

# Contour-Flex™ Valve



**Reliable • Precise • Cosmetically Unobtrusive**

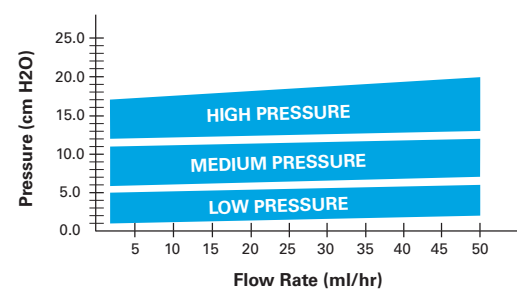
The Integra NeuroSciences Contour-Flex™ Valve is a multi-function membrane valve featuring a rugged design that allows for accurate and precise regulation of CSF flow due to its structural integrity.

The valve incorporates a central reservoir for pumping and injection, and proximal and distal occluders to facilitate two-way flushing. It also features integral connectors to allow for easy catheter connection and a fully flexible profile that easily conforms to the curvature of the cranium. The tantalum impregnated silicone arrow and pressure dot code on the valve housing allow for post-implantation identification of pressure rating.

The Contour-Flex™ Valve is available in two sizes: regular and small. Each size is available in 3 pressure ranges: Low, Medium, and High. The pressure/flow characteristics of the Contour-Flex™ Valve are detailed in the graph and chart to the right.

**CLOSING PRESSURE RESULTS**

Valve Markings	Valve Pressure (Regular and Small)	Acceptable (Closing Pressure)
•	Low	0.1–5 cm H <sub>2</sub> O
• •	Medium	5–11 cm H <sub>2</sub> O
• • •	High	11–17 cm H <sub>2</sub> O



# Contour-Flex™ Ordering Information

## Valve Units—Regular

Catalog Number	Pressure Range
CFRL	Low
CFRM	Medium
CFRH	High

## Valve Units—Small

Catalog Number	Pressure Range
CFSL	Low
CFSM	Medium
CFSH	High

## Shunt Systems—Regular

(Includes: Integral 91 cm, barium-sulfate striped drainage catheter, open-ended; plus separate 15 cm ventricular catheter with stylet and right angle guide)

Catalog Number	Pressure Range
11811	Low
11812	Medium
11813	High

## Shunt Systems—Small

(Includes: Integral 91 cm, barium-sulfate striped drainage catheter, open-ended; plus separate 15 cm ventricular catheter with stylet and right angle guide)

Catalog Number	Pressure Range
14085	Low
14086	Medium
14087	High

## Shunt Systems—Burr Hole—Regular

(Includes: Integral 91 cm, barium-sulfate striped drainage catheter, open-ended; Integral Burr Hole Reservoir; plus separate 15 cm ventricular catheter with stylet and right angle guide)

Catalog Number	Pressure Range
11854	Low
11855	Medium
11856	High

## Shunt Systems—Burr Hole—Small

(Includes: Integral 91 cm, barium-sulfate striped drainage catheter, open-ended; Integral Burr Hole Reservoir; plus separate 15 cm ventricular catheter with stylet and right angle guide)

Catalog Number	Pressure Range
16254	Low
16255	Medium
16256	High

## Shunt Systems—Three Piece—Regular

(Includes: Integral 91 cm, barium-sulfate striped drainage catheter, open-ended; plus separate 15 cm ventricular catheter with stylet and right angle guide)

Catalog Number	Pressure Range
12508	Low
12509	Medium
12510	High

## Shunt Systems—Three Piece—Small

(Includes: Integral 91 cm, barium-sulfate striped drainage catheter, open-ended; plus separate 15 cm ventricular catheter with stylet and right angle guide)

Catalog Number	Pressure Range
12505	Low
12506	Medium
12507	High

**DESCRIPTION:** The Integra NeuroSciences Contour-Flex™ Valve is a multi-function membrane valve with occluders and integral connectors. It is used in treatment of patients with hydrocephalus when shunting cerebrospinal fluid (CSF) from ventricles of the brain. It incorporates a central reservoir for pumping and injection, proximal and distal occluders, and a fully flexible profile. The Contour-Flex™ Valve design includes a flat silicone membrane, which provides resistance to CSF flow. The flat silicone membrane seats on a conical polypropylene base. This base is integral to a rigid outlet port. The design allows for accurate and precise regulation of CSF flow due to its structural integrity. The flat silicone membrane also prevents retrograde flow of CSF.

**INDICATIONS:** The Integra NeuroSciences 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.

### PRECAUTIONS:

- Patients or their representatives should be informed of the warnings and potential complications associated with use of this device prior to implantation.
- Avoid cutting or occluding catheter tubing when securing tubing to valve connector with ligatures. Do not kink catheters at any point. Other than trimming catheters or valve tubing, modifications are not recommended.
- Avoid use of sharp metal instruments when handling silicone components to avoid any damage.
- If a hypodermic injection into the reservoir is required, use a 25-gauge or smaller beveled needle and only inject into the reservoir dome.
- Have duplicates of each component available during implantation.
- Do not lubricate valves. They will be lubricated adequately by the CSF.
- Avoid contaminants such as glove talc and contact with skin oils when handling tubing.
- Do not place the Contour-Flex™ Valve under the skin of the neck, chest or abdomen.



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