

Software Version 2.3



TL-HEX Software User's Guide: Software version 2.3

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 11 or higher

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Safari® 13 or higher

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

Google Chrome™ Browser 79 or higher

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Mobile Safari® 13 or higher

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Other Requirements:

Web Graphics Library (WebGL) availability and minimum screen resolution are checked at login time in order to provide access to HEX-ray. (See Annex A on HEX-ray Software User's Guide on how to configure the browser)

Internet Connection:

Minimum required internet connectivity speed is 512kbps.

Recommended internet connectivity speed is 3mbps or higher.

My Username:	
My Password:	

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UNDERSTANDING TL-HEX SOFTWARE VERSION 2.3

Whether you are a new TL-HEX user or an experienced one, reading this document will help you understand how to approach the TL-HEX Software Version 2.3; the conventions adopted and the logics adopted in order to provide the user with the tools for managing a treatment.

Proper surgical procedure is the responsibility of the medical professional. This software and software user guide are furnished as informative guidelines. 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 for the TL-HEX TrueLok Hexapod System™ that is used in conjunction with this pre and post op planning tool system for specific information on this device.

For new users

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

- have an overview of TL-HEX system (both hardware and software) and understand the basic rules about how to build correct frames in the TL-HEX SYSTEM OVERVIEW section
- understand conventions used by the software to mimic reality in the NOMENCLATURE section
- know how to log in to the GETTING STARTED ... HOW TO LOG IN section
- understand general software's menus and navigation logics by reading the PATIENT AND CASE MANAGEMENT section
- manage an entire case on the software by reading the CASE PLANNING section.

For HEX-perienced 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 new 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 section
- refreshing the background required for using this software
 - take a look at the PATIENT AND CASE MANAGEMENT section to understand how the icons can aid the use of the software
- 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 like sticks option.

The following flow chart provides a sequential overview of the process for case management with TL-HEX software (with or without HEX-ray module)

Obtain an account at www.tlhex.com following the on-screen instructions Log in to the TL-HEX software https://app.tlhex.com Create a new patient Create a new case related to the patient Specify the 'Deformity' parameters and 'End of Correction' parameters, if required Select the ring type and size for the frame Complete the 'Mounting Parameters' to assemble the frame Confirm or adjust postoperative values and strut configurations Determine the schedule for the correction planning. If applicable, apply lengthening/shortening first Visualise, adjust and print the report Visualise and print the prescription for the patient Use the 'Detail & Checkup' function to create a new case starting from the date selected

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

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

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

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 Type, Case ID, Case Description, Planning Created, Side, Bone type).

See ADD NEW CASE

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

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

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

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

see POSTOPERATIVE ASSESSMENT

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

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

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 TrueLok Hexapod 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.



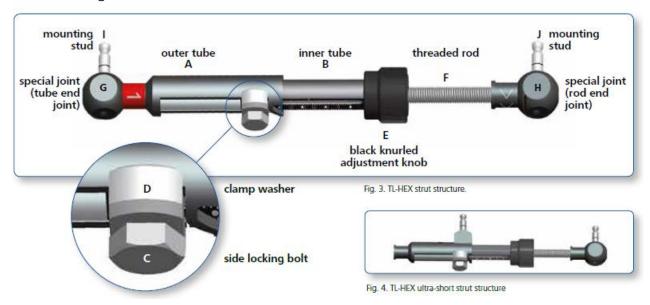
Fig.1 TL-HEX application with two rings and six variable length struts
Fig.2 TL-HEX application with one ring, one footplate and six variable length struts (foot deformity correction)

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.



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.

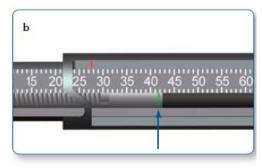
The acute adjustment is achieved by untightening the side-locking bolt, sliding the inner tube relative to the outer tube to the desired length and re-tightening the locking bolt. Acute adjustment is indicated by the inner tube scale in 1-mm increments relative to the orange-line mark on the outer tube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







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.

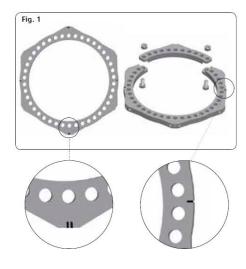
5/8 rings and 3/8 component

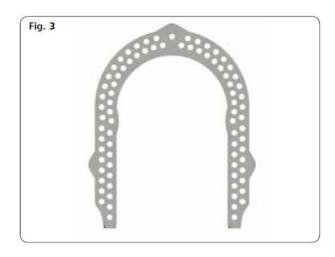
Each 5/8 ring has:

- 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.



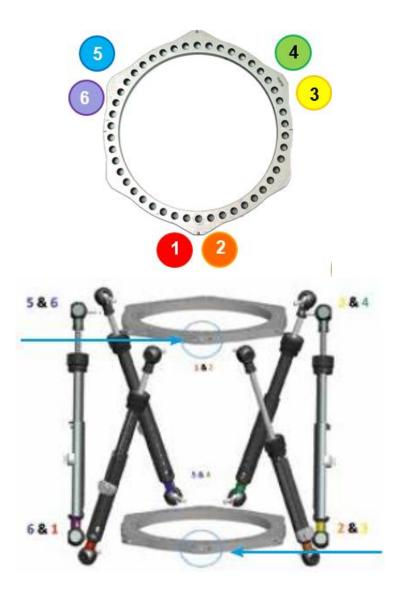


RING ORIENTATION TAB

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 strut 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

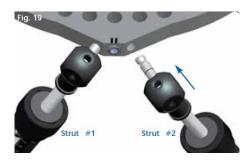
For proper identification, the struts are numbered using color number clips. The clips are numbered from 1 to 6 and colour coded as red (1), orange (2), yellow (3), green (4), blue (5) and purple (6).

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 strut combinations 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.



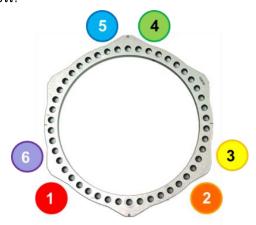
Full rings and 5/8 Open Posteriorly rings, while the ROT is always placed anteriorly.

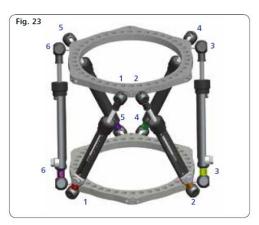
2. For the proximal ring, struts No. 3, 4, 5 and 6 must be attached counter-clockwise as shown below.





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



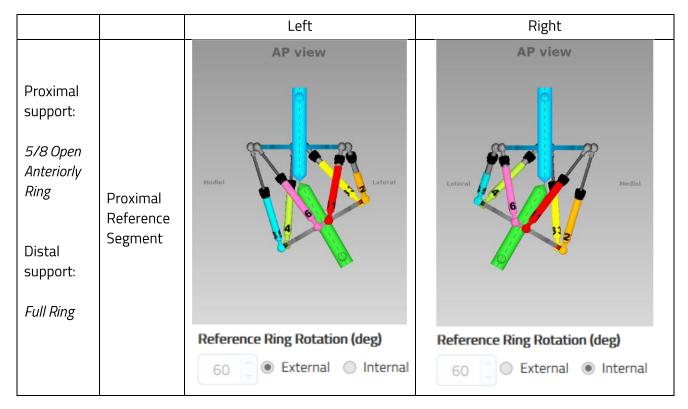


5/8 Open Anteriorly Ring

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:



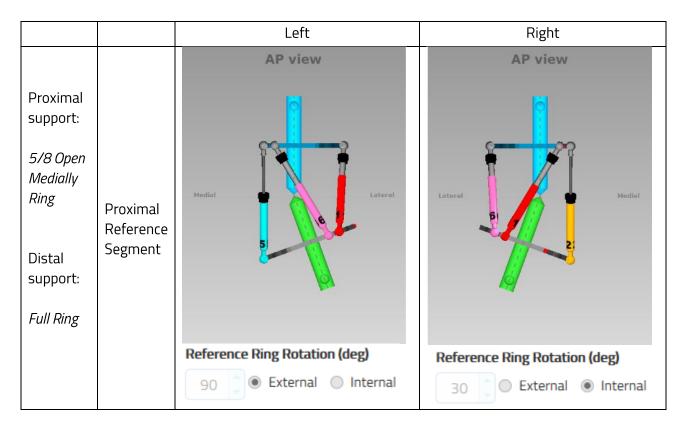
5/8 Open Medially Ring

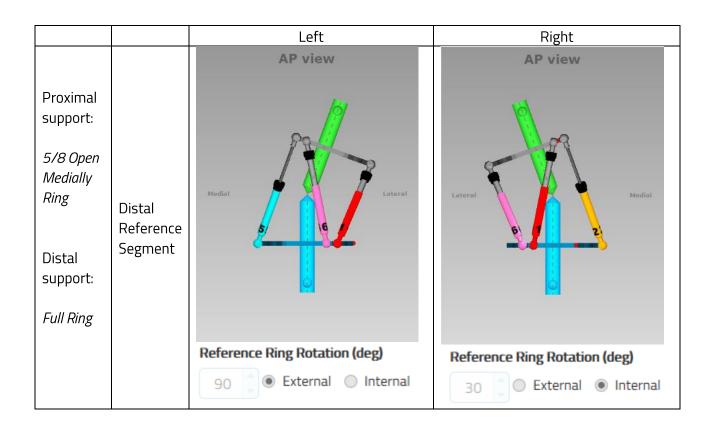
In case the proximal ring is a 5/8 Open Medially Ring, when there is no rotational deformity, according to the software convention, the ROT is the first possible tab that is counter-clockwise from the anterior side for both right and left limb.

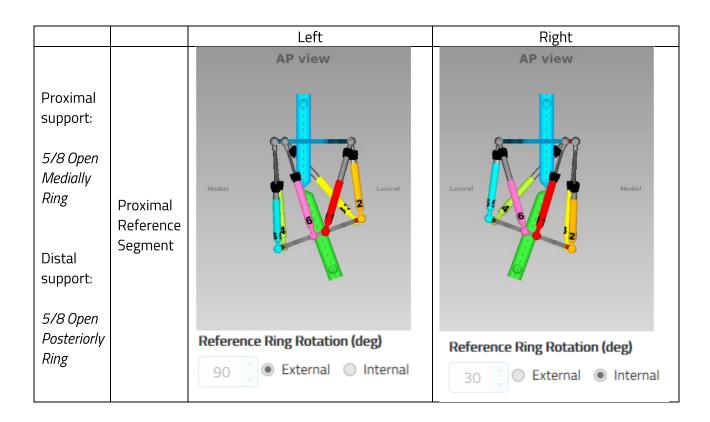
NOTE: it is not possible to have the same ROT rotation between left or right limb. The frame mounting is not symmetrical.

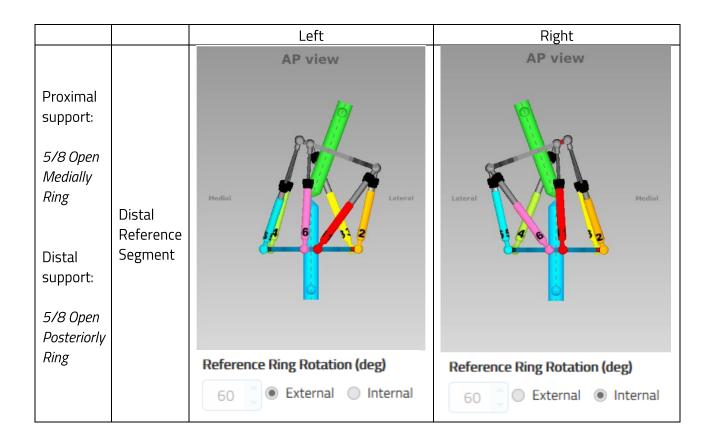
Independently from the reference segment selection, the first possible tab will be externally rotated for the left limb, while the right limb will be internally rotated. Instead, the rotation value changes according to the selected reference segment and distal support. The rotational value is automatically 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:







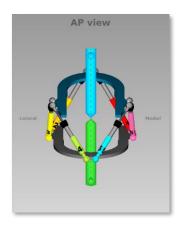


Footplate

When selecting Long Bone as bone type:

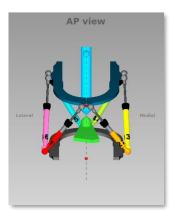
- using **1 footplate**, the footplate will open anteriorly (both distal or proximal)
- using **2 footplates**, the proximal footplate will open anteriorly and the distal footplate will open posteriorly.

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



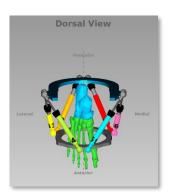
When selecting Ankle as bone type:

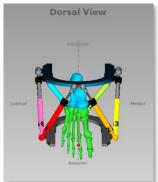
- using **1 footplate**, the foot plate will open anteriorly (both distal or proximal)
- using **2 footplates**, the proximal footplate will open posteriorly and the distal footplate will open anteriorly.



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.

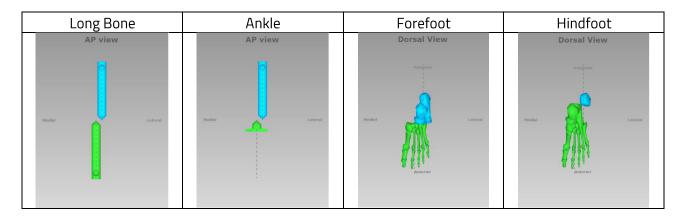




NOMENCLATURE

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.



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**:

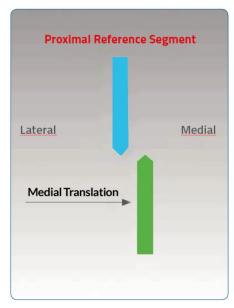
- the deformity and the frame are described relative to the axis of the distal segment
- the measurements would need to be taken in relation to this orientation
- the translation and rotation of the proximal segment are described in relation to the distal segment.

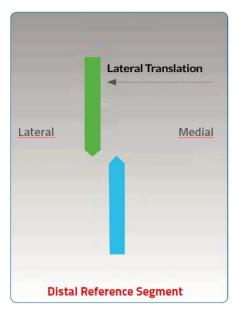
To minimize the measurement errors when using the X-rays related either to the apex of deformity or the osteotomy/level of fracture, the shortest segment should be used as a reference segment.

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.

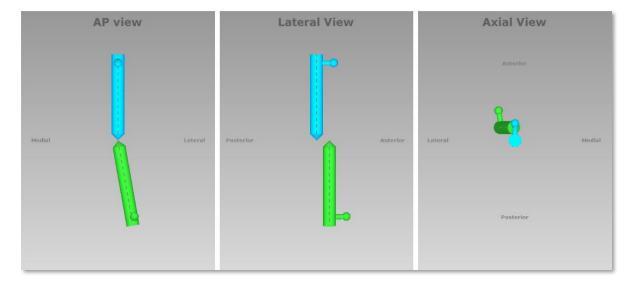
For example, in case of a distal reference segment, medial translation of the distal bone segment would be described as lateral translation because the proximal segment would be translating laterally in relation to the distal (reference) segment as described in the following images.





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.

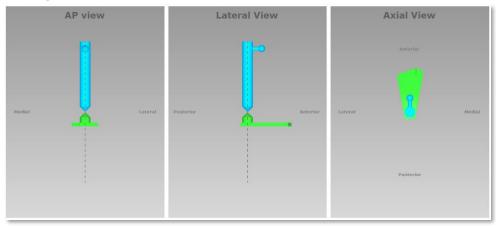
The second is the Lateral view diagram representing the standard ML X-ray of the limb. There are orientation keys on these two views that indicate the medial/lateral and anterior/posterior aspects, respectively.

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 corresponding part of the limb.

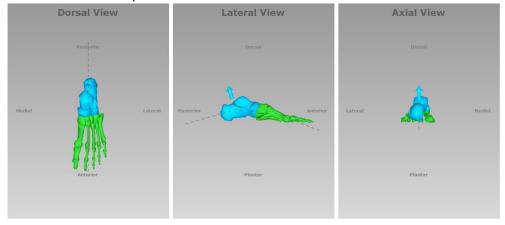
In the description of *Ankle* cases, the software views represent the deformity following the same rules as above, but adapting the simplified foot anatomy:



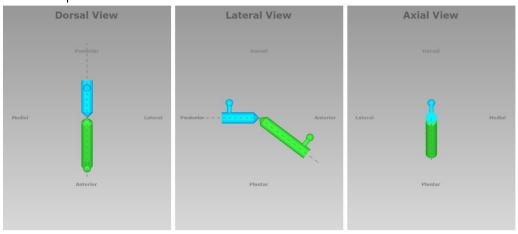
While describing *Foot* deformity, it is possible to select either *Hindfoot* or *Forefoot* level of correction. This indication provides the surgeon with the means to manage different foot deformities in an appropriate way.

If *Forefoot* is selected as bone type, it is possible to choose between two different graphic types in the Deformity Parameters section:

Anatomical Forefoot Graphics

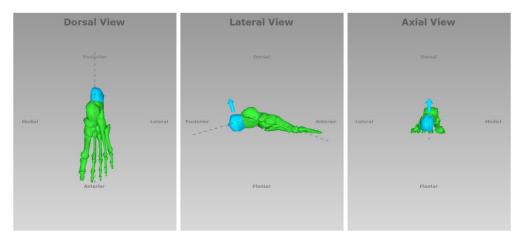


• Dowels Representation of the Forefoot:

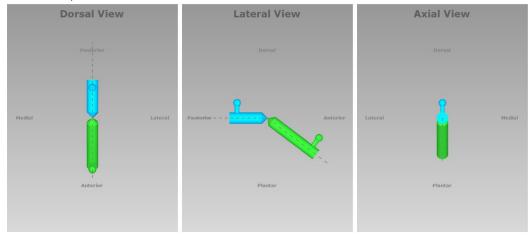


If *Hindfoot* is selected as bone type, the software views represent the foot as follows depending on the selected option in Deformity Parameters tab:

• Anatomical Hindfoot Graphics



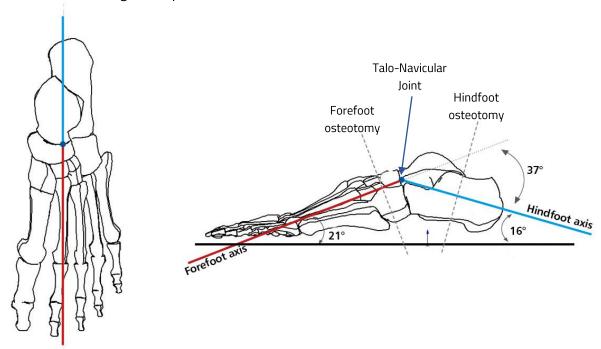
Dowels Representation of the Hindfoot



For both foot bone types, the anatomical graphics have been enriched with an arrow that helps in understanding, especially in the Axial View, the direction of the rotational deformity between the two segments.

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 anatomical foot differently from what is seen on the AP and LATERAL X-rays, but the correction will be performed according to the parameters entered: in these cases, it is suggested to use the dowels option.

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.

The option with dowels keeps the default 37° Apex Dorsal but it can be adapted and used to model a deformity/fracture on a foot in a more abstract and generic way (e.g. midfoot deformities).

MOVING SEGMENT

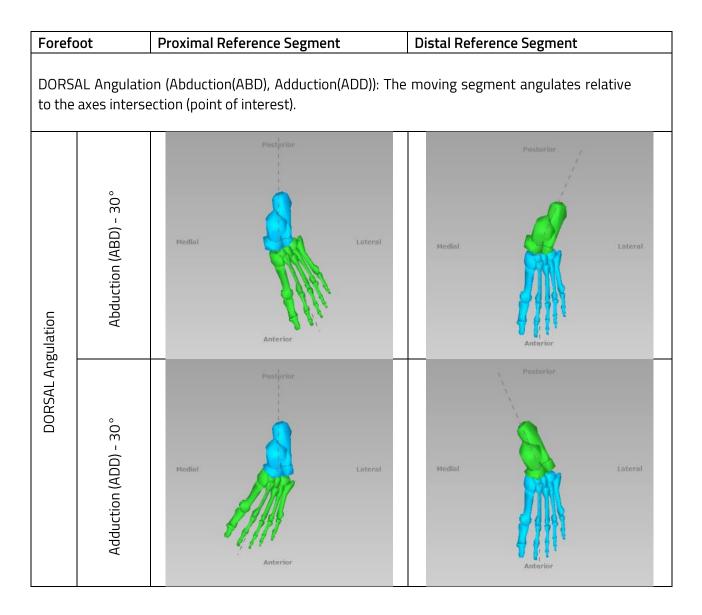
In the following tables, there is a description of how the software interprets the choice of the reference segment (distal or proximal) either for forefoot and hindfoot but, in particular, how the software manages the description of the deformity related to this.

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

NOTE: This will not be done for the representation of the "foot like sticks" since it is more self-explaining.

Forefoot

DORSAL Angulation



LATERAL Angulation

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

LATERAL Translation

AXIAL Translation

AXIAL Rotation

Proximal Reference Segment AXIAL Rotation (Supination, Pronation): The moving segment rotates around its longitudinal axis. | Variable | Vari

Hindfoot

DORSAL Angulation

DORSAL Angulation (Abduction(ABD), Adduction(ADD)): The moving segment angulates relative to the axes intersection (point of interest). | OS - (QQV) | Medial | Medi

LATERAL Angulation

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

LATERAL Translation

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

AXIAL Translation

AXIAL Rotation

Hindfo	Hindfoot Proximal Reference Segment		Distal Reference Segment				
AXIAL Rotation (Varus, Valgus): The moving segment rotates around its longitudinal axis.							
tion	Valgus – 45°	Lateral	Medial	Medial	Dorsal	Lateral	
AXIAL Rotation	Varus – 45°	Lateral	Medial	Medial	Dorsal	Lateral	

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.

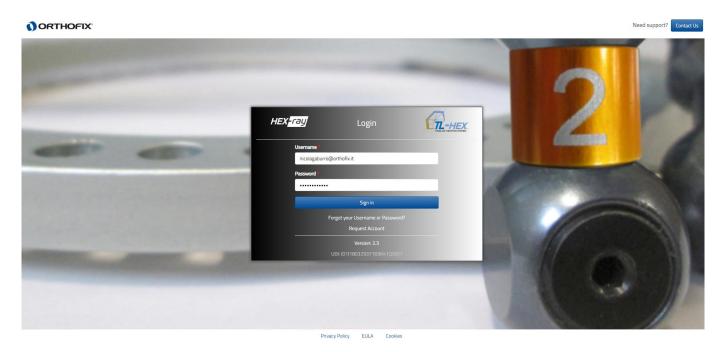
For further information and support, please, send an email to tlhexcustomercare@orthofix.com.

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.





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 for contacting TL-HEX Customer Care.

INSTRUCTION FOR USE



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

notification icon will inform the user about news and new materials available. Hover on the icon to preview the list.



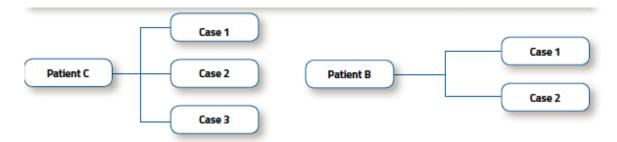
LOG OUT

To log out, just click on the icon

PATIENT AND CASE MANAGEMENT

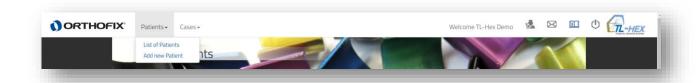
The **Patients** and **Cases** menu includes links to the list of patients or cases, and enables the surgeon to add a new patient or case, respectively.

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



PATIENTS

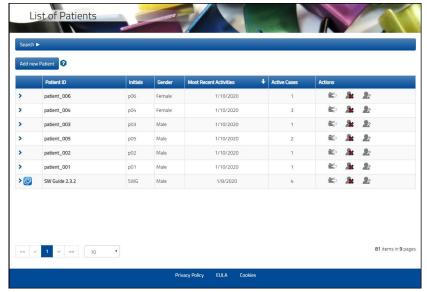
Patients → List of Patients



The List of Patients can be reached 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 most recent date between the case planning creation date and the patient 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.



Click anywhere on a patient row to expand the list of cases related to this patient, grouped by Frame ID.



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.



VIEW/MODIFY PATIENT

Select this option to view or modify the data of an existing patient.

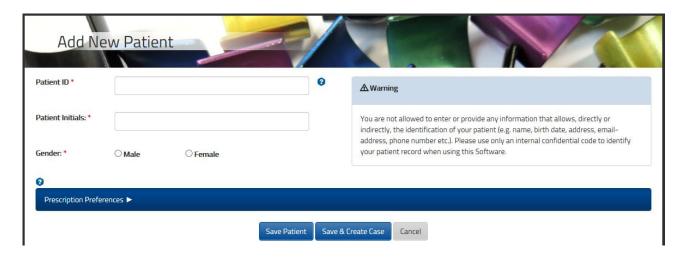
ADD NEW PATIENT

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)

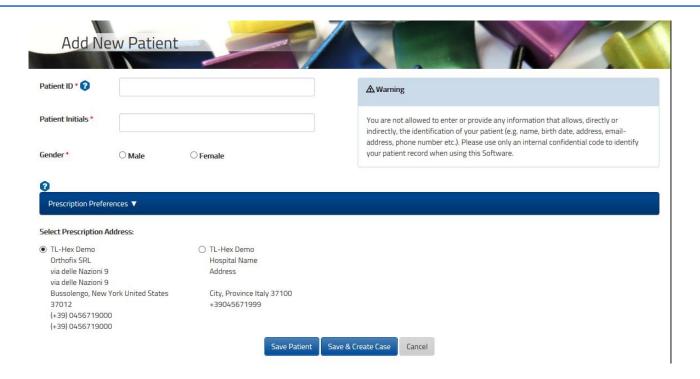


For each new patient, the surgeon should provide the following information

- unique Patient ID
- Patient Initials
- Gender

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon shall <u>never enter information that directly identifies a patient</u>. 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.

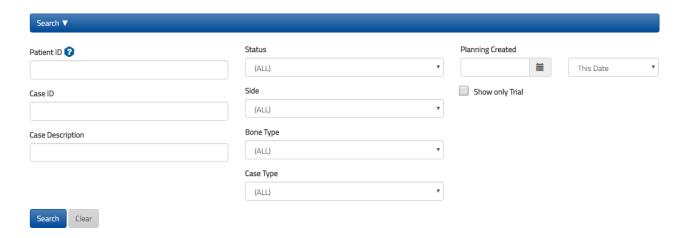


Clicking on the Save Patient button will complete the creation process and open the "List of patients" screen, which will include all previously entered patients as well as the newly created one.

Clicking on the 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 Description, Bone Type, Case 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

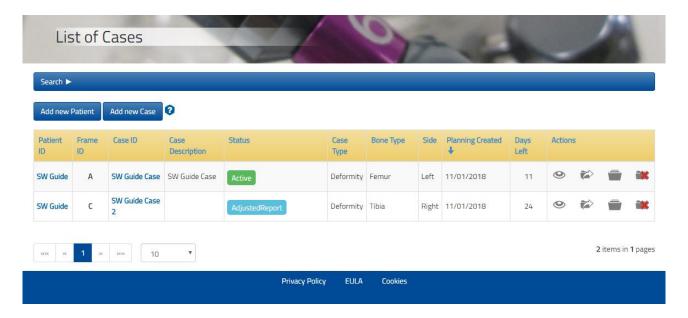
Cases → List of Cases



The list of cases can be reached 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 options:

	Detail
Active	The case can be viewed, modified, deleted, archived or sent to another TL-HEX user.
AdjustedReport	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 to the related case status:

		CASE STATUS			
ACTION		Active	Received	Archived	Adjusted Report
0	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

<u>Archived</u> and <u>Received</u> cases need to be restored to become Active and therefore modifiable.

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

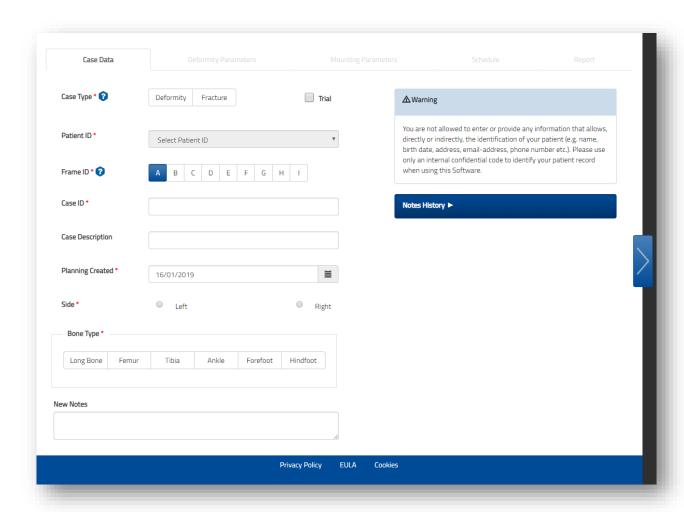
(*) A case can be Upgraded if it has been migrated from one of the previous software versions.

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 a case.



Having selected a Patient, for each new case the surgeon **should assign a unique Case ID for that Patient** and, optionally, a Case Description. Other mandatory fields to be compiled are:

- Case Type: Deformity or Fracture, this will determine the interaction with HEX-ray module (e.g. tools displayed) and will help in filtering the cases. Optionally it is possible to mark the case as Trial; this will help in separating trial cases (e.g. training) from real ones
- Frame ID: Frame identifier to identify applied frame to the patient, especially in case of multiple frames at the same time. Already assigned Frame IDs for that patient are identified with a blue arrow in the bottom right corner of the related label

 ABCDEFGGHI

 I. For the first case associated to a patient, Frame ID is set to Aby default (it is still possible to change it). For subsequent cases for the same patient, Frame ID will be selected by the user.
- Planning Created: for new cases the default is the current date but it can be changed

- Side: left/right
- **Bone Type:** Long Bone, Femur, Tibia, Ankle, Forefoot or Hindfoot. Selection of Femur or Tibia will determine the HEX-ray tools default showing the standard anatomical angles for the chosen bone type and side.

Optionally it is possible to enter **New Notes** associated with this case. Notes cannot be deleted once saved and they will be displayed in the **Notes History**.

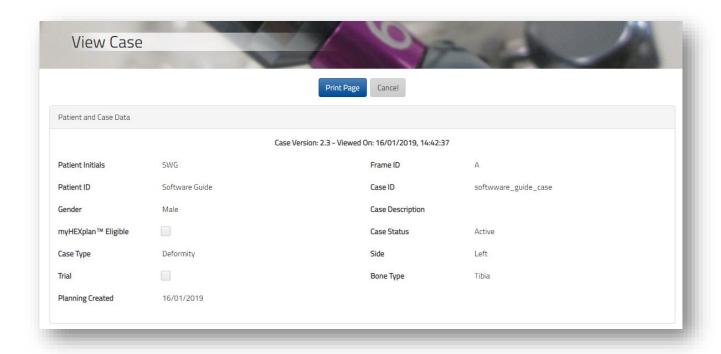
Proceed to the next step in the treatment planning process by clicking on the arrow on the right-hand side.

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon shall <u>never enter information that directly identifies a patient</u>. 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 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 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

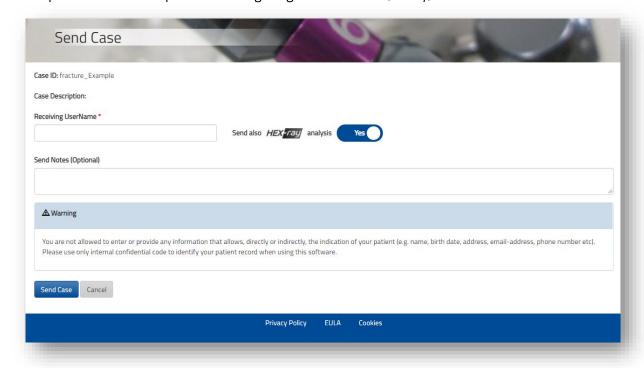
- 1. Click File > Print.
- 2. Click Show Details.
- 3. Next to Orientation, click on the second icon of a man standing sideways.
- 4. Click on Print.

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. If the case is planned with HEX-ray, it is also possible to send the x-ray images along with the HEX-ray analysis using the dedicated option 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 also be displayed in the email body.

In accordance with privacy guidelines, information related to Patient ID, Patient Name, Case ID and Case Description 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





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

RESTORE A RECEIVED CASE



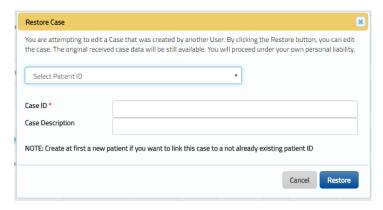
The received case is initially in read-only mode and it can be accessed in view mode by clicking the View Case icon.

However, 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 existing one.

Create a new Case ID and Description.



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



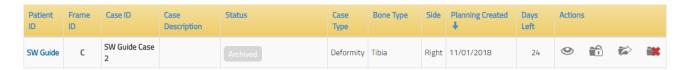
ARCHIVE A CASE

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



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 (HEX-ray analysis included, which will be restored as it was). The report and the prescription need to be recalculated.

Once restored, the new case status is



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.

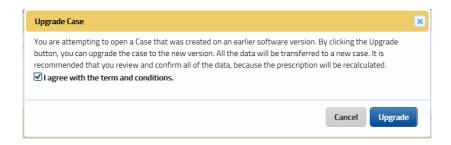


UPGRADE A CASE FROM PREVIOUS VERSIONS TO 2.3

Cases created with prior software versions will be migrated in read-only mode on this version . 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 terms 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 be aware that:

- migrated cases retain postoperative information only, so any preoperative information will be lost
- because the new version includes some improvements on the graphics and label adaption based on bone types, the upgraded new case may differ. Furthermore, some new fields have been added which need to be compiled once the case has been upgraded. The surgeon is highly recommended to review the copied information and confirm them prior to recalculating the prescription.
- in the new version, the algorithm for calculating the prescription has been improved, 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 remains 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.



1.

Define the Case Data details, in particular select the case type, anatomical side and the bone type.

Detail in Case Data section.



2.

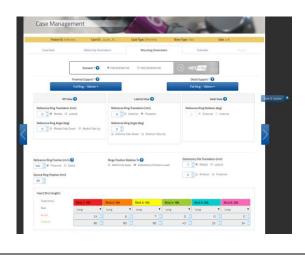
Select the reference segment and provide the deformity parameters to describe and mimic the deformity to treat.

Use HEX-ray module to upload real x-ray images and perform the analysis directly on them.

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.

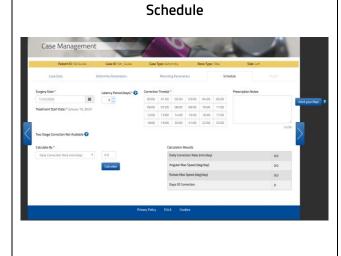
PREOPERATIVE PLANNING - Details in Mounting Parameters – Preoperative Planning section.

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 Assessment section.

Review or provide the parameters to describe how the frame was built on the patients. Preoperative information will be overridden.

Visualize the expected End of Correction results.



4.

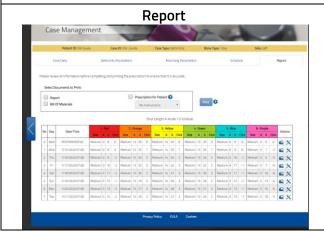
Proceed with the calculus of the prescription through the Schedule Tab by setting time(s) of correction, correction rates or number of days to complete the treatment.

Decide if you wish to proceed with stage treatment by applying shortening/lengthening first, if applicable.

You can also print a document with Print your Plan] which lists the proximal and distal supports and the six strut sizes with their respective Acute and Gradual lengths.

This is particularly helpful to remind you how to pre-build your frame in OR.

Details in *Schedule* section.



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 on 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 to proceed. Where needed, we will highlight any differences 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 Case Type: either Deformity or Fracture. This will determine the interaction with HEX-ray module (e.g. tools displayed) and also help when filtering the cases. Optionally it is possible to mark the case as Trial; this will help in separating trial cases (e.g. training) from real ones.

Select the Patient from the drop-down list.

The Frame ID identifies the applied frame to the patient, especially in case of multiple frames at the same time. Already assigned Frame IDs for that patient are identified with a triangle in the bottom right corner of the related label A B C D E F G H I.

The Case ID must be unique for that patient.

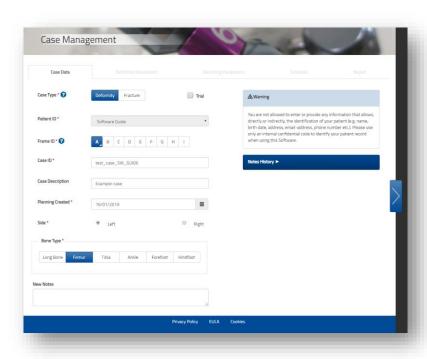
Case Description is not mandatory and can be used, if needed, to add a description about the case.

Change the creation date related to this case (Planning Created), if needed. It defaults to the current date.

Determine the anatomical limb Side, either left or right.

Select the Bone Type applicable for the deformity to be treated; choose between Long Bone, Femur, Tibia, Ankle, Forefoot and Hindfoot. Please, note that selecting Femur or Tibia displays the relative anatomical angles on HEX-ray analysis tools.

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.

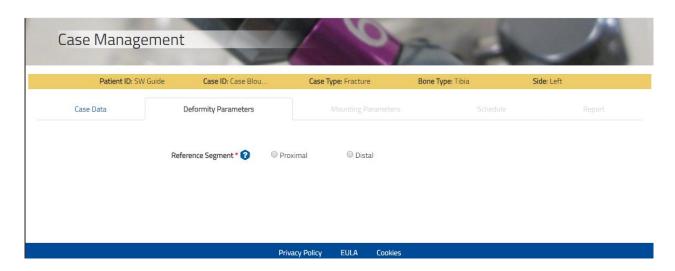
Proceed to the next step in the treatment planning process by clicking on the arrow on the right-hand side. This action, similar to clicking save & Update button, will confirm and save the entered data.

DEFORMITY PARAMETERS AND END OF CORRECTION

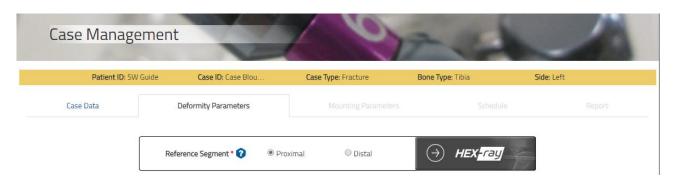
DEFORMITY PARAMETERS

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



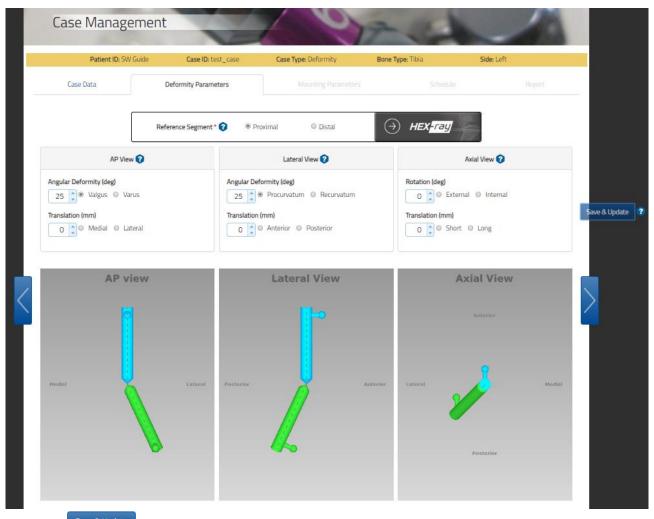
When the reference segment is selected, the uploading x-ray images and performing deformity and mounting analysis. Upon return to TL-HEX, all the parameters will be transferred.



NOTE: DO NOT UPLOAD files that contain any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please anonymize your x-ray image before uploading when using this Software.

If the HEX-ray option is greyed out, i.e. disabled read further information about the reason and understand how to enable it again. For the possible reasons please check the table at the end of the *Few More Things...* section.

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



Click the button after making any changes or updates to deformity parameters in TL-HEX to refresh the display accordingly.

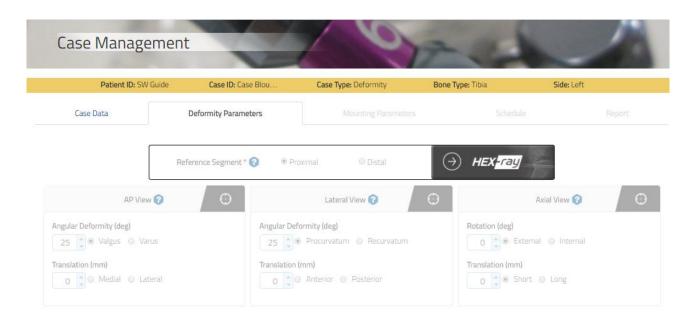
Software will remind you that the images may not be updated and may not represent the entered parameters when you update/change the form by displaying an orange notification under the

button. Save & Update is on the right above the arrow and is enabled when changes have been made to the form. The Save & Update is disabled once the changes have been saved.

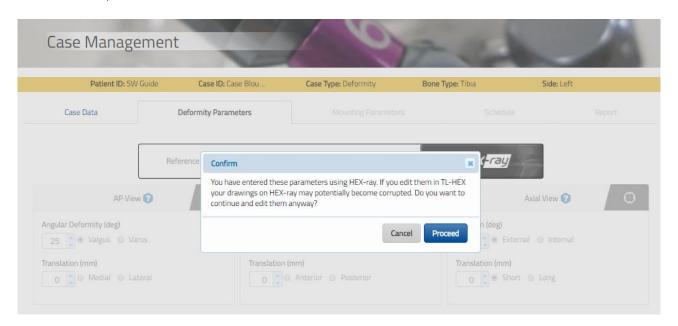
In contrast, is enabled when all the changes on the TL-HEX form have been saved and it is disabled when Save & Update is enabled. This ensures that TL-HEX and HEX-ray are working on the same set of saved data.

If the analysis has been performed in HEX-ray and data has been automatically transferred from HEX-ray,

TL-HEX parameters will be greyed out and the target icon will be displayed to indicate that the values originate from HEX-ray.



Parameters transferred from HEX-ray can be edited and changed in TL-HEX by clicking anywhere on the Reference Segment or on the Deformity/End of Correction View parameters area. The software will remind the user that the changes can corrupt the drawing on HEX-ray and asks for confirmation if the user wants to proceed or not.



Proceed will unblock the fields for further editing. Cancel will leave the parameters as they are.

NOTE: Keeping a consistent singular input flow is recommended.

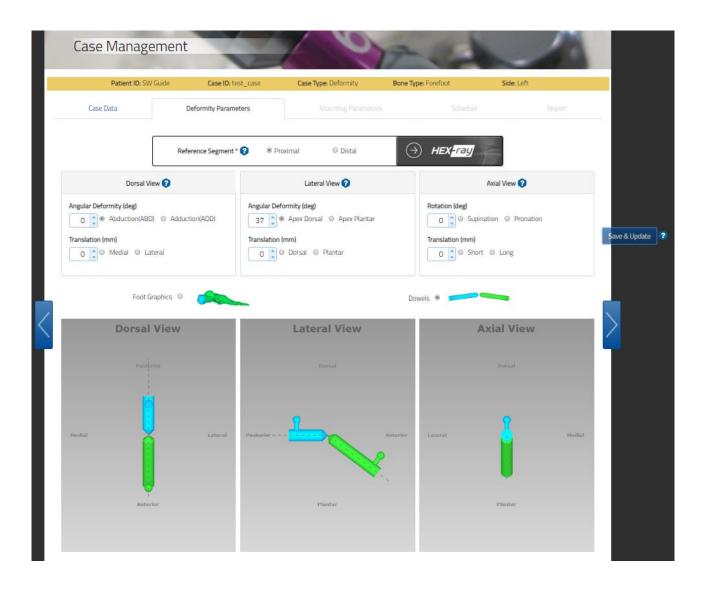
Although possible to mix data flows, the surgeon must be aware that any alteration in TL-HEX will have a potentially conflicting result in HEX-ray. Same logic applies on Mounting Parameters tab.

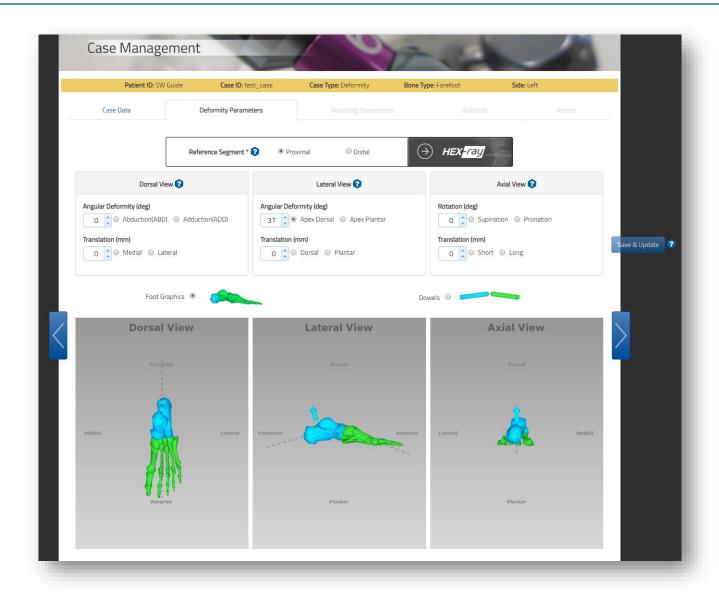
Check to confirm the diagrams on the software correspond to the deformity seen on the patient's X-rays and/or clinically.

DEFORMITY PARAMETERS DEFINITION

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

NOTE: FOREFOOT and HINDFOOT cases can be displayed as either 'Foot Graphics' or 'Dowels' by selecting the relative option (see image below) and updating the views.





The labelling and logic of the 'Dowels' view will be the same as 'Foot Graphics' view but the dowels will display the foot as long bone with a short stick representing the calcaneus and a longer stick representing the forefoot.

Below is a summary of the labelling parameters:

View name	AP View		
Bone type	LONG BONE, FEMUR, TIBIA 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	Valgus	Valgus	
(deg)	Varus	Varus	
Translation	Medial	Medial	
(mm)	Lateral	Lateral	
	AP view AP angulation AP translation Varus Valgus	AP angulation AP translation Varus Valgus	

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) or 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	Abduction(ABD)	Abduction(ABD)	
(deg)	Adduction(ADD)	Adduction(ADD)	
Translation	Medial	Medial	
(mm)	Lateral	Lateral	
	Dorsal View Dorsal angulation Dorsal translation Anterior Adduction (ADD) Abduction (ABD)	Dorsal View Dorsal angulation Dorsal translation Adduction (ADD) Abduction (ABD)	

View name	LATERAL View		
Bone type	LONG BONE, FEMUR, TIBIA ANKLE		
Description	Angular Deformity (deg): Deformity in Sagittal plane depending on whe posteriorly in relation to the reference segment Translation (mm) In the Sagittal plane, the translation can be anterested.		
Angular Deformity	Procurvatum	Equinus	
(deg)	Recurvatum	Calcaneus	
Translation	Anterior	Anterior	
(mm)	Posterior	Posterior	
	Lateral View Lateral translation Anterior Lateral angulation Procurvatum	Lateral View Lateral translation Lateral angulation Calcaneus Equinus	

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 which 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	Apex Dorsal	Apex Dorsal	
(deg)	Apex Plantar	Apex Plantar	
Translation	Dorsal	Dorsal	
(mm)	Plantar	Plantar	
	Lateral View Dorsal	Lateral View	
	Lateral translation Posterior Anterior	Lateral angulation Lateral translation	
	Plantar	Planter	

erally or medially around its longitudinal axis. the rotation is difficult to measure radiologablished clinically. anslation (mm) e Axial translation occurs along the longitudine Short option is applicable when the moving bone segment reference.	ogically, this parameter will be most commonly
formity in Horizontal or Transverse plane deperally or medially around its longitudinal axis. the rotation is difficult to measure radiologicalished clinically. Anslation (mm) A Axial translation occurs along the longituding short option is applicable when the moving the bone segment reference. B Long option is applicable when the moving the longituding the long option is applicable when the moving the long is applicable when t	ogically, this parameter will be most commonly hal axis of the limb. bone segment is translated (<i>compressed</i>) towards
External External Internal	
Short Short	
Long	Long
Axial view Anterior Axial Rotation Medial Posterior Axial Rotation	Axial View Axial Rotation External
	Internal Short Long Axial view Anterior Axial Rotation Medial

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	Short Short		
(mm)	Long	Long	
	Axial View Dorsal	Axial View	
	Lateral Medial Axial Rotation	Axial Rotation	
	Supination Pronation	Varus Valgus	

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 displayed at the bottom of the Deformity screen.

The three graphic view boxes display the position of the bone segments expected at the end of the treatment (deformity correction).

The section can be collapsed by clicking on the blue bar.

As default, at the end of the deformity correction referring to *long bone, femur, tibia* 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.

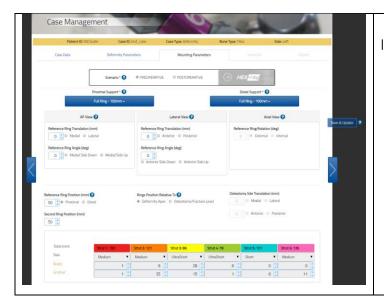


Click the button at any time to refresh the display after entering or reviewing the parameters.

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.



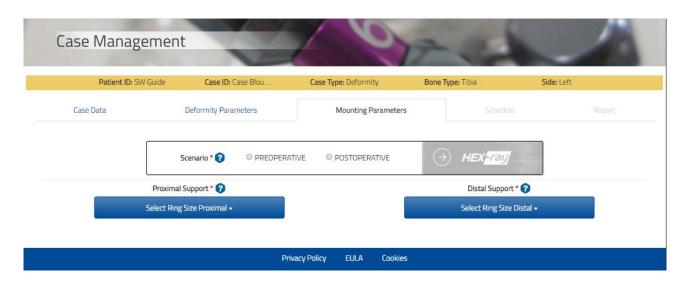
In this tab, the surgeon can:

- 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
- Use the HEX-ray option to perform a preoperative planning or postoperative assessment.
- 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 reviewed the information with the postoperative information, this update overrides the previous ones used and calculated during the preoperative planning.

PLANNING MANAGEMENT AND SUPPORTS SELECTION

Prior to visualizing the Mounting Parameters, the mandatory step is to select both Supports, Proximal and Distal, and the Preoperative or Postoperative scenario.



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 scenarios:

If PREOPERATIVE (Second Ring Position) scenario is selected



- o 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.
- o The Second Ring is assumed to be perpendicular to the corresponding bone segment axis
- o 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.
- o Based on the Reference Ring position, parameter values and the Second Ring Position, when the surgeon clicks 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) scenario is selected:

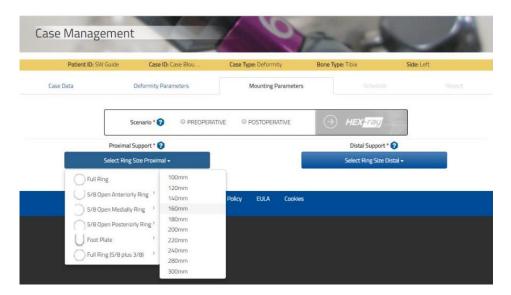


- The reference ring can be angulated based on the user preference and any rotation of the Ring Orientation Tab related to the longitudinal axis of the reference bone segment can be managed.
- o The reference ring is located by default 50 mm, or the value input during the preoperative planning phase,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

Symmetrically to the Deformity Parameters tab, in the Mounting Parameters section it is possible to use HEX-ray option to continue the analysis from the frame building point of view.

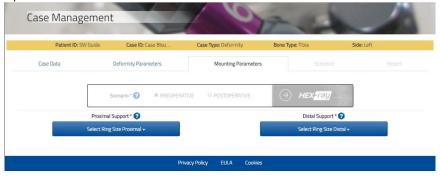
Same indications about HEX-ray option availability and target icons, described previously, also apply here. Furthermore, HEX-ray icon is disabled in this case, unless you have completed and locked your HEX-ray analysis until Correction (for the coherent scenario).

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

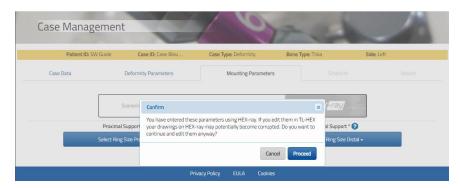


NOTE: If choosing two 5/8 rings, it is better not to choose the openings in the same direction because the proposed solution may not be applicable on a patient due to the position of the struts that can pass through the soft tissues. The surgeon must check the feasibility of the frame before applying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

In case the Deformity Analysis has been done using HEX-ray, the scenario is already set as selected when uploading the x-rays

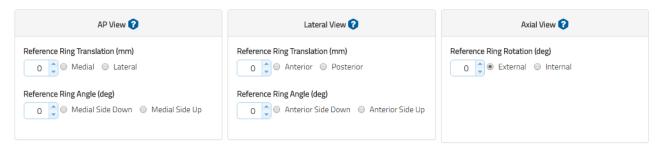


Conditional to the confirmation to proceed, it is possible to change the scenario already set.

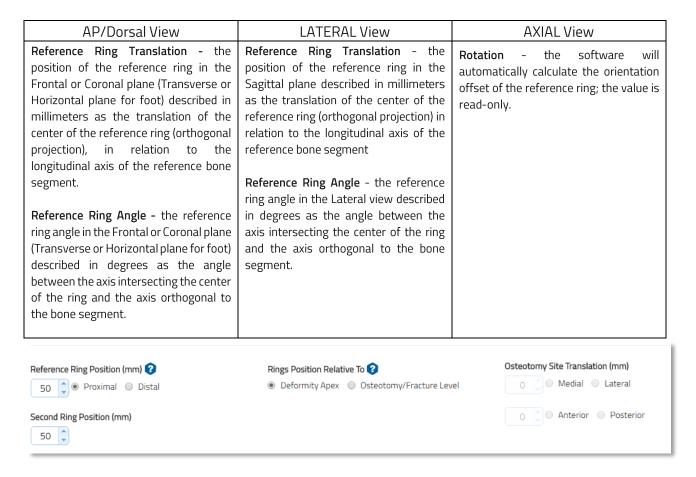


PREOPERATIVE PLANNING

The screen provides the option to adjust:



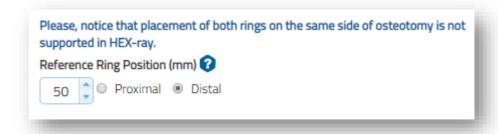
The parameter is described according to the selected bone type. This parameter can be used both for Preoperative and Postoperative Planning.



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).

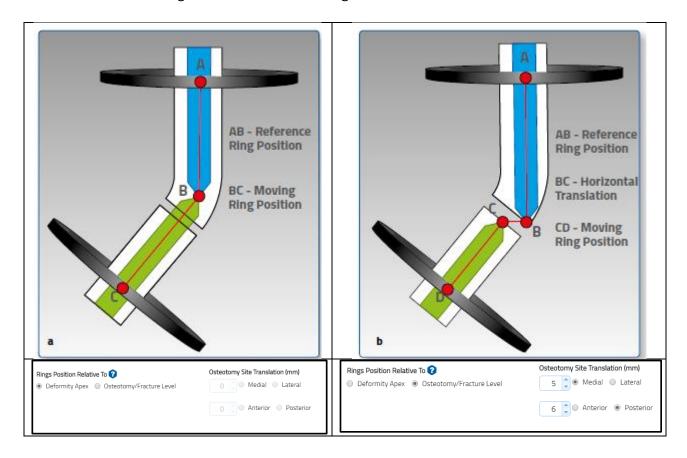
NOTE: if Reference Segment value and Reference Ring Position direction are not equal (e.g. Reference Segment distal and Reference Ring Position proximal), a warning is displayed to remind that this configuration (available in TL-HEX) is not supported in HEX-ray.



NOTE: For anatomical *Forefoot* and *Hindfoot* representation, 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.

In these cases, it can be useful to select the option 'Dowels' and describe deformity and mounting parameters by placing the sticks and their point of reference in their appropriate places in order to better model your case.

• 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)).



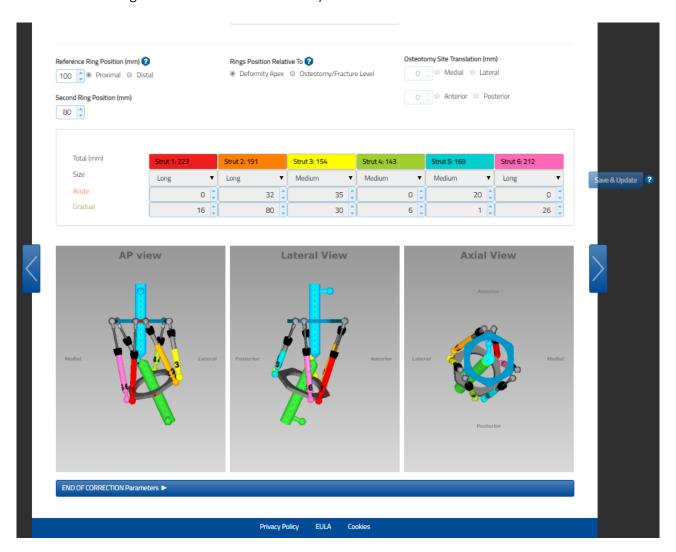
Either the apex of deformity or the level of the osteotomy/fracture can be chosen as the point of interest. If the point of interest is 'Osteotomy/Fracture level', the two fields in the 'Osteotomy Site Translation' 66

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 on the osteotomy site depending on the distance between the point of interest and deformity apex.

At this point, clicking the 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 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.



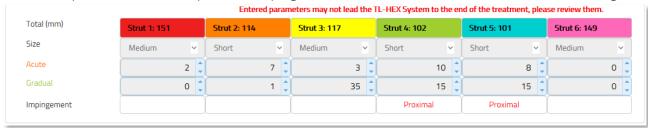
Enlarge the END OF CORRECTION Parameters bar to verify if an out-of-range is present.



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.



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



NOTE: the impingement information should be considered as an informative guideline and not a substitute for the surgeon's experience and review.

Surgeon is highly recommended to review the Mounting Parameters in order to address any highlighted warning prior to building the frame and then proceeding with the postoperative phase.

POSTOPERATIVE ASSESSMENT

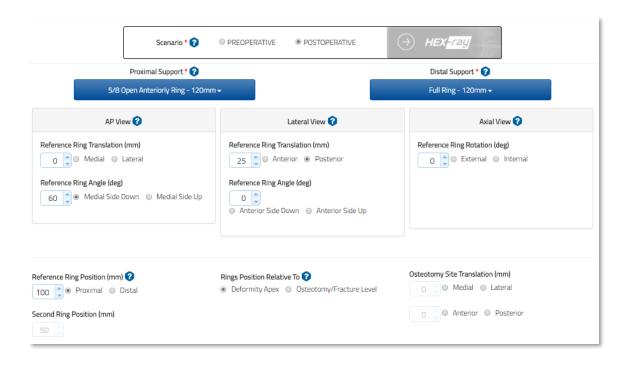
Whenever the surgeon has completed the preoperative planning or he/she has already applied the frame directly on the patient using the postoperative X-rays, he/she has to confirm and/or review the mounting parameters.

In particular, the surgeon is requested to select POSTOPERATIVE scenario in order to insert strut lengths.



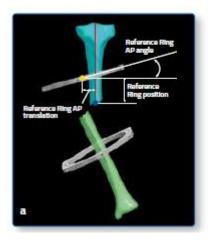
It is important to highlight that even if the surgeon went through a preoperative planning, when he/she reviews the information with the postoperative information, the ones used and calculated during the preoperative planning are overridden.

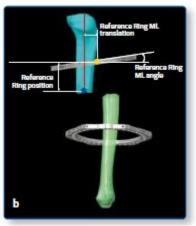
NOTE: The Postoperative mode makes the Reference Ring Rotation and strut sizes and acute/gradual values editable.

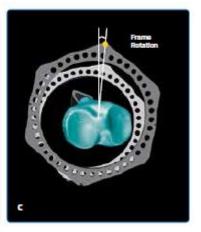


In Postoperative, the surgeon has to review or provide:

- o **Reference Ring Parameters** in the three projections AP/Dorsal, Lateral and Axial views, including any eventual Ring Orientation Tab rotation.
- o 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

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.

LATERAL View

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.

AXIAL View

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.

o **Strut** parameters_

- 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 exceeds 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 Save & Update 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.

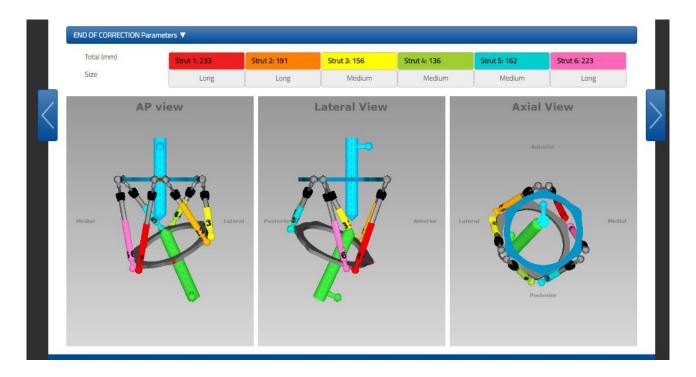
We suggest that in order to easily collect the data, you use the Patient ID form that can be downloaded by accessing the reserved area of the TL-HEX site (click on the Instruction for Use icon).

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 see how the treatment and construct is supposed to end. This simulation takes into account 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 terms of strut type and total length. This is helpful information, especially while running a preoperative plan to visualize strut exchanges, if any.



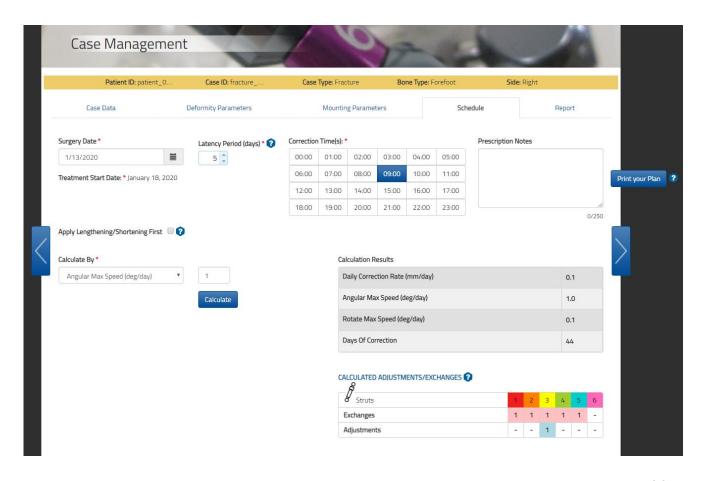
NOTE: The report should be used as reference for final strut position (Acute and Gradual) and strut size.

SCHEDULE

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

Those parameters include:

- Daily correction rate (mm/day): this parameter is available if a lengthening or shortening is required.
- **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)



Treatment start date may be adjusted using **Latency Period** (days), and up to four (4) **Correction Time(s)** 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 solution using decimals.

Along with the Calculation Results, there is a table that recaps any strutexchanges/adjustments that may occur during the treatment.

The CALCULATED ADJUSTMENTS/EXCHANGES table lists for each of the six struts any possible strut exchange or strut adjustment, Furthermore, if present along the treatment, strut impingements and out of range will be displayed.

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 clicking the

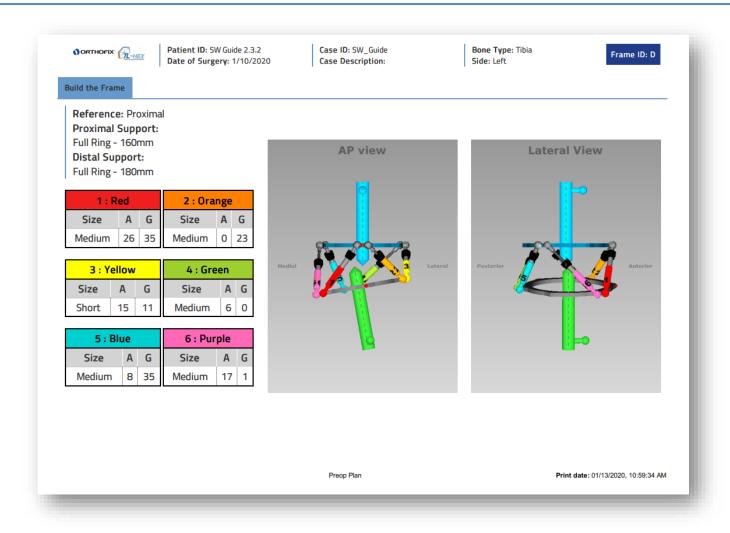


button. A warning message will appear if no value was chosen in either of these boxes.

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).

button allows the user to print a document that summarizes the information needed to pre-build the frame:

- Reference Segment
- Proximal Support type and size
- Distal Support type and size
- Initial strut sizes and lengths (Acute and Gradual)
- AP/Dorsal and Lateral representations of how the frame should look



In the **Prescription Notes** text box, the surgeon has the option of entering notes related to the current case that will be printed on the top right corner of the Prescription issued to the patient. In the Prescription Notes, text can be entered up to 250 characters. A counter on the bottom right corner

APPLY LENGTHENING/SHORTENING FIRST

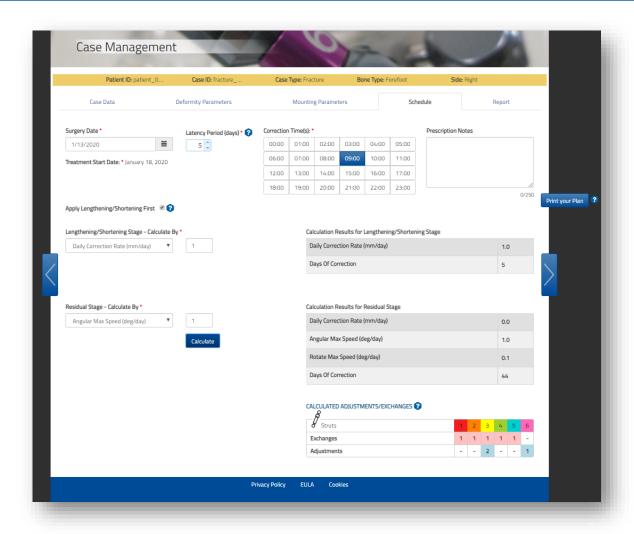
under the text box shows how many characters have been entered.

Clicking the 'Apply Lengthening/Shortening First' checkbox, 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.

'Apply lengthening/Shortening First' is available when either Axial Translation or Bone Length parameters are not zero and they are not equal, i.e. there is a deformity in Axial view to be corrected and/or an End of Correction lengthening/shortening to be introduced.

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

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



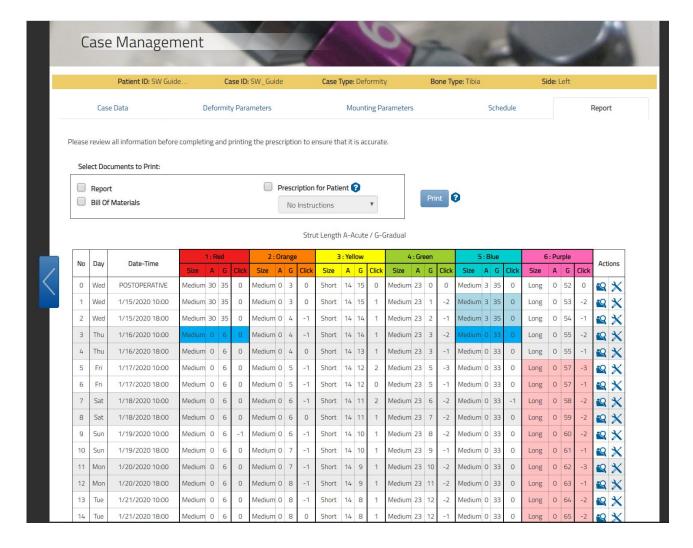
REPORT

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

- Strut size with acute and gradual adjustment values in millimeters and number of clicks.
- Strut 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 (Report), the prescription for the patient (see Prescription section) and the Bill of Materials (see Bill of Materials section).



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 strut 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.

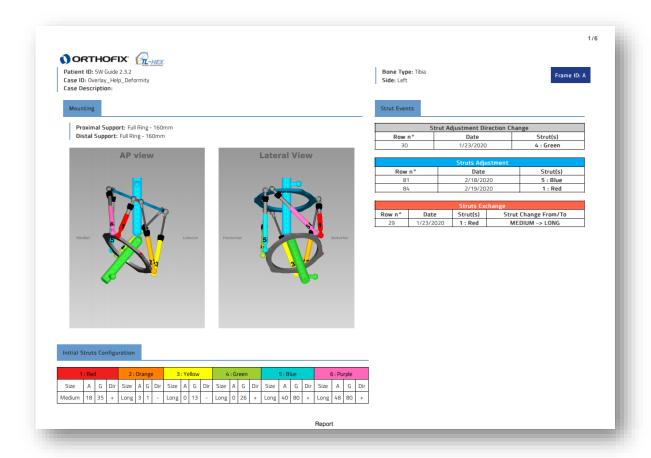


With this option you can edit, on any report step, the Acute and Gradual pairs with a proposed solution ('Propose strut' button) or enter directly the acute and gradual values for a strut given its current length. This functionality allows for printing of the new prescription with the changed values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

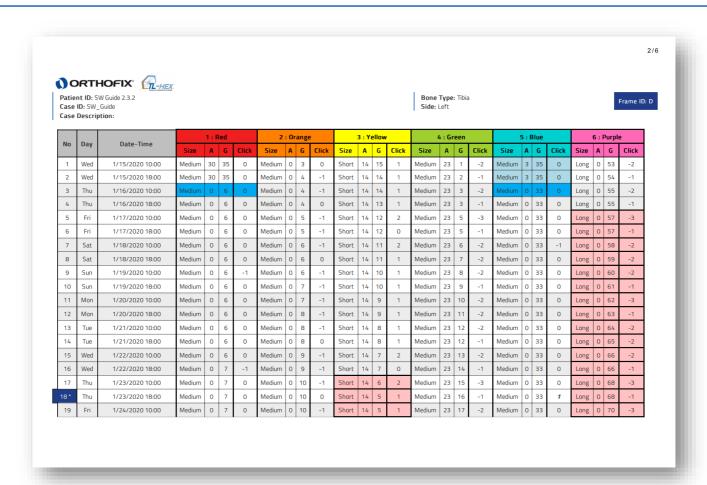
The Surgeon can print the Report by selecting it from the "Select Documents to Print" section and then clicking on the Print [Print] button; it generates a PDF file of the report screen and is intended for the surgeon to print and maintain a hard copy as a permanent record for the patient's file.

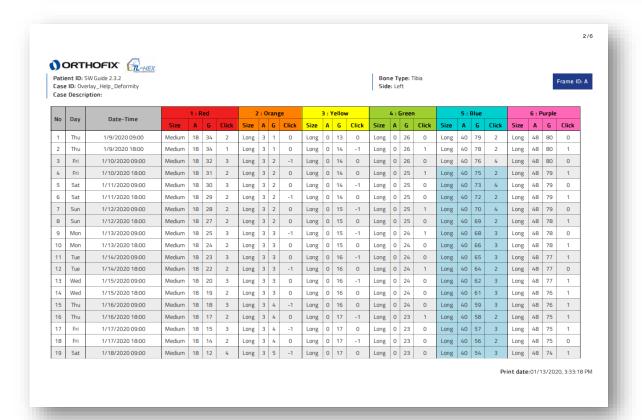
The Report consists of a first-page cover that recaps:

- Mounting section with:
 - Proximal and Distal support types and sizes
 - o AP/Dorsal and Lateral representation of the initial frame configuration
- Initial Strut configurations with:
 - o Size, Acute and Gradual values, and initial click direction for each strut
- Strut Events table sorted by date with:
 - List of Strut direction changes
 - List of Strut adjustments
 - List of Strut exchanges



The remaining page(s) report for each day and time of correction the Size, Acute, Gradual and Click value for each strut





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 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

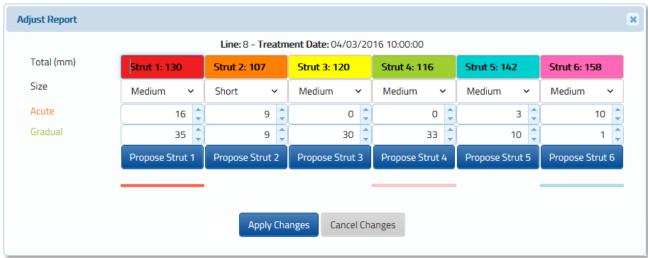
The prescription/report rows will be highlighted when strut adjustment (shaded blue) or exchange (shaded red) is required or suggested.

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 existing 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 adjust/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 can be exchanged 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 by 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).

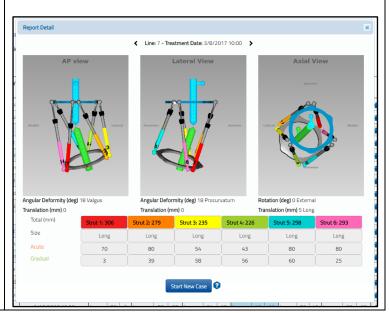
By clicking on the arrows above the images, it is possible to go back and forward in the report and go through the lines to see how views and details change during the correction.

When the Start New Cas

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.

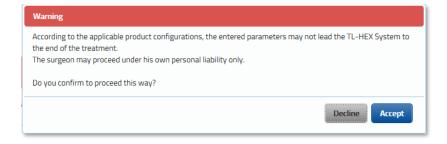
The standard software steps are now followed to complete the new planning from this starting point. The surgeon should check and adjust Deformity Parameters if necessary. The surgeon should proceed to the Mounting Parameters section where mounting parameters and strut parameters should be verified and 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 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.

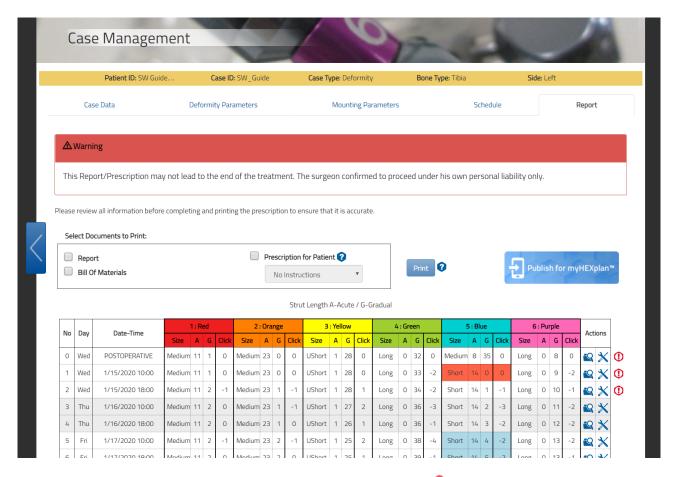
Generally, these situations originate from potential hardware impingements (struts and rings) and outof-range struts.

NOTE: Impingements between external supports are not evaluated.



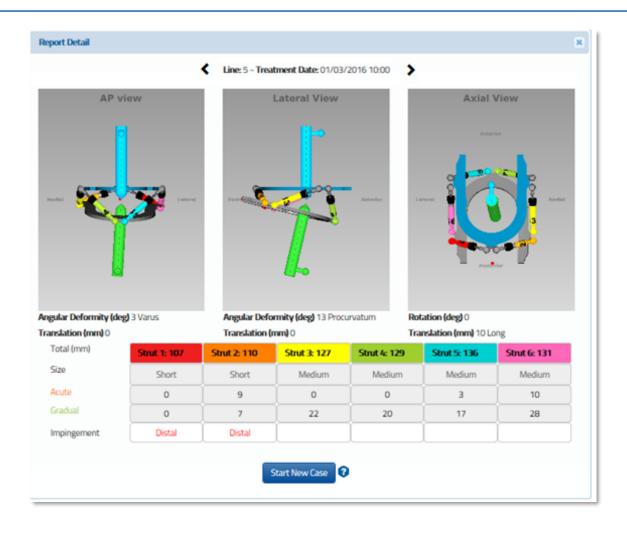
The user is allowed to proceed by clicking the button under his/her own liability only.

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 occurrence icon.



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 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; a copy can also be saved for the record. Along with the adjustment schedule for the patient comes an initial cover page that lists the initial strut Gradual values along with the clicks direction (+ or -).

The surgeon can select the option to provide a visual representation on how to perform strut clicks choosing between two images from the "Prescription for Patient" drop down menu.



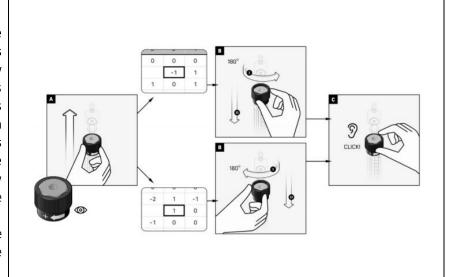
Instructions with Knobs

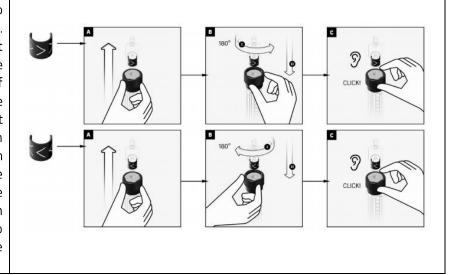
Use this option if you want the patient to follow the strut's direction knob. Patient should pay attention to the signs of the Click's values. If the sign of the Click is positive, the patient must perform the indicated number of Clicks following the Knob direction; if the sign of the Click is negative, they must perform it in the opposite direction.

Surgeon should instruct the patient about how to handle direction changes.

Instructions with Clips

Use this option if you plan to attach direction clips on the struts. With this option the patient must always follow the direction of the clip when performing the clicks. If any strut direction change happens during the treatment (highlighted on the prescription and report with a blue cell and * on first cell and reporting in italics the click with a direction change), the surgeon shouldschedule appointment with the patient to change the orientation of the involved clips.





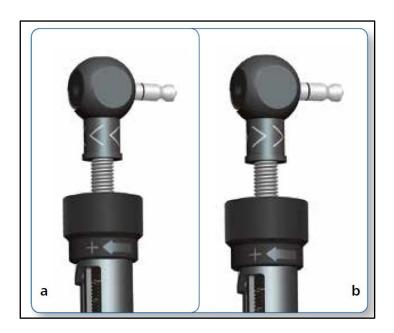
If the Surgeon selects "No Instructions" the printed Prescription will not display visual instructions..

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.

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 clip direction 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 clip's direction themselves.

In the prescription, the n° of day(s) and the strut Click value(s) in which a direction change happens are highlighted with the first (NO) blue cell and *, while the affected strut click will be written in italics.

rthofix ia delle Nazior ussolengo, Ve 456719000,	ni, 9 rona, Italy, 37012	Case ID: SW_Guide Case Description: Bone Type: Tibla Side: Left											rame ID		
	_		1	Strut Ad	djustme:	nt in 'CL 4	ICKS' (a 5	6		1	Strut	Referen	ce Leng	th (b)	6
No	Day	Date-Time	Red	Orange	Yellow	Green	Blue	Purple		Red	Orange	Yellow	Green	Blue	Purp
16	Wed	1/22/2020 18:00	-1	-1	0	-1	0	-1		7	9	7	14	33	66
17	Thu	1/23/2020 10:00	0	-1	2	-3	0	-3	П	7	10	6	15	33	68
18 *	Thu	1/23/2020 18:00	0	0	1	-1	1	-1	П	7	10	5	16	33	68
19	Fri	1/24/2020 10:00	0	-1	1	-2	0	-3	П	7	10	5	17	33	70
20	Fri	1/24/2020 18:00	0	-1	1	-1	0	-1	П	7	11	4	17	33	70
21	Sat	1/25/2020 10:00	0	-1	1	-3	0	-3	П	7	11	4	19	33	72
22	Sat	1/25/2020 18:00	0	-1	1	-1	0	-1	П	7	12	3	19	33	72
23	Sun	1/26/2020 10:00	0	-1	2	-2	1	-3	П	7	12	2	20	32	74
24	Sun	1/26/2020 18:00	0	0	0	-1	0	-1	П	7	12	2	21	32	74
25	Mon	1/27/2020 10:00	-1	-1	2	-2	0	-2	П	7	13	1	22	32	75
26	Mon	1/27/2020 18:00	0	-1	1	-1	0	-2	П	7	13	1	22	32	76
27	Tue	1/28/2020 10:00	0	-1	1	-3	1	-2	П	7	14	0	24	32	77
28	Tue	1/28/2020 18:00	0	-1	0	-1	0	-2	П	7	14	35	24	32	78
29	Wed	1/29/2020 10:00	0	-1	1	-2	1	-2	П	7	15	34	25	31	79
30	Wed	1/29/2020 18:00	0	-1	1	-1	0	-2	П	7	15	34	26	31	80
31	Thu	1/30/2020 10:00	0	-1	2	-2	1	0	П	7	16	33	27	31	0
				rescription											

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 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.



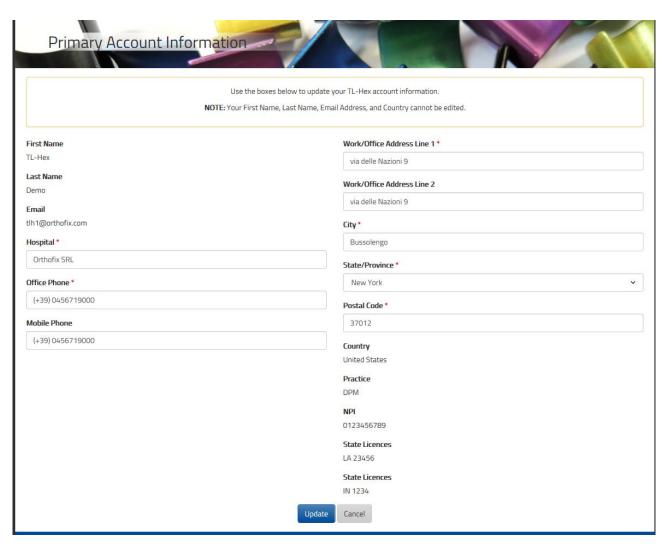
ACCOUNT MANAGEMENT

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

- Display and change account information: go to the section "Edit Account Information". In case 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

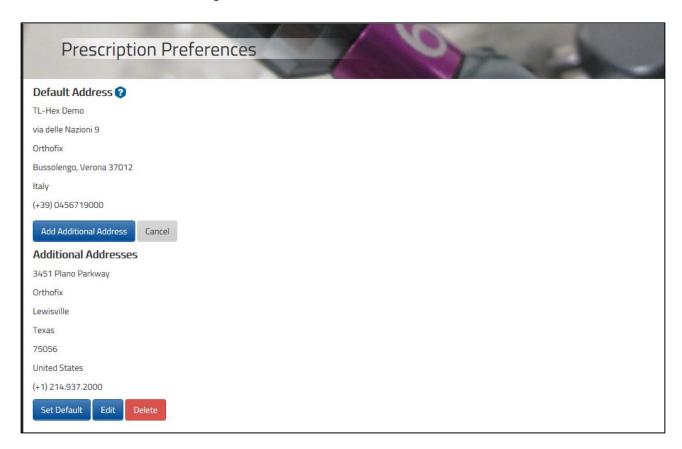
EDIT ACCOUNT INFORMATION

The user can update information about his account. Click on after the updates are 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.

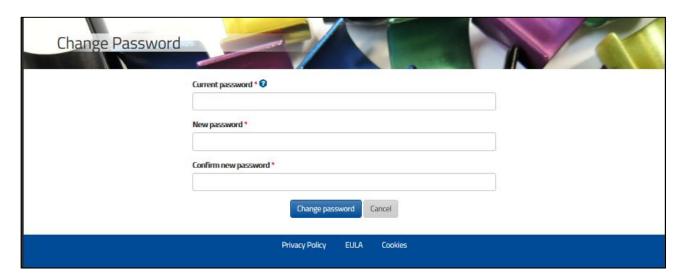
The Change Password screen appears by clicking on the Manage Account icon to change Password.



Simply enter the current password, enter and confirm the new password, then click Change Password.

Password must be six or more characters and 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 enhance confidentiality is to ensure password integrity by changing it at regular intervals and by keeping the password as secure as possible.



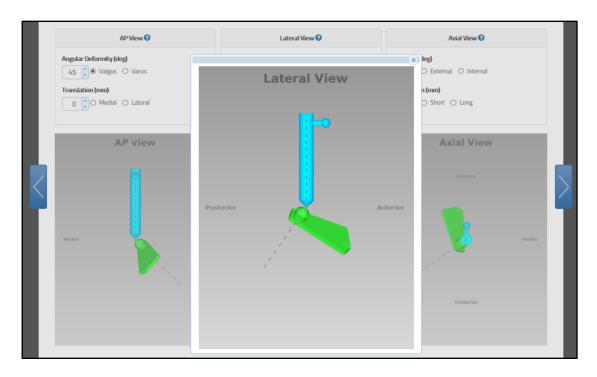
Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon should never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

ONLINE HELP

Online help is available by clicking on ${ rac{ { \circ }}{ }}$ 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 the 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 a good practice to click the parameters. This will provide visual confirmation that the changes are as intended. Regardless of whether the Save & Update 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 is 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.



• In case of temporary loss of internet connection, 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. If the session expires, the surgeon should close the internet browser, then reopen browser, clear the browser history, open TL-HEX application and login.

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HEX-ray DISABLED: REASON & POSSIBLE SOLUTION

\Rightarrow	HEX <mark>-ray</mark>	

REASON	POSSIBLE SOLUTION
You have entered or changed a value on TL-HEX form	Save the data with accessing Hex-ray
You do not have the minimal screen resolution of 1280 x 768 pixels or higher indicated in the Display Settings of this document	Change your screen resolution from screen settings of your device, if possible. If you are already using a maximum resolution, change the device on which you are using TL-HEX in order to achieve at least the minimal screen resolution needed.
You do not have WebGL library on your browser	Please see HEX-ray guide for further reference about this topic.
You are in Mounting Parameter section and you have not yet accessed Hex-ray in Deformity Parameters tab in preoperative or postoperative scenario	Load x-ray images in the coherent scenario or, if you have already done it, complete and lock your Correction analysis in HEX-ray.
Your case is a check-up case	HEX-ray is not enabled for Check-up cases. If you want to use HEX-ray you need to create a brand new case and copy the needed values in order to recreate your case.



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www.tlhex.com

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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.

