Integra™

The ShuntBook

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Hydrocephalus

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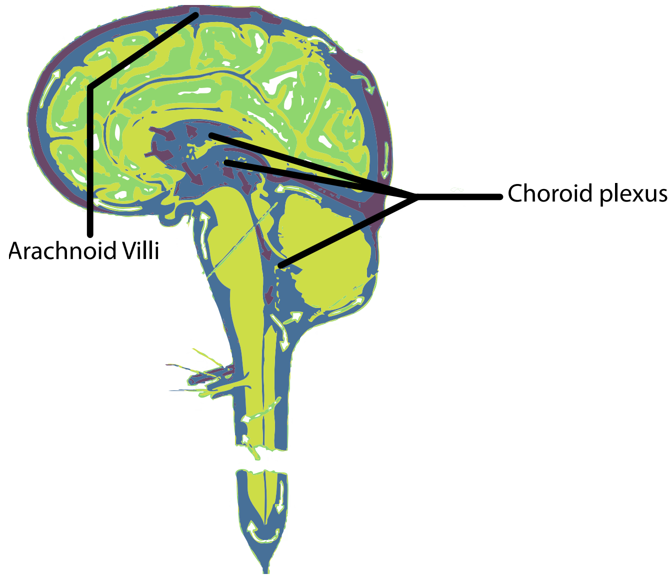
What is CSF ?

1 – What is CSF ?

> Cerebral spinal fluid (CSF) is a clear and colorless liquid, It is ~99% water
> It is produced by Choroid Plexus
> Under normal condition, CSF secretion is approximatively 500 ml by 24 h, means around 20ml/hr.

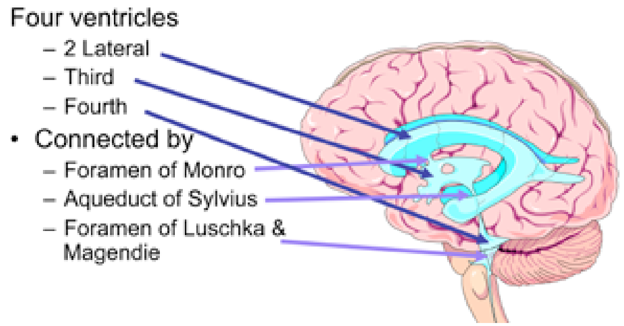


2 – Role of CSF

> Acts as a protective cushion against forceful blows to the head and spine
> Contains many nutrients and proteins that are needed for the nourishment and normal function of the brain
> Carries waste products away from surrounding tissues

3 – CSF pathway

CSF is mainly produced by a structure called the choroid plexus in the lateral, third and fourth ventricles. CSF flows from the lateral ventricle to the third ventricle through the interventricular foramen :foramen of Monro. The third ventricle and fourth ventricle are connected to each other by the cerebral aqueduct called the Aqueduct of Sylvius. CSF then flows into the subarachnoid space through the foramen of Luschka (there are two of these) and the foramen of Magendie (only one of these).



ventricular system

4- CSF absorption

Absorption of the CSF into the blood stream takes place in the superior sagittal sinus through structures called arachnoid villi.

What is Hydrocephalus ?

1 – Definition of hydrocephalus

From the Greek language…

> ***Hydro*** means water
> ***Cephalo*** means head

Hydrocephalus is an abnormal accumulation of CSF within cavities called ventricles inside the brain.

Except in rare cases, hydrocephalus is a life-long condition. There is no known cure for it at this time.

The incidence of congenital hydrocephalus is 1 to 4 / 10 000 children*

2 – Hydrocephalus classification

- Communicating
  - » Hydrocephalus in which the openings between the ventricular spaces and between the fourth ventricle up to the subarachnoid space are functioning.
- Non-Communicating
  - » Hydrocephalus in which there is obstruction of the flow of CSF through the cerebral aqueduct or from the fourth ventricle to the subarachnoid space.

* http://www.ferticon.de/text.php3?artikel=6&seq=11&la=fr

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What is Hydrocephalus ?

3 – Normal Pressure Hydrocephalus (NPH)

> Normal pressure hydrocephalus is a type of hydrocephalus that occurs in adults, usually older adults.
> The average age of people with NPH is older than 60 years.
> NPH is different than other types of hydrocephalus in that it develops slowly over time.

Normal pressure hydrocephalus (NPH) can also occur due to a gradual blockage of the CSF drainage pathways in the brain. Although the ventricles enlarge, the pressure of the CSF remains within normal range. NPH is characterized by:

> memory loss (Dementia),
> gait disorder,
> urinary incontinence
> general slowing of activity.

(Source : Medterms.com)

The prevalence progressively increases to reach 0.5 to 1% among + 65 years old population (Source Neurochirurgie, 2005,51 n'1,38-40). Incidence of NPH is estimated around 1.8 case for 100 000 individuals (Source aim october 2004).

The term 'prevalence' usually refers to the estimated population of people who are managing Hydrocephalus at any given time.

The term 'incidence' refers to the annual diagnosis rate, or the number of new cases of Hydrocephalus diagnosed each year.

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Causes of hydrocephalus

The causes of hydrocephalus can be splitted in 3 categories:

- > CSF underabsorption: Due to intraventricular hemorrhage, meningitis...
- > CSF overproduction: Excessive production of CSF by the Choroid plexus cause by a rare tumor Called Papilloma of Choroid plexus.
- > CSF circulation obstruction: Blockage of the circulation of CSF for instance blockage of the Acqueduct of Sylvius.

They can also be classified as follows*:

- » **Congenital**
  - » Aqueductal Stenosis
  - » Spina Bifida
- » **Acquired**
  - » Hemorrhage
  - » Tumor
  - » Spinal Dysraphia
  - » Chronic Hydrocephalus
  - » Infection
  - » Trauma
  - » Other malformation...

* *The surgical Management of Pediatric Hydrocephalus*, James M. Drake, Vol 62, Nber 2, Feb 2008, Supplement.
www.medterms.com

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Diagnosis

The diagnostic signs and symptoms of hydrocephalus depend upon the age of the person:

> In infants the most obvious sign of hydrocephalus is usually an abnormally large head. (That is one reason a baby's head should be measured at every well-baby visit). Symptoms of hydrocephalus in an infant may include vomiting, sleepiness, irritability, an inability to look upwards, and seizures.

> In older children and adults there is no head enlargement from hydrocephalus, but symptoms may include headache, nausea, vomiting and, sometimes, blurred vision. There may be problems with balance, delayed development in walking or talking, and poor coordination.

(Source : www.medterms.com)

Diagnosis Tools*:

> Clinical symptoms (headaches, etc...)

> Imagery (CT scan / MRI)

» Size of ventricles?

» Obvious blockage in the pathway?

» Flow of CSF?

> Interventional Lumbar puncture or Tap (for communicating hydro) :

» Patient condition improved ?

» Intracranial pressure monitoring + drainage

* *The surgical Management of Pediatric Hydrocephalus*, James M. Drake, Vol 62, Nber 2, Feb 2008, Supplement. www.neurologychannel.com/hydrocephalus/diagnosis.shtml

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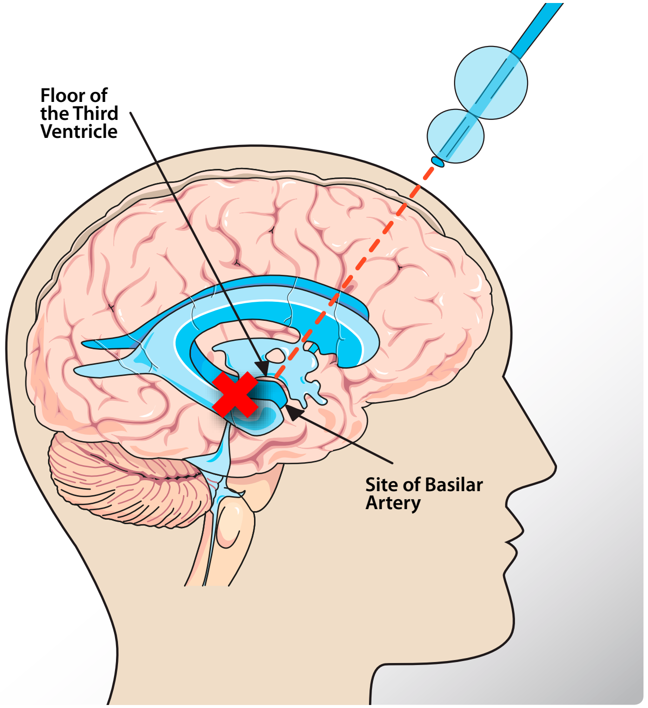
Possible treatments

The most common surgical procedure to manage hydrocephalus patient is the shunt implantation which divert CSF away from the ventricles to another part of the body.

- Principal shunt placement:
  - Ventriculoperitoneal shunt (VP)
  - Ventriculoatrial shunt (VA)
  - Lumboperitoneal shunt (LP)

Third ventriculocisternomies are only indicated for patients with non-communicating hydrocephalus whose obstruction is distal to the third ventricle. This procedure consists in creating a small opening in the floor of the third ventricle. This hole allows the CSF to pass directly into the subarachnoid space and bypass the distal ventricular obstruction.



www.upstate.edu/practice/neurosurgery/education/med_students/3v/

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Shunt description

Two main type of valve regulation available in the market :
Differential Pressure (DP) and Flow Control:

- **Differential pressure valve:**
  this valve works as ***switch on*** or ***switch off*** principle.
  This valve opens if the pressure at the inlet of the valve exceeds the pressure at the outlet, difference depends on the choice of shunt.
- **Flow Regulation Valve:**
  consists of a self-adjusting valve which maintains a constant flow rate at varied differential pressure.

A shunt is composed of 3 components:

- Ventricular proximal catheter (ventricular of lumbar).
- Valve mechanism.
- Peritoneal or distal catheter.


Flow Regulated Concept
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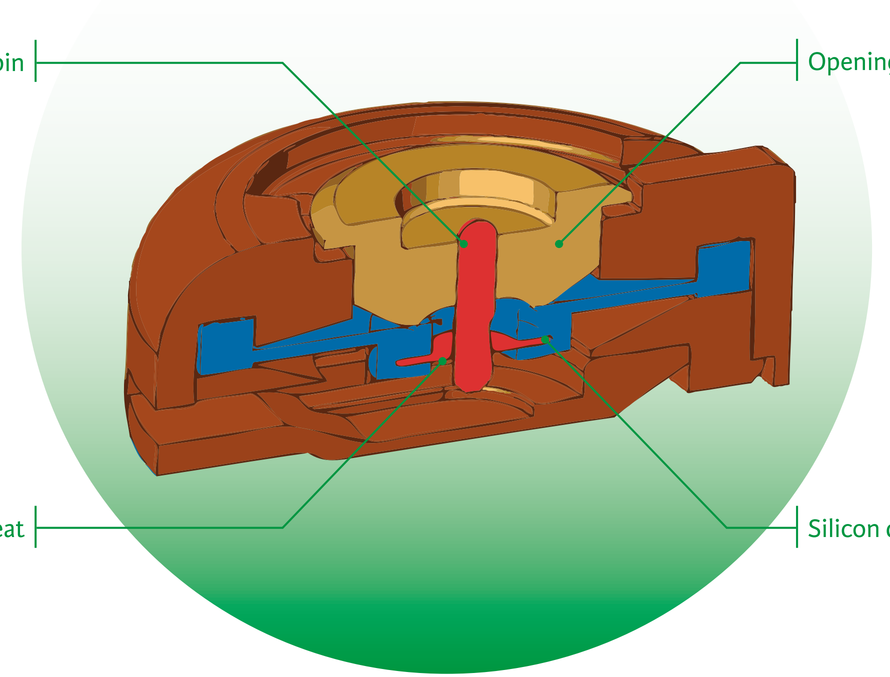
Video - Flow regulated concept

Flow regulated Concept

Flow regulation technology consists of a Self-adjusting valve which maintains a constant flow rate at varied differential pressure by automatically adjusting to postural and vasogenic changes.

Mechanism of the valve :

The membrane goes up and down and as a consequence the space between pin and seat is increased or reduced. This mechanism ensures that the CSF flow rate is maintained constant.



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Flow regulated Concept

Integra Flow Ranges :

> **OSVII™:** designed to regulate flow at normal CSF production rate of 20ml/hr.
> **OSV II Low Pro™:** same technology as OSVII™ with a lower profile of antechamber.
> **Integra NPH™ Low Flow Valve:** designed for patients who require a reduced drainage of 10ml/hr.

Flow Regulated Features:
Automatically adjusting to the patient's changing needs.

» Flow Regulated Valves are self adjusting and maintain physiological ICP by automatically adjusting to the patient's needs.[1]

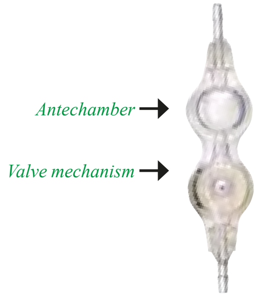
» FR valves technology avoids a rapid decrease of ventricular size and rapid flows through the shunt, minimizing the risk of ventricular catheter obstructions.[2]

» FR valves delivers position-independent performance without programming or frequent adjustments.

» Three stage design enables superior management of both postural and vasogenic overdrainage.[3]

» Contains non-ferromagnetic materials which are compatible with diagnostic procedures, including MRI[4] and CT scans.

OSV II™ - Standard



OSV II Low Pro™

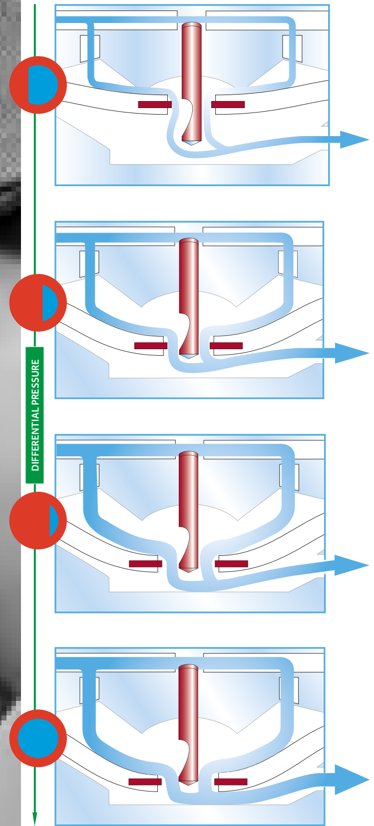
Integra NPH™

Integra NPH™ valve is characterised by the black arrow on the shunt.

1 Sainte Rose C., *A new approach in the treatment of hydrocephalus,* J Neurosurgery, 66 : 213-226, 1987
2 Sainte-Rose, C. *Shunt obstruction: a preventable complication?* Pediatric Neurosurgery. 1993; 19(3): 156-64
3 Cznosnyka, Z. et al., *Comparison of the performance of 10 Hydrocephalus shunts in vitro,* Neurosurgery; 1998, 42(2), 327-334
4 Product considered MRI safe based upon materials of composition

OSV II™ / OSV II Low Pro™

> **OSVII™ / OSVII Low Pro™:** designed for patients who require a drainage of 20ml/hr



Stage I - Low Differential Pressure

Begins when CSF flow rate reaches 5 ml/hr (DP will be between 30 and 80 mm H_2O). Remains in Stage I with flow rates up to 20 ml/hr (DP will be between 40 and 120 mm H_2O).

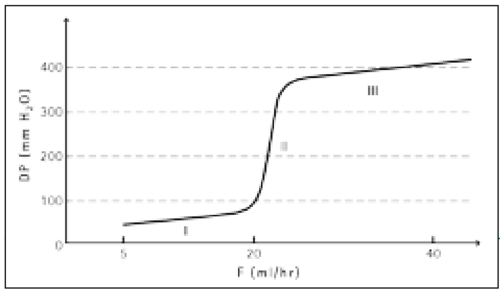
Stage II - Flow Regulation

When DP increases, the valve operates as a variable-resistance flow regulator. At DP ranges between 120 and 300 mm H_2O, it restricts flow around 20 ml/hr.

Stage III - Pressure Relief Mode

Should intraventricular pressure (IVP) abruptly elevate, the rapid flow rate mode engages to facilitate IVP normalization. The valve then reverts to Stage II or I, depending upon conditions.

OSV II™ Self-Adjusting Operating Characteristics



OSV II™ - Standard

OSV II Low Pro™

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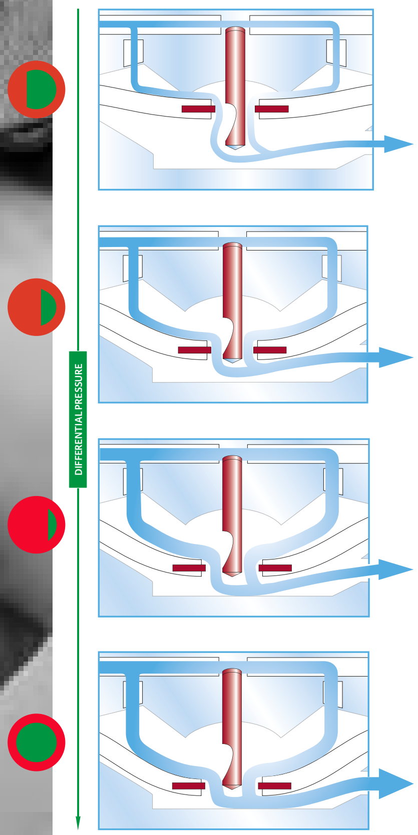
Integra NPH™ Low Flow

> Integra NPH™ Low Flow:
designed for patients who require a reduced drainage of 10ml/hr



Integra NPH™ Low Flow
Self-Adjusting Operating
Characteristics

Stage I - Low Differential Pressure

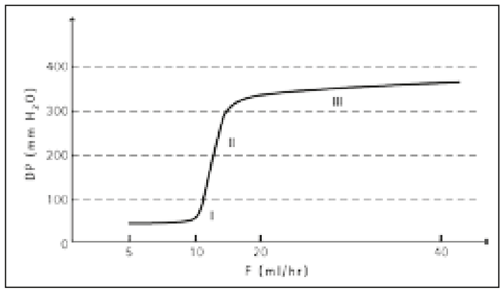
This stage begins when the flow rate through the valve reaches 5 ml/hr (DP will be between 30 and 80 mm H_2O). The valve remains in Stage I with CSF flow rates up to 10 ml/hr (DP will be between 40 and 120 mm H_2O).

Stage II - Flow Regulation

When the DP increases, the valve operates as a variable resistance flow regulator. At DP ranges between 120 and 300 mm H_2O, the valve restricts flow around 10 ml/hr.

Stage III - Pressure Relief Mode

Should the intraventricular pressure (IVP) abruptly elevate, the shunt operates in a rapid flow rate mode to facilitate IVP normalization. The valve then reverts to Stage II or I, depending upon conditions.



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Implantation Procedure

Video - Flow regulated concept

Implantation Procedure – Ventriculoperitoneal approach – Main steps

Please refer to the complete DFU before any implantation.

Before implantation, the valve serial number should be recorded in the patient's file.
The following main steps are based on the use of a separate ventricular catheter, without burr hole cap and a specific type of peritoneal introducer. If a valve with an integral ventricular catheter is used, follow the procedure "Introduction of Integral Ventricular Catheter".

1. Place the patient in the supine position. To facilitate tunneling, the head is turned to the contra-lateral side. **Note:** The skull incision location depends on the ventricular approach (frontal, temporal or occipital).
2. Expose the skull by making a 25 mm linear incision. Using a perforator, make a burr hole 3.0 mm or larger. Make an opening in the dura just large enough for ventricular catheter passage.
3. Create a small pocket under the skin. Pass the Integra disposable malleable tunneler from the subcutaneous pocket to the abdominal area.
   Make the abdominal incision. Remove the handle of the tunneler. Attach the drainage catheter to the connector of the internal tunneler wire, and pass the catheter from the head to the abdominal incisions. Remove the metal outer shaft. Position the valve under the skin.
4. Insert the catheter into the ventricle. Verify adequate CSF flow.
5. Introduce the distal part of the drainage catheter in the peritoneal cavity.
   » Caution- Prior to the introduction of the drainage catheter into abdominal cavity, it is advisable to confirm the patency of the system by observing the formation of CSF droplets at the end of the drainage catheter. Note - The CSF droplets formation rate may be lower than that observed with conventional DP shunts because of the flow restriction mode of the Flow Regulated valve.
6. Close incisions.

Note: X-ray the complete system just after implantation for future reference to determine whether system components have shifted.

Note: Injection into the Valve System.The antechamber can be used access CSF for injections. Use of 25G or smaller needles is recommended. Taking into account to avoid puncturing several times at the same place, the antechamber is qualified to sustain up 40 punctures without leaking.

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Implantation Procedure – Ventriculoatrial approach – Main steps

Please refer to the complete DFU before any implantation.

The procedure is based on the use of a separate ventricular catheter.

1. Place the patient in the supine position. To facilitate tunneling, the head is turned to the contra-lateral side. **Note:** The skull incision location depends on the ventricular approach (frontal, temporal or occipital).
2. Expose the skull by making a 25 mm linear incision. Make a burr hole 3.0 mm or larger. Make an opening in the dura just large enough for ventricular catheter passage.
3. Create a small pocket under the skin. Make a neck incision over the point where of the mandible crosses the anterior edge of the sternocleidomastoid muscle. If the internal jugular vein is used, facilitate entry by mobilizing the common facial vein at its junction with the internal jugular vein. Tunnel the drainage catheter from the skull subcutaneous pocket to the neck incision. Position the valve under the skin.
4. Insert the catheter into the ventricle. Connect a syringe with the provided Luer connector to the ventricular catheter and aspirate 2 to 3 ml of CSF to eliminate possible debris from the CSF. Verify adequate CSF flow.
5. Trim the drainage catheter at the neck incision. Fill the distal part with sterile apyrogenic saline solution. Clamp the proximal end. Introduce the drainage catheter into the vein. Position the distal end of the drainage catheter in the heart's right atrium at the level of the 6th or 7th thoracic vertebra. Determine the exact location by X-ray, radioscopy, ECG, pressure analysis or echography.
   Note: To enhance X-ray visualization, the atrial catheter may be filled with contrast.
6. Connect catheter and valve together using a straight connector.
7. Close incisions.

Note: X-ray the complete system just after implantation for future reference to determine whether system components have shifted.

Note: Injection into the Valve System. The antechamber can be used access CSF for injections. Use of 25G or smaller needles is recommended. Taking into account to avoid puncturing several times at the same place, the antechamber is qualified to sustain up 40 punctures without leaking.

Key Selling Points

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1 *Treatment of hydrocephalus determined by the European Orbis Sigma Valve II survey: a multicenter prospective 5-year shunt survival study in children and adults in whom a flow-regulating shunt was used* PATRICK W. HANLO, M.D., PH.D., and all - Journal of Neurosurgery Volume 99, Number 1:52-57, 2003.

2 Sainte-Rose, C. *Shunt obstruction: a preventable complication?* Pediatric Neurosurgery. 1993; 19(3): 156-64.

3 Product considered MRI safe based upon materials of composition.

4 Belliard H., *The Codman Medos Programmable shunt valve.* Evaluation of 53 implantations in 50 patients. Neurochirurgie. 1996; 42(3); discussion 145-6

5 http://www.medtronic.com/your-health/hydrocephalus/device/our-shunts/strata-valves/index.html

6 Cznosnyka, Z. et al., *Comparison of the performance of 10 Hydrocephalus shunts in vitro.* Neurosurgery; 1998, 42(2), 327-334.

7 Decq P., *Shunt failure in adult hydrocephalus : Flow controlled shunt versus differential pressure shunts - a cooperative study in 289 patients.* Elsevier, 1995.

8 Czosnyka Z., *Posture-related overdrainage : comparison of the performance of 10 hydrocephalus shunts in vitro,* Neurosurgery, Vol 42, No 2, 1998.

9 Sainte Rose C., *A new approach in the treament of hydrocephalus,* J Neurosurgery, 66 : 213-226, 1987.

10 Arnell K., *Evaluation of Strata NSC and Codman hakim adjustable cerebrospinal fluid shunts and their corresponding antisiphon devices,* J Neurosurgery Pediatrics, 3:166-172, 2009.

Key selling points – Flow regulated concept

> Flow regulation technology will automatically adjust around 20ml/hr (OSV II™/OSV II Low Pro™) or 10ml/hr (Integra NPH) in response to a patient's intraventricular pressure, therefore minimizing overdrainage due to hydrostatic pressure, as well as vasogenic increases in pressure due to REM sleep, coughing, sneezing, straining, etc.[1]

> Minimizes the risk of delayed proximal obstruction by avoiding rapid decrease in ventricular size and rapid flow rates, due to repeated overdrainages.[2]

> MRI safe; composed of non-ferromagnetic materials.[3]

> Can function as a general valve in place of low, medium, & high level differential pressure valves.

QUICK SALES ARGUMENTS		
KEY TRIGGER FEATURES	**BEHIND THE FEATURES**	**KEY COMPARATIVE ADVANTAGES**
SELF-ADJUSTING VALVE	- automatically adjusts itself - no need for pressure range changes or programming	- no need to be readjusted by external adjustment tool - safety advantages over programmable valves (risk of reprogramming in strong magnetic fields, such as diagnostic MRI, metal detectors…)[4,5]
PHYSIOLOGICAL DRAINAGE	- flow adapted to the drainage requirements of the patient[9] - drainage with a controlled flow - follows the postural and vasogenic changes[6]	- DP valves don't control the flow but only react to the IVP (intra ventricular pressure)[8] - anti siphon device can be impaired by fibrosis - no placement constraint for FR valves[10]
LIMITS OVERDRAINAGE(1) & PROXIMAL OBSTRUCTIONS	- control overdrainage induced by postural changes and vasogenic events[1] - reduces medium term complication due to proximal obstructions[7]	- DP valves, even with ASD, don't control the flow when patient sits, stands and during REM sleep. They even cause siphoning[1]

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Key selling points – Integra NPH™ Low Flow valve

1. Designed for NPH specifically, where overdrainage and subdural bleeds are a higher risk, the goal of the Integra NPH™ low flow valve is to prevent it.
2. Understanding the alternatives between OSV II™ valve and Integra NPH™ Low Flow valve:
   - » OSV II™ valve is indicated for uses with patient with CSF product rate of 20 ml/hr.
   - » Integra NPH™ Low Flow valve is indicated for use with patient who have a reduced production rate of CSF (10 ml/hr).

Configurations

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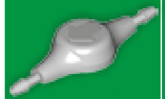
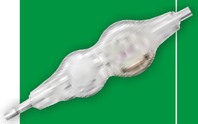
Configurations Available – OSV II™

(for accessories, please see catalog)

	VALVE/KIT TYPE	VALVE ONLY	1PC (UNITIZED) VENTRICULAR CATHETER ATTACHED			BURR HOLE 2PC	2PC KIT			
			7CM V. CATH	9CM V. CATH	13CM V. CATH	W/STD CATH	W/STD CATH	W/ MALLEABLE TUNNELER NO VENTRICULAR CATHETER	WITHOUT VENTRICULAR CATHETER	W/ VENTRICULAR CATHETER AND TUNNELER
	OSV II™ REGULAR WITH ANTECHAMBER	909700	909718	909706	909704	909721	909712	909707	909707S	909714
	OSV II™ REGULAR W/OUT ANTECHAMBER	909701	909719	909705	N/A	909720	909713	909708	909708S	909715
	OSV II™ LOW PRO	909700P	N/A	N/A	N/A	N/A	909712P	N/A	N/A	N/A

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Configurations Available – Integra NPH™ low flow valve

(for accessories, please see catalog)

	VALVE/KIT TYPE	VALVE ONLY	1PC (UNITIZED) VENTRICULAR CATHETER ATTACHED			BURR HOLE 2PC	2PC KIT			
			7CM V. CATH	9CM V. CATH	13CM V. CATH	W/STD CATH	W/STD CATH	W/ MALLEABLE TUNNELER NO VENTRICULAR CATHETER	W/ VENTRICULAR CATHETER & MALLEABLE TUNNELER	W/OUT VENTRICULAR CATHETER
	INTEGRA NPH™ REGULAR WITH ANTECHAMBER	909500	909518	909506	909504	909521	909512	909507	9OS514	909507S
	INTEGRA NPH™ REGULAR W/OUT ANTECHAMBER	909501	909519	909505	N/A	909520	909513	909508	909515	909508S

Accessories

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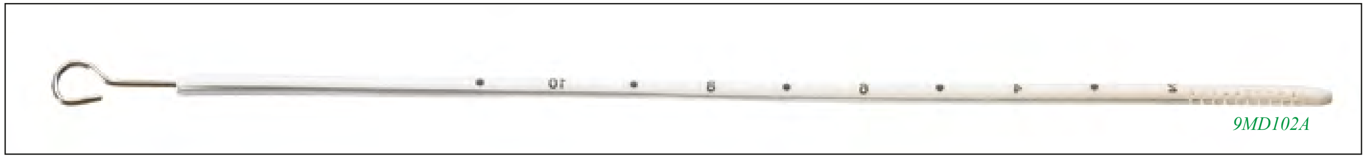
Accessories – Catheters

(See catalog for full list of options)

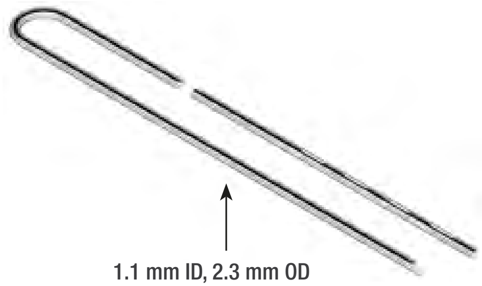
Ventricular



Possible features

> Full barium or barium-striped
> Straight, right angle or finned
> Large or small diameter
> Various lengths

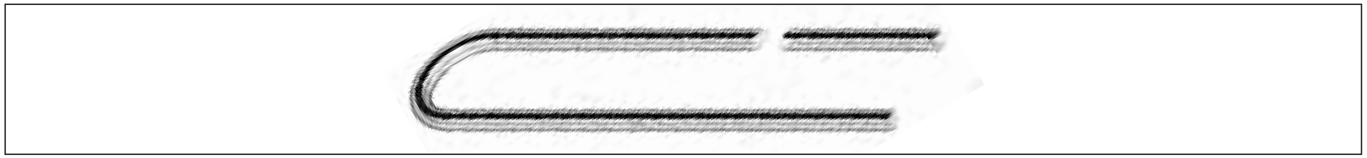
Peritoneal



Possible features

> Open ended with or without slits
> Closed tip with slits

Atrial



Possible features

> Full barium or barium stripe

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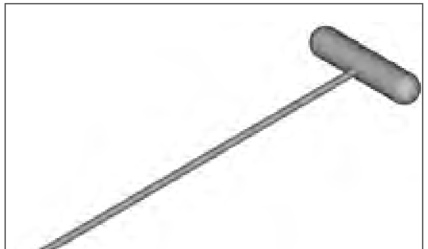
Accessories – Passers

(See catalog for full list of options)

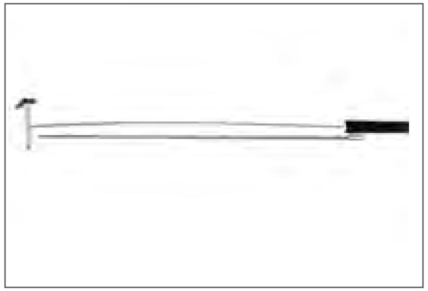
Reusable	Disposable	Disposable Malleable

Reusable



available in 4 lenghts : 31, 46, 61 & 70cm

Disposable

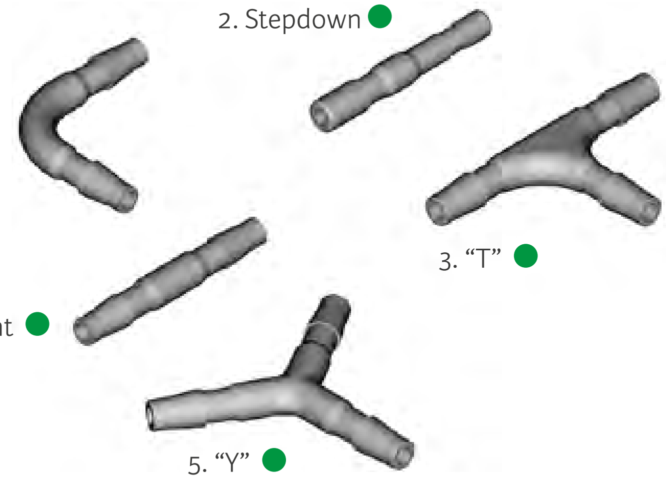


Disposable Malleable

available in 2 lengths : 45 & 65cm

Accessories – Connectors (See catalog for full list of options)

- Stainless steel or radiopaque polypropylene options available.
- Packaged in box of 5.
- See catalog for details.



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Competitors

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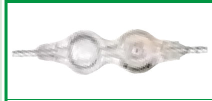
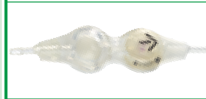
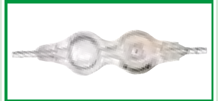
Medtronic

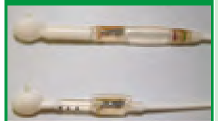
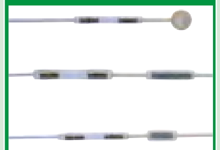
COMMON COMPETITIVE VALVE	DESCRIPTION	INTEGRA SUGGESTED VALVE FOR CONVERSION	BENEFITS OVER COMPETITIVE VALVE
STRATA® PROGRAMMABLE 	Ball and spring programmable valve with anti-siphon 5 programmable settings[4] Requires doctor visit to readjust pressure settings[1] MRI and/or magnetic fields may cause valve to reprogram[1] Verification tool for pressure setting = X-Ray not needed[1]	OSV II™ OR INTEGRA NPH™  	Self-Adjusting, programming not needed MRI safe; composed of non-ferromagnetic materials, no artifact Controls also vasogenic overdrainage
MEDTRONIC DELTA® FIXE PRESSURE 	Medtronic Delta® valve is probably the most common competitive DP valve, which has an integrated anti-siphon device to compensate for postural overdrainage[2] Anti-siphon[2] Available in 5 pressure levels	UPGRADE TO OSV II™ 	Not affected by fibrosis or subcutaneous pressure Controls also vasogenic overdrainage Can function as a general valve in place of low, medium, high level differential pressure valves
		COMPARABLE VALVES ARE EITHER: EQUI-FLOW™ OR NOVUS®  	Novus® and Equi-Flow™: No specific benefit over competitor Both valves features similar design and properties except no Burr hole configuration.
CSF FLOW CONTROL FIXED PRESSURE 	PS Medical flow control valve is NOT a flow control valve in the sense that an OSV II™ valve is flow regulating Flow Control valve is a traditional Differential Pressure diaphragm valve, not a self-adjusting valve[6] No anti-siphon[3] 4 pressure levels[5]	COMPARABLE VALVES ARE EITHER: CONTOUR-FLEX™ OR LPVII™ 	LPVII™, Pudenz Burr-Hole and Contour-Flex™: No specific benefit over competitor Both valves features similar design and properties.

1 www.medtronic.com/your-health/hydrocephalus/device/our-shunts/strata-valves/index.html
2 www.medtronic.com/your-health/hydrocephalus/device/our-shunts/delta-valves/index.html
3 www.medtronic.com/your-health/hydrocephalus/device/our-shunts/csf-flow-control-valves/index.html
4 www.medtronic.com/neurosurgery/ocmplchart.html
5 www.medtronic.com/neurosurgery/cvplchart.html
6 www.medtronic.com/neurosurgery/cvcutaway.html

INTEGRA LIMIT UNCERTAINTY

Shuntbook

Codman

COMMON COMPETITIVE VALVE	DESCRIPTION	INTEGRA SUGGESTED VALVE FOR CONVERSION	BENEFITS OVER COMPETITIVE VALVE
CODMAN® HAKIM® PROGRAMMABLE VALVE   VPV™ VALVE POSITION VERIFICATION PROGRAMMER 	Ball & spring valve with 18 different programmable settings, 30 to 200mm H_2O, with increments of 10mm H_2O[1] Available with or without Siphon Guard[1] Requires doctor visit to readjust pressure settings[1] MRI and/or magnetic fields may cause valve to reprogram[5] Non invasive adjustement with an electromagnetic programmer[1] A separated antibacterian catheter (Bactiseal) can be proposed to customers[3] X-Ray needed to control setting after each programmation[2] If VPV is used X-ray control not needed[2]	OSV II™ OR NPH™ LOW FLOW 	No programming required since OSV II™ is self-adjusting MRI safe; composed of non-ferromagnetic materials, no artifact Controls vasogenic overdrainage Controls postural overdrainage compared to CHPV without Siphon Guard
HAKIM® PRECISION FIXED PRESSURE 	Ball & spring valve with 5 pressure levels Available with/without siphon guard	INTEGRA DP™ 	No specific benefit over competitor - Both valves features similar design and properties.

1 www.codman.com/DePuy/products/Products/Hydro/CHPV/index.html

2 www.codman.com/DePuy/products/Products/Hydro/CHPVfeatures/index.html

3 www.codman.com/DePuy/products/Products/Hydro/Bactiseal/index.html

4 *Shellock, Magnetically programmable shunt valve : MRI at 3-Tesla,* Magnetic Resonance Imaging 25 (2007) 1116-1121

INTEGRA
LIMIT UNCERTAINTY

Shuntbook

Aesculap

1 www.aesculap-extra.net/public/frame_doc_index.html?med_id=100051335

2 www.mrisafety.com/safety_article.asp?subject=175

3 Product considered MRI safe based upon materials of composition.

COMMON COMPETITIVE VALVE	DESCRIPTION	INTEGRA SUGGESTED VALVE FOR CONVERSION	BENEFITS OVER COMPETITIVE VALVE
MIETHKE PROGAV® PROGRAMMABLE 	Titanium housing[1] MRI conditionnal to 3 Tesla without reprogramming[1] Settings 0-20 cm H2O range with 1 cm increments[1] Integrated GAV anti-siphon available in 5 cm increments between 10-35 cm H_2O [2] Requires doctor visit to readjust pressure settings[3] Metallic parts cause artifacts on the image (due to properties of magnet inside the shunt)	OSV II™ OR INTEGRA NPH™ LOW FLOW 	No programming required Compensates also vasogenic overdrainage Non position-dependant valve (No instruction in DFU)

INTEGRA LIMIT UNCERTAINTY

Shuntbook

Sophysa

COMMON COMPETITIVE VALVE	DESCRIPTION	INTEGRA SUGGESTED VALVE FOR CONVERSION	BENEFITS OVER COMPETITIVE VALVE
POLARIS® PROGRAMMABLE  	Ball-in-cone design[2] Requires pressure setting readjustments and verifications[2] Ball-in-cone design adjustable valve self-locking MRI conditionnal to 3 Tesla[2] Polaris has no anti-siphon[2] Metallic and magnet parts cause artifacts on the image[4]	OSV II™ OR INTEGRA NPH™ LOW FLOW 	OSV II™ controls for both postural and vasogenic overdrainage MRI safe; composed of non-ferromagnetic materials, no artifact on MRI No need to readjust No programmer required
SOPHY® PROGRAMMABLE 	Sophy® programmable has no anti-siphon[3] Ball-in-cone adjustable valve[3] 8 pressure settings: 30 to 200mmH_2O[3] Requires pressure setting readjustments and verifications[3]	OSV II™ OR INTEGRA NPH™ LOW FLOW 	Benefits : Self adjusting, no programming needed MRI safe, composed of non ferromagnetic materials, no artifact on MRI Controls for both vasogenic and hydrostatic overdrainage

1 http://www.inami.fgov.be/care/fr/other/implants/general-information/circulars/2008/pdf/200803annexe1part6.pdf

2 http://www.sophysa.com/sophysa-neurosurgical-valve-polaris_142_1.html

3 http://www.sophysa.com/sophysa-neurosurgical-valve-sophy-mini-sm8_142_2.html

4 Allin D., *Investigation of the hydrodynamics properties of a new MRI-resistant programmable hydrocephalus shunt,* Cerebrospinal Fluid Res. 2008; 5: 8.

INTEGRA LIMIT UNCERTAINTY


Literature
INTEGRA
LIMIT UNCERTAINTY

OSV II low pro™

Shuntbook

A new approach in the treatment of hydrocephalus

Sainte-Rose, C. et al.

J Neurosurgery; Volume 66: 213-226, 1987

When To Use This Article:

- ➜ Introducing a surgeon to the flow controlled concept
- ➜ When asked about OSV II™ valve with high protein

Take Home Point:

This study showed that OSV II™ valve could be a good choice for patients with a high protein count.

What This Means For You:

Normal protein levels in humans is 15-45 mg/dl[1] that translates to 0.15-0.45 g/l. High protein content is considered to be 1 g/l (20 times normal concentration).[2] So, OSV valve was tested in vitro to work with protein fluid concentration of 5 to 25 g/liter, equivalent to 100 times to 500 times the normal concentration of protein in human CSF.

Summary

"One OSV system was tested continuously for 7 days and the various parameters (steady and pulse flow, temperature of 20° to 40° C, and protein fluid concentration of 5 to 25 g/liter) were successfully modified. The pressure-flow data obtained throughout the testing procedure varied little, and generally retained the S-shape of the curve. From these results, it can be concluded that the hydrodynamic characteristics of the OSV remain within very acceptable limits under the conditions tested (Fig. 10)" Pg. 218

1 http://en.wikipedia.org/wiki/Cerebrospinal_fluid

2 Vatassery G.T., ***Relationship of total lipids, proteins, and albumine in human cerebrospinal fluid in age,*** Biochemical medicine, Vol 27, Issue 2, 1982, 161-167

INTEGRA LIMIT UNCERTAINTY

OSV II low pro™

Shuntbook

Treatment of hydrocephalus determined by the European Orbis Sigma Valve II survey: a multi-center prospective 5-year shunt survival study in children and adults in whom a flow-regulating shunt was used.

Hanlo, P. et al.

J Neurosurgery; Volume 99(1): 52-57, 2003

When to Use this Article:

- ➜ Programmable or Fixed DP user inquiring about OSV II valve's survival rate.
- ➜ Discussions of overdrainage or slit ventricles.

"While the study couldn't prove the OSV [II™ valve] was significantly better than the DP valves in 1 year they saw decreased overdrainage and proximal catheter obstructions."

Take Home Point:

Flow regulating technology (OSV II™) limits the incidence of overdrainage and other shunt-related complications. The overall 5-year shunt survival rate (62%) compares favorably with rates cited in other recently published series.

What This Means For You:

- ➜ Because the OSV II™ valve keeps a constant flow rate, postural overdrainage (standing) and overdrainage due to vasogenic activities (REM sleep, coughing, straining, etc.) are avoided. In DP valves with an anti-siphon device, only postural overdrainage is addressed.
- ➜ Also, because the ventricles are not becoming slit due to overdrainage, the risk of ventricular catheter obstruction is less than in a patient who has overdrainage and the ventricular catheter comes in contact with the side of the ventricle.

Summary

"This multicenter prospective shunt-survival study of a flow-regulating shunt (the OSV II™ Smart Valve System) shows an overall survival rate of 62% (95% CI 60–64%) at the 5-year follow-up examination, a rate that compares favorably with those cited in other shunt studies." Pg. 56

"Slit ventricles were identified in 3.1% of all patients in the revision group as a result of overdrainage caused by a previously implanted alternative shunt. At the 3-month follow-up examination, approximately 60% of patients were found to have more normally sized ventricles." Pg. 54

"Flow-regulating shunts limit the incidence of overdrainage and shunt-related complications." Pg. 52

"The results of our study compare favorably with those of other studies that only addressed the results of first-implant programmable shunts, reporting a 53.1% survival rate at 5 years." Pg. 55

INTEGRA LIMIT UNCERTAINTY

OSV II low pro™

Shuntbook

Randomized Trial of Cerebrospinal Fluid Shunt Valve Design in Pediatric Hydrocephalus

Drake, J. et al.

Neurosurgery; Volume 43(2): 294-305, 1998.

When to Use this Article:

- ➜ When surgeons reference this article to say all valves are equal
- ➜ Follow up with them and discuss that:
  "While the study couldn't prove the OSV valve was significantly better than the DP valves in 1 year, they saw decreased overdrainage and proximal catheter obstructions."

Take Home Point:

While the study couldn't prove the OSV was significantly better than the DP valves in 1 year, they saw decreased overdrainage and proximal catheter obstructions.

What This Means For You:

- ➜ OSV II™ valve experienced no OD complications and delayed proximal catheter complications were much lower than DELTA or DP valves; such delayed proximal catheter obstruction has been proposed to be a form of OD.
- ➜ The DELTA overdrained (even more than DP valves which incorporated no siphon control mechanisms).
- ➜ OSV II™ valve eliminates guesswork – a single valve type eliminates the need for the surgeon to select a valve that is possibly "inappropriate" for a patient.
- ➜ A hospital with a single OSV valve on the shelf can address the needs of almost any hydrocephalus patient.

Summary

The authors assume, based on prior reports, that 40% of standard cerebrospinal fluid (CSF) shunts implanted for pediatric hydrocephalus treatment fail within the first year.

Two new shunt valves (ORBIS-SIGMA Valve (OSV) and DELTA Valve, designed to limit excess CSF flows, particularly in upright positions (postural overdrainage or "siphoning") were studied to compare treatment failure rates with those for standard differential-pressure (DP) valves (which were the control group in this study).

344 hydrocephalic children (age, birth to 18 yr.) undergoing their first CSF shunt insertion were randomized at 12 North American or European pediatric neurosurgical centers. Patients received one of three valves, i.e., a standard differential-pressure valve; a DELTA valve, which contains a siphon-control component designed to reduce siphoning in upright positions; or an ORBIS-SIGMA Valve, with a variable-resistance, flow-limiting component. Patients were monitored for a minimum of 1 year. Endpoints were defined as shunt failure resulting from shunt obstruction, overdrainage, loculations of the cerebral ventricles, or infection. Outcome events were assessed by blinded independent case review.

150 patients reached an endpoint; shunt obstruction occurred in 108 (31.4%), overdrainage in 12 (3.5%), loculated ventricles in 2 (0.6%), and infection in 28 (8.1%). As a group, 61% of all patients were shunt failure-free at 1 year and 47% at 2 years, with a median shunt failure-free duration of 656 days. The authors conclude that there was no statistically-significant difference in shunt failure-free duration among the three valves

The authors concluded that CSF shunt failure, predominantly from shunt obstruction and infection, remains a persistent problem in pediatric hydrocephalus. Two new valve designs did not significantly affect shunt failure rates.

INTEGRA LIMIT UNCERTAINTY

Long-Term Follow-Up Data from the Shunt Design Trial

Kestle J. et al
Pediatric Neurosurgery; 33:230-236, 2000.

When to Use this Article:

- ➜ When surgeons reference this article to say all valves are equal
- ➜ Follow up with them and discuss that: "While the study couldn't prove the OSV valve was significantly better than the DP valves in 1 year, they saw decreased overdrainage and proximal catheter obstructions."

Take Home Point:

While the study couldn't prove the OSV valve was significantly better than the DP valves after more than 1 year, they saw decreased overdrainage and proximal catheter obstructions.

What This Means for You:

- ➜ The OSV valve experienced no OD complications over the extended course of the study, while the DELTA valve continued to experience OD complications during the long-term follow-up period.
- ➜ The delayed proximal obstruction rate exhibited by the OSV valve continued to remain well below that of the DELTA and DP valve.

Summary

The data in this paper was collected as part of an international, multicenter, prospective, randomized clinical trial protocol that was initiated in 1993.

The initial results were reported in the paper: "Randomized trial of Cerebrospinal Fluid Shunt Valve Design in Pediatric Hydrocephalus". The original study assumption based on prior reports was that forty percent (40%) of standard CSF shunts (DP valves) implanted for the treatment of pediatric hydrocephalus fail within the first year.

The study goal was to determine whether either of two new shunts, which claimed to minimize overdrainage, reduced shunt failures at one year from 40% to 20% - (increase shunt survival from 60% to 80% at that time.)

The conclusion of the initial study was "two new valve designs did not significantly affect shunt failure rates" based upon the study objective. The study was then extended beyond its initial follow-up (>1 year) period through agreement of the investigators with modifications of the original protocol.

INTEGRA
LIMIT UNCERTAINTY

Shuntbook

Posture-related Overdrainage: Comparison of the Performance of 10 Hydrocephalus Shunts in Vitro.

Czosnyka, Z. et al.
Neurosurgery; 42(2), 327-334, 1998

When To Use This Article:

- ➜ Use this article only for doctors very interested in the mechanics of valves (this is a lab bench study).
- ➜ When discussing posture related overdrainage of shunts (OSV II™ valve, fixed DP valves as Medtronic Delta, Codman Medos, Sophysa programmable, and other fixed DP valves).
- ➜ Discussing adjustability differences between a programmable and a more "physiological" OSV II™ valve.

Take Home Point:

OSV II™ valve has a "physiological" response and is therefore less susceptible to siphoning.

What This Means For You:

- ➜ Programmable shunts (alone) cannot prevent posture related overdrainage because the programmed setting cannot be changed automatically.
- ➜ Siphoning devices can help prevent postural overdrainage.
- ➜ OSV II™ valve can help prevent postural overdrainage.

Summary

For shunts with siphon-preventing devices: "All tested shunts (Heyer-Schulte Low Profile Valve, Pudenz™ flushing valve, and Medtronic PS Medical Delta valve) proved to prevent overdrainage when the siphoning occurred". Pg. 330. "Physiologically, the intraventricular pressure is negative in upright body positions; therefore, by definition any siphon-controlling device may close the shunt, allowing the shunt to drain CSF only when the patient is in a horizontal position." Pg. 330

"Both the Codman-Medos programmable and Sophy programmable valves proved fully susceptible to siphoning, i.e., the operational pressure was decreased by -30 cmH2O (-23 mm Hg)." Pg. 330

"As with programmable valves, siphoning could be also demonstrated with differential valves." Pg 330

"For the Orbis-Sigma valve, the flow-pressure performance curve resembled that for cerebral autoregulation, with a lower limit of 7 mm Hg and an upper limit of 25 mm Hg. Therefore, its hydrodynamic resistance is very high (theoretically converging to infinity) within this range, which makes the valve less susceptible to siphoning." Pg. 331

INTEGRA LIMIT UNCERTAINTY

Shuntbook

Predicting slitlike ventricles in children
on the basis of baseline characteristics at the time of shunt insertion.

Kan, P. et al.
J Neurosurgery (5 Suppl Pediatrics); Volume 106: 347-349, 2007.

When To Use This Article:

- ➜ Pediatric Neurosurgeons asking about OSV II™ valve use in children
- ➜ Questions about slitlike ventricles and OSV II™ valve

Take Home Point:

Patients treated with OSVII™ valve presented less slitlike ventricles than patients treated with DP or Delta® valves.

Since slitlike ventricles may be a result of overdrainage, reducing the incidence of slitlike ventricles may indicate a reduction in episodes of overdrainage. Pg. 349.

What This Means For You:

Patients treated with OSVII™ valve presented less slitlike ventricles than patients treated with DP or Delta® valves.

Less slit ventricles is also a sign of less overdrainage.

Summary

"Slitlike ventricles were noted in 10.8% of patients who had DP valves, 10.5% of patients with Delta valves, and 3.6% of patients with Orbis Sigma valves (p=0.007)." Pg. 348

"The regression analysis supported the role of the valve type as the strongest independent predictor of slitlike ventricles. After controlling for age at shunt insertion and cause of hydrocephalus, children with either a DP or Delta valve were found to be 1.66 times more likely to develop slitlike ventricles than children with an Orbis-Sigma Valve." Pg. 348

INTEGRA
LIMIT UNCERTAINTY

INTEGRA NPH™ low flow valve

Shuntbook

Shunt failure in adult hydrocephalus:
Flow-Controlled shunt versus Differential Pressure shunts
A cooperative study in 289 patients

Decq et al.
Surg Neurol, 1995, 43:333-9

When To Use This Article:

- ➜ When introducing a surgeon to OSV II™ valve technology
- ➜ Discussing mechanical complications of valves vs. OSV II™ valve (overdrainage, underdrainage, late obstructions, and subdural hematomas)

Take Home Point:

Flow regulating technology (OSV II™ valve) decreases the risks of mechanical complications related to overdrainage, underdrainage, and obstruction.

What This Means for You:

This study showed flow regulating valves (OSV valve) reduced the risks of mechanical complications versus DP valves, especially when it came to overdrainage and obstruction.

Summary

RESULTS: The actuarial risk of shunt infection in the two groups is respectively 8.3% and 10.9% at 1 year (nonsignificant difference). The actuarial risk of mechanical complications at 1 year is 38% for the DP patients and 10% for the FC patients (p = 0.0001); this difference is largely due to a decrease of complications related to overdrainage phenomenon (14/142 subdural collections were observed in the DP group versus 1/147 in the FC group) (p = 0.0001).

CONCLUSION: The conclusion of this cooperative and retrospective study is that the use of a flow-controlled system decreases the risk of mechanical complications related to the hydrodynamic properties of the shunts used in the treatment of adult hydrocephalus, especially those related to overdrainage.

NeuroBalloon™ Catheter

INTEGRA™
LIMIT UNCERTAINTY

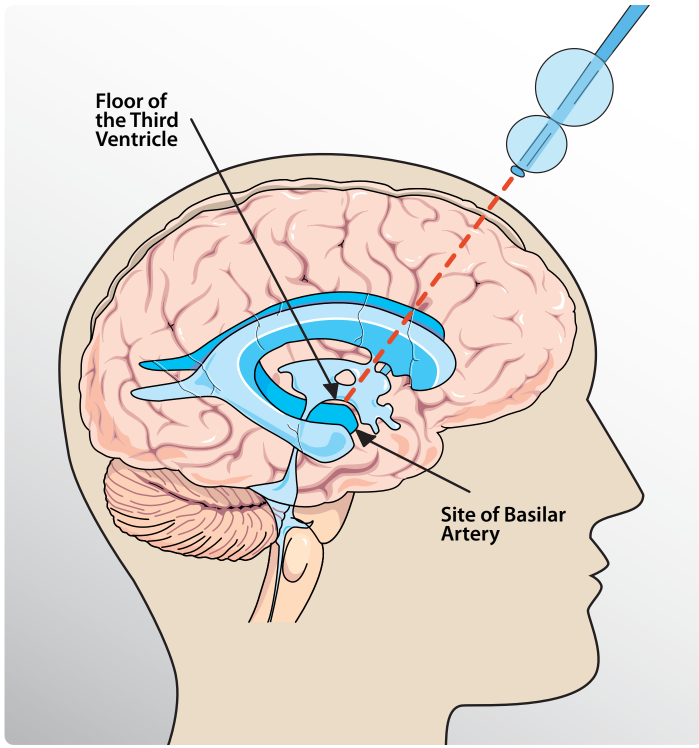
What is the NeuroBalloon™ catheter

Intended use

The NeuroBalloon™ catheter is intended for dilatation of cerebral membrane fenestrations under direct or endoscopic visualization during intracranial procedures.

When to use it ?

Used for Endoscopic Third Ventriculostomies (Procedure creating a hole in the floor of the 3rd ventricle so CSF can circulate and be reabsorbed) to dilate the hole that was created in the base of the 3rd ventricle.



NeuroBalloon™ catheter

Description:

> 64 cm working length

> Polyurethane catheter with female luer lock connector and silicone balloon

> 1 ml (cc) syringe

> Compatible with Neuroendoscopes with 4F (French) working channel lumen diameter (1.35 mm minimum)

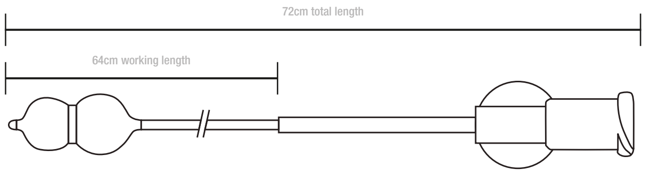
> Diameter of the waist [after a pre-inflation with 1 ml (cc)]

» When inflated with 0.6 ml (cc): 3.5 mm minimum

» When inflated with 1.0 ml (cc): 6.0 mm maximum

Description

Polyurethane catheter with female luer lock connector, attached transparent silicone double balloon. Includes a 1ml (1cc) syringe.



- Black Ink Mark at waist of double balloon
- Diameter when deflated allows compatibility with 4 French working channels (1.35mm)
- Diameter of the waist after a pre-inflation with 1.0ml (1.0cc):
  - When inflated with 0.6ml (0.6cc): 3.5mm minimum
  - When inflated with 1.0ml (1.0cc): 6.0mm maximum

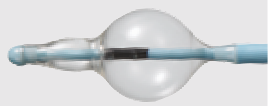
1ml syringe (supplied sterile)

NeuroBalloon™ catheter – Instructions for use – Preparation

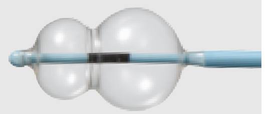
1. The use of the syringe provided within the package is strongly recommended. Fill the syringe with 1 ml (1 cc) of air and connect it to the catheter hub.
   Warning: Do not use more than 1 ml (1 cc) of air; over-inflation may damage the balloon.
2. Inflate the balloon by slowly injecting with 1 ml (1 cc) of air. Carefully inspect the catheter with the balloon inflated. A balloon that leaks or inflates in a grossly asymetric (eccentric) manner should not be used.
3. Completely deflate the balloon by pulling back on the syringe's plunger in order to collapse the balloon over the catheter tip. Disconnect the syringe from the catheter hub.
4. Gently moisten the exterior of the balloon catheter with sterile, non pyrogenic saline solution (or similar isotonic solution) to facilitate balloon introduction into the cannula or other introducing tool.

NeuroBalloon™ catheter – Inflation steps

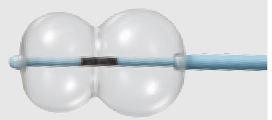
The balloon catheter is positioned within the fenestrated cerebral membrane. The black mark on the catheter indicates the position of the balloon waist. The balloon is inflated by slowly injecting 0.6 ml to 1.0 ml (0.6 cc to 1.0 cc) of air.



The proximal section of the double balloon will inflate shortly before the distal section. This allows the balloon to be held in position on the floor of the third ventricle.



The distal section of the double balloon will then inflate, capturing the membrane and holding the catheter in place for the dilation.



The entire double balloon continues to inflate, progressively dilating the fenestrated membrane with the outer diameter of the balloon waist. The dilation can be visualized through the transparent wall of the proximal balloon section.

Video - NeuroBalloon™ procedure

NeuroBalloon™ catheter – Instructions for use – Procedure

Insertion, Inflation and Withdrawal

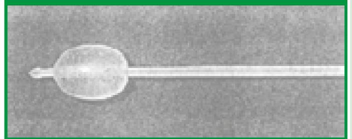
1. Using a technique of choice, insert an introducing tool (e.g.: a neuroendoscope or a multilumen cannula) close to the membrane to be punctured.
2. Create the puncture opening in the cerebral membrane.
3. Connect the syringe unfilled to the catheter hub. Pull back on the syringe's plunger in order to collapse the balloon over the catheter tip and to remove any residual inflation of the balloon. Leave the syringe connected.
4. Carefully introduce the deflated balloon catheter through the 4 French (or bigger) lumen of the introducing tool. Never force the catheter down the lumen as this may damage the balloon.
5. Once the balloon tip clearly appears under direct visualization or on the endoscopy visualization system screen, disconnect the syringe and fill it with 1 ml (1 cc) of air. Then, reconnect the syringe to the catheter hub.
6. Carefully position the balloon within the opening in the cerebral membrane. A black marker within the balloon indicates the balloon waist. This black marker should be positioned within the membrane opening.
7. Inflate the balloon by slowly injecting 0.6 ml (0.6 cc) of air (advance the plunger to the graduation 0.4 ml (0.4 cc) of the syringe).
   Upon inflation, the proximal and distal balloon sections will capture the membrane, progressively dilating the hole to the outer diameter of the balloon waist. The dilatation can be visualized through the transparent wall of the proximal balloon section.
8. Maintain inflation for 2 minutes to facilitate hemostasis of eventual microhemorrhages.
9. It should be noted that air slowly diffuses through the balloon wall. If required, inject the residual 0.4 ml (0.4 cc) left in the syringe to compensate for air loss. If necessary, maintain the inflation for 2 more minutes. **Warning : Do not try to inject more than 1ml of air as overinflation may damage the balloon**
10. Deflate the balloon by completely pulling back on the syringe plunger abd, without disconnecting the syringe, gently remove the catheter from the introducing tool under negative pressure.

INTEGRA LIMIT UNCERTAINTY

Shuntbook

Competition

The NeuroBalloon™ catheter is intended for dilatation of cerebral membrane fenestration under direct or endoscopic visualization during intracranial procedures.

COMMON COMPETITIVE VALVE	DESCRIPTION
FOGARTY BALLOONS 	Difficult to secure the depth of the balloon (risk over the basilar artery) Difficulty to stay in place & inflate at the level of the membrane (Fogarty balloon is not secured in its position)[1] On-Off / quick opening of the balloon (mechanical opening of the system)
FORCEPS 	Difficult to secure the basilar artery with forceps Mechanical opening of the system (on-off)

1 Sainte Rose, ***Endoscopic Third Ventriculostomy, Techniques in neurosurgery,*** 1996, Vol 1, No3, 176-184

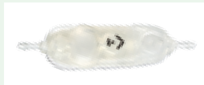
2 http://www.cookmedical.com/di/content/mmedia/PI-BM-ITJHAG-EN-201002.pdf

3 http://ht.edwards.com/resourcegallery/products/vascularsurgery/clotmanagement/pdfs/fogartyarterialembolectomycathetersalessheet.pdf

Other Mechanism Valves

INTEGRA Differential Pressure valves ranges: diaphragm or membrane

Diaphragm / Membrane: A mobile flexible membrane moves in response to pressure differences

VALVE TYPE	BRANDNAME	WITH ASD	WITHOUT ASD	TYPICAL PATIENT TYPE
Diaphragm or membrane	Equiflow™ 	Yes	No (Contour Flex™)	Any patient type Large & small sizes available for adult or peds
	Contour Flex™ 	No (Equi flow)	Yes	
	 Novus®	Yes	No (LPVII™)	
	LPVII™ 	No (Novus)	Yes	
	Pudenz burr hole 	Yes	Yes	Any patient type Great for valve only revisions

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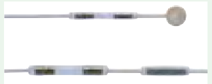
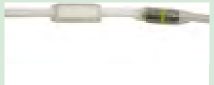
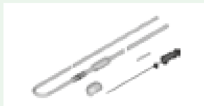
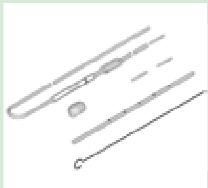
INTEGRA Differential Pressure valve ranges: Ball-in-cone

Ball-in-cone : metallic spring that applies force to a ball made of synthetic ruby located in an occluding orifice.

VALVE TYPE	BRANDNAME	WITH ASD	WITHOUT ASD	TYPICAL PATIENT TYPE
Ball-in-cone	Integra DP™ 	No	Yes	Any patient type Blood or high protein in the CSF, trauma patients Omnishunt or Integra DP pediatric size are great for peds
	Omnishunt™ 	No	Yes	
	Atlas 	No	Yes	
	Minishunt 		Yes	
	Ruby 		Yes	

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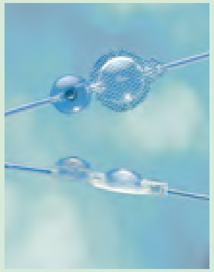
INTEGRA Differential Pressure valves ranges: Duck bill

Duck bill : the orifice is round at the entrance and converges into 2 flat horizontally opposed leaflets of silicone.

VALVE TYPE	BRANDNAME	WITH ASD	WITHOUT ASD	TYPICAL PATIENT TYPE
Duck bill	Ultra VS™ 	No	Yes	Adult or neonate High protein CSF Neonate size is the smallest on the market, suit-able for thin skinned babies where larger valves can actually erode though the skin
	Multipurpose 	Yes	Yes	Patients receiving chemo or other infusion therapy may appreciate the valve « on » for treatment and « off » when not undergoing treatment
	Mishler™ dual chamber 	Yes	Yes	Allows for easier distal and/or proximal flushing Suitable for any type of contrast dye, antibiotic or chemotherapy injections

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Marketing Materials
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Marketing Printed Materials

salesheet OSV II™ low pro™

english ILS 06-01-002-01-09

french ILS 06-01-002-01-09

german ILS 06-01-002-01-09

salesheet NeuroBalloon™

english ILS 06-01-005-01-09

catalogue IDEAFLOW®

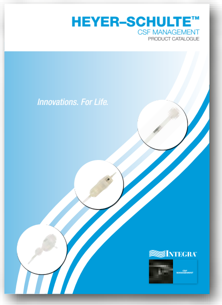
english LS 06-02-005-03-09

french ILS 06-02-006-03-10

german ILS 06-02-007-03-10

catalogue RADIONICS®

english ILS 06-02-001-03-09

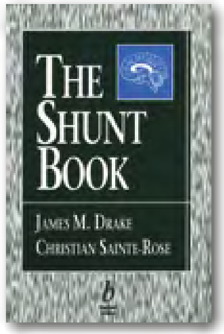


catalogue HEYER-SCHULTE™

english ILS 06-02-002-02-09

french ILS 06-01-002-01-09

german ILS 06-01-002-01-09



The Shunt Book
by Drake & Sainte-Rose

english

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Marketing Materials

Shunts non-sterile product binder

REF 909DEMOCASE

CD Flow Regulated Concept

english ILS 06-03-001-01-10

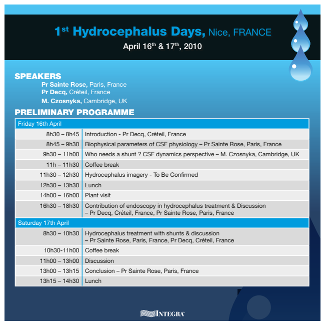
DVD
Integra NeuroBalloon™ Catheter
catheter procedure

english ILS 06-03-004-01-10

DVD Flow Regulating shunts implantation procedure

english ILS 06-03-005-01-10

Events



1st Hydrocephalus Days, Nice, FRANCE
April 16th & 17th, 2010

SPEAKERS
Pr Sainte Rose, Paris, France
Pr Decq, Créteil, France
M. Czosnyka, Cambridge, UK

PRELIMINARY PROGRAMME

Friday 16th April	
8h30 – 8h45	Introduction - Pr Decq, Créteil, France
8h45 – 9h30	Biophysical parameters of CSF physiology – Pr Sainte Rose, Paris, France
9h30 – 11h00	Who needs a shunt ? CSF dynamics perspective – M. Czosnyka, Cambridge, UK
11h – 11h30	Coffee break
11h30 – 12h30	Hydrocephalus imagery - To Be Confirmed
12h30 – 13h30	Lunch
14h00 – 16h00	Plant visit
16h30 – 18h30	Contribution of endoscopy in hydrocephalus treatment & Discussion – Pr Decq, Créteil, France, Pr Sainte Rose, Paris, France
Saturday 17th April	
8h30 – 10h30	Hydrocephalus treatment with shunts & discussion – Pr Sainte Rose, Paris, France, Pr Decq, Créteil, France
10h30-11h00	Coffee break
11h00 – 13h00	Discussion
13h00 – 13h15	Conclusion – Pr Sainte Rose, Paris, France
13h15 – 14h30	Lunch

INTEGRA

1st Hydrocephalus Days

April 16th & 17th 2010 – Nice, France

Integra Neuro Symposium

Sept. 22nd to 24th 2011 – Lyon, France

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Glossary

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ACQUIRED HYDROCEPHALUS
Hydrocephalus that develops after birth, caused by a factor such as an intraventricular hemorrhage, meningitis, head injury, or a brain tumor.

ADJUSTABLE (PROGRAMABLE) VALVES
Shunt valves whose settings can be noninvasively adjusted during an office visit.

AQUEDUCT OF SYLVIUS (CEREBRAL AQUEDUCT)
A narrow channel allowing the flow of cerebrospinal fluid in the midbrain. The aqueduct of Sylvius connects the third and fourth ventricles.

AQUEDUCTAL STENOSIS
A narrowing of the aqueduct of Sylvius. Aqueductal stenosis is one cause of obstructive hydrocephalus and the most common cause of congenital hydrocephalus.

ARACHNOID CYSTS
Cysts filled with cerebrospinal fluid that may occur anywhere in the brain. Some arachnoid cysts are self-contained, while others may be connected by a passageway with the ventricles or the subarachnoid space. The entrapped fluid may block the CSF pathways, producing hydrocephalus.

ARACHNOID GRANULATIONS
Arachnoid villi.

ARACHNOID MEMBRANE
The middle of the three meninges, lying between the dura mater and the pia mater. The arachnoid membrane covers the brain and spinal cord smoothly without conforming to the irregularities of their surfaces.

ARACHNOID VILLI (ARACHNOID GRANULATIONS)
Small projections in the dura mater that protrude into the dural venous (blood) sinuses. Cerebrospinal fluid is reabsorbed from the arachnoid space by passing through the arachnoid villi and entering the venous system.

CENTRAL NERVOUS SYSTEM (CNS)
The part of the nervous system that includes the brain and the spinal cord. The CNS coordinates the activity of the entire nervous system.

CEREBRAL AQUEDUCT
Aqueduct of Sylvius.

CEREBROSPINAL FLUID (CSF)
A clear, colorless liquid secreted primarily by the choroid plexus and contained within the ventricles and the subarachnoid space. CSF functions primarily to nourish and protect the brain and spinal cord.

CHIARI II MALFORMATION
A cause of congenital hydrocephalus in which part of the cerebellum and the fourth ventricle push downward through the opening at the base of the skull, blocking CSF's flow out of the fourth ventricle and thus producing hydrocephalus. This condition is often referred to as spina bifida.

CHOROID PLEXUS
The structures in the lateral, third, and fourth ventricles that produce cerebrospinal fluid.

CISTERN
A sac or cavity in the body that contains fluid (such as cerebrospinal fluid).

COMMUNICATING HYDROCEPHALUS
Hydrocephalus in which the openings between the ventricular spaces,and between the fourth ventricle and the subarachnoid space, are functioning.

CONGENITAL HYDROCEPHALUS

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Hydrocephalus caused by a problem that is present at birth. Hydrocephalus that develops later in life, even in adults, but is caused by a condition that existed at birth, is still considered a form of congenital hydrocephalus. Congenital hydrocephalus can be caused by aqueductal stenosis, a neural tube defect, arachnoid cysts, or Dandy-Walker syndrome.

CYST
Closed sac with a distinct membrane that develops abnormally in a bodily cavity or structure.

DANDY-WALKER SYNDROME
A cause of congenital hydrocephalus in which the fourth ventricle becomes enlarged because its outlets are partly or completely closed, and part of the cerebellum fails to develop. Dandy-Walker syndrome sometimes leads to aqueductal stenosis.

DECOMPENSATED CONGENITAL HYDROCEPHALUS
Hydrocephalus that may have been present at birth, and perhaps even treated in early childhood, but remained largely compensated and asymptomatic for many years.

DURA MATER (DURA)
One of the three meninges. The dura mater, the outermost and heaviest layer of the meninges, lies closest to the skull.

ENDOSCOPIC THIRD VENTRICULOSTOMY (ETV)
A surgical operation that creates an opening through the membranous floor of the third ventricle, permitting cerebrospinal fluid to exit the third ventricle and flow directly into the subarachnoid space at the base of the brain.

FONTANELLE
A membrane-covered opening in the skull of an infant or young toddler.

FORAMEN MAGNUM
The opening in the skull through which the spinal cord passes.

FORAMEN OF MONRO (INTERVENTRICULAR FORAMEN)
An opening between a lateral ventricle and the third ventricle allowing cerebrospinal fluid to flow from the lateral ventricle into the third ventricle.

FORAMINA
Any small opening.

FORAMINA OF LUSCHKA AND MAGENDIE
Small opening in the brain that allows cerebrospinal fluid to flow out of the fourth ventricle, into the subarachnoid space.

FOURTH VENTRICLE
A cavity within the brain that is situated between the brain stem and the cerebellum. Cerebrospinal fluid enters the fourth ventricle from the cerebral aqueduct; it exits via the foramina of Luschka and Magendie, flowing into the subarachnoid space.

HEMATOMA
A localized collection of blood, usually clotted.

HYDROCEPHALUS
An abnormal condition that occurs when there is an imbalance between the rate of cerebrospinal fluid production and the rate of absorption, leading to gradual accumulation of CSF.

HYDROSTATIC
Relating to fluids, such as cerebrospinal fluid, when they're at rest or to the pressures they exert or transmit.

HYGROMA
A sac, cyst, or bursa distended with fluid; a subdural hygroma is a collection of fluid between the brain and the skull.

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HYPOTHALAMUS
A part of the brain that forms the floor of the third ventricle. The hypothalamus includes vital autonomic (involuntary) regulatory centers.

IDIOPATHIC
Without known cause.

INFLOW (PROXIMAL) CATHETER
Shunt catheter that drains cerebrospinal fluid away from the ventricles or the lumbar subarachnoid space.

INTRACRANIAL PRESSURE (ICP)
Pressure caused by a build-up of cerebrospinal fluid, resulting in hydrocephalus.

INTERVENTRICULAR HEMORRHAGE
Bleeding into the ventricles.

LATERAL VENTRICLE
One of two normal cavities within the cerebral hemispheres that contains cerebrospinal fluid. CSF flows from the lateral ventricles into the third ventricle via the foramen of Monro.

LUMBAR
Relating to the vertebrae between the thoracic vertebrae (between the neck and the abdomen) and the sacrum (the part of the vertebral column that is connected with the pelvis).

LUMBAR PUNCTURE
Spinal tap. Clinicians sometimes use a lumbar puncture to help diagnose hydrocephalus, removing cerebrospinal fluid to see whether hydrocephalus symptoms are relieved.

MENINGES
The three membranes covering the brain and spinal cord, including the dura mater, the arachnoid membrane, and the pia mater.

MENINGITIS
Inflammation of the meninges. Meningitis can result from a bacterial or a viral infection. Scarring of the arachnoid membrane resulting from meningitis can restrict or block cerebrospinal fluid flow and absorption.

MENINGOMYELOCELE
Congenital defect of the central nervous system of the baby. Membranes and the spinal cord protrude through an opening or defect in the vertebral column.

MYELOMENINGOCELE
Type of neural tube defect in which the spinal cord is exposed at birth and is often leaking cerebrospinal fluid. It usually leads to the Chiari II malformation.

NEURAL TUBE DEFECT (NTD)
Birth defect of the brain or spinal cord. A neural tube defect can cause hydrocephalus.

NON-COMMUNICATING HYDROCEPHALUS
Hydrocephalus in which the ventricular pathways are blocked. Non-communicating hydrocephalus is caused by the obstructed flow of cerebrospinal fluid through the cerebral aqueduct or from the fourth ventricle to the subarachnoid space.

NORMAL PRESSURE HYDROCEPHALUS (NPH)
Type of adult-onset hydrocephalus whose symptoms usually include difficulty walking, mild dementia, and impaired bladder control. This form of hydrocephalus occurs most often in people over age 60.

OBSTRUCTIVE HYDROCEPHALUS
Hydrocephalus caused by a blockage along the pathway allowing the flow of cerebrospinal fluid.

OUTFLOW (DISTAL) CATHETER
Shunt component that drains cerebrospinal fluid from the valve to the peritoneum, the heart, or another suitable drainage site.

PAPILLEDEMA

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Swelling around the optic nerve, usually due to pressure on the nerve by a tumor. Papilledema is optic disc swelling that is caused by increased intracranial pressure. The swelling is usually bilateral and can occur over a period of hours to weeks. Papilledema occurs in approximately 50% of those with a brain tumor.

PARIETAL
Related to the upper posterior (back) wall of the head.

PERITONEUM
Thin membrane that lines the abdominal cavity. Cerebrospinal fluid is sometimes shunted to the peritoneum, which can act as a suitable drainage site.

PIA MATER
One of the three meninges. The pia mater is the layer closest to the brain.

POSTERIOR FOSSA
Small space at the back of the brain. The posterior fossa houses the brain stem and the cerebellum.

SACRUM
The part of the vertebral column that is connected with the pelvis.

SAGITTAL SINUS
A large vein close to the suture between the parietal bones of the skull.

SHUNT
A hallow plastic tube (catheter) that is placed in the ventricle of the brain. The tube is attached to a valve and is then threaded under the skin from the brain to either the abdomen (Ventricular-Peritoneal shunt) or heart (Ventricular-Atrial shunt).

SPINA BIFIDA
A condition caused by the Chiari II malformation in which part of the cerebellum and the fourth ventricle push downward through the opening at the base of the skull, blocking the flow of cerebrospinal fluid out of the fourth ventricle and thus producing hydrocephalus.

STENOSIS
Obstruction.

SUBARACHNOID PATHWAYS
Pathways in the space under the arachnoid membrane that normally allow the flow of cerebrospinal fluid.

SUBARACHNOID SPACE
The space under the arachnoid membrane.

SUBDURAL HYGROMA
A collection of fluid between the brain and the skull.

SUNSETTING SIGN
Downward turning of the eyes. The sunsetting sign can be a symptom of hydrocephalus in infants.

SYMPTOM OF HYDROCEPHALUS IN YOUNG AND MIDDLE-AGED ADULTS (SHYMA)
Type of adult-onset hydrocephalus whose symptoms usually include difficulty walking, mild dementia, and impaired bladder control, along with chronic headaches, visual problems, and fainting (syncope). This form of hydrocephalus occurs most often in younger adults.

THIRD VENTRICLE
A midline cavity within the brain that is situated between the right and left thalamus. Cerebrospinal fluid enters the third ventricle from each lateral ventricle via the foramen of Monro; it exits the third ventricle via the aqueduct of Sylvius.

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ULTRASONOGRAPHY
A noninvasive diagnostic technique that uses sound waves to image internal body structures. Ultrasonography can be used to diagnose hydrocephalus prenatally or after birth, before the skull's suture lines have closed.

VALVE
A shunt component that regulates differential pressure or controls CSF flow through the shunt tubing.

VENTRICLE
A cavity within the brain that contains cerebrospinal fluid.

VENTRICULO-ATRIAL (VA) SHUNTS
A shunt that is placed into a brain ventricle to drain cerebrospinal fluid (CSF) from the ventricular system into the heart.

VENTRICULO-PERITONEAL (VP) SHUNTS
A shunt that is placed into a brain ventricle to drain cerebrospinal fluid (CSF) from the ventricular system into the abdomen.

VENTRICULAR LINING
The lining of the ventricles.

VERTEBRAL COLUMN
Spinal column.

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