Assembled in the United States of America

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Device Box Components
  1 – The RCStim Device
  1 – Power Supply
  1 – Literature Pack

Orthofix Clinical Helpline: 866-657-7030
Rotator Cuff Repair Study

Thank you for participating in the Orthofix Rotator Cuff Repair Study. This study is being conducted to determine if the RCStim device can improve the healing of medium to full thickness tear rotator cuff injuries after muscle repair.

The RCStim device has not been approved by the FDA for use in patients who have undergone rotator cuff repair and its use is considered investigational. The device used in this study is designed to be centered over the treatment area so that your rotator cuff muscles will receive an adequate amount of electromagnetic field generated by the RCStim device. **The device comes in either a right shoulder or a left shoulder model.**

Your doctor should have instructed you to use the device for **90 minutes each day for 6 months**. It is very important that you use the RCStim device each day as your doctor has directed. If you do not use the device correctly, we may not be able to determine the effects of the treatment on rotator cuff repair surgery healing.

If you have any questions regarding your device, please contact your doctor’s office for assistance.

We sincerely thank you for your participation in the Orthofix Rotator Cuff Repair study.
Device Information

The RCStim device is being evaluated as an adjunctive therapy for the healing of the rotator cuff muscles following rotator cuff repair surgery.

Device Description

The RCStim device is an external device that generates a Pulsed Electromagnetic Field (PEMF) signal as a nonsurgical, prescription treatment to increase the chances of a successful rotator cuff repair. The device is lightweight and portable, including a rechargeable battery that allows freedom of movement during treatment. A Liquid Crystal Display (LCD) and audible indicators provide important feedback during treatment. See “Device Operation” for more information.
How the RCStim Device Works

To enhance rotator cuff repair, PEMF therapy activates and augments the body’s natural healing process.

The RCStim device contains a Control Unit and a Treatment Coil in one integrated device. A micro-processor generates the PEMF signal, which is a highly uniform, low-energy pulsed electromagnetic field sent from the treatment coil. When the coil is centered over the treatment area, the therapeutic signal is delivered through clothing and skin directly to the treatment site.

Device Life
The RCStim device provides 90 minute daily treatments for 6 months.

Putting the RCStim Device on your Shoulder

1. Fasten one end of the elastic strap to the end opposite the control unit.

2. Place the RCStim device so that it is centered over the treatment site (left or right shoulder). The control unit should be in front and visible to the patient.

3. Bring the elastic strap around the body under the opposite arm and fasten on the end of the device next to the control unit.

4. If strap adjustment is needed, loosen or tighten the strap until it feels secure and comfortable.
Device Operation

Turning the Device On and Off

The RCStim device can be turned on by pressing the On/Off Button on the Control Unit of the device.

When the device is turned on, it will display the Compliance Screen with Compliance percentage.

The LCD will then show the Treatment Screen with the prescribed treatment time remaining and the battery status.

The flashing colon (:) on the LCD screen and the flashing On/Off button indicate that the device is on and delivering a treatment.

The RCStim device can be turned off by pressing and holding the On/Off Button until it beeps.

The On/Off Button on the Control Unit doubles as a Backlight button to light up the LCD in low light conditions. Depress and let go to turn on the backlight; it will automatically turn off.
Daily Treatment Instructions

• The first time the RCStim device is worn it should be worn for the full 90 minutes so that the compliance log is initiated.

• The RCStim device should be worn for 90 minutes each day as directed by your physician.

• The RCStim device may be used at any time of day that is most convenient for you.

• The device is programmed to allow one treatment per day and reset daily at midnight central standard time.

• Treatments will be automatically logged in the compliance log of the device the day the treatment is started.

• Because the RCStim device is lightweight and portable, treatment can be received while sitting, walking, reclining, sleeping, etc. However, since each patient is unique, the overall activity level should be based on physician instructions.

Treatment Sessions

• The RCStim device tracks the treatment time; this tracking (or timing) begins when the device is turned on and at least one minute of treatment is complete.

• The LCD shows a countdown of the daily treatment time remaining.

• To stop treatment at any point, simply press and hold the On/Off Button until you hear a beep.

• To resume treatment, press the On/Off button again.

• The countdown will resume at the remaining daily treatment time.

• When daily treatment is completed, the device will automatically turn off.

• The device will allow only one treatment per day.

Charging the Battery

The RCStim device is powered by a rechargeable lithium-ion battery pack. The battery pack will provide at least one full treatment before needing to be recharged. A power supply to charge the battery is provided with the device.

Use only the Orthofix power supply that came with the device to charge the RCStim device (Part no. Orthofix 20110412 or 20114794).
To ensure that the device is functioning properly, the RCStim device constantly monitors battery voltage and the electrical signal. The LCD will display a battery capacity symbol and the device will beep to alert you when the battery is low and will soon need to be recharged.

The RCStim device should be charged before the first use and every day after completing treatment. Do not wear the device while charging. The device will not deliver treatment while charging.

**Follow these steps to recharge the battery:**

1. Open the Charging Port Cover.
2. Plug the Charging Connector into the Charging Port located on the Control Unit.
3. Plug the power supply into any standard AC Wall Outlet. Do not plug in the power supply for the RCStim device where it will be difficult to unplug.
4. The LED on the power supply will light up green as an indicator that the AC Wall Outlet is delivering power.
5. The Control Unit LCD will display a battery symbol filling to verify that the device is charging. When the battery reaches a complete charge, a check mark symbol will be displayed next to the battery symbol. In addition, the device will beep once to alert the patient.
6. If the battery is fully depleted, it may require up to 4 hours to charge completely.
7. After charging is complete, remove the Charging Connector and replace the Charging Port Cover.
Visual and Audio Indicators
The LCD and audible beeps are designed to provide helpful information to the user. The screens, symbols, and beeps are explained below.

Compliance Screen

170/185 = 94.4%

Compliance Screen – Displays a compliance percentage which is calculated by the number of full treatments days completed over the number of available treatment days.

Treatment Screen

RX 1:30

Treatment Screen – displays the treatment time remaining in hours and minutes. The timer counts down to zero until daily treatment is complete.

Treatment Complete

RX ✓

Daily Prescribed Treatment complete

Charging Screen

Battery Charging – Battery symbol filling repeatedly verifies that the device is charging.

Charging Complete

Charging Complete – Indicates when the battery is fully charged.

Low Battery Warning Screen

RX 1:30

Low Battery – Displays along with three fast beeps when recharging is recommended.

Battery must be charged to turn on

Battery Empty – Indicates that the battery must be charged before treatment may continue.

Device Expired

Device Expired – Display of a closed lock indicates the device has been available for treatment and will no longer provide a treatment.

Exception Screen

Exception Codes – Display of ERROR, any E codes (e.g., E01, E02), along with three slow beeps. Contact the Orthofix Clinical Helpline at 1-866-657-7030 for help.
Device Compliance

This device works with an app that can be downloaded from the iTunes App store on your iPhone or iPad; it is free of charge. With this app, you will be able to monitor how long you have worn your device every day and whether or not you are being “compliant” with the study requirements. The App provides detailed views of daily compliance information, will allow you to monitor treatments and also provides additional resource information.

Device Use and Care

• The RCStim device is for single patient use.
• The RCStim device is a technologically advanced electronic device and should be handled with care. Dropping or other mishandling of the RCStim device may damage the device and it may stop working.
• For safe usage, follow your physician’s instructions when using the RCStim device. You are the intended operator of this device.
• Use of the device in any other manner could have harmful effects.
• Inspect the device prior to each use for wear, deterioration or damage.
• Do not use or charge the device if it does not appear to be in suitable condition, displays an error or stops working. Contact the Clinical Studies Helpline (1-866-657-7030) if any of these occur.
• **WARNING:** Do not modify this equipment as this could make it unsafe to use. Do not attempt to open or disassemble the RCStim device as there are no user serviceable parts inside.
• **CAUTION: STRANGULATION HAZARD** – Keep the device and power supply cord out of the reach of children.

Care and Cleaning

When cleaning the RCStim device, follow these instructions:
• **WARNING:** Do not clean the device during treatment or charging.
• Clean the device by wiping surfaces with a damp, soft cloth (dampen with water only).
• **DO NOT** sterilize the RCStim device.
• **DO NOT** expose the RCStim device to excessive moisture.
• **DO NOT** use solvents or alcohol-based liquids (anti-bacterial cleaners, hand sanitizers, perfume, etc.) to clean the RCStim device.
Storage of the Device

Unpacked Storage:
When moving the RCSstim device from very cold or very hot storage areas (like your car), wait at least an hour to use or charge the device. The device requires time to return to operating temperature.

Temperature Range:
- -25°C to 5°C (13°F to 41°F)
- 5°C to 35°C (41°F to 95°F) at up to 90% relative humidity, non-condensing
- 35°C to 60°C (41°F to 140°F) at a water vapor pressure up to 50 hPa

Packed Storage, Shipping and Transport:
Temperature Range: within -40°C (-40°F) to 60°C (140°F)
- Between 10-100% relative humidity
- Including condensation at pressures between 500 hPa and 1060 hPa

Operating Environment:
Temperature Range: within 5°C (41°F) to 40°C (104°F)
- 15-90% relative humidity, non-condensing but not requiring a water vapor pressure greater than 50 hPa
- 700-1060 hPa

Traveling with the RCSstim Device

When traveling by air, the RCSstim device may be packed in carry-on or checked luggage since it only contains a permanently installed lithium-ion battery and no spares. However, it is recommended to pack the device with checked luggage. If taken onboard the airplane, it should be turned off when passing through security screening equipment, as the device could be damaged. The device instruction manual should be taken with you to quickly and easily identify the device for security personnel. Do not wear or operate the PEMF device while onboard the airplane.

Disposal

RETURN THE RCSstim DEVICE TO YOUR DOCTOR’S OFFICE

DO NOT dispose of this device. At the end of your prescribed treatment period in the study, please bring the RCSstim device with you to your study appointment and they will send it back to the study sponsor (Orthofix) for you.
Service

If you have questions concerning the device or require any assistance, please call the Clinical Study Helpline at 1-866-657-7030. There are no serviceable parts in this device.

Contraindications

There are no known contraindications for the RCStim device as an adjunct to rotator cuff repair surgery.

Warnings

• Do not use the RCStim device if you have a cardiac pacemaker or defibrillator because it may interfere with the operation of your pacemaker or defibrillator. If you use the RCStim device and it affects your pacemaker or defibrillator, it may injure your heart. Consult your cardiologist before using the RCStim device.
• Remove the RCStim device prior to any imaging procedures (e.g., CT scan, MRI, etc.). If you wear the RCStim device during these procedures, you could be injured, the imaging being produced may be ruined, and/or the RCStim device could be damaged.

Precautions

• Avoid using the RCStim device if you do not understand the instructions your doctor has given you. If you use the RCStim device incorrectly, it may harm you or may not help your healing process.
Known and Expected Adverse Events

Adverse effects may be experienced when using the RCStim device. These adverse effects may include increased pain, numbness and tingling, headache, migraines, and nausea. These effects may or may not be directly related to use of the RCStim device. Any adverse effects that are related to the RCStim device should stop when you discontinue use.
### Equipment Classification

#### Device Symbol Descriptions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
<th>Symbol Location</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>Attention – Refer to Instruction Manual</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>Type BF Applied Part</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>On/Off</td>
<td>Device</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>Prescription Only</td>
<td>Device</td>
</tr>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>Storage Temperature Range</td>
<td>Device Box</td>
</tr>
<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>Year of Manufacture for Active Device</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>Manufacturer</td>
<td>Instruction Manual</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>Not for General Waste</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>Keep Dry</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image10" alt="Symbol" /></td>
<td>FCC Mark</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image11" alt="Symbol" /></td>
<td>CE Mark</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image12" alt="Symbol" /></td>
<td>Storage Humidity Limits</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image13" alt="Symbol" /></td>
<td>Atmospheric Pressure Limitations</td>
<td>Device Box</td>
</tr>
<tr>
<td><img src="image14" alt="Symbol" /></td>
<td>Catalog Number</td>
<td>Device and Device Box</td>
</tr>
<tr>
<td><img src="image15" alt="Symbol" /></td>
<td>Serial Number</td>
<td>Device and Device Box</td>
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</tbody>
</table>
The RCStim Device Classifications

• Product Family Name: Orthofix PEMF Device
• Internally powered equipment.
• This device generates a non-ionizing pulsed electromagnetic field with an intensity of approximately 2 Gauss and frequency components in the 1Hz-50KHz range. This field is distributed within and near the treatment coil.
• Type BF applied part. The applied part is the treatment coil with integrated control unit.
• IEC 60529 enclosure rating: IP22. IP22 means the enclosure provides protection from solid objects less than 12.5 mm and dripping liquids when tilted 15° from normal use. It is recommended you keep the unit dry.
• Mode of operation: intermittent operation
• This device is non-sterile. It does not require sterilization.
• Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or nitrous oxide.
• The power supply is considered double insulated with Class II construction throughout.
• Power supply ratings:
  Orthofix # 20110412: Orthofix # 20114794:
  Input: 100-240VAC, 50-60Hz, Input: 100-240VAC, 50-60Hz,
  200mA 150-350mA
  Output Voltage: 5VDC, 1.3A Output Voltage: 5VDC, 2.4A

Compliance Statements

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT! Changes or modifications not expressly approved by Orthofix, Inc. could void the user’s authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on,
the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

**Information regarding Electromagnetic Compatibility and Immunity**

The RCStim device complies with IEC 60601-1-2 for electromagnetic compatibility (EMC). The RCStim device needs special precautions regarding EMC and needs to be used in accordance with the EMC information provided in this manual. Wireless communications equipment such as home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect the RCStim device. These types of equipment should be kept at least 0.198 m (7.8 in) away from the RCStim device.
Rx Only
Caution: Investigational Device Limited by Federal (or United States) law to investigational use.

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Clinical Helpline
866-657-7030

orthofix.com