HİPOKRAT
Tıbbi Malzemeler İmalat ve Pazarlama A.Ş.

CE 1014

PECTUS PLATES

Important Information for the Surgeon (Instruction For Use)

Objective

Hipokrat A.Ş. manufactures a variety of orthopedic surgical plates. For this purpose, pectus plates are used.

Materials

Stainless Steel Alloy (ISO 5832-1)

Products

PECTUS PLATES

HPS Pectus Plate Excavatum; AISI316L / 1.4441
HPS Pectus Plate Excavatum Stabilizer; AISI316L / 1.4441
HPS Pectus Plate Excavatum Connection Bolt; AISI316L / 1.4441
HPS Pectus Plate Karinatum; AISI316L / 1.4441
HPS Pectus Plate Karinatum Stabilizer; AISI316L / 1.4441
HPS Pectus Plate Karinatum Connection Bolt M4; AISI316L / 1.4441

Indications

Chest wall deformity, intrauterine pressure, rachitism and posterior traction, scoliosis, unbalanced growth in the costocondral region, marfan syndrome, congenital abnormality, cardiac compression, pulmonary compression, restrictive respiratory pattern in pulmonary function tests, mitral valve prolapse dependent on cardiac compression, bundlebranch block.

Contraindications

Patients with mental or neurological conditions who are unwilling or incapable of following instructions, patients presenting metal sensitivity reactions, patients with insufficient quantity or quality of bone or fibrous tissue to allow remodeling, infection.

Patient selection factors to be considered include;

- Having pain and function disorder
- Ability and willingness to follow instructions, including control of weight and activity level
- Achieved full skeletal maturity

Complications and adverse effects of selected anesthetic method: nausea, throwing up, severe headache, hoarseness, sore throat, tooth injuries, tongue and oral soft-tissue injuries, xerophthalmia and corneal damage, allergical reactions (skin rashes, rubescence, respiratory problems, death), severe pain and/or loss of function at the nerve due to nerve damage (sense disorders, paralysis, incontinence, erectile dysfunctions), infections of central nervous system, (encephalitis, meningitis, intracranial abscess).

Complications and adverse effects of surgical operation: Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.

Complications and adverse effects of implant: Allergical reactions against implant metal, pain, discomfort, or abnormal sensation due to the presence of the device, skin irritation, infection, and pneumothorax, fracture, breakage, migration, or loosening of the implant, inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant, permanent injury or death.

Warnings

- The implant is not intended to replace chest wall structures. While the implant is intended to expand the chest wall cavity eliminating the features of the deformity, the degree of initial reshaping and permanent remodeling for each case cannot be predetermined.

- The surgeon is to be thoroughly familiar with the implants and the surgical procedure prior to surgery.

- The patient should undergo patch testing before operation with allergy test products of the system and the reactions of the body should be carefully evaluated by the surgeon. Metal chest wall deformity correction implants should not be used if any allergic reaction is occured.

- The correct selection and placement of the implant is important. Preoperative planning to determine the most appropriate size and final position of the implant is required. The implant can become dislodged, shift, or flip as a result of improper device selection, improper stabilization, not suturing the device(s), or patient activity too soon after surgery.

- The surgeon should avoid sharp bends reverse bends, or bending the device at a hole.

- Even though the implant is mechanically fixed (sutured) in position, care is to be taken to assure that the device is rigidly in apposition to the area of the deformity, as demonstrated by total or partial elimination of the visible deformity. If the deformity is not partially eliminated, a secondary Pectus Plate may be required or an alternative method of treatment is to be considered.

- During the course of the surgical procedure, and during implantation, extreme care is to be taken to avoid contact with the heart and lungs with either the implant or instruments, as contact to these organs can cause death or permanent injury to the patient.

- When considering removal, the surgeon should weigh the risks verses benefits when deciding when to remove the implant. Where evidence of adequate remolding is present, removal should be performed. Implant removal is to be followed by postoperative monitoring to check for reoccurrence of the deformity. Where reoccurrence is encountered, a secondary treatment or alternative treatment maybe necessary.

- Surgical implants should never be reused. Even though the implant may appear undamaged, it may have imperfections, defects, or internal stress patterns which may lead to breakage or inadequate performance.

(needed to be proved with clinical and radiographical observations), it is recommended to take external support.

- Combining implants produced from different raw materials may lead to corrosion. This situation may cause to infection and/or implant fracture. In combination with usage of two different implants, different plates and screws for the same indication, usage of compatible materials is very important.
- For articular surface any metal implant do not contact with each other directly, UHMW PE implant must be placed between metal implants.
- For non articular surface, never combine and implant metals below;
  - Stainless steel alloy/ CoCr alloy
  - Stainless steel alloy/ unalloyed titanium
- Opinion of Orthopedic Implant Producer Association; when bone union is completed implant function is expired, implant must be extracted. After bone fracture healing, implant must be extracted. Implants may cause loosening, fracture, corrosion, displacement or pain. If implant weren't extracted after treatment, it causes tension fracture, and this may cause fracture on healed patient.
- The surgeon must evaluate risks and benefits while giving the decision for extracting implant. After the extraction of implant with a suitable surgery to not to live fracture again, the surgeon must treat according to clauses in "Disposal of the Product"

Information for Patients

- Surgeon must inform the patient about surgical risks, adverse effects and directions after operation.
- The surgeon must inform of the patient about paying attention of post operative care.
- Surgeon must recommend the patient to take external support with walking aids.
- The surgeon must warn patient about loosening, wear and or fracture of implant as a result of stress, excessive activity, trauma, weight gain and excessive load bearing. Also inform the patient that this situation requires revision surgery.
- The surgeon must warn patient to about the follow-up controls after operation regularly during the implant stays.

Packaging and Sterility

- Plates of trauma groups are sent as non-sterile and put in surgical set trays.
- For sterilization of non-sterile products with instruments before operation; surgical trays including plates and screws are wrapped with two layers of disinfected and sterile dressing and on the outer layer, a paper type including autoclav sterilization indicator and information of patient name, surgeon name, surgical name is applied.
- Before steam sterilization (autoclav), be aware of there is no packaged product or not-related product in surgical tray. Packaged implants must never be put into the steam sterilization equipment.
- Surgical tray is sterilized by vacuum steam sterilizer tecnique (autoclav) after putting sterilization indicator in. Surgical tray must be sterilized at 134°C, 3 bar, 5 minutes at least.
- After sterilization, for cooling and drying of surgical tray, wait 30 minutes at least.
- After sterilization, the wrappings must be dry and not stained, and indicator colour change must be controlled.
- HİPOKRAT A.Ş. doesn't accept any responsibility if conditions and processes weren't applied for sterilization.
- Labels of products which are also presented outside surgical tray. The label includes product barcode, product reference number, product name, size, lot number, production date, material information, if the product is sent sterile information of sterilization type, use by date and other symbols found in "symbols"part of this IFU.

Important Notice:

- Implants are for single use. Implants are not reusable. Even the implant may appear undamaged, previous bearings may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, implanted to a different patient. Reuse of implant causes contamination and/or patient infection or cross infection.
- Implants are helpful for surgeon in bone union and provides fracture healings in reconstructive surgery. The implants in this IFU are the plates and screws which are used until the healing. Applying implants are generally succesful but implants can not stand the loadings as healthy bone tissue. Size and shape of bone and soft tissue are used for determining implant size and strength.
- HİPOKRAT A.Ş. isn't responsible of the complications related with inadequate asepsis, not to prepare suitable bone bed for implants, faulty surgical technique, faulty indication and faulty patient behaviour.
- Particularly, for patient with high energy trauma, the surgeon must realize pre-assesment, must apply systematical medical examination protocol to not to miss other pathologies by focussing on seen pathology and must realize good timing of surgery.
- Carefully assesment of traumas are determining morbidity and mortality range of patients. Requirement for using scopy causes exposure of radiation to patient and surgeon.
- Being exposed to radiation dose changes in every surgeries. Radiation exposure rate can be reduced with experienced surgical team, surgical technique and developped imaging equipments. It is reported that radiation dose exposure for surgeon and patient has no significant problem. Whether radiation exposure dose rate is low, the surgeon must follow up radiation doses being exposed to along a year.

Disposal of the Product

- Products which are expired, should be sent back to HİPOKRAT A.Ş. for disposal.
- Disposal of the product which will be explanted from patient for revision surgery is realized in responsibility of surgeon according to medical waste disposal procedure suitable with related directives of nation, in a condition prevents the contamination which is caused by the product itself.

Attention

- For non-sterile sent products, Hipokrat A.Ş. isn't responsible for the problems as a result of not to apply the processes determined in Packaging and Sterilization part of this IFU.
- Pay attention for description and size information on surgical trays and implants to realize implantation as planned.
- During the surgery, do not use powdered glove.
- Objects, which could damage the surface of the implant, should be kept far.
- Before using the implant, it should be visually inspected for possible damages.
- The components of this system must be used together only with its own components.
- The use of instruments or implant components from other systems can result in inaccurate fit, incorrect sizing, excessive wear and device failure.
- Before implantation, surgical trays must stay at room temperature (21±2 °C).
- HİPOKRAT A.Ş. doesn't accept any responsibility about the usage of the resterilized implants which contacted with body tissue or liquids.
- As soon as the occurence of complications about implants and surgical equipment, contact with HİPOKRAT A.Ş.
- After sales of implants many factors are out of control for HİPOKRAT A.Ş. HİPOKRAT A.Ş. can not control the conditions of impanting, indications for implanting and related procedures. So, HİPOKRAT A.Ş. do not guarantee against this product.
- In case of complication related with implant geometry, surface quality or mechanical stability, the product which will be explanted from patient must be sent to HİPOKRAT A.Ş. in responsibility of surgeon according to medical waste disposal procedure suitable with related directives of nation, in a condition prevents the contamination which is caused by the product itself.
- If implant fracture is occured, without contact of fracture surfaces, explanted implant must be sent to HİPOKRAT A.Ş. in responsibility of surgeon in a condition prevents the contamination which is caused by the product itself.
- Returns for this kind of explanted products can be accepted by HİPOKRAT A.Ş, only if legal document prepared by surgeon including information of situation is also sent with product. Otherwise returns are not accepted.

Storage Conditions Products have no special storage conditions but they should be stored in clean and dry environment avoided from damage. They should be protected from direct sunlight and humidity.

Ordering Information

Implant can be ordered from distributor or directly from manufacturer. Details are below.

For More Information :

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SYMBOLS USED ON THE LABELS OF PRODUCTS