Software User's Guide

Software Version 1.5

ORTHOFIX®

TL-HEX Software User's Guide: Software version 1.5

The applicable End User License Agreement can be found at: http://tlhex.com/policies/Eulapolicy.html
The applicable privacy policy can be found at: http://tlhex.com/policies/privacypolicy.html

Security Precautions:

User is advised to clear the browser history (temporary internet files, cookies, etc.) after logging out of the TL-HEX application.

Computer System Requirements

Display Settings:

Screen resolution of 1280 x 768 pixels or higher.

Supported Browsers:

Microsoft Internet Explorer®: Version 10 or 11

Microsoft and Internet Explorer are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries

Safari® 8

Safari is trademark of Apple Inc., registered in the U.S. and other countries. HomeKit is a trademark of Apple Inc.

Internet Connection:

Minimum required internet connectivity speed is of 512kbps.
Recommended internet connectivity speed is of 3mbps or higher.

My Username: _____

My Password: _____

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UNDERSTANDING TL-HEX SOFTWARE VERSION 1.5

Whether you are a new user or an experienced TL-HEX user, reading this document will help you understand how to approach the TL-HEX Software Version 1.5; the conventions and logics adopted in order to provide the user with the tools for managing a treatment.

For new users

Before using the TL-HEX software for the first time, it is very important to read this document in order to understand:

- which kind of treatments the software can manage in conjuction with the appropriate hardware in the TL-HEX SYSTEM OVERVIEW section
- which are the software conventions and how software mimics reality in the NOMENCLATURE section
- how to log in in the GETTING STARTED … HOW TO LOG IN section
- how the software is organized: menu and navigation logic by reading the PATIENT AND CASE MANAGEMENT section
- the logical flow for managing a case and how the software interprets the provided input by reading the CASE PLANNING section.

For experienced TL-HEX users

Even for experienced users, reading this document is helpful for:

- *upgrading your cases from previous version*
    - the cases from the previous software versions have been migrated to the 1.5 version. They are in read-only format: read the steps required to upgrade them and make them editable in the UPGRADE A CASE FROM PREVIOUS VERSIONS TO 1.5 section
- *refreshing the background required for using this software*
    - the software has been completely restyled; take a look at the PATIENT AND CASE MANAGEMENT section to understand how the new icons can aid the use of the software
- *having an overview of the main differences and novelties introduced by this release*
    - look at the CASE PLANNING section to understand how the case planning flow has been streamlined, potential impingement warning system has been added, and how the prescription has been reviewed to include the strut direction change information
- *understanding how the software can support the clinical activity*

Examine the NOMENCLATURE and CASE PLANNING sections to understand the flow and the new graphics for managing deformity/trauma treatment with the addition of the foot section.

The following flow chart provides a sequential overview of the process for case management with TL-HEX software

Obtain an account at www.tlhex.com following the on-screen instructions

Access to TL-HEX software requires inserting Username and Password. Access credentials can be obtained at www.tlhex.com by requesting a new account and following the instructions.
 # see OBTAINING ACCESS AND INFORMATION

Log in to the TL-HEX software https://app.tlhex.com

Select your country, enter a valid username and password in the appropriate text fields and click 'Sign in' to access the software.
 # see GETTING STARTED… HOW TO LOG IN

Create a new patient

In the 'Add New Patient' screen, create a new patient if the patient does not already exist. Each case must be linked to an existing patient.
 # see ADD NEW PATIENT

Create a new case related to the patient

To start a new treatment, click on 'Create New Case'. Select the patient from the ones available in the drop-down list providing the information required (Case ID, Case Name, Planning Created, Side, Bone type).
 # see ADD NEW CASE

Specify the 'Deformity' parameters and 'End of Correction' parameters providing added over/under correction, if required

Describe the deformity starting from the reference segment identification. Then, provide the relevant parameters relative to the angular deformity, rotation, translation and axial translation. Visualize and, if necessary, specify the eventual over/under correction parameters in the 'End of Correction' section.
 # see DEFORMITY PARAMETERS AND END OF CORRECTION

Select the ring type and size for the frame

Indicate ring type and size for the frame assembly
 # see SUPPORT SELECTION

Complete the 'Mounting Parameters' to pre-assemble the frame

PRE-PLANNING (optional) - If desired, complete this section with details of the planned frame position, relative to either the deformity apex or the osteotomy/fracture level. Strut types and lengths are being suggested.
 # see PREOPERATIVE PLANNING

Confirm or adjust postoperative values and struts configuration

POSTOPERATIVE - Provide the actual frame parameters, position as mounted to the patient, and adjust/modify the struts configuration to adapt them to the configuration obtained during the surgery. Visualize the expected treatment result in the 'End of Correction' section.
 # see POSTOPERATIVE

Determine the schedule for the correction planning. If applicable, apply lengthening/shortening first

Define the schedule by specifying the latency period, the maximum speed rates for correction or the desired days of correction. If applicable, apply lengthening/shortening first.
 # see SCHEDULE

Visualise, adjust and print the report

Visualise and print the prescription for the patient

Once the surgeon approves all data, the schedule is calculated and the prescription is generated. The prescription can be saved and a hard copy will be given to the patient. For each correction step, the number of turns the patient must make are indicated for each strut for both acute and gradual adjustments. A hard copy of the bill of materials and the report may be generated. The report is a more detailed view for the surgeon indicating the length settings for the gradual and acute setting on the strut.
 # see REPORT

Use the 'Detail & Checkup' function to create a new case starting from the date selected

The surgeon can use the check-up function to generate a new case starting from a specific date of the treatment. This new case will report all the parameters updated to the selected date. The surgeon can then proceed to set up a new deformity correction treatment.
 # see DETAILS & CHECKUP

TL-HEX SYSTEM OVERVIEW

INTRODUCTION

The TL-HEX™ is a hexapod system. In essence, the system consists of circular and semi-circular external supports secured to the bones by wires and half pins, and interconnected by six struts. This allows multi-planar adjustment of external supports. The TL-HEX system is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and closed fractures, treatment of non-union or pseudarthrosis of long bones, and correction of bony or soft-tissue defects or deformities.

SOFTWARE

The software, starting from the initial fracture or deformity, is able to calculate a prescription for the surgeon's review and approval, indicating the direction and daily amount of adjustment in length for each strut in order to achieve the treatment goals.

HARDWARE

TL-HEX is a circular external fixator based on Ilizarov's principles. This frame consists of a hexapod made up of two rings (circular external supports - Fig. 1), one ring and one foot plate (U-shaped plate for foot deformity correction - Fig. 2) or two foot plates with the opening in opposite directions and six variable-length struts. The relative strut lengths determine the position of the rings. Due to the rings being attached to bone segments or to a bone segment and foot, their position indirectly determines the position of the bone segment.

Fig.1 TL-HEX application with two rings and six variable length struts
Fig.2 TL-HEX application with one ring, one footplate and six variable length struts (foot deformity correction)

The frame configuration changes according to the lower-limb bone to correct or to lengthen.

Refer to *General Principles of TL-HEX Frame Assembly* for detailed instructions on how to build the different frame configurations.

STRUTS

TL-HEX struts (Fig. 3) consist of two telescoping aluminium tubes that can be locked together at various lengths. The rod moves relative to the inner tube when the knob is rotated providing a gradual change of overall strut length in 0.5-mm increments.

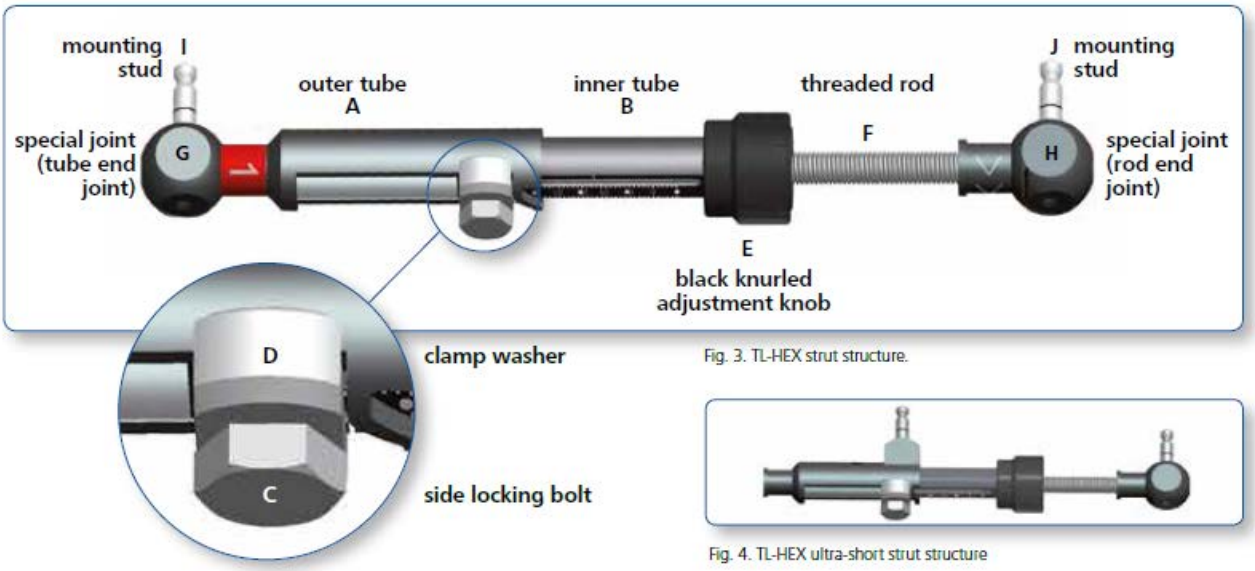


Fig. 3. TL-HEX strut structure.

Fig. 4. TL-HEX ultra-short strut structure

The ultrashort strut has a different design in order to be applied in special cases (for instance, very severe angular deformity and extreme equinus foot), but the most important features (two telescoping tubes, the adjustment knob and the locking bolt) have been preserved (Fig. 4).

The TL-HEX struts allow performing **acute** (orange colour) and **gradual** (green colour) adjustment of the strut length.

The acute adjustment is achieved by untightening the side-locking bolt, sliding the inner tube relative to the outer tube to the desired length and re-tightening the locking bolt. Acute adjustment is indicated by the inner tube scale in 1-mm increments relative to the orange-line mark on the outer tube (Fig. 5a).

The gradual adjustment is achieved by pulling and rotating the adjustment knob, resulting in a noticeable detent (tactile click) every 0.5mm of adjustment. Gradual adjustment is indicated by the same scale, relative to the green-line mark on the end of the threaded rod (Fig. 5b).

The direction of the adjustment is indicated by the direction clips. The arrow of the direction should be oriented according to the prescription.

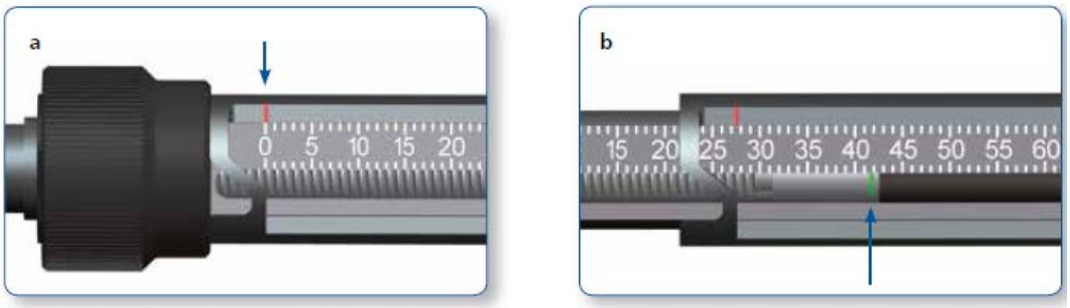


Fig. 5. Indicators for acute (a) and gradual (b) adjustments on the TL-HEX struts.

Struts are available in four different sizes (ultrashort, short, medium and long), providing adjustments ranging from 45mm to a maximum extension of 318mm.

Description	Acute/Gradual	Minimum Length	Maximum Length
UltraShort	0-28	45mm	101mm
Short	0-15	92mm	122mm
Medium	0-35	114mm	184mm
Long	0-80	158mm	318mm

RINGS & FOOTPLATES

The struts are attached to full rings, 5/8 rings or footplates in pairs using special angulated tabs around the circumference of the external support.

Full rings and Footplates

Each full ring has:

- Three working tabs, which will have struts attached to them.
- Three non-working tabs.

Two opposite tabs on each full ring are marked with a double-line indicating the anterior and posterior tabs. In addition, each full ring has two single-line marks oriented 90° relative to anterior and posterior tabs.

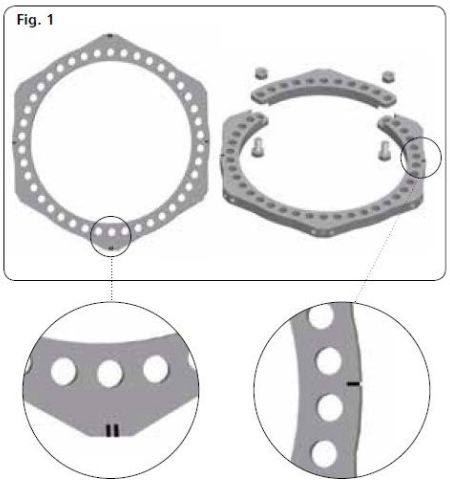
5/8 rings and 3/8 component

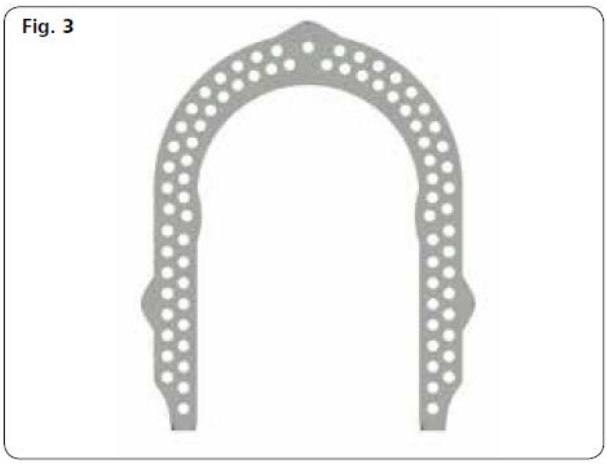
Each 5/8 ring has:

- Three working tabs, which will have struts attached to them.
- Two non-working tabs.

The central tab on the 5/8 ring is marked with a double-line to facilitate its orientation. In addition, each 5/8 ring has two single-line marks oriented 90° relative to central tab to simplify external support alignment and frame assembly.

The 3/8 component allows for transforming a 5/8 into a full ring. It has one tab, working or non-working, depending on the case.



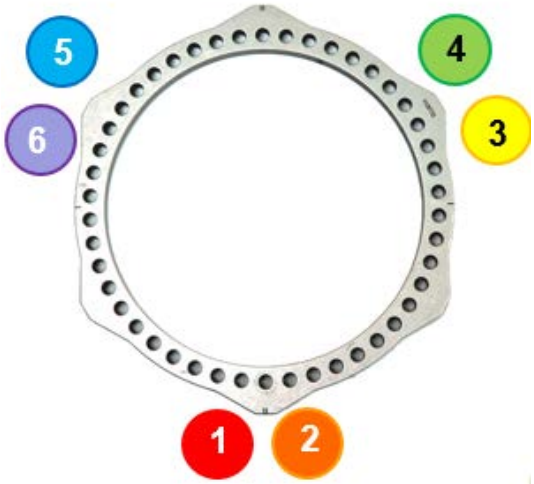


RING ORIENTATION TAB

By convention, the Ring Orientation Tab (ROT) is where struts 1 and 2 originate and it is indicated on the hardware by double-line marking

It is always on the proximal external support, regardless of which segment is chosen as the reference segment.

The software uniquely identifies the Ring Orientation Tab with a red dot to facilitate ring orientation and struts placement.



A second ROT is the tab on the distal external support situated opposite to the proximal one and it is important to determine the way in which the frame is rotated around the limb when referencing distally, as shown in the picture above on the right This second ROT is always on the distal ring, regardless of which segment is chosen as the reference segment.

HOW TO MOUNT THE FRAME

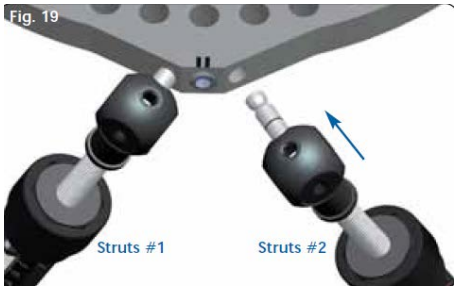
For proper identification, the struts are numbered using color number clips. The clips are numbered from 1 to 6 and colour coded as **red** (1), **orange** (2), **yellow** (3), **green** (4), **blue** (5) and **purple** (6).

The software provides the possibility to preplan the treatment and determine the frame configuration prior the surgery. Based on the provided input, the optional preoperative planning functionality calculates the struts combination in terms of Type, Acute and Gradual in order to prebuild the frame. For further clarification, review the Case Management – Preoperative section.

The following rules apply to TL-HEX frame in order to be consistent with the software graphical representation:

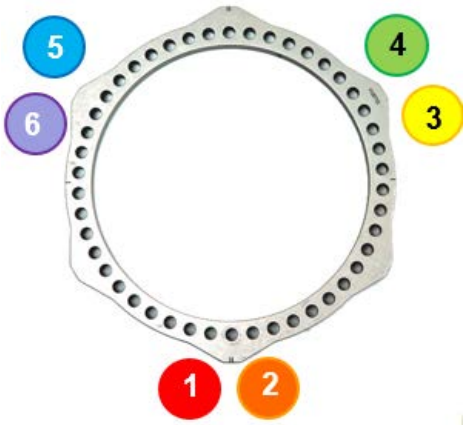
Full Ring and 5/8 Open Posteriorly Ring

1. Identify the Ring Orientation Tab (ROT) of the proximal ring (double-line mark) and start connecting struts 1 on the left and 2 on the right to the reference lines.

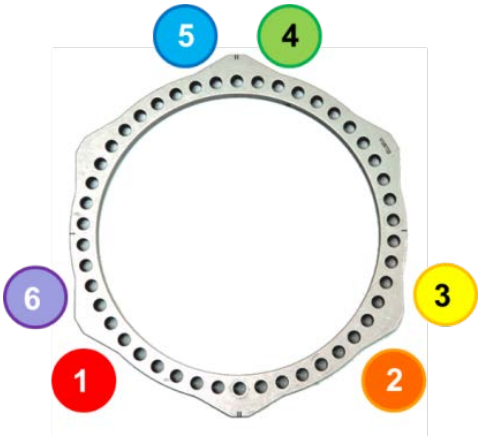


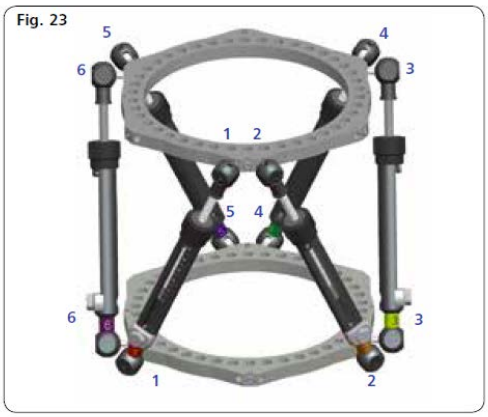
   Full rings and 5/8 Open Posteriorly rings, while the ROT is always placed anteriorly.

2. For the proximal ring, struts No. 3, 4, 5 and 6 must be attached counter-clockwise as shown below.



3. On the distal ring, struts No. 3, 4, 5 and 6 must be also attached counter-clockwise as illustrated below.



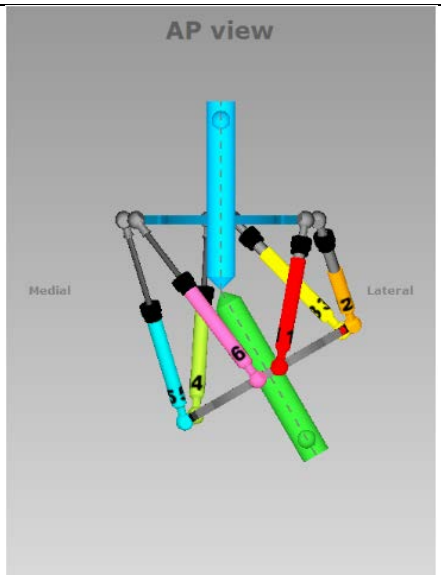
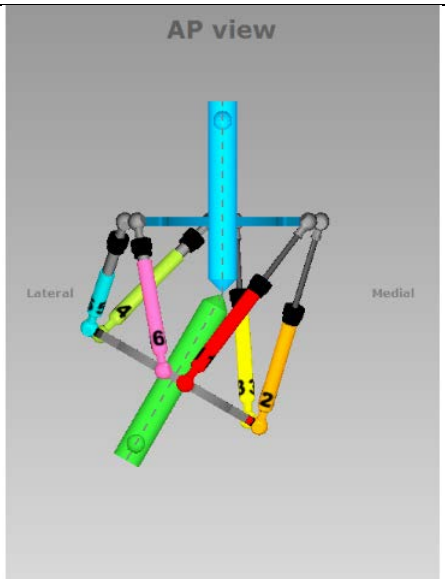


5/8 Open Anteriorly Ring

In case the proximal ring is a 5/8 Open Anteriorly Ring, when there is no rotational deformity, according to the software convention, the ROT is the first possible tab that is counter-clockwise from the anterior side **for both right and left limb.**

NOTE: it is not possible to have the same ROT rotation between left or right limb. The frame mounting is not symmetrical.

Independently from the reference segment selection, the first possible tab will be externally rotated for the left limb, while the right limb will be internally rotated. The rotational value is automatically calculated by the software and is located in the 'Reference Ring Rotation' field. Refer to the tables below to visualize how the frame is represented, based on the mounting rules conventions:

		Left	Right
Proximal support: *5/8 Open Anteriorly Ring* Distal support: *Full Ring*	Proximal Reference Segment	 Reference Ring Rotation (deg) 60 External Internal	 Reference Ring Rotation (deg) 60 External Internal

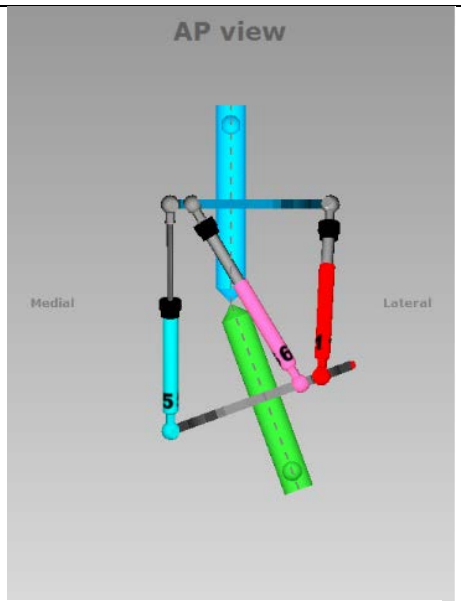
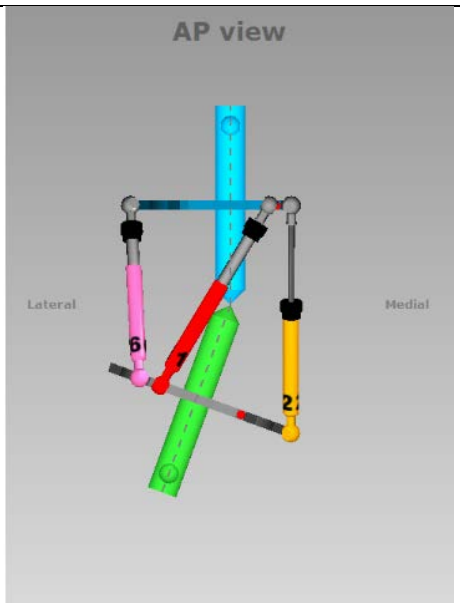
5/8 Open Medially Ring

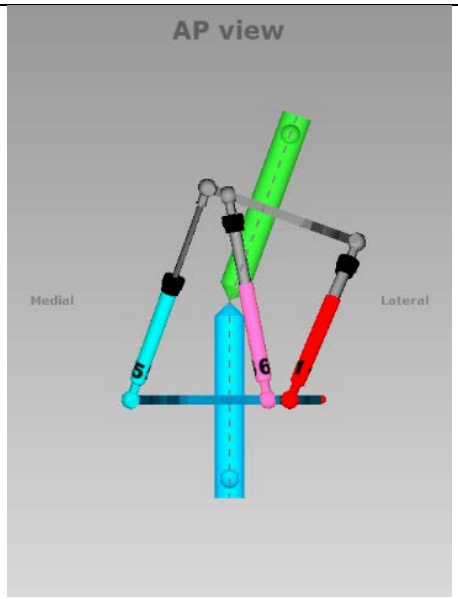
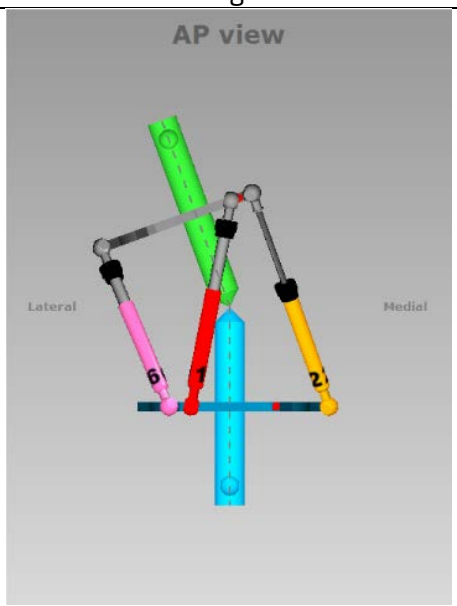
In case the proximal ring is a 5/8 Open Medially Ring, when there is no rotational deformity, according to the software convention, the ROT is the first possible tab that is counter-clockwise from the anterior side **for both right and left limb.**

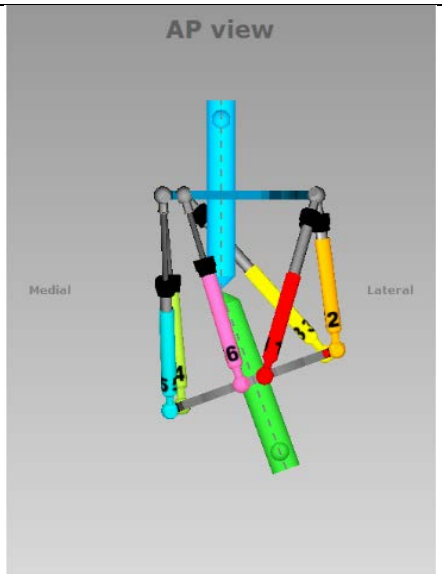
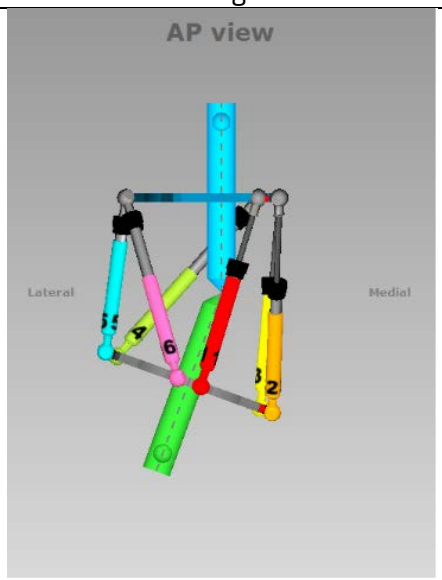
NOTE: it is not possible to have the same ROT rotation between left or right limb. The frame mounting is not symmetrical.

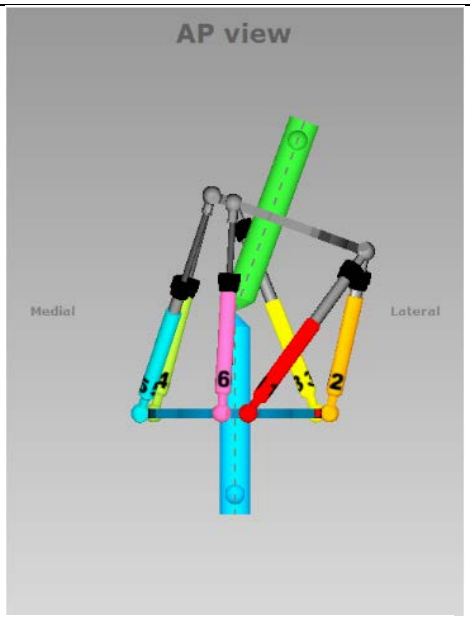
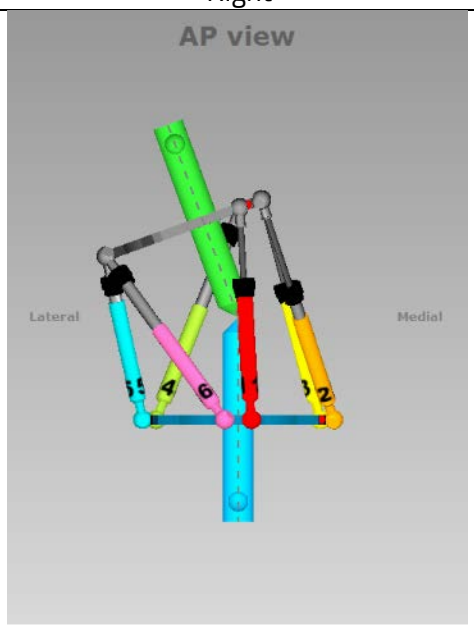
Independently from the reference segment selection, the first possible tab will be externally rotated for the left limb, while the right limb will be internally rotated. Instead, the rotation value changes according with the selected reference segment and distal support. The rotational value is automatically calculated by the software and it is located in the 'Reference Ring Rotation' field.

Refer to the tables below to visualize how the frame is represented based on the mounting rules conventions and different external supports combinations:

		Left	Right
Proximal support: *5/8 Open Medially Ring* Distal support: *Full Ring*	Proximal Reference Segment	 Reference Ring Rotation (deg) 90 External Internal	 Reference Ring Rotation (deg) 30 External Internal

		Left	Right
Proximal support: *5/8 Open Medially Ring* Distal support: *Full Ring*	Distal Reference Segment		

		Left	Right
Proximal support: *5/8 Open Medially Ring* Distal support: *5/8 Open Posteriorly Ring*	Proximal Reference Segment		

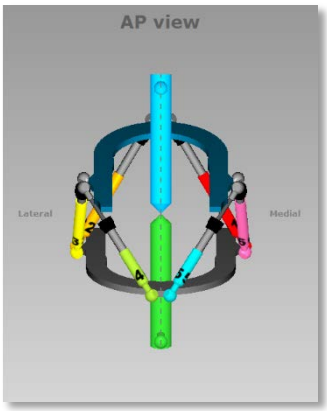
		Left	Right
Proximal support: *5/8 Open Medially Ring* Distal support: *5/8 Open Posteriorly Ring*	Distal Reference Segment		

Footplate

When selecting *Long Bone* as bone type:

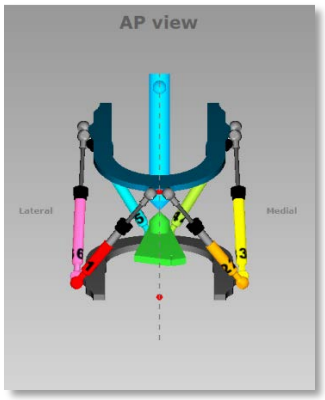
- using **1 footplate**, the footplate will open anteriorly (both distal or proximal)
- using **2 footplates**, the proximal footplate will open anteriorly and the distal footplate will open posteriorly.

With footplate as proximal support, the ROT is at the posterior tab.



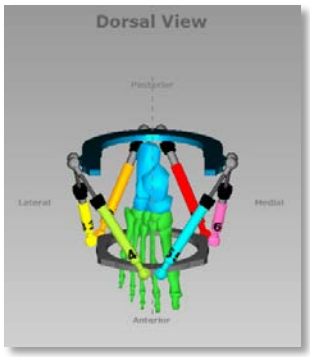
When selecting *Ankle* as bone type:

- using **1 footplate**, the foot plate will open anteriorly (both distal or proximal)
- using **2 footplates,** the proximal footplate will open posteriorly and the distal footplate will open anteriorly.

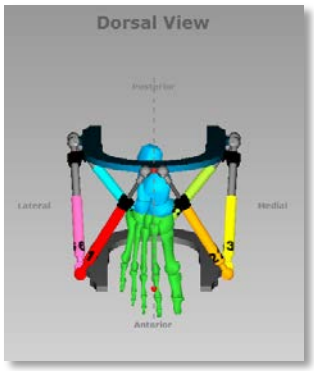


When selecting *Hindfoot or Forefoot* as bone type:

- using **1 footplate** with the Hindfoot/Forefoot, the footplate will open dorsal (both distal or proximal). With the footplate as proximal support, the ROT is at the posterior (plantar) tab.



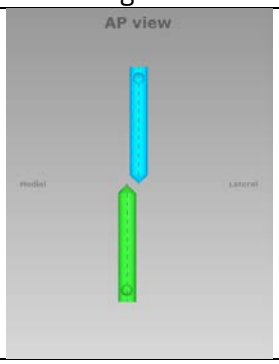
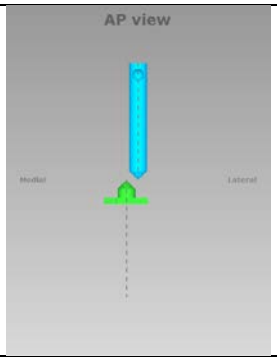
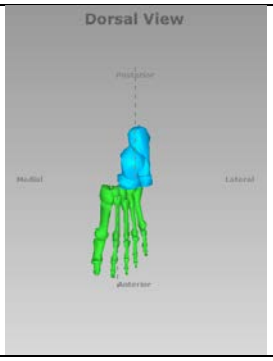
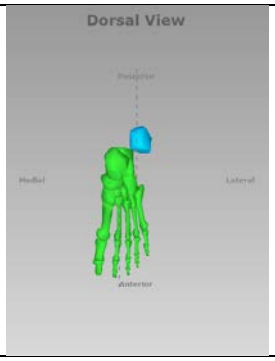
- using **2 footplates**, the proximal footplate will open plantar and the distal footplate will open dorsal. The ROT is on the proximal footplate at the posterior (dorsal) tab.



NOMENCLATURE

This section describes the basic rules and conventions on how the deformity needs to be inputted in the software.

In the description of the fracture or deformity, one of the bone segments is defined as the **reference segment** and the other one as the **moving segment**. In the software views, the **reference segment** is indicated as a **blue** segment, and the **moving** (non-reference) segment as **green**. The surgeon chooses a reference segment, either proximal or distal.

Long Bone	Ankle	Forefoot	Hindfoot
			

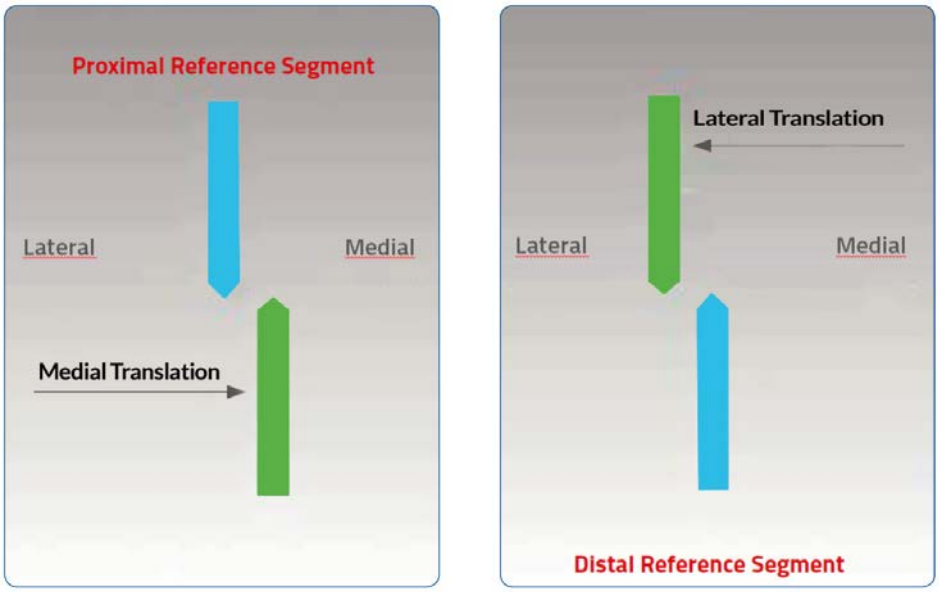
Choosing **proximal** reference **as reference segment** means that:
- the deformity and frame orientation are described relative to the axis of the *proximal* segment
- the deformity parameters (what the bone looks like) should be described accordingly
- the translation and rotation of the distal segment are described in relation to the proximal segment.

Meanwhile, if the **distal** segment is chosen **as reference segment**:
- the deformity and the frame are described relative to the axis of the *distal* segment
- the measurements would need to be taken in relation to this orientation
- the translation and rotation of the proximal segment are described in relation to the distal segment.

To minimize the measurement errors when using the X-rays related either to the apex of deformity or the osteotomy/level of fracture, the shortest segment should be used as a reference segment.
For example, if a proximal tibia osteotomy is performed, the proximal segment should be used as reference. If the surgeon is treating a distal femoral fracture or deformity, the distal segment should be used as the reference segment. If the surgeon has to treat a foot deformity (for example, equinus foot), the proximal segment is almost always used as reference.

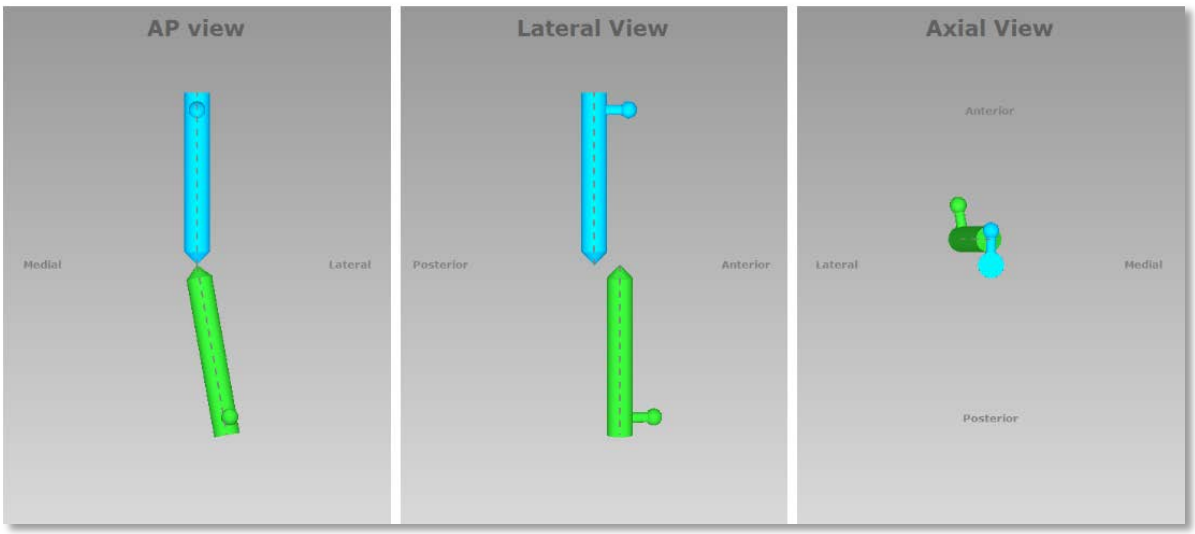
It is important to realize that changing from proximal to distal referencing will change direction of translation in both AP/Dorsal and Lateral views, and the direction of rotation in the Axial view, but will not change length or angulation parameters because these are mathematically independent of the point of reference.

For example, in case of a distal reference segment, medial translation of the distal bone segment would be described as lateral translation because the proximal segment would be translating laterally in relation to the distal (reference) segment as described in the following images.



Description of the moving segment translation depending on proximal or distal selection of the reference segment

In the relevant Case sections, the software proposes a set of three pictures that graphically mimic the input provided to the software in the different stages (e.g., Case Data, Deformity Parameters and Mounting Parameters).



The first is the AP/Dorsal view diagram corresponding to the standard AP/Dorsal X-ray of the limb.

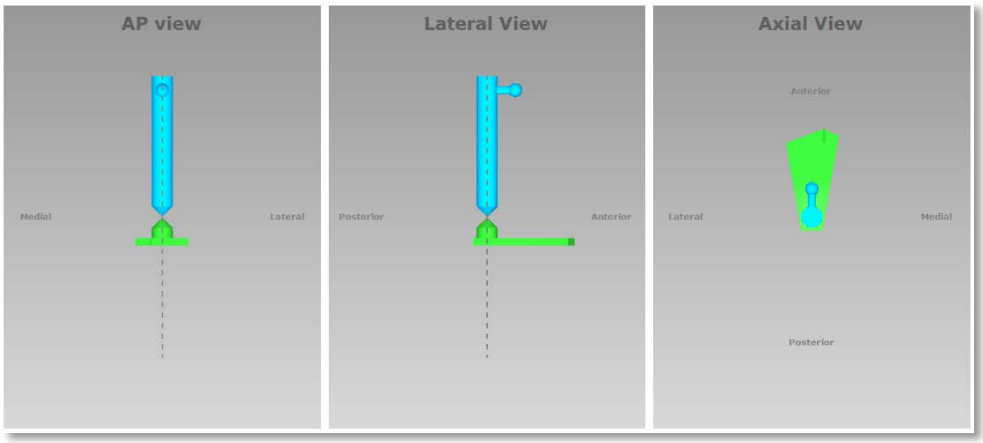
The second is the Lateral view diagram representing the standard ML X-ray of the limb. There are orientation keys on these two views that indicate the medial/lateral and anterior/posterior aspects, respectively.

The third picture is the Axial view, which represents the view we would have when looking either up or down or frontally/posteriorly (foot) at the limb from the reference segment. On this view, the orientation keys are anterior/dorsal, posterior/plantar, medial, and lateral.

To clearly understand what the software is representing related to what the reality looks like, in each projection and for each bone type, the longitudinal axes are traced both in the proximal and distal segments.

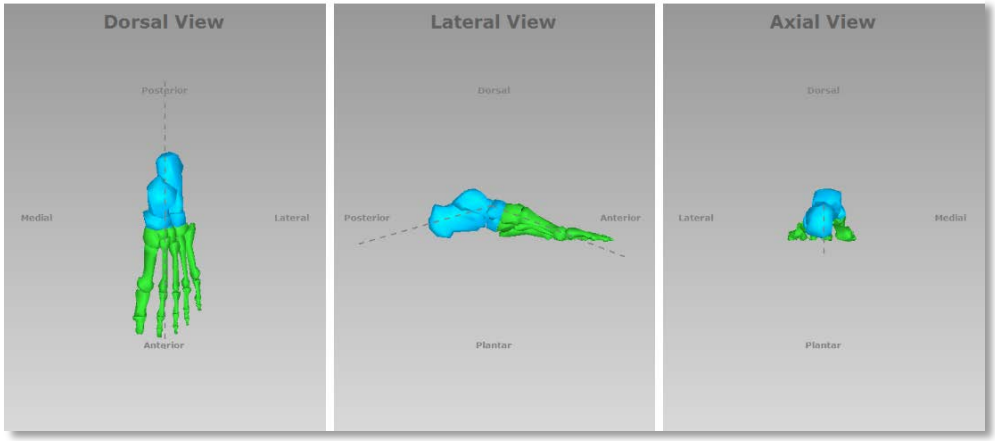
Based on the Bone Type selected - Long Bone, Ankle, Forefoot and Hindfoot - when starting a case, the software accommodates different graphic representations of the bone segments, trying to mimic the correspondent part of the limb.

In the description of *Ankle* cases, the software views represent the deformity following the same rules as above, but adapting the simplified foot anatomy:

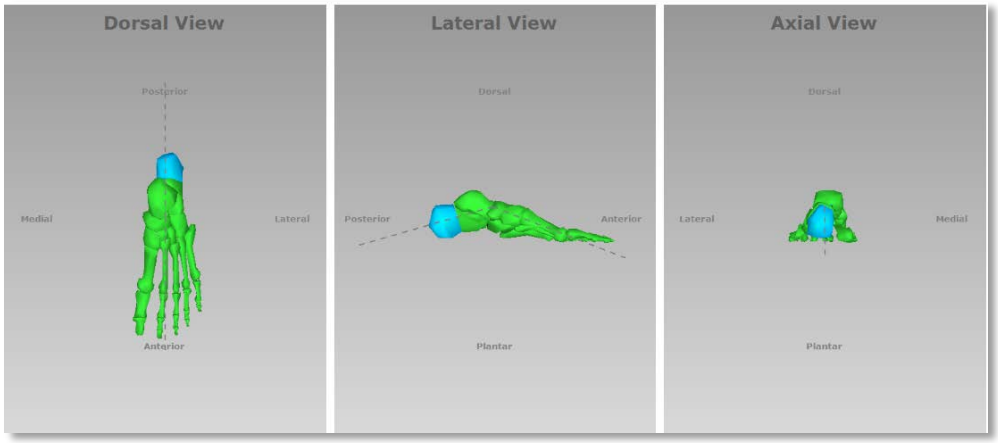


While describing *Foot* deformity, it is possible to select either *Hindfoot* or *Forefoot* level of correction. This indication provides the surgeon with the means to manage different foot deformities in an appropriate way.

If *Forefoot* is selected as bone type, the software views represent the foot anatomy as follows:

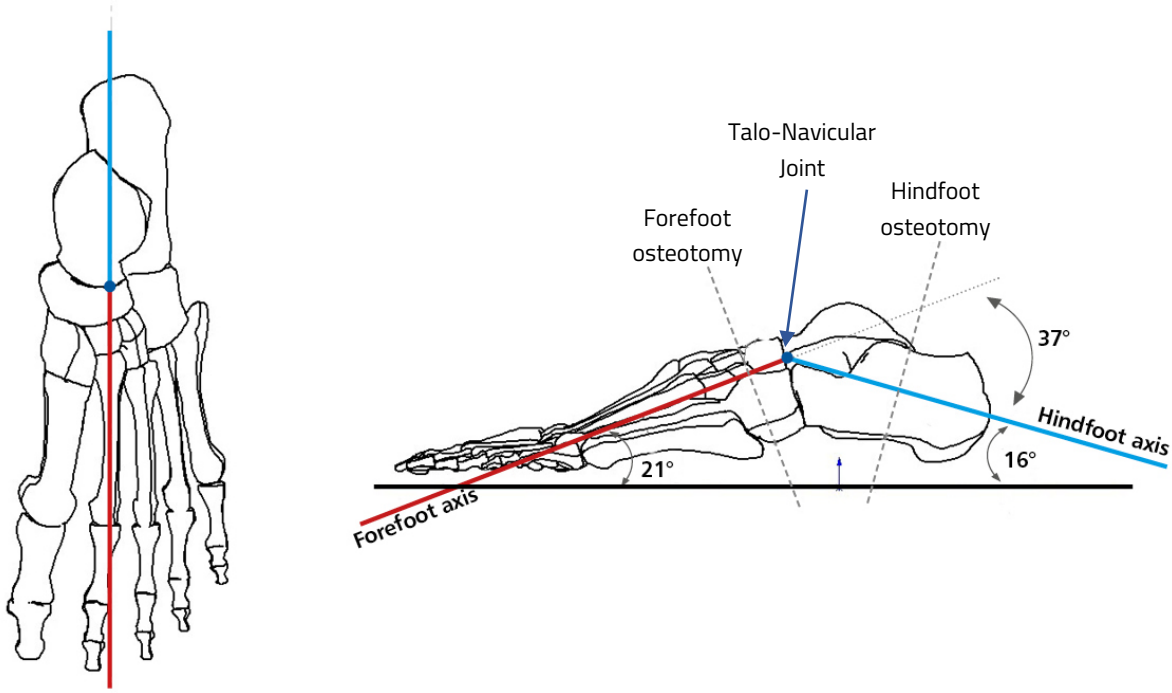


If *Hindfoot* is selected as bone type, the software views represent the foot anatomy as follows:



FOOT NOMENCLATURE

The software conventions behind the foot anatomical representation and deformity description are based on the following assumptions:



The software identifies two axes (solid lines) on the foot graphic representation (as shown in the above picture).
The first axis (Hindfoot axis) is a line that ideally connects the middle of calcaneus with the *talo-navicular joint* along the anatomical axis of the calcaneus.
The second axis (Forefoot axis) drawn on the foot is the line that represents the metatarsal declination angle. The metatarsal declination angle is drawn on the weightbearing lateral foot radiograph between the axis of the second metatarsal and the supporting surface. It is approximately 21°. In general, this axis corresponds to the anatomical axis of the second metatarsal.
These two axes of the foot intersect on the **point of reference** (*talo-navicular joint*) and create an angle of 37° Apex Dorsal. The software considers this value as the default lateral angular deformity.

NOTE 1: This point is also considered as the reference point in relation to which translations and angulations are determined. Also, the point of reference is located neither on forefoot nor hindfoot osteotomy level.

NOTE 2: It is possible to choose different axes to describe foot deformity – but the choice should be consistent in both initial and end-of-correction parameters. The software might represent the foot differently from what is seen on the AP and LATERAL X-rays, but the correction will be performed according to the parameters entered.

The two pictures above describe the two axes, the relative angles and the osteotomies positions. The positions of the two axes remain invariant for both forefoot and hindfoot bone types.
How the software represents the foot and the axes on Dorsal and Lateral view is reported in the Nomenclature section.

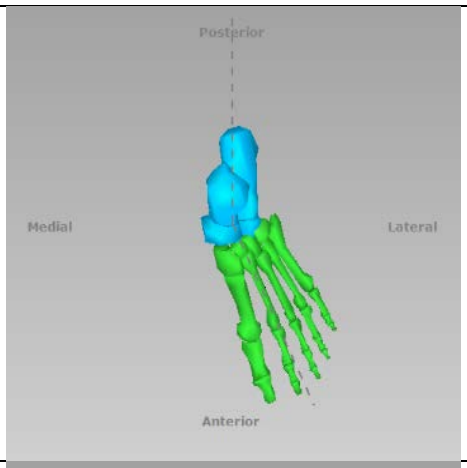
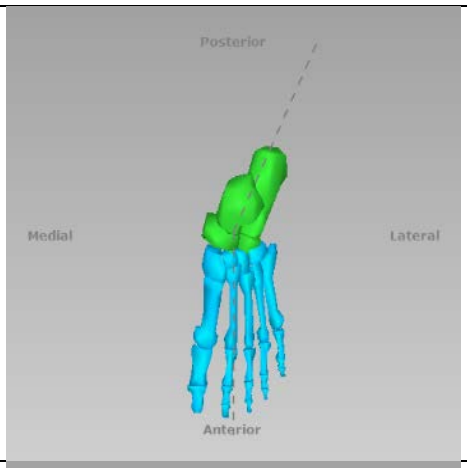
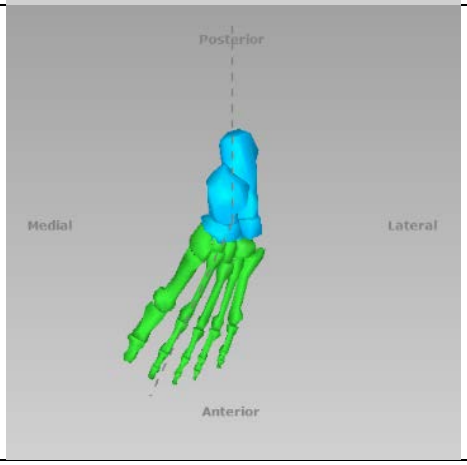
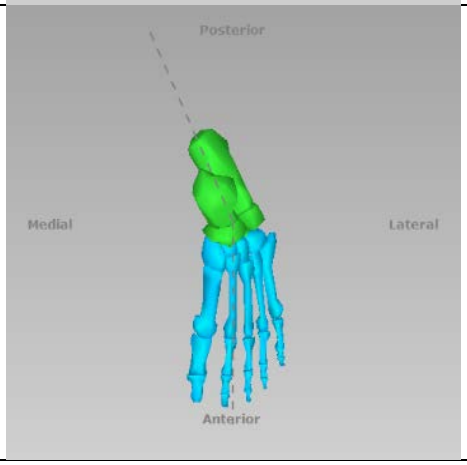
MOVING SEGMENT

In the following tables, there is a description of how the software interprets the choice of the reference segment (distal or proximal) either for forefoot and hindfoot but, in particular, how the software manages the description of the deformity related to this.

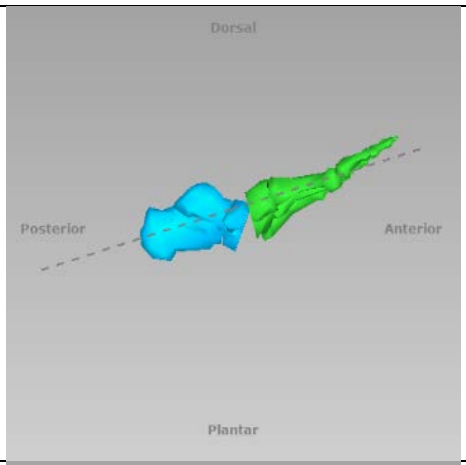
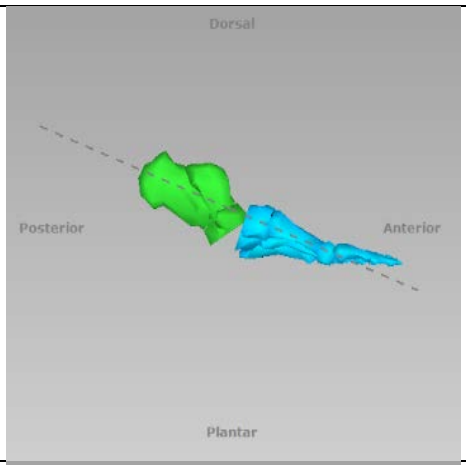
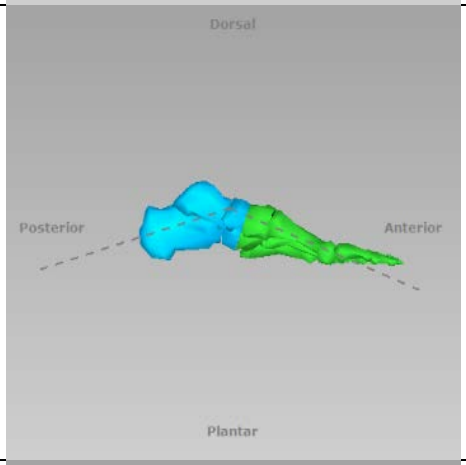
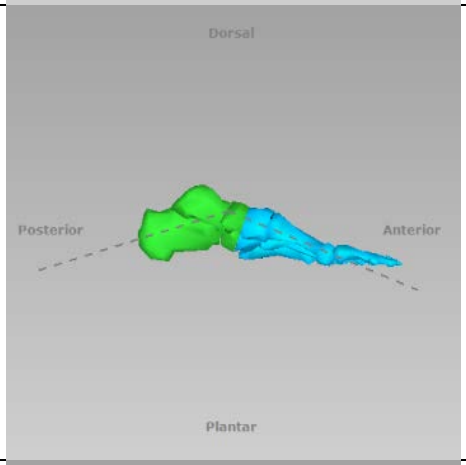
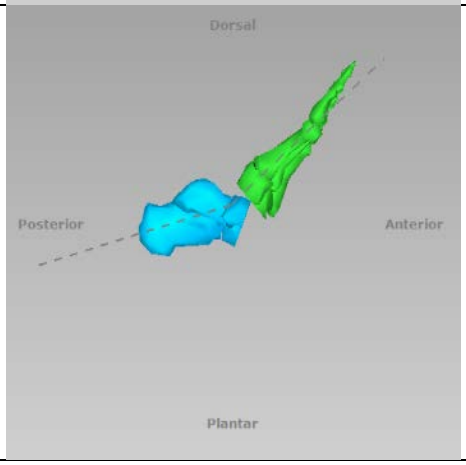
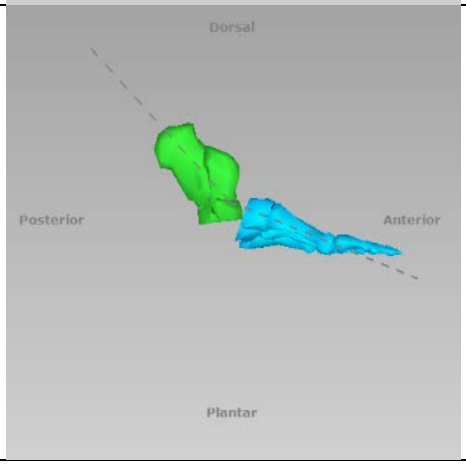
The graphic representations exemplify how the moving segment translates, angulates and rotates relative to the reference segment and the identified axes.

Forefoot

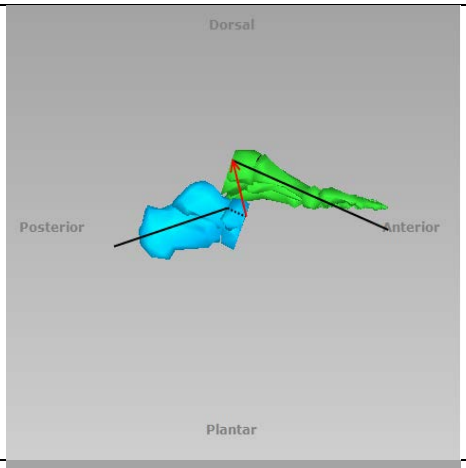
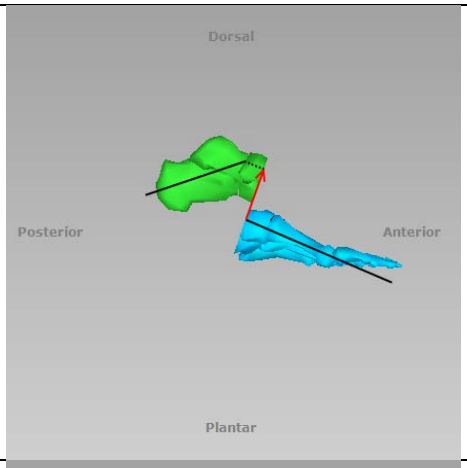
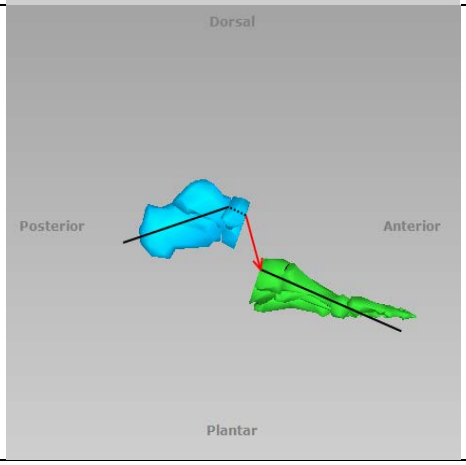
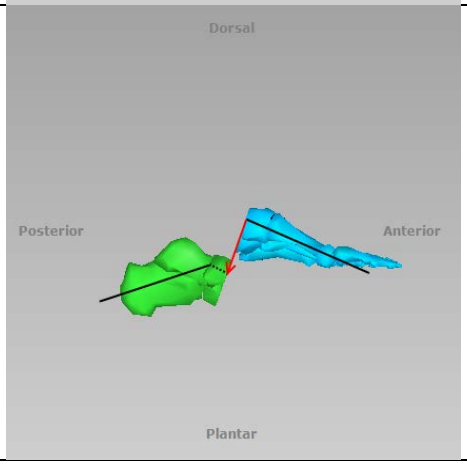
DORSAL Angulation

Forefoot		**Proximal Reference Segment**	**Distal Reference Segment**
DORSAL Angulation (Abduction(ABD), Adduction(ADD)): The moving segment angulates relative to the axes intersection (point of interest).			
DORSAL Angulation	Abduction (ABD) - 30°		
	Adduction (ADD) - 30°		

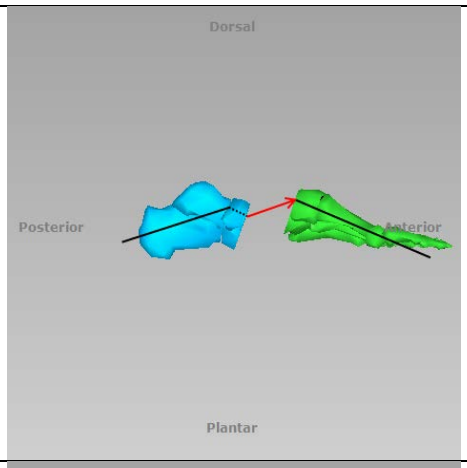
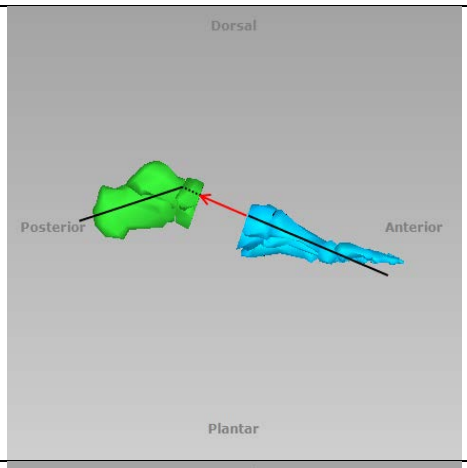
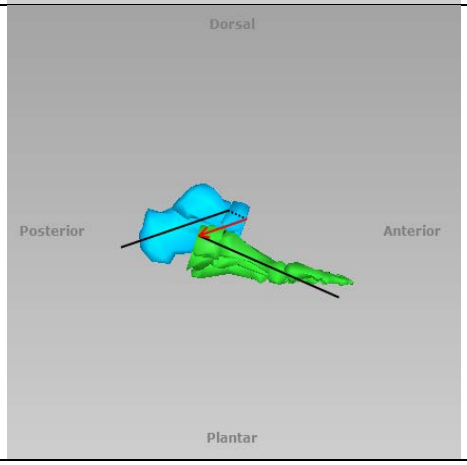
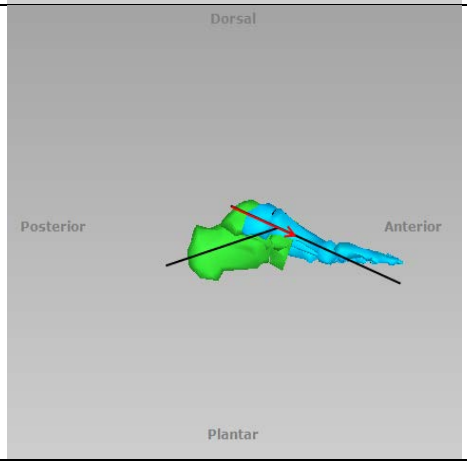
LATERAL Angulation

Forefoot		Proximal Reference Segment	Distal Reference Segment
LATERAL Angulation (Apex Dorsal, Apex Plantar): The moving segment angulates relative to the axes intersection (point of interest).			
LATERAL Angulation	Apex Dorsal / Plantar – 0°		
	Apex Dorsal - 37° **DEFAULT VALUE**		
	Apex Plantar – 25°		

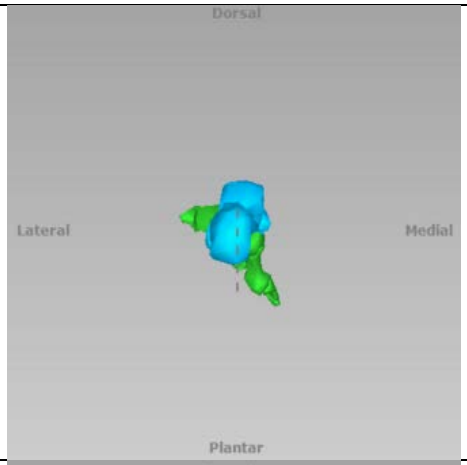
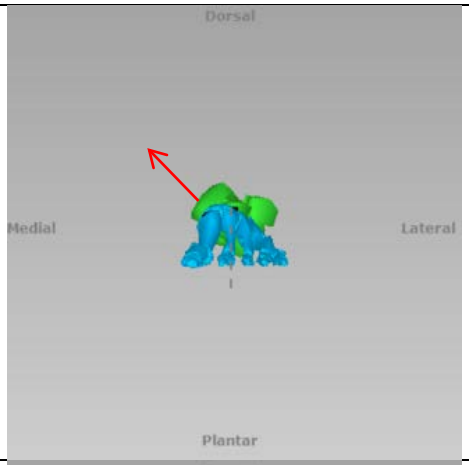
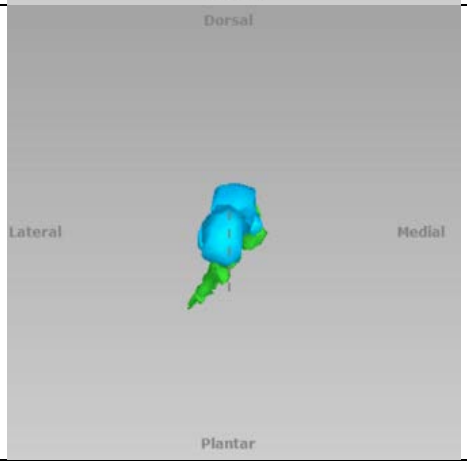
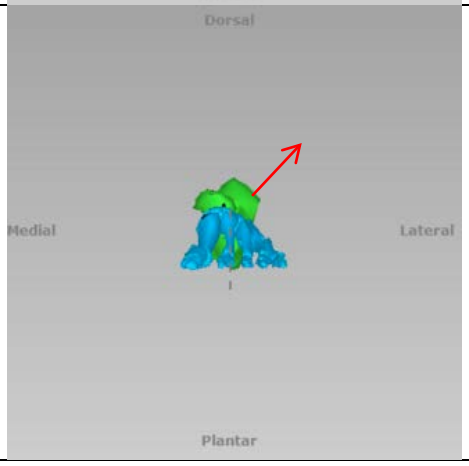
LATERAL Translation

Forefoot		Proximal Reference Segment	Distal Reference Segment
LATERAL Translation (Dorsal, Plantar): The moving segment translates **orthogonally** relative to the reference segment axis.			
LATERAL Translation	Dorsal - 50mm		
	Plantar - 50mm		

AXIAL Translation

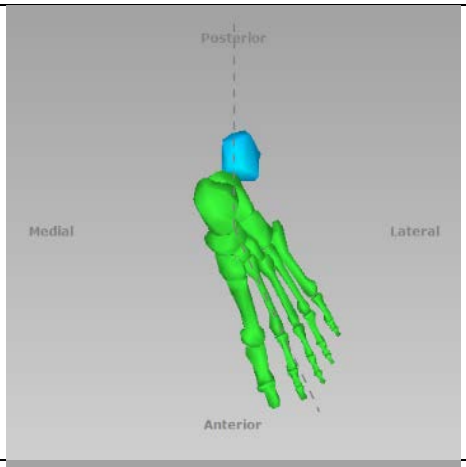
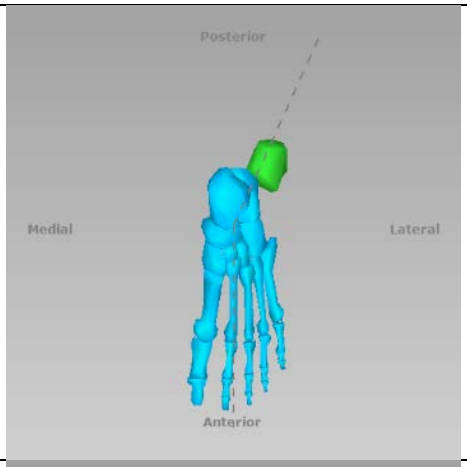
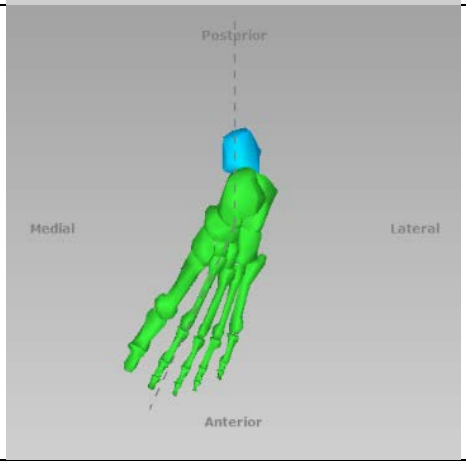
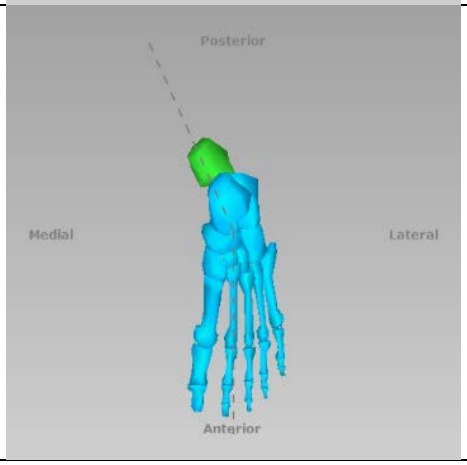
Forefoot		Proximal Reference Segment	Distal Reference Segment
AXIAL Translation (Short, Long): The moving segment translates **along the direction** of the reference segment axis. This is more visible in the LATERAL view.			
AXIAL Translation	Long - 50mm		
	Short - 50mm		

AXIAL Rotation

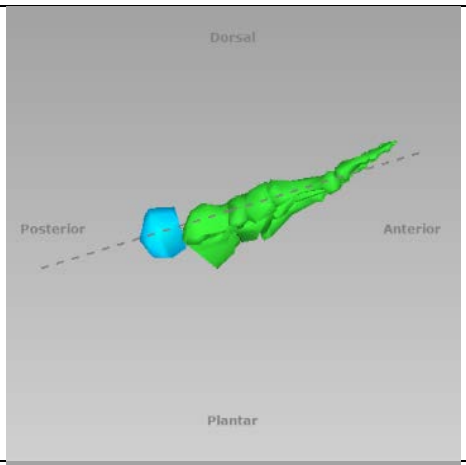
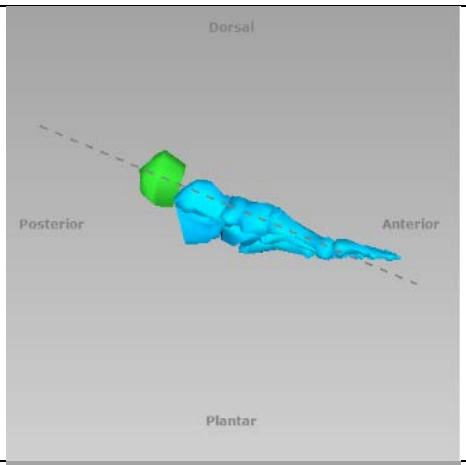
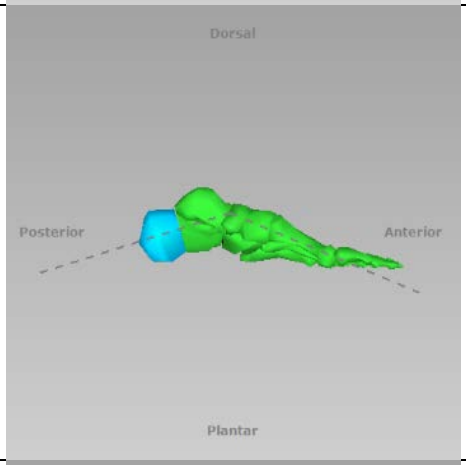
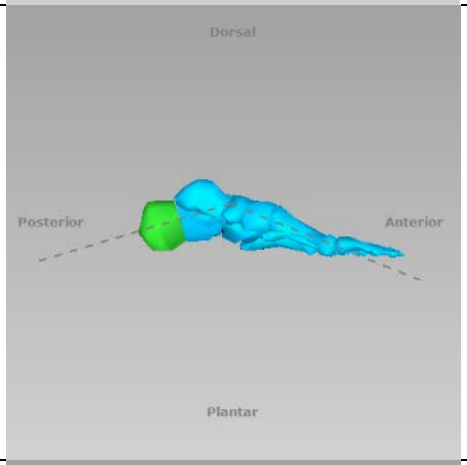
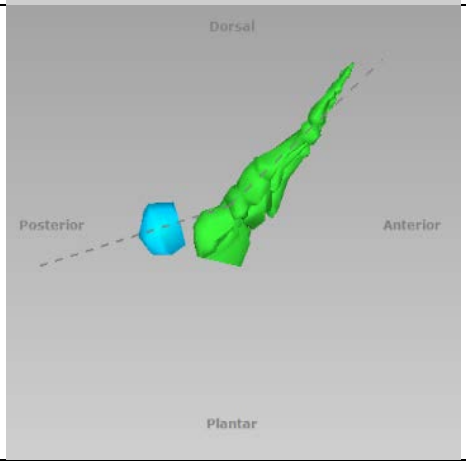
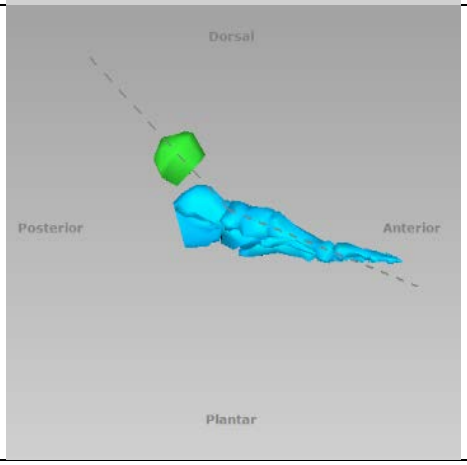
Forefoot		Proximal Reference Segment	Distal Reference Segment
AXIAL Rotation (Supination, Pronation): The moving segment rotates **around** its longitudinal axis. **NOTE:** When selecting the Distal segment as the Reference segment, the rotational deformities are referred to the calcaneus and are opposite to the conventional directions (i.e. pronation becomes supination and vice versa).			
AXIAL Rotation	Pronation – 45°		
	Supination – 45°		

Hindfoot

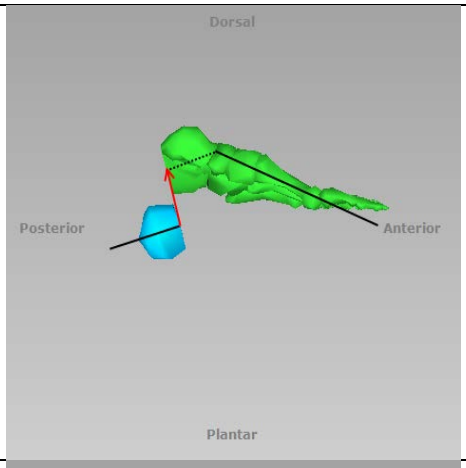
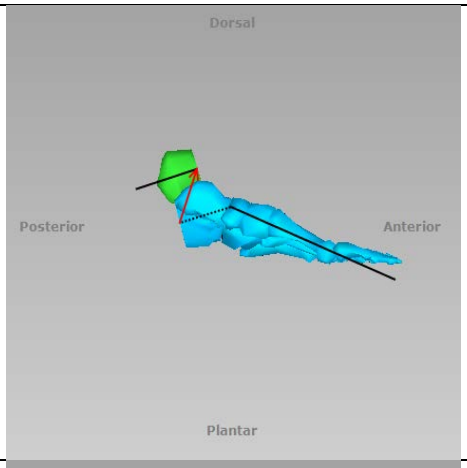
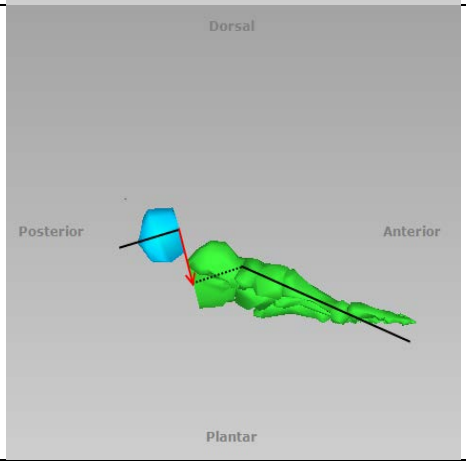
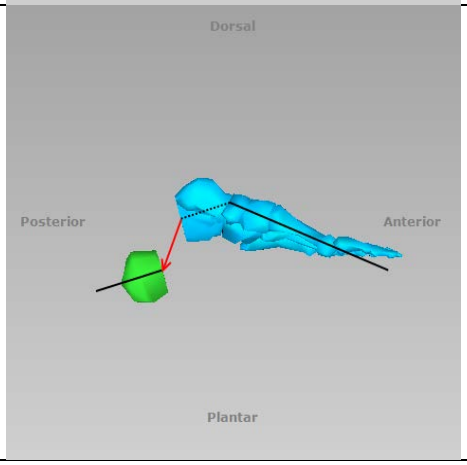
DORSAL Angulation

Hindfoot		Proximal Reference Segment	Distal Reference Segment
DORSAL Angulation (Abduction(ABD), Adduction(ADD)): The moving segment angulates relative to the axes intersection (point of interest).			
DORSAL Angulation	Abduction (ABD) - 30°		
	Adduction (ADD) - 30°		

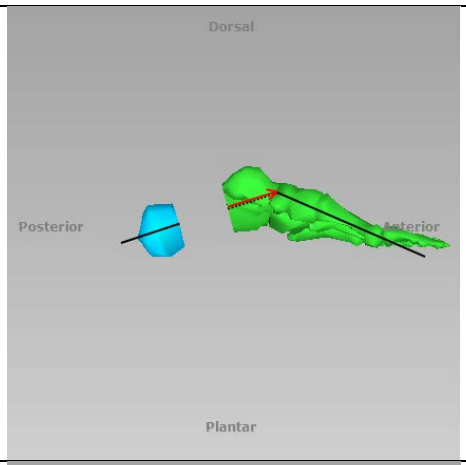
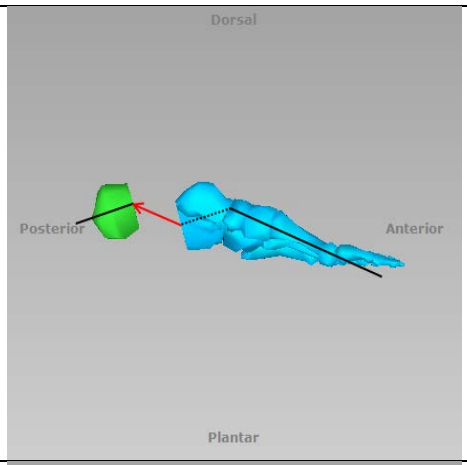
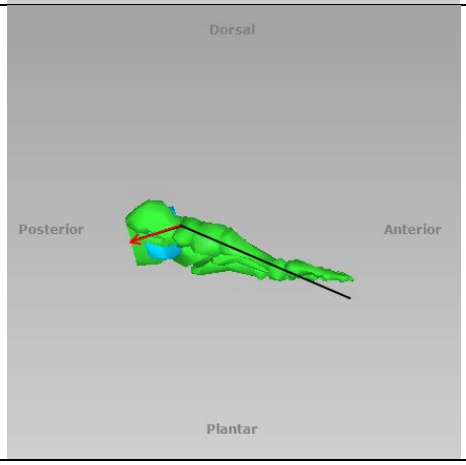
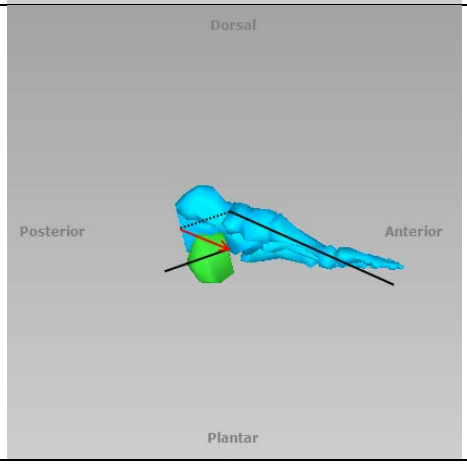
LATERAL Angulation

Hindfoot		Proximal Reference Segment	Distal Reference Segment
LATERAL Angulation (Apex Dorsal, Apex Plantar): The moving segment angulates relative to the axes intersection (point of interest).			
LATERAL Angulation	Apex Dorsal / Plantar – 0°		
	Apex Dorsal - 37° **DEFAULT VALUE**		
	Apex Plantar - 25°		

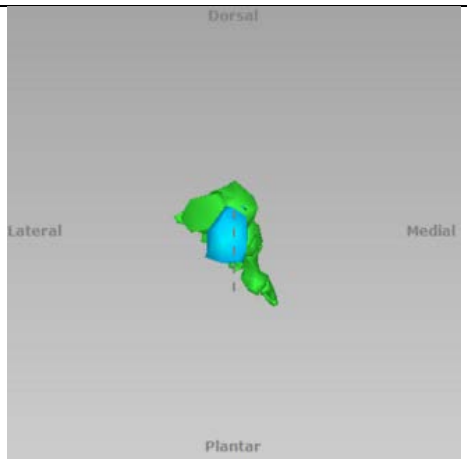
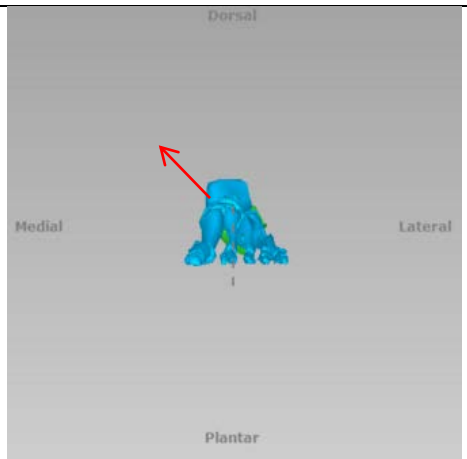
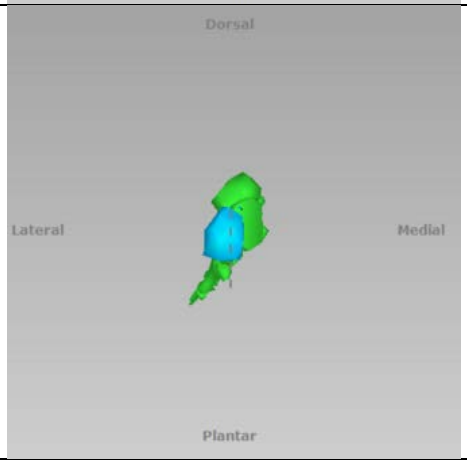
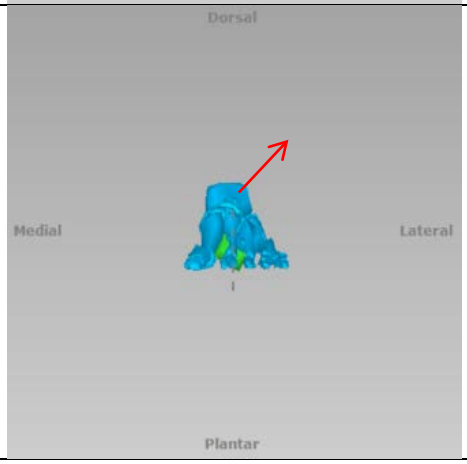
LATERAL Translation

Hindfoot		Proximal Reference Segment	Distal Reference Segment
LATERAL Translation (Dorsal, Plantar): The moving segment translates **orthogonally** relative to the reference segment axis.			
LATERAL Translation	Dorsal - 50mm		
	Plantar - 50mm		

AXIAL Translation

Hindfoot		Proximal Reference Segment	Distal Reference Segment
AXIAL Translation (Short, Long): The moving segment translates **along the direction** of the reference segment axis. This is more visible in the LATERAL view.			
AXIAL Translation	Long - 50mm		
	Short - 50mm		

AXIAL Rotation

Hindfoot		Proximal Reference Segment	Distal Reference Segment
AXIAL Rotation (Varus, Valgus): The moving segment rotates **around** its longitudinal axis. **NOTE:** When selecting the Distal segment as the Reference segment, the rotational deformities are referred to the calcaneus and become opposite to the conventional directions (i.e. varus becomes valgus and vice versa).			
AXIAL Rotation	Valgus – 45°		
	Varus – 45°		

WEBSITE NAVIGATION

OBTAINING ACCESS AND INFORMATION

Access to the TL-HEX software is controlled by Username and Password that can be obtained at www.tlhex.com by requesting a new account from the Home page and following the onscreen 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 surgeon's user account will be activated, and Username and Password will be emailed to the applicant.

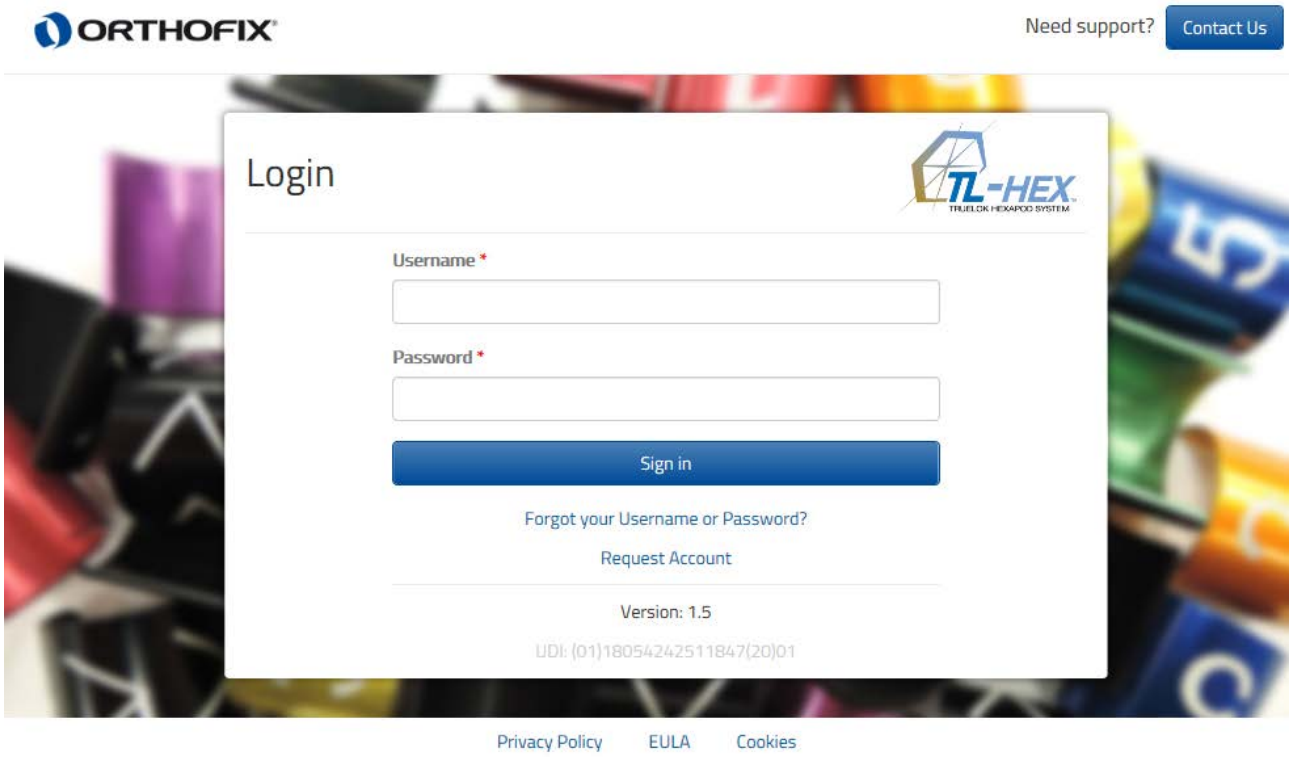
For further information and support, please, send an email to **tlhexcustomercare@orthofix.com**.

GETTING STARTED ... HOW TO LOG IN

Go to: app.tlhex.com

This location provides the login screen after the selection of the user's country. Previous software releases are maintained to serve those countries where this current version has not yet been approved.

Enter username and password and click 'Sign in'. Mandatory fields are marked with a *.



NAVIGATION MENU

The software header allows the user to recall the following menu functions anywhere within the application:

- Patients
  - List of Patients
  - Add new Patient
- Cases
  - List of Cases
  - Add new Case

In addition to the Patients and Cases menu, the icons on the right-hand-side identify the following actions:

MANAGE ACCOUNT

Where the user can manage and update his/her own account information, change the password and manage the prescription preferences.

CONTACT US

A quick link to access the support or obtain more information on the TL-HEX System, both software and hardware, is available by clicking on this icon. This will display the instructions on how being in contact with the TL-HEX Customer Care.

INSTRUCTIONS FOR USE

By clicking on the icon the user is forwarded to the Instruction for Use section where he/she can find the available support material on product usage and additional resources.

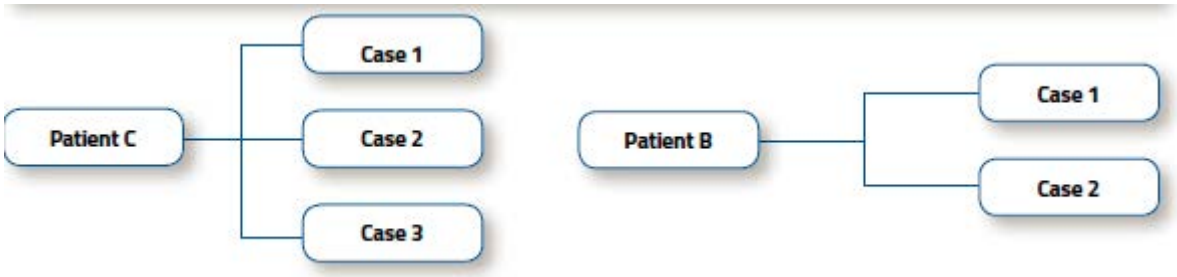
LOG OUT

To log out, just click on the icon

PATIENT AND CASE MANAGEMENT

The **Patients** and **Cases** menu includes links to the list of patients or cases, and enables the surgeon to add a new patient or case, respectively.

All cases are related to a particular patient. At least one patient must be present prior to start any case. There are no restrictions on the number of cases that can be associated with each patient.



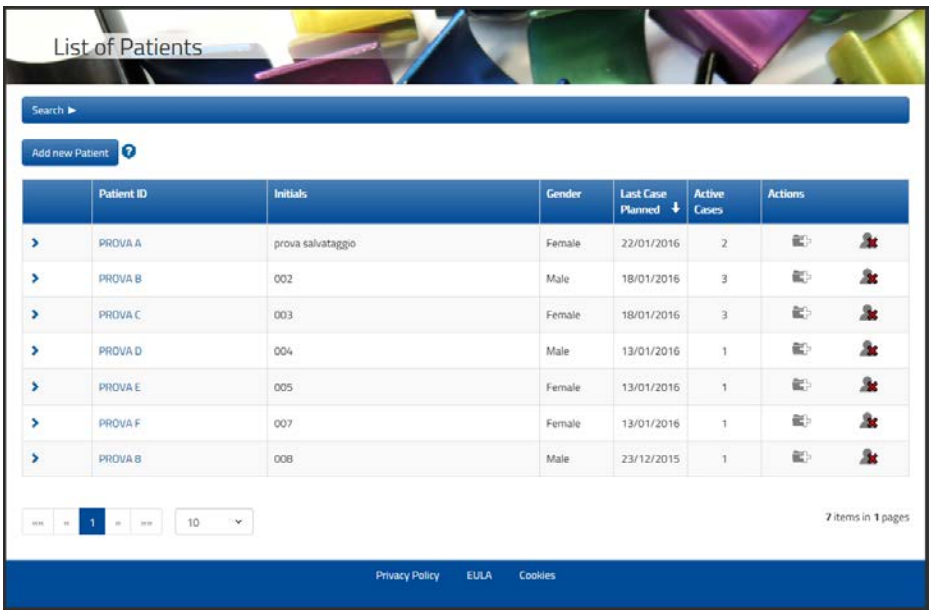
PATIENTS

Patients → List of Patients

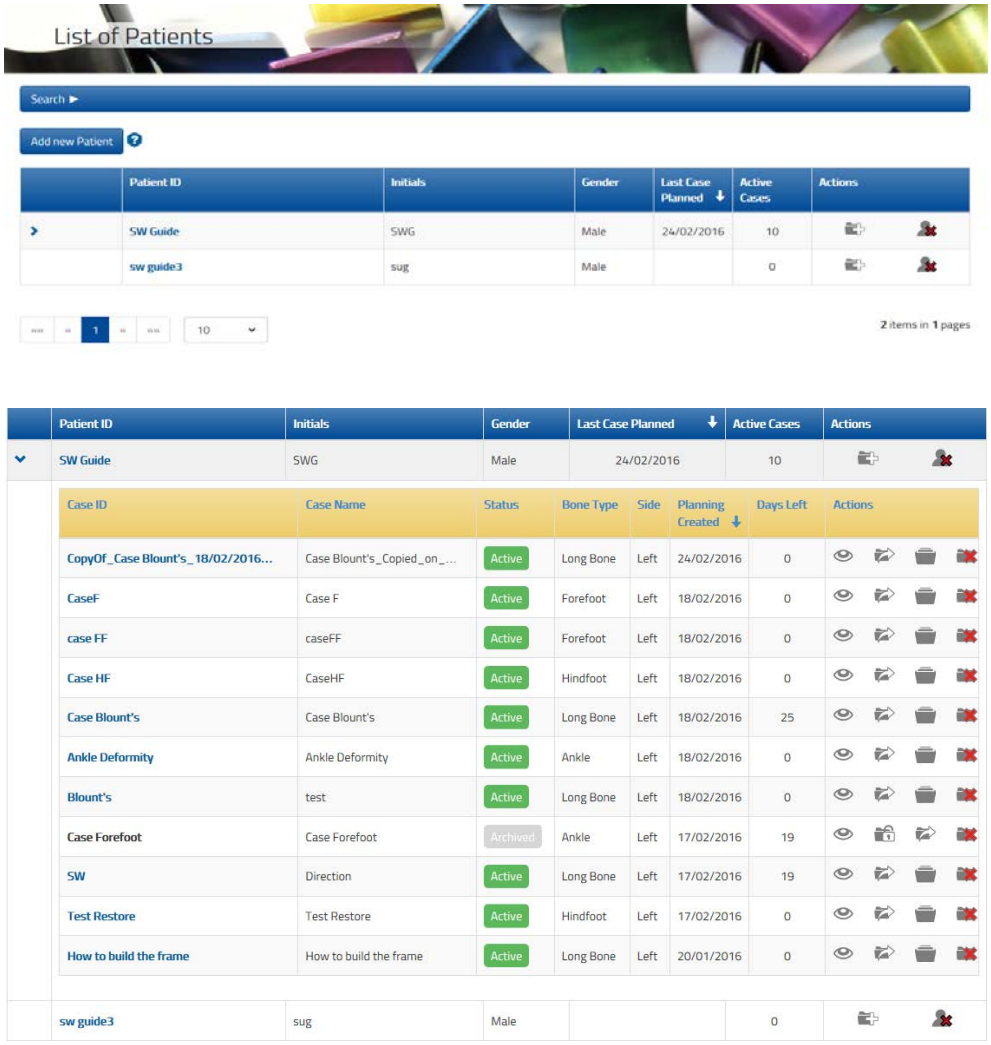
The List of Patients can be found by clicking [List of Patients] in the Patients item from Navigation menu, located in the header section. The list of patients is the homepage of the software.

By default, patients are sorted based on the case planning creation date, in descending order.

The List of Patients can also be sorted in ascending or descending order by clicking on any of the headers except Actions.



Clicking on the icon related to each patient in the list to expand the list of cases related to this 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 records displayed per page [10 – 25 – 50 – ALL].

PATIENT ACTIONS

Actions that can be performed on a patient are:

ADD NEW CASE

Create a new case related to this patient in one click by selecting this icon

DELETE A PATIENT

By selecting this option, the patient and all his/her related cases will be deleted.
The popup window will appear to confirm the removal of the patient. Click on 'Delete' to move on. A warning pop up reminds that the action cannot be reverted, once a patient is deleted.

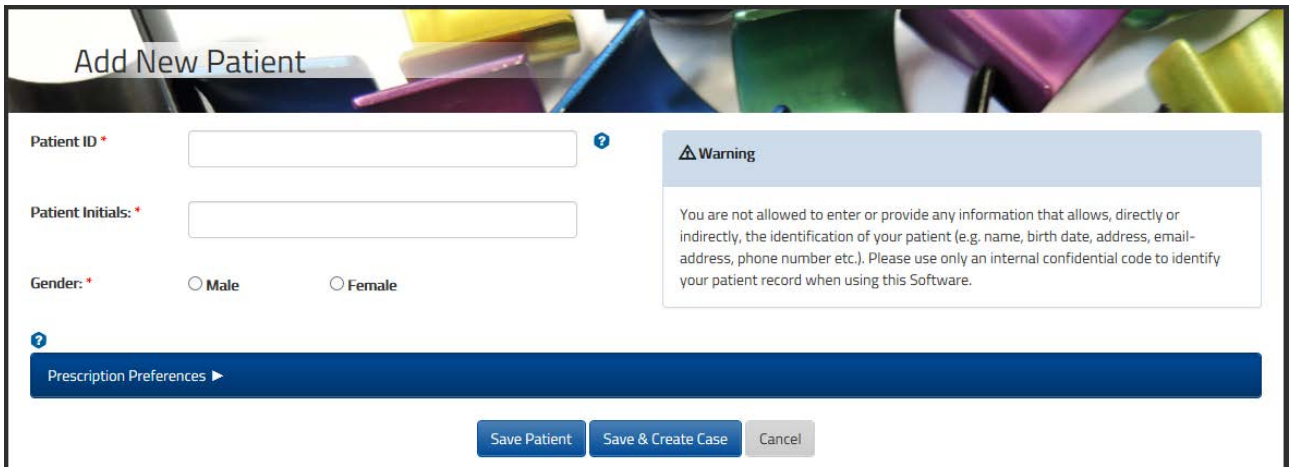
To *view* or *modify* the data of an existent patient click the Patient ID.

ADD NEW PATIENT

Patients → Add new Patient

A new patient can be entered using:

- Add new Patient menu, found in the navigation menu
- Add new Patient button (either in List of Patients or List of Cases screen)

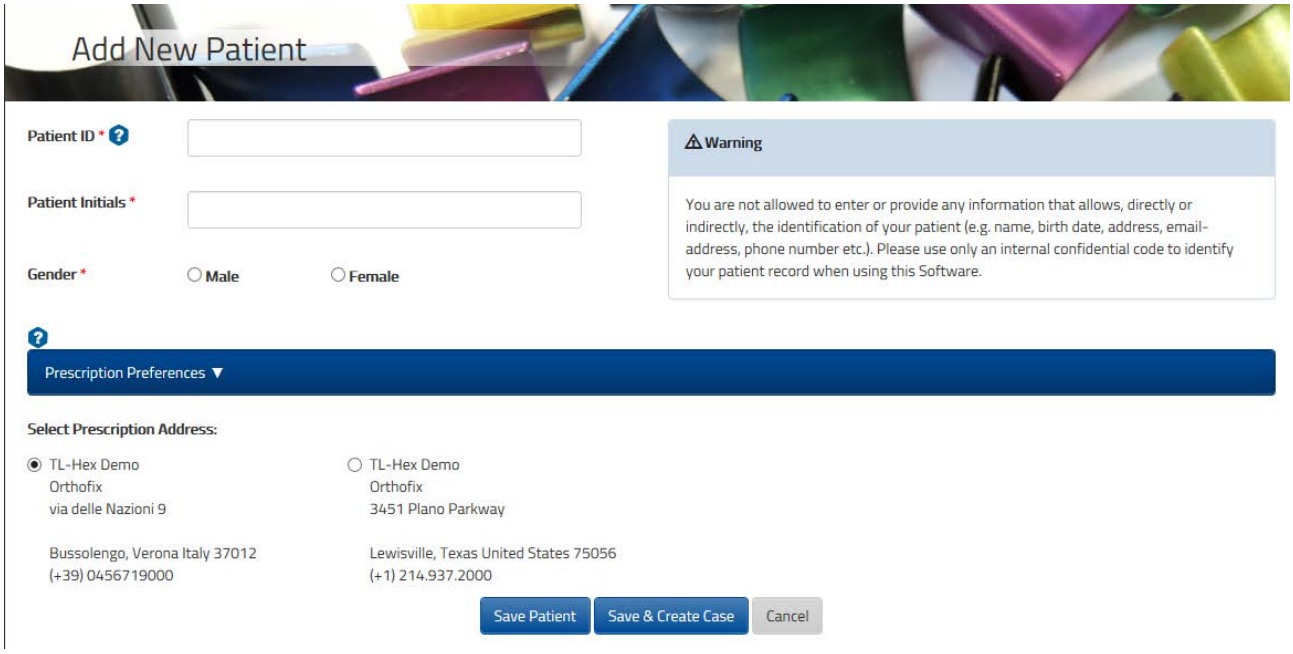


For each new patient, the surgeon should provide the following information

- unique Patient ID
- Patient Initials
- Gender

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

Optionally, the user can associate a specific Prescription Address to a patient by expanding the 'Prescription Preferences' bar (see PRESCRIPTION PREFERENCES for details about setting addresses).



Clicking on the Save Patient button will complete the creation process and open the "List of patients" screen, which will include all previously entered patients as well as the newly created one.

On the other hand, clicking on the Save & Create Case button will save the new patient and will open a new ready-to-use case that is already associated to the newly created patient.

SEARCH

To search a Patient or Case, expand the search bar to search the content based on specific criteria. Enter the search criteria in the relevant field and press the Search button.

User can search by Patient ID, Status, Case ID, Side, Case Name, Bone Type and Planning Created (using the "This Date", "After This Date" or "Before This Date" logic).

To remove any filter, click the Clear button.

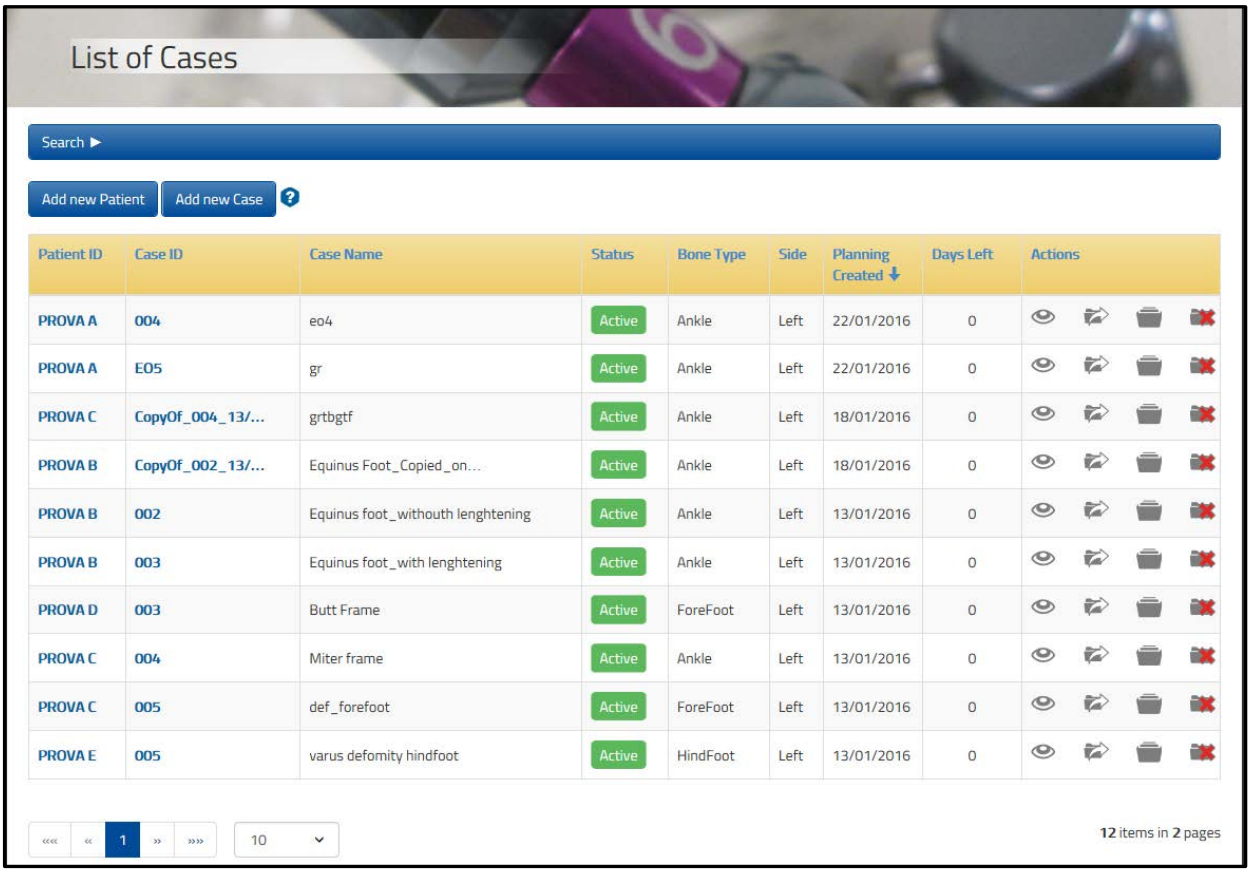
CASES

Cases → List of Cases

The list of cases can be found by clicking List of Cases in the Cases item from the Navigation menu, located in the header section.

By default, cases in the List of Cases are sorted in descending order based on the Planning Created date.

The List of Cases can also be sorted in ascending or descending order by clicking on any of the headers except Actions.



The case 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 records displayed per page [10 – 25 – 50 – ALL].

STATUS OF A CASE

A case can pass through different statuses based on the performed actions. The current case status is color-coded and reported in the Status column in the Case lists. Different actions are available depending on the case status.

Below is reported a summary of the different status:

	Detail
Active	The case can be viewed, modified, deleted, archived or sent to another TL-HEX user.
AdjustedReport	A case with this status is a case where the report has been adjusted and has only the report tab enabled. If you reset the changes using the Reset button in the Report tab, all other tabs will be enabled again and the changes made so far on the report will be lost.
Received	The case has been received from another user. It can be viewed, deleted or restored in order to make it editable.
Archived	The case has been archived by the user and it is in read-only format. It can be viewed, deleted, sent or restored in order to make it editable.

CASE ACTIONS

Different actions are available depending on the case status. Below is a summary of the actions available according with the related case status:

		CASE STATUS			
ACTION		Active	Received	Archived	Adjusted Report
	View Case	X	X	X	X
	Send Case	X		X	X
	Archive Case	X			X
	Restore Case		X	X	
	Delete Case	X	X	X	X
	Upgrade Case(*)	X	X	X	X

Archived and Received cases needs to be restored to become Active and therefore modifiable.

Active cases can be reviewed or modified by clicking Case ID.

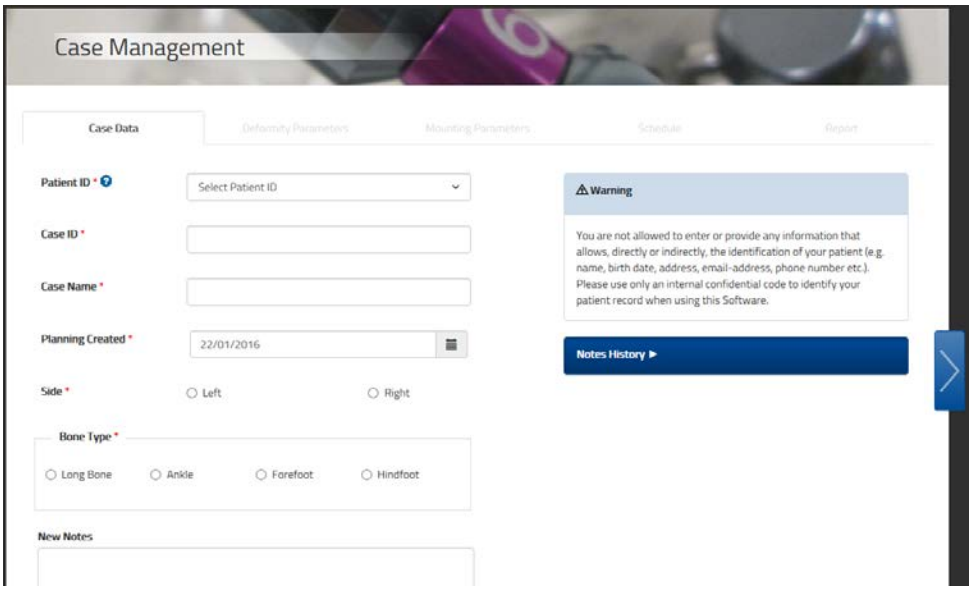
(*) A case can be Upgraded if it has been migrated from one of the previous software versions.

ADD NEW CASE

A new case can be created using one of the following methods:

- Selecting **Add new Case** from the Cases menu
- Clicking **Add new Case** in the List of Cases screen
- Clicking on [Add new Case for this Patient] icon in the List of Patients screen
- Clicking **Save & Create Case** directly in the Add New Patient Screen

NOTE: At least one patient must be present, otherwise it is not possible to create any case.



Having selected a Patient, for each new case the surgeon should assign a unique Case ID, for that Patient, and a Case Name (reference associated with this case), left/right side, bone type (Long Bone, Ankle, Forefoot or Hindfoot) and the planning date, followed by optionally entering Notes associated with this case.

Proceed to the next step in the treatment planning process by clicking on the arrow on the right-hand side.

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

VIEW CASE

All the cases for all patients in each status can be displayed in *View Mode* by clicking on the [View Case] icon.

In this section, all the case details (Case and Frame section, Deformity and End of Correction parameters, Mounting Parameters and End of correction, Schedule, Prescription and Report) are included.

By clicking Print Page, it is possible to print this summary to archive it as part of the patient record.

NOTE: To prevent your summary (in particular Report and Prescription tables) from being cut off when you print it, try printing it in landscape format.
Different printers may yield different results, and the printing dialog box may contain different options, depending upon the specific printer and browser you are using, but generally you should follow these steps:

PC Users

Internet Explorer 10/11

1. Click the **Gear** icon in the upper right-hand corner of the browser.
2. Click **Print** > **Page Setup**.
3. Under Paper Options, select "Landscape".
4. Place a check next to the "Enable Shrink-to-Fit" option.
5. Click **OK**.
6. Print your case summary

MAC Users

Safari

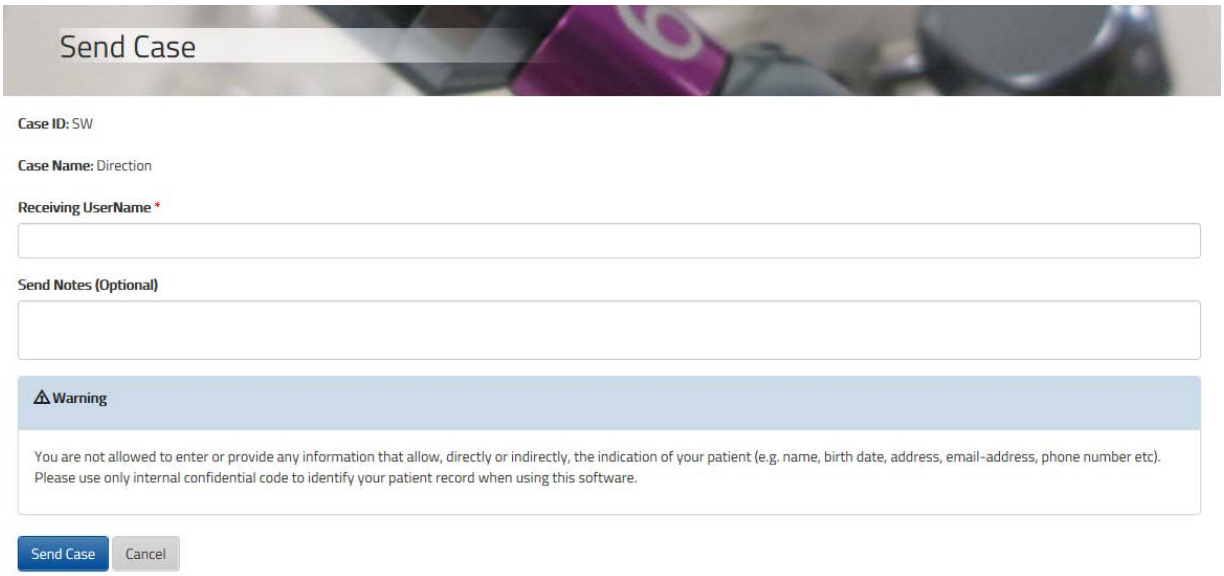
1. Click **File** > **Print**.
2. Click **Show Details**.
3. Next to Orientation, click on the second icon of a man standing sideways.
4. Click on **Print**.

SEND A CASE

Active, Adjusted Report and Archived cases can be sent to another user.

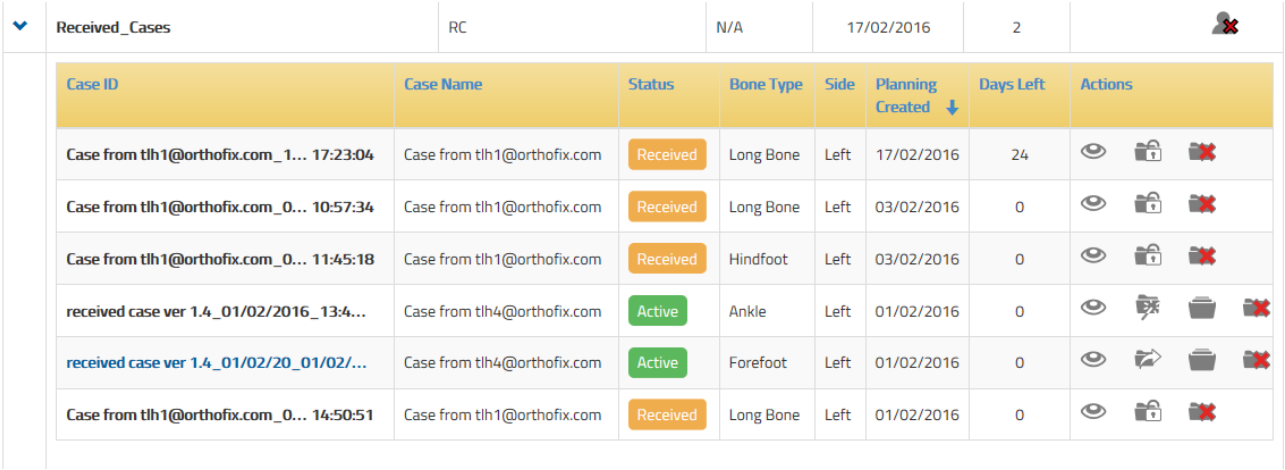
From List of Cases, click on the icon related to the case to be sent. Fill in the Username i.e. the registration username (email) of the receiver. Optionally, add notes for the receiver to accompany the case, they will be embedded at the top of the View Case summary. The receiving user will be notified by email about the received case and the entered notes will be displayed also in the email body.

In accordance with privacy guidelines, information related to Patient ID, Patient Name, Case ID and Case Name is overridden prior to sending. Original Case Notes, if any, will be removed from the case sent.



The receiver will find the received case linked to the Patient ID – Received_Cases.

The case status assigned for this case is Received.



Received_Cases	RC	N/A	17/02/2016	2	

Case ID	Case Name	Status	Bone Type	Side	Planning Created	Days Left	Actions
Case from tlh1@orthofix.com_1... 17:23:04	Case from tlh1@orthofix.com	Received	Long Bone	Left	17/02/2016	24	
Case from tlh1@orthofix.com_0... 10:57:34	Case from tlh1@orthofix.com	Received	Long Bone	Left	03/02/2016	0	
Case from tlh1@orthofix.com_0... 11:45:18	Case from tlh1@orthofix.com	Received	Hindfoot	Left	03/02/2016	0	
received case ver 1.4_01/02/2016_13:4...	Case from tlh4@orthofix.com	Active	Ankle	Left	01/02/2016	0	
received case ver 1.4_01/02/20_01/02/...	Case from tlh4@orthofix.com	Active	Forefoot	Left	01/02/2016	0	
Case from tlh1@orthofix.com_0... 14:50:51	Case from tlh1@orthofix.com	Received	Long Bone	Left	01/02/2016	0	

A received case cannot be sent back to sender or to another user, but you can restore it and after it is possible to send to another TL-HEX user.

RESTORE A RECEIVED CASE

Patient ID	Case ID	Case Name	Status	Bone Type	Side	Planning Created	Days Left	Actions
Received_Cases	Case from tlh1@orthofix.... 17:23:04	Case from tlh1@orthofix. ...	Received	Long Bone	Left	17/02/2016	24	

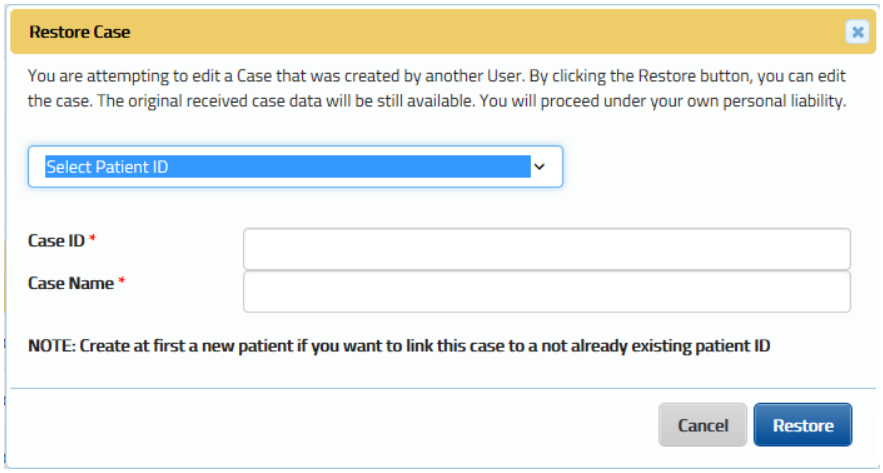
The received case is initially in read-only mode and it can accessed in view mode by clicking the [View Case] icon.

However, starting from this version, the received cases can be restored by clicking the [Restore Case] icon. This action allows you to create an editable case.

Before starting the restoring procedure, create a new patient record to whom you will assign the restored case.

Click the icon to proceed with the restore. Select the Patient ID specifically created for this purpose or link to an existent one.

Create a new Case ID and Case Name.



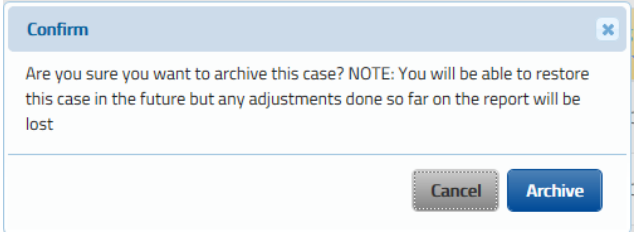
By clicking the Restore button to complete the procedure, a new case with the provided details is created. The Case Data, Deformity Parameters, Mounting Parameters and Schedule tab, when fulfilled and successfully saved, are automatically copied into the new case, while the report and the prescription need to be recalculated.

Once restored, the new case status is Active .

ARCHIVE A CASE

To archive a case, click on the [Archive Case] icon. A Pop-up message appears to inform that, even if the case can be restored and is editable again, any eventual report adjustment completed so far will be lost.

By proceeding with the archive, the new case status will be Archived .

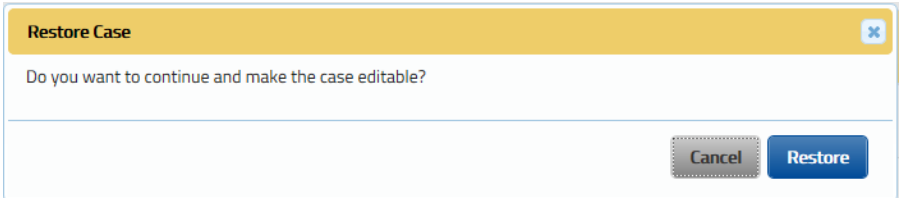


RESTORE AN ARCHIVED CASE

Patient ID	Case ID	Case Name	Status	Bone Type	Side	Planning Created	Days Left	Actions
SW Guide	Case Forefoot	Case Forefoot	Archived	Ankle	Left	17/02/2016	24	

Once archived, a case is accessible in read-only and it can be accessed in view mode by clicking the [View Case] icon.

However the archived cases can be restored by clicking the [Restore Case] icon. This action allows you to make the case editable again.



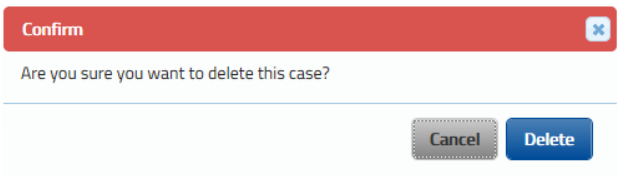
By clicking the Restore button, the case becomes editable and the user can review the Case Data and all the other tabs entered so far until Schedule, but the report and the prescription need to be recalculated.

Once restored, the new case status is Active .

DELETE A CASE

A case can be deleted by clicking the [Delete Case] icon. This action is available for any case.

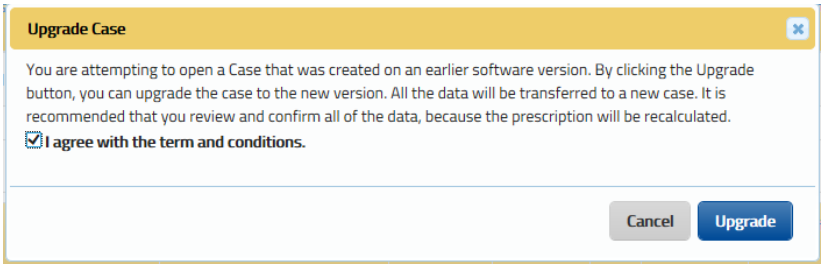
The delete action cannot be reversed. A pop-up message asks the user to confirm the intention to proceed with the case deletion.



UPGRADE A CASE FROM PREVIOUS VERSIONS TO 1.5

Cases created with prior software versions will be migrated in read-only mode in version 1.5.
If the surgeon wants to modify one of these cases, he/she should proceed with the upgrade.

To upgrade a prior version of a case, click on the [Upgrade Case] icon.
A pop-up message will notify the user about the attempt to open a case that was created with a prior software version.



To proceed with the upgrade, the user is requested to agree with the term and conditions declared for this option.
By clicking the Upgrade button, Case Data, Deformity Parameters, Mounting Parameters Data and Schedule settings are copied into a brand new case.
The user is recommended to review these prior to recalculating the report and the prescription.

By upgrading the case, please pay attention that:

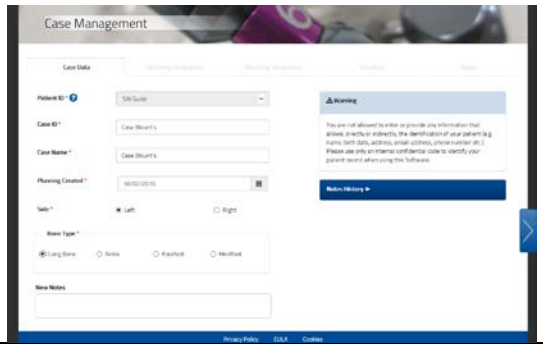
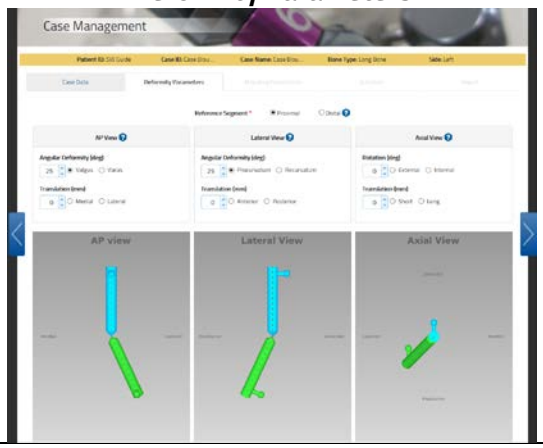
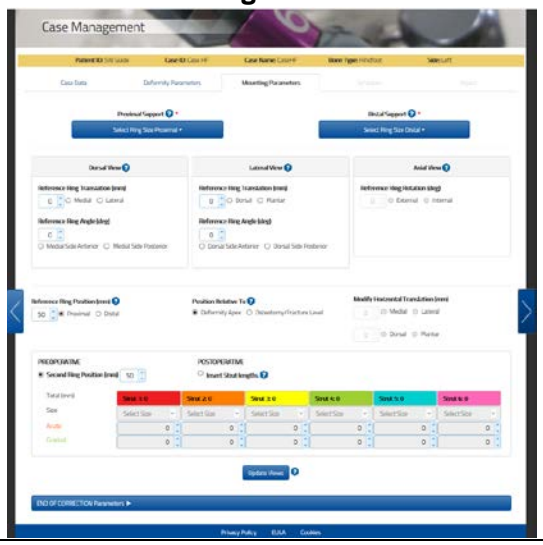
- migrated cases retain postoperative information only, so any preoperative information will be lost
- because the new version (1.5) includes some improvements on the frame rendering and label adaption based on bone types, the upgraded new case may differ. The surgeon is highly recommended to review the copied information and confirm them prior to recalculating the prescription.
- in the new version (1.5), the algorithm for calculating the prescription has been optimized, which means that the recalculated prescription of the upgraded case may differ from the original one. **The surgeon is highly recommended to review the prescription and instruct the patient accordingly.**

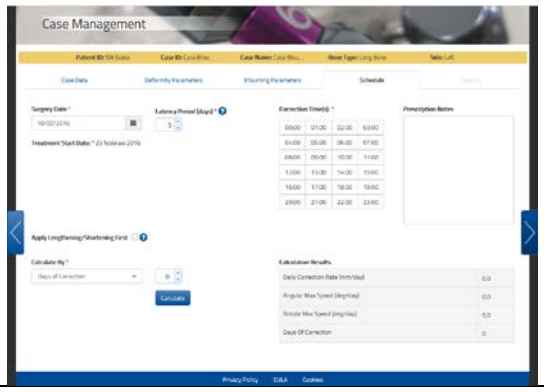
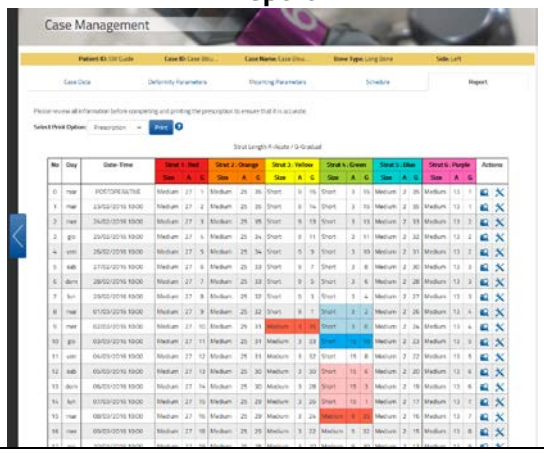
The original case migrated from the previous version remain available in view mode for consultation and comparison.

CASE PLANNING

Prior to starting a case, create the patient, refer to the *Add new Patient* section for details relating to this. To start a new case, refer to the *Add new Case* section.

Planning a case with the TL-HEX Software is a step-by-step process. Below is a summary of the main steps.

Case Data  	**1.** Define the Case Data details, in particular select the anatomical side and the bone type. Detail in *Case Data* section.
Deformity Parameters  	**2.** Select the reference segment and provide the deformity parameters to describe and mimics the deformity to treat. Include any over/under correction expected at the end of the treatment, in the new End Of Correction section. Details in *Deformity Parameters* section recap how the software interprets the provided input and how the software renders the deformity.
Mounting Parameters  	**3.** Select the proximal and distal support type and size. *PREOPERATIVE PLANNING* - Details in *Mounting Parameters – Preoperative Planning* section. In order to obtain a valid combination of the struts, describe how the frame will be positioned. Determine the reference ring parameters and also provide the second ring position. *POSTOPERATIVE* - Details in *Mounting Parameters – Postoperative* section. Review or provide the parameters to describe how the frame has finally been built on the patients. Preoperative information will be overridden. Visualize the expected End of Correction results.

Schedule  	**4.** Proceed with the calculus of the prescription through the Schedule Tab by setting time(s) of correction, correction rates or number of days to complete the treatment. Decide if you wish to proceed with stage treatment by applying shortening/lengthening first, if applicable. Details in *Schedule* section.
Report  	**5.** Review the obtained report and the prescription for the patient. If needed, proceed with a report adjustment or run a checkup of the case in a selected date. Detail in *Report and Prescription* section. Detail in *Checkup* section.

CASE DATA

In order to describe in detail how to plan a case step-by-step, we will refer to a Tibia Blount's Deformity as an example of how proceed. Where needed, we will highlight any difference the surgeon may encounter when planning a case with other bone types or other clinical scenarios.

Start a new case by completing the case data details.

Select the patient from the drop-down list.

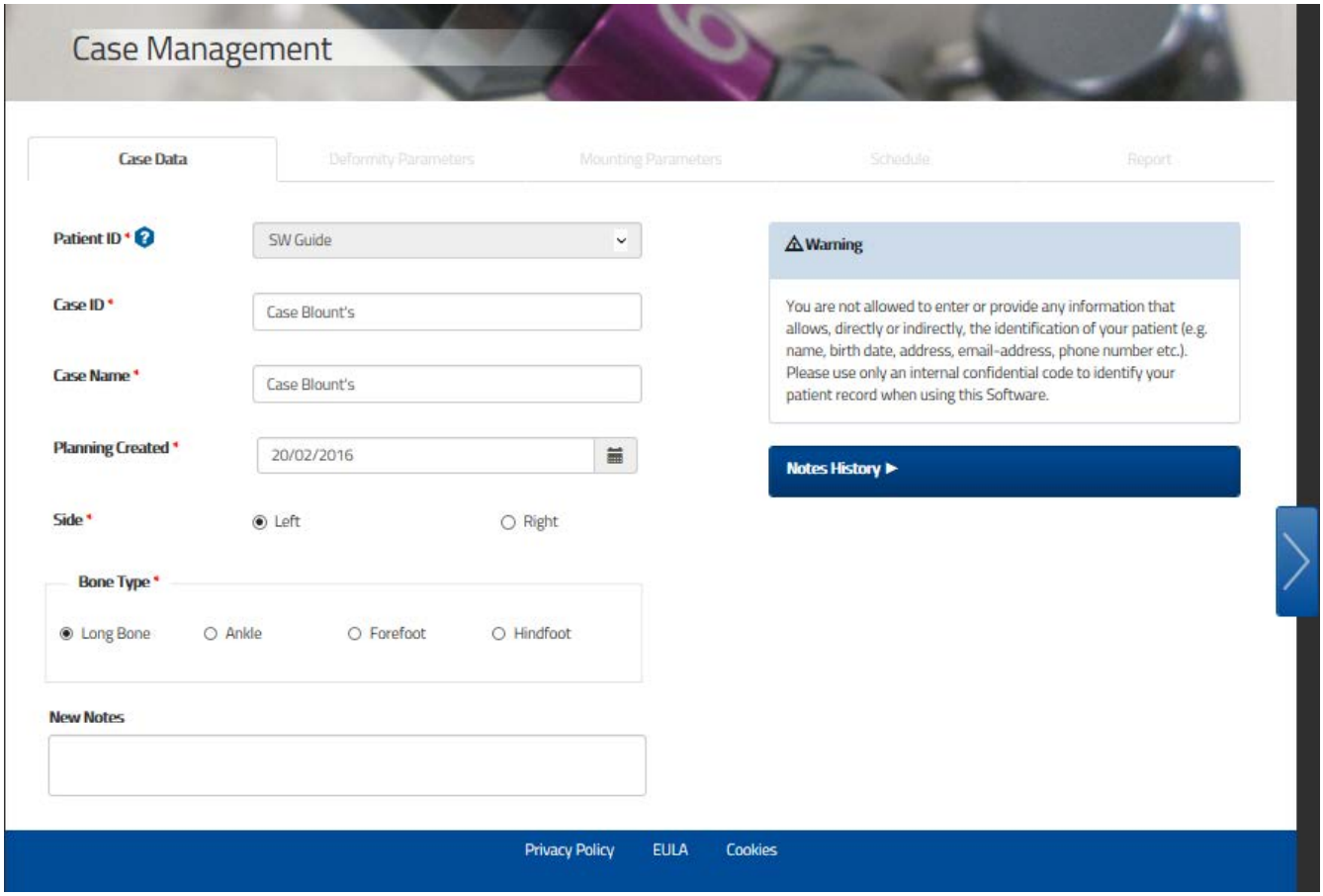
Provide the case name reference. The Case ID must be unique for that patient.

Select the creation date related to this case.

Determine the anatomical limb side, either left or right.

Select the Bone Type applicable for the deformity to be treated; choose between Long Bone, Ankle, Forefoot and Hindfoot.

Include any optional notes, which will be recorded in the Notes History log.



By choosing other Bone Types, such as Ankle, Forefoot or Hindfoot, the deformity parameters are adapted based on this anatomy, as well as the graphic representations.

Proceed to the next step in the treatment planning process by clicking on the  arrow on the right-hand side. This action, similarly to clicking Update Views button, will confirm and save the entered data.

DEFORMITY PARAMETERS AND END OF CORRECTION

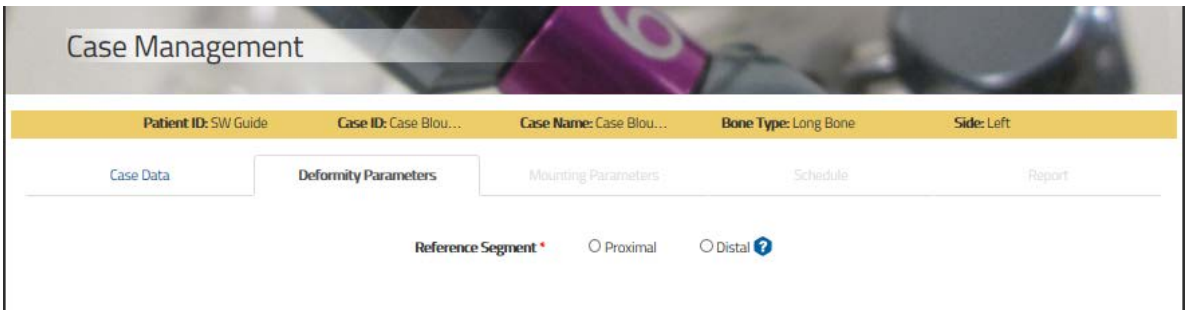
DEFORMITY PARAMETERS

Move to the Deformity Parameters screen to enter the parameters associated with the deformity.

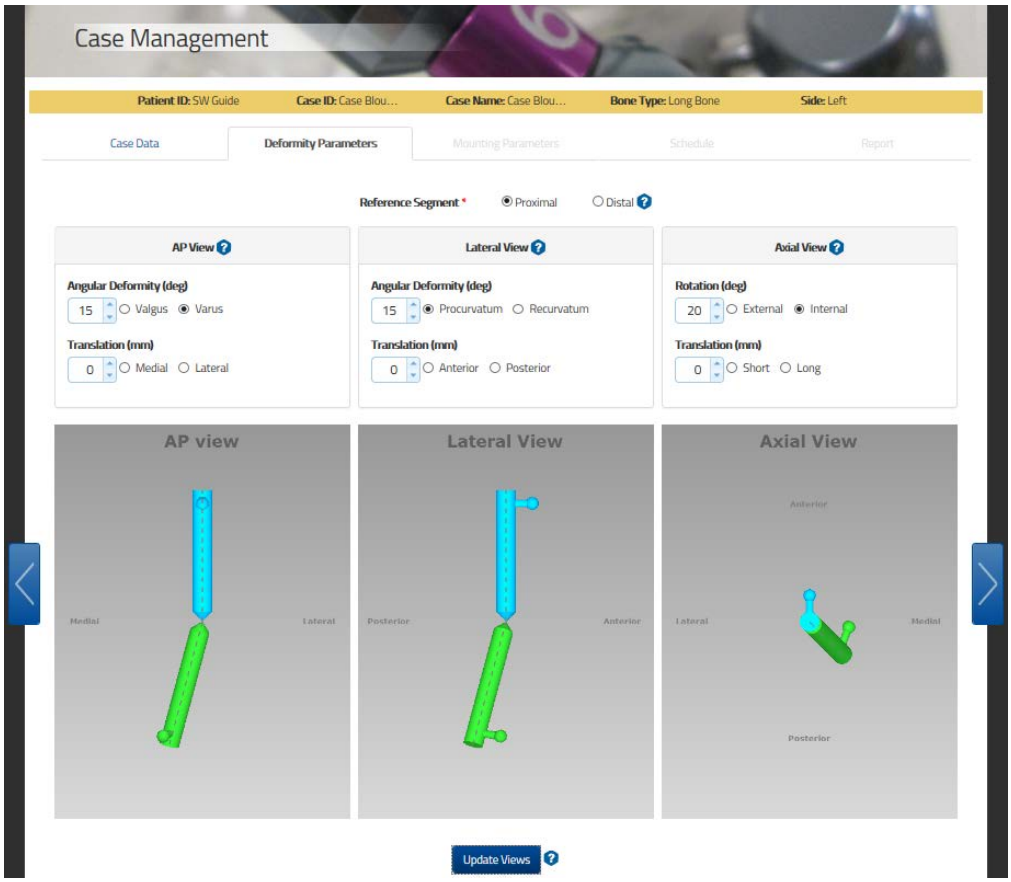
Prior to visualizing the deformity parameters, the first mandatory step is to select the reference segment, either proximal or distal.

Starting from this version, as the reference segment is not selected, the deformity parameters section does not appear.

Review and recap what the reference segment selection implies in the Nomenclature section.



The second step requires the surgeon to describe the deformity in the different views: AP View, Lateral view and Axial view.



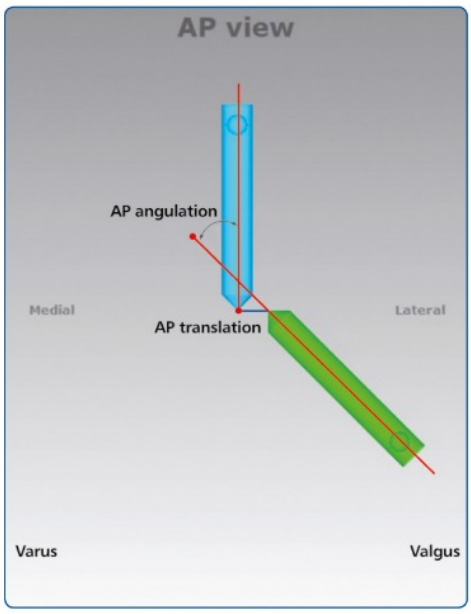
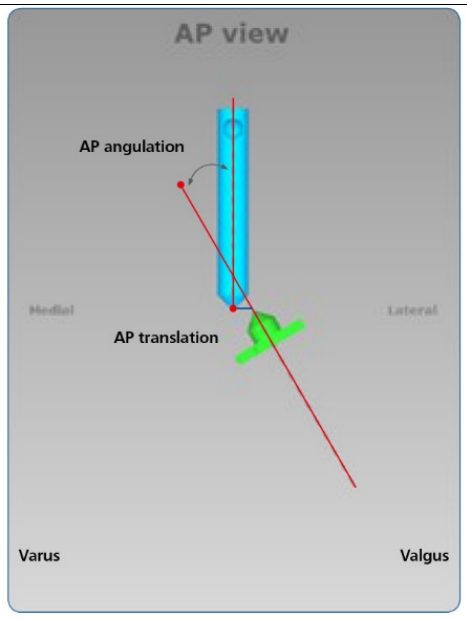
Click the Update Views button after making any changes or updates to deformity parameters to refresh the display accordingly.
Software will remind you that the images may not be updated and may not represents the entered parameters when you update/change the form by displaying an orange notification under the Update Views button.

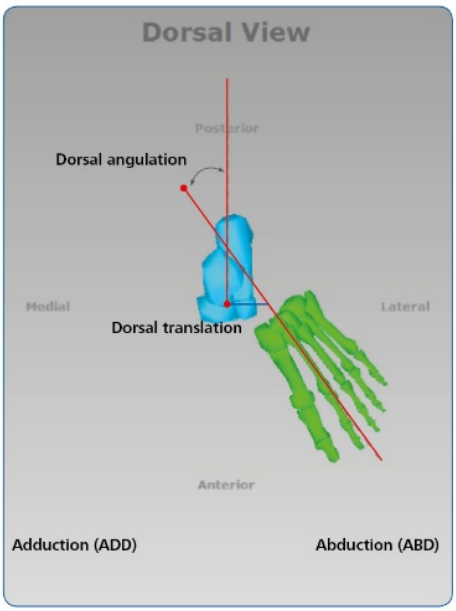
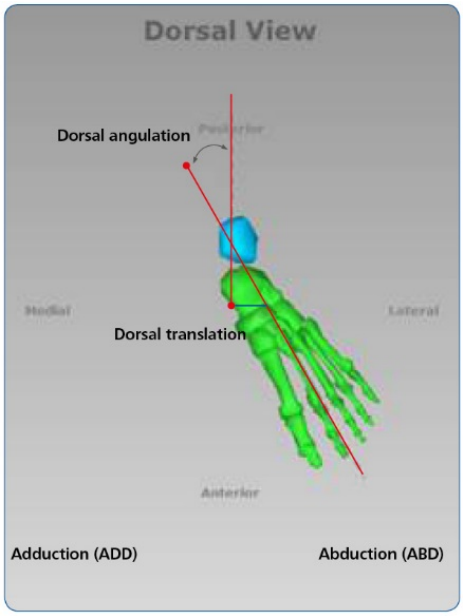
It is recommended to check whether the diagrams on the software correspond to the deformity seen on the patient's X-rays and/or clinically.

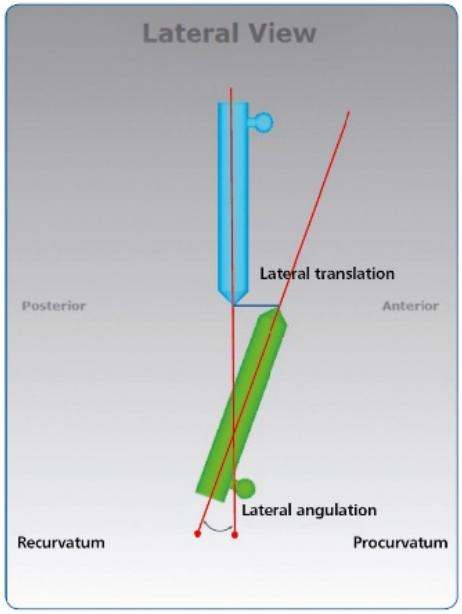
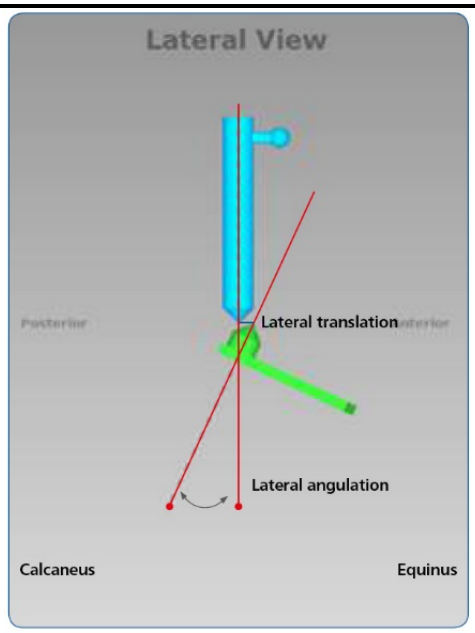
DEFORMITY PARAMETERS DEFINITION

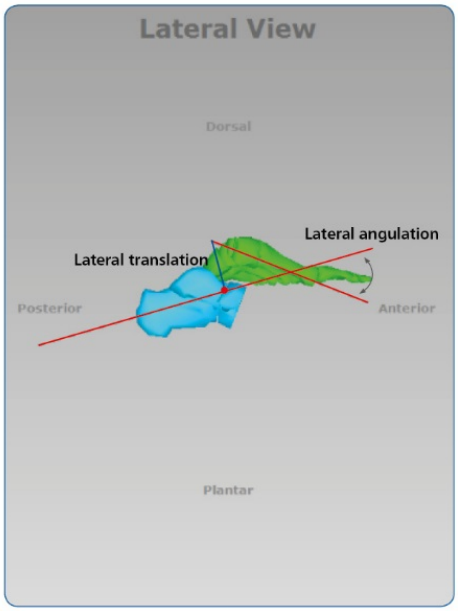
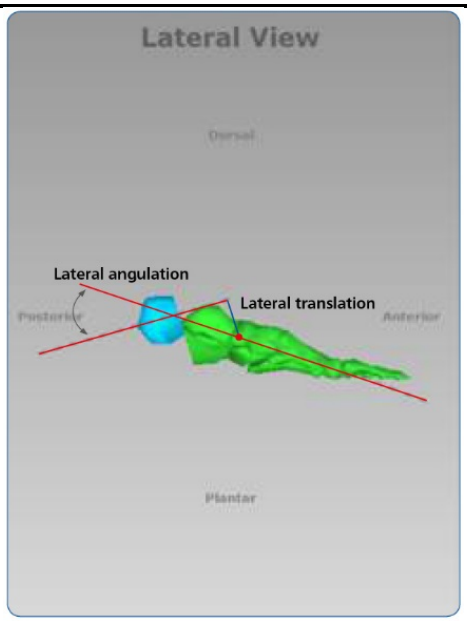
The labelling parameters are bone-type dependent. This means that, in accordance with the selected bone type, the parameters labelling will be adapted.

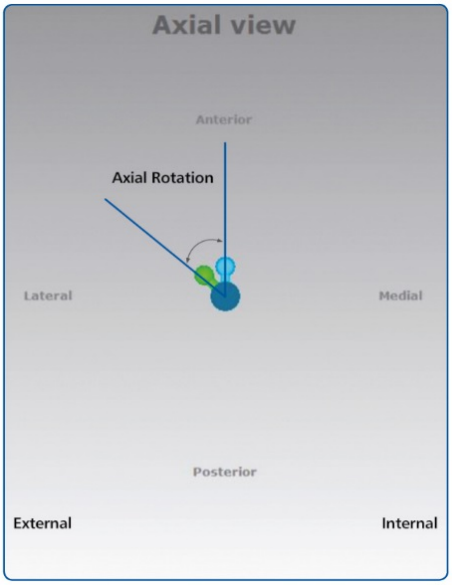
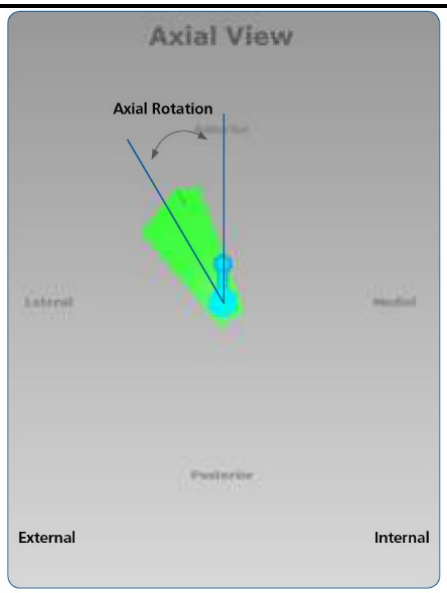
Below is a summary of the labelling parameters:

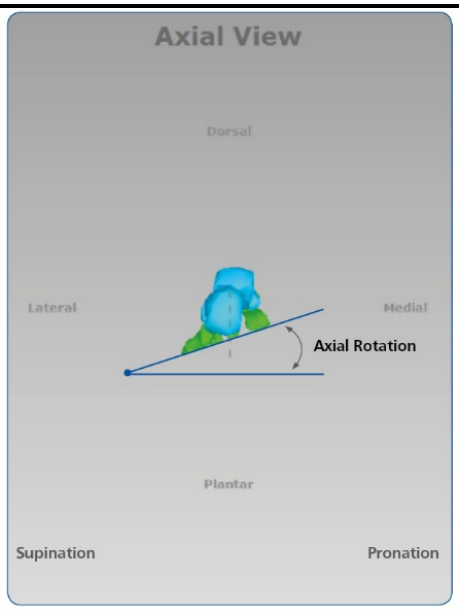
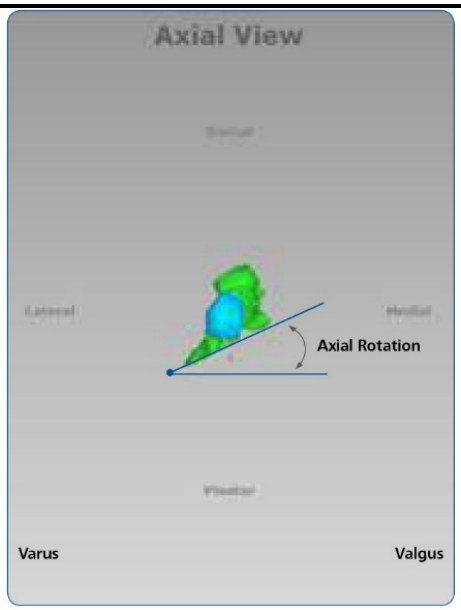
View name	**AP View**	
Bone type	**LONG BONE**	**ANKLE**
Description	**Angular Deformity (deg)** Deformity in the Frontal or Coronal plane depending on whether the distal segment is deviated medially or laterally in relation to the reference segment. It can be either varus or valgus. **Translation (mm)** In the Frontal or Coronal plane, the translation can be medial or lateral. Medial translation, for example, means that the moving segment is translated medially, relative to the reference segment.	
Angular deformity (deg)	Valgus Varus	Valgus Varus
Translation (mm)	Medial Lateral	Medial Lateral
		

View name	**AP View**	
Bone type	**FOREFOOT**	**HINDFOOT**
Description	**Angular Deformity (deg)** Deformity in the Transverse or Horizontal plane depending on whether the distal segment is deviated medially or laterally in relation to the reference segment. It can be either Abduction (ABD) Adduction (ADD). **Translation (mm)** In the Transverse or Horizontal plane, the translation can be medial or lateral. Medial translation, for example, means that the moving segment is translated medially, relative to the reference segment.	
Angular deformity (deg)	Abduction(ABD) Adduction(ADD)	Abduction(ABD) Adduction(ADD)
Translation (mm)	Medial Lateral	Medial Lateral
		

View name	LATERAL View	
Bone type	**LONG BONE**	**ANKLE**
Description	**Angular Deformity (deg):** Deformity in Sagittal plane depending on whether the distal segment is deviated anteriorly or posteriorly in relation to the reference segment. **Translation (mm)** In the Sagittal plane, the translation can be anterior or posterior.	
Angular Deformity (deg)	Procurvatum Recurvatum	Equinus Calcaneus
Translation (mm)	Anterior Posterior	Anterior Posterior
		

View name	LATERAL View	
Bone type	**FOREFOOT**	**HINDFOOT**
Description	**Angular Deformity (deg):** Deformity in Sagittal plane depending on whether the distal segment is deviated dorsally or plantarly in relation to the reference segment. **Translation (mm)** In the Sagittal plane, the translation can be dorsal or plantar. NOTE for foot: The two axes of the foot intersect on the point of reference (navicular talus joint) and originate an angle of 37° Apex Dorsal. The software considers this angle value as default Lateral angular deformity. This point is also considered as the reference point to whom translations and angulations are determined. The point of reference is not located on the forefoot or the hindfoot osteotomy level. For details, refer to Nomenclature section.	
Angular Deformity (deg)	Apex Dorsal Apex Plantar	Apex Dorsal Apex Plantar
Translation (mm)	Dorsal Plantar	Dorsal Plantar
		

View name	AXIAL View	
Bone type	**LONG BONE**	**ANKLE**
Description	**Rotation (deg)** Deformity in Horizontal or Transverse plane depending on whether the distal segment is rotated laterally or medially around its longitudinal axis. As the rotation is difficult to measure radiologically, this parameter will be most commonly established clinically. **Translation (mm)** The Axial translation occurs along the longitudinal axis of the limb. The Short option is applicable when the moving bone segment is translated (*compressed*) towards the bone segment reference. The Long option is applicable when the moving bone segment is translated (*distracted*) away from the bone segment reference.	
Angular Deformity (deg)	External Internal	External Internal
Translation (mm)	Short Long	Short Long
		

View name	AXIAL View	
Bone type	**FOREFOOT**	**HINDFOOT**
Description	**Rotation (deg)** Deformity in the Horizontal or Transverse plane depending on whether the distal segment is rotated laterally or medially around its longitudinal axis. Because the rotation is difficult to measure radiologically, this parameter will be most commonly established clinically. **Translation (mm)** The Axial translation occurs along the longitudinal axis of the limb. The Short option is applicable when the moving bone segment is translated (*compressed*) towards the reference bone segment. The Long option is applicable when the moving bone segment is translated (*distracted*) away from the reference bone segment.	
Angular Deformity (deg)	Supination Pronation	Varus Valgus
Translation (mm)	Short Long	Short Long
		

NOTE: All angulations are expressed in degrees. Their direction is independent from the choice of proximal or distal referencing.

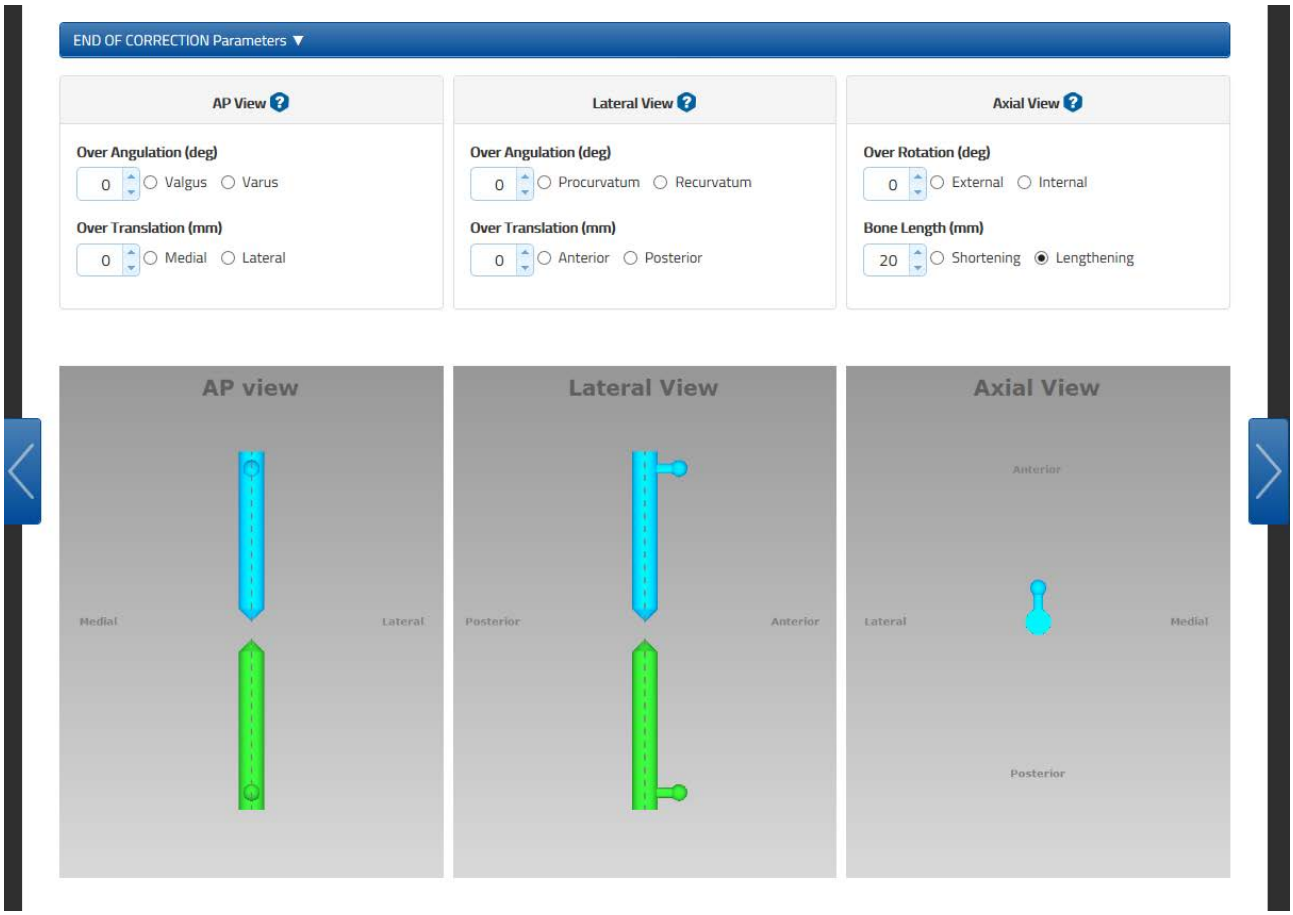
NOTE: All translations are described in millimeters and they are described in relation to the reference segment; changes in the direction of translation, as long as rotation in the Axial View, depend on whether proximal or distal referencing is used (see the Nomenclature section for details).

END OF CORRECTION

End of Correction parameters section related to the deformity is included in the Deformity Parameters Tab and it is collapsed at the bottom of the Deformity screen.

By enlarging this section, the three graphic view boxes display the position of the bone segments expected at the end of the treatment (deformity correction).

As default, at the end of the deformity correction referring to *long bone* or *ankle* applications, the software assumes that the bone segments should be in perfect alignment with no limb discrepancy.

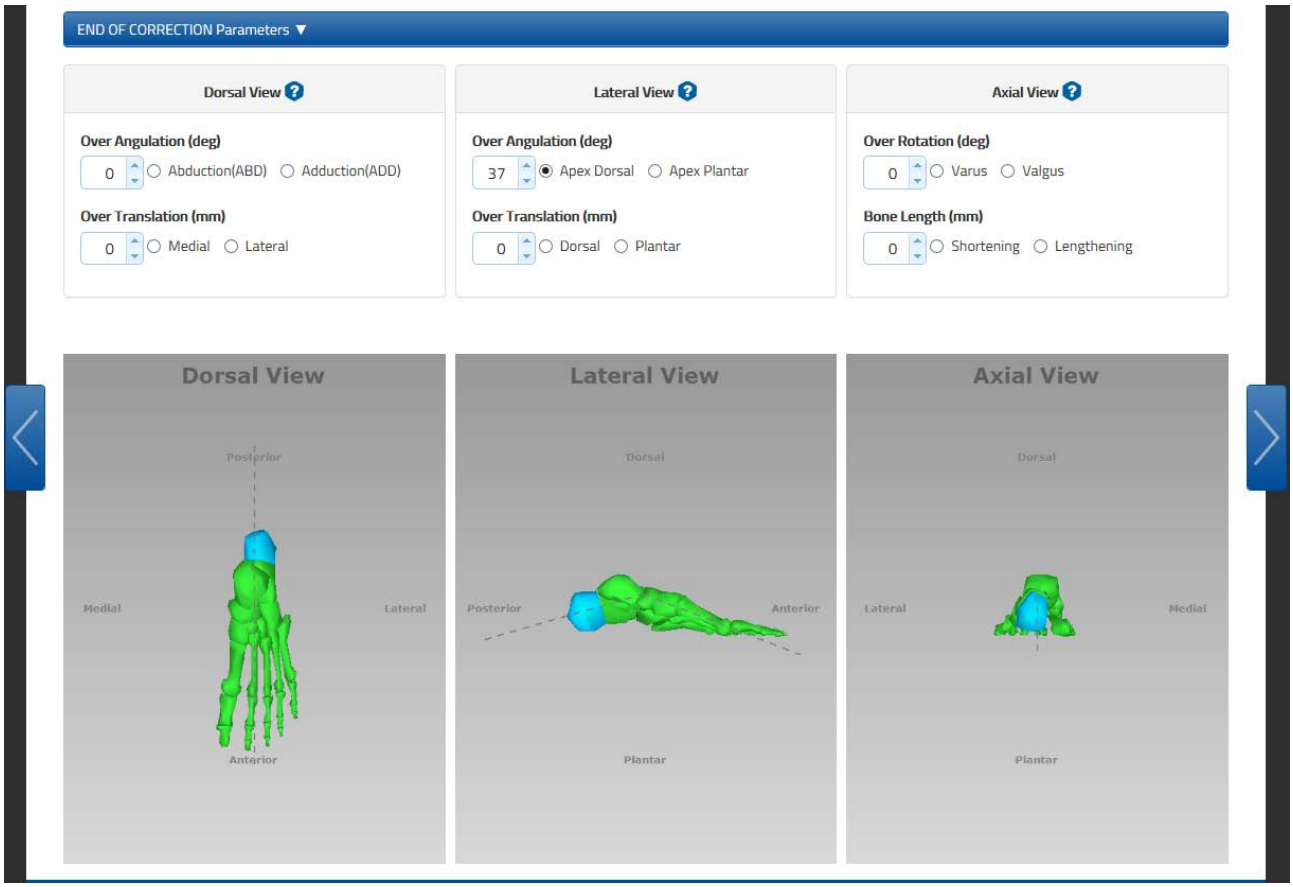


This screen provides the surgeon with the opportunity to override the default position as desired. Additional adjustments include: Frontal or Coronal plane (AP View) and Sagittal plane (Lateral View) angulation and translation.

The Bone Length parameter — the clinical parameter indicating limb length discrepancy relative to contralateral limb — is directly inputted in the End of Correction section.

The values entered represent the desired bone segment position at the end of the deformity correction. This is useful if an over- or under-correction is desired at the deformity correction, e.g. Blount's deformity correction, where a 10° over-correction is desired.

Related to the *foot* application, either forefoot or hindfoot, the assumption is that at the end of the treatment the arch of the foot is 37° Apex Dorsal. The software considers this value as default Lateral angular deformity.

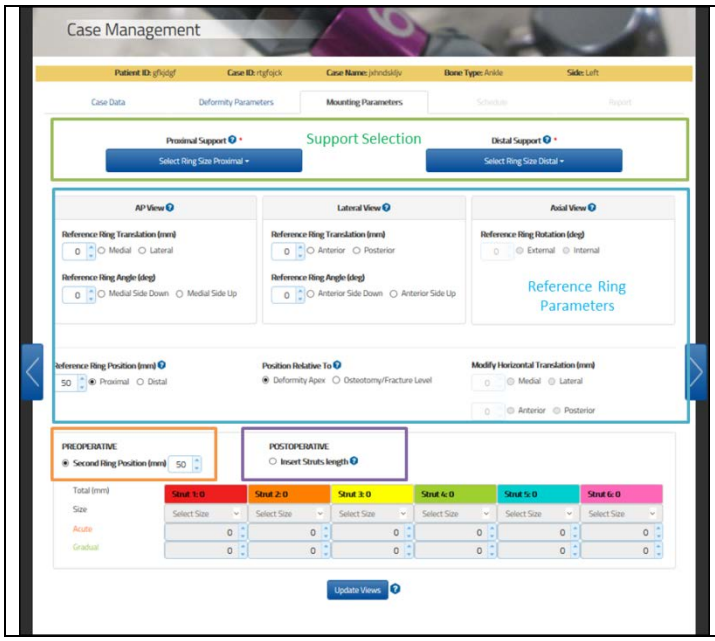


Click the Update Views button at any time to refresh the display after entering or reviewing the parameters.

Once the Deformity Parameters are completed and the End of Correction ones have been confirmed or reviewed, click the 'next' arrow on the right-hand side.

MOUNTING PARAMETERS

The Mounting Parameters tab provides multiple features within the same tab.



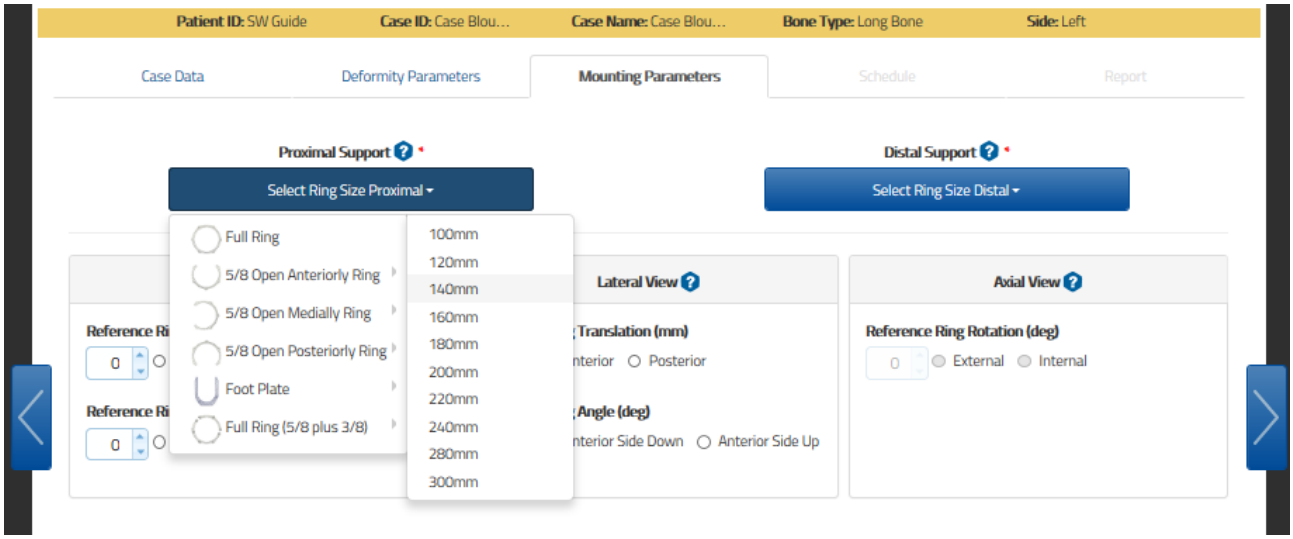
In this tab, the surgeon can:

- Select Type and size of the proximal and distal support
- Proceed with a preoperative planning if necessary
- Confirm or review the configuration with the postoperative information
- Check the frame configuration at the end of the correction.

It is important to underline that even if the surgeon went through a preoperative planning when he/she reviews the information with the postoperative information, this update overrides the previous ones used and calculated during the preoperative planning.

SUPPORT SELECTION

Two drop-down menus for each of the proximal and distal support allow the surgeon to select the type and the size of the desired support.



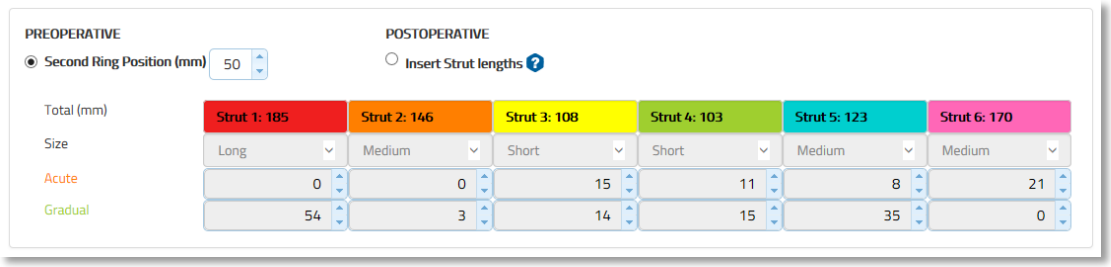
NOTE: If choosing two 5/8 rings, it is better not to choose the openings in the same direction because the proposed solution may not be applicable on a patient due to the position of the struts that can pass through the soft tissues. The surgeon must check the feasibility of the frame before applying on the

patient. These points can be overcome by adding a 3/8 ring. This component enables the 5/8 to be transformed into a full ring, so by using this technique, it is possible to apply two 5/8 rings with the opening on to the same side (very useful in trauma cases).

PLANNING MANAGEMENT

After selecting the type and size either for the proximal and distal support, within this screen the surgeon can proceed with a preoperative plan or if he/she is completing this screen after the surgery with the postoperative information or after a checkup, they can confirm or review the provided parameters.

The software presents these two alternative options:
If **PREOPERATIVE** (Second Ring Position) option is selected – default option

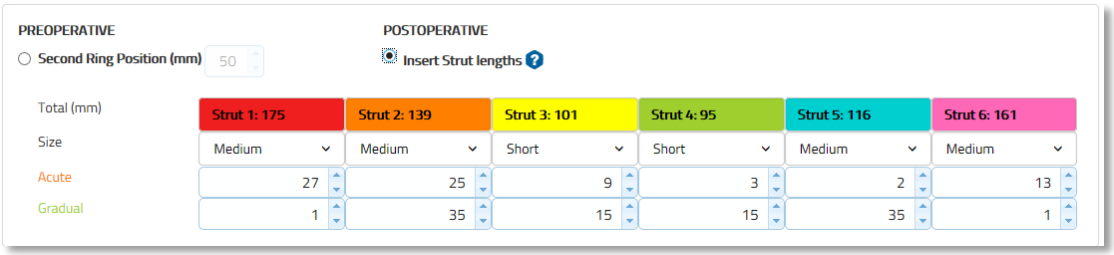


- The Reference Ring can be angulated based on the user preference, but the Ring Orientation Tab is assumed to be aligned with the Longitudinal Axis of the reference segment. No rotation is allowed.
- The Second Ring is assumed to be perpendicular to the corresponding bone segment axis
- Both the external supports are located by default at a 50mm distance from the deformity apex or osteotomy/fracture level. The user can change the default distance
- Based on the Reference Ring position, parameters values and the Second Ring Position, when the surgeon clicks the 

button, the software calculate the six struts configuration in the Struts Table. Those numbers are not editable by the user.

Although the surgeon can skip the Preoperative planning, it is recommended that he/she completes this section; this simplifies the overall data entry. In addition, the application suggests the optimal strut sizes and lengths and warns in case of potential impingements of the frame.

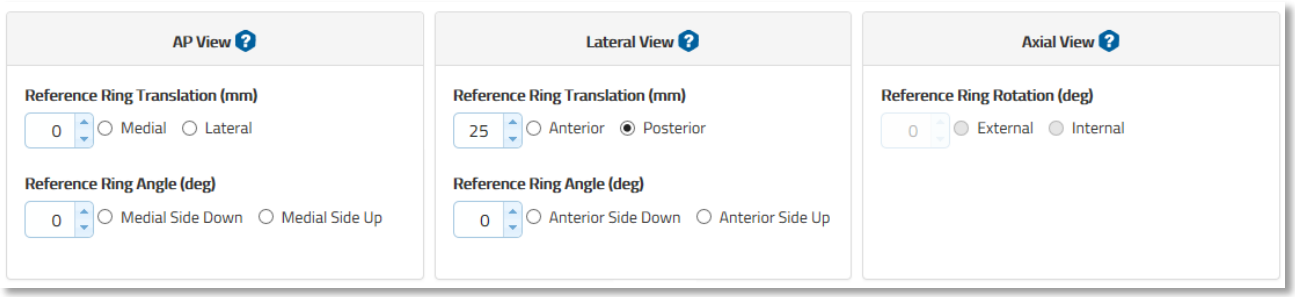
If the **POSTOPERATIVE** (Insert Strut Lengths) option is selected:



- The reference ring can be angulated based on the user preference and any rotation of the Ring Orientation Tab related to the longitudinal axis of the reference bone segment can be managed.
- The reference ring is located by default 50 mm, or the value input during the preoperative planning phase, far from the deformity apex or osteotomy/fracture level. The user can change the default distance.

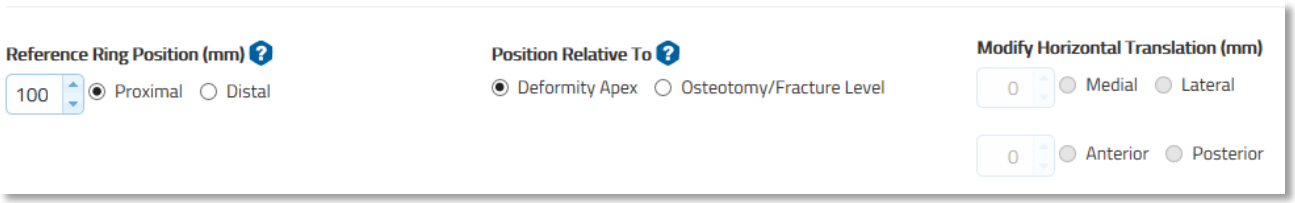
PREOPERATIVE PLANNING

The screen provides the option to adjust:



The parameter is described according to the selected bone type. This parameter can be used both for Preoperative and Postoperative planning.

AP/Dorsal View	LATERAL View	AXIAL View
Reference Ring Translation - the position of the reference ring in the Frontal or Coronal plane (Transverse or Horizontal plane for foot) described in millimeters as the translation of the center of the reference ring (orthogonal projection), in relation to the longitudinal axis of the reference bone segment. **Reference Ring Angle -** the reference ring angle in the Frontal or Coronal plane (Transverse or Horizontal plane for foot) described in degrees as the angle between the axis intersecting the center of the ring and the axis orthogonal to the bone segment.	**Reference Ring Translation** - the position of the reference ring in the Sagittal plane described in millimeters as the translation of the center of the reference ring (orthogonal projection) in relation to the longitudinal axis of the reference bone segment **Reference Ring Angle** - the reference ring angle in the Lateral view described in degrees as the angle between the axis intersecting the center of the ring and the axis orthogonal to the bone segment.	**Rotation** - the software will automatically calculate the orientation offset of the reference ring; the value is read-only.



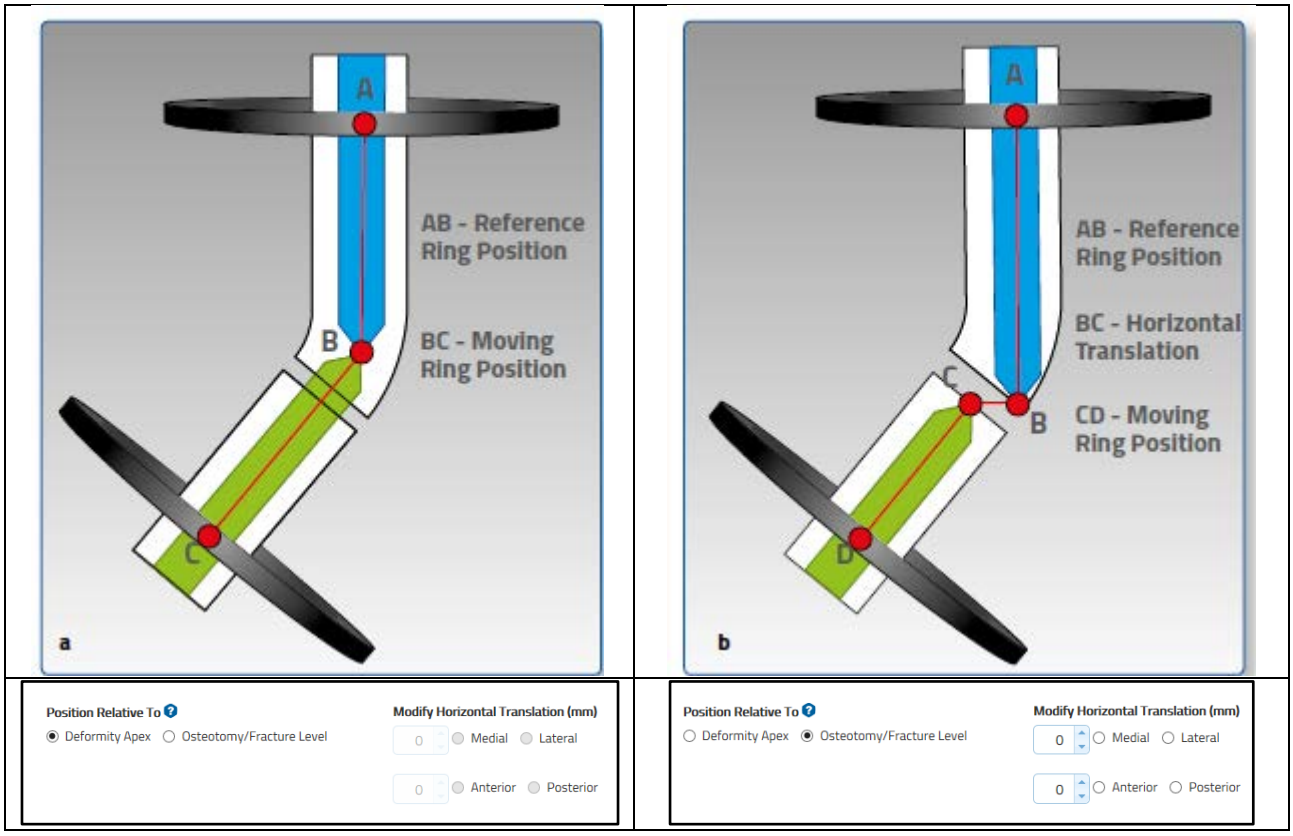
The user also has to provide:

- **Reference Ring Position (mm):** described in millimeters as the distance along the longitudinal axis of the reference bone segment (proximal/distal) from the center of the reference ring to the deformity apex or osteotomy/fracture level (distance AB in figure a below).

  NOTE: For *Forefoot* and *Hindfoot*, the software's graphical representation is always done in relation to the *talo-navicular joint*, so it could not exactly match the real frame position on the foot when the apex of deformity or osteotomy site are not in harmony with the talo-navicular joint. The Larger the distance between the talo-navicular joint and the point of reference (deformity

apex or osteotomy fracture level), the larger the deviation between the representation and the frame on the foot. The calculated treatment will be consistent with the chosen reference system of the measurements.

- **Second ring position (mm)**: described in millimeters as a distance along the longitudinal axis of the moving bone segment from the center of the second ring to the specific point of interest (distance BC in figure (a) or distance CD in figure (b)).

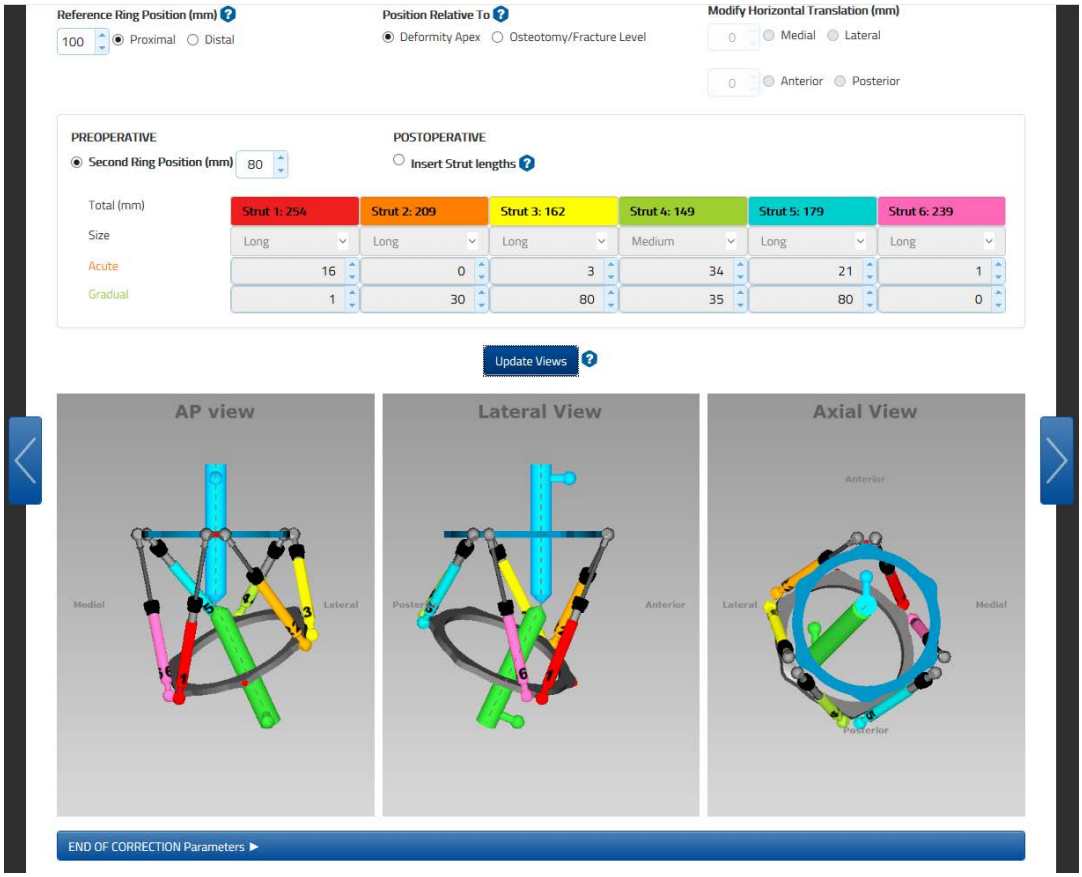


Either the apex of deformity or the level of the osteotomy/fracture can be chosen as the point of interest. If the point of interest is 'Osteotomy/Fracture level', the two fields in the 'Horizontal Translation' section (described in millimeters) are editable and the surgeon can enter the horizontal fragments translation of the osteotomy/fracture.

If deformity apex is selected, these two fields will appear greyed out. If the AP/Dorsal or Lateral translation has been entered into the deformity parameters section, the osteotomy/fracture level is automatically chosen as the point of interest. The surgeon has the ability to adjust previously entered horizontal segment translation depending on the distance between the point of interest and deformity apex.

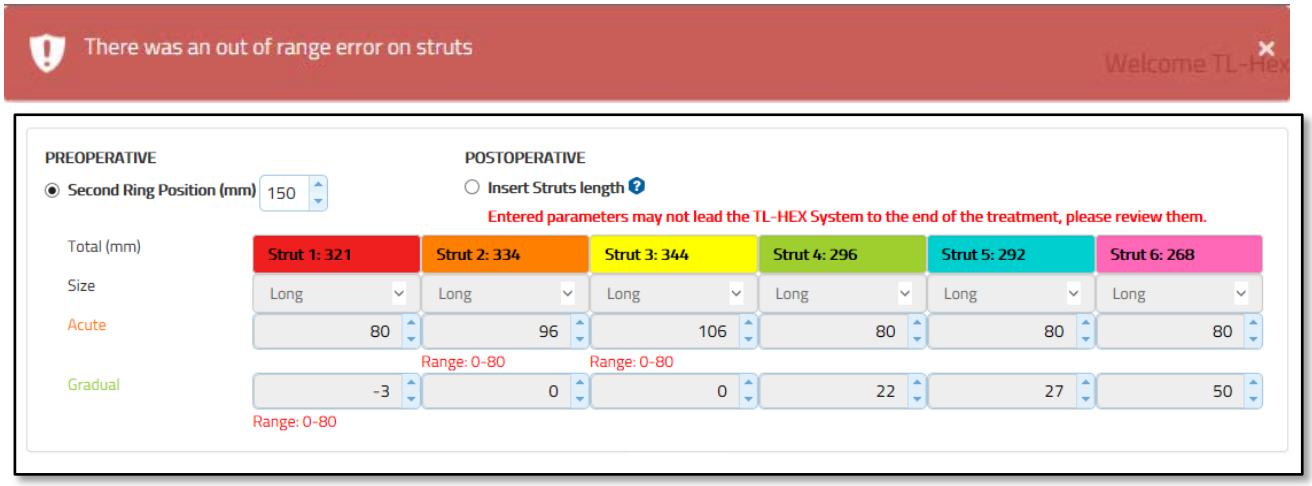
At this point, clicking the Update Views button will reveal the preassembled frame construct and render an optimal set of strut lengths that will result in the required frame.

The Reference Ring is color-coded in blue for easy identification.



WARNING SYSTEM

After clicking on the Update Views button, if a red warning message like the one below is displayed on the top of the screen, check struts that are out-of-range (indicated by a red number) both on initial (Preoperative/Postoperative) and at the End of Correction constructs, by enlarging the End of Correction section. An out-of-range strut can be addressed by modifying the mounting parameters related to the reference ring and the position of the second ring.



Enlarge the END OF CORRECTION Parameters bar to verify if an out-of-range is present.

END OF CORRECTION Parameters ▼

Total (mm)	Strut 1: 322	Strut 2: 322	Strut 3: 322	Strut 4: 323	Strut 5: 322	Strut 6: 323
	Out of Range	Out of Range	Out of Range	Out of Range	Out of Range	Out of Range
Size	Long	Long	Long	Long	Long	Long

NOTE: In Preoperative Planning, the surgeon is not allowed to proceed with the treatment planning until all the out-of-range warnings have been cleared.

In addition to the out-of-range check, the software verifies also potential hardware impingement both on initial and end of correction constructs, in particular, impingements between the struts and the rings.

In the example below, there is a potential impingement between the strut 4, 5 and the reference ring.

PREOPERATIVE

Second Ring Position (mm) 20

POSTOPERATIVE

Insert Strut lengths

Entered parameters may not lead the TL-HEX System to the end of the treatment, please review them.

Total (mm)	Strut 1: 151	Strut 2: 114	Strut 3: 117	Strut 4: 102	Strut 5: 101	Strut 6: 149
Size	Medium	Short	Medium	Short	Short	Medium
Acute	2	7	3	10	8	0
Gradual	0	1	35	15	15	0
Impingement				Proximal	Proximal	

Enlarge the END OF CORRECTION Parameters bar to verify if any impingement is present.

END OF CORRECTION Parameters ▼

Total (mm)	Strut 1: 102	Strut 2: 130	Strut 3: 164	Strut 4: 130	Strut 5: 99	Strut 6: 119
Size	Short	Medium	Medium	Medium	Short	Medium
Impingement		Distal		Proximal		

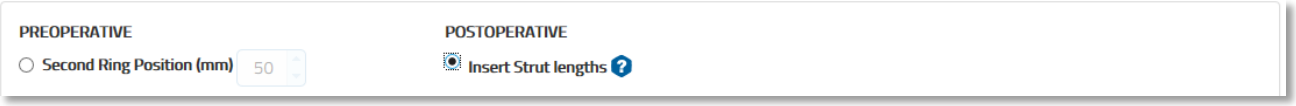
NOTE: the impingement information should be considered as an informative guideline and they not substitute the surgeon experience and review.

Surgeon is highly recommended to review the Mounting parameters in order to address any highlighted warning prior to build the frame and then proceed with the postoperative phase.

POSTOPERATIVE

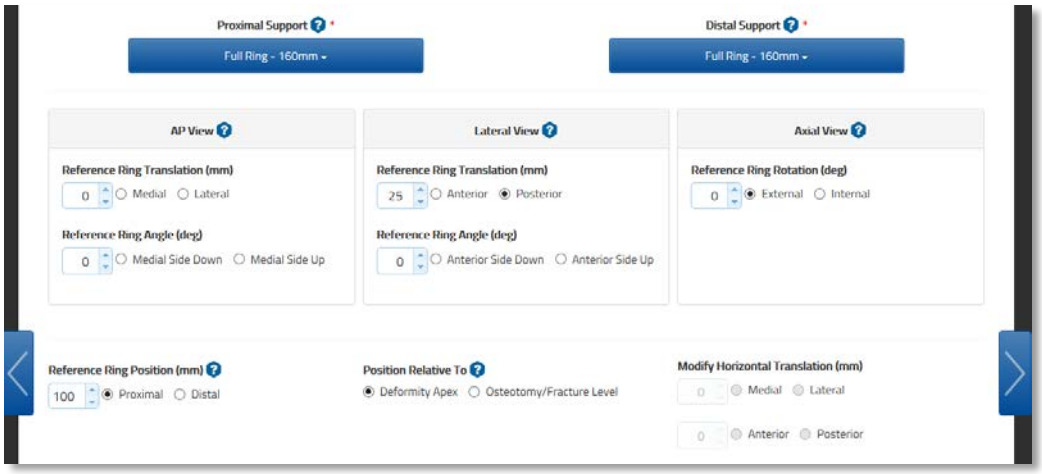
Whenever the surgeon has completed the preoperative planning or he/she has already applied the frame directly on the patient, using the postoperative X-rays, he/she has to confirm and/or review the mounting parameters.

In particular, the surgeon is requested to select Insert Strut Lengths to switch to POSTOPERATIVE mode.



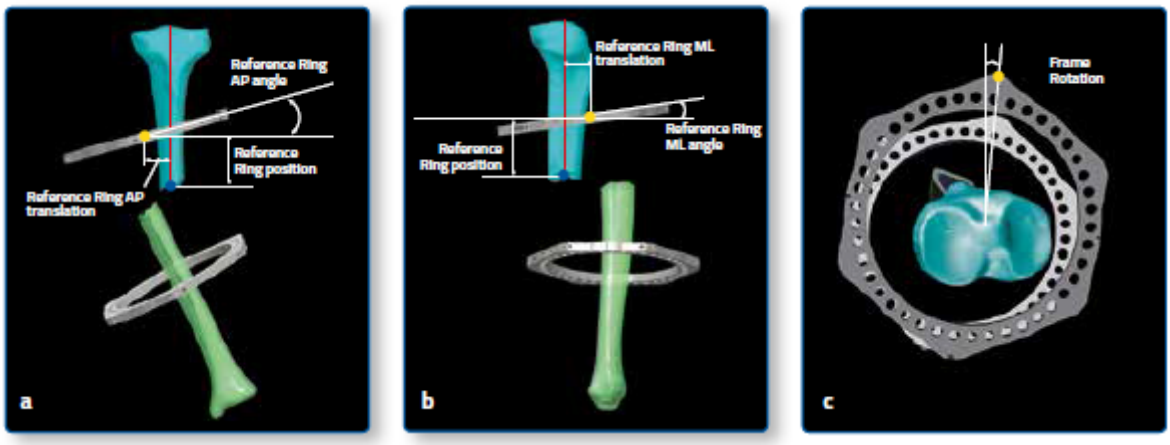
It is important to underline that even if the surgeon went through a preoperative planning, when he/she reviews the information with the postoperative information, the ones used and calculated during the preoperative planning are overridden.

NOTE: The Postoperative mode makes the Reference Ring Rotation and Struts sizes and acute/gradual values editable.



In postoperative, the surgeon has to review or provide:

- **Reference Ring Parameters** in the three projections AP/Dorsal, Lateral and Axial views, including any eventual Ring Orientation Tab rotation.
- **Reference Ring Position (mm):** described in millimeters as the distance along the longitudinal axis of the reference bone segment (proximal/Distal) from the center of the reference ring to the deformity apex or osteotomy/fracture level.

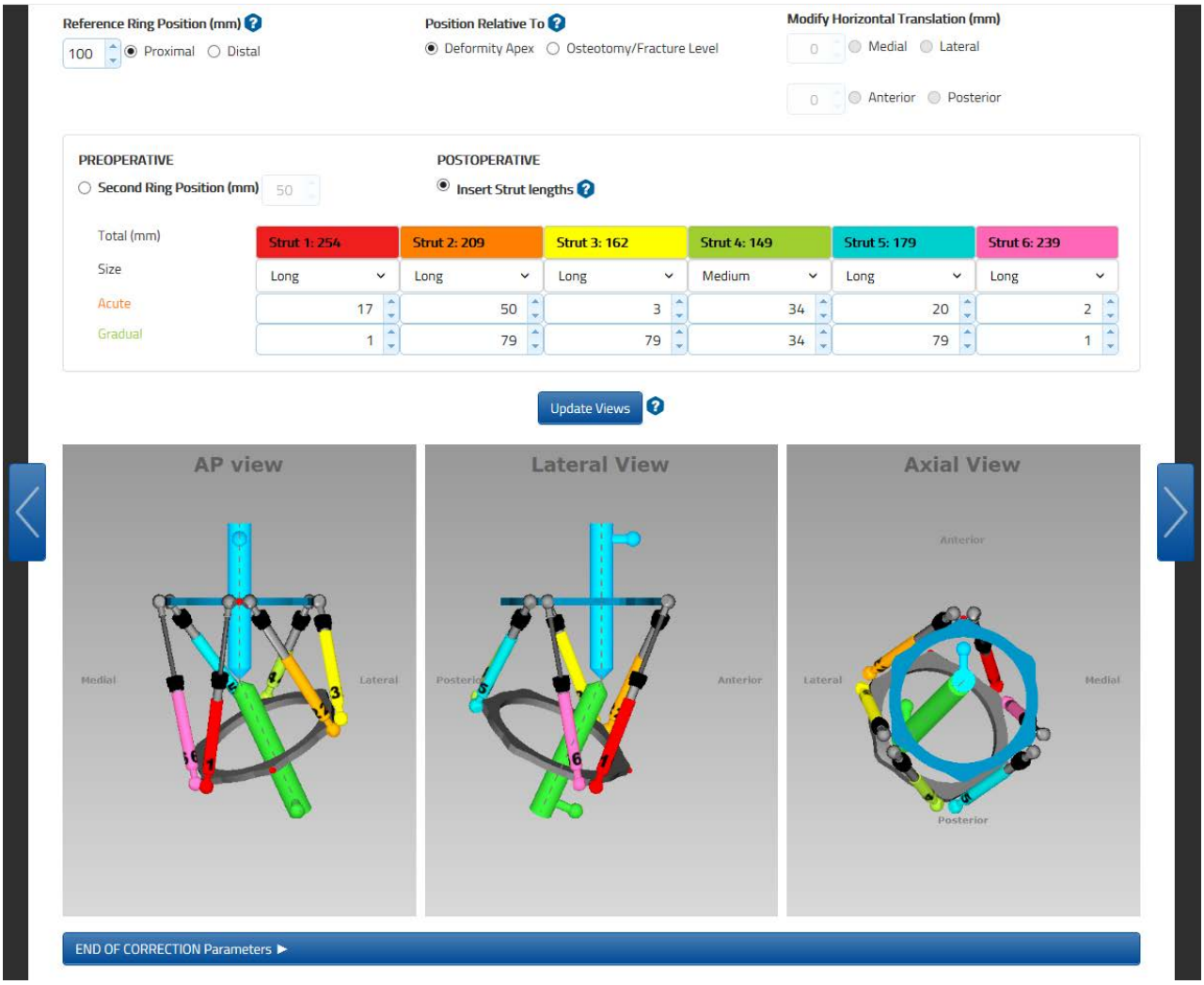


AP/Dorsal View	LATERAL View	AXIAL View
Reference Ring Translation - the position of the reference ring in the Frontal or Coronal plane (Transverse or Horizontal plane for foot) described in millimeters as the translation of the center of the reference ring (orthogonal projection) in relation to the longitudinal axis of the reference bone segment. **Reference Ring Angle -** the reference ring angle in the Frontal or Coronal plane (Transverse or Horizontal plane for foot) described in degrees as the angle between the axis intersecting the center of the ring and the axis orthogonal to the bone segment.	**Reference Ring Translation** - the position of the reference ring in the Sagittal plane described in millimeters as the translation of the center of the reference ring (orthogonal projection) in relation to the longitudinal axis of the reference bone segment **Reference Ring Angle** - the reference ring angle in the Lateral view described in degrees as the angle between the axis intersecting the center of the ring and the axis orthogonal to the bone segment.	**Rotation** - the angular deviation of the reference ring orientation tab from the Anterior (Long Bone and Ankle) or Dorsal (Foot) position in degrees. It is described as External or Internal rotation.

- **Strut** configuration
  - strut size (e.g. ultrashort, short, medium, long)
  - acute length (in millimeters) relative to the orange mark
  - gradual length (in millimeters) relative to the green mark

  Strut type (ultrashort, short, medium and long), as well as both acute and gradual adjustment lengths, are recorded at the end of the surgery and should be confirmed or adjusted in the corresponding fields.

NOTE: In the software, the strut length entries are validated against the type (size) of struts selected (refer to the STRUTS section for size details). If the entered value exceeded the range for any given strut, an error is indicated and the strut size/length should be corrected prior to proceeding to the next step.



Click the Update Views button at any time to refresh the display after entering the parameters.

In the **Postoperative** mode no assumptions are made on the positioning of the frame in relation to the bone segments and the parameters are entered/adjusted in order to accurately reproduce the positioning of the rings and the values of the struts after the surgery.

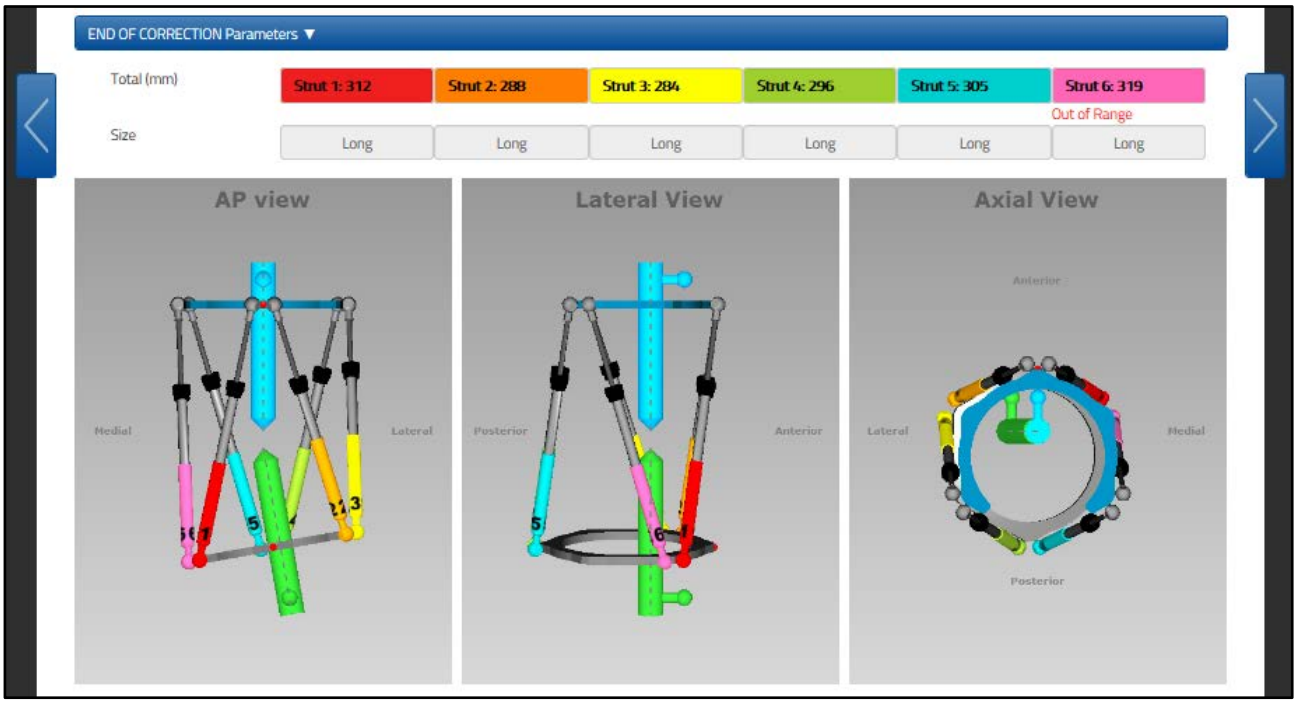
We suggest that in order to easily collect the data, you use the Patient ID form that can be downloaded by accessing the reserved area of the TL-HEX site (click on the Instruction for Use icon).

END OF CORRECTION

The End of Correction section, including the frame information, is collapsed at the bottom of the Mounting Parameters screen.

By expanding this item, the surgeon can check how the treatment and construct is supposed to end. This simulation takes in account of the overcorrection and under correction provided in the corresponding End of Correction section in the Deformity Parameters screen.

The End of Correction provides the final strut configuration in term of strut type and total length. This is a helpful information, especially while running a preoperative planning to visualize strut exchange, if any.



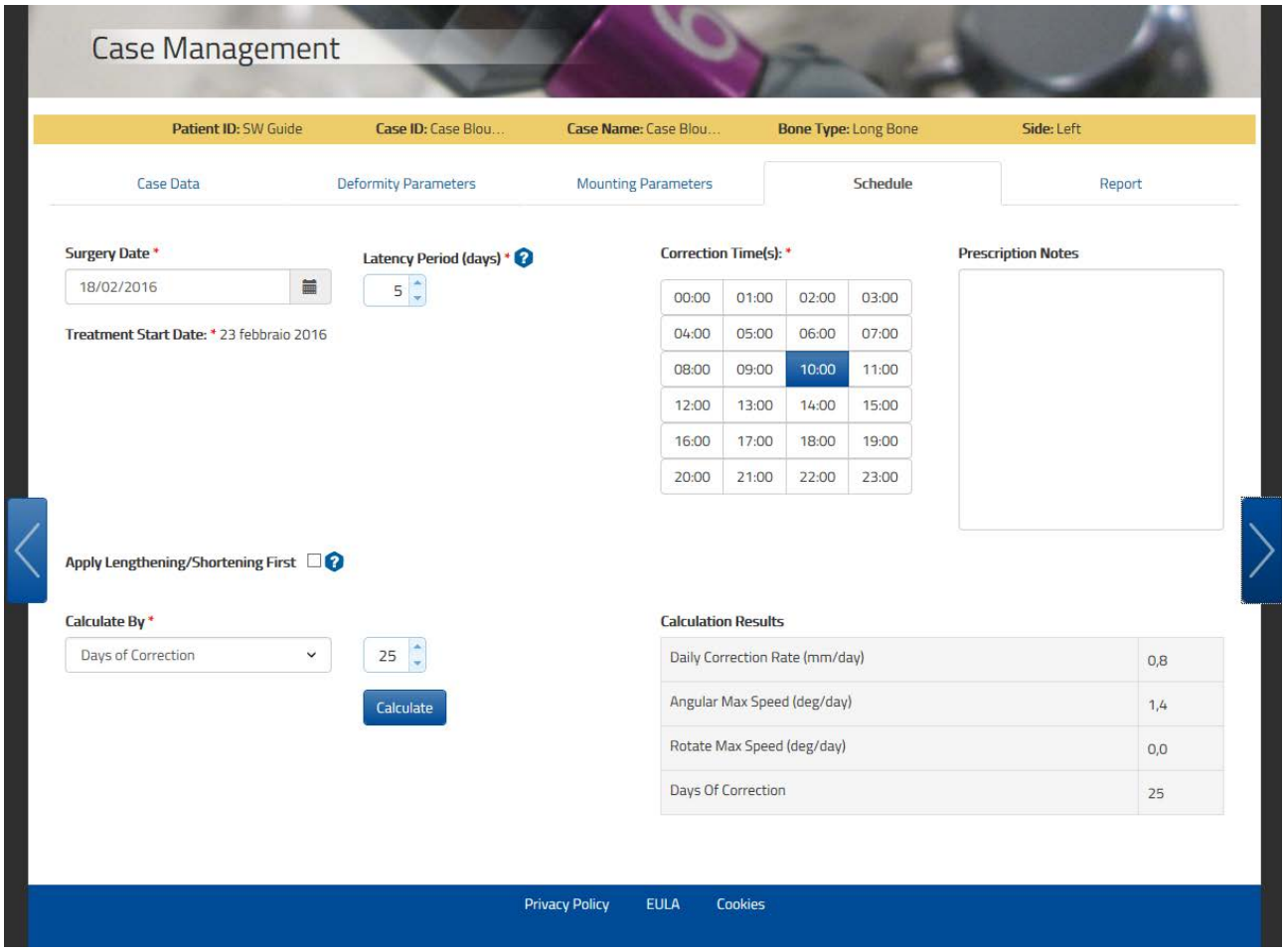
NOTE: The report should be used as reference for final strut position (Acute and gradual) and strut size.

SCHEDULE

The Schedule screen allows the surgeon to enter specific parameters related to bone segment movement during the deformity correction.

Those parameters include:

- **Days of correction**: the desired days of correction
- **Angular Max Speed in degrees/day**: maximum rate of bone segment angular correction speed (e.g. varus-valgus correction)
- **Rotate Max Speed in degree/day**: maximum rate of bone segment rotation correction speed (e.g. external-internal rotation)
- **Daily correction rate (mm/day):** this parameter is available if a lengthening or shortening is required.



Treatment start date may be adjusted using **Latency Period** (days) and **Correction Time(s)**, up to 4, may be selected in the appropriate box.
The correction rates and the days of correction are correlated and, therefore, the surgeon can determine the prescription calculation either by choosing a speed parameter or choosing the Days of Correction.
Once the 'Calculate by' parameter is determined by the surgeon, the other parameters are automatically calculated by the software after clicking on the Calculate button. The software is able to produce a solution using decimals.

NOTE: The surgeon has to carefully review the calculation to ensure it is accurate.

It is necessary to enter a value in the 'Calculate By' box and 'Correction Time(s)' box prior to click the Calculate or button. A warning message will appear if no value was chosen in either of these boxes.

The Correction Times table provides the flexibility to have the prescription calculated for one or more adjustments during each treatment day (up to four different correction times per day can be selected).

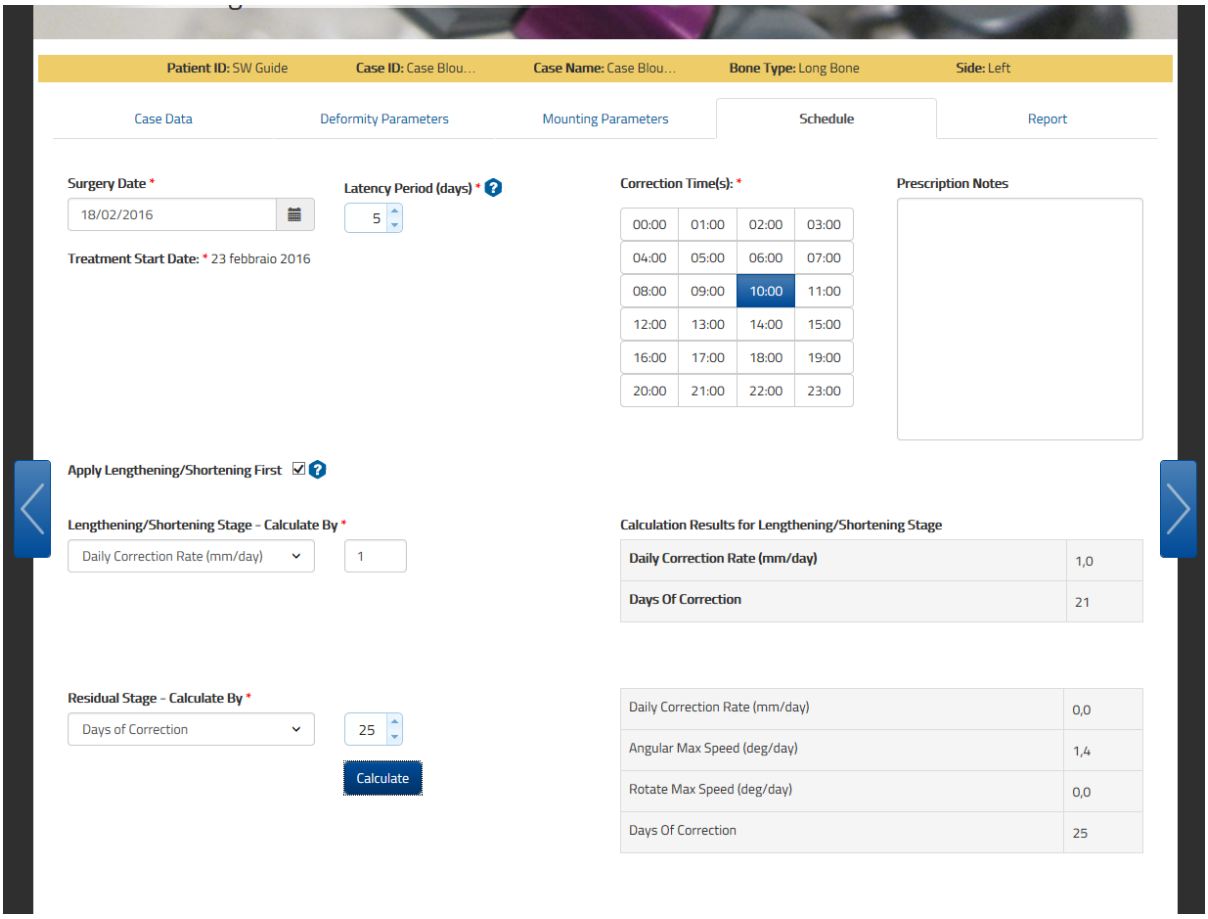
In the **Prescription Notes** text box, the surgeon can enter optionally some notes related to the current case that will be printed on the top right corner of the Prescription issued to the patient.

APPLY LENGTHENING/SHORTENING FIRST

Clicking the 'Apply Lengthening/Shortening' checkbox first, when active, will enable the deformity correction to be performed in two stages: in the first stage, only axial shortening or lengthening will be implemented and then, in the second stage, the remaining deformity will be corrected. This will generate two reports, while the prescription will remain unique for the patient.

It is possible to enter specific parameters related to bone segment movement during first correction stage:

- **Days of correction**: desired days of correction
- **Daily correction rate (mm/day)**

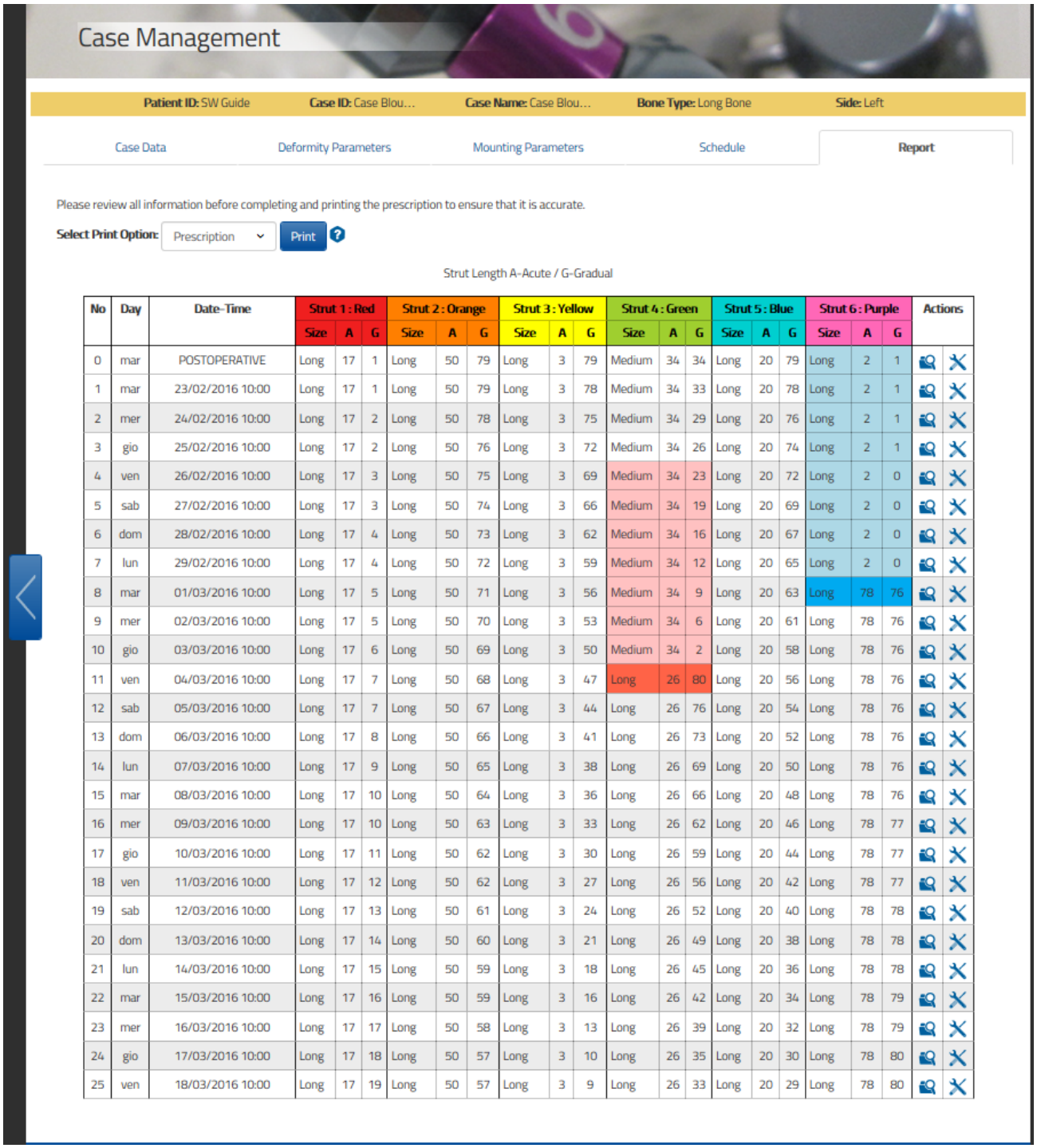


REPORT

The Report screen displays the result of the calculations from previously entered parameters:

- Strut size with acute and gradual adjustment values in millimeters
- Struts exchanges and adjustments that should be done by the surgeon.

These values should be checked by the surgeon, especially in extreme cases.
From Report screen it is possible to print the adjustment schedule for the patient, the prescription (see Prescription section) and the Bill of Materials (see Bill of Materials section).



No	Day	Date-Time	Strut 1 : Red			Strut 2 : Orange			Strut 3 : Yellow			Strut 4 : Green			Strut 5 : Blue			Strut 6 : Purple			Actions	
			Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G		
0	mar	POSTOPERATIVE	Long	17	1	Long	50	79	Long	3	79	Medium	34	34	Long	20	79	Long	2	1		
1	mar	23/02/2016 10:00	Long	17	1	Long	50	79	Long	3	78	Medium	34	33	Long	20	78	Long	2	1		
2	mer	24/02/2016 10:00	Long	17	2	Long	50	78	Long	3	75	Medium	34	29	Long	20	76	Long	2	1		
3	gio	25/02/2016 10:00	Long	17	2	Long	50	76	Long	3	72	Medium	34	26	Long	20	74	Long	2	1		
4	ven	26/02/2016 10:00	Long	17	3	Long	50	75	Long	3	69	Medium	34	23	Long	20	72	Long	2	0		
5	sab	27/02/2016 10:00	Long	17	3	Long	50	74	Long	3	66	Medium	34	19	Long	20	69	Long	2	0		
6	dom	28/02/2016 10:00	Long	17	4	Long	50	73	Long	3	62	Medium	34	16	Long	20	67	Long	2	0		
7	lun	29/02/2016 10:00	Long	17	4	Long	50	72	Long	3	59	Medium	34	12	Long	20	65	Long	2	0		
8	mar	01/03/2016 10:00	Long	17	5	Long	50	71	Long	3	56	Medium	34	9	Long	20	63	Long	78	76		
9	mer	02/03/2016 10:00	Long	17	5	Long	50	70	Long	3	53	Medium	34	6	Long	20	61	Long	78	76		
10	gio	03/03/2016 10:00	Long	17	6	Long	50	69	Long	3	50	Medium	34	2	Long	20	58	Long	78	76		
11	ven	04/03/2016 10:00	Long	17	7	Long	50	68	Long	3	47	Long	26	80	Long	20	56	Long	78	76		
12	sab	05/03/2016 10:00	Long	17	7	Long	50	67	Long	3	44	Long	26	76	Long	20	54	Long	78	76		
13	dom	06/03/2016 10:00	Long	17	8	Long	50	66	Long	3	41	Long	26	73	Long	20	52	Long	78	76		
14	lun	07/03/2016 10:00	Long	17	9	Long	50	65	Long	3	38	Long	26	69	Long	20	50	Long	78	76		
15	mar	08/03/2016 10:00	Long	17	10	Long	50	64	Long	3	36	Long	26	66	Long	20	48	Long	78	76		
16	mer	09/03/2016 10:00	Long	17	10	Long	50	63	Long	3	33	Long	26	62	Long	20	46	Long	78	77		
17	gio	10/03/2016 10:00	Long	17	11	Long	50	62	Long	3	30	Long	26	59	Long	20	44	Long	78	77		
18	ven	11/03/2016 10:00	Long	17	12	Long	50	62	Long	3	27	Long	26	56	Long	20	42	Long	78	77		
19	sab	12/03/2016 10:00	Long	17	13	Long	50	61	Long	3	24	Long	26	52	Long	20	40	Long	78	78		
20	dom	13/03/2016 10:00	Long	17	14	Long	50	60	Long	3	21	Long	26	49	Long	20	38	Long	78	78		
21	lun	14/03/2016 10:00	Long	17	15	Long	50	59	Long	3	18	Long	26	45	Long	20	36	Long	78	78		
22	mar	15/03/2016 10:00	Long	17	16	Long	50	59	Long	3	16	Long	26	42	Long	20	34	Long	78	79		
23	mer	16/03/2016 10:00	Long	17	17	Long	50	58	Long	3	13	Long	26	39	Long	20	32	Long	78	79		
24	gio	17/03/2016 10:00	Long	17	18	Long	50	57	Long	3	10	Long	26	35	Long	20	30	Long	78	80		
25	ven	18/03/2016 10:00	Long	17	19	Long	50	57	Long	3	9	Long	26	33	Long	20	29	Long	78	80		

The 'Actions' column allows the following actions for each row:

DETAILS & CHECKUP

This option icon will generate a pop-up window with the details of the selected row: the three views of the deformity and the frame for the corresponding date/time of the treatment, the related struts values and any warning about potential impingements.
Click 'Start New Case' to create a new case for the selected day/time and all the corresponding deformity and mounting parameters will be transferred to the new case.

STRUT ADJUSTMENT

With this option you can edit, on any report step, the Acute and Gradual pairs with a proposed solution ('Propose strut' button) or enter directly the acute and gradual values for a strut given its current length. This functionality allows for printing of the new prescription with the changed values without creating a new case.

The 'Select Print Option' drop-down menu enables the surgeon to choose which PDF file to print: Prescription, Report and Bill Of Materials.

The 'Print Report' button generates a PDF file of the report screen and is intended for the surgeon to print and maintain a hard copy as a permanent record for the patient's file.

NOTE: When the treatment is staged, i.e. the Apply lengthening/shortening first option is enabled and the case is made of a first part for lengthening/shortening and a second part for correcting the residual deformity, two distinct reports are displayed and can be printed separately (Report Lengthening/Shortening Correction and Report Residual Correction). Prescription will remain a single document and the staging will be totally transparent to the patient.

The Report and Prescription files are optimized for black and white printing.

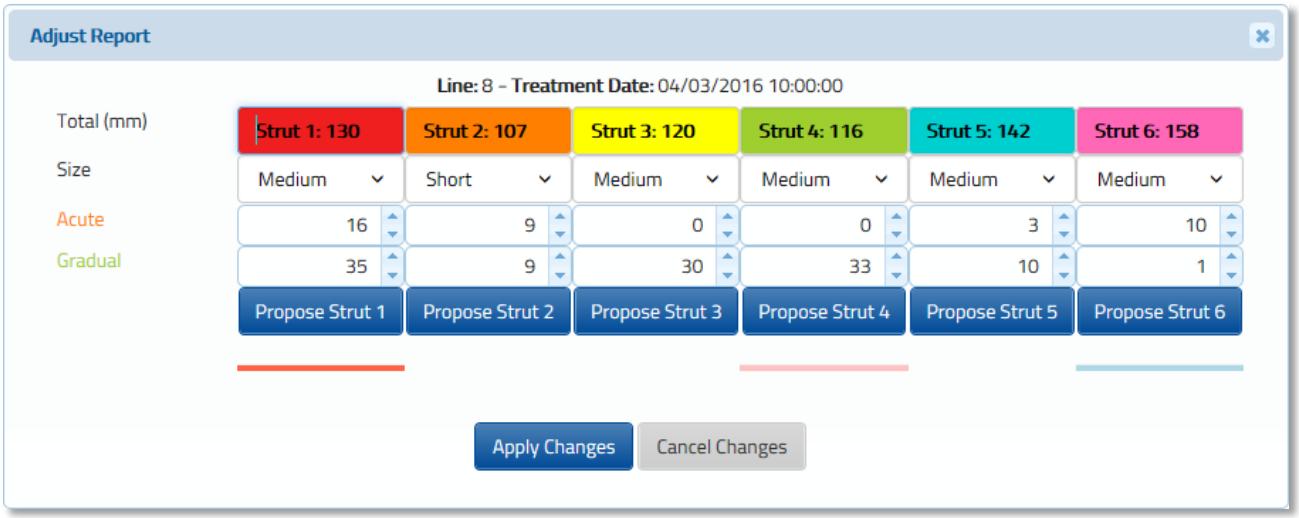
STRUT ADJUSTMENT / EXCHANGE

The prescription/report rows will be highlighted when strut adjustment (shaded blue) or exchange (shaded red) is required or suggested.
The rows of lighter shading indicate the allowable range of days that are suitable for the adjustment/exchange of a strut without adding extra adjustment/exchange to the treatment; the shaded row indicates the last possible day for the strut adjust/exchange.

If the strut adjustment/exchange occurs on the last day (marked by the solid color blue/red box), the existent prescription can be used. If the strut adjustment/exchange occurs prior to the last day, the value can be adjusted using "Adjust", and a new prescription is generated from that date and must be given to the patient.

NOTE: It is possible to adjustment/exchange a strut in any report row, shaded or white, using the 'Adjust' functionality. If adjustment/exchange of a strut is done on shaded areas, no additional adjustment/exchange to the treatment plan will be added. If case adjustment/exchange is done outside shaded areas (white area), the new calculation could lead to a treatment plan with additional adjustment/exchange compared with the previously calculated.

By clicking on the [Adjust] icon, the system will show a pop-up window with the length, size and acute/gradual values of each strut for that time of day.



Clicking the Propose Strut 1 button, allows the software to suggest the optimized acute and gradual values for the selected strut. The proposed solution takes into consideration the current strut direction to calculate the strut proposal. In the event that the Selected Strut is changing directions, the surgeon may want to adjust the Acute Length and Gradual Length Values to eliminate any Acute Changes introduced in the newly adjusted report.

The adjustment can be done to multiple struts at the same time and also on white cells independently of the shading (adjustment of acute values are always possible, size exchange only in the overlapping area described in conversion tables).

The surgeon can also directly input the acute and gradual values for a strut given its current length.

NOTE: Once the struts are adjusted on the report screen, the case is no longer modifiable, but the surgeon can still view the previously entered parameters, in read-only mode, using the 'View' button.

The surgeon can reset the changes made so far on the report using the 'Reset' button. All the adjustments will be lost and the report will revert back to the initial version.

The Acute and Gradual values of the new strut, if the exchange /adjustment occurs prior to the last day of possible adjustment/exchange, can be determined also with support of the conversion tables available online clicking on 'Instructions for Use' link on the footer of the www.tlhex.com site.

NOTE: Please review all information before printing the prescription and issuing it to the patient to ensure it is accurate.

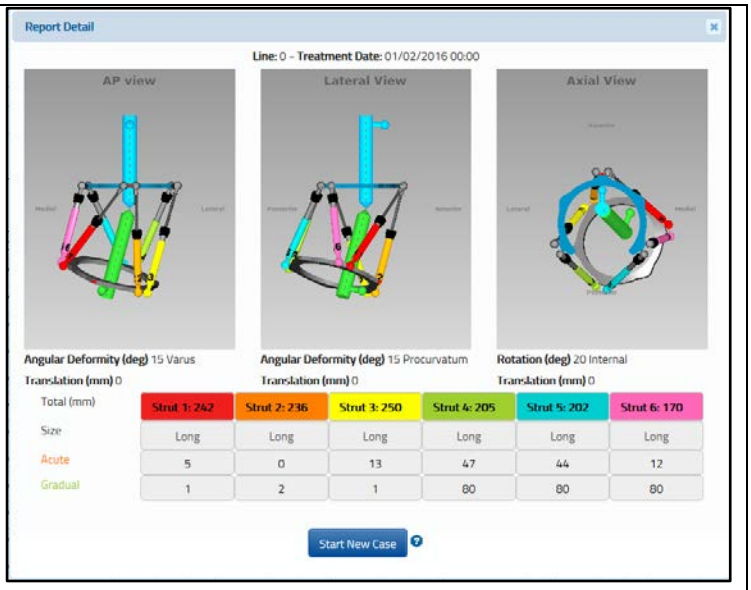
DETAILS & CHECKUP

By clicking on the button, the pop-up window provides the position of the bone segments and the frame with corresponding strut adjustment values on any particular day of treatment (deformity correction).

When the Start New Case button is clicked, it defaults the selected date as Treatment Start Date .

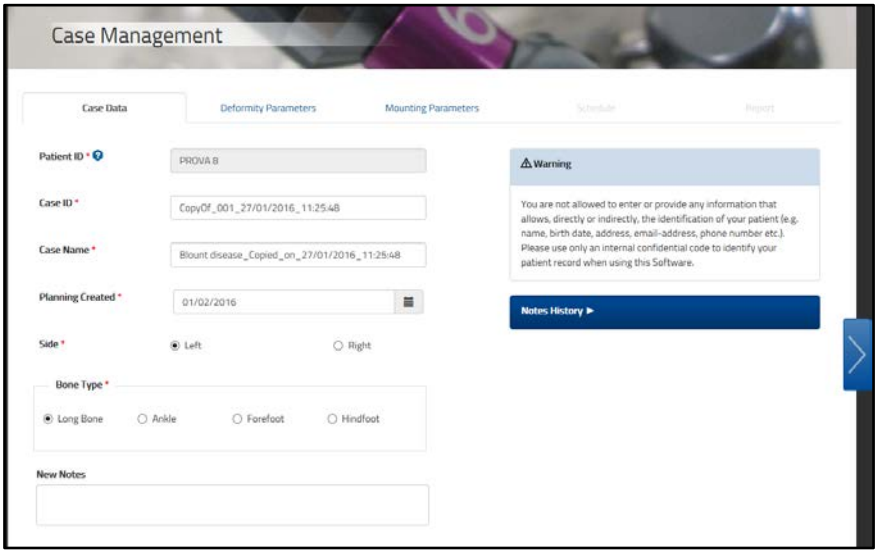
Click the Start New Case button and a new case will be generated using the parameters of the bone segment position and the strut length values (from the date selected) as a starting point. The Create New Case screen is used in the following situations:

- Changes in parameters of strut adjustment.
- Unplanned strut readjustment or exchange.
- Residual correction is required.
- Next treatment phase for the staged correction.



Clicking on the Start New Case button will open the Case Data screen for the newly generated case. All the deformity and frame parameters will be transferred from the previous case at the date of check-up.

The standard software steps are now followed to complete the new planning from this starting point. The surgeon should check and adjust Deformity Parameters if necessary. The surgeon should proceed to the Mounting Parameters section where mounting parameters and strut parameters should be verified and adjusted if necessary. This will result in a new prescription for the patient, based on the starting point as chosen from the Checkup screen.

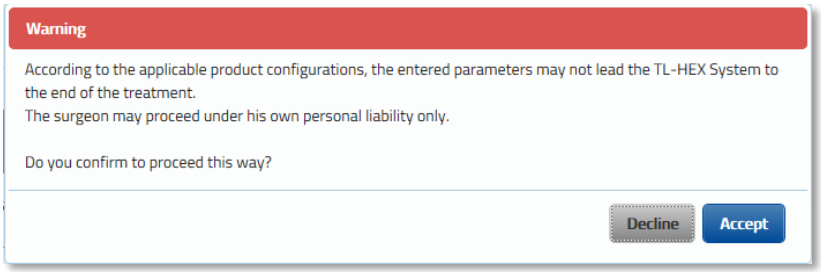


WARNING SYSTEM

By moving to the Report Tab, once the Schedule parameters are set, the 1.5 prescription calculation algorithm verifies and warns the user with a red pop-up if the calculated prescription may not lead to the end of the treatment.

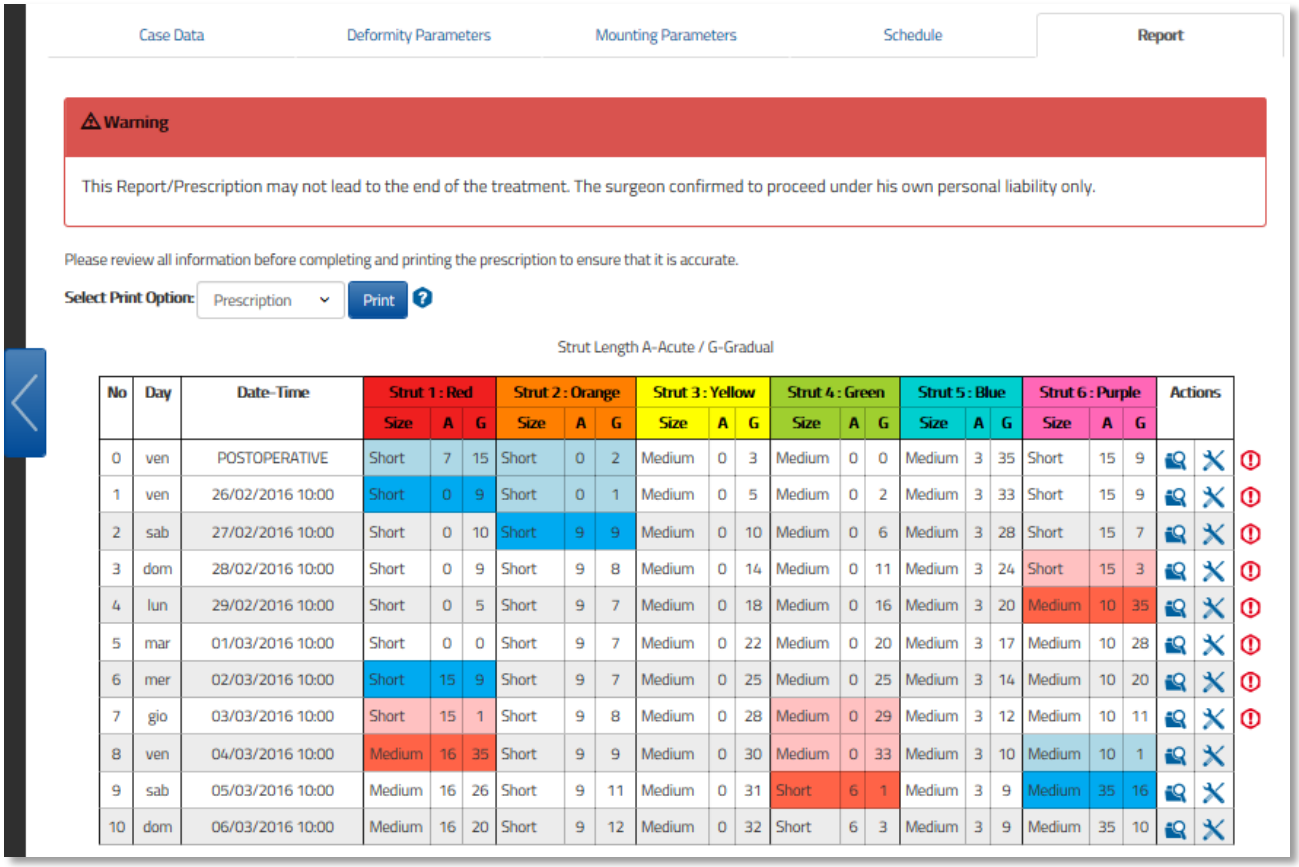
Generally, these situations originate from potential hardware impingements (struts and rings) and out-of-range struts.

NOTE: Impingements between external supports are not evaluated.



The user is allowed to proceed by clicking the Accept button under his/her own liability only.

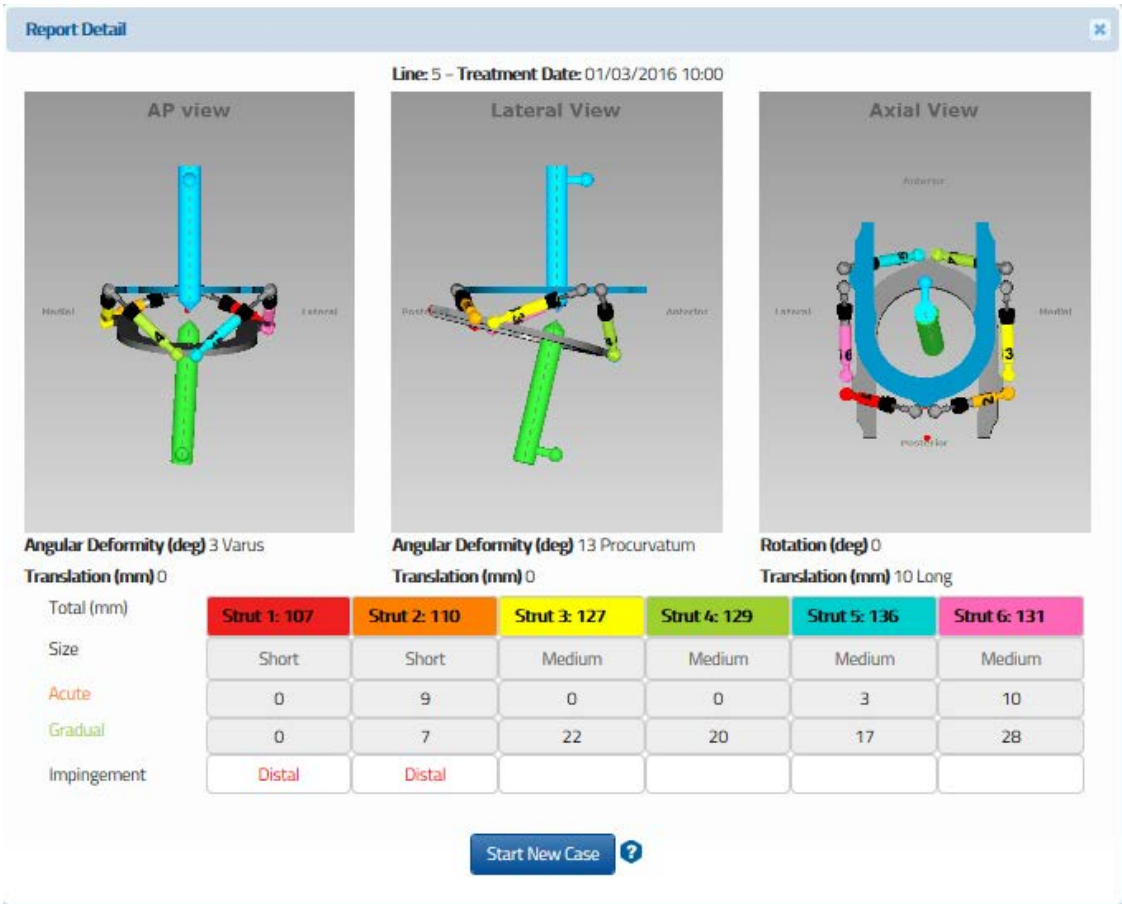
By accepting to proceed, the report is generated and a red banner pops up to remind the user about the issues related to the prescription. In addition to this banner, the affected report rows are highlighted with the icon.



No	Day	Date-Time	Strut 1 : Red			Strut 2 : Orange			Strut 3 : Yellow			Strut 4 : Green			Strut 5 : Blue			Strut 6 : Purple			Actions
			Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G	Size	A	G	
0	ven	POSTOPERATIVE	Short	7	15	Short	0	2	Medium	0	3	Medium	0	0	Medium	3	35	Short	15	9	
1	ven	26/02/2016 10:00	Short	0	9	Short	0	1	Medium	0	5	Medium	0	2	Medium	3	33	Short	15	9	
2	sab	27/02/2016 10:00	Short	0	10	Short	9	9	Medium	0	10	Medium	0	6	Medium	3	28	Short	15	7	
3	dom	28/02/2016 10:00	Short	0	9	Short	9	8	Medium	0	14	Medium	0	11	Medium	3	24	Short	15	3	
4	lun	29/02/2016 10:00	Short	0	5	Short	9	7	Medium	0	18	Medium	0	16	Medium	3	20	Medium	10	35	
5	mar	01/03/2016 10:00	Short	0	0	Short	9	7	Medium	0	22	Medium	0	20	Medium	3	17	Medium	10	28	
6	mer	02/03/2016 10:00	Short	15	9	Short	9	7	Medium	0	25	Medium	0	25	Medium	3	14	Medium	10	20	
7	gio	03/03/2016 10:00	Short	15	1	Short	9	8	Medium	0	28	Medium	0	29	Medium	3	12	Medium	10	11	
8	ven	04/03/2016 10:00	Medium	16	35	Short	9	9	Medium	0	30	Medium	0	33	Medium	3	10	Medium	10	1	
9	sab	05/03/2016 10:00	Medium	16	26	Short	9	11	Medium	0	31	Short	6	1	Medium	3	9	Medium	35	16	
10	dom	06/03/2016 10:00	Medium	16	20	Short	9	12	Medium	0	32	Short	6	3	Medium	3	9	Medium	35	10	

The user can get additional information about the highlighted issue , by reviewing the relevant row detail. Click the icon to check where the eventual hardware impingement are foreseen or if a strut is becoming out-of-range (number in red).

Below is an example that indicates that struts No. 1 and 2 could face up an impingement with the distal ring.



PRESCRIPTION

The 'Prescription' PDF file displays the adjustment schedule for the patient; each row describes the strut adjustment to be made by the patient for each deformity correction step as specified in the schedule. This document must then be printed and the hard copy should be issued to the patient and can also be saved for the record.

NOTE: The print-out should be checked for correctness and readability and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.
NOTE: All information must be reviewed by the surgeon before completing and printing the prescription to ensure it is accurate.

Page 1

Dr. TL-Hex Demo
Prova
Prova
PanamaPanamaPanamaPanamaPanamaPana...
(+39) 0456719000, (+39) 0456719000

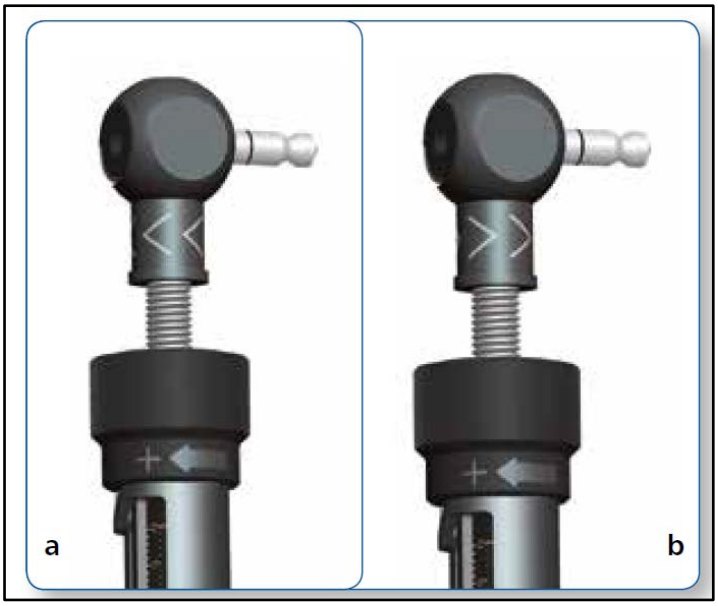
Print date: 18/02/2016, 17:13:59
Case ID: Case Blount's
Case Name: Case Blount's
Patient Id: SW Guide
Side: Left
Bone Type: Long Bone

			Strut Adjustment in 'CLICKS' (a)							Strut Reference Length (b)					
No	Day	Date-Time	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE		RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
			1	2	3	4	5	6		1	2	3	4	5	6
0	mar	POSTOPERATIVE	0	0	0	0	0	0	☐	1	79	79	34	79	1
1	mar	23/02/2016 10:00	0	1	3	3	2	0	☐	1	79	78	33	78	1
2	mer	24/02/2016 10:00	-1	2	6	7	4	1	☐	2	78	75	29	76	1
3	gio	25/02/2016 10:00	-1	3	6	6	5	0	☐	2	76	72	26	74	1
4	ven	26/02/2016 10:00	-1	2	6	7	4	1	☐	3	75	69	23	72	0
5	sab	27/02/2016 10:00	-1	2	6	7	5	0	☐	3	74	66	19	69	0
6	dom	28/02/2016 10:00	-1	2	7	7	4	0	☐	4	73	62	16	67	0
7	lun	29/02/2016 10:00	-1	2	6	7	5	0	☐	4	72	59	12	65	0
8	mar	01/03/2016 10:00	-1	3	6	7	4	0	☐	5	71	56	9	63	76
9	mer	02/03/2016 10:00	-1	2	6	6	4	0	☐	5	70	53	6	61	76
10	gio	03/03/2016 10:00	-1	2	6	7	5	0	☐	6	69	50	2	58	76
11	ven	04/03/2016 10:00	-2	2	6	0	4	0	☐	7	68	47	80	56	76
12	sab	05/03/2016 10:00	-1	2	6	7	4	<<-1>>	☐	7	67	44	76	54	76
13	dom	06/03/2016 10:00	-2	1	6	7	4	0	☐	8	66	41	73	52	76
14	lun	07/03/2016 10:00	-1	2	6	7	5	0	☐	9	65	38	69	50	76
15	mar	08/03/2016 10:00	-2	2	5	7	4	0	☐	10	64	36	66	48	76

1 / 2

Adjustment for each strut is represented by the number of clicks (1/2 rotation of the strut adjustment knob that is 1/2mm) and can be positive (if strut length increases) or negative (when the strut length decreases). In addition, the gradual adjustment scale value in millimeters is displayed as a reference for each strut.

The direction clips are then applied to the rod end joints according to the prescription. If strut elongation is required (positive numbers in the prescription), the arrow on the clip should point in the same direction as the reference arrow on the adjustment knob (Fig. a). If strut shortening is required (negative numbers in the prescription), the clip should be applied with the arrow pointing in the opposite direction of the arrow on the adjustment knob (Fig. b).



Strut Adjustments direction change

In most of the cases, the orientation of direction clips remains the same throughout the treatment. In some cases with a rotational deformity correction, the direction of strut adjustments in the prescription may change from positive to negative or vice versa. In this situation, the surgeon should instruct the patient about the day the change of direction occurs and either schedule a clinic visit for the orientation change of the direction clip or instruct the patient on how to make this orientation change to the direction clip themselves.

In the prescription, any direction change is highlighted with a couple of << >> characters around the number(s) where the direction change happens.

Bone Type: Long Bone

			Strut Adjustment in 'CLICKS' (a)							Strut Reference Length (b)					
No	Day	Date-Time	RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE		RED	ORANGE	YELLOW	GREEN	BLUE	PURPLE
			1	2	3	4	5	6		1	2	3	4	5	6
0	mar	POSTOPERATIVE	0	0	0	0	0	0	☐	1	79	79	34	79	1
1	mar	23/02/2016 10:00	0	1	3	3	2	0	☐	1	79	78	33	78	1
2	mer	24/02/2016 10:00	-1	2	6	7	4	1	☐	2	78	75	29	76	1
3	gio	25/02/2016 10:00	-1	3	6	6	5	0	☐	2	76	72	26	74	1
4	ven	26/02/2016 10:00	-1	2	6	7	4	1	☐	3	75	69	23	72	0
5	sab	27/02/2016 10:00	-1	2	6	7	5	0	☐	3	74	66	19	69	0
6	dom	28/02/2016 10:00	-1	2	7	7	4	0	☐	4	73	62	16	67	0
7	lun	29/02/2016 10:00	-1	2	6	7	5	0	☐	4	72	59	12	65	0
8	mar	01/03/2016 10:00	-1	3	6	7	4	0	☐	5	71	56	9	63	76
9	mer	02/03/2016 10:00	-1	2	6	6	4	0	☐	5	70	53	6	61	76
10	gio	03/03/2016 10:00	-1	2	6	7	5	0	☐	6	69	50	2	58	76
11	ven	04/03/2016 10:00	-2	2	6	0	4	0	☐	7	68	47	80	56	76
12	sab	05/03/2016 10:00	-1	2	6	7	4	<<-1>>	☐	7	67	44	76	54	76
13	dom	06/03/2016 10:00	-2	1	6	7	4	0	☐	8	66	41	73	52	76
14	lun	07/03/2016 10:00	-1	2	6	7	5	0	☐	9	65	38	69	50	76
15	mar	08/03/2016 10:00	-2	2	5	7	4	0	☐	10	64	36	66	48	76

The Prescription Preferences previously entered and associated to a specific patient will be printed in the upper-left corner of this file and Prescription Notes entered in the Schedule tab will be printed in the upper-right corner. The Prescription file has been optimized for black and white printing. In order to distinguish between blue and red shaded rows, a black contour has been added to the red cells. This document must then be printed and the hard copy must be issued to the patient and can also be saved for recording purposes. The print-out should be checked for correctness and readability, and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.

BILL OF MATERIALS

The 'Bill Of Materials' button produces a Bill Of Material file listing the materials that only cover the TL-HEX components needed for the treatment. This includes rings, footplates and struts.

Page 1

Print date: 27/01/2016, 11:13:07

Case ID: 001
Case Name: Blount disease
Patient Id: PROVA 8
Side: Left
Bone Type: Long Bone

Initial Construct

Item	Description	Quantity	Item Number
Strut	Long	6	50-10400
Distal Ring	Full Ring160mm	1	56-20020
Proximal Ring	5/8 Open Posteriorly Ring160mm	1	56-21420

The listed materials only cover the TL-HEX components needed for the treatment. This includes rings, foot plates, and struts.

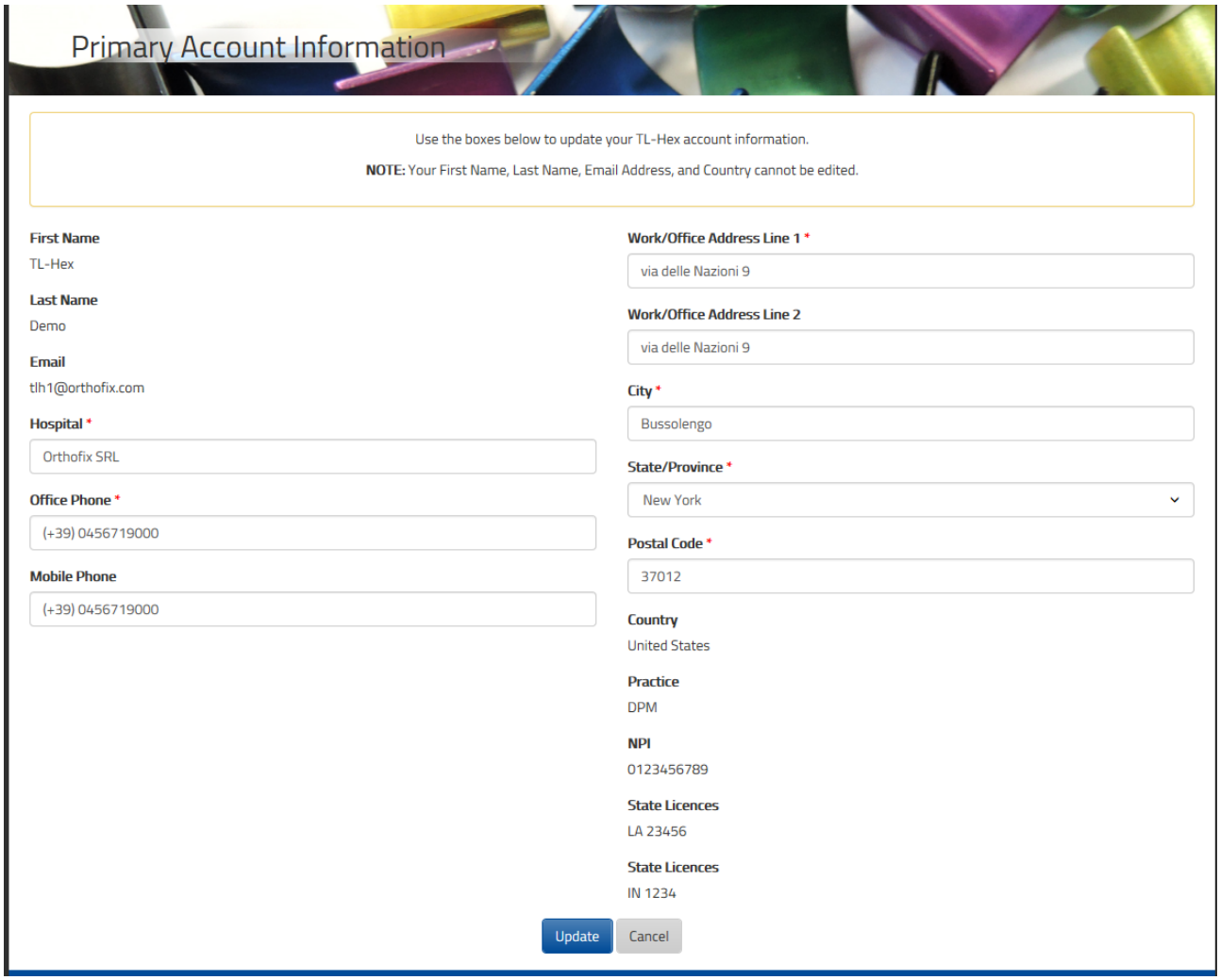
ACCOUNT MANAGEMENT

In this section, clicking on [Manage account] icon, the user can:

- Display and change account information: go to the section ''Edit Account Information'' can in case some changes are applied, click on Update button.
- On 'Prescription Preferences': the user can insert an additional address.
- Clicking on 'Change Password', the user can change password

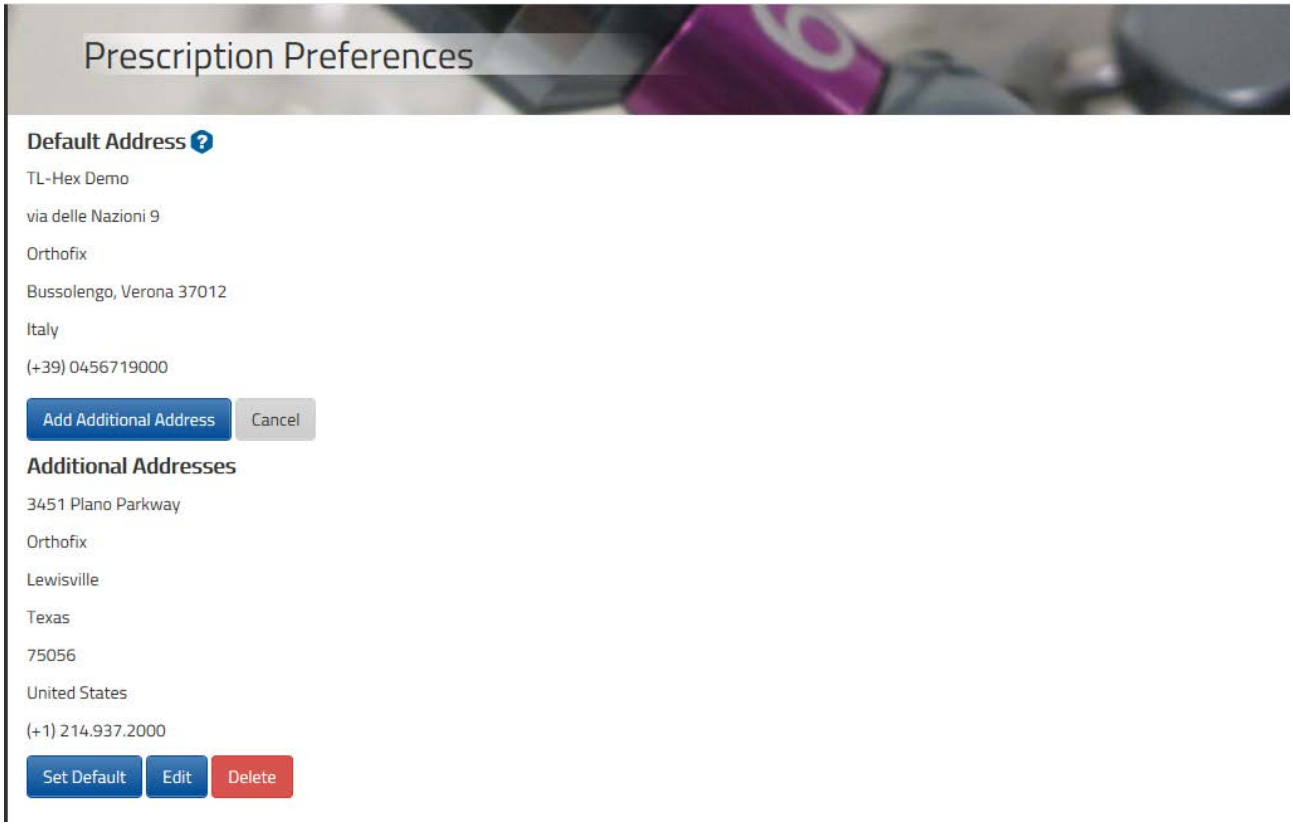
EDIT ACCOUNT INFORMATION

The user can update some information about his account. Click on Update after the updates entered



PRESCRIPTION PREFERENCES

The prescription preferences screen appears after the Prescription Preferences menu item has been selected from the [Manage Account] icon.



The user can optionally add default prescription notes and/or enter addresses different from the first entered during registration phase. At the beginning of the patient creation process, the surgeon can link to a new patient from any of the addresses previously created using this menu. The link between address and patient can be modified using the 'modify' action in the 'List of patients' menu and selecting a new preference.

CHANGE PASSWORD

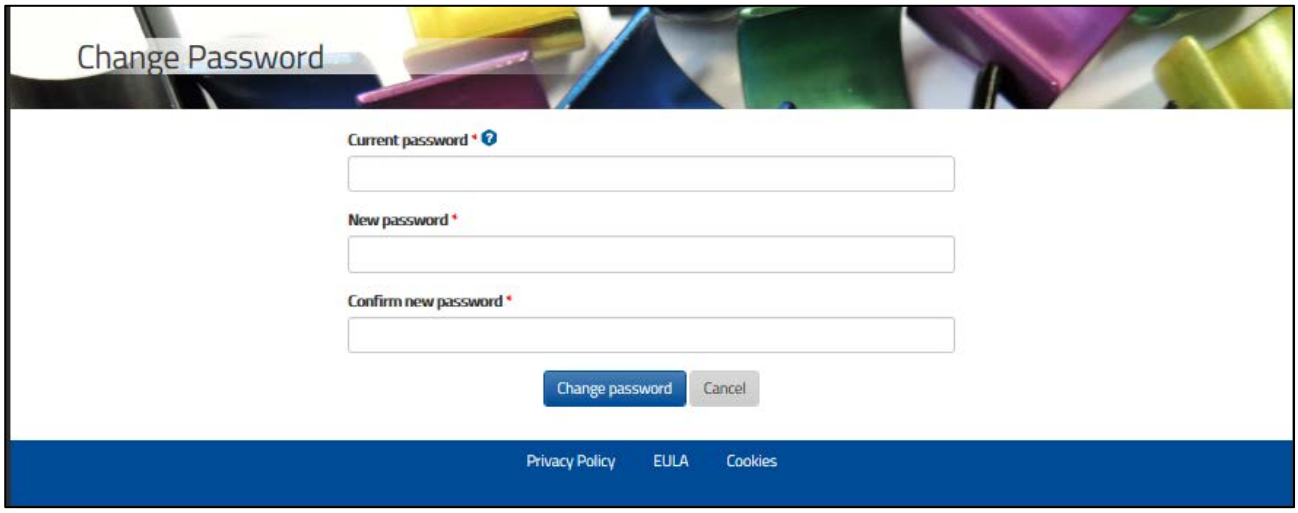
It is recommended that the user changes the password during the first log in and periodically thereafter.

The Change Password screen appears by clicking on the 'Manage Account icon to change Password.

Simply enter the current password, followed by entering and confirming the new password, then click Change Password.

Password must be six or more characters and it is case sensitive.

It is important to remember that the surgeon remains ultimately responsible for the confidentiality of the information entered into the software. One of the ways to guarantee confidentiality is to ensure password integrity by changing it at regular intervals and by keeping the password as secure as possible.



Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon should never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

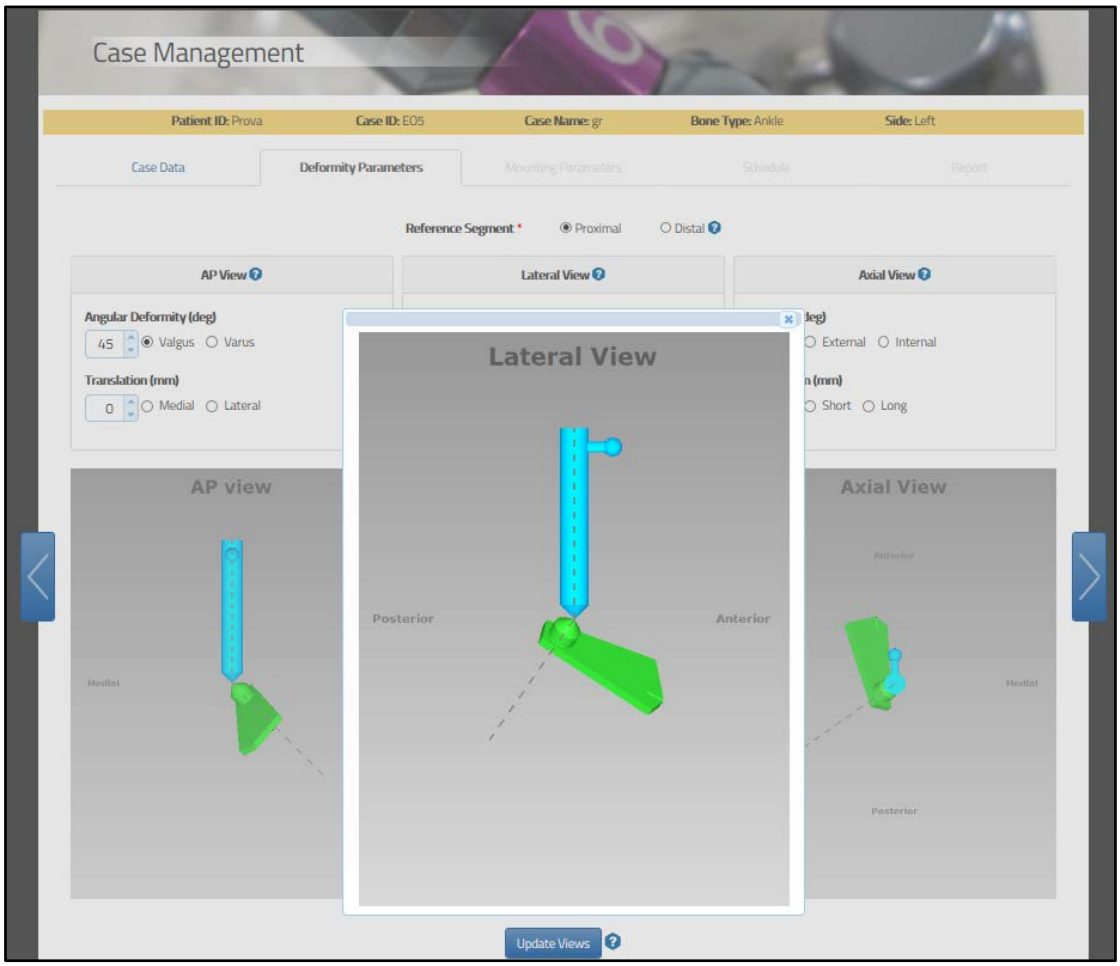
ONLINE HELP

Online help is available by clicking on icons where applicable; the surgeon will be able to view relevant help information.

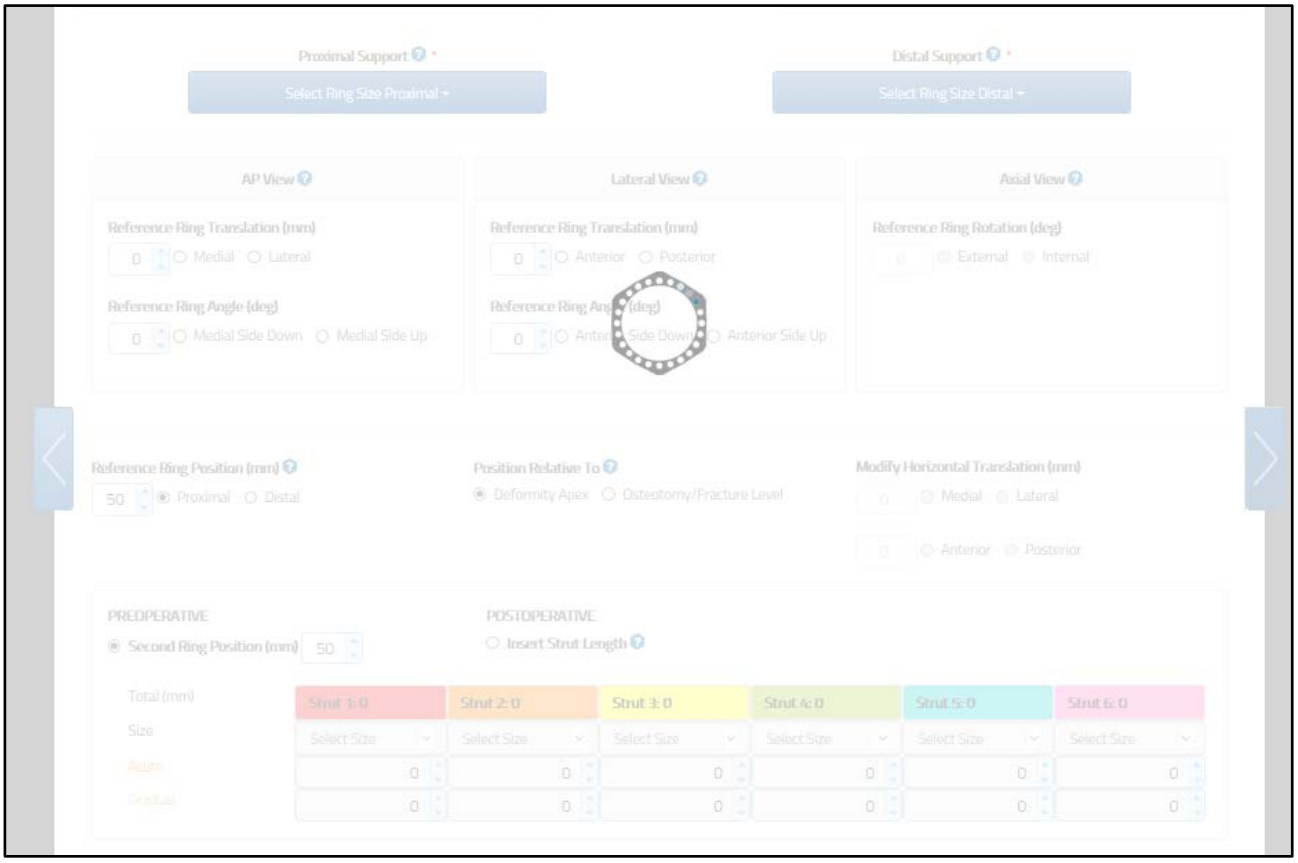
FEW MORE THINGS…

- To create a new case, the user begins with the Case Data tab followed by Deformity Parameters tab, etc. Once the case is completed, the user can navigate freely between tabs and the flow is from the left to the right; tabs that are not appropriate to the next step of the case planning process are greyed out. To return to a previous tab during a case creation process, the user should click the arrow to the left-hand side of the screen or one of the function tabs.
- It is good practice to click the 

button after making any changes to the on screen parameters. This will provide visual confirmation that the changes are as intended. Regardless of whether the Update Views is clicked after changing one or more parameters, the new parameters will be saved once either the 'next' arrow on the right-hand side or one of the function tabs are clicked.
- The user can click on each image to enlarge it in a pop-up window.



- The TL-HEX software is designed for minimal response (wait) time. However, in the event of internet transmission delays, a ring with a dot loading animation is displayed while the user's PC is waiting for a response from the TL-HEX server.



- The pop-up window appears during a ring size change, when recalculation of the strut lengths is required.
- In case of temporary loss of internet connection and/or when the user is finished for the day (by logging off), the surgeon should close the internet browser, then reopen browser, clear the browser history, open TL-HEX application and login.
- The session will automatically time out after 30 minutes. The surgeon should close the internet browser, then reopen browser, clear the browser history, open TL-HEX application and login.
- The 'about' menu contains general information about the product and its website.

The site footer links provide legal information (about Cookies, Eula and Privacy).

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Distributed by:

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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