SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP

WELLONG INSTRUMENTS CO., LTD.

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals.

1. Device identification and general information

1.1. Device trade name(s):

BMI®Medical

1.2. Manufacturer’s name and address

Wellong Instruments Co., Ltd.

2nd Fl., No. 63, Linsen North Rd., Taipei, Taiwan, R.O.C.

1.3. Manufacturer’s single registration number (SRN)

TW-MF-000033081

1.4. Basic UDI-DI

471394566SHUNTSYSTEMFP

1.5. Medical device nomenclature description / text:

MDN1101, MDS1005, MDS1011, MDT2008, MDT2011

1.6. Class of device

Class III

1.7. Year when the first certificate (CE) was issued covering the device

1.8. Authorised representative if applicable; name and the SRN

Luana Med. B. V.

1.9. NB’s name (the NB that will validate the SSCP) and the NB’s single identification number

BSI (CE2797)

2. Intended use of the device

2.1. Intended purpose:

The shunting system is a catheter set intended to remove or transfer cerebrospinal fluid from the lateral ventricles of the brain space to peritoneal cavity or external delivery device, and used by the professional doctor, that the patient with hydrocephalus, intracranial hemorrhage, and any disease needed to be treated by shunting, etc.

2.2. Indication(s) and target population(s)

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 ventricular catheters in selected patients with:

- Severe head injury
- Subarachnoid hemorrhage
- Reyes syndrome or similar encephalopathies
- Hydrocephalus
- Intracranial hemorrhage
- Any disease which needs CSF therapy

2.3. Contraindications and/or limitations

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 he art disease or other serious cardiopulmonary abnormalities is contraindicated.

3. Device description

3.1. Description of the device

BMI Medical Shunting System allows physician to:

- Drainage cerebrospinal fluid (CSF) from the lateral ventricles of the brain space to peritoneal cavity or external delivery device.
- Monitor cerebrospinal fluid (CSF) pressure and flow rate from the lateral

ventricles space.

The CSF-Ventricular Catheters are available in 4 sizes and impregnated with white barium to provide radiopacity fully. The spherical tip of catheter is tantalum-impregnated. The graphitic markers are imprinted at 5, 10, and 15 cm from the catheter tip to show surgeons the depth of penetration of the catheter into the lateral ventricle. There are 4 rows with 4 holes in each row at the end of catheter tubing. The catheter is packaged with a stainless-steel stylet. The stylet facilitates insertion of the catheter into the lateral ventricle.

The peritoneal catheters are available in 2 sizes and provided in three pressure ranges: high, medium, or low. The spherical tip of catheter is tantalum-impregnated. CSF flows from 4 wall slits around the circumference of the catheter near the tip. The graphitic markers are imprinted every 10 cm from the tip of the catheter. Peritoneal catheters are impregnated with white barium to provide radiopacity fully.

The CSF Valve is fabricated of dissimilar materials, thus reducing valve sticking and deformation. The integral structure of the base ensures accuracy and reliable effect. Reservoirs integral design incorporated with a connector and a membrane base.

The connector contributes structural integrity, and facilitates connecting to catheter and the valve.

The External Drainage and Monitoring System (EMDS) consists of a nondistensible patient connection line, patient line stopcock, mounting panel/main system section, two latex-free injection sites and a removable drainage bag with approximate volumetric graduations and microbial filter.

3.2. A reference to previous generation(s) or variants if such exist, and a

description of the differences: NA

3.3. Description of any accessories which are intended to be used in combination with the device: NA

3.4. Description of any other devices and products which are intended to be used in combination with the device: NA

4. Risks and warnings

4.1. Residual risks and undesirable effects

All the risks relative with safety and performance of the device in question under normal conditions of use, through current design controls and actions taken to reduce the residual risks is acceptable. So a conclusion with a justification to be an assessment of any probable benefit to health from the use as intended, against probable risks of injury or illness can be accepted.

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 On rare occ a sions, 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 implan t 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 u sing 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.

4.2. Warnings and precautions

- The appropriate product and size must be chosen for the patient’s needs.
- 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.
- Prior to use p lease ensure all connections and fittings are tight and leak free.
- Pay attention to avert touch valve burr hole with inappropriate mode, especially keep off particles of pollutants invading shunt components.
- Care must be taken to ensure that particulate contaminants are not introduced into shunt components during preimplantation hand ling or testing Introduction of contaminants could result in shunt occlusion, over drainage, or improper performance of the shunt system.
- Small filter vent slide clamp must be opened to allow CSF drainage.
- 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”) ventricles”), investment of the catheter tip in choroid plexus, or embedding of the catheter in brain tissue.
- After being implant ed 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.
- Flow must be monitored to prevent overfilling of the flow chamber.
- Overdrainage of CSF may predispose collapse of the lateral ventricular walls a subdural hematoma or hydroma and result in obstruction of the ventricular catheter.
- During system use with drainage slide clamps closed, fluid accumulation may occur in use with drainage slide clamps closed, fluid accumulation may occur in

flow chamber before it empties.

- In the routing of catheters, care must be taken to prevent catheter 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 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 or adjacent brain tissue by fibrous adhesions, the catheter should not be removed forcibly. y fibrous adhesions, the catheter should not be removed forcibly. It may help to free the catheter 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 f forcible removal.
- Overfilling of the flow chamber will preclude CSF drainage due to wetting of filter vent.
- Avoid contacting implantable products with contaminants, such as glove talc, glove talc, lint, lint, oily residue from skin, residue from skin, and oil based soil based soaps. Introduction of contaminants could result in improper performance of components, allergic reactions, or foreign body reactions, or foreign body reactions.
- Malfunction or obstruction of the shunt system may cause symptoms of increased symptoms of intracranial pressure if the hydrocephalus is not compensated. In the infant, common symptoms may include increased tension of the anterior fontanel, 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, children and adults, common symptoms may include headaches, deterioration of consciousness, consciousness, blurring of vision, vomiting, nuchal rigidity, and neurological abnormalities.
- Manipulation of the drainage bag connection line may be required to establish drainage Manipulation of the drainage bag connection line may be required to establish drainage from flow chamber to drainage bag from flow chamber to

drainage bag.

- To secure catheters to catheters to connectors, the encircling ligatures should fasten them securely but not too tightly, lest they cut through the silicone tubing, lest they cut through the silicone tubing eventually.
- Constant patient monitoring is required if pressure level is set below 0 cmH_2O.
- The time the catheter is immersed in sterile water or saline shall be kept to a minimum.
- The components of a shunt system he components of a shunt system may may separate owing to disconnection or catheter to disconnection or catheter fracture. The separated shunt components he separated shunt components may migrate into the cerebral ventricles, the migrate into the cerebral ventricles, the heart, or the peritoneal cavity. cavity. Shunt systems may fail due to mechanical malfunction, Shunt systems may fail due to mechanical malfunction, bringing about under-- or over--drainage.
- This product is for single use only. Please follow regulations of medical waste for is for single use only. Please follow regulations of medical waste for disposable.

4.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable: NA

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device, if applicable: NA

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

This product was performed a clinical trial study. We collect the CRF data to analyze the performance 56 of BMI products for 88 EVD cases. We analyzed the BMI product with respect to the incidence of malfunction / failure, time to first EVD malfunction / failure, incidence of complication, and incidence of device related adverse events.

The result of this study, We got incidence of shunt malfunction /failure is 30.7%. The

censored cases is 69.3% and event cases is 30.7%. Incidences of complications, infection, and hospitalization are 12.5%, 11.4%, 11.4% respectively. Incidence of device – related adverse events is 12.5%.

5.3. Summary of clinical data from other sources, if applicable

According to the PMS/PMCF activities results, Shunting system products were sold over 130,000 pieces from 2001 to 2013, 404,389 pieces from 2014 to 2022 in Taiwan and sold over 741,309 pieces from 2014 to 2022 in the overseas hospitals. Clinical nurses and doctors got the positive feedbacks from the patients and there were only a few advisory notices and recalls to be active for the PMS /PMCF. We have solved the problems as soon as possible when we were informed. These evidences supported the

same safety and effectiveness of Wellong Shunting System.

5.4. An overall summary of the clinical performance and safety

After retrieving the manufacture and user facility device experience(MAUDE), recall database of the same type of BMI Medical Shunting System, post-market surveillance reports and risk management file, adverse effect and precaution are identified in the IFU. There are not relevant extra adverse events according to PMS data, if the relevant circumstances occur, the amendment will be included in the design basis for improvement. Overall, the referenced information (literature, PMS, and technical data) supports the benefits of BMI Medical Shunting System. Clinical research for BMI Medical Shunting System shows clinical reproducibility and reliable performance is in line with international regulations. Based on the above analysis and assessment of the safety and performance of the BMI Medical Shunting System has met the intended use of the product claims. And after a risk assessment and clinical assessment, when weighing the benefits of medical device, patients, and the risks associated with the use of the device, the risk is acceptable.

5.5. Ongoing or planned post-market clinical follow-up

Post mark surveillance is collected by both proactive and reactive actions on products after marketed.

6. Possible diagnostic or therapeutic alternatives

Currently, most use a shunt system to drain cerebrospinal fluid from the ventricles to other locations in the body, such as the abdominal cavity, peritoneal cavity or atrium. Each site has different advantages and disadvantages, but currently abdominal absorption is the main surgery. In the peritoneal cavity, cerebrospinal fluid is absorbed back into the blood circulation.

7. Suggested profile and training for users

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.

8. Reference to any harmonised standards and CS applied

Graphical symbol for use in the labelling of medical devices

- EN ISO 15223-1:2021 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied.
- IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices
- EN ISO 11135-1:2014 Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- EN ISO 10993-1:2020 Biological evaluation of medical device Part I: Evaluation and

testing within a risk management process

- ISO10993-3 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- EN ISO 10993-5:2009 Biological evaluation of medical device Part 5: Test for in vitro

Cytotoxicity

- ISO10993-6 Biological evaluation of medical devices — Part 6: Tests for local

effects after implantation

- ISO10993-10:2021 Biological evaluation of medical device Part10: Tests for irritation and delayed-type hypersensitivity
- EN ISO10993-11:2018 Biological evaluation of medical device Part11: Tests for systemic toxicity
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for Irritation
- EN ISO 7197:2009 Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components

9. Revision history

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
			☐Yes Validation language: ☐No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)