TST Rakor ve Tıbbi Aletler San. ve Tic. Ltd. Şti.
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CE

English

INSTRUCTION FOR USE INTSRUMENT GROUP PRODUCTS

1. Product Description

The instruments are specially designed for the procedures required for the placement of TST implants in the relevant patient. Instruments are designed for repeated use in accordance with repeated sterilization.

Products can be produced from materials such as Stainless Steel Alloys (CrNi, CrNiMo, etc.), Titanium Alloys (Ti6Al4V, Ti6Al7Nb, etc.), Polyethylene, UHMWPE, Teflon, Carbon fiber, Aluminum Alloys.

Intended Use: The products are surgical instruments designed to be used during surgical application in order to implant the implants specially designed for the relevant indication in orthopedic surgeries.

2. Protecting the Product

Instruments should only be accepted with their original packaging and labels intact. Before use, it should be checked for deterioration. When opening the package, the information on the product label is verified. The product should be kept separate from materials that will damage its surface. Each instrument should be visually inspected prior to use. Damaged or poorly protected products should not be used.

3. Packaging and Sterilization

TST instruments 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

Instruments 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 instruments should be prevented. The use of dry heat in the sterilization process is not recommended as it may affect the instrument 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 instruments. Qualified personnel must perform cleaning and sterilization processes with documented expertise, competence and training.

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

We strongly do not recommend flash sterilization. Sterilization parameters are only valid for properly cleaned instruments. Instruments; 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 conditions and/or tendencies noted in the contraindications described previously should be avoided. Care should be taken when using and storing instruments. Instruments must not be scratched or damaged. Hand tools should be protected during storage and corrosive environments should be avoided. Unless otherwise stated, it should not be combined with components of any other system. All parts must be cleaned and sterilized before use. It should be ensured that all the necessary components for the surgery are ready in the operating room. It is recommended that instruments be checked prior to surgery to determine if they have been damaged during storage. In rare cases, instruments may crack or break during surgery. Tools 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 instrument surface must be avoided. Damaged or misused instruments should be discarded. Shaping or bending of instruments should be avoided as much as possible, as this will reduce fatigue strength and cause failure under load. If shaping is necessary, possible by design, or recommended by the TST, the physician should avoid sharp bends, reverse bends. This should be performed in accordance with the procedures outlined with TST instruments (see surgical technique guide). During surgery, it should be repeatedly checked to ensure that the connection between the implant and handpieces or between instruments is secure for correct positioning and fixation. After the procedure, it should be checked that all implants are properly positioned using an image intensifier. Do not use components of TST product systems together with components from systems from other manufacturers, unless otherwise specified (see surgical technique manual)

7. Post-Operation Planning

N/A.

8. Implant Materials

N/A.

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

TST instruments are manually operated devices for use during orthopedic surgery.

11. Contraindications

Patients with known sensitivity to contact materials, local infection at the operative site, signs of local inflammation, should not be used with components of other systems unless otherwise stated.

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

Important: If the application is determined to be the best for the patient and the patient has one or more of the above-mentioned conditions, it is necessary to inform the patient about how these conditions will affect the operation and product life. It is recommended that the patient be advised of any activities that can reduce the problems that these conditions may present.

TST instruments should be used by specialist physicians with appropriate training and experience in surgeries.

13. Side Effects

- Loosening, bending or breaking of the instrument
- Loss of anatomical reduction and malunion
- Superficial and deep infections
- Thrombophlebitis, pulmonary embolism, hematoma or avascular necrosis
- Very rarely, metal allergy or foreign body reaction (including macrophage and tissue reactions due to foreign body reaction)

14. Warnings and Precautions Before Use

1) It is very important to choose the most suitable type and size of implant for the patient. Improper placement of implants can cause bone separation, bending, cracking, or breakage of the implant. Bone deformity, delayed or nonunion, fracture may occur. It is necessary to use the correct instruments designed for the correct placement of the implants.

2) Instruments should be applied with surgical techniques suitable for their intended use. Inappropriate use of surgical techniques may cause implant loss by disrupting the technical features of the instruments such as thread structure or angular axis.

3) Each instrument must be used in the procedures for which it is designed. These procedures are specified in the Surgical Technique sections in the catalogs of the product system. For precautions regarding the use of instruments, it is necessary to refer to the Surgical Technique Section in the catalogue.

4) When storing or placing the instruments, utmost care must be taken not to scratch or crush the surface. Bending or shaping instruments with hammers and similar heavy objects can significantly reduce instrument durability.

5) The instruments should be used by authorized Medical specialists and operating room personnel.

6) According to the planning during the operation, all instruments must be present completely.

7) Although it is very rare, necessary allergy tests should be performed before surgery in patients with sensitivity to the material.

8) In order to increase the success of the surgery, appropriate hand tools should be used and the application should be controlled with imaging devices.

9) There is no harm in using the products in patients whose immune system is suppressed (AIDS, etc.).

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

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

12) TST instruments group products do not have special storage conditions.

13) The distribution of TST instruments is made 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

Neither manufacturers nor dealers take responsibility for re-sterilization of products by the consumer. The recommendations provided are for informational purposes only.

TST products should not be used together with other manufacturers' products.

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.

See the product catalogs for surgical techniques and application of products.

WARNING: IT CAN ONLY BE USED BY EXPERT PHYSICIANS!