Rev: 01

10. Instruction For Use

CE Technical Files

CE0123

Product Instruction for Metal Intramedullary Nail, sterile

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1. Product Name

Metallic Intramedullary Nail

2. Performance, Structure and Components

The metallic intramedullary nail is designed according the size and dimension of human limbs to finalize the operation plan. The system consists of the nail, locking screws, and end caps. Of which, the quantity of locking screws and end caps are optional during the operation procedures. There are several types of intramedullary nail systems in different clinical applications, includingTibial Intramedullary Nail System, Femoral Intramedullary Nail System, Gamma Intramedullary Nail System, Reconstruction Intramedullary Nail System, Universal Retrograde Nail System and Humerus Intramedullary Nail System. The working principle is to make insertion of the nail after incision, and then make distal locking with the help of targeting device to make sure the insertion is stable and the bone fracture is fixed.

The Intramedullary Nail System applies Implants for *surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy* (ISO 5832-3:1996 E)in manufacture. The final product delivery status is sterile packaging.

3. Type&Specifications

Main Chart of Nails

Product Name	Type	Specification	
		Diameter (mm)	Length (mm)
TibialIntramedullary Nail	DJG	Ø4 ~ Ø12 (in 0.5 mm)	100~420 (in 0.5 mm)
Femoral Intramedullary Nail	DGG	Ø7 ~ Ø8 (in 0.5 mm), Ø8.4, Ø9 , Ø9.2, Ø9.5 ~ Ø13 (in 0.5 mm)	320~440 (in 0.5 mm)
Gamma Intramedullary Nail	DGM	Ø7 ~ Ø13 (in 0.5mm)	170~260 (in 0.5mm)

Reconstruction Intramedullary Nail	DCJ	Ø7 ~ Ø13 (in 0.5mm)	300~440 (in 5 mm)
Universal Retrograde Nail	DTY	Ø2 ~ Ø13 (in 0.5mm)	100~440 (in 5 mm)
Humerus Intramedullary Nail	DHG	Ø7 ~ Ø8 (in 0.5mm)	180~300 (in 5 mm)

Main Chart of Components

Product Name	Type	Specification	
		Diameter (mm)	Length (mm)
Locking Screw	Ⅰ ~ Ⅴ	Ø2.0 ~ Ø5.0 (in 0.5 mm), Ø4.8	10 ~ 115 (in 1 mm)
Lag Screw	Ⅰ ~ Ⅱ	Ø6.4, Ø7, Ø8, Ø9, Ø10	65 ~ 120 (in 1 mm)
End Cap	Ⅰ ~ Ⅲ	Ø6 ~ Ø10 (in 0.5 mm)	/

4. Intended Use

The Intramedullary Nail is used for bone fracture internal fixation.

5. Indication

The Intramedullary Nail System is used for the shaft or end sides fracture internal fixation of tibia , femur and humerus.

6. Contraindications

a) Elderly patients with osteoporosis, fracture site does not have enough integrity
b) Soft tissue infection and defects, calcified tissue metabolism and immune system disorders, systemic nerve diseases.
c) Allergic to metal, and noncompliance.

7. Complications

a) Metal allergy or rejection of allergic reactions. b) Osteoporosis due to stress shielding
b) Discomfort, pain, or sensory abnormalities caused by the implant.
c) Implant loosening, bending or fracture, can make bone nonunion, delayed healing or bone defect.

8. Notes

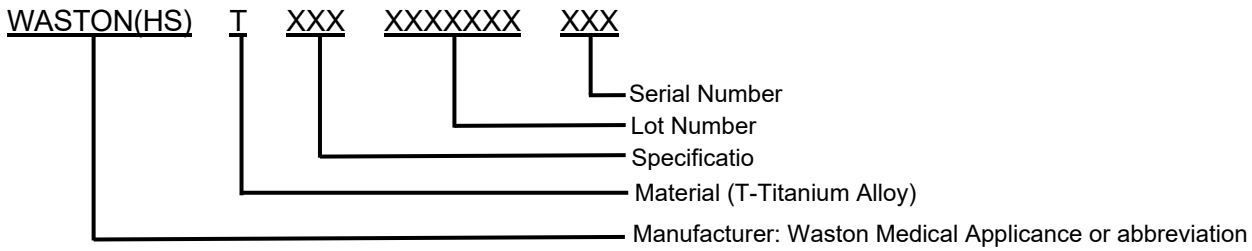
a) The delivery status of the Intramedullary Nail is sterile.It is sterilized with γ ray.
b) Preoperative examination of packaging integrity. The implant can not be used for damage during operation.
c) The doctor should make the patients fully understand the products and operation risks and limitations as well as the importance of compliance before operation
d) Surgeons should be qualified, and familiar with the product implantation technology, skilled use of related surgical instruments

9. Warning

a) The product is for single-use, not reusable.
b) No heavy load before the trauma site was completing healing.
c) the implant will be loosening, bending, and even fracture if the patientdo not follow the doctor's advice.

10. Packaging Labeling

10.1 Product identification



10.2 The packaging provides at least following information:

a) Manufacturer name , address , trademark
b) European representatives name, address
c) CE identification and code of Notify Body
d) Material name or represent
e) Product name , model and specification
f) Sterilization valid period
g) «Do not reuse» should be marked
h) Lot number and date of production
i) Max. storage temperature 40°
j) Min and max humitity 30-80%
k) Sterilization method

11. Application Methods

According to preoperative fracture site of X ray film and soft tissue conditions, formulate detailed preoperative plan , choosing the right implants , on the fracture site to reset , and drilling , tapping , the correct installation of intramedullary nail. The whole procedure of the operation must follow the principle of AO for fracture treatment , and Orthopaedic Surgery.

12. Storage Condition

If the implants are scratched and be collisionduring transportation and operation, it would weaken the strength and mechnical performance, so it is necessary to properly maintain and using the implant, otherwise, there will be risks can not be ignored.The implant should be stored in the relative humidity of no more than 80% , no corrosive gas and well ventilated indoor

13. Service Life

The Internal fixation is the main load before bone fracture healing. The implants should be removed after one year when the fracture is healed. Otherwise , the risk of re-fracture may happen if the doctor’s advice is not followed.

14. Revision Date

26. April 2015