Codman®
SPECIALTY SURGICAL

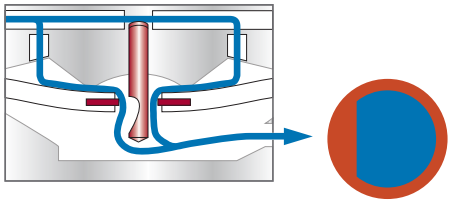
A DIVISION OF INTEGRA LIFESCIENCES

Flow Regulating Valves

INTEGRA®
LIMIT UNCERTAINTY

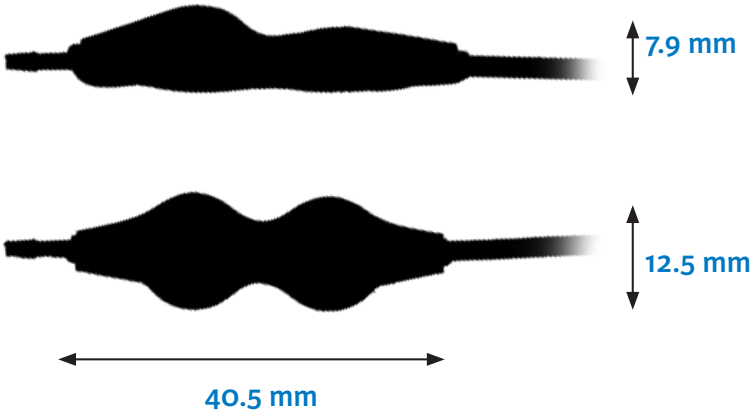
OSV II® Valve System

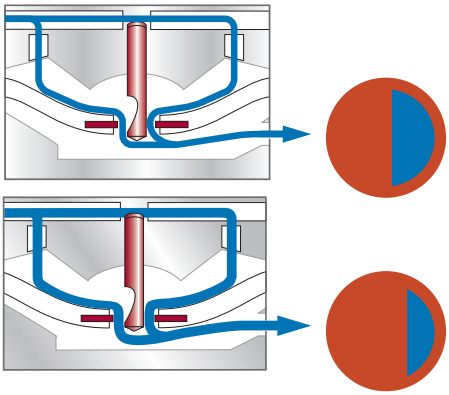
Introduced in 1987, the Orbis-Sigma Valve was the first valve to manage hydrocephalus through flow-regulation rather than conventional differentialpressure regulation. The valve operates a 3-stage, variable resistance mechanism that regulates flow through the valve (Stage II) at a rate close to that of CSF secretion (around 20 ml/h).



STAGE I – 30-120 mm H_2O Differential Pressure (DP) Stage.

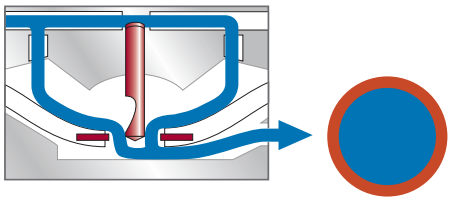
This stage begins when the flow rate reaches 5ml/h.





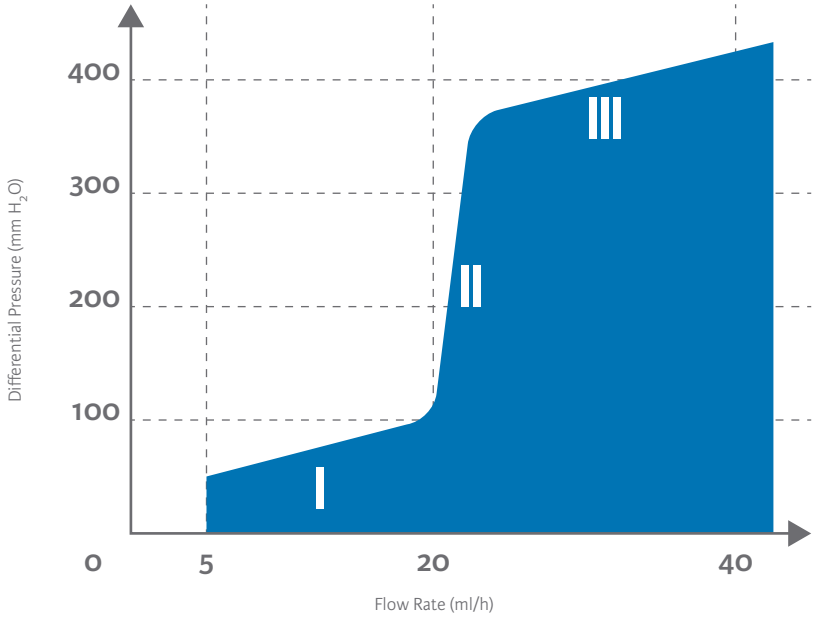
STAGE II – 120-300 mm H_2O Flow Regulating Stage.

Maintains a close balance between CSF flow and production rate, restricting flow around 20 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O Safety Stage.

Immediately restores normal ICP during unexpected pressure elevation. Rarely needed.



Indications For Use

The OSV II® Valve 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.

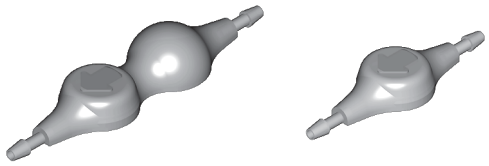
Contraindications

This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body (septicemia, bacteremia). Atrial shunting is not advised for patients with congenital heart disease or other serious cardiopulmonary abnormalities.

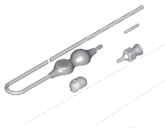
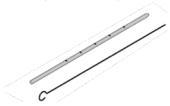
The OSV II Valve System should not be implanted in patients with untreated choroid plexus tumors. Such tumors produce CSF at rates in excess of the specification of the flow regulation Stage II, and the OSV II Valve System would underdrain under these conditions. The OSV II Valve System should not be used for drainage of extraventricular fluid collections such as hygromas or cysts; such conditions are typically treated with very low differential pressure valves.

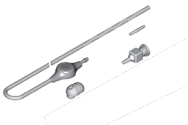
OSV II® Valve Unit

Catalog#	Description
909700	Valve with Antechamber
909701	Valve without Antechamber

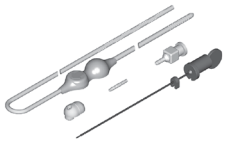


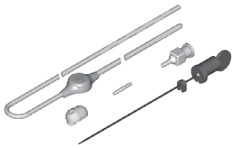
OSV II Two-Piece Shunt System

		Catalog#			
Valve with Antechamber	Description	909707S	909712	909707	909714
	• Integral polysulfone connector, open-ended, striped drainage catheter (110 cm, F7) • Straight, polypropylene connector • Luer connector • Right angle guide	✔	✔	✔	✔
	+ Straight Ventricular Catheter (15 cm, F8) + Introducing Rod	-	✔	-	✔
	+ Malleable Tunneler (65 cm)	-	-	✔	✔

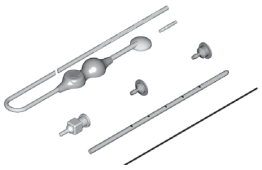
		Catalog#			
Valve without Antechamber	Description	909708S	909713	909708	909715
	• Integral polysulfone connector, open-ended, striped drainage catheter (110 cm, F7) • Straight, polypropylene connector • Luer connector • Right angle guide	✔	✔	✔	✔
	+ Straight Ventricular Catheter (15 cm, F8) + Introducing Rod	-	✔	-	✔
	+ Malleable Tunneler (65 cm)	-	-	✔	✔

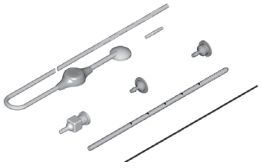
OSV II® One-Piece Shunt System

Valve with Antechamber	Description	Catalog# 909718	909706	909704
	• Integral straight ventricular catheter (F8) and open-ended, striped drainage catheter (110cm, F7) • Ventricular catheter introducer • Right angle guide • Straight, polypropylene connector • Luer connector	• Attached Ventricular catheter 7 cm	• Attached Ventricular catheter 9cm	• Attached Ventricular catheter 13cm

Valve without Antechamber	Description	Catalog# 909719	909705
	• Integral straight ventricular catheter (F8) and open-ended, striped drainage catheter (110cm, F7) • Ventricular catheter introducer • Right angle guide • Straight, polypropylene connector • Luer connector	• Attached Ventricular catheter 7 cm	• Attached Ventricular catheter 9cm

OSV II™ Burr Hole Shunt System

Valve with Antechamber	Description	Catalog# 909721
	• Integral 6.4 mm burr hole cap, and openended, striped drainage catheter (110cm, F7) • Straight polypropylene connector • Regular and shallow polypropylene burr hole reservoirs • Luer connector • Straight ventricular catheter (15cm, F8) with radiopaque length dots, introducing rod	✔

Valve without Antechamber	Description	Catalog# 909720
	• Integral 6.4 mm burr hole cap, and openended, striped drainage catheter (110cm, F7) • Straight polypropylene connector • Regular and shallow polypropylene burr hole reservoirs • Luer connector • Straight ventricular catheter (15cm, F8) with radiopaque length dots, introducing rod	✔

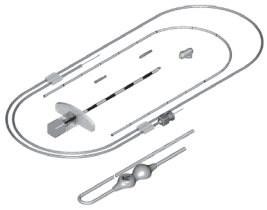
OSV II® Lumbar Valve System

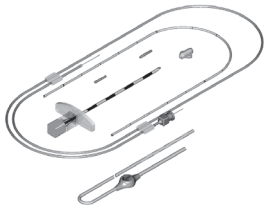
Indications For Use

The OSV II® Lumbar Valve System is an implantable system used in the treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.

Contraindications

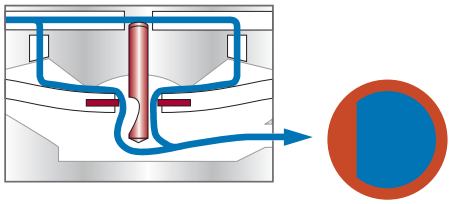
The OSV II Lumbar Valve System should not be used in patients with non-communicating hydrocephalus. This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body (septicemia, bacteremia). The OSV II Lumbar Valve System should not be implanted in patients with untreated choroid plexus tumors. Such tumors produce CSF at rates in excess of the specification of the flow regulation Stage II, and the OSV II Lumbar Valve System would underdrain under these conditions.

Valve with Antechamber	Description	Catalog# 909711
	• With integral proximal tubing (5cm, F8), and open ended, striped drainage catheter (110cm, F7) • Closed tip lumbar catheter (80cm, F5) • Guidewire in dispenser • 14G Tuohy needle • Stepdown polypropylene connector (F8/F5) • Luer connector • Suture clamp (F5) • Straight polypropylene connector	✔

Valve without Antechamber	Description	Catalog# 909710
	• With integral proximal tubing (5cm, F8), and open ended, striped drainage catheter (110cm, F7) • Closed tip lumbar catheter (80cm, F5) • Guidewire in dispenser • 14G Tuohy needle • Stepdown polypropylene connector (F8/F5) • Luer connector • Suture clamp (F5) • Straight polypropylene connector	✔

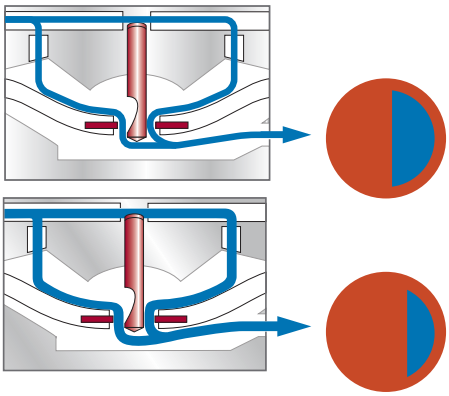
OSV II Low Pro™ Valve

OSV II Low Pro™ Valve utilizes the Self-Adjusting technology in a lower profile design to suit the needs of various patient populations



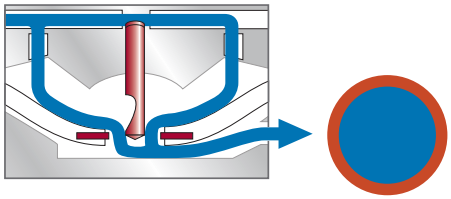
STAGE I – 30-120 mm H_2O Differential Pressure (DP) Stage.

This stage begins when the flow rate reaches 5ml/h.



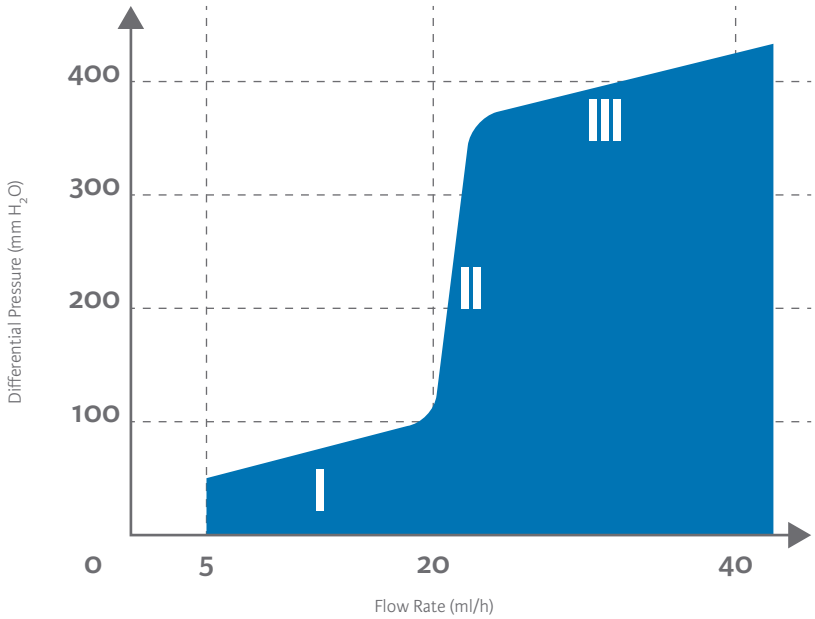
STAGE II – 120-300 mm H_2O Flow Regulating Stage.

Maintains a close balance between CSF flow and production rate, restricting flow around 20 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O Safety Stage.

Immediately restores normal ICP during unexpected pressure elevation. Rarely needed.



Indications For Use

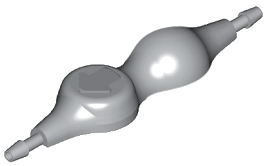
The OSV II® Valve System is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

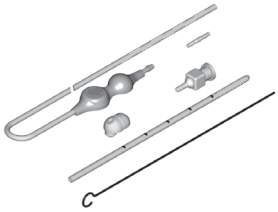
Contraindications

This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body (septicemia, bacteremia). Atrial shunting is not advised for patients with congenital heart disease or other serious cardiopulmonary abnormalities. The OSV II Valve System should not be implanted in patients with untreated choroid plexus tumors. Such tumors produce CSF at rates in excess of the specification of the flow regulation Stage II, and the OSV II Valve System would underdrain under these conditions. The OSV II Valve System should not be used for drainage of extraventricular fluid collections such as hygromas or cysts; such conditions are typically treated with very low differential pressure valves.

OSV II Low Pro™ Valve Unit

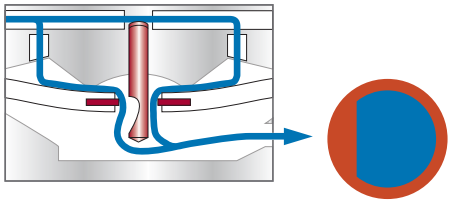
Catalog#	Description
909700P	Valve with Low Profile Antechamber and integral connectors



Valve with Low Profile Antechamber	Description	Catalog# 909712P
	• Integral polysulfone connector, open-ended, striped drainage catheter (110 cm, F7) • Separated straight Ventricular Catheter (15 cm, F8) with radiopaque dots every 2cm • Straight, polypropylene connector • Luer connector • Right angle guide • Introducing Rod	✔

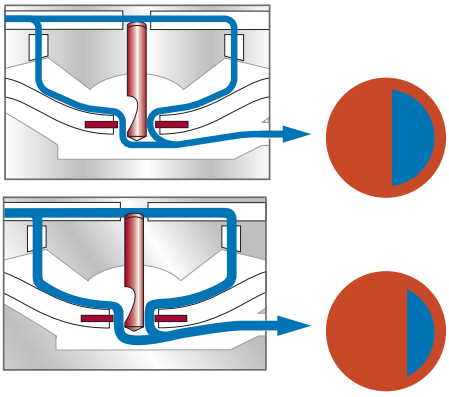
Integra® Flow Regulating Valve Low Flow, Standard

The Integra® Flow Regulating Valve Low Flow, Standard and Integra® Flow Regulating Valve Low Flow, Mini are implantable hydrocephalus valve systems for controlled cerebrospinal fluid (CSF) drainage from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium. Unlike conventional valves, the Integra Flow Regulating Valve Low Flow is a variable resistance valve that maintains drainage at a constant rate, between 8 and 17 ml/hr, within the physiological range of intracranial pressure (ICP). The mechanism incorporates a safety pressure relief mode to prevent accidental intracranial hypertension. The Integra® Flow Regulating Valve Low Flow delivers positionindependent performance, without programming or frequent adjustments.



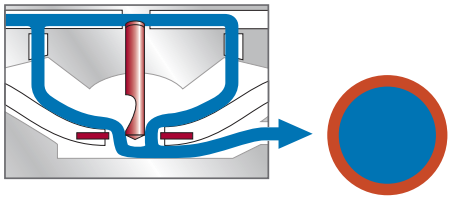
STAGE I – 30-120 mm H_2O Differential Pressure (DP) Stage.

This stage begins when the flow rate reaches 5ml/h.



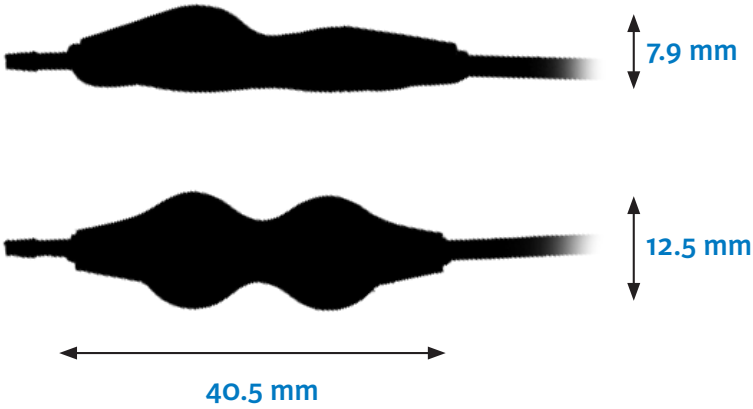
STAGE II – 120-300 mm H_2O Flow Regulating Stage.

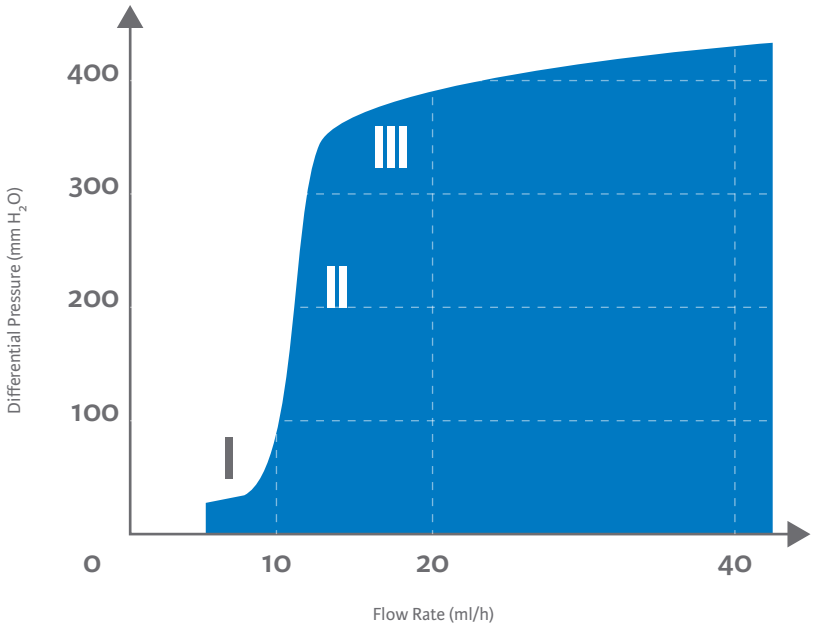
Maintains a close balance between CSF flow and production rate, restricting flow around 10 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O Safety Stage.

Immediately restores normal ICP during unexpected pressure elevation. Rarely needed.





Indications For Use

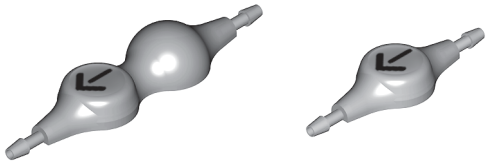
The Integra Flow Regulating Valve Low Flow is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

Contraindications

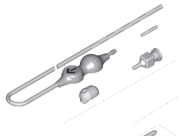
This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body (septicemia, bacteremia). Atrial shunting is not advised for patients with congenital heart disease or other serious cardiopulmonary abnormalities. The Integra Flow Regulating Valve Low Flow should not be implanted in patients with untreated choroid plexus tumors. Such tumors produce CSF at rates in excess of the specification of the flow regulation Stage II, and the Valve would underdrain under these conditions. Integra Flow Regulating Valve Low Flow should not be used for drainage of extraventricular fluid collections such as hygromas or cysts ; such conditions are typically treated with very low differential pressure valves.

Integra® Flow Regulating Valve Low Flow, Standard, Valve Unit

Catalog#	Description
909500	Valve with Antechamber
909501	Valve without Antechamber

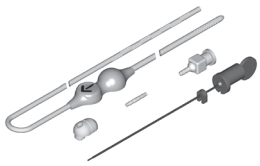


Integra® Flow Regulating Valve Low Flow, Standard, Two-Piece Shunt System

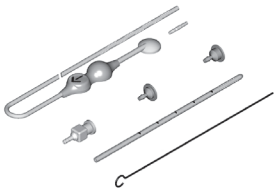
Valve with Antechamber	Description	Catalog# 909507S	909512	909514
	• Integral polysulfone connector, open-ended, striped drainage catheter (110 cm, F7) • Straight, polypropylene connector • Luer connector • Right angle guide	✔	✔	✔
	• Straight Ventricular Catheter (15 cm, F8) • Introducing Rod	-	✔	✔
	• Malleable Tunneler (65 cm)	-	-	✔

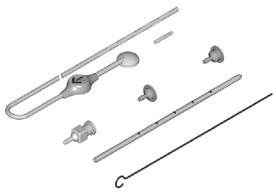
Valve without Antechamber	Description	Catalog# 909508S	909513
	• Integral polysulfone connector, open-ended, striped drainage catheter (110 cm, F7) • Straight, polypropylene connector • Luer connector • Right angle guide	✔	✔
	• Straight Ventricular Catheter (15 cm, F8) • Introducing Rod	-	✔

Integra® Flow Regulating Valve Low Flow, Standard, One-Piece Shunt System

Valve with Antechamber	Description	Catalog# 909506
	• Integral straight ventricular catheter (F8) and open-ended, striped drainage catheter (110cm, F7) • Ventricular catheter introducer • Right angle guide • Straight, polypropylene connector • Luer connector	• Attached Ventricular catheter 9 cm

Integra® Flow Regulating Valve Low Flow, Standard, Burr Hole Shunt System

Valve with Antechamber	Description	Catalog# 909521
	• Integral 6.4 mm burr hole cap, and open-ended striped drainage catheter (110cm, F7) • Straight polypropylene connector • Two (2) polypropylene burr hole reservoirs • Luer connector • Straight ventricular catheter (15cm, F8) with radiopaque length dots, introducing rod	✔

Valve without Antechamber	Description	Catalog# 909520
	• Integral 6.4 mm burr hole cap, and open-ended striped drainage catheter (110cm, F7) • Straight polypropylene connector • Two (2) polypropylene burr hole reservoirs • Luer connector • Straight ventricular catheter (15cm, F8) with radiopaque length dots, introducing rod	✔

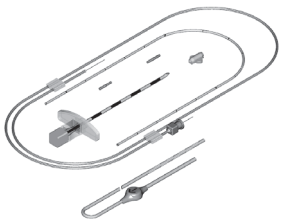
Indications For Use

The Integra® Flow Regulating Valve Low Flow, Lumbar is an implantable system used in the treatment of patients with communicating hydrocephalus to shunt CSF from the lumbar subarachnoid region to the peritoneal cavity.

Contraindications

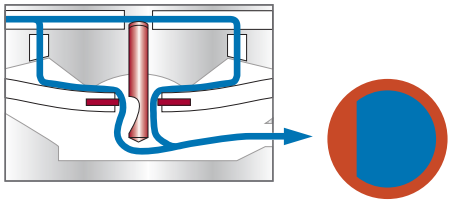
The Integra Flow Regulating Valve Low Flow, Lumbar should not be used in patients with non-communicating hydrocephalus. This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body (septicemia, bacteremia). The Integra Flow Regulating Valve Low Flow, Lumbar should not be implanted in patients with untreated choroid plexus tumors. Such tumors produce CSF at rates in excess of the specification of the flow regulation Stage II, and the Integra® Flow Regulating Valve Low Flow, Lumbar would underdrain under these conditions.

Integra Flow Regulating Valve Low Flow, Lumbar, Lumbo Peritoneal Shunt System

Valve without Antechamber	Description	Catalog# 909510
	• With integral proximal tubing (5cm, F8), and open-ended, striped drainage catheter (110cm, F7) • Closed tip lumbar catheter (80cm, F5) • Guidewire in dispenser • 14G Tuohy needle • Stepdown polypropylene connector (F8/F5) • Luer connector • Suture clamp (F5) • Straight polypropylene connector	✔

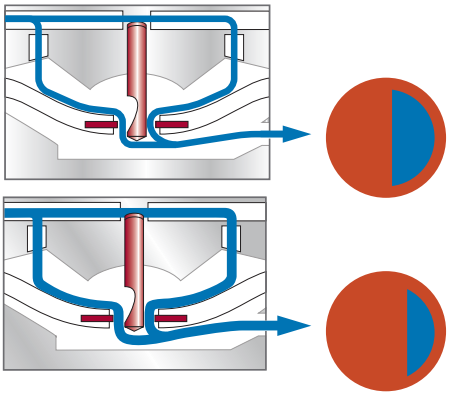
Integra® Flow Regulating Valve Low Flow, Mini

Integra® Flow Regulating Valve Low Flow, Mini utilizes the Self-Adjusting technology in a lower profile design to suit the needs of various patient populations.



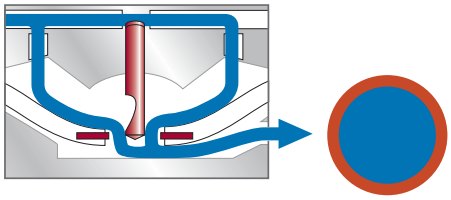
STAGE I – 30-120 mm H_2O Differential Pressure (DP) Stage.

This stage begins when the flow rate reaches 5ml/h.



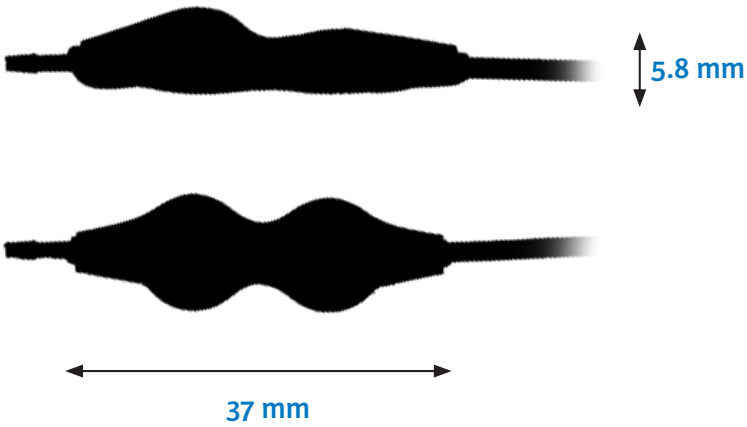
STAGE II – 120-300 mm H_2O Flow Regulating Stage.

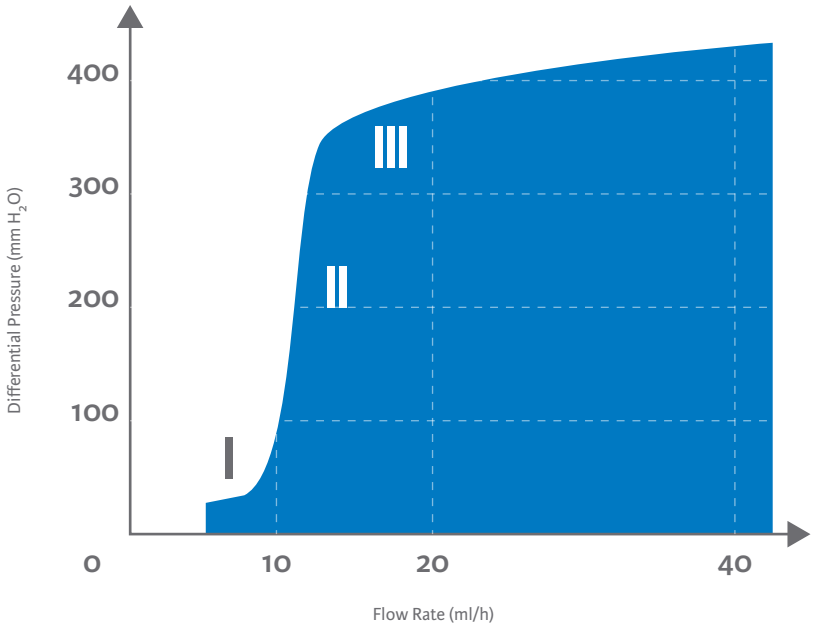
Maintains a close balance between CSF flow and production rate, restricting flow around 10 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O Safety Stage.

Immediately restores normal ICP during unexpected pressure elevation. Rarely needed.





Indications For Use

The Integra Flow Regulating Valve Low Flow 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.

Contraindications

This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body (septicemia, bacteremia). Atrial shunting is not advised for patients with congenital heart disease or other serious cardiopulmonary abnormalities. The Integra Flow Regulating Valve Low Flow should not be implanted in patients with untreated choroid plexus tumors. Such tumors produce CSF at rates in excess of the specification of the flow regulation Stage II, and the Valve would underdrain under these conditions. Integra Flow Regulating Valve Low Flow should not be used for drainage of extraventricular fluid collections such as hygromas or cysts; such conditions are typically treated with very low differential pressure valves.

Integra® Flow Regulating Valve Low Flow, Mini, Valve Unit

Catalog#	Description
909 500P	Valve alone with low profile antechamber and 2 integral connectors

Integra® Flow Regulating Valve Low Flow, Mini, Two-Piece Shunt System

	Catalog#	
Description	**909512P**	**9OS512P**
Valve with small antechamber, One integral connector, Striped peritoneal catheter (110 cm, F7), Right angle guide, Straight connector, Luer connector	✔	✔
Straight ventricular catheter (15 cm) with radiopaque length dots every 2 cm, introducing rod	✔	-
Straight ventricular catheter (15 cm) with printed length marks every 1 cm, introducing rod	-	✔

Page intentianally left blank

Codman SPECIALTY SURGICAL
A DIVISION OF INTEGRA LIFESCIENCES

Page intentianally left blank

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

For more information or to place an order, please contact:

United States, Canada, Asia, Pacific, Latin America
USA 800-654-2873 ▪ 888-980-7742 fax
International +1 609-936-5400 ▪ +1 609-750-4259 fax
integralife.com

INTEGRA®
LIMIT UNCERTAINTY