LCCS Single-Use Epidural Needle Instructions For Use

I. Indication For Use

This product is intended for use in performing epidural blocks (also called as epidural anesthesia) in human patients. Puncture is carried out through the intervertebral space so that the scoop-shape needle bevel enters the epidural space. The anesthesia catheter is advanced through the cone shape lumen of the needle hub so that the catheter can reach predetermined position of epidural space. After the epidural needle is withdrawn, a catheter connector is attached on distal end of the catheter to inject drugs such as anesthetic intermittently and /or continuously after being connected with a syringe. This product is suitable for surgical anesthesia, epidural injections performed in obstetrical patients, epidural injections performed post-operatively and for treatment of chronic pain.

II. Structural Features Of The Product

This product consists of the needle hub, needle shaft, stylet hub, stylet wire and protective sheath.

Needle shaft has a scoop-shape bevel which aids in advancing catheter into epidural space. Needle hub is available with fixed wing or removable wing, which can be used for controlling epidural needle during use. Needle hub is provided with a 6% luer lock connector to reliably connect with syringe so that needle tip can accurately enter the epidural space using a loss of resistance technique. During puncture or when advancing needle, the stylet should remain fully within the needle shaft with the stylet tip flush with the needle tip to prevent human tissue from entering the needle lumen during puncture. The protective sheath is designed to protect needle from damage and to prevent injury.

III. Most Commonly Used Model and Their Technical Parameters

Model	Gauges	External diameter of needle (mm)	Length (mm)	Matching of Cone joint	Outer diameter of matching catheter (mm)
AN-E	22G	Φ0.7	50-160	Luer or Luer Lock joints	Φ0.3
	21G	Φ0.8			Φ0.4
	20G	Φ0.9			Φ0.5
	19G	Φ1.1			Φ0.7
	18G	Φ1.2			Φ0.85
	17G	Φ1.4			Φ1.0
	16G	Φ1.6			Φ1.0
	15G	Φ1.8			Φ1.0

Note:
- Custom sizes and design are available upon request.
- Color code complies with regulations of ISO9006.

IV. Instructions For Use

- Position patients in the appropriate manner for the procedure.
- Determine the puncture point and sterilize the surrounding areas three times with the appropriate antiseptic in a spiral fashion beginning from the puncture point.
- Enclose the disinfected areas with sterile drape and remove the excess disinfectant with sterile gauze.
- Choose the appropriate needle length and gauge based upon the type of procedure performed as well as the patient's size and anatomy.
- Skin at the injection site should be anesthetized with local anesthetics such as lidocaine or bupivacaine.
- Puncture at the predetermined puncture point by holding needle in the pattern of middle entrance or side middle entrance. Resistance will increase when the needle tip penetrates hypodermis into interspinous ligament.
- Remove stylet and connect a loss-of-resistance syringe in which 2ML Physiological Saline or air is filled to the lumen of the needle stand.
- Insert the needle and advance continuously and slowly, at the same time, lightly advance syringe plunger to detect resistance and position of needle insertion. (Resistance is palpably greater when advancing needle through ligamentous tissue. When the tip penetrates the ligamenta flava and enters the epidural space, a loss of resistance will occur and injection therefore becomes easy.)
- Aspirate to confirm that no cerebrospinal fluid and blood exits. This will help to verify that the needle is in the epidural space and not entering blood vessels or the subarachnoid space.
- Insert epidural catheter into the needle shaft via cone lumen of the needle hub into predetermined position of epidural space at the scoop-shape needle tip opening.
- Withdraw the epidural needle, leave the epidural catheter and fix with adhesive tape, and attach a removable connector at distal end of the catheter.
- After aspirating syringe and confirming that there is no blood or cerebrospinal fluid, connect the removable joint to the syringe and inject local anesthetics as required.
- Epidural needle and catheter withdrawn should be put into an appropriately labeled bio-hazard container to prevent microorganism environment contamination and damage of human bodies by sharp objects.

Note: The above described method represents one commonly used technique but does not exclude other safe and proper methods.

V. Contraindication

The product itself doesn't have contraindications, but the following absolute contraindications and relative contraindications of epidural anesthesia should be considered prudently before use of the product.

1. Absolute contraindications:
   - Infection in close proximity to puncture site
   - Mental status of patient
   - Suffered from coagulopathy or other bleeding body conditions

- Severely insufficient blood volume
- Increase of intracranial pressure
- Severe aortic stenosis
- Severe mitral valve stenosis

2. Relative contraindications:
   - Septicemia
   - Incoordination of patients
   - Existing neurological deficits in past
   - Destruction of myelin sheath
   - Valvular stenosis type heart injury
   - Severe abnormality of spine

VI. Precautions & Warning:

- Do not reuse, re-sterilize or modify Epidural Needle. Any reusage, re-sterilization or modifications may compromise patient safety and efficacy of the device.
- The appropriate needle length and gauge should be used based upon the type of procedure performed as well as the patient's size and anatomy.
- Inspect primary packaging, expiration date and products carefully before use. Do not use if packaging is damaged or the product is contaminated, deformed, damaged or expired.
- Only physicians or appropriately trained and certified medical professionals should use product and only in accordance with codes of epidural anesthesia, sterile procedure and commonly accepted medical standards of care.
- Primary packaging should be opened using sterile technique and the product should be used immediately after opening. Contaminated or damaged product should never be used.
- Needle insertion should be slow and the "Loss of Resistance Method" or "Hanging Drop Method" should be used to confirm that the needle reaches the required position and to avoid damage of spinal dura mater or blood vessels.
- Angle and direction of needle insertion should be carefully controlled. Needle tip should not be pushed against vertebra or a neural plate. When advancing the needle, the shaft should not be bent excessively as this could damage the needle or injure the patient.
- If needle shaft is bent, the operator should not attempt to straighten the bend and should consider replacing the needle.
- The catheter should not be retracted or withdrawn through the needle as the needle bevel could sever the catheter. When the catheter is withdrawn from the patient, it should be withdrawn together with the epidural needle.
- The syringe should be aspirated before drug injection to confirm that there is no blood or cerebrospinal fluids. This will aid in avoiding injection into blood vessels or spinal nerves.
- The product should be disposed of in an appropriately labeled bio-hazard container in accordance with local laws and regulations governing medical waste and biological safety. This product should never be discarded in standard waste receptacles.

VII. Transportation and Storage

The products should be with care. No heavy objects should be stacked or leaned against boxes of products as this could potentially damage packaging and contaminate products. The products should be stored in a clean, dry environment at room temperature. The product should not be stored in direct sunlight and the environment should be free of corrosive gases with good ventilation. The products should be stacked on shelves or pallets and should not be directly stored on ground or direct contact with wall surfaces. The principle of "First in, First out" should be implemented and attention should be paid to expiration date of the products.

VIII. Normalized Symbols

	Attention, see instructions for use!		Do not reuse
	Sterilized using Ethylene Oxide		Consult instructions for use
	Do Not Resterilize		Do not use if package is damaged
	Manufacturer information		Use by
	Batch code		Catalogue Number / Part Number
	For or By Order of a physician		

IX. For Further Information

If further information on this product is needed, please contact LCCS customer service or authorized representative.

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