DISPOSAFE
Spinal Needel (Quincke Type Point)

DEVICE DESCRIPTION:

Spinal needles are medical devices used for specific therapeutic or diagnostic medical procedures, such as delivering anaesthetic or analgesic agents intrathecally (in the space under the arachnoid membrane of the brain and spinal cord) for spinal anesthesia (total or partial loss of feeling or sensation), analgesia (absence of pain), and lumbar punctures for collecting cerebral spinal fluid (CSF).

MATERIALS USED.

Stainless Steel, Polypropylene , Polypropylene + Colorant and Epoxy Resin

INTENDED PURPOSE:

Spinal Needle is a sterile, sharp bevel-edged, hollow tubular metal instrument designed to deliver anaesthetic or analgesic agents intrathecally (in the space under the arachnoid membrane of the brain and spinal cord). It is typically fenestrated, spring-tipped, and used for short-term administration; it is typically made of metal and plastic materials. This is a single-use device.

INTENDED USER:

Any registered medical doctor, nurse, enrolled nurse, anaesthetic technician, or a student in any of those fields.

INDICATIONS:

For spinalanaesthesia hip and lower extremity surgery. Pain management during caesarean sections and natural childbirth , for daignosis.

For csf collection suspicion of meningitis. Suspicion of subarachnoid hemorrhage (sah). Suspicion of central nervous system (CNS)

INSTRUCTIONS FOR USE:

• Check the integrity of the needle before use, Do not use the needle if it is bent or damaged.
• Choose the corresponding size of spinal needle.
• Placement of this product must be done under strict aseptic conditions. Check the contents and the integrity of the product packaging.
• Position the patient and identify the insertion site. This should be below the L2 vertebra.
• Disinfect the site and apply a sterile drape.
• Infiltrate the insertion site with local anesthetic.If an introducer is not being used, insert the spinal needle between the spinous processes, then advance to the dura-mater.
• If an introducer is used, insert this a few centimeters in between the spinous processes. Pass the spinal needle through the introducer and advance to the dura-mater.
• Advance the spinal needle through the dura- mater into the subarachnoid space. As you pass through the dura-mater you will normally feel slight resistance followed by a "click" which indicates that you are in the subarachnoid space.
• After the "click", slowly remove the stylet from the spinal needle and confirm the presence of CSF. If there is no CSF reflux to indicate correct positioning in the subarachnoid space, rotate the spinal needle then aspirate if necessary to check for CSF. If there is still no CSF, remove the spinal or repeat the puncture procedure at a new site.
• When dural puncture is achieved (and confirmed by CSF reflux through the spinal needle): proceed to CSF collection if performing lumbar puncture; when performing spinal anesthesia, hold the needle firmly when attaching the syringe (to avoid changing the needle position), then inject the anesthetic.
• Withdraw the spinal needle.
• Withdraw the introducer needle (if used).
• Apply sterile material on puncture area.
• Dispose the needle and syringe according to the medical waste disposal rules.

PRECAUTIONS

• Check the integrity and functionality of the spinal needle before use. Do not use if the Unit Pack is open or damaged.
• Don't force the needle through resistance. If patient complains of pain or paresthesia during the procedure, abandon the procedure and manage the patient for same accordingly.
• Introducer needle allow for easy insertion of spinal needle and provide additional support.
• The use of this product is restricted to a qualified doctor or a paramedic.
• Do not use if the sterile pack is opened or damaged.
• Dispose after single use.
• This product is for single use only, re-use could cause infection or cross-contamination.
• Do not put the Device to Use after the Use by Date or Date of Expiry.

WARNINGS:

-In case of problem or resistance during insertion, it is advisable to remove the spinal and introducer needles simultaneously.
-Maintain strict aseptic conditions throughout the procedure.
-If there is paraesthesia in the lower limbs or pelvis the device must be removed.
-The product should be used according to the instructions for use.
- Do not use the product if the package is damaged or open Consult for instruction for use.
- The product is designed for single use only.
-If reuse it may lead to cross contamination.
-Do not expose to heat or direct sunlight.
-The use of this product is restricted to a qualified doctor or a Paramedic.
-The product should be used according to the instructions for use, read the instructions carefully before use.
-The product should not be used for experiment.
-Used product may have potential to biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state and country laws and regulations.
- Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient

PACKAGING:

The Device packed individually or with an introducer needle in PVC blister packs sealed with medical grade paper, inner carton i.e. Duplex board & Master carton .

CONTRAINDICATION:-

The recognized contraindications for spinal anesthesia and lumbar puncture must be observed.
Be Aware of:

- Sepsis.
- Sever untreated hypovolaemia.
- Skin infection at or near the puncture/ injection site.
- Blood coagulation disorders
- Severe decompensated hypovolemia.
- Shock
- Acute cerebral or spinal cord disease.
- Increased intracranial pressure
- Exisiting infection at the injection site
- Anatomical deformities of patient's back.
- Aminocentesis

STERILIZATION: Device is EO sterilized and sterilization is done by

STORAGE CONDITION:

Based on the stability study report as per ICH guidelines the recommended storage condition in between Temp 10˚C to 45˚C. In case of any tempering in the packaging, the product condition may be affected even in case store at above defined condition.

Product Sterility is valid for Five years, from the manufacturing of the product.

DISPOSAL:

Dispose off/Discard the used Device, in accordance with your country's health care law's and safety regulations.

CLINICAL BENEFITS:

Spinal needle provides an indirect clinical benefit by enabling successful penetration into the subarachnoid space facilitating lumber puncture for the injection of analgesics or anaesthetics and for collection of cerebrospinal fluid (CSF) from the spinal (vertebral) canal.

PERFORMANCE CHARACTERISTICS:

- Device is Sterile
- Pyrogen Free
- Biocompatible
- Non-Toxic
- Phthalate Free

Risk:-
The known risks of lumbar puncture and spinal anesthesia are headache, hypotension and brady-Cardia, cardiac arrest, apnoea or acute toxicity to the local anesthetic are post dural puncture symptoms.
Neurological disorder epidural haematoma or abscess formation, spinal artery syndrome, caude equina syndrome urinary retention,herniation,pain,infection,mispositioning,hypothermia,nausea and vomiting may develop while Total spinal Cerebrospinal fluid syndrome are rare but still recognized complication.
Lumber puncture and spinal anesthesia should be performed by qualified paramedic staff/doctor.
Very rare complications Hearing loss, Epidermoid tumor,retroperitoneal abscess.

SYMBOLS USED ON PRODUCT LABEL

	Do Not Reuse	LOT	Lot Number
STERILIZE	Do Not Resterilize		Date of Manufacturing
	Do not use if package is damaged and consult instruction for use.		Use By / Expiry Date
REF	Reference No.		Consult Instructions For Use
	Manufacturer		Keep dry
STERILE EO	Sterilized by Ethylene oxide Single Sterile Barrier System		Keep away from sunlight
	Non-Pyrogenic	MD	Medical Device
45°C 10°C	Temperature Limit		Caution

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