

INTEGRA NPH™ *low flow valve*

*The automatic,
self-adjusting choice
for NPH.*

The next-generation valve
for the generation who needs it most.

 **INTEGRA™**

Protect aging patients from the ravages of NPH.

Mature patients over sixty, exhibiting gait disturbance, dementia and urinary incontinence may not be suffering from Alzheimer's or other neurodegenerative disorders, but from Normal Pressure Hydrocephalus (NPH). The cause of this debilitating condition is unclear. But many clinicians cite an abnormal accumulation of CSF that dilates and enlarges the ventricles, unnaturally stretching delicate cerebral nerve tissue. NPH does not measurably increase ICP, so unlike most hydrocephalus, it can easily go undetected.

Detection and Diagnosis

When NPH is suspected, it can be identified by clinical assessment, computerized tomography (CT) and/or MRI scans. CSF flow studies and other familiar diagnostic tests can also be used.

The Only Known Treatment

Though the cause of NPH is not clear, the best way to treat it is with a surgically implanted shunt. To date, shunts are the only known effective treatment option for NPH.



Integra's NPH™ *low flow valve.* Automatic Protection.

The Integra NPH™ low flow valve is a next-generation shunt that's physiologically designed to meet the special outflow needs of NPH patients. It is the only self-adjusting valve that automatically provides a CSF flow-regulation rate of approximately 10ml/hr. and is physiologically designed for the outflow needs of NPH patients.

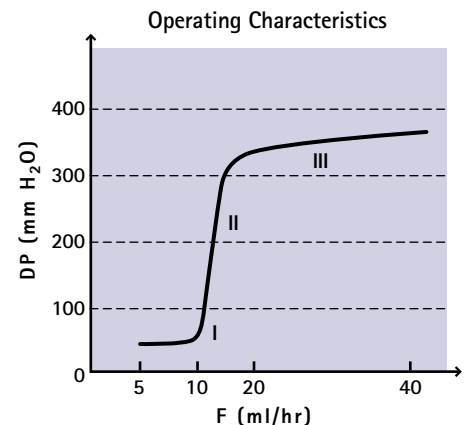
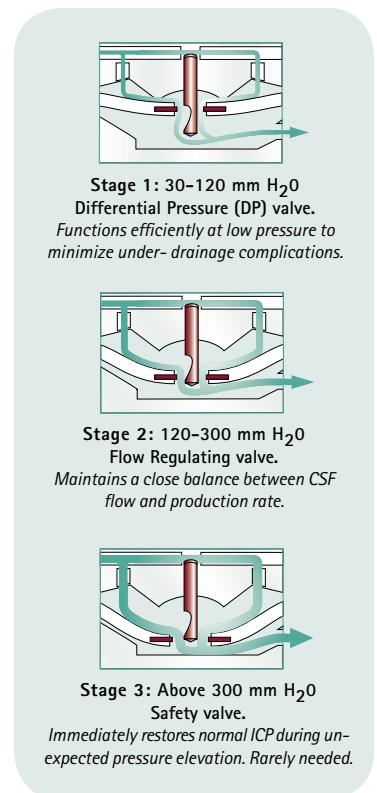
Advantages Over Programmable Valves

The Integra NPH low flow valve delivers position-independent performance, without programming or frequent adjustments. The Integra NPH low flow valve offers safety advantages over programmable valves, which can unpredictably readjust themselves and erratically alter flow rates in the presence of magnetic fields, including diagnostic MRI.

Integra – Peace of Mind for the Young at Heart

Patients who experience difficulty walking, impaired bladder control and/or dementia may incorrectly attribute them to normal aging and not seek medical help. By resigning themselves to their condition, patients' mental acuity and physical abilities can quickly diminish which may reduce mobility and burden family caregivers.

If your patients test positive for NPH, contact your Integra representative to discuss the many clinical advantages of the Integra NPH low flow valve.



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Integra NPH™ low flow valve ordering information

Two Piece Systems (Includes: Valve, 110cm open-ended striped peritoneal catheter, Straight connector and Luer connector.)

CATALOG NUMBER	RESERVOIR	ACCESSORIES
909512	Yes	15 cm ventricular catheter
909513	No	15 cm ventricular catheter
909507	Yes	Malleable 65 cm tunneler
909508	No	Malleable 65 cm tunneler
909507S	Yes	Ventricular catheter and tunneler NOT included
909508S	No	Ventricular catheter and tunneler NOT included

One Piece System (Includes: Valve, 110cm open-ended striped peritoneal catheter, right angle guide, Straight connector and Luer connector.)

CATALOG NUMBER	RESERVOIR	ACCESSORIES
909518	Yes	Attached 7 cm ventricular catheter
909519	No	Attached 7 cm ventricular catheter
909506	Yes	Attached 9 cm ventricular catheter
909505	No	Attached 9 cm ventricular catheter
909504	Yes	Attached 13 cm ventricular catheter

Burr Hole Systems (Includes: Valve, 15 cm ventricular catheter, 110cm open-ended striped peritoneal catheter, right angle guide, Straight connector and Luer connector.)

CATALOG NUMBER	RESERVOIR	ACCESSORIES
909521	Yes	Integral 6.4 mm burr hold cap Regular and shallow burr hole reservoirs
909520	No	Integral 6.4 mm burr hold cap Regular and shallow burr hole reservoirs

Valve Units (Includes built in connectors.)

CATALOG NUMBER	RESERVOIR
909500	Yes
909501	No

CSF PRODUCTION IN THE ELDERLY

CSF production has been found to be reduced in the elderly population. CSF production rate was found to be 24.6 +/- 14.4 ml/hr in the young (28.7 +/- 4.6 years) and 11.4 +/- 4.2 ml/hr in an elderly population (77.1 +/- 6.3 years), in healthy volunteers.^{1,2}

DESCRIPTION

The Integra NPH™ Low Flow Valve is an implantable hydrocephalus valve system 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 NPH™ Low Flow Valve is a variable resistance valve that maintains a drainage at a constant rate, around 10ml/hr, which is within the physiological range of intracranial pressure (ICP). The mechanism incorporates a safety pressure relief mode to prevent accidental intracranial hypertension.

INDICATIONS

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

CONTRAINDICATIONS

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

Integra NPH™ Low Flow Valve should not be implanted in patients with untreated choroid plexus tumors. Such tumors produce CSF at rates in excess of the specification of the flow regulation Stage II, and the valve would underdrain under these conditions.

Integra NPH™ Low Flow Valve should not be used for drainage of extraventricular fluid collections such as hygromas or cysts; such conditions are typically treated with very low differential pressure valves.

PRECAUTIONS

- Closely observe patients with an implanted valve system for shunt failure symptoms (see "Side Effects").
- During implantation, have duplicates of each component available.
- Handle valve tubing carefully. Cover forceps and clamp jaws with silicone elastomer tubing.
- Do not lubricate valves. They will be lubricated adequately by CSF.
- Silicone elastomer requires special handling to prevent contamination. Avoid contact with glove talc or skin oils.
- The drainage catheter may be trimmed to the desired length during implantation. Other modifications are not recommended.
- In children, insert sufficient drainage catheter length into the abdominal cavity to allow for growth.
- To minimize the possibility of underdrainage in patients confined to a supine position (i.e., patients under 3 months of age and bedridden patients), these patients should be elevated at a 45° angle for several hours a day (using a pillow, etc.) until they can sit or stand independently.



Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536
www.Integra-LS.com

Customer Service

USA and Canada:
800-654-2873
609-275-0500 (Outside USA)
609-275-5363 (Fax)

England:
+44 (0) 1264 345 700
+44 (0) 1264 332 113 (Fax)

France:
+33 (0) 493 95 56 00
+33 (0) 493 95 56 60 (Fax)

Germany:
0800 10 10 755
06995 775 477 (Fax)



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References:

1. C. May. Cerebrospinal fluid production is reduced in healthy aging, *Neurology* 40, 1990;
2. M. Czosnyka et al. Age dependence of cerebrospinal pressure-volume compensation in patients with hydrocephalus, *J Neurosurgery*, 2001, 94:482-486