GLW CHARCOT

FusionFrame™

Ring Lock System

Operative Technique

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FusionFrame
Ring Lock System

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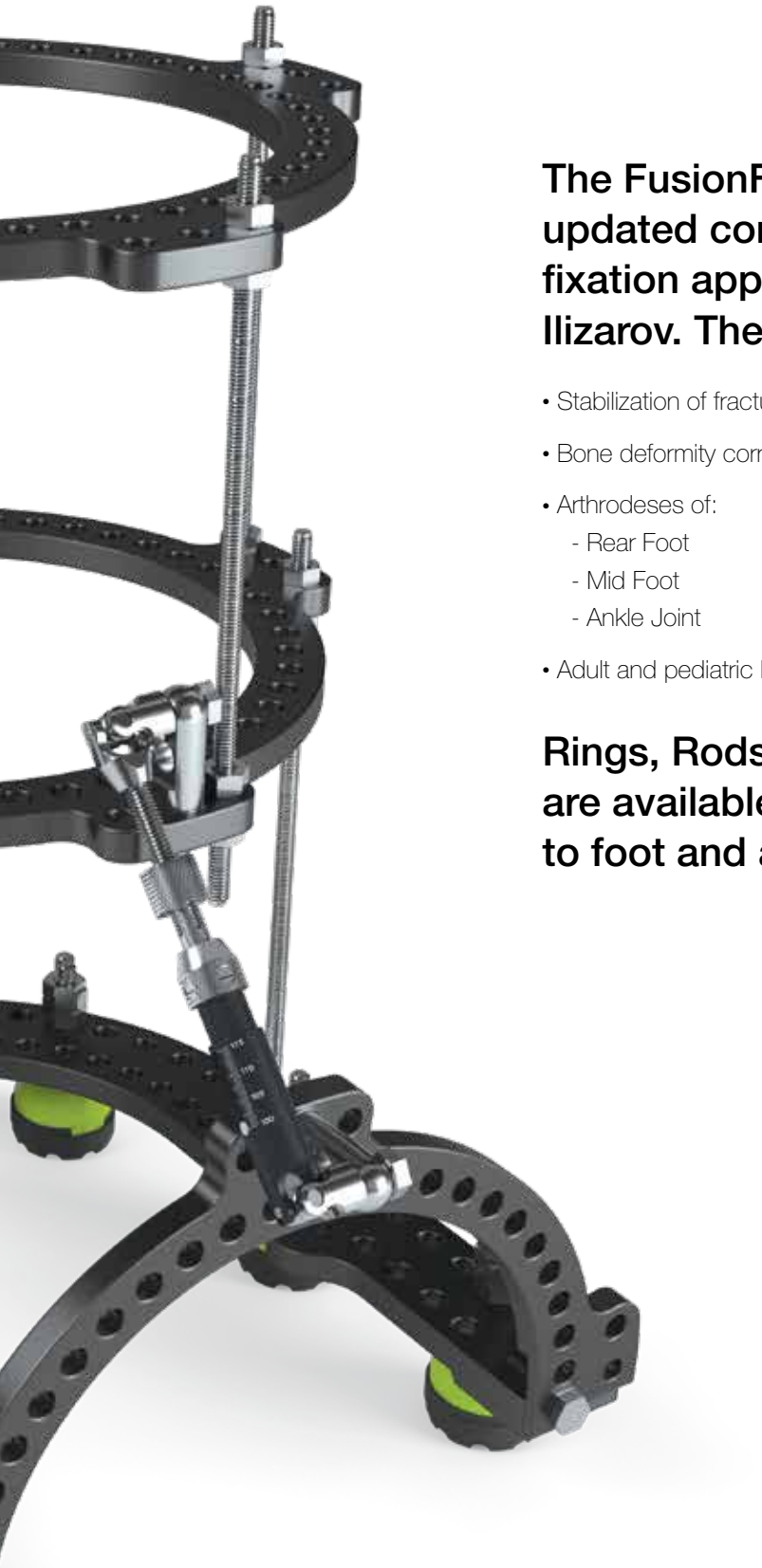


The FusionFrame Ring Lock System is the updated configuration of the circular external fixation apparatus developed by Prof. G. A. Ilizarov. The FusionFrame facilitates

- Stabilization of fractures and osteotomies.
- Bone deformity corrections of lower extremities.
- Arthrodeses of:
  - Rear Foot
  - Mid Foot
  - Ankle Joint
- Adult and pediatric limb lengthening.

Rings, Rods and other Frame elements are available in a range of sizes appropriate to foot and ankle applications.

Indications, Precautions & Contraindications

Indications

The FusionFrame Ring Lock System is an adaptation of the Ilizarov circular external fixator that has been successfully used by orthopaedic, podiatric and foot & ankle surgeons throughout the world to manage a variety of indications and treatments:

- Stabilization of fractures and osteotomies.
- Bone deformity corrections of lower extremities.
- Arthrodeses of the rear foot, mid foot and ankle joint.
- Limb lengthening in pediatric and adult patients.

Before initiating treatment, the patients, and if applicable, their family members and/or care givers must be carefully screened and educated on the implications of the surgery, its post-operative management cycle and the requisite commitments involved.

Consistent patient follow-up by the surgeon or qualified health care professional is required throughout the course of treatment. In certain procedures, such as limb lengthening, the process may take months. As with any surgical intervention, the desired outcome may not necessarily be guaranteed.

Contraindications

For contraindications refer to package insert, Instructions for Use.

Known or suspected allergy to any materials from which the FusionFrame components are made (especially Wires and Half-Pins).

Use of FusionFrame components with components of other origin, not specifically recommended for use with the FusionFrame.

Presence of active infection.

Note:
See Package Insert for complete list of potential adverse effects, warnings, precautions, contraindications and Instructions for Use (IFU).

The FusionFrame Ring Lock System is MR Unsafe.

Note:
U.S. federal law prohibits the use or sale of the FusionFrame or any of its individual components without physician prescription.

Overview

The FusionFrame was developed to specifically address the extensive requirements of orthopaedic surgeons and foot and ankle specialists. Its components have been designed to ensure overall construct stability, versatility, ease of application, functionality and time saving efficiency.

Briefly described, the FusionFrame provides a weight bearing scaffold that in most cases allows patients to remain mobile throughout the course of treatment.

The nearly endless variety of constructs afforded by the FusionFrame provides a systematic platform for ensuring stability, re-aligning bones, applying compressive forces or controlling the distraction of bone fragments over a period of time.

The FusionFrame consists of externally mounted Rings and ancillary components that are interconnected with Rods. The construct is attached to the bone with a combination of percutaneously applied tensioned Wires and/or Half-Pins. Compression / distraction struts may be attached to the frame to systematically control the gaps between bone fragments and distance between Rings to manage a variety of pathologies.

Threaded Rods or struts may be used to reduce and compress fracture zones, lengthen limbs and even correct deformities when used in combination with Hinges.

Why Circular External Fixation?

The modular nature of the circular FusionFrame allows for multiple frame configurations and facilitates control, stability, accuracy and adaptability. By nature of its design, the FusionFrame permits circumferential fixation and the gradual, mechanical manipulation and correction of virtually any deformity. Each segment of bone may be controlled in all three dimensions over time, throughout the entire length of treatment. FusionFrame constructs allow the inclusion of adjacent bones while preserving post-operative joint motion. Numerous adjustments may be made at any point during treatment, many of which are done by the patients themselves under surgeon direction, or in the outpatient clinic.

The FusionFrame's design ensures versatility and circumferential access for precise fixation to address a wide variety of applications. Multi-level constructs can be built to accommodate the foot and ankle, that can precisely target the zone of pathology or apex of a deformity.

The FusionFrame may be used for the purposes of stabilizing fractures and osteotomies, bone deformity corrections in the lower extremities, arthrodeses of the rear foot, mid foot and ankle joint and limb lengthening in adult and pediatric patients.

The apparatus is used with minimally invasive surgical techniques, such as insertion of percutaneous wires or half-pins and percutaneous corticotomies (osteotomies) that leave only minor scars with minimal compromise to surrounding tissues. Circular external fixation has entered into the orthopaedic and podiatric mainstreams, but as with any technology, it may not be appropriate for every specialist nor is it necessarily applicable to every situation. Extensive training and careful preoperative planning on the part of the surgeon must be undertaken to ensure that the FusionFrame is the correct device for a particular patient and that the system is correctly applied.

System Components

The FusionFrame utilizes high-strength, low-density aluminum alloy for most system elements. Hardened stainless steel is used for certain auxiliary structural components, and implant-quality stainless steel alloys have been developed for fixation wires.

The individual elements of the system have been designed to allow the following:

- Wires (and Half-Pins) may be inserted along numerous trajectories, locations and at different anatomical levels.
- Adjustment of the frame intraoperatively or during the course of post-op treatment.
- Maintain stability, positioning and orientation of individual bone segments required to hold continuous reduction.
- Adjustments to the direction and magnitude of forces that act on the skeletal system throughout the treatment cycle.
- Achieve and preserve the stability needed for early weight bearing.

Figure 1

Rings and Half Rings

- The FusionFrame includes four diameters of Ring sizes: 140, 160, 180, and 205mm. Fig. 1 shows a Ring and Half Ring of the same diameter. All Rings and Half Rings are 8mm thick.
- Rings, in all of their shapes and sizes, provide the scaffolding and structural support for the overall frame and are the primary platform from which all other components are connected.
- Two Half Rings, bolted together form a full circular ring. The size is specified by the inside diameter of the ring. All Fusion Frame rings are made of aluminum. Prior to application, the surgeon must determine the Ring diameters as a function of patient size and anatomical features.

Important:
Ring size needs to be matched to the patient's own measurements and limb dimensions. The inner diameter of the Ring must provide a minimum of 20 - 30mm (or "two finger breadths") of soft tissue clearance along the entire inner circumference of the Ring (Fig. 2).

Smaller Ring sizes make it more difficult to accurately place Wires and Half-Pins and may not allow enough room for possible soft tissue swelling. Larger rings, without structural augmentation, are more prone to instabilities and possible deformation. Training and experience offer the best guide to the proper selection of Ring sizes.

Figure 2

5/8 Rings

The 5/8 Rings (Fig. 3) were designed with an open segment entailing 3/8 of the overall circumference of the ring to allow for increased range of motion around a joint or other applications when a Ring with an open segment may be required. The 5/8 Rings are available in 140, 160, 180 and 205mm diameters.

Figure 3

Foot Plates

The FusionFrame also includes four sizes of Foot Plates (Fig. 4):140, 160, 180, and 205mm, each of which are compatible with their corresponding Ring, Half Ring and 5/8 Ring sizes.

Foot Plates are an essential component of the fixator when used for foot and ankle surgery. The Foot Plates are wider than the analogous Full, Half and 5/8 Rings of the same internal diameter.

The Foot Plate's outer set of holes are used for interconnecting the footplate with Threaded Rods or Struts to the proximal ring levels and must be arranged to coincide with the corresponding holes of the Rings / Half / 5 / 8 Rings that are proximal to the Foot Plate. This is necessary to achieve perfect alignment. All unused inner Foot Plate holes and unobstructed outer holes may be used for Wire or Half-Pin placement.

Figure 4

Connectors

Connectors are used to bridge and attach different ring levels together. In combination with Nuts (see below), they may also be used to gradually adjust the spacing between Rings to achieve compression, distraction and tissue transport.

System Components

Threaded Rods

The FusionFrame includes 6mm diameter fully threaded stainless-steel Rods with a 1mm thread pitch, in eight different lengths from 60 to 400 mm (Fig. 5).

In the majority of cases, the Threaded Rods are adjusted so that all rings are parallel to each other. Moreover, the frame is aligned with the mechanical axis of the limb.

For foot and ankle applications, the anterior crest of the tibia is often used as a visual alignment reference.

Figure 5

Quick Connect Struts

The Quick Connect Struts provide a systematic means for achieving controlled distraction (or compression) for the purposes of fracture fixation and bone segment alignment (Fig. 6). Quick Connect Struts are not recommended for limb lengthening.

The Struts likewise permit gradual and rapid length adjustments and feature universal joints on both ends to perform acute deformity corrections and assist with fracture reductions.

The universal joint on the threaded end of the Quick Connect Strut is detachable.

A built-in counting knob facilitates the patient's ability to make accurate, 1/4 turns, achieving precisely measured 1/4mm adjustments in the gradual compression or distraction modes.

There are three sizes of Struts:

Figure 6

Strut Size	Fully Collapsed Length (mm)	Fully Distracted Length (mm)	Total Distraction Length (mm)
100mm	100	115	15
116mm	116	152	36
150mm	150	210	60

Universal Hinges

The Universal Hinges (Fig. 7) provide an unconstrained cardan joint that may be added to any threaded element, especially Threaded Rods, to facilitate acute deformity corrections and fracture reductions.

Figure 7

Threaded Sockets

The 10mm hexagonal cross section sockets (Fig. 8) may be used as fixed spacers to allow rapid connections between two levels of Rings in a frame construct. They are available in 40 and 60mm lengths.

Figure 8

Plates

Plates are used as horizontal spacers, swivels and outriggers to increase the overall adaptability of the FusionFrame to address a broader range of patient anatomies and construct possibilities. They are available in two sizes: 20mm (two hole) and 30mm (one hole, one slot) as shown in Fig. 9.

Figure 9

90° Hinges

The 90° Hinges (Fig. 10) are used to change the plane of the ring by 90° for the purposes of adding a “motor” to a gradual deformity correction construct.

Figure 10

System Components

Oblique Supports

The FusionFrame offers an Oblique Support (Fig. 11) that may be used to connect a Half Ring, mounted across the Foot Plate, to the most distal ring on the tibial block, thereby allowing a more symmetrical distribution of loads between the distal tibia and foot.

Oblique Supports are used to provide additional stability for the forefoot arch which is a Half Ring that is of the same diameter as the Foot Plate and all other Rings in the construct (Fig. 12).

Depending on the combination of Ring and Foot Plate Sizes used in a construct, a Slotted Plate, or other suitable means, may eed to be used to extend the reach of the Oblique Support.

Figure 11

Figure 12

Fasteners

All threaded elements of the FusionFrame are 6.0mm in diameter with a 1.0mm thread pitch.

Hexagonal Nuts

Six-sided Nuts are used for the interconnection and locking of components to ensure stability (Fig. 13). Nuts may also be used to make gradual, incremental adjustments to the frame, such as in compression or distraction to facilitate limb lengthening, deformity correction and tissue transport.

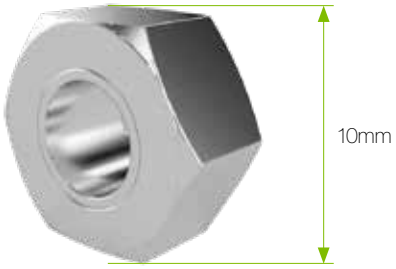


Figure 13

Counting Nuts

The four-sided Counting Nuts facilitate controlled compression or distraction and are used to simplify lengthening, shortening, transport and fusion procedures. Each quarter turn of the Nut represents 0.25mm of travel along a Threaded Rod and the dot-coded faces enable the patient to keep track of each quarter turn (Fig. 14). The Counting Nuts have a 10mm spanner wrench width and are 15mm long.

Figure 14

Adjustments are typically made in 1/4 turn increments, approximately every six hours; i.e., 1/4mm of movement every six hours. These are the typical **rate** and **rhythm** that are used for most procedures.

Over the course of 24 hours, 1mm of lengthening / distraction or shortening / compression may be achieved (Fig. 15).

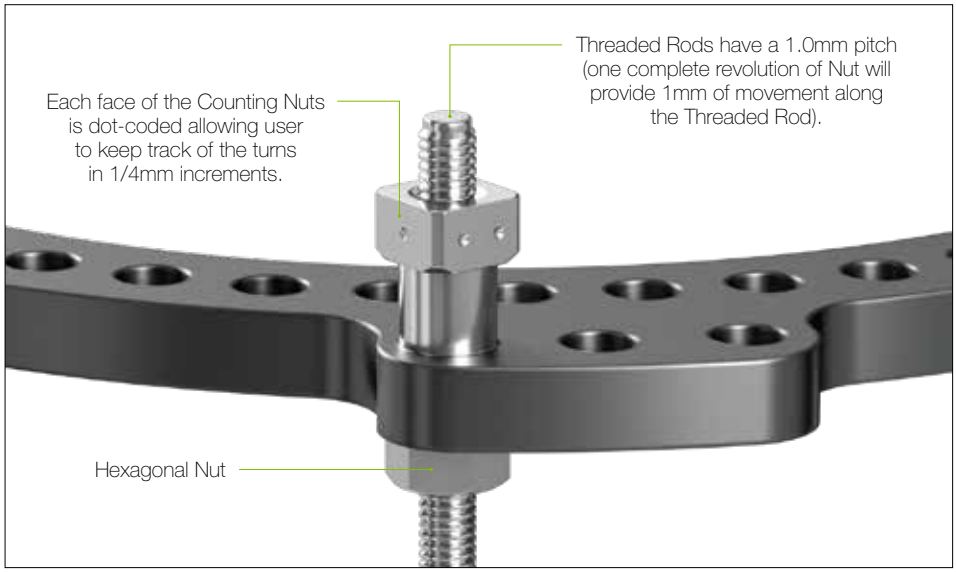


Figure 15

When compressing or distracting, both the **Counting Nut** and **Hexagonal** (standard) **Nut** need to be correspondingly adjusted (Fig. 16).

In most cases, the frame will have four Threaded Rods per segment, these adjustments need to be performed on all Rods for the segment that is being compressed or distracted.

Note:
When lengthening is completed, the frame must remain on the patient in static fixation mode for at least twice the time of actual lengthening.

For example, if lengthening adjustments were made over a period of 30 days, the frame must remain in static fixation for an **additional 60 days,** to allow consolidation of the newly formed bone regenerate.

In all cases, the quality and integrity of the bone regenerate must be verified by the surgeon prior to frame removal.

Figure 16

System Components

Bolts

10mm hexagonal head, 6mm diameter threaded component with 1.0mm pitch. Available in 12, 16 and 20mm lengths (Fig. 17).

Figure 17

Universal Wire Fixation Bolts

Cannulated wire Bolts with a side groove allowing fixation of wires that are either offset with respect to Ring holes or wires that are centrally oriented with respect to the Ring holes wires (Fig. 18).

Figure 18

Half-Pin Fixation Bolts

Are used for the fixation of Half-Pins directly to the surface of a Ring or to one of the holes of a Male or Female Post. The Half-Pin Fixation Bolts (Fig. 19) accept all diameters and lengths of FusionFrame Half-Pins. The oblong bolt head includes 10mm wrench flats.

Figure 19

Half-Pin Fixation Cubes

The Half-Pin Fixation Cubes (Fig. 20) provide a fast means for the fixation of Half-Pins above or below the plane of a given Ring. The trajectories of the pins are constrained to be parallel with the plane of the Ring when placed directly through one of the pin holes of the cube. They are available in 1 – 4 hole towers.

Figure 20

Washers

Used as spacers in combination with Wire Fixation Bolts for securement of wires that are situated above or below the plane of the ring (Fig.21).

The Slotted Washers may also be used in combination with the 12, 16 and 20mm Bolts in lieu of the Wire Fixation boles to capture offset wires.

Figure 21

Conical Washer Couples

The Conical Washer Couples are assemblies consisting of two elements, a “cup” and “saucer,” that are packaged together, as depicted in Fig. 22, and are used in those rare situations when a non-parallel Ring needs to be mounted to the frame construct. The Conical Washer Couples are used in pairs, one complete assembly is placed on both sides of the ring (situated proximally and distally) for each Threaded Rod in that segment of the construct where non-parallel ring placement is required.

Figure 22

System Components

Smooth Wires and Wires with Stopper

The FusionFrame includes both Smooth Wires and Wires with Stoppers (also known as “olive” wires). Both Smooth Wires and Wires with Stoppers are available in 1.8mm diameter and are 430mm long (Fig. 23).

The stopper is machined from single bar stock and is not a discrete component welded to a smooth wire.

Figure 23

Half-Pins

The Half-Pins are available in a variety of thread lengths in 5.0 and 6.0mm thread diameters, with a constant, 6mm shaft diameter for all thread sizes. All FusionFrame Pins feature self-drilling, self-tapping cutting flutes. See Fig. 24.

Figure 24

Note:
NEVER DRILL WIRES CONTINUOUSLY; always use a start / stop technique, allowing ample time for the Wire to sufficiently cool between each drilling cycle. Repetitive irrigation of each Wire during insertion is likewise recommended.

To avoid Wire arcing during insertion, the surgeon should “chuck up” close to the tip, exposing no more than 50mm of Wire at a time and repeatedly “re-chucking” the Wire throughout the insertion process.

Once inserted, all Wires must be properly tensioned with a Wire Tensioner (see below) and securely anchored to the frame using Wire Fixation Bolts. Increasing the tension of the Wires increases the stiffness of the assembly; decreasing tension leads to a corresponding increase in elasticity. Excessive tension may lead to Wire breakage during repeated cyclical loading.

Insufficient tension may cause excessive movement during loading, leading to displacement of bone segments and loss of reduction.

For additional important information regarding Wire insertion, fixation and tensioning, see pages 22-37.

Male and Female Hinges and Posts

The multi-hole Posts are made of stainless steel and come in either male or female configurations, with 1, 2, 3, or 4 holes. Male Posts are shown in Fig. 25 and their female counterparts are illustrated in Fig. 26.

The one-hole Posts are typically referred to as Hinges. One-hole Posts may be used in pairs to form a hinge element for use in gradual deformity correction procedures, or to facilitate reduction. Each of these components features a wrench flat at its base to simplify proper Nut or Bolt tightening.

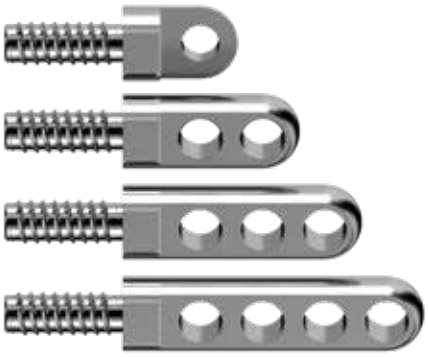


Figure 25

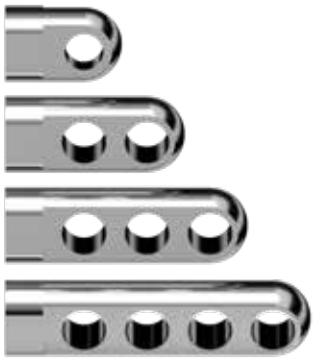


Figure 26

Walkie Pucks

Walkie Pucks are an optional component that may be added to the FusionFrame constuct postoperatively, outside of the sterile field, to facilitate off-loading of the patient's foot during ambulation. Under no circumstances should the Walkie Pucks ever be sterilized, nor should they ever be used or assembled within the sterile field. Each Walkie Puck is provided with two 10mm hexagonal nuts and a removable 10mm spacer as shown in Fig. 26a.

Please see pages 26 and 27 for more information on assembling and mounting the Walkie Pucks.

Figure 26a

Instrumentation Platform

Dynamometric Wire Tensioner

The Wire Tensioner is an indispensable instrument of the FusionFrame (Fig. 27). Each tray should contain two Tensioners because some procedures call for simultaneous tensioning on both ends of a wire. In any case, an additional Wire Tensioner should always be available to serve as a spare.

The Tensioner features a ratcheted plier-handle mechanism that delivers reliable, one-pump tensioning with maximum efficiency and minimal effort.

The instrument holds onto the head of the Wire Fixation Bolt with its adapter jaws. The jaws allow precise access around all possible frame contours.

As the Tensioner handles are squeezed together, its internal catch initially grips the wire. Further squeezing prompts the catch to pull the wire while the Tensioner buttresses itself against the head of the Fixation Bolt. A scale on the barrel of the device indicates the magnitude of tension generated.

By grasping the head of the Wire Bolt itself (not the Ring), the Tensioner performs its function without regard to the shape of the frame or the location of the Wire Bolt. It accepts any Ring or Foot Plate diameter, or straight element such as the multi-hole posts.

Note:
The user should be aware that the force scale readings may be subject to error. In essence, the reading measures the elongation of an internal spring or the elongation of the Wire. Consequently, the surgeon should use these readings as a relative guide and should not treat them as absolute values.

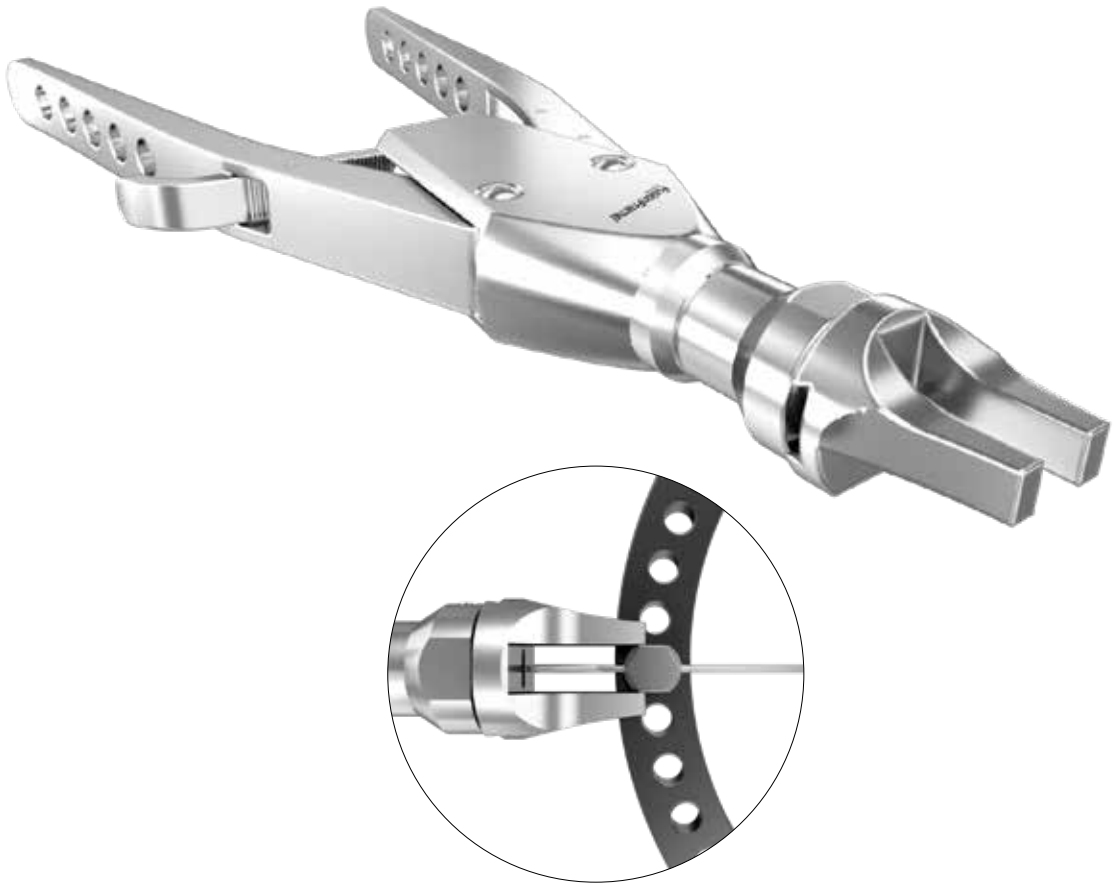


Figure 27

Wrenches

Wrenches are used to tighten 10mm conventional Bolts and hexagonal Nuts, as well as grasping the wrench flats on Male and Female Posts. The 10mm span is likewise compatible with Wire Fixation Bolts and Counting Nuts.

Figure 28

Open Wrench

10mm span (Fig.28).

Angled Wrench

10mm socket with slot allowing placement directly over a threaded rod (Fig.29).

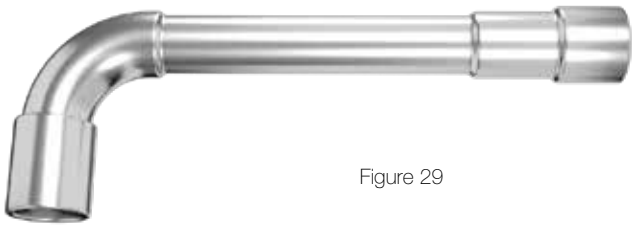


Figure 29

T-Wrench

The Fusion Frame T-Wrench (Fig. 30) is used for the insertion and removal of Half-Pins and accommodates all sizes of FusionFrame Pins. The Instrument assembly includes a set of adaptors for use with power tools.

Figure 30

Surgical Technique

General Considerations

Boney anomalies and alignment can be best assessed with a weight bearing CT prior to surgical consideration. Triple phase bone scan followed by white blood scans may likewise be useful for diagnostic purposes. Prior to application of external fixation, and when appropriate, osteomyelitic bone should be resected.

Also prior to application of an external fixator, one must consider correcting mild to moderate deformities present. Any mild to moderate tendinous deformities should be addressed before fixator placement. This includes Achilles tendon / Gastroc soleal lengthening, and adductor / abductor balancing.

The position of the patient for application of external fixation should be bumped at the hip with a well-padded leg holder atop a bone foam riser. When possible, all incisions should be sutured with drains in place to minimize skin tension on any pin site.

After sterilization of the preconstructed frame, all joining nuts and bolts must be checked and securely ("grunt") tightened, given that the sterilization process may loosen the connections.

The proximal Ring of the frame should be placed well below the fibular head to avoid injury to the peroneal nerve. Care should likewise be taken to ensure two fingerbreadths of clearance between the inner perimeters of the Rings and the soft tissue envelope of the foot and ankle. The foot should extend inferior to the frame by approximately 1cm, such that the plantar aspect of the foot is afforded the ability to touch the ground, should weightbearing be desired. Rolled towels may be used to help maintain these positions during frame application and Wire insertion.

General Considerations

Once the optimal frame position is attained, the most proximal wire should be inserted (Fig. 31). As is the case for insertion of any wire, the wire should be in contact with the surface of the Ring at the start and end of the throw. Washers are available (see Fig. 71, Page 37) to compensate for any vertical displacements from the Ring surface and should be used when necessary to avoid bending Wires. Wires should be pushed through the soft tissue to a boney stop point. The Wire is then advanced through the bone using power (see Page 22).

Once the wire traverses the bone, to prevent arterial and neural injury, the wire should be gently tapped through the soft tissue envelope on the opposite side.

Figure 31

After insertion of the most proximal Wire, a calcaneal Wire is then added (Fig. 32), after which all towels and non-frame related supports may be removed. A third Wire is then inserted into the middle Ring. Prior to tensioning, a C-arm may be used to ensure proper Wire placement and alignment.

The following sections provide detailed instructions for frame assembly, frame application and Wire placements.

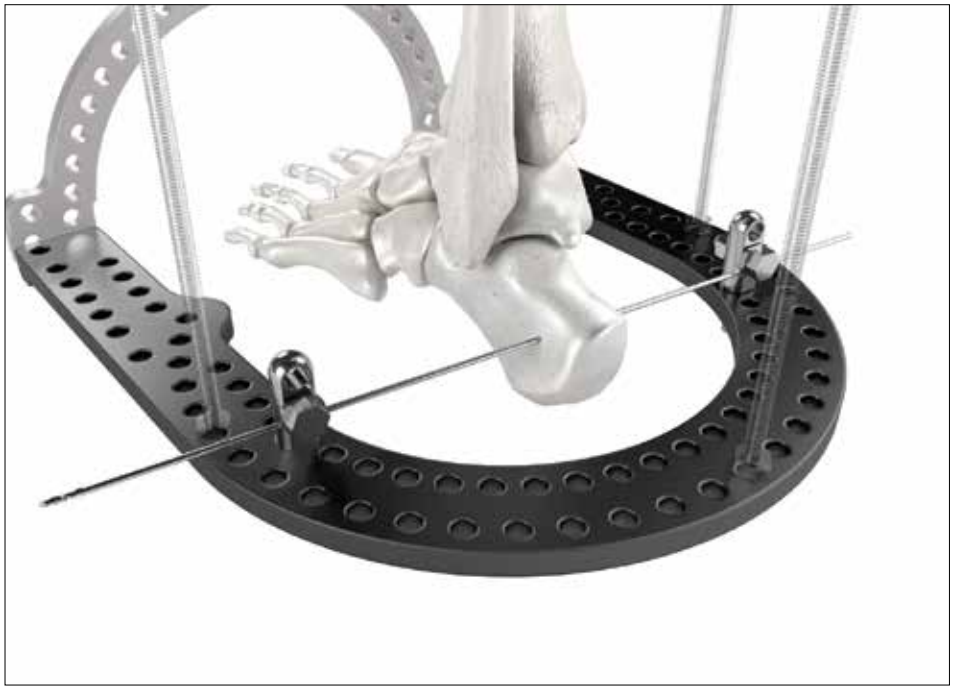


Figure 32

Surgical Technique

Frame Assembly Instructions

The frame construct shown in this example is comprised of two blocks, consisting of the proximal two-ring segment and the Foot Ring segment. Typically, all of the Ring diameters, including the Foot Plate, are the same throughout the construct.

The two proximal Rings are aligned in accordance with their corresponding tabs, making certain that all ring hole positions are coaxial with one another on both rings (Fig. 33). There are several possible ways of connecting the proximal two-ring block to the foot ring. Perhaps the most straightforward technique is to use three long Threaded Rods. These Rods are approximately 300mm in length for the average sized adult, however, depending on the patient's anatomy, shorter or longer Threaded Rods may be used.

The first Rod is placed through the center holes of the most posterior Ring tabs (Fig. 34). To correctly lock the Threaded Rod to the Ring, it is important to place Nuts on both sides of the Ring (i.e., on the "heads and tails" sides of the Ring).

An additional Nut is then placed on the Threaded Rod at a point marking the separation distance at which the surgeon has elected to keep the two proximal Rings apart (Fig. 35). The holes on the second Ring in the proximal block are then aligned exactly with all of the corresponding holes on the first Ring and the second Ring is placed onto the Threaded Rod and positioned at the Nut marking the separation distance. A fourth Nut is now added to the inferior side of the second Ring to secure its position (Fig. 36).

At this point, all Nuts are hand-tightened but not fully locked yet, to allow for any minor adjustments prior to frame application. All four ring tabs on each Ring should be perfectly aligned. Threaded Rods are then placed into the center holes of the medial and lateral tabs, with Nuts applied superiorly and inferiorly at both Rings. Both Rings must be perfectly parallel to each other; if they are not, adjust all Nuts to ensure parallelism (Fig. 37).

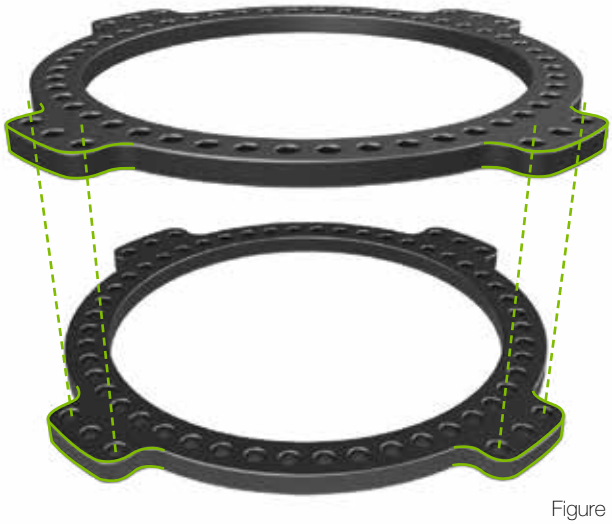


Figure 33

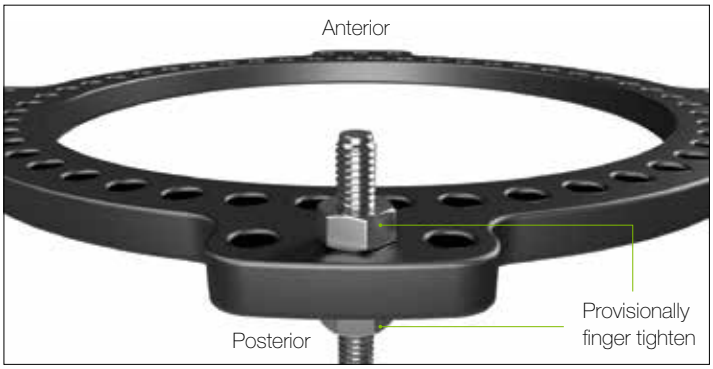


Figure 34

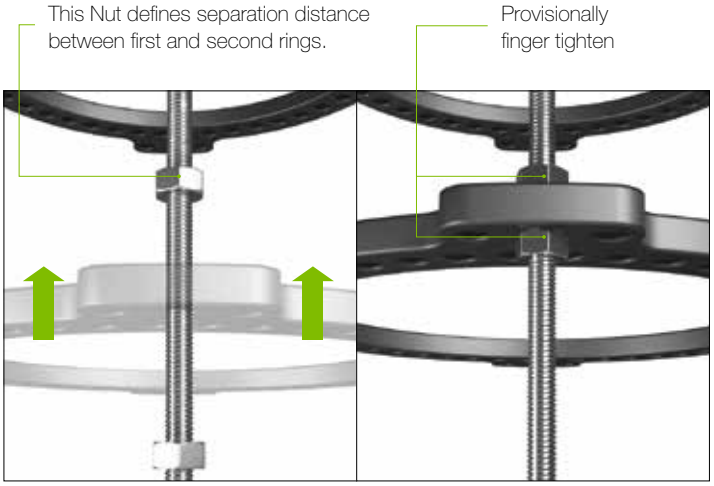


Figure 35

Figure 36

Figure 37

Frame Assembly Instructions

At this time, the Foot Plate is aligned to the two-ring proximal block and attached to the three long Threaded Rods with Nuts in a similar fashion to that described above (Fig. 38).

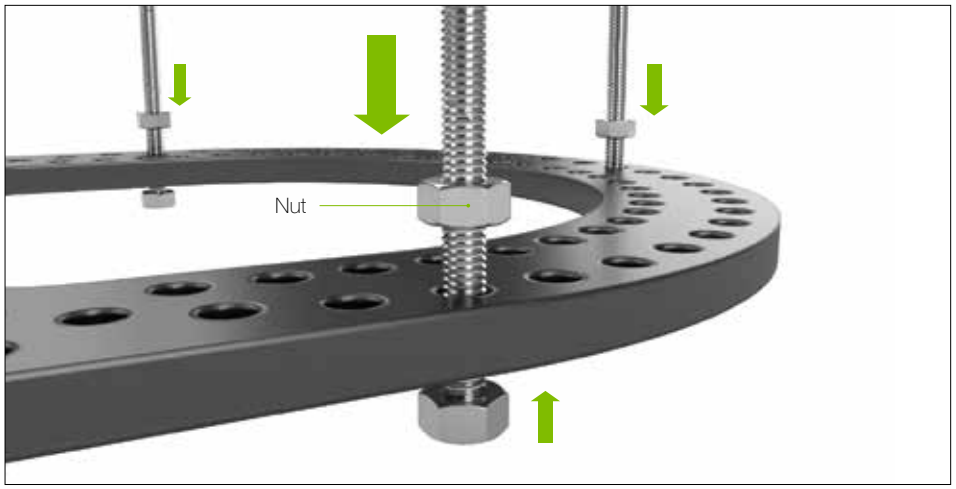


Figure 38

For additional support, a forefoot arch, consisting of a Half-Ring of the same diameter is now attached anteriorly to the threaded holes at the ends of the Foot Plate using 12mm Bolts (Fig. 39).

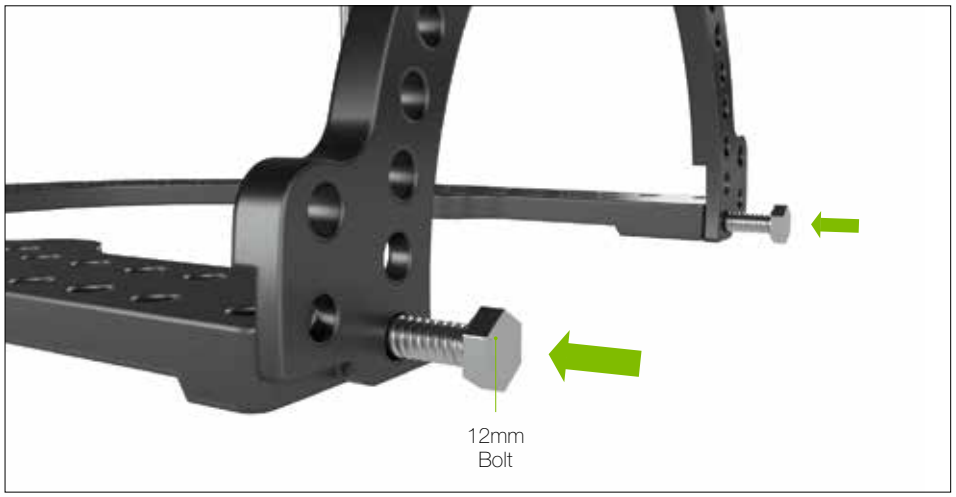


Figure 39

The forefoot Arch Half Ring is additionally connected to the distal ring of the proximal block by means of an Oblique Support, one-hole Male Post and corresponding Nuts and Bolts as shown in Fig. 40.

A Threaded Rod of appropriate length is then added between the anterior tabs of the two proximal rings.

To complete the assembly, all connections (i.e. Nuts and Bolts) must now be firmly tightened ("grunt tight") using the Wrenches provided.

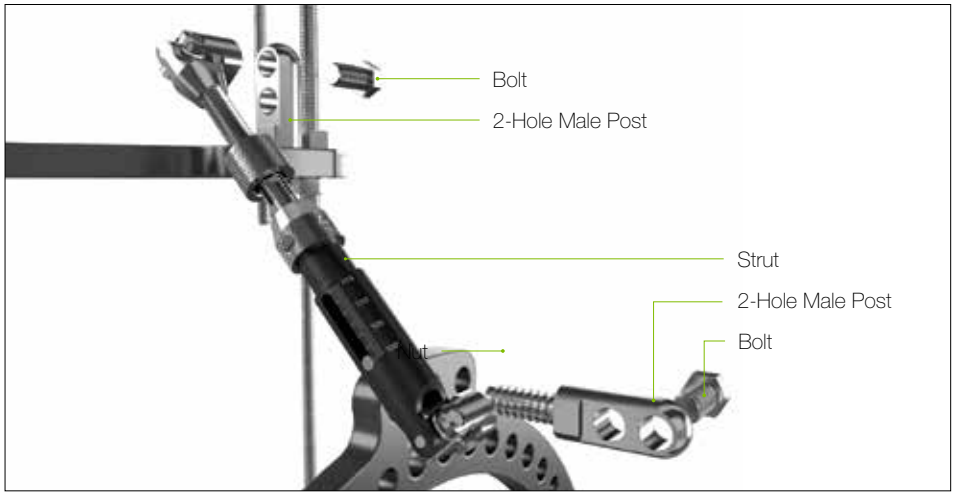


Figure 40

Surgical Technique

Frame Application

Frame Alignment and Placement of Reference Wires

The preconstructed frame assembly is placed onto the patient's extremity (Fig. 41), with the proximal most ring at the level of the tibia's midshaft, and held in position by an assistant. A two-inch cling is placed temporarily between the patient's heel and the frame. No towels should be placed posterior to the calf to prevent soft tissue displacement due to pressure. Such displacement may interfere with correct Wire placement. A towel block is placed proximal to the knee, so that the entire lower extremity is elevated off the table to relieve pressure from the soft tissues. This will facilitate accurate Wire insertion.

Figure 41

Three "reference" Wires are now inserted, one at each of the three Ring levels of the frame. All three of these Wires are inserted parallel to the table, from the lateral side to the medial and are parallel to each other in all planes.

Note:
All "reference" Wires are smooth, without stopper.

The first wire is placed onto the superior side of the proximal Ring (Fig. 42), ensuring that there are at least 20 – 30mm (or "two finger breadths") of soft tissue clearance along the entire inner circumference of the ring (see Fig. 2, Page 6).

Note:
The proximal reference Wire lays the foundation for accurate frame alignment. If this wire is not placed to the satisfaction of the surgeon, it should be removed, and a new Wire inserted to ensure proper frame orientation. The position and alignment of the frame and all subsequent Wires are dictated by the orientation of the proximal reference Wire.

Figure 42

The Wire is attached and tensioned (see Fig. 58, Page 32), but DO NOT cut and curl this Wire until the other two reference Wires are placed and secured. At this point, the frame may be pivoted around the Wire and slid medially and laterally with respect to the tibia to fine-tune the frame's alignment to the mechanical axis of the extremity.

Frame Alignment and Placement of Reference Wires

The second reference Wire is placed into the calcaneus (parallel to the first), attached to the superior side of the Foot Ring and tensioned without cutting or curling the Wire (Fig. 43). This Wire will lock the Frame in the A/P plane. Should there be any axial misalignment of the Frame, the distal reference Wire should be removed and replaced with a new Wire in a more suitable position.

Figure 43

The third reference Wire is placed on the superior side of the middle Ring (Fig. 44), parallel to the other two and attached and tensioned, but not cut or curled yet.

With all three Wires parallel, the frame may still be shifted from medial to lateral to properly center the frame for the purposes of alignment and soft tissue clearance. Once satisfied with the frame's position, all three reference Wires may be cut and curled (see Figs. 59 and 60, Page 33).

Note:
Once the next Wire has been added, the Frame's position will be locked in all planes.

Figure 44

Surgical Technique

Placement of Additional Wires

The remaining Wires are then inserted, with close attention paid to placing the Wires in safe zones (see Figs. 54 and 55, Page 29) and ensuring that there are at least two Wires at each Ring level. The Wire pairs must be placed on opposite sides of each Ring (superior and inferior) to prevent them from colliding within the bone.

Medial face wires are added to the proximal and middle Rings, attached, tensioned, locked, cut and curled (Figs. 45 and 46).

Counteroposing Olive Wires are often preferred at these locations, with stoppers on the lateral side for the proximal Ring Wire and medial side for the middle Ring Wire.

The middle Ring may have a third Wire added to it for augmented stability using the “Drop Wire” technique as described on Page 34. The optional Drop Wire may be placed directly through the fibula. A wire passing through the fibula should always be smooth.

Note:
To prevent internal Wire collisions never attempt to place any additional Wires (beyond the initial pair) directly onto the Ring; always use the Drop Wire technique for supplementary Wires.

A second Wire is now inserted into the calcaneus at approximately 60° with respect to the calcaneal reference Wire; the position of which may be anterior or posterior to the reference Wire (Fig. 47).

Figure 45

Figure 46

Figure 47

Placement of Additional Wires

The next two Wires are inserted through the metatarsals and should be placed as proximally as possible, taking care to position one wire into the first and second metatarsals and the other into the third, fourth and fifth metatarsals (Figs. 48 and 50).

Wires with Stoppers (Olive Wires) may be used throughout the construct to help augment stability. However, Olive Wires may be painful if used in a non-neuropathic foot. Counter-opposing Olive Wires may be used at the discretion of the surgeon but are typically not required. There is no set pattern for Olive Wire placement but they are used when necessary. (Fig. 49).

Figure 48

Walkie Pucks (optional)

Once all Wires have been tensioned, cut and curled and all connections on the frame construct have been checked for "grunt tightness," 4 – 6 Walkie Pucks may be added to the inferior side of the Foot Ring to assist the patient with weight bearing and ambulation (Figs. 49 and 50). The Pucks should be placed symmetrically on the medial and lateral sides of the Foot Plate, spaced as evenly as possible with respect to one another.

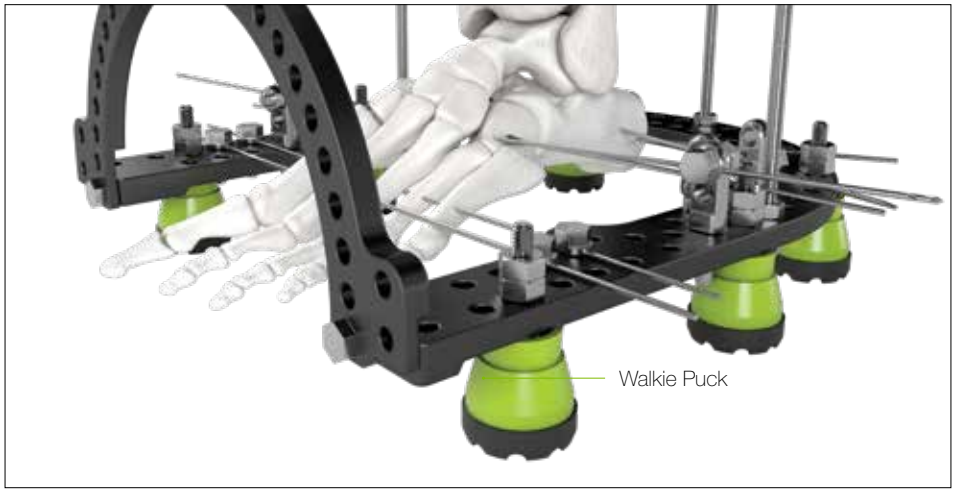


Figure 49

Note:
Walkie Pucks are optional and if used, are added post-operatively, after the patient has been removed from the sterile field.

Note:
Patients must be instructed to avoid walking on wet, oily, greasy or unstable surfaces to prevent slipping and possible injury. Patients should be instructed to always exercise caution when walking.

Figure 50

Surgical Technique

Walkie Pucks Mounting and Assembly Instructions

The Walkie Pucks are placed on the FusionFrame construct after the patient has been removed from the sterile field. This may be done at any time postoperatively. **Walkie Pucks should never, under any curcumstances be sterilized.**

1. Make certain that the Walkie Puck Kit contains six (6) units of the configuration as illustrated in Fig. 1 above and that all constituent elements are present for each unit.
2. Ensure that you have access to one 10mm wrench. A wrench will be needed for proper final tightening of the connections.
3. Preplan the installation arrangement of 4 – 6 Walkie Pucks so that they are positioned as symmetrically and evenly spaced as possible, using the available (empty) holes on the Foot Plate.
4. Decide if the spacer will be used. If not, remove the spacers from all Walkie Pucks. If yes, leave them in place, as shown in Figs. 50a.All Walkie Pucks on any single FusionFrame construct must be of the same height; all Pucks should either include the spacer or all Pucks should have the spacers removed. Never mix Pucks with spacers with those that do not have spacers, and vice-versa, on any given construct.
5. Remove both hexagonal Nuts and place the threaded element of the Walkie Puck base assembly through the inferior side of an available hole in the Foot Plate as shown in Figs. 50a. Use outer holes whenever possible.

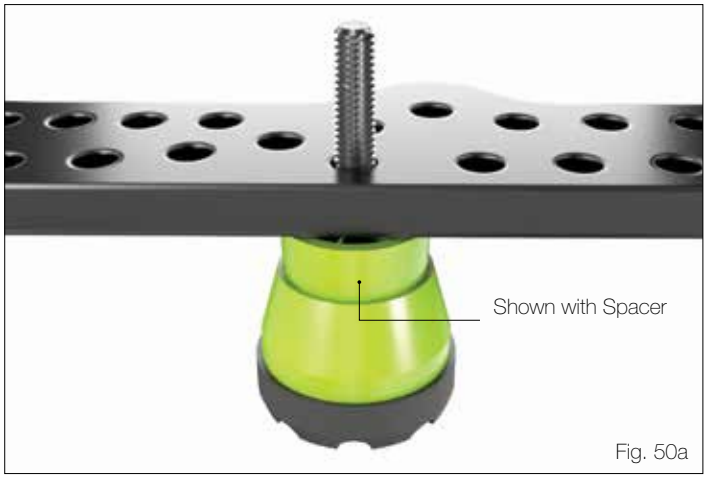


Fig. 50a

6. Place one of the provided 10mm Nuts onto the threaded element that protrudes on the superior side of the Foot Plate and finger tighten (Figs. 50b).


Fig. 50b

7. Securely tighten the connection using a 10mm Wrench (Fig. 50c).


Fig. 50c

8. Place a second 10mm Nut over the first and securely tighten with Wrench (Figs. 50d and 50e). The second Nut is necessary and used to definitively lock the connection. Its presence will minimize loosening caused by the cyclical loading and vibrations due to ambulation and other movements of the patient.

Fig. 50d

Fig. 50e

9. Repeat above steps for the remaining 3 – 5 Walkie Pucks, making certain to position them on the Foot Plate as symmetrically and evenly spaced as possible.

10. Ask the patient to stand and ambulate in your presence to ensure that there is no discomfort, improper gate or suboptimal balance associated with the usage of the Walkie Pucks.

Fundamental Guidelines

General Principles of Wire Insertion

Tensioned Wires (both smooth and with stopper) are used for a number of purposes, including reduction, fixation, preservation of alignment and overall stability of the assembly. For optimal results, the following principles are recommended.

Wire Insertion Technique

1. Poke (do not drill) the Wire through the near soft tissue envelope.
2. Once the near cortex is reached, begin “start/stop” drilling.
3. Hold Wire with sponge or gauze pad soaked in alcohol or saline solution to dissipate heat (Fig. 51).
4. Irrigate the Wire to help further cool it to minimize chances of inducing thermal necrosis to the bone.
5. Upon exiting the far cortex, stop drilling.
6. After drilling the Wire through the entire width of bone, use a mallet to tap the Wire through the remaining soft tissue.

Figure 51

Half-Pin Insertion Technique using Half-Pin Fixation Cube

1. Attach a Half-Pin Fixation Cube to the Ring as shown in Fig. 52, using a 12mm Bolt. Align the Cube so that its smooth (non-threaded) holes align with the intended trajectory of the Half-Pin, using a Wrench to hold the Cube in proper rotational position as the Bolt is being tightened with a second Wrench. Make certain that the connection is “grunt” tight.
2. Secure the proper diameter T-Wrench Adapter to the chuck of the T-Wrench.
3. Insert a Half-Pin of required diameter and proper thread length into the open end of the T-Wrench Adapter.
4. Place the Half-Pin into one of the smooth holes of the Half-Pin Cube, making certain that the unthreaded shaft of the Half-Pin is flush with one of the side walls of the smooth hole.
5. Using a blade, make a stab incision where the sharp end of the Half-Pin meets the skin, pushing its tip down to bone. A small hemostat may be used to spread the incision to facilitate passage of the Half-Pin.
6. Penetrate the near cortex with a firm push, and turn the T-Wrench handle in a clockwise direction to inert the Half-Pin, advancing it slowly until bicortical purchase is obtained. The Half-Pins have self-drilling, self-cutting flutes. Remove the T-Wrench and Adapter. Alternatively, the Half-Pin may be inserted using power, in which case the Adapter is placed directly into the chuck of the power tool. Carefully drill the Half-Pin through the bone, using a start/stop drilling technique to allow for heat dissipation.
7. Secure the Half-Pin by placing a 12mm Bolt into the corresponding threaded hole in the Half-Pin Cube, making certain that the shaft of the Half-Pin does not displace from its position and the Pin remains flush with the side of the wall of the smooth hole when the Bolt is fully tightened.

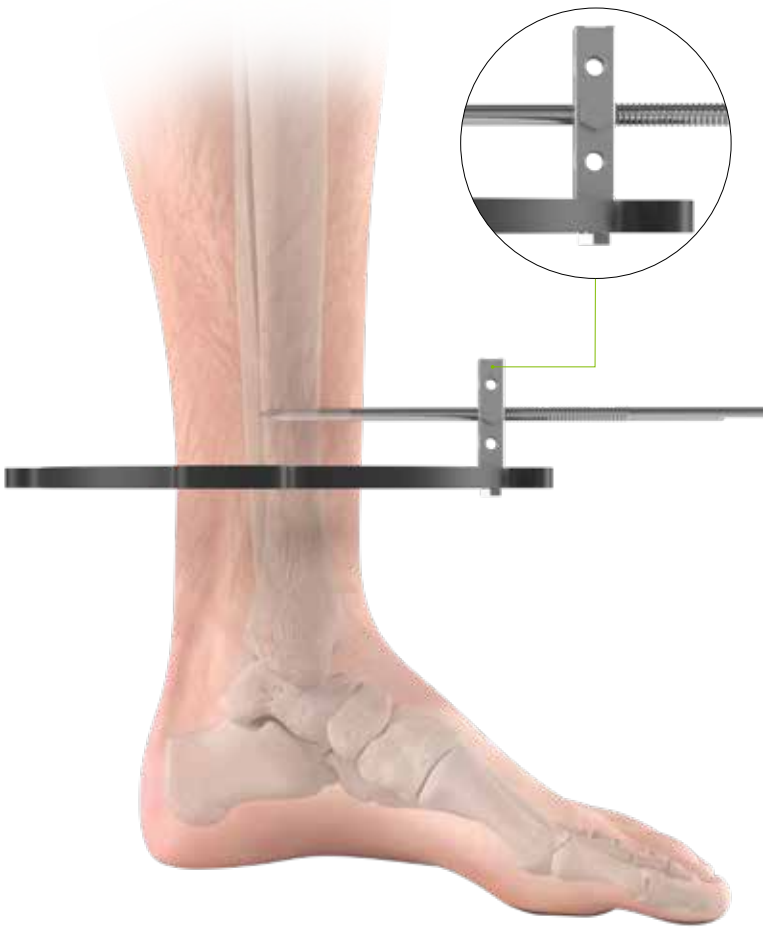


Figure 52

Fundamental Guidelines

Half-Pin Insertion Technique Using Half-Pin Fixation Bolt

1. Attach a Half-Pin Fixation Bolt to the Ring as shown in Fig. 53, using a 10mm Nut and making certain that the bushing is located on the side of the Ring where the Half-Pin shall be placed; a smooth washer may be placed on the opposite side, between the surface of the Ring and 10mm Nut.
2. Rotate the Bolt so that its aperture aligns with the intended trajectory of the Half-Pin. Using your fingers, hand-tighten the nut to hold the Pin Fixation Bolt in temporary position.
3. Attach the T-Wrench Adapter and secure it to the chuck of the T-Wrench.
4. Insert a Half-Pin of required diameter and proper thread length into the open end of the T-Wrench Adapter.
5. Place the selected Half-Pin into the aperture of the Pin Fixation Bolt. The aperture has a “teardrop” shape that is designed accommodate all diameters of GLW Medical Innovation Half-Pins. Use the Half-Pin as a joystick to rotate the Bolt into final alignment with desired trajectory.
6. Using a blade, make a stab incision where the sharp end of the Half-Pin meets the skin,pushing its tip down to the near cortex of the bone. A small hemostat may be used to spread the incision to facilitate passage of the Half-Pin.
7. Dimple the near cortex with a firm push, and turn the T-Wrench handle in a clockwise direction to insert the Half-Pin, advancing it slowly until bicortical purchase is obtained. The Half-Pins have self-drilling, self-cutting flutes. Remove the T-Wrench and Adapter. Alternatively, the Half-Pin may be inserted using power, in which case the Adapter is placed directly into the chuck of the power tool. Carefully drill the Half-Pin through the bone, using a start/stop drilling technique to allow for heat dissipation.
8. Secure the Half-Pin by “grunt” tightening, the 10mm Nut with a 10mm Wrench. As the Nut is being tightened the Half-Pin will be sandwiched between the head of the Bolt and the bushing, securely locking the Half-Pin in place.

Figure 53

Important considerations and anatomical safe zones

- **Avoid structures at risk.** Structures at risk include, but are not limited to, nerves, blood vessels, joint spaces and connective tissues. Wires (and Half Pins) may be inserted only in safe zones (see Figs. 54–57).
- **Manage the soft tissue.** Always enter and exit relative to muscle compartment tension. When lengthening, always be certain to recruit soft tissue on the side opposite to the direction of lengthening.
- **Use proper insertion / fixation techniques.** Wires must never be bent from side to side or up and down. To avoid complications at the pin sites, Wires must be fixed exactly where they lay by using the slot or the cannulation in the Wire Fixation Bolt; and / or washers to build up from the plane of the ring.
- **Provide continuous pin site care.** Pin site infections begin at the surface of the skin and if left untreated may work their way into the bone. Proper pin site care reduces the risk of inflammatory processes (for further information, see pages 34-36.)

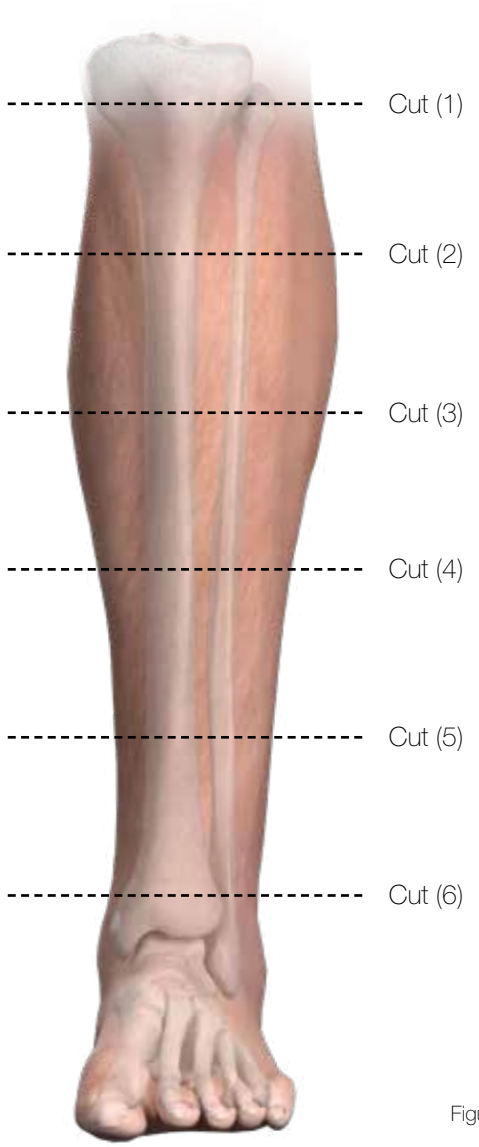
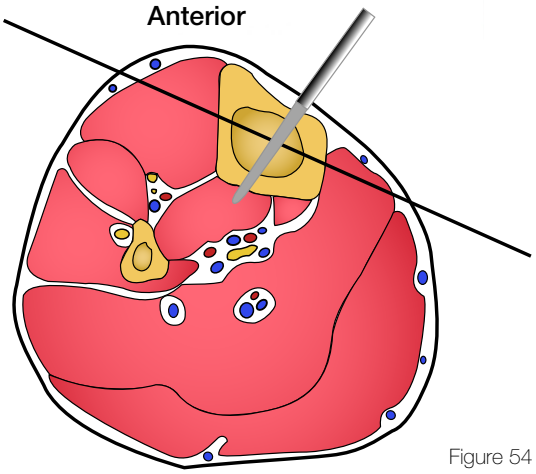
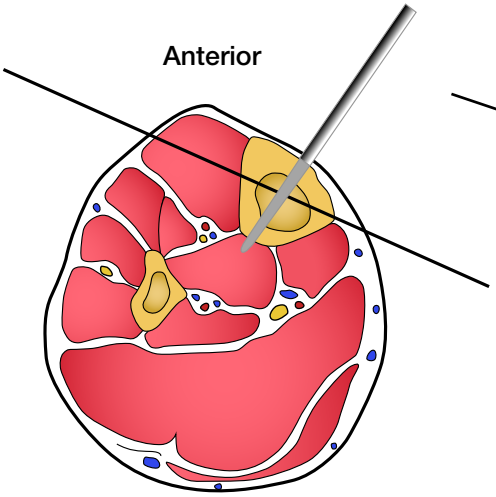


Figure 55



Cut 3

Figure 54



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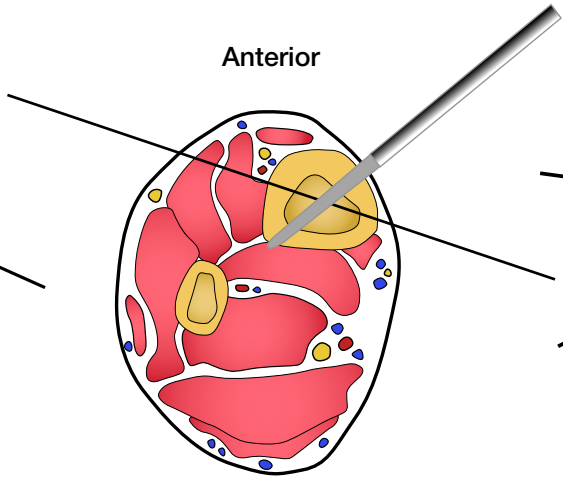

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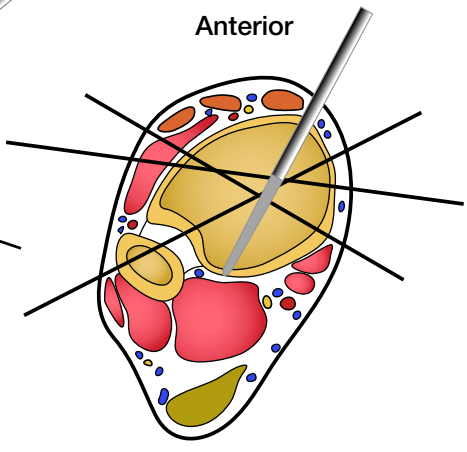
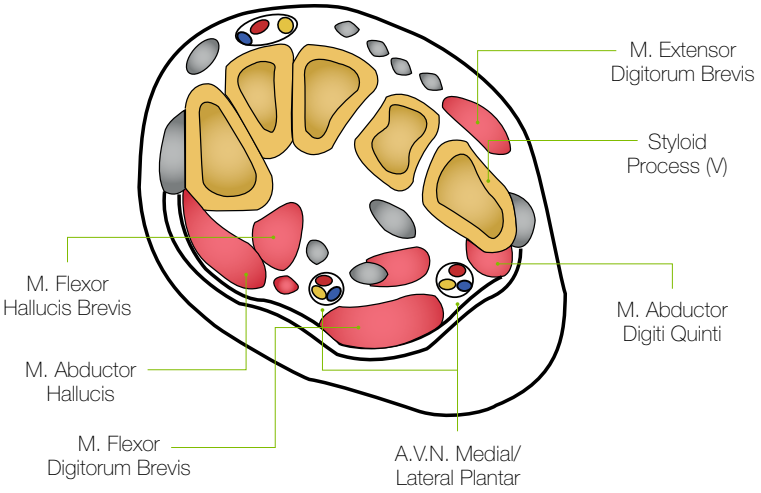
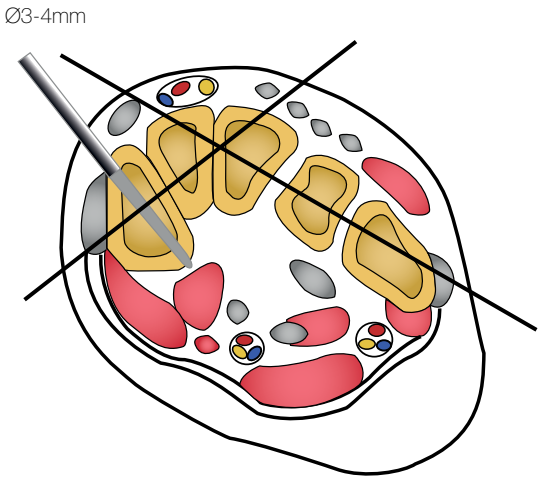


Cut 6

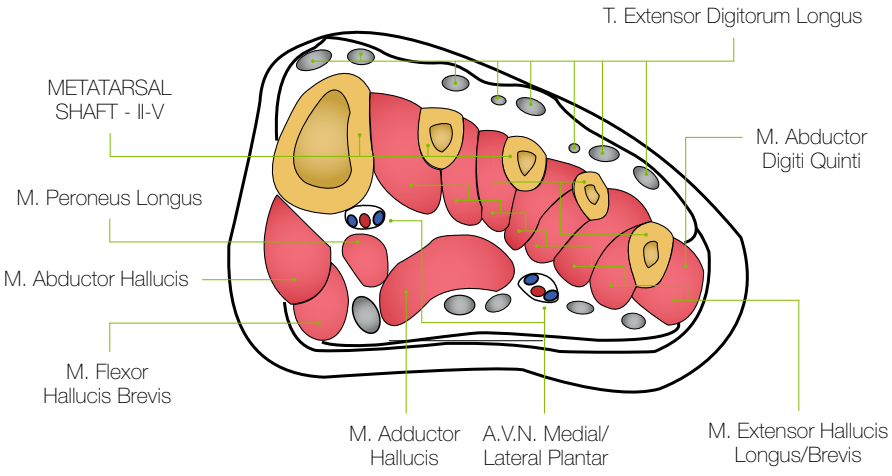
Fundamental Guidelines

Midfoot (Metatarsal Bases)





Forefoot



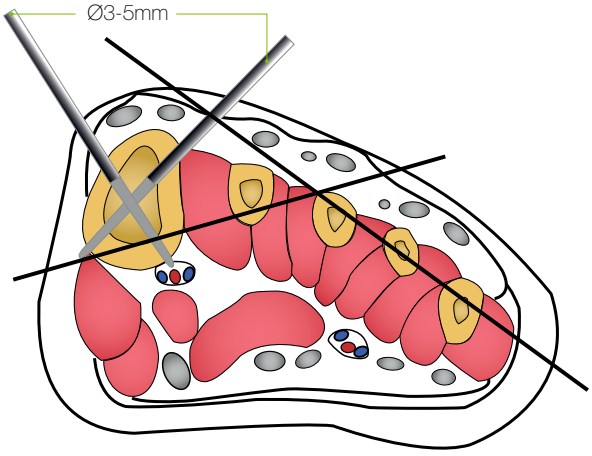


Figure 56

Hindfoot

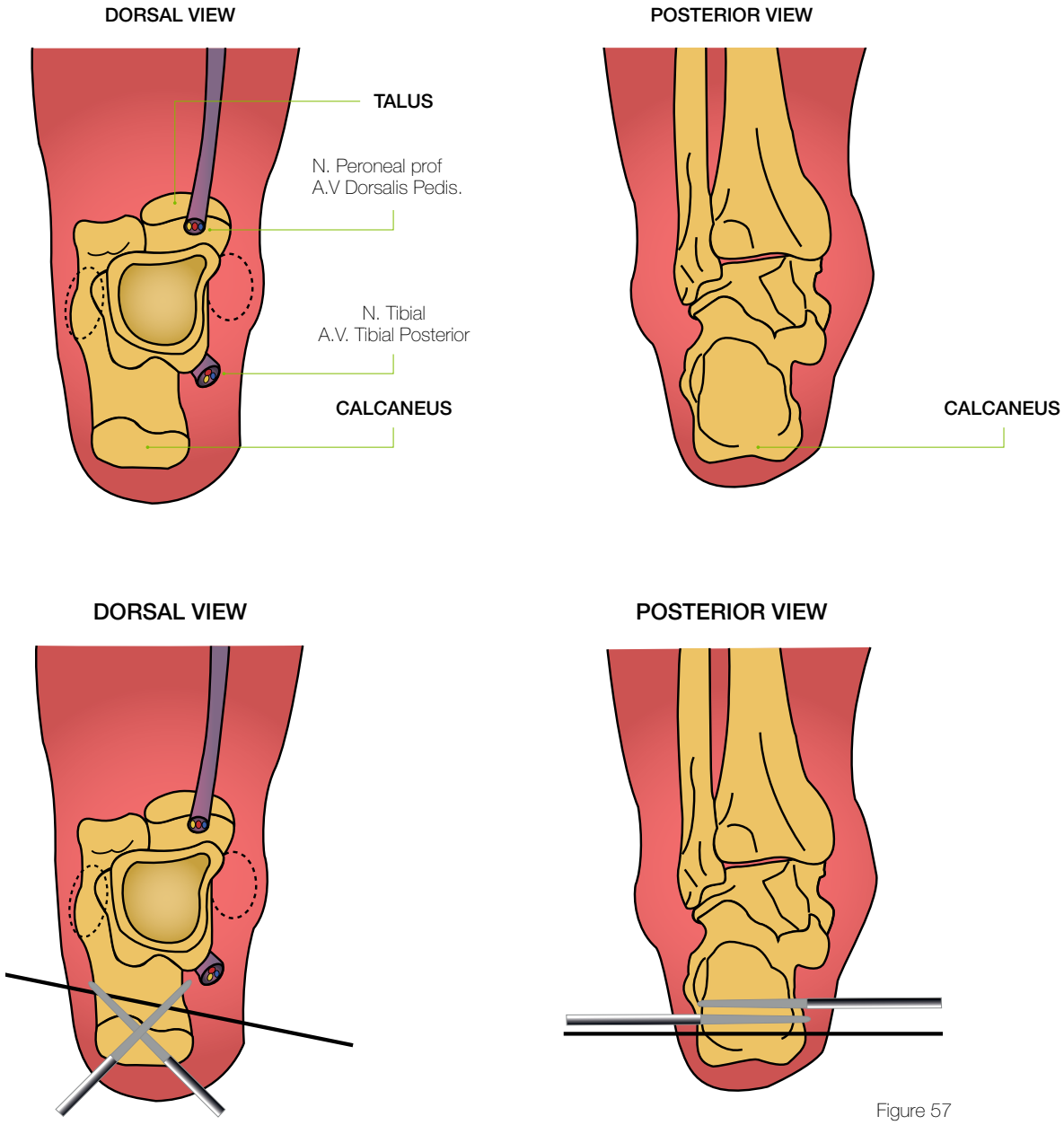


Figure 57

Fundamental Guidelines

Tensioning a Smooth Wire

Wire tensioning is a straightforward procedure that requires a sequence of intuitive, but important steps (Fig. 58).

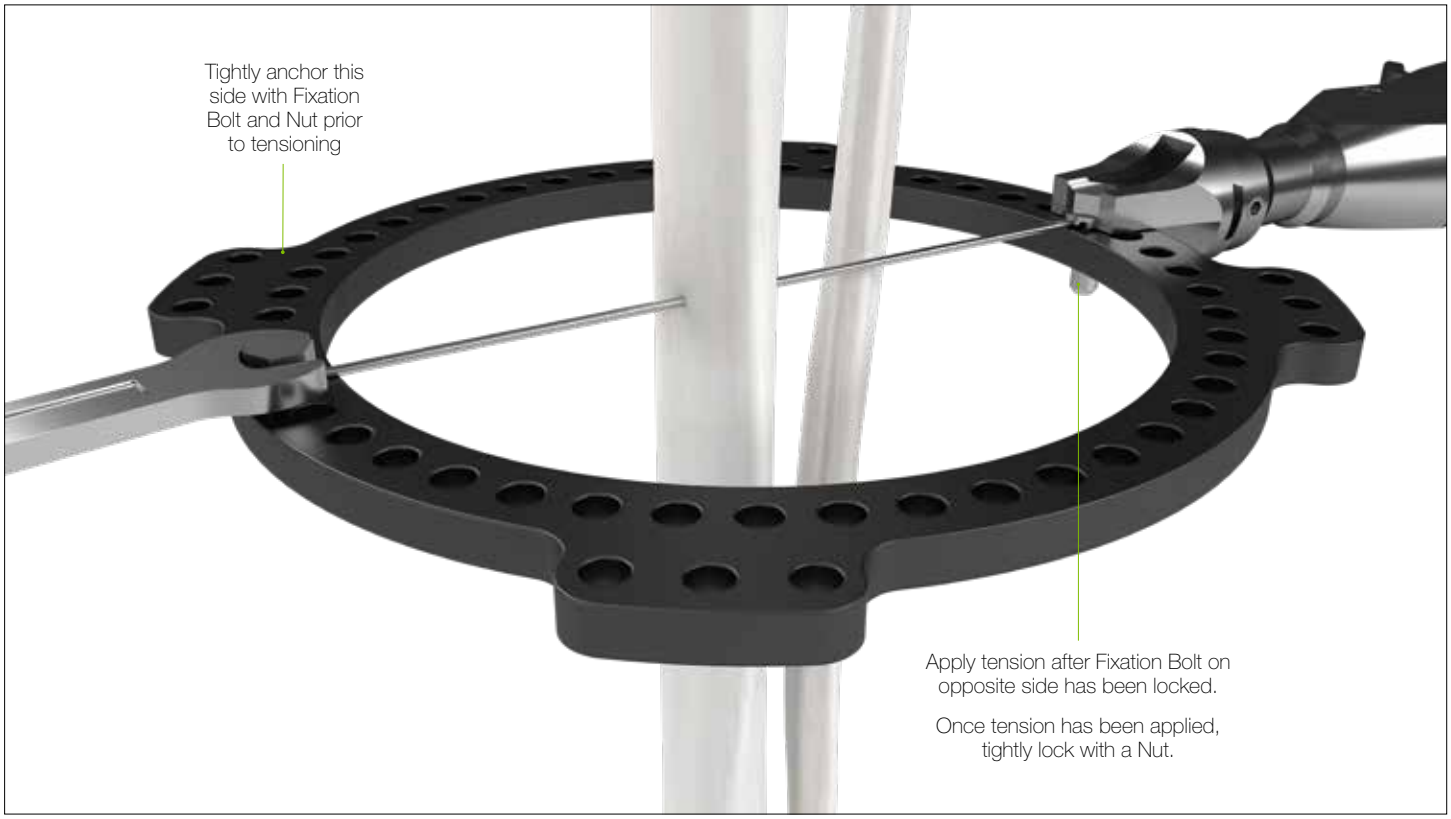


Figure 58

1. Insert Wire using proper technique (as described above).
2. Apply first Wire Fixation Bolt.
3. Securely lock Bolt with Nut (“grunt tight”).
4. Apply second Wire Fixation Bolt (but do not lock it yet with Nut).
5. Slide the Wire Tensioner over the unlocked side of the Wire, symmetrically grasping the Wire Fixation Bolt’s head with the Tensioner’s jaws, apply tension by smoothly closing the instrument’s handles in a single pump. Reading from the scale on the Tensioner’s barrel (apply 80 – 130Kg of tension for Smooth Wires; 80 – 120Kg for Wires with Stoppers).
6. Before removing the Tensioner, lock the second Wire Fixation Bolt with a corresponding Nut (“grunt tight”).
7. Remove Wire Tensioner.

Cutting the Wire

After the Wire has been fixed and tensioned, cut Wire, but ensure that you have 3 finger breadths remaining at each end (Fig. 59). This remaining length of Wire is required, in case postoperative re-tensioning is indicated.

Note:
Hold the end of the Wire that is being cut with other hand to prevent it from shooting across the O.R. during cutting.

Curling the Wire

After cutting the Wire on both sides, smoothly curl at each end (Fig. 60) to protect the patient and caretakers from protruding Wire ends.

Wire Distribution

Typically, two Wires are inserted for each ring, orthogonally with respect to the surface of the long axis of the bone at each point of entry. The biomechanically optimal Wire crossing angle at each Ring level is 90° (as illustrated in Fig. 61).

However, cross-sectional anatomy and the patient's pathology rarely allow such a crossing angle to be achieved on a single Ring level. In practice, such optimized Wire crossing placements may be accomplished by combining multiple Ring levels.

Wire pairs are always placed "heads and tails" on the Rings (i.e., on the superior and inferior sides of the Ring (see Fig. 62). Such placement will avoid possible collision of the Wires within the bone and will help distribute the tension forces more evenly.

Figure 59

Figure 60

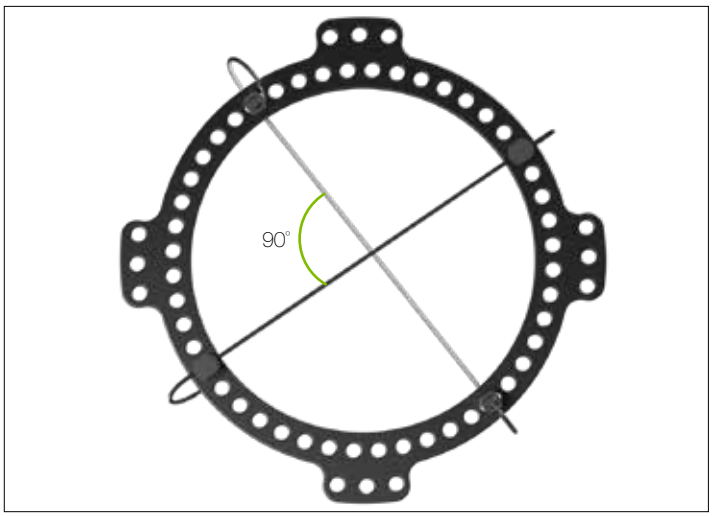


Figure 61

Figure 62

Fundamental Guidelines

Drop Wires

If necessary, additional Wires may be applied to a Ring level by means of a Drop Wire, using Posts as shown in Fig. 63. The Wire is attached to the Posts by using a Wire Fixation Bolt in combination with a counter-opposing Nut.

Drop Wires should not be tensioned to more than 60Kg (typical values range between 40 and 60Kg, see Fig. 64).

Note:
While tensioning a Drop Wire, watch carefully for Ring warpage. At first sign of deformation, stop and slowly release tension until the Ring no longer warps.

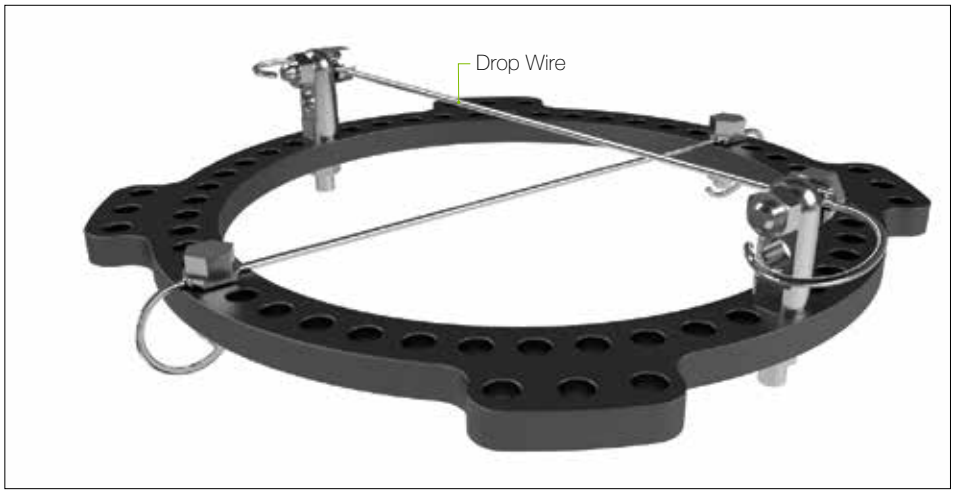


Figure 63

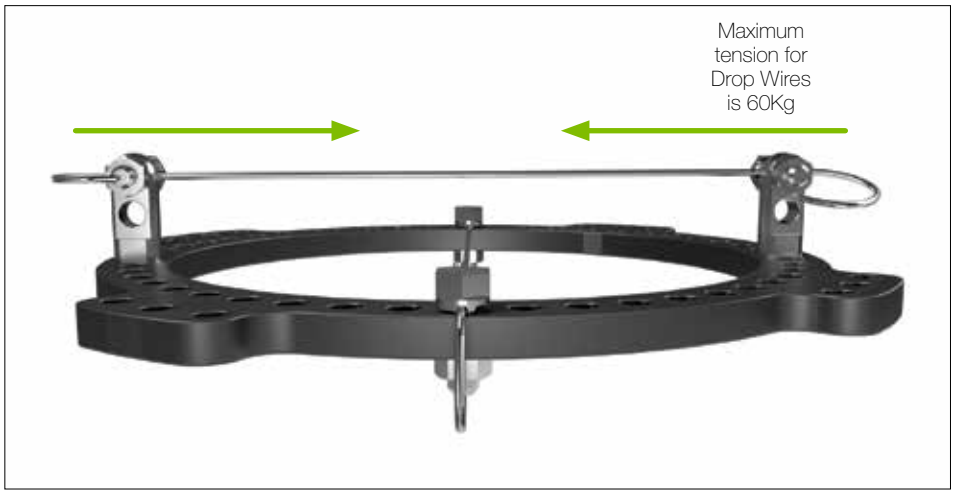


Figure 64

Wire with Stopper (Olive Wire)

Unlike Smooth Wires, the Olive Wires must be inserted (and removed) in a specific direction (see Fig. 65). Olive Wires are inserted cutting tip first; however, the direction of removal is defined by the taper of the stopper and location of the laser hash marks on one side of the Wire.

Olive Wires must always be removed by pulling them out in the direction of the stopper taper (i.e., remove it from the side that has the laser hash marks).

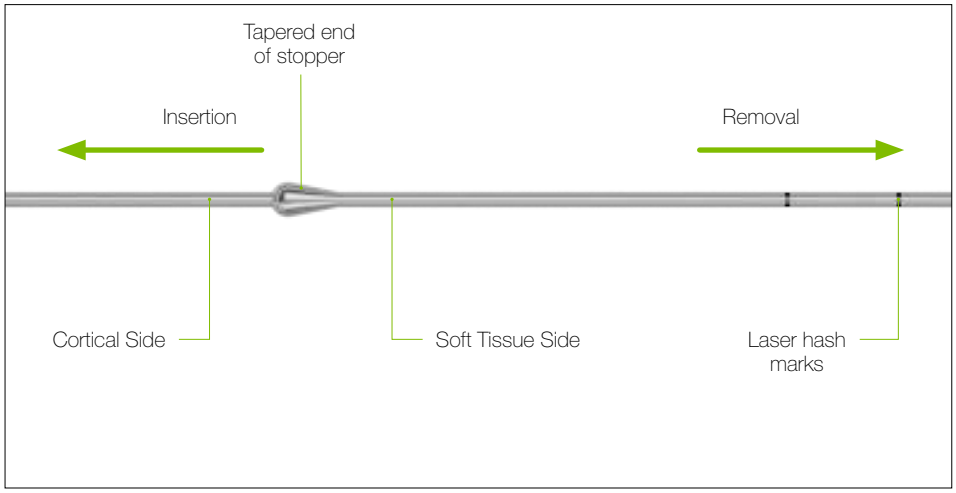


Figure 65

Tensioning an Olive Wire

For Olive Wires, tension must always be applied from the side that is opposite to the stopper as shown in Fig. 66. Tensioning from the olive side will cause the stopper to be pulled away from the cortex, thereby negating the functionality of the stopper.

Note:
Typically, Olive Wires are tensioned to values from 80Kg to 120Kg.
In cases of poor-quality bone, less tension is applied to prevent cortical perforation by the stopper.

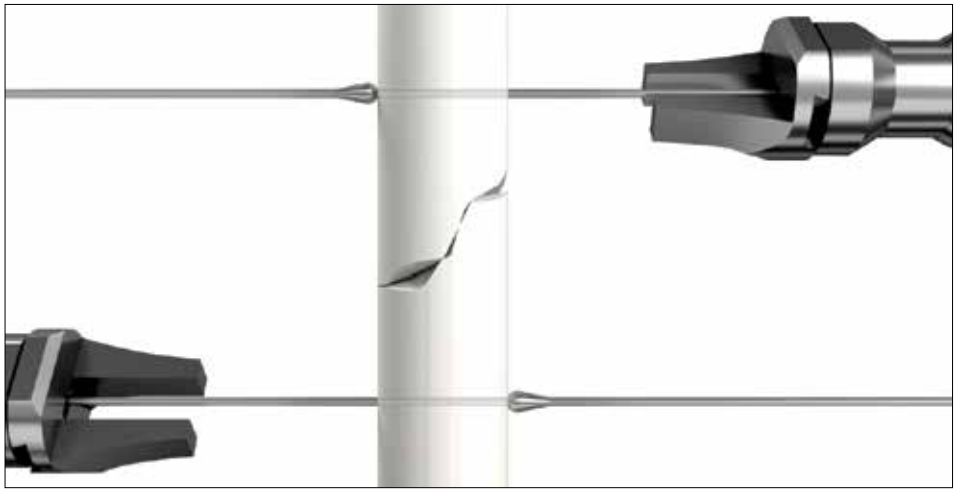


Figure 66

Fundamental Guidelines

Olive Wire Placement for Deformity Correction

Strategically placed Wires with Stoppers (Olive Wires) may be used to augment the procedure by helping align the distribution of "four-point bending" forces on the bone segment being corrected as depicted in Fig. 67.

The olives would be placed proximally and distally with respect to the apex of the deformity at the positions of the thumbs and forefingers, as shown in the example. Olive Wires may also be used to help immobilize bone segments to maintain reduction, or as prophylaxis against formation of induced deformities during lengthening procedures.

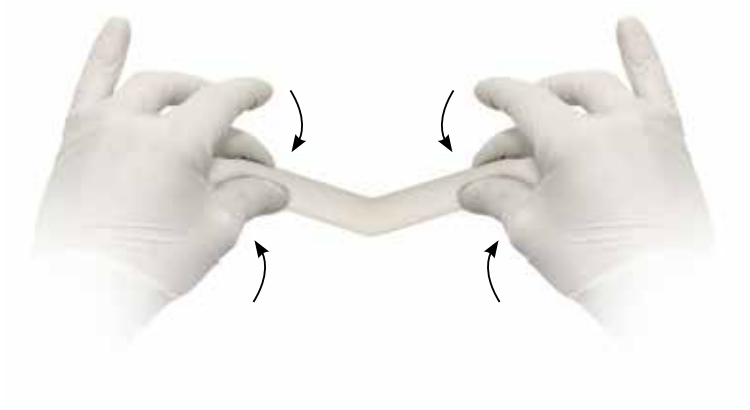


Figure 67

Fixing a Wire to the Ring (Wire Located On-Center with No Elevation)

Wires are anchored to the frame Rings by means of Wire Fixation Bolts and must be fixed without bending the Wires (up and down or side to side), exactly where they rest after insertion. If the Wire is situated flush with the surface of the Ring, while crossing the center of the Ring hole, the Wire is passed through the central cannulation of the Fixation Bolt as shown in Fig. 68 and secured with a nut on the opposite side of the Bolt.

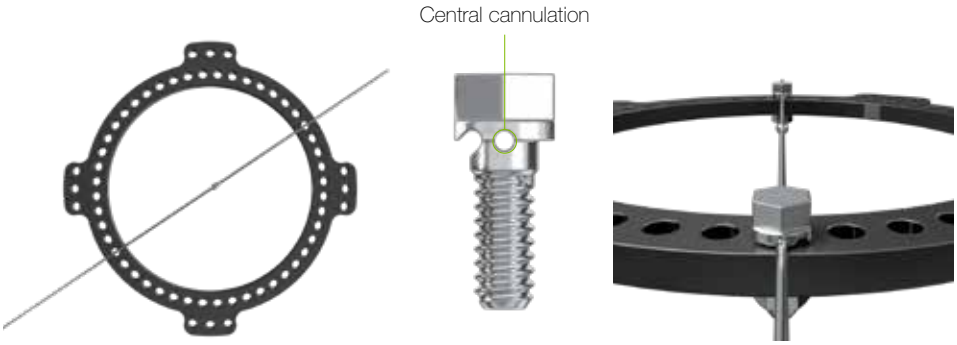


Figure 68

Note:
Unwarranted Wire bending may result in soft tissue compromise, possible swelling, pain and / or infection as shown in Fig. 69.

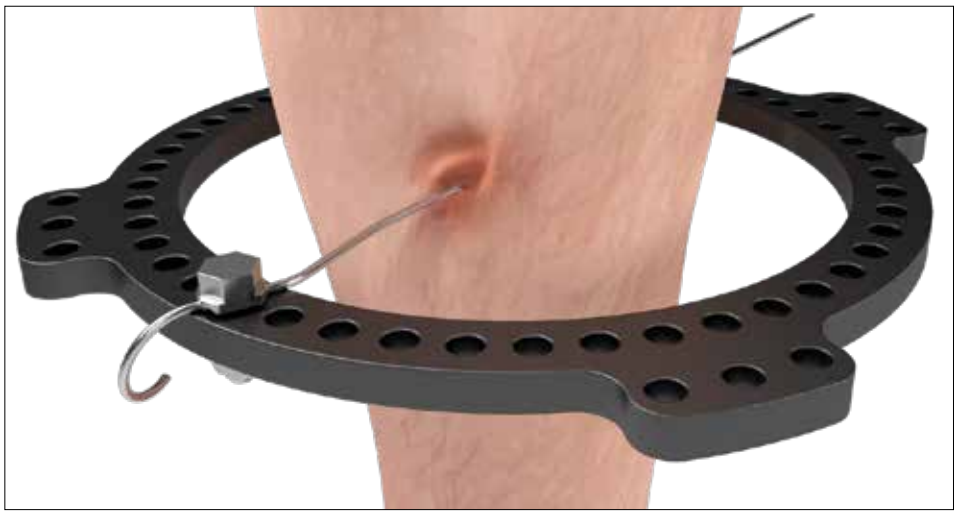


Figure 69

Fixing a Wire to the Ring (Wire Located Off-Center with No Elevation)

If the Wire is situated off-center with no elevation, the Wire is fixed using the Wire Fixation Bolt's side-slot as illustrated in Fig. 70.

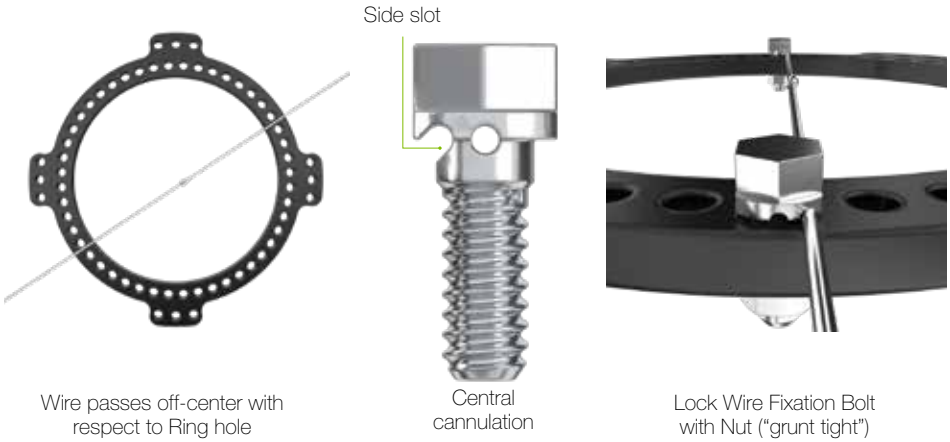


Figure 70

Fixing an Elevated Wire

If a Wire is elevated with respect to the Ring surface, never bend it down to meet the Ring; always build the Ring up to meet the Wire with Washers (see Fig. 71) or Posts (as described in the section for Drop Wires on Page 34).

Note:
The example shown in Fig. 71 illustrates an elevated Wire passing over the center of the Ring hole, in which case the Fixation Bolt's central cannulation is used. If the Wire is elevated **and** off-center, then secure the Wire using the Fixation Bolt's side slot in combination with Washers.

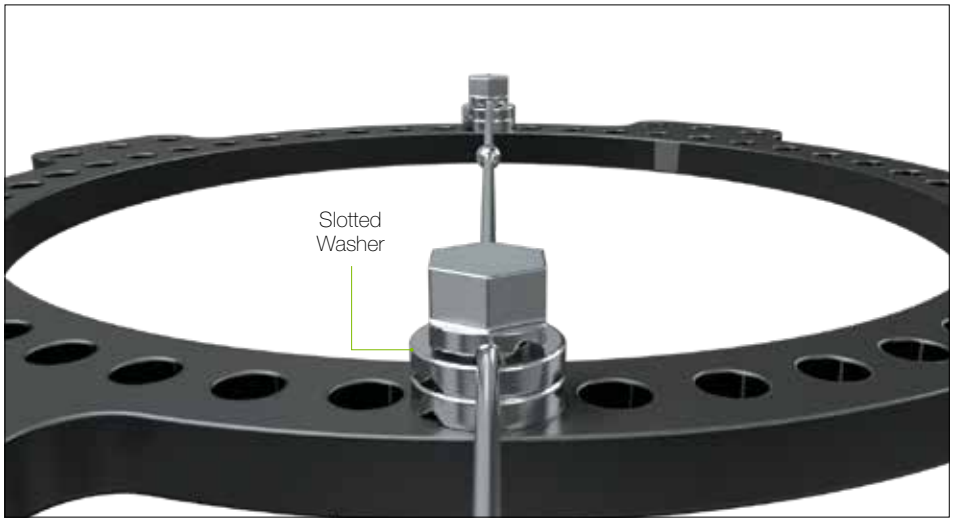


Figure 71

Frame Alignment for Optimal Stability and Load Balance

The mechanical axis of the frame must align with the mechanical axis of the extremity in the A/P and M/L planes (see Fig. 72)

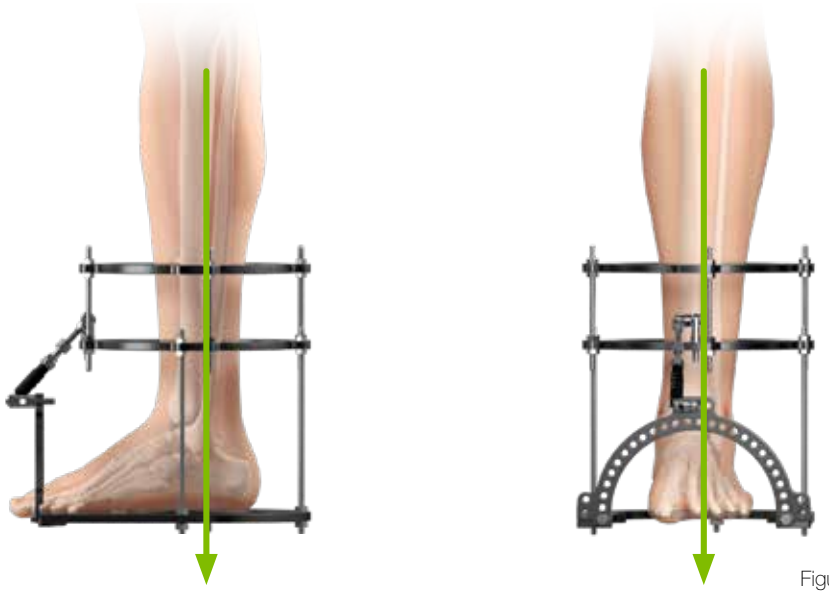


Figure 72

Fundamental Guidelines

Compression / Distraction Using Counting Nuts

When compressing or distracting, both the Counting Nut and Hexagonal (standard) Nut need to be correspondingly adjusted (Fig. 73). In most cases, the frame will have four Threaded Rods for the segment of bone being lengthened; these adjustments need to be made for each Rod. When using Nuts for either limb lengthening or tissue transport, an osteotomy must be performed on the bone being distracted.

Figure 73

Attaching Posts to a Ring

Rotationally align the post as required (Fig. 74). Place the Open Wrench spanner on the wrench flats of the Post to hold it steady and in position while tightening as illustrated. Be certain to lock the Nut, ensuring that it is “grunt tight.”

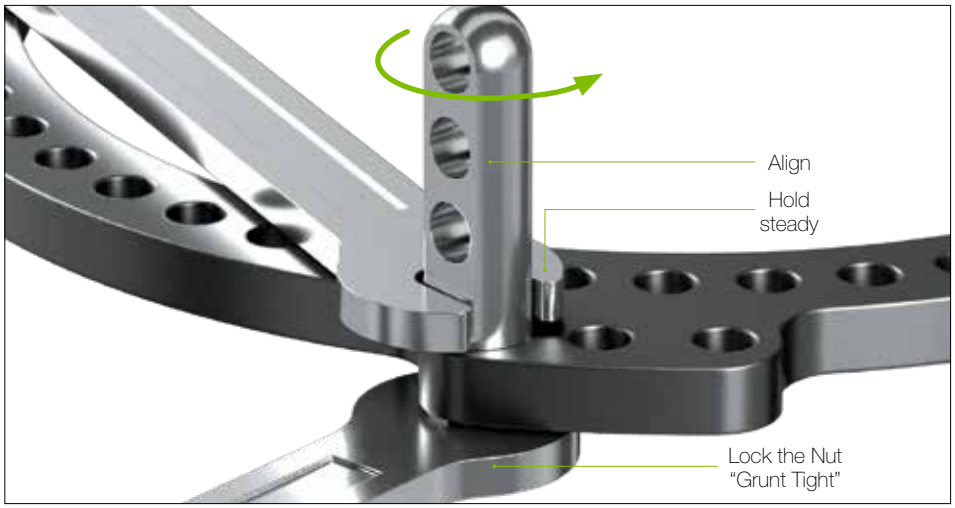


Figure 74

Quick Connect Struts – Key Features at a Glance

The Quick Connect Struts come in three adjustable length ranges and have a number of integrated features that allow both incremental and acute compression or distraction to facilitate fracture fixation and bone segment alignment (Fig. 75).

They likewise feature universal (but non-lockable) joints on both ends to perform acute deformity corrections and assist with fracture reductions. The universal joint on the threaded end of the Strut is detachable (the universal joint on the opposite end is permanently attached) and a built-in, Incremental Adjustment/ Counting Knob facilitates the patient's ability to make accurate, 1/4 turn revolutions for the purposes of precisely measured 1/4mm adjustments. When the Quick Adjustment Release Sleeve is pushed downward, the Incremental Adjustment Knob is disengaged and the length of the Strut may be acutely regulated.

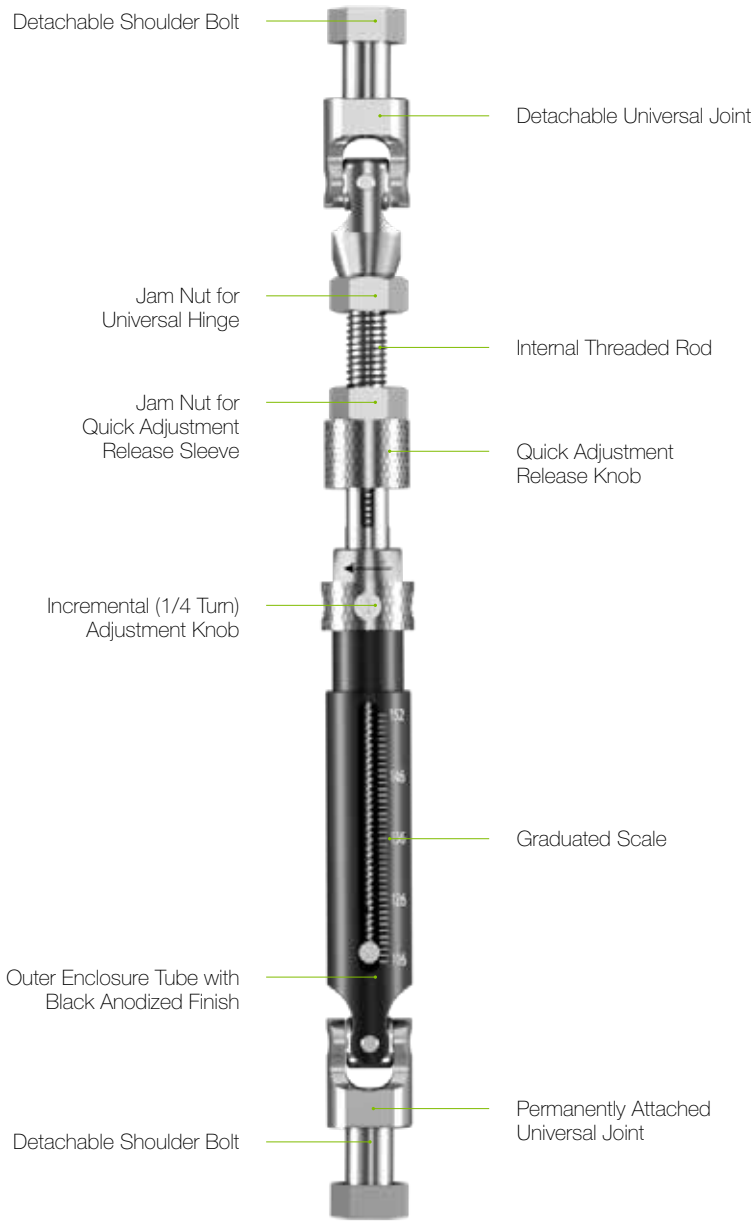


Figure 75

Fundamental Guidelines

Converting Struts to Lockable Mode

Typically, when used for the purposes of acute correction and/or fracture reductions, the construct needs to be locked after the desired frame orientations have been finalized.

This is necessary to maintain proper bone alignment throughout the treatment process. Lockability is achieved by means of replacing the removable universal joint on the threaded end of the Strut with a simple hinge element consisting of a pair of One-Hole Female Posts (or a combination of a One-Hole Female Post coupled with a One-Hole Male Post).

All components and instruments needed for the Strut conversion are shown in Figure 76 and assume a need for four struts.

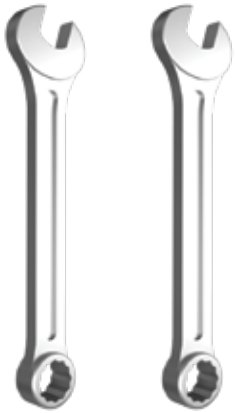
4 x Quick Connect Struts of Required Length

8 x FP-100 Female Posts (1-Hole)

4 x B-M6-1-16 Bolts (16mm)

4 x N-10 Nuts

1 x AW-10 10mm Angled Wrench



2 x OW-10 10mm Open Wrenches

Figure 76

Step 1

Using the two Open Wrenches, remove the universal joints from the threaded ends of all Quick Connect Struts that will be needed for the construct.

Leave the associated jam nuts in place as shown in Figure 77.

Remove the universal joints by backing off the jam nuts and turning the joints counter clockwise, but do not discard the shoulder bolts; you will need them later to attach the Struts to the Rings

Leave the jam nuts on the threaded rods, you will need them later

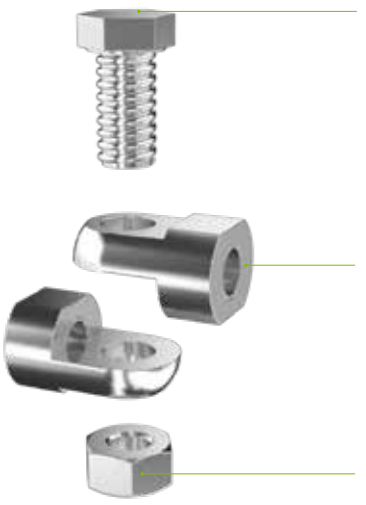
Figure 77

Step 2

Prebuild four basic hinge mechanisms using the 1-Hole Female Posts with 16mm Bolts and 10mm Nuts as shown in Figure 78.

Note:
The FusionFrame Tray contains four of the FP-100 Female Posts; you will need to order an additional four for this conversion. Alternatively, you may substitute with four MP-100 Male Posts. Also, keep in mind that you may likewise need to order further additional posts if they are also being used elsewhere in the construct. The same goes for any additional Nuts and Bolts you may require for other sections of the Frame. Keep track of what you are using and what is needed. All extra parts may be placed in the miscellaneous compartment of the tray.

Note:
To prevent the hinge mechanisms from loosening in the final construct, it may be desirable to utilize “double-stacked” Nuts as shown in figures 81 and 82.



16mm Bolt (B-M6-1-16)

1-Hole Female Posts (FP-100)

10mm Nut (N-10); leave this Nut “finger tight” for now

Figure 78

Fundamental Guidelines

Step 3

Affix the prebuilt hinge mechanisms to each of the four Quick Connect Struts onto the internal threaded rods and tighten the hinge assembly with a nut that is initially secured “finger tight” as shown in Figure 79.

Use the Strut Bolts shown in section “S” of the FusionFrame Tray layout diagram on page 57 to connect this end of the Strut to the Ring in your frame construct. Initially, these bolts will be applied “finger tight to allow the Struts to rotate during alignment and reduction adjustments of the frame. Once all adjustments have been made, these bolts will be locked “grunt tight.”

The hinge Nuts will be initially finger tight, allowing the hinge mechanisms to move freely until all Struts are in their desired alignment and orientation and are ready to be locked. Once this alignment has been achieved, the Nuts will be locked “grunt tight.”

The Nuts attaching the hinge assemblies to the threaded rod must be fastened “grunt tight.”

The jam nuts for the quick adjustment release knobs of the Struts need to remain opened until all Struts are in their desired alignment and orientation.

The sleeves of the quick adjustment release knobs will remain open until all Struts are ready to be locked in their desired alignment and orientation. Once desired positioning has been achieved, the sleeve is closed.

The distal Strut Bolts will be initially finger tight to allow the Struts to rotate while adjustments are being made. Once desired alignment and orientation have been achieved, the strut bolts will be locked “grunt tight.”

Figure 79

The initially loose connections on all Struts permit full range of motion of the hinges, universal joints and length settings so that the bone segments may be properly aligned and reduced before final locking. Once the desired orientation of the Frame is achieved, all connections will be locked, starting with the shoulder bolts on both ends of the Struts. This locks in all rotational settings and is best done by using the Angled Wrench on the bolt heads and an Open Wrench on the flat surfaces of the hinges and joints. The 16mm Bolts interconnecting the two-piece Hinge mechanisms on all Struts will be tightened next, to lock in the angular settings of the Frame.

As a last step, the Quick Adjustment Release Knobs on all struts will be locked down (see Figure 80). The Incremental Adjustment Knobs may be used to dial in any fine tuning of the length settings prior to fastening the jam nuts. At this point, all connections must be fastened “grunt tight.” This will ensure that the entire Frame will maintain its position, in all axes, throughout the entire duration of the treatment process.

Once all connections are locked tightly, the Frame will be mechanically stable and secure and the Struts will hold all reductions and alignments in their proper orientations. If, at some point any post-surgical corrections are necessary, individual connections, or combinations of connections may be loosened to perform the required fine-tuning adjustments. Once these adjustments are completed, all connections are grunt-tightened once again.

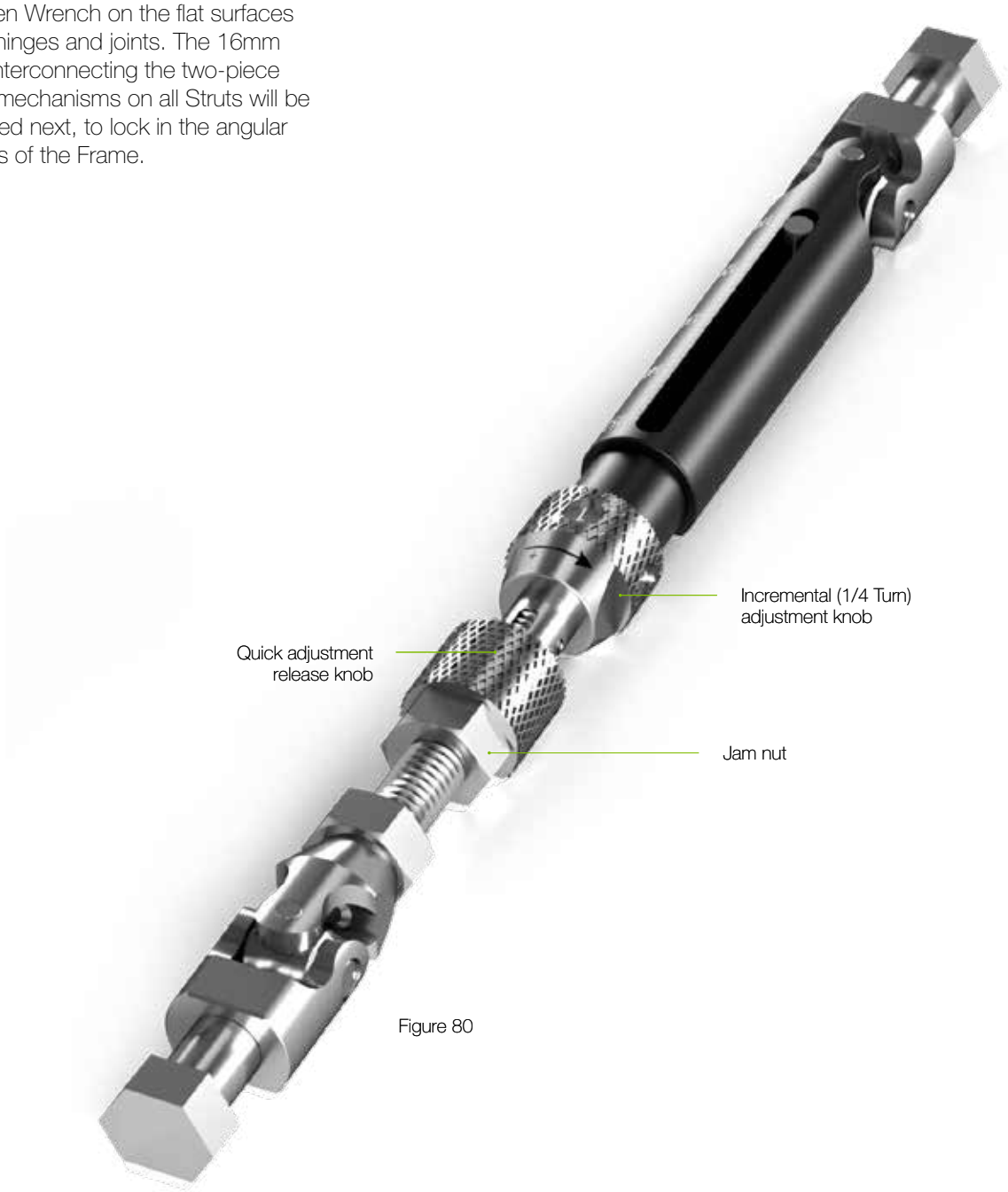


Figure 80

Fundamental Guidelines

Hinge Assembly

Simple hinges allow for controlled, gradual correction of skeletal deformities. Typically, two hinge pairs are used for each segment of bone that needs to be corrected. Each hinge pair is assembled as shown in Fig. 81.

The final assembly of the two hinge pairs is illustrated in Fig. 82.

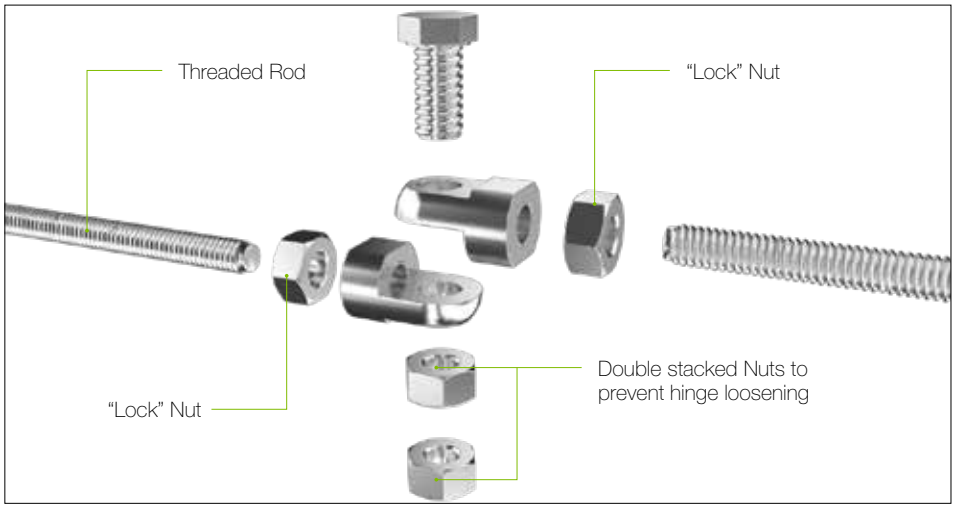


Figure 81

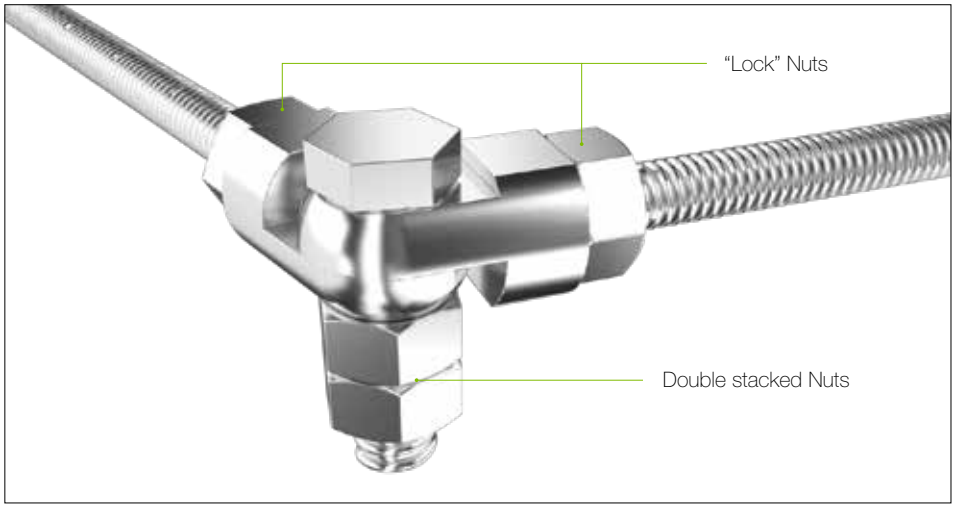


Figure 82

Wire and Pin Site Care

Wires and Half-Pins transmit the mechanical loads on the extremity to the scaffold of the frame, thereby subjecting the pin / soft tissue interface to potential discomfort, irritation and possible inflammation. These processes may lead to further complications which include possible infection and pin loosening, which may require removal of the infected pin. Consequently, a reliable and consistent pin care protocol is necessary.

Each entry and exit point of a Wire or Half-Pin represents an opening that must always be kept clean to minimize the chances or severity of infection. The patient and / or their family members and caregivers must be trained to take an active role in the post-operative treatment regimen and recovery period by treating the FusionFrame with care and by maintaining clean, dry pin sites. This regimen begins on the first day the fixator is applied and ends when the assembly is removed.

Pin sites should be cleaned regularly each day. It is recommended that the following supplies be available for each cleaning:

- Sterile water and cleansing solution (as prescribed by surgeon).
- Disposable cups for cleansing solution.
- Sterile gauze dressing.
- Sterile cotton swabs.
- Bag or other sealable container for waste disposal.

Fundamental Guidelines

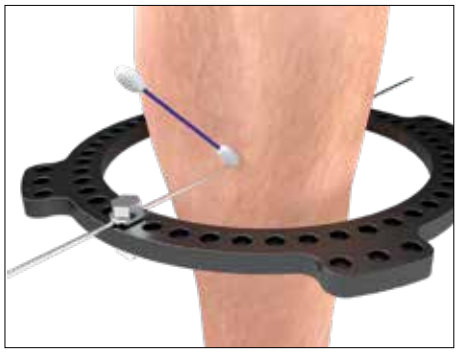
Proper pin site care is a simple, straightforward and painless procedure involving several, intuitive steps:

Wash Hands

The patient or caregiver must wash their hands thoroughly, including between fingers, underneath the fingernails and the backs of each hand. Hand washing is the single most important factor in preventing infection. A paper towel (not reusable cloth) should be used to dry hands and then be immediately disposed of in a sealable container.

Prepare the Pin Site

Wearing gloves, gently massage the skin around the pins with fingertips. This will help bring the drainage to the surface so that it may be cleaned away with greater efficiency and minimal effort.



Cleanse the Pin Site

Pour the cleansing solution into a disposable cup and saturate a sterile cotton swab in the solution. Using the cotton swab, gently apply the solution directly to one pin site at a time. Swab in a circular motion, always moving away from the pin, being certain to methodically wash the entire site. Gently remove any crust which may have formed around the site and do not neglect to change swabs as often as needed. After the drainage has been removed, dry the pin site with a new cotton swab. Repeat the process for each pin site, starting with a new sterile cotton swab for each site.

Cleanse the Pins

Clean the entire length of the Wire or Half-Pin with sterile gauze that has been soaked in the cleansing solution, using a new pad for each pin. Wrap sterile gauze loosely around the pin site and place fingers over the gauze, gently pressing it down on the skin around the pin site and secure in place. After the first several days when the pin sites are dry and upon instructions from the surgeon, the gauze should no longer be used as a cover, leaving the pin sites open and exposed to air.

Note:
Although systematic pin site care will greatly reduce the chances of deep infection, minor infections or other possibly more serious complications may still occur. Symptoms may include:

- Redness and/or swelling at pin sites
- Thick, colored or possibly foul-smelling discharge
- Loosening or movement of pins
- Persistent soreness or pain at pin sites

Oral antibiotics may be prescribed for persistent or deepening infection. The medication must be taken as prescribed and until fully consumed by the patient. Pin sites must still be cleaned twice each day, even when antibiotics are being administered.

Overall Frame Care

The FusionFrame should be cleaned using gauze and cleansing solution on a regular basis. Showering is usually permissible after the fixator has been worn for ten days (or as prescribed by the surgeon).While in the shower, the fixator should be gently cleaned and then thoroughly dried with a clean towel.

At the discretion of and upon instruction from the surgeon, swimming in a private, chlorinated pool is usually permissible. Swimming in fresh water lakes, ponds or rivers is contraindicated.

Ordering Information – Ring Lock System

External Supports

REF	Description	
F-FP-140-48	140mm Foot Plate	
F-FP-160-48	160mm Foot Plate	
F-FP-180-48	180mm Foot Plate	
F-FP-205-48	205mm Foot Plate	
F-FR-140-48	140mm Full Ring	
F-FR-160-48	160mm Full Ring	
F-FR-180-48	180mm Full Ring	
F-FR-205-48	205mm Full Ring	
F-HF-140-48	140mm Half Ring	
F-HF-160-48	160mm Half Ring	
F-HF-180-48	180mm Half Ring	
F-HF-205-48	205mm Half Ring	
F-FER-140-48	5/8 Ring 140mm	
F-FER-160-48	5/8 Ring 160mm	
F-FER-180-48	5/8 Ring 180mm	
F-FER-205-48	5/8 Ring 205mm	
F-WP-TP	Tall Puck	Package of six complete units (Do not sterilize)

Connectors

REF	Description
TR-60	Threaded Rod 60mm
TR-85	Threaded Rod 85mm
TR-120	Threaded Rod 120mm
TR-165	Threaded Rod 165mm
TR-200	Threaded Rod 200mm
TR-250	Threaded Rod 250mm
TR-300	Threaded Rod 300mm
TR-400	Threaded Rod 400mm
QCS-100-115	Quick Connect Strut 100-115mm
QCS-116-152	Quick Connect Strut 116-152mm
QCS-150-210	Quick Connect Strut 150-210mm

FOS-70-M	Oblique Support

Ordering Information – Ring Lock System

Connectors

	REF	Description
	F-H90-10	90° Hinge / Twisted Hinge
	F-UH-10	Universal Hinge
	P-20	Plate 20mm
	P-30	Plate 30mm
	TS-40	Threaded Socket 40mm
	TS-60	Threaded Socket 60mm

Fasteners

	REF	Description
	N-10	Nut 10mm
	CN-10	Counting Nut 10mm
	SW-300	Slotted Washer (3.0mm thick)
	TW-150	Thick Washer (1.5mm thick)
	TW-200	Thick Washer (2.0mm thick)
	F-WFB-M6-17	Wire Fixation Bolt
	F-PFB-10-M6	Pin Fixation Bolt
	F-PFC-100	Half-Pin Fixation Cube 1 Hole
	F-PFC-200	Half-Pin Fixation Cube 2 Hole
	F-PFC-300	Half-Pin Fixation Cube 3 Hole
	F-PFC-400	Half-Pin Fixation Cube 4 Hole
	B-M6-1-12	Bolts (12mm)
	B-M6-1-16	Bolts (16mm)
	B-M6-1-20	Bolts (20mm)
	CW-80	Conical Washer Couple

Ordering Information – Ring Lock System

Posts

REF	Description
MP-100	Male Post (1-Hole)
MP-200	Male Post (2-Hole)
MP-300	Male Post (3-Hole)
MP-400	Male Post (4-Hole)
FP-100	Female Post (1-Hole)
FP-200	Female Post (2-Hole)
FP-300	Female Post (3-Hole)
FP-400	Female Post (4-Hole)

Implants

REF	Description
W-18-430S	Smooth Wire Ø1.8mm; 430mm length
W-18-430P	Olive Wire Ø1.8mm; 430mm length

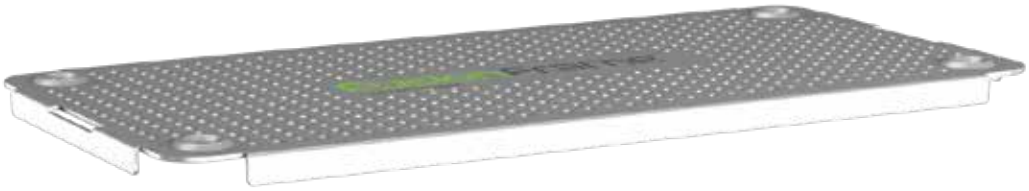
Implants

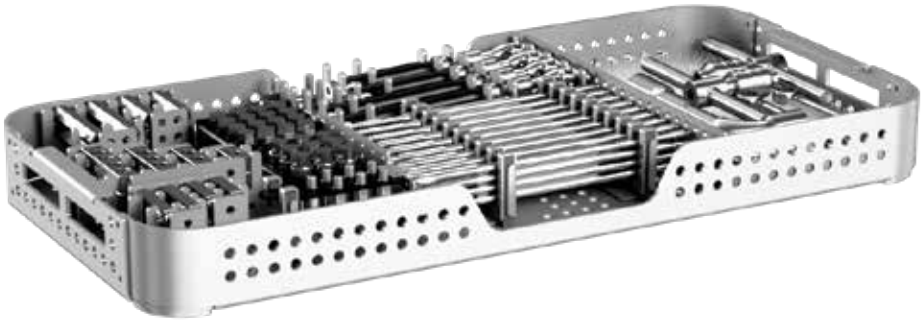
REF	Description
F-HP-6-5-20-180	Half Pin Ø6mm / Ø5mm Thread / 20mm Thread length
F-HP-6-5-25-180	Half Pin Ø6mm / Ø5mm Thread / 25mm Thread length
F-HP-6-5-30-180	Half Pin Ø6mm / Ø5mm Thread / 30mm Thread length
F-HP-6-5-35-180	Half Pin Ø6mm / Ø5mm Thread / 35mm Thread length
F-HP-6-5-40-180	Half Pin Ø6mm / Ø5mm Thread / 40mm Thread length
F-HP-6-6-20-180	Half Pin Ø6mm / Ø6mm Thread / 20mm Thread length
F-HP-6-6-25-180	Half Pin Ø6mm / Ø6mm Thread / 25mm Thread length
F-HP-6-6-30-180	Half Pin Ø6mm / Ø6mm Thread / 30mm Thread length
F-HP-6-6-35-180	Half Pin Ø6mm / Ø6mm Thread / 35mm Thread length
F-HP-6-6-40-180	Half Pin Ø6mm / Ø6mm Thread / 40mm Thread length
F-HP-6-6-50-180	Half Pin Ø6mm / Ø6mm Thread / 50mm Thread length

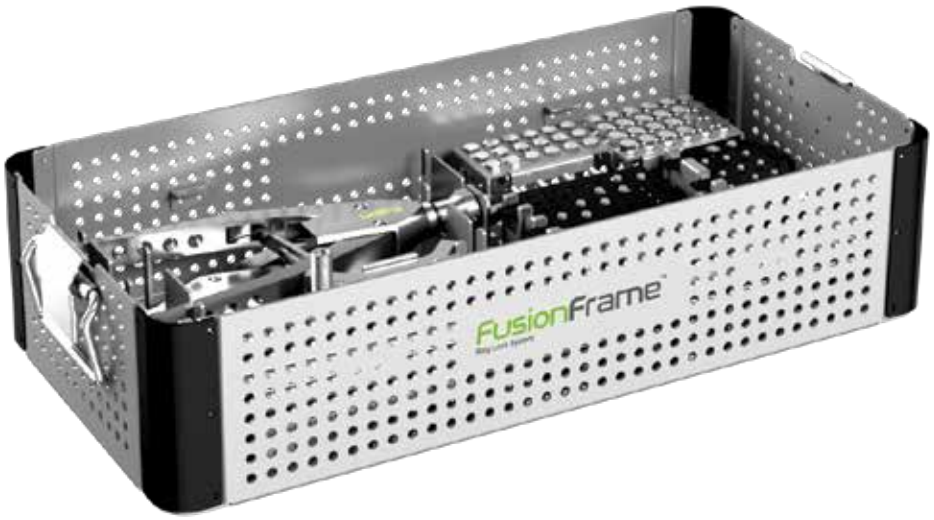
Instruments

REF	Description
F-WT-500	Wire Tensioner
F-HP-TW	T-wrench 6mm
F-HP-TW-6	T-wrench adapter Ø6mm
OW-10	10mm Open Wrench
AW-10	10mm Angled Wrench
RLS-1000	System Tray (See Pages 47-51 for detailed description)

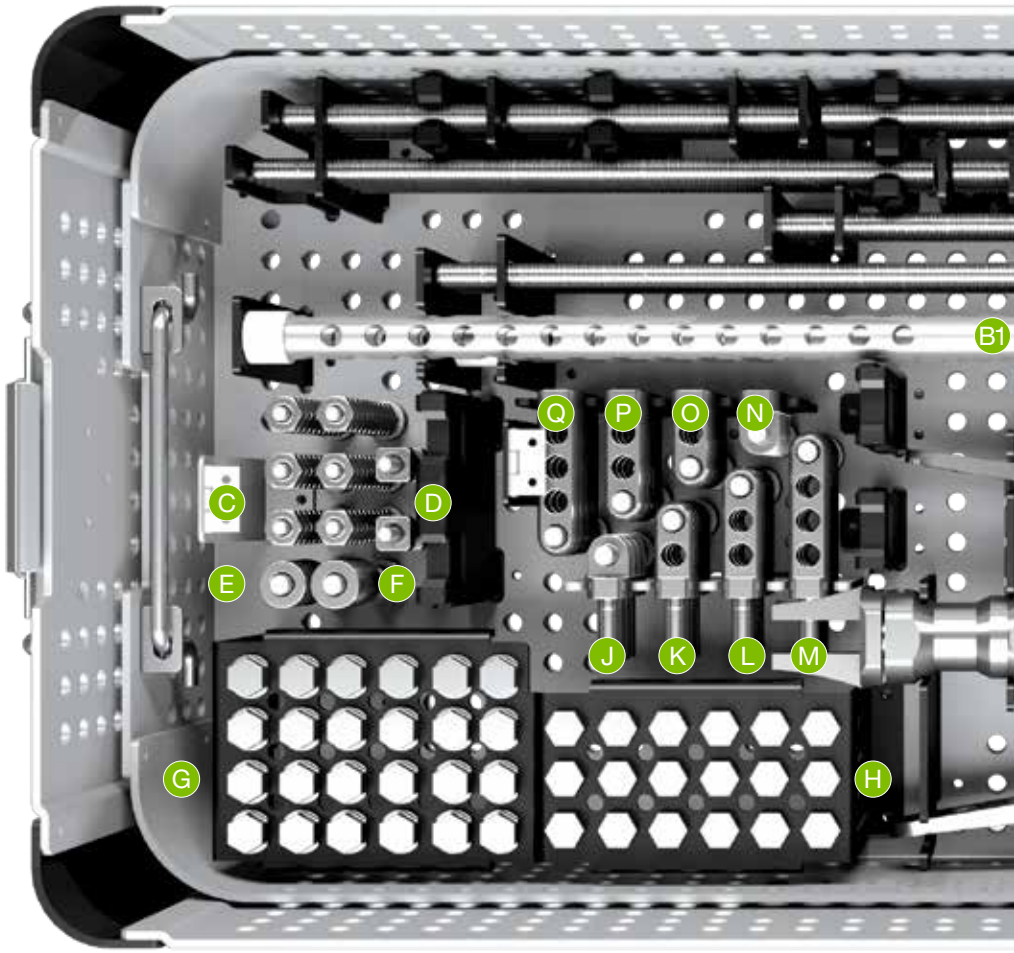
FusionFrame System Tray





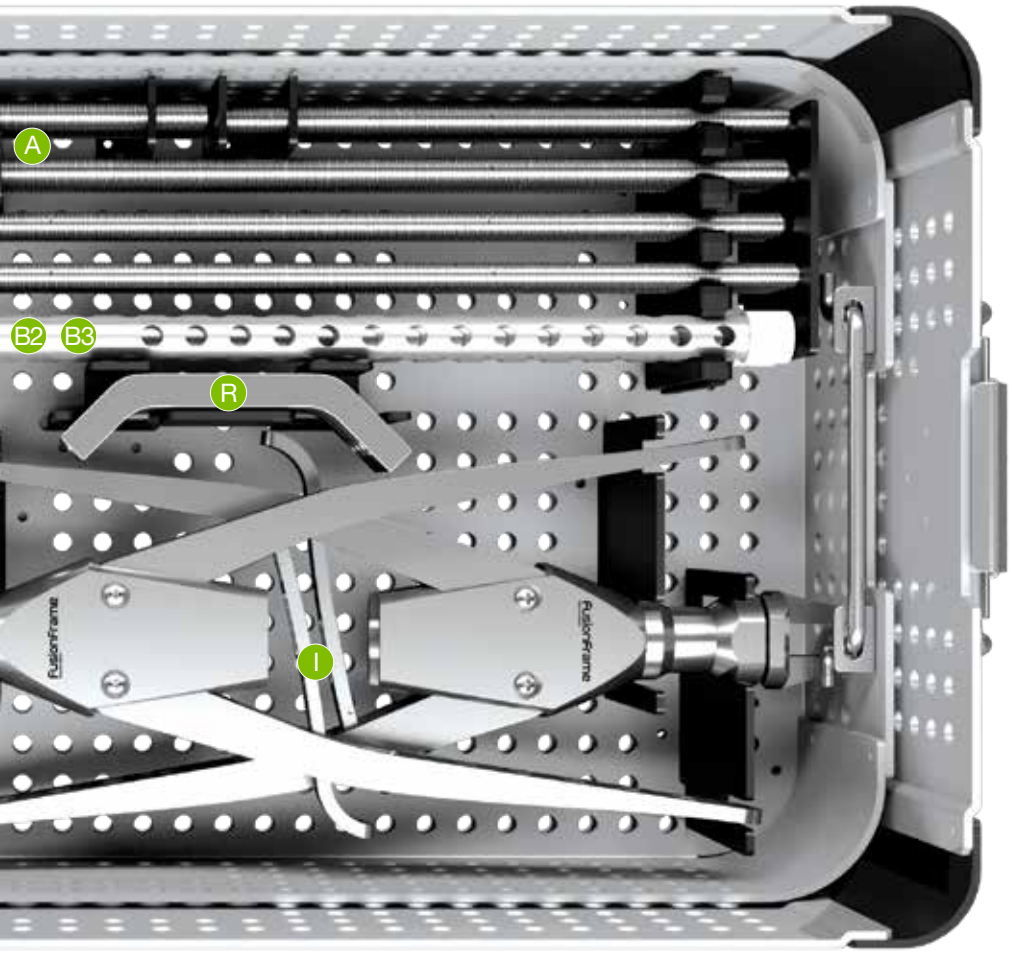


Standard System Tray – Layout



FusionFrame Components

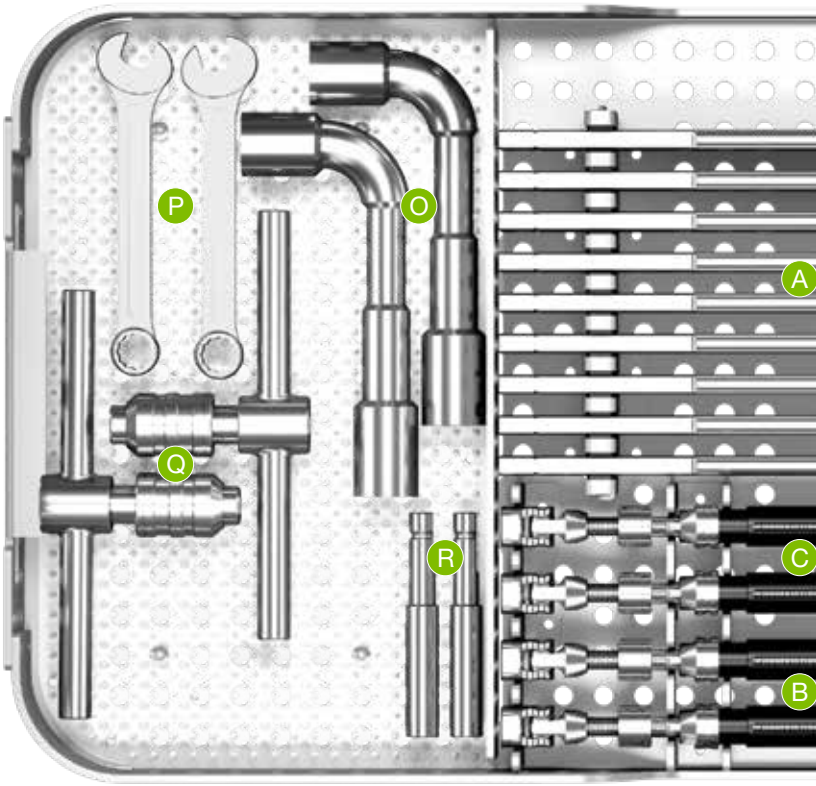
	Part#	Description	QTY
A	TR-60	60mm Threaded Rods	4
	TR-85	85mm Threaded Rods	4
	TR-120	120mm Threaded Rods	4
	TR-165	165mm Threaded Rods	4
	TR-200	200mm Threaded Rods	4
	TR-250	250mm Threaded Rods	4
	TR-300	300mm Threaded Rods	4
	TR-400	400mm Threaded Rods	4
B1	W-18-430S	Smooth Wires	12
B2	W-18-430P	Olive Wires	6
B3	W-18-430P	Olive Wires	6
C	N-10	Nuts	60
D	CN-10	Counting Nuts	6
E	TW-150	Thick Washer 1.5mm	8
	TW-200	Thick Washer 2.0mm	8
F	SW-300	Slotted Washers	8
G	F-WFB-M6-17	Wire Fixation Bolts	24



FusionFrame Components

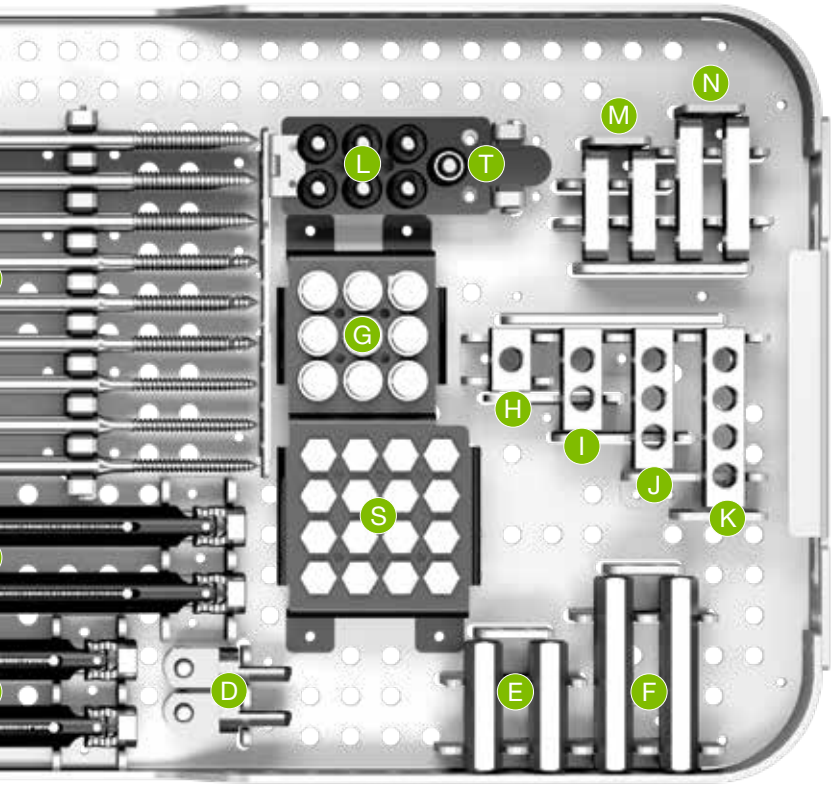
	Part#	Description	QTY
H	B-M6-1-12	12mm Bolts	6
	B-M6-1-16	16mm Bolts	6
	B-M6-1-20	20mm Bolts	6
I	F-WT-500	Wire Tensioners	2
J	MP-100	Male 1 Hole Posts	4
K	MP-200	Male 2 Hole Posts	4
L	MP-300	Male 3 Hole Posts	4
M	MP-400	Male 4 Hole Posts	4
N	FP-100	Female 1 Hole Posts	4
O	FP-200	Female 2 Hole Posts	4
P	FP-300	Female 3 Hole Posts	4
Q	FP-400	Female 4 Hole Posts	4
R	FOS-70-M	Oblique Supports	3

Standard System Tray – Layout



FusionFrame Components

	Part#	Description	QTY
A	F-HP-6-5-20-180	Half Pin Ø6mm/Ø5mm Thread/ 20mm Thread length	2
	F-HP-6-5-25-180	Half Pin Ø6mm/Ø5mm Thread/ 25mm Thread length	2
	F-HP-6-5-30-180	Half Pin Ø6mm/Ø5mm Thread/ 30mm Thread length	4
	F-HP-6-5-35-180	Half Pin Ø6mm/Ø5mm Thread/ 35mm Thread length	2
	F-HP-6-5-40-180	Half Pin Ø6mm/Ø5mm Thread/ 40mm Thread length	2
	F-HP-6-6-20-180	Half Pin Ø6mm/Ø6mm Thread/ 20mm Thread length	2
	F-HP-6-6-25-180	Half Pin Ø6mm/Ø6mm Thread/ 25mm Thread length	2
	F-HP-6-6-30-180	Half Pin Ø6mm/Ø6mm Thread/ 30mm Thread length	2
	F-HP-6-6-35-180	Half Pin Ø6mm/Ø6mm Thread/ 35mm Thread length	2
	F-HP-6-6-40-180	Half Pin Ø6mm/Ø6mm Thread/ 40mm Thread length	2
	F-HP-6-6-50-180	Half Pin Ø6mm/Ø6mm Thread/ 50mm Thread length	2
B	QCS-116-152	Quick Connect Strut 116-152mm	4
C	QCS-150-210	Quick Connect Strut 150-210mm	4
D	F-H90-10	90° Hinge / Twisted Hinge	4
E	TS-40	Threaded Socket 40mm	4
F	TS-60	Threaded Socket 60mm	4
G	F-PFB-10-M6	Pin Fixation Bolt	9



FusionFrame Components

	Part#	Description	QTY
H	F-PFC-100	Half-Pin Fixation cube 1 Hole	2
I	F-PFC-200	Half-Pin Fixation cube 2 Hole	2
J	F-PFC-300	Half-Pin Fixation cube 3 Hole	2
K	F-PFC-400	Half-Pin Fixation cube 4 Hole	2
L	CW-80	Conical Washer Couple	16
M	P-20	Plate 20mm	4
N	P-30	Plate 30mm	4
O	AW-10	Angled Wrenches	2
P	OW-10	Open Wrenches	2
Q	F-HP-TW	T-Wrench 6mm	2
R	F-HP-TW-6	T-wrench adapter Ø6mm	2
S	N/A	Strut Bolt	16
T		Washers (User's choice, miscellaneous)	16 (Maximum)

Notes

Notes

Notes

Notes

FusionFrame™
Ring Lock System

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

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