

ARTFX INSTRUMENT SYSTEMS

Medical Device / Non - Sterile

Manufacturer: ARTFX MEDICAL LLC

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How to use

The ARTFX Instrument System consists of manual operational instruments that are to be used, for example, for the operation and treatment for the hip joint. The individual instruments should be used properly for their own usage according to the operational procedures and the surgical technique brochure which might be obtained from manufacturer or local representative.

(A) Before use

- Any product that has been kept in storage should be checked for its cleanness and sterility in order to be used.
- Anyone who does not wear a sterilized uniform should not be allowed to contact the sterilized instruments.
- All instruments should be inspected on the appearance as well as the functions before use. Instruments which any abnormality observed should not be used.

(B) During use

- They must be used only for the intended use. They should not be used for other usage than their intended use.
- If they suffer any severe impact or fall to the ground, the instruments should be checked immediately if they are damaged or there are any contaminations attached. The damaged instruments, if necessary, should be replaced with another one.
- If corrosions, cracks, pinholes, etc. are found while instruments are used, the affected one should be replace with another one immediately.

(C) After use

- Guideline for Point-of-Use, Preparation for cleaning, Manual/Automated cleaning procedure and packaging is referred in related clause.

Precautions for Use

- The ARTFX Instrument System is to be used with ARTFX Instrument System.
- The ARTFX Instrument System must not to be used with the artificial hip joints of other manufacturers.
- The instruments should be used by medical professionals and should not be used for any other usage than as their intended use.
- If an operational instrument with a sharp edge is to be used, be careful not to allow the operational gloves to be cut or damaged.

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- If not follow the method of use properly so that instruments are not suitably cleaned, disinfected or sterilized, there could have chances to risk side effects as infection etc.
- In order to prevent the stains that are generated by the water drops that condense and evaporate slowly on an instrument, gaskets and valves should be checked for any leakage.
- If the water that contains iron element is used for the washing and sterilizing, rust could be created. Consultation with experts should be taken before use.
- When the operational linens that could contain corrosive detergents and chemicals are used, insufficient cleaning could lead to corrosion. It should be checked before use.
- When there are problems during storage or usage of instruments, the manufacturer should be contacted in order to take corrective actions and prevent recurrence.

Reuse Life

ARTFX MEDICAL LLC does not designate the maximum number of uses for re-usable surgical instruments. Number of re-use would be variable according to method of usages, times, maintenance and storage, etc. Repeated processing of re-use has minimal effect on our stainless steel or other metal instruments. Therefore, end of use life can is determined through specific inspection and functional checking according to procedure in **Inspection** clause. Wear or damage are factors which usually determine use life so that careful inspection is demanded.

Point-of-Use

Surgical instruments used in surgery should be sterilized within 30 minutes after surgery to prevent blood and organic debris from sticking on the instruments. Surgical Instrument used in surgery should be separated from trays and/or cases, and do not allow blood and organic debris to dry and stick on the instruments. It is recommended not to mix heavy instruments and complicated instruments to protect them during transportation to processing area. Be cautious in that having sharp edges like reamer or Drill could make injury and damage other instruments. Blood and organic debris should be removed by using non-shedding disposable paper towel and clean/disinfect after immersing in clear non-corrosive water by hand or device.

Preparation for cleaning

Disassemble instruments as required. All movable or sliding parts should be opened as possible. After disassembling instruments, it is recommended to get parts together to assemble again. List and instruction of instruments which required disassembly is located in download section on the webpage www.artfxmed.com

General Requirement

- Dilution water for cleaning agent and/or disinfectant should be purified water, and sterilized or purified water is recommended to rinse instruments.
- Weak alkaline or neutral(6.0~10.8pH), or enzymatic cleaning agent is recommended. Cleaning agent and/or disinfectant should be intended to clean and/or disinfect medical

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device which consist of plastics and metal, and should be approved by FDA clearance, CE marking or VAH list so that proved the effectiveness. Medizyme® (Manufactured by Whiteley Coporation) was used as cleaning agent in the validation test. To choose cleaning agent and disinfectant, below substance should not be included to prevent the effect on the surface of instruments.

- Organic/inorganic acid, oxidized acid (pH<5.5)
 - Organic solvent (ex - acetone, ether, alcohol, benzene)
 - Caustic soda (Sodium hydroxide)
 - Halogen (ex - chloride, iodide, bromine)
 - Oxidizing agent (ex – peroxide, sodium hypochlorite solution)
 - Halogenation Aromatic hydrocarbon
- Cleaning/disinfection procedure of this instruction is validated its effectiveness by AAMI TIR30 / ASTM E2314-03 / ISO 17664 & 15883-5.
 - If there is a system to allow the instruments to be attached and detached, they need to be dipped into a penetrable water-soluble lubricant completely and dried by allowing the lubricant to flow down, when they are washed and sterilized.
 - **CAUTION:** The trays and cases are intended to use for storage and transport, not cleaning and disinfection where instruments are assembled and seated on the bracket. Therefore, instruments should be separated from trays and/or cases, then cleaned and disinfected.

Manual Cleaning/Disinfection Procedure

Step 1	Immerse instruments into solvent with appropriate cleaning agent for minimum 20 minutes, scrub using soft brush or cleaning wire. Complicated structure as rough surface, screw/hinge, lumen or hard to reach by brush, is required to clean carefully, and do not remain debris on instruments. CAUTION: Method of use such as ratio of solvent cleaning agent must follow the instructions of manufacturer. CAUTION: Using sodium hydroxide (NaOH) is prohibited. Device or agent which could cause corrosion, including metal brush and rough sponge, is not recommended.
Step 2	Wash instruments out in running water for minimum 3 minutes to remove solvent cleaning agent and debris on instruments. Particular attention is required for where hard to clean parts, especially, Hinge, hole, joint. In case of lumen structure, wash out water-penetrating the lumen minimum 3 times. Syringe (volume 1~50ml) should be used to rinse minimum 3 times if diameter is not big enough.
Step 3	Prepare appropriate cleaning agent in ultrasonic cleaner and instruments should be completely immersed in the solution. Operate for minimum 10 minutes above 24kHz, temperature should follow the instructions of manufacturer.
Step 4	Rinse instruments in running water for minimum 3 minutes to remove solvent cleaning agent and debris on instruments. Particular attention is required for where hard to clean parts, especially, Hinge, hole, joint. In case of lumen structure, wash out water-penetrating the lumen minimum 3 times. Syringe (volume 1~50ml) should be used to rinse minimum 3 times if diameter is not big enough.

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Step 5	Immerse instruments in disinfectant, follow the instruction of manufacturer about temperature, time etc.
Step 6	Rinse instruments in running water for minimum 3 minutes to remove disinfectant on instruments. Particular attention is required for where hard to clean parts, especially, Hinge, hole, joint. In case of lumen structure, wash out water-penetrating the lumen minimum 3 times. Syringe (volume 1~50ml) should be used to rinse minimum 3 times if diameter is not big enough.
Step 7	After step 6, immediately remove the moisture by using disposable non-shedding towel. Be careful especially to dry lumen, Hinge, hole, joint part of assembly, laser-marking part and dry using long brush in lumen, hole, etc.

Manual/Automated Cleaning/Disinfection Procedure

- Washer/disinfector should be approved its effectiveness by CE mark or FDA approval according to ISO 15883. And it is required to properly installed, qualified and maintained.
- **CAUTION:** Chemical disinfection system is not recommended in that chemical substances could remain on surgical instruments.

Step 1	Immerse instruments into solvent with appropriate cleaning agent for minimum 20 minutes, scrub using soft brush or cleaning wire. Complicated structure as rough surface, screw/hinge, lumen or hard to reach by brush, is required to clean carefully, and do not remain debris on instruments. CAUTION: Method of use such as ratio of solvent cleaning agent must follow the instructions of manufacturer. CAUTION: Using sodium hydroxide (NaOH) is prohibited. Device or agent which could cause corrosion, including metal brush and rough sponge, is not recommended.
Step 2	Wash instruments out in running water for minimum 3 minutes to remove solvent cleaning agent and debris on instruments. Particular attention is required for where hard to clean parts, especially, Hinge, hole, joint. In case of lumen structure, wash out water-penetrating the lumen minimum 3 times. Syringe (volume 1~50ml) should be used to rinse minimum 3 times if diameter is not big enough.
Step 3	Prepare to seat instruments in washer/disinfector. Connect to rinsing port, if there are pipes in device. In case it is hard to connect directly, position injector sleeve of injector jets or injector basket. During running the device, Be careful to avoid damaging instruments or impeding to clean instruments. Lumen structure instruments should not be horizontal, but also closed holes of instruments should head the bottom in order to drain water easily.
Step 4	Run washer/disinfector. Follow manufacturer instructions about cleaning/disinfection, keep below minimum condition for steps and time. Min 5 minutes prewash with running water Min 5 minutes enzyme soak Min 15 seconds running water rinse (X2) Min 5 minutes detergent wash in water solution Min 15 seconds hot($\geq 50^{\circ}\text{C}$) softened water rinse Min 2 minutes thermal rinse ($93\pm 5^{\circ}\text{C}$) Min 1 minute purified water rinse Min 30 minutes hot air dry ($110\pm 10^{\circ}\text{C}$)

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Step 5	After finishing operation, inspect with bare eyes If all moisture is dried and there are blood or debris on instruments. If there is any residue, repeat above procedures. In case moisture is still on instruments, can remove disposable non-shedding towel. If further dry is needed, wipe the moisture using disposable non-shedding towel.
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Inspection

Before preparing for sterilization, all re-usable instruments should be inspected. Generally unmagnified visual inspection under good light conditions is sufficient. All parts of the devices should be checked for visible damage, wear, soil and/or corrosion. Particular attention should be paid to the below.

- Residues in contacting surface, hinge, flexible spindle etc.
- Reentrant structures (hole, pipe type)
- Features where soil may impact into the device, such as drill flutes adjacent to the cutting tip and sides of teeth.
- Cutting edges should be checked for sharpness and damage.
- Whether if burr was created, which could damage tissues or surgical gloves.
- Check the functional condition and lubricant condition on operating part like hinge, locking mechanism, connector, sliding part etc. (If necessary, medical grade lubricating oil suitable for steam sterilization can be applied.)
- Distortion of long and thin instruments.
- In case of that instrument assembles or combines, check whether if all assembly parts are normally assembled.
- Check whether if the surface of trial instruments is smooth and crack, strain etc.
- Rotating instruments, such as multiple use drill bits, and reamers, should be checked for straightness. This can be achieved by simply rolling the instrument on a flat surface.
- Other distortion, damage and corrosion of functional part or thread, which can affect the function.

Packaging

- Pack instruments seating in tray, or prepare individually.
- If prepared individually, seat onto tray of sterilizer, which can endure temperature and pressure of sterilizer.
- Prepared cases and/or trays for sterilization should be double-wrapped according to AAMI/CSR Technique by wrap to ensure that instruments remain sterile prior to use. The packaging wrap should meet the following requirement.
 - ISO 11607-1
 - FDA cleared or CE marking

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- Suitable for steam sterilization
- Grade appropriate for weight of instrument case

Sterilization

ARTFX Instrument System are delivered NON-STERILE. Hence all instruments used in the surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products must be placed in the operative field.

High-pressured steam sterilization (Autoclave) is recommended as per standard sterilization procedure of hospital, following guideline of autoclave manufacturer. The recommended steam sterilization parameters for ARTFX Instrument System are as following table. Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed in this table. The hospital is responsible for in-house procedures for the reassembly, inspection, and packaging of the instruments after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying.

Cycle type	Parameter	Minimum Setting value
Gravity-displacement	Exposure Temperature	132 °C (270 °F)
	Exposure Time	15 Min.
	Dry Time	20 Min.

Cycle type	Parameter	Minimum Setting value
Vacuum	Exposure Temperature	132 °C (270 °F)
	Exposure Time	4 Min.
	Dry Time	20 Min.

Validated by ANSI/ AAMI/ ISO 11737-1 & 11737-2 / USP <71>

IMPORTANT

- Any explicit instructions/operations by the sterilizer manufacturer must ultimately be followed. The manual of the autoclave manufacturer should be well understood before using the product.
- Instrument sets should be properly prepared and packaged in trays and/or cases that will allow steam to penetrate and make direct contact with all surfaces.
- **CAUTION:** Use of sodium hydroxide (NaOH) is prohibited. Device or agent which could cause corrosion, including metal brush and rough sponge, is not recommended. Verify that the instruments are in operation condition.
- **CAUTION:** Chemical sterilization is not proper to apply on instruments so that it is not recommended.










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Storage before Use

- Instruments should be stored in the place where protected from corrosive environments such as salt air, moisture, etc.
- Do not stack instruments up to avoid crack, change or damage.
- Chemicals what make corrosion and discoloration should isolate from the storage of instruments.

Pictograms

	Catalogue Number		Do not use if package is damaged
	Batch Code		Keep away sunlight
	Date of manufacture		Manufacturer
	Caution: Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner).		Authorized Representative in the European Community
	Caution (follow the instructions for use)		

