INSTRUCTIONS FOR USE

Setting the Performance Level before Implantation
The physician must determine the proper initial performance level setting for each patient and adjust the valve accordingly prior to implantation. Refer to the Instructions for Use which accompanies the adjustment tools for information regarding performance level adjustments prior to implantation.

Before implantation, the Strata NSC lumboperitoneal valve is compatible with the pS medical Strata II Adjustment Kit (labeled Ref 45805) and the StrataVarius Adjustment System. Note: Refer to separate instructions for the Strata II Adjustment Kit and StrataVarius Adjustment System.

Surgical Technique
WARNING: There should be a maximum of 1 cm of tissue thickness over the valve mechanism to facilitate reading and setting the valve.

Surgical Technique (continued)
A variety of surgical techniques may be used in placing the Strata NSC lumboperitoneal valve. The valve is implanted with the flat surface adjacent to underlying tissue. Site of placement is at the discretion of the surgeon. To reduce the possibility of post-operative valve flipping and movement (e.g., as the result of magnetic influence due to MRI), the Strata NSC lumboperitoneal valve should be adequately secured to adjacent tissue by passing a suture through the polyester-fabric-reinforced flanges. As desired, the valve can be sutured up to the dermal layer. Excess valve movement can cause migration of the lumbar and/or peritoneal catheter, and can stress the catheter/valve connections, causing holes or tears.

Setting the Performance Level after Implantation
After implantation, the Strata NSC lumboperitoneal valve is compatible with the StrataVarius Adjustment System only. Refer to the Instructions for Use which accompanies the StrataVarius Adjustment System for information regarding performance level adjustments after implantation.

WARNING: Do not use the pS medical Strata II Adjustment Kit for post-operative adjustment and verification of the valve setting.

CAUTION: Excessive swelling or bandages may make it difficult to determine a valve setting. Wait until swelling is reduced or confirm with radiographic imaging. In addition, tissue thickness can make it difficult to determine the valve setting. If this is the case, confirm valve setting with radiographic imaging.

NOTE: Refer to separate instructions for the StrataVarius Adjustment System.

NOTE: Suggested imaging techniques for confirmation of lumboperitoneal valve settings include: 1) Use fluoroscopy positioning to minimize valve obliqueness and ensure the images are being captured perpendicular to the valve; 2) If fluoroscopy has insufficient power to penetrate through the tissues, use fluoroscopy for positioning, then transition to x-ray photographic plate imaging to collimate or “cone down” on the valve, in order to maximize the contrast and the ability to visualize the valve’s radiopaque markers.

For more information, please contact your Neurologic Technologies representative, or refer to www.medtronic.com.

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Cautions: Federal (USA) law restricts this device to sale by or on the order of a physician. Refer to product package insert for instructions, warnings, precautions and complications.

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Strata® NSC Lumboperitoneal Shunt Equipment Usage Guide

The PS Medical® Strata® NSC Lumboperitoneal (LP) Shunt is used to treat communicating hydrocephalus. The Strata NSC LP Shunt is designed to provide continued cerebrospinal fluid (CSF) flow from the lumbar subarachnoid space into the peritoneal cavity. The Strata NSC lumboperitoneal valve allows the physician to noninvasively adjust the pressure/flow performance level pre- and post-implantation without the need for radiographic confirmation in order to address changing patient needs.

The following information describes the components of the shunt and the necessary steps to follow prior to inserting the Strata NSC LP Valve into the patient.

1 Priming the Catheter

Sterile physiological saline is injected into the distal end of the catheter using a syringe and the supplied 20G blunt needle.

2 Using the Guidewire and Adjustable Stop

Thread the guidewire through both the adjustable stop and the open end of the lumbar catheter, until the guidewire contacts the catheter tip.

3 Catheter Insertion with Tuohy Needle

After insertion of the Tuohy needle in the subarachnoid space, the obturator is removed. The catheter and guidewire are fed through the Tuohy needle. When the hub of the Tuohy needle is at the first length marker on the catheter, the catheter tip is located at the tip of Tuohy needle. Approximately 8cm of the lumbar catheter are inserted in the subarachnoid space cephalad to the needle insertion site.

Carefully remove the Tuohy needle. Do not pull the catheter back against the Tuohy, as it can slice the catheter.

4 Attachment of Lumbar Catheter to Strata NSC LP Valve

Slide the strain relief onto the lumbar catheter, narrow end first, so that the flared end is directed towards the distal end of the catheter.

Attach the lumbar catheter to the proximal valve connector.

Slide the strain relief over the connector and verify that the catheter/connector junction is intact.

Secure the strain relief and the catheter to the connector with a snug secure tie in the groove of the strain relief, using a heavy non-resorbable suture.