

Software User's Guide

Software Version 1.5

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

The applicable End User License Agreement can be found at: <http://tlhex.com/policies/Eulapolicy.html>

The applicable privacy policy can be found at: <http://tlhex.com/policies/privacypolicy.html>

Security Precautions:

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

Computer System Requirements

Display Settings:

Screen resolution of 1280 x 768 pixels or higher.

Supported Browsers:

Microsoft Internet Explorer®: Version 10 or 11

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

Safari® 8

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

Internet Connection:

Minimum required internet connectivity speed is of 512kbps.

Recommended internet connectivity speed is of 3mbps or higher.

My Username:

My Password:

Table of Contents

UNDERSTANDING TL-HEX SOFTWARE VERSION 1.5	4
TL-HEX SYSTEM OVERVIEW	6
INTRODUCTION	6
SOFTWARE	6
HARDWARE	6
STRUTS	7
RINGS & FOOTPLATES	8
RING ORIENTATION TAB	9
HOW TO MOUNT THE FRAME	10
NOMENCLATURE	16
FOOT NOMENCLATURE	19
WEBSITE NAVIGATION	30
OBTAINING ACCESS AND INFORMATION	30
GETTING STARTED ... HOW TO LOG IN	30
NAVIGATION MENU	31
MANAGE ACCOUNT	31
CONTACT US	31
INSTRUCTIONS FOR USE	31
LOG OUT	31
PATIENT AND CASE MANAGEMENT	32
PATIENTS	32
SEARCH	35
CASES	36
CASE PLANNING	44
CASE DATA	45
DEFORMITY PARAMETERS AND END OF CORRECTION	47
MOUNTING PARAMETERS	56
SCHEDULE	66
REPORT	68
ACCOUNT MANAGEMENT	77
ONLINE HELP	79
FEW MORE THINGS	80

UNDERSTANDING TL-HEX SOFTWARE VERSION 1.5

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

For new users

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

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

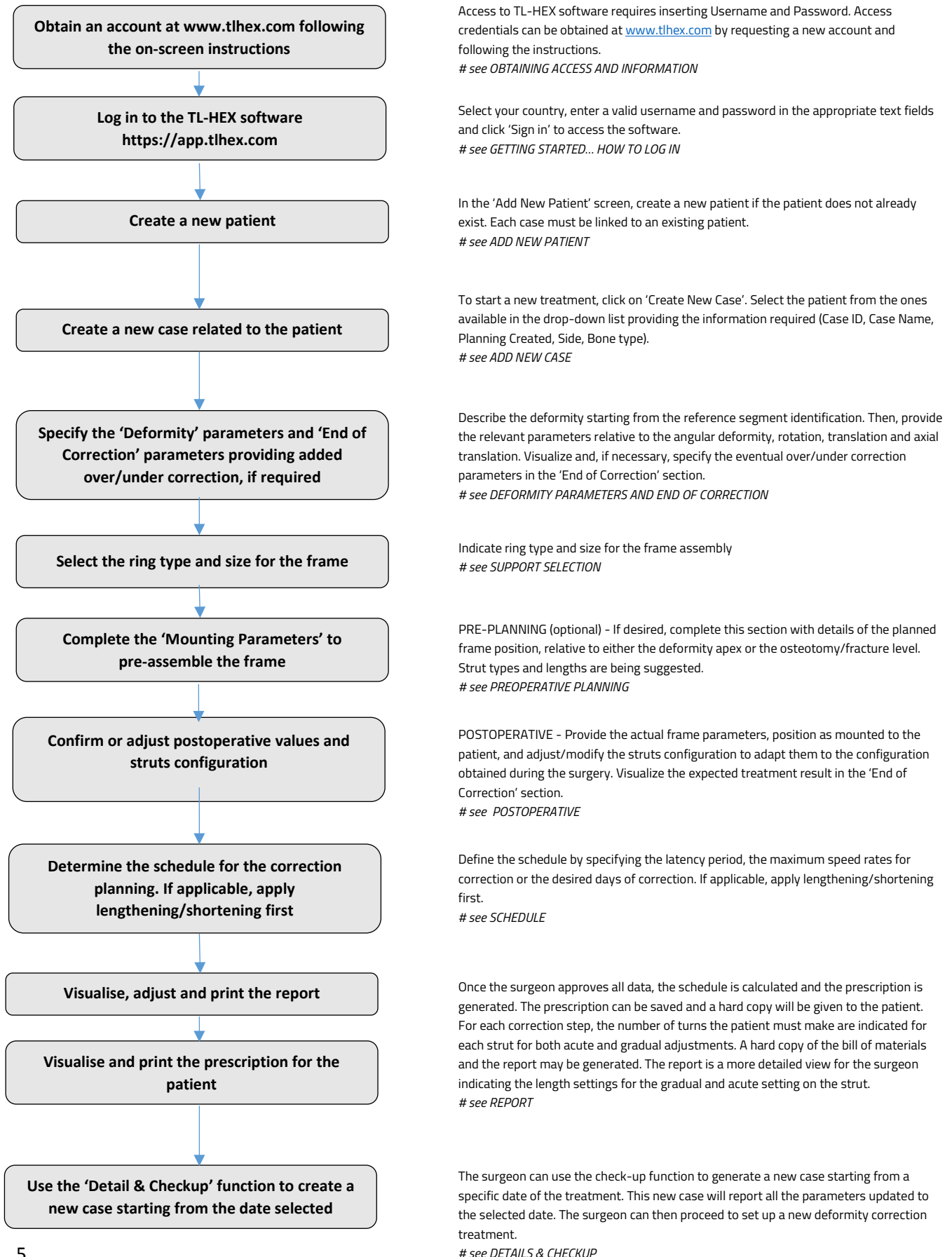
For experienced TL-HEX users

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

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

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

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



TL-HEX SYSTEM OVERVIEW

INTRODUCTION

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

SOFTWARE

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

HARDWARE

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



Fig.1 TL-HEX application with two rings and six variable length struts

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

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

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

STRUTS

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

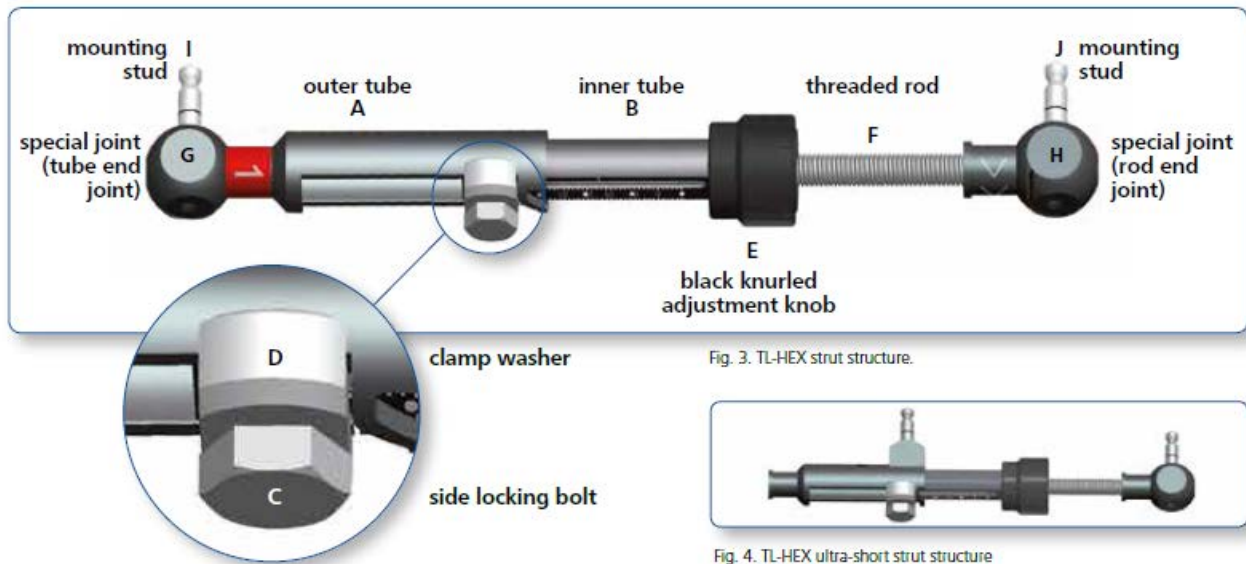


Fig. 3. TL-HEX strut structure.

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

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

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

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

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

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

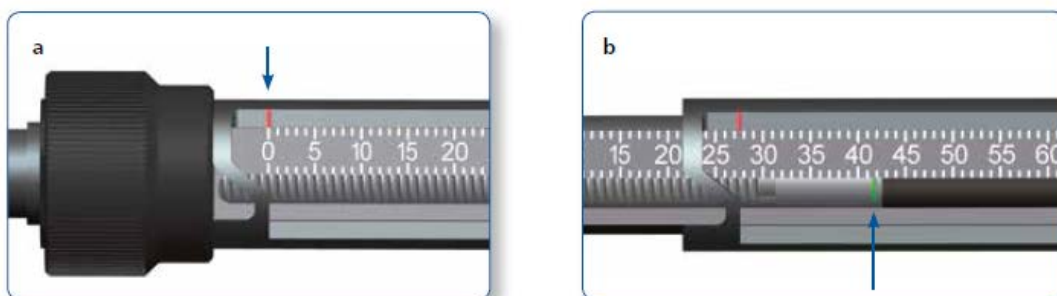


Fig. 5. Indicators for acute (a) and gradual (b) adjustments on the TL-HEX struts.

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

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

RINGS & FOOTPLATES

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

Full rings and Footplates

Each full ring has:

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

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

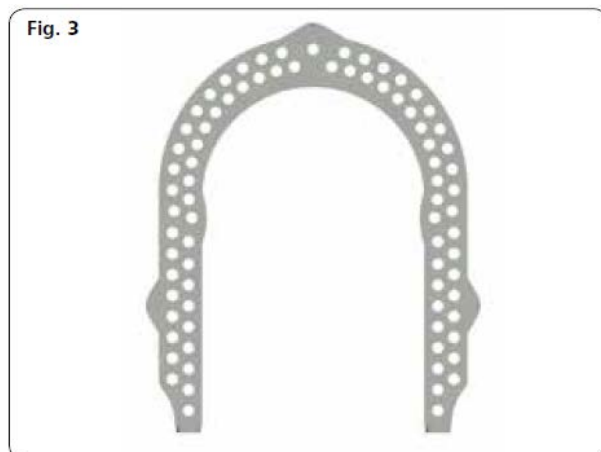
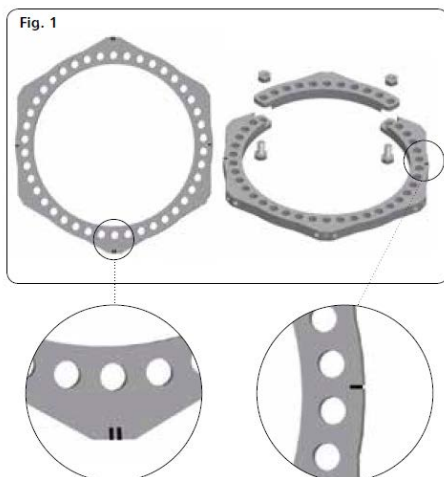
5/8 rings and 3/8 component

Each 5/8 ring has:

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

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

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

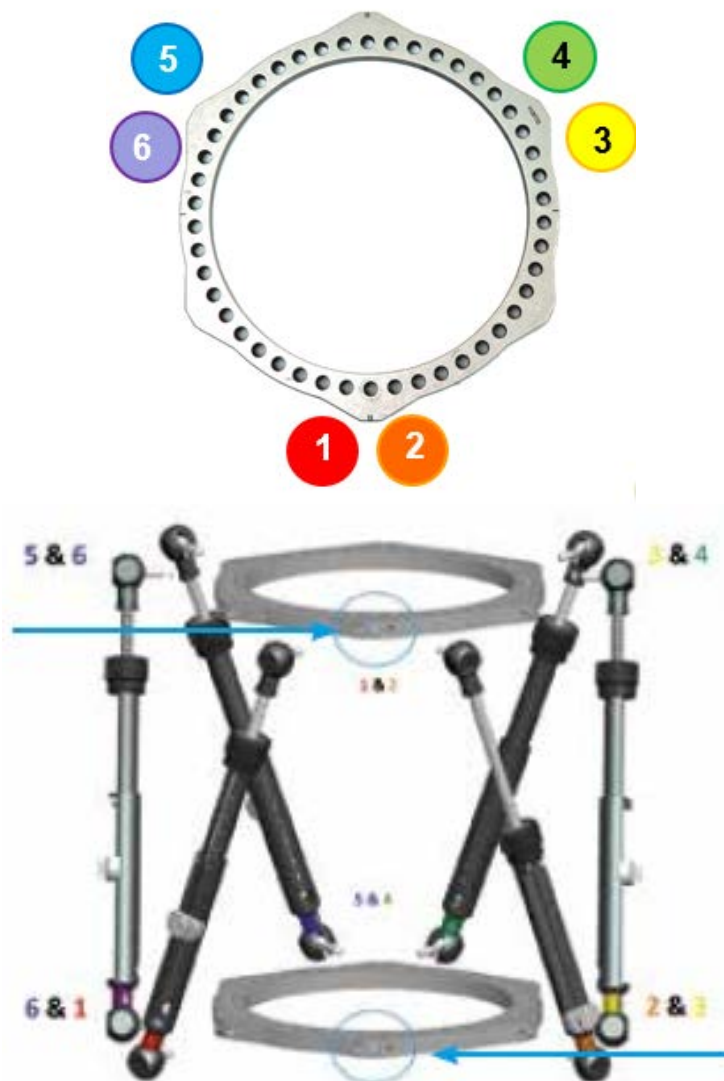


RING ORIENTATION TAB

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

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

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



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

HOW TO MOUNT THE FRAME

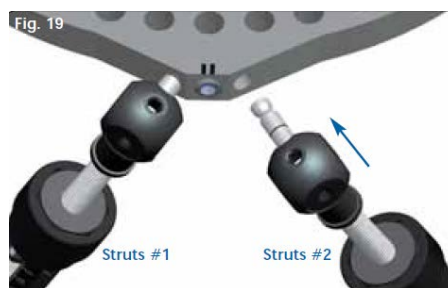
For proper identification, the struts are numbered using color number clips. The clips are numbered from 1 to 6 and colour coded as **red** (1), **orange** (2), **yellow** (3), **green** (4), **blue** (5) and **purple** (6).

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

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

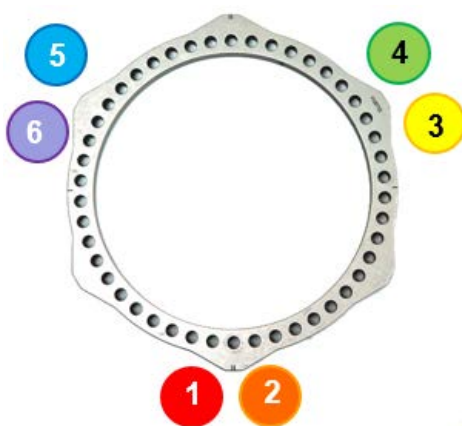
Full Ring and 5/8 Open Posteriorly Ring

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

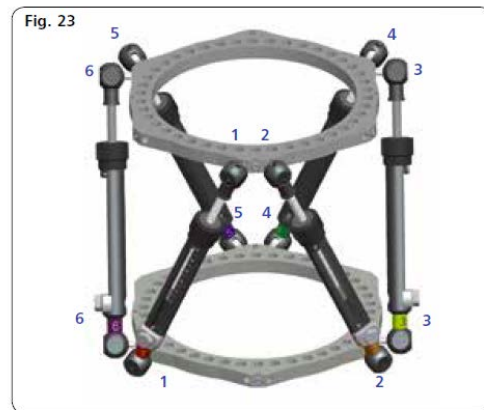
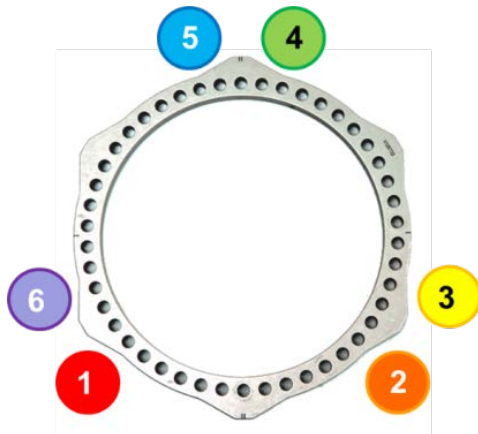


Full rings and 5/8 Open Posteriorly rings, while the ROT is always placed anteriorly.

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



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



5/8 Open Anteriorly Ring

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

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

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

		Left	Right
Proximal support:			
<i>5/8 Open Anteriorly Ring</i>	Proximal Reference Segment		
Distal support:			
<i>Full Ring</i>			
		<p>AP view</p> <p>Reference Ring Rotation (deg)</p> <p>60 <input checked="" type="radio"/> External <input type="radio"/> Internal</p>	<p>AP view</p> <p>Reference Ring Rotation (deg)</p> <p>60 <input type="radio"/> External <input checked="" type="radio"/> Internal</p>

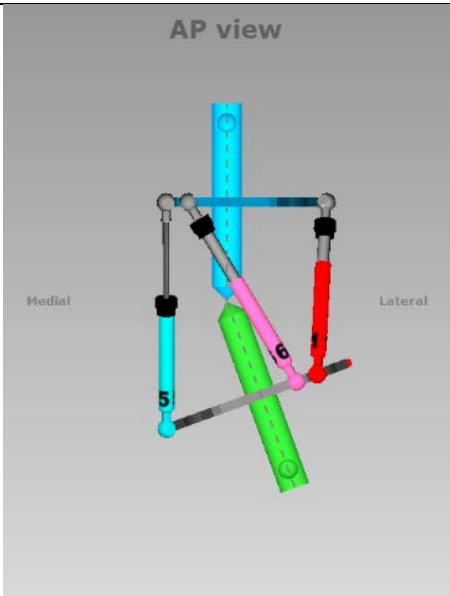
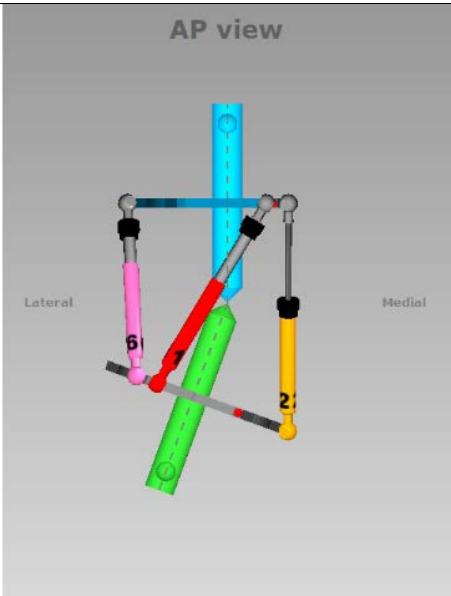
5/8 Open Medially Ring

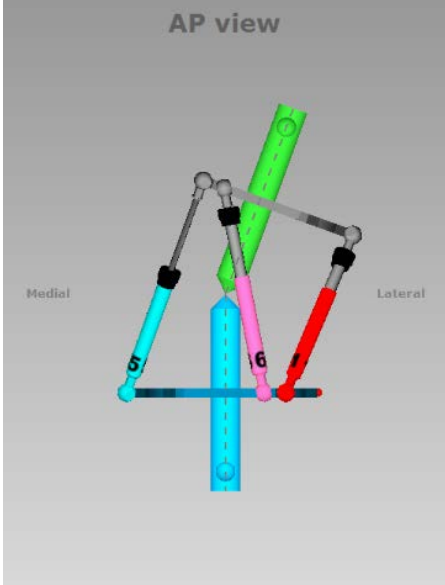
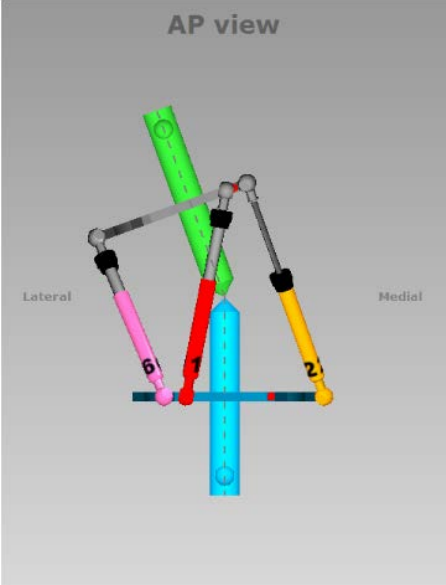
In case the proximal ring is a 5/8 Open Medially Ring, when there is no rotational deformity, according to the software convention, the ROT is the first possible tab that is counter-clockwise from the anterior side **for both right and left limb**.

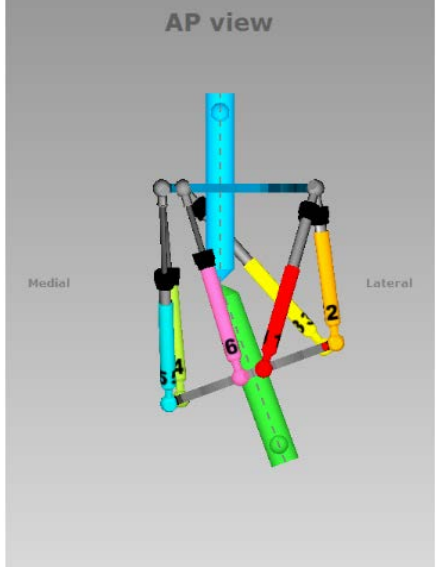
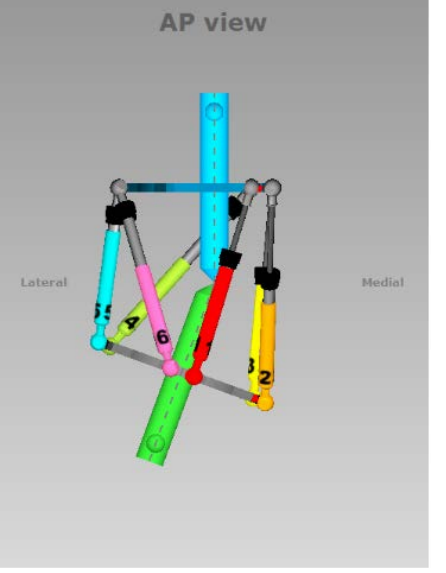
NOTE: it is not possible to have the same ROT rotation between left or right limb. The frame mounting is not symmetrical.

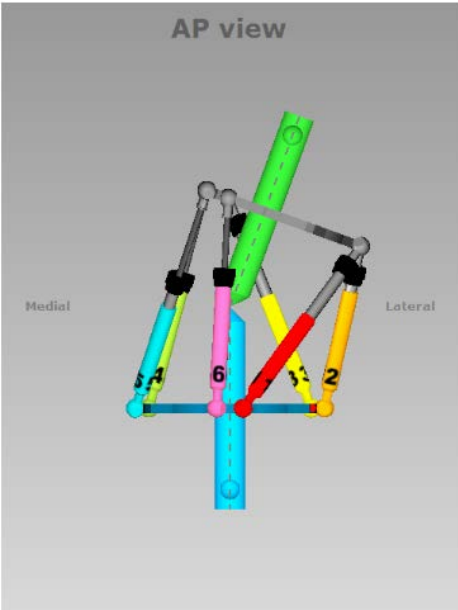
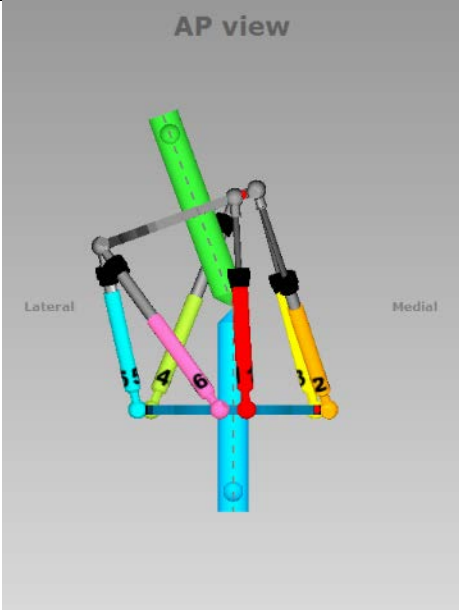
Independently from the reference segment selection, the first possible tab will be externally rotated for the left limb, while the right limb will be internally rotated. Instead, the rotation value changes according with the selected reference segment and distal support. The rotational value is automatically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

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

		Left	Right
Proximal support: <i>5/8 Open Medially Ring</i>	Proximal Reference Segment		
Distal support: <i>Full Ring</i>			
		Reference Ring Rotation (deg) <input type="text" value="90"/> <input checked="" type="radio"/> External <input type="radio"/> Internal	Reference Ring Rotation (deg) <input type="text" value="30"/> <input type="radio"/> External <input checked="" type="radio"/> Internal

		Left	Right
Proximal support: <i>5/8 Open Medially Ring</i>	Distal Reference Segment	 <p>AP view</p> <p>Medial Lateral</p> <p>Reference Ring Rotation (deg)</p> <p>90 <input checked="" type="radio"/> External <input type="radio"/> Internal</p>	 <p>AP view</p> <p>Lateral Medial</p> <p>Reference Ring Rotation (deg)</p> <p>30 <input type="radio"/> External <input checked="" type="radio"/> Internal</p>
Distal support: <i>Full Ring</i>			

		Left	Right
Proximal support: <i>5/8 Open Medially Ring</i>	Proximal Reference Segment	 <p>AP view</p> <p>Medial Lateral</p> <p>Reference Ring Rotation (deg)</p> <p>90 <input checked="" type="radio"/> External <input type="radio"/> Internal</p>	 <p>AP view</p> <p>Lateral Medial</p> <p>Reference Ring Rotation (deg)</p> <p>30 <input type="radio"/> External <input checked="" type="radio"/> Internal</p>
Distal support: <i>5/8 Open Posteriorly Ring</i>			

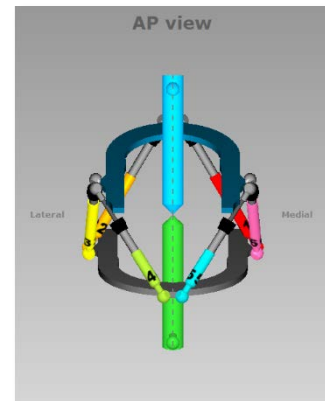
		Left	Right
Proximal support: <i>5/8 Open Medially Ring</i> Distal support: <i>5/8 Open Posteriorly Ring</i>	Distal Reference Segment	<div><p>AP view</p><p>Reference Ring Rotation (deg)</p><div><input type="text" value="60"/> <input checked="" type="radio"/> External <input type="radio"/> Internal</div></div>	<div><p>AP view</p><p>Reference Ring Rotation (deg)</p><div><input type="text" value="60"/> <input type="radio"/> External <input checked="" type="radio"/> Internal</div></div>

Footplate

When selecting *Long Bone* as bone type:

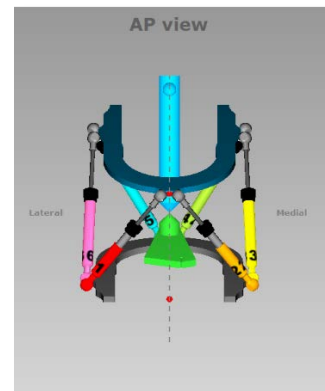
- using **1 footplate**, the footplate will open anteriorly (both distal or proximal)
- using **2 footplates**, the proximal footplate will open anteriorly and the distal footplate will open posteriorly.

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



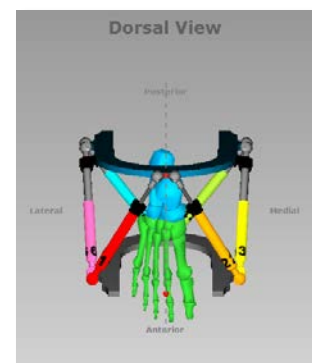
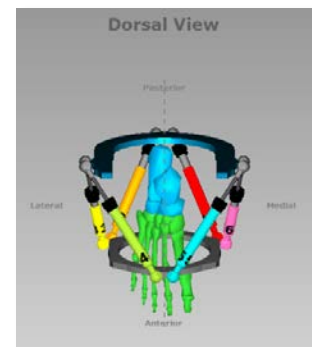
When selecting *Ankle* as bone type:

- 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:

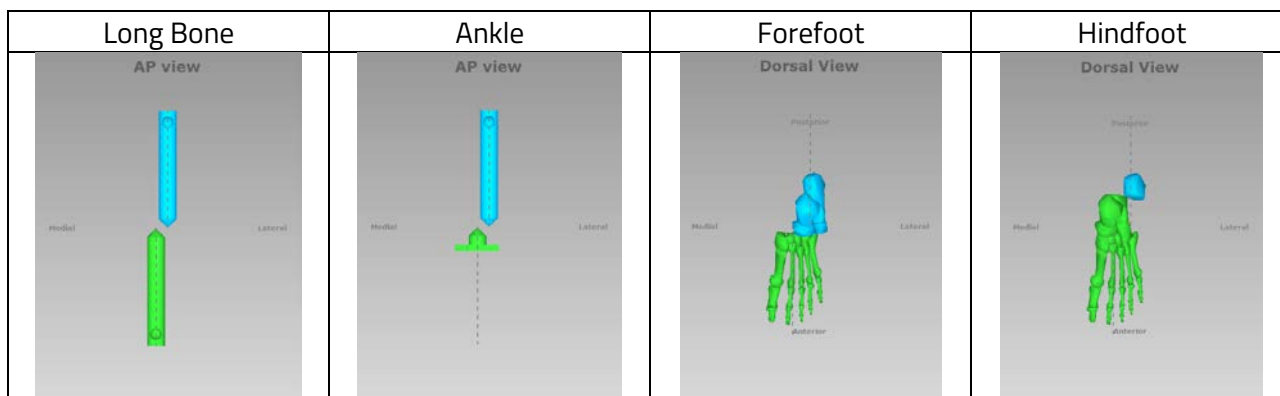
- using **1 footplate** with the Hindfoot/Forefoot, the footplate will open dorsal (both distal or proximal). With the footplate as proximal support, the ROT is at the posterior (plantar) tab.
- using **2 footplates**, the proximal footplate will open plantar and the distal footplate will open dorsal. 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**:

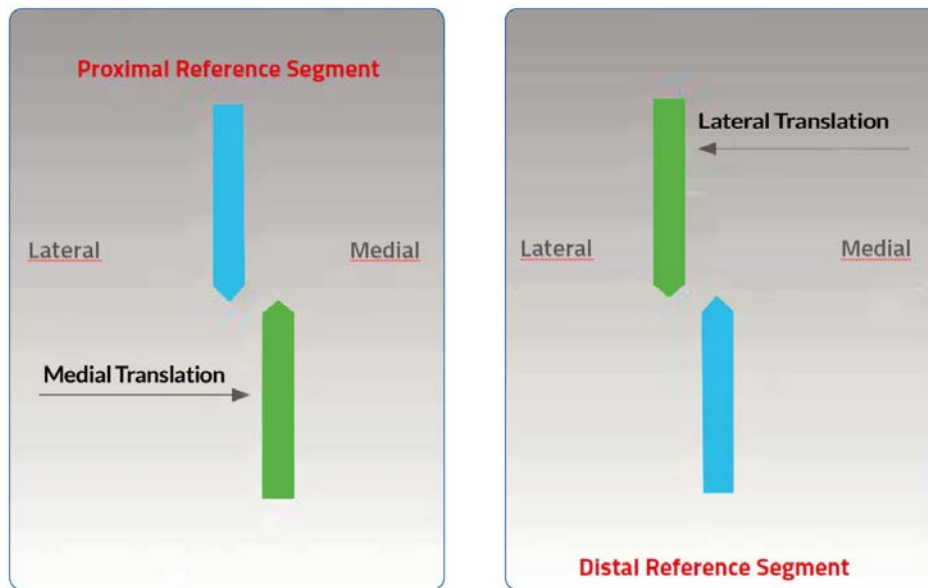
- the deformity and the frame are described relative to the axis of the *distal* segment
- the measurements would need to be taken in relation to this orientation
- the translation and rotation of the proximal segment are described in relation to the distal segment.

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.

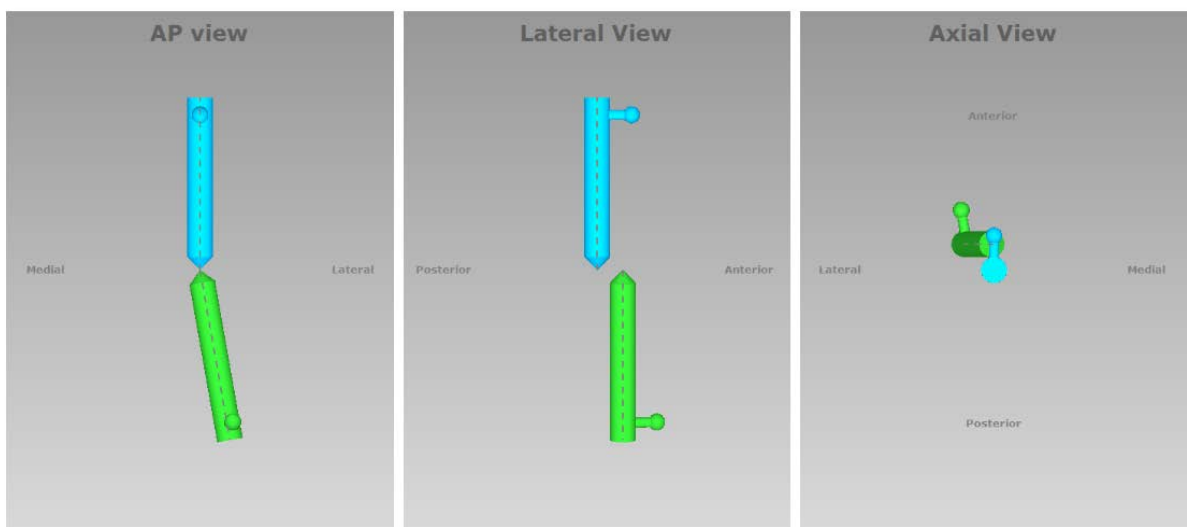
It is important to realize that changing from proximal to distal referencing will change direction of translation in both AP/Dorsal and Lateral views, and the direction of rotation in the Axial view, but will not change length or angulation parameters because these are mathematically independent of the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

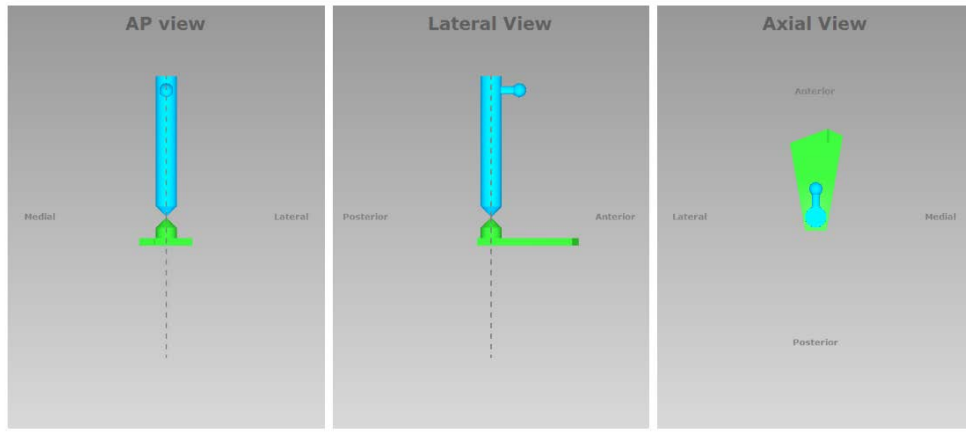
The second is the Lateral view diagram representing the standard ML X-ray of the limb. There are orientation keys on these two views that indicate the medial/lateral and anterior/posterior aspects, respectively.

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.

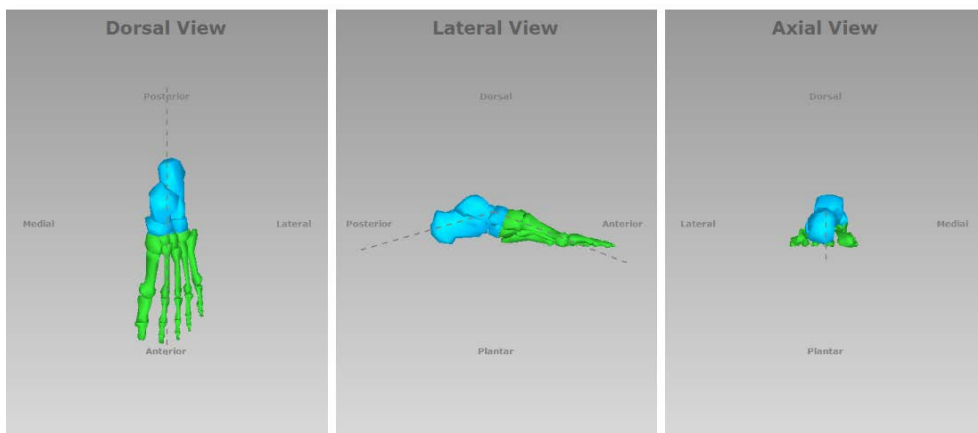
Based on the Bone Type selected - Long Bone, Ankle, Forefoot and Hindfoot - when starting a case, the software accommodates different graphic representations of the bone segments, trying to mimic the correspondent part of the limb.

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

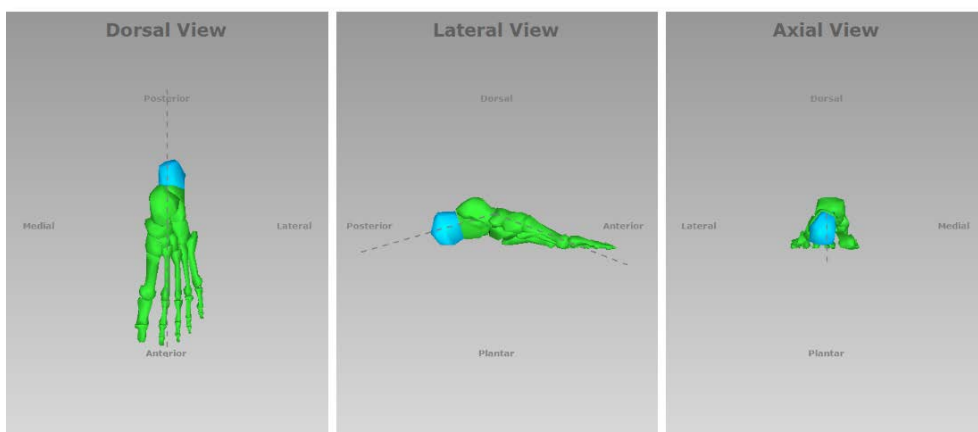


While describing *Foot* deformity, it is possible to select either *Hindfoot* or *Forefoot* level of correction. This indication provides the surgeon with the means to manage different foot deformities in an appropriate way.

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

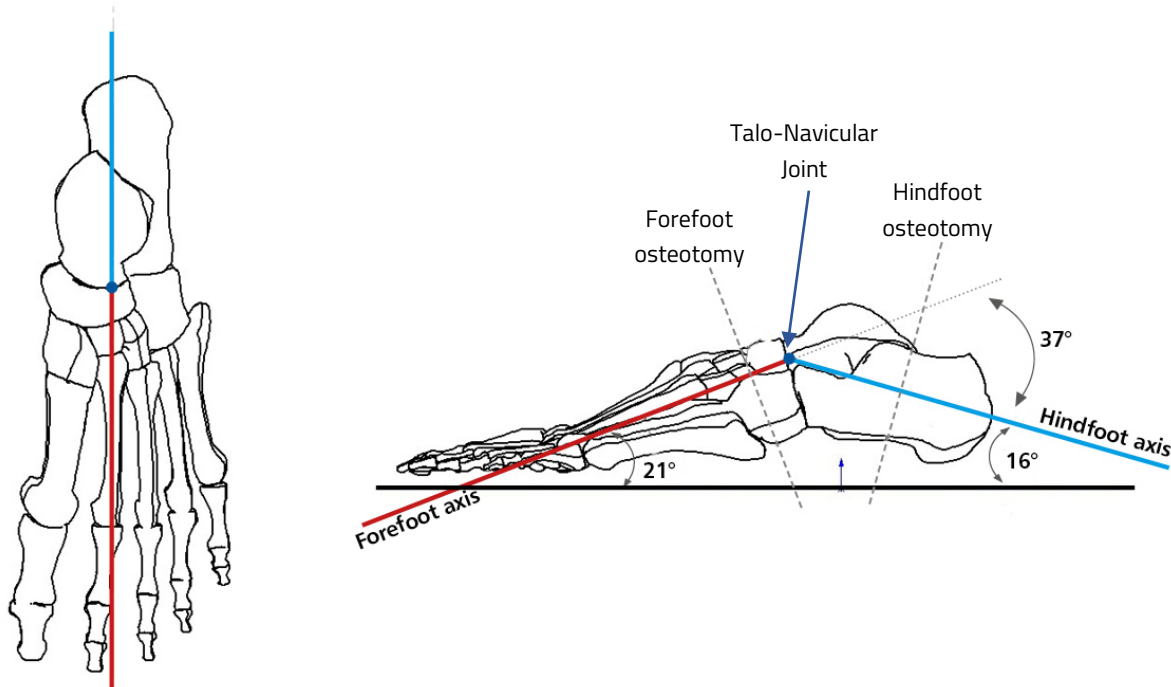


If *Hindfoot* is selected as bone type, the software views represent the foot anatomy as follows:



FOOT NOMENCLATURE

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



The software identifies two axes (solid lines) on the foot graphic representation (as shown in the above picture).

The first axis (Hindfoot axis) is a line that ideally connects the middle of calcaneus with the *talo-navicular joint* along the anatomical axis of the calcaneus.

The second axis (Forefoot axis) drawn on the foot is the line that represents the metatarsal declination angle. The metatarsal declination angle is drawn on the weightbearing lateral foot radiograph between the axis of the second metatarsal and the supporting surface. It is approximately 21° . In general, this axis corresponds to the anatomical axis of the second metatarsal. These two axes of the foot intersect on the **point of reference** (*talo-navicular joint*) and create an angle of 37° Apex Dorsal. The software considers this value as the default lateral angular deformity.

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

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

The two pictures above describe the two axes, the relative angles and the osteotomies positions. The positions of the two axes remain invariant for both forefoot and hindfoot bone types.

How the software represents the foot and the axes on Dorsal and Lateral view is reported in the Nomenclature section.

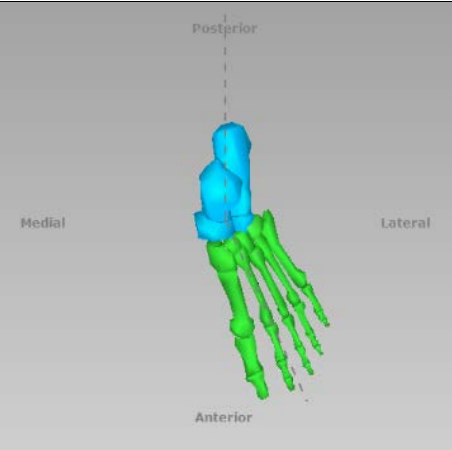
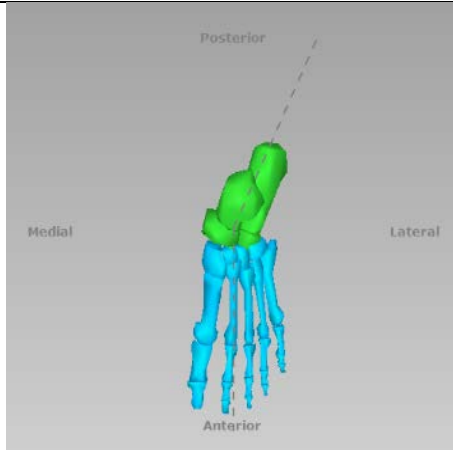
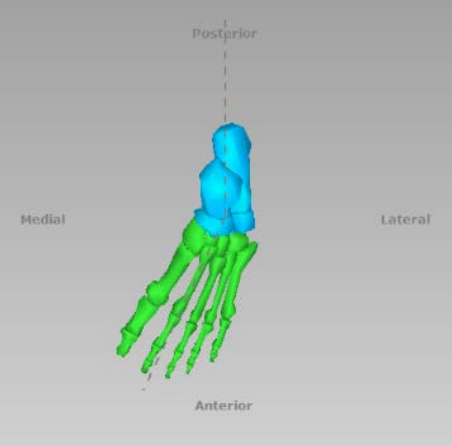
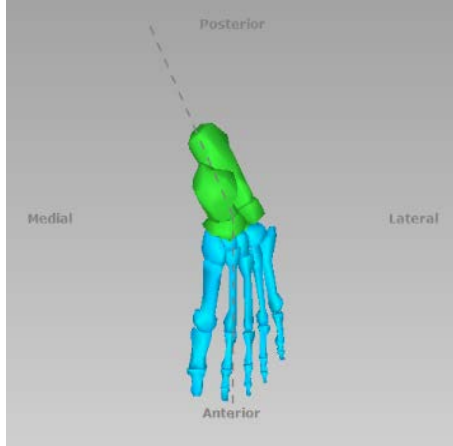
MOVING SEGMENT

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

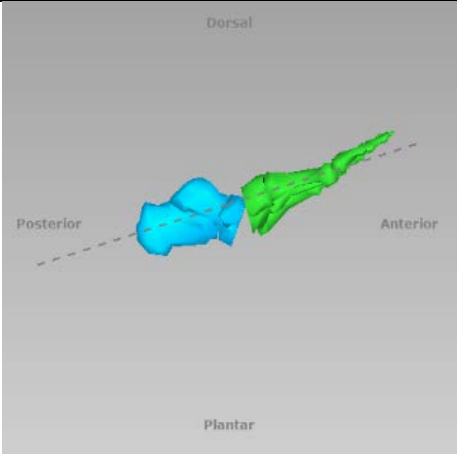
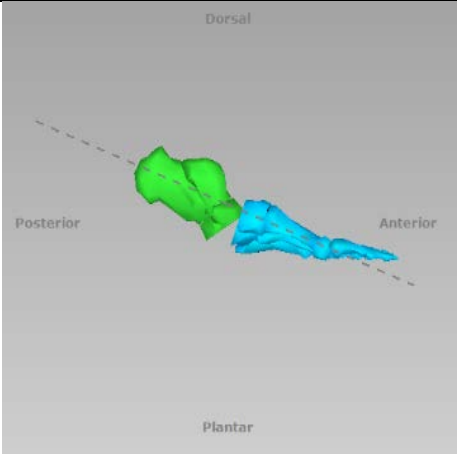
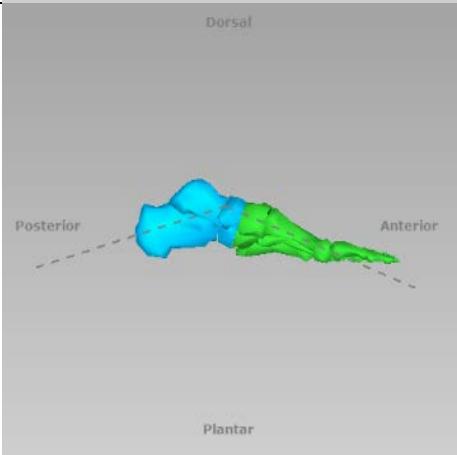
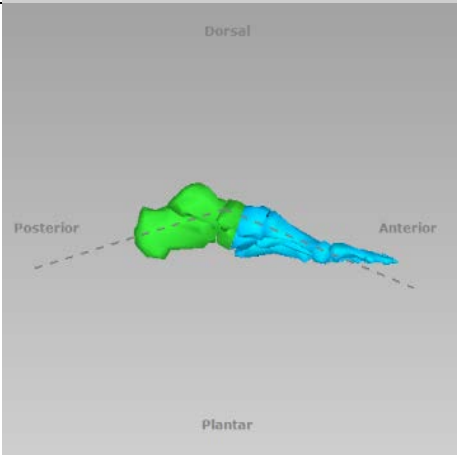
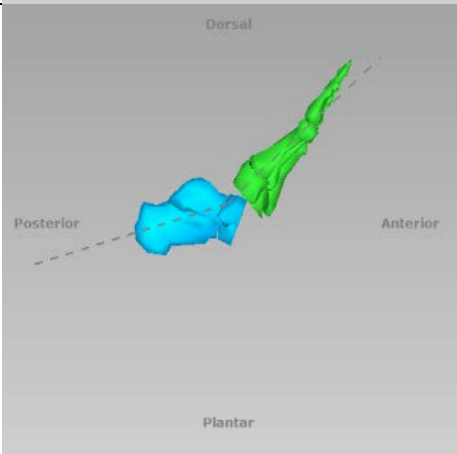
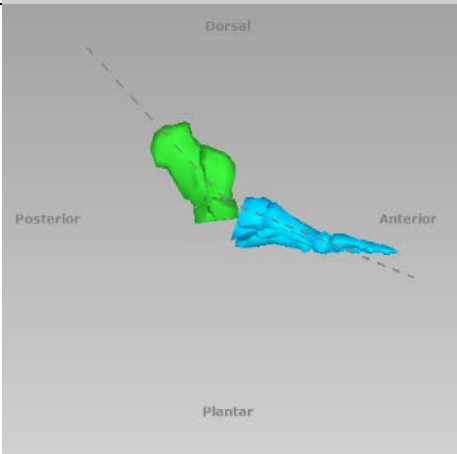
The graphic representations exemplify how the moving segment translates, angulates and rotates relative to the reference segment and the identified axes.

Forefoot

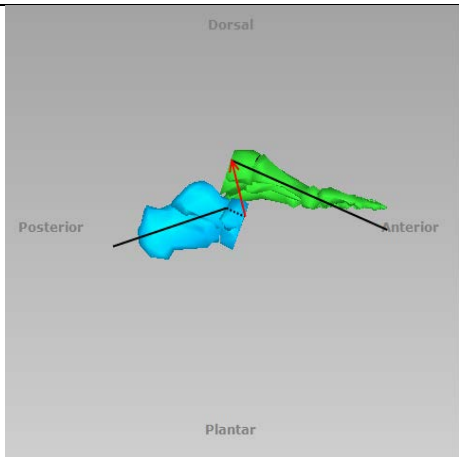
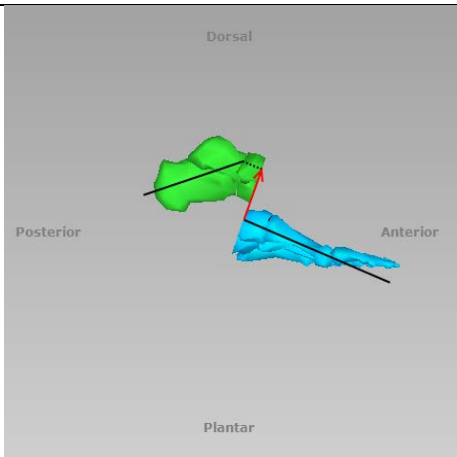
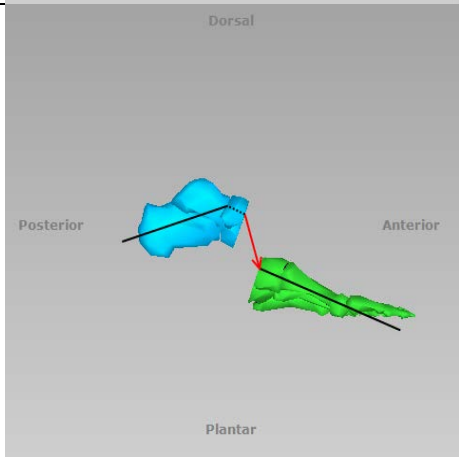
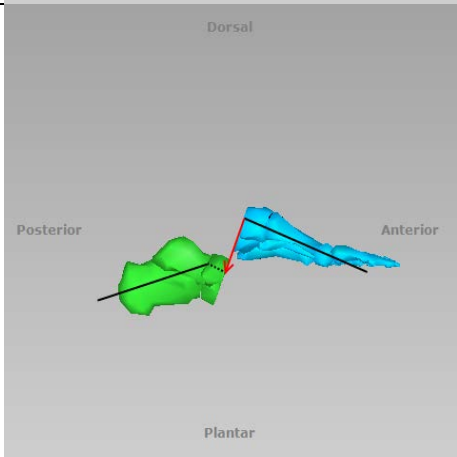
DORSAL Angulation

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

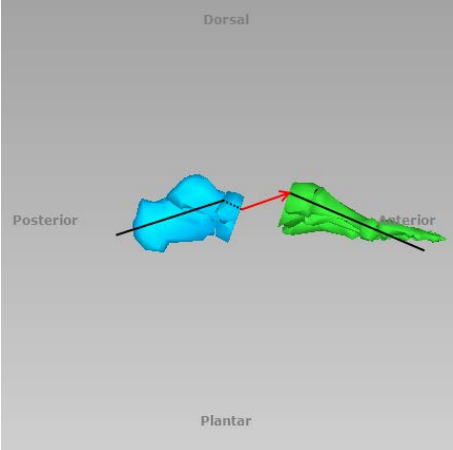
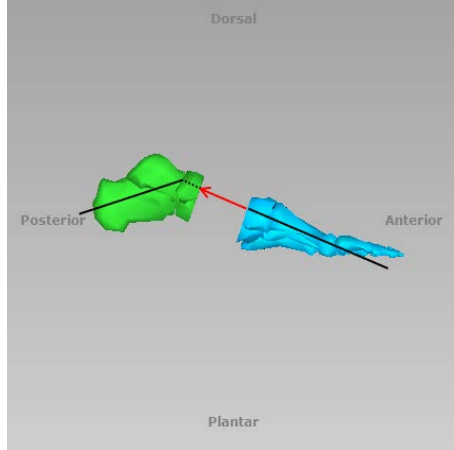
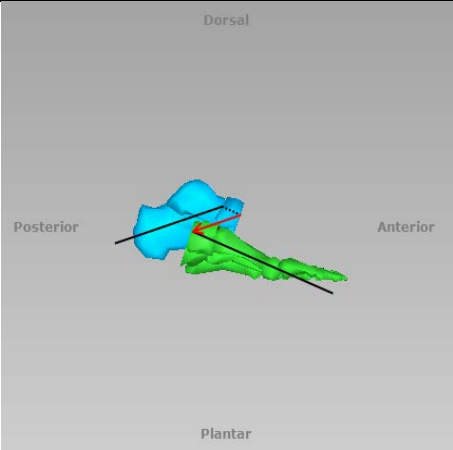
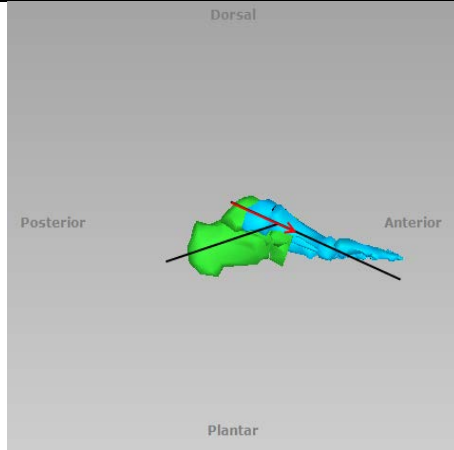
LATERAL Angulation

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

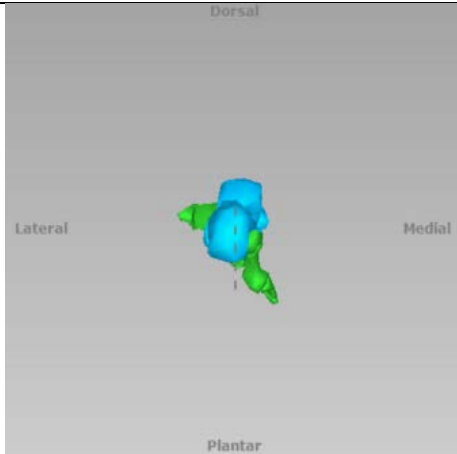
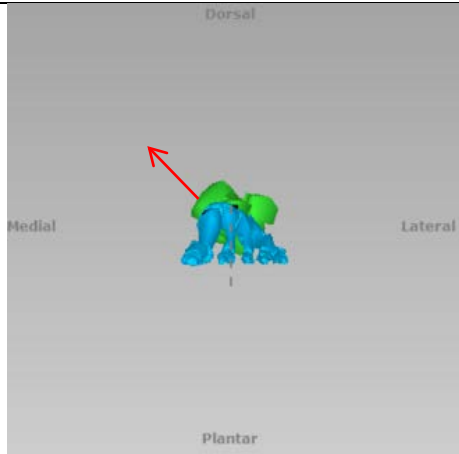
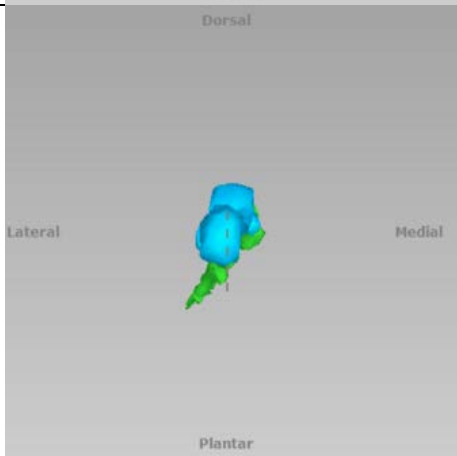
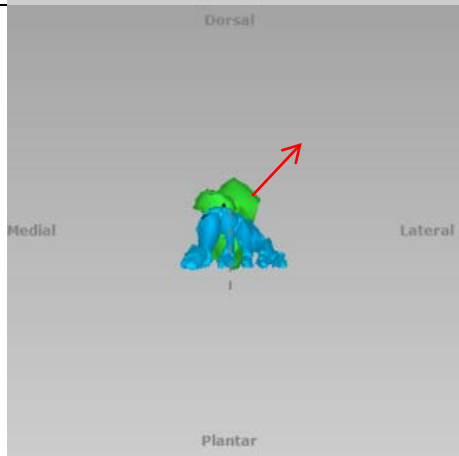
LATERAL Translation

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

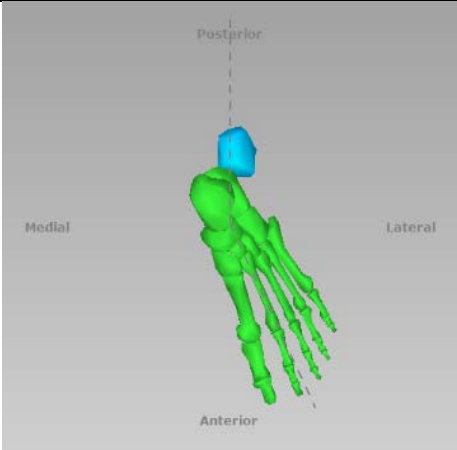
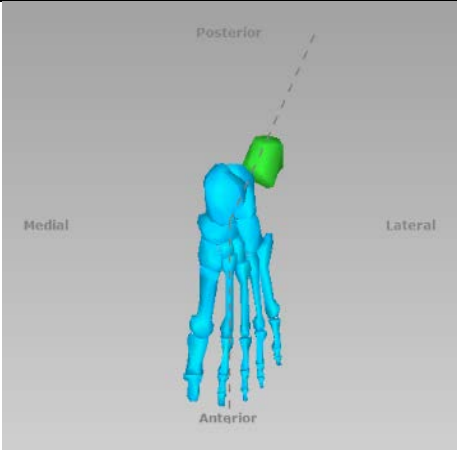
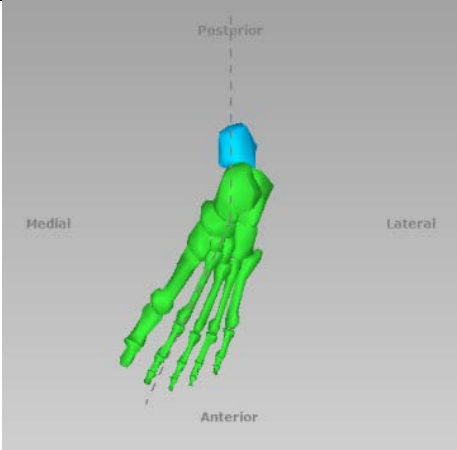
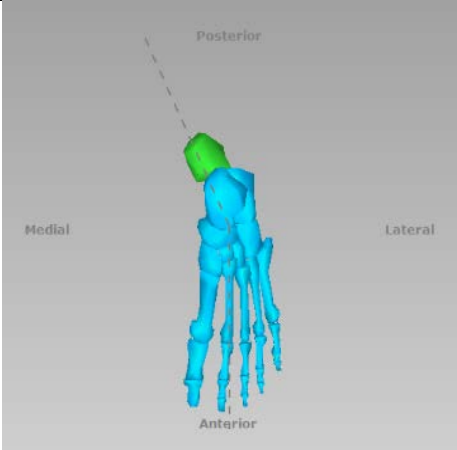
AXIAL Translation

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

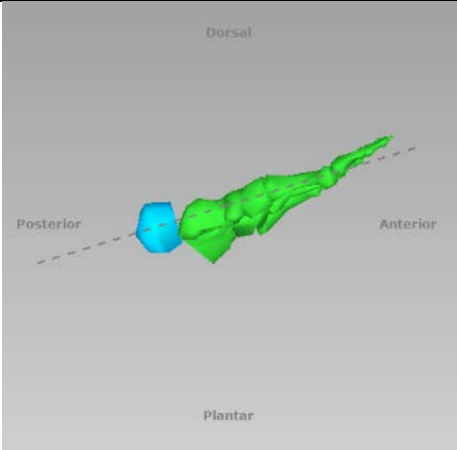
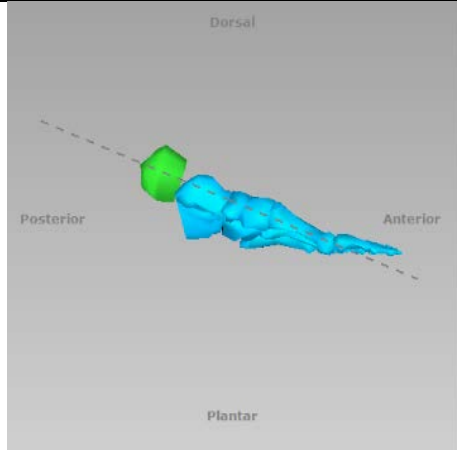
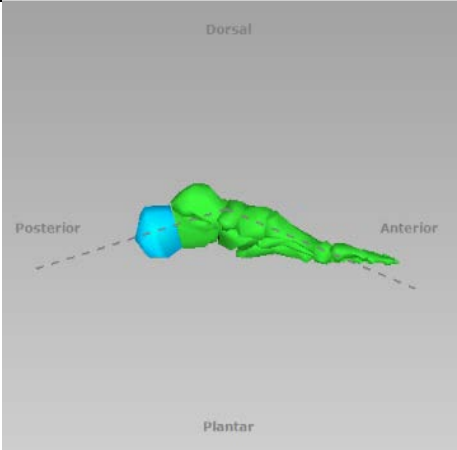
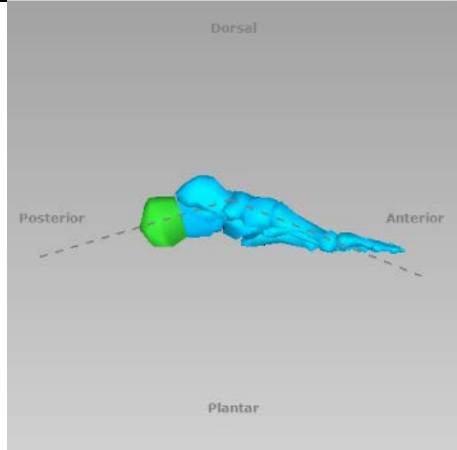
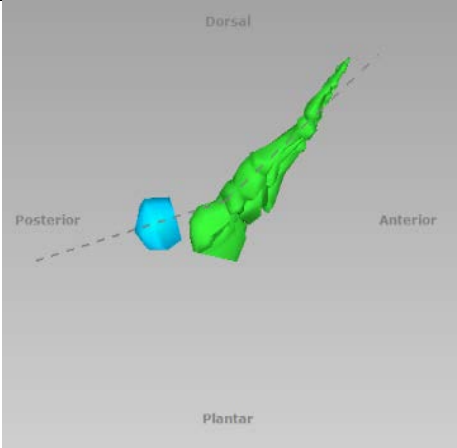
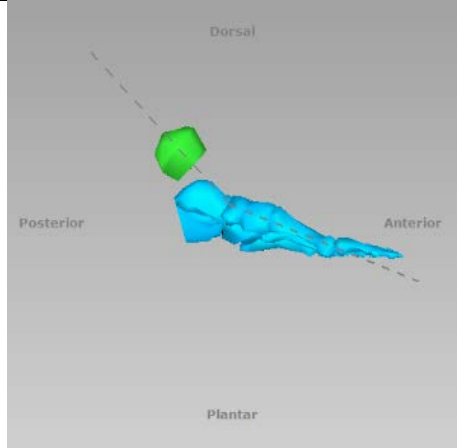
AXIAL Rotation

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

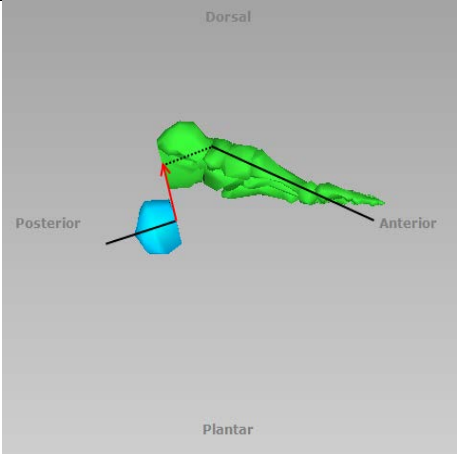
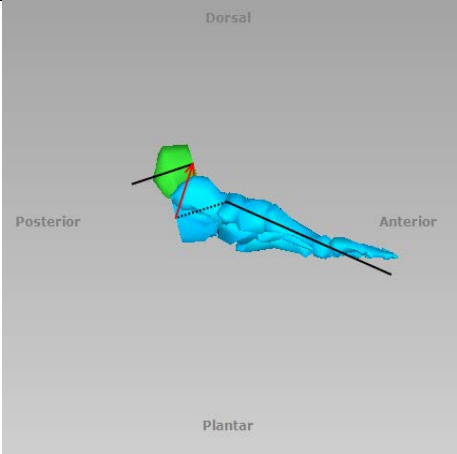
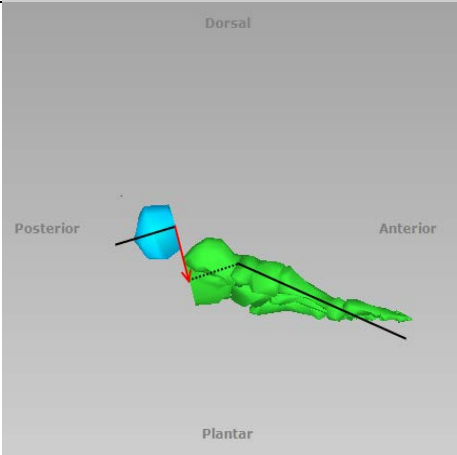
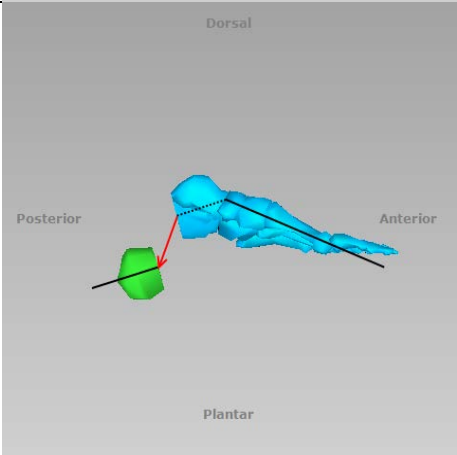
Hindfoot
DORSAL Angulation

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

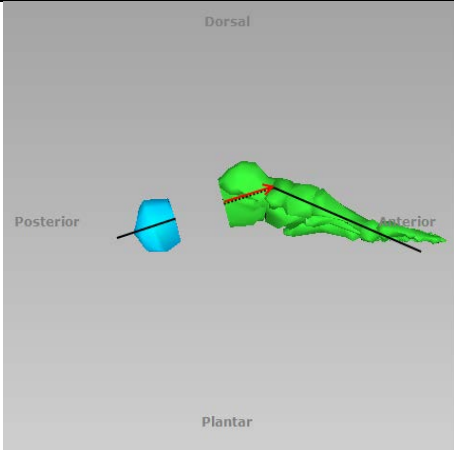
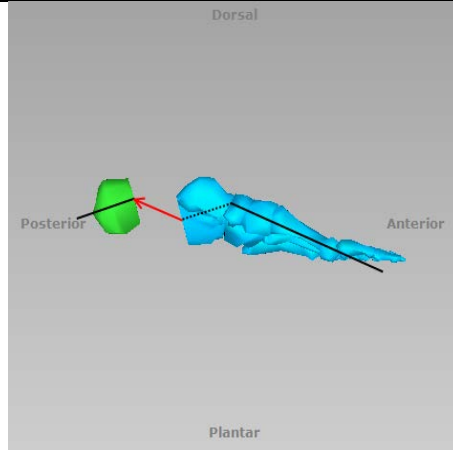
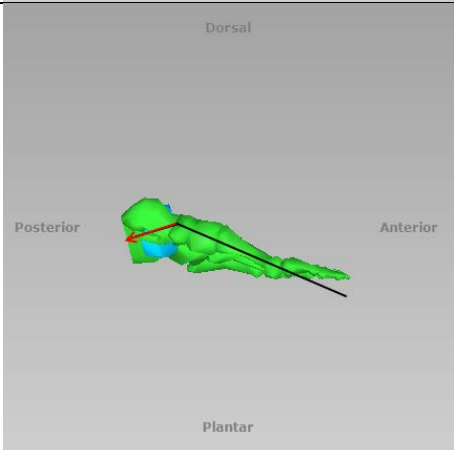
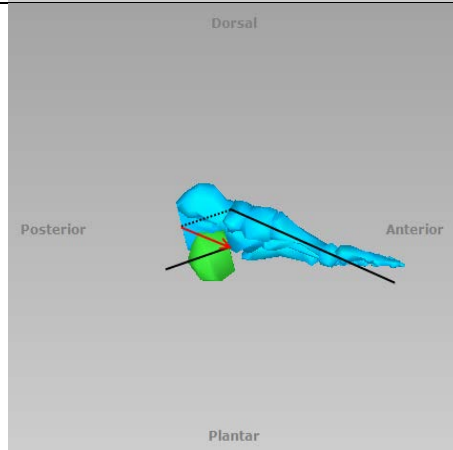
LATERAL Angulation

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

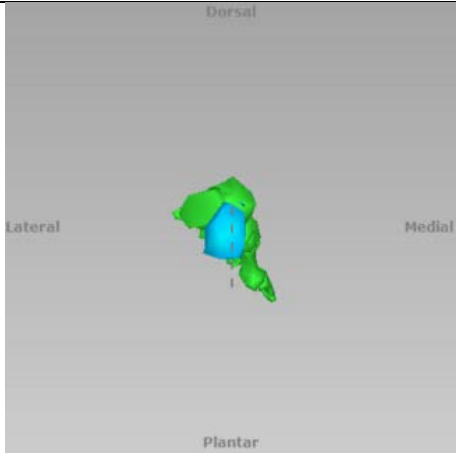
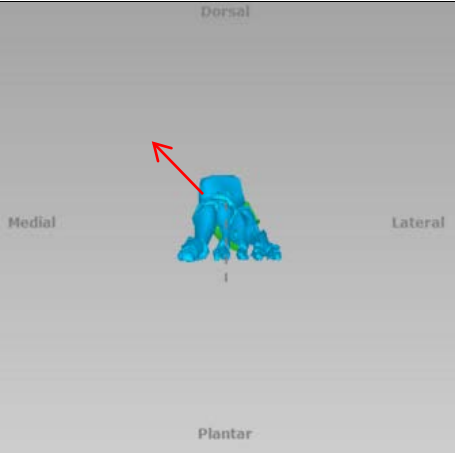
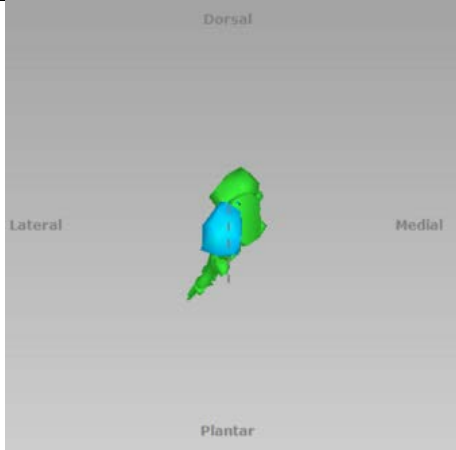
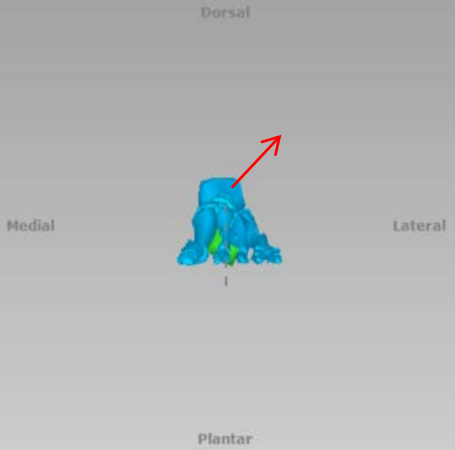
LATERAL Translation

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

AXIAL Translation

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

AXIAL Rotation

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

WEBSITE NAVIGATION

OBTAINING ACCESS AND INFORMATION

Access to the TL-HEX software is controlled by Username and Password that can be obtained at www.tlhex.com by requesting a new account from the Home page and following the onscreen instructions.

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

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

GETTING STARTED ... HOW TO LOG IN

Go to: app.tlhex.com

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

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

ORTHOFIX Need support? [Contact Us](#)

Login

Username *

Password *

[Sign in](#)

[Forgot your Username or Password?](#)

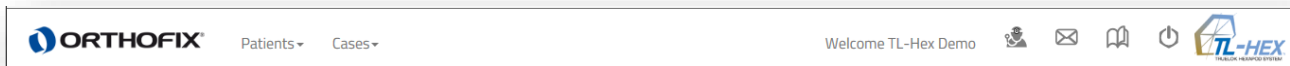
[Request Account](#)

Version: 1.5

UDI: (01)18054242511847(20)01

[Privacy Policy](#) [EULA](#) [Cookies](#)

NAVIGATION MENU



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

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

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



MANAGE ACCOUNT

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



CONTACT US

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



INSTRUCTIONS FOR USE

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



LOG OUT

To log out, just click on the icon

PATIENT AND CASE MANAGEMENT

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

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



PATIENTS

Patients → List of Patients



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

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

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


List of Patients

Search ▶


Add new Patient ?


	Patient ID	Initials	Gender	Last Case Planned ↓	Active Cases	Actions
▶	PROVA A	prova salvataggio	Female	22/01/2016	2	
▶	PROVA B	002	Male	18/01/2016	3	
▶	PROVA C	003	Female	18/01/2016	3	
▶	PROVA D	004	Male	13/01/2016	1	
▶	PROVA E	005	Female	13/01/2016	1	
▶	PROVA F	007	Female	13/01/2016	1	
▶	PROVA B	008	Male	23/12/2015	1	






1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1020 1021 1022 1023 1024 1025 1026 1027 1028 1029 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 1040 1041 1042 1043 1044 1045 1046 1047 1048 1049 1050 1051 1052 1053 1054 1055 1056 1057 1058 1059 1060 1061 1062 1063 1064 1065 1066 1067 1068 1069 1070 1071 1072 1073 1074 1075 1076 1077 1078 1079 1080 1081 1082 1083 1084 1085 1086 1087 1088 1089 1090 1091 1092 1093 1094 1095 1096 1097 1098 1099 1100 1101 1102 1103 1104 1105 1106 1107 1108 1109 1110 1111 1112 1113 1114 1115 1116 1117 1118 1119 1120 1121 1122 1123 1124 1125 1126 1127 1128 1129 1130 1131 1132 1133 1134 1135 1136 1137 1138 1139 1140 1141 1142 1143 1144 1145 1146 1147 1148 1149 1150 1151 1152 1153 1154 1155 1156 1157 1158 1159 1160 1161 1162 1163 1164 1165 1166 1167 1168 1169 1170 1171 1172 1173 1174 1175 1176 1177 1178 1179 1180 1181 1182 1183 1184 1185 1186 1187 1188 1189 1190 1191 1192 1193 1194 1195 1196 1197 1198 1199 1200 1201 1202 1203 1204 1205 1206 1207 1208 1209 1210 1211 1212 1213 1214 1215 1216 1217 1218 1219 1220 1221 1222 1223 1224 1225 1226 1227 1228 1229 1230 1231 1232 1233 1234 1235 1236 1237 1238 1239 1240 1241 1242 1243 1244 1245 1246 1247 1248 1249 1250 1251 1252 1253 1254 1255 1256 1257 1258 1259 1260 1261 1262 1263 1264 1265 1266 1267 1268 1269 1270 1271 1272 1273 1274 1275 1276 1277 1278 1279 1280 1281 1282 1283 1284 1285 1286 1287 1288 1289 1290 1291 1292 1293 1294 1295 1296 1297 1298 1299 1300 1301 1302 1303 1304 1305 1306 1307 1308 1309 1310 1311 1312 1313 1314 1315 1316 1317 1318 1319 1320 1321 1322 1323 1324 1325 1326 1327 1328 1329 1330 1331 1332 1333 1334 1335 1336 1337 1338 1339 1340 1341 1342 1343 1344 1345 1346 1347 1348 1349 1350 1351 1352 1353 1354 1355 1356 1357 1358 1359 1360 1361 1362 1363 1364 1365 1366 1367 1368 1369 1370 1371 1372 1373 1374 1375 1376 1377 1378 1379 1380 1381 1382 1383 1384 1385 1386 1387 1388 1389 1390 1391 1392 1393 1394 1395 1396 1397 1398 1399 1400 1401 1402 1403 1404 1405 1406 1407 1408 1409 1410 1411 1412 1413 1414 1415 1416 1417 1418 1419 1420 1421 1422 1423 1424 1425 1426 1427 1428 1429 1430 1431 1432 1433 1434 1435 1436 1437 1438 1439 1440 1441 1442 1443 1444 1445 1446 1447 1448 1449 1450 1451 1452 1453 1454 1455 1456 1457 1458 1459 1460 1461 1462 1463 1464 1465 1466 1467 1468 1469 1470 1471 1472 1473 1474 1475 1476 1477 1478 1479 1480 1481 1482 1483 1484 1485 1486 1487 1488 1489 1490 1491 1492 1493 1494 1495 1496 1497 1498 1499 1500 1501 1502 1503 1504 1505 1506 1507 1508 1509 1510 1511 1512 1513 1514 1515 1516 1517 1518 1519 1520 1521 1522 1523 1524 1525 1526 1527 1528 1529 1530 1531 1532 1533 1534 1535 1536 1537 1538 1539 1540 1541 1542 1543 1544 1545 1546 1547 1548 1549 1550 1551 1552 1553 1554 1555 1556 1557 1558 1559 1560 1561 1562 1563 1564 1565 1566 1567 1568 1569 1570 1571 1572 1573 1574 1575 1576 1577 1578 1579 1580 1581 1582 1583 1584 1585 1586 1587 1588 1589 1590 1591 1592 1593 1594 1595 1596 1597 1598 1599 1600 1601 1602 1603 1604 1605 1606 1607 1608 1609 1610 1611 1612 1613 1614 1615 1616 1617 1618 1619 1620 1621 1622 1623 1624 1625 1626 1627 1628 1629 1630 1631 1632 1633 1634 1635 1636 1637 1638 1639 1640 1641 1642 1643 1644 1645 1646 1647 1648 1649 1650 1651 1652 1653 1654 1655 1656 1657 1658 1659 1660 1661 1662 1663 1664 1665 1666 1667 1668 1669 1670 1671 1672 1673 1674 1675 1676 1677 1678 1679 1680 1681 1682 1683 1684 1685 1686 1687 1688 1689 1690 1691 1692 1693 1694 1695 1696 1697 1698 1699 1700 1701 1702 1703 1704 1705 1706 1707 1708 1709 1710 1711 1712 1713 1714 1715 1716 1717 1718 1719 1720 1721 1722 1723 1724 1725 1726 1727 1728 1729 1730 1731 1732 1733 1734 1735 1736 1737 1738 1739 1740 1741 1742 1743 1744 1745 1746 1747 1748 1749 1750 1751 1752 1753 1754 1755 1756 1757 1758 1759 1760 1761 1762 1763 1764 1765 1766 1767 1768 1769 1770 1771 1772 1773 1774 1775 1776 1777 1778 1779 1780 1781 1782 1783 1784 1785 1786 1787 1788 1789 1790 1791 1792 1793 1794 1795 1796 1797 1798 1799 1800 1801 1802 1803 1804 1805 1806 1807 1808 1809 1810 1811 1812 1813 1814 1815 1816 1817 1818 1819 1820 1821 1822 1823 1824 1825 1826 1827 1828 1829 1830 1831 1832 1833 1834 1835 1836 1837 1838 1839 1840 1841 1842 1843 1844 1845 1846 1847 1848 1849 1850 1851 1852 1853 1854 1855 1856 1857 1858 1859 1860 1861 1862 1863 1864 1865 1866 1867 1868 1869 1870 1871 1872 1873 1874 1875 1876 1877 1878 1879 1880 1881 1882 1883 1884 1885 1886 1887 1888 1889 1890 1891 1892 1893 1894 1895 1896 1897 1898 1899 1900 1901 1902 1903 1904 1905 1906 1907 1908 1909 1910 1911 1912 1913 1914 1915 1916 1917 1918 1919 1920 1921 1922 1923 1924 1925 1926 1927 1928 1929 1930 1931 1932 1933 1934 1935 1936 1937 1938 1939 1940 1941 1942 1943 1944 1945 1946 1947 1948 1949 1950 1951 1952 1953 1954 1955 1956 1957 1958 1959 1960 1961 1962 1963 1964 1965 1966 1967 1968 1969 1970 1971 1972 1973 1974 1975 1976 1977 1978 1979 1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046 2047 2048 2049 2050 2051 2052 2053 2054 2055 2056 2057 2058 2059 2060 2061 2062 2063 2064 2065 2066 2067 2068 2069 2070 2071 2072 2073 2074 2075 2076 2077 2078 2079 2080 2081 2082 2083 2084 2085 2086 2087 2088 2089 2090 2091 2092 2093 2094 2095 2096 2097 2098 2099 2100 2101 2102 2103 2104 2105 2106 2107 2108 2109 2110 2111 2112 2113 2114 2115 2116 2117 2118 2119 2120 2121 2122 2123 2124 2125 2126 2127 2128 2129 2130 2131 2132 2133 2134 2135 2136 2137 2138 2139 2140 2141 2142 2143 2144 2145 2146 2147 2148 2149 2150 2151 2152 2153 2154 2155 2156 2157 2158 2159 2160 2161 2162 2163 2164 2165 2166 2167 2168 2169 2170 2171 2172 2173 2174 2175 2176 2177 2178 2179 2180 2181 2182 2183 2184 2185 2186 2187 2188 2189 2190 2191 2192 2193 2194 2195 2196 2197 2198 2199 2200 2201 2202 2203 2204 2205 2206 2207 2208 2209 2210 2211 2212 2213 2214 2215 2216 2217 2218 2219 2220 2221 2222 2223 2224 2225 2226 2227 2228 2229 2230 2231 2232 2233 2234 2235 2236 2237 2238 2239 2240 2241 2242 2243 2244 2245 2246 2247 2248 2249 2250 2251 2252 2253 2254 2255 2256 2257 2258 2259 2260 2261 2262 2263 2264 2265 2266 2267 2268 2269 2270 2271 2272 2273 2274 2275 2276 2277 2278 2279 2280 2281 2282 2283 2284 2285 2286 2287 2288 2289 2290 2291 2292 2293 2294 2295 2296 2297 2298 2299 2300 2301 2302 2303 2304 2305 2306 2307 2308 2309 2310 2311 2312 2313 2314 2315 2316 2317 2318 2319 2320 2321 2322 2323 2324 2325 2326 2327 2328 2329 2330 2331 2332 2333 2334 2335 2336 2337 2338 2339 2340 2341 2342 2343 2344 2345 2346 2347 2348 2349 2350 2351 2352 2353 2354 2355 2356 2357 2358 2359 2360 2361 2362 2363 2364 2365 2366 2367 2368 2369 2370 2371 2372 2373 2374 2375 2376 2377 2378 2379 2380 2381 2382 2383 2384 2385 2386 2387 2388 2389 2390 2391 2392 2393 2394 2395 2396 2397 2398 2399 2400 2401 2402 2403 2404 2405 2406 2407 2408 2409 2410 2

Clicking on the  icon related to each patient in the list to expand the list of cases related to this patient.



























List of Patients

Search 

Add new Patient 

	Patient ID	Initials	Gender	Last Case Planned ↓	Active Cases	Actions
	SW Guide	SWG	Male	24/02/2016	10	 
	sw guide3	sug	Male		0	 

10 20 30 40 50 100 2 items in 1 pages

	Patient ID	Initials	Gender	Last Case Planned ↓	Active Cases	Actions		
▼	SW Guide	SWG	Male	24/02/2016	10	 		
	Case ID	Case Name	Status	Bone Type	Side	Planning Created ↓	Days Left	Actions
	CopyOf_Case Blount's_18/02/2016...	Case Blount's_Copied_on_...	Active	Long Bone	Left	24/02/2016	0	 
	CaseF	Case F	Active	Forefoot	Left	18/02/2016	0	 
	case FF	caseFF	Active	Forefoot	Left	18/02/2016	0	 
	Case HF	CaseHF	Active	Hindfoot	Left	18/02/2016	0	 
	Case Blount's	Case Blount's	Active	Long Bone	Left	18/02/2016	25	 
	Ankle Deformity	Ankle Deformity	Active	Ankle	Left	18/02/2016	0	 
	Blount's	test	Active	Long Bone	Left	18/02/2016	0	 
	Case Forefoot	Case Forefoot	Archived	Ankle	Left	17/02/2016	19	 
	SW	Direction	Active	Long Bone	Left	17/02/2016	19	 
	Test Restore	Test Restore	Active	Hindfoot	Left	17/02/2016	0	 
	How to build the frame	How to build the frame	Active	Long Bone	Left	20/01/2016	0	 
	sw guide3	sug	Male				0	 

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

PATIENT ACTIONS

Actions that can be performed on a patient are:



ADD NEW CASE

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



DELETE A PATIENT

By selecting this option, the patient and all his/her related cases will be deleted.

The popup window will appear to confirm the removal of the patient. Click on 'Delete' to move on. A warning pop up reminds that the action cannot be reverted, once a patient is deleted.

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

ADD NEW PATIENT

Patients → Add new Patient



A new patient can be entered using:

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

 A screenshot of the 'Add New Patient' form. The form has a header 'Add New Patient' and a background image of orthopedic implants. It contains three input fields: 'Patient ID *', 'Patient Initials: *', and 'Gender: *'. The 'Gender' field has radio buttons for 'Male' and 'Female'. A blue bar at the bottom of the form is labeled 'Prescription Preferences ▶'. At the bottom right, there are three buttons: 'Save Patient', 'Save & Create Case', and 'Cancel'. A warning box on the right side of the form states: 'Warning: You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software.'

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

- unique Patient ID
- Patient Initials
- Gender

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

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

Add New Patient

Patient ID *

Patient Initials *

Gender * ☐ Male ☐ Female

Prescription Preferences ▼

Select Prescription Address:

☒ TL-Hex Demo
Orthofix
via delle Nazioni 9
Bussolengo, Verona Italy 37012
(+39) 0456719000

☐ TL-Hex Demo
Orthofix
3451 Plano Parkway
Lewisville, Texas United States 75056
(+1) 214.937.2000

Warning

You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software.

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

On the other hand, clicking on the 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 button.

Search ▼

Patient ID

Case ID

Case Name

Status

Side

Bone Type

Planning Created

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

To remove any filter, click the button.

CASES

Cases → List of Cases



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

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

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

List of Cases								
<div>Search ▶</div> <div> Add new Patient Add new Case ? </div>								
Patient ID	Case ID	Case Name	Status	Bone Type	Side	Planning Created ↓	Days Left	Actions
PROVA A	004	eo4	Active	Ankle	Left	22/01/2016	0	
PROVA A	E05	gr	Active	Ankle	Left	22/01/2016	0	
PROVA C	CopyOf_004_13/...	grtbgtf	Active	Ankle	Left	18/01/2016	0	
PROVA B	CopyOf_002_13/...	Equinus Foot_Copied_on...	Active	Ankle	Left	18/01/2016	0	
PROVA B	002	Equinus foot_withouth lenghtening	Active	Ankle	Left	13/01/2016	0	
PROVA B	003	Equinus foot_with lenghtening	Active	Ankle	Left	13/01/2016	0	
PROVA D	003	Butt Frame	Active	ForeFoot	Left	13/01/2016	0	
PROVA C	004	Miter frame	Active	Ankle	Left	13/01/2016	0	
PROVA C	005	def_forefoot	Active	ForeFoot	Left	13/01/2016	0	
PROVA E	005	varus defomity hindfoot	Active	HindFoot	Left	13/01/2016	0	

<<<<
<<
1
>>
>>>>

10 ▼




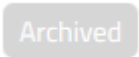
12 items in 2 pages

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

STATUS OF A CASE







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

Below is reported a summary of the different status:

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

CASE ACTIONS

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

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


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

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

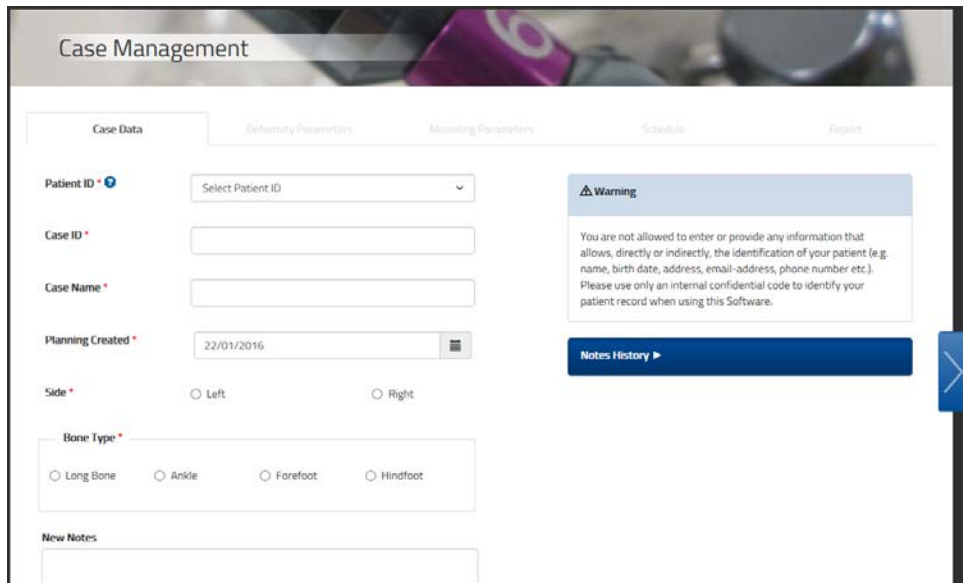
(*) A case can be Upgraded if it has been migrated from one of the previous software versions.

ADD NEW CASE


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

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

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




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

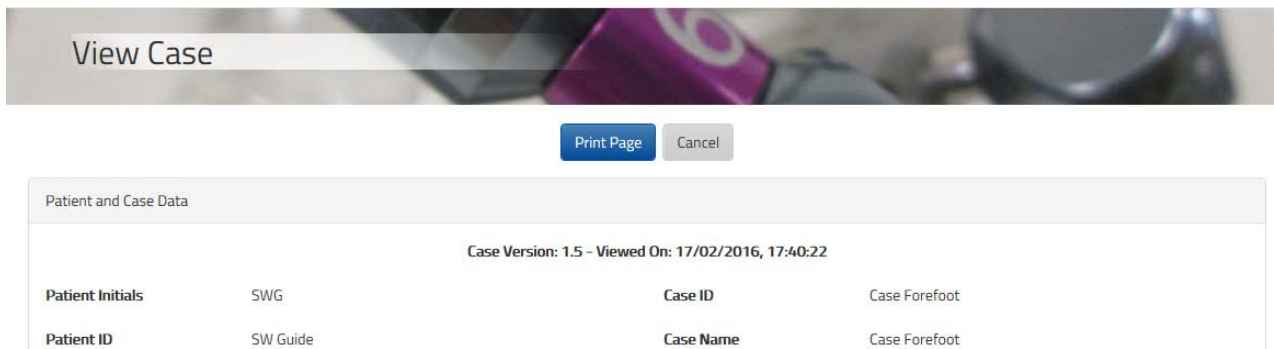
Proceed to the next step in the treatment planning process by clicking on the  arrow on the right-hand side.

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

VIEW CASE

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

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



Patient and Case Data			
Case Version: 1.5 - Viewed On: 17/02/2016, 17:40:22			
Patient Initials	SWG	Case ID	Case Forefoot
Patient ID	SW Guide	Case Name	Case Forefoot

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

NOTE: To prevent your summary (in particular Report and Prescription tables) from being cut off when you print it, try printing it in landscape format.

Different printers may yield different results, and the printing dialog box may contain different options, depending upon the specific printer and browser you are using, but generally you should follow these steps:

PC Users

Internet Explorer 10/11

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


MAC Users

Safari

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

SEND A CASE

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

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

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

Send Case

Case ID: SW

Case Name: Direction

Receiving UserName *

Send Notes (Optional)

Warning





















You are not allowed to enter or provide any information that allow, directly or indirectly, the indication of your patient (e.g. name, birth date, address, email-address, phone number etc). Please use only internal confidential code to identify your patient record when using this software.

Send Case

Cancel

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


The case status assigned for this case is Received.


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

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


RESTORE A RECEIVED CASE

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

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

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

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

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

Create a new Case ID and Case Name.

Restore Case

You are attempting to edit a Case that was created by another User. By clicking the Restore button, you can edit the case. The original received case data will be still available. You will proceed under your own personal liability.

Select Patient ID

Case ID *


Case Name *

NOTE: Create at first a new patient if you want to link this case to a not already existing patient ID


Cancel

Restore

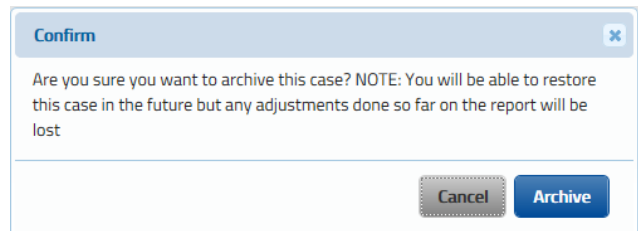
By clicking the Restore button to complete the procedure, a new case with the provided details is created. The Case Data, Deformity Parameters, Mounting Parameters and Schedule tab, when fulfilled and successfully saved, are automatically copied into the new case, while the report and the prescription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

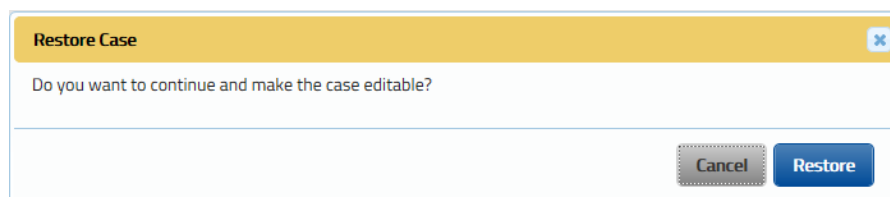


RESTORE AN ARCHIVED CASE

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

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

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



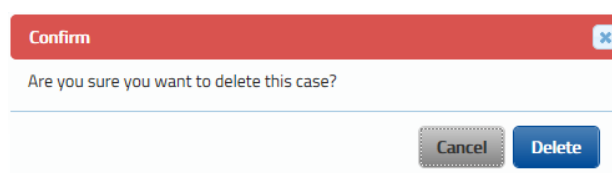
By clicking the Restore button, the case becomes editable and the user can review the Case Data and all the other tabs entered so far until Schedule, but the report and the prescription need to be recalculated.

Once restored, the new case status is **Active**.

DELETE A CASE


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

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

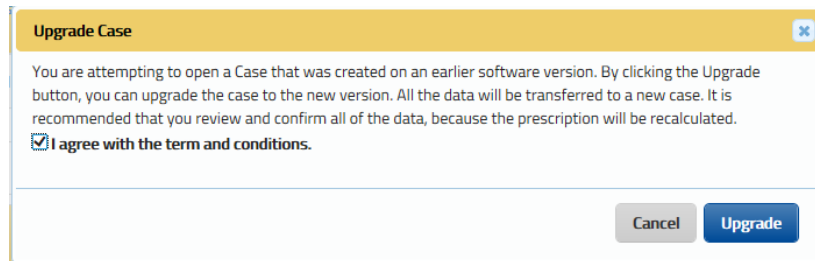


UPGRADE A CASE FROM PREVIOUS VERSIONS TO 1.5

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

To upgrade a prior version of a case, click on the  [Upgrade Case] icon.

A pop-up message will notify the user about the attempt to open a case that was created with a prior software version.



To proceed with the upgrade, the user is requested to agree with the term and conditions declared for this option.

By clicking the Upgrade button, Case Data, Deformity Parameters, Mounting Parameters Data and Schedule settings are copied into a brand new case.

The user is recommended to review these prior to recalculating the report and the prescription.

By upgrading the case, please pay attention that:

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

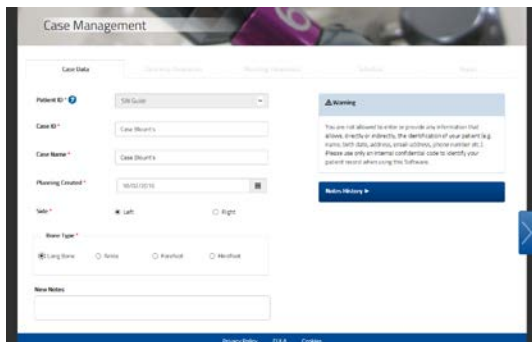
The original case migrated from the previous version remain available in view mode for consultation and comparison.

CASE PLANNING

Prior to starting a case, create the patient, refer to the [Add new Patient](#) section for details relating to this. To start a new case, refer to the [Add new Case](#) section.

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

Case Data

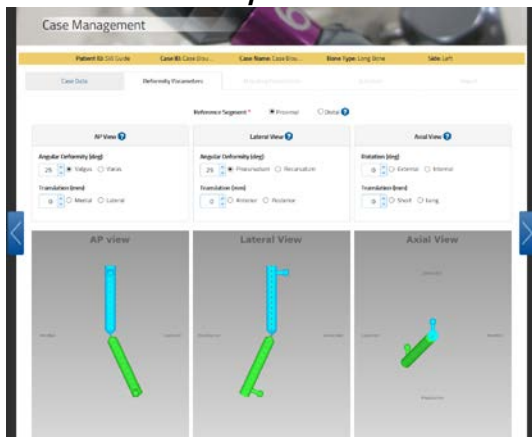


1.

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

Detail in [Case Data](#) section.

Deformity Parameters



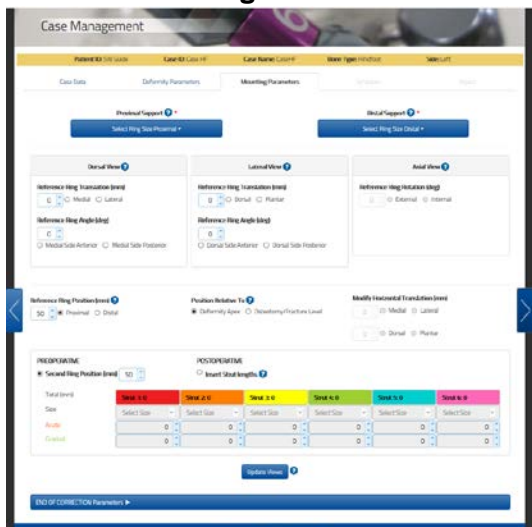
2.

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

Include any over/under correction expected at the end of the treatment, in the new End Of Correction section.

Details in [Deformity Parameters](#) section recap how the software interprets the provided input and how the software renders the deformity.

Mounting Parameters



	Strut 1-6	Strut 2-6	Strut 3-6	Strut 4-6	Strut 5-6	Strut 6-6
Size	Select Size	Select Size	Select Size	Select Size	Select Size	Select Size
Angle	0	0	0	0	0	0
Position	0	0	0	0	0	0

3.

Select the proximal and distal support type and size.

PREOPERATIVE PLANNING - Details in [Mounting Parameters – Preoperative Planning](#) section.

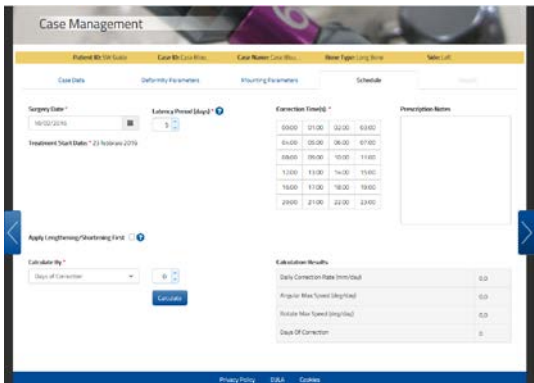
In order to obtain a valid combination of the struts, describe how the frame will be positioned. Determine the reference ring parameters and also provide the second ring position.

POSTOPERATIVE - Details in [Mounting Parameters – Postoperative](#) section.

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

Visualize the expected End of Correction results.

Schedule



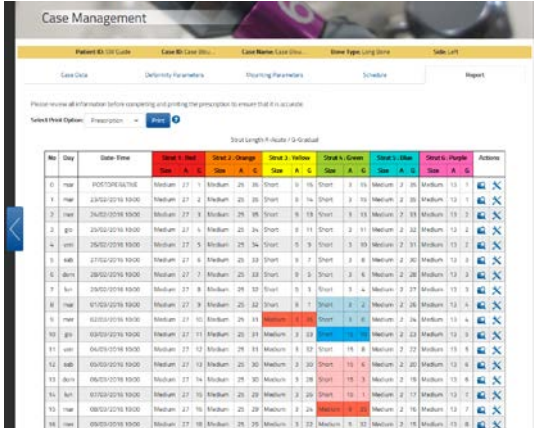
4.

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

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

Details in [Schedule](#) section.

Report



5.

Review the obtained report and the prescription for the patient.

If needed, proceed with a report adjustment or run a checkup of the case in a selected date.

Detail in [Report and Prescription](#) section.

Detail in [Checkup](#) section.

CASE DATA

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



Start a new case by completing the case data details.

Select the patient from the drop-down list.

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

Select the creation date related to this case.



Determine the anatomical limb side, either left or right.

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

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

The screenshot displays the 'Case Management' software interface. The 'Case Data' tab is active, showing fields for Patient ID (a dropdown menu with 'SW Guide' selected), Case ID (text input with 'Case Blount's'), Case Name (text input with 'Case Blount's'), Planning Created (date input with '20/02/2016'), Side (radio buttons for 'Left' and 'Right', with 'Left' selected), and Bone Type (radio buttons for 'Long Bone', 'Ankle', 'Forefoot', and 'Hindfoot', with 'Long Bone' selected). A 'New Notes' text area is at the bottom. A warning box on the right states: 'Warning: You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software.' Below the warning is a 'Notes History' button. The bottom of the interface has a blue bar with links for 'Privacy Policy', 'EULA', and 'Cookies'. A blue arrow button is visible on the right edge of the interface.

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

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

DEFORMITY PARAMETERS AND END OF CORRECTION

DEFORMITY PARAMETERS

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

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


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


Review and recap what the reference segment selection implies in the [Nomenclature](#) section.

The screenshot shows the 'Case Management' interface. At the top, there's a header with 'Case ID: Case Blou...', 'Case Name: Case Blou...', 'Bone Type: Long Bone', and 'Side: Left'. Below this is a navigation bar with tabs: 'Case Data', 'Deformity Parameters', 'Mounting Parameters', 'Schedule', and 'Report'. The 'Deformity Parameters' tab is active. Under this tab, there's a 'Reference Segment' section with two radio buttons: 'Proximal' and 'Distal'. The 'Distal' button is selected and has a blue question mark icon next to it.

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

This screenshot shows the 'Deformity Parameters' section with three view panels: 'AP View', 'Lateral View', and 'Axial View'. Each panel has input fields for 'Angular Deformity (deg)' and 'Translation (mm)', along with radio buttons for 'Valgus/Varus', 'Procurvatum/Recurvatum', 'External/Internal', and 'Medial/Lateral'. The 'AP View' panel shows a value of 15 for angular deformity and 0 for translation. The 'Lateral View' panel shows a value of 15 for angular deformity and 0 for translation. The 'Axial View' panel shows a value of 20 for rotation and 0 for translation. Below the panels are three 3D visualizations of the bone in AP, Lateral, and Axial views. At the bottom, there's an 'Update Views' button with a question mark icon.

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

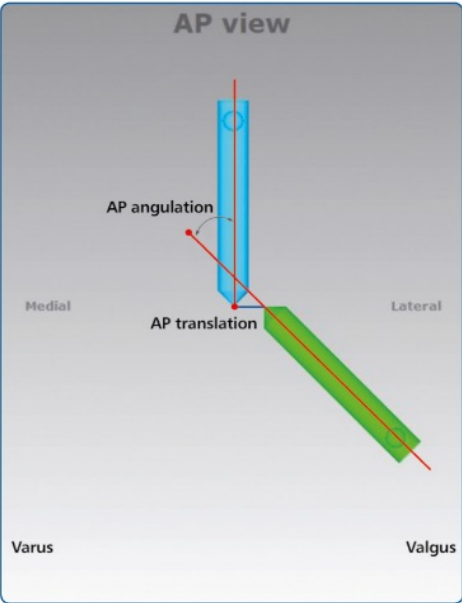
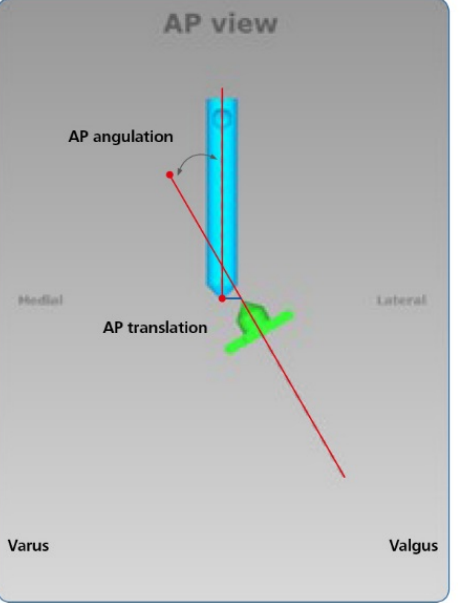
Software will remind you that the images may not be updated and may not represent the entered parameters when you update/change the form by displaying an orange notification under the  button.

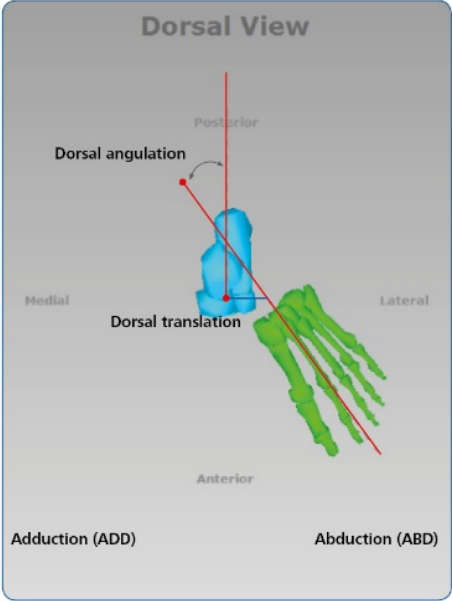
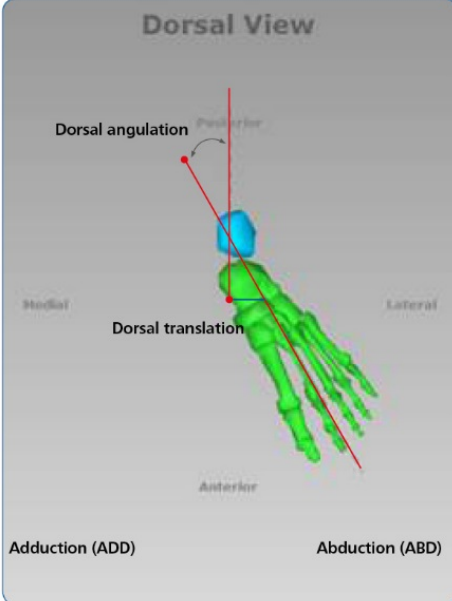
It is recommended to check whether the diagrams on the software correspond to the deformity seen on the patient's X-rays and/or clinically.

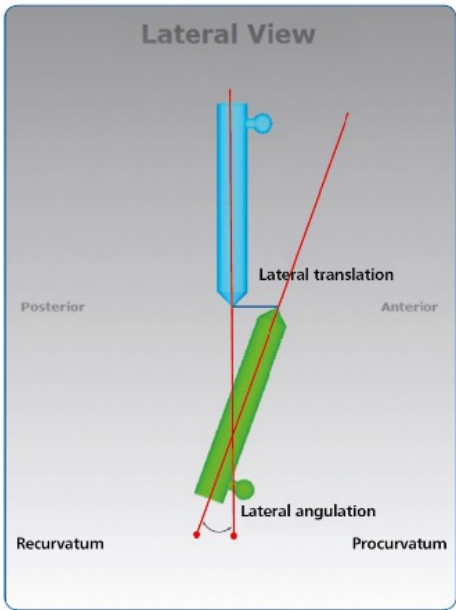
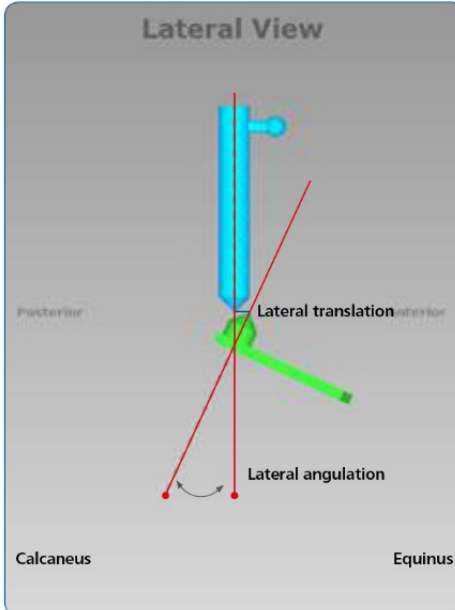
DEFORMITY PARAMETERS DEFINITION

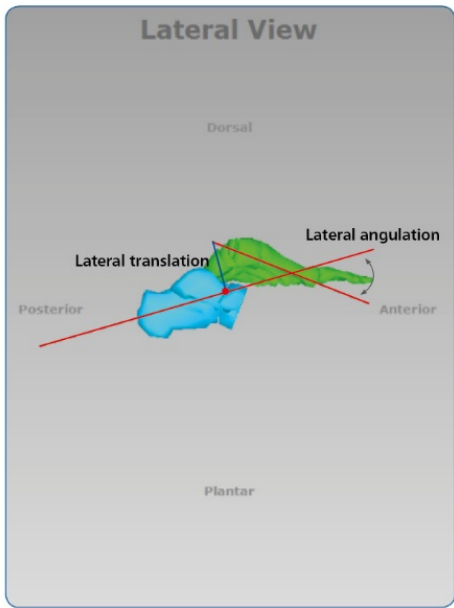
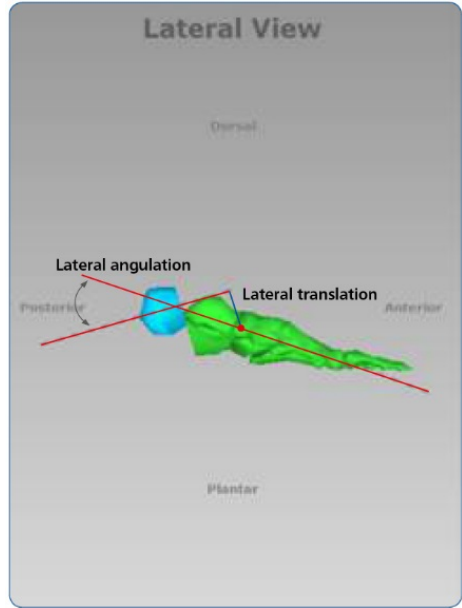
The labelling parameters are bone-type dependent. This means that, in accordance with the selected bone type, the parameters labelling will be adapted.

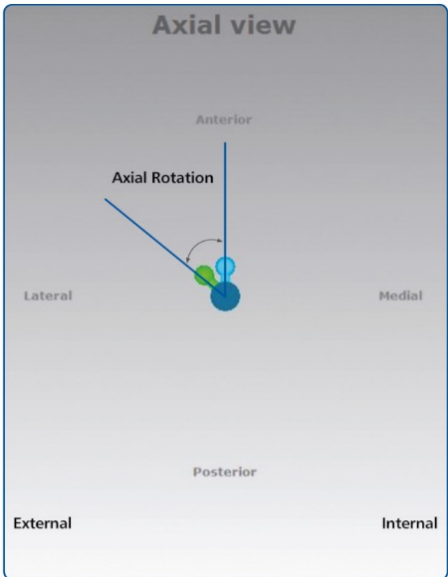
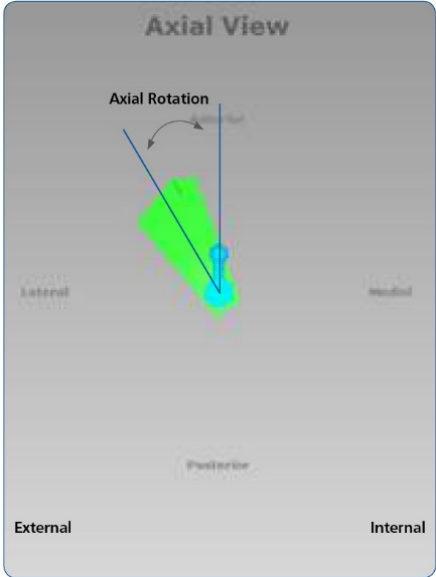
Below is a summary of the labelling parameters:

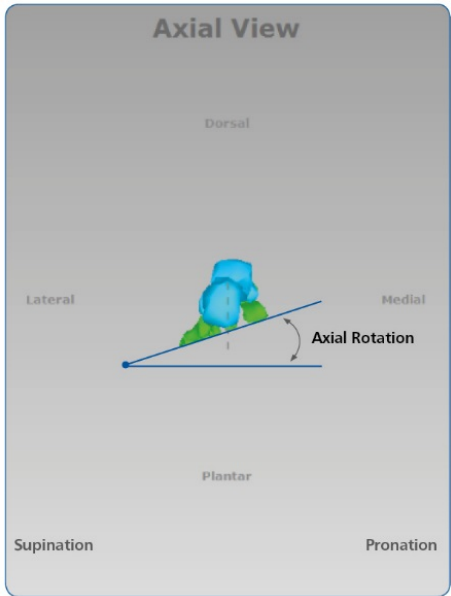
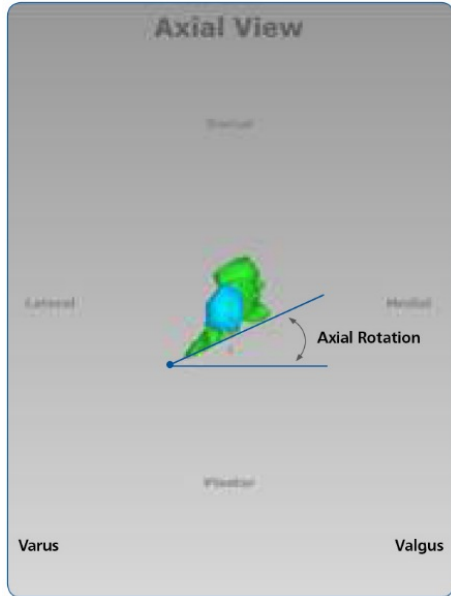
View name	AP View	
Bone type	LONG BONE	ANKLE
Description	<p>Angular Deformity (deg) Deformity in the Frontal or Coronal plane depending on whether the distal segment is deviated medially or laterally in relation to the reference segment. It can be either varus or valgus.</p> <p>Translation (mm) In the 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.</p>	
Angular deformity (deg)	Valgus Varus	Valgus Varus
Translation (mm)	Medial Lateral	Medial Lateral
		

View name	AP View	
Bone type	FOREFOOT	HINDFOOT
Description	<p>Angular Deformity (deg) Deformity in the Transverse or Horizontal plane depending on whether the distal segment is deviated medially or laterally in relation to the reference segment. It can be either Abduction (ABD) Adduction (ADD).</p> <p>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.</p>	
Angular deformity (deg)	Abduction(ABD) Adduction(ADD)	Abduction(ABD) Adduction(ADD)
Translation (mm)	Medial Lateral	Medial Lateral
		

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

View name	LATERAL View	
Bone type	FOREFOOT	HINDFOOT
Description	<p>Angular Deformity (deg): Deformity in Sagittal plane depending on whether the distal segment is deviated dorsally or plantarly in relation to the reference segment.</p> <p>Translation (mm) In the Sagittal plane, the translation can be dorsal or plantar.</p> <p>NOTE for foot: The two axes of the foot intersect on the point of reference (navicular talus joint) and originate an angle of 37° Apex Dorsal. The software considers this angle value as default Lateral angular deformity. This point is also considered as the reference point to whom translations and angulations are determined. The point of reference is not located on the forefoot or the hindfoot osteotomy level. For details, refer to Nomenclature section.</p>	
Angular Deformity (deg)	Apex Dorsal Apex Plantar	Apex Dorsal Apex Plantar
Translation (mm)	Dorsal Plantar	Dorsal Plantar
	 <p>The diagram shows a lateral view of the forefoot with a blue bone segment and a green bone segment. A red line indicates the reference axis. The angle between the reference axis and the green segment is labeled 'Lateral angulation'. The distance from the reference point to the green segment is labeled 'Lateral translation'. The diagram is labeled 'Lateral View' at the top and 'Dorsal', 'Plantar', 'Posterior', and 'Anterior' at the bottom.</p>	 <p>The diagram shows a lateral view of the hindfoot with a blue bone segment and a green bone segment. A red line indicates the reference axis. The angle between the reference axis and the green segment is labeled 'Lateral angulation'. The distance from the reference point to the green segment is labeled 'Lateral translation'. The diagram is labeled 'Lateral View' at the top and 'Dorsal', 'Plantar', 'Posterior', and 'Anterior' at the bottom.</p>

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

View name	AXIAL View	
Bone type	FOREFOOT	HINDFOOT
Description	<p>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.</p> <p>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 (<i>compressed</i>) towards the reference bone segment. The Long option is applicable when the moving bone segment is translated (<i>distracted</i>) away from the reference bone segment.</p>	
Angular Deformity (deg)	Supination Pronation	Varus Valgus
Translation (mm)	Short Long	Short Long
	 <p>The diagram shows an axial view of a foot model. A blue line represents the longitudinal axis. A green arrow indicates 'Axial Rotation' around this axis. The model is colored with a gradient from blue (lateral) to green (medial). Labels include 'Dorsal' at the top, 'Plantar' at the bottom, 'Lateral' on the left, 'Medial' on the right, 'Supination' at the bottom left, and 'Pronation' at the bottom right.</p>	 <p>The diagram shows an axial view of a foot model. A blue line represents the longitudinal axis. A green arrow indicates 'Axial Rotation' around this axis. The model is colored with a gradient from blue (lateral) to green (medial). Labels include 'Dorsal' at the top, 'Plantar' at the bottom, 'Lateral' on the left, 'Medial' on the right, 'Varus' at the bottom left, and 'Valgus' at the bottom right.</p>

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

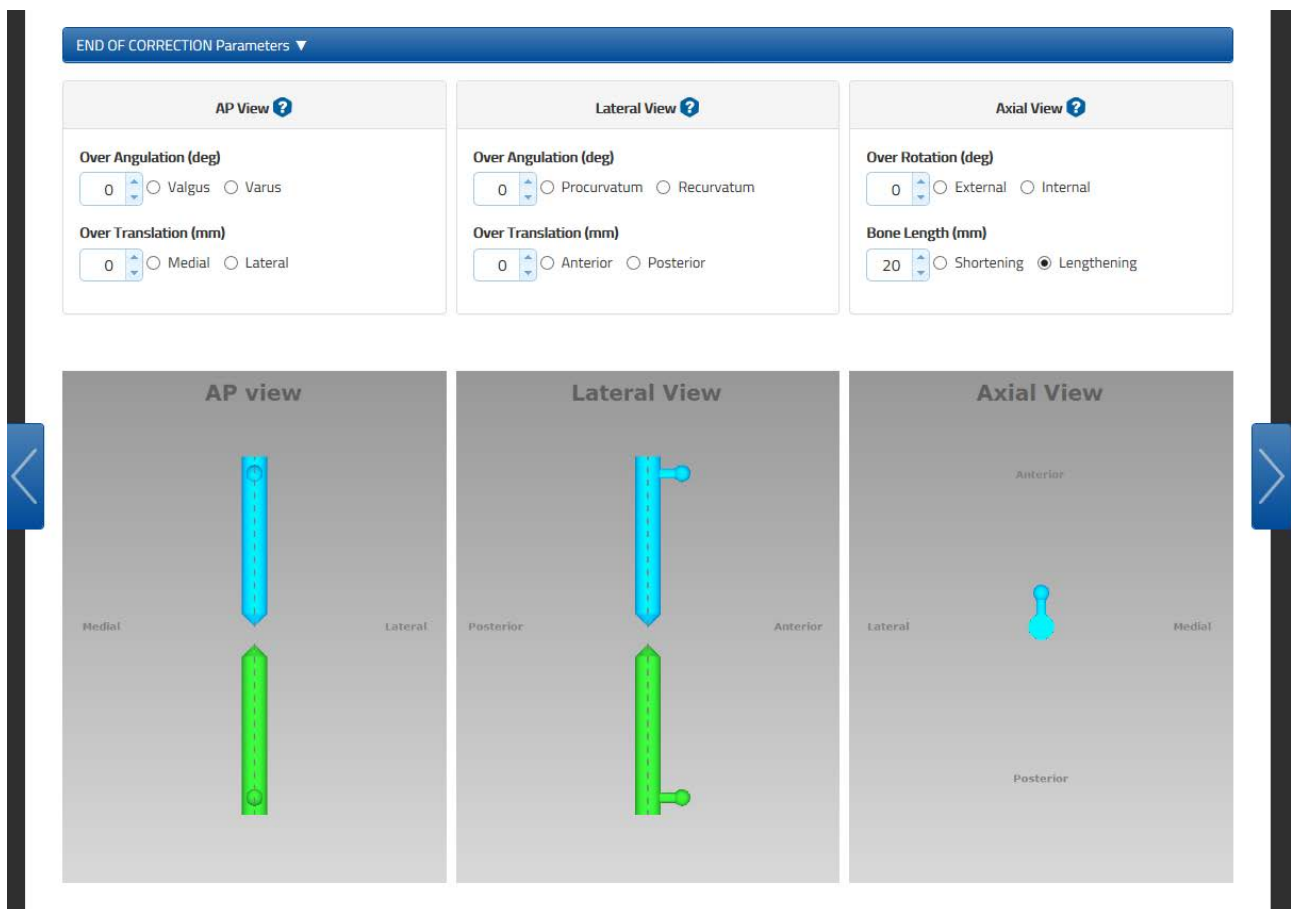
NOTE: All translations are described in millimeters and they are described in relation to the reference segment; changes in the direction of translation, as long as rotation in the Axial View, depend on whether proximal or distal referencing is used (see the [Nomenclature](#) section for details).

END OF CORRECTION

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

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

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



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

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

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

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

END OF CORRECTION Parameters ▼

Dorsal View ?

Over Angulation (deg)
 ☐ Abduction(ABD) ☐ Adduction(ADD)

Over Translation (mm)
 ☐ Medial ☐ Lateral

Lateral View ?

Over Angulation (deg)
 ☒ Apex Dorsal ☐ Apex Plantar

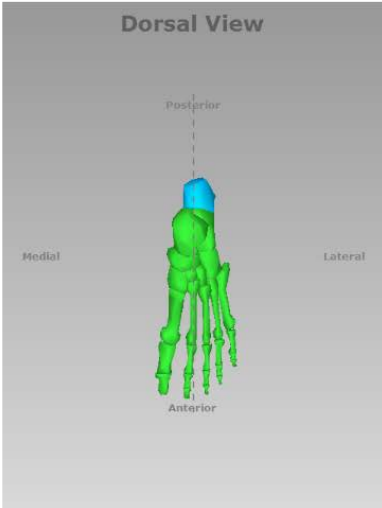
Over Translation (mm)
 ☐ Dorsal ☐ Plantar

Axial View ?

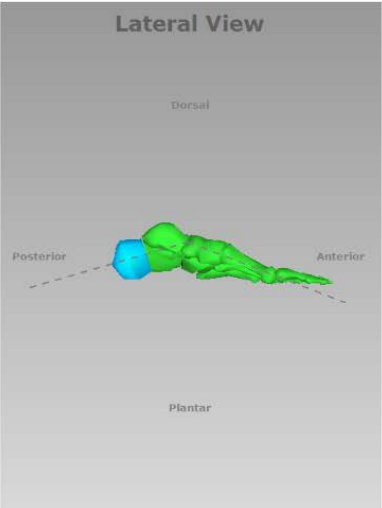
Over Rotation (deg)
 ☐ Varus ☐ Valgus

Bone Length (mm)
 ☐ Shortening ☐ Lengthening

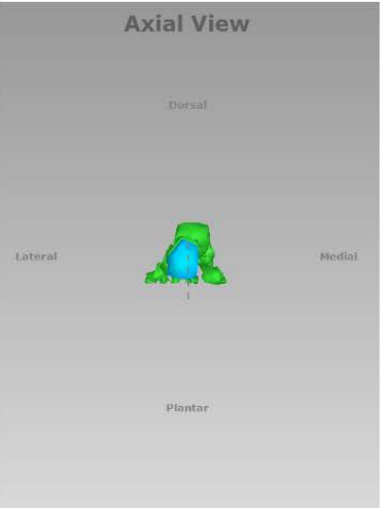
Dorsal View



Lateral View



Axial View

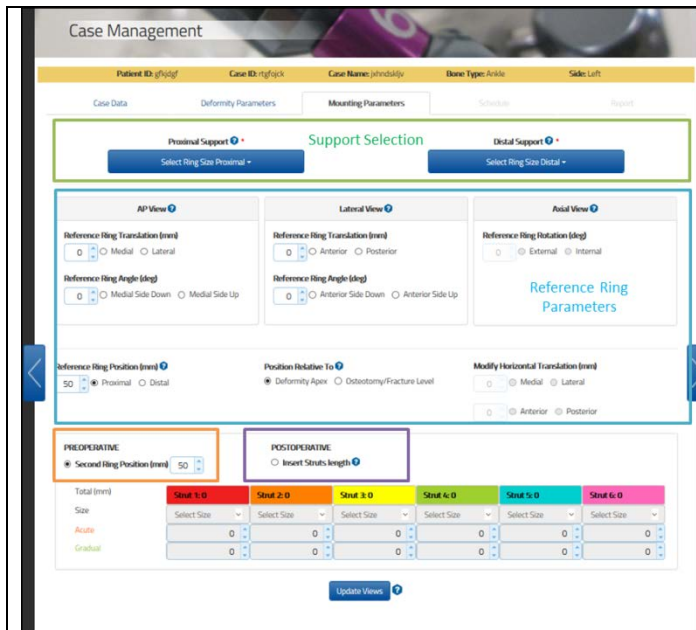


Click the Update Views button at any time to refresh the display after entering or reviewing the parameters.

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

MOUNTING PARAMETERS

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



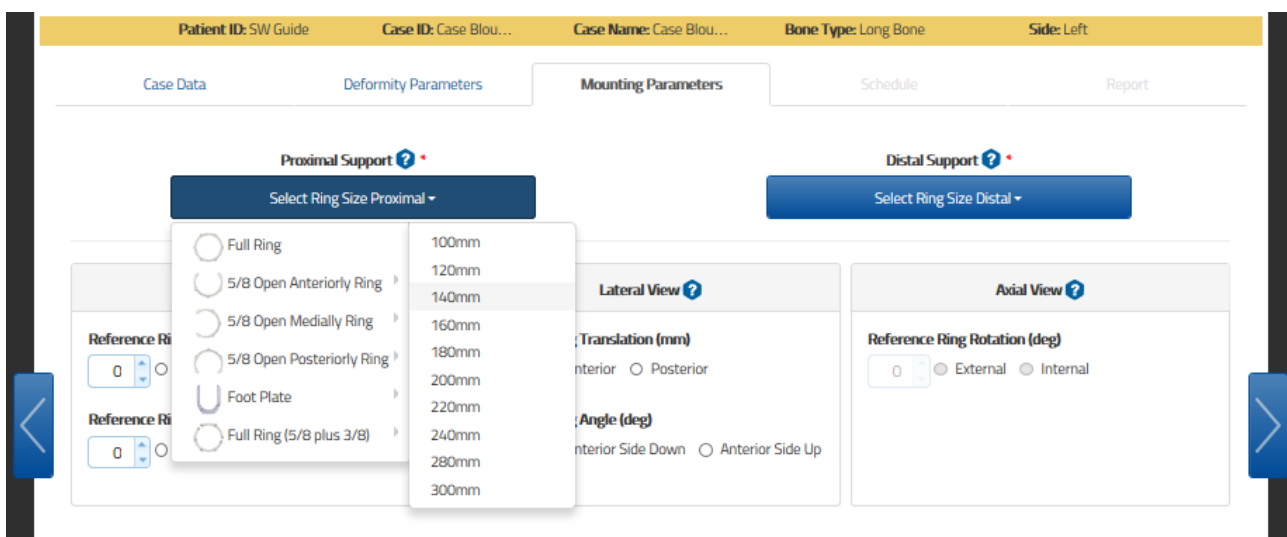
In this tab, the surgeon can:

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

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

SUPPORT SELECTION

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



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

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

PLANNING MANAGEMENT

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

The software presents these two alternative options:

If **PREOPERATIVE** (Second Ring Position) option is selected – default option

	Strut 1: 185	Strut 2: 146	Strut 3: 108	Strut 4: 103	Strut 5: 123	Strut 6: 170
Total (mm)						
Size	Long	Medium	Short	Short	Medium	Medium
Acute	0	0	15	11	8	21
Gradual	54	3	14	15	35	0

- 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, parameters values and the Second Ring Position, when the surgeon clicks the **Update Views** button, the software calculate the six struts configuration in the Struts Table. Those numbers are not editable by the user.

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

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

	Strut 1: 175	Strut 2: 139	Strut 3: 101	Strut 4: 95	Strut 5: 116	Strut 6: 161
Total (mm)						
Size	Medium	Medium	Short	Short	Medium	Medium
Acute	27	25	9	3	2	13
Gradual	1	35	15	15	35	1

- o 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.

PREOPERATIVE PLANNING

The screen provides the option to adjust:

AP View ?	Lateral View ?	Axial View ?
Reference Ring Translation (mm) <input type="text" value="0"/> <input type="radio"/> Medial <input type="radio"/> Lateral	Reference Ring Translation (mm) <input type="text" value="25"/> <input type="radio"/> Anterior <input checked="" type="radio"/> Posterior	Reference Ring Rotation (deg) <input type="text" value="0"/> <input type="radio"/> External <input type="radio"/> Internal
Reference Ring Angle (deg) <input type="text" value="0"/> <input type="radio"/> Medial Side Down <input type="radio"/> Medial Side Up	Reference Ring Angle (deg) <input type="text" value="0"/> <input type="radio"/> Anterior Side Down <input type="radio"/> Anterior Side Up	

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

AP/Dorsal View	LATERAL View	AXIAL View
<p>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.</p> <p>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.</p>	<p>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</p> <p>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.</p>	<p>Rotation - the software will automatically calculate the orientation offset of the reference ring; the value is read-only.</p>

Reference Ring Position (mm) ? <input type="text" value="100"/> <input checked="" type="radio"/> Proximal <input type="radio"/> Distal	Position Relative To ? <input checked="" type="radio"/> Deformity Apex <input type="radio"/> Osteotomy/Fracture Level	Modify Horizontal Translation (mm) <input type="text" value="0"/> <input type="radio"/> Medial <input type="radio"/> Lateral <input type="text" value="0"/> <input type="radio"/> Anterior <input type="radio"/> Posterior
--	---	---

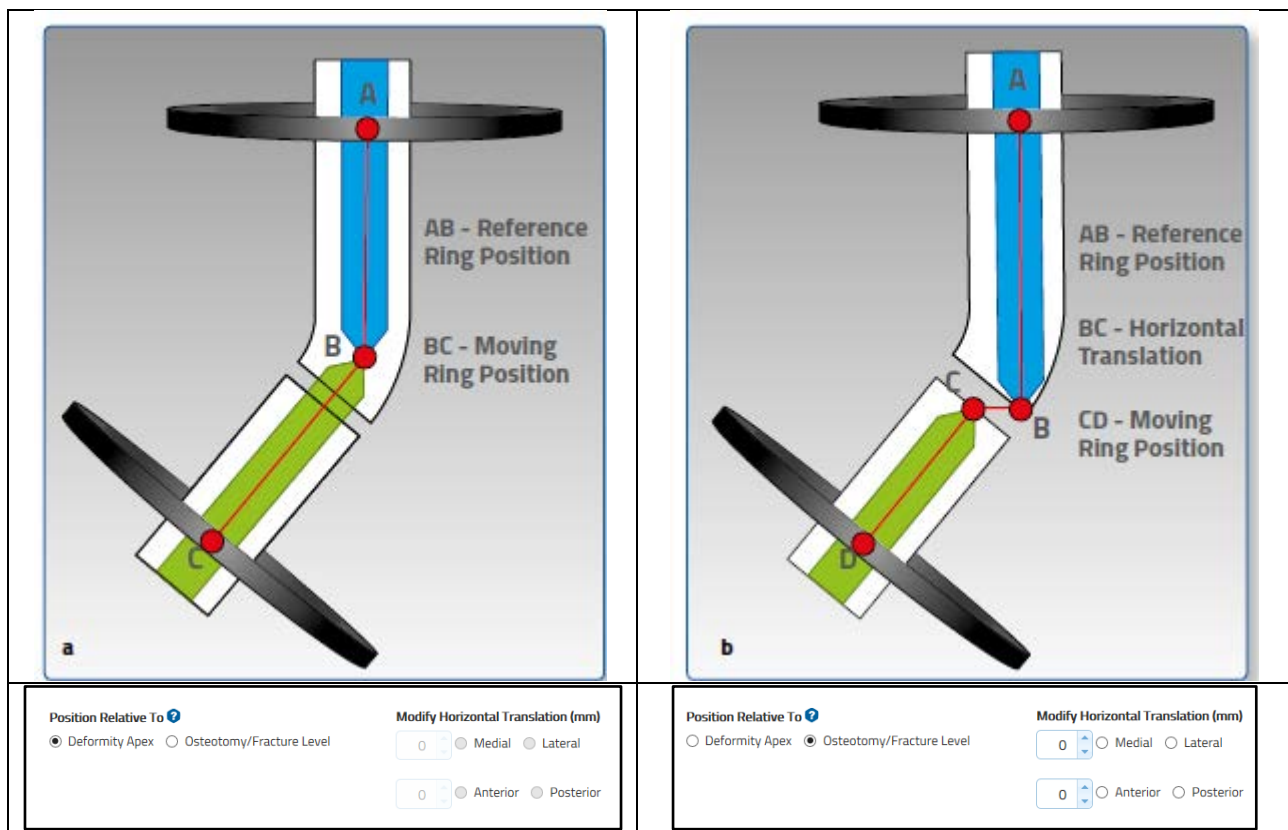
The user also has to provide:

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

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

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

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



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

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

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

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

Reference Ring Position (mm) ? 100 ☒ Proximal ☐ Distal

Position Relative To ? ☒ Deformity Apex ☐ Osteotomy/Fracture Level

Modify Horizontal Translation (mm) 0 ☐ Medial ☐ Lateral

0 ☐ Anterior ☐ Posterior

PREOPERATIVE ☒ Second Ring Position (mm) 80

POSTOPERATIVE ☐ Insert Strut lengths ?

Total (mm)	Strut 1: 254	Strut 2: 209	Strut 3: 162	Strut 4: 149	Strut 5: 179	Strut 6: 239
Size	Long	Long	Long	Medium	Long	Long
Acute	16	0	3	34	21	1
Gradual	1	30	80	35	80	0

Update Views ?


AP view **Lateral View** **Axial View**

Medial Lateral Anterior Posterior

END OF CORRECTION Parameters ▶

WARNING SYSTEM

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

 There was an out of range error on struts Welcome TL-HEX ×

PREOPERATIVE ☒ Second Ring Position (mm) 150

POSTOPERATIVE ☐ Insert Struts length ?

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

Total (mm)	Strut 1: 321	Strut 2: 334	Strut 3: 344	Strut 4: 296	Strut 5: 292	Strut 6: 268
Size	Long	Long	Long	Long	Long	Long
Acute	80	96	106	80	80	80
	Range: 0-80		Range: 0-80			
Gradual	-3	0	0	22	27	50
	Range: 0-80					

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

END OF CORRECTION Parameters ▼						
Total (mm)	Strut 1: 322	Strut 2: 322	Strut 3: 322	Strut 4: 323	Strut 5: 322	Strut 6: 323
	Out of Range	Out of Range	Out of Range	Out of Range	Out of Range	Out of Range
Size	Long	Long	Long	Long	Long	Long

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

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

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

PREOPERATIVE	POSTOPERATIVE					
<input checked="" type="radio"/> Second Ring Position (mm) 20	<input type="radio"/> Insert Strut lengths ?					
Entered parameters may not lead the TL-HEX System to the end of the treatment, please review them.						
Total (mm)	Strut 1: 151	Strut 2: 114	Strut 3: 117	Strut 4: 102	Strut 5: 101	Strut 6: 149
Size	Medium	Short	Medium	Short	Short	Medium
Acute	2	7	3	10	8	0
Gradual	0	1	35	15	15	0
Impingement				Proximal	Proximal	

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

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

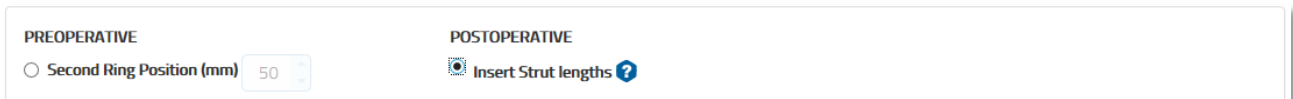
NOTE: the impingement information should be considered as an informative guideline and they not substitute the surgeon experience and review.

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

POSTOPERATIVE

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

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

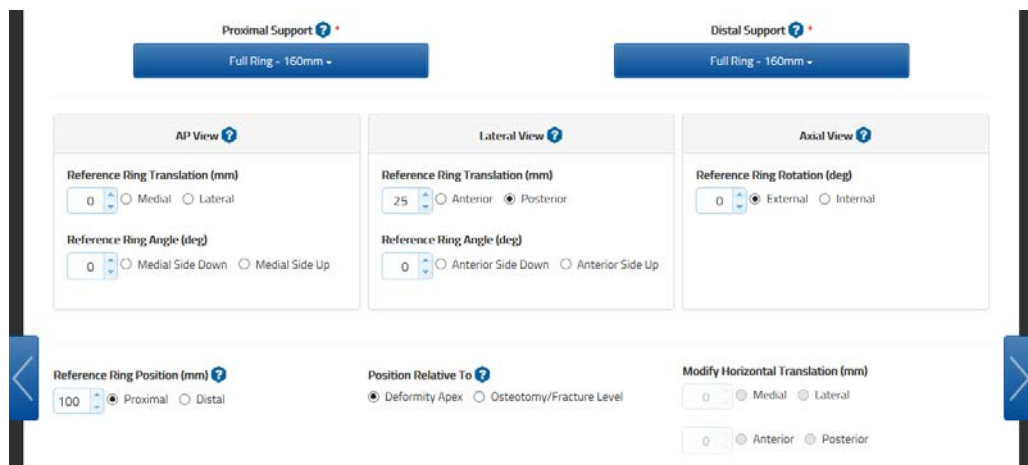


PREOPERATIVE POSTOPERATIVE

☐ Second Ring Position (mm) 50 ☒ Insert Strut lengths ?

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

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



Proximal Support ? Distal Support ?

Full Ring - 160mm - Full Ring - 160mm -

AP View ? Lateral View ? Axial View ?

Reference Ring Translation (mm) Reference Ring Translation (mm) Reference Ring Rotation (deg)

0 Medial Lateral 25 Anterior Posterior 0 External Internal

Reference Ring Angle (deg) Reference Ring Angle (deg)

0 Medial Side Down Medial Side Up 0 Anterior Side Down Anterior Side Up

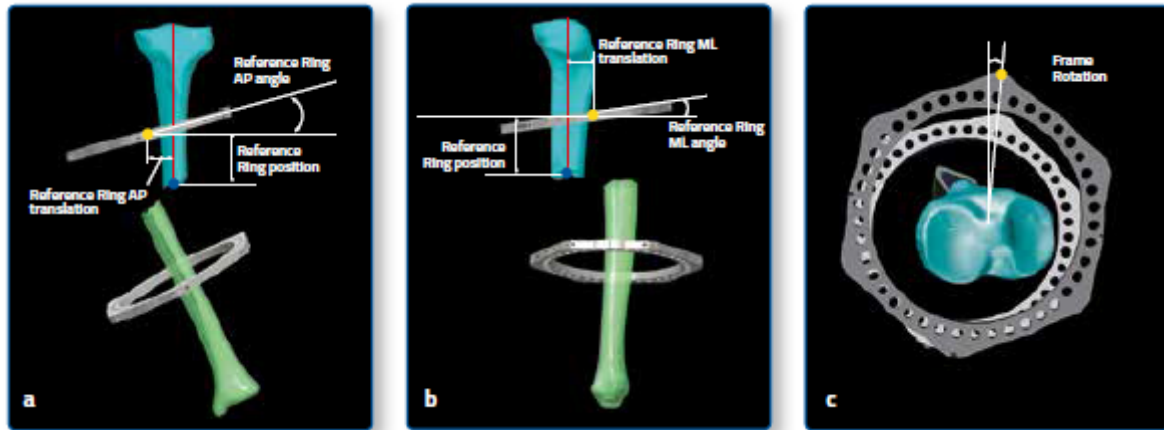
Reference Ring Position (mm) ? Position Relative To ? Modify Horizontal Translation (mm)

100 Proximal Distal Deformity Apex Osteotomy/Fracture Level 0 Medial Lateral

Anterior Posterior

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	LATERAL View	AXIAL View
<p>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.</p> <p>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.</p>	<p>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</p> <p>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.</p>	<p>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.</p>

o **Strut configuration**

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

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

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

Reference Ring Position (mm) ?
100 ☒ Proximal ☐ Distal

Position Relative To ?
☒ Deformity Apex ☐ Osteotomy/Fracture Level

Modify Horizontal Translation (mm)
0 ☐ Medial ☐ Lateral
0 ☐ Anterior ☐ Posterior

PREOPERATIVE
☐ Second Ring Position (mm) 50

POSTOPERATIVE
☒ Insert Strut lengths ?

Total (mm)	Strut 1: 254	Strut 2: 209	Strut 3: 162	Strut 4: 149	Strut 5: 179	Strut 6: 239
Size	Long	Long	Long	Medium	Long	Long
Acute	17	50	3	34	20	2
Gradual	1	79	79	34	79	1

Update Views ?

AP view


Lateral View

Axial View

END OF CORRECTION Parameters ▶

Click the [Update Views](#) button at any time to refresh the display after entering the parameters.

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

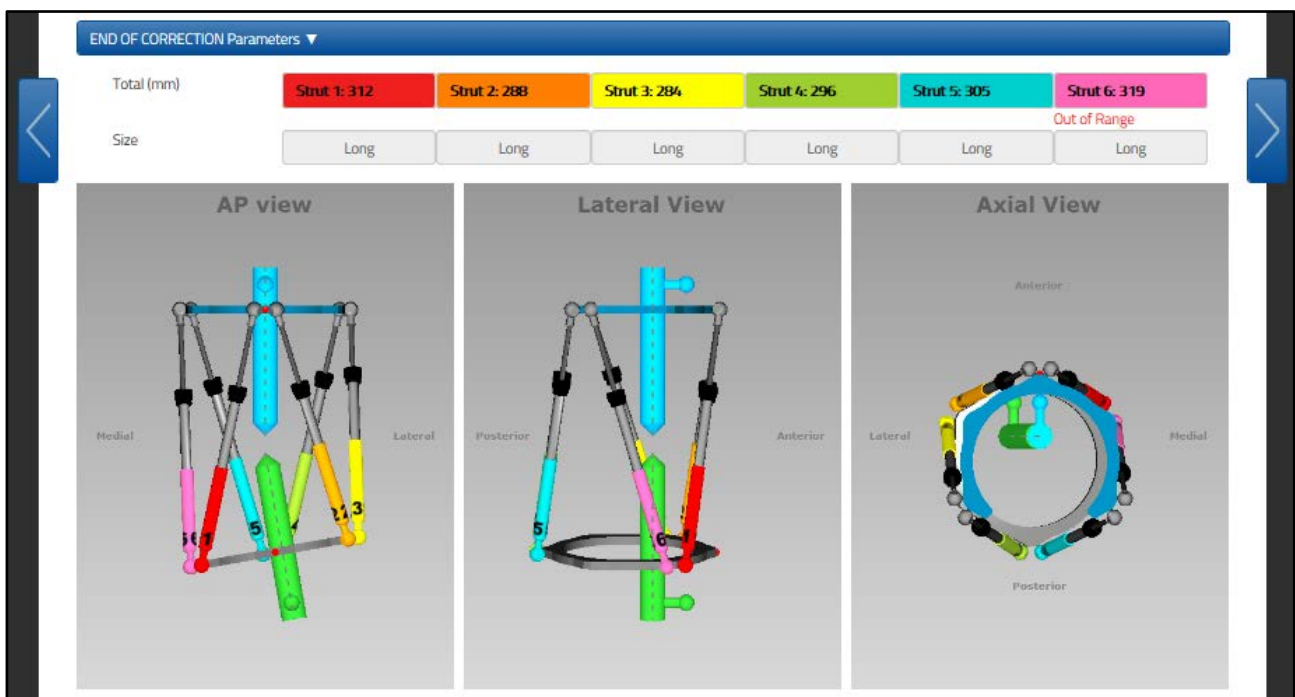
We suggest that in order to easily collect the data, you use the Patient ID form that can be downloaded by accessing the reserved area of the TL-HEX site (click on the Instruction for Use  icon).

END OF CORRECTION

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

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

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



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

SCHEDULE

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

Those parameters include:

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

Case Management

Patient ID: SW Guide Case ID: Case Blou... Case Name: Case Blou... Bone Type: Long Bone Side: Left

Case Data Deformity Parameters Mounting Parameters **Schedule** Report

Surgery Date * 18/02/2016 Latency Period (days) * 5 Correction Time(s) * Prescription Notes

Treatment Start Date * 23 febbraio 2016

00:00	01:00	02:00	03:00
04:00	05:00	06:00	07:00
08:00	09:00	10:00	11:00
12:00	13:00	14:00	15:00
16:00	17:00	18:00	19:00
20:00	21:00	22:00	23:00

Apply Lengthening/Shortening First ☐ ?

Calculate By * Days of Correction 25 **Calculate**

Calculation Results

Daily Correction Rate (mm/day)	0,8
Angular Max Speed (deg/day)	1,4
Rotate Max Speed (deg/day)	0,0
Days Of Correction	25

Privacy Policy EULA Cookies



Treatment start date may be adjusted using **Latency Period** (days) and **Correction Time(s)**, up to 4, may be selected in the appropriate box.

The correction rates and the days of correction are correlated and, therefore, the surgeon can determine the prescription calculation either by choosing a speed parameter or choosing the Days of Correction.

Once the 'Calculate by' parameter is determined by the surgeon, the other parameters are automatically calculated by the software after clicking on the **Calculate** button. The software is able to produce a solution using decimals.

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

It is necessary to enter a value in the 'Calculate By' box and 'Correction Time(s)' box prior to click the

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

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

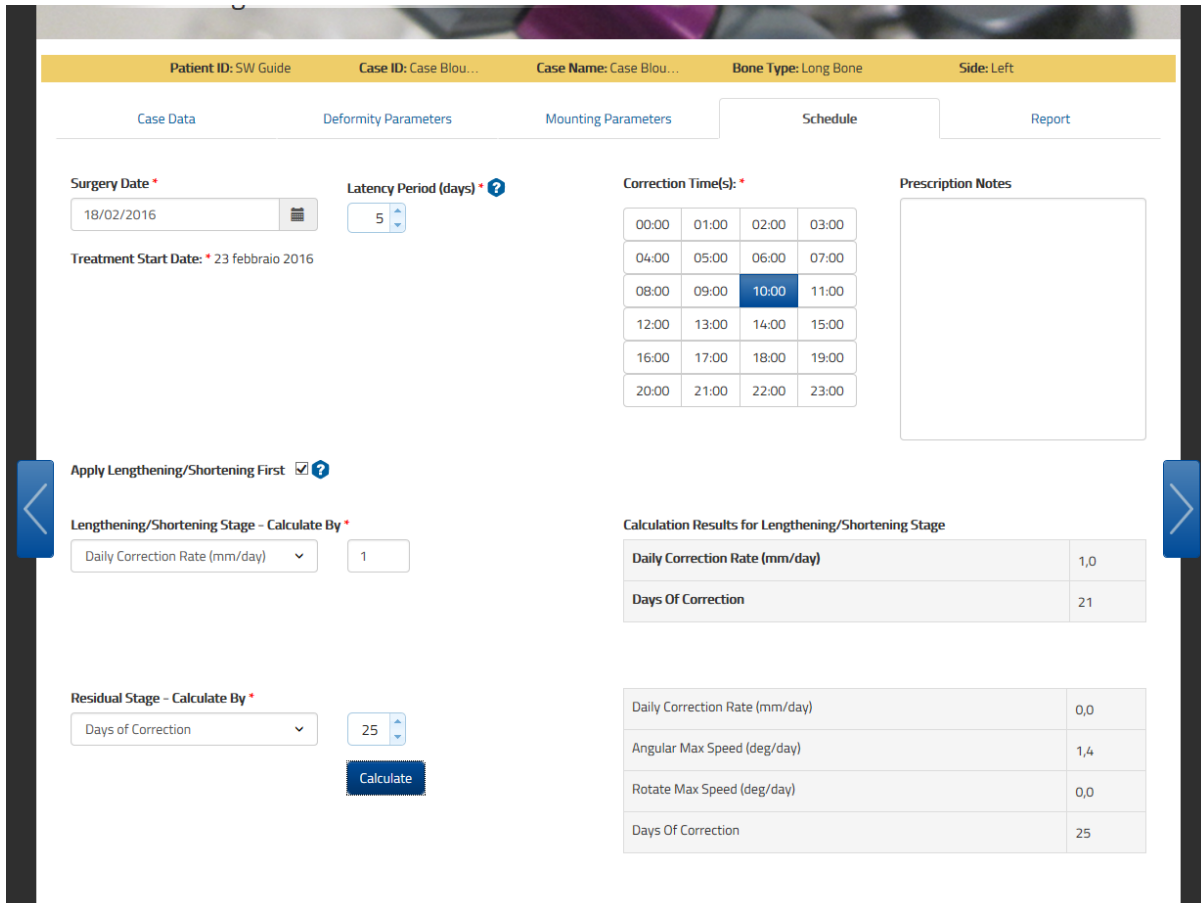
In the **Prescription Notes** text box, the surgeon can enter optionally some notes related to the current case that will be printed on the top right corner of the Prescription issued to the patient.

APPLY LENGTHENING/SHORTENING FIRST

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

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

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



Patient ID: SW Guide Case ID: Case Blou... Case Name: Case Blou... Bone Type: Long Bone Side: Left

Case Data Deformity Parameters Mounting Parameters Schedule Report

Surgery Date * 18/02/2016 Latency Period (days) * 5 Correction Time(s) * 10:00 Prescription Notes

Treatment Start Date: * 23 febbraio 2016

Apply Lengthening/Shortening First ☒ ?

Lengthening/Shortening Stage - Calculate By *
Daily Correction Rate (mm/day) 1

Residual Stage - Calculate By *
Days of Correction 25 Calculate

Calculation Results for Lengthening/Shortening Stage

Daily Correction Rate (mm/day)	1,0
Days Of Correction	21

Daily Correction Rate (mm/day)	0,0
Angular Max Speed (deg/day)	1,4
Rotate Max Speed (deg/day)	0,0
Days Of Correction	25

REPORT

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

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

These values should be checked by the surgeon, especially in extreme cases.

From Report screen it is possible to print the adjustment schedule for the patient, the prescription (see [Prescription](#) section) and the Bill of Materials (see [Bill of Materials](#) section).

Case Management

Patient ID: SW Guide

Case ID: Case Blou...

Case Name: Case Blou...

Bone Type: Long Bone

Side: Left

Case Data

Deformity Parameters

Mounting Parameters

Schedule

Report

Please review all information before completing and printing the prescription to ensure that it is accurate.

Select Print Option:

Prescription

Print

?

Strut Length A-Acute / G-Gradual

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

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

DETAILS & CHECKUP



This option icon will generate a pop-up window with the details of the selected row: the three views of the deformity and the frame for the corresponding date/time of the treatment, the related struts values and any warning about potential impingements.

Click 'Start New Case' to create a new case for the selected day/time and all the corresponding deformity and mounting parameters will be transferred to the new case.

STRUT ADJUSTMENT



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

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

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

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

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


STRUT ADJUSTMENT / EXCHANGE

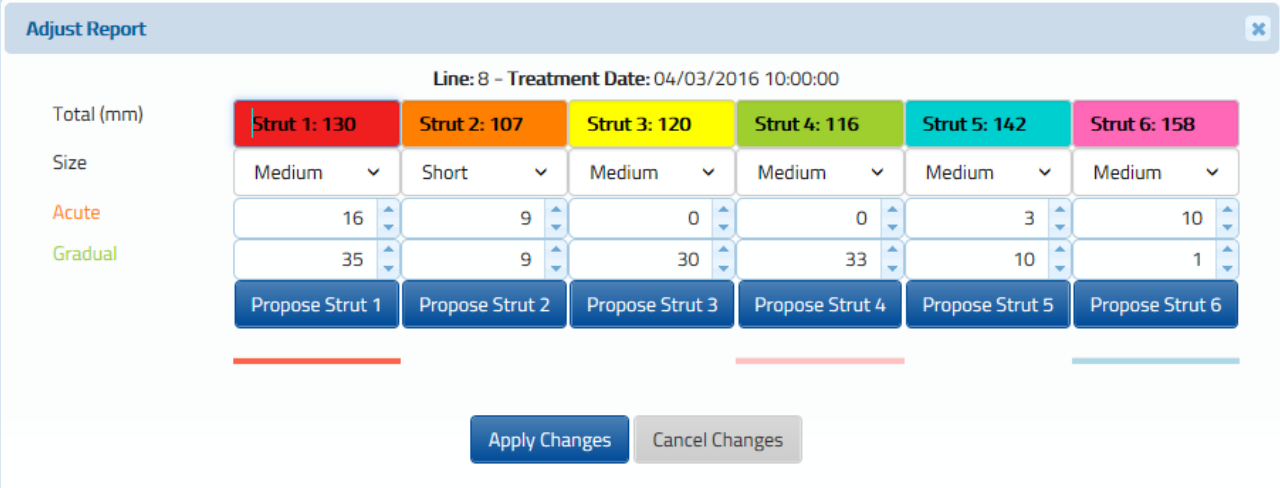
The prescription/report rows will be highlighted when strut adjustment (shaded blue) or exchange (shaded red) is required or suggested.

The rows of lighter shading indicate the allowable range of days that are suitable for the adjustment/exchange of a strut without adding extra adjustment/exchange to the treatment; the shaded row indicates the last possible day for the strut adjust/exchange.

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

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

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




Adjust Report ✕

Line: 8 - Treatment Date: 04/03/2016 10:00:00

	Strut 1: 130	Strut 2: 107	Strut 3: 120	Strut 4: 116	Strut 5: 142	Strut 6: 158
Total (mm)						
Size	Medium ▾	Short ▾	Medium ▾	Medium ▾	Medium ▾	Medium ▾
Acute	16	9	0	0	3	10
Gradual	35	9	30	33	10	1
	Propose Strut 1	Propose Strut 2	Propose Strut 3	Propose Strut 4	Propose Strut 5	Propose Strut 6

Apply Changes Cancel Changes

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

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

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


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


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


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

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

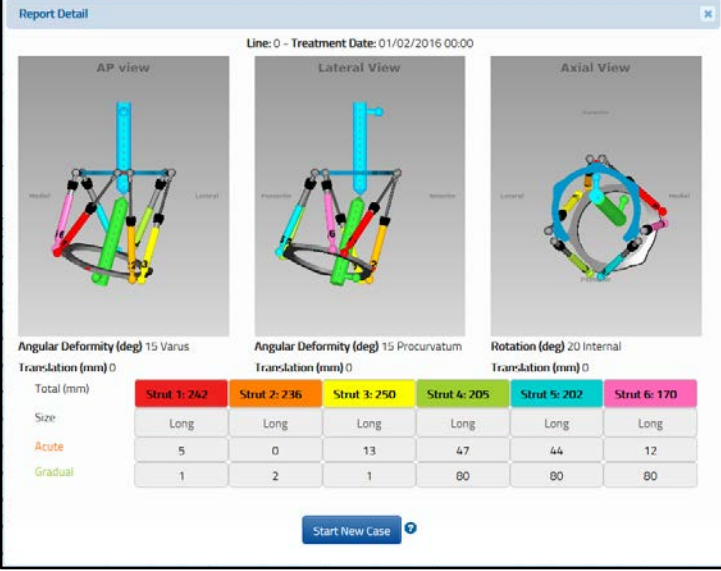
DETAILS & CHECKUP

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


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


Click the  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.



Line: 0 - Treatment Date: 01/02/2016 00:00						
AP view		Lateral View		Axial View		
Angular Deformity (deg) 15 Varus		Angular Deformity (deg) 15 Procurvatum		Rotation (deg) 20 Internal		
Translation (mm) 0		Translation (mm) 0		Translation (mm) 0		
Total (mm)						
Strut 1: 242	Strut 2: 236	Strut 3: 250	Strut 4: 205	Strut 5: 202	Strut 6: 170	
Size	Long	Long	Long	Long	Long	Long
Acute	5	0	13	47	44	12
Gradual	1	2	1	80	80	80




Clicking on the  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.

Case Management

Case Data
Deformity Parameters
Mounting Parameters
Schedule
Report

Patient ID * 

Case ID *

Case Name *

Planning Created *

Side * ☒ Left ☐ Right

Bone Type * ☒ Long Bone ☐ Ankle ☐ Forefoot ☐ Hindfoot

New Notes

Warning

You are not allowed to enter or provide any information that allows, directly or indirectly, the identification of your patient (e.g. name, birth date, address, email-address, phone number etc.). Please use only an internal confidential code to identify your patient record when using this Software.

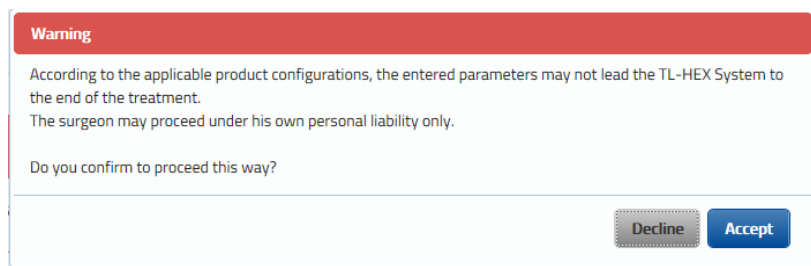
[Notes History](#)

WARNING SYSTEM


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

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

NOTE: Impingements between external supports are not evaluated.



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

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


Case Data

Deformity Parameters

Mounting Parameters


Schedule

Report












 **Warning**



This Report/Prescription may not lead to the end of the treatment. The surgeon confirmed to proceed under his own personal liability only.

Please review all information before completing and printing the prescription to ensure that it is accurate.

Select Print Option: Prescription Print 

Strut Length A-Acute / G-Gradual

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

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

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



PRESCRIPTION

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

NOTE: The print-out should be checked for correctness and readability and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.

NOTE: All information must be reviewed by the surgeon before completing and printing the prescription to ensure it is accurate.

Page 1

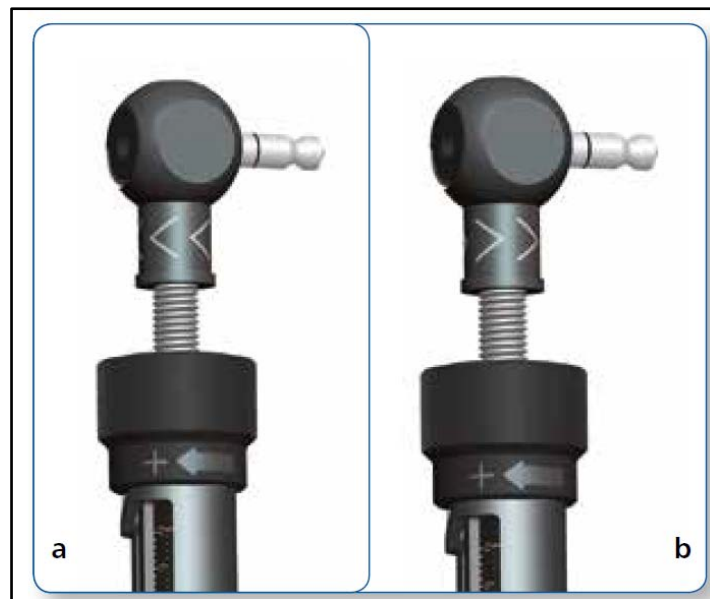
Dr. TL-Hex Demo			Print date: 18/02/2016, 17:13:59		
Prova			Case ID: Case Blount's		
Prova			Case Name: Case Blount's		
PanamaPanamaPanamaPanamaPanamaPana...			Patient Id: SW Guide		
(+39) 0456719000, (+39) 0456719000			Side: Left		
			Bone Type: Long Bone		

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

1/2

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

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



Strut Adjustments direction change

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

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

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

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

BILL OF MATERIALS

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

Page 1

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

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

Initial Construct

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


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


ACCOUNT MANAGEMENT

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

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

EDIT ACCOUNT INFORMATION

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





Primary Account Information


Use the boxes below to update your TL-Hex account information.

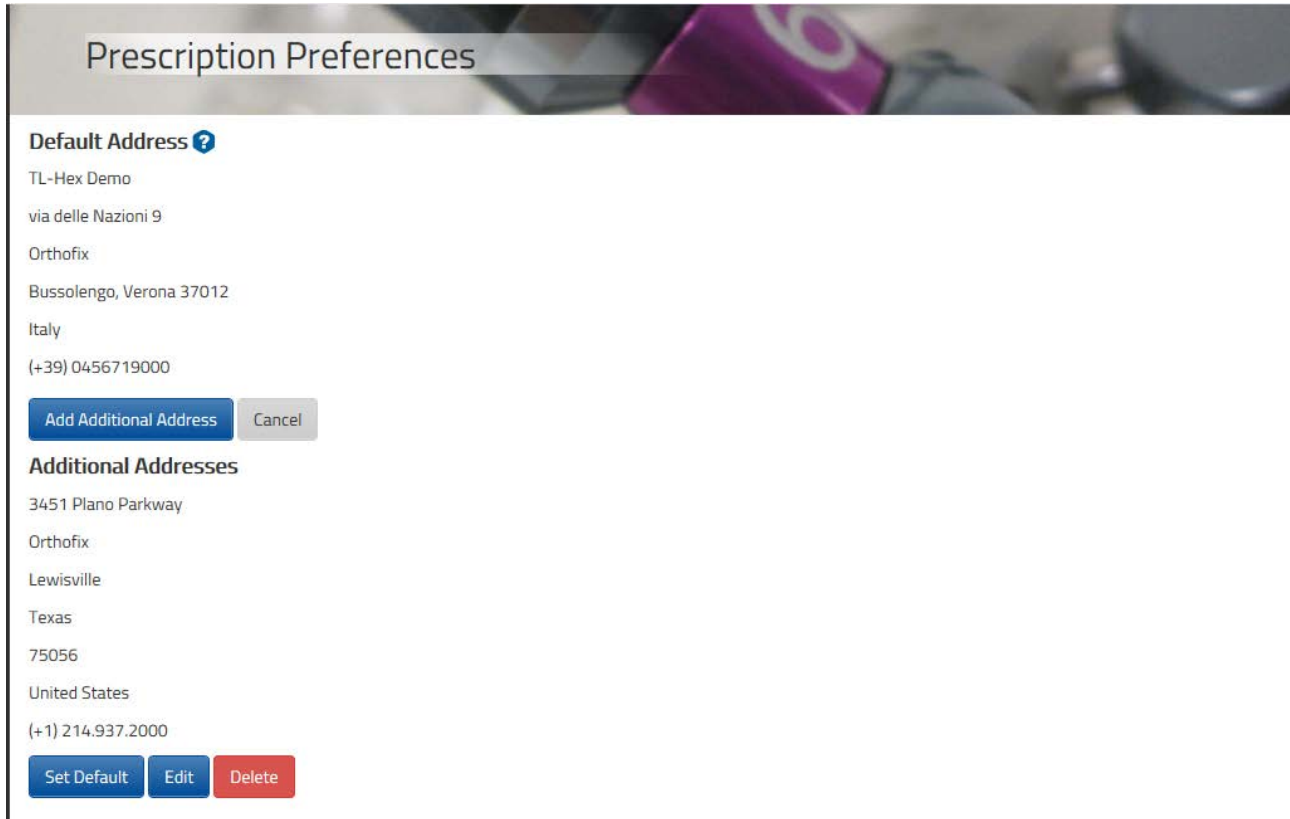
NOTE: Your First Name, Last Name, Email Address, and Country cannot be edited.

First Name TL-Hex	Work/Office Address Line 1 * <input type="text" value="via delle Nazioni 9"/>
Last Name Demo	Work/Office Address Line 2 <input type="text" value="via delle Nazioni 9"/>
Email tlh1@orthofix.com	City * <input type="text" value="Bussolengo"/>
Hospital * <input type="text" value="Orthofix SRL"/>	State/Province * <input type="text" value="New York"/>
Office Phone * <input type="text" value="(+39) 0456719000"/>	Postal Code * <input type="text" value="37012"/>
Mobile Phone <input type="text" value="(+39) 0456719000"/>	Country United States
	Practice DPM
	NPI 0123456789
	State Licences LA 23456
	State Licences IN 1234

PRESCRIPTION PREFERENCES

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




The screenshot shows the 'Prescription Preferences' screen. At the top, there's a header with the title 'Prescription Preferences' over a background image of a purple pill bottle. Below the header, the 'Default Address' section is displayed with a help icon. It lists the following details: 'TL-Hex Demo', 'via delle Nazioni 9', 'Orthofix', 'Bussolengo, Verona 37012', 'Italy', and the phone number '(+39) 0456719000'. Below this list are two buttons: 'Add Additional Address' (blue) and 'Cancel' (grey). The 'Additional Addresses' section follows, listing another address: '3451 Plano Parkway', 'Orthofix', 'Lewisville', 'Texas', '75056', 'United States', and the phone number '(+1) 214.937.2000'. At the bottom of this section are three buttons: 'Set Default' (blue), 'Edit' (blue), and 'Delete' (red).

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

CHANGE PASSWORD

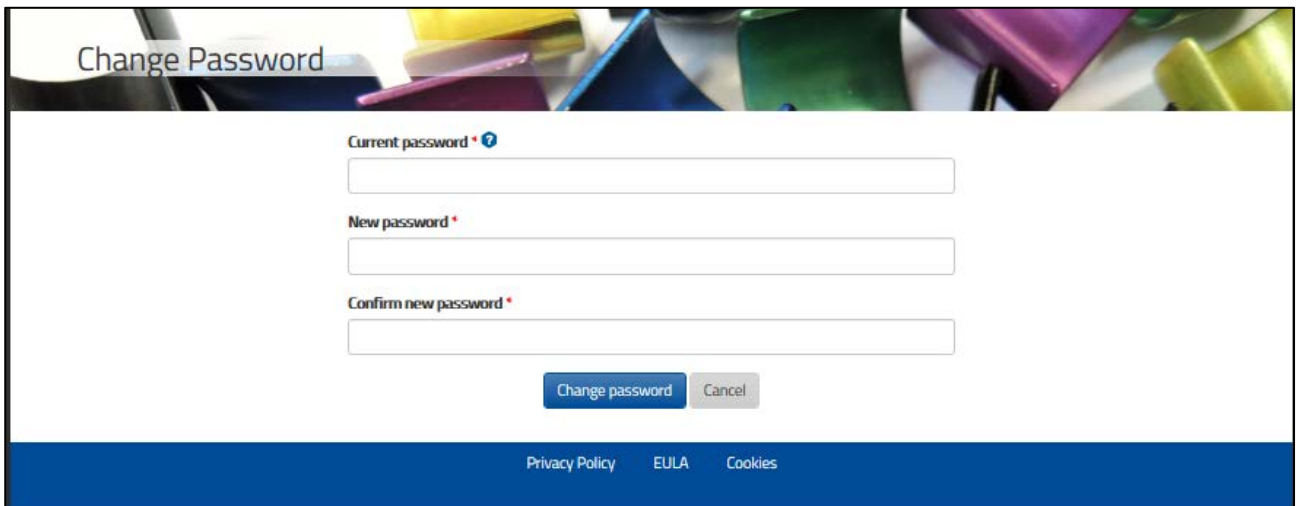
It is recommended that the user changes the password during the first log in and periodically thereafter.

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

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


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

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




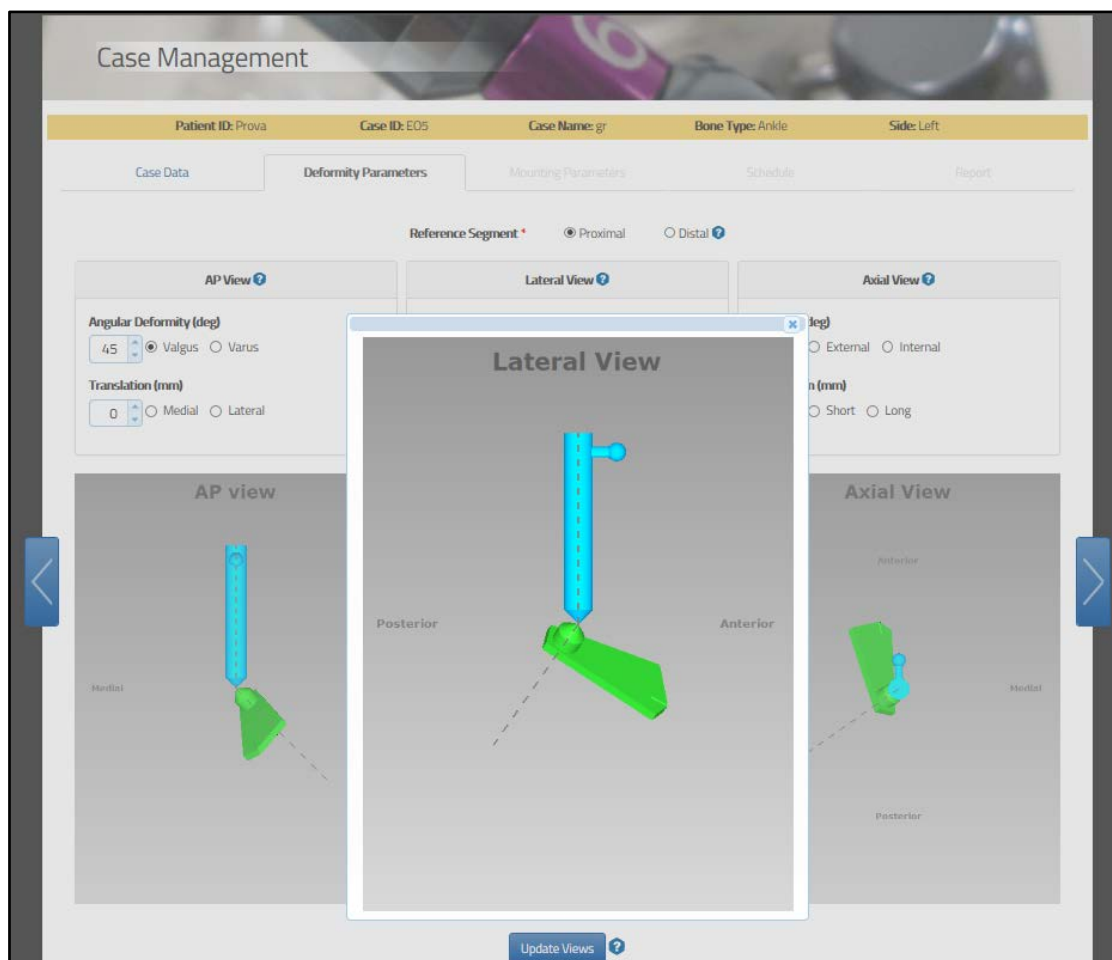
Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon should never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

ONLINE HELP

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

FEW MORE THINGS...

- To create a new case, the user begins with the Case Data tab followed by Deformity Parameters tab, etc. Once the case is completed, the user can navigate freely between tabs and the flow is from the left to the right; tabs that are not appropriate to the next step of the case planning process are greyed out. To return to a previous tab during a case creation process, the user should click the arrow to the left-hand side of the screen or one of the function tabs.
- It is good practice to click the  button after making any changes to the on screen parameters. This will provide visual confirmation that the changes are as intended. Regardless of whether the Update Views is clicked after changing one or more parameters, the new parameters will be saved once either the 'next' arrow on the right-hand side or one of the function tabs are clicked.
- The user can click on each image to enlarge it in a pop-up window.



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

The screenshot displays the TL-HEX software interface with the following sections:

- Proximal Support:** Select Ring Size Proximal +
- Distal Support:** Select Ring Size Distal +
- AP View:**
 - Reference Ring Translation (mm): 0, Medial, Lateral
 - Reference Ring Angle (deg): 0, Medial Side Down, Medial Side Up
- Lateral View:**
 - Reference Ring Translation (mm): 0, Anterior, Posterior
 - Reference Ring Angle (deg): 0, Anterior Side Down, Anterior Side Up
- Axial View:**
 - Reference Ring Rotation (deg): 0, External, Internal
- Reference Ring Position (mm):** 50, Proximal, Distal
- Position Relative To:** Deformity Apex, Osteotomy/Fracture Level
- Modify Horizontal Translation (mm):** 0, Medial, Lateral, Anterior, Posterior
- PREOPERATIVE:** Second Ring Position (mm): 50
- POSTOPERATIVE:** Insert Strut Length
- Table of Strut Lengths:**

	Strut 1: 0	Strut 2: 0	Strut 3: 0	Strut 4: 0	Strut 5: 0	Strut 6: 0
Total (mm)	Select Size	Select Size	Select Size	Select Size	Select Size	Select Size
Size:	0	0	0	0	0	0
Actual:	0	0	0	0	0	0

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

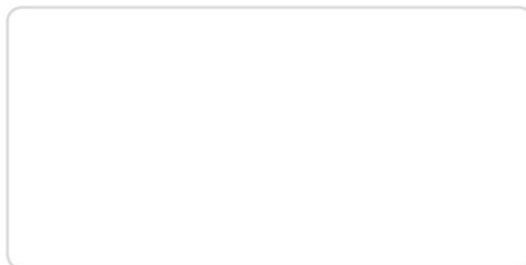
The site footer links provide legal information (about Cookies, Eula and Privacy).



Manufactured by:
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo (Verona), Italy
Telephone +39 045 6719000, Fax +39 045 6719380

CE 0123

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.

www.orthofix.com



TH-1603-PL-E0 B 10/16