

CEREBRAL RESERVOIR

Instructions for use

Sterile, EO Sterilized

DESCRIPTION

The SURGIWEAR "Cerebral Catheter Reservoir" is designed to deliver drugs into cerebrospinal fluid and to draw samples from the ventricles of brain. Each system contains one reservoir and one ventricular catheter.

The systems are available in large and small reservoir. 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 reservoir.

INDICATIONS

The "Cerebral Catheter Reservoir" is to be used for frequent intraventricular medications and CSF sampling.

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 implantation in such cases.

METHOD OF USE

Surgical Procedure

The implantation of reservoir 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 stylet may be used to support ventricular catheter during implantation.

HOW SUPPLIED

"Cerebral Catheter Reservoir" is supplied in two models. These are available sterile by EO gas in double peel open packing.

WARNINGS

This device has not been tested for compatibility with all drugs and therefore should be used with caution.

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If the ventricular catheter becomes disconnected, it may be withdrawn from, or lost into, the lateral ventricle of brain.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

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.

For hypodermic injection or aspiration into the reservoir, 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 "Cerebral Catheter Reservoir". It is implied & understood that since user is highly trained super-specialist. He has experience of "Cerebral Catheter Reservoir" implantation. He is fully aware of all the hazards associated with use of "Cerebral Catheter Reservoir" and he has studied the medical literature well before use.

The principal complications associated with "Cerebral Catheter Reservoir" implantation are obstruction, functional failure of system and infection.

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.

Functional failure of "Cerebral Catheter Reservoir" due to separation of its component parts can result in serious complications. Ventricular catheters may migrate into the lateral ventricles.

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. 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 "Cerebral Catheter Reservoir" is indicated in addition to appropriate therapy.

PRODUCT INFORMATION DISCLOSURE

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