BSS XL – Compression Screw – Instructions for Use and Warnings

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DESCRIPTION

The XL series of the BSS system have 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

Hand:
- Transversal phalanx fracture.
- Transversal metacarpal fracture.
- Interphalangeal arthrodesis.
- Metacarpal/phalangeal arthrodesis.
- Joint fractures on the phalangeal base.
- Phalanx/metacarpus condyle fracture.

Wrist:
- Scaphoid fracture.
- Carpal bone fracture.
- Radio-carpal arthrodesis.
- Intercarpal arthrodesis.
- Radial styloid fracture.
- Ulnar styloid fracture.

Elbow
- Epitrochleal fracture.
- Coronoidal fracture.
- Capitulum humeri fracture.
- Distal humerus fracture.
- Radial capitulum fracture.

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.
- 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.

SPECIFIC SCAPHOIDAL TECHNIQUE

Volar surgical access
- To identify the correct insertion point of the guide wire on the scaphoid tubercle, it is recommended to introduce the pointed guide inside the space between the scaphoid and the trapezius so as to determine the posterior tilting of the trapezius with the extension movement of the guide. Therefore, even in some percutaneous syntheses, a mini-access to the S-T joint can be recommended.
- It is necessary to introduce the 1mm guide wire under fluoroscopic control to determine the screw length and the introduction line in both planes. The 1mm guide wire must reach the cortex of the proximal pole, without penetrating it. An extra eccentric Kirschner wire can, in some conditions, stabilize the fracture before the introduction of the guide wire.
- The depth gauge, inserted along the guide wire, allows you to choose the correct penetration depth of the drill for that type of fracture.
- The drill bit for L series screws has a clearly visible notch which corresponds to 26mm. In the case of proximal fracture, it is advisable to advance the drill to the same depth as the guide wire. In fractures at the body level it is instead advisable to bore 1-2mm less than the end of the guide wire. The guide wire can sometimes come out when the drill bit is removed. In this case, the wire must be repositioned freehand before inserting the screw.
- When screwing the proximal fragment, it is advisable to use a special spatula which, inserted in the radio-scaphoid space between the volar ligaments and the scaphoid, allows you to apply a back pressure on the proximal pole and avoid the risk of rotation.
- The screw must be sunk until the head fillet reaches the surface of the bone. It is important to remember that each turn of the screwdriver corresponds to an approach of the two fragments equal to 0.15mm. If necessary, based on the location of the fracture line, the screw can be further sunk into the bone, thus producing greater compression on the outbreak (see warning).
- In body level fractures it is recommended to choose a screw with a long tip thread, 2mm shorter than the depth measured for the guide wire. In proximal fractures it is recommended to choose a screw with a short tip thread, of the same length as the depth measured with the guide wire.

Warning: a higher compression capacity risks creating an angular deformity in the case of an eccentric position of the screw or of causing a shortening of the scaphoid.

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.

Wrist
- During the dorsal approach, the extensor tendon of the thumb and index finger, as well as the posterior interosseous nerve are at risk.
- During the volar approach, the superficial palmar arch and the recurrent branch of the median nerve may be injured.
- The centering of the screw without central thread on the fracture for screws of shorter length (10 mm or 18 mm) could generate a greater compression, due to its long portion without thread.
- A longer screw determines greater stability during the application of physiological loads for scaphoid fractures (remembering to find the ideal size so as not to penetrate the cortex).
- When it is desired to stabilize the scaphoid fractures with a single screw, the positioning of the central axis is critical to reach the greatest degree of stiffness and load resistance.
- Useful aspects to improve the treatment of intercarpal arthrodesis are the use of magnetic resonance images to define the synchondrosis and show the inflammatory changes due to the pathology, the identification and protection of the dorsal sensory branch of the ulnar nerve to avoid formation of neuroma and the introduction of an adequate quantity of bone graft in the LT interval in order to avoid alterations to the carpal alignment.
- Some precautions to obtain a solid fusion are the meticulous removal of the articular cartilage from the whole union site followed by self-bone graft insertion and compression fixation, post-operative immobilization, smoking cessation and daily activity restrictions up to the achievement of fusion from the radiographic point of view.

Hand
- It is of fundamental importance to perform a careful pre-operative analysis, through measurements of the lateral radiographs, in order to choose in the most suitable way the screw that will be implanted to block the fractures, which must be subsequently verified under fluoroscopy.
- On interphalangeal arthrodesis it is remembered that careful pre-operative planning should include a correct decision on the correct angle of arthrodesis and that this should be the most functional choice for the patient.
- As far as the surgical approach is concerned, it is emphasized that the central tendon must be detached from the P2 dorsal base, any soft tissue or piece of cartilage in excess should be excised so as not to interfere with bone apposition, the beams should be protected neuro-vascular of both parts of the finger and the germinal matrix should not be damaged.
- Removal of articular cartilage and osteophytes to increase bone contact between the distal phalanx and the medial

phalanx, but also care must be taken in not damaging the germinal matrix.

Elbow

- Rapid surgery and good rehabilitation reduce the risk of developing heterotopic ossification.
- Particular attention on two aspects characterizing this type of intervention: the time within which the patient should have operated which must be no later than two weeks after the injury, and the type of approach undertaken surgically.
- Submission of patients to lateral and oblique anteroposterior radiographs of the elbow, computerized tomographies also including a 3D reconstruction of the distal anatomy of the humerus.
- An accurate anatomical reduction of the fracture, a stable fixation and an early mobilization, essential aspects for the achievement of a complete and painless range of movement with the desired functional results.
- In the presence of cartilage lesions of the humeral capitellum, the optimal solution is to debride the lesion and remove the fragments of the lost cartilage.

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 lose of bone segments reduction/correction.
- Damage of the cartilage of the radial joint with associated pain until removal.
- Pseudoarthrosis represents a serious complication of carpal scaphoid fractures that reaches an incidence of 55%, regardless of the type of fracture treatment, when fragment separation is greater than 1 mm
- SNAC (scaphoid nonunion advanced collapse)
- Possible injuries to the ulnar and / or radial nerves
- Secondary arthritis to the radius lunate articulation
- 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.