Be sure to read this instruction manual before using this product.
Keep this manual available for reference when needed.

MES-CK 01-063-21EN-0
PREPARED: (2023-12-28) (Version 2)

Instruction for Use

Trade Name: KIRSCHNER WIRE

Reuse is prohibited

Warning

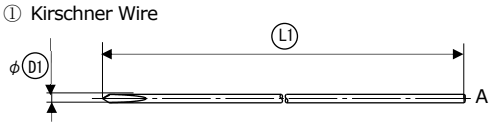
Please read these instructions carefully prior to using this product. Product should be used according to these instructions and pay close attention to the safety of patients. Failure to follow manufacturer's recommendations may cause harm or injury to patient.

Contraindications / prohibitions

1. Use for intended purpose only
   Use devices for their intended purposes only. Incorrect use could cause this product to break.
2. Applicable patients
   Do not use for the following patients.
   - Patients with psychiatric disorders [inability to follow physician's instructions and possibility of inadequate postoperative management.]
   - Patients with osteoporosis, bone resorption and arthropathy, soft tissue defects / fragility, and difficulty in placing implants [possibility to cause fracture / bone union failure]
   - Patients with severe allergies to metals or foreign bodies.
   - Patients with alcohol dependence or drug abuse [inability to follow physician's instructions, and possibility of inadequate postoperative management.]
3. Concomitant medical devices
   Prohibition of use [See Warning/Caution 3. Cautions on use of other tools in combination with this product [Contraindications / prohibitions for combined use]]
4. Instructions for use
   Prohibition of reuse [cause of breakage / risk of infection]
5. Prohibition of secondary processing of this product
   Do not apply any secondary processing to this product. For example, do not apply impacts or vibration markings to the surface of this product. Doing so could break this product.

Specifications

1. Shape
   ① Kirschner Wire

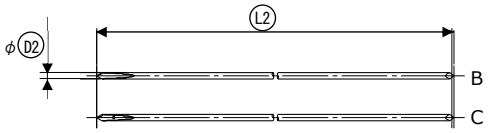


Unit : mm

Code No.	Product Description	ΦD1	L1	Shape
01-063-21	Kirschner Wire A, 1.0 × 300 mm, 10 pcs/pack	1.0	300	A
01-063-22	Kirschner Wire B, 1.2 × 300 mm, 10 pcs/pack	1.2	300	A
01-063-23	Kirschner Wire C, 1.5 × 300 mm, 10 pcs/pack	1.5	300	A
01-063-24	Kirschner Wire D, 1.8 × 300 mm, 10 pcs/pack	1.8	300	A
01-063-25	Kirschner Wire E, 2.0 × 300 mm, 10 pcs/pack	2.0	300	A
01-063-26	Kirschner Wire F, 2.4 × 300 mm, 10 pcs/pack	2.4	300	A
01-063-27	Kirschner Wire G, 3.0 × 300 mm, 10 pcs/pack	3.0	300	A

Unit : mm

②Tajima Kirschner Wire



Code No.	Product Description	ΦD2	L2	Shape
03-001-81	Tajima Kirschner Wire, 0.7 × 100 mm, 10 pcs/pack	0.7	100	B
03-001-82	Tajima Kirschner Wire, 1.0 × 120 mm, 10 pcs/pack	1.0	120	B
03-001-83	Tajima Kirschner Wire, 1.2 × 120 mm, 10 pcs/pack	1.2	120	B
03-001-84	Tajima Kirschner Wire, 1.5 × 120 mm, 10 pcs/pack	1.5	120	B

Unit : mm

2. Raw materials: Stainless Steel（SUS316）
3. Principle
   Kirschner Wire is used for general fracture treatment such as internal fixation at the time of fracture.

Intended purpose

Used for general fracture treatment such as internal fixation at the time of fracture.

Intended user

This product is to be used by health care professionals, including but not limited to surgeons, nurses and biomedical technicians.

Instructions for use

1. Before use
   - The surgeon needs to create a surgical plan that takes implant selection and its dimensions as well as intraosseous positioning before surgery into account.
   - This product is not sterilized. Before surgery, sterilize and use under sterility conditions that have been verified and proved effective as follows:
     Sterilization of the device may be accomplished by steam. The recommended sterilization parameters are as follows;

ISO/TS17665-2	
Temp.	Minimum exposure time
121°C / 250°F*	15 Min
126°C / 259°F*	10 Min
134°C / 273°F*	3 Min

*According to the Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (Update:May 2019)

2. Instructions for use
   Kirschner Wire
   Kirschner Wire is used to fix various fractures.
   When inserting, use a manual pin vise, an electric bone surgery motor, etc.
3. After use
   Under ordinary circumstances, remove after postoperative bone fusion according to the patient's symptoms.

4. Precautions regarding usage
・When using, please use the surgical instruments recommended by us. Also, handle the implant so that it will not be scratched.
・If it comes in contact with other metal equipment, it may be bent, scraped, broken, etc., so check the appearance for any problems.
・Attach a label with "product name, product number, lot number used" to the chart to facilitate traceability of the product implanted in the patient.

Warning/Caution

1. Precautions for use (use with caution for the following patients)
・Patients with infectious diseases [risk of metastasis of infected foci and complications of sepsis]
・Patients with insufficient bone formation, bone mass and quality [if sufficient fixation cannot be obtained and there is possibility a defect may occur due to re-fracture or breakage of the implant material]
・Patients with lifestyle-related diseases such as diabetes and chronic rheumatism [possibility that a defect may occur due to inhibition of bone formation and delay in bone fusion]
・Patients with degenerative diseases [possibility that a defect may occur due to incompatibility with shape of implant material]
・Patients with epilepsy [possibility that a problem may occur due to insufficient postoperative management without following the instructions of physician]
・Obese patients [possibility that a defect may occur due to failure to fix to the bone due to patient's weight or deformation / breakage of the implant material.]
・Elderly patients [See 5. Application to the elderly.]
2. Important fundamental cautions
・If the implant is deformed or bent, the fatigue strength will decrease and it may break when a load is applied.
・Handle with care as scratches on the surface may cause corrosion or breakage.
・Do not use it as a guide pin in combination with a product other than our designated product, as it may cause problems such as breakage or deformation due to differences in the development concept.
3. Cautions on use of other tools in combination with this product
[Contraindications / prohibitions for combined use] (Do not use together.)

Name of medical device	Clinical symptoms Method for measures	Mechanism Risk factor
Implants made by other companies	Wear, looseness, wear powders, etc. occur.	Development concepts do not match, so proper combination is not possible.
Implants made by other companies Implants of different materials	May increase risk of failure due to corrosion.	When dissimilar metals come into contact with each other, electrochemical corrosion occurs.

4. Defect/Adverse event
［The following are expected defects and adverse events caused by the use of this product. If such an abnormality is observed, take appropriate measures.］
1) Serious adverse events
・Implant breakage and re-fracture due to breakage
・Implant loosening and detachment
・Bone shortening
・Bone necrosis
・Metal / foreign body allergic reaction
・Angiopathy including thrombus and surrounding nerve damage caused by postoperative invasion
・Embolism such as pulmonary artery embolism and cardiac arrest
・Secondary infection
2) Other adverse events
・Nonunion, protracted fusion, deformed fusion
・Decreased bone density
・Occurrence of mental instability due to discomfort, uncomfortable feeling or the presence of implants
・Pain
・Difficult to remove
・Inhibition of blood circulation regeneration
・Effects of metal implants on X-rays, CT, and MRI
5. Application to the elderly
When used for the elderly, osteoporosis may cause fractures due to loads and moments caused by intraoperative operations and loosening due to decreased fixation after surgery, so use with caution and pay close attention to the course of treatment.

Storage/Life

Store this product in a place where the temperature and humidity do not change drastically and avoid high temperature and humidity.

Packing

10 piece per pack

Disposal

This device must be disposed of in accordance with local regulations. Please contact your local distributor for proper disposal.

Notice

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in which the user and/or patient is established.

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