

## Frequently Asked Questions

### **How do I use PainShield MD?**

(Please see our more detailed information about the instructions for use and prescribing information by clicking [here](#)).

Once the unit is charged and the patch connected to the driver unit, clean and dry the skin over the painful area. If necessary shave the area to allow good contact with skin and to help patch removal later. Make sure the area is free of wounds or other lesions. Place the patch in position and switch on the control unit. The unit runs for 7 cycles consisting of an ACTIVE period of 30 minutes and an IDLE period of 30 minutes, for a total of 6.5 hours. The unit requires recharging prior to the next use.

### **Do I need a prescription?**

In the USA you will need a prescription from a medical doctor or in those states that allow it, from a Physical Therapist or other medical professional. Most other countries do not require a prescription for PainShield MD.

### **What is the cost of PainShield MD?**

In the United States, PainShield MD costs \$875 (includes ground shipping within continental USA). This includes four patches which can be replaced for \$45 each. Please contact us for details of discounts for volume orders of patches.

### **Is PainShield MD covered by insurance in the USA?**

There is currently no reimbursement code for in-home use of PainShield MD. Some patients have been able to obtain reimbursement through their plans after obtaining a letter of medical necessity. Some patients have been able to use funds from "flexible health spending" accounts.

There are two codes related to ultrasound that may be accepted by some insurance plans. Although these are for in-office use only (i.e. a doctor or physical therapist office), some plans have accepted them for in-home use.

- 97024-Ultrasound diathermy that is reimbursed on a 15 minute usage basis. Many providers allow for up to 1 hour a day-5 days a week and up to 20 hours a month. If the therapy works and is needed some will allow up to 6 months therapy.
- 97035-Ultrasound treatment that is reimbursed on a 15 minute usage basis. Many providers allow for up to 1 hour a day-5 days a week and up to 20 hours a month. If the therapy works and is needed some will allow up to 6 months therapy.

These codes were designed for conventional ultrasound and not the PainShield MD which we believe is best used for up to 6.5 hours a session, i.e. for in-home use.

We have also been informed that some plans have agreed to reimburse based on a code E1399 which is a 'Miscellaneous Code' for Durable Medical Equipment. Check with your insurance plan before relying on this information.

**How big is the PainShield MD and the PainShield patch?**

The PainShield MD driver weighs about 70g (2.6 oz.) and is approximately the same length and thickness of an iPhone 5 and about 2/3 of the width.



The driver's approximate dimensions are 39 x 12 x 125 mm (or 1.5" x 7/16" x 4 7/8"). The patch weighs about 10g (or 0.4 oz.) and its dimensions are 120 mm x 70 mm (or 4 10/16" x 2 5/8")

**Where do I place the PainShield patch?**

Place the center of the patch over or just next to the painful area. You will need to experiment a little to find the best location for your circumstances. For pelvic pain and related conditions, you may want to try the area over the bladder, the suprapubic region, and the lower left or right quadrants (just above the groin region). Some patients have found relief by placing the patch over the area of the sacral bone. You may also change the patch position during treatment. Some patients find the "sweet spot" instantly, for others it is a matter of trial and error.

**Why does the PainShield patch need to be replaced and how often should it be replaced?**

The PainShield patch contains the 'high-tech' element of the PainShield MD Therapeutic ultrasound device. This metal/ceramic disk in the center of the adhesive patch is the ultrasound transducer, which eventually wears out due to the vibrations that it creates, which are the source of the ultrasound waves going into the body. As with all items that undergo vibrations, they eventually wear



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out, so the PainShield MD patch requires replacement when the ultrasound transducer is no longer functional. A “defective patch” icon appears on the screen of the PainShield MD driver and an audible alarm is heard, indicating when the patch requires replacement. The patch is warranted for 50 hours of use or 7 treatment sessions (6.5 hours each). That is about one week based on a daily treatment. Most patients have been able to use their patches for much longer than this, especially if users take care in removing the patch after use, keeping the adhesive moist and storing it carefully in its original bag inside a zip lock bag.

### **When will I feel relief?**

Pain reduction could begin as early as 30 minutes after beginning treatment and up to several hours or days. PainShield MD is believed to work by improving blood flow to muscles and tissues that are in spasm and by normalizing nerve activity, and that is why instant pain relief is not to be expected.

Some patients are able to find the "sweet spot" almost immediately, and other patients will need to experiment to see what works best in terms of:

- where to place the device
- what time(s) of the day to place the device
- for how long to place the device in each position

Working with a physical therapist will help greatly, and we are available to discuss with your doctor or PT strategies that have worked for other patients.

Don't give up! There will be ups and downs. You will have success in some areas first before other areas. To keep track of your progress and to help you remember what works best for you, we have designed a Pain Diary, which you can download for free [here](#).

Remember also that you are beginning to increase blood flow to areas that have, relatively speaking, been deprived of blood. Most of us have experienced the sensation of "pins and needles" after sitting on a foot or hand for some while. Some patients experience new sensations when they use PainShield MD for the first time. Your doctor can help you distinguish between what is a healthy return of sensation and something which is indicating else. If this happens, use the PainShield MD for small amounts of time (10, 20 30 minutes etc.) at a time, gradually increasing your use of the device. You can also place the patch a little further from the "epicenter" of you pain, gradually bringing it closer.

### **Will the pain return as soon as the PainShield MD is switched off?**

Not usually. You should continue to experience pain relief for some time after the unit is switched off. The pain will gradually return when the PainShield is not being used. With repeated use for many days, the level of pain between uses should go down.

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**Should I discontinue other therapies while using PainShield MD?**

You may feel that you can reduce your use of opioids, analgesics and other prescription or non-prescription medications. You should consult with your doctor or other medical professional any time you feel you need to make any changes in your medical treatment.

Please note that 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 pacemakers, electrical stimulators, radiofrequency generators, surgical meshes, Intra-Uterine Devices (IUDs), or other surgical implants. Please consult with your medical doctor and comply with the instructions of the manufacturers of those other devices before using PainShield MD.

**Can PainShield MD be used with physical therapy?**

Yes. PainShield is perfectly suited to be used in concert with a program of physical therapy and can be used in between therapy sessions. For the treatment of pelvic pain and related disorders we strongly suggest that you consult a physical therapist specially trained in pelvic pain and pelvic floor disorders. See our [Links page](#) for referral sources.

The consensus among experts in the field is that a multidisciplinary approach is required for the treatment of pelvic pain and related disorders, involving a team that includes representation from gynecology, urology, urogynecology, physical therapy, general surgery, gastroenterology, pain management, psychology, and nutrition. A number of resources can be found on our links page as well as at <http://www.iscapps.org/> and <http://www.adhesions.org/>.

**Do I need to program PainShield MD or to change any settings?**

No. The only control is the ON/OFF button. PainShield is simple to use and requires no programming or selection of settings.

**Do I need to use an ultrasound gel under the PainShield patch?**

No. You do not need to use ultrasound gel with PainShield MD. However, if you would like to put a small amount of ultrasound gel underneath the transducer in the center of the patch, you can do so to further enhance the conductivity between the transducer and your skin, which may be especially helpful in patients with a lot of body hair.

**Can I use the PainShield patch over a place of medicated or unmedicated cream or ointment?**

You should only place the patch over a clean, dry area of skin. It is possible that PainShield MD may change the absorption of medications or other ingredients of the skin or ointment.



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**Will I feel any vibrations or shocks from the device when it is on?**

Other than mild warmth from the metal transducer in the center of the patch you will feel no vibrations or electric shocks.

**I have a latex allergy. Does the PainShield patch contain latex?**

No, the patch components do not contain latex.

**Why does the PainShield MD have to be on the skin for 30 minutes when other ultrasound machines work in 15 minutes using a wand?**

PainShield MD is unique in that it allows patients to receive treatment on a much longer basis (up to 6.5 hours of intermittent therapy - 30 min ON/30 min OFF), which is why PainShield's results in pain treatment success are so convincing. With the high-intensity ultrasound units, it would be impractical and unsafe to treat a patient for more than 10-15 minutes (due to the risk of tissue overheating).

PainShield operates at a low power of only 0.4 Watts, while traditional wand-based units operate at a power of approximately 5 Watts (12 times higher than the PainShield). The benefit of PainShield, therefore, is that patients can get gentle, long-term treatment with ultrasound on their own time using a self-adherent transducer rather than having to go to expensive office visits to get only infrequent applications or the need to hold and continuously move the hand held unit to prevent overheating and tissue damage.

We often hear from patients that they receive benefit from the in-office ultrasound treatments with traditional units in the therapist's office, but that within a few days the benefits subside, the pelvic floor muscles go back into spasm, and the pain returns. The benefit of PainShield is that it can extend the pain relief obtained in a therapy session and prolong the duration of relief by allowing long, daily multi-session treatments at home.

**Why can't an individual use an ultrasound unit with a wand instead of the PainShield MD?**

The hand held wand produces high intensity, focal ultrasound that requires the patient to use gel and continuously move the wand around the application site, to prevent heating and tissue damage. Doing so for 10-15 minutes is not practical in many cases.

In addition, the use of a wand requires the patient's area of pain to be easily reachable by the patient (e.g. a knee or elbow), or, if the treatment area cannot easily be reached by the patient himself/herself, then an assistant is required to apply the ultrasound therapy. In contrast, the benefit of PainShield MD is that it provides low frequency and intensity ultrasound that affects a larger 4" radius around the application site and can be used for long treatment sessions without any risk for damage.

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The patient can receive treatment in a 'hands-free' manner, since no wand is necessary. Instead, the self-adhesive treatment patch, once applied, can remain in place for the duration of the treatment session of 6 ½ hours. Similar to the benefits of "slow release" medications, receiving low "dosage" therapy for a longer time period is often more effective than receiving high power treatments for a shorter duration.

**Why does the PainShield not require a conductive gel to transmit the ultrasound waves into the tissue?**

The shape of the ultrasound transducer in conventional, hand-held high-frequency/high intensity devices requires the use of a conductive gel to transmit the ultrasound waves into the body. Air is a very poor conductor of high-frequency ultrasound waves. A less than perfect contact between the wand and the patient's skin with air interfering would cause the therapy to be delivered improperly to the patient. Hence, in conventional wand-based ultrasound units, the addition of a conductive gel is a necessary step to ensure that the ultrasound therapy waves reach the targeted parts of the body.

In addition, conventional bulk wave ultrasound transducers heat up during therapy, and the gel helps dissipate the heat to prevent burning of the treated skin. In contrast, the adhesive patch surrounding the flat ultrasound transducer inside the PainShield treatment patch ensures a complete contact with the patient's skin. No gel is necessary to enhance conductivity, if the patch is applied directly to the skin. As for application site warming - the PainShield transducer only warms 1-2 degrees Celsius above skin temperature and no gel is required to prevent the risk of skin burns.

**When I place PainShield MD in certain areas, e.g. over my sacrum, the patch feels very hot. Can I get burned by the PainShield Patch?**

When nerves have been in pain for a long period of time, they may be hypersensitive and perceive the energy from the ultrasound transducer as 'hot'. Since the transducer can only warm 1-2 degrees Celsius above skin temperature, you cannot be burned by the patch. As your nerves become normalized with ultrasound therapy, over time the sensitivity should decrease. Until then, try moving the patch farther away from the area of greatest sensitivity until your nerve sensations normalize.

**How exactly does the PainShield patch differ from a patch used with a TENS unit?**

The PainShield MD patch contains a unique and novel ultrasound transducer, which when placed directly on the skin, sends ultrasound waves into the body tissue, generating a therapeutic effect that is thought to include deep tissue warming, greater oxygenation, decreased muscle spasm, pain relief, faster healing of injured tissues, and a normalization of nerve activity. In contrast, a patch from a TENS unit delivers an electrical current to stimulate nerves and muscle contractions in order to alter pain perception in the patient by creating a tingling sensation. While both the TENS unit and the PainShield have an adhesive patch connected to the patient's skin, the TENS unit's patch contains a wire and an adhesive patch. In contrast, the PainShield MD treatment patch contains the ultrasound transducer, which is what allows hands-free delivery of ultrasound therapy.

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**Is PainShield MD like a TENS Unit?**

No. PainShield Therapeutic Ultrasound and TENS (Transcutaneous Electrical Nerve Stimulation) are very different.

	<b>TENS</b>	<b>PainShield MD</b>
<b>Type of Energy</b>	Electrical	Therapeutic Ultrasound
<b>What does it feel like?</b>	Small electrical shocks felt as tiny pin pricks	Mild skin warming from disc in the patch
<b>How does it work?</b>	Sends "decoy" electrical signals that reach the spinal cord before the "actual" pain signals. The decoy signals are intended to block the actual pain signals.	Therapeutic ultrasound energy warms tissues over a wide area and probably helps to increase blood flow and oxygenation by causing dilation of blood vessels.  Increased blood flow to muscles in spasm helps to relax them and to remove inflammation that is causing or increasing the pain.  The ultrasound energy may also act directly on the nerves, restoring the sensitivity and activity to normal levels.
<b>Does it restore normal tissue function?</b>	Because TENS only blocks signals that come from the area in pain, it is unlikely to have any effect on the affected tissue itself.	Because PainShield MD most likely improves blood flow, conditions are created in which it is possible for tissues to return to normal function, provided the original cause of the problem is also removed.
<b>How quickly will I feel a reduction in pain?</b>	If pain reduction is possible, it will take place quickly.	Pain reduction could begin as early as 30 minutes after treatment and up to several hours or days after treatment begins.
<b>When I use a TENS, the pain comes back as soon as I turn off the unit. Will this happen with PainShield?</b>	Pain returns quickly because TENS only blocks the actual pain signals. As soon as the TENS is switched off, the pain returns.	The pain only returns gradually when the PainShield MD is not in use. With repeated use over a number of days, the overall level of pain even when the unit is switched off should be lower than before treatment was started.

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