

SELF ADHESIVE ELECTRODES



INDICATIONS FOR USE

- Refer to the package of your electrodes for the indications for use.
- Single patient use **ONLY**.

CONTRAINDICATIONS:

- Refer to the package of your electrodes for the contraindications.
- **DO NOT USE:**
 - With cardiac pacemakers, implanted defibrillators, or other implanted metallic or electronic devices. Such use could cause electric shock, burns, electrical interference, or death.
 - If you have suspected or diagnosed heart disease, epilepsy, cancer or have a tendency to bleed internally, without first consulting your physician.
 - Over the pregnant uterus.
 - Over or near reproductive organs (unless device is specifically designed for this).



CAUTIONS:

- Skin irritation may develop due to electrical stimulation, or electrode materials. If you experience any skin irritation or redness after a session, DO NOT continue therapy on that area of the skin.
- Keep out of reach of children.
- To avoid discomfort or burns, use appropriate size and shape of electrode.

ADVERSE REACTIONS:

- Skin irritation and burns have been reported with use of electrodes.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or conductive medium (gel).
- Long-term effects of prolonged electrical stimulation use are unknown.



WARNINGS:

- **DO NOT USE ELECTRODES UNDER THESE CONDITIONS:**
 - On open wounds or rashes, or over swollen, red, infected or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); or on top of, or in proximity to, cancerous lesions.
 - Over areas of skin that lack normal sensation.
 - On the opposite sides of your head since the effects of stimulation of the brain are unknown.

- **NEVER APPLY THE ELECTRODES TO:**






- The head or any area of the face (unless your device is specifically designed for such use).



- The neck or any area of the throat because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

SELF ADHESIVE ELECTRODES



-  Both sides of the thorax simultaneously (lateral or front and back), or across your chest because the introduction of electrical current may cause rhythm disturbances which could be lethal.
-  **DO NOT** place directly on your spine or backbone.
-  **DO NOT** place electrodes simultaneously on both calves, legs, feet, arms, etc. Treat one body part at a time.



ADDITIONAL WARNINGS:

- o Electrodes should **NOT** touch each other when placed onto your skin.
 - o Place the electrodes at least 2" apart but no more than 6" apart per channel.
 - o Pad should **NOT** touch any metal object, such as a belt buckle or necklace.
 - o Electrodes should **NOT** be placed simultaneously on the soles of both feet.
 - o Electrodes should **NOT** be placed simultaneously on the calves of both legs.
 - o Electrodes should **NOT** be placed simultaneously on both arms or hands.
 - o **DO NOT** share electrodes with another person. This may cause a skin irritation or infection. Electrodes are intended for use by one person.
 - o **DO NOT** place or relocate the electrodes while the device is on.
 - o **DO NOT** remove electrodes from treatment area until the device is turned off.
 - o **ALWAYS** turn the power off before removing or changing the pad location.
 - o **DO NOT** leave electrodes attached to the skin after treatment.
 - o **DO NOT** insert the electrode plug into any place other than the jack on the main device.
 - o **DO NOT** pull on the electrode cord during treatment.
 - o **DO NOT** bend or pull the end of the cord.
 - o When pulling out the electrode cord from the device, hold the connector and pull. **DO NOT** pull on the wire itself.
 - o The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical stimulation.
 - o Ensure **NO** residual skin lotions or conductive gels are left on the skin prior to using the electrodes as this can result in burns due to inadequate adhesion.
 - o Use this device **ONLY** with the leads, electrodes, and accessories recommended by the manufacturer.
 - o The size, shape and type of electrodes may affect the safety and effectiveness or electrical stimulation.
 - o Using electrodes that are too small or incorrectly applied could result in discomfort or skin burns.
 - o It is recommended to use the same size electrodes that are supplied with the device for replacement electrodes or recommended by your healthcare provider. Electrodes smaller than those provided may increase the chance of skin irritation or electrode burns. Electrodes larger than those provided may reduce the effect of the stimulation, which could result in a false need to increase the intensity resulting in electrode burn or shocks.
- If replacement electrodes are necessary, use only electrodes that are the same size as the electrodes provided with the device or as instructed by your healthcare provider.

SELF ADHESIVE ELECTRODES



- **NOTE: ALWAYS** use electrodes that are legally marked and sold in the United States under FDA 510(k) regulations.
- Check electrodes for any damage to wires, adhesive, etc. prior to each use. If damage is noticed, or if they no longer adhere firmly to the skin, dispose of them **IMMEDIATELY**.
- **ONLY** apply electrodes to normal, intact, clean, dry, and healthy skin.
- **DO NOT** apply electrodes over or in proximity to cancerous lesions.
- **DO NOT** drive or operate machinery while in use.
- **DO NOT** use in bath/shower, pool or sauna or while sleeping.
- **DO NOT** place hot packs/heating pads or ice/cold packs over electrodes.
- **WARNING: There is a risk that electrodes could become loose or displaced if used during exercise or excessive movement, which can result in burns or other injuries.**
 - Apply electrodes to normal, healthy, dry, clean skin (of adult patients) because it may otherwise disrupt the healing process.
 - Before applying self-adhesive electrodes, it is recommended to wash the area with mild soap and water, completely drying the treatment area before placing.
 - Clip away hair on the skin using scissors; don't use over freshly shaved skin.
 - If you experience any skin irritation or redness after a session, **DO NOT** continue stimulation in that area of the skin.
 - **DO NOT** bend or fold because the electrode may not function properly. Place the electrodes onto the plastic film and then store into the sealed package when not in use.
 - **DO NOT** apply ointment or any solvent to the electrodes or to your skin because it will disrupt the electrodes from functioning properly.
 - To avoid damage to the adhesive surface of the electrodes, put the electrodes **ONLY** on the skin or on the plastic film provided.
 - Make sure the components are connected well and the electrodes are fixed on the part of the body you wish to treat, or the therapy may not be effective.
 - **ALWAYS** place clean electrodes in accordance with your healthcare provider's instructions and/or per the device instructions for use. A general Electrode Placement Guide is available at: <https://www.richmarweb.com/education/electrode-placement-guide-for-pain-management>
 - The life of electrodes is dependent on many factors including, but not limited to, cleanliness of treatment area, oiliness of skin, amount of hair, increased sweating, storage state, etc.
 - If the electrodes are lifting or no longer stick to treatment area, they **MUST** be replaced to avoid sudden shock or possible burns on any of the applied electrodes, including the electrodes adhered correctly and completely.
 - **DO NOT** turn on the device without the electrodes being placed on the body.
 - **DO NOT** use for any other purpose except for that it is intended for.

INSTRUCTIONS FOR USE:

Read all contraindications, cautions and warnings prior to use.



WARNING: Check electrodes for any damage to wires, adhesive, etc. prior to each use. If damage is noticed, or if they no longer adhere firmly to the skin, dispose of them **IMMEDIATELY**.

Application:

1. Clean skin thoroughly prior to each application of electrodes. Electrodes do not stick well if any lotion, perfume, oil, make-up, dirt, etc. is left on skin. You may need to remove excess hair from the treatment area using scissors – **DO NOT** use over freshly shaved skin.
2. **ENSURE** device is off, then insert pin of the lead wire from device into electrode connector.
3. Remove the electrodes from the protective liner and apply firmly to the skin. Adhesion improves when electrodes reach skin temperature. **DO NOT** pull on the lead wire when removing the electrode from liner. Retain liner for storage of electrode after treatment.
4. Apply electrode to the skin according to instructions provided by device manufacturer and/or medical professional. **NEVER** apply electrodes closer than 2 inches apart and no further than 6 inches apart.
5. Turn on the device and gradually adjust output according to instructions provided by manufacturer and/or medical professional).
6. If multiple treatments are applied in the same day, electrodes should be removed between treatments, and should be repositioned so as not to reapply treatment to the same treatment area.

Removal:

1. Make sure device is turned off. Lift at the edge of electrodes and peel. **DO NOT** pull on the lead wires when removing electrodes from the storage liner or skin. You may damage the electrodes if you do so.
2. Place the electrodes on the liner and remove the lead wire by twisting and pulling at the same time.
3. Seal in storage bag provided when not in use to prevent damage to the adhesive quality.

ELECTRODE PLACEMENT GUIDE:

- Place electrodes as instructed by your health care provider or as outlined in the device User Manual. Additionally, refer to the Electrode Placement Guide: <https://www.richmar-web.com/education/electrode-placement-guide-for-pain-management>

CLEANING AND MAINTENANCE:

- **Keeping Electrodes Clean:**
 - o Ensure the device is completely turned off when removing the electrodes from the treatment area.
 - o Disconnect the electrodes from each lead wire and place on protective liner supplied with the electrodes.
 - o **DO NOT** wipe with a tissue or cloth. If the electrodes are still not sticking completely to the treatment area without any lifting, they **MUST** be replaced with new electrodes.
 - o **DO NOT** use a sponge/cloth/share object like a nail on adhesive side, **DO NOT** use detergents, chemicals or soap.

- **Maintenance:**

- o The life of electrodes is dependent on many factors including, but not limited to, cleanliness of treatment area, oiliness of skin, amount of hair, increased sweating, storage state, etc.
- o If the electrodes are lifting or no longer stick to the treatment area, they **MUST** be replaced to avoid sudden shock or possible burns on any of the applied electrodes, including the electrodes adhered correctly and completely.



WARNING

- o It is recommended to use the same size electrodes that are supplied with the device for replacement electrodes. Electrodes smaller than those provided may increase the chance of skin irritation or electrode burns. Electrodes larger than those provided may reduce the effect of stimulation, which could result in a false need to increase the intensity resulting in electrode burns or shocks.
- o If replacement electrodes are necessary, use only electrodes that are the same size as the electrodes provided with the device or as recommended by your healthcare provider.

- **Storage:**

- o After electrodes have been removed from treatment site and disconnected from lead wires, place electrodes on the plastic liner and store in a resealable package.
- o Store electrodes in a cool, dry location, out of direct sunlight.
- o **DO NOT** leave the electrodes uncovered in air as this will decrease the viscosity and performance of the product.

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