10. Instruction For Use

CE0123

Product Instruction for Metallic Bone Screw, sterile

Distributed by: 7s Medical AG, Länggasse 4, 6208 Oberkirch, Switzerland, www.7smedical.com, info@7smedical.com, Tel: 0041 41 925 66 60

Manufacturer Name: Changzhou Waston Medical Appliance Co., Ltd.
Add: No.9Xihu Road, Wujin Hi-Tech Industry Zone,Changzhou, Jiangsu ,PEOPLE'S REPUBLIC OF CHINA
Website: www.wastonchina.com E-mail:wastonchina@yahoo.com info@wastonmed.com
Tel: (+86)519-86522226 Fax: (+86)519-85135555

EC REP Name:Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537Hamburg,Germany
Tel. +49-40-2513175 Fax. +49-40-255726
E-mail:shholding@hotmail.com

1. Product Name

Metallic Bone Screw

2. Function, Structure and Components

The length, diameter, nail head shape and thread of the metallic bone screws are decided by the bone position of human skeleton. It is produced by mechanical process and surface treatment process. The tread of bone screw screwed into the bone bed supports the used of bone plate or gasket, which play a part in cutting, connecting and compression. Screw's rotating part (hexagon socket head or square recessed head) transmit the torque force.

Metallic Bone Screw is made of titanium alloy (TC4), which comply with the requirements of ISO5832-3: 1996(E) "Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy". The final product delivery status is sterile packaging.

Type & Specifications

No.	Name	Type	Specifications(Length mm)〈Fully Thread, Partial Thread〉
1	Cortical Bone Screw	HAQ 01～05	HA1.5×6～30 HA2.0×6～30 HA2.5×10～50 HA2.7×10～50 HA3.0×10～50 HA3.5×10～50 HA4.0×15～55 HA4.5×15～70 HA5.0×15～70
2	Cancellous Bone Screw	HBQ 03	HB4.0×12～60
			HB6.5×25～120
3	Hollow Screw	Ⅰ	HB1.5～HB10 (interval of 0.5) ×6～150
			HB7.3×30~150

		Ⅱ	Ø12×50~145
4	Fixing Screw	Ø4.0/Ø4.5 Length: 12~18	
5	Locking Screw	Ø1.0, Ø1.5, Ø2.0, Ø2.3, Ø2.7, Ø3.0, Ø3.5, Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0, Ø7.5, Ø8.0×2～150	
6	Compression Screw	Ø1.0, Ø1.5, Ø2.0, Ø2.3, Ø2.7, Ø3.0, Ø3.5, Ø4.0, Ø4.5, Ø5.0, Ø5.5, Ø6.0, Ø6.5, Ø7.0, Ø7.5, Ø8.0×4～150	

3. Intended Use

For internal fixation of fracture fragments in orthopedic surgery.

4. Indication

Used with bone plates for the connection and fixation of fracture fragments such as arms, legs and clavicle.

5. Contraindication

a) ged osteoporosis patients, the fractures not have sufficient integrity.

b) Soft tissue infections and defects, disorders of calcified tissue metabolism and immune system, systemic neurological disease.

c) Those who are allergic to the metal and do not comply with the doctor's orders .

6. Complications

a) Allergic or rejection reactions to metal;
b) Limb contraction due to fracture compression or bone resorption;
c) Discomfort, pain or paresthesia generated by implants, which may need to remove the implants.
d) Loosening or bending of the implants may cause nonunion or delayed healing of the fracture and bone defect.
e) Any of the above symptoms after surgery is required for early revision surgery;
f) Osteonecrosis;
g) Nonunion or delayed healing will cause implant fracture.

7. Notes

a) The delivery status of the Intramedullary Nail is sterile. It is sterilized with γ ray.
b) Check packaging's integrity before surgery. If there is any damage, it can not be used.
c) Doctors should perform the preoperative assessment of patients, including the weight, occupation, activity intensity, mental status and allergy history, then determine whether it is suitable for use the product; if applicable, choose the products of corresponding models according to the patient's situation, and prepare products of different models and specifications before the surgery.
d) Unless design allowance or clear instructions in the technical manual, the implant can not be processed and/or changed in any way, including correction, bending, scratching on the shape of the products, all these will make it failure.
e) Doctors should make the patients fully understand the products and the risks and limitations of surgery as well as the importance of compliance with doctor orders.
f) Doctors should be familiar with implantation technique and use surgical instruments

skillfully.

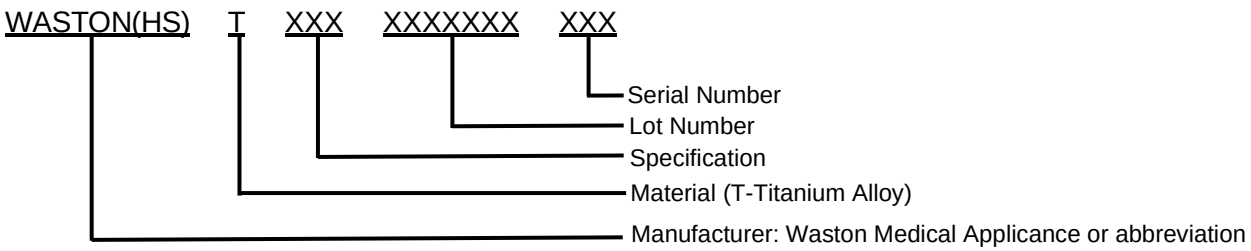
g) Scratches on implant surface during surgery will affect its service life, delayed fracture healing or nonunion will lead to implants loosening, bending or breaking.
h) Under the guidance of doctor, the patient can do slight flexion-extension movement with the aid of the stick at least a month after operation, and the large amount of exercise or weight-bearing exercise is prohibited. After four months the patient can do normal activities under the guidance of doctor. That taking the activities against the requirements of doctors and weight-bearing activities will result in implants shifting or breaking.
i) The removal time of implants should be decided by the rehabilitation of the patients after operation, generally about 12 months after operation.
j) X-ray examination after operation should be done regularly, usually in the 4th, 8th, 12th and 16th week after operation.

8. Warnings

a) This product an implant for single use, which can not be re-used.
b) Metallic bone screws must be used with metallic bone plate of same series produced by the company.
c) Total weight bearing at wound site is forbidden before fracture healing.

9. Packaging Identification

10.1 Product identification



10.2 The packaging provides at least following information:

k) Manufacturer name , address , trademark
l) European representatives name, address
m) CE identification and code of Notify Body
n) Material name or represent
o) Product name , model and specification
p) Sterilization valid period
q) «Do not reuse» should be marked
r) Lot number and date of production
s) Max. storage temperature 40°
t) Min and max humitity 30-80%
u) Sterilization method

10. Application Methods

According to the fracture site and soft tissue situation determined by pre-operative X-ray, the doctor shall draw up detailed preoperative plan for choosing correct implant specifications and sizes, confirming surgical instruments are complete and for fracture reduction, choosing correct bone plates, screws and operation position determination, installing bone plates and screws right after the line drilling, reaming, and tapping.
The entire surgery process must follow *The "AO Principles of Fracture Treatment"* and refer to the relevant chapters of *Orthopedic Surgery.*

11. Storage Condition

Scratch and collision in the processes of transportation and usage will undermine the strength and anti-fatigue performance of implants, so it is necessary to maintain and use the implants properly, otherwise, there will be ignorable risks.
Implant should be stored in the room at a relative humidity not more than 80%, no corrosive gas and ventilation well.

12. Service Life

Internal fixation is mainly responsible for the physiologic loading before bone healing, and generally it removed after a year when bone healing, otherwise, the risks of re-fracture and implants fracture still exists. The patient should follow the doctor's orders and be followed-up on time. It is a normal phenomenon that implants fracture caused by the removal out of body not promptly after bone healing.

13. Revision Date

26. April 2015