Instructions for Use of Epidural Anesthesia Kit

[Product name]: Epidural anesthesia kit
[Type]: AS-E
[Product structure and components]： Mainly consists of epidural needle, epidural catheter (general type or reinforced type）, introducer needle, introducer guide, catheter connector, liquid filter and low-resistance syringe.
[Performance characteristics of the device]: It is used for epidural puncture and injection of liquid drugs into the epidural space. Among them, epidural needles and epidural catheters are typical products used in anesthetic techniques, such as epidural needles and epidural catheters used to deliver anesthetic liquid as a local anesthetic. Local anaesthesia prevents the nerves that exist in the epidural space from transmitting pain messages to the brain, effectively preventing the patient from feeling hurt. Usually, an epidural needle and/or an epidural catheter are used to deliver a special grade of local anaesthesia, called an epidural anaesthesia.
[CMR/endocrine-disrupting substances]： The epidural catheter of this device contains DEHP 0.14% (w/w), the low-resistance syringe of this device contains DEHP 2.5% (w/w), and the needle tube of this device contains Cobalt (Co) 0.21% (w/w). The content of CMR/ED substance exceeds 0.1% (w/w). Our company has confirmed that this device is safe through device testing and toxicological risk assessments.
[Clinical benefits]： As an auxiliary tool in the whole anesthesia process through administration of anesthesia drug to relieve the pain of patients during or after surgery.
[Measuring function accuracy]： There are scales on the surface of the epidural needle tube, and the length of each scale is 10mm±1mm, and the interval distance is 10mm±1mm. The depth inside the patient can be judged by the scales during puncture. The interval between the scales of epidural catheter (general type or reinforced type) was 10mm, and the total scale was 250mm, which could be used to determine the depth of puncture patients during catheterization.
[Device connection instructions]： In this medical device, epidural needle can be connected with low-resistance syringe, (or/and) liquid filter, (or/and) epidural catheter (general type or reinforced type). Epidural catheters (general type or reinforced type) can be used together with the infusion devices to inject liquid drugs.

Among them, epidural needles with sizes of 16G-15G are compatible with epidural catheters (general type or reinforced type) with outer diameter of 1.0mm, epidural needles with sizes of 18G-17G are compatible with epidural catheters (general type or reinforced type) with outer diameter of 0.8mm.
[Sterile]: The product is sterilized by EO.
[Shelf life]: 5 years
[Target population]： Adult patients who require anesthesia.
[Intended user]： The intended user is a professionally qualified "anesthesiologist".
[Intended purpose]: During epidural anesthesia, it is used for epidural puncture, and injection of liquid drugs into the epidural space.
[Instruction for use]:

1. First inspect the integrity of the package, and then remove product from the sterile package, and inspect the integrity of product.

2. Properly disinfect the puncture site before local anesthesia.

3. For a routine epidural puncture, a low-resistance syringe connected to the epidural needle hub can be used to detect whether the needle enters the epidural space. It is necessary to carefully perceive the resistance changes before and after the tip breaks through the ligamentum flavum. After the tip breaks through the ligamentum flavum, the resistance in the needle suddenly disappears, indicating that the needle enters the epidural space.

4. The tip of the epidural catheter (general type or reinforced type) penetrates into the epidural needle lumen through the introducer guide, enters the epidural space 3-5cm, and then withdraws the epidural needle slowly.

5. The inlet end of the epidural catheter (general type or reinforced type) is connected to the catheter connector, the catheter connector is connected to the outlet end of the liquid filter, and the liquid filter is connected to a syringe containing the liquid narcotic drug, and the drug is administered as required by the surgery.

6. In general, the epidural catheter (general type or reinforced type) can be withdrawn after the completion of surgery. If postoperative analgesia is needed, it can be connected with analgesic devices, and the epidural catheter (general type or reinforced type) can be withdrawn after analgesia is completed.

[Medical indications]:
It is used for lumbar puncture and injection of liquid drugs into the epidural space, so as to relieve the pain of patients during surgery.

[Contra-indications/Limitation]:
Absolute contraindications: patient refusal, therapeutic anticoagulation, skin infection at puncture site, raised intracranial pressure, hypovolemia.
Relative contraindications: uncooperative patients, pre-existing neurological disorders, heart failure states, anatomical abnormalities of vertebral, prophylactic use of low dose heparin.

[Residual risk include side effect]:
Arterial hypotension, Bradycardia, Tachycardia, Hypertension, Deep venous thrombosis, Pulmonary Embolism, Urinary retention, Nausea and vomiting, Fever, Cardiorespiratory complications, Pruritus, Shivering, Postoperative cognitive dysfunction (POCD), Paraesthesia, Postdural puncture backache (PDPB), Apnoea, Adverse system toxicity, Severe neurologic symptom, Nerve stimulation, Vertigo, Photophobia, Stiffness of the neck, Post-dural puncture headache (PDPH), Infection, Haematoma, Puncture point bleeding, Neuromechanical injury, Ischemic spinal cord injury and Anterior spinal artery syndrome, and Death.

[Adverse Event Feedback and Measures]: In case of adverse reaction during use, stop use immediately, keep the current sample and seal the stock products. Timely report to the manufacturer and/or the competent authorities of the Member State in which the user and/or patient is located.

[Summary of Safety and Clinical Performance]: The details information of SSCP can be found on EUDAMED, please refer to the link: https://ec.europa.eu/tools/eudamed/#/screen/home

[Notices and warning]:

1. For single patient and single-use only. Not to be re-sterilized or reused, in which case performance of device can be affected, and risk of cross-infection is increased.

2. Inspect the integrity of packaging before use. Do not use if any single packaging is damaged.

3. For safety reason, the device can only be operated by an anesthesiologist and may not be operated by a non-anesthesiologist.

4. Manipulation of puncture should be smooth and gentle. Rude operation is prohibited.

5. To prevent accident, forceful penetration of needle has to be avoided in case bigger resistance is encountered during puncture process.

6. In case with needle bent during operation, do not straighten the needle to continue operation.

7. Needle has to be discarded and destroyed after use.

8. Sterilized with EO. Disinfection is valid for 5 years.

9. To be used before the expiry date on sealed package.

10. Residual quantity is approximately 0.15 ml (tested with distilled water). Effect of residual quantity should be taken into account in the process of injection.

11. The epidural catheter should be removed slowly and smoothly. No forcible or quick withdrawal is allowed. To avoid risk of breaking the epidural catheter, do not withdraw the epidural catheter through the needle.

12. The ISO80369-6 mark indicates that the connection port of the product complies with the ISO80369-6 Standard, and the ISO80369-7 mark indicates that the connection port of the product complies with the ISO80369-7 Standard, please be aware of the matching use.

13. **Warning:** There is no evidence that common drugs can weaken the structure of polyurethane material. However, if an epidural catheter is used for injection of new drug, doctors should consider whether or not the drug can weaken the structure of polyurethane material.

14. **Warning:** To meet environmental protection requirements, the used products should be collected at centralized location in accordance with regulations by local authorities for disposal of medical waste. NO damage to environment in destruction of waste materials has to be made.

15. **Warning:** After the clinical procedure is complete, put the sheath back on the

anaesthesia needle to avoid being punctured or pierced by the sharp needle. Then dispose the product in accordance with environmental protection and local medical device waste regulations.

16. **Warning:** Do not use if the product is contaminated or damaged.

17. **Warning:** MRI unsafe.

[Key symbols]:

MD	Medical Device		Do not use if package is damaged		
	Single Sterile barrier system with protective packaging inside	STERILE EO	Sterilized using ethylene oxide		
UDI	Unique Device Identifier	CE 0123	European Conformity		
PHT DEHP	CONTAINS OR PRESENCE OF PHTHALATE		Contains hazardous substances		
	Consult instructions for use		Caution	REF	Catalogue number
	Keep away from sunlight		Do not re-use	LOT	Batch code
	Manufacturer		Keep dry		Date of manufacture
EC REP	Authorized Representative in the European Community				Use-by date

[Storage and shipping]:

1. Do not stack heavy load on top. Keep away from direct sunlight and rain.
2. Fragile, handle with care.
3. Store in dry, ventilated and clean environment and free of corrosive gases.

Note: A digital version of the printed IFUs can be available at the following website: www.zjrunqiang.com

Zhejiang Runqiang Medical Instruments Co., Ltd.
599 Ruifeng Street, Gaozhao District, Xiuzhou District 314031 Jiaxing City, Zhejiang Province PEOPLE'S REPUBLIC OF CHINA
Tel: +86-573-88106708 Fax: +86-573-88110618

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg Germany
Tel: +49-40-2513175 Fax: +49-40-255726