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Instructions for Use
Non-sterile Metal Bone Plate

CE 0123

Metal Bone Plate is mainly used for internal fixation of fracture. The locking bone plate is designed and manufactured according to the anatomical characteristics of human bones. According to the diameter and shape of human bone, different sizes of locking plates with different radians were designed. According to the characteristics of bone implanted in different sites and the expected bearing weight, the locking bone plates with different diameters and different thickness were designed. In clinical practice, locking bone plate and locking bone screw are used in combination to play the role of temporary internal stent, providing a stable local environment for fracture ends and creating conditions for the healing of fracture ends.

I. Material

Metal Bone Plate: unalloyed titanium, titanium alloy (Ti6Al4V)

II. Intended Use

Metal Bone Plate is provided as non-sterile. It is implanted around the fracture end to correct, fix and stabilize fractures caused by trauma or disease.

III. Indications

The Metal Bone Plate is used in combination with the corresponding specifications and models of bone screws, and it is suitable for the internal fixation of long bones of limbs and irregular bones. For those immature bone whose epiphyseal is not closed, it is up to the operator to decide whether it can be used according to the specific situation of the patient.
Irregular bones here includes collarbone, scapula, and calcaneus.
Below is the exact medical indications:
1.Mini Locking Plate:
indicated for Phalanges, metacarpals, wrist bones and distal radius fracture;
2.Humeral Locking Plate:
(1)Proximal Humeral Locking Plate
-Dislocated two, three, and four-fragment fractures of the proximal humerus, including fractures involving osteopenic bone,
- Pseudarthroses in the proximal humerus
- Osteotomies in the proximal humerus;
(2)Distal Humeral Locking Plate
- intra-articular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies,and nonunions ofthe distal humerus;
3.Radius and Ulnar Locking Plate:
(1)Proximal Ulnar Locking Plate
-indicated for fixation of fractures, osteotomies and nonunions of the olecranon, particularly in osteopenic bone;
(2) Distal Radial Locking Plat
- Intra-articular fractures
- Extra-articular fractures,

- Osteotomies and fractures of other small bone;

4.Reconstruction Locking Plate:

It is suitable for fixation of single segmental clavicle fracture, comminution fracture, osteotomy, malunion and non-union; Lateral clavicle fracture and acromioclavicular dislocation fixation; Fixation of pelvic and other irregular bone fractures.

5.Femoral Locking Plate:

- Distal femoral shaft fracture
- Complex intra-articular fractures (with distal femoral coronal or periprosthetic fractures)
- Exarticular fracture;

6.Tibial Locking Plate:

(1)Proximal Tibial Locking Plate:

Indicated for temporary internal fixation and stabilization of fractures and osteo-tomies of long bones.

- Comprehensive classifications for proximal tibial fractures are the OTAand the Schatzker classifications.
- Stabilization with locking plates is recommended for most of the 41-Aand C type of fracture according to the OTA classification for long bones.
- This includes comminuted fractures and intra-articular and extra-articular condylar fractures;

(2)Distal Tibial Locking Plate:

–Extra-articular and simple intra-articular distal tibia fractures
–Distal tibia fracture, percutaneous or reducible by limited arthrotomy
– Distal tibia fracture extending into the diaphyseal area;

7.Fibular Locking Plate: intended for fixation of fractures,osteotomies and non-unions of the metaphyseal and diaphyseal region of the distal fibula, especially in osteopenic bone;

8.Foot Locking Plate : Intra- and Extra-articular fractures of the foot system, Deformities, Malunions;

IV.Contraindications

1. General or local infection, osteomyelitis.
2. Patient can’t tolerate operation or anesthesia because of poor health.
3. Mental disease, Systemic neurological disease
4. Pregnancy, metabolism disorder of calcified tissue
5. Incision of the tissue can lead to infection or skin necrosis due to poor local soft tissue conditions,
6. Severe osteoporosis prevents effective fixation
7. Patients with influence factors for fracture healing (e.g., diabetes, infection, etc.)
8. Patients with high degree of comminution, III degree open ,severe bone defect and severe damage to surrounding soft tissue

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 Plate 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 implant should be chosen for specific fracture and implant indication. Choose a suitable metal locking bone plate according to preoperative X-ray film. Select a supporting instrument set and metal locking bone screw according to the chosen locking bone plate. 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 relating 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 substance 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. Extreme angles together with small bending radii must be avoided because of the potential risk for postoperative breakage.
11. Excessively aggressive use of bending instruments can cause recognizable macroscopic damage to the implant (indentations, elongated screw holes, etc). In such cases, the implant must be exchanged for a new one.
12. Unless specifically indicated in the surgical technique guide, the modification of size, shape or surface condition is prohibited after supply.
13. The potential hazards to safety and compatibility that should be noticed when the device is used under MR environment include but are not limited to:

-- Heating or migration of the device
-- Artifacts on MR images
14. Patients should be advised to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant.
15. Surgeons should verify whether the implants are positioned correctly using adequate imaging technology.
16. Premature physical activity or load bearing after surgery is prohibited.
17. Postponed or long-term use may bring about implant looseness or crack; therefore, after bone healing, it's suggested to take out the implant if there is implant crack risk, which may bring medical accident.
18. 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.
19. 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.
20.Implant is not allowed to be reused. The risk of reuse is as follows:
(1) Metal strength decreases and fracture occurs easily after being implanted.
(2) As contaminants and bacteria remaining on the surface, re-implantation would result in infection and rejection.
(3) It can damage the surface anodic oxide film and affect the biological properties of the product.

X. Instructions for Product Reprocessing

1. Cleaning

(1) Implants and instruments must be carefully cleaned before initial sterilization. Trained personnel must perform cleaning (manual and/or machine cleaning, ultrasound treatment, etc.) along with maintenance and mechanical inspection prior to initial sterilization.
(2) Where applicable, multi-component instruments should be disassembled for cleaning. Disassembly, where necessary, is generally self-evident. If you have questions concerning the disassembly of any Double Medical instrument, contact your local Sales Representative or Double Medical directly (“Manufacturer/Contact Information”).
(3) Exact compliance with the equipment manufacturer's user instructions and recommendations for chemical detergents is required.
(4)The endotoxin limit of purified water used for final cleaning is 0.2EU/ mL.

Implant Cleaning Instructions

Cautions	1.Do not use cleaning tools (such as metal brushes) that will cause abrasion of the instruments 2. Avoid using strong acid or strong alkaline detergent; It is recommended to use neutral detergent or enzyme detergent with pH 6.5 ~ 7.5 as described in WS 310 to avoid corrosion of some metals. 3. After cleaning, the instrument should be transferred according to the hospital rules/ regulations. Do not touch with bare hands.
Preparation	Disassemble all components according to the instructions of manufacturer(if

before cleaning	applicable)
Manual Cleaning	**Cleaning tools and equipment** Soft brush, syringe, deionized water/purified water, detergent solution, ultrasonic cleaning machine **Pre-cleaning** 1.Rinse: rinse device thoroughly with running tap water for a minimum of 2 minutes. 2.Soak: Prepare the cleaning solution based on the water quality, concentration and temperature recommended by the cleaning agent manufacturer. Completely immerse the product to be cleaned in the cleaning agent for at least 10 minutes. 3.Scrub: Soak again in another freshly prepared cleaning solution. According to the characteristics of the product, choose the appropriate brush to scrub. For small diameter blind holes, the cleaning solution is injected into the syringe(Capacity≥50ml) to wash，brush or rinse at least 5 times； 4.Rinse: Rinse thoroughly with tap water, deionized water or purified water for at least 2 minutes. Use syringe(Capacity≥50ml) or other water spray equipment to flush blind hole and cavity，rinse at least 5 times; 5.Visually inspect: repeat steps 2~5 until no visible soil remains on device. **Ultrasonic cleaning:** (Not applicable for active device) 6.Ultrasonic cleaning: Prepare the cleaning solution based on the water quality, concentration and temperature recommended by the cleaning agent manufacturer. Ultrasonically clean the device in the freshly prepared solution, with frequency of 40 KHz at least 15 minutes. Clean the device ultrasonically for a minimum of 15 minutes, using frequency of 40 KHz. 7.Rinse: rinse device thoroughly for a minimum of 2 minutes with deionized water or purified water. Use a syringe(Capacity≥50ml) or other water sprayer to brush blind hole, cavity, etc.,rinse at least 5 times. 8.Visually inspect: repeat steps 2~8 until no visible soil remains on device. 9.Drying: Use medical compressed air or clean, lint-free disposable rags to dry medical instrument, or heat in an oven below 110 ° C to dry medical instrument.
Automated Cleaning	Soft brush, syringe, deionized water/purified water, detergent solution, ultrasonic cleaning machine,Automated washer-disinfector **Pre-cleaning** 1.Rinse: rinse device thoroughly with running tap water for a minimum of 2 minutes. 2.Soak: Prepare the cleaning solution based on the water quality, concentration and temperature recommended by the cleaning agent manufacturer. Completely immerse the product to be cleaned in the cleaning agent for at least 10 minutes. 3.Scrub: Soak again in another freshly prepared cleaning solution. According to the characteristics of the product, choose the appropriate brush to scrub. For small diameter blind holes, the cleaning solution is injected into the syringe(Capacity≥50ml) to wash, brush or rinse at least 5 times; 4.Rinse: Rinse thoroughly with tap water, deionized water or purified water for at least 2 minutes. Use syringe(Capacity≥50ml) or other water spray equipment to flush blind hole and cavity, rinse at least 5 times; 5.Visually inspect: repeat steps 2~5 until no visible soil remains on device. **Automated Cleaning:** Pre-cleaning（≥120S）→Cleaning（≥300S）→Rinse1（≥60S）→Rinse2（≥120S）→disinfection (93℃, ≥150S)→Drying（≥300S）

	Use a washer-disinfector that meets the requirements of ISO 15883 or YY/T 0734, and the equipment and process have passed CE/FDA/CFDA-approved washer-disinfectors for automatic cleaning and disinfection operations.

2.Inspection and maintenannce

Before preparing for sterilization, all medical equipment should be inspected. Generally speaking, normal visual inspection is sufficient under the condition of sufficient light without using a magnifying glass. The inspection shall cover all parts of the equipment to ensure that there is no visible dirt and/or corrosion. Special attention should be paid to the following below:

• Dirt "retention zones", such as engagement surfaces, hinges, flexible reamer shafts.
• Recessed parts (holes, sleeves).
• Dirt may be pressed into the parts that come into contact with the equipment, such as the drill groove which adjacent to the blade, the side teeth on the hand drill and the rasp.
• The cutting edge should be checked for sharpness and damage.

If possible, a functional check should be performed:

• Check whether the supporting equipment can be assembled correctly.
• Medical equipment with moving parts should be operated to check whether it can operate correctly (medical grade lubricant suitable for steam sterilization can be used as needed).
• Rotating instruments, such as multi-purpose drills, reamers, should be checked for straightness by simply rolling the instruments on a flat surface.
• The "flexible" instruments, such as IM reamer should be checked for damage.

3.Packaging

Before sterilization, the user (hospital) should wrap the product with the double-layer non-woven cloth or place the product in the special sterilization tray and container.

4.Sterilization

If there is no special instructions, the non sterile products need to be sterilized by adopting the verified method(ISO 17665). All tools listed in surgery technical manual can be directly sterilized without disassembly. The following the sterilization method is applicable for the implants and instruments.

Cycle Type	Pre-Vacuum
Minimum sterilization Time	4 minutes
Sterilization temperature	132℃
Minimum drying time	30 minutes
Minimum pulsation time	3 times

Additionally, please note the following:

(1) If a sterilization method other than the one listed above is performed, the user should validate it before sterilization according to ANSI/AAMI ST 79:2010 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities";
(2) Do not sterilize the device with its original package;
(3) Do not sterilize the device which is contaminated by body fluid.
(4)Implants may be reprocessed for 25 times. Implants should be visually inspected. Any implant with corrosion scratches, notches, residue or debris should be discarded.
(5) Devices should be visually inspected. Any implant with corrosion scratches, notches, residue or debris should be discarded. End of life of an instrument is normally determined by wear and damage due to the intended surgical use and not to reprocessing.
(6) When sterilizing multiple devices in one autoclave cycle, ensure that the sterilizer’s maximum load is not exceeded.

5. Storage

Products should be placed in the original packaging and stored in a clean environment to avoid direct sunlight and pests. Products that are not used in time after sterilization should be stored in the sterile storage area.

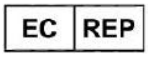
The shelf-life depends on the type of storage used, as well as the environment and handling

conditions. For sterilized medical device, all medical facilities should establish a maximum retention period before use.

6. Transportation

Avoid collision and compression during storage and transportation.

XI.Labels

	Catalogue number		Manufacturer
	Date of Manufacture		Non-sterile
	Batch code		Do not re-use
	Authorized Representative in the European Community		Caution
	Keep away from sunlight		Keep dry
	Consult instructions for use		Importer
	Medical device		

XII. Use of Original Products

Implants and instruments are designed to be used together. The use of products from other manufacturers along with products can involve incalculable risks and/or contamination of the material and misalignments of implant to instrument, thereby endangering the patient, user or third parties.

XIII. Handling Information

Metal Bone Plate is made of unalloyed titanium or Ti6Al4V that follow ISO 5832-2 or ISO 5832-3. The material is biocompatible as widely used in the industry, corrosion-resistant and non-toxic in the biological environment, and produce negligible artifacts by X-ray, CT and MRI.

XIV. 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

(1) Carry out routine disinfection after successful anesthesia.

(2) After the incision, expose to the fracture end layer by layer for reduction of fracture.

(3) The locking bone plate can be allowed to implanted at least after the functional reduction to avoid repeated bending of the locking bone plate.

(4) The locking bone plate is temporarily fixed to the fracture end with bone forceps or kirschner wire

(5) The length of distal and proximal ends of the fracture were measured by a drill depth sounder guided by a guide.

(6)Select an appropriate length of the locking screw and screw it into the bone plate with a screwdriver.
(7) Complete the installation of the other screws one by one by following the procedure of drilling, depth sounding and screwing in locking screw.
(8) Check again if all the screws are tightened.
(9) After the fracture fixation is completed, checked again the locking bone plate to see whether the position is appropriate and whether the fracture end achieves the desired stability effect.
(10) The whole process should follow the principle of aseptic operation.
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 the plate.
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.
5.More detailed operation instructions and selection of supporting instruments could be found in the 《Operation Manual》.

XV. 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)
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