The silicone elastomer Multi-Purpose Valve is a system designed to facilitate the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. This system is composed of:

1. an Occluder,
2. a Flushing Reservoir,
3. a Miter Valve,
4. an On-Off Control, and
5. an Anti-Siphon Device. (some models)

CSF from the ventricular catheter flows through the inlet tube and the occluder into the flushing reservoir, through the miter valve and the anti-siphon device, (some models) then out the distal catheter. (Figure 1.)

To allow the proximal miter valve to determine shunt-flow-control pressure, Integra NeuroSciences recommends the use of a slit valve distal catheter with a closing pressure of 50mm H2O or less. All Integra NeuroSciences low pressure (closing pressure 20 to 50mm H2O) distal catheters are suitable for use with the Multi-Purpose Valve. Each of the components of the valve is described below in the same sequence as it appears in the system—from inlet (proximal) to outlet (distal). The flat-bottom design of the Multi-Purpose Valve eliminates the need for a formal burr hole, provides greater latitude in positioning the device, and allows the ventricular catheter to be revised without disturbing the flushing valve.

1. The Occluder allows occlusion of the ventricular catheter by percutaneous finger pressure to permit opening the On-Off Control and to facilitate flushing the distal catheter.

2. The Flushing Reservoir is marked with an arrow to indicate CSF flow direction, which facilitates directional orientation of the Multi-Purpose Valve. The reservoir dome may be penetrated with a 25-gauge or smaller needle. Such penetration permits the removal of CSF samples, as well as the injection of fluid in either the proximal or distal direction or in both directions at once. The flange extending around the base of the reservoir contains suture holes to facilitate securing the device to the periosteum.

3. The one-way flow Miter Valve is located within the On-Off Control chamber. The valve is available in three closing-pressure ranges to provide the surgeon a choice in meeting individual patient needs. Each valve is individually tested at the time of manufacture for conformance to labeled flow/pressure performance characteristics. However,
due to characteristics of silicone materials, some variation in pressure performance may occur which historically has not compromised effective control and treatment of hydrocephalus. The closing-pressure range is identified by a tantalum-impregnated silicone elastomer dot code on the base of the On-Off Control chamber, as follows:

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Dot Code</th>
<th>Pressure Range (cm H₂O)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NL850-0105</td>
<td>I</td>
<td>Low—15 to 54</td>
</tr>
<tr>
<td>NL850-0125</td>
<td>II</td>
<td>Medium—55 to 94</td>
</tr>
<tr>
<td>NL850-0108</td>
<td>III</td>
<td>High—95 to 150</td>
</tr>
<tr>
<td>NL850-0112</td>
<td>IV</td>
<td>Low—15 to 54</td>
</tr>
<tr>
<td>NL850-0132</td>
<td>V</td>
<td>Medium—55 to 94</td>
</tr>
<tr>
<td>NL850-0125</td>
<td>VI</td>
<td>High—95 to 150</td>
</tr>
</tbody>
</table>

4. The On-Off Control allows the surgeon to achieve either an open (On) or a closed (Off) shunting system by percutaneous finger pressure. The radiopacity of the tantalum-impregnated silicone elastomer plug permits verification of the open or closed position of the On-Off Control by tangential X-ray. Such a control permits on-off regulation of cerebrospinal fluid flow to check for shunt dependence and to control decompression of the ventricle. See Instructions for Use for opening and closing directions.

5. Models with an Anti-Siphon Device are designed to help prevent the excessive drainage of cerebrospinal fluid which might otherwise be caused by the siphonage effect created by a siphoning catheter. The siphonage effect is minimized by the anti-siphon device, which closes under a negative pressure, yet will reopen to allow the flow of CSF to resume before intraventricular pressure becomes excessive.

Indications

The Multi-Purpose Valve, 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.

Valves with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing.

Contraindications

Ventriculocisternal 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, septicaemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

The ventriculocisternal 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 Multi-Purpose Valve, 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.

Valve Patency and Closing Pressure Test

1. Connect a length of sterile tubing to the inlet tube of the valve and elevate the tubing above the valve. (The inlet tube extension may be connected with a 90° or a straight shunt connector). No tubing should be connected to the outlet tube.
2. Orient the valve horizontally on the test table.
3. Using a syringe, fill the tube to approximately 18cm. Use sterile deaerated water to help eliminate air bubbles in tubing and valve.
4. After flow through tubing and valve has been established, examine tubing and valve to ensure bubbles have been eliminated. Do not flush the valve with a syringe. The amount of pressure created by syringe flushing will temporarily deform the silicone elastomer inlet valve, which will cause abnormally low pressure test results.
5. When the water level is within the intended pressure range, (low—15 to 54mm H₂O, medium—55 to 94mm H₂O or high—95 to 150mm H₂O), a noticeable slowing of flow should occur.
6. The valve closing pressure should be checked when the water level is at the lower limit of the range. The discharge from the valve outlet tube should be less than or equal to 0.15ml/min., when measured at the lower limit of the pressure range. The pressure is that recorded by measuring the distance from the base of the valve to the top of the water column in the inlet tube extension. Due to characteristics of silicone materials, some variation in pressure performance may occur.

To close the Multi-Purpose Valve, press the radiopaque, tantalum-impregnated silicone elastomer plug (attached to the dome of the On-Off Control) into the radiopaque circle of the valve seat. (Figure 2.)

Re-opening of the system is achieved by holding the occluder closed with finger pressure, then pressing the reservoir dome to open the On-Off Control. (Figure 3.) Assurance that the control is in the desired position can be verified by tangential X-ray.

To inject fluids into, or check the patency of, the ventricular catheter, close the On-Off Control with percutaneous finger pressure, then press the reservoir dome only. Never inject into the Anti-Siphon Device.

Following removal of the needle, pump reservoir several times to flush the fluids into the ventricular catheter. Re-open the On-Off Control following this procedure. (Figures 4 and 5.)

To inject fluids into, or check the patency of the distal catheter, open the On-Off Control and close the occluder at the inlet side of the reservoir with percutaneous finger pressure to prevent flow in the proximal direction. Following removal of the needle, pump the reservoir several times to flush the fluids into the distal catheter. (Figures 6 and 7.)

How Supplied

The Multi-Purpose Valve is supplied 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 drainage systems must be kept under close observation for signs and symptoms of increasing intracranial pressure due to shunt failure. These signs and symptoms may vary from patient to patient. Increasing intracranial pressure is characterized by headache, vomiting, irritability, listlessness, drowsiness, 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.

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 variations 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 valve. (See *Instructions For Use*.)

The On-Off Control may be inadvertently depressed to the “off” position. Percutaneous manipulation and/or radiological examination can be used to verify the open or closed position of the On-Off Control.

This device 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 this product if it 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.

In order to allow the proximal miter valve (and the Anti-Siphon Device when appropriate) to control shunt pressure, Integra NeuroSciences recommends the use of a low pressure slit valve or distal catheter (closing pressure 50 mm H2O or less) with the Multi-Purpose Valve.

The silicone inlet and outlet tubing should be carefully secured to the connectors in such a manner as to avoid cutting or occlusion of the tubing.

Fluid flow through the flushing valve should be verified immediately prior to implantation. (See Instructions for Use.)

If an injection into the flushing valve is required, utilize a 25-gauge or smaller needle and inject through the reservoir dome only.

The reservoir should be securely attached to the periosteum to prevent movement of the device (and subsequent movement of the ventricular catheter) during the operation of the On-Off Control.

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, functional failure of the shunt system, infection or intracranial hypertension.

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

Cardiac and peritoneal catheters may also be obstructed by particulate matter. The intra-atrial segment of the cardiac catheter may be obstructed by embolism in a thrombus. Emboli from the latter may seed the pulmonary circulation sufficiently to result in pulmonary artery hypertension and cor pulmonale. Peritoneal catheters may be obstructed by the omentum or coiled loops of bowel.

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

Functional failure of the shunt system due to separation of its component parts can result in serious complications. Ventricular catheters may migrate into the lateral ventricles. Should the cardiac catheter become detached, it may lodge in the right atrium or ventricle or, rarely, in the pulmonary circulation. Peritoneal catheters may migrate completely into the peritoneal cavity. Volexus and perforation of intra-abdominal 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. Septicaemia, 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 volexus 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 hematoma, markedly sunken fontanelles, overriding of cranial bones and the conversion of a communicating to a noncommunicating 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 expressed 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 expense, directly or indirectly arising from use of this 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

or

Integra NeuroSciences
Newbury Road, Andover
Hampshire SP10 4DR England
Tel: +44 (0) 1264-345-700
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


### Dimensional Illustrations

(All dimensions are nominal)

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>NL850-0105*</td>
<td>Multi-Purpose Valve, with Anti-Siphon Device Low Pressure</td>
</tr>
<tr>
<td>NL850-0108</td>
<td>Multi-Purpose Valve, with Anti-Siphon Device Medium Pressure</td>
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<tr>
<td>NL850-0112</td>
<td>Multi-Purpose Valve, with Anti-Siphon Device High Pressure</td>
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<td>NL850-0125</td>
<td>Multi-Purpose Valve, Low Pressure</td>
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<td>NL850-0128</td>
<td>Multi-Purpose Valve, Medium Pressure</td>
</tr>
<tr>
<td>NL850-0132</td>
<td>Multi-Purpose Valve, High Pressure</td>
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</tbody>
</table>

Multi-Purpose Valve with Anti-Siphon Device

![Diagram of Multi-Purpose Valve with Anti-Siphon Device]

<table>
<thead>
<tr>
<th>Inlet Tube Size</th>
<th>1.2mm ID, 2.2mm OD</th>
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<tbody>
<tr>
<td>Outlet Tube Size</td>
<td>1.2mm ID, 2.2mm OD</td>
</tr>
</tbody>
</table>

*U.S. Patent No. 3,827,439 3,769,982

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