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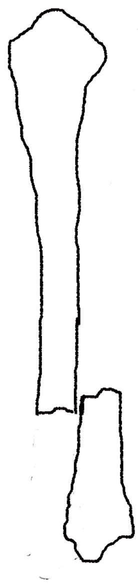
MINI LINEAR RADIOLUCENT FIXATOR POLILOCK

BINARY RADIOLUCENT FIXATOR

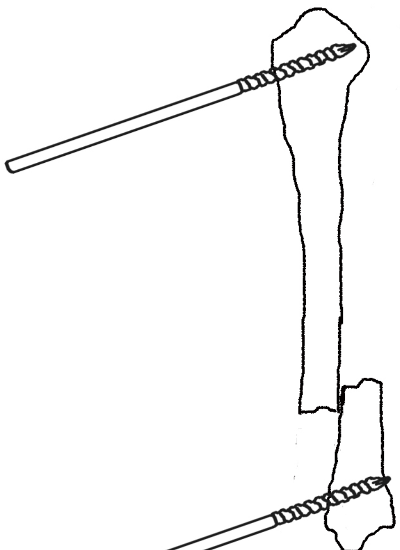
DYNAMIZABLE LINEAR EXTERNAL FIXATOR

TECHNIQUE FOR STABILIZATION OF A DISTAL TIBIA FRACTURE BY MINI RADIOLUCENT LINEAR FIXATOR

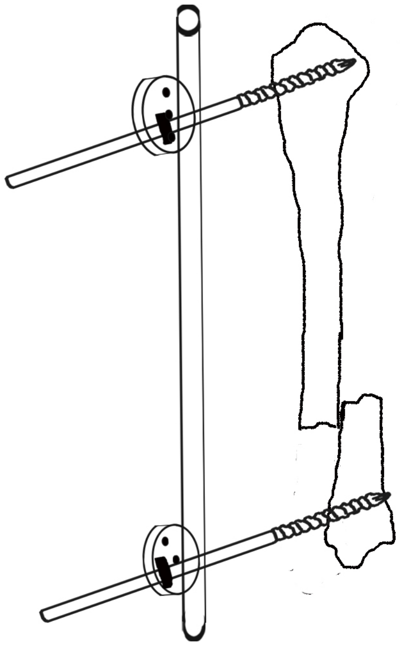
Distal tibia fracture with dislocation



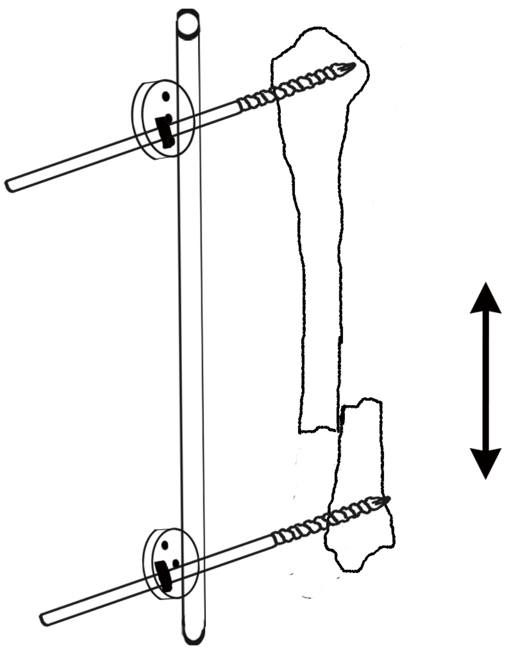
Insert a pin at the proximal end of the proximal bone segment, and at the distal end of the distal one.



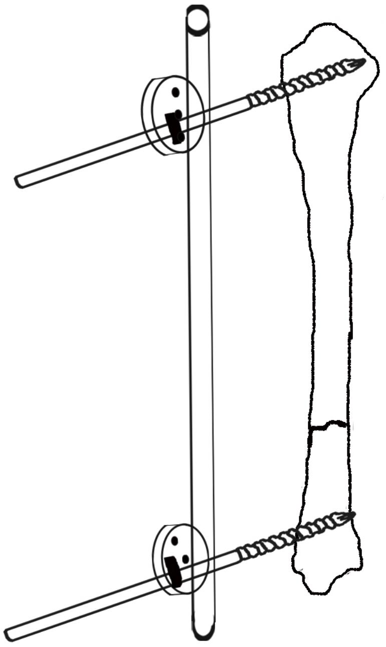
Connect the pins to clamps on a carbon connecting bar, but don't tighten them. Take care the length of the bars is enough to distract the fracture.



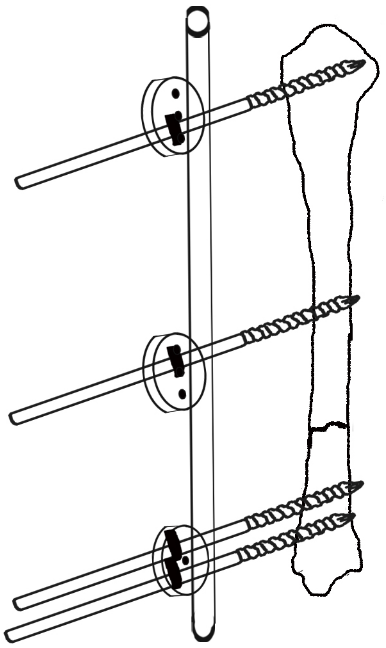
Holding the pins, apply a distraction force to the fracture area.



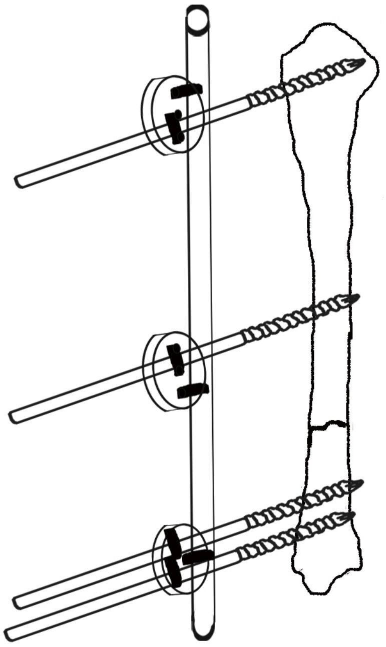
As soon as the fracture is reduced, firmly secure the pin to the clamp, in order to stabilize the fracture.



Add a second pin to the clamp in the distal fragment, and a second pin with a second clamp to the proximal one.

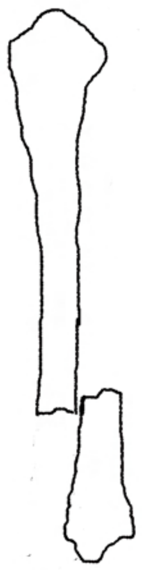


Lock each clamp to the connecting bar. Complete the stabilization as required by the fracture features.

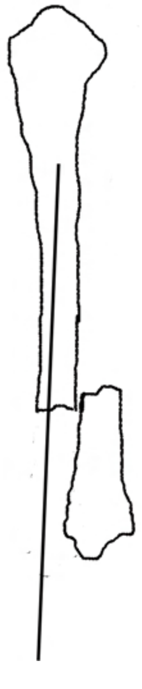


TECHNIQUE FOR STABILIZATION OF A DISTAL TIBIA FRACTURE BY TIE-IN RADIOLUCENT LINEAR FIXATOR

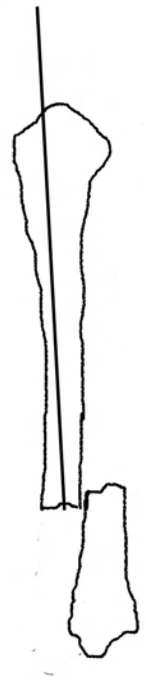
Distal tibia fracture with dislocation



Insert a small-diameter IM pin in a retrograde fashion, starting from the distal end of the proximal fragment.

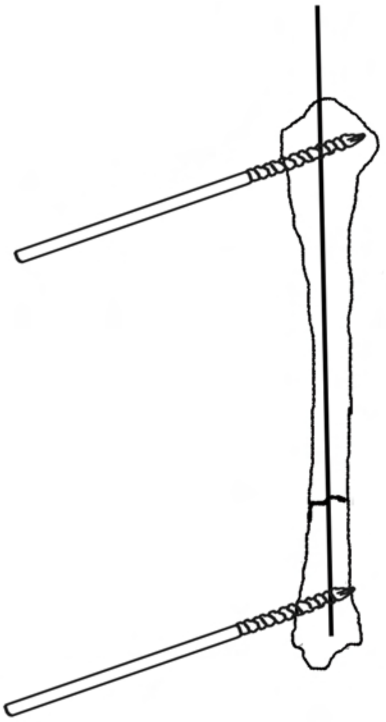


Exit the pin from the proximal tibia, and retract it from the proximal end until the distal tip is barely visible at the fracture line. Take care it doesn't exit too much, to avoid it interferes during fracture reduction.

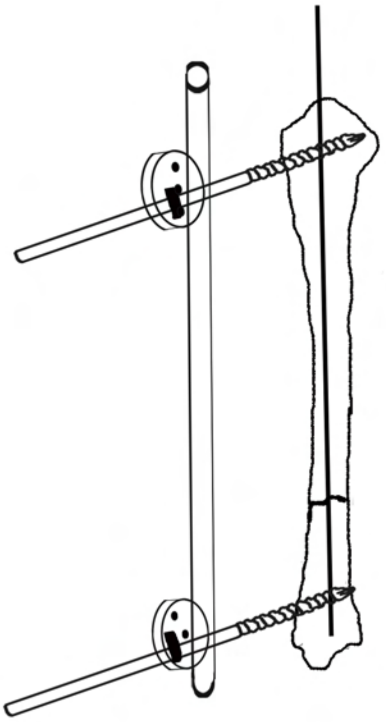


Reduce the fracture and stabilize it inserting the pin in the distal fragment.

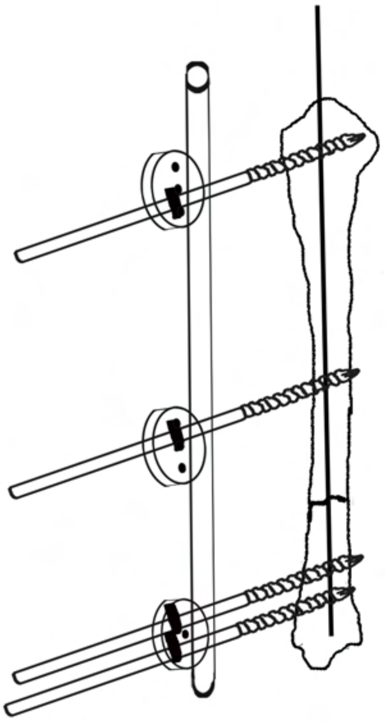
Insert a threaded pin in the most proximal and most distal area of the tibia.



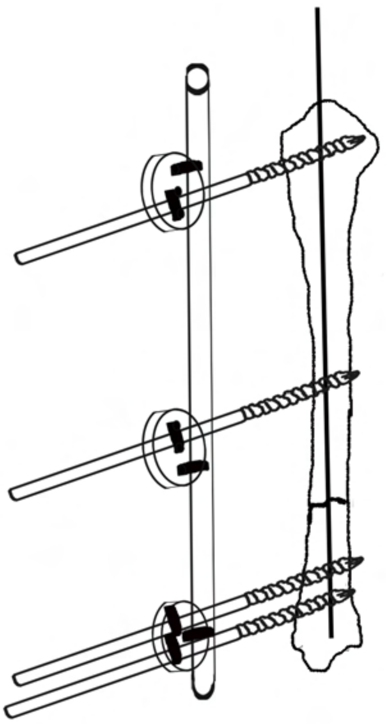
Stabilize the pins by a carbon bar and a hook each pean. DO NOT use any bar hook at this point of the procedure.



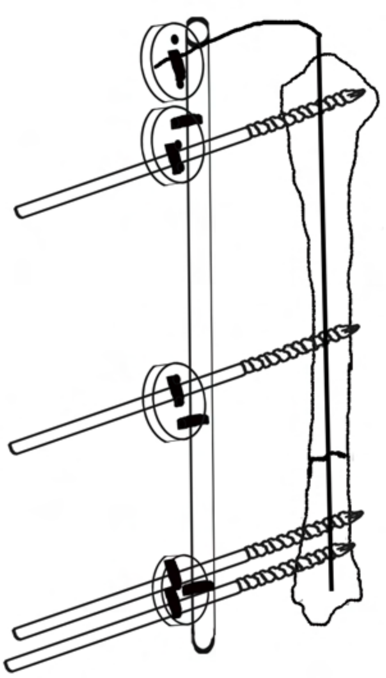
Insert one more pin in the distal part of the proximal fragment, and one in the proximal part of the distal one. The latter should be aligned to the proximal hole of the clamp.



When you are satisfied with the reduction, lock the clamps to the carbon bar by means of the bar hooks.

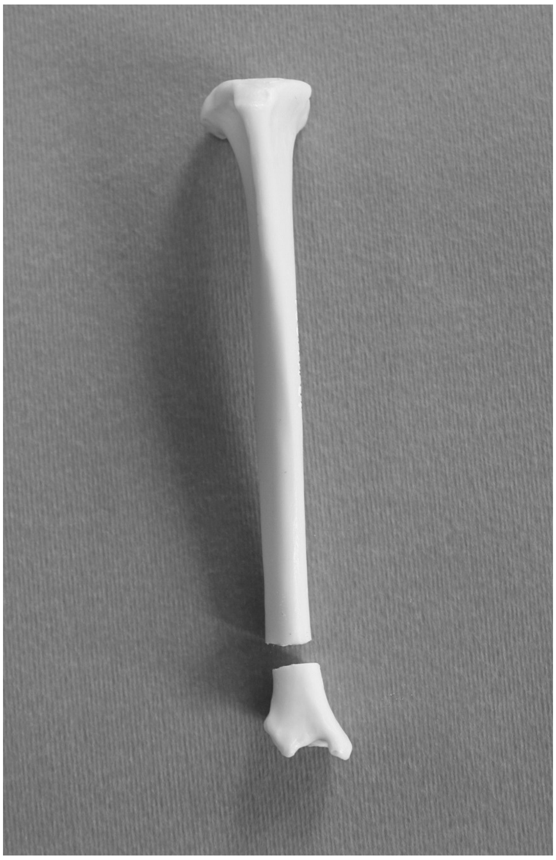


Bend the IM pin and connect it to the carbon bar by means of a clamp with a hook.

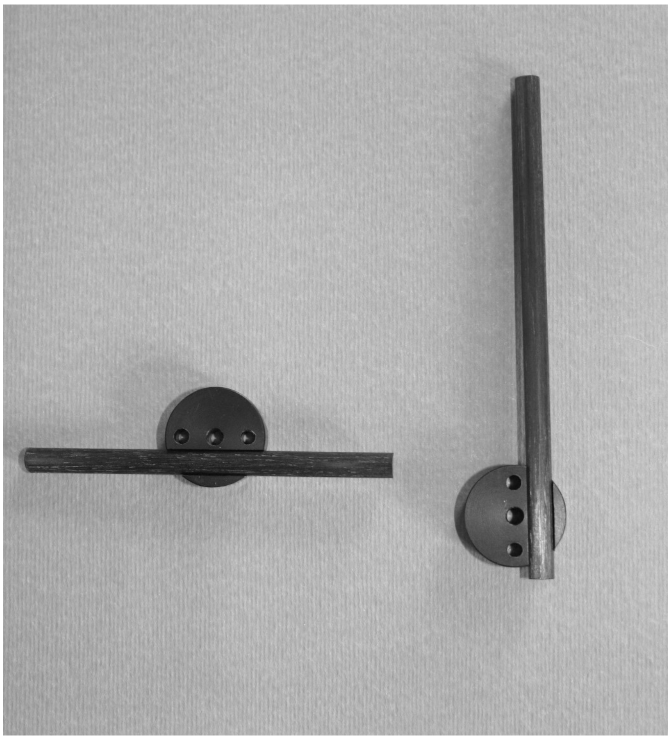


TECHNIQUE FOR STABILIZATION OF A DISTAL TIBIA FRACTURE BY T-FRAME RADIOLUCENT LINEAR FIXATOR

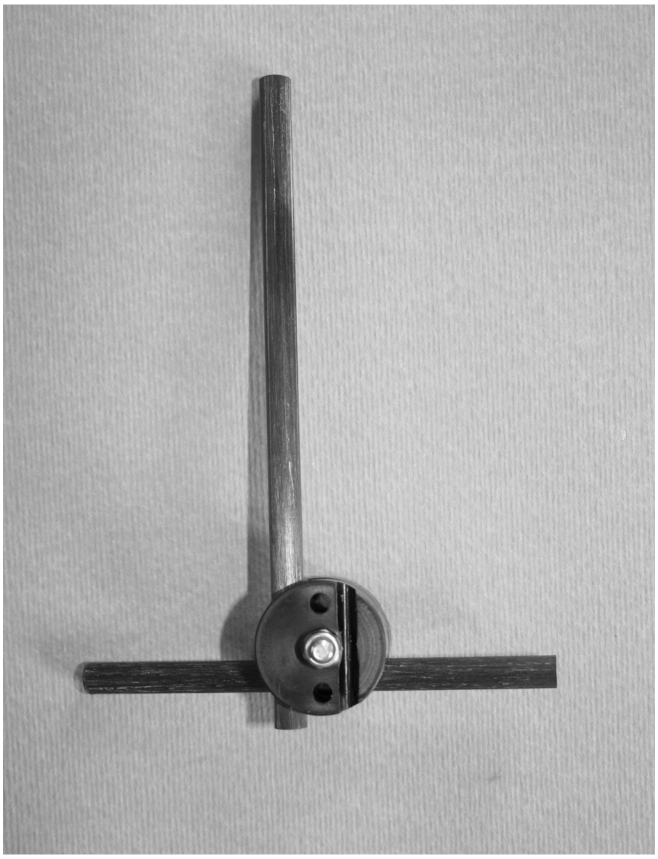
Very distal tibia fracture with dislocation



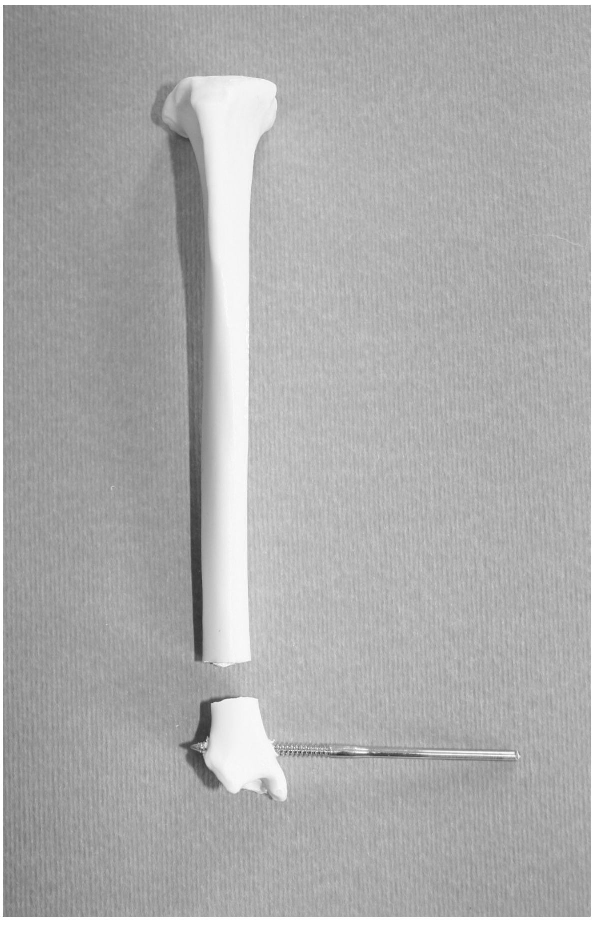
Insert a short and a longer carbon bar in the trough of each clamp with 3 aligned holes.



Connect the two bars tightening the double clamp by means of a M3 screw, in order to form a T frame.

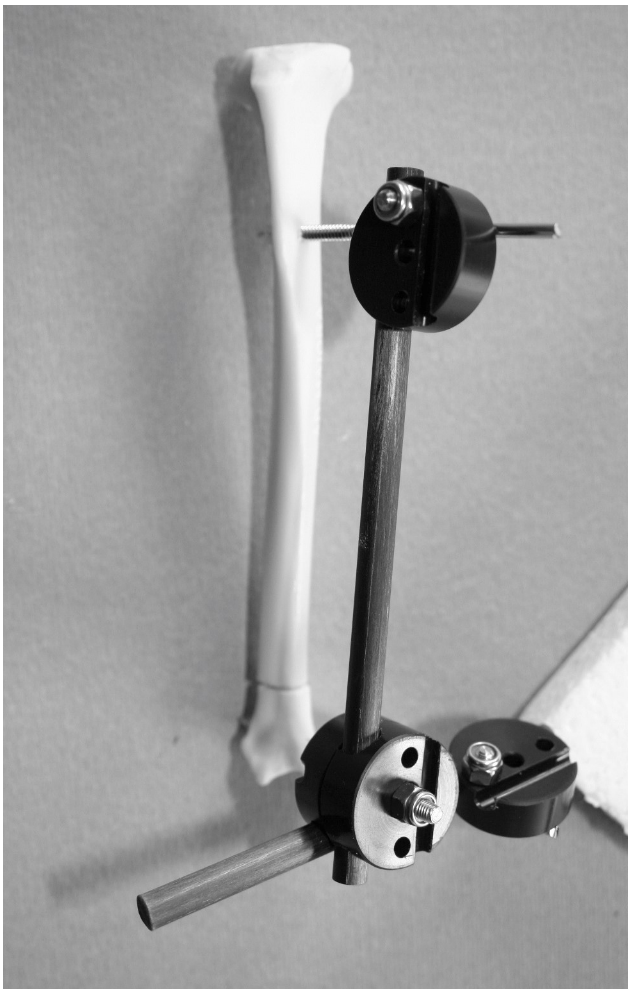


Insert a pin in the distal fragment from cranio-medial to caudo-lateral direction.



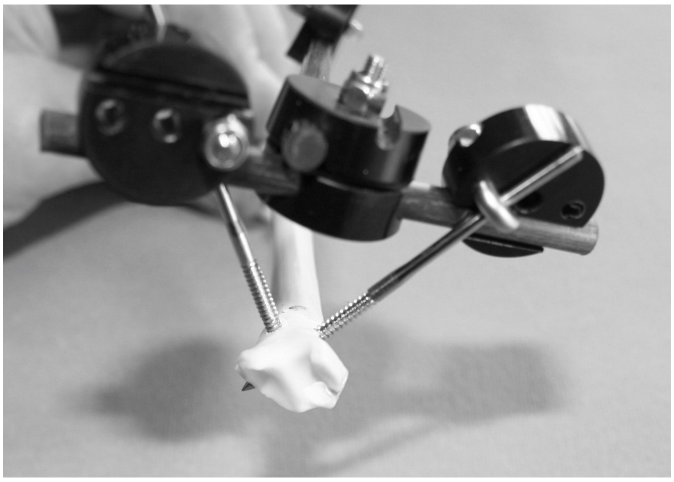
Connect the threaded pin to the shorter carbon bar by a clamp with a hook.

Insert a pin in the proximal fragment and stabilize the frame to the bone connecting it to the longer carbon bar by means of a clamp with a hook.

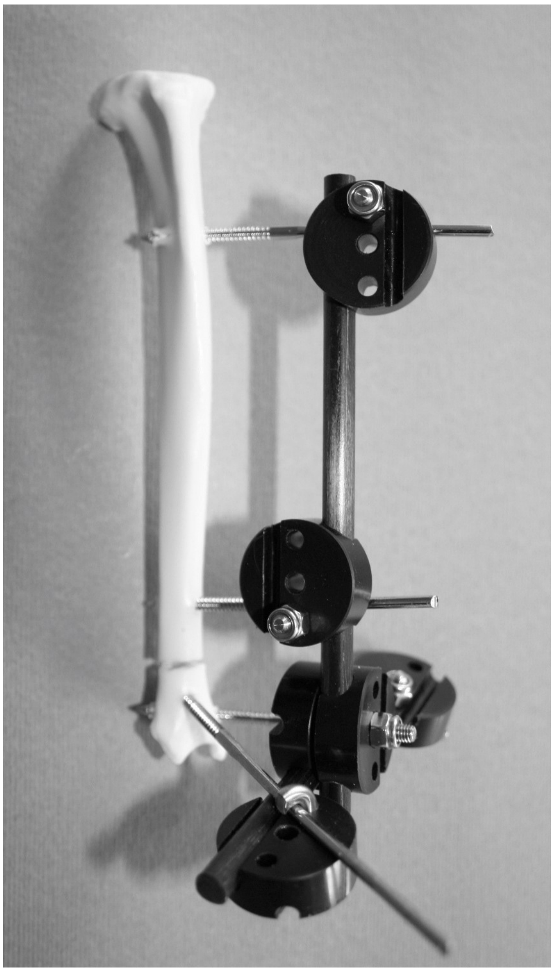


Insert one more pin in the distal fragment in a cranio-lateral to caudo-medial direction, and connect it to the shorter carbon bar by a clamp with a hook.

The angle between the pins is much more stable as they approach 90°.



Stabilize the proximal fragment adding pins as required, and stabilizing them to the longer carbon bar.

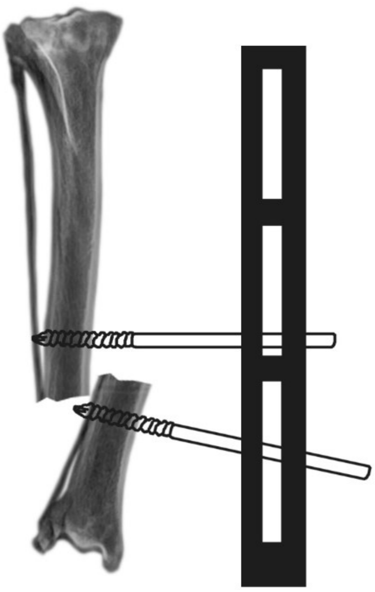


TECHNIQUE FOR REDUCTION AND STABILIZATION OF A DIAPHYSEAL TIBIAL FRACTURE BY A BINARY FIXATOR

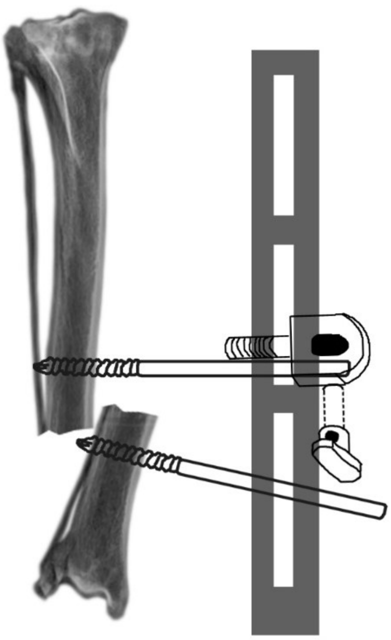
1. Fracture of the distal third of the tibial diaphysis

2. Insert a pin in each fragment close to the fracture site

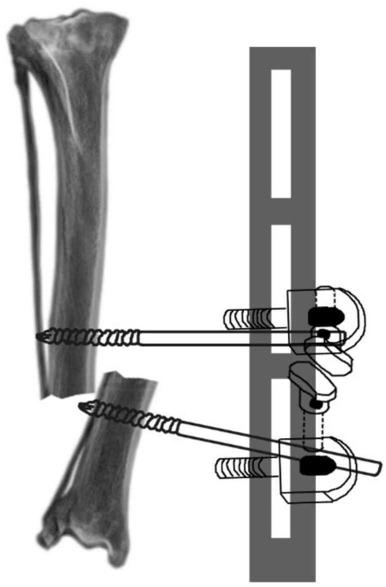
3. Select the binary fixator of the appropriate length



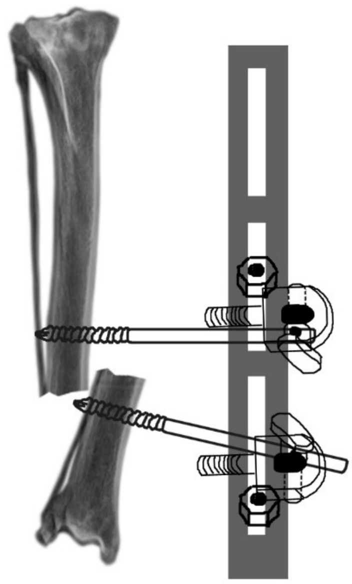
4. Connect the first pin to the binary by means of a post and a clamp, but don't tighten them



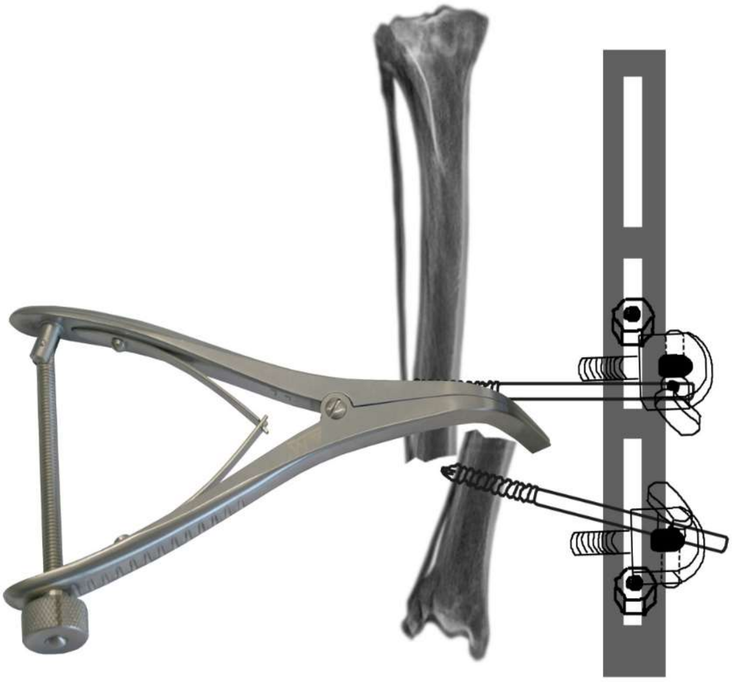
5. Do the same with the distal pin



6. Insert and lock a bolt proximally and distally to the posts



7. Introduce a distractor within the two pins



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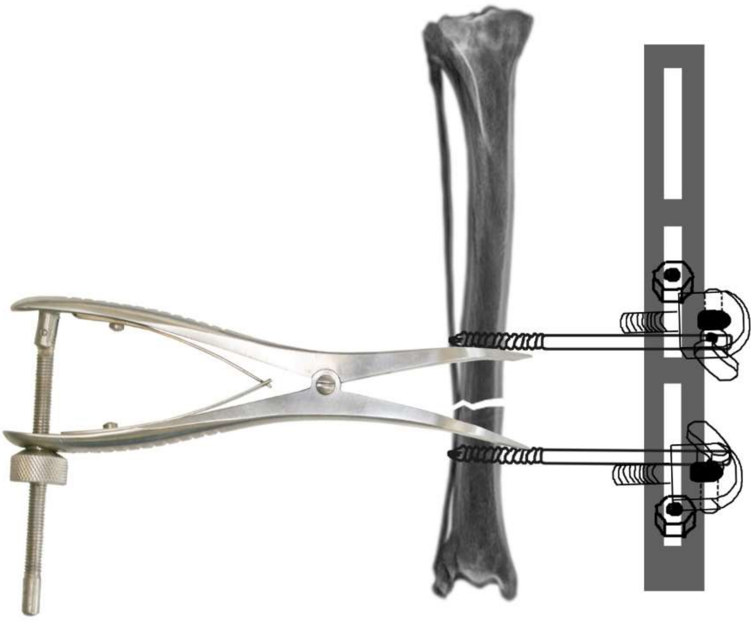
8. Progressively open the distractor, thus distracting the fracture until it can be reduced



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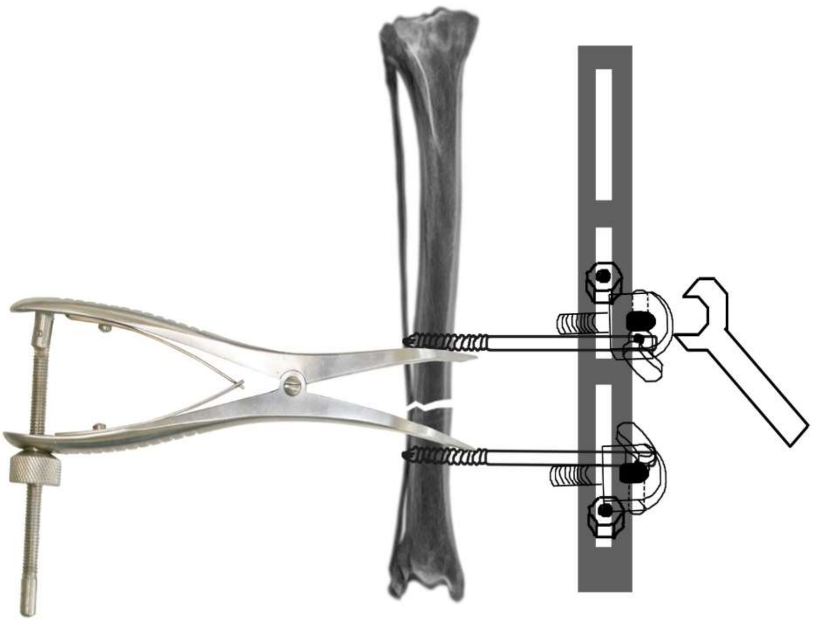
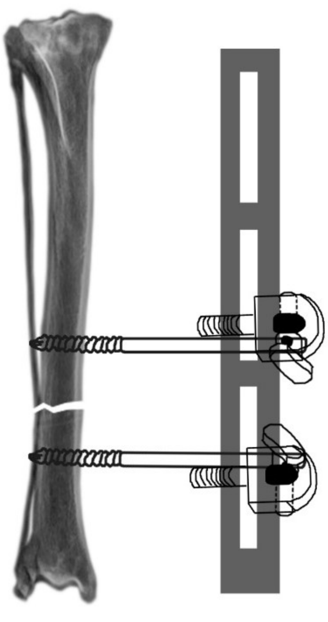
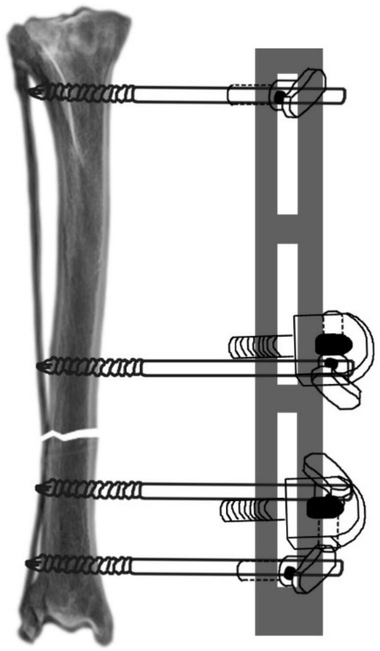
9. Once you're satisfied with the fracture reduction, thighten the post and clamp of both pins in order to stabilize them



10. Check for the fracture reduction, and adjust it as needed



11. Add pins as needed for further stabilization



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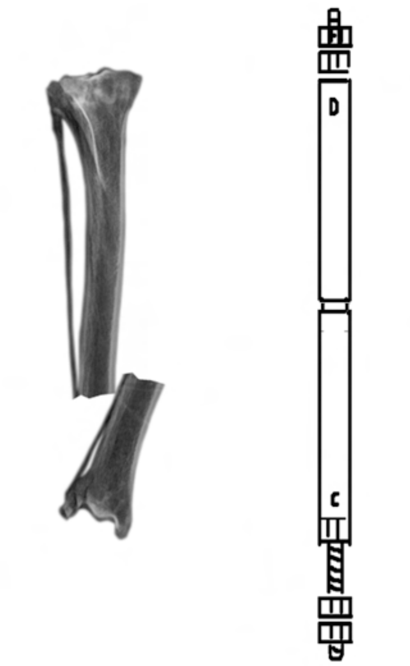
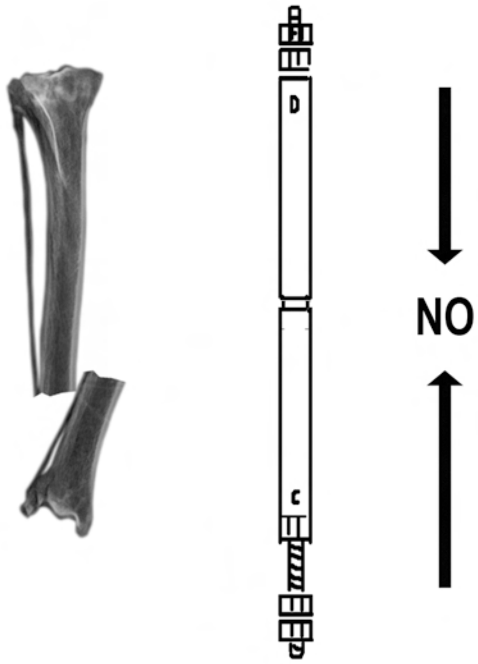
TECHNIQUE FOR REDUCTION AND STABILIZATION OF A DIAPHYSEAL TIBIAL FRACTURE BY A DYNAMIZABLE FIXATOR

Diaphyseal tibia fracture

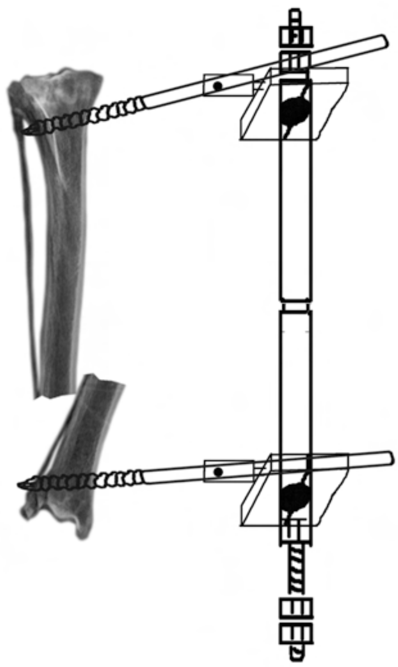
Select the fixator of the proper size. It should span the whole length of the tibia.



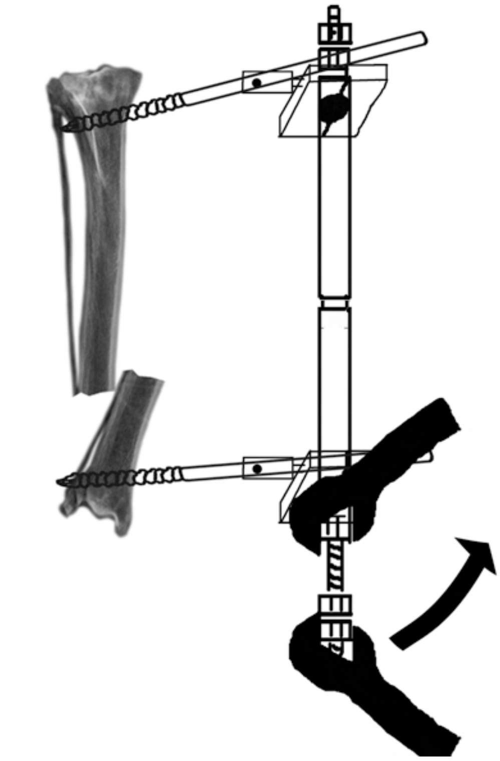
Check that the fixator is in the locked position, i.e. not dynamized. You can use it for intraop distraction only in this state.



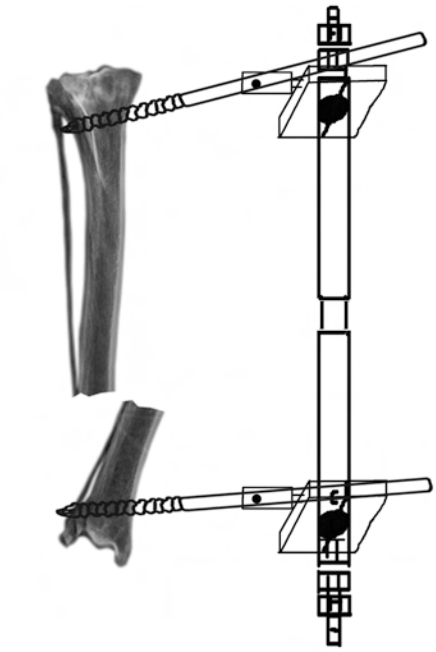
Connect the fixator to each bone stump by means of one threaded pin each, as close as possible to their proximal and distal extremity, respectively. Use clamps with the extension, in order to be able to direct the pins in every plane.



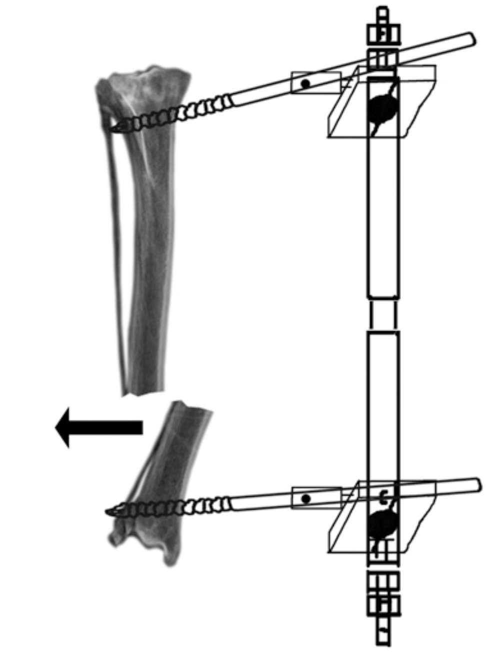
Distract the fracture by lengthening the fixator. Turn the coupled nuts on the C part of the fixator by a wrench, holding the extremity of the fixator by a second wrench.



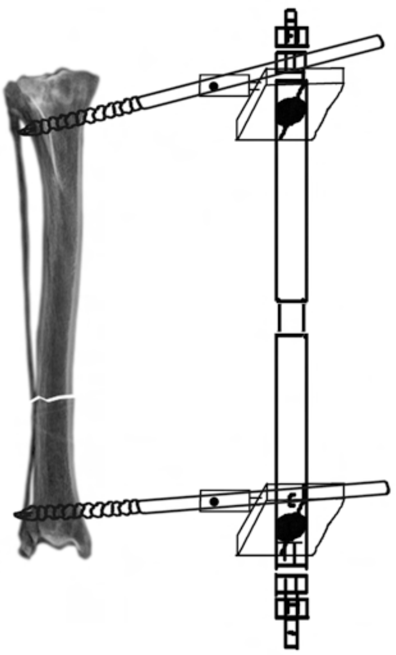
Proceed up to when the fragments are distracted so that they are no more superimposed. The fixator will lenghten during the procedure.



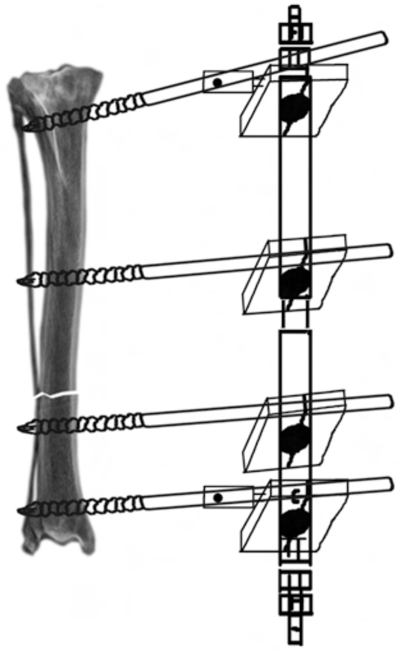
Perform the maneuvers required to correct the fragment axis and position. The clamp with extension will allow adjustments on every plane.



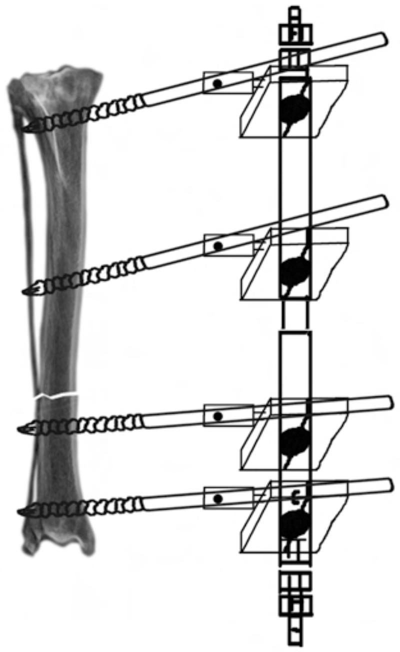
Achieve the correct fracture reduction BEFORE adding any further pin.



When you are satisfied with the reduction, add at least one pin to each fragment. For the intermediate pins it’s not usually necessary to use extensions, but remember the pin will stay perpendicular to the fixator’s axis.



If you need to have inclined pins due to the fracture features, it’s possible to use all the clamps with extensions, in order to hold them at the required angle.



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POLILOCK MINI SYSTEM

INSTRUCTIONS FOR USE

Important notice

Please read carefully the following instructions before applying the Polilock system on clinical patients. This is a veterinary surgical device and requires knowledge of its use and limitations. No attempts should be made to use the device for indications different from those the system was developed for. Any improper use will be under the responsibility of the user.

Description

The Polilock mini system is a radiolucent external fixation system aimed at the stabilization of fractures in small dogs and cats. In its basic frame configuration, i.e. single connecting bar and 2-3 pins for each fracture segment, the patient's weight should not exceed 5 kg. As usual for external fixation, the addition of pins, connecting bars, and changes in the frame structure may profoundly affect the biomechanical properties of the fixator, allowing its use in heavier patients. Being almost impossible to describe all the potential variations of the fixator features that are able to change its biomechanical properties, it is the surgeon's experience that dictates the patient's weight that fits a specific frame configuration. Nevertheless, in the following text suggestions will be given for specific situations, especially for those frame configurations at higher risk.

Kit components

The Polilock kit contains the following items.

1. Sterilization case (Code C00040008a)
2. Eight round clamps ø 20 mm, 3 aligned holes (Code M00010020a)
3. Four round clamps ø 20 mm, 3 offset holes (Code M00010021a)
4. Ten hooks ø 3 mm L 16,5x5 mm (Code G00010001a)
5. Six hooks ø 3 mm L 24,5x5 mm (Code G00010002a)
6. Six hooks ø 3 mm L 16,5x7.5 mm (Code G00010004a)
7. Twenty self-locking, stainless steel M3 nuts (Code D00010019a)

8. Twenty toothed stainless steel washer 3 mm hole (Code R00020006a)
9. Ten stainless steel screw M3x20 mm (Code V00020013a)
10. Two connecting carbon rods ø 5 mm 50 mm long (Code B00010010a)
11. Two connecting carbon rods ø 5 mm 75 mm long (Code B00010011a)
12. Two connecting carbon rods ø 5 mm 100 mm long (Code B00010001a)
13. Two connecting carbon rods ø 5 mm 125 mm long (Code B00010012a)
14. Two connecting carbon rods ø 5 mm 150 mm long (Code B00010002a)
15. Two K-wires ø 1.2 mm L 120 mm negative thread (Code F00020182a)
16. Four K-wires ø 1.5 mm L 120 mm negative thread (Code F00020183a)
17. Two threaded pin ø 2.0 mm L 100 mm (Code F00020173A)
18. Two threaded pin ø 2.4 mm L 100 mm (Code F00020174A)
19. Eight pin covers ø 2.0 mm (Code P00040004a)
20. Two pin covers ø 2.4-2.7 mm (Code P00040005a)

Suggestions for use and reuse of the components

1. Sterilization case. Always perform the sterilization cycle with the cover closed. If left open, it can be bent or damaged during the cycle. The case should be sterilized within a standard sterilization bag, because it is not intended to maintain sterility of the content once it's withdrawn from the autoclave. The case is reusable up to ten sterilization cycles. It is possible to do more cycles, but this is not recommended, and it is up to the user's judgment and responsibility.
2. Round clamps ø 20 mm, 3 aligned holes. They can be sterilized several times. Always allow at least one hour of adaptation at room temperature before their use. They can be clinically used until they appear damaged, although it is not recommended to exceed ten usages. They can be supplied in different materials, of different stiffness and mechanical performance, based on the use they are intended for. Please ask for information about their features for specific uses.
3. Round clamps ø 20 mm, 3 offset holes. The same as for the point 2.
4. Hooks ø 3 mm L 16.5x5 mm. They can be sterilized as many times as requested, but they should not be reused on clinical patients. Their mechanical performances are unpredictable after they were loaded, posing serious risks on their holding power in the following clinical uses.
5. Hooks ø 3 mm L 24.5x5 mm. The same as for point 4.

6. Hooks ø 3 mm L 16.5x7.5 mm. The same as for point 4.
7. Self-locking stainless steel M3 nuts. The same as for point 4.
8. Toothed stainless steel washer 3 mm hole. The same as for point 4.
9. Stainless steel screw M3x20 mm. The same as for point 4.
10. Connecting carbon rods ø 5 mm 50 mm long. They can be sterilized as many time as requested with no problems, and clinically reused until they appear damaged or have a "hairy" appearance. The carbon fibers may be damaged if this happens, and their mechanical performance is unpredictable.
11. Connecting carbon rods ø 5 mm 75 mm long. The same as point 10.
12. Connecting carbon rods ø 5 mm 100 mm long. The same as point 10.
13. Connecting carbon rods ø 5 mm 125 mm long. The same as point 10.
14. Connecting carbon rods ø 5 mm 150 mm long. The same as point 10.
15. K-wires ø 1.2 mm L 120 mm positive thread. They can be sterilized as many times as requested, but should not be clinically reused.
16. K-wires ø 1.5 mm L 120 mm positive thread. The same as for point 15.
17. Threaded pin ø 2.0 mm L 100 mm. The same as for point 15.
18. Threaded pin ø 2.4 mm L 100 mm. The same as for point 15.
19. Pin covers ø 1.6 mm. The can be sterilized as many times as requested, and reused clinically until they are efficient in protecting the pin shaft.
20. Pin covers ø 1.8 mm. The same as for point 20.

Tools not included in the kit

Though not essential for the use of the system, the following tools have ben specifically designed and are offered on request for an easier application of the Polilock system.

1. Socket wrench with straight handle (Code U00010014a)
2. Combination wrench 5.5 mm (Code U00010004a)
3. Wrench for hooks (Code U00010006a)
4. Hexagon wrench 2.5 mm (Code U00010007a)
5. Dedicated drill bit for threaded pin ø 2.0 mm (Code P00060005a)
6. Dedicated drill bit for threaded pin ø 2.4 mm (Code P00060001a)

All the above-mentioned tools can be sterilized as many times as required, and discarded only when damaged or no more functional.

General considerations on the use of the Polilock system

Number and type of pins

The pins provided in the kit are purely indicative of the range of pins available for the patients the kit is intended for. Two pins of each type are usually provided with the kit, although the user can opt to include more pins of a specific type(s), thanks to the second row of holes in the support left empty in the original kit setting. Please note that Ad Maiora cannot be considered responsible for problems related to instability of the fixator due to the use of pins from different producers or for improper use of the pins provided. The general rules for pin application to the patient are the following.

A. K-wires ø 1.2 mm L 120 mm negative thread (Code F00020182a) and K-wires ø 1.5 mm L 120 mm negative thread (Code F00020183a. They can all be inserted directly in the bone, without predrilling. It should be noted, though, that they are mainly aimed to the stabilization of fragments, or to secondary stabilization of very small fracture segments. The main stabilization should always be provided by the use of at least one threaded pin ø 2.0 mm L 100 mm (Code F00020173A) or ø 2.4 mm L 100 (Code F00020174A). They should be inserted at a maximum speed of 500-600 rpm, and continuously chilled by saline flushing during insertion, to avoid heating of the bone, which can induce osteolysis, and secondary pin loosening. A stab wound is performed in soft tissues, and a sleeve is preferentially used, to avoid enrollment of soft tissues during insertion of the pin.

B. Threaded pins ø 2.0 mm L 100 mm (Code F00020173a) and threaded pins ø 2.4 L 100 mm (Code F00020174a). They represent the major holding tool for the fixator, and should be used as the primary mean for connection of the fixator to the bone. A stab wound is performed in soft tissues, and they are slightly dissected by a scissor or a mosquito forcep. Then, a sleeve is inserted in the wound and steadily hold orthogonally to the bone surface. A dedicated drill bit 1.5 mm (Code P00060005a) or drill bit 1.8 mm (Code P00060001a) is used to perforate the bone for the pins ø 2.0 mm or 2.4 mm, respectively. It should be inserted at a maximum speed of 500-600 rpm, and continuously chilled by saline flushing during insertion, to avoid heating of the bone, which can induce osteolysis, and secondary pin loosening. The drill bit is retracted while holding the sleeve in place. The threaded pin is inserted by hand or by drill with low rpm. When the surgeon feels the resistance of the far cortex, the insertion should be continued just until the feeling of resistance stops, adding a couple of turns. The pin is released, and any tension on soft tissues should be released by enlarging the wound.

Setting of the Polilock clamps for connection of pins and carbon bar

For precise sequence of clamp assembly please refer to the pictures that come with these instructions. Some general suggestions can be given on their use.

A. Round clamps ø 20 mm, 3 aligned holes (Code M00010020a). They are designed to hold one pin and the carbon bar. Connect the pin by a hook Ø 3 mm L 16.5x5.0 mm (Code G00010001a) in the hole that fits best with your frame construction, and lock the carbon bar by a hook Ø 3 mm L 16.5x7.5 mm (Code G00010004a) in another hole. Whenever possible, It is preferable using the further holes on the clamp, in order to have more room to tighten the nuts. If necessary, a second pin can be added by a hook Ø 3 mm L 16.5x5.0 mm (Code G00010001a) in the free hole, but this can cause interference between the nuts. To reduce this interference, one hook can be placed on the opposite side of the clamp. This clamp is usually used on fracture segments large enough to accommodate for the use of two or more clamps.

B. Round clamps ø 20 mm, 3 offset holes (Code M00010021a). They are designed to hold two pins and the carbon bar. Connect the first pin by means of a hook Ø 3 mm L 16.5x5.0 mm (Code G00010001a) inserted in one of the lateral holes on the clamp, and connect the second pin using the hole on the opposite side. Then, lock the carbon bar by a hook Ø 3 mm L 16.5x7.5 mm (Code G00010004a) in the central hole. The holes are set so that there is no interference between the nuts. This clamp is usually used on fracture segments so small to accommodate for the use of just one clamp.

C. The pin holding elements are represented by the hooks Ø 3 mm L 16.5x5.0 mm (Code G00010001a) (short shaft/short hook) and the hooks Ø 3 mm L 24.5x5.0 mm (long shaft/short hook) to be used with single- and double-clamp assembly, respectively. They can hold pins up to 2.5 mm in diameter.

D. The hooks Ø 3 mm L 16.5x7.5 mm (Code G00010004a) (short shaft/long hook) are to be used for stabilizing the connecting bar to the clamp. This will prevent torsional instability in the frame constructs at higher risk.

E. The nuts M3 ss selflocking (Code D00010019a) of the hook Ø 3 mm L 16.5x5.0 mm (Code G00010001a) should be tightened until the pin starts bending. Stop tightening when it happens.

F. The nuts M3 ss selflocking (Code D00010019a) of the hook Ø 3 mm L 16.5x7.5 mm (Code G00010004a) should be firmly tightened during the procedure, and tightened again after a while (during postoperative radiographs or bandaging of the frame). Recheck their tightness in 2-3 days during the PO rechecks.

Frame structure

The weakest point of every kind of linear fixator with a single connecting bar is the torsion of the construct around the axis of the bar. This pivoting effect is greatly reduced thanks to the introduction of the hooks G00010004a stabilizing the clamp to the bar, but every effort should be made to keep this risk under control. The following are suggestions about the clinical application of different frame constructs. It should however be VERY CLEARLY STATED THAT:

1. They represent just some suggestions on the potential use of the fixator, and they are not intended as a clinical indication for its use, which pertains to the choice of the surgeon, and it is based on clinical evaluation of the patient and of the fracture features.
2. As usual with external fixation, many different frame configurations and choice of pins and their positioning are possible. For this reason, a unique recommendation cannot be made for a specific fracture, but just general principles that should be applied.
3. So many variables can affect the final outcome of a treatment, including postoperative management of the patient. It is the responsibility of the surgeon to verify those variables, and provide all the personnel and owners with precise instructions on how to check the fixator conditions and provide proper postoperative care.

Monolateral monoplanar single bar construct (Type IA)

It represents the weakest construct from the biomechanical point of view, and it is potentially the frame configuration at higher risk of failure. To reduce this risk at a minimum, the following strategies can be used.

1. Use three pins on each fracture segment, and at least two hooks G00010004a for each fracture fragment.
2. Use a tie-in configuration every time it is possible, connecting the IM pin to the bar by a hook G00010001a on a clamp.
3. Consider using a T configuration (see below) when one fracture fragment is very short.
4. Consider using this type of construct only in very young patients, with a reduced body weight (preferably no more than 3 kg) and with transverse fractures.
5. Consider using a secondary frame with fewer pins on the bending side of the primary frame (Type IB frame). This can be left in place just for the first weeks

of treatment, and then removed destabilizing the frame.

Monolateral T configuration construct

1. It represents a variation of the Type IA construct, and is used for very short distal fragments (see pictures). It is assembled by connecting two carbon bars in a more or less orthogonal way by means of two clamps M00010020a with a screw M3x20 mm (Code V00020013a). In this way, the longer segment is stabilized with pins on the vertical arm of the frame, while the shorter segment is stabilized by pins on the horizontal arm of the frame. To achieve this, a clamp is positioned on each side of the horizontal arm, and the pins are driven in the bone in a converging direction (see pictures of the assembly).
2. At the end of stabilization a bar connecting a proximal and a distal pin can be added for further stabilization.
3. When the short fragment is 5 mm or less, consider a stabilization by circular/hybrid fixation.

Double bar frame construct

One of the most peculiar features of the Polilock system is the possibility to connect pins with a double bar construct with the same clamp. This reduces the overall cumbersomeness of the frame compared to the use of Meynard clamps for example. Torsion is not an issue for this kind of frame construct, and it should be used in every case torsional instabiility could represent a potential source for problems. For precise sequence of clamp assembly please refer to the pictures that come with this instruction.

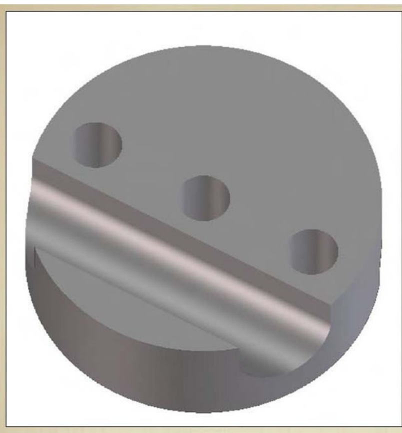
1. Connect two clamps M00010020a with a carbon bar of the desired length each.
2. Rotate one of the clamps with the connected bar upside down, and put it in front of the other one.
3. Use a hook G00010002a to pass through a hole coaxial in the two clamps and stabilize a pin. In this way the hook passes through both clamps. If the three holes are adjusted so that they are superimposed, at least two of them can be used with hooks G00010002a to hold pins.
4. Make the same superimposition of clamps on the opposite extremity of the carbon bars, and use hooks G00010002a to hold the scheduled number of

pins.

5. It is possible to use double-clamp constructs all the fixator long, or use single-clamp constructs between the extremities of the carbon bars, as requested.

EXTERNAL FIXATION LINEAR MINI SYSTEM POLILOCK

Instructions for clamp assembly



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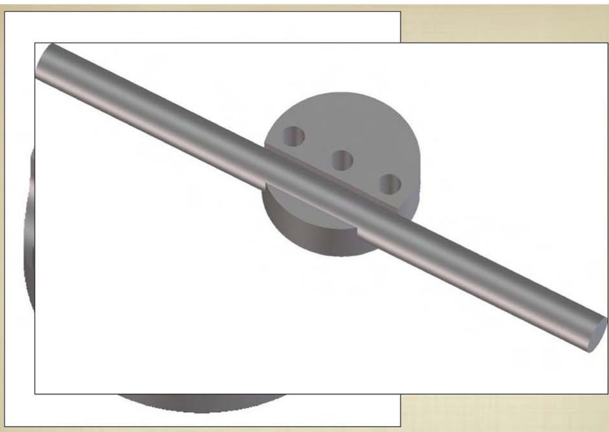

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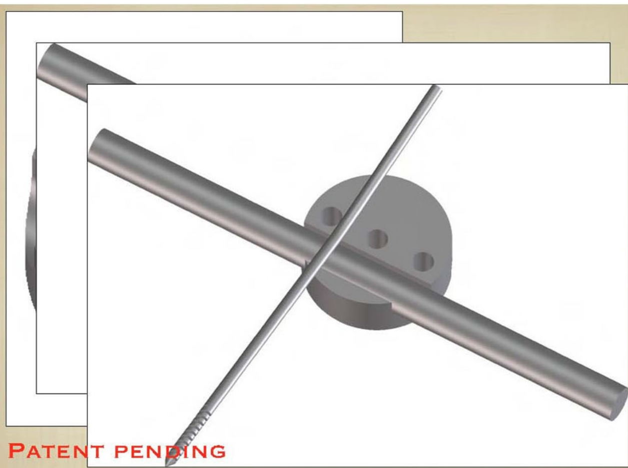

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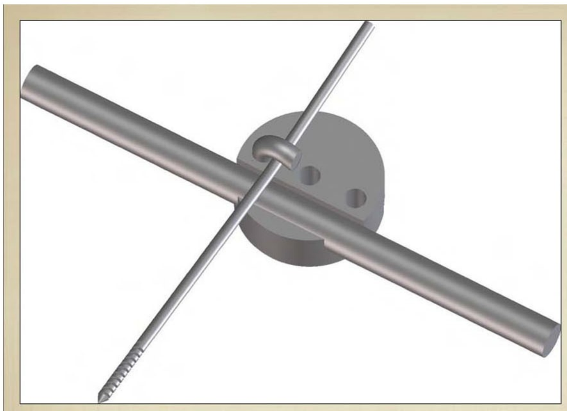

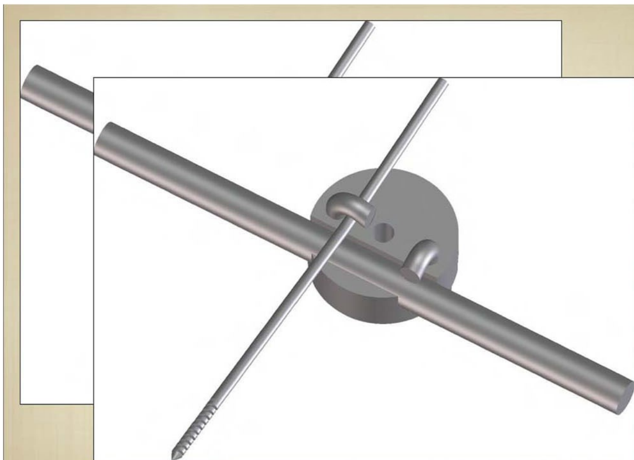

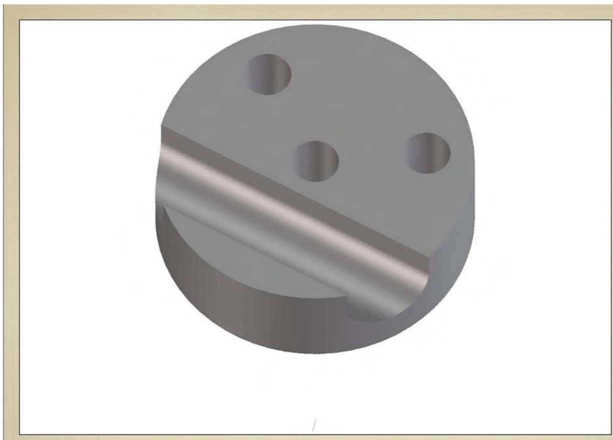

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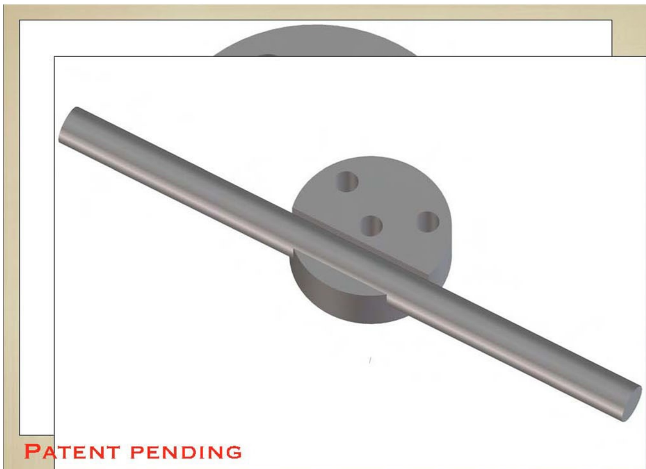

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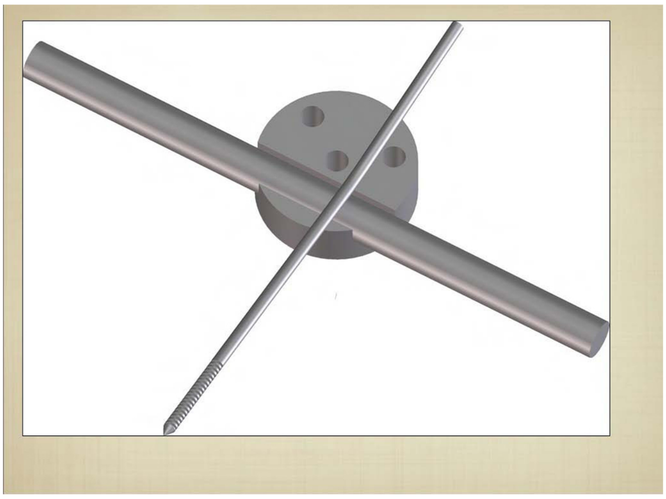
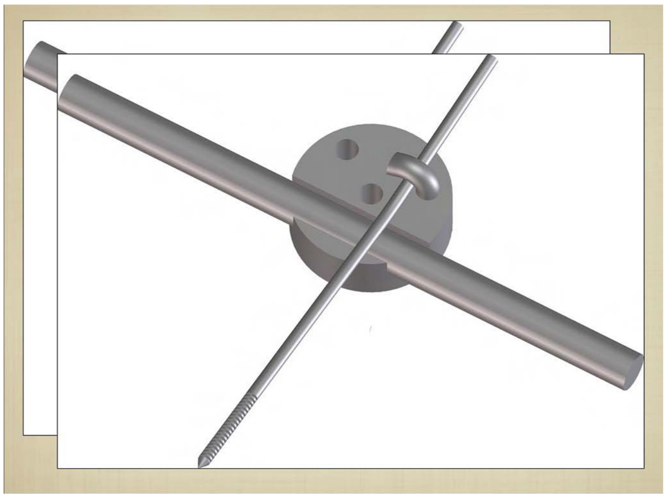
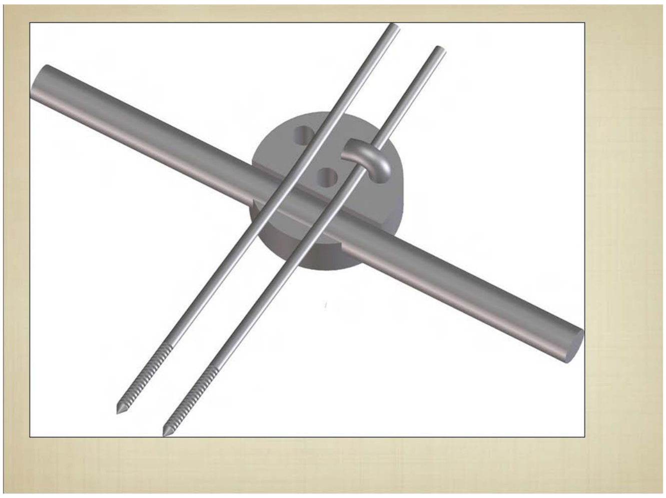
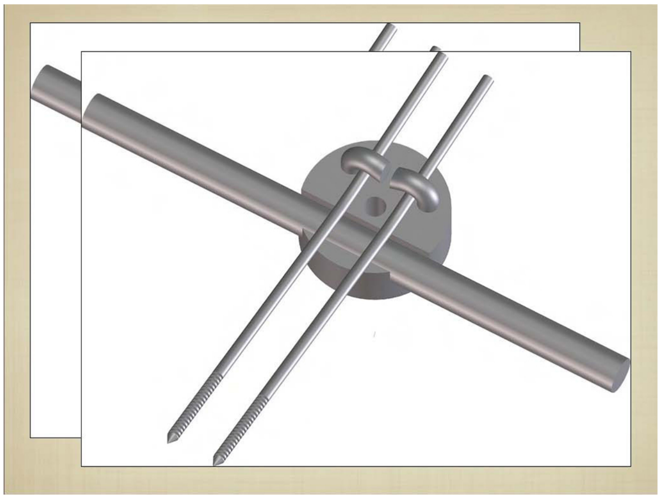
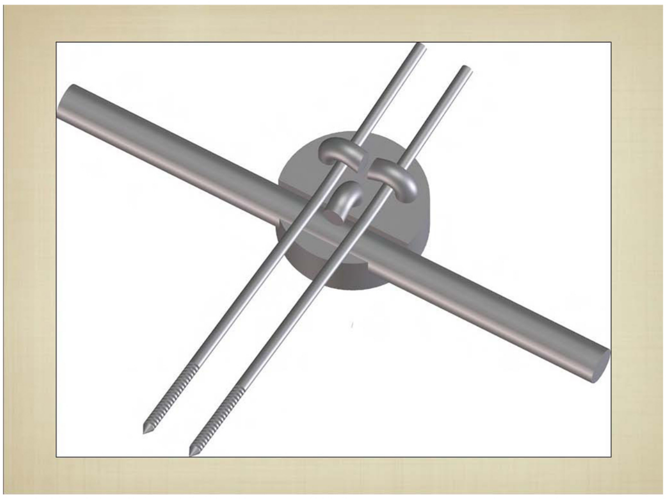

DYNAMIZABLE LINEAR SYSTEM

INSTRUCTIONS FOR USE

Important note

Please read carefully the following instructions before applying the Dynamizable system on clinical patients. This is a veterinary surgical device, and requires knowledge of its use and limitations. No attempts should be made to use the device for indications different from those the system was developed for. Any improper use will be under the responsibility of the user.

Description

The Dynamizable system is an external linear fixation system designed to stabilize fractures in dogs of body weight between 10 and 30 kg. Its peculiar feature, which makes it unique among the veterinary external fixators, is that it allows to perform compression and distraction on the fracture, as well as the dynamization of the bone callus. As usual for external fixation, the addition of pins and changes in the frame structure may profoundly affect the biomechanical properties of the fixator, allowing its use in heavier patients. Being almost impossible to describe all the potential variations of the fixator features that can influence its biomechanical properties, it is the surgeon's experience to dictate the patient's weight that fits with a specific frame configuration.

Kit components

The Dynamizable kit contains the following components.

1. Sterilization case (Code C00040010a)
2. One external linear dynamizable fixator 10 cm (Code F00030001b)
3. One external linear dynamizable fixator 15 cm (Code F00030002b)
4. Six clamps for dynamizable fixator (Code M00010018a)
5. Two extensions for dynamizable clamp (Code E00010001a)
6. Four threaded pins ø 2.7 mm L 120 mm (Code F00020175a)
7. Four threaded pins ø 3.5 mm L 130 mm (Code F00020176a)
8. Four caps for pins ø 2.7 mm (Code P00040005a)

9. Four caps for pins ø 3.5 mm (Code P00040002a)
10. One hexagonal wrench 3.0 mm with spherical tip (Code U00010002a)

Suggestions for use and reuse of the components

1. **Sterilization case**. Always perform the sterilization cycle with the cover closed. If left open, it can be bent or damaged during the cycle. The case should be sterilized within a standard sterilization bag, because it is not intended to maintain sterility of the content once it's withdrawn from the autoclave. The case is reusable up to ten sterilization cycles. It is possible to do more cycles, but this is not recommended, and it is up to the user's judgment and responsibility.
2. **Linear dynamizable fixator 10 cm**. It can be sterilized as many times as required. It can be used on clinical patients many times, but its mechanical function should be checked for each use. To increase its life span, it is suggested to send it about once a year to the Ad Maiora assistance center, depending on the number of sterilization cycles received, to change the parts subjected to wear.
3. **Linear dynamizable fixator 15 cm**. The same as for point 2.
4. **Clamps for dynamizable fixator**. They can be sterilized as many times as required and can be reused on clinical patients. It is strongly recommended, though, to check every component after the mechanical loading during the clinical use, because if the more delicate parts, like threads, are damaged, their biomechanical behavior is unpredictable, posing a serious risk for further clinical applications.
5. **Extensions for clamps**. The same as for point 4.
6. **Threaded pins ø 2.7 mm L 120 mm**. They can be sterilized as many times as requested, but they cannot be reused on clinical patients.
7. **Threaded pins ø 3.5 mm L 130 mm**. The same as for point 6.
8. **Caps for pins ø 2.7 mm**. They cannot be autoclaved, and they should be applied to the protruding stump of the pin at the end of the surgery. They can be used until they are efficient in protecting the pin stump.
9. **Caps for pins ø 3.5 mm**. They cannot be autoclaved. The suggestions for use are the same as for point 8.
10. **Hexagonal wrench ø 3,0 mm with spherical tip**. It can be sterilized as many times as requested, and discarded when it is damaged or no more functional.

Instruments not included in the kit

1. Dedicated drill bit for predrilling for threaded pins ø 2.8 mm
2. Dedicated drill bit for predrilling for threaded pins ø 3.5 mm
3. Combination wrench 8,0 mm

These instruments can be sterilized as many times as requested, and discarded only when damaged or no more functional. It is important, though, to always use sharp bits, because if it is dull the bone is damaged and heated during its perforation, with the potential risk of bone necrosis and subsequent pin loosening.

General considerations on the use of the Dynamizable system

Number and type of pins

The pins provided in the kit are purely indicative of the range of pins available for the patients the kit is intended for. Four units for each of the above-indicated pins are provided, but the surgeon can choose to include in the kit more pins of a specific type, thanks to the empty holes in the support. For example, for bigger patients the use of 4.5 mm threaded pins (Code F00020177A), not provided in the standard kit configuration) could be more appropriate. Please note that Ad Maiora cannot be considered responsible for problems related to instability of the fixator due to the use of pins from different producers or for improper use of the pins provided.

General rules for pin application to the patient

Threaded pins ø 2.7 L 120 mm and 3.5 mm L 130 mm (Codes F00020175a and F00020176a).

They represent the major holding tool for the fixator, and should be used as the primary mean for connection of the fixator to the bone. A stab wound is performed in soft tissues, and they are slightly dissected by a scissor or a mosquito forcep. Then, a sleeve is inserted in the wound and steadily hold orthogonally to the bone surface. A 2.0 mm drill bit for the pins ø 2.7 mm F00020175a or 2.5 mm for the pins ø 3.5 mm F00020176a is used to perforate the bone. It should be inserted at a maximum speed of 500-600 rpm, and continuously chilled by saline flushing during insertion, to avoid heating of the bone, which can induce osteolysis, and secondary pin loosening. The drill bit is retracted while holding the sleeve in place. The threaded pin is inserted by hand, using a chuck as a driver for insertion. When the surgeon feels the resistance of the far cortex, the insertion should be continued just until the feeling of resistance stops, adding a couple of turns. The pin is released from the chuck, and any tension on soft tissues should be released by enlarging the wound.

The same principles apply to the use of the 4.5 mm threaded pins (Code F00020177A).

Setting of the clamp for the connection of the pin to the fixator's body

For a correct sequence of the clamp setting please refer to the pictures that come with this guide.

Clamp for dynamizable fixator (Code M00010018a) (Fig. 1). It is intended for the connection of a threaded pin to the dynamizable fixator. The clamp is connected to the fixator's body by the hole (a) with a close clamp but with the tightening screw (b) released. In case it is necessary to put a clamp in between two clamps already tighten, it is possible to remove the tightening screw (b), opening the clamp in two parts (half-clamps), then putting the open clamp on the fixator's body and tightening the screw (b) again. Please note that the tightening screw (b) should be inserted first through the gliding hole on the first half-clamp, and then screwed into the threaded hole for traction in the second half-clamp. To avoid that an excessive tension is applied on the screw (b), which could open the branches of the clamp on the opposite side, a spacing plate (c) should be put on the opposite side of the clamp. A pin or extension can be inserted through a hole (d), which can accommodate a threaded pin up to a ø 4.5 mm or the shaft of the extension E00010001a. In both cases, locking in the desired position is achieved by means of the locking screws (e). The difference between inserting the pin or the extension in the clamp is due to the fact that inserting just the pin directly in the clamp it is possible to translate it along or rotating it around the fixator's major axis (Fig. 2). Instead, if an extension is connected with the clamp, and the pin is inserted through the extension, it is possible to incline it along the longitudinal axis of the fixator (Fig. 3). Furthermore, the extensions allow a translation orthogonal to the fixator's major axis, so that the pin can be actually moved on four planes.

The extension is locked to the clamp by the locking screws (e), and locks the pins into a hole in the extension's head by a locking screw. All the screws of the clamp and the extension can be turned by the hexagonal wrench ø 3,0 mm with hemispherical tip code U00010002a that is enclosed in the kit.

The head of the extension E00010001a should always be positioned on the side of the clamp opposite to the locking screw of the clamp (b), to avoid any interference between them during intraoperative maneuvers.

Use of the fixator for compression/distraction and for dynamization

The most peculiar feature of the Dynamizable fixator is the possibility it offers to perform maneuvers on the fracture area. In the acute phase of treatment micrometric compression and distraction can be performed, useful for fracture reduction. In the more advanced phase of bone healing, dynamization can be performed. It allows stimulating the bone callus by axial compression forces, preventing those of bending and torsion. Some suggestions for the use of the fixator for fracture reduction and stabilization are given underneath. It should however BE STATED VERY CLEARLY THAT:

1. They represent just some suggestions on the potential use of the fixator, and they are not intended as a clinical indication for its use, which pertains to the choice of the surgeon, and must be based on clinical evaluation of the patient and of the fracture features.
2. As usual with external fixation, many different frame configurations and choice of pins and their positioning are possible. For this reason, a unique recommendation cannot be made for a specific fracture, but just general principles that can be applied.
3. So many variables can affect the final outcome of a treatment, including post-operative management of the patient. It is the responsibility of the surgeon to verify those variables, and to provide all the personnel and owners with precise instructions on how maintain the fixator, check its status, and manage the post-operative care in a correct way.

Compression/distraction

The fixator is made by two metallic cylinders (cylinder D and cylinder C) that are telescopic in their central part. The inner space of the cylinders is occupied by a threaded bar, with two hexagonal nuts at each extremity (nuts D1 and D2 on the extremity D, C1 and C2 on the extremity C). The extremity of the cylinder C has a hexagonal shape, like a nut, to allow for its stabilization by a wrench n. 8 (not included) (Fig. 4 A).

To perform compression/distraction, the fixator should be in static position, and dynamization mechanism should be locked. To check for the fixator's state, i.e. static or dynamized, holding each cylinder by one hand, push each one against the other. If the cylinders shift on each other it means that the fixator is dynamized. On the contrary, if it stays stable it is in static position. In this latter case the fixator can be used for compression/distraction. In the former case it should be locked following the next steps.

1. Bring the nut C1 close to the extremity of the cylinder C, stabilizing the extremity by a wrench n. 8. Tighten the nut C1 against the extremity C of the fixator.
2. Check that the nuts D1 and D2 are disconnected. Holding the fixator by a wrench n. 8 on the extremity C turn the nut D1 clockwise by another wrench n. 8, in this way compressing it toward the center of the fixator (Fig. 4B).
3. Stop the compression of the cylinder as soon as the resistance is felt to rise. Now, doing again the compression of the fixator's cylinders by hand, it should be static (Fig. 5 C). IT IS IMPORTANT not to exert too much compression by the nut D1, because this could be damage the internal spring, making the later dynamization impossible.
4. Lock the static configuration of the fixator by tightening the nut D2 against the nut D1.
5. It is now possible to use the fixator for compression/distraction. When a distraction is scheduled, as usual in the early phase of fracture reduction, disconnect the nut C1 from the extremity C of the fixator, bring it together with the nut C2 to the extremity of the threaded bar, and tighten them together. Holding the fixator by a wrench n. 8 on the extremity C, turn the threaded bar in a counter-clockwise way (it should exit from the fixator's body) using as a holding point the couple of nuts C1-C2. Keep turning until the central part of the fixator is 1-2 mm large. In this way it will be possible to exert a distraction on the fracture area correspondent to the length of the threaded bar out of the fixator body (Fig. 5 D). When a compression on the fracture area is needed, the fixator should have the threaded bar completely inserted in the fixator body by turning it in a clockwise direction, and the central part of the fixator about 25 mm open. In this way it will be possible to exert compression on the fracture area correspondent to the length of the central area of the fixator (Fig. 6 E).

Use of the fixator for fracture reduction and its stabilization

Generally speaking, long bones fractures will present a *dislocation ad longitudinem* with *dislocation ad latus*. Fracture reduction is then achieved distracting the fracture segments, in order to reestablish the original bone length and to allow for realignment. Fracture reduction can be achieved following the next steps.

1. Insert in each fracture segment JUST ONE PIN of correct size. Connect each pin to a clamp with extension, and tighten all the locking screws of the fixator so

that the overall frame is stable (Fig. 6 F).

2. Holding the fixator by a wrench n. 8 on the extremity C, use another wrench n. 8 to turn the nuts C1 and C2 tightened together in a clockwise direction (the threaded bar should go into the fixator's body) (Fig. 7 G). In this way, the central part of the fixator lengthens and the fracture is distracted.
3. Once the distraction is large enough for the fracture segments not being overlapped, it is possible to perform the maneuvers for fracture reduction (Fig. 7 H). Releasing the locking screws of the extension it is possible to correct rotation on the minor axis of the bone segment and translation *ad axim*, while releasing the locking screw of the clamp it is possible to correct translation between the fracture segments. It is important to notice that the correction of torsional deformities in never possible with linear fixation, and then specific attention should be paid when the first pins are inserted in the fracture segments, in order to avoid this kind of deformity.
4. Once fracture reduction is achieved, it is possible to exert a moderate compression between the fragments if the fracture is transverse or short oblique (Fig. 8 I).
5. It is then possible to add pins for further fracture stabilization (Fig. 8 L). The clamps needed for adding pins can be prepositioned on the fixator's body if already scheduled in order to speed the procedure up, or opened and inserted in the requested position even in a later phase. It is important that in this phase the fixator stays in a static position, and for this the nuts C1 and C2 should be released, C1 is tightened against the extremity C of the fixator and C2 against C1. This position is the one that will be used for the management of the first phase of bone healing.

Use of the fixator for the dynamization of the bone callus

Dynamization is different from destabilization of the fracture because it selects the forces that will load the bone callus while maturing. The callus is loaded by axial compression forces, which are considered positive for its maturation, excluding torsion and bending, potentially dangerous for the callus.

The dynamization procedure should be performed only on calluses radiographically visible, vascularized and extended to the majority of the fracture area. Do not dynamize atrophic or too early calluses.

The steps to achieve dynamization of the fixator are the following.

1. Release the nuts C1 and C2, bringing them away from the extremity C of the fixator, and then tighten them together again.
2. Release the nut D2 while holding the nut D1, and bring it away from D1 of a couple of mm. The distance between these nuts represents the amount of the dynamization introduced in the system.
3. Turn the nuts C1 and C2 tightened together in a counterclockwise direction (the threaded bar should exit from the fixator), holding the fixator by a wrench n. 8 on the extremity of the cylinder C, until the nut D2 contacts the nut D1 and stops turning. Stop the turning of the threaded bar at this point.
4. Tighten together the nuts D1 and D2 to keep the dynamization as set.
5. Release C1 from C2, bring C1 back in contact with the extremity C of the fixator and tighten it, and then tighten C2 against C1 to lock the fixator in the new dynamized position. The fixator will now let the axial loads to pass through the fracture area, and this will stimulate the callus maturation (Fig. 9 M).

Universal dynamizable linear fixator
Technique for use

Foreword
The dynamizable external fixator Dynamic 2.0 is a veterinary surgical device, whose use is restricted to veterinary surgeons who are thoroughly familiar with the procedures and directions for use. Ad Maiora is not liable for any use other than the purpose for which it was designed, or not following the correct method of use.
The following guidelines do not represent in any way a suggestion for using the fixator on clinical patients. The decision on its application depends exclusively on the judgment of the surgeon.
Technical note
The current version of the fixator (Dynamic 2.0) is different from the one represented in the images of the instructions. The technique of use, however, has remained the same, so you can still refer to these instructions for all versions of the fixator.
Description
The fixator is made up of 2 telescopic steel cylinders, an inner threaded bar which is coaxial to the cylinders and a spring which is coaxial to the bar. The opposite ends of the cylinders are closed - except for the hole required for the threaded bar to protrude – and marked by a letter. The cylinder end which is marked by the letter C is threaded, and the threaded bar can be screwed onto it. The end of this cylinder is hexagonal, so that it can be firmly held with a wrench. Compression/distraction can be achieved by acting on this end of the cylinder. The cylinder end which is marked by the letter D has the same diameter as the threaded bar which runs inside it. The fixator can be dynamized by acting on this end of the cylinder. The position of the threaded bar which protrudes from the cylinders is adjusted and hold in place by nuts which are

screwed onto the bar in a number of 2 on each side. They are numbered with 1 and 2 starting from the one which lies closer to the cylinder end (C1 and C2, D1 and D2) (Fig. 1).

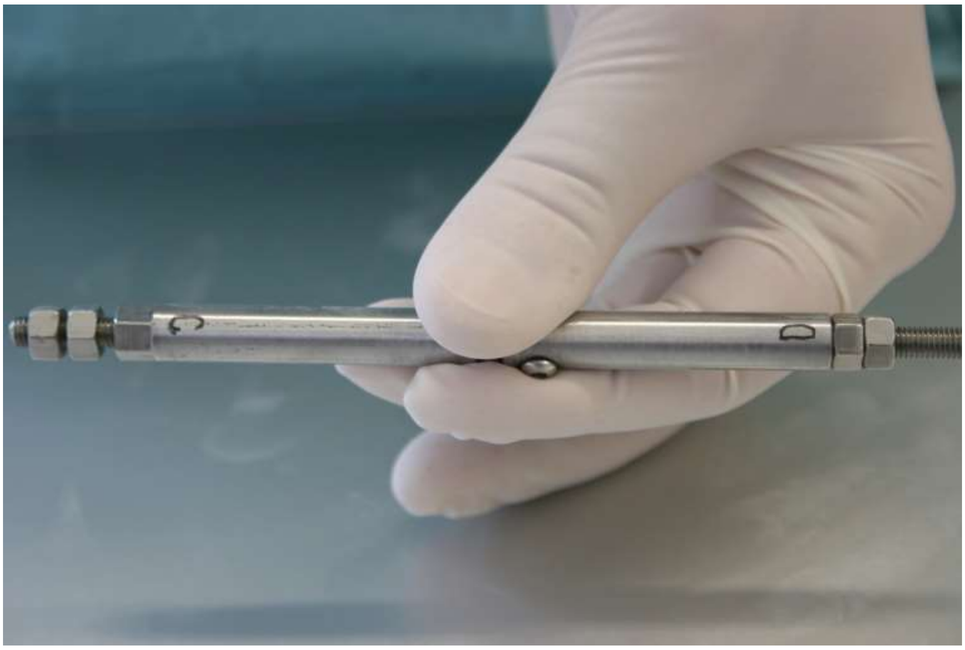

Fig. 1

Static position

There is no motion between cylinder C and D. To be sure that the fixator is in static position, check that there is clearance between the cylinders, then try to push them one against the other (Fig. 2).

Fig. 2

If there is such motion as to allow the cylinders to come close to each other, the fixator is dynamized, while if there is no motion it is in static position. This should take place in the presence of residual clearance between cylinder C and D. The fact that the two cylinders are in contact does not necessarily imply that the fixator is in static position but could simply mean that there can be no motion between the cylinders. If the fixator is already in static position, compression/distraction maneuvers can be performed. If the fixator is not in static position, check that nuts C1 and C2 are uncoupled. This means that they are not tightened to each other, therefore capable of moving independently, while if they are coupled they are fixed together (Fig. 3).

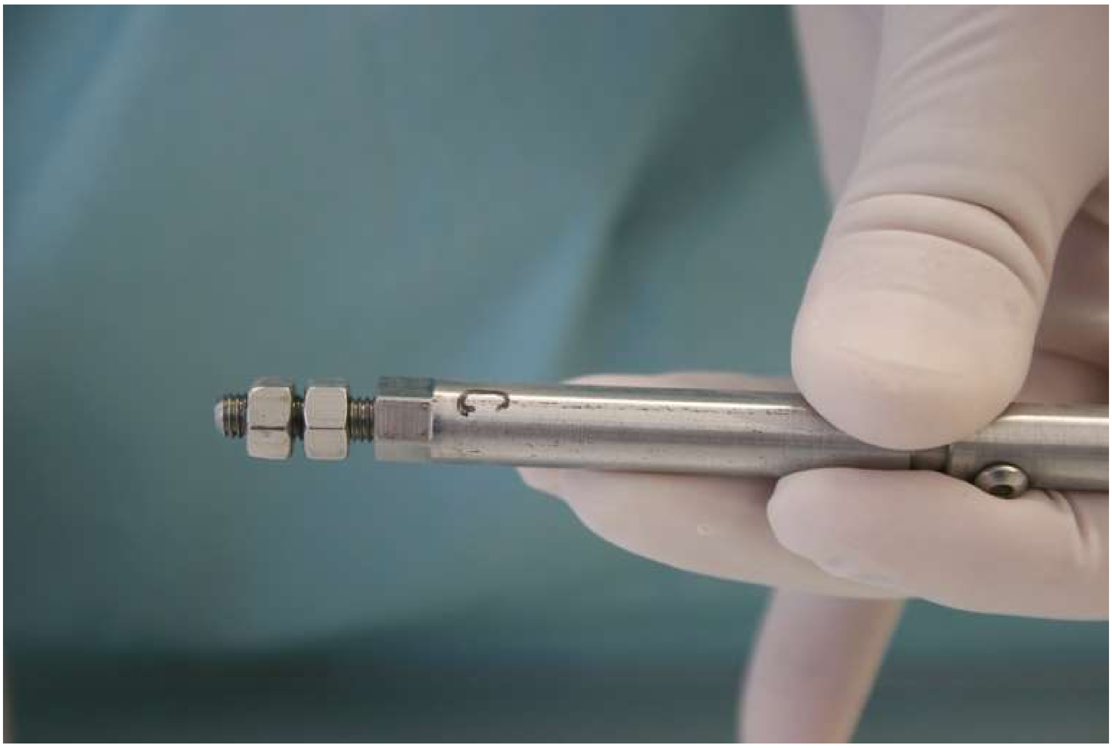

Fig. 3

Bring nut C1 in contact with the C end of the fixator until it becomes tightened. Bring nut C2 in contact with nut C1 and tighten it (Fig. 4).

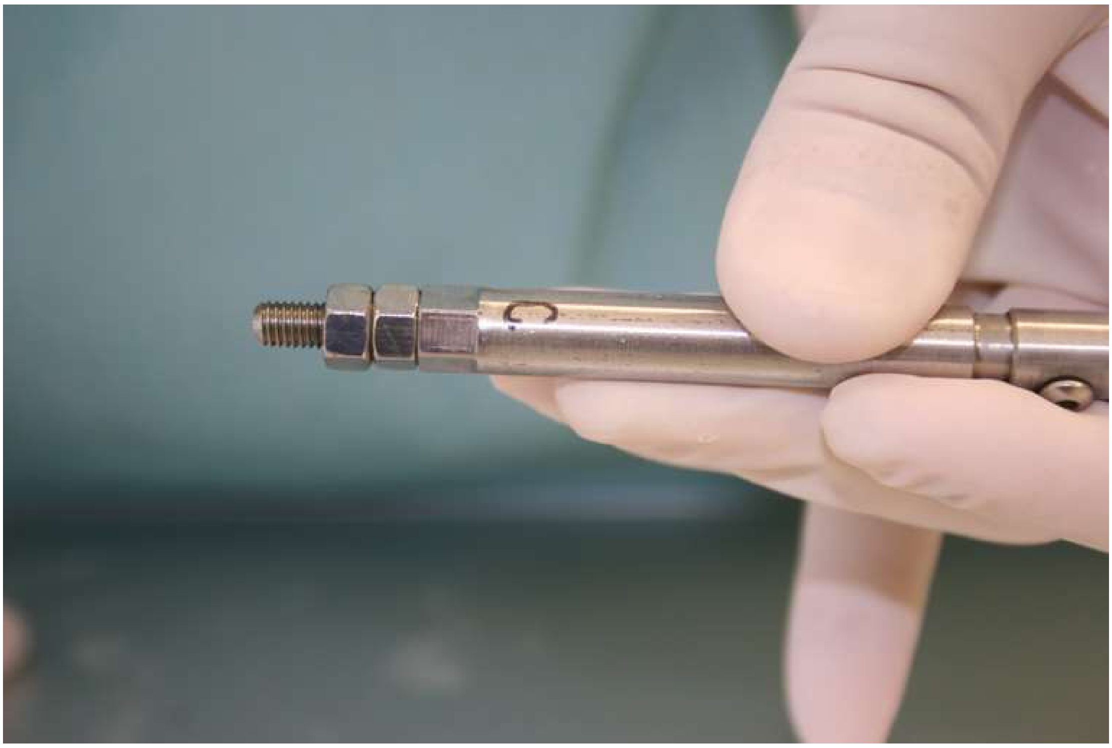

Fig. 4

Make sure that nuts D1 and D2 are uncoupled, then turn nut D1 until it is brought in contact with the end of cylinder D: keep tightening it until no more motion is present, thus preventing the nut from being further screwed in (Fig. 5).

Fig. 5

This maneuver must be done gently, stopping when you feel resistance to screwing the nut. Too strong tightening can damage the internal spring, preventing its proper operation during the step of dynamization.
Bring nut D2 in contact with nut D1 and tighten it. This procedure ensures that the fixator is hold in static position. At this point – in order to check whether the procedure was performed correctly – try to push the cylinders one against the other. No motion should occur.

Compression/distraction

Fixator compression and distraction should be performed in static position, i.e. when the fixator is not dynamized.

Distraction

Nuts C should be uncoupled and removed from cylinder C so that nut C1 is at a distance which corresponds at least to the desired amount of extension of the fixator. Tighten nuts C1 and C2 so as to use them as an anchorage point for threaded bar rotation (Fig. 6).

Fig. 6

Turn the threaded bar clockwise and hold cylinder C with a wrench to prevent it from turning together with the threaded bar (Fig. 7).

Fig. 7

The bar should enter into the fixator and became shorter. The central part of the fixator must lengthen accordingly, determining the distraction of the stumps of the fracture to which the fixator is connected in a clinical setting (Fig. 8).

Fig. 8

Conversely, by rotating the threaded bar counterclockwise, compression can be achieved, provided that there is still motion between the two cylinders.

Once the desired compression/distraction is achieved, nuts C1 and C2 are uncoupled and brought in contact with the C end of the fixator, then tightened. This makes the desired position to be maintained. To change the position by lengthening or shortening the fixator repeat the previous steps.

Dynamization

Nuts C1 and C2 are uncoupled, brought at 2-3 mm from cylinder C, then coupled again. Nuts D1 and D2 are uncoupled, nut D2 should be at a distance from D1 which equals the amount of motion required for dynamization, while D1 is left in its original position, in contact with the end of cylinder D (Fig. 9).

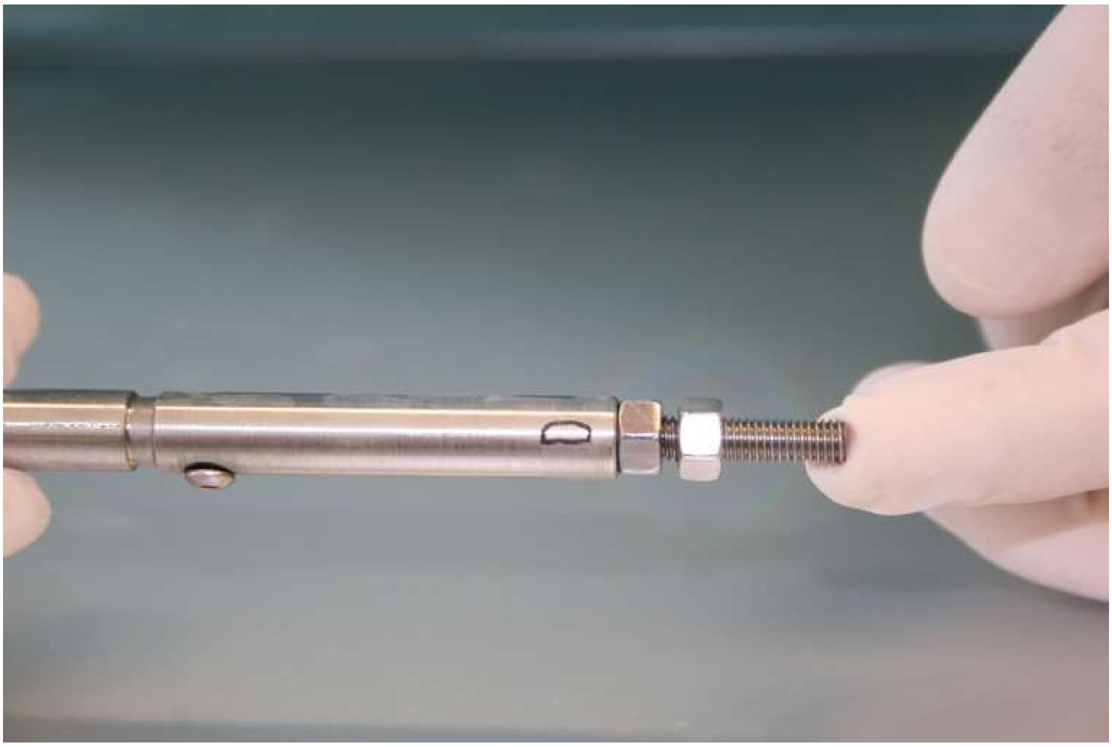

Fig. 9

Using a wrench, hold the fixator in place by stabilizing the hexagonal portion of the end of cylinder C. Using another wrench, turn the coupled C nuts counterclockwise in order to cause the bar to protrude from the cylinder (Fig. 10).

Fig. 10

You will notice that nut D2 starts rotating with the bar. Once it contacts nut D1, dynamization is achieved and the fixator can make the axial motion given by the distance at which D2 was placed compared to D1 (Fig. 11).

Fig. 11

Nuts C are uncoupled, brought into contact with cylinder C and then tightened. Nuts D1 and D2 are coupled by tightening D2 in contact with D1. The position is stabilized and a dynamized fixator is thus obtained, i.e. a fixator which can move only longitudinally.
The axial load of the callus in the absence of torsional and bending stresses is considered a proper condition to stimulate its final maturation.

Universal dynamizable linear fixator

Technique for use

Foreword

The dynamizable external fixator Dynamic 2.0 is a veterinary surgical device, whose use is restricted to veterinary surgeons who are thoroughly familiar with the procedures and directions for use. Ad Maiora is not liable for any use other than the purpose for which it was designed, or not following the correct method of use.

The following guidelines do not represent in any way a suggestion for using the fixator on clinical patients. The decision on its application depends exclusively on the judgment of the surgeon.

Technical note

The current version of the fixator (Dynamic 2.0) is different from the one represented in the images of the instructions. The technique of use, however, has remained the same, so you can still refer to these instructions for all versions of the fixator.

Description

The fixator is made up of 2 telescopic steel cylinders, an inner threaded bar which is coaxial to the cylinders and a spring which is coaxial to the bar. The opposite ends of the cylinders are closed - except for the hole required for the threaded bar to protrude – and marked by a letter. The cylinder end which is marked by the letter C is threaded, and the threaded bar can be screwed onto it. The end of this cylinder is hexagonal, so that it can be firmly held with a wrench. Compression/distraction can be achieved by acting on this end of the cylinder. The cylinder end which is marked by the letter D has the same diameter as the threaded bar which runs inside it. The fixator can be dynamized by acting on this end of the cylinder. The position of the threaded bar which protrudes from the cylinders is adjusted and hold in place by nuts which are screwed onto the bar in a number of 2 on each side. They are numbered with 1 and 2 starting from the one which lies closer to the cylinder end (C1 and C2, D1 and D2) (Fig. 1).

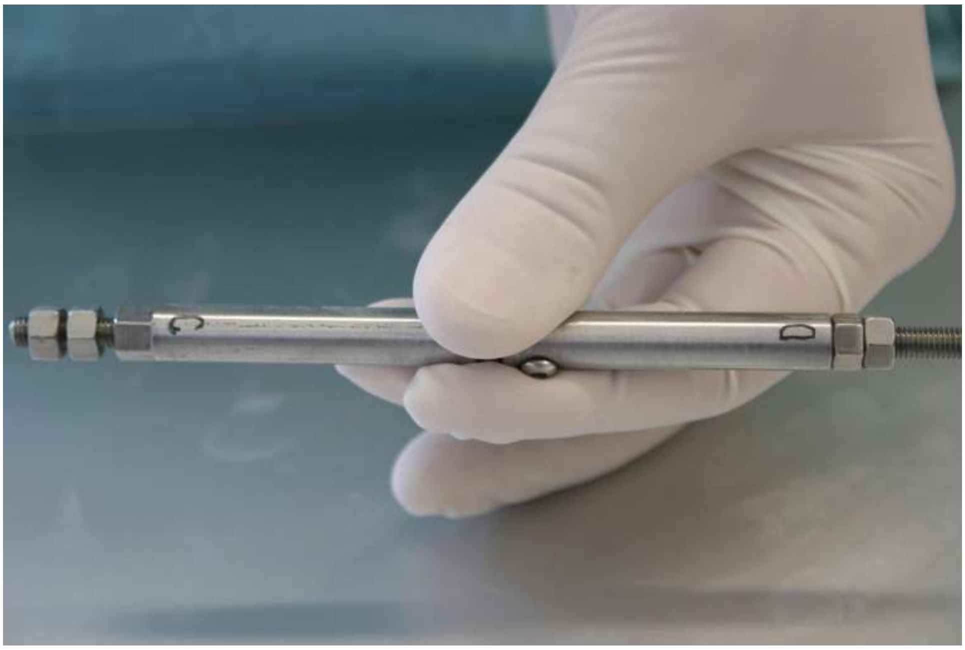

Fig. 1

Static position

There is no motion between cylinder C and D. To be sure that the fixator is in static position, check that there is clearance between the cylinders, then try to push them one against the other (Fig. 2).

Fig. 2

If there is such motion as to allow the cylinders to come close to each other, the fixator is dynamized, while if there is no motion it is in static position. This should take place in the presence of residual clearance between cylinder C and D. The fact that the two cylinders are in contact does not necessarily imply that the fixator is in static position but could simply mean that there can be no motion between the cylinders. If the fixator is already in static position, compression/distraction maneuvers can be performed. If the fixator is not in static position, check that nuts C1 and C2 are uncoupled. This means that they are not tightened to each other, therefore capable of moving independently, while if they are coupled they are fixed together (Fig. 3).

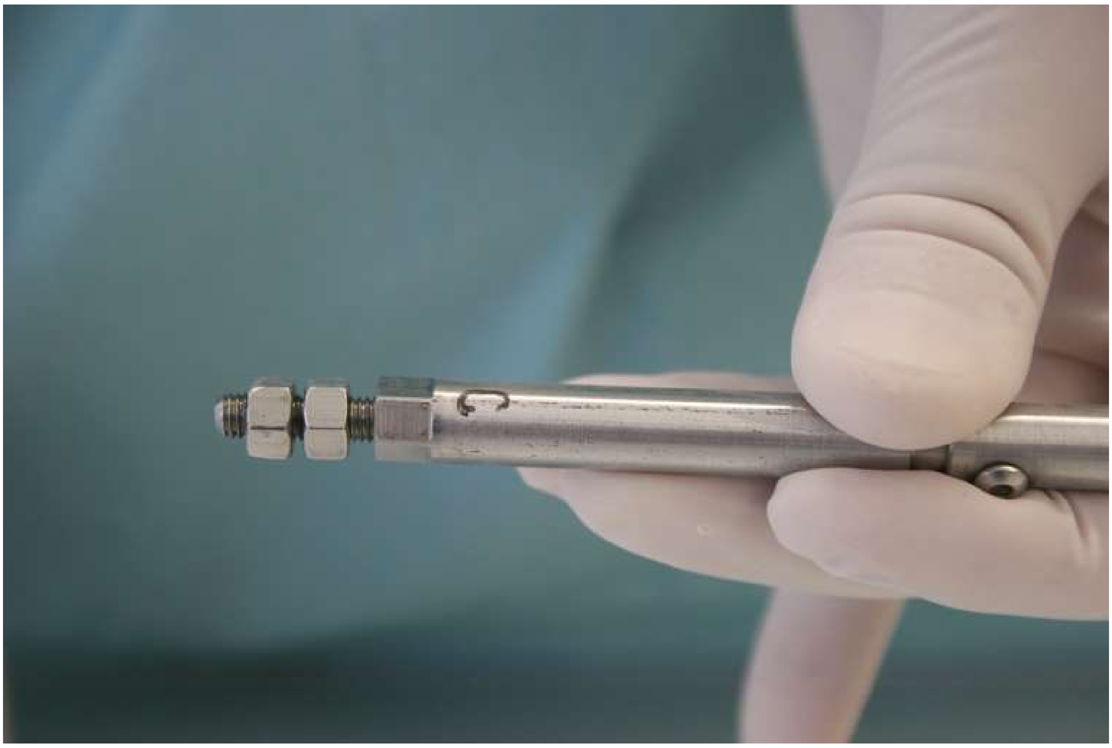

Fig. 3

Bring nut C1 in contact with the C end of the fixator until it becomes tightened. Bring nut C2 in contact with nut C1 and tighten it (Fig. 4).

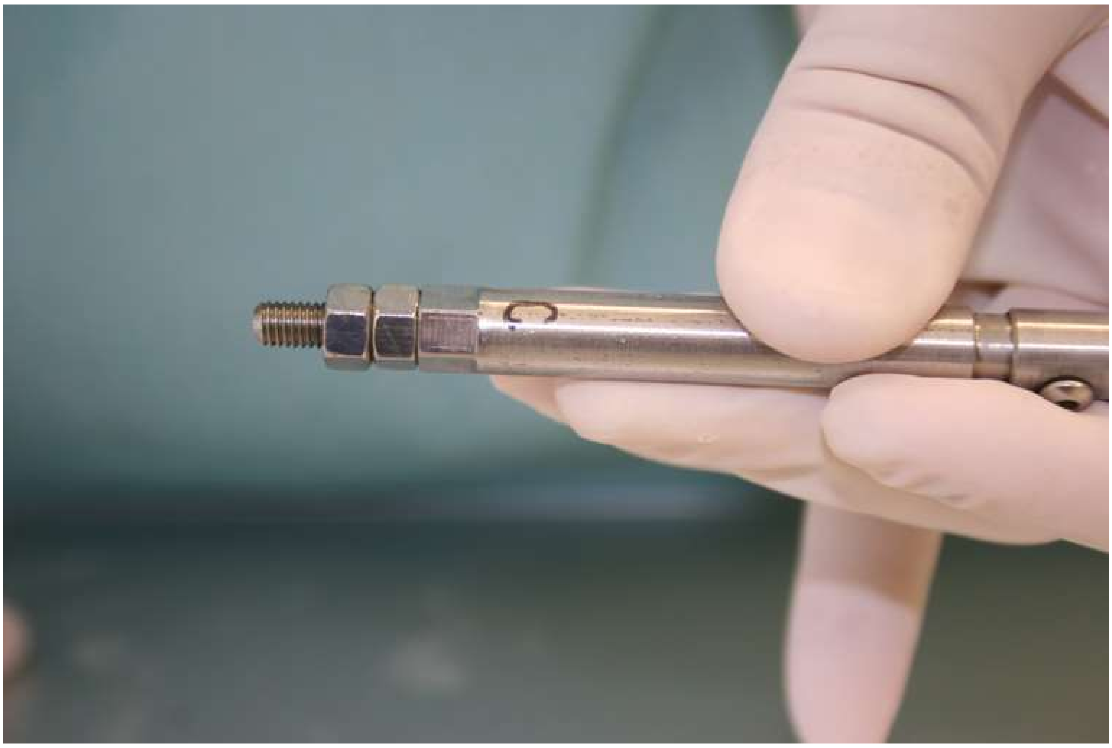

Fig. 4

Make sure that nuts D1 and D2 are uncoupled, then turn nut D1 until it is brought in contact with the end of cylinder D: keep tightening it until no more motion is present, thus preventing the nut from being further screwed in (Fig. 5).

Fig. 5

This maneuver must be done gently, stopping when you feel resistance to screwing the nut. Too strong tightening can damage the internal spring, preventing its proper operation during the step of dynamization.

Bring nut D2 in contact with nut D1 and tighten it. This procedure ensures that the fixator is hold in static position. At this point – in order to check whether the procedure was performed correctly – try to push the cylinders one against the other. No motion should occur.

Compression/distraction

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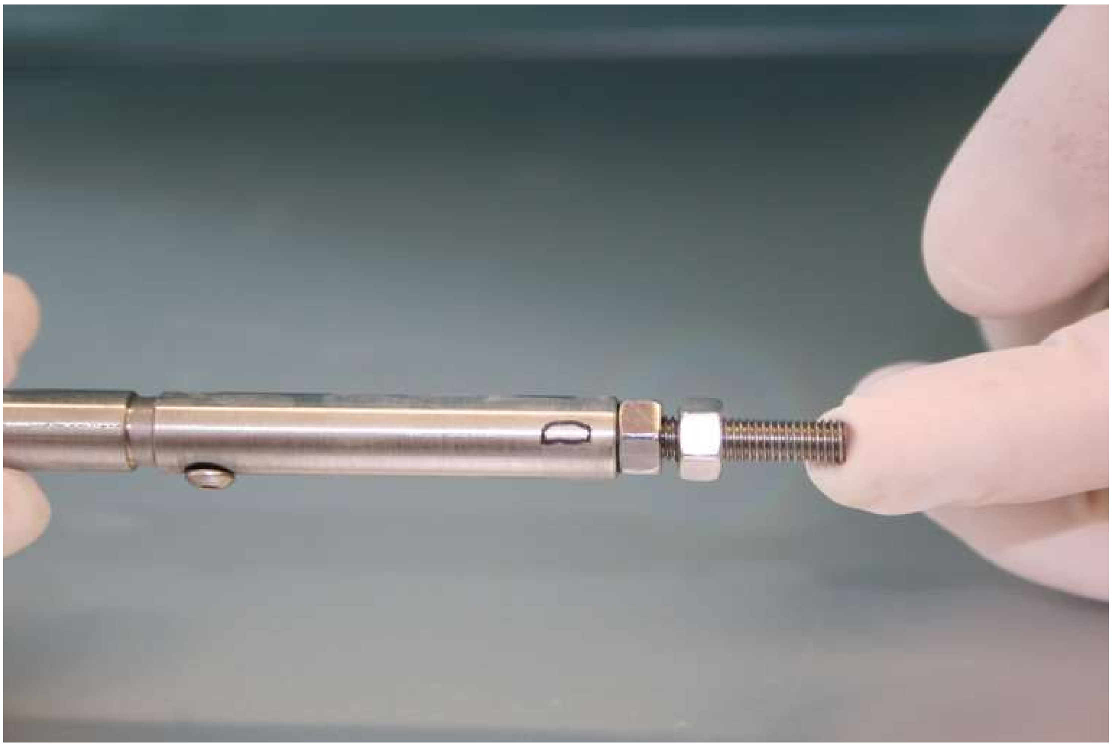

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DYNAMIZABLE EXTERNAL LINEAR FIXATION SYSTEM

Instructions for use of the clamps
Instructions for compression/distraction and dynamization

Fig. 1

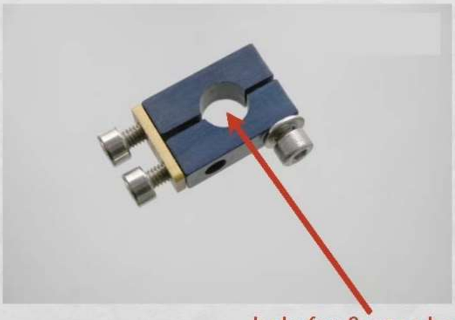


Fig. 1

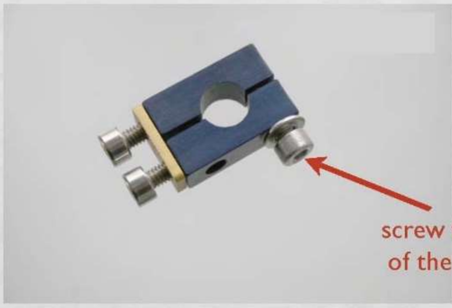
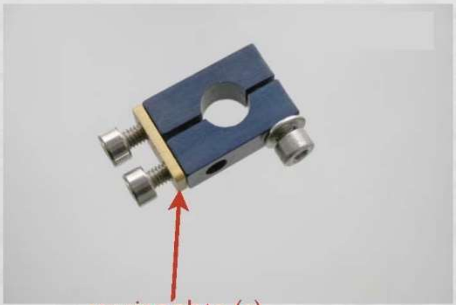


Fig. 1



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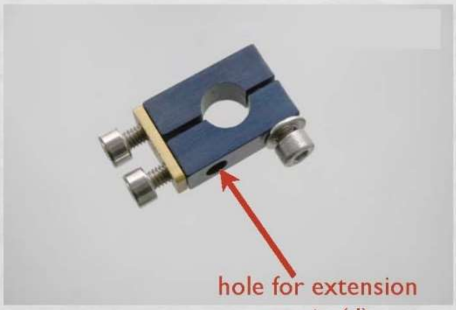

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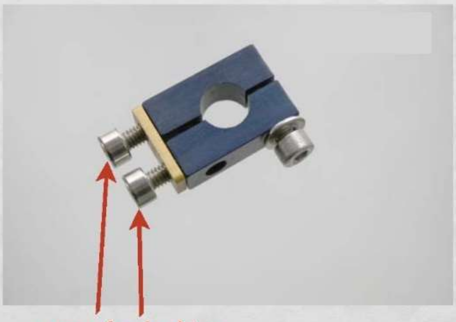


Fig. 1

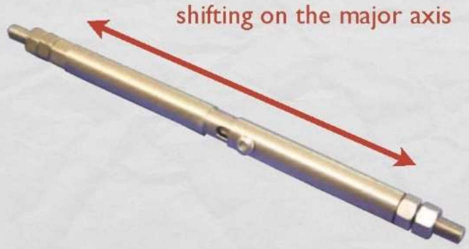


Fig. 2

Fig. 2

Fig. 3

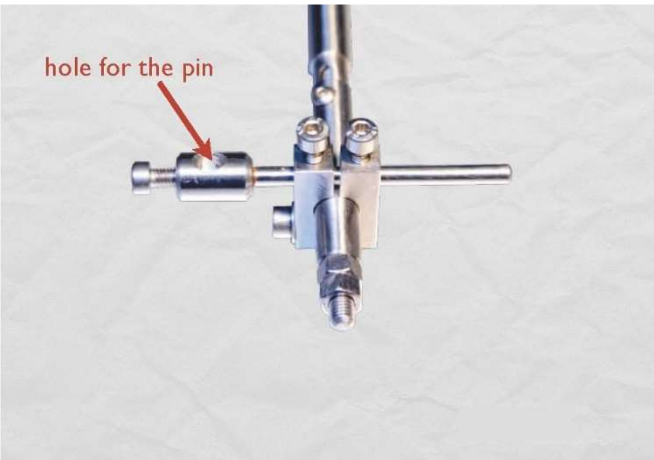


Fig. 3

Fig. 3

Fig. 3

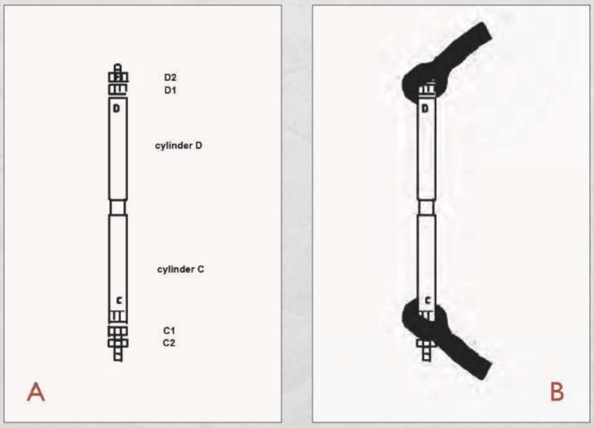


Fig. 4

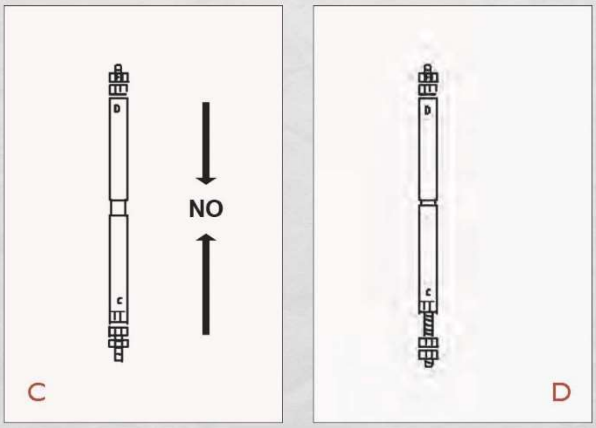


Fig. 5

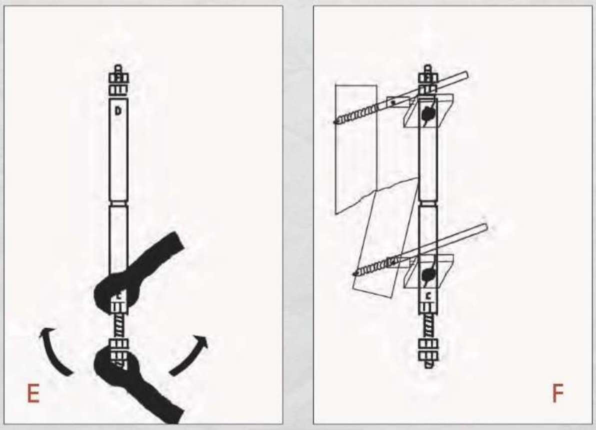
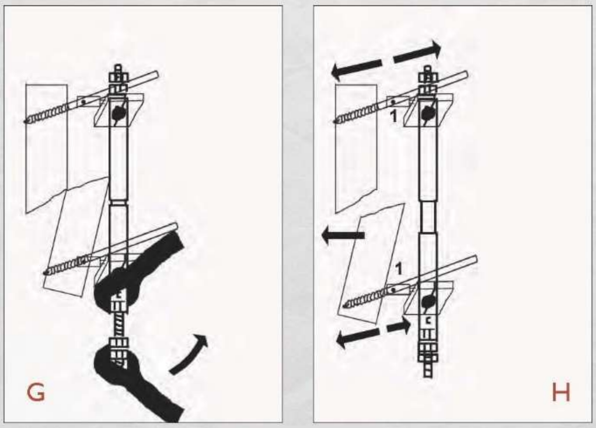


Fig. 6



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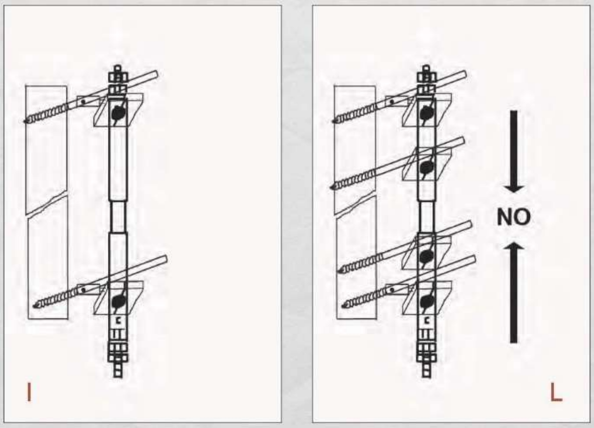

Fig. 8

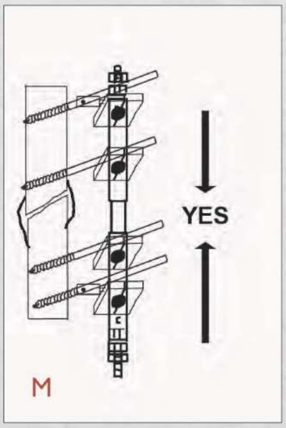

Fig. 9

For further info, please check at
www.veterinary-external-fixation.com

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