

# GSL “DOME VALVE” HYDROCEPHALUS SHUNT SYSTEM

## Instructions for use

*Sterile, EO Sterilized*

### DESCRIPTION

The GSL DOME VALVE Hydrocephalus shunt is designed to deliver cerebrospinal fluid from the ventricles of brain to the peritoneal cavity. Each system contains one DOME VALVE valve peritoneal catheter, connector, stylet and ventricular catheter. The flow control valve is located inside the flushing reservoir.

The systems are available in low, Medium and high pressure range. Catheters contain barium sulfate for x-ray detectability. The ventricular catheter has tantalum tip.

Ventricular catheter has holes at one end. The end also has black tantalum tip. It is to be connected with DOME VALVE Valve.

The DOME VALVE Chamber has regulating valve located inside the . The end of distal catheter is to be put in to the peritoneal cavity or Rt. Atrium.

### INDICATIONS

The GSL DOME VALVE Hydrocephalus shunt system is to be used for treatment of hydrocephalic patients, for shunting of CSF from lateral ventricles of brain to peritoneum or rt. atrium.

### CONTRAINDICATIONS

Presence of all kinds of infection (meningitis, ventriculitis, skin infection, bacteremia, septicemia and peritonitis etc.) whether local or general, prohibits all kind of implantation procedures. It is advisable to avoid shunt implantation in such cases.

### METHOD OF USE

#### Initial flushing of shunt system

***It is a must that all GSL DOME VALVE shunt systems be flushed with either sterile water or normal saline before use.***

Remove plastic tags from slits of distal catheter. Use 5 cc or 10 cc syringe with blunt 14 gauge needle. Use good force to open up the slits of valves.

#### Valve patency test

Using syringe and a blunt needle fill the reservoir with water. Lift the syringe the fluid should come out of distal slits drop by drop. Ensure that there are no air bubbles in the shunt. In case the fluid does not pass, again flush the shunt and repeat patency test.

#### Surgical Procedure

The implantation of shunting system including placement of GSL DOME VALVE valve may be accomplished through variety of procedures. The choice depends upon the training of neurosurgeon, customs in that hospital, country. Therefore the surgeon is best advised to use method, which his/her own practice and training dictate to be best for the patient.

The stylet supplied with the system, may be used to support ventricular catheter during implantation.

### HOW SUPPLIED

GSL DOME VALVE Shunt system is supplied in various models. Whole shunt systems as well as all components are available separately. These are available sterile by EO gas in double peel open packing.

### WARNINGS

Hydrocephalic patients with cerebrospinal fluid shunt systems must be kept under close observation for signs and symptoms of increasing intra-cranial pressure due to shunt failure. These signs and symptoms may vary from patient to patient and are characterized by headache, irritability and vomiting, listlessness and drowsiness. Other signs are deterioration of consciousness and nuchal rigidity. In the infant increased scalp tension at the anterior fontanelle and congestion of scalp veins may be present.

This device is made of silicone rubber, which like most rubber, may stick to itself when dry. This tendency to stick may result in some valve performance variation, which may differ, from label specifications. When wet the tendency for silicone rubber to stick is reduced. Therefore, the surgeon must verify that the valve components are wet and that fluid flows freely through the shunt system. (refer to method of use).

This device has not been tested for drug compatibility and therefore is not intended for drug administration.

Occasionally, fibrous adhesions will bind the catheter to the adjacent choroids plexus. Gentle rotation may free the catheter from the choroids plexus. **Under no circumstances should the catheter be forcefully removed.** If the catheter cannot be removed without force, it is advisable to allow it remain in place, rather than risk intraventricular hemorrhage.

If the ventricular catheter becomes disconnected, it may be withdrawn from, or lost into, the lateral ventricle of brain.

Silicone tubing may be easily cut or torn when instruments are used to secure it to the connector. The use of instruments to attach silicone catheters to connectors should be avoided. When instruments are used, carefully inspect the tubing for nicks or other damage prior to closure.

Performance characteristics may change when components of other manufacturers are used with Chhabra Shunt. Surgiwear does not recommend it and is not responsible for performance.

### PRECAUTIONS

Prior to surgery, prospective patients and or their representative should be informed of the possible complications associated with the use of this product.

The silicone proximal catheter tubing should be carefully secured to the connector with ligatures in such a manner as to avoid cutting or occluding the tubing.

Fluid flow through the flushing valve should be verified immediately prior to implantation. If a hypodermic injection or aspiration into the reservoir is required, use only a 26 gauge or finer needle and insert at an angle less than 50°. Kinking of catheter tubing may result in shunt blockage.

#### **COMPLICATIONS**

Complications which may result from the use of this product include the risks associated with the medication and methods utilized in the surgical procedure, as well as patients response, reaction or degree of intolerance to any foreign object implanted into the body.

The medical literature is full of hazards and complications associated with use of Hydrocephalus shunt. It is implied & understood that since user is highly trained super-specialist. He has experience of hydrocephalus shunt implantation. He is fully aware of all the hazards associated with use of Hydrocephalus shunt and he has studied the medical literature well before use.

The principal complications associated with cerebrospinal fluid shunting into the peritoneum are shunt obstruction, functional failure of shunt system, infection and intracranial hypotension.

Shunt obstruction may occur in either the proximal ventricular catheter or in the distal, peritoneal/ atrial catheter. Ventricular catheter may be obstructed by particulate matter such as blood clots, fibrin or brain fragments. If not properly located in the lateral ventricle, the catheter may become embedded in the ventricle wall or choroids plexus. Occasionally, the catheter may perforate corpus callosum and reach opposite ventricle. Less commonly the catheter may be obstructed by excessive reduction of ventricle size or slit ventricles.

Peritoneal catheters may also be obstructed by particulate matter, the omentum or coiled loops of bowel.

Loss of valves and or reservoir patency may result from obstruction of the fluid pathway by particulate matter such as blood clots or other biological accumulation.

Functional failure of shunt system due to separation of its component parts can result in serious complications.

Ventricular catheters may migrate into the lateral ventricles; peritoneal catheters may migrate completely into the peritoneal cavity. Volvulus and perforation of intra-abdominal viscera may occur or the catheter may be extruded.

Infection is a common and serious complication of shunting system and is most frequently caused by skin contaminants. Septicemia, which occurs most frequently in debilitated infants, can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as a result of a wound infection. The presence of a foreign body (shunt system) may trigger ventriculitis or a dormant meningitis. Intracranial infection may then be disseminated through out the body via the distal catheter. Lesions developing from the breakdown of skin or tissue over the shunting system may also act as foci of serious infections. In the event of an infection, removal of shunt system is indicated in addition to appropriate therapy.

Excessive lowering of intracranial pressure may result in complications particularly in the infant. These include subdural hematomas, markedly sunken fontanelles, overriding of cranial bones and the conversion of communicating to non-communicating hydrocephalus due to obstruction of the aqueduct of Sylvius.

Failure of the shunting system may be evidenced by any or all of the following: continuing symptoms of raised intracranial pressure, the subcutaneous exudation of CSF along the pathway of the shunt and leakage of fluid through the surgical wound. These failures require immediate replacement of the shunting system or of the affected component.

#### **PRODUCT INFORMATION DISCLOSURE**

G. Surgiwear Limited has exercised reasonable care in the choice of materials and manufacture of this product. G. Surgiwear Limited excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness for a particular purpose. G. Surgiwear Limited shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from use of this product. G. Surgiwear Limited neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this product.