



Instructions for Use

Disclaimer: We the Manufacturer declare under our sole responsibility that the following methods of cleaning & Sterilization are the methods recommended and approved for our Instruments. It is the user's responsibility to ensure the proper use, cleanliness and follow the instructions. Modern Arch, LLC makes no other representations or warranties regarding its instruments or products, either expressed or implied. In addition, in no event will Modern Arch, LLC be liable for any incidental, special or exemplary damages or loss of profits in connection with the use of our instruments.

These Instructions for Use do not replace the training and care by the user and risks that result from incorrect use. Any serious incident occurring in relation to our products must be reported back to us and the competent authority of the Member State in which the user and / or patient is established immediately.

Exclusive Warranty

Modern Arch, LLC Instruments carry a 5-year warranty on material, workmanship and corrosion resistance.

Our warranty excludes liability for direct or consequential damage as a result of: - Misuse - Improper use, application or handling - Improper preparation and sterilization - Improper maintenance and repair - Failure to observe these Instructions for Use

Device Name:

Dental, Orthodontic and Laboratory Instruments (Reusable)

Intended Use:

Our Instruments are designed to perform specific functions such as cutting, crimping, grasping, clamping, probing, and bending.

Contraindication:

Our Instruments should not be used for anything other than their intended use. Circumstances listed below may reduce the chances of a successful outcome: 1. Compromised vascularity. 2. Previous history of infections, periodontal disease, patients with poor oral hygiene or caries of infections. 3. Ulcers in the mouth. 4. Mental, physical or neurological conditions, which may impair the patient's ability to cooperate with the treatment. 5. Patients suffering from systemic diseases such as hyperthyroidism, diabetes, tuberculosis, and psychosis are generally not suitable for orthodontic treatment, and those with severe malnutrition and pregnant women.

Cautions:



Warnings Our labels and Instructions for Use (IFU's) have been designed using symbols recognized by ISO 15223-1: 2021.



Read all Instructions for Use before using the device for the 1st time



These products are supplied Non-Sterile and must be sterilized using the recommended method before each and every use.



CAUTION: This product contains Nickel which can cause sensitivity in some patients
CAUTION: Federal law restricts this device to sale and use by professional physicians

General Warnings and Precautions for use:

- Check instruments for breakage, cracks, deformations, damage and functional ability before each use.
- Particular attention should be paid to areas such as cutting & tips, ratchets and moving joint. Worn, corroded, deformed, porous or otherwise damaged instruments must be reported and not used.
- Careful handling and storage of the instruments is required before use, during use and after cleaning.

Materials

All our instruments are made of stainless steel 420, also known as UNS S42000 which is hardened, tempered and polished to achieve maximum corrosion resistance in according to ISO 7153-1 and EN 10088-3

**Recommended Steps in Cleaning, Sterilization & Maintenance of Modern Arch, LLC Instruments****1. Holding/Presoak**

Never hold instruments in a dry container. Doing so allows blood and debris to dry onto instrument surfaces and makes cleaning more difficult. If rinsing and decontamination processes are not immediately available, pre-treat instruments or hold them in a neutral pH holding/presoak enzymatic solution after patient use but before actual cleaning. Simply spray the foam on instruments until they are ready for processing.

As soon as possible, rinse and clean as follows:

- a) Remove gross contaminants with steady stream of lukewarm/cool water (below 110°F/43°C). Rinse each instrument thoroughly. Do not use saline or chlorinated solutions.
- b) Open jaws of hinged instruments for cleaning. Give special attention to joints and serrations. Instruments having more than one part or piece must be disassembled to expose all surfaces to the cleaning process. Retain all parts to facilitate reassembly.
- c) Should any galvanic action be detected, then make sure that all of the instruments being sterilized are of compatible material.

2. Rinse:

Rinse instruments thoroughly under warm distilled or demineralized water

3. Cleaning:

Cleaning Precautions:

- a) If appropriate, disassemble instruments prior to cleaning and sterilization.
- b) Do not soak instruments in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of mucus, blood or other body fluids. Do not exceed two hours soaking in any solution.
- c) Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents to remove soil as these will damage the instrument and lead to corrosion.

A. Manual Cleaning:

To prevent formation of biofilm, cleaning should occur as soon as possible after instrumentation is used.

- a) Choose a cleaning solution appropriate for the instrument and follow manufacturer's instructions for use.
- b) The use of neutral pH detergents is recommended to avoid corrosion, pitting and breakage.
- c) Using a small, clean hand-held brush soft bristle remove soil from all surfaces of instrument while fully immersed in solution.

B. Ultrasonic and Mechanical Cleaning:

- a) For ultrasonic cleaning, follow manufacturer's specifications for water level, concentration levels of cleaning agent and temperature.
- b) Use an ultrasonic cleaner to remove soil from hard-to-reach surfaces such as grooves, crevices and moving parts after gross soil has been removed. We recommend a mild multi purpose ultrasonic cleaning solution.
- c) Open or disassemble instruments as appropriate.
- d) When using a mechanical washer, make sure all instruments stay properly in place and do not touch or overlap with each other.
- e) Always follow the manufacturer's specifications for automatic washer sterilizers and use a free-rinsing, low-sudsing detergent with a neutral pH (6.0 - 8.5). Due to variations in water quality, the type of detergent and its concentration may require adjustment for optimal cleaning.

4. Rinse and Dry:

Rinse all instruments thoroughly with distilled, pyrogen-free water to remove all traces of debris and cleansing agents. Instruments must be thoroughly dried to ensure all residual moisture has been removed before they are stored or proceed to sterilization.

5. Lubricate:

Ultrasonic cleaners remove all lubrication, therefore use only water-soluble instrument lubricant before instruments are sterilized and do not rinse after this step. After cleaning a lite paraffin-oil spray (NOT WD40) can be applied to the hinge joint ONLY as it may stain the outer areas if not careful.

6. Sterilization:

There are many differences between Autoclave sterilization machines in range of temperatures, times, convection heat circulation etc. and therefore it is the responsibility of the user to establish whether the sterilizer you are using meets the minimum recommendations below. Medical device manufacturer's exposure times to sterilization temperature may need to be longer than minimum indicated by sterilizer manufacturer but must never be shorter. **Note: - It is the responsibility of the end user to confirm their Autoclave Manufacturers recommendations for exposure and different temperatures.**

Steam sterilization parameters for Autoclave in accordance with ANSI ST55 & ANSI ST8

Independent laboratory testing conducted according to ISO 11737-2:2019 has validated the following sterilization parameters for a Dynamic-air-removal steam sterilization cycle system . Ref:- Report # 130145/002/005			
Sterilization Method	Temperature	Exposure Time	Dry Time
Wet Steam Heat Mechanical convection			
Wrapped	270 ^F (132 ^{oC}) Minimum	5 minutes minimum	30 minutes @ 140 ^F (60 ^{oC})

Independent laboratory testing conducted according to ISO 11737-2:2019 has validated the following sterilization parameters for a Minimum cycle time for Gravity-displacement steam sterilization cycle system . Ref:- Report # 130146/003/005			
Sterilization Method	Temperature	Exposure Time	Dry Time
Wet Steam Heat Mechanical convection			
Wrapped	270 ^F (132 ^{oC}) Minimum	30 minutes minimum	30 minutes @ 140 ^F (60 ^{oC})

CAUTION: STERILIZATION IS NOT A SUBSTITUTE FOR CLEANLINESS

6.1 Inspection and Maintenance Recommendations for Steam Sterilizers

- a. The manufacturer's instructions with respect to routine inspection and the regular maintenance of the Sterilizer must be observed.
- b. The sterilizer must be cleaned on a regular basis.
- c. Only low contaminated and deionized water (i.e. purified water) should be used.
- d. The sterilized items have to be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

6.2 Material Resistance

Detergents or disinfectants containing the following substances **must not be used**:

- strong alkalines (> pH 9)
- strong acids (< pH 4)
- phenols or iodophors
- interhalogen agents/halogenic hydrocarbons/iodophors
- strong oxidizing agents/peroxides
- organic solvents.

Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool. Water quality may influence the result of the cleaning of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in the area. **With the use of completely deionized or distilled water most water quality problems can be avoided beforehand.**

7. Reusability/Repairs and Maintenance

Our hand Instruments can be reused again and again and their life cycle is only limited by their normal wear and damage. Modern Arch, LLC. does not define the maximum number of usage or preparation cycles of reusable instruments. The life cycle is dependent upon many factors including the type and length of usage, as well as handling, storage and transport of the instruments. Thoroughly exam and function test before the each use.