

INSTRUCTIONS FOR USE: <b>Spinal Needle</b>	
<p><b>INSTRUCTIONS FOR USE:</b></p> <ul style="list-style-type: none"> <li>- Choose the corresponding size of spinal needle.</li> <li>- Prepare patient for the procedure lying on one side or in sitting position.</li> <li>- Select the area for introduction of needle and work up the same with antiseptic solution.</li> <li>- Taking all aseptic Precautions, anaesthetize the puncture area with local anesthetic.</li> <li>- Advance the spinal needle through the dura-mater into the sub-arachnoid space</li> </ul> <p>As you pass through the dura-mater you will normally feel slight resistance followed by a "click" which indicates that you are in the sub-arachnoid space.</p> <ul style="list-style-type: none"> <li>- 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 sub arachnoid space, rotate the spinal needle then aspirate if necessary to check for CSF. If there is still no CSF, remove the spinal needle and carefully adjust the position of the introducer needle, or repeat the puncture procedure at a new site.</li> <li>- 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 anaesthesia, hold the needle firmly when attaching the syringe (to avoid changing the needle position), then inject the anaesthetic.</li> <li>- Withdraw the spinal needle.</li> <li>- Apply sterile material on puncture area.</li> <li>- Dispose the needle and syringe according to the medical waste disposal rules.</li> </ul> <p><b>WARNINGS:</b></p> <ul style="list-style-type: none"> <li>- In case of problem or resistance during insertion, it is advisable to remove the spinal and introduce needles simu-to-neously</li> <li>- Maintain strict aseptic conditions throughout the procedure</li> <li>- If there is paraesthesia in the lower limbs or pelvis the device must be removed.</li> <li>- The product should be used according to the instructions for use.</li> </ul> <p><b>MAIS INDIA DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE.</b></p> <ul style="list-style-type: none"> <li>- The product should not be reprocessed.</li> <li>- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging.</li> <li>- The product is guaranteed non-toxic, sterile &amp; non-pyrogenic if the package has not been opened or damaged.</li> <li>- Do not clean or resterilise. Discard after use.</li> </ul> <p>The product should be used immediately after opening the packaging.</p> <ul style="list-style-type: none"> <li>- Exposure to elevated temperature and ultraviolet light to be avoided.</li> <li>- Shelf life 5 years.</li> <li>- This product is for single use only.</li> <li>- Re-use could cause infection or cross- contamination.</li> </ul>	
<p><b>LOT</b> Lot No./Batch No.</p> <p><b>Manufacturer</b></p> <p><b>MD</b> Medical Device</p> <p><b>STERILE EO</b> Sterilised By Ethylene Oxide</p>	<p><b>Non-Pyrogenic</b></p> <p><b>REF</b> Catalogue Number</p> <p><b>Consult Instruction For Use</b></p> <p><b>Latex Free</b></p>

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<p><b>CONTRAINDICATIONS</b></p> <ul style="list-style-type: none"> <li>- Coagulation problems or anti-coagulation therapy</li> <li>- Lock of patient consent</li> <li>- Anatomical deformities</li> <li>- Localised infection at the puncture site, or general infection (septicaemia)</li> <li>- Hyper sensitive to local anaesthesia and/or any material used for that purpose.</li> </ul> <p>Intracranial hypertension</p> <p><b>COMPLICATIONS</b></p> <p>The known complications are those associated with spinal anaesthesia techniques: hypotension, cardiac arrest, respiratory arrest, haematoma or epidural abscess, backache, acute urine retention, headache, problems with vision and hearing, nausea, vomiting. These are rare. However these devices must only be used by qualified personnel with the necessary means available to treat these complications if necessary.</p> <p><b>CAUTION:</b></p> <p>The use of a smaller diameter will cause less CSF leakage through human dura. It is accepted that this CSF leakage is the contributing cause of the PDPH associated with spinal anaesthesia.</p> <p><b>IMPORTANT:-</b></p> <ul style="list-style-type: none"> <li>- Always introduce spinal needle with stylet.</li> <li>- 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 some accordingly.</li> </ul> <p><b>HAZARDS OF MEDISPINE REUSE:</b></p> <ul style="list-style-type: none"> <li>- Transmission of infection from one patient to other patient</li> <li>- Blunting of the bevel causes difficulty in reintroducing the needle and causes more pain.</li> <li>- Reuse causes loosening of stylet at the hub and may cause tissue coring inside needle.</li> <li>- Reuse weakens the body of the needle and may cause accidental breakage of needle inside body.</li> </ul>	
<p>Manufactured by:  <b>Mais India Medical Devices Pvt. Ltd.</b>            525-P Sector-37, Pace City-II, Gurgaon-122001, Haryana (INDIA)</p>	
<p> Do Not Reuse</p> <p> Date Of Manufacturing</p> <p> Do Not Resterilize</p> <p> Caution</p> <p> Do Not Use If Package Is Damage</p>	<p> Use By / Expiry Date</p> <p><b>EC REP</b> Authorised Representative In The European Community</p> <p> Keep Dry</p> <p> Keep Away from Sunlight</p>

REV BY	Q.A			<b>TITLE : IFU of Spinal Needle</b>  <b>For Party Code 000</b>		SHEET No. 6/6	APPROVED BY:
	Q.C					<b>DRW. No.: A15000-IFU-000</b>	
	Pro.					REV:- 00	
CHD BY	Mkt.			<b>COLOR OF PRINT:</b> Blue 293c			
DGN BY	Prahalad		DATE: 13.03.2024				
SCALE-N.T.S TOLERANCE : ±2 mm				<b>REVISION DETAILS:</b>			
<b>MAIS INDIA MEDICAL DEVICES PVT. LTD.</b> 525-P SECTOR-37, PACE CITY II, GURGAON (HR)							