



Instructions for Use

APICATH™

Epidural Needles

Description:

APICATH™ Epidural Needles are sterile needles used during epidural anaesthesia. The needles are used for puncturing the site for anaesthesia administration, and subsequent placement of a catheter which is left in place to provide access for longer term anaesthesia requirements. The needles are also called 'Tuohy' needles. They have an angled tip to help facilitate the proper placement of an epidural catheter. There are markings at every one centimetre for the convenience of the user.

Indications for Use:

APICATH™ Epidural Needles are used for the placement of an epidural catheter.

Contraindications:

- None Known

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 be used by trained physicians

Precautions:

1. Aseptic techniques must be used wherever possible, especially during removal from packaging.
2. Ensure the needle is straight and intact when the package is opened

Instructions for Use:

1. Using aseptic technique, open the package.
2. Make sufficient and appropriate preparatory arrangements
3. Sanitize the puncture site skin sufficiently
4. Inject an appropriate amount of local anaesthetic at the puncture site of the epidural needle to anaesthetize the supraspinal ligament and its interior
5. Perform epidural puncture
Warning: If resistance is felt while inserting the epidural needle, carefully change the direction of the needle without using excessive force
6. Withdraw the stylet from the epidural needle and position the tip of the needle in the epidural space using the loss of resistance technique
7. Inject local anaesthetic as necessary in accordance with the instructions of the manufacturer.
8. Insert an epidural catheter in accordance with the instructions of the manufacturer & remove the needle

Disposal:

Needles 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 products must be evaluated against the recognized risks and complications of the procedure which include but are not limited to:

- Risks generally associated with epidural anaesthesia
- Risks associated with use of needles such as inflammation of puncture site, toxicity of local anaesthesia, etc
- High epidural block
- Spinal block
- Hypotension
- Epidural Hematoma
- Post-dural puncture headache
- Post Lumbar puncture headache

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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