into three categories based on how thorough they are:

- High-level disinfectants kill all microbial organisms but not necessarily large numbers of bacterial spores (AAMI TIR No. 7: 1999)
- Intermediate-level disinfectants kill viruses, mycobacteria, fungi and vegetative bacteria, but not bacterial spores (AAMI TIR No. 7:1999)
- Low-level disinfectants kill vegetative forms of bacteria, some fungi, and lipid viruses (AAMI TIR No. 7: 1999)

Additionally, never mix different types of metals when disinfecting. Keep like metals together and isolated from others.

Based on the information above, choose an appropriate disinfectant and follow all manufacturer instructions to ensure efficacy.

STERILIZATION

The final step in the sterilization procedure is the sterilization of the instrument itself. Sterilization depends heavily on the correct completion of all preceding steps. It is impossible to sterilize an instrument that has not been properly cleaned and decontaminated. Sterilization, by its nature, demands extreme care and caution. Mistakes during the process could render items contaminated. This results in wasted time and resources or, in a worst-case scenario, adversely affect patient safety. For these reasons, it is imperative that all instructions are adhered to and sterilization is only performed by qualified technicians.

Sterilization by definition requires that there are no living organisms (including bacterial spores) remaining on an instrument. New World Medical instrument should be sterilized, not merely disinfected, to ensure patient safety.

The efficacy of sterilization is affected by several factors:

- The type and number of microorganisms present
- The amount of soil present

Cleaning and disinfection as outlined earlier in this document can dramatically mitigate these factors and make sterilization much more effective.

LUBRICATION

Some automatic washer sterilizers include a lubrication phase that is built into the cycle – if not, ensure instruments are lubricated per the guidelines below prior to sterilization.

An instrument lubricant (often referred to as instrument milk) that is compatible with the method of sterilization to be used is recommended before instruments are sterilized. Ultrasonic cleaners remove all agents. Thus, instruments cleaned with an ultrasonic cleaner must be lubricated routinely after cleaning and before sterilization.

Some lubricants must be diluted in a solution and used by dipping instruments in the open position. Follow the manufacturer's instructions for proper use.

HIGH-TEMPERATURE STERILIZATION

High temperature sterilization is the process of sterilization by using high temperature and pressure steam to kill all microorganisms on a device. Steam is used as it is a much more effective conductor of heat than air. New World Medical recommends Dynamic air removal sterilizers which has vacuum pumps that are used to remove air, ensuring only steam is extant in the sterilization chamber.

It is vital to understand which sterilizer is being used to ensure correct cycle times. The subsequent steps outline the process:

1. As noted previously, before any sterilization process, instrument must be lubricated. Use an approved lubrication agent such as instrument milk. Never use an industrial lubricant such as WD40. Lubricant should not be wiped off instruments prior to autoclaving. Always follow the instructions of machine manufacturer and use validated sterilization equipment.
2. Check the autoclave to ensure that it is working correctly.
3. Place the items in the autoclave either as a group or individually:
   a. Individual items should be placed in disposable paper or plastic pouches. Make sure that the pouch is large enough for the device to be in the open position. Ensure that the pouch is appropriately sealed, but steam permeable.
   b. Make sure all devices are in the open position.
4. It is vital that each part of each instrument be in contact with the sterilization agent (steam). This means that all devices must be open and cannot be placed too close together. Close placement could create pockets where steam cannot fully penetrate. In addition, devices cannot be placed in containers that steam cannot penetrate. All sterilization pouches will allow the penetration of steam.
5. Ensure that the autoclave trays/shelves are not overloaded. This could cause pockets where steam cannot fully penetrate.
6. Following manufacturer instructions begin the sterilization cycle. New World Medical recommends the following exposure times based on temperature and autoclave type:

Dynamic Air Removal Autoclaves	
Item	Exposure Time of **134° C**
Unwrapped Nonporous Items (Mixed Load)	4 mins

7. Do not handle the device any more than is required. Any moisture on a sterile instrument pack means that it could be contaminated.
8. After device is removed and stored securely and sterilely, perform routine maintenance and cleaning on the autoclave, including clearing out the steam drain to ensure it is ready for the next use. Always wait until the autoclave has cooled to perform maintenance or cleaning procedures.

	Consult Instructions for Use
	Manufacturer
	Non-Sterile
LOT	Batch Code
EC REP	Authorized Representative in European Community

 DATE EFFECTIVE: 21 January 2019

NEW WORLD MEDICAL

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NON STERILE

CE

EC REP

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Part #50-0037 Rev D 12/2018

Tube Inserter

Model TI

Product Information

DESCRIPTION AND INTENDED USE

The Tube Inserter (TI) is a reusable stainless-steel forcep designed to assist with tube insertion through a scleral track and into the anterior chamber (AC). The TI forcep features a notched tip to help firmly grasp the tube during the insertion process.

PRECAUTIONS

Care must be taken when working around eye structures especially cornea. Avoid touching the cornea or forcing the tip of the inserter in the needle track.

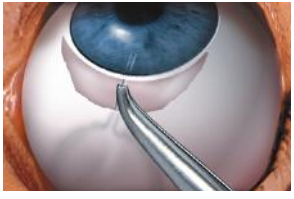
INSTRUCTIONS FOR USE

10.1. After creating a scleral track with a 23 gauge needle, hold the TI forceps at the serrated handle.

10.2. Secure the tube of the implant in the notched tip

10.3. With the TI forcep tip closed guide the tube tip into the scleral track and into the AC through (Fig 1)

Figure 1



HOW SUPPLIED

One TI forcep is supplied per box. The TI forcep is provided in a plastic tray without any seal. The TI is unsterilized and should be sterilized as per facility standards before use.

STORAGE REQUIREMENTS

The TI forcep should be stored in an area which provides protection from extreme temperature and humidity.

CAUTION: Device is provided non-sterile and must be cleaned and sterilized prior to use according to the directions outlined below.

CLEANING INSTRUCTIONS

HOLDING & PRE-CLEANING

HOLDING

Please adhere to the following guidelines for effective holding practices:

- Remove debris from surgical instruments with a sponge and sterile water during procedures to prevent drying on of blood and tissue.
- All instruments should be placed in a distilled water bath immediately after a procedure and before leaving the operating room.
- If a bath is not possible, place the instruments into an instrument tray and cover with a towel moistened with sterile water immediately after the procedure. Foam and spray products, specifically intended to pre-treat surgical instruments, are available to keep the soiled instruments moist, as substances like blood and bodily fluids can be highly-corrosive when allowed to dry.
- Instruments should be rinsed, disinfected and cleaned as soon as possible thereafter to prevent the formation of bio film.

PRE-CLEANING (SOAK & RINSE)

Please note that any time a cleaning solution is referenced in the instructions below, the written instructions of the manufacturer of the cleaning solution must be followed, paying special attention to the instructions for correct dilution, temperatures and soak times, as applicable. Only cleaning products specifically designed for use on reusable surgical instruments should be used. Improper or abrasive cleaning agents can adversely affect instruments. While New World Medical does not endorse specific brands of cleaning products, we recommend that products used are non-abrasive, low-foaming, neutral (pH of 7), free-rinsing, biodegradable, effective on all types of soil and non-toxic.

1. Immediately after a procedure and before the instruments leave the operating room, place them in a distilled water bath or a pre-soak enzymatic cleaning solution bath. Alternatively, if those options are not immediately available, spray the instruments with an enzymatic cleaning prep spray.
   a. Do not use a saline solution as it might damage or corrode the instruments.
   b. Cover the tray/container with a towel moistened with the enzymatic cleaning solution or clean water.
   c. Soiled instruments must be kept moist as substances such as blood and bodily fluids can be highly corrosive when allowed to dry.
   d. If using a bath, immerse instruments fully into the solution in the open, unlocked and/or disassembled position.
2. Transport instruments as soon as possible to the reprocessing area. If they are not already, submerge the instruments at this time in a neutral pre-soak enzymatic cleaning solution bath designed for surgical instruments or a solution of distilled water and neutral detergent (pH of 7 or lower).
   a. Separate instruments of dissimilar metals and ensure sharp tips do not come in contact with each other.
   b. Immerse instruments fully into the solution in the open, unlocked and/or disassembled position.
3. Remove instruments from the enzymatic soak after the time period recommended by the solution manufacturer and rinse them thoroughly with distilled water or lukewarm, neutral pH (pH of 7) water, which is controlled for bacterial endotoxins, removing any remaining organic material.

CLEANING

Cleaning can be done either manually or with the aid of an automated cleaning device. The three options are as follows: I) manual cleaning; II) manual cleaning followed by the use of an ultrasonic cleaner or III) the use of an automated washer. While it is possible to clean devices manually (Option 1), New World Medical recommends the use of a cleaning device (Options I or II) as they have proven to be more effective than manual cleaning.

CLEAN WORK AREAS

It is impossible to clean surgical instruments effectively if the work area itself is not clean. Routine cleaning of work spaces should take place per the following:

- Horizontal work surfaces should be cleaned and disinfected at the beginning and end of each shift.
- Spills should be spot-cleaned immediately.
- Floors should be cleaned and disinfected daily.
- Bio-hazardous waste should be removed at frequent intervals.

CLEANING AGENTS & WATER

It is vital to use high-quality and effective cleaning agents when cleaning surgical instruments. Improper or abrasive cleaning agents can adversely affect the patient, employees or the device itself. While New World Medical does not endorse specific brands of cleaning agents, we recommend that cleaning agents used on New World Medical instrument are:

- Non-abrasive
- Low-foaming
- Neutral (pH of 7)
- Free rinsing (the cleaning agent is completely removed by rinsing)
- Biodegradable
- Allow for rapid soil dispersion
- Non-toxic
- Effective on all types of soil

Water used for cleaning instruments should be clean and distilled. It is important that water used be as close to neutral (pH 7) as possible.

CLEANING OPTION I: MANUAL CLEANING

This option should only be used after instruments are thoroughly pre-cleaned and rinsed per the instructions in Section Holding and Pre-Cleaning.

1. Before hand washing an instrument, it is vital that you ensure your own safety. Soil and fluid proof goggles, gloves, aprons, and shoe covers must always be used. Disinfected instruments are not sterile and must be handled with care.
2. Prepare the cleaning solution by following the detergent manufacturer's instructions.
   a. Pay specific attention to cleaning time, dilution and any other parameters specified in the instructions.
   b. Ensure you are using a neutral pH (pH of 7 or lower) detergent and distilled water.
3. Submerge instruments fully in their maximum open and unlocked positions for the period of time recommended by the detergent manufacturer, ensuring sharp instruments do not touch each other.
4. Carefully and thoroughly remove all soil and biofilm from the instrument while the instrument is submerged in the maximum open position, tips and any other areas that are hidden or difficult to access.
   a. Use a small, clean, soft-bristled hand-held brush to remove all soil and organic material from all surfaces of the instrument while it is fully immersed in the detergent solution. Brushes should be stiff but not abrasive.
   b. Never use abrasives such as steel wool. Wire brushes specifically designed for surgical instruments may be used on particular areas of the instrument such as serrations or files. No other types of wire brushes should be used other than those specifically designed for use on surgical instruments.
   c. Change solutions according to the detergent manufacturer's recommendations.
5. Thoroughly rinse the devices for atleast one minute and then dry with clean, non-abrasive, soft towels. Residual moisture may contain waterborne pathogens and must be removed prior to sterilization.
   a. Pressurized air may be used to aid in drying the instruments, especially for instruments with a flush port or unexposed channels.
6. Inspect each device carefully to ensure that it is functioning properly and free from soil by checking the following:
   a. Ensure instrument tips are aligned.
   b. Ensure there are no signs of residue or discoloration.
   c. Ensure there are no chipped or broken edges on the instrument.
   d. Ensure there is no spotting present on any visible surface of the instrument.
   e. Ensure the instrument is free from blood, body fluids, fat and tissue.

CLEANING OPTION II: MANUAL CLEANING FOLLOWED BY ULTRASONIC CLEANER

New World Medical recommends the use of cleaning devices due to their proven efficacy in cleaning surgical instruments. Option II is the use of an ultrasonic cleaner after the manual cleaning process outlined in Option I is completed.

1. Follow the recommendations of the ultrasonic cleaner manufacturer regarding detergents.
   a. Only use detergents that have been specifically formulated for your specific brand and model of ultrasonic cleaner. These detergents should be pH-neutral and low-foaming to avoid inhibiting the cleaning process.
   b. Stainless steel, titanium, titanium nitride (ceramic coated), insulated and ebonized instruments have the same cleaning instructions, but the detergents used should be formulated for each specific surface finish type.
2. Follow the detergent manufacturer's and the ultrasonic cleaner manufacturer's recommendations for temperature and cycle time. Avoid temperatures above 60 Celsius (140 Fahrenheit) because protein will coagulate and make it more difficult to remove.
3. Place instruments in the ultrasonic cleaner in the open position.
   a. Instruments should be placed in trays designed specifically for use in the ultrasonic cleaner.
   b. Instruments must be fully submerged to ensure cleaning is effective.
   c. Only like surface finishes should be cleaned together in the ultrasonic cleaner.
   d. Do not let sharp instruments touch each other during cleaning.
   e. Follow the ultrasonic cleaner manufacturer's recommendations regarding proper placement of the instrument tray in the ultrasonic cleaner.
4. Rinse instruments with distilled water manually after cleaning in the ultrasonic cleaner to remove all remnants of the cleaning solution. All visible residues should be removed at this point.
5. Change the detergent solution in the ultrasonic cleaner as per the ultrasonic cleaner manufacturer's instructions.
   a. After the detergent solution is changed, the detergent solution must be "degassed." To degas the solution, follow the ultrasonic cleaner manufacturer's written instructions.

CLEANING OPTION III: AUTOMATED WASHER

New World Medical recommends the use of cleaning devices due to their proven efficacy in cleaning surgical instruments. Option III is the use of an automated washer. This option should only be used after instruments are thoroughly pre-cleaned and rinsed per the instructions Section Holding and Pre-Cleaning.

1. Before using an automated washer, ensure that racks are not overloaded and that all washer spray arms can move freely.
   a. If instruments are sticking up or are out of their baskets, they must be relocated so as to be out of spray arm paths.
   b. Failure to do so could result in damage to the washer, the instruments or both.
2. Wash instruments with like finishes together to ensure that there are no adverse effects caused by contact with dissimilar finishes.
   a. Stainless steel, titanium, titanium nitride (ceramic coated), ebonized or insulated instruments should not be washed together in the automated washer.
3. Ensure devices are in the open position and that they are spaced in such a way as to ensure that water and/or detergent can reach all parts of each device. Follow the storage rack manufacturer's written instructions to facilitate proper cleaning.
4. Ensure that detergents/lubricants are prepared prior to beginning the cycle as per the detergent manufacturer's instructions.
5. Follow the automated washer manufacturer's instructions and select the appropriate cycle. Ensure that the cycle chosen has been validated for surgical instruments by the automated washer manufacturer.

FINAL RINSE

Final rinse should occur after the above processes and must be done thoroughly with softened, de-ionized, or distilled water to prevent mineral deposits. It is necessary to manually rinse items after they are done being washed. This rinsing removes chemical cleaning agents that may damage instruments.

DECONTAMINATION

After cleaning is completed, devices must be decontaminated/ disinfected in order to make them safe for transport, handling and inspection. The method required for this decontamination is dependent on the type instrument and the procedure it was used for. Decontamination methods include steam sterilization (without pouches), chemical agents, or heat. This section will deal with chemical decontamination agents, as sterilization will be described below. It is vital to understand that decontaminated instruments are not sterilized. Some living organisms may remain on a decontaminated instrument.

- Type and number of microorganisms. Some microorganisms are more difficult to kill than others. The type of procedure that the device was used for determines this.
- Direct contact with the device. An item to be disinfected must come in direct contact with the disinfecting agent for a time specified by the manufacturer of the chemical agent used.
- Temperature of disinfectant.
- The pH of the disinfectant. Note that New World Medical instrument should only be used with disinfectants that have a pH of 7.
- Hardness of water.
- Material compatibility. Make sure to use a disinfectant that is effective on the metal type of the instrument. In most cases, this would be stainless steel.
- Positioning of devices. Devices should be open, not touching, and must have their lumens soaked vertically.

It is important to select a disinfectant that is appropriate for the metal type and pH level required by the specific surgical instrument. For New World Medical device, this will be stainless steel and 7, respectively.

It is also vital that a disinfectant be selected with the appropriate strength required. Disinfectants are separated