Instructions for use

CE 2862

[Product Name]

Epidural Catheter

[Intended Use]

The Epidural Catheter is intended for administration of local anesthetics into epidural space.

[Type and Specification]

Type	Specification
Normal	19G, 21G, 22G
Reinforced	19G

[Component(s)]

The Normal epidural catheter consists of a tube and an introducer guide. The Reinforced epidural catheter consists of a tube, an introducer guide and a spring wire.

[Indication]

Lower abdominal surgery, anal and perineal surgery, pelvic surgery, lower limb surgery and analgesia.

[Contraindications]

Includes diseases or conditions such as:
1. Patient refusal: psychosis disorders, severe neuroses, and uncooperative child;
2. Severe hypovolemia;
3. Disorders of Coagulation;
4. Infection at the puncture site;
5. Diseases of the central nervous system;
6. Spinal trauma or a history of severe back pain or unknown spinal nerve compression disorders;
7. Systemic infection.

[Patient target group]

Adult and child.

[Intended users]

Professional medical staff

[Use Method]

a) Read the instructions for use carefully before use.

b) Place patients in proper position.

c) Check whether the package is damaged, and it is forbidden to use if it is damaged; Open the single package, wear gloves according to the aseptic operation specification, and check whether the contained device is complete.

d) Perform epidural puncture in the routine way, the epidural catheter is inserted into the epidural space through the epidural needle, and the epidural needle is pulled out while the catheter is fixed.

e) Insert the end of the catheter into the catheter connector and fix it.

f) Use hypodermic syringe to suction the anesthesia drugs, connect the hypodermic syringe to the catheter connector, give the appropriate dose of drugs to verify that the catheter is appropriately positioned, and then secure the catheter properly along the side of the spine on the back. The anesthesia drugs was injected intermittently in stages according to the need for the anesthesia plane as per commmon anesthesiac method.

g) After anesthesia is finished, the epidural catheter is pulled out with even force.

⚠ **The catheter should be pulled out with even force, not quickly or hard, so as not to break the catheter in the body.**

[Warnings and Precautions]

1. The use is prohibited if one of the following situations occurs: (1) the single package is damaged; (2) the product is expired; (3) Deformation or damage of accessories.
2. This device should be used by trained professional medical staff.
3. The use of epidural catheter should be strictly followed by clinical operating procedures and improper use may lead to adverse events/complications, which may cause secondary harm to patients.
4. The beveled opening of the epidural needle should be directed cephalad or caudal to the patient before catheterization.
5. In general, the length of the catheter left in the epidural space is 2~3 cm, and if postoperative analgesia or obstetric analgesia is required, the length left in the epidural space can be 4~6 cm. The shorter the length of the catheter placement, the greater the likelihood of dislodgement; if the catheter is inserted for too long, the tip of the catheter may penetrate out of the epidural space through the intervertebral foramen, resulting in unilateral block or unilateral unicoronary nerve block or extubation may be difficult due to a knot of catheter in the epidural space.
6. This product is for single use. Please destroy it after use, the destruction procedures shall be handled harmlessly by qualified or authorized institutions according to the

local relevant regulations.

7. The product has been sterilized by Ethylene oxide with validity for 5 years. Re-sterilize and/or reuse the product can potentially result in compromised device performance and increased risk of inappropriate destabilization and cross contamination.
8. Please inform the manufacturer in case of any incidents related to the device occur and report to the competent authority of the Member State in which the incidents occurred, if applicable.

[Side effects]

Cardiovascular complications, respiratory complications, Total spinal anesthesia, spinal nerve anomalous block, nausea and vomiting, urinary retention, intradural hematoma, hemorrhage, infection, dural puncture headache, neurological injury, spinal cord ischemic injury and anterior spinal artery syndrome, catheter kinking or knotting.

[Shelf-life]

5 years

[Sterilization Method]

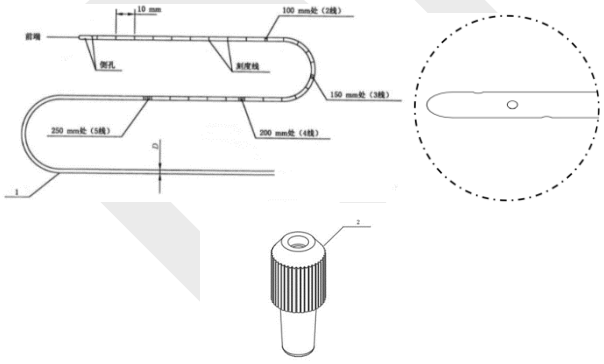
Ethylene oxide

[Cclinical benefits]

Compared with spinal anesthesia, epidural catheter allows for continuous administration by establish a channel to the epidural space for the patient.

[Performance characteristics]

1. The catheter connector meet the requirements of ISO 80369-6:2016.



1- Epidural catheter; 2-Introducer guide

Figure 1 Schematic diagram of Epidural catheter

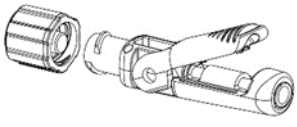


Figure 2 Catheter connector

2. The catheter holes should be within the range of the distal tip to 20 mm, and the holes are 3 holes.

[Flow rate]

Gauge	Flow rate (ml/min)	Catheter length tested
22G	≥4	700mm
21G	≥6	
19G	≥10	

[Storage and Transport Conditions]

1. No heavy pressure, direct sunlight, rain or snow dipping, so as not to damage the device.
2. Handle with care when transporting to avoid violent collision.
3. Keep away from fire and heat sources in case that the device might be out of shape.
4. This product should be stored in a non-corrosive gas, well-ventilated and clean environment.

[Production Date]

See on the package.

[Symbol Explanation]

	Manufacturer	CN	Date of manufacture, Country of manufacture
EC REP	Authorized representative in the European Community/ European Union	LOT	Batch code
	Use-by date		Do not use if package is damaged and consult instructions for use
	Consult instructions for use or consult electronic instructions for use		Caution
	Do not resterilize, Indicates a medical device that is not to be resterilized		Do not re-use
	Single sterile barrier system	STERILE EO	Sterilized using ethylene oxide
MD	Medical device	UDI	Unique device identifier
CE 2862	CE Marking	REF	Catalogue number
	Keep away from sunlight		Keep dry
	Keep away from sunlight		Keep dry

[Additional Information]

The SSCP of this product will be available in the European database on medical devices (Eudamed), where it is linked to the Basic UDI-DI (693811933361J2). The URL to the Eudamed public website is: https://ec.europa.eu/tools/eudamed
For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority. The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en

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[Latest revision]

A/1