

# ROSA<sup>®</sup> Partial Knee

User Manual V1.2



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# 1. General Information

## 1.1 Conventions

This document employs the following conventions:

-  **WARNING:** This symbol is present when a warning alerts you to a potential danger to health or life.
-  **CAUTION:** This symbol is present to prevent a risk of deterioration of the equipment in case of a handling error.
-  **REMARK:** This symbol is present to provide a general observation or information related to procedures, events or practices which are recommended or essential for a successful operation.

## 1.2 ROSA Partial Knee System Description

The ROSA® Partial Knee System, for use with the ROSA Recon Platform, is used to assist surgeons in performing Partial Knee Arthroplasty (PKA) in the medial compartment with features to assist with the bone resections, as well as assessing the state of the soft tissues to facilitate implant positioning intra-operatively.



The ROSA Partial Knee System uses a Medical Device Data System (MDDS) called the Zimmer Biomet Drive Portal, which manages the creation and tracking of the surgical case. The case resides on the portal until it is uploaded to the ROSA Partial Knee System before surgeries. If the case is based on pre-operative imaging (X-ray imaging modality), patient-specific bone models of the femur and tibia are generated by the PSI (Patient Specific Instrumentation) systems (uses X-Atlas® 2D to 3D Technology). The virtual patient case resides on the portal until it is uploaded to the ROSA Partial Knee System before surgeries.

## 1.2 ROSA Partial Knee System Description (cont.)

The intra-operative workflow and surgical steps of the system follow closely to conventional PKA surgery. As such, the system mainly assists the surgeon intra-operatively in determining reference alignment axes in relation to anatomical landmarks, in planning the orthopedic implants location based on these reference alignment axes and orthopedic implant geometry, and in precisely positioning the alignment instruments relative to the planned orthopedic implant location by using a Robotic Arm and using the Zimmer Biomet Persona® Partial Knee (PPK) spacer block to perform the femoral distal cut.

-  **CAUTION:** Federal Law restricts this device to sale by or on the order of a physician.

## 1.3 Contact


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75 Queen Street, Suite 3300  
Montreal (QC)  
H3C 2N6, Canada  
+1 514 396 5422  
1 866 3D ORTHO  
zimmerbiomet.com

## 1.4 Training

This device is a surgery assistance tool. It should only be used by authorized surgeons trained in the use of the device by Zimmer Biomet or by personnel authorized by Zimmer Biomet. Previous training and surgical experience performing Persona Partial Knee procedures with associated standard instrumentation is to be ensured before using this device. This device is not a replacement for the surgeon’s expertise and experience.

## 1.5 Intended Use

The ROSA Partial Knee System, for use with the ROSA Recon platform, is intended to assist the surgeon in providing software-defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic surgery procedures. The system can also be used to assist in joint balancing techniques.

-  The device must only be used for its intended use.

## 1.6 Indications For Use

The ROSA Partial Knee System, for use with the ROSA Recon Platform, is indicated as a stereotaxic instrument system for Partial Knee Arthroplasty (PKA) surgery. It is to assist the surgeon in providing software-defined spatial boundaries for orientation and reference to identifiable anatomical structures for the accurate placement of the knee implant components.

The robotic placement is performed relative to anatomical landmarks as recorded using the system intra-operatively, and optionally based on a three-dimensional representation of the bone structures determined pre-operatively using compatible X-Ray imaging technology.

It includes a Robotic Arm, an optical sensor navigation system and accessories, application system, surgical instruments and accessories.

1.7 Targeted Population

The ROSA Partial Knee System is designed for use on skeletally mature patient population. The target population, with the addition of the below contraindications, has the same characteristics of the population aimed by the implants compatible with the ROSA Partial Knee System.

1.8 Implant Indication

The only implant compatible with the system is Persona® Partial Knee.

1.9 Contraindications

The ROSA Partial Knee System may not be suitable for use in case of:

- Hip pathology with significant bone loss (e.g. avascular necrosis of the femoral head with collapse, severe dysplasia of the femoral head or the acetabulum)
- Hip pathology severely limiting range of motion (e.g. arthrodesis, severe contractures, chronic severe dislocation)
- Active infections of the knee joint area
- Knee replacement revision surgery
- Presence of strong infrared sources or infrared reflectors in the vicinity of the trackers
- Implants that are not compatible with the system
- Contraindications for the implant as given by the implant manufacturer



1.10 Complications

Possible complications associated with the use of the ROSA Partial Knee System may include, but are not limited to the following:

- Infection
- Implant misalignment
- Unstable joint due to erroneous soft tissue balancing

1.11 Restrictions For Use

The ROSA Partial Knee System described in this User Manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible with ROSA Partial Knee System. The list of compatible instruments is listed in section 3.3.3.

-  The device must only be used after reading this User Manual and after receiving the appropriate training. Please contact Zimmer Biomet Customer Service if unsure how to use the device.
-  MR Unsafe: Keep away from Magnetic Resonance Imaging (MRI) Equipment.

1.12 Patents

Patents available online at [zimmerbiomet.com/patents](https://zimmerbiomet.com/patents)







2. About This Manual

This User Manual provides detailed information about the ROSA Partial Knee System. Further, in this document, the ROSA Partial Knee System can be referred to as “the device”. This manual is considered as the reference document for users. It is not a technical maintenance or service manual. For technical instructions about the device, please contact Zimmer Biomet Customer Service or one of its approved representatives. A troubleshooting guide is provided in Section 12- Post-operative Guide/Maintenance of this manual.






2.1 Safety: Warnings, Cautions and Remarks

The correct use of this equipment implies that the operating staff is familiar with the Instructions for Use. This manual must be carefully studied before using the device. Particular attention must be paid to the safety instructions related to people and the device.

Training, Use and Maintenance




-  Only properly trained, qualified personnel with appropriate credentials should operate the device. Users must follow safety guidelines and warnings.
-  The device must only be used for its intended use.
-  Do not open the device. In case of any issue or breakdown, do not intervene. Maintenance and service operations must only be carried out by Zimmer Biomet Customer Service or any of its approved representatives. Do not modify the device.
-  Never attempt to clean the device when it is connected to a power supply. To avoid electrical discharges, always unplug the device from the wall outlet before cleaning or disinfecting it.
-  A knee positioner and thigh bump are recommended to be used with the ROSA Partial Knee System, otherwise accuracy may be impacted.
-  When used in compliance with the indications for maintenance, the device can be run in permanent operation.

Electrical Safety

-  In order to avoid any risk of electric shock, the device must only be connected to an electric power network equipped with grounding. The device is Class I, type BF.
-  Do not simultaneously touch the patient and any component of the device other than those attached to the electrical isolation interface part.
-  When using the robotic surgical instruments of the ROSA Partial Knee System in combination with other medical electrical (ME) equipment the patient leakage currents from multiple devices could create an additive effect.
-  IPX0 Protection: The device does not have any special protection against the penetration of liquids. Do not pour any liquid over the device.
-  Do not exceed the recommended input voltage for the device. Plugging the device to a higher voltage supply could damage the device.










2.1 Safety: Warnings, Cautions and Remarks (cont.)





-  In order to prevent accidental detachment of connectors, ensure the metallic ring is attached to the Robotic Unit's hook, if applicable.
-  Verify the metallic ring of the Optical Unit Cable is attached to the hook on the Rear Panel of the Robotic Unit to ensure electromagnetic compatibility (EMC) protection, if applicable.
-  Do not connect any elements to the Robotic Unit other than those provided with the device.

Radiation Safety




Risks generated by laser beam exposure: the device uses a laser that is integrated into the Navigation Camera.

-  This laser is of Class II (power inferior to 1 mW, eye protection by the palpebral reflex). Do not orient the laser beam toward the eyes or to any light-reflecting surfaces, such as mirrors, to avoid any direct or indirect exposure to laser beam.
-  Do not orient the laser towards the patient's eyes, the user's eyes or anyone else's eyes.
-  MR unsafe: Keep the device away from Magnetic Resonance Imaging (MRI) Equipment.
-  The device requires specific precautions regarding the EMC. It must be set up and initiated according to the EMC information provided in this User Manual.
-  Portable and mobile radio frequency communication devices might affect the operation of the device.
-  Usage of accessories, transducers and cables other than those specified in the User Manual, with the exception of the transducers and cables sold by Zimmer Biomet (as spare parts of internal components), might cause increased emissions or decreased immunity of the device.
-  The device must not be used adjacent to or stacked on top of any other equipment. If necessary, verify its correct operation in the corresponding configuration.







Risks Related to Transport and Immobilization

-  Ensure that the Robotic Unit is not moving once the immobilization system is locked.
-  Risk of pinching: Do not place fingers or feet under the stabilization feet before immobilization of the system.
-  Verify the position of the device and its environment when using the Robotic Unit immobilization system.
-  During transportation, the device can be immobilized by activating the Immobilization Pedal. Do not install the device on an inclined surface, unless stability is guaranteed.













Mechanical Safety

-  Ensure that the Foot Pedal is operating correctly before beginning a procedure. Visually inspect the device and perform a test for interruption/resumption of a Robotic Arm movement.
-  Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.
-  Risk of arm dropping-off: Do not lean on the Robotic Arm.

2.1 Safety: Warnings, Cautions and Remarks (cont.)



-  Risk of pinching: Do not place fingers in accessible parts of the plastic covers of the Robotic Arm.
-  Risk of tracking interruption: Avoid passing obstacles between the camera and the patient references or the Robotic Unit reference.
-  Risk of Navigation Camera motion: Do not lean on the camera support arm.
-  Verify the proper fixation of the Navigation Camera on the Optical Unit.
-  The operating table must not be moved once an instrument guided by the Robotic Unit is connected to the patient anatomy.
-  Test the Tracking mode before any instrument guided by the Robotic Unit is connected to the patient anatomy.

Instruments


-  Before every surgery, the user must verify that all instruments have been sterilized.
-  Verify the integrity of all the instruments prior to each surgery. Visually inspect the instruments for damage.
-  Verify the proper fixation of the NavitrackER® devices on each instrument (ROSA Base & Arm Reference Frame, ROSA Registration Pointer, Tibial & Femoral Reference Frames, ROSA PKA Validation Tool). Always use the NavitrackER Pliers for installation.
-  Verify the proper fixation of the percutaneous pins in the patient's bone anatomy (femur and tibia).
-  Verify the proper fixation of the patient references on the pins (femur and tibia). The femur and tibia references are secured on the pins, close to the patient's skin (without compression), using two hexagonal screws.
-  Bone references MUST be firmly attached to the bone and MUST NOT move at any point during surgery. If a bone reference has moved, the landmarks digitized on that bone must be digitized again.
-  Always verify the proper installation of an instrument to the Robotic Unit or Robotic Arm by making sure screws are firmly tightened.
-  Handle instruments with care. Avoid dropping instruments. Damage to an instrument can have a significant effect on the accuracy of the procedure and consequently, on the post-operative surgical outcome. At the end of the procedure, instruments are placed in their tray for sterilization.
-  Do not apply excessive torque on screws when installing an instrument. Do not use power tools.
-  When configuring the ROSA Partial Knee System, ensure that all additional Medical electrical (ME) equipment integrated into the system configuration also adheres to the safety standards for F-TYPE applied parts.
-  Before every surgery, the user must verify that the ROSA Partial Knee System is compatible with all surgical instruments and other applied parts including those of other medical electrical (ME) equipment as per Section 2.1 Safety.
-  When using the ROSA Partial Knee System together with accessories, other medical electrical (ME) equipment and or non-medical Electrical equipment within the robotic surgery configuration ensure that all components are compatible and safe to use.

2.1 Safety: Warnings, Cautions and Remarks (cont.)

Contamination

-  The device must be used with sterile drapes. These drapes must be installed in accordance with the instructions detailed in this User Manual.
-  Verify the setup of the sterile drapes before beginning a surgery to ensure the asepsis of the surgical field.

Use of the Application

-  Continue pressing the Foot Pedal when pinning or drilling in Collaborative mode to enable Bone Tracking mode, otherwise accuracy may be impacted. Visual and audio notifications are provided if the Foot Pedal is released in Collaborative mode.

Specific Warning for the United States of America

-  **CAUTION:** Federal Law restricts this device to sale by or on the order of a physician.

3. Description

3.1 Overview

The ROSA Partial Knee System, with the ROSA Recon Platform, aims to assist orthopedic surgeons with bony resections and assessment of the state of soft tissues to facilitate implant positioning during a partial knee arthroplasty.

The surgeon may also use the imageless option with the ROSA Partial Knee System to achieve the same goal as an image-based case.

The device is composed of two units, one positioned on each side of the operating table:

- A Robotic Unit consisting of a compact Robotic Arm and Touchscreen
- An Optical Unit and a Touchscreen

The intra-operative workflow and surgical steps of the system closely follow those of conventional PKA surgery. As such, the system mainly intra-operatively assists the surgeon with:

- Determining reference alignment axes in relation to anatomical landmarks
- Planning the orthopedic implant location based on these reference alignment axes and orthopedic implant geometry
- Assisting in joint balancing
- Precisely positioning the Cut Guide relative to the planned orthopedic implant location by using the Robotic Arm



ROSA Partial Knee System

3.2 Operating Principle

The operating principle for a PKA procedure is described below.

3.2.1 Case Information

The case is launched with a USB drive plugged into the Robotic Unit using the case management application. The Welcome screen of the ROSA Partial Knee application confirms the patient ID, the procedure laterality and the implant. Once the user has confirmed this information, the ROSA Partial Knee application can be launched.

3.2.2 Pre-operative Planning

Image-Based Cases

The patient’s knee, reconstructed in 3D using pre-operative X-rays, can be used to display a 3D bone model in some panels of the user interface. Images of the knee joint are taken pre-operatively and a reconstruction application is used to generate a 3D model of the patient’s bones.

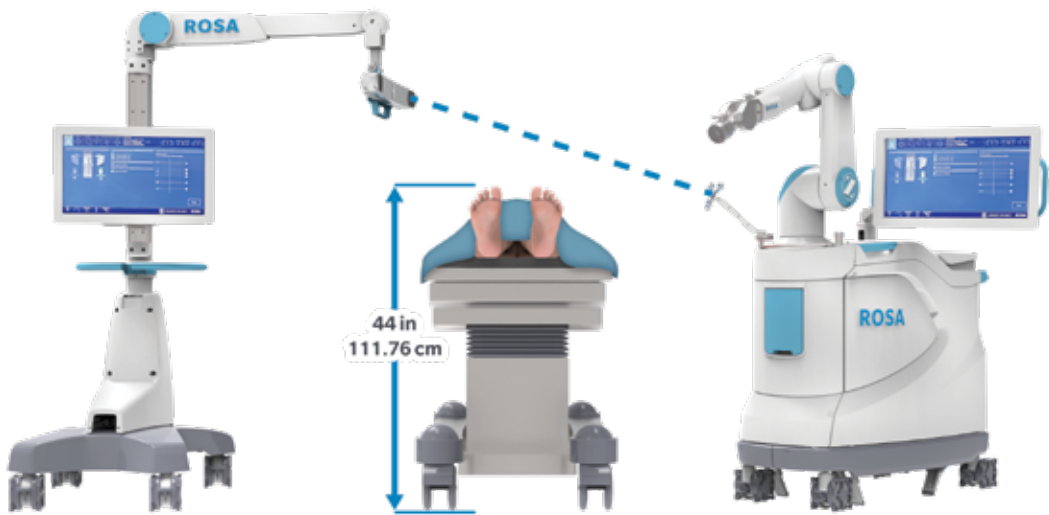
! If the registration of the landmarks taken intra-operatively and the patient knee 3D bone model is unsuccessful, the user will have the possibility to retake the landmarks or switch to an imageless case.

Imageless Cases

The ROSA Partial Knee System can be used without pre-operative X-rays. In this case, generic bone schematics will be displayed on the user interface. A case on the Portal needs to be created to be able to download the case intra-operatively.

3.2.3 OR Setup

The patient is placed on the OR table in supine position. The Robotic Unit is positioned approximately at the patient’s hip and approximately 45° relative to the surgery table. Two patient bone references are installed on the patient’s leg, one on the femur and one on the tibia, as a reference for leg movements. A third reference is placed on the Robotic Unit (on a surgical drape using the ROSA Base Reference Bar post closest to the surgical table), to track where the Robotic Unit is relative to the patient’s leg during the surgery.



Maximum height of patient to minimize tracker visibility problems

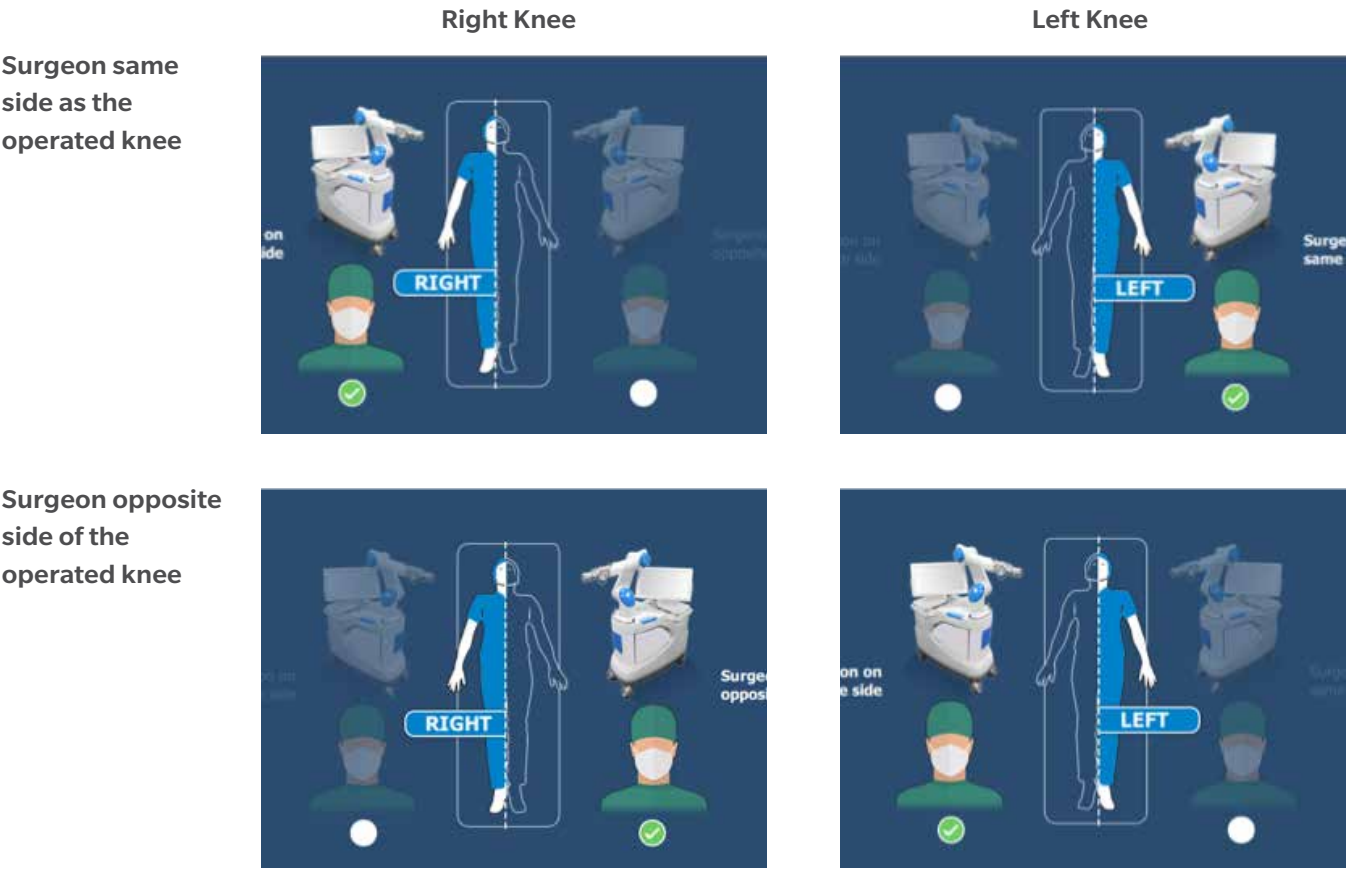
! During the surgery, the surgeon must always stay on the same side as the Robotic Unit.

3.2 Operating Principle (cont.)

! The maximum height of the patient on the OR table should be 44 inches to minimize tracker visibility problems. In case of a patient with a high BMI, lower the table to avoid visibility problems.

There are four possible OR setups:

- Operating on a right knee, with the surgeon on the same side as the operated knee
- Operating on a right knee, with the surgeon on the opposite side of the operated knee
- Operating on a left knee, with the surgeon on the same side as the operated knee
- Operating on a left knee, with the surgeon on the opposite side of the operated knee




Possible OR Setups

3.2.4 Robotic Unit Registration

A registration of the Robotic Unit is performed with a fourth reference mounted on the Robotic Arm prior to the start of the surgery. This ensures the functional verification of the Robotic Arm prior to the start of the surgery. The patient should be on the OR table for this step.



3.2 Operating Principle (cont.)

 Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.

3.2.5 Bony Landmarks & Navigation

Using a Registration Pointer, the surgeon will digitize the bony landmarks to record the patient’s leg coordinate system. Throughout the surgery, real-time tracking of patient movement is provided by the Optical Tracking System.


3.2.6 Planning

The surgeon can only set the surgical plan intra-operatively.

 No pre-operative plan is available.

3.2.7 Surgery

Based on the intra-operative planning values, the Robotic Arm will move to reach the appropriate positions to execute the bone resections.

 Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.

If the LAXITY ASSESSMENT feature (optional) is selected, the ROSA Partial Knee System provides clinical information to assist the surgeon in assessing the soft tissue condition of the knee after the tibia sagittal and proximal cuts.

3.3 System Description

3.3.1 Robotic Unit

The Robotic Unit is composed of the following main components:

- Robotic Arm
- Touchscreen for operating the device
- Immobilization System
- Foot Pedal
- Computer and Software

The Robotic Unit is equipped with swivel wheels and handles allowing the device to be easily moved between operating rooms by a single person. The wheels are equipped with foot pressure brakes to lock the unit in place and with cable pushers to avoid rolling on cables.

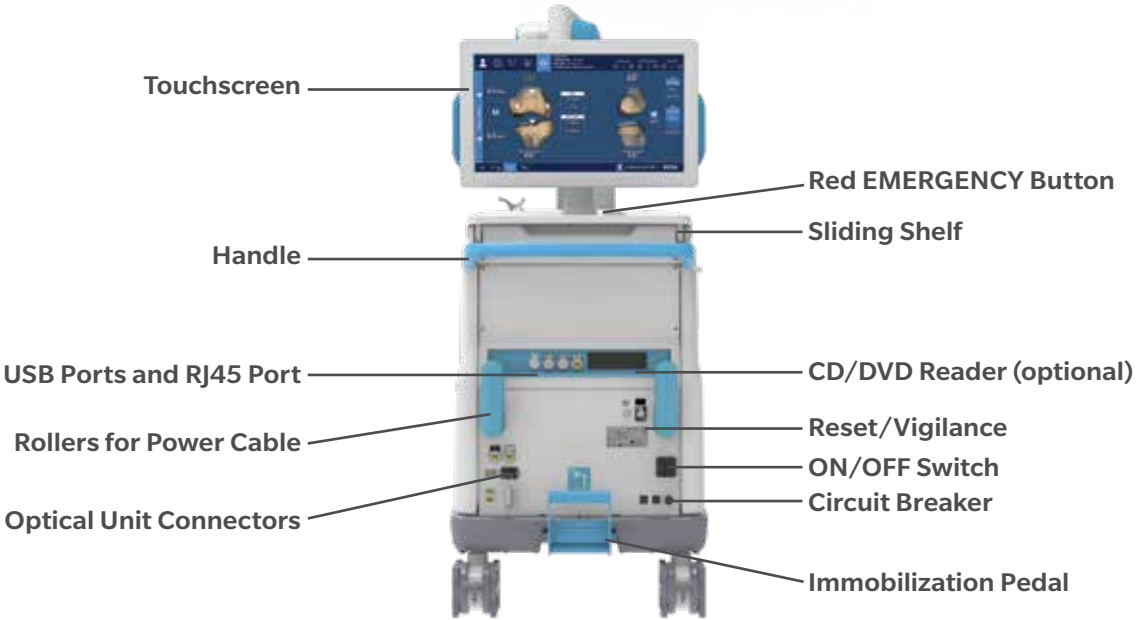
It has optional lateral openings and a sliding shelf providing storage for various items. A fixed bar (ROSA Base Reference Bar) on the front side of the Robotic Unit is used to install the ROSA Base Reference Frame.

The Robotic Unit is powered by the operating room power supply by plugging the Power Cable from the Rear Panel to an outlet compatible with the device characteristics.

The Foot Pedal is linked to the Robotic Unit by plugging the cable to the dedicated connector on the Rear Panel.

The Robotic Unit Power Cable and Foot Pedal cable can be rolled around rollers on the Rear Panel. The Foot Pedal may also be stored in the storage area.

3.3.1 Robotic Unit (cont.)



Rear Panel of the ROSA Robotic Unit



3.3.1 Robotic Unit (cont.)

The Rear Panel includes:

- Main ON/OFF switch to turn the device on and off
- RESET button to restart the computer
- CIRCUIT BREAKER button to restart the device after it has been turned off due to an overvoltage
- Connectors to plug in the Optical Unit and Foot Pedal
- USB ports to import cases
- CD/DVD reader (unplugged and non-functional)
- One USB port in the storage area beneath the sliding shelf to connect a mouse
- RJ45 port to connect the system to an intra-operative imaging system (deactivated)
- Controller servicing port (deactivated)
- Laser button (deactivated)

- ⚠ Do not connect any elements to the Robotic Unit other than those provided with the device.
- ⚠ In order to prevent accidental detachment of connectors, ensure that the metallic ring is attached to the Robotic Unit’s hook, if applicable.
- ⚠ Make sure the metallic ring of the Optical Unit cable is attached to the hook on the Rear Panel of the Robotic Unit in order to ensure EMC protection, if applicable.

3.3.1.1 Robotic Arm

The Robotic Arm is equipped with a Force Sensor that allows the surgeon to manually move the Robotic Unit to the desired location by measurement of forces exerted at the end of the arm and a compensation principle, regardless of the instrument used.



3.3.1.2 Touchscreen

The device includes two Touchscreens that display the user interface: one on the Robotic Unit and one on the Optical Unit.



3.3.1.3 Immobilization System

The Robotic Unit is equipped with a system immobilizing it to the ground. This system is composed of four stabilization feet, activated by a pedal. Two positions are available: the unit is immobilized when the pedal is down, the unit is mobile when the pedal is up. Additionally, each wheel of the Robotic Unit can be locked individually.



Immobilized: Pedal in Down Position



Mobile: Pedal in Up Position

- ⚠ Risk of pinching: Do not place fingers or feet under the stabilization feet before immobilizing the system.
- ⚠ Verify the position of the device and its environment when using the Robotic Unit immobilization system. Make sure cables or wires are cleared from the area of the stabilization feet to prevent damage.

3.3.1.4 Foot Pedal

The device is equipped with a Foot Pedal for monitoring the Robotic Arm movements. The Robotic Arm will only move if the user presses the Foot Pedal. This operating principle applies to the SETUP and RESECTIONS panels. The Robotic Arm movement is interrupted as soon as the user releases the Foot Pedal.



New



Original

Foot Pedal


- ⚠ Ensure that the Foot Pedal is operating correctly before beginning a procedure. Visually inspect the device and perform a test for interruption/resumption of a Robotic Arm movement.


3.3.2 Optical Unit

The Optical Unit is composed of:

- Optical Camera
- Camera Positioning Arm
- Touchscreen

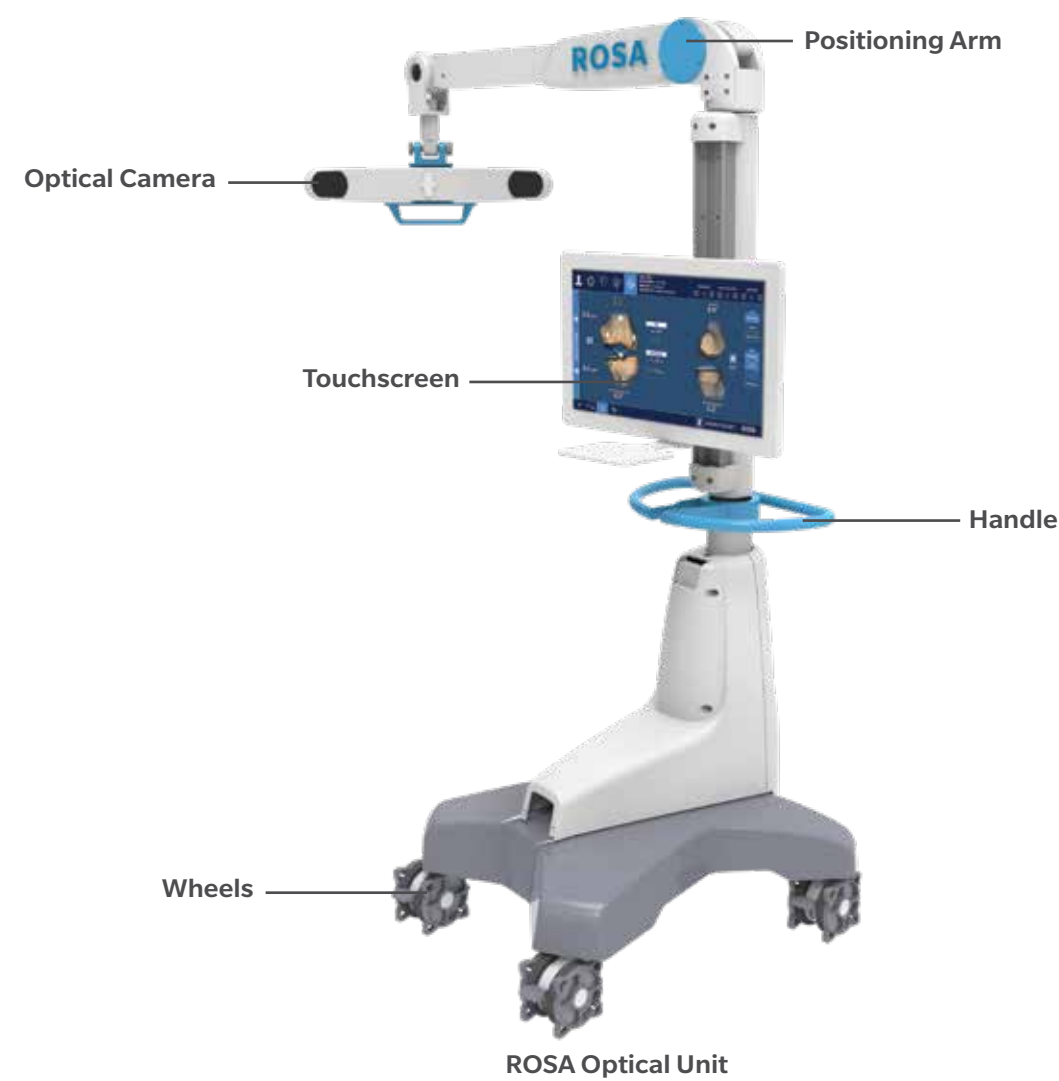
Risks generated by laser beam exposure: the device uses a laser integrated into the Optical Camera.

- 

This laser is Class II (power inferior to 1 mW, eye protection by the palpebral reflex). Do not orient the laser beam to the eyes or to any light-reflecting surfaces (such as mirrors) to avoid any direct or indirect exposure to laser beam.
- 

Do not orient the laser toward the patient’s eyes, the user’s eyes or anyone else’s eyes.

The Optical Unit is powered by the Robotic Unit by plugging the cable into the connector on the Robotic Unit’s Rear Panel. A roller is included to properly store the Optical Unit Cable. The Optical Unit is equipped with swivel wheels and a handle allowing the device to be easily moved between operating rooms by a single person. Each wheel has a brake and a cable pusher system. A laser is integrated into the camera to facilitate the camera positioning and orientation adjustments during the device installation in the operating room.



3.3.3 Instrumentation

All reusable instruments need to be sterilized before each use.

ROSA Knee General Instruments

Component Name	Part Number
3.5 mm HEX Screwdriver	00-5120-087-00
2 Pins Reference Femur TS3	20-8000-010-33
ROSA TTibia Reference A	20-8020-028-00
ROSA Tibia Reference B	20-8020-029-00
Offset 2 Pins Reference Right Tibia Size 6	20-8000-010-35
Offset 2 Pins Reference Left Tibia Size 6	20-8000-010-36
CAS Navitracker Pliers	20-8000-070-05
ROSA Base Reference Frame	20-8020-002-00
ROSA Arm Instrument Interface	20-8020-004-00
ROSA Registration Pointer	20-8020-013-00
ROSA Arm Reference Frame	20-8020-015-00

ROSA Partial Knee Instruments

Component Name	Part Number
ROSA PKA VALIDATION TOOL	20-8020-034-00
ROSA Persona Partial Knee Medial Cut Guide A-L (Left)	20-8020-030-00
ROSA Persona Partial Knee Medial Cut Guide A-R (Right)	20-8020-031-00
ROSA Persona Partial Knee Medial Cut Guide B-L (Left)	20-8020-032-00
ROSA Persona Partial Knee Medial Cut Guide B-R (Right)	20-8020-033-00

Persona Partial Knee Specific Instruments

The Persona Partial Knee specific instruments are compatible with the ROSA Knee General Instruments and the ROSA Partial Knee Instruments and are required to perform the ROSA Partial Knee v1.2 procedure.


Component Name	Part Number
Persona Partial Knee Spacer Block (8 mm)	Refer to 1222.6-GLBL-en Persona Partial Surgical Technique for more information
Persona Partial Knee Spacer Block (9 mm)	
Persona Partial Knee Spacer Block (10 mm)	
Persona Partial Knee Spacer Block (12 mm)	
Persona Partial Knee Spacer Block (14 mm)	
Persona Partial Knee Flexion/Extension Gap Checker (8 mm)	
Persona Partial Knee Flexion/Extension Gap Checker (9 mm)	
Persona Partial Knee Flexion/Extension Gap Checker (10 mm)	
Persona Partial Knee Flexion/Extension Gap Checker (12 mm)	
Persona Partial Knee Flexion/Extension Gap Checker (14 mm)	

3.3.3 Instrumentation (cont.)

Disposables

Disposable Name for Bone References Installation	Part Number
Fix Fluted Pin 3.2x150 mm (non-sterile)	20-8000-000-01
Fix Fluted Pin 3.2x80 mm (non-sterile)	20-8000-000-02
Fix Fluted Pin 3.2x150 mm	20-8000-000-10
Fix Fluted Pin 3.2x80 mm	20-8000-000-11
Disposable Name for Pinning Cut Guides	Part Number
Trocar Tipped Drill Pin (2.5 mm hex) 3.2x75 mm (Persona)	00-5901-020-00
CAS 3.2 mm Headless Trocar Drill Pin	20-8000-000-16
Other Disposables	Part Number
Navitracker Kit A: Knee	20-8000-000-07
ROSA Robotic Unit Drape	20-8020-080-00
ROSA Arm Drape	ROSAS00055
Monitor Drape	ROSAS00056
MIS Headed Screw, 48 mm	00-5983-040-48
Disposable Name for Saw Blades	Part Number
Zimmer Oscillating Saw Blade 1.27 mm	13090127AF1*
Zimmer Reciprocating Saw Blade 1.19 mm	12090119UR1*


\* If necessary, other hub styles are available

 Handle instruments with care. Avoid dropping instruments. Damage to an instrument can have a significant effect on the accuracy of the procedure and consequently, on the post-operative surgical outcome. At the end of the procedure, instruments are placed in their tray for sterilization.

3.3.3.1 ROSA Arm Instrument Interface

The ROSA Arm Instrument Interface is attached to the Robotic Arm in sterile conditions using three captive screws. It enables maintaining sterile conditions when changing tools. This part must be sterilized before each use.



 To avoid touching the non-sterile part of the Robotic Unit and to preserve sterility, always use the handles to hold the ROSA Arm Instrument Interface in place during installation.

3.3.3.2 ROSA Arm Reference Frame


The ROSA Arm Reference Frame is attached to the Robotic Arm Interface with two captive screws. It is used during the Robotic Unit registration prior to the start of the surgery. This part must be sterilized before each use.



3.3.3.3 ROSA Base Reference Frame

The ROSA Base Reference Frame is installed to the Robotic Unit over the ROSA Base Reference Bar, which is covered by a surgical drape using the post closest to the surgical table. It is a reference to follow the relative motions between the Robotic Unit and the Optical Camera. This part must be sterilized before each use.



 If the ROSA Base Reference Frame moves at any time during the procedure, the registration of the Robotic Arm has to be performed again (SETUP panel).


3.3.3.4 ROSA Persona Partial Knee Medical Cut Guides

The ROSA Persona Partial Knee Medial Cut Guide is attached on the ROSA Arm Instrument Interface with two captive screws. There are four Cut Guides:

Configuration	Description	Picture
AL	A: Robotic Unit and surgeon are on the left of the patient L: Left operated leg	
AR	A: Robotic Unit and surgeon are on the left of the patient R: Right operated leg	
BL	B: Robotic Unit and surgeon are on the right of the patient L: Left operated leg	
BR	B: Robotic Unit and surgeon are on the right of the patient R: Right operated leg	

3.3.3.5 ROSA Registration Pointer

The ROSA Registration Pointer enables the digitizing of anatomical landmarks on which final results and accuracy depend. This instrument must be sterilized before each use.

 Care must be taken not to pierce through the cartilage with the tip of the ROSA Registration Pointer.





3.3.3.6 ROSA PKA Validation Tool

The ROSA PKA Validation Tool is used to validate the tibial horizontal, tibial sagittal and femoral distal resections. This instrument must be sterilized before each use.

- ⚠ Verify that the NavitrackER device is correctly installed on the ROSA PKA Validation Tool.
- ⚠ When using the ROSA PKA Validation Tool, ensure resected surfaces are free from bone or tissue fragments and that the corner of the tibia resection is adequately prepared.



3.3.3.7 Patient References

3.3.3.7.1 ROSA Femur Reference

The Femoral Reference Frame on the patient’s femur is used as a reference for monitoring the patient’s motions. It is fixed using percutaneous pins through the vastus medialis in the femur, as proximal as possible, to stay clear of the working area. The pins should be set bicortically in the bone to ensure maximum stability. This part must be sterilized before each use.



Rosa Femur Reference

3.3.3.7.2 ROSA Tibia Reference A/B P/N: 20-8020-028-00/20-8020-029-00

The Tibial Reference Frame on the patient’s tibia is used as a reference for monitoring the patient’s motions. It is fixed using percutaneous pins normal to the medial surface of the tibial diaphysis at approximately four fingers distal to the knee incision. The pins should be set bicortically in the bone to ensure maximum stability. This part must be sterilized before each use.



Tibial Reference B






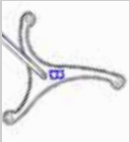


Tibial Reference A

- There is an A and B Tibial Reference Frame. OR setup is dependent on the operative knee and surgeon position.
- A: When the Robotic Unit and the surgeon are on the left side of the patient regardless of the operated knee
  - B: When the Robotic Unit and the surgeon are on the right side of the patient regardless of the operated knee

Insert pins through the pin holes markings L and R. For right legs, use the pin holes labeled R, for left legs use the pin holes labeled L. Use the proper set screws corresponding to the pinholes through which the pins have been inserted to tighten the reference on pins.

3.3.3.7.2 ROSA Tibia Reference A/B P/N: 20-8020-028-00/20-8020-029-00

Utilize the chart below to determine in which marking to insert the pins.

	Right Leg Operated	Left Leg Operated
Tibial Reference A 	Pins through R marking 	Pins through L marking 
Tibial Reference B 	Pins through R marking 	Pins through L marking 

3.3.3.7.3 Offset 2 Pins Reference Tibia P/N: 20-8000-010-35/20-8000-010-36

The Tibial Reference Frame on the patient’s tibia is used as a reference for monitoring the patient’s motions. It is fixed using percutaneous pins into the medial surface of the tibial diaphysis at approximately mid-tibia. The pins should be set bicortically in the bone to ensure maximum stability. This part must be sterilized before each use.



Tibial Reference Frame RT  
Offset 2 pins reference Right Tibia Size 6



Tibial Reference Frame LT  
Offset 2 pins reference Left Tibia Size 6

There is a RIGHT and a LEFT Tibial Reference Frame. OR setup is dependent on the operative knee and surgeon position. Utilize the chart below to determine which Tibial Reference Frame is necessary.

Side of Tibial Reference Frame to Use

	Right Knee Operated	Left Knee Operated
Surgeon Same Side as Operated Knee	RIGHT Frame	LEFT Frame
Surgeon Opposite Side as Operated Knee	LEFT Frame	RIGHT Frame

3.3.3.7.4 : Warnings Associated with Bone References Installation

- ⚠ Before every surgery, the user must verify that all instruments have been sterilized.
- ⚠ Verify the integrity of all the instruments prior to each surgery. Visually inspect the instruments for damages such as cracks, burrs, sharp edges, deformation or a loose weld.
- ⚠ Make sure that the percutaneous pins are not positioned close to the bone resection area. Placing the percutaneous pins close to the bone resection area will increase the risk of breaking the pins with the cutting tools.

3.3.3.7.4 : Warnings Associated with Bone References Installation (cont.)

- ⚠ Verify the proper fixation of the percutaneous pins in the patient’s bone anatomy (femur and tibia).
- ⚠ Verify the proper fixation of the patient references onto the pins (femur and tibia). The femur and tibia references are secured on the pins, close to the patient’s skin (without compression), using two hexagonal screws.
- ⚠ Bone references MUST be firmly attached to the bone and MUST NOT move at any moment during surgery. If a bone reference has moved, the landmarks digitized on that bone must be digitized again.
- ⚠ Be alert to the risk of causing damage to the saphenous artery and vein, femoral artery and vein or the popliteal artery and vein while installing the femoral patient reference.
- ⚠ Ensure the pins are not placed in an area of interference with the implant keel and/or pegs. Impact with the keel and/or pegs or its broaching instruments can cause breakage of the pins as well as movement of the tibial reference, which could result in inaccuracies.
- ⚠ Beware that muscle fibers may apply bending forces on the pins.

3.4 Instrument Assembly

The following instructions explain how to assemble the different instruments.

- ⚠ Always verify the proper installation of an instrument to the Robotic Unit or Robotic Arm by making sure screws are firmly tightened.

3.4.1 ROSA Arm Instrument Interface on the Robotic Arm

1. Align the groove on the back of the ROSA Arm Instrument Interface (laser marked arrow on the side) with the peg of the electric insulator of the Robotic Arm (black dashed line).
2. Assemble instruments together until the base of the ROSA Arm Instrument Interface is completely seated.
3. Secure the ROSA Arm Instrument Interface by firmly tightening the three captive screws using a hexagonal screwdriver.



- ⚠ To avoid touching the non-sterile part of the Robotic Unit and to preserve sterility, always use the handles to hold the ROSA Arm Instrument Interface in place during installation.

3.4.1 ROSA Arm Instrument Interface on the Robotic Arm (cont.)

- ⚠ Do not apply excessive torque on screws when installing the ROSA Arm Instrument Interface. Do not use power tools.
- ⚠ Be careful with the alignment of screws in their thread.

3.4.2 ROSA Arm Reference Frame on the Robotic Arm

1. Align the groove of the ROSA Arm Reference Frame with the peg of the ROSA Arm Instrument Interface (black dashed line).
2. Assemble instruments together until the base of the ROSA Arm Reference Frame is completely seated.



3. Secure the ROSA Arm Reference Frame by firmly tightening the two captive screws by hand.

- ⚠ Do not apply excessive torque on the thumb screws when installing an instrument.

3.4.3 ROSA Base Reference Frame on the Robotic Unit

1. Open the clamp of the ROSA Base Reference Frame and align it on the post closest to the surgical table.
2. Assemble instruments together until the ROSA Base Reference Frame is completely seated vertically.
3. Close the clamp and bring the hand screw over the clamp.
4. Secure the ROSA Base Reference Frame by firmly tightening the screw by hand. Instructions apply for both short and long ROSA Base Reference Frames.



3.4.4 ROSA Persona Partial Knee Medial Cut Guide on the Robotic Arm

- 1. Align the groove of the ROSA Persona Partial Knee Medial Cut Guide with the peg of the ROSA Arm Instrument Interface (black dashed line).
- 2. Assemble instruments together until the base of the ROSA Persona Partial Knee Medial Cut Guide is completely seated.
- 3. Secure ROSA Persona Partial Knee Medial Cut Guide by firmly tightening the two captive screws by hand.

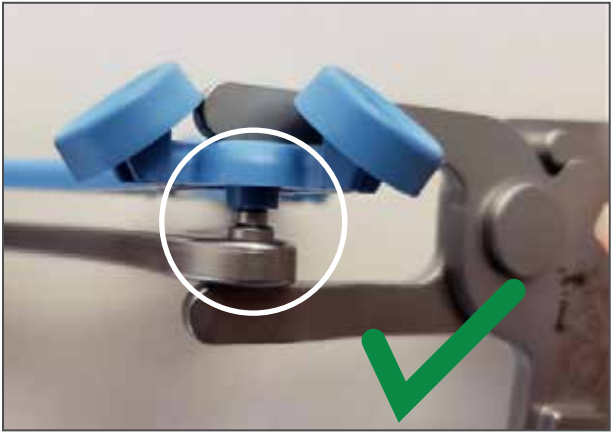
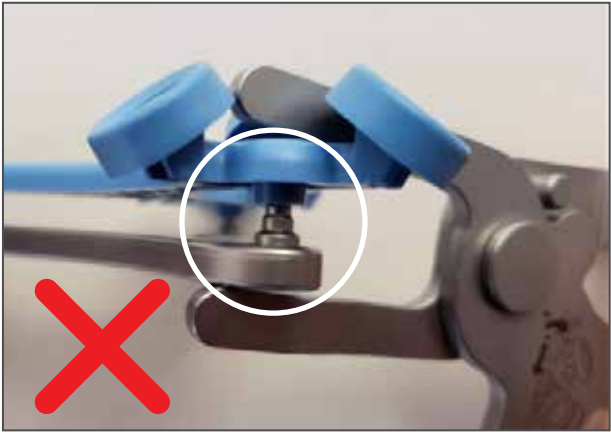


⚠ Do not apply excessive torque on thumb screws when installing an instrument.

3.5 Disposables

3.5.1 Reflective Trackers (NavitrackER) Installation

The NavitrackER devices must be installed on each instrument used for optical tracking.  
To facilitate the installation of the trackers on the instruments, push the marker on each mounting stud using the NavitrackER pliers until it is fully seated.



An audible click should be heard when the NavitrackER is fully seated.

It is important to verify that the NavitrackER reflective material remains clean throughout the surgery (refer to NavitrackER Instructions For Use).

- ⚠ Always use NavitrackER pliers for the installation. Ensure that reflective NavitrackER devices are fully seated.
- ⚠ Verify the proper fixation of the NavitrackER devices on each instrument (ROSA Base and Arm Reference Frame, ROSA Registration Pointer, Tibial and Femoral Reference Frame, ROSA PKA Validation Tool). Always use the NavitrackER pliers for installation.
- ⚠ Always minimize handling of the NavitrackER devices and avoid contact with optical reflective material, since errors may result from the non-uniform reflection of their surface.

3.5.1 Reflective Trackers (NavitrackER) Installation (cont.)

- ⚠ Always use unblemished optical reflective material on NavitrackER.
- ⚠ Each NavitrackER device is single-use and should not be re-sterilized to be reused in surgery.
- ⚠ The use of Optical Trackers other than those provided by Zimmer Cas may lead to loss of accuracy.



3.5.2 Pins

Fix fluted pins (sterile and non-sterile) can be used to fix the bone references. The diameter is 3.2 mm and has a length of 80 mm or 150 mm. Refer to section 3.3.3. for pins for the Cut Guides.

- ⚠ Pins are single-use hardware and should not be re-sterilized to be reused in surgery.

3.5.3 Screws

MIS Headed Screw is to be used to fix the spacer block in preparation for femoral distal resection. Screw has a length of 48 mm (refer to section 3.3.3.).

- ⚠ Screws are single-use hardware and should not be re-sterilized to be reused in surgery.

3.5.4 Drapes












Drapes for the Robotic Arm, Robotic Unit and Touchscreens are required prior to starting the surgery.

- ⚠ Never use a damaged drape (Robotic Arm or base). In case of a tear or in doubt that the sterility is compromised, discard the drape and use a new one.
- ⚠ Never use damaged tape for taping the ROSA Arm Drape to the ROSA Arm Instrument Interface at the end of the Robotic Arm.



## 4. Installation






### 4.1 Warnings and Cautions About Robotic Unit Installation

-  Ensure that the Robotic Unit is not moving once the immobilization system is locked.
-  Risks of pinching:
  - Do not place fingers in accessible parts of the plastic covers of the Robotic Arm
  - Do not place fingers or feet under the stabilization feet before immobilization of the system
-  In order to avoid any risk of electric shock, the device must only be connected to an electric power network equipped with grounding. Device is Class I, type BF.
-  Do not simultaneously touch the patient and any component of the device other than those attached to the electrical isolation interface part.
-  Ensure that the Foot Pedal is operating correctly before beginning a procedure. Visually inspect the device and perform a test for interruption/resumption of a Robotic Arm movement.
-  The operating table must not be moved once an instrument guided by the Robotic Unit is inserted into the patient anatomy.
-  Risks generated by laser beam exposure: the device uses a laser integrated into the Optical Camera. This laser is Class II (power inferior to 1 mW, eye protection by the palpebral reflex). Do not orient the laser beam to the eyes or to any light-reflecting surfaces, such as mirrors, to avoid any direct or indirect exposure to laser beam.
-  Verify the position of the device and its environment when using the Robotic Unit immobilization system.
-  During transportation, the device can be immobilized by activating the immobilization pedal. Do not install the device on an inclined surface, unless its stability is guaranteed.
-  IPX0 Protection: Device without special protection against the penetration of liquids. Do not pour any liquids over the device.
-  Do not connect any elements to the Robotic Unit other than those provided with the device.

### 4.2 Device Start Up

Switching the device ON:

1. Place the Robotic Unit on one side of the operating table and the Optical Unit on the opposite side. Plug the Optical Unit into the Robotic Unit.
  - For Configuration 1 Only: Plug the white and black cables into the corresponding white and black ports
  - For Configuration 2 Only: Plug the USB, Ethernet, Jack and VGA cables into the corresponding ports
  - For Configuration 3 Only: Plug the single connector into its socket and secure the connection
2. Plug the Power Supply Cable into a power source of appropriate voltage.
3. For Configuration 1 and 2 Only: Attach the metallic ring of the Optical Unit cable to the hook on the Robotic Unit Rear Panel. Lock the connector in place using the metallic clip.
4. Switch the robot ON.
  - Allow the camera to warm up for few minutes

-  In order to prevent accidental detachment of connectors, ensure the metallic ring is attached to the Robotic Unit's hook and lock the connector in place using the metallic clip, if applicable.
-  Make sure the metallic ring of the Optical Unit cable is attached to the hook on the Rear Panel of the Robotic Unit in order to ensure EMC protection, if applicable.
-  If the screen remains black at start up: Check that the Touchscreen is powered ON (button on the right side of the screen) and/or restart the computer by pushing the button located on the Rear Panel of the device.
-  To restart the device, wait at least 10 seconds after shutting down and for the RESTART button light to turn off before powering back on.
-  The device may take up to three minutes after being switched ON for the application to communicate with the Robotic Arm.

### 4.3 Camera Errors

#### 4.3.1 Camera Temperature is Too Low/High

When launching the application, if the camera temperature is out of range, a notification will be displayed.

1. Wait for the camera to adjust to room temperature.
2. Click RESUME to continue.

#### 4.3.2 Camera was Bumped

When launching the application, if the camera was bumped during storage or transportation, a notification will be displayed.

1. Revert to standard instrumentation (section 4.5).
2. Please contact Customer Service.



4.4 Emergency Procedure

In case of device failure or an emergency requiring a fast removal of the device to access the patient, it is recommended to follow one of the procedures described below.

The user may choose to move the device away from the operating table partially or completely, depending on the procedure that is needed to cope with the device failure or emergency.

Partial Removal–Moving the Robotic Arm Away


- 1. Remove any instruments that are linking the patient to the Robotic Unit.
- 2. Send the Robotic Arm to the ROSA HOME position to free space around the patient’s knee.

This procedure can be performed by one sterile operator.

Full Removal–Moving the Robotic Unit Away

- 1. Remove any instruments that are linking the patient to the Robotic Unit.
- 2. Deactivate the Robotic Unit immobilization system (one main pedal and brake of the four wheels).
- 3. Move the Robotic Unit away to free up space around the patient.
- 4. If necessary, remove the patient’s bone references (femur and tibia).
- 5. After a full removal of the Robotic Unit, revert to standard instrumentation.

This procedure requires one sterile operator and one non-sterile operator.

 In case of a full removal of the Robotic Unit, if bone references were removed or if there was a problem with ROSA instrumentation that could lead to inaccuracy, the surgeon must revert back to standard instrumentation.

4.5 Reverting to Standard Instrumentation

A full set of the implant system’s standard instrumentation is needed to perform surgery in conjunction with the ROSA Partial Knee System in case the ROSA Partial Knee System cannot be used. It is mandatory to revert to standard instrumentation in case of:

- Full removal of the Robotic Unit
- Problem with the ROSA instrumentation that could lead to inaccuracy

For any other problem encountered at any time during the surgical flow, it is always possible to revert to standard instrumentation.

4.6 Case Management Application

4.6.1 Case Management Application–Interface Overview

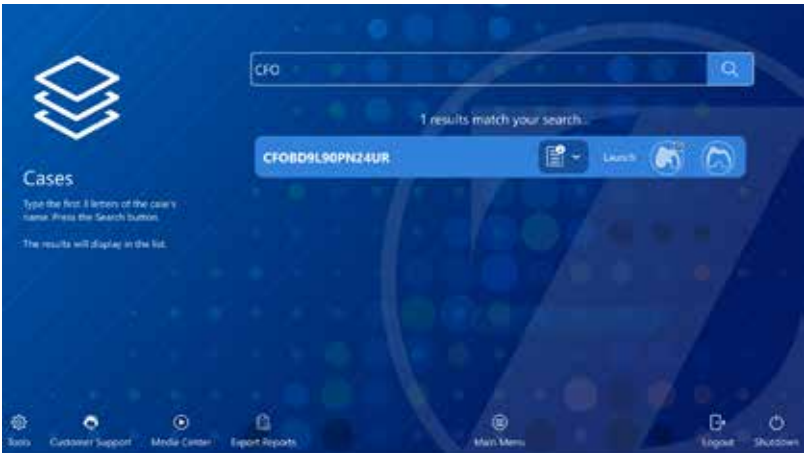


Case Management Application Functions

- SYNC: This function decrypts the case(s) from a USB drive and syncs them with the ROSA Clinical Computer
- CASES: This function lists the cases that were uploaded using the SYNC function. When selecting a case, a PIN will be required to load the case and launch the welcome screen of the ROSA Partial Knee application
- LOGOUT: This function exits the case management application and should only be used by authorized personnel to access the Maintenance mode
- SHUTDOWN: This function shuts down the system
- EXPORT REPORTS: This function encrypts and exports to USB all pending ROSA Reports

4.6.2 Starting a Case

- 1. Insert a USB drive containing the encrypted case(s) into a USB port of the Robotic Unit.
- 2. Use the SYNC function to upload the case(s) to the ROSA Clinical Computer.
- 3. Use the CASES function to search for the case to be launched (at least three letters are required to perform a search).
- 4. Select the appropriate case and click LAUNCH.
- 5. Type in the PIN for the selected case.





ROSA Partial Knee Application: Welcome Screen

5.1 Welcome Screen

Upon launching a case, the welcome screen will appear where the user can confirm the patient ID, procedure laterality and implant family. Once the user has confirmed that the information is correct, the ROSA Partial Knee application can be launched. If the information is incorrect, the user can quit and relaunch the correct case.

5.2 ROSA Partial Knee Application–User Interface Overview

The ROSA Partial Knee user interface consists of a main panel and two task bars on the top and bottom of the screen. The task bars contain features that may be accessible in more than one panel.



5.2.1 Top Task Bar

5.2.1.1 Panel Buttons

The panel buttons allow direct access to a specific panel. An icon featuring a light blue background indicates the currently active panel. Icons featuring white outlines indicate that the panel(s) are directly accessible. Greyed out icons indicate that these panels are not yet accessible. Inaccessible panels will become accessible once all necessary preceding tasks have been completed. The number and order of the displayed icons depend on preferences defined in the SURGEON panel.



Panel Buttons and RESECTIONS Drawer

Mandatory Panels	Optional Panels
SURGEON	
SETUP	
LANDMARKS	
EVALUATION	
PLANNING	
RESECTIONS Drawer: <ul style="list-style-type: none"><li>Tibial Resections</li><li>Femoral Distal Resection</li></ul>	RESECTIONS Drawer: <ul style="list-style-type: none"><li>Laxity Assessment (after tibial resection)</li></ul>

5.2.1.2 Case Information

The case information displays the following details:

- Procedure laterality
- Implant
- Patient ID

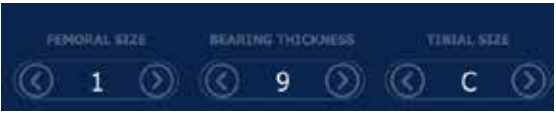
**PROCEDURE:** LEFT PKA  
**IMPLANT:** Persona PK  
**PATIENT ID:** LSB8F8L50CS18UR

Case Information

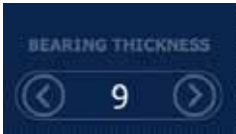


5.2.1.2 Case Information (cont.)


Implant component sizes are displayed directly on the user interface. Supported implants are listed in Appendix A.



Implant Selector - Image-based Cases



Implant Selector - Imageless Cases

 The implant related information can only be modified in the PLANNING panel and in the implant confirmation window.

5.2.2 Bottom Task Bar

5.2.2.1 Menu

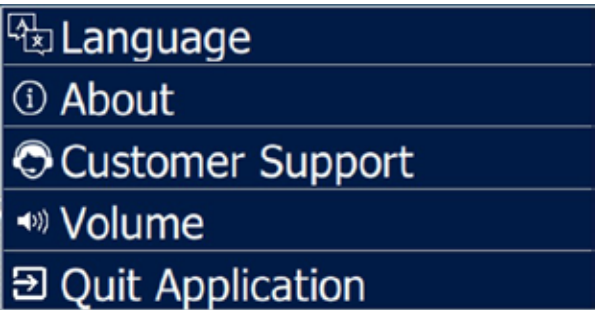
The MENU button consists of:

- Language: Change user interface language
- About: Information about the ROSA Partial Knee application
- Customer Support: Customer Service information
- Volume: Adjustment of the volume of all ROSA Partial Knee System sounds
- Quit Application:
  - With an option to send the Robotic Arm to PARK position
  - With an option to keep the Robotic Arm in the current position to switch to ROSA Total Knee application

The MENU button is accessible at all times during the procedure.



Bottom Task Bar




Menu

5.2.2.2 Camera

The CAMERA button displays the volume viewer, which shows the top view (left side) and frontal view (right side), with the trackers that are needed at this point in the flow. There is an optional button to see all trackers. The CAMERA button is accessible at all times during the procedure.



Camera Volume Viewer

 The camera can be slightly repositioned at any time in order to have the necessary NavitrackER devices visible, except during the acquisition of the femoral head center and in Bone Tracking mode. During bone resections, the camera needs to stay in a volume close to where the registration was initially performed.

5.2.2.3 Snapshot

The SNAPSHOT button allows a capture of the screen. The SNAPSHOT button is accessible at all times during the procedure. Snapshots can be downloaded along with the Surgeon Report.

5.3 Robotic Modes

Three robotic modes are programmed to dictate the behavior of the Robotic Arm during two distinct steps: registration (SETUP panel) and bone resections (RESECTIONS drawer). To trigger robotic movement, the Foot Pedal must be pressed. The interface will inform the user of the current robotic mode with a colored border around the MAIN panel.

Automatic Mode (Orange border)

- The Robotic Arm will move to a predetermined position

Collaborative Mode (Green border)

- The Robotic Arm will move if the surgeon applies a gentle force at the end of it to move it to a desired position
- The Robotic Arm will move at a slow speed when it nears the bone
- During resections, Collaborative mode is coupled with bone tracking.

If the bone moves as the surgeon is moving the Cut Guide, it will stay on plane and track the bone. This is Collaborative mode with bone tracking

Stationary Mode (Grey border)

- The Robotic Arm will not move



5.4 Robotic Positions

At various points during the ROSA Partial Knee System surgical flow, the Robotic Arm can be sent to a predetermined position:

HOME Position:

The Robotic Arm goes to this position:

- After successful Robotic Arm registration and remains there until the installation of the ROSA Persona Partial Knee Medial Cut Guide
- When the ROSA HOME function is selected

PARK Position:

The Robotic Arm is in this position:

- For transportation of the Robotic Unit
- When the Robotic Unit is turned on, it will be in PARK position
- After completing surgery and undraping the Robotic Unit, it will be sent to PARK position to be shut down

5.5 Application Audible Notifications


The application has distinct audible notifications for the following events:

- Robotic Arm is in Automatic mode and moving to a predetermined location
- Robotic Arm is in Bone Tracking mode and a tracker is hidden or the Foot Pedal is not pressed
- FEMORAL RESECTION panel is being used and a tracker is hidden
- Successful landmark acquisition
- Minor or major notification
- Snapshot of the current screen

5.6 Application Visual Notifications

Foot Pedal

- Press and hold the Foot Pedal to move the Robotic Arm
- Further direction on the screen will describe the current action

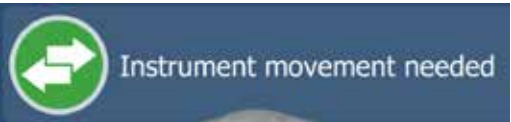
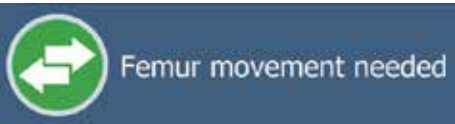
 Continue pressing the Foot Pedal when pinning or drilling in Collaborative mode to enable the Bone Tracking mode, otherwise accuracy may be impacted. Visual and audio notifications are provided if the Foot Pedal is released in Bone Tracking Collaborative mode.



Movement Needed

During landmarking, a movement is needed to start the acquisition. The movement is needed for:

- **Leg:** Leg movement, for flexion/extension poses acquisition
- **Femur:** Femoral head center acquisition
- **Instruments:** ROSA Registration Pointer and ROSA PKA Validation Tool

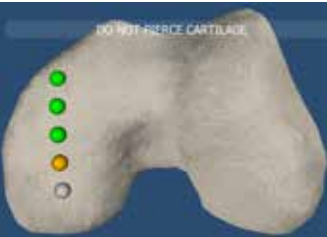


5.6 Application Visual Notifications (cont.)

Landmark Acquisition Points

Landmark acquisition will display recommended locations with three colors:

- **White:** Upcoming landmark points to be registered
- **Yellow:** Current landmark point to be registered
- **Green:** Landmark points successfully registered



Point Too Close

During landmarking, an acquisition point is too close to the previous points and was not recorded. Move away and stabilize again for a successful acquisition.



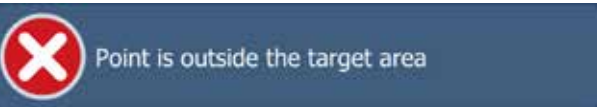
Point on Wrong Side

During the landmarking, an acquisition point was taken on the lateral side of the bone instead of medial side. Reacquire the point on the correct side.



Point Outside the Target Area

During the landmarking, an acquisition point was taken outside the target area of the bone. Reacquire the point in the correct area.



Sagittal & Plateau Reference Inversion

During the landmarking, the sagittal reference point was inverted with the plateau reference or the plateau reference was inverted with the sagittal reference.



Landmark Acquisition Points

A NavitrackER is not visible by the camera. Either something is blocking the view or the camera needs to be readjusted. An icon will be shown for the following:

Instruments:

- ROSA Registration Pointer
- ROSA Arm Reference Frame
- ROSA Base Reference Frame
- ROSA PKA Validation Tool

References:

- Femoral tracker
- Tibial tracker



The camera can be slightly repositioned at any time in order to have the necessary NavitrackER devices visible, except during the acquisition of the femoral head center and in bone tracking. During bone resections, the camera needs to stay in a volume close to where the registration was initially performed.

Notification

NavitrackER not seen

Instrument Icons



Reference Icons



### 5.7 ROSA Knee Application–Surgeon Panel

In the SURGEON panel of ROSA Partial Knee Software, the user can select their preferences for certain intra-operative parameters. Preferences are classified into the following categories:

- Laxity Assessment
- Flexion Angles for Stress Tests



SURGEON Panel

A green checkmark means the option is selected. Depending on the preferences, the panel buttons will show different surgical steps to perform during the procedure (e.g. LAXITY ASSESSMENT sub-panel in the RESECTIONS drawer).

Click DONE when all preferences have been chosen to proceed to the SETUP panel.

#### 5.7.1 Laxity Assessment (optional)

The ROSA Partial Knee System provides the surgeon with an optional tool to measure laxities after performing resections.

If the user selects the option to include LAXITY ASSESSMENT in the workflow, one additional subpanel will be activated in the RESECTIONS Drawer:

- LAXITY ASSESSMENT after tibial resections

Within this subpanel, the user will be required to validate the previous resection performed and reassess the joint space, either with the spacer block or the flexion/extension gap checkers (depending on the surgical step) or with a manual stress test. The system will indicate to the user if there has been a change in the joint space from the planned values in the PLANNING panel.

#### 5.7.2 Flexion Angles for Stress Tests

Within the EVALUATION panel, the user has the option to assess varus/valgus alignment at various angles of flexion: 30°, 45°, 60° and 120°. The 0° and 90° assessments are always enabled.

## 6. ROSA Partial Knee Application-SETUP Panel


### 6.1 OR Setup

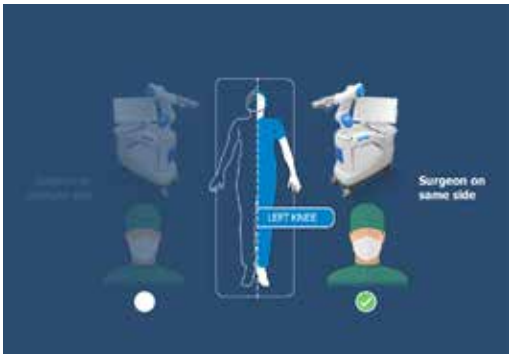
During a ROSA Partial Knee procedure, it is mandatory for the surgeon to stand on the same side as the Robotic Unit, with the Optical Unit on the opposite side.

The ROSA Partial Knee application will automatically display the operated knee in the OR Setup section (right or left).

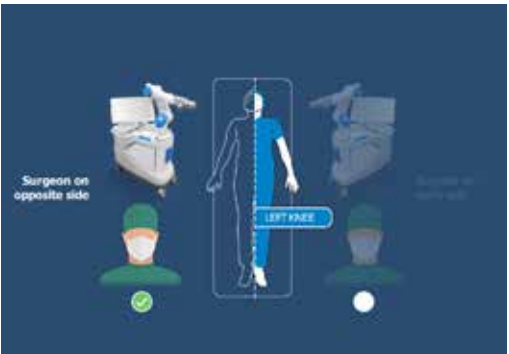
The user must then select one of two configurations:

1. Surgeon on same side as operated knee
2. Surgeon on opposite side of operated knee

 The surgeon is always on the same side as the Robotic Unit.



1



2

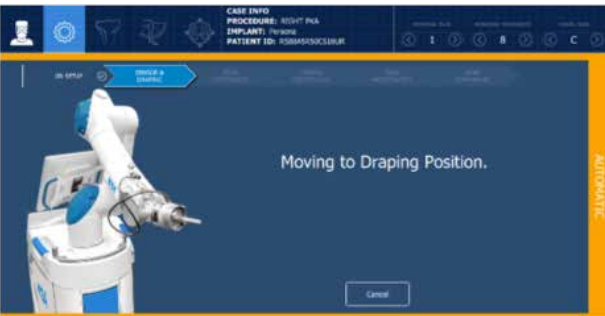
### 6.2 Calibration of Sensor

#### Move the Robotic Arm to DRAPING Position

1. In the SETUP panel, press and hold the Foot Pedal to move the Robotic Arm to the draping position.

#### Install the ROSA Arm Instrument Interface

1. Once the Robotic Arm is in the draping position, install the ROSA Arm Instrument Interface by firmly tightening the three captive screws using the hexagonal screwdriver.
2. Click NEXT to proceed to the calibration of the Force Sensor.





6.2 Calibration of Sensor (cont.)

⚠ Do not apply excessive torque on screws when installing an instrument.  
Do not use power tools.

Calibrate the Force Sensor

- 1. Acknowledge the Robotic Arm is free of any force (checkmarks) and click YES.
- If unsuccessful, redo calibration
- If successful, click NEXT to proceed to draping



⚠ Do not touch the Robotic Arm. Only the ROSA Arm Instrument Interface should be installed on the Robotic Arm.

6.3 Draping

ROSA Partial Knee can be draped using the ROSA Robotic Unit Drape or the ROSA Arm Drape combined with a standard surgical base drape.

- If using the ROSA Robotic Unit Drape, refer to the section below labeled: Install ROSA Robotic Unit Drape
- If using the ROSA Arm Drape combined with a standard surgical base drape, refer to the section below labeled: Drape the Robotic Arm and Robotic Unit

Install ROSA Robotic Unit Drape

The ROSA Robotic Unit Drape box of 20 **Part Number** is: 20-8020-080-00.

- 1. With the help of a non-sterile user, drape the Robotic Unit by following the instructions on the user interface and in the IFU provided with the drape. Install the blue elastic at the end of the sterile drape on the ROSA Arm Instrument Interface, ensuring the elastic does not go beyond the end of the ROSA Arm Instrument Interface.
- 2. Ensure the blue stripe on the ROSA Robotic Unit Drape is aligned on top of the Robotic Arm.
- 3. Ensure the blue circle stickers are aligned with the elbow joint of the Robotic Arm.
- 4. Ensure the green square stickers are aligned with the posts of the ROSA Base Reference bar.
- 5. Click DONE when the draping is complete.



Drape the Robotic Arm and Robotic Unit (Part Number: ROSA00055)

- 1. Cut the tip of the drape 4.75" (120 mm) from the end as indicated.
- 2. With the help of a non-sterile user, drape the Robotic Arm until the cut end is over the ROSA Arm Instrument Interface.
- 3. Tape to seal the drape around the complete circumference of the ROSA Arm Instrument Interface.
- 4. Install a standard surgical drape around the front and sides of the Robotic Unit base, over the Robotic Arm drape and around the lowest joint of the Robotic Arm.
- 5. Click DONE when draping is complete.



6.3 Draping (cont.)

- ⚠ Ensure the ROSA Arm Drape is installed loosely enough to allow free movement of the Robotic Arm.
- ⚠ Verify the proper installation of the sterile drapes before beginning a surgery to ensure the asepsis of the surgical field.
- ⚠ The sterile drape extremity (cut end or elastic) should not go beyond the end of the ROSA Arm Instrument Interface.
- ⚠ The tape must adhere to both the drape and the ROSA Arm Instrument Interface.
- ⚠ The base drape must be installed over the arm drape and around the lowest joint of the Robotic Arm.
- ⚠ Ensure that no excessive force is applied to the Force and Torque Sensor Cable when installing and removing the drape.

6.4 Touchscreen Monitor Draping

- 1. Slide the monitor drape over the screen from top to bottom.
- 2. Fully unfold the drape over the screen.
- 3. Cover the mouse and its support with the lower part of the drape (if draping the Optical Unit Monitor).
- 4. Stretch the drape around the screen and tape it at the back of the screen.
- 5. Click NEXT when both drapes are installed.



6.5 ROSA Partial Knee Positioning


- 1. Install the ROSA Base Reference Frame on the ROSA Base Reference Bar over the draping on the post closest to the surgical table.
- 2. Install the ROSA Arm Reference Frame on the ROSA Arm Instrument Interface by firmly tightening the two captive screws by hand.
- 3. Click NEXT when both instruments are installed.

- ⚠ Verify the ROSA Arm drape is not pulled too tightly before installing the base reference to allow the Robotic Arm to move freely.
- ⚠ The ROSA Base Reference Frame should never move during surgery.

6.5 ROSA Partial Knee Positioning (cont.)

Move the Robotic Arm to SETUP Position

- 1. Press and hold the Foot Pedal to move the Robotic Arm to the SETUP position.


 Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.




Position the Robotic Unit

- 1. Align the axis of the ROSA Arm Reference Frame with the patient’s operative leg axis.
- 2. Align the end of the ROSA Arm Reference Frame (laser marked KNEE with an arrow) with the joint line of the operative knee.
- 3. Click NEXT to proceed to Robotic Unit immobilization.



 To move the Robotic Unit, use the handle on the back of the unit. Never use the ROSA Base Reference Bar or the ROSA Base Reference Frame.

 The Robotic Unit should be at approximately 45° angle to the operating table on the surgeon’s side, as described in Section 3.2.3 OR Setup.

Lock the Robotic Unit


- 1. Lock the four wheels of the Robotic Unit by pressing down on the Foot Pedal on each wheel.
- 2. Activate the immobilization system by pressing down the main lever in the back of the Robotic Unit.
- 3. Click NEXT when the Robotic Unit is locked.



6.6 Camera Positioning

Move the Robotic Arm to Camera Target Position

- 1. Press and hold the Foot Pedal to move the Robotic Arm to the CAMERA TARGET position.

 Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.

Position the Optical Unit

- 1. The Optical Unit should be on the opposite side to the surgeon and Robotic Unit, as shown in the user interface.
- 2. Follow the instructions on the screen to position the camera in the optimal position area and at the optimal height.



6.6 Camera Positioning (cont.)

Adjust the Camera Angle

- 1. Angle the camera so that the laser is aiming at the center of the NavitrackER installed on the ROSA Arm Reference Frame (Robotic Arm).
- 2. Click CONFIRM when the laser is centered on the NavitrackER.



Lock the Optical Unit

- 1. Lock the four wheels of the Optical Unit by pressing down on the Foot Pedal on each wheel.
- 2. Click NEXT when the Optical Unit is locked.



6.7 ROSA Partial Knee Registration


- 1. Press and hold the Foot Pedal to perform the Robotic Unit arm registration (six positions).

Registration Failure

If there is a failure of the registration, a notification will appear on the user interface. Verify the following and re-do the registration:

- Is the ROSA Base Reference Frame firmly tightened?
- Is the ROSA Arm Reference Frame firmly tightened?
- Is the ROSA Arm Instrument Interface firmly tightened?
- Are the NavitrackER devices fully seated on the instruments?
- Were any trackers not seen or only partially seen during registration?
- Is the Robotic Unit immobilized (main lock & four wheels)?
- Has the camera moved? Is it well-positioned?



 Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.

6.8 Bone References

The bone references are used to track the patient’s femur and tibia and show the navigated instruments in relation to their respective positions.

Remove Instrument

- 1. Remove the ROSA Arm Reference Frame.

Perform Incision

- 1. Make an incision to expose the knee for the procedure. This should be performed prior to installing bone references.

Install Trackers

- 1. Install trackers according to the procedures in Section 6.8.1.
- 2. Click DONE when both trackers are installed to proceed to the FEMUR panel.

Verify the proper fixation of the patient references on the pins (femur and tibia). The femur and tibia references are secured on the pins, close to the patient’s skin (without compression), using two hexagonal screws.



Bone references MUST be firmly attached to the bone and MUST NOT move at any moment during surgery. If a bone reference has moved, the landmarks digitized on that bone must be acquired again.



Make sure that the pins are not positioned close to the bone cuts. Placing the pins close to the bone cuts location will increase the risk of breaking the pins with the cutting tools.



Beware that muscle fibers may apply bending forces on the pin and generate inaccuracy.



Knee incision to expose the knee for the procedure should be performed prior to installing bone references.



6.8.1 Patient Femoral Reference

- 1. Place the knee in flexion to install the femoral reference.
- 2. Use two fix fluted pins (3.2x150 mm; refer to Section 3.3.3.) to install the patient femoral reference (2 Pins Reference Femur TS3).
  - Position the pins six fingers proximal to the patella upper pole to stay clear of the working area
  - The pins can be inserted percutaneously through the vastus medialis in the femur
  - The pins should be set bicortically in the bone to ensure maximum stability
- 3. Position the reference close to the skin (without compression) and tighten the two screws to secure to the pins.



Be alert to the risk of causing damage to the saphenous artery and vein, femoral artery and vein, or the popliteal artery and vein while installing the bone reference.

6.8.1.1 ROSA Tibia Reference A/B P/N: 20-8020-028-00/20-8020-029-00

- 1. Use two fix fluted pins (3.2 x 80 mm refer to Section 3.3.3.) to install the patient tibial reference (Tibia Reference A or B).
  - Position the pins four fingers distal to the anterior tibial tuberosity to stay clear of the working area
  - The pins can be inserted percutaneously perpendicular to the medial surface of the tibial diaphysis
  - The pins should be set bicortically in the bone to ensure maximum stability
- 2. Position the reference close to the skin (without compression) and tighten the two screws to secure to the pins.



Bone Reference Installation



Bicortical Pin Placement



There is an A and B Tibial Reference Frame based on the OR setup.



6.8.1.2 Offset 2 Pins Reference Tibia P/N: 20-8000-010-35/20-8000-010-36

- 1. Use two fix fluted pins (3.2 x 80 mm refer to Section 3.3.3.) to install the patient tibial reference (Offset 2 Pins Reference Tibia Size 6; Right or Left).
- 2. Position the pins four fingers distal to the anterior tibial tuberosity, to stay clear of the working area.
  - Orient the NavitrackER approximately 10° toward the camera
  - The pins can be inserted percutaneously into the medial surface of the tibial diaphysis
  - The pins should be set bicortically in the bone to ensure maximum stability
- 3. Position the reference close to the skin (without compression) and tighten the two screws to secure to the pins.



Bone Reference Installation



Bicortical Pin Placement

There is an A and B Tibial Reference Frame based on the OR setup.

6.8.2 Switching to ROSA Total Knee Application

The system allows the surgeon to intra-operatively switch from a ROSA Partial Knee case to a ROSA Total Knee case, using the same OR setup. (The patient is on the surgical table in supine position and the Robotic Unit positioned approximately at the patient’s hip and approximately 45° relative to the surgery table).

ROSA Partial Knee System

In the ROSA Partial Knee application, in the task bar menu, select “Quit Application” and choose the option to “keep current setup (procedure switch).”

“Keep current setup (procedure switch)” option prevents sterility breach issues.

6.8.2 Switching to ROSA Total Knee Application (cont.)

Case Management Application

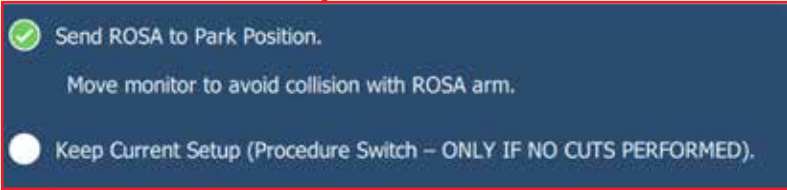
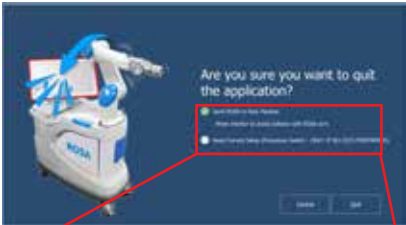
The Case Management Application will be displayed. By clicking “Cases” and selecting the case previously closed, launch the case with ROSA Total Knee Application icon.

- ROSA Knee System (TKA) Instrumentation must be used.
- Arrow on PKA icon means the case has been created as a Partial Knee case.



ROSA Total Knee Application




In ROSA Total Knee application, OR setup must remain identical in order to complete the procedure switch. The user can decide to adjust the incision to expose the knee for a total knee procedure and proceed to the ROSA Total Knee application procedure normally.

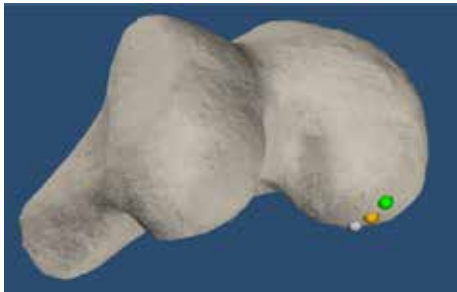


7. ROSA Partial Knee Application-  
LANDMARKS Panel

Digitization of the bony landmarks is required to display the relevant information in the different panels. This system allows automatic registration of points using a stability criterion with the pointer. A movement of the instrument is first required to initiate the registration of the points. Confirmation sounds are played to advise the user that a point has been acquired successfully. The landmark to acquire will display with three colors:

- White:** Upcoming landmark point
- Yellow:** Current landmark point
- Green:** Successful landmark point

- 
- Care must be taken not to pierce through the cartilage with the tip of the ROSA Registration Pointer. Avoid damaged areas and osteophytes.
- 
- Ensure the pointer axis is oriented perpendicular to the resection surface being acquired.
- 
- The user should try to acquire landmarks in the location they are displayed on the bone model on the screen.



Requirements for Femoral Landmarks:




- A minimal distance of 5 mm is required between two consecutive points; except for femoral posterior condyle points which require a minimum distance of 2 mm
- A minimal distance of 20 mm must be observed between the femoral head center leg positions

7.1 Femoral Head Center

Femoral head center detection is a crucial process in defining the mechanical axis that will influence the accuracy of bone resections.

1. Perform the acquisition of the femoral head center by recording 14 static positions of the leg.
  - For each acquired point, the leg should be stabilized until a confirmation sound is heard
  - The points should be taken in a large conical pattern with respect to the femoral reference
  - The minimal distance between each position is 20 mm



- 
- The pelvis and the Optical Camera must remain motionless during the entire femoral head digitization process to ensure that the true femoral head center is found.
- 
- If a non-recommended pattern, such as two unique positions in flexion/extension or a small cone is performed, the center of rotation algorithm will reject the result and a notification will appear asking the user to redo the acquisition.
- 
- Contraindications for femoral head center detection are hip pathologies severely limiting its range of motion (e.g. arthritis and hip dysplasia).

7.2 Malleoli

In order to identify the mechanical axis of the tibia, two points are digitized on the medial and lateral malleoli.

The center of the two points defines one end of the mechanical axis.

The implant varus/valgus, flexion/extension and rotation values are computed relative to the mechanical axis.

1. Using the ROSA Registration Pointer, acquire the medial and lateral malleoli in the preferred order.



7.3 Femoral Canal Entry

Together with the femoral head center, the canal entry point forms the femoral mechanical axis that is used as the mechanical axis of the femoral coordinate system. The varus/valgus, flexion/extension and rotation values are computed relative to the mechanical axis.

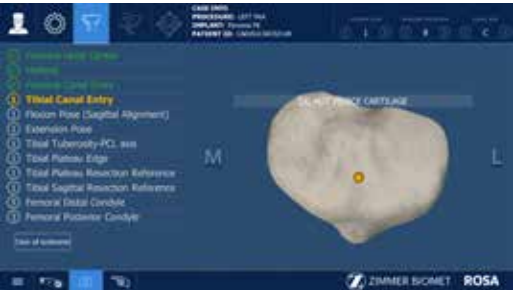
1. Using the ROSA Registration Pointer, acquire the femoral intramedullary canal entry point at the deepest point of the intercondylar notch.
  - It is recommended to determine the desired entry point on a pre-operative radiograph and compare it with the intra-operative location in situ



7.4 Tibial Canal Entry

The tibial canal entry point is identified as the entrance point of the intramedullary canal. This point should be centered along the medial/lateral axis. A/P positioning should fall between the middle and one-third of the anterior edge of the tibial plateau.

1. Using the ROSA Registration Pointer, acquire the tibial canal entry point.



7.5 Flexion Pose (Sagittal Alignment)

The flexion pose (sagittal alignment) serves multiple purposes:

- The tibial AP axis is defined by the projection of the femoral mechanical axis on the tibial axial plane in this pose at 90°. The Flexion Pose defines the default AP axis of the tibia as well as the reference for internal/external rotation of the tibia sagittal resection
- The femoral AP axis is defined by the projection of the tibial mechanical axis on the femur axial plane in this pose
- Sets the initial flexion (“zero”) space in the EVALUATION panel

For the acquisition, ensure that:

- Leg is stationary at 90° +/- 5° of flexion
- Tibia is in natural internal/external rotation with respect to the femur (foot is aligned with the sagittal plan)
- There is bony contact, with no gap between the tibial and femoral bone, during flexion pose (sagittal alignment) acquisition



7.6 Extension Pose

The extension pose serves multiple purposes:

- Defines the Initial Hip-Knee-Ankle (HKA) angle of the patient. This value is reported in the initial HKA parameter of the PLANNING panel and FEMORAL RESECTION panel
- Sets the extension initial (“zero”) space in EVALUATION panel
- Records the initial leg flexion in the femoral resection panel. Maximum extension should be ensured while taking this landmark, as this information can be used at later stages to report flexion contracture.

For the acquisition, ensure that:

- Leg is stationary between 5° extension to 20° extension
- Femoral distal condyles and the tibial plateau are in contact
- Tibia is in natural internal/external rotation with respect to the femur
- There is bony contact, with no gap between the tibial and femoral bone, during extension pose acquisition, to mimic a weight-bearing condition

7.7 Tibial Tuberosity-PCL Axis

The Tibial Tuberosity-PCL axis of the tibia is only used for visual representation in the planning module. The axis is taken by placing the pointer tip on top of the tibia and orienting it in line with the projected femoral mechanical axis on the tibia during the flexion pose (sagittal alignment).



7.8 Tibial Plateau Edge

The Tibial Plateau Edge is used in image-based cases to scale the pre-operative bone model in the mediolateral direction.

1. Using the ROSA Registration Pointer, acquire the most medial edge of the tibia plateau.

⚠️ Avoid osteophytes during acquisition.



7.9 Tibial Plateau Resection Reference

The Tibial Plateau Resection Reference is used to compute the resection level.

1. Using the tip of the ROSA Registration Pointer, acquire the center of the tibial medial plateau.

⚠️ Care must be taken not to pierce through the cartilage with the ROSA Registration Pointer’s tip.



⚠️ Avoid osteophytes during acquisition.

7.10 Tibial Sagittal Resection Reference

The Tibial Sagittal Resection Reference is used as an initial position for the sagittal resection. In the PLANNING panel, the user can set the mediolateral position of the implant on the transverse plane with respect to this landmark.

1. Using the ROSA Registration Pointer, acquire the landmark adjacent to the medial fibers of the ACL attachment where the tibial sagittal cut would be performed. A visual green check is displayed when:

- The pointer is oriented at more than 60° from AP axis on the transverse plane
- The pointer is leaning against the tibial plateau with a maximum elevation of 15°

⚠️ External rotation of the tibia can help with the acquisition.

⚠️ Tibia sagittal resection reference can be acquired anterior, outside of the joint, for example, by placing the saw blade or Angel Wing at the desired sagittal location and capturing the Tibial Sagittal Resection Reference on the side of the used instrument.







7.11 Femoral Distal Condyle (cont.)


These points are used to compute the distal resection level.

- 1. Using the ROSA Registration Pointer, acquire the medial distal condyle using five points in the most distal region. The system will compute the most distal of the five points.

There must be a minimum distance of 5 mm between consecutive points.

 Care must be taken not to pierce through the cartilage with the ROSA Registration Pointer.

 Avoid damaged areas and osteophytes.

 Final results depend on the accurate acquisition of landmarks. For accurate resection depth results, ensure that distal condyles are digitized most distally with respect to the distal cut, taking into account the flexion of the cut.




7.12 Femoral Posterior Condyle

The posterior condyle landmark is used to compute the laxities in the knee throughout the application. This posterior condyle landmark is also used in image-based cases to display the relative position of the femoral implant on the bone.

- 1. Using the ROSA Registration Pointer, acquire three landmarks in the most posterior region of the condyle. The system will compute the most posterior of the points acquired.

There must be a minimum distance of 2 mm between consecutive points.

 To aid in accessibility of the points, the knee should be flexed at least at 90°.

Ensure that the very tip of the ROSA Registration Pointer is in contact with the bone rather than the side of the conical surface. Also ensure perpendicularity of the ROSA Registration Pointer with the surface being landmarked. The femoral posterior condyle landmarks can be re-acquired after tibia resection has been performed, if user determines that perpendicularity with the bone surface could not be ensured at primary acquisition.



When the femoral posterior condyle points are not acquired along the correct mediolateral region, the system rejects their acquisition.

Once femoral and tibial landmarks have been acquired, the software will proceed to the EVALUATION Panel.


7.13 LANDMARKS Panel-Error Notifications

Other error notifications are described in Section 5.6. Software Visual Notifications.

7.13.1 Landmark Registration Not Successful: general error

A discrepancy between the pre-operative bone model and the intra-operative landmarks prevented successful bone registration. The user has two options:

- 1. Retake the specific landmarks displayed by the software, starting with the landmark displayed in yellow text.
- 2. Switch to imageless mode. The pre-operative 3D bone model will not be used or displayed in the PLANNING panel. All landmarks must be re-acquired.

 If the user switches to imageless mode, the landmarks will not be verified using the 3D bone model. Care must be taken to ensure that the landmarks are acquired in the correct locations.

7.13.2 Landmark Registration Not Successful: specific error

If the system detects a specific landmark registration error, a message will be displayed to notify the cause of the unsuccessful bone registration and specific landmarks have to be re-acquired. The user still has two options to reacquire landmarks or switch to imageless mode.

Landmark Registration Errors:

- The curvature of the femoral posterior condyle of the intra-operative acquisition and the pre-operative model does not match. User has to retake the following landmark:
  - Femoral Posterior Condyle
- In the flexion pose (sagittal alignment), the tibial and femoral canal entry landmarks are misaligned in the medio-lateral direction. User has to retake the following landmarks:
  - Femoral Canal Entry
  - Tibial Canal Entry
  - Flexion Pose (Sagittal Alignment)
- The femoral posterior condyle and tibial plateau reference landmarks are too far apart in the flexion pose (sagittal alignment). User has to retake the following landmarks:
  - Flexion Pose (Sagittal Alignment)
  - Tibial Plateau Resection Reference
  - Femoral Posterior Condyle



### 7.13 LANDMARKS Panel-Error Notifications (cont.)

- The rotation of the tibia is different between the flexion pose (Sagittal Alignment) and the extension pose. User has to retake the following landmarks:
  - Flexion Pose (Sagittal Alignment)
  - Extension Pose
- The tibial plateau edge landmarks or the tibia canal entry are too far from the pre-op model. User has to retake the following landmarks:
  - Tibial Canal Entry
  - Tibial Tuberosity-PCL Axis
  - Tibial Plateau Edge



### 7.14 LANDMARKS Panel after Tibial Cut

Once tibial cuts have been performed, landmark acquisition will be restricted to Femoral Posterior Condyle landmark to:

- Avoid landmark acquisition on a cut surface
- Enable the user to reacquire the Femoral Posterior Condyle landmark after tibial cuts . At this point, more clearance is created by the resected tibia, which can improve landmark selection and maintain the ROSA Registration Pointer perpendicularity with the posterior condyle surface



## 8. ROSA Partial Knee Application-EVALUATION Panel

In this panel, the ROSA Partial Knee System will dynamically capture movements of the leg as the user moves it through a series of evaluations. The system will quantify, display and save various characteristics of the knee condition. This assessment can be performed at three distinct stages of the surgery, each in a different tab of the EVALUATION panel: INITIAL, INTRA-OP (intra-operative) and FINAL.



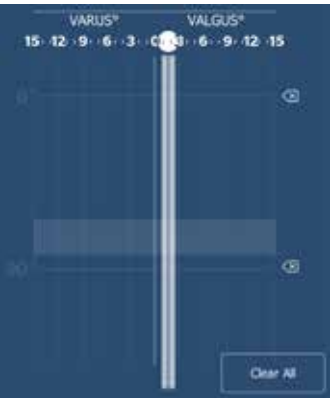
EVALUATION panel

#### Range of Motion

A movement of the leg is first required to initiate the procedure. The surgeon can perform the range of motion test that will capture the minimum and maximum flexion angles of the knee (displayed in blue). The current flexion angle and varus/valgus alignment of the leg is displayed.

#### Knee State Test

The application will display the varus/valgus laxity range for each of the flexion angles selected in the SURGEON panel. The user may move the leg through the full range of motion while applying a varus or valgus stress. The user may also move the leg to a certain flexion angle, and then apply a varus/valgus stress before moving on to another flexion angle. The system will capture the leg position dynamically in both methods. By default, knee laxity is measured in full extension (0° to 20°) and flexion (90° ± 5°). The other preference-based angles available are 30°, 45°, 60° and 120° (SURGEON panel). The maximum varus/valgus angle values are recorded in the indicators for each angle (blue bar). ROSA Partial Knee allows the user to reset individual acquired values of the laxity test by clicking the “X” symbol next to each angle or all values by clicking CLEAR ALL.



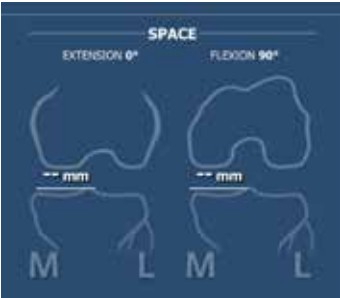
- ! Varus/valgus will only be recorded when the highlighted box is over the flexion angle line.
- ! Maximum HKA captured under valgus stress in extension will also be reported as follows:
  - In the PLANNING panel, as the correctable HKA
  - In the FEMORAL RESECTION panel, as a reference that can be used by surgeon as a correction limit, depicted as correctable HKA



8. ROSA Partial Knee Application-EVALUATION Panel (cont.)

Space Display


- ROSA Partial Knee displays the maximum space between the bones in the medial compartment in millimeters with the knee in extension (0° to 20°) and in flexion (90° ± 5°)
- At all times, the user has the option of clearing all values (CLEAR ALL) or saving the values (SAVE). In all three tabs (Initial, Intra-Op and Final), the same knee assessments can be performed. The acquired values can be used to guide the surgeon in planning implant position (PLANNING panel) and can assist in clinical decisions on soft tissue management



Initial Knee State


In the INITIAL tab, the knee must be in its initial condition, i.e. osteophytes may still be present. The INITIAL tab can be used to evaluate the pre-operative flexion contracture and the varus deformity.

- When clicking SAVE, the user will be asked if the knee was in a prepared state for surgery during the assessment before proceeding to the PLANNING panel. If the knee was not in a prepared state, the user will be prompted to prepare the knee and record the knee state again in the INTRA-OP tab
- After saving the knee state assessment in the INITIAL tab, anytime the user returns to the EVALUATION panel prior to finishing all cuts, the system will show the INTRA-OP tab with the latest saved values

 The Plan Laxity tool will not display the space values if the knee is evaluated without already having the knee prepared for the surgery.


Intra-operative Knee State

The INTRA-OP tab requires that the knee is in a representative state of when the implants will be in place, i.e. large osteophytes removed if applicable. Since the intra-operative knee state evaluation can be done multiple times, the latest saved values will be shown.

 If the knee was not prepared for the INITIAL knee state evaluation, when clicking SAVE in the INTRA-OP tab, the user will be asked if the knee was in a prepared state for surgery during the assessment before proceeding to the PLANNING panel.

Final Knee State

The FINAL tab becomes available upon the completion of all resections. The FINAL tab requires that the flexion-extension gap checkers (thin side for flexion, thick side for extension), trial or final implants are in place during the assessment.

 The final assessment with the trials or final implants should not be evaluated in the Initial or Intra-Operative tabs. The algorithm does not take the implant geometry into consideration.

9. ROSA Partial Knee Application-PLANNING Panel

The PLANNING panel of the ROSA Partial Knee application is used intra-operatively by the surgeon to set the femur and tibia bone cuts according to the chosen implant components. Based on the intra-operative planned values, the ROSA Robotic Arm will move to the appropriate positions to execute the surgical plan.

9.1 PLANNING Panel Overview

PLANNING Panel Image-Based Cases



PLANNING Panel Imageless Cases



Imageless planning does not offer the option buttons for showing the implants, cuts, axes and landmarks.

9.1.1 Implant Size Selectors



Image-Based Cases

The size of the femoral component, bearing thickness and the size of the tibial component can be modified directly on the right side of the top taskbar.



Imageless Cases

The bearing thickness can be modified directly on the right side of the top taskbar.

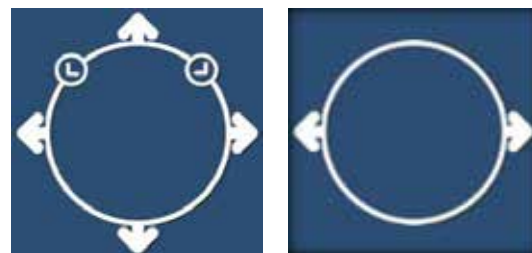


### 9.1.1 Implant Size Selectors

### 9.1.2.1 Implant Manipulator - Image-Based Cases

Touch the femoral or tibial component in any view (extension, flexion or axial (tibial component only), to display the implant manipulator:

- Large up/down arrows control the resection level (for tibia resection)
- Large side arrows control translation (of the sagittal resection or of the implant component position along the mediolateral axis)
- Small encircled arrows control rotation



### 9.1.2.2 Implant Manipulator - Imageless Cases

The implant manipulator arrows are displayed at all times in imageless cases:

### Frontal View

Up/down arrows control:

- Depth of the tibial horizontal resection

Side arrows control:

- Varus/valgus of tibial horizontal resection



### Lateral View

Side arrows control:

- Slope of the tibial horizontal resection

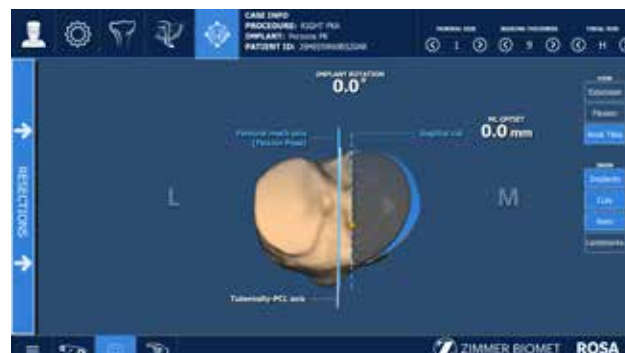


### Axial View

- Side arrows control mediolateral offset on the transverse plane
- Small encircled arrows control rotation on the transverse plane



### 9.1.3 Axial View of the Tibia



## Image-Based Cases



## Imageless Cases

### 9.1.3 Axial View of the Tibia (cont.)

The axial view of the PLANNING panel displays:

- Offset from the Tibial Sagittal Resection Reference landmark
- Rotation of the sagittal resection
- Anteroposterior axis of the tibia as captured during the flexion pose landmark
- Anteroposterior axis of the tibia as captured with the tibial tuberosity-PCL axis (image-based cases only)

The arrows control:

- Offset from the Tibial Sagittal Resection Reference landmark
- Rotation of the sagittal resection / implant rotation ,referenced by the anteroposterior axis of the tibia. By default, anteroposterior axis of the tibia is defined as the projection of the Femoral mechanical axis on the tibia, captured at the flexion pose landmark and represented with a solid blue line. In image-based cases, rotation can also be set with reference to the tibia tuberosity-PCL axis by visually aligning the sagittal resection (dashed blue line) with the “Tuberosity-PCL Axis”, represented by the solid white line. The sagittal resection is displayed when the cuts are showed with the CUTS button in the planning panel.
- Anteroposterior implant position (image-based cases only)

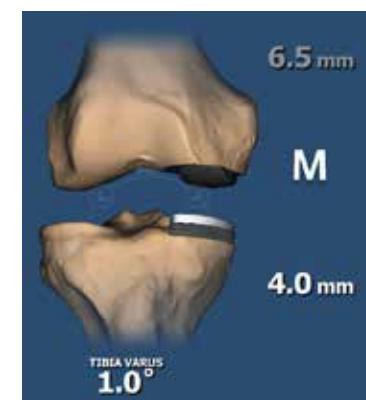


Potential ligament damage warning appears if the implant positioning is more lateral than the tibial sagittal resection reference.

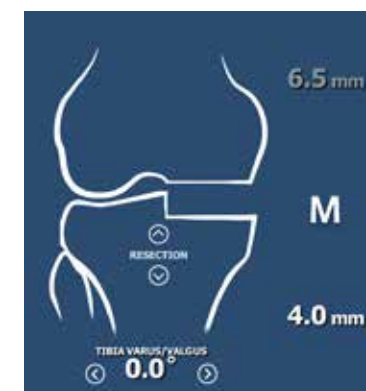


In image-based cases, the system will display a warning if the anteroposterior axis of the tibia defined by the flexion pose landmark is more than 10 degree from the anteroposterior axis of the tibia defined by the Tuberosity-PCL landmark. User should pay additional attention in this case and consider re-acquiring those landmarks for more robust guidance in sagittal resection rotation planning.

### 9.1.4 Frontal View



## Image-Based Cases



## Imageless Cases

The frontal view of the PLANNING panel displays:

### Femoral Bone (flexion and extension)

- Medial distal resection (fixed at 6.5 mm)

The arrows control:

- Mediolateral position of the femoral component in extension view

9.1.4 Frontal View (cont.)

Tibial Bone (flexion and extension)

- Medial proximal resection
- Varus/valgus angle

The arrows control:

- Tibial resection depth
- Varus/valgus of tibial resection
- Mediolateral positioning of the tibial sagittal resection

9.1.5 Lateral View

The lateral view of the PLANNING panel displays:

- Slope angle of the tibial horizontal resection

The arrows control:

- Slope angle of the tibial horizontal resection
- Anteroposterior tibial implant position (image-based cases only)

For image-based cases, it is possible to rotate the 3D bone model in the lateral view:

- House icon: 3D bone model returns to the original lateral view
- Rotation icon: Activates the rotation of the 3D bone model. Swipe the touchscreen left or right to turn the 3D bone model

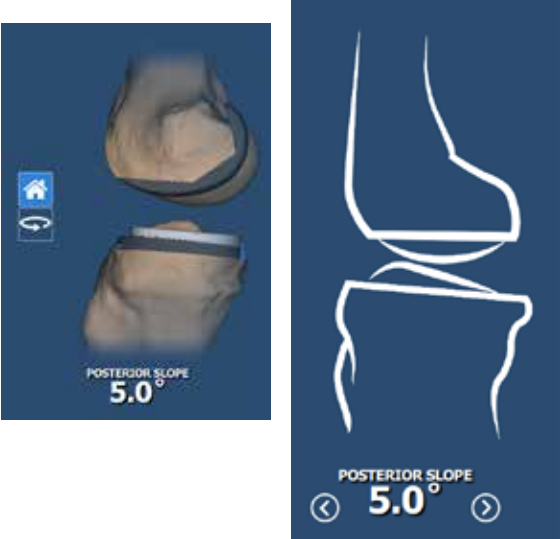


Image-Based Cases

Imageless Cases

9.2 Viewing Options

Image-Based Cases

The viewing options of the PLANNING panel are:

- EXTENSION/FLEXION/AXIAL TIBIA : Displays the knee in extension, flexion or axial view of the tibia
- IMPLANTS/CUTS: Toggles on/off the display of the implants/cuts
- AXES: Toggles on/off the display of the axes (only in axial tibia view)
- LANDMARKS: Toggles on/off the display of the acquired landmarks

Imageless Cases

The viewing options of the PLANNING panel are:

- EXTENSION: Displays the knee in extension
- FLEXION: Displays the knee in flexion
- AXIAL TIBIA: Displays the axial view of the tibia

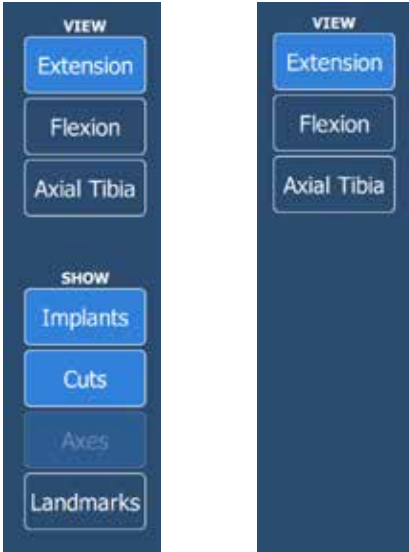


Image-Based Cases

Imageless Cases

9.3 HKA Angle & PLAN LAXITY Tool Along the Workflow

HKA Tool

The HKA tool displays:

- HKA acquired during extension pose in LANDMARK panel (initial HKA), which serves as simulated weight-bearing HKA
- HKA angle acquired during valgus stress in extension in KNEE STATE EVALUATION or LAXITY ASSESSMENT panels (Correctable HKA)

The HKA information is accessible at all times during the procedure in the PLANNING panel.

Plan Laxity Tool

The Plan Laxity tool shows the same information in the EXTENSION/FLEXION and before/after resections:

- Extension planned laxity in the medial compartment
- Flexion planned laxity in the medial compartment

Plan laxities are calculated taking into account gaps at initial knee state, planned cuts and implant component thicknesses, under valgus stress. Laxity calculation cannot be reduced to simple subtraction of component thickness from available space as proprietary algorithms are used to take into account other clinical parameters, such as tibia slope and applied valgus stress.



The Plan Laxity can be modified with resection levels and angles, component thickness, space acquisitions in valgus stress in EVALUATION panel.



The Plan Laxity displays orange values when laxity is too tight, which means the space in the medial compartment is negative.



After Resections & Validation

When bone resection validation is accepted, Plan Laxity values are updated with validation values. When bone resection validation is ignored, Plan Laxity values are not updated with validation values and remain at initial plan with a warning



Values based on initial plan

As workflow progresses, every time user is brought back to the planner, laxities should be reviewed to support clinical decisions such as initial tibia resection parameters, requirements for tibia recut and adjustment in bearing thickness.

9.3 HKA Angle & PLAN LAXITY Tool Along the Workflow (cont.)



Before Resections. Used to plan tibia cut

After tibial resection when validation is accepted. Most accurate laxity based on tibia validation and laxity assessment if performed. Used to determine if tibia recut is necessary and/or to adjust bearing thickness.

After tibial resection when validation is ignored. These values are based on the initial plan and are not taking into consideration the latest tibia cut performed. They must be used with caution as they are assuming tibia cut was performed as planned. This is highlighted with the yellow warning.

After femoral validation. These values use the original plan and don't consider femoral cuts performed. These values should be used with caution since clinical steps (releases, cuts...) could have impacted the laxities values during the procedure.

9.4 Femoral and Tibial Component Planning

The PLANNING panel will display a default plan based on resection values recommended in the Persona Partial Knee Surgical Technique. The user is responsible for reviewing the following elements of the default plan and making adjustments as necessary.

9.4.1 Before Cuts

9.4.1.1 AXIAL View

- 1. Set the rotation of the sagittal resection.
- 2. Set the mediolateral offset of the sagittal resection with respect to the Tibial Sagittal Resection Reference landmark.
- 3. Select the implant size of the tibial component.
- 4. Set the AP position of the tibial component.

9.4.1.2 EXTENSION View

In the frontal view:

- 1. Set the tibial horizontal resection.
- 2. Set the varus/valgus angle of the tibial component.
- 3. The varus/valgus angle of the femoral component will automatically readjust to remain parallel to the tibial component varus/valgus, however this value is not displayed in the PLANNING panel.
- 4. Set the mediolateral position of the femoral component.

In the lateral view:

- 1. Set the slope angle of the tibial component.

9.4 Femoral and Tibial Component Planning (cont.)

9.4.1.3 FLEXION View

In the frontal view, review:

- Femoral size (image-based cases)
- Mediolateral position of the femoral implant
- Tibial horizontal resection

Using the Plan Laxity tool, review the residual space in extension and flexion.

- ! The rotation of the femoral component is displayed parallel to the tibial resection. The final component rotation will be determined during the femoral finishing step with the Persona Partial Knee instrumentation, and not navigated by the ROSA Partial Knee System.
- ! Varus/Valgus of the femoral distal resection is linked to tibial resection parameters in order to reproduce the parallel resections delivered by the Persona Partial Knee Spacer Block instrumentation.

9.4.2 After the Tibial Resections:

- 1. Review the overall surgical plan.
- 2. Review the PLAN LAXITY tool for updated residual space values.
- 3. Review and/or modify the tibial resections values for a recut, if necessary.
- 4. Select the implant sizes and/or bearing thickness.

- ! Do not recut the tibia more than once.

9.4.3 After the Distal Resection:

- 1. Review the PLAN LAXITY tool for updated residual space values.
- 2. Review and/or modify the resection values for a tibia recut, if necessary.
- 3. Review the implant sizes and/or bearing thickness.

- ! Parameters in the PLANNING panel influence each other. Make sure to review the overall surgical plan before proceeding to the RESECTIONS drawer.

- ! A warning is displayed if the tibia varus/valgus value is in valgus.

- ! The Plan Laxity tool can be used at all times to help perform the surgical plan.





9.5 Validated Values

After Tibial Resection

After the tibial resections have been performed, the application requires a validation. During this validation, the options are to discard values, re-validate or apply the validated values to the plan.



After Femoral Resection

After the femoral resection has been performed, the application transitions to a VALIDATION panel, where there is the possibility to validate the femur, as well as the tibia cuts. During the femur validation, there is the option to close the VALIDATION panel. Note, that only the distal resection depth is compared to the planned value (fixed at 6.5 mm for the Persona Partial Knee Spacer Block). Femoral varus/valgus and distal cut flexion are reported but not compared. During the tibia validation, the same three options mentioned above are available.



9.5.1 Apply Validation to Plan

Once the tibial resection is validated and the surgeon wants to apply the values to the plan, he can acknowledge by selecting the APPLY TO PLAN button. The validated values must be applied to the plan, then the tibial bone model (generic bone schematics in imageless) will turn blue. The validated values will be updated on the PLANNING screen and displayed in blue; if the validated values are out of range the application will display them in orange. Once the femoral resection is performed, the warning 'Laxity values outdated, use F/E checkers' will appear on the PLANNING screen.

9.5 Validated Values (cont.)

Tibia Validation Applied and Femoral Resection Not Yet Performed



Image-Based Cases



Imageless Cases

Tibia Validation Applied and Femoral Validation Performed



Image-Based Cases



Imageless Cases

9.5.2 Discard Values

Once the tibial resection is validated and the surgeon does not want to apply the validated values to the plan, the tibial bone model (generic bone schematics in imageless) will turn grey and the validated values will NOT be updated in the PLANNING screen and therefore not displayed in the planning. If the values are discarded the system does not allow a recut on the tibia bone.

Discarded Values for Tibial Validation and Femoral Resection Not Yet Performed



Image-Based Cases



Imageless Cases

9.5 Validated Values (cont.)

Discarded Values for Tibial Validation and Femoral Resection Performed



Image-Based Cases



Imageless Cases

9.5.3 PLANNING Panel - Error Notifications

9.5.3.1 Before Resections

Planning Values Out of Range

A notification will appear in the bottom taskbar (“Planning values out of range”), the affected bone resection value will be displayed in orange and the RESECTIONS drawer will become inaccessible.

Bone resection and varus/valgus can, for example, be adjusted to decrease an excessive bone resection.



9.5.3.2 After a Resection

If a validated value is outside of the planning limits, the value will be displayed in orange but the RESECTIONS drawer will remain accessible.



10. ROSA Partial Knee Application- RESECTIONS Drawer

The RESECTIONS drawer of the ROSA Partial Knee Application is used intra-operatively for the surgeon to perform the tibial horizontal and sagittal resections, femoral distal resection, and validate the resections and laxities throughout the workflow. Based on the intra-operative planned values the Robotic Arm will move to reach the appropriate positions to execute the surgical plan of the tibial resections. For femoral resection, the robotic application will guide the surgeon in proper selection, location and use of the Spacer Block. The RESECTIONS drawer is accessible from the PLANNING panel on the left-hand side of the screen.



Access to the Resections Drawer from PLANNING Panel



RESECTIONS Drawer

10.1 RESECTIONS Drawer Overview


The RESECTIONS drawer is the same for both image-based and imageless cases. It consists of:


- CHECKPOINT: Allows for the verification that the ROSA Base Reference Frame has not moved and that the correct Cut Guide is installed before performing resections
- TIBIAL RESECTIONS: Surgical flow to perform the tibial horizontal and sagittal resections
- LAXITY ASSESSMENT: After tibial resections (optional), validate resections and residual laxity values
- FEMORAL DISTAL RESECTION: Surgical flow to perform the femoral distal resection





10.1 RESECTIONS Drawer Overview (cont.)


The user must start with the tibial resections. While in the RESECTIONS drawer, direct access to other panels is disabled. To access the panel buttons, close the RESECTIONS drawer using the tab to the right of the screen.


- 


A knee positioner is recommended to be used with the ROSA Partial Knee System, otherwise accuracy may be impacted.
- 

The function ROSA HOME is not accessible when entering a cut until the Cut Guide is disengaged. To access the ROSA HOME function, finish the resection, remove the pin and confirm the Cut Guide is disengaged.
- 

Using a retractor on the medial side of the knee is recommended to protect the MCL, however applying too much force on the retractor may cause rotation of the tibia and accuracy may be impacted.
- 

The checkpoint is performed upon entry in the RESECTIONS drawer. The checkpoint can also be performed at any time when the RESECTIONS drawer is accessible, to verify registration (ROSA Base Reference Frame did not move) or to confirm the correct Cut Guide is used.
- 

Once the checkpoint is performed and the RESECTIONS drawer is accessible, the Laxity Assessment (after tibia) becomes accessible when the tibial resection workflow has been performed.
- 

The SHOW PLAN button can be selected to display the values from the surgical plan for the following steps: Pinning of the Cut Guide, sawing and validation.
- 

A Kocher can be clamped on the trocar pin installed in the Cut Guide. The Kocher should prevent a sliding movement of the pin in the Cut Guide.

Two additional features are available in the RESECTIONS drawer:

COLLABORATIVE MODE


Puts the Robotic Arm in Collaborative mode where the user can manually move it by applying a gentle force at the end of the Robotic Arm while pressing down on the Foot Pedal.

VALIDATION

Allows for validation of the cuts and the selection of the bone resection to validate.

- **Tibial Horizontal and Sagittal Resections**

Orient the ROSA PKA Validation Tool so the Navitracker is facing the camera and position the flat surface of the tool on the tibial horizontal surface. Ensure that the ROSA PKA Validation Tool is placed flat on the horizontal surface and pressed flush against the sagittal resection.
- **Femoral Distal Resection**

Orient the ROSA PKA Validation Tool so the Navitracker is facing the camera and position the flat surface of the tool on the resected femoral distal surface. Once the system detects a stable position of the Validation Tool, the validation values will be acquired.
- 

Make sure the bone resection surface is flat and free of bone fragments and soft tissues before validation.

10.2 ROSA Persona Partial Knee Cut Guide Installation and Checkpoint

Cut Guide Installation

1. Upon entry in the RESECTIONS drawer, install the required ROSA Persona Partial Knee Cut Guide (AL/AR or BL/BR) onto the ROSA Arm instrument Interface by firmly tightening the two captive screws by hand.
2. Click NEXT to proceed to the checkpoint step.



Checkpoint

1. Once the ROSA Persona Partial Knee Cut Guide is installed, place the tip of the ROSA Registration Pointer in the checkpoint (divot near the base of the Cut Guide).
2. If the checkpoint is unsuccessful, verify the following and redo the checkpoint
  - Does the labeling on the ROSA Persona Partial Knee Cut Guide correspond to the Cut Guide indicated on the screen?
  - Is the ROSA Persona Partial Knee Cut Guide firmly tightened to the ROSA Arm Instrument Interface?
  - Is the ROSA Arm Instrument Interface firmly tightened to the ROSA Robotic Arm?
  - Has the ROSA Base Reference Frame moved since registration? (If it is the case, registration needs to be re-done.)




10.3 Tibial Proximal Resections

Select Resection to Perform

1. Select the tab for tibial resections.

Automatic Mode: Robotic Arm to Cut Plane

1. Operated leg needs to be positioned between 45 and 145 degrees of flexion inclusively before cut guide motion to tibia cut plane is authorized.
2. Press and hold the Foot Pedal to automatically move the Robotic Arm to the tibial cut plane.
3. Hold pedal until the Robotic Arm switches to Collaborative mode.

- 

Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.






10.3 Tibial Proximal Resections (cont.)

Collaborative Mode: Robotic Arm to Cut Plane

- 1. Once in Collaborative mode, press and hold the Foot Pedal and apply a gentle force on the Cut Guide to move it as close as possible to the bone for pinning.


 The Robotic Arm is in axial mode, i.e. movement is constrained to the horizontal and sagittal resection planes.





Pin Installation and Live Cut Values


- 1. Before installing the pin, verify visually or with an angel wing that the sagittal resection slot is aligned in the desired trajectory.
- 2. Keep the Foot Pedal pressed and install a pin through the corner pinhole (Pinhole 1) in the Cut Guide.
- 3. When the pin is installed, confirm that the live cut values are acceptable by clicking YES.





 When a force is applied on the Cut Guide during pinning, the Robotic Unit switches to Stationary mode. Confirm that the live cut values are acceptable to continue the cut flow.

 The user must use only the specific holes for the primary cut and/or the recut. Pinhole 1 is used for primary tibial cut fixation, and Pinhole 2 is used for tibial re-cut fixation.


 Only one re-cut of the tibia should ever be performed with ROSA.


 Keep the Foot Pedal pressed when pinning in Collaborative mode to enable the Bone Tracking mode, otherwise accuracy may be impacted. Visual and audio notifications are provided if the Foot Pedal is released in Collaborative mode.

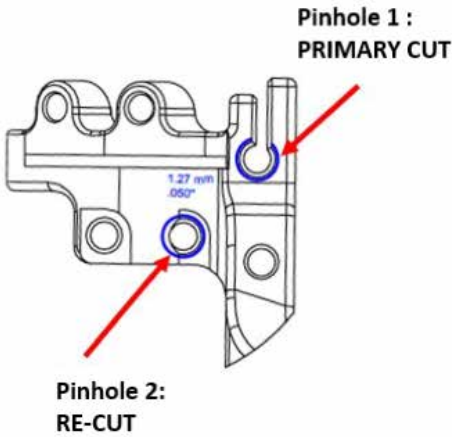
 The user must acknowledge Cut Guide placement by looking at live cut values and deciding if they are acceptable by clicking on the YES button.

 Before performing the resection, it is recommended to verify the cut plane with standard instrumentation, such as the angel wing

 The user must perform the sagittal cut before the horizontal cut.

 When performing a re-cut of the tibia the user must be mindful of the risk of over resecting the tibia and damaging the posterior cortex due to the absence of the corner pin.

 The user must be mindful of external forces applied by soft tissues or the surrounding skin as they can impact accuracy.







10.3 Tibial Proximal Resections (cont.)

Bone Resections

- 1. Once the pin installation has been confirmed along with live cut values, the Robotic Unit will go into Stationary mode and the Foot Pedal can be released.
- 2. Perform the tibial sagittal resection as per the Persona Partial Knee Surgical Technique.
- 3. Perform the tibial horizontal resection as per the Persona Partial Knee Surgical Technique.
- 4. Once the resections are complete, remove the pin then confirm by clicking YES.



-  Before disengaging the Cut Guide, make sure that the pin is removed.
-  Care must be taken to not undercut the eminence of the medial tibial plateau.
-  Care must be taken to not over resect the sagittal cut.
-  Care must be taken in re-cutting the tibia at a different slope than the primary cut to avoid taking an incomplete recut. A resection guide (angel wing) usage before pinning the guide for a tibial recut is recommended.

Disengaging the Cut Guide

- 1. Press and hold the Foot Pedal and disengage the Cut Guide by applying a gentle force to pull it away until the desired position is reached. Make sure Cut Guide is sufficiently retracted to avoid interference in using the ROSA PKA Validation Tool and the Persona Partial Knee Spacer Block and power tools during femoral distal resection.
- The system will prompt the user to validate the cut.




Validating

For accurate validation of the tibial horizontal and sagittal resections, ensure that the ROSA PKA Validation Tool is placed flat on the horizontal surface and pressed flush against the sagittal resection and that no bone or soft tissue fragments are present. Acquisition will be recorded and a transition to the PLANNING panel will be done automatically after validation acknowledgement.

10.4 Femoral Distal Resection

Select resection to perform

Open the resection drawer and select the femoral distal resection tab to access the femoral distal resection panel.


 Femoral and tibial references must be visible at all time for proper function of the femoral resection panel.

Select Spacer Block to be Use

Attach the PK (Partial Knee) handle to the planned spacer block to facilitate insertion into the joint space. Spacer block thickness is associated with planned bearing thickness in the ROSA application.

With the knee flexed between 0–10 degrees insert the spacer block to ensure the tibial resection is sufficient. The thickness is correct when the spacer block can slide easily in and out. If the spacer block is too loose, use a thicker spacer block to fill the extension gap.

If the spacer block or handle has to be firmly gripped to slide in and out, this is too tight. Additional tibia resection is required.

 Planning is defaulted to a 9 mm spacer block to allow the surgeon intraoperative flexibility of +/- 1 mm. It is recommended to keep that setting for planning the surgery:



The live flexion tool located at the left of the femoral resection panel allows:

- Adjusting knee flexion angle for spacer block thickness selection
- Following progression of flexion contractures through the Initial Flexion parameter
- Evaluating distal cut flexion through the provided parameter (can be shown or hidden)
- Expected flexion/extension angle of the femoral distal cut can be visualized by toggling the “show distal cut flexion” button. This value is calculated from the validated tibia slope, the actual knee flexion as well as the 5° flexion which is built in the Persona Partial Knee spacer block.

The live HKA tool located at the right of the femoral resection panel provides real time HKA measurement allowing to:

- Confirm spacer block selection and subsequent bearing thickness to be implanted based on leg HKA
- Perform HKA correction assessment based on initial HKA and correctable HKA (collected as part of the extension pose landmark and knee state evaluation)



10.4 Femoral Distal Resection (cont.)

The live HKA widget provides a white zone highlighting the condition where live HKA is between the initial and correctable HKA. The following information is also provided:

If Leg HKA is in more valgus than the correctable HKA :





Leg HKA is in valgus:




Leg HKA is more in varus than the initial HKA:



 Avoid the use of the alignment tower and alignment rod to prevent contacting the bone references and potentially generating accuracy issues.

 If spacer block selected is different from planned, ensure updating the bearing thickness parameter accordingly as this will impact subsequent laxity assessment and surgeon reports.


Perform Distal Femoral Resection

 Before performing the resection, it is recommended to verify the cut plane with standard instrumentation, such as the angel wing.

Place the knee in extension in a stable position on the OR table. Insert the selected spacer block until the distal femoral cut slot contacts the anterior aspect of the femur or posterior soft tissues prevent further insertion of the spacer block.

It is important to confirm the spacer block is fully inserted, sitting flat on the resected tibia, and contacting the distal femur. Ensure no bone or soft tissue fragments remain on the resected tibia surface and remove any remaining anterior osteophytes if necessary.

Using the live flexion tool of the femoral resection panel, place the knee in the green range of flexion while the spacer block is inserted. This will ensure the distal cut is not made in hyperextension or excessive flexion.

 The use of leg stabilization techniques such as foot holders is encouraged to facilitate this manipulation and maximize distal femoral resection accuracy.



10.4 Femoral Distal Resection (cont.)

With the distal femoral cut slot centered on the femoral condyle, use a 48 mm headed screw to secure the spacer block in place and perform femoral distal resection, then remove the 48 mm headed screw and spacer block.

- It is important to avoid making the distal femoral cut in hyperextension.
- For highest precision, use Zimmer Biomet saw blades as specified in section 3.3.3. (13090127AF1 or equivalent as per hub requirement)



Validating

For accurate validation of the femoral distal resection, ensure that the ROSA PKA Validation Tool is placed flat on the cut surface, with any remaining bone or soft tissue fragment removed. Acquisition will be recorded and a transition to the CONFIRMATION window will be done automatically after validation acknowledgement.

After validation, the following warning will be visible under the balance tool in the planning panel. Laxities are based on initial plan at this point and can be re-evaluated using the flexion/extension gap checkers. Laxity assessment after femur resection can also be performed through final knee state panel, with trials implants. Negative laxity values are shown in orange and should be further evaluated by using the flexion/extension gap checkers to determine the need for femoral/tibial adjustments before trials implantation.



10.5 Laxity Assessment (optional)

10.5.1 After Tibial Resection

This option will be accessible only if the LAXITY ASSESSMENT subpanel was selected in the SURGEON panel.

The application will always be refreshed with the latest laxity values. Using a constant distraction force during the initial knee state and the subsequent laxity assessment is important to obtain consistent tibia cuts.



Tibial Resections Validation

1. Validate the tibial resections.
- Acquisition will be recorded and applied to the planning if confirmed by the user
- To re-validate, click RE-VALIDATE
- For accurate validation of the tibial horizontal and sagittal resections, ensure that the ROSA PKA Validation Tool is placed flat on the horizontal surface and pressed flush against the sagittal resection without any remaining bone or soft tissue fragments on resected surfaces

Display of Validation Values

Once the tibial resection has been validated, all validated values will be displayed.

1. Click APPLY TO PLAN to evaluate the flexion laxity.
2. Click CANCEL to return to the PLANNING panel.
3. Click SHOW PLAN to compare the validation values to the planned resection values.
- A green checkmark beside a resection value indicates that the value is within  $\pm 2$  mm or  $\pm 2^\circ$  of the planned value. An orange X icon indicates that the validated value is not within these bounds

Leg Positioning

1. Put the leg in flexion ( $85^\circ$  to  $95^\circ$ ). The transition to the flexion Laxity Assessment will be done automatically.

Flexion Laxity Assessment

Assess the flexion laxity by stressing the knee in valgus while keeping the leg in flexion ( $85^\circ$  to  $95^\circ$ ). An instrument can be used as a lever arm to distract the joint.

1. Click the X symbol to clear the acquired values.
2. Click NEXT to proceed.
3. Click BACK to return to VALIDATION or CANCEL to return to the PLANNING panel.

Extension Laxity Assessment

Assess the extension laxity by stressing the knee in valgus while keeping the leg in extension ( $0^\circ$  to  $20^\circ$ ).

1. Click the X symbol to clear the acquired values.
2. Click NEXT to proceed.
3. Click BACK to return to VALIDATION or CANCEL to return to the PLANNING panel.

After Tibial Validation, the user can check leg alignment by bringing the leg in extension, inserting metal spacer matching selected bearing thickness and applying axial load to replicate weight bearing conditions. Leg alignment should not be in valgus.





10.5.2 After Femoral Distal Resection

ROSA laxity assessment features are not available after femoral resection. The following table presents the use of spacer block and/or flexion-extension Gap Checkers for laxity evaluation. Laxity assessment through standard instrumentation is possible both after tibia resection and after femur resection.

10.5.3 Performing laxity assessment using standard instrumentation

Should the surgeon prefer to assess joint space with spacer blocks in place, the specific block to be used will vary depending on which surgical procedure step they are performing:

After tibia resection is performed / prior to distal femoral resection being performed, spacer block can be used for extension gap and flexion extension gap checker (thin side) can be used for flexion gap. Both instruments can be used:

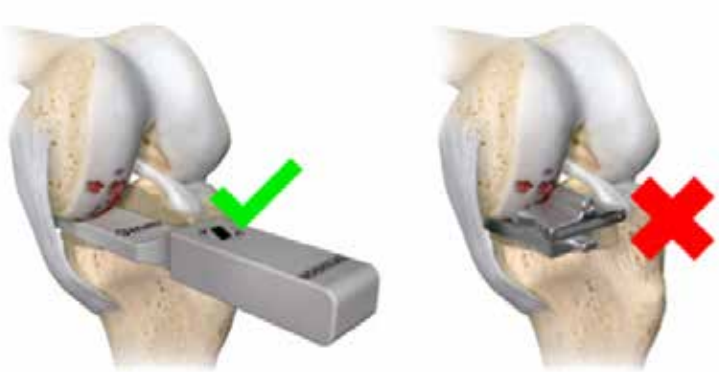
- Without ROSA
- Within ROSA optional laxity assessment panel

Block to Use for Extension Gap



Use PPK Spacer Block

Block to Use for Flexion Gap

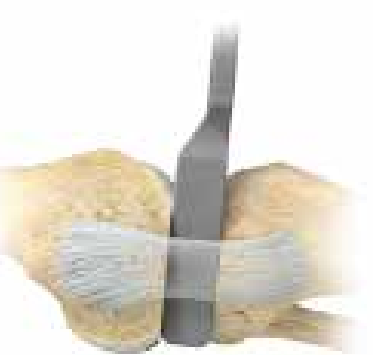


Use THIN side of PPK Flexion Extension Gap Checker\*

After tibia and distal femoral resections are performed, the flexion extension gap checker can be used (thick side in extension, thin side in flexion). Instrument can be used:

- Without ROSA

Block to Use for Extension Gap



Use THICK side of PPK Flexion Extension Gap Checker\*

Block to Use for Flexion Gap



Use THIN side of PPK Flexion Extension Gap Checker\*


\* Corresponding to the previously used spacer block size.

10.6 Implant Confirmation Window

Insert trial implants and confirm the following implant selection:

- Brand
- Femur and Tibial component type and size
- Bearing

If necessary, changes can be made in the implant selector in the top taskbar.

 Persona Partial Knee Anatomic Tibial Sizer must be used as described in standard instrumentation technique.



10.7 RESECTIONS Drawer-Error Notifications

Camera Movement During Resections (Tibia)

If the camera is moved outside a certain volume, a notification will be displayed. Reposition the camera within the registration volume and click NEXT to continue. Click CANCEL and go to SETUP to redo the registration step (Section 6.7).



Knee Movement in Stationary Mode (Femur, Tibia)

If at least one live cut value is outside 2° or 2 mm, a notification of “knee movement detected” will be displayed. Try to reposition the knee so that all checkmarks turn green. If the issue cannot be resolved, click on CANCEL, remove all pins then restart the cut flow.



Ensure the ROSA Partial Knee Cut Guide is Not Pinned to the Patient

When the surgical flow is cancelled during any bone resection, the user interface will display a notification to ensure the Cut Guide is not pinned to the patient. Remove any pins connecting ROSA Persona Partial Knee Medial Cut Guide to the patient. Click CONFIRM once the Cut Guide is unpinned.



10.8. Final Knee Evaluation

1. With trial (or final) implants in place or with the flexion-extension gap checker in place (thin side for flexion, thick side for extension), perform a final knee evaluation.
2. During Final Knee State Evaluation, place the leg in extension, perform an axial loading to simulate weight bearing and click the CAPTURE HKA button for the acquisition. HKA value will be displayed in the Surgeon Report. Please refer to Section 8 ROSA Partial Knee Application–EVALUATION Panel.



### 10.9 Removal of Instrumentations

- 1. Loosen bone reference set screws using the 3.5 mm screwdriver.
- 2. Remove the bone references from the fix fluted pins.
- 3. Remove the fix fluted pins from the patient’s bones using a power tool on the reverse setting.  
Avoid bending the pins to ensure safe removal.

### 11. Robotic Errors

#### Collision Detection

If a collision is detected in Automatic mode, the Robotic Arm will automatically stop, switch to Stationary mode and a notification will appear on the user interface.

MANUAL DISENGAGE: If the ROSA Persona Partial Knee Medial Cut Guide is pinned to the patient or if there is an obstacle in the way:

- 1. Remove pins, if applicable.
- 2. Confirm the Robotic Unit is not pinned to the patient.
- 3. Return to the RESECTIONS drawer MAIN panel.
- 4. Choose the Collaborative mode feature to manually disengage the Robotic Arm.

AUTOMATIC DISENGAGE: If there are no more obstacles, click CONTINUE to restart Automatic mode.



#### Non-Operated Leg Detection

If the Robotic Arm joint is too close to the non-operated leg when the Cut Guide is being engaged for the femoral cut in Collaborative mode, the Robotic Arm will automatically stop, switch to Stationary mode and a notification will appear on the user interface.

MANUAL DISENGAGE: If the ROSA Persona Partial Knee Medial Cut Guide is pinned to the patient or if there is an obstacle in the way:

- 1. Remove pins, if applicable.
- 2. Confirm Robotic Unit is not pinned to the patient.
- 3. Return to the RESECTIONS drawer MAIN panel.
- 4. Choose the Collaborative mode feature to manually disengage the Robotic Arm.

AUTOMATIC DISENGAGE: it there are no more obstacles, click RETRY and restart the femoral cut engage.



11. Robotic Errors (cont.)

Excessive Force on the Robotic Arm

In case of an excessive force on the Robotic Arm, a notification will appear on the user interface:

- WARNING: EXCESSIVE FORCE ON ROSA shown in bottom taskbar: the force applied is more than 70% of load limit, and the surgical flow will not be interrupted.
- ROBOTIC ERROR (pop-up window): When the force applied reaches 100% of load limit, the flow is interrupted and a procedure needs to be followed (see below).



ROSA is Realigning

This notification will appear when the leg was moved too fast and the Robotic Arm could not follow in Tracking mode. At this point, the Robotic Unit is locked in planar mode, aligned with the bone resection plane. Keep the Foot Pedal pressed, wait for the Robotic Arm to readjust (Automatic mode) and reach the bone resection plane again, then the notification will disappear. Or click CANCEL to exit the cut flow.



Cannot Reach Position

This notification will appear if the Robotic Arm can no longer reach the tibia. Verify that:

- Leg is in flexion and not in abduction or adduction
- ROSA Base Reference Frame is stable (checkpoint passes)
- Bone references have not moved since landmark selection
- If the knee was repositioned, click RETRY to resume the surgical workflow or click CANCEL to exit the cut flow



Red EMERGENCY Button

To stop the Robotic Arm at any time, press down on the red EMERGENCY button, which is located on the Robotic Unit near the base of the Robotic Arm.

1. Press down to activate.
2. Turn clockwise to release.
3. Upon the release of the EMERGENCY button, follow the Robotic Error procedure in the following section.



11. Robotic Errors (cont.)

Robotic Error

A robotic error notification will appear in case an excessive force is applied to the Robotic Arm or if the EMERGENCY button is pressed.

1. Ensure no excessive force is applied to the Robotic Arm.
2. Ensure the EMERGENCY button is released.
3. Click RESUME to resume the surgery.
4. Ensure the Robotic Unit is not pinned to the patient.
5. Click YES to confirm the automatic recalibration of Force Sensor.



11.1 Drifting of the Robotic Arm

With the Foot Pedal pressed in Collaborative mode, the Robotic Arm will move without applying any force on it. Please verify:

- Draping: make sure the draping is not pulling on the end of the Robotic Arm where the Force Sensor is located
- Force Sensor: The Force Sensor was calibrated with a tool on the Robotic Arm. Go back in the SETUP panel to re-calibrate the Force Sensor



# 12. Post-operative Guide and Maintenance

## 12.1 Retrieval of Post-Surgical Log File

### 12.1.1 Surgeon Report

The Surgeon Report is intended for research purposes and can only be requested by the surgeon. This report is generated by the ROSA Partial Knee application for each procedure and contains the following information:

- Surgeon name and surgery date
- Case ID and procedure
- Patient gender and age
- Time spent on each surgical step
- Pre-operative plan
- Each set of knee state evaluation data for initial, intra-op and final tabs
- Each set of laxity assessment results
- Intra-operative plan prior to performing the associated bone workflow
- All validated cut data
- Final implant selection



The Surgeon Report will be transferred to a USB drive provided by the surgeon. To get the Surgeon Report once the surgery is completed:

1. Close the application.
2. Click on the SURGEON REPORT button associated with the case for which the report is requested.
3. Insert a USB drive into any of the Robotic Unit’s USB ports.
4. Acknowledge that you are the surgeon responsible for this case and click NEXT.
5. Enter the PIN associated with the case.
6. Click GENERATE.



### 12.1.2 Investigation Logs

The Investigation Logs are intended for the assessment of a specific adverse event or product complaint and can only be requested by a Zimmer Biomet Complaint Handler on behalf of the hospital or surgical team. This report is generated by the ROSA Partial Knee application to provide the entire software log specific to a patient case under investigation and contains the following information:

- System computer’s identification information and list of installed programs
- System computer’s logs
- Case specific logs

### 12.1.1 Investigation Logs (cont.)

The Investigation Logs file is securely encrypted and can be transferred to a standard USB drive. To get the Investigation Logs once the surgery is completed:

1. Close the application.
2. Click the INVESTIGATION LOGS button associated with the case for which the report is requested.
3. Insert a USB drive into any of the Robotic Unit’s USB ports.
4. Acknowledge that the download is related to a specific adverse event or product complaint and click NEXT.
5. Enter the PIN associated with the case.
6. Click GENERATE.








## 12.2 Shutdown

Click the MENU button on the left of the bottom taskbar. Select QUIT to have the following three options:

- Quit and send Robotic Arm to PARK position
- Quit only
- Cancel

If a quit option is selected:


1. Wait until the system is completely shut down.
2. Turn the power switch to the “0” position.
3. Remove the power cable from the power supply plug.
4. Disconnect the Optical Unit from the Robotic Unit.
5. Clean the Robotic and Optical Units (refer to Section 12.3).


-  Risk of collision: When the Robotic Unit is in Automatic mode, stay clear of the Robotic Arm and its path to the next position.
-  By quitting the ROSA Partial Knee application, the user interface will return to the case management application (refer to Section 4.6. Case Management Application). Click SHUTDOWN to power down the device.
-  Wait 10 seconds after the Touchscreen goes dark before turning the power switch of the device to “0” for the operating system to shut down properly.
-  To restart the device, wait at least 10 seconds after shutting down and for the RESET button light to turn off completely.
-  All wastes and residues must follow the hospital recycling guidelines.

12.3 Cleaning, Disinfection and Sterilization

12.3.1 Cleaning the Robotic and Optical Units

Make sure the device is turned off and unplugged before cleaning. After each use, clean the covers, panels and the Robotic Arm with a damp cloth with mild disinfectant, ethanol (70%) or Isopropyl Alcohol (70%). Use a mild alkaline detergent if necessary, to remove scuffs and stains. Do not use any solvents, which may damage or discolor paint finishes or plastic components. Read the labels of the cleaning products carefully. Both the cloth and the cleaning product must be approved for use in an operating room. Robotic and Optical Units are not waterproof. Be careful not to spill or splash liquids where they can enter electronic assemblies.

- 

Never attempt to clean the device when it is connected to power supply. To avoid electrical discharges, always unplug the device from the wall outlet before cleaning or disinfecting it.
- 

IPX0 protection: the device does not have special protection against the penetration of liquids. Do not pour any liquid over the device.

12.3.2 Cleaning the Optical Camera

Camera Housing


Clean the camera housing only if required. Clean the whole surface of the camera using a lint-free, soft cloth dampened with a non-abrasive with mild disinfectant, ethanol (70%) or Isopropyl Alcohol (70%).


Illuminator Filters and Lenses

Clean the illuminator filters and lenses only if required. Carefully wipe them using a damp cloth (Isopropyl Alcohol 70%) that is suitable for optical glasses. Remove fingerprints and pay attention not to cause damage or scratches.



12.3.3 Instrument Reprocessing (Cleaning and Sterilization Methods)

- 

Before every surgery, the user must verify that all instruments have been sterilized.
- 

For reusable instruments, also refer to the Orthopaedic Reusable Devices: Instructions for Care, Cleaning, Maintenance and Sterilization (97-5000-170-00) and Reusable Instrument Lifespan Manual (1219.1).

12.3.3.1 Sterilization Parameters

Steam Sterilization (Autoclave)

Cycle Type	Temperature <sup>1</sup>	Exposure Time <sup>1</sup>	Minimum Dry Time <sup>2</sup>	Minimum Cool Time <sup>3</sup>
Pre-Vacuum	132 °C (270 °F)	4 minutes	30 minutes	30 minutes

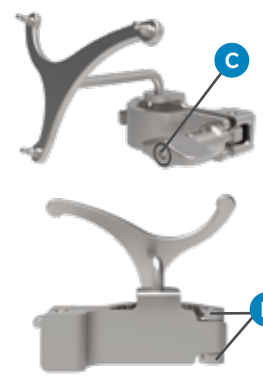


<sup>1</sup> Both the given cycle temperature and time can be increased to 134°C + 3°C (273.2°F + 5.4°F) and 18 minutes according to local requirements outside of the United States such as in the European Union.

<sup>2</sup> Drying times vary according to load size and should be increased for larger loads.




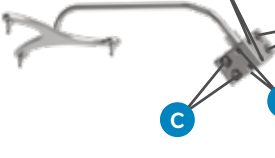
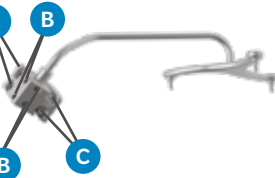
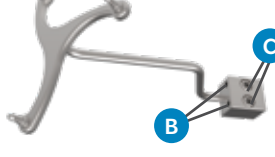

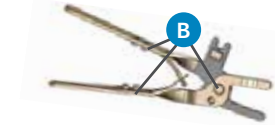
<sup>3</sup> Cooling times vary according to the type of sterilizer used, device design, temperature and humidity of environment, and type of packaging used. Cooling process should comply with ANSI/AAMI ST79.

12.3.3.2 ROSA Partial Knee System Instrument Kit



- A. Requires disassembly
- B. Requires water jet to flush difficult-to-access areas
- C. Screw/unscrew components while flushing the area
- D. Requires a minimum of 10 minutes ultrasonic cleaning cycle in an enzymatic solution
- E. Screws/mechanisms should be checked and lubricated with a medical grade surgical lubricant after each cleaning as determined upon inspection.

Instrument	Description	Sterilization & Specific Cleaning Instructions	Part Number
	<b>ROSA Base Reference Frame</b> * Sterilization and specific cleaning instructions apply both for short and long ROSA Base Reference Frames	Autoclave <b>B C D E</b>	20-8020-002-00
	<b>ROSA Arm Instrument Interface</b>	Autoclave <b>B D E</b>	20-8020-004-00
	<b>ROSA PPK MED Cut Guide A-L</b> <b>ROSA PPK MED Cut Guide A-R</b> <b>ROSA PPK MED Cut Guide B-L</b> <b>ROSA PPK MED Cut Guide B-R</b>	Autoclave <b>B D E</b>	20-8020-030-00 20-8020-031-00 20-8020-032-00 20-8020-033-00

12.3.3.2 ROSA Partial Knee System Instrument Kit (cont.)

Instrument	Description	Sterilization & Specific Cleaning Instructions	Part Number
	ROSA Registration Pointer	Autoclave <b>D</b>	20-8020-013-00
	ROSA Arm Reference Frame	Autoclave <b>B D E</b>	20-8020-015-00
	ROSA PKA Validation Tool	Autoclave <b>B C D E</b>	20-8020-034-00
	ROSA Tibia Reference A	Autoclave <b>B C D E</b>	20-8020-028-00
	ROSA Tibia Reference B	Autoclave <b>B C D E</b>	20-8020-029-00
	CAS 2 Pins Reference Femur – TS3	Autoclave <b>B C D E</b>	20-8000-010-33
	CAS Offset 2 Pins Reference Right Tibia Size 6	Autoclave <b>B C D E</b>	20-8000-010-35
	CAS Offset 2 Pins Reference Left Tibia Size 6	Autoclave <b>B C D E</b>	20-8000-010-36
	Hexagonal Screwdriver 3.5 mm	Autoclave <b>D</b>	00-5120-087-00
	CAS NavitrackER Pliers	Autoclave <b>B D E</b>	20-8000-070-05

12.3.3.2 ROSA Partial Knee System Instrument Kit (cont.)

Instrument	Description	Sterilization & Specific Cleaning Instructions	Part Number
	Persona Partial Knee spacer block (8-9-10-12-14 mm)	Refer to 1222.6-GLBL-en Persona Partial Surgical Technique	
	Persona Partial Knee flexion/extension gap checkers (8-9-10-12-14 mm)	Refer to 1222.6-GLBL-en Persona Partial Surgical Technique	

Disposables

Description	Sterilization & Specific Cleaning Instructions	Part Number
NavitrackER Kit A - Knee	Provided sterile (single use)	20-8000-000-07
Fix Fluted Pin 3.2x150 mm	Autoclave (single use)	20-8000-000-01
Fix Fluted Pin 3.2x80 mm	Autoclave (single use)	20-8000-000-02
Fix Fluted Pin 3.2x150 mm	Provided sterile (single use)	20-8000-000-10
Fix Fluted Pin 3.2x80 mm	Provided sterile (single use)	20-8000-000-11
Trocar Tipped Drill Pin (2.5 mm hex) 3.2x75 mm (Persona)	Provided sterile (single use)	00-5901-020-00
CAS 3.2 mm Headless Trocar Drill Pin	Autoclave (single use)	20-8000-000-16
MIS Headed Screw, 48 mm	Provided sterile (single use)	00-5983-040-48

12.3.3.3 ROSA Partial Knee System Instrument Lifetime Expectancy

The reusable instruments of the ROSA Partial Knee System have a lifetime of five years under normal use, estimated at 500 surgeries over five years. For disposal of reusable instruments, please refer to the Reusable Instrument Lifespan Manual (1219.1).

12.4 Storage and Transport

12.4.1 Storage and Protection

12.4.1.1 Device Storage and Protection

At the end of the procedure, the device should be stored in an area fulfilling the storage conditions defined in the technical specifications.

In order to preserve the device, it should be stored in an area where there is no traffic and where it will not be exposed to fluids. The device must not be placed on sloping ground without the assurance of its stability. The immobilization system may be used during storage. During storage, ensure that the Touchscreen is folded above the Robotic Unit so it is protected in the event of a collision.



12.4.1.2 Instruments Storage and Protection

The instruments shall remain protected from all impacts during handling and storage. Special care should be taken for all instruments because any damage whatsoever may directly affect the registration accuracy and the positioning accuracy of instruments on a planned trajectory.

12.4.1.3 Care of Cables and Connectors

To avoid damage to cables, make sure the cables are not bent at sharp angles. Handle the connectors with care, paying particular attention to the following points:

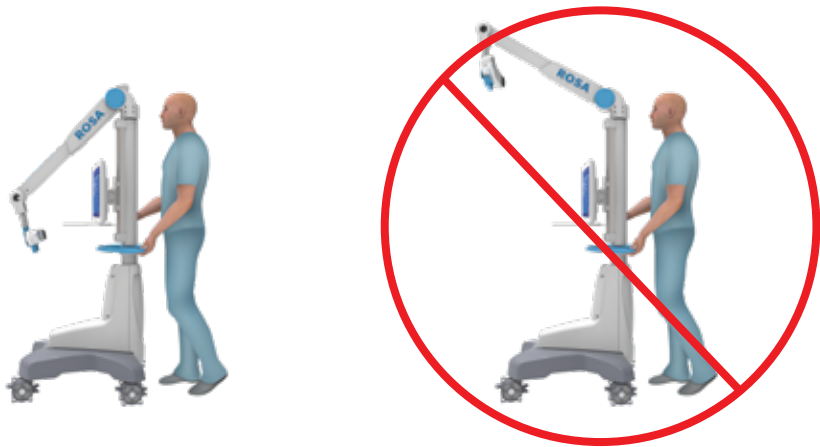
- Pull connections apart by gripping the connector. Do not pull them apart by tugging on the cable as this can damage the connecting cable and connector pins
- Do not leave cable connectors where they will get damaged, particularly on the floor, where they can easily be stepped on or rolled over by heavy equipment
- Do not put heavy objects on cables or cable connectors
- Never force a connection

12.4.1.3 Care of Cables and Connectors (cont.)

- ⚠ Do not connect any elements to the Robotic Unit other than those provided with the device.
- ⚠ In order to prevent accidental detachment of a connector and to ensure EMC protection, make sure that the metallic ring of the Optical Unit cable is attached to the hook on the Rear Panel of the Robotic Unit, if applicable.
- ⚠ For safety reasons and to ensure proper functioning of the device, do not use cables other than those distributed by Zimmer Biomet.

12.4.2 Device Transport

When transporting the Robotic Unit, ensure that the Touchscreen is folded above the Robotic Unit so it is protected in the event of a collision.



When transporting the Optical Unit, ensure that the camera is folded following the indications below so it is protected in the event of a collision.

Transporting the device from one site (building) to another is performed only under the responsibility of the user. Any damages or malfunctions eventually caused during transportation are not covered by Zimmer Biomet.

- ⚠ During transportation, the device can be immobilized by activating the immobilization pedal. Do not install the device on an inclined surface, unless its stability is guaranteed.
- ⚠ Activate the brakes of the wheels of the Optical Unit to ensure its immobilization.
- ⚠ Transportation or displacement of the device can be handled by one person.

12.5 Maintenance Operations

12.5.1 Installation

The device is installed on-site by Zimmer Biomet personnel only or by its approved representatives. The installation requires expert knowledge of the device by the personnel.

12.5.2 Daily Checks

- Regularly perform a safety check of the device. Inspect the device to ensure no defects appear on the:
- Robotic Unit, including the Robotic Arm
  - Optical Unit
  - Optical Camera
  - Force Sensor Connector
  - Immobilization system and locks of Robotic Unit
  - Foot Pedal
  - Instruments

These safety checks are recommended to be done each day of use. Check the instrument’s physical condition to ensure no defects are present. Never use a distorted or damaged component.

12.5.3 Periodic Maintenance

The useful life of the product has been established at 10 years based on system testing with regular preventive maintenance performed by a qualified Zimmer Biomet Field Service Engineer or authorized Service Provider on a schedule set forth in a service plan. The established service plan covers the frequency of the preventive maintenance, every 6 months at a minimum, and identifies the different checks and tests performed. To effectuate the service plan, either a maintenance agreement for preventive and corrective maintenance may be established between the customer and Zimmer Biomet, or the customer may engage Zimmer Biomet on an event-by-event service basis, as determined by Zimmer Biomet and the customer.

Zimmer Biomet Customer Service is committed to dealing with any operational defects that may appear on the device during its useful life. Please contact your company representative before the unit reaches its end of useful life to discuss available options.

- ⚠ Do not open the device. In case of any issue or breakdown, do not intervene. Maintenance and service operations must only be carried out by Zimmer Biomet Customer Service or any of its approved representatives. Do not modify the device.
- ⚠ When used in compliance with the indications for maintenance, the device can be run in permanent operation.

12.6 Troubleshooting

Issue	Cause	Solution
The device does not turn on	The Power Cable is unplugged	Check that the Power Cable is connected
	The ON/OFF switch is turned to OFF	Turn the switch located on the back panel of the device to ON
	Electric current is cut off by an external circuit breaker	Press on the circuit breaker button to reset it
	Electric current is cut off by an internal circuit breaker	Contact Zimmer Biomet Customer Service
The Touchscreen does not work	The screen is off	Turn the Touchscreen on by pressing on the button to the right side of the screen
	The screen Power Cable is unplugged	Ensure that the power, video and USB Touchscreen cables are connected
	The video cable is unplugged	
	The USB cable is unplugged	
	The screen displays the message “No video input” and then goes black. The RESET button indicator located on the Rear Panel of the device is red	Press the “RESET” button on the back panel of the device and check that the RESET button indicator is blue
	The actions of the application do not correspond to the buttons activated The Touchscreen is not calibrated	Contact Zimmer Biomet Customer Service
	The Touchscreen behavior is sporadic, ie some touches on the screen are not working	Contact Zimmer Biomet Customer Service
The CD/DVD reader does not operate	CD/DVD is unplugged and non-functional	CD/DVD cannot be used
A USB port does not work	USB port faulty	Try another USB port. Inform Zimmer Biomet Customer Service
	Connection problem with the USB port	
Case data cannot be uploaded with the USB flash drive	Case data is corrupted	Download the case data on the USB drive and sync again with the device. If unsuccessful, switch to imageless
	USB drive is faulty	Download the case data on new USB drive and sync again with the device. If unsuccessful, switch to imageless

12.6 Troubleshooting (cont.)

Issue	Cause	Solution
The Robotic Unit immobilization system does not work	The immobilization pedal cannot go through its full range down to its locked position	Check that there is no obstacle under the stabilization feet
The Robotic Arm movement is interrupted	The device indicates detection of a collision. An unsuitable tool is installed on the Robotic Arm. The tool does not correspond to the current stage in the procedure	Ensure that the tool installed corresponds to the current stage in the procedure. Restart the movement
	The device indicates that the user interrupted movement. The Foot Pedal is turned off	Check that the Foot Pedal is connected into the Rear Panel of the device
	The light on the RESET button on the back of the device is off and the Foot Pedal doesn't work	Contact Zimmer Biomet Customer Service
The Robotic Arm drifts slowly in Collaborative mode	An unsuitable tool is installed on the Robotic Arm. The tool does not correspond to the current stage in the procedure	Stop the Collaborative mode. Check that the tool installed corresponds to the current stage of the procedure. Launch Collaborative mode once again
	The tool is in contact with an object	Ensure that the elements secured to the Robotic Arm are not in contact with an external object
The interface displays a communication error message with the Robotic Unit	The Force Sensor Cable is unplugged	Connect the cable to the Force Sensor. Restart the device
	The Red EMERGENCY button has been activated and the Robotic Unit remains off	Deactivate the Red EMERGENCY button and restart the device
	The Robotic Arm is not ready to communicate with the application	The device may take up to three minutes after being switched ON for the application to communicate with the Robotic Arm. Once the three minutes has passed, press the RESUME button in the application
	The robotic PC is not powered on correctly. The RESET button indicator located on the Rear Panel of the device is red	Press the RESET button on the Rear Panel of the device and check that the RESET button indicator is blue. Then, wait three minutes to ensure the application is ready to communicate with the Robotic Arm. If the button remains red, power OFF the system completely and wait for one minute before powering it ON again

12.6 Troubleshooting (cont.)

Issue	Cause	Solution
The registration is unsuccessful	Trackers not seen	Make sure the trackers are visible during the registration
	Movement of the Robotic Unit	Verify that the Robotic Unit is immobilized (each wheel and the main immobilization system) during the registration
	Movement of the camera	Verify that the Optical Unit is immobilized during the registration
	ROSA Base Reference Frame was not installed properly	Make sure the ROSA Base Reference Frame is firmly tighten
	ROSA Arm Reference Frame was not installed properly	Make sure the ROSA Arm Reference Frame is firmly tighten
	ROSA Arm Instrument Interface was not installed properly	Make sure the ROSA Arm Instrument Interface is firmly tighten
	NavitrackER devices were not installed properly	Make sure the NavitrackER devices are fully seated on the instruments
The Cut Guide checkpoint is unsuccessful	Wrong Cut Guide installed	Check that you have the correct Cut Guide (operated knee and Robotic Unit/ surgeon on the left or right side of the patient)
	Cut Guide is loosely installed	Check that the ROSA Persona Partial Knee Medial Cut Guide is firmly tightened
	ROSA Base Reference Frame has moved	Redo ROSA registration
The EMERGENCY RED button light is on	The Red EMERGENCY button has been activated	Release the Red EMERGENCY button and restart the device
	The redundancy check of the Foot Pedal triggered an error	Shut down the device and restart

12.7 Product Security Customer Control Considerations

12.7.1 Records Retention and Purging Historical Data


The ROSA Recon Platform will be located at the Healthcare Delivery Organization (HDO) facility and is subject to the regulatory requirements and records retention period. After this period and upon request by the HDO, Zimmer Biomet field service engineers will assist the HDO with purging historical data from the ROSA Recon Platform.


12.7.2 Physical and Environmental Security Controls


The ROSA Recon Platform will be located at the Healthcare Delivery Organization (HDO) facility and is subject to the HDO’s physical and environmental safeguards to mitigate the risks of loss, theft, and physical tampering. ROSA Recon Platform should be stored in a location at the HDO with physical access control to authorized personnel only when not in use.




13. Technical Data

- 

The device requires specific precautions regarding the EMC. It must be installed and operated according to the EMC information provided in the User Manual.
- 

Portable and mobile radio frequency communication devices might affect the operation of the device.
- 



Usage of accessories, transducers and cables other than those specified in the User Manual, with the exception of the transducers and cables sold by Zimmer Biomet (as spare parts of internal components), might cause increased emissions or decrease immunity of the device.
- 

The device must not be used adjacent to or stacked on top of any other equipment. If inevitable, verify its perfect operation in the corresponding configuration.

13.1 Labels & Symbols


13.1.1 Labels

The device labels affixed on the device components are detailed below. Bar codes and 2D Matrix are examples only.

System	Countries	Robotic Unit Label Example
110V	US, Canada, Taiwan	
220V	Australia, Austria, Belgium, China, France, Germany, Greece, Hong Kong, India, Israel, Italy, Netherlands, New Zealand, Singapore, Spain, Switzerland, UAE,UK.	

\* The countries list is not exhaustive and only provides examples where the System could be used. Please contact your local support to determine availabilities in your region.

13.1.1 Labels (cont.)

System	Countries	Robotic Unit Label Example
100V	Japan	

\* The countries list is not exhaustive and only provides examples where the System could be used. Please contact your local support to determine availabilities in your region.



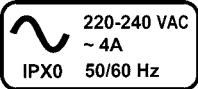
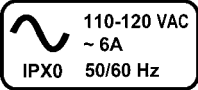
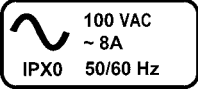







Optical Unit Label Example









Translation Label Examples

System	Robotic Unit Label Example
Robotic Unit 110V	<div><div><div>ROSA® Recon Platform</div><div>Robotic Unit 110V</div><div><div>REF</div>20-8020-110-01</div></div><div><div>http://labeling.zimmerbiomet.com</div><div><div><div></div><div>i</div></div></div></div><div><div>(FR) ROSA® Plateforme de reconstruction</div><div>(IT) ROSA® Piattaforma di ricostruzione</div><div>(DE) ROSA® Rekonstruktionsplattform</div><div>(NL) ROSA® reconstructieplatform</div><div>(EL) ROSA® Πλατφόρμα ανακατασκευής</div><div>(ES) ROSA® Plataforma de reconstrucción</div><div>(DA) ROSA® Recon platform</div><div>(SV) ROSA® rekonstruktion plattform</div><div>(PT) ROSA® Plataforma de reconstrução</div></div><div><div>- Station robotique 110V</div><div>- Unità robotica 110V</div><div>- Robotereinheit 110V</div><div>- Robot-eenheid 110V</div><div>- Ρομποτική μονάδα 110V</div><div>- Unidad robótica 110V</div><div>- Robotenhet 110V</div><div>- Robotenhet 110V</div><div>- Unidade robótica 110V</div></div><div><div>Label PN: LBB-20-8020-110-01 Rev. A</div></div></div>
Robotic Unit 220V	<div><div><div>ROSA® Recon Platform</div><div>Robotic Unit 220V</div><div><div>REF</div>20-8020-110-26</div></div><div><div>http://labeling.zimmerbiomet.com</div><div><div><div></div><div>i</div></div></div></div><div><div>(FR) ROSA® Plateforme de reconstruction</div><div>(IT) ROSA® Piattaforma di ricostruzione</div><div>(DE) ROSA® Rekonstruktionsplattform</div><div>(NL) ROSA® reconstructieplatform</div><div>(EL) ROSA® Πλατφόρμα ανακατασκευής</div><div>(ES) ROSA® Plataforma de reconstrucción</div><div>(DA) ROSA® Recon platform</div><div>(SV) ROSA® rekonstruktion plattform</div><div>(PT) ROSA® Plataforma de reconstrução</div></div><div><div>- Station robotique 220V</div><div>- Unità robotica 220V</div><div>- Robotereinheit 220V</div><div>- Robot-eenheid 220V</div><div>- Ρομποτική μονάδα 220V</div><div>- Unidad robótica 220V</div><div>- Robotenhet 220V</div><div>- Robotenhet 220V</div><div>- Unidade robótica 220V</div></div><div><div>Label PN: LBB-20-8020-110-26 Rev. A</div></div></div>
Robotic Unit 100V	<div><div><div>ROSA® Recon Platform</div><div>Robotic Unit 100V</div><div><div>REF</div>20-8020-110-17</div></div><div><div>http://labeling.zimmerbiomet.com</div><div><div><div></div><div>i</div></div></div></div><div><div>(FR) ROSA® Plateforme de reconstruction</div><div>(IT) ROSA® Piattaforma di ricostruzione</div><div>(DE) ROSA® Rekonstruktionsplattform</div><div>(NL) ROSA® reconstructieplatform</div><div>(EL) ROSA® Πλατφόρμα ανακατασκευής</div><div>(ES) ROSA® Plataforma de reconstrucción</div><div>(DA) ROSA® Recon platform</div><div>(SV) ROSA® rekonstruktion plattform</div><div>(PT) ROSA® Plataforma de reconstrução</div></div><div><div>- Station robotique 100V</div><div>- Unità robotica 100V</div><div>- Robotereinheit 100V</div><div>- Robot-eenheid 100V</div><div>- Ρομποτική μονάδα 100V</div><div>- Unidad robótica 100V</div><div>- Robotenhet 100V</div><div>- Robotenhet 100V</div><div>- Unidade robótica 100V</div></div><div><div>Label PN: LBB-20-8020-110-17 Rev. A</div></div></div>
Optical Unit	<div><div><div>ROSA® Recon Platform</div><div>Optical Unit</div><div><div>REF</div>20-8020-120-01</div></div><div><div>http://labeling.zimmerbiomet.com</div><div><div><div></div><div>i</div></div></div></div><div><div>(FR) ROSA® Plateforme de reconstruction</div><div>(IT) ROSA® Piattaforma di ricostruzione</div><div>(DE) ROSA® Rekonstruktionsplattform</div><div>(NL) ROSA® reconstructieplatform</div><div>(EL) ROSA® Πλατφόρμα ανακατασκευής</div><div>(ES) ROSA® Plataforma de reconstrucción</div><div>(DA) ROSA® Recon platform</div><div>(SV) ROSA® rekonstruktion plattform</div><div>(PT) ROSA® Plataforma de reconstrução</div></div><div><div>- Station optique</div><div>- Unità ottica</div><div>- Optikeinheit</div><div>- Optische eenheid</div><div>- Οπτική μονάδα</div><div>- Unidad óptica</div><div>- Optisk enhed</div><div>- Optisk enhet</div><div>- Unidade ótica</div></div><div><div>Label PN: LBB-20-8020-120-01 Rev. A</div></div></div>





13.1.2 Symbols on the Labels

Label	Description
	Caution
	Refer to instruction manual/booklet
	Power supply specifications for concerned countries (ex: Germany, France). IPX0: No protection against liquids
	Power supply specifications for concerned countries (ex: USA, Canada). IPX0: No protection against liquids
	Power supply specifications for concerned countries (Japan). IPX0: No protection against liquids
	BF type device
	MR Unsafe: Keep away from Magnetic Resonance Imaging (MRI) equipment
	Federal law restricts this device to sale by or on the order of a physician
	European market authorization
	Bureau Veritas/Curtis-Straus nationally recognized testing laboratories mark, with “US” and “C” identifiers, for USA & Canada
	Regulatory Compliance Mark (RCM) for Australia and New Zealand
	Manufacturer’s name and address








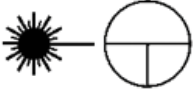

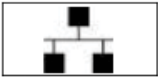

13.1.2 Symbols on the Labels (cont.)

Label	Description
	Manufacturing date
	Authorized representative in the European Community
	Product reference
	Serial number
	Device weight
	The equipment should not be disposed of in the normal waste stream

13.1.3. Other Symbols on the Device







Label	Location	Description
	Bottom of Robotic Unit Rear Panel	OFF – Switch off the device
	Bottom of Robotic Unit Rear Panel	ON – Switch on the device
	Bottom of Robotic Unit Rear Panel	Central unit RESTART button
	Bottom of Robotic Unit Rear Panel	Foot Pedal socket

13.1.3 Other Symbols on the Device (cont.)

Label	Location	Description
	Bottom of Robotic Unit Rear Panel	Socket for black RJ45 cable of Optical Unit wiring
	Bottom of Robotic Unit Rear Panel	Socket for white RJ45 cable of Optical Unit wiring
	Bottom of Robotic Unit Rear Panel	Socket for Optical Unit main cord
	Bottom of Robotic Unit Rear Panel	Controller servicing port (deactivated)
	Bottom of Robotic Unit Rear Panel	Robotic Unit immobilization system Move lever up/down to unlock/lock
	Bottom cover of Robotic Unit, above stabilization feet	Risk of foot crushing
	Middle of Robotic Unit Rear Panel	Distance sensor on/off symbol. Not applicable for Knee application (deactivated)
	Camera handle on Optical Unit	Optical sensor laser pointer ON/OFF symbol. OFF is a stable position, whilst the ON position only remains during the time the button is depressed
	Middle of Robotic Unit Rear Panel	USB port
	Middle of Robotic Unit Rear Panel	Ethernet socket symbol. Not applicable for Knee application (deactivated)
	Middle of Robotic Unit Rear Panel	Do not use USB ports for charging a cell phone. Connection for USB drive, keyboard and mouse only



13.1.3 Other Symbols on the Device (cont.)

Label	Location	Description
	Middle of Robotic Unit Rear Panel	Do not use USB ports for connecting a wireless device. Connection for USB drive, keyboard and mouse only
	Top cover of Robotic Unit	Emergency stop
	Rear of Touchscreen on Robotic Unit	Stored energy hazard
	Optical Unit	Lock Optical Unit in place using the brake on all four wheels
	Optical Unit	Fold the camera arm for transportation
	Rear of camera on the right	Laser beam – Never look directly at the laser beam – Class II laser

13.2 Technical Specifications

13.2.1 Environmental Specifications

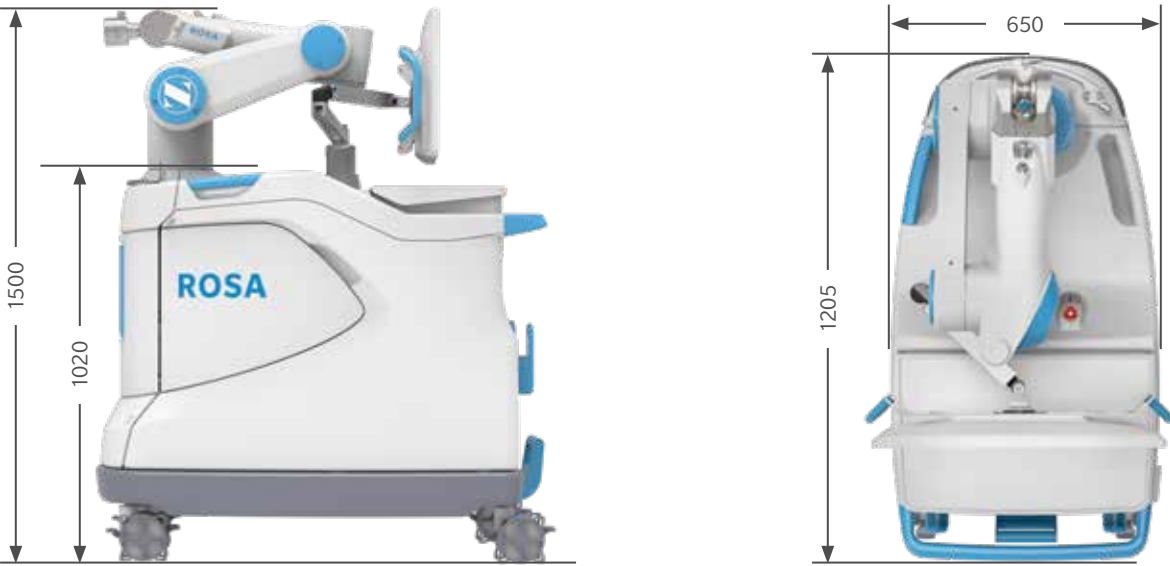
Environment	Storage and Transportation	Operating
Temperature	0°C to 50°Celsius	15°C to 35°Celsius
Relative Humidity	8% to 93% (without condensation)	8% to 75% (without condensation)
Air pressure	800 hPa to 1060 hPa	800 hPa to 1060 hPa

13.2.2 Device Performances

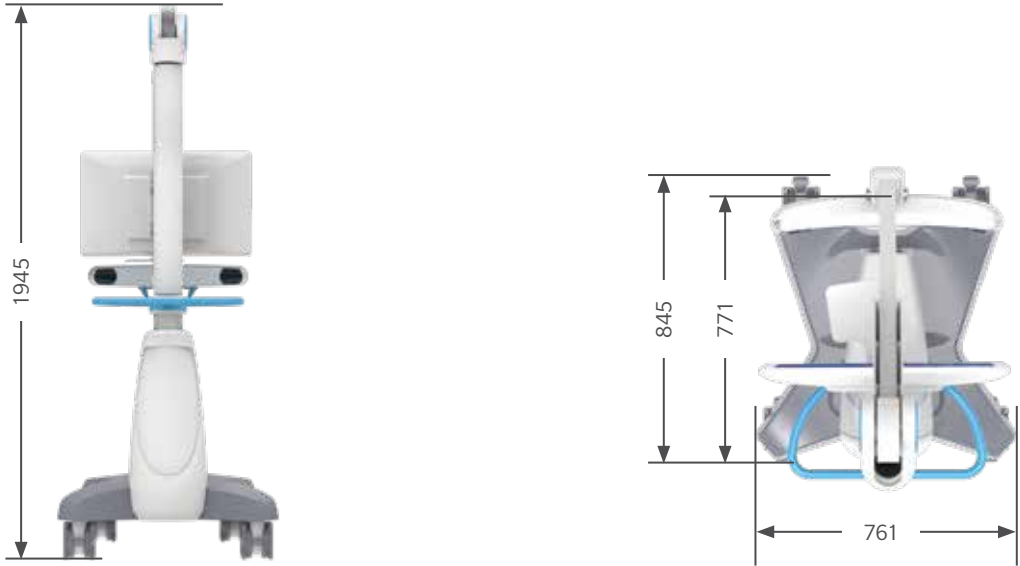
Device Performance	Value
Robotic Arm positioning accuracy	< 0.75 mm RMS

13.2.3 Device Dimensions

The device has the following exterior dimensions in millimeters.



Robotic Unit Dimensions

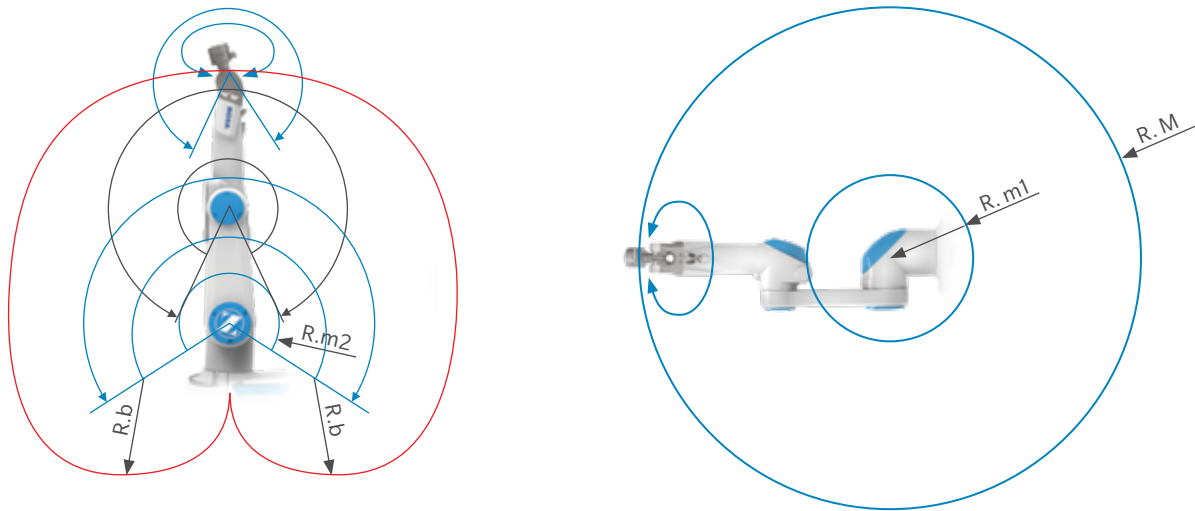


Optical Unit Dimensions

Robotic Unit weight: Approximately 320kg (705 lb)  
Optical Unit weight: Approximately 140 kg (309 lb)

13.2.4 Robotic Arm Working Range

ROSA Partial Knee is equipped with a Stäubli 6-axis Robotic Arm and has 6° of freedom.



Robotic Arm Working Range

Dimension	Value
Maximum radius between joint 1 and 5 (R.M)	850 mm
Minimum radius between joint 1 and 5 (R.m1)	209 mm
Minimum radius between joint 2 and 4 (R.m2)	208 mm
Minimum radius between joint 3 and 5 (R.b)	450 mm

13.3 Safety Classification

The safety classifications are provided in table below.

Type	Classification
Protection against electric shock	Class 1 Patient protection = type BF applied part
Protection against ingress of fluids	Robotic Unit = IPX0 Optical Unit = IPX0 Footswitch = IP68
Protection against laser beam	Navigation camera = Class 2

13.3.1 Cable Lengths

Cable and accessories	Maximum Length	Type of tests	In accordance with
Power Cable Foot Pedal Cable	>3m >3m	RF Emissions	CISPR, Classe A
		Harmonic current	IEC 61000-3-2
		Voltage fluctuations/Flicker	IEC 61000-3-3
Optical Unit Main Cord Force Sensor Cable	>3m <3m	Electrostatic discharge immunity	IEC 61000-4-2
		Radiated immunity – electromagnetic fields	IEC 61000-4-3
		Electrical fast transient/burst immunity test	IEC 61000-4-4
		Surge immunity test	IEC 61000-4-5
		Conducted immunity - Conducted RF	IEC 61000-4-6
		Radiated immunity - Magnetic field	The electromagnetic field strengths of fixed radio frequency transmitters
		Downtimes, dips and variation of the power supply voltage	The electromagnetic field strengths of fixed radio frequency transmitters

13.4 Electromagnetic Compatibility

All the information below is based on the normative requirements to which the manufacturers of Electrical Medical devices are subjected to, in regards with IEC60601-1-2. The medical device complies with applicable electromagnetic compatibility standards, however, the user will ensure that any electromagnetic interference does not create an additional hazard, such as radio frequency transmitters or other electronic devices. In this section, you will find information necessary to ensure the installation and commissioning of your medical device under the best conditions in terms of electromagnetic compatibility.

The different cords of the medical device must be separated from each other. Certain types of mobile telecommunication devices, such as mobile phones, are likely to interfere with the medical device. The separation distances recommended in this chapter must therefore be strictly observed. The medical device must not be used near or on another device. If this cannot be avoided, it must be checked for proper operation under the conditions of use before use. The use of accessories other than those specified or sold by Zimmer CAS as replacement parts, may result in an increase in the emission or a reduction of the immunity of the medical device.

13.4.1 Electromagnetic (EM) Emissions

The device has been designed for use in an electromagnetic environment as specified below. The user must ensure that it operates in this type of environment.

Emission trials	Conformity	Electromagnetic Environment - Guide
RF emissions CISPR 11 <sup>(1)</sup>	Group 1	The ROSA Recon Platform is part of CISPR11 group 1. The ROSA Recon Platform uses RF energy as below: Wi-Fi in the 2.4 GHz band (2400 to 2483,5MHz) or in the 5.0GHz band (5150 to 5250MHz; 5250 to 5350MHz and 5470 to 5725MHz) as a mean of radio communication (5GHz band being restricted to indoor use only). Emission powers in the 2.4GHz band do not exceed 19.92dBm, compliant with ETSI EN 300 328 Emission powers in the 5.0GHz band do not exceed 22.97dBm, compliant with ETSI EN 301 893 The ROSA Recon Platform uses a dipole antenna.
RF emissions CISPR 11 <sup>(1)</sup>	Class A	This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

<sup>(1)</sup>The emission characteristics of this device make it suitable for use in industrial areas and hospitals (class A defined in CISPR 11). When used in a residential environment (for which class B defined in CISPR 11 is normally required), this device may not provide adequate protection for radio frequency communications services. The user may need to take mitigation measures, such as relocating or reorienting of the device.

Ensuring that the system operates in the above environment will maintain basic safety and essential performance with regard to electromagnetic disturbances for the expected service life.

See System information in the Case management application for FCC identifier.



BE	LU	NL	FR	DE
IT	DK	IE	UK	EL
ES	PT	AT	FI	SE
CY	EE	HU	LV	LT
MT	PL	SI	SK	CZ
BG	RO	HR		
NO	CH	IS	LI	

13.4.1 Electromagnetic (EM) Emissions (cont.)

Reference	Performance Specification	If Lost or Degraded due to EM Disturbances
Essential Performance 1	Accurate information display	Information display not accurate
Essential Performance 2	Accurate robot Positioning	Robot positioning not accurate
Basic Safety 1	Collision detection	Collision detection feature affected
Basic Safety 2	No unwanted robot motion	Unwanted robot motion could occur

Using the ROSA Partial Knee with other products or components unless such other products or components are expressly recognized as compatible with the system could affect basic safety and essential performance in terms of EM disturbances.

13.5 Electromagnetic Immunity

The device has been designed for use in an electromagnetic environment such as specified below. The user must ensure that it operates in this type of environment.

13.5.1 Electromagnetic and Magnetic Immunity

Electromagnetic Immunity			
ROSA Partial Knee is intended for use in a professional healthcare facility environment. The user of ROSA Partial Knee should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level of the ROSA Knee	Electromagnetic Environment Guide
Electrostatic discharge (ESD) EN 61000-4-2	±8 kV contact (direct, indirect horizontal, indirect vertical) ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact  ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Main power quality should be that of a professional healthcare facility environment
Electrical fast transient/burst Signal input/output parts PORT (L> 3m) IEC 61000-4-4	± 1 kV/100 Hz	± 1 kV/100 Hz	Main power quality should be that of a professional healthcare facility environment
Electrical fast transient/burst Input a.c power PORT IEC 61000-4-4	± 2 kV/ 100 Hz	± 2 kV/ 100 Hz	
Surge Input a.c power PORT IEC 61000-4-5	± 0,5 kV, ±1 kV line to line  ± 0,5 kV, ±1 kV, ± 2 kV line to ground	± 0,5 kV, ±1 kV line to line  ± 0,5 kV, ±1 kV, ± 2 kV line to ground	Main power quality should be that of a professional healthcare facility environment



13.5.1 Electromagnetic and Magnetic Immunity (cont.)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level of the ROSA Knee	Electromagnetic Environment Guide
Voltage dips Input a.c power PORT EN 61000-4-11	0% U <sub>T</sub> for 0.5 cycles At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°  0% U <sub>T</sub> for 1 cycles and 70% U <sub>T</sub> for 25\30 cycles (500ms) Single phase: at 0°	0% U <sub>T</sub> for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0,5 cycle  0% U <sub>T</sub> for 1 cycle and 70% U <sub>T</sub> for 25/30 cycles (500ms) Single phase: at 0°	Main power quality should be that of a professional healthcare facility environment. If the user of device requires continued operation during power outages, it is recommended that the device be powered from an uninterruptible power supply or a battery
Voltage interruptions EN 61000-4-11	0 % U <sub>T</sub> For 250\300 cycles	0 % U <sub>T</sub> For 250\300 cycles	
RATED power frequency (50\60 Hz) magnetic field Enclosure port IEC61000-4-8	30 A/m³ 50 Hz and 60 Hz	30 A/m³ 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a professional healthcare facility environment

Note: UT is the a.c. main voltage prior to application of the test level.

ª Using a minimum distance of 15cm between the ROSA Partial Knee device and source of power frequency magnetic field.

13.5.2 Electromagnetic Immunity and Portable and Mobile Radio Frequency (RF) Communication Equipment

Electromagnetic Immunity Conducted and Radiated RF			
ROSA Partial Knee is intended for use in a professional healthcare facility environment. The user of ROSA Partial Knee should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level of the ROSA Knee	Electromagnetic Environment Guide
Conducted disturbances induced by RF fields Signal input/output parts PORT (L > 0m) IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V 150 kHz to 80 MHz	Main power quality should be that of a professional healthcare facility environment  Warning: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ROSA Knee device, including cables specified by the manufacturer  Otherwise, degradation of the performance of this equipment could result
	6V in ISM <sup>d</sup> band and band between 0.15MHZ and 80MHZ including amateur radio band	6V in ISM <sup>d</sup> band and band between 0.15MHZ and 80MHZ including amateur radio band	
	80% MA at 1KHz	80% MA at 1KHz	
Conducted disturbances induced by RF fields Input a.c power PORT IEC 61000-4-6	3 V 150 kHz to 80 MHz	3 V 150 kHz to 80 MHz	
	6V in ISM <sup>d</sup> band and band between 0.15MHZ and 80MHZ including amateur radio band	6V in ISM <sup>d</sup> band and band between 0.15MHZ and 80MHZ including amateur radio band	
	80% MA at 1KHz	80% MA at 1KHz	
Radiated RF electromagnetic field IMMUNITY Enclosure port IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	Main power quality should be that of a professional healthcare facility environment  Warning: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ROSA Knee device, including cables specified by the manufacturer  Otherwise, degradation of the performance of this equipment could result
IMMUNITY to proximity fields from RF wireless communications equipment Enclosure port IEC 61000-4-3	385MHz/ 27V/m	385 MHz/ 27V/m	
	450 MHz/ 28V/m	450 MHz/ 28V/m	
	710 MHz/ 9V/m	710 MHz/ 9V/m	
	745 MHz/ 9V/m	745 MHz/ 9V/m	
	780 MHz/ 9V/m	780 MHz/ 9V/m	
	810 MHz/ 28V/m	810 MHz/ 28V/m	
	870 MHz/ 28V/m	870 MHz/ 28V/m	
	930 MHz/ 28V/m	930 MHz/ 28V/m	
	1720 MHz/ 28V/m	1720 MHz/ 28V/m	
	1845 MHz/ 28V/m	1845 MHz/ 28V/m	
	1970 MHz/ 28V/m	1970 MHz/ 28V/m	
	2450 MHz/ 28V/m	2450 MHz/ 28V/m	
	5240 MHz/ 9V/m	5240 MHz/ 9V/m	
	5500 MHz/ 9V/m	5500 MHz/ 9V/m	
	5785 MHz/ 9V/m	5785 MHz/ 9V/m	

<sup>d</sup>The ISM (Industrial Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

13.5.3 Recommended Separation Distances

The ROSA Partial Knee device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user or installer of the medical device can help to avoid electromagnetic interference by maintaining a minimum distance, depending on the maximum power of the radio frequency transmission equipment. RF portable communications equipment (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the ROSA Partial Knee device, including the cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.

14. Software Licenses

14.1 Boost

Boost Software License - Version 1.0 - August 17th, 2003

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14.2 VTK

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14.3 GDCM

Program: GDCM (Grassroots DICOM).

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14.4 ITK

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Object form shall mean any form resulting from mechanical transformation or translation of a Source form, including but not limited to compiled object code, generated documentation, and conversions to other media types.

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14.6 JSON

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15. APPENDIX A: Implants Supported  
by the ROSA Partial Knee System

Femoral Components		
Brand	Side	Size
Persona Partial Knee	Left medial	1, 2, 3, 4, 5, 6, 7, 8
Persona Partial Knee	Right medial	1, 2, 3, 4, 5, 6, 7, 8

Tibial Components			
Brand	Side	Size	Bearing Thickness (mm)
Persona Partial Knee	Left medial	C, D, E, F, G, H, J	8, 9, 10, 11, 12, 14
Persona Partial Knee	Right medial	C, D, E, F, G, H, J	8, 9, 10, 11, 12, 14

All bearing thicknesses are available for every tibial implant sizes.

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