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Instructions for Use: Non-Sterile Reusable Orthopedic Surgical Instruments

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Caution: Carefully read all the instruction and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use. U.S. Federal law restricts this device to sale, distribution, and use by or on the order of a physician.

1 General Instructions

The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the parts, but must also be aware of their mechanical limitations. Diamond Orthopedic instruments should only be used with approved devices and accessories.

2 Description

a) The surgical instrumentation consists of the instruments, a storage tray and a lid. Each instrument is identified by a reference and a manufacturing batch number. This information is seen on the instrument itself.

b) The surgical instrumentation can only be used by a qualified surgeon practicing in accordance with current data on progress in the science and art of surgery and with the manufacturer's recommendations available in the following documents: marketing leaflet, operating techniques, templates, etc.

c) The surgeon must ensure that the equipment is in good working order before using it.

d) **Precautions before use**: On delivery, the instruments are clean but NOT STERILE. It is the hospital's responsibility to decontaminate, clean, and sterilize the instrumentation before use, in accordance with validated methods. The following recommendations do not replace current health regulations (standards, good practice, guides, national recommendations, ministerial documents, etc.).

3 Introduction

a) Before any operations, the packaging should be removed and a visual inspection conducted to ensure that all the instruments are in good condition.

b) The instruments consisting of removable components should be disassembled before decontamination, cleaning, and sterilization. Articulated instruments should be opened to ensure every notch is cleaned.

4 Cleaning and Decontamination

a) Cleaning, decontamination, and sterilization are mandatory before introduction into a sterile surgical field or return of the product to Diamond Orthopedic. Cleaning, decontamination, and sterilization are mandatory after instrument use in a surgical procedure. The aim of cleaning and decontamination is to decrease the initial population of bacteria, to facilitate cleaning at a later stage, to protect staff handling the instruments and to avoid any contamination of the environment.

b) Immediately after use, the instruments should be opened up and immersed in distilled water or placed on a tray covered with a damp surgical field.

c) Saline must not be used because of its corrosive effect on stainless steel. The equipment must be decontaminated as quickly as possible after use. It should also be remembered that certain agents may discolor or corrode the instruments. This includes agents containing bleach, hypochlorite solutions, sodium chloride, formalin, and glutaraldehyde.

d) Rinse water should be highly purified water (treated by reverse osmosis or distillation) or distilled water (if there is not an endotoxin issue).

e) MANUAL CLEANING

- Prepare a decontaminant solution according to manufacturer's recommendations using lukewarm water. The solution must be at a temperature of less than 30°C to avoid the bacteria adhering to the instruments. Fully immerse the articles in the prepared solution, actuating them through their full range of motion, flushing all hard to reach areas using an appropriately sized syringe with a minimum of 50 mL of the prepared detergent per article, and then allow the article to soak for the minimum amount of time as stated in the precautions for the use of the decontaminant.
- After the minimum soak, brush the articles thoroughly using a soft bristled brush (M16) beneath the surface of the prepared solution until all visible soil had been removed. Pay special attention to hard to reach areas.
- Remove the articles from the solution and thoroughly rinse under running water until all solution residues are removed. Actuate the articles through their full range of motion while rinsing. During rinsing, thoroughly brush the articles using a soft bristled brush (M16), paying special attention to hard to reach areas. Actuate the articles through their full range of motion while brushing. During rinsing, flush the articles thoroughly using an appropriately sized syringe with a minimum of 50 mL of water per article, paying special attention to hard to reach areas. Actuate the articles through their full range of motion while flushing.
- Dry the articles using a clean, soft cloth and filtered pressurized air (≤ 40 psi). Visually inspect the articles for cleanliness.

f) AUTOMATED CLEANING

- Automated cleaning should not be used in isolation. It is required that automated cleaning be utilized in conjunction with manual cleaning.
- Thoroughly rinse the articles under running water using a disposable paper towel to remove gross contamination.
- Transfer the articles into the automatic washer/disinfector for processing. Orient the articles at an incline to facilitate drainage.
- Select the cleaning cycle set to the following set of parameters, set to high:

Phase	Recirculation Time	Temperature	Detergent, Concentration
Pre-wash 1	2 minutes	Cold tap water	N/A
Enzyme Wash	2 minutes	Hot tap water	Enzol®, 1 oz/gal
Wash 1	2 minutes	151° F (66° C)	Valsure® Neutral, ¾ oz/gal
Rinse 1	2 minutes	Heated minimum 110°F (43.3°C) tap water	N/A
Drying	7 minutes	Minimum 187.3° F (86.3° C)	N/A

- Remove the articles from the automatic washer/disinfector. If moisture remains on the articles, dry them using a clean, soft cloth and filtered pressurized air.

5 Sterilization

a) The instruments, containers and tray are suitable for sterilization by steam at a temperature of no more than 140°C. We recommend Standard ISO 17665. The instruments should be prepared so that all surfaces are in direct contact with the steam. Hinged instruments and sliding devices should be opened up, complex instruments should be dismantled and all parts should be safely secured in the sterilization box. A complete guide for reprocessing implants may be provided upon request. As a guideline, the following sterilization method is recommended:

STEAM AUTOCLAVE PRE-VACUUM
Method: Steam
Cycle: Pulsed pre-vacuum (double-pouched)
Temperature: 270° F (132° C)
Time: 4 minutes
Drying Time: 20 minutes
Cooling Time: 30 minutes

Note: Drying time is subject to variation depending on machine load.

b) The recommendations from the sterilizer's manufacturer should be strictly adhered to. The sterilization process and adjustment of the autoclaves should be checked regularly. If there is residual dampness in the sterilization box after the sterilization cycle, proceed as follows:

- Do not open the box immediately after use
- Increase the drying time, unless tests show that the exposure time has been adequate to obtain the required time for sterilization
- Make additional perforations in the box to facilitate the run-off of the residual humidity

c) The recommendations on sterilization are only given as a guideline. Under no circumstances can the manufacturer be held responsible for the sterility of devices sterilized within the hospital.

6 Maintenance, Storage, and Handling

a) Surgical instruments should be handled and stored with care. Instruments should be carefully stored in an appropriate, dry, clean environment in their original packaging or sterilization tray. Instruments must not be stored in contact with, or close to, products that may have a corrosive effect.

b) Procedures to be implemented after use: it is the hospital's responsibility to decontaminate, clean and sterilize the instrumentation (full box or single instrument) in accordance with the recommendations of the manufacturer. Any missing or damaged instrument should be reported to your representative or distributor, or directly to the manufacturer.

7 Inspection and Function Testing

Diamond Orthopedic reusable instruments are designed to be used for many procedures and endure many sterilization cycles. Before each sterilization cycle, visually inspect for damage and wear. An instrument should be considered at its end of use if it shows signs of deterioration, corrosion, discoloration, pitting, cracking, nicking of edges, or excessive deformation. Confirm the smooth movement of hinged instruments without excessive "play". Locking (ratchet) mechanisms should be checked for action. Check instruments with long slender features (particularly rotating instruments) for distortion. Where part of a larger assembly, check assembly with mating components.

8 Limited Warranty / Liability

Diamond Orthopedic products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other expressed or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. Diamond Orthopedic shall not be liable for any incidental or consequential loss, damage, or expense, directly, or indirectly arising from the use of this product. Diamond Orthopedic neither assumes nor authorizes any other person to assume for it any other or additional liability or responsibility in connection with this product. Diamond Orthopedic intends that these instruments should be used only by physicians having received appropriate training in orthopaedic surgical techniques.

9 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Diamond Orthopedic location for current information. For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Diamond Orthopedic location as listed below:

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