DOUBLE MEDICAL
Tel: +86 592 6087101
www.double-medical.com

Instructions for Use
Sterile Metal Bone Screw

CE 0123

Metal Bone Screw are used either to fasten plates onto bones or as lag screws to hold bone fragments together. The screws are differentiated by the manner in which they are inserted into bone, their function, their size, and the type of bone they are intended for.

I. Material
Metal Bone Screws are made of titanium alloy.

II. Intended Use
Metal Bone Screw can be used alone or combined with bone plates to treat various fractures of limbs and irregular bones.

III.Indication
Metal Bone Screw can be used in internal fixation of limb bone and irregular bone fracture.

IV. Contraindications
1.Active infection
2.Critical peripheral vascular disease
3.Conditions which tend to retard healing such as blood supply limitations, previous infections, insuffcient quantity or quality of bone to permit stabilization of the fracture
4.Conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process
5.Foreign body sensitivity
6.Cases where the implant(s) would cross open epiphyseal plates in skeletally immature patients
7.Malignant primary or metastatic tumors

V.Intended user
Intended users shall be qualified medical personnel who have received professional training on surgical operation and relevant device information.

VI.Patient group
Adults who have surgical indications, do not have surgical contraindications and can tolerate surgery .

VII.Clinical benefits
Metal Bone Screw is used for internal fixation of bone fracture to achieve bone union.

VIII.Adverse Events
1.Osteoporosis, inhibited revascularization, bone resorption and poor bone formation can cause loosening, bending, cracking or fracturing of the device or premature loss of fixation with the bone, leading to nonunion.

2.Delayed union, malunion or nonunion of the fracture site resulting from improper alignment.
3.Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
4.Early or late infection, both deep and/or superficial.
5.Nerve damage may occur as a result of the surgical trauma.
6.Metal sensitivity reactions in patients following surgical implant have rarely been reported, and their significance awaits further clinical evaluation.
7.Early improper weight loading will lead to metal fatigue crack.

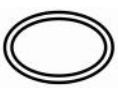
IX.Warnings and Precautions

1. Responsibility for proper selection of patients, adequate training, experience in the choice and placement of implants and the decision to leave or remove implants postoperatively, rests with the surgeon.
2. The surgeon should discuss the expectations of surgery inherent in the use of the product with the patient preoperatively. Particular attention should be paid to a discussion postoperatively and the necessity for periodic medical follow-up.
3. Suitable implants should be chosen for specific fracture and implant indication. Choose a suitable implant according to preoperative X-ray film or the measurement taken by depth gauge. Select a supporting instrument set and metal bone plate according to the chosen implant. Surgery should be finished with the guidance of Manual of Internal Fixation: Techniques Recommended by the AO-ASIF Group and other relevant information.
4. The correct selection of the product is extremely important. The product should be used in the correct anatomic location, consistent with accepted standards for internal fixation. Failure to use the appropriate product for the application may result in a premature clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, or fracturing of the product and/or bone.
5. Careful preoperative planning is a requirement. The surgeons should choose the proper implants according to preoperative images and by using measuring instruments such as depth gauges and trials. Instruments which are intended for the implants should be applied in order to obtain a safe combination.
6. In order to avoid or minimize specific risks associated with implantation, surgeons should have been trained, and the operation should be performed strictly according to the surgical technique guide.
7. Careful handling and storage of the product is required. Scratching or damage to the component can significantly reduce the strength and fatigue resistance of the product.
8. Generally, there is no limitation on substances used in the clinical setting, to which the implant might be exposed.
9. Once applied, the product should never be reused. Although it may appear undamaged, previous stresses may have created imperfections that could reduce its service life.
10.Unless specifically indicated in the surgical technique guide, the modification of size, shape or surface condition is prohibited after supply.
11. Unless stated otherwise, devices have not been evaluated for safety and compatibility within the MR environment. Please note that there are potential hazards which include but are not limited to:
-- Heating or migration of the device
-- Artifacts on MR images
12. Patients should be advised to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant.
13. Surgeons should verify whether the implants are positioned correctly using adequate imaging technology.
14. Premature physical activity or load bearing after surgery is prohibited.

15. Postponed or long-term use may bring about implant looseness or crack and affects healing of bones; therefore, it should be considered to take the implant out as soon as fracture is healed.
16. The patient should be advised to report any unusual changes of the operated site to his surgeon. The patient should be closely monitored if a change at the fixation site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for any measures deemed necessary to aid healing.
17. Considerations for removal of the implant after healing. If the device is not removed after the completion of its intended use, any of the following complications may occur:(1) corrosion, with localized tissue reaction or pain; (2) migration of implant position resulting in injury, (3) Risk of additional injury from postoperative trauma; (4) bending, loosening, and/ or breakage, which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) possible increased risk of infection; and (7) bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.
18. Implants taken out from body should be handled in an anti-pollution way per stipulations of each country in order to prevent cross infection.

X.Sterilization
The implant is provided as sterile. It is sterilized with γ ray, and the validity period is 5 years.

XI.Labels

	Catalogue number		Manufacturer
	Date of Manufacture		Use -by date
	Batch code		Do not re-use
	Sterilized using irradiation		Do not use if package is damaged
	Authorized Representative in the European Community		Caution
	Keep away from sunlight		Keep dry
	Consult instructions for use		Importer
	Medical device		Double sterile barrier system

XII. Storage
The sterilized product should be stored in a clean environment, protected from direct sunlight and pests.

XIII.Transportation
Avoid collision and compression during storage and transportation.

XIV.Use of Original Products
Implants and instruments are designed to be used together. The use of products from other manufacturers along with Double Medical products can involve incalculable risks, injury or corrosion of the material and misalignment of implant and instruments, impeding functionality, thereby endangering the patient, user or third parties.

XV.Handling Information
Metal Bone Screws are made of titanium alloy. The material is biocompatible as widely used in the industry, corrosion-resistant and non-toxic in the biological environment. It produces negligible artefacts by X-ray and CT.

XVI.Surgical Technique
1. Preoperative Plan
(1) Take a X-ray picture of the fractured bone, including adjacent joints.
(2) The recovery of the original bone status and the correction of bone malformation are the main purposes of the treatment.
(3) Assess the condition of soft tissue and exam the neurological and vascular functions.
2. Surgical Approach
The length of incision is decided as needed. Cut the skin, subcutaneous tissue, fascia and periosteum. Expose the fracture and remember to protect nerve and blood vessel.
(1) Position
Determine plate length and bend plate if a plate is used.
Operation can be conducted either on a X-ray penetrative operating table or orthopedic traction table. Chose patient position according to fracture type.
(2) Restoration and Temporary Fixation
Use a restoration pincer and Kirschner wire to restore. Restoration result can be examined when needed.
(3) The Selection of bone plate
Place a model on the surface of fractured bone and select a bone plate with proper length and shape.
(4) Drilling
Drill holes using a proper drill and guide and compress as needed.
(5) Deciding Screw Length
Use a detector to detect the depth of holes and the depth is the length of screws. When detecting, the detector should reach the cortex on the opposite side and hook it.
(6) Tapping
Use a corresponding screw tap to do tapping.
(7) Screw Insertion
Before inserting the first screw, ensure the fracture has been restored. Tap the screw in . If the screw is long or the cortex is too thick, normal saline can be applied to lower the temperature.
3. Removal of Implant
Expose the plate and screws from the original incision and strip tissues on the surface of the bone plate

and screws. Use a hexagonal socket screw driver to unscrew, remove all the screws and finally remove the plate. Please fully connect the hexagonal socket screw driver and the screw to make them in line in case of gear slip.
Notice:
The handling of gear slip or screw crack
(1) When gear slip occurs and it is impossible for the hexagonal socket screw driver to remove the screw, connect a slip extractor to an electrical bone drill and insert vertically into the hexagonal socket and the screw can be removed anticlockwise.
(2) When screw crack occurs, connect a crack extractor to an electrical bone drill and drill the bone cortex around the screw anticlockwise and the screw can be removed.
4. Disposal of Implant
Implants taken out from body should be handled in an anti-pollution way according to hospital protocol so as to prevent cross infection.
Devices must be disposed of as a healthcare medical device in accordance with hospital procedures.

XVII.Manufacturer/ Contact Information

Manufacturer:	Double Medical Technology Inc.
Legal Address:	No. 18, Shanbianhong East Road, Haicang District, 361026, Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA
Manufacturing Address:	No. 18, Shanbianhong East Road, Haicang District, 361026, Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA
Telephone Number:	+86 592 6087101
SSCP(Summary of safety and clinical performance)	Eudamed(https://ec.europa.eu/tools/eudamed/#/screen/home)
e-IFU	http://en.double-medical.com/

Note: If any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Notified Body: TÜV SÜD Product Service GmbH
Address: Ridlerstraße 65, 80339 Munich,Germany

EC REP **Shanghai International Holding Corp. GmbH(Europe)**
Eiffestrasse 80, Hamburg, Germany