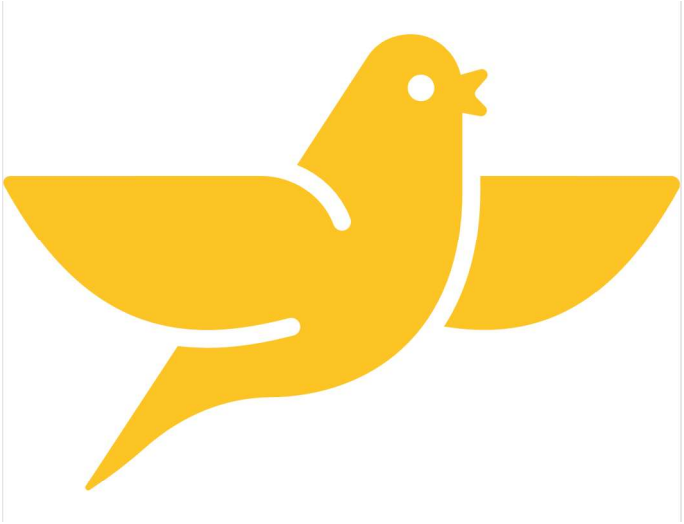
Physician Instructions for Use

Canary Tibial Extension

with

Canary **H**ealth **I**mplanted **R**eporting **P**rocessor

(CHIRP) System



℞ Only

Caution:

Federal law (USA) restricts this device to sale by or on the order of a physician.

Lan Herrington (Jul 17, 2020 16:38 PDT)

Jul 17, 2020

Canary Medical, Inc.

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1. OVERVIEW OF THE CANARY TIBIAL EXTENSION WITH CHIRP SYSTEM

Before using this device, carefully read all instructions for use.

The Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) is a tibial extension implant containing electronics and software. Using internal motion sensors (3-D accelerometers and 3-D gyroscopes), the CTE collects kinematic data pertaining to a patient's gait and activity level following total knee arthroplasty (TKA). The kinematic data produced by the CTE implant is intended as an adjunct to the TKA post-procedure standard of care, as directed by the physician. The CTE implant is assembled with the Zimmer Biomet Persona® tibial baseplate to form a total knee prosthesis. In addition to its data collection capabilities, the CTE implant provides additional stability to the complete knee prosthesis in the same manner as a traditional tibial extension.

The CTE with CHIRP System uses external OR and Home "Base Station" units to query the CTE implant (which has an internal radio and antenna) and upload the data collected by the CTE implant to the Canary Cloud data management platform (the Cloud). Information from the implant is processed by the system's Canary Medical Gait Parameter (CMGP) software into clinically relevant metrics.

To qualify to receive the CTE with CHIRP System, the Patient must meet the following requirements in addition to any requirements for TKA surgery as determined by the patient's HCPs:

1. The Patient's anatomy must be capable of accepting the Zimmer Biomet Persona Tibia Baseplate with Canary Tibial Extension construct sizing. This assessment will be conducted pre-operatively by the HCP using a CTE Template supplied by Canary Medical.

2. The patient must have access to a computer with a USB connection to set up their Home Base Station.

3. The Patient must have wireless internet in their domicile.

The CTE with CHIRP System technology package ultimately allows patients and their Health Care Professionals (HCPs) to view the patient's functional activity data which is collected and processed by the system. Patients and HCPs view the information on HCP and Patient "Dashboards" on the Canary Medical website, which is accessible through the use of the Internet. Figure 1 shows a schematic of the CTE with CHIRP System.

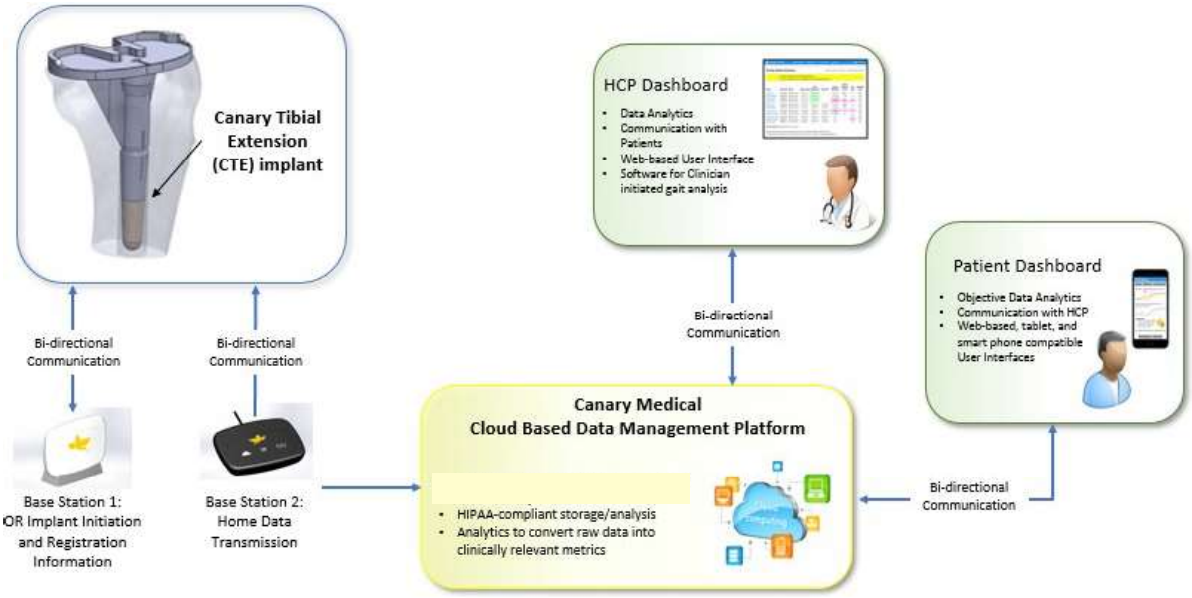


Figure 1: Canary Medical CTE with CHIRP System

2. ADDITIONAL REFERENCED DOCUMENTS

Table 1 lists additional documents relevant to the CTE with CHIRP System which are referenced in this Instructions for Use (IFU).

Table 1

Document Title	Document Number	Location
Canary Medical Surgical Technique	K01-CTE-300005	Printed/electronically available
		www.canarymedical.com
Patient Manual	K01-HBS-300003	Printed Document Shipped with Home Base Station
		www.canarymedical.com
Patient Quick Start Guide – Home Base Station Setup	K01-HBS-300006	Printed Document Shipped with Home Base Station
		www.canarymedical.com

Document Title	Document Number	Location
Patient Quick Start Guide –Setting Up Your Patient Account	K01-HBS-300005	Printed. Provided to patient at surgeon's office.
		www.canarymedical.com
OR Quick Start Guide – OR Base Station Setup	K01-ORBS-300003	Printed Document Shipped with OR Base Station
		www.canarymedical.com
Zimmer Biomet Persona Knee Surgical Technique	97-5026-001-00	
Zimmer Biomet Instructions for Use	87-6204-042-99	

3. TERMS AND ACRONYMS

Table 2 lists terms and acronyms used in this document.

Table 2: Terms and Acronyms

Term	Meaning
CN	Circulating Nurse
CHIRP	Canary Health Implanted Reporting Processor
Cloud	Canary Medical Cloud Based Data Management Platform
CMGP	Canary Medical Gait Parameter
CTE	Canary Tibial Extension
EtO	Ethylene Oxide
HCP	Health Care Professional
Hz	Hertz

Term	Meaning
IFU	Instructions for Use
IM	Intramedullary
IMU	Inertial Measurement Unit
MCU	Microcontroller Unit
OR	Operating Room
PC	Personal Computer
PMMA Cement	Polymethylmethacrylate Bone Cement
PPE	Personal Protective Equipment
RF	Radio Frequency
RoHS	Restriction of Hazardous Substances
ROM	Range of Motion
RTU	Ready to Use
TKA	Total Knee Arthroplasty
USB	Universal Serial Bus

4. DEVICE SYSTEM DESCRIPTION

The Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) is a system that combines physical components, electronics, software, and user interfaces to collect, store, analyze, transmit, and display patient data for use by both physicians and patients. Table 3 lists the components and interfaces of the CTE with CHIRP System.

Table 3: CTE with CHIRP System Components

Component or Interface	Description	Model Number or Catalogue Number
CTE Implant 14mm (D) x 58mm (H)	Tibial Extension with internal electronics and software which allows it to collect kinematic data in addition to providing stability to the patient's knee prosthesis	43-5570-058-14
CTE 14mm x 58mm X-Ray Template	Used to preoperatively determine if the patient's anatomy is appropriate for a CTE implant	43-5570-004-14
Surgical Instrumentation	CTE Impaction Sleeve	43-5399-001-14
	5 deg Left Tibial Resection Cutting Guide	43-5399-051-05
	5 deg Right Tibial Resection Cutting Guide	43-5399-052-05
	Drill Bit	43-5399-058-14
	CTE Provisional	43-5571-058-14
OR Base Station System	OR Base Station unit	43-5570-002-14
	Dedicated Laptop PC	43-5570-003-14

Component or Interface	Description	Model Number or Catalogue Number
	Canary OR Application	TBD
	Barcode Scanner	AC-900001
	USB Power and Data Cables	TBD
Home Base Station System	Home Base Station Unit	43-5570-001-14
	USB Data and Power Cables	AC-900002
	Power Adapter	AC-900003
	Base Station Setup Tool (software application)	TBD
Canary Cloud Data Management Platform (Cloud)	Manages and processes patient data that can be accessed through the patient or physician portal	
Canary Medical Gait Parameter Software	Facilitates outputs to the Physician Dashboard and Patient Dashboard user interfaces. The dashboards allow physicians and patients, respectively, to view selected gait and activity metrics collected from the CTE and processed by the Cloud	

NOTE: Patients need their own USB-enabled laptop or PC with at least one USB port and a wireless Internet connection to connect to their Home Base Station**.**

NOTE: Both physicians and patients can access their respective dashboards via an Internet browser.

4.1. The Canary Tibial Extension (CTE)

The Canary Tibial Extension is a physical implant component that is attached by the orthopedic surgeon or scrub tech to the Zimmer Biomet Persona® tibial baseplate to form the patient's knee

prosthesis. Like a traditional tibial extension, the CTE provides additional stability to the replacement knee joint. In addition, the software and electronics embedded within the CTE collect the patient's functional movement and gait parameter information post-surgery. The CTE is an implantable device that is provided sterile to the customer. It is sterilized via Ethylene Oxide (EtO) and is packed in sterile packaging inside a sealed, tamper-proof outer box. For more information on the Zimmer Biomet Persona® tibial baseplate, refer to the Zimmer Biomet Persona Knee Surgical Technique (97-5026-001-00) and Instructions for Use (87-6204-042-99).

Figure 2 is a representation of the CTE implant.

Figure 2: CTE Implant

Figure 3 is a representation of the assembled Canary Medical CTE and Zimmer Biomet Persona® tibial baseplate devices.

Figure 3: Zimmer Biomet Persona® Tibial Baseplate with Canary Tibial Extension

4.2. CTE Template

The CTE Template is a surgical instrument used to assist the surgeon during preoperative planning. The CTE Template will be used to assess the patient anatomy for the Zimmer Biomet Persona Tibia Baseplate with Canary Tibial Extension construct sizing.

4.3. CTE with CHIRP System Surgical Instrumentation

All CTE with CHIRP System Surgical Instrumentation is supplied non-sterile in an instrument tray. The cleaning and sterilization instructions for surgical instruments are found in the Canary Medical Instrument Care Instructions for Use, document # K01-INT-300019. The surgical instrumentation for the CTE with CHIRP System includes the Impaction Sleeve, Canary Tibia Cut Guides (L/R), Canary Drill Bit, and CTE Provisional.

4.3.1. Impaction Sleeve

The Impaction Sleeve is a single-use (provided non-sterile, see Section 4.3), disposable surgical instrument used to assist in attaching the CTE implant to the Zimmer Biomet Persona® Tibial Plate. The Impaction Sleeve protects the implant's electronic components from impaction forces that occur during assembly. Figure 4 is a graphical representation of the CTE Impaction Sleeve.

WARNING: The Impaction Sleeve is single-use only. It must be discarded as medical waste after use.

Figure 4: CTE Impaction Sleeve

4.3.2. Canary Tibia Cut Guide (5 Degree – L/R)

The Canary Medical Tibia Resection Cutting Guide (left or right option) is used for tibia preparation when implanting a Persona Primary Knee with a Canary Tibial Extension (CTE) Implant. Figure 5 shows the Canary Medical Tibia Resection Cutting Guides.

Figure 5: Canary Tibia Resection Cutting Guides

4.3.3. Canary Drill Bit

The Canary Drill Bit is used to create the cavity in the patient's tibial IM canal to fit the CTE implant and cement mantle. Figure 6 shows the Canary Drill Bit.

Figure 6: Canary Drill Bit

4.3.4. CTE Provisional

The Persona Tibial Keel length ranges from 23.4 mm to 40 mm. The Canary Tibial Extension adds 58 mm to the length of the tibial keel nominally when assembled. This CTE Provisional is used to ensure the fit of the CTE implant within the patient's anatomy prior to CTE implantation. Figure 7 shows the CTE Provisional.

Figure 7: CTE Provisional

4.4. Base Station Systems

The CTE with CHIRP Base Station subsystems are composed of external base station units and associated software that facilitate communication with the CTE implant. There are two Base Station system configurations: an OR Base Station system for use by the Surgical team, and a Home Base Station system for use by the Patient. The Base Station units query a specified CTE implant to transmit data to and from that CTE implant and to the Canary Cloud Data Management Platform for:

- Activation of a CTE implant during surgical procedure
- Linking of a CTE implant with a patient

- Analysis and conversion to Canary Medical Gait Parameters for viewing on the Physician and Patient Dashboards.

The following information describes the Base Station systems.

4.4.1. OR Base Station System

The OR Base Station subsystem is intended to send and receive data to and from the CTE implant over a wireless communication interface. Data sent to the CTE implant from the OR Base Station activates the CTE implant on the day of surgery. Data received from the CTE implant is uploaded to the Canary-supplied computer in the operating room environment and onto the Canary Cloud platform when connected to it through the Internet.

The surgical team uses the OR Base Station during the TKA surgery to register the patient and activate the CTE implant so that it will begin collecting data after the patient's surgery. The hardware functions are "limited to assisting the following software functions: electronic transfer, storage, or display of medical device data."

The OR Base Station subsystem includes an OR software application for perioperative interaction with the CTE intended to wake up the CTE, prior to implant with no risk to the patient. Following activation, the firmware embedded in the CTE manages the data collection control aspects of the implant. The OR software application is a PC-based local application intended for use by Healthcare Professionals. The OR software application will be loaded onto a Canary Medical laptop that will be provided to healthcare facilities that offer the CTE implant to their patients.

The OR software application performs the following functions:

Pre-implant – The OR application allows a self-test of the CTE as well as a sensor check to be performed prior to implantation. The OR Application displays if successful tests have been run in the last 24 hours (in which case the user can elect to not run the tests). If the user elects to perform the tests, the OR application displays information to the user if these tests passed successfully. The CTE implant kinematic data collection is still inactive at this point and is not needed for performing the self-test.

In OR – The OR application allows self-tests to be performed on the CTE during and after the implantation procedure. During or after CTE implantation is completed, the OR App can be used to activate the CTE to initiate its kinematic data collection algorithm via the OR Base Station unit.

Post-implant – After the surgery is completed, the OR application can be used to scan the barcodes on the labels of the CTE and other implanted TKA components; these data can also be manually entered. This information can then be submitted by the OR App to the Canary Cloud. This action associates the particular CTE with the previously registered patient in the Canary

Cloud. The action of associating the CTE with the patient also enables the home base station to recognize the CTE when the patient returns home after surgery, thus enabling upload of kinematic data from the CTE to the Canary Cloud without patient intervention. The OR Base Station System consists of an OR Base Station unit, dedicated laptop PC loaded with the Canary software application, barcode scanner, and USB cables. Figure 8 shows a schematic of the OR Base Station System.

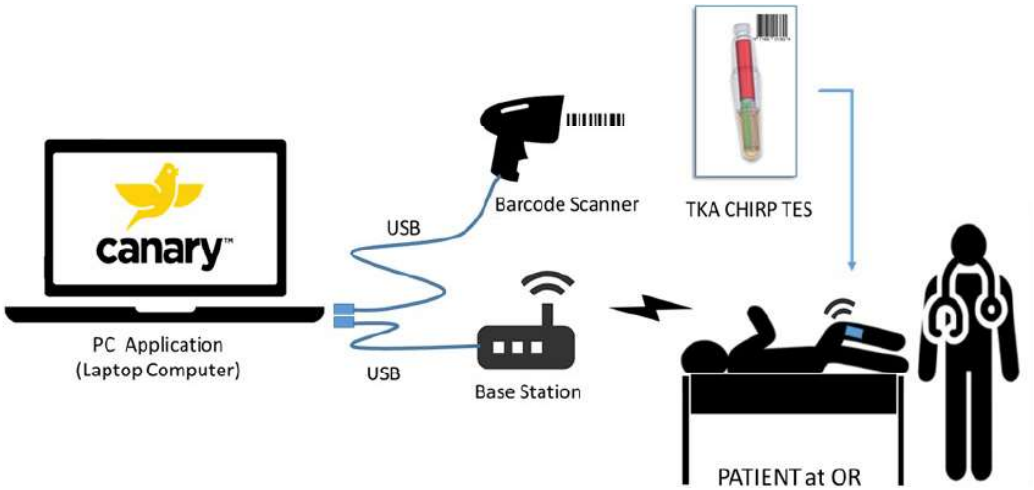


Figure 8: OR Base Station System

4.4.2. Home Base Station System

The Home Base Station System is located at the patient's home, where it is set up by the patient prior to the date of surgery. The Home Base Station System provides an interface for communication with the patient's CTE implant. It consists of a Home Base Station unit, the patient's USB-enabled personal computer, the patient's wireless Internet connection, and a USB power and data cable. After TKA surgery, the Home Base Station unit begins collecting the patient's gait and activity information from the CTE. The Home Base Station unit transmits the data to the Cloud, and has the capability to store the data for up to forty five days.

Figure 9 shows a schematic of the Home Base Station System communication.

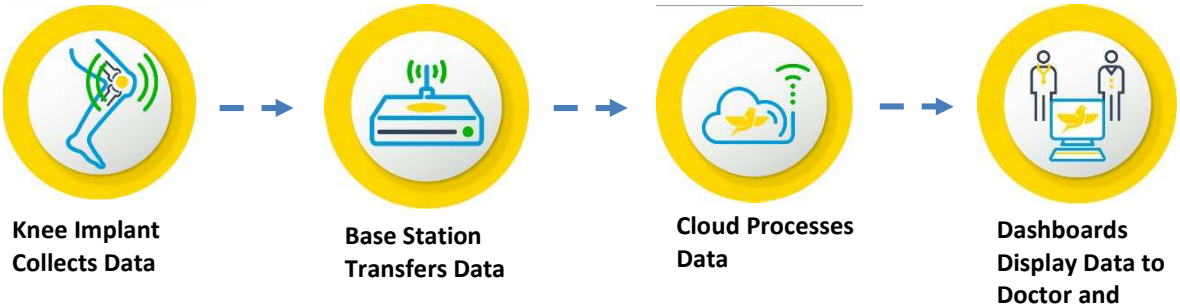


Figure 9: Base Station Communication

4.4.3. The Canary Medical Cloud Data Management Platform (Cloud)

The Canary Cloud Data Management Platform ("Cloud") allows users to access it through a browser-based web application. The Cloud subsystem is intended to receive and store all of the healthcare professional and patient data for pre-operative, day of operation and post-operation activities, including patient kinematic data from the CTE implant. The post-operation patient kinematic data will be used by the surgeons, nurses and patients to monitor the patient post-TKA as an adjunct to the standard of care.

The Cloud is a software environment that collects information from a variety of data sources. The information is then stored in a secure encrypted database for retrieval and processing. The Cloud also contains the CMGP software module that converts the unprocessed kinematic data from the CTE to gait parameters for reporting to the Physician Dashboard and Patient Dashboard Users.

4.5. Physician Portal

The Physician Portal is located on the Canary Medical website (www.canarymedical.com) and is accessible by the patient's health care providers (HCPs) via an Internet browser. HCPs can log into the portal with a username and password to view patient information and CMGPs generated by the patient's CTE implant. CMGPs are displayed on the Physician Dashboard, and include:

- Walking Speed (meters/second)
- Step Count
- Tibia Range of Motion (degrees)
- Functional Knee Range of Motion (degrees)
- Stride length (meters)
- Distance (kilometers)
- Cadence (steps/minute)

The CHIRP system is not intended to provide real time data like a smart watch or smart phone. Rather, it collects data over the course of a day, analyzes it while the patient is asleep, and presents the previous day's data for HCP and patient review the following day.

The CTE implant has the ability to store 30 day of data. Therefore, if the patient's Home Base Station connection is temporarily lost or they are traveling for less than 30 days without a Home Base Station, the full amount of data will be uploaded to the Canary Cloud once a connection is made to the Home Base Station. If there is no connection for periods greater than 30 days, new data will over-write the oldest data until a connection to the patient's Home Base Station and the Canary Cloud is made.

The CTE implant has been programed to collect data using the following schedule.

Time Period	Sampling
Day 0 (surgery) to Day 1	No sampling
Day 2 to Day 365	Daily
Year 2	30 consecutive Days/Quarter
Years 3 and beyond	30 consecutive days commencing on the anniversary of the patient's your surgery date

When the CTE is not sampling, it is in a low power mode to conserve battery power. When viewing a patient's data, if no values are present during a particular day or period of time, it simply means during this period the CTE was not collecting data per its program.

Figure 10 shows a screenshot of the Patient Chart on the Physician Dashboard.

Figure 10: Screenshot of Patient Chart on Physician Dashboard

4.6. Patient Dashboard

The Patient Dashboard is located on the Canary Medical website and is accessible by the patient via his/her Internet browser. Patients can view selected CMGPs generated by their CTE implant, including gait information and activity level. Information available to patients includes:

- Walking Speed (feet/second)
- Step Count
- Range of Motion (degrees)
- Stride length (feet)
- Distance (miles)
- Cadence (steps/minute)

Figure 11 shows a screenshot of the Patient Dashboard.

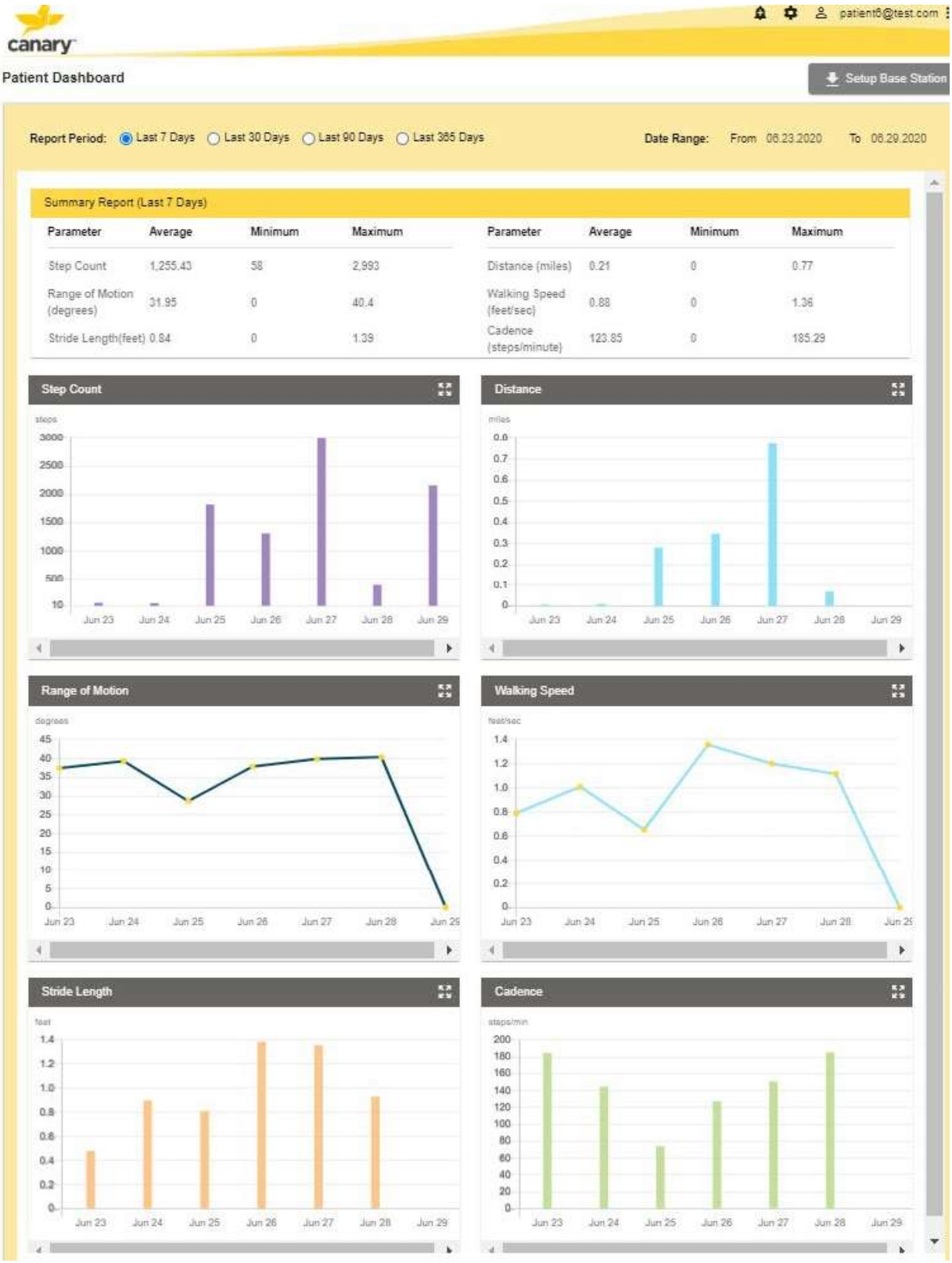


Figure 11: Screenshot of Patient Dashboard

5. INTENDED USE

5.1. Intended Use

The CTE with CHIRP System is intended to provide objective kinematic data while providing additional stability afforded by a traditional tibial extension. The implanted medical device is used to assist the patient and the physician during a patient's TKA post-surgical care. The kinematic data is intended as an adjunct to standard of care and physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery.

5.2. Indications for Use

The Canary Tibial Extension implant is indicated for use with the Zimmer Persona® Personalized Knee System for total knee arthroplasty (TKA) in patients with severe knee pain and disabilities due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis
- Collagen disorders, and/or avascular necrosis of the femoral condyle
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus, or flexion deformities
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

The Canary Tibial Extension with CHIRP System may be used in any instance where additional, objective, kinematic data on total knee replacement function is beneficial to the implant care process as determined by the physician.

This device is intended to be used with cemented knee constructs.

5.3. Users and Component Interfaces

The CTE with CHIRP System is intended to provide objective kinematic data on the patient's activity level and total knee arthroplasty (TKA) function. The OR Base Station System is used to set up, test, and activate the CTE Implant before implantation. It is also used to associate the CTE to the specific patient by recording serial number information for the CTE Implant and associated Zimmer Biomet Persona® Personalized Knee System components. The OR Base Station System transmits these data to the Canary Cloud Data Management Platform linked to the Patient's account.

The implanted CTE collects data from internal motion sensors, and when queried by a Home Base Station, transmits the CTE motion sensor data to the associated Home Base Station System. The Home Base Station System then uploads the data to the Canary Cloud Data Management Platform via the patient's Internet connection.

Users of the System are the Patient with the CTE with CHIRP System and their designated Health Care Professional (HCP) with access to the Patient's CTE data.

Table 4 lists the components of the system and the intended user for each component.

Table 4: CTE with CHIRP System Components

Component/User Interface	Users	Interactions
Canary Tibial Extension (CTE) Implant	Patient, Surgical Team	Patient – Rehabilitate after surgery and acclimate to new implant. Surgical team – assembly, implantation and activation of CTE implant

• Canary Tibial Extension (CTE) Implant
• Canary specialized assembly and insertion components
  ○ Impaction Sleeve
  ○ 5 deg Left Tibial Resection Cutting Guide
  ○ 5 deg Right Tibial Resection Cutting Guide
  ○ Tibial Drill Bit
  ○ CTE Provisional
	Surgical Team	• Activate the CTE with the OR App software and OR Base Station
		• Tibial resection and preparation
		• Attach the CTE to the Zimmer Persona® baseplate
		• Surgically implant the assembled CTE/Zimmer Biomet prosthesis device during TKA

OR Base Station System • Base Station Unit • Dedicated Laptop PC • Software Application • Bar Code Scanner • Power and Data Cables	Surgical Team	• Perform self-test and sensor check on CTE • Link CTE SN with patient information • Activate the CTE with the OR App software

Component/User Interface	Users	Interactions
Home Base Station System • Base Station Unit • Base Station Setup Tool Software Application • Power and Data Cables	Patient	• Set up Base Station components in Patient's home • Connect to personal computing device and home wireless Internet • Download Base Station Setup Tool application to set up communication between the CTE, Base Station Unit, and Canary Cloud
Physician Dashboard	Surgeon, surgical team, primary care provider (PCP), PCP's clinical staff, other HCPs	Review patient's gait analytics and activity level
Patient Dashboard	Patient, possibly patient's family and/or caregiver	Review patient's gait information and activity level
Cloud Data Management Platform	Canary Medical Staff	OR Base Station, Home Base Station, Physician and Patient Information Maintenance and security, Canary Medical Gait Parameter Software

6. LIMITATIONS

The patient needs to have sufficient intramedullary space to accommodate the increased length of the CTE implant in order to avoid cortical perforation. Before choosing the CTE implant for a patient, assess if the patient's anatomy is appropriate by using the Canary CTE implant X-Ray Templates.

The patient must have access to a computer with USB connection and home wireless Internet access in order for their data to be collected, stored, and transmitted by the CTE with CHIRP System.

7. CONTRAINDICATIONS

The Canary Tibial Extension (CTE) is contraindicated for use in patients who are undergoing procedures or treatments at or in the proximity of the CTE using ionizing radiation, as these could damage the CTE.

After a patient receives TKA surgery with the Canary CTE with CHIRP System and Zimmer Biomet Persona® Personalized Knee System, make the patient aware that electrical currents conducted or induced into the body from an external source are contraindicated for patients with an active implantable medical device.

Before performing TKA on any patient, consider the following contraindications.

The Zimmer Biomet Persona® Personalized Knee System is contraindicated for use in patients who have:

- Previous history of infection in the affected joint and/or other local/systemic infection that may affect the prosthetic joint
- Insufficient bone stock on femoral or tibial surfaces
- Skeletal immaturity
- Neuropathic arthropathy
- Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb
- A stable, painless arthrodesis in a satisfactory functional position
- Severe instability secondary to the absence of collateral ligament integrity

Total Knee Arthroplasty is contraindicated in patients who have rheumatoid arthritis (RA) accompanied by an ulcer of the skin or a history of recurrent breakdown of the skin because their risk of postoperative infection is greater. RA patients using steroids may also have increased risk of infection. Late infections in RA patients have been reported 24+ months postoperative.

8. MRI Compatibility

The CTE implant is expected to be MRI conditional. (Pending completion of MRI safety testing).

WARNING: Pending completion of MRI safety testing.

9. GENERAL WARNINGS AND PRECAUTIONS

9.1. CTE

WARNING: Do not use the CTE implant or other sterile packaged components if the package is opened or damaged. This could mean the device is no longer sterile. Use of non-sterile implants or components might result in patient infection, injury, or death.

CAUTION: Do not apply electrocautery directly to or across the CTE implant as this could cause damage to the device.

WARNING: The CTE implant may heat up during an MRI procedure causing pain or tissue damage.

WARNING: Do not apply ionizing radiation to or near the CTE implant as this could damage the implant.

9.2. Surgical and Home Base Stations and Accessories (including Bar Code Scanners, Laptops, and cables)

WARNING: Use only cables and accessories supplied by Canary Medical. Use of other cables and accessories may result in increased emissions or decreased immunity of the CTE with CHIRP System**.**

WARNING: Plug Base Stations and accessories into standard 110V wall outlets only. Attempting to connect these items to a non-standard electricity source could cause injury or cause damage to the equipment.

WARNING: Do not stack the Base Stations and accessories or use them adjacent to other electrical equipment.

WARNING: Do not immerse the Base Station or accessories in water. Electric shock could result.

CAUTION: Do not use electrical converters with the Base Stations or accessories. They have not been tested for this application.

10. PRINCIPLES OF OPERATION

This section provides information describing how the Canary CTE with CHIRP System collects, stores, transmits, and processes the kinematic data generated by the CTE implant.

The CTE implant performs five different active functions:

1) low resolution event marking (step counting and activity detection),

2) medium resolution acquisition events (for gait analysis),

3) high resolution acquisition events (for gait analysis),

4) data storage to memory, and

5) wireless data transfer to a base station.

When not performing one of these active functions, the CTE remains in a state of ultra-low power deep sleep. Prior to implantation, the CTE remains constantly in a state of deep sleep until "woken up" the day of implantation.

After implantation, these active functions are specified to occur for programmed periods of time during what is defined as a "sampling day.". A "sampling day" is a 24-hour period in which the implant spends between 12 to 18 hours in Low-Resolution mode, 30 seconds performing medium resolution acquisition events, and 3 seconds performing high resolution acquisition events along with brief periods of data storage and wireless data transfer. On days that are not "sampling days", the implant stays in deep sleep for the entire 24 hours to maintain the CTE implant's real time clock and non-volatile memory.

After implantation, the CTE implant's useful life is determined by the battery's internal self-discharge rate, power consumption as the implant moves through its active functions on sampling days, and the number of "sampling days." The CTE implant is powered by a "primary" battery so it does not require recharging or any other maintenance during the operational life of the CTE implant.

10.1. Collection, Storage, and Transmission of the CTE Data

The CTE implant will start collecting data on post-operative day 2, and thereafter, data will be transmitted to the Cloud on sampling days via the connection to the patient's Home Base Station.

The CTE has the capability to store up to 30 days of data in memory. If the data contained in the CTE's memory cannot be transmitted to the Cloud due to connectivity issues with a Base Station and the implant has reached its memory limit, new data will overwrite the oldest data first. In this scenario, data will be lost. The Home Base Station can store up to 45 days of transmitted data if it is not able to connect to the Cloud but is still able to communicate with the implant locally.

10.2. Canary Medical Gait Parameters Data Characteristics

The CTE collects raw sensor data that is transferred through a Base Station to the Cloud where it is processed to generate the Canary Medical Gait Parameters listed in Table 5. These gait parameters summarize activity metrics for the clinician after a patient undergoes TKA surgery. The intent of the data is to provide information which is accessible to both the patient and their clinician and to facilitate the delivery of healthcare to the patient by the clinician.

Table 5: Canary Medical Gait Parameters

Parameter	Description	Units
Walking Speed	Mean sagittal plane distance walked per unit time. Directly calculated from cadence and stride length for each gait cycle.	meters per second/s
Cadence	Mean steps per minute. Derived from two consecutive peak angular velocities.	steps per minute
Stride length	Mean distance traveled during one gait cycle.	meters
Knee ROM	Mean sagittal plane functional knee joint range of motion. Difference between maximum and minimum knee joint flexion.	degrees
Tibia ROM	Mean sagittal plane range of motion of the tibia with respect to the floor. Difference between the minimum and maximum tibia to floor angle.	degrees
Step Count	Number of steps taken during a Sampling Day.	steps

Parameter	Description	Units
Distance	Distance traveled. Calculated from step count and stride length	meters

Cadence, Stride, Tibia ROM, and Knee ROM are statistical values calculated on the collected sampling day data. The range of motion measurements are schematically illustrated in Figure 12 for a right leg motion through one gait cycle, where the angle α is the angle calculated based on a combination of tabular hip and femur reference data and the Tibia ROM data.

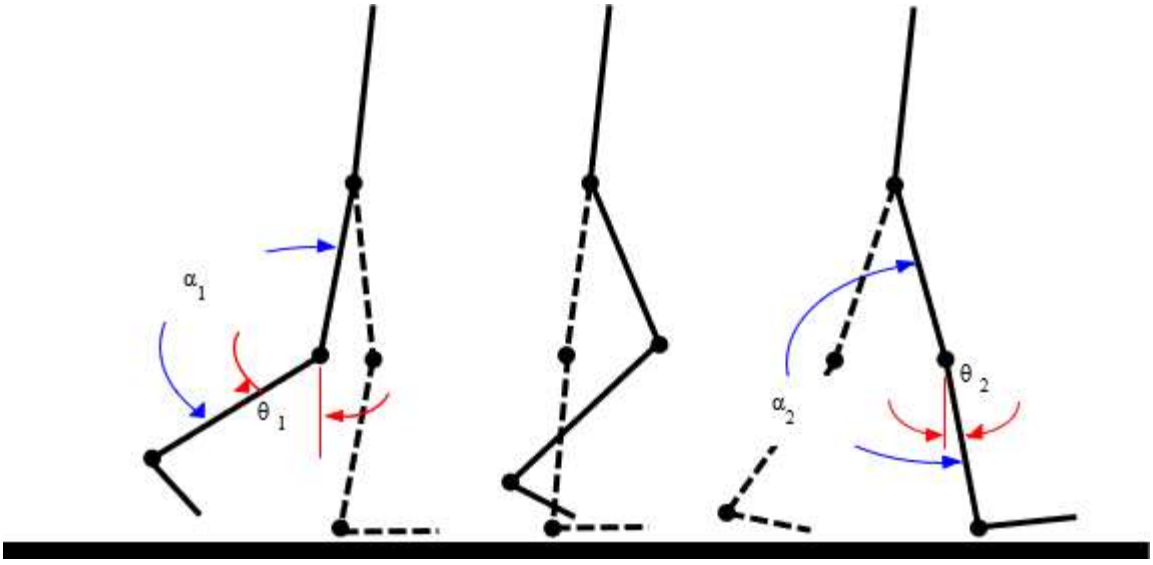


Figure 12: Schematic of Right Leg Motion. Tibia ROM = θ1 + θ2 and

Knee ROM = α2 – α1

11. DIRECTIONS FOR USE

The following information describes the use of the CTE with CHIRP System in chronological order of the system's use. The process starts with the Orthopedic Surgeon/Patient consultation where the patient decides to receive TKA with the CTE and CHIRP System. It follows through to the post-operative period when the CTE begins collecting data, and HCPs and Patients can view selected metrics on their respective Dashboards.

This information is provided from a user perspective. It is intended to provide directions for HCPs (including surgeons, surgeon's staff, physicians, and nurses) in the use of the CTE with CHIRP System. It is also intended to inform HCPs about their patients' role in the use of the system to support patients' understanding of their health care needs.

11.1. Surgeon's Office Patient Account Setup

11.1.1. Orthopedic Surgeon

Meet with the patient and present the risks and benefits of TKA surgery and the use of the CTE with CHIRP System. Assess if the patient's anatomy is appropriate for using the Canary CTE implant X-Ray Templates.

Ensure the patient has access to a computer with USB connectivity and a home Wireless Internet connection..

WARNING: The patient needs to have sufficient intramedullary space to accommodate the increased length of the CTE implant in order to avoid cortical perforation.

When the patient decides on TKA with the CTE and CHIRP System, direct the office staff to onboard the patient using the Physician Portal.

11.1.2. Surgeon's Office Staff

1. Create a new patient account by logging into the Canary Physician account. After logging in, you will see the "Doctor Dashboard" screen in Figure 13. Click on "Patient List."

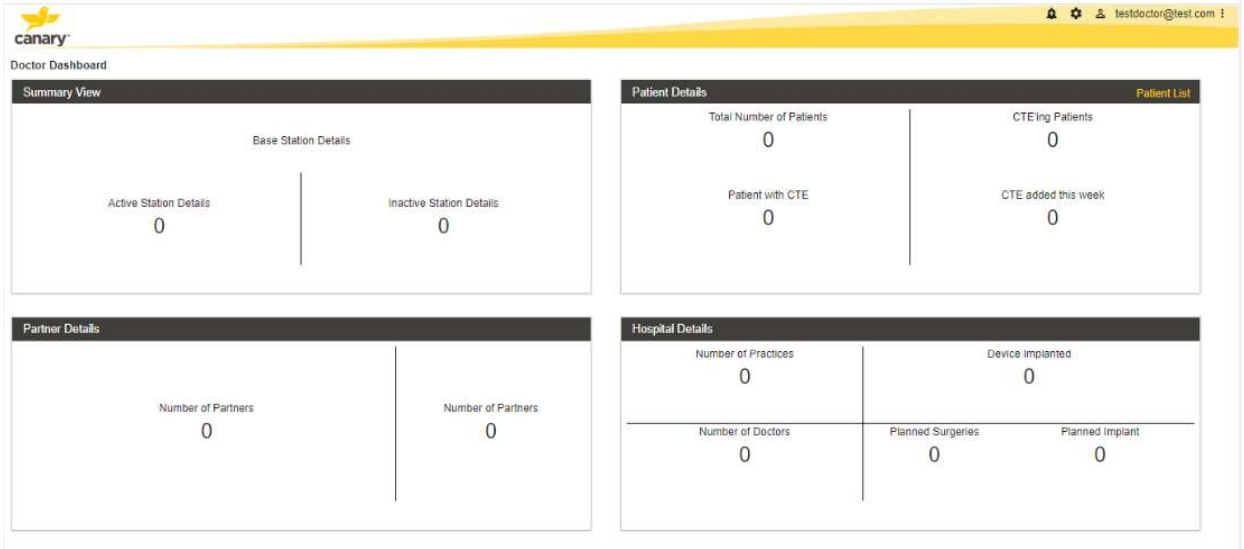


Figure 13

2. Figure 14 shows a screenshot of the Patient List screen. Click on “Create.”

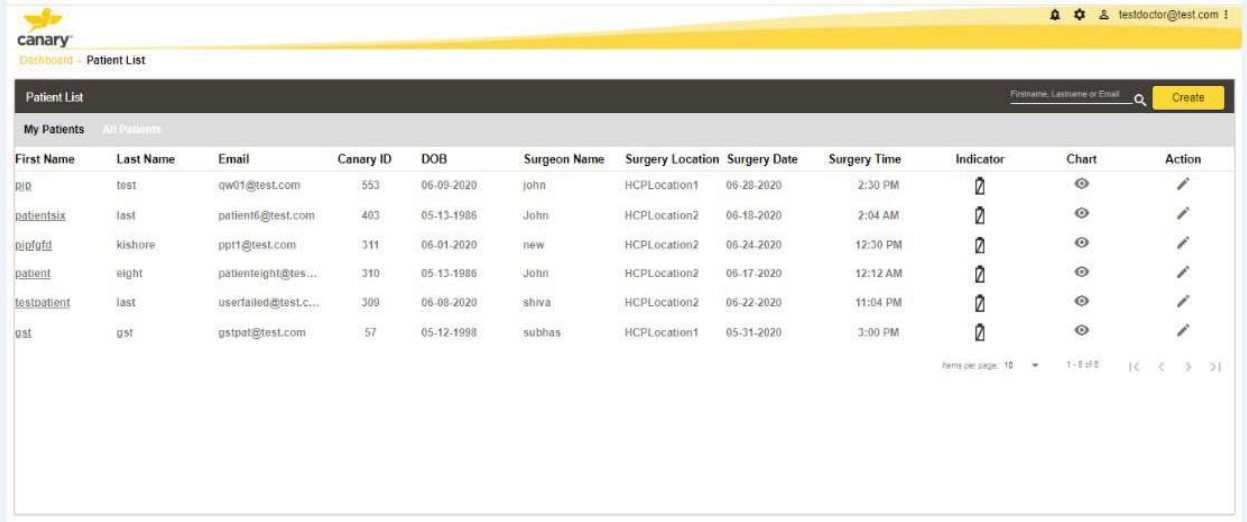


Figure 14: Patient List Screen

3. Use the “Create Patient” screen (Figure 15) to enter the patient’s information (name, DOB, email, etc.). Click “Submit.”

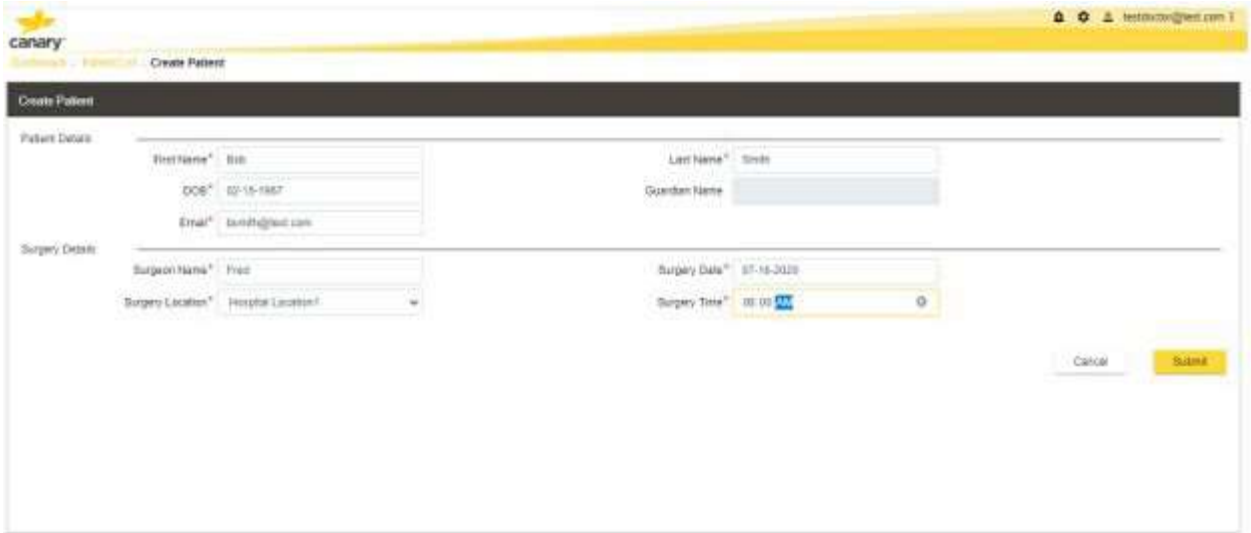


Figure 15: Create Patient Screen

4. Instruct the patient to watch for an email with a link and directions on how to register and set up a patient account.

5. Provide the patient with a copy of the Quick Start Guide, *Setting Up Your Patient Account*, document # K01-HBS-300005

11.2. Patient Registration and Account Setup

11.2.1. Patient

The patient receives the email and uses the Quick Start Guide, *Setting Up Your Patient Account*, document # K01-HBS-300005, to register and set up a patient account. The following are the steps in this process.

1. The Canary Cloud emails the patient a link to create a patient account.

2. The patient clicks the link and creates a patient account.

    a. The patient creates the password for their Canary Patient account and logs in.
    b. The patient provides consent for receiving the CTE and data collection by the CTE.
    c. The patient accepts the Terms and Conditions for use of the CTE with CHIRP System
    d. The patient enters their personal information

3. Upon successful registration, Canary Medical ships the Home Base Station equipment to the patient.

11.3. Home Base Station System Setup

11.3.1. Patient

The patient receives the Home Base Station package, which includes a Quick Start Guide, *Setting Up Your Home Base Station Patient Manual*. The patient sets up the Home Base Station System using the Quick Start Guide (document # K01-HBS-300006) and *Patient Manual* (document # K01-HBS-300003). The steps to set up the Home Base Station System are summarized below.

The Patient:

1. Receives the shipment of Home Base Station components

2. Opens the package, inspects the equipment, and identifies the enclosed Quick Start Guide and Patient Manual.

3. Turns on the patient's personal computer with USB connection, opens a web browser, navigates to the Canary website, and logs into the patient's account, which was created previously.

4. Follows the instructions in the Quick Start Guide and Patient Manual to set up the Base Station.

11.4. Day of Surgery

The following provides instructions on how to set up, test, and activate the CTE implant. It also tells you how to link the CTE implant and associated Zimmer knee components to the specific patient.

This information is a summary. For a complete description of this process, including example screenshots, refer to the *Canary Medical Surgical Technique*, document # K01-CTE-300005, provided at www.canarymedical.com.

11.4.1. Preoperative: CTE Implant Self-Test and Sensor Check

NOTE: The OR App **will not** function and you will not be able to log in without first connecting the OR Base Station to the Laptop.

1. Turn on the Canary Laptop and ensure it has a Wi-Fi connection

2. Gather a CTE implant, the OR Base Station Unit, Bar Code Scanner, and USB data and power cables.

    a. Check the expiration date on the CTE package to ensure the implant is not expired.

WARNING: To avoid potential patient injury, do not use the CTE implant if it is expired.

NOTE: Do not open the CTE package at this time.

3. Set up the OR Base Station system in or near the OR but outside the sterile field, using the steps below:

    a. Place the Base Station stand on a flat surface. Place the Base Station into the stand as shown in Figure 16. Insert the provided screw through the groove in the stand into the Base Station. Tighten the screw with a screw driver.

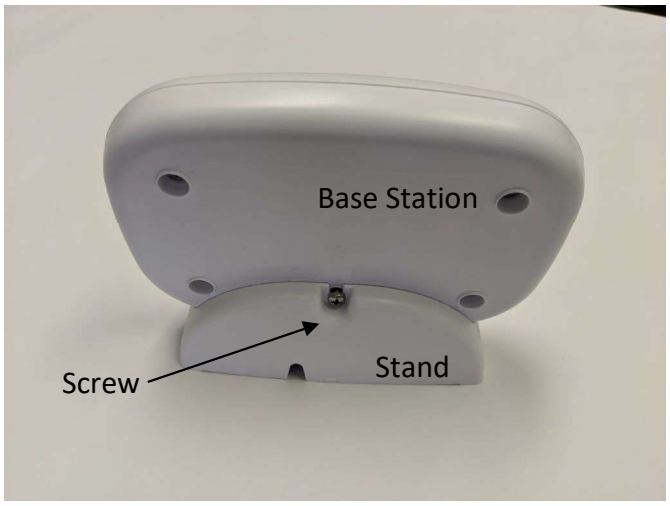


Figure 16: Base Station in Stand – Rear View

b. Connect the USB cable to the OR Base Station on one end and the Laptop PC on the other, as shown in Figures 17 and 18.

Figure 17

Figure 18

c. Connect the Barcode Scanner to the Laptop.

d. Plug the Laptop into a power outlet (if needed).

e. Turn on the Laptop. The Canary Operating Room Application (OR App) will launch automatically.

f. Ensure the OR Base Station and Laptop are connected. This is indicated by the green "Base Station" icon at the top right of the Laptop screen.

g. Ensure an Internet connection has been established and the OR App is connected to the Internet. This is indicated by the green "Internet" icon at the top right of the screen. If the OR App is not connected to the Internet, check the time of last sync. If it has been some time since this has been done, move to a location and attempt to connect to the Internet.

h. Click on the Canary logo in the center of the screen.

i. Enter your authorized Username and Password and click the "Login" button.

j. On the Main Menu screen, under "Preoperative," click on "Setup Implant."

k. Enter or scan the CTE serial number from the implant package and click "OK."

l. The Base Station initiates communication with the CTE implant. Click "OK" when this process is finished.

m. Click on Self-Test.

n. Click on Sensor Check.

o. When the Self-Test and Sensor Check are successful (shown by the "implant status" indicators on the screen), the CTE implant is ready to be used for the patient's TKA surgery. If the Self-Test and Sensor Check have been run successfully within the last 24 hours, the status will reflect that, and the user can elect to not repeat these tests.

11.4.2. Intraoperative: Tibia Resection, Preparation, and Trialing

The tibia resection and preparation is done similarly to the Zimmer Biomet Persona® technique. **However, the CTE with CHIRP System surgical technique deviates from the Persona Knee Surgical Technique in order to properly place the CTE implant**.

Refer to **both** the Canary Medical CTE with CHIRP System and Zimmer Biomet Persona Knee IFUs and Surgical Techniques for the detailed technique steps. See Section # 2 of this IFU for document references.

The steps to complete the tibia resection and preparation are summarized below.

CAUTION: Perform the tibia resection using the Canary Medical Tibia Resection Cutting Guide.

The Zimmer Biomet Persona Tibia Resection Cutting Guides have not been tested for use with the Canary Tibial Extension (CTE).

1. Use the Persona instrumentation to properly align and size the tibia plate

2. Create a pilot hole using the Zimmer Biomet Drill Guide and Persona Tibial Drill Bit. Then use the Canary Medical Drill Bit and Drill Guide to create a cavity in the IM canal for the CTE implant and cement mantle.

3. Broach the tibia using the Persona instrumentation to create a cavity for the Persona Tibia Plate.

4. Assemble the CTE Provisional to the Persona Tibia Plate Provisional and insert the provisional construct into the prepared tibia to assess the fit of the construct. Confirm the final implant sizing.

11.4.3. Intraoperative: Activate the CTE implant

After the CTE implant has been introduced into the sterile field, and before assembly with the Persona tibial plate, activate the CTE implant using the OR PC Application and OR Base Station.

1. Go to the Main Menu screen.

2. Under “Intraoperative,” click on “Activate Implant.”

3. Click in the text box and enter or scan the CTE Serial Number. Click “OK.”

4. Click “Activate.”

5. The Activation Status on the screen will change from “Not Activated” to “Activated.”

11.4.4. Intraoperative: Connection of Canary CTE to Zimmer Biomet Tibial Baseplate and Implantation

NOTE: In order to attach the Canary CTE to the Zimmer Biomet Persona® Knee tibial plate, the following Canary Medical instrumentation is required:

- CTE Impaction Sleeve

CAUTION: Do not attempt to connect the Canary CTE to the Zimmer Biomet Persona® Knee tibial plate without the Canary Medical instrumentation. Use of different instrumentation may result in incorrect connection or damage to the implant components.

After preparation of the patient and confirmation of the trial devices, perform the following steps:

1. Remove and discard the plastic cap on the Zimmer tibial plate.

2. Remove and retain the set screw on the Zimmer tibia plate.

3. Place the CTE implant into the Zimmer tibia plate while aligning the anterior lines on each component.

4. Place the CTE Impaction Sleeve over the CTE implant and strike the CTE Impaction Sleeve multiple times with a 2 pound surgical hammer.
5. Tighten the set screw on the Zimmer tibia plate using the torque limiting Zimmer instrumentation.

6. Remove the CTE Impaction Sleeve.

7. After successful attachment of the CTE implant to the Zimmer tibia plate, discard the impaction sleeve as medical waste.

CAUTION: Be sure to remove the CTE Impaction Sleeve from the assembled prosthesis. Do not implant the Impaction Sleeve.

WARNING: The Impaction Sleeve is single use only. After use, discard the Impaction sleeve as medical waste. Re-use of single use devices can result in serious patient injury, infection, or death.

8. Optional: A Self-Test can be performed from the OR Base Station to ensure the CTE implant is still functional after assembly.

9. Mix and apply the PMMA bone cement and apply it to the Zimmer Biomet tibial plate and CTE implant.

10. Place the assembled knee prosthesis into the anatomy and proceed as usual for a TKA procedure.

11.4.5. Postoperative: Link the CTE implant and Knee Prosthesis Components to the Patient

After the surgery is complete, use the OR PC Application and Bar Code Scanner to link the patient's implant components with the patient in the patient's account using the steps below:

1. Go to the Main Menu screen.

2. Under "Postoperative," click on "Link Implant – Patient."

3. Choose the patient's name from the list or click "Manually Enter Patient" to enter the patient's information. A search function is also available at the top of the screen.

4. Choose the implant location (left or right knee) and click "Next."

5. Click in the text boxes to enter or scan the serial numbers from the labels of the CTE and other Zimmer Biomet Persona® Personalized Knee System implant components. Ensure you enter all the required information (denoted by red asterisks), otherwise you will not be able to submit the information.

6. Click "Submit" to save the information to the patient account.

Dispose of any non-reusable instrumentation as biohazard hospital waste.

11.5. HCP

- Remind the patient to verify upon returning home that the Home Base Station System is located correctly, powered on, and connected to the home wireless Internet connection.
- Remind the patient of the availability of the Patient Dashboard to review gait and activity information.
- After Post-Operative day 3, log on to the Canary Medical account to view the patient's gait and activity information on the HCP Dashboard. The data presented is for the previous sample day's activity.

11.5.1. Patient

When the patient returns home, the patient or a caregiver ensures that the Home Base Station System is functioning by:

- Verifying that the Home Base Station System is still connected to their home Wi-Fi by viewing the status light on the base station and ensuring it is green
- Verifying that the Home Base Station Unit is located within 6 feet of the patient's sleeping area

The CTE with CHIRP System is designed to operate autonomously. Using its proprietary data collection and power management algorithms, the CTE implant will collect, store, and transmit encrypted raw kinematic data from the implant's triaxial accelerometers and triaxial gyroscopes via the patient's home Base Station unit to the Cloud. The data will then be processed, analyzed, and converted to quantifiable Canary Medical Gait Parameter metrics.

After post-operative day 3, the patient can log on to the previously-established Canary account to view the Patient Dashboard. The patient can use an Internet browser to view the Patient Dashboard by following the instructions in the Patient IFU. Gait parameters presented on the Patient Dashboard are for the previous sample day's activity.

12. ADVERSE EVENTS

Potential adverse events associated with TKA and/or the Zimmer Biomet Persona® Personalized Knee System with the CTE with CHIRP System include but are not limited to those listed below:

- Knee-joint infection
- Heart attack
- Stroke
- Blood clots
- Bleeding
- Slow wound healing
- Infection
- Allergic reaction to the knee implant components
- Blood vessel damage
- Nerve damage
- Stiffness
- Poor range of motion
- Swelling and joint pain
- Knee instability and/or dislocation
- Loosening or fracture of the knee implant components
- Bone fracture or break during surgery
- Leg length discrepancy

13. COMPATIBILITY WITH OTHER DEVICES

The CTE implant is designed to interface with the Tibia Plate of the Zimmer Biomet Persona® Personalized Knee System. The surgical team attaches the CTE to the Zimmer device to form the patient's knee prosthesis. Specialized Canary Medical instrumentation is used during the attachment process and tibia preparation.

The CHIRP System is compatible with a range of computing devices and systems. Table 6 lists the compatible device types and operating systems, and minimum specifications that will be required in order for data from the CTE to be accessible from the Canary Medical website to health care providers and patients.

Table 6. Compatible Device Types and Operating Systems

Minimum supported resolution	1024 x 768
Supported browsers and minimum versions	Microsoft Edge Google Chrome
Minimum operating environment for the PC that runs the Base Station Setup Tool (patient PC)	Windows 10 or higher
Minimum number of USB ports for patient PC	1

14. COMPONENT SPECIFICATIONS

Table 7: CTE Specifications

Category	Specification
Weight	25 grams
Dimensions	**OAL (w/Antenna Cover attached):** 3.063 inches (REF) **OAL (without Antenna Cover):** 2.138” [+/- 0.005 inches] **Body OD (Grooved with Canary Medical Imprint):** 0.511” [+ 0.000/ -0.004 inches] **Tip OD:** 0.285” [+/- 0.004 inches] **Antenna Cover Thread:** M10 x .5
Power Source	Battery, Single Cell, Lithium Carbon Monofluoride (Li/CFx) 3.21V (@nom.)
Battery	**Case:** Ti alloy, Grade 2. **Weight** (Battery): 7.6g **Self-Discharge:** Less than 0.5%/year.

Category	Specification
	Long Term Storage: Up to 36 months at 22 +/- 6 degrees C, stored in supplier's ambient environment. **Normal Operating Conditions:** The battery shall meet all performance requirements over a temperature range of 35 to 41°C inclusive.
Current Consumption	**Lowest Usage Current Consumption:** < 200 nA **Communication Standby Current Consumption:** < 500 nA **Low Resolution Mode Current Consumption: <** 15µA. **Medium Resolution Mode Current Consumption: <**2000µA **High Resolution Mode Current Consumption: <**2000µA
Mode of Operation	Five (5) **Modes of Operation** for the CTE implant (without patient involvement**):** • Deep Sleep Mode; • Standby Mode; • Low Resolution Mode (Step count); • High Rate Mode; • Six Degree of Freedom (6DOF) Mode. **Continuous Sampling:** • Step Counting and detection of significant motion; • Detection of linear acceleration and angular rate of motion; • Collection of acceleration data at high sampling rates (up to 800 Hz).
Safe Storage and Transport Temperature Range	**Temperature, Storage:** 15C to 25C. **Temperature, Transportation Environmental:** Per ISTA 3A, method ASTM D4332.
Safe Storage and Transport Relative Humidity	**Relative Humidity, Storage:** 10% to 90%. **Relative Humidity, Transportation Environmental:** Per ISTA 3A, method ASTM D4332.
Protection from Electric Shock	Standard (e.g., 60601-, Type, e.g., BF)

Category	Specification
Protection from Ingress of Liquids	Standard IEC-60601, clause 6.3. [Also identified in ISO-14708-1 and IEC-60529.]
CTE Impaction Sleeve	OAL: 63.5 mm Max OD: 22 mm ID: 13.08 mm Material: 17-4 PH SS

Table 6: OR Base Station System Specifications

OR Base Station Unit	Specification
Weight	1 lb.
Dimensions	18 cm wide by 18 cm long by 5 cm high.
Power Source	AC/DC; external mains; USB AC/DC power adapter or from an external PC.
	Battery
Battery	CR1220, coin cell.

OR Base Station Unit	Specification
Mode of Operation	**Operational Modes:** • Power on (w/self-test) • Normal operating • Fault (self-test failure) **Mode of Operation:** The surgical team uses the OR Base Station System before and during the TKA surgery to register the patient and initiate the CTE implant so that it will begin collecting data after the patient's surgery. The OR Base Station System consists of an OR Base Station unit, dedicated laptop PC loaded with the Canary software application, barcode scanner, and USB cables.
Recommended Operating Conditions	**Temperature:** +5°C to +40°C; **Relative Humidity**: 15% to 93% (non-condensing).
Safe Storage and Transport Temperature Range	**Storage**: 15° C to 25° C **Transportation Environment:** Per ISTA 3A, method ASTM D4332.
Safe Storage and Transport Relative Humidity	**Storage**: 10% to 90% (noncondensing). **Transportation Environment:** 10% to 95% (noncondensing).
Protection from Electric Shock	Per IEC 60601-1-11, clause 10.1.3 b
Protection from Ingress of Liquids	Per IEC-60529, OR base station rated as IP21.
Audible Output Levels	None. (Not applicable.)

OR Base Station Unit	Specification
Personal Computer	**Specification**
Manufacturer	Dell
Operating System	Windows 10
Canary Software	**Specification**
Version	TBD
Bar Code Scanner and Cable	**Specification**
Manufacturer	Aibecy Handheld 2.4G Wireless 1D/2D/QR Barcode Scanner Bar Code Reader with USB Receiver 4000 Code Storage Capacity for POS PC Android IOS.
USB Power and Data Cables	**Specification**
Manufacturer	Qualtek 3021084-03 (OR 3ft USB Data cable)
Dimensions	USB 2.0 Cable A Male to Micro B Male, Up Angle 3.00' (914.4mm) Shielded, USB Data Cable.
Power Source	AC/DC

Table 7: Home Base Station System Specifications

Home Base Station Unit	Specification
Weight	1 lb.
Dimensions	18 cm wide by 18 cm long by 5 cm high.

Home Base Station Unit	Specification
Power Source	AC/DC
	Battery
Battery	CR1220, coin cell.
LED Light Output	Red, Green - 78 mW Blue - 80 mW Red, Green, Blue (RGB) 625nm Red, 525nm Green, 470nm Blue LED Indication - Discrete 1.9V Red, 3.3V Green, 3.3V Blue 4-PLCC
Mode of Operation	**Operational Modes:** • Power on (w/self-test) • Normal operating • Fault (self-test failure) **Mode of Operation:** The Home Base Station System is located at the patient's home, where it is set up by the patient prior to the date of surgery. The Home Base Station System provides an interface for communication with the patient's CTE implant. It consists of a Home Base Station unit, the patient's USB-enabled personal computer, the patient's wireless Internet connection, and a USB power and data cable. After TKA surgery, the Home Base Station unit begins collecting the patient's gait and activity information from the CTE. The Home Base Station unit transmits the data to the Cloud, and also has the capability to store the data for up to thirty days.

Home Base Station Unit	Specification
Recommended Operating Conditions	**Temperature:** +5°C to +40°C; **Relative Humidity**: 15% to 93% (non-condensing).
Safe Storage and Transport Temperature Range	**Storage**: 15° C to 25° C **Transportation Environment:** Per ISTA 3A, method ASTM D4332.
Safe Storage and Transport Relative Humidity	**Storage**: 10% to 90% (noncondensing). **Transportation Environment:** 10% to 95% (noncondensing).
Protection from Electric Shock	Per IEC 60601-1-11, clause 10.1.3 b
Protection from Ingress of Liquids	Per IEC-60529, OR base station rated as IPX1.
Audible Output Levels	None. (Not applicable.)
Personal Computer	**Specification**
Manufacturer	Patient's Choice
Operating System	Windows 10
USB Power and Data Cables	**Specification**
Manufacturer	Molex 687680400 (Home 2m USB cable) CUI SWM6-5-NH-I38 (Home USB Power Supply)
Dimensions	55.6mm x 27.1mm x 37.2mm (Home USB Power Supply)
Power Source	AC/DC

15. DATA SECURITY AND PATIENT PRIVACY

All communication between the CTE implant and the Base Station units employs a unique communication protocol, with each CTE having a unique radio that is assigned to it in manufacturing. Base stations can communicate with only one CTE at a time using this radio ID.

NOTE: A patient could potentially have two CTE implants (one in each knee) but would only need one Base Station in that scenario.

The communication between base stations and CTE is also encrypted (both the data payload and messaging) with the unique encryption key assignment during the manufacture of the CTE. In addition, communication integrity as well as data integrity checks are applied on the data received at both ends.

The Canary Medical Cloud Platform is designed for assuring HIPAA-compliance. When a Home Base Station is set up by the patient, a secure connection is established between the Base Station and the Canary Cloud and is in effect for all communication thereafter. The Home Base Station unit decrypts messages and data from the implant, adds the serial number of the CTE, packages and encrypts the unprocessed data before transmitting the encrypted unprocessed data to the Cloud using standard TLS (Transport Layer Security) protocol. The communication and data are checked for integrity by the Cloud application before it is processed to output the CMGP.

Patients who wish to receive the CTE with CHIRP System must consent to the CTE implant data collection, storage, analysis, and sharing of their implant and basic personal and health data with HCP(s) they designate to provide their healthcare. As such, data will be identifiable to their healthcare providers and authorized administrators of the Canary Medical CTE with CHIRP System. The patient will have the right to be forgotten and will have the ability to turn off the kinematic data collection of the device after a minimum required time for data generation. If the patient does not wish to consent, they can receive a standard of care, non-reporting tibial extension.

Each HCP and patient user are assigned a unique username and will be prompted to enter a password at initial login. The unique username and password is needed for logging into their account thereafter and accessing the physician and patient dashboards, respectively.

16. COMPONENT MAINTENANCE

16.1. CTE

The CTE is an implant that remains in the body indefinitely and therefore cannot be maintained.

16.2. Base Station Units and Accessories

Maintain the Base Station Units and Accessories by keeping them clean, dry, and free of surrounding clutter.

Home Base Station: Dust with a clean, dry, soft cloth.

OR Base Station: The following solutions have been tested for safe cleaning of the OR Base Station unit, part # 43-5570-002-14 only. Wipe the OR Base Station Unit with a soft cloth dampened with one of these solutions.

1. 1:10 Bleach Solution
2. 1:10 Mild Detergent Solution
3. Ammonia Solution (RTU)
4. 70% Isopropyl Alcohol
5. 0.5% Hydrogen Peroxide
6. Phenolic germicidal detergent solution (RTU)
7. Iodophor germicidal detergent solution (RTU)

WARNING: Do not immerse the base stations in water or cleaning agents as this could cause electrocution.

16.3. SOFTWARE MAINTENANCE

All software updates will be initiated by Canary Medical.

17. SERVICE LIFE

17.1. CTE

The service life of the CTE is estimated to be at least ten years based on; a) accelerated discharge testing of the batteries, b) bench testing of current consumption by the CTE electronics, and c) assuming no more than 1000 sampling days are programmed into the CTE. However, the CTE is designed for up to 20 years of service life.

17.2. Base Station Units and Accessories

The Base Station Units and Accessories are intended to last for 3 - 5 years and can be replaced in case of them being non-operational.

18. SERVICING

18.1. CTE

The CTE is an implant, thus, it is unable to undergo service from a mechanical perspective, however, the CTE can receive software updates initiated from the Canary Cloud.

18.2. Base Station Units and Accessories

If a Base Station Unit or accessory is not working properly, please see Appendix 3, Troubleshooting, for a potential solution to the problem. If the issue cannot be fixed, please call Canary Medical for instructions on how to further troubleshoot or return the unit for replacement.

19. DISPOSAL

19.1. CTE

The CTE is a single-use device. If explantation is necessary, do not reuse, reprocess, or resterilize the CTE. Dispose of the explanted CTE according to your facility policy as biohazard medical electronics waste**. Do not incinerate the explanted CTE.**

In the event of the death of a patient who has received the CTE implant, inform end-of-life staff that the patient has an implant containing a battery.

WARNING: Re-use of single-use components could result in patient infection, injury, or death.

WARNING: The CTE contains a battery. Do not incinerate the CTE by cremation or any other means. This could result in explosions that damage equipment or cause injury to people.

19.2. Canary Medical Surgical Instrumentation

The Canary Medical instrumentation, except for the CTE Impaction Sleeve, is reusable. Reprocessing of any of the Canary Medical instrumentation (except the CTE Impaction Sleeve) must be accomplished according to the Canary Medical Instrument Care Instructions for Use, document # K01-INT-300019.

The CTE Impaction Sleeve is single-use only and is not reusable. After use, dispose of the CTE Impaction Sleeve according to your facility policy as biohazard medical waste.

WARNING: Re-use of single-use components could result in patient infection, injury, or death.

19.3. Base Station Units and Accessories

Dispose of Base Station Units and Accessories as electronics waste or return them to Canary Medical.

20. WARRANTY

TBD

21. PATENTS AND TRADEMARKS

The Canary Bird logo (color and black and white) and the following text are pending trademarks of Canary Medical:

- CANARY MEDICAL

- CHIRP
- CHARM
- DIGITAL REFORMULATION

The Zimmer Biomet Persona® Personalized Knee System is a registered trademark of Zimmer Biomet.

APPENDIX 1 – SYMBOLS GLOSSARY

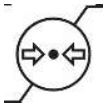
Table 8 shows the symbols used in this document and their meanings.

Table 8

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	Canary Medical Logo		
	The name of the device's manufacturer	ISO 7000 —3082 Graphical symbols for use on equipment -- Registered symbols	Manufacturer
	The catalogue or order number assigned to the device by the manufacturer	ISO 7000 — 2493 Graphical symbols for use on equipment -- Registered symbols	Catalogue Number
	The unique serial number assigned to the device by the manufacturer	ISO 7000 — 2498 Graphical symbols for use on equipment -- Registered symbols	Serial Number
	An indication on the device's package where it is to be opened	ISO 7000 — 3079 Graphical symbols for use on equipment -- Registered symbols	Open Here
	Instructs the user not to re-sterilize the device	ISO 7000-2608 Graphical symbols for use on equipment -- Registered symbols	Do Not Re-sterilize
		ISO 15223-1 clause 5.2.6	

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	Instructs the user not to re-use the device	ISO 7000-1051 Graphical symbols for use on equipment -- Registered symbols	Do Not Re-use
		ISO 15223-1 clause 5.4.2 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	
		IEC 60601-1 clause 7.2 Medical Electrical Equipment	
	Tells the user that the device is sterilized with Ethylene Oxide	ISO 7000-2501 Graphical symbols for use on equipment -- Registered symbols	Sterilized Using Ethylene Oxide
		ISO 15223-1 clause 3.23 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	
		ISO 14708-1, clause 11.2 Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	
	Informs the user not to use the device after the date listed on the package The date is formatted YYYY-MM-DD according to ISO 8601	ISO 7000-2607 Graphical symbols for use on equipment -- Registered symbols	Use by date
		ISO 14708-1, clause 9.7 and 11.5 Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
		ISO 8601-1 A2.1 Date and time — Representations for information interchange — Part 1: Basic rules	
	Date the device was manufactured	ISO 14708-1, clause 9.6 and 11.6 Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	Date of Manufacture.
	Directs the user to read the instructions for use	ISO 7010-M002 Graphical symbols -- Safety colors and safety signs -- Registered safety signs	Refer to instruction manual/booklet
		IEC 60601-1 7.2.3 IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	
	For prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.	
	Instructs the transporter of the device package to keep the device package dry	ISO 7000-0626 Graphical symbols for use on equipment -- Registered symbols	Keep dry.
		ISO 15223-1 clause 5.3.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	
	Instructs the transporter of the device package to	ISO 7000-0624 Graphical symbols for use on equipment -- Registered symbols	Keep away from sunlight

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	protect the device package from sunlight	ISO 15223-1 clause 5.3.2 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	
	Indicates the device is compliant with the RoHS regulation found in the European Union Directive 2002/95/EC		
	transport and storage temperature limit	ISO 14708-1 clause 9.11	Temperature limit
	transport and storage humidity limit ISO 7000-2620	ISO 14708-1 clause 9.11	Humidity limitation
	transport and storage atmospheric limit ISO 7000-2621	ISO 14708-1 clause 9.11	Atmospheric pressure limitation
	Directs the user not to use the device if the package has been opened or damaged	ISO 15223-1 clause 5.2.8 ISO 11607-1 clause 10	Do not use if package is damaged
	defibrillation-proof type CF applied part and IEC 60417-5336 symbol	IEC 60601-1 clause 8.5.5.1	Defibrillation-Proof Type CF Applied Part

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
	electrical classification: Class II and IEC 60417-5172 symbol	IEC 60601-1 clause 7.2.6	Class II equipment
	MRI Conditional with ASTM F2502 7.3.1.1 symbol:	ISO/TR 10974 2018-04 Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	
	FCC Declaration of Conformity		
	NRTL certification symbol		

APPENDIX 2 – DEFINITIONS

Table 12

Term	Definition
Base Station Subsystem	The Base Station subsystem serves as a conduit between the CTE implant and the Cloud subsystem. The Base Station subsystem consists of a Base Station unit and additional components (i.e. network-connected PC, PC Application, etc.) to establish an appropriate transmission center in the use environment.
Base Station unit	The Base Station unit is an intermediary receiver / transmitter that is able to wirelessly communicate with a CTE implant. The Base Station interfaces with either software or the Cloud directly to facilitate retrieving and storing data from the CTE implant for storage and processing in the Cloud.
Cadence	The average amount of steps per minute
CTE implant	The CTE implant is an implantable tibial extension that collects data and wirelessly transmits data from a Patient.
Cloud	Simplified terminology used to refer to the Canary Closed Cloud System. The Canary Closed Cloud System is an external database that resides on the Internet and contains software for driving schedules, settings, and configuration data reporting for the collection system, and stores the telemetry collected from the CTE implant, uploaded via the Base Station system.
Distance	Total distance traveled while walking
Gait	The form of ambulation/locomotion

Term	Definition
Gait Cycle or Stride	Sequence of movements during locomotion in which one foot contacts the ground to when that same foot contacts the ground again
HCP	Persons who have education in health care and are directly related to the provision of health care services (i.e. surgeons, physicians, physician's assistants, nurses, nursing assistants, therapists, technicians)
Kinematic	The geometric mechanics of motion
Processed Data	Analyzed data from the CTE implant, derived from Raw Data.
Range of Motion	The full movement of a joint (i.e. flexion-extension)
Raw Data	Three dimensional Accelerometer and three dimensional Gyroscopic data that is collected on the CTE implant
Step Count	Number of steps taken
Stride Length	Average distance traveled during one gait cycle
Walking Speed	Average sagittal plane distance walked per unit time

APPENDIX 3 – TROUBLESHOOTING

Table lists some issues you might encounter with the CTE and CHIRP System, as well as some suggested actions which may resolve the issues. If you have a problem with the system that is not listed here or that cannot be resolved with the information provided, call Canary Medical.

Table 13

Problem	Action
I can't reach the Canary Medical website	Check your Internet connection and make sure you are connected to the Internet. If connected and still cannot reach the Canary Medical website, try again later.
I can't log in to my Physician Account.	Check your username and password.
I can't see my Physician Dashboard patient data information.	You will only see information on the selected patient the 3rd day after surgery. If the information is still not on your Physician Dashboard after surgery, wait 24 hours and check your Physician Dashboard again.

Manufactured for:

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Suite 350
Carlsbad, CA 92010
https://canarymedical.com/ Customer Service: 1-760-448-5066

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PLEASE READ THIS PROOF COMPLETELY AND CAREFULLY. WE CANNOT ACCEPT RESPONSIBILITY FOR ANY ERRORS WHICH SHOW ON THIS PROOF AND ARE NOT CORRECTED. PLEASE SIGN AND RETURN AS SOON AS POSSIBLE. PROOFS HELD OVER 24 HOURS WILL DELAY PRODUCTION.

☐OK AS IS ☐CORRECTIONS NEEDED

SIGNED_____DATE_____

PLEASE FAX BACK TO (562) 699-2123

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Date of Issue or latest revision of IFU YYYY-MM-DD