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Femur&Tibia
HYBRID EXTERNAL
FIXATOR
SURGICAL TECHNIQUE



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Femur&Tibia
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FIXATOR
SURGICAL TECHNIQUE

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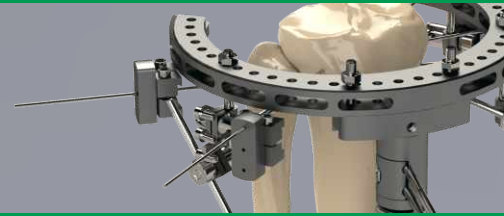
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1. Introduction

Femur&Tibia
Hybrid External Fixator



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Femur&Tibia HYBRID EXTERNAL FIXATOR SURGICAL TECHNIQUE

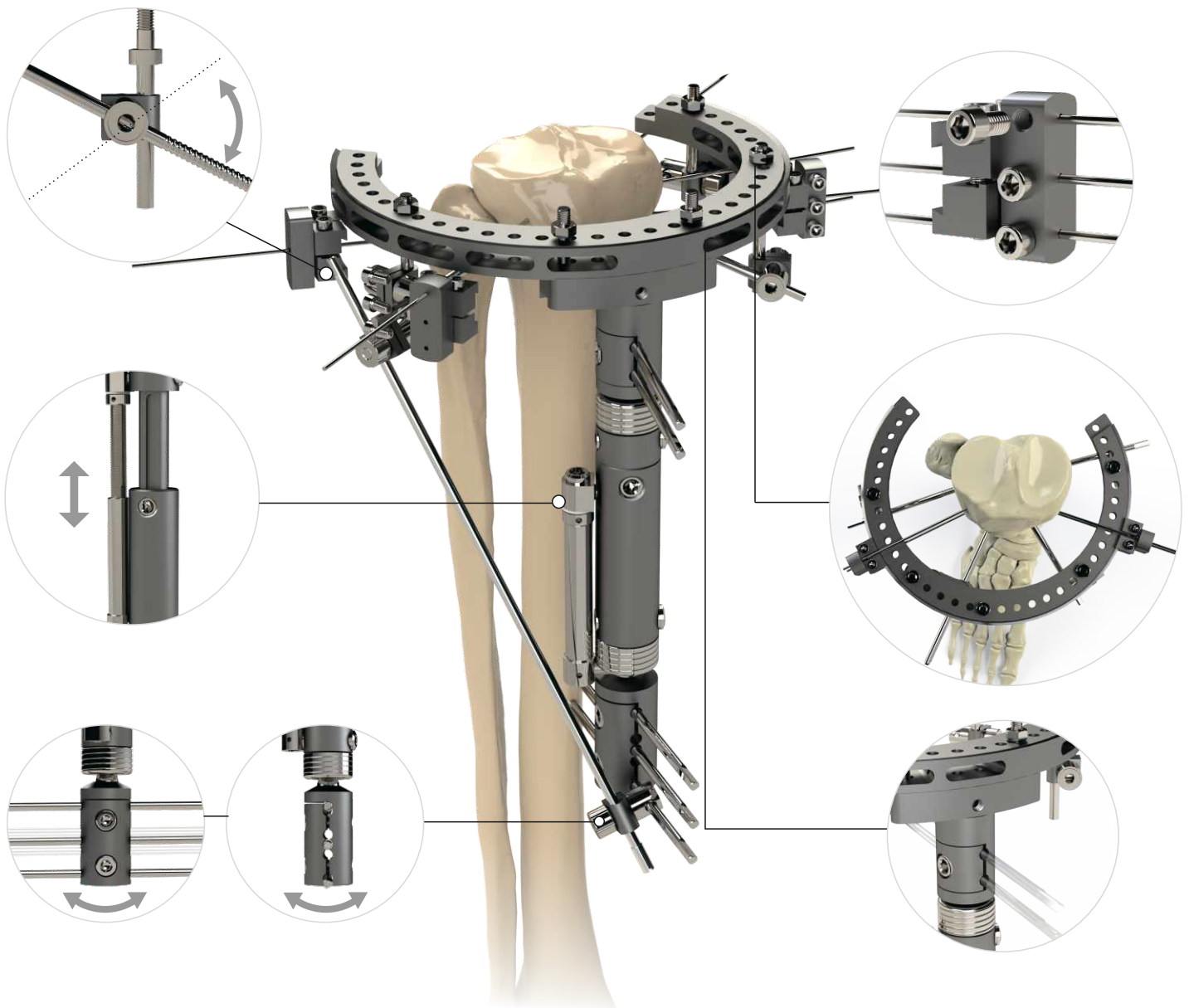
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5294-0000

1.1 Specification

1.1.1 Hybrid Fixators

Hybrid Fixator Systems are designed for use in open fractures, minimal fixations in intra- and extra-articular fractures, poly-trauma fractures, adult and pediatric cell skeletal pins and wires, including leg lengthening, osteotomy, arthrodesis, and other bone indications that can be treated using external fixation. It is designed to be used together. Hybrid Fixators are available both sterile and non-sterile.





1. Introduction

Femur&Tibia Hybrid External Fixator



1.1. Specification

1.1.2 Schanz Screw

It is used for fixation in places where bones are cortical-cancellous, and it is produced from stainless steel (316 LVM) and titanium (Ti6Al4V ELI).

1-Schanz Screw

REF. NO (SS)	LENGTH (mm)	DIAMETER
6011-5140	140	Ø 5mm
6011-5160	160	Ø 5mm
6011-5180	180	Ø 5mm
6011-5200	200	Ø 5mm
6011-5220	220	Ø 5mm
6011-5240	240	Ø 5mm
6011-5260	260	Ø 5mm
6011-6140	140	Ø 6mm
6011-6160	160	Ø 6mm
6011-6180	180	Ø 6mm
6011-6200	200	Ø 6mm
6011-6220	220	Ø 6mm
6011-6240	240	Ø 6mm
6011-6260	260	Ø 6mm

1.1.3 Kirschner Wire&Rod

A Kirschner wire (K-wire) is a thin metal rod that is used to stabilize fractured bones or joints. It can be inserted through the skin or through a small incision. K-wires are often used in combination with other fixation devices, such as plates, screws, or external fixators. K-wires are usually removed after the bone has healed, which may take several weeks or months.

2-Hybrid Fixator Rod 6x400 mm

REF. NO

5255-0640

3-Olive Kirschner Wire Ø 2x440

REF. NO

6251-2044

3-Kirschner Wire Ø 2x440

REF. NO

6041-2044

4-Hybrid Fixator Ring



REF. NO

5254-0170

5254-0190

5-Hybrid Fixator Rod Clamp

REF. NO

5254-0012



6-Hybrid Clamp

REF. NO

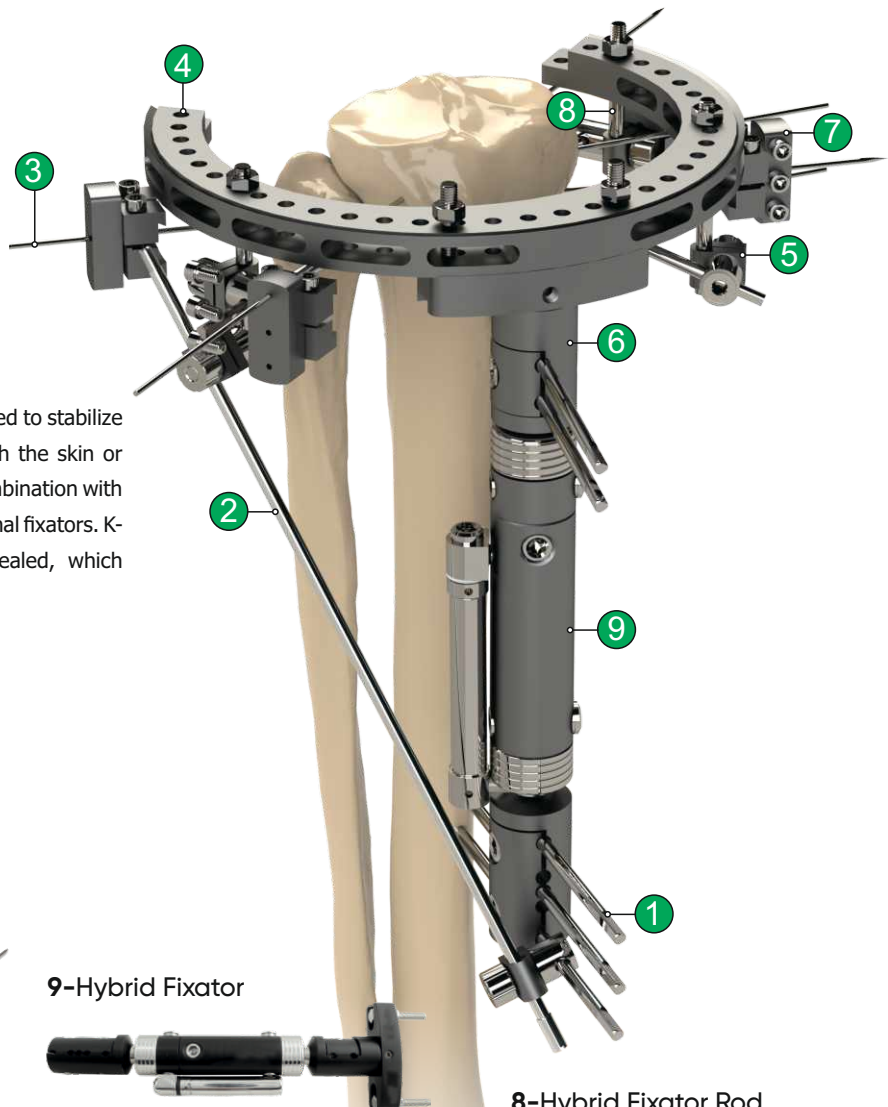
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7-Hybrid Fixator Wire Clamp

REF. NO

5254-0013



9-Hybrid Fixator



REF. NO

5254-0020

5254-0010

5254-0030

SIZE

S

M

L

8-Hybrid Fixator Rod Connection Part



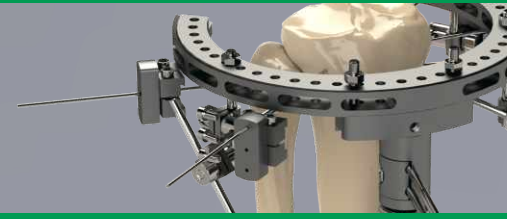
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2. Surgical Technique

Femur&Tibia
Hybrid External Fixator



2.1. Tibial Fractures

2.1.1 Proximal Tibia Fracture

Tibia fractures are seen in various types. According to the cost of the tram, a correct intervention is very important.

In some cases, external fixators are used for temporary fracture fixation in politrauma patients. In some cases, it is used in the process of tissue healing and edema in fractures involving the joint. Sometimes, it is used for permanent treatment.

For example, the fracture is kept with an external fixator for 3 weeks. Then, depending on the situation, nails or plates are applied. If the plate or nail is placed in the first time, increased tissue damage, blood loss, limb loss or even patient loss due to prolongation of anesthesia. Therefore, it is urgently fixed with a fixator and then the actual treatment is performed. *Some sample of tibia fracture (Fig. 1a-3a)*

Simple articular, simple metaphyseal

Simple articular fractures are those that involve only the joint surface of a bone, without extending to the shaft. Simple metaphyseal fractures are those that occur in the region between the joint and the shaft, without affecting the growth plate. (Fig. 1a)



Simple articular, multifragmentary metaphyseal

A proximal tibia fracture is a break in the upper part of the shin bone near the knee joint. A simple articular fracture involves only one fracture line in the joint surface, while a multifragmentary metaphyseal fracture involves multiple fragments in the bone below the joint. These fractures are usually caused by high-velocity injuries and may have severe soft-tissue complications. (Fig. 2a)



Multifragmentary articular fractures

The proximal tibia is the upper part of the shinbone that connects to the knee joint. A fragmentary articular fracture is a type of fracture that involves the cartilage-covered surface of the bone. This can cause pain, swelling, and instability in the knee.

(Fig. 3a)





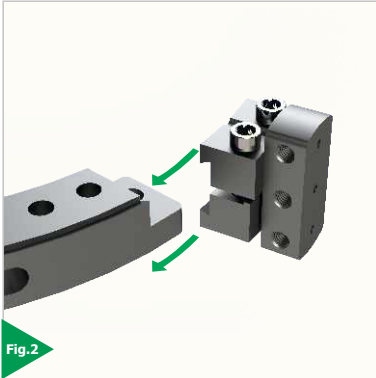
2. Surgical Technique

Femur&Tibia Hybrid External Fixator

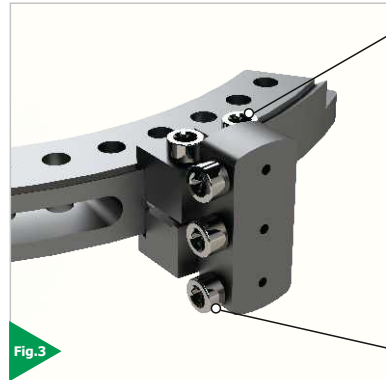


2.2.Assemble

2.2.1.Ring and K-Wire Clamps



Clamps for K-wires are attached from the rails while the ring is being prepared. (Fig.2-3)

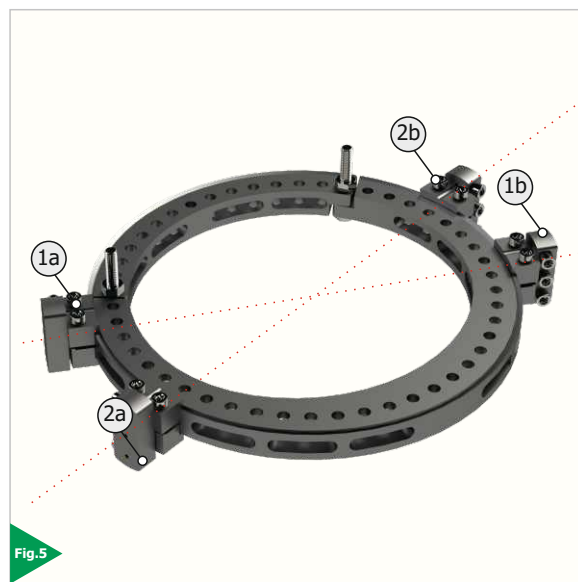


Fix it on the screw ring compressed with L Allen

This screw is for fixing the K-Wires. Compressed with L Allen.



After placing the K-wire clamps, if the ring is to be completed (*Full circle*), the other ring piece is added and the ring is completed and fixed with nuts. (Fig.4)



It can be done regardless of the location when placing the K-wire clamps, but it is important which one to use when attaching the K-wires. (Fig.5)



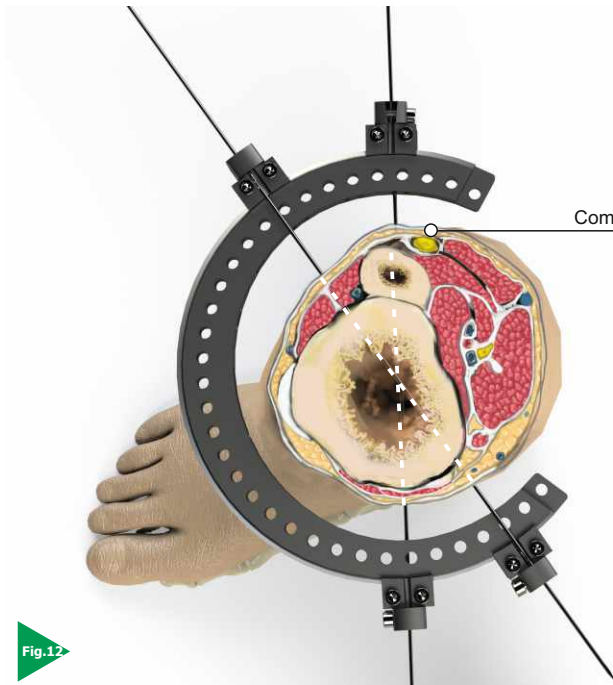
2. Surgical Technique

1.1.Femur&Tibia Hybrid External Fixator



2.2.Assemble

2.2.2.Entry Point



14mm

Common Peroneal Nerve

Fig.13

One entry point starts from the proximal part of the fibula. This region contains the peroneal nerve. This area should be noted. Generally, it should be started approximately 14 mm below the proximal tibia. (Fig.12-13)

2.2.3. First K-Wire



Fig.14

It can be started for entry from the specified entry point. Through the holes on the K wire whichever will be used, it can be started from that hole. The center hole can be used for initial and temporary fixing of the ring. (Fig.14)



Fig.15

The first entry of the K-wire clamp is provided by passing it through the ring. In addition, the clamp fixing screws are fixed so that it does not move on the rail. (Fig.15)



Fig.16

After the outlet is provided from the opposite side of the entry area, the relevant clamp is brought to the appropriate place. Since it is cross-mounted, we need to use 1b for 1a as seen in the picture. If you don't have a preference and use position 2b instead of 1a, 1a for 2a will be unusable. (Fig.16)



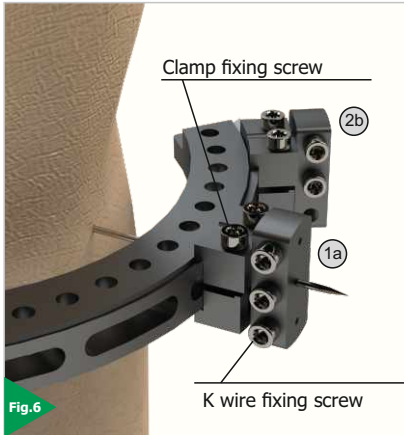
2. Surgical Technique

1.1.Femur&Tibia Hybrid External Fixator

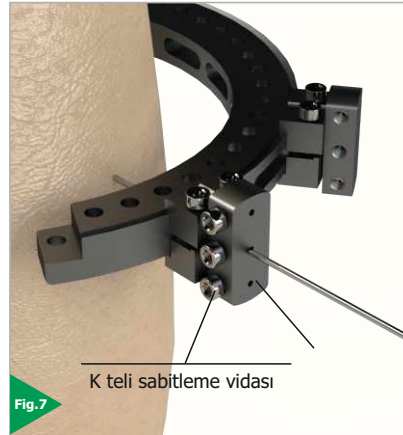


2.2.Assemble

2.2.3. First K-Wire



It is passed through the ring and through the center hole of the Clamp. Fixation is made from the clamp fixing screw. (Fig.6)

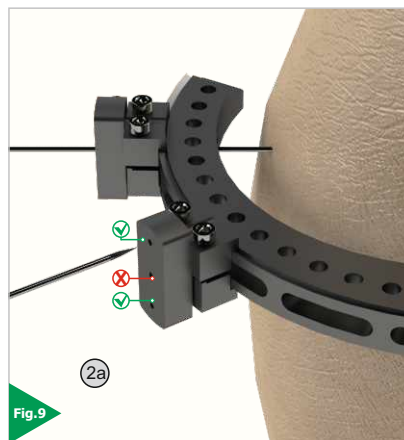


Return to clamp 1a and fix the K wire from the fixing screw. In this way, the ring is fixed from both sides. After this step, a second K wire should be sent from the other clamps from another safe, entry point. (Fig.7)



The sending of the first K wire is complete. Can be switched to another (Fig.8)

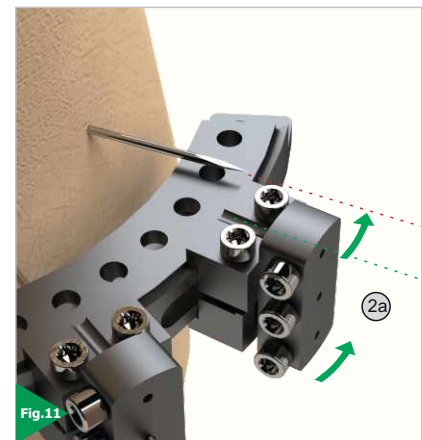
2.2.4. Second K-Wire



For the first K wire, we used the middle one of the holes on the 1a clamp. For the Second K wire, we need to use the upper or lower Clamp 2a. If we try to use the middle one, the K wires may overlap in the center. (Fig.9)



The K wire comes through the hole at the top of the clamp. Clamp fixing screws are tightened. The decision is continued from the entry point. (Fig.10)



The K wire comes through the hole at the top of the clamp. Clamp fixing screws are tightened. Continued from the decided entry point. (Fig.11)



2. Surgical Technique

1.1.Femur&Tibia Hybrid External Fixator



2.2.Assemble

2.2.4. Second K-Wire

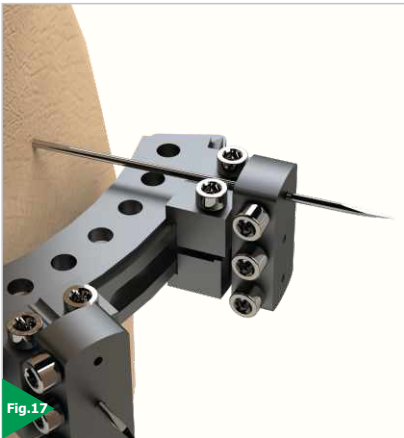


Fig.17

It is passed through the hole on the clamp. K-Wire clamping screws are tightened with L Allen. (Fig.17)

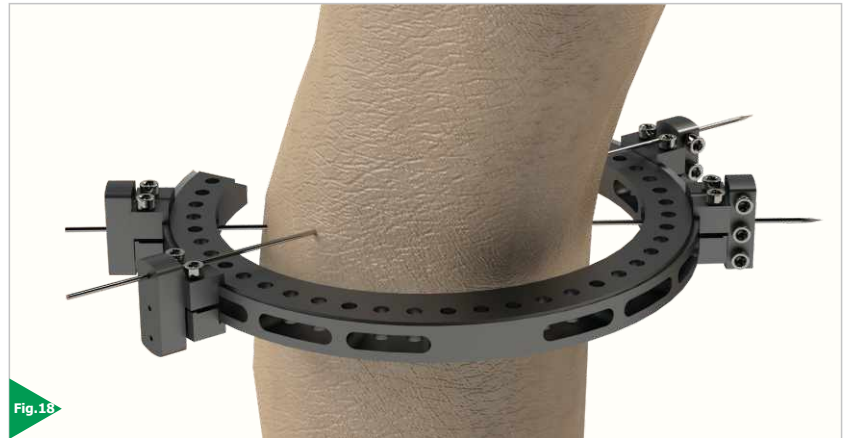


Fig.18

As seen in the picture, the installation of the K-Wires has been completed. The ring part is fixed proximally. It can be passed to the fixator part for the shaft. (Fig.18)

2.2.5. Distal Body



Fig.19

The fixator body can be inserted for the shaft. It is fixed with the help of nuts from the holes on the ring to the appropriate one. (Fig.19)

The Shanz clamps of the fixator body can be moved in some directions. In this way, it provides convenience in adapting it to suitable places for Schances. Make the adjustments according to the entry points and need. After fixing, compression can be achieved by using compression with the compression body. (Fig.20)

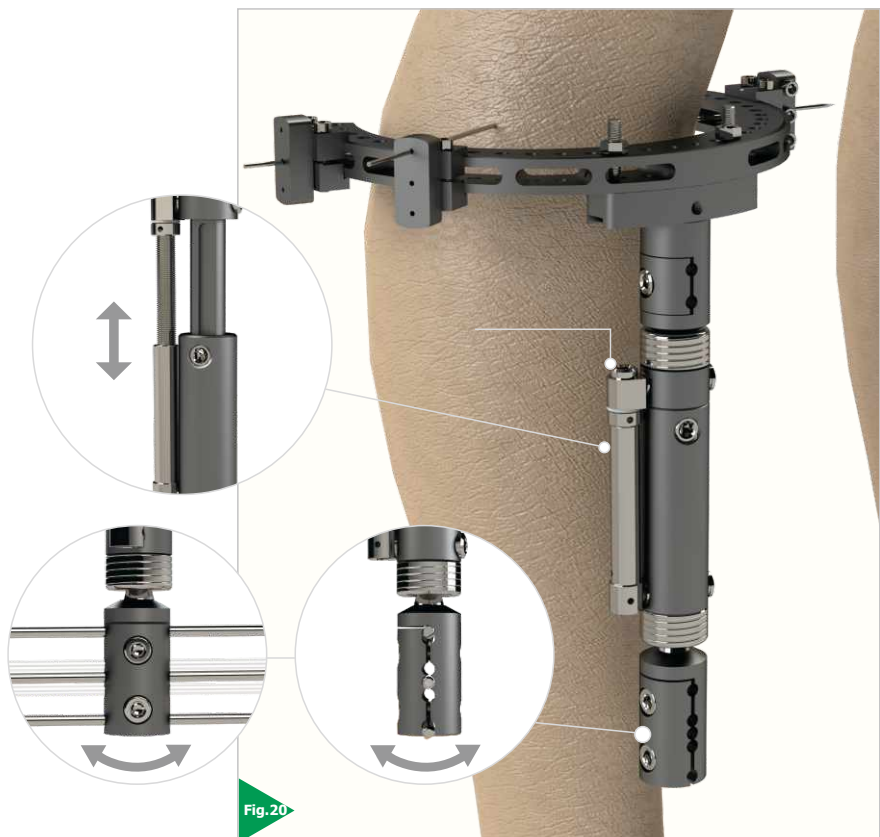


Fig.20



2. Surgical Technique

1.1.Femur&Tibia Hybrid External Fixator



2.2.Assemble

2.2.6. Entry point for Shaft (Schanz)



The entry points for the shaft are as seen in the picture. Schanz can be sent after preparing for suitable zones. (Fig.21)



The safe areas in the shaft area for this fixator are as in the picture. (Fig.22)

2.2.7. Attaching (Schanz)



Cortical Schans are attached for the proximal region. In this way, the proximal tibia is fixed. It can be passed to the distal clamp stage for the shaft. (Fig.23)



The distal body is positioned and the Cortical Schans are attached to the distal Clamps. (Fig.24)



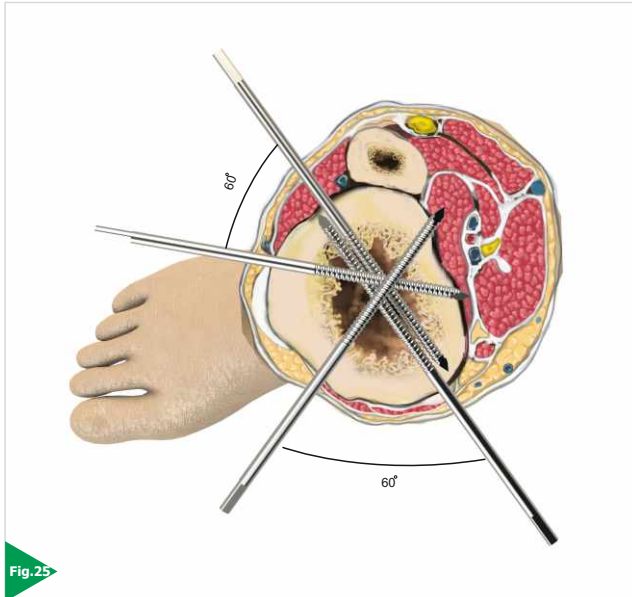
2. Surgical Technique

1.1.Femur&Tibia Hybrid External Fixator



2.2.Assemble

2.2.8. Entry point for proximal (Schanz)



It can be sent as in the image for Tibia Proximal. It should be sent at an angle of approximately 60°.(Fig.25)



2.2.9. Schanz, ring and Schanz Clamp

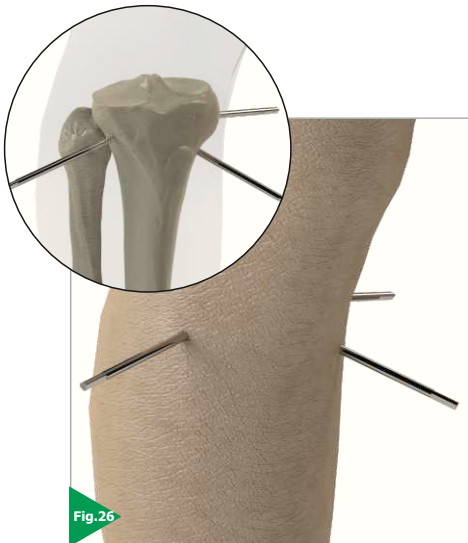


Fig.26

Install the Schanz according to the entry points (Fig.26)

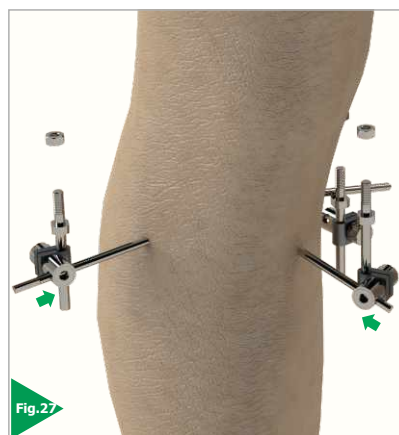


Fig.27

Put the Schanz rods on the Schanz you have attached. Prepare the nuts for mounting on the ring (Fig.27)

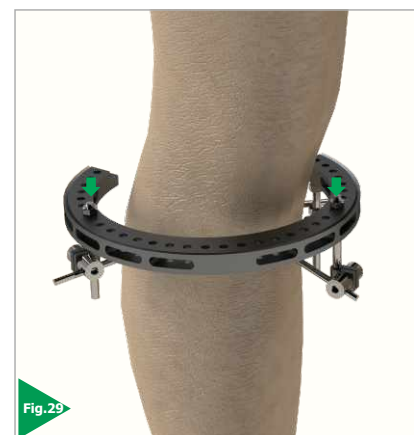


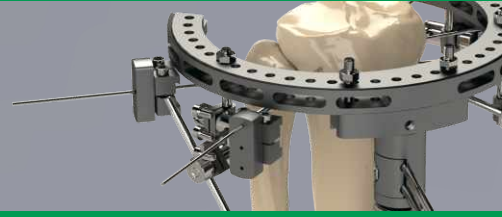
Fig.29

Connect the ring with Schanz rods. Fasten with nuts. The ring is fixed proximally with Schanz. It can be switched to the fixator part for the shaft area.(Fig.28)



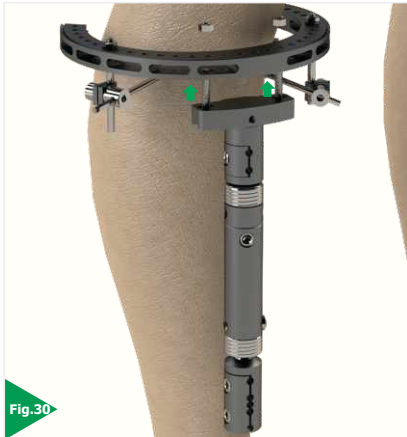
2. Surgical Technique

1.1.Femur&Tibia Hybrid External Fixator



2.2.Assemble

2.2.10. Distal Body and Rod



For the shanz to be sent to the shaft area, the fixator part is mounted on the ring and fixed with nuts. During the installation phase, the locations of the shanz to be sent for Shaft should be observed. (Fig.30)



After temporarily fixing the fixator, the Shanzes are attached to the appropriate areas. (Fig.31)



If a rod is to be fitted, the clamps are placed on the fitting. (Fig.32)

2.2.11. Distal Body and Rod



The rod is attached as shown in the picture. (Fig.33)



Distally, rod clamps are placed on the shanz. (Fig.34)



After it is attached to the shanz, the rod is attached as in the image. (Fig.35)



3.1 DEVICE CLEANING CONDITIONS

Do not use metal brushes or rubbing pads during Decontamination of the tools should be performed immediately after the surgical procedure is completed. Contaminated tools must not be allowed to dry before reprocessing.

Excessive blood or debris must be removed in order to prevent the drying on the surface. All users must be qualified staff with documented evidence of training and competence. Training should include the current guidelines, standards and hospital policies. Even if they are made of high-grade stainless steel, the surgical tools must be thoroughly dried in order to prevent rust formation. Prior to sterilization, all the tools should be examined for the cleanliness of the lumens of the joints of the surfaces. manual cleaning process. Use cleaning agents with low-foam surfactant to be able to see the tools in the cleaning solution. Rinse the cleaning materials easily from the tool in order to prevent residue formation.

Mineral oil or silicon lubricants should not be used on Zimed tools. Neutral pH enzymatic and cleaning materials are recommended for cleaning the reusable instruments. It is very important to neutralize and rinse the alkaline cleaning materials thoroughly from the tools. Anodized aluminum should not contact with certain cleaning or disinfectant solutions. Avoid strong alkaline cleaners and disinfectants and solutions containing iodine, chlorine or certain metal salts.

3.1.1 Manual Cleaning/Disinfection

Prepare the enzymatic and cleaning materials at the dilution rates and temperatures as recommended by the manufacturer. New solutions should be prepared when the existing solutions are heavily contaminated. Place the tools in the enzymatic solution so that they are completely immersed. Operate all the movable parts so that the detergent contacts with all the surfaces.

Keep in the fluid for minimum 20 min. Use a nylon, soft-bristled brush to gently rub the tools until all visible debris is cleaned. Pay particular attention to the accessible areas and use a suitable bottle brush. In order to remove the dirt in the open springs, coils or flexible parts, wash the recesses with plenty of cleaning solution. Rub the surface with a scrubbing brush to remove all the visible dirt from the surface and the recesses. To ensure that all the recesses are cleaned, turn the component while rubbing. Remove the tools and rinse them for minimum 3 min. under running water. Pay particular attention to the cannulas and use a syringe to pass the fluid through the hard-to-reach areas. Place all the tools that are completely immersed in water, in an ultrasonic unit containing the cleaning solution. Operate all the movable parts so that the detergent contacts with all the surfaces. Expose the tools to sonification process for minimum 10 min..

Remove the tools and rinse with deionized water for at least 3 minutes or unless all the blood or dirt traces are eliminated in the rinsing water. Examine the tools under normal light to verify that visible dirt is removed. If

visible dirt is present, repeat the above mentioned sonification procedure and the rinsing steps. Remove the excessive moisture on the tool with a clean, absorbent, lint-free cloth.

3.1.2 Combination Manual / Automated Cleaning and Disinfection

Prepare the enzymatic and cleaning materials at the dilution rates and temperatures as recommended by the manufacturer. New solutions should be prepared when the existing solutions are heavily contaminated. Place the tools in the enzymatic solution so that they are completely immersed. Operate all the movable parts so that the detergent contacts with all the surfaces. Keep in the fluid for minimum 10 min. Use a nylon, soft-bristled brush to gently rub the tools until all visible debris is cleaned. Pay particular attention to the accessible areas and use a suitable bottle brush. A sonicator will help to clean the instruments thoroughly. The use of a syringe or a water fountain will facilitate passing of the liquid from the low-spaced areas and difficult-to-access areas. Remove the tools from the enzyme solution and rinse them for minimum 1 min. under deionized water. Place the tools in a suitable washer / disinfectant basket and perform a standard washer / disinfectant cycle. Specific minimum parameters are essential for a complete cleaning and disinfection. These parameters are given in a below mentioned table.

3.1.3 Automated Cleaning and Disinfection

Automated washing / drying systems are not recommended as the only cleaning method for surgical tools. An automated system can be used as a follow-up operation after manual cleaning. To ensure an effective cleaning, tools must be thoroughly examined before sterilization. For detailed information on Washing and Disinfection see

Specific minimum parameters used for a complete cleaning and disinfection:

	Definition
1	Pre-washing for 2 minutes with cold tap water
2	enzyme spray for 20 seconds with hot tap water
3	Immersion in enzyme after 1 minute
4	rinsing for 15 seconds with cold tap water (Should be repeated twice)
5	Washing with detergent for 2 minutes with hot tap water
6	rinsing for 15 seconds with hot tap water
7	Rinsing with 10 seconds with optional lubricated purified water
8	Drying for 7 minutes with hot air

Note: Follow the instruction of the washer/disinfectant manufacturer

● *Zimed Medical, as the manufacturer of this device, and their surgical consultants do not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each individual patient. Zimed and their surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.*

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ISO 9001
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ST.05.01-11 Rev.00 - 15.05.2023