CE	Technical File
	Heat Packs

File No: JSNE/CE/TF/01\_8

Rev. No: B/1

## Instruction For Use

Please read instructions and warnings before use. To reduce the risk of burns, fire and personal injury, this product must be used in accordance with the warnings and use instructions.

DO NOT MICROWAVE.
FOR EXTERNAL USE ONLY.
KEEP OUT OF REACH OF CHILDREN.

#### **Brief Introduction**

Heat pack is intended to be applied to a body surface to provide heat therapy to that surface and/or underlying tissue, e.g. the muscle. It employs a one-time exothermic chemical reaction such as Tri-iron tetraoxide, Vermiculite, Activated Carbon, Sodium Chloride, Water, Super Absorbent Polymer. The reagents are kept in non-woven bag. The inside of bag is coated with PE porous film, which controls the speed of oxygen penetration. One outside of bag might be coated with hydrogel adhesive or hot melt adhesive. This bag is put into PE seal pouch.

When the user tear PE pouch, the oxygen penetrates the bag to make above components activate and self-generate the heat by the Exothermic reaction described above.

#### **Intended Use**

Provides temporary relief of minor muscular and joint aches and pains associated with overexertion, strains, sprains, and arthritis.

#### **Contraindications**

- Not suitable for people who have diabetes, poor circulation or heart disease.
- Not suitable for people with rheumatoidarthritis.
- Not suitable together with other forms of therapeutic heat, including electric heating.
- Do not use of unhealthy, damaged or broken skin, orsensitive skin.
- Not suitable for people unable to remove the product, including children, infants, pets, pregnant women, and physically impaired elderly people.
- Not suitable for children 12 and under.
- Do not use if your doctor does not recommend its use for you or your condition.

#### Warnings

- For single use only. Do not use while sleeping.
- Do not use if the heat pad material is damaged ortorn.
- Do not use in combination with medicated lotions, creams or ointments.
- Do not use on areas of bruising or swelling that have occurred within last 48hours.
- Do not use if you are not capable of applying and removing the wrap by yourself.
- Do not use if you are bedridden or prone to skin ulcers. Pls be more careful to use for older people or the people whose skin acceptance for heat is lower.

- Do not use on areas of the body where you can't feel heat.
- To lower the risk of low-temperature burn, pls do not place extra stress pressure, e.g. by lying when use the product or wearing tight clothing over the product.
- Please check skin frequently for signs of burns or blisters, please stop use if any damage to skin or unusual skin irritation is detected.
- Immediately stop use and ask a doctor if you experience any discomfort, burning, swelling, rash or other changes in your skin.

# **Advisory Note/Precautions**

It is normal to experience slight skin redness after removing the wrap. If your skin is still red after a few hours, stop using heat packs until the redness goes away completely. Be careful and periodically check your skin. Stop use if the pad feels too hot or uncomfortable.

## Operation

- 1. Open the plastic wrapper when ready to use and remove the heat pack.
- 2. Place on area of pain with adhesive side toward skin. Attach firmly.

#### **Main Technical Features**

- The maximum heating temperature is never more than  $63^{\circ}$ C. However, the patch is designed to operate at average temperatures  $40^{\circ}50$  Centigrade.
- The heat release duration lasts 8-12 hours depending on the size and configuration of the heat elements.
- Stable and evenly distributed heat release over the period of its designed use.

#### Ask A Doctor Before Use

If you are pregnant, or have diabetes, poor blood circulation or heart disease, rheumatoid arthritis.

### **Accessories Or Connected To Other Equipment**

No accessories; No connection to any other device.

### Product Specification(s) / Type

Product	Туре	Specification		
		Measure: 50*50mm weight: 2.6g/pcs		
Heat Packs	50×50mm	Packing: 240pcs/ctn		
	50×80mm	Measure: 50*80mm weight: 4g/pcs		
		Packing: 240pcs/ctn		
	70×80mm	Measure: 70*80 mm weight: 5.5g/pcs		
		Packing: 240pcs/ctn		
	60×90mm	Measure: 60*90mm weight: 5.3g/pcs		
		Packing: 240pcs/ctn		
	85×85mm	Measure: 90*290mm weight: 7g/pcs		

	Packing: 240pcs/ctn
	Measure:95*55mm weight: 30g/pcs
95×55mm	Packing: 240pcs/ctn
	Measure: 95*70mm weight: 18g/pcs
95×70mm	Packing: 240pcs/ctn
100.05	Measure: 130*95mm weight: 40g/pcs
130×95mm	Packing: 240pcs/ctn
	Measure: 130*100mm weight: 42g/pcs
130×100mm	Packing: 240pcs/ctn
	Measure: 140*100mm weight: 46g/pcs
140×100mm	Packing: 240pcs/ctn
	Measure: 140*100mm weight: 48g/pcs
145×100mm	Packing: 240pcs/ctn
205.00	Measure: 295*90mm weight: 44g/pcs
295×90mm	Packing: 240pcs/ctn
	Measure: 235*90mm weight: 30g/pcs
235×90mm	Packing: 240pcs/ctn
	Measure: 280*90mm weight: 40g/pcs
280×90mm	Packing: 240pcs/ctn
	Measure: 348*262mm weight: 150g/pcs
348×262mm	Packing: 240pcs/ctn
	Measure: 880*145mm weight: 100g/pcs
880×145mm	Packing: 240pcs/ctn
	Measure: 800*145mm weight: 92g/pcs
800×145mm	Packing: 240pcs/ctn
	Measure: 720*145mm weight: 82g/pcs
720×145mm	Packing: 240pcs/ctn
	Measure: 95*70mm weight: 32g/pair
95×70mm	Packing: 240pcs/ctn
	Measure:230*75mm weight: 76g/pair
230×75mm	Packing: 240pcs/ctn
250.05	Measure:250*85mm weight: 84g/pair
250×85mm	Packing: 240pcs/ctn
265×85mm	Measure:265*85mm weight: 100g/pair

		Packing: 240pcs/ctn		
	285×95mm	Measure:285*95mm weight: 120g/pair		
		Packing: 240pcs/ctn		
	130×95mm	Measure:130*95mm weight: 40g/pcs		
		Packing: 240pcs/ctn		
	185x80mm	Measure:185*80mm weight: 48g/pcs		
		Packing: 240pcs/ctn		
	250:425 /	Measure:250*135mm weight: 36g/pcs		
	250×135mm(adhesive)	Packing: 240pcs/ctn		
	250×135mm(with bandage)	Measure:250*135mm weight: 46g/pcs		
		Packing: 240pcs/ctn		
	185×70mm	Measure:185*70mm weight: 15g/pcs		
		Packing: 240pcs/ctn		
	340×260mm	Measure:340*260mm weight: 130g/pcs		
		Packing: 240pcs/ctn		
	350×260mm	Measure:350*260mm weight: 140g/pcs		
		Packing: 240pcs/ctn		
	290×120mm	Measure:310*119mm weight:50 g/pcs		
		Packing: 240pcs/ctn		
	410×140mm	Measure:410*140mm weight: 60g/pcs		
		Packing: 240pcs/ctn		

# Life time: 3 years

# Interpretation of labels, symbols, abbreviations, etc.

***	Manufacturer	EC REP	European union authorization representative
M	Date of manufacture	$\square$	Expiry date
LOT	Batch number		Characters of "Do not use if package is damaged"
7	Characters of "Keep dry"	<b>淡</b>	Characters of "Keep away from sunlight"

2	Characters and symbol denote "Do not use repeatedly"	Ţ	Characters and symbol of "Caution"
€0197	CE mark	(i	Characters and symbol of "Consult Instruction for use"

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