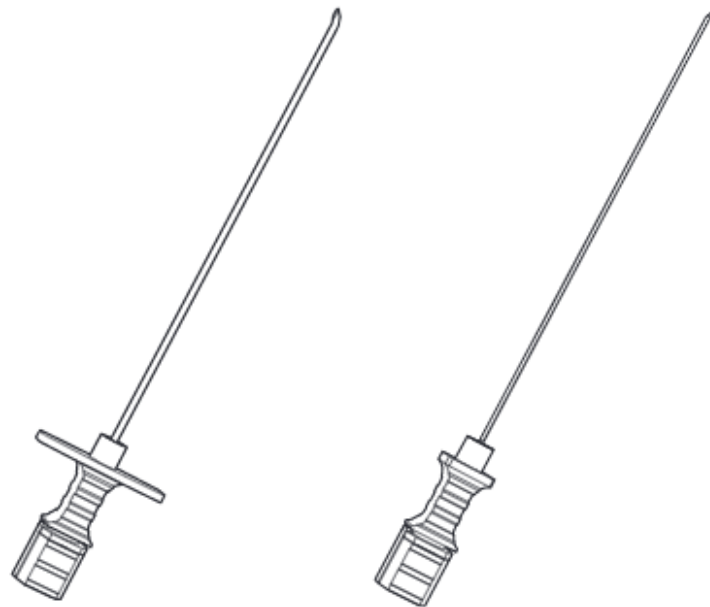


# Perican® / Perican® Paed / Epican® Paed – Epidural Needle for Single Shot Technique and Epidural Catheter Insertion

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## **GB** Instructions for use

### Materials used

Stainless steel, nickel plated brass, PC, PP, PE, epoxid resin

### Applications

Injection of local anesthetic into the epidural space (Single shot technique) or Epidural Catheter Placement (Catheter technique).

### Indications

Epidural anesthesia (lumbar, thoracic, cervical) and caudal block for fast and reliable anesthesia during surgery.

Injection of local anesthetic into the epidural space (single shot technique) and epidural catheter placement (catheter technique) are possible with epidural needles.

### Contraindications

The product should only be used by physicians that have been adequately trained in this technique.

Absolute contraindications include patient refusal, severe uncorrected hypovolemia, increased intracranial pressure, infection at the site of injection and known hypersensitivity to local anaesthetics.

Relative contraindications include coagulation disorders, anticoagulant therapy, anatomical abnormalities of the vertebral column, chronic low back pain, neurological diseases (e.g. nerve lesions, polyneuropathy, multiple sclerosis), cardiovascular diseases (inability to increase cardiac output) and sepsis.

Additional contraindications for cervical epidural anaesthesia are sympathetic blockade in patients with congestive heart failure or severe aortic or mitral stenosis or congestive lung disease.

**Caution:** Do not perform cervical epidural anesthesia for paediatric anesthesia!

Please consult medical textbooks for standard contraindications to performing epidural anaesthesia procedures.

### Risks

Known risks of epidural anaesthesia techniques include hypotension, dyspnoe/apnoea, cardiac arrest, bradycardia, hypothermia, urinary retention, toxicity to the local anaesthetics, inadequate block, temporary neurological complications (e.g. postdural puncture headache (PDPH), paraesthesia), permanent neurological complications (e.g. meningitis, cauda equina syndrome, transverse myelitis or anterior spinal artery syndrome with permanent paralysis), epidural haematoma, inadvertent (epidural) vein placement, epidural space infection and/or abscess, local infection (e.g. at the entry point of the catheter or subcutaneous).

Additional risks for caudal anaesthesia (technique of choice for epidural catheter placement in babies and children) are back pain, intraosseous injections with subsequent pelvic damage and venous air embolism, and in very rare cases the development of epidermoid tumors.

Additional risks for cervical epidural anaesthesia include spinal cord damage, T1 –T4 sympathectomy, phrenic nerve paresis or paralysis, decrease in heart rate by blocking sympathetic heart innervations and modulation of the vagal nerve and blood flow reduction in the verte-brobasilar artery system.

Trained physicians and sufficient emergency equipment, in particular for artificial ventilation and hemodynamic support, must be nearby.

During and after cervical epidural anaesthesia, cardiovascular and respiratory monitoring is important to exclude cardio-pulmonary insufficiency.

### Warning

Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

Should not be used in patients with known hypersensitivity to any of the materials employed.

Do not use if packaging is damaged.

Do not re-sterilise.

The tip of the needle becomes blunt or can even split after bone contact. The needle might bend and eventually break when applying too strong forces during advancement. Needles with damaged tip increase the risk of intrathecal and intravascular placement.

If used with an epidural catheter (catheter technique), never pull the catheter back through the needle as it may shear off!

#### Duration of use

Epidural needles are used for a few minutes for puncture or for the injection of drugs into the epidural space or epidural catheter placement.

The needles are withdrawn from the patient immediately after completion of the procedure.

#### Instructions for use

Epidural anesthesia (Single Shot technique)

**Caution: Aseptic conditions are absolutely required.**

1. Detailed information of the patient is mandatory. Optimal positioning of the patient during puncture and injection. Lumbar epidural anesthesia can be carried out with the patient being in a lateral decubitus (preferred) or sitting position. For both positions it is important to minimize lumbar lordosis and to identify the midline.  
Check emergency equipment (intubation kit, drugs) and ensure continuous monitoring of the patient
2. Identification of the landmarks and the approach area
3. Skin disinfection, local anesthesia of the injection channel.
4. Introduction of the epidural needle (Tuohy needle – Perican®, Crawford needle – Epican®), including the stylet, through the

"median" or "lateral" approach. After passing the interspinous ligament, the needle must be advanced carefully, millimeter by millimeter, in the direction of the ligamentum flavum.

#### Warning

**If any resistance is felt during advancement of the epidural needle carefully correct the orientation of the needle but never apply strong forces in order to overcome the obstacles.**

5. The stylet is removed and a low friction syringe (loss of resistance; L.O.R – syringe) is attached for the identification of the epidural space with the "loss of resistance technique" (LOR). Two different LOR techniques are used, either with air or with sodium saline 0,9 %.
6. Aspiration test
7. Test dose: After negative aspiration test, a test dose of the local anesthetic drug is recommended.
8. Waiting period: If there is no anesthetic effect after 5-10 minutes, the main dose of the local anesthetic is injected as described in the manufacturer's instructions (Single Shot technique) or the catheter is inserted into the epidural space. (Catheter technique) For continuous catheter technique please see corresponding instructions for use (Perifix®).
9. After complete injection of the drug withdraw the needle and

cover the puncture site with sterile plaster. (Single Shot technique)

10. The level of local anesthesia is to be carefully monitored by e.g. cold devices. After reaching complete block of the motoric and/ or sensoric and/or sympathetic nerves in the desired dermatom, surgery can start.

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保存期限：如原廠標示  
製造廠地址：如原廠標示  
藥商名稱：台灣柏朗股份  
有限公司  
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**GB** Epidural Needle for Single Shot Technique and Epidural Catheter Insertion



Do not re-use



Consult instruction for use

LOT

Batch number

STERILE

Sterile



Caution



Use-by date



Date of  
manufacture