

# Activ8

by OrthoCor



Scan to learn more about Pulsed Shortwave Therapy (PST) and what to expect when using the Activ8 System.

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# INTRODUCTION

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## **ABOUT THIS USER GUIDE**

This guide describes the Activ8 System and provides instructions for using it. Please read the entire manual carefully before use. This manual contains information, contraindications, and warnings, which must be observed to assure safe operation and to maintain the device in a safe condition. This device must be used in accordance with the instructions and warnings.

## **TECHNICAL DESCRIPTION**

The Activ8 System is a portable, compact, lightweight, non-invasive system designed to deliver Pulsed Shortwave Therapy (PST), sometimes referred to as non-thermal shortwave diathermy, for temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis.

The device consists of a multiple-use pulsed electromagnetic field (non-thermal shortwave diathermy) therapy device, referenced as the 'Activ8 System,' and a multiple-use, rechargeable battery pack.

# USAGE & PACKAGE COMPONENTS

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## RECOMMENDED USAGE

The Activ8 System is recommended to be worn for two 30-minute treatments per day by adults users. However, your care provider may modify this recommendation to optimize your care.

For prescription use (Rx) only, use adjunctively with standard of care treatment.

## YOUR ACTIV8 SYSTEM CONTAINS:

### Activ8 System:

Multiple-use system designed to provide therapy to specified areas of the body.

### External Battery Pack:

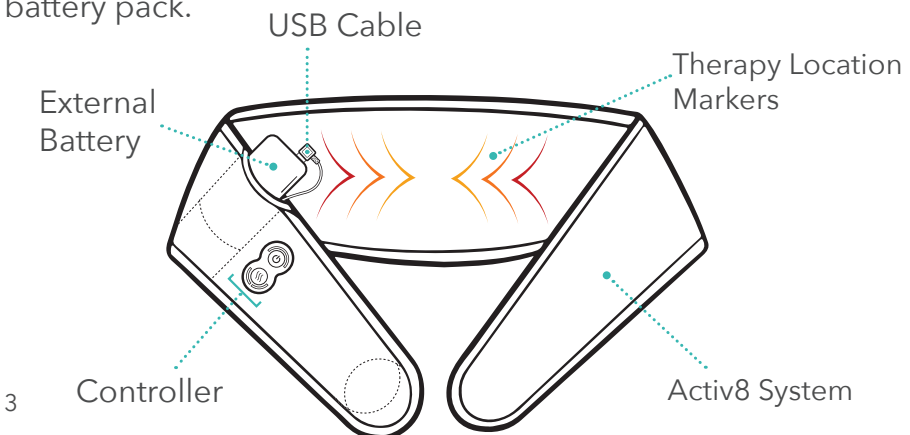
Rechargeable battery designed to power the Activ8 System.

Input (USB-C): 5V== 2.0A

Output (USB1 or USB2): 5V== 2.7A

### AC Adapter/Charger:

USB-C compatible AC charger used to charge the external battery pack.



# INDICATIONS & CONTRAINDICATIONS

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Before using the Activ8 System, please read all of the indications, contraindications, warnings, and cautions in the following sections.

## INDICATIONS FOR USE

The OrthoCor Activ8 System is indicated for adjunctive use in the temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis.

## CONTRAINDICATIONS

- Do not use on patients with a cardiac pacemaker, cardioverter defibrillator, neurostimulator, infusion pump or any implantable electronic device.
- Do not use on patients who have ANY implanted metallic leads (wires) or any type of wire coil implant, or any implanted system that may contain a lead (wire).
- Do not use on patients who are or may be pregnant.
- Do not use on patients with an open wound at the area of application.
- Do not use on patients who are not adults or individuals with open growth plates.
- Do not use on patients not fully aware of the sensation of heat.
- Do no use on patients with poor circulation or heart disease.
- Do no use on patients with diabetes.

# SAFETY INFORMATION

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## SAFETY INFORMATION

- This device has been manufactured and tested in accordance to IEC 60601-1 and IEC 60601-1-2 (Class B).
- There are no serviceable parts inside the Activ8 System.
- Energy from non-thermal shortwave diathermy therapy can be transferred through an implanted system with metallic leads or electrodes, resulting in severe injury or death.
- The Activ8 System may interfere with appliances that are designed to detect and amplify weak radio signals. This includes television, radios, citizen band radios, phones, and other consumer devices in these categories. The interference may be heard as a repetitive tick in an FM radio and may cause tearing of a TV picture.

## CLEANING INSTRUCTIONS

Visually inspect the system for dirt or debris, if any is present wipe clean with a damp cloth. Repeat the inspection, if any dirt or debris remains repeat the cleaning process.

## DISPOSAL

- The Activ8 garment contains no hazardous materials.
- The Activ8 external battery is a lithium-polymer component and must be disposed of according to local environmental regulations.

## **WARNINGS**

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- This device should be used under the continued supervision of a licensed health care practitioner.
- This product contains a lithium-polymer battery. Improper use or charging may cause fire or explosion. Do not crush, puncture, expose to heat, or use an unauthorized charger. Stop use immediately if the battery is damaged or overheating.
- Use carefully. Remove immediately if discomfort occurs.
- Precaution should be taken when using this device on the elderly or incapacitated persons.
- Precaution should be taken when using this device on patients with sensitive skin. If the patient experiences skin irritation, discontinue the use of the device and consult your licensed health care practitioner before using the Activ8 System again.
- Do not over-tighten the Activ8 System as this may restrict blood flow and result in injury.
- Switching the Activ8 System to low heat mode during therapy may result in non-therapeutic heat.

## CAUTIONS

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- Use this device only in the prescribed manner and for the prescribed diagnosis.
- KEEP AWAY FROM WATER. Use in dry environment.
- The device is not indicated for treatment of deep tissue such as internal organs.
- Do not use while the Activ8 System is charging.
- Do not machine wash the Activ8 System.
- Do not crush the Activ8 System as this may damage the electronics.
- NEVER heat the Activ8 System or battery pack in the microwave as the system could catch on fire.  
Pressing the power button will stop the treatment.
- The AC adapter/charger must be disconnected from the battery pack for treatment to occur.
- Keep out of reach of children and pets.
- For external human use only.
- Keep device at least 1" from electrostatic discharge disturbances while charging. Failure to do this could result in a temporary delay in battery charging, or require unplugging the device & plugging it back in.

# INSTRUCTIONS FOR USE

## Step 1: Charge the Activ8 System Battery

- Remove the battery from the garment pocket.
- Disconnect the battery from the Activ8 system.
- Connect the charging cord to the battery using the USB-C port.
- Plug the AC charger into a working electrical outlet.



A blinking light indicates the battery is charging.	
The battery is fully charged when all four LED indicator lights are solid (not blinking).	

Charging may take up to 8 hours for fully depleted batteries.

## BATTERY CHARGE INDICATOR LEDS

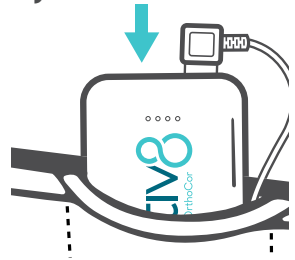
Pressing the button on the side of the pack to show charge level.	25% Full	
	50% Full	
	75% Full	
	100% Full	

# INSTRUCTIONS FOR USE

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## Step 2: Connect the Charged Battery

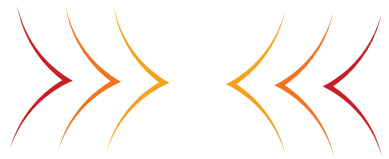
- Connect the fully charged battery to the garment using the USB cable.
- Insert the battery into the garment pocket with the Activ8 logo facing outward.



**Note:** The battery must be on, with LEDs illuminated, to power a therapy session. If the battery has been turned off, disconnect the battery from the garment and reconnect it to wake the battery.

## Step 3: Apply the Activ8 Garment

- Apply the Activ8 garment on the treatment area.
- Align the therapy location markers inside the garment over the area where therapy should be delivered.
- Adjust the garment so it fits comfortably. Do not overtighten.



**Garment specific instructions and video links can be found on pages 13–21 of this guide.**

# INSTRUCTIONS FOR USE

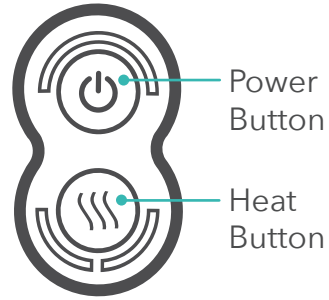
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## Step 4: Start Your Therapy Session

Press the Power Button on the Activ8 Controller to start therapy.

Therapy Session (30 minutes total)

- Pulsed Shortwave Therapy runs for the full 30 minutes.
- Heat therapy:
  - High heat: first 20 minutes
  - Low heat: last 10 minutes



Both therapies stop automatically when the session ends after 30 minutes.

To adjust the heat level during therapy, repeatedly press the Heat Button to cycle through:



HIGH



LOW



OFF

Adjusting the heat does not affect PST therapy delivery.

# INSTRUCTIONS FOR USE

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## Step 5: Complete Your Therapy Session

The Activ8 device will turn off automatically after 30 minutes.

You may also:

- Press the Power Button to stop therapy early.



If a therapy session is ended early, pressing the Power Button again starts a new 30-minute session.

After each session:

- Check the battery indicator lights.
- Recharge the battery if the charge is low.



## What will therapy feel like?

### **Pulsed Shortwave Therapy (PST)**

PST is sub-sensory, which means you will not feel the therapy working. There is no tingling, buzzing, or pulsing sensation as the PST works.





### **Soothing Warmth**

In addition to PST, gentle heat is provided for soothing comfort and should feel pleasantly warm, but is not intended to provide intense heat.

# INSTRUCTIONS FOR USE

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## ACTIV8 LED CONTROLLER LIGHTS

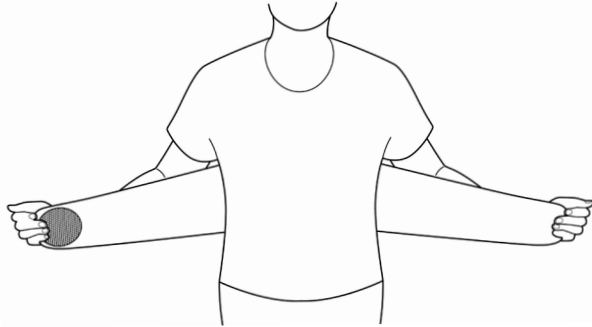
Status	Light	Indication
Therapy is Running	Solid green LED above the power button.	
High Heat	Both orange LEDs below the heat button are lit, with the power LED also lit.	
Low Heat	One orange LED below the heat button is lit.	
No Heat	No orange LEDs below the heat button are lit.	
Device Failure	LEDs flash for ten seconds and then turn off. Contact Customer Service.	

# GARMENT APPLICATION

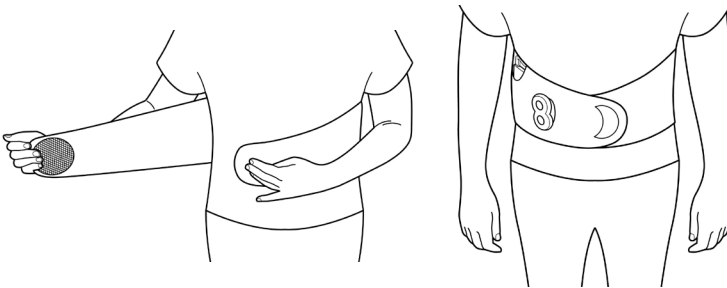
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## Back

1. Position the back device around the waist, centering the two therapy location markers on the inside of the device on either side of the spine - they should be positioned directly over the intended treatment area.



2. Fasten the system comfortably around the front of the body. Adjust to fit, but do not overtighten.



## Video Instructions



# GARMENT APPLICATION (CONT.)

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## Knee

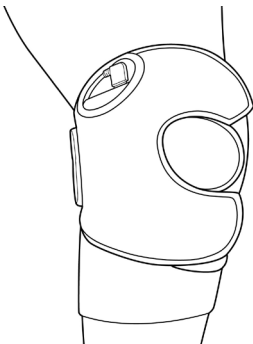
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1. Position the smallest portion of the device behind the knee, and the therapy location markers centered on either side of the knee joint.



2. Attach the upper and lower hook-and-loop portions of the device across the front of the knee - the opening for the battery pocket should be facing upwards (the logo text should be right side up).

Adjust to fit but do not overtighten.



Video Instructions



# GARMENT APPLICATION (CONT.)

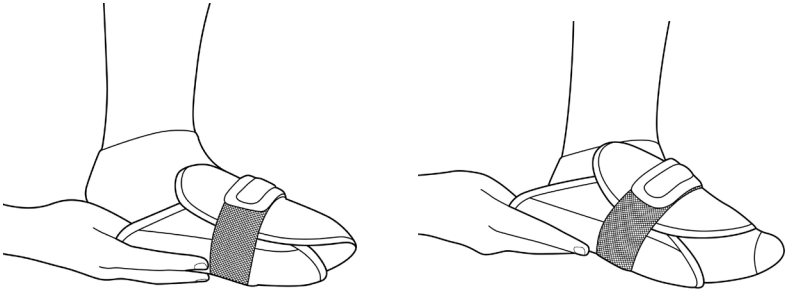
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## Foot

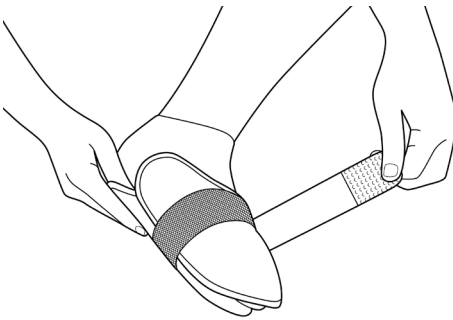
Video Instructions



1. With the smaller flap on the top of the foot, slide the device onto the front of the foot until the therapy location markers are centered over the intended treatment area.



2. Adjust the elastic strap until snug, do not overtighten.

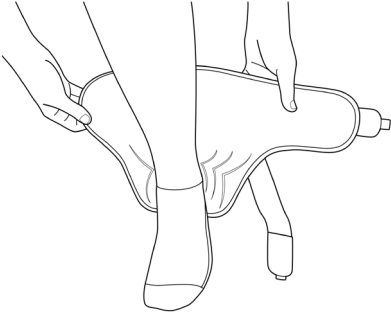


# GARMENT APPLICATION (CONT.)

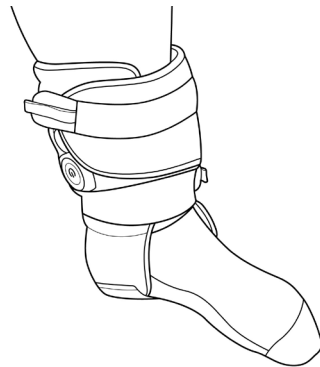
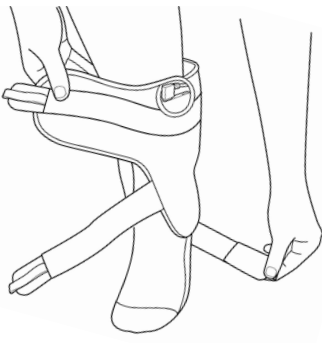
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## Ankle

1. Place the heel of the affected foot into the elastic stirrup, with the open portion of the device facing the front of the foot.



2. Tighten or loosen the elastic stirrup using the hook-and-loop adjustment until the therapy location markers on the inside of the system are centered over the ankle bone or intended treatment area.
3. Attach both of the other straps across the front of the ankle onto the loop portion of the system to secure it.



### Video Instructions



# GARMENT APPLICATION (CONT.)

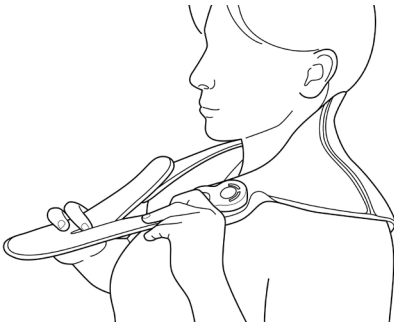
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## Neck

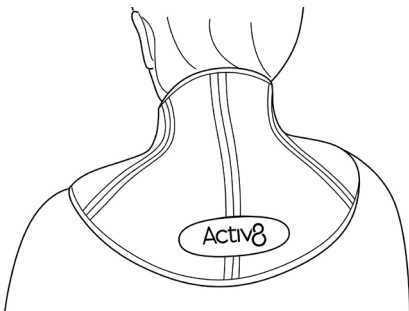
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1. Position the device around the neck ensuring the therapy logos on the inside of the device are positioned at the back of the neck of the neck.

Video Instructions



2. Ensure that the top edge of the back of the device lays against the upper neck where it meets the base of the skull.



# GARMENT APPLICATION (CONT.)

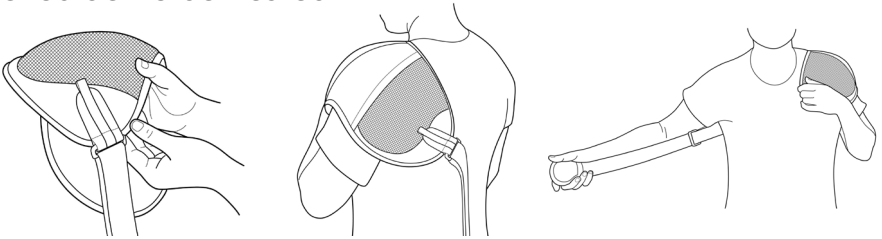
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## Shoulder

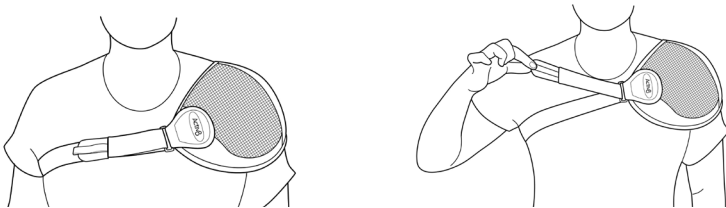
### Video Instructions



1. Determine which shoulder needs to be treated. Using the hook-and-loop, attach the end of the large strap without a logo to the garment so the strap runs behind the shoulder to be treated.



2. Place device on shoulder, let the strap hang down the back. Reach around with the opposite hand to grab the strap, then pull it up and across the chest.



3. Secure the end of the strap with the logo to the system on the front of the chest. Use the strap glider to fine-tune the fit until it feels secure but comfortable.

### Fit Tips:

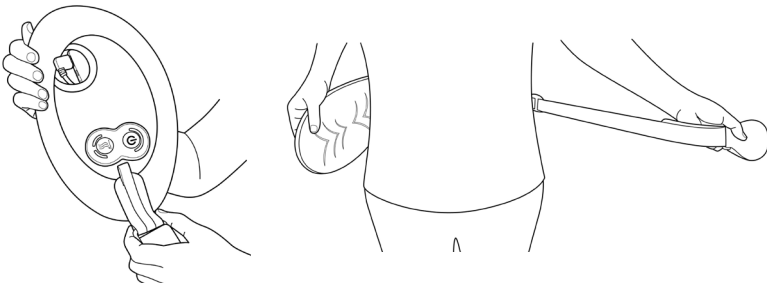
- For a tighter fit across the front of the shoulder, try attaching the loop portion to the top of the shoulder.
- For larger adjustments, the strap and device may need to be removed from the body before adjusting.

# GARMENT APPLICATION (CONT.)

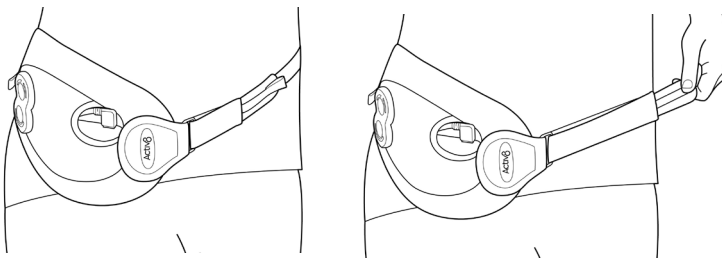
## Universal/Hip

1. Determine the size of strap needed based on the body part to be treated.
  - *Limbs/Extremities: small strap*
  - *Waist/Hip/Torso: large strap*
2. Attach the logo-free hook portion of the strap to the loop perimeter of the device.
3. Position the therapy location markers on the inner portion of the universal device over the intended treatment area.

### Video Instructions



4. Wrap the strap around your body and secure it to loop surface on the system wherever needed to hold the device in place securely.
5. Use the adjustable strap glider to adjust fit until snug, do not overtighten.



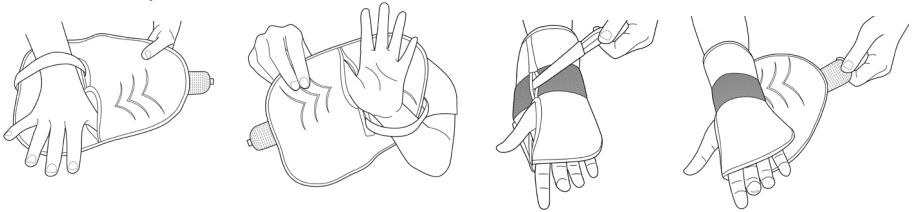
# GARMENT APPLICATION (CONT.)

## Hand/Wrist

### Wrist Fitting

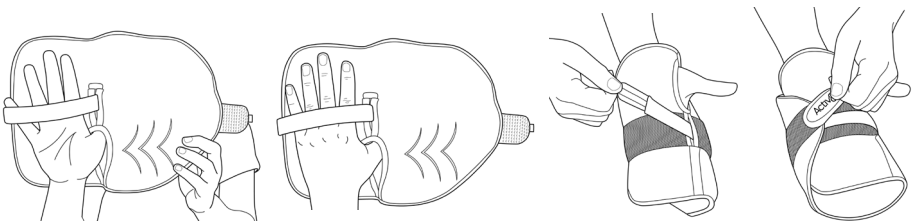
1. Place hand through the elastic strap on the inside of the system, and thumb through the hole.
2. Tighten the elastic adjustment strap until the device is snug, do not overtighten.
3. Close the outer flap and secure it in place with the hook-and-loop closure.

Video Instructions



### Hand Fitting

1. Place fingers through the elastic strap on the inside of the device, and thumb through the hole.
2. Tighten the elastic adjustment strap until the system is snug, do not overtighten.
3. Close the outer flap and secure it in place with the hook-and-loop closure.



# GARMENT APPLICATION (CONT.)

## Elbow

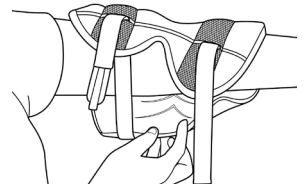
Battery orientation is important when using the elbow device. Regardless of which elbow is being treated, the battery should rest on the outside of the upper arm to keep it away from the sensitive nerves in the forearm.

### Video Instructions



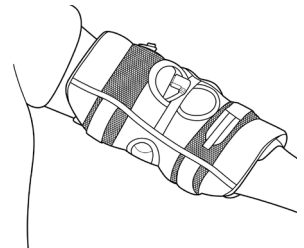
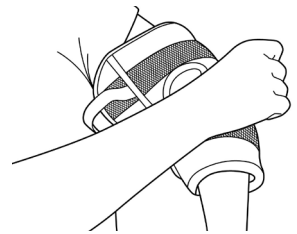
### Left Elbow

1. Slide the device onto the left arm.
2. Position the device on the arm so that the therapy location markers are positioned over each side of the elbow.
3. Pull the elastic straps to tighten the system. Wrap the elastic around your arm until you can fasten the hook-and-loop.



### Right Elbow

1. Slide the device onto the right arm.
2. Position the system on the arm so that the therapy location markers are positioned over each side of the elbow.
3. Pull the elastic straps to tighten the system. Wrap the elastic around your arm until you can fasten the hook and loop.



*Fit Tip: Regardless of arm, it is easier to pull the straps toward the body rather than away from it.*

# WARRANTY & SUPPORT

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## WARRANTY

OrthoCor Medical offers a six-month limited warranty on any defects in materials and workmanship.

## RETURN POLICY

OrthoCor Medical does not accept returns or offer refunds, except for unopened product within 60 days of shipment.

## SUPPORT

If you have questions not covered in this user guide, please email, call, write, or visit our website.

### OrthoCor Medical

8611 W 35W Service Drive NE

Suite 180

Blaine, MN 55449

888-583-6268

[customersupport@orthocormedical.com](mailto:customersupport@orthocormedical.com)









[www.orthocormedical.com](http://www.orthocormedical.com)

### Customer Support Hours:

8:00 AM to 4:30 PM Central Time










# SYMBOL DEFINITION TABLE

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 The symbol consists of the letters 'Rx' in a large, bold, serif font, with the word 'ONLY' in a smaller, bold, sans-serif font directly below it.	Indicates that federal (US) law restricts this device to sale by or on the order of a physician.
 The symbol consists of the letters 'MD' in a bold, sans-serif font, enclosed within a rectangular border.	Indicates the item is a medical device.
 The symbol consists of an open book icon with a lowercase letter 'i' positioned to the right of the book's center.	Indicates the need for the user to consult the instructions for use.
 The symbol consists of a circle containing a diagonal line from the top-left to the bottom-right, with a lowercase letter 's' positioned below the line.	Indicates a medical device that is intended for one single use only.
 The symbol consists of a simple black silhouette of a person standing, enclosed within a rectangular border.	To identify a type BF applied part complying with IEC 60601-1.
 The symbol consists of an umbrella icon with several small dots above it representing rain.	Keep dry.
 The symbol consists of a triangle with the words 'NON' and 'STERILE' stacked vertically inside it.	Indicates a medical device that has not been subjected to a sterilization process.
 The symbol consists of a triangle with a large exclamation mark inside it.	Indicates that attention must be given before using the product.

## SYMBOL DEFINITION TABLE (CONT.)

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	Indicates the temperature limits to which the medical device can be safely exposed.
	Indicates the medical device manufacturer.
	Indicates the medical device is for single-patient, multiple use.
	Indicates a carrier that contains Unique Device Identifier information.
	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates when the medical device was manufactured.
	Indicates the date after which the medical device is not to be used.
	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

# CLINICAL EFFICACY

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## CLINICAL EFFICACY

A clinical trial conducted by MediCept showed for patients with soft tissue and joint pain, the Active System as an adjunctive therapy was significantly more effective at reducing pain than the Standard of Care (SOC) alone. Specifically, the study primarily enrolled participants in the foot, knee and shoulder groups. The clinical data was clinically meaningful in the foot, knee and shoulder. The study examined the change from baseline in pain assessment scores at the end of 2 weeks of study treatment using the Mankowski scale. The SOC group experienced a 10% reduction in pain while the Active System group had 36% reduction in pain.

## NON-THERMAL SHORTWAVE DIATHERMY TECHNICAL SPECIFICATIONS

Average Output Power: 5.5 mW

Peak Output Power: 1.35 W

Frequency: 27.12 MHz

Burst Duration: 2.0 ms

Burst Frequency: 2.0 Hz

## HEATING TECHNICAL SPECIFICATIONS

Number of Heat Generators: 2

Temperature Range of Heat Generators Between System and Patient: 35°C-45°C

Area Under Each Heat Generator Affected: 4.5 in<sup>2</sup>

Heating Volume for Each Heat Generator: 1.5 in<sup>3</sup>

# ESSENTIAL PERFORMANCE

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## ESSENTIAL PERFORMANCE

- The device outputs therapeutic pulses (see NON-THERMAL SHORTWAVE DIATHERMY TECHNICAL SPECIFICATIONS).
- The device outputs heat corresponding to the heating level the device is set at.



Manufactured by  
OrthoCor Medical - Blaine, MN 55449

Made in the USA  
U.S. and foreign patents issued.  
DC Rating: 5.0V  $\approx$  2.7A

This system is intended for a home use environment.





[www.orthocormedical.com](http://www.orthocormedical.com)