**Surgical Technique
Supine Position**

✷ smith&nephew

RI.HIP NAVIGATION

Total Hip Arthroplasty
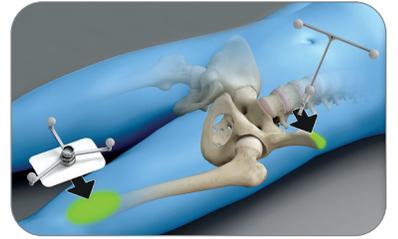

Real Intelligence

Purpose

This surgical technique is based on the Real Intelligence Hip Navigation Software. It documents how RI.HIP NAVIGATION may be used in a clinical setting, but it is not meant as a replacement to the Brainlab HIP7 Software User Guide. For questions regarding recommended use of Brainlab equipment and/or software, always refer to the RI.HIP NAVIGATION Software User Guide as your first level of product support. The training provided to the customer is based on the product-specific training requirements. Users must be trained and qualified to operate the RI.HIP NAVIGATION. Contact Smith+Nephew if new users require training.

Contents

Patient selection, indications

RI.HIP NAVIGATION introduces navigation of the acetabular component relative to the functional (X-ray) plane or the anterior pelvic plane.

The anterior pelvic plane – defined by the Anterior Superior Iliac Spine (ASIS) and the Pubic symphysis – is often used as an established reference frame for cup positioning. RI.HIP NAVIGATION using the functional plane allows correcting pelvic tilt, bridging the gap between pre-operative X-ray templating, intra-operative navigation and post-operative assessment on radiographs.

The tilt of the functional (X-ray) plane relative to the anterior pelvic plane is determined pre-operatively during hip templating using Brainlab's digital templating software TraumaCad™ and the KingMark™ calibration device on a lying hip overview radiographs.

RI.HIP NAVIGATION features the calculation of the anterior pelvic plane without the necessity of registering the pubic tubercles or the contralateral ASIS point. This method is based on statistical relationships of landmarks registered intra-operatively on the patient's anatomy. The accuracy of this anterior pelvic plane calculation method has been proven to be equal to the previous *"gold standard"* – the registration of ASIS and Pubic landmarks.[1] Since the algorithms rely on statistics, a careful patient selection is key to successfully and reproducibly place the acetabular component.

Contraindicated for cup navigation with RI.HIP NAVIGATION are patients with severe deformities of the hip socket, such as neo-acetabuli, high or low dislocations, severely inadequate depth of the acetabulum, or absence of acetabular floor, such as protusio acetabuli.

Dysplasia of the acetabulum, such as shallow or deformed acetabuli might be treated using RI.HIP NAVIGATION. Caution is advised since these patient's anatomies might significantly differ from statistical relationships used in the software.

Pre-operative templating
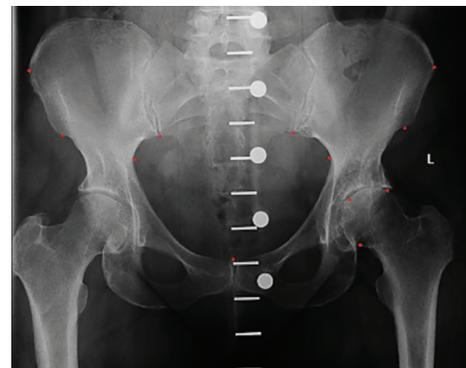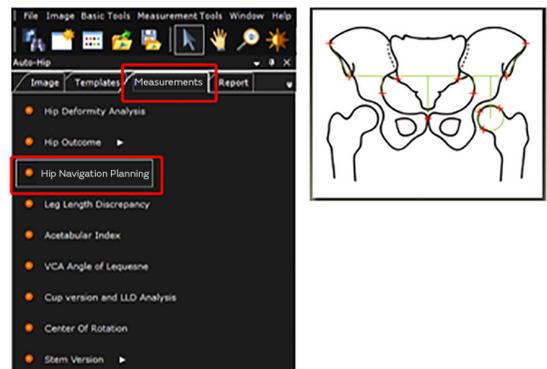
TraumaCad™ hip navigation planning

Open TraumaCad and load the patient's radiograph – taken in supine position using the KingMark™ calibration device – by double-clicking the patient's study. Press *"Next"* to proceed to the Procedure Selection.
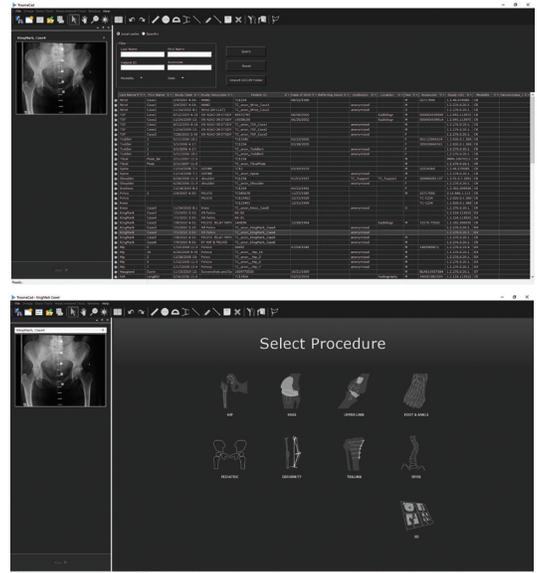
Select the *"HIP"* procedure, define the view and side to be treated and press *"Accept"* to finish the automatic calibration.

Select *"Hip Navigation Planning"* in the *"Measurements"* tab and follow the instructions to define the landmarks. The following points need to be marked in the X-ray image:

• Most lateral points of the iliac crest right/left

• ASIS points (right/left)

• Left and right posterior inferior iliac spine (PIIS) points on the sacroiliac joint line

• Most lateral points of the pelvic inlet on the brim line (left and right)

• Most cranial point of the symphysis pubis

• Three points on the outer contour of the femoral head on the side to be treated

TraumaCad™ will use these landmarks to automatically calculate the tilt angle between the X-ray plane and the anterior pelvic plane.[2]

Once the twelve landmarks have been marked in the image, the hip navigation planning is finished, indicated by the message *"Anatomic measurements completed. The TraumaCad plan can now be used in the RI.HIP NAVIGATION Software."*

To proceed with implant planning, click on the *"Templates"* tab and select the implants. Double-clicking on the desired cup or stem component will preposition the implant(s) on the image, automatically adding a leg length descrepancy measurement tool. Fine-adjust component positions and sizes as desired.
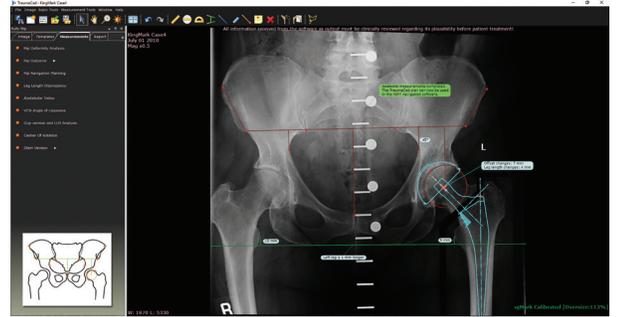
Once your pre-operative planning is completed, open the *"File"* menu and select *"Save Case".*
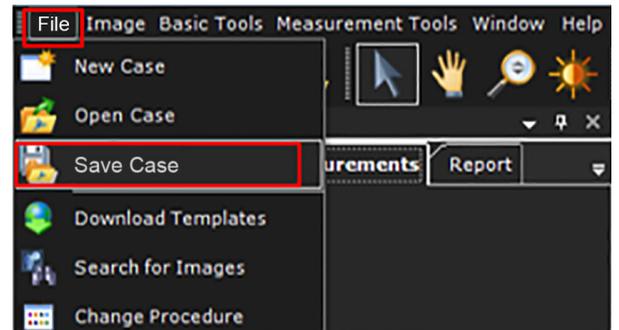
Save the plan to a USB storage device to use it with RI.HIP NAVIGATION. Select *"Save to: Local Folder/Memory Stick"* and press *"OK".*
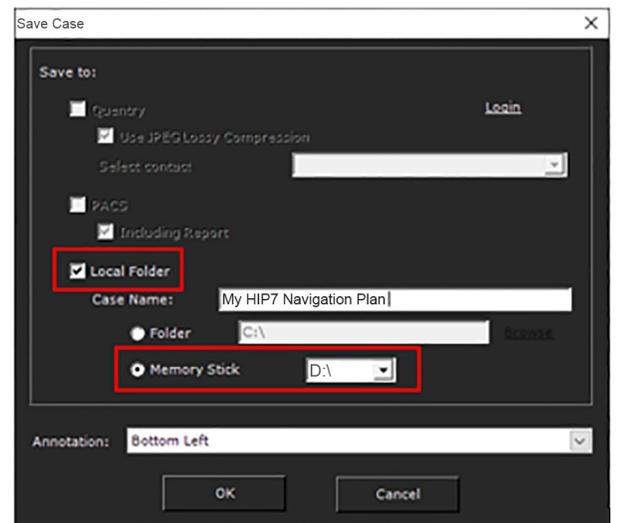
OR Setup

Camera placement

The camera should be positioned at a distance of about 1m to 3m from the operating field and can be placed at the head or foot end of the table depending on patient position and approach to the joint. For a procedure in supine position, a placement on the foot end of the table is recommended.

Note: Consider the patient's positioning, (navigated) instruments, preferred approach to the joint as well as surgeon and assistant(s) position at the table when preparing camera and monitor setup.

Switch the camera on several minutes prior to use, as the infrared sources need time to warm up to reach maximum efficiency. Any light sources or highly reflective objects should not be within the camera's field of view, as reflections can interfere with the procedure.
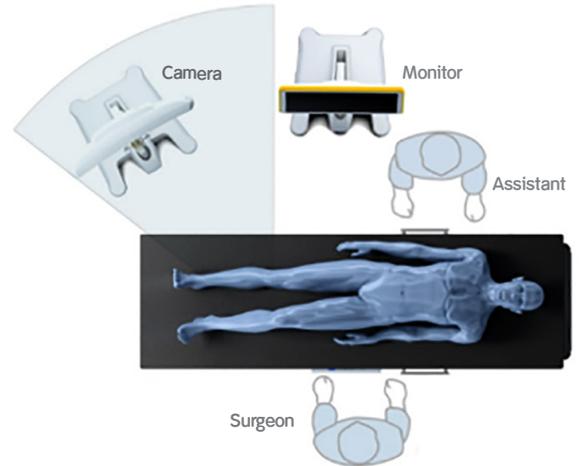
Screen placement

A good position for the display is on the opposite side of the surgeon's position next to the camera, if the system is not operated by the operating surgeon.

If the surgeon wants to operate the system, the monitor can be sterile draped and positioned right next to the surgeon.

Patient selection and navigation software start

Start the Navigation System and wait until it has fully booted.

Select a patient from the Patient Selection dialog. The pre-operative treatment plan can be loaded from different sources such as PACS, local drives, network drives or USB storage media.

If a USB storage device is plugged into the Navigation system's USB port to load the pre-operative TraumaCad™ Navigation Plan in RI.HIP NAVIGATION, Patient Selection will detect that a storage device was connected to the system and will automatically filter and display the patient data available on the connected storage device.

Select the patient to be treated from the patient list and press *"Select"* to proceed.

In the following Workflow Selection dialog, select *"HIP7 Cup and Leg"* to start the hip navigation application.
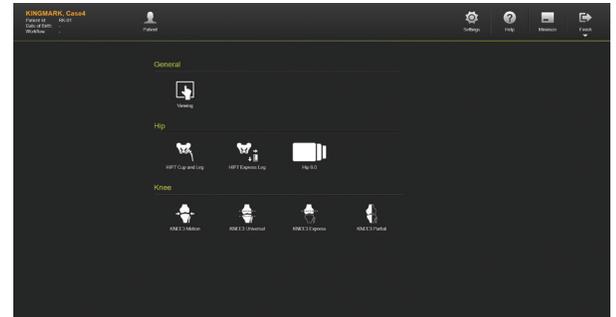
Once the workflow was chosen, the navigation system will switch to the Data Selection Dialog, displaying the data available for the patient selected. Select the previously saved TraumaCad™ plan on the left hand side of the screen and press *"OK"*.
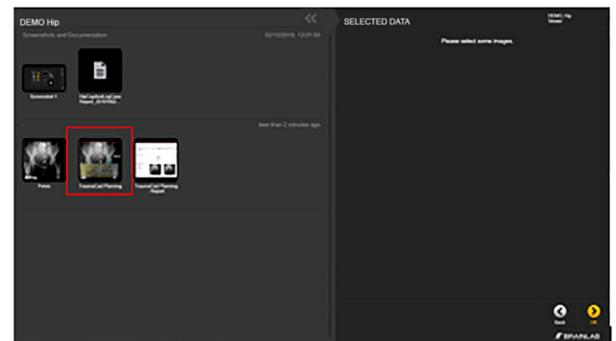
After pressing *"OK"*, the navigation system will return to the application selection. To start the RI.HIP NAVIGATION application, press the HIP7 Cup and Leg icon.
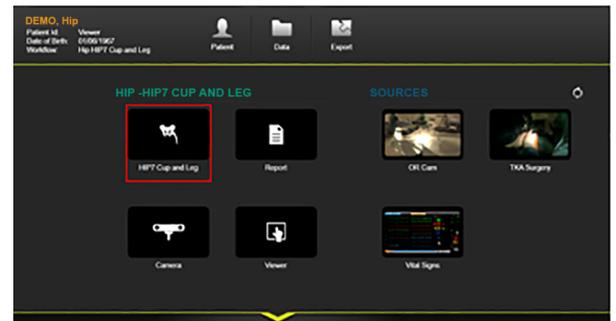
RI.HIP NAVIGATION will open with the procedure overview/procedure settings. In this dialog, enter patient information such as treatment side, gender and patient position, review the pre-operative plan and select the cup inserter.
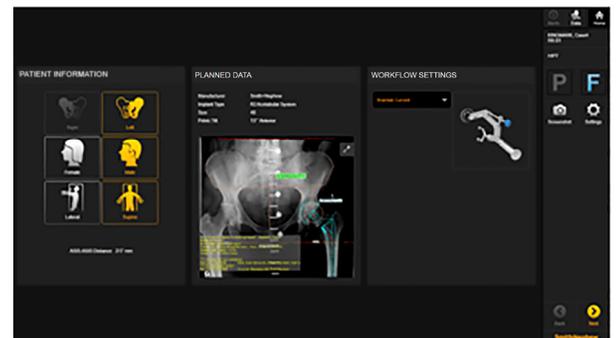
See section *"Procedure Overview Page"* (page 15) for detailed information.

Instruments preparation

At the scrub table, prepare instruments with marker spheres. Twelve disposable marker spheres are needed for a procedure including cup navigation and Pinless Leg length and Offset measurement.

Tightly screw the reflecting marker spheres onto the socket. If a marker is soiled, instruments might not be recognized by the system, or the detected instrument position might be inaccurate. Remove reference arrays during the procedure using the X-Press interface, or cover them with dry cloth to avoid soiling.

The T-shaped bone reference array is placed on the pelvis, in the iliac crest, using a Bone Fixator 2-Pin. During navigation, the array defines the position of the bone.

Art. no. 54241773
Disposable Marker Spheres 90 pcs

Art. no. 52410A
Reference Array
T-Geometry, X-Press

Art. no. 52429
Bone Fixator 2-Pin,
Flip-flop, X-Press

The pinless femoral reference array is placed distally on the thigh on top of the adhesive drape and is secured with an additional strip of adhesive drape or tape. During navigation, the array is used to define the alignment of the femur relative to the pelvis as well as for estimation of the femoral mechanical axis used for leg length and offset measurement.

Art. no. 52400B
Pinless Femur Reference Array Kit

The *"Starlock"* array is attached to the navigated cup impactor to allow navigation of the acetabular shell's orientation in the pelvic coordinate system.

The pointer is used for registration of anatomical landmarks and measurements throughout the case. To ensure that the pointer is not bent, verify it using the corresponding pointer gauge.

Art. no. 55085
Instrument Adapter,
Starlock

Art. no. 53108
Pointer Extended for Hip

Two navigated cup inserters are available with RI.HIP NAVIGATION: a straight as well as an offset cup impactor.

Art. no. 52858
Cup Impactor
Universal Straight

Art. no. 52856B
Cup Impactor
Universal Offset

Patient positioning, draping and array fixation

Preparation for supine patient position

When operating in supine position, drape the patient such that the iliac crest is accessible for attachment of the bone reference array using the two-pin bone fixator. The pelvis reference array may be mounted on the iliac crest of the treated or the non-treated side.

Also, the Anterior Superior Iliac Spine (ASIS) on the treated and the non-treated side need to be registered using the pointer to establish the pelvic reference frame for navigation.

Pelvic reference array fixation

Palpate the iliac crest and place a stab incision at least two to three centimeters posteriorly to the ASIS. Insert the first of two Schanz screws into the iliac crest.

It is recommended to use 3.2mm self-drilling, self-tapping pins as available from Brainlab. Alternatively, threaded pins between 3mm and 4mm can be used based on surgeon's preference. Please refer to the respective user guide for drilling, if using different pins.

Art. no. 54932A
Adapter For AO Coupling (for 54922)

Art. no. 54922
Disposable Schanz Screw (AO) 3,2mm x 100mm (10 pcs)

Art. no. 54908
Disposable Schanz Screw (AO) 4mm x 125mm (10 pcs)

Open the thumb screw of the two-pin bone fixator and slide it over the first pin and mark the location for the second pin. Place a second stab incision at the marked location and drill the second Schanz screw through the bone fixator.
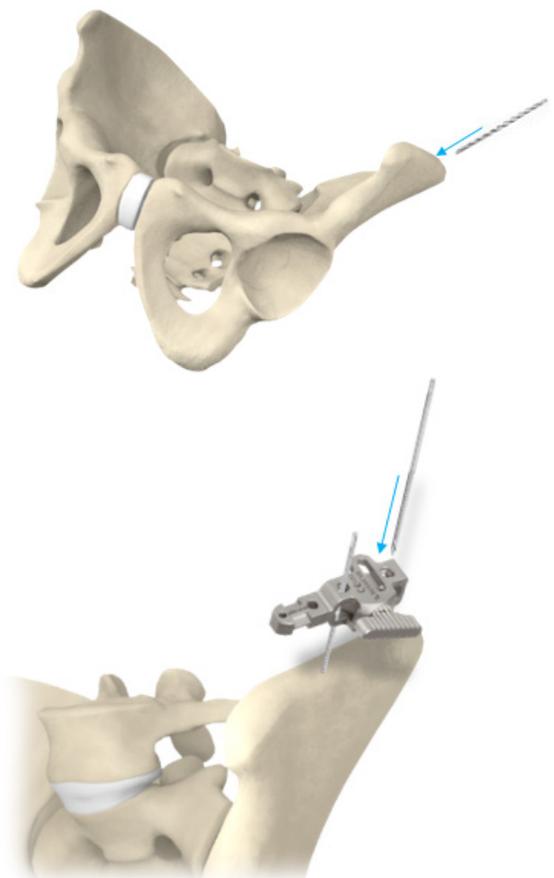
Once both Schanz screws are placed in the iliac crest, securely tighten the thumb screw of the two pin bone fixator to clamp the bone fixator to the screw pins. Do not loosen the two-pin bone fixator or change its position relative to the pelvis once the registration sequence has been started since this would result in registration or navigation inaccuracy and therefore require a new registration procedure.

Femur reference array fixation

The femoral reference array does not require fixation with pins when the *"Pinless Leg Situation"* feature is used. The incision-free femoral reference array is fixed to the anterior femur distally using self-adhesive drapes. The baseplate is being placed approximately 5cm above the knee on top of the drape and fixed using a second strip of tape or incision draping. The array is then placed on top of the base plate.

Note: Make sure the pinless array is placed far enough distally. If the array is placed too close to the pelvic reference, instructions to change the position will appear on the *Patient and Camera Set-up page.*

Ensure visibility of pelvis and pinless femur reference array.
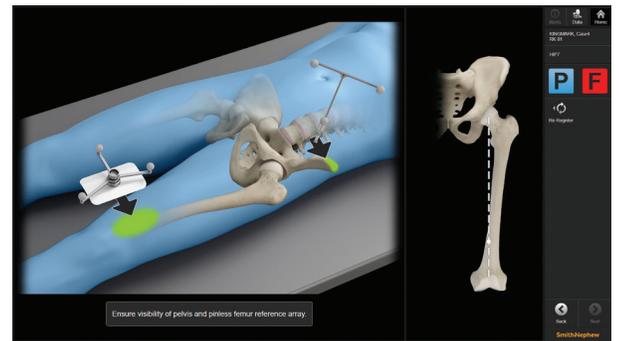
Place the pinless femur reference array in a more distal position.

Incision and exposure

Incision and exposure to the hip joint should be performed based on the surgeon's choice of technique. The instruments provided for hip navigation support standard approaches.
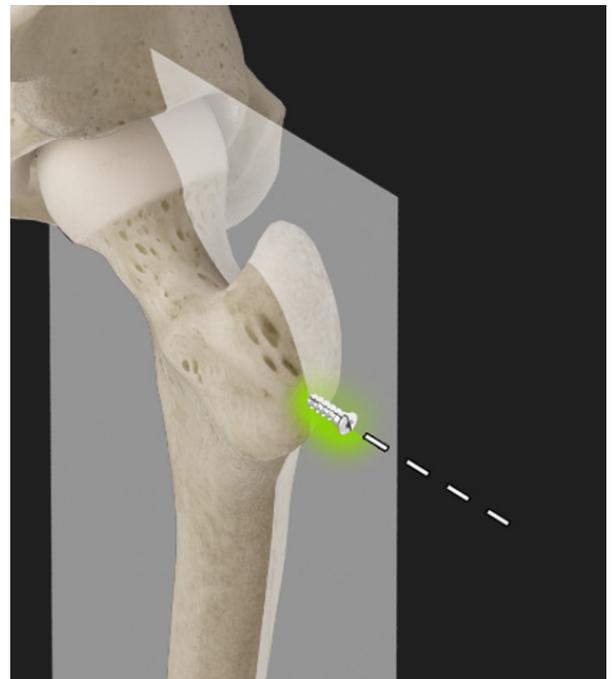
Position the patient in supine position and execute the incision. Once the joint is exposed and the proximal femur is accessible, a reference screw for the intra-operative leg length and offset measurement is being placed in the greater trochanter area, as laterally as possible.

Note: Do not dislocate the joint or resect the femoral neck before the navigated initial leg alignment step and proximal femoral landmark registration has been finished.

Note: Before placing the screw, consider the design of the femoral stem and the broach system. Choose a safe location for the screw to prevent impingement with a broach during femoral preparation or stem insertion.

Inserting a small cortical screw in the greater trochanter area will allow reproducing the exact same landmark before and during the trialing step and/or the final prosthetic components have been implanted.

Note: The ideal location for the cortical screw in the greater trochanter area is as lateral as possible and in line with the neck axis. If a specific approach to the joint does not allow inserting the screw in the suggested location, the robustness of the offset calculation algorithm may potentially be compromised.

Registration for supine patient positioning

RI.HIP NAVIGATION features different registration sequences depending on the patient position selected. The following landmarks are acquired if *"supine"* was selected:

• Anterior superior iliac spine on the treated side

• Anterior superior iliac spine on the non-treated side

• Proximal femur landmark and leg alignment

• Acetabular cavity

• Acetabular fossa

Registration methods

Single landmark registration

To acquire a single landmark, e.g. the ASIS of the treated side, bring the pointer tip to the corresponding bony structure. While leaving the pointer tip stationary (by e.g. controlling the tip with the index finger of the other hand), pivot the pointer to register the landmark.

Surface registration

To acquire bony surface, e.g. the acetabular fossa, bring the pointer tip to the anatomical structure. While leaving the pointer tip stationary, pivot the pointer to set the start point. Then, slide the pointer tip over the surface to register surface points until the registration step terminates automatically and the software proceeds to the next workflow step.

Using the Disposable Clip-on Remote Control

Alternatively to pivoting the pointer, an optional remote control can be utilized. The Disposable Clip-on Remote Control (Art. no. 53153) is clipped on to the pointer, over the first marker sphere's post.(1) It can be set up for left or right hand use.

To install the Disposable Clip-on Remote Control to a pointer, place its center opening (2) over the indicated attachment pin (1) on the pointer handle. Snap the Disposable Clip-on Remote Control fully onto the pointer handle and attach the marker spheres (3) to the pointer

Note: Before attaching, consider the position depending on whether the user is left-handed or right-handed and whether he wants to operate the Disposable Clip-on Remote Control using the index finger or the thumb (4), (5).

Note: The Disposable Clip-on Remote Control is a single-use device and cannot be sterilized. Remove it from the pointer and dispose of after use. For information regarding correct disposal, refer to the instrument user guide.
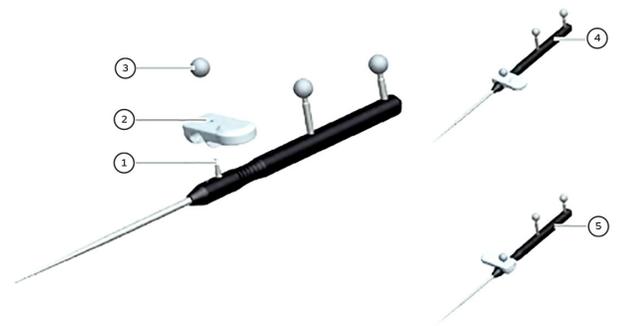
Procedure Overview Page

The *Procedure Overview page* provides a summary of procedure - related settings and is divided into the following three sections:

- Patient Information: lets you select treatment side, patient gender and operating position (supine vs. lateral)

- Planned Data: provides an overview of implant planning data, i.e. sizes and product lines. To review the pre-operative plan touch the image to enlarge

- Cup Inserter Selection: allows selecting a cup impactor from a variety of different cup impactors
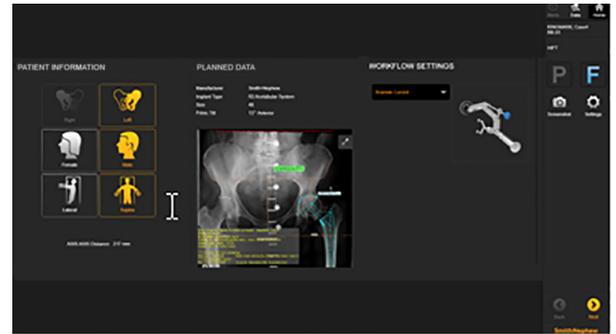

Patient information

In the Patient Information section of the *Procedure Overview page*, treatment side, patient gender and operating position need to be selected.

Since the reconstruction of the anterior pelvic plane with RI.HIP NAVIGATION is based on gender specific statistical relationships of landmarks registered on the patient's anatomy, the patient gender needs to be selected in the patient information section on the *Procedure Overview page*.

Selecting the patient position – *"supine" or "lateral"* – will trigger the corresponding landmark acquisition sequence based on accessibility of the registration points after patient positioning.
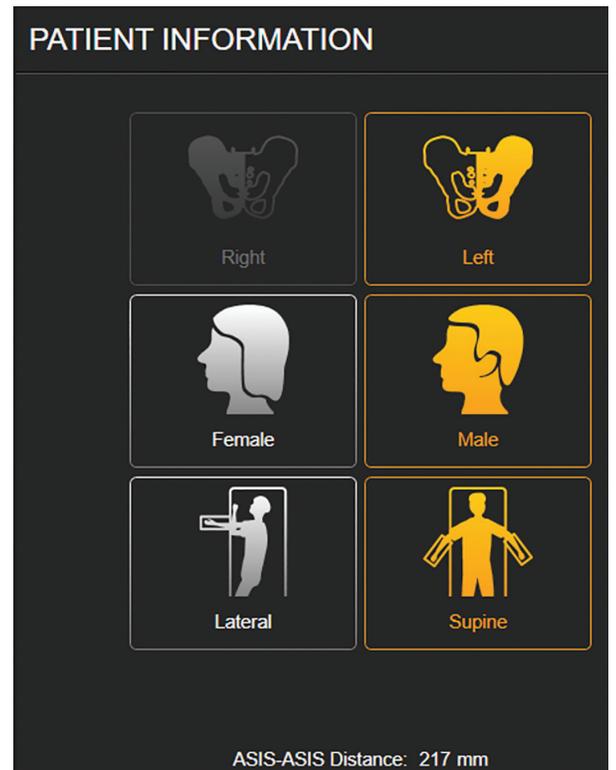
Planned data overview

The Planed Data Overview allows you to review the pre-operative TraumaCad™ plan loaded for the current procedure. Click on the image or on the *"enlarge"* in the upper right hand corner of the preview to enlarge the plan and review the target leg length and offset change as well as the initially planned component sizes and product lines.
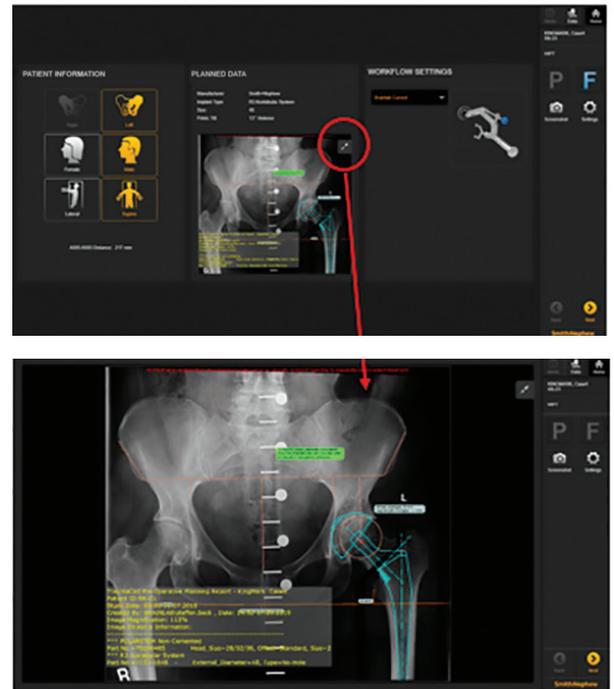
Cup inserter selection

The cup inserter selection allows you to choose your preferred cup impactor from a variety of instruments. Click on the drop down menu to expand the list of instruments selectable.

Once the patient information, planned data and cup inserter are selected, press next to proceed to *Patient and Camera Setup page.*
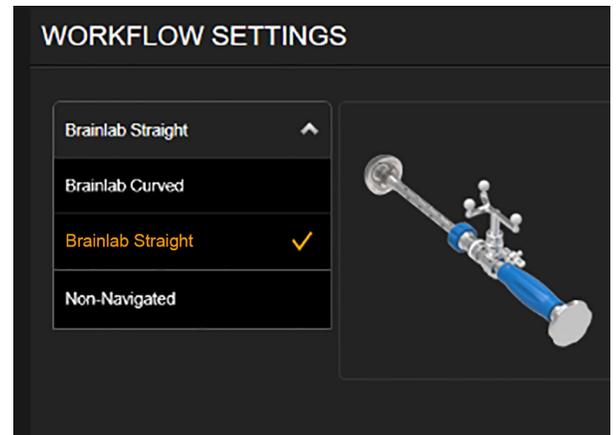
## Patient and Camera Setup pages

The *Patient and Camera Setup pages* allow optimal one reference array and camera positioning for the best marker array visibility throughout the procedure. Status indicators on the upper right hand corner of the screen show whether the reference arrays are visible to the infrared camera. The *"P"* indicates the visibility status of the pelvis reference, while *"F"* represents the femoral array.

The illustration on the *Array Setup page* shows where to position the T-shaped pelvic reference array and the incision-free, pinless femoral reference array.

Once the pelvic array is placed in the iliac crest, RI.HIP NAVIGATION will check whether the femoral reference is placed at the minimum required distance. In case the pinless femoral reference was placed too far proximally on the femur, the software will display instructions to position it in a more distal position.

Once the Camera and Array Setup is finished and both the femur and the pelvic reference arrays are visible to the IR camera, bring the pointer into the camera's field of view to automatically proceed to the first *Landmark Registration page.*

Alternatively press *"Next"* to proceed to the landmark registration.

Ensure visibility of pelvis and pinless femur reference array.
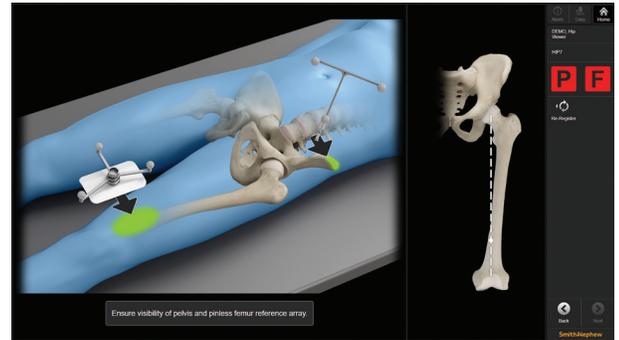
Place the pinless femur reference array in a more distal position.

Landmark registration sequence

Anterior superior iliac spines

Place the pointer tip on the Anterior Superior Iliac Spine (ASIS) on the side to be treated and pivot the pointer (or press the clip-on remote) to register. Once the landmark is acquired, RI.HIP NAVIGATION will automatically proceed to the next registration step, the ASIS on the non-treated side.
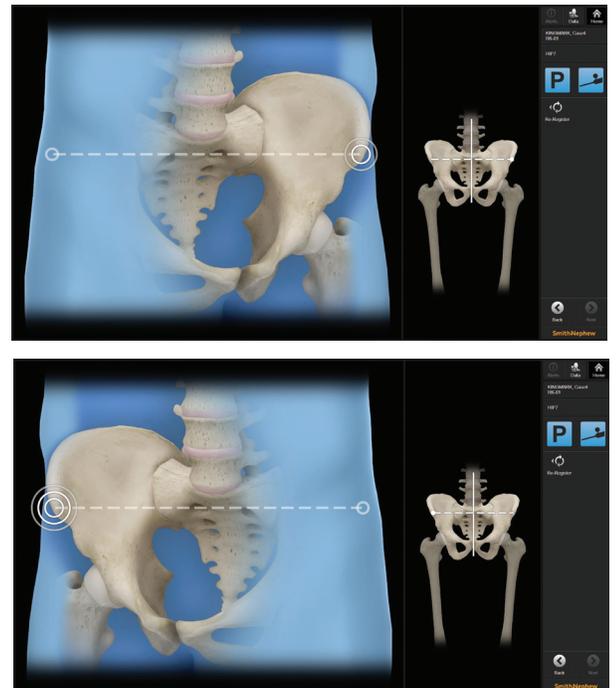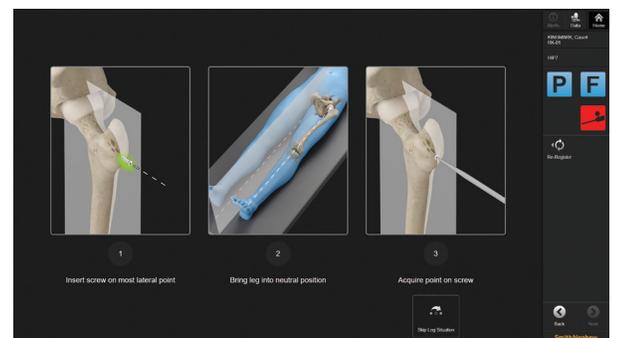

Leg alignment and proximal femur landmark

Bring the leg into neutral weight bearing, standing position relative to the pelvis. Register the proximal femoral landmarks using the head of the cortical screw while holding the leg in neutral position.

The leg orientation as well as the proximal femur landmark are stored during this step and used as landmarks to measure leg length and offset change.

Note: Do not dislocate the joint or resect the femoral neck before the navigated initial leg alignment step and proximal femoral landmark registration has been finished.

Acetabular cavity

Once the initial leg alignment and the proximal femoral landmarks have been acquired, the femoral neck resection can be performed. After neck resection and dislocation of the femoral head from the acetabulum, the registration of the articulating surface of the acetabular cavity can start.

The surface of the acetabular cavity is used to calculate the native acetabular center of rotation as well as the initial cup size for the intra-operative acetabular component planning.

The registration of the articulating surface of the acetabular cavity can start. Remove all accessible osteophytes from the acetabulum and acetabular floor before acquiring these landmarks.

Place the pointer tip on the articulating surface inside the acetabulum and pivot the pointer to start registration.

Once the starting point for the surface acquisition is set, slide the pointer over the articulating surface. Make sure to keep the tip of the pointer in contact with the acetabulum while registering. Each of the three sectors displayed needs to be covered before RI.HIP NAVIGATION automatically proceeds to the next registration step.
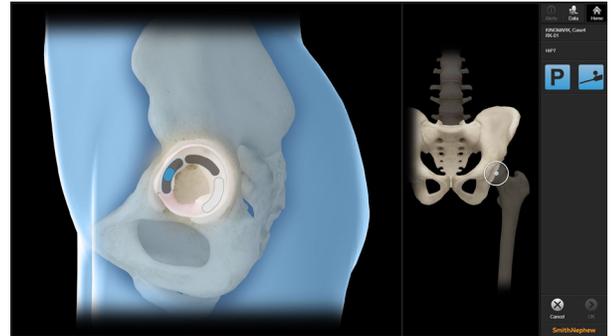

Acetabular fossa

Clear the acetabular floor from the fat pad and from osteophytes before registering the fossa since the true acetabular floor is to be acquired.

The acetabular fossa surface data is used to define the pelvic planes as reference frame for cup positioning.

Note: Do not use a reamer to clear the fossa since reaming might alter the acetabular depth. The software requires points on the true floor of the acetabulum.

Once this last registration step is finished, the software automatically switches to the Cup Navigation screen.
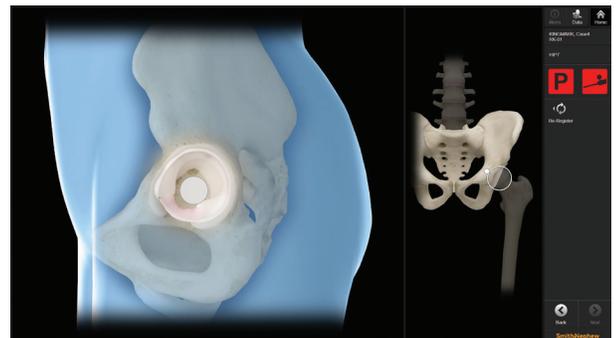
Cup navigation

Overview

RI.HIP NAVIGATION features navigation of the acetabular component relative to two different reference frames for cup orientation measurement: the Anterior Pelvic Plane or the *"tilt corrected"* X-ray Plane.

The anterior pelvic plane is defined by the ASIS landmarks, the native acetabular rotation center and the acetabular fossa, while the X-ray plane takes into account the patient individual pelvic tilt from the pre-operative supine radiograph.

The Cup Navigation screen is divided into two sections initially:

- the anterior pelvic plane reference frame displayed on the left hand side of the screen

- and the tilt corrected reference frame on the right hand side.

The current cup orientation is displayed below the two views during live navigation.

The calculated tilt angle (based on the pre-operative TraumaCad *"Hip Navigation Planning"*) between the functional (radiographic) plane and the anterior pelvic plane is displayed in the bottom center.
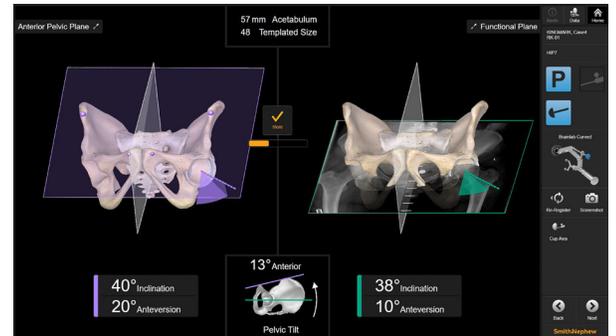
To change the views from oblique to coronal, press *"Back"* and select *"Navigation on Coronal View"* in the workflow settings.
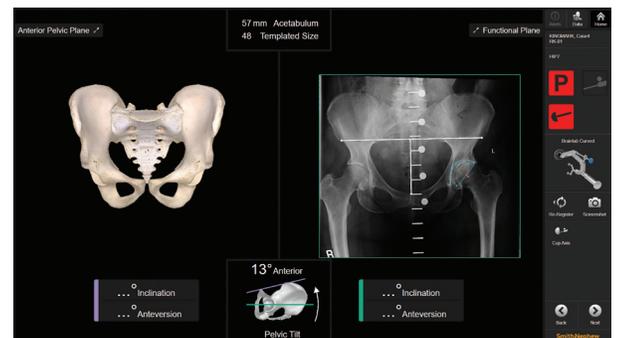
Either of the two views can be enlarged – changing the screen layout to a single view configuration – by using the corresponding button in the upper left hand corner of the views.
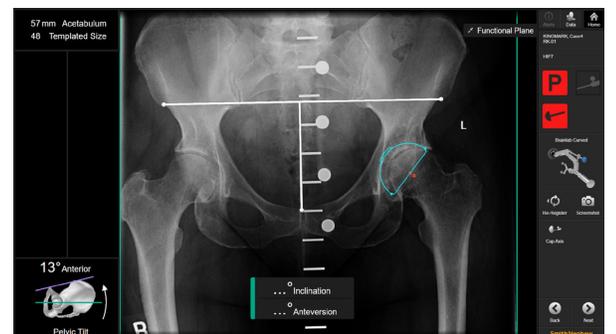
Acetabular preparation

Once landmark registration, femoral neck resection and dislocation of the femoral head have been completed, the acetabular preparation can be performed.

Ream the acetabulum to the appropriate size. Once the reaming is finished, a cup trial component can be navigated or the final, navigated cup impaction can be performed.

Cup trialing

Attach the cup trial component to the navigated cup impactor. The navigation system will automatically switch to navigation mode once the cup inserter's array is visible to the camera and the instrument is close to the region of interest, i.e. the reamed acetabulum.

Adjust the cup impactor's orientation until the acetabular trial component is oriented as desired and well seated in the prepared acetabular cavity.

Navigating the acetabular component

To continue navigating the acetabular component, attach the final cup to the cup inserter. Once the navigated instrument is recognized by the camera, the software will switch to live navigation mode again.

Adjust inclination and anteversion to the desired values. The cup orientation is displayed relative to the selected reference(s) on screen in real-time below the associated view(s).

Start impaction with gentle taps of the hammer until the acetabular component grabs the face of the acetabulum. Double-check the orientation of the acetabular cup as displayed on the navigation screen and impact the cup to its final depth.
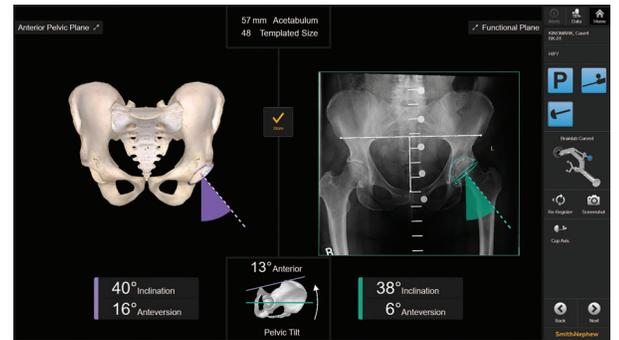

Cup verification

To verify and record the final cup orientation, leave the cup impactor attached to the impacted acetabular component. Select Store to store the values. The cup orientation values displayed on screen will change to orange when the values have been stored.

Alternatively, hold the cup impactor in position for approximately five seconds.

As soon as the cup impactor is moved more than 2 degrees, navigation continues. The stored (orange) values disappear and live (white) values are then displayed. The orientation can be stored as often as desired.

Note: If the impactor was already detached from the acetabular component and removed from the camera field of view, the *"cup axis"* feature in the menu bar can be used to verify the cup orientation by registering points on the opening plane of the cup using the pointer.
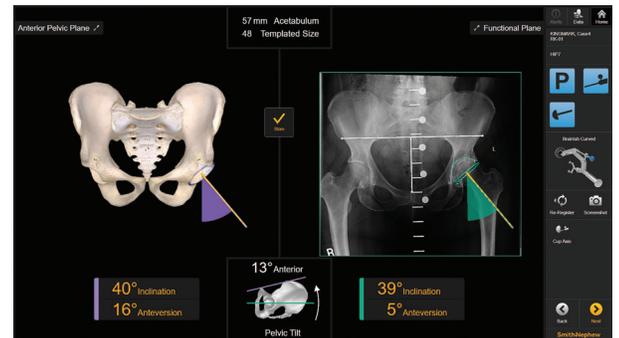
Femoral broaching and trialing

Once the cup is impacted, proceed with conventional femoral preparation.

Start broaching using the smallest broach and iteratively broach up to the most suitable femoral component size.

Once the desired broach position is reached, insert a trial liner into the cup, attach trial neck and head according to the pre-operative plan and reduce the joint.

Leg length and offset navigation

Once the camera recognizes both the pelvic and the femur reference array again after reduction of the joint, the software will automatically proceed to the leg length and offset measurement screen. Alternatively press *"Next"* on the cup navigation screen.

With the joint reduced, bring the leg back into the initially stored reference position by aligning the two crosshairs on the left hand side of the screen.
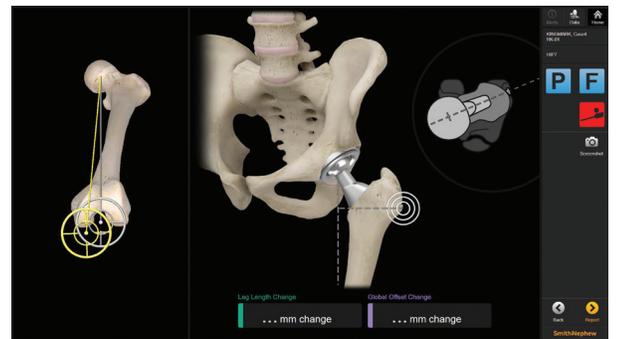

Once the reference position is reestablished, the proximal femoral landmark can be registered using the pointer. The software will display the relative combined leg length and offset change as soon as the proximal femoral landmark was registered.

Repeat the leg length and offset measurement using different head and neck offsets until the pre-operatively templated target length and offset change has been achieved.

The last stored leg Length and offset measurement will be saved in the treatment report.

Note: To document multiple trialing steps, use the screenshot feature in the menu bar.
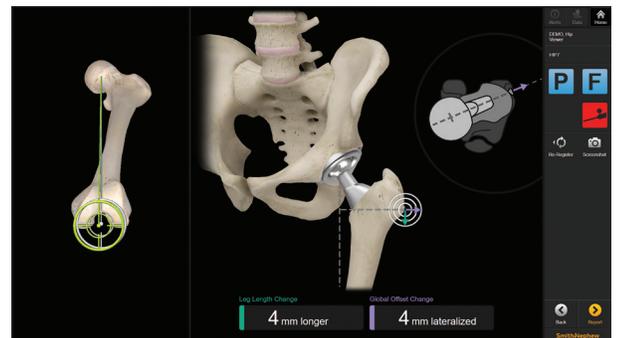
Final component implantation

Remove the trial components and implant the final femoral components
as determined during trialing using the leg length
and offset navigation step.

Complete femoral preparation and impact the stem.

Test joint stability and range of motion.

A final leg length and offset measurement can be performed by
re-aligning the leg and registering the proximal femoral landmark.

Important: Remove the cortical screw from the greater trochanter after
the final navigated leg length and offset measurement. Make sure to
remove the screw before closing the incision.
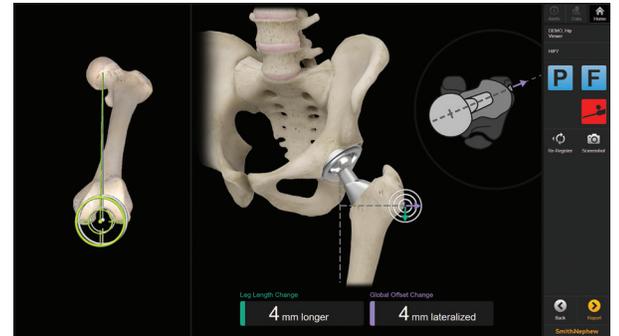
Reviewing the treatment report

RI.HIP NAVIGATION automatically creates a printable case report in PDF format.

Press the *"Report"* button on the lower right hand side of the screen to open the Case Report Application.

The PDF report contains basic patient and navigation information, such as:

- tilt angle between anterior pelvic and functional plane,
- stored cup orientation
- and the last stored leg length and offset change.

To store the treatment data press *"Done"* on the *Case Report page* and open the data export dialog by pressing the *"Export"* button in the top menu bar.
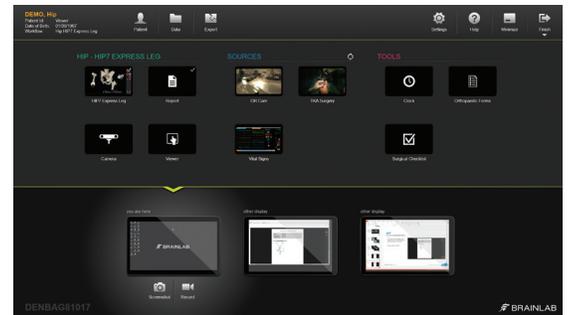
Select the screenshots to be exported and the PDF report.

Press *"Export"* on the lower right hand side of the screen.

Select the data export destination, e.g. a USB storage device, and wait until the data is saved.
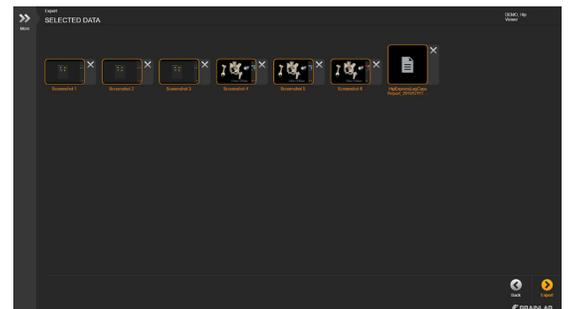
New treatment/system shutdown

Once the data has been exported and the navigated part of the procedure is finished, you can shut down the system or restart for a new treatment.

Press the *"Finish"* button on the upper right hand side in the top menu bar and select *"New Treatment"* or *"Shutdown"* from the drop-down.
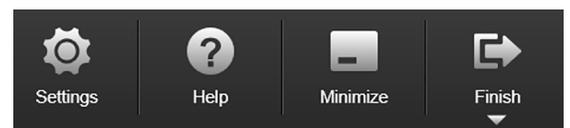
Appendix

Catalog number	Description
Instruments - Article List	
52410A	Reference Array T-Geometry X-Press
52400B	Pinless Femur Reference Array Kit
52429	Bone Fixator 2-Pin, Flip-Flop, X-Press
53108	Pointer Extended For Hip
55085	Instrument Adapter, Starlock
52858	Straight Cup Impactor Universal
52856B	Offset Cup Impactor Universal
52855-03	Insert for Cup Impactor Universal

Catalog number	Description
Instruments - Article List	
52876B	Hip Caliper
54243-11A	KingMark Calibration Device
53153	Disposable Clip-on Remote Control (20 pcs)
52312	Sterilization Tray Hip

References
1. Davis ET, Schubert M, Wegner M, Haimerl M. A New Method of Registration in Navigated Hip Arthroplasty Without the Need to Register the Anterior Pelvic Plane. J Arthroplasty. 2015;30:55-60. **2.** Babisch JW, Layher F, Amiot LP. The Rationale for Tilt-Adjusted Acetabular Cup Navigation. J Bone Joint Surg Am. 2008;90(2):357-365.