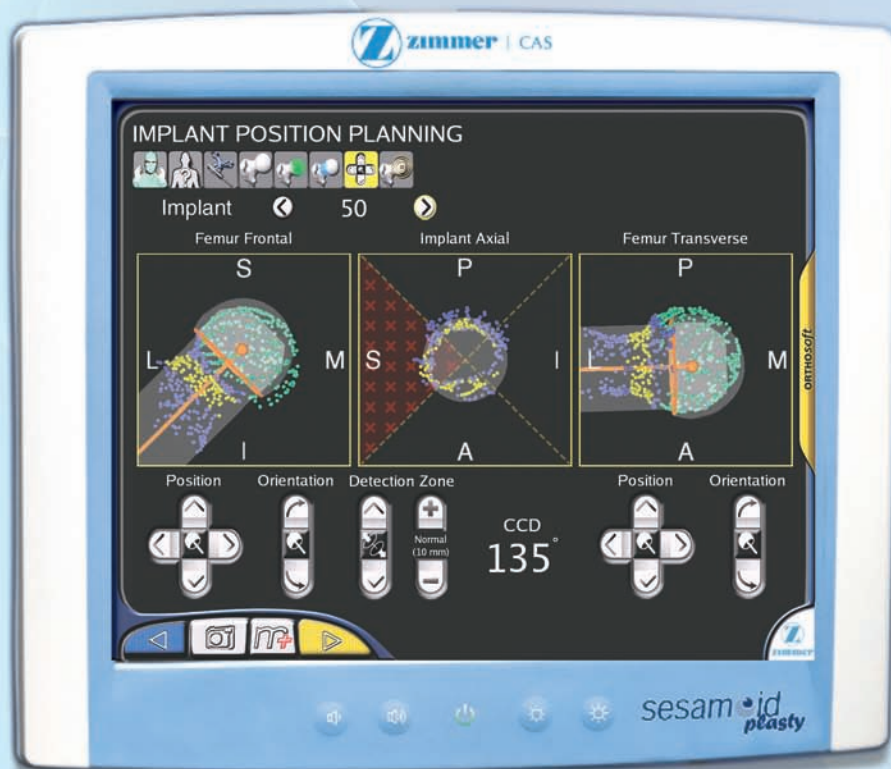




Zimmer® CAS ORTHOsoft® Partial Hip Resurfacing 1.0

Surgical Technique



Simple Solutions for Precise Partial Hip Resurfacing

ORTHOsoft Partial Hip Resurfacing 1.0 Surgical Technique

Table of Contents

SECTION	PAGE
1 OR Setup	1
2 Surgical Workflow	
Technique Summary	3-4
Pre-incision Steps	
Step 1: Define Surgeon Profile	5
Step 2: Verify Patient Information	5
Step 3: Calibrate Instruments	6
Post-dislocation Steps	
Step 4: Install References	6
Step 5: Establish Femoral Coordinate System	7
Digitization	
Step6: Digitize Femoral Head	8
Step 7: Digitize Femoral Neck	8
Planning and Navigation	
Step 8: Plan Implant Position	9
Step 9: Navigate Drill Guide	10
3 Post-Operative Information	11
4 Catalog Information	13-14



1 OR Setup

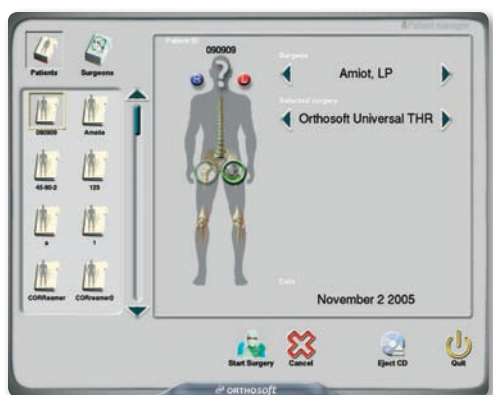
Powering-Up the System

Sesamoid® System/Sesamoid® Plasty System

- Unroll the power cable and connect it to a power outlet.
- Turn on the momentary power switch at the bottom rear of the *Sesamoid*® Computer.
- After the camera warm-up is complete (approximately 20 minutes), you will be ready to launch an application.

Starting the Application

- Click on **Start**, then **Patient Manager** from the Toolchest Menu on the screen.
- When the Patient Manager module is launched and you are using the software for the first time, access the Surgeon Browser by clicking the **Surgeons** button in the upper left portion of the screen. Click on **Create New Surgeon**, then enter the surgeon name, hospital, city, and country.
- To create a new patient file, access the Patient Browser by clicking the **Patients** button in the upper left portion of the screen. Click on **Create New Patient**, and then enter the patient ID number. Additional relevant information can be entered in the Info 1 and Info 2 fields (not required). Once the process is completed, click on the **Save** button.
- Click on the appropriate circle to select the right or left hip. Then click the surgery type (OS Partial Hip Resurfacing 1.0).
- Click on the **Start Surgery** button to launch the application.

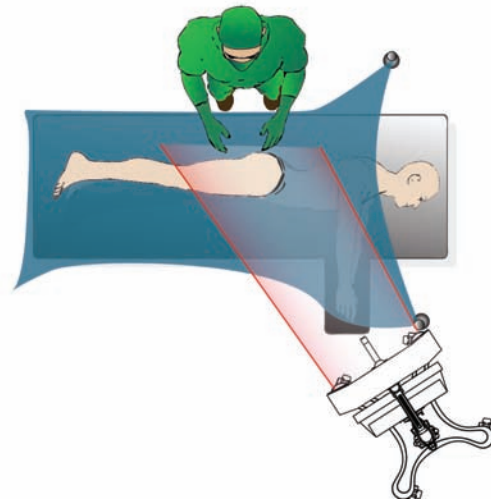


Optimal OR Setup

- The camera position should be determined according to the OR setup, the user preferences, and the position of the tracked instruments on the patient.

With Patient Reference 110.029 Tracker for Modular Reference - Lateral (110.030)

- For navigation of the femoral component, the camera should be placed near the anesthesiologist equipment on the anterior side of the patient.
- An alternate position for the camera is at the feet of the patient.



2 Surgical Workflow

Partial Hip Resurfacing – Technique Summary

Pre-Incision Steps



Step 1
Define Surgeon Profile



Step 2
Verify Patient Information



Step 3
Calibrate Instrument
Calibrate the Modular Handle (with the Drill Guide on) using the Hip Calibration Device.

Post-Dislocation Steps



Step 4
Install References
Install the CAS Reference Base with the CAS Fix Pins Fluted 3.2mm.



Step 5
Piriformis Fossa:
Assemble the Curved Pointer Tip on the Modular Handle, and digitize the piriformis fossa with the Curved Tip.



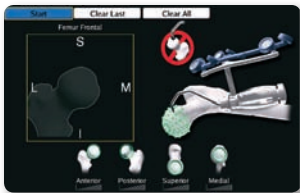
Medial & Lateral Epicondyles:
Digitize the epicondyles with the Curved Pointer Tip.



Medial & Lateral Malleoli:
Digitize the malleoli with the Curved Pointer Tip (the leg must be flexed at 90°, and must not move during the digitization).

Partial Hip Resurfacing – Technique Summary (cont.)

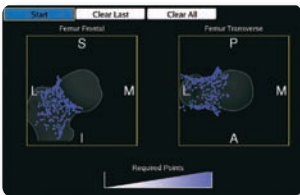
Digitization



Step 6

Digitize Femoral Head

Digitize points on the entire surface of the femoral head using the Curved Pointer Tip (anterior, posterior, medial, superior).

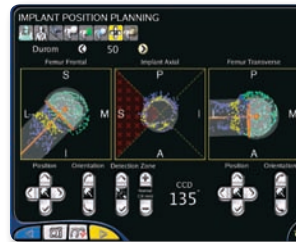


Step 7

Digitize Femoral Neck

Digitize points on the entire surface of the femoral neck using the Curved Pointer Tip (anterior, posterior, inferior, superior).

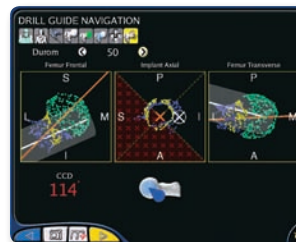
Planning and Navigation



Step 8

Plan Implant Position

Plan the size, position, and orientation of the implant using the arrows on the screen.



Step 9

Navigate Drill Guide

Assemble the Modular Handle with the Drill Guide, and slide the K-wire into it. Align the two crosses in the axial view to define the entry point of the K-wire, and navigate the K-wire to find the planned orientation.

Pre-incision Steps

Step 1: Define Surgeon Profile



The system uses the concept of profiles to store the particular surgical preferences. Once a profile is created, it can be used to perform a surgery without specifying the surgical preferences again.

Implant

This preference allows the surgeon to select his preferred implant used in the partial hip resurfacing surgery. The **Universal** choice can be selected to navigate the K-wire only. The notching detection feature is not available in this sequence.

Caution:

The selection of the wrong implant can lead to misplacement of the implant, femoral neck notching, neck fracture or dislocation.

Show Femur Background Images

If set to **Yes**, a generic image of the femur is displayed in the background of the viewers for clarity.

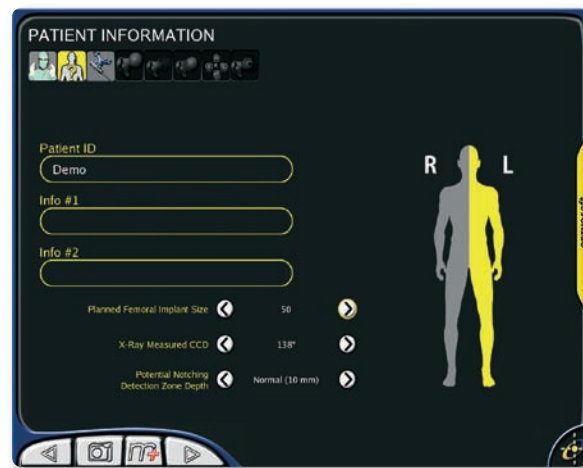
Caution:

Illustrations in the background of the viewers are generic images to help understand the orientation of the viewers. They are not actual representations of the bone.

Manual Positioning of the Potential Notching Detection Zone

If set to **Yes**, +/- buttons are displayed on the Implant Position Planning screen, allowing the user to manually position the detection zone.

Step 2: Verify Patient Information



The patient information that was previously entered in the Patient Manager is summarized in the Patient Information panel.

Other parameters that need to be set for each surgery include:

Planned Femoral Implant Size

The user can enter the templated implant size.

X-ray Measured CCD

The user can specify the CCD angle measured from the preoperative radiograph.

Potential Notching Detection Zone

The user must specify the neck length to adapt the potential notching detection assistance to the femur morphology. **Short, Normal, and Long** correspond to thicknesses of 5mm, 10mm and 15mm respectively.

Step 3: Calibrate Instrument



1. Tighten the appropriate size Modular Drill Guide on the handle.
2. Insert the Drill Guide into the Calibration Device.
3. Make sure that the tip of the Drill Guide is in contact with the base. Fasten the Drill Guide with the Wing Screw.
4. Position the trackers towards the camera.

Post-Dislocation Steps

Step 4: Install Reference

(For posterior approach in lateral decubitus position)

For any type of bone references, use two CAS Fix Pins Fluted 3.2 mm (116.015) to stabilize them firmly to the bone. Movement of the bone reference could lead to severe navigation inaccuracies.

Dislocate the femur before installing the reference in the greater trochanter. It is suggested to insert the pins bicortically without completely drilling through the second cortex of the proximal femur. Tighten the set-screws with the screwdriver.

Tracker used with the CAS Reference Base

Assemble the CAS Tracker for Modular Reference - Lateral (110.031) on the CAS Reference Base with the Wrench for Knob (116.005) in a cranial direction to face the tracking system.

1. Fix straight pins in the proximal area of the greater trochanter. Pins should be inserted on the intertrochanteric line.
2. Firmly tighten the set-screws with the screwdriver.
3. Assemble the tracker to the Modular Reference Base.

Caution:

The reference must be firmly attached to the bone and must not move throughout the procedure.



Step 5: Establish Femoral Coordinate System

Landmarks should be digitized with the Modular Curved Pointer (104.044) following the instructions detailed on each screen.

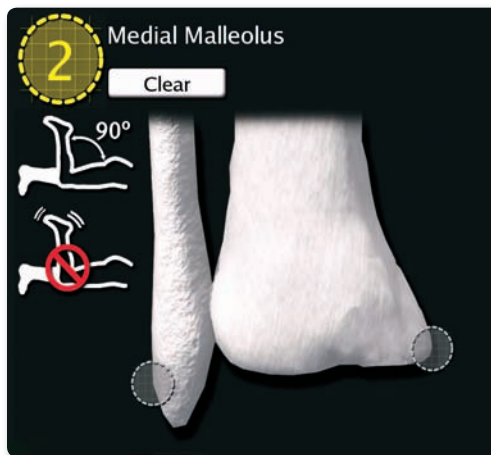
- 1. Piriformis Fossa:** This is the middle point in the transverse plane of the femur taken at the junction between the neck and the greater trochanter.



2. Medial & Lateral Epicondyles



- 3. Malleoli:** With the knee flexed at 90° and the leg still.



Caution:
The knee must be flexed at 90° to digitize the malleoli.

Caution:
The leg must not move while acquiring the malleoli.

Caution:
An inappropriate digitization of the coordinate system could lead to inaccuracies and poor orientation of the viewers.

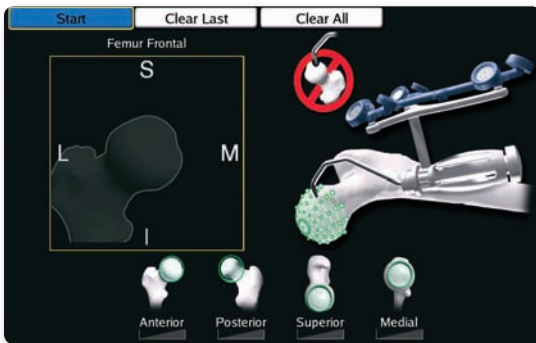
The system provides CCD angle reading according to the following definition: the CCD is calculated as the angle between the projection of the instrument axis on the femoral frontal plane and the longitudinal axis of the femur.



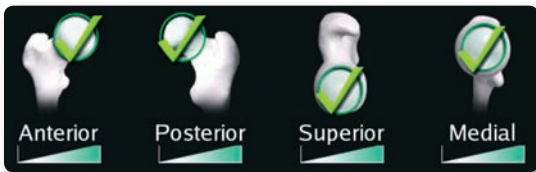
Digitization

Step 6: Digitize Femoral Head

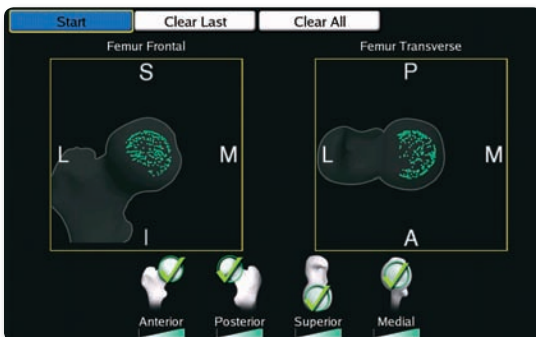
The acquisition of the points, with the Modular Curved Pointer, begins when the user clicks on the **Start** button (using the foot pedal or by having someone touch the button on the screen). Points are continuously acquired until the user clicks on the **Stop** button.



Points must be digitized exclusively on the healthy (anterior, posterior, medial, and superior) sections of the femoral head.



It is suggested to complete one section of the femoral head before completing other regions by making an arc or circle of points from the top of the head to the head/neck junction. Feedback is given to the user when the suggested minimum number of points is acquired in each of the four regions. However, the user can acquire as many points as desired.

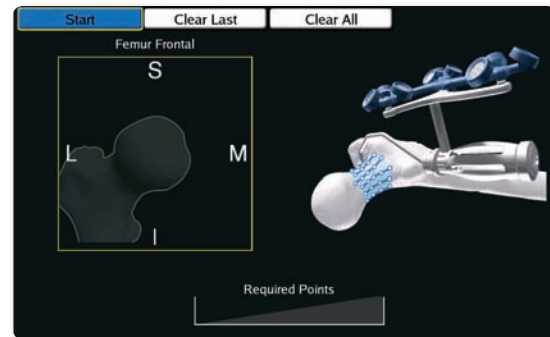


Caution:

The pointer must not be lifted while acquiring points.

Step 7: Digitize Femoral Neck

Acquisition of the points with the Modular Curved Pointer begins when the user clicks on the **Start** button. Points are continuously acquired until the user clicks on the **Stop** button.

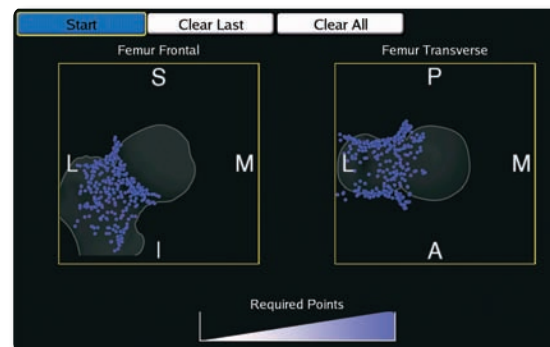


It is recommended to digitize points by drawing lines of points along the axis of the neck. The lines should be close to one another and cover the entire surface of the neck. The user should also carefully digitize the regions where notching may be of concern. Feedback is given to the user when the suggested minimum bone coverage is acquired. However, the user can acquire as many points as desired.

Caution:

The pointer must not be lifted while acquiring points.

The femoral neck and head/neck junction must be carefully digitized because they form the areas to gauge the femoral component placement during the planning step.



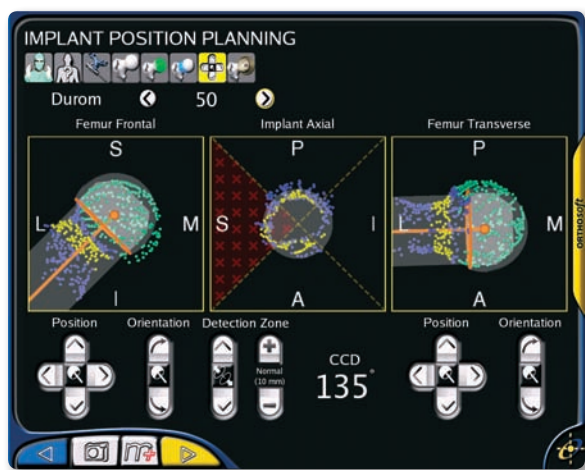
Caution:

If the progress bar is exceeded, the lag may become more noticeable. For instance, if the points are doubled in the progress bar allocation, the lag can be of the order of one second.

Planning and Navigation

Step 8: Plan Implant Position

This screen is used to help the user to accurately plan the femoral component position and orientation. It provides the ability to select the size of the femoral component, translate it in all directions, and modify its orientation to allow precise positioning of the implant. The user uses the controls to position and orient the implant where he wants it to be seated, according to the modeling of the femoral head and neck.



The shape of the inner surfaces of the femoral implant (only when an implant has been selected in the Surgeon Profile) is useful to evaluate the bone support for a planned implant position. The system also displays the CCD angle, measured with respect to the digitized femoral coordinate system.

How to Maintain Sterility

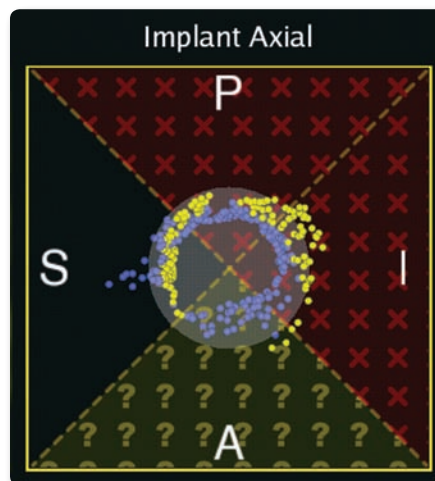
Here are some recommended techniques:

- A circulating nurse/resident operates the system.
- The user can use a sterile tip to touch the screen and perform the planning.
- An auto-adhesive sterile plastic sheet is installed on top of the screen and covers it while the user performs the planning.

Potential Notching Detection Assistant

The assistant helps the user to determine if notching can occur based on the selected implant position. It gives graphical feedback based on four quadrants (anterior, posterior, superior, inferior) in the axial view as to whether or not digitized points on the femoral neck will be resected.

A minimum number of points are needed to activate the assistant. If five points or less are in a quadrant, the quadrant will be shaded with ?. It is then recommended to digitize additional points in the region.

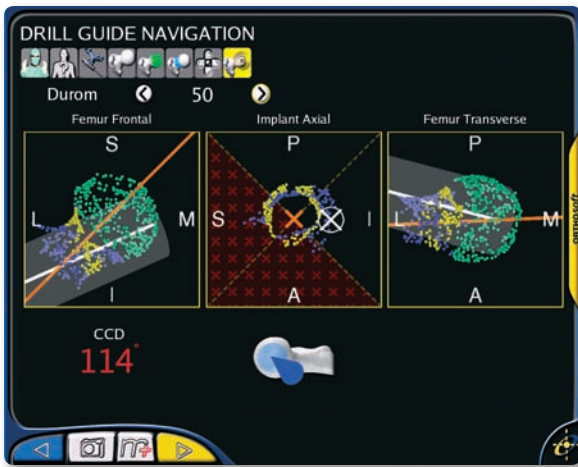


The transparent cylinder depicts the inner volume of the femoral cylinder reamer associated with the implant size. When yellow points are outside of this volume, the corresponding quadrant of the analyzed region of the neck is highlighted with a red X. The user must review the situation to decide if there is notching based on the viewer information. The accuracy of the system to depict the quadrants in which bone is estimated to be resected is approximately within 1mm.

Step 9: Navigate Drill Guide

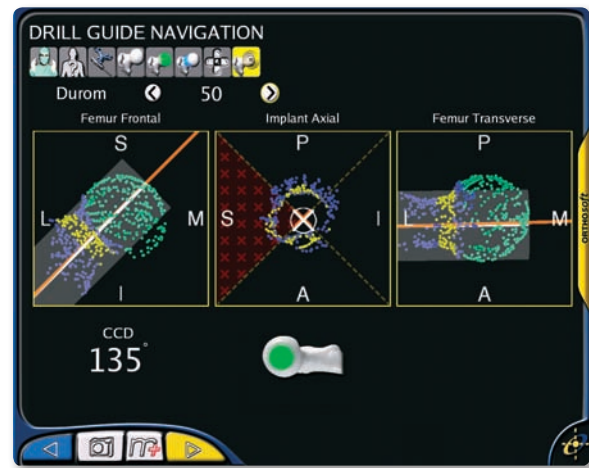
The K-wire is navigated with the Modular Drill Guide. Two Modular Drill Guides are available in the instrument kit for different diameters (2.4/2.5mm & 3.2mm). For any K-wire diameter, it is recommended to use a 12-inch K-wire.

First, navigate the K-wire to find its entry point on the femoral head. The position target in the axial view helps the user to find the entry point. The entry point is located when the moving cross is over the target cross.



Navigate the K-wire to find the planned orientation. The user can rely on the frontal and transverse views by matching the axis of the K-wire to the axis of the planned implant orientation displayed. Alternatively, a bull's eye is also provided to control the orientation. The system displays the CCD angle measured directly with respect to the digitized femoral coordinate system.

Once this alignment is satisfactory, proceed with the insertion of the K-wire. While the K-wire is navigated, the system gives graphical feedback in the axial view with respect to potential notching using the Detection Assistant functionality previously described in Step 8.



3 Post-Operative Information

Exit the Application

- Click on the **Menu** button
- Click on **Quit Application**
- Answer Yes to the question **Are you sure you want to quit the application?**



Archive Patient Files

- Access the Patient Browser by clicking the **Patients** button in the upper left portion of the display;
- Select the patient to be archived;
- Press on the **Select Patient for Archiving** button on the lower left side of the screen;
- Repeat this process with all patient files to be archived;
- Alternatively, all patient files can be archived in a single step using the **Select All for Archiving** button. To remove a patient from the list of files to be archived, press on the **Deselect from Archive List** button. Each patient to remove must be deselected individually;
- Once all patient files to archive have been identified, press on the **Burn CD** button in the lower right-hand part of the screen;
- The computer CD tray will automatically eject when the burning process is finished.

Snapshot Viewer

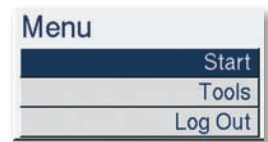
- Access the Patient Browser by clicking the **Patients** button in the upper left portion of the display;
- Select the Patient for which the snapshots has to be viewed;
- Select the anatomy part (right/left hip/knee circle);
- If more than one surgery has been done, select the surgery with the **Procedure** selector at the bottom of the body;
- Press on the **View Snapshots** button. This button is only displayed if snapshots were taken during the selected surgery.
- Press on the thumbnails to select the snapshot to view. To browse through the thumbnails, use the left and right arrows beneath the viewer.
- To close the snapshot viewer, press on the Patient Manager main background.

Exit the Patient Manager

- Press on the **Quit** button on the bottom right corner of the screen.
- Answer **Ok** to the question: **Are you sure you want to quit the Patient Manager?**

Shut Down the System

- From the Menu box, select **Tools**.
- Select **Shut Down** from the drop-down list
- Answer **Yes** to the question: **You are about to shut down, proceed?**

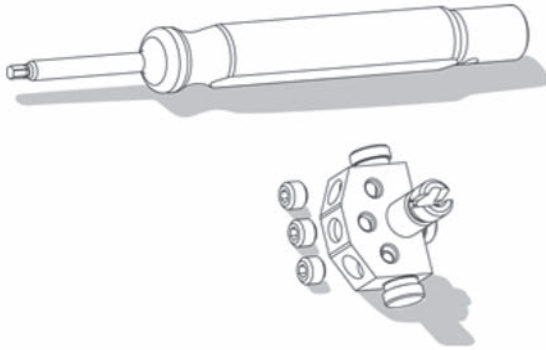


View the Surgery Report

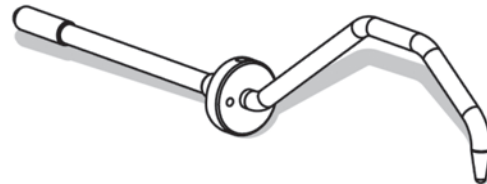
- Insert the CD with the patient files in a computer
- Open the folder **PATIENTS2\PATIENT_NAME\PROCEDURES\DATE_OF_SURGERY**
- Open with a Web Browser the Report.html

4 Catalog Information

**CAS Modular Reference Base -
20-8000-020-12 (110.029)**



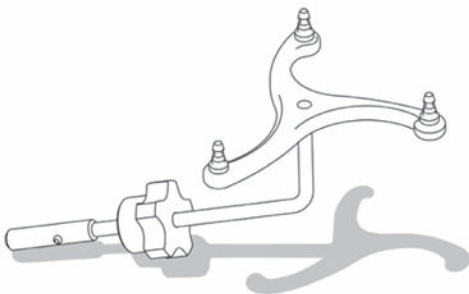
**CAS Modular Curved Pointer -
20-8000-020-07 (104.044)**



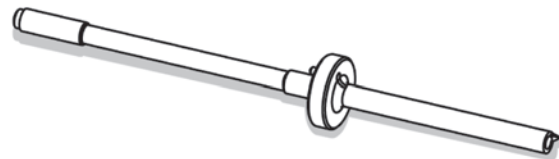
Trackers used with the Modular Reference Base

**CAS Tracker for Modular Reference - Cranial -
Size 3 – 20-8000-020-14 (110.031)**

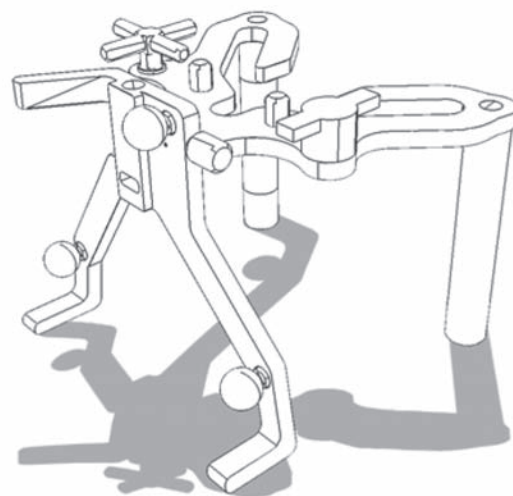
**CAS Tracker for Modular Reference - Lateral -
Size 3 – 20-8000-020-13 (110.030)**



**CAS Modular Drill Guide 2.4/2.5mm or 3.2mm -
20-8000-020-08 (104.045) &
20-8000-020-09 (104.047)**



**CAS Universal Hip Calibration Device with
Handles - 20-8000-020-02 (100.033)**



**CAS Modular Cannulated Handle -
20-8000-020-06 (104.043)**



CAS Partial Hip Resurfacing 1.0 – Instruments

Zimmer Cat. No.	Manuf. No.	Description	Qty
KT-8000-020-04	150.220	CAS Partial Hip Resurfacing Instrument Kit	
		Subcomponents	
20-8000-020-02	100.033	CAS Universal Hip Calibration Device	1
20-8000-020-06	104.043	CAS Modular Cannulated Handle	1
20-8000-020-07	104.044	CAS Modular Curved Pointer Tip	1
20-8000-020-08	104.045	CAS Modular Drill Guide Tip 2.4/2.5mm	1
20-8000-020-09	104.047	CAS Modular Drill Guide Tip 3.2mm	1
20-8000-020-12	110.029	CAS Reference Base (includes CAS Screwdriver 3.5mm)	1
20-8000-020-13	110.030	CAS Tracker for Modular Reference – Lateral – Size 3	1
20-8000-020-14	110.031	CAS Tracker for Modular Reference – Cranial – Size 3	1
20-8000-070-02	115.006	CAS Main Case	1
20-8000-070-03	115.007	CAS Lid	1
20-8000-070-04	115.027	CAS Small Diamond Silicon Mat	1
20-8000-070-05	116.017	CAS <i>NavitrackER™</i> Pliers	1

CAS Partial Hip Resurfacing 1.0 – Other Parts

Zimmer Cat. No.	Manuf. No.	Description	Qty
20-8000-000-09	201.118	<i>NavitrackER™</i> Kit C – Leg Length & Resurfacing	1
20-8000-000-01	116.015	CAS Fix Pin Fluted 3.2d x 150mm	1
20-8000-000-02	116.018	CAS Fix Pin Fluted 3.2d x 80mm	1
20-8000-000-04	116.021	CAS Fix Pin Fluted 3.2d x 150mm	12
20-8000-000-03	116.020	CAS Fix Pin Fluted 3.2d x 80mm	12
98-9000-001-02	–	CAS PPU Partial Hip Resurfacing	1
00-9000-520-04	150.017	CAS PPU Surgery Partial Hip Resurfacing Service	1
20-8000-070-23	215.013	CAS Pedal Steute with Cable	1
20-8000-070-22	215.012	CAS Keypad Uni	1

Caution & Warnings

Caution

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

Warnings

The technique and warnings presented in this guide are intended for trained users.

Note:

Refer to the full User Guide of the application *ORTHOsoft* Partial Hip Resurfacing 1.0 - Universal for all cautions, warnings and detailed user information.

Contact your Zimmer representative or visit us at www.zimmer.com



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