

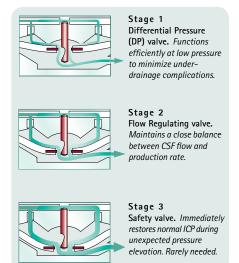


The smarter, simpler way to treat hydrocephalus.

For reliable, automatic CSF management without the need for programming, valve selection or manual adjustments, the self-adjusting OSV II Smart Valve is the right choice. It utilizes next-generation OSV technology to maintain physiological ICP and to automatically adjust to the patient's changing needs. Its unique, three-stage design enables surgeons to effectively manage both postural and vasogenic overdrainage with greater convenience and fewer complications.

There are also safety advantages over traditional valve technologies. For example, in the presence of strong magnetic fields – including MRI – programmable valves may unpredictably readjust themselves, alter flow rates and put patients at risk.^{1,2} The OSV II Smart Valve system contains no magnetic parts and is compatible with diagnostic procedures, such as MRI and CT scans.

The OSV II Smart Valve. Inspired design. Automatic response.



For more information: www.integra-ls.com/smartvalve



The OSV II[®] Smart Valve.™



A recent 5-year prospective multicenter study by Hanlo, et al., reveals an exceptionally low rate of valve-related complications with fewer incidents of mechanical dysfunction than other valves previously studied and no shunt-related deaths with OSV II Smart Valve technology. This research considered previous independent studies that tested other valves and showed a 1-year survival rate of 60%. Hanlo et al., found the OSV II Smart Valve survival rate at 5-years to be 62%.

"The valve's long-term stability, a 62% overall shunt survival rate at 5 years follow-up and low incidence of chronic overdrainage, led us to conclude that flow-regulating shunts can offer numerous clinical advantages over other valve technologies."

-Patrick W. Hanlo, M.D. PhD. 7/03

Stage I begins when CSF flow rate through the valve reaches 5ml/hr (DP between 30 and 80 mm H2O). It remains in this stage with flow rates up to 18 ml/hr (when DP ranges between 40 and 120 mm H2O).

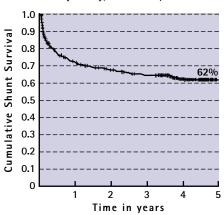
When DP increases, the valve automatically functions as a variable resistance flow regulator. When DP ranges between 120 and 300 mm H2O, it restricts the flow rate to between 18 and 30 ml/hr.

Should intraventricular pressure elevate abruptly, the shunt operates in a rapid flow-rate mode to facilitate IVP normalization. It then reverts to Stage II or Stage I, depending on conditions present.

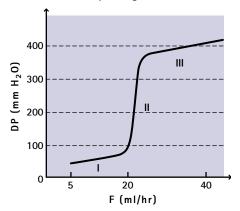
Convenient. Cost effective. Suitable for your patients.

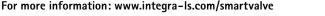
Conventional shunt systems can be time-consuming for the surgeon, inconvenient for the patient and costly for the healthcare provider. Because it adapts to the needs of both adult and pediatric patients, the OSV II Smart Valve minimizes the need and cost of stocking valves of varying pressure ranges.

Overall Shunt Survival at 5 Years (OSV II); Hanlo et al, 2003³



OSV II Operating Characteristics







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References

- 1. Miwa K, Kondo H, Sakai N. Pressure changes observed in Codman-Medos programmable valves following magnetic exposure and filliping. Childs Nerv Syst. 2001 Feb;17(3):150-3.
- 2. Schneider T, Knauff U, Nitsch J, Firsching R. Electromagnetic field hazards involving adjustable shunt valves in hydrocephalus. J Neurosurg. 2002 Feb;96(2):331-4.
- 3,4. Hanlo et al. 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 Journal of Neurosurgery 2003 Jul;99(1):52-7.

