

Persona IQ[®]

THE SMART KNEE[™]

CANARY canturio[®] Tibial Extension with CHIRP[®] System Surgical Technique

R_xonly

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



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1. Introduction

Successful total knee arthroplasty (TKA) depends in part on re-establishment of normal lower extremity alignment, proper implant design and orientation, secure implant fixation, and adequate soft tissue balancing and stability.

The Zimmer Biomet Persona IQ® The Personalized Knee® is designed to help the surgeon accomplish these goals by combining alignment accuracy with a simple, straight-forward technique.

The instruments and technique assist the surgeon in restoring the center of the hip, knee, and ankle to lie in a straight line, establishing a neutral mechanical axis. The femoral and tibial components are oriented perpendicular to this axis. Femoral rotation is determined using the posterior condyles, the epicondylar axis, or Whiteside's line as a reference. The instruments enable accurate cuts to ensure robust component fixation.

A wide variety of component sizes, shapes, and constraint options allow for optimized component fit and soft tissue balancing. The femur, tibia, and patella are prepared independently and can be cut in any sequence using the principle of measured resection (removing enough bone to allow replacement by the prosthesis). Adjustment cuts may be needed later. The anterior referencing technique uses the anterior cortex to set the anteroposterior (A/P) position of the femoral component. The posterior condyle cut is variable.

Additional technique steps are found in the *Zimmer Biomet Persona Knee Surgical Technique* (97-5026-001-00) and the *Zimmer Biomet Persona CPS Surgical Technique* (97-5026-072-00).

1.1 Canturio™ Tibial Extension (CTE) with CHIRP® System

The Canturio™te (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) is a tibial extension containing electronics and software. It can only be used with the Zimmer Biomet Persona IQ® The Personalized Knee®. Using internal motion sensors, the CTE implant collects kinematic data pertaining to a patient's gait and activity level following TKA. The kinematic data produced by the CTE implant is intended as an adjunct to other physiological parameter measurement tools used post-TKA procedure as directed by the physician. The CTE implant also provides stability to the knee implant in the same manner as a traditional tibial extension.

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 58mm 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 Zimmer Persona® Personalized Knee System.

WARNING - The kinematic data 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.

The CTE with CHIRP System consists of the CTE implant, plus the following external components:

- Canary surgical instrumentation
- Canary PC with Operating Room Application (OR App)
- Canary OR Base Station

The external components are used throughout the surgical procedure to activate the CTE implant, prepare the patient anatomy, assemble the CTE implant to the Zimmer Biomet Persona IQ® tibial plate to form the patient's knee prosthesis, and link the implanted CTE implant and Persona IQ components with the specific TKA patient.

Figure 1 shows the CTE implant on the left and a representation of the CTE implant assembled with the ZimmerBiomet Persona IQ tibial plate on the right.



Figure 1

This Surgical Technique document is to be used only when utilizing the CTE with primary Persona IQ® knee implants and is not for use with Persona® Revision, or with other Zimmer Biomet knee systems, such as NexGen® Knee, Vanguard®, or Natural-Knee® II systems.

The surgical technique for implanting the Persona IQ® Knee with the CTE uses a combination of Persona® and Canary Medical™ instrumentation. Pay close attention to the instructions in this Surgical Technique document to ensure you are using the correct instrumentation for each step of the procedure.

See the *Zimmer Biomet Persona Knee Surgical Technique (97-5026-001-00)* for the available implant constraint options.

2. Terms and Acronyms

Table 1 lists Terms and Acronyms used in this document.

Table 1: Terms and Acronyms

Term or Acronym	Meaning
A/P	Anteroposterior
CHIRP	Canary Health Implanted Reporting Processor
Cloud	Canary Medical Cloud Based Data Management Platform
CN	Circulating Nurse
CTE	canturio™ tibial extension (<i>te</i>)
CPS	Constrained Posterior Stabilized
HCP	Health Care Professional
IM	Intramedullary
OR	Operating Room
PC	Personal Computer
PCL	Posterior Cruciate Ligament
RF	Radio Frequency
ROM	Range of Motion
TASP	Tibial Articular Surface Provisional
TKA	Total Knee Arthroplasty
USB Cable	Data cable used to make connections between the OR Laptop and OR Base Station and the OR Laptop and Barcode Scanner

3. Preoperative Planning

Use the information in this section during preoperative planning for the patient's TKA.

1. Obtain 36 inch or 53 inch standing AP and lateral radiographs of the extremity, as well as a sunrise view of the patella.
2. Visualize the entire femur to rule out any structural abnormalities, as the distal femoral cut will be referenced from an intramedullary rod in the medullary canal.
3. Review the patient radiographs.
4. Use the CTE 14mm x 58mm X-Ray Template (available through your Zimmer Biomet representative) on the patient's long-standing film to determine if the patient's anatomy is appropriate for a CTE Implant.

WARNING: 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 for using the CTE 14mm x 58mm X-Ray Template.

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.

5. Determine the angle between the anatomic axis and the mechanical axis. This angle will be reproduced intraoperatively. This surgical technique helps the surgeon ensure that the distal femur will be cut perpendicular to the mechanical axis and, after soft tissue balancing, will be parallel to the resected surface of the proximal tibia.

4. Surgical Approach

The surgeon can choose a midvastus approach, a subvastus approach, or a parapatellar medial arthrotomy. Also, depending on surgeon preference, the patella can be either everted or sublaxed. The femur, tibia, and patella are prepared independently, and can be cut in any sequence using the principle of measured resection or gap balancing.

5. Patient Preparation

To prepare the limb for TKA, adequate muscle relaxation is required. The anesthesiologist should adjust the medication based on the patient's habitus and weight and administer to induce adequate muscle paralysis for a minimum of 30-40 minutes. It is imperative that the muscle relaxant be injected prior to inflation of the tourniquet. Alternatively, spinal or epidural anesthesia should produce adequate muscle relaxation. If desired, apply a proximal thigh tourniquet and inflate it with the knee in hyperflexion to maximize that portion of the quadriceps that is below the level of the tourniquet. Once the patient is draped and prepped on the operating table, determine the landmarks for the surgical incision.












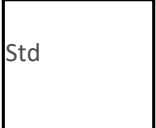

6. Magnet Usage

WARNING: Some instruments in the Zimmer Biomet Persona IQ® system contain magnets. Active implantable medical devices may be adversely affected by magnets. Instruments containing magnets should be kept on an appropriate table or stand when not in use at the surgical site. All Zimmer Biomet Persona IQ magnetic instruments should be kept at a safe distance from both the CTE implant and the patient's existing active implantable medical device(s) (e.g., pacemaker).

7. Symbols

Table 2 shows the symbols that have been established for this Surgical Technique document.

Table 2: Symbols for Surgical Technique

Term	Symbol	Term	Symbol	Term	Symbol
Left		Do Not Implant/Not for Implant		Cemented	
Right		Lock		Stemmed	
Varus/ Valgus		Unlock		Inset Only	
Medial/ Lateral		Anterior Referencing			
Standard		Do Not Impact			

8. Compatible Screw/Pin Information





Table 3 contains information on various 3.2 mm screws/pins that are compatible with the Zimmer Biomet Persona IQ® system and canturio™te with CHIRP® surgical instrumentation.

WARNING: If these screws/pins are used during the procedure for instrument fixation, they must be removed prior to closure as they are **NOT** implantable.

CAUTION: The 2.5 mm female hex screws and 2.5 mm male hex driver should not be used in cortical bone, as this may increase the incidence of stripping of the driver.

Table 3: Screws and Pins Compatible with the Zimmer Biomet Persona® IQ System

Screw/Pin	Screw/Pin Part #	Compatible Driver	Compatible Driver Part #	Shipped Sterile or Non-Sterile	# per Package	Single Use?
 25 mm x 2.5 mm Female Hex Screw	42-5099-025-25*	 2.5 mm Male Hex Driver	42-5099-025-00	Sterile	2	Yes
 75 mm x 3.2 mm Trocar Tipped Drill Pin (2.5 mm hex)	00-5901-020-00	 Pin/Screw Inserter	00-5901-021-00	Sterile	4	Yes
 Hex Headed Screw 33 mm long	00-5901-035-33			Sterile	2	Yes

Screw/Pin	Screw/Pin Part #	Compatible Driver	Compatible Driver Part #	Shipped Sterile or Non-Sterile	# per Package	Single Use?
 <p>MIS Quad-Sparing Total Knee Headed Screw 48 mm long</p>	00-5983-040-48	 <p>Screw Inserter/Extractor</p>	00-5983-049-00	Sterile	1	Yes
 <p>25 mm Shorthead Holding Pin</p>	00-5977-056-03	 <p>Multi Pin Puller</p>	00-5901-022-00	Non-Sterile	1	No

9. Pre-Operative: Setting Up the OR Base Station and Testing the Canturio™ Tibial Extension (CTE)

🔊 Technique Tip: To streamline surgical flow, test the CTE implant prior to entering the OR.

WARNING: Retain the CTE implant in its packaging box. **DO NOT** remove the CTE implant from the packaging box until it has successfully passed Self-Test and Sensor Check and is ready to be introduced into the sterile field.

Use the steps below to set up the OR Base Station and test the CTE implant:

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 Medical Laptop in an area with access to Wi-Fi.
2. Gather a CTE implant, the OR Base Station Unit, Bar Code Scanner, and USB cables.
 - a. Check the expiration date on the CTE implant 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 2**. Insert the provided screw through the groove in the stand into the Base Station. Tighten the screw with a screwdriver.



Figure 2: Base Station in Stand – Rear View

- b. Connect the USB cable to the OR Base Station on one end and the Laptop PC on the other, as shown in **Figures 3 and 4**.

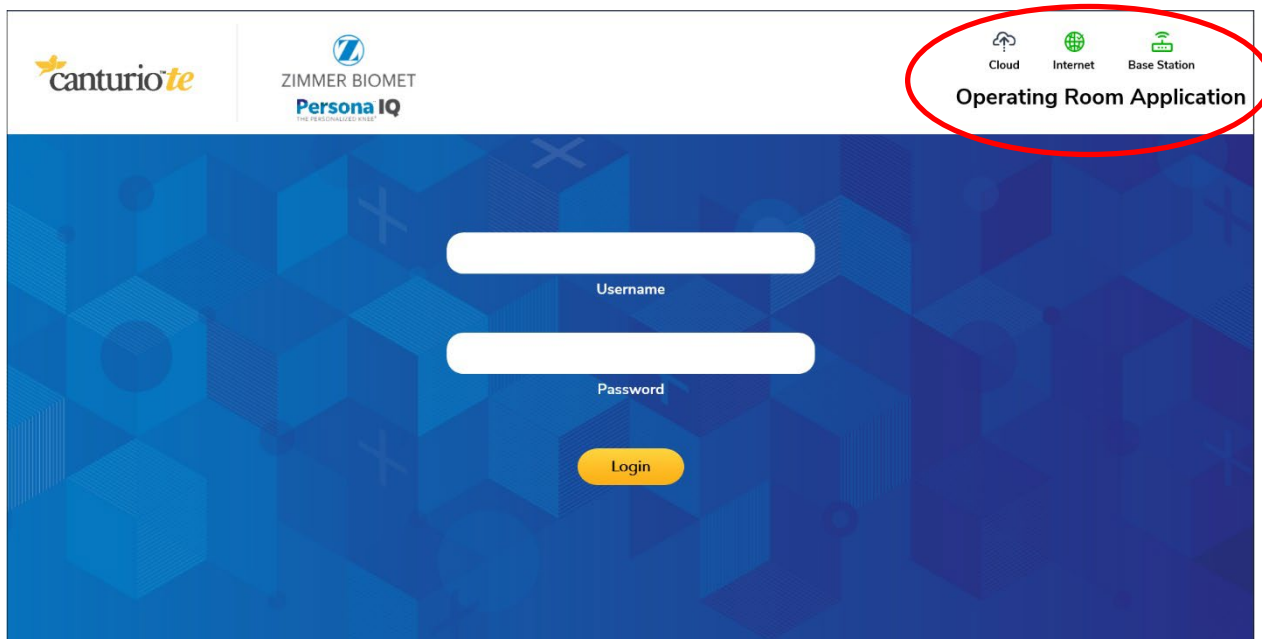


Figure 3



Figure 4

- c. Connect the Barcode Scanner to the Laptop.
- On the Canary Medical laptop, the Canary Medical™ Operating Room Application (OR App) will start automatically, and you will see the image of an implant in the center of the screen.
 - Ensure the OR Base Station and Laptop are connected. This is indicated by the green “Base Station” icon at the top of the Laptop screen. See **Figure 5**.
 - Ensure an Internet connection has been established and the OR App is connected to the CanaryMedical™ Cloud. This is indicated by the green Internet icon at the top of the Laptop screen. See **Figure 5**.



Firmware Version:2:0:0:1607618231

App Version:2.0.51.0

Figure 5

7. Click on the image of the implant in the center of the screen. The login screen will appear. See **Figure 6**.

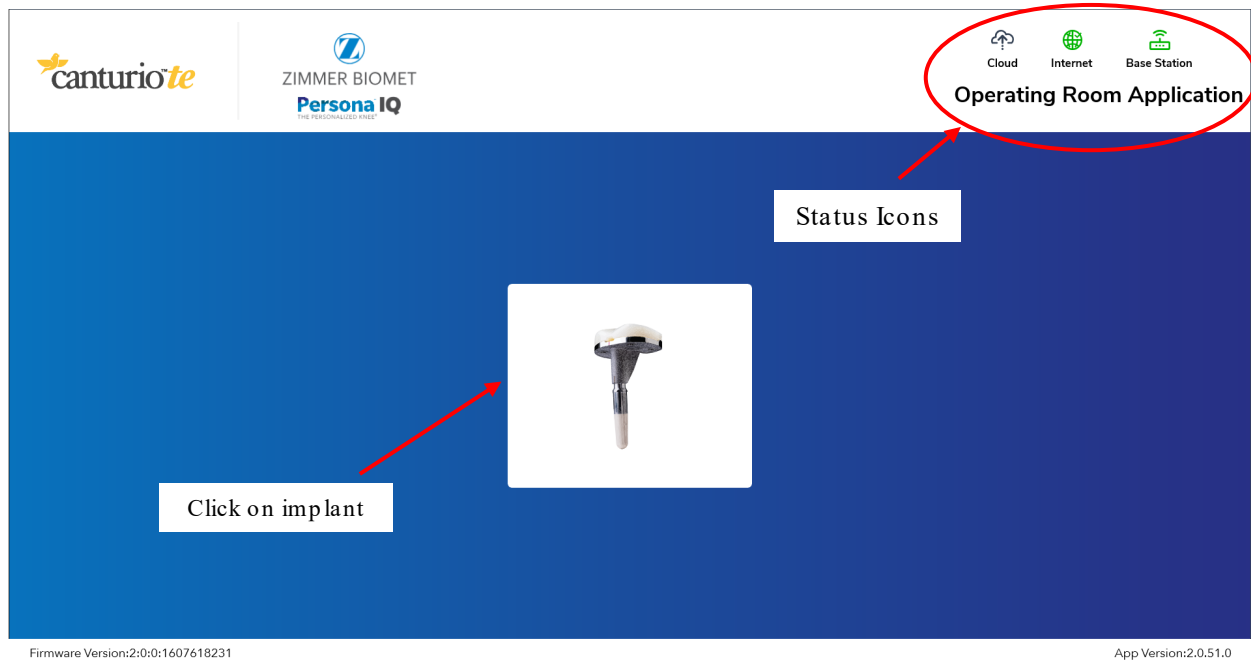


Figure 6: Login Screen

8. Enter your authorized Username and Password and click the “Login” button. This will take you to the Main Menu screen. . **Figure 7**.

NOTE: A sync to the Cloud will automatically occur after the Internet connection is established and the user is logged in. A sync ensures the most recent patient data is loaded. The Cloud icon at the top of the Laptop screen will indicate the sync status and time of last successful sync. Place the implant package’s large face on a flat surface within 6 feet of the OR Base Station that is connected to the Laptop.

NOTE: Placing the implant (within package) more than 6 feet from the OR Base Station or having any large metal objects between or near the components can interfere with communication between the devices.

9. On the Main Menu screen, under “Preoperative,” click on the “Setup Implant” icon (**Figure 7**).

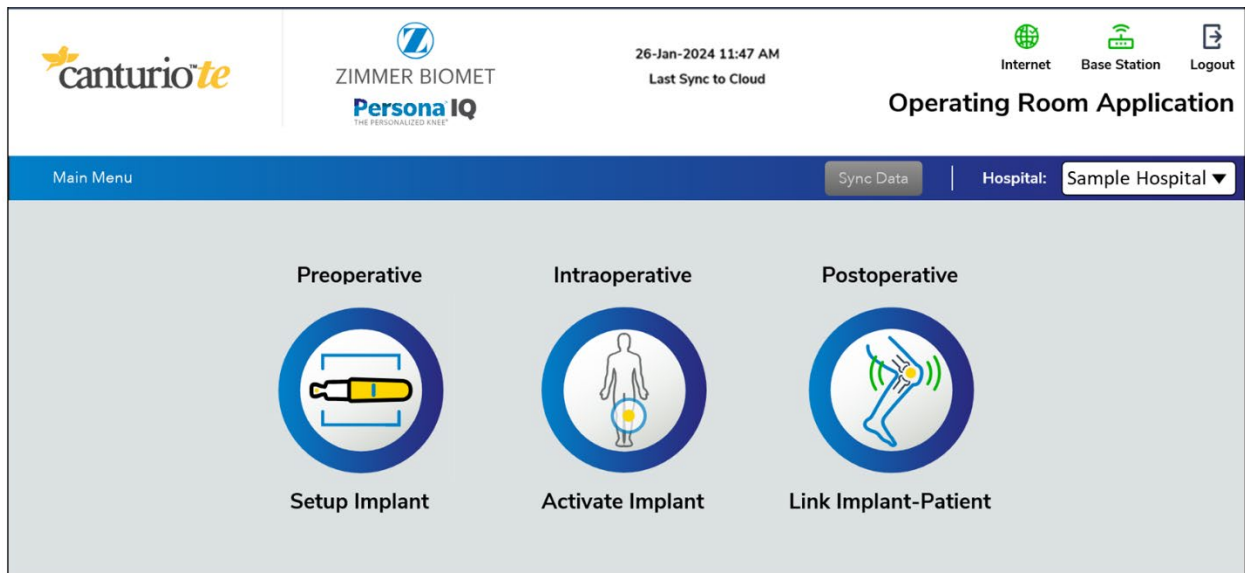


Figure 7: Main Menu

10. Click in the text box and enter or scan the implant serial number from the implant package. Click “OK.” (**Figure 8**).

NOTE: If scanning, place the barcode scanner over the 2D bar code, as shown in the example image below.

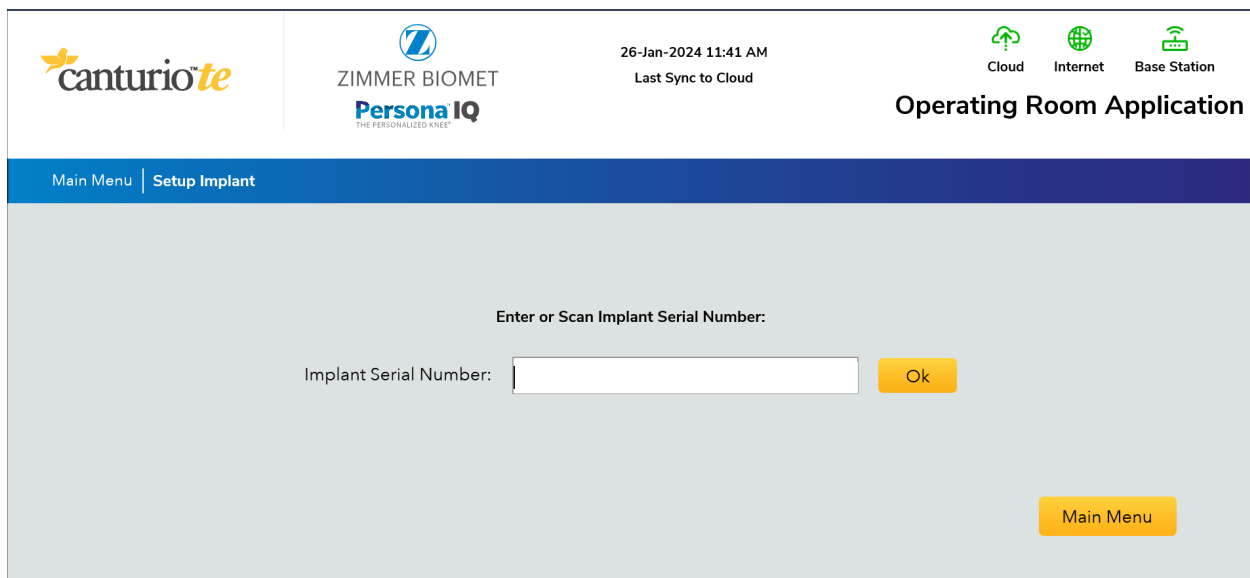


Figure 8: Setup Implant: Enter or Scan Implant Serial Number

11. The implant initiates communication with the OR Base Station. Click “OK” when this process is finished (**Figure 9**).

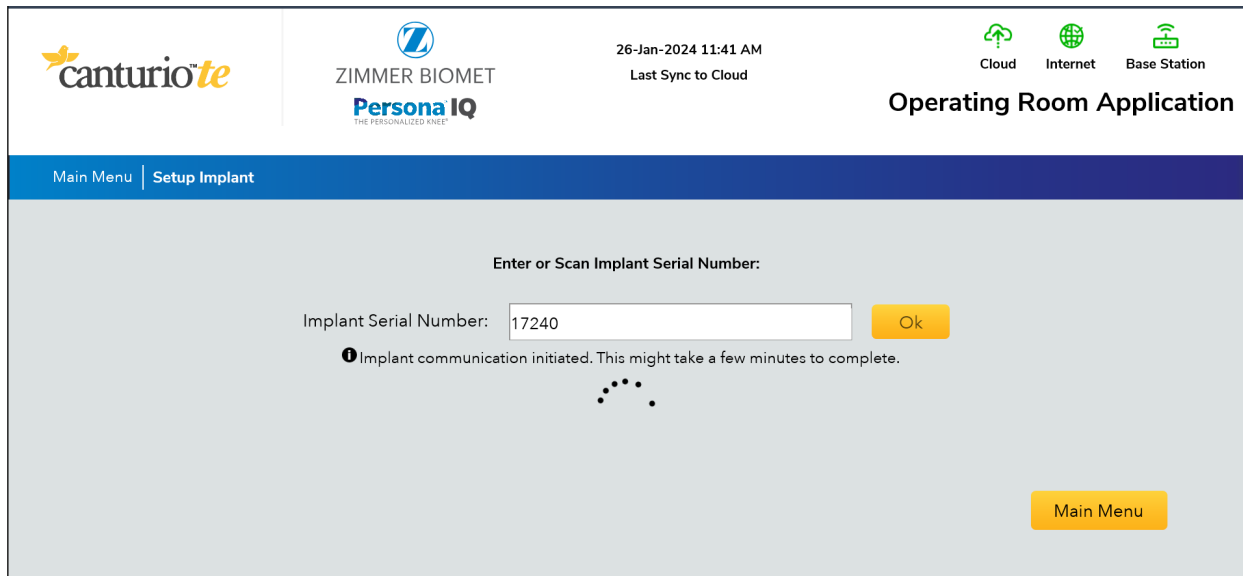


Figure 9: Setup Implant: Communication Initiated

- a. Click on Self-Test (**Figure 10**). Upon initiation of a Self-Test the internal implant 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 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 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.

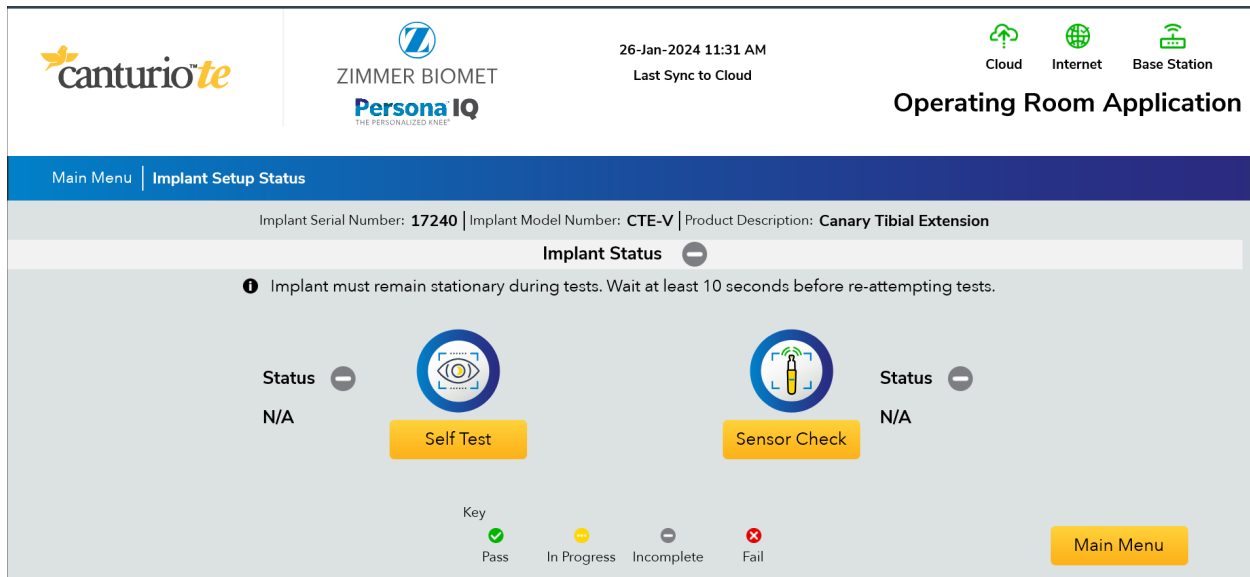


Figure 10: Self-Test

- b. Click on Sensor Check (**Figure 11**). Upon initiation of a Sensor Check the IMU in the implant 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 implant was not stationary during the Sensor Check. Re-attempt Sensor Check after ensuring the implant 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 implant due to proximity or interference. Re-attempt Sensor Check after ensuring the 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 WiFi 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.

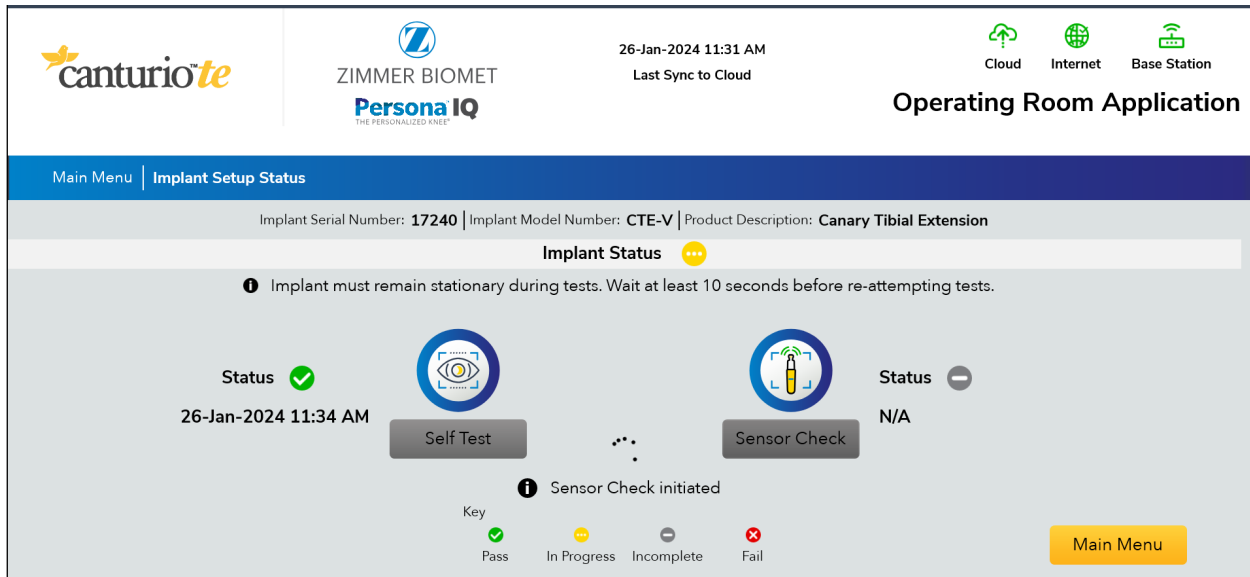


Figure 11: Sensor Check

12. When the Self-Test and Sensor Check are successful, the implant is ready to be used for the patient's TKA surgery. (Figure 12)

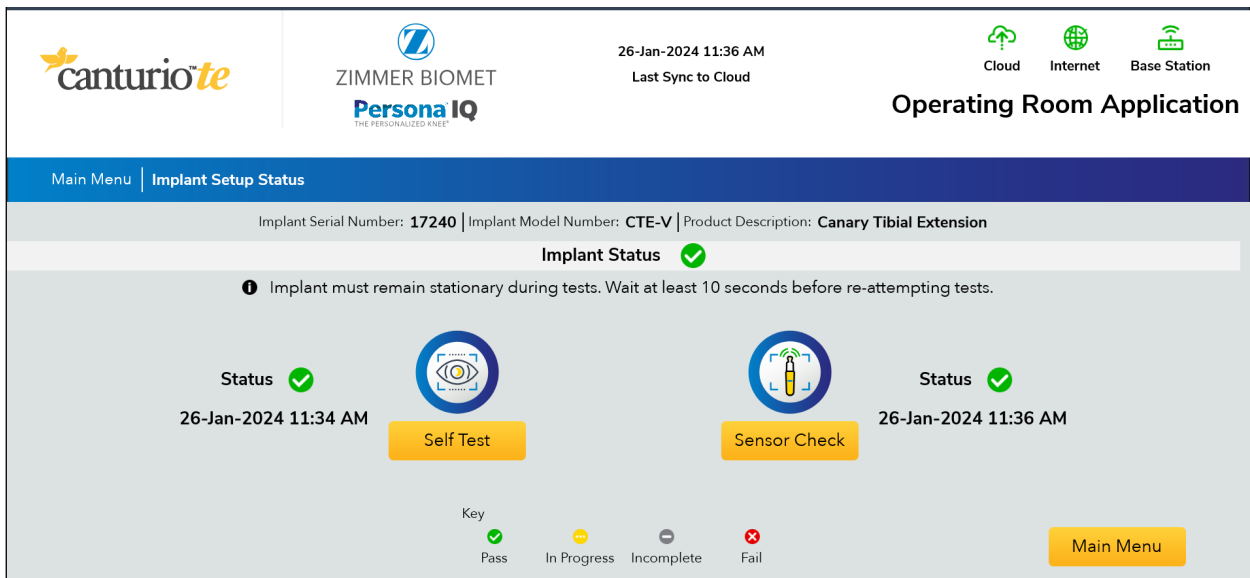


Figure 12: Self-Test and Sensor Check Successful



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.

10. Sizing and Drilling the Tibia

10.1. Resect Proximal Tibia

Table 4 lists the instrumentation for use in this step.

Table 4: Canary Medical Tibia Cut Guides


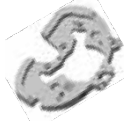
Instrumentation	Image	Catalogue Number
Tibia Resection Cutting Guide, Left, 5 Degree		43-5399-051-05
Tibia Resection Cutting Guide, Right, 5 Degree		43-5399-052-05






Use the Tibia Cut Guide(s) listed in Table 4 or the preferred compatible instrumentation used for preparing the tibial cut as determined from pre-operative planning in Section 3 and follow the Zimmer Biomet *Persona Knee Surgical Technique* (97-5026-001-00) for tibial resection.

10.2. Establish Size and Rotation of Tibia

Table 5 lists the instrumentation for use in this step.

Table 5: Tibia Sizing Instrumentation

Instrumentation	Image	Catalogue Number
Persona Tibial Sizing Plate Handle		42-5399-017-00
Persona Cemented Tibial Sizing Plate Size A-F Right		42-5399-075-02

Instrumentation	Image	Catalogue Number
Multi Pin Puller		00-5901-022-00
Alignment Rod with Coupler		00-5785-080-00
2.5 mm Male Hex Driver		42-5099-025-00
25 mm x 2.5 mm Female Hex Screw		42-5099-025-25
25 mm Shorthead Holding Pin		00-5977-056-03

Use only Persona or Canary Medical tibial sizing, broaching, and provisional instrumentation for preparation of Persona implants.

1. Once tibial osteophytes have been thoroughly removed, select the appropriate right or left sizing plate that provides the desired tibial coverage, without overhang at any location. Appropriate tibial sizing is important as an over-sized tibial component can result in overhang, soft tissue impingement, and pain, or, with stemmed components, potential distal conflict between stem and bone.
2. Attach the tibial sizing plate handle to the cemented tibial sizing plate (**see Figure 13**). The recommended tibial rotational alignment is within 5 degrees of the axis created by the medial $\frac{1}{3}$ of the tibial tubercle and the PCL attachment point. The engraved lines on the cemented tibial sizing plate can be used to aid in establishing the desired tibial rotation.
3. Rotate the cemented tibial sizing plate to attain the desired tibial rotational alignment. The notch in the lateral periphery of the sizing plate is used to establish proper position with respect to the lateral border of the tibia without medialization of the sizing plate.

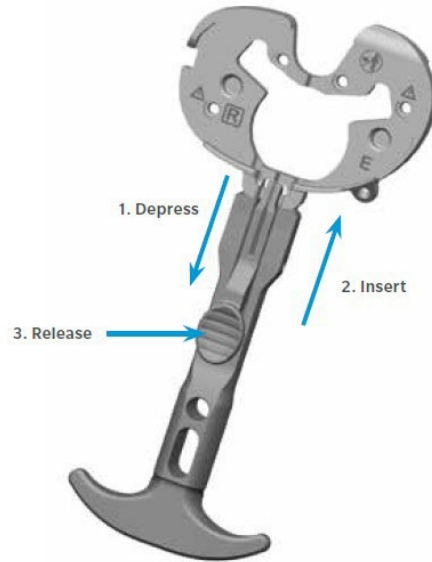


Figure 13: Cemented Tibial Sizing Plate with Handle

4. When the desired position has been obtained, secure the cemented tibial sizing plate by placing 25 mm x 2.5 mm (2.5 mm female hex) screws or 25 mm shorthead holding pin(s) in the medial and lateral holes near the PCL cutout of the cemented tibial sizing plate (**Figure 14**).



Figure 14

The remaining adjunct fixation holes shown on the surface of the cemented tibial sizing plate can be used if necessary. If the cemented tibial sizing plate is to be used as a provisional in later steps, male-headed screws/pins used in these holes must be removed prior to using the tibial articular surface provisionals (TASPs). See **Figure 15**.



Male-headed screws/pins must be removed from these holes for Tibial Articular Surface Provisionals (TASP)

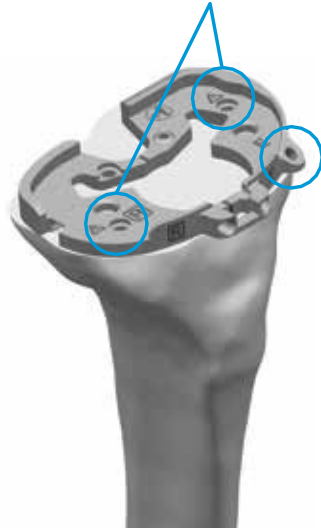


Figure 15

5. Ensure that the cemented tibial sizing plate remains in the proper position when securing it to the bone. Once desired alignment has been verified with the alignment rod, remove the tibial sizing plate handle from the cemented tibial sizing plate.

☰ **Technique Tip:** **DO NOT** impact, lever, or pry the tibial sizing plate handle; this instrument is designed for alignment purposes only. Use the alignment rod in the hole or slot in the tibial sizing plate handle to verify proper tibial plate varus/valgus alignment. (See Appendix A in 97-5026-001-00 for correcting varus/valgus resections.)

☰ **Technique Tip:** If using a screw through the anterior medial hole on the periphery of the cemented tibial sizing plate, ensure that the cemented tibial sizing plate remains in the desired position and does not lift off posteriorly.

10.3. Drilling the Tibia






Table 6 lists the instrumentation for use in this step.

CAUTION: DO NOT use the Canary Medical Cemented Tibia Drill Bit 15.7mm Dia. x 58mm prior to creating a tibial pilot hole with the Persona Cemented Tibial Drill, 15.7 mm.

☰ **Technique Tip:** Insert the Persona Cemented Tibial Drill, 15.7 mm or Canary Medical Cemented Tibia Drill Bit 15.7mm Dia. x 58mm into the cemented tibial drill guide prior to starting the drill. By hand, hold the cemented tibial drill guide flush against the cemented tibial sizing plate while drilling.

☰ **Technique Tip:** When drilling, if you feel that excessive contact with the bone cortex is occurring, stop drilling and remove the drill, guide, and sizing plate. Use the provisional stem extension construct to check whether the fit in the bone is appropriate to allow use of the Canary Medical Tibial Extension. Downsize the tibial base plate if a shorter tibial keel is needed.

Table 6

Instrumentation	Image	Catalogue Number
Persona Cemented Tibial Drill, 15.7 mm		42-5399-018-10
Canary Medical Cemented Tibia Drill Bit 15.7 mm Dia. x 58 mm		43-5399-058-14
Persona Cemented Tibial Drill Guide - 15.7 mm		42-5399-020-00
Persona Cemented Tibial Sizing Plate Size F Right		42-5399-075-02
Canary Medical Straight Taper Stem Provisional 14 x 58 mm		43-5571-058-14

The keel of the tibial implant has a unique location for every size; therefore, it is critical to select the proper size at this step, before drilling and broaching. Once these subsequent steps have been performed, the size should not be changed. If desired, femoral finishing can be performed in conjunction with provisional trialing at this stage to ensure that the desired range of motion and soft tissue balance can be attained with the cemented tibial sizing plate in place prior to drilling and broaching the tibia.

1. By hand, place and hold the cemented tibial drill guide on the tibia cemented tibial sizing plate, by first engaging the posterior tabs in the undercuts in the cemented tibial sizing plate and then making sure that the distal anterior portion of the cemented tibial drill guide is flush against the cemented tibial sizing plate. **Figure 16.**

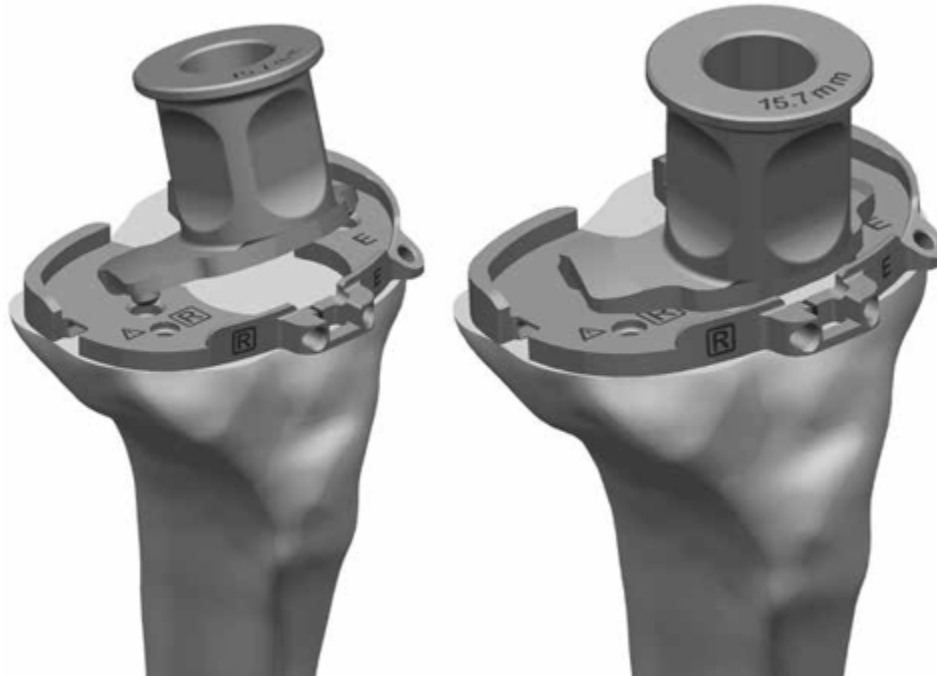


Figure 16

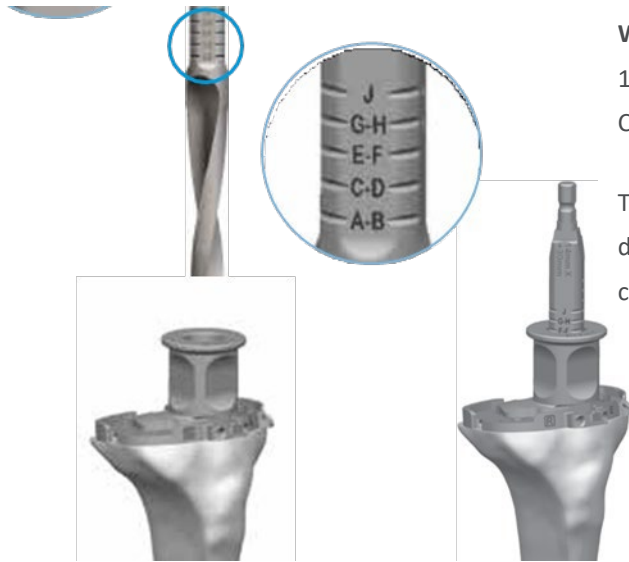
WARNING: The procedure and drill used for the Persona with Canary Medical Tibial Extension (CTE) is different than the current Persona 14 mm x +30 mm, 15.7 mm Diameter Tibial Drill (42-5399-018-14) and 14 mm x +30 mm Tapered Stem Extension (42-5571-001-14). **DO NOT** use the Persona 14 mm x +30 mm, 15.7 mm Diameter Tibial Drill (42-5399-018-14) or the 14 mm x +30 mm Tapered Stem Extension (42-5571-001-14) to prepare the canal for the Canary Tibial Extension. The Persona 14 mm x +30 mm, 15.7 mm Diameter Tibial Drill (42-5399-018-14) will not drill deep enough for the Canary Tibial Extension and the associated cement mantle. Confirm that you are using the Canary Medical drill (43-5399-058-14) with the Canary Medical labeling before drilling.

CAUTION: DO NOT use the NexGen Drill Guide and/or NexGen Sizing Plates with the Canary Medical Cemented Tibial Drill Bit 15.7mm Dia. x 58mm.

2. Use the Persona Cemented Tibial Drill, 15.7 mm (42-5399-018-10) to create a pilot hole by drilling until the center of the size-specific engraved line on the cemented tibial drill is in line with the top of the cemented tibial drill guide (Figure 17). After drilling is complete, remove the Persona Cemented Tibial Drill, 15.7 mm, and attach the Canary Medical Cemented Tibia Drill Bit 15.7mm Dia. X 58mm.
3. Use the Canary Medical Cemented Tibia Drill Bit 15.7mm Dia. x 58mm to drill until the center of the size-specific engraved line on the cemented tibial drill is in line with the top of the cemented tibial drill guide (Figure 17). After drilling is complete, remove the cemented tibial drill guide.

CAUTION: DO NOT use the Canary Medical Cemented Tibia Drill Bit 15.7mm Dia. x 58mm (43-5399-058-14) prior to creating a tibial pilot hole with the Persona Cemented Tibial Drill, 15.7 mm (42-5399-018-10).

Technique Tip: Insert the Persona Cemented Tibial Drill, 15.7 mm or Cemented Tibia Drill Bit 15.7mm Dia. x 58mm into the cemented tibial drill guide prior to starting the drill. Hold the cemented tibial drill guide flush against the cemented tibial sizing plate while drilling.



WARNING: DO NOT use the Persona 14 mm x +30 mm, 15.7 mm Diameter Tibial Drill (42-5399-018-14) for the Canary Medical Tibial Extension tibial preparation.







The Persona Tibial Drill (42-5399-018-14) will not drill deep enough for the stem extension and the associated cement

Figure 17

11. Sizing and Drilling of the Tibia (Alternative Technique)

Table 7 lists the instrumentation for use in this step.

Table 7

Instrumentation	Image	Catalogue Number
Persona Tibial Sizing Plate Handle		42-5399-017-00
Persona Cemented Tibial Sizing Plate Size F Right		42-5399-075-02
Persona Cemented Tibial Drill, 15.7 mm		42-5399-018-10
Canary Medical Cemented Tibial Drill Bit 15.7 mm Dia. x 58 mm		43-5399-058-14
Persona Cemented Tibial Drill Guide – 15.7 mm		42-5399-020-00
Persona Cemented Tibial Drill Stop Collar, 15.7 mm		42-5399-019-00

If desired, the cemented tibial drill stop collar may be used to aid in drilling to the correct depth.

1. Depress the button on the cemented tibial drill stop collar and slide the cemented tibial drill stop collar to the desired size-specific position on the Persona Cemented Tibial Drill, 15.7 mm or Canary Medical Cemented Tibia Drill Bit 15.7 mm Dia. x 58 mm (**Figure 18**).



Figure 18

2. Confirm that the correct size is displayed in the cemented tibial drill stop collar window (**Figure 19**) and that the cemented tibial drill stop collar is locked on the Persona Cemented Tibial Drill, 15.7 mm or Canary Medical Cemented Tibia Drill Bit 15.7 mm Dia. x 58 mm.

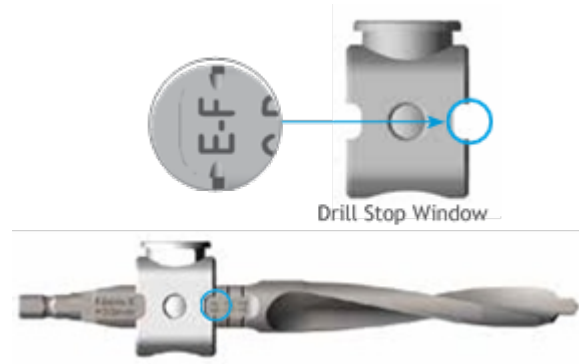


Figure 19

- **Technique Tip:** Verify that the cemented tibial drill stop collar is locked on the Persona Cemented Tibial Drill, 15.7 mm or Cemented Tibia Drill Bit 15.7 mm Dia. x 58 mm (43-5399-058-14) by attempting to slide the cemented tibial drill stop collar on the cemented tibial drill by hand. The cemented tibial drill stop collar will make an audible click when it locks on the drill.
3. Use the Persona Cemented Tibial Drill, 15.7 mm (42-5399-018-10) to create a pilot hole by positioning the cemented tibial drill stop collar in the proper position and drilling through the cemented tibial drill guide until the cemented tibial drill stop collar contacts the cemented tibial drill guide (Figure 17). After drilling is complete, remove the Persona Cemented Tibial Drill.
 4. Using the Canary Medical Cemented Tibia Drill Bit 15.7 mm Dia. x 58 mm, position the cemented tibia drill stop collar in the proper position and drill through the cemented tibia drill guide until the cemented tibia drill stop collar contacts the cemented tibia drill guide (**Figure 20**).

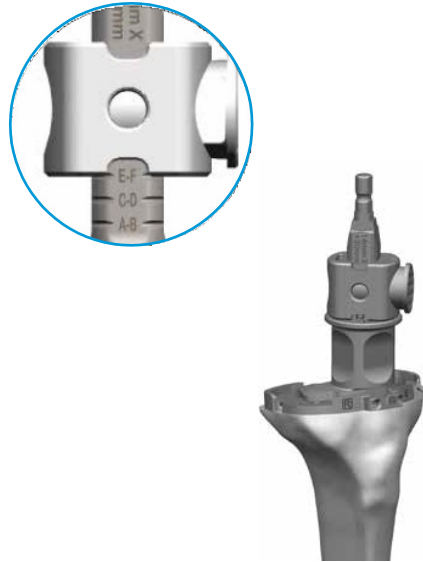


Figure 20

5. After drilling is complete, remove the cemented tibia drill and cemented tibia drill guide from the cemented tibia sizing plate.

CAUTION: DO NOT use the Canary Medical Cemented Tibia Drill Bit 15.7 mm Dia. x 58 mm prior to creating a tibial pilot hole with the Persona Cemented Tibial Drill, 15.7 mm.




☰ **Technique Tip:** Insert the Persona Cemented Tibial Drill, 15.7 mm or Canary Medical Cemented Tibia Drill Bit 15.7 mm Dia. x 58 mm into the cemented tibial drill guide prior to starting the drill. Hold the cemented tibial drill guide flush against the cemented tibial sizing plate while drilling.

☰ **Technique Tip:** When drilling, if you feel that excessive contact with the bone cortex is occurring, stop drilling and remove the drill, guide, and sizing plate. Use the Canary Medical provisional stem extension construct to check whether the fit in the bone is appropriate to allow use of the canturio™ te. Downsize the tibial base plate if a shorter tibial keel is needed.

12. Broaching the Tibia

Table 8 lists the instrumentation used in this step.

Table 8

Instrumentation	Image	Catalogue Number
Persona Cemented Tibial Broach Size EF		42-5399-022-05
Persona Cemented Tibial Broach Inserter/Extractor Handle		42-5399-023-00
Persona Cemented Tibial Sizing Plate Size F Right		42-5399-075-02

1. Insert the correct-sized cemented tibial broach into the cemented tibial broach inserter/extractor handle (Figure 21).

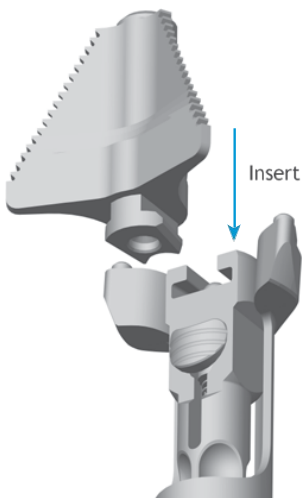


Figure 21

2. Retract the impaction head until it locks in the fully retracted position, which will facilitate placement on the cemented tibial sizing plate.
3. After seating the cemented tibial broach inserter/extractor handle on the cemented tibial sizing plate, tap the impaction head once to seat the cemented tibial broach.

4. Impact the cemented tibial broach inserter/extractor handle assembly with care to prevent fracture of the tibia (**Figure 22**). Impact until the impaction head bottoms out on the cemented tibial broach inserter/extractor handle stop (**Figure 22** inset).



Figure 22

5. While holding the cemented tibial broach inserter/extractor handle, impact the extraction button to remove the cemented tibial broach from the bone (**Figure 23**). Avoid dislodging the cemented tibial sizing plate when removing the cemented tibial broach inserter/extractor handle.

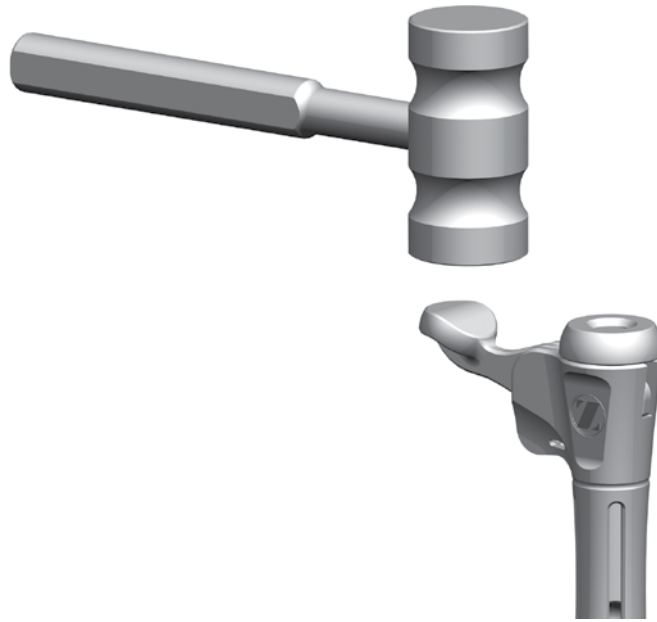


Figure 23

WARNING: Ensure that no metallic debris is present on the magnetic feet of the cemented tibial broach inserter/extractor handle as this may inhibit the mating with the cemented tibial sizing plate and may introduce debris into the surgical site.








☰ **Technique Tip:** Make sure that the cemented tibial broach inserter/extractor handle remains flush against and in full contact with the cemented tibial sizing plate and that the cemented tibial broach inserter/extractor handle does not tip during impaction. The orientation of the cemented tibial broach inserter/extractor handle is important to ensure proper and complete broaching resulting in full seating of the tibial implant on the bone.

☰ **Technique Tip: DO NOT** extract with mallet blows on either the medial or lateral side of the under surface of the impactation head of the cemented tibial broach inserter/extractor handle. **DO NOT** attempt to extract the cemented tibial broach with a horizontal or angled blow on any side of the cemented tibial broach inserter/extractor handle.

13. PROVISIONAL ASSEMBLY AND TRIALING

Table 9 lists the instrumentation used in the steps in this section.

Table 9

Instrumentation	Image	Catalogue Number
2.5 mm Male Hex Driver		42-5099-025-00
25 mm x 2.5 mm Female Hex Screw		42-5099-025-25
Persona 14 mm x +30 mm Stemmed Tibia Provisional		42-5321-075-02
Canary Medical Straight Taper Stem Provisional 14 x 58 mm		43-5571-058-14
Tibial Provisional Extractor		00-5977-017-00
CPS Lock Down Screw, Short		42-5376-001-00
CPS Lock Down Screw, Long		42-5376-001-01

13.1. Assembling the Canary™ Straight Taper Stem Provisional to the Persona® Stemmed Tibial Provisional

When assembling the Canary Medical Straight Taper Stem Provisional 14 x 58 mm with the Persona Stemmed Tibia Provisional:

1. Place the Persona component with the tibia tray facing down on a padded surface.
2. Thread the Canary Medical component into the female end of the Persona component (**Figure 24**).

3. Hand tighten.

NOTE: Thread the tapered stem provisional in first before trialing the knee using the Constrained Posterior Stabilized (CPS) TASP lockdown screw.

NOTE: Only hand-tighten the Canary Medical Straight Taper Stem Provisional 14 x 58 mm.



Figure 24

13.2. Using the Canary Medical™ Stemmed Tibial Provisional Construct

When using the Canary Medical stemmed tibial provisional:

1. Assemble the stemmed tibial provisional to the tibial provisional extractor and insert in the prepared tibial bone.

NOTE: For additional fixation of the fully seated provisional, insert a 25 mm x 2.5 mm screw (2.5 mm female hex) with the 2.5 mm male hex driver through a screw fixation hole located in the medial and/or lateral compartments of the stemmed tibia provisional (**Figure 25**).



Figure 25

WARNING: DO NOT use 48 mm screws for cemented tibial sizing plate fixation. 48 mm screws are not recommended due to the potential for bone perforation.

The Persona Tibial Keel length ranges from 23.4 mm to 40 mm (**Figure 26**). The Canary Tibial Extension adds 58mm to the length of the tibial keel nominally when assembled (**Figure 26**).

Refer to **Table 10** for the depth of the Persona Stem Tibia as illustrated in **Figure 26**.

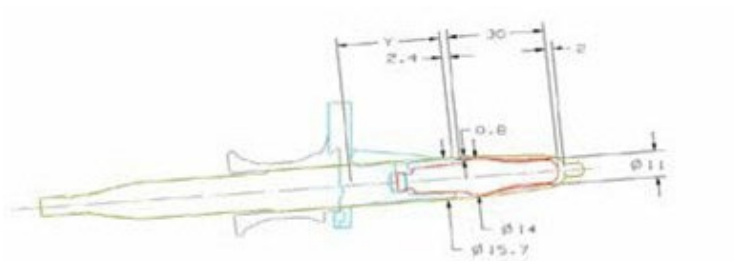


Figure 26 (Dimensions in mm)

Reference Table 10 below for the appropriate tibia-to-stem compatibility. The Canturio Tibial Extension is compatible with all Persona Cemented Stemmed Tibial Plates.

Table 10: Persona with Canary Medical Tibial Extension Compatibility Chart

Tibia Size	Y (Figure 26) mm	Canturio™ Tibial Extension
A	23.4	14 mm x +58 mm
B	23.4	
C	27.7	
D	27.7	
E	32	
F	32	
G	36	
H	36	
J	40	

14. Activating the Implant

After the implant has been introduced into the sterile field, and before assembly with the Persona tibial plate, use the steps below to activate the implant.

1. Place the OR Base Station within 6 feet of the implant. Connect the USB cable to the OR Base Station and Laptop. Connect the Barcode Scanner to the Laptop.
2. Plug the Laptop into a power outlet (if needed) and turn on the Laptop.
3. The Canary Operating Room Application (OR App) will start automatically.
4. Ensure the OR Base Station and Laptop are connected. This is indicated by the green “BaseStation” icon at the top of the Laptop screen.
5. Ensure an Internet connection has been established and the OR App is connected to the CanaryCloud. This is indicated by the green Internet icon at the top of the Laptop screen.
6. Click on the image of the implant in the center of the screen.
7. Enter your authorized Username and Password and click the “Login” button. This will take you to the Main Menu screen. **Figure 27**. Click on the “Activate Implant” Icon.

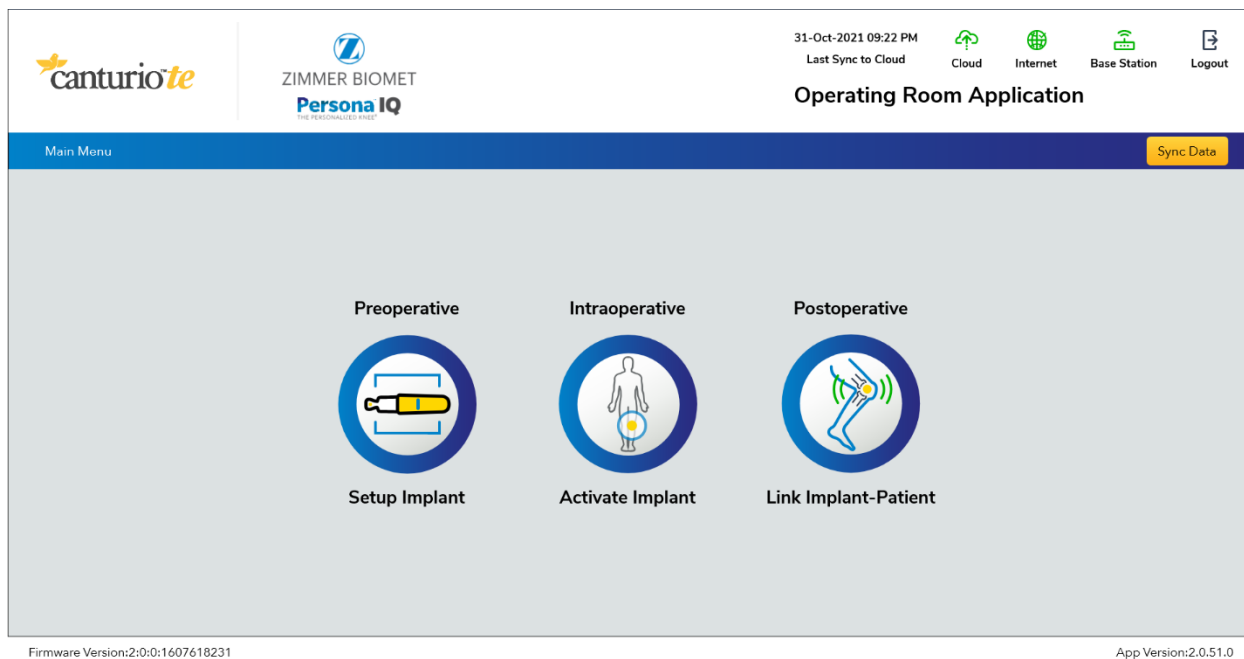


Figure 27: Main Menu

8. Click in the text box and enter or scan the Implant Serial Number, then click “OK.” **Figure 28**.

NOTE: If scanning, place the barcode scanner over the 2D bar code as shown in the example image below.

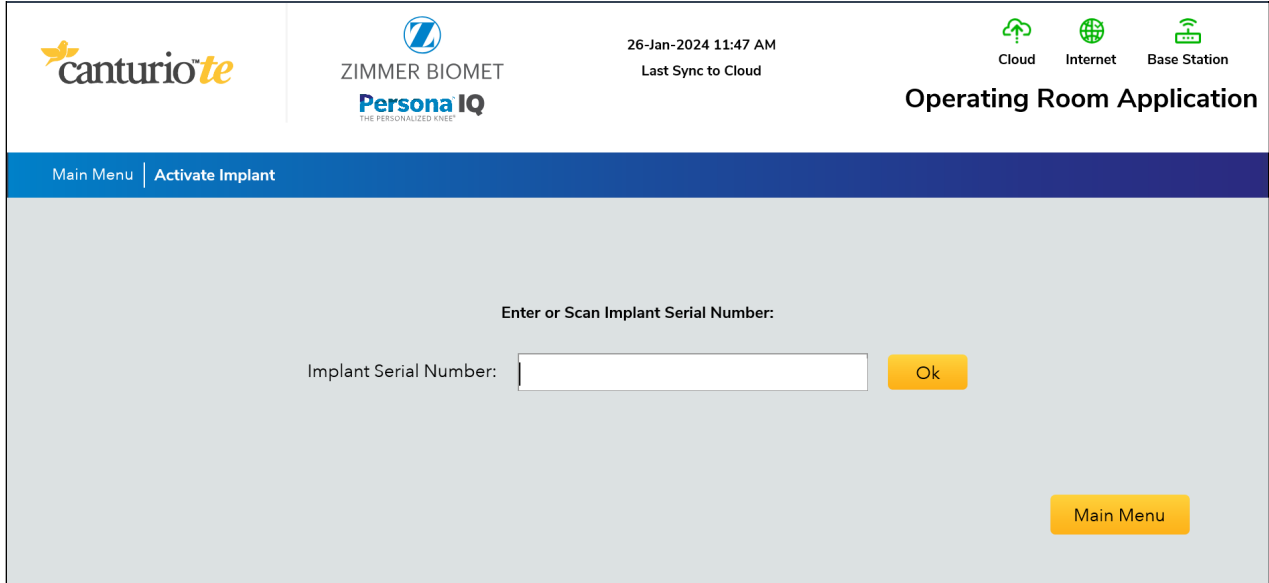


Figure 28: Activate Implant: Enter or Scan Implant Serial Number

9. Click “Activate.” Figure 29.

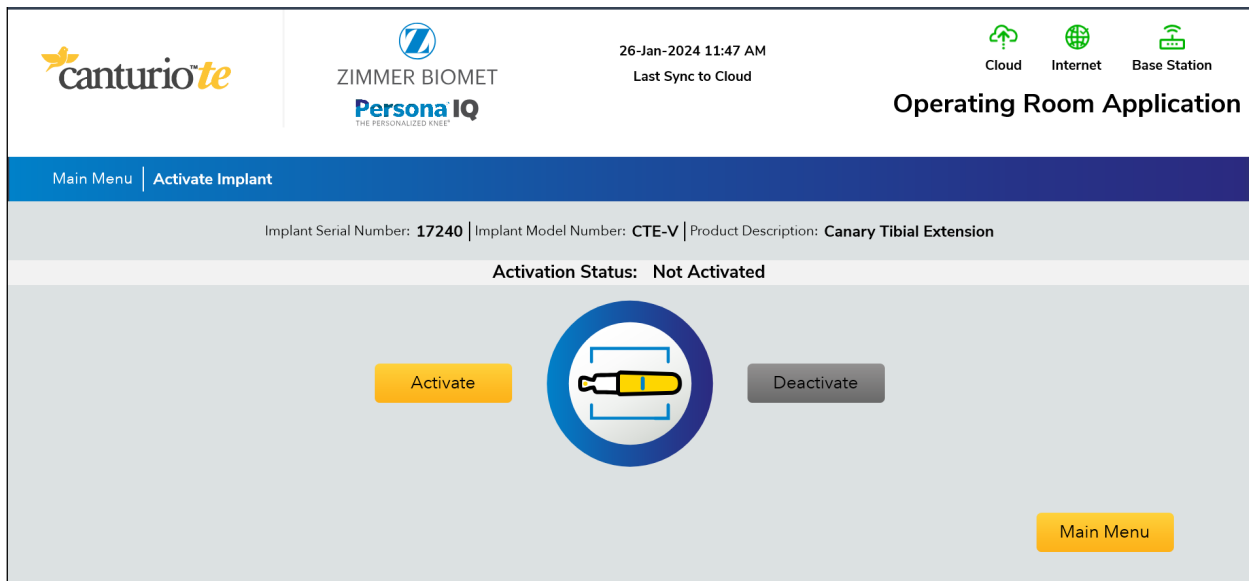






Figure 29: Implant Activation

15. Assembling the CTE Implant with the Persona Tibial Plate

Table 11 lists the instrumentation used in the steps in this section.

Table 11

Instrumentation	Image	Catalogue Number
Persona Cemented Stemmed Tibial Plate Sizes FRight		42-5320-075-02
Canturio™ Medical Tibial Extension (CTE) Implant		43-5570-058-14
Persona Femoral Set Screw Hex Driver		00-5987-071-00
Canary Medical CTE Impaction Sleeve		43-5399-001-14

15.1. Preparing the Canturio™ Tibial Extension (CTE)

To attach the CTE Implant to the Persona Tibial Plate:

1. Position the Persona Tibial Plate with the face plate down on a padded surface (**Figure 30**).

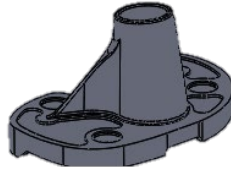


Figure 30

NOTE: The locking mechanism between the Persona Tibial Plate and the CTE Implant is a combination of a taper and a set screw.

2. Using the hex driver, loosen the locking set screw from the Persona Tibial Plate by backing the set screw out only far enough so that you can remove the plastic plug. Remove the plastic plug within the taper (**Figure 31**). Take care not to drop or lose the set screw.

NOTE: Dispose of the plastic plug as medical waste.

3. Confirm that the set screw is not going to interfere with the CTE implant.

CAUTION: Check to ensure that the set screw has not migrated or fallen into the Persona Tibial Plate or package prior to inserting the CTE Implant into the Persona Tibial Plate.



Figure 31

4. Align the alignment mark on the CTE Implant to the alignment mark on the Persona Tibial Plate, and insert the CTE implant taper into the Persona Tibial Plate taper until fully seated (**Figure 32**).

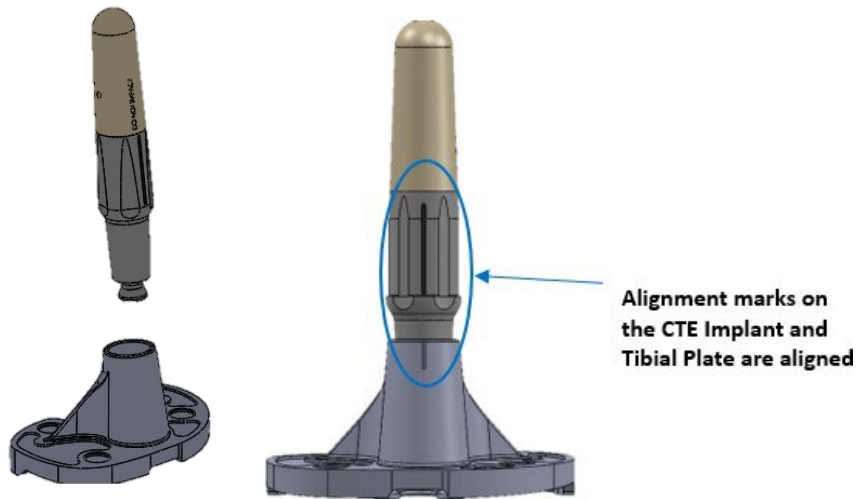


Figure 32

5. When a "snug" fit is achieved, place the assembly on a surgical cart with the tibial plate face down on a padded surface.
6. Place the Impaction Sleeve over the CTE Implant and Tibial Plate assembly until the Impaction Sleeve stops on the CTE Implant. Impact on the Impaction Sleeve with a two- pound mallet solidly multiple times until the CTE Implant is fully seated in the Persona Tibial Plate (**Figure 33**).

CAUTION: DO NOT impact directly on the CTE to insert. Only use the Impaction Sleeve to apply impact force.

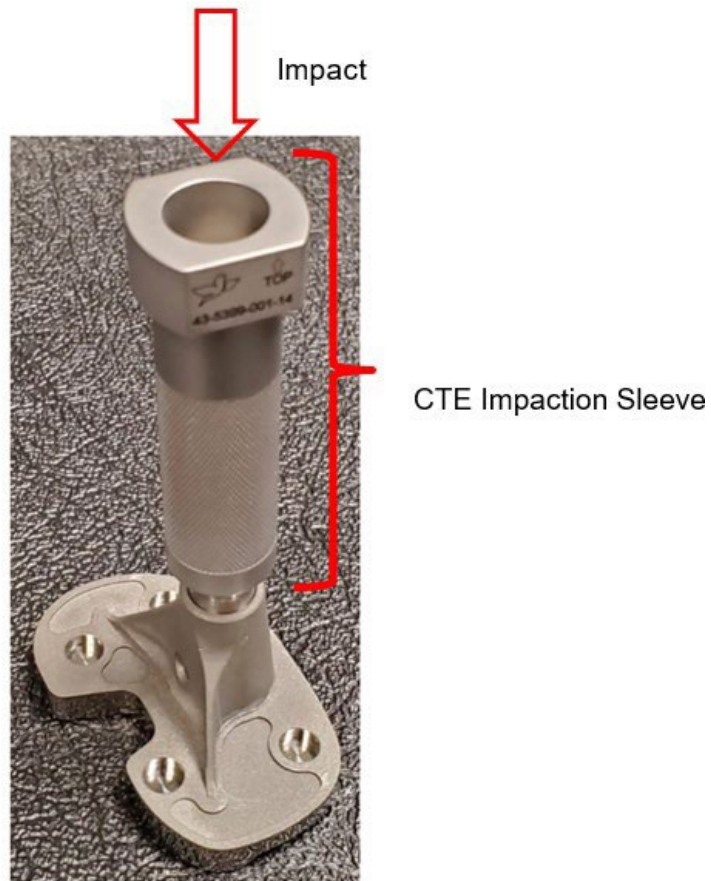


Figure 33

7. Once the CTE Implant is seated into the Persona Tibial Plate, hand-tighten the set screw and torque with the femoral set screw hex driver (**Figure 34**).



Figure 34

8. Verify the CTE Implant is fully seated after impacting and torquing the set screw (**Figure 35**).



Figure 35

CAUTION: The Canary Medical™ Canturio™ Tibial Extension is compatible with the primary Persona Cemented Stemmed Tibial Plates. **DO NOT** use with the Persona® Revision System, nor with other Zimmer Biomet knee systems, such as NexGen® Knee, Vanguard® or Natural-Knee II Tibial Plates. For cemented use only.

ⓘ Technique Tip: **DO NOT** implant the CTE without the set screw. Have a spare set screw available at each surgery. The part number of the set screw is 00-5988-090-00.




CAUTION: The femoral set screw hex driver is designed to limit the amount of torque which can be applied to the screw and is designed to break off if over-torqued. Torque by hand only.

OPTIONAL: After completing the assembly, run Self-Test from the Implant Self-Test instructions in Section 9 to verify the CTE implant is still working.

16. Implanting the CTE and Persona Assembly

Table 12 lists the instrumentation used in this step.

Table 12

Instrumentation	Image	Catalogue Number
Persona Quick Connect Handle		00-5901-034-00
Persona Tibial Impactor Head		00-5901-033-00
Persona Cemented Stemmed Tibial Plate Sizes FRight		42-5320-075-02

Technique Tip: Prior to cementing the implants, remove the provisionals and use pulse lavage to remove debris from the resected bone surfaces and the joint space.

In this step, the final components are implanted, and the Persona tibial bearing is secured to the implanted tibial plate. When using cemented components, it is recommended to use two batches of cement.

After the implants have been chosen, make a final check to ensure that all components are compatible. If the resected surfaces of the tibia and/or femur are sclerotic, drill multiple holes with a small drill (2.0 mm–3.2 mm) to improve cement intrusion. Mix cement following the manufacturer's guidelines for cement preparation including but not limited to mix, work, and set times.

16.1. Tibial Plate

Sublux the tibia anteriorly to allow adequate clearance to insert the tibial implant into the prepared bone. **DO NOT** apply substances other than bone cement to the tibial implant (e.g., **DO NOT** dip implant into antibiotics or other substances). Keep the implant clean and free of debris prior to cementing. At a minimum, place a layer of cement on the underside of the tibial baseplate, around the keel, around the metal component of the CTE implant up to the PEEK-Titanium interface (excluding the PEEK nosecone) as shown in Figure 36, and on the resected tibial surface. When increased fixation is desired, you can use full cementation around the CTE Implant (including the PEEK nosecone) and in the tibial IM canal without affecting the performance or wireless communications of the CTE Implant.

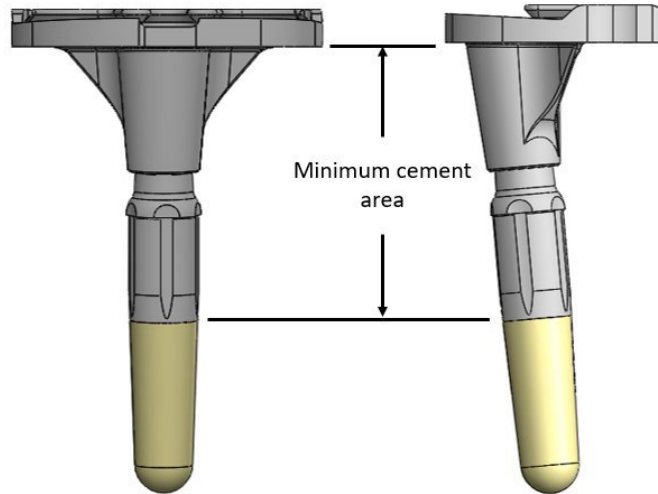


Figure 36

Assemble the quick connect handle to the tibial impactor head. Unlock collar and hold, insert handle into impactor head, release collar, and rotate handle until “click” is heard (**Figure 37**).



Figure 37

Position the tibial plate onto the tibia and use the tibial impactor to impact it until fully seated (**Figure 38**).



Figure 38

Thoroughly remove any excess cement in a consistent manner. Allow the cement to fully cure before performing a trial ROM or inserting the bearing per the manufacturer's recommended guidelines.

OPTIONAL: After completing implantation, run Self-Test from the Implant Self-Test instructions in Section 9 to verify the CTE implant is still working

17. Linking the Implant to the Patient

After the surgery is complete, use the OR PC Application and Barcode Scanner to link the patient’s implant to the patient’s account.

1. Connect the USB cable to the Base Station and Laptop. Connect the Barcode Scanner to the Laptop.
2. Plug the Laptop into a power outlet (if needed) and turn on the Laptop.
3. The Canary Medical™ Operating Room Application (OR App) will start automatically.
4. Ensure the OR Base Station and Laptop are connected. This is indicated by the green “Base Station” icon at the top of the Laptop screen.
5. Ensure an Internet connection has been established and the OR App is connected to the Canary Medical™ Cloud. This is indicated by the green Internet icon at the top of the Laptop screen.
6. Click on the image of the implant in the center of the screen.
7. Enter your authorized Username and Password and click the “Login” button. This will take you to the Main Menu screen. (**Figure 39**)
8. Under “Postoperative,” click on the “Link Implant – Patient” icon (**Figure 39**).

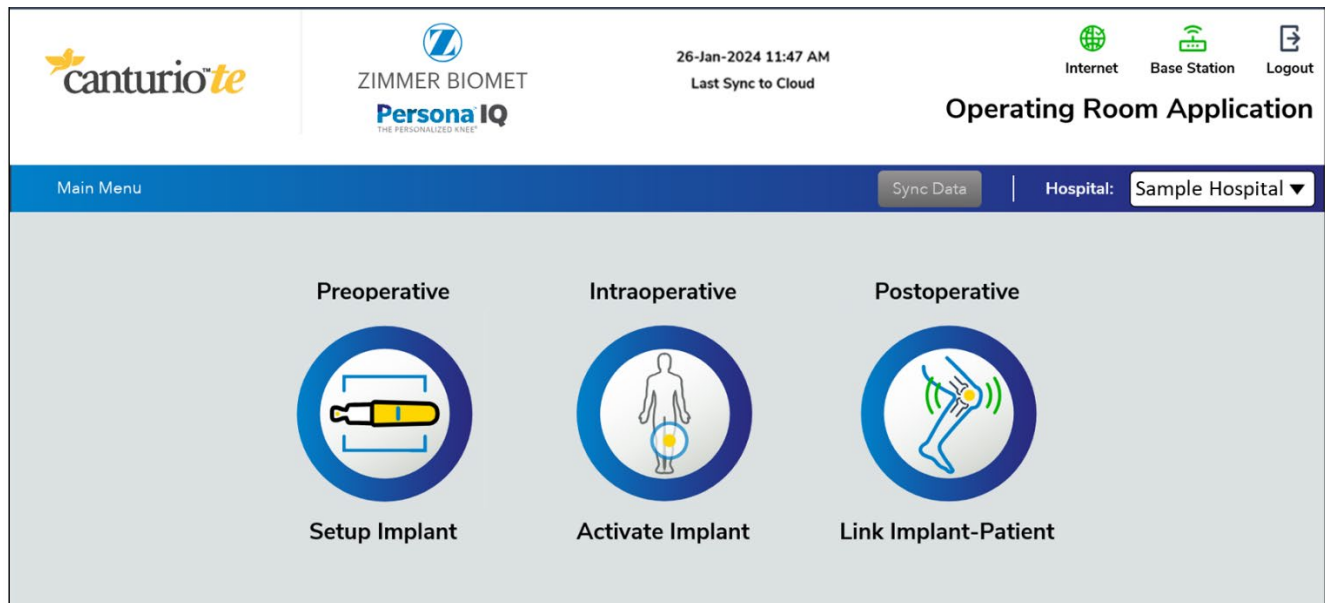


Figure 39: Main Menu

9. Choose the patient's name from the Patient List (**Figure 40**).

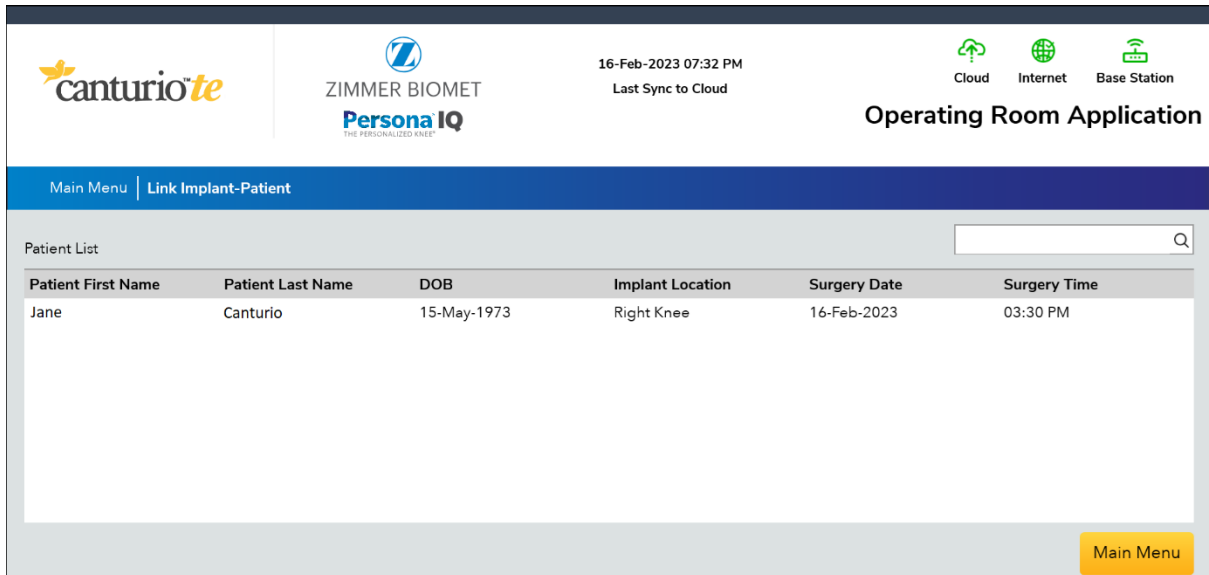


Figure 40: Choose Patient from List

10. Click in the “Implant Serial Number” field to enter or scan the implant serial number and update the “Actual Surgery Date” field to reflect the date of surgery (it will default to the current date). When finished, click “Submit” to save the information to the patient’s account (**Figure 41**).

NOTE: If scanning, place the barcode scanner over the 2D bar code on the label, as shown in the example image below.

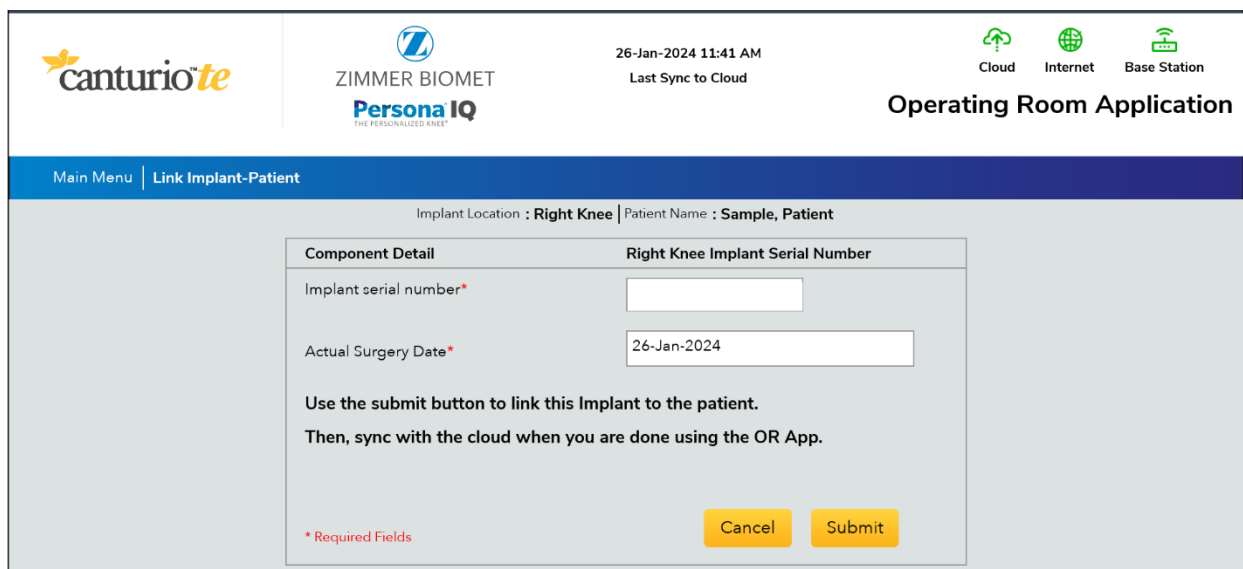


Figure 41: Add Component Information

11. The OR App will display pending implant link and cloud sync actions in red text at the top of the application window (Figure 42).

The screenshot displays the 'Operating Room Application' interface. At the top, there are logos for 'canturio^{te}' and 'ZIMMER BIOMET Persona IQ'. The status bar shows the date and time '16-Feb-2023 07:38 PM' and 'Last Sync to Cloud'. A red notification states: '1 CTEs have been linked and are awaiting sync with the cloud'. On the right, there are icons for 'Cloud', 'Internet', and 'Base Station'. The main content area has a blue header with 'Main Menu' and 'Link Implant-Patient'. Below this is a 'Patient List' section with a search bar and a table with columns: 'Patient First Name', 'Patient Last Name', 'DOB', 'Implant Location', 'Surgery Date', and 'Surgery Time'. The table is currently empty, displaying 'No Records Found'. A 'Main Menu' button is located at the bottom right.

Figure 42: Implant Link and Cloud Sync Status

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Jane Canturio is an imaginary patient with a fabricated surname.

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