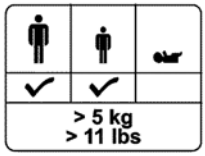
NIKO SURG




EN **NEUTRAL ELECTRODES**




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## UNIVERSAL NEUTRAL ELECTRODES

Read and save this document. Make sure, everyone who will use these neutral electrodes knows and understands all information contained in this document.

## INTENDED USE

Neutral Electrodes are designed as accessories for the use with electrosurgical generators for cutting and coagulation of human tissue.

## WARNING

- Improper use of neutral electrodes can cause patient injuries. These instructions serve patient safety. **NOT FOLLOWING THESE INSTRUCTIONS MAY LEAD TO BURNS, PRESSURE NECROSES OR OTHER SKIN TRAUMA DURING USE.**
- PRODUCT LIMITATION: These Universal Neutral Electrodes have been designed for use on adults and children in traditional monopolar electrosurgical procedures.
  Limit the activation time to maximum 90 seconds in any 3 minute interval.
  Activating beyond this limitation may overload the neutral electrode with current. This may result in a patient burn despite a fully and correctly applied neutral electrode and an activated contact quality monitoring system.
- PRODUCT LIMITATION: In non-traditional electrosurgical procedures that utilize high current, long activation time, or both (e.g. tissue ablation, tissue vaporization, or procedures in which conductive fluids are introduced into the operating field), a patient burn risk exists despite a fully and correctly applied neutral electrode and an activated contact quality monitoring system.
  For such procedures consult the generator and accessory manufacturers' instructions, in particular regarding limitations of activation time. Use additional neutral electrodes when indicated.
- Do not use the neutral electrode if it is damaged, modified or expired. Safe performance may be compromised.
- If an electrosurgical unit offers an electrode contact quality monitoring system like REM™, NESSY®, ARM™, etc., always use a split electrode. Never deactivate the auditory alarm of the contact quality monitoring system during surgery.
- Use the lowest effective safe power settings to achieve a desired surgical effect.
- Always check the neutral electrode site whenever the electrosurgical unit fails to produce the desired effect.

## CAUTION

- If used on children weighing up to 15.0 kg (33 lbs): Surgeons should be familiar with the literature on effects of electrosurgery on small patients and may wish to consider bipolar electrosurgery, which does not require a neutral electrode.
- Do not reduce size by cutting. Do not use additional gel.
- Do not reposition the neutral electrode.
- If you reposition the patient, make sure the entire surface of the neutral electrode sticks well to the skin and verify all cable connections afterwards.
- Should cutting or coagulating effect diminish during surgery, or a higher than normal power setting be requested, a problem may exist. Immediately make sure that the neutral electrode is adequately placed and in full contact with the skin. Inspect all connections of the neutral electrode i.e. clamp, cable, connector plus all active accessories and the generator before turning up power.
- Do not reuse the neutral electrode. If re-used the adhesive and the electrical properties might be insufficient, which could lead to a patient injury. In addition a risk of cross-infection exists from one patient to the other.
- Use all electrodes within 7 days after opening the pouch.

## INSTRUCTIONS FOR USE

**Placement Site Selection and Preparation:**

- Choose a muscular or well vascularized convex skin site as close to the operating field as possible, but not closer than 15 cm, on adults preferably an upper arm or thigh. Make sure the site will not bear the patient's weight during surgery or be subject to other pressure e.g. from a compression stocking. Make sure the site will not be thermally insulated or heated by a warming device during surgery.
  Avoid skin sites over metallic implants or with excessive hair, scar tissue, adipose tissue, bony prominences, injection sites, tattoos, erythema or lesions of any kind. Avoid areas where fluids may pool.
  If the patient has a cardiac pacemaker or other active implant, consult with an accordingly qualified physician on suitability of HF surgery and placement of the neutral electrode and electrosurgical cables.
- For surgical procedures where the HF current could flow through parts of the body having a relatively small cross sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- Monitoring electrodes or other devices, which may provide alternate pathway to ground for the HF current, have to be placed as far away from the operating field as possible. It is recommended to use only ECG and other monitoring cables and leads or systems incorporating HF current limiting devices, e.g. Radio Frequency (RF) suppressors or RF chokes. If this is not possible, the neutral electrode has to be placed closer to the operating field than any of these electrodes or devices. Needle monitoring electrodes are not recommended.
- Remove any hair from the chosen skin area and clean it carefully e.g. of cosmetics. Dry it thoroughly, in particular if alcohol or other skin cleaning fluids are used. Avoid using flammable skin prepping agents or disinfectants e.g. acetone degreasers. **Be aware that failure to shave may lead to skin burns.**
- Avoid skin-to-skin contact, for example between the arms and the body of the patient, e.g. by insertion of dry gauze where skin-to-skin contact would occur.
- Remove metal jewelry.

**Neutral Electrode Application:**

- If an electrosurgical unit offers an electrode contact quality monitoring system like REM™, NESSY®, ARM™, etc., always use a split electrode. A contact quality monitoring system cannot work with a standard un-split electrode and loss of safe contact between the neutral electrode and the patient will not result in an auditory alarm.
  Check the operation of the monitoring system by attempting to operate the unit without a neutral electrode connected. The unit should not activate and an alarm should sound.
- Open the pouch only prior to use and remove a neutral electrode. Check expiration date printed on pouch. Do not use if product is expired. Store any unused electrode in its original pouch. Close pouch by folding open end over one or more times to keep any remaining electrodes fresh. Use all electrodes within 7 days after opening the pouch.
- Remove one tracking sticker from pouch and place it in patient file. Document electrode location, skin preparation and condition in patient file.
- Remove electrode from protective liner by peel tab. Check the electrode and the cord / cable and connector for defects e.g. dried out or missing gel and damage of cable insulation. Do not use a defective product.
- Apply the neutral electrode to the prepped skin site starting from one end and continuing to the far side maintaining uniform pressure without stretching skin or electrode. Avoid air bubble entrapment, or skin folds forming under the electrode. Smooth firmly to ensure good contact of the entire adhesive surface to the skin.
  Do not wrap the electrode completely around a limb. The electrode must not touch or overlap itself.
- For non-corded electrodes: Check the reusable neutral electrode cable for defects. Do not use any neutral electrode cable, the metal electrode contacts of which are soiled, or which shows other defects like damaged insulation.
  Open the clamp of the neutral cable by lifting the lever. Insert the electrode's contact tab completely into the clamp. Lock clamp by fully depressing the lever.
  Make sure the entire tab is inserted in the clamp and does not come in contact with the patient's skin.
  The clamp must not lie under the patient.

- Position cord or cable in such a way that it does not peel the electrode away from the patient's skin. Position cord or cable in such a way that contact with the patient or other leads is avoided and no loops are formed. In particular do not coil or wrap cord or cable around a patient limb or other grounded objects to avoid capacitive coupling type burns.
- Check that the neutral electrode sticks well over the entire surface to the skin and that the clamp connector has been securely fastened to the electrode's contact tab. Check that the clamp does not exert unnecessary pressure on the patient's skin.
- Connect cable or cord to the electrosurgical unit following the instructions provided with the generator.
- Prior to operating the electrosurgical generator refer to its instructions for use. Pay particular attention on the limitations of output power settings and the maximum uninterrupted activation time as well as instructions for the use of neutral electrodes in procedures with high current.
- Never deactivate the auditory alarm of the contact quality monitoring system for neutral electrodes during surgery.
- If you reposition the patient, make sure the entire surface of the neutral electrode sticks well to the skin and verify all cable connections (clamp, cable, connector) afterwards.

**Neutral Electrode Removal and Disposal:**
- After use remove the electrode gently with one hand and support the underlying tissue with the other. Lift the electrode at the tab section at its base, not by the diathermy cable, and peel it off slowly. Tugging, pulling or rapid removal may cause skin trauma.
  Take extra care when skin is overly delicate, e.g. on elderly patients, diabetics, or because of prolonged specific medication e.g. steroids.
- To release the clamp, lift the lever.
- Dispose used neutral electrodes according to hospital or healthcare facility guidelines.

## COMPATIBILITY

For any compatibility questions, in particular regarding compatibility with a specific electrode contact quality monitoring system, please contact your local distributor. In any case, these Split Universal Neutral Electrodes are compatible with the dynamic contact quality monitoring systems REM™, NESSY® and ARM™.