

GISAIMS

PERITONEO-VENOUS SHUNT SYSTEM (Product Brochure and Instruction For Use)

INTRODUCTION

The peritoneo-venous shunt has a limited but definite place in the treatment of a patient who has ASCITES which is resistant to medical management. It reduces abdominal girth and weight, improves plasma volume and is associated with an improvement of renal function and a reduction of salt retention. In contrast medical therapy seems to compromise renal function. Although the peritoneo-venous shunt does not prolong life, it does improve its quality. There are complications associated with its use and it should, therefore, be inserted with care.

DESCRIPTION OF THE GISAIMS SHUNTS

This has three parts :

a. THE PROXIMAL / PERITONEAL CATHETER: It is a 40 cm long tube of which the proximal 30 cm is perforated. There is a cuff at the junction of the perforated and plain segments for a purse string suture.

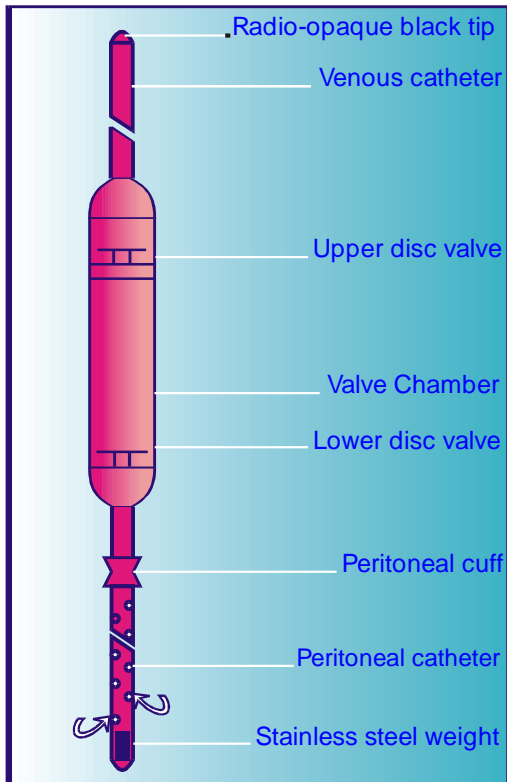


Fig. 1: GISAIMS I PV Shunt

b. MAIN VALVE BODY: This is made of Silicone Elastomer. It has two disc valves to facilitate the pumping action. The valves are unidirectional and allow flow of fluid at a 3-cm water pressure gradient. The valve chamber is placed on the rib cage so that its

middle portion can be depressed to pump the peritoneal fluid upwards.

c. VENOUS CATHETER: This is a plain tube with a radio-opaque distal end. Its tip should lie just proximal to the right atrium.

GISAIMS II for adults & GISAIMS III for children, Single valve types (figure 3).

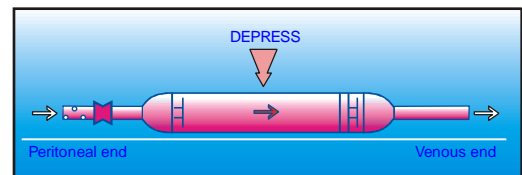


Fig 2: Flushing of GISAIMS Shunt

Here the only difference is that the main valve chamber has a single valve which is placed in the anterior abdominal valve during implantation.

THE MECHANISM OF ACTION OF THE GISAIMS SHUNT

The ascitic fluid enters the peritoneal catheter, forces open the valve and flows towards the right atrium via the distal catheter which discharges the fluid into the venous circulation.

In the double valve type of shunt, depression of the middle of the valve body forces the fluid towards the atrium. This action closes the proximal valve preventing reverse flow and when the pressure is removed, the valve body re-inflates, with closure of the distal valve and opening of the proximal valve.

HOW SUPPLIED

GISAIMS peritoneo-venous shunts are supplied as complete unitised system, sterilized by gamma-rays and ready to use in double peel open packaging. Each packet contains one main valve body with proximal and distal catheter in unitised form and two connectors.

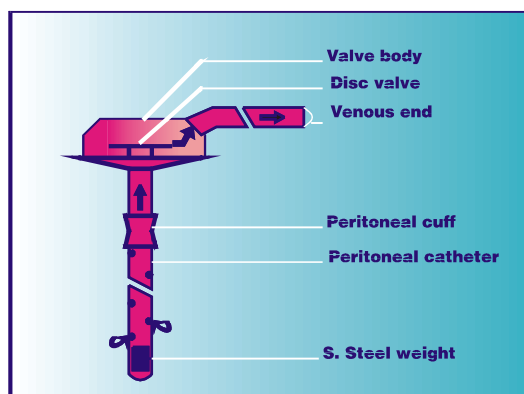


Fig. 3: GISAIMS II PV Shunt

MATERIALS

GISAIMS peritoneo-venous shunts are made of medical grade silicone elastomer. Connectors are made of either stainless steel or polypropylene. The black radio-opaque tip contains tantalum powder.

WARNINGS

Ascitic patients with peritoneo-venous shunt systems must be kept under close observation for signs and symptoms of increasing intra-abdominal pressure due to shunt failure. These signs and symptoms may vary from patient to patient and are characterized by increase in girth of abdomen and vomiting.

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

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

components are wet and that fluid flows freely through the shunt system. (refer to method of use).

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 Gisaims 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 shunt should be verified immediately prior to implantation. Kinking of catheter tubing may result in shunt blockage

INDICATIONS

Failure of adequate conservative treatment for 3 weeks, i.e. low salt intake and diuretic therapy (160 mg frusemide and 400 mg spironolactone) is the main indication for shunt placement. Other patients who cannot afford and do not comply with these massive diuretic doses may do better with peritoneo-venous shunts. The shunt should be placed before the development of hepatic and renal failure in the following conditions.

- malignant ascites
- budd-Chiari syndrome
- chylous ascites
- nephrogenic ascites
- biliary atresia
- amyloidosis
- cryptogenic ascites
- hepatorenal syndrome
- hydrothorax secondary to ascites

CONTRAINDICATIONS

These include peritonitis, recent variceal bleeding, cardiac dysfunction and acute tubular necrosis.

PREOPERATIVE PREPARATION

Base line investigations, full blood picture, serum electrolytes, liver function tests, serum creatinine, coagulation tests, daily urine output, weight and abdominal girth should be done. To reduce the risk of intravascular coagulation, some surgeons drain most of the ascitic fluid before surgery.

CLEANING AND AUTOCLAVING

The GISAIMS shunt as supplied is STERILE. It may also be resterilised. In a clean environment and with gloved hands remove shunt from its package. The packaging is not sterilizable. It should be rinsed and flushed with sterile distilled water. It may be wrapped in lint free material and then autoclaved for 30 minutes at 121°C and 1 kg/cm pressure. Ethylene oxide sterilization is not recommended.

PREPARATION OF THE DEVICE

Some surgeons recommend that the shunt should be immersed in antibiotic solution (80 mg gentamicin sulphate in 500 ml normal saline) and the chamber pumped (GISAIMS I) till the tubes are filled with this solution and flow established. All air bubbles should be expelled by elevating the venous end of the shunt and tapping the valve and tubes.

OPERATIVE PROCEDURE

Valve patency test

Using syringe and a blunt needle fill the shunt with water. Lift the syringe the fluid should come out of distal end 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.

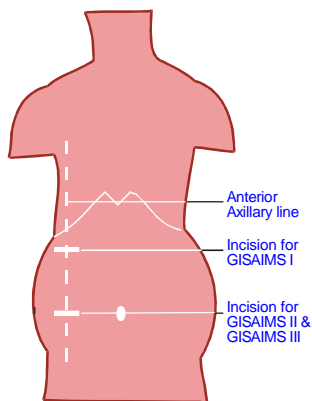
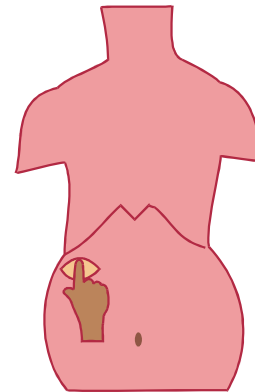
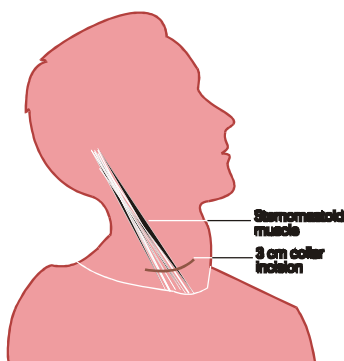


Fig. 4: Incision for implantation

The implantation of shunting system including placement 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 procedure, described below, is to act as guidelines.

Fig 5: Neck incision

The operation is performed using either local or general



anesthesia with the patient in the supine position and the neck slightly extended. (Fig 5-10)

Fig. 5: Dissection of Abdominal incision

A. Valve placement

GISAIMS I

A 5 cm transverse incision is made below the right costal margin in the anterior axillary line and carried down to the muscle. A space is fashioned over the lower chest wall using the index finger to allow placement of the pump chamber. The external and internal oblique muscles are split down to the transversalis fascia and two concentric purse string sutures of 3-0 silk placed (1.5 cm and 2.0 cm diameter).

GISAIMS II

The transverse incision is placed at the level of the umbilicus in the anterior axillary line. The concentric purse string sutures are placed in the transversalis fascia and the space for the valve created deep to the muscle layers.

B. Neck incision

A 3 cm collar incision is made in the right side of the neck extending from the midline to the sternomastoid muscles. The internal jugular vein is isolated and looped with 2-0 silk ligatures.

C. Insertion into the peritoneal cavity

A small hole is made in the peritoneum at the center of the previously placed purse string sutures and the peritoneal catheter inserted so that its tip lies in the pelvis. The sutures are then tied over the cuff to obtain a water tight closure. After confirming that there is free flow of ascitic fluid through the A long introducer (obtainable from Surgiwear) is pushed subcutaneously from the abdominal wound into the neck and a No. 1 silk suture pulled downwards. The tip of the venous tubing is fixed to this suture and pulled up into the neck. The abdominal incision is now carefully closed in layers.

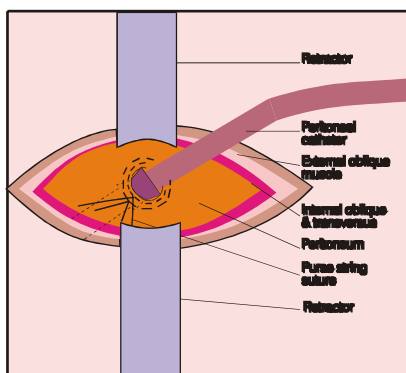


Fig. 6: Placement of Peritoneal Catheter

E. Insertion of venous catheter into the jugular vein

With the patient in the Trendelenburg position (to minimize the risk of an air embolus) the venous catheter is passed in the internal jugular vein so that its tip lies at the level of the second intercostal space (this should be measured carefully and a length should be cut off near the valve body and a connector used to join the cut ends). So that it makes a smooth curve. The clamp should be removed and ascitic fluid should be allowed to flow out freely before insertion of the tube into the jugular vein. The neck incision is then closed.

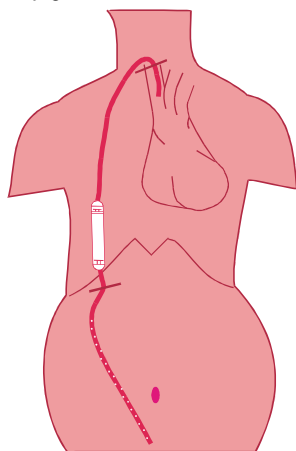


Fig. 7: GISAIMS Shunt after implantation

POSTOPERATIVE MANAGEMENT

The patient is placed in a sitting (45 degree head up) position and given 40mg frusemide intravenous injection immediately. The urine output is measured hourly, coagulation studies are performed daily and the abdominal girth, body weight, serum electrolytes and liver function tests are measured three times a week.

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

Following are some of the major complications:

1. Shunt blockage

This occurs more often if the details of the surgical technique are not followed. Patency can be tested in the GISAIMS I by to compression indicates that the venous end is blocked. If after compression the pump body does not refill this indicates obstruction of the peritoneal tube. The patency of the GISAIMS II type shunt can be determined by a Doppler flow meter, by injecting Technetium Sulphur colloid into the peritoneal cavity or contrast media into the venous tubing using a 26 G needle directed obliquely.

2. Disseminated intravascular coagulation

This is probably due to the presence of procoagulants in the ascitic fluid and its incidence is minimized if most of the ascitic fluid is discarded at the time of shunt placement.

3. Infection

This may occur due to leakage of ascitic fluid around the peritoneal catheter and along the shunt and may necessitate its removal.

4. Fever

Low grade fever occurs during the early postoperative period but is self-limiting.

5. Heart failure

Large amounts of ascitic fluid enter the blood stream through a functioning peritoneo-venous shunt. This can overload an already impaired heart. This complication can be prevented preoperatively by draining the ascitic fluid before the shunt insertion in patients with cardiac disease.

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Patented in India