

A grayscale background image showing a close-up of a person's legs and feet in motion on a running track, with a starting block visible.

User manual
Planning software for PTC In2Bones



SUMMARY

1	General information.....	4
2	Principle of prosthetic positioning in relation to bone models	5
3	Link with the connection, access and interface software.....	6
4	Visualization tools	9
5	Position of the prosthetic assembly.....	11
6	Repositioning Talar/Tibia	Erreur ! Signet non défini.
7	Contact Us	13

Copyright information

This document and what it describes are protected by the Law of 11 March 1957 on literary and artistic property, amended by the Law of 3 July 1985, as well as by the laws on copyrights and international conventions.

No part of this manual, including the products and software described herein, may be reproduced, transcribed, stored in a database system, or translated into any language, in any form or by any means, except for documentation kept by the purchaser for backup purposes, without the written permission of OneOrtho Medical. Any person who does not comply with these provisions will be guilty of counterfeiting and will be liable to criminal penalties provided for by law.

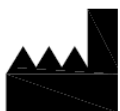
OneOrtho Medical provides this manual "as is" without warranty of any kind, either express or implied, or under conditions of merchantability or fitness for a particular purpose. In no event shall OneOrtho Medical, its directors, officers, employees, agents or agents be liable for any indirect, special, incidental or consequential damages even if OneOrtho Medical has been advised of the possibility of such damages arising from any defect or error in this manual or product.

The names of products and companies appearing in this manual may or may not be registered trademarks or copyrights for their respective companies, and are used only for identification or explanation purposes, and for the sole benefit of the owners, without intent to infringe.

This software is designed for professionals with appropriate medical training. It should not be used in any way in clinical decision-making for diagnosis. It should in no way be used as the sole basis for patient care or management. The plausibility of the information obtained through the software must systematically be clinically verified before its use for the treatment of patients. Any application of the medical information of the program that does not fit into the original concept or intended use of the program is not recommended and will be considered an abuse of the software.

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

<https://github.com/oneorthomedical/DigitalPlannerI2B/issues>



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

© 2019 Oneortho Medical. All rights reserved.

1 General information

The In2Bones planner is part of a global software development project to design custom cutting guides. Chronologically, the Ankle Planner module comes after the pre-planning stage of the overall project workflow.

The url for accessing the site is as follows: <https://in2bones-preprod.digitalsolutions.app>
The current version of this manual is version 3.0.

Warning: The use of the software contains the 3D configuration and planning performed preoperatively by the trained physician. The data presented by the software are not interpreted and the choices are made by trained medical personnel.

It is prohibited to use several web browsers or several tabs of a browser in parallel to access several pages of the application.

When the user validates the final positioning, it conditions the shape of the product cutting guide. The user of the software is informed that the 3D representation proposed to him or her results partly from extrapolations and smoothings made from images of scanned sections every 1 mm. The user must, therefore, remain vigilant when using the product cutting guide to detect any discrepancy between the 3D scene used for positioning and what he or she sees during the surgical procedure.

Installation specifications :

- The platform is totally responsive, i.e. it adapts to the size of the screen.
- The site will be accessible to the following browsers and operating systems:

OS :

- Windows.
- Mac.

Browser :

- Edge 16 and above.
- Firefox 57 and above.
- Chrome 63 and above.
- Safari 11 and above.

Edge [*]	Firefox	Chrome	Safari
		49	
		62	
	57	63	
16	58	64	11

2 Principle of prosthetic positioning in relation to bone models

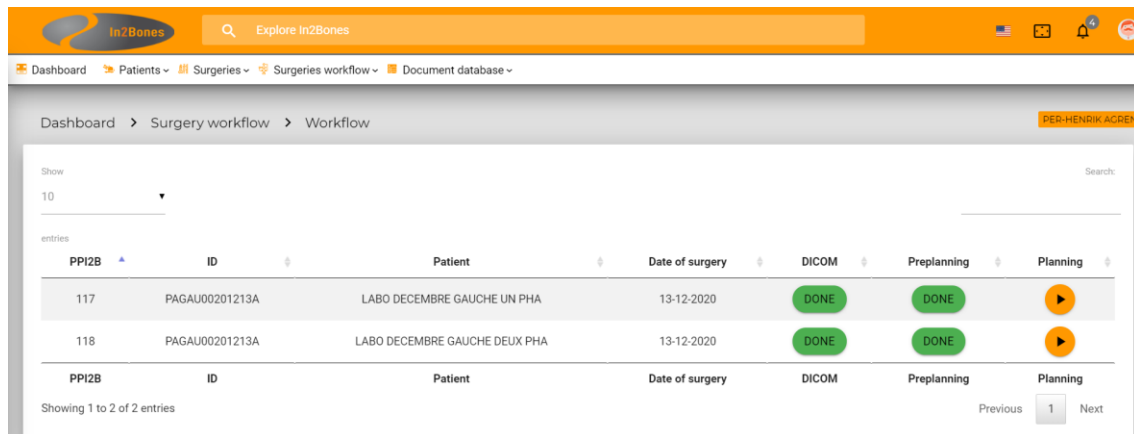
As a reminder, here are the positioning rules that are applied in order to offer the surgeon a pre-planning of his case:


- Dimensions of the prosthetic assembly: it is 16.5mm and the addition of the cutting heights of the subchondral bone is 9mm + 6mm or 15mm.
- If the distance between the two points of the tibial and talar domes (corresponding to the value of the residual cartilage at the tibial and talar level) is less than or equal to 1.5mm then the talus + calcaneum assembly is distalized by the complementary value of 1.5mm.
- If the distance between the two points of the tibial and talar domes is greater than 1.5mm then this distance is reduced to 1.5mm
- Positioning of the X-Y-Z marker in relation to the tibia:
 - The mechanical vertical axis passing through the proximal tibial spines and the top of the concavity of the distal tibia defines the direction of the Y axis from the bottom to the top.
 - The direction of the Z axis is defined as being perpendicular to the Y axis and parallel to the bisector of the two axes defined by the 4 points in the plane perpendicular to the Y axis and delimiting the tibial articular face.
 - A plane parallel to the directions of Y-Z defines the orientation of the sagittal plane.
 - The X axis is the third axis to define an orthonormous reference mark with the previously defined Y and Z directions.
 - The origin of the tibial marker is located on the mechanical tibial axis at the subchondral bone surface of the tibial dome.
 - The X-Y plane is defined as the frontal plane of the tibia.
- Pre-planning of the horizontal tibial section:
 - The position of the "horizontal" section of the pre-planning is in a plane perpendicular to the Y axis located 9mm from the top of the concavity of the tibial dome. Its position in this plane and its orientation are defined from the orientation of the talar implant.
- Positioning of the X-Y-Z marker in relation to the slope:
 - The directions of the X-Y-Z tibia marker are repeated by translating the marker.
- Talar pre-planning:
 - Is performed by placing the origin of the mark by a 6mm distal translation of the upper point of the talar dome along the Y axis. From this origin, the X-Z plane defines the first talar cutting plane.
- Choice of talar implant:
 - The size and position of the talar implant chosen are the most suitable in terms of bone coverage while eliminating any posterior prosthetic overhang in relation to the bone surfaces. From this position and size are defined as the size and position of the tibial implant.
- The choice of tibial implant is made by:
 - Elimination of the anterior overhang as much as possible
 - Optimization of the coverage of the implant surface in relation to the bone cut. If two sizes can meet these criteria, the smaller of the two will be chosen.
 - The proposed implants will be by default the standard type implants of the range proposed by In2Bones.

3 Link with the connection, access and interface software

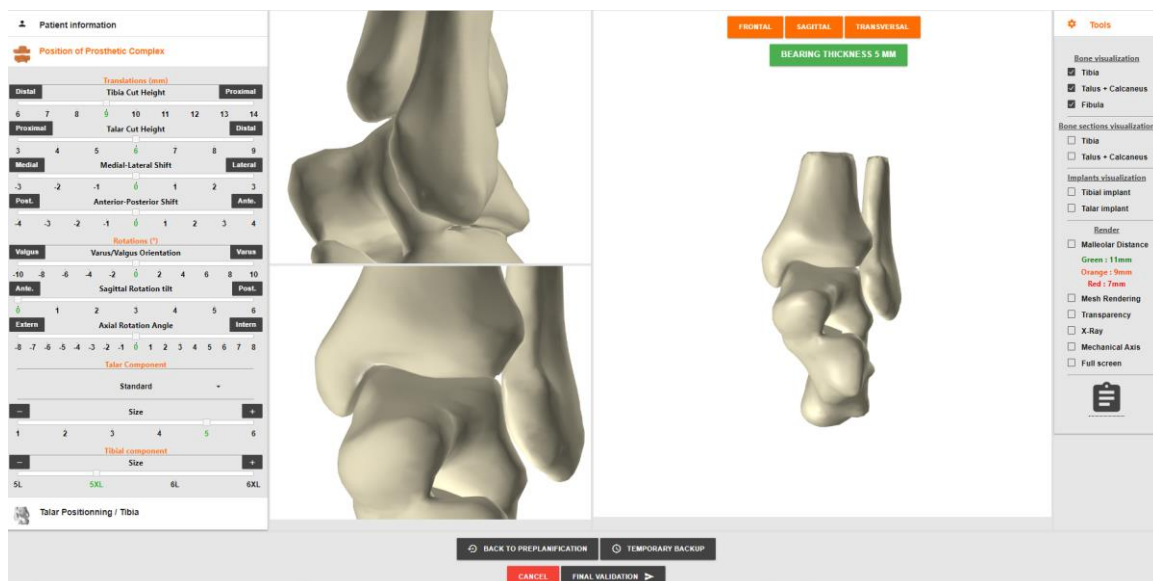
As part of the combination of the management software and the planning platform, an email is sent to the inform the user that the planning is available online and that consultation and modification of it is possible. is the user will be able to connect to the management platform and go to the case tracking module.

The interface is as follows:



In the "Planning" column for each patient ID , the user must select the  button to access the 3D planning page

This new page is presented as follows:




Patient information


Position of Prosthetic Complex

Translations (mm)

Distal

Tibia Cut Height

Proximal

6 7 8 9 10 11 12 13 14

Proximal

Talar Cut Height

Distal

3 4 5 6 7 8 9

Medial

Medial-Lateral Shift

Lateral

-3 -2 -1 0 1 2 3

Post.

Anterior-Posterior Shift

Ante.

-4 -3 -2 -1 0 1 2 3 4

Rotations (°)

Valgus

Varus/Valgus Orientation

Varus

-10 -8 -6 -4 -2 0 2 4 6 8 10

Ante.

Sagittal Rotation tilt

Post.

0 1 2 3 4 5 6

Extern

Axial Rotation Angle

Intern

-8 -7 -6 -5 -4 -3 -2 -1 0 1 2 3 4 5 6 7 8

Talar Component

Standard

-

Size

+

1 2 3 4 5 6

Tibial component

Size

-

Size

+

5L 5XL 6L 6XL


Talar Positionning / Tibia

In the part on the left of the planning page, the user will be able to find 3 menus:

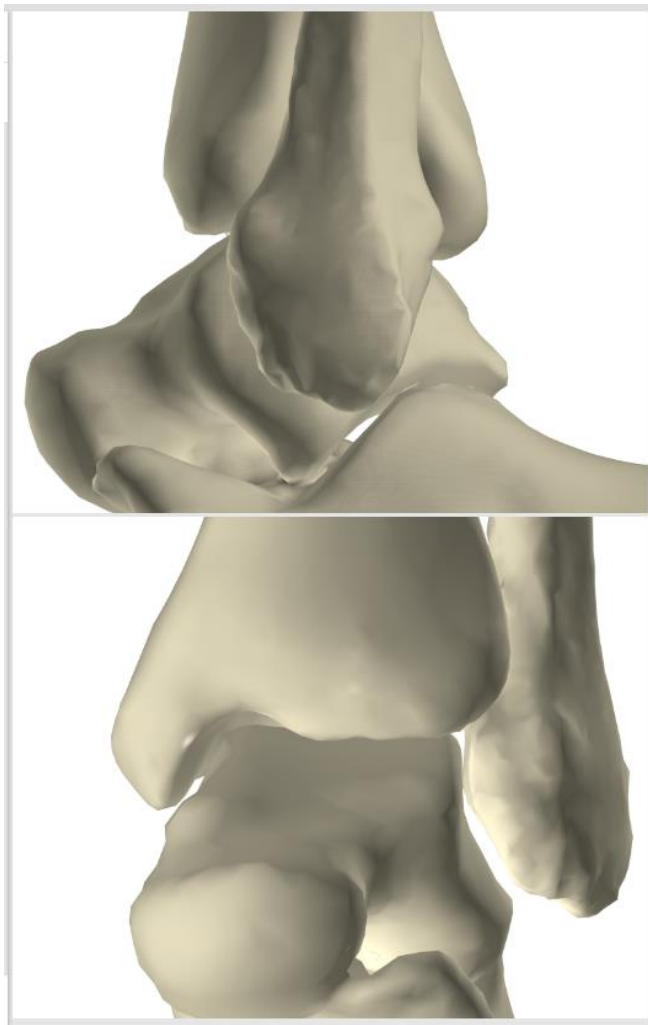
- The "Patient Information" menu: This contains information about the patient and the procedure.

- The "position of Prosthetic Complex" menu: This contains the planning modification tools to adjust the positioning of implants on bone models.

- The "Talar positioning/ tibia" menu: This contains all the tools necessary to modify the positioning of bone models in relation to each other.

A simple right click with the mouse on the menu title allows the user to scroll through the tools that make up the menu.

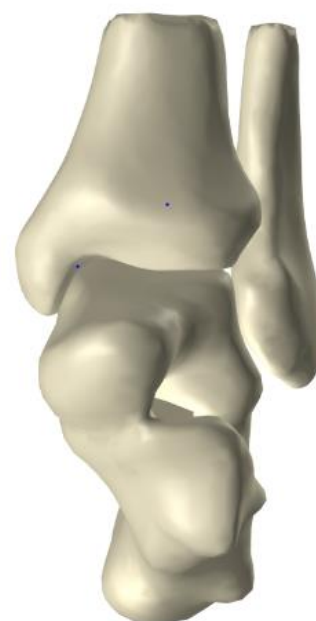
ORTHO-PLANIFY



In addition to the 3 previous menus, the user will be able to view 2 2D views of bone and prosthetic models:

- A sagittal view
- A front view

Each time the user makes a modification using the various tools at his disposal, the changes are made in real-time on the 2 2D views.



In addition, the user will have at his disposal a 3D scene representing bone and prosthetic models as well as all the modifications made in real-time.

The user can move the whole scene by holding down the left click of his mouse. He or she can also zoom in by holding down the mouse wheel and sliding the mouse up (to zoom in) or down (to zoom out).

To translate the models, the user will have to hold the right click of his mouse and move his mouse from left to right.

It also has 3 buttons allowing the 3D scene to return to 3 standard positions of the prosthetic and bone models: "Frontal", "Sagittal" and "Transverse".

4 Visualization tools

Tools

Bone visualization

☒ Tibia
 ☒ Talus + Calcaneus
 ☒ Fibula

Bone sections visualization

☐ Tibia
 ☐ Talus + Calcaneus

Implants visualization

☐ Tibial implant
 ☐ Talar implant

Render

☐ Malleolar Distance

Green : 11mm
 Orange : 9mm
 Red : 7mm

☐ Mesh Rendering
 ☐ Transparency
 ☐ X-Ray
 ☐ Mechanical Axis
 ☐ Full screen

The user will find on the right of the planning page, all the visualization tools necessary for planning his case. A checked box means that the visualization is active, a unchecked box means that the visualization tool is inactive.

4 sections are proposed:

- Bone visualization: allows the user to display or hide the native bones (tibia, talus + calcaneum and fibula) in the 3D scene as well as in the 2D views. By default, bone models are displayed native.

- Bone section visualization: allows the user to visualize or hide the tibial and talar sections in the 3D scene as well as in the 2D views.

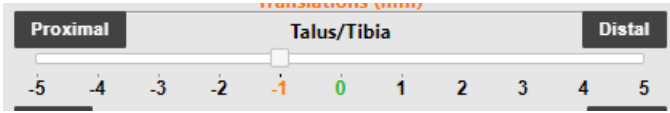
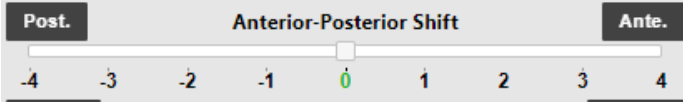
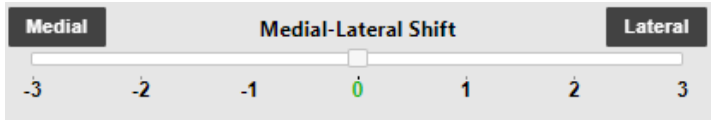
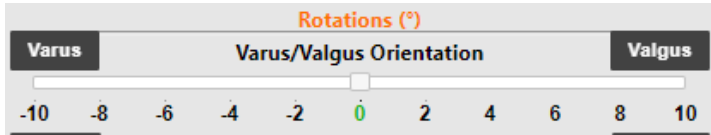
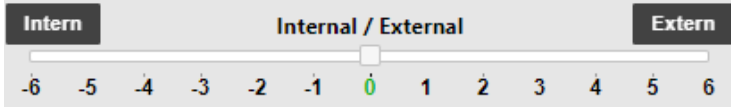
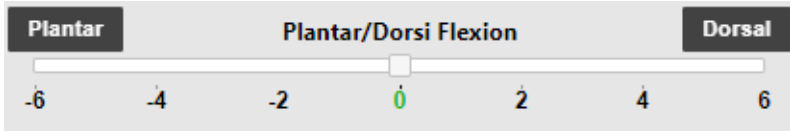
- Implant visualization: Allows the user to display or hide tibial and talar implants in the 3D scene as well as in the 2D views.

- Render: Allows the user to make visual changes to the models inserted in the views and 3D scene. The user can visualize arcs simulating malleolar distance, modify models by displaying only their surface (rendered to the line), put them in transparency, visualize the patient's X-rays in 2D views, display mechanical axes, or even put the 3D scene in full screen.

ORTHO-PLANIFY

5 Repositioning Talus/Tibia

The values on the planning tools are color-coded: the values are in **green** if this is the value that was defined in the pre-planning step. If the selected value is different from the one defined in the previous step, it appears in **orange** on the planner (as defined for the position of the prosthetic assembly).

TRANSLATION TOOL (MM)	
 <p>The slider is labeled 'Talus/Tibia' with 'Proximal' on the left and 'Distal' on the right. The scale ranges from -5 to 5. The value -1 is highlighted in orange, and 0 is highlighted in green.</p>	<p>This tool allows the modification of the space between the tibial and talar sections. The possible values are -5mm and 5mm. This value defines with the tibial cutting height and the talar cutting height, the thickness of the skate.</p>
 <p>The slider is labeled 'Anterior-Posterior Shift' with 'Post.' on the left and 'Ante.' on the right. The scale ranges from -4 to 4. The value 0 is highlighted in green.</p>	<p>This tool allows the antero-posterior positioning of the slope in relation to the tibia. The increment of the modification is from mm to mm with a variation from -4mm to +4mm</p>
 <p>The slider is labeled 'Medial-Lateral Shift' with 'Medial' on the left and 'Lateral' on the right. The scale ranges from -3 to 3. The value 0 is highlighted in green.</p>	<p>This tool allows the medial-lateral positioning of the talar bone in relation to the tibia. The increment of the modification is from mm to mm with a variation from -3mm to +3mm.</p>
ROTATION TOOL (°)	
 <p>The slider is labeled 'Varus/Valgus Orientation' with 'Varus' on the left and 'Valgus' on the right. The scale ranges from -10 to 10. The value 0 is highlighted in green.</p>	<p>This tool allows the modification of the horizontal rotation of the vertical cut. This rotation can vary between -10° and 10° in 2° increments.</p>
 <p>The slider is labeled 'Internal / External' with 'Intern' on the left and 'Extern' on the right. The scale ranges from -6 to 6. The value 0 is highlighted in green.</p>	<p>This tool allows the slope to be oriented outwards or inwards.</p>
 <p>The slider is labeled 'Plantar/Dorsi Flexion' with 'Plantar' on the left and 'Dorsal' on the right. The scale ranges from -6 to 6. The value 0 is highlighted in green.</p>	<p>This tool is used to perform a plantar or dorsal flexion action on the foot.</p>

6 Position of the prosthetic assembly

The values on the planning tools are color-coded: the values are in **green** if this is the value that was defined in the pre-planning step. If the selected value is different from the one defined in the previous step, it appears in **orange** on the scheduler:

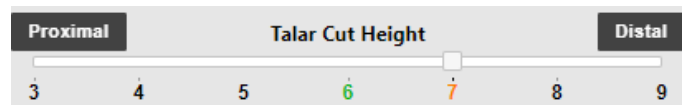


TRANSLATION TOOL(MM)



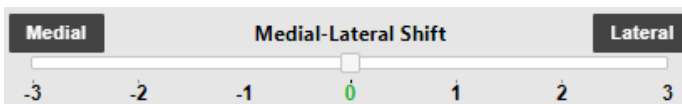
This tool allows the cutting height of the tibia to be modified in 1mm steps. The values are between the minimum cut of 6mm and the maximum cut of 14mm.

This value defines the thickness of the talar cut and the Talus/Tibia positioning, and the PE insert thickness.

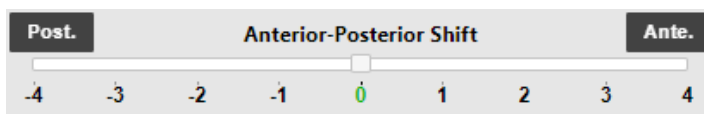


This tool allows the cutting height of the slope to be modified in 1mm steps. The values are between the minimum cut of 3mm and the maximum cut of 9mm.

This value defines the thickness of the tibial cutting and Talus/Tibia positioning, and the PE insert thickness.

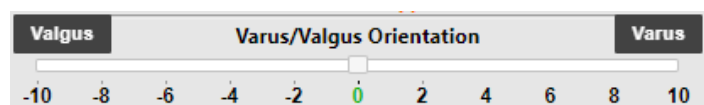


This tool allows the modification of the medio-lateral position of the talar and tibial sections.



This tool allows the modification of the antero-posterior position of the talar and tibial sections.

ROTATION TOOL (°)



This tool allows the modification of the horizontal rotation of the vertical cut. This rotation can vary between +10° and -10° in 2° increments.

This tool allows the modification of the rotation of the sagittal slope. This rotation can vary

<div> <div>Ante.</div> <div>Sagittal Rotation tilt</div> <div>Post.</div> </div> <div> <div>0</div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> </div>	<p>between 0° and 6° in increments of 1°.</p>
<div> <div>Extern</div> <div>Axial Rotation Angle</div> <div>Intern</div> </div> <div> <div>-8</div> <div>-7</div> <div>-6</div> <div>-5</div> <div>-4</div> <div>-3</div> <div>-2</div> <div>-1</div> <div>0</div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> <div>7</div> <div>8</div> </div>	<p>This tool allows the modification of the transverse angle, fixed by the tibial mechanical axis. This rotation can vary between +8° and -8° in increments of 1°.</p>
<h2 style="text-align: center;"><u>TALAR COMPONENT</u></h2>	
<div> <div>Standard</div> <div>▼</div> </div>	<p>This tool allows you to choose the type of implants from the ranges offered by In2Bones.</p>
<div> <div>–</div> <div>Size</div> <div>+</div> </div> <div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> </div>	<p>This tool allows the modification of the size of the talar implant in the standard range proposed by In2Bones. This size will define the limits of the tibial implant size according to the following rule: The size of the tibial implant must be equal to the size of the talar implant or equal to the size of the Talar +1 implant.</p>
<h2 style="text-align: center;"><u>TIBIAL COMPONENT</u></h2>	
<div> <div>–</div> <div>Size</div> <div>+</div> </div> <div> <div>5L</div> <div>5XL</div> <div>6L</div> <div>6XL</div> </div>	<p>This tool allows the modification of the size of the tibial implant. This size is limited by the size of the talar implant according to the following rule: The size of the tibial implant must be equal to the size of the talar implant or equal to the size of the Talar +1 implant.</p>

At any time during slope planning, the user can decide to make a temporary backup of what he has achieved by clicking on **TEMPORARY BACKUP**, to return to the follow-up of the files by clicking on **BACK TO PREPLANIFICATION** or to return to the tibial planning page by clicking on **CANCEL**.

Finally, if the user is satisfied with his planning, he or she can click on **FINAL VALIDATION** to validate it. As its name suggests, this backup is final, the user will not be able to come and modify the schedule once the recording is made.

7 Contact Us

To contact us, you must send an email to the following address:
contact@in2bones.com

DOCUMENT HISTORY

Date	n° Version	Description des modifications
12 Feb 2020	3.0	Creation