

DESCRIPTION

BSS bone screws are medical devices for internal compression synthesis. This compression is obtained in two ways:

1. Leveraging the concept of the Herbert screw (headless screw), a screw featuring two threads with different pitches at each end, whose pitch differential generates compression across the bone fragments, holding them together and facilitating the healing process;
2. Leveraging the protruding head of standard cortical screws, in which the screw features a single thread at the tip that drives the advancement of the device, while compression is achieved through the head pulling the second bone fragment closer, thereby facilitating the healing process.

BSS 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 BSS device family is intended for orthopaedic surgeons experienced in the field of internal synthesis.

MATERIALS

The bone screws and washers of the BSS family are made of Ti6Al4V ELI ISO 5832-3 titanium alloy.

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).

INTENDED USE

Family of medical devices for internal synthesis for the treatment of bone fixation, correction or stabilisation, in adult and paediatric patients.

INDICATIONS FOR USE

Fractures of traumatic and/or pathological origin that may occur in the following anatomical regions or joints:

- Hand;
- Wrist;
- Foot;
- Elbow;
- Shoulder;
- Knee;
- Ankle;
- Femur.

Correction of deformities that may occur in the following anatomical regions and joints:

- Hand;
- Wrist;
- Foot;
- Elbow;
- Shoulder;
- Knee;
- Ankle.

Pseudoarthrosis that may occur in the following anatomical regions and joints:

- Hand;
- Wrist;
- Foot;
- Elbow;
- Shoulder;
- Knee;
- Ankle.

Below are the sizes and their correspondence to each anatomical region:

Anatomical region	Ø1.7 mm	Ø2.5 mm	Ø3.0 mm	Ø4.0 mm	Ø5.0 mm	Ø7.0 mm	Ø8.0 mm
Hand	X	X	X				
Wrist	X	X	X	X			
Elbow		X	X	X			
Shoulder			X	X	X		
Foot		X	X	X	X	X	X
Ankle				X	X	X	X
Knee				X	X	X	X
Femur					X	X	X

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;
- Excessive fragmentation;
- Any neuromuscular deficit that could interfere with the patient's ability to limit the load;
- Any neuromuscular deficit that places an unusually heavy load on the device during the healing period.

DURATION OF USE AND EXPLANATION

The BSS bone screw can remain implanted from 30 up to 180 days, the maximum time in which the intended uses are expected to be achieved. In order to proceed with the explant, the appropriate BSS family instruments must be used.

BSS CUSTOM KIT

The BSS family of bone screws provides custom kits (5003AAASTXX) containing different devices in predefined quantities for the treatment of certain anatomical areas 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.

The description of the custom kit is for information purposes only and may correspond to a word or synthetic phrase. This refers to the indications for use (which must be included among those attributed to the BSS family) if it is a kit commercially aimed at treating a district or pathology.

COMPATIBILITY WITH WASHERS FOR "STANDARD" SCREWS

Compatibility between the screw and the washer is achieved when the inner diameter of the washer is smaller than the outer diameter of the screw head. In this way, the screw head 'traps' the washer between itself and the bone surface. The washer thus transfers the compression from the screw to the bone, allowing the positioning to be maintained.

To avoid incorrect use caused by an improper screw/washer coupling, specific and unique screw/washer diameters have been made.

A washer with an inner diameter smaller than that of the corresponding screw will lock in place, being unable to pass through. On the contrary, a washer with a larger diameter, always with respect to the screw, cannot lock in place on the screw head, bypassing it.

The compatibility table for washers and their corresponding usable screws is provided below:

Code	Washer size	Type of compatible screws
BTR17004WST	Washer - inner Ø 1.7 mm and outer Ø 4.0 mm	Screws with Ø1.7 mm head
BTR25005WST	Washer - inner Ø 2.5 mm and outer Ø 5.0 mm	Screws with Ø2.5 mm head
BTR30006WST	Washer - inner Ø 3.0 mm and outer Ø 6.5 mm	Screws with Ø3.0 mm head
BTR40007WST	Washer - inner Ø 4.0 mm and outer Ø 7.5 mm	Screws with Ø4.0 mm head
BTR50009WST	Washer - inner Ø 5.0 mm and outer Ø 9.0 mm	Screws with Ø5.0 mm head
BTR70013WST	Washer - inner Ø 7.0 mm and outer Ø 13.0 mm	Screws with Ø7.0 mm head

BASIC SURGICAL TECHNIQUE

The installation (implant) steps for a BSS bone screw are listed below.

1. Incise the skin and, after making the incision, reach the bone surface of the selected bone segment respecting any safety corridors.
2. Insert the dedicated Kirschner wire into the bone and check its correct progress with the image intensifier. In order not to deflect or flex the wire during insertion, avoid exerting excessive pressure on it. During the introduction, use the appropriate wire guide.

3. Using the depth gauge, measure the correct length of the screw using the previously inserted Kirschner wire as a reference.
4. In the case of very thick cortical bone or particularly compact/hard bone, pre-drill with the appropriate cannulated drill. In this case, use the dedicated drill guide. If it is impossible to accurately assess the cortical bone, always use the perforator in order to avoid any risk of implant malfunction.
5. Insert the selected screw on the Kirschner wire and start the introduction into the bone. Check with the image intensifier that the screw is correctly positioned and the fracture is reduced.
6. Remove the Kirschner wire, close the access route and carry out the necessary treatments.

WARNINGS AND PRECAUTIONS

Pre-operative

- The use of internal fixation devices requires a thorough knowledge of surgery and of the specific technique of this method;
- 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 BSS bone 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 failure of the reconstructive and rehabilitative therapy;
- 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;
- Early diagnosis and rapid intervention are recommended;
- 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.

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.
- 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;
- Select the length of the bone screws and thread according to the size of the bone and soft tissues. Avoid excessive penetration of the far cortex, which could cause damage to soft tissues;
- Additional instrumentation may be required for implantation and removal, such as a power drill;
- Be careful not to cut the joint surface with the screws/bone wires.

Post-operative

- 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 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;
- Removal of the device: the final decision regarding the removal of the fixation 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;
- Excessive movement at the fracture site due to improper positioning;
- Superficial or deep bone infection, osteomyelitis or septic arthritis along the screw passage tract;
- Oedema or swelling, possible compartment syndrome;
- Joint contracture, subluxation, joint dislocation, deformity or loss of range of motion;
- Failure of bone regeneration, development of non-union or pseudoarthrosis;
- Delayed healing;
- Osteolysis;
- Fractures of the regenerated bone or caused by the bone screw hole, following removal of the device;
- Breakage of devices;
- Bone damage due to the choice of inadequate implants;
- Bone malformation;
- Persistence or reappearance of the initial condition that required treatment;
- Repeat surgery due to inadequate synthesis;
- Rejection of implantable elements;
- Tissue necrosis following the insertion of implantable elements;
- Excessive surgical bleeding;
- Inherent risks associated with anaesthesia;
- Allergic reaction;
- Intractable 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;
- Loss of reduction;
- Migration of implanted elements
- Heterotopic ossification;
- Formation of keloids over the surgical incision scar;
- Hypoaesthesia;
- Vascular disorders, including thrombophlebitis, pulmonary embolism, wound haematoma, vascular necrosis;

- The use of multiple screws within the articular surface may violate the articular cartilage or increase the risk of soft tissue removal;
- Diabetes as a significant risk factor for delayed bone union or non-union;

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 internal fixation device. Pre-operative and operative procedures, which include knowledge of surgical techniques, correct choice and placement of internal synthesis devices, are important factors for the successful use of Mikai internal fixation 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 BSS family.

The BSS 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 BSS 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 BSS 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 re-sterilisation 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
	Code		Do not use if the packaging is damaged
	Batch No.		Do not re-sterilise
	Expiry date		CE mark and identification number of the Notified Body
	Sterilised by Ethylene oxide		Medical device
	Store in a cool, dry place		Single sterile barrier with internal protection
	Unique device identification		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;
- 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