STERILIZATION PROCEDURE FOR WELLS JOHNSON CANNULAS

Each cannula needs to be carefully scrubbed with a cannula brush, dried, packaged and treated in an autoclave at 265 degrees with 25 psi for 15 minutes or more. Cannulas must be sterilized before each use.

Important Notice:
This is if you have a 2-piece cannula with a black Delrin handle. The melting pot is between 329 and 347 degrees. We recommend to autoclave 265 degrees with 25psi for 15 minutes or more. To ensure effective sterilization the handles should be scrubbed and dried before being sterilized. NEVER autoclave the handle with the cannula tip still attached to the handle. The two different materials in the autoclave at the same time can cause damage.

Should you have further concerns or questions, please contact the Wells Johnson Company at 1-800-528-1597. Thank You.
Operating Your M9 & M11 Sterilizer

PRE PROGRAMMED OPERATION

STEP 1: Select and press the appropriate sterilization pre programmed button.

(NOTE: Refer to Standard Cycle Parameters (below) to select the proper sterilization program time and temperature.)

STEP 2: Press the START button.

WARNING: STOP BUTTON MAY BE DEPRESSED AT ANY TIME TO STOP OR INTERRUPT A CYCLE. GOODS MUST NOT BE CONSIDERED STERILE IF THIS OCCURS BEFORE THE DRY CYCLE BEGINS.

PROGRAMMING

STEP 1: Press button 1 or 2.

STEP 2: Press PROGRAM button.

(NOTE: Sterilization temperature can be adjusted from a minimum of 230°F (110°C) to maximum 275°F (135°C))

The button raises temperature 1.

The button lowers temperature 1.

(NOTE: If STOP button is pressed anytime during the Programming Mode any settings entered will be aborted and programming will revert back to the original settings.)

STEP 3: Press PROGRAM button.

(NOTE: Sterilization time can be adjusted from a minimum of 3 minutes to maximum 90 minutes.)

The button raises time 1 minute.

The button lowers time 1 minute.

STEP 4: Press PROGRAM button.

The button changes venting to FAST.

The button changes venting to SLOW.

STEP 5: Press PROGRAM button.

(NOTE: Drying Time can be adjusted from a minimum of 0 minutes to a maximum of 60 minutes.)

The button raises time 1 minute.

The button lowers time 1 minute.

STEP 6: Press PROGRAM button.

The display shows the new programmed settings for the button that was programmed 1 or 2.

(NOTE: The programmed settings entered are retained under that Program button (1 or 2). If power is interrupted or the unit is unplugged, the settings will be retained.)

STANDARD CYCLE PARAMETERS

| Unwrapped | 270°F (129°C) |
| 27.1 psi (186 kPa) |
| Sterilize for 3 minutes | Dry for 30 minutes |
| • Instruments loose on a tray. |
| • Open glass or metal canisters. |
| • Tubing not used in surgical procedures. |
| • Loose items manufacturers recommend for exposure at 270°F (129°C). |
| • The sterility of unwrapped items is compromised on exposure to a non-sterile environment. |

| Pouches | 270°F (129°C) |
| 27.1 psi (186 kPa) |
| Sterilize for 5 minutes | Dry for 30 minutes |
| • Pouched or loosely wrapped instruments. |
| • Multiple layers of instruments separated by fabric. |
| • Wrapped trays of loose instruments. |
| • Tubing not used in surgical procedures. |
| • Wrapped items manufacturers recommend for exposure at 270°F (129°C). |

| Packs | 270°F (129°C) |
| 15 psi (104 kPa) |
| Sterilize for 30 minutes | Dry for 30 minutes |
| • Textiles and surgical packs wrapped for sterilization. |
| • Items, except liquids, manufacturers recommend for exposure at 250°F (121°C) for 30 minutes. |

| Handpieces | 270°F (129°C) |
| 27.1 psi (186 kPa) |
| Sterilize for 6 minutes | Dry for 30 minutes |
| • Dental handpieces |

| Programmable User Defined | 230°F (110°C) to 275°F (135°C) |
| 6 psi (41 kPa) to 31 psi (214 kPa) |
| 3 min. to 90 min. |
| • Items appropriate for user’s defined parameters. |

CAUTION

Temperatures below 250°F (121°C) should only be used disinfection unless otherwise recommended by the device manufacturer.

004-0339-00 Rev. C

OVER FOR M9 / M11 OPERATOR MAINTENANCE
Caring for Your M9 & M11 Sterilizer

**WARNING** - BE SURE THAT UNIT IS COOL WHEN CLEANING TO PREVENT POSSIBILITY OF BURNS.

1. **CLEAN EXTERNAL SURFACES**
   (a) Wipe with a soft dry cloth and occasionally with a damp cloth and mild soap or detergent.

2. **CLEAN INTERNAL SURFACES**
   (a) Drain water from reservoir using drain tube located on front of unit.

   **EQUIPMENT ALERT** - FAILURE TO CHANGE WATER PROMOTES GROWTH OF ALGAE IN RESERVOIR AND MAY CAUSE STERILIZER TO MALFUNCTION.
   (b) Using a mild soap or Speed-Clean Sterilizer Cleaner™ and distilled water, wash inside of chamber, trays, door gasket, and door gasket mating surface. Examine door gasket for possible damage that could prevent a good sealing surface.
   (c) Refill reservoir with clean, distilled water.

**MONTHLY**

**EQUIPMENT ALERT** - FAILURE TO FLUSH UNIT WITH SPEED-CLEAN STERILIZER CLEANER™, OR USE OF OTHER STERILIZER CLEANERS MAY CAUSE SOME COMPONENTS IN UNIT TO FAIL PREMATURELY.

1. **FLUSH SYSTEM**
   (a) Drain reservoir and fill with clean distilled water. Add 1 oz. of Speed-Clean Sterilizer Cleaner™ to a cool chamber.
   (b) Run one POUCH cycle. Instruments should not be sterilized while cleaning the sterilizer.
   (c) Drain cleaning solution from reservoir. Then, refill reservoir with clean, distilled water and run one UNWRAPPED cycle.
   (d) Drain reservoir and allow sterilizer to cool to room temperature.
   (e) Remove door and dam gaskets from gasket housing channel. Clean channel and gaskets using a mild soap or Speed-Clean Sterilizer Cleaner™ and clean, distilled water. A small stiff bristle brush will aid procedure. After cleaning gaskets, inspect for damage, shrinking, or swelling and replace if necessary. Press gasket into the channel and reinstall dam gasket.
   (f) Remove trays, tray rack, and tray plate. Pressing downward on top band of tray rack, pull upward on end of tray plate and slide assembly out of chamber.
   (g) Locate chamber filters on bottom and back of chamber. Grasp filter and pull outward while twisting slightly. (If necessary, a pair of pliers may be used). Filter may be cleaned with mild soap or Speed-Clean Sterilizer Cleaner™ and clean, distilled water. A small stiff bristle brush or ultrasonic cleaner may be helpful to remove foreign objects from filter surface. Rinse filter with clean, distilled water. **NOTE - IF CLEANING METHODS DO NOT EFFECTIVELY CLEAN THE FILTER, REPLACEMENT MAY BE NECESSARY.** Reinstall filters by pressing inwards and twisting slightly.

   **EQUIPMENT ALERT** - DO NOT OPERATE STERILIZER WITHOUT FILTERS IN PLACE.
   (h) Wipe off trays, tray rack, and tray plate. Reinstall assembly by placing back edge of tray plate in chamber. Pushing downward on top of tray rack, slowly push assembly into chamber.

   **EQUIPMENT ALERT** - ANGLED END OF PLATE MUST BE TOWARD BACK OF CHAMBER TO PREVENT INTERFERENCE WITH TEMPERATURE PROBE IN BACK OF CHAMBER.
   (i) Fill the reservoir with clean, distilled water. Sterilizer is now ready for use.

2. **PRESSURE RELIEF VALVE CHECK**
   Refer to the Installation and Operation Manual for this procedure.

Remember to ask your dealer for Speed-Clean Sterilizer Cleaner™ (#002-0396-00) or call 1-800-MIDMARK for information

**OVER FOR M9 / M11 OPERATION**
MATERIAL SAFETY DATA SHEET

SECTION 1- PRODUCT IDENTIFICATION

Product Name: SPEEDCLEAN

Date of Preparation: May 12, 1997
Date of Review: December 15, 2003

Manufactured for: Midmark Corp.
Versailles, Ohio 45380
937-526-3662 Fax 937-526-8285

SECTION II- HAZARDOUS INGREDIENTS

Ingredients: CAS= ACGIH TLV % (w/w)
2-butoxyethanol 111-76-2 25ppm 2.5

SECTION III- PHYSICAL DATA

Specific Gravity: 1.03
Boiling Point: 212 degrees F.
Vapor Pressure: 17.5 mm Hg.
Vapor Density: NA
Evaporation Rate: same as water
Solubility in Water: complete
Appearance: Yellow liquid
Odor: Mild Solvent

SECTION IV- FIRE AND EXPLOSION HAZARD DATA

Flash Point (Deg. F.): None through boiling
Lower Explosive Limit: None
Upper Explosive Limit: None
Extinguishing Media: water, foam, carbon dioxide, dry chemical as for surrounding fires
Special Fire Fighting Procedures: None
Unusual Fire Explosion Hazards: None

SECTION V- REACTIVITY DATA

Chemical Stability: Stable
Conditions to Avoid: Extremely high temperatures
Incompatible Materials: Strong oxidizers, acids
Hazardous Decomposition Products: Carbon dioxide, carbon monoxide
Hazardous Polymerization: will not occur

SECTION VI- HEALTH HAZARD DATA

Effects of Overexposure:

Eyes - Contact can cause irritation, redness.
Skin - Prolonged or repeated contact can cause irritation.
2-butoxyethanol is absorbed through the skin and chronic overexposure may cause blood disorders, liver or kidney injury.
Breath - Mist may irritate nasal and respiratory passages. Acute overexposure to vapor may cause central nervous depression. Chronic overexposure to vapor may cause blood disorders, liver, or kidney injury.

Manufactured by: Miami Products & Chemical Company
P.O. Box 486
Dayton, OH 45401
937-253-8927
SECTION VI-HEALTH HAZARD DATA (Cont.)
First Aid Procedures:
- Eyes: Flush them with water for 15 minutes. Get medical help if irritation persists.
- Skin: Rinse well with water if contact occurs.
- Respiratory System: Remove to fresh air. If necessary, give oxygen, artificial respiration.
- Ingestion: Give large quantities of water. Get medical assistance.
- Carcinogenicity: Not listed as carcinogenic by IARC, NTP, OSHA, ACGIH.

SECTION VII-PRECAUTIONS FOR SAFE HANDLING AND USE
Steps to be taken in case of spill: Absorb on solid absorbent or wash down with water.
Waste Disposal Method: Dispose in accordance with all local, state, and federal regulations.
Precautions to be Taken in Handling and Storing: Store at moderate temperatures. Keep container closed when not in use.
Other Precautions: Keep out of the reach of children. Return empty drums to licensed reconditioning service.

SECTION VIII-SPECIAL PROTECTION INFORMATION
Respiratory Protection: Use NIOSH approved respirator for product mists and vapors.
Ventilation: Recommended
Protective Gloves: Required
Eye Protection: Wear safety glasses or face shield.
Other Protective Clothing and Equipment: Eye wash station.

SECTION IX- HMIS RATINGS
Health: 1  Fire: 0  Reactivity: 0

SECTION X- L313 LISTED MATERIALS
As per the requirements of 40 CFR 372.45, the following components of this product are listed in Section 313 of Title III of the Superfund Amendment and Reauthorization Act of 1986.

Material  CAS= Maximum % by weight
2-butoxyethanol  111-76-2  3

TSCA: All ingredients of this product are listed on the TSCA inventory of chemical substances.

This information is based on data available to us and is accurate and reliable to the best of our knowledge at the time of printing. However, no warranty is expressed or implied regarding the accuracy of completeness of the information contained herein. Final determination of the suitability of this material for the use contemplated is the sole responsibility of the user. Buyer assumes all risk and liabilities. Buyer accepts and uses this material on these conditions.