Manual Surgical Instruments

INSTRUCTIONS FOR USE

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This is not a warranty document. For all warranty information, including disclaimers, exclusions, terms, and conditions, please email support@pacificinstruments.biz and reference PRODUCT WARRANTY whose information shall be incorporated by reference.

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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

These devices consist of both single-use and reusable non-sterile instruments. The devices are delivered nonsterile and must be cleaned and sterilized according to the following instructions before use. Check the package labeling for additional information including if the device is intended to be reused.

B. INTENDED USE

This device is only intended for the medical area given below and must therefore be used in an operation environment suitable for this. Surgical instruments are intended for use in the surgical setting for clamping, cutting, dissecting, grasping, probing, retracting, suturing, impacting, bending, connecting, elevating, scraping, guiding, inserting, fixating in general, orthopedic, or spinal surgical procedures.

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. The licensed medical professional performing any surgical procedure is responsible for determining whether this is the appropriate device for the specific procedure that is being performed for each patient. As the manufacturer, Pacific Instruments does not recommend surgical procedures or offer guidance in such procedures in using the medical devices.
2. Before using this device, read and understand the instructions on the device, maintenance, and use prior to using in a surgical setting.
3. Do not attempt a surgical procedure with faulty, damaged, or suspect devices. Inspect all components preoperatively to assure utility.
4. When reprocessing reusable medical devices, always handle with care, wearing protective clothing, gloves, and eyewear in accordance with local Health and Safety Procedures.
5. To avoid damaging the devices, do not impact or subject to blunt force any devices that are designed to be turned or screwed in. When two devices are intended to be threaded together, ensure that they are fully engaged prior to use.
6. Do not use devices for any purpose other than their intended use. The improper use of a medical device during handling, surgical use, or reprocessing, for which they are indicated may result in damaged and broken instruments.
7. Devices with adjustable components must be handled with care. Overtightening or rough handling of the device may damage the locking mechanism. Locking mechanisms with internal polymer components may become weakened after repeated autoclaving.
8. Do not use a device that is intended to be used with a specific implant on another implant.
9. Flexion of the joint with the device in position in the joint may result in bending or breakage of the device.
10. Federal Law (USA) restricts this device to sale by or on the order of a physician.

H. SPECIAL PRECAUTION -TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY AGENTS

It is outside the scope of this document to describe in detail the precautions that should be taken for Transmissible Spongiform Encephalopathy (TSE) Agents. The agents for transmission of Creutzfeldt-Jakob disease (CJD) are believed to be resistant to normal processes of disinfection and sterilization and therefore the normal processing methods of decontamination and sterilization as described above may not be appropriate where CJD transmission is a risk. In general, the tissues that come into contact with orthopedic surgical instruments are those of low TSE infectivity. However, particular precautions should be taken when handling instruments that have been used on known, suspected, or at-risk patients.

I. LIMITATIONS OF REPROCESSING

Some Pacific Instruments manual medical devices are single-use and are not intended for reprocessing. These devices are identified as single-use with a "Do Not Re-Use" symbol on the label. Reprocessing and reuse of these devices may cause the device to break or not function as intended.

For reusable devices, the following limitations apply:

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 disinfecting 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.

J. CLEANING

It is recommended that reusable devices are reprocessed as soon as is reasonably practical following use. Any visible soil should be removed at point-of-use to prevent the drying of soil. Device cases and trays are considered reusable devices. Trays should be inspected for visible soil and must be cleaned prior to use. They can be cleaned manually or in an automatic washer using a detergent.

I. PRELIMINARY CLEANING

When properly performed, cleaning, disinfection and/or sterilization do not compromise the use and mechanical performance of these devices. These devices are used with or on patients who may harbor both recognized and unrecognized infections. To prevent the spread of infection, all reusable devices must be thoroughly cleaned, disinfected, and sterilized after use on each patient. Note: No assembly/disassembly of these devices is required unless stated on the labeling, directions for use, or literature assembly instructions (LAI) pertaining to cleaning, disinfection, and sterilization.

1. Devices that require disassembly should be disassembled prior to cleaning.
2. Remove dried-on soil from devices, especially in areas such as joints and crevices, prior to washing. Soak in tap water for 10 minutes and brush beneath the water surface until visibly clean. Check the devices for visible soil.
3. Repeat the preliminary cleaning if soil is visible, then reinspect.
4. After the completion of preliminary cleaning, the end user has the option to perform either Manual Cleaning and Disinfection or Machine (Automatic) Cleaning and Thermal Disinfection.
5. Failure to follow a proper procedure of preliminary cleaning can result in physical injury, misuse, assumption of the risk, or damaging the performance of the device. If you have any questions or need additional directions, please contact support@pacificinstruments.biz and reference preliminary cleaning.

II. MANUAL CLEANING AND DISINFECTION

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

CAUTION

Manual cleaning is not an appropriate method for cleaning hand devices containing non-exposed actuating components, e.g., wishbone handle or standard handled graspers, punches, etc. The Machine (Automatic) Cleaning and Thermal Disinfection procedure should be followed for these devices.

1. 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.

2. Immerse the device in detergent and allow it to soak for 20 minutes and treat with ultrasound (35 kHz, below 40° C (104° F)).
3. Rinse the device thoroughly with deionized water for at least one minute after the cleaning process.
4. 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.
5. After disinfection, the devices should be rinsed for at least 15 seconds with deionized sterile water.
6. Check the devices for visible soil. Repeat the cleaning if soil is visible, then re-inspect.
7. 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.

III. MACHINE (AUTOMATIC) CLEANING, AND THERMAL DISINFECTION

After the preliminary cleaning, 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 so that all design features of the device are accessible to cleaning and any that may retain liquid can drain (hinges should be open and cannulations/ holes positioned to drain).
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
	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.

K. INSPECTION AND MAINTENANCE

1. Pacific Instruments non-sterile devices are precision medical instruments and must be used and handled with care.
2. Do not reuse any medical devices identified with the "Do Not Re-Use" symbol on the label.
3. Inspect the devices for damage prior to use and at all stages of handling. If damage is detected, do not use the device prior to consulting Pacific Instruments for guidance. Any damage such as the examples below may indicate the device has reach End of Life. Discard End of Life devices per your hospital procedure or return to Pacific Instruments for disposal.
    a. Damage such as binding, bending, breakage, overt signs of wear and/or any other conditions which may impact the devices safe and effective use.
    b. Devices that interface with other devices (e.g., implants, instruments, handles) – when the mating feature binds, fails to attach or fails to hold the device securely. The device function should be verified prior to each use.
    c. Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a device defect. This condition indicates normal wear. Dull devices may require replacement, if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these edges.
4. Dry the devices thoroughly and lubricate all moving parts with a water-soluble instrument lubricant, prior to sterilization. Acceptable lubricants may include, but are not limited to: Steris Hinge- Free® Instrument Lubricant and Neodisher® IP Spray. Apply lubricants in accordance with manufacturer's instructions.
5. Failure to inspect and properly maintain the device may result in physical injury, misuse, assumption of risk, and cause for non-performance of the device.

L. PACKAGING

Where appropriate, the cleaned, disinfected and inspected instruments should be placed into trays/cases as provided, or in general-purpose sterilization trays. Ensure that any cutting edges are protected and it does not

exceed applicable weight limits. Trays/cases should be double wrapped following AAMI or equivalent guidelines with an appropriate wrap. An appropriate wrap is one that, for example, is cleared by the FDA or the local governing body at the point of use.

M. STERILIZATION

These devices are supplied NON-STERILE. Sterilization must be performed following cleaning and disinfection as described above. Prior to use, the devices 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.

N. 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 device 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.

O. LIABILITY AND WARRANTY

Pacific Instruments, as manufacturer, is not liable for 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.

P. SYMBOLS USED

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

Q. 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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