

Single Patient Use

300
HR

PAiNMASTER[®] **Micro Current Therapy** (M.E.N.S)

ACTIVATE HEALING - NO SENSATIONS

Directions For Use

Specifically Recommended For:

- »» **Back Pain**
- »» **Muscular Aches and Pains**
- »» **Continuous and Occasional Pain**

About the Micro Current Therapy Patch


Thank you for purchasing the Painmaster Micro Current Therapy Patch. You have taken a positive step toward reducing your pain without the use of drugs.

The use of low-level electrical stimulation for pain relief is not a new treatment. It has been used for years by athletic trainers and physical therapists to relieve pain from injuries and chronic muscle and skeletal discomfort. Those treatments are administered in an office using large machines.

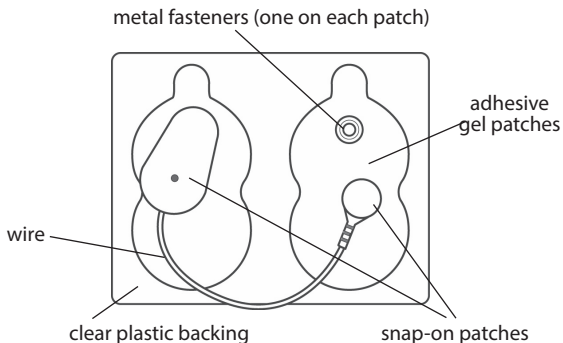
What is new is the Painmaster MCT innovative patch system, which delivers 24-hour-a-day relief using electronic patches worn under your clothing, unseen by others.

The patches look like the electrode used in a doctor's office for administering electrocardiograms. They are applied and removed just as effortlessly.

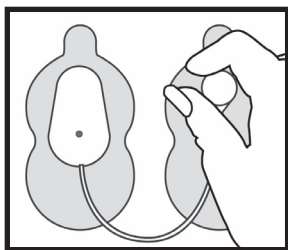
After placing the patches on either side of a painful or aching area, a very small amount of electrical current flows through the pain center to the other patch. A small blinking red light on one patch shows the patch is working. The patch typically is effective for 300 hours of use.

 Remember, pain can be a symptom of physical illness or injury. Consult a physician for medical advice. This product is a non-medical method for treating pain and should never be used in place of seeing a doctor.

Product Diagram



Snap-on/Snap-off patch circuit can be reused.



Always place patches on clear plastic backing and unclip wires when not in use to conserve the battery.

Safety Information



- Caution: This product should never be used by:**
- Anyone using cardiac pacemakers.
 - On or near transdermal drug delivery patches.
 - Anyone under the age of 12 unless under the continued supervision of a physician.

Please Also Note:

- Do not place the patches along the neck region (carotid sinus).
- Do not place patches in a way that causes the flow of current through the head (transcerebrally).
- The safety of this unit during pregnancy has not been established.
- Electronic monitoring equipment such as ECG monitors and ECG alarms may not operate properly when the device is in use.
- This device is to be removed during any high frequency procedure.

In addition, the Micro Current Therapy Patch...

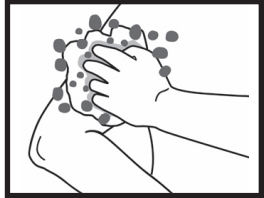
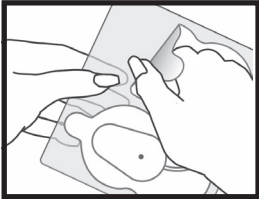
- Is for external use only.
- Should not be placed over an open wound.
- Should be kept out of reach of children.
- Use should be discontinued for a day if a rash appears.
- Should only be used by one person.
- Use should be limited to no more than three sets of patches at one time.

Disposal Information

This product does not contain any environmentally hazardous substances and can be disposed of normally. The battery used in this device should not be mistreated. Do not recharge, disassemble or dispose of in a fire.

Treatment Information

Preparation of skin - Clip excess hair from painful area. Wash area with soap and water and dry completely.



Remove the patches from the clear plastic backing. Save the backing for storing the patches after use or in between treatments.

Placing the patches - Patches should be placed above and below or on either side of the painful area. See Fig. 1. Leave slack in the wire to allow for comfortable movement. Place patch and hold in place for 10 seconds. The blinking red light means treatment is occurring.

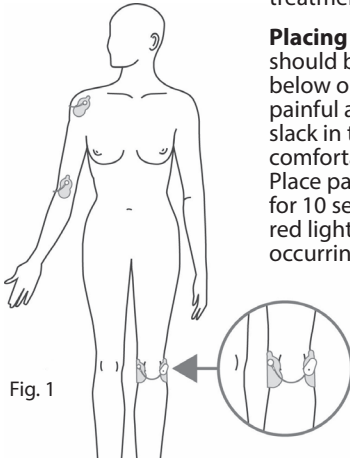
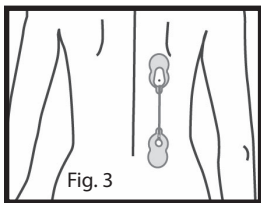
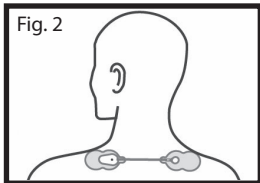


Fig. 1

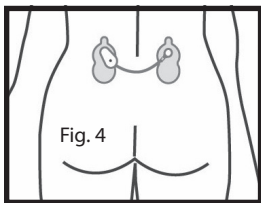
Directions for Placement

Painful tension in the neck and shoulders. Attach patches in accordance with *Fig. 2* over the hard tender spots on both sides

Painful tension in the neck and shoulders.

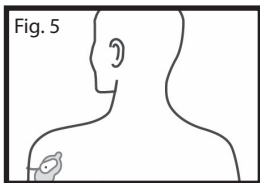


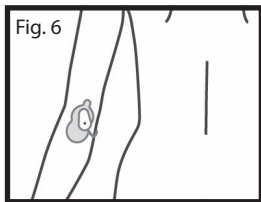
Neck and lower back pain. Apply the patches in the mid-line in accordance with *Fig. 3* (directly along the spinal column) or, in the case of intense one-sided symptoms, next to it on the adjacent muscles, POSITION THE PATCH ABOVE AND BELOW THE PAINFUL AREA.



Sciatica. Apply left and right of the sacrum.

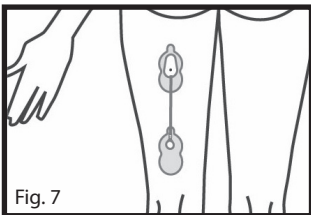
Nerve pain in the buttocks and legs. Position the patches on both sides of the sacrum margins (two visible dimples) in accordance with *Fig. 4*. Pain in the knee or shoulder Joint. Attach patches on both sides of the joint as shown in *Fig. 5* and *Fig. 1* (see page 5).





Tennis elbow - Use the patches as shown in *Fig 6*.

Muscle Strain - Apply patches in a longitudinal direction of the limb above and below the affected area as shown in *Fig. 7*



All over Body Pain Sufferers

Apply the patches across the area of the most severe pain. It is suggested that the patches be kept in the same area for 72 continuous hours and removed only for showering and bathing. Users have reported only slight improvements in the first day and dramatic results by the third day.

Joint Pain Sufferers

Place the patches across the joint area in *Fig. 8* on the following page.

Examples of Placement

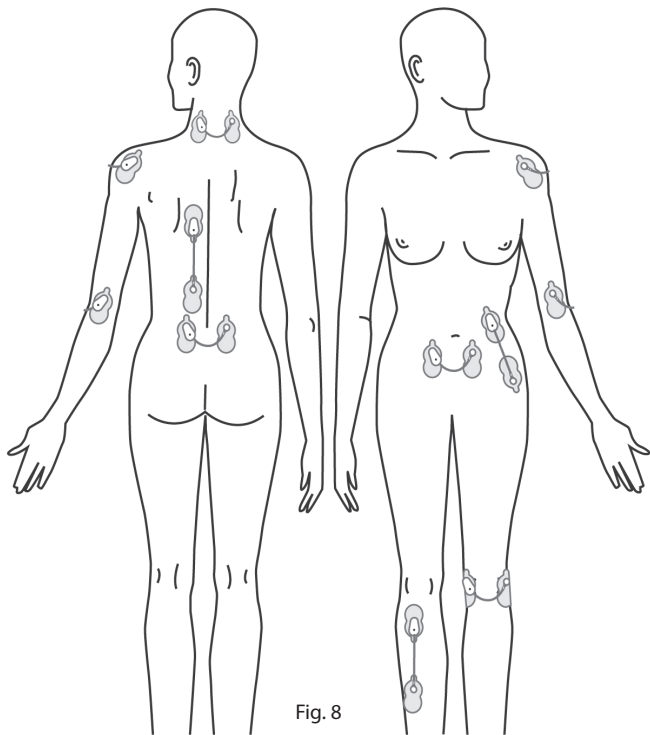
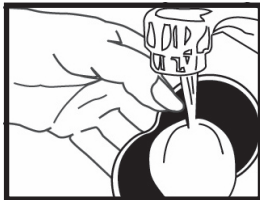
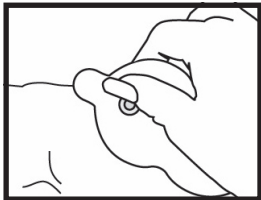


Fig. 8

Use and Care of Patches

After three days of continuous use, the patch should be removed for one to two days. To clean patches, rinse gel side with a small amount of warm water and let dry completely. If there was no skin reaction, reapply. Do not sterilize or disinfect. Many people wear the patch continuously with no problems.

Do not wear while bathing as the added moisture will decrease the adhesive properties of the patches. Removing the patches before bathing will extend their life. Remove patches by pulling each one gently with the tab. Never remove patches by pulling the wire. Store on the correct side of the plastic backing which came with the patch. After showering, completely dry your skin and reapply. If the patches have lost their stickiness, simply rinse the gel sides with warm water and allow them to air-dry before reapplying.



Environmental Conditions That Can Affect Use

The Painmaster MCT Patch should only be used within the temperature range of 10°C to 45°C (SOT to 113°F) and at a relative humidity range of 20% to 90%. If the product has been stored or transported in conditions outside these ranges, keep it within normal ranges for at least 30 minutes before using.

Questions and Answers

Will I feel any sensation?

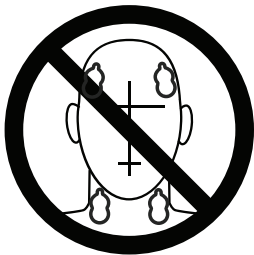
No, the current level is intentionally set below the level that can normally be felt. The red light will begin blinking when good contact is made with the body.

Is the position critical for treatment?

It is best to place the patches on both sides of the painful area. This may be left to right or up and down. Sometimes we cannot determine exactly where the pain is coming from and we suggest moving the patch after 24 hours if relief is not felt. All over body pain sufferers should keep the patch in the same place 72 hours before moving.

Where should I not place the patch?

Safety of use through the head and carotid sinus area of the neck has not been determined. Do not place in areas shown on the drawing.



How long will the power last?

The battery will last for about 300 hours of total use. Battery life depends on the individual usage of the product and the conductivity of the skin.

How long will the patches last?

Generally, the number of times a patch can be reused will vary from patient to patient depending on skin conditions, climate, storage, use and care. If the patches are cleaned and dried as described on page 9, they can be reapplied numerous times.

Indications for Use

The Painmaster MCT Patch is a Class II medical device for the non-medical relief of muscle pains and spasm including neck, back and joint, sciatica, tennis elbow and the pain associated with fibromyalgia and arthritic disorders.

Safety Testing

The Painmaster MCT Patch was tested and in compliance with:

- UL260-1 "Medical Electrical Equipment, Part I";
General Requirements for Safety.
- CSN/CSA C22.2 No 601.1.1-M90, "Medical Electrical Equipment,
Part I"; General Requirements for Safety.
- EN60601-1 "Medical Electrical Equipment, Part I";
General Requirements for Safety.
- CENELEC EN 60601-2-10 "Medical Electrical Equipment, Part 2-10";
Particular Requirements for Safety of Stimulators.
- EN 60601-1-2 Electromagnetic emissions and immunity.
Requirements for medical electrical equipment.

Adverse Reactions

Isolated cases of skin irritation may occur at the site of electrode placement following long term application. The treatment should be paused and this condition, known medically as erythema, will generally resolve within a few hours to a few days.

Occasionally, minor skin irritation at the electrode site has been documented with certain hypersensitive individuals.