



English

Disposable PressOn™ Electrode

Intended Applications

EEG [Electroencephalography], EP [Evoked Potentials], or as a Ground or Reference in an EEG or EP recording.

Intended Use

The PressOn™ Electrode is intended for use in the recording of the Electroencephalogram [EEG], Evoked Potential [EP], or as a Ground and Reference in an EEG or EP recording.

Caution

Federal [USA] law restricts this device to sale by or on the order of a physician and it should only be used in compliance with accepted industry standards. RhythmLink International, LLC is not responsible for injury, infection or other damage resulting from the use or misuse of this product. Product is sterile unless packaging is opened or damaged.

General Information

- PressOn electrodes are supplied sterile, intended for single patient use and are disposable.
- The PressOn EEG leads can be connected to any commercially available EEG equipment.
- PressOn electrodes should only be used by trained or skilled personnel under the direction of a physician.
- PressOn electrodes are approved for prolonged usage.
- Follow hospital guidelines for application and dispensing of the PressOn electrodes.



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STERILE EO

Rx Only



Reuse of this device may cause cross contamination and has NOT been validated for multiple uses.

Re-sterilization of this device may cause unknown malfunctions. EO re-sterilization has not been validated for this device and may contribute to excessive EO gas residuals.

To view a list of symbol definitions found on packaging and instructions for use, please visit Rhythmink.com/symbols.

Rhythmink® is a registered trademark of RhythmLink International, LLC.

Warnings

- Electrodes are only approved for recording.
- Electrodes should be applied only to normal healthy skin.
- The skin, shape and type of electrodes may affect the safety and effectiveness of electrical recording.
- The electrical performance characteristics of electrodes may affect the safety and effectiveness of electrical recording.
- You should contact the manufacturer of the electrical recording device if you do not know if the electrodes can be used with the recording device.

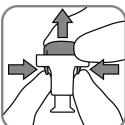
Precautions

- The long term effects of cutaneous electrodes for electrical recordings are unknown.
- Keep electrodes out of the reach of children.
- Use caution if electrodes are applied over areas of skin that lack normal sensation.

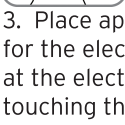
Instructions for Use



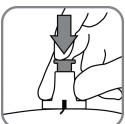
1. Open the PressOn electrode's sterile pouch and remove the electrode applicator from the pouch. One electrode is contained within each applicator.



2. Using your thumb and index finger, press tabs that secure the applicator's cap and pull the cap upward to remove. PressOn electrode is visible and ready to be launched. Discard the cap.



3. Place applicator, electrode end down, onto the site chosen for the electrode's placement. If necessary, part patient's hair at the electrode placement site to ensure the PressOn is touching the skin prior to launch. The applicator should be oriented so that the electrode end is resting on the skin so the applicator's plunger is facing up.



4. Using two fingers on the finger pads of the applicator, press the plunger downward toward the skin with light to moderate pressure to launch the electrode. When the plunger is completely depressed the electrode is deployed. If properly launched the teeth should be equally embedded under the skin. Discard the electrode applicator.

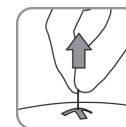


5. If any teeth did not properly engage the skin, remove the electrode [see step 9], discard it and insert a new electrode.

6. Connect the electrode to commercial EEG equipment per manufacturer's instructions.

7. Dispose of PressOn applicator according to standard biomaterial handling protocols.

8. During prolonged monitoring, check the electrode insertion site regularly for signs of infection, reddening or discharge. Replace electrode as needed.



9. To remove a PressOn electrode, grasp the electrode's wire within 1-2 centimeters of the electrode site, then pull quickly upward away from the skin. Pull in a direction perpendicular to the skin until the electrode pulls free. Discard all used electrodes per hospital guidelines.

10. Minor capillary bleeding may be present once an electrode has been removed. Should this occur, press a sterile cotton pad on the site and hold until bleeding has stopped.

11. Dispose of electrodes in a medical sharps container according to standard biomaterial handling protocols.