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

[Product name]: Spinal needle

[Type and size]

Type: AN-S I (Type I /Quincke)

Size: Diameter: 27G~15G (0.4~1.8mm) × Effective length: (25~250mm)

Type: AN-S I (Type I /Quincke with introducer needle)

Size: Diameter: 27G~15G (0.4~1.8mm) × Effective length: (25~250mm)

Introducer needle Diameter: 22G~16G (0.7~1.6mm) × Effective length: 30~50mm

Type: AN-S II (Type II /Pencil Point)

Size: Diameter: 27G~18G (0.4~1.2mm) × Effective length: (38~120mm)

Type: AN-S II (Type II / Pencil point with introducer needle)

Size: Diameter: 27G~18G(0.4~1.2mm) × Effective length: (38~120mm)

Introducer needle Diameter: 22G~16G (0.7~1.6mm) × Effective length: 30~50mm;

[Product structure and components] : The spinal needle consists of stylet hub (color coded for size identification), transparent needle hub with the point of direction indication, stainless steel stylet, needle stainless steel tube and sheath.

[Performance characteristics of the device]: It is a needle used for local anesthesia. The local anesthetic is usually injected into the subarachnoid space by the spinal needle, and the effective length is generally 38mm to 120mm. The tip of a spinal needle has a sharp point or a small beveled surface. The Quincke needle is a sharp, beveled hollow needle (have sharp cutting tips with the hole at the end of the needle). The Pencil Point needle have closed tip, shaped like pencil with the hole on the side of the needle near the tip (distance from tip to hole ≤ 1.2mm). The shorter beveled surface on the tip of the Pencil Point needle acts like a wedge, pushing tissues aside rather than cutting them minimizing damage.

[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.

[CMR/endocrine-disrupting substances] : This product contains hazardous substances (Cobalt).

[Measuring function accuracy] : Not applicable.

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

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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.
3. Carefully insert the spinal needle into subarachnoid space, and observe if there is cerebrospinal fluid flow out to determine whether or not the spinal needle has entered 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 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.

[Contra-indications/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

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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>

















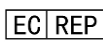



[Notices and warning]:

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 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.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.
- 11.**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.
- 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:** Do not use if the product is contaminated or damaged.
- 14.**Warning:** MRI unsafe.

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[Key symbols]:

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|---|---|--|----------------------------------|---|---------------------|
|  | Medical Device |  | Do not use if package is damaged | | |
|  | Single Sterile barrier system |  | 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.

Note: A digital version of the printed IFUs can be available at the following website:

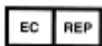
www.zjrunqiang.com



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