ATTACHING LEADWIRES

DRUG/POLARITY	DRUG/ACTIVE ELECTRODE	RETURN ELECTRODE
Negative	Black (Negative)	Red (Positive)
Positive	Red (Positive)	Black (Negative)

1. ⚠ **CAUTION:** Make sure current is not flowing from the iontophoresis device that is to be used before attaching leadwires.
2. Attach leadwires to the electrode according to the instructions for the iontophoresis device being used. Be sure the leadwires are connected properly for the polarity of the drug to be delivered. (See above table reference.)
3. Begin treatment following the instructions provided with the drug delivery device being used.
4. At the end of the treatment, remove and discard both electrodes.

IMPORTANT
Read and follow the instructions that came with the iontophoresis device before initiating any treatment. Ionto[4] Iontophoresis Electrodes (Buffered Iontophoresis Electrode Treatment Kit) may only be used with iontophoretic devices.

Manufactured for

Richmar®

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PROUDLY MADE IN USA

INSTRUCTIONS FOR USE

CAUTIONS & WARNINGS

- **US Federal law restricts this device to sale by, or on the order of, a physician or licensed practitioner.**
- **DO NOT** exceed recommended maximum application current.
- **DO NOT** exceed 80 mA-minutes total dosage with these electrodes.
- Before beginning treatment advise patients that iontophoretic treatment can cause skin irritation or burns.
- Avoid iontophoretic application of drugs that are known to cause adverse reactions in the patient.

NON STERILE • DISPOSABLE • NON-LATEX
NOT MADE WITH NATURAL RUBBER LATEX

BUFFERED GEL TESTED TO WITHSTAND EXTREME TEMPERATURES FOR LIMITED PERIODS OF TIME, BUT OPTIMAL STORAGE TEMPERATURE RANGE IS 41.0° TO 80.6° F (5° TO 27° C).

READ INSTRUCTION MANUAL THOROUGHLY FOR INDICATIONS FOR USE, CONTRADICTIONS, WARNINGS AND PRECAUTIONS, AND METHODS OF APPLYING ELECTRODES BEFORE USE.

INDICATIONS

INDICATIONS FOR USE
Iontophoresis is indicated for the administration of soluble salts or other drugs into the body for medical purposes.

CONTRAINDICATIONS
Iontophoresis is contradicted for patients with:
- Known adverse reactions to the application of electrical current;
- Cardiac pacemakers or other electrically sensitive implanted devices; or
- Known sensitivity to the drugs to be administered.

Iontophoresis should **NOT** *be applied:*
- Over damaged skin or recent scar tissue;
- Across the thoracic region;
- Transcranially (across the brain); or
- In the orbital region.

WARNINGS AND PRECAUTIONS

- In order to provide continuous delivery of ions, iontophoresis delivery devices utilize direct current (DC). This type of current may produce chemical changes under the electrodes. Observe closely during treatment for any skin reaction and advise patient to report any irregular sensation of pain or burning.
- **DO NOT** use electrodes that have been altered or damaged in any way.
- Avoid applying the electrodes over hair follicles or nevi. **DO NOT** shave the application areas - if necessary, clip the hair. A nevus may be covered with a non conductive material such as wax before applying the electrodes if placement is crucial.
- Before giving an iontophoresis treatment, determine if iontophoresis is contraindicated for that patient.
- Before giving an iontophoresis treatment, the patient should be advised of the potential for skin irritation or burns. An area of transient erythema, characterized by a uniform red pattern, can occur directly under one or both electrodes. The redness usually disappears within eight hours. Occasionally burns may occur due to an unusually high current density caused by exceeding the recommended current settings or by skin defects, which create channels of low resistance that tend to carry the most of the current.
- The current settings should never exceed the patient comfort level or the recommended maximum current setting. Advise the patient to report any undue sensation of pain or burning.
- **DO NOT** allow any metal or black parts of the electrode to come into contact with the skin.
- On patients with known skin allergies, use lower current settings than those settings recommended for general use. Observe closely for signs of skin reaction and if blistering of the skin occurs, discontinue use and consult the prescribing physician.
- These electrodes are for single use application only. Discard immediately after use.
- Iontophoresis electrodes are designed for use with iontophoresis devices only. **DO NOT** use for any other purpose.
- Shelf life is two years from date of manufacture.
- Due to the high conductivity characteristics of silver/silver chloride (Ag/Ag Cl), **DO NOT** exceed 80 mA-min.

WARNINGS AND PRECAUTIONS (CONTINUED)

- Keep out of reach of children
- **DO NOT** apply electrodes where the current pathway crosses the heart or brain.
- **DO NOT** use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- **DO NOT** wear electrode during Magnetic Resonance Imaging (MRI) scans as this may result in metal overheating and cause skin burns in the area of the electrode.
- **DO NOT** remove the electrodes from the patient before terminating the current source.
- It is **NOT** recommended that electrodes be applied to any areas that have been treated with pain-relief gels or creams within the last 24 hours prior to iontophoresis treatment.
- Advise patient to remove all jewelry around the treatment area. **DO NOT** allow any metals to come in contact with the electrodes during treatment.

DOSAGE SPECIFICATIONS

SIZE	FILL VOLUME	MAXIMUM CURRENT MAXIMUM DOSE
Small	1.5 cc	4.0 mA 80 mA-min
Medium	2.5 cc	4.0 mA 80 mA-min
Large	4.0 cc	4.0 mA 80 mA-min
Butterfly	2.0 cc	4.0 mA 80 mA-min

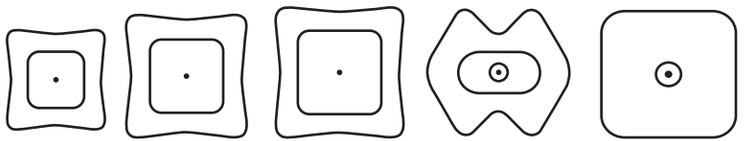
One pack contains:

- One Active Drug Delivery Electrode
- Buffered Return Electrode
- Two alcohol Swabs

THESE ITEMS ARE NOT REUSABLE.

ACTIVE DRUG DELIVERY ELECTRODES

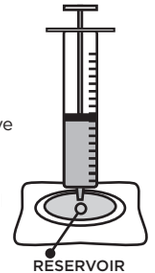
RETURN ELECTRODE



Small Medium Large Butterfly

INSTRUCTIONS FOR TREATMENT

Read the instructions, contraindications and precautions before starting treatment.



RESERVOIR

DRUG DELIVERY ELECTRODE

1. Inspect and thoroughly clean the treatment site before applying electrode. Ensure skin is intact and use one of the two alcohol prep pads provided. Failure to clean the skin thoroughly may cause excessive skin irritation or burns.
2. Mix the appropriate drug solution as prescribed by the physician.
3. Using an appropriately marked syringe, draw up the solutions required to fill the electrode as indicated below.
4. To fill, do not remove the drug delivery electrode from the protective liner. Hold the reservoir side in the palm of your hand. Using a syringe, empty contents into the pad fill hole. Completely saturate the entire surface of the reservoir pad while keeping it level (see graphic above). Fill at a moderate rate, being careful not to spill solution on the adhesive border of the electrode. Check for and eliminate any dry spots or air pockets by applying a slight circular pressure to the reservoir with the blunt tip of the syringe. If necessary add more solution to the pad to ensure it is completely saturated. Amount to fully saturate the electrode may vary slightly. Do not oversaturate.
5. Remove the filled drug delivery electrode from the protective liner.
6. Position the drug delivery electrode directly over the treatment site. Secure the electrode to the skin by pressing around the adhesive border of the foam until a good seal is made. Do not press on the reservoir pad as this may lead to leakage of the solution.

RETURN ELECTRODE

7. Inspect and thoroughly clean the site before applying the return electrode. Use the remaining alcohol prep pad provided. Failure to clean the skin thoroughly may cause excessive skin irritation or burns.
8. Remove the return electrode from its protective liner and apply the electrode over a major muscle at least 4 inches away from the drug delivery electrode site, on the same side of the body. Avoid placing the return electrode over any bony areas that have little tissue thickness.

Ionto4 Electrodes are constructed with silver/silver chloride.

⚠ Due to the high conductivity characteristics of silver/silver chloride (Ag/Ag Cl), **DO NOT** exceed 80 mA-min. Ensure the phoresor is set accordingly.

See the following treatment setup example: 4.0 mA x 20 minutes = 80 mA-min.