Description
The Spetzler® Lumbar Peritoneal Shunt Systems are designed to shunt cerebrospinal fluid (CSF) from the lumbar subarachnoid space to the peritoneum. Due to the small diameter of the catheter tubing, shunting may be accomplished by percutaneous techniques. The lumbar catheter is inserted into the lumbar subarachnoid space through a 3½-inch, 14-gauge Touhy spinal needle with a Huber tip. A catheter passer and peritoneal trocar may be used to bring the peritoneal catheter section around the flank and into the peritoneal cavity.

A variety of devices are available: a one-piece model without a reservoir; separate large or small reservoirs that contain a one-way valve, which may be used when a flushing capability is required; and a separate miter valve, available in low, medium, or high pressure, which may be used when added resistance is desired.

One-Piece Model
The One-Piece Lumbar Peritoneal Shunt Model (Figure 1) is a single, barium-impregnated silicone elastomer catheter, one end of which has the features of the proximal tip of the lumbar catheter, the other end of which has the features of the distal end of the peritoneal catheter. The catheter has sufficient length (80 cm) to pass around the flank of a moderately obese adult. A flushing reservoir is not incorporated in the one-piece model.

Three movable, separate suture collars, provided with the one-piece model, are used to secure both ends and the center portion of the catheter to subcutaneous tissue at the lumbar, flank, and abdominal incision sites. A 3½-inch, 14-gauge Touhy needle is supplied for inserting the lumbar catheter end into the subarachnoid space.

Due to the design of this model, it is more easily implanted by primarily percutaneous techniques. It may be used for diagnostic purposes as well as for the treatment of hydrocephalus. Since it is not used with a reservoir, it may be easily removed when no therapeutic benefit ensues.

The proximal or lumbar end of the one-piece model catheter (Figure 2) is open-ended and cut at an angle. Approximately 18 mm of the tip is multi-perforated to help improve flow and decrease the possibility of obstruction. The stiffer silicone elastomer helps decrease the possibility of kinking and collapse at the segment where the catheter emerges between the laminae and begins its path to the flank. Four black, tantalum-impregnated, silicone elastomer length markers are placed on the lumbar (proximal) end of the shunt. (See Figure 1.) The first (most proximal) marker aligns with the opening in the hub of the Touhy needle when the lumbar end is inserted into the needle so that the tip of the catheter is near the point of the needle. The remaining markers are located at 5 cm intervals from the first marker to allow the surgeon to gauge the length of catheter that has been inserted into the lumbar subarachnoid space.
The distal or peritoneal end of the one-piece model catheter (Figure 3) incorporates a radiopaque, tantalum-impregnated silicone elastomer tip. Two through-slits (making four slits in the catheter wall), spaced 90° radially and 3 mm axially, provide pressure control and resist retrograde flow and obstruction at the distal end.

A separate stainless steel connector is supplied with the one-piece model. In case it is necessary for the surgeon to cut the catheter, the cut ends can be joined with the connector. (Figure 4.)

Both the large and small reservoirs include a one-way flow miter valve in the reservoir-dome-inlet port. The miter valve resists retrograde flow of fluid to the lumbar subarachnoid space. The capacity of the large reservoir is greater than that of other Integra NeuroCare LLC reservoirs. The large reservoir improves palpability and facilitates the use of the reservoir for flushing the peritoneal catheter, for injection of a radionuclide to evaluate shunt function, or for sampling CSF. The small reservoir, however, may be preferable for use in patients with thin skin (e.g., slender patients) or for cosmetic purposes. Fluid-flow direction is indicated by an arrow molded into the reservoir dome top. (Figure 6.)

Additional resistance to flow may be obtained by the placement of a small cylindrically housed miter valve at any point along the Lumbar Peritoneal Shunt. This valve is available in low, medium, and high pressure ranges and contains integral stainless steel connectors for easy insertion at the time of initial shunt placement or revision. Fluid flow direction is indicated by a radiopaque arrow on the valve housing. The differential pressure range is identified by a tantalum-impregnated silicone elastomer dot code on the valve housing. Refer to valve performance chart.

Pressure Values
Since the Lumbar Peritoneal Shunt System is implanted at the level of the lumbar region of the spine, it is designed to provide relatively high resistance to cerebrospinal fluid flow. Pressure control is achieved by the combined action of the double-slit valve at the peritoneal end and the small internal diameter (.7 mm or .028") of the catheter tubing.

Catheter performance characteristics are reported in accordance with the shunt performance test method contained in the American Society for Testing and Materials F647-79, "Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application."
Indications
Percutaneous lumbar peritoneal shunting may be utilized in the treatment of communicating hydrocephalus. It is designed to shunt CSF from the lumbar subarachnoid space to the peritoneal cavity.

The shunt may be used for diagnosis, evaluation or treatment of normal pressure communicating hydrocephalus.

A percutaneous lumbar peritoneal shunt is also useful in the management of persistent cerebrospinal fluid fistulas, bulging cranial and suboccipital decompressions and in transient CSF absorption defects, e.g., post-meningitic or post-hemorrhagic hydrocephalus.

The In-Line Valve, available as a separate component of the system, is desired to alleviate symptoms of low pressure in the small percentage of patients who, after normal drainage and in the normal course of treatment, develop such symptoms.

Contraindications
Lumbar Peritoneal Shunting Systems should not be used for non-communicating hydrocephalus.

Lumbar Peritoneal Shunting Systems should not be used in the presence of known or suspected meningitis, ventriculitis, skin infections, bacteremia, sepsis or peritonitis. It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Lumbar peritoneal shunting systems are contraindicated in cases of spinal abnormalities that would prevent free insertion of the lumbar catheter.

Lumbar peritoneal shunts are contraindicated in infants where the lower end of the spinal cord has not yet migrated to its cephalad L1-2 position.

In view of the marked narrowing of the lumbosacral canal in achondroplastic patients, a lumbar shunt in the subarachnoid space is contraindicated.

The trocar method of peritoneal catheter introduction is contraindicated if there have been previous abdominal operations or if excessive obesity exists.

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.

Instructions For Shunt Patency Test
The components of each shunt model should be tested for patency prior to implantation. The following procedures are recommended:

One-Piece Model and Assembled Three-Piece Model
Using aseptic technique, insert a 20-gauge, blunt syringe needle into the most distal of the side-inlet holes on the proximal, lumbar end. Gently flush the lumen of the entire shunt with 5 to 10 cc. of sterile, isotonic solution. Fluid should flow freely from the slit valves in the distal, peritoneal end (four slits in the tubing wall). If all four slits do not allow the fluid to flow freely, gently roll the slit valve area between the thumb and forefinger to open the slits. Repeat the flushing procedure.

Note: The valve slits are coated with graphite to minimize adherence during storage and should not be flushed with any solution before patency is tested immediately prior to implantation.

Procedural Instructions
The following information relevant to the use of both models of the Lumbar Peritoneal Shunting System is provided by Dr. Robert Spetzler,* based on his experience in the surgical treatment of patients with communicating hydrocephalus.

1. Connect the enclosed length of sterile tubing to the inlet tube of the valve and elevate the tubing above the valve. No tubing should be connected to the outlet connector.

2. Orient the valve horizontally on the test table.

3. Using a syringe, fill the tube to approximately 18 cm. Use sterile de-aerated 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 insure 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 miter 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.

10 cc. of sterile, isotonic solution.
3. Make a 1-centimeter skin incision between the spinous process of L4-5 or L5-S1. Temporarily elevate the head of the table 30° to increase the pressure in the lumbar subarachnoid space.

4. Insert the supplied 14-gauge, 3½-inch extra thin-wall Touhy needle into the low lumbar subarachnoid space with the bevel pointed cephalad or caudad.

5. Pass the open, multi-perforated end of the one-piece catheter through the Touhy needle for a distance of 8 cm (Figure 7). Tilt the operating-room table back to the normal position.

6. Withdraw the needle over the catheter. If the CSF pressure is greater than the flow resistance of the one-piece shunt, CSF may be seen escaping from the slit valves in the distal end of the one-piece shunt.

7. Place a single suture collar around the catheter in the lumbar area and suture it to the subcutaneous tissue to hold the catheter in place (Figure 8).

8. Make a small incision in the flank and pass the malleable Subcutaneous Catheter Passer with the obturator in place through the flank incision, subcutaneously around to the lumbar incision. This specially designed instrument, with the obturator attached, is malleable and may be bent to facilitate this procedure. Remove the obturator and insert the distal end of the one-piece catheter into the lumbar opening of the Subcutaneous Catheter Passer.

Gently push the catheter through the passer. Care must be taken to avoid damage to the catheter, as the slit valve of the peritoneal end can be deformed or torn if too much force is used. In the event the catheter cannot be easily pushed through the passer, the catheter can be pulled through by applying gentle suction to the flank end of the subcutaneous catheter passer. (The end of the catheter passer accepts standard suction tubing.) (Figure 9).

Withdraw the Subcutaneous Catheter Passer over the catheter leaving the flank portion in place. Place a single suture collar around the catheter in the flank incision and suture it to the subcutaneous tissue to hold the catheter in place (Figure 10).

9. Make a small skin incision two centimeters below the umbilicus in the midline through the linea alba.

If the catheter must be retracted and some resistance is encountered, withdraw the Touhy needle approximately ¾ cm, then push the catheter forward slightly to free it and then withdraw the catheter.

Note: See illustrations for detail of the insertion of the one-piece model. Specifics regarding the use of the three-piece model with reservoir attachment are given in the section which follows the one-piece model procedure.

1. A Foley catheter should be inserted in the bladder to minimize the possibility of perforating the bladder when inserting the peritoneal catheter.

2. The back, flank and abdomen are scrubbed and draped with the patient in a lateral position with both knees flexed.
10. Insert the Subcutaneous Catheter Passer, with the obturator in place, through the abdominal incision and pass subcutaneously around to the flank incision. Remove the obturator and insert the peritoneal end of the one-piece model into the flank opening of the catheter passer. Gently push the catheter through the passer. In the event the catheter cannot be easily pushed through the passer, the catheter can be pulled through using gentle suction as outlined earlier (Figure 11). Withdraw the Subcutaneous Catheter Passer over the catheter leaving the abdominal portion in place subcutaneously (Figure 12).

11. If the shunt is to be inserted into the peritoneal cavity using a Peritoneal Trocar, the following procedure is recommended. Secure an Allis clamp on the aponeurosis and apply firm outward traction on the abdominal wall. Insert the trocar through a small stab incision in the superficial layer of the aponeurosis into the peritoneal cavity, while continued outward traction is applied on the Allis clamp. Remove the trocar after insertion.

This manner of introduction allows the trocar to be passed through the thinnest portion of the abdominal wall where it is least likely to encounter any vascular or neural structures.

12. If the trocar is not used to insert the catheter into the peritoneal cavity, insert the catheter under direct vision.

13. Insert any remaining slack tubing into the peritoneal cavity. Place a suture collar around the catheter tubing. Suture the collar to the subcutaneous tissues. Close all incisions in the usual manner (Figure 13).

Note: As the flanges of the collar are brought together, the collar tightens around the tubing.

14. Patency of the implanted shunting system should be checked by injecting approximately 2 mCi of Technetium-99m albumin into the cervical subarachnoid space or, if present, into the reservoir in the flank. Use a scintillation camera to trace the flow of the isotope into the peritoneal cavity.

Three-Piece Model (Assembled From Cut One-Piece Model Plus Reservoir)

Cut the one-piece model at its midpoint, thereby making a lumbar end and a peritoneal end. Trim each end for proper length if necessary. Prepare the patient as in the procedure for the one-piece model, steps 1-4 above.

5. Pass the open, multi-perforated tip of the lumbar end through the Touhy needle for a distance of 8 centimeters. Tilt the operating-room table back to the normal position.

6. Withdraw the needle over the catheter. Clear cerebrospinal fluid will be seen escaping from the end of the lumbar catheter.

Handle the catheter gently to avoid damage to the tube.

7. Introduce the distal end of the lumbar catheter into the flank using the same procedure as with the one-piece model. (See 8 above, one-piece model.)

8. Make a small skin incision two centimeters below the umbilicus in the midline through the linea alba. Introduce the peritoneal catheter into the abdominal incision using the same procedure as with the one-piece model. (See 10-13 above, one-piece model.)

9. When a three-piece model is being implanted, insert the supplied stainless steel connectors into the lumbar peritoneal catheter ends of the cut one-piece shunt and then slip the assemblies into the tubes on the reservoir at the flank incision. The direction of the fluid flow in the reservoir is indicated by an arrow molded into the dome. The reservoir is connected so that flow is in the direction of the arrow (lumbar to peritoneal). Secure the catheters to the connectors and to the reservoir with single encircling ligatures (four required).

Excessive tightening of the ligatures may result in cutting of the shunt tubing.
Flow/Pressure-Range Chart

Flow Rate | One-Piece Model (NL850-7210)
---|---
5 ml/hr. | 50 mm H₂O
50 ml/hr. | 400 mm H₂O

Values shown in the flow/pressure-range chart are the low point of the 5 ml/hr. range and the high point of the 50 ml/hr. range.

Pressure Range of a One-Piece Shunt (NL850-7210)

**Note:** Addition of a large or small reservoir to the one-piece shunt system will add a maximum pressure of 50 mm of H₂O at a flow rate of 23 ml/hr.

Trimming the shunt length by 20 cm will result in an overall decrease in system pressure of approximately 15 mm H₂O at a flow rate of 23 ml/hr.

Valve Performance Chart

<table>
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<tr>
<th>Dot Code</th>
<th>Low Pressure</th>
<th>Medium Pressure</th>
<th>High Pressure</th>
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<tr>
<td></td>
<td>15 mm H₂O</td>
<td>50 mm H₂O</td>
<td>85 mm H₂O</td>
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<td>115 mm H₂O</td>
<td>200 mm H₂O</td>
<td>310 mm H₂O</td>
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**Note:** Valves shown in the flow/pressure range chart are the low point of the established 5 ml/hr. range and the high point of the 50 ml/hr. range.

**Note:** Shaded areas describe limits of in-vitro valve performance tested at the time of manufacture. Due to characteristics of silicone materials some variation in pressure performance may occur which historically has not compromised effective control and treatment of hydrocephalus. Each component of a shunting system affects the overall flow resistance of that system. To determine the approximate combined pressure range (flow pressure) provided by the Spetzler® In-Line valve in series with the one-piece system, add the pressure given in the chart above at a particular flow rate to the pressure given on the pressure chart for the one-piece system at that same flow rate.
10. Position the reservoir subcutaneously above the iliac crest. Secure the reservoir by suturing through the reservoir base flange to the subcutaneous tissue. (Figure 14). Close all incisions in the usual manner (Figure 15).

11. Patency of the three-piece system should be checked as in 14 above (one-piece model).

In-Line Valve

The implantation of the In-Line valve may be accomplished in the same manner as the reservoir, with the following exceptions:

1. The In-Line valve may be implanted at any subcutaneous point along the one-piece system. If the In-Line valve is used with a reservoir and flushing through the system is desired, the In-Line Valve must be placed distally to the reservoir.

2. Because the In-Line Valve contains integral connectors at the inlet and outlet ends, only one ligature is required at each end for catheter connection (two required).

As with other systems, patency of the system created with the In-Line Valve should be checked as in 14 above (one-piece model).

Connector

If the surgeon confronts a situation where it is necessary to cut the one-piece model to adjust the length, a stainless steel connector supplied with the one-piece model is used. Insert the supplied stainless steel connector into one catheter end, then into the other, and secure each with a single encircling ligature (Figure 16). Close the molded suture collars at each end and secure them to the subcutaneous tissue. Close all incisions in the usual manner.

How Supplied

The Three-Piece Lumbar Peritoneal Shunt Model is not supplied as a complete system. The items required to assemble a three-piece shunt are: The one-piece shunt cut in half and the In-Line Valve with integral connectors or a flushing reservoir. Two stainless steel connectors are supplied and packaged with each reservoir.

The One-Piece Lumbar Peritoneal Shunt Model is supplied as a single lumbar-to-peritoneal catheter with three suture collars and a stainless steel connector. The connector is included in case the catheter is cut or shortened. One 3¾-inch, 14-gauge Touhy needle is also supplied.

The One-Piece Lumbar Peritoneal Shunt Model is supplied in a sterile, pyrogen-free double-wrap packaging system. The double-wrap system is 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 shunt failure. These signs and symptoms may vary from patient to patient. Increasing intracranial pressure is characterized by headache, vomiting, irritability, listlessness, drowsiness, nuchal rigidity and other signs of deterioration of consciousness.

The miter valve in the flushing reservoirs and In-Line Valve are made of silicone rubber, which like most rubber, may stick to itself when dry. When wet, the silicone rubber should not stick; therefore, the surgeon must verify that the valve components are wet and that fluid flows freely through the valve. (See Instructions for Use.)

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 elastomer tubing should be carefully secured to the integral connectors on the In-Line Valve, the reservoir, or connector with ligatures in such a manner as to avoid cutting of the tubing.

The shunt should be secured to the subcutaneous tissue by use of the suture collars or through the base flange of the reservoir at all three incision sites.

Due to the low profile, cylindrical design of the In-Line Valve it is not necessary to secure it to the subcutaneous tissue.

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

TO AVOID POSSIBLE TRANSECTION OF THE CATHETER, THE CATHETER SHOULD NEVER BE WITHDRAWN THROUGH THE TOUHY NEEDLE. IF THE CATHETER NEEDS TO BE
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, mechanical failure of the shunt system, infection, or intracranial hypotension.

Shunt obstruction may occur in the lumbar or peritoneal catheter. Peritoneal tubes may be obstructed by particulate matter such as blood clots or fibrin.

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 migration of the tubing into the lumbar subarachnoid space or into the peritoneal cavity.

Infection is a common and serious complication of a shunting system and is most frequently caused by skin contaminants. Septicemia can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as the result of a wound infection. The presence of a foreign body (i.e., the shunting system) may trigger peritonitis, ventriculitis, arachnoiditis, or a dormant meningitis. Infection may then be disseminated throughout the body via the peritoneal catheter.

Lesions developing from the breakdown of skin or tissue over the shunting system may also serve as focus of serious infection. 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. These include subdural hematoma, 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: continued 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 removal of the shunting system or of the affected component.

Other reported complications of shunting systems, both lumbar-peritoneal and lumbar-ureteral, include scoliosis, hyperlordosis, and kyphoscoliosis. Perforation of the bowel or other organs by the shunt tubing may occur.

Unilateral ureteral obstruction can be caused by a non-functioning shunt tube pressing laterally against the ureter. Root signs and symptoms reported are usually transient; however, in some cases they are of sufficient severity to require shunt removal.

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 or 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
Fax: 609-275-5363

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.

Symbols Used On Labeling

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<th>Symbol</th>
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<td><img src="https://example.com/stereile.png" alt="Sterile Symbol" /></td>
<td>Sterile unless package is opened or damaged. Method of sterilization: ethylene oxide.</td>
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Product complies with requirements of directive 93/42/EEC for medical devices.
Bibliography


Spetzler, Robert F. "Lumbo-Peritoneal Shunting in the Diagnosis and Treatment of Normal Pressure Hydrocephalus." Federation of Western Societies of Neurological Science, Mazatlan, Mexico, Feb. 24-27, 1977.


**Dimensioned Illustrations (All dimensions are nominal)**

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>NL850-7210</td>
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<td>NL850-7460</td>
<td>Spetzler® Lumbar Peritoneal Large Flushing Reservoir</td>
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<td>NL850-7440</td>
<td>Spetzler® Lumbar Peritoneal Small Flushing Reservoir</td>
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<td>Spetzler® Lumbar Peritoneal In-Line Valve, Low Pressure</td>
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**Spetzler® Lumbar Peritoneal Flushing Reservoir**

- **Large Reservoir**
  - Inlet and Outlet Tube Size: 0.7 mm ID, 1.5 mm OD
  - Dimensions: 2.9 cm x 1.2 cm

- **Small Reservoir**
  - Inlet and Outlet Tube Size: 0.7 mm ID, 1.5 mm OD
  - Dimensions: 2.2 cm x 0.6 cm
Spetzler® Lumbar Peritoneal Shunt, One-Piece

- 0.7 mm ID x 1.5 mm OD
- Four length marker dots spaced at 5 cm intervals
- Typical
- 10 cm
- 5 cm
- 80 cm

Spetzler® Lumbar Peritoneal In-Line Valve

- 2.1 cm
- 5 mm
- 3.2 cm

Connector *

Suture Collar *

- Suture Holes
- 5.2 mm

14-Gauge Touhy Needle *

* Also sold separately, non sterile. Use standard hospital protocol for sterilization.