



KevMedTM

Living beyond the painTM

Medical Provider Information

Indications for Use

PainShield[®] MD diathermy device is a micro-processor-controlled therapeutic ultrasound device that generates deep heat within body tissues by producing low-frequency, low-intensity ultrasonic waves for the treatment of select medical conditions such as pain, muscle spasms, and joint contractures.

The ultrasonic waves are generated by a unique transducer incorporated into a treatment patch. The treatment patch should be placed on intact skin at the desired treatment area or adjacent to it. For maximal effectiveness, ensure that the ultrasonic transducer is in full contact with the skin.

Contraindications

- Do not use in patients with cancer and bone metastases.
- Do not apply over bone growth centers until bone growth is complete.
- Do not apply directly on the eye.
- Do not apply directly over ischemic tissues in individuals with vascular disease.
- Do not use in patients who are pregnant, over the uterus.

Precautions

- Do not place treatment patch directly on an open wound.
- In children, it is preferable to avoid usage over the epiphyseal growth plate area.
- Use with caution following a laminectomy when major tissue removal has occurred.
- Use with caution over anesthetic areas or areas of impaired skin sensitivity.
- Use with caution when hemorrhagic diathesis is present.

- The safety and effectiveness of this device in pregnant women or children has not been established.
- The safety and effectiveness of PainShield MD has not been established in patients who are being treated by, or who have received, other medical devices including but not limited to pacemakers, electrical stimulators, radiofrequency generators, surgical meshes, Intra-Uterine Devices (IUDs), or other surgical implants.
- Treatment of children should be performed under adult supervision.
- Following treatment, some redness might occur in the treated area. The redness should resolve naturally within a few hours. If the redness persists, or if you experience a rash, itching, pain, swelling or any other abnormality, immediately stop using the device and consult with your medical professional.
- Use with caution in patients who have experienced adverse reactions to other forms of ultrasound.
- The PainShield MD parts are not waterproof. Do not expose them to water or any other liquid.
- The device contains lithium-ion batteries. Do not discard as typical waste. Do not hold the device near water or fire sources.
- For further explanations on symbols, icons and storage instructions, please refer to the PainShield MD User Manual.

Caution: Federal law restricts this device to sale by or on the order of a physician or physical therapist licensed by the law of the State in which that person practices.



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