

**CANARY canturio® Smart Extension with CHIRP®** System

**Surgical Technique** 



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





### Table of Contents

1. Introduction	3
2. Terms and Acronyms	5
3. Preoperative Planning	6
4. Surgical Approach	7
5. Patient Preparation	8
6. Magnet Usage	9
7. Symbols	10
8. Compatible Screw/Pin Information	11
9. Pre-Operative: Setting Up the OR Base Station and Testing the Canturio <sup>®</sup> Smart Extension (CSE)	13
10. Sizing and Drilling the Tibia	20
11. Sizing and Drilling of the Tibia (Alternative Technique)	27
12. Broaching the Tibia	30
13. Provisional Assembly and Trialing	33
14. Activating the Implant	37
15. Assembling the CSE Implant with the Persona Tibial Plate	39
16. Implanting the CSE and Persona Assembly	44
17. Linking the CSE to the Patient	47

### **<u>1.</u> 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<sup>®</sup> The Smart Knee<sup>®</sup> 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).

#### 1.1 Canturio<sup>®</sup> Smart Extension (CSE) with CHIRP<sup>®</sup> System

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

The Canturio Smart Extension (CSE) 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 30mm sized tibial stem extension. The objective kinematic data generated by the **CSE** with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.

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

Figure 1 shows the CSE implant on the left and a representation of the CSE implant assembled with the Zimmer Biomet Persona tibial plate on the right.





This Surgical Technique document is to be used only when utilizing the CSE with primary Persona<sup>®</sup> knee implants and is not for use with Persona<sup>®</sup> Revision, or with other Zimmer Biomet knee systems, such as NexGen<sup>®</sup> Knee, Vanguard<sup>®</sup>, or Natural-Knee<sup>®</sup> II systems. The surgical technique for implanting the Persona<sup>®</sup> knee with the **CSE** uses a combination of Persona<sup>®</sup> and Canary<sup>®</sup> instrumentation. Pay close attention to the instructions in this Surgical Technique document toensure 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.

### **<u>2.</u>** 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 Cloud Based Data Management Platform
CN	Circulating Nurse
canturio® <i>se</i>	Canturio Smart Extension (se) implant
CSE	Canturio Smart Extension (canturio®se)
CPS	Constrained Posterior Stabilized
НСР	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
ТКА	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 asunrise 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 14mm x 30mm X-Ray Template (97-5026-051-00), which is available through your Zimmer Biomet representative, on the patient's long-standing film to determine if the patient's anatomy is appropriate for a CSE implant.

The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 30mm 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 distalfemur 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 subluxed. 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<sup>®</sup> The Smart Knee<sup>®</sup> system contain magnets. Active implantablemedical 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 CSE implant and the patient's existing active implantable medical device(s) (e.g., pacemaker).

### <u>7.</u> SYMBOLS

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

Term	Symbol	Term	Symbol	Term	Symbol
Left		Do Not Implant/Not for Implant		Cemented	CEMENTED
Right	RR	Lock		Stemmed	STEMMED
Varus/ Valgus	VARUS VALGUS	Unlock		Inset Only	
Medial/ Lateral	M/L	Anterior Referencing	AREF		
Standard	Std	Do Not Impact	$\otimes$		

#### Table 2: Symbols for Surgical Technique

### **<u>8.</u>** COMPATIBLE SCREW/PIN INFORMATION

 Table 3 contains information on various 3.2 mm screws/pins that are compatible with the Zimmer Biomet Persona IQ® The Smart Knee® and canturio®se

 with CHIRP®system 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.

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			Sterile	4	Yes
Hex Headed Screw 33 mm long	00-5901-035-33	Pin/Screw Inserter	00-5901-021-00	Sterile	2	Yes

#### 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?
MIS Quad-Sparing Total Knee Headed Screw 48 mm long	00-5983-040-48	Screw Inserter/ Extractor	00-5983-049-00	Sterile	1	Yes
25 mm Shorthead Holding Pin	00-5977-056-03	Multi Pin Puller	00-5901-022-00	Non-Sterile	1	No

# **<u>9.</u>** PRE-OPERATIVE: SETTING UP THE OR BASE STATION AND TESTING THE CANTURIO SMART EXTENSION (CSE)

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

**WARNING**: Retain the canturio *se* implant in its packaging box. **DO NOT** remove the CSE 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 CSE 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 Laptop in an area with access to Wi-Fi.
- 2. Gather a CSE implant, the OR Base Station Unit, Bar Code Scanner, and USB cables.
  - a. Check the expiration date on the CSE implant package to ensure the implant is not expired.

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

**NOTE:** <u>Do not</u> open the CSE package at this time.

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

- c. Connect the Barcode Scanner to the Laptop.
- 4. On the Canary laptop, the Canary Medical Operating Room Application (OR App) will startautomatically, and you will see the image of an implant in the center of the screen.
- 5. 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.
- 6. Ensure an Internet connection has been established and the OR App is connected to the Canary Cloud. This is indicated by the green Internet icon at the top of the Laptop screen. See Figure 5.



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 CSE 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 CSE 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.



	ZIMMER BIOMET Persona IQ	09-Jul-2024 12:56 PM Last Sync to Cloud	مې <sub>Cloud</sub>	Internet Base Station Room Application
Main Menu   Setup Implant				
	Ente	r or Scan Implant Serial Number:		
	Implant Serial Number:		Ok	
				Main Menu

Figure 8: Enter or Scan Implant Serial Number

11. The CSE implant initiates communication with the OR Base Station. Click "OK" when this process is finished. Figure 9.

<b>S</b> canary	ZIMMER BIOMET PersonailQ	09-Jul-2024 12:56 PM Last Sync to Cloud	Opera	Cloud ting F	Internet Room A	Base Station
Main Menu   Setup Implant						
	Er Implant Serial Number: ①Implant communicati	nter or Scan Implant Serial Number: 17226 ion initiated. This might take a few minutes to comp 	Ok Slete.		Main M	lenu



a. Click on Self-Test. **Figure 10**. Upon initiation of a Self-Test the internal CSE 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 CSE 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 CSE 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 contactCanary Medical at 1-833-722-6279 for Return Authorization.





b. Click on Sensor Check. Figure 11. Upon initiation of a Sensor Check the IMU in the CSE captures abrief series of accelerometer and gyroscope (gyro) data which is then evaluated relative to the normal range for asmanufactured 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 CSE was not stationary during the Sensor Check. Reattempt Sensor Check after ensuring the CSE 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 CSE implant due to proximity or interference. Re-attempt Sensor Check after ensuring the CSE 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 andcontact Canary Medical at 1-833-722-6279 for Return Authorization.

<b>S</b> canary	ZIMMER BIOMET Persona IQ	09-Jul-2024 12:56 PM Last Sync to Cloud	ہم <sub>Cloud</sub> Operating F	Internet Base Station
Main Menu   Implant Setup Sta	tus			
Imp	lant Serial Number: <b>17226</b>   Implant Mode	Number: CSE   Product Description: Cantu	urio Smart Extension	
	Im	iplant Status 😐		
Un Status 09-Jul-2024	e 12:59 PM	tests. Wait at least 10 seconds before n	e-attempting tests. Status	
	Key 💽 Pass In	Progress Incomplete Fail		Main Menu

Figure 11: Sensor Check

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

	ZIMMER BIOMET Persona IQ	09-Jul-2024 01:02 PM Last Sync to Cloud	Cloud Internet Base Station Operating Room Application
Main Menu   Implant Setup Sta	tus		
Imp	lant Serial Number: <b>17226</b>   Implant Mode	Number: CSE   Product Description: Cantu	rio Smart Extension
	Im	ıplant Status 🛛 🔗	
❶ In Status 09-Jul-2024	<ul> <li>Plant must remain stationary during</li> <li>12:59 PM</li> <li>Self Test</li> </ul>	tests. Wait at least 10 seconds before re	p-attempting tests. Status ♥ 09-Jul-2024 01:02 PM
	Key 📀 Pass In	😑 😋 😵 Progress Incomplete Fail	Main Menu

Figure 12: Self-Test and Sensor Check Successful

If the Self-Test and Sensor Checkhave 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.

Instrumentation	Image	Catalogue Number
Persona Tibial Cut Guide Left - 3°	REAL PROPERTY OF	42-5399-051-03
Persona Tibial Cut Guide Left - 7°	No. OF CONTRACTOR	42-5399-051-07
Persona Tibial Cut Guide Right - 3°		42-5399-052-03
Persona Tibial Cut Guide Right - 7°		42-5399-052-07

Table 4: Persona Tibial Cut Guides

Use the Tibial 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.

**Technique Tip:** It is recommended to use the 3-degree cut guide for a PS component and the 7-degree cut guide for a CR component. If the ultracongruent articular surface is to be used, the recommended tibial cut slope is 5-7 degrees. Biasing towards a flatter slope cut for the ultracongruent articular surface provides an opportunity to

better match flexion and extension space, considering the flexion space generally increases more than the extension space when the PCL is resected.

#### 10.2. Establish Size and Rotation of Tibia

**Table 5** lists the instrumentation for use in this step.

Instrumentation	Image	Catalogue Number
Persona Tibial Sizing Plate Handle		42-5399-017-00
Persona Cemented Tibial Sizing Plate Size A-F Right	Sig	42-5399-075-02
Multi Pin Puller	1	00-5901-022-00
Alignment Rod with Coupler		00-5785-080-00
2.5 mm Male Hex Driver		42-5099-025-00

#### Table 5: Tibial Sizing Instrumentation

Instrumentation	Image	Catalogue Number
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 tibial sizing, broaching, and provisional instrumentation for preparation of Persona implants.

- 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 ¼ 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.
- 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 borderof the tibia without medialization of the sizing plate.



Figure 13: Cemented Tibial Sizing Plate with Handle

When the desired position has been obtained, secure the cemented tibial sizing plate by placing 25 mm x
 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

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.

**Technique Tip:** Insert the Cemented Tibial Drill 14mm x +30mm 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 canturio *se* implant. Downsize the tibial base plate if a shorter tibial keel is needed.

#### Table 6: Tibial Drill Instrumentation

Instrumentation	Image	Catalogue Number
Persona 14 mm x +30 mm, 15.7 mm Diameter Tibial Drill		42-5399-018-14
Persona Cemented Tibial Drill Guide -		
15.7 mm	40	42-5399-020-00
Persona Cemented Tibial Sizing Plate	1	
Size F Right		42-5399-075-02
Persona 14 mm x +30 mm Tapered Stem Provisional		43-5571-001-14

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.

 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

Use the Persona 14mm x +30mm Tibial Drill, 15.7 mm (42-5399-018-14) and 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.

**NOTE:** The drill to be utilized for the canturio *se* implant is different than the current Persona Tibial Drill (42-5399-018-10). **DO NOT** use the Persona Primary Tibial Drill (42-5399-018-10) to prepare the canal for the 14 mm x +30 mm tapered stem. The Persona Drill (42-5399-018-10) will not drill deep enough for the stem extension and the associated cement mantle. Do not use any other Persona Stem Extension Drills with the canturio *se* implant. Confirm that the drill used has the 14 mm x +30 mm labeling before drilling (**Figure 17**).

**Technique Tip:** Insert the cemented tibial drill 14 mm x +30 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.



Figure 17

# <u>11.</u> Sizing and Drilling of the Tibia (Alternative Technique)

 Table 7 lists the instrumentation for use in this step.

Instrumentation	Image	Catalogue Number
Persona Tibial Sizing Plate Handle	all and a second	42-5399-017-00
Persona Cemented Tibial Sizing Plate Size F Right	S	42-5399-075-02
Persona 14 mm x +30 mm, 15.7 mm Diameter Tibial Drill		42-5399-018-14
Persona Cemented Tibial Drill Guide – 15.7 mm		42-5399-020-00
Persona Cemented Tibial Drill Stop Collar, 15.7mm		42-5399-019-00

 Table 7: Tibial Drill Instrumentation (Alternative Technique)

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

 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 14 mm x +30 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 14 mm x +30 mm.



Figure 19

- **Technique Tip**: Verify that the cemented tibial drill stop collar is locked on the Persona Cemented TibialDrill 14 mm x +30 mm by attempting to slidethe 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.
- Insert the Persona Cemented TibialDrill 14 mm x +30 mm into the cemented tibial drill guide prior to drilling.
- 3. After positioning the cemented tibial drill stop collar in the proper position, drill through the cemented tibial drill guide until the cemented tibial drill stop collar contacts the cemented tibial drill guide (Figure 20).



Figure 20

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

**Example 7 Example 1** For the Persona Cemented Tibial Drill 14 mm x +30 mm into the cemented tibial drill guide prior to drilling. Hold the cemented tibial drill guide flush against the cemented tibial sizing plate while drilling.

**Example 7** 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 canturio *se*. 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.

Instrumentation	Image	Catalogue Number
Persona Cemented Tibial Broach Size EF	<b>F</b>	42-5399-022-05
Persona Cemented Tibial Broach Inserter/Extractor Handle	0	42-5399-023-00
Persona Cemented Tibial Sizing Plate Size F Right		42-5399-075-02

#### Table 8: Instrumentation for Broaching the Tibia

 Insert the correct-sized cemented tibial broach into the cemented tibial broach inserter/extractor handle (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.
- 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.





**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.

**Example 7 Example 1 Example 2 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 impaction 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.

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 TibiaProvisional		42-5321-075-02
Persona 14 mm x +30 mm Tapered Stem Provisional		43-5571-001-14
Tibial Provisional Extractor	t	00-5977-017-00
CPS Lock Down Screw, Short	Ĩ	42-5376-001-00

Table 9 –

Instrumentation	Image	Catalogue Number
CPS Lock Down Screw, Long	Ĩ	42-5376-001-01

## **13.1.** Assembling the Persona Tapered Stem Provisional to the Stemmed Tibial Provisional

When assembling the Persona 14 mm x +30 mm Tapered Stem Provisional with the Persona Stemmed Tibial Stem Provisional:

- 1. Place the stem provisional with the tibia tray facing down on a padded surface.
- 2. Thread the stem onto the female end of the stemmed tibia provisional (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 provisional stem.



Figure 24

#### 13.2. Using the Canary Stemmed Tibial Provisional Construct

When using the 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 canturio *se* adds 30mm 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.

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

Figure 26 (Dimensions in mm)

Tibia Size	Y (Figure 26) mm	Canturio <sup>®</sup> Smart Extension
А	23.4	
В	23.4	
С	27.7	
D	27.7	
	22	
E	32	14 mm x +30 mm
F	32	
G	36	
н	36	
L	40	

#### Table 10: Persona with Canturio Smart Extension Compatibility Chart

### 14. Activating the CSE Implant

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

- 1. Place the OR Base Station within 6 feet of the CSE 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 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 "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.

		(01)00860003118399 (17)230430 (21)123456	
	ZIMMER BIOMET	09-Jul-2024 01:02 PM Last Sync to Cloud	Cloud Internet Base Station
	Persona' IQ		Operating Room Application
Main Menu   Activate Implant			
	E	nter or Scan Implant Serial Number:	
	Implant Serial Number:	17226	Ok
	O Implant communicat	tion initiated. This might take a few minutes to comp	plete.
			Main Menu

Figure 28: Enter or Scan Implant Serial Number

9. Click "Activate." Figure 29.



Figure 29: Implant Activation

## **<u>15.</u>** ASSEMBLING THE CSE IMPLANT WITH THE PERSONA TIBIAL PLATE

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

## Catalogue Number Instrumentation Image Persona Cemented Stemmed Tibial Plate Sizes FRight 42-5320-075-02 Do NOT INFACT Canturio Smart Extension (CSE) 43-5570-030-14 Implant Persona Femoral Set ScrewHex Driver 00-5987-071-00 43-5399-001-14 Impaction Sleeve

#### Table 11

#### 15.1. Preparing the Canturio Smart Extension (CSE)

To attach the CSE 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 CSE implant is a combination of a taperand a set screw.

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 CSE 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 CSE implant into the Persona Tibial Plate.





4. Align the alignment mark on the CSE implant to the alignment mark on the Persona Tibial Plate, and insert the CSE implant taper into the Persona Tibial Plate taper until fully seated (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.
- Place the Impaction Sleeve over the CSE implant and Tibial Plate assembly until the Impaction Sleeve stops on the CSE implant. Impact on the Impaction Sleeve with a two- pound mallet solidly multiple timesuntil the CSE implant is fully seated in the Persona Tibial Plate (Figure 33).

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



Figure 33

7. Once the CSE 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 CSE implant is fully seated after impacting and torquing the set screw (Figure 35).



Figure 35

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

**Technique Tip**: **DO NOT** implant CSE 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 toverify the CSE implant is still working.

### **16.** Implanting the CSE and Persona Assembly

**Table 12** lists the instrumentation used in this step.

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

Table 12

**G** 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 on the resected tibial surface. When increased fixation is desired, you can use full cementation around the CSE implant (including the PEEK nosecone) and in the tibial IM canal without affecting the performance or wireless communications of the CSE implant.

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 36).



Figure 36

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 CSE implant is still working

### **<u>17.</u>** Linking the Implant to the Patient

After the surgery is complete, use the OR PC Application and Barcode Scanner to link the patient's CSE 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.
- Ensure an Internet connection has been established and the OR App is connected to the Canary Cloud. This is indicated by the green Internet con at the top of the Laptop screen.
- 6. Click on the image of the implant in the center of the screen.
- 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.

**NOTE:** A patient may be searched for by entering characters or the first or last name within the search input field

	ZIMMER BIOMET Persona IQ		09-Jul-2024 01:02 PM Last Sync to Cloud	Cloud Interr	Base Station
Main Menu   Link Implant-Pa	atient				
Patient List					Q
Patient First Name	Patient Last Name	DOB	Implant Location	Surgery Date	e
Sample First Name	Sample Last Name	01-Jul-1970	Right Knee	25-Jul-2024	
					Main Menu

Figure 40: Choose Patient from List

10. Click in the text boxes to enter or scan the implant serial number. When finished, click "Submit" to save the information to the patient's account. **Figure 41**.

**NOTE:** A patient may display without a surgery date and implant location. When selecting this patient, input the surgery date and implant location, confirm the information is correct, then "Submit".

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



	ZIMMER BIOMET Personal IQ	09-Jul-2024 01:02 PM Last Sync to Cloud	Operati	Cloud Interne	Base Station Application
Main Menu   Link Implant-Pati	ent				
	Patient Na	me : Last Name, First Name			
	Component Detail				
	Implant Serial Number*				
	Actual Surgery Date*	09-Jul-2024			
	Implant Location*	Right Knee			
		5	\$		
	*Required Fields	Cancel Su	ubmit		

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. See Figure 42 for an example.

<b></b> canary	ZIMMER BIOMET Persona Q He resonanzed over			() Internet	Base Station Application
	Suc	cess : Implant link	ed - pending sync to cloud		
Patient List					Q
Patient First Name	Patient Last Name	DOB	Implant Location	Surgery Date	
					Main Menu

Figure 42: Implant Link and Cloud Sync Status

Canturio<sup>®</sup> Manufactured for:

Canary Medical USA LLC 2710 Loker Ave. West, Suite 350 Carlsbad, California 92010 Customer Service: 1-833-722-6279 or 1-833-7CANARY www.canarymedical.com

Canturio® Exclusively Distributed by: Zimmer, Inc. 1800 West Center St. Warsaw, Indiana 46581-0587 USA zimmerbiomet.com

All trademarks are the exclusive property of Canary Medical and its affiliates except where otherwise indicated.

Persona, The Personalized Knee, Persona IQ, and The Smart Knee are registered trademarks of Zimmer, Inc. All other trademarks are the property of respective owners.

This material is intended for health care professionals. Distribution to anyother recipient is prohibited.

©2024 Canary Medical Inc. All Rights Reserved.

Persona<sup>®</sup> Knee Legal Manufacturer: Zimmer, Inc. 1800 West Center St. Warsaw, Indiana 46581-0587 USA zimmerbiomet.com

K05-STB-300005, Rev. A