The silicone elastomer Anti-Siphon Device (ASD) is designed to help prevent the excessive drainage of cerebrospinal fluid, which may be induced by the siphoning effect of hydrostatic pressure created by elevation of the ventricular catheter with respect to the distal catheter, (i.e., when the patient sits, stands, or is held erect). The siphoning effect is minimized by the anti-siphon device which closes when the pressure inside the unit becomes negative relative to ambient pressure, yet will reopen to allow the flow of cerebrospinal fluid to resume before the intraventricular pressure becomes excessive. The ASD is designed to restrict flow when the shunt system is under substantial hydrostatic pressure. It is not designed to compensate for lowered intracranial pressure brought on by other than large hydrostatic pressure changes.

The Anti-Siphon Device may be connected in series with any Integra NeuroSciences flushing reservoir or proximal control valve. For this purpose two straight shunt connectors are packaged with the device. The anti-siphon device which closes when the pressure inside the unit becomes negative relative to ambient pressure, yet will reopen to allow the flow of cerebrospinal fluid to resume before the intraventricular pressure becomes excessive. The ASD is designed to restrict flow when the shunt system is under substantial hydrostatic pressure. It is not designed to compensate for lowered intracranial pressure brought on by other than large hydrostatic pressure changes.

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The Anti-Siphon Device, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when the patient is in a sitting, standing or erect position.

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

Instructions For Use
The introduction of a shunting system, including placement of the Anti-Siphon Device, 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 Anti-Siphon Device must be connected to the distal outlet of the proximal flushing reservoir or flow-control valve. An arrow on the base of the Anti-Siphon Device indicates the correct direction of flow through the device. (The arrow is pointing in the distal direction, or downstream.)

The flow direction indicator arrow on the base of the Anti-Siphon Device should be placed against the periosteum (skull) when implanted. The device will not function properly if inverted.

How Supplied
The Anti-Siphon Device is supplied individually with two straight connectors 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.
Prior to surgery, prospective patients prior to closure.

The tubing for nicks or other damage to connectors should be avoided. When instruments to attach silicone catheters secure it to a connector. The use of torn when instruments are used to Silicone tubing may be easily cut or changes.

Intracranial pressure brought on by designed to compensate for lowered stands or is held erect. It is not function only when a patient sits, and the Anti-Siphon Device is used in conjunction with components from other manufacturers.

This device may not be suitable for all patients, as excessive intracranial pressure may be required to initiate CSF flow when an Anti-Siphon Device is used in conjunction with a high pressure valve.

The Anti-Siphon Device is designed to function only when a patient sits, stands or is held erect. It is not designed to compensate for lowered intracranial pressure brought on by other than large hydrostatic pressure changes.

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.

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 Anti-Siphon Device should be verified immediately prior to implantation.

Never inject into the anti-siphon device! Any penetration of the anti-siphon diaphragm will jeopardize its fitness-for-use.

The Anti-Siphon Device must be connected to the distal outlet of the proximal flushing reservoir or flow-control valve.

The flow direction indicator arrow on the base of the Anti-Siphon Device must be placed against the periosteum (skull) when implanted. The device will not function properly if inverted.

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 hypotension.

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 investment in a thrombus. Embol 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 artery. Peritoneal catheters may migrate completely into the peritoneal cavity. Volvulus 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. 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 trig 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...
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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
Tel: +44 (0) 1264-345-700
Fax: +44 (0) 1264-332-113

Hampshire SP10 4DR England
Newbury Road, Andover
Fax: 609-275-5363
Outside the US: 1-609-275-0500
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Bibliography


Kuwamura, K., Kokunai, T. "Intraventricular Hematoma Secondary to a Ventriculoperitoneal Shunt." Neurosurgery, 10:3 (March, 1982), 384-386.


### Dimensioned Illustrations (All dimensions are nominal)

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>NL850-0200</td>
<td>Anti-Siphon Device*</td>
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</table>

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

**Side View**

**Bottom View**

Outlet Tube Size 1.2mm I.D., 2.2mm O.D.

Inlet Tube Size 1.2mm I.D., 2.2mm O.D.

**Directional Arrow**

**Top Surface**

**Bottom Surface with Directional Arrow**

3.9mm