

IFU of MAIS EPI™ EPIDURAL CATHETER KIT

Manufactured by Mais India Medical Devices Pvt. Ltd.

Product Name: EPIDURAL CATHETER KIT

Brand Names: MAIS EPI™

Product Features and Components : Consists mainly of epidural needle, spinal needle (Model II), epidural catheter, introducer, catheter adapter, filter, low resistance syringe.

Scopes of Application : Spinal and epidural puncture, and injection of liquid drugs into the epidural space and the subarachnoid space.

Instruction for Use :

1. Remove product from aseptic packaging and inspect the integrity of product.
2. Properly disinfect the puncture site, and perform the local anesthesia in the puncture site.
3. A common method is to apply epidural puncture. Connect low resistance syringe to epidural needle seat and use negative pressure test to detect whether or not epidural needle enters epidural space. Stylet blade should be withdrawn before contact with ligamentum flavum. Operator can position needle through needle markings.
4. Carefully insert spinal needle through epidural needle until resistance is encountered at needle tip. Carefully insert spinal needle into the subarachnoid space, and observe if there is cerebrospinal fluid flow to determine whether or not spinal needle has entered the subarachnoid space.
5. For successful puncture, secure position of spinal needle and connect it to low resistance syringe. Before and after injection, stylet should be withdrawn to see if there is cerebrospinal fluid flow. If cerebrospinal fluid flow is observed, it verifies there is no movement of needle in the subarachnoid space.
6. Anesthetic should be injected at a uniform speed based on diffusion rate of medication. At the same time patient needs to be closely monitored according to requirements for epidural anesthesia.
7. Both epidural and spinal needle should be withdrawn when injection is completed. If resistance is encountered, the spinal needle and epidural needle will be withdrawn, and the operation is restarted.
8. Insert epidural catheter into epidural space through epidural needle. Catheter can be inserted to designed position through catheter markings.

When the catheter reaches normal position, epidural needle is carefully withdraw from rear end of catheter. In the process of needle withdrawal, attention should be paid to prevent undesired withdrawal of catheter from epidural space.

9. Connect catheter to catheter adapter, and secure catheter against drop or twist.
10. With normal subarachnoid space and before filling epidural catheter with medication, first test the precision of position for detection with proper dosage. Then inject anesthetic with dosage according to Standards of Normal Dosage for Epidural Anesthesia. Make sure that anesthesia is correctly applied to site requiring anesthesia.
11. Withdraw catheter smoothly and gently after anesthesia is completed. DO NOT withdraw catheter with force or rapidly, which will cause breakage of catheter inside patient's body and thus harm patient.

Contraindications: Absolute contraindications: patient refusal, therapeutic anticoagulation, skin infection at puncture site, raised intracranial pressure, hypovolemia.

Relative contraindications: Uncooperative patients, sepsis, pre-existing neurological disorders, fixed cardiac output states, anatomical abnormalities of vertebral, bleeding disorders, disorders of the spine, hypotension.

Complications / Risks : Full spinal anesthesia, hypotension, respiratory inhibition, local anesthetic toxicity, nausea and vomiting, lower back pain, epidural hemorrhage, nerve damage, damaged by puncture and procedure-carried pollution, inadvertent high epidural block, epidural haematoma, infection, block failure, cardiac arrest, hypothermia, paraesthesia, urinary retention, pruritus, epidural vein catheter placement, abscess, anterior spinal artery syndrome, cauda equine syndrome.

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, device has to be operated by anesthesiologist only. NO operation by non-anesthesiologist is allowed.
4. Manipulation of puncture should be smooth and gentle. NO rude operation is allowed.
5. To safeguard against 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 needle for continue operation.

7. Needle has to 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. 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. Anesthetic catheter should be removed slowly and smoothly. No forcible and quick withdrawal is allowed. To avoid risk of breaking the catheter, do not withdraw catheter through the needle.

12. **Warning :** There is no evidence that common drugs can weaken the structure of polyurethane material. However, if catheter is used for infusion of new drug, doctors should consider whether or not the drug can weaken the structure of polyurethane material.

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 :** In pediatric application, attention needs to be paid to risks from children's non-cooperation, refusal and activities.

Storage Conditions:

Store in a Cool & Dry Place.

Keep away from sunlight

Shelf life:

5 Years

Type of Sterilization:

EO sterilization

Notice to Users and/ or Patients:

Any serious incident that has occurred in relation to the device, should be reported to the Manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Explanation of symbols used:

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Consult instructions for use (Indicates the need for the user to consult the instructions for use)		Latex free (Indicates a medical device that is Latex free)
	Caution (To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.)		Date of manufacture (Indicates the date when the medical device was manufactured)
	Sterilized using ethylene oxide Single sterile barrier system (Indicates a medical device that has been sterilized using ethylene oxide)		Use-by date (Indicates the date after which the medical device is not to be used)
	Do not re-sterilize (Indicates a medical device that is not to be re-sterilized)		Batch Number (Indicates the manufacturer's batch number so that the batch or lot can be identified)
	Do not re-use (Indicates a medical device that is intended for one single use only)		Reference number (Indicates the manufacturer's catalogue number so that the medical device can be identified)
	Non-pyrogenic (Indicates a medical device that is non- pyrogenic)		Keep away from sunlight (Indicates a medical device that needs protection from light sources)
	Do not use if packaging is damaged and consult instructions for use. (Indicates a medical device that should not be used if its packaging has been damaged or opened, and that the user should consult the instructions for use for additional information)		Manufacturer (Indicates the medical device manufacturer) Manufacturing Unit: 525P, Sector-37, Pace City II, Gurgaon, Haryana-122001, India. Contact Details: +91 8527589990 Fax No: 0124 404 7533 Email ID: info@maisindia.com Website:www.maisindia.com
	Unique Device Identifier (Indicates a carrier that contains Unique Device Identifier information)		Medical device (Indicates the item is a medical device)

Symbols	Title of the Symbol	Symbols	Title of the Symbol
	Keep dry (Indicates a medical device that needs to be protected from moisture)		Fragile, handle with care (Indicates a medical device that can be broken or damaged if not handled carefully)
	Country of manufacture (To identify the country of manufacture of products)		This way up

ISO & CE Certified Company

 **Manufactured by:**
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