Kirschner Wires/Steinmann Pins

INSTRUCTIONS FOR USE

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IMPORTANT NOTE

Read these instructions carefully before each use and keep them accessible for the appropriate skilled user who is trained and qualified accordingly.

Read through the warnings carefully. Improper use of the products can result in serious injuries to the patient, user or third parties.

A. DEVICE DESCRIPTION AND INFORMATION

Pacific Instruments Kirschner Wires (K-Wires) and Steinmann Pins are made from DIN 1.4441 (316LVM) stainless steel in conformance with ISO 5832-1 and/or ASTM F138. They are supplied in varying lengths and diameters, with varying tip configurations, both in single-ended and double-ended versions.

B. INDICATIONS FOR USE AND INTENDED USE

Pacific Instruments Kirschner Wires (K-Wires) and Steinmann Pins are intended to perform as fixation and stabilization of bone fractures or as guide pins for insertion of implants into the skeletal system.

C. INTENDED USERS

Licensed medical professionals and/or qualified professionals directed by a licensed medical professional including but not limited to orthopedic surgeons, orthopedic operating room nurses, physician's assistants, circulating nurses, and central sterile cleaning personnel.

D. INTENDED PATIENT POPULATION

There are no restrictions on patient population.

E. CONTRAINDICATIONS

- Do not use the device in cases of:
    - Any condition that could inhibit the healing process, i.e.:
    - Impairment of blood supply.
    - Inadequate quantity / quality of bone structure.
    - Extreme adiposis.
    - Previous infection.
- Mental conditions which exclude participance in rehabilitation programs (e.g., Parkinson's, alcohol or drug abuse, etc.)
- Physical activities in which the devices are exposed to excessive loading or impact.
- Allergy to constituent materials.
- Significant damage (bending, twisting, or fracture) to the device.

F. POSSIBLE ADVERSE EVENTS

- Clinical failure (i.e., pain or injury) due to bending, loosening, wear and tear, facture, loss of fixation, dislocation and/or migration.
- Pain and/or abnormal sensations due to the presence of the device.
- Primary and/or secondary infections.

- Allergic reactions to constituent material(s).
- Injury to vessels, nerves and/or organ.
- Hematoma and/or impaired/delayed healing.

G. WARNINGS AND PRECAUTIONS

1. Prior to use, thoroughly read these instructions for use and become familiar with the surgical technique.
2. Keep the instructions for use accessible to all staff.
3. The healthcare professional in charge of the surgical procedure is responsible for the proper assessment of patients and providing them with suitable training and information with respect to selecting and using these devices. These devices must be removed following completion of bone healing on a case-by-case basis wherever possible.
4. The surgeon must be specifically trained, experienced and fully familiar with the use of internally attached rigid devices, surgical procedures and post-operative care. Patients must strictly follow the post-operative instructions given by their surgeon. The patient must be made aware of the limitations of their medical device and given guidance on tolerable loads prior to the complete consolidation of the fracture.
5. Repeated bending can weaken the medical device and may lead to its fracture and failure of the device. If the device needs to be molded or shaped, it should not be bent at acute angles, bent in the opposite direction, scratched, or warped. It can only be shaped once.
6. Do not attempt a surgical procedure with faulty, damaged, or suspect devices. Inspect all components preoperatively to assure utility.
7. Osteosynthesis devices are recommended for use in patients whose bones are strong enough to sustain the effectiveness and benefits of rigid fixation.
8. Only clean and sterilized devices may be used when applying the products. Cleaning and sterilization instructions must be carefully followed.
9. Devices must be applied in a sterile environment.
10. Personal protective equipment must always be used when handling or working with contaminated or potentially contaminated medical devices.
11. The correct selection of the medical device is very important. The successful fixation of the fracture increases with the adequate selection of the shape, size, and design of the device. The shape and size of the human bone and soft tissues place restrictions on device sizes and resistances. The selection of the wrong product (such as undersized devices in areas with high levels of functional stress) may result in the loosening, warping, or breaking of the product, as well as the possibility of a bone fracture.
12. Do not mix devices made of dissimilar metals within the same structure. Different metals in contact with each other may accelerate the corrosion process owing to galvanic corrosion.
13. The use of devices from multiple manufacturers is not recommended owing to possible incompatibilities of the metals, mechanics, and the design of the devices.
14. Never use devices if the packaging is damaged. A device with damaged packaging might be damaged and thus may not be resterilized/used.
15. Do not resterilize devices if they have been contaminated by blood or secretions.

16. Supporting the body's weight is not recommended until bone healing has occurred.
17. The devices are single use. Do not use, reuse, or reprocess explanted, contaminated, used or damaged devices (e.g., as a result of scratches). This also applies to contact with bodily fluids. Reusing single-use devices may result in potential mechanical failure and an increased risk of infection. Apparently undamaged devices may present signs of fatigue as a result of unknown previous stress which may result in premature failure or the shortening of the life of the device. Discard defective or used devices per your hospital procedure or return to Pacific Instruments for disposal.
18. During the postoperative phase, in addition to mobility and muscle training, it is of particular importance that the physician keeps the patient well informed about post- surgical behavioral requirements.
19. Federal Law (USA) restricts this device to sale by or on the order of a physician.

H. DIRECTIONS

The operating surgeon draws up an operation plan specifying and documenting the device component(s), their dimensions and proper position of the device component(s)

The following conditions must be fulfilled prior to application:

- All required device component(s) are readily available.
- Aseptic operating conditions are present.
- All requisite medical devices must be available and in working order.

Carefully inspect and verify the devices prior to use.

Follow standard practice for rigid fixation (i.e., the typical AO procedure) when inserting devices.

Only trained, experienced medical professionals must handle the devices.

Warning:

Never use or process damaged or defective devices. The use of a medical device for tasks other than those for which they are intended may result in the cause of damaged / broken devices, misuse, assumption of risk, and patient injury.

- The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of devices to be applied.
- Complete information on these subjects must be readily available at the workplace.

I. CLEANING

Pacific Instruments Kirschner Wires (K-Wires) and Steinmann Pins may be cleaned manually or in an automatic washer using a detergent prior to use. Cleaning and disinfection solutions should always be mixed to the manufacturer's specification for concentration and cleaning should be conducted at ambient temperature unless otherwise stated in the cleaning solution manufacturer's instructions.

CAUTION

Low acid or high alkaline solutions are not recommended, as they corrode metal parts, anodized aluminum, and compromise polymer plastics such as FEP (Fluorinatedethylenepropylene), ABS (Acrylonitrile Butadiene Styrene), Ultem™, Lexan™, and Cycolac™. If non-neutral pH cleaning or disinfection chemistries are utilized, care should be

taken to ensure appropriate rinsing, as validated by the end-user facility, and neutralization steps are taken so as to not negatively impact the fit, finish, or function of the device.

I. MANUAL CLEANING AND DISINFECTION

The instructions for Manual Cleaning and Disinfection may be used as an alternative cleaning method to the Machine (Automatic) Cleaning and Thermal Disinfection.

1. Submerge in tap water for 10 minutes.
2. Brush beneath water surface until visibly clean.
3. Immerse the device in an enzymatic detergent solution. Cleaning solutions may include, but are not limited to: neodisher® Medizyme 0.5% (v/v).

   Cleaning solutions should always be mixed to the manufacturer's specification for concentration and cleaning should be conducted at ambient temperature unless otherwise stated in the cleaning solution manufacturer's instructions.
4. Immerse the device in detergent and allow it to soak for 20 minutes and treat with ultrasound (35 kHz, below 40° C (104° F)).
5. Rinse the device thoroughly with deionized water for at least one minute after the cleaning process.
6. Immerse devices in disinfection solutions for a minimum of 15 minutes. Suitable disinfection solutions may include, but are not limited to: Bomix® plus, BODE Chemie 1 % (v/v) and equivalent products. Use the supplier's instructions for preparing the solution.
7. After disinfection, the devices should be rinsed for at least 15 seconds with deionized sterile water.
8. Check the devices for visible soil. Repeat the cleaning if soil is visible, then re-inspect.
9. Failure to follow a proper procedure of manual cleaning can result in physical injury, misuse assumption of the risk, or damaging the performance of the device. If you have any additional questions or need additional directions, please contact support@pacificinstruments.biz and reference manual cleaning.

II. MACHINE (AUTOMATIC) CLEANING, AND THERMAL DISINFECTION

The instructions for Machine (Automatic) Cleaning and Thermal Disinfection may be used as an alternative cleaning method to the Manual Cleaning and Disinfection.

1. Load the devices in the washer.
2. Run the automatic wash cycle. The minimum cycle parameters are listed below:

Minimum Washing Cycle Parameters		
Step	Parameter	Cold tap water
Pre-rising	Rinsing temperature	Cold tap water
	Soaking time	60 s
Cleaning	Cleaning temperature	55° C (131° F)
	Soaking time	600 s

Minimum Washing Cycle Parameters		
	Cleaning detergent	neodisher® Mediclean forte
	Concentration	0.40%
Post-rinsing	Rinsing temperature	Cold DI water
	Soaking time	120 s
Thermal disinfection	Disinfection temperature	93° C (199° F) (A0 3000)
	Soaking time	300 s
Drying	Drying temperature	100° C (212° F)
	Drying time	20 min

3. Automatic wash cleaning solutions may include, but are not limited to: neodisher® Mediclean forte.
4. Check the devices for visible soil. Repeat the cleaning if soil is visible, then re-inspect.
5. Failure to follow a proper procedure of machine (automatic) cleaning and thermal disinfection can result in physical injury, misuse, assumption of the risk, or damaging the performance of the device. If you have any additional questions or need additional directions, please contact support@ pacificinstruments.biz and reference machine (automatic) cleaning.

J. STERILIZATION

The Pacific Instruments Kirschner Wires (K-Wires) and Steinmann Pins are supplied NON-STERILE. Prior to use, K-Wires and Steinmann Pins should be wrapped in an FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using the following recommended minimum cycle:

Minimum Steam Sterilization Parameters			
	Exposure Temperature	Exposure Time	Drying Time
Pre-Vacuum Cycle	132° C	4 min	20 min

Cooling – The device must be adequately cooled, after being removed from the sterilizer. It should not be touched during the cooling process. Do not place the device on a cold surface or immerse it in a cold fluid.

Failure to follow a proper sterilization procedure can result in physical injury, misuse, assumption of risk, and a cause of non-performance of the device. If you have any additional questions, please contact support@pacificinstruments.biz and reference sterilization.

K. STORAGE

Non-sterile devices should be stored in a clean, dry environment. The shelf life of non-sterile devices is not limited; the devices are manufactured from non-degradable material, which does not raise any question of device stability when stored under recommended conditions. It is the responsibility of the end-user to ensure devices, once sterilized, are stored in such a way as to maintain the sterility of the instrument until use.

Failure to follow a proper storage procedure can result in physical injury, misuse, assumption of risk and a cause of non-performance of the device.

L. MRI SAFETY INFORMATION

The Pacific Instruments Kirschner Wires (K-Wires) and Steinmann Pins have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of Pacific Instruments Kirschner Wires (K-Wires) and Steinmann Pins in the MR environment in unknown. Scanning a patient who has this device may result in patient injury.

M. LIABILITY AND WARRANTY

Pacific Instruments, as manufacturer, is not liable for consequential damage caused by improper use or handling. This particularly applies to the non-compliant use for the defined intended purpose or ignoring the processing and sterilization instructions. This also applies to repairs or modifications on the product made by unauthorized personnel of the manufacturer. These liability exclusions apply likewise to warranty service.

N. SYMBOLS USED

For a listing of Symbols and Explanations, see www.pacificinstruments.biz/eifu.

O. REFERENCES

These instructions were developed using the guidance given in the following standards:

- ANSI/AAMI ST81:2004 (reapproved 2010), Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- ISO 17664, Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.
- ISO 11737-1, Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products; 2009.
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- AAMI TIR30:2011 (reapproved 2016), A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- ANSI/AAMI TIR12:2010, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities - A guide for medical device manufacturers.
- ASTM E 2314: 2003 (reapproved 2014), Standard test method for determination of effectiveness of cleaning processes for reusable medical instruments using a microbiologic method (simulated use test).
- ASTM E 1837: 1996 (reapproved 2014), Standard test method to determine efficacy of disinfection processes for reusable medical devices (simulated use test).
- ISO 17665-1, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.

Please contact Pacific Instruments, Inc. for product inquiries, surgical techniques, or to report any adverse event or complaint.

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