## INSTRUCTIONS FOR TREATMENT:

**IMPORTANT:** Read and follow the instruction manual that came with the iontophoresis device you are using before initiating any treatment. Trivarion Butterfly drug delivery electrodes must be used with FDA Cleared Consent Current lontophoresis 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 (Medium 2.0cc).
- 5. DO NOT under or overfill the drug delivery matrix (drug reservoir).

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

- **6.** Remove the liner and place directly on the treatment area. **DO NOT** compress the electrode specifically on reservoir area, or solution may leak
- 7. Place the ground electrode on a major muscle 4 to 6 inches away from the active electrode.

# INSTRUCTIONS FOR TREATMENT (CONTINUED)

**8.** Attach 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

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



#### ActivaTek Inc.

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# **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

Comments? Questions? Call 800-680-5520 Email:admin@activatekinc.com

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# **EACH TREATMENT POUCH CONTAINS**

- 1- One drug electrode
- 2- One ground electrode
- 3- One alcohol wipe









Ground Electrode

Alcohol Wipe

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



Medium 2.0 cc

## INDICATIONS:

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

# **CONTRAINDICATIONS:**

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.

## WARNINGS 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 gasses (i.e. Oxygen, Anesthetic).

# WARNINGS 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.
- 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.

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