TST Rakor ve Tıbbi Aletler San. ve Tic. Ltd. Şti.
Sanayi Mah. Şehit Cevdet Çelenk Cad. No: 3
34912 Kurtköy-Pendik-İstanbul-Turkey

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KIWA
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English

INSTRUCTION FOR USE OF INTRAMEDULLARY NAILING SYSTEMS-INTERNAL FIXATION

1- Product Description

Intramedullary Nails:

Clavicular Intramedullary Nails; Humeral Intramedullary Nails; Radial Intramedullary Nails; Ulnar Intramedullary Nails; Femoral Intramedullary Nails; Tibial Intramedullary Nails; Fibular; Intramedullary Nails; Intramedullary Nails for Joint Arthrodesis/Fusion

Auxiliary Products:

Proximal Locking Screws; Distal Locking Screws; Collum Screws; Compression Screws; Set Screws; "DSBLS" Screws; "Endopin" Locking Pins; End Caps

Intended Use: Intramedullary Nails and their components are designed for fixation, correction or stabilization of bone fractures in the relevant anatomical regions and repair/correction of variable deformities and pathologies using surgical methods.

Implants are designed to operate minimally (as little invasively as possible) while fulfilling the specific performance expected of them. Special designs have been made so that the operator interventions required to provide each function are minimally traumatic.

Osteosynthesis with intramedullary nails is generally used in cases such as diaphyseal fractures, traumatic arthritis, osteoarthritis, and osteodystrophy. Among the reasons why it is preferred over classical plate-screw osteosynthesis; There are important guiding reasons such as the fact that they can be placed through a very small incision, the risk of infection is less, and the preservation of the fracture hematoma. With this type of internal fixation implants, the product placed in the bone marrow contacts all the tissue from three points along the long bone, and this function provides a reliable immobilization and stabilization.

Intramedullary Nails can be used not only in traumatic situations, but also in deformity corrections.

Product Groups	Product Models	Auxiliary Products
Clavicular Intramedullary Nails	Clavicle Nail (Ti6Al7Nb)	Nail Locking Screws (Titanium)
Humeral Intramedullary Nails	Humerus Insafe Locking Nail (Ti6Al4V)	Nail Locking Screws, End Caps, Compression Screws (Titanium)
Radial Intramedullary Nails	Radius Nail (Ti6Al7Nb)	Nail Locking Screws (Titanium)
Ulnar Intramedullary Nails	Ulna Intramedullary Nails (Ti6Al7Nb) Ulna Insafe Locking Intramedullary Nail (Ti6Al7Nb)	Nail Locking Screws, Compression Screws (Ti6Al4V)
Femoral Intramedullary Nails	A-PFN (Ti6Al4V), Profin (Ti6Al4V), Femur Intramedullary Nails (Ti6Al4V), Femur Insafe Locking Intramedullary Nails (Ti6Al4V), Telescopic Intramedullary Nails (CrNi), Derona (Ti6Al4V)	Nail Locking Screws, Lag Screws, Compression Screw, End Caps (Titanium)
Tibial Intramedullary Nails	Tibia Intramedullary Nail (TIN) Tibia Easy Locking Nail (EasyLock TIN) Artrodez (Retrodez) Nail	TIN End Caps (Extension and Compressing) Distal Supporting Locking Screws Cortex Screw for IM Nail Nail Locking Screw Nail Locking AP Screw
Titanium Elastic Intramedullary Nails	Titanium Elastic Nail (Ti6Al7Nb), Locking Titanium Elastic Nail (Ti6Al7Nb)	Nail Locking Screws (Titanium)

2- Protecting the Product

Implants should only be accepted with their original packaging and labels intact. Before use, the package should be checked for any damage, and if the product is sterile, sterilization control should be done. When opening the package, the information on the product label is verified. The relevant aseptic instructions should be observed when removing the implant from the package. The product should be kept separate from materials that will damage its surface. Each implant should be visually inspected prior to use. Damaged or poorly protected products should not be used. Pay attention to the information on the packaging of the implant you will use. Only use implants of the same alloy together in your patient. Do not mix different alloys or products from different manufacturers.

Use with hand tools that comply with AO principles.

All fracture fixation implants are disposable.

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.

Warning: 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 cause implant damage resulting in patient injury, illness, or death. In addition, reuse or reprocessing of disposable devices may pose a risk of contamination due to the transmission of infectious material from one patient to another. This could result in patient or user injury or death. Although they may appear undamaged, the implant may have minor defects and internal stress patterns that can lead to material fatigue**.**

Fracture fixation materials only aid fracture healing, they cannot assume the functions of normal bone or soft tissues in fracture healing. The anatomy of human bone may limit the physical properties of implant systems that can be placed. Following the use of these implants, unrestricted use of limbs (such as full weight-bearing) until bone healing is complete is at the discretion of the physician and is generally not appropriate. Repetitive loadings can lead to delayed union and healing of bone and soft tissue, or even to stop, ie nonunion (pseudoarthrosis). This can lead to complications such as physical insufficiency of the implant or its separation from the bone.

3- Packaging and Sterilization

Intramedullary Nails are supplied in a non-sterile package in a container. Products are sterilized in hospital sterilization units before use. Before autoclave sterilization, they are removed from their packages and placed in sets and sterilized. Before the sterilization process, the products must be washed for disinfection.

4- Sterilization / Resterilization

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

All parts must be disassembled before sterilizing. Care must be taken to protect parts from mechanical damage. Parts must come to room temperature before use. We recommend the use of cleaning agents in the pH range 7 to 9. Abrasive (corrosive) materials and steel wool should never be used in TST implants. Qualified personnel should perform cleaning and sterilization operations with documented expertise, competence and training.

Our recommendation; For sterilization of TST non-sterile implants, it is sterilized in an autoclave at 121ºC 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 70 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- Sequence of 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 Intramedullary Nail Group products are produced from metals such as ISO 5832-11 (Ti6Al7Nb) and ISO 5832-3 (Ti6Al4V) Titanium alloy and as ISO 5832-1 or ASTM F138 or ASTM F139 CrNi stainless steel.

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

Intramedullary nails are used in small, middle, or large bone fractures or in other orthopedic surgical procedures regarding these bones. For more detailed information please refer to the related medical literature.

11- Contraindications

Physical conditions which hinder bone healing or fixation of the implant to the bone such as circulation problems, osteoporosis, osteomyelitis, obesity, and deformities in the bone which shall prevent implant placement.

Mental disorders which may prevent compliance of the patient with the rehab programs.

For specific contraindications for Intramedullary Nails it is mandatory to consult the corresponding Surgical Technique Guide of the product system being used.

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 Intramedullary Nail 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.

Intramedullary Nail group products should be used by specialist doctors with appropriate training and experience in implant surgeries.

13- Side Effects

- Loosening, bending or breaking of implants
- Loss of anatomical reduction and malunion
- Superficial and deep infections

• Thrombophlebitis, pulmonary embolism, hematoma or avascular necrosis
• Extremity shortness,
• Very rarely metal allergy or foreign body reaction (including tissue reactions due to macrophage and foreign body reaction)
• Implant abrasion, chondrolysis in patients with poor bone quality

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) Intramedullary Nail group products do not have special storage conditions.
18) The distribution of Intramedullary Nails is done in containers that are protected against any damage.

15- Possible Risk

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.
LOT	Product LOT No	REF	Catalog Number
	Instructions for Use		Manufacturer Information
	Do not use it a second time	NON STERILE	Non-Sterile

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.13).
WARNING: IT CAN ONLY BE USED BY EXPERT PHYSICIANS!