Instructions for use

CE 2862

[Product Name]

Anesthesia kit

[Intended Use]

Epidural Kit (AS-E) is intended for administration of local anesthetics into epidural space.

[Type and Specification]

AS-E (A), AS-E (B), AS-E (C), AS-E (D), AS-E (E)

[Contents]

For details, please reference Appendix 1.

[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.

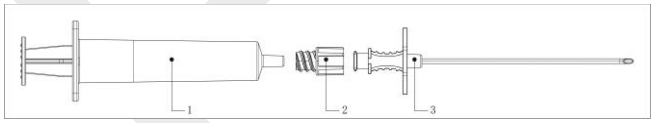
d) Disinfect the puncture position with proper disinfection methods, cover drapes and a hypodermic syringe should be used to suction the anesthesia drugs for subcutaneous local anesthesia.

e) Epidural puncture

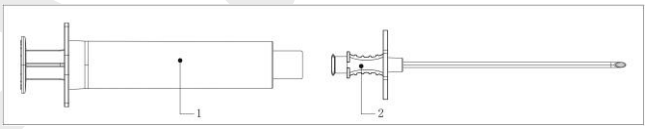
Normal LOR syringe:

1) The epidural needle is inserted through the puncture point, passes through the supraspinous ligament and interspinal ligament, and the resistance increases when it reaches the ligamentum flavum.

2) Pull out the stylet of epidural needle, suction 3-5ml of normal saline with a normal LOR syringe, and connect the Normal LOR syringe with the epidural needle according to the following figure.



1 – 5ml Normal LOR syringe; 2-NRFit connector; 3 – epidural needle.



1 – 10ml Normal LOR syringe; 2- epidural needle.

⚠ **Connections are made strictly in the diagram shown.**

3) Push the plunger of Normal LOR syringe, there is a rebound feeling, and the liquid can not be injected at the same time, continue to slowly advance the needle, and repeatedly push the plunger of Normal LOR syringe for testing. Once the ligamentum flavum is punctured, the resistance suddenly disappears, and there is no resistance to injection, indicating that the needle point reaches the epidural space.

Indicator LOR syringe:

1) Before use, it is necessary to check, use this product to suction about 5ml of normal saline, close the anterior hole with the index fnger, push the plunger 2.5mL forward, the balloon should be raised and maintained without shrinking, remove the index fnger, the saline should be ejected and the balloon collapse rapidly.

⚠ **If the balloon is found to be ruptured, leaking, invalid, etc., it cannot be used.**

2) The epidural needle is inserted through the puncture point, passes through the supraspinous ligament and interspinal ligament, and the resistance increases when it reachs the ligamentum flavum.

3) Pull out the stylet, suction 5ml of normal saline with Indicator LOR syringe, and closely connect it with the epidural needle. Push the plunger 2mL forward to make the balloon raise.

4) After the balloon is raised, continue to keep the needle point not retreating and advance the needle, each time the advance depth of needle should not exceed 1mL, paying attention to observe whether the balloon collapse. When the balloon collapse rapidly, the needle point has reached the epidural space.

⚠ **If it is necessary to adjust the direction of needle insertion during puncture, it is necessary to withdraw the saline from the balloon of Indicator LOR syringe, adjust the direction of the epidural needle, and then make the balloon raise again and re-introduce the epidural needle.**

f) Once the epidural needle is in place, 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.

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

h) Use hypodermic syringe to suction the anesthesia drugs, connect the hypodermic syringe to the NRFit connector and then connect it 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.

i) 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. Be gentle during puncture process, do not operate roughly.
4. If excessive resistance is met during needle insertion, do not force the needle as damage may occur.
5. If the epidural needle is bent during use, it is forbidden to straighten the needle and continue to use it.
6. 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.
7. The beveled opening of the epidural needle should be directed cephalad or caudal to the patient before catheterization.
8. 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.
9. 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.
10. 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.
11. 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]

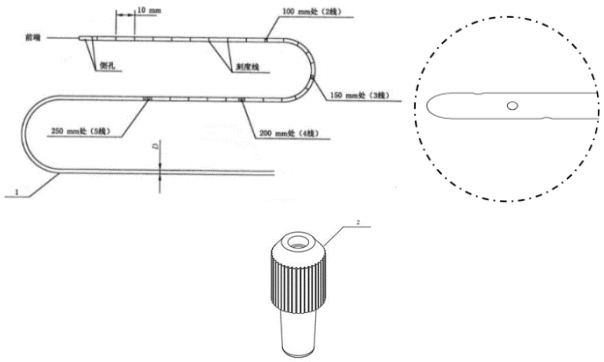
Ethylene oxide

[Clinical benefits]

Compared with spinal anesthesia, continuous administration can be realized.

[Performance characteristics]

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



1- Epidural catheter; 2-Introducer guide
Figure 1 Schematic diagram of Epidural catheter

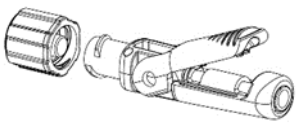


Figure 2 Catheter connector

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

[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 (693811933357JB). 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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Address: Borkstrasse 10, 48163 Münster, Germany

[Issue date]

February 28, 2025

[Latest revision]

A/2

Appendix 1

Type		REF	Normal LOR syringe		Indicator LOR syringe	Epidural needle				Epidural catheter				Filter	Catheter connector			Catheter fixing pad	Nrfit connector	Hypodermic syringe	Hypodermic needles
			5 mL	10 mL	5mL	16G	17G	18G	19G	Normal 19G	Normal 21G	Normal 22G	Reinforced 19G	0.22 μm	19 G	21 G	22 G			10mL	25G/22 G/18G*
Epidural Kit (AS-E)	AS-E (B)	EMNN1605	√			√				√				√	√			√	√		
		EMNR1605	√			√							√	√	√			√	√		
		EMNN1705	√				√				√			√		√		√	√		
		EMNN1805	√					√			√			√		√		√	√		
		EMNN1905	√						√			√		√			√	√	√		
	AS-E(A)	EMNN1610		√		√				√				√	√			√			
		EMNR1610		√		√							√	√	√			√			
		EMNN1710		√			√				√			√		√		√			
		EMNN1810		√				√			√			√		√		√			
		EMNN1910		√					√			√		√			√	√			
	AS-E(D)	IEMN16			√	√				√				√	√			√			
		IEMR16			√	√							√	√	√			√			
		IEMN17			√		√				√			√		√		√			
		IEMN18			√			√			√			√		√		√			
		IEMN19			√				√			√		√			√	√			
	AS-E(C)	EMNN16051	√			√				√				√	√			√	√	√	√
		EMNR16051	√			√							√	√	√			√	√	√	√
		EMNN17051	√				√				√			√		√		√	√	√	√
		EMNN18051	√					√			√			√		√		√	√	√	√
		EMNN19051	√						√			√		√			√	√	√	√	√
		EMNN16101		√		√				√				√	√			√	√	√	√
		EMNR16101		√		√							√	√	√			√	√	√	√
		EMNN17101		√			√				√			√		√		√	√	√	√
		EMNN18101		√				√			√			√		√		√	√	√	√
		EMNN19101		√					√			√		√			√	√	√	√	√
	AS-E(E)	IEMN161			√	√				√				√	√			√	√	√	√
		IEMR161			√	√							√	√	√			√	√	√	√

Type		REF	Normal LOR syringe		Indicator LOR syringe	Epidural needle				Epidural catheter				Filter	Catheter connector			Catheter fixing pad	Nrfit connector	Hypodermic syringe	Hypodermic needles
			5 mL	10 mL	5mL	16G	17G	18G	19G	Normal 19G	Normal 21G	Normal 22G	Reinforced 19G	0.22 μm	19 G	21 G	22 G			10mL	25G/22G/18G*
		IEMN171			√		√				√			√		√		√	√	√	√
		IEMN181			√			√			√			√		√		√	√	√	√
		IEMN191			√				√			√		√			√	√	√	√	√

Note:
1."√" indicates that this accessory is included, and the quantity of accessories is 1.
2.* Indicates that 25G, 22G, and 18G Hypodermic needles are configured.