

Integra

Regulated Flow with
OSV II™, OSV II Low Pro™,
Integra® NPH Low Flow valves

Simplify your choices
with a smart shunt solution



INTEGRA 
LIMIT UNCERTAINTY

Indications / Contraindications

OSV II™ Valve System

Introduced in 1987, the Orbis-Sigma Valve was the first valve to manage hydrocephalus through flow-regulation rather than conventional differential-pressure 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). The OSV II™ Valve delivers position-independent performance, without programming or frequent adjustments.

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, septicemia, bacteremia) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body. 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

OSV II Low Pro™ Valve utilizes the Self-Adjusting technology in a lower profile design to suit the needs of various patient populations. The OSV II Low Pro™ Valve delivers position-independent performance, without programming or frequent adjustments.

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, septicemia, bacteremia) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body. 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.

Integra® NPH Low Flow Valve

The Integra® NPH Low Flow Valve delivers position-independent performance, without programming or frequent adjustments. It is designed for patients who require a reduced drainage of 10 ml/h.

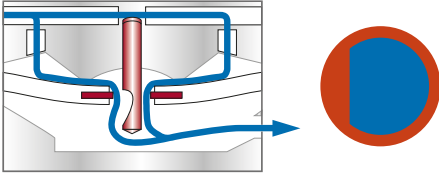
Indications For Use

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.

Contraindications

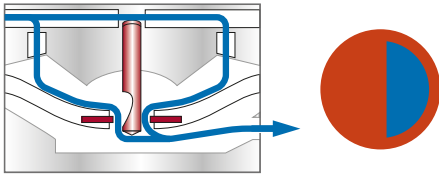
This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis, septicemia, bacteremia) is suspected. It is advisable to postpone valve implantation if an infection is present anywhere in the body. Atrial shunting is not advised for patients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

3 Steps Flow Regulation



STAGE I – 30-120 mm H₂O Differential Pressure (DP) Valve

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

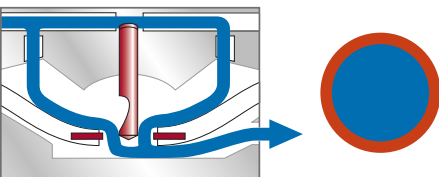


STAGE II – 120-300 mm H₂O Flow Regulating Valve

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

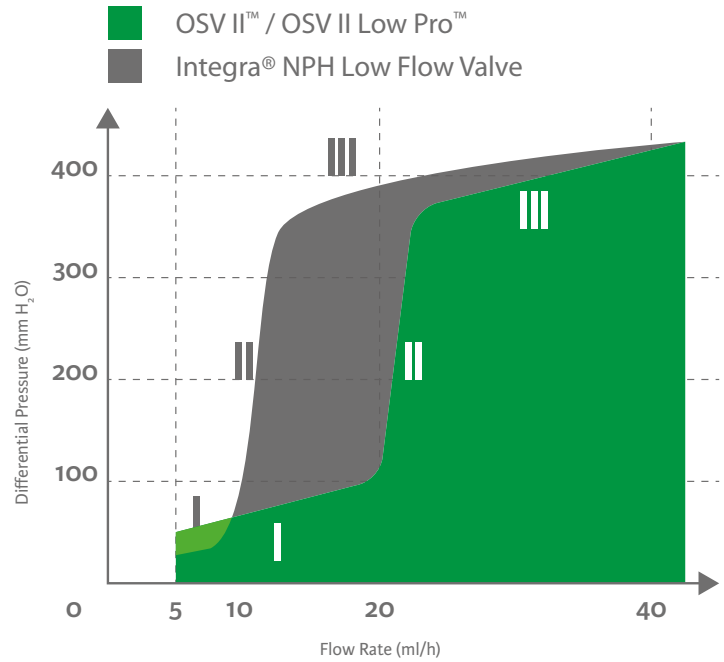


Maintains a close balance between CSF flow and production rate, restricting flow around **20 ml/h**, whatever the differential pressure is.



STAGE III – Above 300 mm H₂O Safety Valve

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



SIMPLIFY YOUR CHOICES WITH A SMART SHUNT SOLUTION

PER-OP

SIMPLIFY YOUR SHUNT CHOICE

- **ONE SIZE** for **PAEDIATRICS AND ADULTS** under 60 years old (OSV II™ valve)
- Flow Regulated Shunt mechanism designed to **MANAGE VASOGENIC AND POSTURAL DAILY PRESSURE CHANGES**^{4,8}
- **NO FURTHER SETTING ADJUSTMENT** needed as self-adjusting
- **NO NEED TO FIND** the right **PROGRAMMER** in **EMERGENCY CASES**

SIMPLIFY YOUR SETTING CHOICES

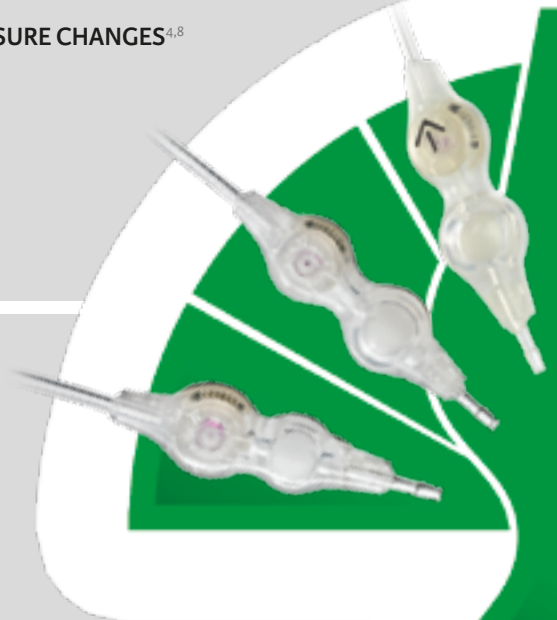
- **NO NEED TO SELECT ANY PRESSURE SETTING** (thanks to Flow Regulated mechanism)
- **NO NEED TO ADD** a Gravity Compensating Accessory (GCA) or Anti-Siphon Device (ASD)⁴
- **NO NEED TO CHANGE GCA/ASD** when the patient grows up⁴

SIMPLIFY YOUR SHUNT PLACEMENT

- Free shunt placement as **NO DIAGNOSTIC IMAGE DISTORTION** with FR shunts⁴
- **NO RESTRICTION OF PLACEMENT** (no need to position at 0 level as for ASD)⁴
- Can be placed in **VENTRICULAR OR LUMBAR** regions without any restriction (ASD need to be placed in ventricular region)⁴
- Flow Regulated shunts **DON'T NEED TO BE PLACED VERTICALLY** compared to GCA⁴

SIMPLIFY YOUR SURGICAL TECHNIQUE

- **FEW CONNECTIONS** as hydrostatic management device is part of the valve design^{1,3,4}
- Many **CONFIGURATIONS AVAILABLE** to fit your patients needs (1, 2 or 3 piece(s), Burr Hole, Lumbar)



For complete product information, please see the Instructions for Use accompanying each product.

POST-OP

SIMPLIFY YOUR PATIENT MANAGEMENT

- **BETTER OVERALL SHUNT SURVIVAL RATE**
(62% at 5 years¹ compared to 53.1% for programmable shunts²)
- **LIMIT OVERDRAINAGES**
as Flow Regulated manages both postural & vasogenic events^{1,3,7}:
overdrainage complication rate from 2.6% to 9.8% for DP & from 0% to 2% for Flow Regulated
- **REDUCE MECHANICAL COMPLICATION RISK**
due to hydrodynamic properties of shunt (overdrainage, underdrainage & late obstruction):
22% for DP compared to 5% for FR shunts at 1 year³
- **REDUCE SLITLIKE VENTRICLES**
10.8% for DP, 10.5% for Delta & 3.6% for Flow Regulated⁵
- **NO ASD RELATED COMPLICATIONS**

SIMPLIFY THE MRI ENVIRONMENT MANAGEMENT

- **NO IMAGE DISTORTION**
as no metal component⁴
- **NO RISK OF PRESSURE SETTING CHANGES**
by MRI or strong magnetic field as no metal component^{4,6}
(MRI caused resetting in 26.8% of cases with DP programmable shunts²)
- **NO NEED OF SYSTEMATIC CONTROL**
after MRI procedure
- **NO GCA NEEDED**

OSV II Low Pro™
OSV II™
Integra® NPH
Low Flow valves



SIMPLIFY

YOUR CHOICES
WITH A SMART SHUNT SOLUTION

SIMPLIFY YOUR CHOICES WITH A SMART SHUNT SOLUTION

Product References

OSV II™ Valve Unit

With Antechamber	Without Antechamber
909700	909701



OSV II Low Pro™ Valve Unit

With Low Profile Antechamber and integral connectors
909700P



Integra® NPH Low Flow Valve, Valve Unit

With Antechamber	Without Antechamber
909500	909501



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