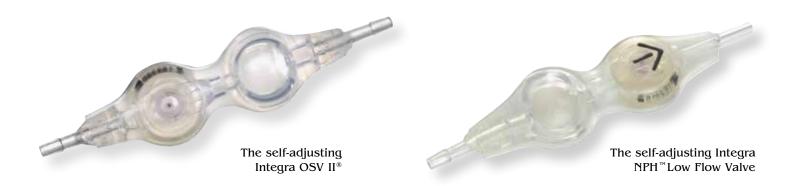
OSV•••II*>





The only self-adjusting valves that address all your patients' CSF flow requirements.



Automatic regulation. Without programming or adjustments.

For reliable, automatic CSF management without the need for programming, pressure selection, or manual adjustments, the solution is the self-adjusting technology featured in the Integra NPH and OSV II Valve Systems. Next generation OSV technology maintains physiological ICP and flow rates to automatically adjust to a 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. Additionally, the OSV II valve system contains no ferromagnetic parts and is safe to use with diagnostic procedures, such as MRI and CT scans. Conversely, programmable valves in the presence of strong magnetic fields—including MRI—may unpredictably readjust or alter flow rates.^{1,2}

With conventional valve systems, common complications such as overdrainage leave patients continually *adjusting* their lives around their shunt system. With OSV II and Integra NPH, the valve system is continually *adjusting* to them.

"The OSV II 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." ³

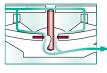
-Patrick W. Hanlo, M.D. PhD.

OSV••••||>

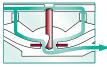


Designed to regulate flow at normal CSF production rate of 18-30 ml/hr.

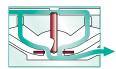
- Self adjusting OSV II Valve System utilizes advanced technology to maintain physiological ICP by automatically adjusting to your patients' needs.
- Incorporates benefits of a low opening pressure without the risk of overdrainage.
- Three stage design enables superior management of both postural and vasogenic overdrainage.
- Contains no magnetic parts and is safe to use with diagnostic procedures, including MRI and CT scans.



Stage I – Low Differential Pressure Begins when DP reaches 30-80 mm $\rm H_20$. The flow rate will be 5 ml/hr. Remains in Stage I with flow rates up to 18 ml/hr (DP will be between 40 and 120 mm $\rm H_20$).



Stage II - Flow Regulation When DP increases, the valve operates as a variable-resistance flow regulator. At DP ranges between 120 and 300 mm H₂0, it restricts flow between 18 and 30 ml/hr.

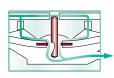


Stage III - Pressure Relief Mode Should intraventricular pressure (IVP) abruptly elevate, the rapid flow rate mode engages to facilitate IVP normalization. The valve then reverts to Stage II or I, depending upon conditions.

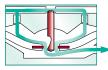
OSV II Self-Adjusting Operating Characteristics 400 T 300 E 200 100 5 20 F (ml/hr)

Designed for patients who require a reduced drainage rate of 8-17 ml/hr.

- Self adjusting Integra NPH Valve System is physiologically designed to meet the special needs of patients requiring a lower flow rate.
- Only self-adjusting valve that provides a CSF flow-regulation rate of approximately 12 ml/hr, since CSF production decreases as part of healthy aging.⁴
- Contains no magnetic parts and is safe to use with diagnostic procedures, including MRI and CT scans.



Stage I – Low Differential Pressure Begins when DP reaches 30-80 mm $\rm H_20$. The flow rate will be 5 ml/hr. Remains in Stage I with flow rates up to 8 ml/hr (DP will be between 40 and 120 mm $\rm H_20$).

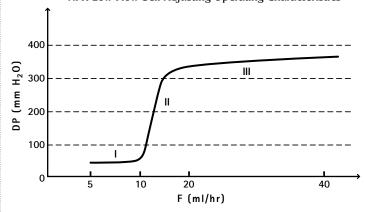


Stage II – Flow Regulation When DP increases, the valve operates as a variable resistance flow regulator. At DP ranges between 120 and 300 mm $\rm H_2O$, it restricts flow between 8 and 17 ml/hr.



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.

NPH Low Flow Self-Adjusting Operating Characteristics



ORDERING INFORMATION

ONE PIECE SYSTEM

Includes: Valve, 110cm Open-ended Striped Peritoneal Catheter, Right Angle Guide, Straight Polypropylene Connector, Ventricular Catheter Introducer, and Luer Connector

Integra NPH Low Flow Valve

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Product Number	Antechamber	Product Details
909518	Yes	Integral 7 cm Ventricular Catheter
909519	No	Integral 7 cm Ventricular Catheter
909506	Yes	Integral 9cm Ventricular Catheter
909505	No	Integral 9cm Ventricular Catheter
909504	Yes	Integral 13cm Ventricular Catheter

OSVII

Product Number	Antechamber	Product Details
909718	Yes	7 cm Ventricular Catheter
909719	No	7 cm Ventricular Catheter
909704	Yes	13cm Ventricular Catheter
909705	No	9cm Ventricular Catheter
909706	Yes	9cm Ventricular Catheter

BURR HOLE SYSTEM

Includes: 6.4mm Integral Burr Hole Cap, 110cm Open-ended Striped Drainage Catheter, Straight Polypropylene Connector, Regular and Shallow Polypropylene Burr Hole Reservoirs, and Luer Connectors

Integra NPH Low Flow Valve

Product Number	Antechamber	Product Details
909520	No	15 cm Full Barium Ventricular
		Catheter with Radiopaque Dots
909521	Yes	15cm Full Barium Ventricular
		Catheter with Radiopaque Dots
9OS521	Yes	15 cm Barium Striped Ventricular
		Catheter with Numbered Markers

OSVII

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Product Number	Antechamber	Product Details
909721	Yes	15cm Full Barium Ventricular
		Catheter with Radiopaque Dots
909720	No	15cm Full Barium Ventricular
		Catheter with Radiopaque Dots
9OS721	Yes	15 cm Barium Striped Ventricular
		Catheter with Numbered Markers

TWO PIECE SYSTEM

Includes: Valve, Integral 110cm Open-ended Striped Peritoneal Catheter, Right Angle Guide, Straight Polypropylene Connector, and Luer Connector

Integra NPH Low Flow Valve

Product Number	Antechamber	Product Details	
909512	Yes	15 cm Ventricular Catheter	
909513	No	15cm Ventricular Catheter	
909514	Yes	15 cm Ventricular Catheter	
		and 65cm Tunneler	
909515	No	15 cm Ventricular Catheter	
		and 65cm Tunneler	
909507	Yes	Malleable 65cm Tunneler	
909508	No	Malleable 65cm Tunneler	
909507S	Yes	Nothing Included	
909508S	No	Nothing Included	

OSV II

USV II		
Product Number	Antechamber	Product Details
909712	Yes	15 cm Straight Ventricular Catheter,
		Radiopaque dots, Introducing Rod,
		& Right Angle Guide
909713	No	15 cm Straight Ventricular Catheter,
		Radiopaque dots, Introducing Rod,
		& Right Angle Guide
909707	Yes	65 cm Malleable tunneler,
		No Ventricular Catheter
909708	No	65 cm Malleable tunneler,
		No Ventricular Catheter
909707S	Yes	No Ventricular Catheter or Tunneler
909708S	No	No Ventricular Catheter or Tunneler

INDIVIDUAL UNITS

Integra NPH Low Flow Valve

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	Product Number	Antechamber	Product Details
	909500	Yes	Valve with Integral Polysulfone
			Connectors, Luer Connector,
			Priming Tubing
	909501	No	Valve with Integral Polysulfone
			Connectors, Luer Connector,
			Priming Tubing

OSV II

USY II		
Product Number	Antechamber	Product Details
909700	Yes	Valve with Integral Polysulfone
		Connectors, Luer Connector,
		Priming Tubing
909701	No	Valve with Integral Polysulfone
		Connectors, Luer Connector,
		Priming Tubing

INDIVIDUAL COMPONENTS

Product Number	Antechamber	Product Details
9MD102A	N/A	15 cm Full Barium Ventricular
		Catheter with Radiopaque Dots
9MD102B	N/A	15 cm Barium Striped Ventricular
		Catheter with Numbered Markers
9MZ1011	N/A	110cm Open-Ended, Striped,
		Peritoneal Catheter
991002	N/A	Right Angle Guide (box/5)



OPERATE WITH CONFIDENCE



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Plainsboro, NJ 08536 www.Integra-LS.com















Integra LifeSciences Corporation Customer Service:

REFERENCES:

- 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. J. 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 fl ow-regulating shunt was used. Journal of Neurosurgery 2003 Jul;99(1):52-7.

 4. May C, et al. Cerebrospinal fluid production is reduced
- in healthy aging. Neurology 1990 March;40:500-503.

INDICATIONS:

The Integra NPH™ Low Flow Valve is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

The OSV II® System is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.



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