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MERIDIAN™

IONTOPHORETIC DRUG DELIVERY ELECTRODE

The Meridian™ drug delivery electrode is designed for convenient iontophoresing of ionic compounds that are labeled for iontophoretic delivery as an alternative to hypodermic injection. This electrode is designed to be used with any FDA-market cleared iontophoretic stimulator, such as the Life-Tech Microphor® model 6111PM/DX.

FEATURES:

- **A see-through plastic chamber:**
Allows a clear view for easy inspection of the contents.
- **A unique circular shape:**
Leaves the area inside the circle untouched by the ionic solution.
- **Constructed from a rigid plastic, three-sided chamber:**
The chamber becomes closed when attached to the patient's skin.
- **Easy to fill:**
Two tubes attached to ports on the chamber, one for filling and the other for overflow, minimize air bubbles as the soluble salt or drug solution of interest is introduced using a syringe.

DETAILED DESCRIPTION:

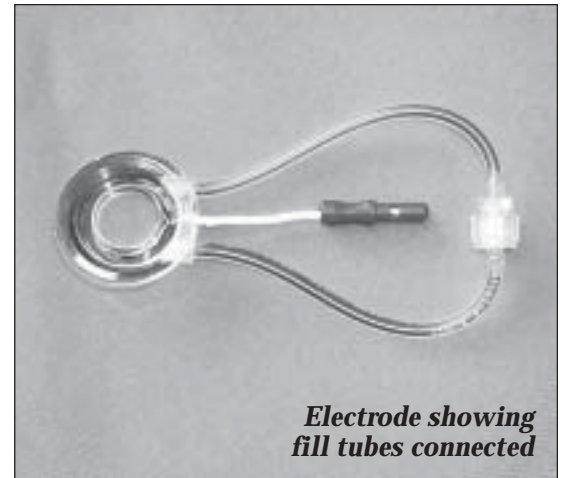
A hold-down bracket with a Velcro® strap can be used to keep the electrode in place. After the electrode is placed open-side down on the patient's skin, a syringe filled with a soluble salt or drug solution of interest is inserted into a fill tube that leads to a port on the circular chamber. The solution is then introduced into the chamber via the fill tube. An overflow tube, affixed to the other port, allows the excess liquid to fill

the chamber, minimizing air bubbles. Lastly, the technician closes the fill tubes. In this way, the soluble salt or drug solution comes in direct contact with both the patient's skin and the stainless steel contact, which is attached to a standard lead connector for use with any one of a number of FDA-approved iontophoretic current generators.

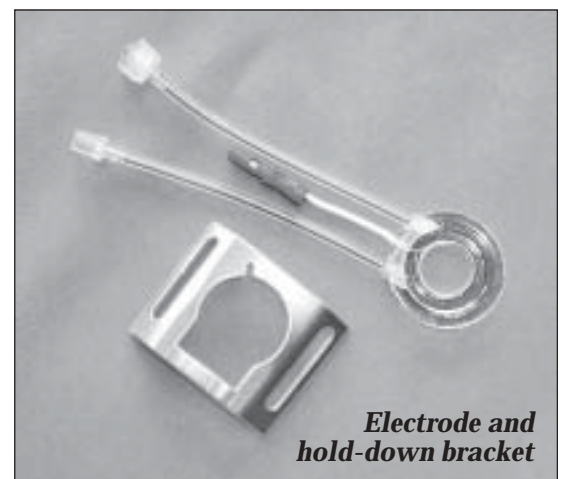
When the current is turned on according to the instructions provided by the maker of the iontophoretic stimulator and according to the maker of the drug, the drug ions are transferred into the skin according to conventional iontophoretic theory.

It should be noted that the physician is responsible for determining which drugs to iontophorese and for ensuring that the drug is used according to its labeling. The physician is also responsible for determining that the drug is suitable for iontophoresis with the iontophoretic drug delivery electrode. This device acts simply as an active iontophoretic reservoir.

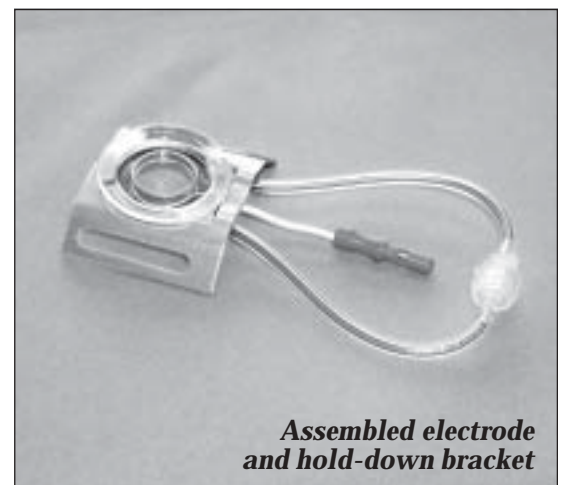
When iontophoresis is finished, the capsule is removed and the excess liquid material on the skin is wiped away with a paper towel.



Electrode showing fill tubes connected



Electrode and hold-down bracket



Assembled electrode and hold-down bracket

— Continued on reverse

SPECIFICATIONS

- Capacity: 1.14 cc
- Delivery surface area: 2.25 sq. cm.
- Made from biocompatible PETG material

INDICATIONS FOR USE

This device is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes. (CFR 890.5525b / Class III)

CONTRAINDICATIONS

Iontophoresis is contraindicated for patients with known adverse reactions to the application of electrical current; cardiac pacemakers or other electrically sensitive implant devices; and known sensitivity to the drugs being administered.

WARNINGS AND CAUTIONS

DANGER:

- During iontophoresis, electrical discharges are possible that could ignite flammable material or vapors.
- Do not use this Iontophoretic Electrode with current over 2.0 mA.
- Do not conduct this test on fragile skin.
- Do not use electrodes that have been altered or damaged in any way.

- Before giving an iontophoresis treatment, determine if iontophoresis is contraindicated for the patient.
- Before giving an iontophoresis treatment, consult the package insert for the drug to be administered for indications, contraindications, and warnings.
- Iontophoresis can cause skin irritation or burns and the patient should be advised of this potential before treatment. It is not uncommon for an area of transient erythema to occur directly under one or both electrodes. It has a uniform red pattern that will usually disappear within 8 hours. Occasionally burns may occur due to an unusually high current density caused by exceeding the recommended current settings or defects in the skin which create channels of low resistance which tend to carry most of that current.
- The current setting should not exceed a comfortable level for the patient and should never exceed the recommended current setting.
- Advise the patient to report any undue sensation of pain or burning.
- Do not allow any metal or current-carrying parts to come into direct contact with the skin, except for the active and return iontophoretic electrodes. Make sure that all wires and contacts are insulated from the skin.
- Patients with known skin allergies should use lower current settings than those recommended for general use. Observe the skin for signs of allergic reaction.
- The entire electrode must be affixed flat and snugly to the skin to ensure that all parts of the face of the electrode which are designed to touch the skin are in fact touching the skin. Do not affix to curved parts of the body which cannot conform to the flat face of the electrode.
- Read and understand the indications, contraindications, warnings, cautions, and instructions for use provided with the iontophoretic stimulator that you choose to use with this drug delivery electrode. Also read and understand the indications, contraindications, warnings, cautions, and instructions for use provided with the ionic solution that you choose to use.
- Electrodes are designed for single use only.
- This device is restricted to sale by or on the order of a physician.

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