ExcelsiusArc

Excelsius Arc KN1
Instruction Manual

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Contents

INTENDED USER PROFILE

INTENDED USE/INDICATIONS

CONTRAINDICATIONS

WARNINGS AND CAUTIONS

SYMBOLS

ENVIRONMENTAL CONDITIONS

HOW TO PUT ON THE KNEE RECOVERY SYSTEM

INSTALLING AND USING THE APP

CHARGING THE KNEE RECOVERY SYSTEM

CLEANING INSTRUCTIONS

MATERIAL CONTENTS

CONTACT INFORMATION

FCC STATEMENTS

WARRANTY

DISPOSAL

Before using the device, please read the following instructions completely and carefully. Correct application is vital to the proper functioning of the device.

Intended User Profile

The intended user should be a licensed medical professional, the patient, the patients care provider, or a family member providing assistance. The user should be able to read, understand and be physically able to perform and follow the directions, warnings, and cautions provided in the information for use.

This device is not intended for use by children

Intended Use Indications

The Knee Recovery System is intended to provide pre and post-operative knee support during the prehabilitation and rehabilitation process. The Knee Recovery System is intended to be used to measure and evaluate survey and exercise compliance and knee joint range of motion during rehabilitation in the pre-operative and post-operative periods of reconstructive knee surgery.

Contraindications

None

Warnings and Cautions

The Knee Recovery System is intended to be worn during waking hours in direct contact with skin and clothing or as directed by a medical professional. If you experience any pain, swelling, sensation changes, or any unusual reactions while using this product, consult your medical professional immediately.

Do not wear the knee band while swimming
Do not wear the knee band while in the shower or bath
Do not wear the knee band while sleeping

Warning: Equipment contains lithium batteries. There is danger of explosion if lithium ion batteries are incorrectly used.

Symbols

	Warning! Read and understand all warnings and instructions for use before using this device
	Temperature range
	Atmospheric pressure range
	Manufacturer
	Non-ionizing electromagnetic radiation
	Humidity range
Rx ONLY	Prescription only

Environmental Conditions

Operating Conditions	Temperatures	50°F (10°C) TO +104°F (40°C)
	Relative Humidity	30% to 75% non-condensing
	Atmospheric Pressure	700hPa to 1060hPa
	Altitude	Maximum of 3000m
Transport and Storage Conditions	Temperatures	-13°F (-25°C) without relative humidity control, up to 140°F (60°C)
	Relative Humidity	5% to 95% non-condensing
	Atmospheric Pressure	700hPa to 1060hPa

When operating after transporting or storage in elevated or low temperature conditions, keep sensors at ambient temperature for at least 25 minutes prior to operation.

What’s in the Box

The Knee Recovery System consists of

- 1 Knee Band
- 1 USB C charging cable
- 1 power adapter
- 2 long straps
- 2 short straps

How to Put on the Knee Recovery System

NOTE: Put the knee band straps over wound dressings or over clothing. Do not place the knee band on incision or open/broken skin.

1. CHECK TO SEE YOU HAVE ALL OF THE PARTS
   For putting on the knee band, you should have
   a. 1 Excelsius Arc band
   b. 2 short guide straps (optional)
   c. 2 long straps (optional)
2. ATTACH THE BAND
   a. In a seated position with your leg extended, place the neoprene knee band on your thigh so that **“Above Knee”** is on your middle thigh and you can read it.

b. Be sure to keep the **WHITE LINES** on the knee band in the **CENTER** of your thigh and your shin.

c. Wrap the thigh tabs around your thigh and attach them:

i. While keeping the white line in the center of you thigh, wrap the right tab under your thigh and then fasten the left tab on top of it.

d. Wrap the calf tab around your calf:

   i. While keeping the white line in the center of your calf, wrap the right tab under your your calf and then fasten the left tab on top of it.

e. Stand up and adjust the straps as needed to keep them in place. Because of the physiology of the thigh, you may need to pull up and then tighten the thigh strap after you stand up.

f. For many people this will be all that is needed to keep the knee band in place. If you feel you need additional tightening, proceed to the next step.

3. OPTIONAL – ATTACH THE GUIDE STRAPS
IMPORTANT NOTE: THE MOST COMFORTABLE POSITION IS WHERE THE STRAP BELOW THE KNEE IS JUST ABOVE THE THICKEST PART OF THE CALF. THIS HELPS MAINTAIN THE KNEE BAND POSITION DURING ACTIVITY.

   a. Attach the short guide straps

      i. Thigh Guide Strap: Attach a short guide strap to the left side of the knee band so that the plastic loop is on the side of your thigh.

ii. Calf Guide Strap: Attach a short guide strap to the left side of the knee band so that the plastic loop is on the side of your calf.

b. Attach the long straps

i. Attach the long strap loop to the right side of your thigh.

ii. Slide a long strap through the short guide strap loop and pull it through

iii. Wrap the long strap around the back of your leg and then thread the end of the long strap through the loop on the right side

iv. Pull back the opposite direction to tighten. Then attach the long strap around the back of the leg.

v. Repeat with the calf strap to complete

4. TEST FITTING

   a. Stand up and take a few steps. Make adjustments as needed to the band's tightness and to the band's position on the leg.

   b. Your clinician may help you set up your knee band and may use a goniometer or other tools to determine proper angles for a custom fitting.

5. FITTING NOTES

   a. The Excelsius Arc will shift over time and may need to be adjusted as you perform your exercises. It's normal to need to tighten or loosen a strap as needed so that you feel comfortable in the recovery process.

Installing and Using the App

1. **Check your email on your phone.** You should have an email from **support@excelsiusarc.com** with instructions for how to install the Excelsius App.
2. Tap the link to download the app. The link will open your app store.
3. Download and then open the app.
4. Enter your email address into the Excelsius App. Press “Continue”.
5. We’ll then send you a registration link to your email.
6. Go back to check your email on your phone. You will have received a new email from support@excelsiusarc.com
7. Open the new email and tap the link in the new email.
8. After tapping the link, it will open the Excelsius App and log you in.
9. Follow the on-screen instructions to set up the app and pair your knee band with your phone.

   NOTE: Connecting to your band only needs to happen once. After you’ve completed the setup process, the knee band will automatically pair with your phone.

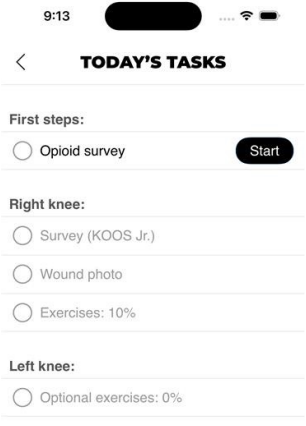
The Home Screen

Once on the home screen, which looks like the image below, tap “Get Started” in the center of the screen to proceed to your recovery task list.

Your Task List

You may be asked to take surveys or and/or perform evaluations. This will be part of your standard routine with the app during your recovery. Proceed through the list of tasks.

When you've completed the other tasks, press the "Start" button next to exercises.

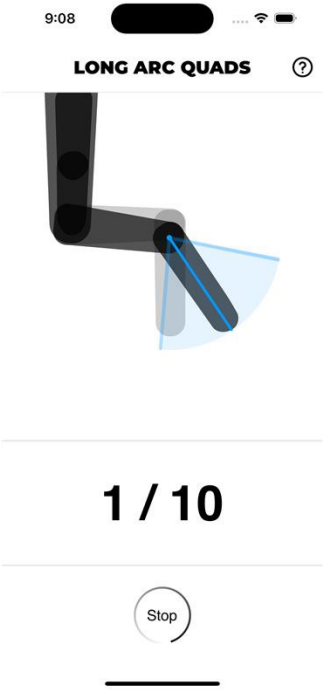


How to Get Ready to Perform Exercises

Note: Your knee band sensors should already be charged. *If they are not, be sure to use the included USB charger and adapter to charge the sensors. The sensors will blink red while they are charging. When the sensors are fully charged, the lights will stop blinking.*

1. The app will automatically connect to the sensors in the knee band
2. The connection screen will provide an indication of battery level.
3. Press Next.
4. You'll be shown a screen for how to put on the knee band. Make sure that the sensors are aligned the the center of the top of the thigh and the middle of the shin.
5. Press Next.
6. You'll be asked to tap the top sensor to confirm it's put on correctly.
7. Press Done
8. Choose an exercise to perform by tapping on it on the exercise screen.
9. You will be shown how to perform the exercise and there will be a text description as well that takes them through the proper steps.
10. Tap "I'm Ready" to proceed with the exercises.

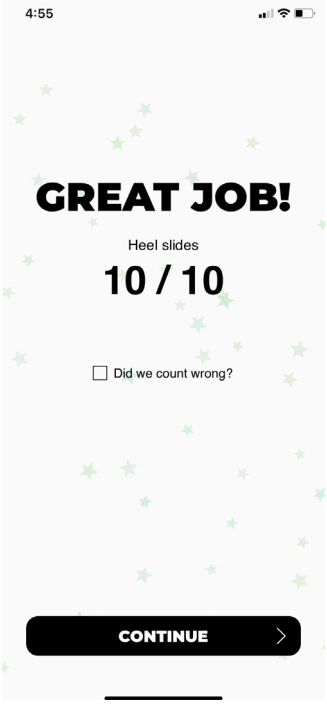
Once ready, get into the position shown on the screen. At which point the black arrow at the bottom of the screen will appear. Tap the black arrow, wait for the countdown to reach 0, and then begin.



While performing the exercise the avatar will move with you in real-time as you perform the exercises. If you've forgotten how to perform the exercise, tap the **"?"** in the top right of the screen to view the video instructions again.

Once you're finished with the exercise, the application will confirm the count.

The app will then ask you about your pain level. Submit and continue to the next exercise until you're done for the day.



Charging the Knee Recovery System Sensors

To charge your knee band's sensors, plug in the USB Y cable provided into the power adapter.

1. Plug the USB cable into the port in the wall adapter.
2. Plug the smaller USB ends of the Y cable into each of the ports in the sensors on the band.
3. Plug the adapter into the wall.
4. Once the band has fully charged, the lights on the sensors will stop blinking.

Cleaning Instructions

DO NOT WASH THE KNEE BAND
Gently wipe knee band with a separate cloth or towel with water (86°F/30°C) using light soap. Wipe again with a damp cloth or towel and then let dry. Repeat as needed.

Material Contents

Nylon, Styrene Acrylonitrile Butadiene Rubber, Chloroprene Rubber, Neoprene, Polyester, mSiO2 nH2O (anti-slip material)

Contact

If you are having any medical issues or need an urgent response, please call your doctor's office directly.

If assistance is needed with the knee band or setting up or using the app, please call or email:

Email: **support@excelsiusarc.com**
Visit: **www.excelsiusarc.com**

FCC Statements

Warning: Changes or modifications to this device not expressly approved by (Globus Medical, Inc.) could void the user's authority to operate the equipment.

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.

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.

This equipment complies with radiation exposure limits set forth for an uncontrolled environment. This equipment is in direct contact with the body of the user under normal operating conditions. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Warranty

Globus Medical, Inc. will repair or replace all or part of the unit and its accessories for material or workmanship defects for a period of three months from the date of sale. To the extent the terms of this warranty are inconsistent with local regulations. The provisions of such local regulations will apply.

Disposal

Sensor is electronic equipment and may include substances that can damage the environment. Do not dispose of the device in municipal waste. Do not puncture. Do not dispose in fire or incinerate. Dispose of the unit according to national, state, and local regulations.

Expected life is 12 months

INTENDED FOR SINGLE PATIENT USE

NOT MADE WITH NATURAL RUBBER LATEX

NOTICE: WHILE EVERY EFFORT HAS BEEN MADE IN STATE-OF-THE-ART TECHNIQUES TO OBTAIN THE MAXIMUM COMPATIBILITY OF FUNCTION, STRENGTH, DURABILITY AND COMFORT, THERE IS NO GUARANTEE THAT INJURY WILL BE PREVENTED THROUGH THE USE OF THIS PRODUCT. THIS DEVICE IS NOT INTENDED TO PREVENT INJURY, BUT AS AN ADJUNCT TO PRE-OPERATIVE AND POST-OPERATIVE THERAPY.

USE CAUTION AND FOLLOW YOUR DOCTOR'S ADVICE

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