

General instruction for use

for the PAINflex® PSMP (Personal Size Mattress Pad)
with CCM™ (Concentric Circle Magnets)



UDI-DI: PPN 11.0356 745 7.36

PZN: 03567457

GTIN: 04040973981100

SRN: DE - MF 0000 48329

**in accordance with Regulation (EU) 2017/745
on medical devices
of 5. April 2017**

Manufacturer:

BIO-PAINflex-Medical-Magnetics Deutschland GmbH
DE-MF 0000 48329, UDI - Basis: PP 00538 PSMP 74
Ender Straße 94, 01277 Dresden, Germany
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Please read these instructions carefully and completely before use

1. Mode of action – purpose

The **PAINflex® PSMP with CCM™** is a registered **Class I medical device**.

The **PAINflex® PSMP with CCM™** is used in the area of regeneration of the body during rest phases. The specially designed magnets (**CCMs™**) act mainly on the blood, lymph and nervous system and are used to relieve nociceptive and neuropathic pain. The use of the pad demonstrably increases blood circulation, slightly warms up the body, relaxes muscles, relieves tension pain and regenerates.

2. Application



The mattress topper has 4 tension corner rubbers with which it is fixed to the mattress. The side with the **PAINflex® LOGO** is facing the body. It is important to make sure that the entire mattress has a certain stability. In particular, the middle area must not be sagging, as this could impair the stability of the incorporated magnets.

The **PAINflex® PSMP with CCM™** is suitable for long-term use. It can be used during the day and at night. The pad requires neither electricity nor charging, so that no electro smog can occur.

The **PAINflex® PSMP with CCM™** is intended for use in children from 10 years of age and adults without height and weight restrictions in a home environment. There are no negative findings on risks in children under 10 years of age with permanent magnets.

There is no negative evidence of risks in children under 10 years of age associated with permanent magnets. In recent decades, no harmful side effects have been known due to static permanent magnetic fields, worldwide in all age groups.

If you are a person who is sensitive to magnets, we recommend that you slowly get used to the **PAINflex® PSMP with CCM™**. For this purpose, you can place an additional layer in the form of a duvet on the **PAINflex® PSMP with CCM™** during the first few weeks of use.

Test your condition in between and repeat the process a few times if necessary.

After a period of acclimatization, they should position the **PAINflex® PSMP with CCM™** on the mattress without additional overlap in order to achieve optimal effect. Protect the **PAINflex® PSMP with CCM™** only with a normal bed sheet.

3. Contraindications



Whenever a condition is negatively affected by blood flow support, the **PAINflex® PSMP with CCM™** should not be used.

Examples:

- unclear headache
- concussion
- risk of acute internal bleeding
- in the first 12 months after organ transplants, or as long as the immune system needs to be suppressed.

In case of side effects or deterioration in health, please contact your family doctor.

4. Safety instructions



Avoid kinking the **PAINflex® PSMP with CCM™** at all costs, as well as exerting greater pressure on the support. If you bend or apply greater pressure, there is a risk of breakage.



Avoid direct contact with chemical cleaning or care products. The ingredients of such agents could damage the **PAINflex® PSMP with CCM™**.



The manufacturer, distributor or seller of the product does not assume **any responsibility** for interventions in the product by unauthorized persons with the intention of modifying the product, e.g. made subsequently by the end user. These companies are also **not responsible** for the consequences of not following the complete instructions in this instruction manual, i.e. in the event of improper use of the product.



Do not use the **PAINflex® PSMP with CCM™** together with electric blankets or similar products! If used incorrectly, there can be a fire hazard due to heat build-up.

4.1 Pacemakers, defibrillators, insulin pumps



People who wear a pacemaker, a defibrillator or an insulin pump are not allowed to use the **PAINflex® PSMP with CCM™** without consulting their doctor!

4.2 Credit cards, data carriers



Credit cards, simple magnetic cards such as parking permits and admission tickets should maintain a distance of at least 10 mm from the support.

4.2.1 Metal implants and electronic Implants



The products of the **PAINflex® PSMP with CCM™** product group can be used with all metal, ceramic or zirconium oxide implants in the body. If you do not know the composition of your implant, consult **your doctor** before using it.

4.3 Pregnancies

There are no findings on the risks of pregnancy, as no studies are carried out on pregnant women for ethical reasons. Please ask your gynecologist.



If serious incidents occur in connection with this medical device, please inform the responsible state authority and the dealer immediately

5. Material compositions

Development and production in Germany. The raw material of the magnets consists of a ferrite mass bound in plastic. Films made from them are permanently magnetized in a complex process. SrO6Fe2O 89%, Chlorinated polyethylene 10%, EBSO 0.5%, Dioctyl phthalate 0.7%.

The **PAINflex® PSMP mattress topper with CCM™** is made of fabric (top 45% viscose, 55% polyester; underside 82% polyester, 18% polypropylene) and 24 biomagnetic magnetic tapes with up to 288 CCM™. All processed fabrics are Ökotex® certified. The mattress topper has 4 tension corner rubbers for fixing to the mattress.

6. Care



For hygienic care, the **PAINflex® PSMP with CCM™** can be washed by hand at a maximum of 30 °C without wringing. **PAINflex® PSMP with CCM™** should not be put in the dryer but should be dried on the line in the shade. Do not iron the pad, or dry on the heater or other direct heat sources. Dry cleaning is not allowed. This can lead to undesirable material changes. Contact with acids or solvents must be avoided.

If there are any changes to the material that are not due to normal wear and tear, contact the sales department or manufacturer.

7. Warranty / Service Life

The manufacturer BIO-PAINflex Medical Magnetics Deutschland GmbH gives a 10-year warranty on the durability of the magnetic field strength for the mattress topper **PAINflex® PSMP with CCM™** **when product registration has been carried out (see attachment)**. We guarantee that the measurable magnetic field strength will not decrease by more than 20% within the first ten years. In the event of a warranty claim, the buyer bears the transport and transit costs. The buyer will be informed of the amount of the costs in advance.

The following are excluded from the **guarantee and warranty**:

- errors caused by improper handling of the product (e.g. excessive force, overload, modifications made by the buyer)
- damage to the cover and the handles (loops) for turning, which can occur due to improper handling
- any defects due to natural wear and tear
- mold stains



- normal wear and tear of the fabric
- loosening of topstitching

Warranty and warranty claims must be made to the seller from whom the product was purchased. The warranty is forwarded by the seller to the manufacturer. The warranty is handled directly by and through the seller.

See also Appendix: Product Registration

8. Disposal - packaging material and product

The packaging material is environmentally friendly and can be fully recycled.

The **PAINflex® PSM with CCM™** falls into the category of "metal oxides with plastic deposits" according to the waste code EAK (European Waste Catalogue, 060401) and can usually be disposed of with normal household waste. The exact regulations can be found in the local waste regulations.

9. Conditions of use, transport and storage

Use and store the product at a temperature between -5 C° and +40 C°. Do not expose the product to direct sunlight or high temperatures (radiators, etc.). Do not store the product at a temperature below -5 C°, otherwise the **CCM™** films could break.

10. Declaration of Conformity

For the **PAINflex® PSMP with CCM,™** BIO-PAINflex - Medical-Magnetics Deutschland GmbH declares conformity in accordance with Regulation (EU) 2017/745 for medical devices on its own responsibility. This can be viewed from the manufacturer if required.

Appendix – Marking

	BIO-PAINflex Medical Magnetics Deutschland GmbH Ender Straße 94 01227 Dresden, Germany	Name and address of the manufacturer
	2025	Manufacturing details year
	71.2025	Lot batch number
		CE marking
		Medical Device
		Hand wash
		Dry in the shade - on the clothesline
		do not wring out
		Do not tumble dry
		no dry cleaning
		Do not iron
		Transport and storage conditions
		Patient page - serves to describe the correct application
		Follow the instructions for use
		Pacemaker warning symbol - minimum distance 1.5 cm
		DANGER
		Warning signal - do not apply pressure - do not bend
		Note distance to magnetic cards at least 10 mm distance