Instructions for use

CE 2862

[Product Name]

Anesthesia kit

[Intended Use]

Spinal Kit (AS-S) is intended for administration of local anesthetics into subarachnoid cavity.

[Type and Specification]

AS-S

[Contents]

For details, please reference Appendix 1.

[Indication]

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

[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.

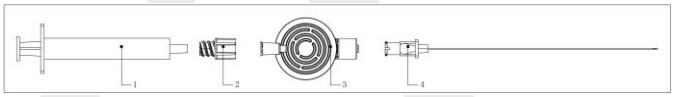
b) Place patients in proper position.

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) Insert the spinal needle into subarachnoid cavity, pull out the stylet, and there will be cerebrospinal fluid flow out.

f) Keep the spinal needle's position unchanged, use the hypodermic syringe to suction the anesthesia drugs, and then connect it according to the way of the following figure.



1 - Hypodermic syringe; 2-NRFit connector; 3 – Filter; 4 spinal needle.

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

g) Slowly and evenly inject the anesthesia drugs, closely monitor patients in accordance with spinal anesthesia requirements during drug injection.

h) Pull out the spinal needle after completion of drugs injection.

[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 spinal needle is bent during use, it is forbidden to straighten the needle and continue to use it.
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, nausea and vomiting, urinary retention, intradural hematoma, hemorrhage, infection, dural puncture headache, neurological injury, spinal cord ischemic injury and anterior spinal artery syndrome.

[Shelf-life]

5 years

[Sterilization Method]

Ethylene oxide

[Clinical benefits]

Establish a channel to the subarachnoid cavity for the patient, so that the anesthetic drug can reach the subarachnoid cavity, and the anesthesia has a faster onset of action than epidural anesthesia.

[Performance characteristics]

The conical connector of the needle hub meet the requirements of ISO 80369-6:2016.

[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 (693811933356J9). 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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MedNet EC-REP CIII GmbH
Address: Borkstrasse 10, 48163 Münster, Germany

[Issue date]

July 30, 2024

[Latest revision]

A/1

Appendix 1

Type	REF	Spinal needle					Filter	Nrfit connector	Hypodermic syringe	Hypodermic needles
		20G	22G	25G	26G	27G	0.22μm		10mL	25G/22G/18G*
Spinal Kit (AS-S)	STM201	√					√	√	√	√
	STM221		√				√	√	√	√
	STM251			√			√	√	√	√
	STM261				√		√	√	√	√
	STM271					√	√	√	√	√

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.