

# Spinal Needles

## Instructions for Use



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### INTENDED USE, INDICATION:

For use in subarachnoid injection of local anesthetics for spinal anesthesia before surgery, and in lumbar puncture for pain management, and diagnosis on the basis of cerebrospinal fluid.

### MEDICAL CONDITIONS

- Cervical herniated nucleus
- Spinal stenosis
- Lumbar herniated intervertebral disc

### CONTRAINDICATIONS

The recognized contraindications for spinal subarachnoid anesthesia and lumbar puncture must be observed, as detailed below.

Caution required with use:

- Blood coagulation disorders
- Skin infections at or near the puncture site
- Septicemia
- Spinal subarachnoid anesthesia should not be carried out with patients hypersensitive to local anesthetics and/or any of the materials included, or patients with any of the following conditions:
  - Severe decompensated hypovolemia
  - Shock
  - Acute encephalopathy or spinal cord diseases
  - Increased intracranial pressure
  - Infection at the puncture site
  - Endogenous or iatrogenic coagulation disorders
  - Anatomic abnormalities at the puncture site
    - The angle for lumbar puncture should be more acute for infants than for older children, and we recommend that the optimal angle for performing a lumbar puncture has to be 50° in infants and 60° in children aged 1 to 12 years.

### COMPATIBILITY

- The small bore type (Model Name : SP.PP-Small Bore and SP.QP-Small Bore) must be used in conjunction with a device conforming to ISO80369-6

### RISK

The generally known risks with spinal subarachnoid anesthesia and lumbar puncture are postdural puncture headache, postlumbar puncture headache, hypotension, cardiac arrest, apnea, and acute toxicity of local anesthetic.

Complications such as neuropathic disorders including epidural hematoma, abscess formation, anterior spinal artery syndrome, and cauda equina syndrome, occur very occasionally.

Spinal subarachnoid anesthesia and lumbar puncture must be carried out by appropriately trained personnel, using the appropriate equipment.

### WARNINGS

- The product must not be used if the packaging is torn, it is dirty or contaminated, or if any abnormalities in the spinal needle can be seen.
- The product must not be re-used.
- The product must not be re-sterilized.

#### ***The problems can be occurred by re-use and re-sterilize***

- 1) ***Re-use: Injury occurrence due to Bio Contamination***
- 2) ***Re-use and re-disposal: Accident occurrence due to malfunction from damaged products***

#### ***Examples of infections by needles are as follows:***

- ***Hepatitis B:***
  - \* ***Symptoms: None, yellowish skin, tiredness, dark urine, abdominal pain***
  - \* ***Complications: Cirrhosis, liver cancer***
- ***Hepatitis C***
  - \* ***Symptoms: fatigue, nausea and vomiting, fever, muscle or joint pains***
  - \* ***Complications: Liver failure, liver cancer, esophageal and gastric varices***
- ***AIDS(HIV)***
  - \* ***Symptoms:***
    - Early: Flu-like illness***
    - Later: Large lymph nodes, fever, weight loss***
  - \* ***Complications: Opportunistic infections, tumors***
- ***Ebola virus***
  - \* ***Symptoms: fever, fatigue, muscle, pain, headache, and sore throat. This is followed by vomiting, diarrhea, rash, symptoms of impaired kidney and liver function, and in some cases internal and external bleeding (e.g. oozing from the gums, blood in the stools).***
  - \* ***Complications: Multiple organ damage caused by low blood pressure and bleeding often results in death around 7 to 14 days after the outbreak.***
  - \*

- It is possible for the spinal needle to bend or break, so excessive force must not be applied when it is being pushed forward.
- Deformation of the needle tip is possible when it comes into contact with bone.
- Use of a spinal needle with a deformed tip can result in widening of the puncture hole, increasing the risk of postdural puncture headache.

## DURATION OF USE

As soon as the lumbar puncture or subarachnoid injection has been completed, the spinal needle should be withdrawn from the patient.

## INSTRUCTIONS FOR USE

Spinal subarachnoid anesthesia and lumbar puncture are carried out under aseptic conditions.

1. With the patient in a bodily position facilitating puncture, either seated or lateral decubitus, confirm that the needle is at the puncture midline.
2. Select a spinal needle appropriate for the device.
  - If the spinal needle used is of a gauge less than 25G (external diameter: less than 0.5 mm), use of a spinal needle guide is recommended.
  - Check the equipment for emergency use, consisting of the intubation kit and the drugs, and ensure continuous monitoring of the patient.
3. Disinfect the puncture site.
4. Inject 1 to 1.5 mL of local anesthetic at the puncture site, using the spinal needle, to anesthetize the supraspinal ligament and the interspinous ligaments.
5. Grip the guide needle between the thumb and index finger, and insert via the spinal needle puncture site.
6. Move the spinal needle, with the stylet attached, into the center of the guide needle.
  - After passing through the ligamentum flavum, and reaching the subarachnoid space, a click can be felt when the needle passes through the dura mater.

## WARNING

If resistance is felt while inserting the spinal needle, the direction of the needle should be carefully corrected, without using strong force.

1. Withdraw the stylet from the spinal needle.
  - In the case of the stylet of the Facil Point product, first carefully rotate the button to the left in order to lock it, and then disengage it, and withdraw.
  - The cerebrospinal fluid sometimes contains a certain amount of blood, but it should be carefully ascertained that the outflow is not blood alone.
  - In the case of the lumbar puncture procedure, after collecting cerebrospinal fluid, cover the puncture site with a sterilized bandage or dressing.
  - In the case of spinal anesthesia, before local anesthetic injection, confirm that there is outflow of cerebrospinal fluid, and that the spinal needle has reliably reached as far as the subarachnoid space, after which the local anesthetic is injected in accordance with instructions from its

manufacturer.

## NOTES

- If the presence of cerebrospinal fluid cannot be confirmed, local anesthetic is not injected.
- If the outflow is of blood rather than cerebrospinal fluid, the needle is withdrawn, and puncture is repeated, at a different intervertebral space.
- If there is no outflow of cerebrospinal fluid, the needle should be rotated 90°, followed by careful aspiration.
- If cerebrospinal fluid outflow cannot be achieved by the above procedure, puncture is carried out from a different direction.
- If there is any abnormal sensation after the needle has reached the subarachnoid space, the needle should be withdrawn a little.
- If there is any abnormal sensation when injecting the drug, the needle position should be changed before continuing with injection.
- After drug injection, the needle is withdrawn, and the puncture site is covered with sterilized bandage or dressing.
- Spreading of the anesthetic is achieved by adjusting the patient's bodily position, depending upon whether the formulation used is hyperbaric, isobaric or hypobaric.
- The level and spread of anesthesia is monitored carefully. Surgery can be initiated once complete block of the relevant motor, sensory and sympathetic nerves has been achieved.
- After use, the product is disposed of as medical waste, by a safe method, taking care to prevent infection.

## IMPORTANT PRECAUTIONS

- If the spinal needle is used with other items of equipment connected, those items should be used in accordance with the relevant documents explaining their use.
- The spinal needle must not be remodeled or reconstructed in any way.

## STORAGE METHOD

The product should be stored at room temperature, with care taken to avoid high temperature, humidity, direct sunlight, and contact with water.

The product should not be stored under fluorescent lights, or near devices that generate ozone.



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#### Labeling Symbols:

Symbols are used for products sold internationally for ease in identification.

No	Used symbol	Description	Used symbol	Description
1		Symbol for 'Manufacturer'	<b>SIZE</b>	Symbol for 'Cannula size'
2	 PEEL TO OPEN	Symbol for 'Peel direction'		Symbol for 'Do not reuse'
3		Symbol for 'Use by'	<b>LOT</b>	Symbol for 'Batch code'
4		Symbol for 'Manufacture Date'	<b>STERILE EO</b>	Symbol for 'Ethylene oxide gas sterilization'
5		Symbol for 'CE marking approved by SGS'		Symbol for 'Needle type (Pencil point)'
6		Symbol for 'Needle type (Quincke bevel)'		