instructions in steps 4, 5, 6 of the ventriculoperitoneal approach).

4. Cut the drainage catheter to length at the neck incision. Fill with sterile solution and clamp the proximal end. Introduce the drainage catheter into the vein. Position the distal end of the drainage catheter in the heart's right atrium at the level of the 6th or 7th thoracic vertebra. Determine the exact location of the catheter by X-ray, radioscopy, ECG, pressure analysis or echography.
   Note - To enhance X-ray visualization, fill the atrial catheter with contrast.

5. When the drainage catheter is positioned properly, occlude the proximal end with a small, rubber-shodded clamp close to the neck incision.

6. Trim the drainage catheter and the valve outlet to length and attach the two using a straight connector. Tie securely using appropriate sutures.

Valve Unit Replacement

Make incisions above and below valve unit. Clamp proximal and distal valve tubing and cut tubing between clamps. Disconnect clamp from proximal tubing, verify ventricular catheter patency (observe CSF flow) and reclamp. Disconnect clamp from distal catheter, verify distal (drainage) catheter patency, and reclamp. **Caution:** Some competitive components incorporate slit valve mechanisms that raise the pressure of the valve unit.
Fill valve unit with solution and insert valve unit (note flow-direction arrow) between proximal and distal catheters using straight connectors. Tie and remove clamp. To verify patency, pump valve unit. If system contains prevalve chamber, refer to "System Test".

SYSTEM TEST

Test system periodically. Tests on implanted systems that include a prevalve chamber indicate only whether valve system is patent. They do no indicate that valve system pressure is adequate for patient's needs.

1. Compress tubing between prevalve chamber (Burr hole reservoir cap or antechamber) and valve. Gradually force fluid toward the ventricle by compressing prevalve chamber. Chamber should compress easily. Release compressed prevalve chamber. Chamber should immediately return to original shape. Release tubing (see Figure 4, page 3).
2. Compress tubing between antechamber and valve. Press valve firmly. It should compress easily. Hold finger over valve. Release tubing between antechamber and valve. The valve should immediately return to original shape. (See Figure 6, page 3).

Caution: Unnecessary pumping can lead to overdrainage especially if ventricular size has been reduced. Approximately 0.1 ml (0.02 ml for pediatric valve) is drained when valve is pumped. With high CSF protein levels, force fluid through the valve by pumping the prevalve chamber about once an hour (see step 1). Pumping may minimize solid material buildup around the valve's operating components.

Problem	Symptom	Remedy	
		a.	**b.**
1. Ventricular catheter occlusion	With tubing between prevalve chamber and valve compressed, prevalve chamber does not compress and/or does not immediately return to original shape.	Allow prevalve chamber to refill. Occlude tubing between prevalve chamber and valve (Fig.4). Press prevalve chamber firmly forcing fluid through ventricular catheter. Repeat, if necessary.	If obstruction cannot be dislodged, occlude tubing between prevalve chamber and valve. Using light pressure, inject solution into prevalve chamber (*) (Fig.5). This action should dislodge the ventricular catheter obstruction.
2. Catheter tip is caught in choroid plexus or insufficient ventricular fluid remains in (slit) ventricles.	With tubing between prevalve chamber and valve compressed, prevalve chamber compresses but does not refill immediately. Ventricular size is reduced.	Do not pump system. Normal CSF production and ventricular enlargement should release the catheter.	
		a.	**b.**
3. Obstruction between antechamber and valve (standard and pediatric valve systems).	When antechamber is pressed and released, it compresses and immediately returns to original shape. When valve is pressed and released, it compresses but does not immediately return to original shape.	Occlude tubing between antechamber and ventricular catheter (Fig.6) Firmly press antechamber forcing fluid through valve unit and drainage catheter. Repeat, if necessary.	If obstruction is not dislodged after a reasonable amount of CSF has been transferred, occlude the tubing between antechamber and ventricular catheter (Fig.6). Using light pressure, inject solution into antechamber(*) (Fig.5).This action should clear obstructions distal to the prevalve chamber.
4. Clogging in valve outlet or drainage catheter.	When antechamber is pressed and released, it readily compresses and returns to original shape. When valve is pressed, it resists compression.	Press valve forcefully. If pressing is ineffective, use the method described in 3b.	

(*) CAUTION: When injecting saline solution to clear obstructions, do not use high pressures or large volumes of fluid.
A 24 - or 25 - gauge short-bevel or Huber point needle should be used for this procedure.