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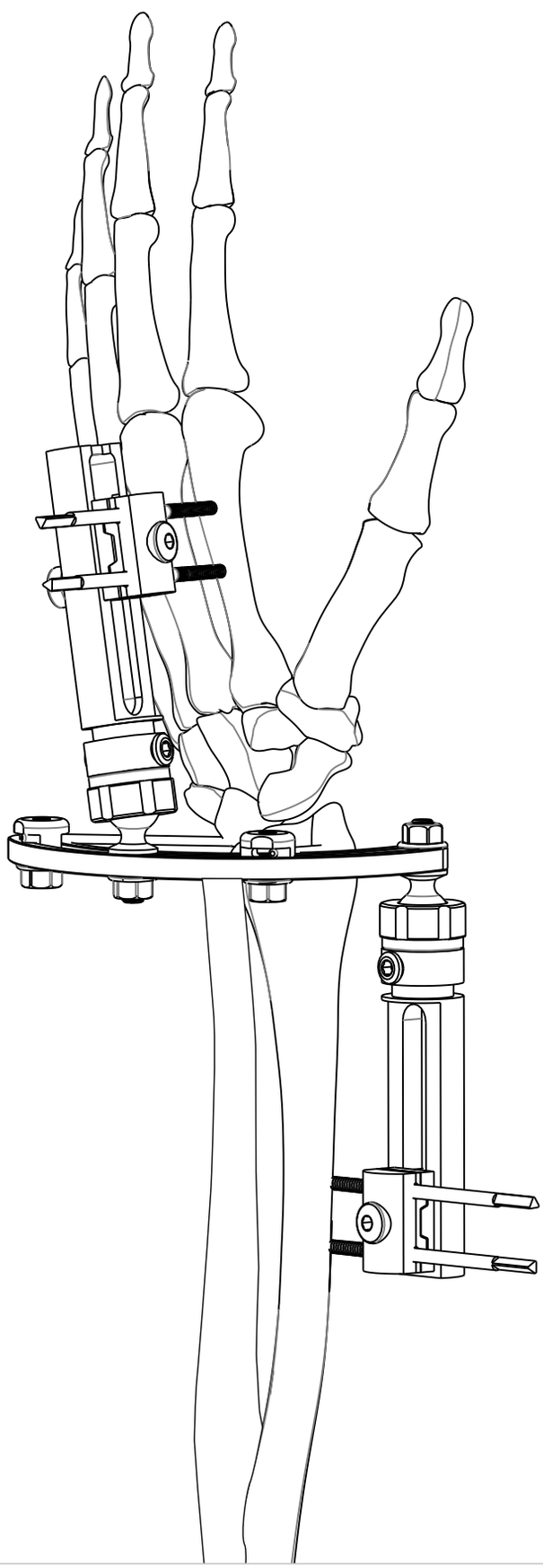
Hand-Wrist

HYBRID EXTERNAL FIXATOR

SURGICAL TECHNIQUE



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Contents

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ISO 9001:2015
ISO 13485:2016
CE 1984

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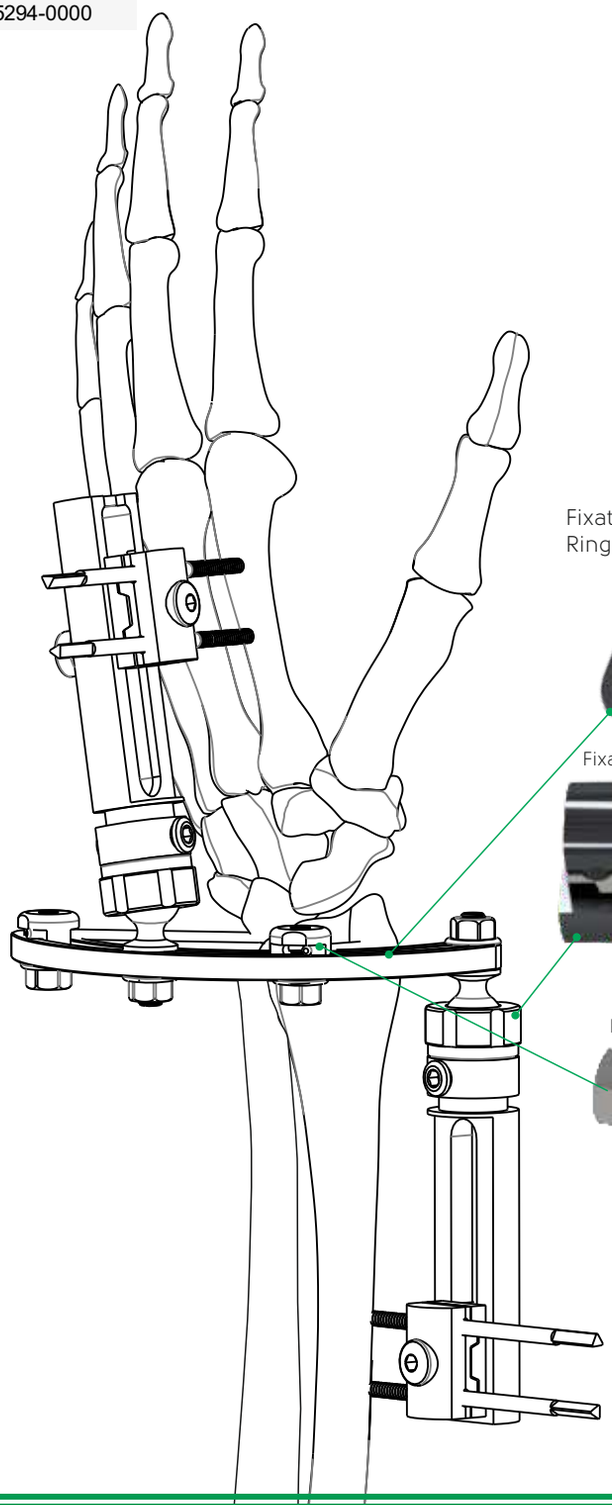
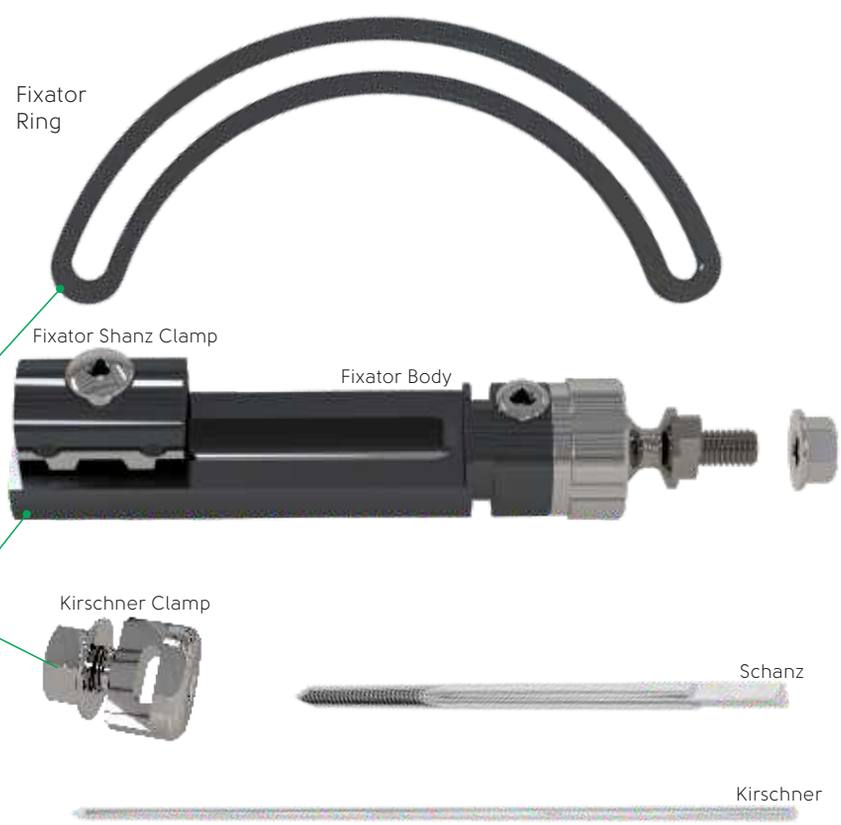
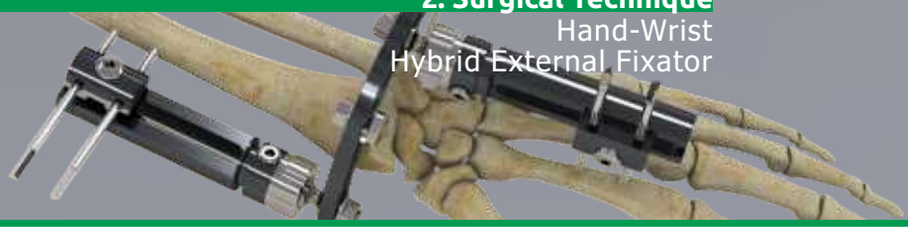
REF. NO
5294-0000

1.1.1 Specification

Hand-wrist Fixator with dynamic angle clamp It can be used in distal radius and / or ulna fractures and unstable intra-articular distal radius fractures (fracture fragments are fixed with other implants). Ball-joint structure makes it possible to lock at different angles. Schanz screws, with the feature of angled clamps, can be sent in different angled plans. It is used in the application of other internal fixation implants and joint fixation in distal radius fractures. It can be used in non-joint and involving joint distal radius and shaft fractures and ulna fractures.







2.1.Types of Distal Radius Fractures

The forearm features two bones; the radius is the larger of these two (Fig.1). The end of the radius that extends to the wrist is known as the distal end. The distal radius may experience a fracture if a strong impact is impressed upon the distal end of the radius.

There are four major types of wrist fractures; they are detailed below.

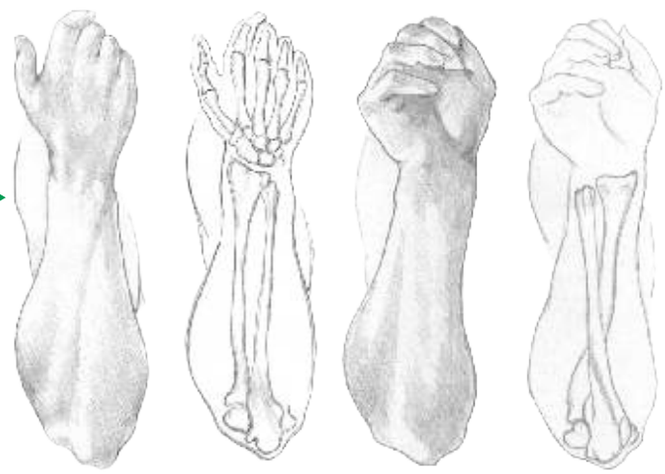


Fig.1

2.1.1. Extra-articular fracture

An extra-articular fracture features a break above the wrist joint; the fracture does not extend into the joint itself (Fig.2).
For such fractures, fixator is placed as in example 1.

Fig.2

2.1.2. Intra-articular Fracture

Intra-articular fractures are wrist fractures that affect the wrist joint. The distal radius is fractured, including the joint (Fig.3).
For such fractures, fixator is placed as in example 2.

Fig.3

2.1.3. Comminuted fracture

Comminuted fractures involve multiple breaks of the distal radius. In this type of injury, the bone is broken into several pieces (Fig.4).
For such fractures, fixator is placed as in example 3.

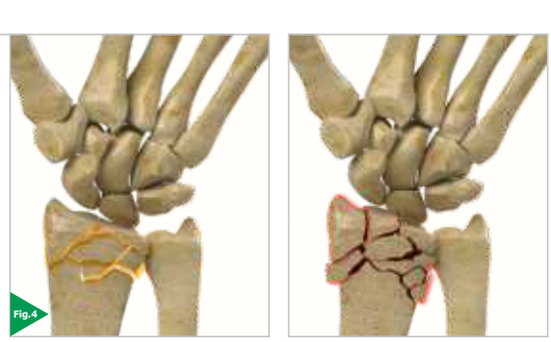
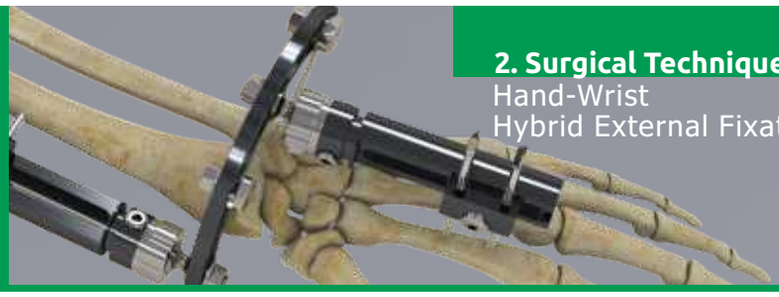


Fig.4

2.1.4.Open Fracture

Open fractures are serious injuries that require immediate medical care. These injuries involve bone fractures which puncture the skin and are externally exposed.

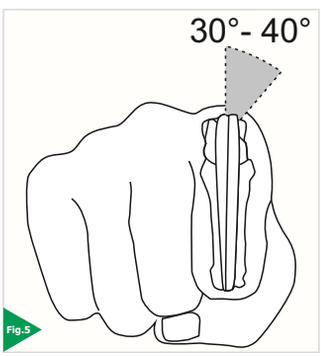
While these different wrist fracture types vary in terms of severity, they all require medical attention in order to heal properly.



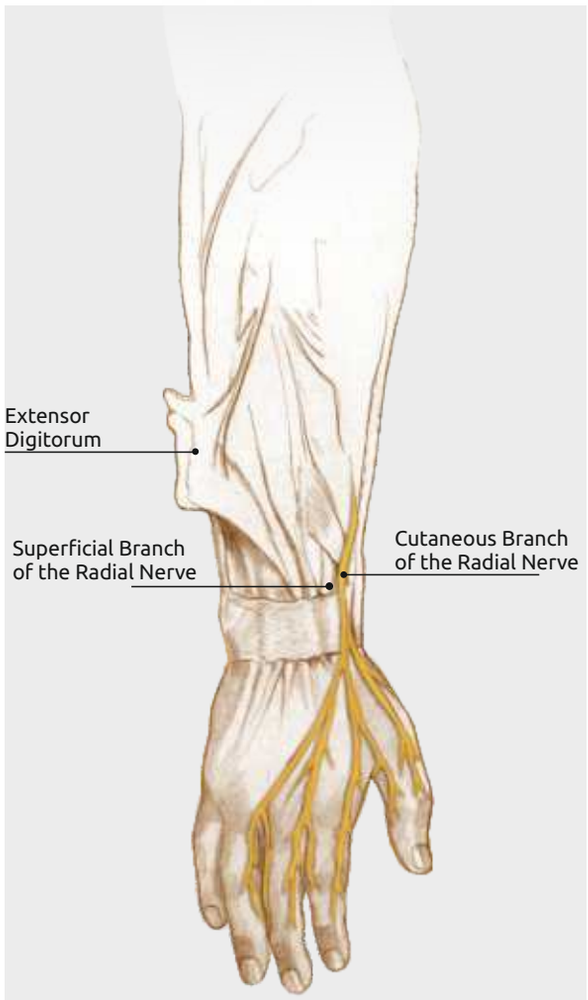
2.2.Pin (Shanz) Insertion Tips (wrist)

2.2.1. Angle

In the frontal plane, the pins should be inserted at an angle of 30°-40° in relation to the sagittal plane to avoid transfixing the extensor tendon/hood.



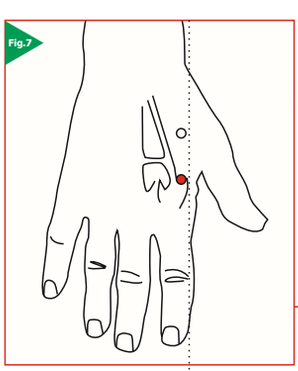
The pins should obtain a good hold in both cortices.(Fig.6)

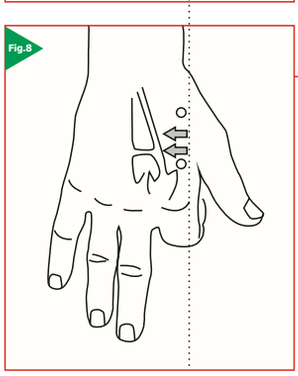


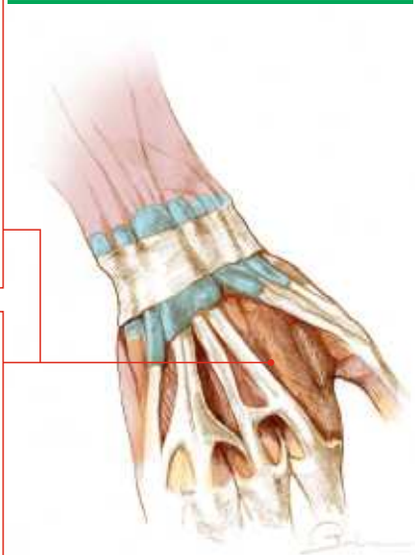
2.2.2. Take advantage of flexion

The extensor tendon hood must not be drilled and do not attached schanz (Fig.7)

To avoid this complication, the index metacarpophalangeal joint should be passively flexed 90° so that the extensor hood moves slightly distally, and the tendons are pulled in an ulnar direction.(Fig.8)







2.3.Fixator Placement
Example 1

Fractures not involving the joint

Fractures that do not extend into the joint.

2.3.1. Kirschner Wire and Ring

Attach Kirschner Wire (Fig.9).

Bend the Kirschner wires according to the clamps and the location of the ring to accommodate the fixator ring (Fig. 10).

Fix the clamps by tightening the nut with a wrench and prevent slipping or distortion in the fracture line (Fig.10).

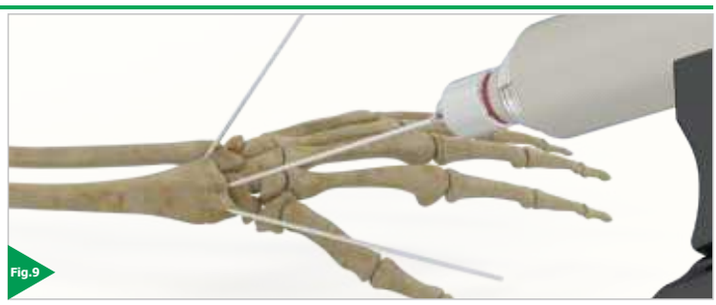


Fig.9


Fig.10


Not: the stability of the clamps,bodies etc. should be checked.

2.3.2.Schanz

Attach the Schanz according to the fracture line and anatomy.(Fig.11-12)


Fig.11


Fig.12

2.3.3.Clamps and Body

Attach the body to the ring then pass the clamps through the schanzes (Fig. 13). Tighten the body and clamps with the wrench and allen key


Not: the stability of the clamps,bodies etc. should be checked.


Fig.13

2.4.Fixator Placement
Example 2

Fractures involving the joint

2.4.1. Kirschner Wire and Ring

Attach Kirschner Wire (Fig.14).
Bend the Kirschner wires according to the clamps and the location of the ring to accommodate the fixator ring
(Fig. 15).


Fig.14

Fix the clamps by tightening the nut with a wrench and prevent slipping or distortion in the fracture line

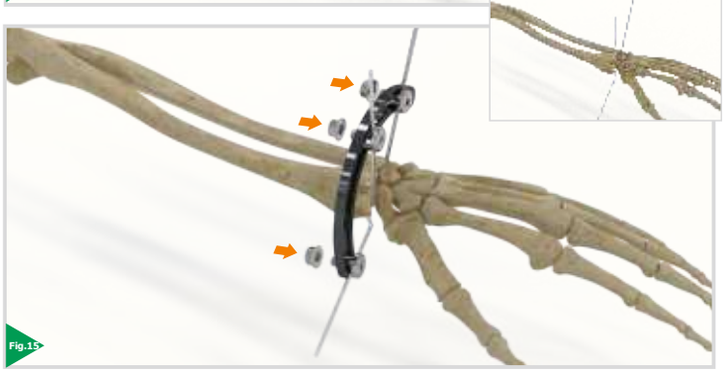


Fig.15

Not: the stability of the clamps,bodies etc. should be checked.

2.4.2.Schanz

Attach the Schanz according to the fracture line and anatomy.(Fig.16-19)


Fig.16


Fig.17


Fig.18

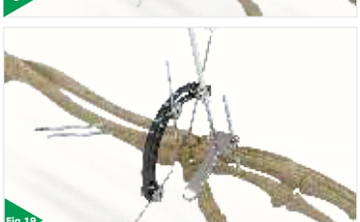


Fig.19

2.4.Fixator Placement
Example 2

Fractures involving the joint

2.4.3.Clamps and Body

Attach the body to the ring then pass the clamps through the schanzes (Fig. 20). Tighten the body and clamps with the wrench and allen key


Fig.20

Not: the stability of the clamps,bodies etc. should be checked.

2.4.4.Removing the distal body and starting wrist motion

It is necessary to start wrist movement after a while *(1 Month)* in order to prevent finger and wrist hardening. For this, the distal body is removed. Treatment is continued as in the picture (Fig. 21).


Fig.21

2.5.Fixator Placement Example 3

Comminuted fracture

2.5.1.Distraction

External fixation is a technique that uses ligamentotaxis to pull fracture fragments into better alignment.The surgeon places the threaded pins in the radius proximal to the fracture and the forefinger distal to the fracture in the metacarpal and carpal joint.The surgeon attaches a threaded mechanical frame to these pins that can be used to apply traction in different directions to pull the hand to reduce fracture fragments.

Plate application may not be possible in fractures with extensive bone degradation. Also, crush injuries can damage the soft tissue envelope in such a way that the surgeon will not want to extensively dissect to apply a plate and screws to achieve a rigid fixation. In such cases, an external fixator is the ideal choice.

A potential disadvantage of the technique is that the fingers become stiff as a result of excessive disintegration with the device because finger movement must be initiated early.

However, wrist motion should wait for the device to be removed.

But the wrist fixator does not need to be completely removed. Wrist fixator consists of 2 main parts. The clamp attached to the distal body is removed. In this way, it allows the wrist to move and continue the treatment at the same time.

The solution for this is to remove the reduction clamp at the end of 1 month and provide motion to the wrist.

2.5.2.Schanz

Attach the Schanz according to the fracture line and anatomy.(Fig.22-25)


Fig.22


Fig.23


Fig.24

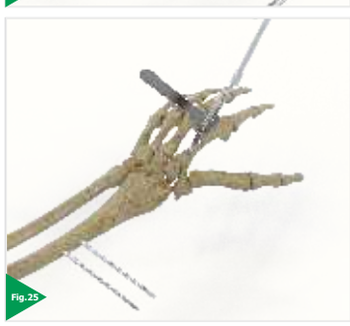


Fig.25

2.5.Fixator Placement Example 3

Comminuted fracture

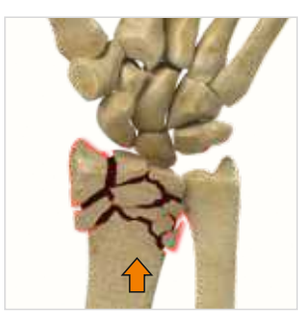
2.5.3.Clamps and Body

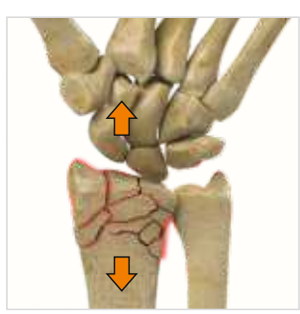
Attach the clamps on the body to the schanz (Fig. 25).Connect the body with the ring. Tighten the body and clamps with the wrench and allen key (Fig. 26).

Not: the stability of the clamps,bodies etc. should be checked.

2.5.4.Distraction

You can achieve the necessary distraction by using it with an allen key (Fig. 27-28).





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 teh 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 / disinfector basket and perform a standard washer / disinfector 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 sprey 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

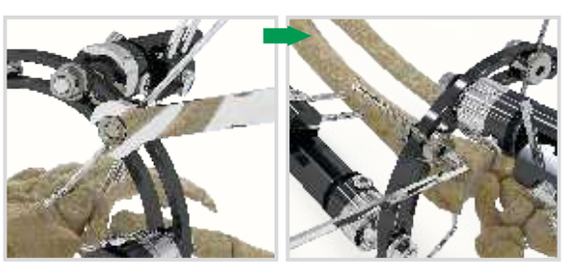
Note: Follow the isntruction of the washer/disinfector manufacturer

2.5.Fixator Placement Example 3

Comminuted fracture

2.5.5.Kirschner Wire

Attached Kirschner wires to ensure fixation (Fig. 29). Bend the Kirschner wires according to the clamps and the location of the ring to accommodate the fixator ring (Fig. 30-31)



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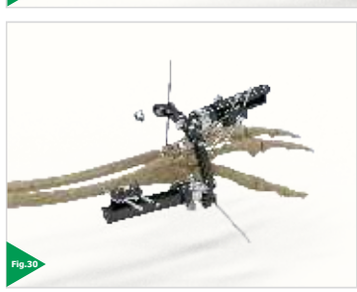
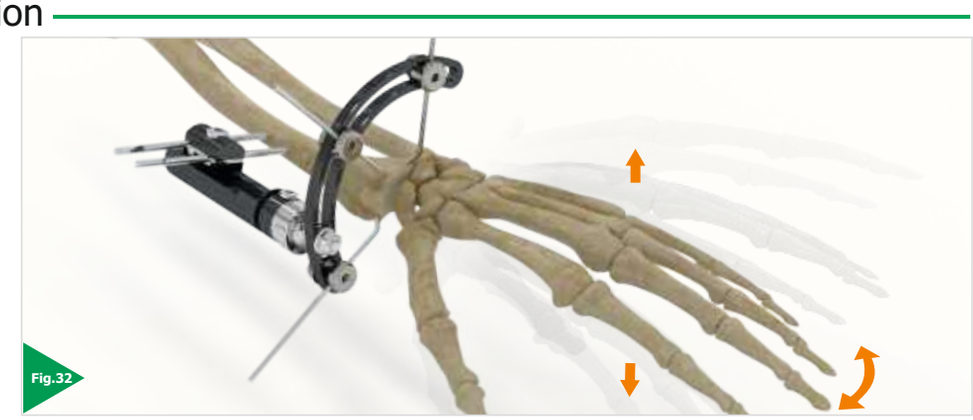


2.5.6.Removing the distal body and starting wrist motion

It is necessary to start wrist movement after a while in order to prevent finger and wrist hardening. For this, the distal body is removed. Treatment is continued as in the picture (Fig. 32).



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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