

**SPINAL ANESTHESIA SET
(WITH QUINCKE/PENCIL POINT/SPECIAL GRINDED ATRAUMATIC TIP SPINAL NEEDLE)**

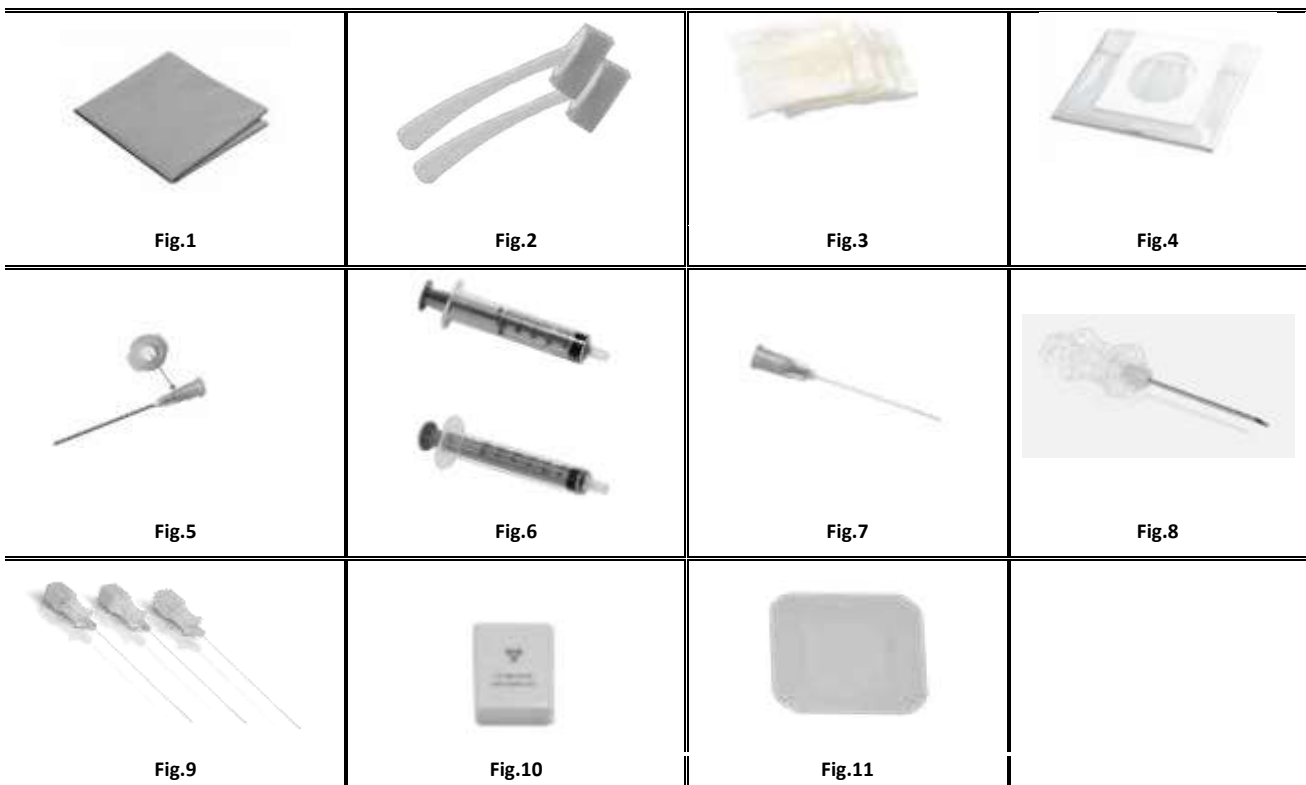
- ⚠ Please read these instructions for use carefully before using this device.
- ⚠ PLEASE DO NOT USE THE DEVICE WITHOUT READING THE INSTRUCTIONS MANUAL.
- ⚠ Informing the patient and the patient consent must be obtained.
- ⚠ This product should be administered by **a physician trained in this technique.**

This instructions for use;

1. *Spinal Anesthesia Set package content*
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4. *Device application*
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1. Spinal Anesthesia Set package content

- › Sterile Surgical Towel (Fig.1)
- › Prep Spanch (Fig.2)
- › Medical Gas Compress (Fig.3)
- › Adhesive Surgical Drape (Fig.4)
- › Filtered Aspiration Cannula (Fig.5)
- › Syringe 3ml - 5ml (Fig.6)
- › Hypodermic Needle 22G - 25G (Fig.7)
- › Guide Needle (Fig.8)
- › Spinal Anesthesia Needle (Quincke / Pencil Point / Atraumatic-Special Grinded) (Fig.9)
- › Waste Needle Box (Fig.10)
- › Square Tape (Fig.11)

2. Device Figures



INSTRUCTION FOR USE





SPINAL ANESTHESIA SET (WITH QUINCKE/PENCIL POINT/SPECIAL GRINDED ATRAUMATIC TIP SPINAL NEEDLE)

Auxiliary components within the set are optional. Contents of the set is stated on the package label. Please examine technical catalogue for more detailed information.

3. Device material information

ABS, PP, PE, non-woven fabric, cast film, hydrophilic cotton, stainless steel.

4. Device application

- 4.1 Open unit pack using sterile technique
- 4.2 Place Sterile Surgical Towel set on the instrument table by a sterile person and pay attention that folded flaps are facing upward. Open accordion type folded Sterile Surgical Towel (Fig.1) by pulling to opposite directions then spread the sheet on the table.
- 4.3 Take set contents out and place them onto sheet
- 4.4 If required fill antiseptic fluid inside emptied sterile tray.
- 4.5 Dip prep sponges (Fig.2) in the antiseptic solution then wipe excess over the channels in the same area and apply antiseptic on the patient.
- 4.6 Use medical gauze compress (Fig.3) to wipe excess antiseptic solution.
- 4.7 Open adhesive surgical drape (Fig.4) is opened duly and adhere to patient's back.
 *While the back cover is attached to the patient's back, the circular hole in the middle should be aligned with the puncture area. While the surgical drape is attached to the back of the patient, the circular hole in the middle should be aligned with the puncture area.*
- 4.8  *The use of Guide Needle is highly recommended with 25G, 26G, 27G and 29G Spinal needles. There can be bending risks on the needles used without guides.*
- 4.8 Use 0.5 micron dark pink Filter Aspiration Cannula (Fig.5) for filtering fluid that is aspirated into 5cc syringe (Fig.6).
- 4.9 Local anesthesia is applied using the standard syringe and orange colored (25G) hypodermic needle (Fig.7) in the set.
- 4.10 Use guide needle (Fig.8) for initial puncture on determined puncture site.
- 4.11 Insert Spinal needle (Fig.9) through guide needle and advance to enter subarachnoid space. Pull out stylet and monitor CSF flow in order to confirm that needle tip is inside subarachnoid space. If no CSF flow can be monitored, place stylet back on needle hub and advance further.
- 4.12 After confirming CSF flow, attach syringe with anesthetic drug onto spinal needle and inject it.
- 4.13 When the procedure is completed, first the Spinal Needle and then the guide needle are withdrawn and removed and the Waste Needle Box (Fig.10) is inserted to be disposed of according to the medical waste procedure.
- 4.14 The application area is covered with a sterile bandage included in the set.

5. Indications

- > Spinal anesthesia applications (pain management, diagnosis-treatment and other operational procedures)
- > Lumbar region attempts (puncture)

6. Contraindications

6.1 Absolute Contraindications

- > Patient refusal
- > Coagulopathy
- > Skin infection at the puncture site or near the injection site
- > Hypersensitivity to the local anesthetic agent or any of the materials used
- > Incurable hypovolemia
- > Increased intracranial pressure
- > Shock
- > Acute cerebral or spinal cord disease
- > Presence of spinal cord anomaly and / or deformation

6.2 Relative Contraindications

- > Severe dehydration (hypovolemia) due to the risk of hypotension *
- > Sepsis
- > Septicemia-bacteremia

* Risk factors for hypotension include hypovolemia, age over 40 to 50 years old, emergency surgery, obesity, chronic alcohol consumption and chronic hypertension.



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In general, it is recommended to perform the operation by performing a benefit / risk analysis by the specialist doctor / clinician before the procedure is performed.

7. Risks

- > Postdural puncture headache
- > Hypotension and bradycardia
- > Hypothermia
- > Nausea and vomiting after the procedure
- > Low cerebrospinal fluid pressure syndrome
- > Cardiac arrest
- > Apnea or local anesthetic toxicity
- > Epidural hematoma or abscess formation
- > Anterior spinal artery syndrome
- > Cauda equina syndrome
- > Urinary retention
- > Lumbar hernia and back pain
- > Infection at the puncture site
- > Temporary neurological symptoms due to patient positioning
- > Total spinal anesthesia
- > Difficulty breathing
- > Loss of consciousness
- > Possibility of a stroke
- > Nerve damage
- > Transient neurological symptoms (paresthesia, burning sensation in the hip, itching, dysesthesia)

8. 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.
- > Cannula can be bended or broken upon applying excessive force during the intervention. The cannula tip may curve or become blunt when the cannula interacts with the bone. The cannulas with damaged tips may increase of post-dural headache of the patient because of the widen perforation of the dura-meter.
- > The tape in the adhesive surgical drape may cause an allergic reaction on sensitive skin.
- > 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 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

9. Device List

9.1 Spinal Anesthesia Set with Quincke Type Spinal Anesthesia Needle

Colour Code:	Reference-Order Code:	Product Description:
Pink	PSPQ1875	Spinal Anesthesia Set With Quincke Type Spinal Needle 18GX75 mm
Pink	PSPQ1890	Spinal Anesthesia Set With Quincke Type Spinal Needle 18G X 90 mm
Ivory	PSPQ1990	Spinal Anesthesia Set With Quincke Type Spinal Needle 19G X 90 mm
Yellow	PSPQ2075	Spinal Anesthesia Set With Quincke Type Spinal Needle 20G X 75 mm
Yellow	PSPQ2090	Spinal Anesthesia Set With Quincke Type Spinal Needle 20G X 90 mm
Green	PSPQ2190	Spinal Anesthesia Set With Quincke Type Spinal Needle 21G X 90 mm
Black	PSPQ2240	Spinal Anesthesia Set With Quincke Type Spinal Needle 22G X 40 mm
Black	PSPQ2275	Spinal Anesthesia Set With Quincke Type Spinal Needle 22G X 75 mm
Black	PSPQ2290	Spinal Anesthesia Set With Quincke Type Spinal Needle 22G X 90 mm
Black	PSPQ22120	Spinal Anesthesia Set With Quincke Type Spinal Needle 22G X 120 mm
Blue	PSPQ2390	Spinal Anesthesia Set With Quincke Type Spinal Needle 23 G X 90 mm
Purple	PSPQ2490	Spinal Anesthesia Set With Quincke Type Spinal Needle 24G X 90 mm
Orange	PSPQ2575	Spinal Anesthesia Set With Quincke Type Spinal Needle 25G X 75 mm
Orange	PSPQK2590	Spinal Anesthesia Set With Quincke Type Spinal Needle and Guide Needle 25X90mm
Orange	PSPQK2590	Spinal Anestezi Seti-Keskin Uçlu (Quincke) Spinal Anestezi İğneli 25 G x 90 mm, Kılavuz İğneli



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SPINAL ANESTHESIA SET (WITH QUINCKE/PENCIL POINT/SPECIAL GRINDED ATRAUMATIC TIP SPINAL NEEDLE)

Orange	PSPQK25103	Spinal Anesthesia Set With Quincke Type Spinal Needle 25G X 103 mm and Guide Needle
Orange	PSPQK25120	Spinal Anesthesia Set With Quincke Type Spinal Needle 25G X 120 mm and Guide Needle
Brown	PSPQK2690	Spinal Anesthesia Set With Quincke Type Spinal Needle 26G X 90 mm and Guide Needle
Brown	PSPQK26103	Spinal Anesthesia Set With Quincke Type Spinal Needle 26G X 103 mm and Guide Needle
Brown	PSPQK26120	Spinal Anesthesia Set With Quincke Type Spinal Needle 26G X 120 mm and Guide Needle
Gray	PSPQK2790	Spinal Anesthesia Set With Quincke Type Spinal Needle 27G X 90 mm and Guide Needle
Gray	PSPQK27103	Spinal Anesthesia Set With Quincke Type Spinal Needle 27G X 103 mm and Guide Needle
Gray	PSPQK27120	Spinal Anesthesia Set With Quincke Type Spinal Needle 27G X 120 mm and Guide Needle
Red	PSPQK2990	Spinal Anesthesia Set With Quincke Type Spinal Needle 29G X 90 mm and Guide Needle
Red	PSPQK29120	Spinal Anesthesia Set With Quincke Type Spinal Needle 29G X 120 mm and Guide Needle

9.2 Spinal Anesthesia Set with Atraumatic Type (Pencil Point) Spinal Anesthesia Needle

Colour Code	Reference-Order Code	Product Description
Black	PSPPP2290	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 22GX90 mm
Black	PSPPK2290	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 22GX90 mm and Guide Needle
Blue	PSPPP2390	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 23G X 90 mm
Blue	PSPPK2390	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 23G X 90 mm and Guide Needle
Purple	PSPPP2490	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 24G X 90 mm
Purple	PSPPK2490	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 24G X 90 mm and Guide Needle
Orange	PSPPK2590	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 25G X 90 mm and Guide Needle
Orange	PSPPK25103	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 25G X 103 mm and Guide Needle
Orange	PSPPK25120	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 25G X 120 mm and Guide Needle
Brown	PSPPK2690	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 26GX90 mm and Guide Needle
Brown	PSPPK26103	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 26G X 103 mm and Guide Needle
Brown	PSPPK26120	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 26G X 120 mm and Guide Needle
Gray	PSPPK2790	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 27G X 90 mm and Guide Needle
Gray	PSPPK27103	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 27G X 103 mm and Guide Needle
Gray	PSPPK27120	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 27GX120 mm and Guide Needle
Red	PSPPK2990	Spinal Anesthesia Set With Atraumatic Type(Pencil Point) Spinal Needle 29 G X 90 mm and Guide Needle

9.3 Spinal Anesthesia Set with Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle

Colour Code	Reference-Order Code	Product Description
Orange	PSPAK2590	Spinal Anesthesia Set With Specially Grinded-Curved Type Atraumatic Spinal Needle 25 G X 90 mm and Guide Needle
Orange	PSPAK25100	Spinal Anesthesia Set With Specially Grinded-Curved Type Atraumatic Spinal Needle 25 G X 100 mm and Guide Needle
Brown	PSPA2650	Spinal Anesthesia Set With Specially Grinded-Curved Type Atraumatic Spinal Needle 26 G X 50 mm
Brown	PSPAK2688	Spinal Anesthesia Set With Specially Grinded-Curved Type Atraumatic Spinal Needle 26 G X 88 mm and Guide Needle



INSTRUCTIONS FOR USE



SPINAL ANESTHESIA SET (WITH QUINCKE/PENCIL POINT/SPECIAL GRINDED ATRAUMATIC TIP SPINAL NEEDLE)

10. Symbols



Sterilized using ethylene



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

11. Manufacturer Information



TMT TIBBİ MEDİKAL MALZ. SAN. TİC. AŞ.

Address: Fatih Mah.1188 Sok.No14 PK 35414

Sarnıç, Gaziemir – İzmir / Türkiye

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

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

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



Emergo Europe

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

Instructions in this manual and all other Egemen International® (TMT Tibbi 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.