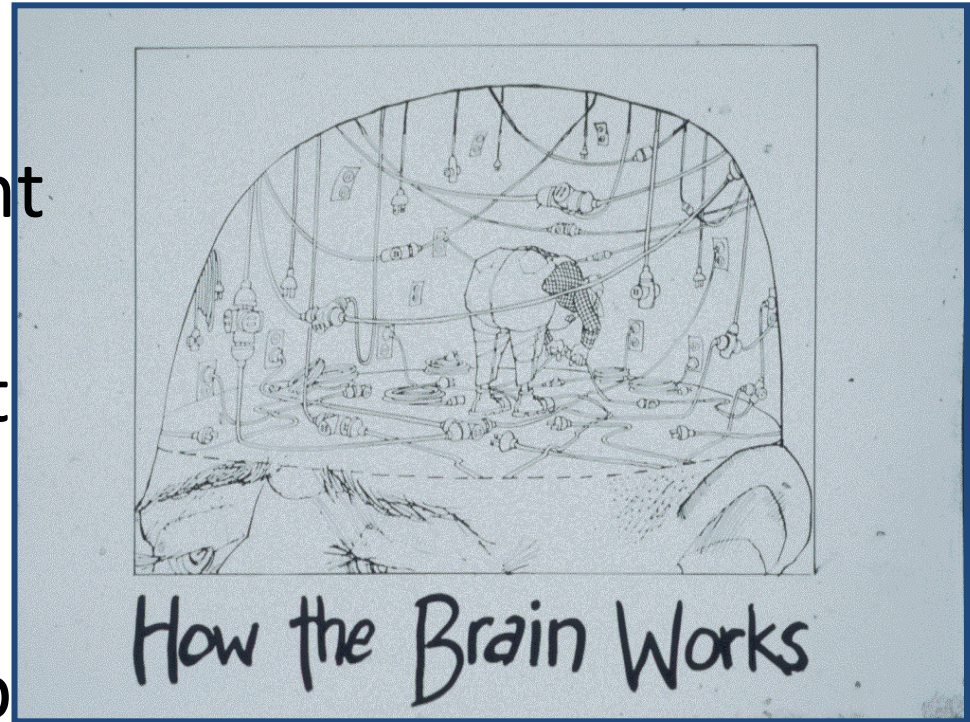


Shunt Technologies

Presented by – Dr Vivek Tandon

Introduction

- Controversial topic – which shunt is best?
- Confusion- how it works?
- Knowing the principles will help in intelligent selection of device.



How Shunts work

History

Hippocrates

- First attempted ventricular puncture for HCP

Nulsen and
Spitz
Pudenz

VP shunt = 1908

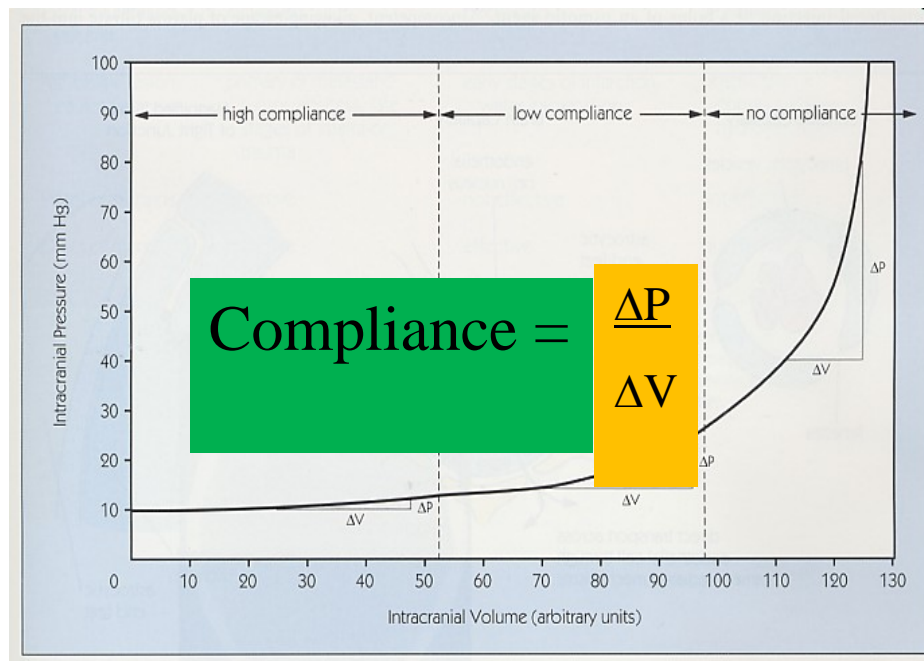
- ventriculojugular shunt –spring & ball.
- Used silicone tubing

Cerebrospinal fluid - shunt hydrodynamics

- CSF is formed by the choroid plexus in the ventricles
- CSF is absorbed by the arachnoid villi
- Circulatory system
 - CSF production is balanced by arachnoid villi absorption

Compliance dynamics

- The brain and skull contain three primary components:
 - Brain Tissue
 - Blood
 - Cerebrospinal fluid
- A change in any one of these components results in adjustment to the other two which is called **compliance**



Shunt provides a low resistance pathway for CSF diversion

Shunt Hydrodynamics

Flow rate = P/R

- P = Driving pressure
- R = Resistance to flow

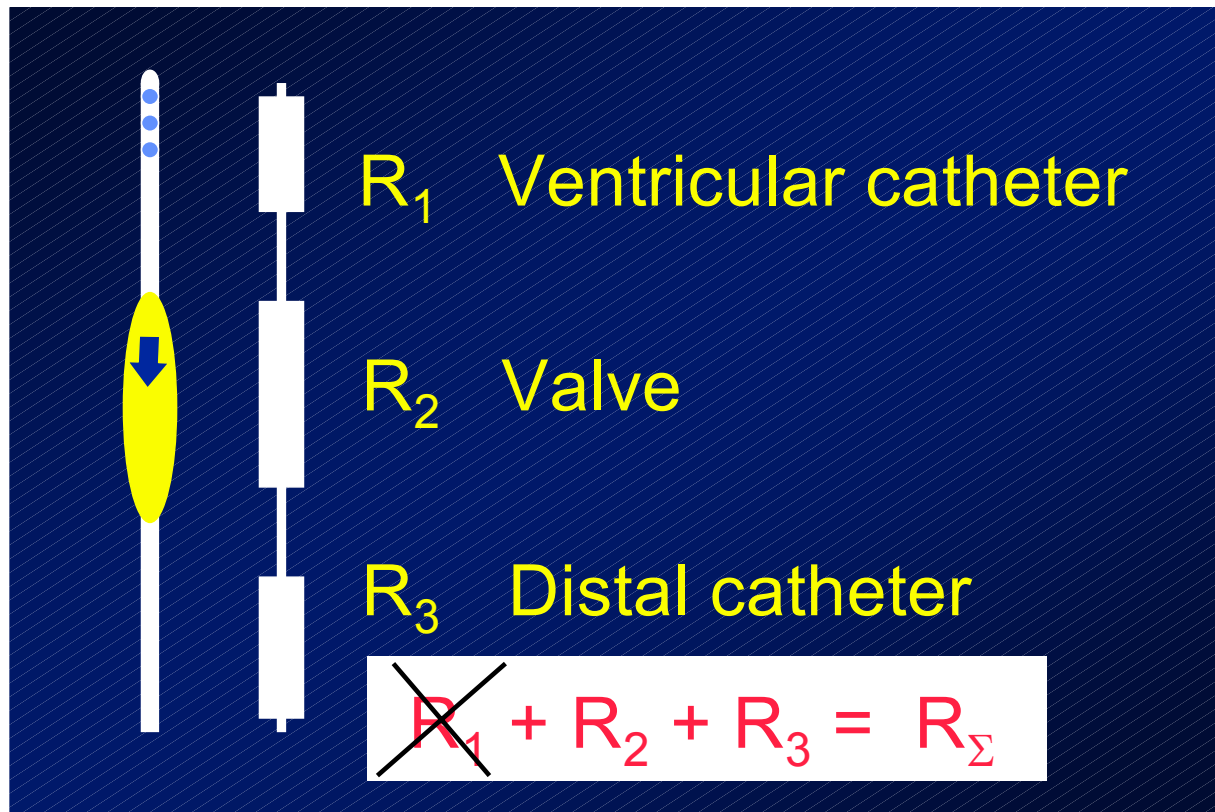
Resistance from shunt tubing = R_t

- Length and inner diameter of the tubing.
- Viscosity of the CSF .
- $R_t = 8nL / \pi r^4$ (Poiseuille's law)
- n = coefficient of absolute viscosity.

Resistance from valve components = R_v .

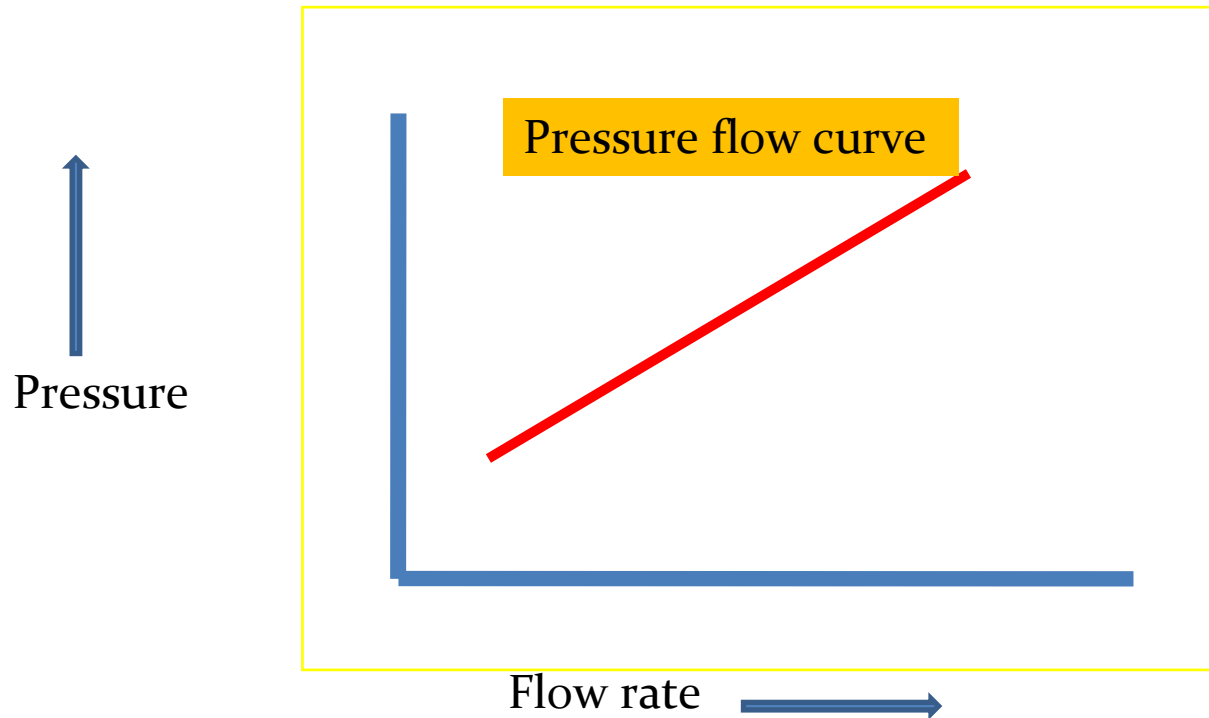
- Its not constant in the range of physiologic flow rates & a curved flow relationship is seen.

Shunt Resistances are Additive



R_1 is negligible

Hydrodynamics contd.



Linear pressure versus flow curve for valveless tubing with constant resistance.

Hydrodynamics contd.

The pressure gradient driving the flow in a ventriculoperitoneal shunt system is determined by-

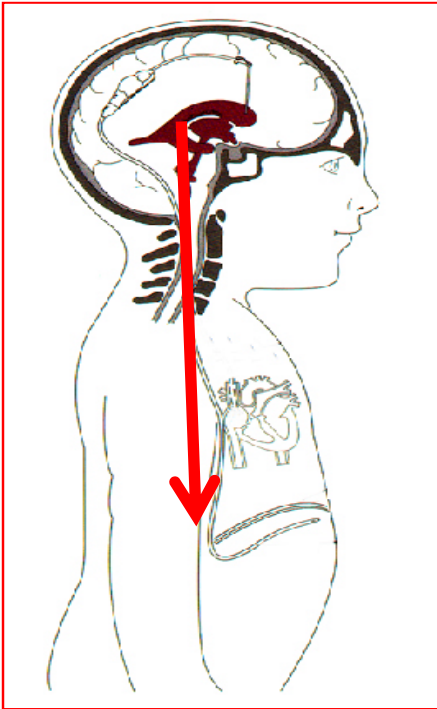
$$\Delta P = IVP + \rho gh - OPV - DCP$$

ρ = density.

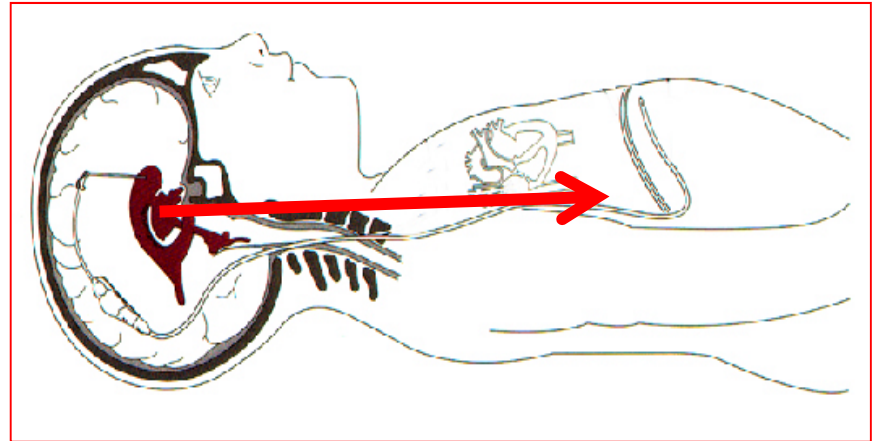
OPV = opening pressure of the valve.

DCP = distal cavity pressure.

OPV=5, Intra abd pressure = 0,
Hydrostatic Pressure =30, IVP= -25



OPV= 5, IAP =0, HP= 0, IVP =25



Applied importance

$$Rt = 8\eta L / \pi r^4$$

- Kinking can reduce flow significantly.
- Shortening distal catheter will alter dynamics.
- Air bubbles can cause failure.
- For higher density CSF, low pressure systems work better.

$$\rho gh$$

- Higher flow rate in sitting and standing position = "Siphoning"

Biomaterials

Biomaterials currently used include:

- **Silicone elastomer** – catheters, valve housings / suture clamps, siphon devices, etc.
- **Polypropylene/Polysulfone/Nylon/Polyethersulfone** – valve housings/seats, needle stops, connectors, reservoirs.
- **Ruby/Sapphire** – valve pins, balls, seats
- **Titanium/Stainless Steel** – valve housings, needle stops
- **Tantalum** – radiopaque markers.
- **Barium** – radiopacifier (homogenous or stripe).

Shunt Systems

- Shunt systems come in a variety of configurations and models but they have similar functional components:
 - Valve Mechanisms – flow or differential
 - Fixed, programmable, or variable settings
 - Catheters
 - Ventricular (proximal)
 - Peritoneal/Atria (distal)
 - Accessories
 - Reservoirs, Siphon Devices
 - Connectors, Filters, Pumping Chambers

Shunt valves

```
graph TD; A[Shunt valves] --> B[Differential pressure valves]; A --> C[Flow regulated valves]; A --> D[Gravity actuated valves]; A --> E[Programmable valves];
```

Differential pressure valves

Flow regulated valves

Gravity actuated valves

Programmable valves

Differential pressure valve

```
graph TD; A[Differential pressure valve] --> B[Slit valves]; A --> C[Miter valve]; A --> D[Diaphragm v.]; A --> E[Ball in cone valve];
```

Slit valves

Miter valve

Diaphragm v.

Ball in cone valve

Defined by their opening and closing pressure.
As the IVP climbs above the valve opening pressure,
the valve opens to allow egress of CSF at a rate determined
by the resistance of the system, until the pressure falls below
the closing pressure and flow of CSF ceases.

Slit valves

```
graph TD; A[Slit valves] --> B[Proximal slit valves]; A --> C[Distal slit valves];
```

Proximal slit valves

Holter Hausner valve

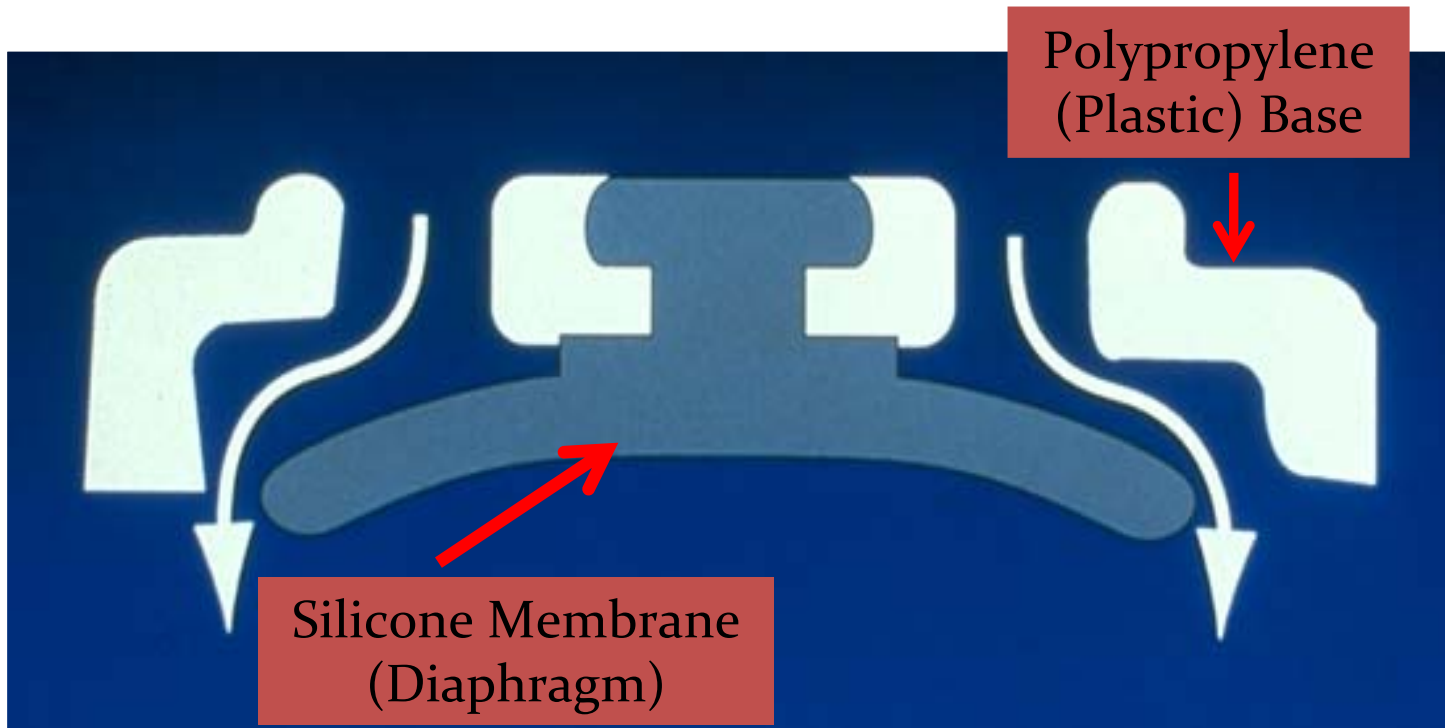
Distal slit valves

Codman unishunt valve
Chhabra shunt.

They offer the least resistance to flow and in fact no significant difference in resistance can be measured between a tube with a distal slit valve and an equally long open ended tube.

Diaphragm valve

- Most commonly used type of valve.
- Involve the deflection of a silicone membrane in response to pressure in order to allow flow of CSF



Diaphragm valve

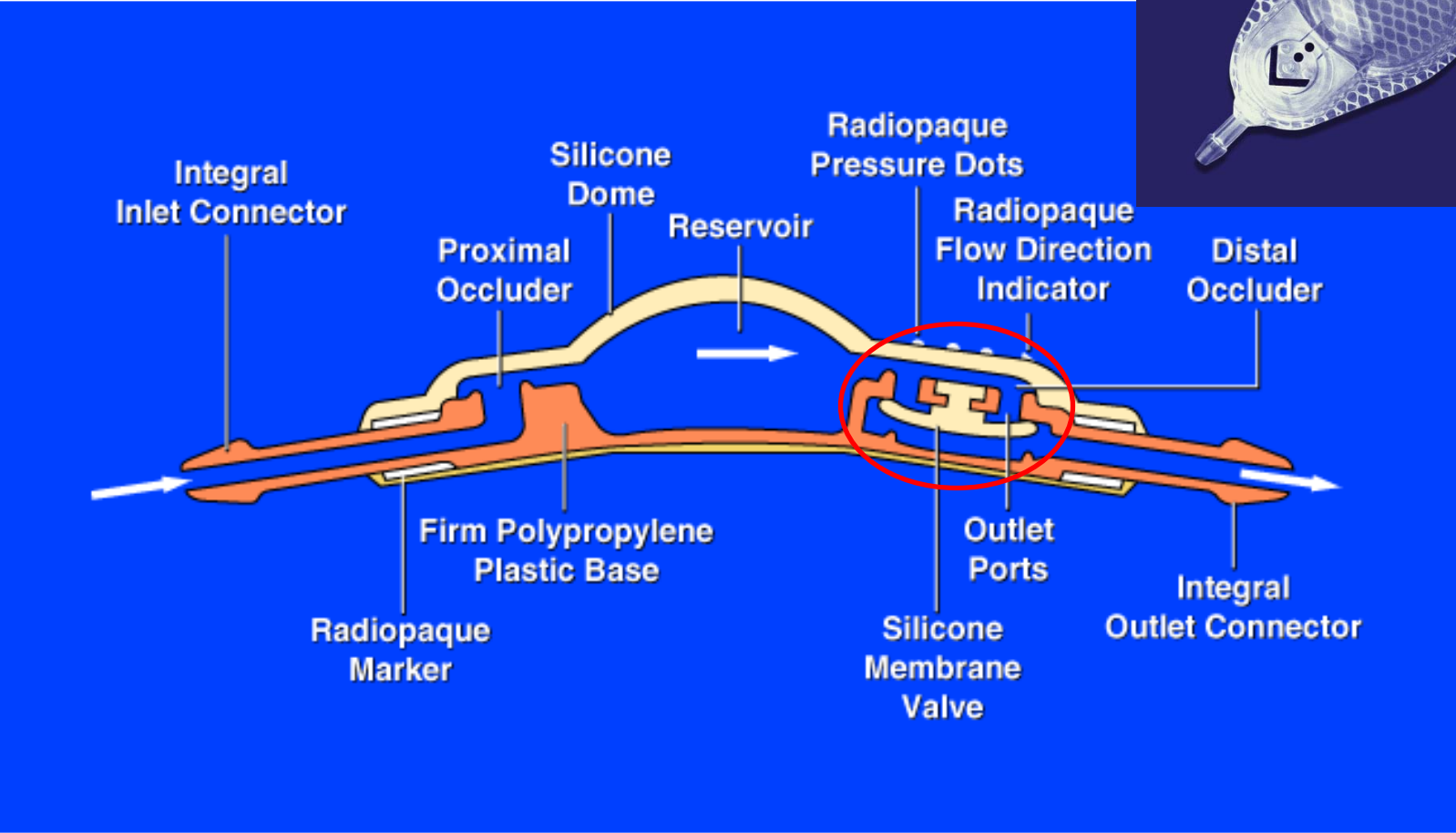
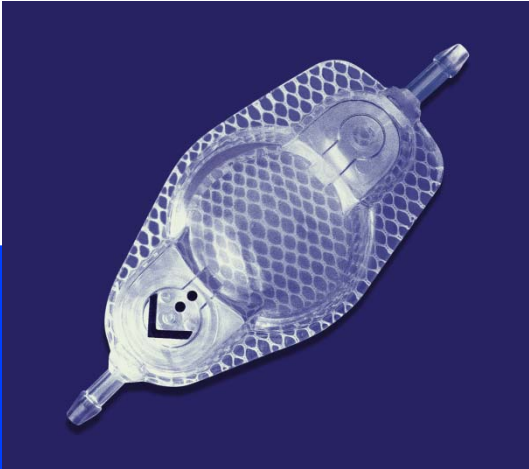


Ceredrain



Medtronic valve

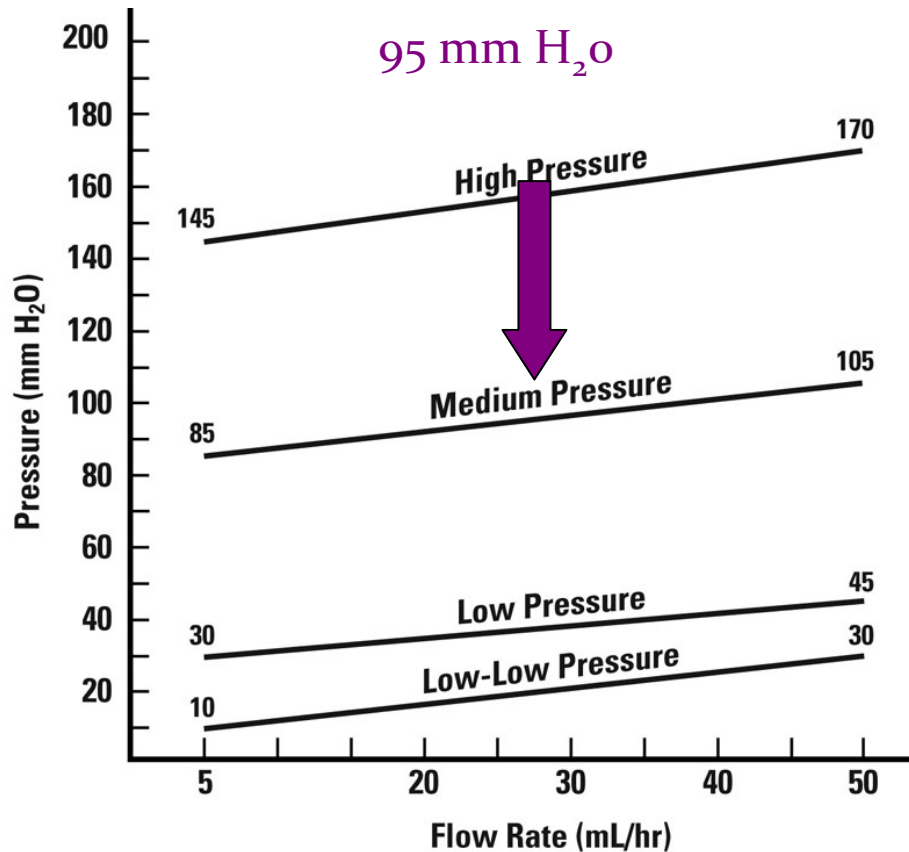
Medtronic PS Medical *CSF-Flow Control Valve, Contoured*



Basic Valve Features

- Valve mechanism of dissimilar materials
 - Differential pressure mechanism
 - When the sum of inlet and outlet pressure exceed a threshold value, valve opens and drains
- Central reservoir for percutaneous CSF access
- Plastic base for rigidity and stability
- Non-metallic design

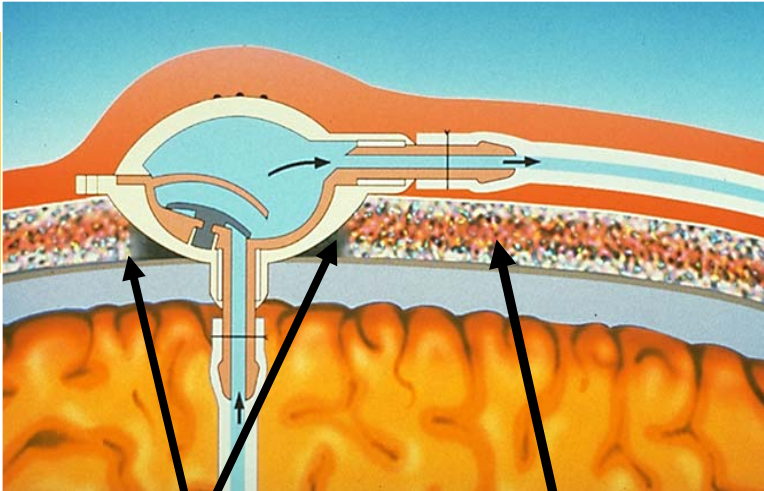
Pressure/Flow Ranges



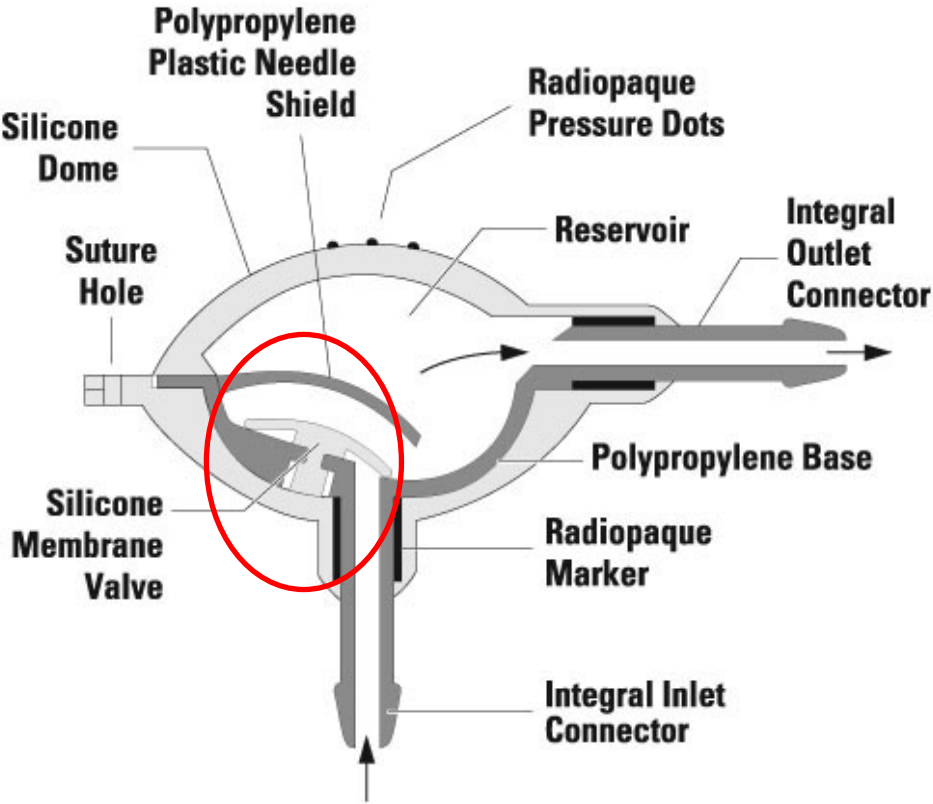
ICP » 95 mm H₂O
Shunt will drain

ICP « 95 mm H₂O
Shunt will not drain

Burr Hole Valves

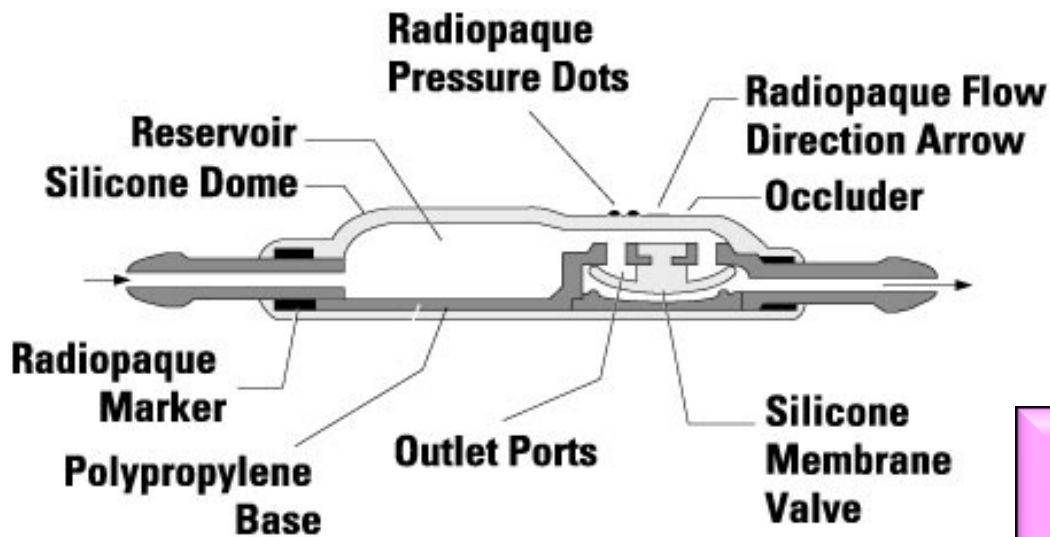


Burr Hole
(12 mm or 16 mm
twist drill hole)

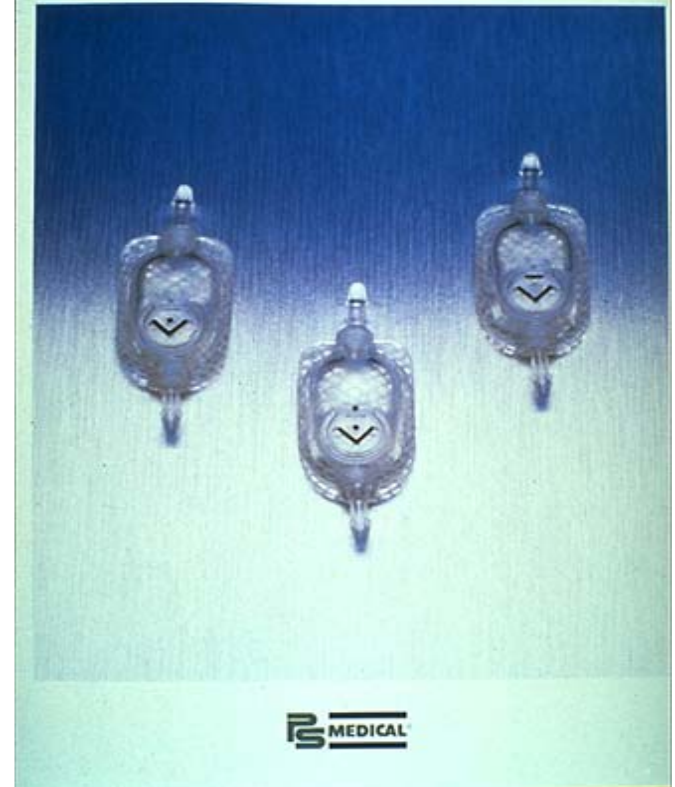


Type of diaphragm valve

Ultra Small Valve



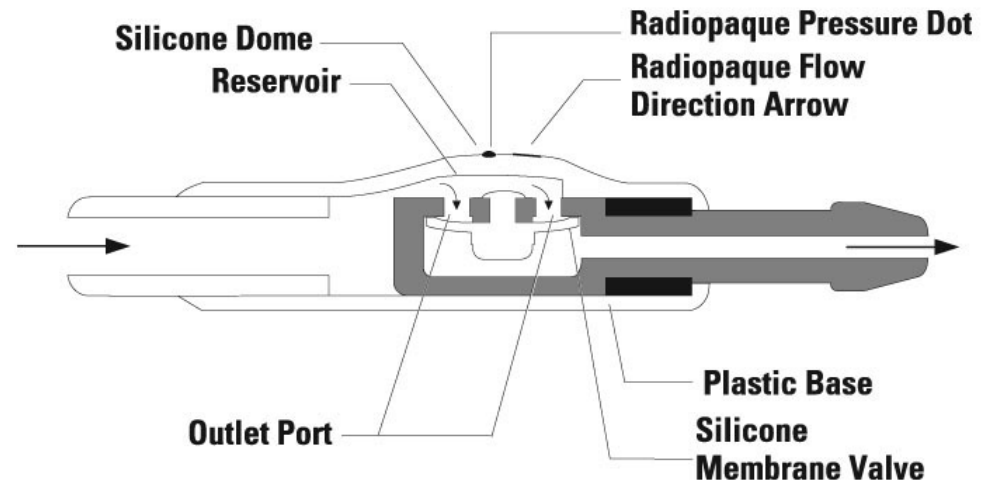
CSF-Flow Control Valves - Ultra Small



Neonatal and Infant Use
No Inlet Occluder
Smaller Reservoir Size

Button Valve

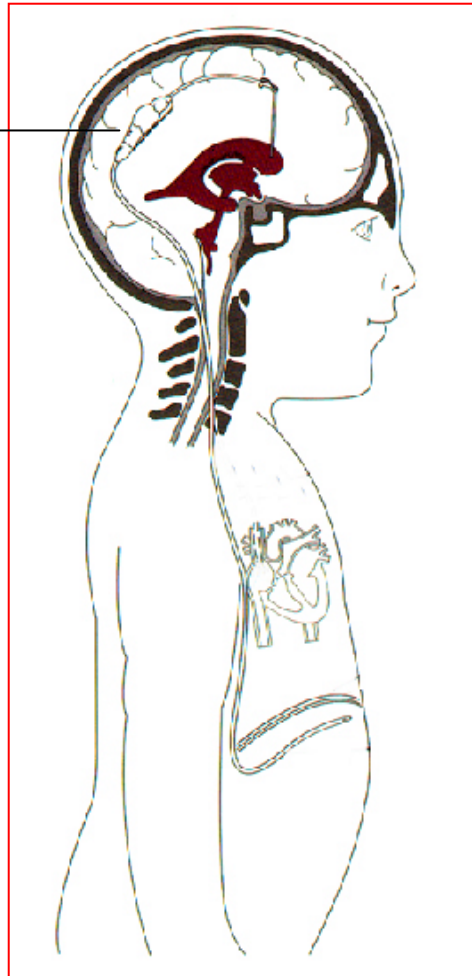
- For neonatal use (premature infants)
- Profile: 4 mm
- Requires use of separate reservoir
- No occluders



Differential Pressure Valve

Theoretical Example

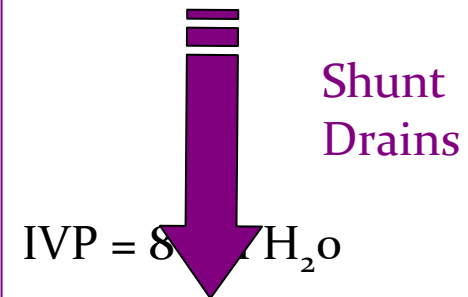
+ 8 cm H₂O
Medium Pressure Valve



Intraventricular Pressure (IVP)

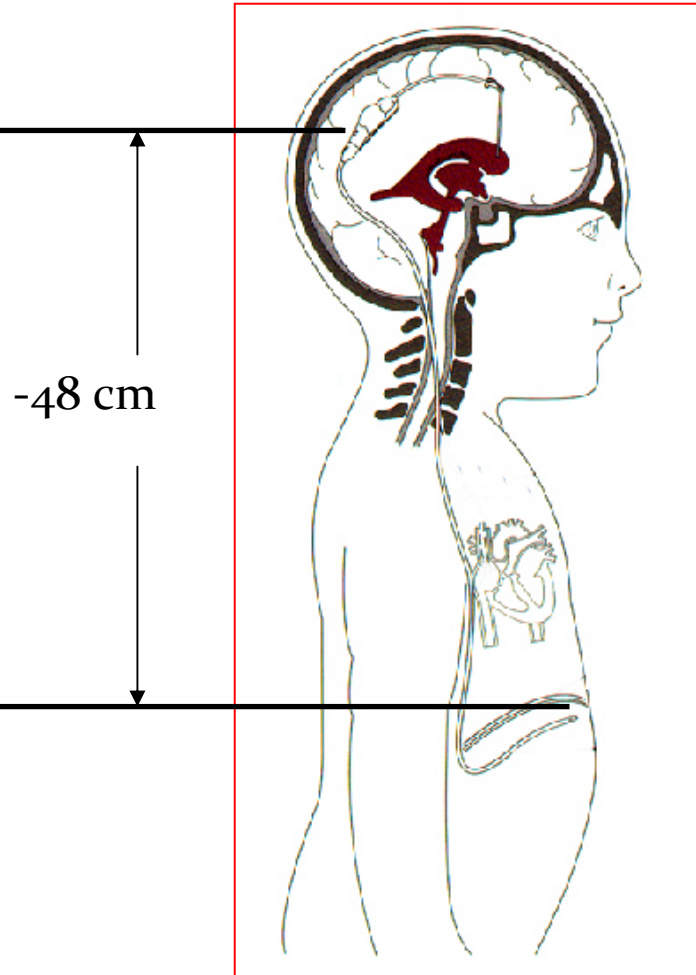
IVP = 10 cm H₂O

IVP (Ventricles)



Differential Pressure Valve *In Reality*

+ 8 cm H₂O
Medium Valve



8 cm H₂O (valve) + -48 cm H₂O (distal catheter) = -40 cm H₂O

IVP (Ventricles)

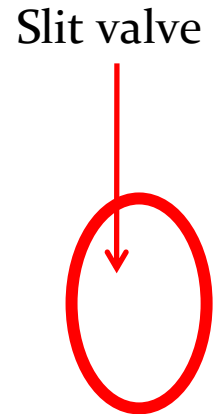
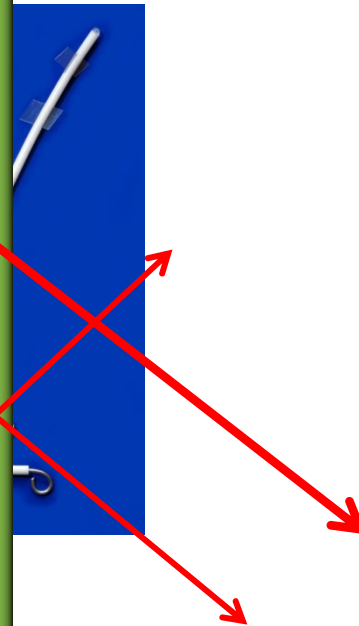


Shunt
Overdrains

IVP = -40 cm H₂O
Siphoning

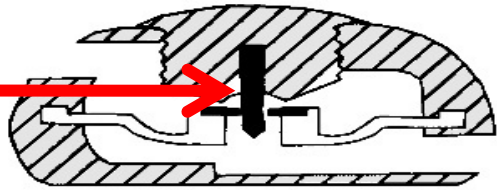
Chhabra shunt

- Slit and spring valve system.
- The systems are available in 2 ball, 3 ball, 4 ball range.
- Catheters contain barium sulfate for x-ray detectability.
- The ventricular catheter has tantalum tip.
- Regulating valve contains a stainless steel sleeve and balls and a sapphire ball.



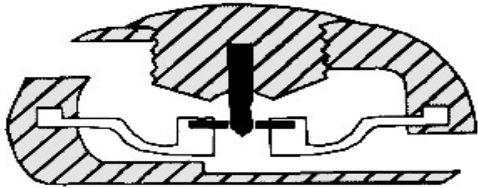
Flow Regulated Valves

Contoured synthetic ruby flow control pin that fits inside a movable ruby ring



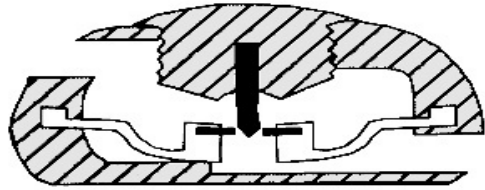
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Low Resistance



High Resistance

As the pressure increases, the ruby ring is deflected downwards, the ruby ring is tapered the flow aperture decreases which increases resistance and reduces flow.



Low Resistance at High Pressure (safety pressure release)

Orbis Sigma Valve

If the pressure is further increased the ruby ring is further deflected down until resistance is lowered to allow rapid increase in flow rate.

Flow Regulated Valves

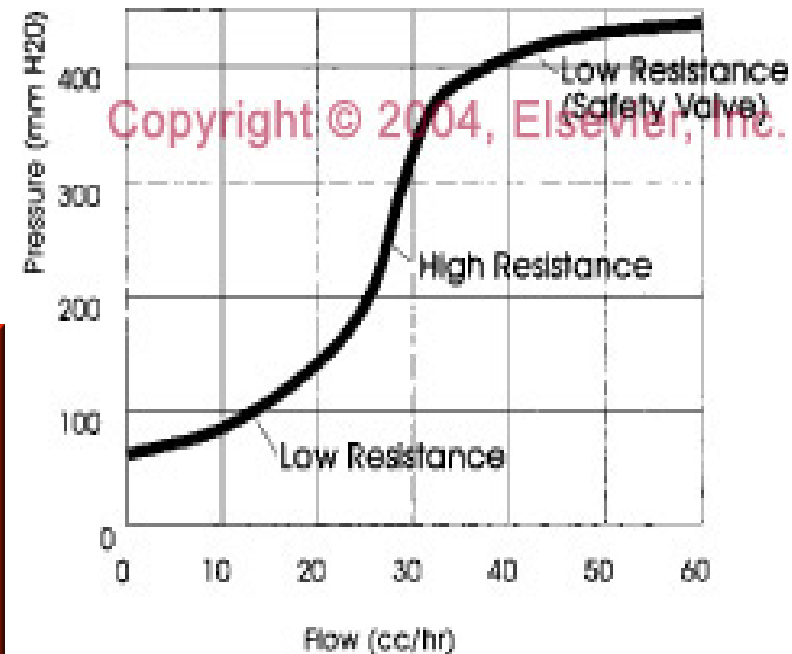
Advantage

Flow regulated valves are less likely to be associated with siphoning and over drainage

Disadvantages

- Due to small orifice high chances of obstruction.
- High resistance has a propensity to cause fluid collections under the scalp in young children unless they are nursed upright with a compressive dressing

Orbis Sigma



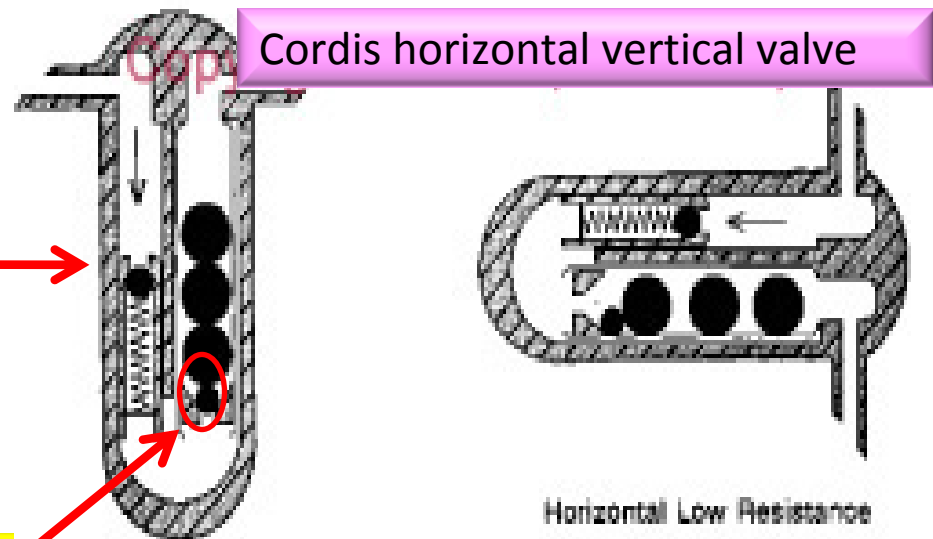
Gravity Actuated Valves

Horizontal-Vertical Valve

They attempt to prohibit or reduce siphoning by increasing opening pressure with the assistance of gravity.

Inlet valve = ball spring valve and does not change resistance with position

Outlet valve has a synthetic ruby ball that sits in a conical seat and there are three stainless steel balls that sit on top of it which weigh it down in upright position and fall away in recumbent position.



Vertical High Resistance

Horizontal Low Resistance

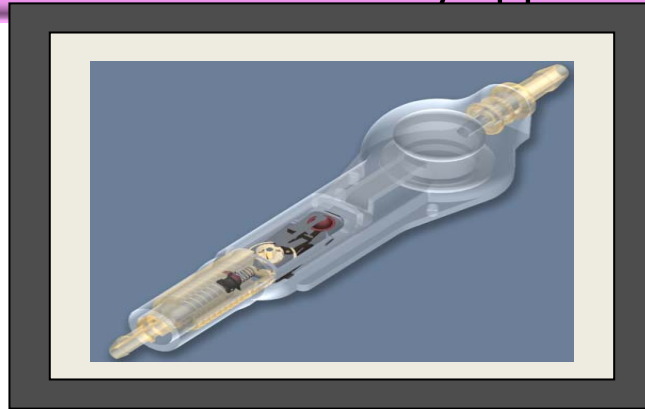
Programmable valves

- They are externally adjustable differential pressure valves.
- Surgeon has the option of altering the opening pressure with an external device and thus altering the need for surgical shunt revision.
- They are also susceptible to siphoning.

Programmable valves

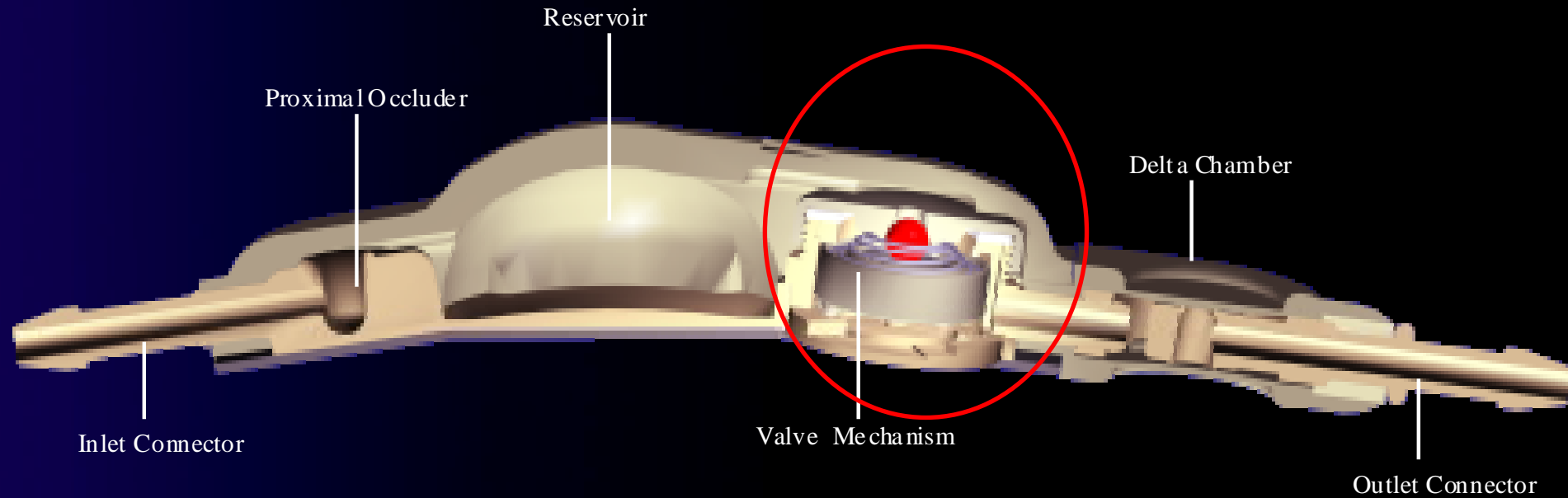
They have an adjustable ball and spring mechanism. A step motor assembly.
Radiopaque markers.

Motor assembly can be adjusted with externally applied magnets.



Strata Adjustable Delta Valve

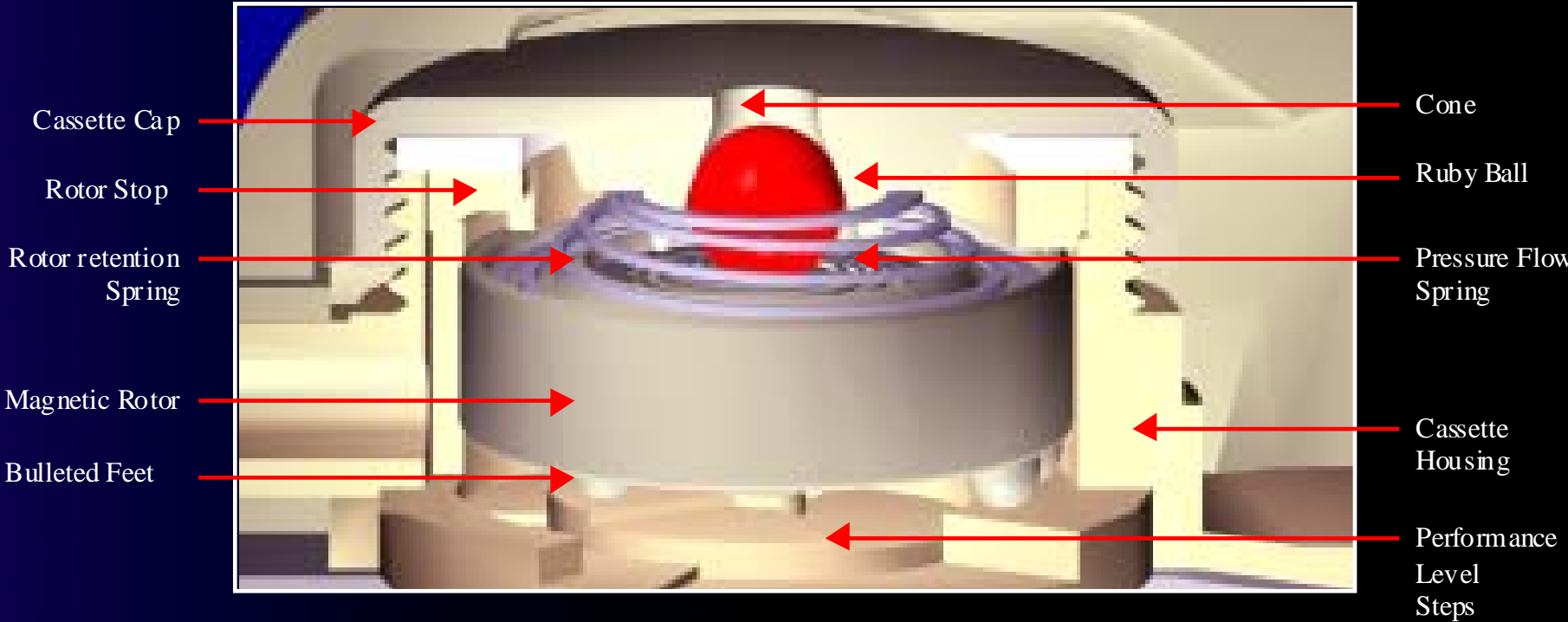
Cutaway of Regular Valve



Basic design is same as in diaphragm valves with addition of a motor assembly and a spring ball mechanism.

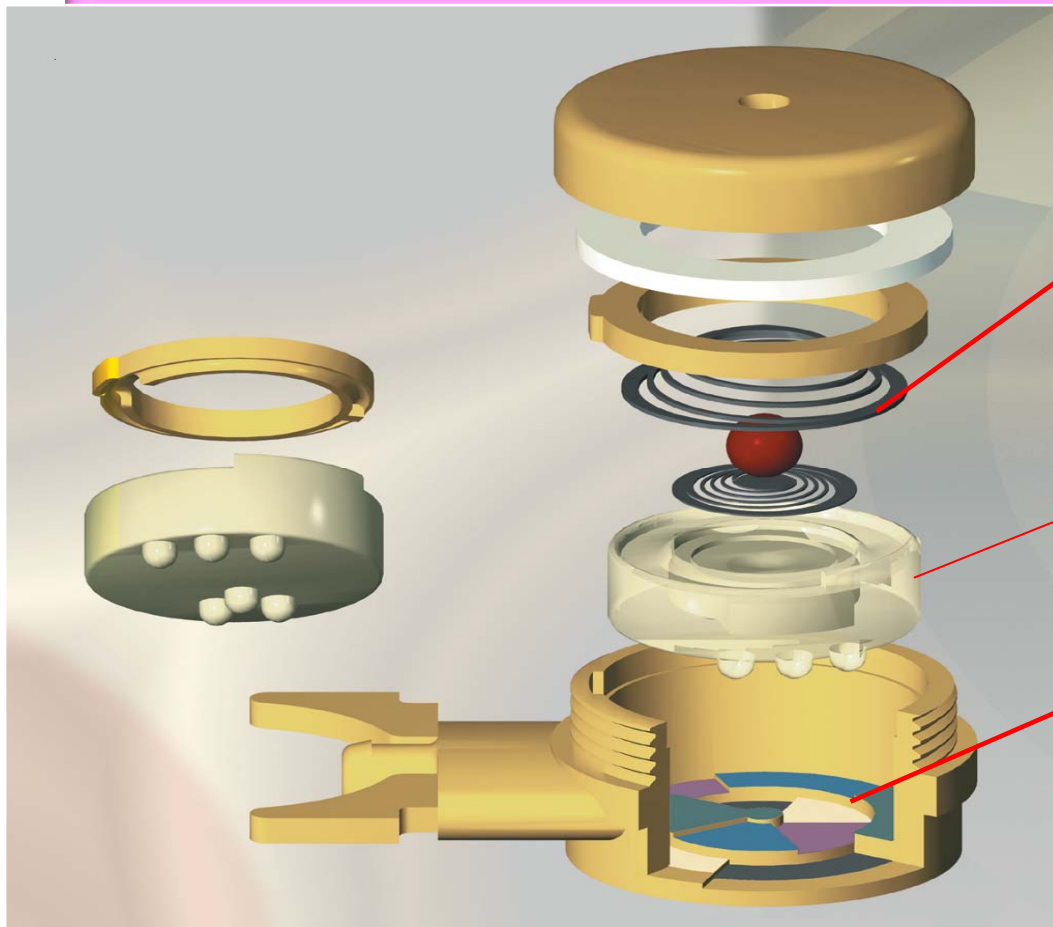
Strata Adjustable Delta Valve

Cutaway of Valve Mechanism



Strata Valve Mechanism

Exploded View...



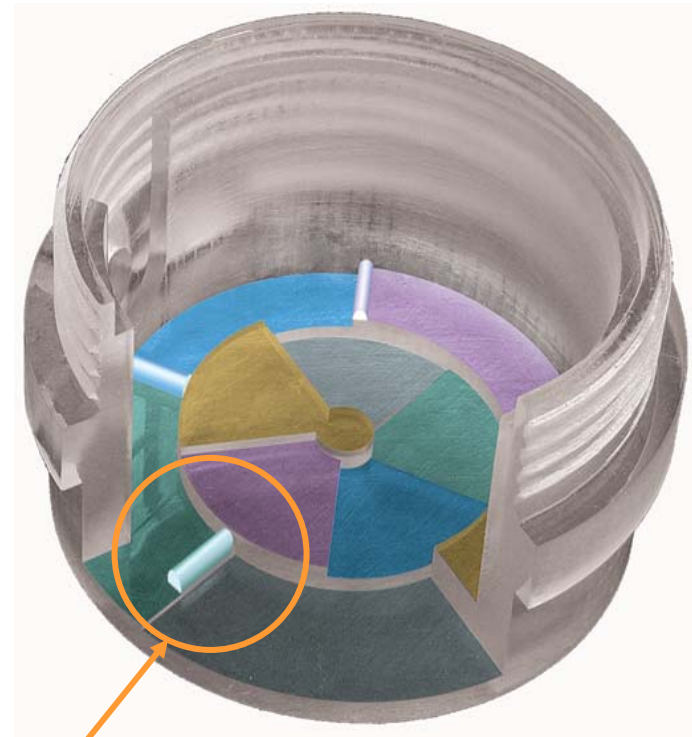
Ball & Spring
Mechanism

Rotor with Magnet

Five Symmetric
Platforms

Platform Stops

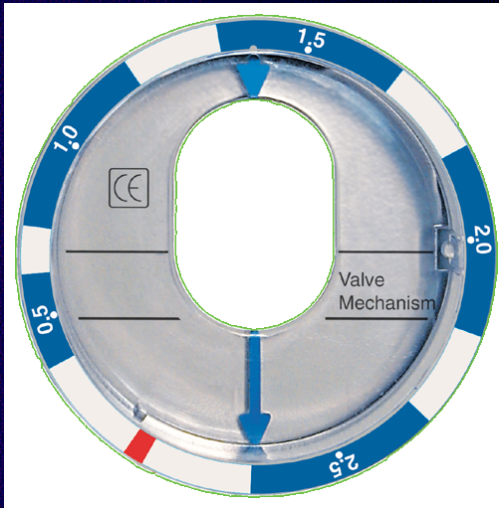
- Platform stops inhibit rotor movement from one platform to the next
- Need extra strong magnet to lift the rotor over the stop to the new platform



Platform Stop

Strata Adjustable Delta Valve

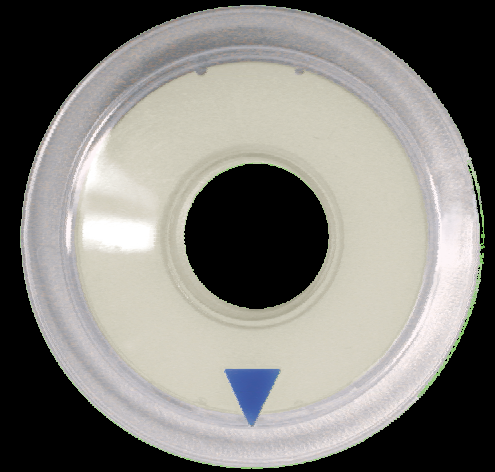
Adjustment Tools



Locator Tool



Indicator Tool



Adjustment Tool



Strata Adjustable Delta Valve

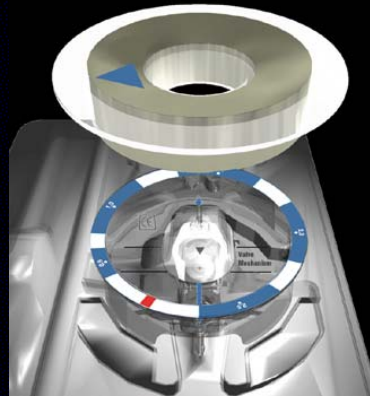
Preimplantation Adjustment



Position Locator Tool with valve making certain that the flow direction arrows on the valve match the flow on the tool



Position Indicator Tool into the Locator Tool; note that the tools are keyed preventing misplacement. Making sure that the Adjustment Tool is far enough away not to influence readings, record performance level setting



Remove Indicator Tool, and place Adjustment Tool in Locator Tool making sure to align large blue arrow with current performance level setting



Rotate Adjustment Tool so that the arrow points to new desired level. Remove Adjustment Tool



Re-place Indicator Tool and confirm adjustment of new Performance level



Programming technique



StrataVarius

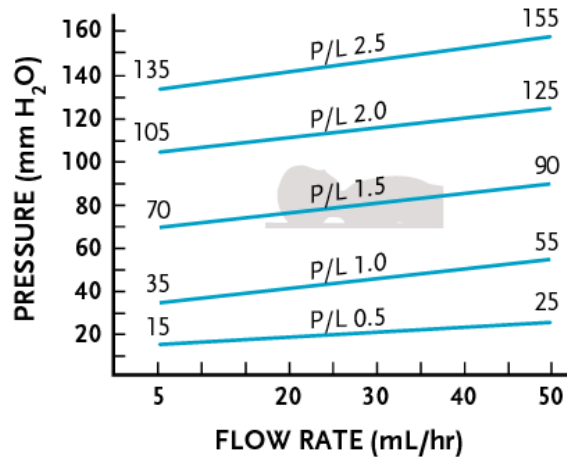
- Handheld instrument designed to be ambidextrous
- Battery powered device (2-AA)
 - 100 uses
 - Power-down after 3 minutes of idle time.
- LCD readout screen
- Portal for valve palpation and magnetic adjustment
- Magnet is 2 times stronger



Strata Adjustable Delta Valve

Performance Levels

0 cm H₂O HP (Hydrostatic Pressure)



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:

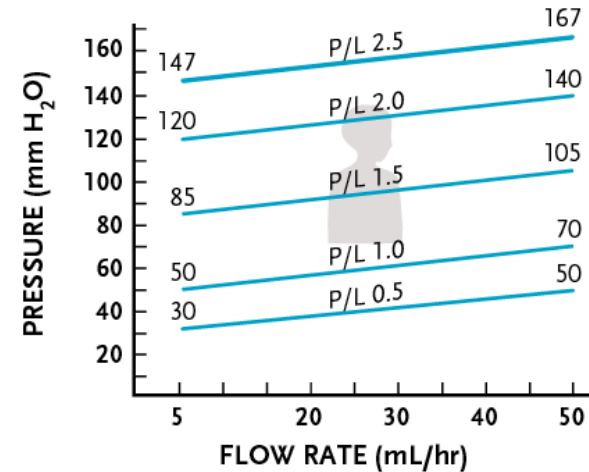
Performance Level 0.5:

- +/- 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

-50 cm H₂O HP (Hydrostatic Pressure)



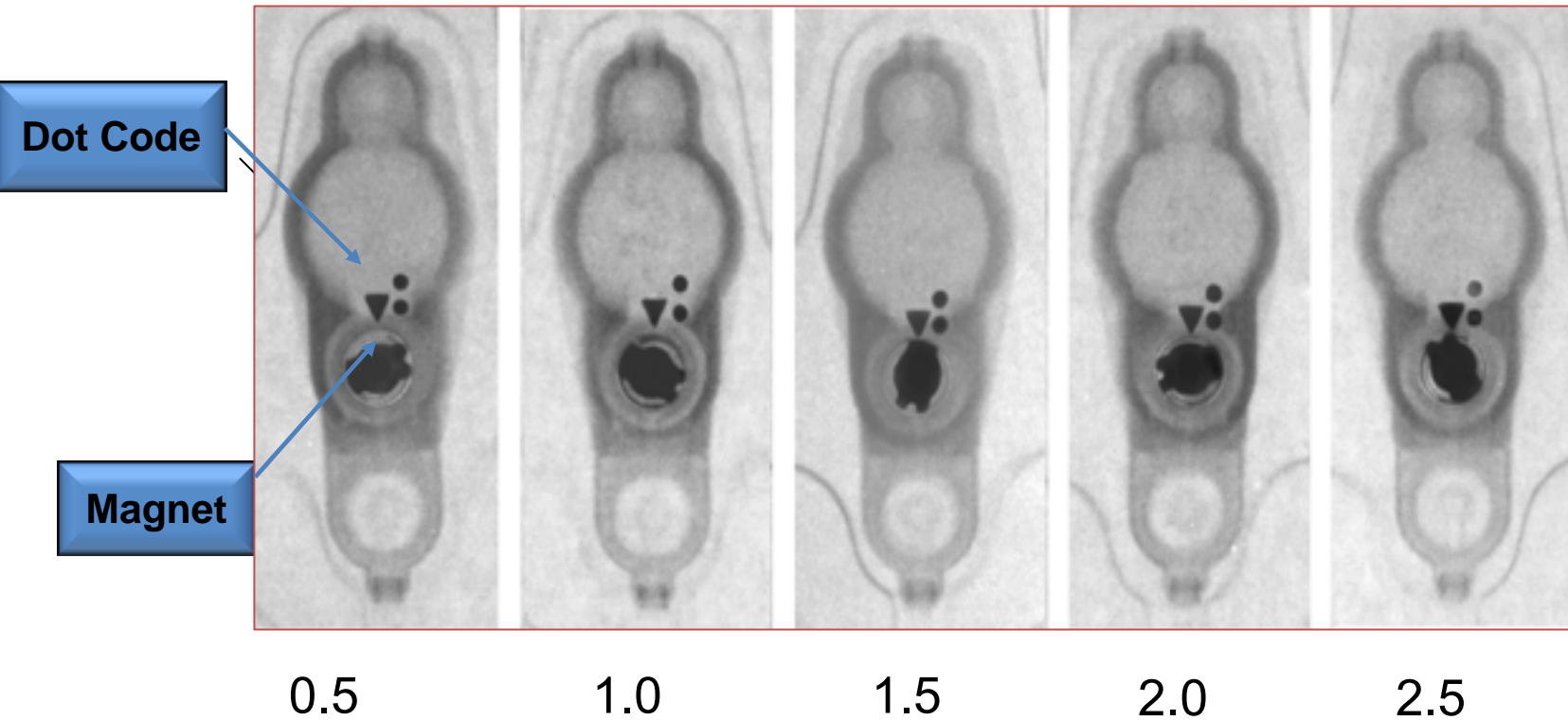
NOTE: Levels depicted are median values. All valves perform within a tolerance range of these median values when tested at time of manufacture as follows:

Performance Level 0.5:

- +/- 25 mm H₂O

Performance Level 1.0, Level 1.5, Level 2.0, and Level 2.5

- +/- 40 mm H₂O



The performance level can be verified by X-ray based on the orientation of the magnet relative to the dot code.

Strata Valve

Valve Adjustment Reliability

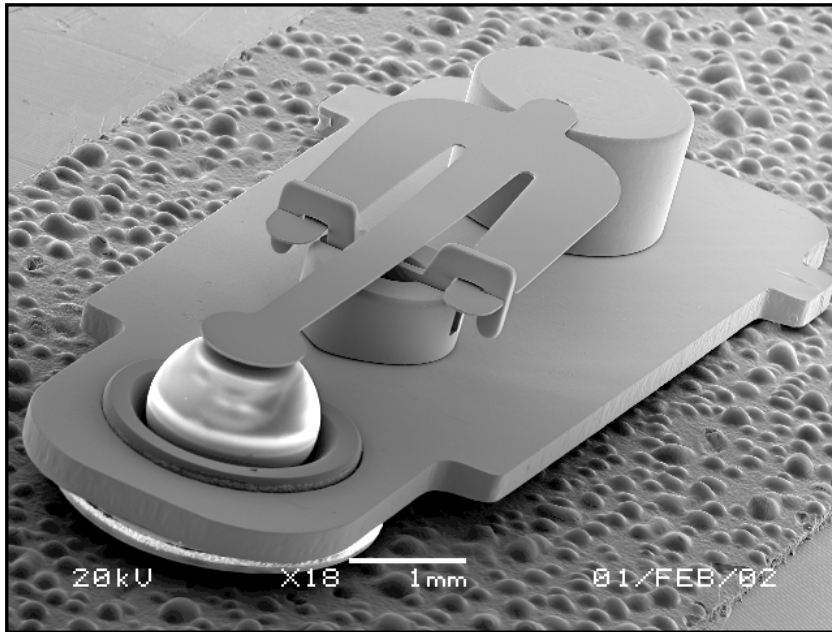
98% ACCURACY RATE

- All initial valve settings were confirmed by X-ray
- All post-operative adjustments were confirmed by X-ray
- 238 valve adjustments
- 4 instances where the x-ray did not match patient chart

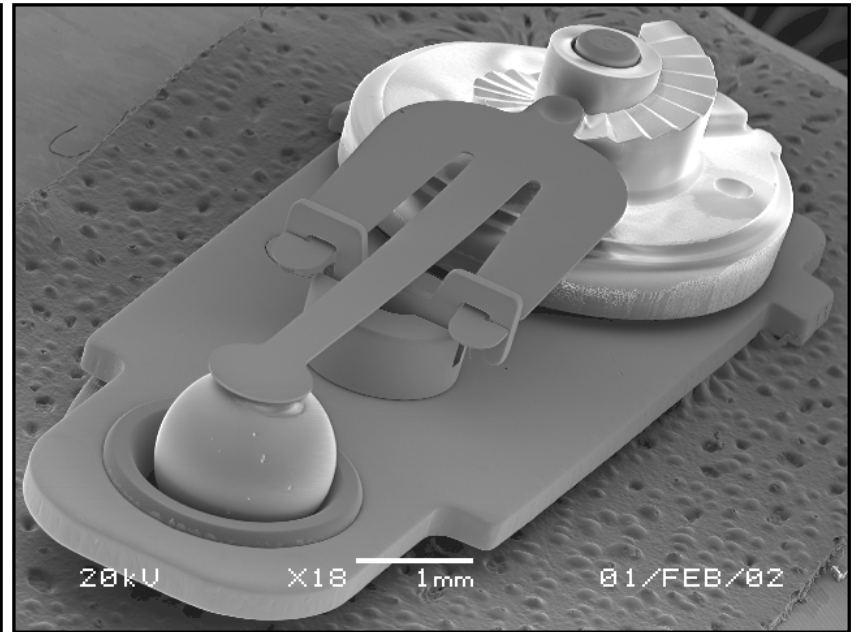
X-ray	Patient Chart
0.5	1.0
1.0	0.5
1.5	0.5
2.0	2.5

The 4 discrepancies

Codman Hakim Programmable Valve

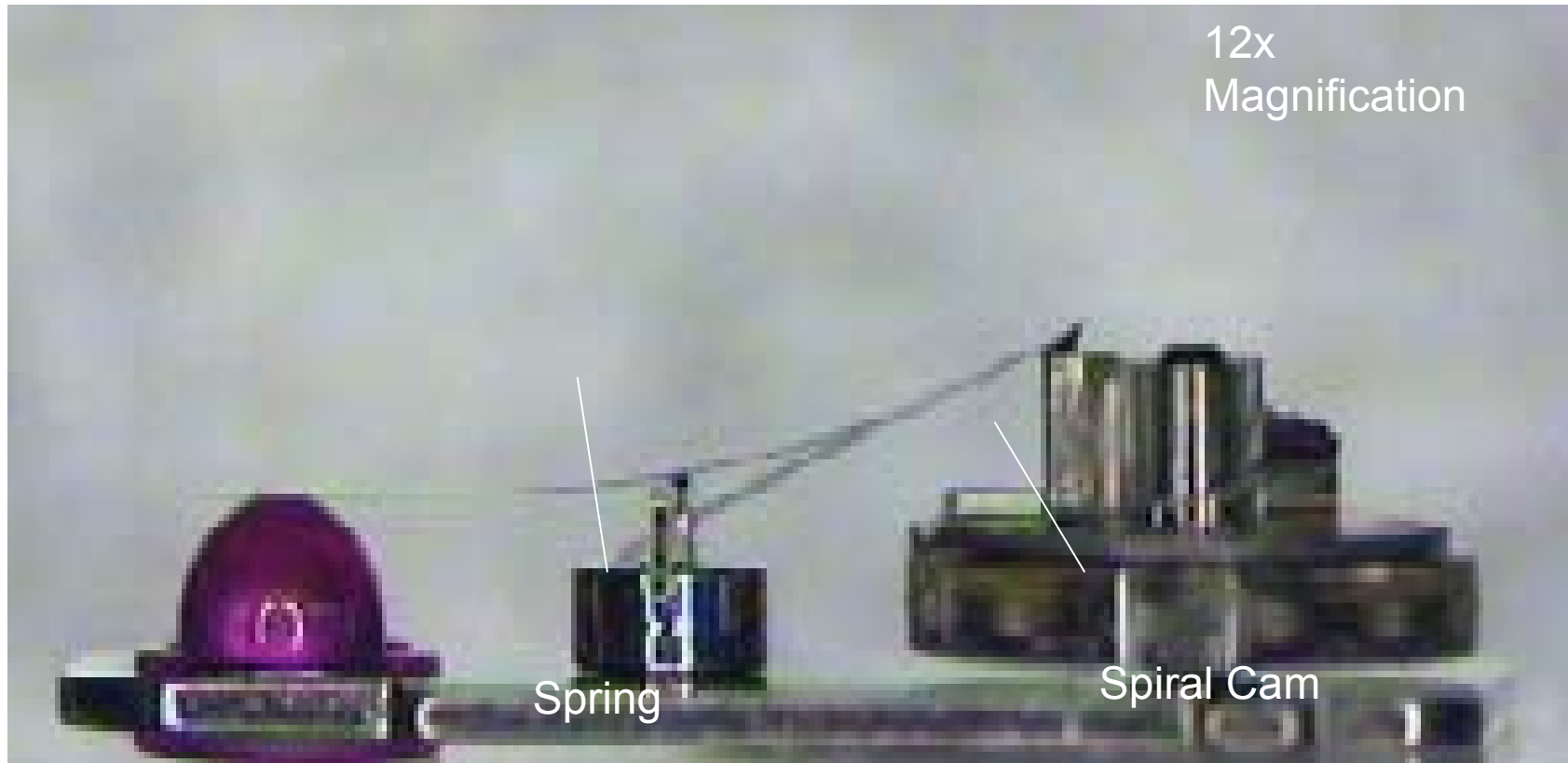


Precision

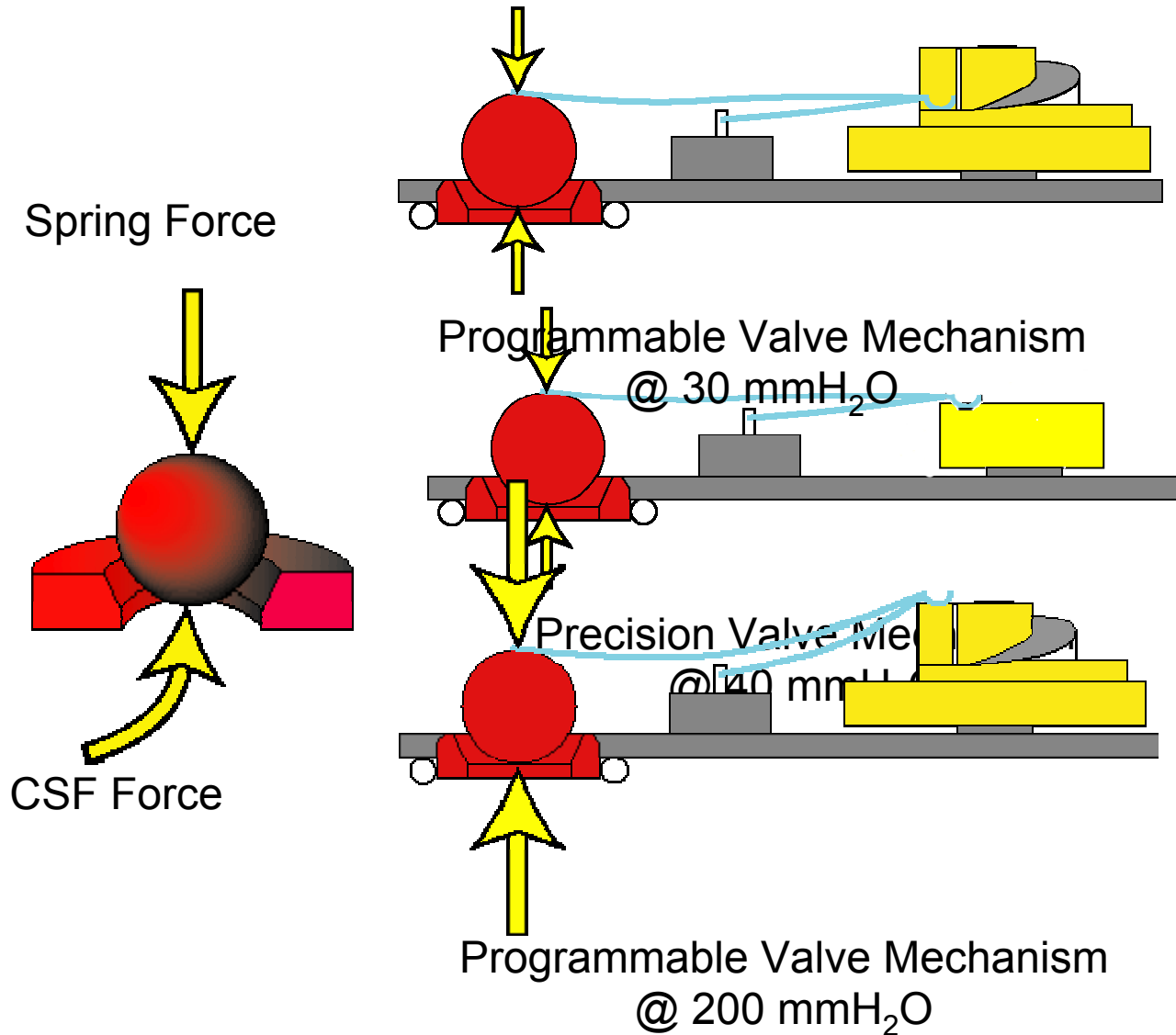


Programmable

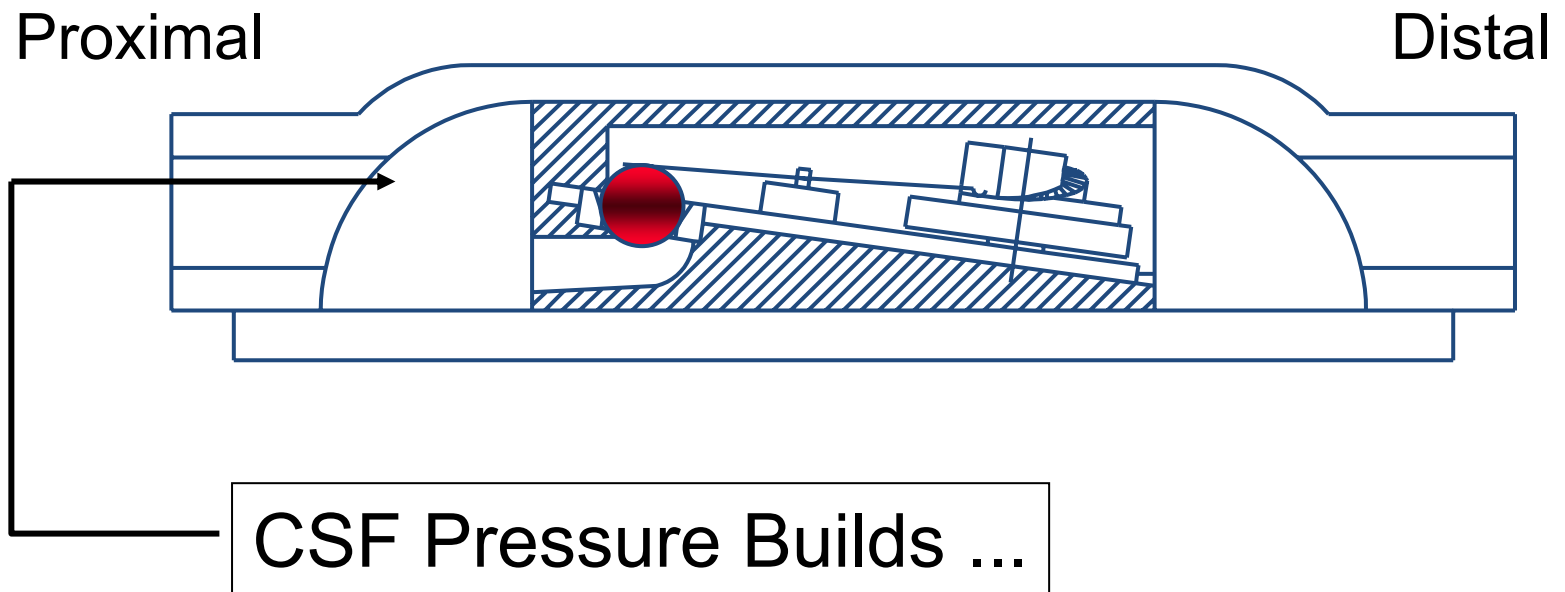
Spring Tension



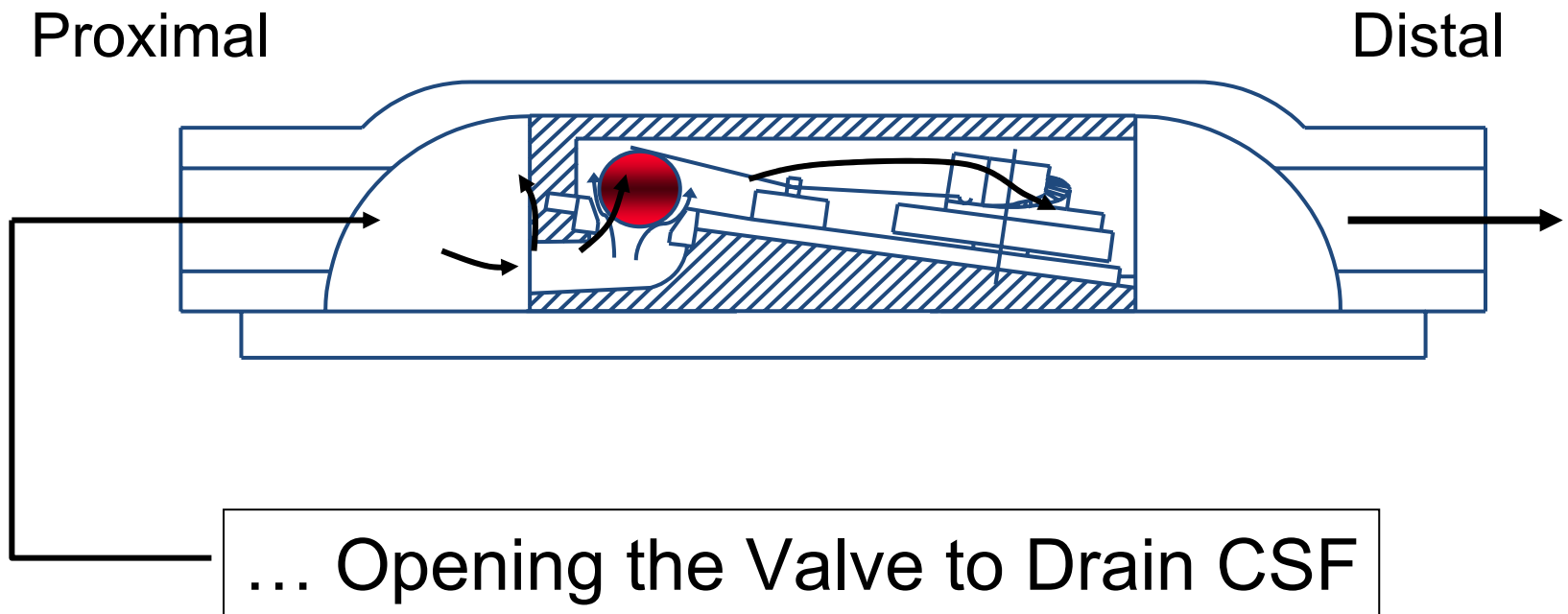
Valve Function



How Does It Work?



How Does It Work?



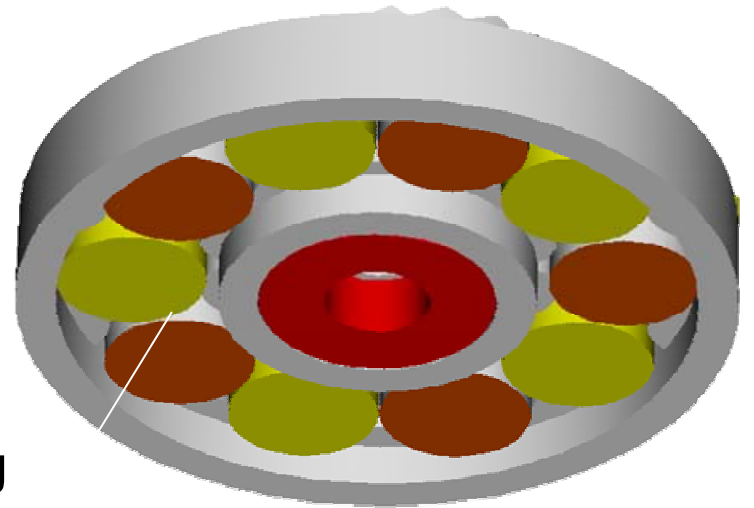
Valve Programming

Top View



Spiral Cam
with Steps

Bottom View

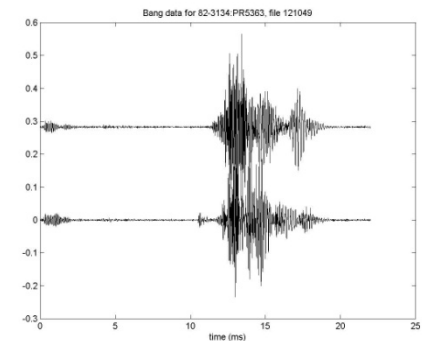
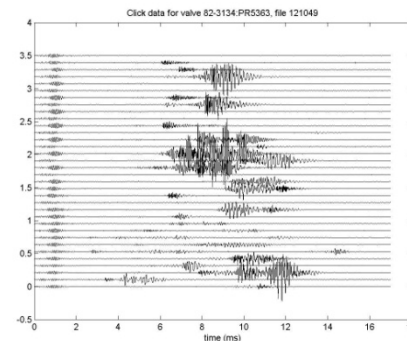
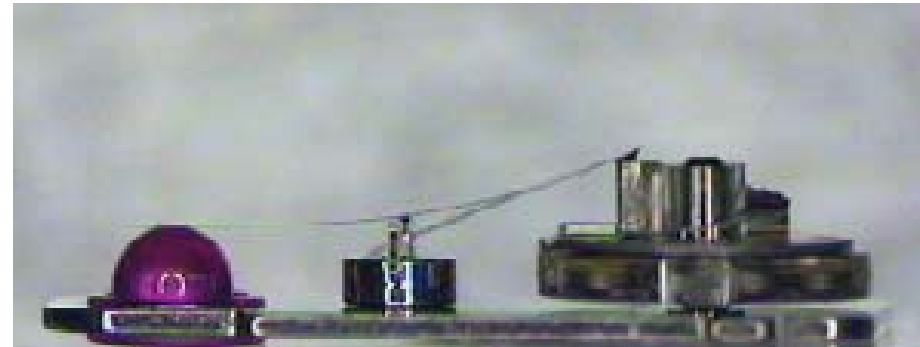
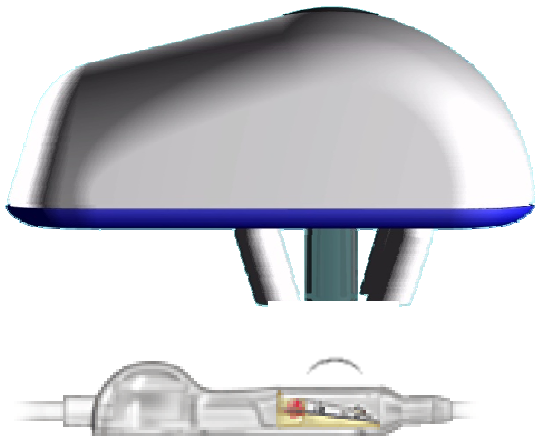


Alternating
North-South
Magnets

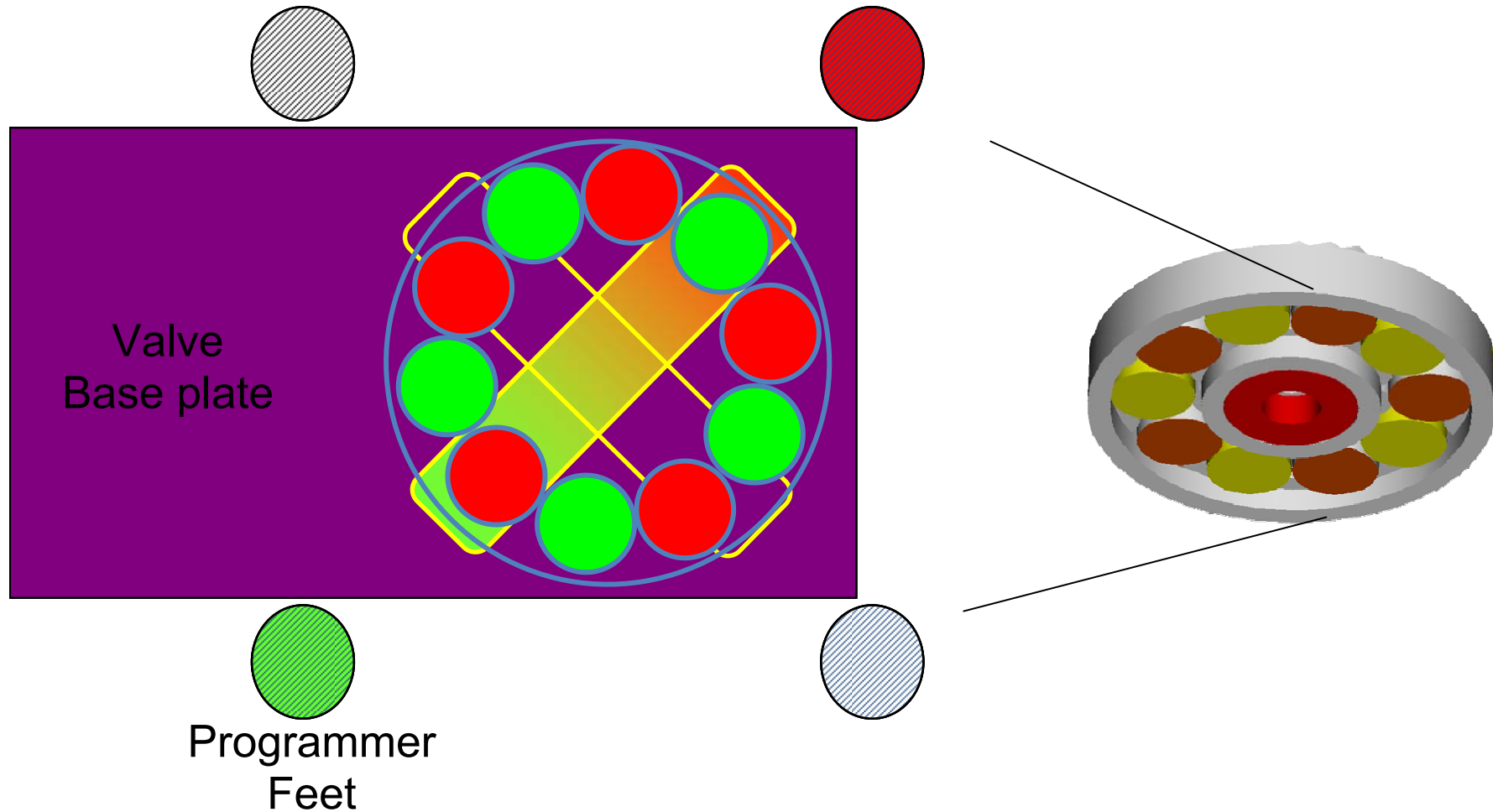
Valve programming System

Acoustic Verification

- Acoustic sensor embedded in the programmer.
- Listens for “clicks” of the spring on the cam



Programming Steps



Valve programming verification system

Acoustic communication with the valve

- High degree of accuracy
- Simplicity for clinician and patient



Trade offs:

Codman

- Cannot confirm pre-existing pressure setting

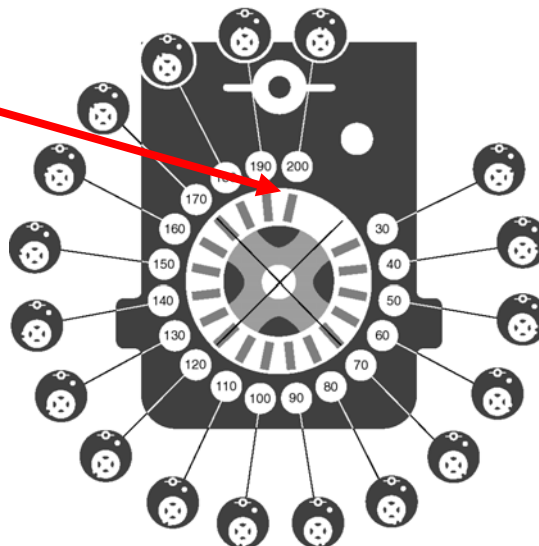
Strata/Sophy

- Inability to detect +/- 10mm H₂O
- Increased magnetic susceptibility
- Technique sensitive

X-ray Verification

- There is a direct correlation between the position of the programming unit control panel pressure selector buttons and the position of the pressure indication on the valves as seen when x-rayed.
- When the valve is programmed to 70, 120, or 170, the pressure indicator aligns with the “X” in the center of the valve.

Valve Cross



Magnetic Vs. Acoustic Verification

Magnetic Verification

PROS:

- Small
- Intuitive
- No power cords
- Immediate indication of current position

CONS:

- Increased susceptibility to magnetic fields
- Image artifact
- Inability to detect ± 10 mm H₂O

Acoustic Verification

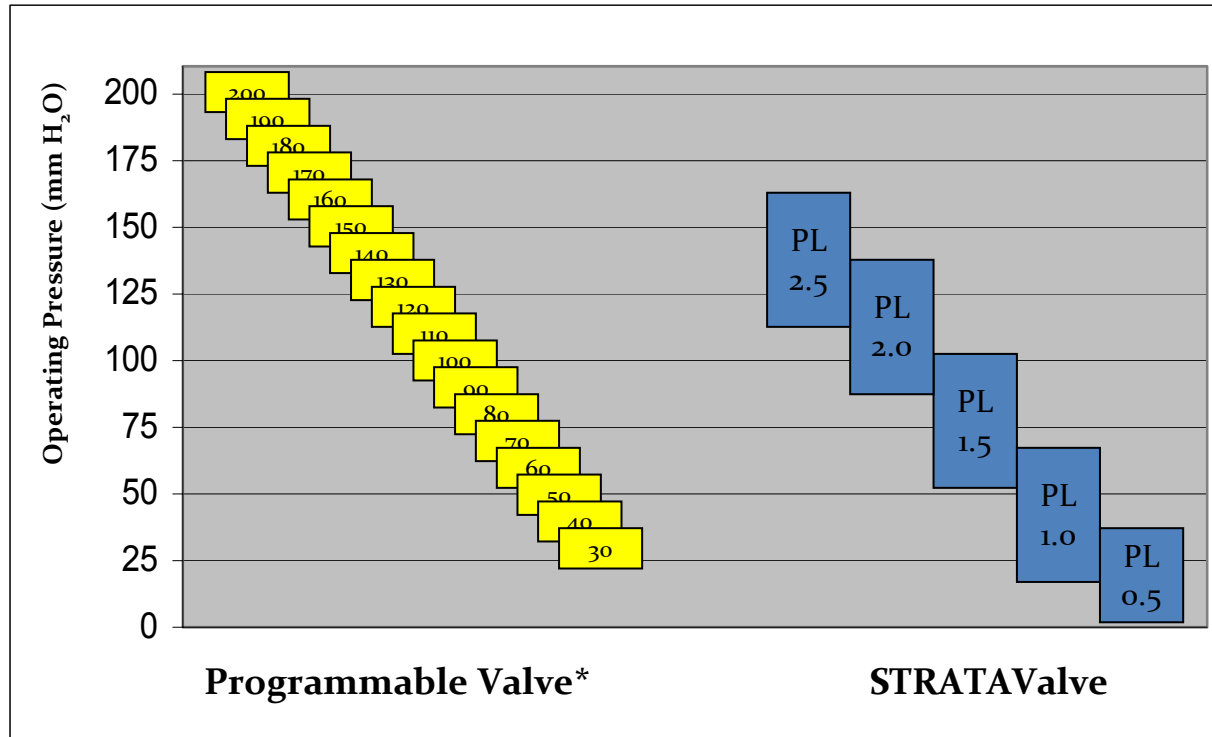
PROS:

- Improved accuracy
- No change to valve – backwards compatible

CONS:

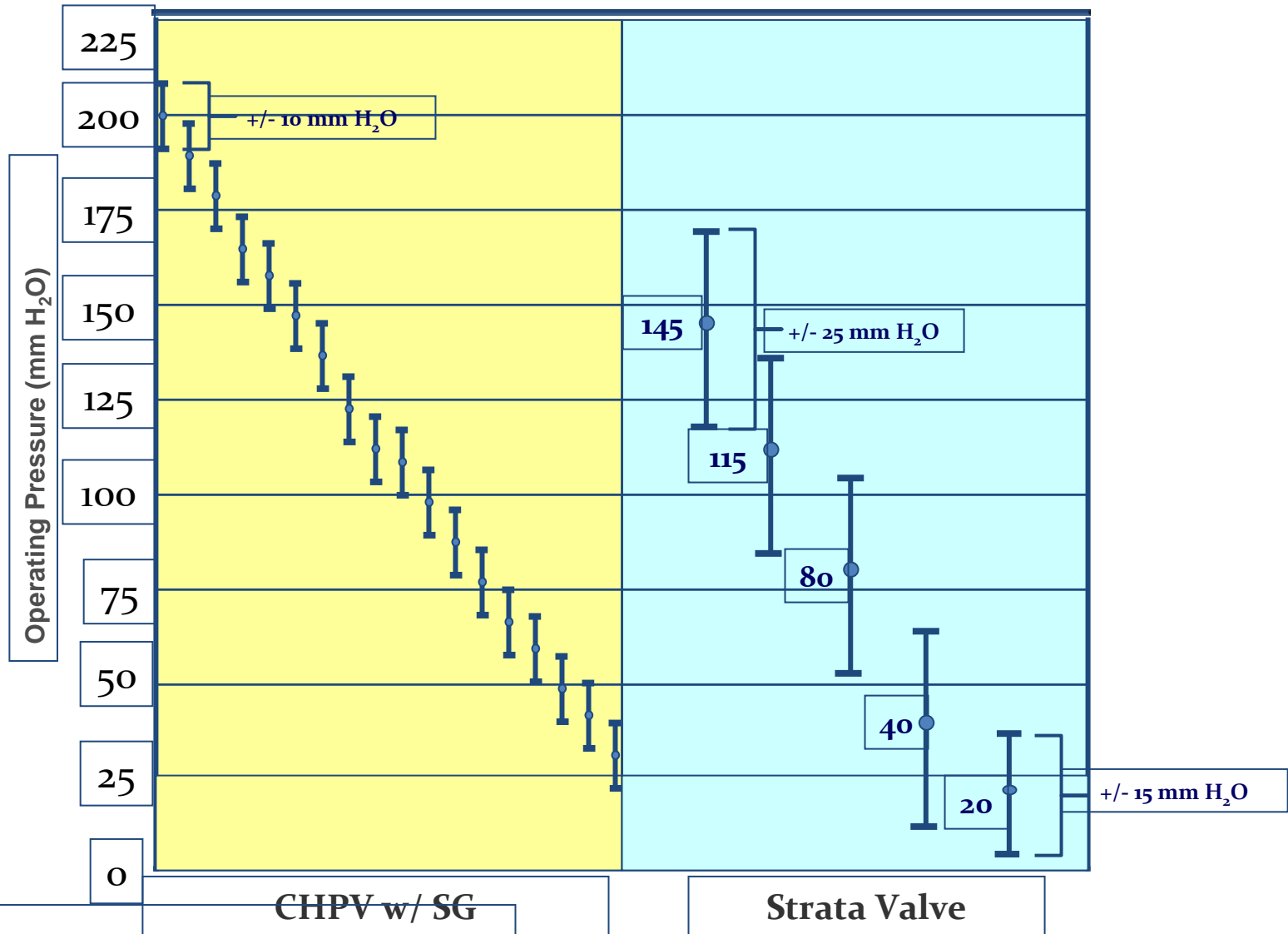
- Requires reprogramming valve
- Only verifies new programmed valve setting not prior one

Performance Characteristics CODMAN HAKIM™ Programmable Valve vs. STRATA Medtronic valve



- True pressure settings, not performance levels
- Tight operating ranges
- Higher operating pressures available

Opening Pressure Accuracy



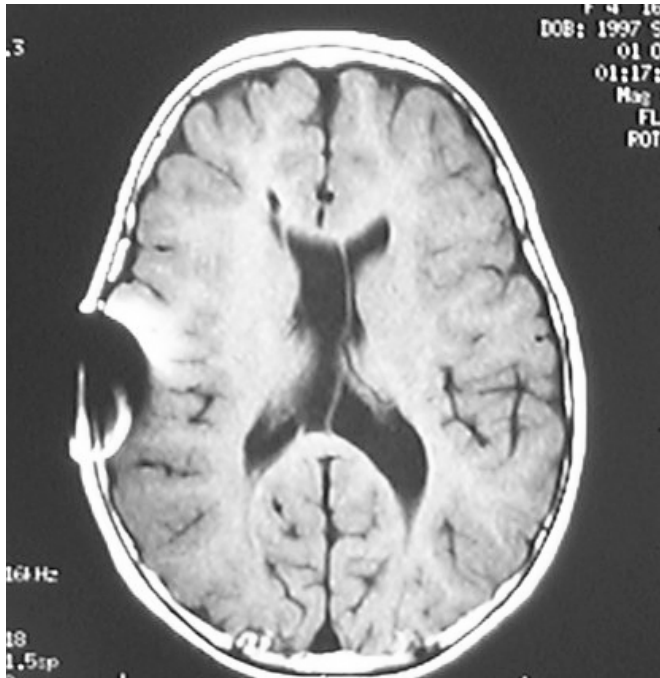
MRI Studies

- Safe for use; “MRI Conditional”
 - no movement of valve in tissue pocket
 - no selective heating
 - no effect on valve performance

MUST Reprogram after each MRI
MRI will change the pressure setting

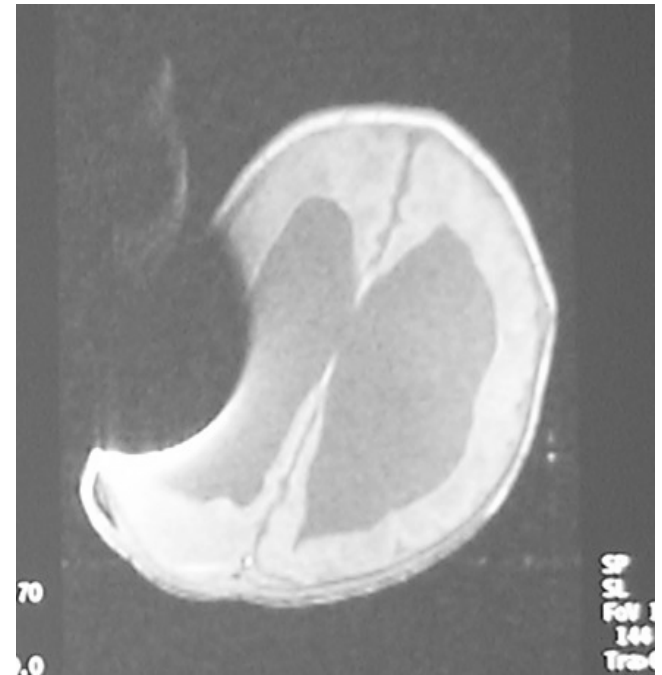
MRI Artifact

CHPV



- Artifact can be seen
- Small Effective radius 2.5cm from scalp

Strata



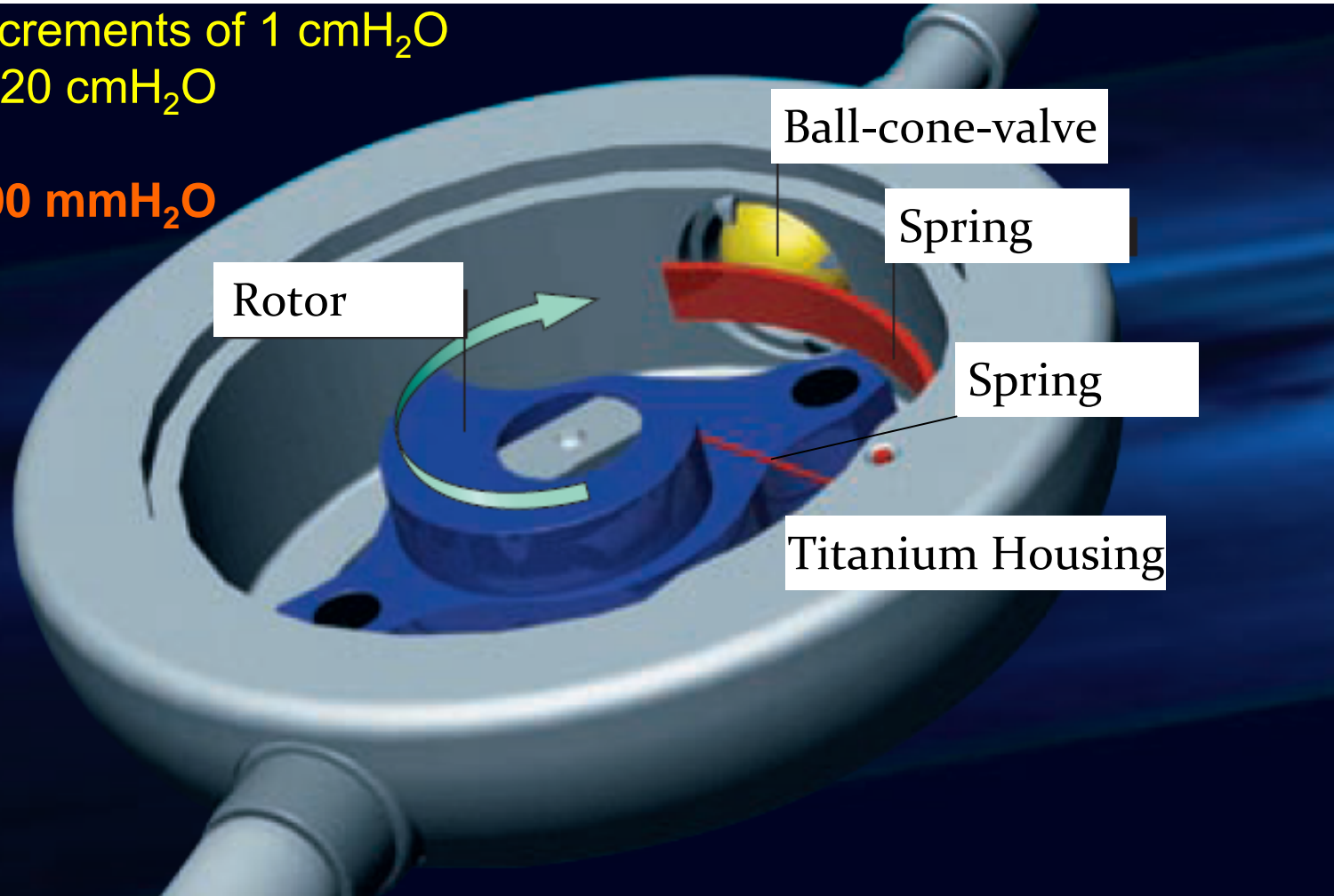
- Large artifact can be seen
- Effective radius 5cm from scalp

proGAV®

- Design -

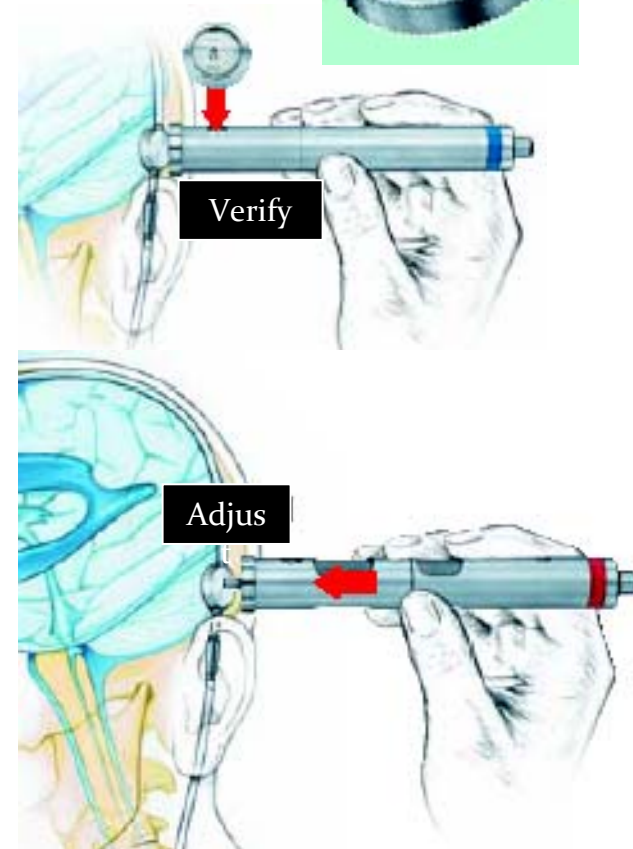
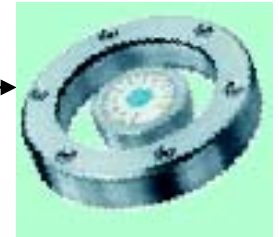
Adjustable in increments of 1 cmH₂O
between 0 and 20 cmH₂O

10 cmH₂O = 100 mmH₂O



proGAV Tools

1. Compass
2. Adjustment Pen
3. Verification Pen
4. Masterdisk
5. Locator Tool

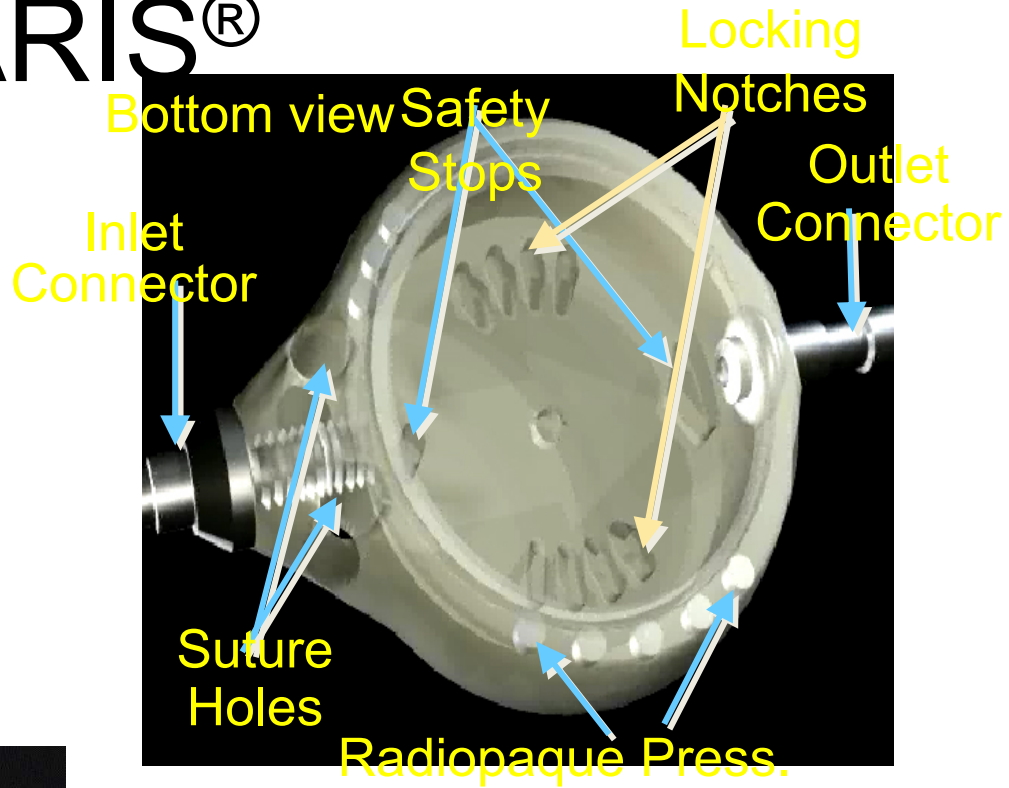
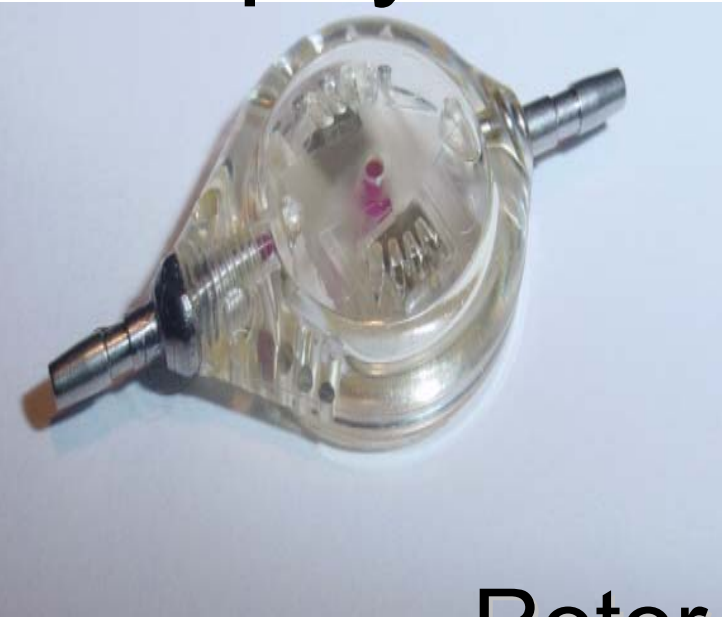


Ease of Use?

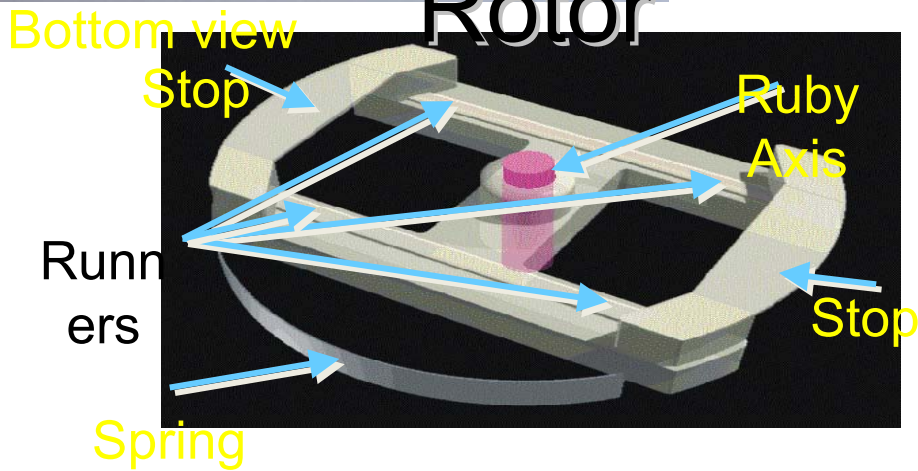
proGAV Summary

- Adjusting can be painful and you must be precise with the tools to avoid errors.
- Limited locations for implanting and shunt with ASD must be implanted vertically.
- Currently no published clinical evidence on long-term failure or improved outcomes.

Sophysa POLARIS[®]

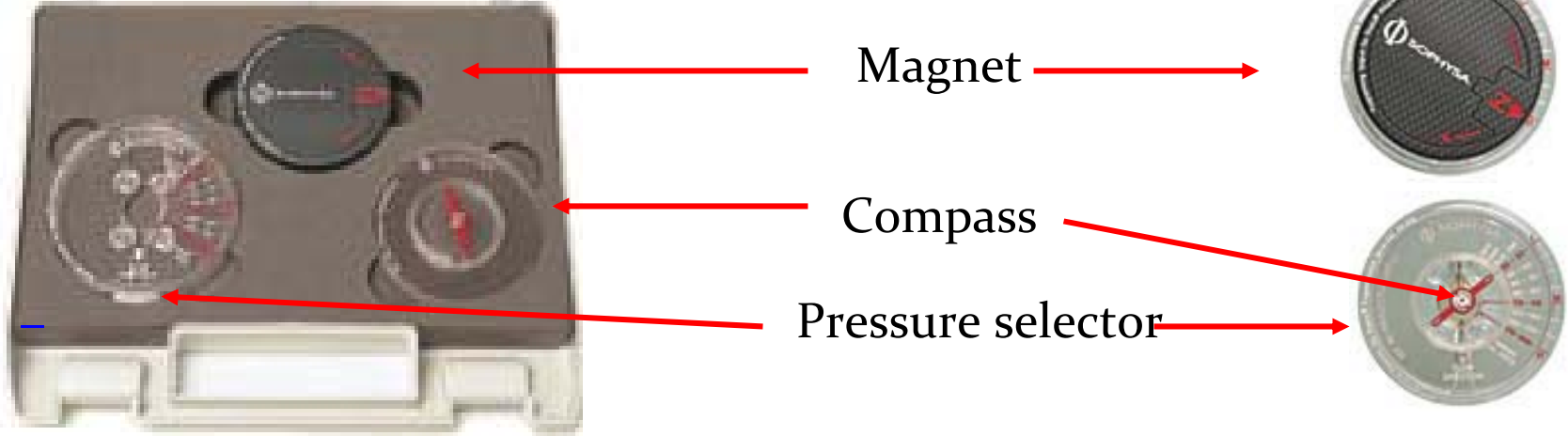


Rotor



BODY

Programming Procedure

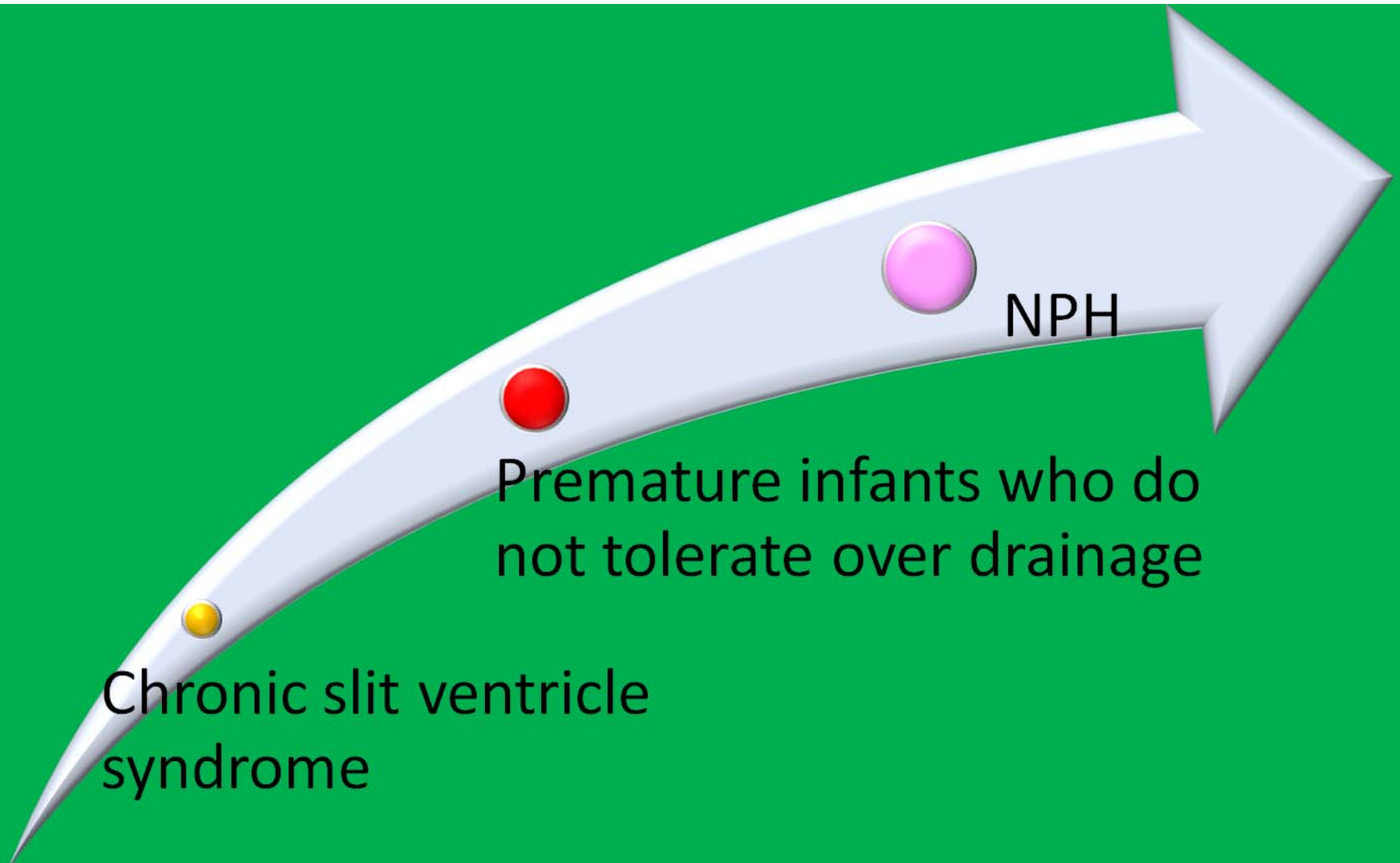


- The pressure selector enables the compass and the magnet to be positioned in relation to the valve. The internal graduated dial allows a precise reading of the 8 positions as well as the associated values of operating pressure (in mm H₂O). The outer dial of the selector shows the programming range of the magnet.
- The magnet (1 Tesla) provides for adjustment of the rotor
- Through the compass there is a simplified reading procedure: the compass has to be placed on the selector to read the value of the selected pressure, in the direction of the red needle

Sophysa drawbacks

- **A rigid valve system doubles in size when Anti siphon device is added**
- **Large Sizes, Rigid Profiles may not be optimal for pediatric Hydrocephalus population**
- **Large MRI artifact due to radiopaque markers.**

Indications for Programmable valve



Chronic slit ventricle syndrome

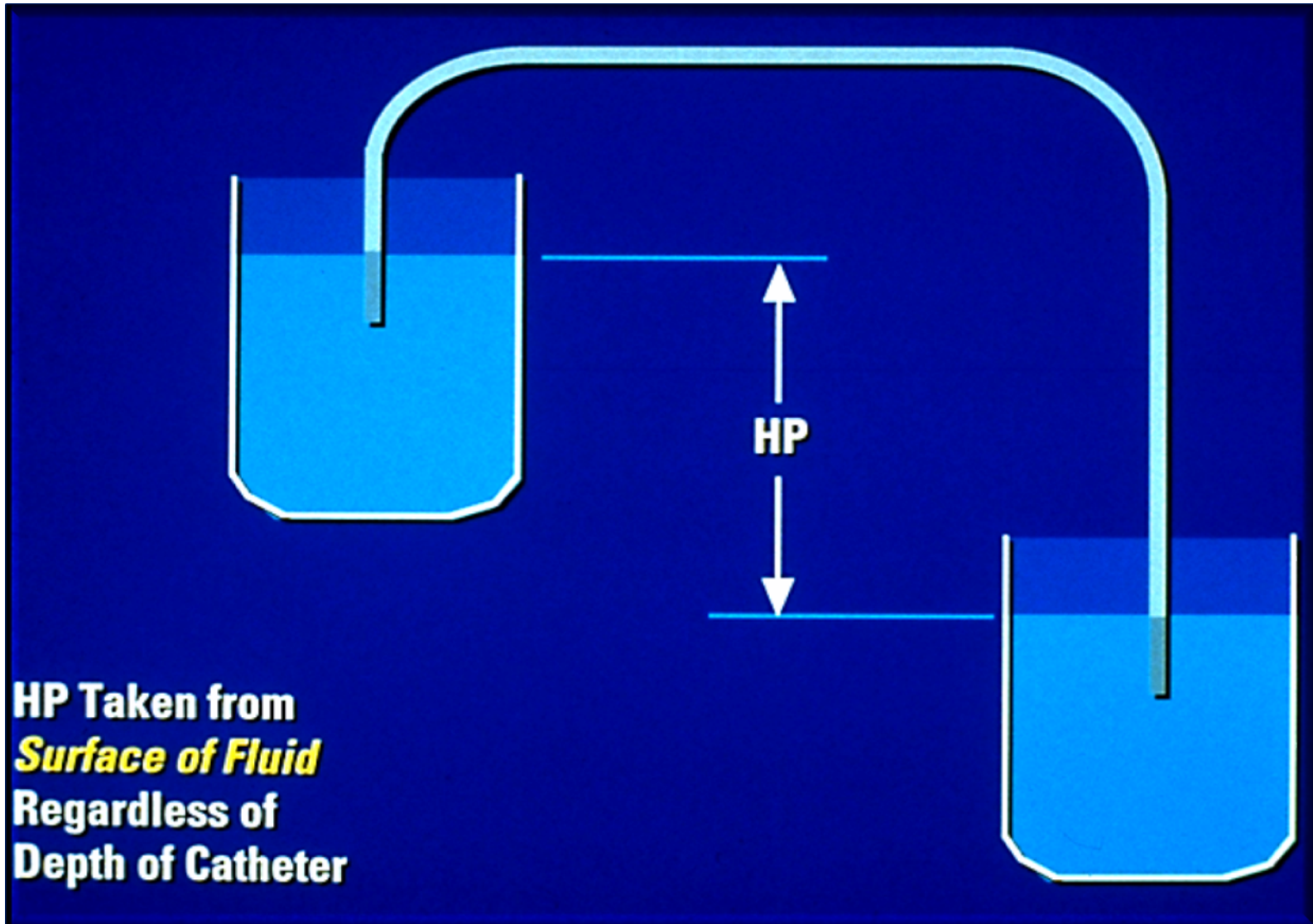
Premature infants who do not tolerate over drainage

NPH

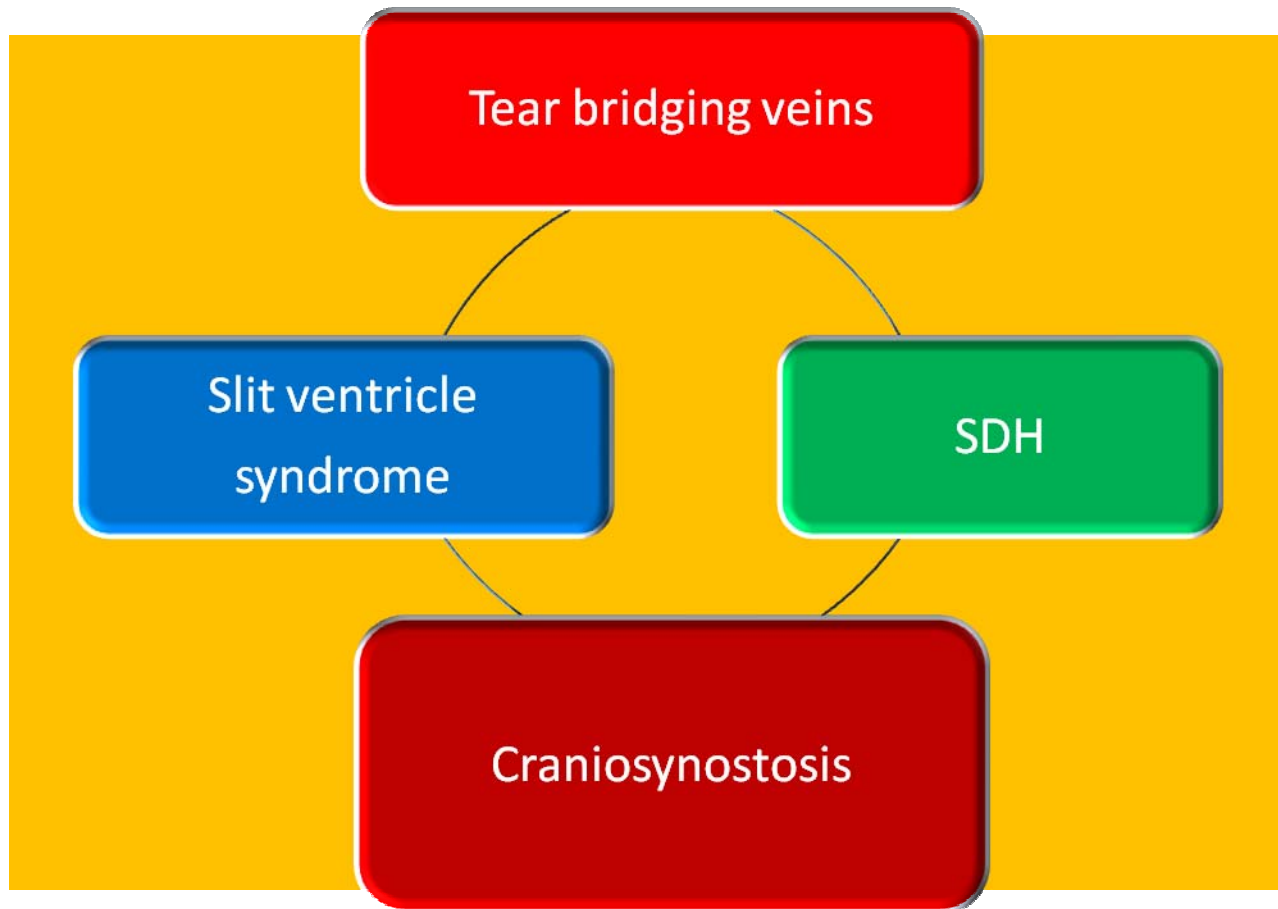
Warnings / Precautions

- Valve is supplied without a preset pressure and must be programmed prior to implantation
- Aseptic surgical technique
- Don't flush, fill or pump valve with lint-containing fluid
- Take care to prevent shunt from touching surface
- Don't tie sutures tightly
- Don't move the transmitter during programming

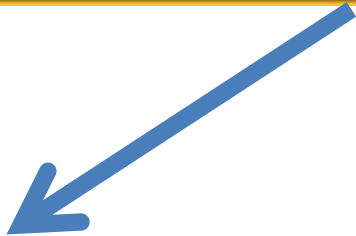
Siphoning



Effects of siphoning



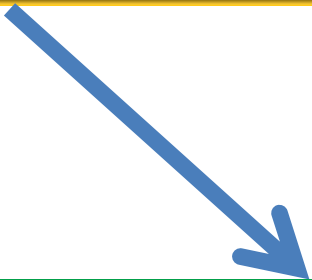
To prevent siphoning



Change the shunt valve to one with higher opening pressure



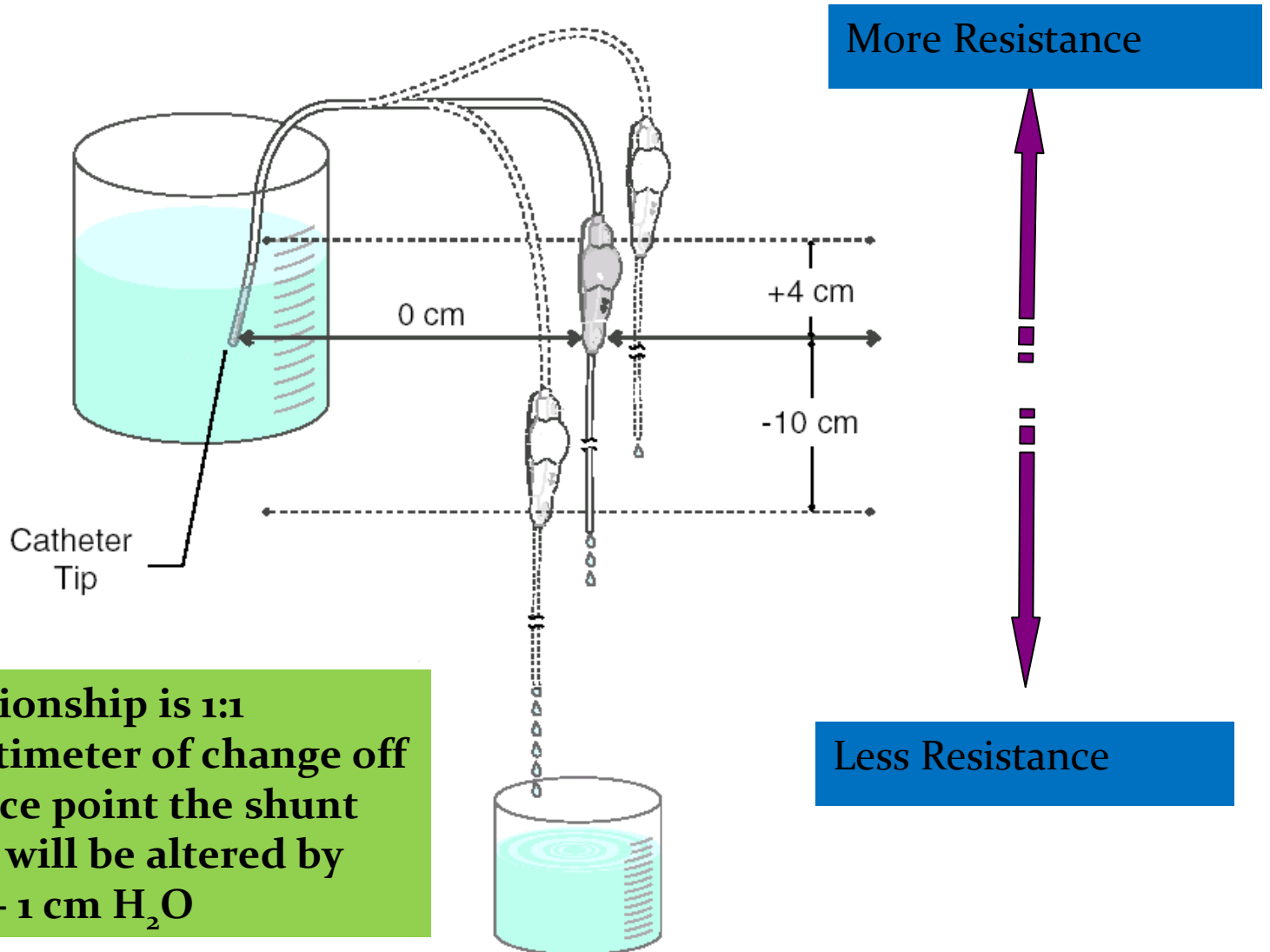
Will only delay ventricular collapse
But will not prevent it.



Use ant siphon device



Ideal antisiphon shunt



Relationship is 1:1

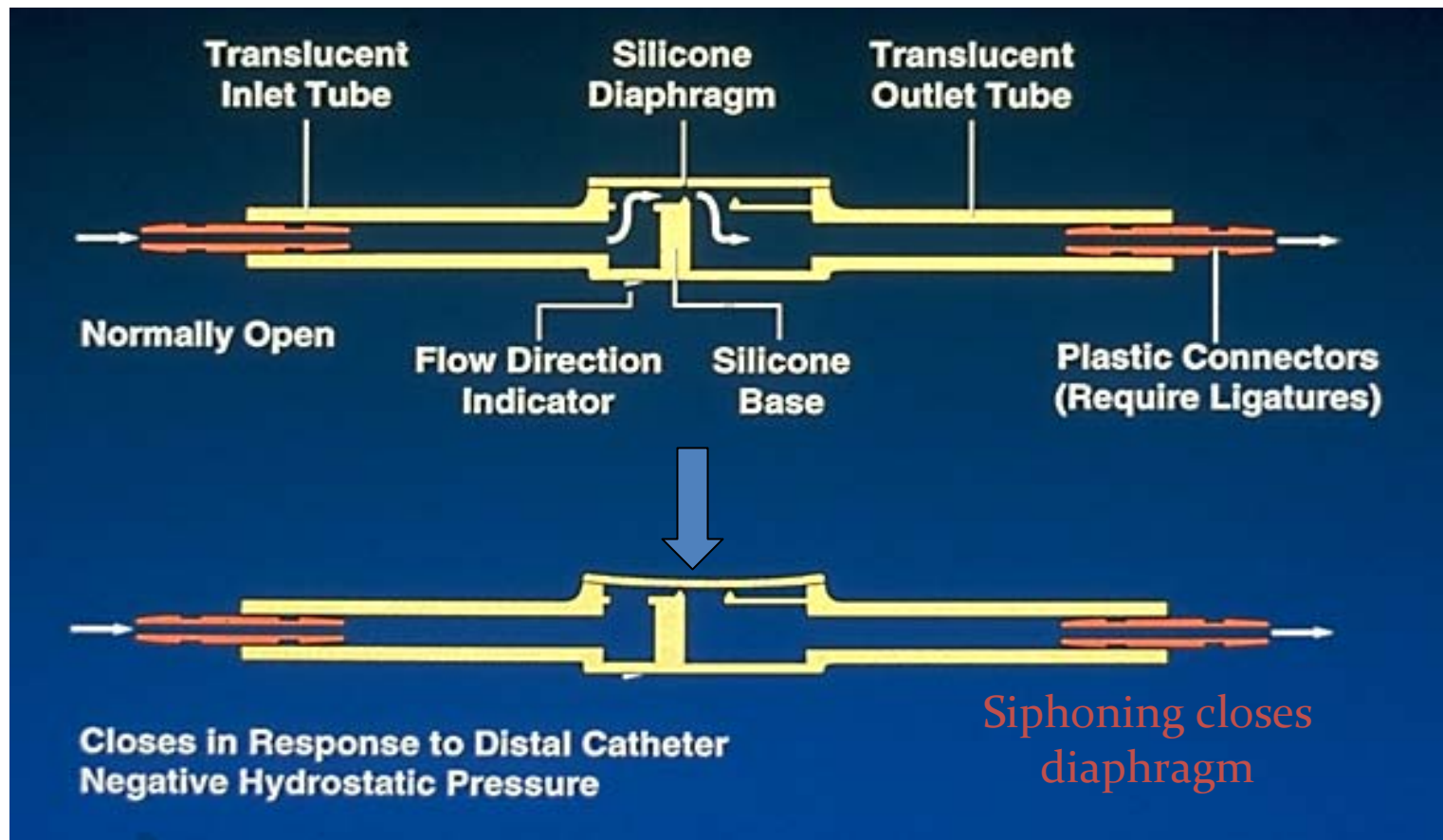
For every centimeter of change off the reference point the shunt resistance will be altered by $\pm 1 \text{ cm H}_2\text{O}$

Ant siphon device

Has a small diaphragm that reduces the flow of CSF when the pressure inside the shunt falls below the atmospheric pressure

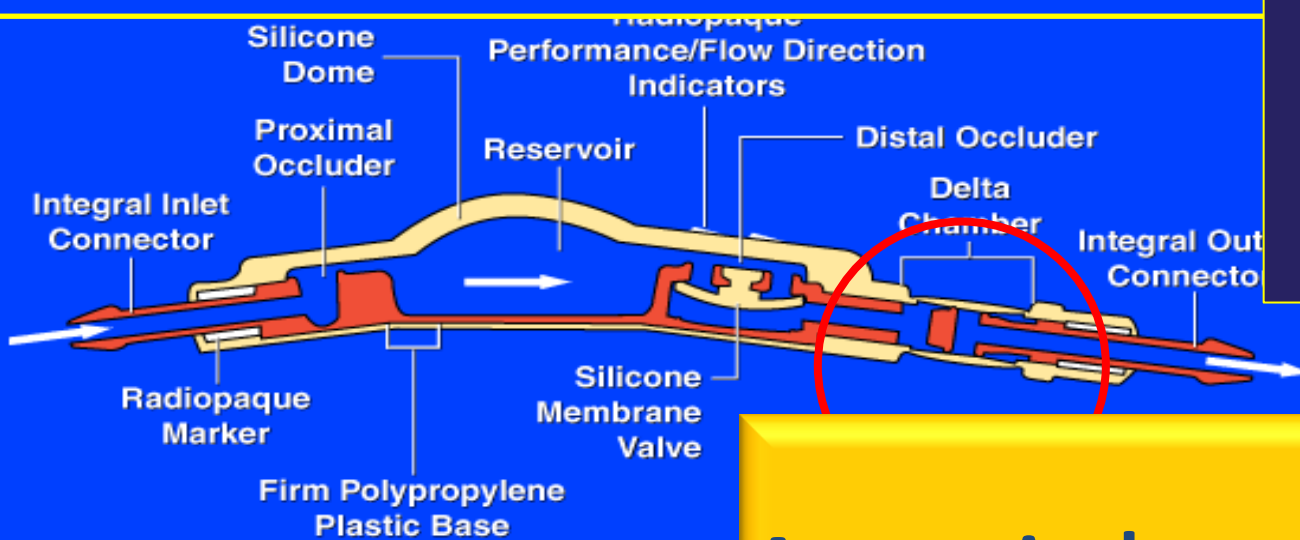
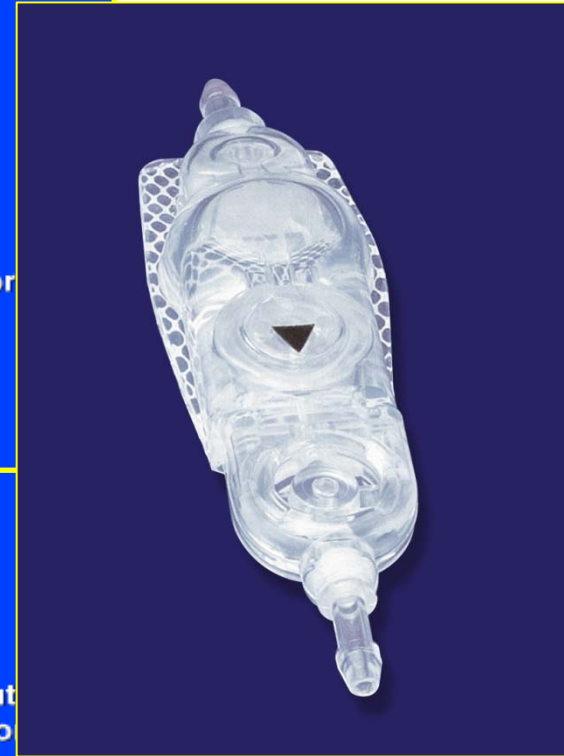
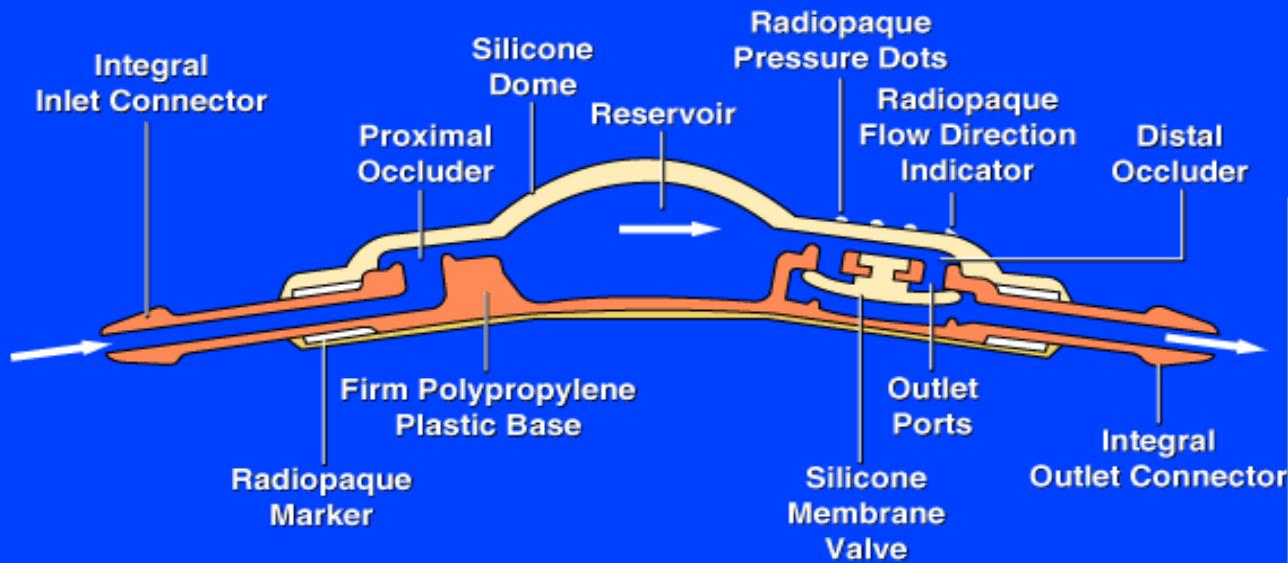
Integra (Heyer-Schulte)

Anti-Siphon Device – Circa 1975



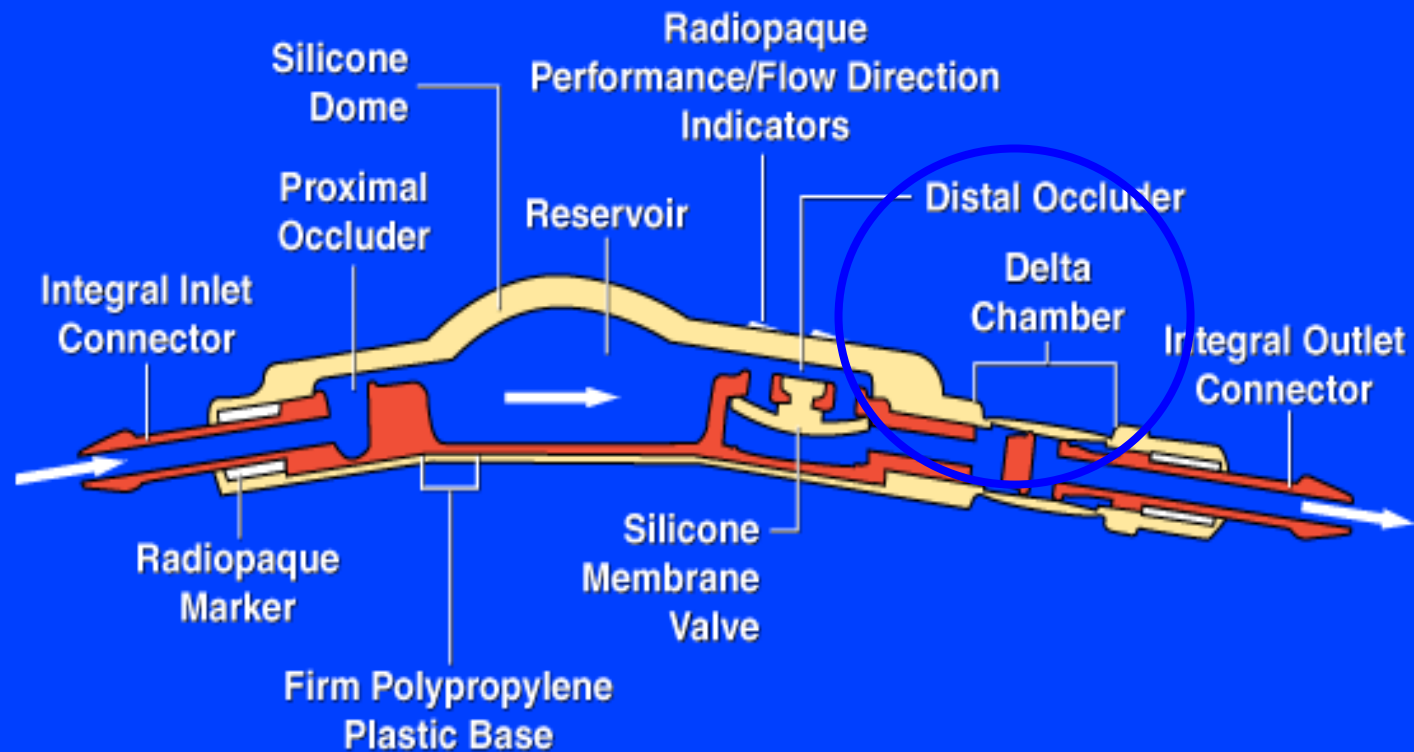
Integra (Heyer-Schulte) Anti-Siphon Device (ASD)

- After numerous publications, the product is coined the name “anti-function device” by clinicians
- All silicone construction was subject to distortion from overlying tissue.
- Single, exposed, diaphragm was subject to compression from overlying tissue
- 8:1 Hydrodynamic Leverage Ratio resulted in increased shunt resistance



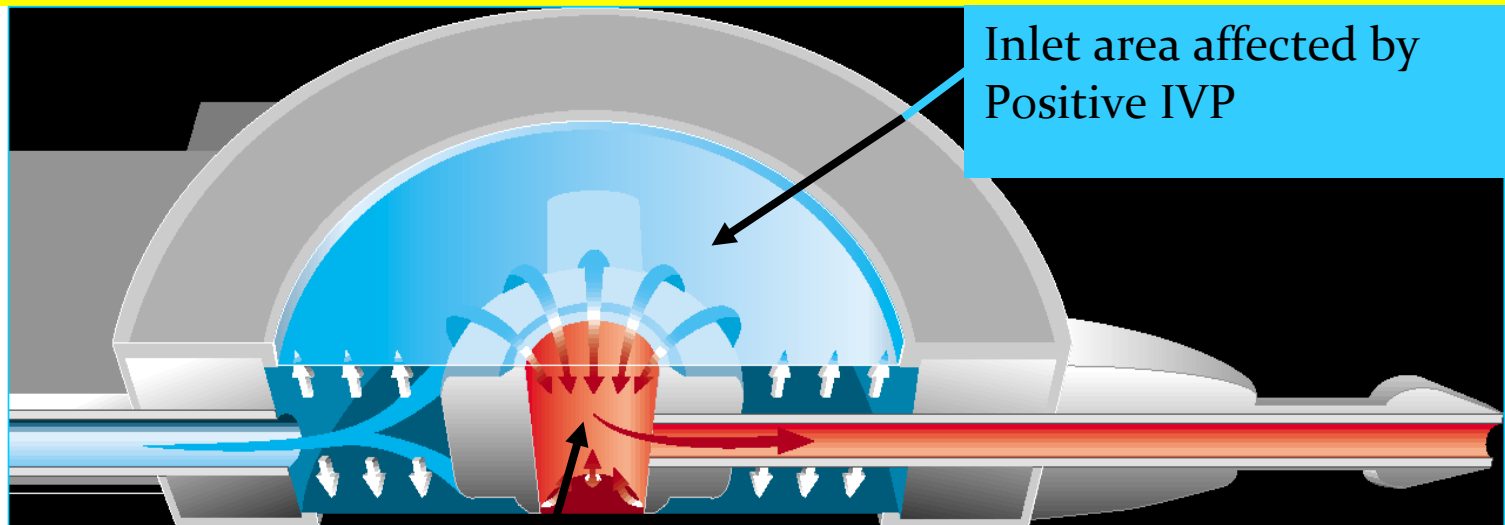
Ant siphon device

Antisiphon device



Delta Chamber

- The Delta Chamber uses a hydrodynamic leverage ratio of 20:1 to reduce the effect of negative hydrostatic pressure, and allow the valve to operate in its specified Performance Level, regardless of body posture.



Inlet area affected by Positive IVP

Outlet affected by distal siphoning

Delta Valve Message

- The Delta chamber senses both positive inlet pressure, and negative outlet pressure, and manages both.
- The Delta chamber manages negative outlet pressure without adding significant resistance to the shunt.
- The dissimilar material and recessed design of the Delta chamber diaphragms help to minimize the risk of compression from overlying tissue.

Siphon / Flow Control

Siphon Guard™ is a unique device designed to reduce the risk of CSF over drainage complications.



- Rugged
 - No encapsulation or external pressure influence – flow not totally blocked
 - Avoids damage due to errant needle
- Unaffected by implant location
- Available as an integrated or stand alone device.
- Device is always open unlike other on and off devices.

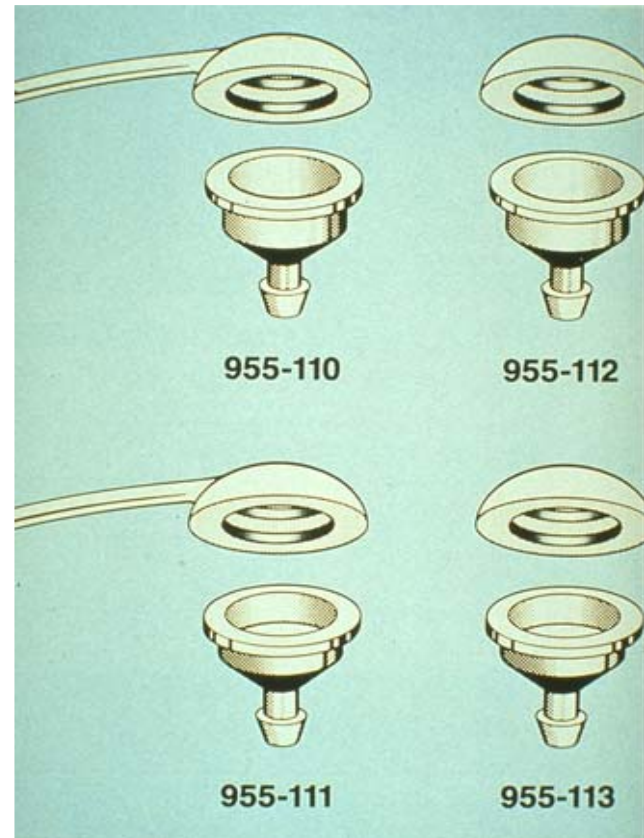
Siphon / Flow Control

Primary Flow Path



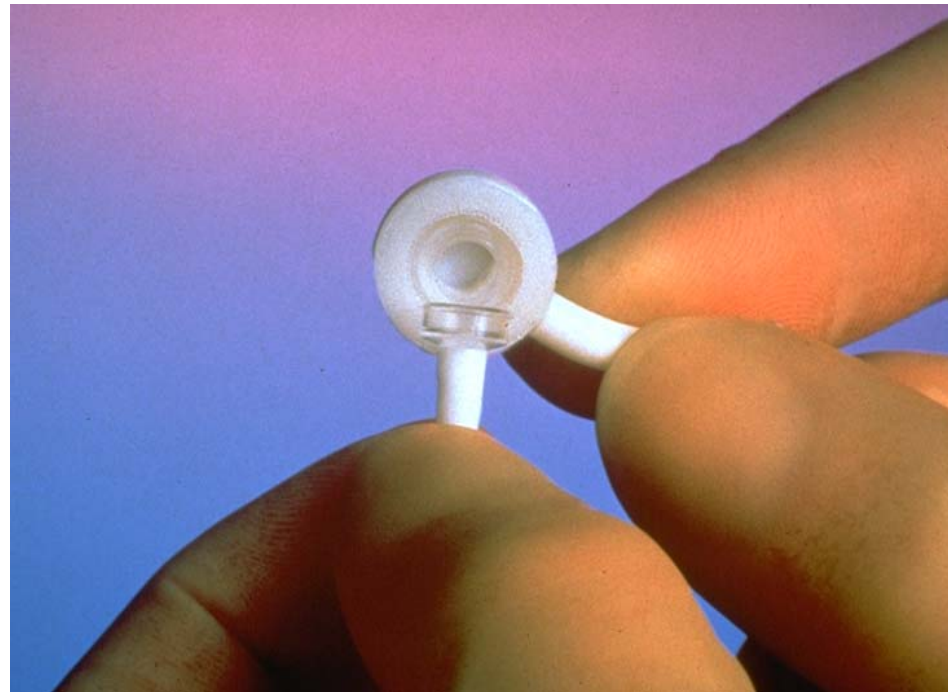
Neonatal Shunt Requirements

- Ventriculostomy “Rickham” style reservoir
- Used in conjunction with a valve
- Low profile
- Two-piece assembly
- 6 mm burr hole



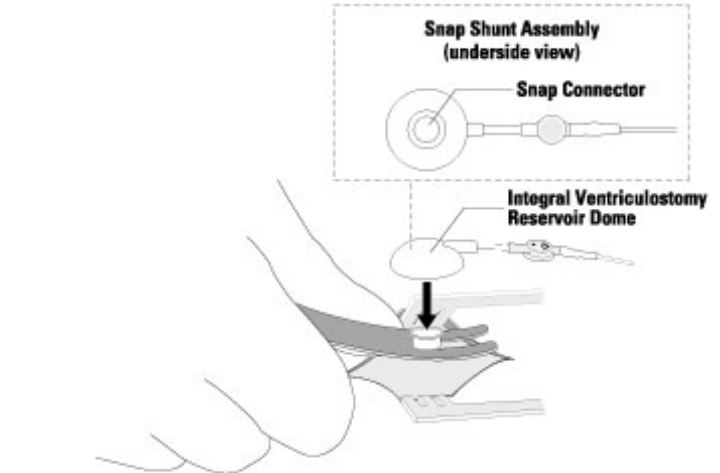
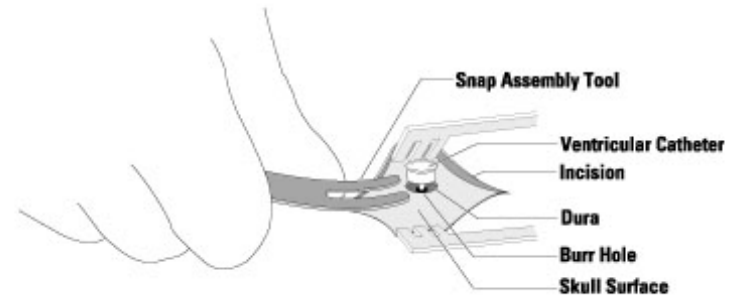
Snap Shunt Reservoir

- Ventriculostomy “Rickham” style reservoir
- Two-piece assembly that “snaps” together



Shi

- Available separately
- Reusable
- A virgin snap reservoir can be stiff and a platform is needed so pressure is not applied to the infants skull



Button Snap Shunt Assembly

- Allows for CSF access
- Snap Reservoirs are available on all valves styles



Advancements in biomaterials

- Antibiotic impregnated shunt tubings.
- Coated silicone tubings for converting them into hydrophilic and more lubricious material.

Antibiotic impregnated shunts

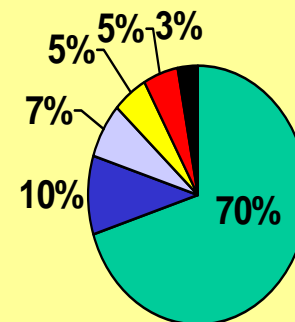
»Bacteria In Shunting

↳Most common bacteria in shunt infections?

Account for approx. 77% of shunt infections.

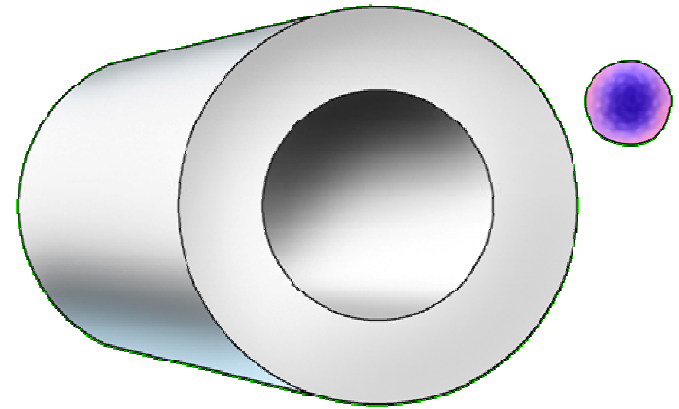
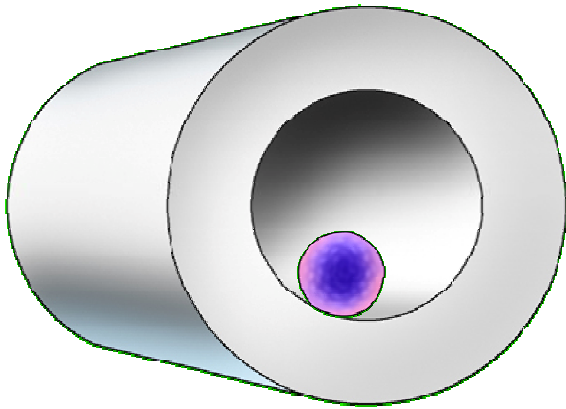
- ↳ *S. epidermidis*
- ↳ *S. aureus*
- ↳ *Coryneforms*
- ↳ *Streptococci*
- ↳ *Enterococci*

Causative organisms of shunt infections



■ Staph. epidermidis	■ Other species of CoNS
■ Staph. aureus	■ Coryneforms
■ Enterococci & other Gram pos.	■ Gram negatives and others

Internal or External ?

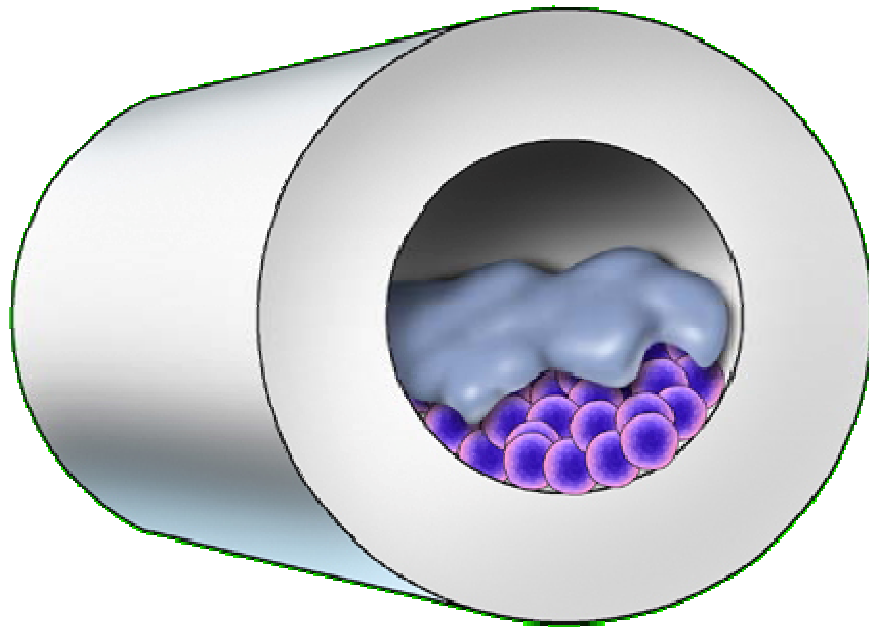


- » *Internal*
- » *Majority*
- » *S. epidermidis or Coryneforms*

- » *External*
- » *Minority*
- » *Wound infection complicated by foreign body*
- » *S. aureus*

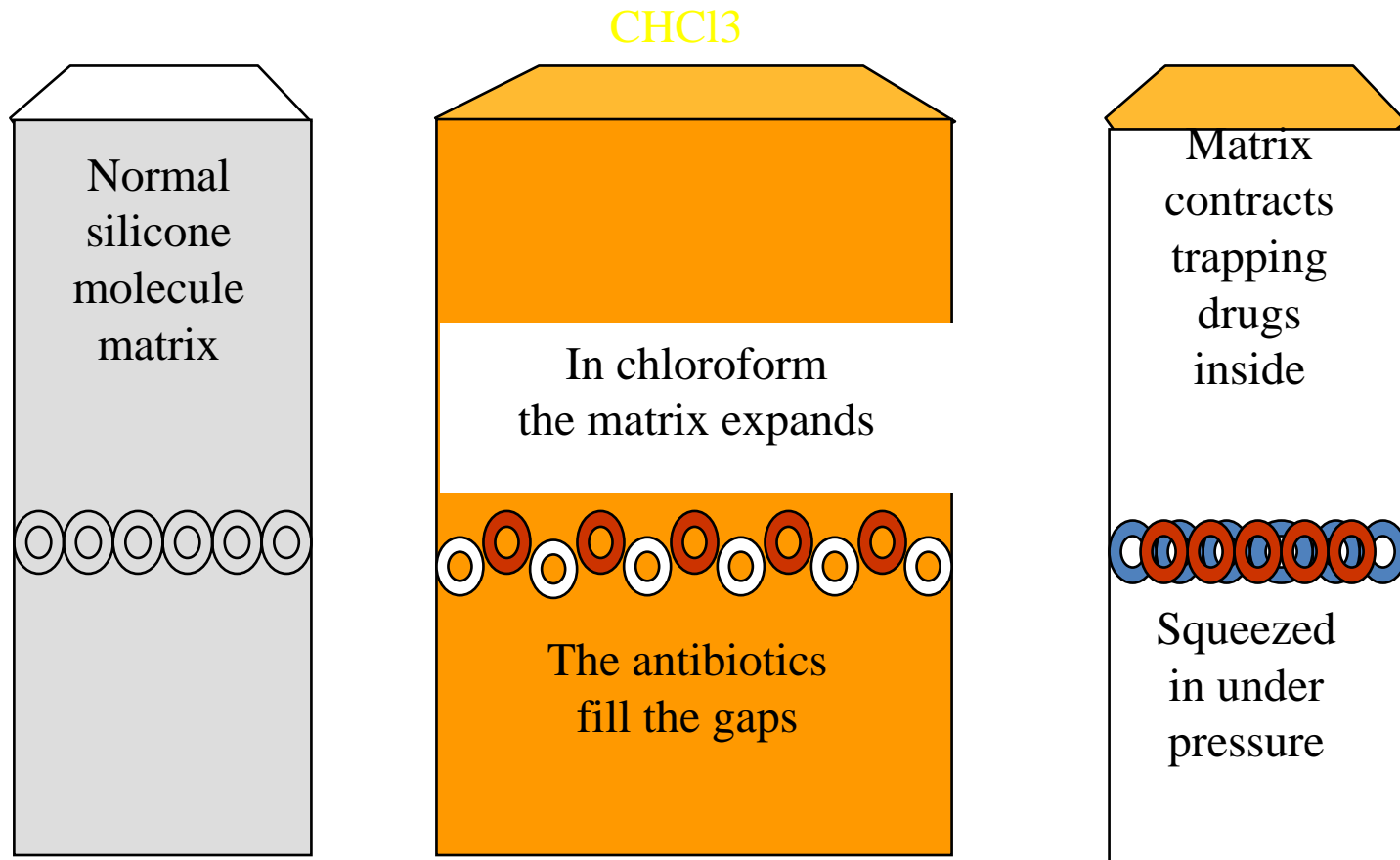
Contd..

Internal Shunt Infection

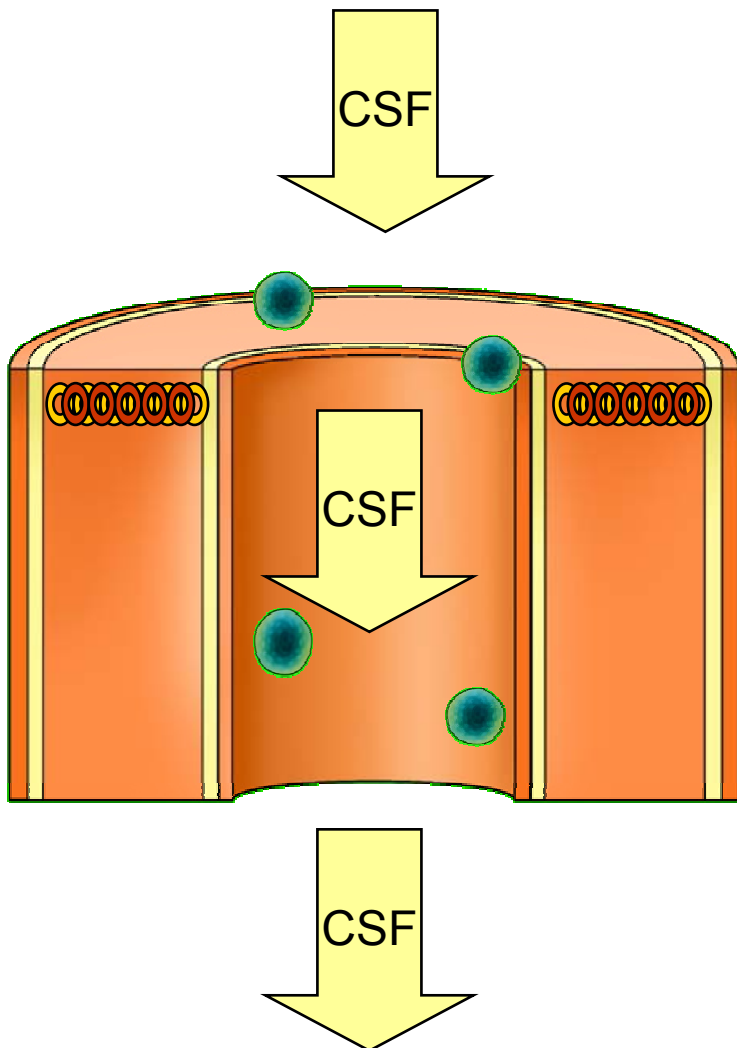


- » *The organisms start to multiply*
- » *And they produce extracellular slime*
- » *This can, in time, completely block the shunt*

How are antibiotic impregnated shunts made?



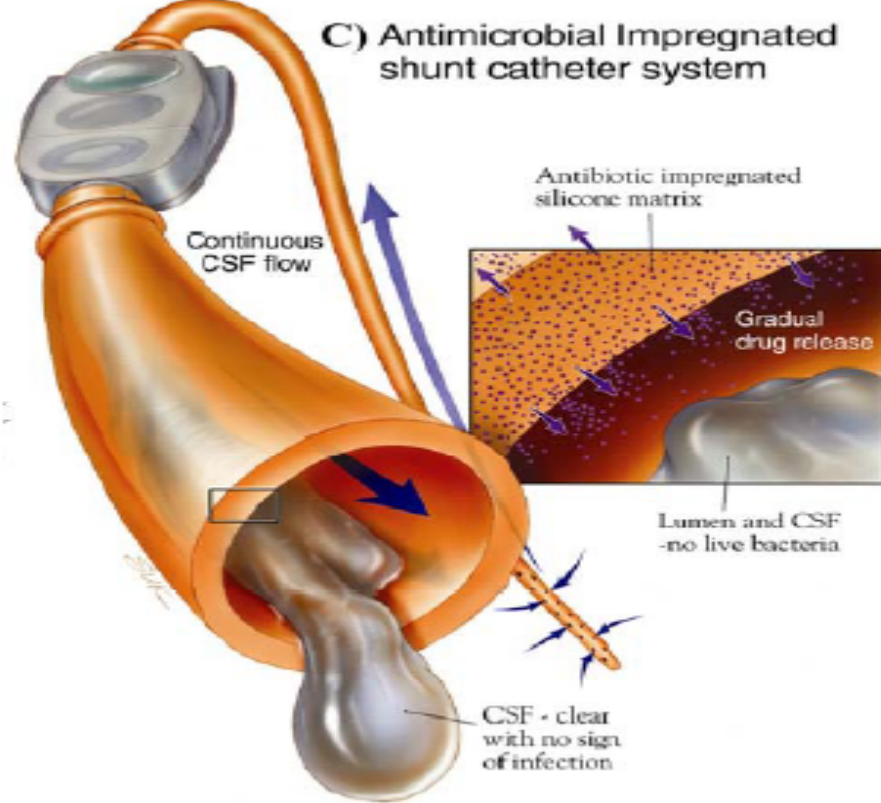
Contd..
How Do They Work?



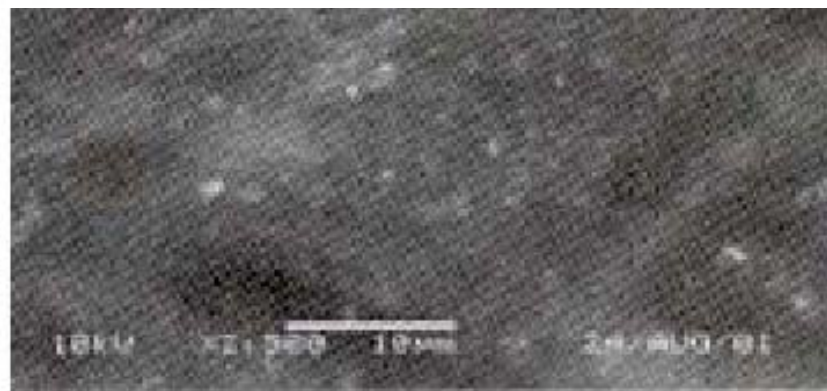
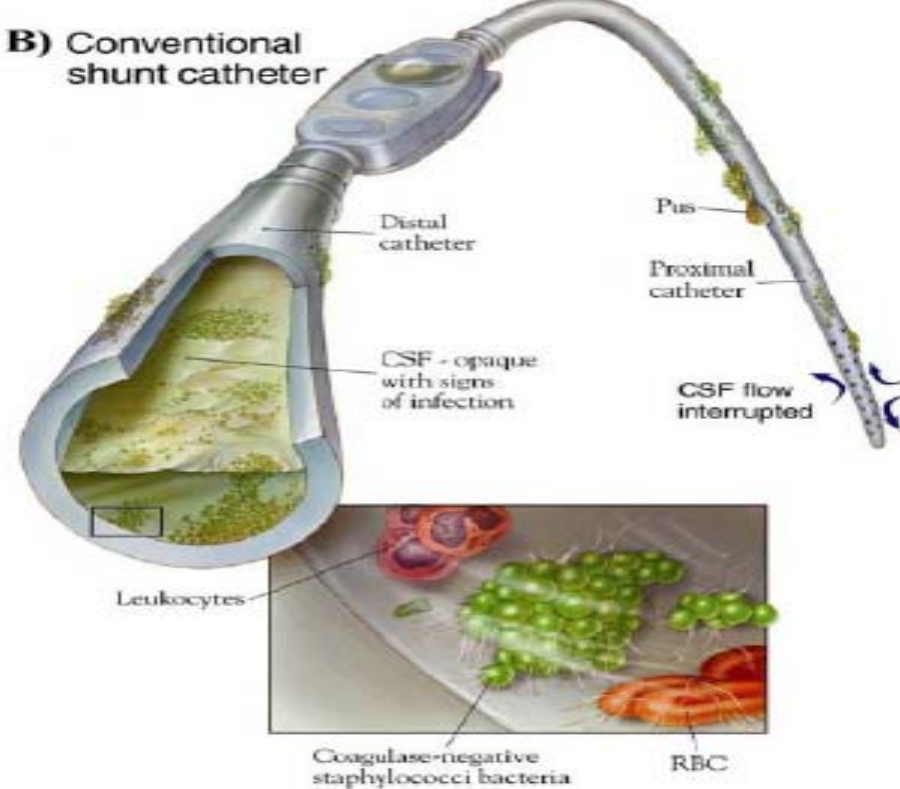
Due to the concentration difference between the catheter and the external environment, there is a positive diffusion gradient which causes the drugs to slowly diffuse out of the silicone.

The concentration of drugs at the surface of the catheter is high enough to inhibit colonization.

C) Antimicrobial Impregnated shunt catheter system



B) Conventional shunt catheter



BACTISEAL™ Catheter

No bacterial colonization is seen in the antibiotic-impregnated BACTISEAL™ shunt surface after being exposed to an antigen for 28 days.



**Standard, conventional catheter
(Not treated with antibiotics)**

When challenged with coagulase- negative staphylococci, bacterial seeding is seen on the surface of the untreated antibiotic shunt.

Precaution

Pre Implant Technique

- *Surgeon should not pre soak Bactiseal in saline or antibiotic solutions prior to implantation because the diffusion process will be activated.*

Reduction in infection

- Significant reduction in shunt infection rate with antibiotic impregnated shunt.(from 6.5% to 1.2%).
- P value- 0.0015.

*Chris X et al, dept of NS, Vic. Australia.
J. Of clinical neurosciences JUNE 2007.*

Infection rates

Potential
Impact of
Antibody-
impregnated
CSF catheter
(AIC) on
Shunt
Infection (SI)
rates

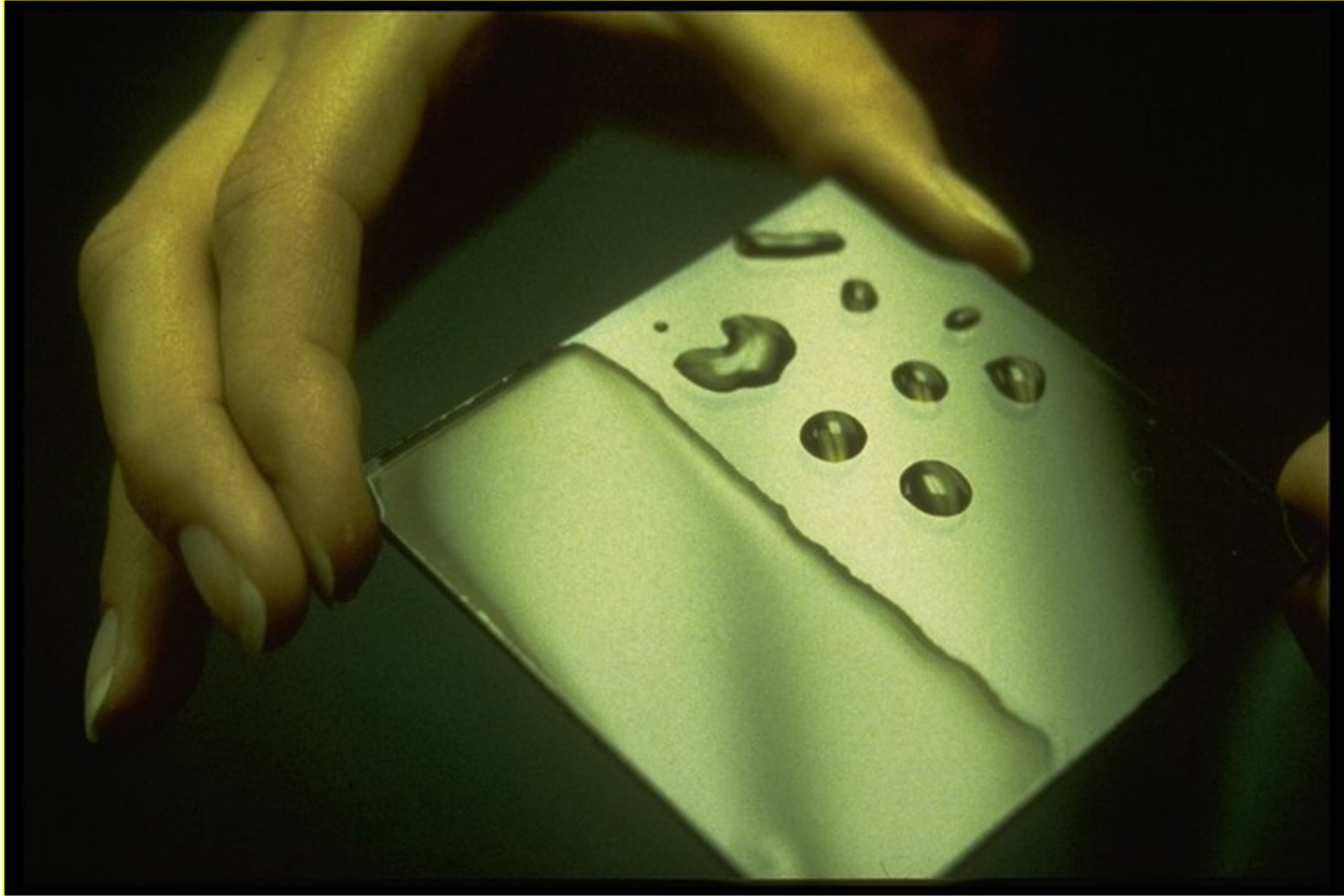
References	Year	Country	Control (Prospective P vs. historical H)	# Patients Std/AIC	SI rates for non-AIC (std) CSF shunts (%)	SI rates for AIC CSF shunts (%)	P- value
Govender, S et al	2003	South Africa	P	60/50	17	6	0.084
Zabramski J et al *	2003	USA	P	139/149	9.4	1.3	0.002
Aryan HE et al	2005	USA	H	46/31	15.2	3.1	0.09
Sciubba DM et al	2007	USA	H	(211)*	12	1.4	0.01
Richards H et al	2006	UK	H	715/715	4.3	2.2	0.04
Clayton J et al *	2007	UK	H	74/87	9.1	2.9	NR
Pattavilakom A et al	2007	Australia	H	NR/178	6.5	1.2	0.0015
Kan P et al	2007	USA	H	65/64	8.8	5	0.534
Zweckberger et al #	2006	Germany	-	0/48	-	10.4	-
Ritz R et al #	2007	Germany	H	126/72	7.9	6.94	0.86
Ritz R et al ##	2007	Germany	H	46/14	2.17	0	NR
Hayhurst et al	2008	UK	H	65/150	10.4	9.8	0.884
Average Rates					9.34	4.18	

- *=External ventricular catheters study;
- ¥= Total number of patients in the study was 211. Individual patient numbers are not reported.
- # Patients with > one risk factor (high risk group)
- ## Patients with no risk factors
- NR= not reported
- With the exception of Govender et al and Zabramski, all non-AIC shunts are with historical controls.

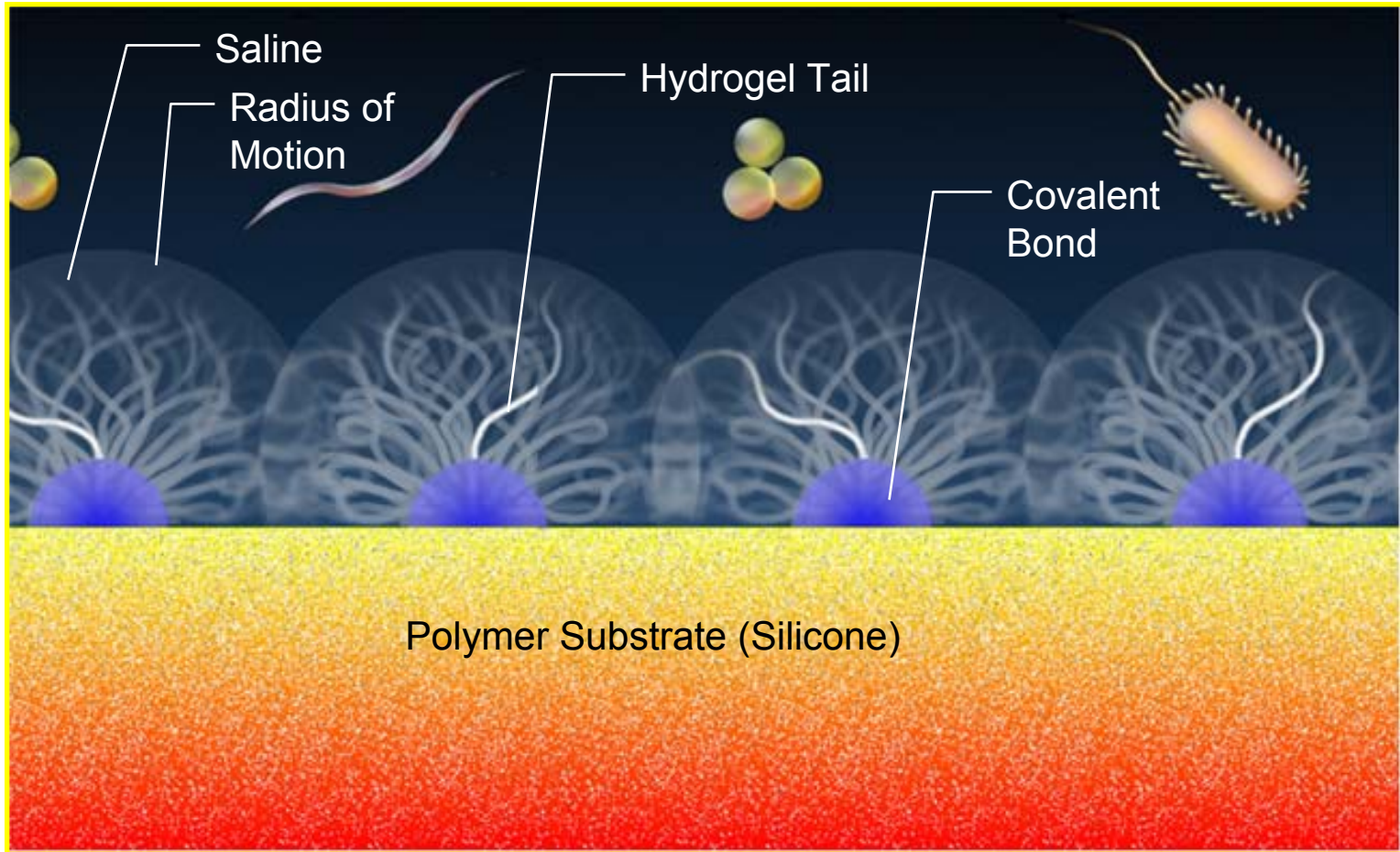
BioGlide

- BioGlide is a covalently-bonded hydrogel that aids with ease of insertion, reduces bacterial adhesion, and absorbs water-soluble antibiotic solutions
- Created to address the issue of “infection”

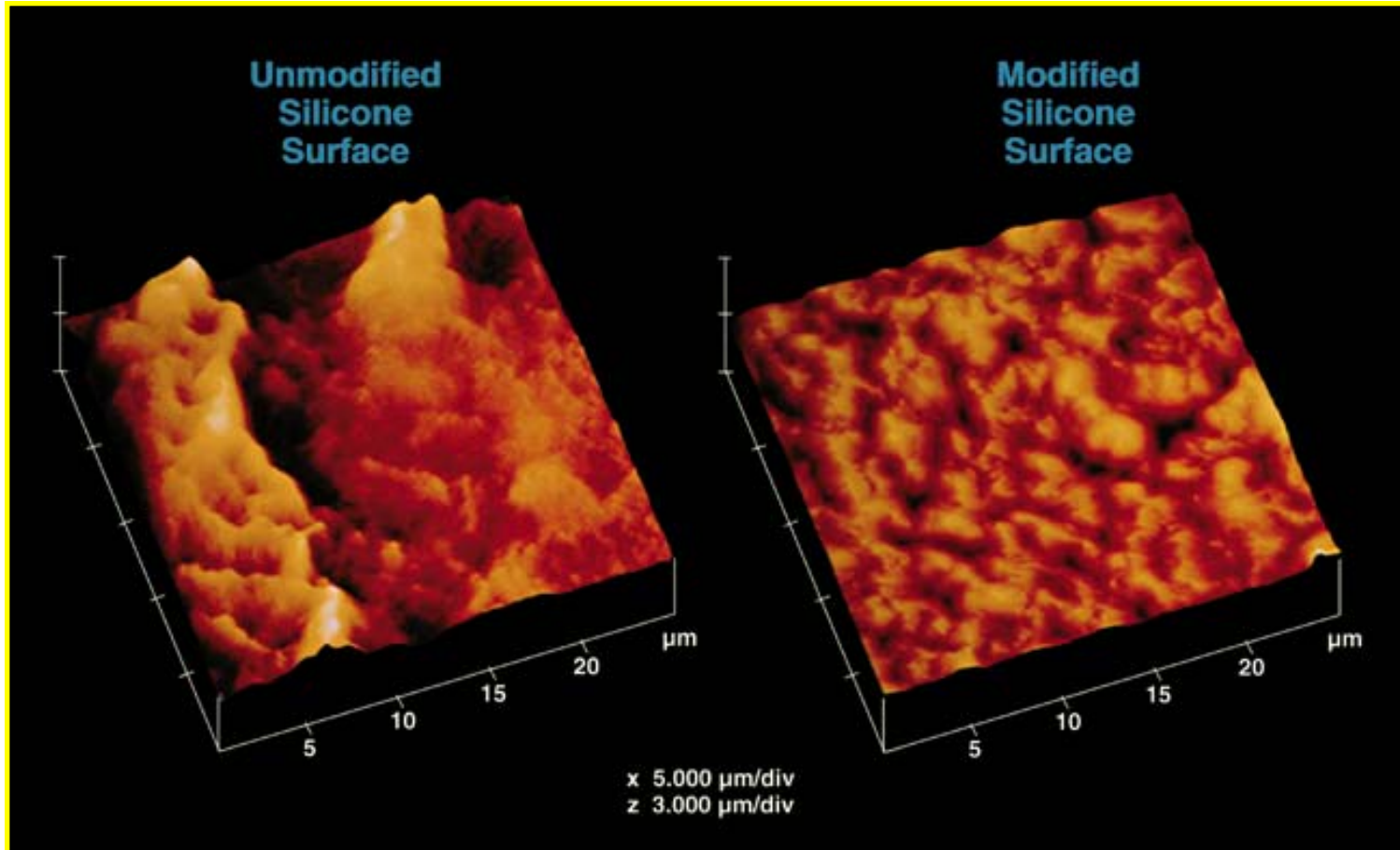
BioGlide



BioGlide



BioGlide



BioGlide

- **We can say:**
 - Hydrophilic, lubricious surface facilitates insertion
 - Smoother surface than non BioGlide treated surface
- **We should be cautious saying:**
 - Biocompatibility
 - Reduced Bacterial Adhesion
 - Absorption of Antibiotics

Specific requirements

- Posthemorrhagic hydrocephalus of the premature newborn/Pressure differential valve of ball-in-cup or diaphragm design, because of the forgiveness of high protein and cellular debris.
- High brain turgor patients (achondroplasia, Crouzons, others) =Highest pressure valve tolerated. May even need valves in series.
- Low brain turgor patients (Normal Pressure Hydrocephalus) / Low pressure valve with a mechanism that prevents or retards siphoning.

Specific requirements

```
graph TD; A[Specific requirements] --> B[Post hemorrhagic hydrocephalus of the premature]; A --> C[High brain turgor patients (achondroplasia, Crouzons, others)]; A --> D[Low brain turgor patients (NPH)]; B --> E[Pressure differential valve of ball-in-cup or diaphragm design]; C --> F[High pressure shunts May even need valves in series.]; D --> G[LP shunt with ASD];
```

Post hemorrhagic hydrocephalus of the premature

Pressure differential valve of ball-in-cup or diaphragm design

High brain turgor patients (achondroplasia, Crouzons, others)

High pressure shunts
May even need valves in series.

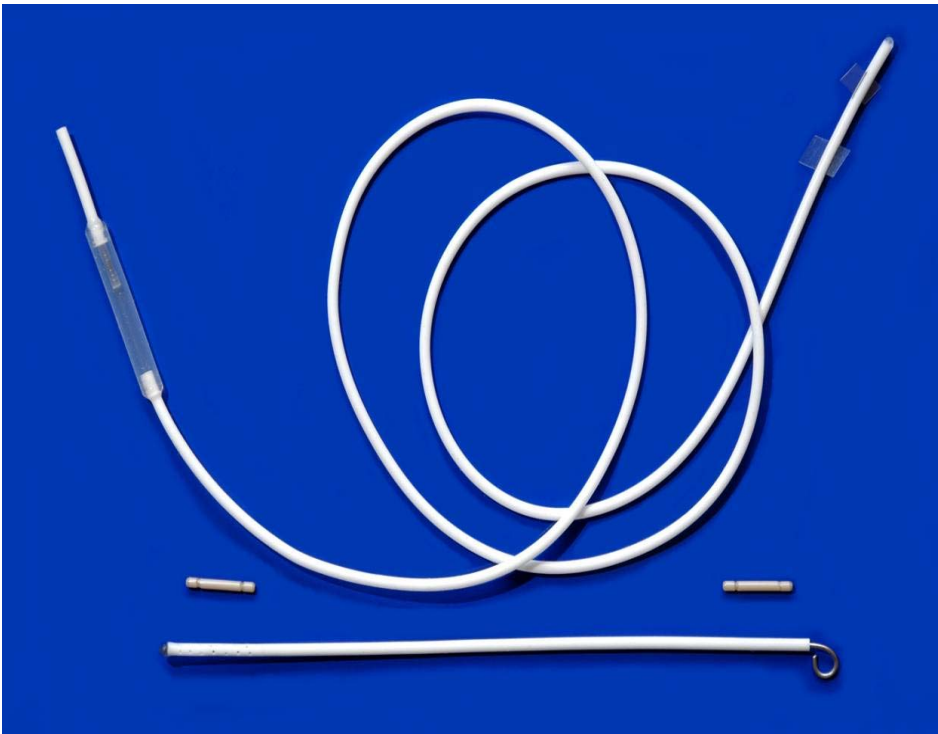
Low brain turgor patients (NPH)

LP shunt with ASD

Cost of various shunt systems

No.	Name	Rupees
1	Codman programmable	45,000
2	Medtronic programmable	39,000
3.	Diamond (vygon)	17,000
4.	Bactiseal	12,000
5.	Phoenix(vygon)	5,000
6.	Ceredrain	1,300
7.	Chhabra	1,240

Indian Scenario



- “The inexpensive Chhabra shunt in comparison to Codman shunt had no statistically significant diff in outcome” (J Neurosurgery {peds 4}102:358-362,2005)

Valve design trials

- “Multicentre randomized trials of CSF shunt valve design have failed to demonstrate any difference among the valves in cases of shunt failure.”
 1. *DRAKE Jm et al-RCT of CSF valve design in pediatric pts. Neurosurgery 43:294-305. 1999*
 2. *Pollack et al- RCT of a programmable valve versus a conventional valve for patients with HCP. Neurosurgery 45:1399-1408,1999.*
- *Exception = Antibiotic impregnated shunt.*

Unmet Medical Needs

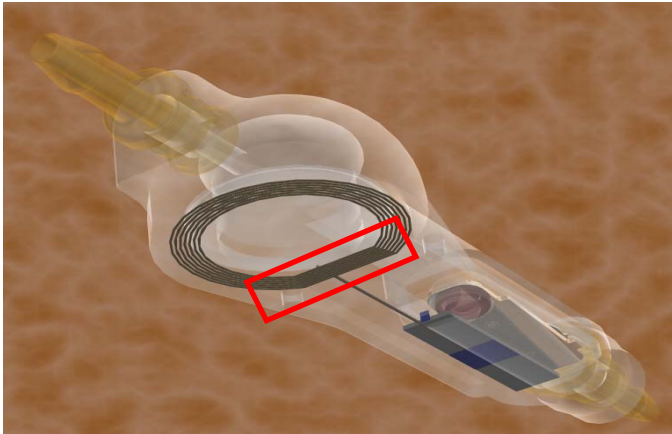
Shunting

- “Smart Shunting”
 - Intracranial Pressure Sensing
 - CSF Shunt Flow Sensing
 - Internal Feedback Control
- Reduction of Shunt Infection Rates
- Self-healing properties and the ability to elongate with patient growth, may be characteristic of future biomaterials.

Next Generation Valve

Staged Development Plan

Phase A



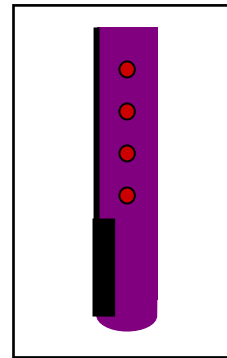
ICP Sensor
Location

Integrated Into
CHPV Reservoir

Key Valve
Specs

Existing Config
Modified Reservoir

Phase B

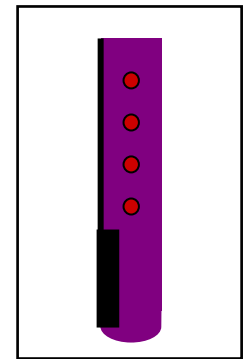


Ventricular
Catheter Based?
Parenchymal?

Existing Config

Phase C

New Engine
"Open"



Ventricular
Catheter Based?
Parenchymal?

Non Magnetic / On-off
Inc P Range / VP-LP
Flow Control



Thank you

**Apply Medical
technology in order
to alleviate pain,
restore health and
extend life.**