Reprocessing Instructions

for MASTEL PRECISION Products

Manufacturer of Ophthalmic Surgical Instruments and Systems

Manufacturer:

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1. General Information

These reprocessing instructions apply to all MASTEL PRECISION products. Insofar as special statements are made regarding individual products (e.g., instructions for dismantling or using cleaning adapters), these are enclosed with the respective product and are to be considered supplemental to these instructions.
Any deviations from these instructions (e.g., other sterilization processes or deviations from the manual or mechanical cleaning and disinfection methods) are the responsibility of the user.
MASTEL PRECISION will accept no liability for damage to products resulting from deviations from the current instructions. For the rest, our General Terms and Conditions shall apply.
MASTEL PRECISION reserves the right to amend these instructions in response to recent findings.
The current version of the instructions can be obtained from MASTEL PRECISION, Rapid City, SD, or downloaded at www.mastel.com.

2. Background Information

Products are supplied in a non-sterile state and are not to be used without having previously been cleaned/disinfected and sterilized.
Effective cleaning/disinfection is an essential prerequisite for effective sterilization of the products. Sterilization in delivery packaging is not permissible unless the case is clearly marked as 'Sterilizable Case'.
Please ensure that only sufficiently validated devices and product-specific processes are used for cleaning/disinfection and sterilization and that the validated parameters are adhered to in each cycle.
In addition, please observe the statutory regulations in your country as well as the rules of hygiene of your facility, hospital or clinic.

3. Cleaning/Disinfection

Due to their distinctly greater effectiveness, mechanical processes (disinfectors) should be used for cleaning/disinfection.
For effective reprocessing, pre-treatment should begin as soon as possible, or, at the latest, 30 minutes after the operation has been performed. Cleaning/disinfection should then follow within the next two (2) hours.

3.1 Pre-treatment

Immediately after a procedure instruments should be minimally rinsed with BSS or other solution to remove bio-material from all surfaces. The aid of a sponge or foam cleaning system such as OptiKleen can/should be used to remove lodged materials from diamond scalpels.

3.2 Ultrasonic Cleaning

Cleaning in an ultrasonic bath is optional (not the preferred method for diamond scalpels). If ultrasonic cleaning is done, care must be taken that the exposure time and concentrations recommended by the manufacturer of the cleaning solution are observed. At the same time, the liquid level specified by the manufacturer of the ultrasonic bath is to be adhered to (e.g., filled up to the mark).
Even when the bath has been correctly prepared, errors can be prevented by taking the following precautions:

- Products must be completely covered by the cleaning solution
- Products with hinges and/or joints, must be treated in an open state
- In order not to impair the effect of the ultrasound, instruments are to be placed in the bath on perforated instrument trays

Contamination of the ultrasonic bath impairs effective cleaning and increases the risk of corrosion. Therefore, depending on the amount of use, the cleaning solution must be replaced regularly. The main criterion is visible contamination. In any case, frequent replacement of the bath - at least once a day - is necessary.

For cleaning diamond blades, it is recommended that a cleaning system such as Opti-kleen® be used (see B). However, the ultrasonic cleaner may be used in conjunction with Opti-kleen® if done before contaminants have a chance to dry on the blade.

A. Using the ultrasonic cleaner:

Prepare the ultrasonic unit before surgery:

1. Place one plastic cup (approximately 470ml or 16 ounces), filled with approximately 10ml or 1/3oz of recommended ultrasonic cleaning solution (such as Branson® Jewelery Cleaner) and the remainder with distilled water into the ultrasonic tank. (The cleaning solution is a wetting agent that will allow water molecules to get closer to the blade which is naturally hydrophobic).
2. Fill a second identical sized cup with distilled water for rinsing in the ultrasonic cleaner. This can be placed in the unit also if there is room for both or can be switched with the first cup as needed.
3. Fill the ultrasonic tank with distilled water to a level just below the fluid in the cups to prevent buoyancy. The water level should be close to 2.5cm (1 inch) below the edge to obtain optimal effect from the ultrasonic transducers. Water level in the cup may be adjusted accordingly.
4. Turn on the heat and run the ultrasound for 5 minutes to charge the fluid medium and purge it of trapped gasses that inhibit cavitation.

Always start with fresh distilled water, new cups, and cleaning solution each day of surgery.

Now you are ready to clean the diamond:

1. Keep the diamond blade wet after the surgical procedure, using warm tap water if the ultrasonic is not immediately available.
2. Suspend the distal portion of the blade in the cup with the cleaning solution for 30 – 45 seconds. Do not allow any portion of the scalpel body to be submerged in the sonic solution although this will not cause any harm to the scalpel.
3. Rinse the blade for 10 - 15 seconds in the 2nd cup.
4. Inspect the diamond under a microscope.
5. If the diamond is clean, retract the diamond and place the handle in the sterilization case for a normal sterilizing procedure (see Section 6.2 below). It is recommended that a drying cycle be used after the last sterilization. Ensure that the entire scalpel is dry before storing.

B. Using Opti-kleen diamond cleaner:

Prepare by peeling foil lid from the cleaning kit and place the kit into the holding tray.

1. Proceed by gently inserting the scalpel blade into the first compartment (1. Clean) media as if to make an incision. Move the blade back and forth gently for 5 seconds, similar to the cutting motion. Repeat this step until clean.
2. Insert the scalpel into second compartment (2. Rinse). For 2 seconds, use the same motion as you did in step 1. This removes the cleaning solution.
3. Insert the scalpel into the third compartment (3. Rinse) for a final rinse and, for 1 second, use the same motion as in the previous steps (1. & 2.).
4. A quick inspection under magnification can reveal any material remaining. Repeat steps 1., 2., & 3. if necessary.
5. Retract the blade, making sure the blade is retracted all the way and secure. Return the scalpel to the case.
6. Discard the cleaning media at the end of the surgical day.

Caution: Do not use weckcells or cotton swabs to clean the diamond blades. These create a force, contrary to the designed direction, that can cause damage to the blade. Do not immerse the handle beyond the footplate assembly. Solution allowed in the barrel may deposit material on the internal mechanism. Hydrogen peroxide may discolour titanium instruments.

3.3 Mechanical Cleaning/Disinfection (Disinfector)

The following must be taken into account when selecting a disinfector:

- Only disinfectors are to be used whose effectiveness has been verified (e.g., DGHM or FDA approval or CE marking).
- Because of the risk of disinfectant residues remaining on products when disinfecting with chemicals, instruments should be disinfected thermally with a proven disinfection program (at least 10 minutes at (150° F).
- The program used must be appropriate for the products and must include a sufficient number of flushing cycles.
- Only sterile or low-bacteria (max. 10 bacteria/ml) distilled or deionized water is to be used.
- The compressed air used for drying must meet your facility's requirements.

- The disinfector must be serviced regularly and checked according to the guidelines of your facility and/or manufacturer.

The following must be taken into account when selecting cleaning agents:
- The cleaning agents must be suitable for the cleaning of the products.
- If one chooses not to disinfect thermally (at least 10 minutes at 93°C (199°F)), a suitable disinfectant whose effectiveness has been verified (e.g., DGHM or FDA approval or CE marking) and which is compatible with the detergent selected should be used.
- If an alkaline detergent is used, adequate neutralization in accordance with the manufacturer's instructions is to be performed.
- The chemicals used must be compatible with the products.
- The detergent and disinfectant concentrations specified by the manufacturer must be adhered to without fail.

Mechanical Cleaning and Disinfecting Sequence:
1. Place the products in the protective perforated sterilizing tray. (When preparing the products for cleaning, ensure that they do not touch each other).
2. Place the perforated sterilizing tray containing the products in the disinfector (Attention: The manufacturer's instructions must be followed when stacking several disinfector baskets or perforated sterilization trays one on top of the other.).
3. Start the program.
4. When the program is finished, remove the perforated sterilization tray from the disinfector.
5. If possible, package the products or the perforated sterilization tray containing the products immediately following removal from the disinfector (see Chapter 5).

3.4 Manual Cleaning/Disinfection

The following must be taken into account when selecting detergents and disinfectants:
- The agents must be suitable for the cleaning and disinfecting of the products. Furthermore, they must be compatible with each other (due to the possibly heavy contamination, combining detergents/disinfectants is not recommended).
- The effectiveness of the disinfectant must have been verified (e.g., DGHM or FDA approval or CE marking).
- The chemicals used must be compatible with the products.

The concentrations and exposure times specified by the manufacturer of the detergent/disinfectant must be adhered to without fail. Only freshly produced solutions are to be used, and the disinfectant solution must not foam.
Use only sterile or low-bacteria (max. 10 bacteria/ml) distilled or deionized water for flushing. Also, ensure that the endotoxin and particle levels are adequately low (e.g., aqua purificata as stipulated in the Pharm. Eur. or USP).

Manual Cleaning Sequence:
1. Place the products in the cleaning solution for at least the period of time specified by the manufacturer of the detergent/disinfectant.
2. Contaminants adhering to the outside of the instruments are to be removed using the additional help of a soft bristled toothbrush. Make sure the diamond is retracted before performing this operation.
3. Thoroughly rinse the products at least 5 times each with freshly distilled or deionized water. Repeat the cleaning process if the last rinsing solution is not clear or if impurities are still visible on the product.

Manual Disinfection Sequence:
1. Place the products in the disinfectant for at least the exposure time specified by the disinfectant manufacturer.
2. Thoroughly rinse the products at least 5 times each with freshly distilled or deionized water. Redo the entire cleaning/disinfecting process if the last rinsing solution is not clear or if impurities are still visible on the product.
3. Dry the products using filtered, compressed air.
4. If possible, package the products immediately.

4. Testing

Following cleaning/disinfection, the products should be macroscopically clean, i.e., free from visible protein residues and other impurities. If this is not the case, the complete cleaning/disinfection process must be repeated. To avoid metal abrasion and corrosion, surgical instruments with movable parts must be cooled prior to the functional test. Hinged / jointed instruments and products with threads must be oiled prior to the functional test.

Worn, damaged and porous products must be sorted out, as these no longer fulfill their function. Corroded products are also to be removed, since these can, as a result of the transfer of extraneous rust, trigger corrosion on products which are still intact.

Surgical products which are in a sound state must not be reprocessed together with products with damaged surfaces. Especially products from old stocks with flaking chromium or nickel coatings can cause discoloration or corrosion of high-grade stainless steel and titanium instruments. Therefore, it is recommendable to sort these products out or package them separately.

5. Packaging and Sterilization

5.1 Packaging

Prior to sterilization, the perforated sterilization tray containing the products is to be placed in an appropriate sterilization tray container which, together with the filter material, must fulfil the following criteria:

- Be in accordance with the standards DIN EN 868/ANSI AAMI ISO 11607
- Be suitable for steam sterilization (thermostable up to 137°C (279°F), adequate steam permeability)
- Be serviced regularly

If disposable sterilization packages are used as an alternative, these must also be suitable for steam sterilization (thermostable up to 137°C (279°F), adequate steam permeability) and be in accordance with DIN EN 868/ANSI AAMI ISO 11607.

5.2 Steam Sterilization (Autoclave)

The times and temperatures specified are minimum requirements. If, for procedural reasons, the values have to be lowered, the user must validate these.

It is possible to exceed the time and temperatures specifications. However, longer sterilization times and higher temperatures stress the materials, causing them to age prematurely.

Only products which have been cleaned and disinfected can be sterilized.

Only the sterilization criteria listed below are to be used. Should the user select other forms of sterilization, then he must validate these (see below):

- Prevacuum high temperature steam sterilizer:
  - four minutes at 132°C/134°C (270°F/273°F), or
  - twenty minutes at 121°C (250°F)
- Gravity displacement autoclave:
  - five minutes at 132°C / 134°C (270°F / 273°F), or
  - twenty minutes at 121°C (250°F)
- The use of gravity displacement process must be approved by means of additional validation (longer sterilization times may be necessary).
- A steam sterilizer in accordance with DIN EN 13060 and DIN EN 285 and validated in accordance with DIN EN 554/ANSI AAMI ISO 11134 (valid selection and product-specific performance qualification)
- Maximum sterilization temperature 137°C (279°F) (plus tolerance range in accordance with DIN EN 554/ANSI AAMI ISO 11134)
- Sterilization times:
  - ❖ **at least 20 minutes at 121°C (250°F), alternatively**
  - ❖ **at least 5 minutes at 132/134°C (270/273°F) ***

The manufacturer will accept no liability for other sterilization processes (e.g., hot-air, ethylene oxide, formaldehyde, radiation or low-temperature plasma sterilization). Should these be selected, validate them in accordance with the applicable standards DIN EN ISO 14937/ANSI AAMI ISO 14937 and/or process-specific standards and, taking into account the specific geometry of the product, be able to provide proof of the suitability and effectiveness of the process (including analyses of the sterilizing agent residue if applicable).

5.3 Storage

Sterilized products should be stored in a dry environment. Apart from this, no special conditions are necessary as far as storage is concerned.
The storage period is dependent on the type of packaging (please refer to Chapter 5.1).

6. Manufacturer Remarks

- Surgical instruments made from high-grade stainless steel and titanium can be reprocessed many times. It must, however, be taken into account that each chemical and thermal treatment stresses the materials, causing them to age.
- If the type of material limits the number of reprocessing cycles, this is indicated on the user instructions enclosed with the product.
- High-grade steels must not be permanently exposed to environments conducive to corrosion (e.g., chloride or iodine ions and their vapors) over long periods of time.
- Long delays before reprocessing must be avoided.
- When reprocessing manually, care must be taken that no damage is caused by the use of metal brushes, scouring agents or by the exertion of too much force.
- Products must be stored appropriately during sterilization (not on top of each other and fixed in place with sterilization strips or sterilization plates).
- The use of distilled or deionized water for all reprocessing cycles (including pre-cleaning) is recommended because tap water can cause the concentrations of ions on the surface of the steels to increase.
- It must be noted that when using alkaline cleaning solutions, certain materials such as aluminum may become corroded. In such cases, the manufacturer of the cleaning solution must be consulted.
- When using hydrogen peroxide H_2O_2, titanium instruments may become discolored. These discolorations can be attributed to changes in the thickness of the oxide layer and do not affect the quality of the instruments. This method is not suitable for products made from aluminum.