

INSTRUCTIONS FOR TREATMENT

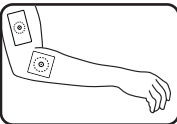
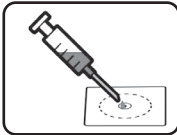
IMPORTANT: Read and follow the instruction manual that came with the iontophoresis device you are using before initiating any treatment. Ionto⁴ Iontophoresis Electrodes must be used with FDA cleared, constant current iontophoresis devices.

1. Remove contents from pouch: one active electrode; one ground electrode; one alcohol wipe.
2. Clean 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: 2.5cc, Large: 4.0cc, Butterfly: 2.0cc).
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 spots are visible, touch up lightly with the tip of the syringe until the dry spots are gone.

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" (10-15 cm) away from the active electrode.



INSTRUCTIONS FOR TREATMENT (CONTINUED):

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

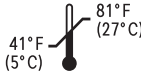
NOTE: Make sure that the dose controller is turned off before attaching the lead wire.

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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ionto⁴

DRUG-DELIVERY IONTOPHORESIS ELECTRODE TREATMENT KIT

INSTRUCTIONS FOR USE

CAUTION:

Federal Law (USA) restricts this device to sale by or on the order of a Physician.

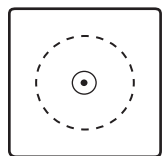
DO NOT exceed 80 mAmp.min
DOSAGE PER SINGLE TREATMENT.

Failure to follow these instructions can result in skin irritation and/or burns.

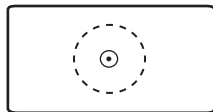
Single Use Only • Disposable • Non Sterile
Do not expose to temperatures above 125°F or (50°C)
Store at room temperature

EACH TREATMENT POUCH CONTAINS:

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



Drug Electrode



Ground Electrode

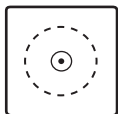


Alcohol Wipe

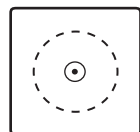
The active electrode is designed for optimum buffering.
Both electrodes are not manufactured with natural rubber latex.
Manufactured with bio-compatible materials



Small 1.5cc



Medium 2.5cc



Large 4.0cc



Butterfly 2.0cc

INDICATIONS:

The Ionto⁴ Iontophoresis Electrode is indicated for the administration of soluble salts or other medications into the body for medical purposes as an alternative to hypodermic injection.

CONTRAINDICATIONS:

Iontophoresis is contraindicated 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 treatment of the orbital (eye) region.

WARNINGS AND PRECAUTIONS:

MODALITY TREATMENTS: Iontophoresis is not recommended for use post treatment with modalities such as Ultrasound/Phonophoresis.

HISTAMINE REACTIONS: Patients treated with Iontophoresis should be advised the proper treatment for any histamine reaction which may occur. Avoid scratching the surface. Reactions typically disappear within 24 hours.

WARNING: Potential systemic adverse effects may result from use of this device. Drugs or solutions delivered with this device have the potential to reach the blood stream and cause systemic effects. Carefully read all labeling of the drug or solution used with this device to understand all potential adverse effects and to ensure appropriate dosing information. If systemic manifestations occur, refer to the drug or solution labeling for appropriate action.

1. Prior to iontophoretic treatment, determine if iontophoresis is contraindicated for the patient. Consult the package insert accompanying the drug to be administered for indications, contraindications and warnings.
2. **DO NOT** use the treatment on a patient who has known allergies to current or drug being administered.
3. **DO NOT** use if electrodes appear to have been altered or damaged in any way.

WARNINGS AND PRECAUTIONS (CONTINUED):

4. **AVOID** applying electrodes over hair follicles or moles. **DO NOT** shave application area. If necessary, clip hair.
5. **DO NOT** apply electrodes to damaged skin, open wounds, pimples, or recently healed tissues (scars).
6. **DO NOT** use iontophoresis in the presence of flammable gases (i.e: oxygen, anesthetic).
7. Prior to 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/or active electrodes. The redness should resolve within a few hours to a day. **ADVISE** the patient to immediately report any burning or discomfort.
8. Avoid leaning against or applying pressure to patches while the product is in use. Do not bind, tape, or compress the electrode.
9. Iontophoresis patches should not be applied to weight bearing areas.
10. The iontophoretic dose controller current setting should **NEVER** exceed the patient comfort level or the recommended maximum current setting.
11. **ADVISE PATIENT** to remove all jewelry around the treatment area.
12. **DO NOT** allow any metals to come into contact with the electrodes during treatment.
13. **DO NOT** remove the electrodes from the patient before terminating the current source.
14. **DO NOT** get electrodes wet as this may cause the electrodes to short.
15. **DO NOT** re-use electrodes (active and dispersion) after single use. Discard immediately after each treatment.
16. **DO NOT** use drug suspensions.
17. It is **NOT** recommended that electrodes be applied to any areas that have been treated with gels, creams, or oils within the last 24 hours prior to iontophoretic treatment.
18. **DO NOT** bind, tape or compress the electrode.
19. It is recommended that no modalities are performed prior to an iontophoresis treatment such as Ultrasound/Phonophoresis.