Reprocessing Instructions- IFU
in accordance with DIN EN ISO 17664
for reusable dental products of MEDICURE INSTRUMENTS.

The following reprocessing instructions apply to all reusable dental products by MEDICURE INSTRUMENTS. The instructions refer to the current standard **DIN EN ISO 17664**. The instruments must be handled carefully and protected from damage to ensure patient safety. Do not use instruments that have been damaged in any way. Do not perform alterations or make repairs. No liability is assumed for alterations or repairs that were not performed by MEDICURE INSTRUMENTS.

All reusable MEDICURE products are delivered in a non-sterile state. The instruments must be processed **prior to the first use and prior to every additional use** in accordance with these instructions. Efficient cleaning/disinfection is an essential prerequisite for effective product sterilization. **It is not permitted to sterilize products in the delivery package!**

Heavy impurities should be rinsed from the instruments and from all their recesses immediately after each use. Do not use fixing agents or hot water (>40°C)! Both may cause residues to become permanently fixed and may affect the reprocessing result.

The **useful life** of reusable MEDICURE products is not limited by design, but can be greatly reduced by external influences, such as **temperature fluctuations**.

Any deviations from these instructions (e.g., use of other sterilization techniques, or deviations from the manual/automatic cleaning and disinfection methods) **are the sole responsibility of the user**. **Only validated methods** for cleaning/disinfection and sterilization (equipment-specific and product-specific) **are to be used, and the validated parameters must be observed for every application cycle**. In addition, country-specific statutory regulations and the hygiene-regulations of the respective hospital or clinic apply. This applies in particular to different regulations concerning effective prion deactivation.

MEDICURE INSTRUMENTS assumes no liability for damage to products as a result of deviations from these instructions. Our general terms and conditions apply.

MEDICURE reserves the right to amend these instructions as appropriate to the current state of knowledge

⚠**GENERAL WARNINGS:** Reusable MEDICURE products are delivered in a non-sterile state and must be processed prior to EVERY use according to the following instructions.

The packaging material cannot be autoclaved.

Improper or inadequate cleaning can cause particles to settle on the instruments and be ejected into the intervention area. The instrument's function and service life may also be affected.
There is a high potential risk of postoperative transmission when instruments are used in patients with suspected prion disease. The decision is solely at the discretion of the user whether the instrument must be destroyed or can be recycled.

To minimize the risk of TASS (Toxic Anterior Segment Syndrome), the use of alkaline enzymatic cleaning solutions and detergents is strongly discouraged.

DECONTAMINATION AND STERILIZATION PROCEDURES

As with any decontamination procedure, personnel should follow accepted guidelines for hand washing, the use of protective attire, etc. as recommended by A.A.M.I. Standards and Recommended Practice, "Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Non-Clinical Settings", ANSI/AAMI ST35:2003.

Decontamination is a two-step process:

1) Thorough cleaning and rinsing.

2) Sterilization or disinfection.

A. MANUAL DECONTAMINATION

PRECLEANING: Remove gross debris from the surgical / dental instruments with a lap sponge and sterile water routinely during the procedure to prevent drying on of blood and body fluids, etc. It is important to rinse instruments that have been exposed to blood and saline solution before these substances dry. Blood and body fluids as well as saline solutions are highly corrosive. In addition, blood can produce a stain that is difficult to remove.

CLEANING: Cleaning should occur as soon as possible after instrumentation is used. Biofilm is an accumulation of a biomass of bacteria and extracellular material that tightly adheres itself to the surface of the instruments. It cannot be easily removed, and protects microorganisms from being easily removed by ordinary cleaning/decontamination methods used in hospitals. It is particularly problematic in lumened medical devices.

Step 1. Maintain moisture: Immediately after the surgical / dental procedure, place the instruments in an instrument tray/container and cover with a towel moistened with sterile distilled water. Foam, spray or gel products, specifically intended for use with surgical / dental instruments, are available to keep the soil moist. Transport tray of soiled instruments in an impervious plastic bag or container with a tight lid to the decontamination environment (keep the outside of the containment clean).

Step 2. Enzymatic Soak: Immerse fully opened and/or disassembled instruments in an enzymatic solution, specific for use with surgical / dental instruments. Prepare the solution and use per enzyme manufacturer's recommendations, paying special attention to instructions for correct dilution, temperature and soak time. Flush air from lumens and fill them with enzymatic solution for full contact with this inner surface during the soak time.

Step 3. Rinse: Remove from enzymatic soak after the time period recommended by the enzymatic manufacturer and rinse thoroughly with tap water. Flush lumens until rinse water runs clear

Step 4. Cleaning Instruments: Choose a cleaning solution appropriate for surgical / dental instruments and follow the manufacturer's instructions for use. The use of neutral pH detergents is vital to the maintenance of surgical / dental instruments. Contact with acidic or alkaline solution will remove the instruments' protective barrier of chromium oxide, often leading to corrosion, pitting, and breakage.

You may find that depending on the type of soil, a detergent that is a little more or less acid or alkaline may be more appropriate. The ideal cleaning agent is nonabrasive, low-foaming and free-rinsing. Using a small clean hand-held brush, remove soil from all surfaces of the instrument while fully immersed in the solution. During manual cleaning, never use steel wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers to remove soil from surgical / dental instruments. These will damage the instruments' protective surface and lead to corrosion. Use a clean soft bristled brush to clean instruments with an accessible channel. Remove the soil from the ratchets, jaws, tips, box locks, and/or hinge mechanism. The box lock and hinge portion of an instrument must be thoroughly cleaned after each use. A build-up of soil, debris, lubricants, etc. in these areas, will make it difficult to use the instrument and eventually irreparably damage it. Vigorously flush channels with the cleaning solution. Deionized water is recommended and preferred because it is free of the many compounds which exist in ordinary tap water. These substances, alone, cause stains and when tap water is combined with some detergents it will form insoluble deposits on the instruments. Manual cleaning should remove all visible residues. It is essential to keep the box locks and hinges open during any manual or automated cleaning process.

Step 5. Rinse: Thoroughly rinse instruments by immersing in tap water and wiping with a clean, soft cloth. Flush lumens until water runs clear.

Step 6. Ultrasonic Cleaning and Rinsing: Follow the recommendations of the ultrasonic manufacturer regarding cycle times, detergents, proper placement of the instrument tray, and conditioning ("degassing") of the cleaning solution, etc. Use an ultrasonic cleaner to remove soil from hard to reach surfaces such as grooves, crevices, lumens, instruments with moving parts, etc., after gross soil has been removed. Open or disassemble instruments as appropriate. Place instruments in a mesh bottom stainless steel instrument tray. Place the tray into the ultrasonic cleaner. Flush air out of lumens and fill them with the ultrasonic cleaning solution (under the solution level in the chamber) for effective removal of soil from that inner surface by the ultrasonic activity.

Step 7. FINAL RINSE should be with "treated water". Softened or deionized water should be used for the final rinse to better remove detergents etc. Softening water removes calcium and magnesium ions that cause water to be hard. Iron ions may also be removed by this treatment. Deionization removes ionized salts and particles from the water. Excessively hard water can spot or stain instruments and excessive chlorine in water can cause pitting of the instrument. Deionized water is preferred for the final rinse.

Step 8. Decontaminate Clean Instruments: Once instruments have been cleaned, they must be rendered safe for handling, inspection and assembly. They may be steam sterilized without a wrapper or disinfected following the instructions from the instrument, sterilizer and disinfectant manufacturers.

Step 9. Visual Inspection and Instrument Set Assembly: Visually inspect the instrument for cleanliness and to ensure all parts are in proper working order, as the set is assembled. Inspection is a vital part of proper care and maintenance. Instruments in need of repair will not perform accurately in surgery and breakage is likely to occur. DO NOT USE damaged instruments. Worn ratchets, loose box locks and misaligned jaws can be repaired at a fraction of the cost of new instruments. Contact your local representative for information regarding a cost-effective instrument repair program.

Step 10. Lubricate: The use of an instrument lubricant, that is compatible with the method of sterilization to be used, is recommended before instruments are sterilized. Be certain that the instrument lubricant is diluted and maintained properly, according to the manufacturer's instructions. This type of lubricant is referred to as "instrument milk" and is usually applied by spraying into the box locks and moving parts or by dipping the opened instruments into a solution. Lubricants that are too concentrated or too heavily applied will result in slippery instruments that will also be mistaken as wet after sterilization. After thoroughly cleaning instruments, proper application of lubricants to joints will keep them moving freely and aid in protecting the surface from mineral deposits. Note that ultrasonic cleaners remove all lubrication; therefore, this maintenance procedure should be done routinely after ultrasonic cleaning and before sterilization. Proper lubrication is an integral step in maintaining the long-life of the surgical / dental instrument. Lubrication will prevent the friction of metal on metal and preserve the smooth function of the instrument thus avoiding corrosion by friction. Furthermore, routine use of lubricating agents, on thoroughly clean instruments, will prevent hinged and other movable parts from sticking. Lubrication will aid in protecting the entire instrument surface from mineral deposits.

Step 11. Drying: Before instruments are wrapped for sterilization or storage, they must be thoroughly dry. If a set of instruments is wet when wrapped for sterilization it is likely to come out of the sterilizer wet. "Wet Packs" are not suitable for use after sterilization because they may be easily contaminated when handled. In addition, remaining moisture, particularly in box locks and hinges may result in corrosion that will weaken the instrument and lead to breakage during use. Prepare instrument sets for sterilization using a wrapper, pouch or rigid sterilization container that is appropriate for the method of sterilization to be used.

B. MECHANICAL DECONTAMINATION

General surgical / dental instrumentation may be processed in a washer sterilizer or washer decontaminator/disinfector. Some of these processes include an enzyme application phase and a lubrication phase that is designed into the cycle. Follow the manufacturer's specifications when using automatic washer-sterilizers or washer decontaminators/disinfectors. They usually require the use of a low foaming, free rinsing detergent with a neutral pH (7.0). A high-foaming detergent may clean effectively but will often leave residual deposits on the instruments and do harm to mechanical washers. Automated washer sterilizers and washer decontaminator/ disinfectors usually have adjustable wash and rinse times. Some washers enable the user to customize extra cycles to process heavily soiled surgical / dental instruments more effectively.

C. TERMINAL STERILIZATION

After following the decontamination recommendations, reusable instruments are ready for sterilization. AAMI Standards and Recommended Practices, "Steam Sterilization and Sterility Assurance in Health Care Facilities", ANSI/AAMI ST46:2002; "Flash Sterilization Steam Sterilization of Patient Care Items for Immediate Use, ANSI/AAMI ST37:3ed. AAMI standards recommend that the sterilizer manufacturer's written instructions for cycle parameters should also be followed. Steam sterilization of lumened instruments requires that they be flushed with sterile water just prior to wrapping and sterilization. The water generates steam within the lumen to move air out. Air is the greatest enemy to steam sterilization, preventing steam contact if not eliminated. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter.

Packaging: Prior to sterilization, the instruments are to be placed into suitable disposable single-use single sterilization packages. The packaging must meet the following criteria: Conforming to standards of DIN EN ISO / ANSI AAMI ISO 11607. Suitable for steam sterilization (heat resistant up to 142°C, sufficient vapor permeability).

STERILIZATION:

A widely used method for steam sterilization is the autoclave, sometimes called a converter. Autoclaves commonly use steam heated to 121–134 °C (250–273 °F). To achieve sterility, a holding time of at least 15 minutes at 121 °C (250 °F) at 100 kPa (15 psi), or 3 minutes at 134 °C (273 °F) at 100 kPa (15 psi) is required.

STORAGE: Sterilized products should be stored **in a dry and clean environment.** The storage period depends on the type of packaging.

⚠WARRANTY:

Our product can be used and reprocessed for maximum 20 times in operation. In case of product defect found replacement will be done within 1 year.

MEDICURE INSTRUMENTS (SRN#: PK-MF-000027959)
Sardar Pura, Muzaffar Pur 51310,
Sialkot – PK
Tel: +92 (52) 3552015 Teléfono: +92 (245) 26212000
Correo electrónico: info@medicure.pk URL: www.medicure.pk

REPRESENTANTE AUTORIZADO
Yellow's Medical Instruments GmbH
Max-Planck St., 3 12489 Berlín, Alemania