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English

INSTRUCTIONS FOR USE OF THE BONE FIXATION PLATE & SCREW GROUP PRODUCTS

1. Product Description

Plates: This is a general term used for describing a medical device which is placed on more than two or more bone fragments with the aid of screws or other fixation methods in order to achieve a more stable fracture fixation than screws alone or casting. They are classified according to their sizes or to the applied bone such as; Humerus, Ulna-Radius, Pelvis, Femur, Tibia, Ankle.

Wires, pins, staples: They are used alone or in conjunction with other implants (including fixators) in fixation of small fragment bone fractures.

Screws: They are used in bone and/or different implant fixation to the bone consist of Cortex, Cortical, Cancellous/spongious, Compression, Malleolar, Connection and Cannulated screws

Purpose of Use: It is used with open reduction internal fixation technique for orthopedic surgeons to fix related fractures in adult patients, malunion, non-union and osteotomy applications. Plate & Screw group implants used for fracture fixation of the applied bone are designed as orthopedic fixation implants suitable for use especially in osteoporotic bones or multi-part fractures, joint fractures, attachment of ligament or tubular soft tissues to bone. The products are suitable for use in primary or revision cases with the orthopedist's decision.

There was no harm in using it in immunocompromised patients (AIDS, etc.). Patients should use the product in accordance with the instructions specified in the user manual.

Product Groups	Product Models	Auxiliary Products
Humerus Plates	Distal Clavicle Plate, Locking Clavicle Hook Plate, Low. Prof. Lock. Clavicle Plate, Low Prof. Lock. Clavicle Plate, LC DCP Lock Humerus Plate, LDC Distal Humerus Epicond. Lat Plate, Distal Humerus Lock. Y Plate, Miss Proximal Humerus Lock. Plate, Scapula Lateral Locking Plate, Scapula Medial Locking Plate, Scapula Spine Locking Plate, Glenoid Locking Plate	Cortical and Cancellous screws locking or nonlocking at head part
Ulna-Radius Plates	Wrist Fusion Lock. Plate, S. Head Distal Radius Dorsal Lock. Y Plate, Distal Radius Straight Plate, Small Head Dist.Radius Dor.Lock. L Plate, S. Head Wide Dist. Radius Lock. Plate, Olecranon Lock. Plate, Lowprofile I.L. Olecranon Plate, Ulna Radius Lock. Plate, 1/3 Ulna Radius Lock. Plate, LowPr 1/3 Radius Ulna I.L. Plate, Low Profile Ulna Radius Interlock. Plate, Proksimal Ulna Plate.	Locking nonlocking Cortical Screw, Locking nonlocking Cancellous Screw, Locking Peg Screw, Small Head Locking-Nonlocking Screw
Pelvis Plates	Lock. Pelvic J Recon Plate, Lock. Pelvic Quadrilateral, Lock. Symphysis Pubis, Lock. Pelvic Recon Plate, Lock. Pelvic Curved Recon Plate, Lock. Hooked Tubular Plate	Locking – Nonlocking Cortical Screw
Femur Plates	LC DCP Bow Lock Femoral Int Lock Plate, Miss Femur Lock Plate, LC Ped. Dist. Femur Osteo. Plate, LC Pediatric Hip Plate, Prox. Femur Lock Plate, Miss LC Prox Femur Plate, Angled Blade Plate Infant, Lock Clamp Plate, LC Dynamic Hip Screw Plate, LC Dynamic Condylar Plate, A-DHS Lock Plate, Pediatric Hip Plate DCP, Angled Blade Adult Plate, Pediarticulated Plate, Angled Blade Plate, Angled Blade Plate DCP, Lowpro Dis Femur İnt Anat Plate, Miss LC Distal Femur Plate, Prox Femur Lock Hook Plate, Eight Growth Plate, Daiphyseal Lock Cable Plate	Cortical and cortical head locking or nonlocking screws, Tapered 5.0-5.5mm screws, Screws with or without head locking in cancellous body thread structure, Cable, Cancellous Screws, Clamp Plate fixing screw, 4 mm diameter screws All threaded cannulated or without cannulas
Tibia Plates	LC DCP Interlock Tibial Plate, LC Pediatric Distal Tibia Medial Plate, Owo Anatomic Plate, Low Prof Prox Tibia İnt. Anat. Plate, Miss LC Proximal Tibia Lateral	Screws in cortical body thread structure with or without locking head, Cancellous body threaded structre head with or without locking, Cannulated or noncannulated, Cancellous body threaded structure screws locking or nonlocking head.
Ankle Plates	Handy Tension Band, LowProfile Calcaneus Interlock Plate, Low Profile Distal Fibula Lock Plate, LCP Pilon Plate Lock, Distal Tibia Lock Anterior Malleolar Plate, LC Distal Tibia Posterior Plate, Miss LC Distal Tibia Medial Plate, Distal Tibia Anterio Lateral Plate	Cortical body threaded structure screws locking or nonlocking head, Cancellous body in threaded structure locking or nonlocking head , Cannulated or noncannulated.
Mini Plates	Jawbone Plate, LC Mini Fragment, Mini Plak, Intercarpal Fusion Plate (Pure Ti and alloys)	Locking and variable angle locking, Nonlocking screws. (Ti alloys)
Cannulated Screws	HCCS, Cannulated Herbert Screw, Cannulated Screw 6.5, Cannulated Screw 4.0, ACCS, MIS A CHS Antirotat Komp Hip Screw	-
U Blade	Staple Step, Staple U Blade, Staple U	-

2. Protecting the Product

Implants should be accepted only with the original packaging and labels intact. Before use, the package should be checked for any damage, and if the product is sterile, its sterilization should be checked. When opening the package, the information on the product label is verified. When opening the package, the information on the product label is verified. When removing the implant from the package, the relevant aseptic instructions should be observed. The product should be kept separate from materials that may damage its surface. Each implant should be visually inspected before use. Damaged or poorly protected products should not be used. Pay attention to the information on the packaging of the implant you will use. Use implants together with your patient according to the above matrix table for the materials. Do not use products from different manufacturers together.

Use with instruments that comply with AO principles.

All fracture fixation implants are for single use only.

The label of the product should be attached to the patient's file and the file should be kept for at least 15 (fifteen) years.

Caution: Single Use Implant

Products designed for single use should not be reused. Reuse or reprocessing (such as cleaning and resterilization) may **compromise** the structural integrity of the device and / or result in implant damage resulting in patient injury, illness, or **death**. In addition, reuse or reprocessing of single-use devices may pose a contamination risk due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user. Although they appear undamaged, there may be minor defects and internal stress patterns in the implant that could lead to material fatigue.

Fracture fixation materials only help fracture healing, they cannot assume the functions of normal bone or soft tissues in fracture healing. Anatomy of human bone may limit the physical properties of implant systems that can be placed. discretion. Repetitive loading may cause bone and soft tissue union and healing delay, or even stop, ie nonunion (pseudoarthrosis). This may lead to complications such as physical failure of the implant or separation from the bone.

3. Packaging and Sterilization

Plates and Screws are supplied in a container with a non-sterile package. The products are sterilized in hospital sterilization units before use. Before autoclave sterilization, they are sterilized after being removed from their packaging and placed in sets. Before the sterilization process, the products must be washed for disinfection.

4. Sterilization and Resterilization

Implants are come into use as "non-sterile" in related sets. Non-sterile products should be removed from the packaging and protective cover before surgery and sterilized after cleaning. During the sterilization and reserialization process, scratching and corrosion of the implants should be prevented. The use of dry heat in the sterilization process is not recommended as it may affect the implant properties.

All parts must be disassembled before sterilizing. Care must be taken to protect the parts from mechanical damage. Parts must be at room temperature before they are used. We recommend the use of cleaning agents in the pH range 7 to 9. Corrosive materials and wire wool should never be used in TST implants. Qualified personnel must perform cleaning and sterilization processes with documented expertise, competence and training.

Our advice; For the sterilization of TST non-sterile implants, it is sterilized in autoclave at 121º C and 30 minutes.

We strongly do not recommend flash sterilization. Sterilization parameters are only valid for properly cleaned implants. Implants; Must be subjected to manual cleaning process in medical device disinfectant for 15 minutes. After manual cleaning process, they should be subjected to ultrasonic washing process for 5 minutes at 70º C temperature. Products are ready for autoclave sterilization after rinsing and drying processes.

5. Pre operation Planning

Only patients who meet the criteria described in the indications section should be selected. Patient situations and / or trends outlined in the previously described contraindications should be avoided. Care should be taken when using and storing implants. Implants should not be scratched or damaged. Implants and instruments should be protected during storage and corrosive environments should be avoided. Unless otherwise stated, the device must not be combined with components of another system. All parts must be cleaned and sterilized before use. The implant is for single use only. It should be ensured that all the necessary components for the surgery are ready in the operating room. It is recommended that implants be checked before surgery to determine if they have been damaged during storage. In rare cases, instruments may crack or break during surgery. Instruments that are overused or subjected to excessive force are more likely to break. Instruments should be inspected for wear or damage prior to surgery.

6. During Operation Planning

Damage to the implant surface must be avoided. Any damaged or abused implants should be discarded. Shaping or bending of the implants should be avoided as much as possible, as this will reduce the fatigue strength and cause failure under load. If shaping is required, if possible by design, or recommended by the TST, the physician should avoid sharp bends, reverse bends or twisting of the device through the screw hole. This operation should be performed with TST instruments in accordance with the specified procedures (see surgical technique manual). During surgery, the connection between the implant and the instrument or between the instruments must be checked over and over for correct positioning and fixation. Check that all implants are properly positioned using image intensifier after the procedure. Do not use components of TST product systems with components from other manufacturers' systems unless otherwise specified (see surgical technique manual).

7. Post Operation Planning

Post-operative patient activity: These implants are not intended to suddenly start carrying the entire burden of the patient or to carry a significant part of the burden for a long time. Therefore, postoperative instructions and warnings are very important for patients. External immobilization (e.g. a brace or cast) may be used until adequate bone consolidation has been confirmed by x-ray or other procedures. Complications such as fracture, loosening of the implant or instability of the implant system occur in the event of late or no union of the bone or if the explantation is not performed. Regular post-operative examinations (e.g. x-ray checks) are recommended. If the patient is obese and / or unable to follow the doctor's recommendations due to any mental illness or neuromuscular disorder, the risk of postoperative complications (e.g. implant failure) is higher. Therefore, these patients should be followed more closely after surgery. Appropriate postoperative management should be applied to prevent fracture or re-fracture of the bone after implant removal.

8. Implant Materials

TST Plates & Screws; are made from ISO 5832-1 or ASTM F138 or ASTM F139 CrNi Stainless Steel; ISO 5832-3 or ASTM F136 Titanium Alloy (Ti6Al4V), ISO 5832-4 CoCrMo alloy and ISO 5832-2 Unalloyed titanium.

9. Magnetic Resonance Environment

TST Products have not been evaluated for safety and compatibility in the MR environment. TST products have not been tested in the MR environment.

10. Indications:

Common indications for all Bone Fixation Plate and Group implants are as follows:

They are indicated for fixation of bone fractures, malunion, non-union and osteotomy applications in adult patients and are used with open reduction internal fixation technique. Bone fixation plates implants; It is suitable for fracture fixation of related bone, especially in osteoporotic bones or multi-part fractures, fractures involving the joint. Products can be used in primary and revision cases

11. Contraindications

Infection (or a history of infection); Acute or chronic, local or systemic, Severe muscular, neurological and vascular deficiencies consistent with the affected extremity condition, Malunion, Nonunion, Locking screw migration, Plate screw fracture, Underdeveloped skeletal structure, Psychologically or physiologically inadequate patient, Inadequate skin, bone, or neurovascular conditions

12. Situations That May Affect the Success of The Procedure

- Severe osteoporosis
- Severe deformation, congenital dislocation
- Regional tumors in the bone
- Systemic and metabolic disorders
- Past infectious disease
- Pill and / or drug addiction
- Obesity
- High levels of physical activity (e.g. physical labor, competitive sports, marathon runs, etc.), creating beating and / or excessive stresses that will jolt the implant.

Important: If the Plates and Screw System is determined to be the best for the patient and the patient has one or more of the above-mentioned conditions, the patient should be informed about how these conditions will affect the operation and product life. It is recommended that the patient be advised of any activities that may reduce the problems.

Plate and Screw group should be used by specialist doctors with appropriate training and experience in implant surgeries.

13. Side Effects

- Loosening, bending, or breakage of the implants
- Loss of anatomic reduction and malunion
- Superficial or deep infections
- Thrombophlebitis, pulmonary embolus, hematoma formation, and avascular necrosis of the femoral head
- Shortening of the extremity, limping
- Very rarely metal allergy or host reaction (including the tissue reactions from macrophage and foreign object reaction)
- Implant failure and chondrolysis in patients with poor bone quality
- Damage to growth plates prior to closure

14. Warnings and Precautions Before Use

1) It is very important to choose the most suitable type and size implant for the patient. Failure to use the largest possible implants or improper placement of the implants may result in bone detachment, bending, cracking or fracture of the implant. Bone deformity, delayed union or nonunion, fracture may occur.

2) In subtrochanteric fractures or osteotomies, enormous loads are placed on the implant. Therefore, the use of internal and external supports (such as bone graft use or medial shift osteotomy) may be required to recover the fracture healing process in this area.

3) In subtrochanteric or trochanteric region partial fractures and osteotomies, it is appropriate to choose long plates to reduce the load on the plates. In such cases, the plate with the highest valgus angle should be selected and full load should not be applied during fracture healing.

4) Screws should not go through the break line. If lag screw is made, screw threads should fit tightly to the bone and should be long enough to allow telescopic slip in case of shortening due to bone resorption in the fracture line.

5) While storing and placing the implant, maximum care should be taken not to scratch or crush its surface. Products should always be stored in their unopened packaging. The bending, twisting or shaping of the implants with hammer or similar heavy objects during the application to the patient can significantly reduce the durability of the implant.

6) The patient should be given extensive information on how to protect the operative extremity postoperatively and appropriate postoperative care should be provided. Putting weight on the implant before fracture healing is complete increases the likelihood of loosening, implant bending and fracture. Early weight bearing may be allowed in patients with a very good and reliable bone contact.

7) Implants can be removed at an appropriate time after fracture healing, but this timing should be decided by the surgeon, taking into account personal factors (age, bone quality, fixation strength, bone coverage.

8) Patients should be informed that the implants can be removed with a second procedure after surgery.

9) Fracture may occur during loading through any hole following removal of screws.

10) During the operation, the whole set should be found in full according to the planning.

11) Although it is very rare, patients with sensitivity to the material should be tested for allergy before surgery.

12) In order to detect implant failure early, especially in comminuted fractures after surgery, monthly radiography control is recommended until callus is seen in at least three planes.

13)To increase the success of the operation, appropriate instruments should be used and the application should be checked with imaging devices.

14) There was no harm in using the products in immunocompromised (AIDS, etc.) patients.

15) TST instruments should be used with TST products in order to maintain patient health and product safety, and to prevent damage to the relationship between components. It is not recommended to use TST instruments with products of other brands.

16) Important note for medical professionals and operating room personnel: These instructions for use do not contain all the necessary information for the selection and use of a device. Please see all labels for all necessary information (related Surgical Technique Information, Important Information)

17) Plates and Screw group products do not have special storage conditions.

18) The distribution of Plates and Screw are done in containers that are protected against any damage.

15. Possible Risks

As with all major surgical procedures, risks, side effects and adverse events may occur. There are many possible reactions, the most common include: Problems arising from anesthesia and positioning of the patient (nausea, vomiting, dental injury, neurological disorders, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, soft tissue damage, including swelling, abnormal scarring, weakening of the musculoskeletal system, Sudeck's disease, allergies / hypersensitivity reactions and hardware prominence, Side effects associated with malunion or nonunion.

16. Meaning of Symbols Used with Product Labels

CE 1984	Notified Body Number 93/42 / EEC compliance		Do not use if package is damaged.
REF	Catalog Number	LOT	Product Lot Number
	Instructions for Use		Manufacturer Information
	Do not use it a second time	NON STERILE	Products are nonsterile

Neither manufacturers nor dealers take responsibility for resterilization of products by the consumer. The recommendations provided are for informational purposes only.
TST implants should not be used with implants from other manufacturers.
All implants are for single use only. The label of the product should be attached to the patient's file and the file should be kept for at least 15 (fifteen) years.
For the surgical technique and the application of the product, see the product catalogs (TST.K.01).

WARNING: IT CAN ONLY BE USED BY EXPERT PHYSICIANS!