

SHOULDER ICE PACK

RHB3037UNI



DUAL-SIDED



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OWNER'S MANUAL

vivehealth.com

SHOULDER ICE PACK

WHAT'S INCLUDED

- 1x Shoulder Ice Pack
- 1x Freezer Bag
- 1x Manual
- 1x Quickstart

PRODUCT DESCRIPTION

The Arctic Flex Shoulder Ice Pack is designed to provide hot or cold therapy to the shoulder area, helping to alleviate pain, reduce swelling, and promote healing for various shoulder conditions including rotator cuff injuries, tendonitis, frozen shoulder, sports injuries, and muscle spasms. It's also suitable for pre and post-surgery care.

INTENDED USE

The medical device is designed to provide support, compression, and/or immobilization for musculoskeletal injuries, post-operative recovery, and chronic conditions. It is intended to aid in the relief of pain, reduce swelling, and promote healing of specific body areas. The device may be used under the guidance of a healthcare professional for rehabilitation, pain management, or daily support.

USER PROFILE

The primary users of bracing and splints are adults ages 18+, healthcare professionals, including physicians, orthopedic specials, physical therapists, and other qualified practitioners. Secondary users may include patients or caregivers, who are instructed by healthcare professionals on the proper application and use of the devices.

The Shoulder Ice Pack is designed to provide targeted cold/heat therapy and compression for shoulder treatment.

ENVIRONMENT

The device is intended for use in various healthcare settings. Suitable for both indoor and outdoor applications within typical residential, commercial, and occupational settings, addressing the requirements of daily living scenarios.

PERFORMANCE CHARACTERISTICS

Main purpose: Provides targeted hot or cold therapy to the shoulder area.

Compression: Adjustable compression for customized support, enhancing blood flow, circulation, and healing benefits.

Targeted application: Shoulder, rotator cuff, and upper arm area.

Adjustability: Fully adjustable straps for a secure and comfortable fit.

All-Day Support: Soft, lightweight, breathable lycra fabric with durable seam stitching for comfort during extended wear.

Versatility: Reversible design suitable for use on left or right shoulder.

Portability: Lightweight and easy to apply, suitable for use at home or on-the-go.

CONTRAINDICATIONS

- Do not use if you have circulatory problems without consulting a doctor.
- Do not apply directly to open wounds or damaged skin.
- Do not use on areas with decreased sensation.
- If you have diabetes, consult your doctor before use.

INSTRUCTIONS FOR USE

Assistance may be required!

1. When pack is at desired temperature, loosely secure the strap through the upper D-ring at the top of the pack.



2. Place the plush side of the pack on the affected shoulder, and pull the strap previously secured, over and under the opposite shoulder. Once under the arm, tighten the strap.



3. Thread the strap on the bicep through the D-ring and back around the arm.



Maximum application time: 20 minutes

Rest period between uses:

1 hour (or until skin returns to normal temperature)

These time limits are important safety precautions to prevent cold-induced injury to the skin and underlying tissues.

Note:

If cooling/heating effects start to lessen, switch the gel pack to the nylon side and repeat the same steps.

HOT/COLD GEL PACK INSTRUCTIONS

Prior to use of the Shoulder Ice Wrap, it is important to understand proper gel pack heating and cooling procedures for safe and effective use.

COOLING INSTRUCTIONS

1. Gently knead the gel pack to ensure that its contents are spread evenly throughout, then lay flat in the freezer for a minimum of 2 hours.

2. Apply the gel pack to the affected area within the included brace. The pack remains flexible when frozen to comfortably contour to the shoulder.
3. Leave the pack on the area for no more than 20 minutes at a time. If used repeatedly, leave the pack off for at least 1 hour before reapplying. Refreeze if needed.

HEAT WITH MICROWAVE

Note:

Gel pack must be at room temperature before heating in microwave.

Caution:

To prevent rupture, ensure pack does not contact microwave waveguide. Fold pack as needed to maintain clearance during heating.



1. Place gel pack flat on a paper towel in microwave.
2. Heat at full power in 20-second intervals until desired temperature.
3. Check for any rupture or leakage.
4. Apply to affected area for 20 minutes maximum.
5. If reheating needed, use 10-second intervals.

CARE INSTRUCTION

Clean using a damp cloth and mild soap. Leave to air dry. **DO NOT** machine wash or dry.

SPECIAL STORAGE & HANDLING CONDITIONS

- Store the gel pack flat when not in use.
- Keep the brace and gel pack away from sharp objects to prevent punctures.
- Store in a cool, dry place when not in use.
- Do not fold or crease the gel pack when storing.
- Keep out of direct sunlight for prolonged periods.
- Do not store the gel pack in the freezer for extended periods (more than 24 hours).
- Handle the gel pack with care, especially when frozen, to avoid damaging the pack
- If the gel pack develops any leaks or damages, discontinue use immediately.

WARNINGS

- Consult your doctor before use, especially for post-surgery support.
- Stop use if pain worsens.
- Assistance may be required during application of the support.
- Do not over tighten, doing so may lead to restricted blood circulation.
- Do not use on open wounds.
- If you experience any swelling, discomfort, or pain, stop use immediately.
- Keep out of reach of children and pets. If gel pack contents are ingested, immediately contact Poison Control Center at 1-800-222-1222.

MATERIALS

- Outer - Nylon and PVC
- Inner - CMC + Glycerin 30% + Water

MANUFACTURE AND PRODUCT INFORMATION

Manufacturer



Vive Health
8955 Fontana Del Sol Way
Naples FL, 34109

service@vivehealth.com
1-800-487-3808
vivehealth.com

Information last updated
10/09/2024

EC	REP
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Compliance Management Solutions Europe
2 Bulgaria Str, 2850 Petrich, Bulgaria.

SIGNS AND SYMBOLS

	Medical device indication ISO/DIS 15223- 1:2020 Reference no. 5.7.7 Indicates the item is a Medical Device.
	CE marking Communauté Européenne Product traded on the extended Single Market in the European Economic Area (EEA); has been assessed to meet high safety, health, and environmental protection requirements.
	Consult instructions for use ISO 7000-1641 Indicates the need for the user to consult the Instructions for Use.
	Manufacturer ISO 7000-3082 To identify the manufacturer of the Medical Device.
	Date of manufacture ISO 7000-2497 To indicate the date on which the Medical Device was manufactured.
	Importer To identify the importer of the Medical Device.
	Caution ISO 15223-1, Clause 5.4.4 To indicate the need for the user to consult the Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the Medical Device itself.
	RHB3037UNI
	Indicates a medical device that has not been subjected to a sterilization process.
	Latex Free
	 00100001150787265415000000000000
	Indicates a medical device that needs to be protected from moisture.
	Indicates a medical device that needs protection from light sources.
	Indicates the temperature limits to which the medical device can be safely exposed.

WARRANTY INFORMATION

Vive Health warrants this product to be free from manufacturing and material defects for a period of one (1) year from the date of purchase under normal use. This warranty extends only to the original purchaser and does not cover:

- Damage from improper use, abuse, or modification
- Normal wear and tear
- Battery or replaceable components
- Products purchased from unauthorized sellers
- Commercial, institutional, or rental use

To obtain warranty service, contact Vive Health customer service with proof of purchase and a description of the defect. Vive Health will repair or replace defective products at our discretion.

IMPORTANT SAFETY NOTICE!!

If you experience any serious incident related to the use of this device, immediately discontinue use and report it to:

1. The manufacturer: Vive Health (8955 Fontana Del Sol Way, Naples FL 34109)
2. Contact your national health authority or medical device regulator.
3. Your healthcare provider.

A serious incident is any incident that directly or indirectly led, might have led, or might lead to:

- Death of a patient, user, or other person.
- Temporary or permanent serious deterioration of a patient's, user's, or other person's state of health.
- A serious public health threat.

For any questions or concerns that are not serious incidents, please contact Vive Health customer service at:

service@vivehealth.com

1-800-487-3808

vivehealth.com

NOTES:

[illegible]

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HAVE MORE QUESTIONS?

Check out our list of Frequently Asked Questions at
vhealth.link/gcm for helpful answers.



And if that doesn't answer your question, our
customer service team would love to help!

Feel free to connect with them by phone,
e-mail, or chat on our website

service@vivehealth.com
1-800-487-3808
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