

**Instructions for Use
2D Hip Planning Software:
Serf Digital Solutions**

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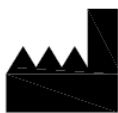
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The software is a decision-aid system designed for professionals having completed the appropriate medical training. It must in no way be used as the only basis for making clinical decisions during the diagnosis, care or treatment of a patient. The plausibility of the information obtained via this software must be systematically clinically checked before being used in the treatment of patients. Any use of the programme's medical information which is not included in the original concept or intended usage is not recommended and will be considered as improper use of the software.

A list of known bugs is available via the following link:

<https://github.com/oneorthomedical/DigitalPlannerHipSerf/issues>



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This device complies with the requirements of directive 93/42/EEC relating to medical devices.
CE mark acquisition year: 2017

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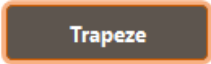

2 General information

The software is accessed via the SERF DIGITAL SOLUTIONS management platform at the following URL: <http://platform.serf-digital-solutions.com/login>
The version presented in this manual is version 1.4

Installation specifications:

- The website is fully responsive, meaning that it adapts to different screen sizes.
- The user must have the following specifications:
 - Browsers: Firefox, Chrome, Safari (current versions offered by the vendors).

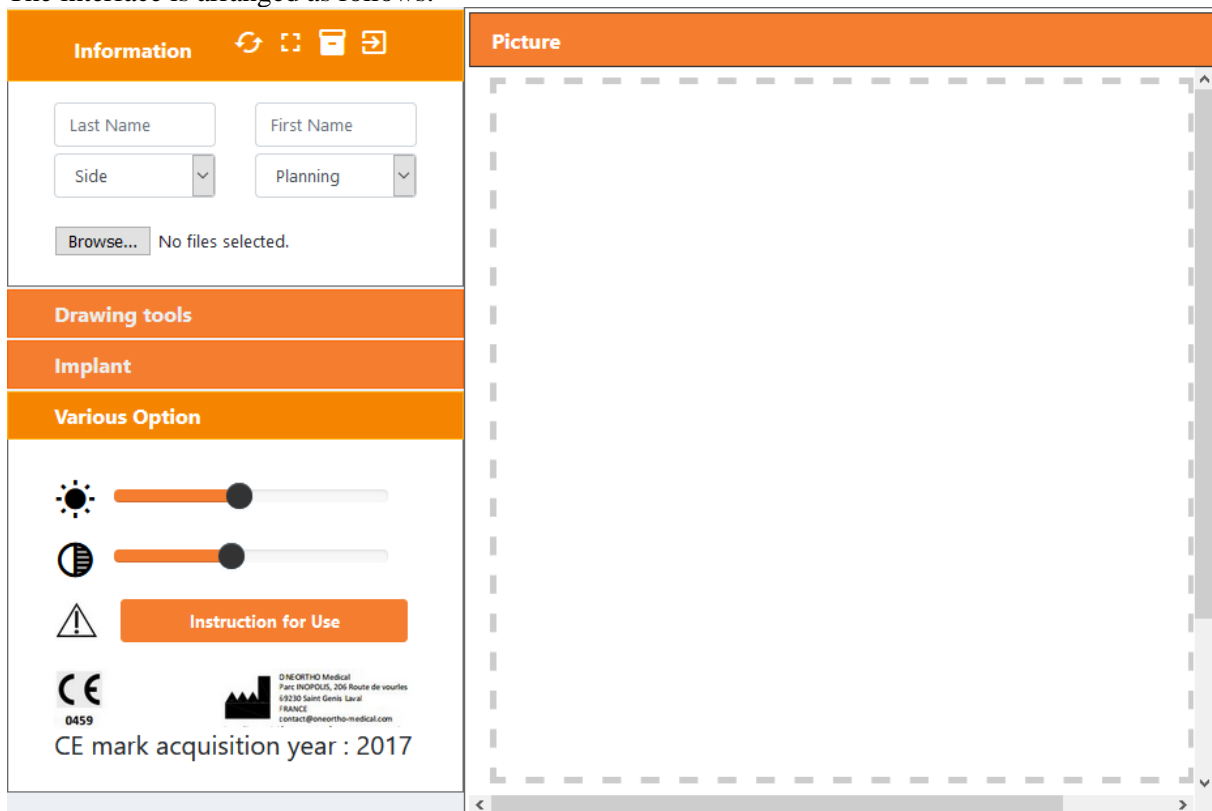
General:

- Functions turn grey with an orange border when selected: 
- Back buttons  cancel all the actions performed in the current tab.

3 Information


To access 2D planning from the SERF platform, click on the "2D planner" module in the dashboard.


The interface is arranged as follows:





The first step is to enter the patient information. Enter the last name and first name by clicking on


and


The  button is used to reload the page, while emptying the form fields.

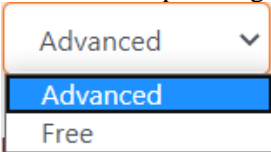
The  button switches the planner to full screen mode.

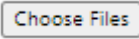
The  button takes you directly to the planning archives page.

The  button allows you to quit planning and return to the platform home page.

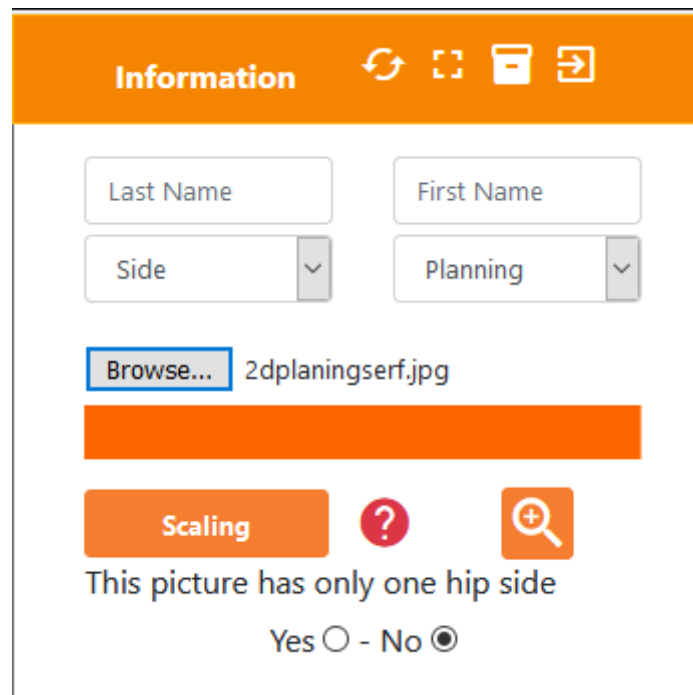
You can then choose the patient's side by clicking on  and selecting Right or Left.





Then select "advanced" or "free" planning by clicking on  then on

 (further details in section §4. Advanced Planning or §5. Free Planning).

Then click on . A browser window opens in which you can choose X-ray images in jpg format and click on OK. The image is displayed again.

The information tab is displayed:





Information    

Last Name First Name

Side Planning


Browse... 2dplaningserf.jpg

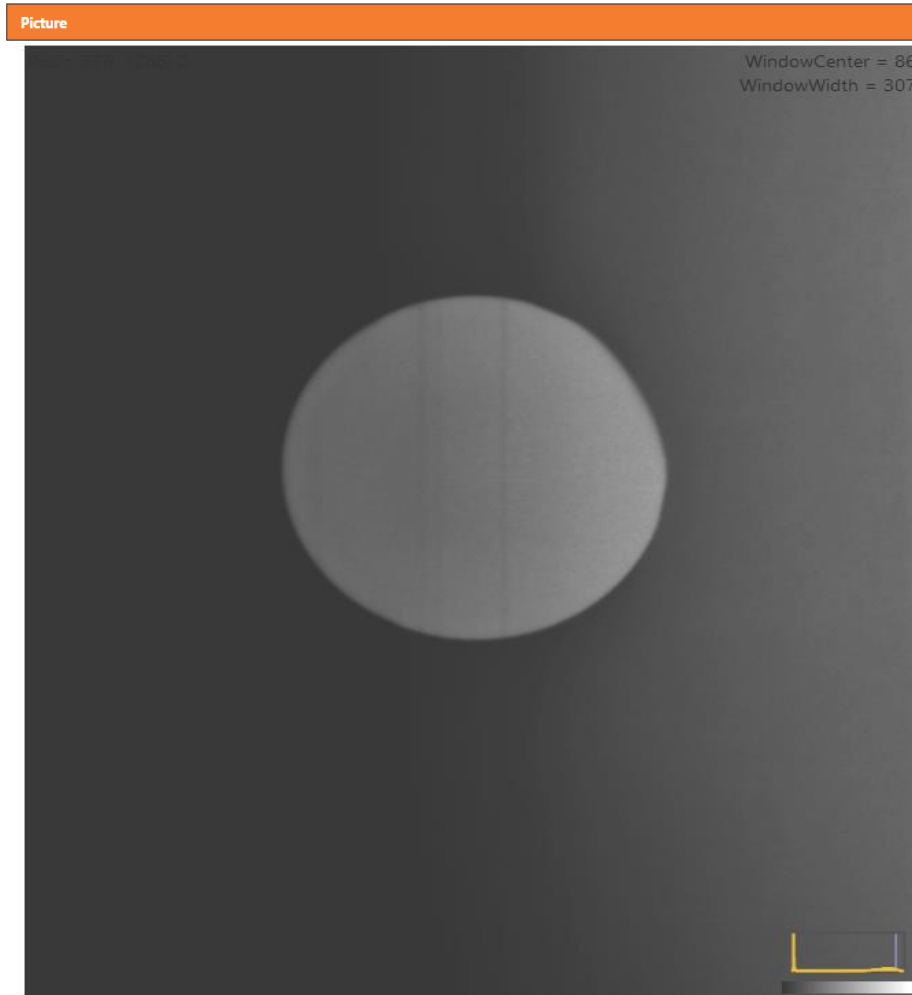
Scaling  

This picture has only one hip side


Yes ○ - No ●

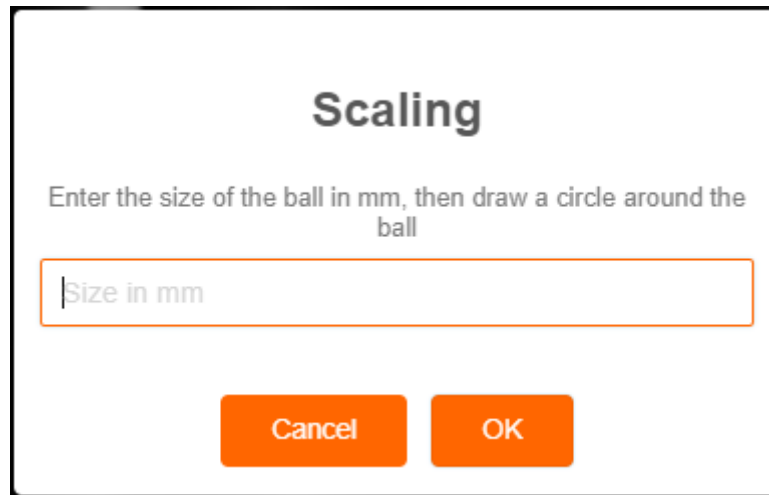


You can then press  and use the mouse wheel to zoom in on the image, particularly the ball which will then be used to scale the image.



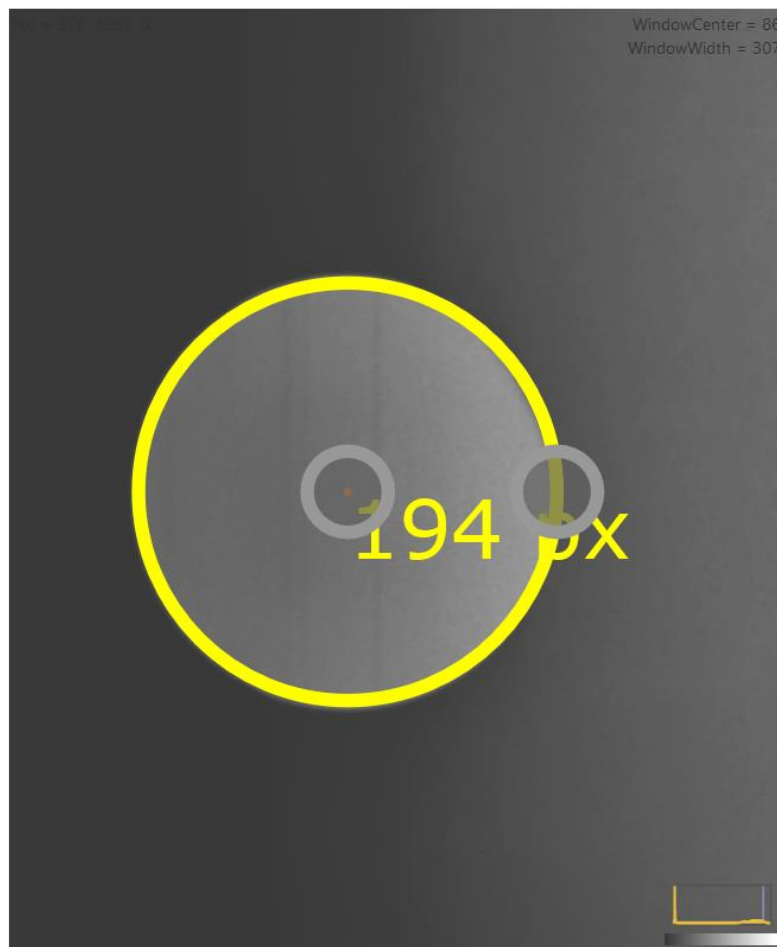
Scaling

Then scale the image by clicking on . A window opens. Enter the size of the ball in mm and click on OK.



Then, using the mouse, draw a circle around the ball to scale the image. Start in the centre of the ball and hold the mouse button down to enlarge the circle until it corresponds with the ball.

Important: The contours of the circle must be inside the contours of the ball or the known size marker. ***Make sure you draw the circle by dragging the mouse from left to right to obtain positive values.***






Selecting the grey dot on the edge of the circle allows you to change its radius while the grey dot in the centre allows you to move the whole circle.

You then need to indicate whether the X-ray shows one or two hips by clicking on:

This picture has only one hip side

Yes No

Click on "Confirm  " to confirm and continue planning.

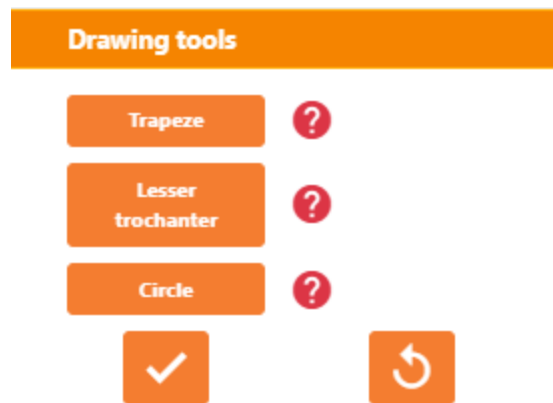
4 "Advanced" Planning


This section describes how to use 2D planning after drawing notable geometric elements like the femoral shaft axis (intramedullary axis) and the acetabular cup centre. These elements will then be used for the automatic positioning of implants.

Important : The femoral stem “calcar-guided” A2 is not available in this planning mode.

4.1 Drawing Tools

The "Drawing Tools" tab opens automatically if you selected "Advanced Planning". You can choose different drawing tools in this tab:

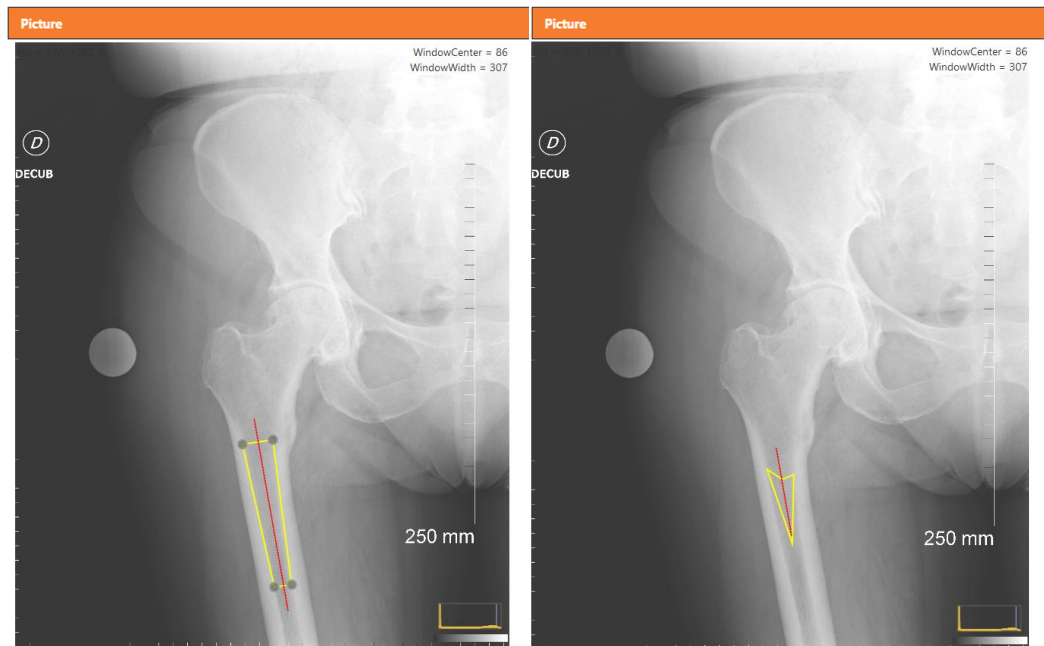


- The  tool is used to draw a trapezium in the femur using the mouse. The trapezium bases represent two levels of femoral shaft section.

The middles of these bases are used to automatically define the anatomical axis of the femur.

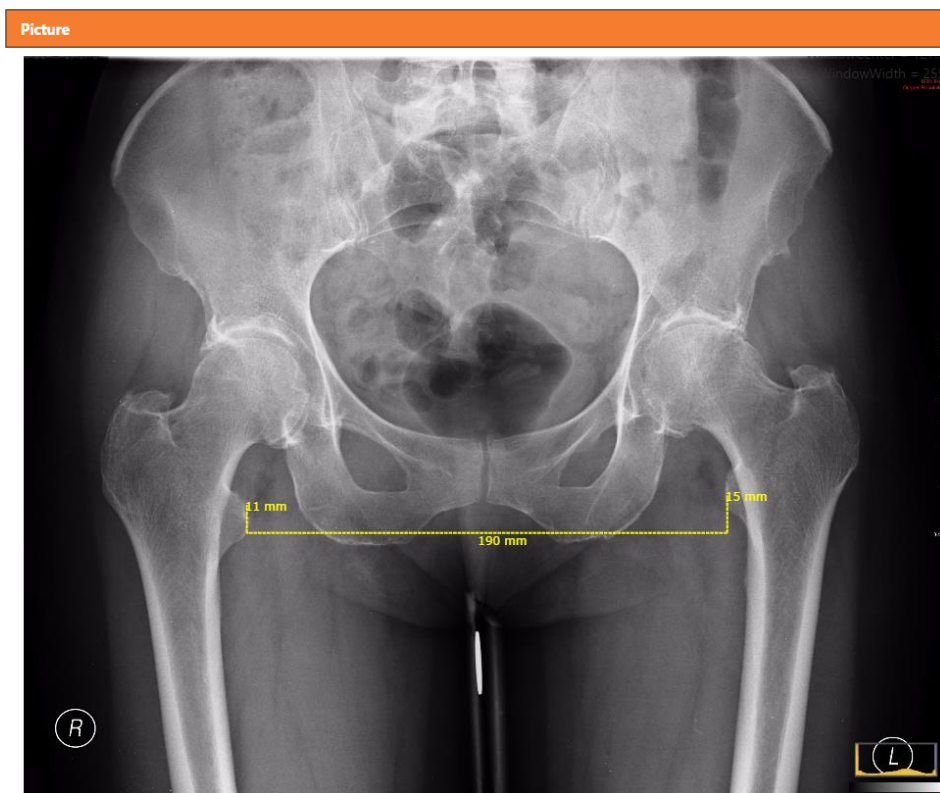
To create the trapezium on the selected side in the "Information" section, stop the mouse at each trapezium corner (for around 1 second) and then move on to the next dot while holding the mouse button down.

You can click on the grey dots to adjust the edges of the trapezium or in the middle to move the whole drawing.



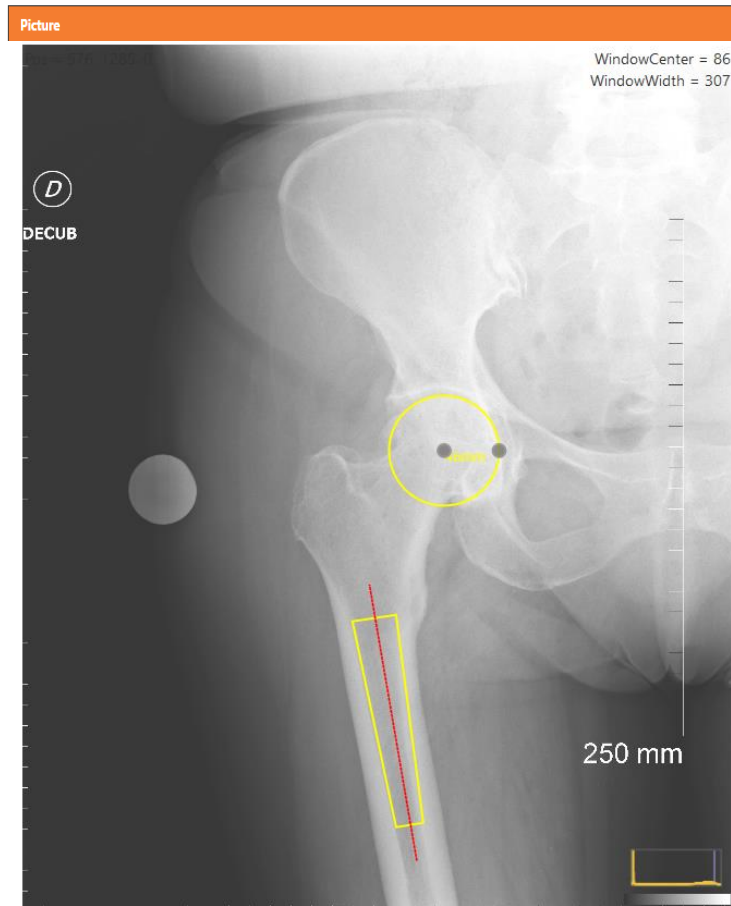
Lesser trochanter


- The Lesser trochanter tool allows you to measure the offset between a patient's two hips. For example, the difference in height in the lesser trochanter between the right and left sides. This tool will be used if there are two hips on the uploaded image.





Circle


- The tool allows you to draw a circle from the centre of the bony acetabulum. Selecting the grey dot on the edge of the circle allows you to change its radius while the grey dot in the centre allows you to move the whole circle.




The  icon appears once these functions have been used. This enables you to delete the line drawn using the relevant function.

To access help at any point during planning, click on  to view an illustration of what you need to do with the corresponding tool.

You can then click on  to continue or  if you want to go back to the "Information" tab to change the information.

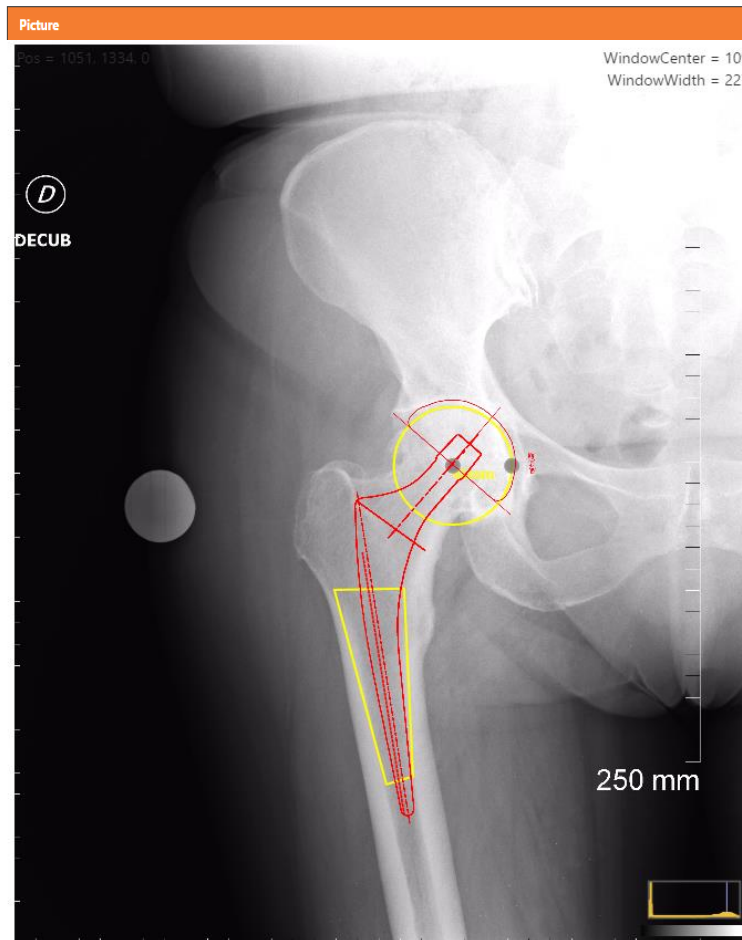
Important: using the  button cancels everything you have just done in the "Drawing Tools" tab.

4.2 Implants





Clicking on  opens the "**Implant**" tab automatically. You can choose which type of femoral stem you want to plan by selecting it from the drop-down menu in the "**Femoral stem**" section, then the type of acetabular cup in the same way in the "**Acetabular cup**" section.

The femoral stem and acetabular cup implants and templates appear on the image.














You can:

- Change the opacity of the drawing tools from 0% to 100% using this slider  for adjustment.
- Change the colour of the stem using the  buttons under the title "Stem", the first three buttons respectively serving to quickly colour the selected stem black, orange or green, and the 4th button used to open a colour picker to choose a precise colour of the user's choice.
- Change the size of the femoral stem by clicking on  and .
- Move the femoral stem along the anatomical axis defined by the trapezium by clicking on the diagonal arrows.
- Use the directional arrows (up down left right) to move the femoral stem horizontally or vertically.



- Change the colour of the cup using the     buttons under the title "Cup ", the first three buttons respectively serving to quickly colour the selected cup black, orange or green, and the 4th button used to open a colour picker to choose a precise colour of the user's choice.
- Change the size of the acetabular cup by clicking on  and .
- Move the acetabular cup along the anatomical axis by clicking on the diagonal arrows.
- Use the directional arrows to move the acetabular cup horizontally. .
- Rotate the acetabular cup by clicking on  or .

Two additional items of information are given and displayed on the X-ray itself: offset and height.




The offset indicates the horizontal gap between the centre of the femoral head at 0 on the femoral stem and the centre of the acetabular cup.

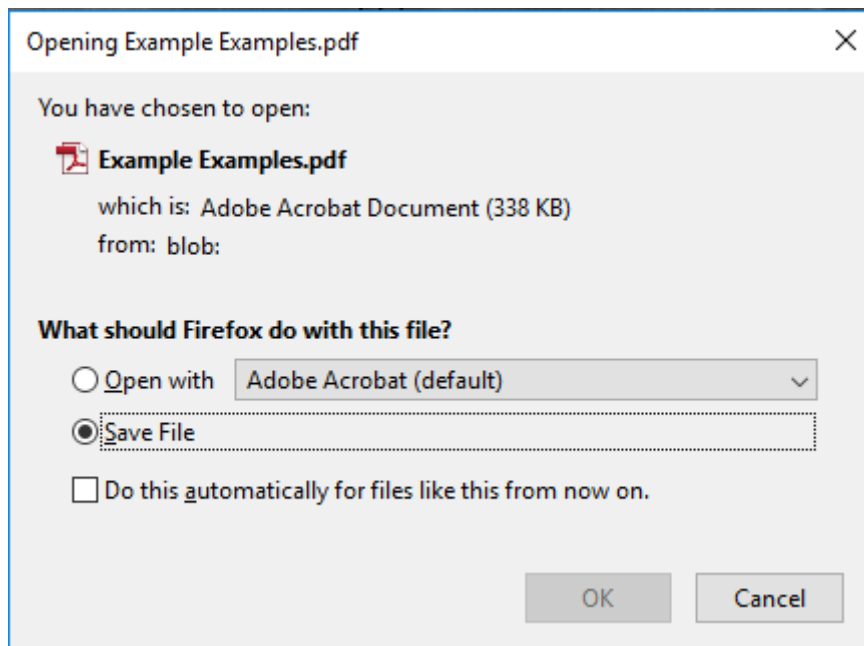
The height indicates the vertical gap between the centre of the femoral head at 0 on the femoral stem and the centre of the acetabular cup.

Click on  to continue or  to go back to the previous step.

Important: using the  button cancels everything you have just done in the implant tab.

Clicking on  opens a window to save the file you have created in PDF format, with the information relating to the patient, the original image and the plan you have just created.

Important: This action may also open the PDF in a browser tab so you need to save it.







5 "Free" Planning



Choosing "**Free**" planning takes you directly to the "**Implant**" tab. You can choose which type of femoral stem you want to plan by selecting it from the drop-down menu in the "**Femoral stem**" section, then the type of acetabular cup in the same way in the "**Acetabular cup**" section.





Options are displayed as follows:






You can:



- Change the colour of the stem using the  buttons under the title " Stem ", the first three buttons respectively serving to quickly colour the selected stem black, orange or green, and the 4th button used to open a colour picker to choose a precise colour of the user's choice.
- Change the size of the femoral stem by clicking on  and  .
- Move the femoral stem on the image  .

- Rotate the femoral stem by clicking on  and .

- Change the colour of the cup using the     buttons under the title "Cup ", the first three buttons respectively serving to quickly colour the selected cup black, orange or green, and the 4th button used to open a colour picker to choose a precise colour of the user's choice.


- Change the size of the acetabular cup by clicking on  and .

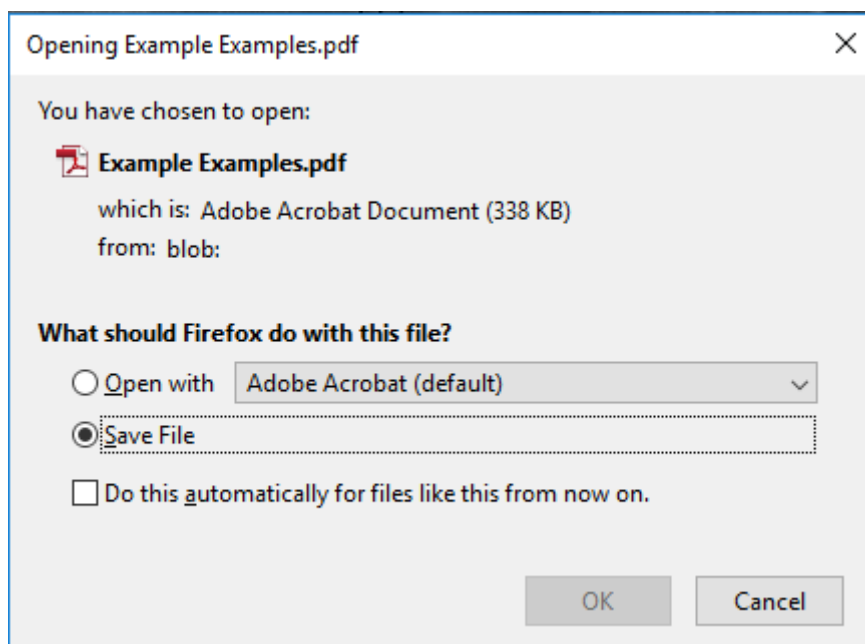
- Move the acetabular cup on the image .

- Rotate the acetabular cup by clicking on  and .

Click on  to continue or  to go back to the previous step.

Important: using the back button  cancels everything you have just done.

Clicking on  opens two windows. One to save in PDF format the file that the user has just created, with the patient information, the original image as well as the schedule they just made:



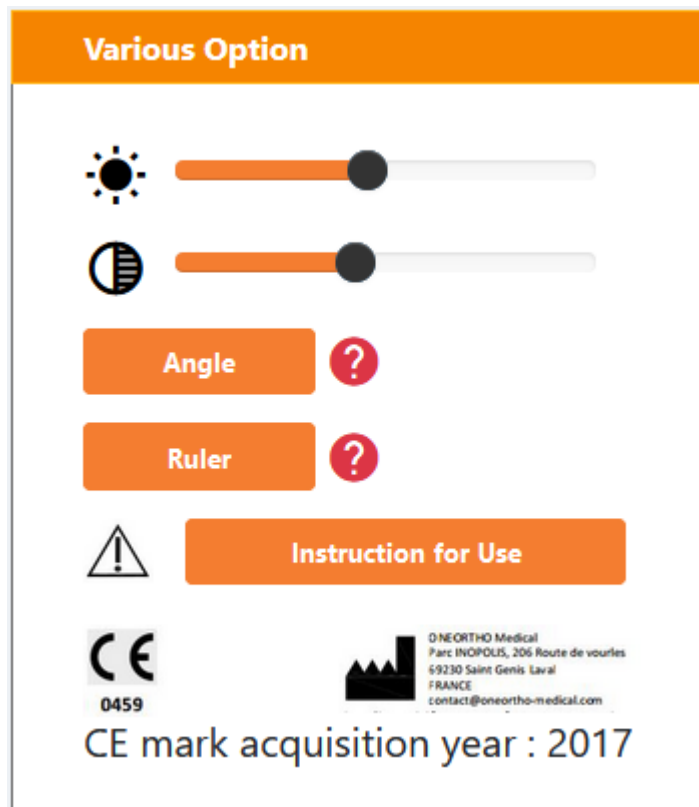
And the other to suggest archiving the intervention:

Archive?

The planification will be saved and available in the Archive module



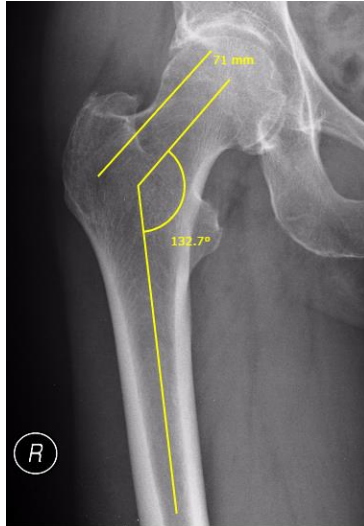
6 Various Options



You can change the background colour in "Various Options".

You can also adjust the image contrast and brightness. These two tools are useful for assessing the size of femoral head and increasing precision when drawing the corresponding circle.

You can also use the "**Angle**" tool to calculate an angle and the "**Ruler**" tool to measure a straight line. These tools are only displayed when the "**Implant**" step is completed.



Instruction for Use

Pressing **Instruction for Use** takes you to the online version of this document.

7 Contact us

You can contact us by phone on:

+33 4 72 05 60 10

By fax:

+33 4 72 02 19 18

By e-mail: infos@oneortho-medical.com



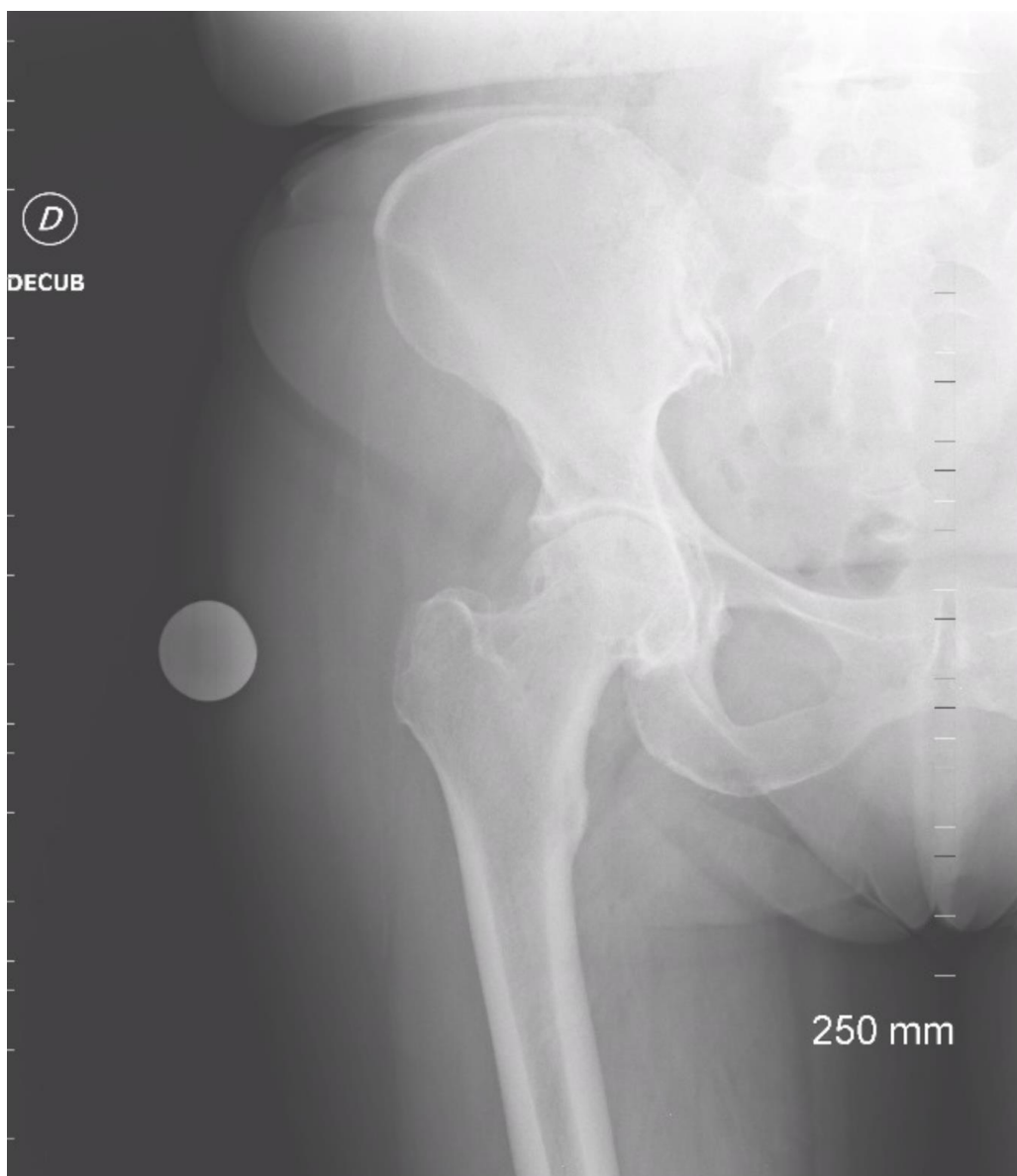
Planning for the patient's hip surgery:

Last name: example

First name: example

The scaling coefficient of the implants is: 0.1419753086419753

Your original image:



Your planning:

Femoral stem used for this planning: HypeT2

Acetabular cup used for this planning: Cup49

Offset = 4.969 mm

Height = 1.095 mm

