Shell Calcaneus Internal Fixation System

CE 1984
KIWA
Belgelendirme
Hizmetleri A.Ş.

TST Rakor ve Tıbbi Aletler San. ve Tic. Ltd. Şti.
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DESCRIPTION & INDICATIONS FOR USE

Shell Calcaneus Implant was developed for the treatment of planovalgus foot deformity in cerebral palsy (CP) by calcaneal lengthening in children and adults. The plate can be inserted into the osteotomy gap based on the amount of talonavicular coverage. Optionally, Locking Peg Screws can be used for the fixation of the implant.

Indications are: - Pes Planovalgus deformity
Hindfoot valgus
Midfoot plantar flexion
Collapsed medial longitudinal arc
Forefoot supination

Shell Calcaneus Implant is made from titanium. The bone-implant adhesion is improved with the surface design of the implant. 15mm and 18mm size option are available. The plate allows expansion from 7.5mm up to 1mm.

All TST devices are intended for Professional use only.

CONTRAINDICATIONS

Infection (or history of infection); acute or chronic, local or systemic, severe muscular, neurological and vascular insufficiencies, malunion, plate and screw breakage, locking screw migration, underdeveloped skeletal structure, psychologically or physiologically inadequate patient, inadequate skin, bone or neurovascular condition.

WARNINGS & PRECAUTIONS

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 the Plates and Screws are done in containers that are protected against any damage.

POSSIBLE ADVERSE EFECTS

1. Loosening, bending or breaking of implants
2. Loss of anatomical reduction and malunion
3. Superficial and deep infections
4. Thrombophlebitis, pulmonary embolism, hematoma or avascular necrosis
5. extremity shortness,
6. Very rarely metal allergy or foreign body reaction (including tissue reactions due to macrophage and foreign body reaction)
7. Implant abrasion, chondrolysis in patients with poor bone quality

Intraoperative and Postoperative Surgical Processes:

For precautions special to determined periods, it is mandatory to consult the corresponding Surgical Technique.

Material

Shell Calcaneus Implants are made from titanium alloy (Ti6Al4V – ISO 5832-3).

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

Sterilisation – Re-sterilisation:
The implants are available for use in their protective packaging in non-sterile form. The implants should be removed from this package and after cleaning be sterilised. Scratching and wearing of the implants should be avoided.
The use of dry heat as a form of sterilisation is not recommended because it may affect the implants physical properties.
All parts must be separated before sterilization. Care must be taken to protect parts from mechanical damage. Parts must be cooled down to room temperature before use.
Cleaning agents with a pH within 7-9 are recommended. **Do not use** steel wool or abrasive cleaners on TST implants. The Cleaning should be done by qualified personnel with documented expertise, competency, and training.
TST implants and instruments are suitable for various steam sterilization procedures between 116 ºC - 138 ºC and from 5 min up to 60 min.
The sterilization process at 121 ºC for 30 min at the autoclave is recommended.
Flash sterilization is **not recommended.**
The sterilization parameters are only valid for devices that are adequately cleaned.
Neither the manufacturer nor the distributor assumes any responsibility for the re-sterilisation of the implants by the purchaser. The recommendations presented are for information purpose only.

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.

WARNING: ONLY BE USED BY THE SPECIALIST DOCTORS

INTERPRETATION OF THE SYMBOLS USED WITH THE PRODUCT LABELS:


"DO NOT REUSE"


"CAUTION, Consult Accompanying Documents"

"BATCH CODE"

REF "CATALOGUE NUMBER"

"NON-STERILE"


"DO NOT USE IF PACKAGE IS DAMAGED"