

Active system

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Para obtener la versión en español de esta guía del usuario, visite nuestro sitio web en: www.orthocormedical.com/patient-resources/

INTRODUCTION

ABOUT THIS USER GUIDE

This user guide describes the OrthoCor Active System® and provides instructions for using it. Please read the entire guide carefully before use. This user guide contains information, contraindications, and warnings, which must be observed to assure safe operation and to maintain the OrthoSource in a safe condition. This system **MUST** be used in accordance with the instructions and warnings.

TECHNICAL DESCRIPTION

The OrthoCor Active System is a portable, compact, lightweight, non-invasive system designed to deliver pulsed electromagnetic field (non-thermal shortwave diathermy) therapy for temporary relief of pain, such as pain associated with over-exertion, strains, sprains, and arthritis. The system consists of a multiple-use therapy device, referenced as the 'Active System,' a multiple-use, rechargeable pulsed electromagnetic field (non-thermal shortwave diathermy) module, referenced as the 'OrthoSource,' and single-use therapy pods, referenced as 'OrthoPods,' which are sold separately. The Active System houses both the OrthoSource and OrthoDocks, which are appropriately positioned to deliver therapy to the treatment site.

USAGE & PACKAGE COMPONENTS

RECOMMENDED USAGE:

The OrthoCor Active System is recommended to be worn for one 2-hour treatment per day by adult 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.

PACKAGE COMPONENTS & ACCESSORIES

Your OrthoCor Active System contains:

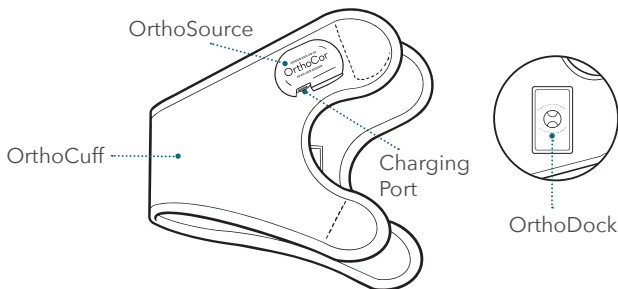
OrthoCuff: Multiple-use device designed to house both the OrthoSource and OrthoPods and direct therapy to the appropriate areas of the body.

OrthoSource: Module that contains electronics necessary to deliver pulsed electromagnetic field (non-thermal shortwave diathermy) technology.

OrthoDock: Where OrthoPods are inserted on the OrthoCor Active System

AC Adapter/Charger: USB-C compatible AC charger used to charge the OrthoSource.

OrthoPods: Single-use, heat delivering therapy pods



INDICATIONS & CONTRAINDICATIONS

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

INDICATIONS FOR USE

The OrthoCor Active 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), 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 not use on patients with poor circulation or heart disease.
- Do not use on patients with diabetes.

SAFETY INFORMATION

SAFETY INFORMATION

- This device has been manufactured and tested in accordance with IEC 60601-1 and IEC 60601-1-2 (Class B).
- There are no serviceable parts inside the OrthoCor Active 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 OrthoCor Active 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 device 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

- This device contains a lithium-ion battery and must be disposed of according to local environmental regulations.

WARNINGS

WARNING: This device should be used under the continued supervision of a licensed health care practitioner.

WARNING: Use carefully. Remove immediately if discomfort occurs.

WARNING: Precaution should be taken when using this device on the elderly or incapacitated persons.

WARNING: 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 OrthoCor Active System again.

WARNING: Do not over-tighten the Active System as this may restrict blood flow and result in injury.

CAUTIONS

CAUTION: Use this device only in the prescribed manner and for the prescribed diagnosis.

CAUTION: KEEP AWAY FROM WATER . Use in dry environment.

CAUTION: The device is not indicated for treatment of deep tissue such as internal organs.

CAUTION: Do not use while the Active System is charging.

CAUTION: Do not machine wash the Active System.

CAUTION: Do not crush the OrthoSource or the Active System as this may damage the electronics.

CAUTION: NEVER heat the OrthoCor Active System or OrthoPods in the microwave as the system could catch on fire.

CAUTION: Removing the OrthoPods will stop the treatment.

CAUTION: The AC adapter/charger must be disconnected from the OrthoSource for treatment to occur.

CAUTION: Keep out of reach of children and pets.

CAUTION: For external human use only.

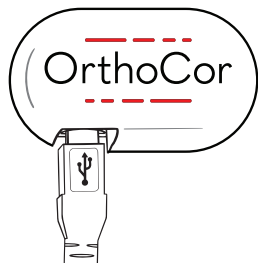
CAUTION: Keep device at least 1" from electrostatic discharge disturbances while charging. Failure to do this could result in a temporary delay in battery charging, or require unplugging the device and plugging it back in.

SYSTEM SETUP

PRIOR TO USE: CHARGING

Make sure to fully charge your device prior to the first time you use it.

1. Plug the power cord into the USB-C port on the bottom of the OrthoSource. A red light will indicate the device is charging.
2. When the device is fully charged, the red light will turn off. The device takes 90 minutes to charge.



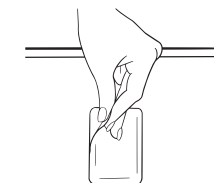
STEP 1: PREPARE PODS

1. Open a new package of OrthoPods 5-10 minutes before you start a therapy session to allow them to warm up.
2. Follow the operating instructions included with the OrthoPods.



STEP 2: INITIATE THERAPY

1. Insert the OrthoPods into the OrthoDocks on the OrthoCor Active System. The magnetic fasteners should ensure a strong connection.
2. A blue light will appear on the OrthoSource, indicating that the therapy session has begun.
3. Therapy will run for 2 hours.



GARMENT APPLICATION

STEP 3:

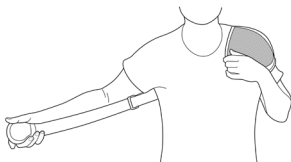
Find your device configuration below and follow the instructions. Adjust to fit comfortably but do not overtighten.

SHOULDER

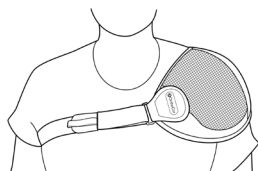
1. Determine which shoulder needs to be treated. Using the hook and loop, attach the end of the large strap without a logo to the garment so the strap runs behind the shoulder to be treated.



2. Place device on shoulder, let the strap hang down the back. Then reach around with your opposite hand and grab the strap from behind your back, pulling it up and across your chest.

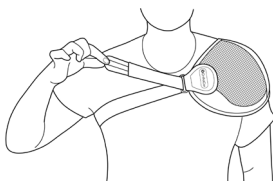


3. Affix the logoed hook portion of the strap to the loop portion of the device on the front of your chest.



(Fit Tip: for a tighter fit across the front of the shoulder, instead attach to the loop portion on top of the shoulder.)

4. Adjust the strap using the adjustable strap glider until it is comfortable.

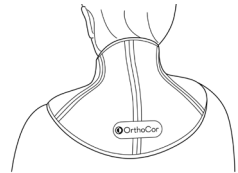
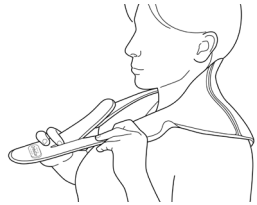


(Fit Tip: for larger adjustments, the strap and device may need to be removed from the body before adjusting).

GARMENT APPLICATION (CONT.)

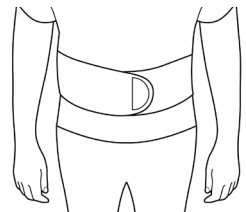
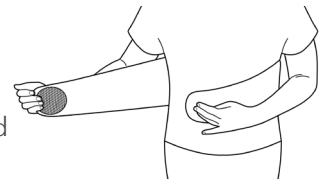
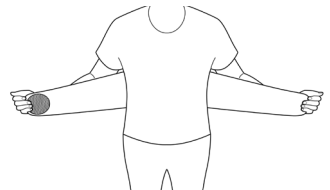
NECK

1. Position the device around the neck, ensuring the OrthoPods are on the inside and rest against the back of the neck.
2. Ensure that the top back of the device lays against the upper neck.



BACK

1. Position the back device around the waist, centering the OrthoPods 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 device comfortably around the front of the body. Adjust to fit, but do not overtighten.

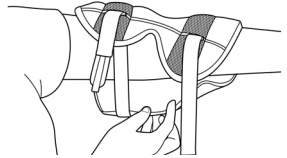
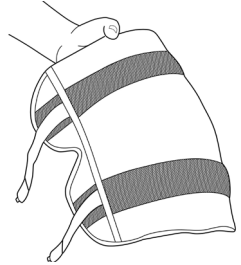


GARMENT APPLICATION (CONT.)

ELBOW

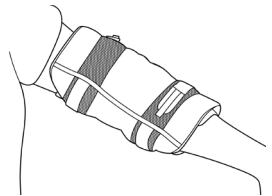
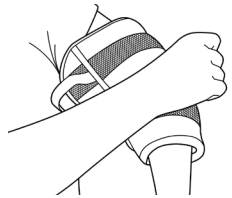
Left Elbow

1. To treat the left elbow, slide the device on so that the OrthoSource is upside down on your forearm.
2. Position the device on the arm so that the OrthoPods are positioned over each side of the elbow.
3. Pull the elastic straps to tighten the device. Wrap the elastic around your arm until you can fasten the hook and loop.



Right Elbow

1. To treat the right elbow, slide the device on so the OrthoSource is right side up on your upper arm.
2. Position the device on the arm so that the OrthoPods are positioned over each side of the elbow.
3. Pull the elastic straps to tighten the device. Wrap the elastic around your arm until you can fasten the hook and loop.

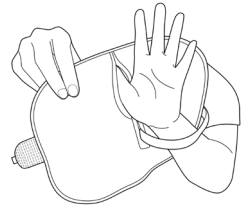
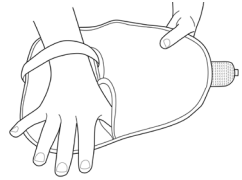
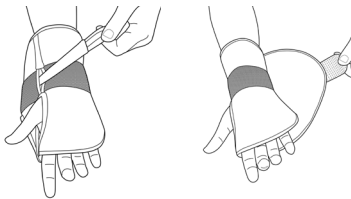


GARMENT APPLICATION (CONT.)

HAND/WRIST

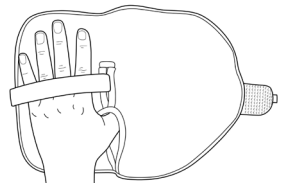
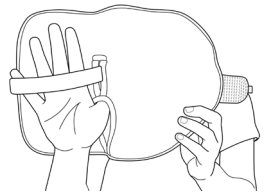
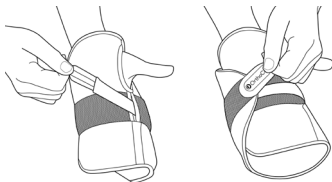
Wrist Fitting

1. Place hand through the elastic strap on the inside of the device, and thumb in the hole.
2. Tighten the elastic adjustment strap until the device is snug, do not overtighten.
3. Close the device around the wrist using the hook and loop attachment.



Hand Fitting

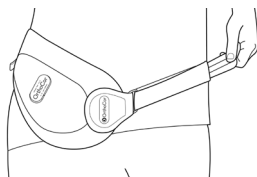
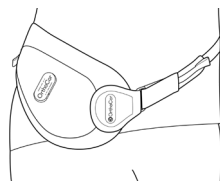
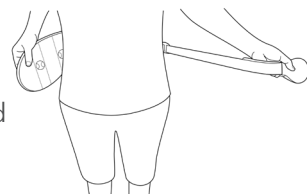
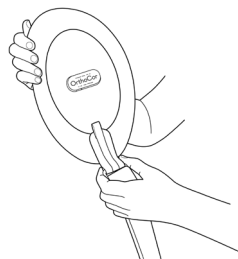
1. Place fingers through the elastic strap on the inside of the device, and thumb through the hole.
2. Tighten the elastic adjustment strap until the device is snug, do not overtighten.
3. Close the device around the hand using the hook and loop attachment.



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 universal device.
3. Position the OrthoPods on the inner portion of the device over the intended treatment area.
4. Wrap the strap around your body and secure it to ring of loop on the device wherever needed to hold the device in place securely.
5. Use the adjustable strap glider to adjust fit until snug, do not overtighten.

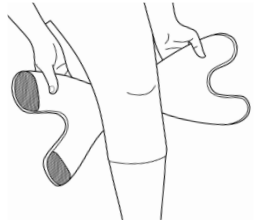


GARMENT APPLICATION (CONT.)

KNEE

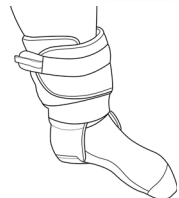
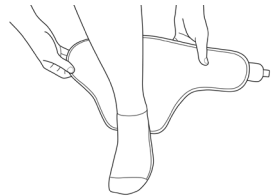
1. Position the smallest portion of the device behind the knee, and center the OrthoPods on either side of the knee joint.
2. Attach the upper and lower hook and loop portions of the device across the front of the knee (the OrthoSource text should be right side up).

Adjust to fit but do not overtighten.



ANKLE

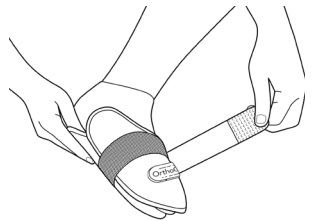
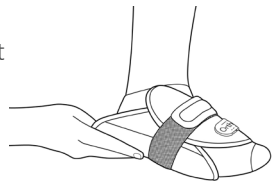
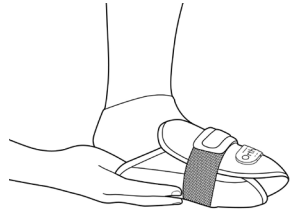
1. Place the heel of the ankle that is to be treated into the elastic stirrup, with the open portion of the device facing the front of the foot.
2. Tighten or loosen the elastic stirrup using the hook and loop adjustment until the OrthoPods on the inside of the device are centered over the ankle bone or intended treatment area.
3. Attach the strap across the front of the ankle onto the loop portion of the device to secure it.



GARMENT APPLICATION (CONT.)

FOOT

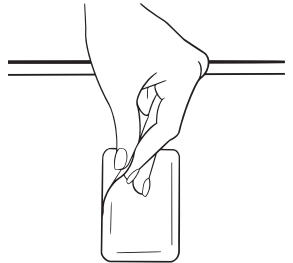
1. With the smaller flap on the top of the foot, slide the device onto the front of the foot until the OrthoPods are centered over the intended treatment area.
2. Adjust the elastic strap until snug, do not overtighten.



CONDUCTING A THERAPY SESSION

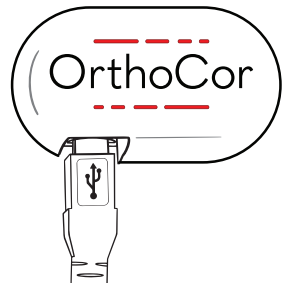
STEP 4: ENDING THERAPY

1. After 2 hours, the blue indicator light on the OrthoSource will flash for 2 minutes before turning off – indicating the end of the therapy.
2. Remove the OrthoCor Active System from the body.
3. Firmly grasp each OrthoPod and pull it away from the device until the connection with the OrthoDock is released. Dispose of the used OrthoPods in the trash.



RECHARGING INFORMATION:

- A freshly charged Active System should have sufficient power for two full therapies before needing to recharge.
- Leaving a fully charged device connected to the charger will not harm the battery; the device may be left charging until the beginning of the next therapy.



FREQUENTLY ASKED QUESTIONS

How do I know when my device is charged?

When your device is fully charged, the red light will turn off.

What if the red light does not come on when I'm charging the device?

The red light will only turn on while the battery is charging. Make sure there is power to the outlet you are using, and the USB-C charger is fully inserted into the OrthoSource charging port. If the red light still will not turn on, please contact OrthoCor Medical.

What if the blue light does not turn on when I insert new OrthoPods?

Make sure the OrthoCor device is fully charged, and the OrthoPods are properly seated in the OrthoDock. The blue light should appear to indicate the therapy session has begun. If the issue persists, please contact OrthoCor Medical.

How do I know that the therapy is completed?

After 2 hours, the blue indicator light on the OrthoSource will flash for 2 minutes indicating the end of the therapy. The light will completely turn off after 2 minutes.

WARRANTY & SUPPORT

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

www.orthocormedical.com










Customer Support Hours:

8:00 AM to 4:30 PM Central Time

SYMBOL DEFINITION TABLE

 <p>R_x ONLY</p>	Indicates that federal (US) law restricts this device to sale by or on the order of a physician.
 <p>MD</p>	Indicates the item is a medical device.
	Indicates the need for the user to consult the instructions for use.
	Indicates a medical device that is intended for one single use only.
	To identify a type BF applied part complying with IEC 60601-1.
	Keep dry.
 <p>NON STERILE</p>	Indicates a medical device that has not been subjected to a sterilization process.
	Indicates that attention must be given before using the product.

SYMBOL DEFINITION TABLE (CONT.)

	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

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

Peak Output Power: 1.35 W

Average Measured Output Power: 5.5 mW

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 Device and Patient: 35°C-45°C

Area Under Each Heat Generator Affected: 4.5 in²

Heating Volume for Each Heat Generator: 1.5 in³

ESSENTIAL PERFORMANCE

ESSENTIAL PERFORMANCE

- The battery can be charged via USB .
- The device outputs therapeutic pulses (see NON-THERMAL SHORTWAVE DIATHERMY TECHNICAL SPECIFICATIONS) .



Manufactured by
OrthoCor Medical - Blaine, MN 55449

Made in the USA
U.S. and foreign patents issued.
3.7 V DC Internally Powered

This system is intended for a home use environment.





www.orthocormedical.com