Instructions for Use of Combined Spinal and Epidural Anesthesia Kit

[Product name]: Combined spinal and epidural anesthesia kit

[Type]: AS-E/SⅡ

[Product structure and components]： Mainly consists of epidural needle, spinal needle (Type II), epidural catheter (general type or reinforced type), catheter connector, introducer guide, liquid filter, low-resistance syringe.

[Performance characteristics of the device]: It is used for spinal and epidural puncture, and injection of liquid drugs into the epidural space and the subarachnoid space. Among them, epidural needles, spinal needles and epidural catheters are typical products used in anesthetic techniques, such as epidural needles, spinal needles and/or epidural catheters used to deliver analgesic drugs as a local anesthetic. Local anesthesia prevents large nerves 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 anesthetic, called an epidural anesthetic. Lumbar anesthesia and combined anaesthesia are used for operations involving the abdomen, pelvis, chest or legs, and are also used during childbirth.

[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) spinal needle, (or/and) epidural catheter (general type or reinforced type), (or/and) catheter connector. After the operation, an epidural catheter (general type or reinforced type) and catheter connector can be connected to an infusion device (such as an infusion pump) to inject fluid as needed.

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 and spinal anesthesia, it is used for spinal and epidural puncture, and injection of liquid drugs into the epidural space and the subarachnoid 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. A common method is to apply epidural puncture. Connect low resistance syringe to epidural needle seat and use negative pressure test to detect whether or not epidural needle enters epidural space. Stylet blade should be withdrawn before contact with ligamentum flavum. Operator can position needle through needle markings.

4. Carefully insert the spinal needle through the epidural needle until resistance is encountered at the needle tip. Carefully insert the spinal needle into the subarachnoid space, and observe if there is cerebrospinal fluid flow out to determine whether or not spinal needle has entered the subarachnoid space.

5. For successful puncture, please fix the puncture site and connect the spinal needle to low-resistance syringe. Before injection, stylet should be withdrawn and to observe if there is cerebrospinal fluid flow out. If an outflow of cerebrospinal fluid is observed, it proves that the needle has reached the subarachnoid space.

6. The syringe (containing anesthetic liquid) is connected with the inlet end of the liquid filter, and the outlet end of the liquid filter is connected with the needle hub of spinal needle. The liquid anesthetic is injected according to the diffusion rate of the liquid medicine, and the patient is observed and monitored according to the requirements of spinal anesthesia.

7. Spinal needle should be withdrawn when injection is completed.

8. The tip of the epidural catheter (general type or reinforced type) penetrates into the epidural needle lumen through the introducer guide, enters to the epidural space 30-50mm, and then withdraws the epidural needle slowly.

9. 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 anesthetic, and the drug is administered as required by the operation.

10. 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 and the subarachnoid space, so as to relieve the pain of patients during surgery.

[Contraindications/Limitation]:

Absolute contraindications: patient refusal, therapeutic anticoagulation, skin infection at puncture site, raised intracranial pressure, hypovolemia.

Relative contraindications: uncooperative patients, sepsis, bleeding disorders, space occupying lesions of the brain, disorders of the spine, hypotension.

[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, don’t 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. Insert epidural catheter (general type or reinforced type) into epidural space through epidural needle. Epidural catheter (general type or reinforced type) can be inserted to the designated position through markings. When the epidural catheter (general type or reinforced type) reaches normal position, epidural needle is carefully withdrawn from the rear end of the epidural catheter (general type or reinforced type). In the

process of needle withdrawal, attention should be paid to prevent undesired withdrawal of epidural catheter (general type or reinforced type) from the epidural space.

12. The epidural catheter (general type or reinforced type) should be fixed with an introducer guide to ensure that the epidural catheter (general type or reinforced type) does not drop or twist.

13. Epidural catheter (general type or reinforced type) should be removed slowly and smoothly. No forcible and quick withdrawal is allowed. To avoid risk of breaking the epidural catheter (general type or reinforced type), don't withdraw the epidural catheter (general type or reinforced type) through the needle.

14. 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.

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

16. **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.

17. **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.

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

19. **Warning:** MRI unsafe.

[Key symbol]:

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

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