INSTRUCTIONS FOR USE

ORTHOPAEDIC SURGICAL INSTRUMENTS

IMPORTANT NOTE

This manual is intended for the maintenance, cleaning, use and protection of reusable orthopedic surgical instruments. Surgical instruments are designed to perform a specific function, such as cutting, grasping, clamping, probing, retracting, reaming, drilling, rasping or tissue removing etc. for use by a surgeon. Instruments should be used only for the purpose of which they are designed. The proper surgical technique for the use of instruments is the responsibility of the surgeon.

Unique Surgical products have been manufactured, inspected and packaged in accordance with the regulations of 93/42/EEC Medical Device Directive and/or ISO 13485 Medical Device Standard as applicable. The quality and the standard of the raw material used comply with the regulations of 93/42/EEC Medical Device Directive and/or ISO 13485 Medical Device Standard according to ISO 7153-1 standard. Orthopaedic surgical instruments manufactured by Unique Surgical are mostly out of stainless steel, polypropylene (Propylux), polyphenylsulfone (Radel), acetal copolymer, and sterilization-resistant silicone.

Surgical instruments are supplied as non-sterile from Unique Surgical and should be cleaned and sterilized prior to use according to the procedures specified in this document.

WARNINGS AND RISKS

New and used tools must be fully processed according to these instructions before use. Users should take responsibility for the cleaning, disinfection, packaging and pre-operation sterilization of all instruments and sets.

1. The instruments should be used according to their design purposes by authorized surgeons.
2. Corroded tools should not be used.
3. The instruments must be sterilized before use.
4. New tools must be cleaned before sterilizing.
5. Cleaning agents should not contain chlorine ions.
6. The pH of the cleaning solution should be 7.0. Enzymatic and cleaning agents at neutral pH should be preferred for cleaning the devices. The choice of the enzyme solution is important for the removal of blood, body fluids and tissues. Since some enzymatic solutions are used to disrupt feces or other organic compounds, they may not be suitable for orthopedic instruments.
7. Cleaning and rinsing water prior to sterilization should be demineralized (pure) water.
8. If new tools are removed from their packaging, they should be stored in a clean environment and cleaned before sterilization.
9. Instruments should not be co-located with corrosive vapor producing chemicals.
10. All instruments should be counted four times during the operation because of the possibility of forgetting the instrument inside the patient:
    i. Before the operation begins,
    ii. Before and after a special procedure,
    iii. Before wound closure and after skin closure.
    iv. At the end of surgery.
11. Additionally, the instruments should be counted before the replacement of the surgical personnel during the operation.
12. All instruments that are not functioning properly must be repaired or discarded.

PRECAUTIONS

1. In case of need, pay attention to wear damage-avoiding gloves during cleaning and sterilization
2. Instruments made of different metals (eg stainless steel and titanium) must be treated separately to avoid electrolytic reactions between different metals.
3. Keep coated tools away from each other in order to prevent the coating from being removed and scratched.
4. Check whether the instruments are damaged before surgery.
5. All hospital personnel who work with contaminated or potentially contaminated medical devices must comply with the general precautions for contamination.
6. Wear personal protective equipment while holding or working on contaminated or potentially contaminated materials, including gowns, masks, glasses or face protection, gloves and overshoes.
7. Upon request, information regarding instrument use can be provided by Unique Surgical. The surgeon must be familiar with the use of the implants, instruments and surgical techniques well before surgery.

CLEANING AND CARE

1. Blood and body fluids must not be allowed to dry on surgical instruments before cleaning.
2. After completion of the surgical procedure, the appropriate cleaning chemicals should be used considering the contamination risks.
3. Do not use metal brushes, wire or metal tools during cleaning. Soft bristle, nylon brushes and pipe cleaners can be used.
4. Use cleaning detergents with a low foam-forming surfactant to allow the instruments to be visible in the cleaning solution during the manual cleaning process.
5. While manual cleaning with brushes, the instruments should always be kept under the cleaning solution to prevent contamination by airborne suspension and splash.
6. In order to prevent accumulation of detergent residue on the instruments, the cleaning agent should be easily and completely rinsed from the instruments.
7. Heavy tools should not be placed on sensitive instruments.
8. Hinged tools should be flattened out before cleaning. Special attention should be paid to precision tools.
9. Aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, iodized salt, cleaning and disinfection solutions are corrosive and should not be used.
10. Mineral oil or silicone lubricants should not be used because they prevent the direct contact of steam to the surface by forming microorganism layers on the tools which create difficulty in cleaning.
11. Descaling agents containing morpholine should not be used in steam sterilizers since they cause abrasion on polymer tools
12. After cleaning, tools should be rinsed and dried.
13. Corrosion stains and the functions of the tools should be checked. Any stained and damaged tools should be removed.
14. The tools should be carefully placed in wire baskets, silicone mats and sterile containers.
15. When cleaning and replacing sharp instruments such as cutters, drills, etc., care must be taken to ensure that people and equipment are not harmed.
16. Automatic cleaning using a washer / disinfector may not be effective for lumens, cannulations, blind holes, matt finishes and other complex orthopedic instruments. Manual or manual / automatic combination cleaning processes are recommended.
17. If applicable, the multi-component tools must be disassembled for cleaning. Make sure that small parts are not lost.
18. Tools must be removed from metal or polymer trays for manual or automatic cleaning processes.
19. Instrument cases, trays and covers are cleaned separately from the instruments.
20. The polymer parts of some instruments cannot withstand the conditions of the washer / sterilizer operating at temperatures equal to or more than 141° C / 285° F and cleaners with fresh steam jets. Polymer surfaces might be damaged under these conditions.
21. The polymer parts can be sterilized using steam / moisture. Polymer materials have a limited lifetime and if the surface of the polymer shows excessive wear (cracking, stratification, peeling etc.), they must be replaced.

CLEANING / DISINFECTION OPTIONS MANUEL CLEANING

1. Separate any mated instruments before cleaning. For any instruments with moving pieces, move the pieces throughout their range of motion during cleaning to clean moving pieces in all positions.
2. Rinse with cold tap water (< 45°C) to remove visible contamination.
3. Bathe in an enzymatic detergent solution prepared per manufacturer directions for 5 minutes. Water temperature 30°C ±5°C (Cleaning bath with %2 (20ml/l) Neodisher Mediclean Forte)
4. Scrub thoroughly with a soft brush and/or pipe cleaner; repeatedly flush any very narrow lumens with enzymatic detergent solution using a syringe.
5. Rinse with cold tap water (< 45°C) for a minimum of one minute; use a syringe to repeatedly flush any very narrow lumens.
6. Sonicate the device in Enzymatic detergents for 10 minutes in an Ultrasonic Cleaner (tap water - 65°C ±5°C) (ultrasonic cleaning bath with 2% (20ml/l) Neodisher Mediclean Forte), 37 kHz Ultrasonic frequency, 200W effective ultrasonic power.
7. Rinse thoroughly/flush with cold tap water for 1 minute.
8. Dry with a clean, soft, absorbent, disposable cloth.
9. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean until it is visibly clean.

AUTOMATIC CLEANING

1. Separate any mated instruments before cleaning. For any instruments with moving pieces, move the pieces throughout their range of motion during cleaning to clean moving pieces in all positions.
2. Rinse with cold tap water (< 45°C) to remove visible contamination. While rinsing, scrub thoroughly with a soft brush and/or pipe cleaner and repeatedly flush lumens and blind holes with a syringe.
3. Transfer to washer for processing. See table below for cycle parameters

Washer Parameters:

Phase	Recirculation Time (Minutes)	Temperature	Detergent/Water Type
Rinse	2	< 30°C	Potable Water
Cleaning	7	55°C	Enzymatic Detergent For Example -Neodisher® MediClean Forte ; Dr. Weigert GmbH & Co. KG. - Potable Water
Intermediate Wash with Water	3	10°C	Deionized Water
Disinfection	7	90°C	Deionized Water
Drying	15	90°C	N/A

4. Visually inspect for cleanliness. All visible surfaces, internal and external, should be visually inspected. If necessary, re-clean until it is visibly clean.

Note: Using a water jet or syringe will provide better cleaning of hard-to-reach areas and mat areas.

POSSIBLE ADVERSE EFFECTS

1. Disassembly, bending, cracking or breakage of components.
2. The risks associated with surgical instruments:
   - Improper use against design purposes,
   - Forgetting in the patient after the surgical precedure,
   - Infection, disease transportation and corrosion due to inappropriate cleaning and sterilization techniques.

Improperly cleaned or sterilized instruments may cause postoperative infections or death. Improper usage of surgical instruments may cause intraoperative and postoperative complications.

PACKAGING

Unique Surgical instruments are dispatched in non-sterile packages.

INSTRUMENT PROTECTION

The most effective method of dealing with instrument problems is to prevent them from occurring. The use of "treated water", careful preliminary cleaning, the use of neutralized pH solutions, adherence to manufacturer's instructions, and visual inspection, will help to keep instruments performing accurately and cosmetically free of troublesome stains. It is important to act quickly should a problem arise. Delay will compound the problem and irreparable harm may result. Any kind of corrosion will lead to rust on steel. Because rust particles can be transferred from one instrument to another, corroding instruments should be removed from service to prevent the formation of rust on other instruments. Every effort should be made to protect sharp cutting edges and fine working tips during all maintenance procedures. Avoid loading retractors and other heavy items on top of delicate and hollow instruments.

HANDLING AND STORING

1. Used instruments should be handled considering the risk of contamination; the regulations of the hospital should be followed.
2. Storage, distribution and recovery of instruments must be carried out by personnel according to the regulations of the hospital.
3. Instruments must be stored in an area only accessible by authorized personnel, with adequate ventilation and pest control, with protection from dust and direct sunlight
4. Before storing instruments make sure they are dry. Store in a dry, clean area at room temperature.

REPAIRING AND MAINTENANCE

Instruments returned for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of the instrument repair.

The assembled (contacting) parts of stainless steel surgical instruments may be lubricated with appropriate instrument oil before steam sterilization.

SHELF LIFE

To increase the lifetime of reusable instruments, follow the instructions in this manual. The shelf life of instruments is determined by the damage and wear caused during surgical use and maintenance.

STERILIZATION / RESTERILIZATION

Unique Surgical instruments are provided as non-sterile., they must be sterilized before use.

In the case of multiple sterilizations of instruments in a single autoclave cycle ensure that the sterilizer provider does not exceed the maximum loading capacity specified and ensure that the products are dry before sterilization. Pack the instruments by placing them in trays that allow the vapor to touch the entire surface. Ensure that the surfaces which come in contact don't damage /scratch each other. If applicable use standard medical grade steam sterilization wrap according to ANSI/AAMI ST79.

The recommended sterilization method for the instruments is as follows:

Steam Sterilization		
Cycle Type	Parameter	Minimum Set Point
Prevacuum 134°C	Exposure Temperature	134°C
	Exposure Time	4 minutes
	Dry Time	15 minutes

Unique Surgical does not recommend the use of low temperature in rapid sterilization or non-pressurized cycles.

Check that there is no damage to the instruments before and after use.

Do not use instruments until any damage is repaired.

After cleaning and sterilization, review functionality before reuse.

SYMBOLS (according to ISO EN 15223-1)

Symbol for "Caution"

Symbol for "The Name and the Address of the Manufacturer"

Symbol for "Contents Packed without Sterilization"

Symbol for "Catalogue Number"

Symbol for "Lot Number"

Symbol for "Electronic IFU"

Symbol for "Date of Manufacture"

Symbol for "Medical Device"

Symbol for "Unique Device Identification"

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