The Integra NeuroSciences Edwards/Barbaro Syringo-Peritoneal Shunt is designed to provide continuous drainage of fluid from within a spinal cord cyst to a site outside the spinal canal (usually the peritoneum, although some surgeons prefer the pleural cavity). The T-tube diameter is small to minimize the size of the myelotomy and the catheter is flexible to minimize the spinal cord manipulation necessary to insert the tube into a spinal cord cyst. The T-shape allows drainage above and below the myelotomy site, helps prevent kinking by providing a right-angle exit through the dura, and reduces the risk of migration out of the spinal cord. The multi-holed catheter reduces the risk of clogging at the spinal end of the system. The suture tab allows the T-tube to be anchored to the dura or paraspinous muscles without the risk of shunt occlusion associated with a circumferential ligature. A step-down connector is provided which adapts the T-tube diameter to the included peritoneal reflux control catheter. A Foltz flat-bottom reservoir is provided which allows percutaneous testing of shunt patency and aspiration of cyst fluid in case of suspected infection.

Indications
A variety of operations are used in the treatment of syringomyelia. The Integra NeuroSciences Edwards/Barbaro Syringo-Peritoneal Shunt can be used alone or in combination with other procedures in the treatment of all forms of syringomyelia, including those associated with Chiari malformations, trauma or arachnoiditis. Fluid contained within cystic spinal cord tumors generally has a higher protein content and may not flow through this system. For this reason, the Integra NeuroSciences Edwards/Barbaro Syringo-Peritoneal Shunt is not recommended in the treatment of cystic spinal cord tumors. Any spinal cord lesion which contains anything other than clear, colorless fluid should be examined carefully for evidence of an associated tumor.

Contraindications
Syringo-Peritoneal 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, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Use of the Integra NeuroSciences Edwards/Barbaro Syringo-Peritoneal Shunt is contraindicated in the presence of spinal tumors. Careful examination of spinal cord lesion fluid should be made to eliminate possibility of tumor.

Instructions For Use
The introduction of a 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 following information relevant to the use of the Integra NeuroSciences Edwards/Barbaro Syringo-Peritoneal Shunt is provided for your reference by Doctors Michael Edwards* and Nicholas Barbaro*, based on their experience in the surgical treatment of patients with syringomyelia.

Placement of a catheter into the spinal cord is generally done using the operating microscope. A myelotomy is made in the thinnest portion of the spinal cord, using the dorsal root entry zone. Prior to inserting the T-tube into the syrinx, the tubing should be brought through a small opening in the dura separate from the midline during opening. This allows for a water-tight dural closure at the midline site. The T-tube arms can then be cut to the desired length and placed into the syrinx. The dura is then closed and the T-tube is secured to the dura and/or

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paraspinous muscles using the suture tab. If the reservoir is to be used, a subcutaneous pocket is made, usually over a bony surface (rib, etc.) so that it can be easily palpated postoperatively. Care should be taken to avoid kinking of the tubing at the reservoir. The distal end is handled in the same manner as any shunt system. It should be noted that the flow of fluid from the distal end of a syrinx shunt is generally much less than seen with shunts for hydrocephalus, especially after the syrinx has been drained with a myelotomy. Therefore, although continuous flow from the distal end of the shunt system indicates a patent shunt, lack of flow does not necessarily indicate shunt obstruction.

How Supplied
The Edwards-Barbaro Syringo-Peritoneal Shunt 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
This product has not been tested for drug compatibility and therefore is not intended for drug administration.

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

An obscure fever in patients with a Syringo-Peritoneal Shunt could suggest the possibility of a shunt-associated, low-grade peritonitis.

A patient with a Syringo-Peritoneal 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 into the abdominal cavity.

Integra NeuroSciences makes no claim for or representation as to the performance characteristics of this product if it is used in conjunction with components from 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.

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.

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. Ventrolus 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. 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 postural headaches. These usually resolve spontaneously, but may require either the placement of an anti-siphon device or removal of the system.

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.

Loss of reservoir patency may result from obstruction of the inlet and outlet tubes by particulate matter such as blood clots, proteinaceous material or other biological accumulations.

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 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

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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**


Dimensioned Illustrations (All dimensions are nominal)

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<td>Integra NeuroSciences Edwards/Barbaro Syringo-Peritoneal Shunt is one step-down connector, one peritoneal catheter and a Foltz flat-bottom reservoir.</td>
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**Syringo-Peritoneal Shunt**

**Peritoneal Reflux Control Catheter**

**Foltz Flushing Reservoir**

**Step-down Connector**

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