iFIXATION®

User Manual

INTRODUCTION

iFIXation® is an advanced computer assisted hexapod external fixator system with wide potentialities for correcting deformities and reducing fractures.

The system is essentially composed by two rings connected through six movable elements (struts) and it is attached to the bone segments through k-wires and/or pins. The lengthening or shortening of the single elements allows the multi-planar movement of one ring with respect to the other and, therefore, the alignment of the bone segments connected to the rings.

The hardware of iFIXation®, which was designed and manufactured in Italy, was developed to guarantee the maximum mechanical stability of the system. Moreover, it is aesthetically pleasant thanks to its red anodized colour.

The software of iFIXation®, which is based on the most updated IT languages and libraries, allows achieving fast and easy reductions and corrections.

The system was designed in order to be fully compatible with the circular external fixator RRS® Dial Medicali; therefore, the elements of RRS® may be applied to complete and expand iFIXation® implants.

INDICATIONS

- 1 –

The system presents a considerable versatility and a wide range of indications, both for adult and paediatric patients:

- Deformity
- Fracture
- Pseudo-arthrosis
- Dysmetria
- Arthrodesis
- Bone transport

HARDWARE

- 2-

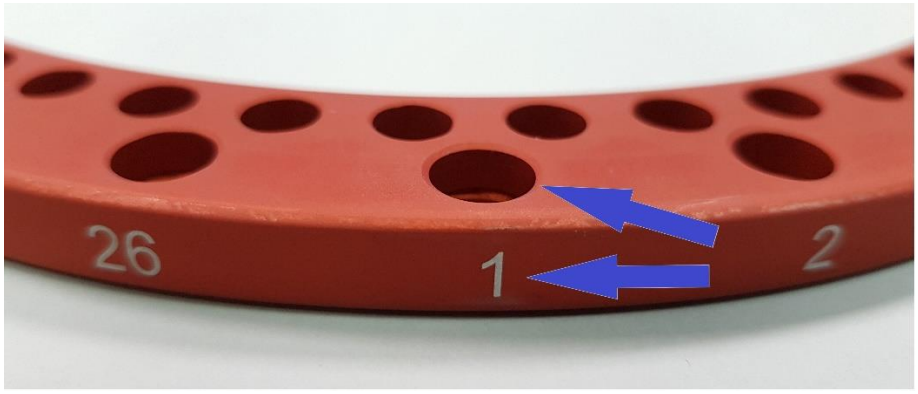
2.1 iFIXation® RINGS

Four different kinds of ring are available:

- *Full ring*
- *Half ring*
- *5/8 ring*
- *Foot ring*

iFIXation® rings are 9 mm thick and are made of anodized aluminium with high mechanical resistance. Each kind of ring is available in different sizes, in order to deal with every clinical requirement.

The rings present a double raw of holes. The internal raw is intended for elements attached to the bone, while the external one is destined for struts mounting. The internal holes inter-axis is the same of the rings of the circular system RRS®. The external holes are progressively counter-clockwise numbered. The numbers are printed on the side of the ring.



Hole + Number (1) = Position 1

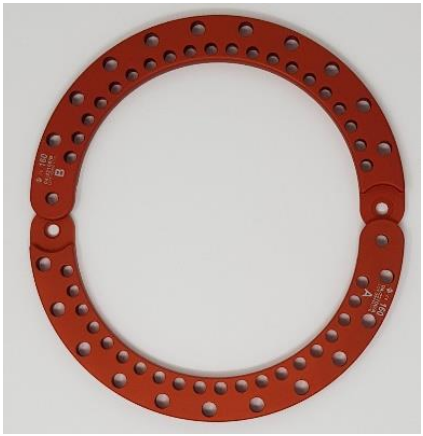
2.1.1 FULL RINGS

Full and half-rings are available in 11 different sizes with an internal diameter between 120 and 240 mm: 120mm, 130mm, 140mm, 150mm, 160mm, 180mm, 200m, 220mm, 240mm.

2.1.2 HALF RINGS (A-B)

Half-rings include A half-rings and B half-rings.

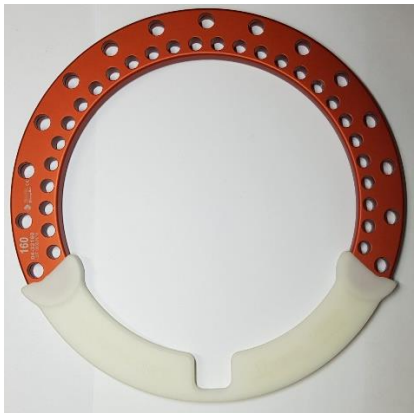
In order to obtain a full ring using two half-rings, it is necessary to join an A half-ring with a B half-ring. Half-rings are designed so that they can be univocally connected.



2.1.3 5/8 RINGS

These rings have a partial circumference, with an opening equal to 3/8 of circumference. They are suited for particular mountings. 5/8 rings are available in 7 different sizes with an internal diameter between 140 and 240 mm: 140mm, 150mm, 160mm, 180mm, 200mm, 220mm, 240mm.

If the 5/8 ring is used as proximal ring, it is necessary to temporarily connect it to the 3/8 completion, before proceeding with radiological analyses. The 3/8 completion is made of plastic material and its mounting is essential for the correct calibration of the images (cfr paragraph 5.4.1.3b); it has to be removed when the x-rays are completed.

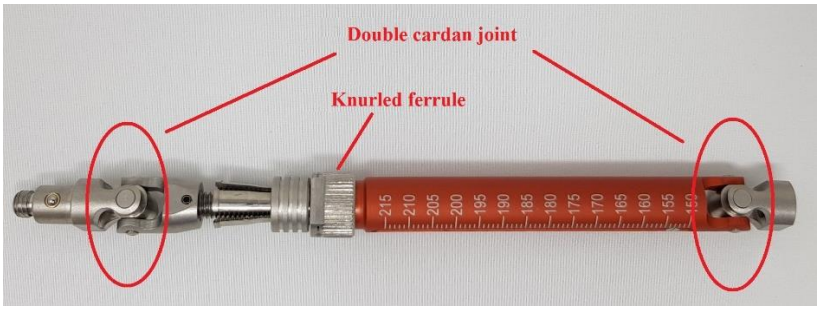


2.1.4 FOOT RING

The foot rings are available in four sizes: 160 mm in diameter x 120 mm in length, 160 mm in diameter x 160 mm in length, 180 mm in diameter x 120 mm in length, 180 mm in diameter x 160 mm in length.

2.2 iFIXation® STRUTS

The struts are manufactured in aluminium alloy and amagnetic stainless steel. They are provided with a double cardan joint, a knurled ferrule, which allows millimetric movements (an entire turn corresponds to a millimetre of lengthening/shortening), a ferrule for quick unfastening, that allows quick lengthening/shortening of the struts, and a millimetric scale for reading the length of the strut. The mini strut represents an exception, since it is not provided with the quick fastening system due to the reduced available space.



Double cardan joint

Quick unfastening system

The struts are available in six different sizes (MINI, SXS, XS, M, L, XL), from 80 to 317 mm.

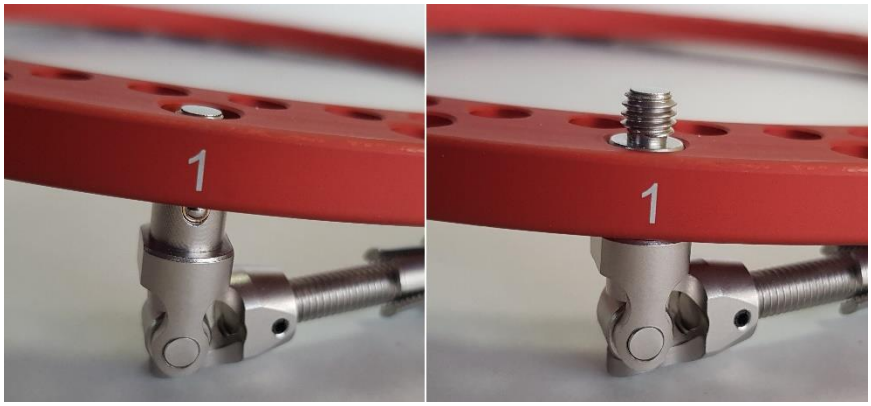
Strut	***Length*** *(min/max)*
MINI	80mm - 105mm
SXS	103mm – 120mm
XS	108mm – 130mm
M	123mm – 161mm
L	150mm – 215mm
XL	202mm – 317mm

Each strut presents a hybrid connection system to the ring: male connection for the proximal ring and female connection for the distal ring. Male connection allows temporarily attaching the strut to the ring with an easy and fast approach, while the female connection simplifies strut changes.

Connection

Female connection

Mini strut



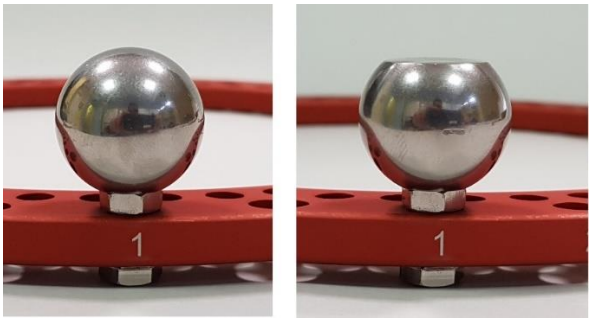
Quick attachment: how it works

In order to recognize the six mounted struts, there are six clips, which are differently coloured and named from A to F. The clips have to be placed on the struts counter-clockwise and following an alphabetical order. Moreover, they work as a block, avoiding accidental unfastening of the ferrule.

Blocking clips

2.3 iFIXation® REFERENCE SPHERES

The system is based on the temporary use of three reference spheres, which have to be fixed on the proximal ring above three nuts of the struts. Two of the three spheres are full spheres, while the third one is truncated in order to be easily identified during the use of the software.



Reference spheres fixed on an iFIXation® nut: full sphere (left) and truncated sphere (right)

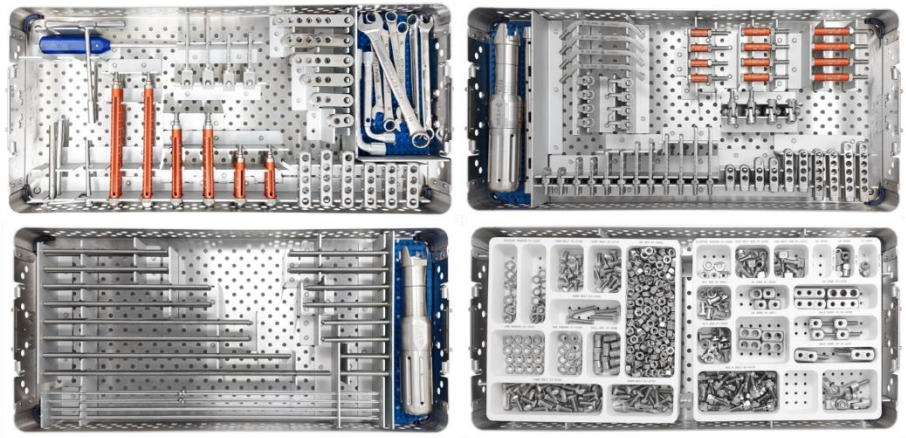
2.4 iFIXation® NUTS

iFIXation® nuts are used to fix the struts and/or to position the reference spheres. They are M6 nuts and are provided with a rubber washer, which improves connection with the sphere.

M6 nuts with rubber washer

2.5 HARDWARE (components)

The system includes many components, such as connectors, K-wire bolts etc.…, which are entirely compatible with the *RRS*® system of Dial Medicali.



Various connectors

ASSEMBLY

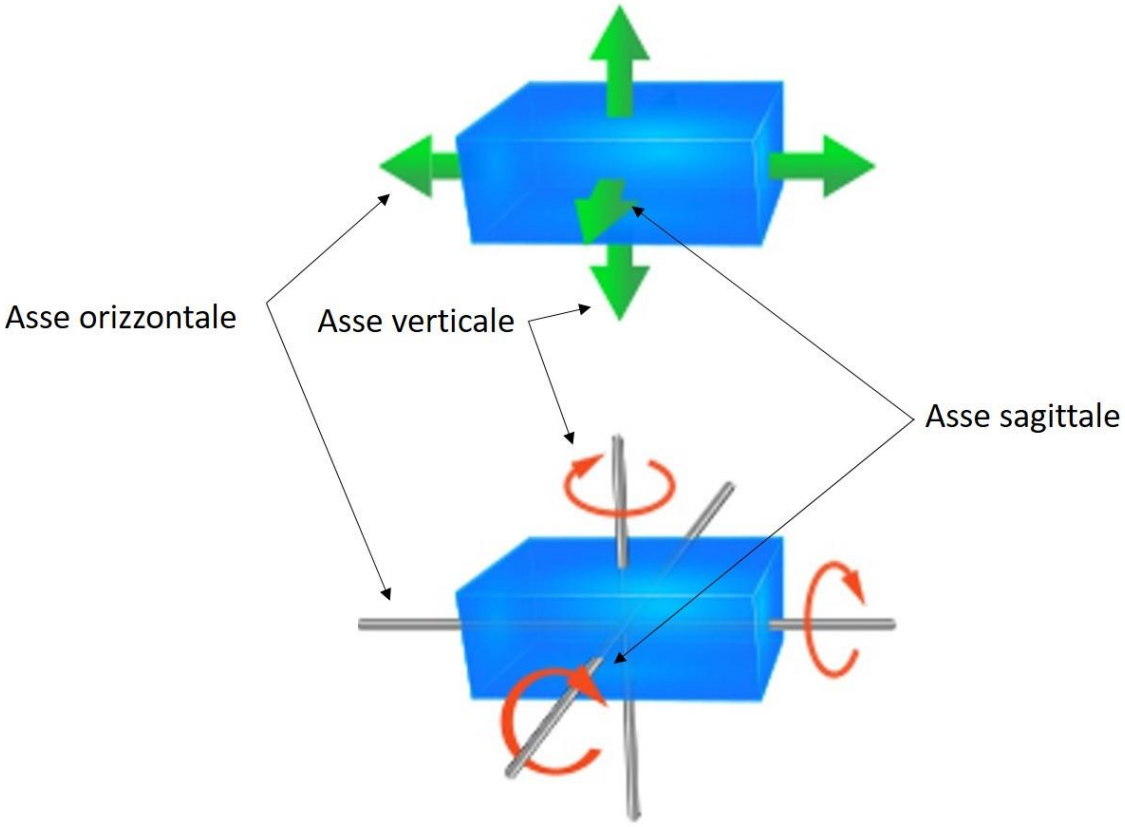
- 3 -

The flexibility of the iFIXation® system allows to assemble it with different configurations, in order to best satisfy the needs of each surgery and the requirements of the orthopaedic surgeon.

The technique and the rules for a basic assembly of the iFIXation® system will be described below. These rules are valid for complex cases too.

3.1 INTRODUCTION

According to classical mechanics, a rigid body can move in a space defined by Cartesian axes x, y, z with 3 different degrees of freedom, three of which translational and three rotational.

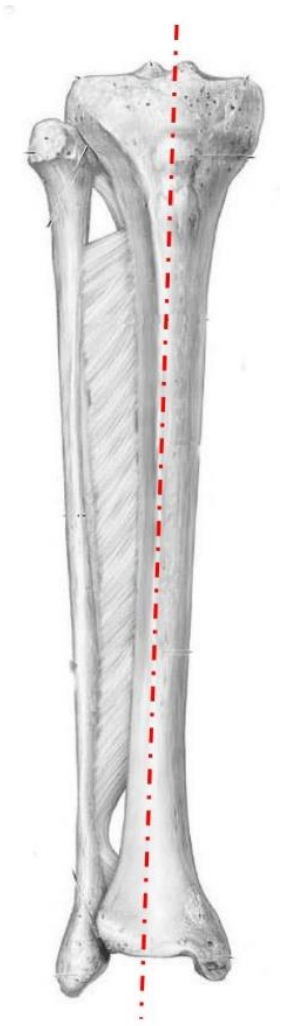


Six degrees of freedom

Therefore, bone fragments and elements of external fixation connected to them, could move in the space with six degrees of freedom:

- 3 translational degrees of freedom:
  - Vertical translations
  - Horizontal translations
  - Sagittal translations
- 3 rotational degrees of freedom:
  - Rotations around the vertical axis (Intra-rotation/ Extra-rotation)
  - Rotations around the horizontal axis (Procurvatum / Recurvatum)
  - Rotations around the sagittal axis (Varus/Valgus)

According to what described above, the sagittal anterior half-plane of a bone segment corresponds to the anterior half of the sagittal plane passing through the anatomical axis of the segment itself.



Sagittal anterior half-plane of the tibia

3.2 RINGS

Choose a size of ring, which allows for at least 2-3 cm of clearance between the ring and the skin.

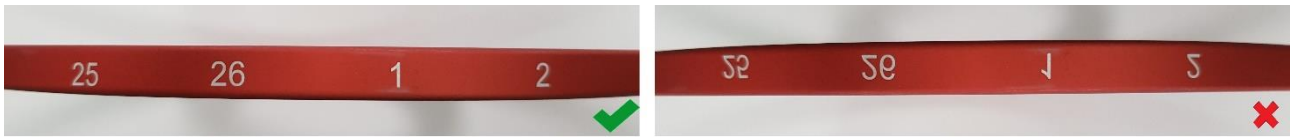
iFIXation® system doesn't require fixed position for the struts. However, in order to improve mechanical stability of the system, a table with the optimal positions for each ring size will be shown below. For struts mounting it is recommended to move two holes at maximum away from the ideal positions.

3.3 iFIXation® PROXIMAL RING

In iFIXation® system, the proximal ring is the reference one.

The proximal ring has to be positioned with numbers pointing upwards.

In case of use of 5/8 rings, it is necessary to connect the 3/8 completion before performing x-rays (cfr. paragraphs 2.1.3 and 5.4.1.3.b for further explanations).



Correct mounting on the left; Incorrect mounting on the right

3.3.1 ADVICES FOR ASSEMBLY

Position the proximal ring so that ***number 1*** is in the sagittal anterior half-plane of the considered bone segment, in order to place the ***anterior sphere*** there. This simplify interactions with the software.

Ideally, proximal ring should be positioned with an inclination equal to 90° +/- 15° with respect to the longitudinal axis of the bone. This direction is not indispensable for iFIXation® functioning. However, it allows:

1. *Increasing mechanical stability of the system:* excessive inclinations of the ring could expose bone-ring connectors to potentially critical tangential mechanical stresses.
2. *Increasing accuracy of the software and the correction:* in case of rotational corrections, (intra-/extra-rotations), inclination of the proximal ring higher than 15° with respect to the bone axis, could produce inaccurate corrections, leading to a parasitic translation. The latter could be eventually corrected using the appropriate tool "total residual".
3. *Reducing the probability of strut changes during correction process.*

3.4 iFIXation® DISTAL RING

Numbers should point upwards, as for proximal ring.

In case of use of 5/8 rings, it is not necessary to connect the 3/8 completion to the distal ring (for x-rays).

3.4.1 ADVICES FOR ASSEMBLY

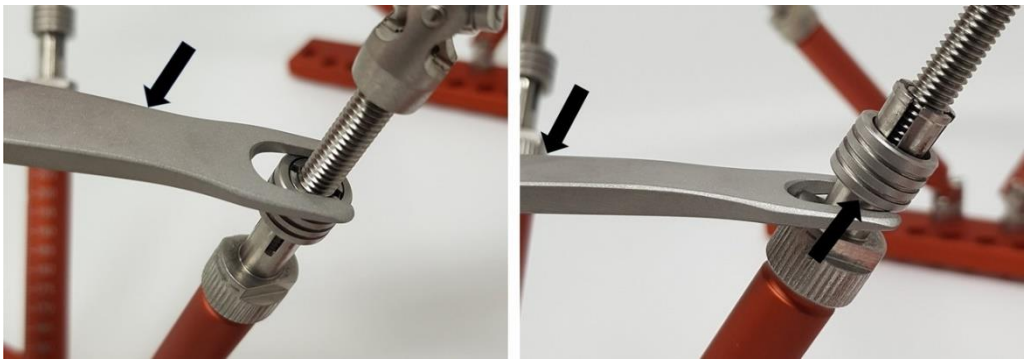
1. Assemble the fixator so that the ***Positions*** result aligned: this will facilitate the individuation of the *Platform Nearest Point* (cfr paragraph 5.4.1.2).

P1 of the two rings are approximately aligned on the longitudinal plane

2. There are not obligations regarding the inclination of the distal ring; however, an orthogonal placement with respect to the longitudinal axis of the bone fragment allows:
    - *Improving stability of the system;*
    - *Reducing the probability of strut changes during the correction process;*
    - *Reducing the probability of impingement between elements of the fixator*.

3.5 CONFIGURATION OF iFIXation® STRUTS

Use the quick unfastening system to modify struts' length rapidly. In order to facilitate the block/release of the quick unfastening, it could be necessary to use the specific fork shaped instrument.

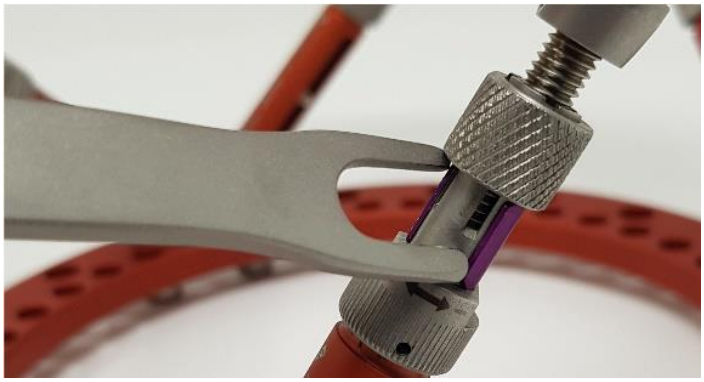


Attach *Male* connections of the struts to the proximal ring in the selected positions; block each strut with an iFIXation® nut using two 10 mm wrenches.

Therefore, position *Female* connections on the distal ring in the selected positions and block each strut with the specific bolt, using two 10 mm wrenches.

In the end, insert the coloured clips counter-clockwise and following the alphabetical order, starting from the first anterior strut.

In case of need, use the fork shaped instrument to remove the clip from the strut.



The struts have to be placed coupled on the proximal and distal rings, according to the following combinations:

Proximal Ring	
A	B
C	D
E	F

Distal Ring	
B	C
D	E
F	A

It is essential that there are not more than two holes between the connections of each couple.

3.5.1 ADVICES FOR ASSEMBLY

iFIXation® system does not require fixed positions for struts placement. Regardless it, suggestions for ideal positions, which optimise mechanical stability, will be provided.

In order to facilitate the assembly of the system, positioning struts ***A*** and ***B*** in holes **1** and **2** respectively is preferred.

Diameter (mm)		Pos. Strut A	Pos. Strut B	Pos. Strut C	Pos. Strut D	Pos. Strut E	Pos. Strut F
120	Proximal Ring	1	2	7	8	13	14
	Distal Ring	17	4	5	10	11	16
130	Proximal Ring	1	2	8	9	14	15
	Distal Ring	17	4	5	10	11	16
140	Proximal Ring	1	2	8	9	14	15
	Distal Ring	18	5	6	11	12	17
150	Proximal Ring	1	2	8	9	15	16
	Distal Ring	20	5	6	12	13	19
160	Proximal Ring	1	2	9	10	17	18
	Distal Ring	21	4	5	12	13	20
180	Proximal Ring	1	2	10	11	18	19
	Distal Ring	24	5	6	14	15	23
200	Proximal Ring	1	2	10	11	19	20
	Distal Ring	25	6	7	15	16	24
220	Proximal Ring	1	2	11	12	21	22
	Distal Ring	26	7	8	16	17	25
240	Proximal Ring	1	2	12	13	23	24
	Distal Ring	29	6	7	17	18	28

NB. The positions are valid for the distal ring if the numbers of the two rings are aligned.

Ideal positions in case of use of the foot ring.

Diameter (mm)		Pos. Strut A	Pos. Strut B	Pos. Strut C	Pos. Strut D	Pos. Strut E	Pos. Strut F
160	Proximal Ring	1	2	9	10	17	18
	Foot Ring	21	4	5	12	13	20
180	Proximal Ring	1	2	10	11	18	19
	Foot Ring	23	5	6	14	15	22

Therefore, three couples of struts are fixed on both the rings. Maximum stability is obtained, if:

- The couples of struts result equidistant on the ring.
- The triangle obtained joining the struts couples on the proximal ring (grey triangle) results opposite to the triangle on the distal ring (blue triangle).

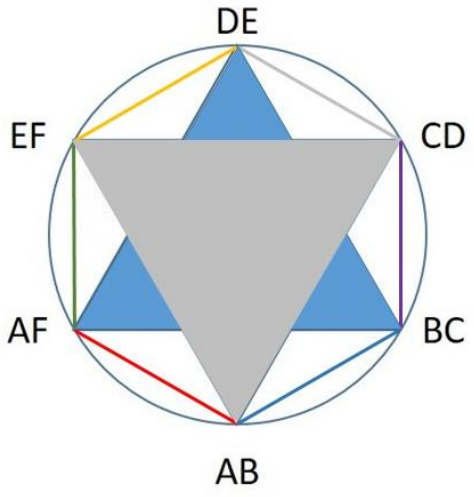


Diagram showing the ideal assembly of the fixator

NOTA BENE

The software develops correction plans regardless of the struts positions and so, even in case of deviations from the given indications, an adequate prescription will be obtained. However, configurations with extremely inclined struts could lead to system instability and/or causing discomfort for the patient. These limitations belong to every hexapod systems based on a free and not predetermined configuration.

Overly VERTICAL struts
Risk of mechanical instability

Overly HORIZONTAL struts
Risk of discomfort for the patient during the correction

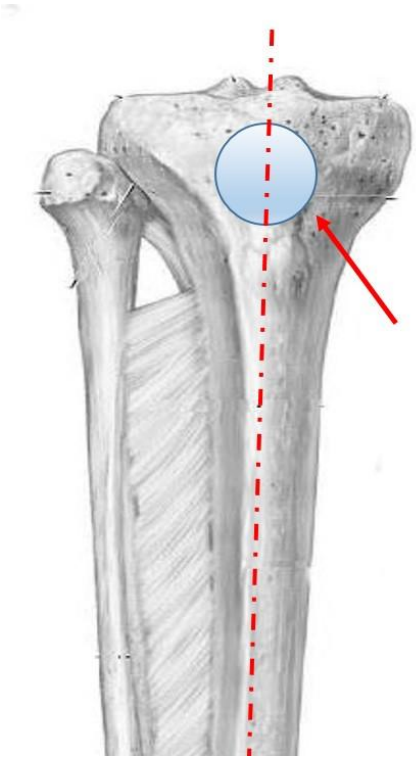
3.6 iFIXation® REFERENCE SPHERES

iFIXation® software is based on the use of three reference spheres, which have to be placed on the proximal ring when the post-operative x-rays are performed. Spheres have to be fixed on iFIXation® nuts. The nuts blocking the struts can be exploited if placed in adequate positions; otherwise, iFIXation® nuts will have to be fixed with bolts in the required positions.

3.6.1 ADVICES FOR ASSEMBLY

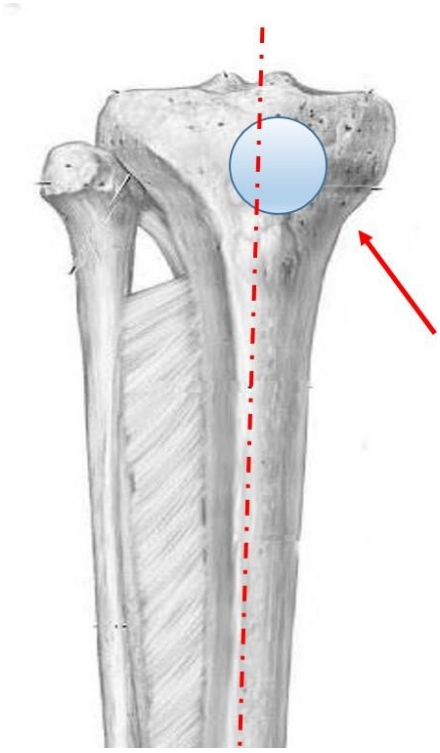
3.6.1.1 ANTERIOR SPHERE

Anterior sphere: Position the anterior sphere in the anterior side of the ring so that it results totally or partially overlapped on the considered bone segment.



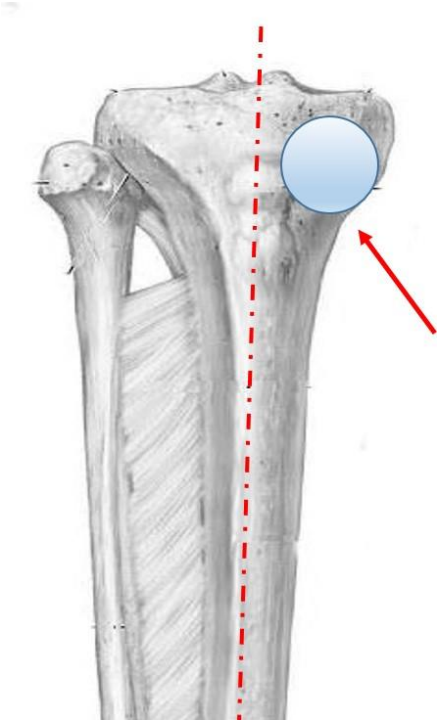
IDEAL

*The Anterior Sphere is centred in the Sagittal Anterior Half-plane (SAH): **IDEAL** Condition.*



ACCEPTABLE

*The Anterior Sphere is located only partially in the SAH: **ACCEPTABLE** Condition; the sphere does not need to be moved.*



NOT ACCEPTABLE

*The Anterior Sphere results completely outside the SAH: **NOT ACCEPTABLE** condition. The Sphere needs to be moved.*

At least acceptable positioning is essential to guarantee accuracy of the system.

3.6.1.2 LATERAL AND POSTERO-MEDIAL SPHERES

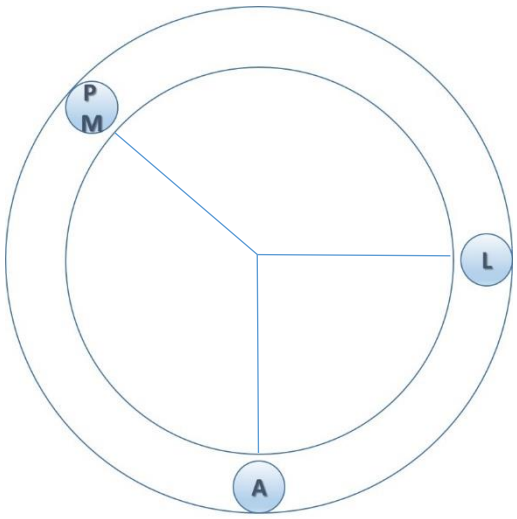
Remember that the **truncated sphere** has to be used as **lateral** sphere.

The **lateral** and the **postero-medial spheres** have to be positioned in the lateral half and in the medial one of the proximal ring respectively.

Both spheres have to be recognizable in the two x-ray projections for software analysis.

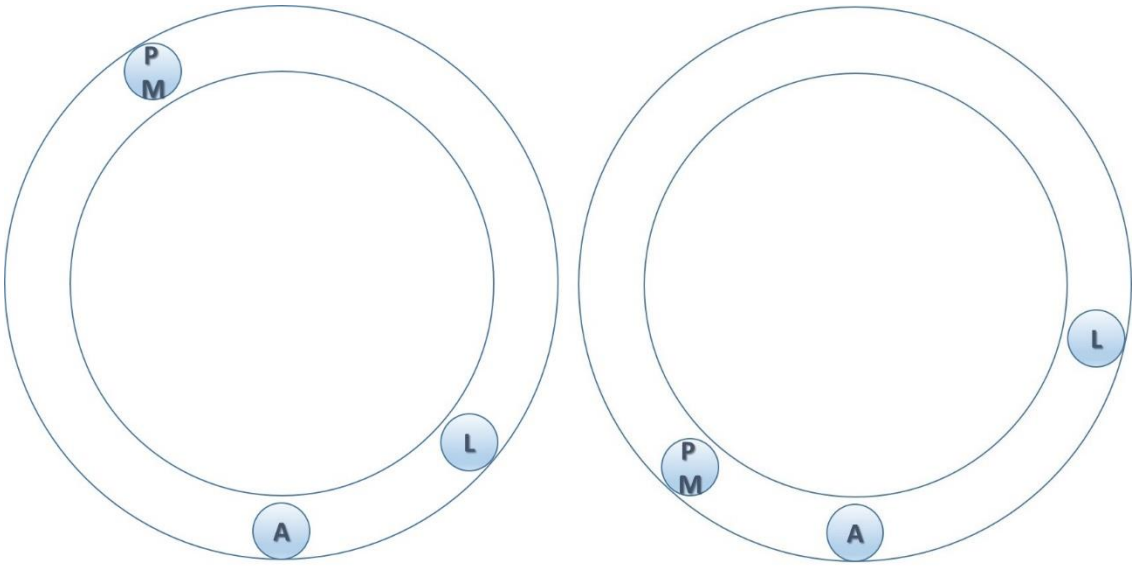
The software deduces the laterality of the system from the lateral sphere. Therefore, all the configurations, in which the spheres are located in their respective halves of ring and are recognizable in the x-rays, are considered acceptable.

In order to limit the risks of radiological overlapping with consequent difficult individuation of the spheres, it is suggested to locate the ***Lateral Sphere*** at 90° in lateral direction from the ***Anterior Sphere***, and the ***Postero-Medial Sphere*** at 120° in the medial direction from the ***Anterior Sphere***.



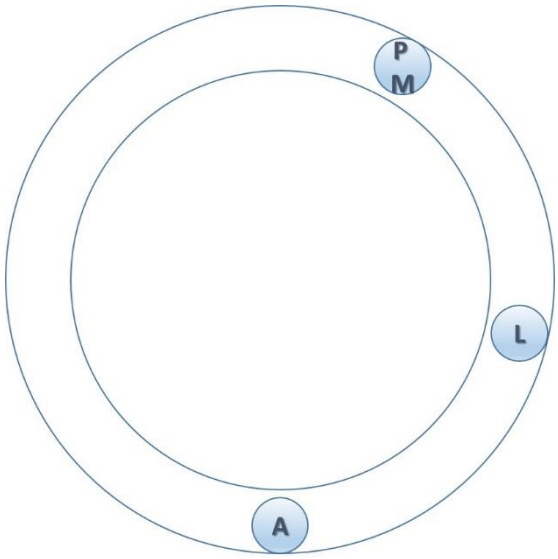
IDEAL

IDEAL *Configuration*



ACCEPTABLE

Lateral spheres in their respective half-rings: ***ACCEPTABLE*** *Configuration*



NOT ACCEPTABLE

Both spheres in the same half: ***NOT ACCEPTABLE*** *Configuration*

3.7 Hardware parameters

At the end of the surgery, it is necessary to write down some parameters related to the fixator, which will be inserted in the software later.

In particular, it is necessary to write down:

1. Kind of used rings
2. Diameter of the proximal and distal rings
3. Position of the three spheres
4. Position of the *platform nearest point* (cfr paragraph 5.4.1.2)
5. Length of the struts (Use the millimetric scale on the strut to read the length)
6. Type of each of the 6 struts (MINI, SXS, XS, M, L, XL)
7. Position of each of the 6 struts on the proximal and distal rings

In order to facilitate this procedure, it is possibile to exploit the form below, where all the requested parameters can be inserted.

Dial Medicali

iFIXATION®

iFIXation - struts lenght and positioning

Hospital:	Patient ID:	Date of surgery:

	Proximal	Distal
Ring Size		
Ring Type	Full	Full
	Half	Half
	5/8	5/8

	Left	Right
Femur		
Tibia		
Other:		

Reference Sphere	A	L	PM

Platform nearest point	

		A	B	C	D	E	F
Strut Lenght							
Strut Size							
Strut Position	Proximal						
	Distal						

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RADIOLOGICAL IMAGES

- 4 -

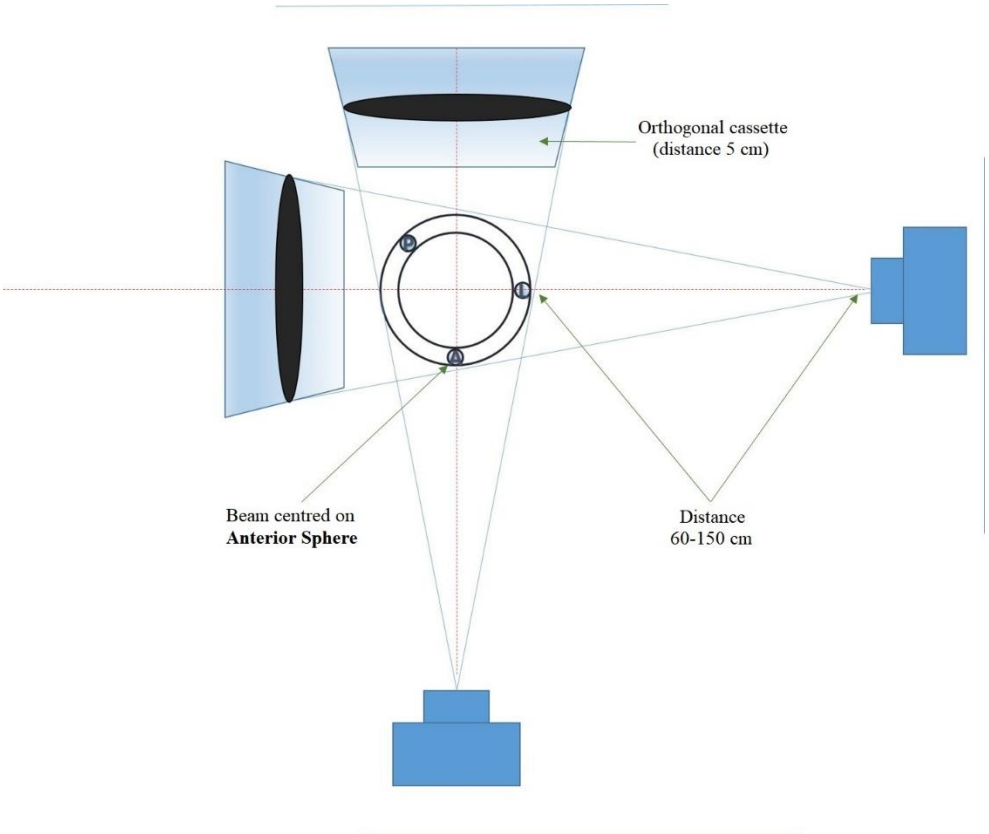
Two different x-ray projections, an antero-posterior and a latero-medial, are necessary for the software. Indications for obtaining optimal x-rays are given below.

4.1 PARAMETRI RADIOGRAFICI

It is recommended to obtain post-operative radiographic images with the following features:

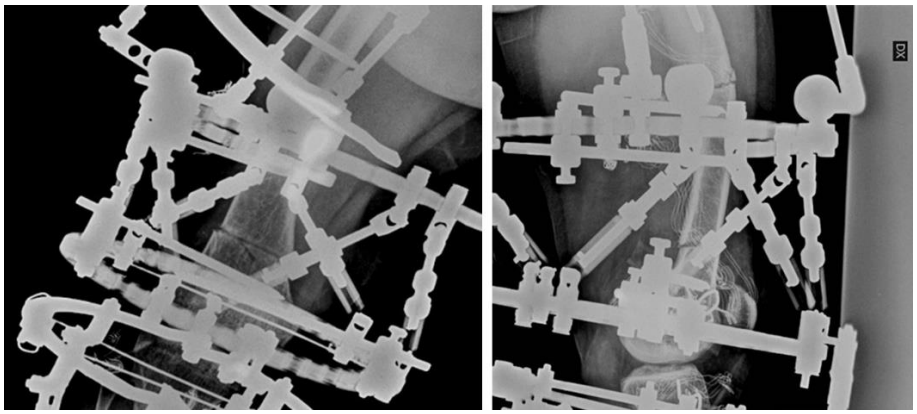
- *Antero-posterior projection:* with the x-rays beam centred on the ***Anterior Sphere***.
- *Lateral projection:* with the x-rays beam at cranio-caudal height alike the *antero-posterior projection* and rotated of 90° +/- 15°. If the **Lateral Sphere** is positioned at 90° with respect to the **Anterior Sphere**, it could be used as reference for x-rays beam pointing.

The distance between the radiogenic source and the radiographic film should be between 600 and 1500 mm. In case of use of a radiogenic machine with free sensitive cassette, this one should be positioned orthogonal with respect to the central beam and less than 50 mm far from the external fixator.

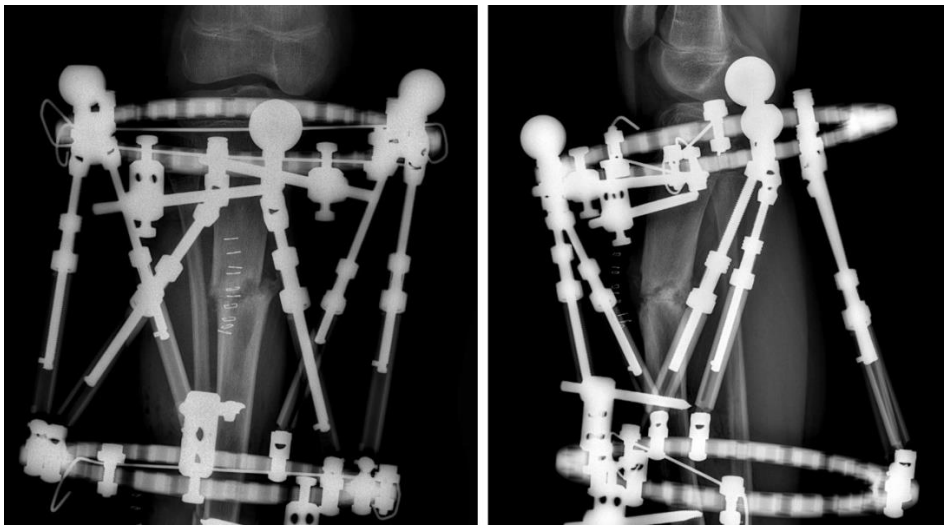


Essential radiological requirements

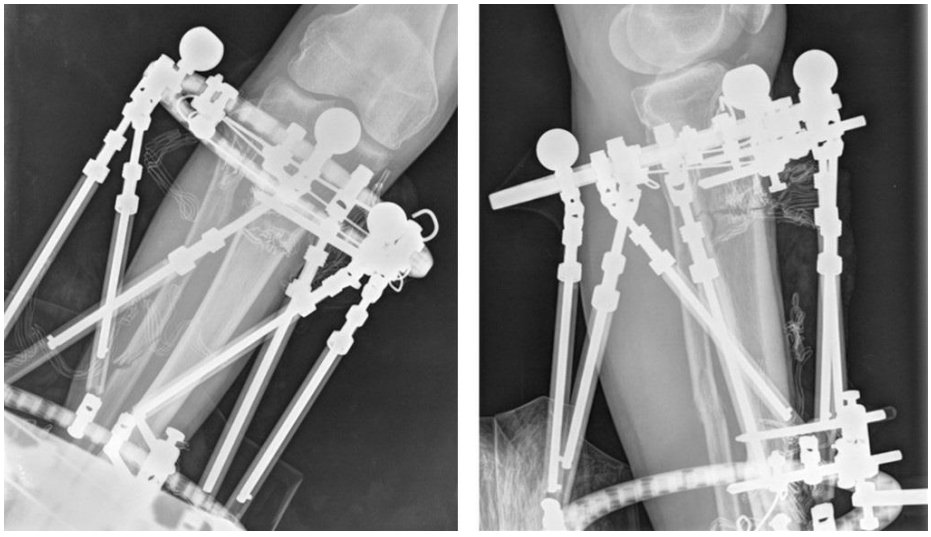
The reference spheres and the proximal ring have to be identifiable in both the projections: partials overlapping among the spheres or between a sphere and other structures of the system are acceptable, provided that the external perimeter of the spheres is perceivable (cfr. paragraph 3.6).



Not acceptable x-rays



Acceptable x-rays



Ideal x-rays

5.1 DICOM IMAGES EXPORTATION

The software is based on the direct analysis of the requested radiological images; therefore, the images have to be uploaded on the website.

The system accepts the following image formats:

- JPEG
- JPG
- BMP
- PNG

Most of the modern digital radiological machines store the images with DICOM format, which is not accepted by the software. Before uploading the image, it is necessary to export it, i.e. convert it from DICOM to one of the accepted formats.

There are many procedures to export DICOM images, for example:

1. **Use a dedicated software:** many online freeware software, which are capable of converting DICOM images in other image formats, are available. In particular, software for conversion are useful in case of images saved on an external storage (CD-ROMs).
2. **Use a dedicated tool available in some PACS systems.**
3. **Use the Windows tool "screenshot":** the tool could be exploited to create images with a useful format from DICOM images.

Procedures for files exportation from external storages, or PACS, or online documents folder, require a deep knowledge of the *Privacy* law and the internal rules of the hospital, in order not to violate the regulations in force.

Moreover, it is advised to use a software for pictures editing in order to remove the parts of the images containing registry information of the patient; however, iFIXation® software is provided with a specific *tool* to cut the image, in order to facilitate the hiding of the sensitive information (cfr. paragraph 5.4.1.1).

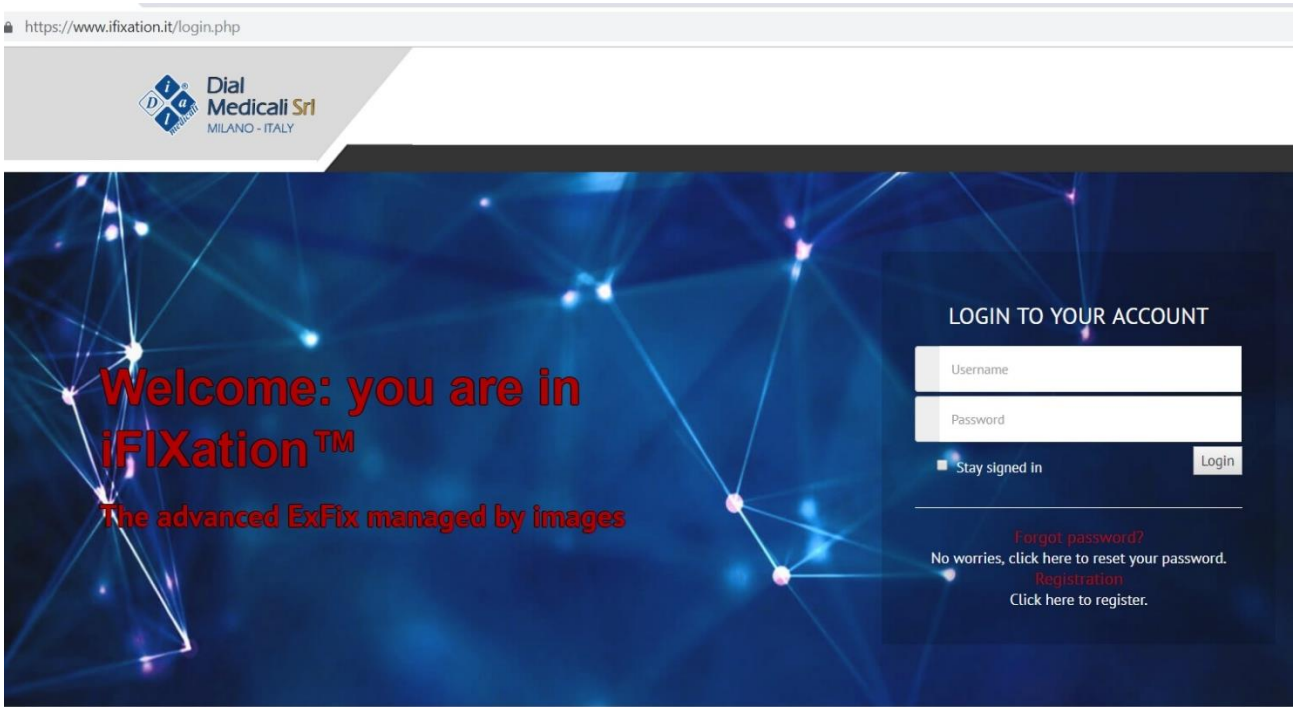
Therefore, it is recommended to respect the regulation about the privacy and the ethical code of the hospital where the radiographic exam is performed.

In case of slow connections, it is suggested not to use files with a dimension higher than 2 megabytes.

5.1.2 TO START

The software has a *Web Based* structure. It is part of the system and it is indispensable to obtain post-operative correction plans.

In order to access the safe iFIXation® website, type entirely: *www.ifixation.it*. A partial typing does not guarantee the correct functioning, due to the EV certification.



Initial screen

The website is "*responsive"* type. It is suitable to be used with different devices, such as notebook, laptop, tablet and smartphone[1]; moreover, it is optimized to be used with the browser *Chrome*, with versions next to the 55. The site is also compatible with the following browsers:

- Edge
- Mozilla Firefox
- Safari
- Internet Explorer

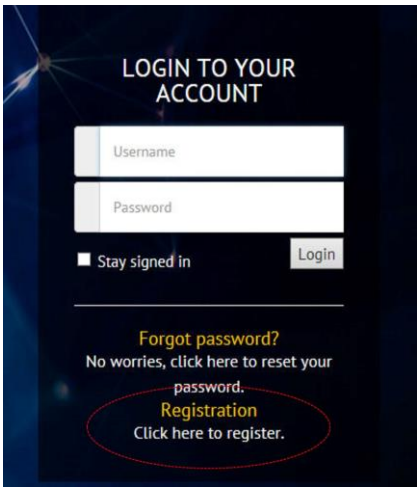
NOTA BENE

In case of use of too much outdated *browsers* (for example, old versions of Internet Explorer), some graphic tools (not essential), such as 3D elements and/or rendering, could not work, without compromising the final functioning of the software.

[1] In order to zoom in/out, use the technique *Pinch to Zoom* for devices with *Touchscreen*, otherwise use the proper tool of the browser. Moreover, it is possible to use the keyboard shortcut *CTRL/+ CTRL/-*

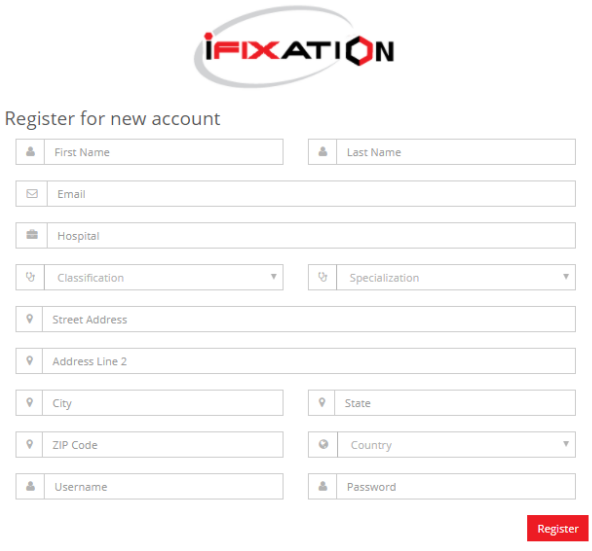
5.2 REGISTRATION

It is possible to access the website, prior to registration and account creation. Registration procedure begins clicking on ***click here*** under the writing *Registration* in the Home Page.



Click on "Click Here" to start the registration procedure

The page with registration *Form* follows.

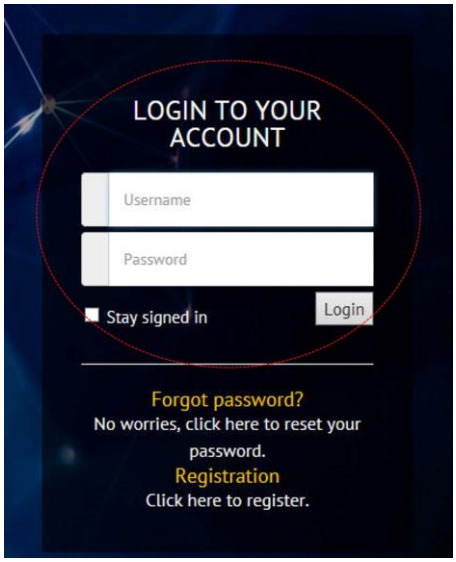


Registration form

Filling in the on-line form allows sending the request for account activation, which will be examined from the administration; the activation will be confirmed in the following 24/48 hours.

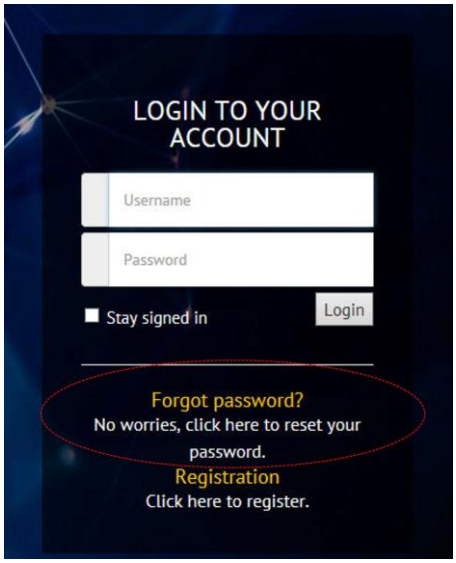
5.3 LOGIN and CREDENTIALS RESET

Once the account creation is completed, click on *Login* in the initial screen inserting credentials (NB: both the *username* and *password* are case sensitive).



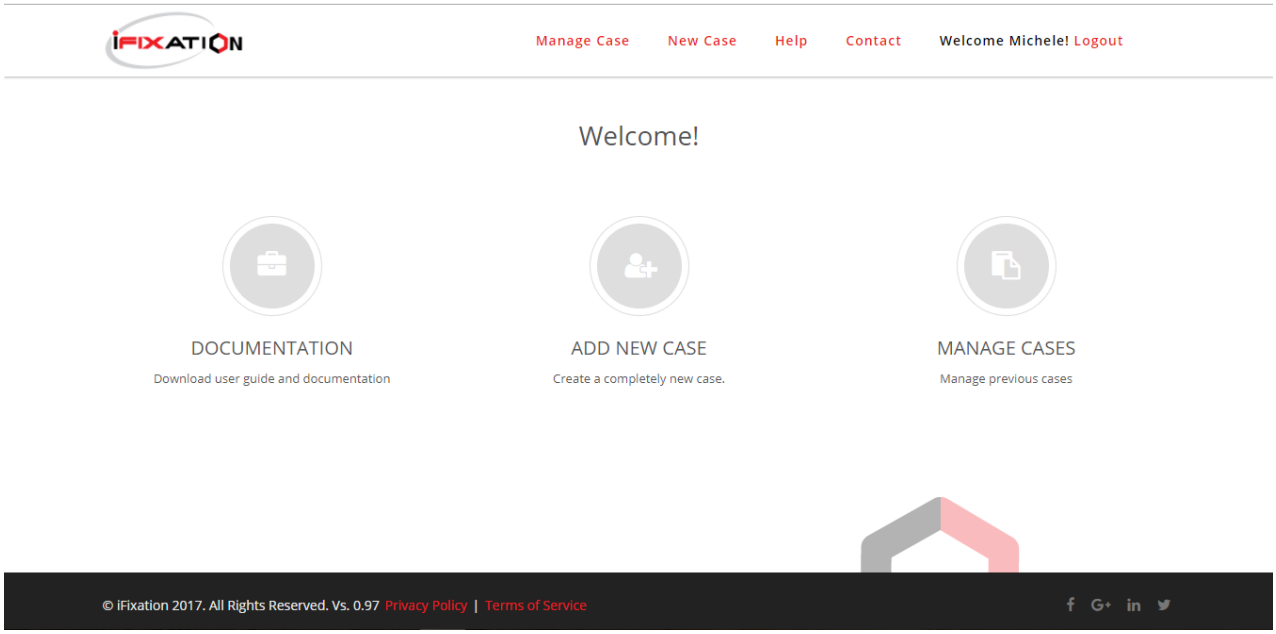
Insert login credentials to access the principal screen

In case of forgotten credentials, it is possible to reset new ones through the dedicated procedure, clicking on ***click here*** under *forgot password*.



Click on "Click here" to reset your credentials

5.4 HOME PAGE



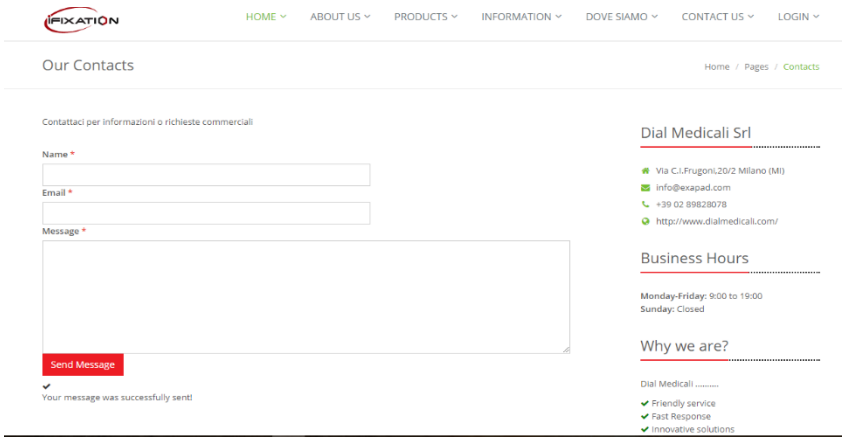
Principal screen

The available selections in the principal screen are:

- ***Documentation:*** storage of useful files such as brochures, operative technique, scientific papers and others.
- ***Add New Case:*** to create a new case
- ***Manage cases:*** to manage cases previously created

The following selections are available up in the page:

- ***Manage case / New Case:*** see above
- ***Contact:*** to send a message to the contact person through the proper *form*
- ***Logout:*** to log out the account

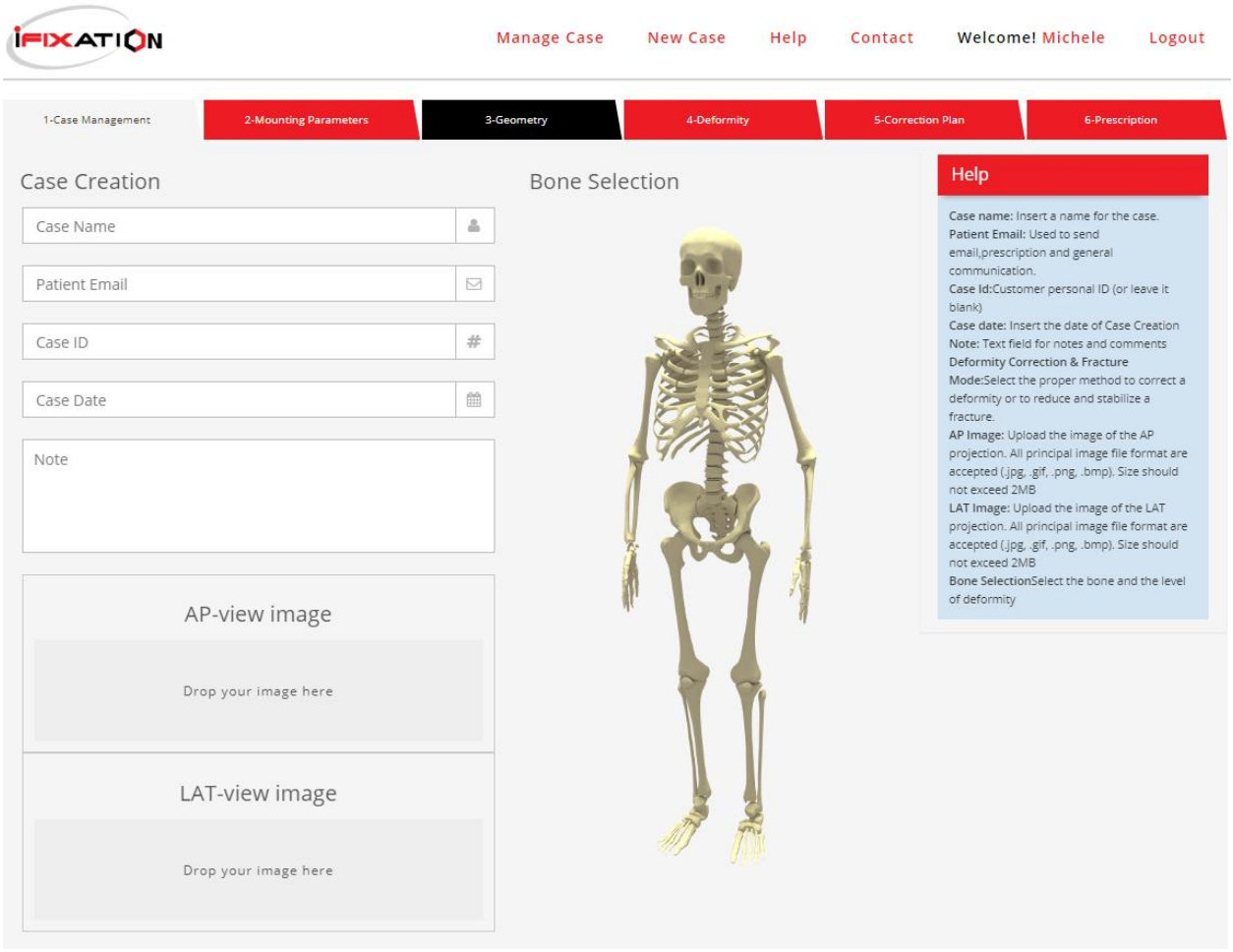


Contact screen

5.4.1 NEW PATIENT – ADD NEW CASE

Filling in all the required information is mandatory to obtain correct treatments. In case of incomplete filling, the software will notify it through a *Warning*; a similar message will be sent in case of input of illogical parameters.

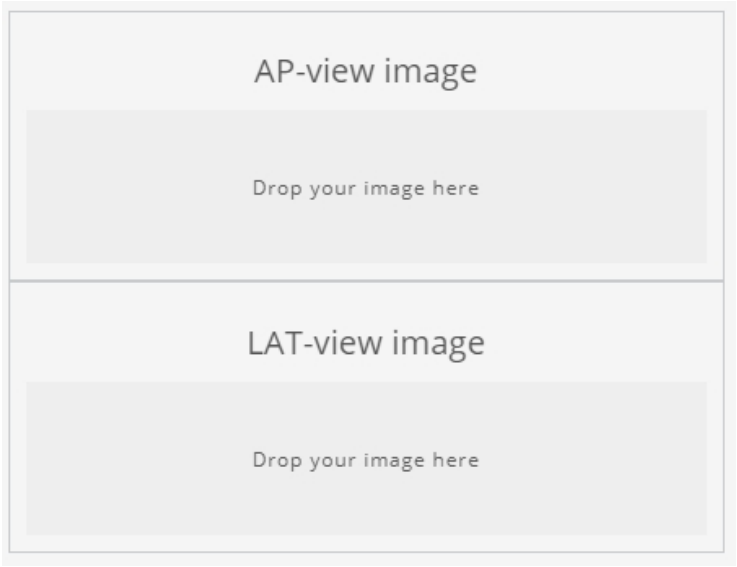
5.4.1.1 CASE CREATION



Insert all the identification data of the case, according to the operator requirements. *Case Name* and *Case Date* are essential parameters.

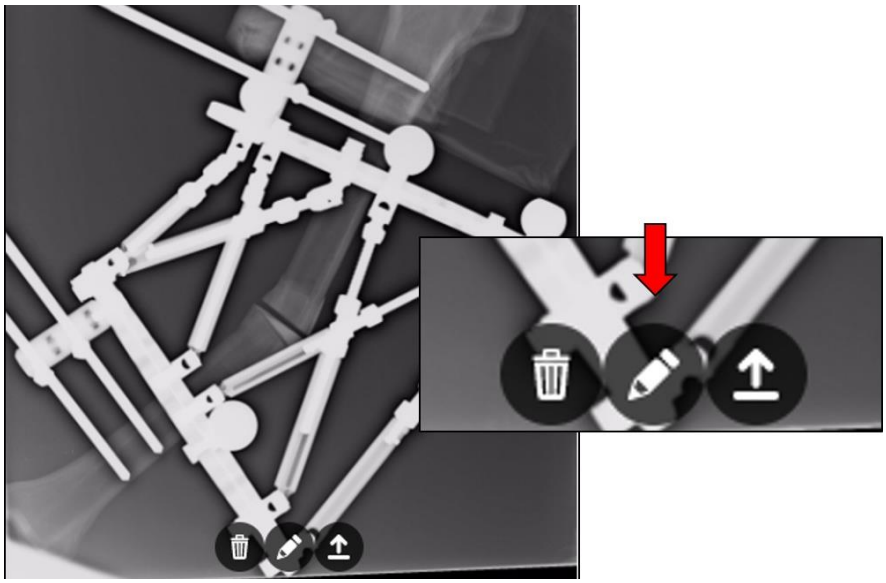
For personal data treatment, refer to the privacy law (GDPR 679/2016) and/or to the fixed rules of the hospital where the patient is managed.

U*pload* the two radiological images in the appropriate format. The upload can be achieved through *Drag&Drop* procedure, or through *Browse*, selecting the correct folder and file.



Upload the images through Drag & Drop or Browse procedure.

If necessary, it is possible to edit the images clicking on the related button:



Editing button

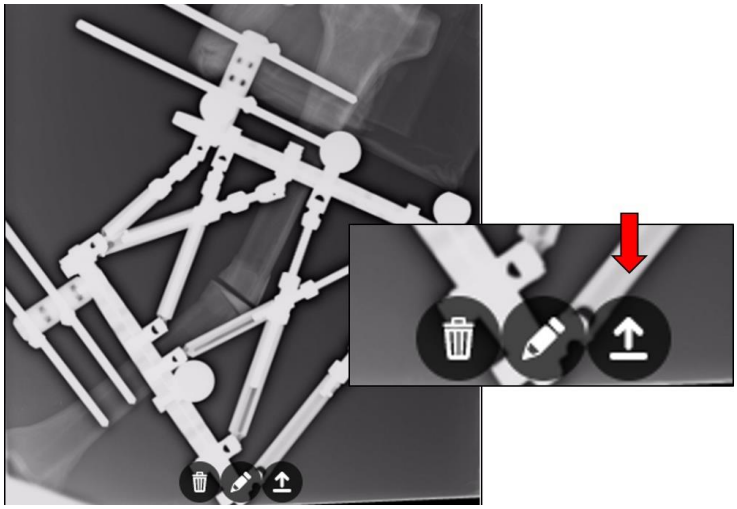
In the *Editing* section, the following functions are available:

- *Rotate:* to rotate the image
- *Crop:* to remove marginal areas of the image

Editing section

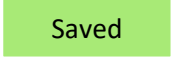
NOTA BENE
In order not to violate the Privacy law (GDPR 679/2016), it is recommended to use the edit tool to remove sensitive data from the radiological images.

Image upload has to be confirmed clicking on the appropriate button.



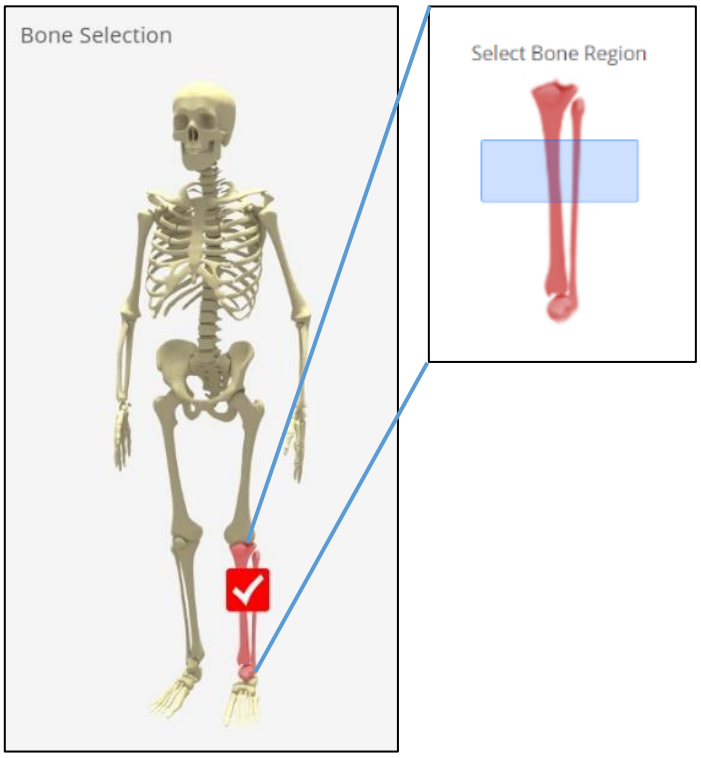
Upload confirmation

The positive ending of the process will be highlighted from the specific *mark* with the writing *saved* in the right upper corner of the image.



Mark for positive ending of the upload procedure

Once the upload is completed, specify the anatomical area selecting the desired bone segment on the skeletal model.



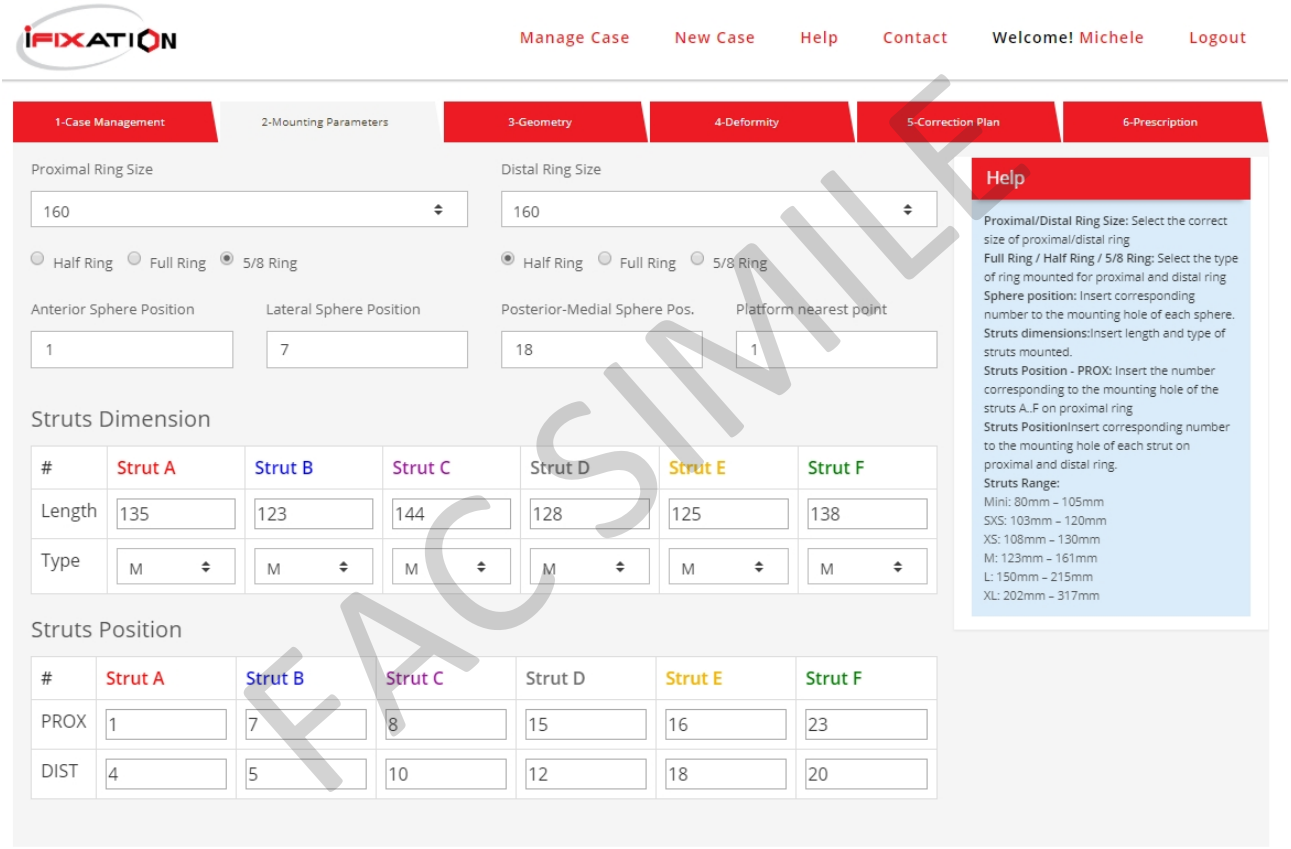
Anatomical district and level of deformity

To go forward, click on n°2 *"Mounting Parameters"*.

Every time you move to a successive page, the software automatically save data of the previous page.

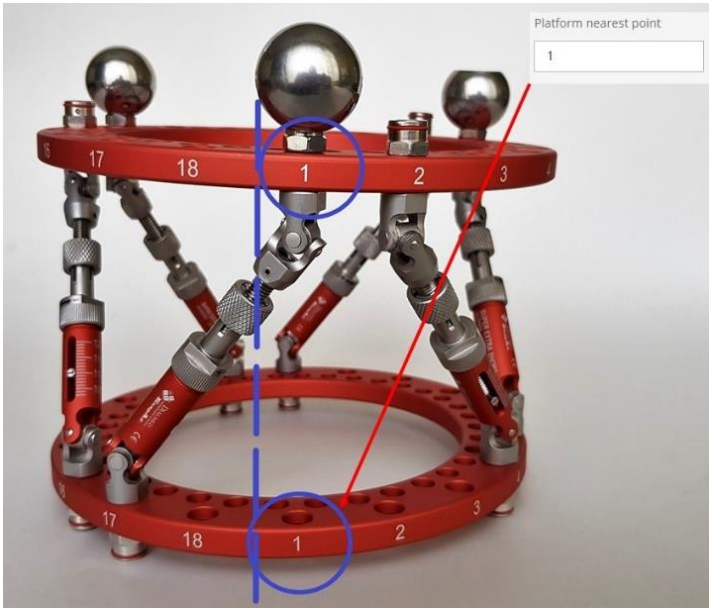
In case of lack of essential parameters, the software will notify it.

5.4.1.2 MOUNTING PARAMETERS



In this screen, it is necessary to fill in the form with every parameter.

The parameter *"Platform Nearest Point"* represents the position on the distal ring corresponding to the position of the ***Anterior Sphere*** on the proximal ring. The picture below shows an example: the platform nearest point is equal to 1. In other words, it represents the position on the distal ring closer to the sagittal anterior half-plane.



Platform Nearest Point

The software exploits this parameter to fix an important geometric constraint for the application of rotations along the longitudinal axis of the bone (intra- and extra-rotations). A wrong platform nearest point can lead to inaccuracy in application of rotations.

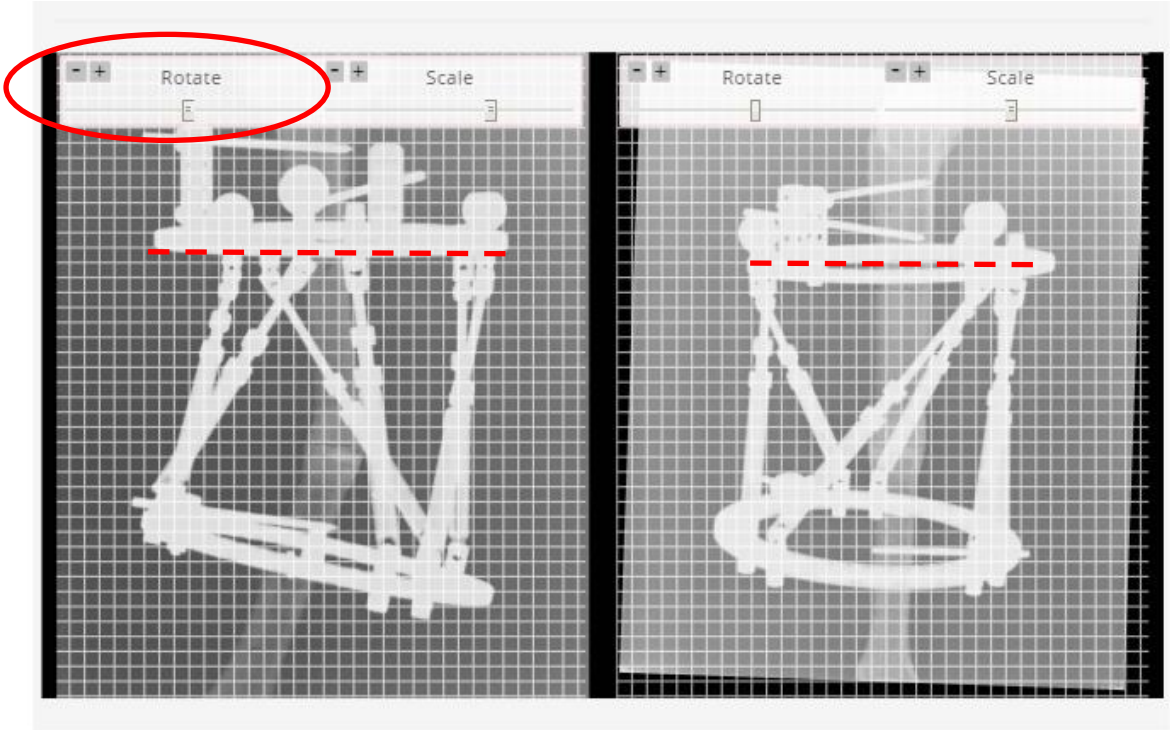
5.4.1.3 GEOMETRY

The procedure for images analysis requires four steps:

a. Adjust Image
b. Ring Diameter Calibration
c. Reference Triangle
d. Bone Segment

5.4.1.3.a ADJUST IMAGE

Using the tool *"Rotate"*, align the latero-medial diameter in the antero-posterior projection and the antero-posterior diameter in the lateral projection with the horizontal axes of the reference grid. For unrefined adjustments use the sliding bar with its relative pointer, while for refined adjustments use + and – buttons.



In the picture, the anterior and lateral diameters are identified by the red dashed lines (NB. The red lines are not present in the software. They are only illustrative): both the diameters have to be aligned with the horizontal lines of the grid.

Through the tool *"Scale"*, it is possible to enlarge or make the image smaller, according to the preference of the operator, so that the successive analyses could be carried out more clearly and easily.

5.4.1.3.b RING DIAMETER CALIBRATION

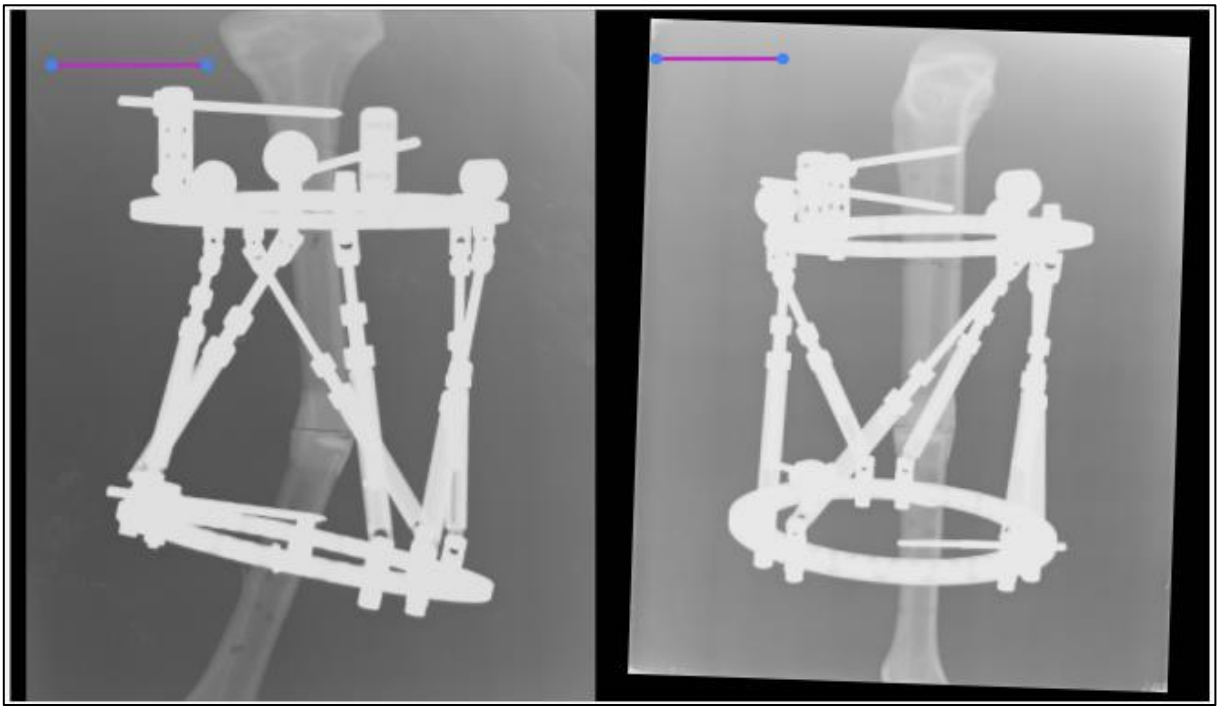
In order to obtain the calibration of the image, trace the medio-lateral and antero-poterior diameters of the proximal ring in the antero-posterior and medio-lateral projections respectively.

The tool *Ring Diameter Calibration* is violet coloured and shows blue pointer at its extremities. Both the pointers have to be dragged until they correspond to:

- Antero-posterior projection → extreme medial and lateral points of the proximal ring.
- Lateral projection → extreme anterior and posterior points of the proximal ring.

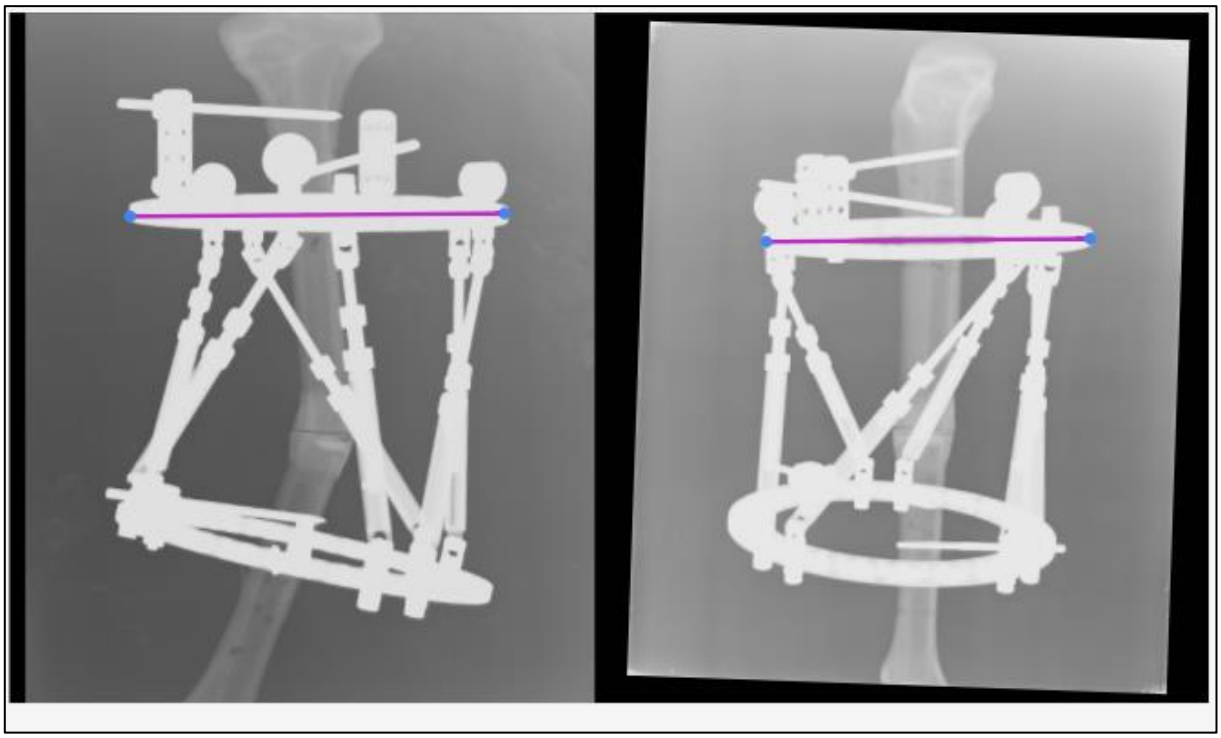
To facilitate the procedure, it is suggested to enlarge the image through the *Zoom* tool of the browser[2].

In case of use of a 5/8 ring, the 3/8 *Completion* should be used to obtain radiographies which allow identifying the complete diameter of the ring (cfr. paragraph 2.1.3).



Adjust Ring: notice the violet line in the left upper corner of both the images. Its extremities have to correspond to the extremities of the anterior and lateral diameters in both the projections.

[2] Cfr. paragraph 5.1, note n°6



The violet lines of the tool "Ring Diameter Calibration" correspond to the LL and AP diameters of the ring

The system calibrates the dimension of the images according to this procedure; it has to be carried out accurately.

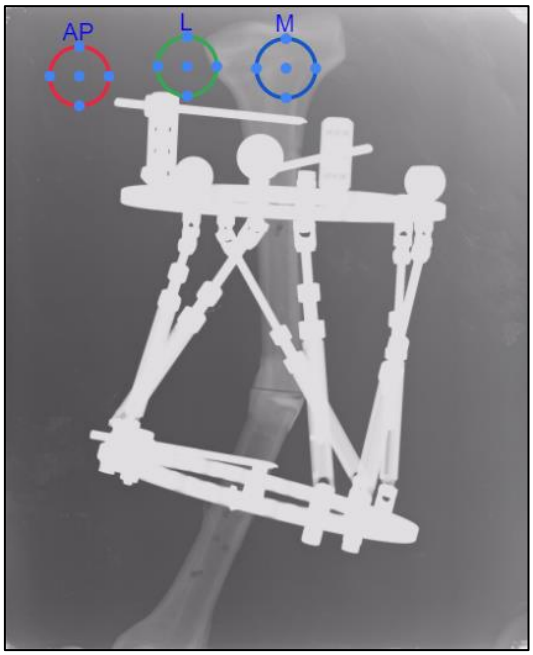
5.4.1.3.c REFERENCE TRIANGLE

In the third step, the *Reference Triangle*, i.e., the triangle obtained connecting the centres of the three reference spheres, has to be identified.

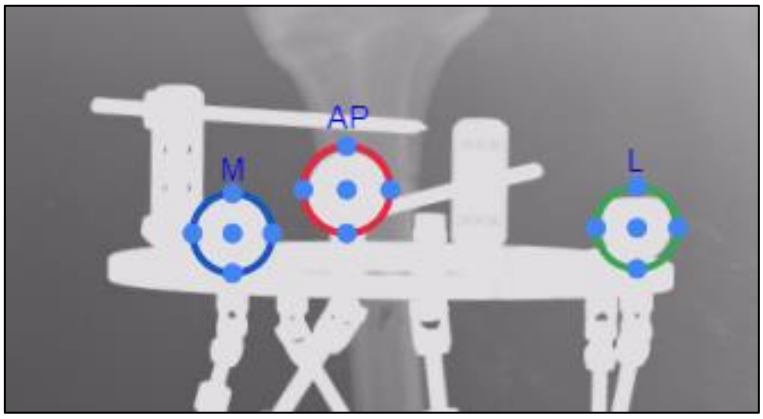
In the upper side of the image three coloured circumferences appear. Each sphere shows 5 points: the central one functions for moving the circumference, while the four external points function for choosing the diameter. Each colour and letter represent a reference sphere:

- Red circumference (letter AP) → ***Anterior Sphere***
- Green circumference (letter L) → ***Laterale Sphere***
- Blue circumference (letter M) → ***Postero-Medial Sphere***

The procedure consists in overlapping each coloured circumference and the external perimeter of the corresponding sphere. In order to distinguish easily the spheres, use the **truncated sphere** as **lateral sphere.**



It is necessary to overlap the three circumferences and the three reference spheres



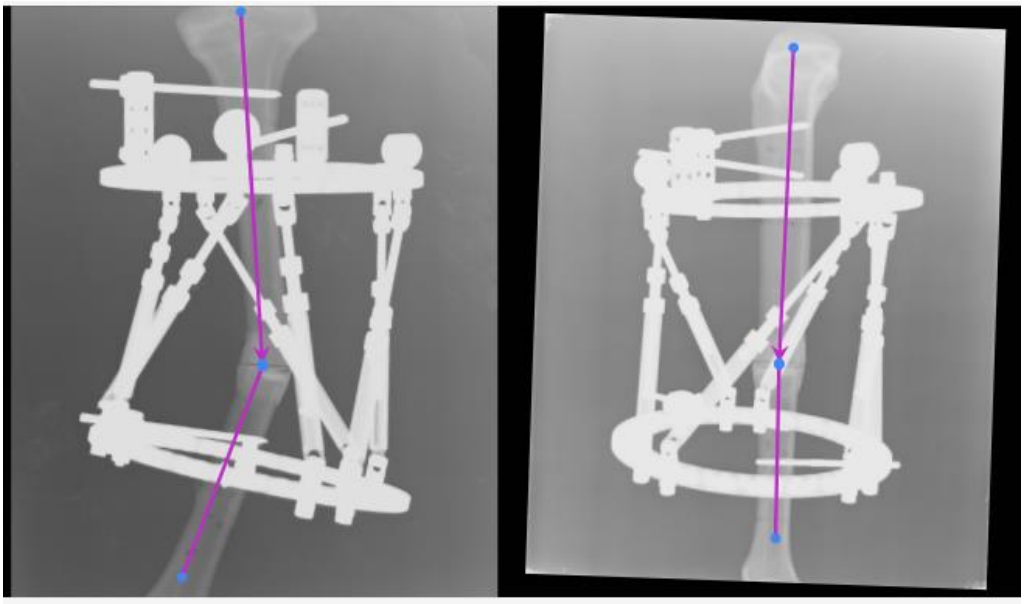
The three coloured circumference overlapping the spheres

The software supposes what follows:

a. ANTERO-POSTERIOR PROJECTION:
   - Left bone: in the image, **LS** appears on the right and **PMS** on the left of the bone.
   - Right bone: in the image, **LS** appears on the left and **PMS** on the right of the bone.

b. LATERO-LATERAL PROJECTION:
   - The ***Anterior Sphere*** indicates always the anterior side of the fixator, independently of eventual flips of the image.

5.4.1.3.d BONE SEGMENT



Identification of CORA and axes of the bone segments to compute the fragments through a vectorial tool

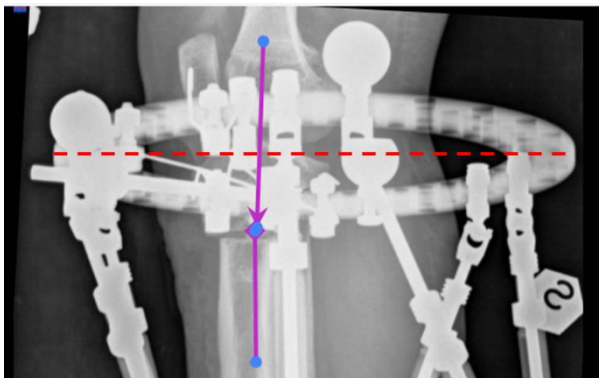
In this screen, a vectorial representation of the deformity or the fracture is obtained through a vectorial tool. The CORA[3] or fracture line is identified.

The tool is made of two vectors, a proximal and a distal one.

- *Proximal Vector:* its apex (arrow tip) has to be dragged to the level of the desired rotational axis (ACA[3]), according to the identified CORA; its back end has to be dragged so that the axis of the vector becomes parallel to the axis of the proximal segment.
- *Distal Vector:* its apex (pike tip) has to be dragged to the level of the centre of the osteotomy, while its back end has to be dragged so that the axis of the vector results parallel to the axis of the distal segment.

The software will examine the angles between the vectors and will calculate the distances between the two tips[4]. Obtained results will be reported in the successive page, *Deformity*.

WARNING: the *Proximal Vector* must be dragged so that it exceeds the level of the proximal ring ***diameter*** previously set (as illustrated in the picture).



[3] Angulation Correction Axis
[4] The distance between the two tips is visible through the dashed line.

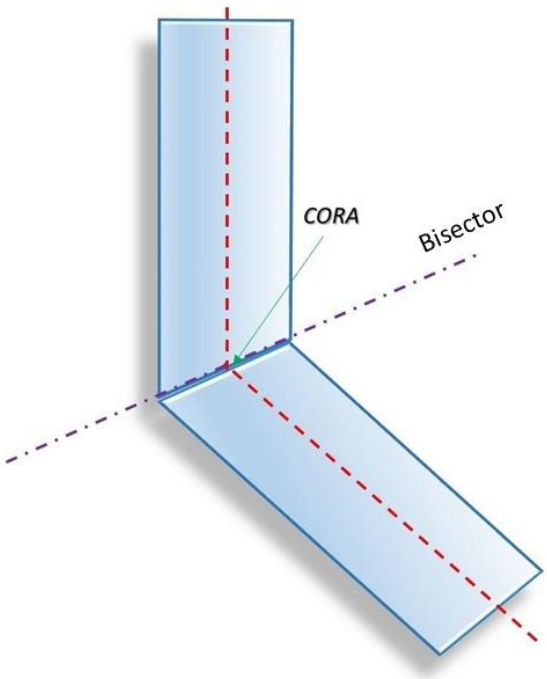
5.4.1.3.e CONSIDERATIONS

Like in all the osteotomies made to correct an angular deformity, the rotations of the distal segment produce translations every time the rotation centre (*Virtual Hinge*) is located outside the bisector of the deformity.

The automatic computation of the deformity of the segment could be considered realistic in case of correct radiological projections[5]; with too much oblique projections, the CORA and *Virtual Hinge* could be identified with difficulty. For these reasons, inadequate projections could lead to a loss of accuracy of the system.

Moreover, the identification of the bisector and the centre of rotation is particularly easy in case of uniplanar angular deformity (for example, presence of only one deformity in varus in the antero-posterior projection). On the contrary, in case of multi-planar deformities, the identification of the bisector and of the centre of rotation could be more complicated, having only two projections. For this reason, it is advisable to have projections, which allow analysing correctly the deformity, available.

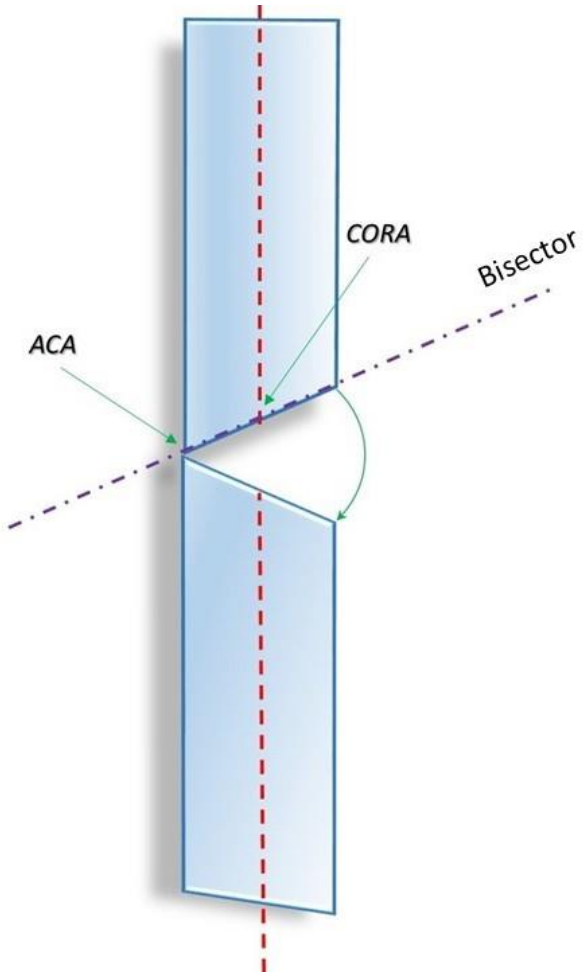
Eventual discordances between the rotation centre and the real CORA of the deformity could lead to corrections compromised by translations in the three planes of the space. The bigger the discordance is, the bigger the entity of translation will result. For this reason, it is advised to consider the diagrams below, where a simple uniplanar deformity is represented.



Principles of deformity correction

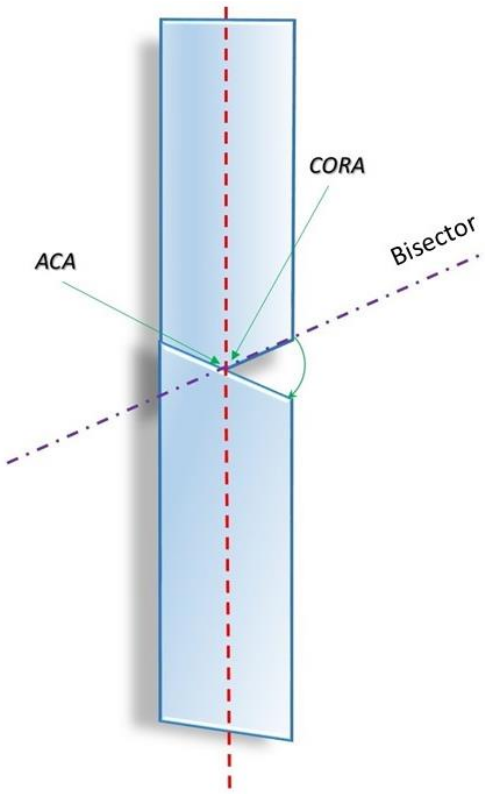
The CORA is represented by the intersection between the anatomical axes of the proximal and distal segments of a deformed bone. In addition, the CORA is located on the bisector of the angle of deformity.

[5] True antero-posterior and lateral projections.



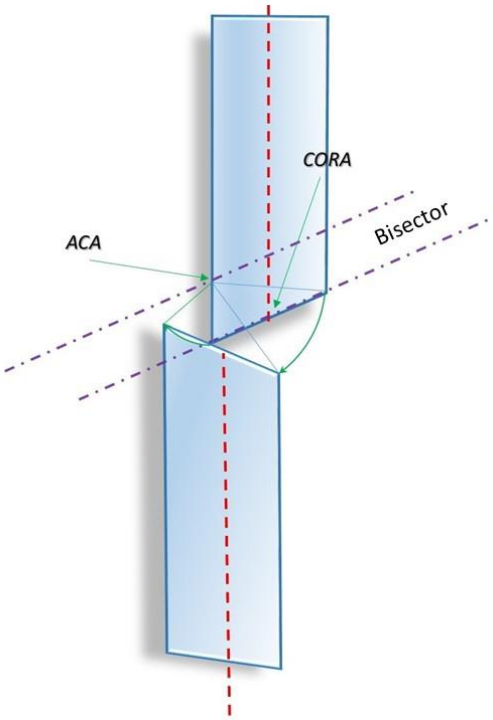
ACA on the bisector, but not corresponding to the CORA: presence of longitudinal translations (lengthening). Lateral translations are absent.

In case of uniplanar deformity, if the ACA does not correspond to the CORA, but it is placed on the bisector at the apex of the deformity, the angular correction would lead to a longitudinal translation of the distal segment, with resulting lengthening of the considered bone.



ACA is corresponding to CORA: there are neither longitudinal nor lateral translations.

In case of correspondence between ACA and CORA, there are neither longitudinal nor lateral translations. Unfortunately, this kind of correction is usually not appropriate with a linear osteotomy, since it causes overlapping of bone tissue in one half-diaphysis.



ACA is not on the bisector: presence of both longitudinal and lateral translations.

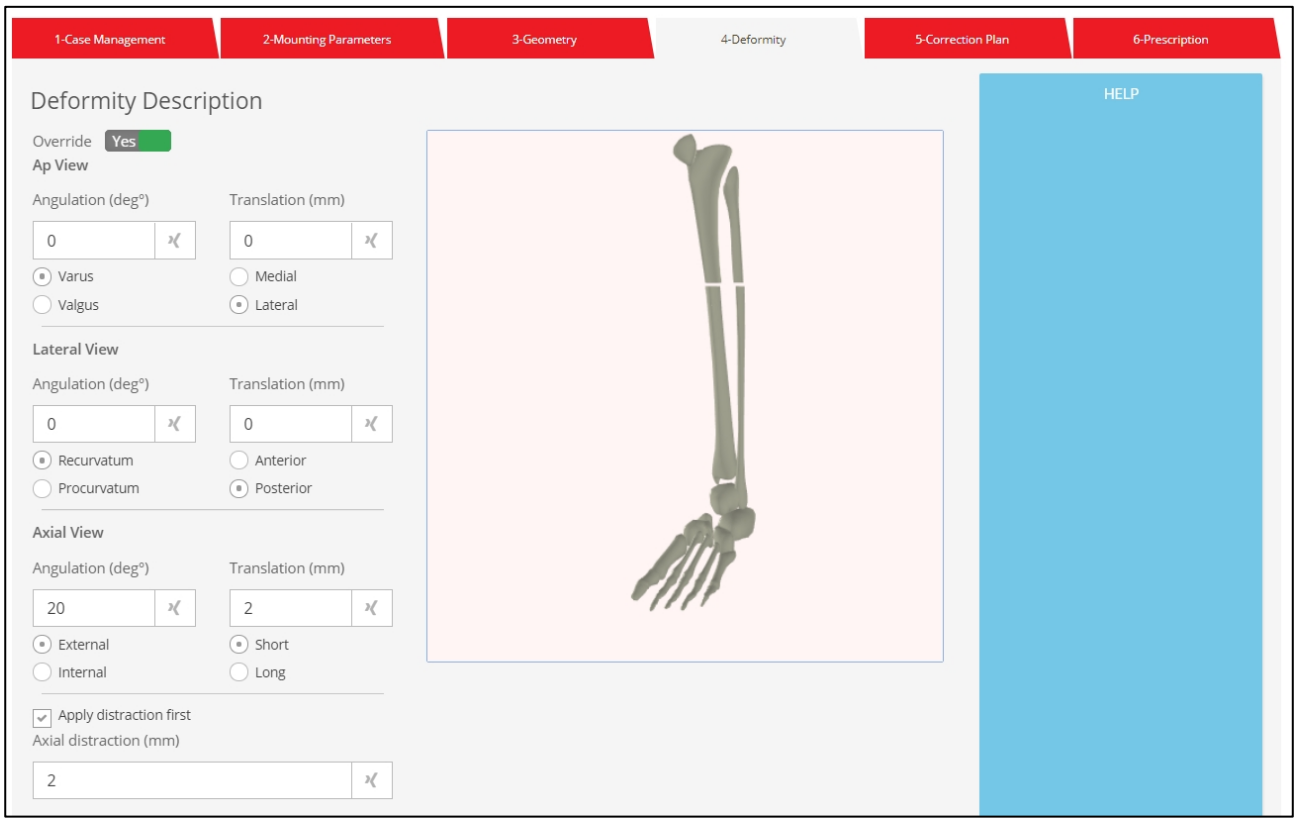
If the ACA is not on the bisector, the angular correction will lead to both longitudinal and lateral translations. If the ACA is proximal with respect to the bisector, the distal segment will result more lateral than the proximal one; on the contrary, if the ACA is more distal with respect of the bisector, the distal segment will result more medial than the proximal one[6].

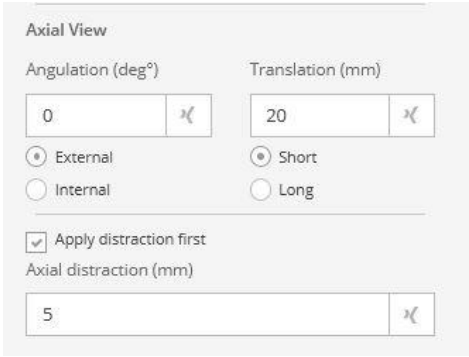
[6]*Skeletal Trauma: Basic Science, Management, and Reconstruction, 5th Edition, 2015* cap. 70, author Dr. Paley.

5.4.1.4 DEFORMITY

In this screen, the deformity or the fracture is described.

The system automatically computes the deformity in the frontal and lateral planes and eventual distances between the bone segments, according to the vectors drawn in step 4 of *Geometry*. Results will be reported in the *Deformity* page.





Manual input of rotational defects and length discrepancies

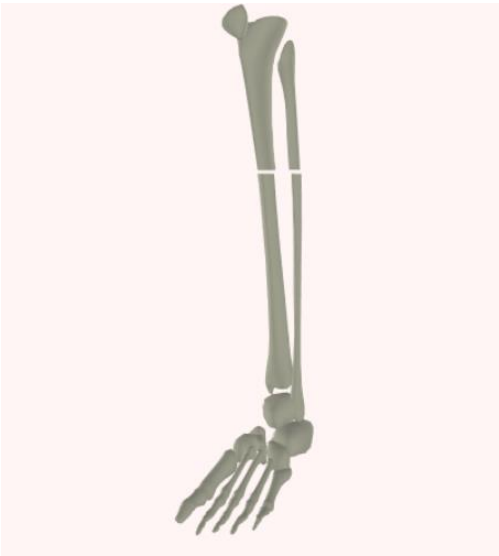
If it is required to apply a distraction before proceeding with the angular correction, the box *Apply Distraction First* has to be marked. Indicate in the underlying box the entity of the lengthening.

If desired, it is possible to proceed with manual over-corrections using the tool *Override*.

Override tool

Indicate eventual rotational deformities or dysmetria on the longitudinal axis, filling in the boxes at the bottom of the screen (*Axial View*).

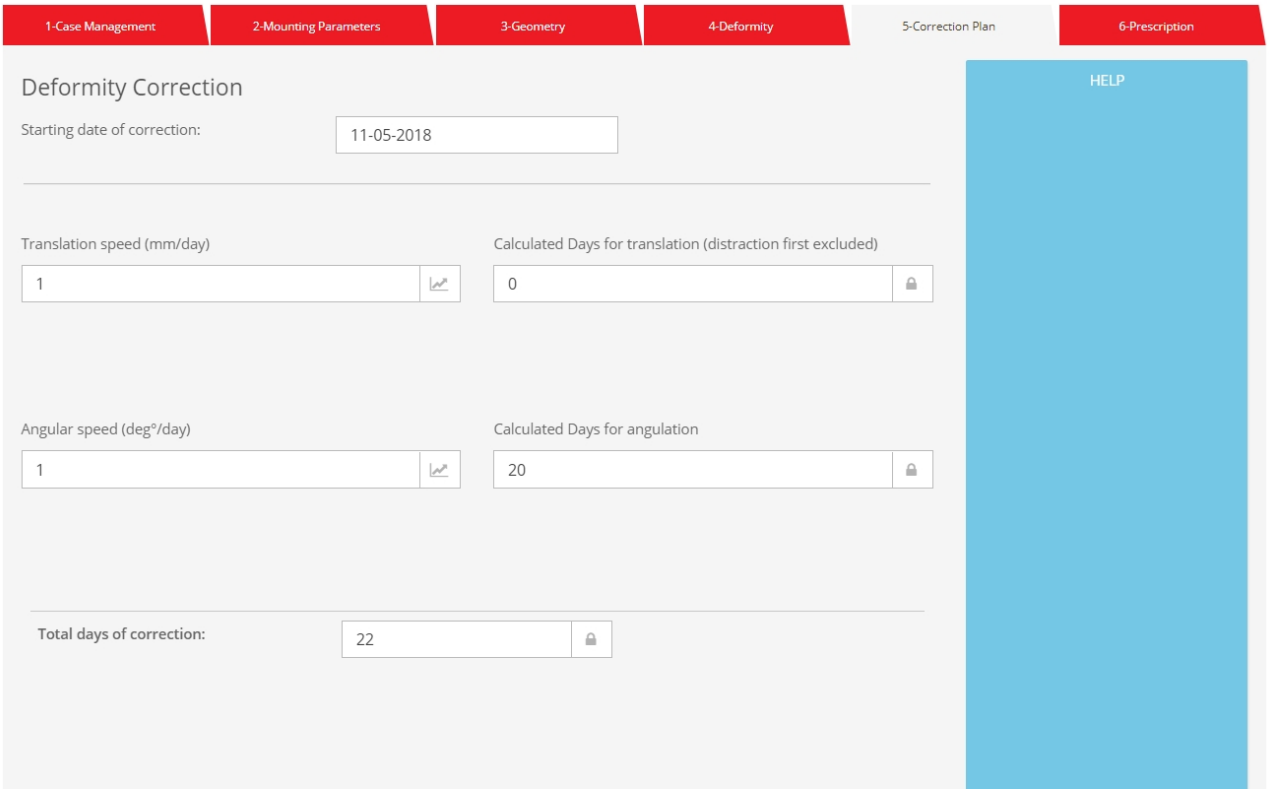
The 3D model helps to verify the correspondence between the extrapolated data and the patient.



3D model

5.4.1.5 CORRECTION PLAN

In this screen, it is possible to adjust the speed of the process of deformity correction or fracture reduction.



Deformity correction: regulate the speed of correction

Indicate the starting day of the correction plan. Choose the speed of linear lengthening and of angular correction, indicating mm/day and deg°/day respectively.

5.4.1.6 PRESCRIPTION

1-Case Management | 2-Mounting Parameters | 3-Geometry | 4-Deformity | 5-Correction Plan | 6-Prescription

Save PDF | Email PDF

Date	Weekday	Strut A	Strut B	Strut C	Strut D	Strut E	Strut F	Total Residual
10/07/18	Tue	128 M	124 M	124 M	131 M	145 M	154 M	total
11/07/18	Wed	129 M	124 M	125 M	132 M	146 M	155 M	total
12/07/18	Thu	130 M	125 M	125 M	133 M	146 M	156 M	total
13/07/18	Fri	131 M	125 M	126 M	133 M	147 M	156 M	total
14/07/18	Sat	131 M	126 M	126 M	134 M	148 M	157 M	total
End of axial translation								
15/07/18	Sun	131 M	126 M	127 M	135 M	147 M	156 M	total
16/07/18	Mon	130 M	127 M	128 M	136 M	146 M	155 M	total
17/07/18	Tue	130 M/XS	127 M	129 M	137 M	146 M	153 M	total
18/07/18	Wed	129 M/XS	128 M	130 M	137 M	145 M	152 M	total
19/07/18	Thu	128 M/XS	128 M	131 M	138 M	144 M	151 M	total
20/07/18	Fri	128 M/XS	129 M	132 M	139 M	143 M	149 M	total
21/07/18	Sat	127 M/XS	129 M	133 M	140 M	143 M	148 M	total
22/07/18	Sun	126 M/XS	129 M	134 M	140 M	142 M	147 M	total
23/07/18	Mon	126 M/XS	130 M	134 M	141 M	141 M	145 M	total
24/07/18	Tue	125 M/XS	130 M	135 M	142 M	140 M	144 M	total
25/07/18	Wed	125 M/XS	130 M	136 M	143 M	139 M	143 M	total
26/07/18	Thu	124 M/XS	131 M	137 M	143 M	139 M	141 M	total
27/07/18	Fri	123 M/XS	131 M	138 M	144 M	138 M	140 M	total
28/07/18	Sat	123 XS	132 M	139 M	145 M	137 M	139 M	total
29/07/18	Sun	122 XS	132 M	140 M	145 M	136 M	137 M	total
30/07/18	Mon	121 XS	132 M	141 M	146 M	135 M	136 M	total
31/07/18	Tue	121 XS	133 M	142 M	147 M	134 M	135 M	total

Prescription table

Clicking on *Prescription*, the Prescription, i.e. the printable table with the daily value of the length of each strut, is obtained. In this way, the progressive correction is possible. The first two columns (*Date-WeekDay*) contain the days when the corrections have to be carried out, while the columns until the eighth show the values of length each strut has to reach each day.

The *Prescription* can be saved as printable PDF file (*Save PDF*) or sent by email to the desired address (*email PDF*).

Send email with the prescription or create PDF

In case of errors or lacks, the system will notify it with a specific *Warning* before proceeding with data elaboration.

5.4.1.7 STRUT CHANGE

During the treatment, it could be necessary to change one or more struts since they are at their minimum/maximum length.

The days useful for the change are coloured in the prescription. In addition, the system indicates the size of the current strut and the size of the strut needed for the change. The last day suitable for the change is highlighted with a coloured box. **Remember that it is necessary to block the hexapod system with an extra grab element before proceeding with the strut substitution.**

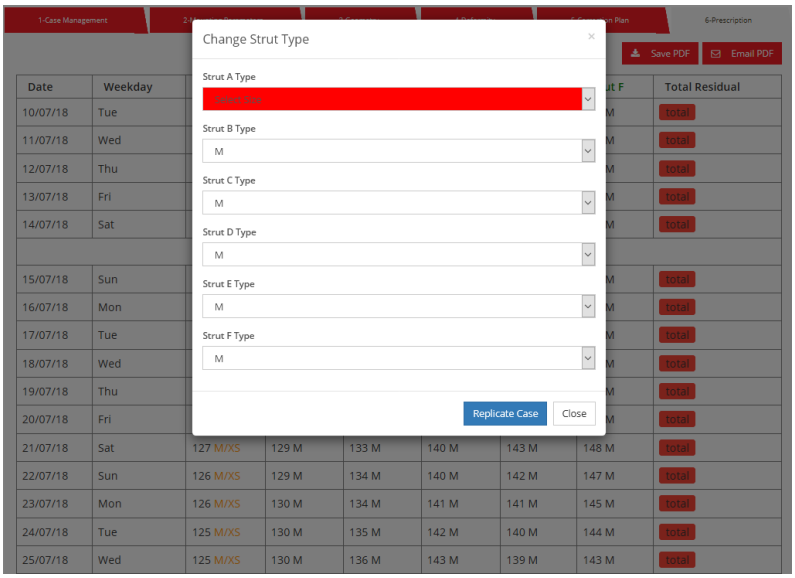
Date	Weekday	Strut A	Strut B
10/07/18	Tue	128 M	124 M
11/07/18	Wed	129 M	124 M
12/07/18	Thu	130 M	125 M
13/07/18	Fri	131 M	125 M
14/07/18	Sat	131 M	126 M
15/07/18	Sun	131 M	126 M
16/07/18	Mon	130 M	127 M
17/07/18	Tue	130 M/XS	127 M
18/07/18	Wed	129 M/XS	128 M
19/07/18	Thu	128 M/XS	128 M
20/07/18	Fri	128 M/XS	129 M
21/07/18	Sat	127 M/XS	129 M
22/07/18	Sun	126 M/XS	129 M
23/07/18	Mon	126 M/XS	130 M
24/07/18	Tue	125 M/XS	130 M
25/07/18	Wed	125 M/XS	130 M
26/07/18	Thu	124 M/XS	131 M
27/07/18	Fri	123 M/XS	131 M
28/07/18	Sat	123 XS	132 M

5.4.1.8 TOTAL RESIDUAL

In the last column on the right of the screen *Prescription*, there is the box *Total Residual* for each day. The total residual allows performing modifications regarding the kind and entity of correction initially set, both during the treatment and at the end of it. Clicking on the box *total* a new case management will appear. In this way, moving to the section *Deformity*, it will be possible to apply the desired changes through the tool *Override* (cfr. paragraph 5.4). The position of the *Virtual Hinge* and the lengths of the struts at the considered day will be unchanged.

Total Residual

In case the total residual is carried out in a day in which it is possible but not mandatory to change a strut, the software will require indicating the kind of strut present in the fixator that day.



5.4.2 MANAGE CASE

Clicking on *Manage Cases*, it is possible to select a previously set case, to see and/or modify it or to re-print the prescription.

Tools of Manage Cases (from left to right): modify case, delete case and see prescription.

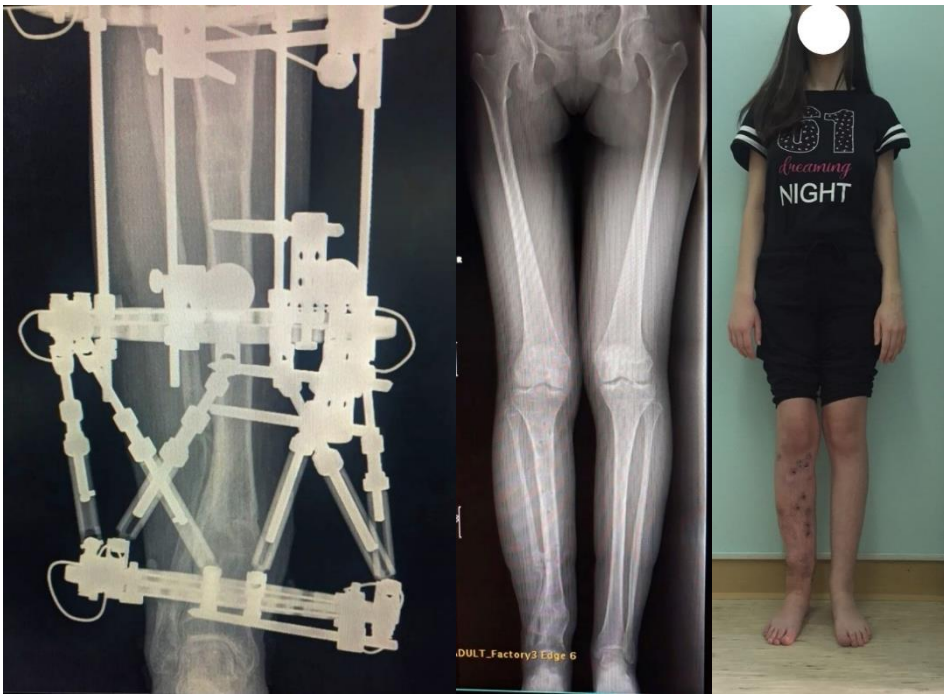
The table with the previous cases could be ordered with the desired criterion clicking on the chosen value in the first raw of the table.

CLINICAL CASES

-7-

7.1 Right tibia, 15 years old patient, 40 mm of hypometria, 40° of intra-rotation, post-traumatic.

Pre-operative

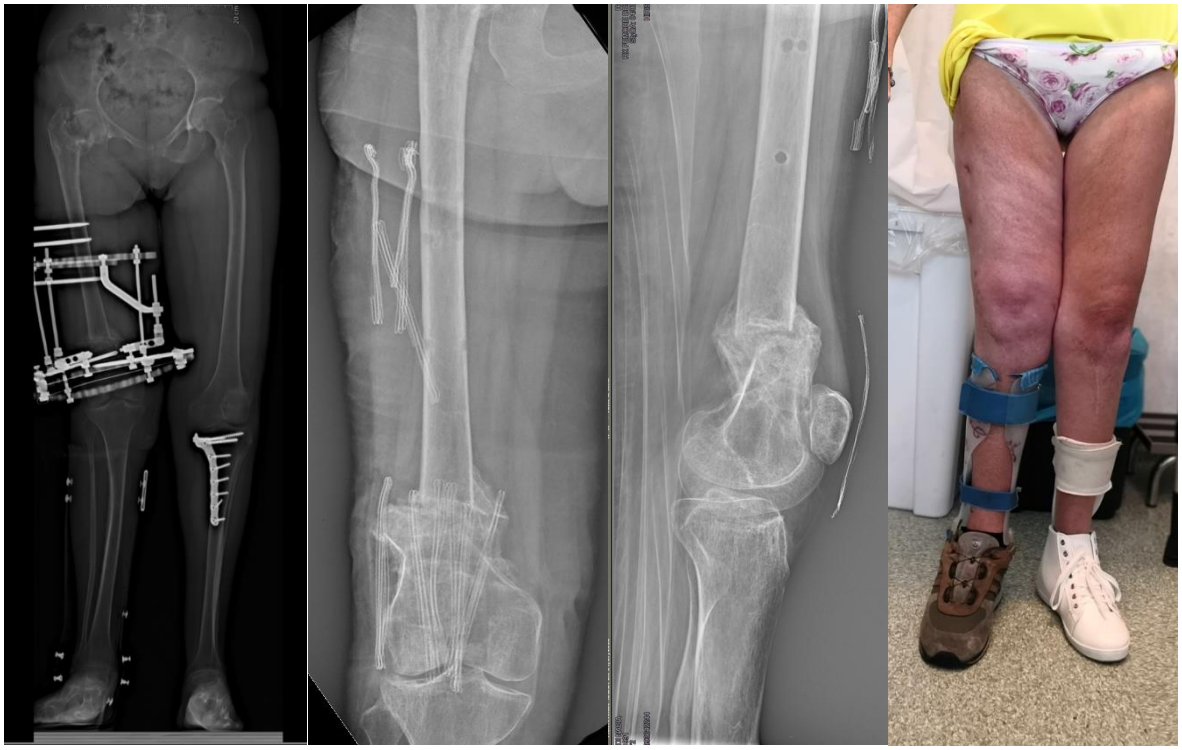


End of treatment

Thanks to Prof. Yasser Elbatrawy, Al-Azhar University Cairo Egitto, for the availability of the case.

7.2 Right femur, 27 years old patient, osteogenesis imperfecta, 10° of valgism, 35° of extra-rotation.

Pre-operative

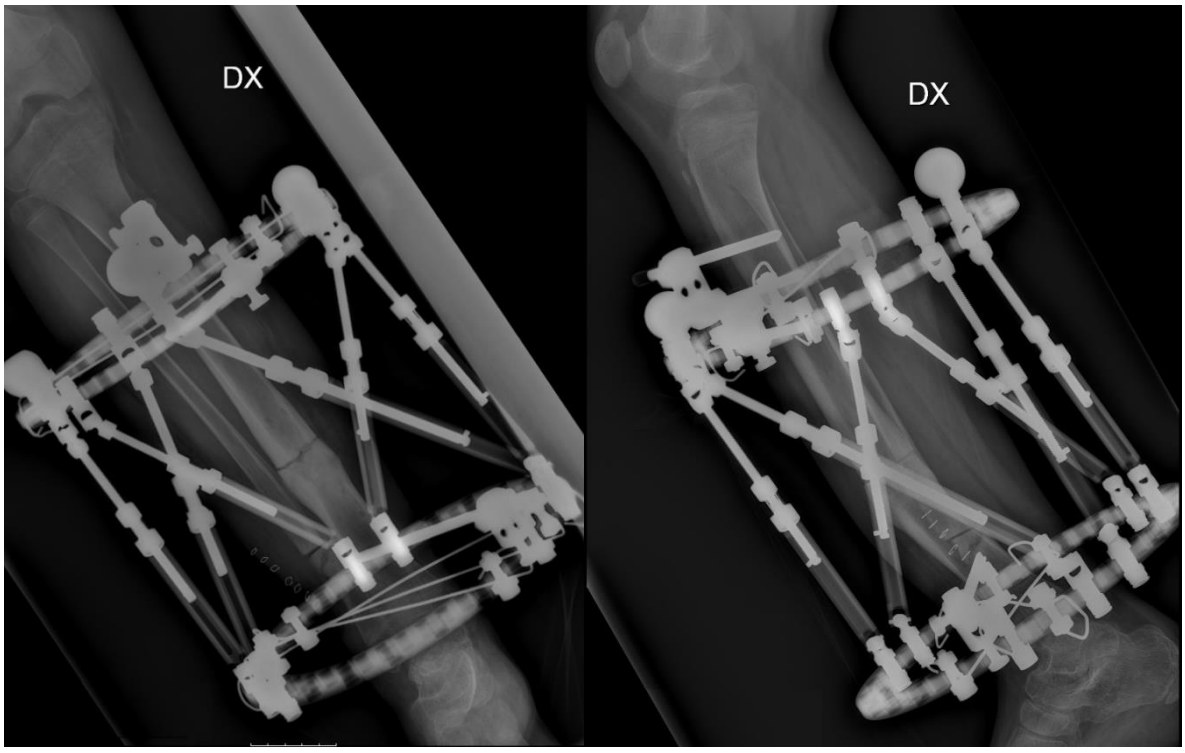


End of treatment

Thanks to Dr. Alexander Kirienko, IRCCS Istituto clinico Humanitas Milano Italy, for the availability of the case.

7.3 Right tibia, 8 years old patient, post-traumatic pseudoarthrosis, 7° of valgism, 20° of procurvatum.

Pre-operative



Post-operative

End of treatment

Thanks to Dr. Fabio Verdoni, IRCCS Istituto Ortopedico Galeazzi, Milano Italy, for the availability of the case.

iFIXation® COMPONENTS

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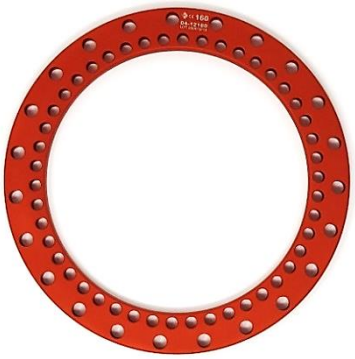


FULL RING

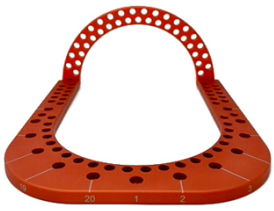
ø (mm)	cod
90	04-12090
100	04-12100
110	04-12110
120	04-12115
130	04-12130
140	04-12140
150	04-12150
160	04-12160
180	04-12180
200	04-12200
220	04-12220
240	04-12240

HALF RING A/B

ø (mm)	cod
160 A	04-22160-A
160 B	04-22160-B
180 A	04-22180-A
180 B	04-22180-B
200 A	04-22200-A
200 B	04-22200-B
220 A	04-22220-A
220 B	04-22220-B
240 A	04-22240-A
240 B	04-22240-B

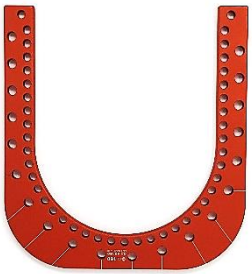
5/8 RING

ø (mm)	cod
100	04-32100
110	04-32110
120	04-32120
130	04-32130
140	04-32140
150	04-32150
160	04-32160
180	04-32180
200	04-32200
220	04-32220
240	04-32240



ORTHOGONAL CLOSING RING

ø (mm)	cod
140	04-62140
160	04-62160
180	04-62180



FOOTPLATE

ø (mm)	cod
100	04-40100
110	04-40110
120	04-40120
130	04-40130
140	04-40140
160	04-40160
180	04-40180

CLOSING RING

ø (mm)	cod
100	04-60100
110	04-60110
120	04-60120
130	04-60130

Size	cod
MINI	04-900010
SXS	04-900000
XS	04-901000
M	04-901020
L	04-901030
XL	04-901040

STRUTS

XRAY-TOOL

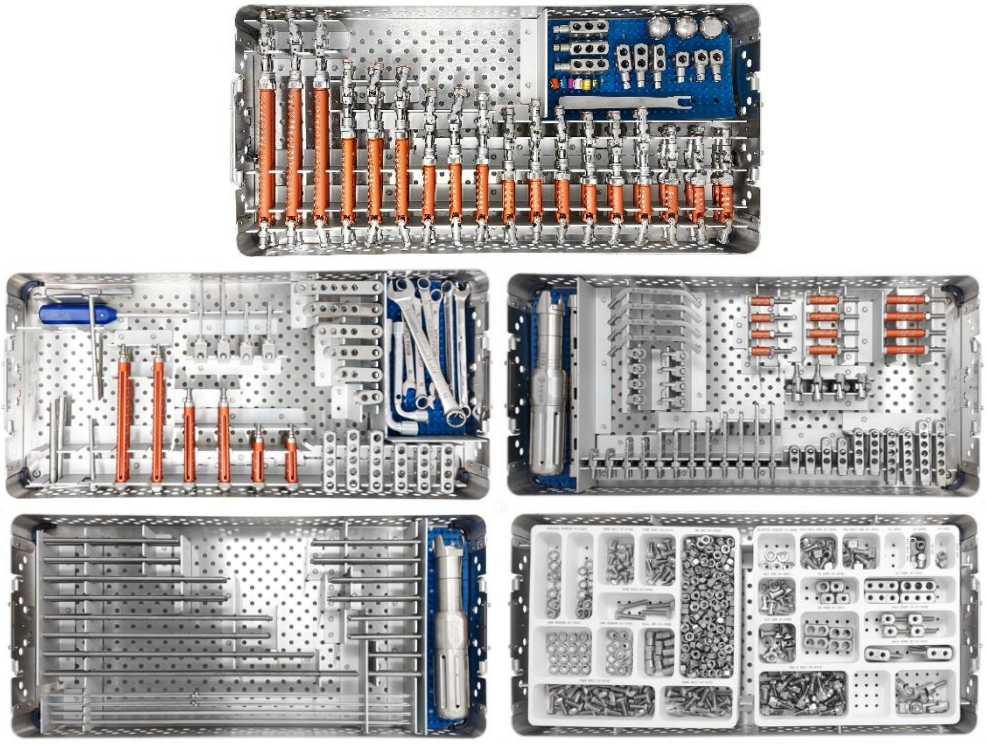
ø (mm)	cod
120	05-4600
130	05-4700
140	05-4500
160	05-4000
180	05-4100
200	05-4200
220	05-4300
240	05-4400

cod
04-901099

ID BANDS STRUTS SET

cod
04-901098

SPHERES SET



SET IFIXATION INSTRUMENTATION

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