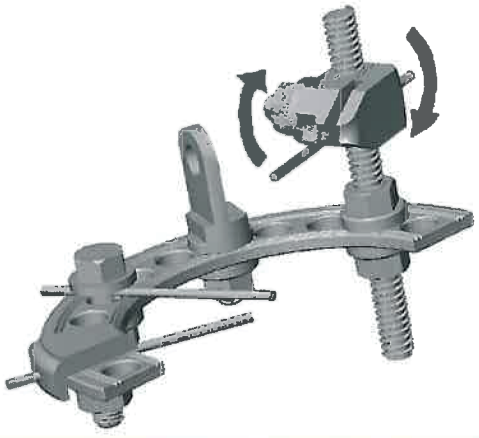
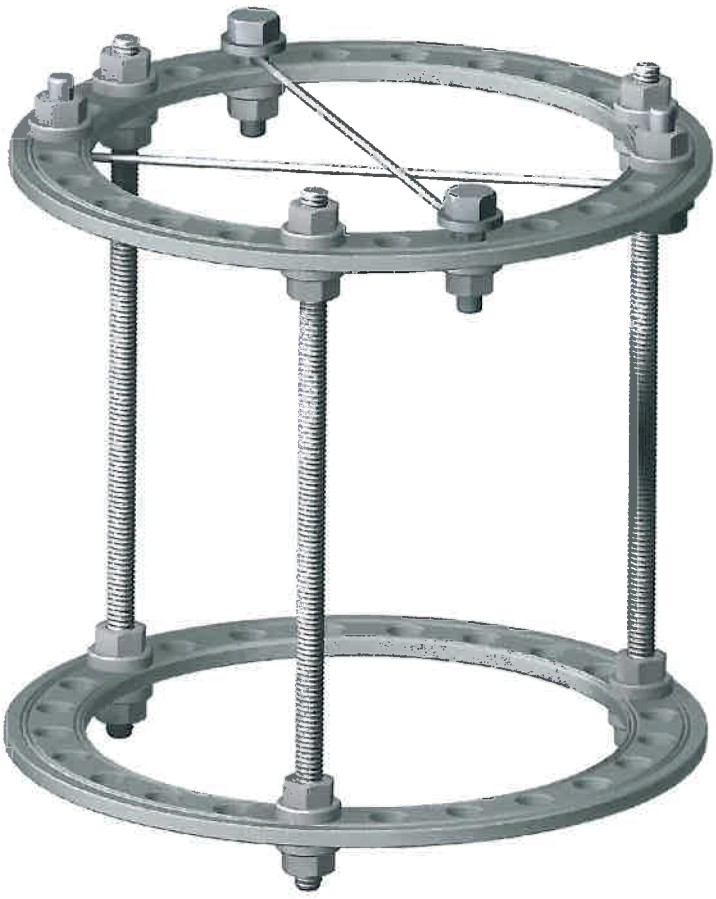
HNM
MEDICAL

TFX
External Fixator





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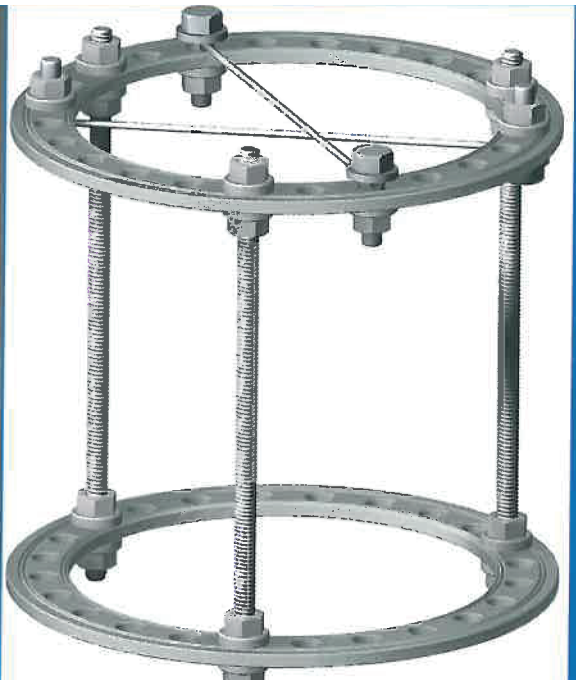

The TFX system has been developed to provide an external fixation according to Ilizarov´s principle in cases of severe articular fractures, pseudo-arthrosis, as well as for limbs lengthening. The main purpose of yhe system is to provide a stable but not completely rigid fixation, in order to stimulate bone growth. The design of the system not only has preserved the basic features of Ilizarov´s principle, it has optimized the shape of the components:
using materials suited to the strength, stiffness, and endurance requirements making the assembling and adjusting procedures simple straight forward to decrease surgery times; widening the field of application to better comply with the needs of orthopedic surgeons.

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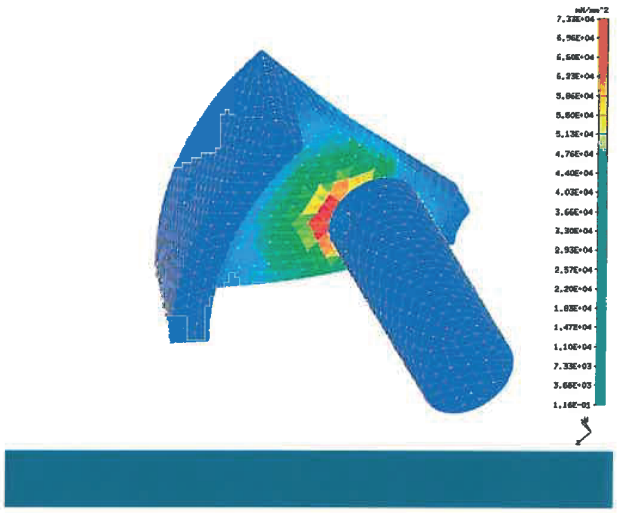
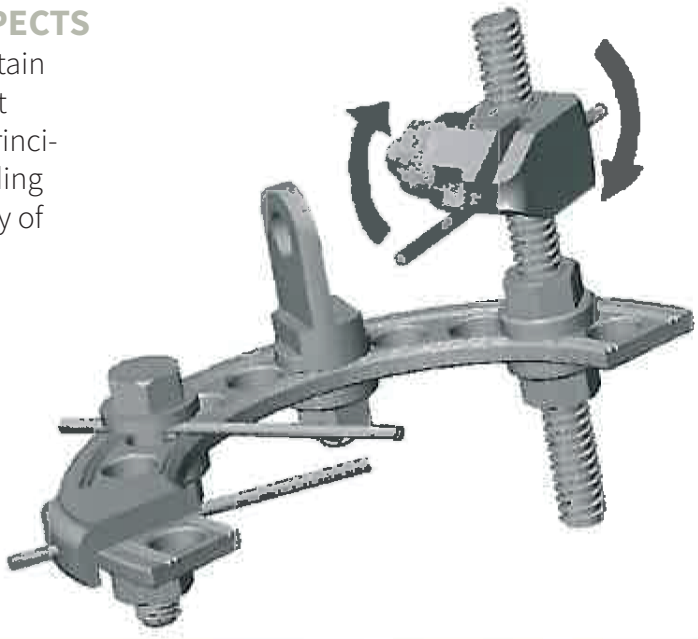


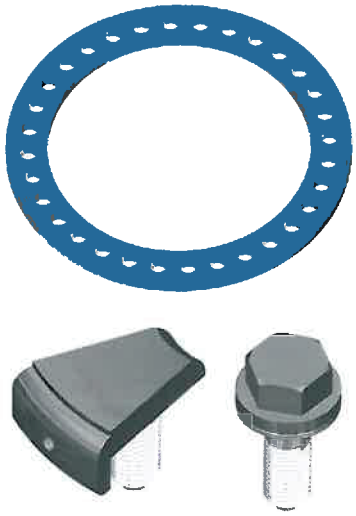
All the components belonging to TFX system have been computer-design by means of finito elements method (FLM), which allows to preliminary compute the stress-and-strain distribution due to the loads application.This allowed the design optimization and the development of devices which, although minimizing weight and volume, are able to safetly factors to take into consideration possible accidental overloads.
The performances of the components have also been preliminarily evaluaret through experimental mechanical and functional tests, devoloped to measure the static and the fatigue capabilities of a statiscally meaninggul number of samples. This allowed to validate the design, as well as to verify the reliability of the system, undergoing the severest conditions of use.

FEATURES AND INNOVATIVE ASPECTS

The TFX system is characterized by a certain number of peculiarities which, althought maintaining the reliability of the basic princi-ple, make it an apparatus unique, regarding the ease-of-assembling and the flexibility of use.

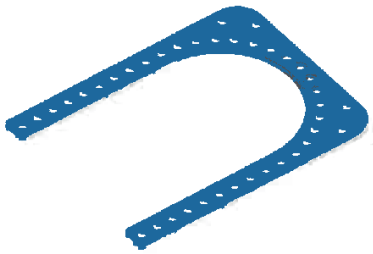
The main features are:
* Strength, stiffness and lightness
* Modularity
* Adjustability
* Mono-lateral of Bilateral-fixation





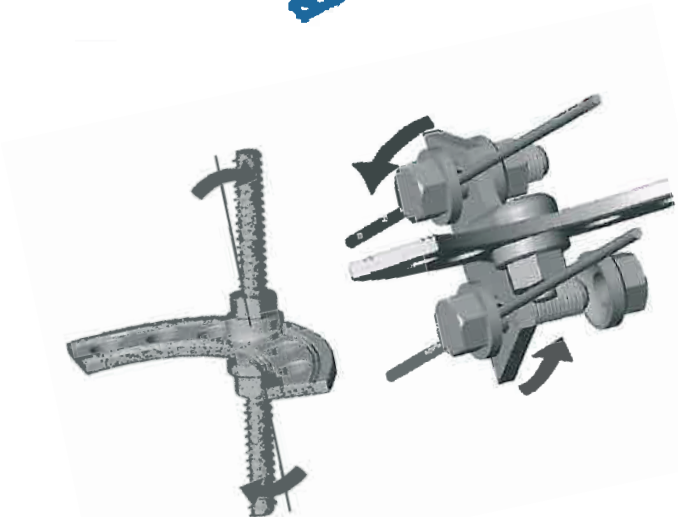
STRENGTH,STIFFNESS AND LIGHTNESS

All the devices which have to supply a high structural efficiency (i.e. ring, clamps and supports) are made of titanium, characterized by a specific strength higher then competitor metallic alloys. This allows to provide constructs which should posseses a tough behavior to avoid sudden failures (i.e. threaded bars and Kirschner wires) are made of ductile AISI 304 and 316L stainless stool. Finally, the system is designed in such a way that all threaded connections (bars/clamps,screws/nuts) put in contact different materials (stainless steel and titanium alloy): this allows easy screwing/unscrewing, as well as the absence of galling in every condition of use.



MODULARITY

The TFX system consist of full and open (1/2, 5/8) rings, suited for long bones and for feet (footplate); fixed and swiveling clamps of different sizes; flat and vertical supports; threaded bars of seven different lengths: they all guarantee wide modularity and flexibility of use.

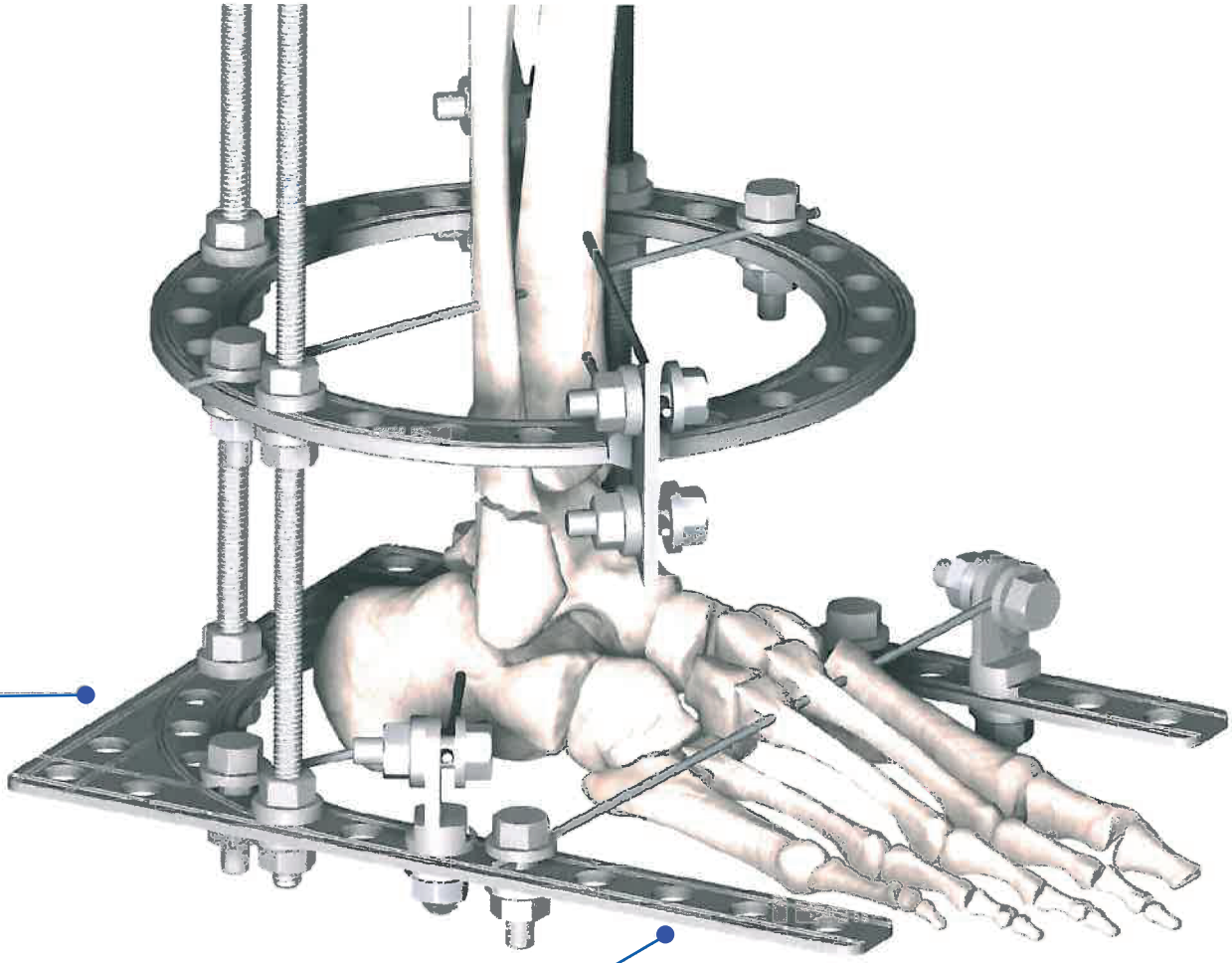


ADJUSTABILITY

The use of swiveling clamps, horizontal or vertical supports and special hemispherical or slotted washer allows to fully adjust the reciprocal position and inclination of the basic system components (i.e. rings, threades bars, wires and screws): this guarantees the complete adaptability to different anatomies and surgical cases.

MONO-LATERAL OR BI-LATERAL FIXATION

Depending on different surgical requirements, the TFX system can be used both as mono-lateral fixation (using ring, vertical supports and Schan/screws) or bi-lateral fixation (using rings, clamps and Kirschner wires), adopting the same basic components.

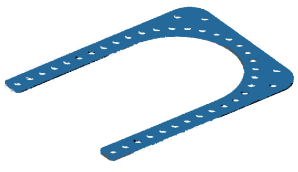


TFX system allows the placement of Kirschner wires in proximity the foot as well, thanks to the adoption of the footplate. Such a device is made of the same strong and stiff titanium alloy used to fabricate rings and its available in three different sizes: 145,167 and 10 mm.

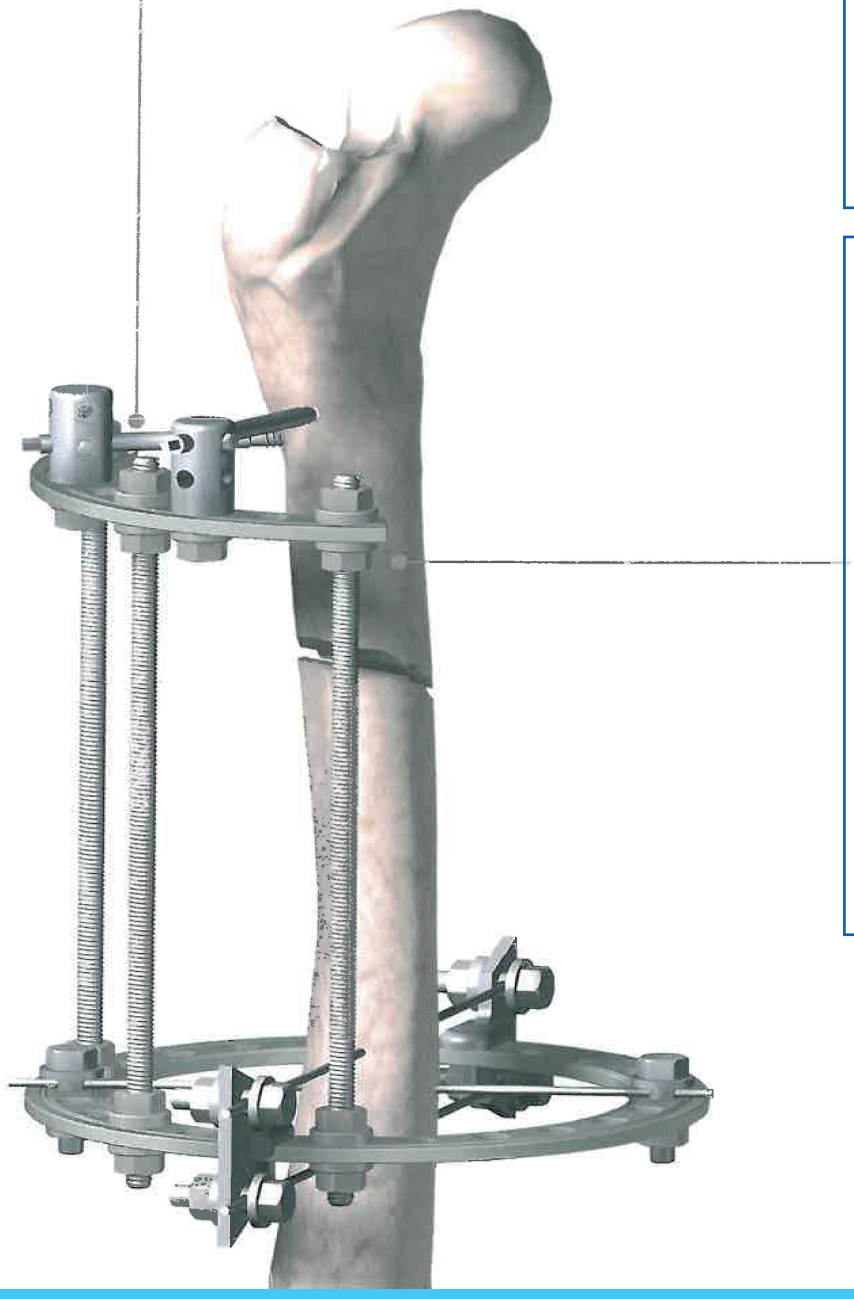
These widths coincide with the intermediate sizes of the rings, thus to make the holes, belonging to the proximal ring an to the footplate, axially coincident.

Along the entire profile or the footplate several equally-spaced 10mm diameter holes are arranged. Such a feature guarantees the complete compatibility of the footplate with all the other components of system and make TFX system an extremely modular and versa tile device.

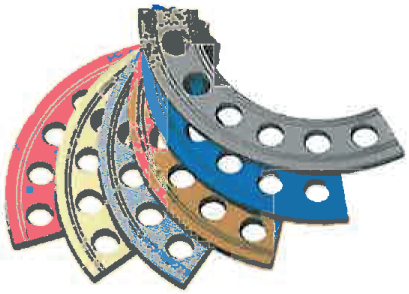
The footplates are clearly laser-marked and colored to make the identification and the coupling with the proximal ring even more easy.



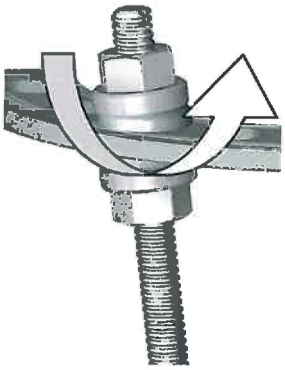
The TFX system can be profitability used as a mono -ateral fixation system when fixed and vertical supports for Schanz screws are used. Both devices are conenected through 1/2 y 3/4 rings sectors. Different multi-nivel types of fixed support existed allowing the optimal placement of Schanz screws curing surgery. The vertical support, which performs the same function of the fixed suport allows the angular adjustment of the Shanz screws in the vertical plane in consideration of the high stress level the Schanz screws are subject to they are made of Ti6A 4V ELI bio-compatible titanium alloy, for exploding the excellent mechanical strength of this material. The special orthopedic thread and the efficient conical point provided wit a wide relief, make the insertion of this self-tapping screw particularly easy.

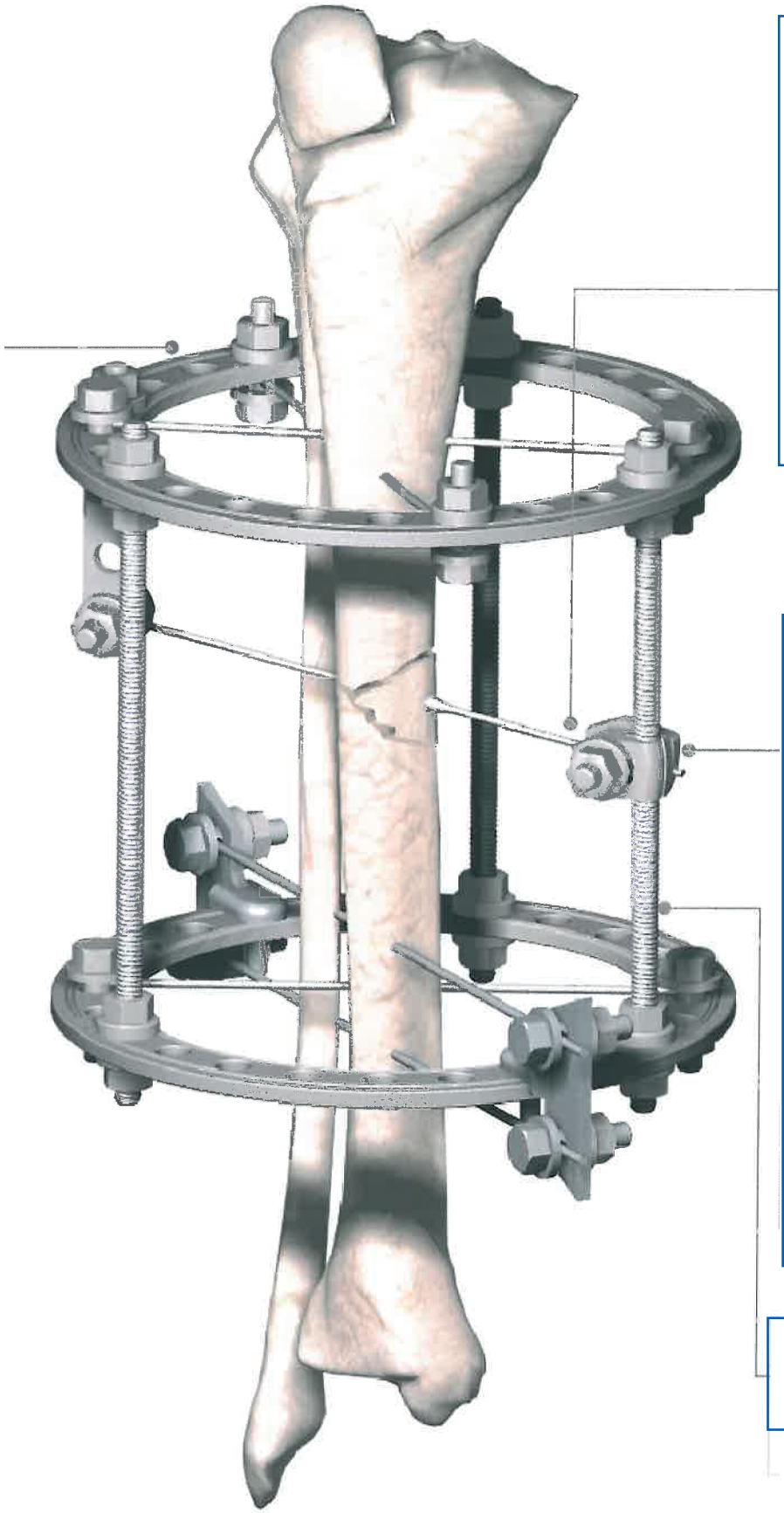


The rings of the TFX system are made of special titanium alloy. This alloy guarantees high mechanical strength and stiffness which compared to its extreme highness make it much more efficient than competition materials. The rings are available in six diameters: 100,122,145,167.190 and 212 mm; 1/2 and 1/8 ring sectors. A pair of 1/2 ring sector cab be securely assembled to give a full ring. Each ring is clearly laser-marked and colored to identify different sizes.



If a threaded rod cannot be inserted into a couple of co-axial ring holes; the conical washers should be used. These allow to incline the rod up to an angle of 15 with respect to the axis of the holes. So doing, rings of different sizes can be assembled, as well as rings with footplates. Besides, the use of conical washers allows to optimize the placement of the clamps for Kirschner wires fixation.

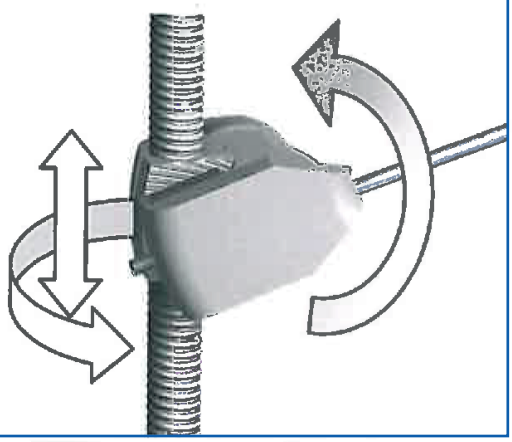




The Kirschner wires are supplied in three diameters:1.8, 2.0 and 2.5 mm.

They are made of AISI 316L bio-compatible stainless steel. A version provided with stopper is also available. Such a feature allows the application of strong longitudinal and transverse loads. all the Kirschner wires of the TFX system are provided with bayonet point.

The vertical clamp consists of two titanium parts that allow the placement of the device along any position of the threaded bar. The Kirschner wires can be directed toward any angular direction, while maintaining a fixed 90 angle with respect to the axis of the rod. The use of the swiveling version of the vertical clamp also allows a + - 20 angular adjustment with respect to the axis of the rod.

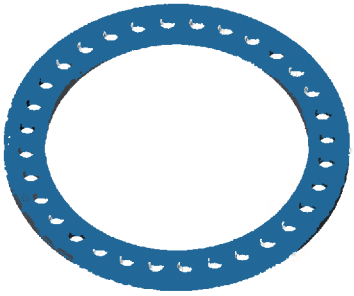


To guarantee a solid and safe connection among rings, threaded rods are used, which are supplied in different lengths: 100, 150, 200, 250, 300, 350 and 400 mm.

TITANIUM

DESCRIPTION

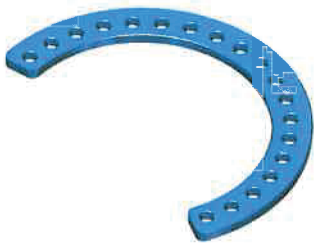
Ring Ø 100mm	TFX-01T31	Pink Fuchsia
Ring Ø 100mm	TFX-01T32	Yellow gold
Ring Ø 100mm	TFX-01T33	Azure
Ring Ø 100mm	TFX-01T34	Bronze
Ring Ø 100mm	TFX-01T35	Dark blue
Ring Ø 100mm	TFX-01T36	Grey



ALUMINIUM

DESCRIPTION

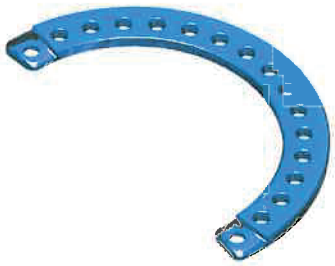
5/8 Ring Ø 145mm	TFX-01T31	Azure
5/8 Ring Ø 167mm	TFX-01T32	Green
5/8 Ring Ø 190mm	TFX-01T33	Dark Blue



ALUMINIUM

DESCRIPTION

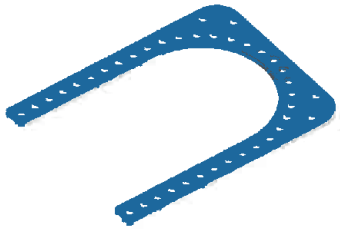
1/2 Ring Ø 145mm	TFX-03A73	Azure
1/2 Ring Ø 167mm	TFX-03A74	Green
1/2 Ring Ø 190mm	TFX-03A75	Dark Blue
1/2 Ring Ø 212mm	TFX-03A76	Grey



TITANIUM

DESCRIPTION

Footplate Ø 145mm	TFX-05T31	Azure
Footplate Ø 167mm	TFX-05T32	Green
Footplate Ø 190mm	TFX-05T33	Dark Blue



Angle plate	TFX-13S61

Fixed clamp	TFX-07TS1

3mm Swiveling clamp-with collar	TFX-08S41
3mm Swiveling clamp-with collar	TFX-08S42
3mm Swiveling clamp-with collar	TFX-08S43
3mm Swiveling clamp-with collar	TFX-08S44
3mm Swiveling clamp-with collar	TFX-08S45
3mm Swiveling clamp-with collar	TFX-10TS1

Louisville clam	TFX-11TS1*

1 hole vertical support-male	TFX-08S41
1 hole vertical support-female	TFX-08S42
2 hole vertical support-male	TFX-08S43
2 hole vertical support-female	TFX-08S44

Nut with collar	TFX-15T31
Nut without collar	TFX-15T32
Conical washer	TFX-15A73
Slotted washer	TFX-15T34
Grooved washer	TFX-15S45
Adapter for Ø 6	TFX-15A76

Accesories for aluminum ring	
Washer Ø 17 mm thickness 1.6mm	TFX-15S62
Hexagonal-headed bolt length 20mm	TFX-15S61
Hexagonal nut height 6.8mm/CH8	TFX-15S60

Threaded rod-length 100mm	TFX-16S41
Threaded rod-length 150mm	TFX-16S42
Threaded rod 200mm	TFX-16S43
Threaded rod 250mm	TFX-16S44
Threaded rod 300mm	TFX-16S45
Threaded rod 350mm	TFX-16S46
Threaded rod 400mm	TFX-16S47

Kirschner wire W/stopper Ø1.8 mm	TFX-20S62
Kirschner wire W/stopper Ø 2.0mm	TFX-20S63

Kirschner wire W/Out stopper Ø1.5 mm	TFX-21S61
Kirschner wire W/Out stopper Ø1.8 mm	TFX-21S62
Kirschner wire W/Out stopper Ø2.0 mm	TFX-21S63
Kirschner wire W/Out stopper Ø2.5 mm	TFX-21S64

Fixed support for Schanz screw	TFX-14S41
Screw	TFX-14T30

Bearing - length 40 mm	TFX-13S640
Bearing 60 mm	TFX-13S660

Connection plate - holes 6-8-8 mm	TFX-13S6688
Connection plate - holes 8-8-8 mm	TFX-13S6888

Small perforated arch	TFX-00S60
Large perforated arch	TFX-00S61

90 Joint-holes Ø6-8 mm	TFX-13S6168

Oblique support	TFX-13S60

Indications

Appropriately utilized, TFX system allows the development of a solid bone regrowth and it used to treat cases of fractures, pseudo-arthrosis and limbs lengthening (to correct certain congenital pathology such as ectromelia, phocomelia, transverse and longitudinal hemimelia or to correct pathologies due to vascular changes such as artery venous shunts and arteries stenosis).

Contraindications

The contraindicatiosn of TFX system are analogous to similar products currently available and include, but are not limited to:

Absolute:

- Infections in the avtivate state
- allergy to the metal components
- patients who are either unwilling or unable to follow instructions.

Relative:

- Metastasis serious muscular, neurological, or vascular disease
- Fever or leucocytosis
- Signs of flogosys at the planned site of the implant
- High level osteoporosis

If the implant of the TFX system is considered the best solution for the patient, and if tge patient presents one or more of the above contraindications, it is essential the patient be informed of the possible negative consequences that might hinder the success procedure.

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