102 CE−7

INSTRUCTION FOR USE

(Backside Spanish / Trasera Español)

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UNIEVER DISPOSABLE SPINAL ANESTHESIA NEEDLE

CE 0120

General Information
Refer to the label on the product or package before use.

*** Symbols on the Label**

	DO NOT REUSE		DO NOT RESTERILIZE		DO NOT USE IF PACKAGE IS DAMAGED
	KEEP DRY		KEEP AWAY FROM SUNLIGHT		USE BY
STERILE EO	STERILIZED USING ETHYLENE OXIDE		CAUTION		CONSULT INSTRUCTIONS FOR USE
LOT	BATCH CODE		MANUFACTURER		DATE OF MANUFACTURE
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY				

Intended Use
** Use for anesthetics injection into the subarachnoid space, and lumbar puncture for collection of cerebrospinal fluid for testing, or injection of medical agent for treatment

Warning
(1) If strong resistance is encountered during insertion (by for example connecting with the skeletal structure), or when the stylet is removed, do NOT force insertion which can cause a bend or breakage of the needle.
(2) During puncture, advance the needle carefully. [Careless puncture may injure nerve etc.]

Contraindications and Prohibitions
(1) Do not reuse the product. Reuse of the product may cause infection.
(2) Do not re-sterilize the product.
(3) Do not use an introducer, the size of which is not compatible with this product.
(4) Do not puncture the skin that is not disinfected.
(5) In case of using an introducer together with a spinal needle, do not further advance the introducer once the spinal needle is inserted into the introducer. Also, if resistance is felt when removing the spinal needle, do NOT remove the spinal needle on its own, but remove BOTH the spinal needle and introducer together. [There is a danger that bending or breakage of the spinal needle may occur. If breakage of the spinal needle occurs, there is a risk of leaving the broken needle tip in patient's body.]

Materials
- Cannula and stylet : Stainless Steel SUS304

Instructions for Use
For General Use
(1) Check the integrity of the needle before use. Do not use the needle if it is bent or damaged.
(2) Confirm that (i) no damage on the tip of the needle, (ii) the stylet bevel is not protruded from the needle bevel (except pencil point) , (iii) the stylet moves smoothly.
(3) Disinfect the skin around the puncture site.
(4) Puncture the spinal needle to the appropriate depth with care, at the appropriate site.
(5) Remove the stylet at the appropriate position, and confirm that the needle tip reached to the sub-arachnoid space by observation of flush back of CSF (Cerebrospinal Fluid).
**(6) Rotate the needle and confirm the flush back of CSF.
**(7) Inject anesthetic agent for Spinal Anesthesia operation, or collect CSF or inject medicinal agent for Lumbar Puncture operation.
**(8) Remove the needle carefully, after the completion of Spinal Anesthesia operation or Lumbar Puncture operation.

<Important>
- At use of 26G (25G for pencil point needle) or thinner needle size, an appropriate introducer should be used to prevent bending or breaking of spinal needle at puncture.

Cautions for Use
1. Important Notes
(1) Read this INSTRUCTION FOR USE carefully prior to use.
(2) This product should be handled ONLY by persons trained and competent.
(3) When using this product, the user should be cognisant of the patient's preexisting conditions.
(4) All procedures should be conducted aseptically. Continuous precautions should be taken to avoid contact of bacteria with blood and body fluid of patients.
(5) Inspect the product carefully prior to use, and do not use the product if any abnormality is detected.
(6) Do not modify the product.
(7) When removing needle-protector, take care not to exert excessive pressure to the needle, and avoid direct contact with the needle.
(8) Stop using the product if any abnormality such as bending of the needle is encountered during use. A forced operation may cause a breakage of the needle and a fragment of the needle may remain in patient's body.
(9) Do not forcibly rotate the product after removal of the stylet. It may cause a breakage of the needle.
(10) There is a risk that the device will be bent or broken if the patient moves during a procedure. Therefore special care and consideration must be exercised when using the product on pediatric patients.
(11) Do not use the product if the integrity of the packaging is compromised in any way.
(12) Do not use the product if the package has no labeling such as expiry date.
(13) Do not use outdated product.
(14) Please use the product immediately after opening the package.
(15) After use, discard the product immediately taking account of sharps disposal procedures.

[Characteristic caution to spinal needle]
(1) Do not inject anesthetic agent without confirming CSF backflow.
(2) If blood backflow is recognized instead of CSF after removing the stylet, change the site and make the puncture again.
(3) In case where CSF backflow is not recognized, rotate the needle tip in all directions until CSF backflow is confirmed. If there is no backflow in spite of the above mentioned operation, replace the needle and try puncture at other site.

2. Interactions (Caution for Combinational Use)
(1) In case of using a syringe with the product, use the one having a nozzle conforming to EN 20594-1:1993/A: 1997 (ISO 594-1:1986 CF: 1992). Use of syringe which is non-conforming to this standard may result in the leakage of anesthetic agent.
(2) When the needle hub of the product made from polycarbonate is used in combination with an injection that contains fat emulsion or solution containing it, or a solubilizer such as oily component, surfactant or ethanol and that may be administrated continuously, it can cause breakage of the needle hub resulting in leakage.
(3) When the product is used in combination with other medical device, please read its attached package insert or INSTRUCTION FOR USE with care and use it according to instructions.

3. Defects and Adverse Events
1)Defects
In association with use of the product, the following defects may occur.
- Breakage and bend.
- Collapse and bend of the needle tip.
- Breakage of the needle hub followed by fluid leaking.

2)Adverse Events
Operator should pay attention to following adverse events that may occur depending on patient's condition, in relation with spinal anesthesia.
- PDPH (Post Dural Puncture Headache)
- Blood pressure lowering
- Respiratory Depression
- Nausea and vomiting
- Headache
- Cranial nerve palsy, spinal nerve palsy
- Meningitis
- Pain at injection site
- Blood vessel puncture
- Bleeding after puncture
- Nerve puncture
- Anaphylactic shock

Storage and Shelf Life
<Storage Method>
Store the product at room temperature keeping out of direct-sunlight, high humidity and exposure to water.
(Impact at low temperature (subfreezing) may cause crack in plastic parts (protector etc.).)
** Do not keep close to the storage of volatile chemicals or the location where the corrosive gases (sulfur dioxide, hydrogen sulfide, hydrogen chloride, etc.) might form. (There is a possibility to corrode the product.)

<Expiry Date>
Expiry date is printed on individual package (based on self-certification).

Package Unit
25 pouches per a box

Warranty
The manufacturer is not liable for any damage resulting from misuse or incorrect operation or failure to adhere to the cautions or instructions contained in this INSTRUCTION FOR USE, or the instruction manual for any compatible medical equipment.

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