

Instruction for Use

1.Product Name

Warmers

(Hot pack、 Instant hot pack、 Heat pack)

2.Specification/Main contents

Sodium acetate, water

3.Use Method

- 1.Locate inner pouch. Squeeze firmly to rupture inner fluid pouch.
- 2.Wrap soft cloth and apply pack to desired area.
- 3.Apply to affected area.



4.Temperature performance

Item		Target
Maximum temperature	The maximum temperature measured from the beginning to the end of heating.	$\leq 55^{\circ}\text{C}$
Temperature guarantee time	The total amount of time that the heating temperature is maintained 38- 55°C.	≥ 30 min

5.Intended Purpose

Warmer is used for providing heat therapy for temporary relief of muscle stiffness and soreness, promotes local blood circulation, and helps relax soft tissues, and to regulate blood and disperse stasis. Suitable for local heat therapy in medical institutions or at home. Refer to the warning instructions for restrictions

6.Intended patient population

The Warmer is applied to most patient. But for the elderly, infants and toddlers, we need to pay attention to them.

The Warmer shall not be applied to following patients:

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

Warmer shall only be used by the people who can read and understand the instruction manual.

8.Indications

Provides heat therapy for temporary relief of mild muscle and joint soreness caused by overexertion, strains, sprains, arthritis, and muscle tension, and promoting blood circulation and remove blood stasis.

9.Contraindications

- Acute abdominal disease
- Preliminary stage of soft tissue bruise or sprain
- Skin eczema/allergic dermatitis
- Healing Wounds
- 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

It may cause rash and burn for people with sensitive skin to heat. 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.

11.Intended clinical benefits

Promote local circulation and tissue repair;
Relieve muscle and joint stiffness;
Relieve chronic and periodic pain;
Preventing discomfort related to low temperature;
and to regulate blood and disperse stasis.

12. Warnings

- For external use only.
- Do not been used on infants.
- Check the packaging bag without leakage and product within expiry date before using.
- Do not apply if skin is impaired in any way.
- Supervise children during use.
- Harmful swallowed. If accidentally swallowed, contact poison control center or physicians immediately.

- If bag breaks and fluid comes in contact with skin or eyes, flush with water immediately.
- Individuals with circulatory problems should consult a physician before using this product.
- Shall pay attention to the elderly, children and people with communication barriers.

13. Cautions

- Consult instructions for use.
- Prior to use, store at room temperature.
- Always wrap a towel or cloth before applying to bare skin.
- If the warmer feels too warm or if there are significant skin color changes, more layers of toweling should be added or the warmer should be removed.
- Patients should not lie with their full body weight on top of a warmer.
- Do not open the warmer.
- Keep out of reach of children.

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 life

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

2025-10-13

21. Revision

A/1

22. Contact information

- JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
- ADD: No. 298 Yandunshan Road, Zhenjiang New District, 212132 Jiangsu P.R. China

Email: sunguihua@intco.com

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.

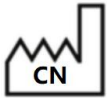
23.



<https://www.intcomedical.com/download.html>

Website: www.intcomedical.com

24. Symbol

No.	Symbol	Meaning
1		Date of Manufacture Country of Manufacture
2		Use-by date
3		Manufacturer
4		EU authorized representative
5		Batch Code
6		CE Marking, and Notified Body Code

No.	Symbol	Meaning
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