Medtronic Neurologic Technologies
Anatomy and Physiology

How the Brain Works
Cerebrospinal Fluid (CSF)

- CSF is formed by the choroid plexus in the brain ventricles
- CSF is absorbed by the arachnoid villi
- Circulatory system
  - CSF production is balanced by arachnoid villi absorption
Cerebrospinal Fluid (CSF)

- CSF is transferred by the arachnoid villi to the sagittal sinus where it exits the body by way of the venous system.
CSF Basic Statistics

• The average person produces 500 ml of CSF a day, or roughly a pint
• CSF is produced by the choroid plexus at a rate of 20-25 ml/hr
• CSF serves to “cushion” the brain, and to provide some basic nutrients
Hydrocephalus

• Greek: “Water-on-the-Head”
  – Hydro – Water
  – Kephale – Head

• Types of Hydrocephalus
  – Obstructive
  – Communicating
  – NPH
Hydrocephalus

- “Non-Communicating/Obstructive: 60% cases
  - CSF flow path blockage
    - Tumor
    - Spina Bifida
    - Aqueductal Stenosis
      - Congenital Defect
Hydrocephalus

- **Communicating: 40% cases**
  - Over-production of CSF
    - Choroid Plexus Palpiloma
  - Under-absorption of CSF
    - Subarachnoid Hemorrhage
    - Intraventricular Hemorrhage
Pediatric Hydrocephalus

Enlarged Head

Sunset Eyes
Adult On-Set Hydrocephalus
Normal Pressure Hydrocephalus (NPH)

• Definition: A hydrocephalus disease of the elderly ( > 60 years) characterized by a classic triad of symptoms: Dementia, Gait Disturbance, Incontinence.

• The triad of symptoms is called the Hakim-Adams Triad.
<table>
<thead>
<tr>
<th>Feature</th>
<th>Early Stage</th>
<th>Late Stage</th>
<th>End Stage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Disturbance</td>
<td>Falling Spells Off-Balance</td>
<td>Slow Shuffling Gait Small Steps Broad-Based Gait</td>
<td>Unable to Walk Bedridden</td>
</tr>
<tr>
<td>Mental Deterioration</td>
<td>Apathy Inattention</td>
<td>Short Memory Deficits</td>
<td>Akinetic Mutism</td>
</tr>
<tr>
<td></td>
<td>Bright Moments</td>
<td>Decreased speed of complex information processing.</td>
<td></td>
</tr>
<tr>
<td>Incontinence</td>
<td>Urge Incontinence</td>
<td>Loss of Sphincter Control</td>
<td>Fecal Incontinence</td>
</tr>
</tbody>
</table>
Normal Pressure Hydrocephalus (NPH)

- Since the symptoms are often associated with aging or other aging diseases, NPH is often misdiagnosed.
  - Senility, Alzheimer's, Parkinson’s
- Incidence: 5% of all dementia cases*
- Numbers will increase with improved healthcare and extended longevity
- Treatment decisions are complex due to co-morbidities in the elderly population

*NPH Guidelines, Neurosurgery, Marmarou et al, 2005
Normal Pressure Hydrocephalus (NPH)

• Idiopathic – Unknown origin
• Secondary to:
  – Head injury
  – Cranial surgery
  – Subarachnoid hemorrhage
  – Meningitis or infection
  – Tumors and cysts
  – Subdural hematomas

• The link between the pathophysiology and clinical presentation is unclear
  – Change in brain compliance.
NPH Diagnosis

- Primary Care Physician – Referral
- Neurologist - Diagnosis
- Neurosurgeon – Shunt Implantation
NPH Diagnosis

• Preliminary Diagnosis
  – Duration and sequence of symptoms
  – CT or MRI scan
  – Neuropsychological Tests
  – ICP Measurements
NPH
Prognostic Tests

- Responsiveness to CSF removal
  - Lumbar CSF Tap Test
    - 50% Specificity
  - External Lumbar Drainage (2-3 days)
    - 90% Specificity
  - Lumbar Infusion Study
    (measures CSF absorptive capacity)
    - 80% Specificity
Hydrocephalus – Final Facts

• Incidence:
  – 1/1000 babies is born hydrocephalic
    • Brain hemorrhage, brain defect, spina bifida
  – 1/10,000 adults will have late onset hydrocephalus
    • NPH, trauma, tumor development, stroke, aneurysm rupture

• Life-Long Condition
## Hydrocephalus – Final Facts

<table>
<thead>
<tr>
<th>Geography</th>
<th>Procedures/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>42,000</td>
</tr>
<tr>
<td>Europe</td>
<td>25,000</td>
</tr>
<tr>
<td>World Wide</td>
<td>164,000</td>
</tr>
<tr>
<td>Untreated</td>
<td>600,000</td>
</tr>
</tbody>
</table>
Hydrocephalus Treatment

• Shunting
  – Differential Pressure Valves
  – Siphon Control Devices
  – Adjustable Valves

• Third Ventriculostomy
  – Endoscopes
The Standard of Care - Shunt

Ventriculoatrial (VA) Shunt: 5%
Ventriculoperitoneal (VP) Shunt: 95%
Shunt Surgery

- Subcutaneous implant (under the skin)
  - Skin flap
  - 3-6 mm burr hole
  - Insertion of ventricular catheter based on anatomical landmarks
  - Tunneling of distal catheter
3rd Ventriculostomy

- Fenestration through the floor of the 3rd ventricle into the basal cistern
- Obstructive hydrocephalus
  - 2 years and older
- “Internal Shunt”
  - Risk of fenestration closure
Hydrocephalus Shunts
CSF-Flow Control Valves

- Regular Size: Older Children & Adults
- Small Size: Infants & Young Children
CSF-Flow Control Valve
Valve Mechanism

- Polypropylene (plastic) Base
- Silicone Membrane (Diaphragm)
**Pressure/Flow Ranges**

**NOTE:** Levels depicted are median values. All valves perform within +/- 25 mm H₂O of these median values when tested at time of manufacture. Low-Low Pressures are within +/- 10 mm H₂O at 5 mL/hr and +/- 20 mm H₂O at 50 mL/hr at time of manufacture.
CSF-Flow Control Valves

- **Variation in Sizes**
  - Pediatric Models
  - Adult Models
- **Surgical Technique**
  - Burr Hole Styles
Shunting Complications

• 40% of all shunts fail within the first post-operative year
  – Infection
  – CSF Overdrainage
CSF Overdrainage

Normal Ventricles

Collapsed/Slit Ventricles
CSF Overdrainage

- Chronic obstruction of the proximal catheter tip by choroid plexus
- Proximal obstruction accounts for 30% of all shunt failures
CSF Overdrainage

- Subdural Collections
  - Subdural Hygroma caused by disruption of the arachnoid
  - Subdural Hematoma caused by stretched subarachnoid blood vessels
CSF Overdrainage

• Craniostenosis
  – Premature closing of the cranial sutures
CSF Overdrainage

• **Slit Ventricle Syndrome**
  – Transient intracranial hypotension which occurs in patients with a functioning shunt and slit-like ventricles

• **Orthostatic Hypotension**
  – Postural headaches and nausea
Hydrostatic Shunt Pressures

- When the patient is reclined, the valve is allowed to react to pressure at the shunt inlet, due to the absence of any distal catheter pressure.
- When upright, gravity acts on the fluid filled distal catheter creating a siphon affect.
Why doesn’t the valve stop it?

- In the upright position, a differential pressure valve doesn’t know the difference between “positive” pressure from the ventricles “pushing” the valve open, or “siphoning” from the distal catheter “pulling” the valve open.

- The valve mechanism responds to whatever hydrostatic force is the strongest – which is typically siphoning.
Delta® Valve

*Includes Delta Chamber for Overdrainage Protection*
Delta® Chamber for Siphon Control

Detail of the siphon regulating mechanism. The ratio of the hydrodynamic leverage inlet area to the outlet area is greater than 20:1.
Delta® Valve Features

• The 20:1 hydrodynamic leverage ratio allows the patient to maintain ICP within a physiologic range, regardless of patient posture.

• Normally closed Delta Chamber diaphragms, respond to upstream positive hydrostatic pressure, but remain closed in the presence of downstream negative hydrostatic pressure.

• Delta Chamber diaphragms are recessed below a protective polypropylene outer ring to minimize the risk of diaphragm compression from overlying tissue.
Strata®; The Adjustable Delta® Valve

Valve Body
Delta Chamber
Adjustable Valve Mechanism
Strata® Valve Mechanism

- Ruby Ball & Cone
- Rotor with Magnet
- Base Platform Stops
- Base Platforms
Strata®
Valve Mechanism

Cap
Seal
Guide Ring
Rotor Retention Spring
Pressure/Flow Spring
Magnetic Rotor

Valve Base
With 5 Concentric Platforms
Strata® Pressure/Flow Ranges

**NOTE:** Levels depicted are median values. All valves perform within a tolerance range of these median values when tested at time of manufacture as follows:

Performance Level 0.5:
- +/- 15 mm H₂O (5 mL/hr)
- +/- 25 mm H₂O (50 mL/hr)

Performance Level 1.0, Level 1.5, Level 2.0, and Level 2.5
- +/- 25 mm H₂O

Performance Level 0.5:
- +/- 25 mm H₂O

Performance Level 1.0, Level 1.5, Level 2.0, and Level 2.5
- +/- 40 mm H₂O
Strata® Adjustment Tools

Verification Tool  Locator Tool  Adjustment Tool
Strata® Valve Adjustments

Pre-operative

Post-Operative
StrataVarius™

• Handheld instrument designed to be ambidextrous
• Battery powered device (2-AA)
  – 100 uses
  – Power-down after 3 minutes of idle time
• LCD readout screen
• Portal for valve palpation and magnetic adjustment
Strata® Valve X-Ray
Medtronic NT Shunt Products

- **CSF-Flow Control Valves** - Provide a set resistance to flow, but do not manage negative hydrostatic pressure.

- **Delta® Valves** - Include overdrainage protection to minimize the risk of slit ventricles and associated complications.

- **Strata® Valves** - Can be non-invasively adjusted to 5 different pressure settings.
Ventricular Reservoirs & Ports

• Commonly called “Ommaya Reservoirs”
  – Pediatric Sizes
  – Adult Sizes
  – Burr Hole

*Ommaya® is a registered trademark of Integra NeuroCare
Indications for Use

1) Administration of chemotherapy for CNS neoplasms including: carcinomatous meningitis, CNS lymphoma or leukemia

2) Fluid aspiration from a chronic tumor cyst that is resistant to therapy

3) Chronic removal of CSF from infants with intraventricular hemorrhage
Ventricular Reservoirs

- Silicone dome is thick
- Tolerate 130 punctures using a 25G or smaller non-coring needle.
  - B-D Needle 305122
- Plastic needle guard to prevent needle penetration.
Ventricular Port

- Tolerate a minimum of 800 punctures using a 22G Huber needle
- Raised septum ring design provides a reference point for needle penetration
- Available in 16 mm and 30 mm sizes
Volume of Reservoirs and Ports

- The product instructions detail the volume capacity of all reservoirs & ports.

<table>
<thead>
<tr>
<th>Fluid volume capacity of reservoirs (nominal):</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mm, Side Inlet ........................................... 2.4 mL</td>
</tr>
<tr>
<td>28 mm, Side Inlet ........................................... 1.1 mL</td>
</tr>
<tr>
<td>28 mm, Bottom Inlet ........................................... 1.1 mL</td>
</tr>
<tr>
<td>28 mm, Bottom Inlet Convertible .................... 1.1 mL</td>
</tr>
<tr>
<td>18 mm, Side Inlet ........................................... 0.3 mL</td>
</tr>
<tr>
<td>12 mm, Burr Hole ............................................. 0.6 mL</td>
</tr>
<tr>
<td>12 mm, Burr Hole Convertible ....................... 0.6 mL</td>
</tr>
<tr>
<td>12 mm, Convertible .......................................... 0.1 mL</td>
</tr>
</tbody>
</table>
Reservoir Puncture

Insert the small needle into the reservoir at an oblique angle. Inserting at an angle allows for the silicone at the hole site to reseal.

![Diagram of reservoir puncture with needle at an oblique angle]
Medtronic Neurologic Technologies

Working to Restore Full Health and Life