



INSTRUCTIONS FOR USE



EPIDURAL ANESTHESIA NEEDLE

1. Used for the purpose of epidural anesthesia.
2. Open unit pack using sterile technique.
3. Remove plastic tip protector and examine needle body and tip in order to confirm its integrity.
4. Remove stylet of epidural needle then place it again to confirm smooth movement.
5. Prepare puncture area for the procedure according to standard aseptic technique and apply local anesthesia.
6. Determine a puncture area (point) according to accepted procedure. When determining distance between puncture area and epidural space, you can use cm markings on the epidural needle. These markings can be in the form of a single thin line or 1cm long heavy lines.
7. Start the puncture with the epidural needle. Continue the procedure with standard Loss of Resistance technique or hanging drop technique and confirm reaching to the epidural space.
8. If the use of Epidural Catheter is intended, advance catheter through epidural needle to the extent that the procedure indicates. During this process pay attention to the cm markings on the catheter. After placement of the catheter at desired length, pull back epidural needle while maintaining catheter position within epidural space.

⚠ IMPORTANT: Do not pull back catheter for any reason during the process of passing it through Epidural Needle. In cases when pulling back epidural catheter is inevitable then withdraw epidural needle first, then remove the catheter. Otherwise there is a risk of cutting the epidural catheter by the epidural needle bevel.

9. Complete Epidural application.
10. Dispose Epidural needle according to medical device waste disposal regulations.

EPIDURAL ANESTHESIA NEEDLES LIST OF MODELS:

Colour Code:	Reference Code:	Product Description:
White	TEP1690	Size 16 G X 90 mm Epidural needle
Pink	TEP1880	Size 18 G x 80 mm Epidural needle
Pink	TEP1890	Size 18 G x 90 mm Epidural needle

INDICATIONS:

- Pain relief during and after a surgical interventions,
- Hip and lower extremity surgery,
- Painless child birth,
- Caesarean section,
- Surgical interventions located below the nipple line:
 - Orthopedics - Surgeries of lower limbs, including hip, knee, and pelvic areas
 - Vascular surgery - Lower limbs, amputations
 - Obstetrics - Cesarean delivery
 - Gynecology - Surgeries of female pelvic organs
 - Urology - Prostate and bladder surgeries
 - General surgery - Lower abdominal surgeries, including appendectomy, bowel surgeries, hernia repair
- Epidural analgesia:
 - Labor epidural analgesia
 - Chronic pain management for Disk herniation, degeneration, and spondylosis. Radiculopathy -Cervical, thoracic, lumbosacral
 - Spinal stenosis and facet arthropathy. Sympathetic mediated/maintained pain of upper or lower extremities and Pelvic pain.

CONTRAINDICATIONS:

- Uncorrected hypovolemia;
- Increased intracranial pressure
- Infection at the site
- Known allergy to local anesthetics;
- Coagulopathy;
- Spine abnormalities and surgeries;
- Sepsis

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RISKS:

- During insertion of epidural needle, if epidural needle tip passes epidural space and penetrates dura membrane, it causes loss of CSF (Cerebro Spinal Fluid) through that hole. Loss of CSF can cause severe headache in the patient. Pain increases while patient is in sitting or standing position. Hole in dura will be healed by itself in a few days.
- Breaking of epidural catheter - This is a very rarely encountered risk however there are some reported incidents. Even though there are warnings in literatures not to pull epidural catheter back while inside the epidural needle, if catheter is pulled back, epidural needle bevel can damage the catheter, part of the tubing can be detained within the patient. For such cases catheter was produced with a radiopaque line and location of the detained part can be detected using scanning devices and based on the decision of the doctor necessary interventions can be actuated.
- Risk of infection,
- Cerebral Herniation and bleeding
- Risk of late onset of epidermoid tumors of the thecal sac
- Complications and side effects to local anesthetics.
- Misplacement or migration of epidural catheter
- Damage to epidural needle or catheter
- Epidural abscess
- Hypotension
- Shivering
- Ringing of ears

SIDE EFFECTS:

- Post-operative nausea and vomiting,
- Lower back ache,
- Stinging and itching in legs,
- Difficulty urinating
- Soreness where needle was inserted

WARNINGS:

- All interventions related with the use of this medical device during and after its application should be conducted only by a doctor specialized in the subject.
- Do not use if package is torn or damaged. These are not sterile.
- Store in cool, dry and dust free environments.
- Needle cannula can be bent or broken upon applying excessive force during insertion. Cannula tip may curve or become blunt when the cannula interacts with a bone. Cannulas with damaged tips may increase the risk of post-dural headache for the patient because of the widened perforation of dura.
- In case of a serious incident occurring, it had to be reported to the manufacturer and the competent authority.
- After use dispose device according to medical waste disposal regulations.
- Do not apply any techniques other than the approved procedure.
- Use this medical device only for the mentioned intended purpose.
- This medical device is for single use only. Reuse or re-sterilization of the original package after opening is dangerous and can cause cross contamination, infection and trauma.

Note: Measurement lines on epidural needle cannula are marked at 1 cm. intervals with a tolerance of +/-2%.

Instructions in this manual and all other Egemen International® (TMT Tibbi Medikal Malz. San. Tic. Aş.) sources are for guidance purpose only. The proper use of this device should be based on clinical training of the physician.

SYMBOLS:



Manufacturer:

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