

## Instruction for Use

### 1.Product Name

Heat Patches

【Trade name】

### 2.Specification/Main contents

H095130C6; H095130A8; H080185B0.5; H070095B6; H095130B8; H095130C8; L055950A8; L130192A12; L095300A12; L140390A12; L090295A12; L130190A12; L095130A12; L070095A8; L100150A8; L090295A8; L095130A8; L095220A8; L130192A8; L095300A8; L095130A16; L130190A16; H070193B0.5; H245404B0.5; H076230B8; H085250B8; H086260B8; H095285B8; H055095B8; H1401100C4; L140390B8; L055950B8; L055950C8; H095130C12; L100200A12

Iron powder, activated carbon, sodium chloride, vermiculite, water-absorbing resin, water

### 3.Use Method

Different types of products shall be used as follows:

#### A. Heat patch with adhesive for applying to the skin

1.Make sure the skin where you're applying the wrap is clean, dry, and free of any makeup, moisturizer or lotions.

2.Tear open the pouch when ready to use.

3.Peel away paper to reveal adhesive side.

4.Place on pain area with adhesive against the skin.

\*Refer to Do not use section for areas where not to apply.

#### B. Heat patch with double sided nonwoven for applying to the skin:

1.Tear open the pouch when ready to use.

2.Place the wrap into the protective gear. Do not fold or bunch as your risk of burn is increased.

3.Place on pain area with darker heat cells towards skin.

4.Make adjustments to firmly "lock" it in place by attaching the Velcro to the elastic, Do not over-tighten.

#### C. Heat patch with adhesive for applying to the cloth:

1.Tear open the pouch when ready to use.

2.Peel away paper to reveal adhesive side.

3.Place on the outside of the underwear on the area of pain, attach firmly.

4.Discard heat patches after single use.

#### D. Heat patch with protective clothing:

1.Tear open the pouch when ready to use.

2.Place on pain area with darker heat cells towards skin.



3.Make adjustments to firmly “lock” it in place by attaching the Velcro to the elastic,Do not over-tighten.

It may take up to 30 minutes to reach therapeutic temperature.

**4.Temperature Performance**

<b>Maximum temperature</b>	Low temperature heat patch: The maximum temperature measured from the beginning to the end of heating.	≤ 43°C
	High temperature heat patch: The maximum temperature measured from the beginning to the end of heating.	≤ 68°C
<b>Temperature rise time</b>	The time required from product activated to temperature rise to therapeutic time.	≤ 30min
<b>Temperature guarantee time</b>	The total amount of time that the heating temperature is maintained above37°C (≤ 43°C) or 40°C (≤ 68°C).	0.5,4,8,12,16h

We can also customize the temperature guarantee time for customers.

**5.Intended Purpose**

Provides heat therapy for temporary relief of Back pain,Knee pain,Neck pain,Joint pain,Muscle Tension and Soreness and Menstrual pain.Suitable for those suffering from acute, chronic and occasional pain.Suitable for local heat therapy in medical institutions or at home.Refer to warnings for limitations of use.

**6.Intended Patient Population**

The heat patch is applied to self-sufficient patient population above 12 years of age, for 55 years or older, your risk of burning increases as you age, monitor skin frequently during use. The heat patch shall not be applied to following patients:

- Children under 12 years old;
- Sensory impaired or unconscious patients;
- Pregnant women;
- Woman experiences abnormal bleeding or other serious symptoms (such as severe pain or fever) during her menstrual period;
- Patients situations mentioned in the contraindications.

**7.Intended user**

Heat Patch shall only be used by adults who can read and understand the instruction manual.

**8.Indications**

Relief of muscle and/or joint pains associated with:

- Overexertion,
- Strains and sprains,
- Arthritis,
- Muscle tension,

- and Primary dysmenorrhea

### **9.Contraindications**

- Acute abdominal disease
- Preliminary stage of soft tissue bruise or sprain
- Skin eczema/allergic dermatitis
- Early stage of wound
- Sensation Impaired
- Cognitive or communication deficits that preclude reporting of pain
- Over areas of acute inflammation
- Fragile skin
- Vascular insufficiency or vascular disease
- Hemorrhage or potential hemorrhage
- Over areas of known malignancy

### **10.Undesirable Side-effects**

Risk of irritation and burn. 55 or older: your risk of burning increases as you age. If you find irritation or a burn, remove product immediately. Most time this symptom is transient and typically resolve within a few hours. If the symptom is not alleviate exceed one day, please turn to medical attention.

- Please read ALL instructions and warnings before use.
- To reduce the risk of Scald and personal injury, this product must be used in accordance with the warnings and use instructions.
- WITHOUT EXTERNAL HEAT SOURCE FOR EXTERNAL USE ONLY.

### **11.Intended clinical benefits**

Relieves pain caused by non-acute muscle strain, injury recovery period, non-acute phase of joint diseases, muscle tension and primary dysmenorrhea, and improves stiffness.

Through gentle hot compress to relax muscles, improve local blood circulation, alleviate musculoskeletal discomfort caused by fatigue and cold exposure, and enhance the comfort of daily activities.

### **12. Warnings**

- For external use only.
- Consider hazards from magnetic fields: To avoid increased risk of burns, remove product before undergoing any MRI (magnetic resonance imaging) procedures.
- Do not use if heat cell contents leak and/or wrap and/or package is damaged.
- Do not use more than 8 hours in a 24-hour period.
- Do not use on people unable to follow all use instructions or unable to remove the product.
- Do not use on areas of the body where you can't feel heat
- Do not use on people with impaired consciousness or unconsciousness
- Do not use under 12 years of age.
- Do not use During Exercise.
- Do not wear while sleeping.
- CHECK SKIN FREQUENTLY DURING USE

- Do not apply wrap too tightly and do not overlap the heat cells.
- Potential Interactions with other products (e.g. medicines, food): Do not use with topical preparations.
- Restrictions in use for combination of other devices: Do not use with other forms of heat.

**13.  Cautions**

- Consult instructions for use.
- If the wrap is damaged or torn during use, remove the product.
- Do not place extra pressure over the product such as leaning against hard surfaces or wearing under tight clothing.
- 55 or older: Your risk of burning increases as you age. monitor skin frequently during use.
- For users that are not self-sufficient, or for users aged 12-18: supervision by a caregiver is required.
- Ask your pharmacist or doctor for advice before using the product (e.g. if pregnant or breastfeeding)
- If product feels too hot, stop use or wear over a layer of clothing, not directly against your skin.
- Stop use and consult a doctor if after 7 days your pain gets worse or remains unchanged.
- Stop use and consult a doctor if you experience any discomfort, burning, swelling, rash or other changes in your skin that persist where the wrap is worn.
- This product can cause burns/blisters.If you find irritation or a burn, remove product immediately and consult a doctor
- If ingested please seek professional assistance immediately.
- If it comes in contact with your skin or eyes, remove wrap, rinse affected area with water and seek professional assistance immediately.
- Keep out of reach of children and pets.

**14.Disposal:**

Dispose of contents/container in accordance with local/regional/national/international regulations.

**15.Storage/Transportation conditions:**

Store at room temperature in a dry place. Avoid direct sunlight..

**16.Shelf time:**

3 years

**17.Importer**



Name

Address [Note: the specific importer information will be printed in the printed version of IFU]

**18.Manufacturer**



JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.

No. 298 Yandunshan Road, Zhenjiang New District, 212132 Jiangsu P.R. China

**19.EU Authorized Representative**



MedNet EC-REP C IIb GmbH  
Address: Borkstrasse 10, 48163 Muenster, Germany

**20.Effective Date:**

2025-11-21

**21.Revision:**

A/1

**22.Contact information**

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For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

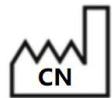
The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:  
[https://ec.europa.eu/growth/sectors/medical-devices/contacts\\_en](https://ec.europa.eu/growth/sectors/medical-devices/contacts_en).

**23.**



<https://www.intcomedical.com/download.html>  
Website: [www.intcomedical.com](http://www.intcomedical.com)

**24.Symbol**

No.	Symbol	Meaning
1		<b>Date of Manufacture Country of Manufacture</b>
2		<b>Use-by date</b>
3		<b>Manufacturer</b>
4		<b>EU authorized representative</b>
5		<b>Batch Code</b>

No.	Symbol	Meaning
6		CE Marking, and Notified Body Code
7		Caution
8		Do not reuse
9		Do not use if package is damaged
10		Catalogue number
11		Medical device
12		Importer
13		Unique device identifier
14		Model number
15		Keep away from sunlight
16		Keep dry
17		Consult electronic instructions for use