Instructions for Use
Epiphyseal Plate

CE 0123

The epiphyseal plate is composed of a series of 8-shaped bone plates of different sizes and structures, and its design is based on the anatomical features of human bones. In clinical applications, the epiphyseal plate needs to be used in conjunction with hollow screws to achieve a temporary unilateral fixation effect, which can effectively limit the growth of one side of the epiphyseal plate and achieve the purpose of orthopedic correction.

I. Material

Epiphyseal Plates are made of unalloyed titanium.

II.Intended Purpose

The intended purpose of the Epiphyseal Plate is to provide temporary hemiepiphysiodesis by bridging the growth plate at the distal femur or proximal tibia in skeletally immature patients. It is used to correct angular deformities of the knee (such as genu valgum or genu varum) by modulating growth, while preserving the growth potential of the physis.

III.Indication

The Epiphyseal Plate is indicated for any growing child or adolescent with any angular deformity, regardless of etiology

IV. Contraindications

- Closed Physis
- Physiologic Deformities
- Skeletal Maturity

V.Intended user

The operation should be performed by professional trained surgeons according to the IFU and surgical technique guide strictly. The surgeon should have a thorough understanding of the intended purpose of the product and the surgical techniques used, and should be trained and certified by relevant institutions (e.g., Association for Internal Fixation Research, AO/ASIF).

VI.Patient group

Typical age range: pediatric and adolescent patients prior to physeal closure.

VII.Clinical benefits

Epiphyseal Plate is used to correct angular deformities of the knee to achieve recover the angle of the knee joint with expected correction deformity rate no less than 78.1%.

VIII. Potential Adverse Events

The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:

- Overcorrection resulting in deformity
- Loss of fixation, attributable to osteoporosis
- Bending, fracture, or migration of the implant
- Metal sensitivity, or allergic reaction to a foreign body
- Pain, discomfort, or abnormal sensations due to the presnce of the device
- Nerve damage due to surgical trauma
- Necrosis of bone
- Infection, both deep and superficial
- Death
- Vascular disorders including

thrombophlebitis, pulmonary embolus,wound hematomas, avascular necrosis These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

IX. Warnings and Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are equally important for the successful use of these products.
- Use extreme care in the handling and storage of implants and instruments. Cutting, bending, or scratching the surface of metal components can significantly reduce the corrosion, strength and fatigue resistance of the implant and instrument system .
- Repeat use of a surgical implant is strictly forbidden. Each implant used once must be disposed of properly. This is the same even where it appears to be intact. The device may have small faults or internal stresses that if the item is re-used may lead to fatigue failure.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from different sources being mixed.
- The system has not been tested for safety and compatibility with MRI. Risks of heating, migration, or image artifacts may exist. Physician experience should dictate acceptability of the use of MRI.
- Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, OrthoPediatrics recommends the retrieval of implants as otherwise they may replace the function of the bone and lead to bone reduction and weakening. This is especially important for young and active patients. Routine removal of internal fixation devices after healing may also reduct the occurrence of symptomatic complications of implant breakage, implant loosening or implant related pain.
- Timing of removal of implants used for growth modulation is critical> if the implants are left in too long, overcorrection may occur. This could result in additional stress to the implants. Overcorrection is the creation of an angular deformity in the opposite direction to the deformity for which the implant was being used to correct. This would require further surgery to correct this new deformity. For example, a varus deformity could be overcorrected to a valgus deformity. Additional stress to the implants may compromise implant integrity leading to implant failure and/or making removal difficult. Be sure to routinely follow patients thoroughout growth modulation until the desired clinical outcome is achieved and remove implants accordingly.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instrument and to take into account the risk of infection if a cut appears.

X. Implant Cleaning & Sterilization Instructions

Implants are provided in two forms: sterile and non-sterile.

-Sterile products are sterilized using gamma irradiation and have a shelf life of 5 years. They are intended for single-use only, and should not be used if the Sterile barrier system is damaged.

-For non-sterile products, it is recommended to follow these steps for cleaning and sterilization before use:

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

Initial treatment after use	1.Do not use cleaning tools (such as metal brushes) that will cause abrasion of the instruments 2 After used, promptly initial processing(Point of Use Care)should be conducted within 60min.Instrument should be transferred according to the hospital rules/ regulations. initial processing method: a. Wipe blood and/or debris from device throughout surgical procedure to prevent it from drying onto the surface. b. Flush cannulated devices with deionized water to prevent the drying of soil and/or debris to the inside. c. Soiled devices should be separated from non-contaminated devices to avoid contamination of personnel or surroundings. d. Devices should be covered with a towel dampened with deionized water to prevent blood and/or debris from drying.
Preparation before cleaning	Disassemble all components according to the instructions of manufacturer(if 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. Cleaning agent: RUHOF ENDOZIME® AW PLUS WITH APA Concentration: 1:270 Temperature: <60℃ 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; Cleaning agent: RUHOF ENDOZIME® AW PLUS WITH APA Concentration: 1:270 Temperature: <60℃
	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. Cleaning agent: RUHOF ENDOZIME® AW PLUS WITH APA Concentration: 1:270 Temperature: <60℃ 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. Cleaning agent: RUHOF ENDOZIME® AW PLUS WITH APA Concentration: 1:270 Temperature: <60℃ 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; Cleaning agent: RUHOF ENDOZIME® AW PLUS WITH APA Concentration: 1:270 Temperature: <60℃ 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, Users (hospital) are recommended to place the product in wrap, pouch, or other methods of maintaining sterility of product before sterilization.

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	3 minutes
Sterilization temperature	134℃
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. A maximum of 7 days is a recommended time.

6. Transportation

Avoid collision and compression during storage and transportation.

XI. Labels

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

XII.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.

XIII. Handling Information

Epiphyseal Plates is made of unalloyed titanium. 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.

XIV. Surgical Technique

1.Detailed operation instructions and selection of supporting instruments could be found in the 《Operation Manual》.

2. 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.

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
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

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

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