s·t·ϕ·r·m®

staffordshire orthopaedic reduction machine

- **Instructions For Use**
- **Surgical Technique**

intelligent orthopaedics

English

Instructions for use

Intended use

INTELLIGENT ORTHOPAEDICS instruments consist of manual surgical instruments and devices intended for use in surgical procedures.

This instrument is a Class I reusable manual device.

Instrument utilisation is determined by the user's experience and training in surgical procedures. Do not use this instrument for any purpose outside the intended use of the device, as it may seriously affect the safety and function of the product.

CAUTION: Handle devices with care to prevent damage to surgical gloves.

Recommendations for care, cleaning and sterilisation

INTELLIGENT ORTHOPAEDICS recommends that the cleaning and decontamination of instruments and devices follow the guidelines set forth by MHRA, AORN/HIMA and AAMI. Both physical and chemical (detergent) processes are necessary to minimise the bioburden on all soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris therefore a careful manual cleaning of each item with soft sponge or cloth is essential for maximum decontamination. Carefully inspect hidden areas, such as recesses, to assure any residual materials are removed.

Once the items have been cleaned and decontaminated they should be thoroughly rinsed with clean water to remove any detergent or chemical residue before sterilisation. The use of mild enzymatic detergent with a low pH is recommended.

Materials used in INTELLIGENT ORTHOPAEDICS devices can be sterilised using steam sterilisation methods. MHRA, AORN/HIMA and AAMI guidelines for sizes, weights and mass should be followed. The device has been certified sterilisable using a Porous Load 134-137°C/3 minute cycle.

1. After sterilisation all instruments should be allowed to cool. The time of cooling is dependent on the load size and mass. Place instruments on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the case is not allowed to cool properly.

   CAUTION: Hot instruments should not be handled or used as they can cause injury.

2. If condensation is observed check to ensure that cooling, as described in 1. above, has been followed. Verify that the steam being used for the sterlisation process has a quality of more than 97%. Also confirm that the sterilisers have been inspected for routine maintenance in accordance with manufacturer's recommendations.

3. Suggested steam exposure times: (ref: HTM2010 Part 3)
   Preferred: 134-137° C / 3 minutes
   Alternatives: 126-129° C / 10 minutes
   121-124° C / 15 minutes
   115-118° C / 30 minutes

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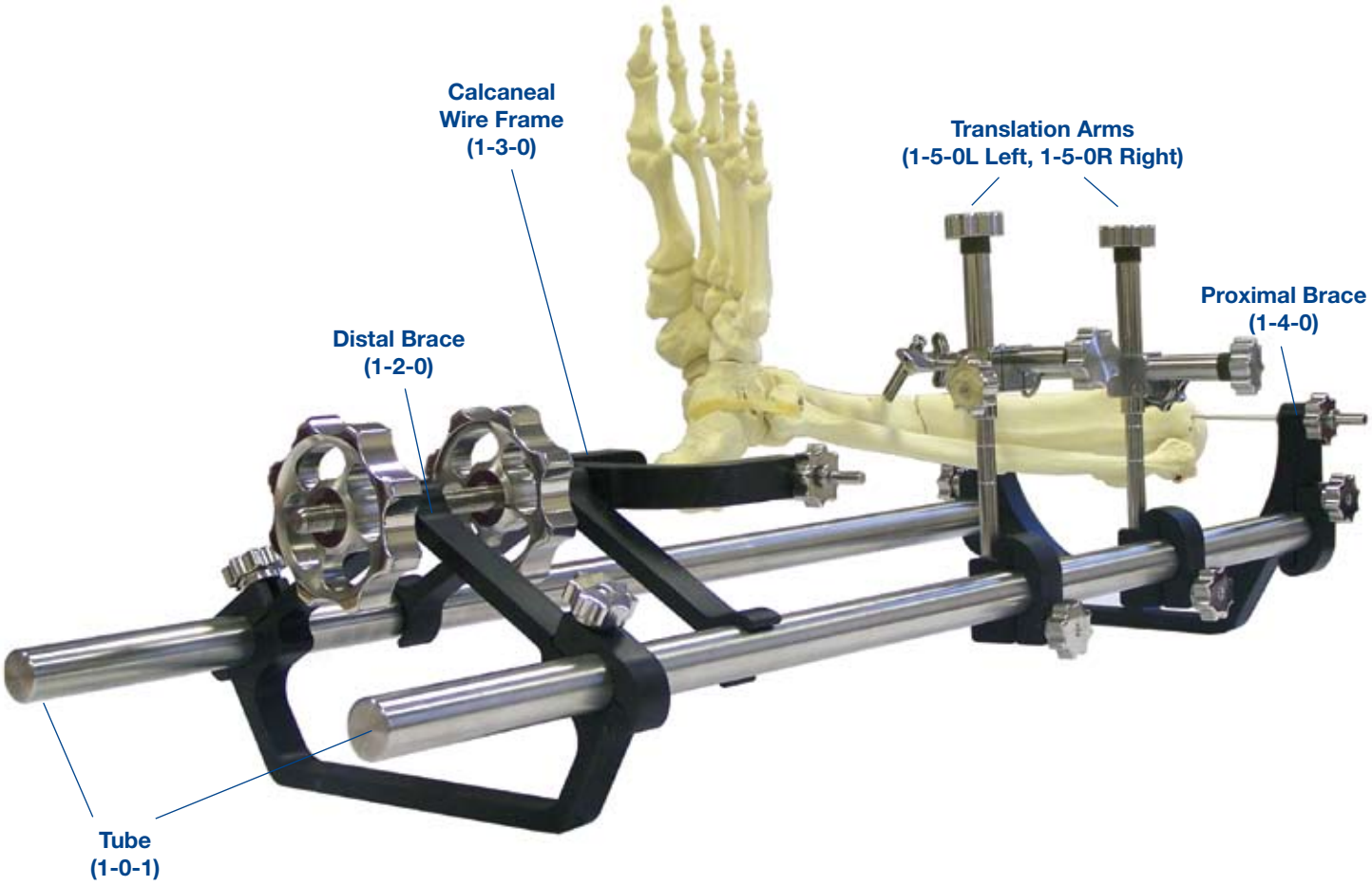


Description

The Staffordshire Orthopaedic Reduction Machine, stϕrm, is a class I re-usable device.

It has been designed to help the orthopaedic surgeon to reduce an unstable lower leg fracture prior to fixation. Used correctly it will help to achieve reliable reductions of high accuracy, shorter operating times, and more consistent operation durations.

An operating kit containing two tension wires, two uni-cortical screws and a bone drill is supplied for each operation (Part 1-10-0). The Staffordshire Orthopaedic Reduction Machine, stϕrm, should only be used with this operating kit.

Contraindications

This device applies traction, the force can be large; care should be taken to avoid injury to the patient. It is not recommended for use on minors or where potential damage to growth plates is expected.

Classification of tibial fractures

- STABLE: Fractures do not shorten or collapse when an axial load is applied.
- UNSTABLE: Fractures shorten or collapse under axial loading.

Surgical Technique

Preparation

1. The stability of the tibial fracture is assessed under anaesthetic. It should be fixed if it falls into the unstable group. Both legs are prepped and draped to above the knee.

2. The normal leg is prepped to allow easier access for X-rays and to allow comparison of rotation with the injured leg.

3. Ensure that wire tensioner assembly (1-0-4 and 1-0-6) is positioned laterally *Fig. 1*.

4. The position of the tibial plateau is marked on the skin after being identified using the X-ray image intensifier and a long radio-opaque marker placed on the skin. *Fig. 2*

Proximal Wire Insertion

1. The leg is then placed in the stϕrm.

2. An assistant holds the leg in the long axis of the stϕrm while the stϕrm operating kit (1-10-0) tension wire is inserted parallel to (about 20 mm below) the tibial plateau just anterior to the centre of the tibia on the lateral view and avoiding undue injury to the patient. *Fig. 3*

3. Use a powered wire driver, in the coronal plane.

4. The wire should be placed a safe distance from the lateral popliteal nerve.

5. The wire should pass through the wire tensioning components first and inserted until the end collet is in contact with the tensioners wire sleeve (1-0-4).

6. Take care not to allow the wire clamp to drop onto the floor.

NOTE: Ensure that the position of the wire does not conflict with the selected method of treatment. For example, if access is needed to the anterior of the knee (as in IM nailing) another position for the proximal wire may be selected. In this situation, ensure that this position will not inhibit application of the selected treatment method nor should it cause undue injury to the patient.

7. Lock the wire by bending it, using the wire bender (1-6-2), to fit the groove in the wire-clamp (1-0-5). *Fig. 4-6*

8. Trim excess wire to length, place a protective sponge on the sharp end to avoid injury or damage.

9. Turn the wire tension nut (1-0-6) clockwise to tension the wire.

10. Use the torque grip (1-0-10) to achieve sufficient tension so that the wire does not sag or deform unduly.


Fig. 1

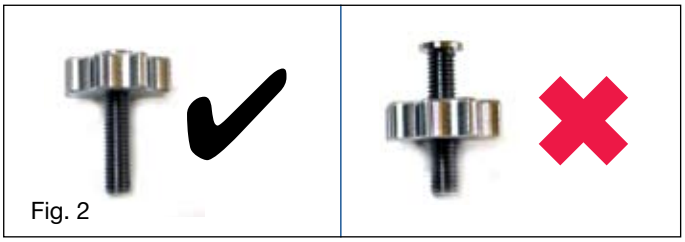


Fig. 2

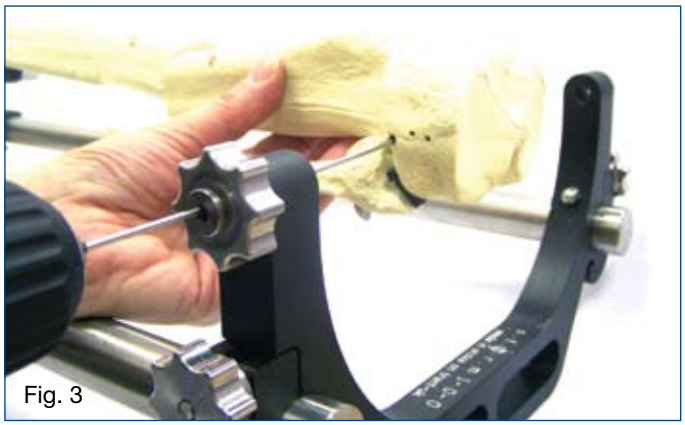
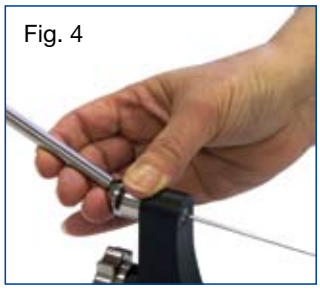


Fig. 3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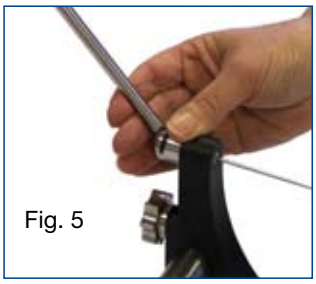


Fig. 5


Fig. 6

Distal Wire Insertion

1. Ensure that the distal traction nut (1-2-2) is unwound to leave 10 mm of the thread protruding. *Fig. 7*

2. Loosen the distal brace tube clamps lock nuts (1-0-8) and adjust carriage so that an assistant is able to support the leg with the heel centred in the calcaneal wire frame (1-3-0).

3. In a similar way to the Proximal Wire, the shorter stφrm k-wire (1-10-0) is then inserted through the calcaneum with the calcaneal wire frame (1-3-0) horizontal and the foot plantargrade vertical. *Fig. 8*

4. Tension the wire as described previously.

Applying Traction

1. The distal brace (1-2-0) is pulled so that it touches the traction nut (1-2-2). *Fig. 9*

2. The distal brace tube clamp lock nuts are tightened using the torque grip (1-0-10) to prevent sliding when traction is applied.

3. Traction is now applied by turning the traction nut (1-2-2). *Fig. 9-10*

4. Ensure that the distal brace does not slip.

5. The position of the fracture ends is checked using the X-ray image intensifier.

NOTE: Do not always expect the fracture to come out to length immediately. It can sometimes take several minutes for the soft tissues to stretch. Be patient during this phase of the reduction.

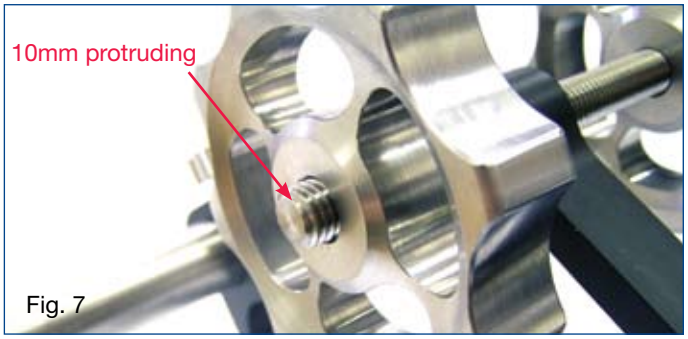
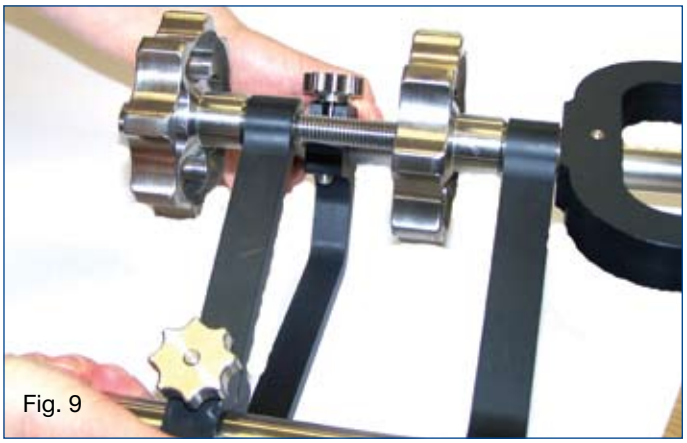


Fig. 7


Fig. 8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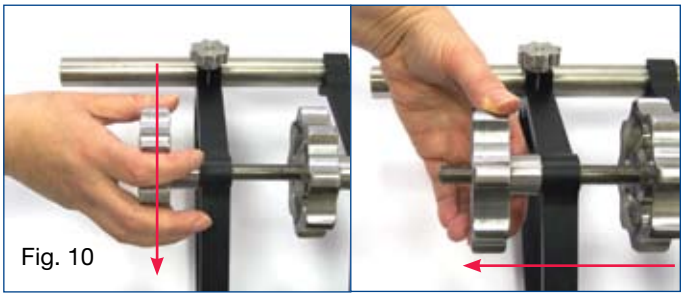
Fig. 10

Correcting Rotation

1. Once the fracture is fully out to length the rotation is corrected using the more proximal traction nut (1-2-2) and calcaneal wire frame (1-3-0).

2. Loosen the nut (1-2-2) and adjust rotation by rotating the calcaneal wire frame (1-3-0) about its axis. *Fig. 11*

3. Check rotation against the opposite leg.

NOTE: When it appears visibly correct, the relative diameter of the fracture ends, as seen on the X-ray image intensifier, and can be used for fine-tuning. Because the tibia is triangular in cross section, the width on the X-ray appears to change as it is rotated. Rotate the distal fragment on the proximal until the width of each fragment appears the same.

4. Once the rotation is correct tighten the more proximal traction nut (1-2-2) *Fig. 12*

NOTE: Ensure that you support the calcaneal wire frame (1-3-0) while tightening the lock wheel to avoid induced errors.

Translation and Angulation

1. The configuration of the stϕrm depends on the leg to be treated.

2. It is important that you select the correct translation arm (1-5-0) configuration as given below: *Fig. 13*

   - For a right leg, a letter R indicates the distal translation arm; a letter L indicates the proximal translation arm.

   - For a left leg, a letter L indicates the distal translation arm; a letter R indicates the proximal translation arm.

NOTE: This ensures that the left translation arm (1-5-0L) is always on the left, and the right (1-5-0R) is on the right.

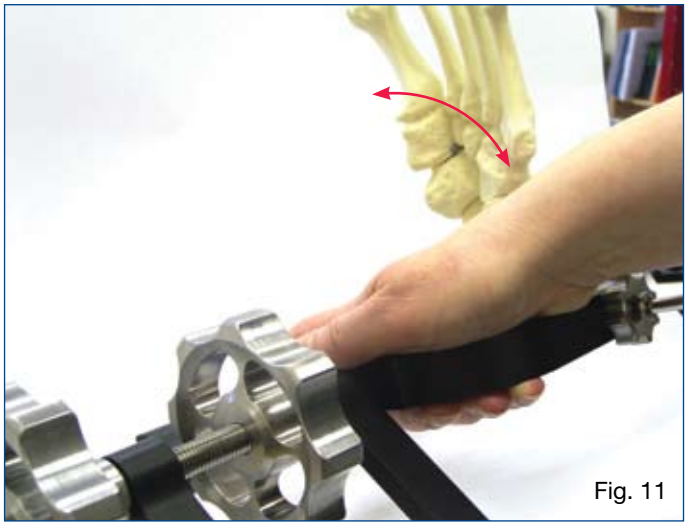
Fig. 11


Fig. 12

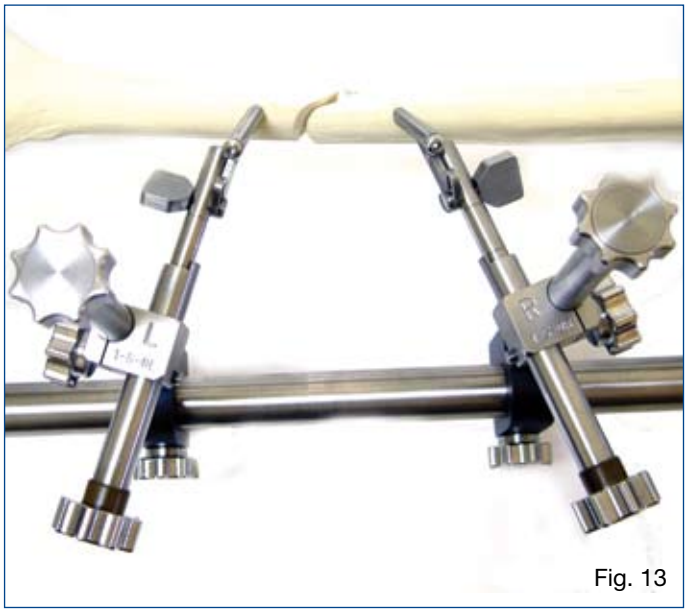

Fig. 13

Application of Proximal Fragment Translation Arm

1. Attach the proximal translation arm (1-5-0) to the lateral tube, pinch tighten the tube clamp. *Fig. 14*

2. Ensure that the arm and column are centred (the second line should be visible).

3. Adjust the position of the translation arm (1-5-0) such that a lateral X-ray view of the fracture is not obscured.

NOTE: The optimum starting point is about 50 mm proximal from the most proximal extension of the fracture.

4. When satisfied with the position, fully tighten the translation arm clamp (1-0-3) with the control column vertical.

5. The translation arm (1-5-0) is attached to the proximal fragment using a single cortical screw (1-10-0).

6. A transverse 10 mm incision is made in the skin at least 10 mm proximal to the most proximal extension of the fracture and 10 mm posterior to the anterior surface of the ridge of the tibia.

7. With the bone screw guide (1-5-8) in the centre of its arc (at 45º), loosen the translation arm lock screw (1-0-2) so that it slides easily. Adjust the arm by sliding the translation arm block (1-5-4 or 1-5-5) such that the screw guide (1-5-8) is in contact with the lateral cortex of the tibia. *Fig. 15*

8. Fully tighten the translation arm lock screw (1-0-2).

NOTE: The attitude of the bone screw guide (1-5-8) may need to be adjusted for individual cases.

9. Insert the drill guide (1-6-1) into the bone screw guide (1-5-8); the lateral cortex is drilled using the 3.2 mm drill.

10. The hole is washed out with saline in a syringe.

11. The stϕrm operating kit uni-cortical 56 mm long, 4.5 mm diameter screw is then inserted.

NOTE: Do not use any other screw.

12. The screw should be tightened and then backed off 1/4 turn to allow some play. *Fig. 16*

Application of Distal Fragment Translation Arm

1. Similarly repeat the procedure for the distal fragment, but with an incision made at least 10 mm distal to the most distal extension of the fracture, and using the distal translation arm.

2. Ensure that the horizontal translation arms point in towards each other. This allows an unimpeded lateral view with the X-ray image intensifier. *Fig. 17*

3. If the view is impeded you can adjust their position by loosening the translation arm tube clamp lock nut (1-0-2) and moving one or both translation arms.

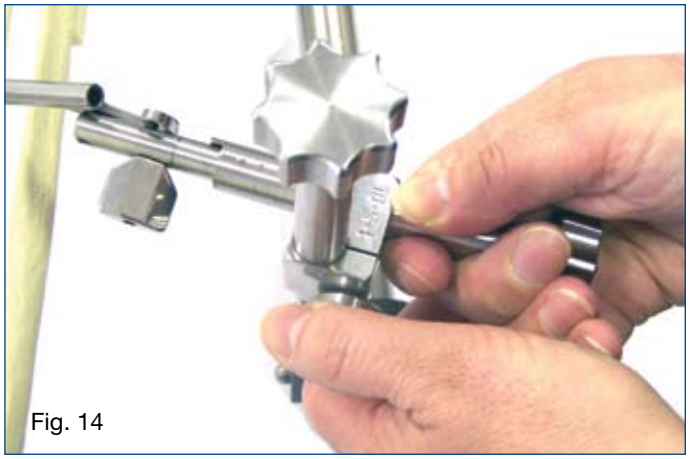
Fig. 14


Fig. 15


Fig. 16

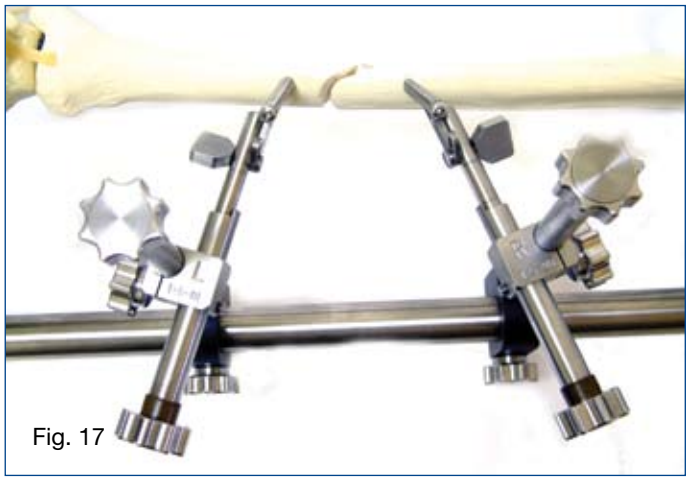
Fig. 17

Manipulation of Fracture Fragments

Misalignment Correction

1. The two translation arms are now used to correct any translational and angular misalignment. This is achieved using the horizontal and vertical adjustment knobs. Monitor the position using the X-ray image intensifier. *Fig. 18, Fig. 19*

NOTE: The translation arms (1-5-0L and 1-5-0R) are designed to be free to rotate about their columns so that extra traction can be applied without applying strain to the uni-cortical screws. If rotation of the distal fragment is to be changed it is very important to loosen the screw guide lock nut (1-5-10) at the end of the arm on the distal fragment. This allows the angle of the uni-cortical screw to change as the distal fragment is rotated.

Marking Fracture Position

1. Using a long radio-opaque marker, the X-ray image intensifier and a marker pen, now mark the position of the distal tibial plafond and the proximal and distal limits of the tibial fracture.

2. These should not be marked before a perfect reduction is obtained because the skin will move in relation to the bone as reduction progresses.

3. The fracture is now ready to be treated using a suitable fracture fixation system.

stϕrm Removal

1. When the fracture has been stabilised by the fixation method of choice the uni-cortical screws are removed.

2. The translation arms are removed and the incisions treated.

3. The two tensioned wires are then loosened, cut, and removed from the proximal tibia and calcaneum and incisions treated.

4. After which the stϕrm is removed, and sent for cleaning and sterilisation.

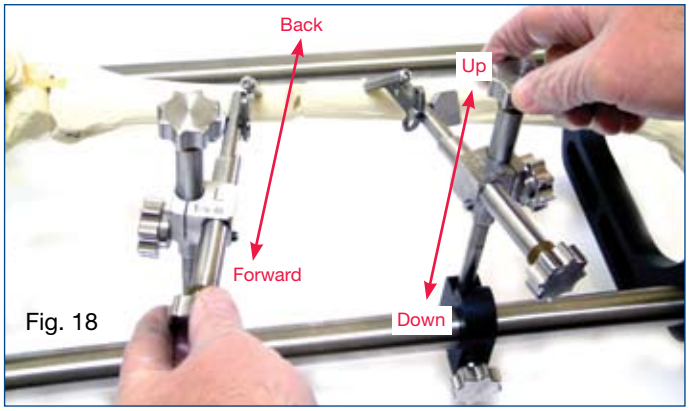

Fig. 18

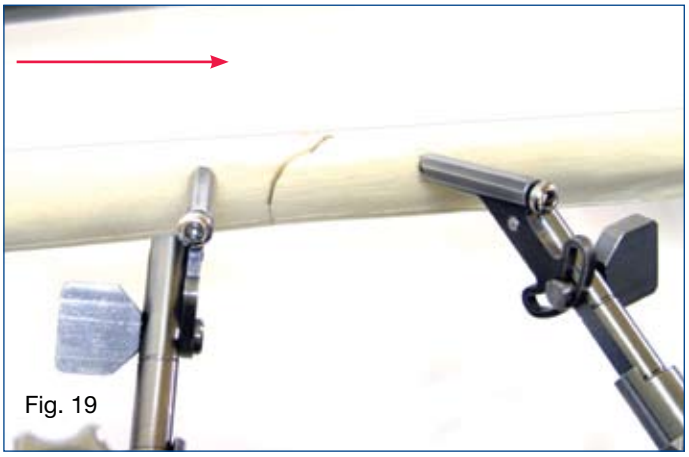
Fig. 19

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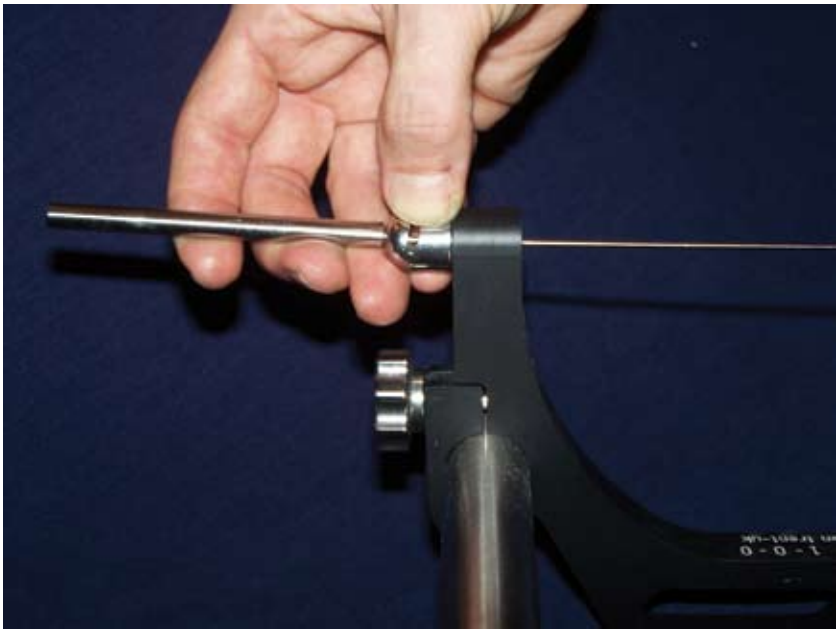

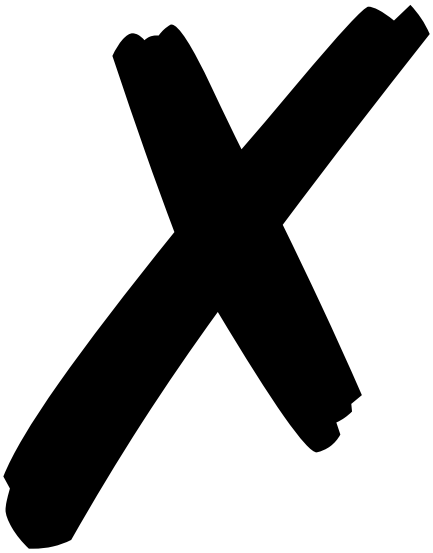

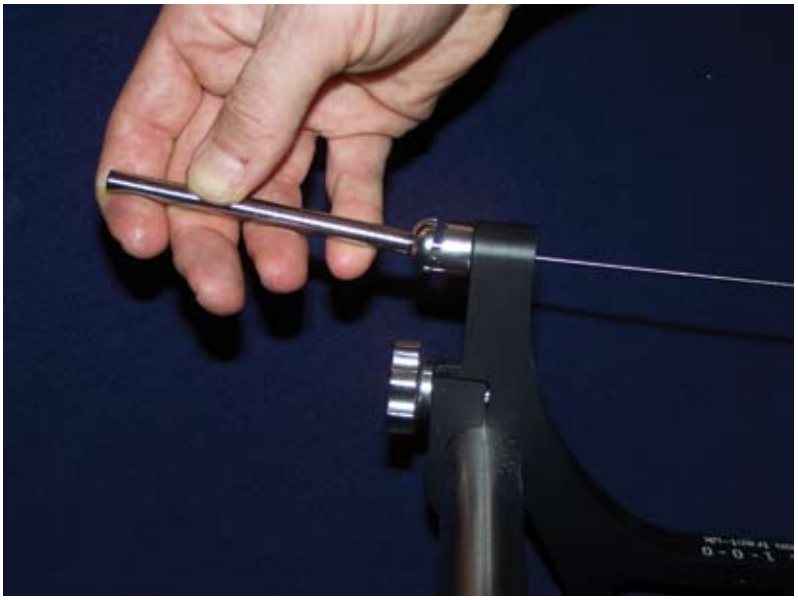

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