“美敦力” 腦脊髓液引流控制閥

“Medtronic” CSF-Flow Control Valves

衛署醫器輸字第 022359 號

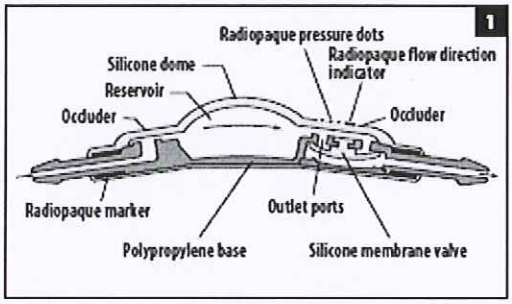
使用前請務必詳閱原廠之使用說明書並遵照指示使用。

型號與規格

23093	Valve, Contoured Regular, Low-Low
27102	Valve, Contoured Small, Low-Low
24003LL	Valve, Button, Low-Low
24003L	Valve, Button, Low
24003M	Valve, Button, Medium

產品敘述

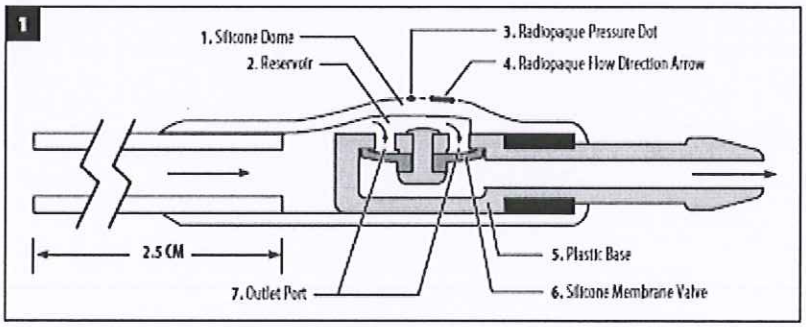
腦脊髓液引流控制閥是以矽膠彈性體及聚丙烯所製成。弧形控制閥共有兩型：一般型(Regular)與小型(Small)，以滿足不同的患者族群。



(弧形控制閥)

所有形式控制閥均以鉭充填的不透射線箭頭作為標記，可辨識從近端至遠端的流動方向，並附有不透射線的點狀編碼，以便利用 X 光辨識控制閥壓力。當使用不透射線導管時，醫師可透過接頭底部的不透射線標記，以 X 光顯影出體內導管和控制閥的相對位置。所有控制閥均配有可注射圓蓋與聚丙烯注射針護套。弧形控制閥配有可雙向沖洗的近端與遠端關閉器。

鈕扣形控制閥有三種壓力範圍：低壓、低-低壓及中壓。因為鈕扣形控制閥極低壓的特性，特別設計用於早產兒。



(鈕扣形控制閥)

控制閥有多種尺寸與壓力範圍可供選擇，其壓力/流動特性與點狀編碼如下。

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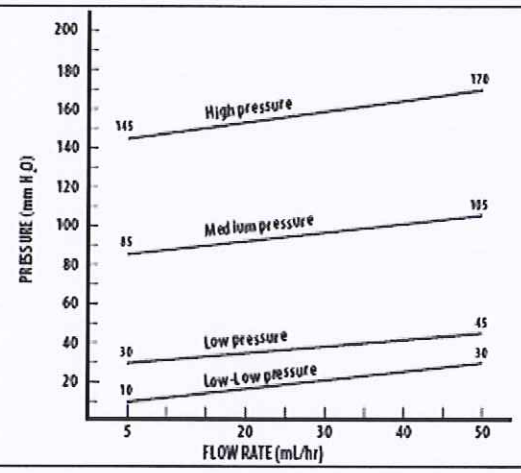


NOTE: Levels depicted are median values.
All valves perform within +/- 25 mm H_2O of these median values when tested at time of manufacture.
Low-Low Pressures are within +/- 10 mm H_2O at 5 mL/hr and +/- 20 mm H_2O at 50 mL/hr at time of manufacture.

Every PS Medical® valve is tested for its performance characteristics using a water-filled system at the time of manufacture. All valves must conform to labeling specifications in these tests. Subsequent testing of the valve may give different results depending on test conditions and condition of the valve. Testing at the time of manufacture serves to assure consistent high quality of every PS Medical valve.

6 **Dot Code**

Low-Low Pressure	—
Low Pressure	·
Medium Pressure	··
High Pressure	···

適應症

腦脊髓液引流控制閥為腦脊髓液引流裝置(Shunt)的組件，用以控制引流從腦室流向右心房或腹腔的腦脊髓液。

使用說明

有多種外科技術可用來植入腦脊髓液引流控制閥。下列外科技術僅供指引參考；醫師必須依據個別患者的需求，來判定實際的植入技術與植入部位。在進行手術之前，應將患者的頭部轉向預定植入引流裝置(Shunt)部位的對側。脖子應稍微向後仰直，並在手術部位的同側肩膀下，放入小型圓墊。為確保通道裝置(tunneling)可筆直通過，頸部不應折起或有皺折。
將控制閥整合式連接器由控制閥連接導管側孔插入，使導管植入腦室再連接控制閥與腹腔導管。導管應將連接器完全覆蓋住。以纏繞的縫線結將導管固定至連接器上。

如要植入弧形控制閥，將其放置緊鄰著顱骨膜的平面。弧形控制閥的上層表面標有指向遠端的不透射線箭頭(指出腦脊髓液的流動方向)。也可利用縫線縫合固定於強化凸緣，將弧形控制閥與鄰近組織縫合。

植入鈕扣形控制閥時，建議將其置入於顱骨與頭皮的皮下組織間，在顱骨與頭皮下以手術器械擴建的囊袋，但是勿置於頭皮切口下。鈕扣形控制閥植入的方向是以平的基底面緊連頭骨膜。鈕扣形控制閥的上層表面標有指向遠端的不透射線箭頭(指出腦脊髓液的流動方向)。
備註：需要外加一個儲水閥(reservoir)作腦脊髓液路徑用。
連接腦室導管至鈕扣形控制閥，需使用直形的連接器。將鈕扣形控制閥的腦室導管裁剪至想要的長度，將直形連接器插入腦室導管一半的位置，用纏繞的縫線結固定。將近端連接器側插入腦室導管，拉長彈性矽膠連接器使完全覆蓋聚丙烯連接器並將腦室導管留置於腦室，再用纏繞的縫線結固定。

注意：若使用尖銳器械來處理這些裝置，可能會劃傷或切割到矽膠彈性體，導致引流裝置(Shunt)滲漏而必須置換。關閉切口時務必小心，確認縫合針並未切割或劃傷控制閥。

注意：引流(Shunt)系統的任一組件均可能會發生引流阻塞，應由臨床表現來判斷。控制閥注滿特性可能不足以用來判斷導管的阻塞情形。請參閱「警告與注意事項」章節。

包裝

腦脊髓液引流控制閥係為無菌與無熱原包裝，且僅供單次(一次)使用。不可重新滅菌。重新滅菌會造成產品損毀，可能導致患者受到傷害。本公司對於產品重新滅菌後的性能，概不負責。若包裝已打開或有破損，請勿使用。

禁忌症

即將植入引流(Shunt)系統組件的部位若出現感染，則不應進行腦脊髓液引流至右心房、腹腔或身體其他部位的植入。這包括引流(Shunt)系統會流過的頭皮及其他皮膚範圍、腦膜與腦室、腹腔、腹腔內及腹腔後器官、肋膜及血流等部位的感染。不論身體任何部位出現感染，均不適合進行腦脊髓液引流。此外，先天性心臟病或其他嚴重心肺異常患者亦禁用採取引流至心房的處置。

患者教育

醫師應負責教育患者及/或其代理人，使其了解腦脊髓液引流的相關資訊。內容應包括說明植入式引流(Shunt)系統可能引起的併發症，以及解釋可能的替代產品與治療選項。

警告與注意事項

為符合個別患者的需求，必須依據診斷用測試結果與醫師經驗，選擇種類、尺寸與壓力或性能範圍適合的產品。產品標示內容已明確說明，適用產品的性能水準或範圍。

植入式產品應避免接觸醫用棉絨、手套的滑石粉、皮膚的油性殘餘物、油性肥皂、合成清潔劑，或其他表面污染物。

植入引流(Shunt)產品時，若操作或使用器械不當，可能會造成組件割斷、裂開、壓壞或斷裂。上述破壞可能導致引流(Shunt)系統喪失完整性，因而必須提前以手術置換引流(Shunt)系統。

植入前測試或操作時必須小心，以確保未將微粒污染物帶入引流(Shunt)組件。若有污染物進入引流(Shunt)系統，可能造成系統表現不正常(引流過量或不足)。進入引流(Shunt)系統的微粒物質，可能會使壓力或引流機制保持在開啟狀態，造成引流過量的情形。

將腦室導管與遠端導管固定於控制閥連接器時，應將纏繞於管路上的縫線固定好，但請勿綁得過緊，以免最後割穿矽膠套管。

安排導管路徑時必須小心，預防沿線出現扭結與不必要的磨損。螺鑽或圓頭銼打開的孔洞邊緣，可加以修整以形成傾斜的凹槽，讓腦室導管從顱骨內露出後能彎曲貼近顱骨。

水腦患者植入引流(Shunt)系統後，必須接受嚴密觀察，檢查是否有顯示引流(Shunt)系統故障的徵象與症狀。臨床表現也可能顯示腦脊髓液出現感染、引流(Shunt)系統阻塞，或者腦脊髓液引流(Shunt)引流過量。

引流(Shunt)系統的各項組件均可能出現阻塞情形。微粒物質(例如：血液凝塊或腦組織碎片)可能會插入脈絡叢的導管末端、或嵌入大腦組織的導管、或在引流過量的情況下與腦室壁結合(「狹縫腦室」)，進而阻斷腦室導管。

心房內導管附近的血塊，可能造成肺動脈分支栓塞，進而導致肺性心臟病與肺性高血壓。脫落的分流系統組件可能進一步進入心臟或腹腔。

引流(Shunt)系統可能會因機械性故障而失效，導致引流不足或過量。

在水腦原因未獲得解決的狀況下，引流(Shunt)系統的故障或阻塞，可能會引起顱內壓力偏

高的徵象與症狀。就嬰兒來說，常見表現為前囟門緊繃程度升高、頭皮靜脈充血、無精打采、嗜睡與易怒、嘔吐與頸部僵直。其他有些孩童與成人會出現與顱內壓力增加相關的徵兆與症狀，例如頭痛、嘔吐、視力模糊、頸背堅硬、意識惡化以及許多異常的神經學表現。腦脊髓液引流過量時，容易形成硬腦膜下血腫或水瘤，或者造成側腦室壁萎陷，進而導致腦室導管阻塞。

假使腦室導管因纖維組織黏連，而沾黏於脈絡叢或鄰近腦組織，最好不要用力取出導管；**輕輕地**旋轉導管或許有助於使其脫離。建議寧願讓導管留在原位，也不要用力取出而引發危險的腦室內出血。

併發症

使用腦脊髓液腦室心房及腦室腹腔引流系統時所引起的併發症，可能類似於局部及/或全身麻醉下進行各種手術時所發生者。這包括對藥物及麻醉劑的反應、電解質失衡與失血過多，特別是針對嬰兒。患者很少因為對植入物體敏感而出現過敏反應的情形。

在腦脊髓液引流過程中，最常見的併發症是由系統阻塞所引起的，請參閱「警告」部分。引流系統的所有組件均可能出現阻塞現象，原因可能是腦組織碎片、血塊及/或腫瘤細胞結塊阻塞在管件沿線的某個位置。此外，引流系統組件脫落，或是導管扭結及/或纏繞，也可能造成阻塞。插入側腦室的腦室導管，與插入心臟及肺動脈分支、腹腔或其他植入導管構造的遠端導管，均可能因此而有移位的傾向。如前所述，在嬰兒或兒童成長時，可能會使遠端導管從心房縮入內頸靜脈，或從腹腔縮入無法吸收液體的組織面。

還有其他潛在的嚴重併發症。局部及全身性感染在引流手術中均很常見。通常感染由存在皮膚上的有機體所引起，特別是表皮葡萄球菌*(Staphylococcus epidermidis)*。其他經血流循環的病原也可能聚集於引流系統繁殖增生，使得大多數患者必須移除引流系統。

Robertson 等人在 1973 年歸納了在此之前的腦室心房及腦室腹腔引流感染發生率報告。腦室心房引流感染發生率的範圍為 7 至 31%；而大多數報告中的腦室腹腔引流感染率範圍為 5 至 10%。由於腦室心房引流容易散播細菌至其他器官，因此一般認為腦室腹腔引流比較不具破壞性。

最近(1993)，Kestle 等人的報告指出，使用抗生素、縮短手術時間(手術經驗)、控制手術室環境(例如：指定手術室、限制人員與流量、包覆皮膚表面)，可明顯降低感染率(低於 4%)。該篇文章並敘明，不使用抗生素也可獲得相同的控制效果，但需要嚴格的手術中環境控制。對引流患者投以預防性抗生素的作法有些爭議，因為這種用藥方式容易遭抗藥性較強的細菌感染。因此，由主治醫師及/或外科醫師決定是否投以預防性抗生素。

引流至腹腔時，可能會因為導管被彎曲腸道或大網膜包圍而失敗。曾有腹腔導管造成腸道穿孔後形成腹膜炎的病例報告。

腦脊髓液引流過量可能導致腦脊髓液壓力過度降低，容易形成硬腦膜下血腫或水瘤，以及腦室空間過度縮小，進而因為腦室壁會緊靠在導管的注入孔導致導管阻塞，。對嬰兒來說，這種壓力過度降低的情形會造成前囟門明顯凹陷、顱骨重疊，而且可能使交通性水腦症轉變成阻塞性水腦症。

曾有在腦室引流後出現癲癇症狀的報告。該研究也指出，癲癇發生率因多次更換導管而升高。

製造廠名稱: Medtronic Neurosurgery
製造廠地址: 125 Cremona Drive, Goleta, CA 93117, U.S.A.
藥商名稱: 美敦力醫療產品股份有限公司
藥商地址: 台北市中山區建國北路二段 120 號 13 樓

English

PS Medical® CSF-Flow Control Valves: Contoured, Standard, Burr Hole, & Ultra Small

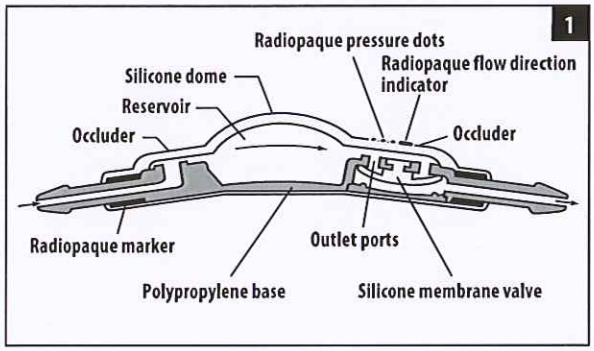
Description

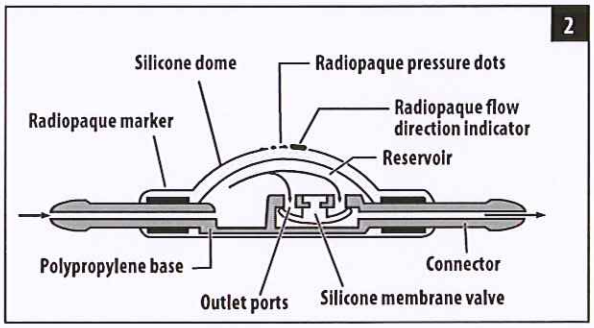
PS Medical® CSF-flow control valves, Contoured, Standard, Burr Hole, and Ultra Small, are diagrammed in Figures 1 through 4. These valves are fabricated from silicone elastomer and polypropylene. The Contoured Valves are available in two models, Regular and Small, to accommodate different patient groups. The Burr Hole Valves are available in two sizes: 12 mm and 16 mm.

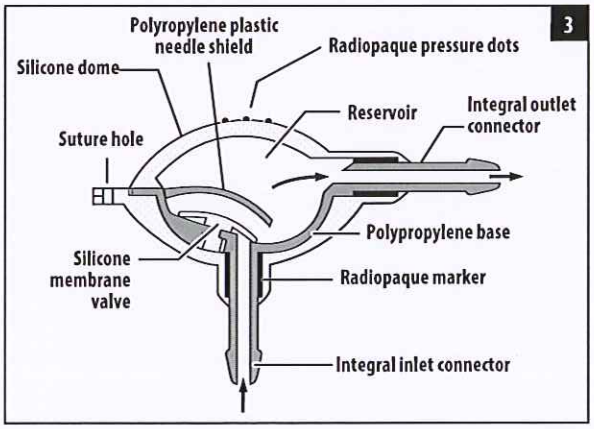
All valves are marked with a tantalum-impregnated radiopaque arrow to indicate proximal to distal flow direction (with the exception of the Burr Hole Valves), and a radiopaque dot code that allows x-ray identification of the valve pressure. Radiopaque markers at the base of each connector allow the physician x-ray visualization of the relative positions of catheters and valve *in vivo* when radiopaque catheters are used.

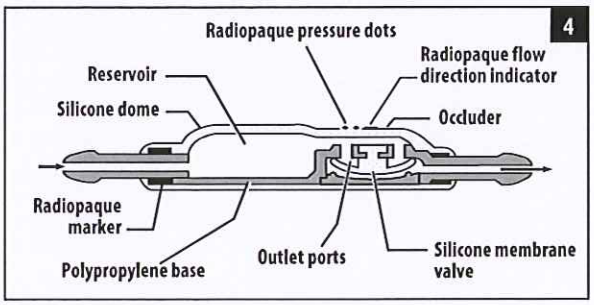
All valves include an injectable dome and a polypropylene needle guard. The Contoured Valves include proximal and distal occluders for two-way flushing. The Ultra Small Valves include one flushing occluder.

The valves are available in a variety of sizes and pressure ranges. Pressure/flow characteristics and dot codes of all the valves are shown in Figures 5 and 6.









Indications

The CSF-flow control valves, Contoured, Standard, Burr Hole, and Ultra Small are the components of CSF-flow control shunts designed to provide controlled CSF flow from the ventricles of the brain into the right atrium of the heart or the peritoneum.

Instructions for Use

A variety of surgical techniques may be used in implanting PS Medical CSF-flow control valves. The following surgical technique is intended to be used only as a guideline; the physician, based on individual patient needs, must determine actual implantation technique and site of placement. Immediately prior to surgery, the patient should be positioned with head turned to the side opposite that of the planned shunt placement site. The neck should be slightly hyperextended, and a small rolled cushion should be placed under the shoulder of the operative side. To ensure that the tunneling device can be passed in a straight line, there should be no folds or creases in the neck.

Connect valve to catheters by inserting valve integral connectors into catheters. Connectors should be completely covered by catheter tubing. Secure catheters to connectors with encircling ligature. Contoured, Ultra Small and Standard Valves are placed with the flat surface adjacent to the pericranium. The Burr Hole Valve is designed to fit into a formal burr hole. The upper surfaces of the Standard, Contoured and Ultra Small Valves are marked with a radiopaque arrow pointed distally (in the direction of CSF flow). Suture holes are provided on the Burr Hole Valve flanges to accommodate valve-to-tissue anchoring. The Contoured, Standard and Ultra Small Valves may be sutured to adjacent tissue by passing a suture through the fabric-reinforced flanges.

CAUTION: USE OF SHARP INSTRUMENTS WHILE HANDLING THESE DEVICES CAN NICK OR CUT THE SILICONE ELASTOMER, RESULTING IN LEAKAGE AND NECESSITATING SHUNT REVISION. CARE MUST BE TAKEN WHEN CLOSING INCISIONS TO ENSURE THAT THE VALVES ARE NOT CUT OR NICKED BY SUTURING NEEDLES.

CAUTION: SHUNT OBSTRUCTION MAY OCCUR IN ANY COMPONENT OF A SHUNT SYSTEM AND SHOULD BE DIAGNOSED BY CLINICAL FINDINGS. VALVE FLUSHING CHARACTERISTICS MAY NOT BE ADEQUATE TO DIAGNOSE OCCLUSION OF THE CATHETERS. SEE WARNINGS AND PRECAUTIONS SECTION.

Injection into the Valve

CSF-flow control valves are designed to allow injection through the dome via 25-gauge or smaller non-coring needles (Fig. 7).

CAUTION: LOW TEAR STRENGTH IS A CHARACTERISTIC OF UNREINFORCED SILICONE ELASTOMER MATERIALS. CARE MUST BE TAKEN ON INSERTION AND REMOVAL OF THE NEEDLE.

The needle should be inserted at an angle no greater than 45° from the scalp or valve base. If the valve will be punctured several times, it is recommended that the needle be inserted at various locations to avoid multiple punctures at a single point. The catheter tubing and occluders should not be used as injection sites.

CAUTION: THE PRESSURE CONTROL MEMBRANE OF THESE DEVICES IS NOT DESIGNED TO ALLOW NEEDLE PENETRATION: SUCH PUNCTURE MAY AFFECT THE PRESSURE/FLOW CHARACTERISTICS OF THE VALVE AND COMPROMISE THE SHUNT SYSTEM.

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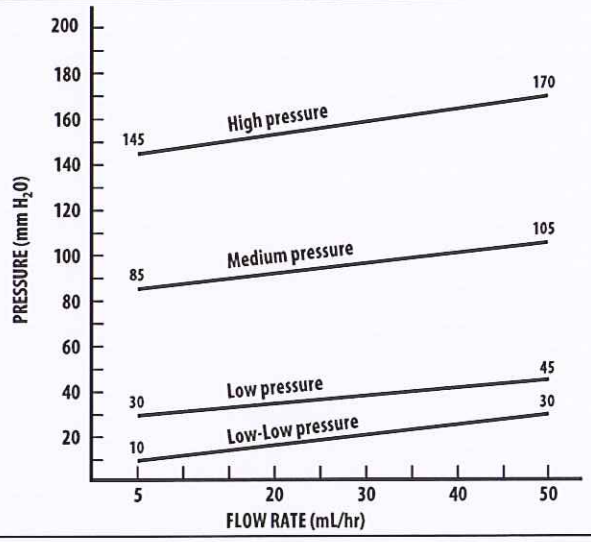


NOTE: Levels depicted are median values.
All valves perform within +/- 25 mm H_2O of these median values when tested at time of manufacture.
Low-Low Pressures are within +/- 10 mm H_2O at 5 mL/hr and +/- 20 mm H_2O at 50 mL/hr at time of manufacture.

Every PS Medical® valve is tested for its performance characteristics using a water-filled system at the time of manufacture. All valves must conform to labeling specifications in these tests. Subsequent testing of the valve may give different results depending on test conditions and condition of the valve. Testing at the time of manufacture serves to assure consistent high quality of every PS Medical valve.

CAUTION: PARTICULATE MATTER IN SOLUTIONS USED TO TEST VALVES MAY RESULT IN IMPROPER PRODUCT PERFORMANCE.

CAUTION: TAKE CARE TO MAINTAIN STERILITY AND TO AVOID PARTICULATE CONTAMINATION.

CSF-Flow Control Valves: Patency Check

Standard and Contoured Valves (Figs. 8 and 9)

a. Place the inlet connector of the valve into sterile isotonic saline.
b. Pump the valve by depressing and releasing the central reservoir section of the valve to fill with fluid and displace all air.
c. Depress and release the valve central reservoir repeatedly until fluid flows out of the outlet connector. (Fig. 11). If fluid flows from the outlet connector each time the central reservoir is depressed, the valve is patent.

CAUTION: EXCESSIVE FLUSHING PRESSURE MAY CAUSE TEMPORARY DEFORMATION OF THE CSF-FLOW CONTROL VALVE MEMBRANE AND RESULT IN ABNORMALLY LOW PRESSURE/FLOW TEST RESULTS.

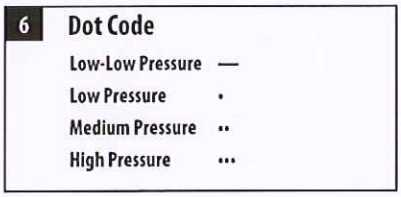
Ultra Small Valves (Fig. 10)

a. Attach 16-gauge blunt needle adapter, tubing, and syringe to the valve inlet.
b. Prefill valve and tubing.
c. Occlude inlet tubing.
d. Depress dome. If fluid flows out of the outlet connector, the valve is patent.

Burr Hole Valve (Fig. 11)

a. Place the inlet connector of the valve into sterile isotonic saline.
b. Depress the valve dome.
c. Place a finger over the opening at the end of the outlet connector.
d. Release the depressed dome. If fluid enters the reservoir, the inlet connector and flow control membrane valve are patent. *

6



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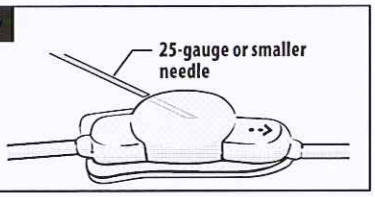

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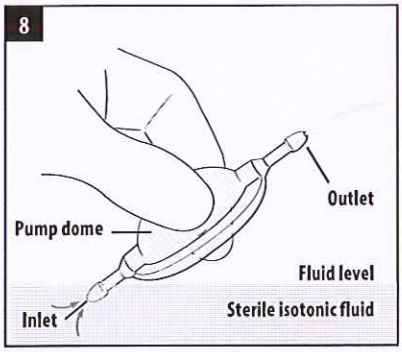

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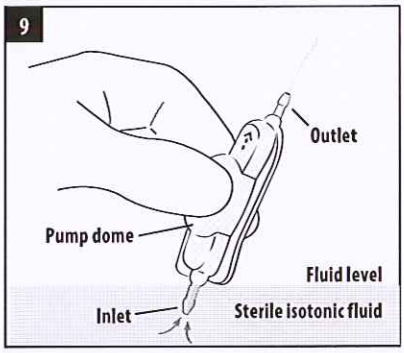

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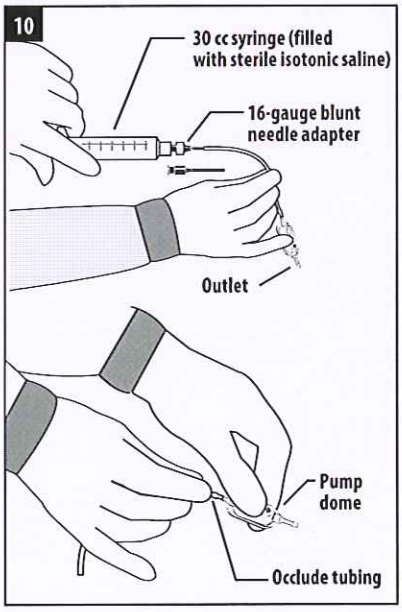

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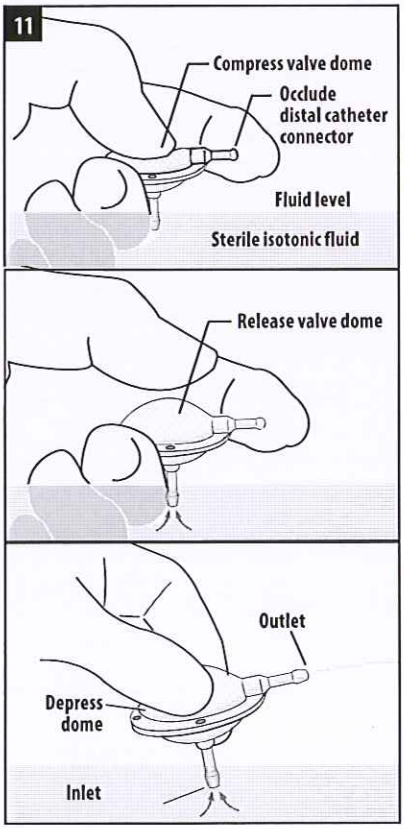


IV. *Test procedure*

NOTE: During testing, the valve must be submerged in the sterile water bath. For correct results, the zero level of the manometer must be properly aligned with the fluid level of the water bath.

1. Connect the sterile valve to be tested to the assembled sterile test apparatus.
2. Turn stopcock as shown in Figure 14 and fill manometer to at least 30 cm H_2O.
3. Turn stopcock to isolate manometer from flow path as shown in Figure 13.
4. Purge all air from the valve and the assembled test apparatus by gently flushing with sterile water from syringe.
5. Gently establish flow through the valve with sterile water from the syringe.
6. Submerge sterile valve in the sterile water bath. The outlet connector of the valve must be under water to obtain correct test results.
7. While gently maintaining flow through the valve, turn stopcock to isolate syringe from flow path as shown in Figure 15. After stopcock is placed in proper position, the water column in the manometer should start to fall. The syringe is now isolated from the valve and continuing flow with the syringe is no longer necessary. If water column does not fall, repeat steps 2 through 7.

NOTE: Allow water level in the manometer to fall for 2 to 2 ½ minutes. Read the resultant pressure from the manometer.

Test Results – Preimplantation Test

The resultant pressure reading may be compared with the following characteristics:

Valve Pressure Range	Acceptable Pressure Range
Low-Low	0–20 mm H_2O
Low	1–50 mm H_2O
Medium	50–110 mm H_2O
High	110–170 mm H_2O

How Supplied

PS Medical CSF-flow control valves are packaged **STERILE** and **NON-PYROGENIC** and are intended for **single** (one-time) **use only. DO NOT RESTERILIZE.** Resterilization can damage the product, potentially leading to patient injury. Medtronic Neurosurgery is not responsible for the performance of any product, which has been resterilized. Do not use if package has been previously opened or damaged.

Special Order Products

If this data sheet accompanies a Special Order product, there may be differences in the physical characteristics between the product and product description in this data sheet. These differences will not affect the safety or efficacy of the special order product. Special order products may be supplied sterile or non-sterile as indicated on the product package label. Non-sterile products must be cleaned and sterilized prior to use.

Contraindications

Shunting of CSF into the right atrium, peritoneal cavity, or other areas of the body should not be carried out if there is infection in any areas in which the various components of the shunt system will be implanted. These include infections of the scalp and other skin area through which the shunt system will traverse, the meninges and cerebral ventricles, peritoneum, and intraperitoneal and retroperitoneal organs, pleura and blood stream. CSF shunting is contraindicated if there is infection present in any area of the body. Additionally, shunting into the atrium of patients with congenital heart disease or other serious cardiopulmonary abnormalities is contraindicated.

Patient Education

It is the responsibility of the physician to educate the patient and/or representative(s) regarding CSF shunting. This should include a description of the complications associated with implantable shunt systems, and an explanation of potential alternative products and treatments.

Warnings and Precautions

The appropriate product, size, pressure, or performance range must be chosen for the specific patient's needs, based on diagnostic tests and physician experience. Product labeling specifies applicable product performance levels or ranges.

Avoid contacting implantable products with lint, glove talc, oily residue from skin, oil based soaps, synthetic detergents or other surface contaminants.

Improper handling or use of instruments when implanting shunt products may result in the cutting, slitting, crushing or breaking of components. Such damage may lead to a loss of shunt integrity, and necessitate premature surgical revision of the shunt system.

Care must be taken to ensure that particulate contaminants are not introduced into shunt components during preimplantation testing or handling. Introduction of contaminants could result in improper performance (overdrainage or underdrainage) of the shunt system. Particulate matter, which enters the shunt system, may also hold pressure/flow controlling mechanisms open, resulting in overdrainage.

In securing the ventricular and distal catheters to the valve connectors, the ligatures encircling the tube should be securely, but not too tightly fastened, lest they eventually cut through the silicone tubing.

Care must be taken in the routing of catheters to prevent kinking and needless abrasion along their course. The rim of the twist drill or burr hole may be trimmed to provide a beveled notch where the ventricular catheter emerges and is curved to lie adjacent to the skull.

Patients with hydrocephalus shunt systems must be kept under close observation in the postoperative period for signs or symptoms suggesting shunt malfunction. Clinical findings may indicate infection, shunt obstruction or overdrainage of CSF.

Shunt obstruction may occur in any of the components of the shunt system. Particulate matter such as blood clots or brain fragments may occlude the ventricular catheter, by investment of the catheter tip in choroid plexus, by embedding of the catheter in brain tissue, or by coaptation of the ventricular walls in the presence of overdrainage ("slit ventricles").

Clotting around the atrial portion of the catheter may lead to embolization of the pulmonary arterial tree with resulting cor pulmonale and pulmonary hypertension.

Disconnected shunt components may further migrate into the heart, or into the peritoneal cavity.

Shunt systems may fail due to mechanical malfunction, leading to underdrainage or overdrainage.

Malfunction or obstruction of the shunt system may lead to signs and symptoms of increased intracranial pressure if the hydrocephalus is not compensated. In the infant, common findings are increased tension of the anterior fontanelle, congestion of scalp veins, listlessness, drowsiness and irritability, vomiting, and nuchal rigidity. Other children and adults will develop signs and symptoms commonly associated with increased intracranial pressure such as headaches, vomiting, blurring of vision, nuchal rigidity, deterioration of consciousness and variable abnormal neurological findings.

Overdrainage of CSF may predispose development of subdural hematoma or hygroma or collapse of the lateral ventricular walls leading to obstruction of the ventricular catheter.

If the ventricular catheter becomes bound to the choroid plexus or adjacent brain tissue by fibrous adhesions, it is suggested that the catheter should not be removed forcibly. It is suggested that **gentle** rotation of the catheter may help to free it. It is advised that the catheter be left in place rather than risk intraventricular hemorrhage which forcible removal may cause.

Complications

Complications associated with ventriculoatrial and ventriculoperitoneal CSF shunting systems may be similar to those experienced in any surgical procedure carried out under local and/or general anesthesia. These include reactions to drugs and anesthetic agents, electrolyte imbalance and excessive blood loss, particularly in infants. A patient may rarely exhibit a reaction due to sensitivity to the implant.

In CSF shunting procedures, the most common complications are due to obstruction of the system as described under "Warnings." Obstruction may occur in any component of the system due to plugging by brain fragments, blood clots, and/or tumor cell aggregates at some point along its course. Obstruction may also occur because of separation of the system components or kinking and/or coiling of the catheter. This may predispose migration of the ventricular catheter into the lateral ventricle and the distal catheter into the heart and pulmonary arterial tree, the peritoneum, or other structure in which the catheter is implanted. As noted previously, growth of the infant or child may cause the distal catheter to be withdrawn from the atrium into the internal jugular vein or from the peritoneum into tissue planes where the fluid cannot be absorbed.

There are other potentially serious complications. Local and systemic infections are not uncommon with shunting procedures. Usually, they are due to organisms inhabiting the skin, particularly *Staphylococcus epidermidis*. Other pathogens circulating in the blood stream may colonize the shunt and, in the majority of patients, require its removal.

In 1973, Robertson et al summarized the incidence of infection in ventriculoatrial and ventriculoperitoneal shunts reported up to that time. The incidence of infection in ventriculoatrial shunting varied from 7 to 31%. Infection in ventriculoperitoneal shunting occurred in 5 to 10% of the patients in most of the reports. Because ventriculoatrial shunting predisposes the spread of bacteria into other organs, ventriculoperitoneal shunting is considered less devastating.

Recently, (1993) Kestle et al reported significant reductions in infection (less than 4%) with the use of antibiotics, short duration of surgery (surgical experience) and control of the operating room environment (e.g., designated operating room, limited personnel and traffic, covered skin surfaces). The article states that results can also be obtained without the use of antibiotics, but with rigorous perioperative control of the environment.

Using prophylactic antibiotics in shunted patients is somewhat controversial as their use may predispose infection by more resistant organisms. Therefore, the decision to use antibiotics prophylactically rests with the attending physician and/or surgeon.

Shunting into the peritoneum may fail because of investments of the catheter in loops of bowel or in the greater omentum. Perforation of the bowel by the peritoneal catheter with subsequent development of peritonitis has been described.

CSF overdrainage may result in excessive reduction of CSF pressure and predispose the development of a subdural hematoma or hygroma, and excessive reduction of ventricular size leading to obstruction because of impingement of the ventricular walls on the inlet holes in the catheter. In the infant, this excessive pressure reduction will cause marked depression of the anterior fontanelle, overriding of cranial bones and may convert communicating into obstructive hydrocephalus.

The incidence of epilepsy after ventricular shunting procedures has been reported. This study also indicated that the incidence of seizures increased with multiple catheter revisions.

Returned Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact, to be accepted for replacement or credit, unless returned due to a complaint of product defect or mislabeling. Determination of a product defect or mislabeling will be made by Medtronic Neurosurgery, which determination will be final. Products will not be accepted for replacement or credit if they have been in the possession of the customer for more than 90 days.

Warranty

A. Standard Limited Warranty. Medtronic Neurosurgery warrants to the original end user purchaser ("Purchaser") that the enclosed single use implantable product ("Product") purchased by Purchaser, at the time of delivery to Purchaser, shall be substantially free from defects in material and workmanship. Medtronic Neurosurgery makes no warranty (express, implied, or statutory) for Products that are modified (except as expressly contemplated herein) or subjected to unusual physical stress, misuse, improper operation, neglect, improper testing, use in combination with other products or components other than those for which the Products were designed, or use in any manner or medical procedure for which the Products are not indicated.

B. Remedy. Purchaser's exclusive remedy and Medtronic Neurosurgery's sole liability for breach of the foregoing warranty shall be, at Medtronic Neurosurgery's sole option and election, to replace the Product or credit Purchaser for the net amount actually paid for any such Product; provided that (i) Medtronic Neurosurgery is notified in writing within ninety (90) days after Purchaser's receipt of the Product that such Product failed to conform, including a detailed explanation in English of any alleged nonconformity; (ii) such Product is returned to Medtronic Neurosurgery within ninety (90) days after Purchaser's receipt of the Product F.O.B. 125 Cremona Drive, Goleta, California 93117, U.S.A. or as otherwise designated by Medtronic Neurosurgery ; and (iii) Medtronic Neurosurgery is reasonably satisfied that the claimed nonconformities actually exist. Except as expressly provided in this paragraph, Purchaser shall not have the right to return Products to Medtronic Neurosurgery without Medtronic Neurosurgery's prior written consent.

C. Exclusion of Other Warranties. EXCEPT FOR THE LIMITED WARRANTY PROVIDED IN (A) ABOVE, MEDTRONIC NEUROSURGERY GRANTS NO OTHER WARRANTIES OR CONDITIONS, EXPRESS OR IMPLIED, AND MANUFACTURER SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTIES AND CONDITIONS OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. MEDTRONIC NEUROSURGERY NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME ANY OTHER LIABILITIES ARISING OUT OF OR IN CONNECTION WITH THE SALE OR USE OF ANY PRODUCT.

English

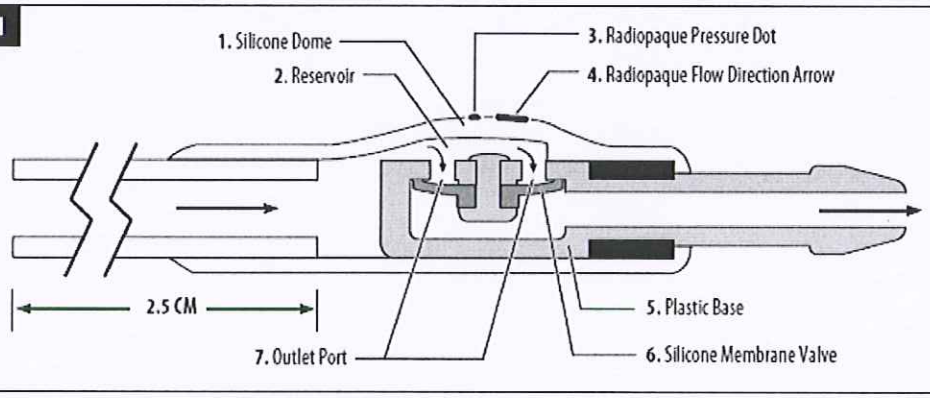
PS Medical® Button Valve

Description

Medtronic Neurosurgery's PS Medical® Button Valve (Fig 1) products are available in three pressure ranges, Low Low, Low, and Medium. The radiopaque dot code on the valve indicates valve pressure ranges (Fig 2). Pressure/flow characteristics of the Button Valves are shown in Figure 3.

The Button Valve, with its ultra-low profile, is designed for use especially in premature infants.

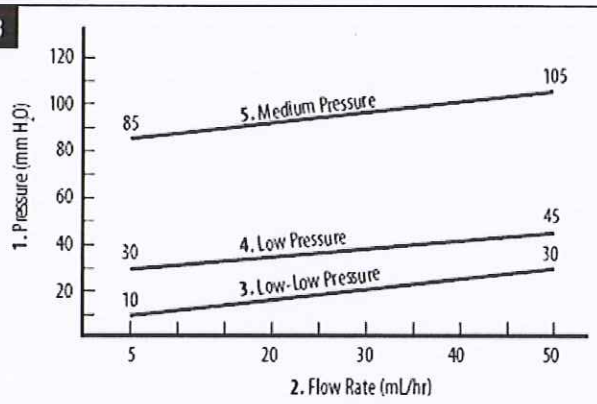
1



2

	1. Low-Low Pressure	2. Low Pressure	3. Medium Pressure
Dot Code	—	•	••

3



6. NOTE: Levels depicted are median values. The tolerance range of the median values is:

+/- 25 mm H_2O. Low-Low

Pressures are within:

+/- 10 mm H_2O at 5 mL/hr

and

+/- 20 mm H_2O at 50 mL/hr

7. Every Medtronic Neurosurgery valve is tested for its performance characteristics using a water-filled test system at the time of manufacture. All valves conform to labeling specifications in these tests. Subsequent testing of the valve may give different results depending on test conditions and condition of the valve. Testing at the time of manufacture serves to assure consistent, high quality of every Medtronic Neurosurgery valve.

Indications

The Button Valve is the component of a CSF-Flow Control Shunt system designed to provide controlled CSF flow from the ventricles of the brain into the right atrium of the heart or to the peritoneal cavity.

Instructions for Use

A variety of surgical techniques may be used in placing the Button Valve on the skull. The site of placement is at the discretion of the surgeon. It is suggested that the Button Valve be placed in a surgically created subgaleal pocket and not under the scalp incision. The Button Valve is implanted with the flat base adjacent to the pericranium. The upper surface of the Button Valve is marked with a radiopaque arrow which is pointed distally in the direction of CSF flow.

NOTE: A separate reservoir is required for CSF access.

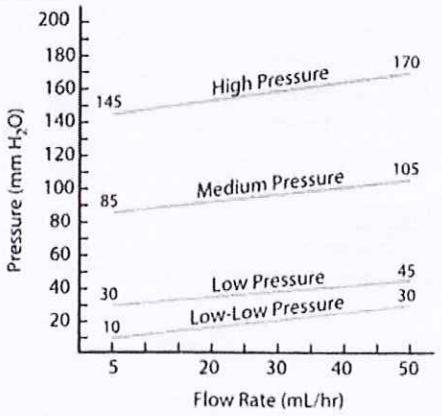
To connect a ventricular catheter to the Button Valve, a straight connector must be used. Cut the inlet tube of the Button Valve to the desired length. Insert the straight connector half-way into the inlet tube of the button valve. Secure with one encircling ligature. Insert the proximal connector into the ventricular catheter completely covering the polypropylene connector. Secure with one encircling ligature.

Valves

PS Medical® CSF-Flow Control valves are fabricated of dissimilar materials — polypropylene and silicone elastomer — reducing valve sticking and deformation. The internal flow path, combined with the membrane valve design, contribute to optimum valve performance. Each valve is individually tested to ensure conformance with individual flow characteristics.

All valve designs include integral connectors to facilitate catheter connection and decrease the possibility of catheter disconnection. The standard, contoured, burr hole, and ultra small models include central reservoirs with needle guards for percutaneous CSF access. Flushing occluders are incorporated in the contoured and ultra small models for proximal and distal flushing. The non-metallic design of the valves ensures non-interference with MRI or CT scans. All PS Medical valves are latex free. Radiopaque indicators show valve pressure, flow direction, and valve-to-catheter approximation.

The exterior surface of the Contoured valve with BioGlide is surface modified with a covalently bonded hydrogel. The BioGlide surface has hydrophilic properties for enhanced lubricity and ease of insertion.

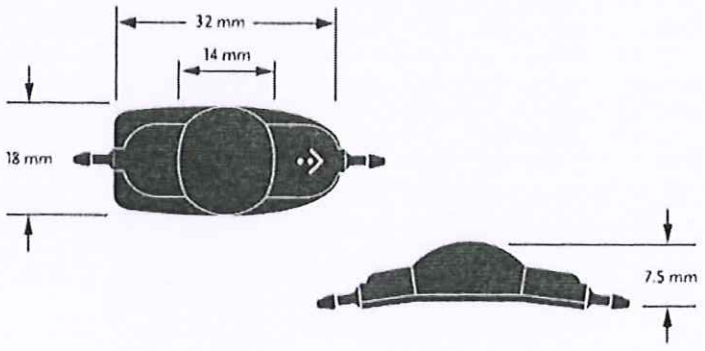


Product Dot Codes

❙ Low-Low Pressure ● Low Pressure ●● Medium Pressure ●●● High Pressure

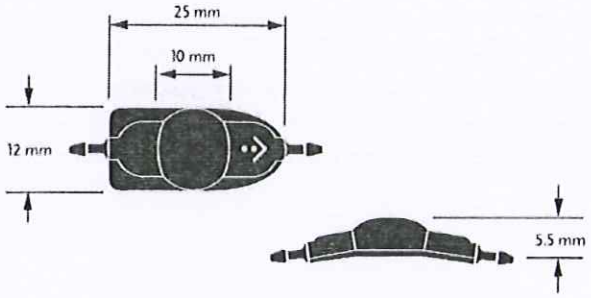
CSF-Flow Control Valve, Contoured Regular

Product	Pressure	Description
23093	Low-Low	
42322	Low	
42324	Medium	
42326	High	
92322	Low	with BioGlide
92324	Medium	with BioGlide
92326	High	with BioGlide



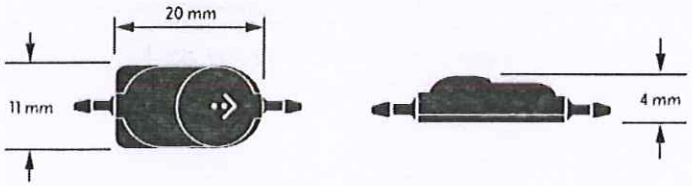
CSF-Flow Control Valve, Contoured Small

Product	Pressure	Description
27102	Low-Low	
42312	Low	
42314	Medium	
42316	High	
92312	Low	with BioGlide
92314	Medium	with BioGlide
92316	High	with BioGlide



CSF-Flow Control Valve, Ultra Small

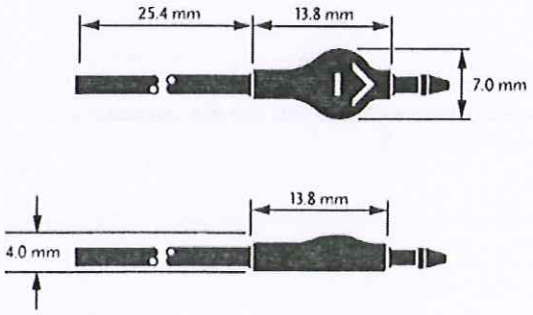
Product	Pressure
42410	Low-Low
42412	Low
42414	Medium



CSF-Flow Control Valve, Button

Included with product:
- Straight Connector (not shown)

Product	Pressure
24003 LL	Low-Low
24003 L	Low
24003 M	Medium



CSF-Flow Control Valve, Burr Hole

Product	Pressure	Size
42532	Low	12 mm
42534	Medium	12 mm
42536	High	12 mm
42542	Low	16 mm
42544	Medium	16 mm
42546	High	16 mm