Empi PHOENIXTM CONDUCTIVE GARMENT

USER'S MANUAL

- Read carefully before using this Garment
- Visit www.djoglobal.com



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IMPORTANT: Please read the Empi[™] Phoenix Device User's Manual (360413 for USA, 360425 for International) before use.

Product Overview

The Empi Phoenix Conductive Garment for the thigh is an accessory to Empi Phoenix device designed to deliver electrical stimulation to muscles to aid with muscle recovery and re-education. This specialized garment is a light-weight, breathable fabric that wraps around the thigh and is secured with Velcro. The Garment is designed to provide a convenient application of therapy.

In the USA, Federal Law restricts this device to sale by or on the order of a physician or other practitioner licensed to use the device.



Intended Use

The Empi Phoenix Conductive Garment is intended for use with the Empi Phoenix device, which is indicated for retarding or preventing disuse atrophy, maintaining or increasing range of motion, and re-educating muscles. The garment provides a conductive pathway between the Phoenix device and the Phoenix Garment Electrodes.

This Garment is only to be used with the Phoenix device's NMES P1 and P2 programs ("Endurance" and "Strength" respectively for the USA, "Disuse Atrophy" and "Reinforcement" respectively for International).

This Garment is intended for use with Empi Phoenix device indoors in a seated position at home or in a clinic environment. Follow your health care provider's directions for more specific use instructions.

Glossary of Symbols

This device may contain one or more of the following symbols:



Refer to Instruction Manual/Booklet



Caution: For Prescription Only Federal law (USA) restricts this device to sale by or on the order of a physician (or licensed practitioner).



Precautionary Instructions



Keep Away from Sunlight

Min and Max storage temperatures.

LATEX FREE No Latex

Warnings and Precautions

For a full list of relevant contraindications, warnings, precautions and adverse reactions, refer to the Empi Phoenix Device User's Manual.

- Single Patient Use Only: Do not share the garment with other persons because of the risks of adverse skin reactions and disease transmission.
- Not a brace: The specialized garment is not intended to be used as a brace/lower leg support.
- Use during activity: This garment is intended to be used in a seated position or in accordance with your clinician's orders. Muscle contractions caused by the device could affect walking or balance.
- Application on broken skin: Should a skin rash or skin burn occur, immediately discontinue use and contact your physician.
- Power connection: Do not connect the garment to an AC power source or other equipment not specified as safe for the garment. Doing so could result in severe shock or burns whether or not the garment is attached to the stimulator. The leadwires should only be connected to the device and the garment.
- Electrodes: The garment should never be used without the three Phoenix Garment Electrodes. Thermal burns may result from use without all electrodes. Electrodes should be securely fastened to prevent inadvertent disconnection. Electrodes will eventually wear out. Check accessories regularly for signs of wear and replace as needed.
- Skin reactions: On rare occasions, therapy can result in transient skin reactions such as rash, inflammation, irritation or burns. These skin reactions may be the result of individual sensitivity, the condition of the skin at the onset of treatment, or a reaction to the materials in the electrodes or garment.
- Safety: The safety and efficacy of the Empi Phoenix system depend on the proper use and handling of the product and accessories. Use only as prescribed. Keep out of reach of children. Keep away from open flame.
- · Use with other devices/accessories: Use only the Phoenix device that is specially designed for this garment. Do not use accessories (including electrodes) or devices manufactured by other companies on this garment. Empi is not responsible for any consequence resulting from using products manufactured by other companies.

Garment Use

- 1. Lay the garment flat with the three conductive silver buttons facing up as pictured.
- 2. Remove the blue plastic lining from the grid side of Phoenix Garment Electrodes and discard.

3. Press the grid side of the Phoenix Garment Electrodes over the silver buttons within the appropriate outlines. If you are using the garment to treat your right leg, place the electrodes in the grey outlines marked with "Right Leg Electrode Placement". If you are using the garment to treat your left leg, place the electrodes in the white outlines marked with "Left Leg Electrode Placement". The large electrode should only be placed within the corresponding larger grey/white dashed outline.

IMPORTANT: Make sure to place ALL THREE electrodes on the garment before using. The electrodes must completely cover each conductive metal button before use.

STOP! If you are using the garment for your LEFT leg, you should have it set up to look like Fig. 1

If you are using the garment for your RIGHT leg, you should have it set up to look like Fig 2.

- Remove the remaining clear liner from the face of the electrodes and SAVE for re-application to Phoenix Garment Electrodes in between uses.
- 5. Sit on the edge of a firm, stable chair with your knee slightly bent and your foot flat on the floor. If your clinician instructed you to use the device and garment in a different setting or position, follow your clinician's instructions.









Fig. 1 Left



Fig. 2 Right

6. Place the wrap over your thigh with the Empi logo facing you and centered on your thigh. The far edge of the garment should be just above your kneecap. The underside of the garment also indicates the proper orientation of the garment in relation to your knee.

IMPORTANT: Do not use this garment on any body part other than the quadriceps/ thigh.

7. Wrap the two straps underneath and around your thigh and affix the Velcro[™] on the softer fabric "landing strip".

With the Phoenix Garment Electrodes aligned over your thigh/quadriceps muscles, gently apply pressure on the top section of the wrap to secure the electrodes against the skin. Do not slide or pull the garment to readjust its position while wearing it as the electrodes may roll up underneath the garment. To adjust, remove the garment completely and reposition.

8. Connect the black plastic leadwire connector to the garment by sliding it onto the port as shown. You should hear an audible click.





- **9.** Attach the Empi Phoenix device by inserting both black leadwire heads into the ports at the top of the device. Press firmly to ensure that the leadwire is fully inserted into the device.
- 10. Begin therapy as directed by your clinician. Unless otherwise directed by your healthcare provider, you should be seated during therapy. You can holster the device in the garment by attaching the device's belt clip and sliding it into the flat, wide strap in the middle section of the garment on top of your thigh. Do not stand up while the device is in place on the garment.

When your session is complete, turn the device off.

IMPORTANT: This Garment is only to be used with the Phoenix device programs P1 and P2. Phoenix device programs P3 and P4 should be used with the direct leadwires and electrodes provided with the device.



Storage

- Gently remove the garment. The Phoenix Garment Electrodes will lift off of your skin and stay attached to the wrap. Electrodes should remain on wrap for storage. If the electrodes remain on your skin instead of the garment, remove them from your skin and place them back on the garment in the appropriate location.
- Replace the saved liner on the electrodes. Be sure to place the "ON" side against the Phoenix Garment Electrode surface.
- Store the garment in its original bag until next treatment. Re-applying the liners, folding up after each use, and storing the wrap in re-sealable bag will prolong the life of the Phoenix Garment Electrodes.

Maintenance

Check the specialized garment before each use for signs of wear and/or damage. Make sure that the electrodes have good tack so that they will stick well to the skin.

Replace the Phoenix Garment Electrodes as required. See "Electrode Use" section for Phoenix Garment Electrodes maintenance suggestions. When electrodes are no longer useful, dispose of them in a receptacle out of the reach of children or pets.

If needed, you may wash the Phoenix Garment. See label on wrap for washing instructions. Make sure the garment is dry before using it. With proper care, this garment is designed to have a life of six months.

Environmental Conditions

Operating Conditions

- Temperature Range: 10° C to 40° C (50° F to 104° F)
- Atmospheric Pressure Range: 50kPA to 106 kPa
- Relative Humidity Range: 30% to 75%

Storage and Transport Conditions

- Temperature Range: -40° C to 70° C (-40° F to 158° F)
- Atmospheric Pressure Range: 50kPA to 106 kPa
- Relative Humidity Range: 10% to 90%

Electrode Use

You can extend the use of your Phoenix Garment Electrodes by following these suggestions:

- · Cleanse, rinse and dry skin prior to use.
- · Store electrodes as indicated above and on electrode packaging.
- If electrode gel becomes dry, adding a few drops of water to each side of the electrode may help restore adhesive gel of electrode. Let the electrode rest to regain tack before applying to skin.

90 Day Warranty

Empi will repair or replace, at its facility, any product found to be defective within 90 days of purchase. This warranty does not apply to any product damaged by misuse, or repaired or altered by anyone other than Empi in Clear Lake, SD, or an officially approved DJO Global service center.

This warranty is in lieu of any or all other warranties expressed or implied. No person is authorized to bind Empi to any representative of warranty other than those specifically set forth herein.

NOTE: Warranty period begins with the date of purchase from manufacturer.

Ordering

To reorder call: Empi at 800.328.2536 (USA Only)

Empi Phoenix Garment - P/N 235684

Phoenix Garment Electrode Pack – P/N 199695 (pack of two 4"x2.75" (10 x 7 cm) and one 6"x3.5" (15 x 9 cm))





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