HFA 305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 7 2000

'00 JUL 10 P1:43

Mr. Steven M. Dolle
3908 ½ River Avenue
Newport Beach, CA 92663

Re: #96P-0444

Dear Mr. Dolle:

This is in response to your letter dated September 11, 1999, to Dr. Jane Henney, Commissioner of Food and Drugs. I apologize for our delay in getting back to you. Since 1996, you have had numerous interactions with staff members of the FDA's Center for Devices and Radiological Health (CDRH). You have advocated improved technology of CNS shunts (particularly anti-siphon shunts) and improved monitoring of hydrocephalus patients who have these devices. Your September 11 letter makes several requests and the following is a point-by-point response.

1. an inquiry into whether discussion of your 1996 Citizen's Petition to the FDA, or other input, was unfairly minimized at the January 8, 1999, STAMP conference on shunt technology;

We (FDA) assigned a member of the Issues Management Staff, Office of Surveillance and Biometrics, CDRH, who had no prior knowledge of the issue or your previous interactions with the CDRH, to review the entire file. This reviewer concluded that the ambitious agenda for the one-day conference on shunt technology was full with previously scheduled scientific speakers. Regrettably, there was little time available for discussion. It may have been preferable to have a multiple-day symposium, which would have allowed for discussion of additional issues, but this was not feasible due to the CDRH's resource constraints. You were, however, invited to the meeting by CDRH and your participation was welcome.

2. assistance in obtaining revisions to anti-siphon shunt labeling, and customary updates from CDRH;

We have enclosed a sample of revised anti-shunt labeling. In addition, you can receive copies of other products' labeling by submitting a Freedom of Information (FOI) request for labeling for a particular 510(k). To access a list of releasable 510(k)s, you can visit our web site at www.fda.gov/cdrh. Click on the Special Interest button, choose Databases, then click on 510(k)s – Premarket Notification. Type in the product code JXG; this will give you a list of all releasable 510(k)s. You may receive a copy of labeling for any of these 510(k)s. Submit an FOI request via FAX to FDA's FOI office at

96P-0444

ANS1

(301) 443-1726 or by mail to FOI, (HFI-35), FDA, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857. We do not have a mechanism in place for providing "customary updates" on labeling changes. You may, however, submit periodic requests for labeling through FOI.

3. facilitation of public discussion, research, and funding, as well as expedient FDA licensing, of new devices to monitor shunt performance;

We facilitate public discussion of issues involving new devices whenever possible, again within the constraints of limited funding and available staff. We have been successful in shortening review times for new device applications, as well as 510(k) premarket notifications, in which a new device is shown to be substantially equivalent to a legally marketed device. However, our mandate is to review marketing applications that are submitted to the Agency by a manufacturer; we do not develop new devices.

4. comment on whether the DiaCeph Test, a monitoring device under development, can be given special assistance in development by the CDRH because its inventor is a disabled patient user responding to an unmet need;

We have considered whether the DiaCeph Test might be eligible for review under the Humanitarian Device Exemption or as an orphan product. However, the number of potential users of such a device would exceed the limitations of those regulatory mechanisms. Medical device legislation of 1976 led the CDRH to establish the Division of Small Manufacturers' Assistance (DSMA), which provides technical and regulatory assistance to all small device manufacturers. DSMA is ready to assist all device manufacturers, including disabled patient users. In addition, you may wish to contact Mr. Neil Ogden, the branch chief for these devices, at (301) 443-8262, for additional assistance.

5. comment on whether the CDRH might require shunt manufacturers to submit additional information on how their devices should be maintained, and trouble-shooting procedures in case of suspected device malfunction.

We review labeling on specific devices, including recommendations for maintenance and trouble-shooting of possible problems, which are submitted by the device's manufacturer. Each manufacturer is most knowledgeable about its own products, as well as any problems associated with use. Manufacturers, therefore, generally are best able to make product-specific recommendations. Revised Quality System Regulations, which went into effect on June 1, 1997 (21 CFR, Part 820), include two new provisions that address your concerns: Design Controls, and Corrective and Preventative Actions (CAPA). The purpose of the design control subsystem is to control the design process to assure that devices meet users' needs, intended uses, and specified requirements. The purpose of CAPA is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. As part of periodic inspections of device manufacturers to determine whether they comply with current device regulations, we assess compliance

with Design Controls and CAPA. If a manufacturer's design controls and CAPA subsystems are in compliance, those systems should indicate when additional information is required in the labeling. We are available to consult with the manufacturer on proposed changes in labeling, including labeling related to maintenance and trouble-shooting in cases of suspected malfunction.

We encourage you to contact DSMA's Manufacturers' Assistance area at (800) 638-2041 if you need specific information on regulatory issues with new devices, or you can access DSMA's web site at www.fda.gov/cdrh/dsma. If you have additional questions regarding this matter, you may contact Janet Morgan, R.Ph. of the Issues Management Staff at (301) 594-4366.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations
and Policy
Center for Devices and
Radiological Health

Enclosure

Authorized EC-representative:
Medtronic B.V.
Wenckebachstraat 10
6466 NC Kerkrade
The Netherlands

Manufacturer:
Medtronic, Inc.
7000 Central Ave NE
Minneapolis, MN 55432 USA

STERILE	EO

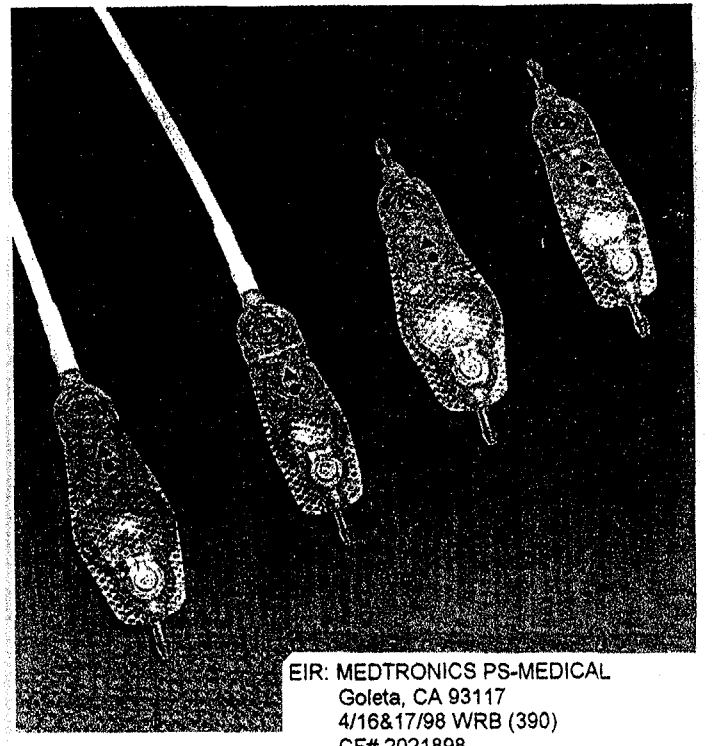
Medtronic

Design & Manufacturing Facility:
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117-5500 USA
(800) 826-5603 USA/Canada
(805) 968-1546 International
(805) 968-6889 FAX

13068-1B 5753
© Medtronic, Inc. 1997
All Rights Reserved
Printed in USA

INSTRUCTIONS FOR USE/GEBRUIKSAANWIJZING/MODE D'EMPLOI/
GEBRAUCHSANWEISUNG/ISTRUZIONI PER L'USO/INSTRUCCIONES DE USO/BRUKSANVISNINGARE

DELTA® VALVES AND SHUNT ASSEMBLIES
DELTA KLEPPEN EN SHUNTSYSTEMEN
VALVES ET ASSEMBLAGE DE DÉRIVATION DELTA
DELTA-VENTILE UND SHUNT-BAUGRUPPEN
VALVOLE DELTA E ASSEMBLAGGI DI DERIVAZIONE
VÁLVULAS Y CONJUNTOS DE DERIVACIÓN DELTA
DELTA-VENTILER OCH-SHUNTUTRUSTNING



EIR: MEDTRONICS PS-MEDICAL
Goleta, CA 93117
4/16&17/98 WRB (390)
CF# 2021898
EXHIBIT 4

Medtronic

Delta® is a registered trademark of Medtronic, Inc.
Delta is een wetig gedeponeerd handelsmerk van Medtronic, Inc.
Delta est une marque déposée de Medtronic, Inc.
Delta ist ein eingetragenes Warenzeichen der Medtronic, Inc.
Delta è un March reistrato della Medtronic, Inc.
Delta es una marca de registrada de Medtronic, Inc.
Delta är ett registrerat varumärke för Medtronic, Inc.

Delta® Valves and Shunt Assemblies

Table of Contents

Delta Valves

Description	4
Indications	4
Instructions for Use	4
Preimplantation Test	7

Delta Shunt Assemblies

Description	9
Indications	9
Instructions for Use	9
How Supplied	10
Special Order Products	10
Contraindications	10
Patient Education	10
Warnings and Precautions	10
Complications	11
Returned Goods Policy	12
Warranty	12
Bibliography	80

Delta® Valves

Description

The Medtronic PS Medical Delta® Valve incorporates a membrane pressure valve in series with a normally closed siphon control mechanism. This combination enables the valve to maintain intraventricular pressure (IVP) within a normal physiological range, regardless of a patient's CSF flow requirements or body position. Flow control is accomplished by combined resistance of the membrane and siphon control diaphragms. Degree of resistance determines the performance characteristics of the valve. Retrograde flow is prevented by the membrane. The siphon effect is controlled by the two normally closed silicone elastomer diaphragms of the Delta siphon control mechanism. The diaphragms open in response to positive upstream IVP.

Delta Valves, Small and Regular, are available in Performance Levels 1, 1.5, and 2. Performance characteristics of the valve are shown in Fig 1 a-b. Pressure/flow performance data with and without siphon effect is provided. Each valve is individually tested to ensure conformance with labeled performance characteristics.

The valves are fabricated with a precision molded firm polypropylene base invested in a smooth, flexible silicone elastomer housing with a convex bottom (Fig 2). The base contributes to structural integrity and pressure/flow reliability, and is designed to prevent the distortion and sticking of the valve seat and membrane, and siphon control ports and diaphragms. The dome is marked with radiopaque tantalum-impregnated direction/pressure arrows showing Performance Level and flow direction.

Delta Valves incorporate connectors designed to decrease possibility of catheter disconnection. One encircling ligature is required to secure each catheter to the valve. Radiopaque markers at the base of each connector (Fig 2) allow the physician x-ray visualization of the relative positions of catheters and valve *in vivo* when radiopaque catheters are used.

The radiopaque ▲ code on the valve indicates the pressure. One ▲ corresponds to Performance Level 1; ▲▲ to Performance Level 1.5, and ▲▲▲ to Performance Level 2. The dome is designed to allow injection or CSF sampling via a 25-gauge or smaller beveled needle (Fig 3). Complete valve penetration by the needle is prevented by the firm polypropylene base. Delta Valves can be flushed in either the distal or proximal direction by percutaneous finger pressure. Occluders are located proximal and distal to the central reservoir to facilitate selective flushing.

Patient Data Survey System

Each Delta Valve is packaged with a patient wallet card and stick-on labels. One set of stickers for each shunt component can be put on the chart in the operating room, a second set on the patient's clinic chart, and a third set on the patient card. The card can be carried at all times, providing a current record of implanted devices.

Indications

The Delta Valve is the shunt component designed to provide controlled CSF flow from the ventricles of the brain into the right atrium of the heart or peritoneal cavity. Additionally, the Delta Valve minimizes the excessive reduction of intraventricular pressure and volume due to excessive drainage of CSF, which may be caused by the siphoning effect of hydrostatic pressure of the distal catheter. The siphon effect may be created by the elevation of the ventricular catheter with respect to the distal catheter (i.e., when the patient sits, stands, or is held erect).

Instructions for Use

Surgical Technique

A variety of surgical techniques may be used in placing Medtronic PS Medical Delta Valves. The valve is implanted with the flat surface adjacent to the pericranium. Site of placement is at the discretion of the surgeon. The valve may be sutured to adjacent tissue by passing a suture through the polyester-fabric-reinforced flanges.

Placement location of a Delta Valve will have an impact on overall shunt performance. The foramen of Monro is one established zero level reference point for intracranial pressure monitoring. Placement of the valve above this reference point will result in an overall increase in the resistance to flow of the shunt system. Placement of the valve below the reference point will result in an overall decrease in the resistance to flow of the shunt system when the patient is sitting, standing or held erect. These changes are directly proportional to the linear distance (mm) above or below the reference point.

The resistance properties of Delta Valves as indicated in the Performance Characteristics charts in this product labeling are specified at the zero reference point.

It is suggested that the valve be placed in a surgically created loose subgaleal pocket, avoiding compression by the overlying scalp, and not under the scalp incision. The Delta Valve should not be placed under the skin of the neck, chest, or abdomen.

Connect valve to catheters by inserting integral connectors into catheters. The connectors should be completely covered by catheter tubing. Secure catheters to connectors with encircling ligature.

Injection into the Valve

The Delta Valve is designed to allow injection or CSF sampling through the dome by use of a 25-gauge or smaller beveled needle (Fig 3a).

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

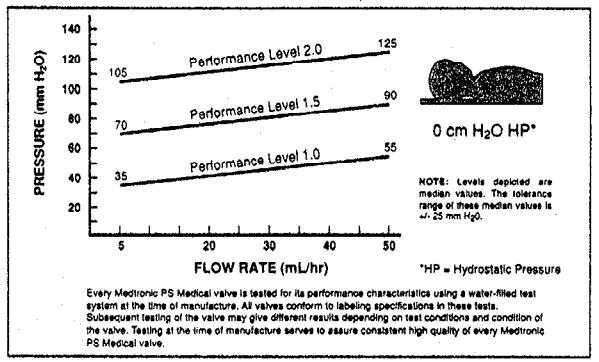


Fig. 1a

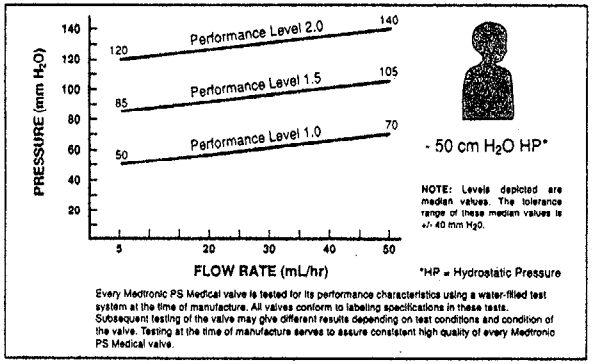


Fig. 1b

The needle should be inserted at an angle of approximately 30 to 45° from the scalp or base of the valve. 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, occluders and siphon control diaphragms should **not** be used as injection sites.

CAUTION: THE SIPHON CONTROL PORTION OF THIS DEVICE IS NOT DESIGNED TO ALLOW NEEDLE PENETRATION: PUNCTURE OF THE DIAPHRAGMS MAY AFFECT THE PERFORMANCE CHARACTERISTICS OF THE VALVE AND COMPROMISE THE SHUNT SYSTEM.

Valve Flushing

The Delta Valve can be flushed in both the *proximal* and *distal* directions by percutaneous depression of the valve dome (Fig. 3b). To selectively flush, depress and occlude either proximal or distal occluder sections of the valve by percutaneous finger pressure, then depress the valve dome. This will cause the fluid to flow in the direction opposite the occluded side of the valve. If there is noticeable resistance to dome compression, the catheter being flushed may be occluded.

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

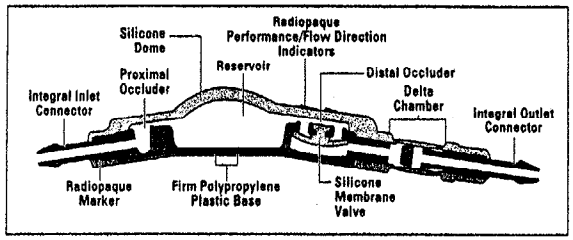


Fig. 2

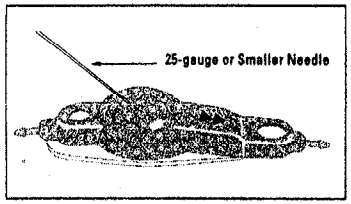


Fig. 3a

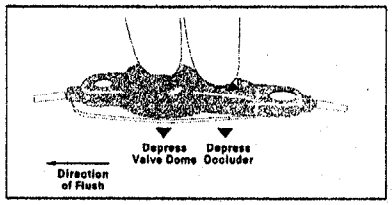


Fig. 3b

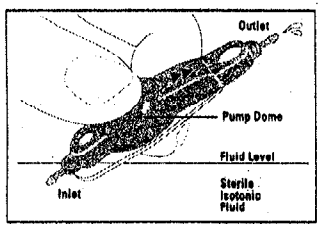


Fig. 4

Patency Check

Place the inlet connector of the valve into filtered, sterile isotonic saline. Depress and release the valve dome repeatedly until fluid flows from the outlet connector (Fig. 4). If fluid flows from the outlet connector each time the dome is depressed, the valve is patent.

CAUTION: DO NOT ATTEMPT TO ASPIRATE FLUID THROUGH THE DELTA VALVE FROM THE DISTAL (OUTLET) END. DAMAGE TO THE VALVE MAY RESULT.

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

Preimplantation Test

Each Delta Valve is tested to ensure conformance with its labeled performance characteristics. Although verification of a valve's dynamic performance characteristics using a static test that can be performed in the operating room is not possible, the surgeon may wish to verify that the Delta Valve conforms to Medtronic PS Medical specifications prior to implantation. The following preimplantation test may be performed in the operating room:

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

NOTE: Performance of the preimplantation test at negative hydrostatic pressure is not recommended as contamination is possible if the sterile field is broken.

Test Method

I. Equipment required for this test:

1. Sterile fluid reservoir or sterile water bath
2. Sterile 30 cm water manometer, graduated in millimeters, with 3-way stopcock at base
3. Sterile syringe, 30 cc to 50 cc
4. Sterile 5μ syringe filter
5. Sterile tubing adapters
6. Sterile silicone tubing

II. Equipment setup:

1. Set up the manometer and water bath so that the zero level on the manometer and the fluid level in the water bath are the same height as shown in Fig 5.
2. Fill syringe with sterile water using 5μ syringe filter. (When refilling syringe always use 5μ syringe filter.) After filling syringe, detach syringe filter.
3. Connect syringe, manometer and silicone tubing as shown in Fig 6 using tubing adapters as needed.
4. To purge all air from the assembled sterile test apparatus, turn stopcock as shown in Fig 7.
5. Submerge silicone tubing in the sterile water bath and flush with sterile water from syringe.

III. Equipment Calibration:

1. Turn stopcock as shown in Fig 8 and fill manometer to at least 5 cm H_2O.
2. With silicone tubing submerged in water bath, turn stopcock to isolate syringe from the manometer as shown in Fig 9.
3. Allow water column in the manometer to fall.
4. Water column should stop at zero level of the manometer as shown in Fig 5.
   Zero the level of the manometer to the water bath as necessary.
5. Manometer is now calibrated to the zero level of the water bath. Fix or mount the manometer to maintain reference position with water bath.

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 Fig 8 and fill manometer to at least 30 cm H_2O.
3. Turn stopcock to isolate manometer from flow path as shown in Fig 7.
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 or the outlet end of the shunt assembly catheter 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 Fig 9. 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 it is no longer necessary to continue flow with the syringe. If water column does not fall, repeat steps 2-7.
8. Allow the water level in the manometer to fall for 2 to 2 1/2 minutes. Read the resultant pressure from the manometer.

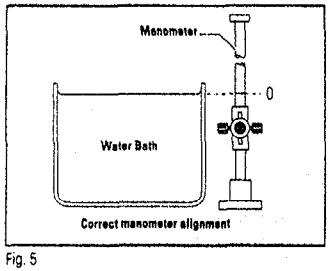


Fig. 5

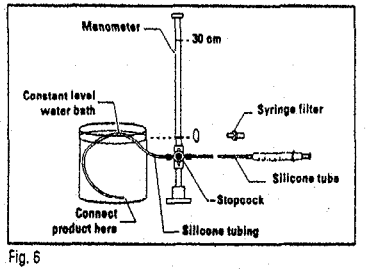


Fig. 6

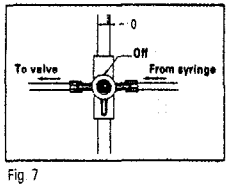


Fig. 7

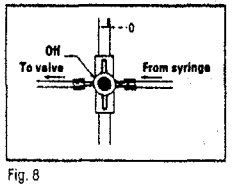


Fig. 8

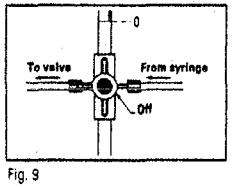


Fig. 9

Test Results - Preimplantation Test

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

Valve Performance Level	*Acceptable Pressure Ranges*
Level 1	1 to 60 mm H_2O at 0 HP
Level 1.5	35 to 95 mm H_2O at 0 HP
Level 2	70 to 130 mm H_2O at 0 HP

Delta® Shunt Assemblies

Description

Delta® Shunt Assemblies, Small and Regular, are available in Performance Level 1, Performance Level 1.5, and Performance Level 2. The radiopaque ▲ code on the valve indicates the pressure. One ▲ corresponds to Performance Level 1; ▲▲ to Performance Level 1.5, and ▲▲▲ to Performance Level 2. The regular size incorporates a Delta Valve, Regular with an integral peritoneal catheter 90 cm in length, standard diameter, barium impregnated, open end with wall slits. The small size incorporates a Delta Valve, Small with an integral peritoneal catheter 90 cm in length, standard diameter, barium impregnated, open end with wall slits. The connection between the siphon control portion of the Delta Valve and the integral distal catheter allows catheter rotation.

Cerebrospinal fluid exits the catheter through four slit openings, placed 90° apart around the catheter circumference near the distal tip. These openings are designed to provide protection from retrograde flow. They are not designed as pressure/flow control valves, but add slight resistance to flow. Maximum resistance to flow at a constant flow rate of 20 mL/hour is 2.0 cm H_2O. The slit openings are coated with graphite during manufacture to minimize the possibility of slitted surface adhesion during storage.

Indications

Delta Shunt Assemblies are designed for use in shunting CSF from the lateral ventricle of the brain into the peritoneal cavity. The distal catheter with wall slits is not recommended for placement into the right atrium of the heart. Additionally, the Delta Valve minimizes the excessive reduction of intraventricular pressure and volume due to excessive drainage of CSF, which may be caused by the siphoning effect of hydrostatic pressure of the distal catheter. The siphon effect may be created by the elevation of the ventricular catheter with respect to the distal catheter (i.e., when the patient sits, stands, or is held erect).

Instructions for Use

Surgical Technique

A variety of techniques may be used in placing Delta Shunt Assemblies. Surgical technique is at the discretion of the surgeon. It is suggested that the valve be placed in a surgically created loose subgaleal pocket, avoiding compression by overlying scalp, not under the scalp incision. The valve may be secured by suturing through its polyester-fabric-reinforced flange.

NOTE: Placement location of a Delta Valve will have an impact on overall shunt performance. For more information on this, see "Surgical Technique" section for Delta Valves.

Ventricular Catheter Attachment to Shunt Assembly

NOTE: A ventricular catheter is not included with the Delta Shunt Assembly.

To connect the shunt assembly to a ventricular catheter, insert the integral polypropylene connector into the catheter tubing, completely covering connector with tubing. Secure with an encircling ligature. Create a subgaleal pocket with appropriate depth to accept the extracranial portion of the shunt assembly which is comprised of the ventricular catheter and the valve component. It is recommended that the implantation of the ventricular catheter be the last step in the procedure to minimize loss of CSF.

Peritoneal Catheter Placement

A variety of surgical techniques may be used to place the integral distal catheter into the peritoneal cavity. Site of placement is at the discretion of the surgeon. The catheter is 90 cm long with wall slits at the distal end. If slits aren't desired, the distal end may be trimmed. The catheter should be checked for patency at the time of surgery. Each Delta Shunt Assembly is packaged with a disposable peritoneal catheter passer 60 cm in length. The catheter passer is designed to be directed subcutaneously in the distal direction with handle and obturator in place. The malleable tubular passer shaft may be hand formed as indicated for the surgical procedure. After passer placement, the obturator is unlocked from the handle and the handle removed from the passer shaft. Then, the distal end of the peritoneal catheter is placed on the obturator end fitting. The obturator and catheter are drawn through the passer shaft by pulling the obturator tip, and the obturator is removed from the catheter tubing. The passer shaft is then withdrawn through the abdominal incision.

Shunt Patency Check

(a) Prefill the shunt using a syringe filled with filtered, sterile isotonic saline to expedite the patency check. (b) Place inlet connector of valve into sterile physiological saline. (c) Depress and release the valve dome repeatedly until fluid flows from the distal catheter. Observe flow from distal end of catheter. (d) Gently rolling the slit opening area between thumb and forefinger will free the slits if they do not appear to open completely. Smooth catheter wall with thumb and forefinger so slit openings are in closed position after completion of the patency check.

CAUTION: DO NOT ATTEMPT TO ASPIRATE FLUID THROUGH THE DELTA VALVE FROM THE DISTAL (OUTLET) END. DAMAGE TO THE VALVE MAY RESULT.

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

How Supplied

Medtronic PS Medical Delta Valves and Shunt Assemblies 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 PS Medical is not responsible for the performance of any product which has been resterilized.

A complete shunt requires a Ventricular Catheter, a Delta Valve, and a Cardiac/Peritoneal Catheter or Peritoneal Catheter.

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 descriptions 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 their 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 and size 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.

Lint, fingerprints, talc, other surface contaminants, or residues from latex gloves can cause foreign body or allergic reactions.

Improper use of instruments in the handling of implantation of shunt products may result in the cutting, slitting or crushing of components. Such damage may lead to 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 (over- or underdrainage) of the shunt system. Particulate matter which enters the shunt system may result in shunt occlusion, or may also hold pressure/flow controlling mechanisms open, resulting in overdrainage.

In securing catheters to connectors, the encircling ligatures 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. Abrasion can result in premature catheter failure (fracture). 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.

"Small" size catheters have thinner walls and lower overall strength as compared with "Standard" size catheters. These characteristics result in a comparatively greater potential failure (fracture) rate and, therefore, shorter life expectancy for "Small" size catheters. Physicians who implant "Small" size catheters for cosmetic reasons must acknowledge the potentially higher rate of catheter revision and weight this against the cosmetic benefit.

Patients with hydrocephalus shunt systems must be kept under close observation in the postoperative period for signs and symptoms that suggest shunt malfunction. The clinical findings may indicate shunt malfunction. The clinical findings may indicate shunt obstruction or overdrainage of CSF.

Shunt obstruction may occur in any of the components of the shunt system. The system may become occluded internally due to tissue fragments, blood clots, tumor cell aggregates, bacterial colonization or other debris. Catheters which contact internal body structures can become kinked or blocked at their tips (e.g., investment of a ventricular catheter tip into the choroid plexus or of the distal catheter tip into the greater omentum or loops of the bowel). Finally, shunt obstruction may occur due to growth of an infant or child, or physical activities which result in disconnection of the shunt components or withdrawal of a distal catheter from its intended drainage site.

Shunt obstruction may occur in any of the components of the shunt system. The ventricular catheter may become occluded by particulate matter such as blood clots or brain fragments, 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 ventricle").

Clotting around the atrial portion of a 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 under- 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, the common symptoms are increased tension of the anterior fontanelle, congestion of scalp veins, listlessness, drowsiness and irritability, vomiting and nuchal rigidity. In older children and adults, the common symptoms are headaches, vomiting, blurring of vision, nuchal rigidity, deterioration of consciousness, and various abnormal neurological findings.

Overdrainage of CSF may predispose development of a subdural hematoma or hydroma 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 tissue adhesions, it is suggested that it should not be forcibly removed. 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 may be caused by forcible removal.

Subcutaneous catheter passers can break at welds or component assembly points, or due to extreme deformation of the malleable shaft. Sudden breakage can lead to trauma of tissues or organs, and damage to the shunt system. Instruments must be inspected prior to use to ensure continued integrity and functionality. Disposable instruments must never be reused, or injury to the patient and physician is possible.

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, ventriculopentoneal 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 PS Medical, 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 PS Medical warrants to the original end user purchaser ("Purchaser") that [Medtronic PS Medical's 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 PS Medical 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 PS Medical's sole liability for breach of the foregoing warranty shall be, at Medtronic PS Medical'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 PS Medical 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 PS Medical 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 PS Medical; and (iii) Medtronic PS Medical 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 PS Medical without Medtronic PS Medical's prior written consent.

C. Exclusion of Other Warranties. EXCEPT FOR THE LIMITED WARRANTY PROVIDED IN (A) ABOVE, MEDTRONIC PS MEDICAL 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 PS MEDICAL 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.

Delta® kleppen en shuntsystemen

Inhoudsopgave

Delta kleppen

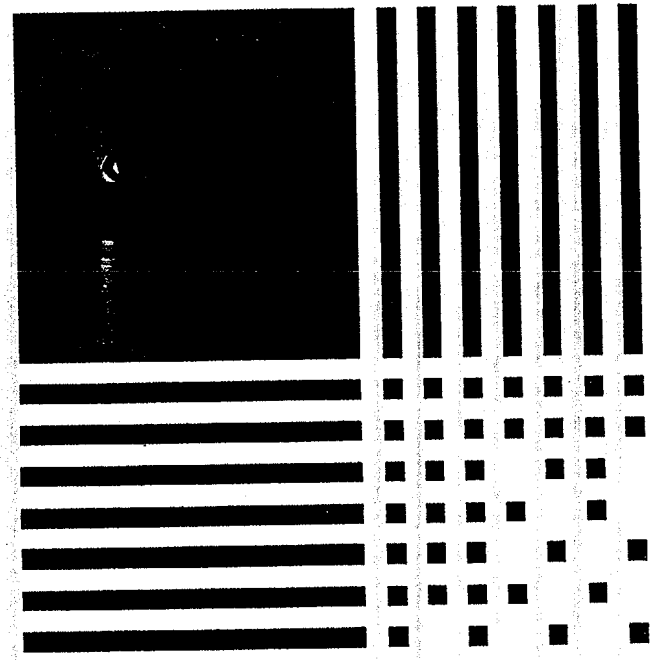
Beschrijving	14
Indicaties	14
Gebruiksaanwijzing	14
Preïmplantatietest	17

Delta shuntsystemen

Beschrijving	19
Indicaties	19
Gebruiksaanwijzing	19
Verpakking	21
Speciaal te bestellen producten	21
Contra-indicaties	21
Informatie voor de patiënt	21
Waarschuwingen en voorzorgsmaatregelen	21
Complicaties	22
Teruggezonden goederen	23
Garantie	23
Bibliografie	80

11032-1
©Medtronic, Inc. 1996
All Rights Reserved
Printed in USA

Hydrocephalus



Patient
Information
Booklet

MEDICAL

Medtronic

Contributing Editors:
Robert Pudenz, M.D.
D. Thomas Rogers, M.D.
Claire S. Houston, R.N., M.S.

Medtronic

Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117 USA
(805) 968-1546 International
(800) 826-5603 USA/Canada

Table of Contents...

Foreword 3
What Is Hydrocephalus? 5
Anatomy and Physiology 6
Types of Hydrocephalus 7
Diagnosis 8
Diagnostic Studies 8
Treatment 10
Shunt Components 11
Surgery and Hospitalization 12
Participating in Your Care 12
Complications 14
Obstruction 14
Infection 15
Overdrainage 15
Emotional Support 16
Glossary 18

Foreword

The purpose of this booklet is to help patients and their families gain an understanding of hydrocephalus and its treatment. Although an ideal treatment is not yet available, numerous advances have contributed to more effective treatment within the past few decades.

What Is Hydrocephalus?

The term **hydrocephalus** is derived from two Greek words, **hydro** for water and **kephale** for head. Hydrocephalus implies an excessive accumulation of cerebrospinal fluid (CSF), within the cavities of the brain known as ventricles. Build-up in CSF volume can result from interference with normal CSF circulation (due to an obstruction in the brain's ventricular system), or as the result of a problem with CSF reabsorption.

Hydrocephalus can be congenital or an acquired condition. Congenital hydrocephalus simply means that the condition existed before birth; acquired hydrocephalus develops after birth, resulting from some other factor, such as trauma, a brain tumor, scar tissue formation, or meningitis.

In most instances, hydrocephalus is a lifelong condition in that the patient is treated rather than "cured." Treatment, by shunting the CSF to another area of the body, generally allows patients to lead full and active lives.

Patients and their families, however, should be aware of the signs and symptoms of complications so that medical care can be sought in a timely manner when necessary.

Anatomy and Physiology

In order to understand hydrocephalus, a basic knowledge of the anatomy of the skull and brain, and the formation and absorption of CSF (see Fig 1.) is necessary.

The brain occupies most of the skull cavity and is surrounded by a cushioning layer of CSF. This fluid is primarily produced and circulated within the four interconnecting ventricles of the brain.

The ventricles contain delicate tufted structures known as choroid plexus. These structures produce most of the CSF, approximately 500 ml (about one pint) per day. The fluid is in continuous circulation and contains many substances essential for nourishment and normal function of the nervous system. CSF also provides a protective cushion within and around the brain.

CSF flows through the ventricular system, and out three small openings in the fourth ventricle before entering the subarachnoid space surrounding the brain and spinal cord. The fluid then flows over the surfaces of the brain and spinal cord, and is eventually absorbed into the blood stream through valve-like structures called pacchionian granulations. Thus, CSF is in a continuous process of formation, circulation, and absorption. Under normal conditions, there is a delicate balance associated with this process.

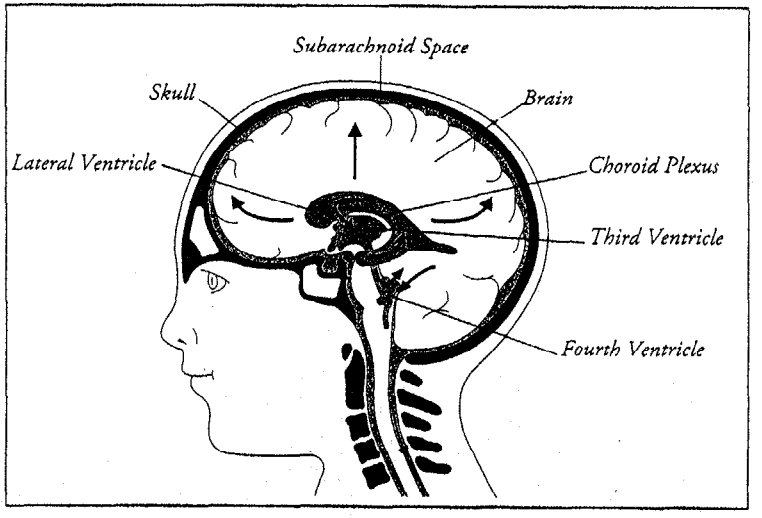


Fig 1. Anatomy of skull, brain, ventricles, and circulation of CSF (arrows). Note that CSF flows from lateral ventricle into third ventricle, aqueduct, and fourth ventricle and then escapes from the fourth ventricle into the subarachnoid space where it is absorbed.

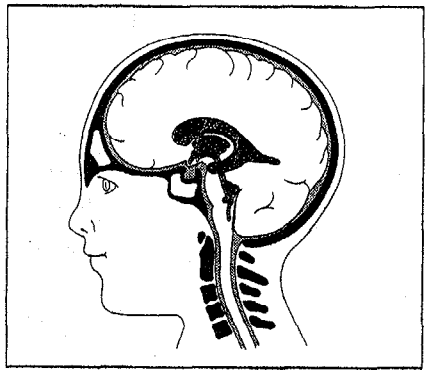
Hydrocephalus will develop if CSF cannot flow through the ventricular system, or if absorption into the blood stream is not normal. Hydrocephalus may also be due to overproduction of CSF by a rare tumor known as a choroid plexus papilloma.

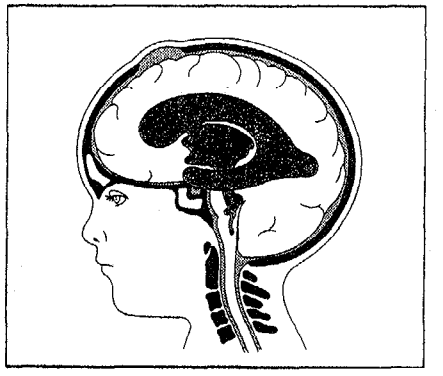
Types of Hydrocephalus

Obstructive or **non-communicating** hydrocephalus occurs when CSF flow is obstructed within the ventricular system.

Non-obstructive, or **communicating**, hydrocephalus occurs when the CSF leaving the fourth ventricle is restricted in its flow over the surface of the brain, or if the sites of absorption are not functioning adequately.

Hydrocephalus is further classified as: A) **congenital** if present before or since birth; or B) **acquired** when developing after birth. A variety of causes, e.g., head injury, meningitis, or tumors can contribute to acquired hydrocephalus.





Diagnosis

In infants and toddlers, the bones of the skull are not yet fused and hydrocephalus is obvious. The child's head will enlarge, and the fontanelle (soft spot) may be tense and/or bulging. The skin may appear thin and shiny, and the veins of the scalp may appear full or engorged. Symptoms may include vomiting, listlessness, irritability, downward displacement of the eyes, and at times, seizures. The signs and symptoms of increasing intracranial pressure are likely to change over time, as the cranial sutures have not yet closed.

In older children and adults, the bones of the skull have joined. These patients have symptoms of increased intracranial pressure due to ventricular enlargement and compression of the brain tissue. Symptoms may include, but are not limited to, headache, nausea, vomiting, visual disturbances, poor coordination, personality changes, lack of concentration, and lethargy. Such symptoms deserve immediate diagnostic evaluation. Enlarged or dilated ventricles can be seen easily with either Computerized Tomography (CT) or Magnetic Resonance Imaging (MRI) .

Shunting CSF from the ventricles or the subarachnoid space and into the abdominal cavity (for absorbtion by the peritoneum), the pleural cavity, or the systemic circulation is generally the treatment of choice for patients with hydrocephalus.

Diagnostic Studies

Ultrasound is a sophisticated method of outlining structures within the head using high frequency sound waves. This procedure can be used only in infants whose fontanelles are open, since the skull otherwise blocks sound waves.

Computerized Tomography (CT Scan) is a technique in which tiny beams of x-ray outline the skull, brain, ventricles, and subarachnoid space. In addition to visualizing the size and shape of the ventricles, abnormalities such as tumors, cysts, and other pathology can also be seen.

Magnetic Resonance Imaging (MRI) is a non-invasive diagnostic tool that uses radio signals and a magnet to form computer images of the brain, its ventricular system and coverings, and pathological lesions.

Cisternography is a test requiring injection of a small amount of radioactive material into the CSF. This test differentiates communicating from obstructive hydrocephalus, and determines CSF flow.

Air Studies are done much less frequently today than in the past. Injection of air into the ventricles, either by direct puncture or through a spinal needle, may be necessary in certain instances.

Angiography is a specialized technique in which contrast material is injected into the arteries supplying the brain. Abnormal blood vessel problems or pathological lesions can be detected with this technique.

Neuropsychological Tests are series of questions and answers used to determine if there is deterioration in brain functioning due to hydrocephalus.

Treatment

At this time, the standard treatment for hydrocephalus is surgery. There is no long term medical treatment. The surgical procedure usually involves diverting CSF to either the abdominal cavity (a ventriculoperitoneal or VP shunt), or to a chamber of the heart called the right atrium (a ventriculoatrial or VA shunt). Occasionally, the CSF is shunted into the pleural cavity.

In order to divert the CSF, the surgeon will implant a shunt system fabricated from silicone rubber and polypropylene plastic. All components of the system are implanted under the skin. There are no external parts.

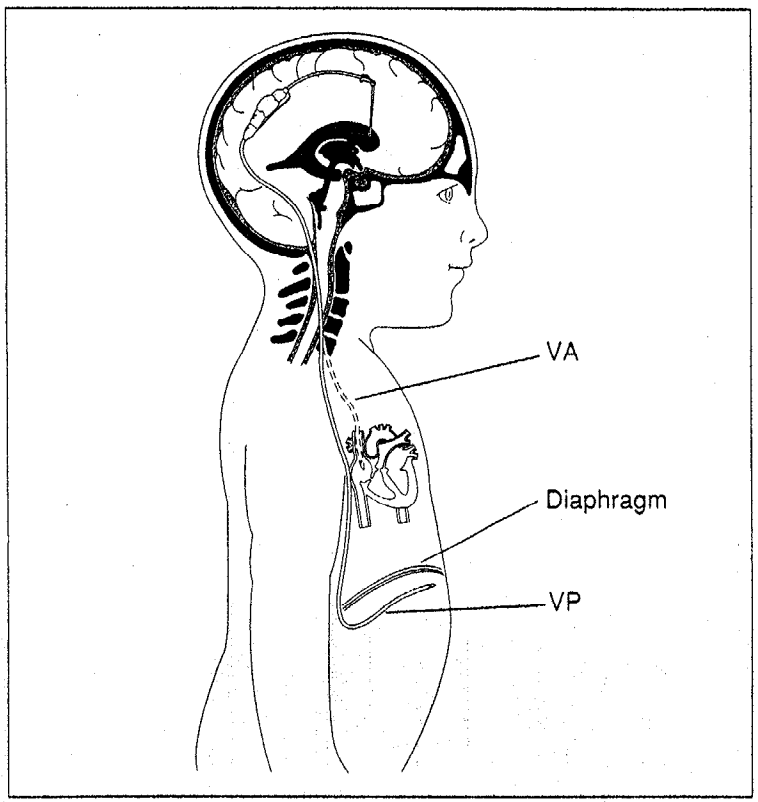


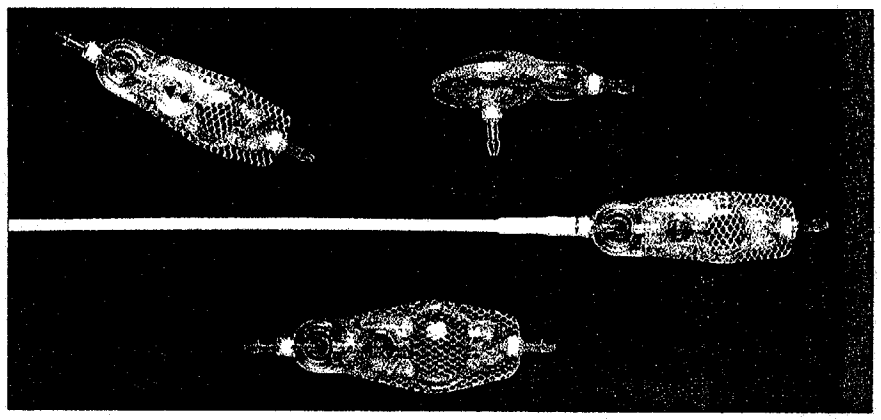
Fig 4. Illustrates the two most common shunts: (1) Ventriculoatrial (VA) shunt from lateral ventricle into the right atrium of the heart; and (2) Ventriculoperitoneal (VP)

Shunt Components

The components of a shunt system usually include two catheters and a one-way valve. (Accessory items are supplied by the hospital at the discretion and request of the doctor). The catheter placed in the ventricle is called the proximal catheter. The catheter placed in either the peritoneal cavity or, occasionally, in the right atrium of the heart, is called the distal catheter. Both catheters are attached to a one-way valve used to regulate the amount, direction, and pressure of CSF flow. CSF valves are designed to operate at different pressure/flow ranges and performance levels. The surgeon's choice of valve is based on an evaluation of the medical problem and the needs of the patient.

In some shunt systems a reservoir is included in the design. A reservoir can be used for a variety of reasons. By flushing the reservoir, shunt function can be tested. Also, samples of CSF for lab studies can be obtained through a reservoir. Patients and their families are discouraged from pressing the reservoir in an attempt to "test" the shunt. This maneuver can be dangerous unless done under explicit instructions from a physician.

Patients with obstructive hydrocephalus must have one catheter inserted into the ventricle. Patients with communicating hydrocephalus, however, can have the CSF drained from the subarachnoid space of the lumbar spine to another cavity of the



body, usually the peritoneal cavity. This is known as a lumbo-peritoneal shunt and is usually reserved for, but not entirely limited to, the adult population.

Surgery and Hospitalization

The surgical procedure is carried out under sterile conditions in the operating room. Although the operation is relatively short, careful preparation for the surgery adds extra time. In order to have optimum conditions for cleanliness, the head must be shaved. The head and body are washed. Sterile linen is used to cover the patient and to maintain the sterile environment.

A small burr hole is made in the skull. Then, a tiny opening is made in the dura, a protective covering of the brain. These openings are made to accommodate the catheter being placed in the lateral ventricle. The surgeon then makes two or three small incisions in order to place the shunt. The peritoneal or atrial catheter is tunneled under the skin to the abdominal or neck incision. Finally, the end of the catheter is carefully placed either in the peritoneal cavity or in a vein of the neck leading to the atrium of the heart. Following the operation, small sterile bandages are applied to each incision.

Immediately after surgery, the patient will go to the post-anesthesia care unit. The patient will remain there for close observation for about an hour and then go to his/her room. The length of hospitalization varies from patient to patient. Most patients leave the hospital within three to seven days, depending on their clinical progress.

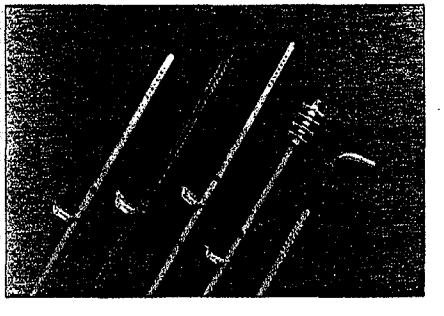
Participating in Follow-Up Care

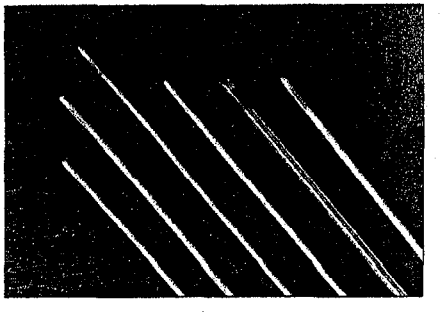
Most patients with hydrocephalus have every right to look forward to a normal future. However, because this condition is "on-going," patients do require long-term, follow-up care by a physician. Having medical check-ups at intervals recommended by the neurosurgeon is sensible. The patient, or his/her parents, must assume a share of the responsibility for follow-up care.

The neurosurgeon will also keep a watchful eye on the patient and pick up subtle changes that may be indicative of shunt malfunction.

Children and adults who have shunts in place will normally require surgical shunt revisions. Children can physically outgrow a shunt, any patient may eventually need a different pressure valve. CT or MRI scanning provide the physician with the tools necessary to make an early and noninvasive evaluation of the shunt's performance. In addition to regular follow-up visits to the neurosurgeon, family members should watch for symptoms of shunt complications. Immediate and accurate reporting of health related problems is very important. Flu symptoms, for example, mimic those of shunt obstruction. The early detection of complications allows revisions to be scheduled, preventing emergency situations.

Fig 6. Medtronic PS Medical Shunt Models





Complications

Patients and their families must be alert for the signs and symptoms resulting from shunt complications. The major complications of shunting are obstruction, infection and overdrainage.

Obstruction

The most common complication of shunting is obstruction of the system. Obstruction may occur at any point along the course of the shunt. The openings of the ventricular catheter may become plugged with brain or choroid plexus tissue. They may become plugged due to an excessive reduction in size of the ventricular cavity (slit ventricle) due to overdrainage of CSF. The peritoneal end may become surrounded by loops of bowel, other structures, or by scar tissue. Shunts in the right atrium of the heart may be obstructed by the clotting of blood around the end of the tube. Shunt tubing may become plugged with blood elements, brain fragments, or tumor cells. The shunt may also become obstructed if the components become separated, or if the position of the inlet or outlet changes with the growth of the infant or child.

Obstruction of the shunt will produce signs and symptoms of increased pressure in the head. These will vary depending upon the degree of obstruction. Partial, or intermittent, obstruction may result in periodic headache, nausea and vomiting, along with drowsiness, listlessness, and decreased mental function. Poor performance in school or at work is common under these conditions.

If complete obstruction occurs, there will be a rapid development of the signs and symptoms—headache, nausea, vomiting, blurring of vision, loss of coordination, and deterioration of consciousness. The patient may become stuporous or comatose. Should this occur, emergency hospitalization for observation and treatment is required. The surgeon will run tests to determine the location and degree of shunt obstruction. Removal and replacement of the obstructed part of the shunt system may be necessary.

Infection

The second most common complication of CSF shunting is infection. This hazard is present in all surgical operations—particularly when a foreign body such as a shunt system is implanted. Infection should be suspected if there is unusual redness or swelling of the wounds or along the course of the shunt system. These changes should be called to the attention of the surgeon. If not treated, infection can lead to erosion and breakdown of the wounds or, more seriously, to systemic infection with chills and high fever. Infection usually requires removal of the shunt system. In some cases, the infection can be controlled with intensive antibiotic therapy, without removing the shunt.

Since the shunt system is a "foreign body,"a patient may develop an allergic or inflammatory reaction at any time. Inflammation or erosion over any part of the implanted system should be brought to the attention of the neurosurgeon immediately.

Overdrainage

Overdrainage of CSF may produce a variety of signs and symptoms. Patients generally experience a headache that is worse when standing and reduced by lying down. Additional symptoms are nausea, vomiting, drowsiness and changes in vision, particularly double vision. Overdrainage should be suspected in school age children if their intellectual performance is deteriorating.

Precautions

In addition to recognizing the signs and symptoms of shunting complications, common sense precautions should always be taken. Since a shunt system is implanted in the attempt to regulate CSF flow and intracranial pressure, participation in activities that might upset the delicate balance should be limited. In particular, rough contact sports and diving should be discussed in advance with the physician.

Emotional Support

The physical aspect of hydrocephalus is only one part of dealing with this condition. Emotional factors must also be considered, for the patient as well as the family.

Although the surgical procedure is likely to control the hydrocephalus, those involved may be upset, fearful, depressed, angry or frustrated. If the patient is a child, keep in mind that children have feelings similar to adults, and may be suspicious that there is a serious problem.

Since the child may not feel up to par, may have had some unusual tests, and is visiting the doctor more than usual, this suspicion is understandable. Rather than allowing the child's fright to escalate, and the imagination to create unrealistic, unnecessary fears, the child's anxiety may be relieved with an explanation. Knowing what to expect increases the cooperation of the child. Children, like adults, generally don't like surprises.

Explain hydrocephalus to the child in terms the child can understand. A quiet, calm atmosphere with a loving, supportive family, and as few distractions as possible is the best environment for such a discussion.

Young children, up to about 3 years of age, are unlikely to understand. They will mostly be concerned with the here and now, especially separation from parents. In this age group, crying is quite typical as a means of attempting to gain control.

Older children, up to about10 years of age, are usually satisfied with simple explanations and honesty. Acknowledge the child's feelings and allow the child to express them. Reassure the child that when the needles hurt, it's okay to cry and be comforted. Although going to the hospital may not be an experience a child looks forward to, telling the child the truth will help to establish and maintain trust.

Children over the age of 10 are usually able to understand more complex concepts. They can associate a variety of signs and symptoms with their condition, and can better accept limitations placed upon them.

Children of all ages are curious, and eventually ask questions. Since parents know their children and have their trust, those questions will probably be directed at Mom and Dad. Honesty is the best policy, in order to maintain the established trust.

Expressing feelings to the doctor will help him/her with professional guidance. Many people can handle their emotions with the help of relatives and friends, but for others, professional help is necessary. Health professionals caring for the patient are interested in a total well-being. Their goal is to do what is best for the patient and his/her family.

As a patient, or as parent of a patient, take control over the dialogue with the doctor. Be an active participant in the communication process, so that the caregivers understand what kind of help is needed.

Glossary

Abdominal Cavity: The area of the body between the chest and pelvis containing the liver, intestines, kidneys and other organs

Angiography: X-ray examination of blood vessels filled with a contrast material (giving the vessels visibility)

Antibiotic: Any substance (such as Penicillin) which destroys or inhibits the growth of bacteria

Atrium: One of the two upper chambers of the heart

CSF: The cerebrospinal fluid

Cerebrospinal Fluid: The fluid filling the ventricles of the brain and surrounding the brain and spinal cord

CAT or CT Scan: Abbreviation for computerized axial tomography, a special x-ray technique which outlines the ventricles and other structures of the brain in cross section

Choroid Plexus: Delicate structures in the ventricles of the brain that produce CSF

Cisternography: Special x-ray technique for seeing the ventricles and CSF filled spaces at the base of the brain

Comatose: A state in which the patient does not respond to stimulation

Congenital: A condition present since birth

Diagnosis: Determination of a patient's problem

Dura: The fibrous membrane that surrounds the brain and spinal cord (also dura mater)

Fistula: An abnormal passage between two structures or organs

Fontanelles: The spaces between the incompletely formed bones of the skull of the infant, commonly called the soft spot

Foreign Body: An object, such as an implant, introduced into a living body from the outside

Hydrocephalus: Excessive build-up of CSF in the ventricles of the brain, causing head enlargement and brain compression

Hydrocephalus, Acquired: Hydrocephalus developed after birth

Hydrocephalus, Communicating: Hydrocephalus in which there is no obstruction between ventricles and subarachnoid space

Hydrocephalus, Congenital: Hydrocephalus existing before or at birth

Hydrocephalus, Non-Communicating or Obstructive: Hydrocephalus in which there is obstruction of CSF flow between ventricles

Isotope: A radioactive material used for determining spinal fluid flow and shunt function

Lumbar Spine: The area of the spine in the small of the back

Meninges: The coverings of the brain and spinal cord

Meningitis: Inflammation or infection of the meninges

MRI: Abbreviation for Magnetic Resonance Imaging. By means of magnetic energy, images are taken, showing the ventricles and other structures within the brain

Peritoneum: Lining of the abdominal cavity

Pneumoencephalogram: X-ray done after filling the ventricles or subarachnoid space with air, or another gas, injected through a spinal needle

Polypropylene: Plastic used in the manufacture of shunt systems

Shunt (noun): A system of tubing used to drain CSF from the ventricles or subarachnoid space into another area of the body

Shunt (verb): Surgical procedure during which a shunt system is implanted

Silicone: A polymer characterized by inertness in the body tissues and used in the manufacture of shunt systems and other medical devices

Slit Ventricle: Excessive narrowing of the lateral ventricle due to overdrainage of CSF

Spinal Cord: The elongated structure of the nervous system lying within the spine

Stuporous: A semi-conscious condition, in which the patient is very sleepy

Subdural Hematoma: A collection of blood between the skull and the brain

Ultrasound: Sound waves of high frequency used to outline structures within the brain

Ventricles: The four cavities (two lateral, one third, and one fourth) lying within the brain

Ventriculogram: An x-ray technique to visualize the ventricles by filling them with air or another gas