

# OrthoNext™

## Software User's Guide

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# ORTHONEXT SOFTWARE USER GUIDE

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The applicable End User License Agreement, Privacy Policy and Data Process Agreement can be found at: <https://request.orthonext.com/legal-terms>

## Security Precautions

User is advised to clear the browser history (temporary internet files, cookies, etc...) after logging out of the OrthoNext System.

## Computer System Requirements

### Display Settings:

Screen Resolution of 1280 x 768 pixels or higher.

### Supported Browsers:

Microsoft Edge Version 44 or higher

*Microsoft Edge is a registered trademark of Microsoft Corporation in the United States and other countries*

Safari® Version 13 or higher

*Safari is a trademark of Apple Inc, registered in the United States and other countries. HomeKit is a trademark of Apple Inc.*

Google Chrome™ Browser Version 83 or higher

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Mozilla Firefox (77 or succ)

*Firefox and Mozilla are trademarks of the Mozilla Foundation*

## Other Requirements

Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provided access to OrthoNext.

NOTE: For an optimal navigation experience, the Annex A provides instructions on how to configure the browser.

### Internet Connection:

Minimum required internet connectivity speed is of 512 kbps

Recommended internet connectivity speed is of 3 mbps or higher

## SAFETY SIMBOLS

The following symbols are used throughout the documentation. The user should pay particular attention at specific points in a procedure when one of the following messages appears:

 **Warning** denotes a hazard. It calls attention to a procedure that, if not correctly performed or adhered to, could result in injury or loss of life. Do not proceed beyond a warning note until the indicated conditions are fully understood and met.

**NOTE:** Provides useful information to help obtain optimum performances from the application.

## INTENDED USE

The OrthoNext™ Platform system is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of Orthofix Product templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.

The OrthoNext™ Platform is not to be used for mammography.

Rx Only - Caution: USA federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

## GETTING STARTED WITH ORTHONEXT PLATFORM SYSTEM

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OrthoNext Platform system is a web-based application intended for preoperative planning of orthopedic surgery.

The Software allows for overlaying of templates on radiological images, and includes tools for performing measurements on the images and for positioning the template.

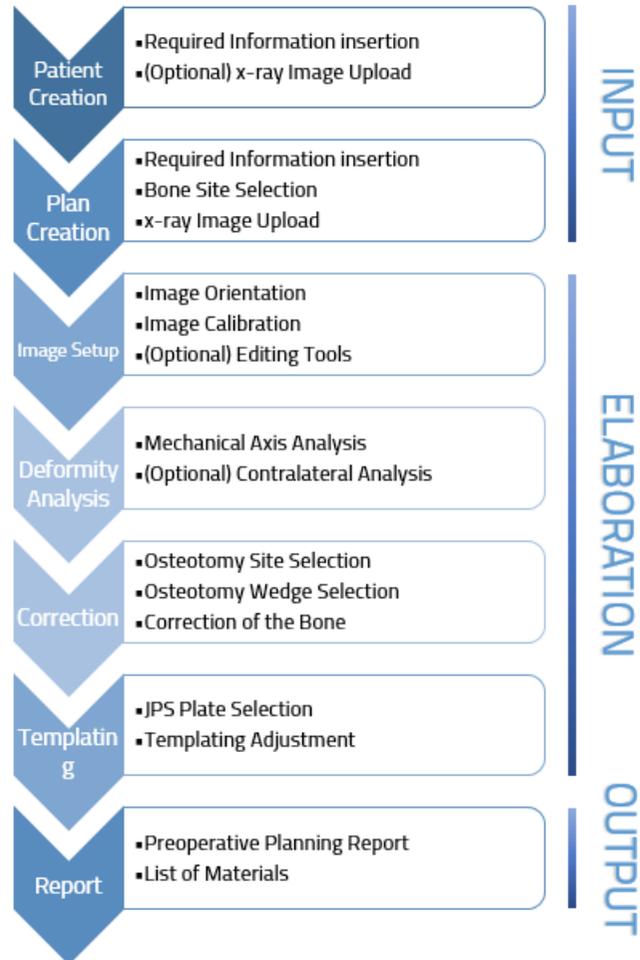
Proper surgical procedure is the responsibility of the medical professional. This Software and Software User Guide are provided as informative guidelines. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

Before using the OrthoNext software for the first time, it is very important to read this document in order to:

- Have an overview of the OrthoNext software in the [WORKFLOW OVERVIEW](#) section
- Understand conventions used by the software to mimic reality in the [NOMENCLATURE](#) section
- Know how to log in and recover your password in the [GETTING STARTED... HOW TO LOG IN](#) section
- Familiarize with the Navigation Menu and its functionalities in the [NAVIGATION MENU](#) section
- Understand how to create a Patient and a Plan, how to search for a specific Patient or Plan, and how to sort them in the [PATIENTS AND PLAN MANAGEMENT](#) section
- Start the planning of a case in the [PLAN ANALYSIS WORKFLOW](#) section

## Workflow Overview

The workflow of the entire system is described by the following picture:

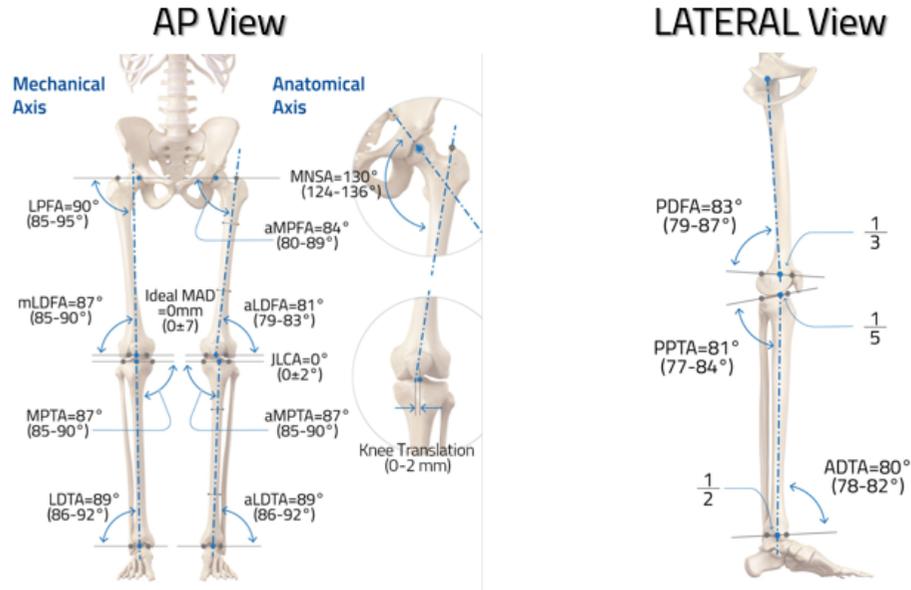


## Nomenclature

The OrthoNext Software performs Deformity Analysis and Correction based on the Mechanical Axis.

Throughout the Plan Analysis, the user will be able to check the Deformity Parameters both on the scene and in the parameters table.

The image below summarizes the parameters that the software provides



MAD: Mechanical Axis Deviation  
MNSA: Medial Neck Shaft Angle  
MPFA: Medial Proximal Femoral Angle  
mLDFA: mechanical Lateral Distal Femoral Angle  
JLCA: Joint Line Convergence Angle  
Knee Translation  
MPTA: Medial Proximal Tibial Angle  
LDTA: Lateral Distal Tibial Angle

PDFA: Posterior Distal Femoral Angle  
PPTA: Posterior Proximal Tibial Angle  
ADTA: Anterior Distal Tibial Angle

## WEBSITE NAVIGATION

### Obtaining Access and Information

Access to the OrthoNext System is controlled by Username and Password that can be obtained at [request.orthonext.com/userRequest](http://request.orthonext.com/userRequest) by filling the form with the required information, and following the on-screen instructions.

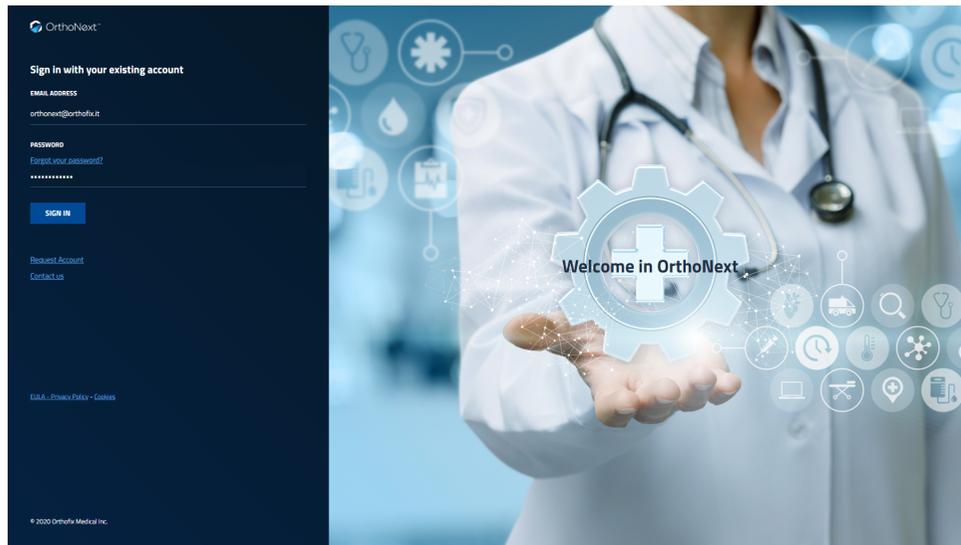
Once the request has been received by Orthofix, it will be validated to confirm whether the applicant has undergone the necessary training to use the System safely and responsibly. Once approved, the account will be activated, and Username and Password will be emailed to the applicant.

For further information and support, please send an email to [orthonext@orthofix.com](mailto:orthonext@orthofix.com)

### GETTING STARTED... HOW TO LOG IN

Open your browser and go to: [app.orthonext.com](http://app.orthonext.com)

Enter your Username and Password and click on 'Sign In'



## Having Troubles With Login ?

Should you have troubles with the login, you can click on the '[Forgot your password?](#)' link and follow the on-screen instructions. After verifying your email address with a verification code, you will be able to set a new password for your account.

## NAVIGATION MENU

Upon successful login, you will land on the '[My Patients](#)' page, the software header allows to recall the following menu functions anywhere within the application:



## ACCOUNT MANAGEMENT

By clicking on the  icon, a Menu will open, with the following options:

### [Edit Profile](#)

In the '[Edit Profile](#)' page, you can change any information you provided when you registered, like Hospital, Work/Office Address, Date of Birth, etc... Please note that your First Name, Last Name, Email address, Role and Country can't be changed.

### [Change Password](#)

Should you desire to change your password to a new one, you can use the '[Change Password](#)' option. After being authenticated with your actual credentials, you will be able to choose a new password following the on-screen instructions.

### [EULA and Privacy Links](#)

To review the OrthoNext System legal documents ( EULA, Privacy Policy and DPA) you can click on the '[Eula and Privacy Link](#)'. You will be able to read the legal documents in a new page.

### [Log Out](#)

To log out from the application, click the '[Log Out](#)' option and you will be redirected to the login screen.

### [Contact Us](#)

You can click on the  icon to quickly write an email to the OrthoNext Customer Care team for any issues or support you may have.

## User Guide

To open the OrthoNext Software User Guide, click on the  icon. The guide will open in a new tab as a downloadable .PDF file.

## PATIENT AND PLAN MANAGEMENT

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Upon login the user lands in the Patients and Plans page, which allows to Create, Edit, Delete, Sort and manage both Patients and Plans.

Plans are related to Patients and at least one Patient must be present before starting any Plan.  
There are no restrictions in the number of Patients and Plans that can be associated to each Patient.

### MY PATIENTS



By default the Software will load the list of Patients, highlighted by the **My Patients** tab.  
In the table, the user can find all the already create Patients with their information.

Each column is sortable in ascending/descending order (alphabetically or numerically according to the field value) with the default order being the most recent creation date.

When at least a Patient is present, the column '**Actions**' allows the user to:

-  **Edit Patient Data**
-  **Delete the Patient**
-  **Create a new Plan for the Patient**

Patient records are paginated and it is possible to navigate between the different pages by selecting the desired page below the list. The user can also change the number of record displayed per page [10 -25 -50 - ALL].

### Add New Patient

Using the dedicated button  the user can create a new Patient.

The user is asked to insert some information (required fields are marked with a \*) in order to create a Patient:

- **Patient ID** (required)
- **Patient Initials** (required)
- **Age** (required)
- **Gender** (required)
- **Weight** (optional)
- **Height** (optional)

By entering both Weight and Height, the Software calculates the **Body Mass Index (BMI)** of the Patient.

Before uploading any x-ray image(s) of the Patient the user should Save the Patient, with one of the two choices:

**SAVE PATIENT**

will complete the Patient creation process and enable the x-ray image library.

**SAVE & CREATE PLAN**

will complete the Patient creation process and will open a new page where the user can create a new Plan for the Patient.

**Cancel**

will discard any information inserted, and the user will return to the **'My Patients'** page.



**Warning:**

Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the user shall **never enter information that directly identifies a Patient**. The Patient ID and Initials are intended to be used as an identifying link to the Patient within the user's patient management system.

## Edit Patient Data

To edit an existing Patient, the user can use the  **'Edit Patient Data'** function, under the **'Actions'** column in the **'My Patients'** tab. The user will be able to edit any of the already present information, and upload or delete new x-ray image(s).

**SAVE PATIENT**

will complete the Patient editing process and save any modification done.

**SAVE & CREATE PLAN**

will complete the Patient editing process and will open a new page where the user can create a new Plan for the Patient.

**Cancel**

will discard any information inserted, and the user will return to the **'My Patients'** page.

## Delete Patient

The  **'Delete Patient'** option allows the user to delete a Patient and all of his/her plans from the system. A warning pop up reminds that the action cannot be reverted once a Patient is deleted.

## Create Plan

The User can create a new Plan for a specific Patient in two ways:

- Upon creation of a Patient, by using the **SAVE & CREATE PLAN** option, in the **'Add New Patient'** page.
- Choosing the  **'Create Plan'** option when a Patient is already created, in the **'My Patients'** page.

When creating a new Plan, the user is asked to insert some information (required fields are marked with a \*)

- **Plan ID** (required)
- **Estimated Surgery Date** (optional)
- **Anatomical Site** (required)
- **Notes** (optional)

**NOTE:** The Anatomical Site allows to select with one click both the side and the anatomical site where the user wants to preplan; this will also determine the interaction with the OrthoNext software (e.g. tool and information displayed)

The user should place the x-ray images in the appropriate box (AP or LATERAL) by dragging them from the x-ray library if already present, or can upload new ones and then drag them.

A Plan requires at least one image, either only AP or LATERAL or both.



**SAVE PLAN**

will complete the Plan creation process and associate the Plan to the Patient.

**SAVE & START ANALYSIS**

will complete the Plan creation process and starts the Deformity, Correction and Templating part of the software.

**Cancel**

will discard any information inserted, and the user will return to the 'My Patients' page.

**Warning:**

Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the user shall **never enter information that directly identifies a Patient**. The Plan ID is intended to be used as an identifying link to the Patient within the user's patient management system.

## MY PLANS



The list of all the Plans created can be found in the 'My Plans' tab.

Each column is sortable in ascending/descending order (alphabetically or numerically according to the field value) with the default order being the most recent creation date.

When at least a Plan is present, the column **'Actions'** allows the user to:

-  **Edit Plan Data**
-  **Delete the Plan**
-  **Start the Deformity Analysis** (only if at least an image is associated to a view (AP or LATERAL) for that Plan)

Patient records are paginated and it is possible to navigate between the different pages by selecting the desired page below the list. The user can also change the number of record displayed per page [10 -25 -50 - ALL].

## Edit Plan Data

To edit an existing Plan, the user can use the  **'Edit Plan Data'** function, under the **'Actions'** column in the **'My Plans'** tab. The user will be able to edit any of the already present information, and upload or delete new x-ray image(s).

**SAVE PLAN**

will complete the Plan editing process and save any modifications done.

**SAVE & START ANALYSIS**

will complete the Plan update and starts the Deformity, Correction and Templating part of the software.

**Cancel**

will discard any information inserted, and the user will return to the **'My Patients'** page.

## Delete Plan

The  **'Delete Plan'** option allows the user to delete a Plan from the system. A warning pop up reminds that the action cannot be reverted once a Plan is deleted.

**NOTE:** The **'Delete Plan'** option will delete only the Plan, if there are any images associated they will remain in the x-ray Image Gallery.

## Start Analysis

Using the  **'Start Analysis'** allows to directly go into the Deformity, Correction and Templating section of the Software. The option is enabled only if the selected Plan has at least one between the AP or Lateral image associated (or both), otherwise it will be disabled.

Please refer to the ['PLAN ANALYSIS WORKFLOW'](#) for more information.

## x-ray IMAGE GALLERY

Each Patient is associated to its own **'Image Gallery'** where the user can upload one or more x-ray image(s), and can be found on the Patient and Plan creation pages. The x-ray Image Gallery is shared between the Patient's page and the Plans page, so uploading an image during the Patient creation means that the user will find that image also in the Plan page and vice-versa.

### x-ray Image Requirements:

- The x-ray image must be perpendicular to the beam, in both views (if both AP and LATERAL are used for the plan).
- Orthogonal (90°) x-ray images are required (if both AP and LATERAL are used for the plan).

### Warning:

x-ray images **must not contain any information that allows, directly or indirectly, the identification of a Patient** (e.g. name, birth date, address, email address, phone number, etc...). x-ray images must be anonymized before uploading them in OrthoNext.

The supported x-ray image formats are **JPG** and **PNG**, with a maximum file size of 10MB.



To upload the image the user can:

- [Choose the file](#) from his file system
- [Copy and Paste](#) any image saved in the clipboard using CTRL+C and CTRL+V
- [Drag and Drop](#) the image directly on the x-ray library box

A positive feedback is shown when the image upload is successful, and a thumbnail of the x-ray image is shown in the **PATIENT X-RAYS**.

User can choose to view the full size version of the image by clicking on the  magnifier icon.

To delete one or more images uploaded, the user should first select  the images to be deleted, and then confirm

**Delete** 



**NOTE:** If the user selects to delete one or more images already associated to one or more Plans, the system will also delete the Plans.

## SEARCH PATIENTS AND PLANS

When multiple Patients and Plans are present, the user can search for a specific subset using the available filters in the 'Search' lateral menu.

The available fields that can be used as search fields are:

- **Patient ID:** The searched text can be an **exact match** or **contained**
- **Plan ID:** The searched text can be an **exact match** or **contained**
- **Estimated Surgery Date:** Can be a **specific date** or a **date range**
- **Plan Creation Date:** Can be a **specific date** or a **date range**

Confirming the entered fields with the **SEARCH** buttons will update the list of Patients or Plans (according to where the user currently is) to show only those that match the searched criteria.

The user can also search for the Patients and Plans using the following filters:

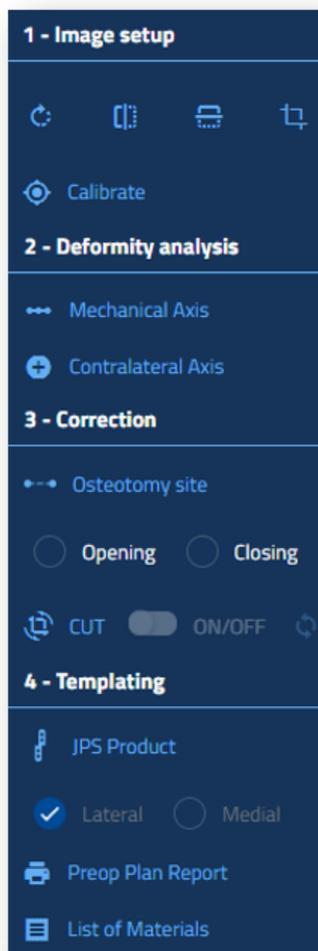
- **Gender:** available options *Male - Female*
- **Side:** available options *Left - Right*
- **Bone Type:** available options *Long Leg - Femur - Tibia*
- **Age:** available options range from **0-100 years**
- **Weight:** available options range from **0 - 250 kg ( 0 - 551.2 Lb )**
- **Height:** available options range from **0 - 250 Cm ( 0 - 8.2 Ft )**

Selecting one or more of the available values in the filters will automatically update and filter the list of Patients or Plans to match the criteria.

To restore the list to default the user can reset it using **Clear filters**.

## PLAN ANALYSIS WORKFLOW

The OrthoNext Software allows performing Deformity Analysis, Correction and Templating in 4 steps.



1 - The first mandatory step consists in the **IMAGE SETUP** and additionally in the adjustment of the x-ray image(s). After the Orientation and Calibration of the x-ray image(s) the user can adjust the image(s) using the dedicated '**Editing Tools**' and re-calibrate the image(s) using the '**Calibrate**' option.

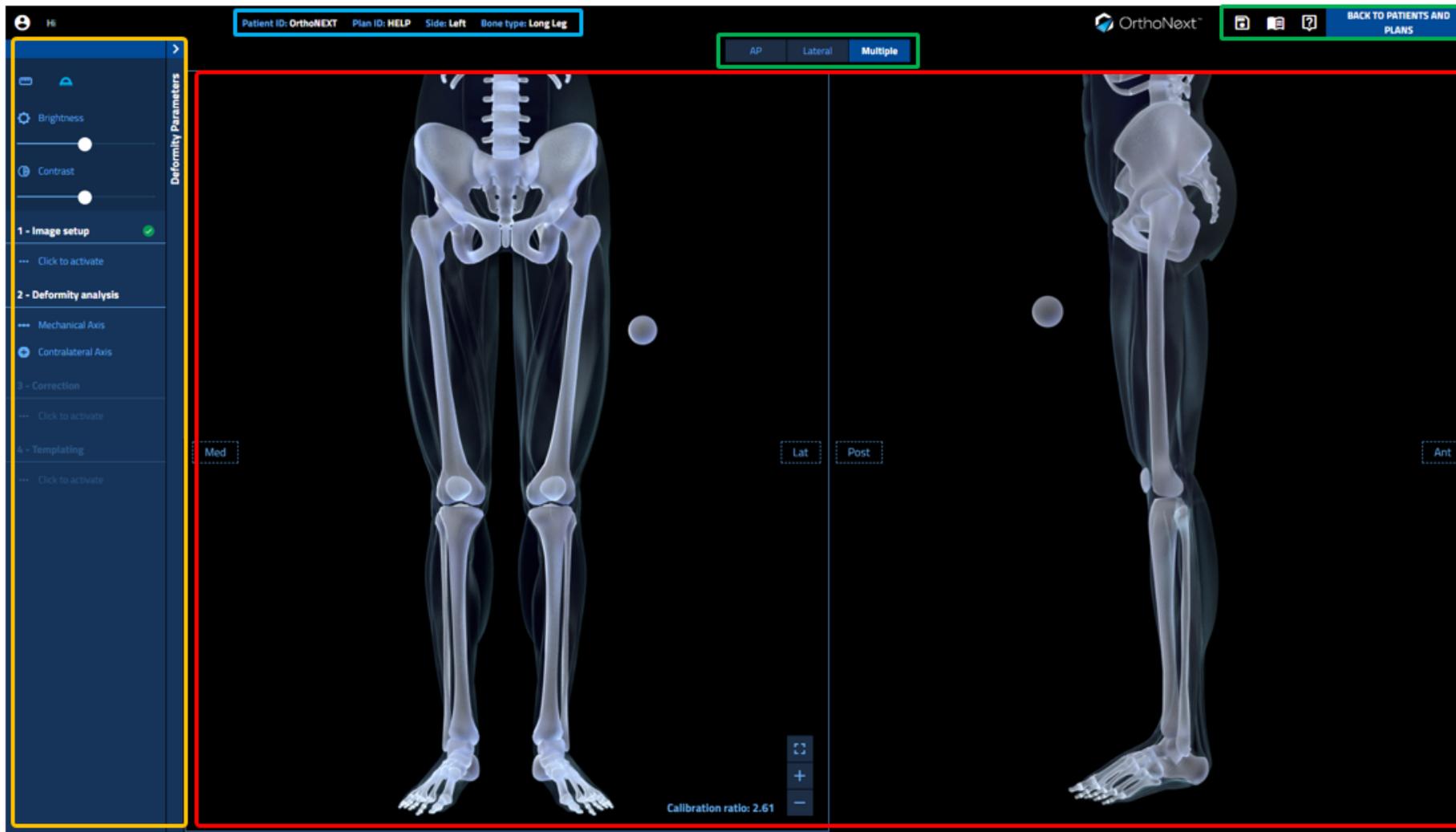
2 - The second step is the **DEFORMITY ANALYSIS**. In this section the user can perform the analysis on the uploaded x-ray image(s). The Software will provide Deformity Parameters according to the bone type selected in the plan creation.

3 - The third step consists in the **CORRECTION** of the leg/bone. In this section the user can simulate the correction of the bone by placing the Osteotomy and selecting whether to perform an opening or closing wedge osteotomy. The Software allows the user to graphically fine-tune the Correction. The corrected Deformity Parameters will be provided to have an instant feedback.

4 - The last step is about the **TEMPLATING** of the Orthofix JuniOrtho Plating System (JPS) on the scene. In this section, the user can overlay on the x-ray image(s) a template of the JPS plates.

## OrthoNext Desktop

The picture below shows the OrthoNext desktop with the main relevant sections:



● Plan Relevant Information

● Common Functions

● Interactive Work Area

● Sections and Tools Sidebar

### Common Functions:

These functions are available through the whole planning analysis, and allow the user to



Save the work done on the Software



Access the OrthoNext .PDF Guide



Open the OrthoNext contextual HELP



Return to the 'My Patients' page, with the option to save the work done



Switch between the AP and Lateral x-ray images or show them both

### Interactive Work Area:

In this area the user interacts with the different tools provided by the Software.

### Sections and Tools Sidebar:

The lateral Sidebar shows the steps to be performed in order to proceed with the planning and allows the user to check the Deformity Parameters and other information.

Whenever the required steps for a specific section are done, a green check will appear to inform the user that he can proceed to the next section.

## IMAGE SETUP

Before performing any analysis on the x-ray image(s) the user has to check for correct Orientation of the images and to Calibrate them. These two steps are crucial for the good outcome of the pre-planning analysis.

When the images are successfully Orientated and Calibrated, the user can choose to apply some simple image processing on the x-ray image(s) in order to adjust them to his needs.

### Image Orientation

In the '**Image Orientation**' step the user is asked to check the orientation of the x-ray image(s) and to verify that they are compliant with the labels on the scene. In the lateral panel an example figure shows how the x-ray image(s) should be oriented; the user has to answer to this question: "*is my x-ray image oriented as depicted in the figure?*"

A  option under the example figure allows the user to:

- YES: Confirm the current orientation
- NO: The current orientation is not the right one and then the System will mirror the image on the scene.

**NOTE:** The option must be individually selected for both AP and LATERAL images if present.

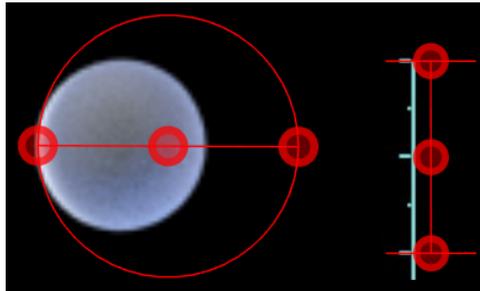
When satisfied with the Orientation, the user can **CONFIRM** and proceed to the '**Calibration**' step.

## Image Calibration

In the '**Image Calibration**' step, the user calibrates the x-ray image with a marker of known dimensions, in order to create a relationship between a measurement made on the scene (pixels) and a measurement made in real life (millimeters).

There are two different tools to use when performing the calibration, according to the marker present on the scene:

- Line calibration tool: The user should click on the marker at the beginning and at the end of it. The software will draw a line that can be fine tuned in order to match the marker on the scene.
- Circle calibration tool: The user should click three points on the borders of the calibration sphere. The software will draw a circle matching the borders of the sphere, that can be fine tuned.



Example of the Circle calibration tool and the Line calibration tool.

The handle in the center of both instruments allows dragging the tool around the scene.

The handles on the borders of the tool allow adjusting the sizes to fit the calibration marker.

**CONFIRM**

When done, the user should insert the value (in millimeters) of the marker in the **MARKER SIZE** box and

**NOTE:** If your plan has both AP and LATERAL x-ray image(s), the software will automatically transition to the LATERAL image when the calibration of the AP image has been confirmed.

**NOTE:** In case of a difference between the calibration ratios greater than 1, an informative message is shown to check the calibration.

## Image Editing Tools

When both '**Image Orientation**' and '**Image Calibration**' are completed, the software shows the '**Image Setup**' section, which contains different tools to adjust the x-ray image(s) in case of need.

The available tools are:

-  **Image Rotation:** The user can adjust the rotation of the selected image by dragging the handles at the border of the image, and following the lateral menu example animation.
-  **Image Flip:** The user can mirror the image on both the horizontal and vertical axis in case of need.
-  **Image Crop:** The user can adjust the size of the image and cut-out unnecessary part of it by dragging the handles at the border of the image, and following the lateral menu example animation.
-  **Calibrate:** With this option, the user can perform a re-calibration of the image in case of need.

**NOTE:** Using any of the previous tools when the user has already performed the Deformity Analysis, Correction or Templating of the plan, will result in a reset of all the work done so far, in order to maintain consistency between the image and the software assumptions (image size, calibration factor, orientation, etc...)

The following tools are always available to the user and can be used in any section of the software:

-  **Brightness:** Dragging the slider, the user can adjust the brightness of the image.
-  **Contrast:** Dragging the slider, the user can adjust the contrast of the image.
-  **Measurement line:** Used to perform measurements of lengths on the scene.
-  **Cross goniometer:** Used to perform measurements of lengths and angles on the scene.

## DEFORMITY ANALYSIS

The 'Deformity Analysis' section allows the user to find the Deformity Parameters describing his x-ray image(s).

The main tool used to perform this analysis is the '**Mechanical Axis Tool**' and works by clicking specific 'key markers' on the x-ray image(s). According to the Bone Site selected during the Plan creation and the current view, (AP - Lateral) the number of markers to be placed may differ:

AP View

Bone Site	n° of Markers
Long Leg	8
Femur	4
Tibia	4

Lateral View

Bone Site	n° of Markers
Long Leg	7
Femur	3
Tibia	4

### Mechanical Axis Analysis

Clicking on the  **Mechanical Axis** button will start the Workflow for the positioning of the markers on the x-ray image(s).

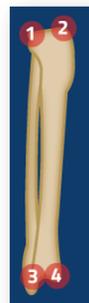


The system will show:

- An **Animation** depicting how to position the markers (on the lateral panel)
- A draggable **Magnifier**, which helps the user in the positioning of the markers by zooming the area around the mouse pointer
- A  **Cancel** option which will stop the workflow
- A  **Reset all points** **Reset** option which will reset any marker point positioned so far.

**NOTE:** The number of markers to be positioned and the results of the '**Mechanical Axis Analysis**' depend on the Bone Type selected in the '**Create Plan**' step, and from the current view (AP or Lateral).

[How to Position the Markers](#)

Bone Type			Results
VIEW:	AP	Lateral	
LONG LEG	 <p>1: Center of the <b>Femoral Head</b>                  2: Tip of <b>Greater Trochanter</b>                  3 and 4: <b>Femoral Condyles</b>                  5 and 6: <b>Tibial Plateau</b>                  7 and 8: <b>Ankle Joints</b></p>	 <p>1: Center of the <b>Femoral Head</b>                  2 and 3: <b>Femoral Growth Plates</b>                  4 and 5: <b>Tibial Plateau</b>                  6 and 7: <b>Ankle Joints</b></p>	<ul style="list-style-type: none"> <li>- <b>Mechanical Axis</b></li> <li>- <b>MNSA Tool</b></li> <li>- <b>Weightbearing</b></li> </ul>
FEMUR	 <p>1: Center of the <b>Femoral Head</b>                  2: Tip of <b>Greater Trochanter</b>                  3 and 4: <b>Femoral Condyles</b></p>	 <p>1: Center of the <b>Femoral Head</b>                  2 and 3: <b>Femoral Growth Plates</b></p>	<ul style="list-style-type: none"> <li>- <b>Mechanical Axis</b></li> <li>- <b>MNSA Tool</b></li> </ul>
TIBIA	 <p>1 and 2: <b>Tibial Plateaus</b>                  3 and 4: <b>Ankle Joints</b></p>	 <p>1 and 2: <b>Tibial Plateaus</b>                  3 and 4: <b>Ankle Joints</b></p>	<ul style="list-style-type: none"> <li>- <b>Mechanical Axis</b></li> </ul>

When the markers have been positioned, the user can **CONFIRM** the work done.

**NOTE:** After positioning the markers and confirming, the user can fine tune the position of the markers.

### Tools Description

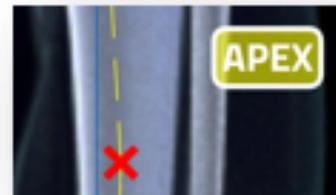
This section explains the different tools obtained from the '**Mechanical Axis Analysis**'

### Mechanical Axis



Identified by **blue lines** on the scene, the **Mechanical Axis** will be drawn with the corresponding joint angle values, these values will update each time the marker points are moved on the scene. If a label is showing the value on a **red background**, it means that the specific joint angle is out of the normal ranges (which can be seen in the 'Deformity Parameters' table); if the label is shown on a black background it means that is within the normal range.

If a joint angle is out of range, a **yellow dashed line** will be projected using the specific joint angle normal value as angle; this will lead in the identification of the **Deformity Apex** (red **X** where the two yellow dashed lines meet).



### MNSA Tool

Proximal Femoral  
Anatomical Axis



Center of  
Femoral Neck Axis

The **Medial Neck Shaft Angle** Tool is present only in Plans where the Bone Type is either Long Leg or Femur and allows to accurately evaluating the Femoral Neck Shaft Angle.

The user should click and drag the handles in order to draw the Proximal Anatomical Femoral axis and the Axis passing through the center of the Femoral Neck.

The **MNSA** label will update to reflect the value of the Neck Shaft Angle.

Weightbearing



The **Weightbearing** line is present only in Plans where the Bone Type is Long Leg, and is the line that joins the **Femoral Head** with the **center of the Ankle Joint**.

## Deformity Parameters



### Deformity Parameters

When the user has confirmed the Mechanical Axis Analysis the Software will list all the Deformity Parameters in the Deformity Parameters Table on the lateral panel.

By clicking on the white arrow the panel will show the parameters grouped in different tables (according to the Bone Site selected in the '[Create Plan](#)' section).

- **Mechanical Axis AP Table:** The table will list all the deformity parameters of the **AP** view
- **LLD Table:** The table will show the length of the Bone / Leg (see the '[Contralateral Analysis](#)' for more information on the LLD Table)
- **Mechanical Axis LT Table:** The table will list all the deformity parameters of the **Lateral** view
- **Apex Table:** The table will list (if present) the **Deformity Apex(es)** identified during the analysis (one deformity apex per bone). The user will also be able to insert a clinically assessed value of **Axial Rotation**.

**NOTE:** Any parameter out of the normal range will be highlighted in red.

The Deformity Parameters table allows the user to override the normal joint angles values, and insert a specific one. In this way, when performing a Correction at the specific site, the software will automatically consider the inserted joint angle (TARGET) (and not the normal one).

	VALUE (Left)	TARGET	CL (Right)
mLDFA (85° - 90°)	99	88	93

The following example shows a deformed **mechanical Lateral Distal Femoral Angle** (value 99°), and by default the software will bring the angle back to the **TARGET** value (88°). The user can enter a valid angle in the TARGET field as desired final angle value.

According to the image, the user may want to override the **TARGET** value and enter 93° in order to make the angle equal to the Contralateral one.

When editing the **TARGET** value, the user will see that the Deformity Apex on the scene will change its position according to the value inserted.

## Contralateral Analysis

In case of a Bilateral x-ray image in the AP view, the user can select the option to perform an analysis also on the Contralateral Bone / Leg. By selecting  **Contralateral Axis** the software will prompt the user to position the marker points as in the '**Mechanical Axis Analysis**' step.

Upon confirmation, the software will draw on the scene the **Mechanical Axis** (and **MNSA Tool** according to the Bone Type) of Contralateral. Additionally the software will calculate the Limb Length Discrepancy in the Deformity Parameters - LLD table.

**NOTE:** The Contralateral tool will appear as an item in the Layers.

## Layers

The Layers table allows the user to quickly show/hide specific tools from the scene, in order to better see the underlying x-ray image(s) when precision is needed. The table will appear after having positioned the '**Mechanical Axis Tool**' or one between the '**Measurement Line**' or '**Cross Goniometer**'.

Each item in the Layers table is color coded to match the corresponding tool on the scene

**NOTE:** According to the Bone Type selected in the 'Create Plan' section, the items displayed in the Layers tool may differ.

The following are the items that will be added to the Layers table during the preplanning:

- **Mechanical Axis**
- **MNSA Tool**
- **Weightbearing**
- **Contralateral**
- **Measurement Line**
- **Cross Goniometer**
- Plate

By clicking on the  Hide icon the specific item will disappear from the scene, clicking on the  Show icon will make it appear again.

**NOTE:** The Layers table can be dragged around the scene, so the user can position it wherever he may need without covering the x-ray image(s).

## CORRECTION

The '**Correction**' section allows the user to plan the Osteotomy strategy and to see the Correction results.

## Osteotomy

Before positioning the Osteotomy on the scene, the user is asked to select the Osteotomy Site. According to the Bone type selected in the Plan creation, the options can be the following:

**Long Leg Plan:** Proximal/Distal Femur and Proximal/Distal Tibia  
**Femur Plan:** Proximal/Distal Femur  
**Tibia Plan:** Proximal/Distal Tibia

**NOTE:** This selection will affect the available JPS product templates in the '**Templating**' section.

The Osteotomy will appear centered on the Deformity Apex of the selected bone site if present, otherwise it will appear at the center of the Mechanical Axis of the selected bone site.

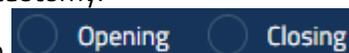
### Osteotomy

**INTERACTION:** To move the Osteotomy on the scene, the user can click on the center handle and drag the tool around the scene. The external handles allow the user to incline/adjust the Osteotomy to the bone cortices.



OrthoNext offers two kinds of Osteotomies, **Opening** or **Closing** wedge Osteotomy.

The user can select which one to use by selecting the corresponding option



Upon selection the **CUT** toggle enables allowing to perform the Correction of the bone by aligning proximal and distal mechanical axis segments.

## Deformity Correction

When the  **CUT**  **ON/OFF** toggle is enabled, the Software will bring the joint angle(s) at the selected bone site back in the normal range (or in the target value, if specified in the '**Deformity Parameters**' table during the Deformity Analysis).

The user can interact with the cropped area, by translating or rotating it.

To translate it is sufficient to click and drag any point of the cropped area, to rotate the user should click and drag the rotation handles that are on the top corners of the cropped area.

**NOTE:** The labels on the scene will update their value in real-time according to the Correction.

In the '**Correction Parameters**' tab the user can find all the Deformity Parameters updated to match the actual Correction.

The  button will bring the Correction back to the one suggested by the Software.

## TEMPLATING

The '**Templating**' sections allows the user to select and position the template of Orthofix Product on the scene.

### ORTHOFIX JPS-JuniOrtho Plating System PRODUCT MODULE

#### Plate Selection

Selecting the  JPS Product option, it is possible to select the plate to position on the scene.

The Anatomical Site is already selected and matches the value selected in the Osteotomy Site of the 'Correction' step. Upon selection of the SCREW DIAMETER the system will show a list of the plates that match the applied criteria.

The user can continue to apply the filters or can select one of the Plates from the results table; by clicking on a specific plate it will appear on the scene at the Osteotomy level.

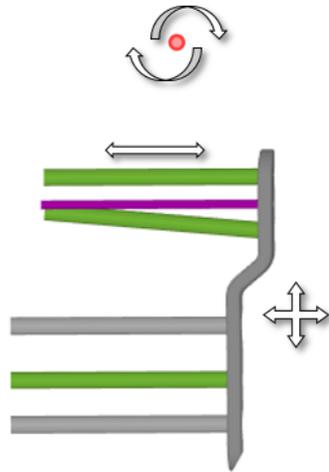
Clicking on **CONFIRM** will complete the workflow and confirm the selected plate on the scene.

If the user wants to select a new plate he should repeat the previous steps.

The  option allows to change the Orientation of the plate after confirmation (default: Lateral with the screws pointing toward the Medial side).

## Plate Interaction

When a Plate is on the scene, the user can interact with it in the following ways:



- Translation:** By clicking on it and dragging it on the scene  
**Rotation:** By clicking and dragging the red dot above or below the plate  
**Screw Adjustment:** By clicking and dragging each screw

A label will show the current length of each screw and will update its value when the screw length is adjusted. The screws are color-coded as follows:

- **Green Screws:** Locking screw
- **Gray Screws:** non-Locking screw
- **Purple:** If the Osteotomy site in the '**Correction**' section is Proximal/Distal femur, the plate will show also the K-Wire

**NOTE:** To have a better view of the Bone and be more precise when adjusting the template, the user can hide the unwanted tools from the '**Layers**' panel and leave only the plate visible.

## PREOPERATIVE PLANNING REPORT

As a result of the planning made with the Software, the user can select the option to print the '**Preoperative Planning Report**'. A .PDF file will be automatically downloaded recapping the planning made.

Patient ID: OrthoNEXT Plan ID: HELP Side: Left Bone type: Long Leg Pre-operative Planning Report Jul 27, 2020, 5:40:16 PM OrthoNext

**Correction Parameters**

Apex (°)	AP	LT	AXIAL
Femur			
Tibia	6 varus		

	Length (Left)	CL Length (Right)	LLD
Long Leg (mm)	546	544	2 Long
Femur (mm)	301	301	0
Tibia (mm)	240	239	1 Long
Femur+Tibia (mm)	541	540	1 Long

**Recommended Clinical Measurements**

Osteotomy level relative to Proximal Tibia Joint (mm): 27

AP Opening Wedge angle (°): 0

LT Opening Wedge angle (°): 6

AP Cortex Gap (mm): 4

Lateral Cortex Gap (mm): 5

Translation (mm): 0 lateral, 1 anterior

Plate: 99-5434002L - JPS 55 3.5MM NARROW MEDIAL TIBIA PLATE LEFT 2 HOLES STERILE

x-ray image(s)

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The first page will show:

- x-ray image(s) showing the Deformity Analysis
- Deformity Parameters

The second page will show:

- x-ray image(s) of the Correction with the applied JPS template
- Deformity Apex table
- LLD Table
- Recommended Clinical Measurements: According to the Bone selected for the plan, some information in order to better replicate the planning in the Operative Room are provided.

The third page will show:

- A visual explanation of the Recommended Clinical Measurements to clarify how the measurements are taken.

**NOTE:** The '**Preoperative Planning Report**' can be also be printed from the '**Deformity Analysis**' and the '**Correction**' tabs, the information contained will be relative to the tab from which the user selects to print the report.

## LIST OF MATERIALS

The 'List of Materials' is a document listing all the hardware needed by the surgeon in the Operative Room. When the option is selected, a .PDF file will be automatically downloaded in the user system.

The documents lists the Plate selected in the 'Templating' section as well as the screws with their lengths. The tables 'JPS Consumables' and 'JPS Instrument Tray' will list the appropriate material according to the selected screw diameter.

Patient ID: OrthoNEXT Plan ID: HELP Side: Left Bone type: Long Leg LIST OF MATERIALS Jul 27, 2020, 5:41:31 PM OrthoNext

**Plate and Screws**

PART NO.	DESCRIPTION - INSTRUMENTS	Qty
99-543400SL	JPS SS 3.5MM NARROW MEDIAL TIBIA PLATE LEFT 2 HOLES STERILE	1
99-5413520	JPS SS LOCKING SCREW L20MM DOUBLE START THREAD 0.35MM STERILE	1
99-5413526	JPS SS LOCKING SCREW L26MM DOUBLE START THREAD 0.35MM STERILE	1
99-5413532	JPS SS LOCKING SCREW L32MM DOUBLE START THREAD 0.35MM STERILE	1
99-5413540	JPS SS LOCKING SCREW L40MM DOUBLE START THREAD 0.35MM STERILE	2

**JPS 3.5mm Consumables**

PART NO.	DESCRIPTION - INSTRUMENTS	Qty
99-154291	SS GUIDE WIRE 02.0MM L200MM PACK OF 2 STERILE	1
99-154293	SS GUIDE WIRE 02.8MM L200MM PACK OF 2 STERILE	2
99-154183	SS DRILL BIT 02.8MM QUICK CONNECT STERILE	1

**JPS GENERAL Instrument Tray**

PART NO.	DESCRIPTION - INSTRUMENTS	Qty
002-A-00009	Depth Gauge With Hook	1
DHD45SCE	Micro Ratcheting Handle with AO Connector Cannulated	1
154276	AL Double Measuring Device	1
154300	SS Triangular Positioning Plate 60 Degrees 100 Degrees 20 Degrees	1
154301	SS Triangular Positioning Plate 70 Degrees 80 Degrees 30 Degrees	1
154302	SS Triangular Positioning Plate 90 Degrees 50 Degrees 40 Degrees	1
154306	SS Osteotomy Gauge	1
154666	SS JPS Template	1
154780	SS Small Bone Clamp	1
154781	SS Large Bone Clamp	1
154994	JPS Modular Base General Instrument	1
154998	JPS Modular Tray Lid	1

**JPS 3.5mm Instrument Tray**

PART NO.	DESCRIPTION - INSTRUMENTS	Qty
154201	SS Drill Guide Locking 02.8mm	4
154212	SS Drill Guide Non Locking 02.8mm	1
154321	SS T10 Retentive Screwdriver Quick Connect	2
154033	SS Medialization Guide Body 3.5mm	1
154031	SS Medialization Guide Mechanism	1
154304	AL Angled Wire Guide 3.5mm and 5.0mm Plates	1
154215	SS Arming Block - 3.5mm Plate	1
154996	JPS Modular Base 3.5mm Instrument	1

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## SUPPORT AND CONTACT INFORMATION

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If you need help using OrthoNext Platform system, please contact our technical support group.

Technical support is available by email at the following address: [orthonext@orthofix.com](mailto:orthonext@orthofix.com) (during normal business hours).

During support session, you may be asked to provide information about your copy of OrthoNext.

The HELP menu displays the software version and access to support contact information.

For a printed copy (in seven (7) business days) of the User Guide, contact Support by email to [orthonext@orthofix.com](mailto:orthonext@orthofix.com)

### Important Notice

#### Third-party Information

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#### Disclaimer

This software is intended as a support system for persons who have received appropriate medical training, and should not be used as a sole basis for making clinical decisions pertaining to patient diagnosis, care, or management. All information derived from the software must be clinically reviewed regarding its plausibility before use in treating patients. Any deviation of the application of medical information from the program, other than the original design or intended user thereof, is not advised and considered a misuse of the software product.

For additional guidance, see published studies.

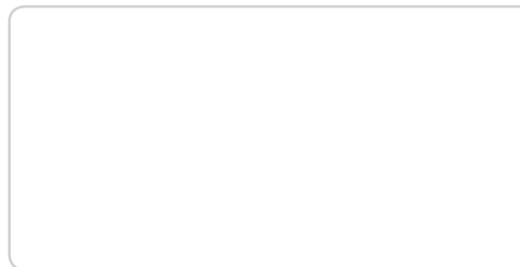
Orthofix Srl has not performed Electromagnetic Compatibility or Electrical Safety testing for its standalone software as it is the user's responsibility to decide the type of IT equipment allowed in the hospital.



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Instructions for Use: See actual package insert for Instructions for Use.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.



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