BSS Foot – Compression Screw Foot – Instructions for Use and Warnings

CE 1936

EN

DESCRIPTION

BSS Screw is available in two different versions: L, S and XL series.

The L series has a 4mm head thread section, 2mm core and 3mm tip thread; the lengths vary from 14mm to 30mm. The median measurements are from 21mm to 26mm are available in two versions with the head thread (6mm and 4mm) based on the expected use.

The S series has a 3mm head thread section, 1.5mm core and 2.5mm tip thread; the lengths vary from 10mm to 28mm. The measurements 10,11,12,13 have a shorter tip thread (4mm).

The XL series has a 5mm head thread section, 2.8mm core and 4mm tip thread; the lengths vary from 20mm to 60mm. all sizes have two tip thread lengths available, proportional to the size of the screw.

The BSS screws have a head thread with a 1.20 mm pitch and a tip thread with a 1.05 mm pitch, generating a compression coefficient (approach between the distal and proximal bone stumps) with each screwdriver turn of 0.15 mm.

The device is provided STERILE and is for SINGLE USE only. The dedicated instrumentation set manufactured for the device must be used for the implantation. The instruments are supplied non sterile and must be properly cleaned and sterilized prior to surgery.

MATERIALS

The construction material for the implants is:

- Titanium alloy Ti6Al4V ELI ISO 5832-3

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

Foot

- Peroneal/tibial malleolus apex osteosynthesis.
- Astragalus and tarsus osteosynthesis.
- Osteochondral astragalic/tarsal fragments osteosynthesis.
- Fracture base of 5th metatarsus and metatarsal/phanlangeal joint fragments.
- Corrective osteotomy of the forefoot.

CONTRAINDICATION

- Insufficient bone tissue quantity.
- Insufficient bone tissue quality.
- Any form of active infection.
- Any inflammation in the implant area.
- Any mental or neuromuscular disorder.
- Sensitivity to materials in the screw composition, both documented or suspected (see label).
- Obesity, diabetes, vascular pathologies.
- Joint laxity and with previous degenerative or inflammatory arthritis.
- Excessive fragmentation.
- Do not use the fixation technique with headless compression screws in the presence of epiphyses or infections in the rupture, in long and oblique fractures or when the continuity of the cortex cannot be re-established in diaphyseal fractures.
- Any marginal fracture (subchondral).
- The use of more screws inside the articular surface could violate the articular cartilage or increase the risk of soft tissue removal.
- Diabetes as a significant risk factor for delayed bone fusion or non-union.
- Multiple fractures of the ipsilateral limb.
- Previous ankle deformities and injuries.
- Patients younger than 16 years of age and pregnant women.

BASE SURGICAL TECHNIQUE

- Incise the skin and, after making the incision, get to the bone surface of the selected bone segment respecting any safety corridors.
- Insert the dedicated Kirschner wire into the bone and check its correct progress with the image intensifier. In order not to deflect or bend the wire during the introduction, avoid exerting excessive pressure on it. During the introduction, use the appropriate wire guide.
- Using the depth gauge, measure the correct screw length using the Kirschner wire previously inserted as a reference.
- In the case of very thick cortex or particularly compact / hard bone, pre-drilling with the appropriate cannulated perforator is recommended. In this case, use the dedicated drill guide. Mikai recommends the use of the perforator always in order to avoid any risk of implant malfunction due to inaccurate evaluation of the cortex.
- Insert the selected screw on the Kirschner wire and begin the introduction into the bone. Check with the image intensifier the correct positioning of the screw and the reduction of the fracture.
- Remove the Kirschner wire, close the access road and perform the duty treatments.

RECOMMENDATIONS AND PRECAUTIONS

- The use of internal fixation devices requires a thorough knowledge of the surgery and the specific technique of this method;
- If a foreign body susceptibility is suspected, a test should be performed prior to implantation to exclude this possibility;
- The patient should be informed of how the device is used and of potential complications associated with small segment screws;
- 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.
- 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;
- It is important to select the components of the device correctly. The correct choice of the implant can minimize the risks of failure and this choice must be made in relation to the size and shape of the affected bone segment and to the loads it is subjected to;
- The dedicated accessories must always be used and approved by the manufacturer and must always be installed with the instruments supplied by the manufacturer;
- The device must be inspected for physical, superficial and functional integrity before proceeding with the implant;
- Excessive or marked deformation of an implant can cause a marked reduction in fatigue resistance;
- Make sure that the devices to be implanted are sterile;
- Store the product in such a way that the packaging is not damaged or altered and do not use it if the packaging (outer box and inner packaging) is damaged.

- Early diagnosis and rapid intervention are recommended;
- Smokers should be informed of the greater possibility of pseudoarthrosis arising during the healing process;
- Psychologically inhibited, obese or debilitated patients risk failure;
- Methods and aids or alternative devices should always be readily available before proceeding with the implant;

- Intra-Operatorie
- 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.
- For components delivered in a sterile package (see the appropriate label on the package), make sure that the sterilization expiration date has not been reached;
- For the components delivered in a sterile package (see the appropriate label on the package), make sure that the casing is free of damage and that the color of the word "GAS" present on the sterilization mark has become green;
- 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;
- Careful not to cut surgical gloves during the procedure;
- Any device implanted in the patient, such as bone screws, threaded wires and in general any device marked as "single use": MUST NOT BE REUSED;
- Select the length of the bone screws and the thread according to the size of the bone and soft tissue. Avoid excessive penetration of the second cortex, which could cause damage to the soft tissues;
- The components are not compatible with all Mikai Fixation systems. For more information on the compatibility of the various components it is recommended to consult the specific operating techniques;
- It may be necessary to use additional instrumentation for application and removal, such as a cutter, wire bending pliers and power drill;
- Check the integrity of the screws and assembly at regular intervals.
- It is necessary to carefully clean the epidermis around the threaded wires (inserting the wires);
- 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.

Foot

- In the case of Tillaux-Chaput fractures, a pre-operative CT analysis with respect to a radiographic plane, to determine the shape of the fracture fragments, the amount of the displacement and the condition of the articular surfaces.
- A closed reduction is recommended in contrast to the more classic open reduction.
- It is important to preserve the integrity and continuity of the anterior tibioperoneal ligament and to remove any fragment of tissue, cartilage and blood clots.
- There are three aspects of the surgical operation that could lead to a subsequent osseous non-union of the joint: the correct positioning of the foot in neutral flexion, the protection of the fibular tendons through retractors and the extension of the K wires from the incision to on the opposite side both for a greater support and to remove the wires if they break or bend using the cannulated drill.
- A combination of 2D and 3D techniques is recommended to clarify the classification of fractures, the position of the largest fragments, the degree of fragmentation, the location of the lost articular cartilage and finally being able to find the optimal entry for surgery.
- Perform the surgery as quickly as possible with respect to the date of injury to the talus.
- The main factors that can influence the clinical result, as well as the union rate, are: bone quality, smoking, a previous tibia-talus fusion, operative technique, and post-operative rehabilitation. Furthermore it is pointed out that the exact positioning (perpendicular to the articulation plane) and the correct measurement of the screws, as well as of the threads, are decisive for ensuring optimal compression at the fusion site.

Post-Surgery

- The patient should be informed that the system will not be as strong as healthy bone;
- Patients should be instructed to report any abnormal or unforeseen effects to the surgeon;
- 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;
- 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;

- Make a strict adherence to physiotherapy and rehabilitation.

PROVISIONS FOR USE

1. The device is intended to use a single use only, a possible reuse, determines the risk of infection for users and cross-contamination between patients
2. The use of osteosynthesis devices by mini-invasive and arthroscopic surgery presumes an in-depth knowledge of the same and of the implant technique.
3. 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.

CAUTIONS

- Never, for any reason whatsoever, use damaged implants;
- Excessive or marked deformation of an implant can cause a marked reduction in fatigue resistance.
- It is strongly recommended to use dedicated instruments during implant while handling sharp instruments.
- Be careful not to cut surgical gloves during the procedure.
- For components delivered in a sterile package (see the appropriate label on the package), make sure that the sterilization expiration date has not been reached.
- For the components delivered in a sterile package (see the appropriate label on the package), make sure that the casing is free of damage and that the color of the word "GAS" of the color change has become green.

UNDESIDERABLE EFFECTS

The following events may represent undesiderable effects after a fixation 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 bone segments reduction/correction;
- Inadequate fixation
- Protrusion of intra-articular screws
- Loss of reduction
- Non-functional rotation
- Screw migration
- Complex regional pain syndrome
- Rotational deformity
- Attachment of tendons
- Temporary and / or residual pain
- Residual swelling

- Heterotopic ossification
- Avascular necrosis
- Hypoesthesia of the median nerve
- Formation of keloids above the scar of the surgical incision

IMPORTANT

Not all surgical procedures have positive outcomes. 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 BSS system.

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.

RISKS CAUSED BY RE-USE OF "SINGLE USE" DEVICES

The BSS system 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 falls entirely under the responsibility of the Hospital and/or the physician.

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

STERILIZATION

The implantable devices are exclusively SINGLE USE and supplied STERILE. These devices contain a label that indicates said status.

The content of the package is STERILE as long as it is not open or damaged. Do not use if the packaging is damaged.

All NON-STERILE products (instruments) must be sterilized using a steam autoclave according to the UNI EN ISO 17665 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.