HOLA – Anchor screw for talar bone elevation – Information and warnings for use

CE 1936

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Mikai S.p.a. Via P. Gobetti 56R – 16145 Genoa (Italy)

DESCRIPTION
The HOLA screw for talar bone elevation is a medical device used in the treatment of flatfoot deformity associated with valgus calcaneus, closely mirroring the 'calcaneal stop' approach.
The HOLA screw features a deep thread and offers the distinct advantage of an eccentric relationship between the head axis and the stem axis, allowing the surgeon to adjust the screw's position according to the desired degree of correction without the need to explant the device.
HOLA family devices are single-use only.
The appropriate instruments (set of instruments) provided by the manufacturer must be used for the implant. If non-sterile multi-use instruments are available, wash and sterilise them before each procedure as indicated in the dedicated instructions for use.
The instruments supplied in sterile kits are SINGLE-USE and must not be reused or resterilised.
The HOLA device family is intended for orthopaedic surgeons experienced in corrective surgery.

MATERIALS
The HOLA screw is available and made of Ti6Al4V ELI ISO 5832-3 titanium alloy. The guide wires are made of AISI 316 LVM ISO 5832-1 stainless steel.
This system has not been tested for magnetocompatibility. Medical personnel must be informed of the composition of the device so that they can make appropriate considerations regarding the exposure of the patient with the implanted device to strong electromagnetic fields, such as in the case of MRI monitoring needs.
Furthermore, the patient must also be informed by the hospital staff about the material used in the manufacture of the implanted device and the specific limitations/contraindications attached to it.

QUALITATIVE AND QUANTITATIVE INFORMATION
The alloys used by Mikai in the manufacture of its devices are:
- Titanium alloy Gr5 Ti6Al4V-ELI (ISO 5832-3)
- AISI 316 LVM stainless steel (ISO 5832-1)

ISO 5832-3 identifies the following limits for the Gr5 Ti6Al4V-ELI titanium alloy:

Element	Compositional limits % (*m*/*m*)
Aluminium	5,5 to 6,75
Vanadium	3,5 to 4,5
Iron	0,3 max.
Oxygen	0,2 max.
Carbon	0,08 max.
Nitrogen	0,05 max.
Hydrogen	0,015 max.[a]
Titanium	Balance

[a] Except for billets, for which the maximum hydrogen content shall be 0,010 % (*m*/*m*).

ISO 5832-1 identifies the following limits for AISI 316 LVM stainless steel:

Element	Mass fraction %
Carbon	0,030 max.
Silicon	1,0 max.
Manganese	2,0 max.
Phosphorus	0,025 max.
Sulfur	0,010 max.
Nitrogen	0,10 max.
Chromium	17,0 to 19,0 max.
Molybdenum	2,25 to 3,00
Nickel	13,0 to 15,0
Copper	0,50 max.
Iron	Balance

INTENDED USE
Family of medical devices for corrective treatment based on the reciprocal positioning of the talus on the heel, in adult and paediatric patients.

INDICATIONS FOR USE
Calcaneo-valgus pathology (foot).

CONTRAINDICATIONS
Conditions that present an increased risk of error include:
- Active or suspected infection;
- Insufficient quantity or quality of bone that prevents proper fixation of the device;
- Physiologically or psychologically unsuitable patient;
- Documented or suspected sensitivity to the constituent materials of screws and wires;
- Conditions of extreme obesity, diabetes, vasculopathies must be carefully evaluated by the doctor;
- Use of the device is contraindicated when it is impossible to perform a manual reduction;
- Non-flexible flat foot;
- Any deficit that could interfere with the patient's ability to limit the load;
- Any condition that places an unusually heavy load on the device during the healing period.

DURATION OF USE AND EXPLANTATION
The HOLA screw can remain implanted for 1 to 2 years, and in any case until the intended use is achieved. In order to proceed with the explant, the appropriate HOLA family instruments must be used.

HOLA CUSTOM INSTRUMENT KIT
The HOLA family of devices provides custom kits (50004AASTXX and STHOAAASTXX) containing different instruments in predefined quantities and optimised according to the reference market/customer. This composition respects, however, the steps of the following surgical technique and includes only Mikai compatible medical devices.

BASIC SURGICAL TECHNIQUE
The installation (implant) steps for a HOLA screw are listed below.
- The patient is placed in the supine position with a support under the ankle, so as to allow the free movement of the hindfoot which must be forced in inversion. The bone landmarks of the lateral malleolus, the lateral prominence of the calcaneal head and the sinus tarsi are identified. A transverse skin incision of approximately 15–20 mm is made at the level of the sinus tarsi;
- The pre-sinus adipose tissue is retracted proximally, and the sinus tarsi is opened using either an inverted T or inverted L incision, skeletonizing the calcaneal floor (calcaneal notch). The trial heads are inserted and held in place using the dedicated forceps included in the surgical instrumentation set, and the most appropriate size is identified;
- The trial head has a central hole if you want to insert it with the guide wire;
- The trial heads can be inserted in different ways depending on the correction to be obtained. The depth of insertion also determines the greater or lesser correction of the back foot;
- Sizes with different diameters are available: from 11 for fixed head screws and from 13 and 15 for polyaxial screws. All the trial heads are available in different heights: 4-6, 6-8, 8-10 mm;
- Once the correct size has been determined, under fluoroscopic guidance and while maintaining the foot in an inverted position, the guidewire is inserted in close proximity to the sinus tarsi wall, directed toward the center of the tibiotalar joint (approximately 60° with respect to the weight-bearing plane, both in the sagittal and frontal planes);
- The polyaxiality of the screw head allows the guide wire to be inserted even if it is not perpendicular;
- The wire can be inserted freehand or using the guide cannulas supplied;
- Once the wire has been inserted, the cannulated tip is used to pierce the heel, in order to prepare the pilot hole for the introduction of the screw;
- The perforation must take place at the desired point of insertion of the screw. The diameter of the chosen screw should be considered, in order to avoid a possible protrusion on the lateral face of the heel;
- The cannula holder devices have been designed to the size of the screw that is used, so the surgeon always has an indication of the position of the screw once implanted. The perforator has a mechanical stop to prevent excessive perforation;
- Then the selected screw is inserted along the guide wire. If a fixed head screw has been chosen, the spherical hexagonal screwdriver can be used. If the polyaxial endorthosis is used, it is recommended to use the dedicated long-tip screwdriver and possibly the hexagonal head screwdriver to position the screw in the desired way;
- In order to avoid rotation of the head, a flat hexagonal key is supplied which must be used while screwing;
- Should the head position not be as desired, prior to final locking the head can be rotated using the flat wrench, after which the screw is fully seated.

WARNINGS AND PRECAUTIONS
Pre-operative
- The use of medical devices for the "calcaneal stop" procedure requires an in-depth knowledge of surgery and of the specific technique of this method;
- If the surgeon is not familiar with the techniques related to such devices, consultation of the scientific and technical documentation on the methods and devices is recommended, in order to correctly assess the possible risks;
- Do not use the device if material hypersensitivity is suspected;
- The patient should be informed of how the device is used and the potential complications associated with HOLA screws;
- The patient must always be informed about the limitations of the implant; shocks, excessive or uncontrolled loads and other factors may lead to the failure or wear of the device with consequent treatment failure;
- The patient should be informed that carrying out heavy physical activities, involving loads, shocks and excessive stress on the implant, can cause the failure or unexpected wear of the device. Impacts to the treated limb must be avoided;
- It is important to select the correct size of the device. The correct choice of implant can minimise the risk of failure and this choice must be made in relation to the size and shape of the bone segment involved and the anticipated loads it will be subjected to;
- Only manufacturer-approved accessories should be used and they must always be implanted with the instruments supplied by the manufacturer. The use of unsuitable or non-original instruments can cause damage to the device and an incorrect implant;
- The evident deformation of an implant can cause a marked reduction in fatigue resistance;
- It is necessary to check the physical and functional integrity of the device before proceeding with its implantation;
- Store the product so that the packaging does not suffer damage or alteration and do not use it if the packaging (outer box and inner packaging) is damaged;
- Psychologically compromised, obese or debilitated patients are at risk of failure;
- Alternative methods and aids or devices must always be available before proceeding with the implant.
- Contact the manufacturer for information on indications, implant technique, implant selection and related risks or hazards.
- Post-operative mobilisation of the implant is one of the possible risks that must be properly understood and evaluated before proceeding with the use of the HOLA screws;
- The concomitant presence of Achilles tendon retraction before surgery does not limit the flexibility of the deformity, but may result in the absence of future spontaneous correction;
- The choice, correct positioning, surgical technique and instruments used are critical factors affecting the success of the implant and post-operative therapy;
- Pay attention to the screw positioning, as there is a risk of damaging the subtalar and ankle joints;
- Incorrect positioning of the screw may result in premature sinking of the screw on the heel floor with pain and stiffness of the subtalar joint;

Intra-Operative
- During implantation dedicated instruments must be used whilst use of instruments that are considered worn or malfunctioning should be avoided; should any worn or malfunctioning devices be identified, they must be returned to Mikai that will promptly replace them with equivalent suitable material;
- For components delivered in sterile packaging (see specific label on the packaging), make sure that the expiry date has not been exceeded;
- For components delivered in sterile packaging (see the specific label on the packaging), make sure that the packaging is free from damage;
- Carefully position the screws to avoid damage to nerves, muscles, tendons and vessels;
- Drill the bone slowly to avoid heat necrosis of the surrounding tissues and bone;
- Intraoperative fractures or instrument breakage may occur;
- Implantation must take place in a sterile environment;
- Do not use damaged implants for any reason;
- Be careful not to cut the surgical gloves during implantation by handling sharp instruments;
- Additional instrumentation may be required for implantation and removal, such as a power drill;
- Check the integrity of the screws at regular intervals;
- Be careful not to cut the joint surface with the screws/bone wires;
- Any device implanted in the patient, such as bone screws, wires and in general any device marked as "single use": MUST NOT BE REUSED. The reuse of the devices entails the risk of causing a re-infection or a cross-infection, as well as compromising the functional performance of the device.

Post-operative
- Adopt wound hygiene procedures with weekly checks in order to reduce the risk of superficial and deep infections;
- Periodically check, also by means of radiological investigation, the tightness of the screws and the maintenance of the correction;

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- Patients should be instructed to report any abnormal or unintended effects to the surgeon;
- Do not use system components with products from other manufacturers;
- The sterile packaging of the device contains 4 detachable labels bearing traceability data, which can be affixed to the patient's medical record;
- The final decision regarding the removal of the device rests with the surgeon;
- Strict adherence to physiotherapy and rehabilitation is required.

POSSIBLE ADVERSE EVENTS OR SIDE EFFECTS

- Damage to nerves or blood vessels, resulting from the insertion of wires and screws;
- Osteolysis;
- Superficial or deep bone infection, osteomyelitis or septic arthritis along the screw passage tract;
- Oedema or swelling, possible compartment syndrome;
- Joint contracture;
- Delayed achievement of the intended use;
- Breakage of devices;
- Bone damage due to the choice of inadequate implants;
- Bone malformation;
- Persistence or reappearance of the initial condition that required treatment;
- Rejection of implantable elements;
- Tissue necrosis following the insertion of implantable elements;
- Excessive surgical bleeding;
- Inherent risks associated with anaesthesia;
- Allergic reaction;
- Intractable pain;
- Infection, pain, swelling or inflammation at the implant site;
- Bone sequestration, resulting from excessive speed of bone cortex perforation with heat generation and bone necrosis;
- Damage to the cartilage at the joint;
- Protrusion of intra-articular screws;
- Migration of implanted elements
- Formation of keloids over the surgical incision scar;
- Hypoesthesia;
- Stress fractures;
- Loss of correction;
- Excessive stress suffered by patients while the HOLA device is in place may cause the screw to loosen.

IMPORTANT

Not all surgical procedures are successful. Further complications may develop at any time due to misuse, for medical reasons or due to device failures resulting in the need for new surgery to remove or replace the device. Pre-operative and operative procedures, which include knowledge of surgical techniques, correct choice and placement of devices, are important factors for the successful use of Mikai devices by the surgeon. Proper patient selection, the patient's ability to comply with the doctor's instructions and to follow the prescribed treatment regimen greatly influence the results. It is important to subject the patient to a thorough examination and choose the optimal therapy in relation to the physical and/or mental requirements and/or limitations. If a candidate for surgery shows contraindications or a predisposition to them, it is recommended NOT TO USE the devices of the HOLA family.

The HOLA family instruments have not been tested for a maximum number of washing cycles. In the event of oxidation, surface defects that compromise the functionality of the instruments or disappearance of the marking, the instruments must be returned to Mikai to proceed with their maintenance/replacement.

STERILISATION

The HOLA family of devices are supplied in **STERILE and SINGLE-USE** packaging and are sterilised using Ethylene Oxide. If the packaging is damaged, it is recommended not to use its contents. The devices are not intended to be re-sterilised.

All NON-STERILE products (instruments) must be steam sterilised in an autoclave (according to the UNI EN ISO 17665 standard).

Procedure	Fractional and/or dynamic pre-vacuum procedure
Exposure duration	≥ 5 minutes
Temperature	134°C

SINGLE USE

The devices of the HOLA family are exclusively single-use. Reusing the device can lead to implant failure due to the alteration of the functional mechanical properties.

The instruments can be reused provided that: rules for their correct storage have been observed; the instruments are not damaged and/or contaminated, and the guidelines for resterilisation indicated above are followed.

In the event of non-compliance with this requirement, the manufacturer accepts no liability.

Mikai recommends that the products be disposed of if they come into contact with pathogens that are difficult to detect, such as the variant of Creutzfeldt-Jakob disease (confirmed or suspected pathogen).

IDENTIFICATION OF DEVICES

Each device is identified by a label placed on the primary or secondary packaging (cardboard box). The following symbols are present on the label with their explanation.

In the event of a serious accident, the manufacturer Mikai S.p.A. and the competent authority of the state in which the accident occurred must be informed.

The manufacturer keeps the summary of safety and clinical performance up to date when necessary, which is made available on the Eudamed portal at the following address: https://ec.europa.eu/tools/eudamed. To consult this document, select the section relating to devices, systems and procedural packages and carry out a search by filling in the "Reference number/catalogue" field.

With regard to disposal, it is essential to follow hospital protocols relating to contaminated materials and biological waste. All surgical instruments should be considered contaminated. Therefore, these instruments must be handled, collected and transported with the utmost care to minimise potential risks to patients, staff and all areas of the hospital.

	Name and full address of the manufacturer		Single use
REF	Code		Do not use if the packaging is damaged
LOT	Batch No.		Do not resterilise
	Expiry date	CE 1936	CE mark and identification number of the Notified Body
STERILE EO	Sterilised by Ethylene oxide	MD	Medical device
	Store in a cool, dry place		Single sterile barrier with internal protection

UDI	Unique device identification	e-IFU	Read the instructions for use available at https://www.mikai.us/downloads/

Note: This device may have the following non-harmonised symbols (abbreviations) in the description:

- ST: indicates the sterility status of the device;
- TI: indicates that the device is made of titanium;
- Fxx: the letter F followed by a number indicates the length of the main thread present in the device;
- Lxx: the letter L followed by a number indicates the main length of the device;
- xxPZ: preceded by a number, indicates in the description the number of devices in the package