

Instruction for Use



1. Product name

Hot/ Cold Packs (Solid gel)

2. Specification/Main contents

XXXX - XX - N,

XXXX - XX - N - R

Note:XXXX:Gel type,XX:Bag material,N:Net weight,R:Color

High absorbent resin (polyacrylamide), glycerol, water, preservative, lycra fabric (nylon and spandex)

3. Use Method

The following processing time is for reference:

| Product net weight / g | Heating time in Microwave oven / s | | | Treated by refrigeration | Treated by freezing |
|------------------------|------------------------------------|-----------|-----------|--------------------------|---------------------|
| | 1000w | 800w | 600w | | |
| 100 | 5*2 | 8*2 | 10*2 | 2h | 30min |
| 150 | 10*2 | 10*2 | 15*2 | | |
| 200 | 10*2 | 15*2 | 15*2+10 | | |
| 250 | 15*2 | 15*2+10 | 15*2+10 | 3h | 1h |
| 300 | 15*2+10 | 15*2+10*2 | 15*2+10*2 | | |
| 350 | 15*2+10 | 15*2+10*2 | 15*2+10*2 | | |
| 400 | 15*2+10*2 | 15*2+10*3 | 20*2+10*3 | | |
| 450 | 15*2+10*2 | 15*2+10*3 | 20*2+10*4 | | |
| 500~1000 | 30*2+10*n | 35*2+10*n | 40*2+10*n | 4h | 2h |

Note:

The above microwave ovens conditions are based on the following conditions:

The initial temperature of the product is 23 °C.

The target temperature of the product after heating is 50 °C.

The actual heating power of the microwave oven is calculated at 75% of the nominal power.

30*2+10*n: 30 indicates heating time, 2 indicates heating cycles, and n indicates the number of heating cycles until the temperature is appropriate.

For heat therapy:

Microwave oven heating

- Put the pack in the microwave oven,
- Heat the product under specified conditions. Turn it over after each heating cycle,
- Check the temperature,if the product is not hot, continue heating for 10 s at a time until the temperature is appropriate,if the temperature is too high, leave it for a while before removing it to prevent burns,
- The best time to use the is within 20 minutes.

For cold therapy:

- Put the pack in the refrigerator for suggested time before using,



- Apply to affected area,
- The best time to use the is within 20 minutes.

4. Temperature performance

Test ambient temp: 20 ~24°C,

The cold performance: Temp ≤ 10 °C within 20min(-18°C Freezer: ≥ 2 h)

The thermal performance:Temp ≥ 40 °C within 20min(When max temp ≥ 55 °C).

Note:Duration depends on product size and weight.

5. Intended Purpose

Hot/cold pack is used for providing heat/cold therapy.

For cold therapy:

for providing cold therapy for temporarily relief of pain, reduces swelling, and aids in cooling.

For hot 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 cold therapy in medical institutions or at home. Refer to the warning instructions for restrictions.

6. Intended patient population

The hot/cold pack is applied to most patient.But for the elderly,children, we need to pay attention to them.

The hot/cold pack shall not be applied to following patients:

Sensory impaired or unconscious patients;

Pregnant women;

Patients situations mentioned in the contraindications;

Do not use on infants.

7. Intended user

Hot/Cold Packs shall only be used by adults who can read and understand the instruction manual.

8. Cleaning method

Use damp cloth to wipe down,lay flat and airy,

Do not wash directly with water or use other cleaning and drying methods.

When not in use, please store it in the plastic protective bag at room temperature.

9. Indications

For cold therapy:

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.

For heat therapy:

Relieve local pain and swelling caused by sprains, strains, impacts, bruises, and other injuries, and use within 48-72 hours after the injury occurs;

Local pain and discomfort caused by toothache and mosquito bites;

Physical cooling for patients with high fever;

Local pain and swelling caused by mild burns;

Used to reduce swelling, pain, and bleeding around the wound after surgery;

Relieve postpartum breast swelling caused by milk stasis.

10. Contraindications

For cold therapy:

- Raynauds Phenomenon
- Cold Hypersensitivity
- Cardiac Conditions
- High Blood Pressure
- Superficial Nerves
- Mid-late stage of the wound

For heat therapy:

- 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

11. Undesirable side-effects

Avoid pressing the hot/cold packs on skin directly, which may cause frostbite or 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.

12. Intended clinical benefits

For cold therapy:

- Rapid relief of local symptoms
- Reduce the risk of secondary injury
- Improving patient comfort and mobility

For heat therapy:

- Promote local circulation and tissue repair
- Relieve muscle and joint stiffness
- Relieve chronic and periodic pain
- Preventing discomfort related to low temperature
- Relieve breast swelling

13. Warnings

- For external use only.
- Check the packaging bag without leakage and product within expiry date before using.
- Do not apply if skin is impaired in any way.
- Don't use on infants.
- 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 and call a physician.
- Individuals with circulatory problems should consult a physician before using this product.
- Shall pay attention to the elderly, children and people with communication barriers.
- Take care when removing from microwave oven or refrigerator, hot/cold pack may be very hot or very cold.

14. Cautions

- Consult instructions for use.
- To avoid burns or frostbite, check if the temperature is appropriate before using.
- If the pack feels too warm/cold or if there are significant skin color changes, the hot/cold pack should be removed. You can also wait until the temperature is suitable before using.
- Patients should not lie with their full body weight on top of a cold pack.
- Prior to use, store at room temperature.
- Patients should not lie with their full body weight on top of a hot pack.
- Do not puncture outer bag.
- When reheating, pay attention to adjusting the heating time to prevent excessive temperature.
- If any damage is found during use, do not use.
- Keep out of reach of children.

15. Disposal

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

16. Storage conditions

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

17. Shelf Life

4 years

18. Importer



Name
address

19. Manufacturer

Jiangsu Intco Medical Products Co., Ltd.

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

20. EU Authorized Representative

MedNet EC-REP C Iib GmbH

Borkstrasse 10, 48163 Muenster, Germany

21. Effective Date:

2025-11-3

22. Revision:

A/3

23. 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.

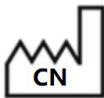
The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website: https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

24.

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

Website: www.intcomedical.com

25. Symbol

| No. | Symbol | Meaning |
|-----|---|---|
| 1 |  | Date of Manufacture Country of Manufacture |



| No. | Symbol | Meaning |
|-----|---|---|
| 2 |  | Use-by date |
| 3 |  | Manufacturer |
| 4 |  | EU authorized representative |
| 5 |  | Batch Code |
| 6 |  | CE Marking |
| 7 |  | Caution |
| 8 |  | Do not use if package is damaged |
| 9 |  | Catalogue number |
| 10 |  | Medical device |
| 11 |  | Importer |
| 12 |  | Unique device identifier |
| 13 |  | Model number |
| 14 |  | Keep away from sunlight |
| 15 |  | Keep dry |
| 16 |  | Consult electronic instructions for use |