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CONCENTRIC NEEDLE ELECTRODE

Instructions for Use

READ ALL PRECAUTIONS AND INSTRUCTIONS CAREFULLY PRIOR TO USE

INTENDED USE

Disposable Concentric Needle Electrodes are intended to be inserted in the subdermal, muscle or nerve tissue to sense bio-electric, electromyography (EMG) or electroencephalography (EEG) signals distally and are intended to be proximally connected to EMG / EEG recording equipment.

INDICATION

These devices are indicated to be used for the recording of EMG and EEG signals in patients undergoing clinical neurophysiological testing.

DESCRIPTION

The Concentric Needle Electrodes are sterile, single-use products which penetrate patient skin and muscle. It shall be connected to Concentric Cable for connection to neurological acquisition system. The needle electrodes must only be used with neurological acquisition systems in compliance with standard with a Type BF Amplifier Input. The Concentric Cable carries a 5 pin 240o DIN designed according to standard. The Concentric Cable can be reused up to 2000 times. The Concentric Needle Electrodes come in different needle lengths and diameters. A protective tube is ensuring protection of the needle.

PRECAUTIONS

- *Federal law (USA) restricts this device to sale by or on the order of a physician.
- Do not use the device if the sterile packaging is opened or damaged or if the use-before-date has passed.
- Inspect the device after opening in a sterile field. Discard if damaged.
- For single-patient use only. Do not reuse or re-sterilize. Cleaning and re-sterilizing the device can affect its safety, performance and effectiveness and expose patients and users to unnecessary risks such as infection and transmissible disease.
- Sterility is guaranteed up to expiration date unless package is opened or damaged.
- The device has been sterilized using ethylene oxide gas. Some patients may be allergic to residuals of this gas.

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- Do not use the device in strong electrical fields, as any induced electrical field may influence the stimulation output on the connected equipment (if applicable), may make the readings on the connected equipment unreliable and may result in localized tissue heating.
- Do not insert the device into patients all the way up to the hub. * Do not straighten or re-insert the device if it bends before, during or after insertion. Bent devices should be discarded and replaced with a new item.

WARNING

This device is not intended for use as stimulating electrode or patient ground electrode

If used as recording electrode, the possible loss of electrocautery return path may result in high current density passing through the needle, possibly resulting in tissue heating and damage.

Applying excessive force to the device may cause it to bend or break. In case the device breaks, parts may remain in the patient and need to be surgically removed.

SETUP OF THE CONCENTRIC NEEDLE ELECTRODE

- Electrode variants-0.5mm diameter-25mm,40mm & 50 mm lengths.
- Meets clinical requirements for different muscle and patient profile ranging from paediatric to adults.
- $0.07mm^2$ pickup area and cable assures noise free recordings with matching impedence.
- 3 pin or 5 pin cables gives connectivity with all machines.
- High production standards in class 100000 Clean Room facility assures reliability and safety of highest order.
- Spictra Concentric Needle Electrodes are sterilized by Eto.
- All needles are meant for single use only
- Destroy after use.

DISPOSAL METHOD

Always discard used devices in a properly marked medical biohazard sharps container.

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CONNECTION OF DEVICES

The Concentric Needle Electrode is connected to the EMG machine through EMG cable as per the custom circuit prescribed by the individual hospitals.

STERILITY

Three years from the sterilization date. Sterile if the package is not damaged.

Manufacturer Information

Medihub Sciencetec Private Limited.,

Plot no.4, NH-7, MMDA Industrial Estate, Maraimalainagar-603 209 Tamilnadu, India.

Telephone No.: 044-47400484

Website: www.spictra.com

Email: enquiry@spictra.com

Information on Symbols

	**Do not resterilize** Indicates a medical device that is not to be resterilized.		**Use-by date** Indicates the date after which the medical device is not to be used
	**Consult Instructions for Use** Indicates the need for the user to consult the instructions for use.		**Do not re-use** Indicates a medical device that is intended for one use or for use on a single patient during a single procedure.
STERILE EO	**Sterilized using ethylene oxide** Indicates a medical device that has been sterilized using ethylene oxide.	LOT	**Batch Code** Indicates the manufacturer's batch code so that the batch or lot can be identified.

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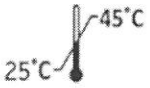
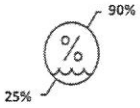
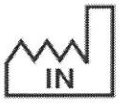
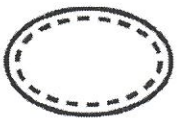
	**Temperature Limits** Indicates the limit of temperature to which the medical device can be safely exposed.		**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed
	**Date Of Manufacture along with Country of manufacture** Indicates the date when the medical device was manufactured.		**Keep away from Sunlight** Indicates a medical device that needs protection from light sources.
	**Manufacturer** **Medihub Sciencetec Private Limited.,** Plot no.4, NH-7, MMDA Industrial Estate, Maraimalainagar-603 209 Tamilnadu, India. **Telephone No.:** 044-47400484. **Website:** www.spictra.com **Email:** enquiry@spictra.com		**Caution** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	**Fluid Path** Indicates the presence of a fluid path		**Single sterile barrier system with protective packaging inside** Indicates Single sterile barrier system with protective packaging inside

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MD	**Medical Device** Indicates the item is a medical device		**Do not use if package is damaged** Indicates a medical device that should not be used if the package has been damaged or opened.
	**Non-pyrogenic** Indicates a medical device that is non-pyrogenic		**Keep dry** Indicated a medical device that needs to be protected from moisture
#	**Model number** Indicates the model number or type number of a product.		

Doc No.: SPT-IFU-CNE

Revision Date: 06.08.2026

Revision No.: 01