INTEGRA®

LIMIT UNCERTAINTY

Integra®
CSF Management
Product Catalogue

INTEGRA
LIMIT UNCERTAINTY

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Pricing:
Prices stated in specific written quotations are firm for thirty days from the date given, and are otherwise subject to change without prior notice. Pricing terms stated on written agreements are governed by such agreements.

Administrative Fees:
For each order, an administrative fee amounting to 25 Euros, 25 GBP or 30 FCH will be applied.

Ordering Procedure:
A written purchase order on the customer's form may be requested for purchases of Integra LifeSciences products.

Acceptance of Orders:
Orders are accepted upon approval by Integra Customer Service.

Return Policy:
- Authorization from Customer Service must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
- Non-sterile product must be returned in unused saleable condition in original package.
- Custom or special order products will not be accepted for credit.
- Credit will be issued for goods returned prior to ninety days from ship date with a 20% restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.

Customer Services Contact Information:

International
+33 (0)4 37 47 59 50 / +33 (0)4 37 47 59 25 (Fax)
csemea@integralife.com

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- Any covered product that is placed by INTEGRA under a lease, rental or installment purchase agreement and that requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement.

If any covered defect occurs during the warranty period or term of such placement agreement, the purchaser or distributor should communicate directly with INTEGRA. If purchaser or distributor seeks to invoke the terms of this warranty, the product must be returned to INTEGRA. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to INTEGRA shall be at sender's risk. INTEGRA's sole responsibility under this warranty shall be repair or replacement, at INTEGRA's sole discretion at INTEGRA's expense, subject to the terms of this warranty and applicable agreements.

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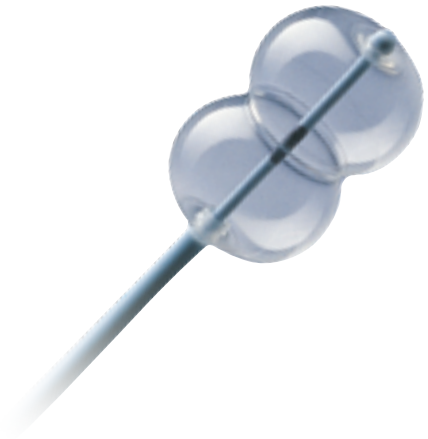
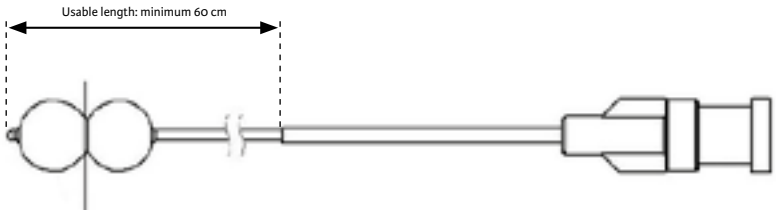
INTEGRA®
CSF Management
I. Neuro Endoscopy
NeuroBalloon™ Catheter

NeuroBalloon™ Catheter

The NeuroBalloon™ Catheter is designed for dilation of prepunctured cerebral membrane fenestrations such as Endoscopic Third Ventriculostomies (ETVs). The unique double balloon design assures its positioning. The dilation of the membrane can be observed through the transparent silicone material of the NeuroBalloon™ catheter. This positioning is especially important during ETVs.





	Package content	Reference
	• 60 cm minimum usable length polyurethane catheter with female luer lock connector and silicone balloon • Compatible with a F4 working channel lumen diameter: 1.35 mm minimum • Diameter of the waist when inflated with 0.6 ml (cc) of air and after a pre-inflation with 1 ml (cc): 3.5 mm minimum • Diameter of the waist when inflated with 1 ml (cc) of air and after a pre-inflation with 1 ml (cc): 6.0 mm maximum	7CBD10
	• **1 ml syringe (supplied sterile)**	

Indications For Use

The NeuroBalloon™ Catheter is intended for dilatation of cerebral membrane fenestrations under direct or endoscopic visualization during intracranial procedures.

WARNING

Not for intravascular use. Do not use in rigid neuro-tissues, such as dilatation of aqueducts stenosis or thick membranes of arachnoid cysts, since the balloon is not designed to withstand high pressure. If the dilatation of the target site is not successful with 1 ml of air, the tissue may be too rigid for this instrument. Over-inflation should not be attempted as it may damage the balloon; another technique should be used.

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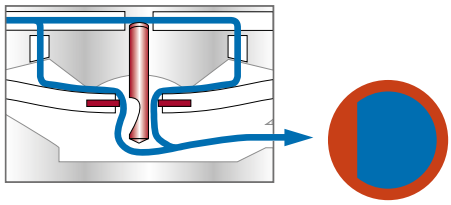
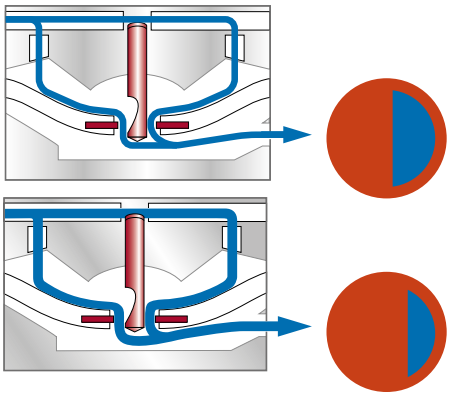
INTEGRA®
CSF Management
II. Flow Regulated Valves

OSV II™ Valve System

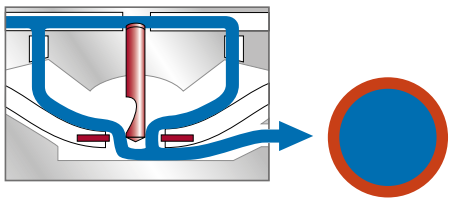
Introduced in 1987, the Orbis-Sigma Valve was the first valve to manage hydrocephalus through flow-regulation rather than conventional differential-pressure regulation. The valve operates a 3-stage, variable resistance mechanism that regulates flow through the valve (Stage II) at a rate close to that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



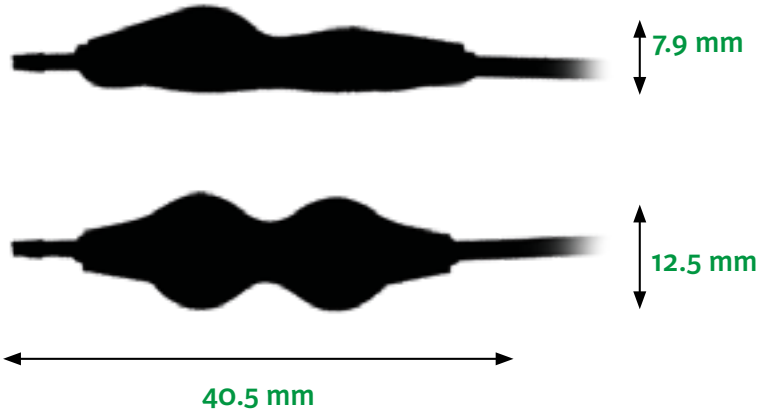
STAGE I – 30-120 mm H_2O Differential Pressure (DP) Valve.
This stage begins when the flow rate reaches 5ml/h.

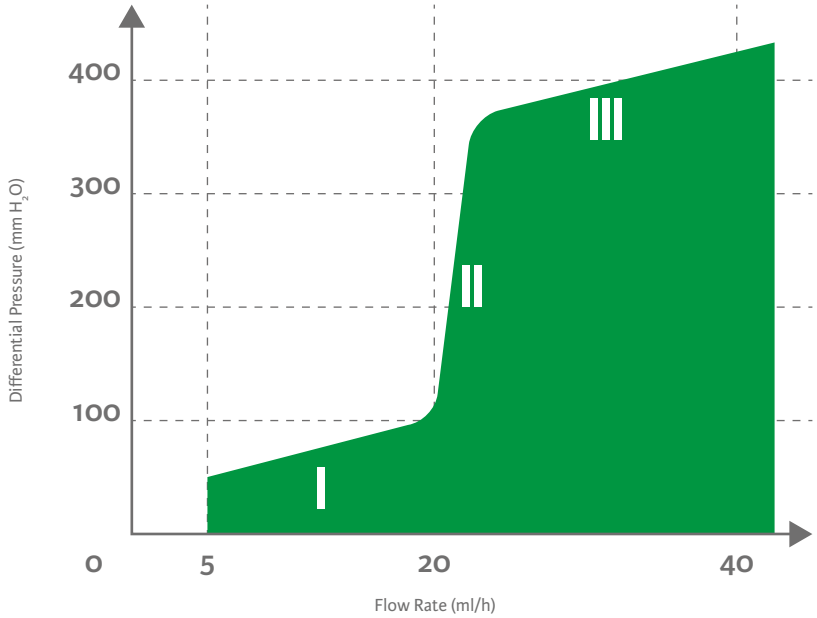


STAGE II – 120-300 mm H_2O Flow Regulating Valve.
Maintains a close balance between CSF flow and production rate, restricting flow around 20 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O Safety Valve.
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

Reference	
With Antechamber	**Without Antechamber**
909700	**909701**

OSV II™ Two-Piece Shunt System

		Reference			
With Antechamber	**Package content**	**909707S**	**909712**	**909707**	**909714**
	• Valve With Antechamber • 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)	–	–	✔	✔

		Reference			
Without Antechamber	**Package content**	**909708S**	**909713**	**909708**	**909715**
	• Valve Without Antechamber • 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

With Antechamber	Package content	Reference 909718	Reference 909706	Reference 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 9 cm	• Attached Ventricular catheter 13 cm

Without Antechamber	Package content	Reference 909719	Reference 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 9 cm

OSV II™ Burr Hole Shunt System

With Antechamber	Package content	Reference 909721
	• Integral 6.4 mm burr hole cap, and open-ended, 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	✔

Without Antechamber	Package content	Reference 909720
	• Integral 6.4 mm burr hole cap, and open-ended, 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

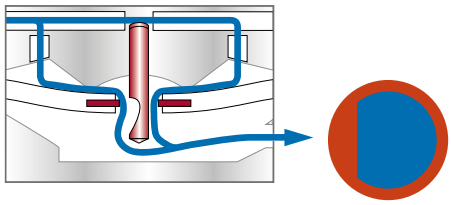
The OSV II™ Lumbar Valve System should not be used in patients with non-communicating hydrocephalus. This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation if an infection 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.

With Antechamber	Package content	Reference 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	✔

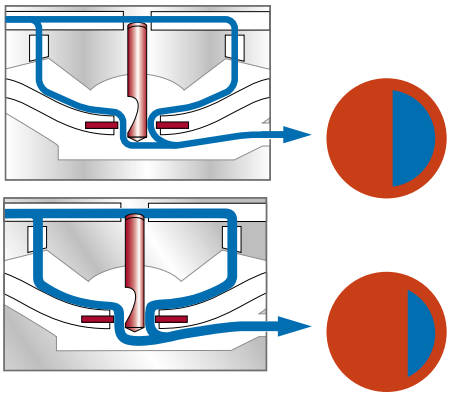
Without Antechamber	Package content	Reference 909710
	• With integral proximal tubing (5cm, F8), and open ended, striped drainage catheter (110cm, F7) • Closed tip lumbar catheter (80cm, F5) • Guidewire in dispenser • 14G Tuohy needle • Stepdown polypropylene connector (F8/F5) • Luer connector • Suture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

OSV II Low Pro™ Valve

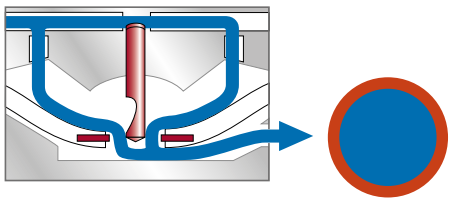
OSV II Low Pro™ Valve utilizes the Self-Adjusting technology in a lower profile design to suit the needs of various patient populations



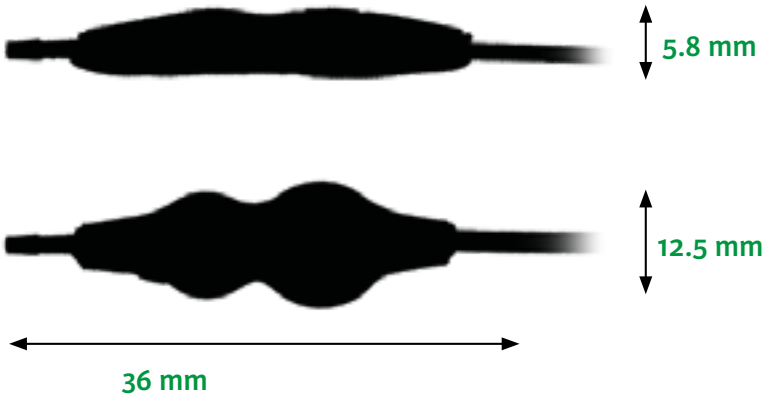
STAGE I – 30-120 mm H_2O
Differential Pressure (DP) Valve.
This stage begins when the flow rate reaches 5ml/h.

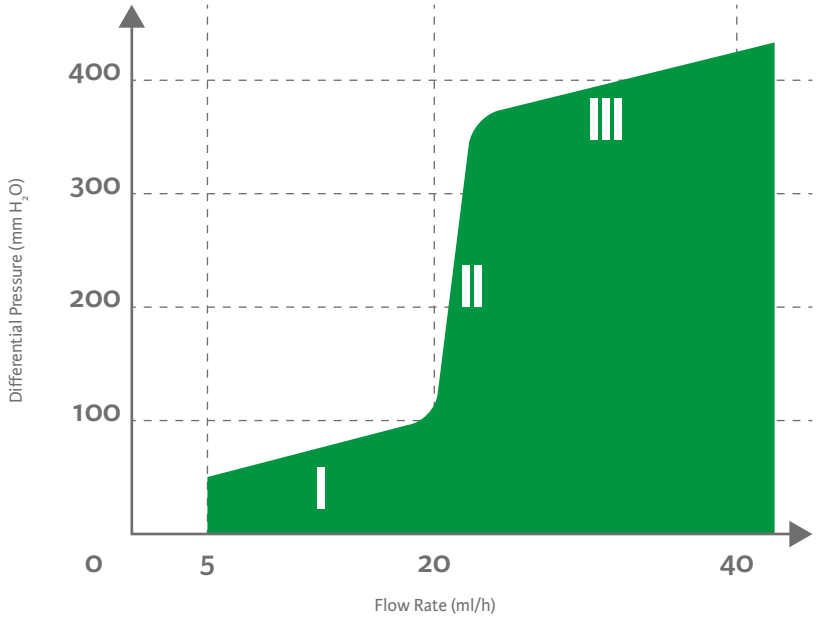


STAGE II – 120-300 mm H_2O
Flow Regulating Valve.
Maintains a close balance between CSF flow and production rate, restricting flow around 20 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O
Safety Valve.
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

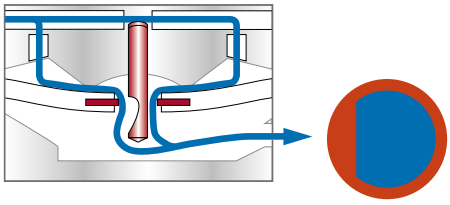
Reference	Description
909700P	With Low Profile Antechamber and integral connectors

OSV II Low Pro™ Two-Piece Shunt System

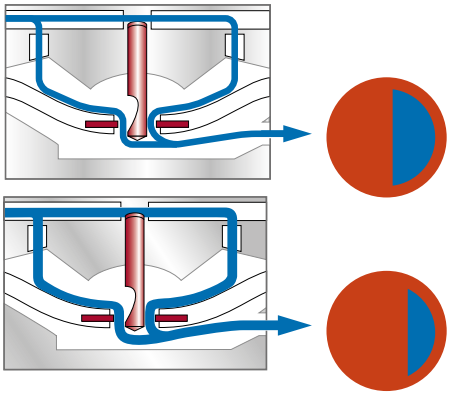
Valve with Low Profile Antechamber	Package content	Reference 909712P
	• Valve with low profile antechamber • Integral polysulfone connector, open-ended, striped drainage catheter (110 cm, F7) • Separated straight Ventricular Catheter (15 cm, F8) with radiopaque dots every 2cm • Straight, polypropylene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

Integra® Flow Regulating Valve Low Flow, Standard

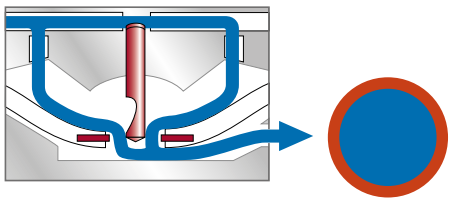
The Integra® Flow Regulating Valve Low Flow, Standard and Integra® Flow Regulating Valve Low Flow, Mini are implantable hydrocephalus valve systems for controlled cerebrospinal fluid (CSF) drainage from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right 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.



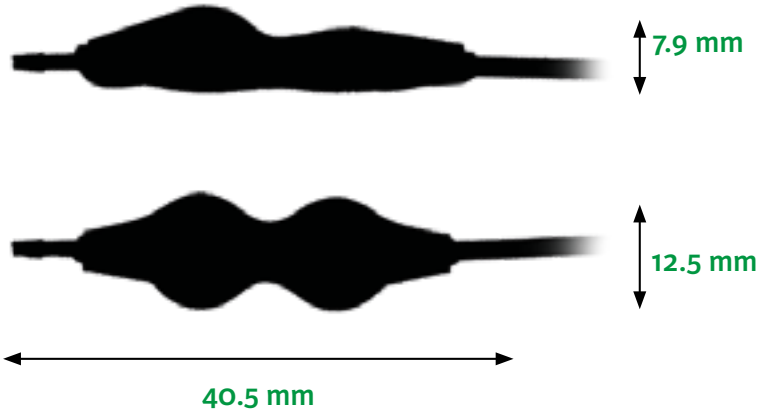
STAGE I – 30-120 mm H_2O
Differential Pressure (DP) Valve.
This stage begins when the flow rate reaches 5ml/h.

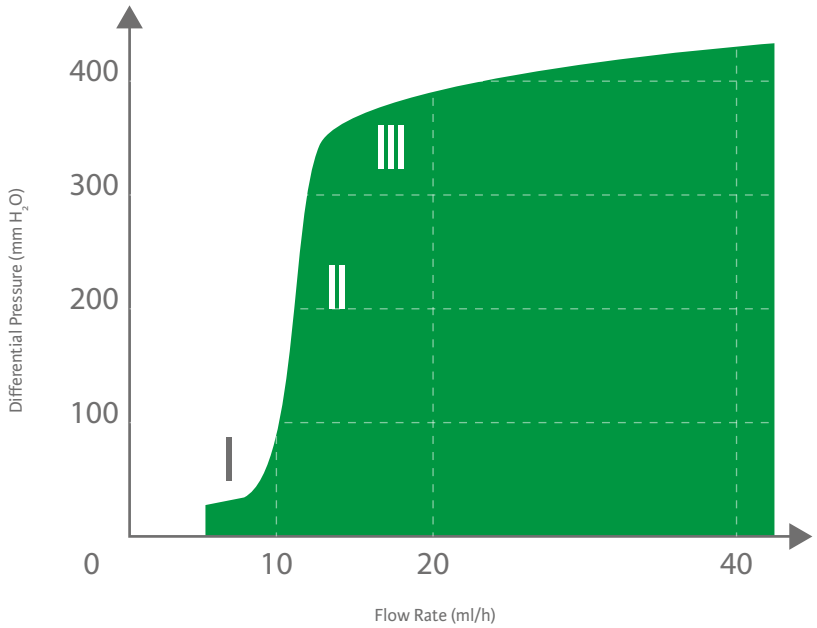


STAGE II – 120-300 mm H_2O
Flow Regulating Valve.
Maintains a close balance between CSF flow and production rate, restricting flow around 10 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O
Safety Valve.
Immediately restores normal ICP during unexpected pressure elevation. Rarely needed.





Indications For Use

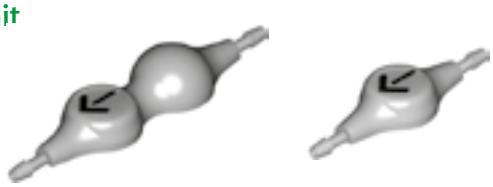
The Integra Flow Regulating Valve Low Flow is an implantable system used in the treatment of patients with hydrocephalus, to shunt CSF from the ventricles to the peritoneal cavity or other appropriate drainage site such as the heart's right atrium.

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

Reference	
With Antechamber	Without Antechamber
909500	909501



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

		Reference		
With Antechamber	**Package content**	**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)	–	–	✔

		Reference	
Without Antechamber	**Package content**	**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

With Antechamber	Package content	Reference 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

With Antechamber	Package content	Reference 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	✔

Without Antechamber	Package content	Reference 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	✔

Integra® Flow Regulating Valve Low Flow, Lumbar

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

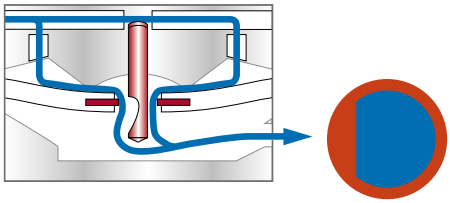
The Integra® Flow Regulating Valve Low Flow, Lumbar should not be used in patients with non-communicating hydrocephalus.
This valve system should not be implanted when an infection along the shunt pathway (e.g. meningitis, ventriculitis, peritonitis) is suspected. It is advisable to postpone valve implantation 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

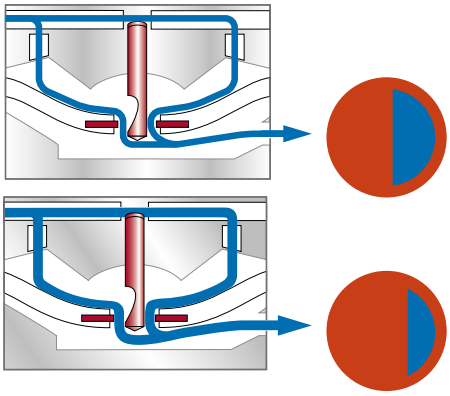
		Reference
Without Antechamber	**Package content**	**909510**
	• With integral proximal tubing (5cm, F8), and open-ended, striped drainage catheter (110cm, F7) • Closed tip lumbar catheter (80cm, F5) • Guidewire in dispenser • 14G Tuohy needle • Stepdown polypropylene connector (F8/F5) • Luer connector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

Integra® Flow Regulating Valve Low Flow, Mini

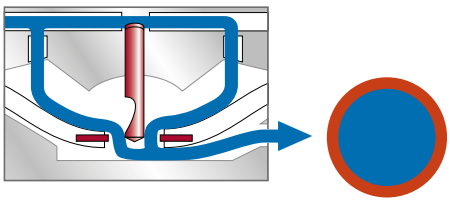
Integra® Flow Regulating Valve Low Flow, Mini utilizes the Self-Adjusting technology in a lower profile design to suit the needs of various patient populations.



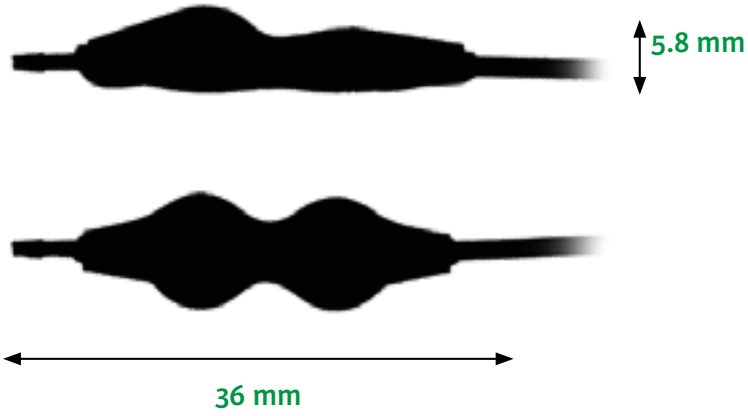
STAGE I – 30-120 mm H_2O
Differential Pressure (DP) Valve.
This stage begins when the flow rate reaches 5ml/h.

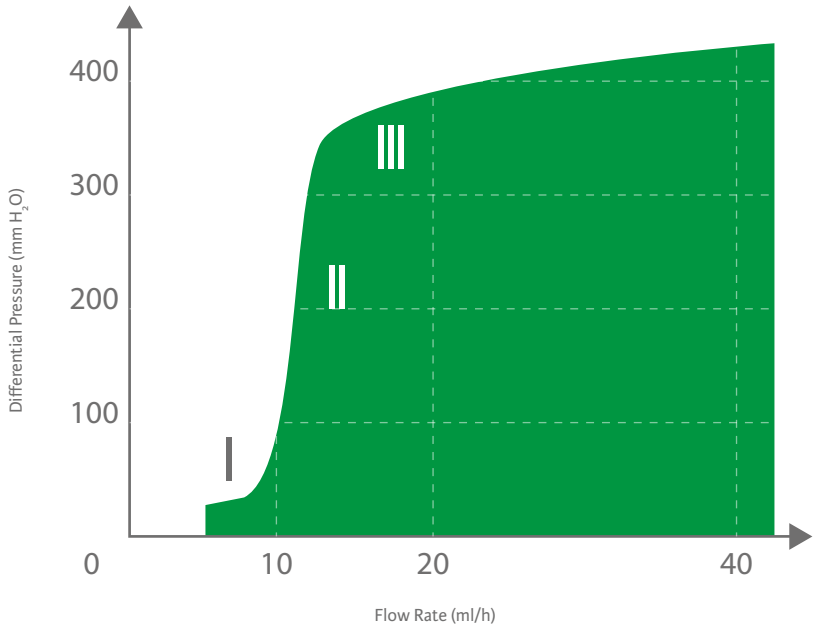


STAGE II – 120-300 mm H_2O
Flow Regulating Valve.
Maintains a close balance between CSF flow and production rate, restricting flow around 10 ml/h, whatever the differential pressure is.



STAGE III – Above 300 mm H_2O
Safety Valve.
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, bactere¬mia). 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

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

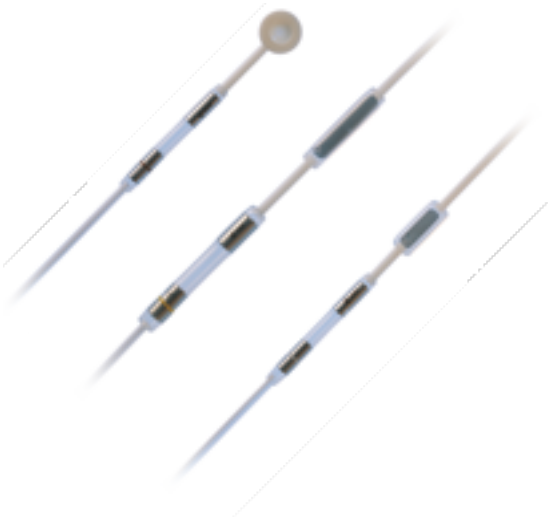
Integra® Flow Regulating Valve Low Flow, Mini, Two-Piece Shunt System

	Reference	
Package content	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	–	✔

INTEGRA®
LIMIT UNCERTAINTY

INTEGRA®
CSF Management
III. Differential Pressure Valves

Integra DP™ Valve System



The Integra DP™ valve is a differential pressure (DP) valve. The original ball-in-cone and spring mechanism is the basis of all our Integra DP™ Valve Systems. Several color-coded pressure ranges are offered in standard and pediatric versions. A variety of system configurations are available, depending on physician preference. Each valve system includes all the necessary components required for implantation. A serial number is engraved on the body of the valve.

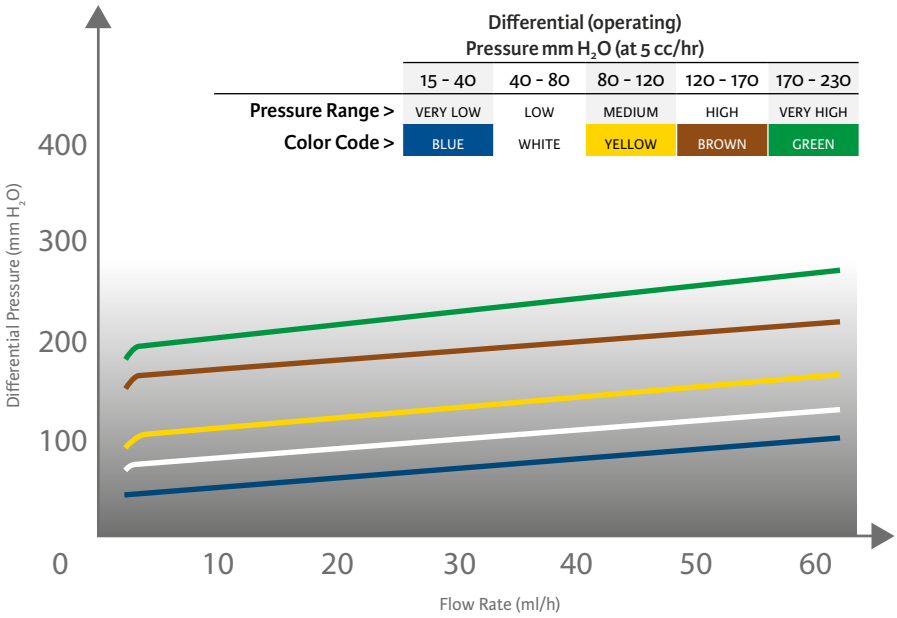
Indications

The Integra DP™ valve is indicated for patients with hydrocephalus or other conditions in which CSF flow and/or absorption is impaired.

Contraindications

The Integra DP™ valve should not be used when an infection exists along the shunt pathway (meningitis, ventriculitis, peritonitis, septicemia and/or bacteremia). The use of the ventriculoatrial approach is contraindicated in patients with serious heart or cardiopulmonary disease.

Flow vs Pressure Curve



Integra DP™ Two-Piece Shunt System

Regular	Package content	Reference 901112*	901122	901142	901162	901145	901165
	Pressure Range >	VERY LOW	LOW	MEDIUM	HIGH	MEDIUM	HIGH
	Color Code >	BLUE	WHITE	YELLOW	BROWN	YELLOW	BROWN
	• Standard Integra DP™ valve unit with integral antechamber and open-ended, striped drainage catheter with slits (110 cm, F7) • Plastic subcutaneous tube passer • Introducing rod • Stainless steel right angle connector • Stainless steel straight connector	✔	✔	✔	✔	✔	✔
	+ Finned ventricular catheter (15 cm, F8)	✔	✔	✔	✔	–	–
	+ Straight ventricular catheter (15 cm, F8) with radiopaque length dots	–	–	–	–	✔	✔

Pediatric	Package content	Reference 902012*	902045	902080	902125	902545	902580	902525
	Pressure Range >	VERY LOW	LOW	MEDIUM	HIGH	LOW	MEDIUM	HIGH
	Color Code >	BLUE	WHITE	YELLOW	BROWN	WHITE	YELLOW	BROWN
	• Pediatric Integra DP™ valve unit with integral antechamber and open-ended, striped drainage catheter with slits (110 cm, F7) • Plastic subcutaneous tube passer • Introducing rod • Stainless steel right angle connector • Stainless steel straight connector	✔	✔	✔	✔	✔	✔	✔
	+ Finned ventricular catheter (15 cm, F8)	✔	✔	✔	✔	–	–	–
	+ Straight ventricular catheter (15 cm, F8) with radiopaque length dots	–	–	–	–	✔	✔	✔

* Recommended for post-operative drainage of hygromas and other extraventricular conditions.

Integra DP™ Valve Unit

Standard	Package content	Reference 901113*	901123	901143	901163	901183
	Pressure Range >	VERY LOW	LOW	MEDIUM	HIGH	VERY HIGH
	Color Code >	BLUE	WHITE	YELLOW	BROWN	GREEN
	• Standard Integra DP™ valve unit with integral, open-ended, striped drainage catheter with slits (110 cm, F7) • Two straight stainless steel connectors	✔	✔	✔	✔	✔

Pediatric	Package content	902123	902143	902163
	Pressure Range >	LOW	MEDIUM	HIGH
	Color Code >	WHITE	YELLOW	BROWN
	• Pediatric Integra DP™ valve unit with integral, open-ended, striped drainage catheter with slits (110 cm, F7) • Two straight stainless steel connectors	✔	✔	✔

* Recommended for post-operative drainage of hygromas and other extraventricular conditions.

Integra DP™ Burr Hole Shunt System

Standard	Package content	Reference 907122	907142	907162
	Pressure Range >	LOW	MEDIUM	HIGH
	Color Code >	WHITE	YELLOW	BROWN
	• Standard Integra DP™ valve unit with integral burr hole cap, and open-ended, striped drainage catheter with slits (110 cm, F7) • Stainless steel burr hole reservoir (6.4 mm diameter) • Straight ventricular catheter (15 cm, F8) with radiopaque length dots • Introducing rod • Stainless steel straight connector	✔	✔	✔

Pediatric	Package content	908122	908142	908162
	Pressure Range >	LOW	MEDIUM	HIGH
	Color Code >	WHITE	YELLOW	BROWN
	• Pediatric Integra DP™ valve unit with integral burr hole cap, and open-ended, striped drainage catheter with slits (110 cm, F7) • Stainless steel burr hole reservoir (6.4 mm diameter) • Straight ventricular catheter (15 cm, F8) with radiopaque length dots • Introducing rod • Stainless steel straight connector	✔	✔	✔

Atlas Valve System

The Atlas valve is a differential pressure (DP) valve. The Atlas Valve mechanism is directly derived from the original Integra DP™ spring and ball-in-cone valve mechanism. Each configuration comes in different color-coded pressure ranges for patient needs. A radiopaque code on each valve readily identifies the pressure range on post-implant images.

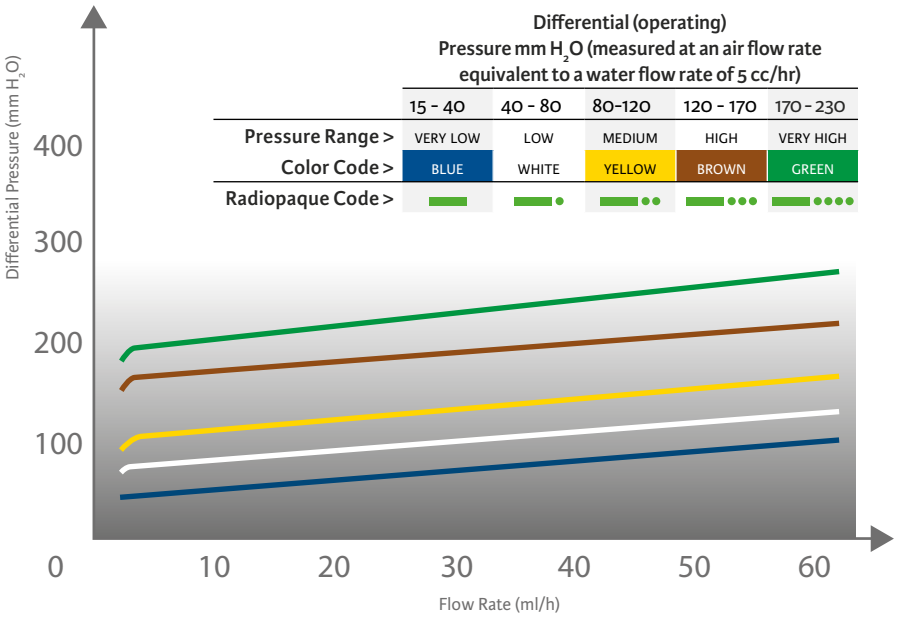
Indications

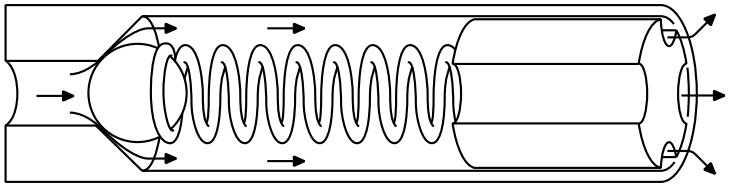
ATLAS Valve Systems are implantable devices which serve as a parallel flow pathway to divert cerebrospinal fluid (CSF) from the cerebral ventricles to an appropriate drainage site. They provide controlled intraventricular pressure and CSF drainage in patients with hydrocephalus or other conditions in which CSF flow and/or absorption is impaired.

Contraindications

Integra Hydrocephalus Valve Systems and components should not be used when an infection exists along the shunt pathway (meningitis, ventriculitis, peritonitis, septicemia and/or bacteremia). Postponement of shunt implantation is advisable if infection is present anywhere in the body. The use of the ventriculoatrial approach is contraindicated in patients with serious heart or cardiopulmonary disease.

Flow Vs Pressure Curve





The compact size of the valve modules provides the Atlas valves with a low profile in all configurations. A serial number printed on the valve body ensures traceability.

Atlas Two-Piece Shunt System

Regular	Package content	Reference 906125	906145	906165
	Pressure Range >	LOW	MEDIUM	HIGH
	Color Code >	WHITE	YELLOW	BROWN
	• Standard Atlas valve unit with integral antechamber and open-ended, striped drainage catheter with slits (110 cm, F7) • Plastic subcutaneous tube passer • Introducing rod • 2 straight polypropylene connectors • Right Angle Guide	✔	✔	✔
	+ Straight ventricular catheter (15 cm, F8) with radiopaque length dots	✔	✔	✔

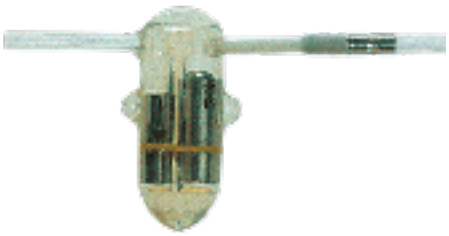
Atlas Valve Unit

Regular	Package content	Reference 906120	906140	906160
	Pressure Range >	LOW	MEDIUM	HIGH
	Color Code >	WHITE	YELLOW	BROWN
	• Atlas valve unit with integral polypropylene connector and open-ended striped drainage catheter with slits (110 cm, F7) • Straight, polypropylene connector	✔	✔	✔

Atlas Burr Hole Shunt System

Regular	Package content	Reference 9MA1221	9MA1421
	Pressure Range >	LOW	MEDIUM
	Color Code >	WHITE	YELLOW
	• Atlas valve unit with integral, 6.4 mm burr hole cap, and open-ended striped drainage catheter with slits (110 cm, F7) • Straight polypropylene connector • Ventricular catheter (15 cm, F8) with radiopaque length dots • Introducing rod • Polypropylene burr hole reservoir (diam. 6.4 mm)	✔	✔

H-V Lumbar Valve



Horizontal-Vertical (H-V) Lumbar Valve System

Each Horizontal-Vertical (H-V) lumbar valve system adjusts for changes in posture to maintain pressure at appropriate levels in the standing and recumbent positions. When the valve unit is horizontal, the spring-actuated, ball-in-cone inlet valve alone controls the lower pressure limit. When the valve unit is vertical, the gravity-actuated, ball-in-cone outlet valve combines with the inlet valve to control the higher pressure. Each valve unit is color-coded according to its combination of horizontal and vertical closing pressures for easy identification.

Selection of Pressure Range

The horizontal pressure range should generally be selected according to the extent of the patient's ventricular enlargement. If ventricular enlargement is extreme, valves with lower horizontal pressure ranges are usually selected. If the degree of ventricular enlargement is minor, higher horizontal pressures are generally applied. The vertical valve pressure should be selected on the basis of the patient's height from the base of the spine to the head.

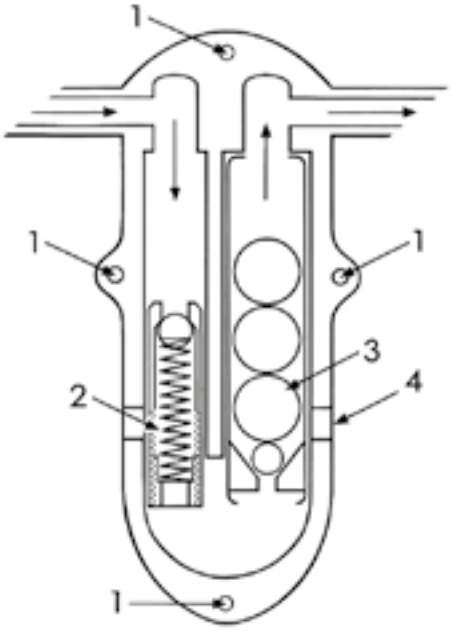
Indications

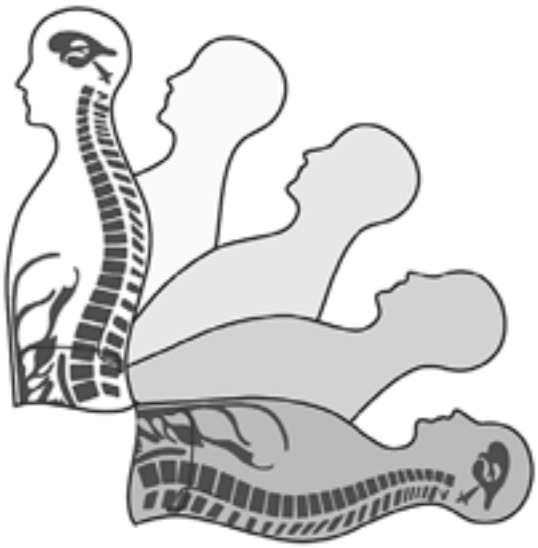
Horizontal-Vertical Lumbar Valve Systems are implantable devices used in the treatment of patients with communicating hydrocephalus to shunt cerebrospinal fluid (CSF) from the lumbar subarachnoid region to the peritoneal cavity.

Contraindications

The H-V Lumbar Valve System should not be used in patients with non-communicating hydrocephalus. Integra NeuroSciences hydrocephalus valve system components should not be used when infection exists along the shunt pathway (meningitis, ventriculitis, peritonitis, septicemia, bacteremia). Postponement of shunt or component implantation is advisable if infection is present anywhere in the body.

Cross Section Of Valve Unit





1) Suture holes
2) Inlet valve
(controls pressure in the horizontal position)
3) Outlet valve (controls pressure in the vertical position)
4) Color-coded band

Horizontal-Vertical (H-V) Lumbar Three-Piece Shunt System

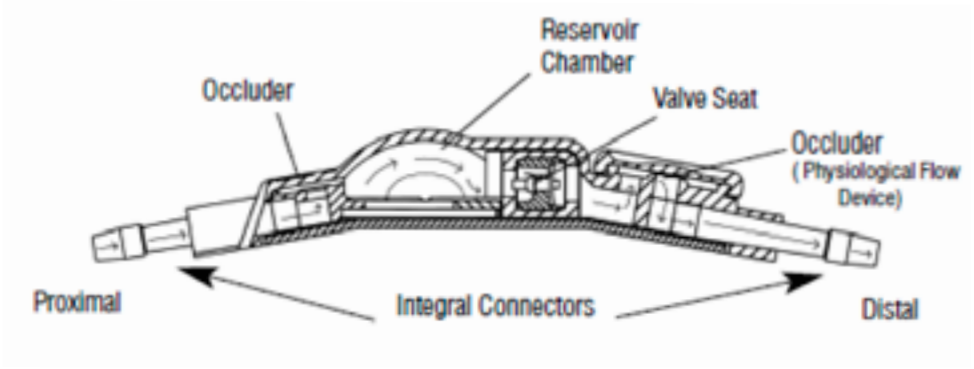
			Reference		
For patients with minor ventricular enlargement	**Package content**		903325A	903335A	903345A
		Color Code >	BLUE	YELLOW	GREEN
		Suggested Application >	SMALL CHILDREN	TALL CHILDREN, ADULTS	TALL ADULTS
	Closing Pressure ($mm H_2O$) **>**	**Horizontal >**	85-125	85-125	85-125
		Vertical >	205-285	265-365	325-445
	• 2 side-by-side, ball-in-cone valves in a silicone elastomer housing • Closed tip lumbar catheter (80 cm, F5) • Suturable tubing clamp F5 • Stainless steel straight connector • Stainless steel stepdown connector F8/F5 • Open-ended, striped peritoneal catheter (91 cm, F7) • Antechamber • Guidewire in dispenser • 14G Tuohy needle • Luer Connector		✔	✔	✔

			Reference		
	Package content		903320A	903330A	903340A
For patients with extreme ventricular enlargement		**Color Code >**	RED	WHITE	BROWN
		Suggested Application >	SMALL CHILDREN	TALL CHILDREN, ADULTS	TALL ADULTS
	Closing Pressure ($mm H_2O$) **>**	**Horizontal >**	50-80	50-80	50-80
		Vertical >	170-240	230-320	290-400
	• 2 side-by-side, ball-in-cone valves in a silicone elastomer housing • Closed tip lumbar catheter (80 cm, F5) • Suturable tubing clamp F5 • Stainless steel straight connector • Stainless steel stepdown connector F8/F5 • Open-ended, striped peritoneal catheter (91 cm, F7) • Antechamber • Guidewire in dispenser • 14G Tuohy needle • Luer Connector		✔	✔	✔

NOVUS™ Valve, Standard and NOVUS™ Valve, Mini Valve

The NOVUS™ Valve, Standard and NOVUS™ Valve, Mini Valve are silicone elastomer valves used for the treatmentof hydrocephalic patients when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. The valves incorporate an internal low or medium pressure valve assembly which is mounted distal to an integral pumping reservoir for proximal control of CSF flow. The devices also provide one-way flow control. An integral occluder is incorporated on the proximal end of the valves, while an integral Physiological Flow Device is mounted on the distal end and also serves as an occluder. The occluder and Physiological Flow Device are designed to manually control the flushing or pumping of CSF proximally or distally. The devices are fitted with a polypropylene needle guard, designed to prevent inadvertent needle puncture during percutaneous injection. The valves contain an integral plastic connector on each end to simplify the assembly procedure. The valves contain no metal parts to inter fere with computerized axial tomography.

The Integra Hydrocephalic Shunt Kits are designed to deliver CSF from the ventricles of the brain to the peritoneal cavity. Each kit contains either a NOVUS Valve, Standard or NOVUS Valve, Mini Valve, a Pudenz Ventricular Catheter and an integral, open-ended kink resistant catheter attached to the outlet of the valve. The kits are available in low and medium pressure ranges. All valves and catheters contain barium sulfate for xray detectability. No metal parts are used anywhere in the system, to eliminate any possibility of interference with CT scanning or MR imaging.



Indications For Use

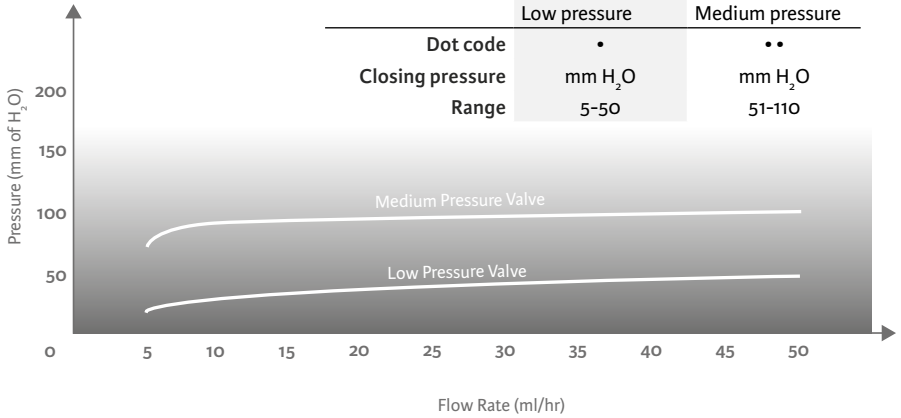
The NOVUS Valve, Standard and NOVUS Valve, Mini utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The NOVUS Valve, Mini valve can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients. Valves with a Physiological Flow Device are intended to reduce the hazard of negative intraventricular pressure (respect to atmospheric pressure) when the patient is sitting, standing or semirecumbent.

Contraindications

Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia, or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. The ventriculoatrial method of shunting is contraindicated for patients with congenital hear t disease or other anomalies of the cardiopulmonary system.

Valve performance chart frome the NOVUS™ DFU

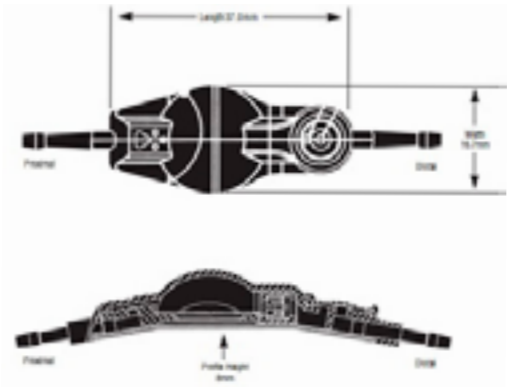
	Low pressure	Medium pressure
Dot code	•	••
Closing pressure	mm H_2O	mm H_2O
Range	5-50	51-110



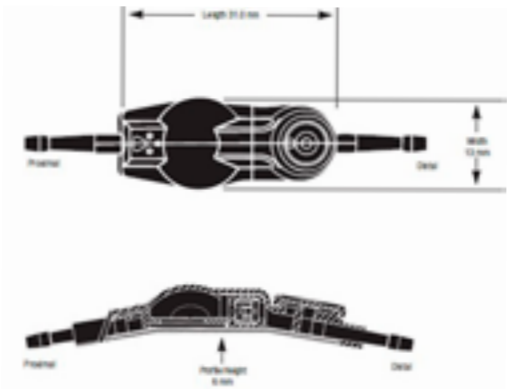
Novus™ Valve Unit

Each Novus™ Hydrocephalus Valve is packaged with a barium impregnated silicone right-angle ventricular catheter guide.

Novus™ Valve Unit, Standard Size	
Pressure range	Reference
Low	NL8509010
Medium	NL8509020

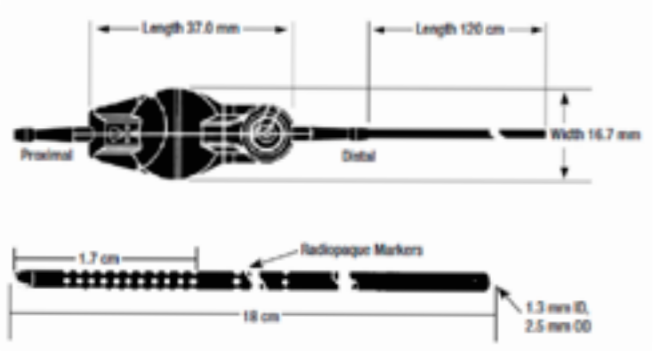


Novus™ Valve Unit, Mini Size	
Pressure range	Reference
Low	NL8509011
Medium	NL8509021

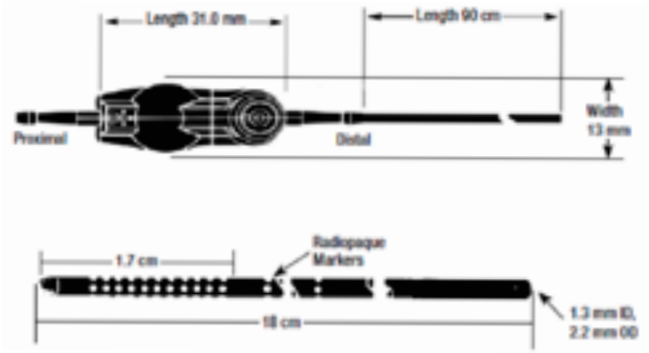


Novus™, Two Pieces Shunt System

	Standard Size	
Package content	**Pressure range**	**Reference**
One (1) Standard Novus™ hydrocephalus Valve with integral 120 cm open-ended, barium embedded striped peritoneal catheter • One (1) 18 cm standard Pudenz ventricular catheter with stylet • One (1) barium-impregnated silicone right-angle ventricular catheter guide	**Low**	**NL8509610**
	Medium	**NL8509620**



	Mini Size	
Package content	**Pressure range**	**Reference**
• One (1) Mini Novus™ hydrocephalus Valve with integral 90 cm open-ended, barium embedded striped peritoneal catheter • One (1) 18 cm small Pudenz ventricular catheter with stylet • One (1) barium-impregnated silicone right-angle ventricular catheter guide	**Low**	**NL8509311**
	Medium	**NL8509321**



Contour-Flex™ Valve System

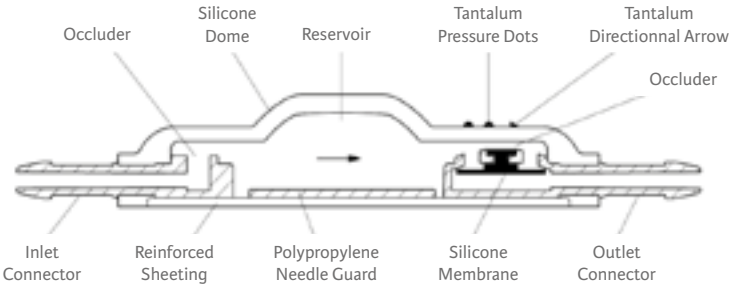
Using a silicone membrane pressure control element, all valves provide a consistent pressure/flow characteristics and a closing pressure. The Contour-Flex™ valve has proximal and distal occluders to facilitate two-way flushing. This valve has a flexible profile to conform to the curvature of the cranium.

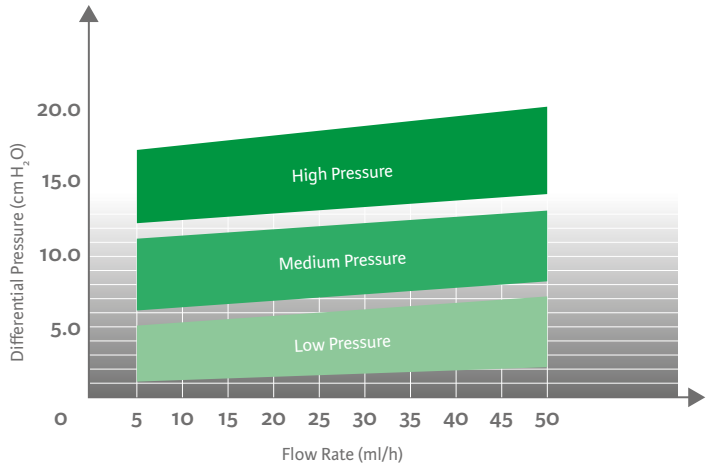
Indications

The Contour-Flex™ Valve is used in treatment of patients with hydrocephalus. It is a component of a system designed to shunt cerebrospinal fluid from the ventricles of the brain to an appropriate drainage site such as the atrium of the heart or to the peritoneal cavity.

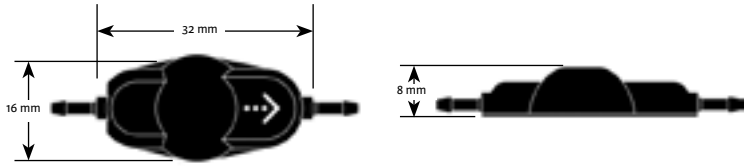
Contraindications

Hydrocephalus shunt systems should not be implanted when the patient has known or suspected infections in the vicinity of any of the implanted components (meningitis, ventriculitis, skin infections, bacteremia, septicemia, peritonitis, etc.). Avoid implanting hydrocephalus shunt systems if infection is present anywhere in the body. Shunting into the atrium of patients with congenital heart disease or other cardiopulmonary anomalies is contraindicated.

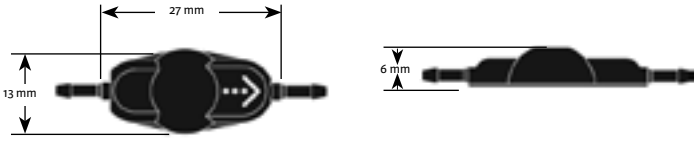




Contour-Flex™ Valve Unit



Regular	Pressure Range	Reference
	LOW	CFRL
	MEDIUM	CFRM
	HIGH	CFRH



Small	Pressure Range	Reference
	LOW	CFSL
	MEDIUM	CFSM
	HIGH	CFSH

Contour-Flex™ Two-Piece Shunt System

Regular	Performance Level	Reference
• Contour-Flex™ Regular valve with integral 91 cm, barium-sulfate striped drainage catheter, open ended	LOW	11811
• Separate 15 cm, barium-sulfate impregnated ventricular catheter with stylet and right angle guide 	MEDIUM	11812
	HIGH	11813

Small	Performance Level	Reference
• Contour-Flex™ Small valve with integral 91 cm, barium-sulfate striped drainage catheter, open ended	LOW	14085
• Separate 15 cm, barium-sulfate impregnated ventricular catheter with stylet and right angle guide 	MEDIUM	14086
	HIGH	14087

Contour-Flex™ Three-Piece Shunt System

Regular	Performance Level	Reference
• Contour-Flex™ Regular valve 	LOW	12508
• Separate 91 cm, barium-sulfate striped drainage catheter, open ended		
• Separate 15 cm, barium-sulfate impregnated ventricular catheter with stylet and right angle guide 	MEDIUM	12509

Small	Performance Level	Reference
• Contour-Flex™ Small valve 	LOW	12505
• Separate 91 cm, barium-sulfate striped drainage catheter, open ended		
• Separate 15 cm, barium-sulfate impregnated ventricular catheter with stylet and right angle guide 	MEDIUM	12506

Contour-Flex™ One-Piece Shunt System

Regular	Performance Level	Reference
• Contour-Flex™ valve	LOW	14161
• Integral 91 cm, barium-sulfate striped drainage catheter, open ended • Integral 15 cm, barium-sulfate impregnated ventricular catheter with stylet and right angle guide	MEDIUM	14162
• Ventricular catheter introducer	HIGH	14163

Contour-Flex™ Burr Hole Shunt System

Regular	Performance Level	Reference
• Contour-Flex™ Regular valve with integral 91 cm, barium-sulfate striped drainage catheter, open ended • Integral Burr Hole cap & reservoir  • Separate 15 cm, barium-sulfate impregnated ventricular catheter with stylet and right angle guide 	LOW	11854
	MEDIUM	11855
	HIGH	11856

Small	Performance Level	Reference
• Contour-Flex™ Small valve with integral 91 cm, barium-sulfate striped drainage catheter, open ended • Integral Burr Hole cap & reservoir  • Separate 15 cm, barium-sulfate impregnated ventricular catheter with stylet and right angle guide 	LOW	16254
	MEDIUM	16255
	HIGH	16256

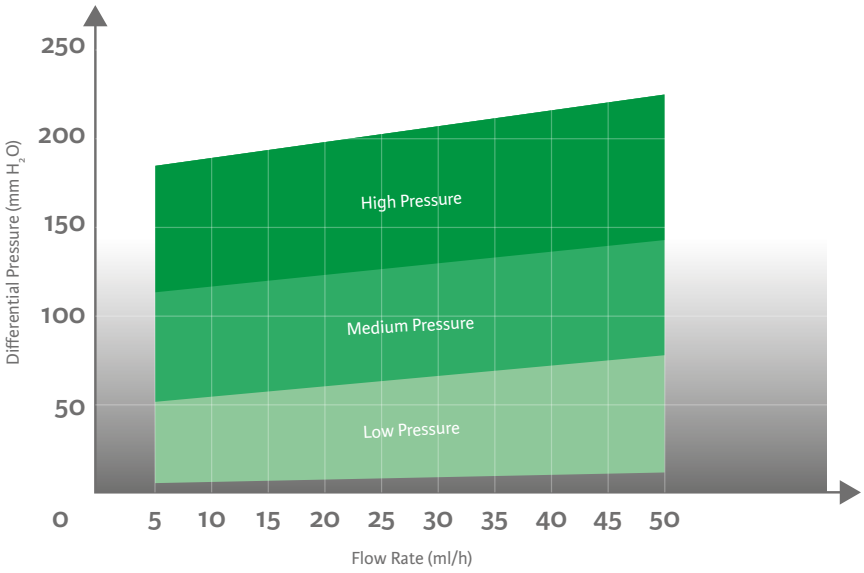
Pudenz Valve

The addition of integral connectors to facilitate catheter attachment and the availability of an integral Anti-Siphon Device provides flexibility. All Pudenz Flushing Valves feature an injectable reservoir for CSF sampling, distal flushing and distal patency testing. A one-way diaphragm-type flow control valve and radiopaque pressure range indicators are incorporated in all Pudenz Valves.

Valve Performance Chart

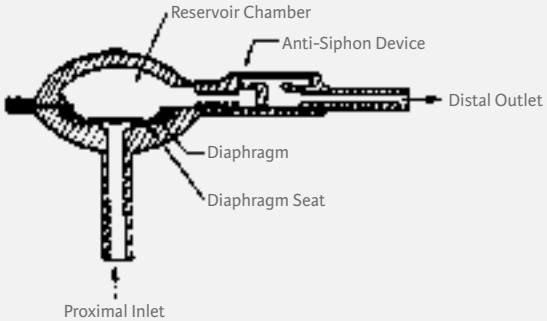
		Closing Pressure Range mm H_2O		
		5-50	51-110	111-180
	Pressure Range >	LOW	MEDIUM	HIGH
Flow/Pressure >	**@ 5 ml/h**	5 mm H_2O	50 mm H_2O	110 mm H_2O
	@ 50 ml/h	75 mm H_2O	140 mm H_2O	220 mm H_2O
	Radiolucent Code >	●●●	●●	●

Note: Values shown in the flow/pressure-range chart are the low point of the established 5-ml/h range and the high point of the 50 ml/h range.

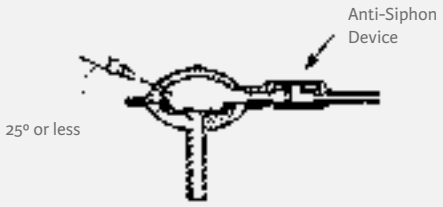


Flushing Procedure for Pudenz CSF Valve

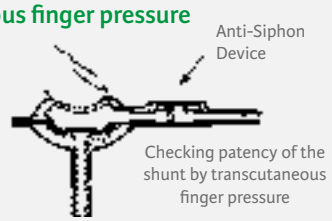
Diagrams are shown here for illustration purposes only. Always refer to the relevant Instructions for Use for complete clinical instructions.



Injecting fluids into the distal catheter



Checking patency of the shunt by transcutaneous finger pressure



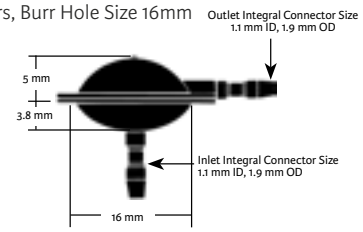
Indications For Use

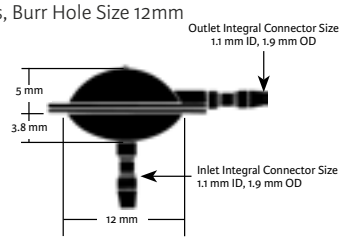
The Pudenz Flushing Valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum.

Contraindications

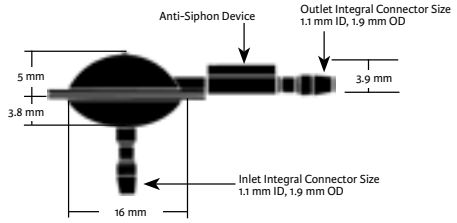
Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. The ventriculoatrial method of shunting is contraindicated for hydrocephalic patients with congenital heart disease or other anomalies of the cardiopulmonary system.

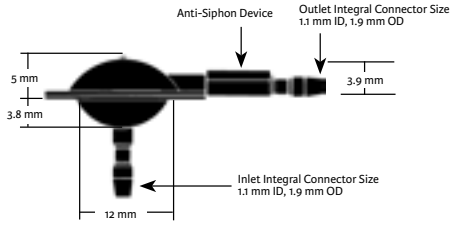
Pudenz Flushing Valves

Regular	Pressure Range	Reference
• Pudenz Flushing Valve, with integral connectors, Burr Hole Size 16mm 	LOW	NL8501330
	MEDIUM	NL8501356
	HIGH	NL8501358

Small	Pressure Range	Reference
• Pudenz Flushing Valve, with integral connectors, Burr Hole Size 12mm 	LOW	NL8501331
	MEDIUM	NL8501357
	HIGH	NL8501359

Pudenz Flushing Valve with Anti-Siphon Device (ASD)

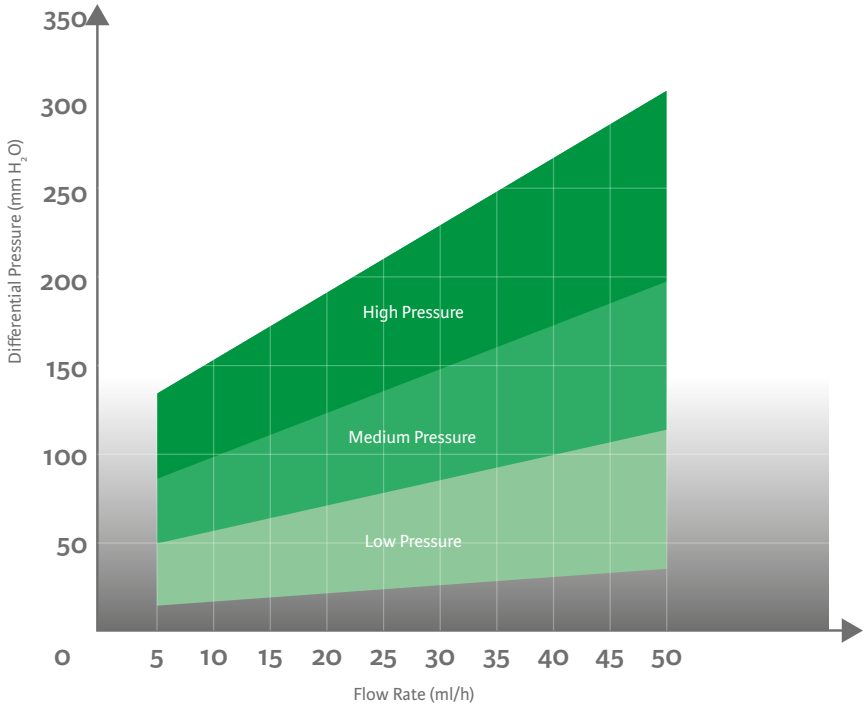
Regular	Pressure Range	Reference
• Flushing Valve, with ASD*, with integral connectors, Burr Hole Size 16mm 	LOW	NL8501410
	MEDIUM	NL8501412
	HIGH	NL8501414

Small	Pressure Range	Reference
• Flushing Valve, with ASD*, with integral connectors, Burr Hole Size 12mm 	LOW	NL8501411
	MEDIUM	NL8501413
	HIGH	NL8501415

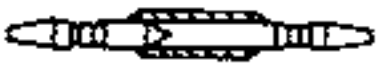
* ASD: Anti-Siphon Device

UltraVS™ Valve System

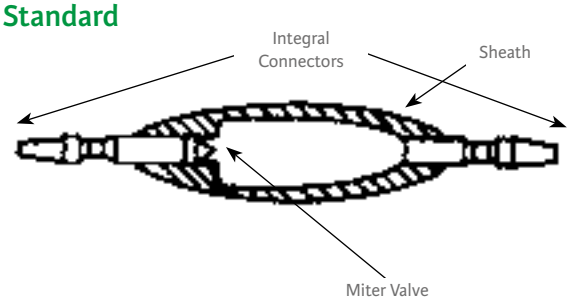
The cylindrical shape of UltraVS™ Valve lowers the profile of the valve system. At only 13 mm long and 3.8 mm wide, the UltraVS™ Neonate is appropriate for neonatal patients. UltraVS™ Cylindrical Valve incorporates a miter valve mechanism, a design that naturally opens more slowly in response to hydrostatic pressure than a diaphragm type valve. All UltraVS™ Cylindrical Valves incorporate integral connectors to allow catheter connection. The addition of an integral injectable Rickham-style reservoir allows CSF sampling. UltraVS™ Cylindrical Valves are available in two sizes, and each size is available in three pressure ranges.



Neonate



Standard



Indications For Use

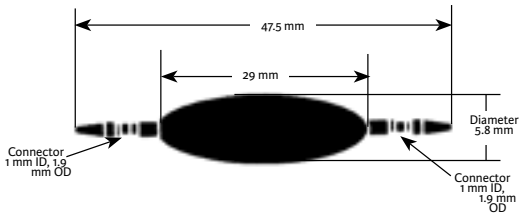
The UltraVS™ In-Line Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid (CSF) from the lateral ventricles into either the peritoneal cavity or the right atrium of the heart. The in-line and burr-hole systems are designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneal cavity. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated. The Small and Neonate Models can be used in (but are not restricted to) situations where skin erosion may be a problem, as with premature infants, pediatric patients and older patients.

Contraindications

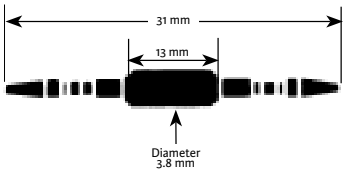
Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. The ventriculoatrial method of shunting is contraindicated for hydrocephalic patients with congenital heart disease or other anomalies of the cardiopulmonary system.

UltraVS™ Valve Unit

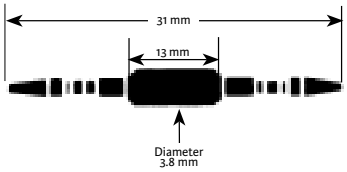
Regular	Pressure Range	Reference
• UltraVS™ Cylindrical Valve 	LOW	NL8501109
	MEDIUM	NL8501110
	HIGH	NL8501111

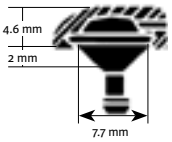


Neonate	Pressure Range	Reference
• UltraVS™ Cylindrical Valve 	LOW	NL8501126
	MEDIUM	NL8501127
	HIGH	NL8501128



UltraVS™ Two-Pieces Shunt System



Neonates	Package content	Reference NL8501123	NL8501124	NL8501125
	Pressure Range >	LOW	MEDIUM	HIGH
	• Neonates UltraVS™ Cylindrical Valve with integral 120 cm, open-ended, barium embedded striped peritoneal catheter with side slits and integral Rickham-style reservoir	✔	✔	✔
	• 18 cm small Pudenz ventricular catheter with stylet	✔	✔	✔
	• Integral Rickham-style reservoir	✔	✔	✔

Essential Valve System

Indications For Use

The Essential Shunt Kit-Flat bottom design, utilized in the treatment of hydrocephalic patients, is designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into the peritoneum. The Essential Shunt Kit-Flat bottom design, can be used in (but is not restricted to) situations where skin erosion may be a problem, as with older patients. The CSF Flow control valve, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. Note : this kit provides a peritoneal catheter. For cardiac shunting, a cardiac catheter must be purchased separately.

Contraindications

Ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia, or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Essential Two-Piece Shunt System

Flat Bottom Design	Pressure Range	Reference
• Essential valve with integral 120 cm kink resistant striped peritoneal catheter • Separate 18 cm ventricular catheter with stylet and right angle guide	LOW	NL8504120
	MEDIUM	NL8504121

Burr-hole Design	Pressure Range	Reference
• Essential valve with integral 120 cm kink resistant striped peritoneal catheter • Separate 18 cm ventricular catheter with stylet and right angle guide	LOW	NL8504110
	MEDIUM	NL8504111
	HIGH	NL8504112

INTEGRA®
LIMIT UNCERTAINTY

INTEGRA®
CSF Management
IV. Speciality Drainage Products

Gravity Compensating Accessory

The Gravity Compensating Accessory (GCA) is designed to be mounted in line with the Integra DP™ valve or any other differential pressure valve system in order to counteract the siphoning effect of hydrostatic pressure when the patient is in the erect position. The GCA can be used in all cases where an anti-siphon device is deemed necessary. Its operating characteristics are not dependent on its location along the shunt distal tubing and they are not sensitive to external pressure.

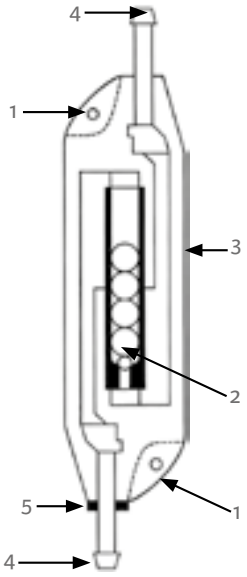
Indications

The GCA is an implantable device which is implanted in series with a hydrocephalus valve to control cerebrospinal fluid (CSF) drainage from the cerebral ventricles to an appropriate drainage site. It is designed to minimize the excessive reduction in intraventricular pressure (relative to atmosphere) and CSF volume caused by the "pull" exerted by the fluid column within the outflow catheter when the patient is sitting or standing.

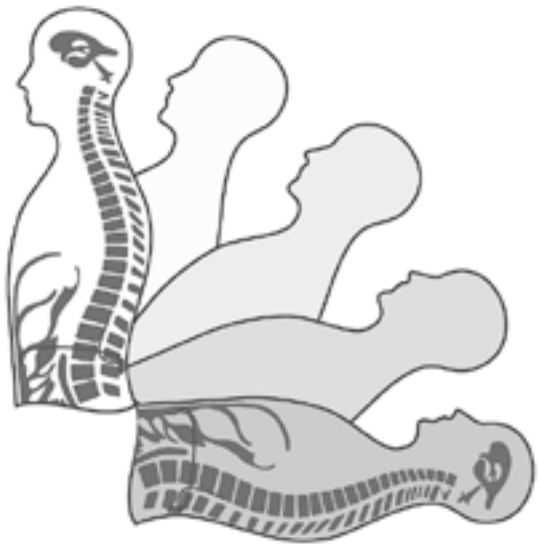
Contraindications

The GCA should not be implanted when an infection exists along the shunt pathway (meningitis, ventriculitis, septicemia and/or bacteremia). Postponement of shunt or component implantation is advisable if infection is present anywhere in the body. The use of the Gravity Compensating Accessory is not recommended in shunt systems containing flow regulating or antisiphon mechanisms.

Cross Section Of The Gravity Compensating Accessory



1) Suture holes
2) Gravity actualised, ball-in-cone mechanism
3) Silicone elastomer housing
4) Integral plastic connectors
5) Color band



Gravity Compensating Accessory

		Reference		
Standard	Package content	903430	903435	903440
	Pressure Range >	LOW	MEDIUM	HIGH
	Color Code >	WHITE	YELLOW	BROWN
	Suggested Application >	CHILDREN	SMALL ADULTS	TALL ADULTS
Additional Resistance to flow (mmH_2O) (Vertical orientation) >	at 5ml/h >	140-170	200-250	260-320
	at 50ml/h >	170-200	230-280	290-350

Anti-Siphon Device

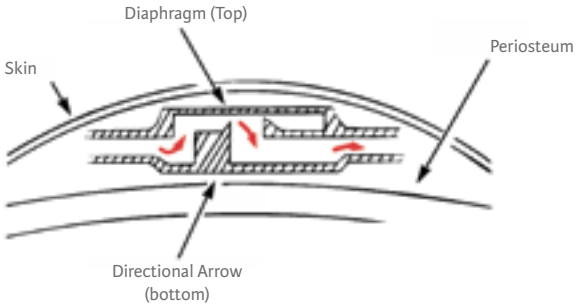
Indications

The Anti-Siphon Device, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum. The device is designed to reduce the potential hazards of excessive lowering of intraventricular pressure (with respect to atmospheric pressure) when the patient is in a sitting, standing or erect position.

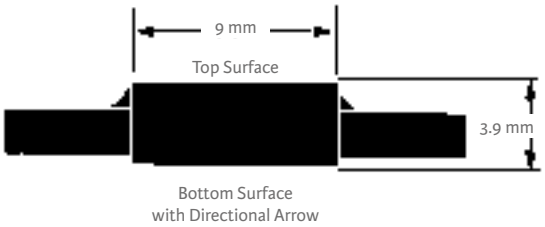
Contraindications

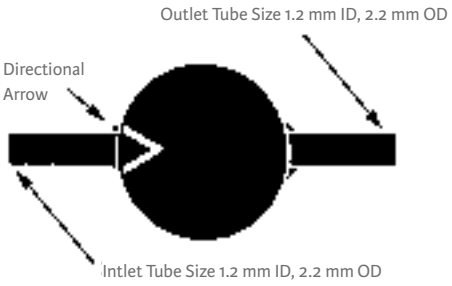
Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

The original physiologically designed siphon control mechanism, the Anti-Siphon Device, is normally open. The anti-siphon device reacts only as needed to changes in hydrostatic pressure. When a patient sits or stands, the device resists the hydraulic siphoning common to differential pressure CSF-control valves, preventing over-drainage and keeping the patient's intra-ventricular pressure within the physiological normal range. The Anti-Siphon Device may be connected in series with any flushing reservoir or proximal control valve using the connectors packaged with the device. The Anti-Siphon Device is an integral component of many Integra valve systems.



Anti-Siphon Device minimizes siphon effect by closing as the hydrostatic pressure changes relative to patient position (standing, sitting or supine).



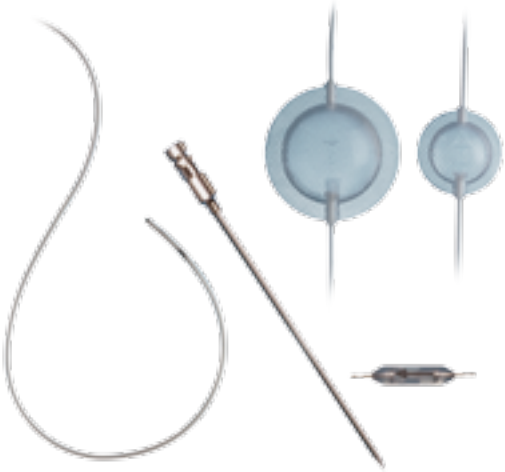


Anti-Siphon Device Kit

	Package content	Reference
	• One Anti-Siphon Device	NL8500200
	• Two Pudenz Straight Connectors	

Spetzler™ Lumbar-Peritoneal Valve

The original lumbar-peritoneal shunt designed for the treatment of communicating hydrocephalus in adults can be inserted without a laminectomy. Pressure control is achieved through a combination of the double slit valve at the peritoneal end and the small inner diameter catheter. Each Spetzler™ Lumbar-Peritoneal Shunt is packaged as a complete kit. Optional in-line valves and reservoirs are also available.



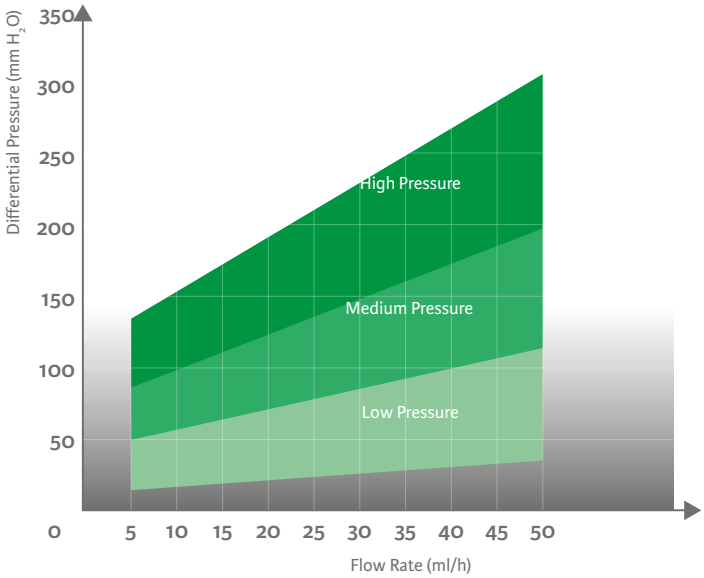
Indications

Percutaneous lumbar peritoneal shunting may be utilized in the treatment of communicating hydrocephalus. It is designed to shunt CSF from the lumbar subarachnoid space to the peritoneal cavity. The shunt may be used for diagnosis, evaluation or treatment of normal pressure communicating hydrocephalus. A percutaneous lumbar peritoneal shunt is also useful in the management of persistent cerebrospinal fluid fistulas, bulging cranial and suboccipital decompressions and in transient CSF absorption defects, e.g., postmeningitic or post-hemorrhagic hydrocephalus. The In-Line Valve, available as a separate component of the system, is indicated for use where added resistance is desired to alleviate symptoms of low pressure in the small percentage of patients who, after normal drainage and in the normal course of treatment, develop such symptoms.

Contraindications

Lumbar Peritoneal Shunting Systems should not be used for noncommunicating hydrocephalus. Lumbar Peritoneal Shunting Systems should not be used in the presence of known or suspected meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis. It is advisable to avoid shunting procedures if infec tion is present anywhere in the body. Lumbar peritoneal shunting systems are contraindicated in cases of spinal abnormalities that would prevent free insertion of the lumbar catheter. Lumbar peritoneal shunts are contraindicated in infants where the lower end of the spinal cord has not yet migrated to its cephalad L1-2 position. In view of the marked narrowing of the lumbosacral canal in achondroplastic patients, a lumbar shunt in the subarachnoid space is contraindicated. The trocar method of peritoneal catheter introduction is contraindicated if there have been previous abdominal operations or if excessive obesity exists.

Valve Performance Chart



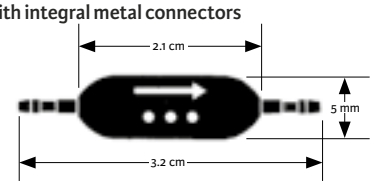
		Closing Pressure Range mm H2O @ 9 ml/Hr		
		15-54	55-94	95-150
Flow/ Pressure >	Pressure Range >	LOW	MEDIUM	HIGH
	@ 5 ml/Hr	5 mm H_2O	50 mm H_2O	85 mm H_2O
	@ 50 ml/Hr	115 mm H_2O	200 mm H_2O	310 mm H_2O
	Radiolucent Code >	●●●	●●	●

Note: Addition of a large or small reservoir to the one-piece shunt system will add a minimum pressure of 50 mm of H_2O at a flow rate of 23 ml/h.

Trimming the shunt length by 20 cm will result in an overall decrease in system pressure of approximately 15 mm H_2O at a flow rate of 23 ml/h.

Note: Valves shown in the flow/pressure range chart are the low point of the established 5 ml/h range and the high point of the 50 ml/h range.

Spetzler™ Lumbar-Peritoneal In-Line Valves

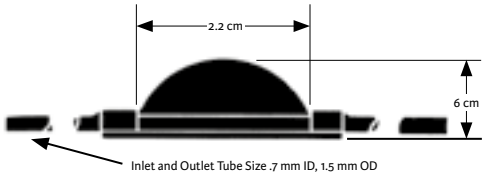
Regular	Pressure Range	Reference
• With integral metal connectors 	LOW	NL8507420
	MEDIUM	NL8507421
	HIGH	NL8507422

Spetzler™ Lumbar-Peritoneal One-Piece, with Tuohy Needle Kit

Package content	Reference NL8507210
• One (1) metal connector • One (1) 14 gauge Tuohy needle • Three (3) suture collars	✔
+ One (1) lumbar-peritoneal catheter 80 cm	✔

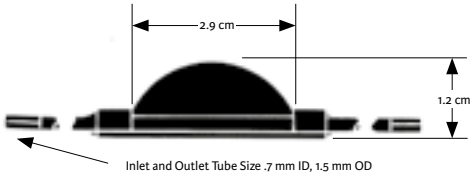
Spetzler™ Lumbar-Peritoneal Flushing Reservoir

Small Reservoir



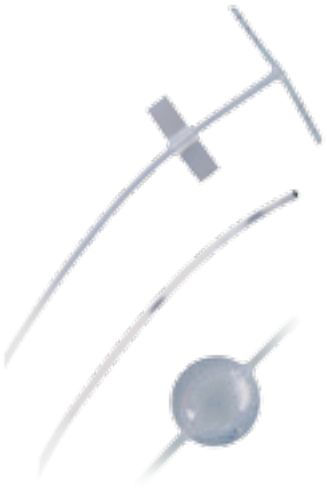
Package content	Reference NL8507440
• Spetzler™ Lumbar-Peritoneal Flushing Reservoir • With 2 metal connectors	✔

Large Reservoir



Package content	Reference NL8507460
• Spetzler™ Lumbar-Peritoneal Flushing Reservoir • With 2 metal connectors	✔

Edwards-Barbaro Syringo-Peritoneal Shunt Kit



Edwards-Barbaro Syringo-Peritoneal Shunt is the original T-tube catheter, designed to provide continuous drainage of fluid from within a spinal cord cyst (syrinx) to the peritoneum. The small T-tube diameter (approximately 5FR) minimizes the size of the myelotomy, and the "T" shape allows drainage from above and below the myelotomy site.

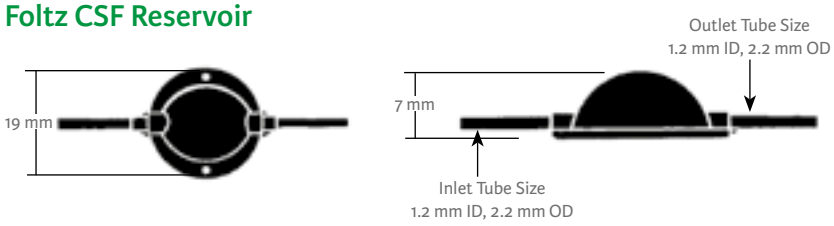
Indications

A variety of operations are used in the treatment of syringomyelia. The Integra Edwards/Barbaro Syringo-Peritoneal Shunt can be used alone or in combination with other procedures in the treatment of all forms of syringomyelia, Including those associated with Chiari malformations, trauma or arachnoiditis. Fluid contained within cystic spinal cord tumors generally has a higher protein content and may not flow through this system. For this reason, the Integra Edwards/Barbaro Syringo-Peritoneal Shunt is not recommended in the treatment of cystic spinal cord tumors. Any spinal cord lesion which contains anything other than clear, colorless fluid should be examined carefully for evidence of an associated tumor.

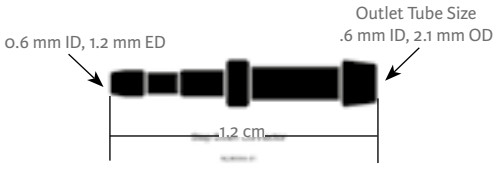
Contraindications

Syringo-Peritoneal Shunting systems should not be used In the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. Use of the Integra Edwards/Barbaro Syringo-Peritoneal Shunt is contraindicated in the presence of spinal tumors. Careful examination of spinal cord lesion fluid should be made to eliminate possibility of tumor.

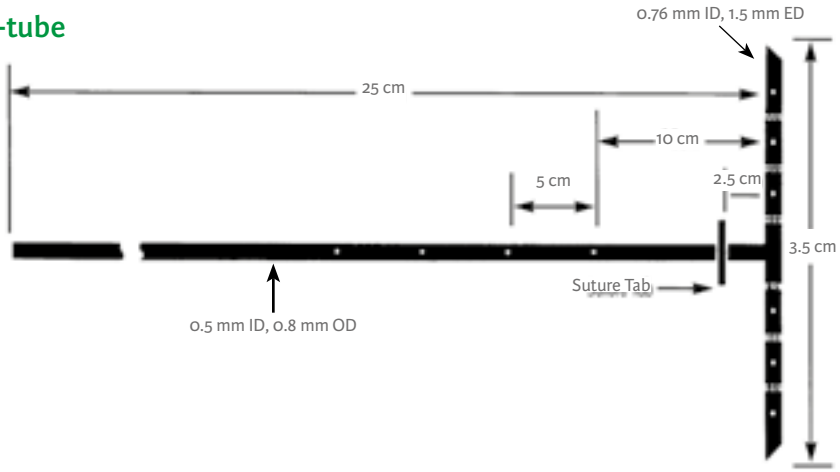
Foltz CSF Reservoir



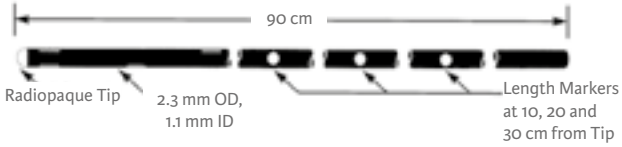
Stepdown Connector



T-tube



Peritoneal Reflux Control Catheter



Package content	Reference
• One (1) 25 cm x 3.5 cm 5FR T-tube • One (1) 90 cm peritoneal reflux control catheter • One (1) step down connector • One (1) Foltz CSF Reservoir	NL80076S01

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CSF Management
V. CSF Reservoirs

Integra Reservoirs

Designed as a closed ventricular access system, the Integra Reservoir facilitates CSF withdrawal as well as delivery of radioisotopes and chemotherapeutic agents. Several models are offered to accommodate many different treatment protocols. The reservoir may also be converted to or added in-line to an existing shunt system. Each Standard Integra CSF Reservoir is packaged with a small Pudenz ventricular catheter (NL8501504).

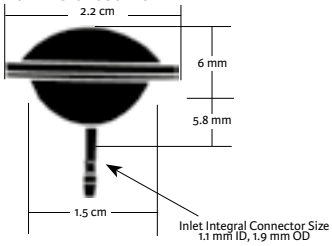
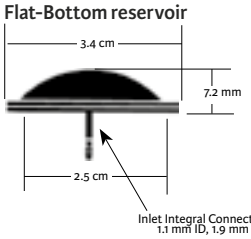
Indications

The Integra CSF Reservoir provides access to the lateral cerebral ventricles via hypodermic puncture. It is useful in obtaining CSF samples for cytological and chemical studies, for monitoring ventricular fluid pressure and for ventricular drainage. The reservoir provides easy access to the lateral ventricles and to cystic tumors for the injection of chemotherapeutic agents and/or radio-isotopes. The Convertible Integra CSF Reservoir may be utilized in hydrocephalic patients as a component in systems designed to shunt CSF from the lateral ventricles into either the right atrium of the heart or the peritoneum.

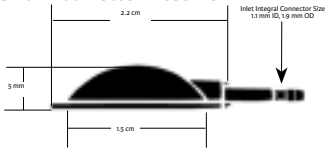
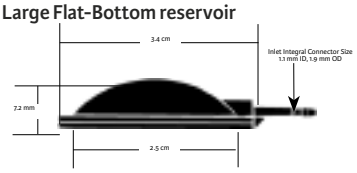
Contraindications

If the Convertible Integra CSF Reservoir is used as part of a shunting system, the following contraindications should be noted: Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

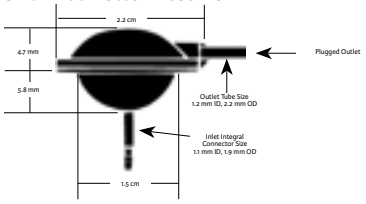
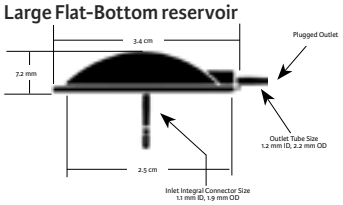
Standard Integra CSF Reservoir

	Size	Flushing Volume	Reference NL8501210	Reference NL8501211
• Burr Hole reservoir 	1.5 CM	0.68 ML	✔	–
• Flat-Bottom reservoir 	2.5 CM	1.26ML	–	✔
• One (1) small Pudenz ventricular catheter [redacted]	–	–	✔	✔

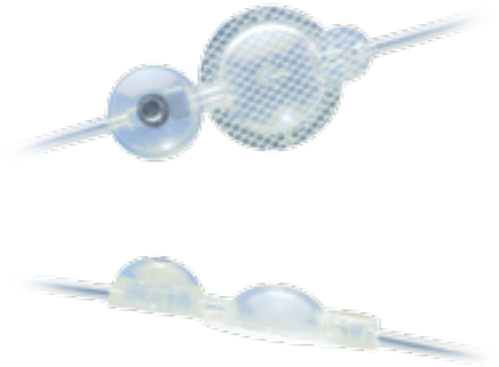
Side-Inlet Integra CSF Reservoir

	Size	Flushing Volume	Reference NL8501214	Reference NL8501212
• Small Flat-Bottom reservoir 	1.5 CM	0.31 ML	✔	–
• Large Flat-Bottom reservoir 	2.5 CM	1.14 ML	–	✔
• One (1) small Pudenz ventricular catheter 	–	–	✔	✔
• One (1) right-angle catheter guide	–	–	✔	✔

Convertible Integra CSF Reservoir

Regular	Size	Flushing Volume	Reference NL8501215	Reference NL8501213
• Small Flat-Bottom reservoir 	1.5 CM	0.68 ML	✔	–
• Large Flat-Bottom reservoir 	2.5 CM	1.31 ML	–	✔
• One (1) small Pudenz ventricular catheter 	–	–	✔	✔
• One (1) right-angle catheter guide	–	–	✔	✔

On-Off Flushing Reservoirs



On-Off Flushing Reservoirs feature the On-Off Device, a proximal occluder and reinforced flat-bottom. The reservoir is offered with or without an Anti-Siphon Device.

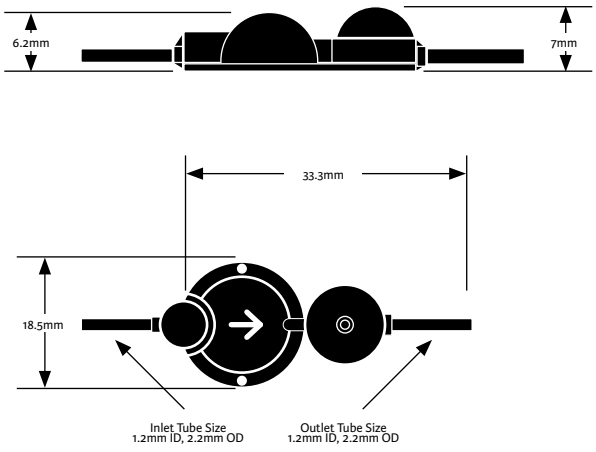
Indications

The On-Off Flushing Reservoir, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum. Reservois with an Anti-Siphon Device are intended to reduce the hazard of negative intraventricular pressure when the patient is sitting, semi-recumbent or standing.

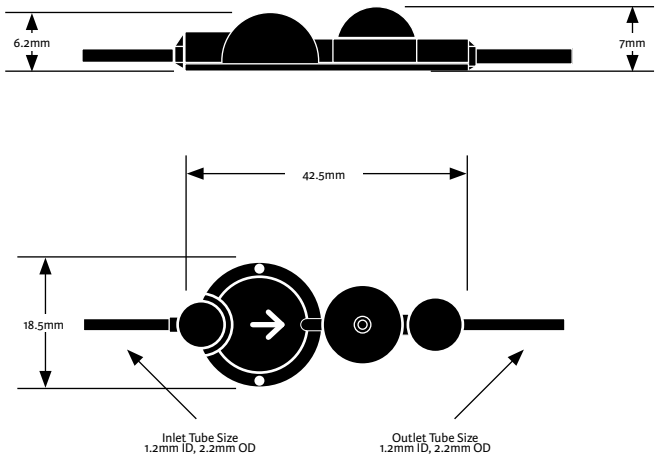
Contraindications

Ventriculatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. The ventriculoatrial method of shunting is contraindicated for hydrocephalic patients with congenital heart disease or other anomalies of the cardiopulmonary system.

On-Off Flushing Reservoir



On-Off Flushing Reservoir with Anti-Siphon Device



	Reference	
Package content	**NL8500150**	**NL8500155**
• Without Anti-Siphon device	✔	–
• With Anti-Siphon device	–	✔

Burr Hole Reservoirs And Caps

Indications

Hydrocephalus valve components are elements used in the implantation of hydrocephalus valve systems. In addition, the burr hole reservoir may be used in conjunction with a ventricular catheter to access ventricular CSF.

Contraindications

Hydrocephalus valve components should not be implanted when an infection exists along the shunt pathway (meningitis, ventriculitis, septicemia and/or bacteremia). Postponement of component implantation is advisable if infection is present anywhere in the body.

Burr Hole Reservoirs And Caps with X-ray Detectable Side Arms

- Burr hole reservoir
- Radiopaque silicone elastomer cap

Diameter: 6.4 mm, radiopaque polypropylene	Depth	Reference
	• Regular Depth 2.5 mm	999110
	• Shallow Depth 0.8 mm	999111

Diameter: 6.4 mm, stainless steel	Depth	Reference
	• Regular Depth 2.5 mm	955110
	• Shallow Depth 0.8 mm	955111

Diameter: 10 mm, stainless steel	Depth	Reference
	• Regular Depth 2.5 mm	955140
	• Shallow Depth 0.8 mm	955141

Burr Hole Reservoirs And Caps without Side Arms

Diameter: 6.4 mm, radiopaque polypropylene	Depth	Reference
	• Regular Depth 2.5 mm	999112
	• Shallow Depth 0.8 mm	999113

Diameter: 6.4 mm, stainless steel	Depth	Reference
	• Regular Depth 2.5 mm	955112
	• Shallow Depth 0.8 mm	955113

Diameter: 10 mm, stainless steel	Depth	Reference
	• Regular Depth 2.5 mm	955142
	• Shallow Depth 0.8 mm	955143

Integral Ventricular Reservoirs

Indications

The Ventricular Antechamber is a CSF reservoir allowing CSF transmission into a shunt system and access to the CSF compartments for sampling or injection. The Integral Ventricular Reservoir may be used as a ventricular access port, and later, if needed, connected to a valve for hydrocephalus patients. The Antechamber should be punctured with a 25G needle.

Contraindications

Implantation should be postponed when an infection exists anywhere in the body. For further information, refer to the Instructions for Use of the Integra NeuroSciences Valve Systems.

		Length = X	Reference
	• Translucent silicone elastomer dome • Radiopaque silicone elastomer base with 4 suture indicators • Polysulfone needle guard • Ventricular catheter introducer and introducing rod • Integral right angle catheter of different lengths • Radiopaque polypropylene, straight connector and plug • Volume: 0.3 ml	3cm	999015
		4cm	999016
		7cm	999017

CSF Reservoirs

Indications

The CSF Reservoir is an implantable device used in conjunction with a ventricular catheter to access ventricles.

Contraindications

The CSF Reservoir should not be implanted when an infection is suspected.

		Reference			
	Package content	999301	999302	999303	999304
	CSF Reservoir: • Translucent silicone elastomer dome • Resist up to 250 punctures* • Radiopaque polypropylene needle guard • Volume: 0.6 ml • Radiopaque polypropylene, integral connector • 4 suture indicators	✔	✔	✔	✔
	+ Right angle Ventricular catheter (7 cm, F8) + Introducing rod	–	✔	–	–
	+ Right angle Ventricular catheter (9 cm, F8) + Introducing rod	–	–	✔	–
	+ Straight Ventricular catheter (15 cm, F8) with radiopaque length tantalum dots every 2 cm up to 10 cm from tip + Right angle guide + Introducing rod	–	–	–	✔

* With a 25G needle

Rickham-Style Reservoirs

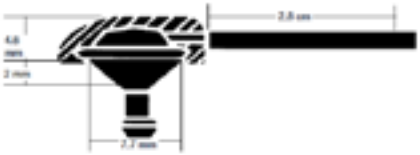
Indications

The UltraVS In-Line Valves, utilized in the treatment of hydrocephalic patients, are components in systems designed to shunt cerebrospinal fluid (CSF) from the lateral ventricles into either the peritoneal cavity or the right atrium of the heart. The in-line and burr-hole systems are designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneal cavity. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated. The Small and Neonate Models can be used in (but are not restricted to) situations where skin erosion may be a problem, as with premature infants, pediatric patients and older patients.

Contraindications

Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. The ventriculoatrial method of shunting is contraindicated for hydrocephalic patients with congenital hear t disease or other anomalies of the cardiopulmonary system.

Large	Size	Reference
	Large	NL8501132

Small	Size	Reference
	Small	NL8501121

Notes

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CSF Management
VI. Catheters & Other Accessories

CSF Ventricular Catheters

Indications & Contraindications for following references

Cat. #	Description
951101	Ventricular Catheters
951101A	
951102	Ventricular Catheters
951102A	
9MD102A	25 cm Ventricular Catheter
9MZ203	Right Angle Ventric. Catheter F8 3 cm
9MZ204	Right Angle Ventric. Catheter F8 4 cm
9MZ205	Right Angle Ventric. Catheter F8 5 cm
9MZ206	Right Angle Ventric. Catheter F8 6 cm
9MZ207	Right Angle Ventric. Catheter F8 7 cm
9MZ208	Right Angle Ventric. Catheter F8 8 cm
9MZ209	Right Angle Ventric. Catheter F8 9 cm
9MZ210	Right Angle Ventric. Catheter F8 10 cm
9MZ211	Right Angle Ventric. Catheter F8 11 cm
9MZ213	Right Angle Ventric. Catheter F8 7-5 cm

Indications

The ventricular catheters are intended for ventricular shunting of cerebrospinal fluid (CSF). Catheters featuring radiopaque dots allow the surgeon to determine the location and depth of the catheter during implantation and on X-Ray.

Contraindications

Ventricular catheters should not be used when an infection exists along the shunt pathway (meningitis, ventriculitis, peritonitis, septicemia, bacteremia). Postponement of shunt or component implantation is advisable if infection is present anywhere in the body. The use of the ventriculoatrial approach is contraindicated in patients with serious heart or cardiopulmonary disease.

Indications & Contraindications for VC1 & PC1

Indications

The Integra NeuroSciences Ventricular Catheter and Peritoneal Catheter are used in treatment of patients with hydrocephalus. They are components of a system designed to shunt cerebrospinal fluid from the ventricles of the brain to the peritoneal cavity.

Contraindications

Hydrocephalus shunt systems should not be implanted when the patient has known or suspected infections in the vicinity of any of the implanted components (meningitis, ventriculitis, skin infections, bacteremia, septice¬mia, peritonitis, etc.). Avoid implanting hydrocephalus shunt systems if infection is present anywhere in the body.

Indications & Contraindications for following references

Cat. #	Description
953100	Atrial Catheter
953101	Peritoneal Catheter
9MZ100	46 cm Atrial Catheter
9MZ101	91 cm Peritoneal Catheter
9MZ1011	110 cm Peritoneal catheter

Peritoneal Catheter

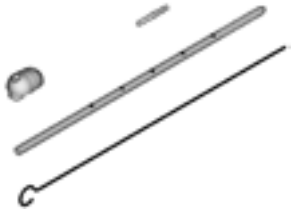
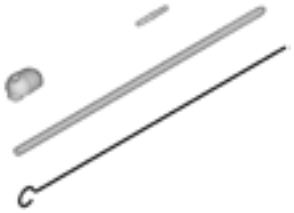
The 91cm peritoneal catheter is used to drain CSF from the outlet of the valve unit into the peritoneum. The distal end of the catheter has four staggered rows of 6-mm slits, which are not readily visible. If the distal outlet hole of the catheter becomes obstructed, the slits open for drainage. The slits perform optimally in a saline environment after soaking for 24 hours at 37°C. To view the slits in a dry environment, pinch the tubing about one inch from the distal end of the catheter and rotate the catheter using thumb and index finger. If the slits still are not visible, dip the distal end of the catheter into sterile saline solution for about one minute. Then insert a metal rod (such as the introducing rod supplied with Integra NeuroSciences ventricular catheters) into the same end. Grasp the tubing about two inches from the distal end. With the other hand, grasp the tubing near the distal end and gently compress the tubing by moving the hands together until the slits appear.

Atrial Catheter

The 46cm atrial catheter is used to drain CSF from the outlet of the valve unit into the right atrium of the heart. The distal end of the catheter does not have any slits. Materials in contact with body tissues or body fluids are silicone elastomer with barium sulfate.

Contraindications

Hydrocephalus shunt systems should not be implanted when the patient has known or suspected infections in the vicinity of any of the implanted components (meningitis, ventriculitis, skin infections, bacteremia, septicemia, peritonitis, etc.).Avoid implanting hydrocephalus shunt systems if infection is present anywhere in the body. Shunting into the atrium of patients with congenital heart disease or other cardiopulmonary anomalies is contraindicated.

Standard Ventricular Catheters		Length	Size	Style	Reference
	• 15 cm Ventricular catheter with radiopaque length dots every 2 cm up to 10cm from tip (F8) • Straight polypropylene connector • Right angle guide • Introducing rod	15 cm	ID: 1.4mm OD: 2.7mm	Full Barium	9MD102A
	• 15 cm Ventricular catheter • Straight polypropylene connector • Right angle guide • Introducing rod	15 cm	ID: 1.4mm OD: 2.7mm	Full Barium	951102A
	• 15 cm Ventricular catheter • Stainless Steel Right angle guide • Introducing rod	15 cm	ID: 1.4mm OD: 2.7mm	Full Barium	951102
	• 25 cm Ventricular catheter (F8) • Right angle guide • Introducing rod	25 cm	ID: 1.4mm OD: 2.7mm	Full Barium	VC1

Finned Ventricular Catheters		Length	Size	Style	Reference
	• 15 cm Finned Ventricular catheter • Straight polypropylene connector • Right angle guide • Introducing rod	15 cm	ID: 1.4mm OD: 2.7mm	Full Barium	951101A
	• 15 cm Finned Ventricular catheter • Stainless Steel Right angle guide • Introducing rod	15 cm	ID: 1.4mm OD: 2.7mm	Full Barium	951101

Pudenz Ventricular Graduated Model Catheters

Indications

The Pudenz Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into either the right atrium of the heart or the peritoneum.

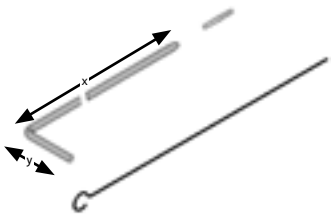
Contraindications

Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infec tions, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. The ventriculoatrial method of shunting is contraindicated for hydrocephalic patients with congenital heart disease or other anomalies of the cardio pulmonary system.

Standard Pudenz Ventricular Graduated Model Catheter		Length	Size	Style	Reference
	• Radiopaque tantalum markings between 4cm and 10cm intervals with larger markings at 5cm and 10 cm aid in catheter placement.	18 cm	ID: 1.3mm OD: 2.5mm	Barium Stripe	NL8501228

Small Pudenz Ventricular Graduated Model Catheter		Length	Size	Style	Reference
	• Radiopaque tantalum markings between 4cm and 10cm intervals with larger markings at 5cm and 10 cm aid in catheter placement.	18 cm	ID: 1.3mm OD: 2.5mm	Barium Stripe	NL8501504

Right Angle Ventricular Catheters

Right Angle Ventricular Catheters		Length (x)	Length (y)	Size	Style	Reference
	• F8 ventricular catheter • Straight polypropylene connector • Introducing rod	3 cm	2.2 cm	ID: 1.4 mm OD: 2.7 mm	Barium Stripe	9MZ203
		4 cm				9MZ204
		5 cm				9MZ205
		6 cm				9MZ206
		7 cm				9MZ207
		8 cm				9MZ208
		9 cm				9MZ209
		10 cm				9MZ210
		11 cm				9MZ211
		7 cm	5 cm			9MZ213

Portnoy Ventricular Catheter

Indications

The Portnoy Ventricular Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into either the right atrium of the heart or the peritoneum.

Contraindications

Ventriculoatrial or ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia, or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Portnoy Ventricular Catheter	Length	Size	Style	Reference
	18 cm	ID: 1.3mm OD: 2.2mm	Barium Impregnated, Flanged	NL8501229

Cyst Puncture Catheter

Indications

The Cyst Puncture Catheter is used for the puncture and drainage of intracranial cysts. It is especially designed to facilitate the puncture of cystic lesions that cannot be entered with standard ventricular catheter, because they either have walls too tough to be penetrated by blunt ended catheters, or because they are relatively mobile and are displaced by the catheter rather than punctured.

The patients' clinical pathology dictates whether the Cyst Puncture Catheter is connected to either an internal drain (cystoperitoneal shunting) or an external drainage system.

Contraindications

None known.

Cyst Puncture Catheter		Length	Size	Reference
	• Radiopaque silicone elastomer catheter with radiopaque length dots at 5, 10 and 15cm from tip, with open, tapered tip and with 2 large side holes • Blunt introducing rod for catheter placement • Sharp introducing rod for cyst puncture	25 cm	ID: 1.4mm OD: 2.7mm	951401

CSF Peritoneal, Lumbar & Cardiac Catheters

Pudenz Peritoneal Graduated Model Catheters

Indications

The Pudenz Peritoneal Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneum. A ventriculoperitoneal shunting system may be indicated to avoid the cardio - vascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated.

Contraindications

Ventriculoperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

	Differential Pressure Range mm H2O		
	15-54	55-94	95-150
Pressure Range >	LOW	MEDIUM	HIGH
Radiolucent Code >	•	••	•••

Pressure Range	Length	Size	Style	Reference
LOW	90 cm	ID: 1.4mm OD: 2.7mm	Barium Stripe	NL8501380
MEDIUM	90 cm	ID: 1.4mm OD: 2.7mm		NL8501381
HIGH	90 cm	ID: 1.4mm OD: 2.7mm		NL8501382

Peritoneal Catheters Open-Ended with Slits

Length	Size	Style	Reference
120 cm	ID: 1.3mm OD: 2.5mm	Barium Stripe	NL8501376
90 cm	ID: 1.1mm OD: 2.3mm		PC1
91 cm	ID: 1.1mm OD: 2.3mm		953101
91 cm	ID: 1.1mm OD: 2.1mm	Full Barium	9MZ101
110 cm	ID: 1.1mm OD: 2.1mm		9MZ1011

Reflux Control Peritoneal Catheter

Indications

The Peritoneal Reflux Control Catheter and Peritoneal Open-Ended Catheter With Slits, utilized in the treatment of hydrocephalic patients, are components for systems designed to shunt cerebrospinal fluid from the lateral ventricles into the peritoneum. A ventriculoperitoneal shunting system may be indicated to avoid the cardiovascular complications of an atrial shunt or for a hydrocephalic patient in whom an atrial shunt is contraindicated.

Contraindications

Ventriculperitoneal shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Length	Size	Style	Reference
			
120 cm	ID: 1.3mm OD: 2.5mm	Barium Stripe	NL8501375

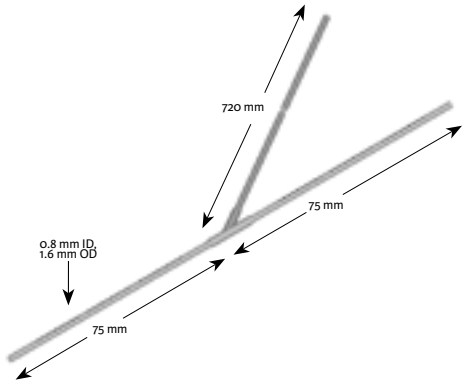
Y-Lumbar Catheter

Indications

The Y-Lumbar Catheter is an implantable device designed to be connected to a hydrocephalus shunt system, for cerebrospinal fluid drainage from the lumbar subarachnoid space to the peritoneal cavity.

Contraindications

Integra NeuroSciences hydrocephalus valve system components should not be used when infection exists long the shunt pathway (meningitis, ventriculitis, peritonitis, septicemia, bacteremia). Postponement of shunt or component implantation is advisable if infection is present anywhere in the body.



Package content	Reference
• Radiopaque silicone elastomer catheter (720 mm, F5) • 2 open-ended, proximal branches (75 mm, F5) with 3 series of 10 holes • Open distal outlet • Suturable tubing clamp for F5 catheters • Radiopaque polypropylene F8/F5 stepdown connector	951103

Cardiac Catheters

Indications

The Pudenz Cardiac Catheter, utilized in the treatment of hydrocephalic patients, is a component in systems designed to shunt cerebrospinal fluid from the lateral ventricles of the brain into the right atrium of the heart. The Infant Cardiac Catheter is utilized when the common facial and/or internal jugular veins are too small to accommodate the larger cardiac catheter.

Contraindications

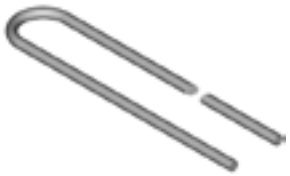
Ventriculoatrial shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body. The ventriculoatrial method of shunting is contraindicated for hydrocephalic patients with congenital heart disease or other anomalies of the cardiopulmonary system.

Indications and Contraindications of references 953100 & 9MZ100 are on page 57.

Cardiac Catheter Standard	Length	Size	Style	Pressure Range	Reference
	60 cm	ID: 1.4mm OD: 2.7mm	Barium Stripe	LOW	NL8501201
				MEDIUM	NL8501200
				HIGH	NL8501202

Cardiac Catheter Pediatric	Length	Size	Style	Pressure Range	Reference
	60 cm	ID: 1.3mm OD: 2.2mm	Barium Stripe	LOW	NL8501221
				MEDIUM	NL8501220
				HIGH	NL8501222

Atrial catheter (F7)	Length	Size	Style	Reference
	46 cm	ID: 1.1mm OD: 2.3mm	Barium Stripe	953100

Atrial catheter (F6)	Length	Size	Style	Reference
	46 cm	ID: 1.1mm OD: 2.1mm	Full Barium	9MZ100

Shunt Accessories

Integra offers a variety of disposable accessories, including catheter connectors, guides, passers and introducers. All connectors and guides are packaged sterile, unless otherwise indicated.

Indications and contraindications for ref NL8501900, NL8501902, NL8501908, NL8501911, NL8501913, NL8501919 :

Indications
Integra connectors are utilized principally in the treatment of hydrocephalic patients, as components in systems designed to shunt cerebrospinal fluid from the lateral cerebral ventricles of the brain into either the right atrium of the heart or the peritoneum.

Contraindications
Integra connectors are designed for use as components in systems which provide access to the ventricles of the brain, particularly hydrocephalic shunt systems. Hydrocephalic shunting systems should not be used in the presence of known or suspected infections along the course of the shunt (meningitis, ventriculitis, skin infections, bacteremia, septicemia or peritonitis). It is advisable to avoid shunting procedures if infection is present anywhere in the body.

Indications and contraindications for ref 991002 :

Indications
The Right Angle Guide is a component of Integra NeuroSciences Hydrocephalus Valve Systems. It is used to form a right angle bend in a F7, F8 ventricular catheter at the burr hole (diameter 5 mm). Implanted materials are silicone elastomer impregnated with barium sulfate.

Contraindications
Integra NeuroSciences hydrocephalus valve components should not be implanted when an infection exists along the shunt pathway (meningitis, ventriculitis, septicemia and/or bacteremia). Postponement of shunt or component implantation is advisable if infection is present anywhere in the body.

Indications and contraindications for ref 999004, 999005, 999007 :

Indications
The Integra Suturable Tubing Clamps are used to anchor a ventricular or a lumbar catheter to the surrounding patient's tissues, for use with an Integra Lumbo-Peritoneal Hydrocephalus Valve System, an Integra External CSF Drainage Set or an Integra Intraventricular Monitoring Catheter Set.

Contraindications
Integra hydrocephalus valve systems and components should not be used when an infection exists along the shunt pathway (meningitis, ventriculitis, peritonitis, septicemia and/or bacteremia). Postponement of shunt or component implantation is advisable if infection is present anywhere in the body. ICP monitoring and external CSF drainage systems are contraindicated in patients: with a history of bloodclotting abnormalities, receiving anticoagulants, with scalp or skin infections.

Catheter Connectors and Right Angle Guides

	Package content	Reference
	• Pudenz Straight Connector	NL8501900
	• Pudenz Right Angle Connector	NL8501902
	• Pudenz Three-Way ("Y") Connector	NL8501908
	• Threaded Straight Connector	NL8501911
	• Threaded Right Angle Connector	NL8501913
	• Double-Threaded Straight Connector	NL8501919
	• Right Angle Guide for F8 Catheters (5 per box)	991002
	• Suturable Tubing Clamp for F7 Catheters (5 per box)	999004
	• Suturable Tubing Clamp for F5 Catheters (5 per box)	999005
	• Suturable Tubing Clamp for F8 Catheters (5 per box)	999007

Radiopaque Polypropylene Connectors

	Package content	Size	Packaging	Reference
	• Straight Connector	OD: 2.0 mm ID: 1.0 mm	5 sterile units per box	999410
	• Right Angle Connector	OD: 2.0 mm ID: 1.0 mm	5 sterile units per box	999411
	• Three-Way (“Y”) Connector	OD: 2.0 mm ID: 1.0 mm	5 sterile units per box	999412
	• Three-Way (“T”) Connector	OD: 2.0 mm ID: 1.0 mm	5 sterile units per box	999414
	• Stepdown (F8 to F5), OD:1.8-1.5mm; ID 0.8mm	OD: 1.8 - 1.5 mm ID: 0.8 mm	5 sterile units per box	999415

Stainless Steel Connectors

	Package content	Size	Packaging	Reference
	• Straight Connector	OD: 1.8 mm ID: 1.2 mm	5 sterile units per box	901410
	• Right Angle Connector	OD: 1.8 mm ID: 1.2 mm	5 sterile units per box	901411
	• Three-Way (“Y”) Connector	OD: 1.8 mm ID: 1.2 mm	5 sterile units per box	901412
	• Three-Way (“T”) Connector	OD: 1.8 mm ID: 1.2 mm	5 sterile units per box	901414
	• Stepdown (F8 to F5), OD:1.8-1.5mm; ID 0.8mm	OD: 1.8 - 1.5 mm ID: 0.8 mm	5 sterile units per box	901415

* Special order - contact your Integra NeuroSpecialist

Shunt Implantation Instruments

Catheter Passer and Introducer

Description

The Tunneler is a single-use instrument consisting of a stainless steel cannula with removable handle, plastic line with bullet-shaped end and barbed end, and sheath. The tunneler is used to make a subcutaneous tunnel between two incisions for procedures such as the subcutaneous insertion of the peritoneal drainage catheter of a hydrocephalus shunt. The barbed end is intended to be connected to a 0.8 to 1.4 mm internal diameter catheters. The tunneler is available in 45 and 65 cm lengths.

Contraindications

None known.

Package content	Length	Reference
• Malleable Shunt Tunneler ID 3.5mm (Box of 5)	45 cm	990001
	65 cm	990010

Reusable Peritoneal Introducers

Description / Indications

The Integra Peritoneal Introducer is a reusable, stainless steel obturator with a suture hole in the bullet-shaped tip and a stainless steel handle. The introducer is designed to be used with a sheath (inner diameter: 4 mm) to make a subcutaneous tunnel between two incisions for the subcutaneous insertion of the peritoneal drainage catheter of a hydrocephalus shunt. When ordering additional sheaths, specify Catalog No. 990-012 (31 cm), Catalog No. 901-118 (46 cm) or Catalog No. 901-124 (61 cm).

Contraindications

None known.

Package content	Length	Reference
• Stainless steel • Non sterile (multiple use)	31 cm	901212
	46 cm	901218
	61 cm	901224
	70 cm	9MD270*

Replacement Peritoneal Introducer Sheaths

Descriptions / Indications

The Peritoneal Introducer Sheath from Integra is designed to be used with a Peritoneal Introducer of appropriate length during the placement of a peritoneal drainage catheter in the treatment of hydrocephalus (also see instructions supplied with the Peritoneal Introducers from Integra NeuroSciences). It features a tapered tip to facilitate subcutaneous insertion and passage.

The 31 cm sheath (Catalog N° 990012) is to be used in the usual manner with the 31 cm Integra NeuroSciences Peritoneal Introducers, the 46 cm sheath (Catalog N° 901118) with the 46 cm Introducers, and the 61 cm sheath (Catalog N° 901124) with the 61 cm Introducers. The sheath is made of polypropylene.

Precautions

This product is for single use only. All components are extremely difficult to clean after being exposed to biological materials and adverse patient reactions may result from reuse. This product is sterilized with ethylene oxide. Do not use if the package is open or damaged. Use the device prior to the "Use Before" date on the package label. Caution: Do not re-sterilize. Integra will not be liable for any or all damages including, but not limited to, direct, indirect, incidental, consequential or punitive damages resulting from or related to re-sterilization.

Package content	Length	Reference
• Translucent polypropylene 5 sterile units per box (single use)	31 cm	990012
	46 cm	901118
	61 cm	901124
	70 cm	9MD170*

Tuohy Needle

Indications

The Integra 14G Tuohy Needle is an instrument used to facilitate implantation of a F5 lumbar catheter into the subarachnoid space of the spine, for use with an Integra lumboperitoneal shunt or an Integra lumbar external drainage set.

Contraindications

Bleeding disorders and infections.

Package content	Reference
For placement of F5 lumbar catheter • Tuohy Needle, 14G, 90mm	990003

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