INSTRUCTIONS FOR USE

GD-PAD PATIENT RETURN ELECTRODES

(NON-STERILE)

D7506 **D7506NC**
D7507 **D7507NC**

IMPORTANT INFORMATION - PRIOR TO USE, NOTE THE FOLLOWING:

- Carefully read all instructions in this document prior to use. Observe all contraindications, warnings and precautions noted in these instructions.
- Failure to properly follow instructions may lead to improper functioning of the device and may result in patient injury.
- In addition, read, understand, and follow the full information provided in the instructions for use for other devices intended to be used with this device.
- Keep all literature for future reference.
- By law, this device is restricted to sale by or on the order of a physician.

INTRODUCTION

The Single Use GD-Pad Patient Return Electrodes (*also known as Neutral Electrodes*) are packaged in sealed pouches in quantity of 1 electrode per pouch for corded and in quantity of 5 electrodes per pouch for non-corded.
Devices are available in following configurations.

D7506
CORDED
GD-Pad Patient Return Electrode

D7506NC
NON-CORDED
GD-Pad Patient Return Electrode

D7507
CORDED (split type)
GD-Pad Patient Return Electrode

D7507NC
NON-CORDED (split type)
GD-Pad Patient Return Electrode

Diagram above shows graphical representation of each device configuration

The Single Use GD-Pad Patient Return Electrodes are used to provide path for electrosurgical current from the patient during monopolar electrosurgical procedures. The electrode disperses the current over a wide surface area and returns it to the electrosurgical generator. Larger surface area of conductive foil covered by hydrogel greatly decreases the possibility skin burn under the device.

INTENDED USE

GD-Pad Patient Return Electrode is used to provide a path for the high frequency current removed from the patient and returned to the generator during electrosurgical procedures. Device is designed for use in traditional monopolar RF procedures as an accessory for RF electrosurgical generator (also referred to as an electrosurgical unit or ESU).

CONTRAINDICATIONS

Radiofrequency treatment is contraindicated on patients with a cardiac pacemaker, implanted defibrillator, implanted neurostimulator, or any active electrical implant.

WARNINGS

- Improper use of GD-Pad Patient Return 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 GD-Pad Patient Return Electrodes have been designed for use on adults in traditional monopolar electrosurgical procedures. Limit the activation time to maximum 90 seconds in any 3 minutes interval. Activating beyond this limitation may overload the GD-Pad Patient Return Electrodes with current. This may result in a patient burn despite a fully and correctly applied GD-Pad Patient Return Electrodes 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 GD-Pad Patient Return Electrodes 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 GD-Pad Patient Return Electrodes when indicated.
- Do not use the Return Electrode if it is damaged or modified. Product performance may be compromised. Replace before proceeding.
- If an electrosurgical unit offers an electrode contact quality monitoring system, always use a split electrode. Never deactivate the auditory alarm of the contact quality monitoring system during surgery.
- Confirm proper electrosurgical generator settings before proceeding with surgery. Consult the generator and accessory manufacturers' recommendations and technical specifications regarding minimum required size of return electrode.
- Use the lowest power settings to achieve the desired surgical effect.
- Always check the GD-Pad Patient Return Electrodes placement site whenever the electrosurgical unit fails to produce the desired effect.
- During a surgical procedure, the amount of current delivered in any given time determines the amount of heat that occurs under the return electrode. It is not possible to foresee what combination of current and duty cycle may be safely used in every situation.
- Non-traditional procedures that utilize high current, long duty cycles, or both (for example: tissue lesioning, tissue ablation, tissue vaporization, and procedures in which conductive fluids such as saline or lactated Ringer's solution are introduced into the surgical site for distention or to conduct the RF current) increase the risk of excessive heating under a fully applied return electrode to the point of injuring the patient. Use of more than one patient return electrode may help mitigate the increased risk
- Improper use of the GD-Pad Patient Return Electrodes can result in burns to patient
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.
- Use only on patients weighing more than 15 kg (33 pounds)
- This device shall be used by trained physicians only.

CAUTIONS

- Correct application and proper site selection can prevent the possible burn.
- D7507 and D7507NC split type return electrodes must be used with equipment that has an activated monitoring system.
- Check the electrode for defects, such as insufficient amounts of gel or adhesive.
- Do not cut, modify or use additional gel.
- Do not overlap.
- Do not reposition.
- Place as far as possible from ECG electrodes.
- Place ECG electrodes as far as possible from the surgical area.
- Do not apply over the area with excessive hair, adipose tissue, scar tissue, skin directly over bone or traumatized skin area of any kind.
- After initial application, avoid removing and/or reapplying GD-Pad Patient Return Electrodes to the skin site.
- Skin-to-skin contact (for example between the arms and body) should be avoided, for example by insertion of dry gauze.
- Do not use the return electrode if package seal is broken or conductive gel or adhesive are dry.
- Electrode gel should not be used with this return electrode as it will compromise return electrode performance.
- Position surgical electrode cables to avoid contact with patient or other leads.
- If the patient is repositioned, confirm that the entire surface of the electrode adheres well to the skin and verify all cable connections.
- After placement and before power delivery, run a hand over the electrode to verify that the entire surface of the electrode adhered to the patient. Avoid rolled up, peeled, curled, loose edges and corners.
- During power delivery, the patient should not be allowed to have contact with grounded metal or any other conductive surfaces.
- Do not leave a return electrode attached to the patient for longer than 24 hours.
- Do not use a return electrode beyond its expiration date.
- Do not reuse the return electrode to avoid cross-contamination and electrical burn. Device is for a single use only.
- Do not use a GD-Pad Patient Return Electrode if gel is dry or dislodged from the aluminum-foil of the GD-Pad Patient Return Electrode.
- Do not attempt to sterilize. Sterilization of this product may compromise its performance and safety.
- Whenever the failure occurred to produce the desired effect, make sure that the return electrode is in full contact with the skin site before turning up power.
- Store in a dry and cool place.
- Use all electrodes within 7 days after opening the pouch.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

Refer to the RF Generator Operator's Manual for additional cautions and warnings.

DIRECTIONS FOR USE

PLACEMENT SITE SELECTION AND PREPARATION:

- Select a well vascularized, convex area in close proximity, but not closer than 15 cm, to the outside of sterile field for the return electrode application. 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, excessive 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 return 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, shall 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 return electrode shall 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 would occur.
- Remove metal jewelry.
- Shave the chosen site, clean and dry it thoroughly if necessary.
- Special clinical circumstances may require alternate application sites. If alternate sites are necessary, ensure maximum patient-to-return-electrode contact.

GD-PAD PATIENT RETURN ELECTRODE APPLICATION:

- If an electrosurgical unit offers an electrode contact quality monitoring system, 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 return 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 return electrode connected. The unit should not activate, and an alarm should sound.
- Open the pouch only prior to use and remove a return 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 return 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 return electrode cable for defects. Do not use any return electrode cable, the metal electrode contacts of which are soiled, or which shows other defects like damaged insulation.
  Open the clamp of the return 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 return 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 return electrodes in procedures with high current.
- Never deactivate the auditory alarm of the contact quality monitoring system for return electrodes during surgery.
- If reposition the patient, make sure the entire surface of the return electrode sticks well to the skin and verify all cable connections (clamp, cable, connector) afterwards.

GD-PAD PATIENT RETURN ELECTRODE REMOVAL:

- 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.

- For non-corded electrodes - to release the clamp, lift the lever.

COMPATIBILITY

The Single Use GD-Pad Patient Return Electrodes are compatible with Diros RF Generators.
For any compatibility questions, in particular regarding compatibility with a specific electrode contact quality monitoring system, please contact your local distributor or Diros Technology Inc..

⚠ WARNING
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

STORAGE
Keep away from extreme temperature, humidity and direct sunlight. Store in a cool, dry place.

DISPOSAL
Dispose of components according to institutional protocol(s) for biohazardous products and country-specific regulations for medical devices.

THESE DEVICES ARE INTENDED FOR SINGLE USE ONLY.

PRODUCT INFORMATION DISCLOSURE
Diros Technology Inc. has exercised reasonable care in the manufacture of this product. Diros Technology Inc. excludes all warranties, whether express or implied by operation of law or otherwise, including but not limited to any implied warranties of merchantability or fitness, since handling and storage of this device by the user, as well as factors relating to the patient's diagnosis, treatment and other matters beyond Diros Technology Inc.'s direct control affect this device and the results obtained with its use. Diros Technology Inc. shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this device. Diros Technology Inc. neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with this device.
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This document has been drafted in the English language. It is also available in other languages.

LABELING SYMBOLS

The following symbols can be found on product labels:

SYMBOL	DESCRIPTION		SYMBOL	DESCRIPTION		SYMBOL	DESCRIPTION
REF	CATALOGUE NUMBER			DO NOT RE-USE			CONSULT INSTRUCTONS FOR USE
LOT	BATCH CODE			USE-BY DATE			CAUTION
QTY	QUANTITY			KEEP AWAY FROM SUNLIGHT			MANUFACTURER
GTIN	GLOBAL TRADE ITEM NUMBER			TEMPERATURE LIMIT		Rx only	CAUTION: US FEDERAL LAW RESTRICTS THIS DEVICE TO PRESCRIPTION ONLY.
MD	MEDICAL DEVICE			KEEP DRY		Latex	LATEX FREE
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		CE 2862	CE MARK – EUROPEAN COMPLIANCE SYMBOL			CONSULT INSTRUCTONS FOR USE
NON STERILE	SUPPLIED NON-STERILE.			WEEE MARKING			

CUSTOMER SUPPORT

For any questions or additional information, please contact Customer Service at:

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D7506NC	0825114DN7506NC3Q
D7507	0825114DN7507AP
D7507NC	0825114DN7507NC3V

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