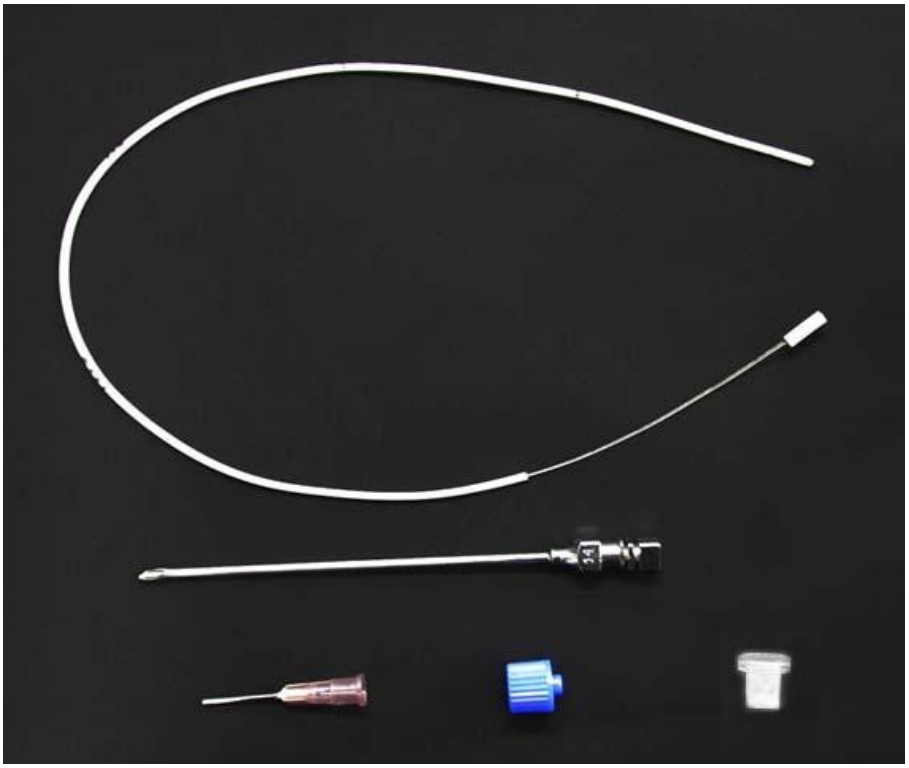
BMI® Medical

CSF Lumbar Catheter

Surgical Technique



Wellong Instruments Co., Ltd.

Company address:

2F, No. 63, Linsen North Road, Taipei, Taiwan, R.O.C.

Factory address:

5th Floor, No.7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New Taipei City, Taiwan, R.O.C.

Tel: +886-2-2571-9829, +886-2-2541-2961

Fax: +886-2-2562-7884

E-mail: cctco@ms35.hinet.net

Labels

CE 2460	The device totally complies with European Directive 93/42/EEC
	Caution
	Use by
STERILE EO	Sterilization by Ethylene-Oxide Gas
	Do Not Reuse
REF	Model No.
LOT	Lot Number
	Manufactured at
	Date of manufacture
	Read and follow the instruction manual before use
	Temperature Limitation
	Do not use if package is damaged
	Do not resterilize
EC REP	Luana Med. B.V. 2627 AL, Abtswoudseweg 18, Delft, the Netherlands

Warnings

- **STERILE and NON-PYROGENIC unless damaged or open.**
- **The law restricts this device to sell by or on the order of a surgeon.**
- **Medical devices labeled “single-use only” should never be reused. Reuse of these devices is strictly prohibited. Re-using of single use device may result in serious patient illness or harm. Examples of hazards related to the reuse of these devices include, but are not limited to: cross-infection, contamination, and significant degradation in device performance.**

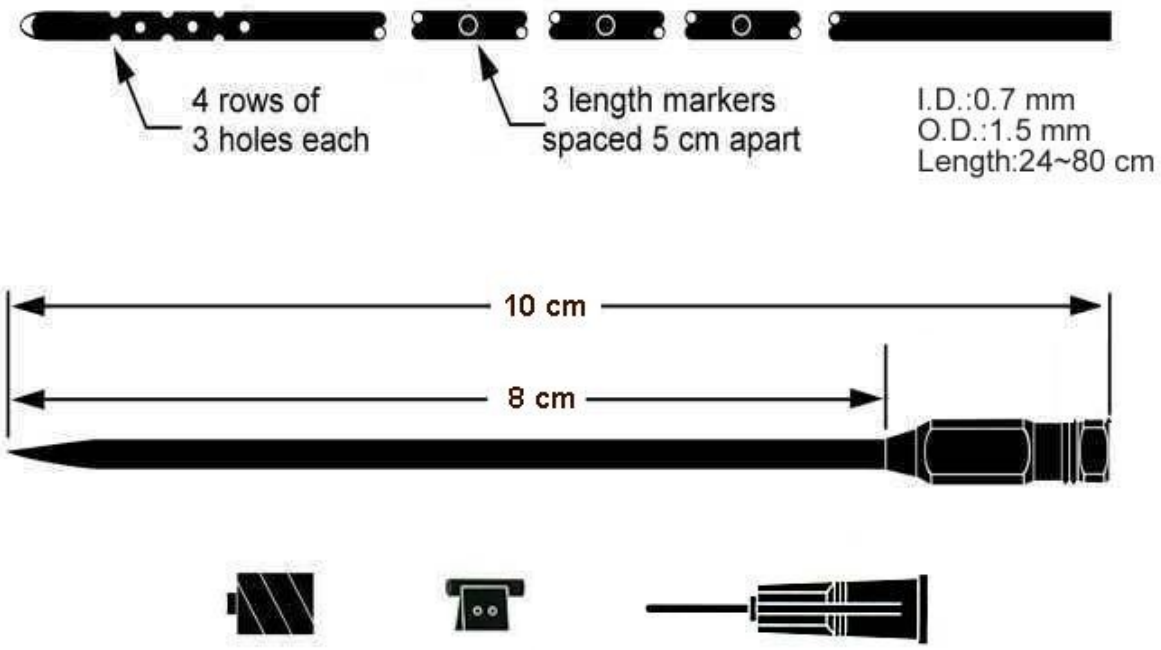
BMI® Medical CSF Lumbar Catheter

BMI® Medical CSF Lumbar Catheter is designed for the diversion of CSF from the lumbar subarachnoid space into the peritoneal cavity using simplified surgical techniques.

Indications

For use in the treatment of hydrocephalus as a component of a shunt system when draining or shunting of cerebrospinal fluid (CSF) is indicated.

Use of CSF Lumbar Catheter is indicated in the treatment of communicating hydrocephalus, CSF fistulas, selected problems associated with increased intracranial pressure and in the diagnosis and treatment of normal pressure hydrocephalus.



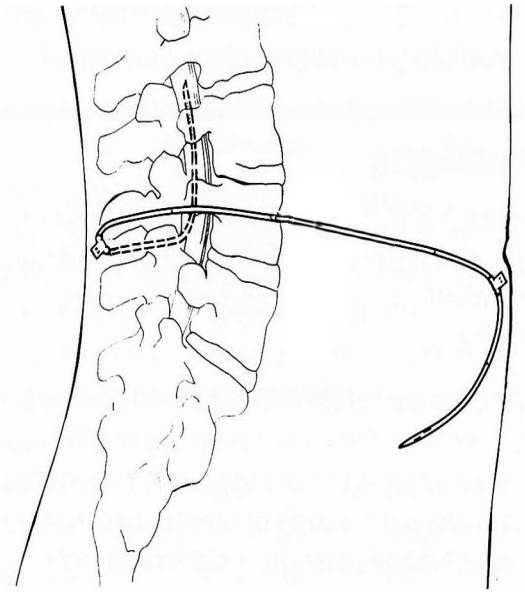
Description

- **06418** Lumbar catheter, 24 cm~80 cm, Silicone Barium Impregnated
  I.D.: 0.7 mm, O.D.: 1.5 mm, round closed end
- Tuohy Needle, 14 gauge, 8 cm with huber tip
- 1 blunt needle/ luer lock cap

- Fixation tab

Instructions for use

1. Insert the blunt needle into the distal lumbar end of the catheter, flush with saline.
2. Implantation of the lumbar tip of the catheter in the subarachnoid space.
3. Insertion of the distal end of the catheter into the peritoneal cavity.



Contraindications

Shunting of CSF into the peritoneal cavity, right atrium, or other areas of the body should not be carried out if there is infection in any area of the body. Shunting in the atrium of patients with congenital heart disease or other serious cardiopulmonary abnormalities is contraindicated.

Warnings and precautions

- Improper use of instruments in implanting or handling shunt products may result in the crushing, cutting, or slitting of components, which may cause loss of shunt integrity, and necessitate premature surgical revision of the shunt system.
- Care must be taken to ensure that particulate contaminants are not introduced into shunt components during preimplantation, handling, or testing. Introduction of contaminants could result in shunt occlusion, over drainage, or improper performance of the shunt system.
- Shunt obstruction may occur in any component of the shunt system. It may result from growth of the child, or physical activities which cause the disconnection of the shunt components or withdrawal of a distal catheter from its intended drainage site. The ventricular catheter may be occluded by particulate (e.g. blood clots, brain fragments,

and bacterial colonization), coaptation of the ventricular walls in the presence of overdrainage (“slit ventricles”), investment of the catheter tip in choroid plexus, or embedding of the catheter in brain tissue.

- After being implanted hydrocephalus shunt systems, patients shall be kept under close observation in the postoperative period for signs and symptoms that suggest shunt malfunction, such as shunt obstruction, overdrainage of CSF, and/or infection, showed in clinical findings.
- Overdrainage of CSF may predispose collapse of the lateral ventricular walls, a subdural hematoma or hydroma and result in obstruction of the ventricular catheter.
- In the routing of catheters, care must be taken to prevent catheters from kinking and needless abrasion, which may lead to premature catheter failure or fracture. The rim of the twist drill or burr hole may be trimmed to provide a beveled notch where the ventricular catheter emerges and is bent to lie adjacent to the skull.
- If the ventricular catheter becomes bound to the choroid plexus or adjacent brain tissue by fibrous adhesions, the catheter should not be removed forcibly. It may help to free the catheter by gently rotating the catheter. It is suggested that the catheter be left in place rather than risk intraventricular hemorrhage which may be caused by forcible removal.
- Avoid contacting implantable products with contaminants, such as glove talc, lint, oily residue from skin, and oil based soaps. Introduction of contaminants could result in improper performance of components, allergic reactions, or foreign body reactions.
- Malfunction or obstruction of the shunt system may cause symptoms of increased intracranial pressure if the hydrocephalus is not compensated. In the infant, common symptoms may include increased tension of the anterior fontanel, listlessness, congestion of scalp veins, vomiting, irritability, drowsiness, and nuchal rigidity. In older children and adults, common symptoms may include headaches, deterioration of consciousness, blurring of vision, vomiting, nuchal rigidity, and neurological abnormalities.
- To secure catheters to connectors, the encircling ligatures should fasten them securely but not too tightly, lest they cut through the silicone tubing eventually.
- The time the catheter is immersed in sterile water or saline shall be kept to a minimum.
- The components of a shunt system may separate owing to disconnection or catheter fracture. The separated shunt components may migrate into the cerebral ventricles, the heart, or the peritoneal cavity. Shunt systems may fail due to mechanical malfunction, bringing about under- or over-drainage.

Patient education

It is physician’s responsibility to educate the patient and their relatives about shunting of

CSF. It shall include a description of associated complications, and an explanation of potential alternative product and treatments.

Complications

- Obstruction of the shunting system is the most common complications in all CSF shunting procedures. Due to plugging by blood clots, brain fragments, or tumor cell aggregates, any component of the system may occur obstruction. The separation of components, or kinking and/or coiling of the catheter may also result in obstruction. This may predispose migration of the ventricular catheter into the lateral ventricle or the distal catheter into the peritoneum, the heart and pulmonary arterial tree, or any other structure in which the catheter is implanted.
- Growth of the child may cause the distal catheter to be withdrawn from the peritoneum into tissue planes where the fluid cannot be absorbed, or from the atrium into the internal jugular vein. Besides the shunt obstructions, there are other potentially complications. Local and systemic infection is also one of complications. It results from organisms inhabiting the skin, Staphylococcus epidermidis in particular. Other pathogens circulating in the bloodstream may colonize the shunt and, most of patients, require to remove the shunt.
- Overdrainage of CSF may lead to reduction of CSF pressure and predispose the development of a subdural hematoma or hydroma, and excessive reduction of ventricular size, resulting in obstruction because of impingement of the ventricular walls on the inlet holes in the catheter. In the infant, this excessive reduction of pressure will cause depression of the anterior fontanel, overriding of cranial bones, and may convert communicating hydrocephalus into obstructive hydrocephalus.
- Investments of the peritoneal catheter in loops of bowel or in the greater omentum may fail to shunt into the peritoneum. Perforation of the bowel by the peritoneal catheter may trigger peritonitis.
- Surgical complications associated with ventriculoatrial and ventriculoperitoneal CSF shunting systems may be similar to any surgical procedure performed under local and/or general anesthesia. These include excessive blood loss, electrolyte imbalance, and reactions to drugs and anesthetic agents, particularly in infants. On rare occasions, the patient may exhibit a reaction due to sensitivity to the implant. Use of sharp instruments while handling these devices may nick or cut the silicone implant and lead to leakage. Care must also be taken when suturing incisions to ensure that the implants are not cut or nicked by suture needles.
- According to Robertson et al. (1973), the incidence of infection in ventriculoatrial shunting varied from 7 to 31% while infection in ventriculoperitoneal shunting occurred

in 5 to 10% of the patients, reported up to that time. Because ventriculoatrial shunting predisposes the spread of bacteria into other organs, ventriculoperitoneal shunting is considered less devastating.

- The incidence of epileptic seizures increased with multiple catheter revisions after performing ventricular shunting surgery, indicated by the study.
- According to Kestle et al. (1993), infection is significantly reduced (less than 4%) with the use of antibiotics, short duration of surgery and control of the operating room environment (e.g. limited personnel and traffic and covered skin surfaces). It states that if the environment is under rigorous perioperative control, the same result can be obtained without using antibiotics.
- The use of prophylactic antibiotics in shunted patients may predispose infection by more resistant organisms. The decision to use antibiotics prophylactically rests with the attending physician and/or surgeon.