	Disposable Anaesthesia Needle and Anaesthesia Kit	
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Instructions for Use of Spinal Anesthesia Kit

[Product name]: Spinal anesthesia kit

[Type]: AS-S

[Product structure and components]: Mainly consists of spinal needle (type I), liquid filter and low-resistance syringe.

[Performance characteristics of the device]: It is used for spinal puncture and injection of liquid drugs into the subarachnoid space. Among them, the spinal needle is a typical product used in the spinal anesthesia technology, such as the spinal needle used to deliver analgesic drugs as a local anesthesia.

[CMR/endocrine-disrupting substances]: 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]: Not applicable.

[Device connection instructions]: This medical device (spinal needle) can be connected with low-resistance syringe, (or/and) liquid filter.

[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 spinal anesthesia, it is used for spinal puncture, and injection of liquid drugs into 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 anaesthesia.
3. Carefully insert the spinal needle into the subarachnoid space, and observe if there is cerebrospinal fluid flow out to determine whether or not the spinal needle has entered the subarachnoid space.
4. If the spinal needle has an introducer needle, first puncture the skin with the introducer needle, and insert the spinal needle through the hub of the introducer needle, and then follow Step 2.
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 Before injection, stylet should be withdrawn and to observe if there is cerebrospinal fluid flow out.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 the spinal needle. The liquid anesthesia is injected according to the diffusion rate of the

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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.

[Medical indications]:

It is used for lumbar puncture and injection of liquid drugs into 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, do not straighten the needle to continue operation.
7. Needle has to be discarded and destroyed after use.

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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 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.
12. **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.
13. **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.
14. **Warning:** Do not use if the product is contaminated or damaged.
15. **Warning:** MRI unsafe.

[Key symbols]:

	Medical Device		Do not use if package is damaged		
	Single Sterile barrier system with protective packaging inside		Sterilized using ethylene oxide		
	Unique Device Identifier		European Conformity		
	Contains hazardous substances				
	Consult instructions for use		Caution		Catalogue number
	Keep away from sunlight		Do not re-use		Batch code
	Manufacturer		Keep dry		Date of manufacture
	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.

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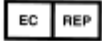
Note: A digital version of the printed IFUs can be available at the following website:
www.zjrunqiang.com



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