Pudenz Peritoneal Catheter

Sterile For Single Use Only

Description

The silicone elastomer Pudenz Peritoneal Catheter is designed to deliver cerebrospinal fluid (CSF) to the peritoneal cavity through a slit valve near the distal tip. The slit valve consists of four individual slits placed in the catheter wall. The slit valve may be used to control shunt-system closing pressure. It also serves to help resist retrograde flow of fluids into the distal end of the catheter. Three pressure ranges are available. The closing pressure range (differential pressure range at 9 ml/hr flow rate) is identified by a dot code at the proximal end of the catheter, as follows:

<table>
<thead>
<tr>
<th>Dot Code</th>
<th>Pressure Rating</th>
<th>Closing Pressure Range (mm of H2O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low</td>
<td>15-54</td>
</tr>
<tr>
<td>2</td>
<td>Medium</td>
<td>55-94</td>
</tr>
<tr>
<td>3</td>
<td>High</td>
<td>95-150</td>
</tr>
</tbody>
</table>

Graduated Model

The Graduated Model of the Pudenz Peritoneal Catheter is manufactured from a high durometer (firm) silicone elastomer, which helps resist kinking and occlusion caused by the bending or twisting of the catheter. The tip of the catheter contains a radiopaque tantalum-impregnated, silicone elastomer plug to aid in determining location during and subsequent to implantation. The catheter displays radiopaque markers at. These markers allow the surgeon to measure the length of tubing placed within the body during surgery and to monitor the position of the catheter postsurgically.

Indications

The Pudenz Peritoneal Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneum. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated.

Contraindications

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, septicaemia or peritonitis).

It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Instructions for Use

The introduction of a peritoneal shunting system 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 functioning of the catheter slit valve should be checked prior to use. The following testing procedure is intended only as an aid to the physician in determining the approximate, not absolute, closing pressure. Test results do not necessarily reflect the actual slit valve functioning of an implanted catheter and may not always be appropriate for Barium containing catheters.

Note: The slit valve is coated with lubricant to minimize adherence during storage and should not be flushed with any solution until closing pressure is tested immediately prior to implantation.

Recommended Slit Valve Closing-Pressure Test

1. Insert a syringe filled with sterile isotonic fluid (we recommend physiological saline or deaerated water) into the proximal end of the catheter.

2. Establish a steady stream through
each of the four slits by gently rolling the slit valve region of the catheter between thumb and forefinger while flushing the catheter with fluid.

Note: Any mechanical or fluid manipulation of the slit valve may temporarily lower the normal operating pressure.

3. Hold both ends of the catheter in one hand.

4. After filling the catheter with testing solution, remove the syringe and slowly lower the distal end until the catheter is hanging vertically. Fluid should run freely from the slits. Starting from the moment fluid begins to flow from the slits, allow 1¼ minutes for the fluid level to stabilize.

Note: While waiting, inspect for air bubbles. If air bubbles are present, start the test procedure over.

Caution: Extreme care must be taken during this test to eliminate any air bubbles in the column of testing fluid. One bubble is enough to impede or even completely stop the descent of fluid and give a false reading.

Should a bubble occur, flush out the catheter completely and carefully refill per the instructions.

5. Measure the column of fluid in centimeters from the top of the slit valve to the top of the fluid column in the catheter to obtain the closing-pressure reading.

How Supplied

The Pudenz Peritoneal Catheter is supplied individually in a sterile, double-wrap, pyrogen-free packaging system. The double-wrap system facilitates the preferred method of sterile product transfer from the circulating area to the sterile field.

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 shunting failure. These signs and symptoms may vary from patient to patient. Increasing intracranial pressure is 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 will be noted.

Perforation of abdominal viscera may occur from any foreign object retained in the abdomen.

An obscure fever in patients with a ventriculoperitoneal shunt should suggest the possibility of a shunt-associated low-grade peritonitis.

A patient with a ventriculoperitoneal shunt in whom gram-negative ventriculitis occurs, recurs, or persists should be checked for a possible perforation of the intestinal wall by the peritoneal catheter.

If the peritoneal catheter becomes disconnected, peristaltic action may draw the catheter completely into the abdominal cavity.

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

Integra NeuroSciences makes no claim for or representation as to the performance characteristics of a shunting system if this product is used in conjunction with components of other manufacturers.

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.

Precautions

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

Fluid flow through the slit valve should be verified prior to implantation. (See Instructions For Use.)

The slits of the valve should not be removed, lengthened or altered in any other manner.

Catheter tubing should be carefully secured to a connector with ligatures in such a manner as to avoid cutting or strangulation of the tubing.

Kinking of the catheter tubing may result in shunt blockage.

Although a ventriculoperitoneal shunt system may function for years without revision in adults, it cannot be considered to remain permanently operational in infants or young children. A child’s growth results in the progressive withdrawal of the peritoneal catheter, and the catheter may require periodic revisions.

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 peritoneum are shunt obstruction, functional failure of the shunt system, infection or intracranial hypotension.

Shunt obstruction may occur in either the proximal ventricular catheter or in the distal, peritoneal 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.

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

Functional failure of the shunt system due to separation of its component parts can result in serious complications. Peritoneal catheters may migrate completely into the peritoneal cavity. Volvulus and perforation of intraabdominal viscera may occur or the catheter may be extruded.

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 or 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 a communicating to a 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 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 Disclosure**

Integra NeuroSciences has exercised reasonable care in the choice of materials and manufacture of this product. Integra NeuroSciences excludes all warranties, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Integra NeuroSciences shall not be liable for any incidental or consequential loss, damage, or use of the product. Integra NeuroSciences neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

**Product Order Information**

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

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Telephone: 1-800-654-2873
Outside the US: 1-609-275-0500
Fax: 609-275-5363

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Hampshire SP10 4DR England

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Fax: +44 (0) 1264-332-113

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.

**Bibliography**


**Symbols Used On Labeling**

See instructions for use
Expiration date
Do not reuse after opening
Lot number
Sterile unless package is opened or damaged.
Method of sterilization-ethylene oxide.
Product complies with requirements of directive 93/42/EEC for medical devices.
### Dimensioned Illustrations (All Dimensions Nominal)

<table>
<thead>
<tr>
<th>Model</th>
<th>Catalog Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Graduated</td>
<td>NL850-1380</td>
<td>Pudenz Peritoneal Catheter, Low Pressure</td>
</tr>
<tr>
<td></td>
<td>NL850-1381</td>
<td>Pudenz Peritoneal Catheter, Medium Pressure</td>
</tr>
<tr>
<td></td>
<td>NL850-1382</td>
<td>Pudenz Peritoneal Catheter, High Pressure</td>
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</tbody>
</table>

**Graduated Model**

- 1.3mm ID, 2.5mm OD
- 1cm Typical
- 90cm

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