20418

WarmGel® Infant Heel Warmer with Lift & Stick Tape **Directions for Use**

DESCRIPTION

The WarmGel® Infant Heel Warmer with Lift & Stick Tape is a disposable heel warmer for use when circulation needs to be stimulated in the newborn or infant heel in order for blood sampling to occur. When the Infant Heel Warmer is activated at 75° F (24° C), the temperature of the Infant Heel Warmer rises from 75° F (24° C) to a maximum of 107° F (42° C), then gradually diminishes over time.

INDICATIONS FOR USE

An instant warm pack intended to be used on an infant's heel to increase blood circulation to the area to aid in the drawing of blood for analysis. It is a single use, non-toxic, non sterile, disposable warmer.

The device is primarily used in hospitals, doctor's offices, and other healthcare facilities.

CAUTION

U.S. Federal law restricts this device to sale by or on the order of a physician.

WARNINGS: Failure to follow these warnings can lead to severe burns

- Do not apply to injured, swollen, infected, or inflamed areas of skin or skin
- Do not leave on skin longer that 10 minutes
- · Routinely and regularly check the infant's skin for redness while the device is on the skin.
- · Do NOT apply a covering or wrap around the Infant Heel Warmer that has been placed on the infant's foot.
- Consult a physician when using this product on premature newborns
- · Do not use in the presence of poor circulation, or if the infant has sensory
- The unattended use of the Infant Heel Warmer by childen or incapacitated persons may be dangerous.
- · Single Use only. Do not reuse or reheat.
- Use before expiration date to prevent risk of burn.
- Do not store at temperatures above 72° F (22° C)

INSTRUCTIONS FOR USE

- 1. Locate metal disc and grasp with thumb and forefingers of both hands.
- 2. Flex (bend) disc rapidly until crystals begin to form.
- 3. Place on heel. Remove the paper strip that covers the adhesive strap. Place around the foot, carefully placing the sticky part of the strap to the bag. Be careful not to adhere to the skin.
- 4. Do not leave on skin longer than 10 minutes.
- 5. Do NOT apply a covering or wrap around the Infant Heel Warmer that has been placed on the infant's foot.
- 6. Dispose of appropriately.

CONTENTS

LOT

Non-toxic Sodium acetate (food grade), water and Cellosize™ (thickening agent). All contents are non-toxic.

EXPLANATION OF SYMBOLS

Batch code

Use-by date

REF Reorder number





Do not re-use

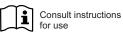


Not made with natural rubber latex.





Authorized Representative in the European Community





Product conforms to the C 60086 Medical Device Directive 93/42/EEC

Made in the USA

WarmGel® is a registered trademark of CooperSurgical, Inc.

Cellosize $\ensuremath{^{\text{TM}}}$ is a trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow.

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Manufactured for:



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EMERGO EUROPE Molenstraat 15 2513 BH, The Hague The Netherlands

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EXPLANATION OF SYMBOLS

REF Reorder number



Caution



Use-by date

Rx ONLY Caution: U.S. Federal

law restricts this device to sale by or

Batch code



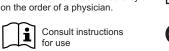
Do not re-use

Not made with

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EC REP Authorized Representative in the European Community





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Manufactured for:



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