

## CAUDAL ANESTHESIA SET

- ⚠ Please read these instructions for use carefully before using this device.
- ⚠ PLEASE DO NOT USE THE DEVICE WITHOUT READING THE INSTRUCTIONS MANUAL.
- ⚠ Informing the patient and the patient consent must be obtained.
- ⚠ This product should be administered by a physician trained in **this technique**.

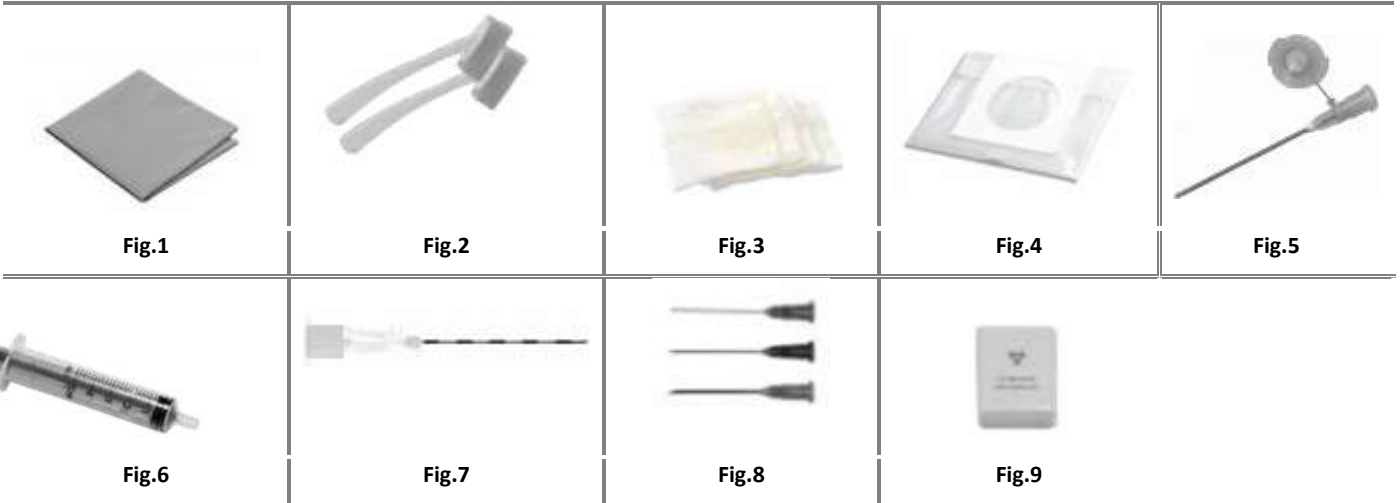
This instructions for use;

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### 1. CAUDAL ANESTHESIA SET CONTENT

- > Sterile Pack (Fig.1)
- > Spanch (Fig.2)
- > Medical Gas Compress (Fig.3)
- > Adhesive Surgical Drape (Fig.4)
- > Filtered Aspiration Cannula (Fig.5)
- > Syringe 3ml - 5ml (Fig.6)
- > Caudal Anesthesia Needle (Fig.7)
- > Hypodermic Needle 22G - 25G (Fig.8)
- > Needle Waste Box (Fig.9)
- > Dialysis Tape

### 2. CİHAZ GÖRSELLERİ



### 3. DEVICE COMPONENT MATERIAL INFORMATION

Stainless Steel, PE, ABS, Polypropylene, Non-woven, Cast Film

### 4. DEVICE APPLICATION

- 4.1 It is used for anesthesia in the caudal region.
- 4.2 Open the package using sterile technique.
- 4.3 The pack (Fig.1) kit is left on the instrument table by the sterile person with the flap ears facing up. Package ears, folded in accordion shape, are opened in both directions and laid on the table.
- 4.4 The set content is carefully placed on the bundle.



# INSTRUCTION FOR USE



## CAUDAL ANESTHESIA SET

- 4.5 If desired, an antiseptic solution is poured into the empty sterile container.
- 4.6 The dyeing sponge (Fig.2) is immersed in an antiseptic solution and after removing the excess in the ducted area in the same chamber, antiseptic application is performed on the patient.
- 4.7 Gas compresses (Fig.3) are used to remove excess antiseptics on the skin.
- 4.8 Adhesive Surgical Drape (Fig.4) is opened according to the procedure and adhered to the patient's back.
  - ⚠ While sticking the back cover on the patient's back, the circular space in the middle should be coincided with the puncture area.
- 4.9 Anesthetic drawn into a 5 cc syringe (Fig.6) is filtered using a dark pink Filtered Aspiration Cannula (0.5 micron) (Fig.5).
- 4.10 Check the Caudal anesthesia needle (Fig.7) tip and body by removing the needle tip guard and make sure it is not damaged in any way.
- 4.11 Confirm that it moves smoothly by withdrawing and relocating the caudal needle stylet.
- 4.12 Define the puncture site (point) according to the accepted procedure.  
(Duration of Use: Caudal needles are used for a few minutes for puncture or drug injection into the epidural space.)
- 4.13 Start puncture with a caudal needle.
- 4.14 Confirm that there is no CSF fluid or blood coming from the needle with an empty syringe and make sure the needle is in the correct spot.
- 4.15 Complete the caudal application.
- 4.16 Dip the end of the caudal needle into the sponge in the needle waste box (Fig.9) and dispose of it according to medical waste rules

### 5. INDICATIONS:

- > Early hernia treatment of premature babies
- > Pediatric urological interventions
- > Orthopedic intervention on the lower extremities in children
- > Anorectal interventions in children
- > All other surgical interventions that are below the nipple line

### 6. CONTRAINDICATIONS:

#### 6.1 Absolute Contraindications

- > Patient's refusal to treat
- > The presence of infection in and around the injection site
- > Increased intracranial pressure
- > Pilonidal cyst
- > Known hypersensitivity to local anesthetics

#### 6.2 Relative Contraindications

- > Septicemia
- > Severe false hypovolemia
- > Coagulopathy
- > Congenital anomaly in the spinal cord
- > Neurological diseases (nerve lesions polyneuropathy, multiple sclerosis)
- > Hypovolemia

### 7. RISKS

- > Dyspnoea / Apnea
- > Hypotension
- > Cardiac arrest
- > Bradycardia
- > Hypothermia
- > Urine retention
- > Toxicity related to local anesthetic agents
- > Accidental injection of anesthetic substance into the dura or into the vein instead of the extradural area
- > Temporary neurological complications (such as postdural puncture headache (PDPH), paresthesia)
- > Permanent neurological complications (such as meningitis, transverse myelitis or anterior spinal artery syndrome with permanent paralysis, arachnoiditis / cauda equina syndrome)
- > Hematoma



# INSTRUCTION FOR USE



## CAUDAL ANESTHESIA SET

- › Epidural space abscess and / or infection
- › Local infection (at the catheter or subcutaneous entry)
- › Air embolism
- › Septicemia
- › Complications as a result of the patient's allergy to the local anesthetic
- › The local anesthetic used can temporarily numb the nerves that control blood pressure (such as numbness in the legs)

### 8. WARNING:

- › 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 the bone. Cannulas with damaged tips may damage body tissues.
- › In case of a serious incident is occurred, 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 needle cannula are marked at 5mm. intervals with a tolerance of +/-1%

### 9. CAUDAL ANESTHESIA SET MODEL LIST

PKAU20	Caudal Anesthesia Set 20 G
PKAU22	Caudal Anesthesia Set 22 G
PKAU23	Caudal Anesthesia Set 23 G
PKAU25	Caudal Anesthesia Set 25 G

### 10. SYMBOLS:



Sterilized using ethylene oxide



Keep dry



Do not re-use



Humidity limitation



Do not use if package is damaged



Batch code



Use-by date



Do not re-sterilize



Date of manufacture



Non-pyrogenic



Temperature limit



Keep away from sunlight



Consult (e IFU) instructions for use  
[www.egemen.com.tr](http://www.egemen.com.tr)

### 11. MANUFACTURER INFORMATION



TMT TIBBİ MEDİKAL MALZ. SAN. TİC. AŞ.

**Address:** Fatih Mah.1188 Sok.No14 PK 35414

Sarıç, Gaziemir – İzmir / Türkiye

Tel: + 90232 278 15 93; Fax: + 90 232 279 32 08

**Sterilization Address:** Fatih Mah.1188 Sok. No:14 PK:35414 Sarıç / Gaziemir / İzmir /TÜRKİYE

**Warehouse Address:** Fatih Mah. 1188 Sok. No: 12/A PK:35414 Sarıç / Gaziemir / İzmir /TÜRKİYE



**Emergo Europe**

**Address:** Prinsessegracht 20, 2514 AP, The Hague, The Netherlands.

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