Cleaning and Disinfection Instructions for MASTEL PRECISION Products

Manufacturer of Ophthalmic Surgical Instruments and Systems

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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 processes or deviations from the manual or mechanical cleaning and disinfection methods herein) 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. Disinfectors are not recommended for cleaning diamond scalpels.

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.

Pre-treatment: Immediately after a procedure, instruments should be minimally rinsed with BSS or other solution to remove biomaterial from all surfaces. The aid of a sponge or foam cleaning system such as the Diamond Blade Cleaning System (DBCS) can and should be used to remove lodged materials from diamond scalpels.

***Regarding Manual Cleaning/Disinfections for Scalpels and Instruments:**

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 European Pharmacopoeia or USP).

3.1 DIAMOND SCALPELS

For cleaning diamond blades, it is recommended that a cleaning system such as the Diamond BladeCleaning System (DBCS) be used.

Manual Cleaning Sequence for Scalpels:

1. Always make sure the diamond is completely retracted. Do not submerge the scalpel body or expose it to running or excess fluids. Impurities may be carried into the mechanism which, over time, may hamper or impair the functionality and/or accuracy of settings.
2. **Dampen** a soft cloth with distilled water. (Do not saturate the cloth or water with detergents.)
3. Wipe the handle avoiding the footplates or open diamond end.
4. Repeat this process if impurities are still visible.
5. Impurities can accrue in the internal scalpel mechanism and cannot be cleaned in the field. It is recommended to send the scalpel in for annual cleaning and inspection.

Make sure the diamond is retracted before performing this operation.

<u>Caution</u>: Do not use weckcells or cotton swabs to clean the diamond blades. These create a force, contrary to the designed direction, which 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 discolor titanium instruments.

Manual Disinfection Sequence for Scalpels:

1. Dampen a cloth with the disinfectant (do not saturate).
2. Wipe the entire scalpel body with the exception of the footplates or open diamond end of the scalpel.
3. With a clean cloth dampened with distilled water (do not saturate), wipe the body to remove impurities.
4. Inspect the handle and if impurities are still visible, repeat the sequence as many times as necessary.

Using The Diamond Blade Cleaning System:

Prepare by opening the DBCS's plastic lid, removing and disposing of foil cover. Keep lid closed when not in use. If using a holding tray, place kit in tray.

1. Proceed by gently inserting the scalpel blade into the first compartment's (Labeled "1. Clean" in tray) blue 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.
   ***Avoid motion of the blade contrary to its designed cutting direction.**
2. Insert the scalpel into second compartment's white media (2. Rinse). For 2 seconds, use the samemotion as you did in step 1. This removes the cleaning solution.
3. Insert the scalpel into the third compartment's white media (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 remaining material. Repeat steps 1., 2., & 3. ifnecessary.
5. Retract the blade, making sure the blade is completely retracted and secure (handle is locked). Return the scalpel to its case.
6. Discard the cleaning media at the end of the surgical day.

3.2 INSTRUMENTS (RINGS AND MARKERS)

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.

***REGARDING MECHANICAL CLEANING/DISINFECTION (Disinfector) FOR INSTRUMENTS:**

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 – Instruments only:

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.

Manual Cleaning Sequence – Instruments only:

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. CAUTION: Do not use excessive pressure and do not brush crosshairs ifpresent.
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 – Instruments only:

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 stillvisible 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 beoiled 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. 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 thematerials, 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.

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 toincrease.

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.