Portnoy Ventricular Catheter
Sterile For Single Use Only

Description
The Portnoy Ventricular Catheter is designed for shunting cerebrospinal fluid (CSF) from the ventricles of the brain. This silicone elastomer catheter employs silicone elastomer flanges near the proximal tip to help reduce the possibility of obstruction of the drainage holes during insertion and resultant occlusion of the catheter.

The Portnoy Ventricular Catheter has seven flanges, spaced approximately 2.5mm apart along 15mm of the proximal end. During insertion, these flanges tend to fold back in a closed-umbrella position to protect the drainage holes which are in the catheter tube between the flanges (Figure 1). The flanges may resume their normal expanded position upon entering the ventricle, thus helping prevent the catheter tubing from resting against the ventricular wall or the choroid plexus.

A stripe, made of barium sulfate-impregnated silicone elastomer, is imbedded in the wall of the catheter. The stripe provides a catheter which is radiopaque throughout its entire length, while keeping barium sulfate away from the surface of the catheter and allowing visual observation of flow through the catheter during implantation. The catheter tip is made from a radiopaque, tantalum-impregnated silicone elastomer to aid in determining location during and subsequent to implantation. Black length markers (tantalum-impregnated silicone elastomer), located at 10 and 15cm from the tip, assist in determining the position of the catheter.

Indications
The Portnoy Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

Contraindications
Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, sepsis, or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

The ventriculoatrial method of shunting is contraindicated for hydrocephalic patients with congenital heart disease or other anomalies of the cardiopulmonary system.

Instructions For Use
The introduction of a shunting system, including placement of the ventricular catheter, may be accomplished through a variety of surgical techniques; therefore, the surgeon is best advised to use the method which his/her own practice and training dictate to be best for the patient.

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

How Supplied
The Portnoy Ventricular Catheter is supplied individually, complete with stylet, sterile and pyrogen-free in a double-wrap packaging system. The double-wrap system is the preferred method of sterile-product transfer from the circulating area to the sterile field.

Figure 1. Umbrella action of flanges during insertion procedure
**Do Not Resterilize**

This product is for single use only.

**Warnings**

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

If the ventricular catheter becomes disconnected, it may be withdrawn from, or lost in, the lateral ventricle of the brain. Integra NeuroSciences makes no claim or representation as to the performance characteristics of this product if it is used in conjunction with components from other manufacturers.

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 choroid plexus. Gentle rotation may free the catheter from the choroid plexus. Under no circumstances should the catheter be forcefully removed. If the catheter cannot be removed without force, it is advisable to allow it to remain in place, rather than risk intraventricular hemorrhage.

**Precautions**

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

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

Kinking of catheter tubing may result in shunt blockage.

A ventricular catheter should not be subjected to unusual tension at any time.

Silicone tubing may be easily cut or torn when instruments are used to secure it to a 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.

**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 the patient’s response, reaction or degree of intolerance to any foreign object implanted in the body.

The principal complications associated with cerebrospinal fluid shunting into the right atrium or peritoneum are shunt obstruction, mechanical failure of the shunt system, infection or intracranial hypotension.

Shunt obstruction may occur in the ventricular catheter. Ventricular catheters 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 ventricular wall or choroid plexus. Less commonly, the catheter may be obstructed by excessive reduction of ventricular size to slit-like proportions.

Functional failure of the shunt system due to separation of its component parts can result in serious complications. For example, ventricular catheters may migrate into the lateral ventricles.

Infection is a common and serious complication of a 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 (i.e., the shunting system) may trigger ventriculitis or a dormant meningitis. Intracranial infection may then be disseminated throughout the body via the distal catheter. Lesions developing from the breakdown of skin tissue over the shunting system may also serve as foci of serious infections. In the event of an infection, removal of the shunt system is indicated, in addition to the 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 a non-communicating hydrocephalus, due to destruction of the aqueduct of Sylvius.

Failure of the shunting system may be evidenced by any or all of the following: continuing symptoms of increased 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**

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**Product Order Information**

All products can be ordered through your Integra NeuroSciences Neuro Specialist or customer service representative or by contacting:

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Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Do not use if the package has been opened or damaged.


