

Instruction for Use



1. Product name

Gel Beads

2. Specification/Main contents

XXXX - XX - N,

XXXX - XX - N - R

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

Water, glycerin, sodium polyacrylate.

3. Use Method

The following processing time is for reference:

Product net weight / g	Heating time in Microwave oven / s			Heating in hot water (80-95°C)	Treated by refrigeration	Treated by freezing
	1000w	800w	600w			
100	13	16	21	1min	2h	0.5h
150	19	24	32			
200	25	32	42			
250	15+15	20+20	25+25	2min	3h	1h
300	20+20	25+25	30+30			
350	20+20	25+25	35+35			
400	25+25	30+30	40+40			
450	30+30	35+35	45+45			
500	30+30	40+40	50+50	3min	4h	2h
550	35+35	45+45	60+60			
600	40+40	50+50	65+65			
650	40+40	50+50	70+70			
700	45+45	55+55	75+75			
750	50+50	60+60	80+80	4min	4h	2h
800	50+50	60+60	85+85			
850	55+55	65+65	90+90			
900	55+55	70+70	95+95			
950	60+60	75+75	100+100			
1000	60+60	80+80	105+105			

Note1:

The above 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.

Since microwave ovens vary, more or less heating time may be required to heat to proper temperature.

After heating, rub the pack with your hands to make the temperature more uniform.

For cold therapy:

A) 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,
- Then wrap it in a towel or a piece of cloth for hot therapy, apply to affected area,

B) Hot water heating:

- Heat the water in a container until the temperature reaching 80-95 °C, remove the container from the heat source,
- Soak the product in hot water,
- Check the temperature. If the bag is too hot, let it cool down a bit,
- Then wrap it in a towel or a piece of cloth for hot therapy, apply to affected area,
- Apply to the painful area,
- The best time to use the is within 20 minutes.

For cold therapy:

- Put the pack in the refrigerator for suggested time before using,
- Then wrap it in a towel or a piece of cloth for cold therapy,
- 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: ≥2h)

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

5. Intended Purpose

gel beads 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 gel beads is applied to most patient. But for the elderly, children, we need to pay attention to them.

The gel beads 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

The gel beads shall only be used by adults who can read and understand the instruction manual.

8. Cleaning method

Wash with warm water and use dishware cleaner if necessary. Then dry the water with a clean towel.

If the device material shows signs of deterioration such as hardening, brittleness, or liquid leakage, do not use it again.

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 hot 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 hot therapy:

- 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

11. Undesirable side-effects

Avoid pressing the gel beads 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 hot 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, gel beads 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.
- Always wrap a towel or cloth before applying.
- If the pack feels too warm/cold or if there are significant skin color changes, more layers of toweling should be added or the gel beads 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

3 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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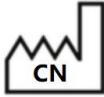
For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized 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
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



Jiangsu Intco Medical Products Co., Ltd.

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