Changing Lives For The Better....

Instructions for Use

APICATH™

Epidural Catheter Sets

Description:

The APICATH™ Epidural Catheters are sterile, single use range of catheters designed to allow access to the epidural space in cases requiring epidural block. This allows physicians to be able to provide essential pain-relieving anaesthetics during labour. The catheters are packaged as kits along with the components and accessories considered necessary for their use. The kits are sterilized by ethylene oxide.

Indications for Use:

The APICATH™ Epidural Catheter kit permits access to the epidural space for the administration of epidural anaesthetic.

Contraindications:

- Infection or cut wound around the puncture area.
- Raised intracranial pressure
- During the anticoagulant treatment.
- Symptoms of inadaptability to puncture operation.
- Use longer than 3 days

Warnings:

1. Please read all packaging insert warnings, precautions, and instructions before use. Failure to do so may result in loss of blood and delay to the procedure.
2. Sterile by EO, Single Use: Do not reuse, reprocess or re-sterilize under any circumstance. Blood and other foreign material can collect in the inner parts of the product which cannot be removed.
3. Do not use if the packaging is damaged or opened unintentionally before use. This will lead to loss of sterility.
4. Rx Only. The products must only be used by trained physicians
5. The manipulation of the catheter during puncture should be soft. If there is stiffness please do not proceed.
6. If the needle bends during use, a new needle must be used. Do not straighten the bent needle for reuse.
7. The residual or priming volume of the catheter is about 0.15ml (tested with distilled water). The effect of the residual quantity must be taken into consideration during injection.

Precautions:

1. Aseptic techniques must be used wherever possible, especially during removal from packaging.
2. Do not withdraw an epidural catheter through an epidural needle because of danger of shearing the catheter.
3. After a positive aspiration test and/or test dose for inadvertent subarachnoid placement - the epidural catheter should be withdrawn or be treated as a spinal catheter.
4. After a positive aspiration test and/or test dose for inadvertent intravascular placement - the epidural catheter should be withdrawn and no further injections be made through it.
5. Do not insert the epidural catheter more than 3 cm inside the epidural space because of potential to kink and/or malposition.
6. Any connections should be hand tightened, but not over tightened as that can lead to cracks which may cause an embolism.

7. Check puncture site daily to detect any signs of infection or any disconnection/disposition of the catheter
8. There is no evidence that shows the ordinary drugs can weaken the structure of polyurethane materials. However, if the catheter is used to infuse new drugs, doctors should consider whether the drug can weaken the structure of Polyamide materials.
9. The catheter should be drawn out slowly and evenly. Do not attempt to quickly or forcefully withdraw the catheter.

Instructions for Use:

Preparation

1. Check that the catheter will pass through the Needle and confirm patency of the epidural catheter lumen by assembling the catheter, connector and filter if used and simulate an epidural injection.
2. Prepare the puncture site using aseptic technique and local anaesthesia according to standard practice.

Insertion

3. Using the epidural needle, the epidural space is reached by the loss of resistance technique or the hanging drop technique, while the proximal opening of the epidural needle enters the epidural space through the epidural needle.
4. An aspiration test and a test dose are done. If it is negative, the anaesthetic solution is injected gradually until the required dose effect is achieved.
5. The epidural needle is withdrawn after the epidural catheter insertion or after the epidural catheter aspiration test and test dose.
6. The epidural catheter length inside the epidural space should be 3 cm. This is measured in each patient according to the markings in the epidural needle and epidural catheter.
7. Attach proximal end of epidural catheter to the Tuohy Borst adaptor by inserting the catheter into the tapered channel of the adaptor and twist the tightening nut clockwise.
8. Attach the filter to the epidural catheter adaptor and aspirate to confirm catheter is not in the subarachnoid space.
9. Secure epidural catheter in place by acceptable methods of practice.

Catheter Removal

1. At the completion of procedure, withdraw the epidural catheter gently. Inspection of its completeness should be done after its withdrawal.
2. Apply dressings in accordance with standard hospital protocols.

Disposal:

Catheters can be a biological hazard if disposed incorrectly. They should be disposed using recognised medical procedures and industry best practices. Local laws and regulations should be taken into account during disposal

Potential Complications / Adverse Effects

The clinical benefit of the use of Epidural Catheters must be evaluated against the recognized risks and complications of the procedure which include but are not limited to:

- Infection, necrosis of the puncture point.
- hypotension,
- inadvertent high epidural block,
- local anaesthetic toxicity,
- full spinal anaesthesia,
- haemorrhage at peridural
- inhibition of respiration, nausea and vomitus,
- lumbago,
- headache after anaesthesia,
- nerve damage,
- damage by paracentesis and carried in polluter,
- cardiac arrest,
- paraesthesia,
- urinary retention,
- pruritus,
- abscess,
- anterior spinal artery syndrome,
- cauda equine syndrome

Facilities for resuscitation should always be available whenever epidural anaesthesia is performed.

Warranty and Limitations

Products are sold in 'as is' condition. The entire risk as to the quality and performance of the product is with the buyer. ALSPL disclaims all warranties, expressed or implied, with respect to its products, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ALSPL shall not be liable to any person for any medical expenses or any direct or consequential damages resulting from the use of any product or caused by any defect, failure, or malfunction of any product, whether a claim for such damages is based upon warranty, contract, tort, or otherwise. No person has any authority to bind ALSPL to any representation or warranty with respect to its products.

Symbols Glossary

	Caution, Consult Indications for Use
	Date of Manufacture
	Do not re-use
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Keep away from sunlight
	Batch code
	Catalogue Number
	Manufacturer
	Use-by date
	Keep dry
	Temperature Limit

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