Packaging and Sterilizing MASTEL PRECISION Marking Instruments

Manufacturer of Ophthalmic Surgical Instruments and Systems

Manufacturer:

MASTEL PRECISION SURGICAL INSTRUMENTS, INC.
2843 Samco Road, Suite A
Rapid City, South Dakota 57702
USA
Phone: (605) 341-4595
(800) 657-8057
Fax: (605) 343-3631
E-Mail: mastel@mastel.com
Web: www.mastel.com

Packaging and Sterilizing MASTEL PRECISION Marking Instruments

Validation

The sterilization data in the sections below was validated (07/09/2013) by Life Science Outsourcing, Inc. utilizing the following standards:

Primary:

- ANSI/AAMI/ISO 17665-1:2006 Sterilization of health care instruments – Moist Heat – Part 1: Requirements fro the development, validation, and routine control of a sterilization process for medical devices.
- AAMI TIR12:2010, Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.
- ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health card facilities.

Secondary:

- ISO 11138-1-2017 Sterilization of health care product – Biological indicators – Part 1 General.
- Premarket Notification [510(K)] Submission for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA. Office of Device Evaluation, draft released for comment on March 7, 2002.
- ISO 11737-2:2009 Sterilization of Medical Devices – Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process. Geneva: ISO, 2009.
- ISO 14161:2009 Sterilization of health care products – Biological indicators – Guidance for the selection, use, and interpretation of results. Geneva: ISO, 2009.
- ISO 11138-1:2017 Sterilization of health care products – Biological Indicators – Part 1: General Requirements. Geneva: ISO, 2006
- ISO11138-1:2017 Sterilization of health care products – Biological Indicators – Part 3: Biological indicators for moist heat sterilization processes. Geneva: ISO, 2006.
- ISO 17665-2:2009 Sterilization of Healthcare Products – Moist Heat – Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1. Geneva: ISO, 2009.

1. Packaging

Prior to sterilization, the perforated sterilization tray containing the instrument 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 ANSI/AAMI ST79:2017.

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 the user 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) wrapped
- Gravity displacement autoclave:
    - five minutes at 132°C / 134°C (270°F / 273°F), or
    - twenty minutes at 121°C (250°F) unwrapped
    - thirty minutes at 121°C (250°F) wrapped
- Statim® steam sterilizer with radiant heat drying:
    - three- and one-half minutes at 135°C (275°F) for unwrapped, or
    - ten minutes at 135°C (275°F) wrapped
- 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 ISO 17665 (valid selection and product-specific performance qualification)
- Maximum sterilization temperature 137°C (279°F) (plus tolerance range in accordance with ISO 17665.

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).

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 1 above).

4. 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.