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ORTHOPEDIC AND TRAUMA IMPLANT SYSTEMS

INTENDED USE

Orthopedic and Trauma Implant Systems (plates and screws) are used to ensure bone integrity and to support the healing process. The detailed intended uses are as follows:

- To provide anatomical reduction of bone fragments in the surgical treatment of fractures of long bones, pelvis, or joint surfaces caused by acute trauma,
- To stabilize bone segments in the correct position during osteotomy (bone cutting) procedures,
- To achieve fusion of bones in arthrodesis (joint fusion) procedures,
- To restore bone integrity after tumor resections,
- To provide bone stabilization in cases of malunion (improper healing) and nonunion (failure of healing),
- To accelerate bone healing and facilitate patient mobilization through appropriate fixation.

These systems may be used alone or in combination with other implants.

PATIENT POPULATION

Deva Tıbbi Orthopedic and Trauma Implant Systems are intended for use in adult patients. They are not suitable for pediatric use. To ensure geometric compatibility between the plate and bone in patients with different anthropometric characteristics, the products are designed in various sizes. Universal use is intended. General principles are applied in patient and implant selection. Correct implant selection is of critical importance. The appropriate type and size should be determined by considering the patient's age, activity level, weight, bone and muscle condition, previous surgical history, and other relevant anatomical and biomechanical factors.

RAW MATERIALS

- Plates and Screws: Ti6Al4V-ELI (ISO 5832-3 / ASTM F136)
- Cables : CoCrMo (ISO 5832-12)

PRODUCT SHELF LIFE

The product does not have a defined shelf life.

INDICATIONS

- Intra-articular fractures
- Open/closed, simple, comminuted, and segmental fractures
- Trochanteric and subtrochanteric femoral fractures
- Diaphyseal, supracondylar, and intercondylar fractures
- Malunion and nonunion conditions
- Osteotomies and tumor resections

CONTRAINDICATIONS

- Active infection / sepsis
- Osteoporosis or insufficient bone/soft tissue quality
- Metal allergy
- Spinal use (cervical, thoracic, lumbar)
- Pediatric patients of young age

ADVERSE EFFECTS

- Pain, discomfort, implant breakage
- Nerve and soft tissue damage
- Superficial or deep infections
- Thrombophlebitis, pulmonary embolism
- Metal allergy and foreign body reactions

USER GROUP

The product must only be used by specialist physicians trained in orthopedics and traumatology, with surgical experience.

SURGICAL TECHNIQUE

The surgeon must be familiar with the procedure before using the products. It is also the surgeon's responsibility to consult with experienced colleagues and to be informed about relevant publications prior to use.

APPLICATION STEPS

- **Plate–Screw Application**

1. Based on the MRI results of the patient's trauma site, the specialist selects the appropriate plate.
2. An incision of at least 5 cm is made over the soft tissue.
3. Muscles and tissues are separated from the bone, exposing the trauma site.
4. The length and diameter of the plate are determined according to the condition of the fracture.
5. The selected plate of appropriate length and diameter is positioned along the fracture line.
6. The plate is temporarily fixed with Kirschner wires.
7. Fluoroscopic imaging is performed. Plate conformity with the fracture site is verified, and screw lengths are calculated.
8. Using a surgical drill and motor, holes are drilled through the plate into the bone with the diameter suitable for the screws to be applied.
9. Screws are inserted into the bone through the plate using a T-screwdriver.
10. After the screws are placed and the plate is fixed, the Kirschner wires are removed.
11. Soft tissue is sutured.

Implant Removal

The implant is designed to remain in the patient for approximately 3 months and should be removed at the surgeon's discretion.

An incision is made according to the length of the plate used. With the aid of a soft tissue retractor, the tissue is displaced, and the plate on the bone is exposed. A screwdriver is used to remove the screws by turning counter-clockwise. After the screws are removed, the plate is extracted. The incision made according to the plate length is then closed with sutures.

- **Plate–Cable Application**
  - Select the appropriate cable plate according to the anatomical location and fracture pattern.
  - Make an incision of sufficient length to access the application site.
  - Retract the tissue gently with a soft tissue retractor to expose the bone surface.
  - Position the cable plate on the bone and adapt it to the anatomical contour if necessary.
  - Pass the cables around the bone through the designated slots of the plate.
  - The cable plate can be fixed using two methods:

  Method 1: Fixation with clamp and clamp screw.

  Method 2: Fixation using only the domino.
  - Tension the cables appropriately and secure them.
  - Cut off excess cable length using surgical cutters.
  - Verify the stability of the fixation.
  - Close the incision with sutures in accordance with standard surgical practice.

Implant Removal

The implant is designed to remain in the patient for approximately 3 months and should be removed at the surgeon's discretion.

Make an incision according to the length of the cable plate used.Retract the tissue with a soft tissue retractor to expose the cable plate.Removal is performed according to the fixation method:

Method 1 (If fixed with clamp and clamp screw): Loosen the clamp screw counterclockwise with a screwdriver and remove the clamp.

Method 2 (If fixed with domino): Loosen and remove the domino using the appropriate surgical instrument.

Cut the cables using surgical scissors or cutters.Remove the cable plate together with the cables from the bone.Close the incision with sutures in accordance with standard surgical practice.

USAGE INFORMATION

Factors Affecting the Success of Implantation:

- The surgeon's experience and skill in the procedure,
- Selection of implant type and size suitable for the patient,
- Physical conditions that may hinder bone healing or implant fixation to bone (e.g., circulatory disorders, osteoporosis, osteomyelitis, obesity, bone deformities prevent-
- ing implant placement),
- Presence of mental disorders that may interrupt the patient's recovery process,
- Infections resulting from failure of sterilization.

WARNINGS

- For safe and effective use, the surgeon must be thoroughly familiar with the implant,application techniques, instruments, and devices, and should follow the recommended surgical technique.
- This device is not designed to withstand the stresses of weight-bearing, heavy load,or excessive activity.
- The implant may be at risk of breakage or damage if subjected to increased loads associated with delayed union, nonunion, or incomplete healing.
- Incorrect insertion during implantation may increase the risk of loosening or displacement.
- Patients should be warned—preferably in writing—regarding the use of this implant,its limitations, and potential adverse effects. These include risks of fixation loosening,device failure due to stress, overactivity, load-bearing, and possible nerve or soft tissue injury associated with surgical trauma or implant presence, especially in cases of delayed or failed bone healing.
- The surface of the implant must be free of scratches during surgery.
- The device must not be cut. As the implant is pre-contoured during manufacturing,intraoperative bending will reduce its mechanical strength.
- In case of complications, the patient must be advised to contact their physician.
- Implants may cause image distortion or obscure anatomical structures in radiographic examinations. Safety regarding MRI use (migration, heating, or compatibility) hasnot been verified. MR safety has not been established.
- Instruments must be inspected for wear and damage before use.
- Protect implants from stress concentrators such as scratches and notches that maylead to failure.
- Correct selection of implant type and size is crucial. Failure to use adequately sized implants or incorrect placement may result in implant loosening, bending, cracking, or breakage, as well as bone deformity, delayed healing, or re-fracture.
- In subtrochanteric fractures or osteotomies, implants are subjected to very high loads. Additional internal or external support (such as bone grafts or medial displacement osteotomy) may be required to support healing.
- In comminuted fractures or osteotomies of the subtrochanteric or trochanteric regions, long plates should be selected to reduce load. Plates with the highest valgus angle should be used, and full weight-bearing must be avoided until fracture healing is complete.
- Screws must not pass through the fracture line. If a lag screw is applied, its threads must engage tightly with the bone, and in case of shortening due to bone resorption,the screw should allow telescopic sliding.
- Although implants manufactured from Ti6Al4V-ELI material can be used in MRI devices, they may cause image distortion.
- Care must be taken not to scratch or deform the implant surface during storage and handling. Products must always be stored in unopened packaging. Bending, hammering, or reshaping implants during application may significantly reduce their strength.
- Patients must be provided with detailed postoperative instructions regarding protection of the operated extremity and proper postoperative care. Premature loading before fracture healing may result in loosening, bending, or breakage of the implant.Early loading may be allowed only in cases with secure bone contact.
- Implants may be removed once fracture healing is achieved; however, the timing should be determined by the surgeon considering patient factors (age, bone quality,fixation stability, bone coverage, etc.).

- Patients must be informed that implant removal may require a secondary procedure.
- Fractures may occur during loading through any screw holes after screw removal.
- All necessary instruments and implant sets must be available according to preoperative planning.
- Although rare, patients with material sensitivity should undergo appropriate allergy testing preoperatively.
- Following surgery, particularly in comminuted fractures, monthly radiographic follow-up until callus formation in at least three planes is recommended to detect early implant failure.
- Appropriate surgical instruments and imaging devices should be used to improve surgical success.
- Damaged packaging or storage under uncontrolled conditions may lead to increased bioburden, ineffective sterilization, endotoxin contamination, and consequently, in flammation, infection, toxicity, allergy, or tissue damage. Ensure packaging integrity and that opened products are reprocessed according to manufacturer's recommendations.
- During plate–cable application, ensure that the cables are secured firmly at their application points on the plate to prevent slipping, which may otherwise lead to implantation failure or prolonged treatment.
- Bending, twisting, or cutting the products may compromise their biomechanical properties. Do not bend, twist, or cut the implants.
- Proper patient positioning during application is critical. The patient should be posi-tioned appropriately to facilitate correct application of the product.

WARNINGS FOR SURGICAL INSTRUMENTS

It is of great importance that the surgeon is familiar with the instrument, its applicationv methods, and the recommended surgical technique to ensure the safe and effective use of all Deva Tıbbi instruments.
If an instrument is used under excessive load, handled carelessly, or used for purposes other than intended, it may break, become damaged, and cause injury to tissue.
In addition, instruments must be clean for surgical use after sterilization.
The patient should preferably be informed in writing about the risks associated with the use of such instruments.
Before reuse, surgical instruments must undergo the recommended cleaning procedure and be sterilized.
Previously applied stress may cause various defects in the instrument and may result in device malfunction.

WARNING

- An implant must not be reused. Each product is intended for single-patient use only.
- Products must be sterilized prior to use.
- These Instructions for Use are intended exclusively for DTM branded products
- Any adverse event or serious device malfunction must be reported to the manufacturer and the national competent authority..
- Users should contact the manufacturer regarding adverse effects and feedback.
- These Instructions for Use are provided exclusively in electronic format in accordance with the European Union Medical Device Regulation (MDR 2017/745) and the Regulation on Electronic Instructions for Use (EU 2021/2226).

For access to previous versions, please contact us.

Upon request, a printed copy of the current version will be provided free of charge.

Contact: kalite@devatibbi.com

IMPLANT CLEANING AND DISPOSAL REQUIREMENTS

Implants are single-use devices and must not be reused after sterilization or any other processing.
After contact with body fluids or biological tissues, reuse is strictly prohibited.
After use, implants must be disposed of as medical waste.
Implants with surface damage, scratches, or deformation must never be used.
All users must wear appropriate personal protective equipment and take necessary precautions against infection risk during the disposal process of implants.

STERILIZATION

It is recommended that products be sterilized by the user prior to use using the autoclave method. The suggested parameters for autoclave sterilization are as follows:

Temperature (°C)	Time (Minutes)
134	30

RE-STERILIZATION

Implants must not be resterilized.

MAINTENANCE

Deva Tıbbi Orthopedic and Trauma Implant Systems are intended for implantation into the human body. Therefore, postoperative care instructions provided by the physician must be strictly followed. To prevent breakage or reduced performance, the warnings specified in the “Warnings” section must be observed.Implants must be handled with care to prevent damage, particularly scratches caused by contact with other surgical instruments used during the procedure. Prior to opening the containers, they must be inspected for any damage. All patient-related precautions must be communicated to the patient by the physician..

WARNINGS REGARDING TRANSPORT AND STORAGE

- During transport and storage, protect the product from direct sunlight and keep it under room conditions.
- Ensure that the product remains dry under all circumstances.
- Keep the product away from materials that may damage its surface.
- Products should only be accepted if the original packaging and labeling are intact.
- Before use, inspect the packaging for any damage.
- When opening the package, verify the information on the product label.
- Damaged or improperly stored products must not be used.

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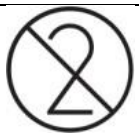
Explanations of Symbols Found on the Product Label:

CE 2292 European Conformity Marking – Notified Body: UDEM (2292)	The product complies with the European Medical Device Directive 93/42/EEC and meets the applicable health, safety, and environmental requirements. If a number accompanies the CE mark, conformity has been verified by the designated Notified Body.		REFERENCE NUMBER
	NON STERILE		LOT NUMBER
	DO NOT REUSE		MANUFACTURING DATE
	DO NOT USE IF PACKAGE IS DAMAGED		MANUFACTURER
	REFER TO ELECTRONIC INSTRUCTIONS FOR USE		CAUTION
	MEDICAL DEVICE		