TracPatch Knee

Instructions for Use

Important information for healthcare provider: please read prior to using this device in a clinical setting. The healthcare provider should be familiar with the application technique.
This document contains instructions for use for the TracPatch wearable device system.

DEVICE DESCRIPTION

The TracPatch Knee Surface Sensor Technology is a physical tracker that is recommended for patients undergoing joint arthroplasty surgery, or patients recovering from musculoskeletal injuries, under the guidance of trained medical professionals. The system is a combination of a commercially available smartphone, smartphone application and electronic sensors, that monitor the patient's ambulation, body position, frequency of motion of the affected joint, and the temperature near the surgical site for the purpose of assessing whether icing of the surgical site was performed according to the prescription.
The smartphone receives data from the sensors and displays data to the patient and trained medical professionals. The trained medical professionals use the data to assess the degree of compliance by the patient according to the medical professional's prescribed joint rehabilitation regimen.
TracPatch is not intended to diagnose, treat, prevent, cure or mitigate any disease or condition; and it is intended to only capture and display the data to the patient and medical professional.

1) TracPatch can be used to:
    a) Track and trend the knee ROM of the patient's affected knee, without patient intervention
    b) Track and trend the skin temperature at the site of placement, without patient intervention
    c) Track and trend the patient's step count, without patient intervention
    d) Display the angle of the patient's affected knee in near-real time- with use of the ROM Goal Meter
    e) Assist the patient as they perform 4 key rehabilitation exercises and record sets and repetitions as they are performed
        i) Sitting Lift
        ii) Heel Slide
        iii) Knee-to-Chest
        iv) Sit-to-Stand

» Submit Wound Photos for review by the Healthcare Provider
» Submit VAS Pain Scores for review by the Healthcare Provider
» Submit PROMs Surveys for review by their Healthcare Provider:

- Oxford Knee Score
- WOMAC Score
- KOOS Jr.
- Global Health 10

THE TRACPATCH WEARABLE DEVICE SYSTEM CONTAINS:

- TracPatch white and blue devices
- Charger
- Adhesive Disposable Patches
- Wall Mount Power Supply

MOBILE DEVICE COMPATIBILITY

The TracPatch system is compatible with the mobile devices and operating systems listed below.
Apple® iOS™: 12 and above. Android®: 4.3 and above
Apple iPhone 6 and above
OS: Windows® 8, and 10 and MacOS® 11 and above
Apple, iPhone, and iOS are Registered Trademarks of Apple Corporation.
Android and Windows are Registered Trademarks of Google LC and Microsoft.

INTENDED USE

The TracPatch system is intended to support the collection, recording, and display of pre- and post-op rehabilitation activities that have been prescribed by a healthcare professional and used by a qualified healthcare professional and patients. With the collected data, healthcare professionals can monitor the patient's exercise compliance.

INDICATIONS FOR USE

The TracPatch system is indicated for the pre-op and post-op rehabilitation phase of patients who have undergone a reconstruction or musculoskeletal surgery, who needed a corrective surgery or who are recovering from an injury.

CONTRAINDICATIONS

A. The TracPatch devices are not intended to be used in any areas of active or suspected latent infections in or about the TracPatch device application site.
B. The TracPatch devices are not intended to be used on critical care patients.

WARNINGS

A. Discontinue use if significant pain or discomfort and redness, drying and cracking of the skin are present, please immediately contact your health care professional.
B. Do not attempt to open the TracPatch wearable device. Materials contained in this product and/or its battery may damage the environment and/or human health if handled and disposed of improperly.
C. Use only as prescribed by your health care provider for the specific recovery exercises and frequency of treatment.
D. Keep micro USB cable out of pathways to avoid a risk of tripping.
E. To charge the device, use only the charger provided.
F. Keep the wall mount power supply and charger away from heated surfaces. Do not plug in the device where it is difficult or obstructed from being disconnected.
G. Never operate this product if it has a damaged wall mount power supply, charger, or plug, which could result in electric shock. Contact TracPatch support if the charger or wall mount power supply becomes damaged.
H. Avoid flammables and oxidizers. Do not use in places with flammable vapors or gasses (e.g. flammable anesthetics), high oxygen concentrations, or other oxidizers (e.g. nitrous oxide).

PRECAUTIONS

A. Do not attempt to disassemble or open your TracPatch. It does not contain serviceable or repairable components.
B. Do not leave your TracPatch in direct sunlight for an extended period of time, or near open flame.
C. Do not expose your TracPatch to extremely high or low temperatures.
D. Do not use abrasive cleaners to clean your TracPatch.
E. Do not place your TracPatch in a dishwasher, washing machine or dryer.
F. Do not submerge TracPatch under water for an extended period.
G. The TracPatch wearable device may cause electromagnetic or other interference with other electrical devices. Should this occur, contact TracPatch support for further assistance.
H. Prolonged skin contact or repeated exposure to Adhesive Remover is not likely to cause significant skin irritation unless there was a pre-existing skin disorder. Symptoms may include warmth, redness, drying and cracking of the skin.
I. TracPatch device requires to be used with patient using loose fitting clothing and patient should not wear device to bed or wear stockings or clothing that restricts airflow to the device.

FOR BEST RESULTS

A. Apply the adhesive disposable patches to skin that is clean, dry and absent of hair.
B. For improved performance, keep your smartphone within 30 feet of the TracPatch.
C. When changing the ADP and after Adhesive Remover has been used, wipe off residue, then wash immediately with plenty of soap and water and allow to air dry for a minimum of 2 minutes before applying a new ADP.

LED INDICATOR LIGHTS

LED Indicator Lights for White and Blue Devices

- Blinking Green - Devices are connected
- Blinking Blue - Devices are disconnected
- Blinking Red – Error: Place in charger & contact your TracPatch Specialist

LED Indicator Lights While Devices are Charging

- Cycle of Red, Green, and Blue - Charger recognizes devices and
- quickly runs a test charge cycle
- Blinking Green - Devices charging: Blinks will speed up when close to full charge
- Solid Green - Fully charged devices

LED Indicator Lights for Charger

- Solid Blue - Devices are in charge mode
- Solid Red - Charger Error: Reset by reconnecting power cable

PRODUCT SPECIFICATIONS

FCC ID	
Product #	4000-0-1000 (TracPatch Assembly)
Weight	Adhesive Disposable Patch: 2.66 g Device: 12:53 g Device with Adhesive Disposable Patch: 15.17 g
Bluetooth Operating Range	0'-30' (0m-9.114m)
Expected Service Life	90-120 days from first use
Dimensions	2.197" L x 1.51" W x .5" H
Battery Life	Rechargeable Lithium Battery
Power Supply	Manufacturer: Rated Input: 100-240V, 50-60Hz Model: QFAW-05-05 Output: 5Vdc, max. 1.0A
Environmental Conditions **1. Transport & Storage** **2. Use**	 –13°F (-25°C) no humidity control to 158°F (70°C) up to 93%RH 41°F to 100°F (5°C to 40°C) 15-93%RH - 700 hPa to 1060 hPa
Transmission Distance (BLE)	TracPatch will transmit up to 30 feet away from smart device
Compatible Smart Devices	Smartphones with Bluetooth 4.0 running Apply iOS 7 or later or Android 4.3 or later
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 Bluetooth Version 4.2 and 5.0
Radio Regulations	FCC Part 15 ISO/IEC 60601-1-2 Electromagnetic Compatibility
Water Protection Level	IP68

HOW PRODUCT IS SUPPLIED

All components of the TracPatch device are supplied non-sterile and contained in individual boxes or packages. The devices should be collected at the end of use.

FCC STATEMENT AND LEGAL NOTICES

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.

FCC WARNING: any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment under FCC regulations.

Note: Changes or modifications not approved by TracPatch and/or Consensus Orthopedics could void the user's authority to operate the equipment. This device meets the FCC requirements for RF exposure in public or uncontrolled environments.

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 interference to radio communications.

TRACPATCH KNEE FEATURES

TracPatch Blue
Tibia

TracPatch White
Femur

Adhesive Disposable Patch

Waterproof

10 Day Wear

Mesh center for breathability

Snap on/off tab

LED Indicator Lights

Place Large End of Device in First

BATTERY

A charging cradle is provided in the TracPatch box. To charge the Blue and White TracPatch Knee devices, place them with the top of the device pointed down into the cradle. Ensure devices are fully seated into the cradle to get a proper charge.

Each TracPatch Knee device contains a rechargeable lithium ion battery that should be charged every night.

TracPatch Knee batteries are not replaceable. If the devices do not charge, contact TracPatch Support.

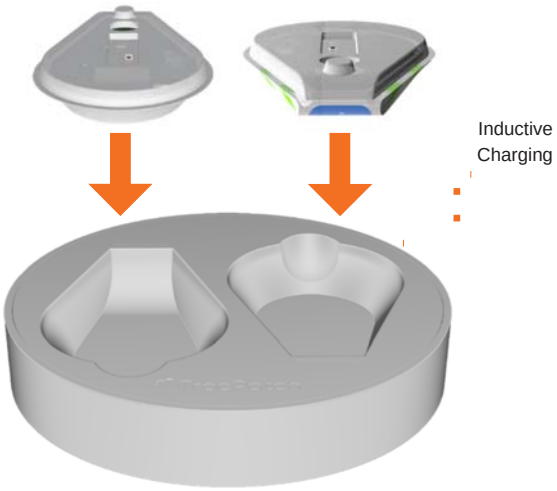
Note: Batteries are shipped with less than 30% charge due to US shipping requirements.

CHARGER

The TracPatch charging cradle should only be used with the provided wall adapter. The White and Blue TracPatch Knee devices will be placed into the cradle upside down, so that the top of the device contact the cradle.

The charging cradle works through inductive charging and could take up to 6 hours for a complete charge. Make sure the lights on the White and Blue TracPatch devices are blinking green to ensure they are charging.

The White and Blue TracPatch devices should be left on the charging cradle for a minimum of 5 seconds before removal. After charging, let both devices cool down before inserting them into the adhesive disposable patches (approximately 1 minute).



ADHESIVE DISPOSABLE PATCHES

The blue and white Adhesive Disposable Patches (ADP) secure TracPatch devices to the skin in the intended locations/orientations. ADPs are intended to be disposed of every 10 days and replaced in approximately the same location. A skin scribe or regular pen can be used to mark the previous ADP placement by creating dots in the 4 indents on each side of the ADP (figure 1). ADPs are also completely waterproof and can be worn while bathing or swimming. Make sure the ADPs are completely dry before snapping in the TracPatch devices.

On the narrow end of the ADP, there is a lever that acts as a snap feature to hold the TracPatch device into place. Placing the TracPatch devices into the ADP can be done by placing the larger end of the TracPatch into the ADP first then pressing down on the narrow end until it snaps into place. Removal of the TracPatch devices is done by pushing down on the snap feature on the narrow end of the ADP and pulling up on the TracPatch devices (figure 2).
Before the application, the skin should be prepped by shaving the leg where the ADPs will be placed. The leg can be in any position when applying the ADPs.

Figure 1

Figure 2

TRACPATCH KNEE WHITE

The White ADP should be placed 3-5 inches, or one palm's distance above the kneecap, 60º-120º on the outside part of the femur (thigh). The narrow end of the device should point down towards the knee cap. Once the ADP is on the leg, snap the White TracPatch Knee device into the ADP by placing the large end of the device in first (figure 3).

TRACPATCH KNEE BLUE

The Blue ADP should be placed approximately 3 inches below the kneecap, 60º-120º on the outside part of the tibia (shin). The narrow end of the device should point up towards the knee joint. Once the ADP is on the leg, snap the Blue TracPatch Knee device into the ADP by placing the large end of the device in first (figure 4).

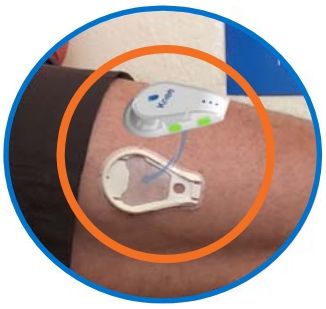


Figure 3

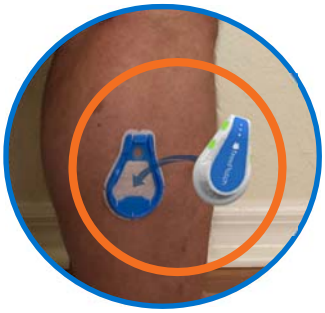


Figure 4

CHARGING THE DEVICES

CONNECTING THE DEVICES

PLACING THE DEVICES

SYMBOLS USED ON THE TRACPATCH IFU AND DEVICE

Symbol	Standard	Ref #	Title	Definition
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.1.4	Use-by Date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.1.5	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.1.6	Catalog Number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.2.7	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process.
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.2.8	Do Not Use if Package is Damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.4.2	Do Not Reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	5.4.3	Consult Instructions For Use	Indicates the need for the user to consult the instructions for use.
	21 CFR 801.15(c)(1)(i)F		Prescription only	Indicates a medical device that requires prescription in the United States.
	IEC 60417-5333		Applied Part - Type BF	Indicates a device that comes into contact with the body, having medium or long term contact with the patient.
	BS EN 50419		WEEE (Waste Electrical and Electronic Equipment)	Indicates the device is WEEE per European Community Directive 2012/19/EU

TracPatch
Knee

TracPatch Health, Inc.
888.954.4044 www.tracpatch.com
2020 L Street, Ste 220, Sacramento, CA 95811

99026-01C