



Instructions for Use

APICATH™

Spinal Needles

Description:

APICATH™ Spinal Needles are sterile needles used for spinal anaesthesia. They are composed of a stainless-steel cannula and a plastic hub. Needles hubs are colour coded by size for easy identification. The needles also have a trocar to provide stiffness and prevent kinking during insertion.

Indications for Use:

APICATH™ Spinal Needles are used for puncture and infusion during spinal anaesthesia

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
3. The connection should be hand tightened, but not over tightened as that can lead to cracks

Instructions for Use:

1. Using aseptic technique, open the package.
2. Make sufficient and appropriate preparatory arrangements
3. Confirm in advance that the puncture needle tip is not impaired, that the spinal needle tip and the stylet are matched and that the stylet moves smoothly
4. Sanitize the puncture site skin sufficiently
5. Sting the needle vertically and slowly to the skin between the spinous processes
6. After puncture to the yellow ligament and dura matter, extract the stylet slowly and confirm that a sufficient amount of the cerebrospinal fluid flows out
7. After confirming that the cerebrospinal fluid flows out, keep the stylet extracted and rotate the puncture needle 90° from side to side and up and down. Only when the flow-out of the cerebrospinal fluid is confirmed at all directions, infuse the topical anaesthetic drug

Note: Hold the needle firmly in place during infusion as it may be pushed back by the pressure

8. Withdraw once complete
9. After withdrawing the spinal needle, cover the puncture site with appropriate dressing material.

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 use 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, spinal & local anaesthesia
- Risks associated with use of needles such as inflammation of puncture site, toxicity of local anaesthesia, etc
- Spinal block
- Hypotension
- 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

 Manufactured By: Advanced LifeSciences Pvt. Ltd. D-22 Okhla Industrial Area Phase – 1, New Delhi – 110020, India
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E-mail: customerservice@alspl.com
Phone: +91 9818237529