EXTERNAL FIXATION DEVICES

DESCRIPTION & INDICATIONS FOR USE

TST External Fixation System consists of a series of monolateral or circular external fixators intended to be used in conjunction with TST bone screws, threaded wires or Kirshner wires and the fragment fixation System. These devices are designed for stabilizing bone segments in a broad range of indications, including fractures, joint fusion, joint distraction, bone transport, lengthening and angular corrections. The TST components are not intended to replace normal healthy bone. The use of external supports (e.g. walking aids) is recommended as a part of the treatment. The system consists of various modules to be applied in different anatomical sites, i.e. tibia, femur, pelvic, humerus, forearm, hand and foot. All TST devices are intended to professional use only.

CONTRAINDICATIONS

The TST External Fixation System is not designed or sold for any use except as indicated.
- Patients with mental or physiological conditions who are unwilling or incapable of following postoperative care instructions.
- Arthrodiatasis of the hip utilizing TST external fixation in inflammatory arthropathies and for patients over the age of 45.
- Patients with severe osteoporosis, patients who are HIV positive and patients with severe, poorly controlled diabetes mellitus.
- Patients with foreign body sensitivity. Where material sensitivity is suspected, tests should be made prior to implant insertion.

WARNINGS & PRECAUTIONS

1. Compression is never recommended in a fresh fracture.
2. Axial displacement may occur if the body of the fixator is not in line with and parallel to the bone.
3. Medial or lateral translation may occur if the body of the fixator is not placed parallel to the diaphysis.
4. Particular care should be taken that screws do not enter the joints or damage the growth plates in children.
5. Dynamization and physical therapy guidelines should be followed based on each individual case and the fixation system used, and should be instituted as and when considered appropriate by the surgeon, in accordance with clinical and radiological findings.
6. Any device implanted into the patient, such as bone screws, threaded wires, Fragment Fixation System implants, and in general any device which is labelled “single use only”, includingams, bushes of any external fixation device, MUST NOT BE RE-USED.
7. Screw length and thread length should be selected in accordance with bone and soft tissue dimensions. The screw thread is conical in design and tapers, for example, from 6 mm to 5 mm between the shaft and the tip of the Standard fixators. Thread length should be such that at least one full thread will remain outside the entry cortex and the screw tip will project just beyond the second cortex. Screw thread lengths are provided in increments of 5 mm, so that no more than 5 mm of thread should be exposed outside the entry cortex. Excessive penetration of the second cortex by any type of screw should be avoided, because of the risk of damage to the bone.
8. Due to the conical thread design, any attempt to back out an screw once it has been inserted may cause it to become loose.
9. Screw diameter should be selected in accordance with bone diameter; for a bone diameter greater than 20 mm, 6 mm or 5 mm bone screws should be used; for a bone diameter between 12 and 20 mm, 4 mm or 5 mm bone screws; and for a bone diameter between 9 and 12 mm, 3 mm or 2 mm bone screws should be used.
10. Self-drilling screws should never be inserted with a power tool, but always by hand or with hand drill.
11. For more stable fixation of a fracture with a fixator, we recommend that the nearest bone screw is applied fairly close to the fracture margin (a minimum of 2 cm is recommended) and that these distances are equal on both sides of the fracture.
12. The bone screws are designed to be self-drilling and direct insertion with a hand drill is advised in most cases. However, when insertion of self-drilling screws is performed in diaphyseal bone, pre-drilling is recommended, with a 4.5 mm drill bit through a drill guide. Screw insertion, whether or not pre-drilling has been performed, should always be with the hand drill or T-Wrench only. It is important that moderate force is applied for the screw to gain entry into the first cortex. Insertion can be completed with the T wrench. Diaphyseal bone screws should always be inserted in the centre of the bone axis, to avoid weakening it.
13. When screws are to be held in one of the range of 3 or 5 seat screw clamps, it is very important that they are inserted with the correct procedure, so that they are parallel when in position. This is achieved by using screw guides in the templates or fixator clamps provided, and pre-drilling the screw hole, when required, through the correct size of drill guide. The clamps should be tightened so that the screw guides are gripped evenly, and held in correct relationship to each other.
14. When screws are inserted into one of the fixator clamps, in such a way that one of the screw seats at the end of the clamp is empty, it is important that this is filled with a short, dummy screw, so that the clamp cover grips all the screws with an equal pressure.
15. The T Clamp of the External Fixator allows for either parallel or convergent positioning of the proximal screws. When using T Clamp, the first screw to be inserted should always be in the screw seat which is part of the fixed straight clamp; subsequent screws should be in the converging section of the T clamp. When the convergent mode is used, the fixator should be positioned at the correct distance from the bone before inserting the second screw, as the fixator will not slide along convergent screws.
16. For more stable fixation of a fracture with a fixator, we recommend that the nearest bone screw is applied fairly close to the fracture margin (a minimum of 2 cm is recommended) and that These distances are equal on both sides of the fracture.
17. When unusually high loading conditions are likely, such as weightbearing with a femoral application or when the patient is very heavy, before the ball joints are locked the fixator body should be aligned so that the body locking nut is at minimum 90° to the plane of the screws. In addition for increased stability the compression-distraction unit may be applied to the fixator body and locked into place.
18. Threaded wires and fragment fixation system implants are drilled directly into the bone, and have a cylindrical thread which allows them to be backed out following insertion. When the chamfer of the fragment fixation implant is close to the cortex, the screw insertion must be reduced.
19. No attempt should be made to insert a Kirschner wire more than once; since the tip may have become blunt and is the only cutting surface, undesirable healing of the bone may occur.
20. Appropriate instrumentation should be used to insert bone screws and Kirschner wires correctly.
21. Wherever a Kirschner wire or Guide wire is used to guide a cannulated reamer, drill bit or screw into position:
   a) The Kirschner or Guide wire should always be New.
   b) The wire should be checked before insertion to exclude any scratches or bends.
   c) During the introduction of any instrument or implant over a wire, the surgeon should screen the wire tip as continuously as possible to exclude inadvertently driving the wire further than intended.
   d) During each pass of the instrument or implant, the surgeon should check that there is bony or other debris built up on the wire or inside te instrument or implant which might cause it to bind on the wire and push it forward.
22. It is impossible to clean the inside of a cannulated drill bit adequately to exclude organic or other debris remaining after use. Cannulated Drill Bits should be therefore never be re-used. They are single patient use only. If a cannulated drill bit is to be used for a second time on the same patient, the surgeon must check that the drill bit is free from obstruction, by removing it from the power unit and passing a wire through it.
POSSIBLE ADVERSE EFFECTS

1. Nerve or vessel damage resulting from insertion of wires and screws.
2. Superficial or deep bone screw tract infection, osteomyelitis, or septic arthritis, including chronic drainage of bone screw sites after device removal.
3. Oedema or swelling, possible compartment syndrome.
4. Joint contracture, subluxation, dislocation or loss of range of motion.
5. Premature bone consolidation during distraction osteogenesis.
6. Possible tension to soft tissues and/or frame during callus manipulation (i.e. correction or bony deformity and/or bone lengthening).
7. Failure of bone to regenerate satisfactorily, development of nonunion or pseudarthrosis.
8. Fracture of regenerate bone or through bone screw holes after device removal.
9. Loosening or breakage of bone screws.
10. Bony damage due to inappropriate bone screw selection.
11. Bone deformity or equinus of the foot.

Material

TST External Fixation System components are manufactured of stainless steel, aluminium alloy and plastic components. Human contact components such as bone screws, K-wires, drill bits, guides, trocars, and bone depth gauges are manufactured from surgical grade stainless steel and titanium. Some of the products are supplied with HA coating.

ANY DEVICE WHICH IS LABELLED “SINGLE USE ONLY” MUST NEVER BE REUSED. TST IS ONLY RESPONSIBLE FOR SAFETY AND EFFECTIVENESS FOR THE FIRST PATIENT USE OF SINGLE USE DEVICES. The institution or practitioner bears full responsibility for any subsequent use of these devices.

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