



85 avenue des Bruyères
69150 Décines-Charpieu
Tel: 04 72 05 60 10
Fax : 04 72 02 19 18
E-mail: serf@serf.fr

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



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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>

 ONEORTHO Medical
Parc INOPOLIS, 206 Route de vourles
69230 Saint Genis Laval
FRANCE
contact@oneortho-medical.com

This device

CE mark acquisition year: 2017

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CE
0459

nts of directive 93/42/EEC relating to medical devices.



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 1.0.3.

Installation specifications:

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

General:

- Functions turn grey with an orange border when selected:  Trapeze
- 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 screenshot shows the 'Information' tab of the osserf software interface. On the left, there's a sidebar with sections for 'Information', 'Drawing tools', 'Implant', and 'Various Option'. Under 'Information', there are fields for 'Last Name' and 'First Name', dropdown menus for 'Side' (set to 'Right') and 'Planning' (set to 'Planning'), and a 'Choose Files' button with the message 'No file chosen'. The main area is titled 'Picture' and contains a large dashed rectangular frame for drawing or placing images. At the bottom of the sidebar, there's a CE mark acquisition year section showing '0459' and '2018'.

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

Last Name

First Name

and

You can then choose the patient's side by clicking on

Side

and selecting Right or Left.

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

Advanced

then on

Advanced
Advanced
Free

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

Then click on **Choose Files**. 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

Example Example

Right Advanced

Choose Files hanche_test... 28 mm.jpg

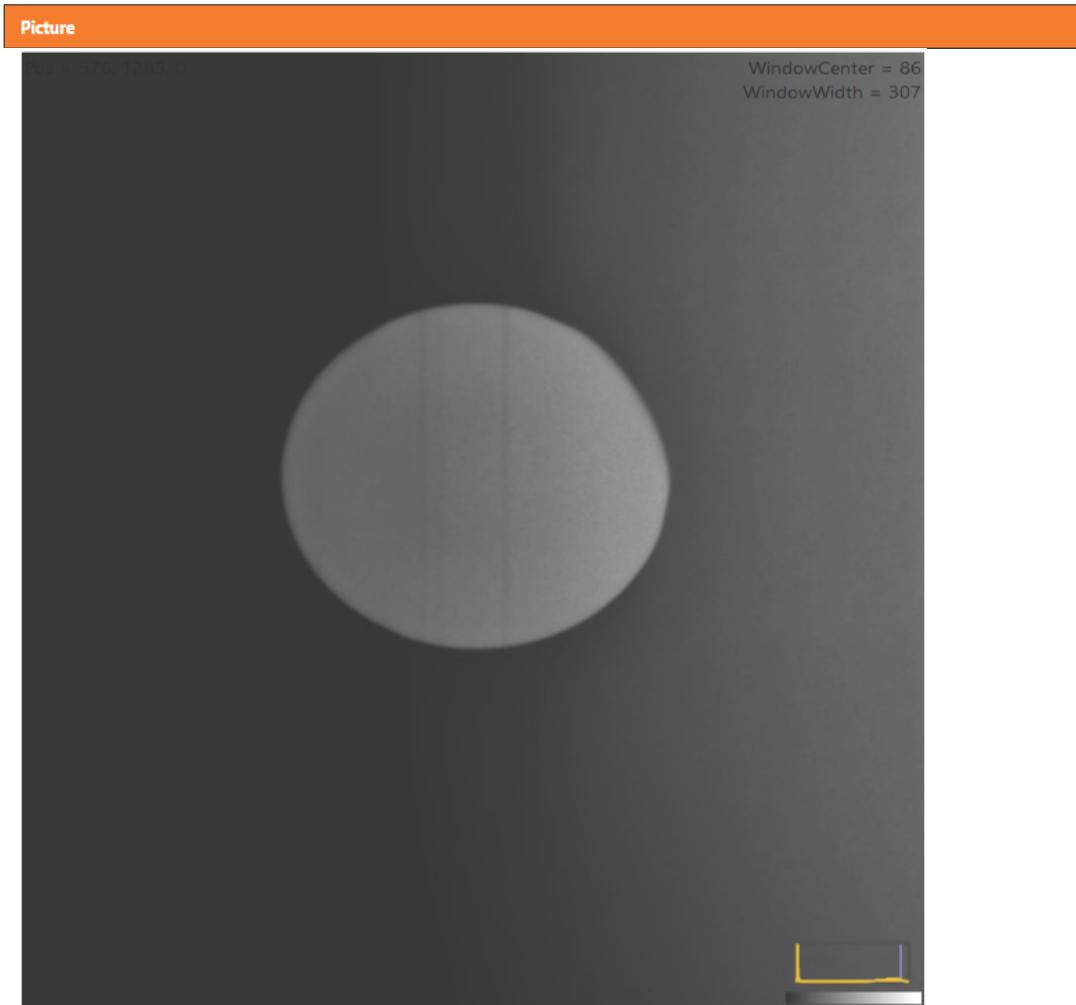
Scaling ? +

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.

Scaling

Enter the size of the ball in mm, then draw a circle around the ball

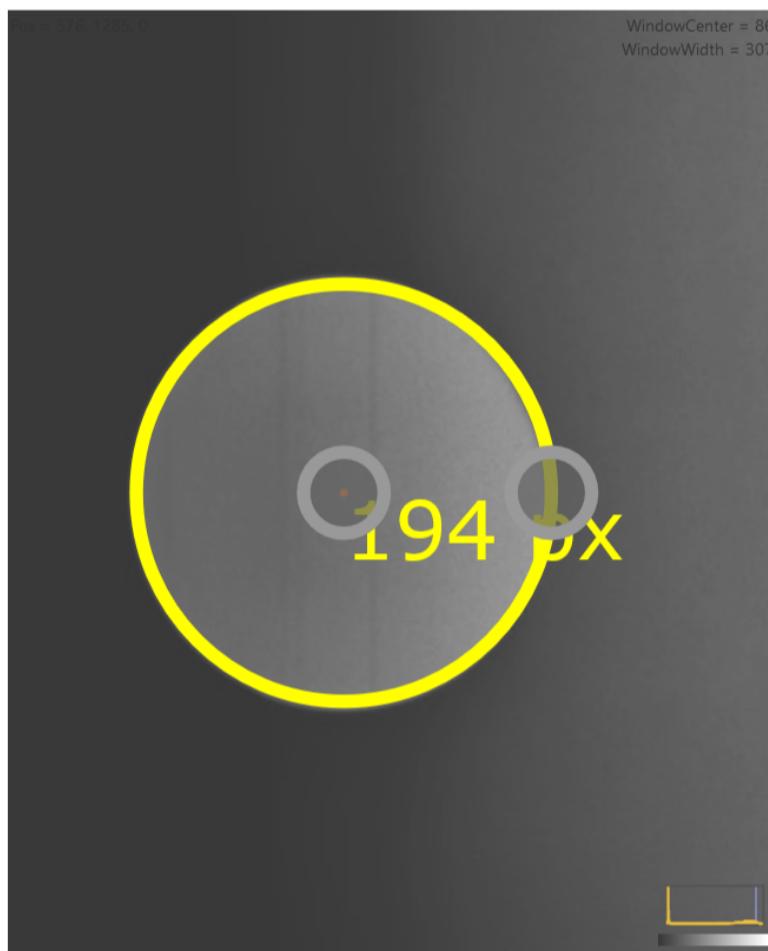
Size in mm

Cancel

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

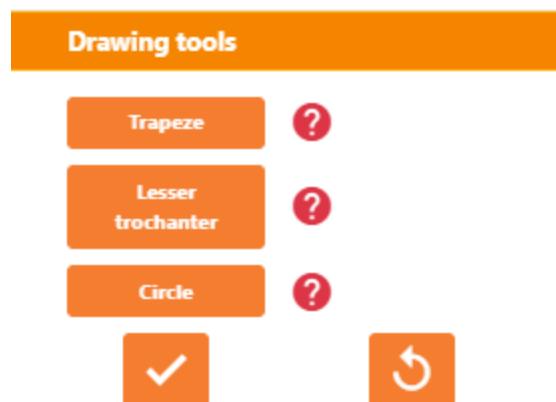
Click on "Confirm  " to confirm and continue planning.

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.

4.1 Drawing Tools

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

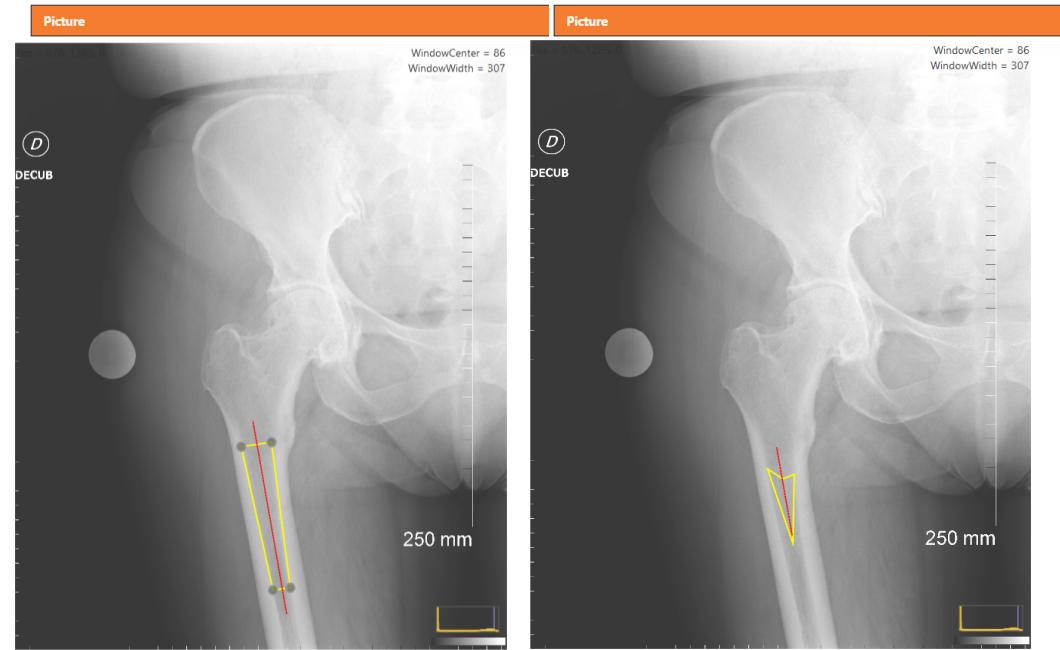


- The **Trapeze** tool is used to draw a trapezium in the femur using the mouse. The trapezium bases represent two levels of femoral shaft section.

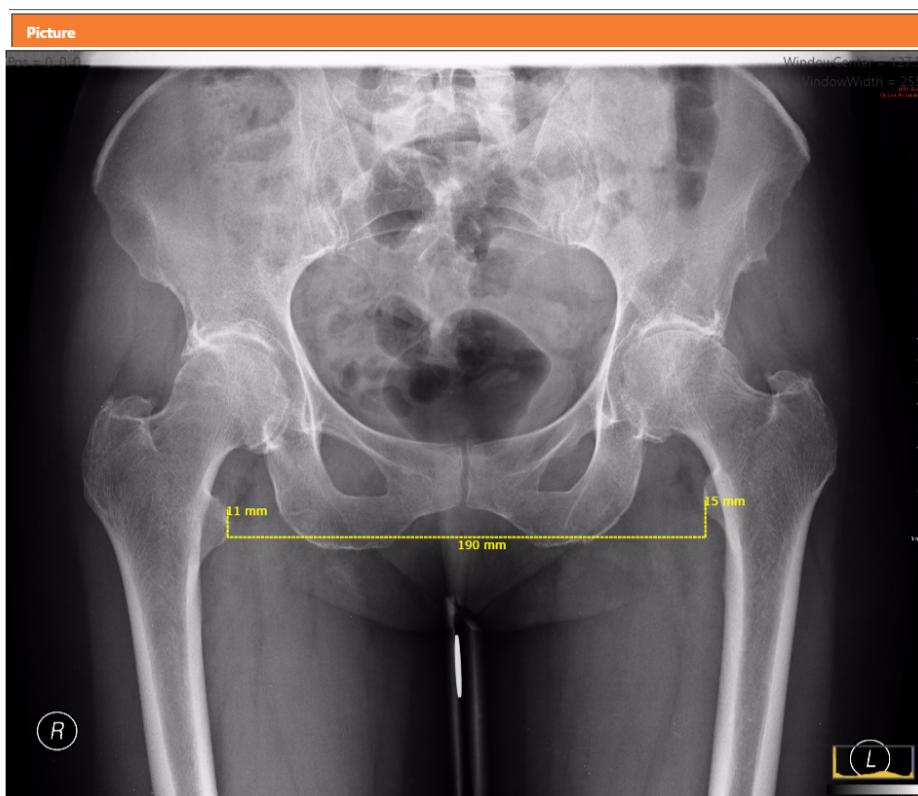
The middles of these bases are used to automatically define the anatomical axis of the femur.

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.



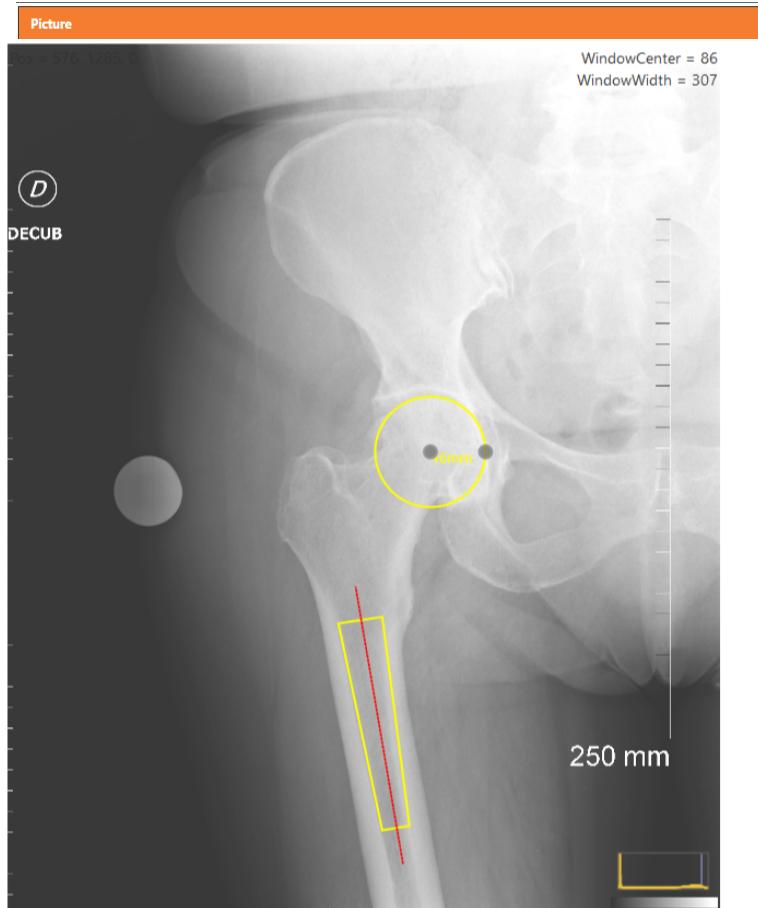
- The **Lesser trochanter** tool allows you to measure the offset between a patient's two hips. For example, the difference in height in the lesser trochanter between the right and left sides. This tool will be used if there are two hips on the uploaded image.





Circle

- The **Circle** 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

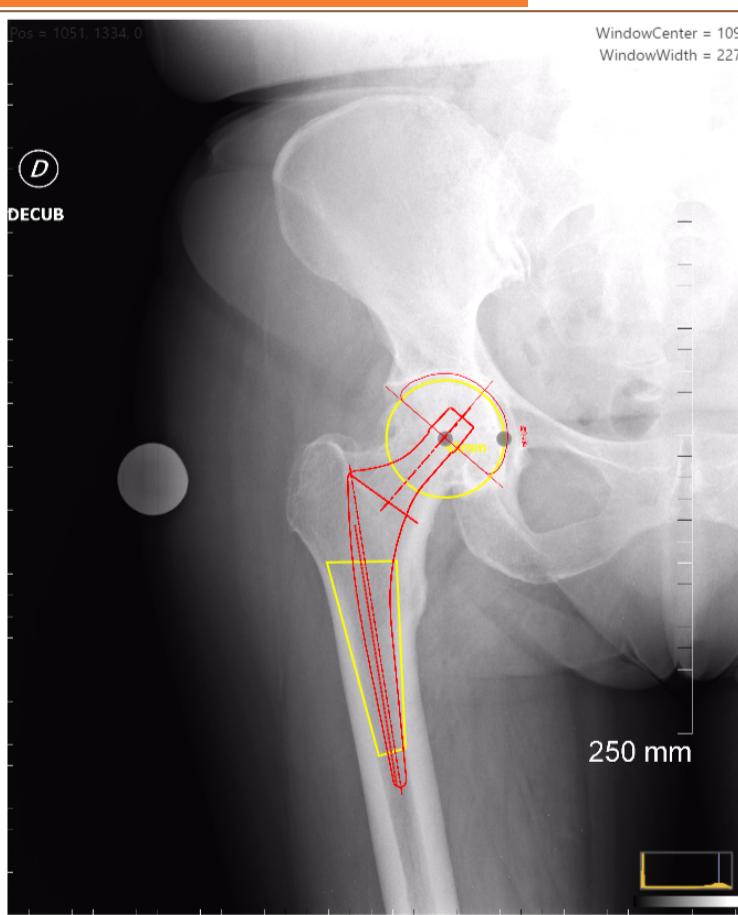


Clicking on  opens the "**Implant**" tab automatically. You can choose which type of femoral stem you want to plan by selecting it from the drop-down menu in the "**Femoral stem**" section, then the type of acetabular cup in the same way in the "**Acetabular cup**" section.

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



Picture



You can:



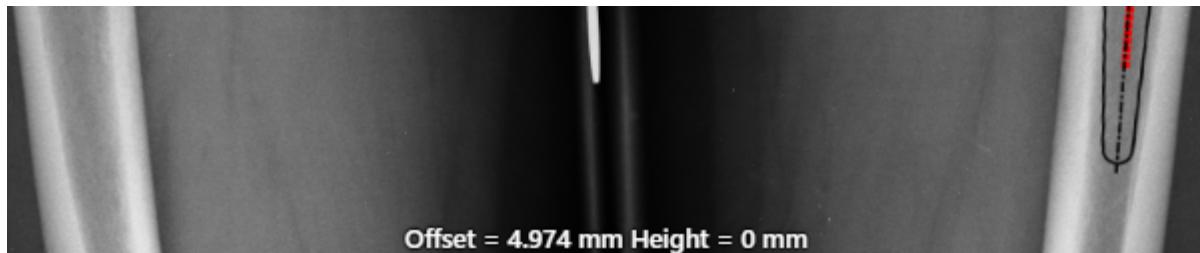
- Change the size of the femoral stem by clicking on and .
- Move the femoral stem along the anatomical axis defined by the trapezium by clicking on the diagonal arrows.
- Use the directional arrows (up down left right) to move the femoral stem horizontally or vertically.



- Change the 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.

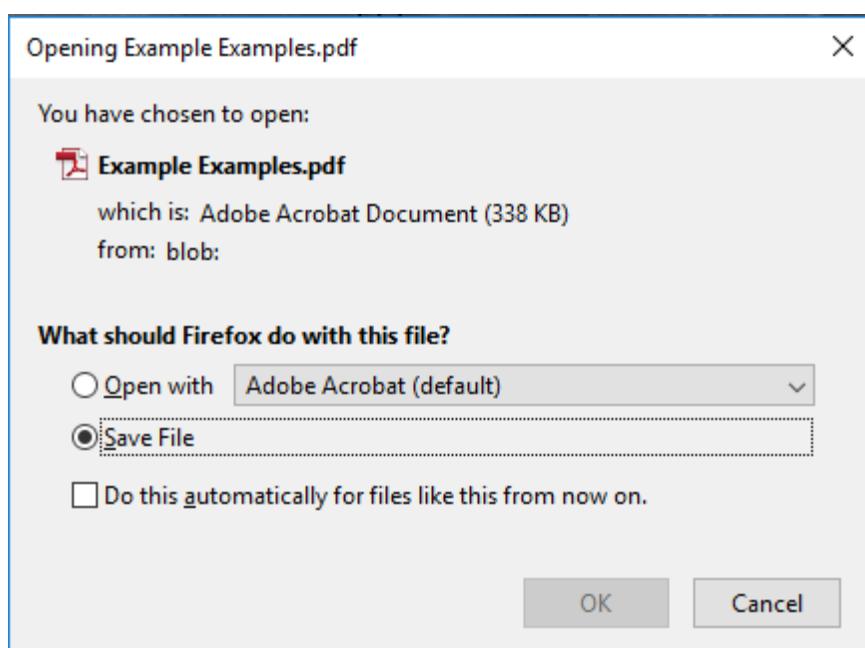
The height indicates the vertical gap between the centre of the femoral head at 0 on the femoral stem and the centre of the acetabular cup.

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:



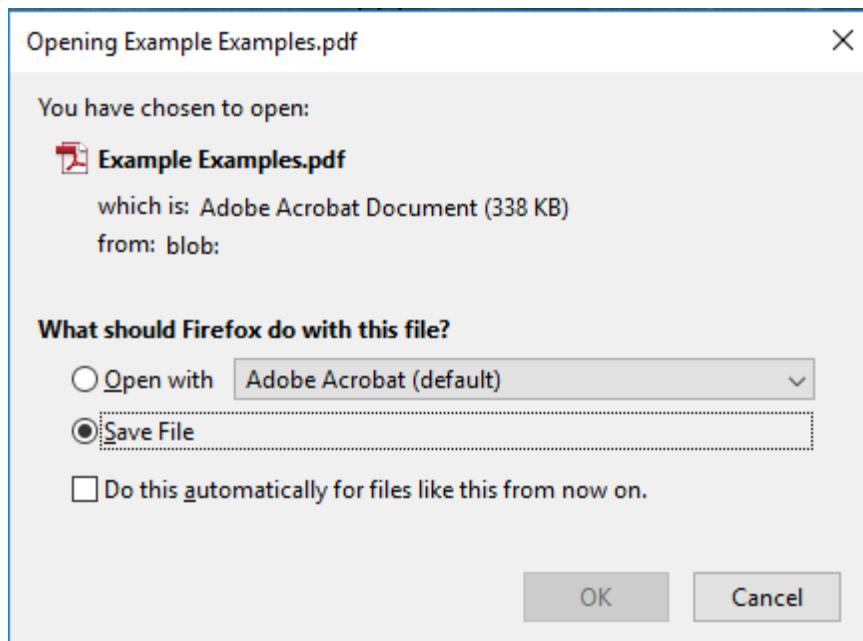
- Change the size of the femoral stem by clicking on and .
- Move the femoral stem on the image .
- Rotate the femoral stem by clicking on and .

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

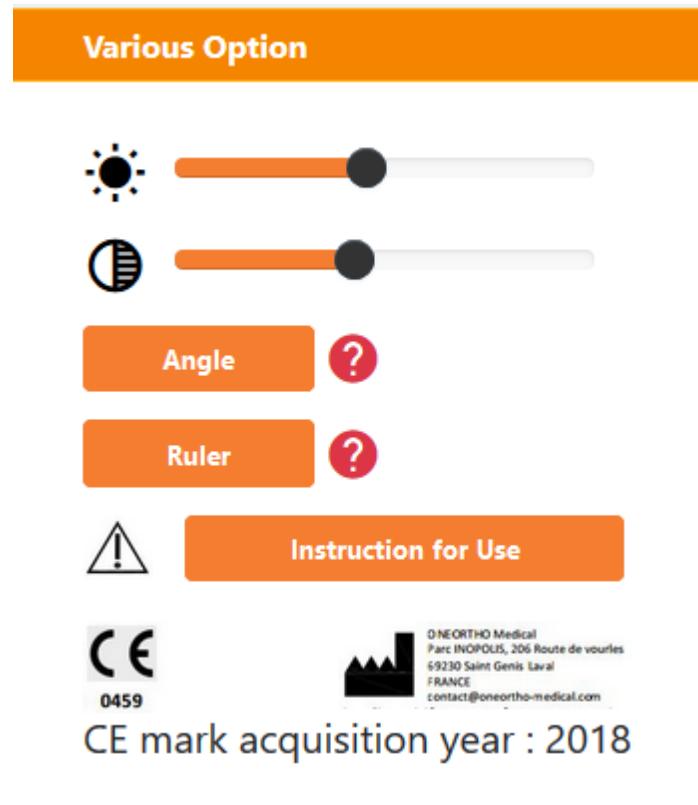
Click on to continue or to go back to the previous step.

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

Clicking on Finish 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.



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



8 Appendices

XX/XX/2019



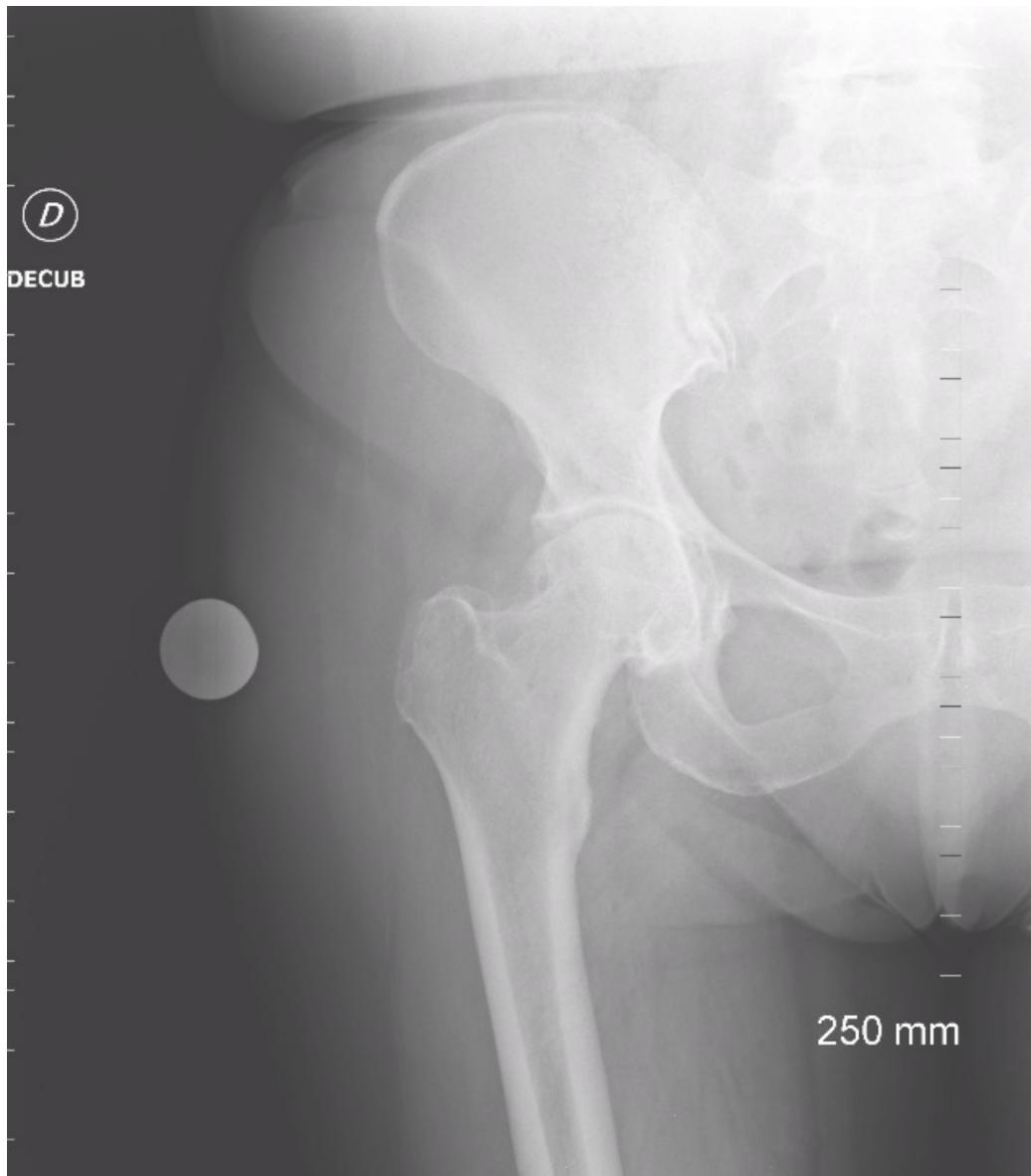
Planning for the patient's hip surgery:

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

