



Buffered Iontophoresis Drug Delivery Electrode

Instructions For Use

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR
ON THE ORDER OF A PHYSICIAN.

CAUTION

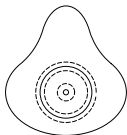
- Do not exceed **80 mA-minutes** per single treatment.
- Failure to follow these instructions can cause skin irritation and/or burns.

NON STERILE • SINGLE USE ONLY • STORE AT ROOM TEMPERATURE

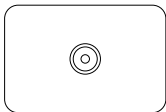
For comments or questions, call
800-680-5520
Email: admin@ActivaTekinc.com

EACH TREATMENT POUCH CONTAINS

- One drug electrode
- One ground electrode
- One alcohol wipe



Drug Electrode

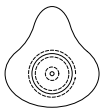


Ground Electrode

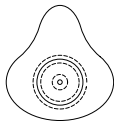


Alcohol Wipe

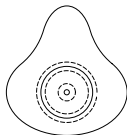
The active electrode is designed for optimum buffering. Both electrodes are latex free and manufactured of biocompatible materials:



Small 1.5cc



Medium 2.0 cc



Large 3.5cc

INDICATIONS

The Trivariation Electrode is indicated for the administration of soluble salts or other medicaments into the body for medical purposes as an alternative to hypodermic injection.

CONTRA INDICATIONS

Iontophoresis is contra indicated for patients with:

- Cardiac pacemakers or other electrically sensitive implanted devices.
- Known sensitivity to the drugs to be administered.
- Known adverse reactions to the application of electrical current.
- **DO NOT** use on damaged skin or recent scar tissue.
- **DO NOT** use across the temporal regions or for the treatment of the orbital region.

WARNING AND PRECAUTIONS

- Prior to iontophoretic treatment, determine if iontophoresis is contra indicated for the patient. Consult the package insert accompanying the drug to be administered for indications, contra indication and warnings. **DO NOT** use the treatment on a patient who has known allergies to current or the drug being administered.
- **DO NOT USE** if electrodes appear to have been altered or damaged in any way.
- **AVOID** applying electrodes over hair follicles or nevi. **DO NOT** shave the application site area. If necessary clip the hair.
- **DO NOT** apply electrodes to damaged skin, pimples, or recently healed tissues (scars).
- **DO NOT** use iontophoresis in the presence of flammable gases (i.e. Oxygen, Anesthetic)

WARNING AND PRECAUTIONS (CONTINUED)

- Prior to administering an iontophoretic treatment, the patient should be advised of the potential for skin irritation or burns. An area of erythema, characterized by a uniform red pattern, can occur under the ground and active electrodes. The redness should resolve within a few hours to a day. **ADVISE** the patient to immediately report any burning or discomfort sensations.
- The iontophoretic dose controller current setting should **NEVER** exceed the patient comfort level or the recommended maximum current setting.
- **ADVISE PATIENT** to remove all jewelry around the treatment area. **DO NOT** allow any metals to come into contact with the electrodes during treatment.
- **DO NOT** remove the electrodes from the patient before terminating the current source.
- **DO NOT** get electrodes wet as this may cause the electrodes to short.
- **DO NOT** re-use electrodes (active and dispersion) after single use. Discard immediately after each treatment.
- **DO NOT** use drug suspensions.

INSTRUCTIONS FOR TREATMENT

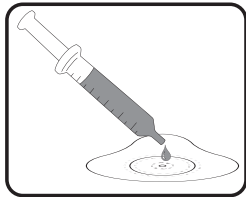
IMPORTANT: Read and follow the instruction manual that came with the iontophoresis device you are using before initiating any treatment. Trivariation drug delivery electrodes must be used with FDA Cleared Constant Current Iontophoresis Devices.

1. Remove contents from pouch; 1 Active Electrode; 1 Ground Electrode; 1 Alcohol Wipe.
2. Cleanse the skin on both sites where the electrodes are to be placed thoroughly with the alcohol wipe.
3. With a marked syringe draw the appropriate drug volume to hydrate the drug delivery electrode.
4. Turn over the electrode with the drug delivery matrix facing up. Hydrate the drug matrix with the required dosage (Small: 1.5cc, Medium 2.0cc; Large 3.5cc)

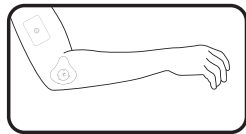
5. **DO NOT** under or over fill the drug delivery matrix (drug reservoir).

NOTE: make sure that there are no dry spots visible. If dry spot are visible touch them up lightly with the tip of the syringe until the dry spots are gone (do not overfill).

6. Remove the liner and place directly on the treatment area. **DO NOT** compress the electrode specifically on the drug matrix.



7. Place the ground electrode on a major muscle 4 - 6 in. away from the active electrode.



INSTRUCTIONS FOR TREATMENT (CONTINUED)

8. Hook up the leadwires to the electrodes with the appropriate polarity:

NOTE: Make sure that the dose controller is turned off before attaching the lead wire.

Drug/Polarity	Drug Electrode	Ground Electrode
Negative	Black (Negative)	Red (Positive)
Positive	Red (Positive)	Black (Negative)

9. To begin treatment, set iontophoresis unit to deliver recommended total charge (dose). For example:

Recommended Total Charge	Current	Time (in Minutes)
40 mA-Min	1 mA	40
40 mA-Min	2 mA	20
40 mA-Min	3 mA	13.5
40 mA-Min	4 mA	10

10. When treatment terminates make sure that the unit is off before removing the electrodes.



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