Persona IQ®
THE SMART KNEE®

CANARY canturio® Tibial Extension with CHIRP® System

Physician Instructions for Use

℞ only

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

ZIMMER BIOMET

canary

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1. Overview of the Canturio® Tibial Extension with CHIRP® System

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

The Canturio® Tibial Extension (*te*) with Canary Health Implanted Reporting Processor (CHIRP®) system is a tibial extension implant containing electronics and software. Using internal motion sensors (3-D accelerometers and 3-D gyroscopes), the canturio®*te* (CTE) implant 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 are intended as an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery, 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 device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58mm sized tibial stem extension. The objective kinematic data generated by the CTE with CHIRP system is not intended to support clinical decision-making and has not been shown to provide any clinical benefit.

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.

In order 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 Health Care Professionals (HCPs):

1. The Patient's anatomy must be capable of accepting the Zimmer Biomet Persona Tibial Baseplate with canturio®*te* construct sizing. This assessment will be conducted pre-operatively by the HCP using a CTE X-ray Template available through your Zimmer Biomet Representative.
2. The patient must have access to a computer with a USB connection to set up their Home Base Station or have access to a compatible smartphone to set up their Home Base Station (Bluetooth).
3. The Patient must have wireless internet in their domicile.

The CTE with CHIRP system technology package ultimately allows patients and their 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. Patients may also view their information on the Canary Medical Mobile Application.

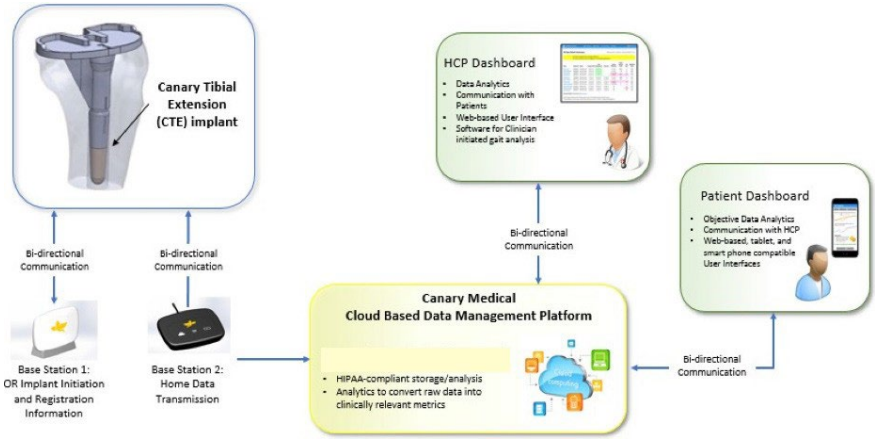

Figure 1: CTE with CHIRP System

WARNING: The kinematic data obtained from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.

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).

Document Title	Document Number	Location
Surgical Technique	K01-CTE-300005	Electronically available at canarymedical.com
Patient Manual	K01-HBS-300003	Electronically available at canarymedical.com
Patient Quick Start Guide – Home Base Station Setup	K01-HBS-300006	Printed document received with Home Base Station and electronically available at canarymedical.com
Patient Quick Start Guide – Home Base Station (with Bluetooth®)	K01-HBS2-300006	Printed document received with Home Base Station (with Bluetooth®) and electronically available at canarymedical.com
Patient Quick Start Guide – Setting Up Your Patient Account	K01-HBS-300005	Electronically available at canarymedical.com
OR Quick Start Guide – OR Base Station Setup	K01-ORBS-300003	Electronically available at canarymedical.com
Canary® Recovery Curves® Analytics – Instructions for Use	K01-CTE-300014	Electronically available at 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

Term	Meaning
CN	Circulating Nurse
CHIRP	Canary Health Implanted Reporting Processor
Cloud	Canary Cloud Based Data Management Platform
CMGP	Canary Medical Gait Parameter
CTE	Canturio Tibial Extension
EtO	Ethylene Oxide
HCP	Health Care Professional
Hz	Hertz
IFU	Instructions for Use
IM	Intramedullary
IMU	Inertial Measurement Unit

Term	Meaning
MR	Magnetic Resonance
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 Canturio® Tibial Extension (*te*) 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 Interface and 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 deter- mine 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
	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
	Canary OR Application	
	Barcode Scanner	AC-900001
	USB Power and Data Cables	AC-900004

Component or Interface	Description	Model Number or Catalogue Number
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)	
Home Base Station System (with Bluetooth®)	Home Base Station (with Bluetooth®) Unit	43-5570-001-15
	USB Data and Power Cables	AC-900002
	Power Adapter	AC-900003
	Canary Medical Mobile Application	
Canary Cloud Data Management Platform (Cloud)	Manages and processes patient data that can be accessed through the Patient or Physician Dashboard	
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 implant and processed by the Cloud	
Canary Recovery Curves Analytics	Accessory and optional software module. Provides aggregation and visualization of patient population data with certain demographics for each gait parameter.	

NOTE: The patient must have access to a computer with a USB connection to set up their Home Base Station or have access to a compatible smartphone to set up their Home Base Station (Bluetooth).

NOTE: Both physicians and patients can access their respective dashboards via an Internet browser. Patients may also access their dashboard via the Mobile Application.

4.1 Canturio Tibial Extension (CTE)

The CTE is a physical implant component that is attached by the orthopedic surgeon or scrub tech to the Zimmer Biomet Persona® The Personalized Knee® 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.

The CTE patient contacting components include titanium alloy (Ti-6AI-4V), Natural PEEK (polyether ether ketone) and Loctite M-31 epoxy. 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 CTE and Zimmer Biomet Persona Tibial Baseplate.

Figure 3: Zimmer Biomet Persona® The Personalized Knee® Tibial Baseplate with Canary Canturio® Tibial Extension

4.2 CTE X-Ray Template

The CTE X-Ray Template is a surgical instrument used to assist the surgeon during preoperative planning. The CTE X-Ray Template will be used to assess the patient anatomyfor the Zimmer Biomet Persona® The Personalized Knee® Tibia Baseplate with CTE construct sizing.

4.3 CTE with CHIRP System Surgical Instrumentation

All CTE with CHIRP system surgical instrumentation are supplied non-sterile in an instrument tray. The cleaning and sterilization instructions for surgical instrumentsare found in the Canary Medical Instrument Care, Cleaning and Sterilization 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. The CTE instrument consist of 17-4 PH Stainless Steel (passivated).

4.3.1 Impaction Sleeve

The Impaction Sleeve is a reusable (provided non-sterile, see Section 4.3), surgical instrument used to assist in attaching the CTE implant to the Zimmer Biomet Persona Tibial Baseplate. 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.

Figure 4: CTE Impaction Sleeve

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

The Canary Tibia Resection Cutting Guide (left or right option) is used for tibia preparation when implanting a Persona Primary Knee with a Canturio Tibial Extension (CTE) Implant. Figure 5 shows the Canary 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 intramedullary 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 Canturio Tibial Extension adds 58 mm to the length of the tibial keel nominally when assembled.

This CTE Provisional is used to ensure thefit 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 Base Station, intact skin contacting, material consists of polycarbonate and acrylonitrile / butadiene styrene (PC/ABS), Cycoloy.

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 laptop 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 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 Cloud. This action associates the particular CTE with the previously registered patient in the 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 Cloud without patient intervention. The OR Base Station System consists of an OR Base Station unit, dedicated laptop PC loaded with the Canary Medical software application, barcode scanner, and USB cables. Figure 8 shows a schematic of the OR Base Station system.

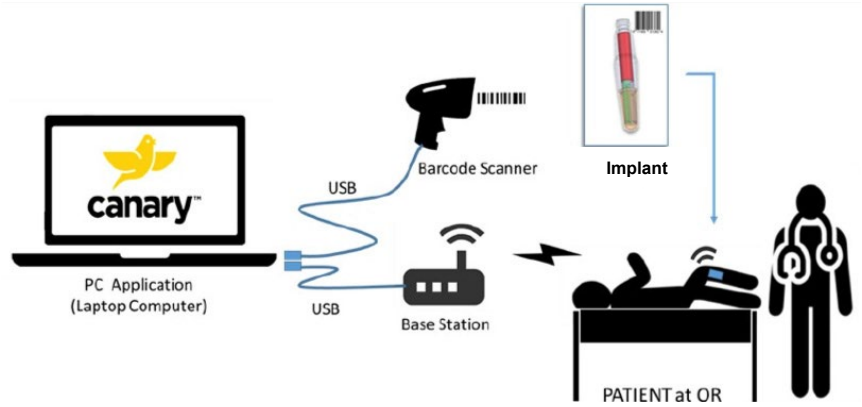

Figure 8: OR Base Station System

4.4.2 Home Base Station System

The Home Base Station system is located at the patient's home, where it is setup by the patient. 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 or smartphone, the patient's wireless Internet connection or smartphone internet/cellular connection, and a USB power and data cable. After TKAsurgery, 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 and compares Home Base Station model differences.

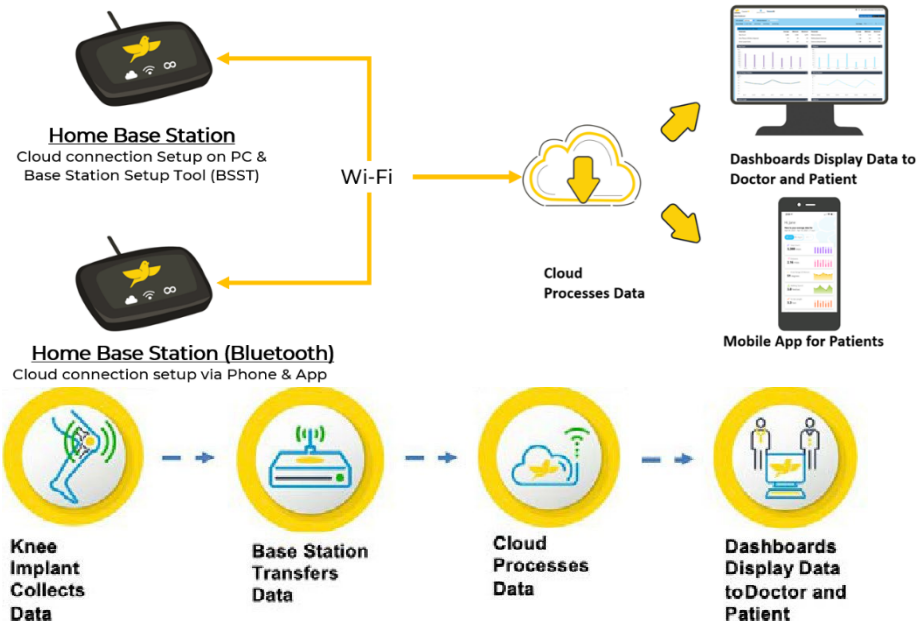

Figure 9: Base Station Communication

4.4.3 Cybersecurity Protection

The CTE implant does not have any open ports. Dedicated ports used in the system for data bases and application are not used by typical computer system users as laptops/smart Phone/Tablets and require valid access certificates.

4.4.4 Canary® Cloud Data Management Platform

The Canary Cloud Data Management Platform (the 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, healthcare professionals and patients to monitor the patient post-TKA as an adjunct to other physiological parameter measurement tools.

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.

4.4.5 Data Security

The CMGP databases are contained on the Microsoft Azure cloud platform in order to keep the data secure and facilitate back and restore functions.

4.5 Physician Dashboard

The Physician Dashboard 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 dashboard 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)
- Cadence (steps/minute)
- Functional Knee Range of Motion (degrees)
- Stride length (meters)
- Distance (kilometers)

When the HCP is viewing the Patient Chart on the Physician Dashboard, the HCP will have the option to view the patient's data with Canary® Recovery Curves® analytics via an actionable button. Clicking on the button will take the HCP to the Canary Recovery Curves view. *Refer to the Canary Recovery Curves analytics instructions for use (K01-CTE-300014) for additional information.*

Figure 10 shows an image of the actionable button on the Patient Chart.

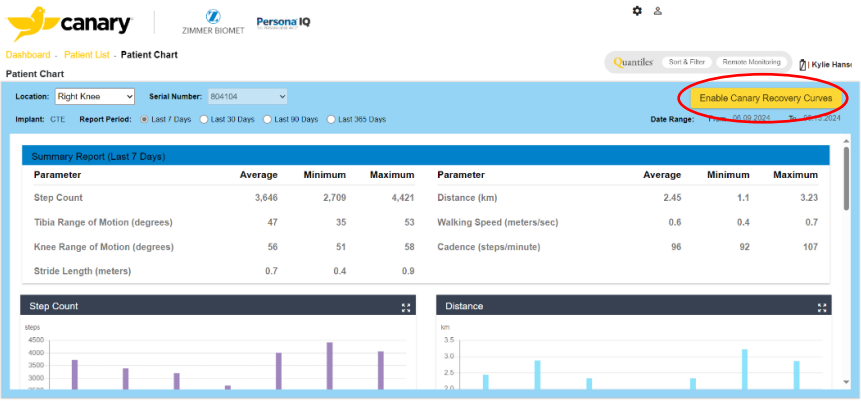

Figure 10: Image of Actionable Button on Patient Chart on Physician Dashboard

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, then that data is uploaded to the Cloud to be processed and reviewed. So the most recent data displayed is the previous day's data for HCP and patient review the following day.

The CTE implant has the ability to store 30 days 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 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 Cloud is made.

The CTE implant has been programmed 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	36 consecutive Days/Quarter
Years 3 and beyond	36 consecutive days commencing on the anniversary of the patient's 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.

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 include:

- 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 Chart on the Patient Dashboard.

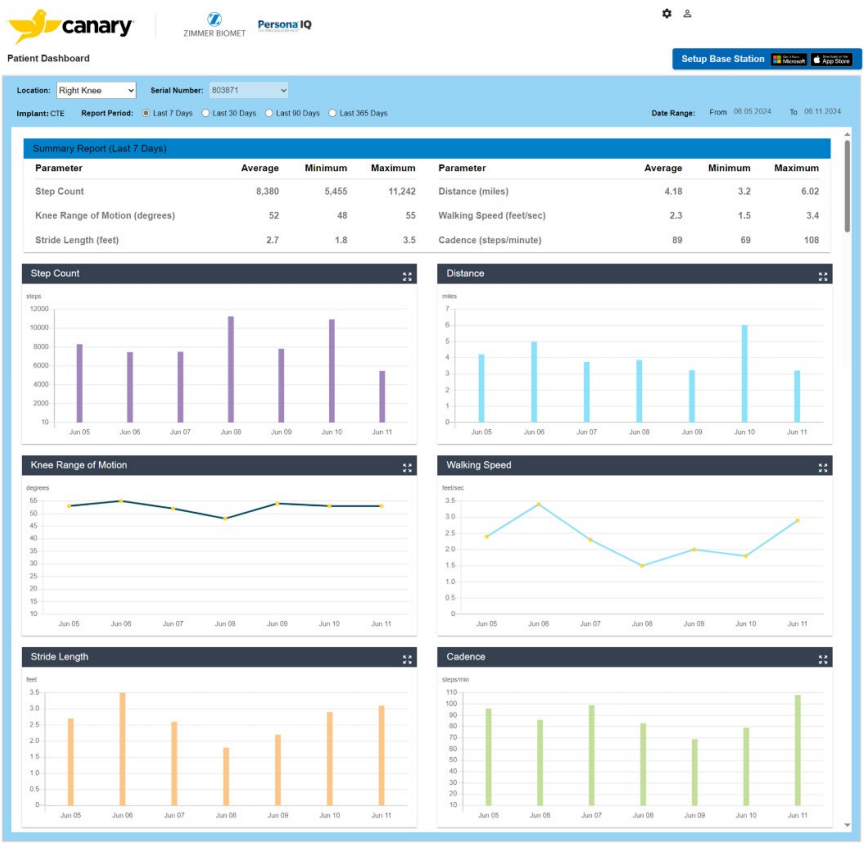

Figure 11: Screenshot of Patient Dashboard

4.6.1 Patient Mobile App Dashboard

The Patient may also login to the Mobile App to view their implant(s) data. Figure 12 shows a screenshot of the Patient Dashboard on the Mobile App along with an example of one of the gait metrics charts.

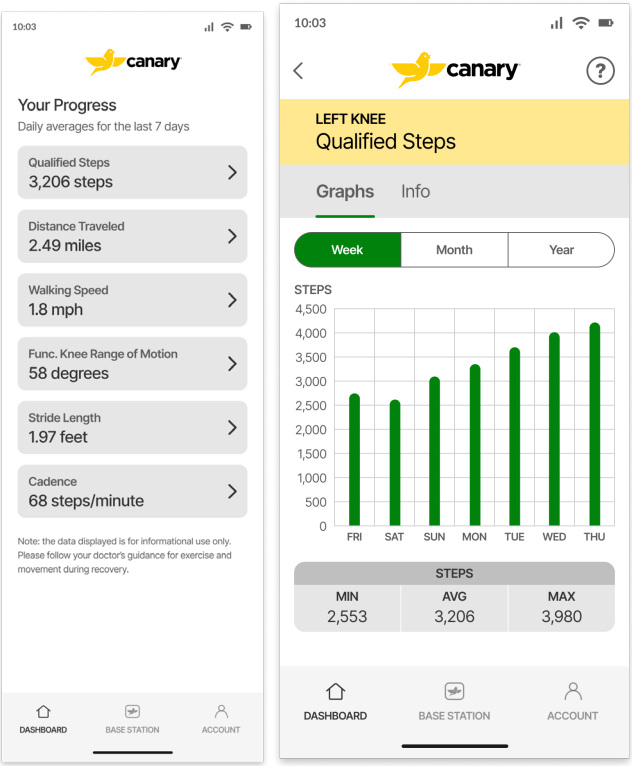

Figure 12: Screenshot of Patient Dashboard on Mobile App

5. Intended Use

5.1 Intended Use/Indications for Use

The Canturio® Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) system is intended to provide objective kinematic data from the implanted medical device during a patient's total knee arthroplasty (TKA) post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery.

The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

The objective kinematic data generated by the CTE with CHIRP system are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.

The CTE with CHIRP system is compatible with the Zimmer Biomet Persona® The Personalized Knee® system.

5.2 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 IQ® The Smart 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
Canturio® Tibial Extension (CTE) Implant	Patient, Surgical Team	Patient – Rehabilitate after surgery and acclimate to new implant. Surgical team – assembly, implantation and activation of the CTE implant
• Canturio Tibial Extension (CTE) Implant • Canary specialized assembly and insertion components 1. Impaction Sleeve 2. 5 deg Left Tibial Resection Cutting Guide 3. 5 deg Right Tibial Resection Cutting Guide 4. Tibial Drill Bit 5. 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 Biomet Persona® Tibial 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
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 the Cloud

Home Base Station (Bluetooth®) System • Base Station Unit • Power and Data Cables	Patient	• Set up Base Station components in Patient's home • Connect to home wireless Internet via Mobile Application Bluetooth • Download Mobile Application to set up communication between the CTE, Base Station Unit, and the 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
Mobile Application	Patient	Setup and manage the Home Base Station (Bluetooth®) for communication between the CTE, Base Station Unit, and the Cloud. Review patient's gait information and activity level
Canary® Cloud Data Management Platform (Cloud)	Canary Medical Staff	OR Base Station, Home Base Station, Physician and Patient In-formation 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 CTE X-Ray Template.

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

The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

The sale, distribution, and use of Canturio Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) system are restricted to prescription use in accordance with 21 CFR Part 801.109.

The outputted data from Canturio Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) system are not intended to be utilized for clinical decision-making and has not been evaluated for such a purpose.

7. Contraindications

The Canturio Tibial Extension (CTE) is contraindicated for use in patients who are undergoing procedures or treatments at or in the proximity of the CTE using therapeutic ionizing radiation which can result in shortened battery life or premature failure of electronic components. Damage to the CTE by therapeutic ionizing radiation may not be immediately detectable.

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

The Zimmer Biomet Persona 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 Safety Information

Non-clinical testing and electromagnetic simulation have demonstrated the CTE implant is MR Conditional when assembled with the Zimmer Biomet Persona knee system. A patient with this device can be safely scanned in an MR system meetingthe following conditions:

- Static magnetic field of 3-T
- Maximum spatial field gradient of 2500 gauss/cm (25mT/m)
- Maximum MR system reported, whole body averaged specific absorption rate(SAR) of 2 W/kg for 15 minutes of scanning for patient landmarks above the acetabulum and 0.5 W/kg for patient landmarks below the acetabulum.

Under the scan conditions defined above, the CTE is expected to produce a maximum temperature rise of less than 4.0º C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 80 mm from the CTE when imaged with a gradient echo pulse sequence and a 3-T MRI system.

9. General Warnings and Precautions

9.1 CTE

WARNING: The kinematic data obtained from this device have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.

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.

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

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 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	Note
Walking Speed	Mean sagittal plane distance walked per unit of time. Derived from acceleration sensor data.	Meters per second	Canary's proprietary algorithm identifies when a patient is walking and calculates their gait parameters during the qualified gait activity. The gait parameters calculated have been tested at walking speeds of 0.5 to 1.4 meters/sec (~1-3 mph).
Cadence	Mean steps per minute. Derived from two consecutive peak angular velocities.	Steps per minute	The mean steps (left and right) per minute derived from the IMU sensor.
Stride Length	Mean anterior distance traveled over one gait cycle.	Meters	Average distance traveled during one gait cycle.
Functional Knee ROM	Mean sagittal plane functional knee joint range of motion when walking. Difference between maximum and minimum knee joint flexion.	Degrees	Functional range of motion during a qualified gait cycle. Calculated from tibia range of motion.
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	Novel proprietary unique measurement that is determined directly from the sensor in tibial extension.
Qualified Step Count	Number of steps taken during a sampling day.	Steps	Sustained forceful meaningful steps recorded from 7AM to 10PM local time from the pedometer sensor. For a step to be counted (qualified), it must be between those times and with sufficient acceleration in a sequence of consecutive steps.
Distance	Distance traveled. Calculated from step count and stride length.	Kilometers	Total distance traveled while walking between 7AM to 10PM local time from the pedometer sensor and the IMU sensor.

Cadence, Stride Length, Tibia ROM, and Knee ROM are 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 reference sagittal plane hip joint data and the measured Tibia ROM data.

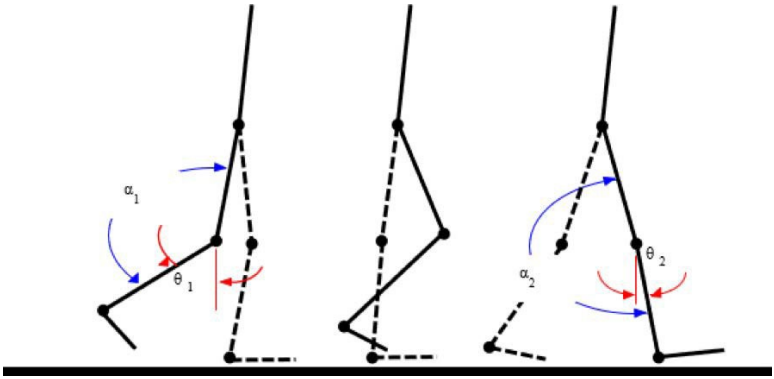

Figure 12: Schematic of Right Leg Motion. Tibia ROM = Ø1 + Ø2 and Knee ROM = α2 – α1

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, nurses and healthcare professionals) 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 Hospital Administrator Account Setup

NOTE: All users of the Canary Medical system must receive training.

11.1.1 Surgeon's Office Hospital Administrator Staff

1. Create your new Hospital Administrator account by clicking on the "Create Password" link sent from a Canary Medical email address.

NOTE: The password link expires after a set period of time. If your password expires, click "Forgot Password" on the Canary login screen to receive a new password link.

It is recommended that anti-virus and anti-malware software protection be installed to protect computer systems from cyber-attack.

2. Create your password following the password rules and log in to the Canary Dashboard. By selecting "Agree", you acknowledge that you have voluntarily entered into a contract.

3. Figure 13 shows a screenshot of the Hospital Admin Dashboard. You can create a Practice, Doctor or Healthcare Professional account by clicking on the number directly below either "Practices," "Doctors" or "Healthcare

Professionals". A Doctor or Healthcare Professional account must be assigned to at least one Practice.

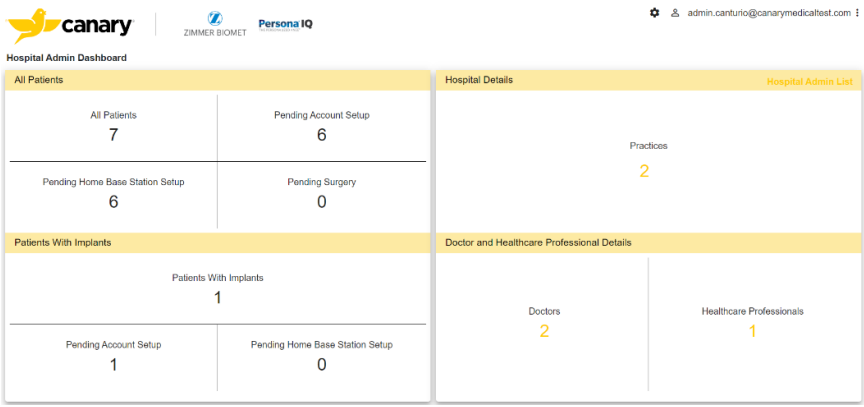

Figure 13: Hospital Admin Dashboard

4. To create a new Practice:
   a. Click the number directly under “Practices” to take you to the Practice List.
   b. Click “Create” to add a new practice. Add the name of the new practice and click “Submit.”
   c. Click “Dashboard” located in the upper right-hand corner to take you back to the Hospital Admin Dashboard.

5. To create a new Doctor or Healthcare Professional account:
   a. Click the number directly under “Doctors” or “Healthcare Professionals” to take you to the Doctor List or Healthcare Professionals List.
   b. Click “Create” to add a new Doctor/Healthcare Professional. Complete the required fields, selecting either Doctor or Healthcare Professional in the “Role” drop-down list.
   c. If the Healthcare Professional will be using the OR app, check the "Perform OR Nurse" checkbox. Click “Submit.”
   d. Instruct the Doctor/Healthcare Professional to watch for an email with a link and directions on how to register and finish setting up their account.

NOTE: Doctor and Healthcare Professional accounts have the same dashboard privileges and follow the same account setup process. Both roles will have access to view and manage all patients within their assigned practices.

11.2 Surgeon's Office Doctor/Healthcare Professional Account Setup

11.2.1 Doctor/Healthcare Professional/Surgeon Office Staff

1. Create a new Doctor account by clicking on the "Create Password" link in the email sent by the Hospital Administrator.

NOTE: The password link expires after a set period of time. If your password expires, click "Forgot Password" on the Canary login screen to receive a new password link.

It is recommended that anti-virus and anti-malware software protection be installed to protect computer systems from cyber-attacks.

2. Create your password and log in to the Canary Dashboard. By selecting "Agree", you acknowledge that you have entered into a contract for Persona IQ with Zimmer Biomet.

3. Click on "Patient List" located at the upper right-hand side of the screen.

4. Patient List Features:
   a. "Implant": The default view shows patients with and without activated implants. To see only patients with active implants, select "Patients with an Implant" in the "Implant" drop-down list. Click "Go."
   b. "Account Setup": The default view shows patients in all stages of the account setup process. Select to only see patients who 1) have not set up their account, 2) have not set up their Home Base Station, 3) have completed account registration and set up their Home Base Station or 4) patients who have upcoming surgery dates. Click "Go."
   c. Practice: The default view shows patients in all of the practices assigned to your account. Select an individual Practice to view only the patients assigned to that specific Practice.
   d. Click on the patient's first name (underlined) to view the patient's "Personal Information" and "General Information."
      - Click the pencil icon to edit a patient's "General Information." Click "Save."
      - Click the eye icon to view patient's kinematic data.
   e. Click the pencil icon under the "Action" column to modify the patient's

first name, last name, date of birth, assigned doctor, practice, implant location, surgery date, surgery time or to add a surgery.

f. Click “Create” to create a new patient account. (More detail in section 11.3.2)

g. Search patients by using the “Firstname, Lastname or Email” field. Clickthe magnifying glass icon.

11.3 Surgeon’s Office Patient Account Setup

11.3.1 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 CTE implant X-Ray Template.

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

The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

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 Dashboard.

11.3.2 Surgeon’s Office Staff – Patient Account Creation via Physician Account

1. Create a new patient account by logging into the Physician account. After logging in, you will see the “Doctor Dashboard” (**Figure 14**). Click on “Patient List.”

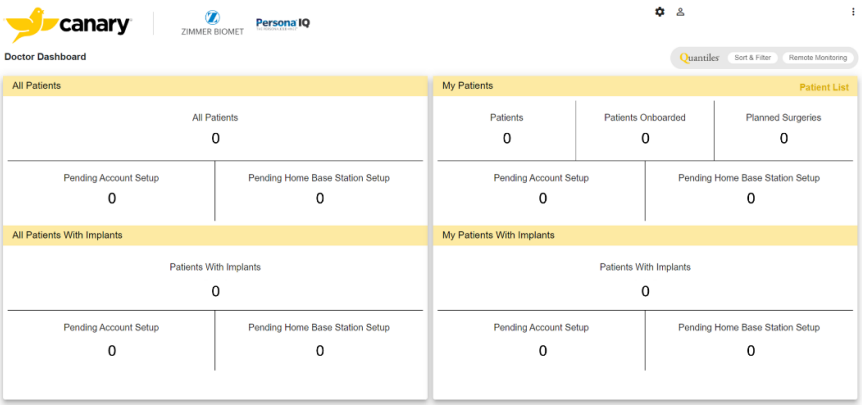

Figure 14: Doctor Dashboard Screen

2. **Figure 15** shows a screenshot of the Patient List screen. Click on "Create."

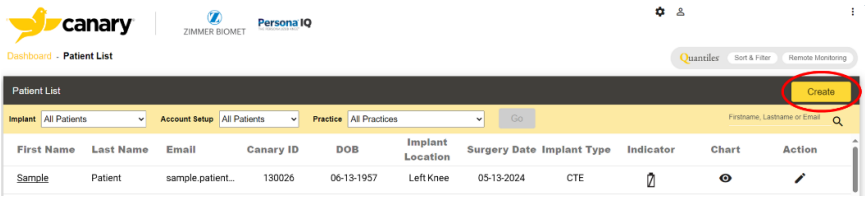

Figure 15: Patient List Screen

3. Use the "Create Patient" screen (**Figure 16**) to enter the patient's information(name, DOB, email, etc.).

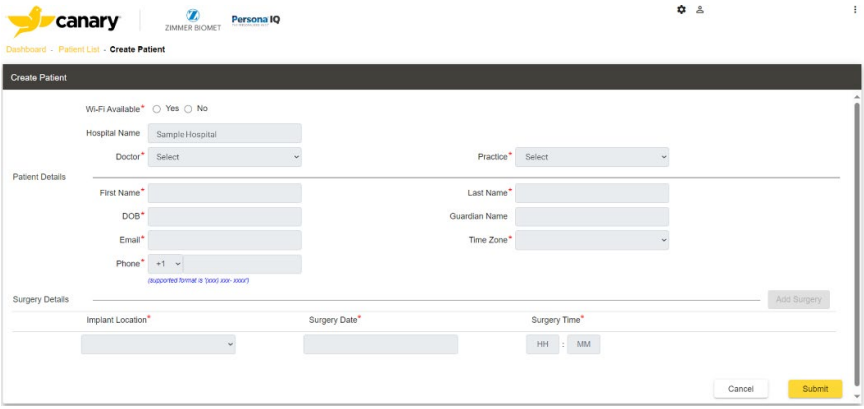

Figure 16: Create Patient Screen

a. Verify Patient has access to Wi-Fi at home.
   - If patient has access, click "Yes" to the "Wi-Fi Available" radio

button to proceed.

- If patient does not have access to either a computer with a USB connection or wireless internet access, the patient is not eligible to receive the Canary implant.

b. Choose the patient's doctor by selecting it from the dropdown. This selection determines which doctor the patient is primarily assigned to.

c. Choose the patient's practice by selecting it from the dropdown. The dropdown will be limited to only the practices the patient's doctor are assigned to. All doctors and healthcare professionals within the patient's assigned practice will have access to manage the patient.

d. Each surgery requires its own entry. “Add Surgery” remains disabled until the required surgery details (implant location, surgery date and time) are completed. Click “Add Surgery” to add another surgery.

e. Complete fields and click “Submit.”

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.

11.3.3 Surgeon’s Office Staff – Patient Account Creation via QR Code

1. Canary Medical will provide a unique QR code associated with the Physician Account and Practice (***Figure 17)***.

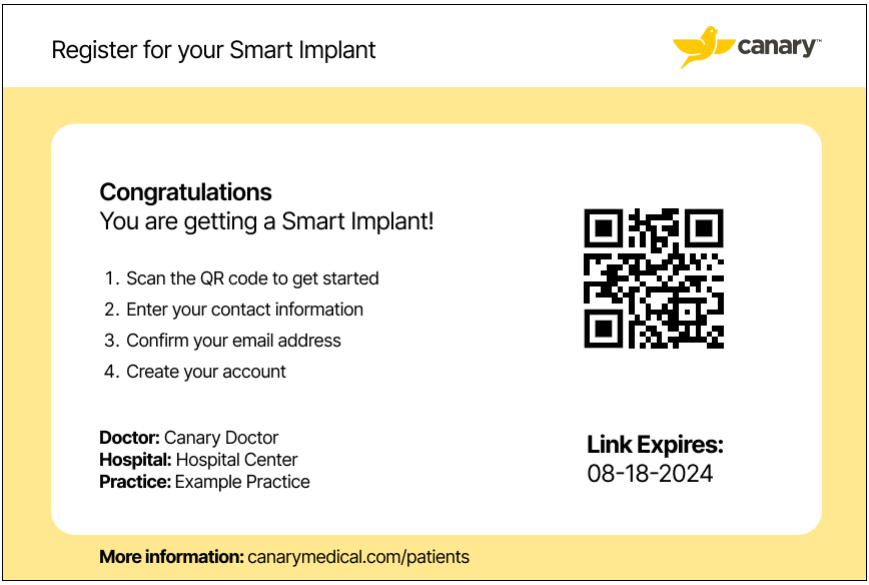

Figure 17: Doctor QR Code for New Patient

2. Instruct the patient to scan the QR Code with their smartphone, fill out the required information, and confirm their input details to initiate their patient account (*Figure 18)*.

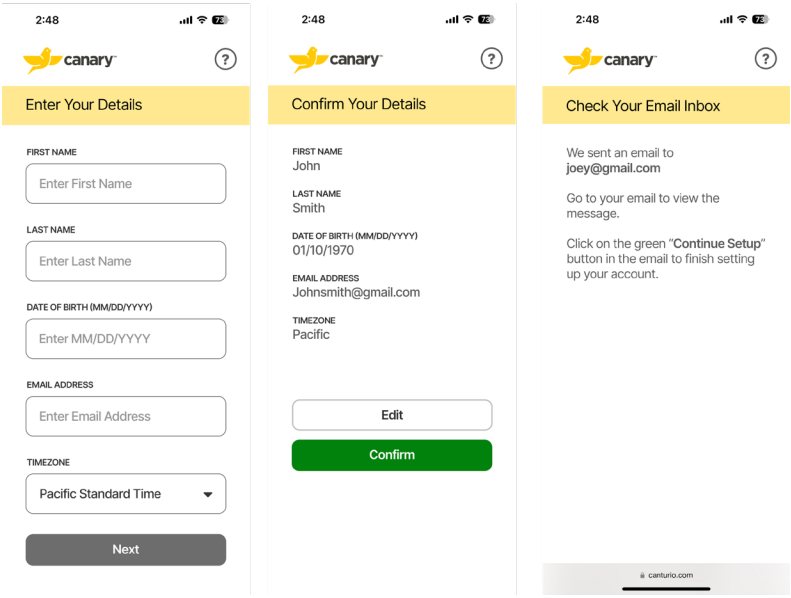

Figure18: Patient Screen

3. Instruct the patient to check for an email with a link and directions on how to finish setting up their patient account.
4. Provide the patient with a copy of the Quick Start Guide, Setting Up Your Patient Account, document # K01-HBS-300005.

11.4 Patient Registration and Account Setup

11.4.1 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.

For patients with Zimmer Biomet mymobility® accounts:
Patients created in mymobility will not need to activate a separate Canary account and should follow instructions for mymobility account setup as provided by Zimmer Biomet.

For patients with Canary® accounts (no account in mymobility):

1. The Canary Cloud emails the patient a link to create a patient account.
2. The patient clicks the link and finalizes their patient account by:
   a. The patient creates the password for their Patient account.
   b. The patient accepts the Terms and Conditions for use of the CTE with CHIRP system.
   c. The patient provides consent for receiving the CTE and data collection by the CTE.
   d. The patient enters their personal information.

Upon successful registration in either mymobility or the Canary Cloud, the Home Base Station can then be set up by the patient.

11.5 Home Base Station System Setup

11.5.1 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 or K01- HBS2-300006 (for Home Base Station (Bluetooth®)) and Patient Manual (document # K01- HBS-300003). The steps to set up the Home Base Station system are summarized as follows:

The Patient:

1. Receives the Home Base Station components.
2. Opens the package, inspects the equipment, and identifies the enclosed Quick Start Guide.
3. Follows the instructions in the Quick Start Guide and Patient Manual to set upthe Base Station.

NOTE: Keep the USB cable out of reach of children because strangulation could result from baby or child entanglement in the charge cable.

11.6 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 Biomet 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 Surgical Technique, document (K01-CTE-300005), provided at **canarymedical.com.**

11.6.1 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 19. Insert the provided screw through
      the groove in the stand into the Base Station. Tighten the screw with a screwdriver.
   b. Connect the USB cable to the OR Base Station on one end and the Laptop PC on the other, as shown in Figures 20 and 21.

Figure 19: Base Station in Stand – Rear View

Figure 20

Figure 21

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 Medical 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 by the “Cloud” icon at the top right of the Laptop screen. 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 image of the implant 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.”

NOTE: It is possible for a “Time Out” message to be displayed if a wireless connection could not be established between the Base Station and CTE implant due to proximity or interference. If a “Time Out” message is displayed, then lack of wireless communication may be the cause. Re-enter the CTE serial number after ensuring the CTE implant and Base Station; a) are within 2 meters of each other, b) are not near large metal objects such as metal tables or metal shelves, and c) are not near Wi-Fi radiators such as mobile phones or computers. If a "Time Out" message is still displayed, do NOT unpackage the device and return the device contact to Canary Medical at 1-833-722-6279 with a completed for Return Material Authorization form.

l. The Base Station initiates communication with the CTE implant. Click "OK" when this process is finished.
m. Click on Self-Test. Upon initiation of a Self-Test the internal CTE electronics perform a series of self-tests and system communication integrity checks for all essential functions. If any of the self-tests fail, the microcontroller will log a permanent and specific error code in memory. These logs are then uploaded and evaluated. A "pass" result is only possible if all self-tests were successfully passed. If any of the self-tests failed or if any other non-passing log was generated since the time of manufacturing, a "fail" result will be displayed.

NOTE: It is possible for a "Time Out" message to be displayed if a wireless connection could not be established between the Base Station and CTE implant due to proximity or interference. If the Self-Test takes more than 15 seconds to display a result, then lack of wireless communication may be the cause. Re-attempt Self-Test after ensuring the CTE implant and Base Station; a) are within 2 meters of each other, b) are not near large metal objects such as metal tables or metal shelves, and c) are not near Wi-Fi radiators such as mobile phones or computers. If the Self-Test continues to display a "Time Out" message, do NOT unpackage the device and contact Canary Medical at 1-833-722-6279 for Return Authorization.

n. Click on Sensor Check. Upon initiation of a Sensor Check the IMU in the CTE captures a brief series of accelerometer and gyroscope (gyro) data which is then evaluated relative to the normal range for as-manufactured devices. A "pass" result is only possible if both accelerometer and gyro data are within the normal range.

NOTE: It is possible for a "fail" result to be displayed if the CTE was not stationary during the Sensor Check. Re-attempt Sensor Check after ensuring the CTE is stationary for 10 seconds after starting Sensor Check. If the Sensor Check continues to display a "fail" result, do NOT unpackage the device and contact Canary Medical at 1-833-722-6279 for Return Authorization.

NOTE: It is possible for a “Time Out” message to be displayed if a wireless connection could not be established between the Base Station and CTE implant due to proximity or interference. Re-attempt Sensor Check after ensuring the CTE implant and Base Station; a) are within 2 meters of each other, b) are not near large metal objects such as metal tables or metal shelves, and c) are not near Wi-Fi radiators such as mobile phones or computers. If the Sensor Check continues to display a “Time Out” message, do NOT unpackage the device and contact Canary Medical at 1-833-722-6279 for Return Authorization.

- 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. If either the Self-Test or the Sensor Check is unsuccessful do NOT unpackage the device and contact Canary Medical at 1-833-722-6279 for Return Authorization.

NOTE: Keep the USB cable out of reach of children because strangulation could result from baby or child entanglement in the charge cable.

NOTE: Use only the USB cable and stand provided with the Base Station.

11.6.2 Intraoperative: Tibia Resection, Preparation, and Trialing

The tibia resection and preparation is done similarly to the Zimmer Biomet Persona Knee Surgical 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 CTE with CHIRP system and Zimmer Biomet Persona The Personalized 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.

Perform the tibia resection using the appropriate Tibia Resection Cutting Guide to achieve the desired slope.

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

11.6.3 Intraoperative: Activate the CTE Implant

After the CTE implant has been introduced into the sterile field, and before assembly with the Persona Tibial Baseplate, 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.”

11.6.4 Intraoperative: Connection of CTE to Zimmer Biomet Tibial Baseplate and Implantation

NOTE: In order to attach the CTE to the Zimmer Biomet Persona Knee Tibial Baseplate, the following Canary Medical instrumentation is required:

- CTE Impaction Sleeve

CAUTION: Do not attempt to connect the CTE to the Zimmer Biomet Persona Knee Tibial Baseplate without the Canary 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 Biomet Persona Knee Tibial Baseplate.
2. Remove and retain the set screw on the Zimmer Biomet Persona Knee Tibial Baseplate.
3. Place the CTE implant into the Zimmer Biomet Persona Knee Tibial Baseplate 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 Biomet Persona Knee Tibial Baseplate using the torque limiting Zimmer Biomet instrumentation.
6. Remove the CTE Impaction Sleeve.

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

7. Optional: A Self-Test can be performed from the OR Base Station to ensure the CTE implant is still functional after assembly.
8. Mix and apply the PMMA bone cement and apply it to the Zimmer Biomet Persona Knee Tibial Baseplate and CTE implant. Refer to the Surgical Technique for cementing technique tips (K01-CTE-300005), provided at canarymedical.com).
9. Place the assembled knee prosthesis into the anatomy and proceed as usual for a TKA procedure.

11.6.5 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 surgery from the list. A search function is also available at the top of the screen.

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

    - If applicable, also enter and confirm the surgery date and implant location.
5. Click “Submit” to save the information to the patient account.

11.7 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 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.

11.7.1 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 or Mobile App 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® The 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 Tibial Baseplate of the Zimmer Biomet Persona® The Personalized Knee® system. The surgical team attaches the CTE to the Zimmer Biomet device to form the patient's knee prosthesis. Specialized Canary 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 version 42.17134.1.0
Minimum operating environment for the PC that runs the Base Station Setup Tool (patient PC)	Windows 10 or higher version71.0.3578.80
Minimum number of USB ports for patient PC	1
Minimum operating system that runs the Mobile App (patient smartphone)	Operating Systems: iOS 14 or above Available Storage: 0.5 GB or Operating Systems: Android 11 or above Available Storage: 0.5 GB

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 **Long Term Storage**: Up to 36 months at 22 +/- 6 degrees C, storedin supplier's ambient environment **Normal Operating Conditions**: The battery shall meet all performance requirements over a temperature range of 35 to 41°Cinclusive
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
Wireless Quality of Service	The CTE operates in the 402-405 MHz frequency and the maximum effective radiated power of the implant communication is below the limit of 25 µW < ERP/EIRP as specified by FCC 47 CFR Part 95; Subpart I. The implant has to be within 2 meters of the base station for optimal communication.
Wireless Technology	**Wakeup Receiver Band Frequency:** 2.4 - 2.5 GHz **MICS Band Frequency:** 402 – 405 MHz **MICS Channel Bandwidth:** 300 kHz **MICS Channels:** 10 (channel 0 to channel 9) **Data Transfer Rate on MICS Band:** Uplink > 50 kbits/second Downlink > 5 kbits/second **Transmitter Power:** -16 dBm max EIRP **Communication Range:** ~ 2 meters

Category	Specification
Mode of Operation	**Five (5) Modes of Operation for the CTE implant (without patient involvement):** • Deep Sleep Mode where the CTE is inactive and only listening for a radio wakeup periodically, typically once every 10 seconds to conserve battery longevity. • Standby Mode after recent activity where the CTE is inactive and listening for radio wakeup more frequently, typically once every 1 second to improve response times while conserving battery longevity. • Low Resolution Mode where the IMU in the CTE is performing step counting. • High Rate Mode where the IMU in the CTE is sampling accelerometer data at a high sampling frequency. • Six Degree of Freedom (6DOF) Mode where the IMU in the CTE is sampling both accelerometer and gyroscope data at a moderate sampling frequency to capture kinematic information. **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**: 15°C to 25°C **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	**Degree of protection (applied part) against electric shock**: The entire device is an applied part and is classified as of type BF (see symbol to the left) per IEC 60601-1
Protection from Ingress of Liquids	Standard IEC-60601, clause 6.3. [Also identified in ISO-14708-1 and IEC- 60529.]
Impaction Sleeve	**OAL:** 63.5 mm **Max OD**: 22 mm ID: 13.08 mm **Material:** 17-4 PH SS

Table 8: 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 anexternal PC
	Battery
Battery	CR1220, coin cell
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 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 softwareapplication, 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 fromElectric 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)

Personal Computer	Specification
Manufacturer	Dell
Operating System	Windows 10
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 StorageCapacity 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
	Degree of protection (applied part) against electric shock: The entire device is an applied part and is classified as of type BF(see symbol to the left)

Table 9: Home Base Station System Specifications

Home Base Station Unit (non-Bluetooth and Bluetooth versions)	Specification
Weight	1 lb.
Dimensions	18 cm wide by 18 cm long by 5 cm high
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. The Home Base Station System provides an interface for communication with the patient's implant. It consists of a Home Base Station unit, the patient's USB-enabled personal computer or smartphone device, 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 implant. The Home Base Station unit transmits the data to the Cloud, and has the capability to store the data for up to thirty days.
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 10.1.2

Home Base Station Unit (non-Bluetooth and Bluetooth versions)	Specification
Protection from Ingress of Liquids	Per IEC-60529, Home base station rated as IPX1
Audible Output Levels	None. (Not applicable.)
Personal Computer or Smartphone (Home Base Station (Bluetooth version) only)	**Specification**
Manufacturer	Patient's Choice
PC Operating System	Windows 10
Smartphone Operating System	Operating Systems: iOS 14 or above Available Storage: 0.5 GB or Operating Systems: Android 11 or above Available Storage: 0.5 GB
USB Power and Data Cables	**Specification**
Manufacturer	Molex 687680400 (Home 2m USB cable) Globetek WR9HA2000USBFMR6B (Home USB Power Supply)
Dimensions	55.6mm x 27.1mm x 37.2mm (Home USB Power Supply)
Power Source	AC/DC
	Degree of protection (applied part) against electric shock: The entire device is an applied part and is classified as of type BF(see symbol to the left)

15. Electrical and Safety Standards

15.1 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The transmitter is intended for use in the electromagnetic environment specified in the next table. The customer or the user of the transmitter should ensure that it is used in such an environment.

It is possible that certain wireless Wi-Fi routers, Wi-Fi boosters, Bluetooth devices (such as mobile phones, wireless audio devices, or computers), radio-frequency identification (RFID) readers, electronic security systems (e.g., metal detectors, electronic article surveillance), near-field communications (NFC) systems, wireless power transfer (WPT) and unique medical emitters such as electrocautery, MRI, electrosurgical units, and diathermy equipment (i.e. high-frequency surgical equipment) may interfere with the Base Station wireless communications. If you experience delays in Base Station communications, try moving either the Base Station or other the other wireless device away from each other.

15.2 Electromagnetic Immunity Specifications

Phenomenon	Basic EMC standard	Immunity test levels	
		Professional healthcare facility environment	Home healthcare environment
Electrical fast transients / bursts [a) l) o)]	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges [a) b) j) o)] Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	
Surges [a) b) j) k) o)] Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances induced by RF fields [c) d) o)]	IEC 61000-4-6	3 V [m)] 0,15 MHz – 80 MHz 6 V [m)] in ISM bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]	3 V [m)] 0,15 MHz – 80 MHz 6 V [m)] in ISM and amateur radio bands between 0,15 MHz and 80 MHz [n)] 80 % AM at 1 kHz [e)]
Voltage dips [f) p) r)]	IEC 61000-4-11	0 % U_T; 0,5 cycle [g)] At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° [q)]	
		0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles [h)] Single phase: at 0°	
Voltage interruptions [f) i) o) r)]	IEC 61000-4-11	0 % U_T; 250/300 cycle [h)]	

a) This test applies only to output lines intended to connect directly to outdoor cables.
b) SIP/SOPS whose maximum cable length is less than 3 m in length are excluded.
c) Testing may be performed at other modulation frequencies identified by the RISK MANAGEMENT PROCESS.
d) Calibration for current injection clamps shall be performed in a 150
e) Connectors shall be tested per 8.3.2 and Table 4 of IEC 61000-4-2:2008. For insulated connector shells, perform air discharge testing to the connector shell and the pins using the rounded tip finger of the ESD generator, with the exception that the only connector pins that are tested are those that can be contacted or touched, under conditions of INTENDED USE, by the standard test finger shown in Figure 6 of the general standard, applied in a bent or straight position.
f) Capacitive coupling shall be used.
g) If the frequency stepping skips over an ISM or amateur radio band, as applicable, an additional test frequency shall be used in the ISM or amateur radio band. This applies to each ISM and amateur radio band within the specified frequency range.
h) r.m.s., before modulation is applied.
i) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

15.3 Electromagnetic Emissions

The Canturio Tibial Extension (CTE) is intended for use in the electromagnetic environment specified in the next table. Ensure that the transmitter is used in such an environment.

Phenomenon	Professional healthcare facility environment [a)]	HOME HEALTHCARE ENVIRONMENT [a)]
Conducted and radiated RF EMISSIONS	CISPR 11	CISPR 11 [c), d)]
Harmonic distortion	See IEC 61000-3-2 [b)]	See IEC 61000-3-2
Voltage fluctuations and flicker	See IEC 61000-3-3 [b)]	See IEC 61000-3-3

a) This test is not applicable in this environment unless the ME EQUIPMENT and ME SYSTEMS used there will be connected to the PUBLIC MAINS NETWORK and the power input is otherwise within the scope of the Basic EMC standard.

b) ME EQUIPMENT and ME SYSTEMS intended for use in aircraft shall meet the RF EMISSIONS requirements of ISO 7137. The conducted RF EMISSIONS test is applicable only to ME EQUIPMENT and ME SYSTEMS that are intended to be connected to aircraft power. ISO 7137 is identical to RTCA DO-160C:1989 and EUROCAE ED- 14C:1989. The latest editions are RTCA DO-160G:2010 and EUROCAE ED-14G:2011. Therefore, use of Section 21 (and category M) of a more recent edition, e.g. [39] or [40], should be considered.

c) Standards applicable to other modes or EM ENVIRONMENTS of transportation for which use is intended shall apply. Examples of standards that might be applicable include CISPR 25 and ISO 7637-2.

15.4 Electromagnetic Immunity

The CTE was tested for electromagnetic compatibility in accordance with IEC 60601-1-2 and it is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Interference can affect the RF communication between the canturio®*te* and the Base Station. Kinematic data uploading may be delayed when that occurs. To help prevent electromagnetic interference, avoid high electromagnetic radiators and/or environments. If electromagnetic interference is suspected, distance yourself from the interference sources and maintain a minimum separation distance per the guidelines in the next table. The separation distances are calculated based on the max output power of the transmitter.

Rated Max Output Power of Transmitter (W)	**Separation Distance According to Frequency of the Transmitter**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
0.01	4.7 in. (0.12 m)	4.7 in. (0.12 m)	1 ft 6 in. (0.46 m)
0.1	15 in. (0.38 m)	15 in. (0.38 m)	4 ft 10 in. (1.46 m)
1	3 ft 11 in. (1.2 m)	3 ft 11 in. (1.2 m)	15 ft 1 in. (4.6 m)
10	12 ft 6 in. (3.8 m)	12 ft 6 in. (3.8 m)	47 ft 11 in. (14.6 m)
100	39 ft 4 in. (12 m)	39 ft 4 in. (12 m)	150 ft 11 in. (46 m)

Note 1: at 80 MHz or 800 MHz, use the separation distance in the higher frequency range.

Note 2: These guidelines may not be applicable for all situations. Electromagnetic propagation can be affected by the environment through reflection and absorption. If interference is suspected, move away from interference sources as far as possible.

15.5 FCC Disclosure

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150-406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radio communication Service.

Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

FCC Compliance Statement

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 environment. 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. Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user’s authority to operate the equipment.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

RF Exposure Information (SAR)

This equipment is an implanted device in the body of a user with aggregated maximum power under all circumstances of less than 1 mW, therefore SAR test exclusion was applied. The maximum available output power of the implanted transmitter, under all operating conditions was supported by power measurement results, based on the device design and implementation requirements, and fully justified in a SAR exemption analysis report.

US Federal Communications Commission (FCC)

The FCC ID of the CTE is 2AYAJ-CTE1. The FCC ID of the OR Base Station and Home Base Station is 2AYAJ-BS1 (Home Base Station (Bluetooth) contains FCC ID: 2AYAJ-WF1 and FCC ID: R7T1201102). For FCC compliance information, please go to https://canarymedical.com/compliance-fcc.

16. 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 to prevent unauthorized access and cyber-attacks. 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 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 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 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 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.

17. Component Maintenance

17.1 CTE

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

17.2 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 at least once per week.

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 after each use:

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)

The OR Base Station, Bar Code Scanner and laptop may be cleaned and disinfected using CaviWipes® as necessary. When cleaning and disinfecting the Bar Code Scanner, disassemble the bumper from the scanner and follow the steps listed below. CaviWipes® is an intermediate level disinfectant (10-3 SAL) and is effective for cleaning and disinfecting the OR Base Station, Bar Code Scanner and laptop.

1) Disassemble the Bar Code scanner from the bumper prior to cleaning.
2) Wipe with a CaviWipes to remove soil.
3) Using a fresh wipe, wipe down to ensure the CaviWipes solution is in

contactwith seams, creases, crevices, and mated surfaces.

4) Allow to remain visibly wet for 2 minutes, per CaviWipes manufacturer recommendation.
5) Allow to air dry at ambient temperature.

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

NOTE: The Base Station Unit and Accessories are resilient to dust, lint, and light (including sunlight). However, lint or dust may get into the USB receptables or the receptacles may become degraded and interfere with power to or communications with the Base Station or Accessories. Children, pets, and pests may have similar effects on the USB receptacles and similar degraded performance of Base Station or Accessories. Do not attempt to clean or repair the USB receptacles. Instead contact Canary Medical for a replacement.

17.3 Software Maintenance

All software updates will be initiated by Canary Medical.

18. Service Life

18.1 CTE

The service life of the CTE is estimated to be at least ten years based on;
a) accelerated discharge testing of the batteries and b) bench testing of current consumption by the CTE electronics,. However, the CTE is designed for upto 20 years of service life.

18.2 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.

19. Servicing

19.1 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 Platform.

19.2 Base Station Units and Accessories

If a Base Station Unit or accessory is not working properly or even changes in performance, 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.

20. Disposal

20.1 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 as biohazard medical electronics waste according to your facility policy or contact your local authorities to determine proper method of disposal. **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: 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.

20.2 Canary Surgical Instrumentation

Canary instrumentation is reusable. Reprocessing of any of the Canary instrumentation must be accomplished according to the Canary Instrument Care Instructions for Use, document (K01-INT-300019).

20.3 Base Station Units and Accessories

Contact your local authorities to determine proper method of disposal of Base Station Units and Accessories as electronics waste or return them to Canary Medical.

21. Warranty

Canary Medical (or such other legal entity as may be referred to as manufacturer on the labeling of this device, hereinafter “Canary Medical”) warrants the Canary Base Station (hereinafter “Product”) to the original purchaser of the Product against defects in material and workmanship for a period of one (1) year from the date the Product is purchased. During the warranty period, Canary Medical will replace or repair, at its discretion, any defective Product, subject to the conditions and exclusions stated herein. This warranty applies only to new devices. In the event a Product is replaced, the warranty period will not be extended past its original expiration date. This warranty is valid only if the Product is used in accordance and for the purposes set forth in the manufacturer’s instructions.

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
REF	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
SN	The unique serial number assigned to the device by the manufacturer	ISO 7000 — 2498 Graphical symbols for use on equipment — Registered symbols	Serial Number
EDI	Computer-to-computer exchange of business documents in standardized formats		Electronic Data Interchange
	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
STERILIZE	Instructs the user not to re-sterilize the device	ISO 7000-2608 Graphical symbols for use on equipment — Registered symbols ISO 15223-1 clause 5.2.6	Do Not Re-sterilize
	Instructs the user not to re-use the device	ISO 7000-1051 Graphical symbols for use on equipment — Registered symbols ISO 15223-1 clause 5.4.2 Medical devices — Symbols to be used with medical device labels,	Do Not Re-use

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
		labelling and information to be supplied	
		IEC 60601-1 clause 7.2 Medical Electrical Equipment	
STERILE EO	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	
		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 de-	Date of Manufacture

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
		vices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	
	Device that is normally provided sterile in the same or similar packaging has not been sterilized	ISO 70-0-2609 Graphical symbols — Safety colors and safety signs — Registered safety signs	Non-sterile
	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.	
	To identify a type BF applied part complying with IEC 60601-1	ISO 7000-5333 Graphical symbols for use on equipment — Registered symbols	Type BF applied part
	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, labeling and information to be supplied	
	Instructs the transporter of the device package to protect the device package from sunlight	ISO 7000-0624 Graphical symbols for use on equipment — Registered symbols	Keep away from sunlight
		ISO 15223-1 clause 5.3.2 Medical devices — Symbols to be used with	

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
		medical device labels, labeling and information to be supplied	
	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
	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
MR	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	
	Non-ionizing radiation includes RF ISO 7000-5140	IEC 60601-1-2:2007, Clause 5.1.1	Non-ionizing electromagnetic radiation
	Direct current	ISO 7000-5031 Graphical symbols for use on equipment — Registered symbols	Equipment is suitable for direct current only
IP22	Protected from touch by fingers and objects greater than 12 millimeters, and protected from water spray less than 15 degrees from vertical	IEC 60601-1, (IEC 60529) clause 6.3; Table D.3	Degree of protection
IPX7	Protected against immersion in water. Immersion for 30 minutes to a depth of 1 meter	IEC 60601-1, (IEC 60529) clause 6.3	Degree of protection

Symbol	Meaning	Designation Number and Title of the Standard	Title of the Symbol in the Standard
(01)00860003118313 (21)123456	Data Matrix Barcode intended provide single, globally harmonized positive identification of medical devices through distribution and use, requiring the label of devices to bear a globally unique device identifier (to be conveyed by using Automatic Identification and Data Capture	21 CFR 830	Unique Device Identification
	Bluetooth® wireless technology		
+H124435570002141B *+$123456A20B_*			Health Industry Bar Code (HIBC)

Appendix 2 – Definitions

Term	Definition
Base Station Subsystem	The Base Station subsystem serves as a conduit between the 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 an implant. The Base Station interfaces with either software or the Cloud directly to facilitate retrieving and storing data from the 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 re-porting for the collection system, and stores the telemetry collected from the implant, uploaded via the Base Station system.
Distance	Total distance traveled while walking.
Gait	The form of ambulation/locomotion.
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.
Hospital Administrator	The Hospital Administrator is a designated person who receives training to use the Canary Medical software to set up Canary user accounts for other Hospital Administrators, Doctors, Healthcare Professionals, and other authorized personnel. They also manage Practices and the assignment of Doctors and Healthcare Professionals to those practices. The Hospital Administrator does not have to be a hospital employee.
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).

Term	Definition
Kinematic	The geometric mechanics of motion.
Processed Data	Analyzed data from the 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 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 13 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.

NOTE: Do not attempt to modify or service the Base Station since this may damage the device or result in unsafe conditions.

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.
Data on the Dashboard is delayed or not up-to-date.	In very rare situations, other wireless devices including radio-frequency identification (RFID) readers may interfere with the communication of the implant and the Home Base Station which may cause delays in the transmission of data. To avoid interference, ensure the implant is within 2 meters (6 feet) of the Home Base Station and there are no other wireless communication equipment nearby.

To learn more about Persona IQ®, email SmartKneeSupport@zimmerbiomet.com or call 844-799-8208.

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