DOUBLE MEDICAL
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Instructions for Use
Non-sterile Metal Cannulated Screw

CE 0123

Metal Cannulated Screw consists of a series of screws with different sizes and structures, which is designed according to the anatomical characteristics of human bones. In clinical practice, Metal Cannulated Screw is used alone, which acts as a temporary internal support, provides a stable local environment for the fractured end, and creates conditions for the healing of the fractured end.

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

II.Intended Use
Metal Cannulated Screw consists of headless compression screw, cannulated screw and washer .
Metal Cannulated Screw is provided in non-sterile state. Headless compression screw and cannulated screw are intended for internal fixation of fractures of various limb and metaphyseal, hand, foot and irregular bone and orthopaedic fixation.

III.Indication
Indication of cannulated screw and headless cannulated screw.
Internal fixation of fracture, fusion and correction of limb bone and metaphysis, hand, foot and irregular bone.

IV. Contraindications
1. Osteoporosis
2. Infection
3. Sepsis
4. Insufficient quantity or quality of bone or soft tissue and material sensitivity
5. Cervical, thoracic, or lumbar spine
6. Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for these devices

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 Cannulated Screw is used for internal fixation of bone fracture to achieve bone union.

VIII. Adverse Events
1. Headless compression screw: surface infection

2. Cannulated screw:
(1) Persistent slight pain
(2) Nonunion, pain, implant fracture

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. Select a supporting instrument set and metal bone screw 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 operation instructions.
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. 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
The detailed information shall be given in Operation Manual if any.
12Patients 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 the 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 so as to prevent cross infection.

19. 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 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. 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°C, ≥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

REF	Catalogue number		Manufacturer

	Date of Manufacture		Non-sterile
LOT	Batch code		Do not re-use
EC REP	Authorized Representative in the European Community		Caution
	Keep away from sunlight		Keep dry
	Consult instructions for use		Importer
MD	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 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

Metal Cannulated Screws is 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.

XIV. Surgical Technique

1. Preoperative Plan

(1) Take an X-ray picture of the fractured bone, including adjacent joints.

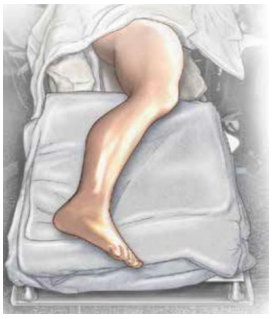
(2) The recovery of the original bone status and the correction of bone malformation are the main purposes of the treatment.

(3) Assess the condition of soft tissue and exam the neurological and vascular functions.

2. Treatment of calcaneal osteotomy with 7.0mm HCS

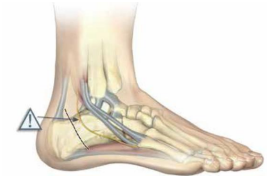
Surgical Approach

(1) patient position: The patient is in a semi-lateral position (Healthy limbs on the bottom, sick limbs on the top)

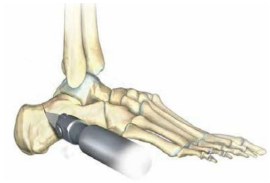


(2) Surgical approach: Make an incision at the end of peroneal tendon perpendicular to the calcaneal body.

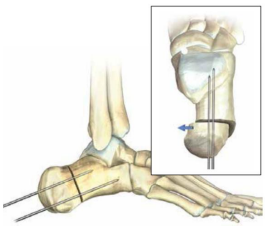
Draw the skin apart on both sides with a hook. Care must be taken to protect the peroneal tendon and sural nerve during the incision.



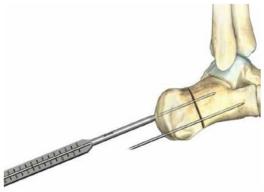
(3) Establishment of osteotomy: Osteotomy incision perpendicular to the calcaneal body with a swing saw should be performed, and medial cortex should be cut with a bone chisel (osteotomy) in order to prevent damage to medial nerve and vascular structure.



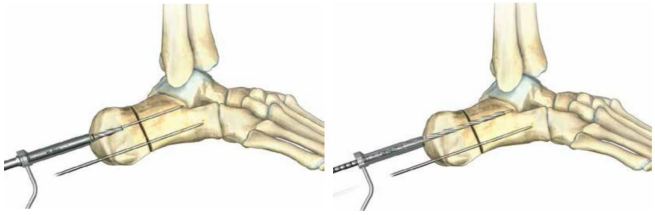
(4) Place a guide needle: Transposition the calcaneal body to medial side and insert a guide needle(REF: 112480600, specification:φ2.4×250). Fix the osteotomy end stably in the best position and confirm the position of the guide pin under fluoroscopy.



(5) Measuring depth and selecting screw: Use depth gauge to measure the insertion depth of guide needle, and select cannulated screw of suitable size according to the measuring depth. (REF of depth gauge: 112480400)

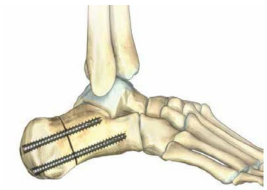


(6) Drilling: Place soft tissue protection drill sleeve along the guide pin, use corresponding countersink to drill holes in the proximal cortex, and then use corresponding cannulated drill bit to drill holes. The drilling depth is the same as the length of the selected screw.(countersink, type III, REF:112481900, specification:φ7.5×180. cannulated drill bit, type III, REF: 112481800, specification: 112481800. REF of protection drill sleeve: 112480700).



(7) Screw in: Use cannulated hexagonal screwdriver to screw in the proper position along the guide pin. Confirm the screw position under fluoroscopy, exit the guide pin. Use solid hexagonal screwdriver to finally screw in to ensure that the screw tail and bone surface are even (Screw in other screws in turn

according to this operation step).



(8) Suture and dress up the wound.

3. Removal of the implant

Expose the screw from the original incision and remove the surface tissue of the screw. Use a hexagonal screwdriver to spin out and remove all the screws. Connect the hexagonal screwdriver and the screw completely so that they are in a straight line in case the tool slips.

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.

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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