HOLA - Heel Osteo-Lift Anchor – Instructions for Use and Warnings Device and Instrument Set CE 1936

EN

DESCRIPTION
The HOLA Heel Osteo-Lift Anchor screw is used for nonunion external sinus tarsi syndrome of pediatric or adolescent valgus flatfoot.
The conical screw features deep threading so that it can grasp the cancellous bone.

MATERIALS
These screws are available in the following composition material (see label) Titanium Alloy Ti6Al4V ISO 5832-3/ASTMF136.
The system hereby presented has not be tested for MRI compatibility. Medical personnel must be informed of the composition material of the device so that they can make appropriate considerations regarding the exposure of the patient equipped with the implanted device to strong electromagnetic fields. as in the case of control requirements in MRI.
Furthermore, the patient must also be informed by the hospital staff about the material used in the realization of the implanted device and the specific limitations / contraindications attached to it.

INDICATIONS FOR USE
Surgical treatment of infant calcaneal valgus deformity.

CONTRAINDICATION
The HOLA device has not been designed and cannot be sold for any use other than those indicated.
- Insufficient bone tissue quantity.
- Insufficient bone tissue quality.
- Any form of active infection.
- Any inflammation in the screw zone.
- Any mental, neurological or neuromuscular disorder.
- Sensitivity to materials making up the screws, both documented or suspected (see label).
- Obesity, diabetes, vascular pathologies.
- The technique is not indicated when it is impossible to perform a manual reduction.
- The absence of pain and dysfunction.
- A non-flexible flatfoot is not a surgical indication for this treatment.
- It is a contraindication to use the device on children outside the age group (8-14 years).

SURGICAL TECHNIQUE
- With the patient in a supine position and keeping the foot inwards, perform about a 1cm incision near the sinus tarsi.
- Under radiography while maintaining a manual correction of the talocalcaneonavicular joint, insert the guide wire, closely behind the calcaneal region with the direction aimed at the center of the tibiotarsic joint (about 60° with respect to the support with either the sagittal plane or the frontal plane). Perform a preliminary perforation of the calcaneus with an awl to prepare an access for the screw insertion, the perforation must be done in the desired insertion point taking into account the screw's head diameter such as to avoid protrusions.
- A screw is selected based on the desired correction, with diameters ranging between 11 and 15 mm and then it must be introduced. Adjust the depth of the screw until complete sinking of the eccentrical head, then proceed with the suture of the soft tissues.

RECOMMENDATIONS AND PRECAUTIONS
Pre- Surgery
- The use of orthopaedic devices by mini-invasive and arthroscopic surgery presumes an in-depth knowledge of the same and of the implant technique.
- If the surgeon should not be informed on the techniques related to this type of device it is advisable to consult the scientific and technical documentation on methodologies and devices in order to correctly assess possible risks.
- Postoperatory mobilisation on the implant as one of the possible risks must be adequately known and assessed before proceeding with this system.
- The device can not be implanted without its respective instrument set.
- Contact the manufacturer for get information on indications, implant techniques, implant choice and risks or hazards.
- For the correct use of the devices under discussion comply with the following provisions:
  - The implants must be sterile.
  - Implants must always be performed with instruments supplied by the manufacturer.
  - Implants must follow adequate operating techniques in suitable conditions.
- Smokers should be informed of the greater possibility of pseudoarthrosis arising during the healing process.
- The patient must be informed that any heavy physical activity, involving excessive loading, impacts, and stresses on the neoligament fixed with a synthesis system, may cause undue tearing or wear on the device. Any impacts loading the implant or affected limb or articulation should be absolutely avoided.
- The indications for the surgical procedure provide that the patient reach a minimum age of 10 years and it is advised to not exceed 15 years, please refer to the experience and discretion of the surgeon for the determination of the patient's developmental age at the time of surgery.
- It is advised for the treatment of the pathology of flatfoot with associated pain
- Pathology of the flatfoot with shortening of Achilles tendon. The concomitant presence of a retraction of the Achilles tendon before surgery does not limit the flexibility of the deformity but may determine the absence of a spontaneous correction in the future
- The choice, correct positioning, surgical technique, and instruments are critical factors in conditioning the success of the implant and post-op therapy.

Therefore:
- The working life of the device is strictly linked to biological and biomechanical factors. the correct choice of the implant size can minimise the risk of failure and this choice must be made in relation to the dimensions and form of bone correction or to the articular reconstruction involved and the presumed loading it will undergo.
- The patient must always be informed of the implant's limitations and risks it entails. excessive, uncontrolled loading, impacts, and other factors can involve tearing or wearing of the device with consequent failure of the reconstruction and rehabilitation therapy.
- Psychologically inhibited, obese or debilitated patients risk failure.
- Careful as to the positioning of the screw, there may be the risk of damaging the subtalar joint and ankle joint.
- In the application on the adult, due to the anatomy of the tarsal canal, there was a lower rate of satisfaction compared to children.
- Due to incorrect positioning of the screw, premature grafting of the screw may occur on the calcaneus floor with pain and stiffness of the subtalar.
- The device must be controlled for physical, superficial and functional integrity before proceeding with the implant.
- It is essential that all information, cautions, indications and contraindications, precautions are respected and the patient is informed wherever necessary.
- Methods and aids or alternative devices must always be readily available before proceeding with the surgery.
- If a foreign body susceptibility is suspected, a test should be performed prior to implantation to exclude this possibility.
- Make sure that the devices to be implanted have not exceeded the expiry date.
- Store the product in such a way that the packaging is not damaged or altered and does not use it if the packaging (outer box and inner bags) is damaged.

Intra- Surgery
- Intra-operative fractures or instrument rupture may occur.
- It is strongly recommended to use dedicated instruments during implant and to avoid the use of instruments considered by the surgeon to be worn-out or malfunctioning, in case the instruments are found to be worn-out or malfunctioning they must be shipped back to Mikai that will provide equivalent functioning instruments.
- Carefully position the screws to avoid damage to the nerves, muscles, tendons and vessels.
- Slowly pierce the bone to avoid heat necrosis of surrounding tissues and bone.
- The device must be implanted in a sterile environment.
- Any implant device requires specific instruments for implanting provided by MIKAI. the use of unsuitable instruments may cause damage to the device and an incorrect implant.
- Their own accessories must always be used and approved by the manufacturer and must always be installed with the instruments supplied by the manufacturer.
- Never, for any reason whatsoever, use damaged implants.
- Excessive or marked deformation of an implant can cause a marked reduction in fatigue resistance.
- Keep attention not to cut surgical gloves during the procedure.
- For screws delivered in a sterile package (see the appropriate label on the package), make sure that the sterilization expiry date has not been reached.
- The devices under discussion are for single use and must never be reused. the re-use of the devices involves on the one hand the risk of causing a re-infection or cross-infection, on the other hand compromising the functional performance of the device.

Post- Surgery
- Adopt wound hygiene procedures with weekly controls to reduce the risk of superficial or in-depth infections.
- Periodically ascertain the grip of the screws and the functional articulation recovery with radiological imaging.
- Patients should be instructed to report any abnormal or unforeseen effects to the surgeon.
- Do not use system components with products from other manufacturers unless otherwise indicated, as combined use is not covered by the required validation.
- Removal of the device: the final decision about the removal of the device is up to the surgeon.

UNDESIDERABLE EFFECTS
The following events may represent undesiderable effects after a fixator or correction implant:
- Inflammation affecting the skin.
- Inflammation affecting muscle and bone tissue.
- Osteolysis with loss of grip between bone and screw with the loss of neo-ligament fixation or wrong bone correction.
- Ankle joint effusion or haemarthrosis.
- contracture of the peroneal muscles due to an antalgic position in pronation.
- Stress fractures.
- Loss of correction.
- Resorption of the adjacent cortical surface of the talus and calcaneus.
- Serious traumatic stresses suffered by patients while the screw was in place can cause a screw mobilization.

IMPORTANT
Not all surgical procedures have a positive outcome. Further complications may develop at any time due to improper use, medical reasons or device failures resulting in a need for a new surgical procedure to remove or replace the device. The pre-surgical and surgical procedures, which include the knowledge of surgical techniques, the correct choice and positioning of the devices, are important factors for the success of the use of Mikai devices by the surgeon. Proper selection of the patient, his ability to follow the doctor's instructions and follow the prescribed treatment regimen greatly influence the results. It is important to subject the patient to a careful examination and to choose the optimal therapy in relation to physical and / or mental requirements and / or limitations. If a candidate for the intervention shows contraindications or predisposition to the same, it is recommended NOT TO USE the HOLA devices.
With respect to the wear/functioning state of the given instrument set, it is referred to the competence/experience of the user its corresponding evaluation.

SINGLE USE
The HOLA device is SINGLE USE, therefore every single component must be destroyed and properly disposed after the first use on a patient.
CAUTION: Never reuse devices labeled "SINGLE USE". MIKAI is solely responsible for the safety and efficacy of single disposable devices when first used in the patient. Any subsequent use of these devices is improper contraindicated by the manufacturer.
It is also essential to follow hospital protocols for the disposal of contaminated materials and biological waste. All used surgical instruments must be considered contaminated. It is therefore necessary to handle, collect and transport these instruments with rigorous care to minimize potential risks for patients, staff and all areas of the hospital

IMPLANTABLE DEVICE*
The single use implantable device* by MIKAI is identifiable by the symbol "" shown on the product label. After removal from the patient the implantable device* must be destroyed. Re-use of an implantable device* presents risks of contamination for users and patients. The re-use of an implantable device * cannot guarantee the original mechanical and functional performance, compromising product efficacy and presenting health risks to patients.
* Implantable device - Any device that has been designed to be totally or partially introduced into the human body through surgery and to remain in place after the procedure for at least 30 days is considered an implantable device.

STERILIZATION
Devices are supplied exclusively in the STERILE version and have a label indicating this status. The contents of the package are STERILE unless the package is opened or damaged. Do not use if the package has been opened or damaged.
All NON-STERILE products (dedicated instruments of the HOLA device) must be sterilized using a steam autoclave according to the UNI EN ISO 17664 standard:

Procedure	Fractionated and dynamic pre-vacuum process
Exposure time	≥ 5 min
Temperature	134°C

	Name and full address of the manufacturer		See instructions for use
REF	Code		Single use only
LOT	Lot No.		Do not use if package is damaged
	Expiration date		Do not resterilize
STERILE EO	Sterilization mode ETO	CE 1936	CE marking and identification number of the Notified Body

Note: The following device may contain the following non-harmonized symbols (abbreviations) in the description:
- ST: indicates the sterility status of the device;
- Ti: indicates that the device is made of titanium;
- d.: in some cases, indicates the diameter of the device in the description;
- Txx: the letter T followed by a number indicates the length of the main thread in the device;
- Lxx: the letter L followed by a number indicates the main length of the device;
- xxPZ: preceded by a number, indicates the number of devices in the package in the description.