3M ESPE

Sof-Lex™ Mandrels

ENGLISH

Cleaning, Disinfection and Sterilization of Re-Usable Mandrel

Cautions

- Do not use a metal brush or steel wool to clean mandrels, as this will damage the finish of the mandrels.
- Do not expose mandrels to temperatures higher than 141°C (286°F).
- Do not use detergents or disinfectants containing the following substances:
  - Strong alkalines (>pH9)
  - Strong acids (<pH4)
  - Phenols or iodophors
  - Hydrogen peroxide (H_2O_2)
  - Interhalogenic agents / halogenic hydrocarbons / iodophors
  - Strong oxidizing agents / peroxides
  - Organic solvents
  - Aldehydes
- Use only sterile or high quality water, for example; purified water/ highly-purified water (PW/HPW according to the pharmacopeias) for post-rinsing, as well as for other processing steps that require water. Water quality may influence the result of the cleaning and disinfection of the mandrels.
- Select a cleaning detergent and disinfectant that are suitable for this type of device and are compatible with the mandrel.
- User is responsible for inspecting mandrels prior to each use.

Manual Cleaning

Note: If an automated or ultrasonic cleaning method is preferred, please refer to Solutions.3M.com/wps/portal/3M/en_US/3M-ESPE-NA/dental-professionals/resources/msds for Cleaning, Disinfection and Sterilization Information.

1. Preparation at Point of Use
   - 1.1. Remove abrasive or polishing instrument from mandrel and properly dispose of it as medical waste.
   - 1.2. Reprocess mandrels as soon as is reasonably practical following use.
   - 1.3. Remove excess soil with disposable cloth/paper wipes.
2. Containment and Transportation: Contain contaminated mandrels in an approved, sealed container during transport from the point of use to the decontamination area.
3. Cleaning procedure: Follow instructions of the cleaning detergent manufacturer regarding concentration and soaking time.
   - 3.1. Preparation: Use a soft brush for manual removal of coarse impurities. Do not use metal brushes or steel wool.
   - 3.2. Completely submerge mandrels in the cleaning solution and soak for the recommended soaking time of the cleaning detergent manufacturer. Use a soft brush to carefully brush instrument.
   - 3.3. Remove mandrels from cleaning solution and rinse thoroughly at least 3 times for at least one-half minute each time with high quality water. (See Cautions section).
   - 3.4. Inspect the mandrels for good cleaning result and repeat procedure, if necessary.

Disinfection procedure:

1. Follow instructions of the disinfectant manufacturer regarding concentration and soaking time.
2. Completely submerge the mandrels in the disinfectant solution. There should be no contact between the mandrels.
3. Remove mandrels from the disinfectant solution and post-rinse thoroughly at least 5 times for at least one-half minute each time with high quality water. (See Cautions section).
   - 3.1. *The fundamental suitability of the instruments for effective cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the cleaning detergent Cidezyme/Enzol and the disinfectant Cidex OPA (ASP, Irvine, USA / Johnson & Johnson GmbH, Norderstedt, Germany) considering the specified procedure.*
4. Drying
   - 4.1. Perform post-drying step in a clean place, or use filtered air for drying to prevent recontamination.
   - 4.2. Completely dry mandrels before repackaging.
5. Inspection, Maintenance, Testing: Inspect mandrels for contamination, damage and wear. If mandrels are still dirty, repeat cleaning and disinfection procedures.

Directions for Sterilization

1. Consider the following in the selection of suitable sterilization containers and/or packaging:
   - 1.1. Conformity with ANSI AAMI (EN) ISO 11607 (EN 868-2 or EN 868-8).
   - 1.2. Suitable for steam sterilization (temperature resistance up to 141°C (286°F).
   - 1.3. Sufficient protection of the instruments and the sterilization packaging against mechanical damage.
   - 1.4. If a sterilization container is used, follow regular maintenance according to the manufacturer's instructions.
2. Sterilization Procedure
   - 2.1. The sterilizer should be validated according to ANSI AAMI (EN) ISO 17665 (and HTM 2010 if required by local regulations and guidelines).
   - 2.2. Do not exceed a sterilization temperature of 138°C (280°F).
   - 2.3. Do not exceed sterilizer's maximum load when sterilizing multiple mandrels in one autoclave cycle.
   - 2.4. Steam sterilize according to EN 13060, and EN 285 if required by local regulations and guidelines.
   - 2.5. **Use only the procedures recommended below. Other sterilization procedures are the responsibility of the user.**
   - 2.6. Place instruments in sterilization packaging.
   - 2.7. Run sterilization cycle (see table below).

Note: If other validated sterilization conditions are needed, please refer to Solutions.3M.com/wps/portal/3M/en_US/3M-ESPE-NA/dental-professionals/resources/msds for Cleaning, Disinfection and Sterilization Information.

Cycle	Temperature	Time	Packaging
Gravity	121°C	30 min.	Wrapped
Gravity	132°C	15 min.	Wrapped
Gravity	132°C	3 min.	Unwrapped (Flash)

The fundamental suitability of the mandrels for effective steam sterilization was demonstrated by an independent accredited test laboratory by application of the steam sterilizer Systec V-150 (Systec GmbH Labor-Sytemtechnik, Wettenberg) and of the fractionated vacuum procedure as well as of the gravity procedure. For this, typical conditions in the clinic and doctor's practice as well as the specified procedure were considered.

Storage and Use

- Store mandrels after sterilization in a dry and dust-free place.
- Sterilization can only be maintained if the mandrels remain packaged or wrapped, impermeable to microorganisms, following a validated sterilization process. The status of the sterilization has to be clearly indicated on the wrapped packages or the containers.
- For safety reasons, keep sterile and non-sterile mandrels separated.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty

3M ESPE warrants that these instruments will be free from defects in materials or workmanship for a period of 1 year from the date of purchase. Failure to follow recommended use, maintenance, cleaning, disinfection and sterilization procedures will void all warranty claims. User is responsible for inspecting instruments prior to each use.

3M MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

3M ESPE Customer Care/MSDS Information:
U.S.A. 1-800-634-2249 and Canada 1-888-363-3685.

3M ESPE
Dental Products
2510 Conway Avenue
St. Paul, MN 55144-1000 USA

EC REP

3M Deutschland GmbH
Dental Products
Carl-Schurz-Straße 1
41453 Neuss – Germany

2013-01

44-0007-7333-1-A