

**SPINAL ANESTHESIA NEEDLE
(QUINCKE / PENCIL POINT / ATRUMATIC-SPECIAL GRINDED)**

- ⚠ 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.**

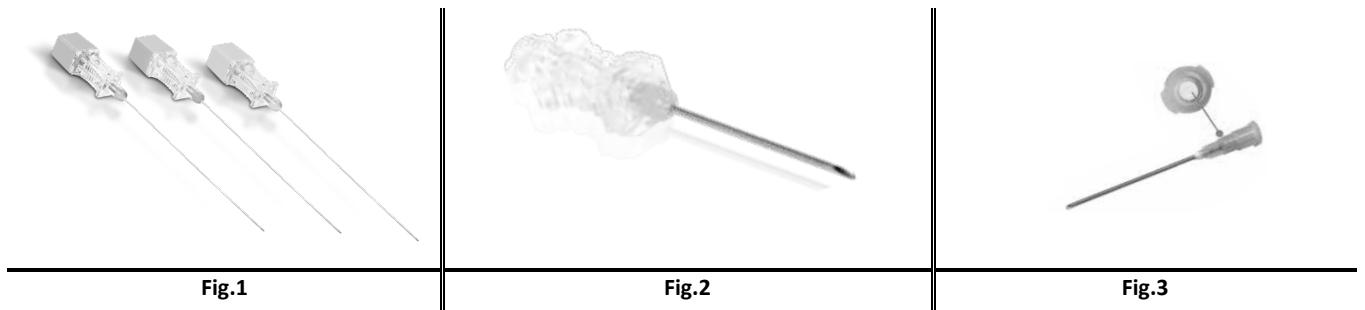
This instructions for use;

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1. Spinal Needle package content

- › Spinal Anesthesia Needle (Fig.1)
 - › Guide Needle * (Fig.2)
 - › Filtered Aspiration Cannula * (Fig.3)
- *It is optional.

2. Device Figures



3. Device material information

Stainless steel, ABS, UV adhesive

4. Device application

- 4.1 Open unit pack using sterile technique.
- 4.2 Remove plastic tip protector and examine needle body and tip in order to confirm its integrity.
- 4.3 Remove stylet of Spinal needle then place it again to confirm smooth movement.
- 4.4 Prepare puncture area for the procedure according to standard aseptic technique.
 - NOTE:** Based on the physician's clinical training, local anesthesia may be necessary for needles with larger size than 25G.
 - ⚠ 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
 - ⚠ Use the filtered aspiration cannula (included in the package) only to aspirate the anesthetic from the glass ampoule.
- 4.5 Determine a puncture area (point) according to accepted procedure and advance until you reach subarachnoid space. You can pull back stylet and monitor CSF flow in order to confirm needle tip being inside subarachnoid space.
- 4.6 After confirming that needle tip is inside subarachnoid space, remove stylet and inject anesthetic drug.
- 4.7 After completing the procedure, remove Spinal Needle and dispose it according to local medical device disposal regulations (Duration of Use: Used for a few minutes for lumbar puncture or drug injection into the subarachnoid space)

5. Indications

- › Spinal anesthesia applications (pain management, diagnosis-treatment and other operational procedures)

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- › 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.

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.
- › 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 Quincke Type Spinal Anesthesia Needles Model List

Reference Code	Product Description
TSPQ1875	Quincke Type Spinal Anesthesia Needle 18G x75mm



INSTRUCTION FOR USE



SPINAL ANESTHESIA NEEDLE (QUINCKE / PENCIL POINT / ATRUMATIC-SPECIAL GRINDED)

TSPQF1875	Quincke Type Spinal Anesthesia Needle 18G x75mm with Filtered Aspiration Cannula
TSPQ1890	Quincke Type Spinal Anesthesia Needle 18G x 90mm
TSPQF1890	Quincke Type Spinal Anesthesia Needle 18G x 90mm with Filtered Aspiration Cannula
TSPQ1990	Quincke Type Spinal Anesthesia Needle 19G x 90mm
TSPQF1990	Quincke Type Spinal Anesthesia Needle 19G x 90mm with Filtered Aspiration Cannula
TSPQ2075	Quincke Type Spinal Anesthesia Needle 20G x 75mm
TSPQF2075	Quincke Type Spinal Anesthesia Needle 20G x 75mm with Filtered Aspiration Cannula
TSPQ2090	Quincke Type Spinal Anesthesia Needle 20G x 90mm
TSPQF2090	Quincke Type Spinal Anesthesia Needle 20G x 90mm with Filtered Aspiration Cannula
TSPQ2190	Quincke Type Spinal Anesthesia Needle 21G x 90mm
TSPQF2190	Quincke Type Spinal Anesthesia Needle 21G x 90mm with Filtered Aspiration Cannula
TSPQ2240	Quincke Type Spinal Anesthesia Needle 22G x 40mm
TSPQF2240	Quincke Type Spinal Anesthesia Needle 22G x 40mm with Filtered Aspiration Cannula
TSPQ2275	Quincke Type Spinal Anesthesia Needle 22G x 75mm
TSPQF2275	Quincke Type Spinal Anesthesia Needle 22G x 75mm with Filtered Aspiration Cannula
TSPQ2290	Quincke Type Spinal Anesthesia Needle 22G x 90mm
TSPQF2290	Quincke Type Spinal Anesthesia Needle 22G x 90mm with Filtered Aspiration Cannula
TSPQ22120	Quincke Type Spinal Anesthesia Needle 22G x 120mm
TSPQF22120	Quincke Type Spinal Anesthesia Needle 22G x 120mm with Filtered Aspiration Cannula
TSPQ22150	Quincke Type Spinal Anesthesia Needle 22G x 150mm
TSPQF22150	Quincke Type Spinal Anesthesia Needle 22G x 150mm with Filtered Aspiration Cannula
TSPQ2390	Quincke Type Spinal Anesthesia Needle 23G x 90mm
TSPQF2390	Quincke Type Spinal Anesthesia Needle 23G x 90mm with Filtered Aspiration Cannula
TSPQ2490	Quincke Type Spinal Anesthesia Needle 24G x90mm
TSPQF2490	Quincke Type Spinal Anesthesia Needle 24G x90mm with Filtered Aspiration Cannula
TSPQ2575	Quincke Type Spinal Anesthesia Needle 25G x75mm
TSPQF2575	Quincke Type Spinal Anesthesia Needle 25G x75mm with Filtered Aspiration Cannula
TSPQ2590	Quincke Type Spinal Anesthesia Needle 25G x 90m
TSPQF2590	Quincke Type Spinal Anesthesia Needle 25G x 90m with Filtered Aspiration Cannula
TSPQK2590	Quincke Type Spinal Anesthesia Needle 25G x 90mm with Guide Needle
TSPQFK2590	Quincke Type Spinal Anesthesia Needle 25G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSPQK25103	Quincke Type Spinal Anesthesia Needle 25G x 103mm with Guide Needle
TSPQFK25103	Quincke Type Spinal Anesthesia Needle 25G x 103mm with Guide Needle and Filtered Aspiration Cannula
TSPQK25120	Quincke Type Spinal Anesthesia Needle 25G x 120 mm with Guide Needle
TSPQFK25120	Quincke Type Spinal Anesthesia Needle 25G x 120 mm with Guide Needle and Filtered Aspiration Cannula
TSPQ2690	Quincke Type Spinal Anesthesia Needle 26G x 90mm
TSPQF2690	Quincke Type Spinal Anesthesia Needle 26G x 90mm with Filtered Aspiration Needle
TSPQK2690	Quincke Type Spinal Anesthesia Needle 26G x 90mm with Guide Needle
TSPQFK2690	Quincke Type Spinal Anesthesia Needle 26G x 90mm with Guide Needle and Filtered Aspiration Cannula



INSTRUCTION FOR USE



SPINAL ANESTHESIA NEEDLE (QUINCKE / PENCIL POINT / ATRUMATIC-SPECIAL GRINDED)

TSPQK26103	Quincke Type Spinal Anesthesia Needle 26G x 103mm with Guide Needle
TSPQFK26103	Quincke Type Spinal Anesthesia Needle 26G x 103mm with Guide Needle and Filtered Aspiration Cannula
TSPQK26120	Quincke Type Spinal Anesthesia Needle 26G x 120mm with Guide Needle
TSPQFK26120	Quincke Type Spinal Anesthesia Needle 26G x 120mm with Guide Needle and Filtered Aspiration Cannula
TSPQ2790	Quincke Type Spinal Anesthesia Needle 27G x 90mm
TSPQF2790	Quincke Type Spinal Anesthesia Needle 27G x 90mm with Filtered Aspiration Cannula
TSPQK2790	Quincke Type Spinal Anesthesia Needle 27G x 90mm with Guide Needle
TSPQFK2790	Quincke Type Spinal Anesthesia Needle 27G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSPQK27103	Quincke Type Spinal Anesthesia Needle 27G x 103mm with Guide Needle
TSPQFK27103	Quincke Type Spinal Anesthesia Needle 27G x 103mm with Guide Needle and Filtered Aspiration Cannula
TSPQK27120	Quincke Type Spinal Anesthesia Needle 27G x 120mm with Guide Needle
TSPQFK27120	Quincke Type Spinal Anesthesia Needle 27G x 120mm with Guide Needle and Filtered Aspiration Cannula
TSPQ2990	Quincke Type Spinal Anesthesia Needle 29G x 90mm
TSPQF2990	Quincke Type Spinal Anesthesia Needle 29G x 90mm with Filtered Aspiration Cannula
TSPQK2990	Quincke Type Spinal Anesthesia Needle 29G x 90mm with Guide Needle
TSPQFK2990	Quincke Type Spinal Anesthesia Needle 29G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSPQK29120	Quincke Type Spinal Anesthesia Needle 29G x 120mm with Guide Needle
TSPQFK29120	Quincke Type Spinal Anesthesia Needle 29G x 120mm with Guide Needle and Filtered Aspiration Cannula

9.2 Atraumatic-Pencil Point Spinal Anesthesia Needles Model List

Reference Code	Product Description
TSP2290	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 90mm
TSPPK2290	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 90mm with Guide Needle
TSPPF2290	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 90mm with Filtered Aspiration Cannula
TSPPFK2290	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSP22120	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 120mm
TSPPK22120	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 120mm with Guide Needle
TSPPF22120	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 120mm with Filtered Aspiration Cannula
TSPPFK22120	Atraumatic-Pencil Point Spinal Anesthesia Needles 22G x 120mm with Guide Needle and Filtered Aspiration Cannula
TSP2390	Atraumatic-Pencil Point Spinal Anesthesia Needles 23G x 90mm
TSPPF2390	Atraumatic-Pencil Point Spinal Anesthesia Needles 23G x 90mm with Filtered Aspiration Cannula
TSP2490	Atraumatic-Pencil Point Spinal Anesthesia Needles 24G x 90mm
TSPPF2490	Atraumatic-Pencil Point Spinal Anesthesia Needles 24G x 90mm with Filtered Aspiration Cannula
TSP2525	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 25mm
TSPPF2525	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 25mm with Filtered Aspiration Cannula
TSP2550	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 50mm
TSPPF2550	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 50mm with Filtered Aspiration Cannula
TSP2590	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 90mm
TSPPK2590	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 90mm with Guide Needle



INSTRUCTION FOR USE



SPINAL ANESTHESIA NEEDLE (QUINCKE / PENCIL POINT / ATRUMATIC-SPECIAL GRINDED)

TSPPF2590	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 90mm with Filtered Aspiration Cannula
TSPPFK2590	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSPPK25103	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 103mm Guide Needle
TSPPFK25103	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 103mm with Guide Needle and Filtered Aspiration Cannula
TSP25120	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 120mm
TSPPF25120	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 120mm with Filtered Aspiration Cannula
TSPPK25120	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 120mm with Guide Needle
TSPPFK25120	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 120mm with Guide Needle and Filtered Aspiration Cannula
TSP25156	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 156mm
TSPPF25156	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 156mm with Filtered Aspiration Cannula
TSPPK25156	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 156mm with Guide Needle
TSPPFK25156	Atraumatic-Pencil Point Spinal Anesthesia Needles 25G x 120mm with Guide Needle and Filtered Aspiration Cannula
TSP2690	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 90mm
TSPPF2690	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 90mm with Filtered Aspiration Cannula
TSPPK2690	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 90mm with Guide Needle
TSPPFK2690	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSPPK26103	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 103mm with Guide Needle
TSPPFK26103	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 103mm with Guide Needle and Filtered Aspiration Cannula
TSPPK26120	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 120mm with Guide Needle
TSPPFK26120	Atraumatic-Pencil Point Spinal Anesthesia Needles 26G x 120mm with Guide Needle and Filtered Aspiration Cannula
TSP2750	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 50mm
TSPPF2750	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 50mm with Filtered Aspiration Cannula
TSP2790	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 90mm
TSPPF2790	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 90mm with Filtered Aspiration Cannula
TSPPK2790	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 90mm with Guide Needle
TSPPFK2790	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSPPK27103	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 103mm with Guide Needle
TSPPFK27103	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 103mm with Guide Needle and Filtered Aspiration Cannula
TSPPK27120	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 120mm with Guide Needle
TSPPFK27120	Atraumatic-Pencil Point Spinal Anesthesia Needles 27G x 120mm with Guide Needle and Filtered Aspiration Cannula
TSPPK2990	Atraumatic-Pencil Point Spinal Anesthesia Needles 29G x 90mm with Guide Needle
TSPPFK2990	Atraumatic-Pencil Point Spinal Anesthesia Needles 29G x 90mm with Guide Needle and Filtered Aspiration Cannula

9.3 Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needles Model List

Reference Code	Product Description
TSPAK2590	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 25G x 90mm with Guide Needle














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TSPAFAK2590	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 25G x 90mm with Guide Needle and Filtered Aspiration Cannula
TSPAFAK25100	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 25G x 100mm with Guide Needle
TSPAFAK25100	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 25G x 100mm with Guide Needle and Filtered Aspiration Cannula
TSPA2650	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 26Gx50mm
TSPAFA2650	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 26Gx50mm with Filtered Aspiration Cannula
TSPAFAK2688	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 26Gx88mm with Guide Needle
TSPAFAK2688	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 26Gx88mm with Guide Needle and Filtered Aspiration Cannula
TSPAFAK26100	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 26Gx100mm with Guide Needle
TSPAFAK26100	Specially Grinded – Curved Type Atraumatic Spinal Anesthesia Needle 26Gx100mm with Guide Needle and Filtered Aspiration Cannula

9.4 Guide Needle Model List

Reference Code	Product Description
KIH18	Guide Needle 18G
KIH20	Guide Needle 20G
KIH21	Guide Needle 21G
KIH22	Guide Needle 22G
KIH23	Guide Needle 23G

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
	Conformité Européenne						

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 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.