INSTRUCTION FOR USE

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SPINAL ANESTHESIA 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 Needle package content*
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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

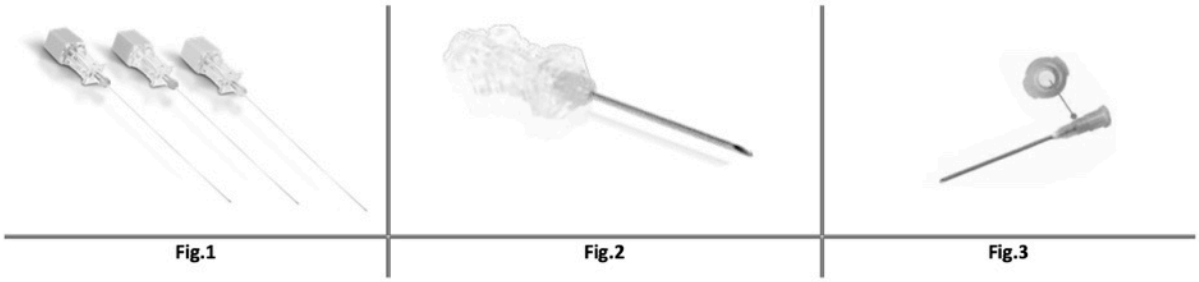

Fig.1 **Fig.2** **Fig.3**

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